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Foreword

Mexico has been facing significant economic challenges, including falling oil prices, tighter monetary policy in the United States and a sharp depreciation of the peso. Ambitious structural reforms and sound macroeconomic policies have supported the resilience of the Mexican economy in the face of challenging global conditions. Mexico's productivity growth has recently picked up in sectors that benefitted from structural reforms, such as the energy, financial and telecom sectors. Yet, important challenges remain in eliminating the gaps between Mexico and other OECD economies.

Addressing weak competition is essential in this effort. Many of Mexico's product markets remain among the most heavily regulated in the OECD. This affects the ability of new firms to enter these markets and hampers innovation, efficiency and productivity. Weak competition and barriers to entry result in less choice and higher prices for Mexican consumers, less investment for the Mexican economy and fewer jobs. Enhancing competition is therefore critical to Mexico's prosperity.

The OECD has been working closely with Mexico to analyse competition levels in numerous sectors and provide support and training to judges specialised in competition. At the request of the Mexican government, the OECD conducted this assessment of regulatory constraints on competition in two key sectors of the Mexican economy: medicines (production, wholesale, retail) and meat products (including animal feed, growing of animals, slaughterhouses, wholesale, retail).

By scrutinising 228 pieces of legislation at the federal level, the OECD Competition Assessment Project identified 176 problematic regulations and 107 provisions where changes could be made to foster competition. If implemented, these recommendations could yield large benefits for the Mexican people and the Mexican economy while preserving the lawmakers' main objectives in these sectors, namely to protect the Mexican population against sanitary risks in the medicine sector and to prevent the entry of animals, animal products and sub-products that could pose a health risk for their citizens in the meat sector.

It is never possible to quantify entirely the benefits arising from enhanced competition. However, OECD calculations estimate that the annual effect of a selected number of quantifiable recommendations in this report, if implemented, could be of the order of MXN 10 billion to MXN 44 billion (equivalent to 0.06-0.24% of GDP), depending on the scenarios and methodologies used. A number of the recommendations in this report, such as remodelling the system for maximum prices for patented medicine or avoiding double controls in the meat sector were not quantified. However, these are likely to bring significant benefits, in the form of lower prices for consumers and increased turnover and competitiveness for the Mexican economy.

This assessment provides the Mexican government with detailed policy solutions for addressing persistent structural malfunctions in these sectors and promoting a more level playing field. As such, it makes a valuable contribution to reform efforts to put Mexico on a sustainable growth path by enhancing its competitiveness, encouraging investment, stimulating productivity and promoting inclusive economic growth and job creation.

Angel Gurría

Secretary-General, OECD

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Meat: the Mexican Meat Council (Consejo Mexicano de la Carne, COMECARNE); the Mexican Confederation of Pig Producers (Confederación de Porcicultores Mexicanos, Porcimex); the National Poultry Association (Unión Nacional de Avicultores, UNA); the Mexican Cattle Feeders Association (Asociación Mexicana de Engordadores de Ganado Bovino, AMEG); and private companies.

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Abbreviations and acronyms

AMEG	Mexican Cattle Feeders Association (Asociación Mexicana de Engordadores de Ganado Bovino)
AMEGI	Mexican Association of Interchangeable Generics Manufacturers (Asociación Mexicana de Fabricantes de Medicamentos Genéricos Intercambiables)
AMIIF	Mexican Association Industries for Research (Asociación Mexicana de Industrias de Investigación Farmacéutica)
AMIS	Mexican Association of Insurance Institutions (Asociación Mexicana de Instituciones de Seguros)
ANADIM	National Association of Medicine Distributors (Asociación Nacional de Distribuidores de Medicinas)
ANAFAM	National Association of Medicine Manufacturers (Asociación Nacional de Fabricantes de Medicamentos)
ANAFARMEX	National Association of Pharmacies in Mexico (Asociación Nacional de Farmacias de México)
ANETIF	National Association of TIF Establishments (Asociación Nacional de Establecimientos Tipo Inspección Federal)
CAF	Adjacent office next to the pharmacy (Consultorio Adyacente a Farmacia)
CANIFARMA	National Chamber of the Pharmaceutical Industry (Cámara Nacional de la Industria Farmacéutica)
CCE	National Business Council (Consejo Coordinador Empresarial)
CDTMAEOGC	Commission to Define Treatments and Medicines Associated with Diseases Causing Catastrophic Expenses (Comisión para Definir Tratamientos y Medicamentos Asociados a Enfermedades que Ocasionan Gastos Catastróficos)
CEDRSSA	Centre of Studies for Rural Sustainable Development and Alimentary Sovereignty (Centro de Estudios para el Desarrollo Rural Sustentable y la Soberanía Alimentaria)
CEFPP	Promotion and Protection Livestock State Committees (Comités Estatales de Fomento y Protección Pecuaria)
CETIFARMA	Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (Consejo de Ética y Transparencia de la Industria Farmacéutica)
CIDRS	Interministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable)

CMDRS	Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable)
CMN	Committee on New Molecules (Comité de Moléculas Nuevas)
CNA	National Agricultural Council (Consejo Nacional Agropecuario)
CNOG	National Confederation of Livestock Unions (Confederación Nacional de Organizaciones Ganaderas)
COFECE	Federal Economic Competition Commission (Comisión Federal de Competencia Económica)
COFEPRIS	Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios)
COMECARNE	Mexican Meat Council (Consejo Mexicano de la Carne)
CONEVAL	National Council for the Evaluation of Social Development Policy (Consejo Nacional de Evaluación de la Política de Desarrollo Social)
CPFEUM	Permanent Commission for the Mexican Pharmacopeia (Comisión Permanente de la Farmacopea de los Estados Unidos Mexicanos
CSG	General Health Council (Consejo de Salubridad General)
CZE	Zoosanitary Export Certificate (Certificado Zoosanitario de Exportación)
CZI	Zoosanitary Import Certificate (Certificado Zoosanitario para Importación)
CZM	Zoosanitary Transport Certificate (Certificado Zoosanitario de Movilización)
DENUE	INEGI's National Statistical Directory of Economic Units (Directorio Estadístico Nacional de Unidades Económicas)
DGN	General Directorate of Standards (Dirección General de Normas)
DOF	Federal Official Gazette (Diario Oficial de la Federación)
DTP	Direct-to-pharmacy
ENIGH	National Survey of Household Income and Expenditure (Encuesta Nacional de Ingresos y Gastos de los Hogares)
FAAR	Agricultural and Rural Insurance Funds (Fondos de Aseguramiento Agropecuario y Rural)
FDA	US Food and Drug Administration
FIRA	Trust Funds for Rural Development (Fideicomisos Instituidos en Relación a la Agricultura)
GDP	Gross domestic product
GMO	Genetically modified organism
GMP	Good manufacturing practice
GVA	Gross value added
HHI	Herfindahl-Hirschman Index
HRZ	Zoosanitary Requirements Form (Hoja de Requistos Zoosanitarios)

ICHA-HC	International Classification of Health Accounts of Health Care Functions
IMPI	Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Industrial)
IMSS	Mexican Social Security Institute (Instituto Mexicano del Seguro Social)
INEGI	National Institute of Statistics and Geography (Instituto Nacional de Estadística y Geografía)
INN	International Nonproprietary Name
ISSSTE	Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado)
MSME	Micro, Small and Medium Enterprises
MVO	Official Veterinary Surgeon (Médico Veterinario Oficial)
MVRA	Authorised Responsible Veterinary Surgeon (Médico Veterinario Responsable Autorizado)
NAFTA	North American Free Trade Agreement
NMX	Mexican Standards (Normas Mexicanas)
NOM	Mexican Official Standards (Normas Oficiales Mexicanas)
OASA	Animal Health Auxiliary Organisms (Organismos Auxiliares en Sanidad Animal)
OEIDRUS	State Offices for the Information for Sustainable Rural Development (Oficinas Estatales de Información para el Desarrollo Rural Sustentable)
OTC	Over-the-counter medicines
PECDRS	Special Competition Programme for Rural Sustainable Development (Programa Especial Concurrente para el Desarrollo Rural Sustentable)
PEMEX	Petróleos Mexicanos
PMPRB	Canadian Patented Medicine Prices Review Board
Porcimex	Mexican Confederation of Pig Producers (Confederación de Porcicultores Mexicanos)
PROFECO	Federal Attorney's Office of Consumer (Procuraduría Federal del Consumidor)
PROFEPA	Federal Attorney for Environmental Protection (Procuraduría Federal de Protección al Ambiente)
PPP	Purchasing power parity
SAGARPA	Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación)
SCIAN	North American Industry Classification System (Sistema de Clasificación Industrial de América del Norte)

SCT	Ministry of Communications and Transportation (Secretaría de Comunicaciones y Transportes)
SE	Ministry of Economy (Secretaría de Economía)
SEDATU	Ministry of Agrarian, Territorial and Urban Development (Secretaría de Desarrollo Agrario, Territorial y Urbano)
SEDENA	Ministry of National Defence (Secretaría de la Defensa Nacional)
SEDESOL	Ministry of Social Development (Secretaría de Desarrollo Social)
SEMAR	Ministry of Navy (Secretaría de Marina)
SEMARNAT	Mexican Ministry of Environment and Natural Resources (Secretaría de Medio Ambiente y Recursos Naturales)
SENASICA	National Service for Agro-Alimentary Public Health (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria)
SENER	Ministry of Energy (Secretaría de Energía)
SEPB	Biotechnological Products Assessment Sub-Committee (Subcomité de Evaluación de Productos Biotecnológicos)
SHCP	Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público)
SIAP	Agrifood and Fisheries Information Service (Servicio de Información Agroalimentaria y Pesquera)
SIAVI	Tariff Information System (Sistema de Información Arancelaria vía Internet)
SNAM	National Service of Transport Notices (Servicio Nacional de Avisos de Movilización)
SNIDRUS	National Information System for Sustainable Rural Development (Sistema Nacional de Información para el Desarrollo Rural Sustentable)
SNIIM	National System of Markets Information and Integration (Sistema Nacional de Información e Integración de Mercados)
SP	Popular Health Insurance (Seguro Popular)
SSA	Ministry of Health (Secretaría de Salud)
TIF	Federal Inspection Type (Tipo Inspección Federal)
TSS	Ministry of Health Inspection Type (Tipo Secretaría de Salud)
UNA	National Poultry Association (Unión Nacional de Avicultores)
UNEFARM	National Union of Pharmacy Entrepreneurs (Unión Nacional de Empresarios de Farmacias)
USDA	United States Department of Agriculture
VUCEM	Mexican Foreign Trade Single Window (Ventanilla Única de Comercio Exterior Mexicana)
WHO	World Health Organization

Preface

by
Ildefonso Guajardo Villarreal
Minister of Economy

Over the past two decades, successive Mexican governments have faced the challenge of raising the country's competitiveness, a continuous task since the North American Free Trade Agreement (NAFTA) came into force. Yet, it was only with the present administration that a consensus was reached for initiating the structural reforms necessary for increasing the country's productivity, competitiveness and development.

Structural reforms were approved in the financial, energy, broadcasting and telecommunications sectors, as well as in competition legislation.

The 2013 constitutional reforms of broadcasting, telecommunications and competition, as well as the Federal Economic Competition Law (Ley Federal de Competencia Económica, LFCE), the new competition law introduced in 2014, made competition an important tool in reaching the kind of inclusive economic growth the country so needs.

In particular, the new LFCE allowed the Federal Executive, by itself or through the Ministry of Economy (Secretaría de Economía, SE), to file complaints against monopolistic practices or unlawful concentrations as well as to request special procedures to determine the existence of barriers to competition, essential facilities, or the absence of conditions for effective competition. Using these new powers, the SE implemented an action plan to contribute to market efficiency and so benefit enterprises and consumers.

As part of this programme, and based upon an agreement with the OECD to strengthen Mexican competitiveness, the Ministry asked the OECD to conduct, for the first time in the country, a Competition Assessment Toolkit (CAT) project in the medicine and meat-products sectors.

The OECD studied more than 228 pieces of legislation in the two sectors, and found 176 potential restrictions to competition. After analysing these in detail, in collaboration with the sectors' regulators, the OECD issued 107 recommendations (50 for medicines and 57 for meat products). It estimated that recommendations if implemented could save Mexican consumers up to MXN 43.8 billion in the medicine sector and up to MXN 348 million in the meat sector annually.

It is difficult to find any market without regulations that aim to protect against negative consequences that can result from market transactions, such as harm to consumers or the environment, or even questions of national security. However, based upon international best practices, Mexican governments at all levels – federal, state or

local – need to design and apply regulations that fulfil these legitimate objectives, while allowing for the possibilities of competition and free market access.

Indeed, regulation and competition are two sides of the same coin and both are needed to contribute to the efficient functioning of markets. Efficient markets are, in turn, the foundation upon which Mexico can base the inclusive growth it requires.

Ildefonso Guajardo Villarreal

Minister of Economy, Mexico

Executive summary

The OECD was asked by the Mexican government to carry out an independent policy assessment to identify rules and regulations that may hinder the competitive and efficient functioning of markets in two sectors of the Mexican economy along the vertical supply chain. These were medicines (production, wholesale, retail) and meat (animal feed, growing of animals, slaughterhouses, wholesale and retail).

The project has proceeded in five stages. Stage 1 defined the exact scope of the two sectors. A list of 228 pieces of sector-relevant federal legislation was collected. In Stage 2, this legislation was screened using the OECD's *Competition Assessment Toolkit* to identify potential competition barriers: 176 prima facie restrictions of competition (100 in medicines and 76 in the meat sector) were identified. Additionally, an economic overview for each sector was prepared, which contained important economic indicators such as output, employment and price trends. In Stage 3, the policymaker's objective for each provision was investigated. An in-depth analysis was carried out qualitatively and, whenever permitted by availability of data, quantitatively. A number of meetings were held with officials of the relevant authorities, as well as with representatives of private associations, to reach a better understanding of lawmakers' motivations and objectives. In Stage 4, draft recommendations for those provisions that were found to restrict competition were developed, taking into account similar provisions in comparable countries, notably the EU and the US. In the final stage, recommendations were finalised. Additionally, during the project, the OECD team organised two workshops with officials from relevant authorities to build competition-assessment capabilities in the Mexican administration and to discuss preliminary recommendations.

As a result of this work, the report makes 107 recommendations on specific legal provisions that should be abolished or amended.

The recommendations detailed in this report, if implemented, would benefit consumers in Mexico and the Mexican economy in both sectors. More specifically, if the recommendations are implemented, the OECD has calculated a positive effect for the Mexican economy of at least MXN 10 228.7 million, which could rise to MXN 44 161.9 million. As this estimated amount is based upon the small number of quantifiable issues, the final benefits from full implementation could be larger.

The main recommendations by sector are summarised below.

Medicines sector

- Issue a binding regulation determining the exact conditions under which pecuniary advantages or benefits of significant value to doctors can be granted.
- With respect to the current sale of branded drugs and the ban on substitution by a pharmacist if a brand name was part of the doctor's prescription, the OECD provides two optional recommendations. Option 1) Oblige pharmacists to inform patients about the cheapest available generic and allow prescribed medicines to be substituted with a cheaper generic when the patient agrees, unless the doctor has specified

"substitution not allowed". Option 2) Introduce a provision that requires doctors to prescribe only International Nonproprietary Name (INN) medicines.

- Rebuild the basket used to calculate maximum prices for patented drugs in Mexico, taking into account not only prices in six countries with the highest sales volumes (as currently), but also other factors, such as income level of reference countries and out-of-pocket expenses.
- Make public the amendment to the price-regulation agreement between CANIFARMA and the Ministry of Economy.
- Require that entries into the sanitary registry, necessary for marketing drugs, must be renewed only once, after five years, and then become perpetual. This recommendation will first require increasing the quality and frequency of in-situ controls; introducing large fines if pharmaceutical companies do not report changes in a medicine in time to COFEPRIS; and granting adequate resources to COFEPRIS to fulfil this task.
- Abolish the requirement to rely on an incumbent registry holder's permission (usually the official importer) to import medicines into Mexico.
- Continue with an ongoing project to make the Mexican Pharmacopoeia available online as soon as possible.
- Harmonise NOMs that state that they are not in line with international norms with current international standards.

Meat sector

- Issue NOMs for the national classification of beef, pork and chicken carcasses, to foster interstate trade and exports.
- Abolish the requirement of various Mexican states for transport documents (*guías de tránsito*), which impose additional zoosanitary controls to those established by the national authority SENASICA.
- Abolish the requirement to acquire certification from a local livestock association to transport livestock across Mexican territory.
- Eliminate the requirement for SENASICA to authorise establishments in countries whose sanitary authorities have previously been authorised to export to Mexico animals, their products and sub-products. This should be conditional on establishing bilateral agreements that abolish any additional requirements for Mexican exporting companies with countries that have at least the same sanitary standards as Mexico.
- Replace the requirement to inspect 100% of imported lots of meat, carcasses, viscera and offal with a system under which both the timing and number of controls, as well as the amount of samples taken to be inspected, would be chosen based on a risk assessment.
- Guarantee that VUCEM, an Internet platform created by the Mexican government that centralises communication and compliance issues for Mexican federal agencies with border-management responsibilities, is fully functional at all times. Furthermore, clarify management responsibilities.
- Update those NOMs that state that they are not in line with international norms.

Chapter 1

Assessment and recommendations

This assessment identifies distortions to competition in Mexican federal legislation and proposes recommendations for removing regulatory barriers to competition in two sectors of the Mexican economy: the vertical chain of production for medicines (production, wholesale, retail) and meat products (animal feed, growing of animals, slaughterhouses, wholesale, retail). It identifies and analyses 176 potential regulatory restrictions, and makes 107 specific recommendations to remove potential barriers and increase competition. Benefits from increased competition will include lower prices, and greater choice and variety for consumers. This report identifies the sources of those benefits and, where possible, provides quantitative estimates. If the particular quantified restrictions are lifted and the expected effects are realised, the OECD has calculated a positive effect for the Mexican economy of at least MXN 10 228.7 million, which could rise to MXN 44 161.9 million.

Laws and regulations are key instruments to achieving public-policy objectives, such as consumer protection and public health. When they restrict market forces more than necessary to achieve their objectives or when they impose unnecessary costs in light of their policy objectives, a comprehensive review can help identify restraints and develop alternative, less restrictive policies that still achieve government objectives.

The Mexican Competition Assessment of Laws and Regulations project has identified and evaluated market regulations along the vertical supply chains in the chain of production for medicines (production, wholesale, retail) and meat products (animal feed, growing of animals, slaughterhouses, wholesale, retail). This work aims at identifying regulatory barriers which, among others, restrict entry into a market; constrain firms' ability to compete (e.g. by regulating prices, limiting advertising); treat competitors differently (e.g. by favouring incumbents); facilitate co-ordination among competitors; or restrict consumers' ability to change suppliers. The methodology followed in this exercise is summarised in Annex A, which also provides full references to the OECD Competition Assessment methodology.

1.1. Market regulation and competition

Industries where there is greater competition experience faster productivity growth. This has been confirmed in a wide variety of empirical studies, as summarised in OECD (2014c). Other benefits from competition can also be important, including lower consumer prices, greater consumer choice and better quality of products and services, higher employment, greater investment in R&D, and faster adoption of innovation.

In addition to this evidence of competition promoting growth, there have been studies directly of the effects of product market deregulation, which is the most relevant area for this project. Arnold et al. (2011) studied firm-level data in 10 countries from 1998 to 2004, conducting the analysis using the OECD's Product Market Regulation (PMR) index at industry-level.[1] The authors found that more stringent product market regulation reduces the multifactor productivity (MPF) of firms. In a study of 15 countries and 20 sectors, from 1985 to 2007, Bourlès et al. (2013) estimate the effect of regulation of upstream service sectors on productivity growth downstream. They find that anti-competitive regulations have an impact that goes beyond the sector in which they are applied, and that this effect is more important for the sectors closer to the productivity frontier.

Innovation and investment in knowledge-based capital (KBC), such as computerised information, IPRs and economic competencies, are also negatively affected by stricter PMR, according to Andrews & Criscuolo (2013). The authors set out the channels through which this effect takes place. For instance, PMR affects innovative efforts, as higher firm entry rates can increase new ideas and put pressure on incumbents to innovate. In addition, it influences innovation because it enables innovative firms to combine the resources needed to market new ideas and products more efficiently. The paper notes that "a policy reform that would alleviate regulatory barriers in business services from the OECD average (i.e. France) to the low level in Sweden is associated with a 30% increase in investment in innovative firms" (Andrews & Criscuolo, 2013).

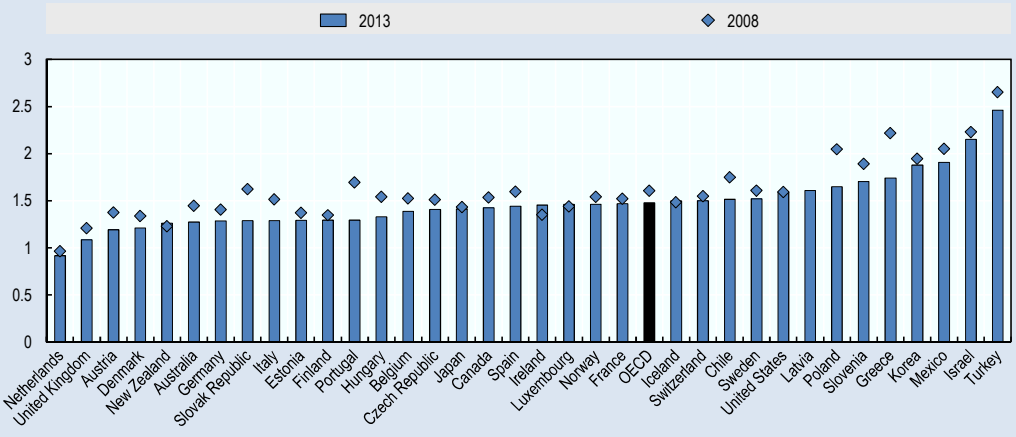
Box 1.1. **Product Market Regulation (PMR) in Mexico**

Mexico has made progress in lifting restrictive regulation. Over the period from 2008 to 2013, it showed an improvement in the OECD's PMR indicator, dropping from 2.05 in 2008 to 1.91 in 2013 (the most recent measurement).

That figure remained above the OECD average (1.48), however, suggesting that there is still considerable scope for improvement. "While extensive structural reforms have taken place in certain sectors, product market regulatory stringency in the economy remains relatively high, well above the OECD average overall. This limits the ease with which new firms can enter these markets and recruit workers." (OECD, 2015a)

An analysis of the sub-components of the 2013 PMR indicator showed significant differences among different areas of regulation. The areas in which Mexico applied more restrictive regulations than the OECD average were mostly barriers to trade and investment and price controls.

Figure 1.1. **Economy-wide PMR**
(Index scale of 0-6, from least to most restrictive)



Notes: 1) The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law. 2) The year 2008 refers to the situation in 2007 for all countries with the exception of Chile, Estonia, Israel and Slovenia (2008).

Source: OECD, Product Market Regulation Database.

Another benefit from greater regulatory flexibility in PMR is higher employment. A recent OECD study (Criscuolo et al., 2014) finds that across 18 countries over a ten-year period, small firms that are five years old or under on average contribute to about 42% of job creation. As noted in OECD (2015b), "such a disproportionally large role by young firms in job creation suggests that reducing barriers to entrepreneurship can contribute significantly to income equality via employment effects".

The impact of lifting anti-competitive regulations on income inequality is uncertain a priori. On the one hand, greater flexibility leads to higher employment; on the other, deregulation is also associated to greater wage dispersion. Using the OECD's summary index of product market regulation in seven non-manufacturing industries, covering energy, telecom and transport sectors, Causa et al. (2015) find a negative impact of stringent product market regulation on household disposable income. This result holds both on average and across the income distribution, and leads to greater inequality. The authors interpret the finding noting that lower regulatory barriers to competition would

"tend to boost household incomes and reduce income inequality, pointing to potential policy synergies between efficiency and equity objectives".

Further recent OECD work (Ennis & Kim, 2017) investigates the relationship between competition and inequality. The authors calibrate a model to assess the redistributive effects of market power in eight countries.[2] They find that market power benefits the wealthiest households and that, in their model, the share of wealth of the top 10% of households deriving from market power may lie between 10% and 24%.

PMR also has an impact on trade and in Foreign Direct Investment (FDI). Fournier et al. (2015) find that national regulations, as measured by the economy-wide PMR index, have a negative impact on exports and reduce trade intensity (defined as trade divided by GDP). Heterogeneity in regulation across countries also reduces trade intensity. The benefits of PMR convergence among EU member states would increase trade intensity within the EU by more than 10%. Fournier (2015) studies the impact of heterogeneous PMR in OECD member states. He finds that lowering regulatory divergence by 20% could increase FDI by about 15%. The paper investigates specific components of the PMR index and finds that command and control regulations and measures protecting incumbents (antitrust exemptions, entry barriers in networks and services) are especially harmful in reducing cross-border investments.

1.2. Key findings from the Competition Assessment project in Mexico

The main aim of the Competition Assessment of Laws and Regulations in the Mexican project is to improve competition in two sectors of the Mexican economy, medicines and meat products, through the removal of regulatory barriers. These two sectors had a combined manufacturing gross value added (GVA) of 1.43% (Medicine:[3] 0.48%, and Meat:[4] 0.95%) of GDP by output in 2015. These figures do not include the entire chain of production and sale, so are lower bounds.

In 2013, according to the INEGI Census, these two sectors represented 711 905 jobs. This was composed of medicine[5] with 367 056 jobs of which production, 83 336; wholesale, 38 198; and retail, 245 552 jobs; and meat[6] with 344 849 jobs of which production, 104 396; wholesale, 27 309; and retail, 213 144 jobs. This represented 3.3% of total employment in Mexico in 2013 (the total number of employees reported in the 2014 Census in Mexico was 21 576 358). Lifting the restrictions to competition in these sectors is therefore likely to have a significant positive economic impact, both in the short and long term.

The outcomes discussed in this section were reached by identifying regulatory barriers to competition, assessing their impact in terms of harm to competition, and suggesting specific recommendations to lift the restrictions. This is not an economic-impact assessment; it is a methodical analysis of the legislative texts related to the sectors under analysis.

The work has led to the identification of 176 regulatory restrictions found in the 228 legal texts selected for assessment. In total, the report makes **107 specific recommendations** to mitigate harm to competition. These are all available in Annex B.

Table 1.1. **Legal provisions analysed by sector**

	Medicines	Meat products	Total
Legislation scanned	107	121	228
Prima facie restrictions found	100	76	176
Recommendations made	50	57	107

Source: OECD analysis.

1.3. Main restrictions identified and recommendations

The restrictions are found below and briefly summarised, as are the main recommendations in the medicines and meat sectors. They will be discussed in detail in their respective chapters.

1.3.1. Medicine

The main recommendations in the medicines sector are as follows:

- **Legal lacuna concerning pecuniary advantages to incentivise doctors**. Mexico currently has no law regulating which benefits, such as conference participations or speaker engagements, pharmaceutical companies can provide to doctors. A lack of binding governmental regulation in this field may hinder competition among similar products and potentially give doctors an incentive to prescribe more expensive products that in turn provide them with more benefits. The OECD recommends issuing a binding regulation determining the exact conditions under which pecuniary advantages or benefits of significant value to doctors can be granted. If this OECD recommendation is fully implemented, the benefit to consumers is estimated to be MXN 7 743.1 million a year.
- **Mandatory sale of the branded drug, unless substitution is expressly allowed**. When prescribing a medicine, doctors in Mexico can either prescribe the generic name or the generic and distinctive designations (brand name) jointly. When doctors prescribe the distinctive designation, pharmacists must comply (at least by regulation) with that brand name and the medicine can only be substituted if the doctor has expressly authorised the replacement, even if the replacement is a generic with the same active ingredient. As a consequence, consumers are locked in to buying branded medicines if their doctor prescribes them. The OECD recommends the following options to the Mexican government.

  Option 1) Amend the provision to oblige pharmacists to inform customers about the cheapest available generic and allow pharmacists to substitute prescribed medicines with this generic when the patient agrees, unless the doctor has specifically specified that substitution is not allowed. The substitution should be optional, not mandatory due to the fact that most purchases in Mexico are customer out-of-pocket spending and customers should be able to purchase the medicine they perceive to be best.

  Option 2) Introduce a provision that requires doctors to prescribe only medicines on International Non-proprietary Name (INN), which contains the active substance, but is not sold under a brand name.

If either of these OECD recommendations is fully implemented, the potential benefit to consumers is estimated to range between MXN 6 177.4 and 34 544.8 million a year.

- **Adjacent Offices (Consultorios Adyacentes a Farmacias, CAF)**. In 2015 in Mexico, according to COFEPRIS, 53.5% of all pharmacies had adjacent doctors' offices or CAF (Consultorios Adyacentes a Farmacias, CAF). CAF provide patient consultations at extremely affordable prices, or even for free. While CAF business models may vary, most doctors working at CAF receive some form of compensation from the pharmacies, be it through a fixed salary, a bonus, or some other form of remuneration. As practically all CAF belong to pharmacies, doctors are not completely independent of the pharmacies in their prescription practice, and this could distort competition among medicines. The OECD recommends the following three options to the Mexican government. Options 1 and 2 are possible as stand-alone solutions, but could also be combined; Option 3 would mean keeping the status quo, leaving the current CAF business model unchanged.

  Option 1) Issue a provision prohibiting CAF doctors from prescribing branded products and mandate them to only prescribe the INN or the generic name.

  Option 2) Issue a code of conduct or regulation prohibiting pharmacies from exerting pressure on or incentivising doctors to prescribe certain products, especially by rewarding them according to volume or number of prescribed medicines.

  Option 3) No recommendation. The policymaker's objective of granting quick and easy medical access to the Mexican population could prevail over any possible conflict of interest. This recommendation could leave the current CAF business model unchanged.

- **Direct sales of pharmaceutical companies to pharmacies (especially pharmacy chains).** Many (if not most) pharmaceutical companies in Mexico refuse to sell directly to pharmacies, even to large pharmacy chains, and prefer selling through wholesalers. This problem concerns only the private market as the public sector generally purchases medicines through public tenders. For big retailers (i.e. chain pharmacies), buying from a wholesaler imposes an unnecessary cost, as they have to pay an extra margin to wholesalers instead of acquiring the products directly from the producers. Also, market participants at retail level complain that many medicines are distributed by only one wholesaler and there is no or only very limited intra-brand competition. Promoting intrabrand competition is particularly relevant when there is insufficient interbrand competition. The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market. Before moving forward with such a measure however it is recommended that a study in coordination with the relevant authorities assesses the impact on the market of introducing such an obligation, whose purpose would be to allow new wholesalers to compete in the concentrated Mexican wholesale market and increase intra-brand competition. A comparable obligation exists in most EU member countries, where the distribution of medicines is considered a public-service function. However, as this proposed recommendation would interfere with contractual freedom, it should only be implemented if such study would demonstrate that other measures to strengthen intrabrand competition do not lead to any results. If an obligation to supply full-line wholesalers were to be

implemented, the benefit to consumers is estimated to range between MXN 128.1 million and MXN 3 074.6 million a year.

- **Maximum prices for patented drugs**. A 1996 agreement between the Ministry of Economy and CANIFARMA (amended in 2004) establishes a formula for maximum retail prices for patented medicines. The maximum price for a patented medicine in Mexico is determined as the average of the ex-manufacturer price of that medicine in the six countries with the largest sales in the world. The current price-setting mechanism seems to result in high final prices in the Mexican market, especially when compared with other Latin American countries. This might be due to the current price-regulation system's tendency to take high-income countries as benchmarks. The OECD recommends rebuilding the basket to calculate maximum prices for Mexico. Firstly, by taking into account not only sale volumes (as currently), as well as other factors, such as income level of reference countries and consumer out-of-pocket expenditures. In addition, the OECD recommends revising the basket periodically – for example, every five years – to ensure that it continues to satisfy the needs of the Mexican population.

- **Secrecy of the amendment of the agreement between CANIFARMA and** the **Ministry of Economy**. The amendment to the agreement between the Ministry of Economy and CANIFARMA determining how maximum prices are set is confidential; its content is unavailable to the public. The OECD recommends making both the agreement and the modification available to the public.

- **Renovation of sanitary registries**. According to Mexican law, sanitary registries need to be renewed every five years. Requiring that the sanitary registry is renewed every five years imposes an extra cost on firms. The costs can be quite significant for producers that are often marketing several hundreds of products. The OECD recommends that the sanitary licence should be renewed only once after five years and then be perpetual. This would require increasing the frequency of in-situ controls; introducing large fines if pharmaceutical companies do not report changes in a medicine in time to COFEPRIS; and granting adequate resources to COFEPRIS to fulfil this task. If this OECD recommendation is fully implemented, the benefit to consumers is estimated to amount to MXN 4.8 million. However, two caveats should be noted. First, this estimation does not take into account the internal savings (preparation of documents, etc.) that pharmaceutical companies will experience if they do not have to perform all the tests presented when the sanitary registry was granted every five years. Second, the annual costs related to the annual revisions might be underestimated. A significant improvement of the Mexican control and supervision system will add extra costs that will probably have to be carried by the pharmaceutical companies.

- **Necessity to count on the registry holder's permission to import medicines into Mexico**. Importers of pharmaceutical products with commercial purposes need an entry into the sanitary registry from the Ministry of Health before they can import medicines into Mexico. If a potential importer is not the holder of the registry, it must obtain the consent of the registry's owner. The incumbent importer can thus prevent market entry of other importers. The OECD recommends abolishing this restriction. Every importer should be able to get an authorisation from the Ministry of Health, independently of the consent of the incumbent holder of a registry. Additional importers should not have to fulfil the same documentation requirements as the first importer for acquiring a registry

since the safety of the imported drug will have been proved in the first application already.

- **Geographical and population requirements for interchangeability tests**. When introducing a new generic to the Mexican market, tests performed to determine whether the generic medicine produces a similar effect to the reference product, known as interchangeability tests, must be performed by authorised third parties in Mexican territory with a Mexican population sample, even if similar studies have already been performed before abroad. This requirement may impose unnecessary extra costs on pharmaceutical companies that operate abroad, discouraging them to sell generic medicines in Mexico. The OECD recommends abolishing the requirement that pharmaceutical companies conduct tests on the Mexican territory and population and accept interchangeability studies that have been accepted by foreign authorities as long as their control systems are regarded as at least equivalent to the Mexican one. COFEPRIS should recognise those authorities (similar to COFEPRIS recognising eight foreign authorities for the issuance of Good Manufacturing Practice certificates). Only in exceptional cases, for which there must be guidelines, should the Ministry of Health order additional tests with the Mexican population.

- **The Mexican Pharmacopoeia is only available as a printed document**. Currently the Mexican Pharmacopoeia, which is the exclusive guide to available pharmaceuticals in Mexico, is not available online and is only updated every three years. Companies have therefore to acquire a hard copy, which might delay entry. The OECD recommends continuing an ongoing project that will make the Pharmacopoeia available online as soon as possible.

- **Non-harmonised standards.** In Mexico, there are two kinds of standards: Mexican Official Standards (Normas Oficiales Mexicanas, NOM), which are issued by the federal government, and have mandatory compliance; and Mexican Standards (Normas Mexicanas, NMX), which are voluntary and issued by national standard-making bodies. The OECD team found 10 Mexican Official Standards that contain statements that are not in line with international norms. The non-harmonisation with international standards – be it partial or total – may hinder foreign competitors' access to the Mexican market, as well as Mexican producers' access to foreign markets. In particular, producers might have to apply different sets of norms in Mexico to those applied abroad, which might lead to extra costs. Even if Mexican producers have (partially) adapted their standards to international standards, confusion among market participants might result if the legal text is not updated. The OECD recommends updating all norms so that they are, as far as possible, in line with international standards.

The main recommendations for the medicine sector are described in Chapter 2 and are listed analytically in Annex B.

1.3.2. Meat products

The mains issues and recommendations in the meat sector are as follows:

- Absence of NOMs related to the classification of beef, pork and chicken carcasses; discrimination against non-local meat producers. Currently, there are no compulsory official standards (NOMS) in Mexico related to the classification of beef, pork or chicken carcasses at a federal level. The absence of a compulsory

meat-classification system has negative impacts on both the domestic and the export markets. For the domestic market, the absence of a compulsory meat-classification system is aggravated by the existence of several state livestock laws that discriminate against non-local meat producers and hinder interstate trade. For the export market, exporters have to sell their meat at lower prices, since importing countries only grant Mexican meat the lowest classification status, independent of its actual quality. The OECD recommends introducing NOMs for the classification of beef, pork and chicken carcasses. Ideally, these NOMs should not only fit the needs of meat producers who export, but also those of producers serving the Mexican market.

- **State transport documents.** Several state governments require a transport document in order to transport live animals, their products and sub-products within states. Several state livestock laws refer to transport documents as *guías de tránsito*. Furthermore, in several states, transport documents are not issued by public authorities, but by local livestock associations. Producers interested in commercialising their products in different states must pay for several transport documents in order to move their products from the point of production to the points of sale. This makes their products more expensive and puts them at a competitive disadvantage against producers who produce and commercialise their products in the same state. The OECD recommends abolishing state transport documents. If this OECD recommendation is fully implemented, annual benefits are estimated to range between MXN 13.3 million and MXN 39.8 million.

- **Certification from the local livestock association.** In order to transport livestock across the Mexican territory, it is necessary to obtain a certification from the local livestock association that operates at the municipality of origin. These kinds of certifications only seem to exist for cattle. To obtain these certifications, it is obligatory to provide the local livestock association with proof of ownership of the animals to be transported. These certifications for cattle represent a double control, as there is already a federal ear-tag identification system, the National System of Individual Cattle Identification (Sistema Nacional de Identificación Individual de Ganado, SINIIGA). Furthermore, local livestock associations might have incentives to discriminate against competitors, particularly against livestock producers from other geographic areas or those not belonging to the association. The OECD recommends abolishing these certifications.

- **Double authorisation to import.** Animals, their products and sub-products must come from authorised establishments within authorised countries. For a foreign country to be authorised, its veterinary services must be recognised by SAGARPA as working to standards at least equivalent to the ones applied in Mexico. In addition, SAGARPA must authorise and inspect establishments in foreign countries, which might be seen as an unnecessary additional barrier to entry for foreign producers. The OECD recommends eliminating that additional establishment authorisation. However, this should be based on bilateral agreements with countries that abolish additional requirements for authorisation of Mexican exporters by their sanitary authorities. In these bilateral agreements, each country's sanitary authorities will ensure the quality of all exporting establishments and their products within their jurisdiction.

- **Inspecting all imported meat, carcasses, viscera and offal.** Currently, 100% of imported lots of meat, carcasses, viscera and offal must be inspected in line with the specifications laid out in the Zoosanitary Requirements Form. This requirement is excessive and unnecessarily costly, and might not even be feasible in practice. The OECD suggests implementing a system under which both the timing and number of controls, as well as the number of samples taken to be inspected, are chosen based on a risk assessment that takes into account an exporter's past compliance with zoosanitary requirements. If this OECD recommendation is fully implemented, annual benefits are estimated to range between MXN 32.9 million and MXN 253.9 million. This estimate is based on the assumption that currently 100% of imported lots are inspected as required by NOM-030-ZOO-1995. However, benefits might be lower if the percentage of currently inspected lots was smaller in practice.

- **Malfunctioning of VUCEM.** The Mexican Digital Window of Foreign Trade (Ventanilla Única de Comercio Exterior Mexicana, VUCEM) is an Internet platform created by the Mexican government that centralises communication and compliance issues for Mexican federal agencies with border-management responsibilities. Currently, VUCEM is not fully functional, since it experiences frequent downtimes. Downtimes are particularly problematic for meat and meat products, as they can lead to perishable imports of meat and meat products waiting for long periods at the border. The OECD recommends that the authorities guarantee that VUCEM is fully functional at all times. The OECD team also recommends clarification about which authority (i.e. SAT) is fully responsible for VUCEM's functioning in terms of SENASICA procedures, and about how other agencies should fully support that authority. To implement this recommendation correctly, sufficient funds should be provided.

- **Decision-making of livestock associations.** Livestock associations can have as one of their objectives to "[g]uide production according to market conditions, either intensifying or withholding it". The OECD's interpretation of this provision is that it enables livestock associations to control production and so indirectly, price levels. The OECD recommends abolishing the provision that allows livestock associations to pursue this objective.

- **Information gathering and sharing by livestock associations.** Livestock associations must create statistics, as well as encourage members to keep proper internal accounting so they know their own production costs and price studies concerning the products they market. The exact entries and aggregation level of the statistics created by livestock associations are unknown, and it is unclear whether this information is later shared with other associations' members. Livestock associations' accounting information may include sensitive data that, if shared between livestock-association members, might facilitate collusion. The OECD recommends amending the provisions that promote this information gathering and sharing, so that it is clear that the exchange of sensitive information between livestock association members, as well as between livestock associations, is prohibited.

- **Non-harmonised standards.** The OECD review of meat legislation found 32 standards (29 compulsory NOM and 3 voluntary NMX) that are not in line with international standards. Non-harmonisation with international standards – be it partial or total – may hinder foreign competitors' access to the Mexican market,

as well as access to foreign markets by Mexican producers. In particular, producers might have to apply different sets of norms in Mexico and abroad, which might lead to extra costs. With the exception of four standards (two NOM and two NMX), linked with other restrictions and so dealt with separately, we recommend that these standards are brought into line with international standards, and that they state when there are no existing international standards or best practices.

- **TIF veterinary services.** Federal Inspection Type (Tipo Inspección Federal, TIF) abattoirs are regulated by SAGARPA. TIF-certified abattoirs and processing plants must have, during working hours, at least one Authorised Responsible Veterinary Surgeon (Médico Veterinario Responsable Autorizado, MVRA), who is an employee of the TIF establishment and approved by SENASICA. MVRAs at TIF establishments are in charge of ensuring compliance with the Federal Law on Animal Health and related regulations. In addition to MVRAs, each TIF must have an Official Veterinary Surgeon (Médico Veterinario Oficial, MVO); they are employees of SENASICA and work as inspectors at TIF-certified establishments. The presence of an MVRA is required even if an MVO is already present at the abattoir or processing plant. This might see certain veterinary functions duplicated and imposes an extra burden on companies, especially small TIF establishments. The OECD recommends progressively reducing TIF establishments' reliance on MVRAs, with the long-term goal being that TIF establishments will pay SENASICA for veterinary services, which in turn will pay veterinary surgeons. These veterinary surgeons would then verify compliance with SENASICA regulations. If this OECD recommendation is fully implemented, benefits are estimated to range between MXN 5.4 million and MXN 54.4 million.

The main recommendations for the meat-products sector are described in Chapter 3 and are listed analytically in Annex B.

1.4. Quantification of the recommendations

It was not possible to quantify the effects of all the identified restrictions, either because of a lack of data, or because of the nature of the regulatory change. However, it is clear from the above that the consequences for the Mexican economy in terms of long-term positive economic effects on productivity and growth will be significant, provided all the recommendations are implemented in full.

More specifically, if the particular restrictions identified and quantified during the project are lifted, the OECD has calculated a positive effect for the Mexican economy of between MXN 10 228.7 million and MXN 44 161.9 million. This amount is based upon the few recommendations that the OECD team was able to quantify; in other words, the full effect on the Mexican economy is likely to be even larger. The total is the estimated resulting positive effects on consumer surplus in the sectors analysed as a result of removing current regulatory barriers to competition.

Although only a small number of the restrictions could be fully quantified, the OECD team considers that the cumulative, long-term impact on the Mexican economy of lifting all of the restrictions identified as harmful, including those that were more technical in nature (e.g. regulations on foodstuffs), should not be underestimated. The rationalisation of the body of legislation in these sectors will also positively affect the ability of

businesses to compete in the longer term, provided that the recommendations are implemented fully. Finally, by removing obsolete or redundant legislation, investors will face a more transparent and certain business environment.

Table 1.2 summarises the quantifiable effects of lifting the regulatory barriers to competition for selected obstacles.

Table 1.2. **Synthesis of positive effects quantified by item**

Sector	Number of provisions affected	Benefits / year (MXN, million)
Medicines	4	
Regulation of incentives to doctors	1	7 743.1
Substitution at pharmacy/Doctors only prescribe INN*	1	6 177.4 – 34 544.8
Obligation for producers to supply all full-line wholesalers in the private market	1	128.1 - 3 074.6
Introduction of single renewal of the sanitary registry, with subsequent random controls	1	4.8
Total medicines (including discount for possible overlap)		10 177.1 - 43 813.8
Meat products	3	
Removal of overlapping veterinary services at TIF establishments	1	13.3 - 39.8
Abolition of state transport documents	1	5.4 - 54.4
Adopting an inspection system of imported lots based on a risk analysis	1	32.9 - 253.9
Total meat		51.6 348.1
Total	7	10 228.7 - 44 161.9

Notes: The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market only after conducting a study in coordination with the relevant authorities to assess the impact on the market of introducing such an obligation. Also, as this proposed recommendation would interfere with contractual freedom, it should only be implemented if such study would demonstrate that other measures to strengthen intrabrand competition do not lead to any results

The recommendation "**Introduction of single renewal of the sanitary registry, with subsequent random controls**" was not taken into account in the estimation of total consumer benefit. It would not be methodologically appropriate to add up consumer benefits that result from implementing the recommendations "**Regulation of incentives to doctors**"" and "**Substitution at pharmacy/Doctors only prescribe INN**" because there would be a double counting. We therefore constructed cases to allow overlapping consumer benefits derived from implementing both recommendations.

* In August 2017, COFECE published a "Study on free market and competition in the expired-patent drug markets in Mexico", see https://www.cofece.mx/cofece/ingles/attachments/article/38/Studies-drug%20markets_vF-BAJA.pdf. This study was performed independently of the OECD competition assessment project and published after the preliminary version of the OECD report was provided to the Mexican Ministry of Economy. In this study, COFECE estimated the benefits of its recommendations to amoun to around MXN 2 552 million.

1.5. Conclusion

The present chapter summarises the main findings and recommendations resulting from the analysis of 228 provisions. If the OECD recommendations are fully implemented, dynamic effects should bring benefits to consumers in Mexico and to the Mexican economy in both sectors and their many subsectors, and throughout the economy as a whole.

Throughout this report, the OECD team has sought to identify the sources of those benefits and, where possible, provide quantitative estimates. Because the benefits of competition arise from innovative actions by many private-sector agents – perhaps not even currently operating in the market – any such estimates are highly uncertain and must be regarded as providing, at best, orders of magnitude for likely effects. The aim of the report is to assess the harm to competition, and the expected benefits to consumers from lifting barriers, but quantifying the effects of lifting all restrictions proved impossible because in many cases they were not measurable. Out of the modest number of quantifiable issues the OECD finds total effects in the range of **MXN 10 228.7 million up to MXN 44 161.9 million**, arising from efficiency gains and lower prices on goods and services for consumers. The positive effects on the Mexican economy over time, however, are likely to be far greater.

Benefits generally take the form of lower prices, greater choice and variety for consumers. Often they will result from the entry of new, more efficient firms, or from existing suppliers finding more efficient forms of production under competitive pressure. As noted earlier, more competitive markets result in faster productivity growth over a longer timescale, but no attempt is made to estimate this effect.

The remainder of this report describes the results of the assessment in the two sectors. For each of the provisions or groups of provisions identified as potentially harmful, the report describes the nature of the restriction, the harm it causes to competition, the policymakers' objectives and the recommendations and associated benefits identified by the OECD.

Annex A to the report describes in detail the methodology followed in the process, both to screen the laws and regulations, and also to assess the harm to competition from the restrictions, as well as the benefits to the Mexican economy and to consumers from removing the barriers to competition.

Annex B to the report provides, line by line, a summary of all the regulations identified, to help the reader identify the analysed law or article, as well as a summary description of all the analyses carried out.

Notes

1. The methodology followed in this project is consistent with the product market regulations (PMR) developed by the OECD; see OECD (2014b), Box 2.1. In 1998, the OECD developed an economy-wide indicator set of product market regulations (PMR) to measure a country's regulatory stance and track reform progress over time. The indicator has since been updated in 2003, 2008 and 2013.
2. These are Australia, Canada, Germany, France, United Kingdom, Japan, Korea and USA.
3. Only includes SCIAN code 3254 (Medicine manufacturing). GVA related to wholesale and retail of medicines was not available, hence, GVA of the total medicine sector should be higher.
4. Only includes SCIAN code 3116 (Animal slaughtering and processing). GVA related to livestock raising, meat wholesale and meat retail was not available, hence, GVA of the total meat sector should be higher.

5. Using the following SCIAN codes: 325411 (Pharmaceutical industry input manufacturing) and 325412 (Medicine manufacturing) for production, 433110 (Medicine wholesale) and 46411 (Medicine retail).

6. Using the following SCIAN codes: 3111 (Animal-feed manufacturing); 3116 (Animal slaughtering and processing) for production; 431121 (Red-meat wholesale); and 431122 (Poultry-meat wholesale) for wholesale; and 461121 (Red-meat retail) and 461122 (Poultry-meat retail) for retail.

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Chapter 2

Medicines

The medicines sector has enormous economic and social implications for Mexico. It is an important source of employment (367 056 people, as of 2013) and contributor of GVA (from 2005 until 2015, the GVA for medicine manufacturing was, on average, 0.67% of total GDP). Among its main constraints are a lack of regulation concerning pecuniary advantages pharmaceutical companies can provide to doctors; patients' restricted possibilities to substitute branded medicines for generics; a regulatory model of maximum prices for patented medicines that leads to high prices for Mexican consumers; the confidentiality of the amendment to the medicines-pricing agreement; and provisions that allow the sector's regulators unguided discretion. In addition, several dispositions discriminate against foreigners, in both the private and the public sectors. The report also finds various Mexican standards that expressly state that they are not in line with international norms.

2.1. Economic overview of the medicines sector

2.1.1. Definition of the subsectors and main concepts

This report analyses the medicine sector and covers the manufacture, wholesale, and retail of medicines. The investigation does not cover industrial-use alcohols; equipment for medical and dental use and for laboratories; disposable supplies for medical use; ophthalmic items; optical goods and orthopaedic items.[1]

According to the Mexican General Health Law,[2] a medicine is "every substance or mix of substances of natural or synthetic origin with a therapeutic, preventive or rehabilitating effect, presented under a pharmaceutical form and identified like this owing to its pharmacological activity and to its physical, chemical and biological characteristics. In the case of a product with nutriments, it will be considered as a medicine whenever it refers to a preparation containing in an individual or associated way, vitamins, minerals, electrolytes, amino acids or fatty acids, in concentrations higher than natural food and if it is also presented in a defined pharmaceutical form and whose indications of usage include therapeutic, preventive or rehabilitating effects."[3]

The General Health Law classifies medicines according to their method of preparation and nature.[4] Under Mexican law, "generics" are medicines that can be used instead of original patent medicines once there is proof that their characteristics (e.g. pharmaceutical form, active substance, route of administration) are identical to the reference medicine.[5] Since 2011, the Federal Commission for the Protection Against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) has promoted the adoption of generics in Mexico. As a result, generics' market penetration has increased, both in terms of market value and volume. In 2010, about 30% of market value was made up of generics; by 2013, this percentage had increased to 52%. Similarly, in 2010, generics accounted for 54% of the market volume, while in 2013, they accounted for 84% (COFEPRIS, 2016).

Consumers in Mexico can purchase medicines with or without prescription. If sold without prescription, medicines are commonly known as "prescription-free medicines" or "over-the-counter" (OTC).

2.1.1.1. Price Regulation

Mexico has established a price-regulation mechanism that aims to protect consumers and prevent excessive pricing for patented medicines.[6] The Ministry of Economy, with the support of the Ministry of Health, approves maximum sale prices for medicines. In practice, only patented medicines are subject to price regulation; pharmaceutical companies set the prices of generics without regulation.

To determine the price of patented medicines, pharmaceutical companies submit their "selling reference prices" to the Ministry of Economy. The selling reference price is equal to the international reference price, which, in turn, is a weighted average of the medicine's ex-factory price in the six countries where the product enjoys the highest sales, plus the estimated (non-regulated) wholesale and retail mark-ups (OECD, 2008). The Ministry of Economy regularly publishes a list of patented medicines with their maximum prices.

2.1.1.2. Basic Formulary of Inputs, and Input Catalogue

The General Health Council (Consejo de Salubridad General), a collegial body of the Mexican government reporting directly to the President of Mexico, is mandated to issue the Basic Formulary of Inputs (Cuadro Básico de Insumos) for the first level of medical care.[7] Additionally, the General Health Council issues an Input Catalogue (Catálogo de Insumos) for the second and third levels.[8]

Public-sector institutions, mainly the Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS) for regular workers (*trabajadores formales*) and the Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, ISSSTE) for employees of federal and state governments,[9] can only buy medicines and inputs included in the Basic Formulary of Inputs or Input Catalogue.[10] In addition, professionals from public institutions are generally obliged to prescribe only medicines contained in these documents.[11]

2.1.1.3. Pharmacopoeia

The Mexican Pharmacopoeia determines the composition a product must possess in order to be considered as a medicine or as an input for a medicine. It provides the requirements for the identity, purity and quality of medicines, as well as general methods for their analysis, according to the Regulation on Health Inputs (Reglamento de Insumos para la Salud). In addition, the Mexican Pharmacopoeia and its supplements provide rules to all establishments[12] that are active in obtaining, processing, manufacturing, preparing, conserving, mixing, conditioning, packaging and handling medicines.[13] Finally, there are also Mexican Pharmacopoeia supplements that provide general rules for pharmacies.

The Ministry of Health, through the Permanent Commission for the Mexican Pharmacopoeia (Comisión Permanente de la Farmacopea de los Estados Unidos Mexicanos, CPFEUM), constantly updates the Mexican Pharmacopoeia. Complete new editions are issued every three to ten years, though annual updates are published as supplements. The current edition is the eleventh and was issued in 2014.[14] According to the Regulation on Health Inputs, other countries' pharmacopoeias can be used in place of the Mexican Pharmacopeia, if the latter does not provide the necessary information for allopathic, homeopathic or herbal medicines.

2.1.1.4. Regulatory scheme: sanitary authorisations and other certificates

In Mexico, sanitary authorisations (*autorizaciones sanitarias*; "sanitary" is here used in its sense "of or in relation to health") along the value chain of medicines are necessary in order to guarantee that medicines are risk-free for end consumers. Pharmaceutical companies must have a sanitary registry for every medicine they commercialise, which must be renewed every five years. The export of narcotics or psychotropic medicines requires a sanitary permit. Establishments engaged in the development, manufacture or preparation of medicines require a sanitary licence to operate.

According to the General Health Law, the Ministry of Health – through COFEPRIS – allows private companies that hold sanitary authorisations to trade in medicines. These include licences, permits and sanitary registries.

- **Sanitary licences (licencias sanitarias).** Companies require a sanitary licence to manufacture medicines. They are necessary for:

- establishments engaged in the development, manufacture or preparation of medicines
- establishments engaged in the manufacture of biotechnological products or their inputs.

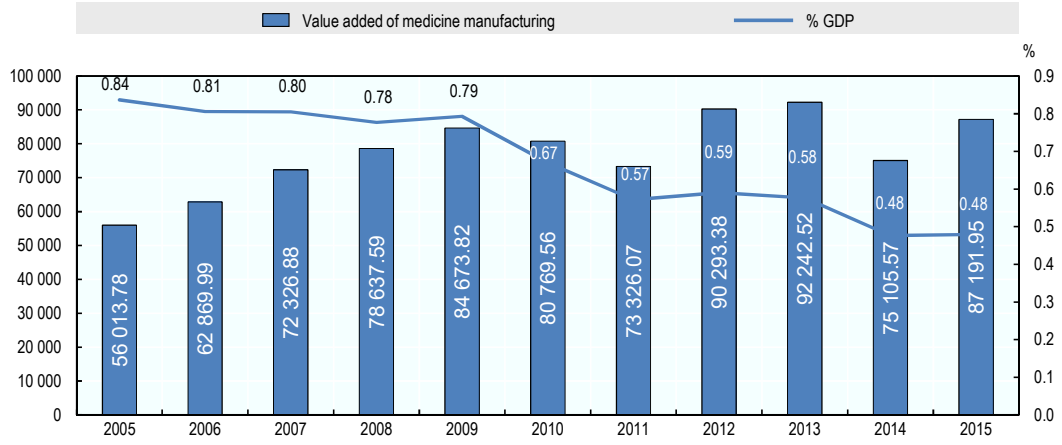
According to the General Health Law, the export of health inputs does not require a sanitary licence but rather an "export certificate" (*certificado de exportación*) issued by the Ministry of Health. If the exporter proves the buyer has accepted the medicine, it is not necessary to obtain a sanitary registry in addition to the export certificate.

- **Sanitary permits (permisos sanitarios).** A sanitary permit is mandatory for the following activities:
  - pharmacies possessing control books for narcotic drugs or psychotropic substances.
  - medical prescription of narcotics or psychotropic substances made by any of the following professionals: physicians; surgeons; veterinary doctors when drugs are prescribed for animals; dental surgeons and interns.
  - advertising related to medicines.
  - import of medicines, import and export of narcotics and psychotropic substances or products containing them.
- **Sanitary registries (registros sanitarios).** To be commercialised in Mexico, medicines, narcotics or psychotropic substances are required to obtain a sanitary registry (*registros sanitarios*), which is managed by the Ministry of Health. In order to obtain a sanitary registry, the Ministry of Health or Authorised Third Parties (Tercero Autorizado)[15] verify compliance of the products with best practice, and grant good manufacturing practice (GMP) certificates for health inputs. COFEPRIS issues such GMP certificates itself, which last 30 months; it also recognises eight foreign authorities as valid GMP issuers. COFEPRIS also confirms that the applicant has the necessary GMP certificates for all active substances in a medicine, even when these substances have been manufactured abroad. Mexican health authorities will recognise the foreign certification of active substances as long as there is an international treaty between Mexico and the country of origin.[16] In cases where a Mexican pharmaceutical manufacturer wants to buy substances from a supplier based in a country with no international treaty, COFEPRIS will send inspectors to certify the foreign supplier's plant. The Mexican producer is liable for the costs, including fees (MXN 84 080.88 for every visit) and travel expenses (the visits last at least five days and longer if more than one ingredient is involved).[17] Sanitary registries have to be renewed every five years.

2.1.2. Gross value added of the medicine manufacturing

From 2005 until 2015, the gross value added (GVA) for medicine manufacturing was, on average, 0.67% of total gross domestic product (GDP), peaking at 0.84% in 2005, before dropping to 0.48% by 2015. In total numbers, the GVA in 2015, measured in real terms, was MXN 87 192 million.

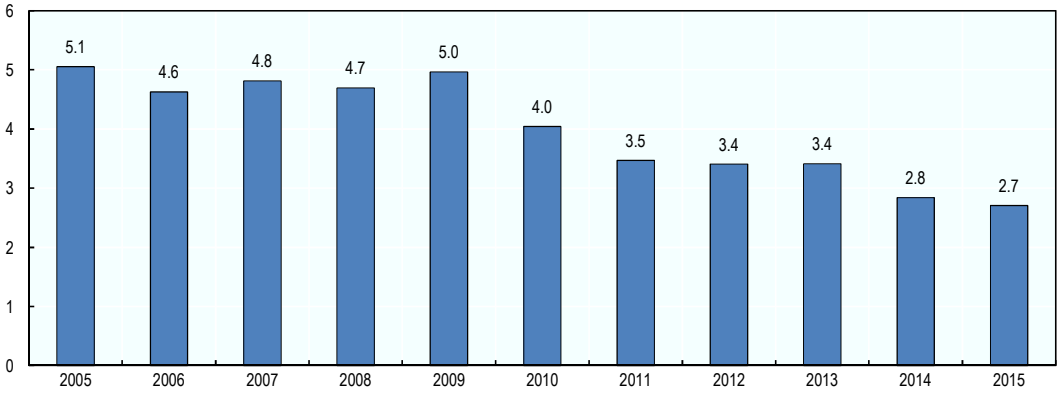
Figure 2.1. **Medicine manufacturing: GVA (2015 MXN, millions) and percentage of GDP, 2005-2015**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

Medicine manufacturing's share of GVA as part of the manufacturing sector's total GVA steadily declined, except for 2009, from 5.1% in 2005 to 2.7% in 2015, averaging 4% during those years.

Figure 2.2**. Share of GVA (%) of medicine manufacture in manufacturing sector GVA, 2005-2015**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

2.1.3. Market structure and main indicators

2.1.3.1. Manufacturing

Market participants

According to data from COFEPRIS, as of 17 March 2017, 241 different pharmaceutical companies held valid sanitary licenses for manufacturing medicines (allopathic and homeopathic) in Mexico, including nine that also manufactured raw materials. Additionally, 36 pharmaceutical companies only manufactured raw materials. The top ten leading pharmaceutical companies accounted for 42% of the medicine-manufacturing market (by value) in 2014, of which two were Mexican-owned companies (Laboratorios Sanfer and Laboratorios Senosiain).

Table 2.1. **Top 10 leading corporations by value in the total market (August 2014)**

Company	Country of origin	Market Share (%)
Pfizer	United States	6.4
Sanofi	France	5.7
Bayer	Germany	5.4
Novartis	Switzerland	4.6
Schering-Plough*	United States	4.4
Boehringer Ingelheim	Germany	3.8
Sanfer	**Mexico**	**3.2**
Merck-Serono	Germany	3.1
Johnson & Johnson	United States	3.0
Laboratorios Senosiain	**Mexico**	**3.0**

* In November 2009, Merck & Co., Inc. and Schering-Plough merged.
(see, www.sec.gov/Archives/edgar/data/310158/000089882209000096/pressrelease.htm).

The statistics in this table, from Healthcare Life Sciences & Review, still use the name Schering-Plough.

Source: *Healthcare Life Sciences & Review*, published by PharmaBoardroom in collaboration with CANIFARMA (November 2015), with data from IMS Health.

Table 2.2. **Top ten OTC pharmaceutical companies in Mexico, 2012**

Company	Country of origin	Market Share (%)
Bayer	Germany	8.7
Genomma Lab Internacional	**Mexico**	**8.7**
Merck & Co.	United States	5.8
Johnson & Johnson	United States	5
Procter & Gamble	United States	4.7
Boehringer Ingelheim	Germany	4.7
Laboratorios Pisa	**Mexico**	**4.7**
Bristol-Myers Squibb	United States	4.6
Sanofi	France	4.2
Novartis	Switzerland	3.7

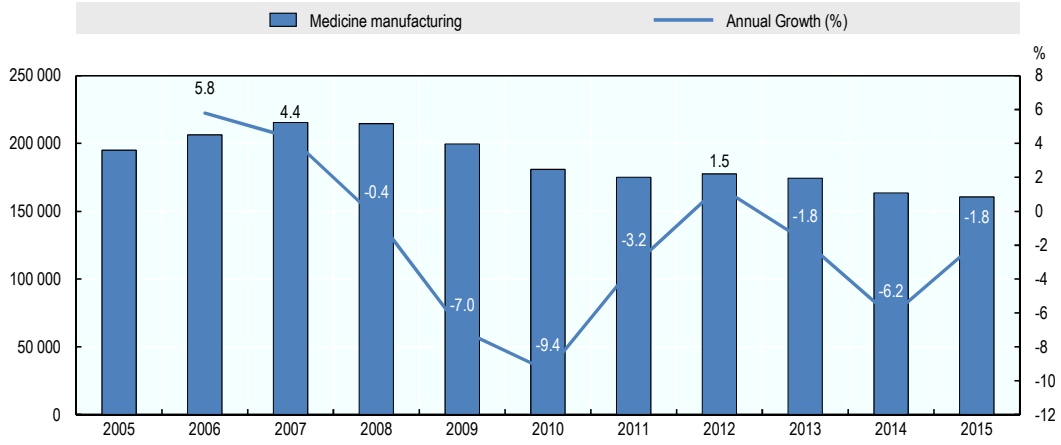
Source: PROMÉXICO, Unidad de Inteligencia de Negocios (2013), *Industria Farmacéutica*

For the manufacture of OTC products in Mexico, data from PROMÉXICO – a Mexican governmental body promoting foreign investment – put two Mexican firms in the top ten in 2012, with the caveat that recent data are not readily available.[18]

Manufacturing by value

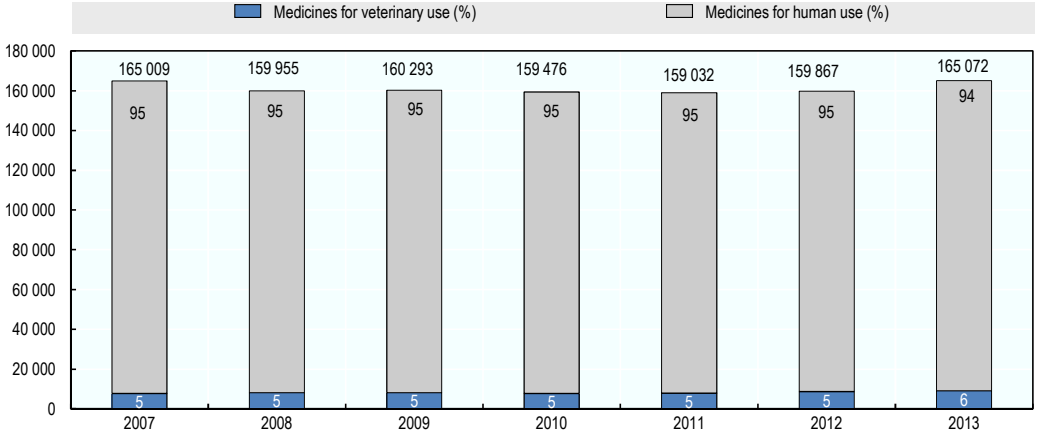
The manufacture of medicines in Mexico has declined steadily. From 2005 to 2015, according to INEGI, the value of medicine manufacturing, measured in real terms, decreased at an average annual rate of 1.9%. In 2015, medicine manufacturing in Mexico was worth MXN 160 588 million.

Figure 2.3. **Medicine manufacturing (2015 MXN, millions), 2005-2015**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

Figure 2.4. **Ex-factory sales of medicines for human and veterinary use (2015 MXN, millions), 2007-2013**

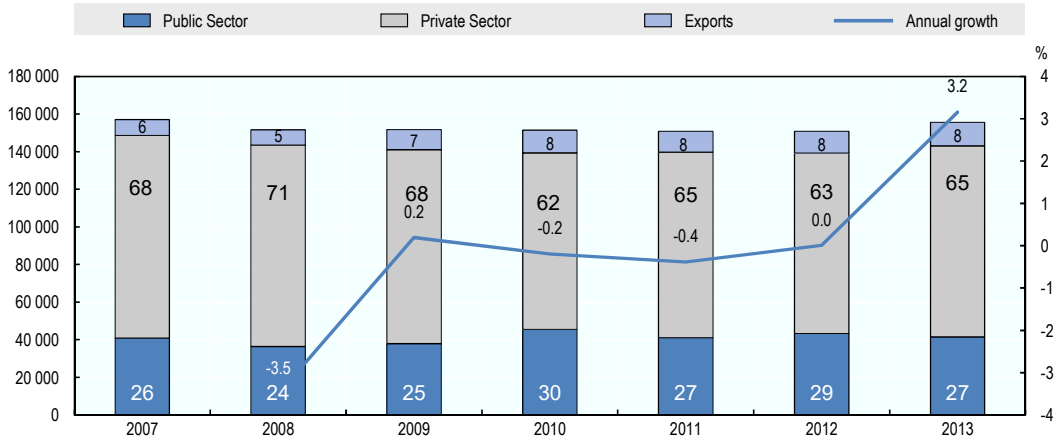


Source: CANIFARMA (2015), *Compendio Estadístico de la Industria Farmacéutica en México (2007-2013)*

According to pharmaceutical-industry body CANIFARMA, in 2013, its members' ex-factory sales accounted for MXN 165 072 million in real terms, which includes the manufacturing of human and veterinary medicines. Based on this data, ex-factory sales of CANIFARMA members showed an insignificant increase between 2007 and 2013: an average annual rate of 0.006%, from MXN 165 009 million in 2007 to MXN 165 072 million in 2013 (CANIFARMA, 2015).

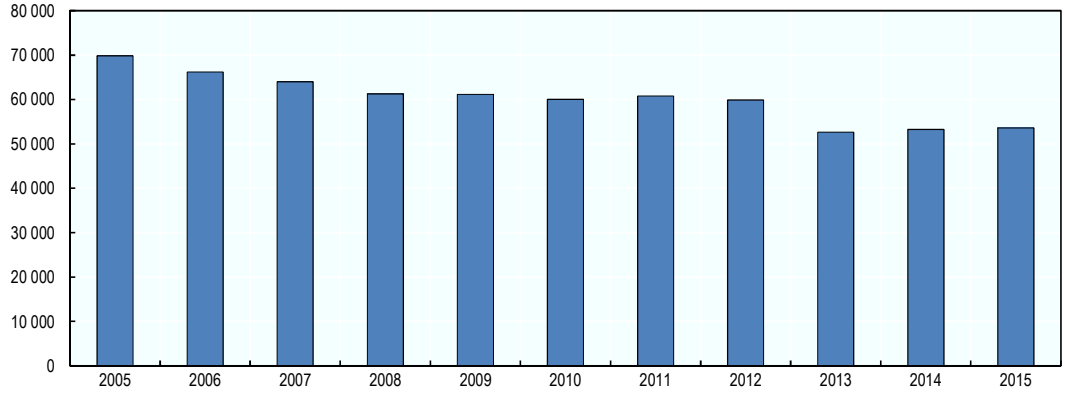
CANIFARMA members' ex-factory sales of medicines for human use to the private sector during the period 2007-2013 oscillated between 62% and 71%, while the share of sales to the public sector oscillated between 24% and 30%, and the share of exports remained below 10%.

Figure 2.5. **Ex-factory sales of medicines for human use (2015 MXN, millions), destination shares (%) and annual growth (%), 2007-2013**



Source: CANIFARMA (2015), *Compendio Estadístico de la Industria Farmacéutica en México (2007-2013)*

Figure 2.6. **Number of employees in medicine manufacturing**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

Number of employees

From 2005 to 2015, the number of employees active in medicine manufacturing decreased continuously, at an average annual rate of 2.6%, from 69 846 employees in 2005 to 53 535 in 2015.

2.1.3.2 Wholesale

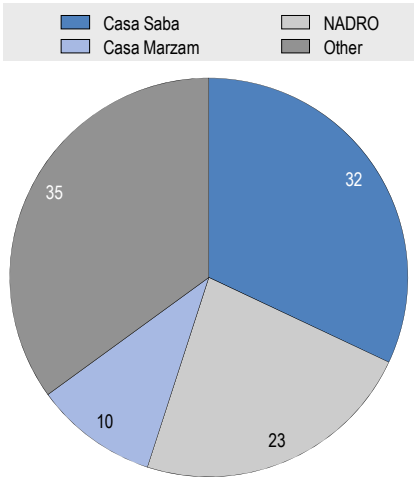
Most laboratories neither distribute nor trade their products directly (not even to pharmacy chains), but rather sell them through wholesale distributors. Those wholesalers manage, store, transport and deliver final products to pharmacies and hospitals. Wholesalers sometimes provide additional services, such as granting credits and handling payment processes.

Market participants

In 2012, four firms accounted for 58% of medicine distribution to the private sector: Casa Saba[19] Nacional de Drogas (NADRO), Casa Marzam and Fármacos Nacionales. Two medium-sized players, Proveedoras de Medicamentos and Almacenes de Drogas, and 33 smaller firms specialised in regional distribution shared the remaining market (Fundación Mexicana para la Salud, 2013).

In 2013, the *Mexican Health Review* (2015) found that the three biggest competitors – Casa Saba, NADRO and Casa Marzam – controlled as much as 65% of the total distribution market (Casa Saba: 32%; NADRO: 23%; Casa Marzam: 10%).

Figure 2.7. **Market share of wholesalers, 2013 (%)**

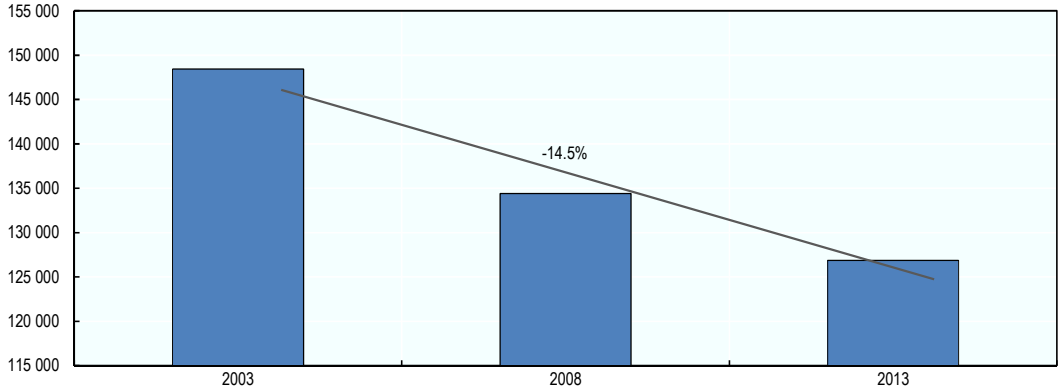


Source: Mexico Health Review (2015)

Turnover by value and number of employees

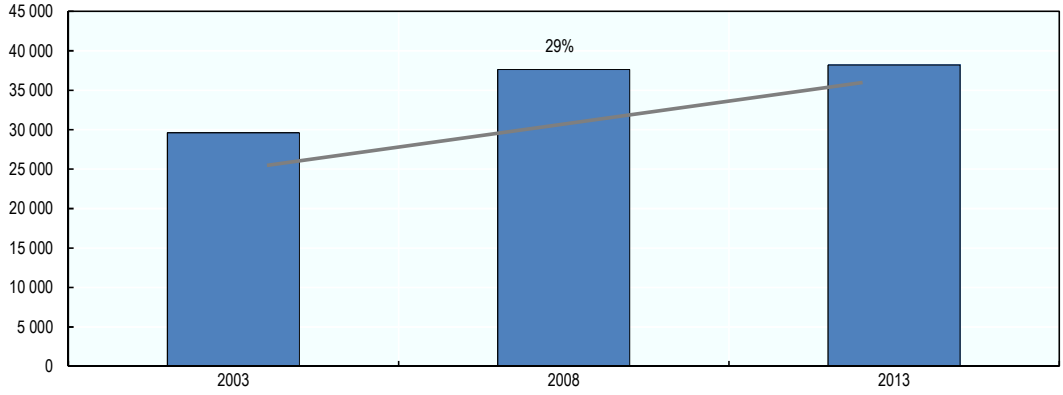
According to INEGI census data, the aggregated turnover of all wholesalers constantly decreased between 2003 and 2013, while turnover decreased in real terms by 14.5%. Yet somewhat surprisingly, the number of employees increased by 29% during the same period. As of 2013, there were 38 198 employees.[20]

Figure 2.8. **Turnover of medicine wholesale distribution (2015 MXN, millions)**



Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

Figure 2.9. **Number of employees in medicine wholesale distribution**



Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

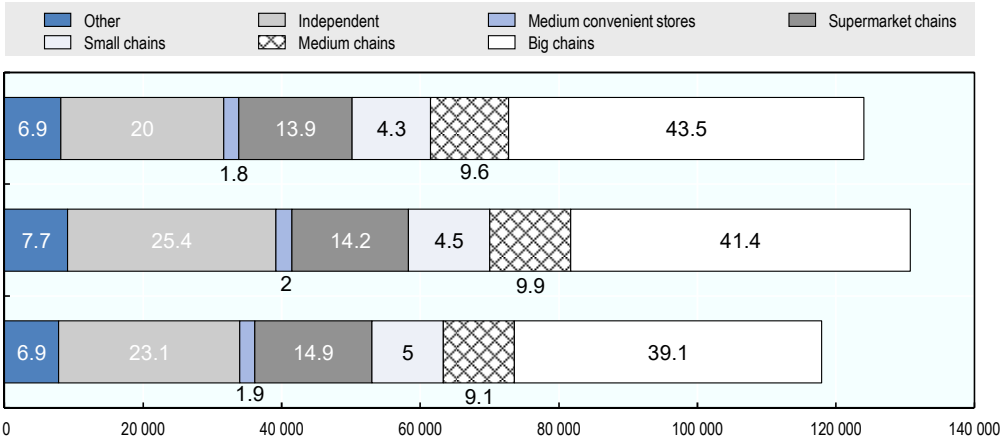
2.1.3.3. Retail

Market participants

As of 22 March 2017, there were 56 699 active pharmacies in the Mexican retail market.[21] There were also 20 131 establishments that did not sell allopathic medicines, but rather homeopathic medicines, herbal medicines and/or food supplements.

Pharmacies can be independent, belong to chains, to supermarkets or to the government. The share of chain pharmacies in total pharmacy sales steadily increased between 2012 and 2014: from 53.2% to 57.4%.

Figure 2.10. **Sales in the retail sector (nominal MXN, millions) and share of pharmacy formats (%)**



Source: Mexico Health Review (2015)

According to press sources,[22] Farmacias del Ahorro, Farmacias Guadalajara and Farmacias Benavides were the three largest pharmacy chains in 2015.

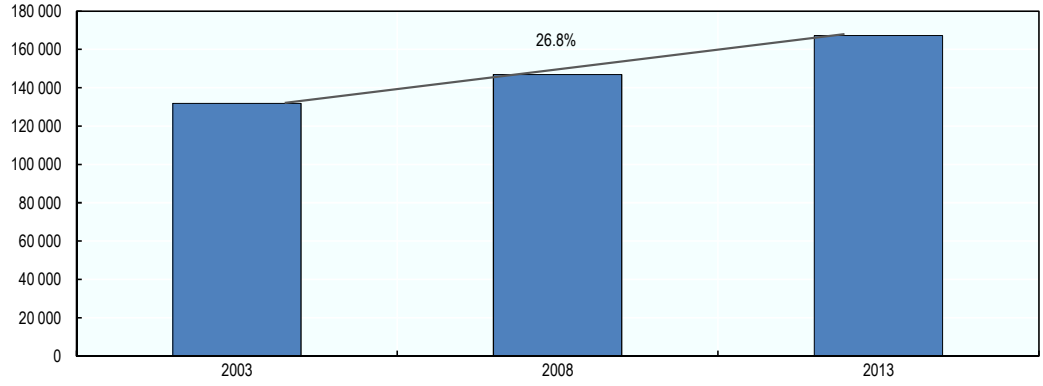
In February 2015, just over half of pharmacies in Mexico (53.5%) had an adjacent doctor's office (Consultorio Adyacente a Farmacia or CAF), according to COFEPRIS.[23]

CAF play an important role in Mexico's health system, assuring fast and affordable medical access to a significant part of the population. Indeed, in 2013, CAF provided over 250 000 daily medical visits, while IMSS provided nearly 290 000.[24] However, as virtually all CAF belong to pharmacies, doctors are not always completely free in their prescription practice as they can receive financial incentives from pharmacies based on their prescription practices (e.g. bonuses for high volumes of medicines prescribed).

Turnover, number of establishments and number of employees

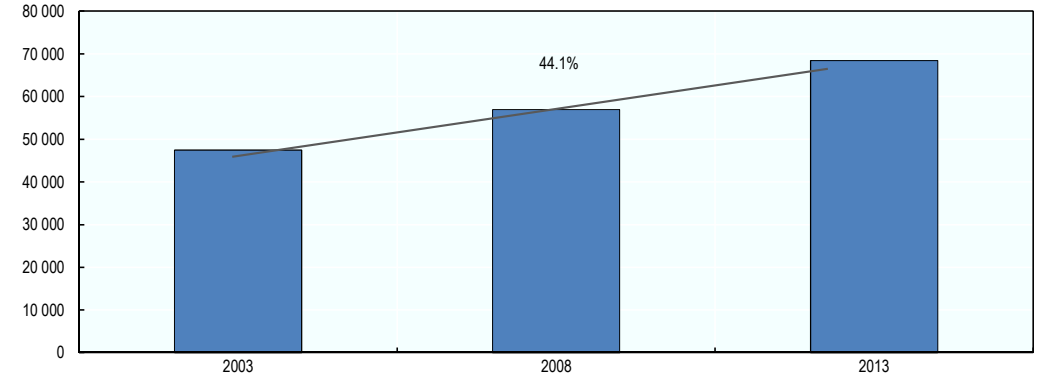
Over the past decade, in contrast to wholesale-distribution turnover, the retail sector in pharmaceuticals has been growing significantly. According to INEGI census data, aggregated turnover, measured in real terms, increased by 26.8% between 2003 and 2013, an implied average annual growth rate of 2.4%. In addition, between 2003 and 2013, the number of establishments and employees increased by 64.2% and 44.1%, respectively (to 68 395 establishments and 245 522 employees in 2013).[25]

Figure 2.11. **Turnover of pharmaceutical retail (2015 MXN, millions)**



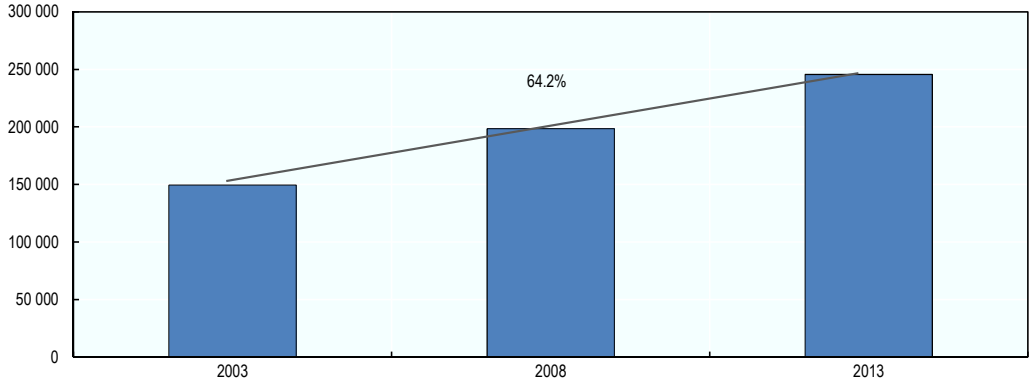
Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

Figure 2.12. **Number of establishments in pharmaceutical retail**



Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

Figure 2.13. **Number of employees in pharmaceutical retail**



Source: INEGI, 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

2.1.3.4. Demand side

Main health institutions

The main institutions providing health insurance in Mexico and so purchasing pharmaceuticals are the following.[26]

- **IMSS.** IMSS is in charge of the administration of social insurance, the basic instrument of social security in Mexico. IMSS provides benefits under its compulsory and voluntary regimes: in the compulsory regime, employers are mandated to register their employees. In turn, the voluntary regime is meant for workers who are no longer employed, but who wish to continue contributing to IMSS in order to benefit from health coverage and pensions (e.g. the self-employed, communal landholders, employers, domestic workers or public-sector workers at the federal, state or municipal levels, who are excluded or not covered by a social-security regime). In 2015, IMSS covered approximately 59.1% of the Mexican population (IMSS, 2015).
- **ISSSTE.** ISSSTE provides health insurance to officials/employees working for the federal and state governments. ISSSTE covers approximately 10.6% of the Mexican population.
- **Other public insurance programmes.** PEMEX, the Ministry of Navy, and the Ministry of National Defence each has its own special public system, providing health coverage to employees. The three institutions jointly cover 1.6% of the Mexican population.
- **Seguro Popular (SP).** Created in 2004, SP is a system of voluntary public insurance established by the Mexican government in an effort to expand health-care coverage. By 2014, SP had gradually expanded to cover more than 57 million people or 47.6% of the Mexican population.

Private insurance

Approximately 8% of the Mexican population is covered by private health insurance.[27]

According to the National Council for the Evaluation of Social Development Policy (Consejo Nacional de Evaluación de la Política de Desarrollo Social, CONEVAL), 18.2% of the Mexican population had no access to medical coverage in 2014, making all their medicines out-of-pocket expenses (CONEVAL, 2015).

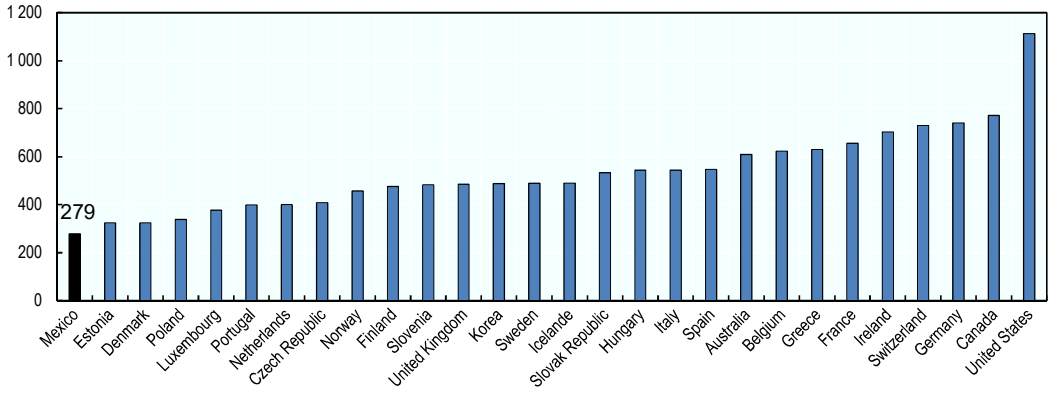
Public institutions that provide health insurance in Mexico have their own networks of hospitals and medical units, including physicians and required health suppliers, to guarantee medical care to their affiliates.

These public health institutions mostly use public-tender procedures when purchasing health supplies. Since 2012, IMSS has been bundling its purchases together with ISSSTE and, gradually, other public institutions.[28] In December 2016, for example, IMSS and ISSSTE consolidated their purchases with PEMEX, the Ministry of Navy and the Ministry of National Defence, and other 18 state-government institutions and 17 institutions from the Ministry of Health, for the biggest public-sector order in Mexican history, worth MXN 41 861 million.[29]

Medical spending in Mexico

In 2014, per-capita pharmaceutical spending in Mexico was USD 279,[30] one of the lowest among a selection of 28 OECD countries.

Figure 2.14. **Pharmaceutical spending per capita (USD) across OECD countries, 2014***

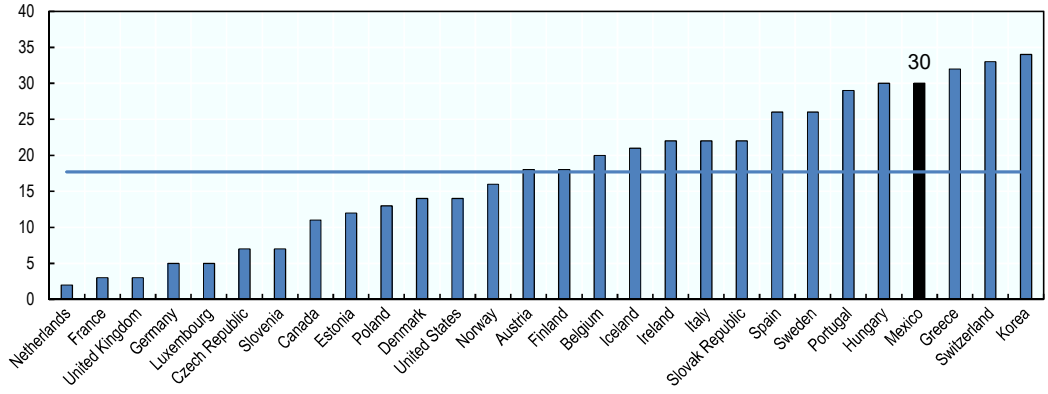


* The value for the Netherlands is underestimated as it excludes compulsory co-payments by patients to health insurers; if these were taken into account, the share would double.

Source: OECD (2017), "Pharmaceutical spending (US dollars/per capita)"

However, as shown in Figure 2.15, out-of-pocket medical spending in Mexico as a share of household consumption was among the highest among the OECD 28 in 2015. While the average out-of-pocket spending share among the OECD 28 was 17.7%, Mexican spending accounted for 30% of household consumption. In Mexico, the OECD has found that out-of-pocket spending "has not fallen significantly across the past decade, despite efforts to achieve universal health coverage through the SP reform. Reasons for sustained, high levels of spending out-of-pocket are unclear. Part of the reason may be dissatisfaction with the quality or accessibility of services provided by institutions to which individuals are affiliated, leading them to seek care from private health providers" (OECD, 2016d).

Figure 2.15. **Share of out-of-pocket medical expenditure in household consumption (%) across OECD countries, 2015***

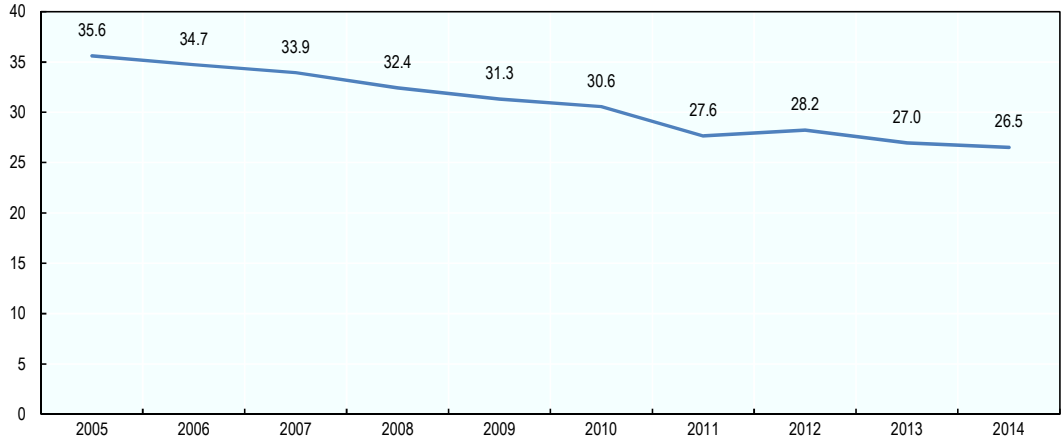


* The ranking for the Netherlands is overrated as it excludes compulsory co-payments to health insurers.

Source: OECD (2015), *Health at a Glance 2015*

The share of pharmaceutical spending as a part of health spending steadily decreased from 35.6% in 2005 to 26.5% in 2014. This is probably due to increasing use of generics.

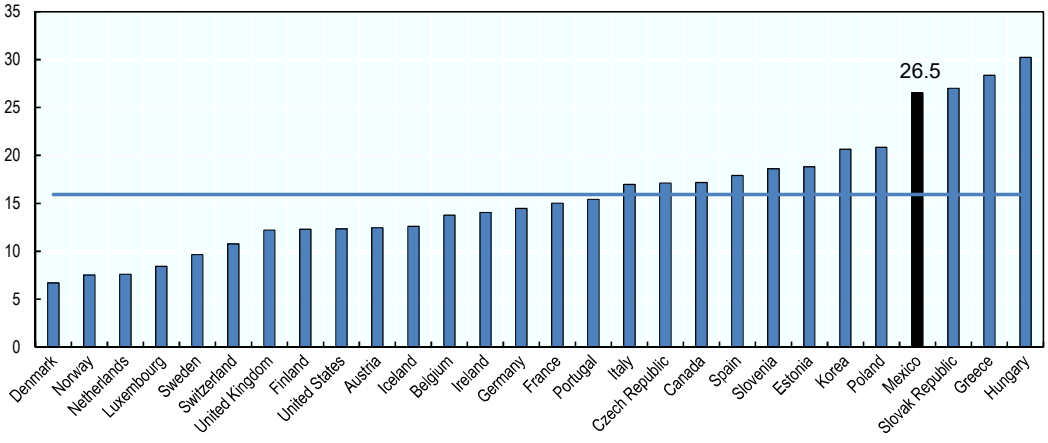
Figure 2.16. **Pharmaceutical spending as a percentage of health spending (%), 2005-2014**



Source: OECD (2017), "Pharmaceutical spending (% of health spending)"

In spite of this downward trend, pharmaceutical spending as part of health spending in Mexico is still relatively high when compared to other countries. In 2014, among the OECD 28, Mexico ranked 25th with 26.5%, above the average of 15.9%.

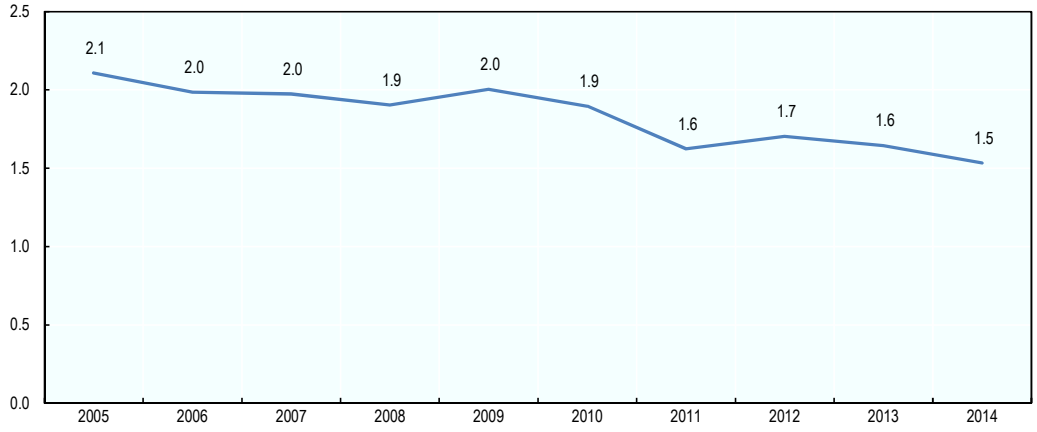
Figure 2.17. **Pharmaceutical spending as a percentage of health spending (%) across OECD countries, 2014**



Source: OECD (2017), "Pharmaceutical spending (% of health spending)"

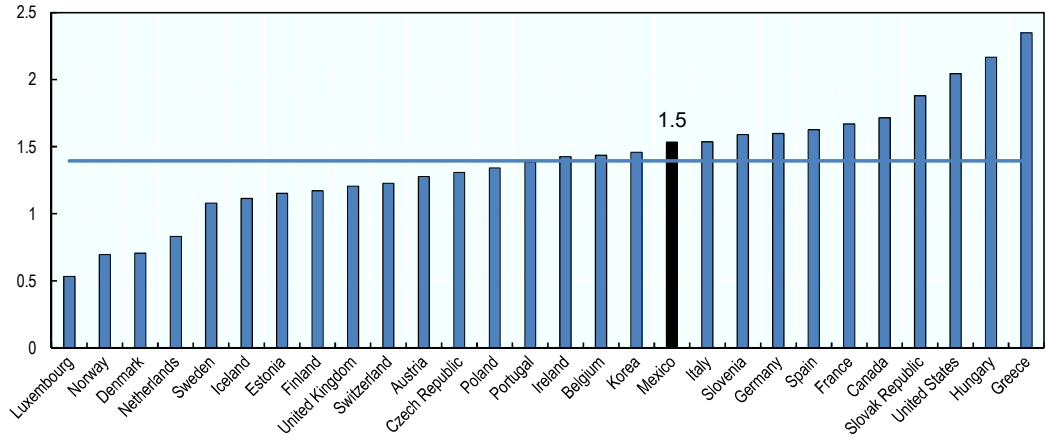
As depicted in Figure 2.18, Mexico's share of pharmaceutical spending as percentage of GDP decreased from 2.1% in 2005 to 1.5% in 2014. This percentage was close to the 1.4% average of the OECD 28.

Figure 2.18. **Pharmaceutical spending as a percentage of GDP (%), 2005-2014**



Source: OECD (2017), "Pharmaceutical spending (% of GDP)"

Figure 2.19. **Pharmaceutical spending as a percentage of GDP (%) across OECD countries, 2014**

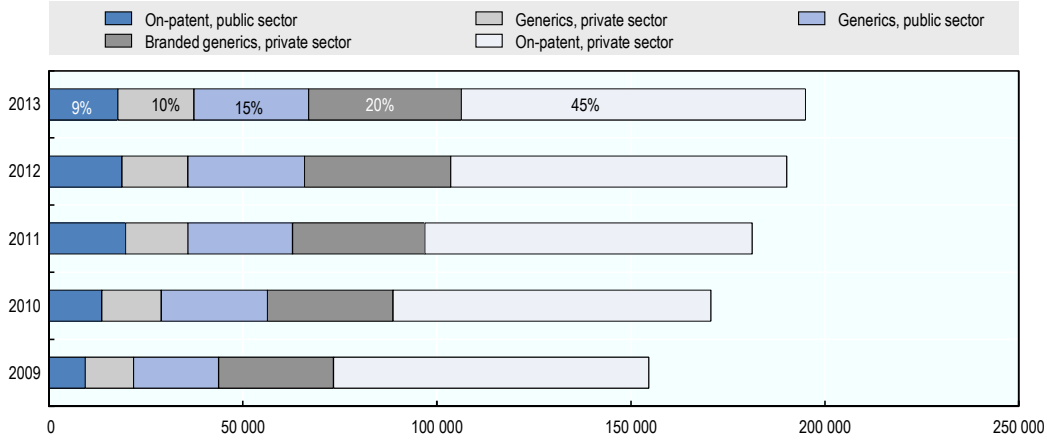


Source: OECD (2017), "Pharmaceutical spending (% of GDP)"

2.1.4. Sales of generics and patented medicines by value and volume

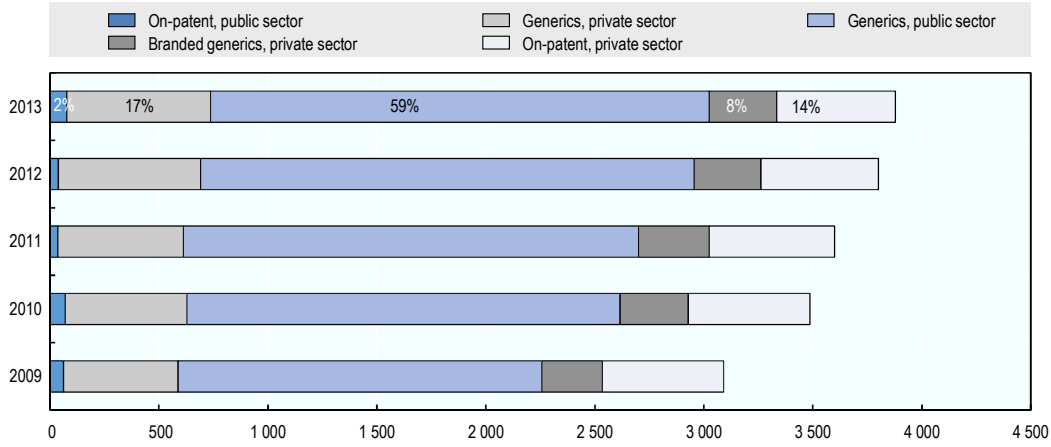
Figures 2.20 and 2.21 show the Mexican medicine market broken down by type, in value and volume, respectively. In 2013, generics accounted for the largest part of the market in units (84%), while on-patent medicines represented the biggest part of the market by value (54%).[31]

Figure 2.20.**Total medicine market by value (MXN, millions), by type, 2009-2013**



Source: PharmaBoardroom in collaboration with CANIFARMA (June 2015), *Healthcare Life Sciences & Review*, with data from IMS Health

Figure 2.21. **Total medicine market in units (millions), by type, 2009-2013**

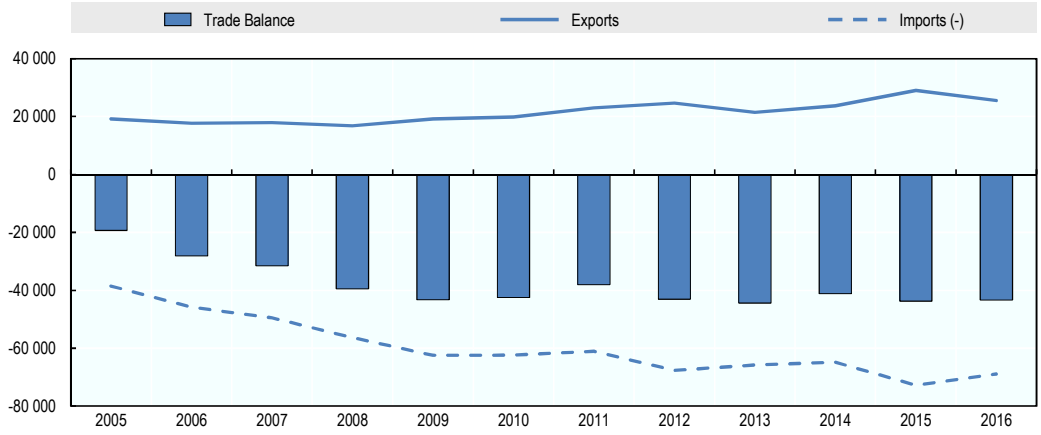


Source: PharmaBoardroom in collaboration with CANIFARMA (June 2015), *Healthcare Life Sciences & Review*, with data from IMS Health

2.1.5. International trade

Between 2006 and 2016, the value of imports of all medicines – including both on- and off-patent – grew, in real terms, at an average annual rate of 4.2%, while the value of exports increased by 3.7%. Over the same time period, and on a month-by-month basis, imports were constantly higher than exports, however; on average, 2.8 times exports. This resulted in a constant negative trade balance for medicines in Mexico.

Figure 2.22. **Imports and exports of medicines (2015 MXN, millions), 2006-2016***



* Import and export values were obtained from INEGI's External Sector Statistics, including values in the chapter "Pharmaceutical products", which is part of section VI, "Products from the chemical industry or related industries", minus the value of the subchapter "Wadding, gauze, bandages". The values are monthly thousands of USD from January 2006 until December 2016. The monthly FIX exchange rate for MXN to USD from Banxico was used. After obtaining the value in thousands of MXN, each monthly value was deflated using INEGI's Producer Price Index of and converted to millions. Finally, an annual estimation was obtained considering the sum of the monthly values.

Source: INEGI, Banco de Información Económica, Sector Externo

According to PROMÉXICO, medicines imported into Mexico in 2014 came from the United States (21%), Germany (18%) and France (11%);[32] the main final export destinations for medicines in 2015 were Switzerland (23.1%), the United States (22.4%) and Panama (7.8%).[33]

Table 2.3. **Country of origin of imported medicines (2014)**

Country	Value (USD, millions)	Market share
United States	1 045	21%
Germany	901	18%
France	559	11%
Puerto Rico	423	9%
Switzerland	303	6%
Italy	215	4%
Canada	189	4%
Ireland	118	2%
Belgium	115	2%
Spain	112	2%
Other	958	19%

Source: PROMÉXICO, Unidad de Inteligencia de Negocios (2015), *Industria Farmacéutica y Oportunidades de Negocio en México*

Table 2.4. **Country of destinations of exported medicines (2015)**

Country	Value (USD, millions)	Market share
Switzerland	452	23%
United States	438	22%
Panama	153	8%
Venezuela	128	7%
Colombia	109	6%
Ecuador	75	4%
Guatemala	75	4%
Brazil	72	4%
Canada	64	3%
France	53	3%
Other	339	17%

Source: PROMÉXICO, Unidad de Inteligencia de Negocios (n.d.), *Diagnóstico Sectorial Farmacéutico*

Before 5 August 2008, companies wishing to import medicines into Mexico were required to own infrastructure in the country. Since then, foreign medicines producers can import their products into Mexico without owning infrastructure as long as they hold a licence to produce medicines in their countries of origin.

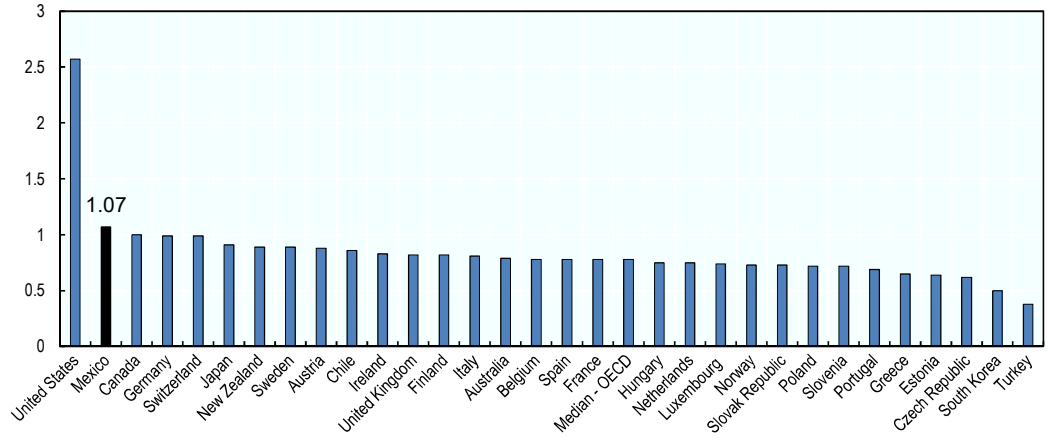
2.1.6. International price comparisons

There are no recent studies of comprehensive price comparisons between Mexico and other countries. However, some representative studies do exist, including one from 2015 that uses a sample of patented medicine prices in OECD countries, which is then compared to Canadian prices.

2.1.6.1. OECD prices 2015

In its *Annual Report 2015*, Canadian Patented Medicine Prices Review Board (PMPRB) compared prices for medicines in Canada with other OECD countries. In 2015, according to the price comparison shown in Figure 2.23, Mexican prices for patented medicines were higher than all other OECD countries except the United States.

Figure 2.23. **Average foreign-to-Canadian price ratios, patented medicines, OECD countries, 2015***



* Canadian and international prices reported in health-data consultancy IMS's MIDAS database were used. MIDAS summarised data obtained from IMS's audits of pharmaceutical purchases. The index of the average foreign-to-Canadian price ratios were constructed using Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual medicines.

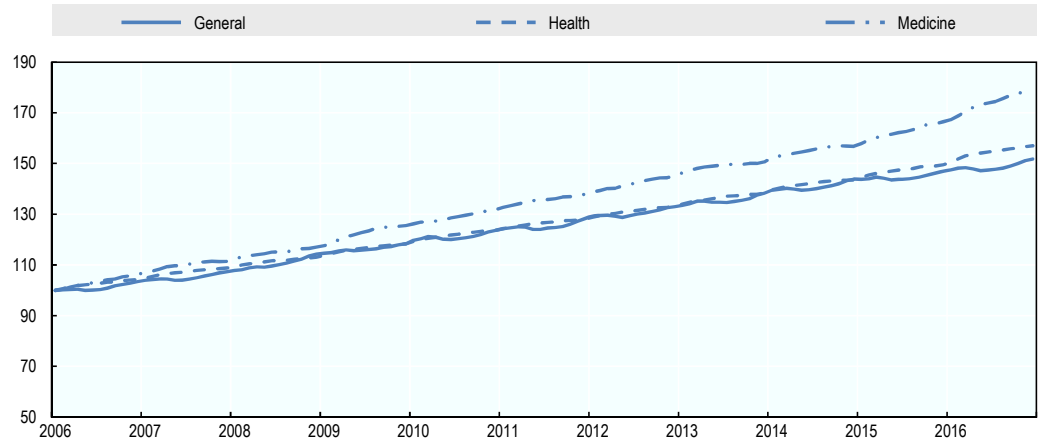
Source: PMPRB (2015), *Annual Report 2015*

2.1.6.2. Medicine prices compared to other consumer prices

Since 2006, medicine prices in Mexico have been rising more quickly than both health-sector prices and general prices, as measured by the Consumer Price Index.[34] Over the past six years (December 2011-December 2016), medicine prices increased at an average annual rate of 5.4%, resulting in a total rise of 30% over the period. Over the same period, general prices only increased by 18%, with average annual growth of 3.4%.

As shown in Figure 2.24, health-care price levels and general prices followed a very similar trajectory between December 2006 and December 2016 (on average, health price levels were 1.3% higher than general prices). Medicine prices, however, have increased more than general prices and shown a greater and growing gap: on average 8.7% for the same period and 11.7% for the past five years.

Figure 2.24. **Consumer Price Indexes, 2006-2016**

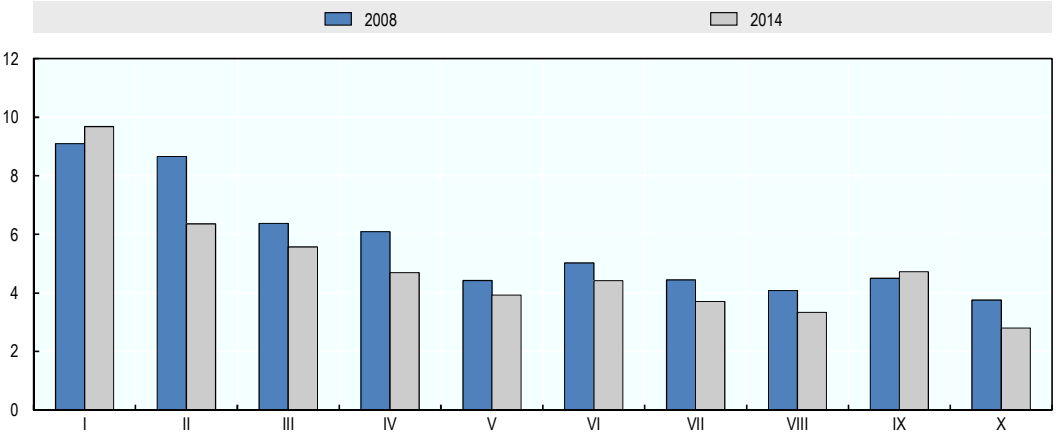


Source: INEGI, Índices de Precios al Consumidor

2.1.6.3. Pharmaceutical spending as share of household spending

Recently, average per-household, out-of-pocket spending on pharmaceuticals (medicines with prescription, OTC and healing material) has decreased. In 2008, the average Mexican household spent MXN 1 143 on pharmaceuticals, which represented 5.2% of its overall expenses. In 2014, it spent MXN 1 193, or 4.5% of its total expenses. Poorer households, however, continue to assign a higher share of their spending to medicines. Indeed, the poorest 10% of households (decile I) spent MXN 592 on average in 2008 (9.1% of their total spending) and MXN 759 in 2014 (9.7%), while the richest households (decile X) spent MXN 2 271 on average in 2008 (3.8% of their total spending) and MXN 2 286 in 2014 (2.8%).[35]

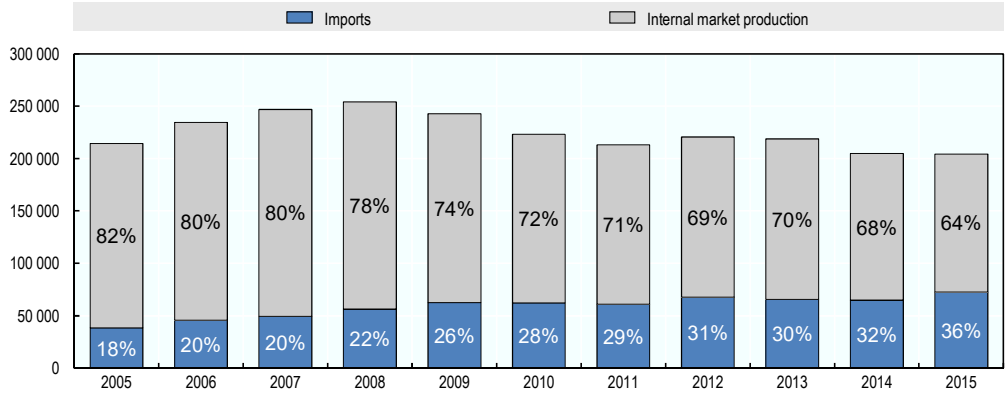
Figure 2.25. **Household expenses on pharmaceuticals (%) per income deciles, 2008 and 2014**



Source: INEGI, Encuesta Nacional de Ingresos y Gastos de los Hogares

With the exception of 2013, imports of medicines steadily increased as a percentage of apparent domestic consumption between 2005 and 2015:[36] in 2005, it represented 18% of apparent domestic consumption, by 2015, the figure was 36% (OECD, 2015).[37]

Figure 2.26. **Domestic consumption of medicines (2015 MXN, millions), 2005-2015**



Source: INEGI, Sistema de Cuentas Nacionales de México and INEGI, Sector Externo

2.1.7. Relevant authorities and associations

2.1.7.1. Authorities

In Mexico, the main health authorities dealing with medicines are the President of Mexico, the Ministry of Health and the state governments, the Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS), and the General Health Council (Consejo de Salubridad General).

- **President of Mexico.** The President of Mexico appoints the Minister of Health, as well as the members of the General Health Council, and approves the regulation of the organisation and functioning of the General Health Council. He is also responsible for designating the Federal Commissioner in charge of COFEPRIS.
- **Ministry of Health.** The Ministry of Health implements the President's national health policy by:
  - coordinating the National Health System (Sistema Nacional de Salud), which comprises public administration entities, both federal and local, and the natural and legal persons from social and private sectors providing health services to the Mexican population
  - laying down Mexican Official Standards (Normas Oficiales Mexicanas, NOMs) related to the provision of health services
  - verifying compliance with NOMs, the General Health Law and any other applicable legal provision in health matters
  - evaluating the provision of health services.
- **Federal Commission for the Protection against Sanitary Risk (COFEPRIS).** COFEPRIS protects the Mexican population against health risks by issuing or revoking sanitary authorisations (mainly licences, permits and registries) concerning establishments that provide health services, manufacture and process medicines, health inputs and food supplements. Further tasks for COFEPRIS include:

- controlling and monitoring health facilities
- prevention and control of environmental effects harmful to human health
- regulation, control and promotion of occupational health and basic sanitation
- sanitary control of products and services, imports and exports
- control of advertising related to health.

COFEPRIS, which is also involved in drafting NOMs, is overseen by the Ministry of Health.

- **General Health Council (Consejo de Salubridad General).** The General Health Council is in charge of issuing opinions about scientific research projects and studies, as well as those related to human-resources training for the health sector. It is composed of a president (the Minister of Health), a secretary and 13 other members.[38] The Council elaborates, updates and distributes the Basic Formulary of Health Inputs for the first level of medical care, as well as the Input Catalogue for the second and third levels.

- **Federal Attorney's Office of Consumer (Procuraduría Federal del Consumidor, PROFECO).** PROFECO, a body of the Ministry of Economy, is in charge of consumer-protection policy. Its powers are regulated by the Federal Law on Consumer Protection. In particular, PROFECO manages a database comparing selected prices of medicines in various cities and stores across Mexico as part of the "Who's Who in Prices" (Quién es Quién en los Precios) programme.[39] PROFECO occasionally publishes special reports for particular products, and has done so for medicines. PROFECO also resolves complaints related to service contracting and product purchasing, and produces and publishes reports on the quality and features of different products and services in order to guide and protect consumers. In these reports, it makes specific mention of brands; companies are not, however, permitted to quote PROFECO's opinions of brands.

- **Committee on New Molecules (Comité de Moléculas Nuevas, CMN).** The CMN is a consultation body that issues opinions on the safety, quality and effectiveness of medicines that require an evaluation. The Ministry of Health demands CMN's opinion when placing medicines featuring new molecules on the sanitary registry. It is composed of a president (COFEPRIS' Sanitary Authorisation Commissioner), a vice president (COFEPRIS' Executive Director of Product Authorisation and Establishments), a technical secretary (Director of the National Pharmacovigilance Centre) and representatives of Mexican academic associations.

2.1.7.2. Trade associations

- **CANIFARMA** is the Mexican pharmaceutical industry's main trade association. Created in 1946, it currently has 186 members, including companies that manufacture medicines (patented and generics) for human and veterinary use, as well as companies that produce medical devices.[40]

- **National Association of Medicine Manufacturers (Asociación Nacional de Fabricantes de Medicamentos, ANAFAM)** is an association of 26 national pharmaceutical companies. According to its website, ANAFAM members

produce 60% of all medicines sold to the public sector and 17% of all medicines sold to the private sector in Mexico.[41] One of ANAFAM's objectives is to promote generics.

- **Mexican Association Industries for Research (Asociación Mexicana de Industrias de Investigación Farmacéutica, AMIIF)** represents more than 40 national and international pharmaceutical and biotech companies operating in Mexico. Its mission includes promoting pharmaceutical research.
- **National Association of Medicine Distributors (Asociación Nacional de Distribuidores de Medicinas, ANADIM)** is an industry association representing 19 Mexican companies active in the regional distribution and retail of medicines, perfumes and personal-care products. According to its website, in 2015, ANADIM accounted for 54.7% of national pharmaceutical retail market (by value).[42] Its members operate 7 550 points of sale.[43]
- Mexican Association of Interchangeable Generics Manufacturers (Asociación Mexicana de Fabricantes de Medicamentos Genéricos Intercambiables, AMEGI) is a representative body for generic producers composed of six members. According to its website, AMEGI's members produce 80% of the units consumed by the health sector.[44]
- **National Union of Pharmacy Entrepreneurs (Unión Nacional de Empresarios de Farmacias, UNEFARM)** is a Mexican trade association comprising 25 groups of independent pharmacies. According to its website, UNEFARM organises joint purchases for its members.[45]
- **National Association of Pharmacies in Mexico (Asociación Nacional de Farmacias de México, ANAFARMEX)** is a national trade association of pharmacies. According to its website, ANAFARMEX represents more pharmacies than any other representative body. It provides training to pharmacy operators on medicine dispensing.[46]

2.2. Overview of the legislation

The pharmaceutical sector is heavily regulated: "All aspects of the life cycle of new drugs are regulated, from patent application, to market approval, commercial exploitation, patent expiration and competition with generics" (OECD, 2000: 7). All relevant actors in the pharmaceutical sector (i.e. manufacturers, wholesalers, retailers, and prescribing doctors) are also subject to legal control.

The main objectives of regulation are preserving incentives for research and development and the flow of new innovative drugs, while assuring the efficacy of pharmaceutical products, their quality, as well as their safety (OECD, 2000: 7).

From both an ethical and economic perspective, pharmaceutical products have special characteristics. They tend to be considered as "merit goods" meaning that patients should be able to acquire them irrespective of their ability to pay for them. This feature usually leads governments to provide public-health services that tend to include the supply of medicines and, often, the regulation of prices.

In addition, pharmaceutical products are so-called "credence goods" (OECD, 2014: 4). This implies that their consumption is subject to specific knowledge about when and how they should be used. As patients usually lack the medical knowledge to assess the

medical advice they receive, they rely entirely on a doctor's good judgement about which particular medicines should be part of their medical treatment. The asymmetries of information between the doctor and the patient usually require some type of protection to ensure doctors' prescribing practices respond to patients' best interests and not to arrangements doctors may have with pharmaceutical companies.[47] In Mexico, this is currently regulated by a code of conduct of one of the main pharmaceutical associations; this code contains a legal lacuna that the OECD recommends resolving.

The mapping of Mexican legislation for the pharmaceutical sector included 117 legal provisions, including laws, regulations, ministerial decrees, as well as guidelines and agreements from official authorities. Almost 40% of the regulations address the production of medicines; the remaining 60% refer almost evenly to the wholesale of pharmaceutical products, retail, and horizontal legislation. Ultimately, we found 100 restrictions, for which we have issued 50 recommendations.

Pharmaceutical legislation in Mexico is extensive. Two main pieces of legislation act as general frameworks: the General Health Law (Ley General de Salud) and the Regulation on Health Inputs (Reglamento de Insumos para la Salud).

The General Health Law was first enacted in February 1984; it has been constantly amended since then.[48] It regulates the right-to-health protection granted by the Mexican Constitution, providing a general guideline on most health topics, including marketing authorisations, import of medicines, advertising of pharmaceutical products, the transport of medicines, qualifications necessary to act as a health professional, health education, access to health, and health promotion.

The Regulation on Health Inputs came into force on 4 February 1998 and was last modified in 2014. It regulates the sanitary control of medicinal inputs, herbal medicines, as well as the control of all medical establishments, activities, and services related to them. This regulation is an important complement to the General Health Law, clarifying many topics discussed in this report such as the prescription of medicines, marketing authorisations, the import and export of medicines, advertising of pharmaceutical products, and labelling of medicines.

The main restrictions identified are presented in detail in the following sections. It is the OECD's belief that the implementation of its recommendations would have a significant effect on the Mexican economy. The OECD's best estimates indicate benefits amounting to at least MXN 10 177.1 million and might go up to MXN 43 813.8 million, which derive from recommendations that would affect the incentives to doctors; the ability of consumers to switch to generics when doctors prescribe branded medicines; and the direct sales from pharmaceutical producers to retailers.

2.3. Restrictions to competition in the pharmaceutical sector

2.3.1. Incentivisation of doctors

Patients seek doctors' assistance because they assume that doctors are in the best position to provide a diagnosis of their health and suggest the correct treatment. Medical treatment often involves the prescription of medicines. This prescription practice requires specific knowledge to determine when and how a medicine should be used. Given the asymmetry of information between the prescribing doctor and the patient, medicines are known as "credence goods", i.e. a good whose utility impact is difficult or impossible for

the consumer to ascertain and where the patient has to believe the doctor (OECD, 2014: 4).

This asymmetry may lead to problems if doctors benefit from the sale of specific medicines. Conflicts of interest can especially arise when doctors are allowed to dispense pharmaceutical products themselves (OECD, 2014: 7) or when they receive pecuniary advantages from pharmaceutical companies, such as invitations for out-of-town conferences, the free provision of medical equipment that they would otherwise need to purchase, or speaker fees. These conflicts of interest may lead to the over-prescription of drugs. If doctors somehow benefit from the number of units sold, they may have incentives to prescribe more medicines than necessary.

Also, doctors may not prescribe the most cost-effective medicine, but the one that provides them with a pecuniary benefit, e.g. by prescribing a patented drug even when there are generics in the market. When there is only one patented medicine in the market to cure a certain disease, doctors have no alternative but to prescribe the patented drug and patients have no alternative but to purchasing it. However, after patents expire, patients may usually benefit from generics entering the market at a lower price than the innovative product. Studies have shown that generics generally work as well as innovative drugs.[49] Nonetheless, despite their similar effectiveness, doctors may prescribe the more expensive alternative if they obtain an extra benefit from prescribing the innovative product.

In this report, all forms of pecuniary benefits given by pharmaceutical companies to doctors, and which might motivate doctors to prescribe a certain drug are referred to as the "incentivisation of doctors". In this area, the OECD makes two recommendations for filling the legal lacuna about the granting of financial advantages, as well as the monitoring of doctors' prescription practice.

2.3.1.1. Legal lacuna concerning pecuniary advantages to incentivise doctors

Description of the relevant obstacle. Mexico currently has no law regulating which benefits pharmaceutical companies can provide to doctors, such as conference participations or speaker engagements. There is, however, an ethics code issued by CETIFARMA, a subsidiary of pharmaceuticals trade association CANIFARMA, which regulates and monitors the ethics code that addresses pecuniary incentives. This ethics code, however, only applies to CANIFARMA members. According to CETIFARMA, providing financial incentives of significant value to doctors is forbidden. Infringement of the code is subject to admonition, pecuniary penalties (though no amounts are detailed), as well as temporary or definitive suspension of the rights as a CANIFARMA affiliate.

Harm to competition. Despite the existence of CETIFARMA's Ethics Code, according to market participants, providing pecuniary advantages to doctors is not a rare practice among pharmaceutical companies. Not all pharmaceutical companies are members of CANIFARMA (87%, according to its own figures) and so bound by its code of conduct. A lack of binding governmental regulation in this field may hinder competition among similar products. Doctors might be provided by some pharmaceutical companies with benefits that lead them to prefer one product over one that they might regard as best suited to, or most economical for, the patient. Pharmaceutical companies that comply with the CETIFARMA code of conduct or that do not supply any benefits to doctors for other reasons might be discriminated against. The problem might be aggravated by the fact that pharmaceutical companies are, at least theoretically, able to

gather data concerning the prescribing practice of individual doctors – which allows them to target and monitor these doctors.

Policymaker's objective – International comparison. The risk described above has led to various regulatory responses. Two main models have emerged:

1. The European model bans pecuniary advantages, as a general rule.[50] According to European Union Law, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. Also, hospitality at sales-promotion events shall always be strictly limited to the events' main purpose and must not be extended to persons other than health-care professionals.[51]
2. The US model is mainly based on self-regulation and requires pharmaceutical companies to disclose financial agreements they may have with doctors. Nonetheless, the US model also bans, as a general rule, gifts of significant value.[52]

Box 2.1. **Prescribing patterns and pecuniary advantages***

In 2016, ProPublica, a US-based "independent non-profit newsroom that produces investigative journalism", carried out an analysis examining if there existed a relationship between industry payments and brand-name prescribing by doctors in the United States. The study found that physicians in five common medical specialties who accepted at least one industry payment were more likely to prescribe high rates of brand-name drugs than physicians who did not receive any payments. ProPublica also compared average prescribing rates among physicians based on whether they received payments or not; those who received large USD amounts of payments and those who received smaller amounts; and those who received certain types of payments (e.g. meals, speaking) and those who did not.

In all cases, the group receiving larger payments had, on average, a higher brand-name prescribing rate. Also, the type of payment made a difference: those who received meals alone from companies had a higher rate of brand-name prescribing than physicians who received no payments, and those who received speaking fees showed a higher rate of prescribing branded drugs than those who received other types of payments.

Similarly, Toshiaki Iizuka, in a 2007 study carried out in Japan, found that doctors' prescribing patterns were affected by the margin they can earn, discovering over-prescription as well as the prescription of sub-optimal drugs. Nonetheless, there were differences among insured and non-insured patients. Doctors tended to overprescribe more for the former group of patients than the latter.

* Jones, Ryan Grochowski & Charles Ornstein (2016), "Matching Industry Payments to Medicare Prescribing Patterns: An Analysis", https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf?22; Iizuka, Toshiaki (2007), "Experts' Agency Problems: Evidence from the Prescription Drug Market in Japan", RAND Journal of Economics 38:3, pp. 844-862, www.jstor.org/stable/25046339.

Recommendation. The OECD recommends issuing a binding regulation determining the exact conditions under which pecuniary financial advantages or benefits of significant value to doctors can be granted. This regulation should contain sanctions in case of infringement of the conditions. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 1983, as well as the CETIFARMA Code of Ethics, might be used as a starting point.

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to be MXN 7 743.1 million. This calculation is explained in detail in Annex 2.A2.

2.3.1.2. Data records concerning retained prescriptions

To help steer their marketing efforts, pharmaceutical companies are interested in monitoring doctors' prescription practices. To do this, they generally find it helpful to acquire data about those practices that is as detailed as possible.

Description of the relevant obstacle. According to Article 117 of the Regulation on Health Inputs for Health, the pharmaceutical retailer registers in a control book or an automatised system the name, address and professional-licence number of the prescribing physician at the moment of the sale of medicines and this prescription is retained by the pharmacy. It is unclear what happens to this data and whether they might be sold directly or via specialised companies to pharmaceutical companies.

Harm to competition. If a pharmaceutical company could buy data about individual doctors' prescription practices, it would be able to monitor whether doctors prescribe its products and favour it over others. This would be harmful as there are currently no binding rules to clarify the conditions under which incentives can be granted to doctors by pharmaceutical companies. Theoretically, pharmaceutical companies could monitor the prescription practice of all active doctors and only incentivise those doctors (e.g. by inviting them to conferences) who mainly prescribe their products.

Policymaker's objective. The objective of the provision is to ensure a prescription's authenticity and to control a pharmacy's stock of prescription products (e.g. antibiotics, psychotropics and narcotics). This allows health authorities to control the stock of prescription drugs and ensure that they are only sold after a doctor has prescribed them.

Recommendation. The OECD recommends prohibiting pharmacies from passing personalised data from doctors or patients to pharmaceutical or any other companies (such as companies that collect and market data). Selling of aggregated data – data that do not allow the prescribing practices of individual doctors or the drugs used by an individual patient to be tracked back – should still be allowed, however, as they allow pharmaceutical companies to efficiently benchmark, plan and calculate their output and marketing efforts.

2.3.2. Generics

According to a definition by the US Food and Drug Administration, generics "are copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use".[53] Potential competitors may copy a brand-name drug – also known as an innovative drug – and submit a series of tests to the relevant health authority to show the interchangeability of the copied drug with the referent one, either after the patent has expired, or even before that, in order to be ready to market a product immediately after the patent of the innovative drug has ended. In order to be considered as interchangeable, generics must prove their identity, strength, quality, purity, and potency, which is not allowed to vary considerably from the parameters of the referent medicine.[54]

Studies have shown that generics generally work as effectively as innovative drugs.[55] The proof of an interchangeable therapeutic effect between the generic drug and the innovative drug, within a permissible margin of variability, is one of the ends of interchangeability tests.

Entry of generics into the market usually leads to lower price levels and enhanced access to medicines. According to the OECD, generics typically sell for 30-50% below

their branded equivalent. In the United States, it is not unusual for a generic to achieve a 50% market share (by volume) within a year of the patent expiring (OECD, 2002: 37).

Theoretically, the prices of the original innovative drugs should decrease to the level of generics after generics enter the market (OECD, 2014: 10).[56] This is not always the case, however. Economic studies have shown that sometimes there are even considerable price rises for innovative drugs after the entry of generics.[57] Other studies have shown that the prices of innovative drugs do not decrease after the entry of generics (Frank, Richard G., and David S. Salkever, 1997: 75-90). Authors have called this phenomenon the "generic paradox", originating in the widespread perception that branded and non-branded drugs have a different therapeutic efficacy. In addition, this may be complemented in some jurisdictions by the presence of insurance contracts, which means that some consumers are not price sensitive.[58]

The OECD makes three recommendations for generics: concerning their prescription; the valuation rate that generic producers must meet; and the so called "linkage problem".

2.3.2.1. Mandatory sale of the branded drug, unless substitution is expressly permitted

Description of the relevant obstacle. According to Article 31 of the Regulation on Health Inputs, doctors can either prescribe an International Nonproprietary Name (INN; as defined by the World Health Organization, a unique, globally recognised name that is public property) or a jointly generic and distinctive designation, which is a mix of a generic drug and a brand name (e.g. salbutamol and "Ventolin"; ibuprofen and "Advil"; or paracetamol and "Tylenol"). When doctors prescribe a distinctive designation, pharmacists must comply with that designation; the medicine can only be substituted when the doctor expressly authorises it.

Harm to competition. Consumers are locked into purchasing a branded medicine if that is what is prescribed by the doctor. Generics may face a competitive disadvantage if doctors tend to prefer certain branded medicines and do not include generics in their prescriptions or authorise the substitution of the branded product. The harm to the consumer might be aggravated if doctors are not objective in their prescription practice, e.g. due to incentivisation of the pharmaceutical companies (see discussion under Incentivisation).

Policymaker's objective. The objective of this provision is to protect the Mexican population against sanitary risks.

There is a widespread belief in the Mexican population that generics are not as effective as the original drug (i.e. medicine protected by a patent or whose patent has expired). However, concerns over generics' safety and effectiveness compared to original medicines seem generally unfounded. Generics are therapeutically equivalent to the original medicine, and offer significant cost savings with no adverse health effects.

In a number of OECD member states (Denmark, Estonia, Finland, Germany, Italy, Slovak Republic, Spain and Sweden), pharmacists have to substitute a medicine with its cheaper alternative. For instance, in Italy since 2012, pharmacists have to substitute the innovative medicine with the lowest-priced generic, while in Sweden, they are obliged to substitute with the lowest-cost substitutable product unless the doctor states in the prescription that substitution is not allowed. In a majority of OECD countries, pharmacists are allowed to inform the patient about possible substitution and substitute

brand-name medicines with generics if the patient agrees and the prescribing doctor does not object in the prescription (e.g. Czech Republic) (OECD, 2016c: 30).

Also, several OECD member states require doctors to prescribe the generic denomination, e.g., Estonia, Portugal, Spain and France (OECD, 2016b: 182).[59]

Providing patients the possibility of choosing between the innovative or generic drug assures they benefit from the placebo effect: "Research has shown that a placebo treatment can have a positive therapeutic effect in a patient, even though the pill or treatment is not active (as long as the patient believes the treatment is taking place). This is known as the 'placebo effect' or 'placebo response'."[60]

Recommendation. The OECD recommends the following options to the Mexican government:

Option 1) Amend the provision in order to oblige pharmacists to inform patients about the cheapest available generic and allow the substitution of prescribed medicines with this generic when the patient agrees, unless the prescription specifically states "substitution not allowed" (which might be necessary if certain patients do not react well to substitutes of a certain medicine). The OECD recommends making the substitution optional, not mandatory, due to the fact that most customer purchases in Mexico are out-of-pocket spending and customers must be able to purchase the medicine they perceive to be best (placebo effect).

Option 2) Introduce a provision that requires doctors to prescribe only INN medicines, which is the active substance, but not the brand name.

If either of these OECD recommendations is fully implemented, the benefit to consumers is estimated to range between MXN 6 177.4 million and MXN 34 544.8 million. This calculation is explained in detail in Annex 2.A3.

2.3.2.2. Fixed percentage of valuation for interchangeability tests

Description of the relevant obstacle. According to the General Health Law, to be considered as generic, medicines must be interchangeable with a reference drug, i.e. the generics must produce the same therapeutic effect. In order to be considered as an interchangeable medicine the "percentage of valuation" of the test medicine must be within the limits stated in the Pharmacopoeia; this is a difference of up to 5% with the reference medicine.[61] The method of determining the 5% threshold is not clearly described (at least to the lay reader).

Harm to competition. The standard for the "percentage of valuation" may work as a barrier to entry for products that do not meet the 5% difference threshold. The rule might also be too inflexible, not taking account the specifics of each medicine. Some generics might only require a maximum difference of 1%, others 10% to perform the same function. From the disposition, it is not clear whether a margin of error applies. It is also not completely clear whether the Mexican test applied is equivalent to those of other jurisdictions, such as the European Union or the United States.

Policymaker's objective. The objective of this provision is to define the criteria and specifications that should be observed during the performance of the tests carried out to demonstrate the interchangeability of generic medicines. According to COFEPRIS the valuation rate could vary if the medicine is considered to be "variable". However, the NOM-177-SSA1-2013 does not provide a clear description of when a medicine is considered to be variable and which valuation rate would apply in that case.

International comparison. In the European Union, a generic medicine is defined as a medicine that "has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies" and "[f]ollowing the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form".[62] In order to demonstrate bioequivalence, some characteristics are measured to prove that there is at least a probability of 90% that the results will fall between two values (i.e. the acceptance interval). The acceptance interval can be tighter or wider for some characteristics in special cases.

It might well be that the methodology currently applied in Mexico to determine equivalence conforms with international standards and avoids the problems described above in practice; however, several outside experts had difficulty in assessing that result, due to the lack of a clear description of the methodology.

Recommendation. The OECD recommends clarifying the methodology used to determine if a medicine can be considered as variable. Also, clarify if the applied method is equivalent to other jurisdictions (especially, the European Union and United States). The methodology should also be made easily available on the COFEPRIS website.

2.3.2.3. Linkage

Description of the relevant obstacle. When applying for a sanitary registry, a company needs to prove that it is the holder of the patent of the active substance or alternatively, that no patent will be infringed when producing the medicine in question. Once an application is received, COFEPRIS consults with the Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Industrial, IMPI) to determine if there is any patent infringement. This is called "linkage".

According to industry participants, it is often unclear if the reference medicine is still protected by patents and if so, which patents they are. This is known as the "linkage problem". Although COFEPRIS and IMPI communicate to determine which patents are related to the medicine for which a company wants to offer a generic version and applies for sanitary registry, IMPI's current list of patents does not provide enough clarity and certainty to market participants.[63] There is a searchable version of the Official Gazette for medicine patents. However, market participants find it impossible to obtain definitive answers before they start producing generics. COFEPRIS and IMPI usually provide solutions on a case-by-case basis.

Harm to competition. According to market participants, the searchable version of the Official Gazette is difficult to use and does not always return all possible results. This contradicts the official COFEPRIS explanation.

The lack of sufficient information related to the patents protecting a certain medicine makes it more likely that pharmaceutical companies could unintentionally infringe a patent when manufacturing a generic medicine. In case of infringement, the producer would need to change the medicine formulation and again apply for a new sanitary registry with COFEPRIS.

Policymaker's objective. The objective of the linkage is to protect intellectual property rights and prevent sanitary registries being falsely granted – and in so doing, avoid the need to revoke them later due to infringement of existing patents.

International comparison. Other jurisdictions, such as the United States and Canada, have easily searchable online databases of the patents protecting specific molecules, and which drug is considered as the referent. The US government publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved by the Food and Drug Administration (FDA) and related patent and exclusivity information.[64]

Recommendation. The OECD recommends that COFEPRIS publish a list of all patents related to each medicine with a sanitary registry. The US Orange Book may serve as a blueprint.

In the future, companies asking for a sanitary registry might be required to provide a list of all patents they consider relevant to the medicine. This list could then be published by COFEPRIS. Generic producers would then be able to easily investigate which patents must be respected.

2.3.3 Adjacent Doctors' Offices (Consultorios Adyacentes a Farmacias, CAF)

More than half of all pharmacies in Mexico have adjacent doctors' offices or Consultorios Adyacentes a Farmacias (CAF). These are an important part of the Mexican health system as patients can access medical services promptly and at affordable prices or even for free. Nonetheless, these benefits do not come without risks as most adjacent offices are in some way funded or at least financially supported by pharmacies.

As previously indicated, a prescription model where doctors benefit from the price paid by the patient or the volume of medicines prescribed generates risks of unethical practices that may lead to excessive or sub-optimal prescription practices (OECD, 2014: 6-7). In this case, the risk stems from the relationship among the prescribing doctor with the pharmacy which the doctor works for. Adjacent pharmacies need funding to operate, and it seems likely that funds may come from excessive or sub-optimal prescriptions.

2.3.3.1. Legal lacuna concerning prescription practices of doctors working in CAF

Description of the relevant obstacle. According to COFEPRIS, in 2015, 53.5% of all pharmacies in Mexico have a CAF (COFEPRIS, 2015). CAF mostly belong to pharmacy chains. Consultations in these CAF are provided at affordable prices or even for free. While CAF business models may vary, most doctors working at CAF receive some form of compensation from the pharmacies, be it through a fixed salary, a bonus or some other form of remuneration.

CAF have shown a rapid expansion in Mexico as a result of the government's 2010 policy of discouraging self-medication. Known as the "Agreement to determine the guidelines for the sale and dispensing of antibiotics" ("Acuerdo por el que se determinan los lineamientos a los que estará sujeta la venta y dispensación de antibióticos"), it saw the Mexican authorities enact a prescription-only requirement to mitigate self-medication and control the dispensing of antibiotics.

To the best of our understanding, there is no provision that addresses the relationship between pharmacies and doctors, and limits the incentives pharmacies can provide to

CAF doctors for prescribing certain medicines. The Mexican Pharmacopoeia Supplement for Establishments[65] only forbids pharmacies to have "direct communication, through windows, doors or aisles, with other businesses, such as doctors' offices".

Harm to competition. As practically all CAF belong to pharmacies, doctors are not completely independent in their prescription practice. This could distort competition among medicines in three ways, as doctors could:

- prescribe the pharmacy's branded products (in the case where a pharmacy had its own brand of medicines) instead of, perhaps, the best-suited medicines
- prescribe products that might not be the ones that best fit consumers' needs, but which are in stock at the pharmacy and need to be used
- prescribe more products than needed (e.g. extra vitamins) if doctors receive payments linked to the quantity of products they prescribe.

These problems might be complemented by the inability of consumers to substitute branded drugs for generics. According to Mexican law, specific branded drugs prescribed by doctors cannot be exchanged by the patient or the pharmacist.[66] Hence, if doctors tend to prescribe a pharmacy's own brands or the pharmacy's preferred products (e.g. due to a bulk order of those medicines), some generics or even branded medicines may face a competitive disadvantage against the pharmacies' preferred products.

Policymaker's objective. CAF play an important role in Mexico's health system, assuring fast and affordable medical access to a significant part of the population.

International comparison. The practice of creating CAF has now been extended to countries including Guatemala, Chile and Argentina (Diaz-Portillo, Sandra. P. et al., 2015: 320-328). Many other countries, however, believe that doctors and pharmacists should remain independent of each other and so forbid the preference or sale of certain producers (e.g. for Germany, § 10 ApoG).

Recommendation. The OECD recommends the following three options for the Mexican government. Options 1 and 2 are possible as stand-alone solutions, but could also be combined; Option 3 would mean keeping the status quo, leaving the current CAF business model unchanged.

Option 1) Issue a provision prohibiting CAF doctors from prescribing branded products and mandate them to prescribe only the INN or the generic name. This solution was discussed in the Generics section above. Patients would be able to choose the drug they consider the best in terms of price or quality from different medicines. This option would solve the problem of CAF doctors prescribing expensive branded drugs. However, it would not solve the problem of over-medication when those doctors prescribe more drugs than necessary.

Option 2) Issue a code of conduct or regulation prohibiting pharmacies from exerting pressure on or incentivising doctors to prescribe certain products, especially by rewarding the volume or number of medicines prescribed. As pharmacies would not be able to influence doctors' prescription habits, irrational prescription patterns (e.g. prescribing specific brands instead of generics or prescribing unnecessary products) would disappear. However, this solution might change the existing business models of CAF. Pharmacies' incentives to invest in CAF might be reduced and CAF might have to raise fees for their services. Indeed, many CAF might even close if they were no longer cross-subsidised by pharmacies.

Option 3) No recommendation. The policymakers' objective of granting quick and easy medical access for the Mexican population might take preference over any possible conflict of interest. This recommendation would leave the current CAF business model unchanged.

2.3.4. Direct sales by pharmaceutical companies to pharmacies (especially pharmacy chains)

Pharmaceutical companies generally use wholesalers to deliver their medicines to retailers, especially to small vendors (OECD, 2014: 20). Wholesalers are middlemen between pharmaceutical companies and retailers, bulk-buying drugs from the former and reselling them in smaller quantities to the latter. Since not all retailers have enough capacity to stock all the drugs they may require, wholesalers ensure regular drug deliveries and usually provide a number of related services, such as inventory and stock management, treatment of expired products, and support in storing patient information (OECD, 2014: 20).

Wholesalers either buy, stock, and deliver all type of medicines or just specialise in a selection of drugs. The first are known as full-line wholesalers; the second, short-line wholesalers. Full-line wholesalers tend to compete for consumers, offering frequent delivery and low prices; short-line wholesalers tend to offer less frequent delivery and lower prices (OECD, 2014: 20). It is relatively common for jurisdictions to require wholesalers to follow the full-line model to ensure continued availability of medicines to the general public. This is the case in most EU member countries, where the distribution of medicines is considered a public-service function (European Association of Pharmaceutical Full-Line Wholesalers, 2015: 1).

For pharmacies, it may be costlier to deal with short-line wholesalers, since this model requires dealing with multiple financial relationships and multiple deliveries. As previously mentioned, in some European countries the law requires distributors to follow the full-line model. This stems from the public-service nature of medicine wholesaling. Yet, even in EU member states, the interpretation of this obligation varies.

The full-line model in Europe does not stop the parallel operation of different distribution models. Agency (or direct-to-pharmacy) arrangements may coexist with reduced-wholesaler arrangements, according to which manufacturers can completely (in the case of agency) or partly (in the case of a reduced-wholesaler model), or a combination thereof, avoid the traditional supply chain and supply pharmacies directly (Kanavos, Panos, W. Schurer, & S. Vogler, 2011: 75).

Distributors can be independent or have exclusive arrangements with particular manufacturers meaning that only one distributor can market certain drugs. In a growing number of jurisdictions manufacturers have vertically integrated, providing services related to stock, demand managements, and direct sale to pharmacies (OECD, 2014: 22). Indeed, in several countries, wholesalers as described above no longer exist (e.g., US, Canada and Chile) (Kanavos, Panos, W. Schurer, & S. Vogler, 2011: 32). In many other jurisdictions, the wholesale level is extremely concentrated.[67] This is also the case in Mexico.

In this section, the OECD makes one recommendation in order to enhance competition in the distribution segment of the market, namely to introduce an obligation to supply full-line wholesalers.

Description of the relevant obstacle. The wholesale and retail sale of medicines and other health products, narcotics, psychotropic substances, and products containing narcotic or psychotropic substances requires a sanitary authorisation (i.e. licence).[68] The sanitary authorisation for manufacturing medicines granted to pharmaceutical companies is not limited to the manufacturing. There are therefore no provisions prohibiting direct selling by pharmaceutical companies to pharmacies.

However, in practice, many (if not most) pharmaceutical companies in Mexico refuse to sell directly to pharmacies, even to large pharmacy chains, but prefer selling through wholesalers. It is common practice for pharmaceutical companies to sign exclusive contracts with one distributor. Thus, wholesalers often become the only channel used to commercialise a certain medicine. According to industry participants, pharmaceutical companies usually pay a service fee to distributors when they sell their products (a scheme known as "fee for service").

This situation concerns the private market as in the public market authorities generally purchase medicines through public tenders.

Harm to competition. For the largest retailers (i.e. pharmacy chains), buying from a wholesaler imposes an unnecessary cost, as they have to pay an extra margin to wholesalers instead of acquiring the products directly from the producers. Also, market participants at retail level complain that many medicines are distributed by only one wholesaler and there is no, or only very limited, intra-brand competition.

Policymaker's objective. According to COFEPRIS, direct sales from pharmaceutical companies to pharmacies are not restricted. The sanitary licence granted to a pharmaceutical company to manufacture medicines can include, among other listed activities, the distribution of medicines. If distribution is not included, it is easy to make changes to the sanitary licence.

International comparison. European Union law sees wholesalers as having a "public-service function".[69] That means that full-line wholesalers that provide all relevant medicines have to be supplied by pharmaceutical producers so national coverage of the population with adequate medicines is guaranteed. The public-service function is applied in different ways throughout the EU; some countries (e.g. Germany), however, have introduced a quasi-obligation to supply all full-line wholesalers.[70]

The obligation to supply wholesalers does not exclude direct supply of pharmaceutical companies to pharmacies.

Recommendation. The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market, which would have the aim to allowing new wholesalers to compete. Before moving forward with such a measure however it is recommended that a study in coordination with the relevant authorities assesses the impact on the market of introducing such an obligation, whose purpose would be to allow new wholesalers to compete in the concentrated Mexican wholesale market and increase intra-brand competition. However, as this proposed recommendation would interfere with contractual freedom, it should only be implemented if such study would demonstrate that other measures to strengthen intra-brand competition do not lead to any results.

If an obligation for medicine producers to supply all full-line wholesalers in the private market were to be implemented, the benefit to consumers is estimated to be

between MXN 128.1 million and MXN 3 074.6 million. This calculation is explained in detail in Annex 2.A4.

2.3.5. Price Regulation

Drugs are essential to human health and even survival. Patients tend to be insensitive to the prices of drugs, at least when medicines treat serious medical conditions. Due to this lack of price elasticity for medicines and the market power held by many manufacturers of original drugs, pharmaceutical prices are regulated in many countries at various level of the supply chain.[71]

Pharmaceutical products are also considered "merit goods", meaning patients should be able to acquire them irrespective of their ability to pay for them.

Price regulation faces the challenging task of assuring access to medicines on the one hand, without distorting incentives to invest and market products on the other hand. Worldwide, there are two main approaches to price regulation of patented medicines. The first, usually known as "international reference pricing" or external reference pricing (ERP), consists of setting maximum prices according to the prices charged in other countries for the same drug. The second, named "internal reference pricing" regulates maximum prices taking account of prices of other drugs from the same therapeutic class within the same country. Mexico follows the first approach (OECD, 2014: 11).

In this section, the OECD makes two recommendations. Firstly, amending the current price-regulation system for patented medicines, and secondly, publicising the mechanism that determines how maximum prices are set.

2.3.5.1. Maximum prices for patented drugs

Description of the relevant obstacle. A 1996 agreement between the Ministry of Economy and CANIFARMA (amended in 2004) establishes maximum retail prices for patented medicines. The maximum price for a patented medicine in Mexico is determined as the average of the ex-manufacturer price of that medicine in the six countries with the largest sales in the world.

Harm to competition. Having maximum prices for patented drugs raises several potential competition problems. First, the agreement mentioned above restricts the ability of firms to choose prices freely. Second, considering the labelling duty to inform about maximum prices on the packages of a medicine (as discussed in Section 2.3.10), this provision may facilitate collusion and restrict competition at the retail level. Third, and most importantly, the current price-setting mechanism seems to result in high final prices in the Mexican market, especially when compared with other Latin American countries. This might be due to the current price-regulation system's tendency to focus on high-income countries as a benchmark. Maximum prices are determined based on the average of the six countries with largest sales in the world, but these countries are often also the countries with comparatively high prices. For example, in 2005, the United States, Japan, Germany, France, Italy, and the UK were the six countries with the largest expenditure on pharmaceuticals.[72]

Policymaker's objective. The objective of the agreement is to protect Mexican consumers from pharmaceutical companies charging excessive prices, as well as to promote investments in pharmaceutical development, by assuring the participation of the industry in the setting of maximum prices.

The World Health Organization (WHO) reports that in 2015, 24 out of 30 OECD member states used a pricing system based on ERP with varying reference proxies (World Health Organization, 2015: 14). The WHO recommends applying ERP only in combination with other methods, however, as ERP alone may lead to inappropriate final prices, especially if reference countries are badly chosen (e.g. if the reference countries have substantially different market structures or prices) (World Health Organization, 2015: 15). For example, in Canada, ERP is used together with other criteria, such as the sale price of medicines in relevant markets; the prices of other drugs from the same therapeutic class in relevant markets; the prices of the same medicine and other medicines in the same therapeutic class in specific foreign comparison countries (namely, France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States); and changes in the Consumer Price Index (Daley, J., 2010).

Recommendation. The OECD recommends rebuilding the basket used to calculate maximum prices for Mexico, taking into account not only sale volumes (as it does currently), but also other factors, such as income level of reference countries and out-of-pocket expenditures. In addition, the basket should be periodically revised – for example, every five years – to ensure that it satisfies the needs of the Mexican population.

2.3.5.2. Confidentiality of the amendment to the CANIFARMA and Ministry of Economy agreement

Description of the relevant obstacle. The original maximum-price agreement between the Ministry of Economy and CANIFARMA is available to the public. In 2004, however, it was amended and, according to Mexican transparency law, this amendment remains confidential. There does not seem to be a plausible justification for keeping this document secret and no objective was found in law. Its confidential nature makes it impossible for the public to assess its contents and look for mechanisms that may lower prices for the Mexican consumer. The OECD recommends making public both the agreement and any modifications.

2.3.6. Authorisations

The pharmaceutical sector is heavily regulated. The manufacturing of medicinal products requires strict ex ante control to ensure the protection of public health and that chemical products with therapeutic utility provide the expected benefits. In addition, the distribution and sale of medicines is subject to strict control to monitor retailers.

Authorisations can impose a non-negligible cost on market participants. If entry is too burdensome, this may prevent potential competitors from entering the market and impose higher degrees of competitive pressure on incumbents. Thus, legislators should make sure that authorisation processes do not become more onerous than is necessary to achieve the sought regulatory objectives (OECD, 2016a: 13).

In this section, the OECD makes seven recommendations concerning the renewal of sanitary registries; sanitary registries for biosimilar products and requests for new studies; how to determine the reliability of dogs and cats used for scientific research; the discretion to grant reductions in the frequency of analytical tests for inputs used in the manufacture of medicines in Mexico; the possibility of making applications online; and the applicability of the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios.

2.3.6.1. Renewal of sanitary registries

Description of the relevant obstacle. Sanitary registries need to be renewed every five years. According to Article 195-A of the Federal Fees Law (Ley Federal de Derechos), for a sanitary-registry renewal, applicants shall pay 75% of the new sanitary-registry fee. The sanitary-registry fee for generics currently costs MXN 71 334.41 and for new molecule medicines MXN 127 549.79.

Harm to competition. Requiring that the sanitary registry is renewed every five years imposes an extra cost on firms. The costs can be quite significant for producers that are often marketing several hundreds of products.

Policymaker's objective. The objective of this provision is to protect the Mexican population against sanitary risks. During the renewal period of sanitary registries, the Ministry of Health examines the same aspects as examined during the first application for a sanitary registry. According to COFEPRIS, in more than 50% of all applications for renewal of the sanitary registry, the companies do not meet the necessary requirements to obtain or renew the sanitary registry.

International comparison. In the European Union, a marketing authorisation is valid for five years and may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the competent authority of the authorising member state. Once renewed, the marketing authorisation shall be valid for an unlimited period.[73] In the Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[74] the European Commission even suggested that the marketing authorisation should be valid for an unlimited period. Concerning the EU comparison, COFEPRIS pointed out that EU member states generally have a different supervision system and carry out more visits in-situ, which currently might not be possible for COFEPRIS to implement due to a lack of resources.

A different system is applied in the United States, where marketing authorisations (known as New Drug Applications) are granted once for an unlimited time, but the final product is reviewed once a year through an annual report for minor changes.[75]

Recommendation. The OECD recommends that the sanitary registry should be renewed only once after five years and then be perpetual. The OECD team agrees with COFEPRIS that such a change in system should only be implemented after the Mexican control and supervision system has been significantly improved. This would require increasing the frequency of in-situ controls; introducing large fines if pharmaceutical companies do not report changes in a medicine in time to COFEPRIS; and granting adequate resources to COFEPRIS to fulfil this task.

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to amount to MXN 4.8 million. This estimation does not take into account the internal savings (preparation of documents etc.) that pharmaceutical companies will experience if they do not have to perform every five years all the tests presented when the sanitary registry was granted. Also, the annual costs related to the annual revisions might be underestimated. A significant improvement of the Mexican control and supervision system will bring additional costs which will probably have to be carried by the pharmaceutical companies. This calculation is explained in detail in Annex 2.A5.

2.3.6.2. Sanitary registries for biosimilar products and requests for new studies

Description of the relevant obstacle. Producers need to apply to the Ministry of Health in order to obtain a sanitary registry for biosimilar products. In addition to the normal requirements specified in the regulation, the Ministry of Health can impose additional requirements, such as tests and studies for the registry of biosimilar medicines. The Ministry of Health establishes these requirements upon hearing the recommendation of the Committee on New Molecules, which in turn consults the Biotechnological Products Assessment Sub-Committee (Subcomité de Evaluación de Productos Biotecnológicos, SEPB).

Harm to competition. Authorities are granted a large degree of discretion, as they operate on a case-by-case basis. The requirements imposed on companies might vary and so discriminate between them.

Policymaker's objective. Biotechnological products are relatively new products that pose various risks. The Mexican government has therefore put up various additional requirements for those products with the aim of protecting the Mexican population against health risks.

Recommendation. The OECD recommends issuing guidelines that specify in which cases it is necessary to fulfil additional requirements to obtain a sanitary registry for biosimilar products. These guidelines would reduce the degree of discretion in granting sanitary registries for biosimilar medicines. This solution presupposes that it is possible as the nature of biotechnological products means requirements for the sanitary registry of biosimilar medicines may vary according to the product.

2.3.6.3. Reliability of suppliers of cats and dogs used for scientific research

Description of the obstacle. All dogs and cats used in scientific research, technological development and innovation, laboratory testing and teaching, must be obtained from suppliers that are considered to be reliable by the Committee for the Care and Use of Laboratory Animals (an internal committee that each company carrying out research must have). To the best of our understanding no provisions or guidelines exist that establish how the reliability of suppliers is to be determined.

Harm to competition. This provision restricts the offer of available dogs and cats used for scientific research; this might raise prices of an important input.

Policymaker's objective. The objective of this provision is to ensure that animals are given adequate treatment and care, so they are not stressed, which would make them susceptible to disease.

International comparison. The authorisation seems to be in line with international practice. For example, in the European Union, the use of animals taken from the wild for medical tests should be limited to cases where the purpose of the test cannot be achieved using animals bred specifically for this use.[76] Member states must ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period. Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the law.

Recommendation. Publish binding guidelines with criteria to determine whether a supplier is reliable.

2.3.6.4. Discretion to grant reductions in the frequency of analytical tests for inputs used in the manufacture of medicines in Mexico

Description of the relevant obstacle. Article 10.2.3.2.5 of NOM-164-SSA1-2015, "Buenas prácticas de fabricación de fármacos", sets the minimum requirements necessary to manufacture medicines' inputs, such as how often a process should be monitored. In order to reduce frequencies and/or the analytical tests for the inputs used in the manufacture of medicines in Mexico, a medicine manufacturer must receive an authorisation from the Ministry of Health. If the authorisation is granted, according to "Procedimiento normalizado de operación para reducción de la frecuencia de muestreo y de las determinaciones en materia prima y/o producto terminado no biológico", a document issued by the Ministry of Health, the manufacturer receives an official letter of authorisation for decreasing the sampling frequency. This authorisation has a validity of three years.

Harm to competition. To the best of our understanding, there are no clear guidelines with regard to granting such authorisations; this might lead to unequal treatment between producers.

Policymaker's objective. The objective of this provision is to minimise administrative burdens and set the minimum requirements necessary for the manufacturing process of medicines to be commercialised in Mexico.

Recommendation. The OECD recommends clarifying in the NOM the criteria and procedure to modify frequencies of control and analytical tests.

2.3.6.5. Electronic submissions to COFEPRIS

Currently, only around 20% (70 of 365) of all applications to COFEPRIS can be made electronically. The impossibility of submitting applications to Mexican authorities this way raises administrative costs for companies. COFEPRIS has an ongoing project to allow more electronic applications. In a recent report, the World Economic Forum concluded (not only for the medicine industry, but in general) that administrative processes in Mexico can be slow and they may affect trade.[77] The OECD recommends continuing with the ongoing project to allow the electronic submission of all applications to COFEPRIS or the corresponding authority.

2.3.6.6. Unclear scope of Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios

Some articles of the Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios refer to health inputs, narcotic and psychotropic substances and medicines. According to COFEPRIS, this regulation does not apply to medicines. However, this is not clear in the law's text. This lack of clarity may increase search costs for companies. The OECD recommends amending this regulation to delete references to medicines.

2.3.6.7. Difficulty to find official guidelines on the COFEPRIS website

Currently, various guidelines issued and used by COFEPRIS are difficult to find on its website. For example, in June 2017, the "Lineamientos que deberán cumplir los medicamentos alopáticos de referencia y selección de medicamento de referencia internacional" and "Lineamientos que establecen los requisitos que se deben cumplir para

la acreditación de los certificados de buenas prácticas de fabricación para la solicitud de modificaciones, prórrogas y registros sanitarios de medicamentos" were impossible to find. This difficulty may increase companies' search costs. The OECD therefore recommends revising the COFEPRIS website to make easily available all guidelines that pharmaceutical companies must follow, and constantly update the list.

2.3.7. Imports and exports

Medicines are tradable goods that can be imported and exported from one country to another. The import of medicines may bring considerable cost savings to patients in one country because importers can be an important alternative source of supply. However, due to public-health concerns, international trade in medicines is subject to strict regulation as imported medicines should not be of worse quality, safety and efficacy than those produced in the internal market.

Parallel imports differ from standard imports in that they concern goods authorised for sale in one country by the manufacturer that owns the relevant intellectual property rights, but which are subsequently imported into another country without the original manufacturer's authorisation and compete in this market with authorised imports (OECD, 2014: 19). In this sense, parallel trade may encourage intra-brand competition (OECD, 2014).

In the area of imports, the OECD makes one recommendation concerning registries to import medicines.

2.3.7.1. Requirement to count on the registry holder's permission to import medicines into Mexico

Description of the relevant obstacle. A registry with the Ministry of Health is required before importing pharmaceutical products for commercial purposes. If a potential importer is not the holder of the registry, it must obtain the consent of the owner before it can get an authorisation from the Ministry of Health to begin importing.

Harm to competition. The incumbent importer can prevent market entry of other importers. The law grants the first holder of the registry a de facto monopoly since it will generally not have an incentive to authorise potential competitors and allow intra-brand competition.

Policymaker's objective. The law does not mention any specific objective. However, a possible justification may be to assure the traceability of medicines and facilitate their control and the eventual imposition of liability in case adverse effects emerge.

Traceability, however, can also work with more than one importer, as current labelling regulations require a mention of the importer's identity.

Recommendation. The OECD recommends abolishing this restriction. Every importer should be able to get an authorisation from the Ministry of Health, independently of the consent of the incumbent holder of a registry. Additional importers should not have to fulfil the same documentation requirements as the first importer for acquiring a registry as the safety of the imported drug will have been proved by the first application already. However, the first importer that has to bear the costs for providing all required documents for the registry to import the drug for the first time might be granted a limited time of exclusivity by law (alternatively, this could be left to private exclusivity agreements between foreign pharmaceutical producers and importers).

2.3.8. Discrimination against foreign companies

This section describes provisions that potentially discriminate against foreign companies. Here, the OECD makes three recommendations: concerning clinical studies for biotechnological innovative medicines; interchangeability tests; and origin denomination for the sale of ethyl alcohol.

2.3.8.1. Geographic requirement for clinical studies for biotechnological innovative medicines

Description of the relevant obstacle. To be granted a sanitary registry by the Ministry of Health, pharmaceutical companies must conduct clinical studies. For biotechnological innovative medicines, these clinical studies must take place in Mexico when the medicine is produced in Mexico. If the medicine is produced abroad, the Ministry of Health, based on the opinion of the New Molecules Committee, can request additional tests in Mexico.

Harm to competition. This rule imposes extra costs on foreign companies as they may have to perform medical studies twice, once in their home country and then again in Mexico.

In addition, according to pharmaceutical industry participants some of the tests are excessive (i.e. phase II and III) and require the participation of a large number of Mexican patients. Finally, there is a risk of discretion from the Ministry of Health when deciding whether or not to require additional internal tests to companies producing abroad.

Policymaker's objective. A possible justification for the provision may be that the Mexican authorities seek to ensure that a medicine is suitable for the Mexican population. According to COFEPRIS, studies must be performed in Mexico when foreign biotechnological producers choose Mexico as the country where the product will be registered for the first time. For biosimilar products, Mexican authorities accept foreign studies as long as medicines are similar.

Recommendation. The OECD recommends amending the provision so that, unless Mexico is the first country where the medicine is marketed, the sanitary registry of biotechnological products is not conditional on studies conducted in Mexico if the company has already conducted studies abroad, as long as the foreign country's control system is regarded as at least equivalent to the Mexican. Only in exceptional cases, in which the effects of drugs may vary due to phenotypic differences in the Mexican population, should the Ministry of Health order additional tests in Mexico. This exception should be made explicit in guidelines.

2.3.8.2. Geographical and population requirements for interchangeability tests

Description of the relevant obstacle. Interchangeability tests (i.e. tests performed to determine whether a generic medicine produces a similar effect to the reference product) must be performed by authorised third parties on Mexican territory and with a Mexican population sample.

Harm to competition. This requirement may impose unnecessary extra costs on pharmaceutical companies that operate abroad, discouraging them to sell generic medicines in Mexico. For example, a pharmaceutical company that has already performed interchangeability tests in the United States before introducing a generic there and then

later wishes to introduce the same product in Mexico would have to perform the interchangeability test again in Mexico, with a Mexican population sample.

Policymaker's objective. The NOM-177-SSA1-2013 does not mention any specific objective. However, a possible justification may be that the Mexican authorities are seeking to ensure that a medicine is suitable for the Mexican population. As with the restriction discussed above, there may be the cases when the population characteristics of other countries do not coincide with those of Mexicans and that Mexicans respond differently to a certain medicine. However, the OECD considers this scenario to be an exception and not the rule.

International comparison. Similar policy considerations do not seem to exist in European or American legislation.

Recommendation. Similar to the recommendations discussed before, the OECD recommends abolishing the requirement that pharmaceutical companies conduct tests on Mexican territory and population samples, and that the authorities accept interchangeability studies that have been granted by foreign authorities as long as their control systems are regarded as at least equivalent to the Mexican one. COFEPRIS should recognise those authorities, in the same way as it has recognised the right of eight foreign authorities to issue Good Manufacturing Practice certificates. Only in exceptional cases for which there must be guidelines, may the Ministry of Health order special additional tests with Mexican population samples.

2.3.8.3. Origin denomination for the sale of ethyl alcohol

The packaging of ethyl alcohol (used as a disinfectant) should clearly feature the following mention on the label: "HECHO IN MÉXICO" ("MADE IN MEXICO"). The objective of the provision is to provide consumers with clear information on ethyl alcohol and the conditions for its safe use. However, as this requirement applies to all packages of ethyl alcohol commercialised in Mexico, foreigner companies producing ethyl alcohol might be excluded from the Mexican market. The OECD therefore recommends abolishing the section of the NOM requiring the MADE IN MEXICO label in order to allow foreign producers of ethyl alcohol to participate in the Mexican market.

2.3.9. Advertising

Companies advertise their products to remain visible in the marketplace and gain market share.[78] Incumbents may need to advertise their products to avoid consumers switching from one brand to another or in order to gain business from its rivals. For newcomers to a market, advertising may even be more important so they can reach and inform potential customers (OECD, 2016a: 16). Consumers will have no experience with respect to the nature and quality of new products, so sellers will need to induce consumers to purchase them, probably switching from an already known competitor. Without advertising, consumers may not have enough information to engage in such behavioural change. Advertising is crucial for market penetration and market competition.

Nonetheless, in the medicines sector advertising can have negative side-effects. Advertising may encourage self-medication, as well as lead people to believe they may have symptoms mentioned in advertising campaigns. Because of this, advertising in most countries is restricted to over-the-counter medicines. For prescription medicines, pharmaceutical companies may only inform doctors (and in some countries also

pharmacists) of their products and their effects, so the latter consider patients' best interest when prescribing medicines.

In this section, the OECD makes five recommendations, concerning advertising authorisations; the targets of advertising; the possibility of mandate additional warnings in advertising; advertising of biotechnological products; and the use of the results of PROFECO's investigations in advertising campaigns.

2.3.9.1 .Advertising of medicines restricted to health professionals

The advertising of prescription drugs in Mexico is only allowed when it targets health professionals. It is not allowed to be aimed at final consumers or pharmacies. This restriction might make it difficult for market participants to gain market share and may especially place new entrants at a competitive disadvantage.

A likely objective of the restriction may be to discourage people to acquire a medicine that might relate to symptoms they believe to have. Similar restrictions exist in most other jurisdictions. For example, in European Union law, advertising of prescription medicinal products to the general public is banned in member states.[79] Only in the United States and New Zealand is direct-to-consumer advertising allowed.

In the European Union, advertising to pharmacists is permitted, however. This can be especially important for new generic producers trying to reach pharmacists and convince them to substitute patented drugs or branded generics with their product. The OECD recommends allowing advertising targeted at pharmacists, especially after it becomes possible for pharmacists to substitute the medicine prescribed by doctors for one with the same therapeutic effect.

2.3.9.2. Ex ante authorisation to advertise medicines

Description of the relevant obstacle. Advertising about the availability, quality and features of medicines, as well as promoting the use, sale or consumption directly or indirectly of health products, requires previous authorization from the Ministry of Health.

Harm to competition. This provision may prevent incumbents, as well as potential entrants, from gaining market share, by limiting free advertising. Ex ante control delays advertising and imposes an administrative burden on the producer and the administration.

Policymaker's objective. The objective of the law is likely to ensure the validity of the statements provided to health professionals in advertisements.

Generally, control of advertising is possible ex ante or ex post. In Europe, for example, advertising generally does not have to be authorised ex ante, but is subject to strict ex post control. Advertisers are subject to fines in case of breaching the regulatory requirements. [80]

Recommendation. The OECD recommends abolishing ex ante authorisation system and controlling advertising ex post, under a liability regime. Fines should be introduced in case of regulatory breach to guarantee compliance of pharmaceutical companies.

2.3.9.3. Unregulated ministerial power to mandate additional warnings in advertising

The Ministry of Health can mandate additional warnings in the advertising of these products. The law does not further specify on the conditions or content of those warnings.

The provision therefore provides the authorities with a high degree of discretion. Additional warnings may channel demand towards a certain product while discriminating against other producers. The objective of this provision consists of providing consumers with an accurate description of the risks that medicines may impose on them. The OECD recommends issuing guidelines that specify in which cases additional warnings are allowed (ex ante or ex post) and ensure that they are then applied on a non-discriminatory basis.

2.3.9.4. Restricted advertising for biotechnological products

Advertising for biotechnological products may not use qualifiers that present them as superior to conventional products or to similar products not obtained biotechnologically. This provision forbids comparisons based on objective facts and so may restrict the competitive pressure between biotechnological products and conventional products, since comparison is one of the key elements of advertising. A possible reason for the restriction might be that biotechnological products are more expensive for buyers, involve more complex and riskier production methods, and are still subject to intensive research. The OECD team was not able to identify similar advertising rules for biotechnological products in other jurisdictions, showing that those rules are not absolutely necessary to reach the policymakers' objective. The OECD therefore recommends abolishing this provision, allowing comparison on an objective basis within the constraints of comparative-advertising provisions in Mexican law.

2.3.9.5. Impossibility of using the results of PROFECO's reports as advertising

The Mexican Federal Attorney's Office of Consumers (Procuraduría Federal del Consumidor, PROFECO) produces and publishes reports on the quality and features of products and services, in order to guide and protect consumers. In these reports, PROFECO makes specific mention of brands. However, Article 44 of the Federal Law on Consumer Protection forbids companies from quoting these reports. The provision limits the freedom of suppliers to use public information to advertise their products, even when this information is based on objective grounds.

According to anecdotal evidence, the goal of the provision is to guarantee PROFECO's independence by preventing companies from trying to exert undue influence on the authority, as well as to prevent them from misquoting PROFECO's report (e.g. "recommended by PROFECO"). However, these goals can also be reached without restricting competition. The OECD recommends abolishing Article 44 of the Federal Law on Consumer Protection, since these concerns appear unjustified as the law already contains an article that forbids misleading or abusive advertising.[81] At the same time, measures should be taken to guarantee the independence of PROFECO officials from lobbying efforts and ensure that there are efficient mechanisms (including sanctions) in place to avoid misleading advertising.

As PROFECO's reports do not only deal with medicines, but with all industries, the same recommendation is made in this report concerning meat.

2.3.10. Labelling

Labelling laws ensure that pharmaceutical products are properly labelled so that patients can find relevant information before purchase (e.g. the name of the product and its expiration date) and during treatment (e.g. side effects). In this report, the OECD makes only one recommendation concerning contradictory norms on re-labelling.

2.3.10.1. Contradictory norms on relabelling

According to the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios, imported products packaged at the origin country are allowed to keep their original labelling if they also have an additional label containing all the requirements indicated in Mexican law. The NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios, however, states that it is forbidden to relabel on the top of original information.

The two quoted provisions contradict each other. According to COFEPRIS, the first quoted Regulation does not apply to medicines. However, this is not clear in the text of the provisions. The OECD therefore recommends clarifying the Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios to clarify that it does not apply to medicines and delete all references to medicines in this provision.

2.3.11. Pharmacopoeia

A Pharmacopoeia is an official publication containing a list of medicinal drugs with their effects and directions for their use. Mexico has issued its own Pharmacopoeia since 1846.[82] In this area, the OECD makes three recommendations about lifting discriminatory provisions against foreigners; making the Pharmacopoeia available online; and providing guidelines about which sources to follow if the Mexican Pharmacopoeia is silent on a particular topic.

2.3.11.1. Discrimination against foreign buyers

The Mexican Pharmacopoeia is 50% more expensive for purchasers paying in US dollars: USD 760 vs. MXN 8 600 (or USD 473, at 11 June 2017 exchange rates). Entry to the market is thus slightly costlier for companies paying in US dollars, which will mostly be foreign companies. The OECD therefore recommends applying the same price for all subscribers independently of their nationality or their chosen currency.

2.3.11.2. The Mexican Pharmacopoeia is unavailable online

The Mexican Pharmacopoeia is not currently available online. Companies therefore have to acquire a hard copy, which might delay entry. Market participants have indicated that they have experienced no significant problems with acquiring hard copies of the Pharmacopoeia, though they would prefer an online version. COFEPRIS has already started a project to make the Pharmacopoeia available online. The OECD recommends continuing this project and making the Pharmacopoeia available online as soon as possible.

2.3.11.3. Lack of clear guidelines about the correct sources to use when the Mexican Pharmacopoeia does not regulate

Several dispositions concerning Mexican health law specify that when the Mexican Pharmacopoeia does not regulate a particular issue, foreign pharmacopoeias and other sources of scientific international information may be used. These norms create uncertainty, however, as no clear rules apply when the Mexican Pharmacopoeia is silent on a particular matter. Though market participants indicated that this is not considered as a serious problem, as there is an informal agreement in place on which other sources of information can be considered as valid, the OECD recommends compiling a list of

specific alternative documents that market participants could consider as sources of authoritative knowledge in case of the Mexican Pharmacopoeia not covering a topic.

2.3.12. Non-harmonised standards

Description of the obstacle. In our review of medicine legislation, the OECD found 10 NOMs that contain statements that are not in line with international norms.

These were:

- NOM-073-SSA1-2015, on stability of drugs and medicines and herbal medicines
- NOM-177-SSA1-2013, on tests and procedures to determine when a medicine is interchangeable
- NOM-249-SSA1-2010, on sterile mixtures and their preparation
- NOM-257-SSA1-2014, on biotechnological medicines
- NOM-012-SSA3-2012, establishing criteria for research projects involving humans
- NOM-248-SSA1-2011, on good manufacturing practices for establishments dedicated to the production of herbal medicines
- NOM-164-SSA1-2015, on good manufacturing practices of medicines
- NOM-138-SSA1-1995, on sanitary specifications for denatured, antiseptic and germicide alcohol
- NOM-072-SSA1-2012, on labelling of medicines and herbal medicines
- NOM-062-ZOO-1999, on technical specifications for the production, care and use of laboratory animals.

Harm to competition. Non-harmonisation with international standards – be it partial or total – may hinder foreign competitors' access to the Mexican market, as well as Mexican producers' access to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which might lead to extra costs.

Even if national standards have recently been (partially) adapted to international standards, if the legal text is not updated, this might lead to confusion among market participants.

Policymaker's objective. There is no underlying objective behind the non-harmonisation of NOMs. In Mexico, Article 41, Letter VI of the Federal Law on Metrology and Standardisation states that the non-harmonisation of NOMs must be disclosed and that NOMs must have the degree of accordance with international norms and criteria.

Recommendation. For all norms, the OECD recommends updating all NOMs so that they are, as far as possible, in line with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. The law should also point out the cases in which no international standards or best practices exist.

2.3.13. Various

The following section describes various problems that do not fall under any of the headlines above. In total, the OECD makes six recommendations. These cover issues such as distance regulation for pharmacies operating inside retail stores; size regulation for the sale of denatured ethyl alcohol; academic members part of the Committee on New Molecules; and the voting system to reform the Internal Regulation of the Commission to define treatments and medicines associated with diseases causing catastrophic expenses.

2.3.13.1. Distance regulation for pharmacies operating inside stores

Description of the relevant obstacle. Pharmacies operating inside stores must be located in specific areas, and be at least 10 metres away from areas where alcohol, perishable foods and other substances that may threaten the integrity, purity and conservation of medicines are sold (Mexican Pharmacopoeia Supplement for Establishments, 2010).[83]

Harm to competition. This restriction limits pharmacies to stores where there is enough room for the sale of medicines in addition to alcohol and perishable foods. Small shops with space limitations might be impeded from operating a pharmacy section.

Policymaker's objective. To protect Mexican population against sanitary risks by regulating the sanitary control of establishments. Placing pharmaceutical products together with other products may lead consumers to think that pharmaceutical products are just a mere regular good, which may lead to overconsumption.

However, since medicines are usually packaged, a provision regulating distances between different types of products seems unnecessary since there is no risk of contamination. Also, many pharmacies/stores do not seem to comply with this rule in practice.

Recommendation. The OECD recommends abolishing the provision, as long as a pharmacy only sells packaged products and these are sold in separate areas.

2.3.13.2. Regulation of the size of sale of denatured ethyl alcohol in drugstores

Description of the relevant obstacle. Ethyl alcohol in pharmacies or drugstores aimed at end consumers shall be sold in bottles no bigger than one litre.

Harm to competition. This requirement prevents consumers from buying packages larger than one litre. For some consumers, this may impose higher costs. For example, companies using ethyl alcohol regularly may require larger volumes. This restriction impedes them from buying larger packages that might be cheaper and better fit their needs.

Policymaker's objective. The objective is to regulate sales volumes to end consumers. Even though ethyl alcohol is one of the most popular curative products due to its antiseptic and germicidal characteristics, its addictive power and toxicity can pose a health risk. It is unclear why there is a provision regulating the size of packages for end consumers when ethyl alcohol is not sold as a controlled medicine. If there is a risk associated to the consumption of ethyl alcohol, it is not associated with the size of the package.

Recommendation. Abolish Provision I-d) of the Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol and the section of the NOM-138-SSA1-1995 related to the size of packaging of denatured ethyl alcohol.

2.3.13.3. Regulation of the size of ethyl alcohol packaging for health-care units

Description of the relevant obstacle. Denatured ethyl alcohol for the exclusive use of health-care units (e.g. hospitals) may only be sold or marketed in packages of more than 1 litre and not more than 20 litres.

Harm to competition. This provision prevents buyers from acquiring packages bigger than 20 litres. This may impose higher costs. For example, hospitals may find it more efficient to acquire packages larger than 20 litres.

Policymaker's objective. The objective of this provision is to regulate sales volumes of ethyl alcohol to end consumers, including hospitals. Even though ethyl alcohol is one of the most popular curative materials because of its antiseptic and germicidal characteristics, its addictive power and its toxicity can pose a health risk. It is unclear, however, why there is a provision regulating packages size for end consumers when ethyl alcohol is not sold as a controlled medicine. If there is a risk associated to the consumption of ethyl alcohol, it is not associated with the size of the package.

Recommendation. Abolish provision I-e) of the Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol and the part of the NOM-138-SSA1-1995 related to the size of the package of denatured ethyl alcohol.

2.3.13.4. Ad honorem status of academic members of the Committee on New Molecules

Description of the relevant obstacle. The work of representatives of academic associations on the Committee on New Molecules shall not be subject to any remuneration. The Committee is defined as being auxiliary and as an independent consultative body (i.e. not paid for by the pharmaceutical industry).

Harm to competition. Members of the Committee might not be sufficiently incentivised to fulfil their task adequately. Market participants consider that sessions of the Committee are not scheduled with the needed frequency (only four sessions are organised each year), which might delay the entry of new products.

Also, according to industry stakeholders, it is problematic that some Committee members are not experts in the matters under discussion, but rather staff of government institutions that later purchase medicines (e.g. IMSS). Some members of the Committee are therefore mostly concerned about ensuring low-cost public procurement, and might block the introduction of new products with high therapeutic value.

Policymaker's objective. The Regulation does not mention any specific objective, but the avoidance of possible conflict of interests may be one.

Industry stakeholders believe that it would not be feasible for Committee members to be remunerated twice (i.e. a remuneration from IMSS and another remuneration for being part of this Committee), as the Ministry of Finance and Public Credit would oppose to the payment of a double salary for a public official.

Similar committees exist in other jurisdictions. For example, in the United States, the Food and Drug Administration's Center for Drug Evaluation and Research (CDER) uses advisory committees to obtain outside advice and opinions from expert advisors so that final agency decisions will have the benefit of wider national expert input.

Recommendation. The OECD recommends amending the provision in order to introduce remuneration of Committee members. This could be paid by the Ministry of

Health and could be indirectly financed by pharmaceutical companies paying for submitting new files to the Committee. The Ministry of Health should guarantee that members of the Committee do not receive direct financial incentives from companies, e.g. through inclusion of sanctions for Committee members who violate conflict of interest rules. Implementation with this recommendation will have to be coordinated with the Ministry of Finance and Public Credit.

2.3.13.5. Unanimity of votes required to amend the internal regulations of the Commission to Define Treatments and Medicines Associated with Diseases Causing Catastrophic Expenses

Description of the relevant obstacle. The Commission to Define Treatments and Medicines Associated with Diseases Causing Catastrophic Expenses (Comisión para Definir Tratamientos y Medicamentos Asociados a Enfermedades que Ocasionan Gastos Catastróficos, CDTMAEOGC), which supports the General Health Council, must vote unanimously to reform its own internal regulations. The Commission is composed of the Secretary of the General Health Council, two representatives of the Ministry of Health, and a representative from each of the following institutions/ministries: IMSS; ISSSTE; the Ministry of National Defence; the Ministry of Navy; the National Autonomous University of Mexico; the National Polytechnic Institute; the National Academy of Medicine; the Mexican Academy of Surgery; the National Association of Universities and Institutions of Higher Education; and the Mexican Health Foundation. All have the right to vote.

Harm to competition. Requiring unanimity hinders the updating of the regulation, such as for the introduction of a new drug to the market, as incumbents may have incentives to influence the committee to maintain the status quo.

Policymaker's objective. The Regulation does not mention any specific objective.

Recommendation. The OECD recommends abolishing the part of the provision related to the unanimity of votes and introduce a provision for (qualified) majority voting.

2.3.13.6. Divergent regulation of time period on notice of ceasing operation

Description of the relevant obstacle. Article 108 of the Reglamento de Insumos para la Salud states that if a holder of a sanitary licence wishes to cease operating an establishment, it must give notice to the Ministry of Health of its decision at least 30 days in advance, unless an unforeseen event or a case of force majeure takes place. However, according to Article 141 of the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios, the same notice must be provided at least five days in advance. Consequently, there is a contradiction in the regulatory framework, which leaves it unclear when notice needs to be given to the Ministry of Health.

Harm to competition. Criteria on the number of days of notice required is not homogeneous across regulations; this may lead to confusion among market participants.

Policymaker's objective. The objective of these provisions is to protect public health. Chemicals that, if left unregulated, might be used as inputs for illicit drugs should be controlled.

Recommendation. Article 108 of the Reglamento de Insumos para la Salud and Article 141 of the Reglamento de la Ley General de Salud en Materia de Control

Sanitario de Actividades, Establecimientos, Productos y Servicios should be harmonised so that both articles state the same time frame within which notice must be given to the Ministry of Health.

2.4. Horizontal legislation: intellectual property and public procurement for medicines

Most of the horizontal legislation the OECD analysed deals with intellectual property and public procurement. Concerning intellectual property legislation, the OECD does not make any recommendations for the medical sector, except in terms of the linkage problem for generics discussed above. Concerning public procurement in the medical sector, it makes four recommendations for various forms of discrimination in tender processes.

2.4.1. National preference as a tie-breaker in international tenders

Description of the relevant obstacle. The Ley de adquisiciones, arrendamientos y servicios del sector público establishes that there are three types of public tenders:

1. national
2. international under treaty coverage
3. international open.

Type 2 consists of tenders in which both Mexican and foreign suppliers may participate with goods that are either of national origin or from countries with which Mexico has entered into free-trade agreements. For international public-tender bids that are considered "equal", public institutions must prefer those that employ national staff or use nationally produced goods.

Harm to competition. Foreign or Mexican suppliers participating with foreign products might face discrimination. Furthermore, it is unclear how it is determined when circumstances are "equal" as two offers are almost never identical in all features, even with identical prices in a tender procedure that usually involves covered bids.

Policymaker's objective. The objective of this provision is to promote and help the development of national industries.

International comparison. The European Commission generally advocates open international public-procurement markets and grants market access to non-EU countries to its public-procurement markets for certain goods and services. However, some non-EU countries, including the United States, have maintained or introduced protectionist or discriminatory measures in public procurement (i.e. the Buy American Act).

Recommendation. The OECD recommends the following options for the Mexican government:

Option 1) Abolish the part of the provision related to the preference for national staff or nationally produced goods, under equal circumstances.

Option 2) Issue guidelines in order to clarify how to determine when circumstances are "equal" for which case the preference for national products and labour should apply.

Option 3) No recommendation, provided there is no harm to competition. In fact, it is unlikely that two products are ever completely equal (including identical price in tender procedures that usually involve covered bids), so it should be easy to identify when one option is better than another.

2.4.2. Origin requirements to participate in national tenders

Description of the relevant obstacle. Only Mexican nationals or Mexican companies can participate in national tenders, while offered goods (in this case, pharmaceutical products) must have at least 50% national content (ingredients, human labour).

Harm to competition. Foreign pharmaceutical companies and foreign nationals are potentially discriminated against in two ways. First, there is a restriction concerning a bidder's nationality, which includes the nationality of the company. For instance, foreign nationals producing in Mexico are prevented from participating in national tenders even if they have lower prices than their all-Mexican competitors. The provision also restricts the composition of products. A Mexican bidder could not participate with an offer of pharmaceutical products produced either abroad or in Mexico, but with more than 50% foreign ingredients. This could force producers to use more expensive national ingredients.

Policymaker's objective. The objective of this provision is to promote the development of national industry.

International comparison. Many other jurisdictions, such as the United States,[84] have also adapted protectionist procurement measures for the nationality of products.

Recommendation. The OECD recommends the following options for the Mexican government:

Option 1) Abolish the nationality requirement for participants in calls for tenders, while keeping the requirement of the product having at least 50% national content. That would allow foreigners producing in Mexico to also participate in national tenders. In addition, it is recommended that a time limit be introduced for this provision of nationality, giving Mexican producers a transitional period to adapt to having new competitors.

Option 2) Do not change national-tender procedures. As far as possible, however, international tenders should be used.

2.4.3. Preference for more expensive Mexican goods in international tenders

Description of the relevant obstacle. In general, in Mexico, the bidder who meets all the requirements and offers the lowest price wins the tender. However, in the context of international tenders, Mexican goods can have be priced up to 15% higher than the lowest foreign price and yet still be considered as the lowest bid.

Harm to competition. This provision discriminates against foreign producers that might be able to offer a product cheaper than their Mexican competitors. The Mexican consumer will pay higher prices.

Policymaker's objective. The objective of this provision is to promote the development of national industry. However, favouring the Mexican industry in public procurement might be at the expense of the Mexican consumer.

International comparison. Similar provisions exist in other jurisdictions. For instance, in the United States, the Federal Acquisition Regulation implementing the Buy American Act states that: "[i]f there is a domestic offer that is not the low offer, and the restrictions of the Buy American statute apply to the low offer, the contracting officer must determine the reasonableness of the cost of the domestic offer by adding to the price of the low offer, inclusive of duty – (1) 6 percent, if the lowest domestic offer is from a large business concern; or (2) 12 percent, if the lowest domestic offer is from a small

business concern [...] The price of the domestic offer is reasonable if it does not exceed the evaluated price of the low offer after addition of the appropriate evaluation factor."

Recommendation. The OECD recommends abolishing discrimination against foreigners when an international open tender takes place. If the Mexican government wants to promote national industry, it might use national tender procedures or introduce direct subsidies. In addition, it is recommended that a time limit be introduced for this provision to be in force, so that Mexican producers have a transition period during which they can adapt to the new situation and become more competitive.

2.4.4. Preference for micro, small and medium enterprises in Mexican public procurement

Description of the relevant obstacle. Industrial policy aimed at supporting the development of micro, small and medium enterprises (MSME) shall ensure that public procurement is increasingly served by MSME. The objective is that 35% of public procurement shall be served by MSME.

Harm to competition. Low-cost offers from non-MSME participants might not be considered. In particular, larger firms may be discriminated against.

Policymaker's objective. The objective of this provision is to promote the development of MSME. However, according to market sources, the policy seems to be only partially implemented and the participation of MSME in the pharmaceutical sector is currently much lower than 35%, at approximately 8%.

International comparison. Many countries promote MSME development in public procurement, e.g. member states of the European Union,[85] Korea,[86] and the United States.[87]

Recommendation. The OECD recommends the following options for the Mexican government:

Option 1) No recommendation for change as the policy is not binding and only partially applied. Also, helping MSME is a legitimate policymaker objective.

Option 2) Abolish the part of the provision related to target the minimum percentage of public procurement to be awarded to MSME and consider introducing direct subsidies.

2.4.5. Companies under investigation pay for costs of surprise inspections even when no case is proved

Description of the relevant obstacle. Authorities can perform surprise inspections of establishments, such as labs performing tests using measurement instruments, in order to verify compliance with the Law on Metrology and Standardisation. The verified establishment must pay for the expenses of the inspection.

Harm to competition. The company subject to inspection must pay the expenses even if no infringement is found. This may raise costs for some firms and also imposes risks of arbitrary behaviour, for example, if a company is excessively controlled.

Policymaker's objective. The objective of this provision is to protect Mexican population against health risks.

Recommendation. Limit the number of surprise inspections every year to avoid possible abuses. However, additional surprise inspections shall remain possible in case of reasonable suspicion.

Notes

1. The report focuses on North American Industry Classification System (Sistema de Clasificación Industrial de América del Norte, SCIAN) groups 32, 43 and 46, including the relevant subgroups. SCIAN (known as NAICS in the United States and Canada) was developed jointly by the United States, Canada and Mexico to make it easier to compare business statistics between the three countries. Nevertheless, there remain differences between certain SCIAN codes in Mexico and those in the United States and Canada. With respect to the manufacturing of medicines, the main category of pharmaceutical-products manufacturing (SCIAN 32541) is covered, and addresses the following subsectors: inputs for pharmaceutical-industry manufacturing (SCIAN 325411) and pharmaceutical-preparation manufacturing (SCIAN 325412). SCIAN 33911 is excluded in its entirety and includes: manufacture of not-electronic apparatuses for medical and dental use and for laboratories (SCIAN 339111); manufacture of disposable instruments and apparatus for medical use (SCIAN 339112); and the manufacture of ophthalmic items (SCIAN 339113). Inputs for the pharmaceutical industry include alkaloids, antibiotics, hormones and other compounds, and bulk actives, while the manufacture of pharmaceutical preparations includes pharmaceutical and botanical medicines, antiseptics for pharmaceutical use, diagnostic substances, food supplements, plasmas and other blood derivatives. It also includes veterinary medicinal products, but these are not included in this study. Wholesale of pharmaceutical products, allopathic, homeopathic and herbal medicines for human consumption (SCIAN 433110) are covered. Finally, in the retail sector, pharmacies without a minimarket (SCIAN 464111) but which also sell perfumery, hygiene or groceries are considered; pharmacies with a minimarket (SCIAN 464112), which differ from pharmacies without a minimarket as products are organised in sections or small specialised exhibition areas that simplify direct consumer access to the goods, as well as all other stores selling primarily herbal products, homeopathic medicines and food supplements for human consumption (SCIAN 464113). Stores specialised in lenses (SCIAN 464121) and orthopaedic items (SCIAN 464122) are, however, excluded.

2. The General Health Law is the Mexican framework law for the health sector. It establishes the conditions for access to health services and regulates the cooperation between the Mexican Federation and states in matters of public health.

3. When used in this report, the term “pharmaceuticals” covers not only medicines, but also other medical non-durable goods such as bandages, plasters and syringes.

4. There are three different classifications for a medicine with regards to its nature: 1) **Allopathic**, which consists of all substances or mixes of substances of natural or synthetic origin that have a therapeutic, preventive or rehabilitating effect presented under a pharmaceutical form and identified as such owing to their pharmacological activity and to their physical, chemical and biological characteristics, and registered with the Mexican Pharmacopoeia as allopathic medicines. 2) **Homeopathic**, which consists of all substances or mixes of substances of natural or synthetic origin with a therapeutic, preventive or rehabilitating effect, registered in the Mexican Pharmacopoeia or in other countries’ pharmacopoeias or other scientific sources of information. 3) **Herbal**, which includes all the products made with vegetal material or any derivative of this, whose main ingredient is a plant or extracts and tinctures, also its juices, resins, fatty and essential acids presented in a pharmaceutical mode whose therapeutic efficiency and security has been verified scientifically. Another type of

medicine mentioned in the General Health Law is **biotechnological medicine,** whose main characteristic is that it is produced by molecular biotechnology. Regarding the methods of preparation, a medicine can be: 1) **Magisterial**, which refers to medicines prepared according to a formula prescribed by a doctor; 2) **Officinal**, which refers to a combination prepared according to the Mexican Pharmacopeia; 3) **Pharmaceutical speciality,** which are medicines prepared with formulas authorised by the Ministry of Health, in accordance with the chemical-pharmaceutical industry.

5. According to Article 2, Paragraph XIV of the Regulation on Health Inputs, a "generic medicine" is a "pharmaceutical speciality with the same active substance and pharmaceutical form, with the same concentration or power, that uses the same route of administration and that through regulated required tests, has proved that its specifications from the pharmacopeia, dissolutive profiles or its bioavailability or other parameters, depending of the case, are equivalent to the reference medicine". A reference medicine is a medicine that is registered with and approved by the Ministry of Health, is available on the market, and is selected by the Ministry of Health according to criteria of the Mexican Official Standards (Normas Oficiales Mexicanas, NOM). According to NOM-177-SSA1-2013, a dissolutive profile is an experimental determination of the amount of drug in its pharmaceutical form dissolved at different times, under controlled experimental conditions. According to Article 2, Paragraph II of the Regulation on Health Inputs, bioavailability refers to the share of the drug that is absorbed into general circulation after the administration of a medicine, as well as to the time that such absorption takes. According to the General Health Law, in order to be denominated as a generic, medicines must be interchangeable. Interchangeable tests are published in the Federal Official Gazette (Diario Oficial de la Federación, DOF).

6. The Ministry of Economy and the National Chamber of the Pharmaceutical Industry (Cámara Nacional de la Industria Farmacéutica, CANIFARMA) set up a scheme of self-regulation for prices in 1996, which in 2004 was modified by an Addendum to the Consensus Agreement (Adenda al Convenio de Concertación). While the original agreement is public, the Addendum remains confidential, according to the the Law of Transparency and Access to Public Information (Ley Federal de Transparencia y Acceso a la Información Pública).

7. According to Articles 28 and 77 bis 1 of the General Health Law and Article 70 of the Regulation of the General Health Law on Delivery of Healthcare Services (Reglamento de la Ley General de Salud en materia de prestación de servicios de atención médica), there are three levels of medical care. The first level covers outpatient services, which are medical procedures or tests that can be done in a medical centre without an overnight stay. The second level covers outpatient and general inpatient services (i.e. care of patients whose disease requires admission to a hospital) and includes internal medicine, general surgery, gynaecology and obstetrics, paediatrics and geriatrics. Finally, the third level covers outpatient and inpatient services, as well as palliative care to people with specific diseases, with system conditions or diseases affecting specific age groups.

8. The Basic Formulary of Inputs and the Input Catalogue are updated once a year and published in the DOF in order to include, modify or exclude inputs approved by the Basic Formulary and Health Sector Input Catalogue Inter-Institutional Commission (Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud). This Commission was specially created to elaborate, update and promote the Basic Formulary and the Input Catalogue; it consists of the Secretary of the General

Health Council as president, as well as representatives of the Ministry of Health, the Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS), the Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, ISSSTE), the Ministry of Navy (Secretaría de Marina, SEMAR), the Ministry of National Defence (Secretaría de la Defensa Nacional, SEDENA), and Petróleos Mexicanos (PEMEX). The Commission's internal regulations allow public-institution providers of health services, academies and suppliers, among others, to request updates to the Basic Formulary or Input Catalogue. The committee in charge of delivering opinions on updates must submit its opinion within a maximum period of 90 days from the receipt of the update request, which may be extended for up to 30 days if more information is required. Requesting an update is free.

9. According to "Comparing access of new drugs in the public health system in Mexico", IMSS and ISSSTE account for 60-70% of the value of the total institutional market, in *Access Point*, www.imshealth.com/files/web/Global/RWE/RWE-Collateral/IMS RWE AccessPoint.pdf.

10. According to Article 50 of the Internal Regulation of the Basic Formulary and Health Sector Input Catalogue Inter-Institutional Commission (Reglamento Interior de la Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud).

11. According to Article 32 of the Regulation on Health Inputs (Reglamento de Insumos para la Salud).

12. According to "Censos económicos 2014 Metodología" ("Economic Census 2014 Methodology") issued by the National Institute of Statistics and Geography (Instituto Nacional de Estadística y Geografía, INEGI), an establishment is defined as an economic unit in a single physical location, settled permanently in a place and separated by buildings and fixed installations that acts and uses its resources under the control of a single owner or controlling entity to perform activities related to the production of goods, the sale and purchase of merchandises and the provision of services, profitable or not ("Unidad económica que en una sola ubicación física, asentada en un lugar de manera permanente y delimitada por construcciones e instalaciones fijas, combina acciones y recursos bajo el control de una sola entidad propietaria o controladora para realizar actividades de producción de bienes, compra-venta de mercancías o prestación de servicios; sea con fines de lucro o no"). http://internet.contenidos.inegi.org.mx/contenidos/productos//prod_serv/contenidos/espanol/bvinegi/productos/nueva_estruc/702825075330.pdf.

13. Article 258 of the General Health Law.

14. The Pharmaceutical Academy of Mexico City published the first Mexican Pharmacopoeia in 1846.

15. An Authorised Third Party is a natural or legal person licensed by the Ministry of Health to perform studies related to sanitary procedures, and issue authorisations and opinions regarding the compliance of products with the regulation or Mexican Official Standards. To select Authorised Third Parties, the Ministry of Health issues periodical calls for proposals and forms technical committees of experts, representatives of chambers and associations to decide on the selection.

16. For example, 1) the free-trade agreement, originally between Mexico, Colombia and Venezuela, but since 2006 only between Mexico and Colombia, that came into effect

in 1995 states that medicines, medical equipment and devices, pharmacochemical products and other human, animal- and plant-health supplies that are subject to sanitary registration within the territory of one of the countries shall, where appropriate, be registered, recognised or evaluated on the basis of a single national system. Also, certificates showing compliance with the technical standards and regulations shall be accepted if they have been issued by the competent regulatory authorities of the parties; 2) Article 906 of the 1994 North American Free Trade Agreement between the United States, Mexico and Canada states: "Each Party shall, wherever possible, accept the results of a conformity assessment procedure conducted in the territory of another Party, provided that it is satisfied that the procedure offers an assurance, equivalent to that provided by a procedure it conducts or a procedure conducted in its territory the results of which it accepts, that the relevant good or service complies with the applicable technical regulation or standard adopted or maintained in the Party's territory."

17. Article 195-A of the Federal Fee Law (Ley Federal de Derechos).

18. Last year with available data.

19. "Casa Saba left the Mexican Stock Exchange in May 2013. It sought partnerships to maintain its business; however, it sold the assets of its distribution and wholesale division to two United States Investment Funds", OECD (2014), *Competition Issues in the Distribution of Pharmaceuticals: Contribution from Mexico*, p.8, footnote 9.

20. These statistics include the wholesale of allopathic, homeopathic and herbal medicines for human consumption.

21. INEGI's National Statistical Directory of Economic Units (Directorio Estadístico Nacional de Unidades Económicas, DENUE). This statistic include pharmacies with minimarket (11 030) and without minimarket (45 669), each unit corresponds to a one single establishment.

22. See http://eleconomista.com.mx/industrias/2015/04/08/farmacias-cadena-curan-mas-mexicanos, accessed 6 April 2017, and PharmaBoardroom in collaboration with CANIFARMA (November 2015), *Healthcare Life Sciences & Review*, p.86.

23. COFEPRIS's statistics differ from INEGI's, and put the total of Mexico's pharmacies at more than 28 000 pharmacies.

24. PharmaBoardroom in collaboration with CANIFARMA (November 2015), *Healthcare Life Sciences & Review*, p.86.

25. Pharmaceutical retail include pharmacies without a minimarket (SCIAN 464111), but which also sell perfumery, hygiene or groceries are considered; pharmacies with a minimarket (SCIAN 464112), which differ from pharmacies without a minimarket as products are organised in sections or small specialised exhibition areas that simplify direct consumer access to the goods, as well as all other stores selling primarily herbal products, homeopathic medicines and food supplements for human consumption (SCIAN 464113).

26. Mexicans can belong to more than one public system of health coverage: this explains why the percentages of the population covered by public health insurance total more than 100%. Furthermore, people can take out private health insurance in addition to public health insurance.

27. According to the Mexican Association of Insurance Institutions (Asociación Mexicana de Instituciones de Seguros, AMIS), just under 9.25 million people in Mexico were covered by private health insurance in 2014, accounting for 7.7% of Mexican population.

28. According to a 2015 testimonial of *Transparencia Mexicana*, available at: http://compras.imss.gob.mx/pics/pages/tsociales2014_base/LA_019GYR047_T60_2014_.pdf, accessed on 6 April 2017.

29. According to a Mexican Government press release of 11 January 2017, www.imss.gob.mx/prensa/archivo/201710/009, accessed 25 April 2017. See also, "Acta correspondiente al acto de comunicación de fallo del procedimiento de licitación pública nacional electrónica consolidada número LA-019GYR047-E60-2016", www.imss.gob.mx/sites/all/statics/compraconsolidada/2016/FALLO-E41-2016.zip, accessed 25 April 2017.

30. "Pharmaceuticals" is a category in the International Classification of Health Accounts of Health Care Functions (ICHA-HC) of the OECD System of Health Account. Pharmaceuticals include prescribed medicines, OTC medicines and other non-durable goods such as bandages, plasters and syringes. Non-durable goods account for only a minor share of the overall pharmaceuticals total, typically around 5-10%. Pharmaceuticals are delivered to patients via pharmacies and other retail outlets, but those consumed in other care settings – primarily, the hospital inpatient sector – are excluded. For international comparisons, Purchasing Power Parities (PPPs) are spatial deflators and currency converters that take into account and eliminate the effect of different price levels thus allowing comparisons of spending in a common currency; in this case, US dollars. To measure temporal changes in volume, relevant price indices are used to deflate national spending. Both measure the changes in price for a basket of comparable and representative goods either over time or between countries.

31. Article 24 of the Regulation on Health Inputs states that it is optional for pharmaceutical companies to display a "distinguishing denomination" in labels in the case of generics. Consequently, many generics are sold under a brand name. In 2013, out of all generics sold, branded generics amounted to 44% of the market value and 10% of the market volume.

32. To construct this statistic, PROMÉXICO used information from the Global Trade Atlas, an online database of trade statistics . PROMÉXICO, Unidad de Inteligencia de Negocios (2015), *Industria Farmacéutica y Oportunidades de Negocio en México*, http://mim.promexico.gob.mx/work/models/mim/Resource/99/1/images/091115_PPT_Farmaceutico_esp.pdf..

33. To construct this statistic, PROMÉXICO used information from the Global Trade Atlas, an online database of trade statistics . PROMÉXICO, Unidad de Inteligencia de Negocios (n.d.), *Diagnóstico Sectorial Farmacéutico*, www.promexico.gob.mx/documentos/diagnosticos-sectoriales/farmaceutico.pdf.

34. INEGI computes the Mexican Consumer Price Index on a monthly basis using a Laspeyres formula that weights the following categories of good and services: food, beverages and tobacco; clothing, footwear and accessories; housing costs; furniture, appliances and household goods; health and recreation; and other services. The Consumer Price Index for medicines weights different categories of medicines. Generally, the Laspeyres index estimates the variation in the value of a basket of products under the assumption that the quantities bought of every article composing

the basket are the same as in the base period. When new weights are incorporated to the index, in order to have a historical series, it is necessary to link the newly weighted index to the earlier index series. In order to do this, a linking factor is constructed: the quotient between the index with the earlier weights and the newly weighted index with the new weights, in a given same period (creating an overlap). The factor is then multiplied by the newly weighted index in the periods after the overlapping period.

35. INEGI data from the *2014 National Survey of Household Income and Expenditure* (*Encuesta Nacional de Ingresos y Gastos de los Hogares*, *ENIGH*).

36. Internal-market production is defined as medicine manufacturing minus exports of medicines.

37. The OECD reports 30% as the figure of out-of-pocket medical expenditure in household consumption.

38. Those members include the president of the National Academy of Medicine of Mexico and the president of the Mexican Academy of Surgery.

39. The database is available at www.profeco.gob.mx/precios/canasta/default.aspx.

40. www.canifarma.org.mx, accessed 6 April 2017.

41. www.anafam.org.mx, accessed 6 April 2017.

42. http://anadim.com.mx/PDF/ANADIM_RESULTADOS.pdf, accessed 6 April 2017.

43. www.anadim.com.mx, accessed 6 April 2017.

44. www.amegi.com.mx/conocenos.html, accessed 12 May 2017.

45. http://unefarm.org.mx, accessed 6 April 2017.

46. www.anafarmex.com.mx, accessed 6 April 2017.

47. See, for example, OECD (2017), *Tackling Wasteful Spending on Health*, Chapter 7: Wasting with intention: Fraud, abuse, corruption and other integrity violations in the health sector. http://dx.doi.org/10.1787/9789264266414-en.

48. The last amendment dates to 27 January 2017; see, official website of the Chamber of Deputies, www.diputados.gob.mx/LeyesBiblio/ref/lgs.htm (accessed 2 May 2017).

49. For example, Kesselheim A.S. et al. (2008), *Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis*, *JAMA*,300:21, pp.2514-2526.

50. See, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use.

51. Article 94 of Directive 2001/83/EC.

52. See, Department of Health and Human Services (2003), *Office of the Inspector General OIG Compliance Program Guidance for Pharmaceutical Manufacturers*. Fed Register, and Pharmaceutical Research and Manufacturers of America (2008), *PhRMA Code on Interactions with Healthcare Professionals*, Washington, D.C.

53. See, the Food and Drug Administration site, defining generics and illustrating their effects,

www.fda.gov/Drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm, (accessed 1 June 2017).

54. In Mexico, NOM-177-SSA1-2013 regulates the rules and procedures to show when a medicine is interchangeable. Mexican law states a maximum of 5% of variability for drugs to be considered as interchangeable with the referent product (Article 6.2.8, NOM-177-SSA1-2013).

55. See, for example, Kesselheim A.S., et al. (2008), "Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis", *JAMA*, 300:21, pp. 2514-2526.

56. This is the case of Germany, however, in many other countries, such as the US, the UK, and Sweden, the prices of innovative drugs tend to increase after the entry of generics. In "The Generics Paradox Revisited: Empirical Evidence from Regulated Markets" (2013), Sotiris Vandoros and Panos Kanavos write: "When including all six countries in panel data models, the OECD finds strong evidence that prices of originators increase with generic entry and penetration. When considering each country separately, the OECD finds evidence that the generics paradox is present in the United Kingdom and Sweden, as originator prices increase post-patent expiry. In the Netherlands, prices also increase post-patent expiry, but part of this increase is offset as generic penetration takes place, while in Denmark and Norway generic entry does not affect originator prices. The only country in which generics lead to lower originator prices is Germany" (*Applied Economics*, 45.22, p.3238).

57. See, for example, Grabowski, Henry G., and John M. Vernon (1992), "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act", *The Journal of Law & Economics*, 35:2, pp.331-350, www.jstor.org/stable/725543.

58. See, for example, Vandoros, S. and K. Panos (2013), pp.3230-3239.

59. Prescribing with INN is permitted in most EU countries and is mandatory in a few countries (e.g. Estonia since 2010, Portugal and Spain since 2011, and France since 2015). Similarly, pharmacists are allowed to substitute brand-name drugs with generics in a majority of EU countries. While generic substitution is mandatory in some countries (e.g. Denmark, Finland, Spain, Sweden, Italy), the United Kingdom has high generic penetration without any substitution mandate.

60. Definition from drugs.com, www.drugs.com/article/placebo-effect.html, accessed 1 June 2017.

61. Article 6.2.8. of the NOM-177-SSA1-2013 that regulates interchangeability procedures and tests.

62. Directive 2001/83/EC.

63. List at http://siga.impi.gob.mx/newSIGA/content/common/principal.jsf.

64. See, www.fda.gov/drugs/informationondrugs/ucm129662.htm, accessed 1 June 2017.

65. Fourth edition, 2010.

66. Article 31 of the Reglamento de Insumos para la Salud.

67. OECD (2014), *Competition Issues in the Distribution of Pharmaceuticals*, p.21.

68. Conditions for the granting of this authorisation are set in Article 167 of the Reglamento de Insumos para la Salud.

69. Article 76 et seq. of Directive 2001/83/EC.

70. For example, see implementation in Germany, § 52b AMG.

71. For example, see implementation in Germany, § 52b AMG.

72. See following paragraphs citing the World Health Organization and OECD previous work.

73. Article 24 of Directive 2001/83/EC.

74. Draft European Parliament Legislative Resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2014)0557 – C8-0142/2014 – 2014/0256(COD)), www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2016-0035+0+DOC+XML+V0//EN.

75. According to Volume 5 of Title 21 of the Code of Federal Regulations, "[c]hanges in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product must be documented by the applicant in the next annual report" and a "supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product".

76. Directive 2010/63/EU on the Protection of animals used for scientific purposes.

77. See World Economic Forum (2015), *Enabling Trade: Unlocking the Potential of Mexico and Vietnam*, www3.weforum.org/docs/WEF_Enabling_Trade_2016.pdf.

78. See, e.g., Erickson, Gary M. (1985), "A Model of Advertising Competition", *Journal of Marketing Research*, 22:3, pp.297-304, www.jstor.org/stable/3151426.

79. Article 88 of Directive 2001/83.

80. See Article 4 of Council Directive 84/450/EEC of 10 September 1984 relating to the Approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising.

81. Article 32 of the law forbids misleading or abusive advertising, which is defined as advertising that "refers to features or information related to a good, product or service, which might be true or not, and that induces mistakes or confusion because of its inexact, false, exaggerated, partial, deceptive or biased form".

82. www.uam.mx/difusion/casadeltiempo/29_iv_mar_2010/casa_del_tiempo_eIV_num29_63_67.pdf.

83. Mexican Pharmacopeia (fourth edition), Section II Supplement, p.79.

84. The US Code, Title 41 – Public Contracts, Subtitle IV – Miscellaneous, Chapter 83 – Buy American states that "[o]nly unmanufactured articles, materials, and supplies that have been mined or produced in the United States, and only manufactured articles, materials, and supplies that have been manufactured in the United States substantially all from articles, materials, or supplies mined, produced, or manufactured in the

United States shall be acquired for public use unless the head of the department or independent establishment concerned determines their acquisition to be inconsistent with the public interest or their cost to be unreasonable." According to the same law, materials shall be considered to be mined or produced in the United States if the cost of the national products used in such materials constitutes more than 50% of the cost of all the products used in such materials.

85. See Directive 2014/24/EU, e.g. Germany § 97 Paragraph 4, Act against Restraints of Competition.

86. For instance, in Korea, according to Article 4 of the Act on Facilitation of Purchase of Small and Medium Enterprise-Manufactured products and support for development of their markets: "[w]hen the heads of public institutions intend to conclude contracts for the procurement of goods [...], they shall provide small and business proprietors with increased opportunities for receiving orders."

87. In the United States, Subpart 19.7 of the Small Business Subcontracting Program of the Federal Acquisition Regulation states that any contractor must agree in the contract that small businesses will have the maximum practicable opportunity to participate in contract performance consistent with its efficient performance.

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Annex 2.A1

Summary of quantifications for the medicine sector

If this set of OECD recommendations[1] for the medicine sector is fully implemented, the benefit to consumers is estimated to range between MXN 10 177.1 million and MXN 43 813.8 million. A summary of the estimated benefit to consumers is shown in Table 2.A1.1.

It would not be methodologically appropriate to add up consumer benefits that result from implementing recommendations A1 and A2 because it would involve double counting. Once A2 has been implemented, the additional benefit from implementing A1 should be discounted. The OECD team has therefore constructed two cases to show two possible discounts. Case 1 consists of discounting by 20% the benefit from A1, while Case 2 consists of discounting it by 50%.[2]

Table 2.A1.1. **Estimated benefit**

Recommendation	Benefit (MXN, millions)	
	Lower end	Upper end
A1. Removal of incentives to doctors	7 743.1	7 743.1
A2. Substitution at pharmacy / doctors only prescribe INN drugs	6 177.4	34 544.8
A3. Implementation of obligation for producers to supply every full-line wholesaler in the private market	128.1	3 074.6
A4. Introduction of only one renewal of the sanitary registry, with subsequent random controls*	4.8	4.8

* This recommendation was not taken into account in the estimation of total consumer benefit shown in Table 2.A1.2.

Source: OECD analysis.

Table 2.A1.2. **Total consumer benefit**

Recommendation	Total consumer benefit (MXN, millions)	
	Lower end	Upper end
Case 1	12 500	43 813.8
Case 2	10 177.1	41 490.9

Source: OECD analysis.

Notes

1. Annex 2.A2, 2.A3 and 2.A4.
2. In cases where substitution at pharmacies takes place and incentivisation is not proscribed, doctors prescribing branded medicines would not have any effect unless they specify that substitution is not allowed. However, due to incentivisation, doctors may overprescribe patented medicines. Hence, even if it seems that by implementing recommendation A2, recommendation A1 does not have any impact, it prevents overprescription of medicines or the "substitution not allowed" specification in prescriptions.

Annex 2.A2

Incentives to doctors

If this OECD recommendation is fully implemented, the benefit is estimated to be MXN 7 743.1 million.

Description and harm

Mexico currently has no law regulating the benefits pharmaceutical companies can provide to doctors (such as conference participation or speaker engagements). There is, however, an ethics code issued by the Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (Consejo de Ética y Transparencia de la Industria Farmacéutica, CETIFARMA), which belongs to CANIFARMA.

This ethics code, which addresses financial incentives, only applies, however, to CANIFARMA members (87% of all pharmaceutical companies). According to the CETIFARMA document, providing financial incentives of significant value to doctors is forbidden. Infringement of the code is subject to reprimand, financial penalties (no specific amounts are detailed, however), and temporary or definitive suspension of the rights as a CANIFARMA affiliate.

A lack of binding governmental regulation in this field may hinder competition among similar products. Some doctors receive benefits from pharmaceutical companies with the result that they may prefer those companies' products rather than those they might otherwise regard as best clinically suited or most economic for the patient.

Recommendation

Issue a binding regulation determining the exact conditions under which financial advantages or benefits of significant value to doctors can be granted. This regulation should contain sanctions in case of infringement of the conditions. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, as well as the CETIFARMA ethics code, might be used as a starting point.

Estimates of the benefits arising from the recommendation

Methodology

Effects of implementing a provision and/or regulation that prohibits supplying financial advantages or benefits of significant value to doctors, by estimating the consumer benefit if all doctors behave the same way (i.e. receiving no payments from the pharmaceutical industry).

There is no data publicly available in Mexico of the percentage of doctors who receive payments from the pharmaceutical industry. However, in the United States, data revealing the payments doctors receive from pharmaceutical companies is available

online. Using available US data, Jones and Ornstein (2016), showed the relationship between industry payments and prescription of branded medicines (Jones, Ryan Grochowski & Charles Ornstein, 2016).

The main results from that study, using a sample of doctors with more than 1 000 claim counts, are shown in Table 2.A2.1.

Table 2.A2.1. **Prescription patterns of doctors receiving incentives versus non-incentivised doctors**

	Doctors with >1 000 claim count	Subset who received an industry payment	Subset who did not received an industry payment	Percentage who received a payment	Percentage who did not receive a payment	Mean brand-name prescribing rate (no payments)	Mean brand-name prescribing rate (payments)
Family medicine	65 651	46 753	18 898	71.21%	28.79%	18.70%	20.20%
Internal medicine	51 607	36 329	15 278	70.40%	29.60%	19.80%	22.00%
Cardiology medicine	13 817	12 308	1 509	89.08%	10.92%	19.20%	21.60%
Psychiatry medicine	11 052	8 650	2 402	78.27%	21.73%	13.60%	15.60%
Ophthalmology medicine	8 196	7 117	1 079	86.84%	13.16%	46.40%	56.90%
Total	**150 323**	**111 157**	**39 166**	**73.95%**	**26.05%**	**19.6%**	**22.94%**

Source: Jones and Ornstein (2016), *Matching Industry Payments to Medicare Prescribing Patterns: An* Analysis and OECD Analysis.

Current situation

$$Private\ Market\ Value = X\ (\%Doctor\ with\ incentives * \%\ BNM + \%Doctor\ without\ incentives * \%\ BNM) + 0.2X\ (\%Doctor\ with\ incentives * \%\ generics + \%Doctor\ without\ incentives * \%\ generics)$$

where X is the private market value of medicines if all final consumers buy brand name medicines (BNM) and 0.2X is the private market value of medicines if all final consumers buy generics, since the implicit price ratio of generic medicines to brand-name medicines is 0.2,

$$MXN\ 147\ 715.91\ million = X\ (73.95\% * 22.94\% + 26.05\% * 19.6\%) + 0.2X\ (73.95\% * 77.06\% + 26.05\% * 80.4\%)$$

$$MXN\ 147\ 715.91\ million = X * (22.07\%) + 0.2X * (77.93\%)$$

$$X = MXN\ 392\ 312\ million$$

and MXN 78 462.4 million is the private market value of medicines if all final consumers buy generics.

With a change in regulation (i.e. if doctors no longer receive incentives) it is assumed that all doctors would prescribe the same share of generics and brand-name medicines with the same frequency as currently non-incentivised doctors do:

$$Private\ Market\ Value = X\ (\%Doctor\ without\ incentives * \%\ BNM) + 0.2X\ (\%Doctor\ without\ incentives * \%\ generics)$$

$$Private\ Market\ Value = MXN\ 392\ 312\ million\ (19.6\%) + 0.2\ (MXN\ 392\ 312\ million)\ (80.4\%)$$

$$Private\ Market\ Value = \ MXN\ 139\ 972.8\ million$$

Therefore, savings (i.e. consumer benefit) that final consumers would receive if all doctors were not incentivised are MXN 7 743.1 million.

References

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Annex 2.A3

Substitution of prescribed medicines with generics

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to range between MXN 6 177.4 million and MXN 34 544.8 million.

Description and harm

When prescribing a medicine, doctors can either prescribe the generic name or the generic and distinctive designations (or brand name) jointly. The former is known as an International Nonproprietary Name or INN, and defined by the World Health Organization as a unique name that is globally recognized and public property. The latter is a mix of generic drug and brand name: for example, salbutamol and "Ventolin"; ibuprofen and "Advil"; or paracetamol and "Tylenol". When doctors prescribe the distinctive denomination, pharmacists must comply with that wish; the medicine can only be replaced when the doctor expressly authorises it.

Consumers are locked into buying a branded medicine if it is prescribed by the doctor. Generics may therefore face a competitive disadvantage if doctors tend to prefer certain branded medicines and do not include generics in their prescriptions, or authorise the substitution of the branded product.

Recommendation

The OECD recommends the following options for the Mexican government:

Option 1) Amend the provision in order to oblige pharmacists to inform patients about the cheapest available generic and allow the substitution of prescribed medicines with this generic when the patient agrees, unless the doctor has specified "substitution not allowed" in the prescription (this might be necessary if certain patients do not react well to generic substitutes of a certain medicine). The OECD recommends making the substitution optional, not mandatory because most purchases in Mexico are out-of-pocket spending by customers and that customers must be able to purchase the medicine they perceive to be best (placebo effect).

Option 2) Introduce a provision that requires doctors to prescribe INN medicines (i.e. the active substance).

Either option will bring the same consumer benefit.

Estimates of the benefits arising from the recommendation

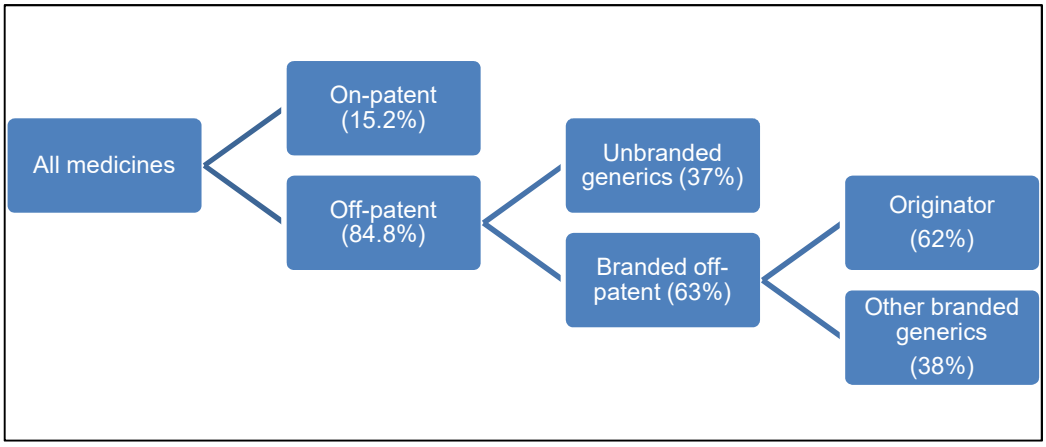
Methodology

To calculate the consumer benefit of allowing substitution of prescribed medicines with generics or requiring doctors to only prescribe medicines on INN we followed two different methodologies. Given the limited time and resources available, we relied heavily

on existing market research and a detailed bibliographical review of academic research from the relevant experience in this market from Mexico and other OECD countries.

According to PharmaBoardroom (PharmaBoardroom, 2015), the Mexican market value for medicines in 2012 was MXN 190 181 million. According to Funsalud (Fundación Mexicana para la Salud, 2013), out of this value, on-patent medicines represented 15.2% market share, whereas off-patent medicines 84.8%. Out of the later, branded off-patent medicines (i.e. originators plus branded generics) accounted for 63% market share of the off-patent medicines, hence unbranded generics (including private labelled generics which are generics labelled with the name of the pharmacy chain or laboratory, not particularly advertised and whose prices are very close to unlabelled generics) for 37% market share. The final classification of interest is between originator and other branded off-patent medicines. The value market share (within the branded off-patent category) of originator medicines was approximately 62%, while branded generics accounted for 38%. Figure 2.A3.1 summarises this information.

Figure 2.A3.1. **Value market shares of different types of medicines in Mexico**



Source: OECD analysis.

The pharmaceutical market in Mexico has traditionally been a physician-driven market, as many E.U. markets, such as France, Spain, Italy or Germany, and in contrast to the more pharmacy-driven markets, such as the US, Canada or the UK (Danzon and Furukawa, 2011). In physician-driven markets where pharmacists are either not authorised or incentivised to substitute towards the cheapest alternative, generics penetration is significantly lower (for instance, in 2009, penetration varied from 60% in the UK to 89% in the US in the pharmacy-driven markets compared to a range from 22% in Spain to 50% in France in the physician-driven countries, with Mexico around 30%). Moreover, in countries with a weaker institutional framework and enforcement of law where generic quality is uncertain, brand plays a much more important role. For example, whereas the vast majority of generics are unbranded in countries such as the US, the UK, France or Germany, the opposite is true for countries such as Brazil or Mexico, where most sales are generated by branded generics.[1] Competition to build brand equity undermines competition on price and as a result branded generics keep prices relatively high.

OECD's recommendation essentially focuses on the potential savings that could be achieved by intensifying competition within the off-patent category. Unbranded generics are not considered for our estimates since OECD's recommendation would not result in a price reduction in this category as the current legislation does only restrict substitution of prescriptions of a certain brand.

The first methodology utilises the following formula to estimate the consumer benefit of allowing substitution of prescribed medicines with generics at the pharmacy (OECD, 2015: 100):

$$CB = \left(\rho + \frac{\varepsilon}{2}\rho^2\right) R$$

Where:

CB: standard measure of consumer benefit

ρ: absolute value of percentage change in price related to restriction

R: sector revenue

ε: absolute value of price elasticity of demand.

The OECD assumes the value of price elasticity of demand to be zero, as we make the simplifying assumption that demand is driven by doctors' prescriptions and it is not responsive to price in the short run (OECD, 2017: 197). This restriction concerns categories D1[2] and D3[3] of the Competition Assessment Toolkit. ρ is assumed to take either a value of 0.16 (i.e. the minimum ρ between D1 and D3) or a value of 0.32 (i.e. the maximum ρ between D1 and D3) (Ennis, 2017). Following our previous market description (see Figure 2.A3.1).

Taking account of the the so called "generic paradox" (i.e. originator prices do not decrease after the entry of generics),[4] this scenario assumes that originator prices do not change in the short run while branded generics do. Thus, R is considered to be equal to the 38% of the branded off-patent medicines or MXN 38 608.87 million.

Hence, the computation of the consumer benefit of allowing substitution of prescribed medicines with generics is estimated to be between of MXN 6 177.42 million (lower bound) and MXN 12 354.84 million (upper bound).

The second methodology to calculate consumer benefits borrows directly from the work of Danzon and Furukawa (2011). Using very detailed data from 10 countries (US, UK, Germany, France, Spain, Italy, Japan, Canada, Brazil and Mexico) over the period 1998-2009 they examine the performance of generic markets at the level of drug presentation (molecule-form-strength) as this is where pharmacy substitution can legally take place. They estimate a four equation model: for any generic entry; number of generic firms, conditional on entry; generic or originator price; and generic volume share. They run separate regressions for each country, allowing all coefficients to vary by country.

Focusing on their estimated results on prices, the authors show that the main driving force of lowering prices is the entry and number of unbranded generic manufacturers (see Danzon and Furukawa [2011], Table 5). Finally, based on the whole set of results from all four equations, they calculate the potential payer savings based on the generic-originator price difference and on the share of prescriptions that are dispensed generically. For our purposes, we utilise the total percentage savings that basically measures how much lower expenditure would have been if all branded off-patent medicines (i.e. originator medicines plus branded generics) were sold as unbranded

generics. To calculate the consumer benefits in this case we multiply the total percent savings with the revenues from branded off-patent medicines:

$$CB = \frac{(P^O - P^G)Q^G}{(P^O Q^G + P^O Q^O)} R$$

where:

CB: measure of consumer benefit

Q : denotes units, superscripts O and G denote originator and generic, respectively

P : denotes price, superscripts O and G denote originator and generic, respectively

R : revenue of originator medicines

The OECD team assumes that the ratio is equal to either 0.340 (see Danzon and Furukawa [2011], Table 8) which the latest estimate based on the years 2006-2009 for Mexico or 0.166 which is the average savings over the whole period (1998-2009). Based on our previous market description (see Figure 2.A3.1), R is considered to be equal to the 63% of the off-patent medicines or MXN 101 602.3 million.

The computation of consumer benefit of allowing substitution of branded off-patent medicines with generics is estimated to be between of MXN 16 899.85 million (lower bound) and MXN 34 544.78 million (upper bound).

Therefore, both methods seem to indicate significant consumer benefits from the enhanced competition in this market. Given the history and the current state of the Mexico market, OECD's recommendations are more likely to affect first the competition between branded generics and unbranded medicines (first methodology). More intense competition among generics will also affect the originator medicines prices (second methodology), but this is more likely in the medium to long run. The lesson from other OECD countries (mostly European) is that complementary policies, such as reference pricing systems, are particularly effective in bringing down originator prices (Kanavos, 2014: 224-241).

Notes

1. See Figure 7 in Danzon and Furukawa (2011).
2. "Limits the ability of consumers to decide from whom they purchase"
3. "A restriction that fundamentally changes information required by buyers to shop effectively"
4. For instance, Frank and Salkever (1997) reported that the entry of an additional generic seller is associated with an average 0.7% increase in the price of the originator medicine, Regan (2008) reported 1% and Danzon and Furukawa (2011) stated that "originator prices are generally stable in response to generic entry, but at different levels reflecting different regulatory regimes".

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Annex 2.A4

Direct sales

If an obligation for medicine producers to supply all full-line wholesalers in the private market would be implemented, the benefit is estimated to be between MXN 128.1 million and MXN 3 074.6 million.

Description and harm

Wholesale and retail of medicines and other health products, narcotics, psychotropic substances, and products containing narcotic or psychotropic substances requires a sanitary authorisation (i.e. a licence). This licence granted to pharmaceutical companies is not limited to the manufacture of medicines. The OECD team did not find any provision prohibiting direct selling by pharmaceutical companies to pharmacies.

In practice, however, many pharmaceutical companies in Mexico refuse to sell directly to pharmacies, even to big pharmacy chains, preferring to sell through wholesalers. It is common practice for pharmaceutical companies to sign exclusive contracts with one distributor. Wholesalers therefore often become the only channel through which to commercialise a certain medicine.

For large retailers (i.e. pharmacy chains), this purchasing from a wholesaler imposes an unnecessary cost, as they have to pay an extra margin to wholesalers instead of acquiring the products directly from the producers. Also, market participants at retail level complain that many medicines are distributed by only one wholesaler and there is no, or only very limited intra-brand, competition for many medicines in Mexico.

The described problem concerns the private market as the public authorities generally purchase medicines via public tenders.

Recommendation

The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market, which would have the aim to allowing new wholesalers to compete. Before moving forward with such a measure however it is recommended that a study in coordination with the relevant authorities assesses the impact on the market of introducing such an obligation, whose purpose would be to allow new wholesalers to compete in the concentrated Mexican wholesale market and increase intra-brand competition. However, as this proposed recommendation would interfere with contractual freedom, it should only be implemented if such study would demonstrate that other measures to strengthen intrabrand competition do not lead to any results.

Estimates of the benefits arising from the recommendation

Methodology

Effects of implementing an obligation for producers to supply every full-line wholesaler in the private market, which will mainly impact pharmacy chains' income.

Large pharmacy chains' income in 2014 was MXN 51 243 million; if these pharmacies stopped purchasing medicines through wholesaler distributors and began to purchase directly from pharmaceutical companies, they would not incur payments to wholesaler distributors (i.e. wholesalers' margin, which is a share of the final price or income), but would still allocate resources to their distribution networks. The OECD presents four different scenarios for wholesalers' average margins (5%, 10%, 20% and 30%) and assumes that by creating their own distribution system, big pharmacy chains will spend between 80% and 95% of the wholesaler distributors' margin.

Three scenarios for savings rates are presented in Table 2.A4.1: 5%, 10% and 20%.

Table 2.A4.1. **Scenarios for large pharmacy chains' savings (MXN, millions)**

		Wholesalers' average margin			
		5%	**10%**	**20%**	**30%**
Savings rate	5%	128.11	256.22	512.43	768.65
	10%	256.22	512.43	1 024.86	1 537.29
	20%	512.43	1 024.86	2 049.72	3 074.58

Source: OECD analysis.

Annex 2.A5

Sanitary-registry renewal

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to amount to MXN 4.8 million.

Description and harm

Sanitary registries need to be renewed every five years. According to Article 195-A of the Federal Government Fees Law, for a sanitary-registry renewal, applicants must pay 75% of the new sanitary-registry fee (the sanitary-registry fee for generics is MXN 71 334.41 and for new-molecule medicines MXN 127 549.79).

Requiring that the sanitary registry is renewed every five years imposes an extra cost on firms. The costs can be quite significant for producers often marketing hundreds of products.

Recommendation

Renew the sanitary registry only once after five years; after that time, it should become permanent. The OECD agrees with COFEPRIS that such a change in system should only be implemented after the Mexican control and supervision system has been significantly improved. This would require increasing the frequency of on-site controls; introducing large fines if pharmaceutical companies do not report changes in a medicine to COFEPRIS in time; and granting adequate resources to COFEPRIS to fulfil this task.

Estimates of the benefits arising from the recommendation

Methodology

Effects from changing the sanitary registry renewal to annual controls.

Last year, sanitary registries of 573 allopathic medicines, 34 herbal medicines, 42 homeopathic medicines and 34 vitamin medicines were renewed. For every sanitary registry renewal, applicants pay 75% of the original fee, which is MXN 71 334.41 for generics and MXN 127 549.79 for new molecule medicines if medicines are allopathic. If medicines are herbal, homeopathic or vitamins, applicants shall pay 75% of the original fee, which is MXN 16 962.82.

If pharmaceutical companies were no longer required to apply for a sanitary registry renewal, savings for firms every five years will be MXN 32 055 395.35 (assuming that all applicants obtained sanitary registries for generics); annually, they will be MXN 6 411 079.07; assuming that annual controls will cost MXN 2 322.61 (the fee stated by the Federal Fee Law for a sanitary compliance visit), total annual costs will be MXN 1 586 342.63. The net savings from changing sanitary-registry renewal to annual controls are therefore calculated at MXN 4 824 736.44 every year.

This estimation does not take into account the internal savings (e.g. preparation of documents) that pharmaceutical companies will experience if they do not have to repeat every five years all the required tests when the sanitary registry was first granted. Also, the annual costs related to the annual revisions might be underestimated. A significant improvement of the Mexican control and supervision system will bring additional costs, which will probably have to be financed by the pharmaceutical companies.

Chapter 3

Meat

The meat sector is important in Mexico, both as a source of employment (344 849 people, as of 2013) and as a contributor of GVA (animal slaughtering and processing accounted for 0.95% of Mexican GDP in 2015). Regulatory reforms could bring efficiency gains that would benefit Mexican households, particularly the poorest. The major constraints in the meat sector include unnecessary documentation to transport livestock, their products and sub-products (e.g. state transport documents and certifications granted by local livestock associations); excessive controls for imports (e.g. double authorisation of establishments and countries; inspection of all imported meat, carcasses, viscera and offal); anti-competitive legislation on livestock associations; and the non-harmonisation of several Mexican standards with international norms.

3.1. Economic overview of the meat sector

3.1.1. Definition of the subsectors, and description of the value chain

The meat sector and its subsectors cover the vertical meat-production and commercialisation value chain, including farm-product raw materials and farm supplies, slaughtering and meat-processing activities, pet-feed manufacturing, and wholesale and retail grocery sales. Also included are support activities for the raising of livestock, such as logistics, warehousing and transportation related to meat production.

Not included in this assessment are economic activities related to animals not raised for meat, such as fur-bearing, or animals whose meat is not widely consumed by the general public, such as rabbits, deer, horses and other equine production. Also, neither hunting and trapping activities nor special outlets, such as pet-supply stores and accommodation and feed services, fall under the scope of this assessment.[1]

The vertical value chain of the meat industry is:

- animal feed
- raising livestock
- transport intermediation
- slaughtering and meat processing
- meat wholesaling
- retail.

3.1.1.1. Animal feed

The first stage of the vertical value chain concerns livestock feed. In general, livestock can be fed with forage, grain[2] or balanced feed. The last is composed of forage and other ingredients such as pre-mixtures and additives. The combination of forage, grain and balanced feed in an animal diet varies depending on the species. In general, balanced feed is more commonly used in intensive production systems.

Animal feed is generally the highest production cost in raising cattle for beef, pigs for pork, or chickens. In 2008, according to the Federal Economic Competition Commission (Comisión Federal de Competencia Económica, COFECE) (COFECE, 2015),[3] animal feed amounted on average to 71% of costs in livestock production: 69.2% for beef cattle raised (49.2% forage and 20% balanced feed); 77.3% for pigs (25.4% forage and 51.9% balanced feed); and 73.1% for chickens raised for meat production (13.1% grains and cereals, and 60% balanced feed). According to the *Compendio de indicadores económicos del sector avícola Edición 2016* published by the National Poultry Association (Unión Nacional de Avicultores, UNA), in 2016 animal feed accounted for 66% of the production costs of chicken raised for meat production.

3.1.1.2. Raising livestock

Raising livestock for meat encompasses the methods and practices by which producers raise live animals. There is a wide array of livestock-raising productive systems, ranging from the highly technical to the traditional.

A livestock-raising productive system can be intensive, extensive, or mixed. An extensive system involves raising animals in pastures, while an intensive system involves raising them indoors. A combination of both production systems is also possible. For instance, calves can be raised in pastures where they feed on forage (extensive system), until they reach a certain weight and are brought into feedlots (intensive system), where they are fed on grain, forage and balanced feed.

In Mexico, the majority of pig and chicken production is intensive. The main companies in the pork and chicken-meat industries own farms and facilities where they handle the breeding, feeding, raising and slaughtering of animals. Beef production tends be more extensive. According to an interview with the Mexican Cattle Feeders Association (Asociación Mexicana de Engordadores de Ganado Bovino, AMEG), there are as many as 1.2 million small-scale beef producers in the country. An important part of beef production is carried out on communal "social property"[4] lands, known as *ejidos*.[5] Strict limitations on the consolidation of this communal land partially explain the prevalence of small-scale beef production.[6]

3.1.1.3. Transport intermediation

Transport intermediation is whenever industry participants other than livestock producers transport live animals from the facilities where they are raised to the abattoirs where they are slaughtered. In this regard, among the three meat industries, the chicken-meat industry is the most vertically integrated; the pork industry exhibits an intermediate level of integration; and the beef industry includes numerous intermediaries. It is a common practice for producers on ranches in southern Mexican states to raise calves, which then are bought by intermediaries ("coyotes") and transported to feeders in northern states, where calves are fed and, eventually, slaughtered.

Transport of livestock, meat and meat products and sub-products across the Mexican territory can be subject to various authorisations. Firstly, it requires a Zoosanitary Transport Certificate (Certificado Zoosanitario de Movilización, CZM) issued by the National Service for Agro-Alimentary Public Health (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, SENASICA) or a third-party specialist either authorised by SENASICA or that are authorised at zoosanitary certification centers belonging to an official certification body.[7] Secondly, several state governments demand transport documents from intermediates moving livestock, meat, meat products and sub-products within states.[8] Thirdly, to transport livestock across the Mexican territory, it is necessary to obtain certification from the livestock association operating in the municipality of origin.[9]

3.1.1.4. Slaughtering and processing

There are three types of government-regulated abattoirs: private abattoirs, municipal abattoirs, and Federal Inspection Type (Tipo Inspección Federal, TIF) abattoirs.[10] Municipal abattoirs – also known as Ministry of Health Inspection Type (Tipo Secretaría de Salud, TSS) – and private abattoirs are regulated by the Ministry of Health (Secretaría de Salud, SSA), through its body Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS).

TIF abattoirs are regulated by the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA), through its body, SENASICA. There is also uncontrolled illegal slaughtering, carried out in "clandestine abattoirs" (*rastros*

clandestinos) or on site. In 2015, according to the Mexican Meat Council (Consejo Mexicano de la Carne, COMECARNE), 22% of beef cattle slaughtering and 21% of pig slaughtering were carried on site (COMECARNE, 2016).

Municipal or TSS abattoirs are available to any party in need, but in practice they serve mainly three kinds of clients:

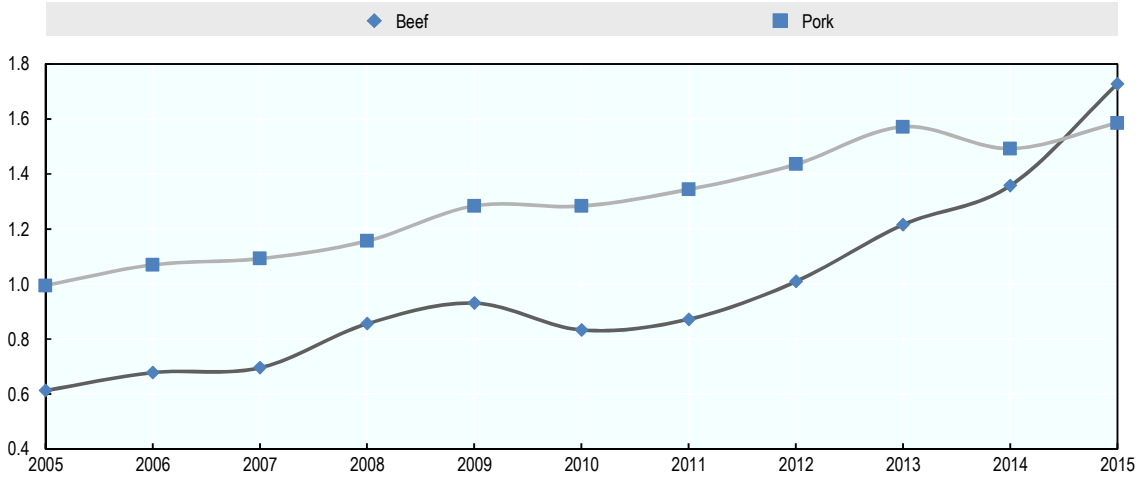
1. livestock intermediaries
2. butchers
3. livestock associations.

These abattoirs comprise areas for livestock reception, sanitary inspection and slaughtering.

TIF abattoirs are subject to stricter standards than TSS abattoirs[11] and are the only establishments that can export meat. TIF abattoirs tend to have higher productivity than TSS abattoirs (USDA, 2014). In 2013, according to the United States Department of Agriculture (USDA), TIF abattoirs accounted for less than 10% of the total number of abattoirs,[12] but 87% of poultry and 44% of pigs and beef slaughters took place in them. TIF abattoirs are mainly used by large, vertically integrated meat companies.

Over the past decade, TIF abattoirs have slaughtered an increasing share of livestock. Figure 3.1 presents the evolution of the ratio of TIF to TSS slaughters between 2005 and 2015, for cattle and pigs. In 2005, the number of pigs slaughtered in TIF and TSS abattoirs was approximately the same; in 2015, there were 1.59 pigs slaughtered at a TIF abattoir for each pig slaughtered at a TSS abattoir. More cattle have been slaughtered in TIF abattoirs than TSS abattoirs since 2012; in 2015, there were 1.73 TIF slaughters for each TSS slaughter. This tendency shows the increasing industrialisation of the slaughtering subsector.

Figure 3.1. **Ratio of animals slaughtered at TIF to TSS abattoirs, 2005-2015***

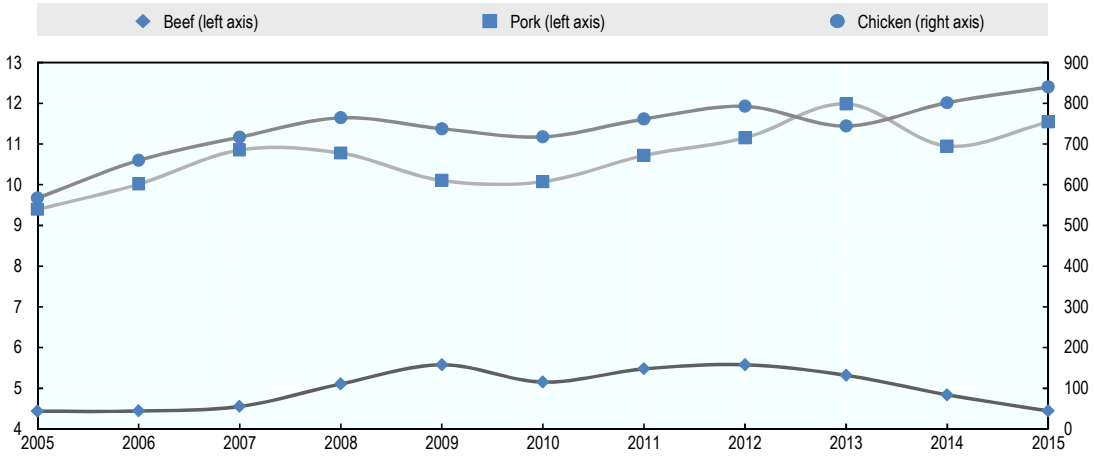


* The ratio is only presented for cattle and pigs, as registries of chicken slaughtered at TSS abattoirs were not readily available.

Source: National Confederation of Livestock Unions (Confederación Nacional de Organizaciones Ganaderas, CNOG) (2016), *Información económica pecuaria 25*, www.cnog.org.mx/archivos/BOL_ECONOM_25.pdf.

Figure 3.2 depicts the evolution of the volumes of animals slaughtered at TIF and TSS abattoirs.[13] There has been an increase in the number of slaughtered chickens and pigs; the number of cattle slaughtered in 2015 was almost identical to 2005, even though there were two peaks in 2009 and 2012.

Figure 3.2. **Animals slaughtered at TIF and TSS abattoirs, in millions, 2005-2015**



Source: CNOG (2016), *Información económica pecuaria 25*

3.1.1.5. Wholesaling and retail

The distribution channels through which meat is commercialised vary depending on whether the supply chain is traditional or integrated. Meat carcasses are commercialised both warm or cold. Meat intended for sale in public markets and butchers is usually commercialised warm, and has a shorter expiration date. Meat intended for sale in supermarkets is refrigerated while stored, distributed and commercialised. Keeping a cold supply chain is more easily achieved by vertically integrated companies with their own equipment and infrastructure. Mexican meat commercialised in supermarkets comes from TIF establishments.

Large meat producers tend to operate more than one distribution channel. Some large companies have a portfolio of clients (retailers), such as supermarkets and grocery stores. Other companies have their own retail stores, where they distribute and sell their meat products.

As Figures 3.3 to 3.5 illustrate, Mexican consumers still prefer to buy meat at traditional markets and butchers or poulterers' shops. For each of the three types of meat, these two commercialisation channels account together for at least 59% of consumers' buying-channel preferences.

Figure 3.3. **Composition of buying-channel preferences for beef, 2015**

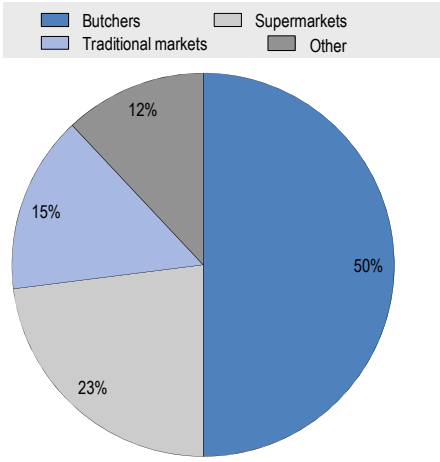


Figure 3.4. **Composition of buying-channel preferences for pork, 2015**

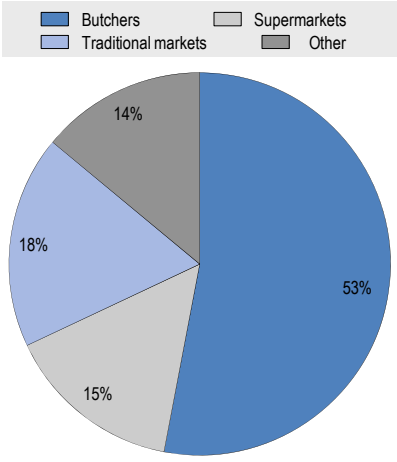
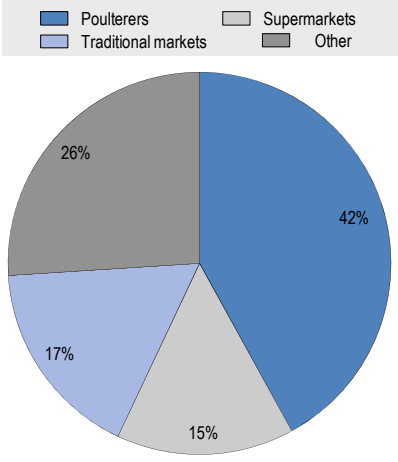


Figure 3.5. **Composition of buying-channel preferences for poultry meat, 2015**



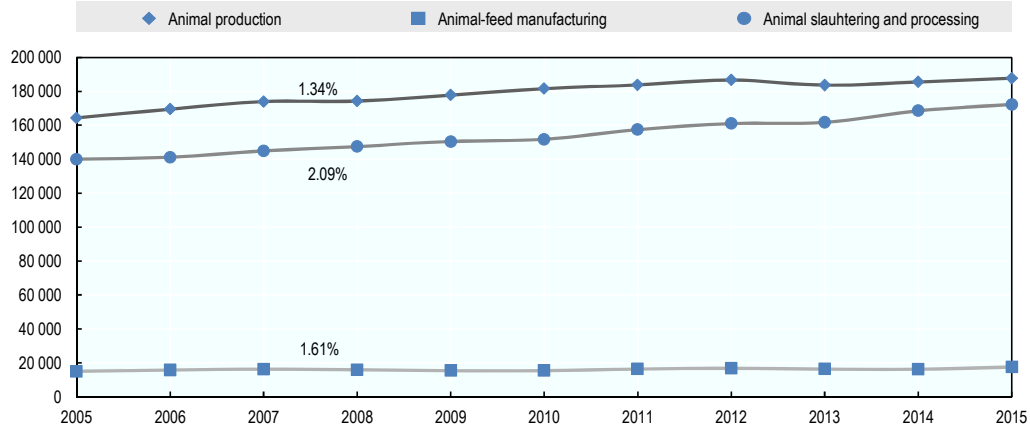
Source for Figures 3.3, 3.4 and 3.5: COMECARNE (2016), *Compendio estadístico 2015 de la industria cárnica mexicana*, http://infocarne.comecarne.org/compendio/visualizar?comp=8.

3.1.2. Gross value added of meat subsectors

This section contains rough estimates for the gross value added of animal-feed manufacturing, animal production, and animal slaughtering and processing between 2005 and 2015.[14] As Figure 3.6 illustrates, these three sub-sectors have exhibited growth over that period, albeit in different magnitudes.

In terms of value, animal production and animal slaughtering and processing have been more significant than animal-feed manufacturing. Furthermore, the three sub-sectors displayed low average annual growth rates: 1.34% for animal production; 2.09% for animal slaughtering and processing; and 1.61% for animal-feed manufacturing.

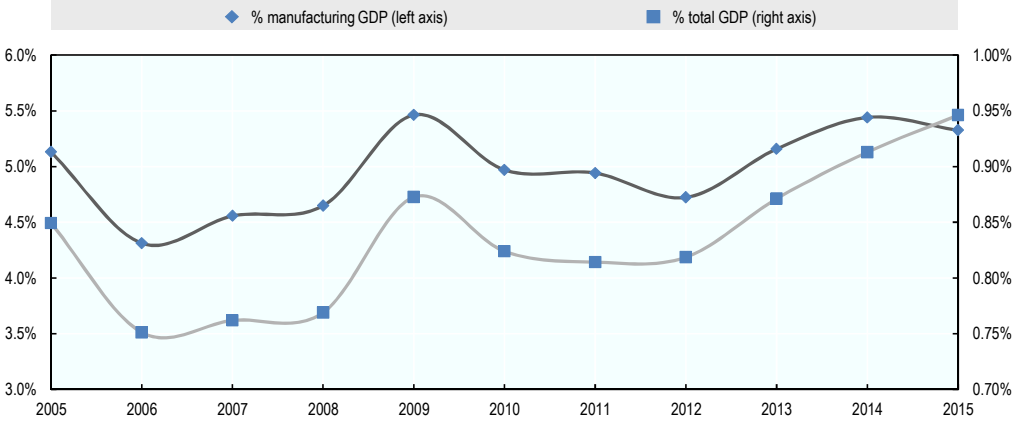
Figure 3.6. **Gross value added (constant 2015 MXN, millions), 2005-2015**



Source: INEGI, Banco de Información Económica; the following SCIAN codes were used: 1121, 1122, 1123, 3111 and 3116; www.inegi.org.mx/sistemas/bie/.

Between 2005 and 2015, animal slaughtering and processing, represented, on average, 4.97% of manufacturing GDP and 0.84% of total GDP. Its share of total GDP has steadily increased since 2011 with 0.95% of total GDP in 2015.

Figure 3.7. **Animal slaughtering and processing, gross value added as a percentage of manufacturing and total GDP, 2005-2015**



Source: INEGI, Banco de Información Económica, www.inegi.org.mx/sistemas/bie/.

3.1.3. Market structure and main indicators

3.1.3.1. Main indicators

The three key indicators of the meat industry's vertical-value chain – turnover, number of employees, and number of establishments – increased between 2003 and 2013.

The following three Figures characterise, in terms of these three indicators, the sub-sectors of animal-feed manufacturing; animal slaughtering and processing; and meat wholesaling and meat retailing. If these sub-sectors are aggregated, it is possible to see growth in turnover, number of employees and number of establishments between 2003 and 2013.

Figure 3.8. **Turnover, (constant 2015 MXN, millions)**

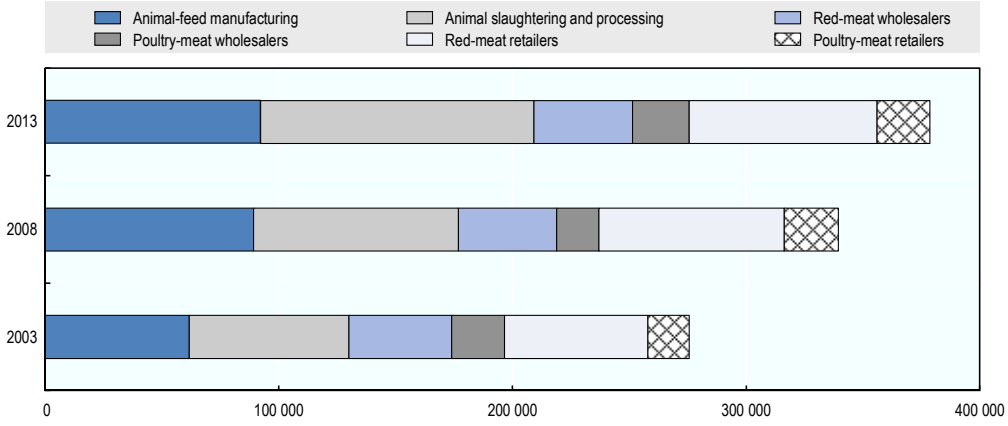
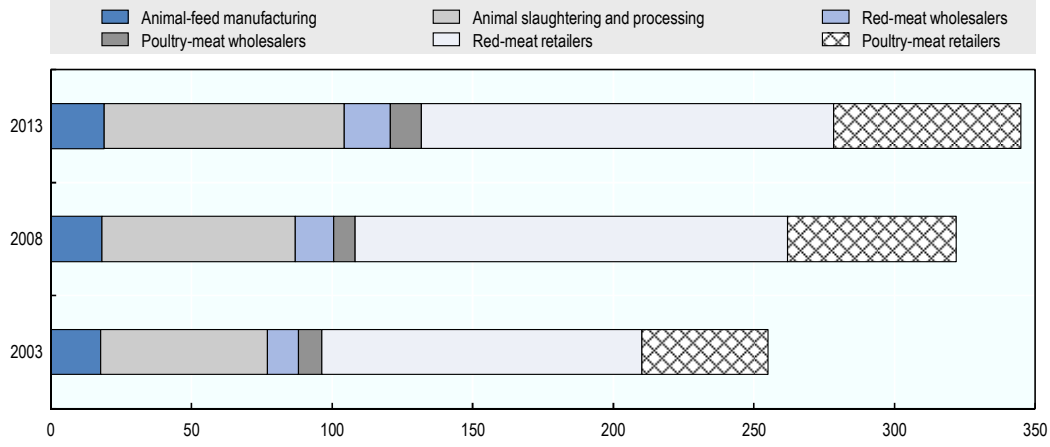


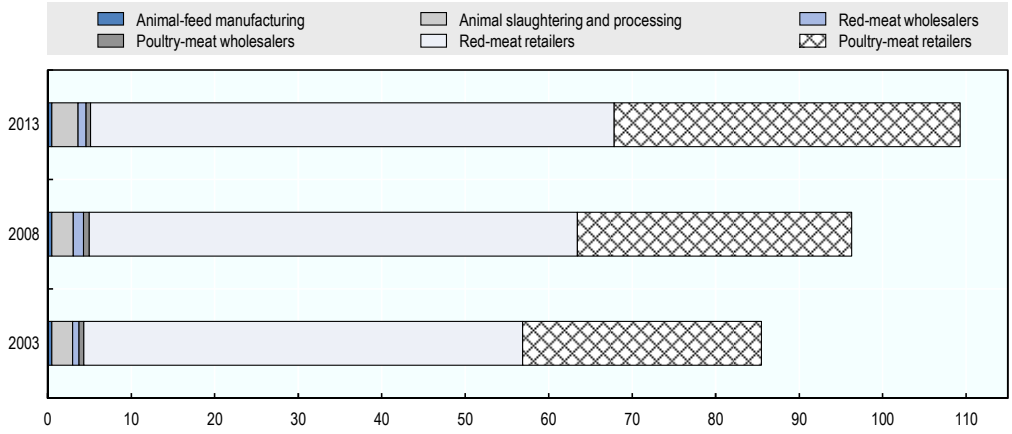
Figure 3.9. **Number of employees, in thousands**



Source for Figures 3.8 and 3.9: INEGI, 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal. www.beta.inegi.org.mx/app/saic/default.aspx

In 2013, the sub-sector with the highest turnover was slaughtering and processing, followed by animal-feed processing and red-meat retailing. In terms of employees, the main activities were red-meat and poultry retailing, followed by slaughtering and processing. Finally, most of establishments operated in the red-meat- and poultry-retailing sub-sector. In 2013, there were more than 104 000 such establishments.

Figure 3.10. **Number of establishments, in thousands***



* According to INEGI, an establishment participates in a defined commercial activity, confined to fixed locations or buildings, and combining actions and resources under the control of a holding, to produce goods and services, whether it be for commercial purposes or not.

Source: INEGI. 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

3.1.3.2. Concentration levels at different stages of the meat value chain[15]

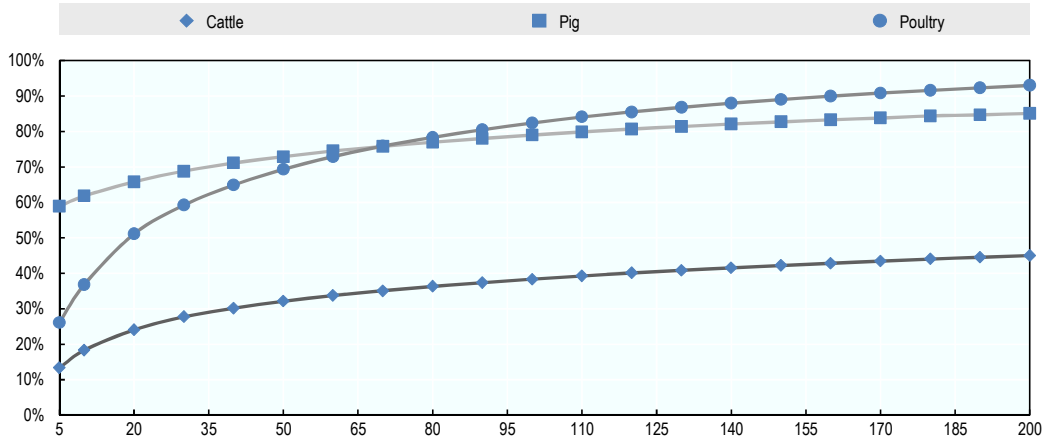
The following section shows concentration levels along the various stages of the meat value chain, with the caveat that recent data are not readily available.[16]

Animal-feed manufacturing. According to COFECE, as of 2008, the four biggest producers of animal feed accounted for 31.4% of accumulated market share, while the six and eight biggest producers accounted for 38% and 44% respectively. Furthermore, animal feed in Mexico scores 424 on the Herfindahl-Hirschman Index (HHI),[17] indicating a low to moderate degree of market concentration.

Production. Overall, available data suggests that chicken-meat market has undergone changes in the recent past, while the markets of beef and pork meat have remained relatively stable.

As can be seen in Figure 3.11, in 2007, concentration in the markets of beef and poultry live-weight meat production[18] was relatively low, while concentration in the market of pork live-weight meat production was moderate. In 2007, the top five producers of beef and poultry live-weight meat accounted for 13.3% and 26.1% of total market sales respectively, while the top five producers for pork live-weight meat accounted for 58.9%.

Figure 3.11.**Top producers of live-weight meat and cumulative shares of sales volumes, 2007**



Source: COFECE (2015), *Reporte sobre las condiciones de competencia en el sector agroalimentario*

In a 2011 report *Mexico: Market Concentration in Selected Agricultural and Food Subsectors*,[19] the USDA published volume shares of top producers for the three types of meat; as of 2010, the top three chicken-meat producers accounted for 64% of total volume, while the respective top three producers of beef and pork only accounted for 27% and 25% of total volume, respectively.[20]

Table 3.1. **Beef producer company shares, by feedlot processing capacity, 2010**

Company	Market share
Grupo Viz	16%
Grupo Gusi	6%
Praderas Huasteca	5%
Others	73%
Total	100%

Source: USDA (2011), *Mexico*: *Market Concentration in Selected Agricultural and Food Subsectors*

Table 3.2. **Chicken-meat producer company shares, by volume, 2010**

Company	Market share
Industrias Bachoco	38%
Pilgrim's Pride	14%
Tyson de México	12%
Others	36%
Total	100%

Source: USDA (2011), *Mexico: Market Concentration in Selected Agricultural and Food Subsectors*

Table 3.3. **Pork producer company shares, by volume, 2010***

Company	Market share
Kekén (Grupo Porcícola Mexicano)	10%
Grupo Kowi	8%
Norson	7%
Sonora Agropecuaria	6%
Grupo Bafar	5%
Others	64%
Total	100%

* This data differs from Figure 3.11. According to COFECE, in 2007, in the market of pork production, the top five producers accounted for 58.9% of sales, but data from the USDA suggests that three years later, the top five producers only accounted for 36%. These differences could stem from different methodologies or changes in market structures.

Source: USDA (2011), *Mexico*: *Market Concentration in Selected Agricultural and Food Subsectors*

Since 2010, the structure of the chicken-meat production market has changed, and in 2015, Pilgrim's Pride acquired Tyson de México.[21] COFECE approved the transaction[22] since it found that in all the various markets in which the two parties were both active, there existed a competitive fringe of small producers that accounted for at least 37% of the market – the remaining 63% being composed of the merging parties and Bachoco.[23]

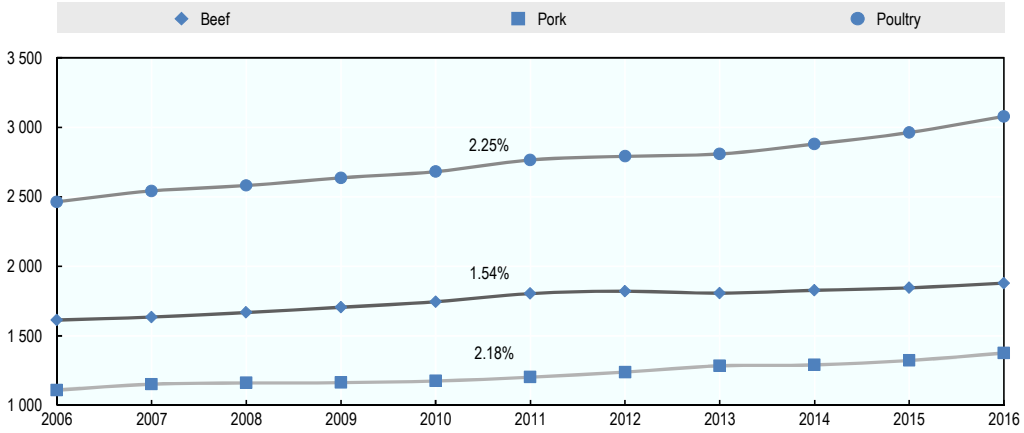
Using data from the March 2017 edition of the magazine *Industria Avícola*, as well as data from SAGARPA's Agrifood and Fisheries Information Service (Servicio de Información Agroalimentaria y Pesquera, SIAP), the OECD team estimated that in 2016 Industrias Bachoco and Pilgrim's Pride accounted, respectively, for 35.48% and 28.03% of all chicken raised in Mexico.[24]

Slaughtering. The 2011 USDA report also states that, in 2010, seven companies accounted for 75% of all beef from cattle slaughtered in TIF abattoirs: SuKarne (part of Grupo Viz), Grupo Agro Industrial Arias, Frigorífica Contreras, ProCarnes (Don Fileto), Carnes ViBa, Carnes El Alba, Consorcio Dipcen and Frigorífico Tabasco. This high concentration of TIF-abattoir ownership was partially due to the high cost of compliance with TIF hygiene standards.[25] In contrast, ownership of non-TIF establishments was highly fragmented.

3.1.4. Production

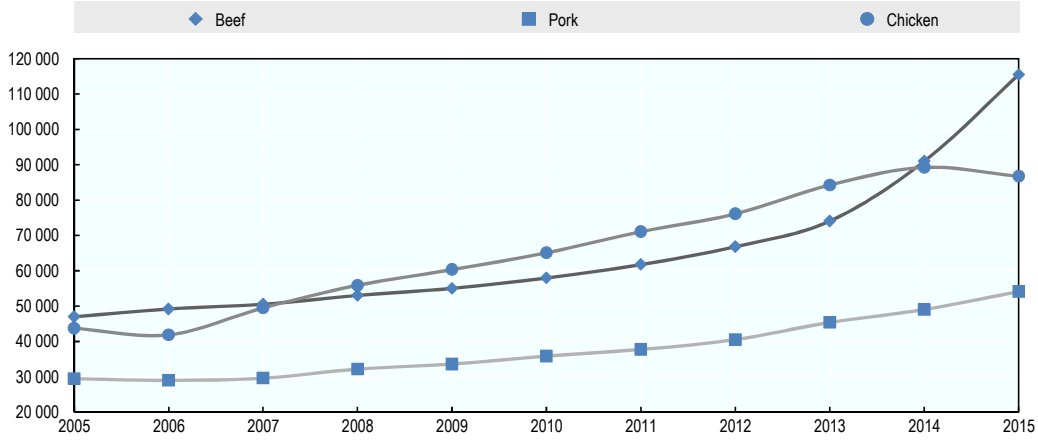
Between 2006 and 2016, production of all types of meat exhibited moderate growth: the production of beef, pork and poultry carcasses grew at average annual growth rates of 1.54%, 2.18% and 2.25%, respectively. In 2016, out of the total production volume of these three types of meat, 48.6% was chicken, while 29.7% was beef and 21.7% pork. For each year between 2006 and 2016, the volume of chicken production was higher than that of pork or beef.

Figure 3.12. **Production of meat carcasses (thousands of tonnes)**



Source: Agrifood and Fisheries Information Service (Servicio de Información Agroalimentaria y Pesquera, SIAP), Annual livestock production: national review, http://infosiap.siap.gob.mx/anpecuario_siapx_gobmx/ResumenNacional.do

Figure 3.13. **Value of the production of meat carcasses (current MXN, millions)***



* The value of livestock production depends on the number of animals slaughtered and the prices received by producers.

Source: SIAP, Annual livestock production: national review, http://infosiap.siap.gob.mx/anpecuario_siapx_gobmx/ResumenNacional.do

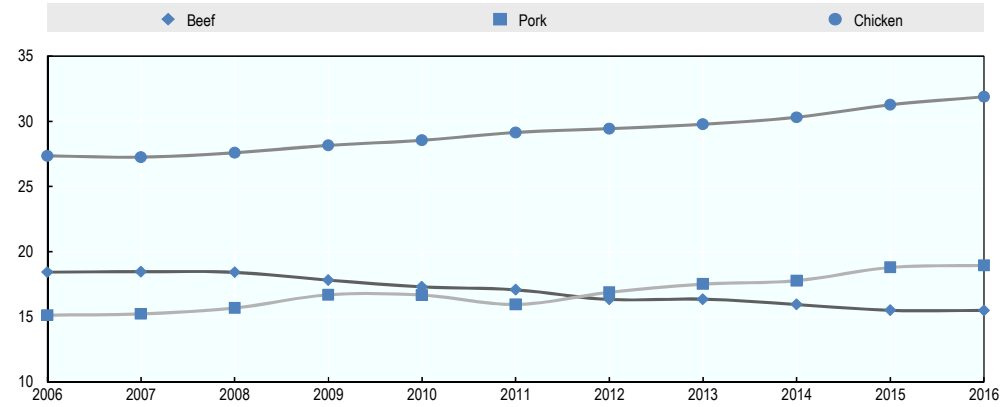
From 2008 until 2013, the value of chicken-meat production was higher than that of beef production. However, in 2014 and 2015, the value of beef production was higher than that of chicken meat. This was due to many factors, including an increase in beef prices.

3.1.5. Consumption patterns and price indexes

Consumption of the three varieties of meat in Mexico exhibits different trends. Between 2006 and 2016, per capita consumption of beef decreased at an average annual rate of -1.72%, while chicken and pork consumption increased at average annual rates of 1.54% and 2.28%, respectively. As can be seen in Figure 3.14, between 2006 and 2011,

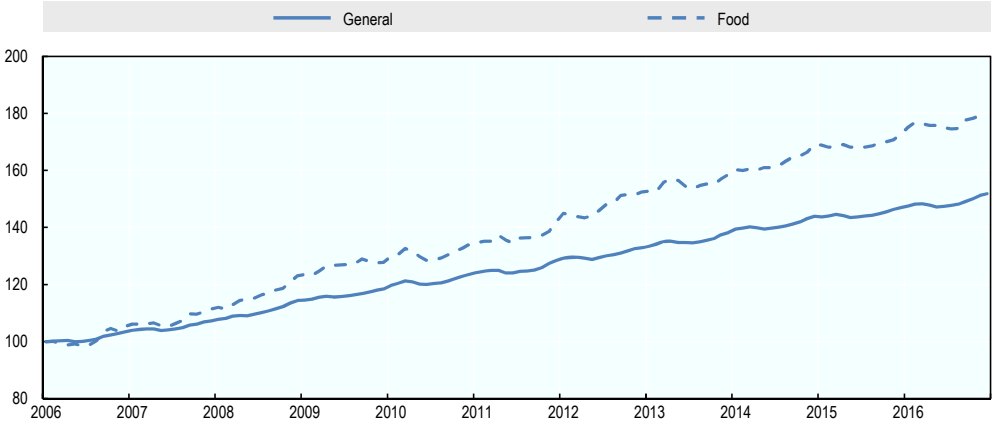
per capita consumption of beef was higher than that of pork. However, since 2012, this trend has been reversed. In period 2013-2016, pork consumption per capita increased, while beef consumption per capita decreased.

Figure 3.14. **Annual per capita meat consumption (kilograms)**



Source: SIAP and Tariff Information System (Sistema de Información Arancelaria vía Internet, SIAVI)

Figure 3.15. **Consumer price indexes: general and food**

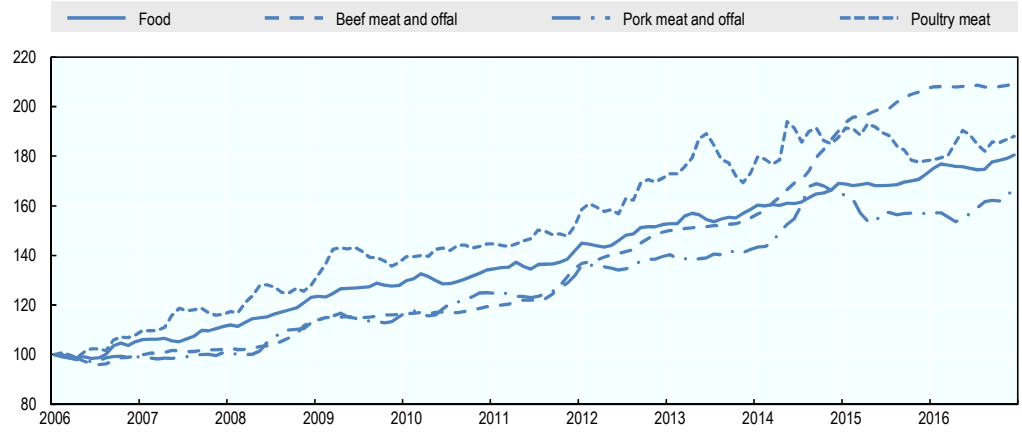


Source: INEGI, Índice de Precios al Consumidor, www.inegi.org.mx/sistemas/indiceprecios/Estructura.aspx?idEstructura=112000200070&T=%C3%8Dndices%20de%20Precios%20al%20Consumidor&ST=INPC%20Nacional

Figure 3.15 shows the evolution of general and food consumer-price indexes between January 2006 and December 2016. Both price indexes were normalised to 100 for January 2006. From September 2006 onwards, the food-price index was higher than the general-price index. In the aforementioned period, the general index and the food index showed average annual inflation rates of 4.3% and 6.1%, respectively.

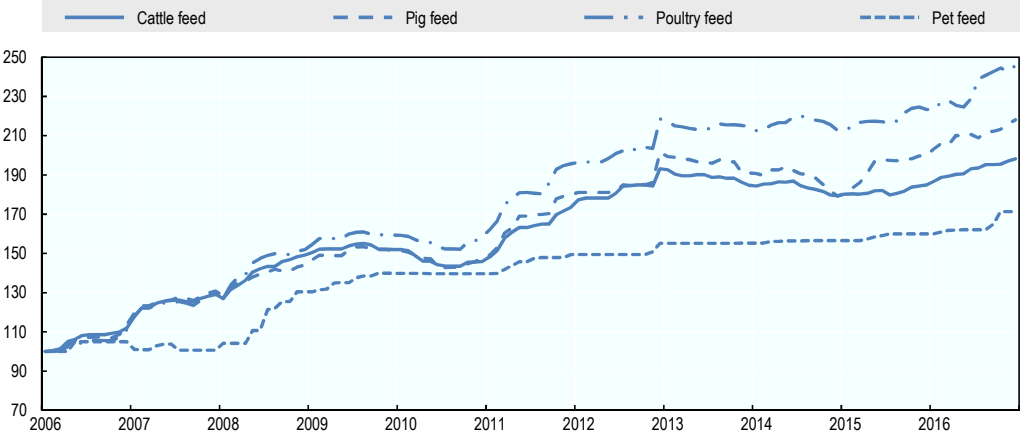
Figure 3.16 depicts the evolution of consumer prices indexes of beef meat and offal, pork meat and offal, and poultry meat, taking as a benchmark the food-price index. For the period in question, the beef, pork and poultry price indexes registered average annual inflation rates of 7.7%, 5.3% and 6.5%, respectively. Only the pork meat and offal price index exhibited lower overall inflation than the general food-price index.

Figure 3.16. **Consumer price indexes: food and varieties of meat**



Source: INEGI, Índice de Precios al Consumidor

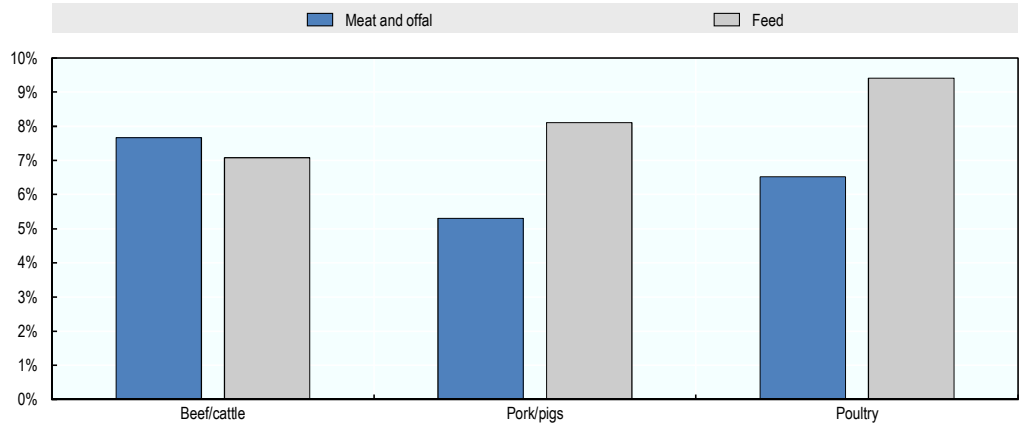
Figure 3.17. **Producer price indexes: types of animal feed**



Source: INEGI, www.inegi.org.mx/sistemas/indiceprecios/Estructura.aspx?idEstructura=112000800010&T=%C3%8Dndices%20de%20Precios%20al%20Productor&ST=Producci%C3%B3n%20total%2C%20seg%C3%BAn%20actividad%20econ%C3%B3mica%20de%20origen%20SCIAN%202007

Similarly, Figure 3.17 shows producer-price indexes of four types of animal feed for between 2006 and 2016. During that time, feed for cattle, pigs, poultry and pets registered average annual inflation rates of 7.1%, 8.1%, 9.4% and 5.5%, respectively. Finally, Figure 3.18 compares average annual inflation rates of animal feed and meat and offal, for three categories of animals. Cattle feed registered the lowest average inflation rate among the three kinds of animal feed, but, as noted above, beef meat and offal had the highest average inflation rate among the three kinds of meat.

Figure 3.18. **Average annual inflation rate (between 2006 and 2016): animal feed and meat and offal***

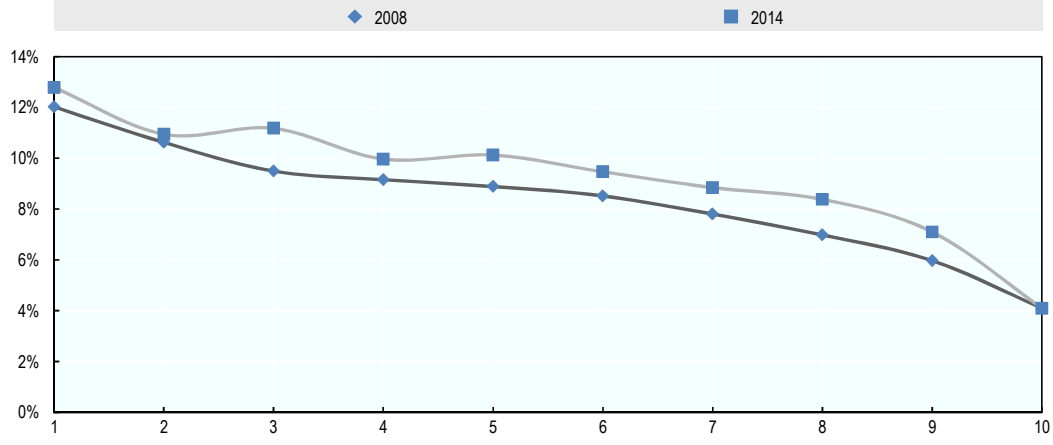


* Only meat, and not meat and offal, in the case of poultry.

Source: INEGI, Índice de Precios al Consumidor and Índice de Precios al Productor

The share of household expenses assigned to meat purchases increased between 2008 and 2014. According to the 2008 and 2014 editions of INEGI's *National Survey of Mexican Household Income and Expenditures* (Encuesta Nacional de Ingresos y Gastos de Hogares, ENIGH), in 2008, 7.1% of the average Mexican household's expenses were on meat, while in 2014, that spend was 7.8%. The share of spending assigned to meat decreases as households' income level increases. In 2014, the first income decile assigned 12.8% of its expenses to meat, while the fifth and tenth percentile assigned only 10.1% and 4.1% respectively. This shows that meat price increases have a stronger impact on low-income households. In 2014, with the exception of households belonging to the tenth income decile, on average households assigned a higher share of their expenses to meat than in 2008.

Figure 3.19. **Percentage of household expenditures on meat per household-income decile**

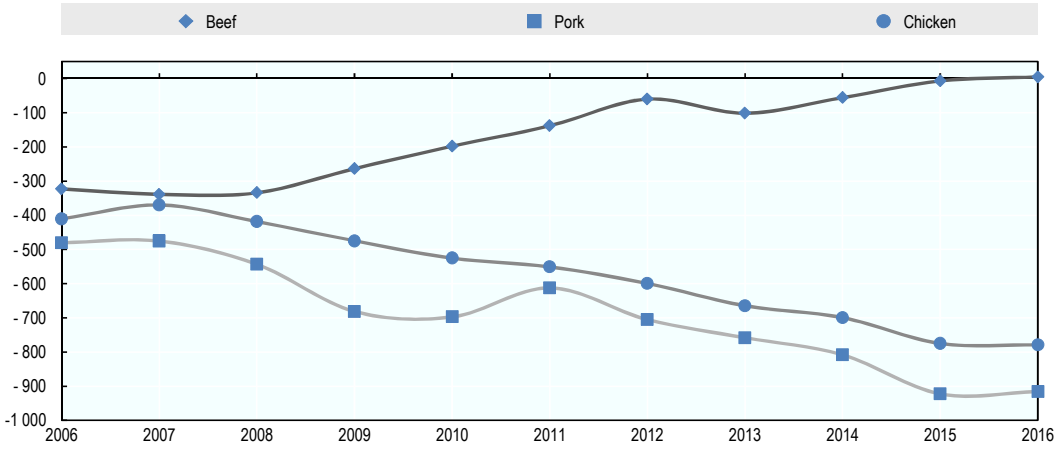


Source: INEGI, ENIGH of 2008 and 2004;
www.beta.inegi.org.mx/proyectos/enchogares/regulares/enigh/nc/2012/ and
www.beta.inegi.org.mx/proyectos/enchogares/regulares/enigh/nc/2014/default.html

3.1.6. International trade

Between 2006 and 2016, Mexico was consistently a net importer of chicken and pork meat. It was also a net importer of beef meat until 2015, but became a net exporter in 2016. Trade balance has exhibited different trends for each type of meat.[26] In the case of pork and chicken meat, domestic consumption has increasingly relied on imports. During the aforementioned 11-year period, volumes of imported pork and chicken meat increased by 92.9% and 90.4%, respectively. In contrast, the volume of imported beef decreased by 46.4%. Figure 3.20 depicts the evolution of the trade balance in volume, for the three meat varieties.

Figure 3.20. **Trade balance (thousands of tonnes)**



Source: SIAVI, www.economia-snci.gob.mx

Importing meat, and any other "regulated product",[27] to Mexico requires a double control: the origin country and the origin establishment must both be authorised by SENASICA. A country is authorised if SENASICA considers its veterinary services to be at least equivalent to Mexico's. All imported "regulated products" require a Zoosanitary Import Certificate (Certificado Zoosanitario para Importación, CZI), which implies complying with the Zoosanitary Requirements Form for Imports (Hoja de Requisitos Zoosanitarios para la Importación); this can be adapted to the specific zoosanitary conditions of the exporting country. Furthermore, SENASICA has the power to impose custody-and-control quarantines for "regulated products" before their introduction to the Mexican territory.

Exports of meat and other "regulated products" are subject to physical inspections prior to export certification from SENASICA. These controls are designed to satisfy the regulatory requirements of the importing country and, if satisfied, end with the issuance of a SENASICA Zoosanitary Export Certificate (Certificado Zoosanitario de Exportación, CZE).[28]

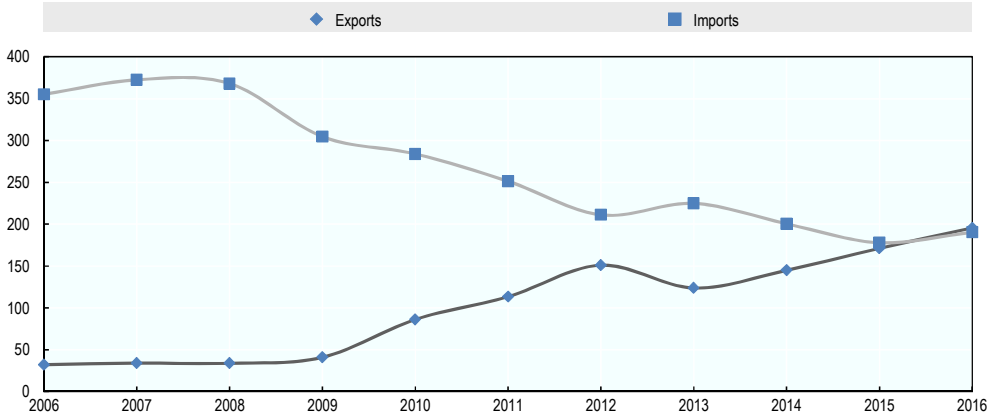
The large majority of Mexico's imports for the three types of meat come from the United States. In 2016, 84.6% of the total volume of beef imports was from the United States, while for pork and chicken meat, it was 81.7% and 90.5% respectively.[29]

Between 2006 and 2016, the volume of chicken and pork exports accounted for just 0.8% and 9.9% of their respective import volumes. In this period, the export of both was

possibly hindered by periodic animal-disease epidemics.[30] During the same period, beef exports accounted for 38.3% of import volumes.

While Mexico is almost self-sufficient in terms of beef consumption, it increasingly relies on imports to meet apparent domestic consumption needs for chicken and pork. Between 2006 and 2016, the share of domestic beef consumption served by national production (i.e. total national production minus exports) increased from 81.7% to 89.8%. Chicken meat's share decreased from 85.7% to 79.7%, while pork's share dropped from 66.5% to 55.2%.

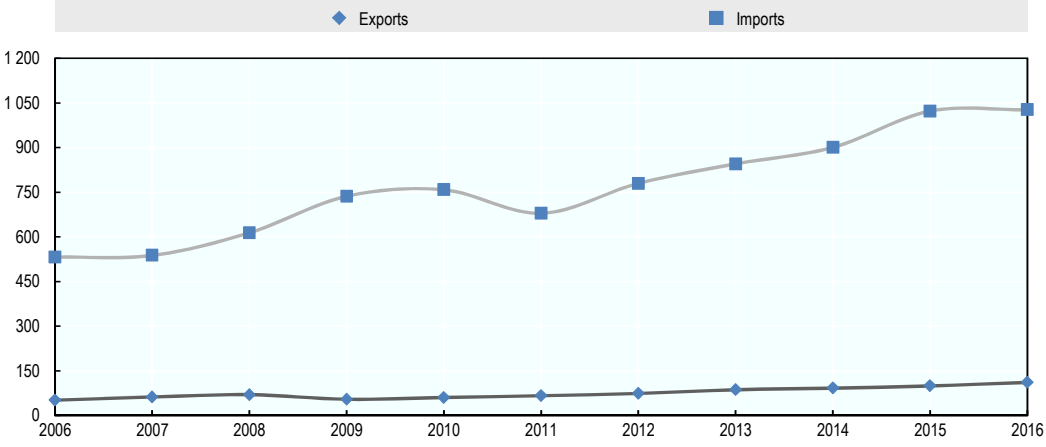
Figure 3.21. **Beef exports and imports (thousands of tonnes)***



* The following tariff codes from the SE's Tariff Information System (Sistema de Información Arancelaria vía Internet, SIAVI) were used for the beef series: 02.01.10.01, 02.01.20.99, 02.01.30.01, 02.02.10.01, 02.02.20.99, 02.02.30.01, 02.06.10.01, 02.06.21.01, 02.06.22.01, 02.06.29.99, 02.10.20.01, 16.02.50.01, and 16.02.50.99.

Source: SIAVI, www.economia-snci.gob.mx.

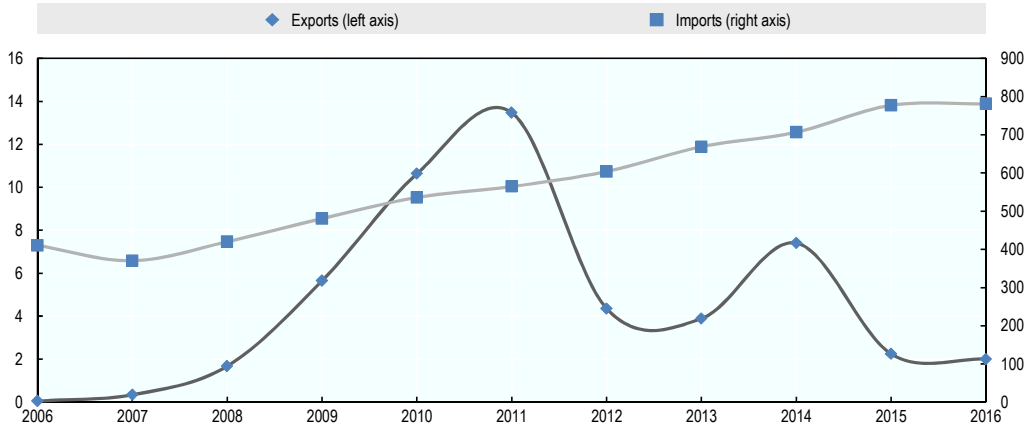
Figure 3.22. **Pork exports and imports (thousands of tonnes)***



* The following tariff codes from the SE's Tariff Information System (Sistema de Información Arancelaria vía Internet, SIAVI) were used to construct the pork series: 02.03.11.01, 02.03.12.01, 02.03.19.99, 02.03.21.01, 02.03.22.01, 02.03.29.99, 02.06.30.01, 02.06.30.99, 02.06.41.01, 02.06.49.01, 02.06.49.99, 02.09.00.99, 02.10.11.01, 02.10.12.01, 02.10.19.99, 16.02.41.01, 16.02.42.01, and 16.02.49.01.

Source: SIAVI.

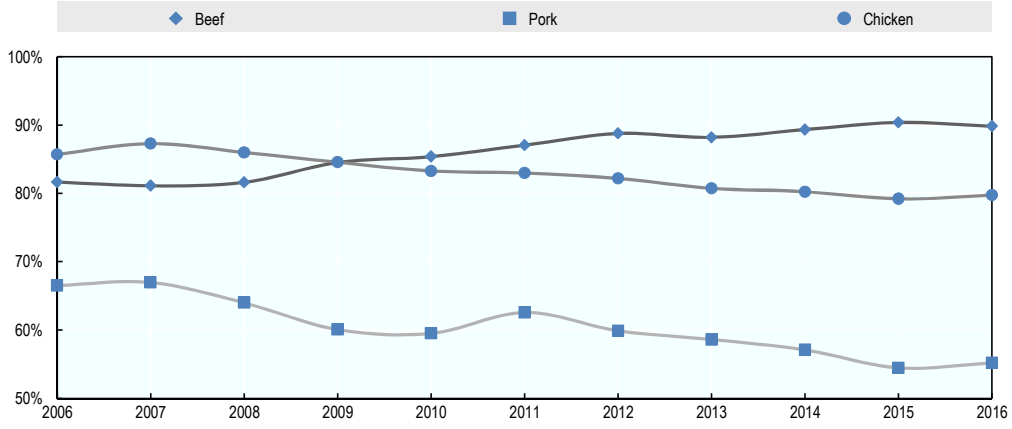
Figure 3.23. **Chicken-meat exports and imports (thousands of tonnes)***



* The following tariff codes from the SE's Tariff Information System (Sistema de Información Arancelaria vía Internet, SIAVI) were used to construct the chicken-meat series: 02.07.11.01, 02.07.12.01, 02.07.13.01, 02.07.13.02, 02.07.13.03, 02.07.13.99, 02.07.14.01, 02.07.14.02, 02.07.14.03, 02.07.14.04, 02.07.14.99, and 02.10.99.03.

Source: SIAVI

Figure 3.24. **Share of apparent domestic consumption served by national production**



Source: SIAP and SIAVI

Imports of beef, chicken and pork coming from the United States are tariff-free, under the North American Free Trade Agreement (NAFTA). Imports of meat and meat products coming from countries with which Mexico has not signed an international trade agreement are ruled by the Law of the General Taxes of Import and Export (Ley de Impuestos Generales de Importación y de Exportación).[31]

Mexican foreign-trade stakeholders are subjected to a large number of procedures (e.g. authorisations, approvals, tax payments) with Mexican government agencies. To facilitate trade and reduce transaction costs, the federal government created the Mexican Foreign Trade Single Window (Ventanilla Única de Comercio Exterior Mexicana, VUCEM), an Internet platform designed to process import, export and transit transactions electronically. The use of VUCEM is mandatory for all imports and exports.[32] Request

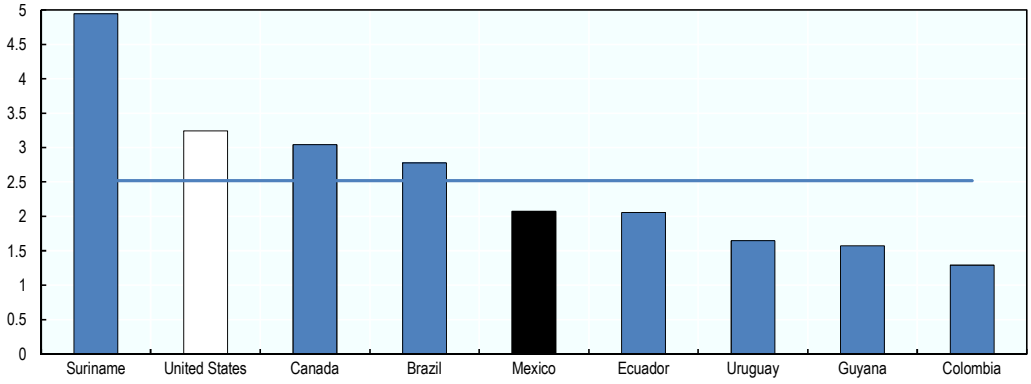
for import permits of livestock goods subject to SAGARPA controls must be made through VUCEM. Before applying, an importer must access the zoosanitary requirements contained in the requirements module on the SENASICA website.

3.1.7. International price comparisons

The following three figures compare average live-weight meat producer prices in Mexico and other American countries in 2015. Dotted lines represent the average producer prices for the set of selected countries.

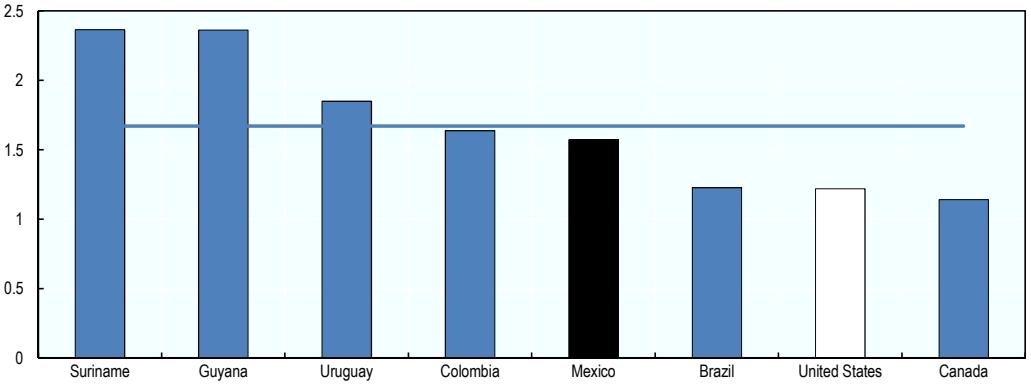
For each variety of meat, Mexican producer prices were lower than the selected countries' averages, lying at the middle or at the low end of the distribution. However, in the case of pork and chicken, prices were higher than those in the United States by 28.97% and 10.80%, respectively. This is consistent with the fact that a large share of imports of these two varieties of meat came from the United States.

Figure 3.25. **Producer price (USD/kg), live-weight beef across American countries, 2015**



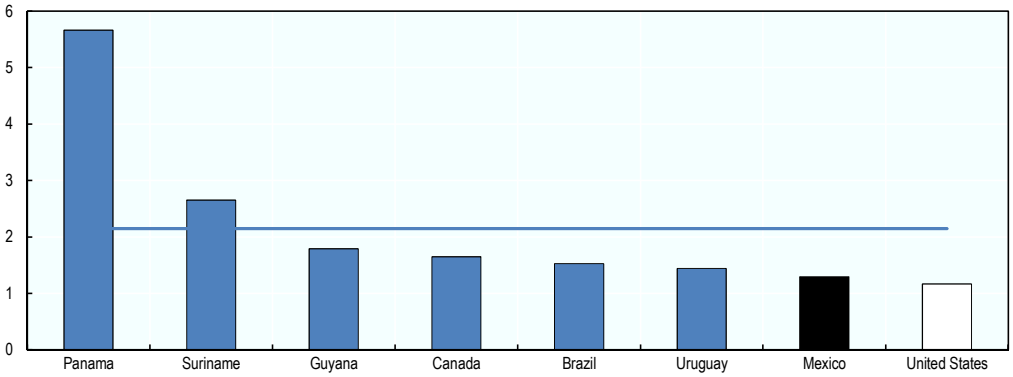
Source: Food and Agriculture Organization of the United Nations (FAO), Producer Prices – Annual, www.fao.org/faostat/en/#data/PP.

Figure 3.26. **Producer price (USD/kg), live-weight pork across American countries, 2015**



Source: FAO, Producer Prices – Annual.

Figure 3.27. **Producer price (USD/kg), live-weight chicken meat across American countries, 2015**



Source: FAO, Producer Prices – Annual

3.1.8. Relevant authorities and trade associations

3.1.8.1. Governmental authorities

A number of governmental authorities regulate and control the meat industry's activities:

- **Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA).** SAGARPA is the federal government ministry in charge of the agricultural sector. Two bodies within SAGARPA are of particular importance to the meat industry:

- **National Service for Agro-Alimentary Public Health (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, SENASICA).** SENASICA is a body of SAGARPA whose tasks include the oversight of animal health and welfare, imports and exports of animals and animal products, animal-disease surveillance, and the control of products used in or consumed by animals. SENASICA regulates TIF establishments for the slaughtering of livestock, and the cutting, deboning, processing, stocking, and freezing of meat.[33] In Mexico, TIF establishments require the presence of an official veterinary surgeon (*médico veterinario oficial*, MVO) from SENASICA, and an authorised responsible veterinary surgeon (*médico veterinario responsable autorizado*, MVRA), who is a staff member at the TIF establishment.

- **Agrifood and Fisheries Information Service (Servicio de Información Agroalimentaria y Pesquera, SIAP).** SIAP is a body within SAGARPA producing statistics on the agricultural and livestock sectors. In particular, SIAP manages the National Information System for Sustainable Rural Development (Sistema Nacional de Información para el Desarrollo Rural Sustentable, SNIDRUS), an information system whose objective is to disseminate data on agricultural and livestock markets (e.g. offer, demand, stocks, forecasts, prices) at regional, national and international levels.

- **Ministry of Health (Secretaría de Salud, SSA).** The Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) is a body within SSA and establishes sanitary

specifications for municipal[34] and TIF abattoirs, as well as meat retailers.[35] However, as stated above, TIF abattoirs also have to comply with SENASICA's specifications.

- **Ministry of Economy (Secretaría de Economía, SE).** The following branches of SE are relevant to the meat industry:
  - **Tariff Information System (Sistema de Información Arancelaria vía Internet, SIAVI).** The SE establishes and administers the system of tariffs. SIAVI is an Internet-based platform operated by SE, contains trade information for all tariff codes.
  - **National System of Markets Information and Integration (Sistema Nacional de Información e Integración de Mercados, SNIIM).** SNIIM is an Internet-based platform operated by SE that monitors wholesale prices of several agricultural products commercialised in Mexico. For instance, prices are available for live-weight meat, carcasses, viscera and offal at various establishments, including abattoirs and processing plants.[36]
  - **Under-Secretariat for Competitiveness and Business Regulation (Subsecretaría de Competitividad y Normatividad).** This under-secretariat, through the General Directorate of Standards (Dirección General de Normas, DGN), is responsible for the operation of the catalogue of Mexican Official Standards.
- **Federal Attorney's Office of Consumer (Procuraduría Federal del Consumidor, PROFECO).** PROFECO, a body of SE, is in charge of consumer-protection policy. It operates a programme that publishes municipal prices for over 2 000 items, including several types of meat.[37] PROFECO also resolves complaints related to the contracting of services and buying products. It produces and publishes reports on the quality and features of products and services in order to guide and protect consumers. While PROFECO mentions specific brands in these reports, companies cannot quote these opinions.
- **Ministry of Agrarian, Territorial and Urban Development (Secretaría de Desarrollo Agrario, Territorial y Urbano, SEDATU).** SEDATU was created in 2013 to replace the Ministry of the Agrarian Reform (Secretaría de la Reforma Agraria, SRA). The National Agrarian Registry (Registro Agrario Nacional), a body within SEDATU, is in charge of administering the registry of social-property lands and the granting of certificates for *ejidos* privatisation.
- **Inter-Ministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable, CIDRS).** CIDRS is a cross-sector horizontal commission for the promotion of rural development within the Mexican federal government. CIDRS is made up of the ministers of ministries involved to a greater or lesser extent in rural development (e.g. SAGARPA, SE, SEMARNAT, SHCP, Ministry of Communications and Transportation (Secretaría de Comunicaciones y Transporte, SCT), SSA, Ministry of Social Development (Secretaría de Desarrollo Social, SEDESOL), SEDATU, SEP and SENER), and by any other ministries or entities that the executive power might consider necessary. CIDRS is overseen by SAGARPA and responsible for developing national plans that set goals and actions for those federal agencies related to the rural sector.[38] Furthermore, according to Article 149, Letter II of the

Law on Rural Sustainable Development (Ley de Desarrollo Rural Sustentable), among CIDRS's responsibilities is the promotion of Product Systems, committees of the Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable, CMDRS). These committees have among their objectives to "determine the strategic expansion and contraction plans for the output and quality of each product".

3.1.8.2. Trade associations

The following associations participate in the development of their respective meat industries:

- ***Mexican Meat Council (Consejo Mexicano de la Carne, COMECARNE).*** Founded in 1985, COMECARNE is a trade association of meat-processing companies. Its members include both large (i.e. Sigma, Grupo Bafar and Grupo Viz) and small companies. COMECARNE's members all operate abattoirs or packing houses, which include activities such as meat processing, cut and deboning.
- ***Mexican Confederation of Pig Producers (Confederación de Porcicultores Mexicanos, Porcimex).*** Porcimex is an umbrella organisation of pork-producer associations, as well as individual pork producers. Founded in 2002, Porcimex has 43 members based in 18 Mexican states, as well as 10 associate members, which are mainly veterinary-drug companies (e.g. Zoetis, Pfizer and Boehringer Ingelheim). Porcimex is a member of various national and international trade associations, such as the National Agricultural Council (Consejo Nacional Agropecuario, CNA), National Business Council (Consejo Coordinador Empresarial, CCE) and Iberoamerican Pig Producers Association (Organización Iberoamericana de Porcicultores).
- ***National Poultry Association (Unión Nacional de Avicultores, UNA).*** UNA resembles local poultry and egg producers from 14 Mexican states. Founded in 1958, it works closely with local and federal governmental authorities (e.g. SAGARPA) in campaigns against poultry diseases. It also collects industry statistics (e.g. censuses of poultry producers and information about granting funds).
- ***Mexican Cattle Feeders Association (Asociación Mexicana de Engordadores de Ganado Bovino, AMEG).*** AMEG is an association of beef producers created in 1994. It promotes exports of TIF-slaughtered beef to trading partners such as Japan, Korea, Russia, Chinese Taipei, Singapore, and the USA, and participates in the design and reform of laws and development programmes along the beef value chain. AMEG also provides support to beef producers in obtaining agricultural credits from Trust Funds for Rural Development (Fideicomisos Instituidos en Relación a la Agricultura, FIRA). Finally, AMEG elaborates sectoral reports and statistics.
- ***National Association of TIF Establishments (Asociación Nacional de Establecimientos Tipo Inspección Federal, ANETIF).*** ANETIF is a trade association for meat-processing companies that own TIF-accredited establishments for the three types of meat. ANETIF lobbies for issues related to regulations, and the development of legislation and standards. ANETIF says that it has institutional relations with more than 40 public and private institutions. It

also provides various services to its members, such as processing and extending TIF certifications, tax consulting on meat importation and the fulfilment of export requirements, and animal-health training and assistance.

3.1.8.3. Livestock associations

- ***Animal Health Auxiliary Organisms (Organismos Auxiliares en Sanidad Animal, OASA).*** OASA are livestock-producer organisations that support SAGARPA in coordinating and implementing zoosanitary campaigns and programmes on good livestock practices. There are different OASA denominations depending on whether members are arable, livestock or aquaculture producers. For livestock producers, OASA are known as Promotion and Protection Livestock State Committees (Comités Estatales de Fomento y Protección Pecuaria, CEFPP). CEFPP operate under the supervision of SAGARPA's state branches, as well as of state governments. CEFPP are authorised to operate by SAGARPA, who can revoke their authorisation if it considers them no longer able to fulfil their objectives. Each of the Mexican states, except Mexico City, has a CEFPP.
- ***Livestock associations / organisations.*** The Law on Livestock Associations enables livestock producers to gather in associations, which can be general or specialised (i.e. only for a particular type of livestock) and operate at a municipal, regional or state level. Among livestock associations' objectives are promoting the adoption of common technologies and production methods; the use of Normas Oficiales Mexicanas (NOM, Mexican Official Standards) and Normas Mexicanas (NMX, Mexican Standards) related to livestock production and animal health; the creation of cooperatives; and to "guide production according to market conditions, be it intensifying it or withholding it".
- ***National Confederation of Livestock Unions (Confederación Nacional de Organizaciones Ganaderas, CNOG).*** CNOG was founded in 1936 and represents more than 800 000 farmers from Mexico, 2 000 local livestock associations, 44 regional livestock unions and 26 specialised associations.[39] Livestock associations for the three types of meat belong to CNOG.

3.2. Overview of the legislation

The regulatory framework applicable to the meat sector in Mexico is both extensive and fragmented. Regulation covers all the segments of the meat vertical chain (i.e. from the feeding and raising of livestock to meat retail), but also aspects related to the organisation of livestock production and the promotion of rural development. A large part of this legislation aims to prevent health risks associated with the production and commercialisation of meat and meat products.

Using the methodology outlined in its Competition Assessment Toolkit, the OECD has examined 121 pieces of legislation for this report. These documents include laws, regulations, agreements, statutes and decrees, as well as mandatory and voluntary Mexican standards.[40] Ultimately, 76 prima facie restrictions were identified and 57 recommendations are made.

All the legal documents scanned were at the federal level. In addition, Mexican states – within their scope of powers – also issue and apply regulations and controls in the meat

sector. For instance, Mexican states have their own livestock laws, which regulate, among other issues, the transportation, ownership and commercialisation of livestock. Furthermore, these state laws also aim to promote the economic development of their respective livestock sectors. The state laws dealing with meat were subject to an extensive report by the Mexican competition authority COFECE; published in September 2016, it is not part of this investigation.[41]

The following six federal laws mark the general frameworks in the meat sector: Law on Livestock Associations, Federal Law on Animal Health, General Health Law, Law on Rural Sustainable Development, Agrarian Law, and the General Law on Cooperative Societies. These laws are briefly described below.

The Law on Livestock Associations (Ley de Organizaciones Ganaderas)[42] sets the basis and procedures for the creation, organisation and operation of livestock associations. These associations aim to organise livestock production at municipal and regional levels, and promote the standardisation of products and productive processes.

The Federal Law on Animal Health (Ley Federal de Sanidad Animal)[43] is the legal framework for the regulation of animal health and food safety. This law grants the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA), acting through the National Service for Agro-Alimentary Public Health (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, SENASICA), the power to act as the competent authority concerning the oversight of animal health and welfare, livestock-production practices, imports and exports of live animals, their products and sub-products, as well as the conduction of risk analysis and the surveillance of animal diseases. Furthermore, SAGARPA also oversees Federal Inspection Type (Tipo Inspección Federal, TIF) abattoirs and meat-processing plants, and controls the products for use in or consumption by animals.

The General Health Law (Ley General de Salud)[44] assigns the Ministry of Health (Secretaría de Salud, SSA) the power to issue regulations related to human health. In particular, the SSA regulates municipal abattoirs and processing plants and, alongside SAGARPA, regulates TIF abattoirs and processing plants.[45] Furthermore, SSA may also randomly sample and inspect imported meat and meat products to ensure compliance with Mexican requirements.

The Law on Rural Sustainable Development (Ley de Desarrollo Rural Sustentable)[46] deals with various aspects of industrial policy for the rural sector, with an emphasis on sustainability and social development. The third paragraph of Article 1 of this law states that rural sustainable development is a matter of public interest, and that it encompasses the planning and organisation of livestock and agricultural production, its industrialisation and commercialisation, as well as those actions aimed at raising the living standards of the rural population.

The Agrarian Law (Ley Agraria)[47] regulates the extensions of lands for livestock production. Furthermore, this law sets the basis and procedures for the creation, organisation and operation of common property (i.e. *ejidos* and communities).

Finally, the General Law on Cooperative Societies (Ley General de Sociedades Cooperativas)[48] regulates the organisation and operation of cooperative societies. According to Article 21 of this law, there are three types of cooperative societies:

1. consumption

2. production

3. saving and lending.

The second type of cooperative in particular consists of members who work communally to produce goods and/or services, including in the meat sector, by providing their personal, physical or intellectual work. The General Law on Cooperative Societies defines the terms through which members can stock, preserve, transport and commercialise their products.

The main restrictions identified are presented in detail in the following sections and corresponding recommendations made. The benefits of implementing the main recommendations for the meat sector are estimated to range between MXN 51.6 million and MXN 348.1 million

3.3. Restrictions to competition in the meat sector

The following section describes a total of 57 recommendations for the Mexican meat sector.

Parts of other countries' meat sectors have been analysed in previous OECD competition assessment projects: the 2013 competition assessment in Greece (OECD, 2013),[49] as well as the 2016 competition assessment in Romania (OECD, 2016)[50] included chapters on food processing, and so the processing of meat. The 2017 competition assessment project in Greece (OECD, 2017)[51] covered the wholesale trade sector, and with it the subsector of agricultural, meat and fishery products

Unlike those projects, which only covered one stage of production, the following analysis for Mexico covers the entire vertical supply chain of the meat industry.

The chapter takes account of previously published reports by the Mexican competition authority COFECE dealing with the Mexican meat sector, especially a 2015 report on competition conditions in the agricultural and livestock sector (COFECE, 2015), which partly analysed federal law in the meat sector, and a 2016 report that aimed to identify anti-competitive provisions in state-level legislation for several sectors (COFECE, 2016), including the meat sector.

3.3.1. Movement of goods

The OECD team identified several regulations that limit the flow of meat products within the Mexican territory, thus artificially reducing the geographic area for competitors to provide these goods.

The main rationale for those provisions, especially regulating the transport of live animals, their products and sub-products within a country is to protect animal and human health and to ensure traceability of goods, i.e. to be able to track goods along the production chain.[52] Both objectives are complementary, since a functional system of traceability helps to address animal health and food-safety issues.[53] The OECD makes a total of five recommendations in the "movement of goods" category. These are:

1. abolishing certifications of livestock associations

2. abolishing support for producers so that they are geographically closer to consumers

3. introducing a national meat classification system

4. abolishing state transport documents

5. abolishing the requirement of these documents for abattoirs.

3.3.1.1. Certification from the local livestock association

Description of the obstacle. According to Article 13 of the Law on Livestock Associations, in order to transport livestock across the Mexican territory, it is necessary to obtain certification from the local livestock association that operates at the municipality of origin.[54] To obtain this authorisation, it is obligatory to provide the local livestock association with a proof of ownership of the animals to be transported. Ownership can be justified through several means, such as a certificate of the registry of a branding iron, a mark or a tattoo.

For cattle, there exists a federal identification system that uses ear tags: the National System of Individual Cattle Identification (Sistema Nacional de Identificación Individual de Ganado, SINIIGA).[55] This system aims to improve the sanitary control, ensure traceability and prevent cattle rustling (theft).

Harm to competition. Local livestock associations might have incentives to discriminate against competitors, particularly against those livestock producers from other geographic areas or those not belonging to an association. In addition, the procedure to appeal the decision of a livestock association that denies certification is not clear. While in theory a local livestock association should not be able to refuse the certification if proof of animal ownership is provided, the local livestock association might still find means (e.g. delaying the granting of the certification) to discriminate against non-member livestock producers.

Finally, regarding the transport of cattle across the Mexican territory, the certification from a local livestock association is an additional, double control, as cattle are already equipped with an ear tag under the SINIIGA system.

Policymaker's objective. The objective of the provision is to prevent cattle rustling. However, interviews with industry participants suggest that it is not clear that the certification granted by local livestock associations is an efficient means to prevent this problem.

Only cattle seem to need an association certification. Theft of chicken or pigs, though of course possible, does not seem to pose a significant problem in practice.

Recommendation. The OECD recommends abolishing Article 13, Letter B of the Law on Livestock Associations, as well as Article 104, Letter II of the Regulation of the Law on Livestock Associations. In the case of cattle, we consider that the SINIIGA system has already introduced sufficient safeguards against cattle rustling.

3.3.1.2. CIDRS support for producers so that they are geographically closer to consumers.

According to Article 111[56] of the Law on Rural Sustainable Development, the Inter-Ministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable, CIDRS),[57] with the participation of the Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable, CMDRS), and in accordance with international trade agreements signed by the Mexican federal government, decides on the agricultural products whose producers

are eligible to receive support. The restriction analysed consists of CIDRS having the power to support producers so that they are geographically closer to consumers. This provision aims to increase the income of producers whose products are difficult to commercialise.

If some producers get support so that their customers are geographically closer, while other producers do not receive this type of support, competition would be distorted. Furthermore, a consequence of this provision is that government institutions might be biased to buy only from geographically close producers, even though producers farther away could make more competitive offers. Thus, the OECD recommends modifying Article 111 of the Law on Rural Sustainable Development so that the CIDRS no longer has the power to promote geographical proximity between buyers and production zones. We consider that a more pro-competitive way to sustain the development of producers might be through the granting of direct subsidies instead.

3.3.1.3. Absence of NOMs related to the classification of beef, pork and chicken carcasses; discrimination against non-local meat producers

Description of the obstacle. Currently, there are no compulsory official standards related to the classification of beef, pork or chicken carcasses at the federal level.[58] However, there are NMX – compliance with which is voluntary – for this classification.[59] According to industry participants, these NMX are neither widely applied nor regularly updated. The absence of a compulsory meat-classification system has negative impacts on both the domestic and the export markets.

For the domestic market, the absence of a compulsory meat-classification system is aggravated by the existence of several state livestock laws that discriminate against non-local meat producers.[60] For the export market, exporters have to sell their meat at lower prices, since importing countries such as the United States only grant Mexican meat the lowest classification, independent of its actual quality.

Harm to competition. Where state level laws or standards prevent non-local meat producers from obtaining comparable classification to that of meat of comparable quality from local producers, non-local producers have to sell their meat in the state in question at lower prices. This hinders interstate trade and the movement of meat and meat products.

Policymaker's objective. It is unclear why there are no NOMs related to the classification of beef, pork or chicken carcasses.

The problem has been recognised and partially tackled in the National Standardisation Programme (Programa Nacional de Normalización, PNN) for 2017, published in the Federal Official Gazette on 3 February 2017, which states that SAGARPA's Specialised Subcommittee on Competitiveness is currently working on the preliminary draft of a NOM that aims to put in place a system of classification for beef.[61]

Recommendation. The OECD recommends introducing NOMs for the classification of beef, pork and chicken carcasses. Ideally, these NOMs should not only fit the needs of meat producers who export, but also those of producers serving the Mexican market. To facilitate meat exports, these NOMs should take account of existing international standards for the classification of carcasses (e.g. United Nations Economic Commission for Europe Standards for Meat or USDA Standards for Grades of Slaughter Cattle and Standards for Grades of Carcass Beef).

3.3.1.4. State transport documents

Description of the obstacle. Several state governments require a transport document in order to transport live animals, their products and sub-products within states.

Transport documents have different names, depending on the state. Several livestock laws[62] refer to them as *guías de tránsito*; others call them, for instance, *permisos de internación* (entry permits) or *pases de ganado* (cattle passes). Furthermore, in several states,[63] transport documents are not issued by government authorities but by local livestock associations.

According to several industry participants, most of the information contained in state transport documents is already included in the Zoosanitary Transport Certificate (Certificado Zoosanitario de Movilización), which is issued by SENASICA. They are therefore an unnecessary double control.

Harm to competition. Producers interested in commercialising their products in different states must pay for several transport documents in order to move their products from the point of production to the points of sale. This makes their products more expensive and puts them at a competitive disadvantage against producers who produce and commercialise their products in the same state.

These state laws might also infringe federal law. Article 67 of the Federal Law on Animal Health states that SAGARPA has the exclusive power to determine the zoosanitary requirements to transport "regulated products"[64] across the country, and that state authorities cannot impose requirements stricter than those determined by SAGARPA. Hence, provisions in state livestock laws that require obtaining transport documents arguably infringe Article 67.

Furthermore, according to a 2016 COFECE report, the provisions in the state laws might even be unconstitutional: "Related to this, the Supreme Court of Justice of the Nation has determined that the provisions that restrict the movement of products violate the freedom of trade protected by Article 5 of the Constitution, since they impose a limitation to the individual's freedom to commercialise his products" (COFECE, 2016: 16).

Policymaker's objective. State governments claim that transport documents are a measure to prevent the entry of animals, animal products and sub-products that could pose a health risk for their citizens. Market participants, on the other hand, claim that they are often used as a means to raise additional income for the states.

Recommendation. The OECD recommends abolishing the requirement for state transport documents. The Zoosanitary Transport Certificate and the Transport Notice (Aviso de Movilización) should replace state transport documents in all instances.

If this OECD recommendation is fully implemented, the benefits are estimated to range between MXN 5.4 million and MXN 54.4 million. This calculation is explained in detail in Annex 3.A3.

3.3.1.5. Requirement of transport documents at municipal abattoirs

According to Article 6.6.2.1. of NOM-194-SSA1-2004, all animals arriving to a municipal abattoir must have a zoosanitary certificate[65] or a cattle transport document.[66] Furthermore, a record must be kept of origin, destination, meat temperature, the temperature of the means of transport, and data to identify the vehicle (e.g. licence plate,

driver, company). The objective of Article 6.6.2.1 is most probably to guarantee the traceability of animals arriving at abattoirs. However, it is not clear why the two documents – a cattle transport document and the zoosanitary certificate – are referred to as substitutes. The OECD recommends amending NOM-194-SSA1-2004 so that only a Zoosanitary Transport Certificate is required for animals arriving at municipal abattoirs, and state transport documents are no longer accepted.

3.3.2. Authorisations

The revision of meat legislation involved an analysis of several authorisations within the meat value chain.[67] Generally, authorisations have the potential to act as legal barriers to entry into the markets and to protect incumbents from competition. However, authorisations in the meat sector tend not to be an obstacle to competition, as they are based on reasonable requirements that do not discriminate between applicants. The OECD makes only one recommendation in this category; this concerns the current lack of a workable definition of a drainage system.

3.3.2.1. Drainage system of TIF establishments

Description of the obstacle. An authorisation to build and operate a TIF abattoir or a meat-processing plant requires a functioning drainage system. If the drainage system is considered to be insufficient, the location of the abattoir and/or processing plant will not be approved. However, Article 5.2 of the NOM-008-ZOO-1994 is unclear about what is meant by an insufficient drainage system.

Harm to competition. Entrants need ex ante authorisation, which can be a barrier to entry if requirements are burdensome or too costly. Furthermore, in this case, the lack of clarity of these requirements might favour discrimination.

Policymaker's objective. Most probably the objective is to prevent the accumulation of waste (e.g. blood, fat) that would be a source of human and animal diseases.

Other jurisdictions give a definition of adequate drainage facilities. In the EU, for example, Number 8, Chapter I, General requirements for food premises (other than those specified in Chapter III) of Annex II of Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004, states that drainage facilities "are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled".

Recommendation. Article 5.2 of this NOM should contain an explanation of what constitutes a sufficient drainage system. The quoted paragraph from Regulation (EC) No. 852/2004 might serve as a blueprint for a definition.

3.3.3. Imports, exports and double control

International trade allows consumers of trading partner countries to access more goods at lower prices. Typically, countries can restrict imports and exports through tariffs, but also through non-tariff measures, such as standards, administrative procedures and subsidies to national producers. In the case of imports and exports of live animals, their products and sub-products, zoosanitary requirements mainly pursue the policy goal of protecting animal health, and so indirectly, human health. However, when such

requirements are excessive, they can constitute non-tariff barriers to trade. We make four recommendations in the category of imports, exports and double control; these are:

- eliminating the need for a double authorisation for imports
- adopting a risk assessment-based inspection system for imported lots of meat, carcasses, viscera and offal and viscera
- clarifying in which instances livestock importers can be given the right to move quarantined animals to their own installations
- ensuring full functionality of the VUCEM platform.

3.3.3.1. Double authorisation to import

Description of the obstacle. Animals, their products and sub-products must come from authorised establishments within authorised countries.[68] For a foreign country to be authorised, its veterinary services must be recognised by SAGARPA as working with standards at least as high as the ones applied in Mexico.

Harm to competition. The provision leads to a double control: of the establishment that raises livestock or produces meat and the country where it is located. Country authorisations should be sufficient to guarantee adequate zoosanitary conditions as foreign animal-health authorities should – at least, in theory – regularly inspect establishments within their countries. The additional requirement that SAGARPA also authorises and inspects establishments in foreign countries might therefore be seen as an unnecessary additional barrier to entry for foreign producers.

COFECE's 2015 report *Reporte sobre las condiciones de competencia en el sector agroalimentario* states: "this scheme creates strong barriers to entry, as it requires that products come from authorised countries and establishments. In this sense, sanitary risk could be dealt with only through the first filter, mainly when the origin country applies standards that are at least as rigorous as those established under the Mexican regulation. Otherwise, trade could be probably restricted and, consequently, the free competition and entry process could be affected." (COFECE, 2015: 405).

Policymaker's objective. The objective of the double authorisation is to ensure that imported live animals, their products and sub-products do not constitute a danger for the health of Mexican consumers. According to interviews with industry participants, this double authorisation might be justified, as foreign countries do contain zones that are free of an animal disease, and others that are not. Also, several foreign countries to which Mexican producers export live animals, their products and sub-products, also follow the same procedure, authorising foreign animal-health authorities, as well as regularly visiting individual foreign establishments.

Recommendation. The OECD recommends eliminating the additional establishment authorisation. This elimination, however, should be based on bilateral agreements with countries that abolish any additional requirements for Mexican exporting companies to be authorised by their sanitary authorities. In these bilateral agreements, both sides would agree that their internal sanitary authorities ensure the quality of all exporting establishments and their products within their jurisdiction (even if those products are not meant to be sold on the home market).

3.3.3.2. Inspection all imported meat, carcasses, viscera and offal

Description of obstacle. Article 4.1 of NOM-030-ZOO-1995 states that all imported lots of meat, carcasses, viscera and offal must be inspected in line with the specifications laid out in the Zoosanitary Requirements Form (Hoja de Requisitos Zoosanitarios); this is necessary to obtain a Zoosanitary Import Certificate (Certificado Zoosanitario para la Importación). This requirement is a third control after the authorisation of foreign countries to export to Mexico, and the verifications of foreign establishments as described above.

Harm to competition. It seems excessive and unnecessarily costly to inspect all imports of meat, carcasses, viscera and offal in line with the Zoosanitary Requirements Form. Moreover, according to industry participants, compliance with this requirement is not operationally feasible, which might allow wide discretion and lead to discrimination.

Policymaker's objective. The objective of this provision is to ensure that imported meat, carcasses, viscera and offal originate in foreign plants that, at least, comply with requirements as strict as those in Mexican plants.

Recommendation. The OECD recommends amending NOM-030-ZOO-1995 replacing the requirement to inspect all imported lots of meat, carcasses, viscera and offal with a system under which both the timing and number of controls, as well as the amount of samples taken to be inspected, would be chosen based on a risk assessment. The controls should be random so that an exporter would not be able to forsee when the next control might take place. Furthermore, the frequency of controls as well as the size of the sample inspected during each control could be based upon a risk assessment that took into account, among other factors, an exporter's past compliance with zoosanitary requirements.

In the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will be revoked during 2017. According to SENASICA, the NOM will be replaced by a set of inspection procedures based on a risk assessment.[69]

If this OECD recommendation is fully implemented, the benefits are estimated to range between MXN 32.9 million and MXN 253.9 million. This calculation is explained in detail in Annex 3.A4.

3.3.3.3. Facilities for importing live animals in quarantine

Imported live animals whose Zoosanitary Requirements Form states that they must be quarantined will be stopped at their arrival point as long as it is "strictly necessary to determine that their presence in the country and at the destination does not constitute a zoosanitary risk" (Article 7, NOM-054-ZOO-1996). In practice, however, animal importers are allowed to take animals to their own installations, where SENASICA staff subsequently visits the animals periodically and monitor their health status. This allowance, however, is not clear from the reading of NOM-054-ZOO-1996.

The objective of the provision is to prevent the entry of foreign animal diseases into Mexico. However, the term "strictly necessary time" grants wide discretion to customs authorities and, in theory, imported live animals could be blocked for substantial periods, delaying their transport and commercialisation in Mexico.

The OECD recommends clarifying in the introductory paragraph of Article 7 that livestock importers can be allowed to bring their quarantined animals to their own installations.

3.3.3.4. Malfunctioning of VUCEM

VUCEM, an Internet platform created by the Mexican government, centralises communication and compliance issues for Mexican federal agencies with border-management responsibilities. Article 22 of the Decree that established the Mexican Digital Window of Foreign Trade states that the development and management of VUCEM, once implemented, will be the responsibility of the Tax Administration Service (Servicio de Administración Tributaria, SAT), a body of the SHCP.

According to several industry participants, VUCEM is not fully functional, since it experiences frequent downtimes. One industry participant estimated that VUCEM malfunctioned (i.e. entered a so-called "contingency phase") up to 40% of the time that he tried to use the system. This type of downtime is particularly problematic for meat and meat products, which are perishable goods, as it can lead to imports of meat and meat product waiting for long periods at the border.

The OECD recommends that the authorities work to guarantee that VUCEM is fully functional at all times. It also recommends that it is clarified that only one authority (i.e. the SAT) is fully responsible for VUCEM's functioning in terms of SENASICA procedures, and that other agencies should support that authority. Furthermore, sufficient funds should be given to all authorities that are part of VUCEM.

3.3.4. Involvement of associations

Industry associations often adopt rules regulating their members' conduct. Such regulations can have various benefits. For instance, in the meat sector, livestock-producer associations can foster the development of the industry through the adoption of best practices, the standardisation of production, commercialisation and production processes, and the collection of industry data for producing national statistics. However, self-regulation or co-regulation can sometimes also reduce competition between suppliers of goods: for example, if an association discriminates against livestock producers that are not members. We have identified several provisions in the revised legislation that might lead to an undue influence of livestock associations. In total, we make four recommendations in the involvement of associations category. These are:

- stricter supervision of Animal Health Auxiliary Organisms
- not allowing livestock associations to have as one of their objectives the guiding of "production according to market conditions, either intensifying or withholding it"
- clarifying the extent of information exchange between livestock associations
- ensuring that livestock producers cannot be forced to belong to livestock associations.

3.3.4.1. Animal Health Auxiliary Organisms

Description of the obstacle. Animal Health Auxiliary Organisms (Organismos Auxiliares en Sanidad Animal, OASA)[70] are organisations of livestock producers that

support SAGARPA in the coordination and implementation of zoosanitary campaigns and programmes on good farming practices.[71] OASA are supervised by SAGARPA's state branches and state governments. They are authorised to operate by SAGARPA, which can revoke their authorisation if it considers that they no longer fulfil their objectives.

Harm to competition. The OECD considers that granting organisations of livestock producers the power to coordinate and implement zoosanitary campaigns and programmes on good livestock practices might lead to undesired outcomes. For example, it could lead to a situation where an OASA used its power to foreclose on individual livestock producers. In theory, an OASA could refer an individual livestock producer to SAGARPA if it did not comply with good livestock practices or a zoosanitary campaign, with the result that the producer would have to exit the market.

Policymaker's objective. SAGARPA grants OASA the power to coordinate and implement zoosanitary campaigns and programmes on good livestock practices, since it considers OASA to be a cost-effective alternative to doing this work itself. According to industry participants, the tasks carried out by OASA are operational; they are not linked to determining the zoosanitary status of geographical areas. It is therefore unlikely that OASA are used by livestock producers to foreclose on competitors. In fact, according to SENASICA, authorisations to operate have already been revoked for OASA in several states when misconduct was detected.

Recommendation. There is no recommendation concerning the structure of OASA, since we consider that the current regulatory framework gives sufficient power to SAGARPA to supervise and revoke OASA. However, the OECD does recommend stricter supervision of the use of the funds granted to OASA, as well as their behaviour in terms of the implementation of zoosanitary campaigns and programmes on good livestock practices. In this regard, the OECD suggests issuing guidelines that provide clear criteria for revoking authorisations.

3.3.4.2. Decision-making of livestock associations

Article 5 of the Law on Livestock Associations provides a list of the objectives that livestock associations can pursue. Letter II of Article 5 states that livestock associations can seek to "[g]uide production according to market conditions, either intensifying or withholding it". Arguably, the objective of the provision is to allow livestock associations to jointly develop and improve the production and commercialisation processes of livestock products. However, the provision could be seen as enabling livestock associations to control production and so indirectly, price levels. If this were the case, the provision might constitute a severe restriction of competition.[72] The OECD therefore recommends abolishing this provision.

3.3.4.3. Information gathering by livestock associations

Article 16 of the Regulation of the Law on Livestock Associations states that livestock associations must create statistics and encourage members to keep proper internal accounting so that they are aware of their own production costs and of price studies concerning the products they market. The exact entries and level of aggregation of the statistics that are created by livestock associations is unknown, and it is unclear whether this information is later shared with other associations' members.

Most probably, the objective of the provision is to help livestock producers to improve their decision making (e.g. by spotting industry trends or allowing benchmarking), and to facilitate the creation of national statistics. On the other hand, accounting information of livestock associations may include sensitive data that, if shared between livestock associations' members, might facilitate collusion. The OECD therefore recommends amending Article 16, Letters II and III of the Regulation of the Law on Livestock Associations, so that it is clear that the exchange of sensitive information between members of livestock associations, as well as between livestock associations, is prohibited. COFECE's guidelines, *Guía-007/2015: Guía para el Intercambio de Información entre Agentes Económicos* provide a useful guide about when information exchange might be a competition concern.

3.3.4.4. Compulsory membership of livestock producers

Article 6 of the Law on Livestock Associations states that livestock producers have the right to associate freely and voluntarily. According to COFECE's report *Miscelánea de obstáculos regulatorios a la competencia: Análisis de la normatividad estatal* (COFECE, 2016: 16-17), however, livestock laws in several Mexican states[73] establish that it is mandatory for livestock producers to join a local livestock association. These state livestock laws arguably infringe Article 6 of the Law on Livestock Associations.

Voluntary membership allows livestock producers to benefit from the economies of scale that livestock associations might generate. In contrast, mandatory membership to a local livestock association could reduce competitive behaviour between farmers, as farmers belonging to a livestock association are held to behave according to the association's statutes. The OECD recommends amending Article 6 of the Law on Livestock Associations so that it clearly states that under no circumstances can livestock producers be forced by state laws to join a livestock association. Implementing this recommendation might entail abolishing provisions in state laws that oblige livestock producers to associate.

3.3.5. Discrimination against foreigners

The OECD has analysed provisions that treat foreign and Mexican companies differently. Two obstacles were analysed as prima facie restrictions to competition. However, after a detailed analysis, the OECD has decided not to make any recommendation in this category.

3.3.5.1. Agricultural and Rural Insurance Funds

In Mexico, agricultural and livestock producers can access agro-insurance either through Agricultural and Rural Insurance Funds (Fondos de Aseguramiento Agropecuario y Rural, FAAR)[74] or through private providers. In the case of FAAR, only two kinds of members are allowed: Mexican citizens or Mexican corporate entities that do not admit foreign stockholders. FAAR are considered to be "subjects of promotion and support" by the Mexican federal government and, thus, are eligible to receive subsidies.

The OECD team assessed the risk that the provision might discriminate in favour of Mexican agricultural and livestock producers, but concluded that the restriction was unlikely to impact upon foreign producers, since most are large commercial producers and would not be interested in membership.

3.3.5.2. Subsidies to national producers to offset inequalities caused by international trade

The federal government can grant subsidies to national producers in order to offset inequalities between them and foreign producers. When granting these subsidies, whether products are basic and strategic for food sovereignty is taken into consideration. The OECD assessed the risk that foreign meat producers might be discriminated again if they were not able to receive the same subsidies as their Mexican competitors. The objective of these subsidies is to increase the productivity and competitiveness in agriculture and ensure employment for the rural population. As providing support to agricultural and livestock producers is a common policy in many other jurisdictions (e.g. the United States and the EU), the OECD does not recommend any changes, as long as the subsidies comply with WTO commitments and international trade agreements.

3.3.6. Non-harmonised standards

Description of the obstacle. In our review of meat legislation, we found 29 NOMs and 3 NMX that are not in line with international norms. NOMs are issued by the federal government and compliance with them is mandatory, whereas NMX are voluntary standards. The list of such NOMs and NMX containing such clauses is the following:

- NMX-F-315-1978, setting methods for determining the drained mass of packaged food
- NMX-FF-078-SCFI-2002, setting quality standards for the classification of beef carcasses
- NMX-FF-081-SCFI-2003, setting quality standards for the classification of pork carcasses
- NOM-001-ECOL-1996, setting maximum limits for pollutants in national waters
- NOM-002-SCFI-2011, setting methods for verifying the net contents of pre-packaged products
- NOM-008-ZOO-1994, setting sanitary specifications to build and equip establishments for the slaughtering of animals and the processing of meat products
- NOM-009-ZOO-1994, dealing with the sanitary processing of meat
- NOM-012-ZOO-1993, setting specifications for chemical, pharmaceutical and biological products for animals, as well as animal feed
- NOM-022-ZOO-1995, setting zoosanitary specifications for the facilities, equipment and operation of establishments that commercialise chemical, pharmaceutical and biological products for animals, as well as animal feed
- NOM-023-ZOO-1995, dealing with a test to identify the animal species of meat
- NOM-024-ZOO-1995, setting specifications for transporting animals, their products and sub-products, chemical, pharmaceutical and biological products for animals, as well as animal feed
- NOM-025-ZOO-1995, setting sanitary specifications to build and equip establishments that manufacture animal feed

- NOM-026-ZOO-1994, setting zoosanitary specifications for facilities, equipment and operation of establishments that manufacture chemical, pharmaceutical and biological products for animals
- NOM-027-ZOO-1995, dealing with the processing of cattle and pigs' semen, and the operation of facilities for this activity
- NOM-030-ZOO-1995, dealing with inspections of imported meat, carcasses, viscera and offal
- NOM-031-ZOO-1995, setting quality standards for conducting campaigns against bovine tuberculosis
- NOM-033-ZOO-1995, setting standards for the humane slaughtering of animals
- NOM-041-ZOO-1995, setting specifications for conducting campaigns to eradicate bovine brucellosis
- NOM-046-ZOO-1995, setting quality standards for campaigns against animal diseases
- NOM-051-SCFI/SSA1-2010, dealing with methods used for calculating the nutritional values (energy or proteins) displayed on pre-packaged food products and non-alcoholic beverages
- NOM-054-ZOO-1996, including quarantine specifications to prevent, control and eradicate animal diseases
- NOM-059-ZOO-1997, dealing with zoosanitary specifications for advertising chemical, pharmaceutical and biological products for animals, as well as animal feed
- NOM-061-ZOO-1999, dealing with zoosanitary specifications for animal feed
- NOM-067-ZOO-2007, dealing with specifications for conducting campaigns to eradicate rabies in cattle
- NOM-086-SSA1-1994, dealing with nutritional specifications for food and non-alcoholic beverages with modifications to their composition, and packaged foods and cereals for infants and children with added nutrients.
- NOM-092-SSA1-1994, dealing with specifications to detect aerobic bacteria
- NOM-112-SSA1-1994, dealing with a procedure for detecting bacteria (E. coli) in food products
- NOM-114-SSA1-1994, dealing with specifications to detect salmonella in food products
- NOM-130-SSA1-1995, dealing with sanitary specifications for hermetically sealed packaged food subjected to thermal treatment
- NOM-158-SCFI-2003, setting standards for ham, such as nomenclature, number of microorganisms allowed, etc.

- NOM-194-SSA1-2004, setting sanitary specifications for establishments whose activity is the slaughtering and processing of animals for wholesale, stock, transport and retail
- NOM-213-SSA1-2002, dealing with sanitary specifications for processed meat products.

Harm to competition. The non-harmonisation with international standards – be it partial or total – may hinder foreign competitors' access to the Mexican market, as well as access to foreign markets by Mexican producers. In particular, producers might have to apply different sets of norms in Mexico and abroad, which might lead to extra costs.

Even if in practice, Mexican companies have recently (partially) adapted their operations to international standards, the legal texts for the NOM and NMX should be updated to avoid confusion among market participants.

Policymaker's objective. There would appear to be no underlying objective behind the non-harmonisation of NOMs and NMXs. In Mexico, non-harmonisation of NOMs must be disclosed according to Article 41, Letter VI of the Federal Law on Metrology and Standardisation, which states that NOMs must contain a degree of concordance with international norms and criteria.

Recommendation. The OECD recommends that all these NOMs and NMX (except for NOM-009-ZOO-1994, NOM-030-ZOO-1995, NMX-FF-078-SCFI-2002 and NMX-FF-081-SCFI-2003)[75] are brought into line with international standards. Interviews with industry participants revealed that some current practices may already be in accordance with international standards, which would significantly ease the transition. The law should also contain mentions when there are no existing international standards or best practices. The National Standardisation Programme for 2017 mentions that several of these NOMs are in the process of being cancelled and/or modified.

3.3.7. Administrative burdens

Administrative burdens do not have a direct bearing on competition. Nonetheless, they constitute burdens on business and affect the general business environment. They can be an impediment to incumbent meat companies, but also to potential entrants into the markets. Furthermore, excessive administrative burdens can even threaten the existence of small producers.

In total, the OECD makes three recommendations for the Administrative burdens category. These are:

- flexibilise the required presence of specific professionals at establishments that manufacture animal-feed products
- flexibilise the required presence of specific professionals at establishments that manufacture chemical, pharmaceutical and biological products for use in animals
- flexibilise the required presence of veterinary surgeons at TIF establishments.

The three analysed restrictions all force establishments to employ professionals who potentially have overlapping functions.

3.3.7.1. Manufacturing of animal-feed products

According to Article 7 of NOM-025-ZOO-1995, establishments that manufacture animal-feed products must employ an authorised veterinary surgeon, a production specialist and a quality-control specialist. This NOM does not explicitly state the exact tasks to be performed by the production and the quality-control specialists. Complying with this requirement requires employing three experts, which can impose high costs on a business. This provision could discriminate against small businesses.

While the provision seeks to ensure that establishments manufacturing animal feed products have the required staff to implement feed-safety and quality specifications contained in this NOM, the OECD recommends allowing production and quality-control activities to be fulfilled by the same employee. This recommendation presupposes that both activities require comparable knowledge and qualifications.

3.3.7.2. Manufacturing of chemical, pharmaceutical and biological products for use in animals

According to Article 7 of NOM-026-ZOO-1994, establishments that manufacture chemical, pharmaceutical and biological products for use in animals must employ an authorised veterinary surgeon, a biological scientist in the production area, and a biological scientist in the quality-control area. As in the case of Article 7 of NOM-025-ZOO-1995, this NOM does not explicitly state what tasks are to be performed by each of the two biological scientists. Complying with this requirement could constitute a high cost for businesses – especially small ones – since three employees must be hired. This provision could discriminate against small businesses.

While the provision seeks to ensure that establishments that manufacture chemical, pharmaceutical and biological products to be used in animals have the required staff to implement the zoosanitary specifications contained in this NOM, the OECD suggests allowing the production and the quality-control activities to be fulfilled by the same professional. This recommendation presupposes that both activities require comparable knowledge and qualifications.

3.3.7.3. TIF veterinary services

Description of the obstacle. TIF-certified establishments must have, during working hours, at least one Authorised Responsible Veterinary Surgeon (Médico Veterinario Responsable Autorizado, MVRA). An MVRA is a veterinary surgeon approved by SAGARPA, in charge of ensuring compliance with the Federal Law on Animal Health and related regulations at a TIF establishment. In addition to MVRAs, each TIF may have an Official Veterinary Surgeon (Médico Veterinario Oficial, MVO). MVO are employed by SENASICA and work as inspectors at TIF-certified establishments. The presence of MVRA is required even if an MVO is already present at the abattoir or processing plant.

Harm to competition. Requiring the presence of an additional MVRA even when an MVO is already present at a TIF establishment might see certain veterinary functions duplicated. The requirement imposes an extra burden on companies, especially small TIF establishments.

Also, TIF-employed MVRAs face a potential conflict of interest as they are in charge of ensuring compliance with SENASICA regulations, but are paid by the TIF establishment itself.

Policymaker's objective. The aim of the provision is to ensure that a veterinary surgeon is present at TIF establishments and in charge of animal welfare, epidemiological surveillance, zoosanitary measures and good livestock practices.

According to SENASICA, in the United States, all veterinary surgeons in charge of verifying compliance with animal-health regulations at abattoirs and meat-processing plants are government staff.

Recommendation. The OECD recommends progressively reducing TIF establishments' reliance on MVRAs. To achieve this, two actions could be undertaken: 1) Article 108 of the Federal Law on Animal Health should be amended so that, during working hours, either an MVRA or an MVO must be present, allowing for greater flexibility; 2) The outsourcing of veterinary services by TIF establishments should be encouraged.

The long-term goal is for TIF establishments to outsource veterinary services to SENASICA. This would see each establishment paying a fee to SENASICA, which in turn would pay the veterinary surgeons, who would then verify compliance with SENASICA regulations, without any conflict of interest. Reaching that goal, however, will require an increase in funding to SENASICA.

If this OECD recommendation is fully implemented, the benefits are estimated to range between MXN 13.3 million and MXN 39.8 million. This calculation is explained in detail in Annex 3.A2.

3.3.8. Others

This category includes several restrictions besides the main categories discussed above. These restrictions concern subjects as diverse as industrial policy, unguided discretion by a public authority, and limitations to advertising. In total, the OECD makes five recommendations; these are:

1. restrict CIDRS's industrial policy so that it no longer includes specifications about volumes or prices
2. establish that all sanctions related to environmental harm are linked to previously published NOMs
3. monitor livestock series statistics on the SNIDRUS information system, so that data cannot be tracked back to individual businesses
4. enable companies to quote PROFECO reports in which their products are cited
5. issue detailed guidelines for the specific tasks of MVOs.

3.3.8.1. Industrial policy of CIDRS

Description of the obstacle. According to Letters I and II of Article 149 of the Law on Rural Sustainable Development, the CIDRS will promote the creation of CMDRS committees called product systems (*sistemas producto*), which will have among their objectives to "set up the agricultural and livestock production programmes of the country" and to "determine the strategic expansion and contraction plans for the output and quality of each product".

Harm to competition. This provision suggests that the CIDRS could influence the determination of production volumes of agricultural and livestock goods.

Policymaker's objective. The provision's objective is to develop the meat industry's value chains by increasing productivity and competitiveness. This article enables the federal government to carry out industrial policy for agricultural and livestock goods.

Recommendation. The OECD recommends abolishing Letter II, Article 149 of the Law on Rural Sustainable Development. For Letter I, we suggest clarifying that "agricultural and livestock production programmes" do not include any specifications about volumes or prices.

3.3.8.2. Wide discretion of SEMARNAT

According to the Federal Law on Environmental Liability, SEMARNAT will issue NOMs that determine environmental-harm thresholds on a case-by-case basis. However, Articles 2, 6 and 7 of the law, interpreted in conjunction, state that even if no NOMs dealing with sanctions are issued, SEMARNAT is still be able to penalise firms for environmental harm. The objective of the provision is to deter companies from damaging the environment. However, the degree of discretion contained in the provision – which arguably violates the nulla poena sine lege principle – could be problematic if government officials were to apply different standards of harm to different producers.

Recommendation. The OECD recommends amending Article 7 of the law so that it clearly states that all sanctions related to environmental harm must be based on previously published NOMs. In that regard, the OECD considers that NOMs could be issued to address different types of environmental harm (e.g. thresholds for pollutants in water or in soil) in the light of cases that arise. This is possible as Article 48 of the Federal Law on Metrology and Standardisation has established fast-track procedures for public institutions to issue NOMs under "cases of emergency".[76]

3.3.8.3. Information transparency on the SNIDRUS system

SNIDRUS is an information system managed by the Agrifood and Fisheries Information Service (Servicio de Información Agroalimentaria y Pesquera, SIAP), a body of SAGARPA. The objective of SNIDRUS is to disseminate information on agricultural and livestock markets (e.g. offer, demand, stocks, forecasts, prices) at regional, national and international levels. SNIDRUS was created by the Law of Rural Sustainable Development and the Internal Regulation of SIAP, and its operation is based upon the document, *Norma Técnica para la Generación de Estadística Básica Agropecuaria y Pesquera*. In Chapter 3 of that document, it is established that several livestock statistical series (e.g. volume of carcasses, live animals, slaughters) must be generated at a municipal level.

Harm to competition. There is a theoretical concern that, in some instances, the availability of recent livestock series at a municipal level might facilitate price coordination between livestock producers.

Policymaker's objective. The provision's objective is to provide economic decision makers in the Mexican agricultural and livestock sectors with trustworthy, timely and relevant information.

While it seems that in practice there are no current competition concerns related to the operation of SNIDRUS, there remains the possibility that there will be in the future.

Recommendation. The OECD recommends that all present and future SIAP guidelines related to the gathering and presentation of agricultural and livestock data, put an emphasis on restricting the issuance of data that allows information to be tracked back to an individual business.

3.3.8.4. Quoting PROFECO consumer reports

PROFECO produces and publishes reports on the quality and features of products and services in order to guide and protect consumers. In these reports, PROFECO makes specific mentions of brands, but Article 44 of the Federal Law on Consumer Protection forbids companies to quote these reports. The provision limits the freedom of suppliers to use public information to advertise their products, even when this information is based on objective grounds.

Policymaker's objective. According to anecdotal evidence, the goal of the provision is to guarantee PROFECO's independence by preventing companies from trying to take undue influence on the authority, as well as to prevent them from misquoting PROFECO's report (e.g. "recommended by PROFECO"). However, these goals can also be reached without restricting competition.

Recommendation. The OECD recommends abolishing Article 44 of the Federal Law on Consumer Protection, since the concerns it addresses would appear unjustified as the law already contains an article that forbids misleading or abusive advertising.[77] At the same time, measures should be taken to guarantee the independence of PROFECO officials from lobbying efforts and secure that there are efficient mechanisms (including sanctions) in place to avoid misleading advertising.

The same recommendation concerning PROFECO has been made for the medicines sector.

3.3.8.5. Guidelines for MVOs at TIF establishments

According to industry participants, the application of specifications by MVOs at TIF establishments varies widely. This problem probably stems from the fact that the relevant NOM-009-ZOO-1994 does not describe in sufficient detail all the tasks expected of MVOs. Since not all TIF establishments are subject to the same sets of standards, competition between TIF establishments could be distorted.

To guarantee harmonised practices, the OECD recommends issuing an updated NOM or guidelines that discuss in detail how specific tasks described in the NOM-009-ZOO-1994 are to be carried out by MVOs. The National Standardisation Programme for 2017 mentions that this NOM will be cancelled and replaced during 2017.

3.4. Horizontal legislation: cooperatives and common land, and public procurement

In addition to the legislation specifically dealing with meat, the OECD team also analysed horizontal legislation in the areas of cooperatives and common land, as well as public procurement. Legislation in these areas not only applies to the meat sector, but to a wide range of industries.

3.4.1. Cooperatives and common land

This category addresses restrictions related to cooperatives and the Mexican regime of common land called *ejidos*.

Ejidos are common lands. Currently over half of Mexican territory is made up of *ejidos*. Since a 1992 constitutional amendment, *ejidos* can be privatised, but complexities in property rights have severely limited the number that have gone into the private domain. This, in turn, has promoted small-scale farming, and the accompanying limited economies of scale (OECD, 2015: 31). The OECD's four recommendations aim to simplify *ejidos* property rights. These are:

- consider the abolition of or the expansion of the limits of what is defined as a "small livestock property"
- remove limits on the holding of agricultural, livestock and forest lands by stock and civil companies
- consider removing the limits to foreign participation in agricultural, livestock and forest lands
- simplify the process to privatise parcels of land within *ejidos*.

The competition analysis of cooperatives is complex. While it is true that cooperatives can in some instances restrict output or raise prices, there are also pro-competitive reasons for their creation, such as economies of scale and scope, the maintenance of a brand such as an *appellation*, and shared investment in advertising and research (OECD, 2004: 22).

If competition policy is to have a greater role in the development of agricultural policies, clear criteria for the analysis of cooperatives are necessary. As a previous OECD analysis put it: "If farmers seek guidance about what sorts of activities are permissible, government policy statements can clarify those types of conduct that would be considered in the public interest and clearly permissible as well as those types of conduct that would be considered harmful" (OECD, 2004: 15). The OECD's recommendations concerning cooperatives aim to clarify the competition regime of cooperatives in Mexico.

3.4.1.1. Operation of cooperatives

Description of the obstacle. Article 86 of the General Law on Cooperative Societies states that cooperatives will "design and implement strategies for the integration of their activities and productive processes with the objective of […] influencing prices".

Harm to competition. It is unclear what is meant by "influencing prices", which might be interpreted as an allowance for cooperative-production enterprises to jointly sell their products. This, in turn, could facilitate collusion between members of cooperative-production enterprises.

Policymaker's objective. Most probably, the law allows the creation of cooperative production enterprises to enjoy economies of scale, and reduce investment risks incurred by agricultural and livestock producers.

It is worth noting that in several jurisdictions, there are competition-law exemptions for agricultural and livestock cooperatives. For instance, in the United States, the Capper-Voltstead Act of 1922, and marketing orders issued pursuant to the Agriculture Marketing Agreement Act of 1937, state that the creation of cooperatives of agricultural and livestock producers does not trigger competition-law scrutiny, and cooperatives are allowed to collectively market products. However, the Capper-Voltstead Act requires that cooperatives are entirely composed of producers of agricultural and livestock products, and the exemption of scrutiny does not extend to predatory or coercive conduct, or to collaborations or mergers with companies not covered by the Act (OECD, 2004: 183).

To the best of our knowledge, in Mexico currently there is no law that exempts cooperative production enterprises from competition law.

Recommendation. The OECD recommends amending Letter III, Article 86 of General Law on Cooperative Societies, so that it is clear that the integration of cooperative production enterprises does not include joint selling. In addition, the OECD recommends issuing guidelines that describe the principles of cooperation between competitors (i.e. livestock producers). These two measures would ensure that cooperative production enterprises could still exploit the economies of scale in the preparation, processing and handling of their products, while risks of collusion would be minimised.

3.4.1.2. The concept of "small livestock property" for ejidos

In the case of an *ejido* whose main activity is livestock production, an *ejido* member is allowed to hold land up to 5% of the *ejido*'s total size or the threshold for "small livestock property", whichever is reached first; this is known as "parcellary rights". Consequently, an *ejido* member would not be allowed to hold land with a size equal to small livestock property if that was larger than 5% of the total *ejido*'s size. Small livestock property corresponds to the amount of land necessary to raise 500 head of major livestock (e.g. cattle) or its equivalent in minor livestock (e.g. pigs).

These limits on the holding of *ejido* lands seek to prevent the concentration of lands, but they make it difficult for producers to reach scale and compete with large producers.

The OECD sees three possible options, depending on how the Mexican government decides between the conflicting goals of preserving the current distribution of land through the institution of the *ejido* – and so preventing the concentration of this land – and allowing for more efficient production.

Option 1) Remove limits to land holdings of *ejido* members. This requires the removal of the concept of "small livestock property" and an amendment to Article 27 of the Mexican Constitution.

Option 2) To increase the size of a "small livestock property"; this option requires an amendment to article 27 of the Mexican Constitution.

Option 3) No change as it is the policymaker's objective to prevent the concentration in the holding of *ejido* lands.

3.4.1.3. Agricultural, livestock or forest land owned by stock and civil companies

Stock and civil companies cannot own agricultural, livestock or forest land whose area is more than 25 times the size of a "small property" (the size of which depends on an assessment of each individual land holding and its classification as agricultural, livestock or forest land). Furthermore, these companies must be made up of as many natural persons as the number of times that the held land exceeds the "small property" size.

The provision aims to prevent the concentration of holdings of agricultural, livestock and forest land. Companies deciding whether to use agricultural, livestock and forest lands (for instance, to raise livestock) might be deterred from doing so in cases where the size of a piece of land is equivalent to 25 times the size of "small property", but is not enough to reach the necessary scale. Thus, the OECD recommends removing limits on the holdings of agricultural, livestock and forest land by stock and civil companies. This would involve abolishing Articles 126 and 132 of Agrarian Law, and amending Article 27 of the Mexican Constitution.

3.4.1.4. Foreign participation in agricultural, livestock and forest land

Stock and civil companies that own agricultural, livestock or forest lands must issue a special series of shares (T shares) that represent the acquisition value of these lands. Foreign ownership of T shares is limited to 49% of total holdings. The probable objective of this restriction is to guarantee food sovereignty, but the provision might also hinder foreign investment in agricultural, livestock and forest land.

The OECD sees two possible options, depending on how the Mexican government decides to balance the conflicting goals of restricting foreign ownership of land and allowing foreign investment and, possibly, more efficient production. These are:

- **Option 1)** Abolish Article 130 of the Agrarian Law, and Article 7, Letter III, Subletter R of the Law on Foreign Investment; this option would involve an amendment to article 27 of the Mexican Constitution.
- **Option 2)** Make no change as it is the policymaker's objective to prevent foreign majority holdings of agricultural, livestock and forest land.

3.4.1.5. Privatisation of ejidos

According to the Agrarian Law, it is possible to privatise parcels of land in *ejidos*. Such privatisation is referred as an adoption of a "full-rights regime". Article 23 of the Agrarian Law states that the competent body within the *ejido* for deciding on the privatisation of parcels is the *ejido* assembly, the *ejido*'s governing body that includes all the members. In order to privatise parcels in an *ejido*, it is necessary to obtain two-thirds of the votes in that assembly. This seems unnecessarily strict and makes it difficult to reallocate lands between different farming activities, which might be a barrier to entry for rearing livestock.

The objective of the restriction is clearly to preserve the *ejido* regime. The OECD recommends creating more flexible mechanisms that allow *ejidos* to adopt the full-rights regime. For instance, it might be possible to adopt a decision by simple majority instead of by two-thirds majority.

3.4.2. Public procurement

We make two recommendations in the area of public procurement of meat, both dealing with limitations for producers to participate in public procurement. The first concerns a list of goods supported by the CIDRS; the other concerns preferential treatment of MSME in public procurement.

3.4.2.1. List of goods supported by the CIDRS

The CIDRS, with the participation of the CMDRS, and in accordance with international trade agreements signed by the Mexican federal government, can set up a list of products that can be granted preferential treatment in public procurement. This restriction aims to increase the income of agricultural and livestock producers of goods whose commercialisation is particularly difficult. Nonetheless, a list of products that are granted preferential treatment on public procurement has the potential of preventing the choice of foreign products.

The OECD recommends the following options for the Mexican government, depending on how it decides to balance the conflicting goals of including foreign

competitors – and possibly offering better prices to consumers – and supporting the national meat industry. These are:

- **Option 1)** Amend Article 111 of the Law on Rural Sustainable Development so that agricultural and livestock goods whose commercialisation is particularly difficult are not given preference in public procurement; instead, direct subsidies might be considered.
- **Option 2)** Make no change as providing support to agricultural and livestock goods whose commercialisation is particularly difficult is a legitimate policy objective.

3.4.2.2. Preferential treatment of MSME in public procurement

Article 3, Letter IX of the Law to Promote the Sustained Increase of Productivity and Competitiveness of the National Economy aims to promote the participation of Micro, Small and Medium Enterprises (MSME) in public procurement. It does not, however, establish a quota of public-procurement purchases that must be served by MSME.

While the objective of this provision is to promote the growth and development of MSME, there is a potential discrimination of non-MSME. In particular, some non-MSME might be able to sell in public-procurement markets at lower prices than the MSME due to economies of scale.

The OECD sees two possible options, depending on how the Mexican government decides to balance the conflicting goals of including larger competitors and possibly offering better prices to consumer, and supporting MSME. These are:

- **Option 1)** Abolish Article 3, Letter IX of the law and give no preference to Mexican companies or MSME in public procurement. Direct subsidies should instead be considered.
- **Option 2)** Make no change as providing support to MSME is a legitimate policy objective. This option might be at the expense of Mexican consumers.

Notes

1. To define the sector, this analysis relies on the Mexican classification system SCIAN 2013 (henceforth SCIAN). This system classifies all economic activities along the vertical production chain in standardised categories. Some SCIAN codes coincide with those of NAICS 2012 (henceforth NAICS), the classification system used in the United States and Canada. While it is important to note that SCIAN was conceived to be the Mexican counterpart of NAICS, some of SCIAN codes are not directly comparable to similarly numbered NAICS codes.

   The report focuses on SCIAN groups 11, 31, 43, 46 and 48-9, including the relevant subgroups. The scope of the investigations covers the following SCIAN codes: 112 (Animal production and aquaculture), 1152 (Support activities for animal production), 3111 (Animal-feed manufacturing), 3116 (Animal slaughtering and processing), 431121 (Red-meat wholesalers), 431122 (Poultry-meat wholesalers), 43117 (Sausage wholesalers), 434 (Wholesalers of raw materials for agriculture, forestry and industrial activities, as well as waste), 4611 (Grocery retail), 461121 (Red-meat retailers), 461122 (Poultry-meat retailers), 461150 (Retailers of milk, other dairy

products and sausages), 462111 (Supermarkets) and 462112 (Convenience stores). Also included are activities horizontally related to the meat sector, namely meat transportation, warehousing and storage activities (SCIAN codes 48-49 Transportation, mailing and warehousing). The following codes are the same in both SCIAN and NAICS: 112, 1152, 3111 and 3116. The remaining SCIAN codes (i.e. 431121, 431122, 43117, 434, 4611, 461121, 461122, 461150, 462111, 462112) are not standardised. Finally, not included in the investigation are most of the activities included under SCIAN codes 1129 (Other animal production), 1142 (Hunting and trapping), 465911 (Pet retailers), and 72 (Accommodation and food services). Further information on SCIAN and NAICS can be found at: 1) United States Census Bureau. North American Industry Classification System, 2012 NAICS Keyword search, www.census.gov/cgi-bin/sssd/naics/naicsrch (accessed 11 April 2017). 2). Instituto Nacional de Estadística y Geografía. Libro SCIAN, www.inegi.org.mx/est/contenidos/proyectos/SCIAN/presentacion.aspx?_file=/est/contenidos/proyectos/SCIAN/doc/scian2013.pdf.

2. For instance, cattle can be fed with sorghum or soybean; pigs with maize and sorghum; and chicken with maize.

3. These are the most recent available figures.

4. Article 27 of the Mexican Constitution recognises three regimes of land property: public, private and social.

5. *Ejidos* in Mexico are lands communally held by members who do not own their parcels, but can farm them. *Ejidos* are extremely important to the Mexican agricultural sector. According to the Centre of Studies for Rural Sustainable Development and Alimentary Sovereignty (Centro de Estudios para el Desarrollo Rural Sustentable y la Soberanía Alimentaria, CEDRSSA), part of the Chamber of Deputies, agrarian communities (another variant of "social property") and *ejidos* accounted for 51% of the Mexican territory in 2014.

6. For instance, according to Article 27, Letter XV of the Mexican Constitution, and Article 120 of the *Ley Agraria* (Agrarian Law), a "small livestock property" (*pequeña propiedad ganadera*) is the biggest surface extension that an individual can hold (not own). A small livestock property is defined as the surface necessary to maintain up to 500 heads of "major livestock" (e.g. cattle) or its equivalent in "minor livestock" (e.g. pigs). Furthermore, Article 47 of the *Ley Agraria* states that no *ejido* member can hold more than 5% of the total surface of any *ejido*.

7. Article 68 of the Federal Law on Animal Health (Ley Federal de Sanidad Animal) states that the transport of "regulated products" inside the Mexican territory requires a CZM. "Regulated products" are defined as animals, products of animal origin, products for use or consumption by animals, livestock equipment, and any other articles or goods related to animals that might involve a zoosanitary risk. For certain products that SENASICA considers to be of low zoosanitary risk (e.g. pigs and their products and sub-products; poultry, its products and sub-products coming from an area free of influenza), it has replaced the CZM with a Transport Notice (Aviso de Movilización), which is free of charge and can be filled in online at the National Service of Transport Notices (Servicio Nacional de Avisos de Movilización, SNAM).

8. Several state livestock laws refer to transport documents as *guías de tránsito*, but they can have different names depending on the state. According to industry participants, in addition to transport documents, state governments can also require the payment of disinfection certificates and entry permits.

9. Article 13 of the Law on Livestock Associations (Ley de Organizaciones Ganaderas). See Section 3.1.8, "Relevant authorities and trade associations", for a brief description of livestock associations.

10. According to Article 115, Letter III of the Mexican Constitution, TSS abattoirs are public services under the control of municipal governments.

11. In Mexico, there are two kinds of standards: Mexican Official Standards (Normas Oficiales Mexicanas, NOM), issued by the federal government, and with mandatory compliance; and Mexican Standards (Normas Mexicanas, NMX), which are voluntary and issued by national standard-making bodies. For instance, TIF abattoirs must comply with standards such as NOM 008-ZOO-1994 (related to sanitary specifications for the construction and equipment of abattoirs), NOM 009-ZOO-1994 (related to the sanitary processing of meat) and NOM 033-ZOO-1995 (related to humane slaughtering).

12. In 2013, according to the USDA, there existed 113 TIF abattoirs, 844 TSS abattoirs and 144 private abattoirs.

13. Data on animals slaughtered at clandestine abattoirs were not readily available.

14. INEGI's data on value added are not sufficiently disaggregated for the definition set in this assessment. SCIAN code 1121, cattle raising, also includes the production of milk. SCIAN code 1123, poultry production, includes chicken meat, but also chicken eggs and turkey meat. SCIAN code 3111, animal-feed manufacturing, includes feed manufacturing for beef, pigs, poultry, dogs, cats and other animals. SCIAN code 3116, animal slaughtering and processing, includes animals different from chicken, beef and pigs. As a consequence, the value added of animal production, animal-feed manufacturing and animal slaughtering and processing activities with the sole purpose of producing meat are likely to be overestimated.

15. References to "market shares" or "markets" included in this section do not necessarily reflect the definitions used for the purposes of applying competition law.

16. For instance, the last agricultural census carried out by INEGI dates from 2007.

17. The HHI is a measure of concentration that is equal to the sum of the squared market shares of each firm within a market. The HHI takes values between 0 and 10 000.

18. Live-weight meat refers to animals that are commercialised alive, be it for feeding or for slaughtering.

19. https://gain.fas.usda.gov/Recent%20GAIN%20Publications/.

20. With the exception of Pilgrim's Pride and Tyson de México, all the listed companies in Tables 3.1 to 3.3 are Mexican companies.

21. In May 2015, Brazilian company JBS, through its subsidiary Pilgrim's Pride, notified COFECE of its intention to purchase three Mexican subsidiaries of US company Tyson Foods, including Tyson de México.

22. Docket CNT-088-2014. The final resolution is at: www.cofece.mx:8080/cfcresoluciones/docs/Concentraciones/V704/0/2070270.pdf.

23. COFECE determined that in Mexico, Pilgrim's Pride and Tyson competed in the markets of production and distribution of feeder chickens, live chickens and fresh chicken meat (in the market segments of traditional markets, poulterers' shops, supermarkets, and chicken sold in pieces) and added-value fresh chicken products.

24. http://infosiap.siap.gob.mx/anpecuario_siapx_gobmx/ResumenNacional.do, accessed 31 August 2017.

www.industriaavicola-digital.com/201703/#/24, accessed 31 August 2017.

In 2016, according to SIAP, 1 676.866 millions of heads of chicken were slaughtered in Mexico, while the March 2017 edition of the magazine Industria Avícola states that Pilgrim's Pride and Industrias Bachoco produce, annually in Mexico, 470 and 595 millions of heads of chicken, respectively. The volume markets shares result from dividing the number of heads held by each company by the number of slaughtered heads in 2016.

25. Individual market shares of the main meat producers, according to their number of TIF facilities are not readily available.

26. In this section, meat also includes viscera and offal. For more precision on what presentations of meat, viscera and offal were analysed, please see to the tariff codes listed under Figures 3.21, 3.22 and 3.23.

27. See endnote 7 for a definition of "regulated products" in the Federal Law on Animal Health.

28. Article 51 of the Federal Law on Animal Health.

29. The relevant tariff codes used for calculating these percentages are listed under Figures 3.21, 3.22 and 3.23.

30. According to FIRA, between 2005 and 2015 the main epidemiological events for pigs were a pandemic influenza (H1N1) and a classic swine fever outbreak in late 2009, and epidemic porcine diarrhoea in mid-2014. For poultry, the main epidemiological events between 2011 and 2015 were two outbreaks of Newcastle disease in 2011, and five outbreaks of highly pathogenic avian influenza (one each in 2012, 2013 and 2014, and two in 2015). FIRA (2016), *Panorama Agroalimentario. Carne de cerdo 2016*, www.gob.mx/cms/uploads/attachment/file/200634/Panorama_Agroalimentario_Carne_de_Cerdo_2016.pdf; FIRA (2016), *Panorama Agroalimentario. Avicultura carne 2016,* www.gob.mx/cms/uploads/attachment/file/200631/Panorama_Agroalimentario_Avicultura_Carne_2016.pdf.

31. Tariffs on such imports, as of April 2017, were between 20% and 25% for beef (excluding tariff code 02.10.20.01); 75% for chicken meat (excluding tariff codes 02.07.14.02 and 02.10.99.03); and between 10% and 20% for pork (excluding tariff code 02.06.49.01). Data on transport costs for importing meat were not readily

available. Import tariffs for specific tariff codes can be consulted on the website of the Law of the General Taxes of Import and Export (www.siicex-caaarem.org.mx, accessed 11 April 2017).

32. VUCEM currently cooperates with 10 federal public agencies: Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público, SHCP), Ministry of Economy (Secretaría de Economía, SE), Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA), Ministry of Environment and Natural Resources (Secretaría de Medio Ambiente y Recursos Naturales, SEMARNAT), Ministry of National Defence (Secretaría de la Defensa Nacional, SEDENA), Ministry of Health (Secretaría de Salud, SSA), Ministry of Energy (Secretaría de Energía, SENER), National Institute of Anthropology and History (Instituto Nacional de Antropología e Historia, INAH), National Institute of Fine Arts (Instituto Nacional de Bellas Artes, INBA), and Federal Attorney for Environmental Protection (Procuraduría Federal de Protección al Ambiente, PROFEPA).

33. According to Article 6, Letter LIX of the Federal Law on Animal Health (Ley Federal de Sanidad Animal), SAGARPA can certify, verify and inspect the implementation of good livestock practices at TIF establishments.

34. The most relevant NOM for municipal abattoirs is NOM-194-SSA1-2004, Products and Services: Sanitary specifications in establishments dedicated to the slaughter and rendering of livestock for food market, storage, transportation and sale, and sanitary specifications of products, documents and registration.

35. According to Article 3, Letter XXII of the General Health Law (Ley General de Salud), the SSA can inspect the sanitary process of exports and imports. Hence, all abattoirs (including TIF ones) can be inspected by the SSA.

36. For data produced by SIAVI, see www.economia-snci.gob.mx, and for SNIIM, see www.economia-sniim.gob.mx (both accessed 11 April 2017).

37. "Quién es quién en los precios" (Who's Who at Prices), www.profeco.gob.mx/precios/canasta/home.aspx?th=1, accessed 11 April 2017.

38. The Law on Rural Sustainable Development (Ley de Desarrollo Rural Sustentable) states that CIDRS is responsible of submitting the Special Competition Programme for Rural Sustainable Development (Programa Especial Concurrente para el Desarrollo Rural Sustentable, PECDRS) to the President. The last two PECDRS covered, respectively, the periods 2007-2012 and 2014-2018.

39. According to Article 4 of the Regulation of the Law on Livestock Associations (Reglamento de la Ley de Organizaciones Ganaderas), for the livestock sector, SAGARPA will coordinate with CNOG on the national level, and with livestock unions and local livestock associations at state and municipal level.

40. See endnote 11 for an explanation of the two types of standards.

41. www.cofece.mx/cofece/images/Promocion/Miscelanea_Estatal_210916.pdf.

42. This law was first published in the Federal Official Gazette (Diario Oficial de la Federación, DOF) on 6 January 1999. The consulted version of the law was the one with the most recent amendment on 9 April 2012.

43. This law was first published in the DOF on 25 July 2007. The consulted version of the law was the one with the most recent amendment on 7 June 2012.

44. This law was first published in the DOF on 7 February 1984. The consulted version of the law was the one with the most recent amendment 27 January 2017.

45. Through its body the Federal Commission for the Protection Against Sanitary Risks (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS).

46. This law was first published in the DOF on 7 December 2001. The consulted version of the law was the one with the most recent amendment on 12 January 2012.

47. This law was first published in the DOF on 26 February 1992. The consulted version of the law was the one with the most recent amendment on 27 March 2017.

48. This law was first published in the DOF on 3 August 1994. The consulted version of the law was the one with the most recent amendment on 13 August 2009.

49. In the case of this assessment, there were very few recommendations related to the meat sector (e.g. requirement of a separation between workshop and meat retail store; traditional preparations at butcher shops).

50. In the case of this assessment, while several recommendations related to sanitary veterinary norms were made, the overall conclusion was that Romanian meat legislation was harmonised with EU legislation.

51. There were very few recommendations made in respect to meat (e.g. requirements for imported packaged meat) in this *Review*.

52. The relevance of traceability is acknowledged in Volume I of the OIE's Terrestrial Animal Health Code (2016); two chapters (4.1 and 4.2) address this subject.

53. Britt, A.G., C.M Bell, K. Evers, K., R. Paskin (2013), "Linking live animals and products: traceability", *Rev. Sci. Tech.*, 32(2), pp.571-582.

54. Article 4 of the Law on Livestock Associations makes a distinction between "general local livestock associations" and "specialised local livestock associations". The former are associations of livestock producers that rationally rear any animal species within a municipality, while the latter gathers livestock producers of a specific animal species.

55. SINIIGA ear tags are lifetime identification for cattle and can include a microchip that helps farmers monitor health and production of animals.

56. This article also contains another restriction, which deals with public procurement; it is analysed in the Public Procurement category.

57. CIDRS is composed of the ministers of ministries involved to some extent in rural development (i.e. SAGARPA, SE, SEMARNAT, SHCP, SCT, SSA, SEDESOL, SEDATU, SEP and SENER) and by any other ministries or entities that the executive

considers necessary. CIDRS is managed by SAGARPA. In turn, CMDRS is composed by the CIDRS along with accredited representatives from social and private national organisations working within rural areas.

58. In Mexico, there are two types of standards: Mexican Official Standards (Normas Oficiales Mexicanas, NOM), issued by the federal government, which are mandatory; and Mexican Standards (Normas Mexicanas, NMX), which are voluntary and issued by national standard-making bodies.

59. NMX-FF-078-SCFI-2002; NMX-FF-081-SCFI-2003; and NMX-FF-128-SCFI-2016.

60. For instance, according to COFECE (2016), the state livestock law of Sonora (Ley de Ganadería) stipulates that retailers must separate – be it in fridges, shelves or showcases – livestock products from Sonora from livestock products coming from other Mexican states or abroad. Another problem, although more related to the absence of quality standards, is that of "plumping" or "enhancing" of pork. According to industry participant, in severe cases, 40% of the total weight of pork can actually be brine.

61. Some of the elements covered by that classification system are food safe, agro-alimentary quality, authenticity and labelling; allowed denominations; and assessment procedures that will enable the differentiation of meat, "based upon its organoleptic properties".

62. For instance, the state livestock laws of Chiapas (Ley de Fomento y Sanidad Pecuaria), Coahuila (Ley de Fomento Ganadero), Puebla (Ley Ganadera), Querétaro (Ley de Desarrollo Pecuario), Quintana Roo (Ley de Fomento y Desarrollo Pecuario), San Luis Potosí (Ley de Ganadería) and Yucatán (Ley Ganadera).

63. For instance, Chiapas, Coahuila, Puebla, Querétaro and Yucatán.

64. According to Article 4 of the Federal Law on Animal Health, "regulated products" are defined as animals, products of animal origin, products for use or consumption by animals, livestock equipment, and any other articles or goods related to animals that might entail a zoosanitary risk.

65. The language in the NOM is unclear, but presumably this refers to a Zoosanitary Transport Certificate.

66. The language in the NOM is unclear, but presumably this refers to state transport documents.

67. For instance, we examined authorisations related to the operation of TIF abattoirs and meat-processing plants; to the certification of organic products; and the commercialisation of genetically modified organisms.

68. SENASICA, a body of SAGARPA, authorises countries and establishments that export to Mexico.

69. That assessment will take into account variables, including sanitary risks, historical non-compliance, and destination of the product (i.e. TIF establishment or not).

70. The OASA denomination depends on whether their members are agricultural, livestock or aquaculture producers. In the case of livestock producers, OASA are known as Promotion and Protection Livestock Committees (Comités Estatales de Fomento y Protección Pecuaria, CEFPP). Each one of the 32 states of Mexico, except Mexico City, has a CEFPP.

71. Article 4 of the Federal Law on Animal Health provides definitions for the terms "campaign" and "good livestock practices". The former is a set of zoosanitary measures for the prevention, control or eradication of animal diseases or disease outbreaks within a determined geographical area and a phase. Whereas, "good livestock practices" are procedures, activities, conditions and controls applied at animal production units or TIF establishments to reduce the dangers associated to physical, chemical and biological agents, as well as the risks associated with animal-based products consumed by animals.

72. Furthermore, the anti-competitive effect of this provision might be compounded by state legislation. According to COFECE (2016), several state livestock laws promote mechanisms that enable local livestock associations to jointly set the prices or quantities at which they sell their products.

73. The states are Campeche, Coahuila, Tlaxcala, Yucatán, Guerrero and Sinaloa.

74. FAAR are associations of agricultural and livestock producers that provide insurance to their members.

75. This recommendation does not apply to the following five standards, as they are associated with other restrictions: NOM-009-ZOO-1994 (heterogeneity of criteria applied by official TIF veterinary surgeons; NOM-030-ZOO-1995 (the requirement to inspect the totality of lots of imported meat, carcasses, viscera and offal); NMX-FF-078-SCFI-2002 and NMX-FF-081-SCFI-2003 (the absence of NOMs related to the classification of beef, pork and chicken meat carcasses).

76. Emergency cases are defined as unexpected events that are an obstacle to achieving NOMs' objectives set out in Article 40 of the Federal Law on Metrology and Standardisation. NOMs issued under the fast-track procedure must follow scientific principles and aim to prevent irreversible or irreparable harm.

77. Article 32 of the law forbids misleading or abusive advertising, which is defined as advertising that "refers to features or information related to a good, product or service, which might be true or not, and that induces mistakes or confusion because of its inexact, false, exaggerated, partial, deceptive or biased form".

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Annex 3.A1

Summary of quantifications for the meat sector

If these OECD recommendations for the meat sector are fully implemented, benefits are estimated to range between MXN 51.6 million and MXN 348.1 million.

Table 3.A1.1. **Benefits in MXN million**

Restriction		Benefits, lower bound, (MXN, million)	Benefits, upper bound, (MXN, million)
	Veterinary services at TIF establishments	13.3	39.8
	State transport documents	5.4	54.4
	Inspecting 100% of imports	32.9	253.9
Total		**51.6**	**348.1**

Source: OECD analysis.

Annex 3.A2

Veterinary services at TIF establishments

If this OECD recommendation is fully implemented, the benefits are estimated to be between MXN 13.3 million and MXN 39.8 million.

Description and harm

According to Article 108 of the Federal Law on Animal Health, at Federal Inspection Type (Tipo Inspección Federal, TIF)[1] establishments (i.e. abattoirs and meat-processing plants), an Authorised Responsible Veterinary Surgeon[2] (Médico Veterinario Responsable Autorizado, MVRA) must be present during all working hours. According to Article 4 of the Federal Law on Animal Health, an MVRA is: "a professional authorised by the Ministry to collaborate and issue documents at […] TIF establishments for the slaughtering and processing […] to guarantee that what is stated in this law and related regulations is fulfilled. Such a professional will be responsible behind the Ministry." MVRAs are not, however, the only veterinary surgeons present at TIF establishments. Official Veterinary Surgeons (Médicos Veterinarios Oficiales, MVOs) from SENASICA are also present at TIF establishments, although not at all times.

Harm to competition stems from the potential doubling of tasks of MVRAs and MVOs, and interviews with industry participants provided anecdotal evidence that this does take place. Furthermore, the Federal Law on Animal Health and its Regulation states that some tasks can be carried out either by an MVRA or an MVO.[3] The requirement of having an MVRA present during all working hours could be a bigger burden for small TIF establishments.

Recommendation

Amend Article 108 of the Federal Law on Animal Health so that, during all working hours, either an MVRA or an MVO is required. Furthermore, promote a progressive reduction in TIF establishments' reliance on MVRAs. This would allow more substitution between the services of both types of veterinaries and create more flexibility in hiring MVRAs, reducing the overlap of veterinary surgeons. This change would be easier if SENASICA could charge abattoirs and meat-processing plants for the services of MVOs.

Estimates of the benefits arising from the recommendation

The benefit of implementing this recommendation depends on the degree of overlap in the tasks carried out by MVRAs and MVOs. The current degree of overlap is unknown. The OECD team has constructed scenarios to account for this uncertainty.

As of 19 May 2017, there were 790 MVRAs working at TIF establishments.[4] According to SENASICA, MVRAs are paid on average around MXN 14 000 per month, or an annual salary of MXN 168 000.

The estimate of the sum of the salaries of all 790 MVRAs working at TIF establishments is:

$$\text{MXN 132.72 million} = (\text{Number of MVRAs}) \times (\text{Annual salary of MVRA})$$

If TIF establishments were allowed not to have an MVRA during all working hours, they would reduce the number of hired MVRAs. The extent of the reduction of hired MVRAs is unknown and depends on the overlap between tasks carried out by MVRAs and MVOs. The following table shows the savings of TIF establishments depending of the percentage reduction of MVRAs hired.

Table 3.A2.1. **Savings of TIF establishments depending on the percentage reduction of MVRAs hired**

	Scenario 1: 10%	Scenario 2: 20%	Scenario 3: 30%
Savings(MXN, millions)	13.27	26.54	39.82

Source: OECD analysis.

Notes

1. TIF abattoirs and meat-processing plants are establishments regulated by the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA). These facilities have more rigorous controls of sanitary conditions than municipal abattoirs and processing plants.
2. MVRAs are veterinary surgeons hired by TIF establishments and in charge of ensuring compliance with SENASICA regulation; they are paid by TIF establishments.
3. For instance, Article 247, Letter II, Sub-letter b) of the Regulation of the Federal Law on Animal Health states that zoosanitary documents that attest to tests, vaccines or treatments having been carried out can be signed either by an MVO or an MVRA.
4. The list of MVRAs that, as of 19 May 2017, worked at TIF establishments is available at: www.gob.mx/cms/uploads/attachment/file/224409/DIRECTORIO_MVRATIF_19-05-2017.pdf, accessed 25 May 2017.

Annex 3.A3

State transport documents

If this OECD recommendation is fully implemented, the benefits are estimated to be between MXN 5.4 million and MXN 54.4 million.

Description and harm

Several state governments require transport documents to transport live animals, their products and sub-products within states. These transport documents focus on documenting ownership, but can also focus on zoosanitary issues. In some states, these documents can be issued by local livestock associations.

At the federal level, there already exist zoosanitary documents for transporting live animals, their products and sub-products: a Zoosanitary Transport Certificate (Certificado Zoosanitario de Movilización, CZM), issued by SENASICA, for goods with moderate to high zoosanitary risk; and a Transport Notice (Aviso de Movilización), for goods with low zoosanitary risk. The Federal Law on Animal Health states that SAGARPA, of which SENASICA is a body, has the exclusive power to determine the zoosanitary requirements to transport "regulated products" across the country, and that state authorities cannot impose stricter requirements.

There is harm to competition, as producers interested in commercialising their products in different states have to pay several transport documents to bring their products from the point of production to points of sale. This makes their products more expensive and discriminates in favour of producers that produce and commercialise their products in the same state.

Recommendation

Our recommendation is to abolish the requirement of state transport documents. The Zoosanitary Transport Certificate and the Transport Notice should replace in all instances state transport documents.

Estimates of the benefits arising from the recommendation[1]

A major difficulty for estimating the benefit of the recommendation is that transport-document fees vary between states.[2] Furthermore, rates of fees are not readily accessible and in some instances, are determined by municipal authorities.[3] Moreover, these fees can be per head or per lot.

SENASICA provided the OECD with the following table, which contains data of the number of transport documents for cattle, for the states where transport documents are issued through the Electronic Cattle Transport Registry (Registro Electrónico de Movilización de Ganado, REEMO).[4] The table only contains statistics for 23 of the 32 Mexican states.

Table 3.A3.1. **Transport documents issued at several Mexican states**

State	Starting month	No. of transport documents issued up to April 2017	Number of animals
Aguascalientes	December 2016	100	492
Baja California	September 2016	2 685	20 279
Baja California Sur	October 2016	3 147	26 397
Campeche	February 2012	180 784	868 818
Chihuahua	February 2015	386 435	2 650 621
Ciudad de México	December 2016	29	119
Coahuila	July 2015	48 883	331 499
Colima	September 2016	16 181	58 904
Durango	May 2014	210 381	1 040 832
Guanajuato	February 2017	4 838	11 897
Guerrero	July 2016	5 053	20 130
Hidalgo	September 2015	8 360	25 740
Jalisco	July 2016	8 843	38 090
Estado de México	June 2016	10 032	27 308
Nuevo León	January 2016	8 478	138 462
Puebla	June 2016	1 391	5 844
Quintana Roo	January 2015	10 787	54 769
San Luis Potosí	July 2016	3 147	11 977
Sinaloa	June 2015	50 981	121 887
Tabasco	April 2017	743	9 727
Tamaulipas	October 2014	143 100	882 773
Yucatán	March 2015	32 220	174 143
Zacatecas	May 2014	102 029	293 673
Total	**-**	**1 238 627**	**6 814 381**

Source: SENASICA, with data from REEMO.

The following table was created using that data:

Table 3.A3.2. **Annual number of transport documents issued, by state**

State	Number of months between the starting month and April 2017	Monthly average of transport documents issued	Annual average of transport documents issued
Aguascalientes	5	20	240.0
Baja California	8	336	4 027.5
Baja California Sur	7	450	5 394.9
Campeche	63	2 870	34 435.0
Chihuahua	27	14 312	171 748.9
Ciudad de México	5	6	69.6
Coahuila	22	2 222	26 663.5
Colima	8	2 023	24 271.5
Durango	36	5 844	70 127.0
Guanajuato	3	1 613	19 352.0
Guerrero	10	505	6 063.6
Hidalgo	20	418	5 016.0
Jalisco	10	884	10 611.6
Estado de México	11	912	10 944.0
Nuevo León	16	530	6 358.5
Puebla	11	126	1 517.5
Quintana Roo	28	385	4 623.0
San Luis Potosí	10	315	3 776.4
Sinaloa	23	2 217	26 598.8
Tabasco	1	743	8 916.0
Tamaulipas	31	4 616	55 393.5
Yucatán	26	1 239	14 870.8
Zacatecas	36	2 834	34 009.7
Total	**-**	**45 419**	**545 029**

Source: SENASICA, with data from REEMO, and OECD Analysis.

According to this computation, on average 545 029 transport documents are issued annually in these 23 Mexican states. The average fee for transport documents is unknown; in 2017, the SENASICA-issued CZM costs MXN 99.82. The OECD hypothesizes three scenarios for the average cost of transport documents:

1. This cost is 10% of the cost of a CZM: MXN 9.982
2. This cost is 50% of the cost of a CZM: MXN 49.91
3. This cost is the same as that of a CZM: MXN 99.82

Benefits arising from the recommendations are equal to:

(Number of transport documents issued)×(Average fee of a transport document)

The following table provides benefit estimates for these three scenarios:

Table 3.A3.3. **Savings due to the elimination of transport documents**

	Cost of a state transport document as a percentage of the cost of a CZM		
	Scenario 1 10%	Scenario 2 50%	Scenario 3 100%
Benefit (MXN)	5 440 481.17	27 202 405.86	54 404 811.71

Source: OECD Analysis.

Notes

1. This estimate does not take account the internal savings that meat companies might experience if they no longer had to research the fees of transport documents for various states, or the costs for preparing documents. Savings might therefore be even higher.
2. For instance, transport documents seem to be free in some states, and one instance was found where it cost as much as MXN 500.
3. According to a press article, in the case of Chihuahua state, which has 67 municipalities, fees can vary between MXN 0.81 and MXN 75, https://www.relevanciachihuahua.com/single-post/2017/04/06/El-pase-de-ganado-tendr%C3%A1-la-misma-tarifa-en-todo-el-Estado-Diputado-Villarreal (accesed 10 October 2017).
4. As the REEMO platform was only recently adopted, it is possible that it does not keep track of all state transport documents.

Annex 3.A4

Inspecting 100% of imported lots of meat, carcasses, viscera and offal

If this OECD recommendation is fully implemented, the benefits are estimated to be between MXN 32.9 million and MXN 253.9 million.

Description and harm

According to Article 4.1 of NOM-030-ZOO-1995, all imported lots of meat, carcasses, viscera and offal must be inspected in line with the specifications laid out in the Zoosanitary Requirements Form (Hoja de Requisitos Zoosanitarios). This requirement is excessive and unnecessarily costly, and might not even be feasible.

Recommendation

The OECD suggests implementing an inspection system under which both the timing and number of controls as well as the amount of samples taken to be inspected would be chosen based on a risk assessment.

Estimates of the benefits arising from the recommendation[1]

The OECD assumes that currently 100% of imported lots of meat, carcasses, viscera and offal are inspected in line with the specifications laid out in the Zoosanitary Requirements Form. Following is an estimate of the benefits arising from adopting a system under which both the timing and number of controls, as well as the amount of samples to be inspected, would be chosen based upon a risk assessment. As not 100% of lots are currently inspected in practice – since compliance with this requirement is not always feasible – the benefits of adopting a new inspection system might be lower than stated.

To begin with, suppose that the new system is such that a proportion $\mathbf{x}$ ($0<x<1$) of lots are inspected. Furthermore, suppose that the cost of inspecting any given volume of imported lots amounts to a proportion $\mathbf{y}$ ($\mathbf{0 < y < 1}$) of its value. If V is the value of all imported lots, then the cost of inspecting the totality of lots equals $\mathbf{yV}$. Under the new system, where only a proportion of $\mathbf{x}$ of lots is inspected, the cost of inspection equals $\mathbf{xyV}$. Hence, savings from adopting the new system are equal to:

$$\mathbf{yV - xyV = (1 - x)yV}$$

From the formula, it can be seen that savings decrease in the sample size of the new inspection system, and increase in the cost of inspection. The OECD estimates the benefits from adopting a new system of inspection by computing $\mathbf{V}$, and then making assumptions on $\mathbf{x}$ and $\mathbf{y}$.

For estimating the value of imported lots of meat, carcasses, viscera and offal, the OECD team consulted the Mexican Tariff Information System (Sistema de Información

Arancelaria Vía Internet, SIAVI).[2] NOM-030-ZOO-1995 does not specifically state what tariff codes are subject to inspection, so codes whose title refers to meat, carcasses, viscera or offal were selected. However, there is a possibility that the following table includes tariff codes for which an inspection is not required, in which case benefits would be overestimated.

Table 3.A4.1. **Value of imported meat, carcasses, viscera and offal (USD, 2016)**

Beef		Pork		Chicken	
Tariff code	Value	Tariff code	Value	Tariff code	Value
02.01.10.01	0	02.03.11.01	7 412 855	02.07.11.01	3 029 967
02.01.20.99	26 778 144	02.03.12.01	948 557 707	02.07.12.01	696 855
02.01.30.01	662 367 304	02.03.19.99	127 820 337	02.07.13.01	97 498 273
02.02.10.01	0	02.03.21.01	58 216	02.07.13.02	24 502 564
02.02.20.99	4 155 721	02.03.22.01	13 017 760	02.07.13.03	180 703 519
02.02.30.01	39 085 974	02.03.29.99	215 428 477	02.07.13.99	96 896 928
02.06.10.01	8 819 636	02.06.30.01	60 981 403	02.07.14.01	35 370 122
02.06.21.01	15 632 526	02.06.30.99	24 168 749	02.07.14.02	0
02.06.22.01	2 825 774	02.06.41.01	71 319	02.07.14.03	348
02.06.29.99	136 334 593	02.06.49.01	21 225 462	02.07.14.04	88 153 970
02.10.20.01	27 058	02.06.49.99	86 490 709	02.07.14.99	176 734 759
		02.10.11.01	3 929 212	02.10.99.03	420 409
		02.10.12.01	64 220 903		
		02.10.19.99	22 437 746		
Sum	896 026 730		1 595 820 855		704 007 714
Total			**3 195 855 299**		

Source: SIAVI, www.economia-snci.gob.mx.

From the table, it can be observed that, in 2016, the value of all imported lots of meat, carcasses, viscera and offal of beef, pork and chicken, was equal to USD 3 195 855 299. Taking an exchange rate of 18.691 MXN per USD[3] for 2016, **V** equals MXN 59 733 731 394.

Estimating the benefits of adopting the new system requires allowing for scenarios for **x** and **y**. For instance, if x=0.15 and y=0.003, it means that, under the new inspection system 15% of lots are inspected and the cost of inspection amounts to 0.3% of the value of imports. In that case, using the previously introduced formula, savings from adopting the new system would be equal to:

$$\text{MXN } (1-0.15)\times 0.003\times 59\,733\,731\,394 = \text{MXN } 152\,321\,015.05$$

For the sample size of the new inspection system (**x**), values of 0.15, 0.30, 0.45 were chosen, whereas for the parameter (**y**), associated to costs of inspections, values of 0.001, 0.003 and 0.005 were chosen. There was no particular reason for the selection of these values of **x** and **y**.

The following table summarises savings associated to nine combinations of scenarios on the inspection costs and the new inspection system's sample size.

Table 3.A4.2. **Scenarios of savings from adopting a new inspection system (MXN)**

		Scenarios on the sample size of the new inspection system (x)		
		0.15	0.30	0.45
Scenarios on the cost of inspection (y)	0.001	50 773 671.68	41 813 611.98	32 853 552.27
	0.003	152 321 015.05	125 440 835.93	98 560 656.80
	0.005	253 868 358.42	209 068 059.88	164 267 761.33

Source: OECD analysis

Notes

1. These savings do not take into account the opportunity cost of increased waiting periods at the frontier caused by inspecting 100% of lots. Savings might therefore be even higher.
2. www.economia-snci.gob.mx.
3. This is based upon the average of monthly average exchange rates for settling debts in foreign currency (FIX), reported by the Central Bank of Mexico (Banco de México) (www.banxico.org.mx/SieInternet/consultarDirectorioInternetAction.do?sector=6&accion=consultarCuadro&idCuadro=CF86&locale=es).

Annex A

Methodology

This study covers two sectors of the Mexican economy: the production and marketing of meat and medicines in Mexico along the vertical value chain (production, wholesale, and retail). The sectors to be studied were selected in consultation with the Mexican Ministry of Economy.

The assessment of laws and regulations in these sectors and its subsectors has been carried out in four stages. The present annex describes the methodology followed in each of these stages.

Stage 1: Mapping the sectors

The objective of Stage 1 of the project was to identify and collect all sector-relevant laws and regulations. As a prior condition, it was necessary to define the scope of the two sectors and their respective subsectors in detail. For this purpose, the OECD team relied on the Mexican classification system SCIAN 2013 (henceforth SCIAN), which classifies all economic activities in standardised categories. Some SCIAN codes coincide with those of NAICS 2012 (henceforth NAICS), the United States and Canada's classification system. However, it is important to note that while SCIAN was conceived as the Mexican counterpart of NAICS, some of SCIAN codes are not directly comparable.

The task of collecting the relevant legislation for each of the sectors was conducted by the OECD team using a variety of sources. The main tools used to identify the applicable legislation were the online databases of the Mexican Chamber of Deputies,[1] the Federal Official Gazette (Diario Oficial de la Federación, DOF),[2] and the website of the Mexican Supreme Court.[3] This was complemented by websites of the relevant authorities and of trade and consumer associations. In addition, in order to ensure that all important pieces of legislation were covered by the study, input was solicited from all the competent authorities involved in the selected sectors, as well as from stakeholders. In total, 228 different pieces of legislation were identified during Stage 1.

Stage 2: Screening the legislation and selection of provisions for further analysis

In the Stage 2 of the project, the main work was screening the legislation to identify potentially restrictive provisions, as well as providing an economic overview of the relevant sectors. Every piece of legislation was scanned by two team members ("four-eyes-principle").

Box A.1. **OECD Competition Checklist**

Further competition assessment should be conducted if a piece of legislation "answers yes" to any of the following questions:

A. Limits the number or range of suppliers

This is likely to be the case if the piece of legislation:

1) grants a supplier exclusive rights to provide goods or services
2) grants a licence, permit or authorisation process as a requirement of operation
3) limits the ability of some types of suppliers to provide a good or service
4) significantly raises the cost of entry or exit by a supplier
5) creates a geographical barrier to the ability of companies to supply goods, services or labour, or invest capital.

B. Limits the ability of suppliers to compete

This is likely to be the case if the piece of legislation:

1) limits sellers' ability to set the prices of goods or services
2) limits the freedom of suppliers to advertise or market their goods or services
3) sets standards for product quality that provide an advantage to some suppliers over others or that are above the level that some well-informed customers would choose
4) significantly raises the costs of production for some suppliers relative to others (especially by treating incumbents differently from new entrants).

C. Reduces the incentive of suppliers to compete

This may be the case if the piece of legislation:

1) creates a self-regulatory or co-regulatory regime
2) requires or encourages information on supplier outputs, prices, sales or costs to be published
3) exempts the activity of a particular industry or group of suppliers from the operation of general competition law.

D. Limits the choices and information available to customers

This may be the case if the piece of legislation:

1) limits the ability of consumers to decide from whom they purchase
2) reduces the mobility of customers between suppliers of goods or services by increasing the explicit or implicit costs of changing suppliers
3) fundamentally changes the information required by buyers to shop effectively.

Source: OECD (2011a)

The legislation collected in Stage 1 was analysed using the framework provided by the OECD *Competition Assessment Toolkit*. This toolkit, developed by the Competition Division at the OECD, provides a general methodology for identifying unnecessary obstacles in laws and regulations, and developing alternative, less restrictive policies that still achieve government objectives. One of the main elements of the toolkit is a

Competition Checklist that asks a series of simple questions to screen laws and regulations that have the potential to unnecessarily restrain competition.

Following the toolkit's methodology, the OECD team compiled a list of all the provisions that answered any of the questions in the checklist positively. The final list consisted of 176 provisions across the sectors, broken down by the sectors as follows:

- Meat: 76
- Medicines: 100.

For both sectors, the OECD team also prepared an extensive economic overview, covering industry trends and main indicators, such as output, employment and prices, including comparisons with other OECD member countries where relevant. The team also analysed summary statistics on the main indicators of the state of competition typically used by competition authorities, especially information on the market shares of the largest players in each sector. Where possible, these statistics were broken down by sub-sector. The analysis conducted at this stage was aimed at finding background information to better understand the sectors' mechanisms, provide an overall assessment of competition, and explain each sector's most important players and authorities.

Stage 3: In-depth assessment of the harm to competition

The provisions carried forward to Stage 3 were investigated in order to assess whether they could result in harm to competition. In parallel, the team researched the policy objectives of the selected provisions so as to better understand the regulations. An additional purpose in identifying the objectives was to prepare alternatives to existing regulations, taking account of the objective of the specific provisions when required, for Stage 4. The objective of the policymaker was researched in the recitals of the legislation, when applicable, or through discussions with the relevant public authorities.

The in-depth analysis of the harm to competition was carried out qualitatively and involved a variety of tools, including economic analysis and research into the regulations applied in other OECD countries. All provisions were analysed, based upon guidance provided by the OECD's *Competition Assessment Toolkit*. Interviews with government experts complemented the analysis by providing crucial information on the lawmakers' objectives, as well as the actual implementation and effects of the provisions.

An extremely important task begun during Stage 3 was establishing contact with the market through the main industry associations active in each sector. Interviews with market participants contributed to a better understanding of how the sub-sectors under investigation work in practice and helped in the discussion of potential barriers deriving from the legislation.

Stage 4: Formulation of recommendations

Building on the results of Stage 3, we developed preliminary recommendations for those provisions that were found to restrict competition. We tried to find alternatives that were less restrictive for suppliers but were still close to the policymaker's initial objective. In this process, we relied on international experience whenever available.

Additionally, to analyse the benefits of removing barriers to competition, whenever feasible and appropriate for the analysis of the issue under consideration, the OECD team gathered data that could be used for quantifying the effects. In these cases, the data were

analysed using econometric techniques. In other cases, the expected impact of a regulatory restriction could not be modelled directly because of the lack of sufficient data. Therefore, we relied on the standard methodology of measuring the effect of policy changes on consumer surplus. In particular, we followed the approach in OECD (2015), which derives a formula for changes in consumer benefit when only sector revenue and the average price effect of the restriction found are available. This is explained in Box A.2 below.

In a workshop held in April 2017, the OECD team presented preliminary recommendations to the relevant Mexican authorities and asked for their views on recommendations. Their comments were taken into account when deciding on final recommendations.

In total, 107 recommendations were submitted to the Mexican Ministry of Economy:

- Medicines: 50
- Meat: 57.

Capacity building

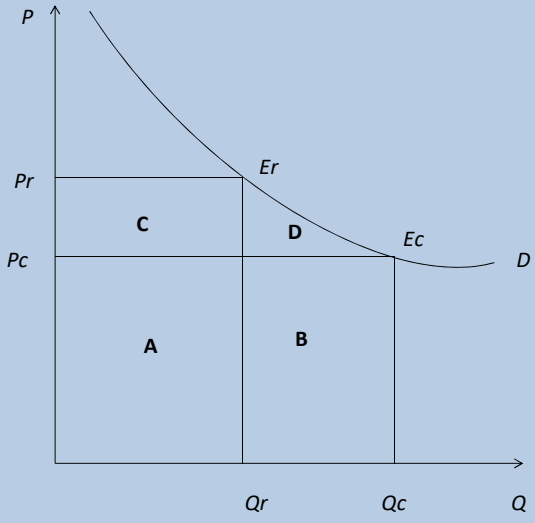
Another important work stream in the project was to provide assistance in building up the competition-assessment capabilities of the Mexican administration. To this end, officials from the relevant Mexican authorities participated in two full-day workshops to gain exposure to the application of the OECD *Competition Assessment Toolkit*. Experts participated from the Ministry of Economy; National Service for Agro-Alimentary Public Health (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria); Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS); Federal Telecommunications Institute (Instituto Federal de Telecomunicaciones, IFT); Federal Attorney's Office of Consumer (Procuraduría Federal del Consumidor, PROFECO); Federal Economic Competition Commission (Comisión Federal de Competencia Económica, COFECE); Federal Commission for Regulatory Improvement (Comisión Federal de Mejora Regulatoria, COFEMER); Federal Judicial Council (Consejo de la Judicatura Federal); Ministry of Health; and Central Bank of Mexico (Banco de México, Banxico).

More specifically, at the beginning of the project in September 2016, the OECD team organised a workshop that provided an overview of the Mexican Competition Assessment Project and gave an introduction to competition policy, as well as the OECD *Competition Assessment Toolkit*. The workshop explained the tasks in Stage 1 and 2 and explained the principles for screening of legislation. In April 2017, the team held an additional full-day workshop during which the methodology for qualitative and quantitative analysis of restrictive provisions was discussed and preliminary results presented. The team discussed harm to competition with reference to specific provisions and asked for feedback on possible alternatives to achieve the same policy objectives while minimising harm.

Box A.2. **Measuring changes in consumer surplus**

The effects of changing regulations can often be examined as movements from one point on the demand curve to another. For many regulations that have the effect of limiting supply or raising prices, an estimate of consumer benefit or harm with the change from one equilibrium to another can be calculated. Graphically, the change is illustrated by a constant elasticity demand curve. *Er* shows the equilibrium with the restrictive regulation; *Ec* shows the equilibrium point with the competitive regulation. The competitive equilibrium is different from the restrictive regulation equilibrium in two important ways: lower price and higher quantity. These properties are a well-known result of many models of competition.

Figure A.1 **Changes in consumer surplus**



Source: Ennis, S. (2017), "Estimating consumer benefits of pro-market regulatory reform", draft working paper, Competition Division, OECD, January 2017.

Under the assumption of constant elasticity of demand, the equation for consumer benefit is:

$$CB = C + D \approx (P_r - P_c)Q_r + \frac{1}{2}(P_r - P_c)(Q_c - Q_r)$$

Where price changes are expected, a basic formula for such a standard measure of consumer benefit from eliminating the restriction is:

$$CB = \left(\rho + \frac{1}{2}\epsilon\rho^2\right)R_r$$

Where CB represents consumer harm, ρ represents the percentage change in price related to the restriction, R_r represents sector revenue and ε is the demand elasticity.

When elasticity is not known, it is worth noting that if |ε|=2, which would correspond to more elastic demand than in a monopoly market, but also far from perfectly elastic as in a competitive market, the expression above simplifies to:

$$CB = (\rho + \rho^2)R_r$$

Source: OECD (2015).

Notes

1. www.diputados.gob.mx/LeyesBiblio/index.htm.
2. http://dof.gob.mx.
3. http://legislacion.scjn.gob.mx/Buscador/Paginas/Buscar.aspx.

References

OECD (2011a), *Competition Assessment Toolkit: Principles*, www.oecd.org/daf/competition/46193173.pdf.

OECD (2011b), *Competition Assessment Toolkit: Guidance*, www.oecd.org/daf/competition/45544507.pdf.

OECD (2015), *Competition Assessment Toolkit, Volume III: Operational Manual,* www.oecd.org/daf/competition/COMP_Toolkit_Vol.3_ENG_2015.pdf.

Annex B

Legislation screening by sector

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
1.	**No law addresses this issue yet**		Relationship between the industry and doctors / Incentives	Mexico currently has no law regulating which benefits pharmaceutical companies can provide to doctors, such as conference participations, speaker engagements, etc. There is, however, an ethics code issued by CETIFARMA (a subsidiary of CANIFARMA, which regulates and monitors the ethics code), which addresses financial incentives. This ethics code, however, only applies to CANIFARMA members. According to the CETIFARMA document, providing financial incentives of significant value to doctors is forbidden. Infringement of the code is subject to admonition, pecuniary penalties (no amounts are detailed, though), as well as temporary or definitive suspension of the rights as a CANIFARMA affiliate.		D1	A 2016 analysis by ProPublica showed that doctors in the United States who received pecuniary advantages were two to three times more likely to prescribe brand-name drugs instead of generics. Doctors who received more than USD 5 000 worth of advantages from companies in 2014 typically had the highest brand-name prescribing percentages. (See, www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs). **International comparison** The risk described above has led to various regulatory responses. Two main models have emerged: 1) The European model bans pecuniary advantages, as a general rule. See, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use. According to Article 94 of the directive, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or	Despite the existence of CETIFARMA's Ethics Code, according to market participants, providing pecuniary advantages to doctors is not a rare practice among pharmaceutical companies. Not all pharmaceutical companies are members of CANIFARMA (87%, according to the trade association itself) and so bound by its code of conduct. A lack of binding governmental regulation in this field may hinder competition among similar products. Some pharmaceutical companies might provide benefits to doctors with the result of those doctors preferring their product instead of the one they regard as best suited or most economic for patients. Products of pharmaceutical companies that comply with the CETIFARMA code of	Issue a binding regulation determining the exact conditions under which pecuniary advantages or benefits of significant value to doctors can be granted. This regulation should contain sanctions in case of infringement of the conditions. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, as well as the CETIFARMA Code of Ethics might be used as a starting point.

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							pharmacy. Also, hospitality at sales-promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than health-care professionals. 2) The US model is mainly based on self-regulation and requires pharmaceutical companies to disclose financial agreements they may have with doctors. Nonetheless, the US model also bans, as a general rule, gifts of significant value. (See, Department of Health and Human Services – Office of the Inspector General OIG compliance program guidance for pharmaceutical manufacturers. Federal Registry, 2003, and Pharmaceutical Research and Manufacturers of America. PhRMA code on interactions with healthcare professionals. Washington, D.C., 2008).	conduct or whose producers do not supply any benefits to doctors for other reasons might be discriminated against. The situation might be aggravated by the fact that pharmaceutical companies are, at least theoretically, able to gather data concerning the prescribing practice of individual doctors – which allows them to target and monitor those doctors.	
2.	**Reglamento de Insumos para la Salud**	117	Pharma. Retail/ Risk of foreclosure	The pharmaceutical retailer registers in a control book or in an automatised system the name, address and professional-licence number of the prescribing physician at the moment of the sale of medicines whose prescription is retained by the pharmacy. It is unclear what happens to this data and whether they	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas	C2	The objective of the provision is likely to assure the prescription's authenticity and to control a pharmacy's stock concerning prescription-only products (e.g. antibiotics, psychotropic and narcotics). This allows health authorities to control the stock of prescription drugs and ensure that they are only sold to	Pharmaceutical companies are interested in monitoring the prescription practice of doctors to steer their marketing efforts. To do this, the former generally find it helpful to acquire data as detailed as possible	Prohibit pharmacies from passing on personalised data from doctors or patients to pharmaceutical or any other companies (e.g. companies that collect and market data). Selling of aggregated data – data that cannot be traced back to the prescribing

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
				might be sold directly or via specialised companies to pharmaceutical companies.			patients with a doctor's prescription.	about doctors' prescription practices. If pharmaceutical companies could buy data about the prescription practice of individual doctors, it would allow them to monitor whether those doctors prescribe their products and favour their company over others. This practice might be harmful as there are currently no binding rules that clarify the conditions under which incentives can be granted to doctors by pharmaceutical companies (see above). Theoretically, pharmaceutical companies might monitor the prescription practice of all active doctors and only incentivise doctors (e.g. through conference invitations) that mainly prescribe their products.	practice of individual doctors or the drugs used by an individual patient – should be allowed, however, as it allows pharmaceutical companies to efficiently benchmark, plan and calculate their output and marketing efforts.
3.	**Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de**	64	Pharma. Prescription of medicines / Information monitoring	Prescriptions of a medicine by a doctor must contain the doctor's name, the name of the institution that issued his/her professional title, the	a) Ministry of Health (Secretaría de Salud) b) State	C2	The law does not specify any particular objective. However, a possible explanation may be to ensure a prescription's authenticity. This objective	Theoretically, pharmacies could collect this data and sell them, directly or through intermediate	No recommendation. Assuring the authenticity of a prescription is a valid objective. Monitoring of the

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
	Atención Médica			number of the professional certificate issued by the competent educational authorities, the address of the establishment (e.g. a hospital or a pharmacy), and the date of issue.	governments (Gobiernos de las entidades federativas)		seems reasonable.	companies, in individualised or aggregated form to pharmaceutical companies. This data could be used for monitoring doctors. This issue might be aggravated by the fact that there are no binding rules regulating the sponsoring of doctors in Mexico.	prescribing practice of individual doctors by pharmaceutical companies can be avoided by the solutions presented above.
4.	**Acuerdo por el que se determinan los lineamientos a los que estará sujeta la venta y dispensación de antibióticos.**	Second	Pharma. Sale of medicines / Information monitoring	For prescriptions of antibiotics, pharmacies must register, among other data, the name of the doctor prescribing the medicine, his or her professional-licence number, and address.	a) Ministry of Health (Secretaría de Salud)	C2	The law does not specify any particular objective. Nonetheless, possible objectives may be to ensure a prescription's authenticity, control the prescription antibiotics stocks, and avoid patient self-medication. These objectives are reasonable, especially when considering the importance of controlling antibiotic overconsumption.	Theoretically, pharmacies could collect this data and sell them, directly or through intermediate companies, in individualised or aggregated form to pharmaceutical companies. This data could be used for monitoring doctors. This issue might be aggravated by the fact that there are no binding rules regulating the sponsoring of doctors in Mexico.	No recommendation. Assuring the authenticity of a prescription is a valid objective. Monitoring of the prescribing practice of individual doctors by pharmaceutical companies can be avoided by the solutions presented above.

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
5.	**Reglamento de Insumos para la Salud**	31	Pharma. Sale of medicines / Consumer choice	When prescribing a medicine, doctors can either prescribe the International Nonproprietary Name (INN, defined by the WHO as a unique name that is globally recognised and is public property) or the joint generic and distinctive designation (brand name) (such as, salbutamol and "Ventolin"; ibuprofen and "Advil"; or paracetamol and "Tylenol"). When doctors prescribe a distinctive denomination, pharmacists must follow the prescription and the medicine can only be replaced if the doctor expressly authorises it.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	D1, D2	To protect the Mexican population against sanitary risks. There is a widespread belief among the Mexican population that generics are not as effective as the original drug (i.e. medicine protected by a patent or whose patent has expired). However, concerns over generics' safety and effectiveness compared to original medicines would appear unfounded as generics are therapeutically equivalent to original medicines, while offering significant cost savings with no adverse health effects. **International comparison** In several OECD member states, substitution by pharmacists is mandatory (Denmark, Estonia, Finland, Germany, Italy, Slovak Republic, Spain and Sweden) meaning that the pharmacist is obliged to substitute a medicine with its cheaper alternative. For instance, since 2012 in Italy, pharmacists have to substitute branded drugs with the lowest-priced generic, while in Sweden, they have to substitute with the lowest-cost	Consumers are forced to buy the branded medicine if the doctor prescribes it. Generics may face a competitive disadvantage if doctors prefer certain branded medicines and do not include generics on their prescriptions or authorise the substitution of the branded product. The harm to the consumer might be aggravated if doctors are not objective in their prescription practice, e.g. following incentivisation by the pharmaceutical companies (see, restrictions related to incentivisation of doctors).	Option 1) Amend the provision in order to oblige pharmacists to inform patients about the cheapest available generic and allow the substitution of prescribed medicines with this generic when the patient agrees, unless the doctor has specified "substitution not allowed" in the prescription (which might be necessary if certain patients do not react well to substitutes of a certain medicine). The OECD recommends making the substitution optional, not mandatory because most purchases in Mexico are customer out-of-pocket spending and customers must be able to purchase the medicine they perceive to be best (placebo effect). Option 2) Introduce a provision that requires doctors to only prescribe INN medicines, i.e. containing the active substance, but without a brand name.

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							substitutable product unless the prescription states that substitution is not allowed. In a majority of OECD member states, pharmacists are allowed to inform patients about generic substitutions of brand-name medicines, if the patient agrees and the prescribing doctor does not object in the prescription (e.g. Czech Republic). See, OECD (2016), Health Working Paper No.87 "Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges", p.30. Several OECD member states require doctors to prescribe the generic denomination, e.g., Estonia, Portugal, Spain, and France. See, OECD (2016), *Health at a Glance: Europe 2016 State of Health in the EU Cycle*, p.182. Giving patients the possibility of choosing between the patented or generic drug ensures they benefit from the placebo effect. "Research has shown that a placebo treatment can have a positive therapeutic effect in a patient, even though the pill or treatment is not active (as long as the patient believes the treatment is taking place). This is known as the 'placebo		

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							effect' or 'placebo response'." (www.drugs.com/article/placebo-effect.html).		
6.	**Reglamento de Insumos para la Salud**	32	Pharma. Public procurement / Limitation, discrimination	Doctors working for public institutions can only prescribe generics that are included in the Basic Formulary of Inputs. The Basic Formulary specifies the features a product must have in order to be considered as a public-sector option. This list does not specify manufacturers, but sometimes requires extremely specific features (e.g. alcohol contained in 120ml bottles).	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A3	The purpose of the Basic Formulary is to keep an updated list of the medicines required by the Mexican health-sector institutions to address the main health problems affecting the Mexican population and to guarantee the effectiveness and safety of medicines, their efficient and timely supply, rational prescription, and sale at a reasonable cost. Medicines in the Basic Formulary have been evaluated and approved by the Basic Formulary and Health Sector Input Catalogue Inter-Institutional Commission (Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud) taking into account disease prevalence and public-health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness. **International Comparison** According to the WHO, essential medicines are those that satisfy the priority health-care needs of the population. The WHO publishes a Model List	This provision excludes all pharmaceutical companies whose generics are not part of the list from the public-sector market, because, for example, an active ingredient or dosage type manufactured by a pharmaceutical company does not figure on the list. The manufacturer is therefore unable to supply its medicines to the public sector.	No recommendation for change as the Basic Formulary seems to be in accordance with international standards.

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							(www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1), which serves as a guide for the development of national and institutional essential medicine lists. Several other OECD countries besides Mexico have comparable national medicines list, including Chile, Slovak Republic and Slovenia. In Mexico, the Basic Formulary has helped to homogenise procurement policies of the national health system's federal public institutions.		
7.	**NOM-177-SSA1-2013, Que establece las pruebas y procedimientos para demostrar que un medicamento es intercambiable**	6.2.8.	Pharma. Production of medicines / Limitation, barrier to entry	According to the General Health Law, to be considered as generic, medicines must be interchangeable with a reference drug, i.e. the generics must produce the same therapeutic effect. In order to be considered as an interchangeable medicine the "percentage of valuation" of the test medicine must be within the limits stated in the Pharmacopoeia. This difference can only be up to 5% from the reference medicine. The method of determining the 5% threshold, however, is not clearly described (at least	a) Ministry of Health through COFEPRIS b) State governments (Gobiernos de las entidades federativas)	A3	The objective of this provision is to define the criteria and specifications that should be observed during the performance of the tests carried out to demonstrate the interchangeability of generic medicines. According to COFEPRIS, the valuation rate could vary if the medicine is considered to be "variable". However, the NOM does not provide a clear description of when a medicine is considered to be variable and which valuation rate would apply in that case. **International comparison** In the European Union, a generic medicine is defined as	The standard for the "percentage of valuation" may work as a barrier to entry for products that do not meet the 5% difference threshold. The rule might also be too inflexible, not taking into account the specifics of each medicine. Some generics might only require a maximum difference of 1% to perform the same function, while others might be 10%. It is not clear whether a margin of error	Clarify the methodology to determine if a medicine is considered to be variable. Also, clarify if the applied method is equivalent to other jurisdictions (e.g. the United States, European Union). Make the methodology easily available on the COFEPRIS website.

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
				to the lay reader).			a medicine that "has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies" and "[f]ollowing the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form". In order to demonstrate bioequivalence, certain characteristics are measured to prove that there is at least a probability of 90% that the results will fall between two values (i.e. the acceptance interval). The acceptance interval can be tighter or wider for some characteristics in special cases.	applies. It is also not completely clear whether the Mexican test applied is equivalent to those of other jurisdictions, such as the EU or the US.	

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							It might well be that the methodology currently applied in Mexico to determine equivalence conforms with international standards and avoids the problems described above in practice; however, several outside experts had difficulty in assessing that result, due to the lack of a clear description of the methodology.		
8.	**Reglamento de Insumos para la Salud**	167 bis	Pharma. Production of medicines / Limitation, discrimination	When applying for a sanitary registry, a company needs to prove that it is the holder of the patent of the active substance or alternatively, that no patent will be infringed when producing the medicine in question. Once the application is received, COFEPRIS will consult the Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Industrial, IMPI) to determine if no patent is infringed. This is called "linkage". According to industry participants it is often not clear if the reference medicine is still protected by some patents and which patents are related to the reference medicine. This is known as the "linkage problem". Although COFEPRIS and IMPI communicate to	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	The objective of the linkage is to protect intellectual-property rights and prevent falsely granted sanitary registries and avoid their being revoked later due to accidental infringement of existing patents. **International comparison** Other jurisdictions, such as the US or Canada, have online databases allowing stakeholders to search easily for patents protecting molecules, and which product is considered as the referent. The US publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly Known as the Orange Book) identifies drug products approved by the Food and Drug Administration (FDA) and related patent and exclusivity information.	According to market participants, the searchable version of the Official Gazette is difficult to use and does not always yield all necessary results, contrary to COFEPRIS' opinion. The lack of sufficient information related to patents protecting a certain medicine makes it more likely that pharmaceutical companies will unintentionally infringe a patent when manufacturing a medicine. In case of infringement, the producer would need to change the medicine formulation and apply for a new sanitary registry with	COFEPRIS should publish a list for each medicine that has a sanitary registry with all relevant patents. The US Orange Book may serve as a blueprint. In the future, companies seeking a sanitary registry might be required to provide a list with all patents they consider relevant for the medicine. This list could then be published by COFEPRIS. Generic producers would then be able to easily investigate which patents they have to respect.

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
				determine which patents are related to the medicine that a company wants to offer a generic version and applies for sanitary registry, this is not reflected in IMPI's current list of patents. COFEPRIS and IMPI usually provide solutions on a case-by-case basis. Also, there is an online, searchable version of the Official Gazette for medicine patents.				COFEPRIS.	
9.	**Lineamientos que deberán cumplir los medicamentos alopáticos de referencia y selección de medicamento de referencia internacional. (issued on 25 January 2016)**	6	Pharma. Production of medicines / Limitation, barrier to entry	When a company holding a sanitary registry of a reference medicine decides to withdraw its product from the market, pharmaceutical companies that manufacture the generic version of that medicine are required to seek a reference medicine abroad in any of the seven countries recognised by COFEPRIS (as listed in the guidelines issued on 25 January 2016). According to market participants, producers of reference medicines withdraw them for various reasons, including as a business strategy to hurt competitors.	COFEPRIS	A3, A4	Point 9 of the COFEPRIS guidelines issued on 25 January 2016 provides a solution for cases in which there is no available reference medicine abroad. It states that when the national or international reference medicinal product is not available, the applicant shall conduct a pharmacokinetic study (i.e. looking at the action of the medicine in the body over a period of time, including the absorption, distribution, metabolism and elimination) in order to describe the medicine's pharmacokinetic profile or its major active metabolite (i.e. a substance produced when the body metabolises the medicine into a modified form that will continue to produce a therapeutic effect in the body).	If the producer of the reference medicine withdraws its product from the Mexican market, generics manufacturers will not be able to produce the generic medicine based upon the withdrawn reference medicine until they find a reference medicine in a listed foreign country. According to industry participants, finding a new reference medicine abroad can be difficult and time consuming. This situation reduces available options of medicines to consumers.	No recommendation as the COFEPRIS guidelines issued on 25 January 2016 introduces the option to provide a pharmacokinetic study in case there is no longer a reference medicine on the market. Consideration might also be given to the possibility of using a generic medicine as a reference.

Sector: Medicines									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							The results should be similar to those already reported in the literature.		
10.	**Guía para las buenas prácticas sanitarias en farmacias y consultorios**		Doctors' offices / Incentives	According to COFEPRIS (2015), 53.5% of all Mexican pharmacies have a CAF. Consultations in these CAF are provided at affordable prices or even for free. While CAF business models may vary, most doctors working at CAF receive some form of compensation from the pharmacies, be it through a fixed salary, a bonus, or some other form of remuneration. CAF generally belong to pharmacy chains and have expanded rapidly in Mexico as a result of the government's 2010 non-self-medication policy, known as the Agreement that determines the guidelines for the sale and dispensing of antibiotics. This enacted a prescription-only requirement for antibiotics to mitigate self-medication and control their use. To the best of our understanding, there is no provision to address the relationship between pharmacies and doctors, and limit the incentives that pharmacies provide CAF doctors for prescribing certain medicines. The fourth edition	Ministry of Health – COFEPRIS	D1, D2	CAF play an important role in Mexico's health system, assuring fast and affordable medical access to a significant part of the population. **International comparison** CAF have opened in Guatemala, Chile and Argentina (Diaz-Portillo, Sandra P. et al. (2015), "Consultorios adyacentes a farmacias privadas en México: infraestructura y características del personal médico y su remuneración", *Salud pública Méx*, 57:4, pp.320-328, www.scielosp.org/scielo.php?script=sci_arttext&pid=S0036-36342015000400010&lng=en&nrm=iso). Many other countries, however, ensure doctors and pharmacists remain separate and are prohibited from preferential prescribing or selling medicines (e.g. for Germany, § 10 ApoG).	Practically all CAF belong to pharmacies, meaning doctors in CAF are not always completely independent of pharmacies in their prescription practice. This could distort competition among medicines in three ways: Doctors could: 1) prescribe pharmacy-brand products (in cases where the pharmacy has its own medicine brand), rather than the best-suited medicines 2) prescribe products less suitable for patients' needs, but which are in stock at the pharmacy and need to be exhausted 3) prescribe more products than needed (e.g. extra vitamins) if doctors receive payments related to the number of products they prescribe.	The OECD recommends three options to the Mexican government. Options 1 and 2 are possible as stand-alone solutions, but could also be combined; Option 3 would mean keeping the status quo, leaving CAF's current business model unchanged. 1) Issue a provision prohibiting CAF doctors from prescribing branded products and mandate them to prescribe only INN or the generic name (as discussed above). Patients would be able to choose the medicine they consider the best in terms of price or quality from a selection. This option would solve the problem of CAF doctors prescribing expensive branded drugs. However, it would not solve the problem of over-medication, meaning that those doctors might prescribe more drugs than necessary.

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				of the Mexican Pharmacopoeia Supplement for Establishments (2010) only forbids pharmacies to have "direct communication, through windows, doors or aisles, with other businesses, such as doctor's offices".				These problems might be aggravated by patients' inability to substitute branded drugs for generics. According to Article 31 of the Reglamento de Insumos para la Salud, specific branded drugs prescribed by doctors cannot be exchanged by the patient or the pharmacist. Hence, if doctors tend to prescribe a pharmacy's own brands or the pharmacy's preferred products (e.g. due to a bulk order of those medicines), some generics or even branded medicines may face a competitive disadvantage against a pharmacy's own products.	2) Issue a code of conduct or regulation prohibiting pharmacies from exerting pressure on or incentivising doctors to prescribe certain products, especially by rewarding prescription numbers or prescribed drug volumes. As pharmacies would no longer be able to influence doctors' prescriptions, irrational prescription patterns (e.g. prescribing specific brands instead of generics or prescribing products that are not needed) would disappear. This solution might change the existing business models of CAF, however. Pharmacies' incentives to invest in CAF could be reduced and many CAF might have to raise fees for their services. Indeed, CAF might even close if no longer being cross-subsidised by pharmacies. 3) No recommendation. The policymakers' objective of granting quick and easy medical access for the Mexican

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									population could prevail over any possible conflict of interest. This recommendation would leave the current CAF business model unchanged.
11.	**Ley General de Salud**	204	Pharma. Production of medicines / Authorisation, barrier to entry, exclusivity agreements	The wholesale and retail of medicines and other health products, narcotics, psychotropic substances, and products containing narcotic or psychotropic substances require a sanitary authorisation (i.e. a licence). The sanitary authorisation for manufacturing granted to pharmaceutical companies is not limited to medicines manufacturing. There are no provisions to prohibit direct selling of pharmaceutical companies to pharmacies. However, in practice, many (if not most) pharmaceutical companies in Mexico refuse to sell directly to pharmacies, even to big pharmacy chains, preferring to sell through wholesalers. It is common practice for pharmaceutical companies to sign contracts of exclusivity with one distributor. Wholesalers therefore often become the only channel through which to commercialise a certain medicine. According to	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, A3	According to COFEPRIS, direct sales from pharmaceutical companies to pharmacies are not restricted. The sanitary licence granted to a pharmaceutical company to manufacture medicines can also include, among other listed activities, the distribution of medicines. If distribution is not included, it is easy to make changes to the sanitary licence. **International comparison** EU law considers that wholesalers have a "public-service function". This means that full-line wholesalers providing all medicines have to be supplied by pharmaceutical producers so as to guarantee coverage of the entire national population with adequate medicines. The public-service function is applied in different ways throughout the EU, though: some countries (e.g. Germany) have introduced a quasi-obligation to supply all full-line wholesalers.	For large retailers such as pharmacy chains, buying from a wholesaler imposes an unnecessary cost, as they have to pay an extra margin to wholesalers instead of acquiring the products directly from the producers. Also, market participants at retail level complain that many medicines are distributed by only one wholesaler and there is no or only very limited intra-brand competition. Promoting intrabrand competition is particularly relevant when there is insufficient interbrand competition.	The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market, which would have the aim to allowing new wholesalers to compete. Before moving forward with such a measure however it is recommended that a study in coordination with the relevant authorities assesses the impact on the market of introducing such an obligation, whose purpose would be to allow new wholesalers to compete in the concentrated Mexican wholesale market and increase intra-brand competition. However, as this proposed recommendation would interfere with contractual freedom, it should only

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				industry participants, pharmaceutical companies usually pay a service fee to distributors that sell their products (a scheme known as "fee for service"). This problem concerns only the private market; public-sector authorities generally purchase medicines through public tenders.			The obligation to supply wholesalers does not exclude direct supply of pharmaceutical companies to pharmacies.		be implemented if such study would demonstrate that other measures to strengthen intrabrand competition do not lead to any results.
12.	**Adenda al Convenio de Concertación**	Appendix 3	Pharma. Pricing of medicines / Price regulation	A 1996 agreement between the Ministry of Economy and CANIFARMA (amended in 2004) establishes maximum retail prices for patented medicines. In Mexico, this is calculated as the average ex-manufacturer price of that medicine in the six countries with the largest sales in the world.	a) Ministry of Economy (Secretaría de Economía)	B1, C1	The objective of the agreement is to protect Mexican consumers from pharmaceutical companies charging excessive prices, while also promoting investments in pharmaceutical development by assuring industry participation in setting maximum prices. **International Comparison** WHO reports that in 2015, 24 out of 30 OECD member states used a pricing system based on external reference pricing (ERP) with varying reference proxies; see, WHO (2015), *Guideline on Country Pharmaceutical Pricing Policies*, p.14. However, WHO recommends applying ERP only in combination with other methods as ERP alone may lead to inappropriate final prices, especially if the choice of reference countries have, for example, substantially	Having maximum prices for patented drugs raises several potential competition problems: 1) The 1996 agreement restricts the ability of firms to choose prices freely. 2) Considering the duty to place maximum prices on the labels on medicine packages (as discussed below), this provision may facilitate collusion and restrict competition at the retail level. 3) Most importantly, the current price-setting mechanism seems to result in higher final prices in the Mexican market, especially when	Rebuild the basket to calculate maximum prices for Mexico, taking into account not only sale volumes (as currently), but also other factors, such as income levels in reference countries and out-of-pocket expenditures. In addition, revise the basket periodically – for example, every five years – to ensure that it satisfies the needs of the Mexican population.

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							different market structures or prices. For example, in Canada, ERP is used together with other criteria: the sale price for the medicine in the relevant market; the prices of other drugs from the same therapeutic class in the relevant market; the prices of the same medicine and other medicines in the same therapeutic class in specific foreign comparator countries (namely, France, Germany, Italy, Sweden, Switzerland, the UK, and the US); and changes in the Consumer Price Index. (See, Daley J., *Pharmaceutical Pricing and Reimbursement in Canada: An Overview for Innovative Drug Manufacturers*, http://whoswholegal.com/news/features/article/27744/pharmaceutical-pricing-reimbursement-canada-overview-innovative-drug-manufacturers).	compared with other Latin American countries. This might be due to the current price-regulation system's tendency to focus on high-income countries as a benchmark. Maximum prices are determined based on the average of the six countries with largest sales in the world, but these countries are also countries with comparatively high prices. For example, in 2005, the United States, Japan, Germany, France, Italy, and the UK were the six countries with the largest expenditure on pharmaceuticals; see, OECD (2008), *OECD Health Policy Studies: Pharmaceutical Pricing Policies in a Global Market*, p.25.	
13.	**Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica**	39	Pharma. Sale of medicines / Price regulation, risk of collusion	The Ministry of Economy (on the advice of the Ministry of Health) shall set maximum prices for the sale of medicines and supplies to the public.	a) Ministry of Health (Secretaría de Salud) b) State governments	B1	To protect consumers in Mexico from pharmaceutical companies that may charge excessive prices. According to COFEPRIS, however, no prices are set for generics, but	In practice, maximum prices in Mexico are only regulated for patented medicines according to the agreement between	The recommendation is referred to above, addressing the agreement between the Mexican Ministry of Economy and

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					(Gobiernos de las entidades federativas)		rather unilaterally decided by pharmaceutical companies.	CANIFARMA and the Ministry of Economy, as described above. It is therefore not clear whether this provision is actually applied and how the Ministry of Health participates in regulating maximum prices.	CANIFARMA.
14.	**Adenda al Convenio de Concertación**	Ley General de Transparencia y Acceso a la Información Pública, Articles 13, 14,15 & 16	Pharma. Pricing of medicines / Price regulation	The amendment to the agreement between the Ministry of Economy and CANIFARMA determining how maximum prices are set is confidential, and its contents are not available to the public.	a) Ministry of Economy (Secretaría de Economía)	B1, C1	No objective was found in law. There does not seem to be a plausible justification to keeping this document confidential.	The document's confidentiality makes it impossible for the public evaluation of its content and research of price-lowering mechanisms for Mexican consumers.	Make the agreement and its modifications available to the public.
15.	**Adenda al Convenio de Concertación**	Appendix 1	Pharma. Pricing of medicines / Price regulation	The price-regulation scheme sets maximum prices based upon information provided by the pharmaceutical firms themselves, after examination by an external auditor.	a) Ministry of Economy (Secretaría de Economía)	B1, C1	There is no particular objective set out by the agreement. However, a likely objective may be to gather information in a cost-effective manner, since pharmaceutical companies can easily access their market data and provide them to the Ministry of Economy. An external auditor then verifies the authenticity of the information to guarantee that no manipulation took place.	This mechanism to gather information may facilitate firms to provide biased information to justify higher prices. Often in practice, actual prices paid are much lower than list prices due to discounts granted to big customers. Theoretically, companies might only	No recommendation, as long as the Ministry of Economy ensures that auditors are working independently – for example, by rotating auditors every five years, or by selecting from different candidates proposed by companies.

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								report list prices, not real prices. However, due to the external auditor, this danger seems small.	
16.	**Ley General de Salud**	198	Pharma. Production of medicines / Authorisation, barrier to entry	Establishments engaged in 1) the production of medicines containing narcotics or psychotropic substances; vaccines; toxoids; serums and antitoxins of animal origin, and blood products; and 2) the development, manufacture or preparation of medicines, require an authorisation before they start operating in the market. Conditions for granting this authorisation are set in Article 162 of the Reglamento de Insumos para la Salud.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	To protect the Mexican population from sanitary risks by regulating the sanitary control of health inputs. The conditions in this provision seem neither excessive nor discriminatory. **International comparison** Comparable provisions exist in other jurisdictions. For instance, in the US, according to 21 US Code, § 360 – Registration of producers of drugs or devices, every person who owns or operates an establishment engaged in the manufacture of drugs shall register with the Secretary of Health and Human Services. Every establishment that is required to be registered is subject to inspection. Also, in EU member states, medicines producers need permission (e.g. § 13 AMG in Germany).	Restricted market entry	No recommendation
17.	**Ley General de Salud**	222 bis	Pharma. Production of medicines / Authorisation, barrier to entry	In order to obtain a sanitary registry for biotechnological products, an applicant must submit to the Ministry of Health clinical and sometimes in-vitro studies (studies performed outside a normal biological context) to	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las	B4	Biotechnological products are relatively new products that present various risks. The Mexican government has therefore put up various additional requirements for their registry, and seeks support from the New	Conditions for the application of a sanitary registry that are not previously defined, but set on a case-by-case basis might lead to discretionary	No recommendation. Due to the nature of biotechnological products, requirements may vary significantly according to the product, making it impossible to develop general

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				demonstrate the safety, efficacy and quality of the product. As requirements are not set ex ante, they are defined by the Ministry of Health on a case-by-case basis, taking into account the opinion of the Committee on New Molecules (an auxiliary advisory body for registry requests of medicines containing a new molecule submitted to the Ministry of Health), supported by the Biotechnological Products Assessment Sub-Committee (Subcomité de Evaluación de Productos Biotecnológicos, SEPB), which is composed of specialists and scientists in the field of pharmaceutical biotechnology.	entidades federativas)		Molecules Committee when there are no provisions. This has the aim of protecting the Mexican population against health risks. According to COFEPRIS, each new biosimilar approved by the New Molecules Committee, has guidelines that are preserved for other biosimilars from the same biotechnological product. To date, six guidelines for six different biosimilar products exist. **International comparison** Comparable provisions exist in other jurisdictions. For example, in the EU, Article 8 of Directive 2001/83/EC states that an application needs to be submitted before an authorisation to put a medicinal product on the market can be granted. In the case of biological medicinal products – such as immunological medicinal products derived from human blood or plasma – there are additional requirements.	decisions.	guidelines. However, authorities should ensure that the guidelines issued for each biosimilar product are available online and easy to find.
18.	**Ley General de Salud**	230	Pharma. Production of medicines / Authorisation	In order to legally commercialise their products, developers of blood-derived products must obtain an authorisation from the Ministry of Health. Information on requirements and forms is	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos	A2	Processing blood into a medicine is a highly specialised process as blood products are inherently variable due to the nature of the source materials. The Mexican government	Restricted market entry	No recommendation

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				available: www.cofepris.gob.mx/AS/Paginas/Establecimientos%20y%20productos%20biologicos/PermisoVentaODistribucionProductos.aspx.	de las entidades federativas)		therefore seeks to ensure that blood products are of demonstrated quality and safety in order to be commercialised. **International comparison** Comparable provisions exist in other jurisdictions. For example, in the EU, Article 114 of Directive 2001/83/EC states that "[w]here, in the interests of public health, the laws of a Member State so provide, the competent authorities may require the marketing authorization holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk and/or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose".		
19.	**Ley General de Salud**	236	Pharma. Production of medicines / Authorisation	To commercialise or transport narcotic products within Mexico, a permit delivered by the Ministry of Health is required. The conditions for the permit are summarised at: www.gob.mx/cntse-rfts/tramite/ficha/53a44cdd89c0b26a3000168d.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	This provision is a result of the Mexican government concern for public health and social problems related to the illicit traffic of drugs containing narcotic and psychotropic substances.	Restricted market entry	No recommendation
20.	**Reglamento de Insumos para la**	43	Pharma. Wholesale and	For the distribution or sale of biological products and blood	a) Ministry of Health	A2	These products are more sensitive to cross-	This provision may impose excessive	No recommendation

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	Salud		retail of medicines / Authorisation, raises costs	products of national or foreign manufacture, each batch is required to be previously authorised based on analytical results issued by the Ministry of Health or by an authorised third party. The latter are authorised by COFEPRIS to support the authorities in health control and surveillance through the performance of various analytical tests, in order to verify compliance with law or to carry out studies on bioequivalence and/or biocomparability. According to COFEPRIS, there are currently 201 authorised third parties: 20 that function as verification units; 61 as clinical and analytical units authorised to conduct interchangeability and biocompatibility studies on biotechnological products; and 120 as testing laboratories. Applicants for authorisations must apply at the Ministry of Health. Conditions are described at: www.cofepris.gob.mx/AS/Documents/Establecimientos/lineamientos43.pdf. An approved authorisation is valid for two years. Authorisations can be renewed with a notice period of 30 days before the	(Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)		contamination, alteration or to becoming a health risk for personnel working with them. The Ministry of Health therefore seeks to be cautious, authorising single batches, prior to distribution and commercialisation.	costs on sellers because every batch needs to be checked separately.	

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				authorisation expires. A summary of the requirements to becoming an authorised third party can be found at: www.gob.mx/cms/uploads/attachment/file/187533/Requisitos_para_Evaluar_la_Competencia_T_cnica.pdf. These include filling out and signing a no-conflict-of-interest and confidentiality form, paying MXN 7 954.73, and having a quality-management system.					
21.	**Reglamento de Insumos para la Salud**	84	Pharma. Production of medicines / Authorisation, barrier to entry	New models for inputs (i.e. raw materials for medicines, narcotics, and psychotropics) require a new authorisation if they introduce technological innovations. This new authorisation follows the same rules as its predecessor (compare, Article 167 of Reglamento de Insumos para la Salud).	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	To guarantee the safety and efficacy of health inputs, innovative drugs require newly revised production to guarantee that safety and efficacy requirements are still fulfilled.	The new authorisation may raise costs for innovative producers.	No recommendation
22.	**Reglamento de Insumos para la Salud**	113	Pharma. Production of medicines / Licence, barrier to entry	Establishments that manufacture biotechnological products or their inputs require a sanitary licence and must comply with additional requirements with regard to other medicines, such as separate areas for strains (i.e. a group of closely related living things) or cell lines (i.e. an homogenous group of cells selected from a cell population) of animal or	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	Biotechnological products are relatively new products that are difficult to produce. They are more sensitive to cross-contamination, alteration or to becoming a health risk for personnel working with them. The Ministry of Health has therefore established special requirements for facilities where these products are processed.	Restricted market entry	No recommendation

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				vegetable origin. Foreign producers must have a good manufacturing practice (GMP) certificate. Criteria to grant a GMP certificate can be found in the document "Lineamientos que establecen los requisitos que se deben cumplir para la acreditación de los certificados de buenas prácticas de fabricación para la solicitud de modificaciones, prórrogas y registros sanitarios de medicamentos" (www.gob.mx/cms/uploads/attachment/file/163174/Lineamientos_Acreditaci_n_CBPF_Oficio_CAS-1-OR-20-2016.pdf).			**International Comparison** Many countries issue GMP certificates, including the United States and EU member states. In the US, Current Good Manufacturing Practice regulation for human medicines ensures proper design, monitoring, and control of manufacturing processes and facilities, as well as ensuring that companies use up-to-date technology and systems (www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm). In the EU, according to Directive 2001/83/EC, in order to obtain an authorisation to place a medicinal product on the market, the application made to the competent authority of the concerned member state shall include "a written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of good manufacturing practice by conducting audits". Directive 2003/94/EC lays down GMP principles and guidelines for medicinal products for human use. Among other		

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							requirements, the personnel shall receive initial and on-going training, the manufacturer shall establish an effective pharmaceutical quality-assurance system and hygiene programmes adapted to the activities to be carried out.		
23.	**Ley General de Salud**	376	Pharma. Production of medicines / Authorisation, barrier to entry	Sanitary registries need to be renewed every five years. A summary of renewal requirements can be found at: www.cofepris.gob.mx/AS/Documents/RegistroSanitarioMedicamentos/INDICE%20PARA%20TRAMITES/INDICE%20PRORROGA.pdf. According to Article 195-A of the Ley Federal de Derechos, for a sanitary registry renewal, applicants shall pay 75% of the new sanitary registry fee (the sanitary registry fee for generics is currently MXN 71 334.41 and for new molecule medicines MXN 127 549.79).	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	To protect the Mexican population against sanitary risks. During the renewal period of sanitary registries, the Ministry of Health examines the same aspects as examined during the first application for a sanitary registry. According to COFEPRIS, in more than 50% of all applications for renewal of the sanitary registry, the companies do not meet the necessary requirements to obtain or renew the sanitary registry. **International comparison** In the EU, according to Article 24 of Directive 2001/83/EC, "a marketing authorisation shall be valid for five years [and] may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the competent authority of the authorising Member State. [...] Once renewed, the marketing authorisation shall be valid for	Requiring a sanitary registry to be renewed every five years imposes an extra cost on firms. The costs can be quite significant for producers that are often marketing several hundreds of products.	Renew the sanitary registry only once after five years; it should then become perpetual. The OECD agrees with COFEPRIS that such a change should only be implemented after the Mexican control and supervision system has been significantly improved. This would require increasing the frequency of in-situ controls, the introduction of large fines if pharmaceutical companies do not report changes in a medicine to COFEPRIS within time limits, as well as the allocation of adequate resources to COFEPRIS to fulfil this task.

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							an unlimited period". In the Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (Official Journal 075 E, 26/03/2002, 0189-0215), the European Commission even suggested: marketing "authorisation shall be valid for an unlimited period". COFEPRIS points out that EU member states generally have a different supervision system and carry out more visits in-situ, which might not be currently possible for COFEPRIS to implement due to a lack of resources. A different system is applied in the US, where marketing authorisations (New Drug Applications) are granted once for an unlimited time, but the final product is reviewed for minor changes in an annual report. According to Volume 5 of Title 21 of the Code of Federal Regulations, "[c]hanges in the drug substance, drug product, production process, quality		

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							controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product must be documented by the applicant in the next annual report" and a "supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product".		
24.	**Reglamento de Insumos para la Salud**	167	Pharma. Production of medicines / Authorisation, barrier to entry	Medicines require a sanitary registry to be commercialised in Mexico. To apply for a sanitary registry, and for each renewal (currently every five years; see above), pharmaceutical companies need to show that their suppliers possess a Good Manufacturing Practices (GMP) certificate for health inputs. COFEPRIS issues GMP certificates itself, but also recognises certificates from eight foreign authorities: the Food and Drug Administration	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	To protect the Mexican population against sanitary risks by regulating the sanitary control of health inputs. According to COFEPRIS, it has recently introduced a new control system for suppliers abroad. Medicines are now classified in two categories: low risk and high risk (i.e. blood products, vaccines); for low-risk medicines, COFEPRIS will accept all certificates of the national sanitary authority even if they come from unrecognised authorities and	There are several problems with the current practice of requesting GMP certificates for Mexican producers' suppliers. According to market participants, foreign producers of medicines only have to provide a GMP certificate for their plant, not their suppliers', and thus do not face the following problems:	No recommendation due to introduction of new system by COFEPRIS.

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				(US); Agência Nacional de Vigilância Sanitária (Brazil); Health Canada (Canada); European Medicines Agency (EU); Pharmaceutical and Food Safety Bureau (Japan); Therapeutic Goods Administration (Australia); Ministry of Food and Drug Safety of the Republic of Korea (Korea); and Swiss Agency for Therapeutic Products (Switzerland). The duration of a COFEPRIS-issued GMP certificate is 30 months; other authorities sometimes grant the GMP certificates for longer periods, such as the PFSB in Japan. In addition, various authorities of countries with important suppliers, especially China and India, are currently not recognised by COFEPRIS. If a Mexican pharmaceutical producer wants to use a supplier of ingredients of an unrecognised country, COFEPRIS sends inspectors to certify the foreign supplier's plant. The Mexican producer has to cover those costs, including fees (MXN 84 080.88 for every visit to foreign suppliers; see, Article 195-A of the Ley Federal de Derechos), and travel expenses (the visits last			will not send inspectors abroad to inspect those suppliers. According to COFEPRIS, this new system will lead to 80% fewer inspections of foreign suppliers. The OECD team has not, however, been able to find the new guidelines on the COFEPRIS website. **International comparison** GMP certificates are required in many countries. For instance, in the US, according to the FDA website (www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm), to determine if a company is complying with GMP regulations, the FDA "inspects pharmaceutical manufacturing facilities worldwide, including facilities that manufacture active ingredients and the finished product". GMP certificates are also necessary in the EU: each consignment (batch of goods) needs to be accompanied by confirmation by the competent authority of the producer country that it conforms to GMP standards equivalent to those elsewhere in the EU, unless a waiver applies (www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/	1) COFEPRIS does not recognise the authorities of many countries, including those with the most important suppliers, e.g. India and China. COFEPRIS therefore needs to certify each individual supplier from an unrecognised country, which leads to high costs for Mexican producers. 2) If a Mexican producer replaces one of its suppliers, it has to apply for a sanitary registry modification and pay 75% of a new sanitary registry fee. This will lead to additional costs and various practical problems (e.g. the Mexican producer cannot use the new supplier until it has been certified, which grants significant bargaining power to the old supplier). 3) The validity period of Mexican GMP certificates is not always in line with those of foreign	

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				at least 5 days and more if more than one ingredient is involved).			general/general_content_001205.jsp&mid=WC0b01ac0580027088). The EU has also signed mutual-recognition agreements (MRAs) with third-country authorities.	authorities. According to market participants, COFEPRIS still requires a new GMP certificate every 30 months for each supplier, regardless of foreign GMP's duration or validity. For foreign suppliers, obtaining a new GMP certificate every 30 months may be difficult when its home authority foresees a longer duration. (For example, PFSB will only grant a new certificate once the old certificate has expired).	
25.	**Reglamento de Insumos para la Salud**	168	Pharma. Production of medicines / Licence, barrier to entry	In order to obtain a sanitary registry for a particular medicine, the producer must possess a sanitary licence for its plants or laboratories producing medicines or biological products for human use. According to Article 162 of the Reglamento de Insumos para la Salud, when applying for a manufacturing sanitary licence, a manufacturer shall submit the official application form (see,	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	The sanitary registration of medicines is a means to guarantee that public health is protected. This authorisation allows Mexican health authorities to verify the safety, efficacy and quality of medicines sold. The requirement for sanitary licences for plants allows Mexican health authorities to evaluate if the authorised manufacturing lines and pharmaceutical forms (i.e. external condition of	Restricted market entry.	No recommendation

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				www.gob.mx/cntse-rfts/tramite/ficha/560d582b8217e65139001256). According to Article 195-A of the Ley Federal de Derechos, pharmaceutical companies must accompany their application with a MXN 84 080.88 fee.			medicines that facilitates dosage and administration) are in accordance with the medicines submitted by pharmaceutical companies.		
26.	**Reglamento de Insumos para la Salud**	177 bis 2	Pharma. Production of medicines / Risk of discrimination	In order to obtain a sanitary registry for biosimilar products, producers need to apply to the Ministry of Health. The authority can request additional studies if the Committee on New Molecules recommends this, after hearing the opinion of the Biotechnological Products Assessment Sub-Committee (Subcomité de Evaluación de Productos Biotecnológicos, SEPB), part of the main Committee.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, B4	Biotechnological products are relatively new products that pose various risks. The Mexican government has therefore put up various additional requirements for those products with the aim of protecting the Mexican population against health risks.	In addition to the normal requirements specified in the regulation, the Ministry of Health can impose additional requirements, such as tests and studies for the registry of biosimilar medicines. The Ministry of Health establishes these requirements upon hearing the recommendation of the Committee on New Molecules, which in turn consults the SEPB. Authorities are granted a large degree of discretion, as they operate on a case-by-case basis. The requirements imposed on companies might vary and be discriminatory.	Issue guidelines that specify in which cases it is necessary to fulfil additional requirements to obtain a sanitary registry for biosimilar products. These guidelines would reduce the degree of discretion in the granting of sanitary registries of biosimilar medicines. This solution presupposes that it is possible to do so as the nature of biotechnological products means requirements for the sanitary registry of biosimilar medicines may vary according to the product.

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27.	**Reglamento de Insumos para la Salud**	177 bis 5	Pharma. Production of medicines / Authorisation, barrier to entry	An innovative biotechnological medicine can obtain authorisation for therapeutical uses other than those for which the original authorisation was issued as long as there are valid scientific grounds, based on the opinion of the Ministry of Health.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	Biotechnological products are relatively new products that pose various risks. The Mexican government has therefore put up various additional requirements for those products with the aim of protecting the Mexican population against health risks. **International comparison** Other jurisdictions also follow stricter procedures for biotechnological products. For instance, the EU requires mandatory marketing authorisation granted by the European Medicines Agency, not the member state, according to the "centralised procedure", which is stricter than the procedure applied for normal medicines. See, Article 3 of Regulation 726/2004 and Annex 1 of the same regulation.	Restricted market entry	No recommendation. The nature of biotechnological products renders this requirement reasonable.
28.	**Reglamento de Insumos para la Salud**	183	Pharma. Production of medicines / Permit, barrier to entry	Companies other than the holder of a sanitary registry may produce the medicine subject to registry only if they obtain the holder's authorisation and follow the same conditions under which the registry was granted in the first place.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A1	This provision allows manufacturers to use plants, other than those named when applying for a sanitary registry, for a limited period of time when special circumstances arise (e.g., a demand shock). It does not, however, allow for the possibility of intervening in the production of other pharmaceutical companies.	If read literally, an incumbent with a sanitary registry would be able to prevent market entry to its competitors as the law grants the first registry holder a *de facto* monopoly and it will have no incentives to authorise competitors	No recommendation

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								to enter the market. A pharmaceutical company with a sanitary registry for a generic could thus refuse authorisation to other pharmaceutical companies to manufacture the same generic. However, in fact, the provision deals with a different concern, see policymaker's objective.	
29.	**NOM-257-SSA1-2014, En materia de medicamentos biotecnológicos**	5.1.1.	Pharma. Production of medicines / Authorisation, barrier to entry	Prior to submitting a request for a sanitary registry for innovative biotechnological medicines, applicants must submit them evaluation to the Committee on New Molecules (CMN). The medicines are then studied by the Biotechnological Products Assessment Sub-Committee (Subcomité de Evaluación de Productos Biotecnológicos, SEPB) to determine if there are technical and scientific elements to demonstrate their safety, quality and effectiveness. Also, the Ministry of Health, based upon the opinion of the CMN, after consulting the SEPB, will determine the particular biocomparability	Ministry of Health (Secretaría de Salud)	A2	Biotechnological products are relatively new products that pose various risks. The Mexican government has therefore put up various additional requirements for those products with the aim of protecting the Mexican population against health risks.	Restricted market entry	No recommendation. The nature of biotechnological products means that tests may vary significantly according to the product and therapeutic indications.

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				tests that will allow pharmaceutical companies to be granted authorisation for the therapeutic indications of biosimilar products.					
30.	**NOM-257-SSA1-2014, En materia de medicamentos biotecnológicos**	9.1	Pharma. Production of medicines / Authorisation, barrier to entry	For a medicine to be recognised as a reference biotechnological medicine, it is necessary to obtain a sanitary registry issued by COFEPRIS. NOM-257-SSA1-2014 foresees that biotechnological medicines can be recognised as reference medicines if they are commercially available in Mexico. Furthermore, when a local reference no longer exists, a biosimilar (a non-innovative biotechnological product) may be considered as the reference medicine, provided that biocomparability has been demonstrated in respect of a valid reference medicine at the time of the study.	Ministry of Health (Secretaría de Salud)	A2	To guarantee producers of biosimilar products that a reference product will be on the market.	When the patent of a biotechnological product expires, a pharmaceutical company could be tempted not to apply to become a reference medicine with the aim of making entry of biosimilar products more difficult.	No recommendation, because biosimilar products can be authorised by COFEPRIS to become the reference biotechnological medicine if necessary.
31.	**NOM-012-SSA3-2012, Que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos.**	5.2	Pharma. Production of medicines / Authorisation, barrier to entry	The Ministry of Health must authorise any research project or protocol for the use of medicines or materials for which there is not yet sufficient scientific evidence for its therapeutic or rehabilitative efficiency or for the modification of the therapeutic indications of already existing products.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2	This NOM applies to any research project involving humans. The objective is to guarantee the care of the ethical aspects, and the well-being and physical integrity of the people who participate in a research project.	Restricted market entry.	No recommendation

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32.	**Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol.**	IV	Pharma. Purchase of medicines / Licence, barrier to entry	Purchasers of undenatured ethyl alcohol whose final destination is human use must provide COFEPRIS with a notice stating when their establishments will start operating or obtain a sanitary licence from COFEPRIS, and expressly indicate, as part of the description of its industrial process or production, how the purchaser will use undenatured ethyl alcohol.	a) Ministry of Health (Secretaría de Salud) through COFEPRIS b) State governments (Gobiernos de las entidades federativas)	A2	Ethyl alcohol is denatured by the addition of chemicals that render it undrinkable and unsuitable for human consumption. The provision's objective is to prevent the use of undenatured ethyl alcohol in the manufacture of adulterated alcoholic beverages (i.e. corrupted by the addition of an inferior and less valuable ingredient with the aim of preparing it for sale). The consumption of such beverages is linked to serious health problems, such as coma and, in some cases, even death.	Restricted market entry.	No recommendation
33.	**NOM-062-ZOO-1999, Especificaciones técnicas para la producción, cuidado y uso de los animales de laboratorio.**	5.3.1.3.	Pharma. Production of medicines / Licence, barrier to entry	All dogs and cats used in scientific research, technological development and innovation, laboratory testing and teaching, must be obtained from suppliers considered reliable by the Committee for the Care and Use of Laboratory Animals (an obligatory internal committee in every research company). To the best of our understanding no provisions or guidelines exist that establish how the reliability of suppliers is to be determined.	a) Official staff of the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA) b) Verification units	A2	To ensure that animals receive adequate treatment and adequate care to reduce stress and disease. **International comparison** The authorisation seems to be in line with international practice. For example, in the EU, Directive 2010/63/EU on the Protection of animals used for scientific purposes, states that "for reasons of animal welfare and conservation, the use of animals taken from the wild in procedures should be limited to cases where the purpose of the procedures cannot be achieved using animals bred specifically for use in procedures […]	This provision restricts the offer of available dogs and cats for scientific research. This might raise prices of an important input.	Publish binding guidelines with criteria to determine whether a supplier is reliable.

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					approved by SAGARPA		Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period. Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive". (Paragraph 20 and Article 20).		
34.	**NOM-062-ZOO-1999, Especificaciones técnicas para la producción, cuidado y uso de los animales de laboratorio.**	5.4.3.	Pharma. Production of medicines / Licence, barrier to entry	In order to raise and commercialise non-human primates (e.g. monkeys), a licence must be granted by the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food.	a) Official staff of the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA) b) Verification units approved by SAGARPA	A2	To ensure that animals receive adequate treatment and adequate care to reduce stress and disease that could influence test results. In addition, unhealthy primates can easily spread disease. **International comparison** In the EU, Directive 2010/63/EU on the Protection of animals used for scientific purposes state that "[t]he capture of non-human primates from the wild is highly stressful for the animals concerned and carries an elevated risk of injury and suffering during capture and transport [...] for reasons of animal welfare and conservation, the use of animals taken from the wild in procedures should be limited to cases where the purpose of	Entry to the market is restricted. Regulations or administrative practice can operate as a barrier to entry.	No recommendation. Authorisation seems to be in line with international practice.

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							the procedures cannot be achieved using animals bred specifically for use in procedures […] Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period. Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive".		
35.	**NOM-164-SSA1-2015, Buenas prácticas de fabricación de fármacos.**	10.2.3.2.5	Pharma. Production of medicines / Risk of discrimination	This NOM sets the minimum requirements necessary to manufacture medicine inputs such as process-monitoring frequencies. In order to reduce frequency and/or the analytical tests for inputs used in the manufacture of medicines in Mexico, a medicine manufacturer must receive an authorisation from the Ministry of Health. If the authorisation is granted, according to the document, Procedimiento normalizado de operación para reducción de la frecuencia de muestreo y de las determinaciones en materia prima y/o producto terminado no biológico, issued by the Ministry of	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, B3	To minimise administrative burdens and set the minimum requirements necessary for the manufacturing process of medicines to be commercialised in Mexico.	As the OECD understands the NOM, there are no clear guidelines for granting such authorisations. This might lead to discrimination of some producers compared to others.	Clarify in the NOM the criteria and procedure to modify frequencies of control and analytical tests.

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				Health, the manufacturer receives an official letter of authorisation for decreasing the sampling frequency. This authorisation has a validity of three years.					
36.			Pharma. Production of medicines	Currently, only 70 of 365 (approximately 20%) applications to COFEPRIS can be made electronically.	COFEPRIS	A4	The World Economic Forum recently stated that generally, administrative processes in Mexico can be slow and that this may affect trade. See, World Economic Forum (2015), *Enabling Trade Unlocking the Potential of Mexico and Vietnam*, www3.weforum.org/docs/WEF_Enabling_Trade_2016.pdf.	Being unable to submit applications to Mexican authorities electronically raises companies' administrative costs.	Continue the ongoing project to allow for the electronic submission of all applications to COFEPRIS or a corresponding authority.
37.	**Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios.**	21, 88, 119, 146, 240, 241, 242	Pharma. Production of medicines / Authorisation, raises costs	Some articles of the Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios refer to health inputs, narcotic and psychotropic substances and medicines. According to COFEPRIS, this Regulation does not apply to medicines. However, this is not clear in the text of the law.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	The objective of the Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios is to regulate specific activities, services, establishments and products for health-control purposes.	This lack of clarity may increase search costs of companies	Amend the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios to delete references to medicines.
38.			Pharma. Production of medicines / Authorisation, raises costs	Currently, various guidelines issued and used by COFEPRIS are difficult to find on its website. For instance, in June 2017, the OECD team could find neither the guidelines for "Lineamientos	COFEPRIS	A4, B4		This lack of clarity may increase search costs of companies.	Revise the COFEPRIS website to make the guidelines pharmaceutical companies must follow easily available, and then constantly update

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				que deberán cumplir los medicamentos alopáticos de referencia y selección de medicamento de referencia internacional" nor "Lineamientos que establecen los requisitos que se deben cumplir para la acreditación de los certificados de buenas prácticas de fabricación para la solicitud de modificaciones, prórrogas y registros sanitarios de medicamentos".					the list.
39.	**Ley General de Salud**	295	Pharma. Import of medicines / Limitation, barrier to entry	The import of medicines and raw material for the production of medicines requires authorisation from the Ministry of Health. Summary of requirements: www.gob.mx/tramites/ficha/permiso-sanitario-de-importacion-de-materias-primas/COFEPRIS687.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, A5	To protect the Mexican market from the entry of products that may not fulfil the safety, efficacy, and quality conditions required by Mexican law. **International comparison** Comparable provisions exist in other jurisdictions. In the EU, for example, importers of medicines need to obtain a licence if products are produced outside the European Economic Area (EEA). See, Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, Articles 8, 46 f), and 46 b).	Restricted market entry	No recommendation
40.	**Ley General de**	285	Pharma. Import	Importers of medicines must	a) Ministry of	A5	To assure the traceability of	It might impose	No recommendation

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	Salud		of medicines / Limitation, barrier to entry	be resident in Mexico.	Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)		medicines and facilitate their control and the eventual imposition of liability. In the 2017 OECD *Competition Assessment Review: Greece*, it was recommended that a comparable provision be abolished so that importers could be active in various countries and achieve economies of scale. However, the case is different due to the larger Mexican territory and population.	unnecessary costs on foreign incumbents and potential entrants.	
41.	**Ley General de Salud**	286 bis	Pharma. Import of medicines / Raises costs, barrier to entry	The Mexican Ministry of Health can sign agreements with foreign authorities in order to consider foreign marketing authorisations valid in Mexico. Mexico has concluded such agreements for example with the EU, Japan, and the US. If imported medicines do not require an authorisation due to one of those agreements, the Ministry of Health may still randomly sample and analyse imported products.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	The law does not provide a particular objective for this provision. However, a possible justification may be to minimise risks for consumers in Mexico related to products that though they may have fulfilled tests of safety, efficacy, and quality abroad still may pose a risk for the Mexican population (e.g. due to non-compliance with foreign controls). This should only be in exceptional cases, however.	This provision allows for the sampling and analysis of products that already have a marketing authorisation abroad. The double control may impose unnecessary additional costs and create risks of discrimination.	No recommendation
42.	**Ley General de Salud**	286 bis	Pharma. Import of medicines / Raises costs, barrier to entry	New products set to be introduced to the market for the first time, as well as those set to be introduced in Mexico for the first time (i.e. those that have already been marketed abroad), will be sampled and analysed at	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las	A5	The law does not provide any justification for this provision. However, a possible explanation may be to minimise sanitary risks concerning products with which there is little prior experience in terms of their	This analysis is in addition to the authorisation already received by the importer and might lead to a double control.	No recommendation

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				accredited laboratories to test for compliance with Mexican official standards or provisions.	entidades federativas)		quality, efficacy, and safety.		
43.	**Ley General de Salud**	289	Pharma. Import of medicines / Authorisation	The import and export of narcotic drugs, psychotropic substances and products or preparations containing them, require authorisation from the Ministry of Health. These requirements are summarised at: www.gob.mx/cntse-rfts/tramite/ficha/54d142458217e6c1820003cf.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, A5	The law does not give any specific objective. However, a possible justification may be to control the import of products that are subject to strict sanitary control. This objective would appear reasonable. **International comparison** Similar provisions exist in other jurisdictions. For example, EU law has similar controls for narcotics and psychotropic products. See, Article 20 of Council Regulation (EC) No. 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.	Restricted market entry	No recommendation
44.	**Ley General de Salud**	289	Pharma. Import of medicines / Authorisation	The import and export of narcotic drugs, psychotropic substances and products or preparations containing them cannot be done by post. Article 289 also mentions that the import and export of those products must be by air. Annex 21 of the General Rules on Foreign Trade, indicates the customs authorisation needed to clear this type of good.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	The law does not provide any specific objective. However, a possible justification may be to avoid the loss/theft of products during transit. This objective seems reasonable since it facilitates the control of imports of narcotic drugs and psychotropics thanks to control by specialised customs.	The restriction may impose unnecessary costs for the import of narcotic products, psychotropic substances and products or preparations containing them.	No recommendation

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45.	**Reglamento de Insumos para la Salud**	131	Pharma. Import of medicines / Authorisation, barrier to entry	A registry before the Ministry of Health is required before importing pharmaceutical products for commercial purposes. If a potential importer is not the holder of the registry, it must obtain consent from the owner before it can get an authorisation from the Ministry of Health to begin importing.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A1, A5	The law does not provide any specific objective. However, a possible justification may be to assure the traceability of medicines and facilitate their control and the eventual imposition of liability in case adverse effects emerge. Traceability, however, can also work with more than one importer, given current labelling regulations that require mention of the importer's identity.	The registry-holding importer can prevent the market entry of other importers. The law grants the registry holder a de-facto monopoly since it has no incentive to give authorisation to potential competitors and create intra-brand competition.	Abolish this restriction. Every importer should be able to get an authorisation from the Ministry of Health, independently of the registry holder's consent. Additional importers should not have to fulfil the same documentation requirements as the first importer for acquiring a registry as the safety of the imported drug will have been proven in the first application. However, as the initial importer has to bear the cost of providing all required documents for the registry to import the drug the first time, it might be granted a limited period of exclusivity by law (alternatively, this could be left to private exclusivity agreements between the foreign pharmaceutical producer and the importer).
46.	**Reglamento de Insumos para la Salud**	131	Pharma. Import of medicines / Authorisation, barrier to entry	The importation of medicines is only possible for products that will expire more than 12 months after their entry into Mexico. The Ministry of Health can exempt drugs that by their nature have reduced stability	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos	A5	The law does not provide any specific objective. A possible justification may be to prevent the risk of selling expired products. Nonetheless, 12 months is usually the minimum expiration dates for	This restriction limits the number of medicines that can enter Mexico. For example, batches of medicines that expire 11 months after	No recommendation.

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				from this restriction.	de las entidades federativas)		medicines (the range is usually between 12 and 60 months), and this time is also referred to in some international regulations, such as WHO's *Guidelines for medicines donation* (www.who.int/medicines/publications/med_donationsguide2011/en/). Drug products marketed in the US typically have expiration dates that extend from 12 to 60 months from the time of manufacture (www.drugs.com/article/drug-expiration-dates.html).	import would be excluded from the Mexican market.	
47.	**Reglamento de Insumos para la Salud**	133	Pharma. Import of medicines / Production of medicines, raises costs, barrier to entry	The import of raw materials for narcotics and psychotropics, as well as the import of narcotics and psychotropics, can only be performed in authorised customs offices.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	To concentrate the control of imports regarding substances that can be used for the production of narcotics or psychotropics, as well as the import of narcotics or psychotropics themselves. Indeed, authorised customs office can count on specialised staff and better technology. The objective seems reasonable.	This provision restricts the possible territories where products can enter the Mexican market. This may raise costs, depending on how many customs offices are authorised for these kinds of drugs and where they are located.	No recommendation.
48.	**Reglamento de Insumos para la Salud**	134	Pharma. Import of medicines / Production of medicines, raises costs, barrier to entry	To import narcotics, psychotropics or products that contain them, it is necessary to show the original invoice, as well as a copy of the invoice certified by a Mexican Consul in the country of origin.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades	A5	The law does not provide any specific objective. However, a possible objective may be to assure the validity of the original receipt, which proves the legal origin of products. **International comparison** Requiring certified documents is a widespread practice. For	This procedure requiring the Consul's intervention may impose an unnecessary cost on the import of narcotics and psychotropics, and products containing	No recommendation.

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					federativas)		example, in the EU, when the import authorisation needs to be presented to a customs office in a member state other than that of the issuing authority, the importer must make available certified translation of parts or all information contained in the authorisation, upon request; see, Article 22 of Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.	them.	
49.	**Reglamento de Insumos para la Salud**	138	Pharma. Import of medicines / Authorisation, barrier to entry	The importation of biological and blood-related products produced abroad requires an authorisation from the Ministry of Health. The requirements are summarised at: www.gob.mx/tramites/ficha/permiso-sanitario-de-importacion-de-medicamentos-con-registro-sanitario/COFEPRIS689.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, A5	To assure the traceability of medicines and facilitate their control and the eventual imposition of liability in case adverse effects emerge. Biological products are also subject to stricter conditions than most other medicines in other jurisdictions (e.g. in the EU, Article 114 of Directive 2001/83/EC). This is because biological and blood-related products are made with human fluids, which pose risks of transferring infectious diseases from donors of biological material to medicine users.	Entry to the market is restricted. Regulations or administrative practice can operate as a barrier to entry.	No recommendation
50.	**Reglamento de Insumos para la Salud**	160	Pharma. Import of medicines / Authorisation,	Import authorisations remain valid for up to 180 days, renewable for a similar period, provided conditions under	a) Ministry of Health (Secretaría de Salud)	A2, A5	The law does not provide any specific objective. However, a possible justification may be to assure importation conditions	The maximum validity of 180 days would appear short as it is not clear why	No recommendation as the provision seems to be in line with other jurisdictions. However, in

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			barrier to entry	which they were granted remain unchanged.	b) State governments (Gobiernos de las entidades federativas)		are met regularly. **International comparison** This period of six months is consistent with international practice. For instance, EU law follows an almost identical rule: the period of validity of the import authorisation within which the scheduled substances must have been entered into the Union's customs territory shall not exceed six months from the date of issue of the import authorisation. Under exceptional circumstances, the period of validity may be extended, upon request; see, Article 25 of Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.	conditions for the import should change within this timeframe and why a new authorisation process would be required.	the future consideration should be given to extending this time limit even if other jurisdictions remain unchanged.
51.	**Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios**	146	Pharma. Export of medicines / Permit, barrier to entry	The export of narcotics and psychotropics requires a sanitary permit.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, A5	The law provides no specific objective. A possible justification may be to control the availability of products subject to strict sanitary control. **International comparison** Other jurisdictions follow a similar control mechanism. In the EU, for example, Article 12 of Council Regulation (EC) No. 111/2005 of 22 December	Entry to the market is restricted.	No recommendation.

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							2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.		
52.	**Reglamento de Insumos para la Salud**	170	Pharma. Production of medicines / Raises costs	To obtain a sanitary registry to sell medicines produced abroad containing new molecular entities that have not been marketed in any other country, a certificate of free sale (which is required for imports and exports) may be substituted by a clinical study involving the Mexican population.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, A5	The law does not mention any specific objective. However, a possible justification may be to control the import of products that are subject to a strict sanitary control and where no prior experience facilitates assessment of the medicine. Different phenotypes of people around the world may justify a requirement for studies involving the Mexican population.	This regulation may impose an unnecessary cost on pharmaceutical companies if they have already performed tests, but are required to perform them again with Mexican population samples.	No recommendation.
53.	**Reglamento de Insumos para la Salud**	177 bis 1	Pharma. Production of medicines / Risk of discrimination	To be granted a sanitary registry by the Ministry of Health, pharmaceutical companies must conduct clinical studies. Clinical studies of biotechnological innovative medicines must take place in Mexico when the medicine is produced in Mexico, or when the medicine is produced abroad and the Ministry of Health requests additional tests in Mexico based on the New Molecules Committee's opinion.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5, B4	A possible justification for the provision may be that the Mexican authorities are seeking to ensure that a medicine is suitable for the Mexican population. According to COFEPRIS, studies must be performed in Mexico when foreign biotechnological producers choose Mexico as the country where the product will be registered for the first time. For biosimilar products, Mexican authorities accept foreign studies as long as medicines are similar.	This rule imposes extra costs on foreign companies as they may have to perform medical studies twice: once, abroad and again in Mexico. In addition, according to industry participants in the pharmaceutical industry some of the tests are excessive (i.e. phase II and III) and require the participation of a large number of Mexican patients. Finally, there is a risk of discretion from the Ministry of Health	Amend the provision so that the sanitary registry of biotechnological products is not conditional on Mexico-based studies if the company has conducted studies in another country, as long as that country's control system is as at least equivalent to the Mexico's, unless Mexico is the first country where the medicine is marketed. Only in exceptional cases, in which the effects of drugs may vary due to phenotypic differences in the Mexican population,

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								when deciding whether or not to require additional internal tests to companies producing abroad.	should the Ministry of Health order additional tests in Mexico. Guidelines for this should be put in place.
54.	**NOM-177-SSA1-2013, Que establece las pruebas y procedimientos para demostrar que un medicamento es intercambiable**	6.1.2.	Pharma. Production of medicines / Raises costs	Interchangeability tests (i.e. tests performed to determine whether a generic medicine produces a similar effect to the reference product) must be performed by authorised third parties on Mexican territory with Mexican population samples.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	The NOM-177-SSA1-2013 does not provide any specific objective. A possible justification, however, may be that Mexican authorities are seeking to ensure that a medicine is suitable for the Mexican population. As with the restriction discussed above, there may be the cases when the phenotypic characteristics of foreign populations do not coincide with those of Mexicans, so Mexicans would respond differently to a certain medicine. This scenario is an exception, however, and not the rule. **International comparison** Similar policy considerations do not appear to exist in EU or US legislation.	This requirement may impose unnecessary extra costs on pharmaceutical companies operating abroad, discouraging them from selling generic medicines in Mexico. For example, if a pharmaceutical company has performed interchangeability tests in the US before introducing a generic there, but later wishes to introduce the same product in Mexico, the company would have to perform the interchangeability test with a Mexican population sample.	Abolish the requirement that pharmaceutical companies conduct tests on the Mexican territory and population samples, and accept interchangeability studies already accepted by foreign authorities, as long as their control system is regarded as at least equivalent to the Mexico's. COFEPRIS should recognise those authorities, as it does eight foreign authorities for the issuance of Good Manufacturing Practice certificates. Only in exceptional cases for which guidelines should be in place, should the Ministry of Health order to perform additional tests on the Mexican population.
55.	**NOM-138-SSA1-1995, Que establece las especificaciones sanitarias del**	8.1 4.5.1.1	Pharma. Production of medicines / Limitation,	Packaging of ethyl alcohol (used as an antiseptic) must carry the following mention on its label: HECHO EN MÉXICO	Ministry of Health (Secretaría de Salud)	A5	Provide consumers with clear information on ethyl alcohol and the conditions for its safe use.	This requirement applies to all packaging of ethyl alcohol commercialised in	Abolish the part of the NOM that requires the HECHO EN MÉXICO label in order to allow foreign ethyl-alcohol

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	alcohol desnaturalizado, antiséptico y germicida (utilizado como material de curación), así como para el alcohol etílico de 96ºG.L., sin desnaturalizar y las especificaciones de los laboratorios o plantas envasadoras de alcohol.		barrier to entry	(MADE IN MEXICO).				Mexico. Foreign ethyl-alcohol manufacturers might be de facto locked out of the Mexican market.	manufacturers to participate in the Mexican market.
56.	**Ley General de Salud**	310	Pharma. Advertising / Limitation, barrier to entry	Advertising prescription drugs in Mexico is only allowed when it targets health professionals. Advertising of prescription drugs to end consumers and pharmacies is banned.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B2	A likely objective of the restriction is to discourage people from self-medicating and requesting a specific medicine for symptoms they may have seen or read about in advertising campaigns. **International comparison** Similar restrictions exist in most other jurisdictions. See, for example, Article 88 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use: "Member States shall prohibit the advertising to the general public of medicinal products which: (a) are available on	This restriction might make it difficult for market participants to gain market share and may especially place new entrants at a competitive disadvantage.	Allow advertising targeted at pharmacists especially after it becomes possible for pharmacists to substitute medicine prescribed by doctors for one with the same therapeutic effect (as discussed above).

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							medical prescription only." Only in the US and New Zealand is direct-to-consumer advertising allowed. Advertising to pharmacists is permitted in the EU, however. This can be important for new generic producers trying to reach pharmacists and convince them to substitute patented drugs or branded generics with their product.		
57.	**Ley General de Salud; Reglamento de la Ley General de Salud en Materia de Publicidad**	301, 79	Pharma. Advertising / Advertising, barrier to entry	Advertising about the availability, quality and features of medicines, as well as promoting the use, sale or consumption directly or indirectly of health products, requires previous authorisation from the Ministry of Health.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A2, B2	The law's objective is perhaps to ensure the validity of statements provided to health professionals in advertisements. Generally, control of advertising is possible ex ante or ex post. **International comparison** In the EU, for example, advertising generally does not have to be authorised ex ante, but is subject to strict ex post control. Advertisers are subject to fines in case of breaching the regulatory requirements. See, Article 4 of Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising.	By limiting advertising, this provision may prevent incumbents, as well as potential entrants, from gaining market share. Ex ante control delays advertising and imposes an administrative burden on both producer and administration.	Abolish. Control advertising ex post, under a liability regime that introduces fines for regulatory breaches to guarantee pharmaceutical companies' compliance.

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58.	**Ley General de Salud**	312	Pharma. Advertising / Advertising, consumer choice	The Ministry of Health can mandate additional warnings in the advertising of products. The law does not further specify on the conditions or content of those warnings.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B2	Provide consumers with an accurate description of the risks that medicines may impose on them.	The provision provides a high degree of discretion for authorities. Additional warnings may channel the demand towards a certain product thus discriminating other producers.	Issue guidelines that specify in which cases additional warnings are allowed (ex ante or ex post) and ensure that they are applied on a non-discriminatory basis.
59.	**Reglamento de la Ley General deSalud en Materia de Publicidad**	46	Pharma. Advertising / Advertising, barrier to entry	Advertising of narcotics – like for other prescription drugs – is only allowed when targeted at health professionals. Advertising of prescription drugs to end consumers and pharmacies is banned.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B2	Discourage self-medication of narcotics. **International comparison** This restriction is concordant with international standards. See, Article 88 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, which states: "Member States shall prohibit the advertising to the general public of medicinal products which […] contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971."	By restricting advertising to health professionals, it may be harder for market participants to gain market share, and especially for newcomers to enter the market. Permitted advertising targeted at consumers would allow consumers to ask their doctors for specific products, eventually raising demand in the market.	No recommendation.
60.	**Reglamento de la Ley General de Salud en Materia de Publicidad**	70	Pharma. Advertising / Advertising, barrier to entry	Advertising for biotechnological products may not use qualifiers that present them as superior to conventional products or to similar products not obtained	a) Ministry of Health (Secretaría de Salud) b) State governments	B2	A possible reason for the restriction might be that biotechnological products are more expensive for buyers, involve more complex and riskier production methods,	The provision forbids comparisons based on objective facts. Since comparison is a key element of advertising, this may	Abolish. Allow comparison on an objective basis within the constraints of comparative advertising provisions in Mexican

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				biotechnologically.	(Gobiernos de las entidades federativas)		and are still subject to intensive research. The OECD team was not able to identify similar advertising rules for biotechnological products in other jurisdictions, showing that those rules are not absolutely necessary to reach the policymaker's objective.	restrict competitive pressure between biotechnological products and conventional products.	law.
61.	**Ley Federal de Protección al Consumidor**	44	Consumer protection / Advertising	PROFECO, the Mexican Federal Attorney's Office of the Consumer, produces and publishes reports on products and services' quality and features, in order to guide and protect consumers. PROFECO makes specific mention of brands in these reports, but Article 44 of the *Ley* Federal de Protección al Consumidor forbids companies from quoting these reports.	Federal Attorney's Office of the Consumer (Procuraduría Federal del Consumidor)	B2	According to anecdotal evidence, the goal of the provision is to guarantee PROFECO's independence by preventing companies from attempting to place undue influence on the authority as well as to prevent them from misquoting PROFECO reports (e.g. "recommended by PROFECO"). However, these goals can also be reached without restricting competition.	The provision limits the freedom of suppliers to use public information to advertise their products, even when this information is based on objective grounds.	Abolish Article 44 of the Ley Federal de Protección al Consumidor, as these concerns appear to be unjustified: the law already contains an article that forbids misleading or abusive advertising. Also, measures should be taken to guarantee the independence of PROFECO officials from lobbying efforts and ensure efficient mechanisms (including sanctions) to avoid misleading advertising. As PROFECO's reports do not only deal with medicines but with all industries, the same recommendation will be made concerning meat.
62.	**Ley General de Salud**	225	Pharma. Production of medicines /	Drugs shall be identified by their distinctive and generic names for their use and sale.	a) Ministry of Health (Secretaría	A4, A5	The law does not provide a particular objective. A possible aim, however, may	This provision may increase the costs of entry for foreign	No recommendation. Trademark and labelling requirements that oblige

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			Labelling, trademarks, raises costs, barrier to entry	The generic name (or International Nonproprietary Name, INN, as defined by the WHO, a unique name that is globally recognised and public property) is mandatory. Distinctive names (brand names) of medicines can include neither the drugs' composition nor their therapeutic use. Indications concerning diseases, syndromes, symptoms, or those that are reminiscent of anatomical data or physiological phenomena, except for vaccines and biological drugs, are not allowed. The exact manner in which the names should be used in advertising and labelling is regulated by a labelling regulation (NOM 072-SSA1-2012).	de Salud) b) State governments (Gobiernos de las entidades federativas)		be to identify the medicine clearly while avoiding the possibility of overconsumption by referring to particular symptoms. **International comparison** Similar restrictions for trademarks apply in other jurisdictions. In the EU, for example, the main criteria for the European Medicines Agency's Name Review Group (NRG) states that the invented name of a medicinal product should: "1. not be liable to cause confusion in print, handwriting or speech with the invented name of another medicinal product, 2. not convey misleading therapeutic and/or pharmaceutical connotations, and 3. not be misleading with respect to the composition of the product." Furthermore, the invented name shall not be derived from an INN – as assigned to an active pharmaceutical substance by the WHO – and shall not include an INN stem (which signifies a certain therapeutic class) in the stem position attributed to it by the WHO. (Title V, Directive 2001/83/EC on the Community code relating to medicinal products for human use).	companies, if it differs from their home-country regulations because foreign companies may need to develop new brand names for the Mexican market.	pharmaceutical companies to produce particular brands and packages for specific national markets are a widespread practice.

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63.	**NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios**	5.1, 5.2, among many others, such as 5.7; 5.24.10.6. 5.	Pharma. Labelling of medicines / Raises costs, barrier to entry	Several labelling provisions require manufacturers to produce specific packaging for the Mexican market.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4, A5	The law does not provide a particular objective. A possible aim, however, may be to identify the medicine clearly, as well as its conditions of safe use. **International comparison** Different packaging for different countries is common practice. For example, in the EU, Article 5 of Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets, allows member states to include supplementary labelling requirements, in addition to those minimum requisites mandated by EU law.	Labelling requirements not in line with international standards force producers to manufacture new packaging for the Mexican market, which imposes extra costs.	No recommendation. Labelling requirements that oblige pharmaceutical companies to produce particular packaging for specific national markets are a widespread practice.
64.	**NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios**	5.2	Pharma. Labelling of medicines / Information, prices	The package of a medicine must indicate the maximum price for which the drug can be sold to the public. The law does not distinguish between patented and generic medicines.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B1	Protect consumers from retailers charging excessive prices, especially in geographically remote areas. Market participants indicated, however, that prices tend to be regularly lower than those referred as maximum prices and do not lead to price coordination in practice.	This provision may facilitate collusion since it provides a benchmark that may allow the coordination of prices at retail level.	No recommendation.
65.	**Reglamento de Insumos para la Salud**	24 bis	Pharma. Labelling of medicines / Limitation, barrier to entry	Labelling of biological products must feature: 1) the name of the producer and country of origin; and 2) where appropriate, the importer's identity. Innovative biotechnological	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos	A4, A5	The law does not specify a particular objective. However, a possible justification might be to facilitate the traceability of companies that may later be subject to liability. This provision may also serve to	If these requirements are not in line with international practice, they may impose additional costs to foreign producers who may want to	No recommendation.

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				biocomparable products must be labelled BM (for biological medicine), as well as the INN (generic name).	de las entidades federativas)		facilitate a clear identification of the medicine. This objective seems reasonable.	export their products to Mexico.	
66.	**Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios / NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios**	58 / 5.3	Pharma. Import of medicines / Labelling, confusion	According to this Regulation, imported products packaged in the origin country must keep their original packaging, and carry an additional label with the information necessary to comply with Mexican law. However, NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios, states that it is forbidden to re-label on the top of original information. The two quoted provisions seem to contradict each other. According to COFEPRIS, the first quoted Regulation does not apply to medicines. However, this is not clear in the text of the provisions.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	A possible objective of this restriction may be to assure that labelling conditions are fulfilled, providing consumers in Mexico with the data they need to make an informed decision.	These contradictory rules are confusing for business.	Clarify the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios, so it does not apply to medicines and delete all references to medicines in this provision.
67.	**Ley General de Salud**	200	Pharma. Production of medicines / Lack of transparency, discrimination	The Mexican Pharmacopoeia is 50% more expensive for buyers paying in USD: USD 760 vs. MXN 8 600 (or USD 473, at 11 June 2017 exchange rates).	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B4	The Mexican Pharmacopoeia is a binding document that every producer, distributor, and retailer of medicines must follow. The provision offers specific guidance on issues that require detailed regulation and constant updates, such as technical standards for the preparation of medicines. The price companies have to pay to	Entry to the market is slightly costlier for companies paying in USD. This will mostly be foreign companies.	Apply the same price for all subscribers independently of their nationality or currency they use to pay.

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							acquire a hard copy of the Mexican Pharmacopoeia helps to fund the committee in charge of its updating.		
68.	**Ley General de Salud**	200, 258	Pharma. Production of medicines / Lack of transparency, discrimination	The Mexican Pharmacopoeia is not available online.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	COFEPRIS has an ongoing project to make the Pharmacopoeia available online.	Having to acquire a hard copy might delay entry. Market participants have indicated that they see no significant problems with regards to acquiring hard copies of the Pharmacopoeia, though they would prefer an online version.	Continue with the ongoing project and make the Pharmacopoeia available online as soon as possible.
69.	**NOM-001-SSA1-2010, Que instituye el procedimiento por el cual se revisará, actualizará y editará la Farmacopea de los Estados Unidos Mexicanos.**	4	Pharma. Production of medicines / Raises costs	The Ministry of Health is in charge of updating the Mexican Pharmacopoeia, at least every three years, with the support of the Mexican Pharmacopoeia's Permanent Commission.	Ministry of Health (Secretaría de Salud) through the Executive Vice Directorate on Risk Policy (Subdirección Ejecutiva de Políticas de Riesgo) of the Evidence and Risk Management Commission (Comisión de Evidencia y	A4	To keep an updated version of the document, and hear the view of diverse stakeholders. **International comparison** Updating time is consistent with international practice. The three-year period is identical with, for example, the EU standard. See, WHO (2012), *Review of World Pharmacopoeias*, www.who.int/medicines/areas/quality_safety/quality_assurance/resources/InternationalMeetingWorldPharmacopoeias_QAS13-512Rev1_25032013.pdf.	Updates only every three years may be too long given the dynamism of today's market. It may also create uncertainty for producers of innovative medicines if the Mexican Pharmacopoeia has no clear guidelines on which rules apply on a particular topic. Market participants have indicated that this is not considered as a serious problem, however, since there is informal agreement on which alternative sources of information	An online version as recommended above would be able to be constantly updated.

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					Manejo de Riesgo) of COFEPRIS.			as considered as valid.	
70.	**Reglamento de Insumos para la Salud**	8, 167 & 178	Pharma. Production of medicines / Risk of discrimination	Several articles of Mexican health law specify that when the Mexican Pharmacopoeia does not regulate a particular issue, foreign pharmacopoeias and other sources of scientific international information may be used.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	The provision offers alternatives in cases where the Mexican Pharmacopoeia does not deal with specific matters.	This norm imposes uncertainty as no clear rules apply for when the Mexican Pharmacopoeia is silent on a particular matter. Market participants have indicated that this is not considered as a serious problem, however, since there is informal agreement on which other sources of information can be considered as valid.	Elaborate a list of specific alternative documents that market participants can consider as sources of authoritative knowledge in case of the Mexican Pharmacopoeia not covering a topic.
71.	**NOM-073-SSA1-2015, Estabilidad de fármacos y medicamentos, así como de remedios herbolarios.**	11	Pharma. Production of medicines / Stability of medicines	This NOM on medicine stability expressly states that it is only partially in line with international norms.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice,	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.

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								Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	
72.	**NOM-177-SSA1-2013, Que establece las pruebas y procedimientos para demostrar que un medicamento es intercambiable**	12	Pharma. Production of medicines / Interchangability	This NOM on procedures and tests to determine when a medicine is interchangeable expressly states it is only partially in line with international norms.	a) Ministry of Health (Secretaría de Salud) through COFEPRIS b) State governments (Gobiernos de las entidades federativas)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.

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73.	**NOM-249-SSA1-2010, Mezclas estériles: nutricionales y medicamentosas, e instalaciones para su preparación.**	23	Pharma. Production of medicines / Sterile mixtures	The NOM on sterile mixtures expressly states it is only partially in line with international norms.	a) Ministry of Health (Secretaría de Salud)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.
74.	**NOM-257-SSA1-2014, En materia de medicamentos biotecnológicos**	11	Pharma. Production of medicines / Biotechnological medicines	The NOM on biotechnological medicines expressly states it is not in line with any international norm.	a) Ministry of Health (Secretaría de Salud)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no

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								In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	existing international standards or best practices.
75.	**NOM-012-SSA3-2012, Que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos.**	13	Pharma. Production of medicines / Research projects on humans	The NOM on criteria for research projects on humans expressly states it is only partially in line with international norms.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.

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								standards, the legal text of NOMs should be updated to avoid confusion among market participants.	
76.	**NOM-248-SSA1-2011, Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de remedios herbolarios**	16	Pharma. Production of medicines / Herbal medicines	The NOM on good practices for manufacturing herbal medicines expressly states that it is partially in line with international norms.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.
77.	**NOM-164-SSA1-2015, Buenas prácticas de fabricación de fármacos.**	17	Pharma. Production of medicines / Manufacturing medicines	The NOM on good practices for manufacturing medicines expressly states that it is only partially in line with international norms.	a) Ministry of Health (Secretaría de Salud) b) State governments	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the	The non-harmonisation with international standards – be it partial or total – may hinder access to the	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be

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					(Gobiernos de las entidades federativas)		degree of accordance with international norms and criteria.	Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.
78.	**NOM-062-ZOO-1999, Especificaciones técnicas para la producción, cuidado y uso de los animales de laboratorio.**	13	Pharma. Production of medicines / Laboratory animals	The NOM on production, care and use of laboratory animals expressly states it is not in line with international norms.	a) Official staff of the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Ali-mentación,	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.

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					SAGARPA) b) Verification units approved by SAGARPA			Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	
79.	**NOM-138-SSA1-1995, Que establece las especificaciones sanitarias del alcohol desnaturalizado, antiséptico y germicida (utilizado como material de curación), así como para el alcohol etílico de 96ºG.L., sin desnaturalizar y las especificaciones de los laboratorios o plantas envasadoras de alcohol.**	10	Pharma. Production of medicines / Alcohol	The NOM on health specifications for denatured, antiseptic and germicidal alcohol, as well as undenatured ethyl alcohol at 96% ABV (alcohol by volume), expressly states it is not in line with international norms.	Ministry of Health (Secretaría de Salud)	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.

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80.	**NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios**	11	Pharma. Production of medicines / Labelling	The NOM on labelling of medicines expressly states it is not in line with any international norm.	a) Ministry of Health (Secretaría de Salud) b) Federal Attorney's Office of the Consumer (Procuraduría Federal del Consumidor) for maximum-price surveillance	A5	Article 41, Letter VI of the Ley Federal sobre Metrología y Normalización states that in Mexico, non-harmonisation of NOMs has to be disclosed and NOMs must contain the degree of accordance with international norms and criteria.	The non-harmonisation with international standards – be it partial or total – may hinder access to the Mexican market for foreign companies, as well as access to foreign markets of Mexican producers. In particular, producers might have to apply different norms in Mexico and abroad, which might lead to extra costs. Even if in practice, Mexican standards have recently been (partially) adapted to international standards, the legal text of NOMs should be updated to avoid confusion among market participants.	Update the NOM to make it as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. State in the law when there are no existing international standards or best practices.
81.	**Reglamento de Insumos para la Salud**	12	Pharma. Production of medicines / Raises costs	It is forbidden to use remains of previous production batches for the production of new batches. The law does not foresee any exceptions to this rule.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	The Regulation does not provide any specific objective. However, a possible justification may be the traceability of medicines. **International comparison** According to the *Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in*	This provision may increase the costs of producing certain types of medicines.	No recommendation

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							international commerce, a batch (or lot) is a "defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous" (www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index6.html). Homogeneity in batches helps in tracing specific batches and to maintain records covering manufacture and distribution, which is in line with Good Manufacturing Practices (GMP); see, Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use; the WHO's *Good manufacturing practices for pharmaceutical products: main principles* (www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex2.pdf) and the US *Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination*		

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							Products (www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM429304.pdf).		
82.	**Reglamento de Insumos para la Salud**	57	Pharma. Production of medicines / Limitation, barrier to entry	It is prohibited to provide medical samples or gifts containing narcotic or psychotropic substances.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B2	The objective of the provision is to control chemicals that can be used as inputs for illicit drugs, as well as medicines containing narcotics or psychotropic substances. **International comparison** Similar provisions exist in other jurisdictions. For example, in the EU, "no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied" (Article 96 (1) (g) of Directive 2001/83/EC).	This restriction limits the ability of sellers, especially new market entrants, to market their products to doctors, who may be willing to offer samples to their patients.	No recommendation as the provision seems to follow international standards.
83.	**Reglamento de Insumos para la Salud**	114	Pharma. Retail/ Limitation, barrier to entry	Pharmacies operating inside stores must be located in determined areas, and be at least 10 metres away from areas where alcohol, perishable foods and other substances that may threaten the integrity, purity and conservation of medicines are sold (Fracción II Suplemento FEUM 4 Ed. p.79). A summary of the conditions for pharmacies to comply with good practices: www.cofepris.gob.mx/Docum	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A3	To protect Mexican population against sanitary risks by regulating the sanitary control of establishments. Placing pharmaceutical products together with other products may lead consumers to think that pharmaceutical products are just a mere regular good, which may lead to overconsumption. Medicines usually are packaged, however, so a provision regulating distances between different types of	This restriction may limit the entry of pharmacies into stores where there is not enough room for the sale of medicines in addition to alcohol and perishable foods. Small shops with space limitations might be impeded from operating a pharmacy section.	Abolish this provision as long as a pharmacy only sells packaged products and they are sold in separate areas.

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				ents/LoMasReciente/Guia_Farmacias.pdf.			products seems unnecessary since there is no risk of contamination. Also, many pharmacies/stores do not seem to comply with this rule in practice.		
84.	**Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol.** **NOM-138-SSA1-1995, Que establece las especificaciones sanitarias del alcohol desnaturalizado, antiséptico y germicida (utilizado como material de curación), así como para el alcohol etílico de 96ºG.L., sin desnaturalizar y las especificaciones de los laboratorios o plantas envasadoras de alcohol.**	III d), 4.5.1.1, 4.5.3.1	Pharma. Purchase of medicines / Limitation	Sales of denatured ethyl alcohol in pharmacies or drugstores to final consumers should be sold in containers no bigger than 1 litre.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	B3	To regulate the sale volumes to final consumers. Even though ethyl alcohol is one of the most used curative materials because of its antiseptic and germicidal characteristics, its addictive power and its toxicity can be a health risk. However, it is unclear why there is a provision regulating container size for final consumers as ethyl alcohol is not sold as a controlled medicine. If there is a risk associated to the consumption of ethyl alcohol, it is not associated to container size.	This requirement prevents consumers from buying containers of more than 1 litre. For some consumers, this may impose higher costs. For example, companies using ethyl alcohol regularly may require larger volumes. This restriction prevents them from buying larger packages that might be cheaper and better fit their needs.	Abolish Provision I-d) of the Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol, and the part of NOM-138-SSA1-1995 related to container size of denatured ethyl alcohol.
85.	**Acuerdo que establece las**	III e), 6.10,	Pharma. Purchase of	Denatured ethyl alcohol for the exclusive use of health-	a) Ministry of Health	B3	To regulate the sale volumes to final consumers, including	This provision prevents buyers from	Abolish provision I-e) of the Acuerdo que

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	medidas para la venta y producción de alcohol etílico y metanol. **NOM-138-SSA1-1995, Que establece las especificaciones sanitarias del alcohol desnaturalizado, antiséptico y germicida (utilizado como material de curación), así como para el alcohol etílico de 96ºG.L., sin desnaturalizar y las especificaciones de los laboratorios o plantas envasadoras de alcohol.**	A.5.3.1	medicines	care units (e.g. hospitals) may only be sold or marketed in containers of more than 1 litre and no more than 20 litres.	(Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)		hospitals. Even though ethyl alcohol is one of the most used curative materials because of its antiseptic and germicidal characteristics, its addictive power and its toxicity can be a health risk. However, it is unclear why there is a provision regulating container size for final consumers when ethyl alcohol is not sold as a controlled medicine. If there is a risk associated to the consumption of ethyl alcohol, it is not associated to container size.	acquiring containers of more than 20 litres. This may impose higher costs on some of them. For example, hospitals may find it more efficient to acquire containers of more than 20 litres.	establece las medidas para la venta y producción de alcohol etílico y metanol, and the part of NOM-138-SSA1-1995 related to container size of denatured ethyl alcohol.
86.	**Reglamento Interior del Comité de Moléculas Nuevas**	9	Pharma. Production of medicines	The work of representatives of academic associations on the Committee on New Molecules shall not be subject to any remuneration. The functioning of the Committee is defined as an auxiliary and independent (i.e. unpaid by the pharmaceutical industry) consultative body.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	The Regulation does not provide any specific objective, but conflicts of interest should be avoided. Industry stakeholders believe that it would be impossible for Committee members to be remunerated twice (i.e. by both IMSS and the Committee), as the Ministry of	Members of the Committee might not be sufficiently incentivised to fulfil their task adequately. Market participants consider that Committee sessions are not scheduled with the necessary	Amend provision in order to introduce an additional remuneration to the Committee members that might be paid by the Ministry of Health and could be indirectly financed by pharmaceutical companies paying for

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							Finance would oppose the payment of a double salary to a public official. **International comparison** Similar committees exist in other jurisdictions. For example, in the US, the Centre for Drug Evaluation and Research (CDER) uses advisory committees to obtain outside advice and opinions from expert advisors to ensure final agency decisions have the benefit of wider national expert input.	frequency (only four sessions each year), which might delay the entry of new products. Also, some Committee members are not experts in the subjects discussed, but rather staff of government institutions that later purchase medicines (e.g. IMSS), which industry stakeholders believe is problematic. These Committee members are therefore most concerned about ensuring low-cost public procurement, and might block the introduction of new products with high therapeutic value.	submitting new files to the Committee. The Ministry of Health should guarantee that members of the Committee do not receive direct financial incentives from companies, through the inclusion of sanctions for Committee members who violate rules on conflict of interest. Implementation of this recommendation will have to be coordinated with the Ministry of Finance.
87.	**Reglamento Interior de la Comisión para Definir Tratamientos y Medicamentos Asociados a Enfermedades que Ocasionan Gastos Catastróficos**	17	Pharma. Public programmes / Risk of corruption	To reform the internal regulations of the Commission to Define Treatments and Medicines Associated with Diseases Causing Catastrophic Expenses, Commission members must vote unanimously. The Commission supports the General Health Council in the study, analysis and definition of treatments, medicines and	Comission to define treatments and medicines related to diseases causing catastrophic expenses (Comisión para definer	A3	The Regulation does not provide any specific objective.	Requiring unanimity hinders necessary regulatory updating. For example, unanimity is required to include as an alternative treatment a new drug that treats a disease covered by this public programme. Incumbents may	Abolish the part of the provision related to the unanimity and introduce (qualified) majority voting.

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				other health inputs associated with diseases that cause catastrophic expenses. The Commission is composed of the Secretary of the General Health Council, two representatives of the Ministry of Health, and a representative from each of the following institutions/ministries: IMSS; ISSSTE; PEMEX; the Ministry of National Defence; the Ministry of Navy; the National Autonomous University of Mexico; National Polytechnic Institute; the National Academy of Medicine; the Mexican Academy of Surgery; the National Association of Universities and Institutions of Higher Education; and the Mexican Health Foundation. All have voting rights.	tratamientos y medicamentos asociados a enfermedades que ocasionan gastos catastróficos) of the General Health Council (Consejo de Salubridad General)			have incentives to influence the committee to maintain the status quo.	
88.	**Ley General de Salud**	200	Pharma. Production of medicines / Barrier to entry, discrimination that raises production costs for some suppliers	Establishments engaged in the production of medicines containing narcotics and psychotropic substances; vaccines; toxoids; serums and antitoxins of animal origin, and blood products; and the development, manufacture or preparation of drugs, pesticides, plant nutrients and toxic or hazardous substances are required to hire a Sanitary Responsible Person, a qualified employee	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	A Sanitary Responsible Person is needed to ensure the identity, purity and safety of the products, as well as the processes carried out in the establishment. **International comparison** Similar provisions exist in other jurisdictions. In the US, a pharmacy or any other person authorised by law to dispense or administer prescription medicines must have a valid licence under	The provision might make it more difficult for small companies to enter the market as the extra costs involved in hiring an additional full-time employee could be a proportionally higher share of total expense than for larger enterprises.	No recommendation

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				with at least a bachelor's degree. The Sanitary Responsible Person in factories supervises the manufacturing process of medicines and verifies compliance with good storage practices, authorises standard operating procedures and is present during surprise inspections. The Sanitary Responsible Person in pharmacies verifies that medicines have a sanitary registry, and their batch number and expiration date; preserves health inputs according to indicated conditions; verifies entries and exits in control books for narcotics and psychotropic drugs; is present during surprise inspections; and analyses prescriptions. The required specific degree varies depending on the type of establishment (e.g. herbal-medicine manufacturer, biotechnological-product manufacturer).			state law. For example, in California, in order to be licensed, a pharmacist must satisfy the requirements of the Business and Professions Code section 4200. Upon approval by the California State Board of Pharmacy, a pharmacist can also be the manager responsible for ensuring the pharmacy's compliance with all state and federal regulations (known as pharmacist-in-charge).		
89.	**Ley General de Salud**	230	Pharma. Production of medicines / Raises costs, barrier to entry	Blood products require internal control in the manufacturing plant's laboratory and external control in Ministry of Health laboratories. The same analyses are made during both controls.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las	A4	These products are more sensitive to cross-contamination, alteration or becoming a health risk for personnel working with them. Stricter controls have therefore been established by the Ministry of Health to	Double control may impose unnecessary additional costs.	No recommendation. Due to the nature of these products, double controls seem reasonable.

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					entidades federativas)		guarantee the quality of raw materials used in processing biological products, and the verification of their identity, purity, sterility and safety.		
90.	**Reglamento de Insumos para la Salud** **Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios**	108, 141	Pharma. Production of medicines / Raises costs, uncertainty	According to Article 108 of the Reglamento de Insumos para la Salud, if a holder of a sanitary licence ceases to operate an establishment, he or she must give notice to the Ministry of Health of his or her decision at least 30 days in advance, unless in the case of an unforeseen event or force majeure. According to Article 141 of the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios, however, the same notice must be provided at least five days in advance. There is a contradiction in the regulatory framework and a lack of clarity as to when notice needs to be served to the Ministry of Health.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos de las entidades federativas)	A4	To protect public health. Chemicals that, if left unregulated, might be used as inputs for illicit drugs should be controlled.	Contradictory criteria on the number of days of notice may lead to confusion of market participants.	Article 108 of the Reglamento de Insumos para la Salud and Article 141 of the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios should be harmonised so that both articles require the same time frame for serving notice to the Ministry of Health.
91.	**Reglamento de Insumos para la Salud**	108	Pharma. Production of medicines / Exit costs, barrier to exit	A provision states that existing stocks of narcotics or psychotropic substances held before an establishment's closure should be handed to the Ministry of Health with the corresponding control books.	a) Ministry of Health (Secretaría de Salud) b) State governments (Gobiernos	A4	To protect public health. Namely, to control and monitor chemicals that, if left unregulated, might be used as inputs for illicit drugs. **International comparison** Similar provisions exist in	Producers who exit the market must hand their leftover stock to the Ministry of Health instead of being able to sell it. This may be an unnecessary cost	No recommendation. However, consider amending Article 108 of the Reglamento de Insumos para la Salud in order to include an explanation regarding

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				The provision does not, however, include an explanation of what will happen with the medicines afterwards.	de las entidades federativas)		other jurisdictions. For example, in the US, measures are undertaken to ensure that such substances do not enter the market without sufficient control. The Attorney General "may, in his discretion, seize or place under seal any controlled substances or list I chemicals [controlled substances] owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned" (21 US Code, §824 – Denial, revocation, or suspension of registration).	to exit.	the destination and use of narcotics and psychotropic medicines that are to be handed to the Ministry of Health.
92.	**Ley de Adquisiciones, Arrendamientos y**	14	Public procurement / Discrimination,	The Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público establishes	a) Ministry of Finance and Public Credit	A3	To promote and aid the development of the national industry.	Foreign or Mexican suppliers participating with foreign products	The OECD proposes three options for the Mexican government:

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	Servicios del Sector Público		barrier to entry	that there are three types of public tenders: 1) national; 2) international under treaty coverage; and 3) international open. Type 2) consists of tenders in which both Mexican and foreign suppliers can participate with goods that can be either of national origin or from countries with which Mexico has a free-trade agreement. For international public tender bids, under equal circumstances, public institutions must prefer national staff or nationally produced goods.	(Secretaría de Hacienda y Crédito Público) b) Ministry of Economy (Secretaría de Economía) c) Ministry of Public Administration (Secretaría de la Función Pública)		**International comparison** The European Commission generally advocates open international public-procurement markets and grants market access to non-EU countries to its public-procurement markets for certain goods and services. Some non-EU countries, such as the US have maintained or introduced protectionist or discriminatory measures in public procurement (e.g. the Buy American Act).	might be discriminated against. Furthermore, it is unclear how it is determined how or when "equal" circumstances are decided as two offers will almost never be identical in all features, including price in tender procedures that usually involve covered bids.	1) Abolish the part of the provision related to the preference for national staff or nationally produced goods, under equal circumstances. 2) Issue guidelines that make clear how to determine when circumstances are "equal" and for which cases the privilege for national products and labour should apply. 3) No recommendation, provided that there is no harm to competition. In fact, it is unlikely that two products are ever completely equal, including for price, so it should be easy to identify when one option is better.
93.	**Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público**	28	Public procurement / Discrimination	In the case of national tenders, only people or companies with Mexican nationality can participate, while offered goods must have at least 50% of national content (e.g. ingredients, human labour). Only Mexican nationals can therefore submit bids and pharmaceutical products must contain at least 50% of Mexican content.	a) Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público) b) Ministry of Economy (Secretaría de Economía) c) Ministry of Public	A3, B4	To promote the development of national industry. **International comparison** Many other jurisdictions have also adopted protectionist procurement measures about product nationality, including the US. The US Code, Title 41 – Public Contracts, Subtitle IV – Miscellaneous, Chapter 83 – Buy American states that: "Only unmanufactured articles, materials, and supplies that have been	Foreign pharmaceutical companies and foreign natural persons are potentially discriminated against in two ways. First, there is a restriction concerning a bidder's nationality that includes the company's nationality. For	The OECD proposes two options for the Mexican government: 1) Abolish the nationality requirement for participants in calls for tenders, while keeping the requirement of the product having at least 50% national content. That would allow foreigners producing in Mexico to participate in national tenders. In

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					Administration (Secretaría de la Función Pública)		mined or produced in the United States, and only manufactured articles, materials, and supplies that have been manufactured in the United States substantially all from articles, materials, or supplies mined, produced, or manufactured in the United States shall be acquired for public use unless the head of the department or independent establishment concerned determines their acquisition to be inconsistent with the public interest or their cost to be unreasonable." According to the same law, materials shall be considered to be mined or produced in the United States if the cost of the national products used in such materials constitutes more than 50% of the cost of all the products used in such materials.	instance, a foreign person producing in Mexico would be prevented from participating in national tenders, even though he or she might be able to offer better prices than Mexican competitors. Second, the provision restricts the composition of products. A Mexican bidder could not participate with pharmaceutical products produced abroad or those produced in Mexico with more than 50% of foreign ingredients. This might force the producers to use more expensive national ingredients.	addition, the OECD recommends introducing a time limitation for this nationality provision to be in force, so that Mexican producers have a transition period to adapt to having new competitors. 2) Do not change the national tender procedure. However, as far as possible, international tenders should be used.

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94.	**Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público**	28	Public procurement	Generally in Mexico, the bidder that meets all the requirements and offers the lowest price wins the tender. In the context of international tenders, however, in order to determine the lowest price, Mexican goods can have a price up to 15% higher than the lowest foreign price and still be considered as the lowest bid.	a) Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público) b) Ministry of Economy (Secretaría de Economía) c) Ministry of Public Administration (Secretaría de la Función Pública)	A3, B4	To promote the development of national industry. **International comparison** Similar provisions exist in other jurisdictions. For instance, in the US, the Federal Acquisition Regulation that implements the Buy American Act states that: "If there is a domestic offer that is not the low offer, and the restrictions of the Buy American statute apply to the low offer, the contracting officer must determine the reasonableness of the cost of the domestic offer by adding to the price of the low offer, inclusive of duty – 1) 6 percent, if the lowest domestic offer is from a large business concern; or 2) 12 percent, if the lowest domestic offer is from a small business concern [...] The price of the domestic offer is reasonable if it does not exceed the evaluated price of the low offer after addition of the appropriate evaluation factor."	This provision discriminates against foreign producers that might be able to offer the product cheaper than their Mexican competitors. However, favouring the Mexican industry in public procurement will be at the expense of the Mexican consumer.	Abolish discrimination against foreigners during an international open tender. If the Mexican government wants to promote national industry, it could use national tender procedures or introduce direct subsidies. In addition, the OECD recommends introducing a time limitation for this provision, so that Mexican producers are given a period of adaptation to the new situation and can become more competitive.

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95.	**Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público**	41	Public procurement	Public tenders are not considered to be necessary when the public institution involved can prove that there are no alternative goods or services or "rational technical substitutes" available. In this case, the authority might directly purchase from the supplier.	a) Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público) b) Ministry of Economy (Secretaría de Economía) c) Ministry of Public Administration (Secretaría de la Función Pública)	A3	When the lack of substitutes is evident, direct procurement can save resources that would otherwise be necessary for the preparation and publication of the call for tenders. The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. The ATC can be consulted online (www.whocc.no/atc_ddd_index/).	It might not always be clear whether substitutes for given goods or services do or do not exist. Therefore, there might be a risk of discretion and authorities freely deciding about substitutability. For example, an authority could favour a certain producer by defining a required product so narrowly that competitors' products would not be regarded as substitutes.	No recommendation. Authorities can easily determine if there are substitutes for a certain drug, using the ATC classification.
96.	**Ley para el Desarrollo de la Competitividad de la Micro, Pequeña y Mediana Empresa**	10	Public procurement / Discrimination	Industrial policy that supports the development of micro, small and medium enterprises (MSME) aims to ensure that public procurement is increasingly served by MSME. The objective is for 35% of public procurement to be served by MSME, although no time frame is given.	Ministry of Economy (Secretaría de Economía)	A3	To promote MSME development. According to market sources, the policy seems to be only partially implemented and the participation of MSME in the pharmaceutical sector is much lower than 35% (currently around 8%). **International comparison** Many countries promote MSME development in public procurement, e.g. EU member states (Directive 2014/24/EU), such as Germany (§ 97 para. 4 Act against Restraints of Competition), Korea, and the US. In Korea, according to	Low-cost offers from non-MSME participants might not be considered. In particular, larger firms may be discriminated against.	The OECD proposes two options for the Mexican government: Option 1) No recommendation as the policy is not binding and only partially applied. Also, helping MSME is a legitimate objective. Option 2) Abolish the part of the provision related to targeting a minimum percentage of public procurement to be awarded to MSME and consider introducing direct subsidies.

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							Article 4 of the Act on Facilitation of Purchase of Small and Medium Enterprise-Manufactured products and support for development of their markets, "[w]hen the heads of public institutions intend to conclude contracts for the procurement of goods [...], they shall provide small and business proprietors with increased opportunities for receiving orders". In the US, the Subpart 19.7 – The Small Business Subcontracting Program of the Federal Acquisition Regulation states that any contractor must agree in the contract for small businesses to have the maximum practicable opportunity to participate in contract performance consistent with its efficient performance.		
97.	**Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público**	8	Public procurement / Import substitution	Public institutions must design programmes that strengthen the development of national suppliers in order to generate supply chains of goods offered in regularly held public tenders.	a) Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público) b) Ministry of Economy (Secretaría de Economía) c) Ministry of	A3, B4	To promote the development of national industry, especially MSME development. **International comparison** This appears to be a general practice among countries, e.g. EU Directive 2004/18/EC.	Mandated preference for national suppliers can imply a barrier to entry for foreign suppliers.	No recommendation, but evaluate policy. Possible alternative might be the payment of direct subsidies.

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					Public Administration (Secretaría de la Función Pública)				
98.	**Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público**	23	Public procurement/ Discretion, risk of discrimination	Public institutions may create commissions as advice bodies regarding their type of public-procurement processes. Commissions will have as an objective to promote and implement programmes for efficient import substitution. This provision applies to the purchase of medicines.	a) Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público) b) Ministry of Economy (Secretaría de Economía) c) Ministry of Public Administration (Secretaría de la Función Pública)	A3, B4	To promote the development of national industry.	Mandated preference for national suppliers is a barrier to entry for foreign suppliers. It might lead to price increases if foreigners are barred from the national market even though they might be able to supply producers at better prices.	No recommendation, but evaluate policy. Possible alternative might be the payment of direct subsidies.
99.	**Ley de la Propiedad Industrial**	74	Intellectual property / Risk of discrimination	A person may request a compulsory license to exploit a patent that has not been exploited by the patent holder three years from the date the patent was granted, or four years after the filing of the application, whichever occurs later (Article 70 of Ley de la Propiedad Industrial). The patent holder, as well as license holders, can request that the Mexican Institute of Intellectual Property (Instituto Mexicano de la Propiedad	The President of Mexico through IMPI	A3	IMPI is interested in the diffusion of technological knowledge. "Supervening causes" grants IMPI sufficient flexibility in the application of the provision. The costs for an application seem reasonable. **International comparison** According to the World Trade Organization, compulsory licensing is "when a government allows someone else to produce the patented product or process without the	As there is not clear definition of what constitutes "supervening causes" and what conditions will be modified (e.g. time), there is a risk of discretionary behaviour that may lead to anticompetitive outcomes.	No recommendation

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				Intelectual, IMPI) modifies the conditions of a compulsory license only when justified by "supervening causes". However, there are no clear guidelines on what constitute "supervening causes". Applicants must pay MXN 2 864.85 for an evaluation of a mandatory licence or its conditions (https://eservicios.impi.gob.mx/seimpi/ayudaSEIMPI/Preguntas_Frecuentes_RDUdi.pdf).			consent of the patent owner". (www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm). Compulsory licencing is one of the flexibilities of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The Doha Declaration on TRIPS and Public Health confirms that countries are free to determine grounds for granting compulsory licences.		
100.	**Ley Federal sobre Metrología y Normalización**	91	Administrative procedure / Risk of discrimination	Authorities can perform surprise inspections on establishments in order to verify compliance with the Ley Federal sobre Metrología y Normalización (such as labs performing tests using measurement instruments). The establishment must pay the expenses of the inspection.	The President through the Federal Public Administration units with competence in the regulated matters.	B4	To protect the Mexican population against health risks by regulating sanitary control of establishments and ensuring Mexican pharmaceutical companies meet legal requirements.	The company subject to inspection must pay for the expenses even if no infringement is found. This may raise costs for some firms and also impose risks of arbitrary behaviour, for example, if a company is excessively inspected.	Limit the number of surprise inspections per year to avoid possible abuses. Additional surprise inspections will remain possible in case of reasonable suspicion.

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1.	**Ley de Organizaciones Ganaderas DOF 09-04-2012 Reglamento de la Ley de Organizaciones Ganaderas DOF 24-12-1999**	Law: 13 Regulation: 104	Livestock transport / Livestock farming, associations, transportation	To transport livestock across Mexican territory, it is necessary to acquire a certification from the local livestock association in the municipality of origin. To obtain this certification, it is necessary to provide the local livestock association with proof of ownership of the animals to be transported. This can be a certificate of the registry of a branding-iron, a mark or a tattoo. For cattle, there is also a federal identification system that uses ear tags: the National System of Individual Cattle Identification (Sistema Nacional de Identificación Individual de Ganado, SINIIGA). SINIIGA ear tags are lifetime identification for cattle and can include a microchip that helps farmers monitor health and production of animals. SINIIGA aims to foster sanitary control, ensure traceability and prevent cattle rustling. There are no equivalent identification systems for pigs and chicken. SINIIGA is described in NOM-001-SAG/GAN-2015,	SAGARPA	A2, C1	The objective is to prevent cattle rustling (theft). However, according to an industry participant, the certification granted by local livestock associations is not a sufficient means to prevent this problem. Only cattle seem to need an association certification. The theft of chicken or pigs, though of course possible, does not seem to pose a significant problem to producers in practice.	The local livestock association might have incentives to discriminate against competitors, particularly against those from other geographic areas or not belonging to the association. Furthermore, the Ley de Organizaciones Ganaderas and the Reglamento de la Ley de Organizaciones Ganaderas are not clear as to what procedure should be followed to appeal the decision of a livestock association in denying certification. While, in theory, a local livestock association should not be able to refuse certification if proof of ownership is provided, the local livestock association might still find means to discriminate against livestock producers that do not belong to it (e.g. delaying the granting of the certification). Finally, in terms of transporting cattle	Abolish Article 13, Letter B of the Ley de Organizaciones Ganaderas, and Article 104, Letter II of the Reglamento de la Ley de Organizaciones Ganaderas. NOM-001-SAG/GAN-2015 already introduced sufficient safeguards against cattle rustling.

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				Sistema Nacional de Identificación Animal para Bovinos y Colmenas, published on the Federal Official Gazette on 29 May 2015.				across the Mexican territory, certification from a local livestock association is a double control, as cattle are already equipped with an ear tag under the SINIIGA system.	
2.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012**	111	Meat production	The Inter-Ministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable, CIDRS), with the participation of the Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable, CMDRS), and in accordance with international trade agreements signed by the Mexican federal government, decides on those agricultural products whose producers are eligible to receive support. In particular, CIDRS can undertake actions to ensure that consumers are geographically closer to favoured producers. (Article 111 of the Ley de Desarrollo Rural	CIDRS, SAGARPA	A5	According to Article 111 of the Ley de Desarrollo Rural Sustentable, support granted by CIDRS has the objective of increasing the income of producers whose products are prone to commercial difficulties.	If some producers get support so that their customers are geographically closer, while other producers do not receive this type of support, competition would be distorted. Furthermore, government institutions might be biased to buy only from geographically close producers, even though producers farther away could make more competitive offers.	Modify Article 111 of the Ley de Desarrollo Rural Sustentable so that CIDRS does not have the power to promote geographical proximity between buyers and the production zones. A more pro-competitive way to sustain the development of producers might be through direct producer subsidies

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				Sustentable also contains another restriction which deals with public procurement). The CIDRS is composed of the ministers of ministries involved in rural development (i.e. SAGARPA, SE, SEMARNAT, SHCP, SCT, SSA, SEDESOL, SEDATU, SEP and SENER), as well as by any other ministries or entities that the executive considers necessary. SAGARPA oversees CIDRS. CMDRS is composed of CIDRS along with accredited representatives from social and private national organisations whose scope of action falls within rural areas.					
3.	**Absence of NOMs related to the classification of beef, pork and chicken carcasses; discrimination against non local meat producers**	N/A	Meat production / Geographical	Currently, there are no Mexican Official Standards (Normas Oficiales Mexicanas, NOMs) related to the classification of beef, pork or chicken carcasses. However, there do exist voluntary standards dealing with this subject: Mexican Norms (Normas Mexicanas, NMX) NMX-FF-078-SCFI-2002, NMX-FF-081-SCFI-2003 and	SAGARPA	B3, B4	It is unclear why there are no NOMs related to the classification of beef, pork or chicken carcasses. The problem has been recognised and partially tackled in the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, which	Whenever state level laws or standards prevent non-local meat producers from obtaining grades comparable to those of meat of similar quality from local producers, non-local producers have to sell their meat in the state in question at lower prices. This	Introduce NOMs related to the classification of beef, pork and chicken carcasses. These NOMs should not only fit the needs of exporting meat producers, but also of producers serving the domestic market. Furthermore, NOMs should take account of existing international

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				NMX-FF-128-SCFI-2016. According to industry participants, these NMX are neither widely applied nor regularly updated. The absence of compulsory meat classification systems has a negative impact on both the domestic and the exports markets. **Domestic market.** The absence of NOMs related to the classification of beef, pork or chicken carcasses is aggravated by the existence of several state livestock laws containing provisions that discriminate against non-local meat producers. COFECE's report, *Miscelánea de obstáculos regulatorios a la competencia. Análisis de la normatividad estatal*, notes that, for instance, the *Ley de Ganadería* of Sonora state establishes that retailers have to separate – in fridges, shelves or showcases – livestock products from Sonora from livestock products coming from other Mexican states or abroad. In the case of the states of Tamaulipas			states that SAGARPA's Specialised Subcommittee on Competitiveness is working on a preliminary draft of a NOM aiming to set a system of classification of beef, which will include specifications for food safety, agroalimentary quality, authenticity, labelling, allowed denominations, as well as assessment procedures that will enable the differentiation of meat, on the basis of its "organoleptic properties".	hinders inter-state trade and movement of meat and meat products.	standards for the classification of carcasses (e.g. UN Economic Commission for Europe standards for meat; USDA's Standards for Grades of Slaughter Cattle and Standards for Grades of Carcass Beef) to facilitate exports.

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				(Reglamento para el Funcionamiento del Servicio de Clasificación de Carnes) and Veracruz (Reglamento del artículo 95-A de la Ley Ganadera), cattle-meat boxes coming from other states are automatically graded as "meat of commercial quality", which is the lowest grade for cattle carcasses in the classification systems of both states. Furthermore, according to industry participants, in the case of pork, there is the problem of "plumping" or "enhancing". In severe cases, 40% of the total weight of pork can be brine. **Export market.** As Mexican meat cannot be differentiated, exporters have to sell their meat at lower prices, since importing countries (e.g. the United States) grant Mexican meat the lowest classification, independent of its actual quality.					
4.	**Ley Federal de Sanidad Animal DOF-07-06-2012 Reglamento de la Ley Federal de Sanidad Animal**	Law: 68 Regulation: 110, 111, 112	Transport / Transport	Transport of "regulated products" inside Mexico is subject to the issuance of a Zoosanitary Transport Certificate (Certificado Zoosanitario de	SAGARPA	A2	The objective is to prevent the transmission of animal diseases across Mexican regions. Live animals, according to SENASICA, can only	The validity period of CZMs might be unnecessarily short and raise costs for producers that have to apply for a new	No recommendation.

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	DOF-21-05-2012			Movilización, CZM) from SAGARPA or third-party specialists either authorised by SAGARPA or that are authorised at zoosanitary certification centers belonging to a certification body. According to Article 4 of the Ley Federal de Sanidad Animal, "regulated products" are defined as animals, products of animal origin, products for use or consumption by animals, livestock equipment, and any other articles or goods related to animals that might entail a zoosanitary risk. The CZM has to be used within five days of its issuance. Issuance of this certificate depends on compliance with a number of technical requirements (e.g.campaigns, quarantine, contamination risks, national emergency system, animal welfare and national epidemiologic vigilance system), which are listed and described in detail in Articles 110 and 111 of the Reglamento de la Ley Federal de Sanidad Animal.			be transported continuously during 14 hours. In the case of live animals, a CZM therefore allows companies to plan their transportation well in advance. Industry participants did not complain about the validity duration of the CZM.	certificate.	

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				The Ley Federal de Derechos, with the last amendment published on the Federal Official Gazette on 7 December 2016, states in Article 86-A, Letter II, that a CZM costs MXN 99.82. Concerning livestock, Article 111, Letter VI of the Reglamento de la *Ley* Federal de Sanidad Animal states that the CZM is granted either for each individual animal or per lot, depending on the animal species.					
5.	**State transport documents**	N/A	Transport / Transport	COFECE's report *Miscelánea de obstáculos regulatorios a la competencia. Análisis de la normatividad estatal* states that several state governments require a transport document in order to transport live animals, their products and subproducts within states. Transport documents have different names, depending on the state. For example, state livestock laws of Chiapas (Ley de Fomento y Sanidad Pecuaria), Coahuila (Ley de Fomento Ganadero), Puebla (Ley Ganadera), Querétaro (Ley de Desarrollo Pecuario),	SAGARPA	A2, A5	Most likely state governments require transport documents to meet two objectives: 1) to prevent the entry of animals, animal products and subproducts that could constitute a health danger for their citizens; and 2) to prevent the theft of live animals, their products and subproducts. Markets participants, on the other hand, claim that states often use transport documents as a means to raise additional income.	Producers interested in commercialising their products in different states have to pay for several transport documents and disinfection certificates in order to move their products from the point of production to points of sale. This makes their products more expensive and discriminates in favour of local producers. In this regard, Article 67 of the Ley Federal de Sanidad Animal states that SAGARPA	Abolish the requirement of state transport documents (*guías de tránsito*). The Zoosanitary Transport Certificate (Certificado Zoosanitario de Movilización, CZM) and the Transport Notice (Aviso de Movilización, AM) should replace in all instances state transport documents regarding the zoosanitary conditions. The theft of chicken or pigs does not seem to pose a significant problem to producers in practice while for cattle a federal identification

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				Quintana Roo (Ley de Fomento y Desarrollo Pecuario), San Luis Potosí (Ley de Ganadería) and Yucatán (Ley Ganadera) refer to this document as a *guía de tránsito*. In several states (e.g. Chiapas, Coahuila, Puebla, Querétaro and Yucatán), transport documents can be issued by local livestock associations. According to several industry participants, state transport documents usually have a cost, and contain information that is already included in the CZM. Thus, transport documents constitute an unnecessary double control. Sometimes, in addition to transport documents, state governments also require the payment of disinfection certificates and entry permits.				has the exclusive power to determine the zoosanitary requirements to transport "regulated products" across the country, and that state authorities cannot impose requirements stricter than those determined by SAGARPA. Therefore, provisions in state livestock laws that require transport documents with additional requirements to those established by SAGARPA arguably infringe Article 67 of the Ley Federal de Sanidad Animal. Finally, COFECE's report *Miscelánea de obstáculos regulatorios a la competencia. Análisis de la normatividad estatal*, states the following about transport documents (p.16): "Related to this, the Supreme Court of Justice of the nation has determined that the	system (i.e. SINIIGA) exists that ensures traceability and prevents cattle theft. It should be further examined as to whether this recommendation can be implemented through an amendment or clarification in federal law (e.g. a statement that additional state transport documents are forbidden), or whether more extensive measures will need to be taken.

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								provisions restricting the movement of products violate the freedom of trade protected by Article 5 of the Constitution, since they impose a limitation to the individual's freedom to commercialise his or her products."	
6.	**Oficio Circular No. B00.03.- 08/06/2016 de SENASICA** **Acuerdo por el que se da a conocer la campaña y las medidas zoosanitarias que deberán aplicarse para el diagnóstico, prevención, control y erradicación de la Influenza Aviar Notificable, en las zonas del territorio de los Estados Unidos Mexicanos en las que se encuentre presente esa enfermedad. DOF-21-06-2011**	Issued circular: II, III, IV Agreement: 68	Transport / Traceability	It is necessary to fill in a Transport Notice (Aviso de Movilización, AM) in order to transport pigs, and their products and subproducts, and poultry, its products and subproducts from an area free of influenza. AMs are free and can be filled in via the National Service of Transport Notices (Servicio Nacional de Avisos de Movilización, SNAM). Poultry, its products and subproducts from areas that are not free of influenza need a Zoosanitary Transport Certificate (Certificado Zoosanitario de Movilización, CZM) instead; there is a charge for a CZM.	SAGARPA	A2	The regulation's objective is to ensure the existence of a traceability system for pigs, their products and subproducts, as well as for poultry, its products and subproducts coming from an influenza-free area.	Several industry participants complained that AMs are unnecessary as companies have their own traceability systems.	No recommendation. AMs have simplified the transport of low-risk "regulated products", when compared to obtaining a CZM. Abolishing AMs is not recommended as in their absence it would not be possible to guarantee that all companies have an adequate traceability system.
7.	**NOM-194-SSA1-2004, Productos y**	6.6.2.1, 6.7.1	Slaughtering and meat processing /	All animals arriving at an abattoir must have a	Surveillance: SSA through	A2	The most likely objective is to guarantee the	Entrants need ex ante authorisation,	Amend articles 6.6.2.1 i) and 6.7, so that only a

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	servicios. Especificaciones sanitarias en los establecimientos dedicados al sacrificio y faenado de animales para abasto, almacenamiento, transporte y expendio. Especificaciones sanitarias de productos		Raises costs	zoosanitary certificate (the NOM refers to *certificado zoosanitario*, which is presumably a CZM) or a "Cattle Transport Document" (the NOM refers to *guía de traslado de ganado*, which is presumably is a state transport document). Furthermore, registry must be kept of information concerning origin, destination, meat temperature, means of transport temperature, and data to identify the vehicle (such as licence plate, driver, and company).	COFEPRIS, state governments, and authorised third parties.		traceability of animals arriving at abattoirs.	which can be a barrier to entry if requirements are too burdensome or costly. Furthermore, it is not clear why two documents – a Cattle Transport Document and a Zoosanitary Certificate – are referred to as substitutes.	CZM is required for animals arriving to abattoirs. Cattle Transport Documents should not be accepted at abattoirs.
8.	**Ley de Productos Orgánicos DOF-07-02-2006** **Reglamento de la Ley de Productos Orgánicos DOF-01-04-2010** **Acuerdo por el que se dan a conocer los Lineamientos para la Operación Orgánica de las actividades agropecuarias DOF-29-10-2013**	Law: 8, 15, 19 Regulation: 5, 6 Agreement: general	Organic / Labelling, organic	Agricultural and livestock producers wanting to commercialise their products as "organic" need a certification granted by SAGARPA or by an organic certification body. The latter are private firms (e.g. Certificadora mexicana de productos y procesos ecológicos), approved by SAGARPA to certify that a product is organic. As of November 2015, there were nine organic certification bodies in Mexico. To obtain the organic certification, a producer	SAGARPA	A2	The objective of the regulation is to enable clear identification of agricultural and livestock products whose production processes, broadly speaking, do not involve the use of pesticides or synthetic agrochemicals. The conversion period ensures that in a specified period past production has been carried out using only approved organic inputs. As a consequence, consumers are not misled and trust in	Compliance with conversion periods delays entry into the organic-meat market.	No recommendation. SAGARPA is working on an amendment to the Acuerdo por el que se dan a conocer los Lineamientos para la Operación Orgánica de las actividades agropecuarias. That amendment – Acuerdo por el que se modifican, adicionan y derogan diversas disposiciones del diverso por el que se da a conocer los lineamientos para la operación orgánica de las actividades agropecuarias.

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				must submit an Organic Plan to an organic certification body and its production must go through a "conversion period". The Organic Plan describes all production stages and proves compliance with the relevant law and its regulation. The "conversion period" is the time during which a producer cannot label its products as organic, but during which production is carried out using approved organic inputs. A previous period can be recognised retroactively as being part of the conversion period if the producer has an analysis registry proving that only permitted inputs were used in the production process. The length of the conversion period depends on the animal species (i.e. the bigger the animal species the longer conversion period). Article 17 of the Acuerdo por el que se dan a conocer los Lineamientos para la Operación Orgánica de las actividades agropecuarias establishes that, in the case of animals raised for			organic labels is improved. **International comparison** Conversion periods for organic meat production also exist in the EU. Article 38 of the Commission Regulation (EC) No. 889/2008 of 5 September 2008 establishes specific conversion periods for livestock and livestock products. Furthermore, the length of conversion periods for cattle, pigs and poultry for meat production is established in the regulation, and are the same as those established in the Acuerdo por el que se dan a conocer los Lineamientos para la Operación Orgánica de las actividades agropecuarias. These periods are not so long as to delay entry for a significant time.		Publicado en el Diario Oficial de la Federación el 29 de octubre de 2013 – was published on the website of the Federal Regulatory Improvement Commission (Comisión Federal de Mejora Regulatoria, COFEMER) and is at post public-consultation phase. Among other proposals, the amendment proposes a further reduction in the conversion period for poultry for meat production (from 10 to 7 weeks).

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				meat, the conversion periods are at least 12 months for cattle, 6 months for pigs and 10 weeks for poultry. The list of inputs permitted in organic production is also established in the Acuerdo por el que se dan a conocer los Lineamientos para la Operación Orgánica de las actividades agropecuarias.					
9.	**Reglamento de la Ley de Productos Orgánicos DOF-01-04-2010**	27	Organic / Labelling, organic	Organic certifications are granted for a one-year period, which can be renewed if requirements continue to be fulfilled.	SAGARPA	A2	The objective is to ensure that there is a continuity of compliance with the requirements of organic certification. To obtain a renewal of organic certification, organic producers must show that they have fulfilled the criteria related to the issuance of the original certification. **International comparison** In the EU, organic certification is not subject to renewals. Instead, Article 65 of the Commission Regulation (EC) No. 889/2008 of 5 September 2008 states that control authorities or bodies carry out a physical inspection of all	The duration of organic certifications may be unnecessarily short, and renewal procedures may create excessive costs, especially for small producers.	No recommendation.

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							operators at least once a year. During these inspections, samples are taken to check that production techniques are in conformity with organic-production rules. Furthermore, random inspections, primarily unannounced, are conducted based on a risk evaluation of non-compliance with organic-production rules. In case of infringement or irregularities, Article 30 of the Council Regulation (EC) No. 834/2007 of 28 June 2007, states that the control authority or body will ensure that no reference is made to organic production methods in the labelling and advertising of the concerned lot or production run. Severe infringements can lead to the prohibition from marketing products with reference to organic production methods in the labelling and advertising, for a period to be agreed by the concerned EU Member State. According to SENASICA,		

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							the current Mexican system for renewing organic certifications is equivalent to the EU system. This is the case as the EU inspection system, even if not properly a renewal system, relies on physical inspections carried out at least once a year, which fully assess compliance with Council Regulation (EC) No. 834/2007 and, thus, entail a comparable level of regulatory burden.		
10.	**Ley Federal de Sanidad Animal DOF-07-06-2012** **Reglamento de la Ley Federal de Sanidad Animal DOF-21-05-2012** **Acuerdo por el que se dan a conocer los Criterios generales aplicados por México para el establecimiento y modificación de requisitos en materia de sanidad e inocuidad animal, vegetal,**	Law: 32, 33, 34 Regulation: 40 Agreement: General	Animal health. Meat production / Zoosanitary, sanitary, animal health	To import "regulated products" (*mercancías reguladas*), a Zoosanitary Import Certificate (Certificado Zoosanitario para Importación, CZI) must be granted by SAGARPA at Mexican entry points. In order to obtain a CZI, the requirements in the Zoosanitary Requirements Form (Hoja de Requisitos Zoosanitarios, HRZ) must be fulfilled. The HRZ has specific requirements for the importation of all "regulated products". The HRZs can be adapted to the specific sanitary conditions of exporting	SAGARPA	A2	The objective is to prevent the entry of foreign animal diseases into Mexico. According to SENASICA, all HRZs are generated from universal HRZs, so all countries are generally subject to the same standards. Also according to SENASICA, there has been a substantial simplification of HRZs in the recent past: the number of all possible HRZs combinations for livestock products has been reduced from around 10 000 to around 3 000. Currently, there are two	HRZs are necessary for obtaining a CZI. As HRZs can be adapted to the specific sanitary conditions of exporting countries, a very high number of HRZs exist (around 3 000). This means that it might be difficult to ensure that all exporting countries are subject to the same standards. HRZs could therefore theoretically be used to prevent certain foreign countries from exporting to Mexico.	No recommendation. Requirements in HRZs should be regularly revisited, however, to prevent them containing outdated or unnecessary criteria (e.g. animal diseases that have been eradicated). All HRZs should be published and be easily and permanently accessible on SENASICA's website.

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	acuícola y pesquera para la importación de mercancías reguladas por la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación a través del Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria. DOF-29-05-2014.			countries.			safeguards against misuse of HRZs modifications: 1) The agreement published in the Federal Official Gazette on 29 May 2014, establishes that all modifications to HRZs will be subject to a public consultation. 2) Article 39 of Reglamento de la Ley Federal de Sanidad Animal states that HRZs must be based on technical and scientific diagnosis, as well as on international recommendations or risk assessments. This provides certainty to Mexico's trading partners about which conditions that they have to comply.		
11.	**NOM-008-ZOO-1994, Especificaciones zoosanitarias para la construcción y equipamiento de establecimientos para el sacrificio de animales y los dedicados a la industrialización de productos**	4	Slaughtering and meat processing / Sanitary rule	To build and operate a Federal Inspection Type (Tipo Inspección Federal, TIF) abattoir and/or meat processing plant, records must be kept (e.g. monthly bacteriological tests, equipment lists, insect- and rodent-control programmes, quality-control programmes). This NOM does not apply to	Surveillance: SAGARPA and state governments Application: SAGARPA	A2	The objective of the regulation is to allow pre- and post-mortem inspection of animals at TIF abattoirs to ensure that facilities and equipment are adequate.	Entrants need authorisation ex ante, which can be a barrier to entry if requirements are too burdensome or costly.	No recommendation.

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	cárnicos (Modificada)			municipal abattoirs, whose concessions are regulated under municipal legislation.					
12.	**NOM-008-ZOO-1994, Especificaciones zoosanitarias para la construcción y equipamiento de establecimientos para el sacrificio de animales y los dedicados a la industrialización de productos cárnicos (Modificada)**	5.2	Slaughtering and meat processing / Sanitary rule	An authorisation to build and operate an abattoir and/or a meat processing plant relies on fulfilling the conditions for a functioning drainage system. If the drainage system is considered insufficient, the abattoir and/or processing plant's location will not be approved. It is not clear what is meant by an insufficient drainage system.	Surveillance: SAGARPA and state governments Application: SAGARPA	A2	The objective is probably to prevent the accumulation of waste (e.g. blood, fat) that could be a source of human and animal diseases. **International comparison** Adequate drainage facilities in the EU, for example, are laid out in No. 8, Chapter I of General requirements for food premises (other than those specified in Chapter III) of Annex II, of Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004, which states that: "Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area	Entrants need authorisation ex ante, which can be a barrier to entry if requirements are too burdensome or costly. Furthermore, the lack of clarity of these requirements might favour discrimination.	Article 5.2 of this NOM should contain an explanation of what constitutes a sufficient drainage system. The quoted paragraph from Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 could serve as a model for such an explanation.

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							towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled."		
13.	**Ley de Bioseguridad de Organismos Genéticamente Modificados DOF 18-03-2005**	91, 92	Rearing livestock / Sanitary rule	Genetically modified organisms (GMO) for human or animal consumption require the authorisation of the Ministry of Health (Secretaría de Salud, SSA). This authorisation involves submitting a risk-assessment study to the SSA.	SAGARPA, SEMARNAT and SSA	A2	The objective is probably aimed at minimising the risk of commercialising GMOs that could prove a danger to public health. The conditions for an authorisation seem sufficiently clear. On 3 January 2014, a NOM was published in the Federal Official Gazette that establishes the characteristics and content that must be included in the reports of released GMOs, in relation with the possible dangers for the environ-ment, biological diversity, and animal, vegetable and fisheries health; see, NOM-164-SEMARNAT / SAGARPA-2013, Que establece las carac-terísticas y contenido del reporte de resultados de la o las liberaciones realizadas de organismos genéticamente modificados, en relación con los posibles riesgos para el medio ambiente y	Entrants need authorisation ex ante, which can be a barrier to entry if requirements are too burdensome or costly.	No recommendation.

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							la diversidad biológica y, adicionalmente, a la sanidad animal, vegetal y acuícola. **International comparison** The release and commercialisation of GMOs is subject to risk assessments. For instance, in the EU, Directive 2001/18/EC of the European Parliament and of the Council requires risk assessments to be undertaken before GMOs are commercialised.		
14.	**Ley de Bioseguridad de Organismos Genéticamente Modificados DOF 18-03-2005**	93	Rearing livestock / Sanitary rule	Any corporate entity wanting to import a GMO must provide the SSA with documentation that proves the GMO is authorised in the origin country. If this is not the case, the importer must disclose this situation, and provide the SSA with documentation that will allow it to decide whether to grant the import authorisation.	SAGARPA, SEMARNAT and SSA	A2	The objective is probably to minimise the risk of importing GMOs that could prove a danger to public health. **International comparison** The release and commercialisation of GMOs is subject to risk assessments. For instance, in the EU, Directive 2001/18/EC of the European Parliament and of the Council requires risk assessments to be undertaken before GMOs are commercialised.	Entrants need authorisation ex ante, which can be a barrier to entry if requirements are burdensome or too costly.	No recommendation, as the conditions for foreign companies interested in exporting GMOs to Mexico are clear.

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15.	**Ley Federal de Sanidad Animal DOF-07-06-2012**	25, 26, 38	Imports / Barrier to entry, zoosanitary, sanitary, imports	Animals, their products and subproducts must come not only from authorised countries, but also from authorised establishments within authorised countries. For a country to be authorised, its veterinary services must be recognised by SAGARPA as working at least at to the same standards as in Mexico. SAGARPA, through SENASICA, authorises countries and establishments that export to Mexico.	SAGARPA	A2, A4, A5	The objective is to ensure that imported live animals, their products and subproducts do not constitute a danger to the health of Mexican consumers. According to interviews with industry participants, this double authorisation is often justified by the possible existence of zones within foreign countries that are free of animal disease and others that are not. Foreign authorities do not always seem able to prevent exports from zones where diseases exist. Also, several foreign countries to which Mexican producers export live animals, their products and subproducts, also follow the same procedure, i.e. they authorise foreign animal-health authorities and regularly visit individual foreign establishments.	This provision leads to a double control, of the country and the establishment. It would seem that country authorisations would be sufficient to guarantee adequate zoosanitary conditions as foreign animal-health authorities should, at least in theory, regularly inspect all establishments within their countries. The requirement that SAGARPA also authorises and inspects establishments in foreign countries might therefore constitute an additional and possibly unnecessary barrier to entry. Related to the double authorisation, COFECE report, *Reporte sobre las condiciones de competencia en el sector agroalimentario*, states (p.405): "this scheme creates	Eliminate additional establishment authorisations, but with eliminations based only on bilateral agreements with other countries that also abolish the additional requirement for Mexican exporting establishments to be authorised by the foreign sanitary authorities. Both sides would have to agree that their own internal sanitary authorities ensure the quality of all exporting establishments and their products within their jurisdiction (even if those products are not meant to be sold on the home market).

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								strong barriers to entry, as it requires that products come from countries and establishments that have been authorised. In this sense, sanitary risk could be dealt with through only the first filter, mainly when the country of origin applies standards that are at least as rigorous as those established under the Mexican regulation. Otherwise, trade could be probably restricted and, consequently, the free competition and entry process affected."	
16.	**Ley Federal de Sanidad Animal DOF-07-06-2012 Reglamento de la Ley Federal de Sanidad Animal DOF 21-05-2012**	Law: 80 Regulation: 57	Animal health, imports / Zoosanitary, imports	SAGARPA can prohibit or restrict imports of animals and related products in case of a zoosanitary emergency; it can also establish quarantine or conduct inspections of products entering Mexico. According to the Reglamento de la Ley Federal de Sanidad Animal, a zoosanitary emergency is a situation where, due to the high prevalence of an	SAGARPA	A3	The objective is to diagnose and prevent the introduction, establishment and spread of animal diseases that would have a negative incidence on animal and public health. The definition of what constitutes a zoosanitary emergency is clear and does not give the authority in charge wide discretion. Furthermore,	The entry requirements and controls established for imported products may work against foreign producers, putting them at a disadvantage compared to national producers.	No recommendation

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				animal disease, there is a risk of introduction of this disease into the Mexican territory, which consequently would have a large economic impact, reduce productivity, or create a public-health risk.			on 4 May 2016, SAGARPA further specified the requirements of a zoosanitary emergency by publishing in the Federal Official Gazette an agreement (Acuerdo mediante el cual se dan a conocer en los Estados Unidos Mexicanos las enfermedades y plagas exóticas y endémicas de notificación obligatoria de los animales terrestres y acuáticos) that lists all the exotic and endemic diseases and infectious diseases in terrestrial and aquatic animals about which Mexican stakeholders are obliged to notify SAGARPA. According to SENASICA, an updated version of this agreement is being currently drafted.		
17.	**Ley Federal de Sanidad Animal DOF-07-06-2012**	41	Imports / Barrier to entry, zoosanitary, sanitary, imports	Live animals imported into Mexico must be checked abroad at points of verification, undergo zoosanitary inspection, and be certified and inspected at Mexican entry points. SAGARPA can determine in which cases the import of live animals is subject to inspection and certification	SAGARPA	A2, A4, A5	The objective is to diagnose and prevent the introduction, establishment and spread of animal diseases that would have a negative incidence on animal and public health. The zoosanitary risk is higher for live animals. It is not uncommon for	This provision foresees a double import control. If live animals have already been inspected abroad, it appears that certification / verification on Mexican territory is not necessary.	No recommendation.

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				only at Mexican entry points.			animals to become infected during transport to Mexico. An additional control upon entry into Mexico therefore seems justified.		
18.	**NOM-030-ZOO-1995, Especificaciones y procedimientos para la verificación de carne, canales, vísceras y despojos de importación en puntos de verificación zoosanitaria**	4	Meat imports / Imports, inspections	Article 4.1 of this NOM states that 100% of imported lots of meat, carcasses, viscera and offal must be inspected, following the specifications laid out in the Zoosanitary Requirements Form (Hoja de requisitos zoosanitarios, HRZ). This restriction constitutes a "third control", in addition to the authorisation of foreign countries to export to Mexico, and the foreign establishment-by-establishment authorisation.	Surveillance and application: SAGARPA	A5, B4	The objective is to ensure that imported meat, carcasses, viscera and offal do not carry animal diseases that would have a negative impact on public health.	It seems excessive and unnecessarily costly to inspect 100% of imported meat, carcasses, viscera and offal, following the HRZ. Moreover, according to market sources, it is not feasible to inspect all imports, which might allow for wide discretion and lead to discrimination between suppliers.	Amend Article 4.1 of this NOM so that the inspection of 100% of imports, following the specifications in the HRZ, is replaced with a system under which both the timing and number of controls, as well as the number of samples taken to be inspected, would be chosen based upon a risk assessment. The controls should be random so that an exporter would not be able to predict the timing of the next control. Furthermore, the frequency of controls, as well as the size of the sample inspected during each control, could be based upon a risk assessment that took into account, among other factors, an exporter's past compliance with zoosanitary requirements. In the National

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									Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will likely be cancelled in 2017. According to SENASICA, the NOM will be replaced by the Acuerdo por el que se establecen las Reglas para la inspección y verificación de carne, canales y víscera y despojos que se importen a los Estados Unidos Mexicanos. That document, according to SENASICA, should set an inspection procedure based on risk assessment, taking into account the following variables: sanitary risks, historical non-compliance, destination of the product (i.e. TIF establishment or not), etc.
19.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012**	149	Rearing livestock / Tariffs	The Interministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable, CIDRS) will promote the creation of	CIDRS, SAGARPA	C1	The objective of the provision is to develop the meat-industry value chain, in the sense of increasing productivity and competitiveness. Agricultural and livestock producers only have a	The scope of the actions undertaken by CIDRS in practice is unknown. However, this provision suggests that the CIDRS can promote the	No recommendation, as it is in the power of the Mexican government to set tariffs as long as they comply with international agreements, such as the North American

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				Product Systems, committees of the Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable, CMDRS). These committees will have among their objectives to "participate in the setting of tariffs, quotas and categories of imports".			consultative role in the setting of tariffs. According to Article 4 of the Ley de Comercio Exterior (last amendment published in the Federal Official Gazette on 21 December 2006), the Federal Executive has the power to create, increase, decrease or abolish tariffs, through decrees published in the Federal Official Gazette, and in accordance with Article 131 of the Mexican Constitution. In many other jurisdictions, it is common for governments to consult market producers before making decisions related to establishing tariffs.	participation of agricultural and livestock producers in setting tariffs. Theoretically, producers could ask the CIDRS to restrict imports and protect them from foreign competitors.	Free Trade Agreement (NAFTA) and the rules established by the World Trade Organization (WTO).
20.	**NOM-054-ZOO-1996, Establecimiento de cuarentenas para animales y sus productos**	7.2	Meat production / Sanitary rule, excessive discretion	This restriction concerns imported animals whose SENASICA-issued HRZ states that they must be put in quarantine as long as it is "strictly necessary to determine that their presence in the country and at the destination does not constitute a zoosanitary risk". In practice, animal importers are allowed to take their animals to their own installations, where	Surveillance: SAGARPA and state governments Application: SAGARPA	A4, A5, B4	The objective is to prevent the entry of foreign animal diseases into Mexico.	The term "strictly necessary time" grants wide discretion to customs authorities. In theory, imported live animals could be blocked for substantial periods, delaying their transport and sale within Mexico.	Clarify the introductory paragraph of Article 7, as in its current state, it is not completely clear that livestock importers are allowed to take their quarantined animals to their own facilities, and for SENASICA to visit them periodically and monitor the animals' health status.

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				SENASICA staff subsequently visit the animals periodically and monitor their health status. This allowance, however, is not clear from the reading of the NOM.					
21.	**Decreto por el que se establece la Ventanilla Digital Mexicana de Comercio Exterior DOF 14-01-2011**	General	Imports, exports / Imports, Internet platform	This decree establishes the Mexican Digital Window of Foreign Trade (Ventanilla Digital Mexicana de Comercio, also known as Ventanilla Única de Comercio Exterior Mexicana, VUCEM), an Internet platform that centralises all communication and compliance for Mexican federal agencies with border management responsibilities. Article 22 of the decree establishes that the development and management of VUCEM, once implemented, will fall within the responsibility of the Tax Administration Service (Servicio de Administración Tributaria, SAT), a body of the SHCP.	SAT	A4, A5, B4	The objective of the regulation is to reduce bureaucratic procedures, centralising compliance with foreign-trade requirements. This objective, however, can only be reached if the platform performs adequately.	The decree by itself is pro-competitive. However, according to several industry participants, VUCEM is not fully functional. One industry participant estimated that in 2016 VUCEM malfunctioned (was in a "contingency phase") up to 40% of the time. This downtime can lead to perishable imported meat and meat products waiting long periods on the frontier.	It is essential that VUCEM functions correctly and consistently. It should therefore be clarified that only one authority (i.e. the SAT) is fully responsible for VUCEM's functioning in terms of SENASICA procedures, and that other agencies must support such an authority. Furthermore, sufficient funds should be granted to all authorities to ensure that VUCEM functions correctly.
22.	**Ley Federal de Sanidad Animal DOF-07-06-2012 Reglamento de la Ley Federal de Sanidad Animal**	Law: 143, 58, 59 Regulation: 280	Industry participation, rearing livestock / Corregulation, zoosanitary measures,	Animal Health Auxiliary Organisms (Organismos Auxiliares en Sanidad Animal, OASA) are organisations of livestock producers that support the Ministry of Agriculture,	SAGARPA	C1	SAGARPA grants OASA the power to coordinate and implement zoosanitary campaigns and programmes on good livestock practices, since it considers OASA	Granting organisations of livestock producers the power to coordinate and implement zoosanitary	No recommendation concerning the structure of OASA, since the OECD considers that the current regulatory framework gives sufficient power to

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	DOF 21-05-2012		associations	Livestock, Rural Development, Fisheries and Food (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, SAGARPA) in the coordination and implementation of zoosanitary campaigns and programmes on good livestock practices. Article 4 of the Ley Federal de Sanidad Animal provides definitions for the terms "campaign" and "good livestock practices". A "campaign" is a set of zoosanitary measures for the prevention, control or eradication of animal diseases or disease outbreaks within a determined geographical area and time period. "Good livestock practices", in turn, consist of procedures, activities, conditions and controls that are applied to animal production units or Federal Inspection Type (Tipo Inspección Federal, TIF) establishments to reduce the dangers associated to physical, chemical and biological agents, as well the risks associated to animal-based products that			to be a cost-effective option to doing this work itself. OASA operate under the supervision of SENASICA. According to industry participants, the tasks carried out by OASA are operational, and not linked to the determination of the zoosanitary status of geographical areas. It therefore seems unlikely that OASA are used by livestock producers to foreclose on competitors. According to SENASICA, authorisations to operate have already been revoked for OASA in several states, when misconduct was spotted.	campaigns and programmes on good livestock practices could lead to undesired outcomes if an OASA were to use this power to foreclose on individual livestock producers. In theory, an OASA could refer to SAGARPA an individual livestock producer that does not comply with good livestock practices or a zoosanitary campaign, causing negative consequences for this producer (e.g. its exit from the market).	SAGARPA to supervise and revoke OASA status. However, stricter supervision of the spending of funds granted to OASA, as well as OASA's behaviour concerning the implementation of zoosanitary campaigns and programmes on good livestock practices is recommended. In this regard, the OECD suggests considering issuing guidelines that provide clear criteria for revoking authorisations.

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				are consumed by animals. The classification of Auxiliary Organisms depends on whether members are agricultural, livestock or aquaculture producers. In the case of livestock producers, OASA are known as Promotion and Protection Livestock State Committees (Comités Estatales de Fomento y Protección Pecuaria, CEFPP). CEFPP operate under the supervision of SAGARPA's state branches, as well as of state governments. CEFPP are authorised to operate by SAGARPA, which can revoke their authorisations if it considers them to no longer fulfil their objectives. Each one of the Mexican states, except Mexico City, has a CEFPP.					
23.	**Ley de Organizaciones Ganaderas DOF 09-04-2012**	5	Rearing livestock / Livestock farming, associations, price and quantity fixing	According to Article 5, Letter II of the Ley de Organizaciones Ganaderas, one of the objectives of livestock associations is guiding "production according to market conditions, either intensifying or withholding it".	SAGARPA	C1	One of the objectives of livestock associations is to develop and improve the production and commercialisation of livestock products. However, no justification is provided for Article 5, Letter II of the Ley de Organizaciones Ganaderas.	Controlling production, and indirectly, price levels, is a severe restriction of competition. Furthermore, as is mentioned in COFECE's report *Miscelánea de obstáculos*	Abolish Article 5, Letter II of the Ley de Organizaciones Ganaderas.

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								regulatorios a la competencia. Análisis de la normatividad estatal (pp.20-21), several state livestock laws (i.e. Sinaloa, Sonora, Tlaxcala, Veracruz, Zacatecas and Mexico City) promote mechanisms that enable local livestock associations to jointly set the prices of their products or the quantities sold.	
24.	**Reglamento de la Ley de Organizaciones Ganaderas DOF 24-12-1999**	16	Rearing livestock / Livestock associations, statistics, sensitive information, information sharing	Livestock associations must, on the one hand, create statistics (the exact data and level of aggregation of these statistics is unknown) and, on the other hand, encourage members to keep proper internal accounting so that members are aware of their own production costs, as well as price studies about products they market. It is unclear what is meant by price studies, as is whether this information is later shared between association members.	SAGARPA	C2	The objective of the provision is not mentioned in the Reglamento de la Ley de Organizaciones Ganaderas. Most probably, it is to help livestock producers improve their decision making (e.g. by spotting industry trends or allowing benchmarking); and to facilitate the creation of national statistics.	Accounting information about livestock associations and their members may include sensitive data which, if shared between livestock associations members, might facilitate collusion.	Amend Article 16, Letters II and III of Reglamento de la Ley de Organizaciones Ganaderas, so that it is clear that the exchange of sensitive information between members of livestock associations, as well as between livestock associations, is prohibited. A useful reference for livestock associations regarding situations where information exchange could constitute a competition concern is COFECE's guidelines, *Guía-007/2015: Guía para el Intercambio de*

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									Información entre Agentes Económicos.
25.	**Ley de Organizaciones Ganaderas DOF 09-04-2012**	6	Rearing livestock / Livestock farming, associations	Article 6 of Ley de Organizaciones Ganaderas states that livestock producers have the right to associate freely and voluntarily. According to COFECE's report *Miscelánea de obstáculos regulatorios a la competencia. Análisis de la normatividad estatal* (pp.16-17), livestock laws from several Mexican states (i.e. Campeche, Coahuila, Tlaxcala, Yucatán, Guerrero and Sinaloa) make membership of a local livestock association mandatory for livestock producers. These state livestock laws therefore arguably infringe Article 6 of Ley de Organizaciones Ganaderas.	SAGARPA	C1	The *Ley de Organizaciones Ganaderas* enables livestock producers to associate freely and voluntarily, so that they can benefit from the economies of scale that livestock associations might generate. However, the law also leaves the possibility open to producers not to join an association, depending on individual producers' preferences.	Mandatory membership of a local livestock association could reduce rivalry between farmers, as farmers belonging to a livestock association are bound to behave according to that association's statutes. As the content of statutes may vary, the degree to which farmers are limited in their ability to behave independently may also vary.	Amend Article 6 of the Ley de Organizaciones Ganaderas so that it states that in no case can livestock producers be forced by state laws to join a livestock association. It might also be necessary to abolish all provisions in state laws that set an obligation for livestock producers to associate.
26.	**Ley de Fondos de Aseguramiento Agropecuario y Rural DOF 13-05-2005**	26, 74, 87	Rearing livestock / Agro-insurance	Agricultural and livestock producers need access to agro-insurance that can cover them from contingencies such as damage to animals, crops and facilities, deaths and individual accidents. In Mexico, agricultural and livestock producers have two	SHCP	A5, B4	The objective of FAAR is to offer mutualist protection to its members. Subsidies granted to them by the federal government aim to support small agricultural and livestock producers. FAAR are a low-cost alternative to cover the biological,	Since foreign natural persons and foreign corporate entities cannot belong to FAAR, they will have to contract agro-insurance with private providers. This provision discriminates in favour of Mexican	No recommendation. This restriction is unlikely to impact upon foreign producers, since most are not small producers and carry out their activities in a more industrialised fashion than that targeted by FAAR, and would therefore not be

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				options to access agro-insurance: 1) Agricultural and Rural Insurance Funds (Fondos de Aseguramiento Agropecuario y Rural, FAAR) 2) Private providers. FAAR are associations of agricultural and livestock producers that provide insurance to their members. FAAR only allow two kinds of members: Mexican natural persons or Mexican corporate entities that bar foreign stockholders. Article 74 of the law establishes that a violation of this clause is a reason for the Ministry of Finance and Public Credit (Secretaría de Hacienda y Crédito Público, SHCP) to revoke a FAAR's registry. In early 2013, there were 440 FAAR and 20 private agro-insurance providers. According to Article 87 of the Ley de Fondos de Aseguramiento Agropecuario y Rural, FAAR are considered to be "subjects of promotion and support" by the Mexican federal government. FAAR are therefore eligible to receive subsidies from the Mexican federal government.			climate, estate and life risks associated with livestock producers' commercial activity.	agricultural and livestock producers.	interested in membership. Furthermore, support granted to Mexican agricultural and livestock producers through FAAR is concordant with the social policy set by the Mexican state.

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27.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012**	79, 110, 179	Meat production / Subsidy, international trade	The federal government can grant subsidies to national producers in order to offset inequalities between them and foreign producers. To grant these subsidies, the government assesses whether products are basic and strategic for food sovereignty. According to Article 179 of the Ley de Desarrollo Rural Sustentable, beef, pork and chicken are considered to be basic products and strategic for food sovereignty.	CIDRS, SAGARPA	A5, B4	Subsidies to agricultural and livestock producers are granted to increase the productivity, competitiveness, income levels and employment of the rural population. This policy is common in many other jurisdictions (e.g. the United States and the EU).	Foreign meat producers might be discriminated against if they do not receive subsidies, while their Mexican competitors do.	No recommendation, as long as the granting of the subsidies is in compliance with WTO commitments, as well as with international trade agreements.
28.	**Ley General de Sociedades Cooperativas DOF 13-08-2009** **Ley de Inversión extranjera DOF 18-12-2015**	Ley General de Sociedades Cooperativas : 7 Ley de Inversión Extranjera: 7, 18, 19.	Rearing livestock / Cooperatives	Foreign investors can only own, either directly or indirectly, up to 10% of the ownership interest in a Mexican cooperative production enterprise. Furthermore, foreign citizens cannot hold management and administrative positions in Mexican cooperative production enterprises.	SE, SEDESOL, SHCP	B4, A5	Probably the objectives of this provision are: 1) to guarantee food sovereignty 2) to prevent foreigners benefiting from subsidies that might be granted to members of cooperative production enterprises. Foreigners can make additional investments, under the concept of so called "neutral investment". According to Article 18 of the Ley de Inversión Extranjera, a neutral investment is not considered when determining the amount of foreign investment in	Harm to competition might stem from foreigners not being able to invest freely in cooperative production enterprises. In some cases, 10% could be too low an ownership stake, and foreign investors could decide not to invest at all.	No recommendation. There do not seem to be practical consequences to this restriction, as foreign investors generally prefer other forms of investments to cooperatives. Also, the concept of "neutral investment" opens the participation of foreigners into cooperative production enterprises, albeit without voting rights. It appears that in the recent past there have been few, if any, applications by foreigners for neutral

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							the capital stock of Mexican companies. However, the corresponding shares of neutral investment do not have voting rights, but only rights related to dividend payments.		investments in cooperative production enterprises.
29.	**Ley General de Sociedades Cooperativas DOF 13-08-2009**	86	Rearing livestock / Cooperatives	This article states that cooperatives will "design and implement strategies for the integration of their activities and productive processes with the objective of […] influencing prices".	SE, SEDESOL, SHCP	B1	Most probably, the law allows the creation of cooperative production enterprises for the exploitation of economies of scale, and a reduction of investment risks incurred by agricultural and livestock producers. **International comparison** Several jurisdictions have competition-law exemptions for agricultural and livestock cooperatives. For instance, in the United States, the Capper-Voltstead Act of 1922, and marketing orders issued pursuant to the Agriculture Marketing Agreement Act of 1937 allow for the creation of cooperatives of agricultural and livestock producers, which do not trigger competition law scrutiny, and mean	It is unclear what is meant by "influencing prices". This provision might be interpreted as an allowance for cooperative production enterprises to jointly sell their products. This, in turn, could facilitate collusion between members of cooperative production enterprises.	Amend Article 86, Letter III of Ley General de Sociedades Cooperativas, so that it is clear that the creation of cooperative production enterprises does not include the possibility of joint selling. In addition, issue guidelines that describe the principles of cooperation between competitors (i.e. livestock producers). These two measures would ensure economies of scale that would allow cooperative production enterprises to exploit economies of scale in the preparation, processing and handling of their products, while minimising risks of collusion.

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							cooperatives can collectively market products. However, the Capper-Voltstead Act requires cooperatives to be entirely composed of producers of agricultural and livestock products, and the exemption of scrutiny does not extend to predatory or coercive conduct, or to collaborations or mergers with companies not covered by the Act. It appears that in Mexico there is currently no law that exempts cooperative production enterprises from competition law.		
30.	**Ley Agraria DOF 27-03-2017**	47, 120, 124	Rearing livestock / Land	*Ejidos* in Mexico are jointly held common lands. *Ejido* members can use their part of the land for their own purposes, e.g. for farming production. In the case of an *ejido* whose economic activity is livestock production, an individual cannot hold land whose area is larger than either 5% of the *ejido* or the threshold of the "small livestock property" (*pequeña propiedad ganadera*), which corresponds to the land	SEDATU	A4	Prevent the concentration of *ejido* lands.	The provision makes it difficult for producers to reach scale in *ejido* lands and compete with big producers. For example, an *ejido* member might be discouraged from producing certain products because production might only be profitable after reaching a certain scale.	The OECD sees three possible options, depending on how the Mexican government decides between the conflicting goals of preserving the current distribution of land through the institution of the *ejido* – and so preventing the concentration of this land – and allowing for more efficient production. 1) Remove limits to land holdings of *ejido*

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				extension necessary for raising 500 head of major livestock (e.g. cattle) or its equivalent in minor livestock (e.g. pigs).					members. This requires removing the concept of "small livestock property" and an amendment to Article 27 of the Mexican Constitution. 2) To increase the size of a "small livestock property". This option requires an amendment to Article 27 of the Mexican Constitution. 3) No change as it is the policymaker's objective to prevent the concentration in the holding of *ejido* lands.
31.	**Ley Agraria DOF 27-03-2017**	126, 132	Rearing livestock / Land	Stock and civil companies cannot own agricultural, livestock or forest lands whose area exceeds 25 times the size of a "small livestock property". Furthermore, these companies must be integrated by as many natural persons as the number of times that the held land exceeds the "small property" size.	SEDATU	A4	Prevent the concentration of agricultural, livestock and forest lands holdings.	A company will decide to exploit agricultural, livestock or forest lands (for instance, to raise livestock) only if it is profitable to do so. If land of a size equivalent to 25 times the size of "small property" is not sufficient for reaching the necessary scale, this provision might restrict investments and even entry into the livestock rearing market.	Remove limits on the holding of agricultural, livestock and forest lands by stock and civil companies. Thus, Articles 126 and 132 of the Ley Agraria should be abolished. This option requires an amendment to Article 27 of the Mexican Constitution.

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32.	**Ley Agraria DOF 27-03-2017 Ley de Inversión extranjera DOF 18-12-2015**	Ley Agraria:130 Ley de Inversión Extranjera: 7	Rearing livestock / Land, foreign investment	Stock and civil companies that own agricultural, livestock or forest lands must issue a special series of shares (T shares) that represent the acquisition value of these lands. Foreign ownership of T shares is limited to 49% of total holdings.	SEDATU	A4, A5	Restricting the concentration of agricultural, livestock and forest lands by foreigners is probably seen as a way to guarantee food sovereignty.	This provision hinders foreign investment in agricultural, livestock and forest.	The OECD sees two possible options, depending on how the Mexican government decides to balance the conflicting goals of restricting foreign land ownership and allowing foreign investment and, possibly, more efficient production. 1) Abolish Article 130 of the Ley Agraria, and Article 7, Letter III, Subletter R of the Ley de Inversión extranjera. This option would involve an amendment to Article 27 of the Mexican Constitution. 2) Make no change as it is the policymaker's objective to prevent foreign majority holdings of agricultural, livestock and forest land.
33.	**Ley Agraria DOF 27-03-2017**	23, 26, 27	Rearing livestock / Land	In order to privatise parcels in an *ejido* (adoption of "full rights"), it is necessary to obtain a two-thirds majority in the *ejido* assembly, the *ejido*'s supreme body, which includes all its members.	SEDATU	A4	Preserve the *ejido* regime.	Obtaining two-thirds of the votes of the ejido members in order for ejido parcels to adopt "full rights" makes it difficult to reallocate lands between different farming activities, and might be a barrier to entry for rearing livestock.	Create more flexible mechanisms for *ejidos* to adopt the "full-rights" regime (e.g. simple majority).

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34.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012**	111	Meat production / Public procurement	The Inter-Ministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable, CIDRS), with the participation of the Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable, CMDRS), and in accordance with international trade agreements signed by the Mexican federal government, can set up a list of products that can receive preferential treatment in public procurement.	CIDRS, SAGARPA	A3, A5, B4	The objective is to increase the income of agricultural and livestock producers whose goods are particularly difficult to sell. However, no cases were found where this provision was applied in practice for a public tender of meat.	The list of products given preferential treatment could prevent foreign products from participating in public procurement.	The Mexican government has two options, depending on how it decides to balance the conflicting goals of including foreign competitors – and possibly offering better prices to consumers – and supporting the national meat industry. These are: 1) Amend Article 111 of the Ley de Desarrollo Rural Sustentable so that agricultural and livestock goods whose commercialisation is particularly difficult are not given preference in public procurement. Instead, direct subsidies might be considered. 2) Make no change as providing support to agricultural and livestock goods whose commercialisation is particularly difficult is a legitimate policymaker objective.
35.	**Ley para Impulsar el Incremento Sostenido de la Productividad y la Competitividad de**	3	Horizontal legislation / Productivity, MSME	This article promotes the participation of micro, small and medium enterprises (MSME) in public procurement. However, it	SE	A3	Promote the growth and development of MSME. Many jurisdictions include provisions in their procurement laws that	There is potential discrimination against non-MSME. Some non-MSME could sell in public-procurement	The Mexican government has two options depending on how it decides to balance the conflicting

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	la Economía Nacional DOF 17-05-2017			does not establish a quota of public-procurement purchases that must be served by MSME.			support MSME.	markets at lower prices because of economies of scale.	goals of including larger competitors and possibly offering better prices to consumer, and supporting MSME. These are: 1) Abolish Article 3, Letter IX of the law and give no preference to Mexican companies or MSME in public procurement. Direct subsidies should instead be considered. 2) Make no change as providing support to MSME is a legitimate policy objective. This option might be at the expense of Mexican consumers.
36.	**NOM-051-SCFI/SSA1-2010, Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados - Información comercial y sanitaria**	5, 11	Meat labelling / Labelling	This norm deals with methods used for calculating the nutritional values (energy or proteins) that are displayed in labels of pre-packaged food products and non-alcoholic beverages. The norm specifically states that it is only partially in line with international norms. However, it leaves open the possibility of using other calculation methods for proteins.	Verification and surveillance: PROFECO and SSA through COFEPRIS	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards were (partially) adapted to	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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							international norms and criteria.	international standards recently, if the NOM's legal text is not updated, there might be confusion among market participants. One procedure for which the non-accordance of this NOM with international norms is not a burden for foreign producers attempting to access the Mexican market, is the protein calculation, since other calculation methods are allowed.	
37.	**NOM-158-SCFI-2003, Jamón-Denominación y clasificación comercial, especificaciones fisicoquímicas, microbiológicas, organolépticas, información comercial y métodos de prueba**	14	Meat labelling / Labelling, ham	The norm specifically states that it is only partially in line with international norms. This norm sets standards for ham, such as nomenclature, amount of microorganisms allowed, etc.	Surveillance: SE, PROFECO, SAGARPA, SSA, SHCP	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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								standards, if the NOM legal text is not updated, there might be confusion among market participants.	
38.	**NOM-009-Z00-1994, Proceso sanitario de la carne**	19	Meat processing / Sanitary rules	The norm specifically states that it is not in line with international norms. The norm deals with the sanitary processing of meat.	Surveillance: SAGARPA and state governments. Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Please refer to restriction No. 76
39.	**NOM-213-SSA1-2002, Productos y servicios. Productos cárnicos procesados. Especificaciones sanitarias. Métodos de**	10.1	Meat processing / Processing	The norm specifically states that it is only partially in line with international standards. This norm deals with sanitary specifications for processed-meat products.	Surveillance of compli-ance: SSA, state governments and authorised third parties	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
	prueba						according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	transition. It should be noted in the NOM if there are no existing international standards or best practices.
40.	**NOM-130-SSA1-1995, Bienes y servicios. Alimentos envasados en recipientes de cierre hermético y sometidos a tratamiento térmico. Disposiciones y especificaciones sanitarias**	12	Meat processing / Processing	The norm specifically states that it is only partially in line with international standards. This norm deals with sanitary specifications for food in hermetically sealed packaging and subjected to thermal treatment.	Compliance surveillance: SSA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
41.	**NOM-086-SSA1-1994, Bienes y servicios. Alimentos y bebidas no alcohólicas con modificaciones en su composición. Especificaciones nutrimentales**	13	Meat labelling / Labelling, packaging	The norm specifically states that it is not in line with international standards. This norm deals with nutritional specifications for food and non-alcoholic beverages with modifications of their composition, as well as packaged foods and cereals for infants and children with added nutrients.	Surveillance of compliance: SSA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
42.	**NOM-002-SCFI-2011, Productos preenvasados-Contenido neto-Tolerancias y métodos de verificación**	11	Meat labelling / Labelling, quantity	The norm specifically states that it is only partially in line with international standards. This norm deals with methods for verifying the net contents of pre-packaged products.	Compliance and surveillance: SE and PROFECO	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							contain a degree of accordance with international norms and criteria.	Mexican standards standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	
43.	**NMX-F-315-1978, Determinación de la masa drenada o escurrida en alimentos envasados**	8	Meat labelling / Labelling, quantity, drained mass, packaged meat	The norm specifically states that it is not in line with international standards. This norm deals with methods for determining the drained mass of packaged food.	Voluntary standard	A5	There would appear to be no underlying objective behind the non-harmonisation of this NMX.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NMX legal text is not updated, there might be confusion among market participants.	Update the NMX so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NMX if there are no existing international standards or best practices. Furthermore, since the norm is currently only voluntary, consider making it a NOM.
44.	**NOM-008-ZOO-1994, Especificaciones zoosanitarias para la construcción y**	22	Slaughtering and meat processing / Sanitary rule	The norm specifically states that it is not in line with international norms. The norm deals with sanitary specifications to	Surveillance: SAGARPA and state governments Application:	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
	equipamiento de establecimientos para el sacrificio de animales y los dedicados a la industrialización de productos cárnicos (Modificada)			build and equip establishments for the slaughtering of animals and the processing of meat products.	SAGARPA		harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices. In the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will be modified during 2017.
45.	**NOM-023-ZOO-1995, Identificación de especie animal en músculo de bovinos, ovinos, equinos, porcinos y aves, por la prueba de inmunodifusión en gel**	11	Slaughtering and meat processing / Chemical test	The norm specifically states that it is not in line with international norms. The norm deals with a test to identify the animal species of meat.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
								legal text is not updated, there might be confusion among market participants.	
46.	**NOM-025-ZOO-1995, Características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que fabriquen productos alimenticios para uso en animales o consumo por éstos**	9	Animal feed, Authorisation / Sanitary rule, facilities	The norm specifically says that it is not in line with international norms. The norm deals with sanitary specifications to build and equip establishments that manufacture animal feed.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
47.	**NOM-030-ZOO-1995, Especificaciones y procedimientos para la verificación de carne, canales, vísceras y despojos de importación en puntos de**	9	Meat imports / Imports. inspections	The norm specifically states that it is not in line with international norms. The norm deals with inspections of imported meat, carcasses, viscera and offal.	Surveillance and application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41,	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of	Please refer to restriction No. 18

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
	verificación zoosanitaria						Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	
48.	**NOM-026-ZOO-1994, Características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que fabriquen productos químicos, farmacéuticos y biológicos para uso en animales**	9	Animal feed / Sanitary rules, facilities	The norm specifically states that it is not in line with international norms. The norm deals with zoosanitary specifications for facilities, equipment and operation of establishments that manufacture chemical, pharmaceutical and biological products for animals.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
49.	**NMX-FF- 078-SCFI-2002, Productos pecuarios - Carne de bovino en canal - clasificación (cancela a la NMX-FF-078-1991)**	8	Meat production / Meat quality	The norm specifically states that it is not in line with international norms. The norm sets quality standards for the classification of beef carcasses.	Voluntary standard	A5	There would appear to be no underlying objective behind the non-harmonisation of this NMX.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NMX legal text is not updated, there might be confusion among market participants.	Please refer to restriction No. 3
50.	**NMX-FF-081-SCFI-2003, Productos pecuarios - Carne de porcino en canal - Calidad de la carne - Clasificación (cancela a la NMXFF-081-1993-SCFI)**	12	Meat production / Meat quality	The norm specifically states that it is not in line with international norms. The norm sets quality standards for the classification of pork carcasses.	Voluntary standard	A5	There would appear to be no underlying objective behind the non-harmonisation of this NMX.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican	Please refer to restriction No. 3

Sector: Meat									
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								standards have recently been (partially) adapted to international standards, if the NMX legal text is not updated, there might be confusion among market participants.	
51.	**NOM-046-ZOO-1995, Sistema Nacional de Vigilancia Epizootiológica**	10	Raising of livestock / Sanitary rule, raises costs	The norm specifically states that it is not in line with international norms. The norm sets quality standards for campaigns against animal diseases. Campaigns are strategic plans for eradicating and / or controlling animal diseases that have a negative incidence on animal production.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices. In the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will be cancelled during 2017. According to SENASICA, the drafting work of the legal document that will replace NOM-046-ZOO-1995 is already underway.

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
52.	**NOM-194-SSA1-2004, Productos y servicios. Especificaciones sanitarias en los establecimientos dedicados al sacrificio y faenado de animales para abasto, almacenamiento, transporte y expendio. Especificaciones sanitarias de productos**	11	Meat production / Sanitary rule, raises costs	The norm specifically states that it is not in line with international norms. The norm sets sanitary specifications for establishments slaughtering and processing animals for wholesale, stock, transport and retail.	Surveillance: SSA through COFEPRIS, state governments and authorised third parties	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
53.	**NOM-061-ZOO-1999, Especificaciones zoosanitarias de los productos alimenticios para consumo animal**	8	Animal feed / Sanitary rule	The norm specifically states that it is not in line with international norms. The norm deals with zoosanitary specifications for animal feed.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							contain a degree of accordance with international norms and criteria.	where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	In the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will be cancelled during 2017. According to SENASICA, the drafting work of the legal document that will replace NOM-061-ZOO-1999 is already underway.
54.	**NOM-027-ZOO-1995, Proceso zoosanitario del semen de animales domésticos**	10	Animal reproduction / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with the processing of cattle and pig semen, and the operation of facilities for this activity.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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55.	**NOM-054-ZOO-1996, Establecimiento de cuarentenas para animales y sus productos**	18	Meat production / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm includes specifications for quarantine to prevent, control and eradicate animal diseases.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
56.	**NOM-022-ZOO-1995, Características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que comercializan productos químicos, farmacéuticos, biológicos y**	8	Animal feed / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with zoosanitary specifications for the facilities, equipment and operation of establishments that commercialise chemical, pharmaceutical and biological products for animals, as well as animal feed.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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	alimenticios para uso en animales o consumo por éstos						contain a degree of accordance with international norms and criteria.	where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	
57.	**NOM-024-ZOO-1995, Especificaciones y características zoosanitarias para el transporte de animales, sus productos y subproductos, productos químicos, farmacéuticos, biológicos y alimenticios para uso en animales o consumo por éstos**	10	Animal feed / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with specifications for transporting animals, their products and subproducts, chemical, pharmaceutical and biological products for animals, as well as animal feed.	Surveillance: SAGARPA and state governments Application: SAGARPA and Federal Highway Police	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
58.	**NOM-059-ZOO-1997, Salud animal. Especificaciones**	9	Animal feed / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals	Surveillance: SAGARPA and state governments	A5	There would appear to be no underlying objective behind the non-harmonisation of this	Access of foreign competitors to the Mexican market may be hindered, as may	Update the NOM so that it is as far as possible in accordance with international standards.

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
	de productos químicos, farmacéuticos, biológicos y alimenticios para uso en animales o consumo por éstos. Manejo técnico del material publicitario			with specifications for the advertising of chemical, pharmaceutical and biological products for animals, as well as animal feed.	Application: SAGARPA		NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
59.	**NOM-112-SSA1-1994, Bienes y servicios. Determinación de bacterias coliformes. Técnica del número más probable**	12	Meat productions / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with a procedure for detecting bacteria (*E. coli*) in food products.	Surveillance of compliance: SSA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

Sector: Meat									
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							criteria.	international standards, if the NOM legal text is not updated, there might be confusion among market participants.	
60.	**NOM-041-ZOO-1995, Campaña Nacional contra la Brucelosis en los Animales**	21	Raising of livestock / Sanitary rule	The norm specifically states that it is not in line with international norms. The norm deals with specifications for conducting campaigns to eradicate bovine brucellosis.	Surveillance and application: SAGARPA and state governments	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices. In the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will be cancelled during 2017. According to SENASICA, the drafting work of the legal document that will replace NOM-041-ZOO-1995 is already underway.

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61.	**NOM-114-SSA1-1994, Bienes y servicios. Método para la determinación de salmonella en alimentos**	10	Meat production / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with specifications to detect salmonella in food products.	Surveillance of compliance: SSA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
62.	**NOM-092-SSA1-1994, Bienes y servicios. Método para la cuenta de bacterias aerobias en placa**	12	Meat production / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with specifications to detect aerobic bacteria.	Surveillance of compliance: SSA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal obre Metrología y Normalización, which states that NOMs must contain a degree of accordance with	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
							international norms and criteria.	standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	
63.	**NOM-012-ZOO-1993, Especificaciones para la regulación de productos químicos, farmacéuticos, biológicos y alimenticios para uso en animales o consumo por éstos**	13	Animal feed / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm sets specifications for chemical, pharmaceutical and biological products for animals, as well as animal feed.	Surveillance: SAGARPA and state and municipal governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices. In the National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, it is stated that this NOM will be modified during 2017.
64.	**NOM-067-ZOO-2007, Campaña nacional para la prevención y control de la rabia**	17	Raising of livestock / Sanitary rule	The norm specifically states that it is not in line with international standards. The norm deals with specifications for	Surveillance: SAGARPA, state governments, OASA,	A5	There would appear to be no underlying objective behind the non-harmonisation of this	Access of foreign competitors to the Mexican market may be hindered, as may be access for	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices

Sector: Meat									
No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
	en bovinos y especies ganaderas			conducting campaigns to eradicate rabies in cattle.	CEFPP, SEMARNAT Application: SAGARPA		NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
65.	**NOM-031-ZOO-1995, Campaña Nacional Contra la Tuberculosis Bovina (Mycobacterium bovis)**	19	Raising of livestock / Sanitary rule	The norm specifically states that it is not in line with international norms. The norm sets quality standards for conducting campaigns against bovine tuberculosis.	Surveillance: SAGARPA and state governments Application: SAGARPA	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices. In the National Standardisation Programme for 2017, published in the Federal Official Gazette on

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No.	**Title of Regulation**	**Article**	**Thematic category/ Keyword**	**Brief description of potential obstacles**	**Relevant authority**	**Toolkit question**	**Policymaker's objectives**	**Harm to competition**	**Recommendations**
								standards, if the NOM legal text is not updated, there might be confusion among market participants.	3 February 2017, it is stated that this NOM will be cancelled during 2017. According to SENASICA, the drafting work of the legal document that will replace NOM-031-ZOO-1995 is already underway.
66.	**NOM-001-ECOL-1996, Que establece los límites máximos permisibles de contaminantes en las descargas de aguas residuales en aguas y bienes nacionales**	7	Environment / Environment, water contamination	The norm specifically states that it is not in line with international norms. The norm sets maximum limits for pollutants in national waters.	National Water Commission (Comisión Nacional del Agua, CONAGUA)	A5	There would appear to be no underlying objective behind the non-harmonisation of this NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	Access of foreign competitors to the Mexican market may be hindered, as may be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Update the NOM so that it is as far as possible in accordance with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
67.	**NOM-033-ZOO-1995, Sacrificio humanitario de los animales**	10	Slaughtering / Humane	The norm specifically states that it is not in line with international norms. The norm sets standards	Surveillance: SAGARPA and state governments	A5	There would appear to be no underlying objective behind the non-harmonisation of this	Access of foreign competitors to the Mexican market may be hindered, as may	Update the NOM so that it is as far as possible in accordance with international standards.

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	domésticos y silvestres.			for the humane slaughtering of animals.	Application: SAGARPA		NOM. In Mexico, non-harmonisation of NOMs has to be disclosed according to Article 41, Letter VI of the Ley Federal Sobre Metrología y Normalización, which states that NOMs must contain a degree of accordance with international norms and criteria.	be access for Mexican producers to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which could mean extra costs. Even in the case where Mexican standards have recently been (partially) adapted to international standards, if the NOM legal text is not updated, there might be confusion among market participants.	Some current practices may already be in accordance with international standards, which might ease the transition. It should be noted in the NOM if there are no existing international standards or best practices.
68.	**NOM-025-ZOO-1995, Características y especificaciones zoosanitarias para las instalaciones, equipo y operación de establecimientos que fabriquen productos alimenticios para uso en animales o consumo por éstos**	7	Slaughtering and meat processing / Raises costs	Establishments that manufacture animal-feed products must have an authorised veterinary surgeon, a production professional and a quality-control professional. This NOM does not explicitly state what are the tasks performed by the production and the quality-control professional.	Surveillance: SAGARPA and state governments Application: SAGARPA	A4	To ensure that establishments manufacturing animal-feed products have the necessary staff to implement this norm's feed safety and quality specifications.	Compliance with this requirement constitutes a high cost for businesses, since three employees must be hired. This provision could especially impact upon small businesses.	Modify the law to allow production and quality-control activities to be fulfilled by the same professional. This option is contingent to both activities requiring equivalent knowledge and qualifications.
69.	**NOM-026-ZOO-1994, Características y especificaciones**	7	Animal feed / Raises costs	Establishments subjected to this norm (i.e. those that manufacture chemical, pharmaceutical and	Surveillance: SAGARPA and state governments	A4	To ensure that establishments manufacturing chemical, pharmaceutical and	Compliance with this requirement constitutes a high cost for businesses,	Modify the law to allow production and quality-control activities to be fulfilled by the same

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	zoosanitarias para las instalaciones, equipo y operación de establecimientos que fabriquen productos químicos, farmacéuticos y biológicos para uso en animales			biological products for use in animals) must have an authorised veterinary surgeon, a biological scientist in the production area, and a biological scientist in the quality-control area. This NOM does not explicitly state what tasks are to be performed by each of the scientists.	Application: SAGARPA		biological products to be used in animals, have the required staff to implement the zoosanitary specifications contained in this norm.	since three employees must be hired. This provision could especially impact upon small businesses.	professional. This option is contingent to both activities requiring equivalent knowledge and qualifications.
70.	**Ley Federal de Sanidad Animal DOF-07-06-2012**	108	Slaughtering and meat processing / Sanitary rule	Federal Inspection Type (Tipo Inspección Federal, TIF) certified establishments must have at least one Authorised Responsible Veterinary Surgeon (Médico Veterinario Responsable Autorizado, MVRA) during working hours. Such a professional is a veterinary surgeon hired by the TIF establishment, approved by SAGARPA, and in charge of ensuring the compliance with Ley Federal de Sanidad and related regulations. In addition, there is an Official Veterinary Surgeon (Médico Veterinario Oficial, MVO) who is employed by SENASICA and works as an inspector at TIF-certified establishments. The presence of MVRA is	SAGARPA	A4	To ensure that at TIF establishments a veterinary surgeon is in charge of animal welfare, epidemiological surveillance, zoosanitary measures and good livestock practices. On 8 April 2015, the Plenary of the Chamber of Deputies approved, in an almost unanimous decision, an amendment to Article 108 of the Ley Federal de Sanidad Animal, so that TIF establishments need at all times either a MVRA or an MVO. Subsequently, the Plenary of the Chamber of Deputies submitted this amendment to the Chamber of Senators, which is still analysing	Requiring the presence of a MVRA when a MVO is already present at a TIF establishment, is unnecessary and can create duplication of functions for veterinary surgeons. This requirement can impose a more significant burden on smaller TIF establishments. When TIF establishments rely intensively on MVRAs, there is also a potential conflict of interest as MVRAs are in charge of ensuring compliance with SENASICA regulations, but are paid by TIF establishments.	Promote a progressively lower reliance of TIF establishments on MVRAs. In order to achieve this, two actions could be undertaken. 1) Article 108 should be amended so that at all times *either* a MVRA or an MVO is required (rather than necessarily the MVRA), allowing for more substitution between both types of veterinary surgeons. 2) The outsourcing of veterinary services by TIF establishments should be encouraged. The long-term goal is that TIF establishments outsource their veterinary services to

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				required even if an MVO is already present at the abattoir or processing plant.			the initiative. According to SENASICA, as an example, in the United States all veterinary surgeons in charge of verifying compliance with animal-health regulations at abattoirs and meat-processing plants, are government staff. Several importing countries require that documents are signed only by MVOs.		SENASICA (at a fee, which in turn would be paid to veterinary surgeons), and these veterinary surgeons would verify compliance with SENASICA's regulations, without any conflict of interest. To reach that goal it is, however, necessary to grant SENASICA more resources.
71.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012**	149. I, II	Raising of livestock / Industrial policy	The Inter-Ministerial Commission for Sustainable Rural Development (Comisión Intersecretarial para el Desarrollo Rural Sustentable, CIDRS) will promote the creation of Product Systems (Sistemas Producto), which are committees of the Mexican Council for Sustainable Rural Development (Consejo Mexicano para el Desarrollo Rural Sustentable, CMDRS). Among these committees' objectives is to "determine the strategic expansion and contraction plans for the output and quality of	CIDRS, SAGARPA	B1, B4, C1	The objective is to develop the Mexican meat industry.	The scope of actions undertaken by the CIDRS in practice is unknown. However, this provision suggests that the CIDRS influences production volumes of agricultural and livestock goods.	Abolish Letter II of Article 149 of the Ley de Desarrollo Rural Sustentable. Concerning Letter I of Article 149, add a clarification that the "livestock and agricultural production programmes" should not include any specifications of volumes or prices.

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				each product".					
72.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012**	166	Raising of livestock / Stock density	The CIDRS sets the number of animals allowed on an area unit (such as a hectare), a measure of animal concentration. Known as stocking density, these limits are set at a national level, depending on soil quality and the kind of animals being raised.	CIDRS, SAGARPA	A4	Most probably stocking density limits are determined to prevent overgrazing, as well as the spread of livestock diseases.	Stocking density limits are set at a national level, so there is no risk of potential discrimination of livestock producers.	No recommendation
73.	**Ley Federal de Responsabilidad Ambiental DOF 07-06-2013**	7, 2, 6	Horizontal legislation / Environmental harm, excessive discretion	The Ministry of Environment and Natural Resources (Secretaría de Medio Ambiente y Recursos Naturales, SEMARNAT) will issue NOMs that determine thresholds for environmental harm on a case-by-case basis. However, even if these NOMs are not issued, SEMARNAT will still be able to issue sanctions to firms for environmental harm.	SEMARNAT	B4	To deter companies from damaging the environment.	SEMARNAT may have been granted excessive discretionary powers. Theoretically, government officials could apply different harm standards to different producers when issuing sanctions. Also, Articles 2, 6 and 7 of the Ley Federal de Responsabilidad Ambiental could violate the principle of nulla poena sine lege.	Modify Article 7 of the Ley Federal de Responsabilidad Ambiental so that it states that all sanctions related to environmental harm can only be based on previously published NOMs. Alternatively, infringements and sanctions could be described within the law. This modification would reduce SEMARNAT's discretion and would probably accelerate the issuance of necessary NOMs. Issuance of NOMs on a case-by-case basis seems to be feasible. For instance, Article 48 of the Ley Federal sobre Metrología y Normalización, with the last amendment published on the

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									Federal Official Gazette in 18 December 2015, sets a fast-track procedure for public institutions to issue NOMs in "emergency cases". These are defined as unexpected events that are an obstacle to achieving the NOMs' objectives as set out in Article 40 of the Ley Federal sobre Metrología y Normalización. NOMs issued under the fast-track procedure must follow scientific principles and aim to prevent irreversible or irreparable harm.
74.	**Ley de Desarrollo Rural Sustentable DOF 12-01-2012** **Reglamento interior del Servicio de Información Agroalimentaria y Pesquera 29-08-2013** **Norma Técnica para la Generación de Estadística Básica Agropecuaria y**	Law: 109, 134 Regulation: 2 Norm: Chapter 3	Meat production / Market transparency	The National Information System for Sustainable Rural Development (Sistema Nacional de Información para el Desarrollo Rural Sustentable, SNIDRUS) is an information system managed by the Agrifood and Fisheries Information Service (Servicio de Información Agroalimentaria y Pesquera, SIAP), a body of SAGARPA. The objective of SNIDRUS is to disseminate information on	SAGARPA	C2	Most probably, the objective is to provide economic decision makers in the Mexican agricultural and livestock sectors with trustworthy, timely and relevant information. This, in turn, facilitates the trade of agricultural and livestock products.	The availability of recent livestock data at the municipal level could facilitate price coordination between livestock producers.	While there do not appear to be any current competition concerns related to the operation of SNIDRUS, this cannot be excluded in the future. Therefore, it is recommended that in all present and future SIAP guidelines related to the gathering and presentation of agricultural and livestock data, the issuance of data that can be tracked back to

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	Pesquera (undated)			agricultural and livestock markets (e.g. offer, demand, stocks, forecasts, prices, etc.) at regional, national and international levels. SNIDRUS was created by the Ley de Desarrollo Rural Sustentable and the Reglamento interior del Servicio de Información Agroalimentaria y Pesquera, and its operation is based upon the document Norma Técnica para la Generación de Estadística Básica Agropecuaria y Pesquera. In Chapter 3 of that document, it is established that several livestock statistics series (e.g. volume of carcasses, live animals, slaughters) must be generated at the municipal level. The website of SNIDRUS contains links to its State Offices for the Information for Sustainable Rural Development (Oficina Estatal de Información para el Desarrollo Rural Sustentable, OEIDRUS). Consulting several OEIDRUS websites					individual holdings should be restricted.

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				confirmed that several livestock statistics series are indeed published on a monthly basis at a municipal level.					
75.	**Ley Federal de Protección al Consumidor DOF 13-05-2016**	44	Meat production / Advertising	The Federal Attorney's Office of the Consumer (Procuraduría Federal del Consumidor, PROFECO) produces and publishes reports on the quality and features of products and services, in order to guide and protect consumers. In these reports, PROFECO makes specific mention of brands. However, companies cannot quote PROFECO's mentions of brands.	PROFECO	B2	The objective is most likely to prevent misuse of PROFECO reports. For instance, if a producer were to quote a PROFECO report, it could be interpreted as a PROFECO endorsement of that producer. According to anecdotal evidence, the provision also aims to guarantee that PROFECO remains independent from companies that would be interested in unduly influencing it. However, these goals can be reached without restricting competition.	This provision restricts companies' ability to quote consumer reports of PROFECO, which are useful for consumers.	Abolish Article 44 of the Ley Federal de Protección al Consumidor. The concern over misuses of PROFECO reports is unjustified, as the law contains an article that forbids misleading or abusive advertising. Indeed, Article 32 of the Ley Federal de Protección al Consumidor forbids misleading or abusive advertising, this being defined as advertising that "refers to features or information related to a good, product or service, which might be true or not, and that induces mistakes or confusion because of its inexact, false, exaggerated, partial, deceptive or biased form". In addition, measures should be taken to guarantee independence of

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									PROFECO officials from lobbying efforts. The same recommendation concerning PROFECO has been made for the medicines sector.
76.	**NOM-009-Z00-1994, Proceso sanitario de la carne**	General	Slaughtering and meat processing / Inspections	NOM-009-ZOO-1994 deals with the sanitary processing of meat at TIF establishments, and contains relevant specifications for the inspections carried out by Official Veterinary Surgeons (Médicos Veterinarios Oficiales, MVOs) at these establishments. According to industry participants, the application of specifications by MVOs varies greatly between TIF establishments. This problem probably stems from the fact that NOM-009-ZOO-1994 does not describe in sufficient detail the tasks expected of MVOs.	SAGARPA	B4	There is not a clear policymaker's objective behind the lack of sufficiently detailed descriptions of the tasks performed by MVOs. The National Standardisation Programme for 2017, published in the Federal Official Gazette on 3 February 2017, foresees that the NOM will be cancelled during 2017 and, according to SENASICA, be replaced by a new document.	Not all TIF establishments are subject to the same sets of standards. The high variability in the application of criteria by MVOs distorts competition between TIF establishments.	Issue an updated NOM or guidelines that discuss in detail how specific tasks described in the NOM-009-ZOO-1994 are to be carried out by MVOs, to guarantee harmonised practices.

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MEXICO

OECD Competition Assessment Reviews present an analysis of regulatory restrictions on competition in the countries reviewed and make specific policy recommendations for reform. These reviews help governments eliminate barriers to competition while identifying less restrictive measures that still achieve government policy objectives. Using the OECD Competition Assessment Toolkit to structure the analysis, the regulations in sectors identified as targets for reform - such as construction, gas, media, liberal professions, pharmaceuticals, retailing, tourism and transport – are systematically reviewed one by one for any restriction to competition. The resulting recommendations allow governments to introduce more competition into the economy and foster long-lasting growth.

Many of Mexico's product markets remain among the most heavily regulated in the OECD. These structural flaws adversely affect the ability of firms to effectively compete in the markets and hamper innovation, efficiency and productivity. Against this backdrop, this report analyses Mexican legislation in the medicine (production, wholesale, retail) and meat sector (animal feed, growing of animals, slaughterhouses, wholesale and retail) along the vertical supply chain. Using the OECD Competition Assessment Toolkit to structure the analysis, the report reviews 228 pieces of legislation and identifies 107 legal provisions which could be removed or amended to lift regulatory barriers to competition. The analysis of the legislation and of the Mexican sectors has been complemented by research into international experience and consultation with stakeholders from the public and private sectors. The OECD has developed recommendations to remove or modify the provisions in order to be less restrictive for suppliers and consumers, while still achieving Mexican policy makers' initial objectives. This report identifies the potential benefits of the recommendations and, where possible, provides quantitative estimates.

Consult this publication on line at ***http://dx.doi.org/10.1787/9789264288218-en***.

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