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Pharmaceutical Pricing Policy

A TAXONOMY AND FRAMEWORK FOR DESCRIBING AND ASSESSING PHARMACEUTICAL PRICING POLICIES

**To be held at the Château de la Muette, Paris 16 (métro la Muette)
December 1-2, 2005, beginning at 9.30 on the first day and concluding at 12.00 on the second day**

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NOTE BY THE SECRETARIAT

1. This paper presents draft proposals for describing pharmaceutical pricing policies and assessing their impact in the course of the OECD Project on Pharmaceutical Pricing Policy. The paper is presented as a working draft for discussion, with further development and refinement to follow. The first intended use of this taxonomy and assessment framework will be to guide work on the case studies undertaken in the Project. It will later provide structural support for the analysis presented in the final report on the Project, which will draw upon findings from the case studies and literature reviews, building on work already undertaken to describe and assess pharmaceutical pricing policies in the OECD and elsewhere.

2. Experts participating in the 1-2 December meeting of experts on pharmaceutical pricing policy are invited to:

- **COMMENT** on the draft proposals, including the appropriate scope of inquiry for this study and the proposed definitions of terms and approaches; and
- **SUGGEST** refinements, improvements, revisions or enhancements.

TABLE OF CONTENTS

NOTE BY THE SECRETARIAT	2
Introduction	4
Scope of inquiry	4
Describing pharmaceutical pricing policies	4
Differentiating types of prices	4
The type of price regulation.....	5
Application of pricing policies	6
The timing of pharmaceutical pricing decisions.....	7
Describing the price regulation process	7
Nature of pricing process.....	8
Key actors and their roles in the pricing process	8
Factors considered in pricing decisions.....	8
The scope of regulation and existence of specific rules	9
Other related regulation schemes.....	9
Transparency and accountability of the process	9
Regulation of other determinants of prices.....	10
Assessing the impact at the national level.....	10
Availability and accessibility of pharmaceuticals	10
Price levels.....	10
Pharmaceutical expenditure levels	10
Affordability	11
Market characteristics, competition and efficiency	11
Information given to the regulator on production costs.....	11
Assessing the cross-national impact of pharmaceutical pricing policies	11
GLOSSARY OF TERMS	13

Introduction

3. The aim of this paper is to define the scope and terms of inquiry to be used in the OECD Pharmaceutical Pricing Policy Project. A first section sets forth the scope of the study and defines key terms and their use. A second section provides an explanation of how pharmaceutical pricing policies will be described and categorised, distinguishing among various types of policies. The following two sections propose an approach for assessing the national and cross-national impacts of pharmaceutical pricing policies. The final section presents a glossary of technical terms to be used in the Project.

Scope of inquiry

4. The OECD Pharmaceutical Pricing Policy study will focus primarily on *those policies implemented by governments intended to set or affect prices paid by consumers or other purchasers within a country for pharmaceuticals*. A further focus will be on those pharmaceuticals that are subsidised by national health systems or public health insurance funds. While the primary focus will be on pharmaceuticals used by patients outside the hospital (purchased from a pharmacy or other retailer), policies pertaining to pharmaceuticals dispensed through hospitals will be noted.

5. While the study, by design, will focus on pricing policies, it will not be possible to assess these without provision of adequate context. *Both the nature and extent of context required to meet the Project objectives should be a key subject of discussion at the expert meeting*. For example, policies pertaining to drug reimbursement will clearly be relevant, as will policies that affect the availability and affordability of pharmaceuticals, and policies that affect the supply of pharmaceuticals to patients (including regulation of pharmacists/pharmacies). The question of how much detail is required, in terms of attention to important decision-making processes that precede pricing policy decisions, such as policy decisions by regulators to certify a product for sale (usually based on a judgment regarding safety), and decisions by insurers whether to include a given product on a positive list, negative list, or formulary, should be subject to discussion by the expert group.

6. The taxonomy and framework for assessment presented in this paper focuses on pharmaceutical pricing policy.

Describing pharmaceutical pricing policies

7. A range of important issues pertaining to how pharmaceutical pricing policies will be described in the OECD study are put forward below. These issues include differentiation of different types of prices that may be present in a system, approaches to pricing policy, and timing for pricing decisions.

Differentiating types of prices

8. It is essential to distinguish among various types of prices in OECD health systems. Depending on design of the health-system and the approach taken to regulation of pharmaceuticals, some or all of the following types of prices may be distinguished and addressed through the pricing policies set by government:

- **List price.** The manufacturers' posted price. This price does not include any discounts or other incentives offered by manufacturers.
- **Manufacturer price.** Also referred to as the ex-factory price. This is the price that pharmaceutical companies receive for their products.

- **Reimbursement price** (or **reimbursed price**). The maximum amount that the insurer will pay towards the cost of a subsidised pharmaceutical.
- **Retail price**. The price charged by retail pharmacists to the general public. It includes any pharmacy mark-up or dispensing fees.
- **Wholesale price**. The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

The OECD Pharmaceutical Pricing Policy Project will treat these types of prices separately and examine the ways in which these types of prices are addressed in, or affected by, the pricing policies used in OECD member countries.

The type of price regulation

9. For the purposes of the Project, the Secretariat proposes to distinguish among three general approaches taken to pricing policy in OECD countries: “free” pricing (in which manufacturers set prices at will, according to what the market will bear), direct control of prices (in which government sets prices through regulation or negotiation with manufacturers), and indirect control of prices (in which government influences the reimbursement prices, or prices paid by insurers).

Free or market pricing

10. Among OECD countries, free pricing – under which a manufacturer sets the price(s) at which to sell its product to buyers in a given market without intervention from the State – is relatively rare.¹ In some cases, free pricing is offset by other regulation schemes that either imply the payment of rebates by the pharmaceutical industry beyond a pre-defined threshold of manufacturers’ profits (as in the UK) or leading to financial compensation if drugs are proved to have been sold at ‘excessive price’ (as in Canada).

11. In unregulated markets, as in the US, prices may be negotiated by group purchasers, such as insurers. The way in which prices are negotiated by purchasers in such markets is relevant to the inquiry undertaken in the OECD Project, in that these negotiations collectively determine relative price levels, one key outcome of any national pricing policy (in this case, the policy of free pricing for pharmaceuticals).

Direct control of prices

12. Direct control of drug prices is used in many countries and may take various forms. A number of characteristics of the price-setting process are of interest in this study, including the nature of the pricing process, the identity of the regulator, the role played by stakeholders, and the criteria used to set prices. A detailed description of the characteristics of the price-setting process that will be studied is presented later in this paper.

1 One point of inquiry in the OECD Pharmaceutical Pricing Policy Project will be whether, in fact, manufacturers are legally free to market their products at the price they choose in certain OECD countries, but choose not to do so. This might be the situation, for instance, if manufacturers do not believe the market will be adequate, taking into account the importance of *insurance reimbursement policies*, which may be set or influenced by government policies (particularly in countries with a single insurer or multiple insurers following common reimbursement rules).

Indirect price control or control of reimbursed price

13. Insurers or other third-party payers for health care establish reimbursement prices for pharmaceuticals, which constitute the maximum price they will pay towards the cost of a pharmaceutical. Sometimes the reimbursement price designated by the insurer includes a portion to be paid by the patient out-of-pocket (either a co-payment, a particular contribution amount; or co-insurance, a pre-determined share of the price).

14. A regulatory body may influence or control the reimbursed price used by insurers, which can be said to constitute a form of indirect price control.

15. For example, in some countries, so-called reference prices are defined by a regulatory entity, which sets a price cap that serves as the basis for the reimbursement by the payer (social health insurance scheme or national health service).² The reference price refers to a designated group of pharmaceuticals, which may be variously defined. Patients may have to pay a price that is higher than the reimbursement price, where the retail price of a pharmaceutical exceeds the reimbursed price (as defined by the reference price).

16. Reference pricing has spread among OECD countries since its first adoption by Germany in 1989. These policies have to be precisely described to measure their impact, according to the following attributes: What is (are) the level(s) of grouping? Are patented drugs included in groups? What is the formula used to compute the level or reference price?

17. All of these aspects are important to evaluate the potential of the system and its impact. When reference prices apply to narrow groups of bio-equivalent products (same active ingredient), potential savings are less important than if they are used for larger groups gathering products according to their therapeutic effects. However, equivalence in larger groups is often contested by stakeholders. The possibility to include new patented drugs in existing groups is also an important feature. It clearly puts pressure on prices of new drugs likely to be included in such groups and is generally highly contested by the industry. Finally, the level of price chosen to set the reference is important both for potential savings and for the provision of the market.

Application of pricing policies

18. Defining the pharmaceuticals subject to attention in pricing policies is another consideration of great importance. Various drugs may be treated differently in regulatory schemes, and pricing policies may not apply to all types of drugs. The OECD Project will consider the application of pricing policies to branded pharmaceutical products, both on-patent and off-patent, and generic drugs. Policy description and assessment undertaken in the Project will consider the treatment of pharmaceuticals available by prescription, over-the-counter (OTC) and in hospital. The Project will look assess whether and how pharmaceuticals are treated as special cases in the pricing policy process, such as, for example, drugs defined as particularly innovative or costly, where these are singled out for special treatment.

2 Importantly, reference pricing can also be used by insurers, whether publicly or privately financed and administered, in setting reimbursement levels. Reference pricing is a tool deployed not only by regulators.

The timing of pharmaceutical pricing decisions

Regulation at entry on the market

19. Price regulation often occurs at the time of a product's market entry. This may be the case when prices of all types of drugs are regulated (including OTC products that are not reimbursed) and when the pharmaceutical benefit is defined through negative lists – which means that every drug entering the market is immediately reimbursed by default, until a decision of exclusion is made.

Price regulation as part of national formulary design

20. In a number of countries, price regulation is closely linked to inclusion of the drug in the positive list or formulary. In some countries, an agreement on the price with the manufacturer is a pre-requisite for inclusion in the list. In other cases, the price is taken into account in formulary decisions, particularly when economic evaluation plays an important role. In these cases, though there is no explicit price regulation, prices are put under pressure. The UK represents an interesting feature in that the traditional system of free pricing and negative lists was enhanced by the recourse to economic evaluation (by the National Institute for Clinical Excellence) for determining funding by the National Health Service.

Regulation of price changes / existing drugs prices

21. Unfettered introductory pricing does not necessarily equate with manufacturer freedom to change prices following the introduction. For instance, in the UK, pricing at introduction to the market is at the manufacturer's discretion, but further increases are limited. In some countries, manufacturers have the option to apply for price changes but their request has to be approved by the regulating authority. In other countries, negotiations occur on a regular basis: It can be each year or every three years for all the marketed drugs or according to pre-defined terms after marketing (*e.g.* in Switzerland prices are reviewed after 2, 7 and 17 years). The motivations for changes may be found in changes in production costs, in changes in the consumer price index (CPI), in volumes of sales, or in entry of competitors (prior to or after patent expiry), etc.

22. The occurrence of overall price reductions should be noted, as well as the conditions under which they occur: Is there any legislative provision which allows governments to proceed to such reductions? Or were these measures enforced by an exceptional provision?

Regulation of products upon patent expiry

23. One area for particular attention will be to assess the ways in which pricing policies treat brand-name products upon the expiry of their patents, and the pricing of generic drugs. In some countries, products continue to be reimbursed at the price approved initially, which can create opportunities for pharmacy profits, depending on regulation in this area.³

Describing the price regulation process

24. A number of features of the price regulation process will be addressed, including whether it can be characterized primarily as a negotiation or formal decision-making procedure, the entities involved in the process and the roles they play, factors considered in pricing decisions, and other features, as discussed below.

3 Regulations may encourage or require generic substitution.

Nature of pricing process

25. First, the nature of the pricing process should be defined: the price may be either determined through negotiation with the manufacturer, or by decisions taken by either the State or the buyer in light of established criteria for decision-making (in cases where the buyer has monopsony power in a particular market).

Key actors and their roles in the pricing process

Regulatory agent.

26. The identity of the price regulator(s) will be defined as relevant to the pricing process and its outcome. The nature of the price regulating entity or entities varies among countries, ranging from one department of the State itself to an agency composed of stakeholders. In regulatory bodies that include several stakeholders, their identity and roles have to be addressed: Who are the representatives of the State (do they come from health departments, financial departments or industry departments)? Are buyers represented? Is the pharmaceutical industry represented? What are the roles of each participant? Do they have 'voting rights' or simply a consultative role?

Involvement of stakeholders or other actors.

27. Systematic census of the parties involved in the pharmaceutical pricing process should be undertaken. The involvement and roles of the following stakeholders and parties playing a role in the process should be described and assessed:

- The State, with information about departments involved;
- Health insurance funds (if relevant);
- The pharmaceutical industry;
- Medical and pharmaceutical experts and scientists;
- Consumers and/or patients; and
- Other stakeholders (for instance, private health insurance funds providing complementary health coverage, medical and pharmacy profession, etc.).

Factors considered in pricing decisions

28. The set of criteria used to establish prices may be very different between countries but also between types of drugs (according to their degree of innovation, for instance). Among OECD countries, criteria such as the following are used:

- Reference to price(s) set within the country for existing drugs that are judged to be comparable, based on therapeutic equivalence or therapeutic improvement;
- Use of cost-effectiveness analyses, comparing the drug to existing therapies (drug or other types of therapies);
- International benchmarking (or external reference), based on comparison with prices in other countries;
- Expected volume of sales;
- Expected cost of treatment;

- Appropriateness of prescription and/or consumption;
- Expected results in health outcomes (risk-sharing arrangements); and
- Production costs of the drug.

The scope of regulation and existence of specific rules

29. The scope of regulation has to be described: do policies apply only to drugs dispensed in ambulatory care? Or also to drugs sold to hospitals? Are certain drugs (*e.g.*, the ones judged as particularly expensive or innovative) subject to different policies? What policies apply to the pricing of generic drugs?

30. Specific regulations applying to drugs dispensed in hospitals have to be addressed. The mode of funding of hospital drugs (which can be disconnected from price regulation) is also an important matter. Depending on whether drugs are included in global budgets or per-case-payments or are paid on the top of these, incentives to price competition and availability of funds are not the same.

31. Specific regulation may also exist for very expensive and/or innovative drugs; they should be described.

Other related regulation schemes

32. Some countries do not regulate drug introductory prices but have set mechanisms to ensure that the price paid for drug is not 'too high' according to pre-defined criteria. In the UK for instance, return on capital (ROC) of pharmaceutical companies is capped to 21% and companies are asked to refund to the National Health Service any excess profits beyond a tolerance margin. Canada assesses prices after the market entry of a pharmaceutical. If prices paid for drugs are found to be 'excessive' compared to prices paid by other countries, companies have to compensate any 'excess' revenues attained. In France, the increase in pharmaceutical companies' sales revenues is moderated by a rate set each year by the Parliament (+1% in 2005). To the extent that the collective (not company-specific) pharmaceutical sales revenues increase by more than the designated rate, companies are required to furnish rebates to health insurance funds. To assess the impact of these regulation schemes, the refunds or rebates have to be tracked and corresponding amounts evaluated in order to estimate the after-rebate price paid for drugs and possible disconnect between that amount and the amount presented publicly as the price.

Transparency and accountability of the process

33. The transparency of the price regulation process will also be described and assessed. Transparency has been put forward by the pharmaceutical industry as a critical aspect of price regulation, as it increases the ability to assess a new pharmaceutical's market prospects. Transparency of the price regulation process has been established by the European Commission as mandatory for EU member states and has been a point of negotiation in certain bilateral trade agreements. The degree of transparency may be evaluated, in part, by the availability of information on criteria used in the pricing process and on the comprehensiveness of guidelines provided for applications.

34. The extent to which the pharmaceutical pricing policy-making process can be judged publicly accountable will also be reported. Accountability will be assessed by looking at the frequency and the level of information provided on the results of regulator activities, as well as the availability of this information to stakeholders.

Regulation of other determinants of prices

35. Other determinants of the pharmaceutical price paid by purchasers should be described. The regulation of the distribution sector should be described: are wholesalers' and pharmacists' margins regulated? Are distributors legally allowed to negotiate prices with manufacturers? If so, who benefits from price reductions (the distributor, the patient, health insurance)?

36. Values of distribution margins should be collected, where such information can be obtained.

Assessing the impact at the national level

37. The impacts of price regulation, including costs and benefits, to the extent these can be evaluated, must be assessed. It must be noted here that objectives of national regulation may vary from one country to another. These national policy objectives will be noted in the course of assessment, in cases where the objectives are publicly described. Assessment of policy impact will be evaluated according to a common set of measures across OECD countries reviewed, as described below.

Availability and accessibility of pharmaceuticals

38. Delays in market entry due to price regulation have to be considered. Once a drug is licensed by the approval authority, it can be sold by the manufacturer. However, its funding by public or health insurance coverage may require its inclusion on a positive list or a decision from an advisory body. In certain cases, this advice/decision takes the price of the drug into account (in particular, when cost-effectiveness analysis is used). In other cases, the inclusion of the drug in the positive list is a pre-requisite for its pricing by relevant authorities.

Price levels

39. The relative level of prices in a country, compared to other countries, is an essential component of the assessment of price regulation. Comparison of pharmaceutical price levels raises many methodological questions, which have to be addressed, not the least of which is ensuring that the same types of prices (*e.g.*, amount received by manufacturer, amount paid by consumer) are compared. Moreover, the results of any such comparisons must be interpreted with caution. Furthermore, drug prices in any given country must be interpreted in relation to the country's willingness or ability to pay for drugs, given that every country will not seek to have the lowest possible price.

40. In light of the well-known methodological challenges and significant difficulties associated with comparisons, the OECD Pharmaceutical Pricing Policy Project will not include original data collection on pharmaceutical price levels. In the course of the study, existing studies will be reviewed and evaluated for potential use as input to the OECD study. Expert advice as to the availability of information on relative price levels, as well as the relative appropriateness of findings from existing studies as input to the OECD Project, is welcomed by the Secretariat.

Pharmaceutical expenditure levels

41. As cost-containment and efficient health expenditure are goals of many national health policies, we propose to consider the level and evolution of pharmaceutical expenditures in the assessment of drug pricing impact. In particular, the volume-price components of the evolution could be compared to those of other countries, where such data are available.

Affordability

42. In many countries, ensuring that pharmaceuticals are accessible to individuals by avoiding imposition of financial barriers to access is a priority objective of pharmaceutical policies. In addition to looking for national evidence of affordability, such as results from consumer surveys, the Secretariat proposes to include the following indicators of drug coverage: percentage of people benefiting from coverage for pharmaceuticals by insurance or a nationally financed scheme, and the percentage of drug expenditures financed by out-of-pocket payments. The extent to which individuals rely on supplementary or complementary private health insurance to finance costs of pharmaceuticals will also be evaluated.⁴

Market characteristics, competition and efficiency

43. The degree of competition achieved on different segments of national markets should also be considered. However, data useful to assess the degree of competition on in-patent markets will probably be difficult to collect. For instance, the number of substitutes in a therapeutic class may be a proxy to estimate the existence of entry barriers, price reactions to a new entry could be an indicator of the extent of competition, but generally these data are not readily available.

44. The competition on off-patent markets may be easier to assess. The following indicators may be proposed: share of off-patent market in total market, share of off-patent market with generic substitutes (potential generic market) and share of generic sales in potential generic market.

Information given to the regulator on production costs

45. One of the aims of public regulation is to reduce informational asymmetry between the producer and the payer. The level and the nature of information provided in the regulating process may thus be considered as an outcome of the regulation. Information provided to regulators varies from one country to another. It generally includes one or several items among the following:

- Information on the therapeutic value of the drug, according to studies sponsored by the producer. In some countries guidelines for these studies impose a minimum standard of quality. The provided data are sometimes assessed by a separate agency in charge of effectiveness or cost-effectiveness assessment for the purpose of reimbursement decisions. In this case, the price regulator normally relies heavily on the work of this agency.
- Data on production costs of the drug;
- Expected volumes of sales;
- Data on the companies activity (sales revenue, R&D expenditures); and
- Data on products in the pipeline likely to enter the market in the short run.

Assessing the cross-national impact of pharmaceutical pricing policies

46. The level of revenues attained by the pharmaceutical industry is one of the more direct results of national price regulation policies, given that revenues are directly determined by price and volume levels. Nevertheless, evaluating the impact of price regulations on revenues is not a simple assessment. The net

4 This may be assessed qualitatively, by reviewing coverage arrangements in primary health insurance arrangements, and quantitatively, in some cases, where countries have reported data using the System of Health Accounts, which provides a break-down of spending components for particular categories of health care.

impact can be determined by comparison to a situation of free pricing by a monopoly exerting price discrimination among consumers presenting different willingness-to-pay for pharmaceuticals (income being one factor in willingness-to-pay discrepancies, but not the only one).

47. The extent to which loss of revenue associated with pricing policies affects R&D could be addressed in at least three ways.

- First, what is the revenue-elasticity of R&D expenditures? Or in other terms, what is the increase of R&D expenditures when revenue increases by 1%?
- Second, what is the link between increase in revenues (or profitability) and ability to raise funds for investments in the pharmaceutical industry?
- Third, to what extent does national regulation affect choices in R&D investments between alternative disease treatments. This latter issue is likely to prove particularly difficult to assess, but it may be possible to address this through consideration of the incentives created by pricing decision criteria.

48. The impact of pharmaceutical pricing policies on parallel trade between low-price and high-price countries will be considered. The importance of parallel trade should be assessed, as well as its costs and benefits for importer and exporter countries and in a worldwide perspective. This part of assessment will essentially consist in a literature review. As far as possible, possible impact of the threat of parallel trade perceived by the manufacturer on price regulation will be addressed.

GLOSSARY OF TERMS

Technical terms that will be used in the OECD Pharmaceutical Pricing Policy Project are defined below. This glossary was adapted for use in this Project by the OECD Secretariat from one published by the Australian Productivity Commission in a 2001 report, *International Pharmaceutical Price Differences*, although the Secretariat has made a number of modifications to the definitions, particularly ones to broaden their applicability to pharmaceutical pricing policies outside Australia.

Active ingredient. The primary chemical substance contained in pharmaceuticals. Some pharmaceuticals contain more than one active ingredient (combination molecules).

Anatomical Therapeutic Chemical (ATC) codes. ATC codes provide a method of grouping pharmaceuticals according to their anatomical site of action, and therapeutic and chemical characteristics.

Bioequivalence. Pharmaceuticals are considered to be bioequivalent if they contain the same molecule (in the same dosage type and strength) and are released into, and absorbed by the body at the same rate.

Combination molecules. Pharmaceuticals that contain more than one active ingredient. An example is the pharmaceutical containing *amoxicillin* and *clavulanic acid*.

Co-payment. A patient contribution towards the cost of subsidised pharmaceuticals that is defined by the insurer.

Cost-effectiveness analysis. Compares the cost per unit of outcome of alternative therapies with the aim of identifying the most efficient therapy.

Economic evaluation (or **pharmacoeconomic evaluation**). An assessment the clinical and economic impact of pharmaceuticals, requiring evaluation of the costs and health benefits to patients.

Generic drug (or **generic equivalent**). A drug which is the bioequivalent of a brand-name drug, and which is allowed to be sold after the brand-name drug's patent has expired.

Generic substitution. Substitution of a generic bioequivalent version by the pharmacist.

Indications. Denotes the situations (such as symptoms) in which a pharmaceutical may be used.

Innovative pharmaceuticals. Pharmaceuticals for which there are no pharmaceutical alternatives, and with efficacy, quality of life and/or safety improvements, including better modes of delivery of active ingredients.

International price benchmarking (or **external reference pricing**). The practice of comparing pharmaceutical prices across countries, usually for the purpose of determining reimbursement prices.

List price. The manufacturers' posted price. This price does not include any discounts or other incentives offered by manufacturers.

Manufacturer price. This is the price that pharmaceutical companies receive for their products.⁵

Marketing approval. Before a new pharmaceutical is sold in the market, the supplier first must obtain marketing approval from the relevant authority. The quality, safety, and efficacy of the product are assessed before awarding marketing approval.

Molecule. Active ingredient.

Pharmaceutical. Chemical entities that are designed to treat or prevent a variety of illnesses and conditions. May be available in many different forms.

Price-volume agreement. The agreed price of a pharmaceutical is based on a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the pharmaceutical is usually reviewed downwards.

Reference pricing. The practice of setting a ceiling on the amount that will be reimbursed to patients or pharmacists for defined groups of molecules. For example, it might involve setting a maximum reimbursement price for a group of molecules based on the price of the cheapest product in the group.

Reimbursement price (or reimbursed price). The maximum amount that the insurer will pay towards the cost of a subsidised pharmaceutical. In some cases, the manufacturer or retailer may be free to price above the reimbursement price, leaving the patient to pay the difference out-of-pocket (or through complementary private health insurance).

Retail price. The price charged by retail pharmacists to the general public. It includes any pharmacy mark-up or dispensing fees.

Therapeutic group. Group of molecules for treating the same condition.

Therapeutically interchangeable. When two molecules both deliver the same therapeutic (health) benefits to patients.

Wholesale price. The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

5 The Secretariat believes this definition is likely to require further precision. This will be determined in the course of conducting the OECD Project.