

COMPETITION ASSESSMENT TOOLKIT

3 operational
manual



COMPETITION ASSESSMENT CHECKLIST



Competition assessment should be conducted if a legal provision has any of the following effects:

A Limits the number or range of suppliers

This is likely to be the case if the provision:

- A1** Grants exclusive rights for a supplier to provide goods or services
- A2** Establishes a license, permit or authorisation process as a requirement of operation
- A3** Limits the ability of some suppliers to provide a good or service
- A4** Significantly raises cost of entry or exit by a supplier
- A5** Creates a geographical barrier for 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 provision:

- B1** Limits sellers' ability to set prices for goods or services
- B2** Limits freedom of suppliers to advertise or market their goods or services
- B3** Sets standards for product quality that provide an advantage to some suppliers over others, or are above the level that some well-informed customers would choose
- B4** Significantly raises 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 provision:

- C1** Creates a self-regulatory or co-regulatory regime
- C2** Requires or encourages information on supplier outputs, prices, sales or costs to be published
- C3** Exempts the activity of a particular industry, or group of suppliers, from the operation of general competition law

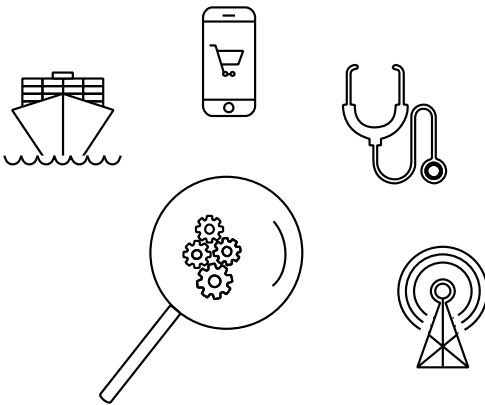
D Limits the choices and information available to customers

This may be the case if the provision:

- D1** Limits the ability of consumers to decide from whom they purchase
- D2** Reduces mobility of customers between suppliers of goods or services by increasing the explicit or implicit costs of changing suppliers
- D3** Fundamentally changes information required by buyers to shop effectively

Competition Assessment Toolkit

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Foreword

Increased competition improves a country's economic performance, opens business opportunities for its citizens and reduces the cost of goods and services throughout the economy. However, numerous laws and regulations may unduly restrict competition in the marketplace. Governments can reduce unnecessary restrictions by applying the methods described in the OECD's "Competition Assessment Toolkit". The Toolkit provides a general methodology for identifying unnecessary restraints and developing alternative, less restrictive policies that still achieve government objectives. A key element of the Toolkit is the "Competition Checklist" that asks a series of simple questions to screen for laws and regulations that could unnecessarily restrain competition. This screening focuses limited government resources on areas where competition assessment is most needed.

Governments can use the Toolkit in three ways:

- To evaluate draft new laws and regulations (for example, through regulatory impact assessment programmes)
- To evaluate existing laws and regulations (either in the economy as a whole, or specific sectors)
- To evaluate the competitive impacts of regulation (either by the government bodies that develop and review policies -or the competition authority).

It is designed for use in a decentralised fashion across government, at both national and sub-national levels. The Toolkit materials were designed with this flexibility because restrictions on competition can be implemented at different levels of government, and competition assessment is useful at all levels. One of the most successful examples of pro-competitive reform occurred in a federal system when Australia implemented broad, pro-competitive reforms at both national and state level in the mid-1990s. Since that time, Australia has experienced strong economic performance, with

high and steady growth that has raised Australia's economy from a mid-level performer to one of the top performing OECD economies. In a 2013 large competition assessment project, economic benefits from implementing recommended changes amounted to around EUR 5.2 billion (OECD, 2014a). In another project, benefits were estimated at around 2.5% or more of GDP (Sims, R., 2013 and Productivity Commission, 2005). While not all projects will have such large impacts, benefits from competition assessment can often be substantial.

The Toolkit can be used by officials without specialised economic or competition policy training. Potential users include: ministries, legislatures, government leaders' offices, state governments and external policy evaluators.

The Competition Assessment Toolkit is available in many languages to encourage its broad use and adoption. It contains three volumes: Volume 1 - *Competition Assessment Principles* - gives examples of the benefits of competition, provides an introduction to the Competition Checklist and shows ways that governments assess the competitive effects of their policies; Volume 2 - *Competition Assessment Guidance* - provides detailed technical guidance on key issues to consider when performing competition assessment; and, Volume 3 - *Operational Manual for Competition Assessment* - is a step-by-step guide for performing competition assessment. All related materials can be found on the OECD's website at www.oecd.org/competition/toolkit.

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Chapter 1

Introduction to competition assessment

This manual shows how to assess laws, regulations and policies for their competition effects, and how to revise regulations or policies to make them more pro-competitive. This process is called competition assessment. The process can yield substantial benefits to consumers and can significantly increase productivity. In one large project of competition assessment, economic benefits from implementing recommended changes would amount to around EUR 5.2 billion (OECD, 2014a). In another, benefits were estimated at around 2.5% or more of GDP (Sims, R., 2013 and Productivity Commission, 2005). While not all projects will have such large impacts, benefits from competition assessment can often be substantial.

Laws, regulations and government interventions often restrict competition in the marketplace. Removing unnecessary restraints to competition and developing alternatives which still achieve the same policy objectives can bring substantial benefits. The assessor can develop pro-competitive regulations by:

1. Identifying restrictions to competition.
2. Developing policy options.
3. Comparing policy options.
4. Recommending one or more preferred options.

Many governments have already engaged in competition assessment exercises. This volume seeks to bring together these experiences into a practical approach for completing competition assessments, with illustrative examples. The approach is well-suited either to ex-ante reviews of new regulations or ex-post reviews of existing ones. One key lesson from reform experiences is that stopping anti-competitive regulation at the draft stage is much easier than advocating change to the regulation after it has entered into force. To have an

effective regime of competition assessment, regulations should be reviewed for anti-competitive effects before the regulation enters into force.

Competition assessment is most effective when those people doing it (the assessors) have a clear understanding of the government policy objectives that need to be met, knowledge of technically feasible means for achieving these objectives, sufficient information for comparing options, sufficient resources for conducting an analysis, and sufficient technical skills for performing the analysis. Competition authority staff may be well placed for this type of work; other bodies of government may also have staff with the necessary skills.¹

This chapter distinguishes different types of competition assessment.

1. Types of competition assessment

Competition assessment can be performed in a wide variety of situations where government policy interventions are occurring. Assessors can focus on new regulations or pre-existing regulations. Assessors can focus broadly on entire sectors or more narrowly on a particular product market that does not function well.

1.1. Review of new regulation

When a new regulation is developed or introduced, many countries review the new regulation for its competitive effects. This process is called regulatory impact analysis (RIA). The RIA process can include an explicit competition element. Sometimes existing regulation has sunset clauses that require review before the regulation can be re-enacted. Such sunset clauses are also good opportunities to review regulations for their competitive effects.

¹ This manual can be supplemented by information from the two companion volumes of the Competition Assessment Toolkit: Vol. 1 Principles and Vol. 2 Guidance.

Box 1. Examples of review systems for new regulations

Australia

In Australia, government agencies are required to complete a regulatory impact statement (RIS) for “every policy proposal designed to introduce or abolish regulation” if it is “likely to have a measurable impact on business, community organisations or individuals”. Further, any proposal being considered by Cabinet must include a RIS, even if there appears to be no regulatory impact on businesses, community organisations or individuals, in order to ensure that the government is aware of the regulatory impacts of any decision it may make. If a proposal is likely to restrict competition, the RIS must demonstrate benefits that outweigh the costs and that no alternative means of achieving the same objective is available.

Regulatory impacts may include:

- Changes to the number or type of products that businesses can offer, such as:
 - Banning products or industry practices.
 - Changing the way in which products can be offered.
- Impacts on consumer demand for certain products, such as:
 - Increasing prices brought about by the regulation’s requirements.
 - Changing the information available to consumers.
- Impacts on the ability or incentives of businesses to compete in the market, such as:
 - Creating either a self-regulatory or co-regulatory regime.
 - Changing the requirements for a license, permit or other authorisation.
 - Influencing the price or quantity of goods which are sold.
 - Setting standards for product/service quality.
 - Changing the price or type of inputs available to businesses.

Mexico

In Mexico, new federal regulations are subject to review by COFEMER, the regulatory review body, which will consult the competition authority when there is a competitive impact of the new regulations. Starting in 2013, government bodies preparing new regulations must complete a Checklist of Competitive Impact for regulations with a high or moderate impact. When there is a restriction to competition indicated, the regulator must:

- Identify the article that would have a potential restriction on competition.
- State the impact checklist item(s) that indicate a potential restriction of competition.

- Describe how the rule may restrict or promote competition or market efficiency.
- Justify the need for the inclusion of the rule.
- Indicate alternative(s) and explain why the selected rule is the best alternative.

Korea

In Korea, the Regulatory Reform Committee (RRC) of the national government, the regulatory review body, adopted the 'Guidelines on Regulatory Impact Assessment' in 2008, taking into account the OECD's Competition Assessment Toolkit released in 2007. Before 2008, government bodies preparing new regulations could consult the competition authority (the KFTC) about whether the new regulation would include an anticompetitive regulation, and then the KFTC could recommend revising or deleting an anticompetitive part of the proposed regulation. Consultation was not a mandatory. The institutionalisation of competition assessment in 2008 resulted in comments on about 7% of regulations under the following process:

- Government body submits a draft regulation to the RRC for regulatory impact analysis.
- The RRC sends it to the KFTC for competition assessment.
- The KFTC conducts competition assessment on the draft regulation through a two-step process (preliminary and in-depth assessment) and reports the result of competition assessment back to the RRC:
 - Preliminary assessment: apply a checklist of four questions: entry of supplier, competitiveness, competition incentives and consumer choice.
 - In-depth assessment: detailed and comprehensive analysis for those potentially anticompetitive regulations, exploring alternative ways to achieve policy goals while minimising competitive impact.

The RRC takes into consideration the competition assessment result of the KFTC when reviewing the concerned regulation and makes a decision to revise or withdraw the anticompetitive regulation. After the decision of the RRC, the government body submits the modified draft regulation to the National Assembly.

1.2. Focused market study

A market study takes a market where competition does not appear to work well and examines whether the market really has a competition problem and, if so, the likely origins of the problem, and possible policies for reducing or eliminating the problem.

A market study is a form of ex-post analysis rather than ex-ante RIA review.

Box 2. Market studies and sector enquiries

The UK competition authorities have carried out market studies when there is a market in which competition does not appear to work well. For example, reviews have been performed in the sectors of groceries, taxis, pharmacies and airports.

Similarly, Germany's Bundeskartellamt has conducted sector enquiries to gain an impression of the competition situation in certain economic sectors such as, inter alia, the recovery and recycling of sales packaging discarded by private consumers, the rolled asphalt industry, district heating, milk, fuel, electricity and gas transmission.

1.3. Sectoral review

In a sector review, the regulations relevant for a sector are systematically identified and then considered one by one for any restrictions on competition. Like a market study, sector reviews are a form of ex-post analysis as opposed to an ex-ante review conducted by a RIA exercise. Sector reviews do not start with a general presumption that competition is not working in the sector, but instead begin with a search for individual regulations that may unduly restrict competition. Sector reviews may be carried out by the ministry responsible for the sector, though at times such ministries may be committed to existing regulations and-or may not have the necessary expertise in competition assessment. Another alternative for sector reviews is that they be completed by outside entities, such as other bodies of government, like a competition authority, or outside experts.

Box 3. Greece 2013 Competition Assessment Review

In Greece, an OECD review of four sectors (retail, food processing, tourism and building materials) illustrates how reviews of many regulations can, in aggregate, produce substantial improvements in economic performance. The sector reviews identified 555 problematic regulations, made 329 specific recommendations on provisions where changes could be made to foster competition, with potential positive impacts to the economy from the reforms estimated at around EUR 5.2 billion annually, roughly 2.5% of GDP.

Source: OECD (2014).

2. Process

The process of competition assessment is built around **6 steps**.

Step 1. Identify policies to assess. Identifying the policies to assess can be straightforward (in the case of a review of new legislation or regulations) or complex, as in the case of a sector review, or potentially a market study.

Chapter 2 provides guidance where, as in the case of a sector review, there may be discretion in choosing the boundaries of what is reviewed. Defining the boundaries of the “building materials” sector, for example, would require determination of what constitutes relevant regulations for the sector of building material. Regulations concerning raw steel, for example, might not be considered relevant to the building material sector, while steel rebars might be considered building materials.

Perhaps the most common situation will be one in which there is no discretion for choosing what regulations are reviewed, for example, because it is a RIA requirement. In this situation, **Chapter 2** can be skipped.

Step 2. Apply the Checklist. The Competition Checklist (“Checklist”) is a set of four lead questions, each with sub-questions, that identify regulations with the potential to restrict competition. ‘Yes’ answers to the questions suggest a need for more detailed analysis of competitive effects of the regulations.

The Checklist questions lie at the heart of competition assessment. They can be found at the beginning of this guide. **Chapter 3** explains the questions and how to interpret them.

If the Checklist indicates the potential for a restriction of competition, further investigation should be performed to assess whether there is an actual and significant restriction on competition. **Chapter 4** explains how to perform a detailed review of regulation. If there is no significant restriction, the review can stop. If there is a substantial restriction on competition, alternative options should be developed.

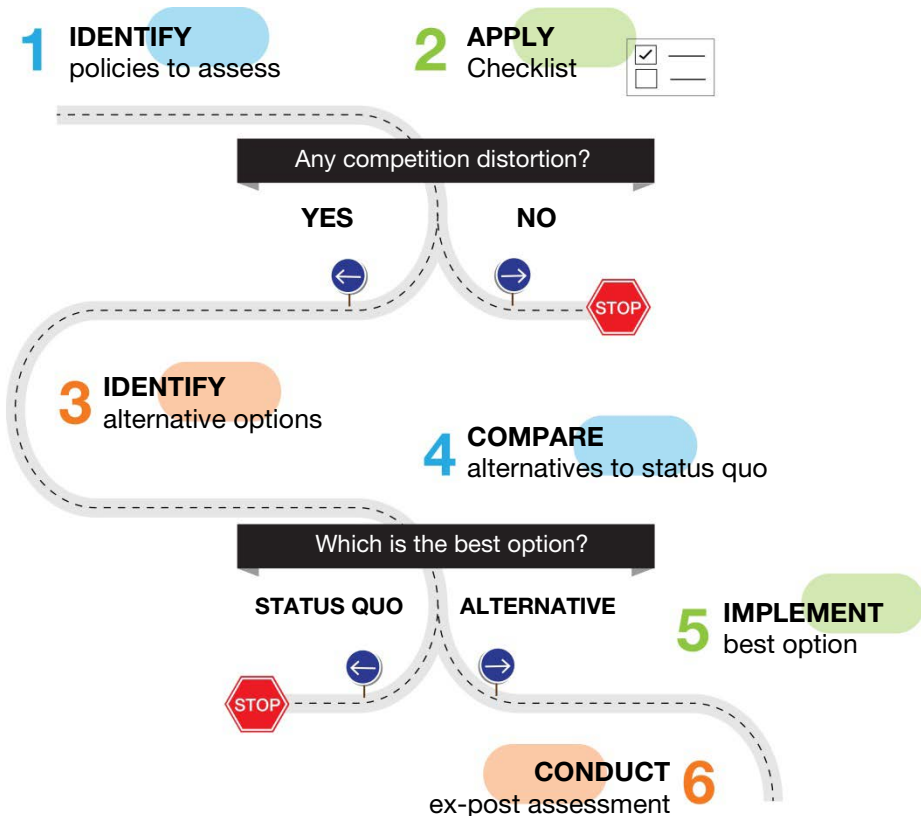
Step 3. Identify alternative options. When a restrictive regulation is found, it may be possible to identify alternative less restrictive measures that can be used to achieve the relevant policy objectives based on an understanding of the rationale for the regulation, the broader regulatory environment and the technical features of the sector being regulated. This is explored in **Chapter 5**.

Step 4. Select best option. Between the options that are identified, the reviewer of the competitive impacts of the regulation must make a judgment about what is (are) the best option(s) – see **Chapter 6**. There may be more than one best option. Differences between the preferred option and currently proposed or existing regulations must be clearly explained.

Step 5. Implement best option. Once the best option is identified, appropriate legislation must be drafted and recommendations made to the competent authority. (**Chapter 7**).

Step 6. Review impact. Once an option has been implemented, particularly if it restricts competition, it is important to review its impacts (**Chapter 8**).

Figure 1. Steps in Competition Assessment





Chapter 2

Selection of public policies for examination

Indications for use: This chapter is relevant only for those reviews in which the policies to assess are not already decided. If, as in most cases, the regulations under review are already decided by the policymaking apparatus, for example with Regulatory Impact Analysis review of new regulations or in a case of ex post review of a specific regulation, this chapter can be skipped. This chapter may be particularly useful in the context of sector or market studies.

When reviewing competitive impacts of a government intervention, governments usually assess individual regulations. At times they may also perform general reviews of all the existing legislation in a sector, or even across the economy. In Australia, for example, a broad multi-sector review of legislation took place in the late 1990s, as a result of the establishment of a National Competition Policy, resulting in the in-depth review of about 1800 laws and regulations. In Greece in 2013, four sectors were reviewed, involving scanning more than 1000 regulations. In many countries, market studies are performed when a market does not appear to be working well.

For such general reviews, policymakers must prioritise and select the policies that will undergo an assessment. The need for prioritisation arises from the often large volume of policies that exist in each sector of the economy. Because of the resources requirements for a complete review, including the limited supply of skills for performing such reviews and the cost of using these resources, assessors will often wish to limit the scope of the review to the most important sectors and the most relevant pieces of legislation. Having said that, the benefits from a multi-sectoral review can be far in excess of the costs of performing such a review, so investing sufficient resources to perform a wide-ranging review can be valuable.

This Chapter provides some indications of how to select the sectors on which to focus, when a review across the whole economy is planned. It also gives some suggestions on how to identify the legislation that falls within a specific sector and on how to prioritise the policies to be assessed within each single sector.

This chapter is also useful in the context of market studies. These are often markets that form a specific part of a sector, rather than an entire sector. For example, many markets are included within the “financial sector” including retail banking, insurance, payment systems, mortgage lending, etc.

1. Selecting the sectors

When a government decides to perform a review of all the existing legislation to remove unnecessary barriers to competition, it is necessary to start by selecting a group of sectors on which to focus. One, or a combination, of the following prioritisation principles can be used as guidance:

- Select sectors in which greatest constraints on competition are believed to exist (which may be possible to identify using readily available information on restrictions of competition, the frequency of complaints regarding competition restrictions, prices, margins and/or the number of antitrust interventions).
- Select sectors with widespread impact on a country’s international cost competitiveness (such as infrastructure sectors).
- Select sectors with a significant impact on consumer expenditure.
- Select sectors that represent a high share of GDP.
- Select sectors that constitute a high share of exports.
- Select sectors that have a higher employment potential or are labour intensive.

These principles might also be considered in determining markets warranting an ex-post market study.

These principles help to determine the economic relevance of specific sectors and allow ranking them. The choice of the most appropriate one(s) to assess depends on the characteristics of the country that is performing the review. For example a country with a very open economy may want to concentrate its attention on the sectors that contribute the most to its exports.

Box 4. Mexico's review of existing legislation

In 2008, Mexico launched a multi-year project to improve the competitiveness of the Mexican economy, in co-operation with the OECD. This project included a review of the existing regulations and policies to remove unnecessary restrictions on competition.

The sectors to be analysed were chosen based on their impact on the economy. Two different criteria were used and 15 sectors were identified.

Criteria:	Sectors:
Sectors with widespread impact on competitiveness	<ul style="list-style-type: none"> • Telecommunications • Financial services • Energy • Freight transportation
Sectors with significant consumer expenditure	<ul style="list-style-type: none"> • Corn and tortilla • Carbonated beverages • Beer • Passenger transportation • Dairy • Personal and home care • Insurance • Retail banking • Medicines • Hospital services • Pensions

In addition to these sectors, the Mexican project identified four different areas of cross-sectoral regulation with a high impact on competitiveness: fiscal policy, international trade, subsidies and technical regulation. The review was extended to include these.

The number of sectors selected for review will depend on the nature of the exercise, but should also be based on the time, the financial resources and the technical skills available. In Australia, for example, the process of reviewing 1 800 laws and regulations believed to contain substantial restrictions on competition across the whole economy lasted about 5 years. In Greece the review of four sectors, which involved scanning around 1 000 pieces of legislation, was undertaken over a period of 11 months prior to legislative drafting, passage of laws and regulations, and implementation.

2. Mapping the sectors

When the sectors have been selected, it is then necessary to identify all the relevant legislation that applies to and in them. This requires establishing the boundaries of each sector to be mapped, i.e. defining those economic activities that fall within it and, perhaps implicitly, those that lie without. Mapping can be based on standard industry classifications (SICs), such as the ISIC, the NACE or the NAICS (explained in the box below), but support from specialists, such as relevant line ministries and market actors, is also necessary to make sure that all relevant activities are correctly identified. Sometimes sectoral studies from international agencies, consultancies and ministries could also provide useful information.

Box 5. Standard industry classifications

When a regulatory review is broader than simply a review of a new regulation, such as when there is a review of a sector, the determination of the boundaries of a sector is a frequent challenge. Ways to determine boundaries include:

- Focus on legislation relevant to one ministry;
- Focus on legislation in one law (or more) sector laws and regulations.
- Focus on standard definitions of activities.

Three well-known standard industry classifications are:

- **International Standard Industrial Classification of All Economic Activities**
This is a United Nations system for classifying economic data:
<http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=27>.
- **Nomenclature statistique des activités économiques dans la Communauté européenne (NACE)** or Statistical Classification of Economic Activities in the European Community
A European industry standard classification system consisting of up to 6 digit code: http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&StrNom=NACE_REV2&StrLanguageCode=EN&IntPcKey=&StrLayoutCode=HIERARCHIC.
- **North American Industry Classification System (NAICS)**
www.census.gov/eos/www/naics/.

The classifications are commonly used for classifying products and predominant activities of companies. However, some activities will invariably be mixed in terms of the sectors involved, so that a producer will be affected by multiple legislative sectors. For example, a ferry service may provide both freight transport and passenger transport, which are likely to be two distinctly regulated activities. Examining regulation of ferries would then involve both aspects. But the competitive environment for a transporter of passengers by ferries may be affected by rules over maritime transport of freight (and relevant port rules over loading and unloading), to the extent that such rules also apply to ferries.

Using the standard industry definitions can lead to slicing and dicing of sectors in ways that are counter-intuitive. For example, the NACE system would not classify elevators as a sector, but would separate elevator manufacturing under one code (28), with elevator installation, repair and maintenance under another code (43). Therefore it is important to decide whether one seeks intuitive definitions of sectors.

One of the advantages of the intuitive definitions, building around a broad product category, is that they may better reflect the range of business activity performed around a product category. Companies that are focused on a sector such as elevators may cover multiple relevant codes. In such cases, it is difficult to determine one code that would apply to a company, as it will perform activities that lie under multiple codes. The private and other business interests who are met when performing a competition assessment may be aware of competitive constraints across the spectrum of different parts of the intuitive definition. Limiting results to one NACE code may then exclude restrictions that are identified for the same intuitive sector but under a different NACE code.

An advantage of standard industry codes is that there is less discussion about where the boundary of a sector may lie, thus the boundary is less subject to dispute. However, closely linked (and relevant) activities can be excluded from an excessively strict interpretation. For example, limits on outputs of wheat per planted hectare may be an agriculture restriction, technically; however such limits automatically translate into a restriction on output for manufacture of wheat, and therefore may be considered part of the regulatory environment (and a restriction on output) for the manufacture of flour.

The next step consists in compiling an exhaustive list of all the laws and regulations that influences the economic activities that take place in each of the sectors under examination. When performing this exercise it is important to remember that, in addition to sector specific regulation, there also exists horizontal, cross-sectoral, legislation (such as planning restrictions or environmental standards) that may have a considerable impact on the economic activities performed in that sector and may be a cause of additional competition restrictions. At times legislation at national, regional and municipal level may interact; when appropriate, legislation at all relevant levels should be considered.

National legal databases can help to identify all the legislation applicable in the sectors under scrutiny, but input should also be solicited from stakeholders, such as industry or consumers associations, and competent line ministries involved in the selected sectors.

The time required to map regulation in a sector is non-trivial and should not be underestimated in the timeline for performing a competition assessment of a sector. To ensure that all the relevant legislation is included in the review, it is important to assemble a full and appropriate universe of laws and regulations. This needs to include relevant

implementing provisions such as ministerial decrees, circulars and other forms of implementing guidance for regulations.

Determination of the full set of relevant government acts and processes may be an iterative process. In some systems, laws and regulations are not necessarily kept in one place and may not be electronically searchable. Amendments to one law may be found in another later law that appears unrelated. When laws and regulations are codified and electronically accessible, the process of searching for relevant laws and regulations will proceed with greater speed, but will still require speaking to industry experts and will still likely not be complete, due to the existence of ministerial decrees, circulars and guidance that may not be found in such databases.

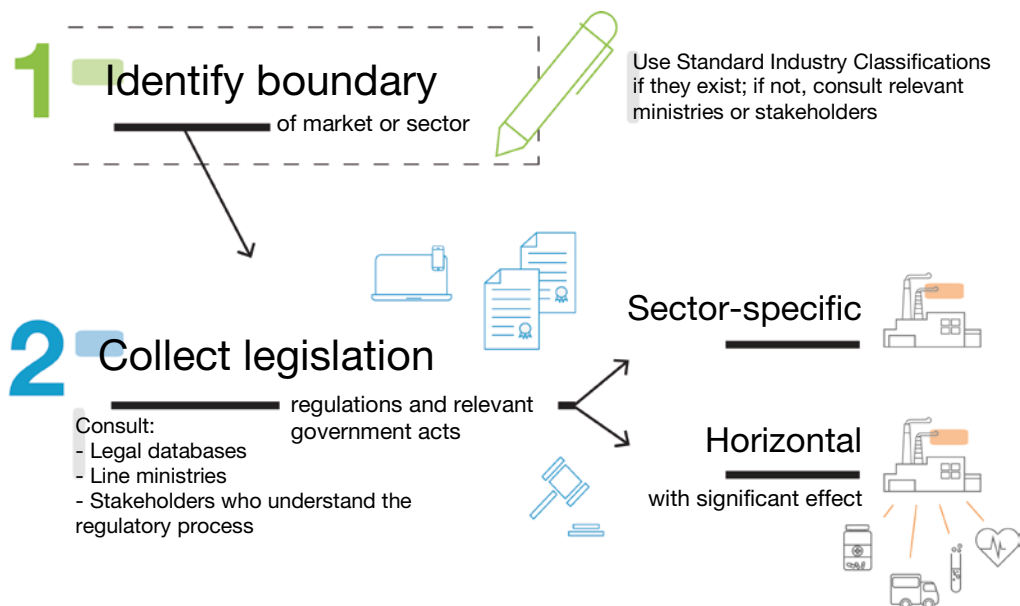
While mapping a sector, it is worth considering processes for applying regulations. In practice, the processes of regulation can affect the legal framework faced by a potential competitor. For example, if a competitor needs an authorisation from a certain office before starting business, and only one person at the office can provide the authorisation but is on leave for six months, there is an effective barrier to starting a new business as a result of problems with process. Such process challenges should be recorded where information is found about them, as recommendations from competition assessment could apply to process as well as to legal frameworks.

Box 6. Complexity in finding relevant legislation

In Greece, a piece of tourism legislation was located in a broader law on hooliganism in sports stadiums. Such legislation would not easily be found without the aid of industry experts, whether in a ministry or in the private sector

Source: See OECD (2014).

Figure 2. Steps for mapping sector regulation



Box 7. Mapping the tourism sector in Greece

The approach of using standard industry codes was not applicable to defining the tourism sector in Greece since no such category exists within the NACE classification. In light of this limitation, the OECD project team reviewing sector regulation defined tourism on the one hand as the activities that fall under the remit of the Ministry of Tourism and/or the bodies under its supervision, and the remit of the Directorate of Sea Tourism and of the Department of Sea Leisure Activities and Tourism within the Ministry of Maritime Affairs and the Aegean and on the other hand as any activity explicitly classified as “touristic” in the applicable legislation.

Source: OECD (2014).

3. Identifying the key policies

A list of all the legislation relevant to a specific economic sector is likely to be extensive. Hence, further simplifications may be necessary. The following suggestions can be followed to limit the list of policies on which to focus:

1. Start with framework laws that apply to the entire sector.
2. Remove obsolete legislation that has been superseded by newer legislation (noting that at times, only one article in a decree is nullified or superseded).
3. Exclude the obsolete legislation still in place but harming competition, by recommending its elimination.
4. Do not consider the legislation that transposes international agreements and treaties or super-national directives (such as EU ones), if no scope for additions and changes is allowed.

Once at this stage, the Checklist should be applied to identify those policies that may have a negative impact on competition.

Detailed example Pharmaceutical Sector Competition Recommendations

This box begins a detailed example that will illustrate the respective steps in each chapter of the manual. This first section provides an introduction to the sector, specific regulations, and regulatory background. The example is not intended to provide a precise reflection of regulation in any specific country, but rather to illustrate how competition assessment can work in practice, using one case for illustration. The focus here on pharmaceuticals is not intended to suggest that pharmaceutical regulation generally creates a special need for competition assessment.

Introduction

This report provides Health Department findings and recommendations in response to the Health Minister's January 2013 Directive to the Department to examine and make recommendations for potential pro-competitive reforms to the pharmaceutical sector. The Directive reflects a government commitment to promote the benefits from competition for consumers and the economy combined with concerns generated by studies suggesting that pharmaceutical costs in the country are excessive compared to other countries. In 2011, pharmaceutical costs of USD 9.7 billion represented close to 20% of all health care costs compared to average OECD in the range of 16%.

Factors that the Minister has directed the Department to take into consideration in developing recommendations include their:

- impact on pharmaceutical costs;
- implementation and ongoing obstacles and costs;
- implications for the quality and efficiency of the health care system; and
- anticipated public and health sector support or opposition.

The report is organised as follows. Part 1 provides background information on pharmaceuticals. Part 2 defines the scope of the Departmental review taking into consideration the potential for, legislation, regulation and policies (regulation) applying to the pharmaceutical sector to have unwarranted anti-competitive effects. Part 3 identifies regulations potentially having significant anti-competitive effects using the OECD Competition Checklist (the “Checklist”). Part 4 provides a preliminary competition assessment of the restrictions identified using the Checklist to identify restrictions warranting more in depth analysis and outlines key findings from the in depth analysis. Part 5 outlines potential options for remedying competition concerns developed in Part 4. Part 6 analyses and compares the potential options for reform. Finally, Part 7 provides recommendations for reforms.

Part 1. Background

Pharmaceuticals are restricted medicines that can only be provided to patients if they are listed on the national drug dispensing list. To be listed on the national list, pharmaceuticals must be approved by the Health Department Pharmaceutical Assessment Division (the “PAD”). In determining whether or not to add a pharmaceutical to the list, the division taking into account evidence provided by the manufacturer on its therapeutic effects and safety for human consumption.

Most pharmaceuticals are small molecule drugs (SMPs) having one or more chemically derived active ingredients (AIs). However, an increasing share are biologically-based in that they are isolated from natural sources (biologics). In contrast to drugs that are chemically synthesised with a known structure, most biologics are complex mixtures that are not easily identified or characterised.

Pharmaceuticals containing a new AI are entitled to an initial 20 year patent protection period. In order for these drugs to be added to the national dispensing list, detailed evidence, including extensive clinical trials, must be provided supporting their therapeutic benefits and safety for human consumption. Follow-on improved or altered versions of these drugs are also entitled a 20 patent protection period if they are deemed sufficiently innovative to be patented. A pharmaceutical’s period of patent protection may be extended when there is a lengthy delay in their approval for marketing following the granting of the patent.

In order for a generic version of an SMP (generic) to be added to the national dispensing list, evidence must be provided to the PAD by the manufacturer demonstrating it to be bio-similar to the relevant brand drug in that its rate of release of the AI is within an acceptable range of the brand drug’s rate of release.

Because of the relative complexity of biologics, the PAD requires manufacturers to provide more extensive evidence in order for them to be listed on the national dispensing list. This evidence must include clinical trials establishing that the follow on biologic has the equivalent therapeutic results as the relevant brand biologic.

Pharmaceuticals can only be provided to patients if prescribed by a physician, or, in certain cases, another qualified healthcare professional. Other than limited dispensing by physicians direct to their patients, dispensing of pharmaceuticals is performed by licensed pharmacists. Pharmacists are required to dispense patented products prescribed by physicians, but may substitute a generic for its corresponding brand product unless the prescription specifies that no substitution is to be made.

The costs of medically necessary drugs are covered by the government run National Pharmaceuticals Insurance Plan (NPIP) subject to an age and means-based patient co-payment scheme and a maximum annual out-of-pocket payment by patients. In order to be reimbursed under the NPIP pharmaceuticals must be approved for listing on the NPIP dispensing list based on its costs and therapeutic value. Patients are responsible for the costs of drugs not on the NPIP dispensing list or not deemed to be medically necessary.

Private drug plans provide supplemental coverage to the NPIP. The private plans may cover some or all of the relevant patient's co-payments as well as the costs of pharmaceuticals listed on the national dispensing list but not covered by the NPIP.

Part 2. Scope of the review

Due to the nature of pharmaceuticals, they are subject to a high level of regulation at all levels of supply, from the manufacturing of APIs to dispensing. To focus further analysis on areas having the highest potential to provide significant pro-competitive benefits, Ministry staff mapped out key areas of primary and secondary or delegated legislation, professional and other regulation, and policies (regulation) applying to the pharmaceutical sector. Areas of regulation having little or no potential for delivering significant competition benefits, clearly overriding health and safety concerns, limited likelihood of reform and/or that could be eliminated for other reasons were removed from further analysis.

Key areas of regulation eliminated from further analysis

- *Physician and pharmacist professional qualifications:* Entry qualifications for physicians and qualifications are highly technical and involve fundamental patient health and safety concerns. While they may restrict the numbers of physicians and pharmacists in the country, they are only indirectly relevant to the costs of pharmaceuticals.
- *Follow-on biologic entry requirements:* While biologics are a significant and increasing source of pharmaceutical costs, the development of subsequent entry biologics and appropriate tests for their approval remain at early stages of development. In respect of these considerations, the PAD has an ongoing review of the issues that will provide an effective forum for addressing potential competition issues in the future.

- *Patent term:* While patents are a major obstacle to generic entry, the current patent term, 20 years from the date of filing is an accepted international norm that is incorporated into the country's international trade and intellectual property agreements.
- *Safety and therapeutic standards for adding pharmaceuticals to the national dispensing list:* Strict therapeutic and safety standards are essential for protecting and promoting the health and safety of patients with respect to new drugs. These concerns clearly dominate the potential concern that strict standards for new drugs may restrict competitive entry. Moreover, conducting a detailed review of the current standards for listing would be complex and time consuming, and would be performed in the absence of evidence or widespread concern that the current standards are unnecessarily restricting new entry.
- *AI and drug manufacturing licensing restrictions:* Ensuring that pharmaceuticals are safe and therapeutically effective are also the prime concerns underlying the licensing of active ingredient and pharmaceutical manufacturing facilities. The licensing requirements are non-discriminatory in that they do not distinguish between domestic and foreign facilities and the Health Department's licensing practices have not been the subject of complaints.
- *Expanded private sector insurance role:* Due to widespread public support for the NPIP, the incoming government has stated that it will not be reducing the NPIP's role.



Chapter 3

Competition screening using the Checklist

The screening method uses a set of threshold questions embodied in the Checklist that show when proposed regulations may have significant potential to harm competition. The Checklist is found at the beginning of this manual. The majority of regulations are unlikely to draw a positive response from the Checklist. When the Checklist does elicit a positive response, a preliminary assessment of competitive effects is suggested. In many cases, a preliminary assessment indicates significant harm to competition could be expected. In those situations where harm to competition is most likely, an investigation of competitive restrictions is warranted (see Chapter 4.)

The rest of this chapter explains the four categories of the Checklist and provides examples of the sorts of regulations that would fall into each category.

Checklist A Limits on the number or range of suppliers

Limiting the number of suppliers creates a risk that market power² will be created and competitive rivalry will be reduced. Furthermore the incumbent firms may not be the firms that are best at meeting customer needs, particularly over the long run. When the number of suppliers declines, the possibility of co-operation (or collusion) between them

² Market power of suppliers is the ability to profitably increase price, decrease quality, or decrease innovation relative to the levels that would prevail in a competitive market.

increases and the ability of individual suppliers to raise prices can be increased. The resulting decline in rivalry can reduce incentives to meet consumer demands effectively and can reduce economic efficiency. While there are sound policy reasons why policy makers may sometimes limit the number or range of suppliers, as discussed below, any policy benefits of entry limits need to be balanced against the fact that ease of entry by new suppliers can help prevent existing suppliers from exercising market power. Market power can lead to higher prices, lower quality and less innovation.

A1 *Grants of exclusive rights*

A grant of an exclusive right to produce a certain good or provide a certain service represents the establishment of a private monopoly. Historically, the grant of an exclusive right frequently occurred in the context of a “natural monopoly”.³ The grant of exclusive rights, particularly of long duration, has frequently been considered a means of encouraging substantial investments in infrastructure that may be unlikely to occur without the incentives provided by the guaranteed market access which the grant of an exclusive right provides.

Exclusive rights are likely to yield monopoly pricing and other problems of market power. Such results may not be fully avoided through regulation because regulators often experience a low level of success in preventing the exercise of market power and protecting consumers. Therefore, such rights should be established only with great care and after careful consideration of alternative ways to achieve the same objectives. If established, the duration of such rights can be limited. In addition, public authorities may consider distributing such exclusive rights through bidding to ensure that they are allocated in the most efficient fashion. For example, establishing private curb-side pickup of household waste through a competitive tendering process can often cost less than government provision of the same service.

³ A monopoly exists when a good or service can only reasonably be purchased from one supplier. In a “natural monopoly”, one supplier can produce desired output more efficiently and at a lower total cost than two or more suppliers.

Box 8. Water market concessions

Many local governments choose to give the exclusive right to provide drinking water and process waste water to one private company. The company demands a price for its service, which often increases by renegotiation from year to year, absent competition. The locality has the choice between automatic renewal of the management contract or public tendering. Public tendering can help to achieve better outcomes, though it is complex, particularly when dealing with annual renegotiation of prices. When public tendering of water contracts was required in France, prices paid for the private company services fell by about 10%.

Source: Brunet, E., Guérin-Schneider, L. and Bonnet, F. (2002).

Box 9. Airport concession

At Yerevan Airport in Armenia, a 30-year concession has been granted to a company to operate the airport. This concession includes the exclusive right to provide ground services (like baggage handling, aircraft cleaning and fuelling of aircraft), unlike in most airports in which this right is not exclusively limited to the airport operator. Airlines serving the airport have complained that prices for ground services at Yerevan airport are considerably higher than in nearby comparable airports. For example, one study finds ramp handling charges at Yerevan airport are 39% above the average for comparable airports. Higher prices and potentially lower service quality can be the result of a monopoly on ground services, which is an activity that can work with multiple providers.

Source: Pape F., D. Lurje and E. Satas (n.d.), Competition Impact Assessment Report of the Airway Sector.

A2

Establishment of a licence or permit system as a requirement of operation

Licenses or permits required for operation restrict entry. Qualifications requirements can take the form of minimum standards for formal education and/or experience and may include good character requirements. At times, a “public interest” test may be applied that requires that potential entrants demonstrate the “need” for an additional service to be provided and, in some cases, even that their entry would have no negative impact on the businesses of existing industry participants. In extreme cases, there may be fixed numbers of licensees. While licensing schemes will sometimes have well-founded consumer protection objectives, such barriers frequently have the effect of protecting incumbent producers from competition. At

times, licensing regimes are distorted from their legitimate purposes in a way that turns their application into a clear barrier to entry, creating long delays for issuance, opportunities for official corruption or simply eliminating any realistic possibility of entry by worthy applicants for a license.

Box 10. Licensing for taxis

In Dublin, Ireland in the year 2000, the number of taxis was restricted and all taxi drivers needed a license. The resulting taxi shortage meant that on popular nights for going out, people would sometimes have to wait hours in line in order to get a taxi home. In 2001, a court struck down the government limits on the number of licenses, saying the law did not authorise such restrictions. When the restrictions were lifted, taxi licenses were given out to all qualified comers, and the number of taxi licenses increased by more than 300%, with a substantial decline in waiting times at the most popular hours for travel. The dramatic increase in the number of licenses showed how the regulation by the government had been leading to a substantial under-service of the market and the liberalisation led to higher levels of employment.

Source: OECD (2007).

License or permit requirements are often stricter than is necessary for consumer protection and can unnecessarily reduce consumer choice and create artificial scarcity that raises prices. Licensing restrictions can be particularly problematic in professions where concerns often rise that licensing restrictions are for the purpose of protecting the interests of members of the profession rather than the public. A guiding principle is to ensure that licenses and permits are required only when necessary, and rejections must be reasoned and subject to challenge in court. When licensing regimes are simply unnecessary or consumer protection can be achieved in another way, they can be eliminated.

A3

Limits the ability of some types of suppliers to provide a good or service

At times, governments seek to promote suppliers from certain regions, small suppliers, or suppliers with other special characteristics by limiting the ability of some types of qualified suppliers to participate in a business activity, particularly with public procurement. Such restrictions are typically excessive because they unduly restrict the number of suppliers participating in procurement, reducing competition between suppliers and resulting in higher prices or less desirable contract terms for the government.

Box 11. Fertiliser support programme: Minimum time of operation

Zambia operates a farmer support programme that subsidises fertiliser purchases by farmers. The programme issued tenders for the provision of fertilisers. One of the conditions of the tender was that participants had to have operated in the fertiliser market for at least five years. This effectively excluded potential new suppliers who, if they wanted to serve the market, had to sell on a commercial market, in competition with subsidised fertiliser, for at least five years in order to have a chance of winning a spot with the government tender. As a result, bids allegedly went to the same two firms year after year, with a small third place award. This process has now been changed to give farmers electronic vouchers that they can spend directly with the supplier of their choice.

Source: Klissas, N. (2014).

Box 12. Latvia: Example of local restrictions

In Latvia, there was a legislative proposal in 2013 that providers of services in a port would need to own or lease land in the port area. This legislation would have limited the number of potential suppliers of services to those who had a physical presence in a restricted area. Such restrictions could be used to control which companies gain access to scarce port land and thus determine which companies can supply a service and which ones are excluded. The competition authority opposed this legislative proposal due to its likely restriction of competition and the proposal was not successful.

Where regional or small business policy objectives are sought, alternatives include direct subsidies and/or tax benefits when the subsidies or taxes do not create competition problems, provision of a more favourable regulatory environment in key areas, or the use of publicity/educational campaigns. In some cases, targeted subsidies will enhance efficiency by ensuring that more suppliers can actively seek business.

A4 ***Significantly raises the costs of entry or exit***

Regulations that raise the costs of entry to, or exit from, a market will tend to discourage some potential entrants and so reduce the number of participants in the market over time. Such regulations can replace a market performance test with a regulatory one and can prevent consumers from obtaining desired or efficiently manufactured products. Examples of this kind of regulation include rigorous product testing requirements and requirements to meet unnecessarily high educational or technical qualifications. Governments have sometimes acted to minimise the

competitive impacts of such provisions by providing targeted exemptions. For example, low-volume car manufacturers are often exempted from aspects of vehicle testing regulations, or subject to less onerous testing protocols.

Box 13. Repeating experiments requirement

The patent holder of pharmaceutical products has exclusive rights to the innovation for a given time period. When that time period passes, generic drugs can be sold, usually offering much lower prices than the initial patented medication. The regulations over when a generic drug can be marketed have important competitive consequences. In Mexico, generic pharmaceutical manufacturers not only had to show that their active substance was the identical molecule to that of the former patented medicine, they also had to repeat the experiments that had initially been performed with the patented medicine to show that the drug would be effective with the Mexican population.

While ostensibly reasonable, such a requirement had the effect of limiting the number of suppliers willing to provide generic drugs. The rationale that the initial drug seller had to perform the research, so new suppliers should also have to bear similar costs (otherwise the new suppliers would have a cost advantage) does not consider that the seller of the patented drug benefitted from monopoly rights for many years, which were intended to compensate the costs of developing the innovation and showing its effectiveness. Generic sellers were also constrained by the requirement that they had to own a production facility in Mexico. Many generic drugs were therefore more expensive in Mexico than in the neighbouring United States, where generic competition was vigorous.

Box 14. Audit requirements for closing firms

Moldova requires tax audits and other reviews upon closure of a business. While such reviews can help to ensure that government debts are properly paid, this process can take a year, significantly delaying the final closure of a business and, in turn, reducing the willingness of a potential supplier to set up a business in the first place.

A5

Restricts the flow of goods, services, capital and labour

Regulations sometimes limit the flow of goods, services, capital and/or labour across jurisdictional boundaries, often as an instrument of regional policy. Such limitations, however, artificially reduce the geographic area of competition for provision of a good or service. This may reduce the number of suppliers and potentially allow suppliers to exercise market power and increase prices. The resulting protection may also deny customers product choice and prevent increases in productivity.

Box 15. Geographical service areas

In the Mexican state of Chiapas, the municipality granted licenses for the sale of tortillas in the capital city of Tuxtla. These licenses divided the city into four areas and did not permit sellers to sell outside their designated area, thus creating four local monopolies.

In India, taxi drivers from adjacent localities are sometimes not allowed to deliver clients picked up in the area in which they are registered to go to another locality, including in the cities contiguous with Delhi, so that at a border, passengers must get off one taxi and find another licensed in the adjacent locality.

Box 16. Labelling requirements

In a country with a popular branded lemon drink, a ministry has issued a rule requiring that all drinks with oranges on their label contain at least 10% content of oranges, in order to avoid deceptive packaging. The popular branded drink, which is normally sold with pictures of oranges on the label, therefore has a different label in the state with the 10% content requirement. While the intent to avoid deceptive advertising is worthwhile, one result is that stores in that municipality cannot purchase the drink from neighbouring areas if they find their local bottler is selling at unfavourable conditions or if they are offered good deals from wholesalers with the genuine branded drinks with the lemon pictures on the label.

Potential restrictions should be assessed based on whether there is a clear link between the restrictions and the achievement of specific policy goals, whether the restrictions are the minimum necessary for achievement of the goal, whether a reasoned analysis suggests the policy goal will be achieved by means of the restriction and whether the restrictions have a limited time span via explicit regulatory provisions. There is a substantial risk that “temporary” protections develop into quasi-permanent arrangements due to substantial lobbying by the suppliers that benefit from the restrictions. As with the above case of Zambian restrictions on procurement, there will often be superior alternatives available to achieve the regulatory objective, including direct subsidies that do not pick a winning company and favourable regulatory treatment.

Checklist B**Limits on the ability of suppliers to compete**

Regulation can affect the ability of suppliers to compete by restricting the actions that suppliers can take in competing with each other. The restrictions discussed here include advertising and marketing restrictions,

setting of standards for product or service quality and controls over prices at which goods or services are sold. These limits can reduce the intensity and dimensions of rivalry, yielding higher prices for consumers and less product variety.

B1***Controls the prices at which goods or services are sold***

Governments often regulate prices in traditional monopoly sectors, such as utilities. These types of price controls are probably helpful to consumers and serve as a counterweight to a lack of competing alternatives. However, price controls are also sometimes applied in situations where there are many potential suppliers to the same consumer. When minimum prices are set, low-cost suppliers are prevented from winning market share by providing better value to consumers. Similarly, when maximum prices are set, supplier incentives to innovate by providing new and/or high-quality products can be substantially reduced and suppliers may effectively co-ordinate their prices around the maximum price.

Box 17. Maximum markups

In Greece, maximum markup prices were in place for almost all vegetables and fruits. These maximum mark-ups were intended to protect consumers from retailers setting extremely high margins on important food products. The maximum mark-ups were eliminated in 2011. After this repeal, average retail and wholesale prices actually fell, suggesting that the maximum mark-up rule had served as a basis for suppliers to co-ordinate their prices. While it may have protected some consumers from retailers who charged extremely high mark-ups, on average the rule had led to higher prices for food products.

Source: Genakos C., P. Koutroumpis and M. Pagliero (2014).

Minimum price regulation is sometimes a response to extremely vigorous price competition. In these cases, minimum price regulation is generally seen as a means of protecting small suppliers from “unfair” competition. The impacts of such price regulations merit careful evaluation because the result is likely higher prices for consumers or unmet demand. Maximum price regulations are frequently introduced as a necessary corollary to restrictions on entry. An alternative is to permit freer entry to the market.

B2***Restricts advertising and marketing***

Regulations that restrict suppliers' ability to advertise or market goods and services often exist to limit false or misleading advertising. Sometimes advertising restrictions are intended to reduce advertising for products or services that are deemed to have a socially negative value or which are subject to excess consumption. At other times, advertising to certain "vulnerable" groups, such as children, may be restricted. Restrictions of this nature, when circumscribed to ensure they are not overly broad, can have significant social benefits.

Box 18. Advertising restrictions for opticians

Advertising restrictions for opticians are often pursued by professional associations. One argument for such restrictions is that they prevent wasteful spending on advertising, thus ensuring that costs (and prices) are maintained at a lower level. Another is that advertising would cause a negative spiral of lower price and lower quality products. Another is that advertising can affect the dignity of a profession. A study of optician advertising restrictions in the United States compared cities with advertising restrictions for opticians to those without. It found that advertising led to significantly lower prices for consumers, on average, without having an average reduction in quality. The study found that average prices of an eye examination and eyeglasses in the most restrictive cities were, on average, 33.6% higher in the most restrictive cities than in the least restrictive ones, while there was not a statistically significant difference between average quality in the most and least restrictive cities. The findings were consistent with the hypothesis that the primary effect of the advertising restrictions was to prevent competition and keep revenues higher for the profession.

Source: Summary by the US FTC on Bond et al. (1980) in OECD (2004b).

In many cases advertising and marketing restrictions are too broad and unduly restrict competition. Restrictions on advertising and marketing are likely to be particularly onerous for potential entrants, as they restrict an entrant's ability to inform potential customers of their presence in the market and of the nature and quality of the goods and services that they are able to offer. Regulations that restrict only false and misleading advertising are often a viable alternative.

Box 19. Taxes on advertising

Taxes on advertising can lead to an increase in costs for goods and a loss of jobs, and can also have a competitive impact by raising costs of reaching the market for new products which have a comparatively greater need for advertising than pre-existing ones. There is some evidence on broad effects of taxes on advertising. Before 2000, each

federal state in Austria had a different tax rate for advertising. In 2000, as a result of nationwide harmonisation of the tax rate to 5%, the cost of advertising increased in some regions, decreasing in others. Rauch (2013) examines in detail the change in the marginal cost of advertising on both advertising expenditure and consumer prices by comparing the experience across the different Austrian states. Three key results emerge from his analysis. First, a 1% increase in the advertising costs resulted in a 1.6% reduction in advertising expenditure, conditional on firms not exiting the advertising market. Second, the increase in advertising costs increased the exit of firms from the advertising market by 17.5% overall. Third, although some product prices increased and some decreased, on average, Rauch estimates that if the 5% tax was to be abolished, prices would decrease by 0.25% across the whole economy.

Source: See Rauch, F. (2013).

B3 *Sets standards for product quality that provide an undue advantage to some suppliers over others or that are above the level that many well informed customers would choose*

Regulations setting standards often provide benefits to consumers and can help to promote new types of products by ensuring that new products from different suppliers are compatible. But standard setting can also provide undue advantages to some suppliers over others. One common example is environmental regulations that limit the allowable emissions of a mildly toxic substance. While limiting emissions is often appropriate to protect public health, regulations can be designed in ways that unfairly advantage a small number of suppliers, for instance by requiring a particular technology or by setting unduly strict standards that are difficult or impossible for less well-resourced producers to meet. Another example in which standard-setting can have significant anti-competitive impact is setting minimum quality standards for particular product types. There are often sound objectives underlying such standard-setting, such as protection of consumers from risks associated with the use of the product. However, when many consumers prefer lower cost over increased safety, the need for the standard is unclear. Consumer welfare can be reduced by such standards as consumers are prevented from buying cheaper, lower quality goods that they would prefer, even when fully informed of all associated risks.

Box 20. Widespread professional licensing

Many professions are licensed by the state. In these cases, standards for certification must be met by someone practicing that profession. Affected professions include lawyers, doctors, pharmacists, accountants, manicurists, funeral directors and many others. According to some reports, as much as 30% of workers need professional licenses. At times, certification requirements are likely excessive. For example, in Minnesota, qualifying as a manicurist requires twice as many hours of instruction as qualifying as a paramedic. There is often a reason for the state to regulate a profession though the need may be exaggerated, with some politicians having vetoed licensing requirements, for example, for diabetes counsellors, anaesthesiologist assistants, and dieticians. The reason for vetoing such licensing is that consumers may face higher prices and employment may fall.

Source: Kleiner, M. (2014).

Alternatives exist to stricter product standards regulations. For example, when minimum standards are pursued for consumer protection reasons, it may instead be possible to require the disclosure of certain product characteristics. Where major changes in emissions standards are contemplated, governments can seek to minimise anti-competitive impact by permitting trading of emission rights or providing temporary assistance to smaller suppliers in order to help them meet the new requirements.

B4***Raises the costs of some suppliers relative to others***

At times, regulations have the unintended effect of raising costs for some suppliers relative to others. Regulations can raise the costs of some suppliers versus others in various ways. One source of cost asymmetry is regulations that unnecessarily require the use of one technology of production over another. Subsidies, depending on how they are provided, can give some competitors a cost advantage over others. Regulations relating to state-owned enterprises can provide them with various direct and indirect cost advantages versus private enterprises. Regulations with these effects can result in inefficient production methods and prevent the adoption of new and better technologies.

Box 21. Subsidies to ensure long-term viability of an enterprise

When one company faces financial difficulties and receives a substantial subsidy from the government in order to re-organise, while competing profitable companies do not, the profitable companies may argue that the subsidy is anti-competitive, and actually placed them at a cost disadvantage with respect to the company that received a subsidy.

In the framework of the EU State aid rules, conditions applied by the European Commission for allowing rescue and restructuring aid to firms in difficulty are very strict, as this type of aid has a high potential to distort competition and risks impairing structural adjustment and ultimately economic growth, since the exit and replacement of inefficient firms is one of its key drivers. In particular, the European Commission authorises restructuring aid only when: the restructuring plan can be expected to bring the firm back to long-term viability without further public support; the firm will bear a sufficient proportion of the cost of its restructuring and the plan provides for adequate measures, such as asset sales or capacity reductions, to keep the distortion caused by the aid to a minimum.

The decision adopted in July 2013 on the restructuring of the PSA group is a good illustration. To return to long-term viability, the PSA group reoriented its activity, reducing production capacity in some segments and increasing the specialisation of its production sites. An asset sale programme ensured that the firm bore a sufficient proportion of the restructuring costs. Finally, mechanisms preventing the aid being used to harm competition were put in place.

Sources: European Commission (2014), http://ec.europa.eu/competition/publications/cpb/2014/009_en.pdf and European Commission (2013), http://europa.eu/rapid/press-release_IP-13-757_en.htm.

Another source is “grandfather clauses” that exempt current suppliers from a regulation but apply the regulation to new entrants. Such arrangements have substantial potential to distort competitive relations within the industry by raising costs to some suppliers to a substantially greater extent than others. This can impede entry, reduce innovation and lower the intensity of competitive pressure in the market. While creating cost differentials can be harmful, that is not to say that regulations should affirmatively seek uniform supplier costs.

For occupational qualifications, grandfather clauses are often implemented based on the belief that extensive practical experience of long established practitioners is an adequate substitute for a higher level of formal qualification. In relation to productive technologies, grandfather clauses are often implemented to ensure adequate time exists to amortise the sunk costs of previous investments. The anti-competitive impact of grandfather clauses can be minimised by ensuring that they are time-

limited, rather than permanent. More generally, a sceptical approach is appropriate for arguments in favour of grandfather clauses, as the clauses often defend vested interests from potential competition.

Checklist C **Reductions in the incentives for suppliers to compete vigorously**

Regulations can affect suppliers' behaviour not only by changing their ability to compete but also by changing their incentive to act as vigorous rivals. Two of the main reasons why suppliers may compete less vigorously are, first, that some regulations may have the effect of facilitating co-ordination between suppliers and, second, that some regulations may have the effect of reducing the willingness, ability or incentive of customers to switch between different suppliers. Other reasons suppliers may compete less vigorously exist, such as profit or market share limits that restrict the potential reward to competing. Cartel-like behaviour⁴ may be formulated in self-regulatory or co-regulatory regimes, by increasing the sharing of supplier output and price information or by excluding an industry or sector from the reach of competition law. Cartels are harmful because they restrict output and raise prices, making consumers worse off.

C1 **Self-regulation and co-regulation**

When an industry or professional association takes full responsibility for regulating the conduct of its members, without government legislative backing (often at the urging of government) the term "self-regulation" is used. However, when government provides legislative backing to rules that are developed at least in part by the industry/professional association, the term "co-regulation" is used. Self-regulatory and co-regulatory structures can yield substantial benefits by ensuring that technical standards are appropriate and that standards advance with technology.

However, these structures can have significant anti-competitive impacts. In particular, industry/professional associations often adopt rules that reduce incentives or opportunities for vigorous competition between suppliers of goods or services, such as advertising restrictions and rules that prevent discounting. In addition, unduly strict qualification

⁴ A cartel exists when competitors make an agreement with a goal of increasing their collective profits by restricting competition, for example by setting a price, limiting supply, sharing profits or rigging bids.

requirements may reduce entry to the market. Government should retain powers to prevent attempts by the industry/professional association to use regulatory powers in an anti-competitive manner. This may include ensuring that the relevant government authorities have the right to approve, or refuse to approve, association rules and, as required, to substitute their own should the association continue to propose unacceptable rules. Another option is to include independents or consumer representatives in bodies deciding rules subject, of course, to concerns that regulators have been “captured” by industry and act more for the good of the existing companies than for potential new companies, consumers or other public policy objectives.

Box 22. Self-regulation and minimum prices

Self-regulation can be particularly problematic. In Kenya, corn (maize) is a crucial food, accounting for one third of caloric intake and produced by 98% of small-scale farmers. The millers who grind the maize into flour are all members of an association. The association recommended a minimum price for the services of its members. The competition authority reviewed the behaviour and found that the recommended prices were a form of price co-ordination. When the price recommendation ceased to be operational, the price of maize flour fell by about 15%.

Source: Klissas, N. (2014).

C2

Requirements to publish information on supplier prices, outputs or sales

Regulations that require market participants to publish information on their prices or output levels can significantly assist in the formation of cartels, since a key requirement for cartel operation is that participants in the cartel can effectively monitor their competitors’ (or co-conspirators’) market behaviour. Cartels are more likely to arise where there are fewer participants in the market, where entry barriers are high, where suppliers’ products are relatively homogeneous and where information about price or output changes is available either before or soon after the price or output changes.

Box 23. Transparency in cement market

In Denmark, legislation was passed to further transparency in cement market sales, to help consumers to know average actual prices for transactions (which were typically negotiated down from list prices, so difficult for consumers to know). The problem with the legislation was that it provided cement companies with a way to observe actual prices of competitors with high accuracy, and thus provided information useful for co-ordinated action. The transparency legislation was then followed by an increase in transacted prices of 15-20 per cent within a year. This example illustrates the potential risks from government requirements to publish detailed information about actions of competitors, because such requirements can support price co-ordination between companies who would otherwise enter into secret contracts with their customers and could not be sure of each other's prices.

Source: Albæk, S., P. Møllgaard, and P. B. Overgaard (1997).

Regulations requiring the publication of information such as price and output levels may be adopted to improve consumer information and, at times, can improve the efficiency of markets. However, when cartel formation is likely, such requirements are more likely to have a net negative impact. Alternatives exist to publishing all collected data. When the information is gathered primarily for government policy making, there may be no need to publish it at all. When the purpose is to aid consumers or provide general statistics, aggregate statistics support cartels less than supplier-specific statistics.

C3 Exemptions from general competition laws

In many countries, particular suppliers or economic sectors benefit from exemptions from the general competition law. In some cases, these sectors are subject to their own, sector-specific competition laws. In other cases, no restrictions exist on anti-competitive conduct in these sectors. At times the lack of competition law oversight may be a result of the presence of regulation. Where a substantial derogation from the general application of competition law exists there is a clear risk of development of cartels, pricing abuses and anti-competitive mergers⁵.

⁵ A merger is a combination of two (or more) previously independent suppliers to form one larger supplier.

Box 24. Agriculture co-operatives and competition law exemptions

In many countries, agricultural co-operatives are permitted to form marketing organisations for their products. These co-operatives may be exempted from competition laws. Sometimes such exemptions are beneficial. For example, in Italy, there is a co-operative for marketing of Parma ham. The co-operative is able to maintain high quality standards (and restrict supply of Parma ham to ensure farmers have an interest in maintaining the standards and to ensure there is sufficient funding available for common marketing). Other producers, in Italy and elsewhere (such as San Daniele), could make similar ham, so the restriction by one supplier would not be anti-competitive (though if multiple suppliers of ham agreed to a restriction on quantity, that could be considered problematic). In contrast, in the United States, orange producers who grew a large percentage of overall orange production in the country, changed their standards for an acceptable orange to sell in stores in a way that limited supply in years of good growth and expanded the percentage of oranges that could be sold in stores in bad years, effectively seeking to maintain a stable output into stores from year to year. This type of action by a co-operative might have anti-competitive effects because the association accounted for a large share of actual sales of oranges and its actions did not seem to have the simple objective of raising quality.

Source: OECD (2004).

Where a specific rationale for the continued existence of exemptions has been identified, consideration should be given to the means by which their scope can be minimised. One possible way to do this is to clearly specify the activity to which exemption may apply, and the activity not subject to exemption. Examples include EU block exemptions, the Canadian Copyright law on collectives or business review letters issued by the US competition authorities, though these do not have formal binding status.

Checklist D

Limits the choices and information available to consumers

D1 *Limits the ability of consumers to decide from whom they purchase*

At times, regulations may limit the ability of consumers to purchase from their desired supplier. One consequence of such restrictions is that consumers would not receive the desired price or quality for a service, with a regulation effectively forcing consumers to purchase from higher costs suppliers or products that are not their preferred choice.

Box 25. Electronic cigarette regulation

In October 2013, the European Parliament considered and rejected the provision of a law that would require the sale of electronic cigarettes in pharmacies. This would have made electronic cigarettes – generally considered a much safer form of smoking than cigarette smoking – much less available than cigarettes which could be purchased from widely dispersed tobacco selling outlets. The change to selling electronic cigarettes in pharmacies would have impacted competition between cigarettes and electronic cigarettes. Sales of cigarettes were decreasing substantially at the same time that electronic cigarettes have been increasing their penetration. The European Parliament chose not to restrict sales of electronic cigarettes to pharmacies, particularly because this reduction in competition could have had negative health consequences through reducing the availability of a presumably safer form of smoking.

For example, some regulations or state insurance reimbursement rules limit consumer purchases of pharmaceutical products over the internet. The alleged reason for limits can often be consumer safety, though long-distance pharmacies have proven track records of safe and effective operation in some countries. Perhaps the most direct effect of regulations that limit where or from whom consumers can purchase, is to protect the traditional businesses from competition.

D2***Reduces the mobility of customers by increasing the costs of changing suppliers***

Regulations can make consumers more willing to switch suppliers by affecting “switching costs” – the explicit and implicit costs borne by a consumer in changing from one supplier to another. Switching costs may arise for various reasons, including unduly long contract terms or tying of assets to suppliers in a way that makes switching inconvenient, as with tying a phone number to a given service provider. When consumers face high switching costs, it can be difficult for customers to ensure that suppliers do not exploit this by charging higher prices or failing to provide the expected quality. Suppliers therefore often seek to create or maintain high switching costs, sometimes through promoting policies that will ensure high switching costs.

Box 26. Account closing fees in banks

In the UK, banks had imposed fees for closing an account. This provided an explicit switching cost that would make users think twice before closing an account. While there are some costs to the banks associated with closing an account, the government considered these were not very significant in comparison to the competitive harm and provided for regulations that would make such costs illegal.

Another form of switching cost that is less direct arose from Brazil's former practice of requiring that checks include information allowing the receiver to know the length of time in which the account had been open. This would make check receivers interested in having checks from an account that had been open for a long time, and in some cases reluctant to accept checks from new accounts, thus leading consumers to prefer to stay with their pre-existing bank.

In Mexico, banks used to have fees that applied to transfers of funds from one bank to another, meaning that account holders receiving salaries from their employer's bank preferred to be with the same bank as their employer, to avoid the transfer fees.

The pro-competitive impact of reducing or eliminating switching costs can be large, so policymakers should seek to avoid policies that raise switching costs for consumers. Where there is a clear risk of switching costs being imposed, the inclusion of provisions in the regulatory structure that will limit or prohibit their use may be advisable. Due care should be taken to ensure that legitimate costs of consumer switching are considered. This may be the case, for example, where payment for services occurs after they are consumed and switching may result in these costs being "stranded". An example of where regulation has been used to prevent the imposition of unnecessary switching costs is phone number portability. This allows consumers and businesses to switch across suppliers without the additional costs and inconvenience of possible missed calls and having to inform others of a change in number.

D3

Fundamentally changes information required by buyers to shop effectively

At times, regulations restrict the information that consumers have available to them or, alternately, affirmatively require that information be provided, though in a way that is confusing and results in consumers making poor decisions. Information labels on food, for example, have been introduced as a result of regulation and often permit better comparative decision making between products. Ensuring that such regulations deliver consumers the information they would value and do not result in poor decision making that distorts competition is particularly important.

When information is particularly crucial to consumer decision making and has long-run consequences, there is a particular tendency to regulate that information.

Box 27. Standardised information reporting

Many countries have regulations that require the provision of an annual percentage rate reported using a standard definition, to ensure that lenders or retailers do not misstate interest rates when selling mortgages. A study performed by the US Federal Trade Commission showed that the way information is provided can lead customers to focus on the wrong terms. For example, when commissions are reported for non-bank lenders but not for bank lenders, consumers may focus on the wrong terms and actually choose contracts that are overall more expensive in terms of interest rate, for example from a bank that does not have a commission reported.

Source: Lacko, J. and J. Pappalardo, (2004).

Conclusion

This chapter has focused on a technique for identifying potential restrictions on competition. In some cases, upon further review, these may be the best way to overcome a substantial market failure. Consequently, it is important to examine potential restrictions of competition further to determine whether they merit the development of alternatives and a recommendation for change.

Detailed example.

Identification of potential competition restrictions

This box continues the detailed example that runs throughout this manual.

To identify potential competition restrictions staff applied the Checklist to all areas of pharmaceutical regulation not exempted from review. The main potential competition restrictions identified are listed in the following table.

Checklist Category	Sub-Category	Relevant Legislation, Regulation or Policy	Potential Competition Effect
A. Limits the number or range of suppliers	Grants exclusive rights for a supplier to provide goods or services	Drug patent legislation allows brand companies to obtain further patents on improvements or alterations to drugs containing a pre-existing AI.	A high number of complaints have been made to the Health Department and the National Competition Authority that brand drug companies strategically use such patents to restrict competitive generic

A. (Con't.)	<p>When more than 15 years pass between the time a drug receives a patent and it is approved for marketing, the patent term may be extended to provide the patent owner an exclusive supply period of 5 years. Pharmacists are not permitted to substitute a generic for a brand product when a prescription states that no substitution is to be made.</p>	<p>entry beyond the normal 20 year protection period. Can delay entry by generic competition and extend the patent owner's exclusive supply right beyond the basic 20 year period.</p> <p>Prevents pharmacists from dispensing lower costs generics for their corresponding brand products, or lower cost therapeutic substitute products.</p>
Establishes a license, permit or authorisation process as a requirement of operation	<p>To be certified, must meet lay-out, stocking, oversight, equipment and other requirements set out by the Pharmacy Profession Oversight Authority.</p> <p>Generic drugs must meet Health Department bio-similarity criteria in order to be listed on the national dispensing list.</p>	<p>Increases costs of entry into the pharmacy sector potentially reducing the number of, and competition between pharmacies.</p> <p>Costs of testing and trials required to show generics to be bio-similar to brand drugs may create an excessive barrier to entry by competing generics.</p>
Significantly raises cost of entry or exit by a supplier	<p>The supplier of a generic that is put on the market prior to expiry of the relevant brand drug's patent protection is required to withdraw their product and reimburse the brand drug supplier's lost profits and costs.</p>	<p>The potential for high damage awards to have to be made to a brand drug company can create a barrier to generic entry where the remaining claimed patents are of questionable validity.</p>
Creates a geographic barrier to the ability of companies to supply goods, services or labour or invest capital	<p>Under health legislation, imports of pharmaceuticals direct to patients are prohibited.</p>	<p>Prevents competition in the form of parallel imports by patients.</p>

B. Limits the ability of suppliers to compete	Limit sellers' ability to set the prices for goods or services	Prices for patented pharmaceuticals listed on the national dispensing list may not exceed the average price for a subset comparator countries. For generic drugs to be listed on the national and NPIP formularies they must provide savings of at least 35% versus the brand drug they are designed to replace.	Regulates maximum patented drug prices possibly serving as a barrier to entry for some drugs, and as a high price point for others. In some cases, the price cap may be too low to support entry by generic suppliers, while, in others, it may provide a reference price leading to higher prices.
	Limits freedom of suppliers to advertise or market their goods or services	Direct to consumer pharmaceutical advertisements must include warnings regarding possible negative patient reactions. Under the NPIP, patients are only required to pay a small portion of the costs of pharmaceuticals.	Imposes advertising requirements that may restrict consumer demand for pharmaceuticals. Limits the effectiveness of low prices as a means to increase demand for pharmaceutical products as patients bear only a small portion of their costs.
C.Reduces the incentive of suppliers to compete	Requires or encourages information on supplier outputs, prices, sales or costs to be published	All pharmaceutical products' list prices are published on the national dispensing list.	Publicises pricing information potentially promoting co-ordinated pricing.
D. Limits the choices and information available to customers	Limits the ability of consumers to decide from whom they wish to purchase	Patients are required to pay the full costs of pharmaceuticals that are on the national dispensing list but not the NPIP dispensing list. Under NPP reimbursement policy, when a generic is prescribed, the pharmacist amount invoiced to the NPIP can be no more than the lowest cost interchangeable generic on the National Dispensing list.	May limit choice by requiring patients to pay the full price of some pharmaceuticals but not others that may be used to treat an ailment. Can restrict pharmacists' choices of generic to acquire by providing incentive to acquire the lowest priced generic on the dispensing list.



Chapter 4

Examination of potential restrictions

While the competition assessment checklist can identify regulations that may restrict or distort competition, it does not necessarily indicate the seriousness of these restrictions, or the level of analysis required to select the best policy option. In many cases, while a proposed measure may trigger a ‘yes’ response under the checklist, it may have limited potential anti-competitive effects.

Once a potential restriction to competition has been identified, a preliminary assessment may be conducted to assess whether a more detailed assessment of the competitive effects is warranted. While this may not require in depth knowledge of the underlying market, some knowledge of these markets and market contacts will generally be required. The full impact of many restrictions is not obvious from reading a regulation. Even seemingly *de minimis* regulations (e.g., over the production standards for low-pollution automotive fuel or the shelf life of foods) can have large and unanticipated competitive effects.

Often much of the information required for a preliminary competition assessment, such as the identity of suppliers or consumers of products, and the volume of commerce affected may be obtained in connection with other requirements for performing regulatory impact assessments. Also, officials involved in the relevant sector or policy area, in the course of their work in the sector or policy area may have acquired information about the markets that can be used to assess whether a proposed regulation could significantly affect competition. Initial contacts with businesses, consumers or others affected by a restriction can provide a means to perform a preliminary assessment of the potential effects of a competition restriction.

External sector or economic expertise may be valuable even for the purpose of conducting a preliminary assessment. Such expertise may be important, for example, for assessing competitors claims that they will or will not be substantially affected by proposed regulation, or identifying key

competitive dimensions in a relevant market. External expertise may be particularly valuable for a preliminary assessment in cases where officials proposing a regulation, in the normal course of their work, are not required to obtain an understanding of the markets affected by the proposed regulation.

1. Indicators of need for in-depth analysis

Indicators of when more in-depth analysis of a regulation is likely required include:

- The regulation affects a market or markets having a high volume of commerce;
- The regulation significantly affects an important competitive dimension, for example, innovation in high technology markets, or the relative costs of competitors in markets in which price is a particularly important competitive factor;
- The regulation restricts the ability of one or a subset of suppliers to compete in markets having a limited number of competitors;
- The regulation raises substantial concerns among some of the competitors, consumers or other parties affected; or
- The regulation particularly affects an aggressive, innovative or otherwise unique competitor or potential entrant.

2. Indicators that in-depth analysis is not required

In many cases, limited competition analysis may be required as the restriction is clearly necessary to address an overarching health, safety, security or other public policy objective. To determine whether in-depth competition analysis is needed, the examiner should take account of the fact that anti-competitive restrictions may be proposed with rationales that allege improvements in health, safety or other policy objectives even when the true objective on the part of industry is to reduce competition. Where little in-depth analysis is conducted, the value of ex-post review of effects of regulations is particularly important. Examples where this may be the case include:

- Bans on the use of chemicals or products carrying severe health and safety risks;
- Limits on advertising to vulnerable groups or requirements for advertising to provide important health and safety information;

- Limits on which competitors may supply goods and services where this creates serious national security issues; and
- Prohibitions of dangerous production methods or processes, or the imposition of workplace safety standards that are clearly needed to protect the health and safety of workers, or the health and safety of customers, for instance in places where food is handled (restaurants, butchers).

Limited competition assessment is also likely to be needed where the potential competition impact of a regulation is clearly *de minimis*. Examples when this could be the case include:

- A license requirement where the requirement is inherently reasonable and there is no effective restriction on the number of licenses, the price of the license (if any) is in line with costs and any refusal to grant a license must be accompanied by a written explanation of why the case at hand specifically does not fit published licensing criteria;
- A regulation that imposes additional costs on only a small number of suppliers (though concerns would surface if these competitors are uniquely innovative or efficient) in a market with many competitors;
- Potential competitors would not be significantly affected with respect to their ability to enter the market or compete effectively;
- Competitors would not be prevented or inhibited from expanding production or market share, developing new products or marketing to new customers, changing price or terms, or adopting alternative methods of production; and
- Customers would not be prevented or inhibited from choosing products or suppliers they prefer.

Finally, limited competition assessment may be required when alternative equally effective regulations for obtaining a policy objective can be used, one of which does not raise a potential competition issue. Where this is the case, other things equal, the regulation that does not restrict competition may be selected without having to conduct an in depth competition assessment of the other measure.

If a preliminary assessment indicates that a proposed regulation may significantly restrict competition, it may be possible to identify alternatives

to the regulation that may be used to achieve the underlying policy objective that are less likely to restrict competition. Examples of cases where less restrictive measures may be used to achieve various policy objectives are provided in the next chapter. Ultimately, after a review of alternatives, the regulation imposing a substantial restriction on competition may be preferred, for example due to the infeasibility of alternatives. But the default presumption is that substantial restrictions on are not necessary and should be changed.

3. Depth of investigation

The depth of the investigation required will depend on the potential seriousness of the competitive restriction, the feasibility of gathering information, the resources available the timeline for the review⁶ and the level of analysis that is required to select between the alternatives under consideration.

Highest priority regulations for review should include those that are likely to place large restrictions on competition, by, for example, resulting in undersupply of a product, blocking potentially more efficient entrants or creating unduly high prices or eliminating products that are highly demanded by consumers.

When relevant data is available, it is useful to gather this and examine it. Including data analysis in the final recommendation will make the recommendation both more complete and more convincing. Data may pertain, for example, to costs of business operations, comparative prices between regions or countries, and output restrictions.

4. Considerations in conducting analyses

When investigating the competitive effects of a regulation, bear in mind that when regulations restrict competition, those companies operating in the regulated industry may be pleased with the impacts of the regulation, because it allows them to operate with less rivalry and higher profits. Regulations are often suggested by companies in the industry who will typically act according to their self-interest. Obtaining control over entry, prices and other elements of competition in a market is in the self-interest of many industries and professions. To get an unbiased

⁶ At times, only days may be available for a review, due to timing considerations.

perspective, one key to doing good analysis is to ensure that independent input is received from persons with no vested interest in the outcome (such as competition authorities or academics) or that, failing this, input is received from persons who would have interests conflicting with each other.

Though developed for a different context, many of the analytical concepts developed for competition law analysis may also apply to the analysis of the competitive effects of regulations. Suggested parameters and concepts for such an analysis are developed much more extensively in Volume 2: Guidance of the Competition Assessment Toolkit.

Information and expertise for investigating the competitive effects of regulations may be possible to obtain from a wide range of sources including:

- Technical experts in government, regulatory or oversight agencies and NGOs;
- Competition authorities;
- Representative business associations;
- Businesses subject to the regulation;
- Businesses who deal with those businesses subject to regulation;
- Industry or sector experts, such as consultants or academics;
- Government statistics gathering departments or agencies;
- Consumer associations; and
- Consumers (particularly when consumers are well-informed or large, such as businesses that are consumers for an intermediate product).

Detailed example: Competition analysis

This box continues the detailed example that runs throughout this manual.

Health Ministry staff conducted a competition analysis of the potential competition restrictions identified by the Checklist in 2 phases. In the first phase, a preliminary competition assessment was performed of the restrictions identified by the Checklist to identify ones having the greatest potential for pro-competitive reform. In the second phase, a detailed competition analysis was done of the restrictions identified for further analysis.

Preliminary Competition Assessment

To perform their preliminary competition assessment, staff relied on statistical and other information available to the Health Department, as well as publicly available data information and analysis. Staff also obtained analytical support from the national Competition Authority.

Key findings from the preliminary assessment are as follows.

Restriction	Preliminary Assessment
<p>Drug patent legislation allows brand companies to obtain further patents on improvements or alterations to drugs containing a pre-existing AI.</p>	<p>The granting of patent protection for drug improvements or alterations does not prevent entry of generic versions of the original drug, however, it can lead to many patients being switched to the new drug prior to expiry of the initial patent. This can create a barrier to generic entry and expansion as patients may be reluctant to switch back to the initial formulation.</p> <p>Concerns have been expressed to the Health Department and the national Competition Authority that such patents are being strategically used by drug originators to prevent or delay effective entry by generics. However, brand companies assert that new products incorporating an existing AI provide important therapeutic benefits and warrant patent protection.</p> <p>The National Competition Authority has informed the Health Department that it is examining potential competition law and policy issues pertaining to such patents. In respect of the ongoing work of the Competition Authority, a Health Department review of the matter is not warranted at this time. However, the Health Department will be providing input to the with the Competition Authority's review.</p>

When more than 15 years pass between the time a drug receives a patent and it is approved for marketing, the patent term may be extended, as required, to provide the patent owner an exclusive supply period of 5 years.

In order to qualify for patent extension, patent owners must demonstrate that the delay in obtaining Health Department approval was necessary to meet the requirements for listing on the national dispensing list.

While patent extension can limit competitive entry, it maintains incentive for brand companies to invest in the high up-front research and development needed to develop new pharmaceuticals products. Moreover, any attempt to reduce the minimum exclusivity period could have serious consequences for the country's international trade relations as it is incorporated in a number of international trade agreements

Pharmacists are not permitted to substitute a generic or relatively low cost therapeutic substitute for a product where the physician indicates that no substitution is to be made.

Physicians are actively encouraged to take cost considerations into account when prescribing medication and follow guidelines on the prescribing of low cost medication subject to exceptions where warranted on treatment grounds. While this approach, overall, has been highly successful, with the country having one of the highest levels of generic use in the OECD, a recent study indicated that physicians continue to require dispensing of more expensive products in some cases where a generic or lower cost patented product might be used.

While this may result in some higher costs, further restricting physician prescribing, for example by requiring them to justify the prescription of high cost products, could result in cases where less effective pharmaceuticals are prescribed, or treatment is delayed due to cost considerations as well as placing additional demands on physician's time. In addition, attempts to further restrict physician prescribing practices would be subject to a high level of opposition from physicians and patient groups.

Under health legislation pharmacies, to be certified, must meet lay-out, stocking, oversight, equipment and other requirements set out by the Pharmacy Profession Oversight Authority.

While these requirements increase the costs of entry into the pharmacy sector, they help to ensure that pharmacies are properly designed, equipped and operated to accurately and safely dispense pharmaceuticals. The specific requirements imposed by the Oversight Authority have not been the subject of significant complaints that they are excessive, and there is no evidence that they have significantly reduced pharmacy entry.

Generic drugs must meet Health Department bio-similarity criteria in order to be listed on the national dispensing list.

Although they can be a major barrier to entry for generic drugs, bio-similarity requirements are essential for ensuring the safety and therapeutic effectiveness of generic drugs. The PAD's bio-similarity requirements are consistent with generally accepted international norms and relevant medical research and have not been the subject of substantial generic manufacturer complaints.

Generic suppliers frequently challenge patents in order to enter potentially resulting in high litigation costs and damage awards.

On one hand, the potential for high litigation costs and damage awards can be a major barrier to entry even in cases where the patent being challenged is weak. On the other hand, the ability of brand companies to protect their valid patents is essential in order for them to have incentive to invest in the high costs needed to bring new pharmaceuticals to the market. Determining whether the appropriate balance is currently being struck between generic entry and pharmaceutical patent protection requires careful analysis of complex issues pertaining to, among other things, the current patent approval process, the patent legal framework and brand and generic company entry and litigation strategies. However, the Health Department has been informed that this issue will also be an area of concern in the above-noted National Competition Authority examination.

Under health legislation, imports of pharmaceuticals direct to patients are prohibited.

Allowing direct importing of pharmaceuticals by patients could generate savings on pharmaceutical costs in some cases (for example, where patients wish to reduce the amount of their NPIP co-payments, or are obtaining pharmaceuticals not covered by the NPIP).

However, direct to patient imports of pharmaceuticals also raises important health and safety issues. Because the dispenser is located outside of the country, the Health Department would be limited in its ability to ensure that drugs being dispensed are safe, that prescriptions are being properly filled and that patients are being properly consulted. In cases where a mistake is made, or poor quality drugs are dispensed leading to patient harm, related medical costs would be borne by the country's healthcare system. The development and management of a regulatory framework to address these concerns would be a complex, costly and long-term process and would encounter strong domestic pharmacy sector resistance.

Prices for patented pharmaceuticals listed on the national dispensing list may not exceed the average price for a subset comparator countries.

The capping of prices on the national dispensing list prevents brand companies from exercising their patent monopoly rights to extract higher prices in the country than the average amount charged in comparator countries having similar wealth and health sector profiles. Most OECD countries apply some form of maximum price regulation to patented drug prices, with the comparator country approach being used by a number of jurisdictions. Given the widespread use of this approach internationally, its use in the country does not present a major barrier to entry for new pharmaceutical products and its removal could result in higher prices.

For generic drugs to be listed on the national and NPIP formularies they must provide savings of at least 35% versus the brand drug they are designed to replace.

This requirement ensures that competitive entry by generics, in most cases, provides at least a 35% savings to payers. In order not to prevent entry for relatively high cost generics, exceptions are permitted where the manufacturer can demonstrate to the PAD that they are warranted.

The policy creates a limited barrier to entry to for high cost generics but more importantly, as discussed further below, it has provided a high price point for generics pricing.

Direct to consumer pharmaceutical advertisements must include warnings regarding possible negative reactions.

Although these warnings may limit the effectiveness of direct to consumer advertising of pharmaceuticals, they provide valuable health and safety information to assist patients, in consultation with their physician, to make informed decisions on their potential use.

Under the NPIP, patients are only required to pay a small portion of the costs of pharmaceuticals.

Raising patient co-payments under the NPIP could increase the price sensitivity of physician prescribing behaviour and patients' acceptance of lower priced pharmaceuticals, especially generics. However, given the NPIP's high level of public support, any proposal to significantly patient co-payments would likely encounter strong public opposition. Moreover, it would engender serious public policy concerns. Such a policy would have to be carefully designed in order not to impose a disproportionate burden on lower income persons and families. Studies have also shown that higher co-payments can have negative health effects by resulting in patients deciding not to take prescribed medications particularly among lower income groups. Moreover, an increase in the number of patients not taking prescribed medications could also raise treatment costs in other parts of the health care system.

All pharmaceutical products' prices are published on the national dispensing list.

The publishing of pharmaceutical list prices is intended to provide all payers with access to pharmaceuticals at the same price.

However, a PAD staff scan of national dispensing list prices for recently genericised pharmaceuticals found them to be priced at 65% of the corresponding brand products' prices suggesting that the publishing of prices is contributing to a price point being established at the maximum permitted by legislation. This was the case even where multiple generic versions of the brand product were available. The potential for the policy to be serving as a high price point for generics is consistent with third party studies indicating that domestic generic drug prices are high compared to most other countries.

Patients are required to pay the full costs of pharmaceuticals that are on the national dispensing list but not the NPIP dispensing list.

The exclusion of some drugs listed on the national dispensing list from the NPIP dispensing list is a cost control measure designed to limit the dispensing of relatively high cost pharmaceuticals when other effective less expensive alternatives are available within the therapeutic class, and to avoid the reimbursement under the NPIP of medically unnecessary pharmaceuticals. Restriction of the NPIP dispensing list to relatively low cost pharmaceuticals can actually promote competition among different pharmaceuticals within the same therapeutic class. To prevent the policy from having excessive negative health and redistributive effects, exceptions are permitted where they are medically justifiable.

Under NPIP reimbursement policy, when a generic is prescribed, the pharmacist amount invoiced to the NPP can be no more than the lowest cost interchangeable generic on the National Dispensing list.

While this policy may restrict pharmacy choice, it is intended to promote more effective generic price competition. The policy ensures that the NPP pays no more than the price of the lowest cost interchangeable generic product on the dispensing list.

Detailed Competition Analysis

Based on the preliminary competition assessment, restrictions chosen for in-depth competition assessment include the requirements:

- for generic drugs to be listed on the national and NPIP formularies they must provide savings of at least 35% versus the brand drug they are designed to replace; and

- all pharmaceutical products' prices to be published on the national dispensing list.

To perform a detailed competition assessment of these restrictions, in addition to relying on internal sector and economic expertise, Ministry staff:

- retained external sector and economic experts and obtained analytical advice and input from the national competition authority;
- obtained access to NPIP price and quantity data;
- acquired third party data on domestic prices and quantities for pharmaceuticals paid for by private drug plans and out of pocket, as well as on selected foreign drug prices;
- sought data and input from industry associations and sector participants at all levels of supply;
- consulted with relevant professional and patient groups; and
- examined relevant international experience.

Key findings of the analysis

A high level of generic competition exists with respect to many brand drugs. Many of these drugs, particularly high volume ones, have multiple generic copies listed on the national dispensing list, as many as 8 or more.

Although a high level of competition exists for many generic drugs, it is not reflected in NPIP and national dispensing list prices. Dispensing list price and NPIP reimbursement data obtained for all new generic drug versions of brand drugs losing their patent protection over the past 5 years found these prices to be equal to 65% of the relevant brand drug price, or the maximum added permitted under pharmaceutical legislation. Overall average prices are 61% of their corresponding brand drug price potentially reflecting past price changes and developments.

Rather than competing by offering lower dispensing list or NPIP prices, the principal way that generic drug suppliers compete is by providing rebates to pharmacies. Generics suppliers list their products on the national dispensing list at the maximum price permitted and use this price invoiced to pharmacies. Pharmacies, in turn, bill the NPIP and private payers based on the invoiced price. Because generic versions of the same brand drug are deemed interchangeable, pharmacies only need to stock one or two. Generics suppliers compete to be stocked by pharmacies by offering them off-invoice rebates.

This form of competition reflects the incentive structure created by the NPIP and national dispensing list listing practices for generics. Generic drugs manufacturers have little or no incentive to list generic drugs on the national dispensing list or invoice pharmacies at prices below the maximum allowed by legislation.

Offering a lower dispensing list price provides, at best, a temporary or small competitive advantage even though pharmacies must dispense the least cost generic. Because the lower price is published on the national dispensing list, competitors have the opportunity to rapidly match it. Moreover, a supplier that lowers its dispensing list prices,

hence the potential size of pharmacy rebates, faces the prospect of pharmacies retaliating by no longer acquiring, or cutting back on purchases of their products.

Precisely estimating the size of generic rebates was not possible as would require extensive confidential pharmacy and generic supplier information. However, suppliers contacted have admitted to providing rebates estimated to be, on average, about 55% of the dispensing list price of generics. This level of rebates is supported by a comparison of domestic prices for high volume generic drugs accounting for more than 35% to their prices in two comparator countries in which competitive generic prices are available. Reflecting their high volume, these products have multiple suppliers and are subject to strong competition. The comparison found the foreign prices to be, on average, more than 60% below the domestic dispensing list price.

Although generics generate lower dispensing fees, rebates provide a strong incentive for pharmacies to dispense them rather than more expensive brand drugs. The size of the incentive is indicated by the following table using the current dispensing price mark-up allowed for pharmacies of 15%, a representative brand prescription price of USD 40, a generic price equal to 61% of the brand price and a competitive price net of rebates of 55%. This amount is in addition to a flat dispensing fee of USD 4.

Pharmacy returns for dispensing brand and generic products

Category	Brand	Generic
Price	USD 40.00	USD 24.40
Dispensing Fee	USD 4.00	USD 4.00
Mark-up	USD 6.00	USD 3.66
Rebate	USD 0.00	USD 13.42
Net Pharmacy Return	USD 10.00	USD 21.08

This competitive framework has had important indirect effects on the pharmacy sector. High returns on generics also provided incentive for more pharmacies to enter. While this has had some indirect benefits, such better access to pharmacies due to shorter travel distances and longer open hours, has also led to the development of an inefficient pharmacy sector. An econometric study conducted for the department of average pharmacy dispensing costs, including fixed and variable costs, indicates that they decline substantially with the total number of prescriptions filled. To yield estimated dispensing costs of USD 10 or less, it is estimated that an average cost pharmacy would need to dispense in excess of 75 000 prescriptions annually. In contrast, estimated average dispensing fees for a pharmacy filling 42 000 prescriptions annually, the current sector average, are in the range of USD 14.50.



Chapter 5

Identifying the options

The competition assessment review aims at identifying the policy option that allows the policy maker to achieve the objective at stake with the minimum distortion of competition. Sometimes the right candidate may be the policy under review, but on other occasions there may be less restrictive alternatives that can be used. Hence, if the checklist shows that the policy under review is likely to distort competition, the potential for other less distortive measures to be used to achieve the same objective should be considered. This exercise implies identifying all the policies that achieve the objective, estimating the competitive effects for each option, and choosing the option that would yield the highest benefit. This Chapter provides guidance on how to identify less restrictive alternatives to achieve the objective at stake.

Identifying less restrictive alternatives to a given policy is a fact-specific exercise that requires a good understanding of that policy, as well as substantial industry expertise.

1. Identify purpose of policy

The first step consists in clearly identifying the purpose of the policy. If the policy is intended to address a market failure, a clear description of the market failure is needed, along with the mechanism by which the policy intends to solve or reduce the intensity of the market failure. This means that it is necessary to determine the ultimate objective, as well as the tangible outcome that the policy under exam aims to achieve. Understanding the overall regulatory environment is also important. The purpose of a policy can sometimes be found in the regulation itself, in higher level legislation, in legislative debates or in supporting documents to the legislation when it was enacted.

Many policies are not put in place due to market failures but for social or other reasons.⁷ If there are other policies that operate in the sector and that address the same objective, it is important to identify any links that may exist between them and the policy at stake. These should be taken into account in the development of the alternatives.

Often policies that restrict competition have strong business and political interests that back them. Businesses that are currently in an industry may seek to use the regulatory process to protect themselves from stronger competition. Such efforts are likely because they may lose profits when there is more competition. Keeping in mind the relevance of incumbents' interests is important when seeking to understand the reasons why anti-competitive regulations exist.

When identifying objectives to be pursued by regulation, a key issue can be ensuring that they are not defined in a way that unnecessarily rules out less restrictive approaches for achieving the same core objective. This can occur where the specified objectives predetermine the approach to be used in achieving an underlying goal rather than allowing consideration of a full range of options.

For example, a pollutant like sulphur dioxide may come from multiple sources. Policies that have the objective of reducing the pollutant by regulating output from each source may achieve the desired objective of an overall reduction in the pollutant, but at the same time may rule out approaches that allow the use of markets and competition to more efficiently meet the underlying broad objective.

Box 28. Market for pollution permits

One way to reduce sulphur dioxide outputs from factories is to set limits on the output from each source. However, where the underlying public policy objective is to reduce the total amount of a pollutant from all sources, the establishment of a total reduction target for the pollutant may allow the creation of a market for pollution permits, with tradable pollutant allowances. Emissions trading, or the establishment of a price for the right to emit the relevant pollutant, may provide a way for the overall target to be met by those who are able to reduce their emissions at the lowest cost.

Source: OECD (2011).

⁷ In the banking sector, for example, ensuring the safety and soundness of banks, and preventing system-wide instability, is a regulatory purpose that does not arise from traditionally conceived market failures.

2. Identify specific elements of regulation that generate the competition problem

The next step is to determine the nature of the competition problem, or problems, caused by the policy under exam and whether they are necessary to achieve the objective. This can be done with the help of the checklist. It is also necessary to identify the specific elements, or provisions, of the policy that generate the competition problems. The question to ask is whether these elements or provisions are strictly necessary to attaining the objective or if they could be amended so as to reduce or eliminate their negative impact on competition. This process allows the development of a set of alternative options that achieve the same objective as the policy at stake, but cause no or lesser distortions to competition.

Box 29. Understanding the market failure, determining the outcome and developing alternatives

A review of the legislation on the retail sale of pharmaceuticals reveals that internet sales of prescription and non-prescription medicines are banned.

This legislation imposes a limit on the nature of the sellers of these products, which, according to the checklist, is a distortion of competition.

Medicines often require specific knowledge, that consumers may lack, to be chosen and employed properly. Pharmacists (who in some countries have the authority to prescribe medicines like doctors) have this knowledge. Requiring that a pharmacist gives advice on how to use certain medicines to the users and verify that the medicine is effectively necessary is one means of ensuring the safe consumption of medicines. These considerations show that, in order to protect consumers, specialist advice should be dispensed to the user when such a medicine is sold. Hence some form of regulation on who is allowed to sell them is required.

But not all medicines require specialist advice on when and how they are to be consumed. For example, many pain relief medications (like aspirin and paracetamol/acetaminophen) are sold over the counter in many countries. Indeed in many countries non-prescription medicines can be sold also in retail establishments where a pharmacist is not present. This suggests that prohibiting the sale of all medicines over the internet imposes a constraint on competition that is unnecessary. There is a category of medicines that could be sold online without jeopardising the safety of their users.

Moreover, like a bricks-and-mortar pharmacy prescription counter, the internet is a two-way communication device over which a pharmacist and a customer can interact. Some customers or patients may prefer to avoid travel time and travel expense by shopping at an on-line pharmacy or simply find they can obtain lower prices there.

Hence some elements of the legislation banning internet sales of medicines do not appear necessary to achieve the objective of protecting the health and safety of consumers. Nevertheless, if in the country under consideration also the physical sale of all

non-prescription medicine outside a pharmacy is also prohibited, internet and bricks-and-mortar reform efforts should consider harmonising policies on the role of the pharmacist in both internet and bricks-and-mortar sales channels.

With respect to prescription-only medicines and to medicines that require specific advice even if a prescription is not required, the objective of the existing legislation is to ensure that appropriate advice is given by competent persons. The requirement that the sale of these medicines is supervised by pharmacists seems an appropriate solution for which no real alternatives exist. However, the obligation to perform such service physically rather than remotely seems less necessary to the fulfilment of the policy's objective. Indeed in some countries sale over the internet of these kinds of medicines is allowed provided an in-house pharmacist supervises the sale, gives written advice and verifies the validity of the prescription when one is required. In other countries an obligation will be imposed that prescription-only medicines are collected in brick and mortar pharmacies, where a pharmacist can provide advice on their use and can check the prescription. Again these considerations and the international examples provide further elements for developing alternatives to the existing legislation that avoid the competitive restrictions.

3. Technical expertise

The alternatives that are feasible may depend on technical features of the subject matter being regulated. The types of technical expertise needed for developing regulations will vary with the regulation under consideration. Technical expertise can lie within the ministry or government body overseeing the regulation. Such expertise would at times be biased in favour of the current regulatory regime. Alternative technical expertise may lie outside the ministry, for example in academia or outside the country when it appears that domestic experts would have a bias in one direction or another. Businesses may have relevant expertise as well, but can be biased in favour of regulations that they view as protecting them. Potential new businesses that are facing difficulty in starting up due to regulations may be able to point out competitive restrictions in a less biased manner than established enterprises.

Potential findings can usefully be presented to technical experts and affected interest groups at an early stage, prior to the final determination of a recommendation. Giving experts and interested parties an opportunity to comment can avoid basing conclusions on misunderstandings. It can also ensure that there is a consultation on a reform prior to its establishment in law. Assessors can seek comments in writing but also in meetings; face-to-face interaction often proves very productive.

In order for assessors to get the most useful feedback from experts, they can usefully provide a short workshop on competition assessment and the checklist to experts. At times, the experts will then be able to detect

restrictions on competition that are difficult for a non-expert to extract from the relevant regulations.

Box 30. Varied expertise

Often the expertise required to evaluate a regulation will involve a variety of experts. For example, if a regulation concerns environmental effects of asphalt plants, expertise on tar, environmental risks and nuisance factors are valuable.

4. Understand broader regulatory environment

When considering alternatives, it is important to take into account not only the regulation under consideration, but also the web of related regulations, including general regulations that have an effect on the market in question, in order to develop alternatives.

Box 31. Regulatory environment for sale of hearing aids

In the United States, the health regulatory body (the Food and Drug Administration) classifies hearing aids as medical devices. The body introduced a rule to require that hearing aids be sold by qualified practitioners (audiologists) after seeing a medical doctor or that patients sign a form to acknowledge they are taking a risk by not following the Food and Drug Administration recommendations. Audiologists have state professional associations with particular rules for membership and practice. The US Department of Education in turn has specific rules for training and qualification. While some consider that the market delivers products that are too expensive as a result of lack of competition, changing one regulation, without considering the web of surrounding regulation, will not necessarily deliver desired outcomes. Alternatives must either take into account the other existing regulation or require that other regulations also be changed. As seen here, this is particularly the case where the laws and regulations of multiple overlapping jurisdictions must be taken into account.

5. Understand changed business or market environment

When evaluating a proposed regulation or suggesting alternative options, it is important to take into account how business conditions have changed since the last policy implementation. If the market conditions have changed, any initial regulation could be re-evaluated. The necessity of a more restrictive regulation may be considered, just as would maintaining the current regulation or lifting a regulation altogether.

Box 32. Discounts on retail price of books

Some countries regulate the discounts that can be offered from the retail price of books. One example is through permitting maximum discounts that booksellers can provide off the retail price set by publishers. Another is through limiting the value and types of “free gifts” that are provided by booksellers.

In 2003, Korea adopted a book price regulation that obliged bookstores to sell their books within a given discount range off the retail price set by publishers. Under the regulation made by the cultural ministry (MCST), book price discounts were up to 10% off list price. Additional free gifts were permitted as well, under guidelines on the notification on giveaways run by the competition authority (Korea Fair Trade Commission, KFTC). The guidelines allowed all retailers to discount indirectly by granting free gifts whose value was less than 10% of the client spending. Therefore, all bookstores could sell their books at a maximum 19% discount combining the direct and indirect reductions.

In 2009, the KFTC decided to abolish its guidelines on giveaways in order to facilitate retailer’s creative marketing activities and to give consumers more choices of product or service. After the abolition of the guideline, the MCST proposed an amendment to the Publishing Industry Promotion Act that periodicals can be sold at 10% off the regular price, taking into account *all* ‘economic gains’ such as mileage points and discount coupons, along with direct discounts. That is, the proposed amendment would cause a sharp reduction of maximum discount rates from 19% to 10%.

When the KFTC screened the proposed regulation, it found that including all economic gains in the scope of book discounts could significantly restrict marketing strategies of the retailers because there was already a limitation on direct discounts to 10% off the retail price. Also, the proposed regulation could decrease incentives for active competition to achieve innovation in services by using various ways to provide discounts.

Ultimately, the MCST withdrew its proposed amendment to the Enforcement Decree following the KFTC suggestion that the scope of discounts should be maintained at least at the current level. So booksellers can still provide direct and indirect discounts for books up to a maximum of 19% off the publishers’ retail price.

6. Techniques for developing alternatives

The competition assessment review aims at identifying the policy option that allows the objective at stake to be achieved with the minimum distortion of competition. To do this, if the checklist shows that the policy under examination is likely to distort competition, it is necessary to determine if there could be a less distortive way of achieving the same objective. This involves the identification of any other feasible policy approaches for achieving the objective that are less likely to distort competition, and the consideration of possible ways to redesign the proposed measure to reduce its impact on competition while still achieving the policy objective. Identifying feasible

alternatives to a given policy is a fact-specific exercise that often requires a good understanding of that policy, as well as substantial industry expertise.

The experience of other jurisdictions can sometimes be helpful to develop alternatives, provided the circumstances are comparable. Similarly consulting the relevant stakeholders can provide interesting suggestions, as these have a good knowledge of the sectors and of what alternatives can and cannot be implemented.

Box 33. International comparison of petroleum regulation

In a review of potential competition restrictions in a country's petroleum sector, a possible competition issue identified was the reporting requirements for emergency petroleum reserves which potentially required the release of confidential information. As part of the assessment of these requirements, related regulation in comparator countries was reviewed to determine whether they had similar requirements.

To determine which countries to use as comparators, a focus was placed on other EU countries with similar approaches to meeting emergency reserves requirements. The focus on other EU countries ensured that the countries considered would also be subject to any relevant EU legislation and regulations. Within the EU, focus was placed on countries that, like the country in question, meet their emergency petroleum storage requirements by directing suppliers of petroleum products to maintain adequate reserves.

International Energy Agency reports and surveys on emergency petroleum reserves and policies were used as a starting point for identifying the relevant policies, legislation and regulation, but did not provide adequate detail on specific reporting requirements. Rather, to obtain the necessary information, relevant guidelines and regulations for each of the comparator countries had to be identified and reviewed.

As these guidelines and regulations were national in scope, language barriers in comparing them had to be overcome. This was possible to achieve using generally available online text translation services. Given limitations on, and differences between these services, more than one was used to confirm essential details.

However, the following examples illustrate less restrictive measures that may be possible to use in place of more restrictive ones in a wide range of cases.

6.1. Using economic incentives rather than regulation to deal with external effects

External effects are environmental, economic, health, safety or other costs or benefits generated by a product that are not reflected in its price or costs. Thus external effects are not likely to be properly considered by the purchaser. If a product or activity generates external costs, it will tend to be oversupplied

as its full costs are not reflected in its price or marketplace return. If a product generates external benefits, it will tend to be undersupplied since the full benefits it provides are not reflected in its price or marketplace return.

Regulation of the quantity supplied, price or characteristics of externality-generating products or activities is one possible approach for attempting to correct for their external effects. An alternative approach is to use general economic incentives, such as subsidies, taxes, or fees, to internalise these products' external effects into their market price. This approach, where it is feasible and does not create undue distortions between firms, can use competitive market forces to determine efficient prices, quantities and product characteristics. Government can introduce market solutions where none existed before such as by creating emissions rights and permitting the trading of these rights.

6.2. Adjustment programmes versus business subsidies to address loss of employment in declining industries

Subsidies to businesses to maintain jobs in declining industries may only delay adjustments that must eventually be made to adapt to changing market conditions. Subsidies that are targeted to the least efficient companies may actually lead more efficient companies to stop serving the market. Rather than attempting to reverse marketplace developments, worker and regional adjustment programs, can help to provide the means for individuals and businesses to adapt effectively to changing market conditions without distorting competition.

Box 34. Understanding the underlying objective, determining the outcome and developing alternatives

The automotive industry is one of the most important sources of employment. Over time sales starts to decline and firms start firing workers. The government decides to intervene to maintain the level of employment by giving subsidies to car and truck producers.

This policy can distort the incentives to compete by favouring national producers over international importers and it also penalises producers of alternatives and innovative means of transportation, such as electric cars, bicycles and the like. This policy also can absorb investment capital that would otherwise go to more productive sectors of the economy.

Since the key objective is to avoid job losses, supporting the producers is not a necessary part of the policy and any intervention should be directly aimed at helping workers. For example an alternative could involve investing money in projects to retrain workers, so that they can be employed in other industries, or in temporary redundancy payments to support workers while they look for another job.

In principle, retraining support or redundancy payments would not distort competition.

6.3. Consumer information and education requirements versus mandatory product characteristics

Protecting consumers is often said to be a reason for establishing mandatory product characteristics. At times, information disclosure may be sufficient, such as fat content labelling for products. Some consumers may prefer to take risks and it is not always the role of government to prevent that, but instead government can provide useful information to consumers for their individual decision making.

6.4. Bans on direct sales to consumers versus ensuring provision of adequate information to consumers

Door-to-door and direct to consumer sales are common practices in many markets. However, their use, particularly in newly deregulated markets, often leads to complaints or concerns that many consumers are buying products based on misleading or inadequate information provided by their door-to-door or direct salesperson. One way to address such concerns is to ban door-to-door or direct sales. An alternative approach is to establish requirements for door-to-door or direct salespersons to provide consumers with the information they need to make adequately informed product choices. Another possible alternative is to require contracts to include cooling off provisions providing consumers with the opportunity to review purchase decisions. Maximum contract lengths or prohibition of automatic renewals may protect vulnerable or uninformed consumers. Such measures may provide a way to maintain the beneficial aspects of door-to-door and direct sales, while ensuring that consumers are adequately informed.

6.5. Controls on advertising content, rather than advertising bans to prevent harmful advertising

Controls on advertising content, as an alternative to advertising prohibitions, may provide a way to address harmful aspects of advertising, while allowing its beneficial aspects to continue. For example, advertising of a good as having a discounted price, relative to a previous or recommended price, can at times be misleading. An alternative to banning price discount advertising is to ensure that regulations restrict advertising of artificial discounts (for example, by a company raising the price of a good from EUR 20 to EUR 40 and then the next day returning the price to EUR 20 and advertising the good as 50% off).

6.6. Reliance on competition law versus regulation to deal with complaints of inappropriate competitive behaviour

Aggressive or innovative business practices often lead to complaints of unfair or inappropriate competition requiring corrective regulation. For example, price floors are frequently proposed to protect vulnerable businesses from excessively low pricing by competitors. As an alternative to regulation, competition law provides a generally effective framework for preventing business practices when they are likely to harm competition and consumers, while allowing such practices when they promote competition, innovation and consumer benefits. For example, low pricing strategies may be predatory or raise significant competition concerns only in limited circumstances. Price floors, rather than preventing harmful business behaviour, may prevent consumers from obtaining the benefits from low prices.

6.7. Voluntary versus mandatory product standards and business codes

Whereas mandatory standards require that all relevant products meet minimum performance, reliability or other standards, voluntary standards, where they are feasible, can provide a way for suppliers to signal that some of their products meet minimum standards, while allowing them to continue to provide other products that do not meet the standards where such products are preferred by some consumers. Voluntary business codes may provide a less restrictive means for addressing consumer-related marketplace concerns than regulation. Rather, than requiring all business to adopt the same business standards and processes, voluntary codes can provide less-informed or more concerned consumers with information allowing them to make better supplier choices.

Box 35. Mandatory standard for defining fresh milk in Greece

In Greece, by Presidential Decree 113/1999, the maximum shelf-life of fresh pasteurised milk cannot exceed five days. This mandatory standard for the lifespan of fresh milk is atypical. In most European countries, the shelf life is determined by the producers, and the duration is generally twice as long. Most Greek producers operate in northern Greece and five days is not a sufficient time for them to compete with the large producers that dominate the urban areas, or to reach the markets in the south of Greece, and the islands. A longer shelf-life would allow smaller producers to reach these attractive markets and create alternative channels of supply that depend less on intermediate processors. This would benefit both the producers (larger volumes by reaching more retail markets) and consumers (lower prices, greater product variety). The industry, however, stridently opposed any reform of the shelf life. At the same time, fresh milk prices in Greece were among the highest in Europe.

Source: OECD (2014).

6.8. High compliance burdens versus small business light touch regulation

Burdens from regulatory oversight and filing requirements can be disproportionately heavy for small business, potentially leading to closing down or hindering market entrance of small businesses and potentially reduced competition. To ensure that these competitors can remain or become operational, when they are otherwise efficient, less stringent regulatory oversight or filing requirements may be appropriate.

The set of alternatives should always include a “do nothing” option as a benchmark against which to examine the alternatives. The number of alternatives could be large or small: it is not necessary to have many options, provided all possible solutions have been explored. There may also be cases where no valid alternative options can be found, as the elements of the policy that give rise to the competition distortions are essential to the attainment of its objective. But before reaching such a conclusion a thorough consideration of all the possible alternatives must be carried out.

6.9. Competitive outsourcing versus internal supply of products

Where a government agency can source products competitively, the use of competitive out-sourcing rather than the internal supply of products may provide a way to use market forces to promote their more efficient, innovative and least costly supply.

Box 36. No valid alternative exists

A regulation aimed at decreasing the energy consumption of washing machines prohibits the production and import of any machine that does not meet a certain minimum energy efficiency requirement.

This regulation addresses the problem of the externalities caused by the consumption of energy: acquiring more efficient appliances imposes a cost on individual users (which they could internalise without the regulation), while the benefits from lower energy use, and less pollution, accrue to the whole population.

In order to achieve this result the regulation causes a distortion on competition, because it excludes from the market all those national and international manufacturers that do not meet the energy efficiency requirement.

There may have been alternatives to the regulation, such as taxes on all electricity use, consumer friendly labels that indicate future electricity costs at a range of prices and given usage, and utilities providing loans or grants to consumers for purchasing the more efficient appliances.

All alternative options need to be fully spelt out to understand all their implications, implementation requirements and effects. This allows determining whether they indeed achieve the same objective as the policy under review, whether they reduce the competitive problem identified through the checklist, and consideration of additional costs and benefits they generate compared to the policy under exam. The checklist should be applied to each alternative to ensure that the alternatives do not introduce other competition distortions.

Detailed example: Options for reform

This box continues the detailed example that runs throughout this manual.

Options for promoting competitive generic drug prices were developed using the economic analysis of the existing competition framework as well as a survey of relevant generic drug policies in other jurisdictions. The main approaches identified are outlined below.

1. Prohibit Pharmacy Rebates

To encourage greater competition in price and other dimensions, generic suppliers would be prohibited from granting, and/or pharmacies would be prevented from accepting rebates.

2. Clawback of Pharmacy Rebates

Generics suppliers continue to compete by offering pharmacy rebates. However, a mechanism would be put in place to monitor the actual level of rebates being provided. Pharmacies would either be required to pay a portion of the rebates back to the NPIP and other payers, or maximum reimbursement prices would be lowered to capture some portion of the rebates for payers. Countries using this basic approach include, for example, the UK and Australia.

3. Comparator Country Price Caps

Maximum generic prices would be established based on a basket of comparator countries' prices. As noted above, this approach is currently used to establish maximum prices for patented pharmaceuticals.

4. Pharmacy Network Competition

Pharmacies would be required to compete to be included in the network of pharmacies allowed to dispense pharmaceuticals under the NPIP. Pharmacy network competition is widely used in the United States resulting in low dispensing fees as well as generic drug prices.

5. Competitive Tendering

Where there are multiple suppliers of a generic, a competitive tendering process would be used to select one or a limited number of products to be listed on the NPIP and/or national dispensing list. Competitive tendering is currently used by hospitals in the country to control their pharmaceutical costs and is a core feature of New Zealand's pharmaceuticals policy.



Chapter 6

Comparing the options

Once the options have been identified, they must be compared. In practice, most decisions about which options to prefer are qualitative, that is, not based on quantitative comparisons of options. Relevant data for a quantitative comparison is not always available and, even when available, may not be amenable to analysis. It may even be that very important competitive impacts are practically unmeasurable. For example, changes in competitive conditions can affect incentives to innovate and develop new products. But the impacts of increased or reduced innovation are extremely difficult to quantify. Qualitative analysis combines facts and argumentation to arrive at reasoned judgments about which options to prefer. Qualitative analysis of reform options is a form of critical thinking. Qualitative analysis has the advantage of being widely understood, requiring little data, potentially quick and ultimately practical. At the same time, qualitative analyses do not identify the value of enhancing competition, so may miss one of the primary arguments for pro-competitive regulations. This chapter will lay out techniques of both qualitative and quantitative comparison.

Quantitative analysis involves careful and rigorous use of numbers to estimate benefits of particular options compared to others. While quantitative analysis may involve less need for judgment in comparing options, the techniques used can require more technical skills than qualitative analysis and certainly require some availability of data. For particularly significant or controversial issues, quantitative analysis is preferred, when possible. Quantitative analysis can, for example, provide estimates of the social benefits of a reform, such as how much less consumers will pay for products after a reform, or how many jobs will be created. The limit on data that is available or time to perform a comparison will often restrict the occasions on which quantitative analysis can be performed. Likewise, it can be difficult or impossible to quantify the

consumer value of product differentiation and improved service. So while quantitative analysis can help in selecting pro-competitive options, it will often have to be buttressed by qualitative evidence.

Table 1. Pros and cons of qualitative and quantitative methods

	Qualitative Methods	Quantitative Methods
Pros	<ul style="list-style-type: none"> • Rapid • Limited quantitative information required • Results easily explained, quick analysis 	<ul style="list-style-type: none"> • Provides numerical range of impacts, allowing for a sense of relative importance of preferring more pro-competitive options • Establishes hurdle for challengers to meet for arguing against analysis
Cons	<ul style="list-style-type: none"> • More subject to external criticism, though in many cases can be compelling when argumentation is sound or draws from a wide literature review or analysis • Value of contribution difficult to measure 	<ul style="list-style-type: none"> • Data requirements • Potentially slow to complete

Before talking about the qualitative and quantitative techniques, consider some of the background concepts useful for comparisons.

1. Background concepts

1.1. Establish a baseline and compare options against it

To compare one or more options, it is helpful to identify a baseline option. This is often the status quo. Deciding on a baseline allows us to say how a policy option might improve economic performance relative to the baseline.

Box 37. Ways that baselines enter into the analysis of policy options

Example 1. “Baseline option A is no regulatory action. Introducing option B would likely lead to a 5-8% reduction in price from this baseline, resulting in an increase in consumer welfare valued at USD 45 to 72 million over six years. This is a greater improvement over the baseline than any of the other options.”

Example 2. “The Baseline is option C, which is in the already passed but not yet implemented legislation. None of the other options would yield more consumer benefits than option C. So option C is preferred.”

Selecting a baseline is not essential to comparisons, however; to determine a “best” policy option, what matters is to know the relative impact of one option compared to another.

Box 38. Comparing relative Impacts to determine preferred option

Option A will leave consumers with an extra EUR 40 million in their pocket over six years compared to Option B. Option C would leave consumers with only EUR 25 million more over six years than option B. So of the three options, Option A is the preferred option.

1.2. Potential to achieve objective

Not all policy options that are proposed are equally likely to achieve the policy objective.

At times the policy objective is itself not defensible. In this case, it may be worth questioning the policy objective, for example because it is outdated, based on an analysis using old technology or hiding an ulterior objective.

Box 39. Unstated reasons for regulation

A regulation is passed by a local city council that forbids sales of food from trucks throughout the city. The ostensible policy objective is to ensure good hygiene in food service establishments. But the media assert that the real reason is to protect established restaurants against competition from trucks that are mobile and have lower cost structures than traditional restaurants.

Inherently policy options should be designed to achieve the objective. However, some policy options that are proposed will not always do so.

Box 40. Interested parties’ legislative proposals

When a regulatory objective is proposed for the banking sector that would have the effect of reducing bank profits, banks may reasonably propose and advocate rules that would not be as effective in achieving the regulatory objective. For example, regulators may propose to eliminate risky assets from consideration as assets in the financial ratios that banks must satisfy. Banks might then argue that the value of such assets should be included, but on a risk-weighted basis in which they underweight the value of risk, thereby providing an incentive for banks to achieve regulatory ratios through high risk activities. Regulators therefore need to watch out especially for situations in which interested parties propose regulations that do not achieve the regulator’s policy objective or that would transform a regulation from having its intended effect.

1.3. Benefits

When considering policy options, there are two types of benefits to consider. The first and most obvious are direct benefits. But the less obvious effects are indirect benefits.

Direct benefits

Direct benefits are those that arise directly from a policy. For example, a policy aimed at improving pre-natal health should have a direct effect improving pre-natal health care. A policy aiming at reducing fires in warehouses should have a direct effect of reducing the number of losses from warehouse fires.

Indirect benefits

Certain policy interventions could affect other policy priorities, such as enhancing the environment, benefitting social welfare, and promoting small business. For many local development projects, indirect economic benefits are reckoned to have a significantly larger size than the direct effects. For example, they lead to the development of road or other infrastructure that may also be used by other businesses or residents.

Certain policy interventions may have effects in downstream markets from that in which the policy operates. For example, a policy that lowers the price of energy for aluminium smelters will create lower prices for aluminium products downstream.

Box 41. Value of indirect benefits

A regulation that eases restrictions on air freight transports by allowing more suppliers is expected to have the *direct benefit* of speeding the processing of freight and reducing the cost of air freight by 40%. The *indirect benefit* may arise from increased economic activity in exports. Industry predictions are that the output of exotic flowers will quadruple to USD 58 million per year in response to lower air shipping costs and faster delivery, creating 370 new jobs.

1.4. Institutional capacity

The institutional setting for proposed new regulations can have a substantial impact on their success in achieving their goal. Two particularly important factors affecting institutional setting are the enforcement institution for the regulation (if any institution is required) and the legal setting.

At times, regulations require a high level of technical expertise that is either not available or scarce. For example, technical regulations in telecommunications may require extremely complex modelling to determine access conditions for new entrants that would, in turn, promote competition. While the modelling may be feasible, the resource commitments, or knowledge required to implement them, may not justify the investment, for example in very small countries with limited staffing and small budgets for the regulator. In this example, the evaluation of a technical regulation to promote competition would reasonably consider the institutional limits in enforcing a regulatory option that requires sophisticated modelling.

The evaluation of a regulation also needs to consider the overall legal environment in which the regulation will be applied. If appeals are fast against clear and transparent application of legislative acts but slow against the application of ministerial decrees or agency implemented rules, there may be benefits from placing detailed rules in legislation, even if this limits long-term discretion of a regulator to adapt rules as the social and technological context evolves.

1.5. Unintended consequences

Many regulations have unintended consequences. The unintended consequences can sometimes be significant enough to make the policy intervention either ineffective or counter-productive. Care needs to be taken when developing original policies to ensure unintended consequences would have only second order effects. One way to reduce the likelihood of unintended consequences is to adopt policy reforms that have been tried in other countries and where unintended consequences have been limited.

Box 42. Elevator regulation deadline creates supply scarcity

After elevator accidents in France, regulations for elevator security changed and effectively created a requirement for many buildings to change their elevators (Arrêté du 18 novembre 2004) if the elevators had been installed before 1982, (even if they were operating well and safely). The consumer representative organisation estimated that this law would cost consumers EUR 6 billion. The initial date required for meeting the new standards was 2008, placing a significant pressure on the market for installing replacement elevators. In fact, Que Choisir, a French consumer representative organisation, found that many quotes for replacement elevators were extremely high. One reason for this may have been that so much demand was created for installation (by the new law requiring widespread replacement of elevators), that all installation companies were working at full capacity, and so did not need to bid competitively to win business. In

fact, management committees of some buildings stated that they were not able to obtain multiple bids for installation of elevators, but could only get one supplier to bid, suggesting that bidding would not be very aggressive.

Thus the unintended consequence of the law to make elevators safer seemed to be a decrease in the effectiveness of competition between suppliers (and an increase in prices) because it was not possible for the installation companies to dramatically increase supply in a short period of time, so they knew, when bidding, that they would have full order books whether they won a particular bid or not. Ultimately, the deadlines were extended to allow more time for installing new elevators, because elevator companies did not have the capacity to perform all the work that was required by the initial deadline. For the current version of the regulation.

Sources: French Government (2004), Arrêté du 18 novembre 2004 and Que Choisir (2008), www.quechoisir.org/immobilier-logement/copropriete/communiqu-e-copropriete-le-grand-derapage-financier-de-la-renovation-des-ascenseurs.

Although best attempts may be made to avoid unintended consequences, they can still occur. Accordingly, it is important that the effects of regulations be monitored after they are implemented and that regulations are subject to periodic review. Such reviews can have the purpose of mid-course modification of a regulation to prevent the unintended consequences. If the companies under regulation expect substantial change in regulations, they may limit their investments. So even minor reviews must be undertaken with care and potentially avoided, to the extent that constant fine-tuning can deter investment in capital-intensive industries.

2. Qualitative analysis

Qualitative analysis is the most common technique for evaluating alternatives. Qualitative analysis can take a variety of forms. Some of these are discussed below. The examples provided are illustrative and not intended to constitute a complete list of possible types of analysis.

2.1. Argumentation

Argumentation is probably the most common form of qualitative analysis. The use of “critical thinking” or “informal logic” to select among alternatives will:

- Combine reasons, evidence and appropriate assumptions to reach conclusions;
- Account for the credibility of sources, to ensure that no undue weight is placed on self-interested and biased argument;

- Gather information to complete arguments and test plausible hypotheses;
- Consider challenges that may be made to conclusions and have appropriate responses; and
- Evaluate the quality of arguments about the strengths and weakness of alternative policies.

Examples of using arguments to compare alternatives can be found in Annex B of Volume 2: Guidance of the Competition Assessment Toolkit.

The argumentation technique begins by stating the overall situation, including the reasons for developing the current proposals and a description of the existing regulatory environment. The analysis then states the objectives of the policy and sets forth the alternatives. Each option is analysed, considering its strengths and weaknesses, using any evidence available and identifying assumptions, particularly where the assumptions may be questioned. Finally, a value judgment is made about which option is strongest, weighing the analyses of the options and considering the evidence and reasons to support each.

2.2. Comparison of pros and cons in a list

One alternative form of comparison to basic argumentation is to identify pros and cons of one regulation compared to a baseline (which could be an alternative proposal or the existing state of affairs). The pros and cons can then be lined up against each other to find counterbalancing equivalences. For example, one pro may counterbalance one or more cons. After weighing the pros against the cons of a policy compared to an alternative, if the pros outweigh the cons, then the reviewer would favour the policy and if the cons outweigh the pros, the reviewer would favour the alternative. When there are more than two policies subject to comparison, the process of bilateral comparison can be repeated, with the winner of one comparison than being compared to another policy option, until the overall winner has been determined.

The balancing of pros and cons against each other is particularly prone to an accusation of being arbitrary. It would nonetheless have the advantage of transparency and of a structured approach.

Box 43. Weighing pros and cons: Asphalt Plant Example

Suppose that there are regulations over asphalt plants and how they operate that include a minimum size requirement. One reason given for the size restrictions is that the regulating ministry believes small operators will be difficult to regulate and less efficient than large operators. The regulatory determination of the minimum size is actually quite large and appears to prevent entry of new plants because entry at the large scale required would not be profitable without taking an immediate and large share of the market from the existing operators.

Pros and cons can be identified and listed from moving to a regulation without a size restriction. These may then be weighed against each other to determine a preferred policy option. In the example below, the reviewer determined that allowing a greater geographic spread distribution of asphalt plants would deliver a pro of making asphalt available closer to its end use point and this was found roughly equivalent to the con that more facilities would have to be visited by the regulators. The reviewer may then determine that a wider geographic distribution of environmental impacts (a pro for avoiding concentrated points of pollution) would counter-balance two cons: the first, that small operators might not operate with the same due care as large companies, which was considered lower risk because inspectors would visit and apply the same rules to the small companies as to the large ones, and the increase in burden from local authorities having more environmental impact statements to review. This then left a pro with no counter-balancing cons, meaning that the pros outweighed the cons.

Pros	Cons
<ul style="list-style-type: none"> - Permits entry of small asphalt plants, introducing more competition for provision of an essential building material - Allows for greater geographic distribution of asphalt plants that may be nearer to the sites using asphalt - Environmental impacts will be more evenly distributed 	<ul style="list-style-type: none"> - Will require more facilities to be visited by regulator - Small operators may not follow rules with same care as large ones - Local authorities will have to review more environmental impact statements

2.3. Points-based analysis

In points-based analysis, important policy variables relevant to a given policy are identified. For each policy option, the achievement of objectives for each variable is evaluated. Points are assigned to indicate high or low levels for achieving the objective on each variable, with more points assigned to the desirable outcome. The maximum number of points for one variable may be higher than for another, for example because some variables are clearly more important than others. Once each policy option

has been given points for its achievements by variable, the points are added. The policy option that garners the most points is the preferred option.

This method must be used with care, particularly to avoid manipulation of comparisons (and point values) to deliver one pre-selected option. Its value lies in creating a framework around which clear debate can be structured.

Box 44. Points-based analysis: Incinerator impact

Comparison of two policies for limiting environmental impacts of incinerators

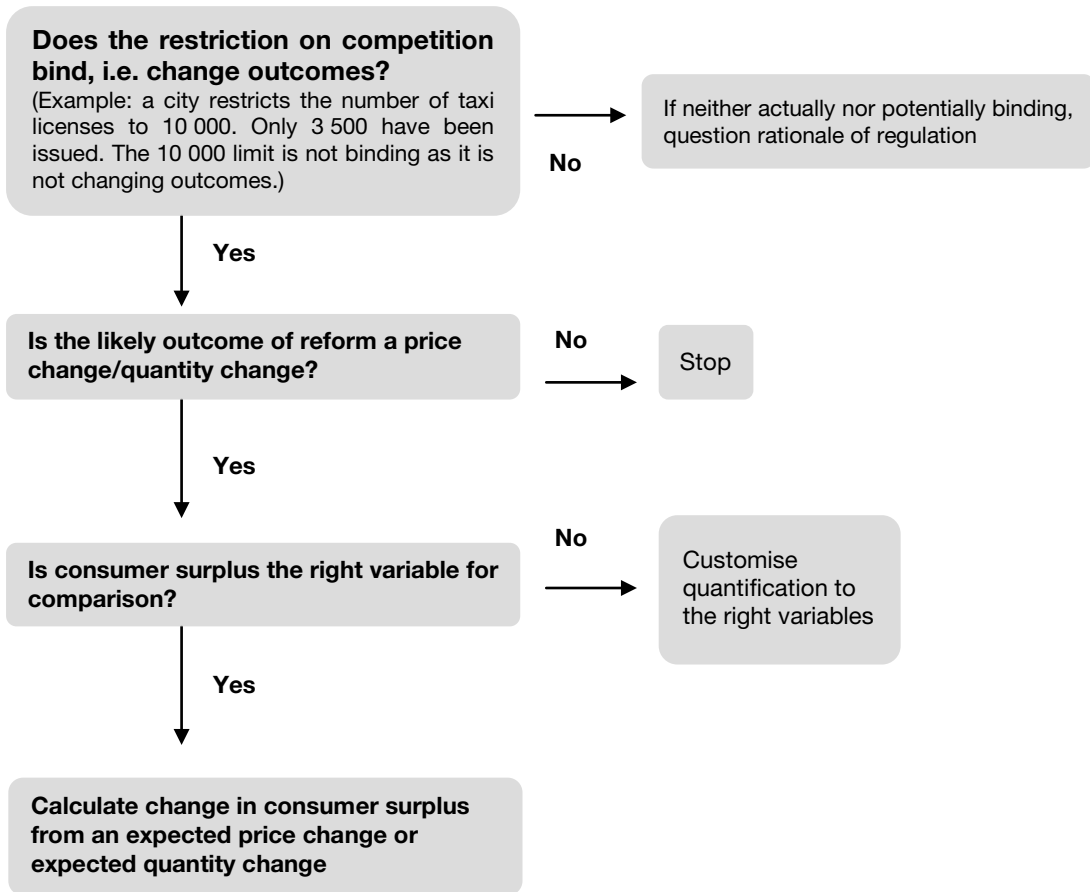
A government has decided that it needs to regulate the output of waste incinerators to reduce harmful emissions. In one approach, a company has come to the government with a particularly effective and innovative technology for removing CO₂ from the incinerator outputs by incorporating the CO₂ into solid waste. It wants a license to be the sole company with the authorisation to incinerate medical waste and merchant ship waste. In the alternative approach being considered, the government would simply allow any incinerator meeting its basic limits on output compared to input to operate. Other incinerator operators claim that putting CO₂ into solid waste creates only a minor benefit compared to the cost of doing so, particularly as other burning businesses (such as electricity generating plants based on gas) do not have such requirements and are actually considered relatively clean producers of electricity. Hospitals complain that they risk paying a high price if there is only one incinerator. The government requires incineration of medical and merchant ship waste to avoid potential health hazards from such waste.

	One operator license	Licenses on meeting requirements to all comers
CO ₂ reduction (1 – 3 points, 3 is no emission)	3	1
Particulate emissions (1 – 5 points, 5 is no emission)	3	4
Expected price (1 – 5, with 1 being high price, and 5 a low price)	1	5
Ease of implementation and oversight (2 is easy, 1 is difficult)	2	1
TOTAL	9	11

3. Quantitative analysis

To decide whether to perform the quantitative analysis described in this section, first go to the flow chart.

Figure 3. Flow Chart for deciding whether to perform quantitative analysis



When performing quantitative analysis, different variables can be useful for measuring benefits and costs. The relevant variables will depend upon the subject of the regulation and the type of data that is available. Potential methods for examining variables range from simple methods to ones that involve varying degrees of complexity.

4. Measuring benefits and costs

Quantitative analysis involves data by definition. But data availability should not drive the analysis. Rather, the analysis must determine specific variables that would be useful to examine because their measurement

would be useful for evaluation of a hypothesis. In light of reasonable hypotheses, the assessor must decide what variables to focus on and, if no pre-existing data is available, how to collect it. Two fundamental questions are then:

- What is measured?
- How is the information collected?

Answering these questions will be a highly fact-specific enquiry related to the particular regulation or sector under consideration. The required data will depend on the hypotheses that will be tested with the data. The data available (or potentially available) may restrict the universe of hypotheses that could be tested. Certain sectors such as health and transport have substantial pre-collected data available. But specific and narrow data on health care utilisation might not be available to the policy analyst as a result of confidentiality rules. In such cases, waivers may be requested or applications made to designated bodies for use of data in a way that strips all personally identifying information.

4.1. What is measured

Data commonly subject to measurement include consumer benefits, costs, employment, output, productivity, time, and profitability. Some of these variables are intrinsically monetary, such as costs, others can be converted into monetary measures, such as consumer benefits and others are primarily non-monetary, such as employment.

Monetised variables are valuable because they provide a common scale for measuring impacts across different products and for comparing to any costs of a policy that may be identified. Many different variables can in fact be monetised even if only for the purpose of the study in hand.

Non-monetised variables can have high value. Statistics about employment can be of strong interest to various audiences, including to the public and politicians.⁸ For example, in considering the effects of an import quota, it may be possible to calculate how much it costs consumers to

⁸ Measurement of employment effects is sometimes complicated by the diffuse effects of employment increases from an efficiency gain in one sector, and that job reductions, to the extent they occur in one company, may be offset by gains over the long-run, but not immediately.

save one job in the automotive industry for one year. Other variables that can be estimated include reduced waiting times (e.g., for taxis), increasing accessibility of workforce to transport, and QALYs (quality adjusted life years, sometimes used in health care work).

Box 45. Converting non-monetary variables in monetary value

At times, non-monetary variables (such as waiting times for taxis) can be converted into monetary values. Suppose that peak waiting times for taxis will fall, after a reform, from 40 minutes to 10 minutes. Suppose further that before the reform, 10 000 people take a taxi at peak times every day. Then the wait time would fall by 30 minutes, yielding a gain of 30 minutes per day for a typical peak time taxi passenger. If an average person hour of leisure time is worth EUR 8, then the reform would yield user benefit of EUR 4 per day for 10 000 people, or EUR 40 000 per day or, annually, EUR 14.6 million. Note that this estimate does not yet take account of new users of taxi services who may be attracted by lower wait times.

Intangible measures of consumer benefits can be both important and difficult to access. For example, a rule that raises the price or restricts access to hearing aids will affect the hearing of many people; their social, family and professional interactions will be affected. Placing a value on the losses from fewer interactions is inherently difficult, but can be done, for example through a survey of the willingness to pay speaking to family or a study of lost profits arising from limited communication at work. In some cases knowing how the quantity of an item purchased varies with changes in price enables the assessor to estimate consumer benefits, or calculate a minimum bound.

The information gathered should be relevant to the question under consideration. If all available industry information is not relevant to assessing the questions under consideration, it is important to look for other sources of information.

4.2. How to gather data

Collecting relevant information is a crucial role for the assessor. Government statistical offices collect large varieties of information and, at times, this can be available to government reviewers, useful and available at no charge. At times data collected is not intended for release, but is kept in readily usable forms. For example, price data collected to estimate rates of inflation can be quite detailed and product specific. While it might not be publicly released, the holders of the data can make it available for use within government. But often the best data on a topic is confidential and in

the possession of private parties or included in commercial databases whose access can be costly. Obtaining such information can require that the government purchase the data. Often, discounts from the full commercial rate can be negotiated given that government use does not generally have a commercial purpose. In some countries, bodies conducting a competition assessment may have the ability to require mandatory disclosure of data. But this is not yet standard. As a result, reviewers may seek voluntary disclosure of data by parties interested in a regulation.

Relevant information will often be held by others besides interested parties. Common sources of information are:

- Government data sources (e.g., statistical offices, sectoral ministries);
- Private surveys (e.g., survey companies that produce reports about market conditions, consumer habits and preferences or other subjects);
- Industry associations (often industry associations collect, compile and distribute information that is of common interest to the industry, including figures on outputs, capacity utilisation and prices);
- Businesses' annual reports (annual reports can contain not only financial information in the form of balance sheets and income statements, but also more general information about market conditions, technological change and corporate strategy);
- Analyst reports (stock analyst reports or sector analyst reports can contain very useful information about industry trends, changes in technology and market conditions);
- Commercial data gathering organisations (commercial data gathering organisations may collect a variety of information that is of use for companies in evaluating their products and markets, such as store specific data on sales and prices);
- Competition cases (in the interest of transparency, competition law cases can be particularly useful for providing data and examining market. More generally, regulatory cases and private law suits can also provide useful information); and
- Sector experts (sector experts may collect data on their own that has substantial value).

At times, for particularly important regulations, information may be gathered specifically for deciding how to structure a regulation. Gathering information is not necessarily an arduous task. It may involve, for example, a day of making phone calls to perform an informal survey.

At times data may be available in other countries that could test the hypothesis in questions. Using such data can be an acceptable substitute when no domestic data is available and when consumer and regulatory conditions are comparable.

4.3. Simple methods

While complex econometric methods may underlie more sophisticated analysis, permitting estimation of cost and demand functions, for example, simple methods of providing quantitative estimates often provide results that are comprehensible, testable and transparent. One of the advantages of simple methods is that they are typically easy to explain and consequently more convincing for decision makers than complex methods that might rely on econometrics or non-intuitive economic models. If simple methods are not available, quantitative estimates will often not be made at all.

Price comparisons

One of the simplest tests of the effect of pro-competitive reforms is the comparison of prices in a set of suppliers where competition is present to that in which competition is not present. If there is no difference between the prices, then competition would be found to have a minimal effect. On the other hand, if there is a large difference in prices (while other conditions remain the same), then increasing competition may be expected to have large impacts.

Price comparisons would not necessarily be restricted to domestic comparisons (e.g., between states or cities.) At times, domestic prices may be compared to prices in other countries. This is increasingly feasible as a result of international efforts to collect comparable price data both by private and governmental bodies. International comparisons can be complicated by factors such as the need to adjust for changing exchange rates and the need for comparability. Factors that might prevent instant comparability of prices include different cost structures that may exist in one country compared to another and different definitions of a product. For example, costs of postal deliveries may be substantially different in densely populated areas (such as The Netherlands) compared to largely rural areas (as in Australia), so the ultimate prices for letter delivery are likely to differ as well. The product “Fresh milk” may be defined differently in one country

compared to another, and differences in definition can also sometimes explain price differences. When products and cost structures are comparable between jurisdictions, differences in prices are more likely to be explained by differences in competition.

Price comparisons may have limited value when a change in price may not occur but instead a change in quantity would occur. For example, taxi regulations may keep prices constant by using meters, while restricting aggregate supply of taxis. In such a case, focusing only on price, and not quantity, would overlook the main consumer impact of a regulation.

Box 46. Price comparisons for non-prescription drugs

In the UK's Office of Fair Trading study of retail pharmacies (2003), a substantial variation in prices of non-prescription drugs was observed across pharmacies within the UK. It was assumed that deregulation would lead pharmacies generally to set prices in the lower quarter of that distribution.

Box 47. Market provision of services to small communities

A major concern regarding deregulation of entry to Canada / US trans-border air travel routes in 1994 was that travellers and businesses in smaller communities would be harmed by the shifting of trans-border air travel services to major population centres. However, over the next 10 years under market-based entry and exit on trans-border routes, the number of Canadian population centres with scheduled non-stop trans-border air service increased from 14 to 24, with the total number of trans-border routes rising from 58 to 148.

Source: House of Commons Canada (2005).

Box 48. Exclusive contracting raises prices in duty free shops

In the Korean competition authority's (KFTC) market study on duty free shops in the Incheon International Airport in 2012, a sharp increase in prices of liquor and tobacco items was observed just after the ICN (a state-owned company that rented retailing space in the airport) consolidated its contracting to start allowing one corporation an exclusive contract for duty-free liquor and tobacco sales in the airport for 5 years (2008.3-2013.2). Comparing prices before and after changing to monopoly contract for liquor and Tobacco sale, the price of 30 kinds of liquor and tobacco products increased by an average of 9.8% for one year (2008-2009). The KFTC recommended that the ICN change the regulation of procurement to allow more companies to operate duty free liquor and tobacco shops in the airport, just as for cosmetics or electronics. The ICN then contracted with two companies for duty free liquor and tobacco from March 2013.

Outcome effects in cross-regulation studies

Comparable regulatory reforms are frequently carried out for different products. Information about the effects of regulatory reform or regulatory differences in one product can frequently serve as a lesson for potential reforms in other products. For example, a competitive emissions trading programme could be set up for the pollutant SO_x, in which rights to pollute SO_x are distributed in some way (e.g., to existing polluters) and then traded, with an annual decrease in net permits. After some time, there may be an interest to set up an emissions trading programme for other pollutants, such as NO_x, benzene, or micro-particles. Experiences with emissions trading, and how it worked for SO_x, may provide valuable information about how to make emissions trading work for other pollutants such as NO_x. The comparisons may not be exact, though. For example, SO_x pollution sources might typically have stable point sources, such as specific factories and energy generation plants, while atmospheric benzene may have sources that, in addition to industrial applications, include automobile driving and smoking. Implementing an emissions trading programme for benzene then may pose substantially different challenges (and be impractical) compared to emissions trading for SO_x.

Outcome effect in regulatory reform elsewhere

At times regulatory reforms are carried out in one jurisdiction that may be similar to those being contemplated in the local jurisdiction. Simple case studies of reform can provide important and relevant examples of potential benefits. The jurisdictions can be national ones as well as regional and local ones.

Information about outcomes from reforms in other jurisdictions can be found with officials responsible for reform in other jurisdiction, academics or international organisations. Searching the internet for academic studies of such reforms can identify relevant work, or relevant experts. The OECD has produced a database of empirical studies of impacts of pro-competitive reforms that includes reform studies not only in English and French but also in other languages, with an aim to be the most complete collection of information on impacts of reforms. This database will be available electronically and in searchable format on the OECD website to enable identification of studies of reforms in particular sectors.

For the most part, impacts of reforms are not studied. Therefore the list of studies is much smaller than the actual number of pro-competitive reforms that have been performed by governments.

Experiments

Increasingly, experiments are recognised as a source of information about microeconomic behaviour. Experiments with regulations can be particularly useful to see how reporting requirements affect consumer behaviour or how communications affect outcomes.

The methodology underlying experimental studies is to identify a hypothesis for how behaviour would change from a change in the environment of relevant actors, then test this hypothesis, by observing actions of a control group (that is the base group with no reform) and a treatment group (that has experienced the proposed reform). Behaviours of the two groups can be compared using basic statistical methods and with estimates of level of confidence that expected changes would have. Many experimental studies use students, but the ideal study group is of people comparable to those who would be the target of pro-competitive reforms. For example, a reform of retail advertising laws might be tested on retail consumers.

Box 49. Experimental studies of disclosure

An experimental study of mortgage disclosure forms by the US Federal Trade Commission found that trial forms that provided information to home purchasers would have had unexpected effects and confused purchasers of mortgages, frequently leading them to prefer worse financial deals to better ones. The method used for this study was to test information impacts on consumer decision-making with experimental groups, rather than an actual implementation of the forms. An alternative, redesigned form had much better information value for consumers, according to comparable experimental studies.

Source: Lacko, J. and J. Pappalardo, (2004).

Demonstration projects

Demonstration projects are some of the most convincing forms of evidence about the benefits of regulatory change. These projects are a form of experiment that looks at the impact of adopting a proposed regulatory change, but do not require a nationwide roll-out of such a change all at once. Rather, they examine the impacts of the change for a relevant sub-population or geographic area. If the change is considered a success based on the demonstration project, it may be adopted on a wider scale. An advantage of demonstration projects is that they can ensure that proposed reforms will have the predicted effects and quantify those

effects. If demonstration projects do not have the predicted effects, they can ultimately save substantial government resources by avoiding the costs of a widespread roll-out.

Demonstration projects are policy experiments. Sometimes, policy experiments may arise without being formally declared a demonstration project. For example, federal governments may observe different types of state regulations and compare their effects.

Box 50. Price comparisons between federal and state regulated flights

One of the original rationales for airline de-regulation in the United States arose from comparing prices of in-state flights (within California) to comparable length flights governed by federal regulation that applied to cross-state airline flights. The in-state more liberal regulation was effectively a demonstration project for a broader national liberalisation.

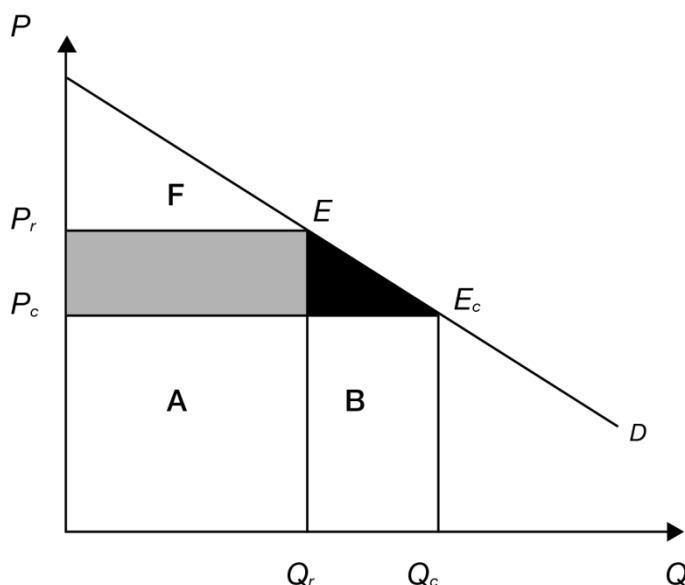
The less regulated California market (notably the San Francisco – Los Angeles route) had considerably lower airfares per passenger mile than for comparable routes covered by national regulations (such as Washington, DC – New York City).

Source: Keeler, T. (1972).

4.4. Value estimates

4.4.1. Consumer benefits

Competitive effects from regulation can often be examined as changes from one point on the demand curve to another. This can be considered a change in equilibrium approach. For many regulations that have the effect of limiting supply or raising price, an estimate of consumer benefits or harm from the change from one equilibrium to another can be calculated relatively easily for the linear demand and constant elasticity of substitution (CES) demand cases. The linear demand case will generally provide a lower estimate of the benefit of reform than the CES demand case. The two cases can be considered as bounds on the estimate, with the linear demand providing the lower bound and the CES demand providing the upper bound.

Figure 4. Consumer harms*Standard Measure*

In many sectors, minimal information is available about pricing, firm sales and other more technical economic indicators.⁹ This limitation of data could prevent the calculation of benefits via a change in equilibrium approach. For this reason, a simplified technique can be valuable, though second best to a change in equilibrium approach. This section outlines a standard measure for use in circumstances where better information is not available.¹⁰ The benefit of such standard measures is that they help to characterise the level of benefits that may exist, and help to provide a reasonable and comparable indicator of value of pro-competitive regulatory

⁹ These sources could have helped to determine the supply curves that would apply with the baseline regulation and the competitive one.

¹⁰ The standard measure assumes a market elasticity of -2 (or $|\epsilon|=2$, in a constant elasticity demand function). It is intended to represent a typical product elasticity with moderate competition and distant but feasible alternatives. The measure may be made more accurate if further information is available, or if there are reasons to believe the demand is either particularly inelastic, as with electricity or insulin, or particularly elastic, as may be the case with certain basic commodities.

change. The key inputs for such a measure are: sector revenue, elasticity of demand and average price effect of type of restriction found.

If price changes can be predicted by the type of restriction that is being eliminated, a formula¹¹ for estimating the consumer benefit from eliminating the restriction is:

$$CB = \left(\rho + \frac{1}{2} |\epsilon| \rho^2 \right) R_r$$

Where:

- CB_s : standard measure of consumer harm
- ρ : percentage change in price related to restriction
- R : sector revenue
- $|\epsilon|$: absolute value of elasticity of demand

The derivations of this formula can be found in Appendix A1.

Where the elasticity for the sector is unknown, the assumption of $|\epsilon|=2$ can be assumed, for a reasonably typical market with competitors, some consumers willing to cease purchases in response to higher prices and no price regulation, to yield an estimated benefit from eliminating the restriction of:

$$CB = (\rho + \rho^2) R_r$$

Revenues

Revenues are a valuable measure because they are often readily available and, even if not, less confidential than the two constituent elements of revenues, price and quantity sold.

The revenues should be those in the market directly affected by the regulation. More distant, but related markets would typically not have their revenue included in the revenue figure. Some judgment must be exercised

¹¹ See derivation in Annex 1.

in determining the bounds of the market for the purpose of the revenue estimate.

Example: Suppose revenues are known for a national market, but the regulation has only a local effect. The local revenue can be estimated from national revenue, for example by making per capita revenue calculations, per outlet revenue calculations, or calculations per unit of geographic area.

Revenues are measured in currency units, allowing for the calculation of benefits from promoting competition that are also measured in currency units.

Percentage change in price

Many studies have been performed that examine the price impact of different types of pro-competitive changes in regulation. These studies have been amalgamated, through the table in Annex 2, into benchmark figures for estimating the value of restrictions in different areas. The benchmarks are listed in table 2.

To find the appropriate benchmark, identify the type of restriction that has been identified. For each restriction, the table lists a benchmark effect. If more specific figures are known, for example from sector specific studies, these may be more appropriate than the general benchmark. In absence of appropriate studies, the benchmark serves as a useful first approximation.

When multiple restrictions are identified, a conservative approach is to select the restriction which has the largest price difference and use this as the basis for the percentage change in price.

Type of competitive restriction eliminated

Eliminating a binding competitive restriction often yields price change. Other possible measured impacts include output and jobs. Table 2 shows average price impacts of pro-competitive regulatory options. These figures are based on a survey of ex-post studies of changes in government policies.

Table 2. Mean price impact from moving to pro-competitive regulatory option

Benchmark price change (ratio of price change to less competitive price)	Category and sub-category of regulatory restriction
-0.20	(A) Limits the number or range of suppliers
-0.19	1 Grants exclusive rights for a supplier to provide goods or services
-0.23	2 Establishes a license, permit or authorisation process as a requirement of operation
-0.15	3 Limits the ability of some types of suppliers to provide a good or service
-0.19	4 Significantly raises cost of entry or exit by a supplier
-0.12	5 Creates a geographical barrier to the ability of companies to supply goods services or labour, or invest capital
-0.18	(B) Limits the ability of suppliers to compete
-0.19	1 Limits sellers' ability to set the prices for goods or services
-0.14	2 Limits freedom of suppliers to advertise or market their goods or services
-0.16	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
-0.39	4 Significantly raises costs of production for some suppliers relative to others (especially by treating incumbents differently from new entrants)
-0.20	(C) Reduces the incentive of suppliers to compete
-0.28	1 Creates a self-regulatory or co-regulatory regime
-0.10	2 Requires or encourages information on supplier outputs, prices, sales or costs to be published
-0.25	3 Exempts the activity of a particular industry or group of suppliers from the operation of general competition law
-0.20	(D) Limits the choices and information available to customers
-0.32	1 Limits the ability of consumers to decide from whom they purchase
-0.12	2 Reduces mobility of customers between suppliers of goods or services by increasing the explicit or implicit costs of changing suppliers
-0.16	3 Fundamentally changes information required by buyers to shop effectively

4.4.2. Other benefit measures

Benefits from eliminating competitive restrictions may be measured in other ways than through price. For example, at times prices are regulated, but the quantity supplied is restricted. This restriction of quantities also harms consumers. In fact, a 1% reduction in quantity supplied, even with prices fixed, may harm consumers more than a 1% price increase. This is because the 1% price increase will result in those consumers with the lowest marginal benefit from the product stopping their purchases. In contrast, a decline of quantities will not necessarily be allocated to those consumers with the lowest marginal benefit, but can equally likely apply to all consumers, including those with very high personal benefit from consumption. The type of estimate performed in the standard benefit measure can be close to or above that from eliminating quantity (see Annex 1). Interestingly, if a price impact could be estimated from the type of quantity restriction in place, an estimated consumer benefit from eliminating the restriction is:

$$CB = \frac{1}{2}(1 - \rho)R_f$$

There are many benefit-related variables that can be used in addition to quantity. The appropriate variable to measure will depend on the sector, what matters to consumers, and what data is available.

Box 51. Selecting relevant variables

- Taxi rates may be fixed, but limiting the number of taxis means that taxi wait times for passengers are high, or that some districts are underserved. Relevant variable to measure: wait time X value of time of those who wait. [See OFT (2003) The regulation of licensed taxi and PHV services in the UK http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.of.gov.uk/shared_of/reports/comp_policy/oft676.pdf]
- Pharmacy prices may be fixed, but limiting the number of pharmacies may mean that patients seeking medication have to travel further than they desire: increased travel time X (value of time + cost of transport).

4.4.3 *Adjustments to values*

Discounting

In many cases, benefits and costs provided by proposed measures will occur over years, and the timing of benefits and costs generated by different options may vary. In such cases, discounting is often required to correctly compare proposed options. Discounting can allow for costs and benefits that occur over time to be compared based on societal preferences for receiving benefits earlier, and other factors, such as the opportunity cost of funds and inflation. It is common in estimates of competitive benefits to truncate the benefits (by limiting the length of time considered, e.g., to five years) to account for the imperfect foresight of regulators.

Discounting allows each option's stream of future benefits to be expressed in net present value (NPV) terms. In general, options having the highest NPV should be selected. No proposed option should be selected unless it has an NPV higher than the do nothing case.

To calculate NPV, future benefits and costs for each year must be discounted to their present value (PV) according to the following formula, where t is the year starting from 0 and r is the discount rate:

- The present value at time 0 (now) of a net benefit at time t is: $\text{Present Value} = (\text{Benefits}-\text{Costs})_t / (1+r)^t$. The sum of the present value of the net benefit at each time under consideration yields the present value of a policy.

One possible source of discount rates is the implicit interest rate on government bonds, which may reflect the governments cost of funds (or societal benefits from gains). Another source is national regulators, when they must produce present discounted values of asset investment streams. Broadly, many options exist for selection of a discount rate; this manual will not take a position on the appropriate discount rate for government policy making.

NPV for an option is the sum of the PVs for all relevant years in which benefits and costs occur.

Where benefits and costs occur over time, selecting the appropriate discount rate can be critical to the selection of the best option. The choice

of the underlying real discount rate may depend on countries' general cost-benefit guidance.¹²

Example: Two options are being considered to achieve a policy objective. Option 1 involves substantial up-front investments initially leading to relatively low net economic benefits but resulting in higher net benefits later. Option 2 involves less up-front costs allowing it to generate higher net benefits early but at the expense of benefits later on. Under national cost benefit guidelines, a discount rate of 5% is applied.

Table 3. Discounting in the comparison of options

Year	1	2	3	4	5
	Option 1 (Benefits- Costs) (USD 000 000s)	Option 2 (Benefits- Costs) (USD 000 000s)	5% Discount Factor	Option 1 Discounted (Benefits- Costs) (USD 000 000s)	Option 2 Discounted (Benefits- Costs) (USD 000 000s)
0	100	1200	1	100	1200
1	500	1100	.952	476	1047
2	750	1000	.907	680	907
3	1000	750	.864	864	648
4	1200	500	.823	988	412
5	1300	000	.784	1019	0
Total	4850	4550		4127	4214

Based on nominal benefits and costs, option 1 is preferred as it provides USD 300 million in additional net benefits. However, when returns are discounted the preferred option is 2 which delivers additional PV benefits of USD 87 million.

¹² For further information on techniques for measuring and comparing the risk and uncertainty of proposed options see, for example, UK HM Treasury (2018) *The Green Book: Appraisal and Evaluation in Central Government*, US Office of Budget and Management, *Circular No. A-94 Revised* and Treasury Board Secretariat of Canada (2007), *Canadian Cost-Benefit Analysis Guide: Regulatory Proposals*.

4.4.4 *Risk / Uncertainty*

In most cases, the benefits and costs associated with proposed policy options are subject to substantial risk and uncertainty. Normally, estimates of benefits and costs of proposed measures are based on projections and estimates that are themselves subject to a high degree of uncertainty, such as projections of economic growth, interest rates, demand for products, and health and environmental impacts. In these cases, the riskiness of outcomes and tolerance of risk may be an important criterion in the selection of a policy option.

Useful information for comparing the risk and uncertainty of options may include the key sources of uncertainty; expected value estimates of outcomes; the sensitivity of results to important sources of uncertainty; and where possible, the probability distributions of benefits, costs, and net benefits.

Techniques for estimating and comparing risk and uncertainty include the development of scenarios, and sensitivity analysis. But a key constraint on estimates of the risks is that not all private sector practices may be predicted in advance of the implementation of a new regulation.

The development of scenarios can be used to draw attention to the major technical, economic and political uncertainties relevant for the selection of a proposal. For low or medium impact regulations, this may involve asking simple 'what if' questions. More detailed models of future states may be warranted for high impact regulations. In either case, comparisons should be based on the relative NPVs of the scenarios and options.

Sensitivity analysis involves changing the key parameters used to determine the benefits and costs of a proposed policy and studying how this affects the net present value of outcomes. Parameters that may be varied include, for example: (i) benefits and costs; (ii) the discount rate; and (iii) the general inflation rate.

More sophisticated models for addressing uncertainty are also available, such as Monte Carlo analysis. For the moment, this is likely not suited to competition assessment because the range of uncertainties is difficult to state, for example because unintended consequences of regulation are difficult to characterise.

Detailed example. Assessment of the options for reform

This box continues the detailed example that runs throughout this manual.

This Part provides the Department's assessment of the above options. Section A outlines key findings from the Department's analysis of each option. Section B provides a comparison of the options according to the criteria set out in the Minister's Directive to the Department.

A. Analysis of the options

A preliminary assessment was conducted of the above options resulting in 2 being rejected from more in depth analysis. These options and reasons for them not to receive more in depth review are as follows:

- *Prohibit Pharmacy Rebates:* Any attempt to monitor and prohibit rebates would involve major challenges. Rebates would have to be broadly and carefully defined to prevent competition between suppliers from simply being shifted to other competitive dimensions. For example, a standard definition of generic rebates would not prevent suppliers from competing in such dimensions as funding for non-dispensing services, the granting of preferential prices on non-pharmaceutical products or funding for trips or other perks. Moreover, the mere prohibition of rebates would not guarantee the development of price competition among generic suppliers in the absence of a mechanism to drive such competition. Rather, it may simply allow generic manufacturers to retain the rebates currently be in provided.
- *Pharmacy Network Competition:* As noted, pharmacy competition can be a highly effective driver of low generic prices. However, attempting to use this approach in the domestic context would involve fundamental and complex changes to the current competitive framework. Further, the potential exists for many pharmacies to be left out of the NPIP, in turn, negatively affecting many patients. This could have particularly serious consequences for the elderly and less mobile patient groups forcing many to switch pharmacists and travel further to consult their pharmacists.

Key findings from detailed analysis of the other options identified and the base case of leaving the current framework in place are as follows.

1. Status Quo

Unless major changes are made to the current competitive framework it can be anticipated that high generic prices will continue into the future. Using the average rebate level reported by suppliers, 55%, in 2011 rebates increased pharmaceutical costs by an estimated USD 2.9 billion out of USD 9.7 billion in expenditures, or by just under 30%. Moreover, the size of these costs are likely to increase over the next several years as more widely used patented drugs lose patent protection.

The current framework also imposes important indirect resource costs on the economy by resulting in less than efficient scale pharmacy sizes. Increasing average pharmacy size from the current 42 000 prescriptions per year to 75 000 per year would result in estimated resource cost savings to the economy between an estimated USD 1.4 and USD 1.5 billion.

The current high cost of generics also indirectly affects the overall quality of healthcare. On one hand, the high number of pharmacies under the current framework may make it more convenient for some patients to access pharmacy services. The high margins provided to pharmacies by rebates may also be promoting the supply of some beneficial patient services as a way to compete, such as longer opening hours and longer patient consultations.

On the other hand, high generic costs mean that fewer resources are available in other parts of the healthcare system. Further, studies have found that pharmaceutical costs can be an important determinant of their use particularly by low income patients which are generally less likely to have supplemental private insurance. Accordingly, the high prices being paid for pharmaceuticals, where they significantly increase patients' co-payments, may be resulting in a significant number of cases where patients do not use medications prescribed to them.

2. Claw-back of pharmacy rebates

A claw-back approach has the benefit of retaining the existing competitive framework. However, net savings to payers will depend on the level of rebates that are actually reported and the portion of these rebates that pharmacies are permitted to retain.

Obtaining accurate information on the actual size of rebates and net competitive prices would be a major challenge. As noted above, rebates would have to be broadly and carefully defined to prevent competition between suppliers from simply being shifted to other competitive dimensions, and a monitoring framework would also be needed to prevent underreporting of rebates. Even if such a framework was put in place, given the wide range of inducements that suppliers could provide to pharmacies to stock their products and the high level of competition in the supply of many generics, it would not be expected to fully capture competitive generic prices.

A further concern in using a claw back approach would be ensuring a continued high level of generic substitution. Maintaining a financial incentive for pharmacies to dispense generics would require either that they receive mark-ups and rebates on generics in the range of 25% or more of current generic list prices. As indicated by the following table a claw back of 75%, leaving pharmacies with 25%, provides a net return to the pharmacy of USD 10.10 for dispensing a generic versus USD 10 for the brand product based on the generic being priced at 61% of the brand price.

Pharmacy returns for dispensing brand and generic products under a 75% claw back

Category	Brand 15% Mark-Up	Generic 25% Mark-Up
List Price	USD 40.00	USD 24.40
Dispensing Fee	USD 4.00	USD 4.00
Mark-up	USD 6.00	USD 6.10
Net Pharmacy Return	USD 10.00	USD 10.10

It may be noted, however, that a 25% mark-up would not provide a financial incentive for pharmacies to dispense generics whose prices are less than 60% of the brand price. Rather, a higher mark-up would be needed to incentivise pharmacies to dispense these generics.

As an alternative to incentivising pharmacies to dispense generics, they might be mandated to dispense generics subject to being prevented from doing so by the prescribing physician. However, effectively enforcing this requirement would likely require a high level of monitoring and enforcement of pharmacy dispensing practices.

Another alternative for maintaining a high level of generic substitution would be to cap the maximum reimbursement for genericised pharmaceuticals at the generic price level unless the prescription states that no substitution is to be made. Patients still wishing to obtain the brand product would be permitted to do so but would be required to pay the additional costs.

A further complication concerning the use of a claw back approach would be ensuring that private payers also benefit. This could be particularly problematic for persons paying for pharmaceuticals out of pocket unless a claw back payment is made at the time of sale. A possible means to avoid this issue would be to use reported rebates to reduce maximum dispensing list prices.

A claw back approach would involve substantial ongoing costs to monitor rebates and settle accounts with pharmacies. Indirect effects of a claw back approach on the pharmacy sector would depend on the level of rebates that they are permitted to retain. If permitted to retain rebates equal to 25% of generic drug prices, this would increase total dispensing fees from approx. USD 2.83 billion to about USD 3.45. In contrast, current dispensing fees and rebates received by pharmacies are in the range of USD 6.28 billion.

While this net loss would likely lead a significant number of pharmacies to exit, it is unlikely to raise significant access issues particularly in urban areas where there is a high density of pharmacies. The potential exists for some rural areas to be significantly affected which may require some remedial action in the future.

Attempts to claw back a much higher level of rebates could substantially affect the density of the pharmacy network and patient access to pharmacist services. To ensure that this does not happen, alternative means for funding pharmacy might be required, such as increased dispensing fees or funding for other pharmacist services such as medication assessments, the prescription of medication for minor ailments, diabetes medication management, vaccine administration and the ordering and interpreting lab tests in medication related cases.

Pharmacy opposition to a rebate claw back would largely depend on the net impact on their returns as well as the amount of any additional costs imposed on them relating to the reporting and settlement of rebates. Substantial supplier opposition may be encountered depending on the reporting requirements imposed on them. Otherwise, the approach largely maintains the framework under which generic suppliers currently compete.

3. Comparator country price caps

The establishment of price caps based on comparator country prices also has the potential to result in large drug cost savings. Data purchased by the Health Department on generic drug prices for a basket of relatively low cost, comparator countries, found the foreign prices to be, on average, 35% below domestic prices. Foreign prices were particularly low compared to domestic prices for relatively large volume generics. Using a weighted average approach reflecting the volumes of different generics, foreign prices were 39% below domestic prices. Applying these price caps in 2011 would have resulted in generic cost savings of approximately USD 2.46 billion.

While price caps set at these levels would result in large drug cost savings, they are well below the 55% level of rebates reported by domestic generics suppliers. This reflects important limitations in the available foreign drug price data. Most of this data reflects simple ex-factory prices. Accordingly, it includes competitive rebates or discounts that may be provided to pharmacies or payers in other countries and, generally, does not accurately reflect the underlying competitive price.

The potential impact on pharmacy revenues is indicated by the following table comparing net pharmacy revenues for dispensing a brand product, a generic under the current market conditions, and a generic under a comparator country price cap it reduces the current generic price by 39%.

Pharmacy brand versus generic revenues under a comparator country price cap

Category	Brand	Generic Current	Comparator Country Priced Generic
Price	USD 40.00	USD 28.00	USD 17.08
Dispensing Fee	USD 4.00	USD 4.00	USD 4.00
Mark-up	USD 6.00	USD 4.20	USD 2.56
Rebate	USD 0.00	USD 15.40	USD 2.73
Pharmacy Revenue	USD 10.00	USD 19.04	USD 9.29

As indicated by the table, under a low-price comparator country price cap, average pharmacy revenues on a 40 prescription, including rebate, would be USD 9.29 versus USD 10.00 on a brand product. Accordingly, this approach would generally not maintain a substantial financial incentive for pharmacies to dispense generics.

To prevent this from significantly reducing generic dispensing higher priced comparator countries might be used, a mandatory generic dispensing policy might be put in place, or additional incentives might be provided to pharmacies to dispense generics such as an increase in allowable generic mark-up. Alternatively, a mandatory pharmacy substitution regime or patient-based substitution incentive would be required.

While there may be significant supplier opposition to a comparator country price cap approach, the prices used to calculate domestic maximum prices would actually be based on these same suppliers' foreign prices for essentially the same product.

The approach would likely encounter substantial opposition from pharmacies due to its impact on their net returns. However, using the above-noted basket of countries, it would provide pharmacies with net revenues of USD 3.07 billion exceeding their current level of negotiated dispensing fees by an estimated USD 0.244 billion, or 8.6%.

Implementation of this approach would not involve major obstacles and costs, and is similar to the approach currently used to calculate maximum patented pharmaceutical prices. Limited ongoing costs would be necessary to purchase the data needed to calculate the domestic price caps.

4. *Competitive tendering*

Competitive tendering, where it is feasible, has the potential to result in the lowest generic drug prices. By directly shifting the focus of competition to payers and placing strong competitive pressure suppliers, this approach could lead to average cost savings significantly exceeding the reported level of rebates of 55%.

The possible transition to a competitive tendering approach also raises a number of potential areas of concern. They include:

- the potential for supply interruptions to occur due to the inability of winning bidders to meet demand;
- the possible erosion, over time, of effective generic competition; and
- the stranding of inventory in pharmacies in the event of a switch in supplier.

Also, the approach may not be effective for generics having a small number of suppliers.

Careful design of a competitive tendering process would greatly mitigate these concerns. For example, to minimise the threat of supply interruptions, bidders might be required to demonstrate their ability to meet demand, more than one supplier may be qualified or suppliers may be required to post performance bonds that would cover the costs of dealing with a failure to meet demand.

Erosion of competition might occur if concentration of demand under competitive tendering leads to a smaller number of generic suppliers remaining active, or if the margins available on competitively tendered generics are considered too low for suppliers to invest the costs required to develop their products and have them approved for marketing in the country.

In practice, given the small scale of domestic demand versus demand for generics in other countries and lack of domestic generic drug manufacturing, a competitive tendering approach is unlikely to prevent companies from engaging in the basic research and development required to develop generic products. Domestic marketing approval costs could still be a significant barrier to entry in some cases.

However, should the erosion of effective competition become a concern, a variety of approaches may be used to prevent it from happening. These include, for example:

- allowing suppliers to bid subject to them subsequently obtaining approvals to market their products;
- qualifying more than one bidder to supply competitively tendered generics; or
- tendering the right to supply generics to sub-regions of the country.

Potential options for preventing significant quantities of products from being stranded include, for example, the awarding of contracts significantly in advance or the acquisition of predetermined quantities of generics based on projected demand. To ensure that tendering is effective in obtaining low prices, it may be limited to cases where there is an adequate number of competing suppliers, with other generics being subject to price caps at or below the current level.

Using pharmacy mark-ups to incentivise pharmacies to dispense generics would be problematic under competitive tendering as many high volume products would be priced

well below the relevant brand product. Accordingly, ensuring a high level of generic dispensing under competitive contracting would require that a mandatory substitution or maximum reimbursement framework be put in place, or that the current dispensing fee framework be redesigned.

Replacing the current competitive process with one based on competitive tendering would have to overcome a number of other obstacles. It would require the Department to acquire new competitive contracting capabilities. Significant ongoing costs would also be required to periodically tender out contracts.

Pharmacy dispensing fees would also have to be reviewed to ensure that the decline in prices and full loss of rebates that would result from competitive tendering does not impact the pharmacy network excessively. This might be accomplished by restructuring dispensing fees or increasing financing for the provision of other medical services by pharmacists. The high level of pharmaceutical costs savings that would be anticipated under competitive contracting should provide ample funding for enhancing the current role of pharmacists in the health care system.

The move to competitive tendering would likely encounter strong resistance from generic suppliers as it would increase competitive pressure on them and would fundamentally change the current distribution framework. Strong pharmacy opposition would also be likely but might be substantially mitigated by enhancements to current pharmacy funding mechanisms.

B. Comparison of the options

Impact on pharmaceutical costs

Among the options considered, competitive tendering has the potential to result in the greatest pharmaceutical cost savings. These would potentially be equal to or in excess of the current estimated level of rebates reported by generic suppliers of 55%, or more than USD 2.9 billion based on 2011 pharmaceutical costs. In contrast, potential savings under a claw back approach are likely to be significantly less than the reported 55% rebates depending on the ability of a reporting framework put in place to capture all forms of inducements provided by generic suppliers to pharmacies to stock their products. In contrast, maximum savings using a comparator country approach are likely to be in the range of USD 2.46 billion or less based on 2011 pharmaceutical costs.

Implementation and ongoing costs and obstacles

A common implementation and ongoing issue for all of the above approaches is ensuring continued high level of generic dispensing. The high level of generic rebates provided under the current competitive framework has been effective in promoting substitution but has led to the development of an inefficient pharmacy sector.

Options for dealing with this concern are to continue to encourage generic dispensing through dispensing fees, mandate generic substitution or cap reimbursement at generic price levels. As indicated above, continuing to use pharmacy incentives to promote generic substitution through the retention of rebates and generic mark-ups would significantly erode the benefits from lower pharmaceutical prices. To do this, dispensing fees have to be increased by more than USD 0.6 billion and, even then, some erosion of generic dispensing could occur. Moreover, the use of pharmacy incentives to promote

generic dispensing would create a dispensing fee framework that does not reflect actual pharmacy costs.

Among the other alternatives, mandating generic substitution would require the establishment of a monitoring and enforcement framework and may still result in some reduction of generic dispensing. Capping reimbursement to generic price levels, could result in a decrease in generic dispensing, however, the additional costs would be borne by patients.

Otherwise, a comparator country approach involves the lowest implementation obstacles and ongoing costs among the above options as it maintains the existing competitive framework and uses a basic approach already applied to patented pharmaceuticals.

A claw back approach would leave the current competitive framework in place. However, important obstacles and costs would be involved in implementing and maintaining this approach pertaining to the needs to obtain accurate information on actual size of rebates and allocate rebates.

Implementation costs and obstacles would be highest for a competitive tendering approach to develop an appropriate competitive tendering process and framework, develop tendering capabilities, and reorganise the distribution of generics. The approach would also involve significant ongoing tendering costs.

Implications for quality and efficiency of health care system

A common issue in regard to each of the above options is ensuring that patients have adequate access to pharmacist services. This can be achieved, most clearly, using a competitive tendering process. Among the above options, competitive tendering is the only one clearly indicating competitive generic prices and net pharmacy returns from their dispensing activity. By providing substantially higher pharmaceutical savings than the other options, competitive tendering also provides a larger source of funds for promoting better use of pharmacist services within the health care system.

Opposition

Opposition from sector participants would likely be highest for a competitive tendering approach. Whereas the other options above leave the current competitive framework largely intact, competitive tendering fundamentally changes and directly shifts the focus of competition to benefit payers. Particularly strong objections may be expressed by generic suppliers which will be placed under new competitive pressures.

A high level of pharmacy opposition to competitive tendering should also be expected, as competitive tendering would eliminate rebates as a source of funding for them. Pharmacy opposition may be possible to mitigate by offering alternative enhancements to their reimbursement, and, potentially, an expanded healthcare role. A high level of pharmacy opposition should also be anticipated in regard to the other above options depending on the net impact on their returns.

Other things equal, less opposition may be expected to a comparator country approach than a claw back approach as it places a lower reporting burden on pharmacies and suppliers.



Chapter 7

Recommendations

The purpose of comparing the options is to make one or more final recommendations for government action.

1. Selecting the best option

Using the criteria identified in the previous chapter, a judgment can be made about the best option, the second best option and so forth. At times there may be only one reasonable option even when an effort is made to find more than one.

In the most straightforward case, if monetary estimates of benefits and costs of different options have been made, the option with the highest net benefits would be ranked above the other options.

Box 52. Net benefit comparison to determine best option

If costs and benefits are as follows, then option B has the highest net benefit, option A the second highest and option C the least net benefit.

Table 4. Examples of calculating net benefit

	Benefit	Cost	Net Benefit
Option A	300	10	290
Option B	440	10	430
Option C	30	5	25

If monetary estimates of the benefits and costs are not easily available, alternative qualitative techniques can yield the ordering.

At times, non-price effects such as innovation impacts or new entry, may at times be the most important impacts from a new regulation and can have substantial competitive value.

2. Presenting the recommendation

The recommendation always must be presented to a decision maker prior to its implementation. The decision maker will then determine how to proceed.

The information submitted to the decision maker would typically be sufficiently complete to allow the decision maker to understand the competition benefits that could arise from the most pro-competitive solutions and clearly enunciate the benefits and harms from different options, allowing for a clear following of the reasoning process for determining an outcome.

When policy changes are recommended at multiple levels of government (such as national and regional legislation) the recommendation should be prepared in a way that would be relevant to each respective decision maker. When multiple layers of government must act together, the changes are more likely to require a long time to implement.

Often, there will be many recommendations, each related to a different provision of the relevant laws or regulations. These can be presented in summary form using a table like Table 5 at the end of this chapter. The last column titled Recommendations shows the recommendation for each provision. Prior columns arise from the mapping of laws and regulations, the identification of potential restrictions on competition, the explanation for the original objective of a provision and an explanation (in these instances, qualitative) of the competitive harm that would arise from the provisions. This summary chart would then be supplemented with additional written materials explaining the competition concerns and, where possible, making quantitative estimates of impacts.

Although in many cases quantitative estimates might not be possible, when they are reliable, they should be included with the recommendation. One of the values of having numerical estimates of impacts from different options is that such estimates can help to establish a more objective outcome than that which would arise from a purely political process based on interest group pressures. This is particularly simple when there are only two policies to compare (for example, in an ex-post review of a regulation because there is only one reasonable option to the existing regulation.).

3. Drafting the new regulation

The drafting of the new regulation is of key importance for the effective implementation of regulations. Often the team involved in evaluating regulatory options may not be the appropriate body for drafting of technical regulations. For example, in some countries, all legislation is performed by a legislative drafting office. As a result, policymakers will often give the legislative drafting tasks to others. Nonetheless, the team that performed the evaluation can provide useful information to the drafters, and the drafters should affirmatively seek out the advice of the regulatory reviewers, to ensure the drafted legislation achieves the desired pro-competitive effect as well as the desired primary purpose of the regulation.

4. Final approval

The steps necessary for final approval will vary according to the type of regulation or regulatory change. For example, if a proposed regulation is issued at the will of a regulatory agency, the board of the regulatory agency may be able to adopt the regulatory change directly, including potentially via a simple elimination of the regulation. If the proposed regulation must originate in a legislative act, the process can be quite different. Obtaining a place on the legislative calendar is thus of critical importance in such instances. It is thus important to know who keeps the legislative calendar and ensure that the appropriate political process is in place for the regulation to follow its course. To have a proposed regulation included on the legislative calendar, strong arguments regarding the benefits of the proposal and its relation to governmental priorities may be required. This is one reason that quantification of economic benefits of change, using the methods explained earlier, can be of use.

5. Implementation

In cases where a new regulation is the adopted solution and formally in place, the institutional apparatus to activate the regulation also needs to be put into effect. In some places, for example, regulations may be on the books but not in force because no one is responsible for enforcing the regulation or because the responsible body does not place a high priority on the regulation. Once the regulation is officially enacted, the appropriate steps need to be taken to establish enforcement procedures.

The date at which a regulation takes force can have a substantial impact on the ability to make competitive processes work. In particular, when only one company can currently meet a standard, but others might

be able to meet it in the future, consideration should be given to making the regulation take effect when the others have had time to develop their products. Dates of implementation should be chosen in order to ensure that effective competition can take place.

Box 53. Time of implementation and effect on competition

The date on which a regulation becomes effective can substantially affect the number of competitors. Suppose for example that a regulation to establish low-noise, low-emissions outboard motors for motor boats operating in marine reserves is passed and the plan is to implement the standard in six months. At the time of passing the regulation, only one company has the technology required to satisfy the standard, it has a patent that stops others from using the same technology, and no other company would be ready with alternatives in six months. As a result, all the purchases to satisfy the standard would have to be with one company, which would be able to charge high prices, because its products must be purchased by law. If the regulator chooses to extend the time of implementation by two years, other companies would have the time to invent around the patent and offer their own motors, meaning that purchasers would have real choices and price competition would help to ensure prices remain aligned with costs.

The competent body for establishing the regulation will need to:

1. Identify the appropriate body to apply the regulation;
2. Affirmatively assign a responsibility to this body;
3. Ensure the appropriate body puts a mechanism in place to enforce the regulation (e.g., through requiring that the mechanisms be in place within a certain period of time);
4. Ensure that the affected businesses and consumers are informed of the regulation (e.g., through a workshop, through letters or other forms of reaching out to the effected community);
5. Ensure that the private sector knows who to contact about the regulation; and
6. Ensure that regulatory decisions are taken with due speed and reasons behind decisions, if any discretion is applied, and applied within a timespan that favour competitive processes.

Table 5. Exemplar Table for Presenting Results -- Building Materials

No and title of Regulation	Article	Thematic category	Brief description of the potential obstacle	Policy maker's objective	Harm to competition	Recommendations
Law 3054/2002 Organisation of the oil market and other provisions	Art. 6 par 5	Asphalt	The legal person must have a minimum share capital of EUR 500,000 so as to be granted a licence to trade asphalt.	The objective is to ensure the financial capacity and sustainability of the companies trading oil products, taking into consideration the high value of these products	Barrier to entry for small suppliers since it raises the entry costs. The provision may limit the number of suppliers and lead to higher concentration in the relevant market and possibly to higher prices.	Abolish the provision.
Law 3054/2002 Organisation of the oil market and other provisions	Art. 6 par 5	Asphalt	The minimum amount of storage space in order to trade asphalt must be of 2,000 m ³ .	It was not possible to identify the objective of the provision. However, to our understanding, the objective is to ensure sufficient supply of the specific product.	Barrier to entry for small suppliers since it raises the entry costs. The provision may limit the number of suppliers and lead to higher concentration in the relevant market and possibly to higher prices.	Abolish the provision.
Law 669/1977 "Quarries-licences for exploitation"	Art. 4 par. 3	Mines / Quarries	The exploitation licence for marble quarries is granted as a single area for a minimum surface of m ² 20,000 and a maximum surface of m ² 100,000.	We understand from the Ministry of Environment that the objective of the provision is to limit the commitment of big quarry areas which would lead to significant environmental impact. Following communication with the Ministry of Environment, we understand that it is allowed to join neighbouring marble quarries (applies to both private and public). The minimum area for exploitation of marbles is set at m ² 20,000 because this surface is considered as the lowest scale needed for exploitation.	The minimum and maximum scale of a marble quarry constitutes a barrier to entry which possibly discourages potential entrants, reduces the number of suppliers and may lead to higher prices. The maximum surface set by this provision appears proportionate to the objective of protecting the environment in cases of direct assignment of exploitation, where a prior exploitation licence has been issued. Its potential impact is mitigated by the fact that the exploiter of neighbouring quarries can join them into one.	Abolish the provision as per the minimum area of the exploitation of marble quarries and with reservation to art. 11 par.1a), par. 2 and art. 17 of Presidential Decree 285/1979 for which the restriction should remain.

No and title of Regulation	Article	Thematic category	Brief description of the potential obstacle	Policy maker's objective	Harm to competition	Recommendations
Ministerial Decision Δ7/οικ.24023/4220/2011 "Amendment of JMD Δ7/Α/φ1/12901/580/26-6-1997 'Re-adjustment of the amount of State fees and royalties provided for in the legislation on mines (Government Gazette 574/B)."	Unique article	Mines / Quarries	Determination of fees paid under L. 210/1973, i.e. fee of EUR 10,000 to apply for the concession of a mine, letter of guarantee of EUR 20,000 to apply for a concession of up to km2.5, letter of guarantee of EUR 30,000 to apply for a concession of over km2.5.	It was not possible to identify the objective of the specific provision. However, it is our understanding that the objective is to raise public revenue.	While the provision constitutes an administrative burden we have no evidence of distortion of competition.	No recommendation for change.
residential Decree 405/1996 Shipment and unshipment of dangerous products in ports	ANNEX C, par. 10 law	Framework law	The provision defines that in passenger ferries only up to 5 transporters can transport dangerous products in restricted quantities, as defined in Annex C, with the exception of products falling under class 2, 3, 4.1., 4.3 and 5.2 for which only maximum two transporters per passenger ferry are allowed.	It was not possible to identify the objective of the specific provision. However, to our understanding, the objective is the safety of people and transports.	The International Maritime Goods (IMDG) Code provides for an unlimited quantity to be shipped in passenger ships. The national provision potentially may raise transport costs and lead to higher prices.	The Presidential Decree should be reviewed in the spirit of the IMDG and be fully compatible with it. Additionally, it should be directly amended every time the IMDG Code is updated, in order to be fully compatible with it.

Source: OECD (2014) OECD Competition Assessment Review: Greece. OECD: Paris. <http://www.oecd.org/daf/competition/Greece-Competition-Assessment-2013.pdf>

Detailed example: Recommendation

This box continues the detailed example that runs throughout this manual.

Based on the Department's analysis it is recommended that the government proceed to develop a competitive tendering process for generics combined with a NPIP maximum reimbursement policy.

Reasons:

A competitive tendering process provides the greatest potential cost savings to the healthcare system. Using 2011 pharmaceutical costs as a benchmark, competitive tendering could have yielded total drug cost savings in excess of USD 2.9 billion, which is more USD 0.6 billion more that might have been achieved using a comparator country approach. While the size of the savings that a claw back approach might feasibly achieve are difficult to estimate as they depend on the price effect increased competitive pressures under competitive tendering and the ability to effectively monitor rebates, it is anticipated that they would also be much less than under competitive tendering.

A competitive tendering process would also have the benefit of revealing competitive generic prices and net pharmacy returns on dispensing pharmaceuticals. Accordingly, it would provide a clearer basis for the development of optimal pharmacy fees for dispensing and other medical services. The additional savings that would be anticipated from competitive tendering would also provide possible funding for enhancing the health system role of pharmacists.

The implementation of a competitive tendering process would have to overcome some major obstacles. An effective competitive tendering process would have to be developed, pharmacy remuneration would have to be redesigned and the generic distribution framework would have to be reorganised. Significant ongoing costs would also be required in relation to the tendering process. However, these costs and obstacles are outweighed by the potential cost savings and health system benefits that competitive tendering would be expected to deliver.

The main obstacle to implementation of a competitive tendering process is likely to be stakeholder opposition. Particularly strong objections can be expected from generics suppliers which will be forced to operate in a strengthened competitive framework. Strong pharmacy sector opposition would also be anticipated, potentially subject to enhancements to their existing remuneration framework.

As a possible second best option, the Department recommends the adoption of a comparator country price cap approach employing low-cost comparator countries. As compared to a rebate claw-back approach, a comparator country approach would deliver more certain cost savings. Also, as compared to either a competitive tendering or rebate clawback approach, comparator country price caps entail limited implementation and ongoing costs and obstacles.

In conjunction with implementation of any of the above options, to ensure a high level of generic dispensing, it is recommended that a maximum reimbursement policy be adopted under the NPIP based on the relevant generic price. While this policy might encounter significant patient group opposition, it would help to ensure a high level of

generic substitution while retaining the option for patients to pay for brand products out-of-pocket, or where applicable, through private insurance.

In comparison, using a mandatory pharmacy substitution approach to promote generic substitution would entail substantial enforcement costs and would likely encounter stronger patient group opposition. Maintaining financial incentives for pharmacies to dispense generics would substantially reduce the net benefits from competitive generic drug prices and require the use of a dispensing fee structure not based on actual costs.



Chapter 8

Ex post evaluation

Regular ex-post evaluations of competition assessments should be performed to assess whether the option chosen following the review process had the anticipated effects and was the most appropriate. This allows the assessor to identify any error that may have been made and the causes, so that the competition assessment process could be improved.

Competition assessments inevitably involve making assumptions about the likely effects on competition of the policy alternatives examined and, therefore, there is some uncertainty on the actual costs and benefits of each option. Only time can tell whether the option chosen was the most appropriate to fulfil the objective while addressing concerns about competition distortions.

The option selected may have had consequences that had not been predicted and may have led to a different outcome from the one originally forecast. This may have been due to an incomplete or imperfect analysis, or to factors that could not have been predicted at the time in which the competition assessment was performed. Only an ex-post assessment can allow observers to determine if the original analysis was complete and correct. Ex-post evaluation can find that even though the original analysis was reasonable, given the information available at the time, the ultimate outcomes suggest that policy options should be reconsidered.

Box 54. Impact evaluation of State aid

The European Commission has recently established new evaluation requirements in State aid control. The Commission will require evaluations for a selected number of State aid schemes in order to identify their impact and allow for improvements to subsequent schemes and, potentially, to future State aid rules.

Evaluation should aim in particular at providing solid evidence useful in answering

questions such as whether the aid really changed the behaviour of the beneficiaries, whether the effects differed significantly across beneficiaries, whether the scheme led to spill-over effects on the activity of other firms, whether the scheme contributed to the desired policy objective or whether the chosen aid instrument was the most appropriate one.

The Commission published in May 2014 a methodological guidance paper describing the most relevant methods for counterfactual impact evaluations, in line with the most recent literature and the best practices at international level. The guidance paper also describes the key elements of the evaluation plans, in order to assist Member States in preparing and conducting evaluations of their aid schemes.

The aim of the ex-post assessment is therefore to determine the effective impact on competition of the option selected and verify it was the most appropriate choice. Ideally assessors will perform this step by comparing the outcome of the selected option against all the alternatives considered at the time of the assessment. However such an analysis can be too complex and time consuming. Hence a single counterfactual will normally be selected.

Selecting appropriately the counterfactual is very important to ensure that the exercise is valuable and informative. The counterfactual should be the option that would have been preferred if the competition impact assessment had not been undertaken. When the original competition assessment concerned an existing policy that was then changed, the counterfactual should be the continuation of the policy eliminated. Instead, when the assessment concerned a new policy, the analysis should consist in comparing the effect of the policy selected, against the one originally proposed. However, if the option chosen after the competition impact assessment was the one originally preferred, the counterfactual should be the second best alternative which was considered at the time.

To ensure that analysis is impartial and objective, the ex-post assessment should be performed by a different team from the one that performed the original competition assessment. This should guarantee that the selection of the counterfactual and the subsequent is not affected by the desire or need to prove that the original assessment process had reached the appropriate conclusions. Lessons can be learnt only if genuine mistakes are identified.

The results of an ex-post assessment can also be influenced by the amount of time that has elapsed since the decision. On the one hand, if only a short period has gone by there may not be enough data in order to estimate correctly all effects of the option chosen. On the other hand, if too much time elapses it is more difficult to separate the effects of the policy from other events that may have affected the sector. This is especially true

for very dynamic and innovative sectors. Hence, a balance needs to be struck between these two opposing effects. We suggest that 2 to 3 years should elapse before an ex-post assessment is carried out.

Box 55. Ex-post assessment of the removal of a regulation that imposed entry restrictions

A specific sector had a regulation that allowed entry by new players only when the existing ones considered that the market was able to support a new supplier and its skills and expertise had been verified. The aim was to ensure that the quality of the supplier was verified to protect consumers from unsafe or substandard services. The regulation was suppressed on the ground that it limited the number of suppliers, thus distorting competition, and that the same result could be achieved by introducing a licensing regime.

The ex-post assessment should verify whether, following the removal of the barrier to entry, the quantity and the variety of services on offer in the sector had increased and/or their price decreased. It should also ascertain if consumers had suffered by these changes, for example if the number of complaints had increased. The outcome of the licensing regime should then be compared with the market conditions that would have prevailed if the regulation had not been removed (the counterfactual). If no major changes had occurred in the sector, possibly the counterfactual could be the state of the sector before the intervention. However if changes has occurred it would be necessary to estimate what would have happened if the change had not occurred.

Reconstructing the counterfactual is clearly the major challenge in this kind of exercise. Surveys of consumers, suppliers or other market participants can help to obtain data and identify changes that have affected the sector but have not been due to the regulatory change (e.g. a technological shock, a large merger, a fall in demand, etc.). With sufficient data, regression or other statistical techniques can be used to estimate how certain variables would have evolved in the counterfactual scenario.

Box 56. Ex-post assessment

UK market study on pharmacies

In 2010, the UK's Office of Fair Trading released an ex post assessment of its 2003 market study "The control of entry regulations and retail pharmacy services in the UK." This ex post assessment evaluated the impacts of government actions to implement the 2003 recommendations which had, as it turned out, not been as extensive as the recommended changes. See OFT (2010) Evaluating the impact of the 2003 OFT study on the Control of Entry regulations in the retail pharmacies market. (See UK OFT (2013) http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.of.gov.uk/shared_of/reports/Evaluating-OFTs-work/OFT1219.pdf)

German analysis of recovery and recycling of sales packaging

In July 2012, the Bundeskartellamt launched a sector inquiry into compliance schemes (“dual systems”) which analysed the effects of liberalisation on the market for the recovery and recycling of sales packaging discarded by private end consumers. The sector enquiry was based on detailed data covering a period of 19 years. The corresponding report showed that as a result of liberalisation annual total costs for the collection of waste packaging from households and recycling of around EUR 2 billion had fallen to under EUR 1 billion a year. (See Bundeskartellamt (2012), www.bundeskartellamt.de/SharedDocs/Meldung/EN/Pressemitteilungen/2012/03_12_2012_SU-duale-Systeme.html).

Irish study on taxis

A 2014 study of Ireland’s taxi markets examines the subsequent market development and impacts from a major liberalisation that occurred in 2000. (See Paul Gorecki (2014), “Ex-post assessment of government intervention in the taxi market in Ireland: 1978-2014”, [https://one.oecd.org/document/DAF/COMP/WP2\(2014\)6/en/pdf](https://one.oecd.org/document/DAF/COMP/WP2(2014)6/en/pdf)).

Another difficult decision is which review to assess ex-post. Ideally ex-post assessment should be performed with some regularity and should focus on the more difficult or controversial reviews.

The candidate interventions for ex-post assessment should be identified when the competition assessment reviews are being completed so that data on the market and its evolution can be collected. This will simplify the work once the ex-post assessment is performed. At that stage the counterfactual should also be identified, as after some time it will be harder to determine what other options were considered and discarded.

Box 57. Australia: Ex post assessment when no ex ante assessment has been performed

In Australia, exemptions from the regulatory review process for new legislation can be granted in exceptional circumstances by the Prime Minister and in writing. Such exemptions are granted only when :

“truly urgent and unforeseen events arise, requiring a decision before an adequate RIS can be undertaken”, or

“where there is a matter of budget or other sensitivity and premature announcement (even of options) could cause unintended market effects or lead to speculative behaviour which would not be in the national interest.”

When such an exemption is granted, a “post-implementation review” is required for the regulation that received the Prime Minister’s exemption.

Source: Australian Government (2013).



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Statistical Classification of Economic Activities in the European Community http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&StrNom=NACE_REV2&StrLanguageCode=EN&IntPcKey=&StrLayoutCode=HIERARCHIC

The North American Industry Classification System <http://www.census.gov/eos/www/naics/>



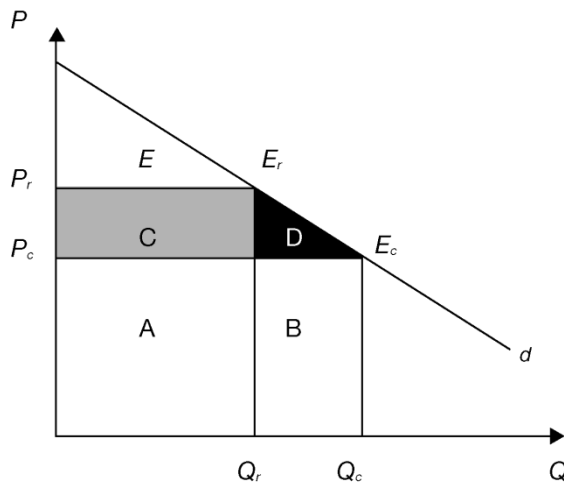
Annex 1.

Derivation of change in equilibrium benefits

This annex derives the consumer benefits that arise when moving from a restrictive regulation equilibrium to a competitive equilibrium. Two demand curves are examined: the linear demand curve and CES demand curve.¹ E_r shows the equilibrium with the restrictive regulation; E_c shows the equilibrium point with the competitive regulation. Finally, a simplified formula is calculated for a CES demand function.

1. Demand function

1.1. Linear demand



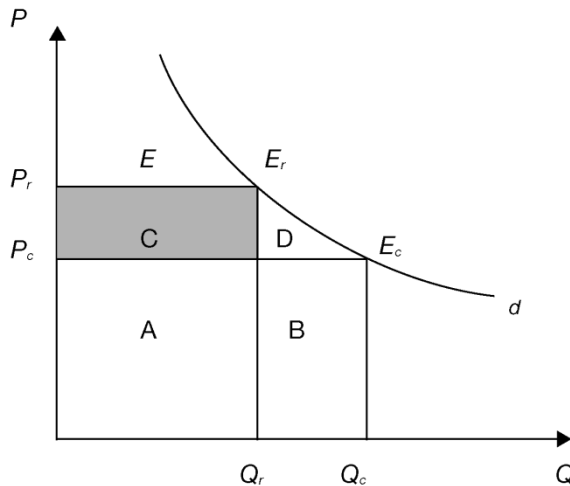
¹ A linear demand curve is easy to model with an equation, however a CES demand curve may exhibit properties that are more in conformity with real demand curves. Both may be considered simplifications, which will vary by product and which may, at times, exhibit complex behaviours.

With a linear demand curve, the consumer benefit of moving from the restrictive equilibrium to the competitive equilibrium is the sum of areas C and D. The equation for the consumer benefit (CB) from changing from the restrictive equilibrium to the competitive one is:

$$CB = C + D = (P_r - P_c)Q_r + \frac{1}{2} (P_r - P_c)(Q_c - Q_r)$$

1.2. CES demand

The CES demand function is curved. It has the quality that the elasticity of demand is not dependent on price or quantity, i.e., the location in the curve. Despite the substantial differences in the demand curve itself, the change in equilibrium from restricted to competitive has essentially the same formula as for the linear demand model.



The equation for consumer benefit is very close to that for the linear demand model:

$$CB = C + D \approx (P_r - P_c)Q_r + \frac{1}{2} (P_r - P_c)(Q_c - Q_r)$$

Formula of benefit estimates

The equation for change in consumer benefit can also be derived from revenue and the percent price change, where the price change ratio, ρ is

derived from a table of estimated impacts by type of regulatory restriction. (A 10% price change in moving from the regulatory restriction to the competitive outcome is represented as $\rho = 0.10$). The absolute value of the price change from the restrictive price P_r to the competitive price P_c is then given by $\Delta P = \rho P_r$ where $0 < \rho < 1$. The smaller the price change, the closer ρ is to 0.

The consumer benefit CB can be derived from the linear demand or the approximation of the CES demand, in which changes in price and quantity are represented as ΔP and ΔQ , respectively.

$$\begin{aligned} CB &= \Delta P Q_r + \frac{1}{2} \Delta P \Delta Q \\ &= \rho P_r Q_r + \frac{1}{2} (\rho P_r) (\epsilon \rho Q_r) \\ &= \rho P_r Q_r + \frac{1}{2} (\epsilon \rho^2) P_r Q_r \\ &= \left(\rho + \frac{1}{2} \epsilon \rho^2 \right) R_r \end{aligned}$$

If industry elasticities are known, then they may be substituted into this equation along with the standardised price change and the level of revenue, R_r .

In the standard case when such elasticities are not known, a generic standard elasticity of 2 is assumed, representing a moderately elastic good. Substituting $\epsilon = -2$, the result is simplified to:

$$CB = (\rho + \rho^2) R_r$$

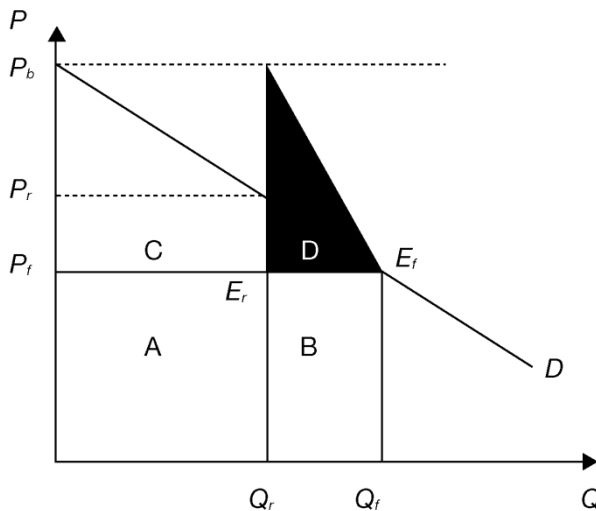
Quantity change

The previous estimates have been based on change in price. There are various situations in which there will be only a change in quantity from eliminating a restriction, not a change in nominal price. For example, the taxi prices may be regulated at the same time as the number of taxi licenses is restricted. Opening up the licenses to more drivers will increase the quantity of the service provided but not the price. The value of changing

quantity provided in the presence of unchanged price regulation can be estimated.

A precursor is to make a reasonable estimate of the change in quantity (restriction) as a result of the regulation. If the regulation rationing quantity is already in place, the challenge is to identify the quantity that would prevail absent the regulation. Sometimes quantity restrictions are large, while sometimes they may be relatively small, so general rules for this are difficult to elaborate. It is worth noting, though, that there are examples, such as in the Irish taxi liberalisation, in which the quantity has increased by more than 300% after liberalisation.

Suppose that a product is provided in the more competitive allocation at a fixed price P_f and the point Q_f on the demand curve's intersection with that price. With the rationing, the price remains P_f but the quantity is reduced to Q_r . For consumers who lose the product as a result of the rationing (or quantity restriction) they lose their consumer surplus.



The amount of consumption affected is $Q_f - Q_r$. However, not only the marginal customers will be affected. Rationing will affect all consumers with some probability. When taxis are rationed, all customers may be affected. Assuming an equal probability of each consumption unit being rationed, the consumer harm will be based on the area under a “compressed” version of the demand curve, depicted as the shaded triangle with area D.

The consumer benefit from moving from the restricted quantity out to the demand curve, where the demand curve has the slope $-m$, is:

$$CB = \frac{1}{2}(P_b - P_f)(Q_f - Q_r)$$

Note that:

$$P_b - P_f = mQ_f$$

Defining slope m with reference to two points, the point (Q_r, P_r) is selected as a comparator to the point of:

$$-m = \frac{P_f - P_r}{Q_f - Q_r}$$

As a result,

$$P_b - P_f = \frac{P_f - P_r}{Q_f - Q_r} Q_f$$

The consumer benefit from eliminating rationing can then be rewritten as:

$$CB = \frac{1}{2} \frac{P_f - P_r}{Q_f - Q_r} Q_f (Q_f - Q_r)$$

Which simplifies to:

$$CB = \frac{1}{2}(P_f - P_r)Q_f$$

$$CB = \frac{1}{2}(1 - \rho)P_f Q_f$$

$$CB = \frac{1}{2}(1 - \rho)R_f$$



Annex 2

Effects of eliminating competitive restriction by type of competitive constraint

This annex provides estimates of the potential price impact of moving to pro-competitive outcomes based on an OECD database of quantitative estimates of ex post impacts from regulatory changes. This annex will be updated occasionally in the future to reflect additional sources in the database, with updated versions available on the Competition Assessment Toolkit web page of the OECD. The underlying summaries of the quantitative results will be available and searchable.

Table 6. Mean and range of price impact from moving to pro-competitive options (Nov 2014 version)

Mean price change (ρ) *	95% Confidence Interval	Number of results	Category and sub-category of regulatory restriction
-0.20	-0.23 to -0.16	111	(A) Limits the number or range of suppliers
-0.19	-0.28 to -0.10	28	1 Grants exclusive rights for a supplier to provide goods or services
-0.23	-0.27 to -0.19	55	2 Establishes a license, permit or authorisation process as a requirement of operation
-0.15	-0.24 to -0.060	10	3 Limits the ability of some types of suppliers to provide a good or service
-0.19	-0.24 to -0.13	4	4 Significantly raises cost of entry or exit by a supplier
-0.12	-0.17 to -0.070	14	5 Creates a geographical barrier to the ability of companies to supply goods services or labour, or invest capital

Mean price change (ρ) *	95% Confidence Interval	Number of results	Category and sub-category of regulatory restriction
-0.18	-0.23 to -0.14	45	(B) Limits the ability of suppliers to compete
-0.19	-0.24 to -0.14	22	1 Limits sellers' ability to set the prices for goods or services
-0.14	-0.24 to -0.053	8	2 Limits freedom of suppliers to advertise or market their goods or services
-0.19	-0.24 to -0.081	13	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
-0.28	-1.00 to 0.22	2	4 Significantly raises costs of production for some suppliers relative to others (especially by treating incumbents differently from new entrants)
-0.20	-0.26 to -0.14	29	(C) Reduces the incentive of suppliers to compete
-0.28	-0.48 to -0.080	5	1 Creates a self-regulatory or co-regulatory regime
-0.10	-0.13 to -0.064	11	2 Requires or encourages information on supplier outputs, prices, sales or costs to be published
-0.25	-0.35 to -0.16	13	3 Exempts the activity of a particular industry or group of suppliers from the operation of general competition law
-0.20	-.30 to -0.10	18	(D) Limits the choices and information available to customers
-0.32	-0.49 to -0.15	7	1 Limits the ability of consumers to decide from whom they purchase
-0.13	-0.24 to 0.009	9	2 Reduces mobility of customers between suppliers of goods or services by increasing the explicit or implicit costs of changing suppliers
-0.074	-0.33 to 0.011	2	3 Fundamentally changes information required by buyers to shop effectively

Note: * Ratio of the price difference (between the competitive and uncompetitive price) and the uncompetitive price.

Source: Revised calculations using method in operational manual.

About the OECD Competition Assessment Toolkit

The OECD Competition Assessment Toolkit helps governments to eliminate barriers to competition by providing a method for identifying unnecessary restraints on market activities and developing alternative, less restrictive measures that still achieve government policy objectives. It consists of 3 volumes: Principles, Guidance and Operational Manual. Read more about the toolkit at [oe.cd/cat](https://www.oecd.org/cat).



Toolkit Principles

Volume 1 sets down the toolkit principles, describing benefits of competition, the checklist and examples of government processes.



Technical guidance

Volume 2 provides detailed technical guidance on key issues to consider when performing a competition assessment.



Operational manual

Volume 3 is an operational manual which provides a step-by-step process for performing competition assessment.

The OECD Competition Assessment toolkit helps governments eliminate barriers to competition. It consists of three volumes.

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