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Pharmaceutical Pricing Policies in a Global Market

Chapter 4

The Impact of Pharmaceutical Pricing Policies on Performance in Meeting Health Policy Goals

This chapter reviews OECD countries' efforts to achieve prompt access to, and appropriate use of, effective medicines, to control pharmaceutical expenditure and to increase value for money in public pharmaceutical expenditures. It begins with an assessment of the role of pharmaceutical pricing and reimbursement policies in promoting public health. Analysis of the impact of pricing and reimbursement policies on pharmaceutical price levels follows. In the subsequent section, the means by which these policies are used to contain costs is examined. The final section looks at how successful pharmaceutical pricing and reimbursement policies are in getting good value for money in pharmaceutical spending

Introduction

As is true in other areas of health policy, pharmaceutical policy decisions may well require trade-offs across competing policy objectives. The primary reason why policy makers intervene in pharmaceutical markets is, of course, to promote public health by fostering prompt access to effective medical treatments. And as elsewhere, payers are increasingly concerned with being able to demonstrate that they attain good value for money in their expenditures in pharmaceuticals.

Subsidisation of individuals' pharmaceutical consumption limits the likelihood of access being threatened on affordability grounds. But public subsidisation of individuals' pharmaceutical consumption often creates pressure to contain costs. Policy makers respond in a number of different ways that attempt to control both price and volume, but these force trade-offs with other policy goals.

Promoting public health

Pharmaceuticals play an important role in the prevention and treatment of disease. Innovative medicines are one of the key factors in medical advances that have helped populations worldwide to live longer and healthier lives. Pharmaceutical breakthroughs in the past decade have been responsible for undisputed advances in preventing and treating diseases, such as AIDS, cervical cancer and influenza. Innovations with broader, but less dramatic public health impact, such as new forms of asthma medicines, have also made it possible for patients to be treated with greater convenience and comfort.

Recognising the central role of pharmaceuticals in the practice of medicine today, policymakers in all OECD countries have intervened significantly in pharmaceutical markets in their efforts to foster prompt access to effective medical treatments. Good access to medicines depends on a number of conditions, primarily availability and affordability. At least in the short term, policies to ensure availability and promote affordable access may most readily appear to be at odds with cost-containment objectives. However, as discussed below, certain pharmaceutical pricing and reimbursement policies aid in meeting both objectives.

Ensuring prompt access to effective medical treatments

Below we identify and assess various pharmaceutical pricing and reimbursement policies that impact on access to effective medical treatments.

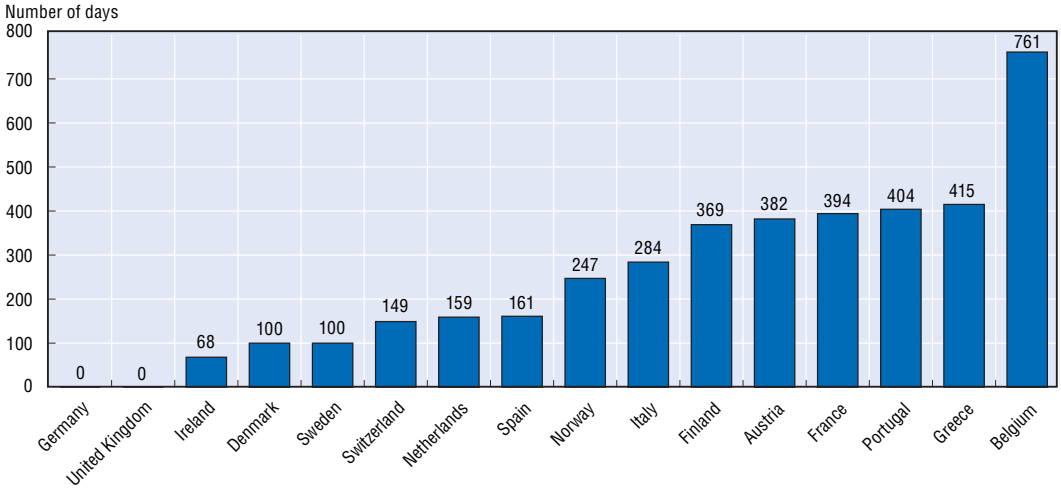
Pricing and reimbursement policies explain only a small part of differentials in drug availability in OECD countries

Availability of medicines on the market depends on several factors discussed earlier in this report, including manufacturers' launch decisions and factors pertaining to marketing approval. The most obvious way pricing and reimbursement policies affect availability is in

the delays in issuing pricing and reimbursement decisions; another way is via the potential influence on manufacturers' launch strategies.

Figure 4.1 illustrates the variation across several European countries in the average time from a manufacturer's pricing and/or reimbursement application to decision for drugs approved for marketing between 1997 and 2001. These data show considerable variation, with the average delay in Belgium being particularly long – almost twice as long as the country with the second longest delays, Greece. At the other extreme, reimbursement and pricing delays do not exist in Germany and the United Kingdom in which drugs are reimbursed as soon as they are approved, unless or until added to the negative list. More recent data suggest that some countries (notably Austria, Belgium and Finland) have made substantial progress in reducing these delays – perhaps in response to the EU Transparency Directive[1] – although delays were noted to have increased in most countries (PICTF, 2006).

Figure 4.1. **Average number of days from pricing and reimbursement application to decision, 1997-2001**



Note: The data pertain to 78 pharmaceutical products granted marketing approval – between 1 January 1997 and 30 June 2001 – through the European Commission's centralised or mutual recognition procedures. The data were derived from a questionnaire sent to the holders of marketing authorisations for each of these products in each of 14 EU member states (excluding Luxembourg) plus Norway and Switzerland. The total delay calculated for each drug includes three types (where relevant): 1. Pricing delay – the elapsed time from the date the pricing application was made to the date price approval was granted; 2. Reimbursement delay – the elapsed time from the date the reimbursement application was made to the date the company "was first informed about the reimbursement decision"; 3. Publication delay – (only in countries for which publication of a decision in an official journal is a prerequisite for reimbursement) the elapsed time from the date the company was notified of the reimbursement decision to the date the authorities published the decision.

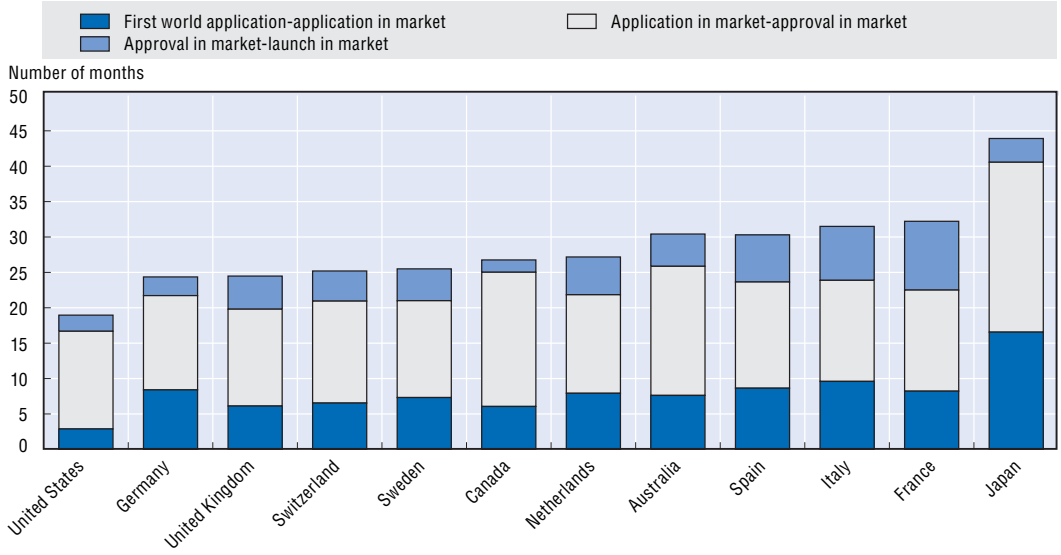
Source: Cambridge Pharma Consulting (2002).

Though firms may launch new products immediately after obtaining approval from the relevant marketing authority, they generally wait for reimbursement and pricing decisions in countries with national coverage schemes using positive lists (*i.e.*, most European countries). In the United Kingdom[2] and Germany, for which the default status of new prescription medicines is coverage, any delay between market authorisation and the launch of new products is not due to pricing or reimbursement decisions. The situation in the United States and Canada is different in that manufacturers may launch their products just after market approval but without any guarantee that they will be subsidised by health

insurance plans. In Canada, private insurers generally cover all marketed drugs (except in Quebec), while public purchasers establish positive lists, with variable and significant delays associated with reimbursement decisions (ranging from 300 to 600 days). In the United States, private and public plans use more or less restrictive formularies, but no listing time is reported.

A 2006 study (PICTF, 2006) looked at delays between first worldwide launch and availability in twelve OECD countries, for the set of new products launched between 1999 and 2003 (Figure 4.2). New products were available most quickly in the United States, with an average 19-month lag. The European countries had lags ranging from 24 to 32 months, with Germany and the United Kingdom having the shortest delays, but only marginally shorter than Switzerland and Sweden. Japan came in with the longest lag, an average of 44 months.

Figure 4.2. **Average number of months between first world application for marketing authorisation and launch in country, 1999-2003**



Source: Pharmaceutical Industry and Competitiveness Task Force, Competitiveness and Performance Indicators 2005, from Association of the British Pharmaceutical Industry calculations

The elapsed time between the first application for marketing authorisation in the world and the launch of the product in a particular market can be divided into three distinct periods: 1) time from first world application to application in market, 2) time from application in market to approval in market, and 3) time from approval in market to launch in market. The third period roughly corresponds with pricing and reimbursement delays in many countries, although there are further launch delays even in those countries (*i.e.,* Germany and the United Kingdom) where pricing and reimbursement considerations should not be a factor. Figure 4.2 shows that delays associated with marketing authorisation explain most of the total delay, accounting for an average of half the total time elapsed between first world application and launch. Canada and the United States had the shortest average delays in launch following market approval. Pricing and reimbursement policies can be designed to minimise delays so as to reduce the potential for inducing delays in product launch. Sweden, for example, took steps to minimise the

impact of its stricter reimbursement assessment process, which took effect in 2002 (Moïse and Docteur, 2007b). Recognising that formal cost-effectiveness requirements can delay market access, the agency responsible for pharmaceutical pricing in Sweden allows a manufacturer to make an application for reimbursement as much as 180 days in advance of expected receipt of market authorisation. It is thus feasible for a product to be placed on the positive list at the same time as the granting of marketing authorisation in Sweden. Similarly, France allows those who have applied to the EMEA for centralised marketing authorisation to file an application to French reimbursement and pricing authorities before market approval has been granted. Moreover, the French Economic Committee on Health Products has committed itself to examine first and with shorter delays, those drugs that have been classified as innovative by the Transparency Commission.[3]

Beyond delays imposed by listing procedures, pricing and reimbursement policies have been found to influence the availability of drugs by affecting manufacturers' launch strategies. Several studies have investigated this issue, examining whether the presence of price regulations in a given country has an effect on launch probability and delay. They used multivariate models to control for the impact of other variables on launch strategies. Danzon *et al*. (2005) found that countries with strict price regulation (as assessed by the authors) had a lower probability of launch, even when market conditions (expected price and volume) are controlled for. Lanjouw (2005)[4] found that extensive price regulation had a negative impact on the probability of launch within two years. The negative impact of moderate regulation was found to depend on the country's income level, however, with no reduction in the probability of entry when GDP per capita is over USD 12 088. On the other hand, Kyle (2007) found price regulation to have a substantial impact, reducing the probability of launch by 25% in countries with price regulation.

The studies concur that the existence of price regulation and scope or stringency can delay market launches, even when controlling for other factors, although the researchers found differences in the extent of the impact. Pricing and reimbursement delays were found to have a significant impact, but were not the most important determinant. As discussed in Chapter 1 of this report, many factors other than price regulation serve as key determinants of launch timing.

If price regulations limit pharmaceutical prices to an amount below the manufacturer's reservation price (the price beneath which it will not agree to sell the product), it may choose not to launch the product in the market. In addition, decisions not to reimburse medicines – to not add them to a positive list or to place them on a negative list – are very likely to affect availability in the country; manufacturers may choose not to launch the product in the market because low expected sales may be insufficient to offset market entry costs. Negative reimbursement decisions can also reduce sales by reducing effective demand; physicians are less likely to prescribe medicines – not listed on a formulary – in coverage schemes where they face incentives to prescribe medicines on a formulary or preferred list and patients may be less willing to consume a medicine for which the effective price as increased in comparison with covered medicines that are comparable.

Policies can improve access to medicines not available on the market

Even if best practices to ensure availability of medicines are followed, variability in the timing and availability of medicines across markets will persist. However, this does not in and of itself necessarily indicate that access to those medicines is compromised. OECD

countries often have policies to foster access to medicines not available on the market, which help to ensure that patients can get exceptional access when needed. For example, in Switzerland, doctors and pharmacists may obtain authorisation to treat a specific patient by importing pharmaceuticals which are not yet, or no longer, approved in the country (Paris and Docteur, 2007). Canada has a similar programme, although eligibility is limited to those with a serious or life-threatening condition (Paris and Docteur, 2006). These types of policies minimise the impact of delays in terms of their impact on access.

Pharmaceutical coverage affects the affordability of expensive new medicines

As was described in the previous chapter, comprehensive pharmaceutical coverage is the norm in almost all OECD countries. Cost-sharing levels vary, but patients are generally responsible for paying at least a portion of their medicines' costs, even if general safeguards are in place so that these costs are not unduly burdensome. Nevertheless, in some cases access may be hindered for patients with costly or chronic conditions in countries where some patients face relatively high out-of-pocket costs for medicines. For example, cost-sharing levels in some Canadian provinces are in some cases high enough to have impaired use of needed medicines (Paris and Docteur, 2006). Knaul *et al.* (2006) showed that pharmaceutical expenditure is most onerous for the poorest households in Mexico; among households that had spent at least 30% of their disposable income on health in 2000, spending on pharmaceuticals accounted for half of their expenditure on health.

Despite some limitations, policies can be used to limit the risk of affordability problems. As described in Chapter 3, many OECD countries make special coverage provisions for those in need, including exemptions and caps on out-of-pocket spending, and, accordingly, relatively few patients in OECD countries are unable to obtain needed medicines simply because they cannot afford them. For example, Sweden uses a graduated cost-sharing mechanism whereby the co-payment diminishes as out-of-pocket payments increase over the course of a year. Total yearly outlays for patients are capped at SEK 1 800 (Moïse and Docteur, 2007b).

Of course, patients can face significant affordability problems, particularly in the case of payers that decide not to subsidise or reimburse certain very high-priced products that are found not to be affordable, from a budgetary perspective, or cost-effective at the offered price. These exceptional situations provide the most clear-cut examples of the trade-off between the policy goals of cost containment and access.

Very expensive drugs sold mainly in hospitals are a case in point. Under some circumstances, a drug may be available and listed for reimbursement but not purchased by hospitals, either because the budget is not sufficient or because the payment scheme does not provide the right incentives. Typically, payment per case does not provide incentives to furnish exceptionally expensive treatments to patients in a given diagnostic-related group (DRG – a unit for payment in the remuneration system for hospitals based on diagnosis and services rendered), unless specific funding is made available, through earmarked annual budgets or through drug reimbursement on top of DRG payments.

The problems of uptake of expensive drugs is vividly illustrated in a study by the Karolinska Institute on the uptake of new cancer drugs (Jönsson and Wilking, 2007). Though the authors show that uptake is highly variable across products, some general trends are observable. The United States has, in most cases, the most rapid uptake and

higher levels of per-capita sales than other countries have, even several years after introduction. Within Europe, Austria, France and Switzerland show the fastest uptake; the United Kingdom generally has lower uptake than other countries. Canada, Australia, Japan and New Zealand all had lower uptake of new cancer drugs than the European average, although Canada and Australia had higher uptake than the United Kingdom. New EU members (Poland, Hungary and the Czech Republic) had the slowest uptake, likely reflecting relative affordability.

Another analysis shows high discrepancies in formulary listing for ten orphan drugs in European countries, ranging from one in Hungary to ten in France (de Varax *et al*., 2004). The study notes that real accessibility is further defined by hospital payment schemes and available budgets, with possible discrepancies at the regional level in some EU countries.

Similarly, the availability of very expensive drugs may differ within countries, as was the case in England and Wales prior to the creation of the NICE. In Canada, the Cancer Advocacy Coalition (2005) showed that the effective access to 20 cancer drugs was highly variable, treatments being available in some provinces but not others at any point in time.

The role of pricing and reimbursement policies in averting under-use of effective medicines

Ensuring appropriate use of effective medicines is a goal that policy makers share. And here, there is evidence that OECD countries have some progress to make in ensuring a better match between need and use. The extent to which pricing and reimbursement policies may help to tackle these shortcomings in the quality of care is analysed in this section.

Even in OECD countries, many people do not get the medicines they need

There is evidence to suggest significant variability across countries in the use of medicines, although this is based on limited data (see Chapter 1). While international differences in disease incidence and treatment guidelines contribute to some of the differences seen (National Heart Foundation of Australia *et al*., 2005; Hockley and Gemmill, 2007), the degree of variation in use supports the hypothesis that there is under-use of some medicines in some countries, as compared with the level of use that could benefit patients.

Even within countries, the research literature provides evidence that not all patients get the medicines they need. A recent study of medication use among US adults found evidence that medications appropriate for a patient's condition were not prescribed for 63% of patients studied (Shrank *et al*., 2006).[5] Somewhat surprisingly, given the differences in coverage across the US population, insurance status was not found to be a factor contributing to the quality differences found, suggesting that this quality shortfall was not likely to be attributable to differences in the level of coverage and cost-sharing for particular medicines. The underuse of effective medicines is not confined to the United States. For example, a study of the use of antihypertensive medicines in seven OECD countries found that two-thirds to three-quarters of hypertensives in the European countries studied were untreated, compared with slightly less than half in the United States (Wolf-Maier *et al*., 2004).

There is ample evidence that patients fail to comply with prescribed treatment regimes, both for long-term chronic conditions and shorter acute episodes (such as antibiotic use). The World Health Organization estimated that adherence to long-term therapies for chronic illnesses in developed countries averages just 50% (WHO, 2003).

Beyond the affordability of very expensive medicines, patients' demand for pharmaceuticals has been found to be price sensitive for certain populations and types of products, although the degree of sensitivity varies for different effective price levels and populations (see Box 4.1). As cost-sharing requirements in most OECD countries are low, the impact of small changes in the effective price patients face is also minimal. However, significantly higher prices or higher cost-sharing requirements will inevitably create some barriers to access for low-income populations or those with chronic needs, with possible consequences for the consumption of health care services and patients' health status.

Averting clinically inappropriate use of medicines

There is some evidence of drug misuse and overuse. For example, some European countries and the United States have had to face high antibiotic resistance due to the over-consumption of antibiotics (Schrag *et al.*, 2001; and Goossens *et al.*, 2005).

Box 4.1. **The price sensitivity of consumer demand for pharmaceuticals and potential consequences of increases in cost-sharing**

Affordability is a difficult concept to measure, in part because it is sometimes hard to disentangle problems relating to people's ability to pay from their willingness to do so. However, research has found that some consumers are sensitive to the prices they pay out-of-pocket for pharmaceuticals, reducing and foregoing consumption when prices are perceived as excessive and changing consumption patterns in response to price changes.

Many studies investigated the link between patients' out-of-pocket costs and the demand of pharmaceuticals. Some of them estimated the price-elasticity of the demand for pharmaceuticals, at aggregate as well as at individual levels (see Gemmil *et al.*, 2007 for a recent review). Though related to different contexts (different countries, different population sub-groups, different therapeutic classes and different types of cost-sharing), these studies show that higher out-of-pocket payments are linked to lower volumes of consumption. However, when data from the studies were combined for the purpose of meta-analysis, the authors found that the demand for prescription drugs is relatively inelastic (–0.2), implying that across the developed world, consumers are not particularly responsive to changes in out-of-pocket prices for prescription drugs. The authors speculate that this may be due to a perceived necessity of prescription medications and a lack of suitable substitutes. It could also be explained by the fact that cost-sharing tends to be low in most developed countries, given that price elasticity of demand varies at different price points.

Poor and vulnerable parts of the population are more likely to be sensitive to changes in cost-sharing. Lexchin and Grootendorst (2004) reviewed studies measuring the impact of increases in cost-sharing on vulnerable populations (poor, beneficiaries of social assistance, people with chronic diseases and/or with poor health status) in OECD countries. Though the review included all studies published in English and French ,the 24 studies found were all based in the United States or Canada, with the exception of two studies which were based in Belgium and New Zealand. Virtually all studies demonstrated that an increase in cost-sharing resulted in decreases in drug use by low-income people and the chronically ill. The authors estimated the price elasticity of demand for these vulnerable populations to range between –0.34 and –0.50, *i.e.* demand was more elastic than it was for the entire population.

Box 4.1. **The price sensitivity of consumer demand for pharmaceuticals and potential consequences of increases in cost-sharing** *(cont.)*

The Cochrane collaboration undertook in 2006 an exhaustive review of the impact of pricing policies on a range of outcomes (Aaserud *et al.*, 2006). Of 246 studies reviewed, only 20 met the high standard of evidence quality set by the authors and only 15 of them were effectively assessed for technical reasons. All but one analysed the impact of reference price policies, *i.e* policies which result in one or several drugs (the reference drug) being available at no out-of-pocket expense, while other drugs of the same therapeutic class will generally be available to patients willing to pay the price differential out-of-pocket. Four studies reported an increase in the use of the reference drug after the implementation of reference prices, ranging from 60% to 196%, and persisting after 6 months. Four studies similarly reported a decrease in use of drugs with cost-sharing ranging from -19% to -42%. Changes in total drug consumption in the affected therapeutic class were inconsistent or not significant.

A few studies analysed the impact of changes in cost-sharing for different types of drugs, classified according to their clinical value. At least two studies show that consumers forego both "essential" and less essential medicines in response to changes in cost-sharing (Tamblyn *et al.*, 2001; and Leibowitz *et al.*, 1985). Results from the Rand Health Insurance Experiment (Leibowitz *et al.*, 1985) showed that consumers reduced both essential and less-essential services in response to increased cost-sharing requirements. In Tamblyn's study of Quebec seniors, the decrease in consumption was higher for non-essential medicines than for essential ones.

Sometimes patients get medicines they do not need. A Rand study of quality of pharmacology care for US adults found that inappropriate medicines were prescribed in 16% of cases (Shrank *et al.*, 2006). In France, therapeutic protocols in the treatment of hypercholesterolemia published by the agency in charge of health technology assessment are not always followed by doctors. Though the protocols recommend prescribing medications for patients who are above a certain threshold of low-density lipoprotein (LDL)-cholesterol, a study found that one third of French doctors prescribed medicines for patients who had a LDL-level inferior to the recommended threshold (CNAMTS, 2003).

Payers can employ a range of techniques to improve quality of care and contain costs by limiting the inappropriate use of medicines. As seen in Chapter 3, some of these techniques directly rely on formulary management, such as limitations in drug prescriptions (prior authorisation, second line treatment). Across-the-board cost-sharing increases have been used periodically in OECD countries, with the double aim of increasing the private share of funding and offsetting consumption increases induced by moral hazard. However, these blunt instruments run the risk of impairing access to needed medicines in addition to those that are less effective or unnecessary.

While coverage, pricing and reimbursement policies are important to ensure access to medicines, these are necessary but not sufficient to ensure appropriate use. Pharmaceutical policy may encourage appropriate use of medicines by many other means, such as providing doctors with evidence-based and balanced information about pharmaceutical products or ensuring that professional bodies have engaged in these activities. These policies were described in Chapter 3, with some examples taken from the

case studies conducted as part of the present study, although no in-depth assessment of their impact was made.

The impact of pricing and reimbursement policies on pharmaceutical price levels

The outcome of pricing policies, in terms of aggregate impact on price levels, largely depends on the market power of the purchaser or regulator (population represented in terms of number and income), as discussed in Chapter 3. But also important are the purchaser's motives and ability to act in ways that influence the volume of a product consumed.

Purchasers and regulators do not necessarily aim to get the lowest possible price

Pharmaceutical purchasers seek to maximise an array of objectives, not limited to cost containment. Private health insurance firms operating on a for-profit basis have strong incentives to contain their pharmaceutical expenditures. Consequently, they will seek the lowest possible price for any given pharmaceutical and try to minimise the volume of subsidised pharmaceuticals used by insured populations, with the exception of those products for which use may be considered to save the insurance company costs, by avoiding hospitalisation, for example. Balancing these incentives to limit expenditures, depending on market or regulatory pressures, is the need to provide pharmaceutical benefits that are adequately comprehensive and accessible.

Responsibility for public cost containment and pressure to achieve good value for money provides public purchasers with the incentive to achieve low prices, but this is very often tempered in practice by other goals. Notably, payers are under pressure from citizens and stakeholders to promote public health and to ensure prompt access to effective medical treatments. In several OECD countries (*e.g.*, Canada), there is pressure to use pharmaceutical policy to serve the objectives of industry policy, by offering relatively high ex-manufacturer prices or other concessions intended to incent or reward domestic pharmaceutical industry activity[6] (see Box 4.2).

Purchasers in some OECD countries (*e.g*, Sweden, Switzerland) seek to use their purchasing arrangements to reward and/or foster firms' investments in pharmaceutical R&D. Sweden, for example, reimburses products at any price proposed by the manufacturer that allows for use of the product to be cost-effective in Sweden from a social perspective. The reimbursement authority does not seek to obtain the lowest possible price (Moïse and Docteur, 2007b). Another example is the "innovation premium" awarded in Switzerland to products that are first or second entrants in a class, accounting for a premium of 10-20% over the price of therapeutic comparators already on the market (Paris and Docteur, 2007).

For all these reasons, price regulation may not necessarily result in lower prices than what could be obtained in a market where insurers compete on the basis of their performance in furnishing best value for money. Indeed, proponents of the idea that competition among private insurers would result in the lowest possible prices available in a market made these arguments in the recent US debates on expansion of the Medicare programme to offer prescription drug coverage.[7]

Box 4.2. **Pharmaceutical cost containment and industry policy: conflicts between policy goals**

Examples of pharmaceutical policies that benefit the pharmaceutical industry without obvious benefits for governments, citizens or patients can be found in a number of OECD countries and jurisdictions within countries with a significant domestic presence of the pharmaceutical industry. For example, the Canadian province of Quebec uses a reference-pricing scheme to set common reimbursement levels for off-patent original products and generic alternatives, but reimburses off-patent originals at the list price for 15 years after listing, irrespective of patent status (Paris and Docteur, 2006). In Sweden, manufacturers' applications for reimbursement and negative reimbursement decisions are kept confidential by the pricing and reimbursement authority, benefiting manufacturers who may not want information on their pricing strategies to be public knowledge (Moïse and Docteur, 2007b).

The desire of governments to attract pharmaceutical industry activities (*i.e.*, R&D, production) may well influence pharmaceutical policy, although there is little reason to believe that providing favourable market conditions (*e.g.*, high prices) will be a significant determinant of firms' decisions as to where to establish headquarters and undertake R&D, in particular. For example, pharmaceutical R&D activities in Canada have not appreciated significantly, despite a pricing policy linking Canadian prices of patented medicines to the prices in countries with significant pharmaceutical sectors, and agreement with the industry to increase R&D activities in Canada (Paris and Docteur, 2006).

The increasing globalisation of R&D has forced governments to rethink the basic premises behind policies intended to attract domestic activity (Karlsson, 2006). Government policies must now take into account the nature of the globalisation of private R&D: characterised in large part by companies seeking "centres of excellence" to maximise knowledge spillovers (Karlsson, 2006; Nilsson, 2006). Industrial policies such as low corporate taxes* may influence manufacturers' decisions regarding location of production facilities, but pharmaceutical pricing policies are unlikely to be a factor, given that firms benefit from industry-friendly market characteristics whether or not they are based in the country.

* For example, Ireland's 10% corporate tax rate on manufacturing has played a key role in attracting direct foreign investment from pharmaceutical multinationals (OECD, 1997), leading to an almost twelve-fold increase in pharmaceutical production between 1985 and 2002, with R&D increasing only five times during the same period (OECD, 2007).

The ability of purchasers to obtain price concessions varies across purchasers and products

Private and public payers alike may be motivated to obtain a low price and be able to influence volume by formulary and benefits management. Therefore, the difference between price negotiation between two interested parties (*i.e.*, a pharmaceutical benefits manager covering 60 million people with multiple plans and formularies) and reimbursement price regulation is not necessarily obvious, in terms of outcome.

Payers and purchasers who are constrained by forces of competition or regulation from taking actions that affect the quantity of a pharmaceutical product purchased will have no ability to negotiate or limit its price. So, for example, indemnity insurers in Canada and the United States are purely price-takers, in that they reimburse insured persons for the cost of any prescribed pharmaceutical product authorised for marketing, less the cost-sharing amount defined by the rate of co-insurance established in the insurance policy.

Similarly, public coverage schemes in some OECD countries are obliged to cover every drug authorised for marketing and are effectively price-takers, able to obtain price concessions only if they have discretion to put restrictions or limits on coverage, or to steer consumption to one drug over another. Typically, countries with national formularies do not select drugs within a therapeutic class: during price negotiation – where this occurs – manufacturers are virtually assured that their drug will be listed, the question being more "at what price"? Under such circumstances, they may be less inclined to consent to discounts or rebates.

In the United States, pharmaceutical benefit management (PBM) companies are not required to list all drugs in a therapeutic class, thus having power to direct volume when there are competing drugs in a therapeutic class.[8] A report by the US Federal Trade Commission (FTC, 2005) showed that PBMs generally do not list all statins available on the US market, for instance. Where competing products are available, PBMs contract with manufacturers to obtain payments (usually considered to be rebates) in exchange for an advantageous formulary status for their drug, *i.e.* "preferred drug" status, listing without restrictions, etc.

If a new pharmaceutical product is effective and without therapeutic competition, both public payers and private insurers will be under pressure to provide coverage and will have limited bargaining power to obtain concessions from the manufacturer. On the other hand, to the extent there is competition from generic or therapeutic alternatives, the outcome will depend on market power and objectives of the purchaser, public or private. Of course, manufacturers also have negotiating power, even when therapeutic competition exists; they may choose not to launch a product, or not to seek a listing on a formulary or positive list, if they believe that profits can be maximised by focusing their sales efforts in selected markets. Variation across markets in the availability of products suggests that these decisions are common.

Strategies used in pricing have different predictable impacts on outcomes

The multiple policy instruments used in pricing and reimbursement have a predictable impact on price levels, as reviewed below.

Methods widely used to cap prices are arguably arbitrary and gameable

A fundamental problem in pharmaceutical price regulations is defining the appropriate price level or cap. A range of approaches, described in Chapter 3, are used.

In practice, external price benchmarking is often used, but the rationale for selecting particular benchmarks is not always explicit. As a result, the impacts can be unpredictable. Despite very different contexts, price regulation in both Canada and Switzerland has reduced the gap in prices with the richest European countries, but increased the gap with US prices (Paris and Docteur, 2006 and 2007). In Mexico, on the other hand, there may be no impact on prices obtained by manufacturers because the system is loosely regulated and readily gameable (Moïse and Docteur, 2007a).

The widespread use of this pricing scheme across OECD countries presents a number of drawbacks. First, it provides a strong motive for strategic launch and pricing, raising questions as to the appropriate level of price in the early launch countries. Manufacturers have incentives to launch first in countries that do not regulate entry prices and that can afford high prices in order to have the list prices in these countries referenced by others. As

demonstrated in previous chapters, Germany and the United Kingdom – early-launch countries that allow free pricing for innovative drugs at market entry – are two of the three countries most commonly used as references, suggesting that many countries using external benchmarking to limit prices are, in fact, referencing the price selected by the manufacturer rather than a regulated price.

Second, in some countries the list price is disconnected from the price actually paid by purchasers. If regulators of referencing countries rely on listed prices to make their decisions, they may pay higher prices than they intend to pay.

Finally, the way in which caps are defined and the way in which negotiations are led have a predictable impact on the outcomes of regulation. Fixed and well-defined rules, such as capping the allowable price at the average of prices in comparator countries, makes the system highly predictable for manufacturers. Choosing the median has the advantage of not being sensitive to outlier prices in comparator countries. When definition of the maximum price is more vague, such as "should be consistent with prices of comparators" (like in France) or when the negotiation is described as "flexible", there is more room for case-by-case negotiation between authorities and manufacturers, which renders the process less transparent and its impact less predictable.

Internal price referencing – pricing drugs by reference to therapeutic comparators – seems reasonable on the surface; however, the referenced products must themselves have price levels that are consistent with consumer willingness to pay for the product. Beyond this, internal referencing still requires decisions as to which variations warrant premia and at what level those premia should be established.

Price caps are sometimes linked to production costs, an approach used mainly for generic products. The ability of firms to manipulate cost data makes such systems of dubious ability as a control. All of these methods face challenges on the grounds that they are arbitrary and readily gameable by manufacturers with strategic launch and pricing strategies.

Product-specific agreements linking volumes and prices

The discounts and rebates on list prices consented to by manufacturers as part of product-specific price-volume agreements with purchasers and/or regulators are generally not known, since these agreements are most often confidential. In France, these rebates amounted to 0.94% of French companies' turnover in recent years and are highly concentrated on a few products and firms (Cour des Comptes, 2004; Comité économique des produits de santé, 2007).

Similarly, US public and private purchasers do not publish information about the discounts they get from manufacturers. However, the US Federal Trade Commission (FTC, 2005) obtained confidential information on contracts between a sample of PBMs (among which were the largest ones) and 11 big pharmaceutical companies, using these data to estimate the discounts granted by PBMs to plan sponsors on the average wholesale prices (AWP) in 2003. For brand-name drugs, those discounts ranged from 16% to 27.9% of sales in contracts with less restrictive or open formularies, with larger discounts in contracts with more restrictive formularies (FTC, 2005, p. 37). In addition, the study provides estimates of payments furnished by manufacturers to have their drug included in the PBM's formulary. In total, the FTC study revealed that manufacturers consented to rebates of USD 6.34 per brand prescription,[9] on average, for inclusion of their drugs in PBMs formularies, 71% of

which were concentrated on the top 25 brand name drugs. PBMs sometimes share these rebates with plan sponsors, with retention rates ranging from 37% to 91%.

Tendering, mainly used by public plans for generic listing, can be considered as a specific type of volume-price agreement since it offers the manufacturer the opportunity to set a price conditional on a specified volume of sales.

The definition of fixed reimbursement amount for drug clusters fosters price competition

Reference prices schemes commonly foster price competition and result in harmonisation of prices within clusters. Where they have been applied, pharmaceutical firms have generally dropped their list prices for products upon inclusion in reference groups because of concern about the prospective loss of market share. In Germany, in April 2006, only 7.5% of all products included in reference-price groups were priced above the reference price (Paris and Docteur, 2008). However, there have been a few recent exceptions in which manufacturers have chosen not to drop their prices, indicating either that manufacturers believe that consumers will be willing to pay extra for these products, or that the potential cost in terms of impact on prices in other markets is too significant.

The prospective impact of reference price schemes depends heavily on both the design of the scheme (nature and number of clusters, the way reimbursement amount are set, whether patented drugs are included or not) as well as other characteristics of the health systems likely to foster competition within clusters (such as the substitution option or obligation for the pharmacists, obligation of the physician to inform patients about potential cost-sharing, etc.). The schemes with the greatest scope of prospective impact, in terms of the downward pressure exerted on price, undertake clustering at the therapeutic level (rather than the bioequivalent level), set a reference price at a level allowing generic competitors to enter the market and allow clustering of patented products with similar and efficacy and safety profiles. However, this type of clustering is technically and politically difficult to implement.

Some analysts have argued that prices of non-clustered drugs may be inflated by reference price policies because manufacturers will seek to recuperate losses in revenues in this market segment. In fact – except in specific contexts such as the British one – manufacturers have incentives to maximise the price of each individual product at each period rather than to accept unnecessary price concessions in the non-clustered market. What is likely to happen, however, is that manufacturers will focus their promotional efforts on non-clustered products, with the aim of increasing consumption of those products which are more profitable.

What are the comparative price levels of pharmaceuticals in OECD countries?

Academics, public institutions and private stakeholders have tried to provide estimates of the impact of pricing policies on price levels, using approaches that rely on normative assumptions. In the following section, we assess the effectiveness of countries' approaches to pharmaceutical pricing by comparing retail price levels of pharmaceuticals to general consumer price levels in OECD countries.

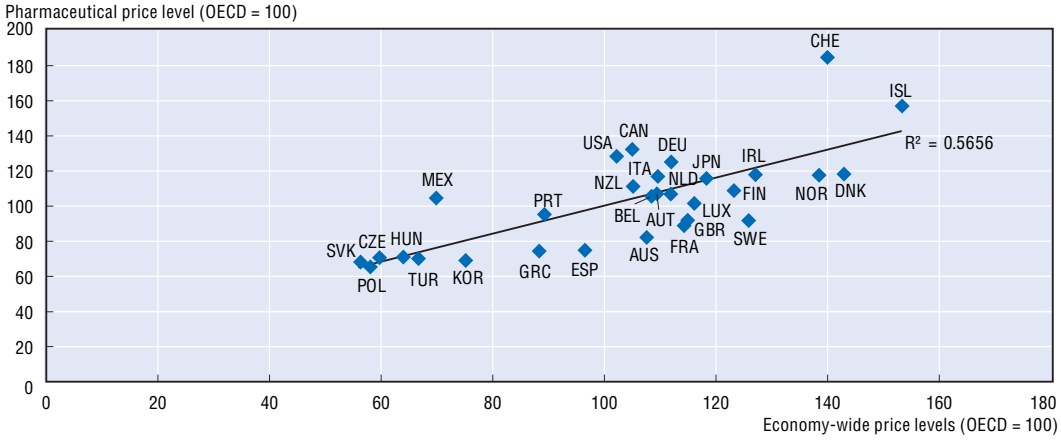
Pharmaceutical price levels roughly correspond with economy-wide consumer price levels in most countries

A comparison of retail pharmaceutical price levels with economy-wide price levels can offer some insights into the impact of pharmaceutical pricing policies on retail prices for

pharmaceuticals. It is important to keep in mind that pharmaceutical prices that are out of line with economy-wide prices may reflect factors other than pharmaceutical pricing policies. Notably, value-added taxes on pharmaceuticals are often lower than VAT on other goods; in many cases (*e.g.,* Australia, Belgium, Greece, Finland, France, Hungary, Italy, the Netherlands, Poland, Sweden, the Slovak Republic, and the United Kingdom) pharmaceuticals are exempt from this tax. On the other hand, Austria, Denmark, Ireland, and Norway apply the standard VAT to all pharmaceuticals (PPRI, forthcoming).

Annex 4.A1 provides details of an analysis demonstrating that two-thirds of OECD countries had retail pharmaceutical price levels in 2005 that were consistent with their economy-wide price levels.[10] The results are summarised in Figure 4.3. Retail pharmaceutical to economy-wide price differentials in Switzerland, Mexico, Canada and the United States exceeded the OECD average by a considerable margin. Sweden, France,[11] the United Kingdom, Denmark, Spain and Australia had pharmaceutical price levels that were notably lower than their economy-wide price levels. Exemption from VAT or lower rates for pharmaceuticals explains much of the observed deviation in the case of France, the United Kingdom and Sweden.

Figure 4.3. **Retail pharmaceutical price levels and economy-wide price levels, 2005**



Note: Prices were converted to a common currency using the 2005 average exchange rate. The OECD average is the geometric mean. The coefficient on the independent variable "Economy-wide price levels" (0.7917) was statistically significant at the 1% level (t-statistic = 6.04).

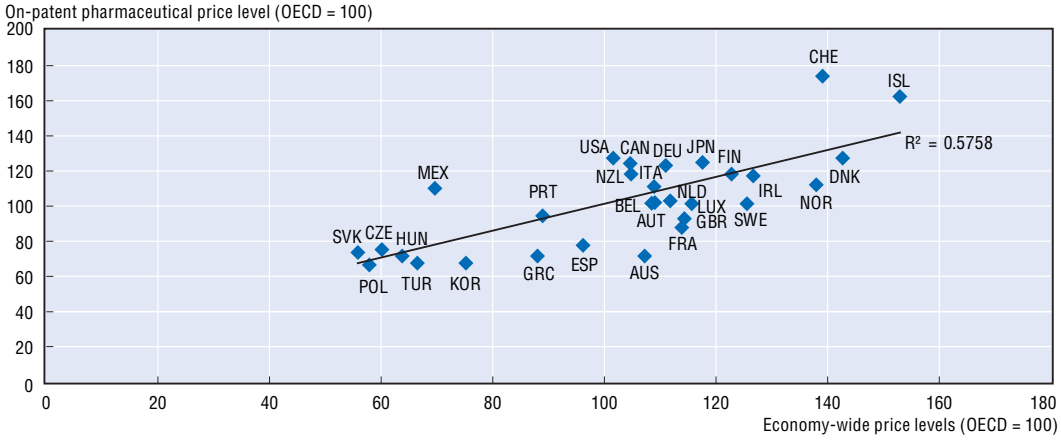
Source: Eurostat-OECD Purchasing Power Parity Programme, 2007.

In addition to differences in VAT rates, inconsistency between price levels for pharmaceuticals and those seen economy-wide may be partly attributable to the effects of pharmaceutical pricing schemes. For instance, Switzerland subsidises pharmaceuticals at the level proposed by the manufacturer, as long as the price is generally consistent with that offered in European comparator countries (Denmark, Germany, the Netherlands and the United Kingdom). However, as Switzerland is not uncommonly the first launch country in Europe and uses international benchmarking in a very flexible manner, manufacturers tend to obtain relatively high prices for their products (Paris and Docteur, 2007). In the United States, significant subsidies for pharmaceuticals provided by insurance (approximately 75% of the total expenditure on prescribed medicines is financed by private insurance or public coverage) may be a contributing factor to higher pharmaceutical prices

relative to economy-wide prices. Relatively high US prices may have a spill-over effect for Canada and Mexico, in that manufacturers will be less inclined to price to market in those countries that have cross-border trade with the United States, as discussed in Chapter 5.

Because price regulation is often justified by the perceived need to counterbalance the market power of manufacturers, it is interesting to look at relative price levels for original products (Figure 4.4).[12] Five countries – Switzerland, Mexico, the Slovak Republic, Canada and the United States – had retail price levels for original medicines that exceeded their relative position in the OECD in terms of economy-wide prices in 2005, *i.e.* the differences between original price levels and economy-wide price levels were greater than one standard deviation from the OECD average.[13] Australia, France, Sweden and the United Kingdom appear to have had relatively low retail prices for original products in 2005, as does Norway.

Figure 4.4. **Original pharmaceutical price levels and economy-wide price levels, 2005**



Note: Retail prices were converted to a common currency using the 2005 average exchange rate. The OECD average is the geometric mean. The coefficient on the independent variable "Economy-wide price levels" (0.7604) was statistically significant at the 1% level (t-statistic = 6.16).

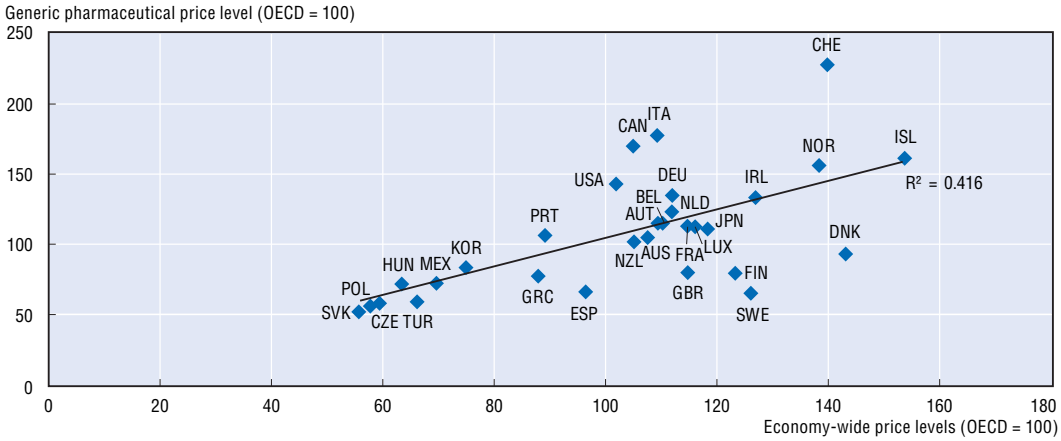
Source: Eurostat-OECD Purchasing Power Parity Programme, 2007.

In Canada's case, the gap between original product and economy-wide price levels may partly reflect the impact of its pharmaceutical price regulation, at least to the extent that retail price levels for original products are consistent with ex-manufacturer prices of on-patent medicines. As noted in Paris and Docteur (2006), the aim of Canada's regulation was not to bring on-patent ex-manufacturer price levels in line with its prices economy-wide, but rather to bring them in line with the average of its European comparators, to which it has succeeded. However, these comparators (France, Germany, Italy, Sweden, Switzerland, and the United Kingdom) all have economy-wide price levels that exceed Canada's.[14]

Finally, a look at price levels for generic products provides a sense of the extent to which countries have achieved price competition upon patent expiry (Figure 4.5), Most countries do not rely on market forces to foster generic competition, rather setting maximum reimbursement prices for generic drugs (see Chapter 3).

The vast majority of OECD countries had retail pharmaceutical price levels in 2005 that were consistent with their economy-wide price levels, *i.e.* difference in price levels was

Figure 4.5. **Generic pharmaceutical price levels and economy-wide price levels, 2005**



Note: Retail prices were converted to a common currency using the 2005 average exchange rate. The OECD average is the geometric mean. The coefficient on the independent variable "Economy-wide price levels" (0.9942) was statistically significant at the 1% level (t-statistic = 4.47).

Source: Eurostat-OECD Purchasing Power Parity Programme, 2007.

less than one standard deviation from the OECD average. Notable exceptions are Switzerland, Italy and Canada, with generic pharmaceutical prices in 2005 greatly exceeding prices economy-wide, and Sweden and Denmark, with generic drug prices that were far below economy-wide prices.

This finding is consistent with the conclusions of the OECD case studies of Canada and Switzerland, which in both cases pointed to regulatory failures and lack of competition in the countries' off-patent markets. However, these countries have very different generic market profiles: while generics account for 41% of the total market value in Canada, they only account for 6% of the market in Switzerland (see Chapter 2).

These results also lend support to the findings from the case study of Sweden, a country which has established very strong incentives for generic price erosion through its policy mandating substitution of the lowest-priced bioequivalent and substitutable product, and permitting monthly price changes (Moïse and Docteur, 2007b). Furthermore, the financial incentives faced by physicians, pharmacies and patients are aligned to favour lower-cost generics (and parallel imports, where available), which has allowed Sweden to achieve high generic penetration of the market with a relatively low share of the value.

Pricing and reimbursement policies certainly influence the prices of generics and off-patent original drugs. Differential cost-sharing (with higher co-payments for brand-name drugs) have been shown to have a significant impact on generic penetration. Such policies are widely used by PBMs in the United States in formulary design. However, other incentives directed at physicians, pharmacists and patients for generic prescribing, dispensing and use play a crucial role are in shaping competitive markets. These policies and their impact have not been systematically investigated in the course of this project, but analysed in case study reports.

Policies succeed in containing price growth

Pharmaceutical price growth is readily controlled in most countries, as is consistent with the evidence on the factors responsible for recent growth in the value of

pharmaceutical sales presented in Chapter 1. Many countries *(e.g.,* Sweden, the Slovak Republic) do not permit increases in pharmaceutical prices, except under exceptional circumstances, or limit pharmaceutical price growth to growth in prices in the economy *(e.g.,* Canada, Mexico). The United States is notable among OECD countries for its annual growth in pharmaceutical prices, which have in recent years exceeded growth the economy and in other parts of the health sector. This finding provides support for the idea that manufacturers use so-called penetration pricing (launching a product at a price below competitors followed by price increases) for me-too products to gain foothold in a competitive market, as discussed in Chapter 2.

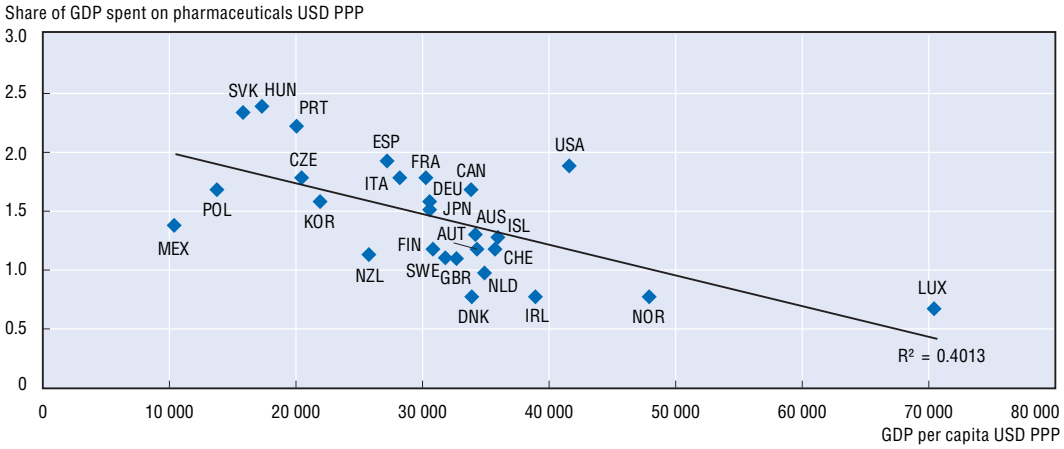
Pharmaceutical cost containment

The variation across OECD countries in the share of national income devoted to pharmaceuticals is significant – varied between 0.7% and 2.4% – and greater than the variation seen in the share of income devoted to health expenditure (net of pharmaceutical expenditure), which varied between 4.3% and 13.4% in OECD countries in 2005.

This wide variation raises questions about whether and which countries may be over or under-spending, although the most appropriate benchmarks for spending are debatable. It is interesting to observe the spending levels in the countries that can be said to have markets for pharmaceuticals that are closest to operating freely. For example, Germany spends 1.6% of its income on pharmaceuticals and the United States spends 1.9%. However, in both countries, about three-quarters of pharmaceutical spending is financed by insurance, which will tend to inflate spending.

This overly simplistic observation fails to take into account the relationship between income and pharmaceutical expenditure, however. Countries with higher per capita incomes tend to spend a lower share of total income on pharmaceuticals (Figure 4.6), contrary to the share they spend on health expenditure as a whole (Figure 4.7). This is consistent with the idea that pharmaceuticals are considered a necessity, for which

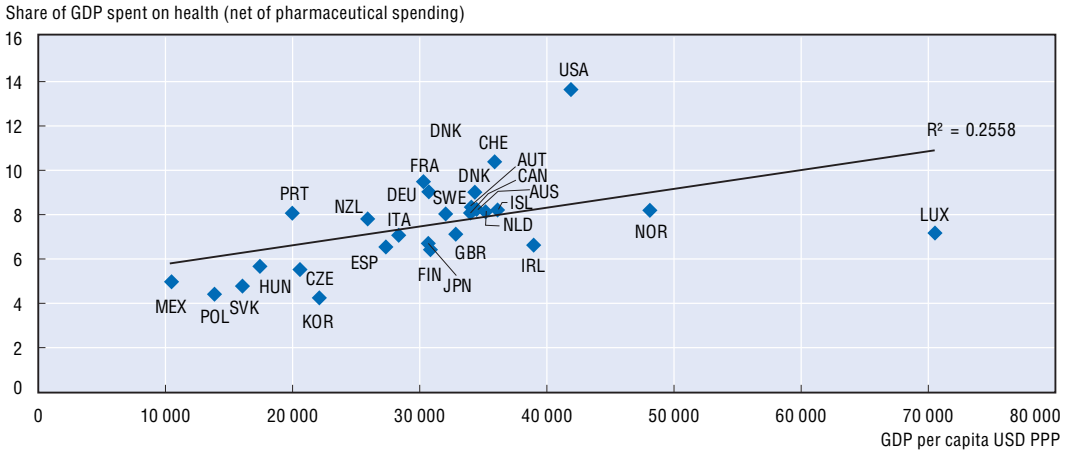
Figure 4.6. **Share of GDP spent on pharmaceuticals and income per capita, 2005**



Note: The coefficient on the independent variable "GDP per capita" (–0.00003) was statistically significant at the 1% level (t-statistic = –4.09).

Source: OECD Health Data 2007.

Figure 4.7. **Share of GDP spent on health (net of pharmaceutical spending) and income per capita, 2005**



Note: The coefficient on the independent variable "GDP per capita" (–0.00008) was statistically significant at the 1% level (t-statistic = 2.93).

Source: OECD Health Data 2007.

spending will rise with income, but not as fast as income does. The difference in what is seen between pharmaceutical and health expenditure may be partly due to the role of health-care related labour costs, which rise with national income, as well as the tendency of poorer countries to under-report a portion of health expenditure consisting of informal or under-the-table payments to health care providers.

Another consideration is the level of spending relative to other valued goods and services. In 2005, for example, Canada devoted 1.7% of its income to pharmaceutical expenditure. In the same year, 2.2% of GDP went to clothing, 3.4% to motor vehicles, 1.1% to alcohol and 1.0% to tobacco. It is difficult to use such macro-level information to inform decision-making at a micro level, however.

Setting aside the difficulty in assessing the appropriateness of pharmaceutical spending levels, a policy objective in some countries has been to constrain the rate of growth in pharmaceutical expenditure. Pharmaceutical spending that rises faster than the rest of health spending and economic growth raises concerns about affordability and sustainable financing. Nevertheless, rapidly growing pharmaceutical spending is not necessarily undesirable, from the perspective of social welfare, as long as there is no more valuable use of available resources. It is also possible that some added spending on pharmaceuticals, particularly ones that prevent hospitalisations or conditions requiring further treatment, could offset spending in the health sector(see Chapter 2) or in other areas where costs are borne socially.

Means to contain drug expenditures through financial incentives have only marginal impact

Chapter 3 provided an overview of a full arsenal of approaches used by payers in efforts to control their expenditures on pharmaceuticals, including profit controls, clawbacks, negotiated rebates, price-volume agreements, risk-sharing arrangements, tendering, cost-sharing (or cost-shifting), and using parallel trade. In the sections below, we assess the relative utility of these approaches to assist in pharmaceutical cost containment.

Macro-level cost-containment tools allow countries to obtain marginal discounts on pharmaceuticals

Macro-level cost-containment measures generally lead to small repayments from the industry and have arguable effectiveness on containing costs. Several countries use macro-economic rebates and clawbacks to contain pharmaceutical expenditures. Though these tools respond to different approaches – profit caps, turnover caps, clawbacks – and are geared towards different actors – industry, pharmacists – they generally allow national health insurers or governments to recuperate a small share of total expenditures.

The British profit control scheme (Pharmaceutical Price Regulation Scheme, PPRS) led to profit repayments representing only 0.01% of companies PPRS revenues over the period 1999-2004 (OFT, 2007).[15] Pharmaceutical companies generally managed to price products in a manner to not exceed the cap set by negotiation, though the scheme incidentally provided incentives to innovate in accounting methods to shift part of companies' profits to other countries. Moreover, the rationale for setting the profit cap is arguable and the scheme does not guarantee that it leads to the best possible use of available resources (*op. cit.*).

Rebates paid annually by the pharmaceutical industry to the French health insurance funds are higher. It is generally not possible to distinguish between annual repayments related to the macro-level cap regulation from those related to product-specific confidential agreements. Nevertheless, between 2000 and 2003, total repayments ranged from a low of 0.86% of total turnover in 2002 to a high of 2.03% in 2000 (Cour des Comptes, 2004). In 2006, an exceptional year during which the turnover cap set for out-patient reimbursable drugs was not exceeded, companies did not pay any rebate relating to the macro-level cap (Comité économique des produits de santé, 2007).

In Germany, the government periodically takes measures to reduce the deficits of the health insurance funds. In 2004, it required rebates from both pharmaceutical manufacturers (16% of the price of non- clustered drugs in 2004) and pharmacists (EUR 2 per prescription pack in 2004). In addition, a moratorium on price increases in the non-clustered market and the lowering of reference prices have contributed to cost-containment in 2004. German measures are generally proportionate to financing needs and thus can be considered as effective cost-containment measures. However, rebates are set in relation to the funding needs of health insurance funds and may seem arbitrary and unpredictable (compared to regulations based on annual caps for pharmaceutical expenditures).

Tendering can be used to achieve significant savings

Tendering can often lead to significant savings in cases where the purchasing power is great and there are multiple potential sources for the product. Manufacturers and wholesalers will have very strong incentives to provide the best possible price, given that providers who are not successful will not sell any products to the purchaser. Where generic alternatives are available, bidding can be successful in reducing payments to the level of marginal production costs. The VA estimates that it has achieved over USD 1.5 billion in total cost avoidance through national contracting efforts between 1996 and 2003 (Sales *et al.*, 2005). Mexico's social insurance programmes use tendering for interchangeable generics to achieve very significant savings over the retail cost of medicines (Moïse and Docteur, 2007a).

Cost-sharing is possibly the most effective instrument to contain costs, but raises other problems

Pharmaceutical cost-sharing *(e.g.,* co-payments, deductibles) that is not differentiated by type of medicine can be considered to have two purposes: tempering demand for medicines (by reducing moral hazard) and obtaining co-financing for subsidised pharmaceuticals.

Cost-sharing has been shown to be effective in reducing demand although the effects may fall disproportionately on lower-income and chronically ill patients (see Box 4.1).

Reference price policies are an often used means to co-finance subsidised pharmaceuticals. Their net impact in terms of cost-containment is difficult to assess. First, not only does such an assessment require evidence on costs trends for clustered products, but also for those which are not clustered in order to capture all potential effects on pharmaceutical expenditure trends. Second, it requires a sound empirical methodology that allowing for the disentangling of the effect of the reference price policy from the effects of other concurrent policies and contextual market features (Puig-Junoy, 2005).

According to the Cochrane collaboration review (Aaserud *et al.*, 2006), only two studies provide reliable estimates of the impact of reference prices on health plans' drug expenditures. They both analysed the introduction of reference prices in the British Colombia health benefit for seniors. They showed contrasting results across therapeutic classes: a 5% increase in expenditures after six months in the ACE inhibitors class, contrasted with an 18% decrease in the class of Calcium Channel Blockers (both anti-hypertensives), a 47% decrease in the nitrates class (cardiac drugs), and a 38% decrease in the H2RAs class (antacids).

The prospective impact of reference price schemes depends on several factors: how products are clustered, how reimbursement amounts are set, and what are the other incentives established in the system. Beyond this, reference pricing systems may result in increases in cost-sharing which may, in turn, hamper access to treatments and have negative health outcomes, especially in vulnerable parts of the population (see Box 4.1).

Encouraging parallel trade may have a short-term impact on public insurers expenditures, though cost-savings may be captured by distributors

Parallel trade has resulted in moderate savings for health insurers and the national health systems of importing countries of the European Economic Area, thanks both to increased use of cheaper imported drugs and to decreases in prices due to competition, though the main beneficiaries of parallel trade have been intermediaries (see Enemark *et al.*, 2006 for a review). The most recent study estimated both direct (consumption at a lower price) and indirect (downward pressure on prices) savings achieved in Denmark and Sweden thanks to parallel trade. In 2004, these savings represented, respectively, 1.4% and 1.9% of Danish and Swedish total pharmaceutical expenditures (Enemark *et al.*, 2006; and OECD, 2007). Only direct savings were estimated for Germany and the United Kingdom; they represented 0.4%[16] and 1.7%, respectively, of total pharmaceutical expenditures.

However, savings from parallel trade have been declining (Enemark *et al.*, 2006) and the potential for further savings may be limited by price harmonisation within Europe and by strategies employed by manufacturers to limit parallel trade (see Chapter 5).

Pursuing good value for money in spending on pharmaceuticals

There is no single measure by which to assess the value for money that OECD countries attain in their pharmaceutical expenditure. Ideal indicators would assess the amount of health improvements attributable to pharmaceutical expenditure. Lacking these, it is useful to look at a range of partial indicators that provide information that is actionable from a policy perspective. For example, countries differ in the extent to which they achieve price competition of different sorts: for products (whether or not on-patent) with therapeutic alternatives and for products that have gone off-patent and are subject to competition from generic alternatives. In addition, countries vary in the degree to which they have established cost-effective pharmaceutical distribution systems. We review differences in cross-country performance by these indicators, together with information on the role of pricing and reimbursement policies in contributing to performance, below.

Pricing and reimbursement practices that affect value for money

In the pharmaceutical sector, securing value-for-money means concentrating public spending on pharmaceuticals which are necessary, effective, and used appropriately, and obtaining the best possible price. Interventions at both micro- and macro-levels are likely to improve value-for-money of pharmaceutical spending.

Subsidy design is a means to achieve value-for-money

The first objective for OECD countries should be to concentrate public subsidies on drugs which are effective and considered necessary to prevent or treat illnesses. However, the frontier between health problems and well-being issues is not always easy to draw. Recent debates about the inclusion/exclusion of life-style drugs in public and private drug benefits illustrate the dilemma that purchasers may face (Walley, 2004). For instance, the English NHS decided to cover smoking cessation drugs and obesity treatments on public health grounds while Germany decided to not cover these drugs. In France, obesity drugs are not covered because they are not considered to be effective enough and smoking cessation drugs have been subsidised only since 2007 up to EUR 50 per year.

Many countries do not subsidise, or have stopped subsidising, OTC and low-cost medicines. However, it should be kept in mind that OTC status is determined on safety grounds by the authorities that grant marketing authorisations, which is not necessarily linked to therapeutic utility and effectiveness. This means that de-listing OTC drugs may render some important and effective drugs (for instance, pain-killers or antihistamines) unaffordable for some groups of patients. Countries can help ensure access to OTC drugs by vulnerable populations by organising the distribution chain in a way that promotes price competition, *i.e.* authorities should not restrict the distribution of OTC medicines to pharmacies. Countries could also erect safety nets for the most vulnerable parts of the population, although the design of such a scheme may be difficult for drugs that are not subsidised.

The problem is different for private purchasers since they can offer different levels of guarantees and premiums, among which plan sponsors or consumers are able to choose their preferred option.

Obtaining the best possible price for a given therapeutic value

A range of policies aim at obtaining the best possible price for a given therapeutic value, including promoting price competition in off-patent market segments, setting common reimbursement amounts for groups of drugs clustered according to bioequivalence, class or therapeutic similarity, and encouraging parallel importation of the cheapest products. As the impact of the two last options has been assessed in earlier sections of this chapter, we examine below the prospective impact of policies promoting competition on the off-patent market.

Patent expiry opens the road for generic competitors and may put pressure on prices of off-patent products. Although price competition does not always result in lower prices for off-patent originator products, the use of cheaper generics is expected to lower substantially the average cost of treatment. However, a number of conditions are important to maximise the impact: patients (though cost-sharing) must be price sensitive, doctors and/or pharmacists must have incentives to prescribe or dispense cheaper drugs, and several generics – qualified as substitutable for the originator – must be available in the market.

We have already shown that countries perform very differently in terms of generic market share by value and by volume. However, success in generic competition is not necessarily linked to market share. Some countries have obtained low generic prices but still have low penetration of the market by volume (indicating that the incentives of physicians, pharmacists or patients may not be aligned in favour of the lowest-price alternative). Others have obtained high penetration of the market by volume, but have not obtained significant price erosion.

The impact of efforts to link a medicine's price with the value and benefits it offers

As discussed in Chapter 3, some pricing and reimbursement schemes consider a product's value either explicitly or implicitly. Pharmaceutical purchasers are increasingly making efforts to link the price or reimbursement level with the incremental benefits offered by new drugs with therapeutic comparators. Often, new products are compared in terms of relative cost-effectiveness with comparable products, as variously defined. Less commonly, regulators or purchasers define explicit thresholds at which products may be considered cost-effective at a given price, given assumptions regarding use and effectiveness.

The characteristics of the scheme will largely determine the prospective impact of the use of pharmaco-economics in decision-making on efficiency of health and/or drug expenditure.

First, an important issue emerges in the question of which costs and benefits to value in a cost-effectiveness assessment, depending on whether the payer's perspective[17] or a social perspective[18] is adopted (see Chapter 3). These different approaches will result in different assessments of absolute and relative value of a product. Moreover, their potential impact on health systems varies.

In a free and unsubsidised market, the willingness and ability to pay of individual consumers would define price elasticity, suggesting that the payer perspective results in a better approximation of market outcomes. However, to the extent that there are externalities associated with pharmaceutical consumption *(e.g.,* health improvements resulting in increased worker productivity), markets would underestimate the value of the

products. This suggests that adopting the social perspective would result in an outcome that comes closer to maximising social welfare.

The social perspective can be at odds with responsibilities and objectives of decision-makers in charge of ensuring efficient use of resources allocated to the health system, however (Brouwer *et al.*, 2006). Interventions deemed cost-effective at the societal level may well be costly and not cost-effective at the health-payer level.

Another important feature is the definition of cost-effectiveness thresholds for decision making. As seen in Chapter 3, countries have been reluctant to define thresholds and sometimes seem to employ several implicit thresholds, as well as ignoring them, as sometimes is the case for orphan drugs or for drugs treating life-threatening diseases for which no treatment is yet available (Eichler *et al.*, 2004). Beyond these considerations, how should the cost-effectiveness threshold be set to reflect citizens' willingness-to-pay for drugs?

The World Health Organisation (2002) has suggested that a cost-effectiveness threshold equal to three times the GDP per capita per DALY (Disability Adjusted Life Year) could be a cut-off point for financing health interventions, endorsing the implicit assumption that revenue is the main determinant of citizens' willingness to pay. According to such a principle, the cost-effectiveness threshold in 2004 would be 108 000 USD/DALY in the United States and 53 000 USD in New Zealand (figures presented in Eichler *et al.*, 2004). Several studies have inferred implicit cost-per-QALY thresholds from past decisions of assessment bodies, but give somewhat contradictory results (Eichler *et al.*, 2004; Henry *et al.*, 2005). Henry *et al.* (2005) found that NICE and the Australian Pharmaceutical Benefits Advisory Committee (PBAC) had very comparable upper thresholds (49 000 AUD/QALY for NICE and 52 400 AUD/QALY for PBAC), beyond which the probability of listing or positive recommendation for use is virtually nil.

Finally, pharmaco-economic assessments do not always operate from the same perspective. NICE assessments generally consider a class of products or different interventions, while other assessment bodies consider isolated products (Sweden[19]) or even a product's indications separately (Canada, Australia). Most often, regulators and payers respond to evidence that products are less cost-effective for certain indications by restricting listing of the product to cost-effective uses, rather than to establish distinct prices – though such a solution could be envisaged (for instance by asking the manufacturer to produce different packages for different indications). However, this might be difficult to enforce in practice, particularly as various actors in the distribution chain would face incentives to substitute a lower-priced equivalent product.

Only a few studies considered the extent to which recommendations or decisions from pharmaco-economic processes had an impact on the uptake of products with positive recommendations or listings. Sheldon *et al.* (2004) showed that positive recommendations for the use of taxanes in treating breast cancer and for the use of anti-obesity drugs had a significant impact on NHS doctors' prescribing. McMahon *et al.* (2006) showed high variation in provincial and federal drug plans formulary listings in Canada after the Common Drug Review's decisions, likely to influence drug consumption.

In a context of fixed budget constraints, adoption of new and costly technologies (either high priced or with large population targets) are likely to divert health funds from other health interventions that could potentially be more cost-effective. In order to avoid such distortions in fund allocations, the governments in England and Wales decided

in 2002 that any positive recommendations of NICE should be allocated the corresponding funds to allow local providers to purchase the new technology. Any new technology approved is thus supposed to lead to supplemental funding – though NHS authorities may incorporate future expected decisions in their annual budgetary exercise.

In the case of recommendations or listings for restricted use, incentives or regulatory controls have a role to play. Wherever health providers are constrained by budgets, they will tend not to use drugs beyond listed or recommended indications. In other circumstances, controls may be necessary to ensure that drugs are prescribed appropriately.

The reliability of information submitted by those with financial interest in drug coverage, as well as the uncertainty of clinical claims raise problems for decision-makers. A study on PBAC decisions showed that the probability of acceptance of a technology was higher – cost-effectiveness being constant – when the level of confidence in clinical claims was higher (Harris *et al.*, 2006).

Risk-sharing arrangements may provide a means of linking price to value and reducing the cost of mistaken or inadequately informed decisions regarding subsidies. However, until now, these schemes have only rarely been used and overall results are not available. In any case, periodic reviews of assessment are highly desirable since effectiveness in "real use" has sometimes proved to be different than claimed efficacy.

Efficient distribution of medicines

The share of retail prices accruing to wholesalers and pharmacists is highly variable across countries (see Table 1.A1.1 in Chapter 1). Though these differences are partly explained by differentials in labour costs across OECD countries, they undoubtedly reflect differences in the efficiency of drug distribution, representing a significant frontier for value improvements in many OECD countries.

Some countries or purchasers recently introduced fixed fees to pay pharmacists' services. Fixed fees present the advantage of not being linked to the prices of medicines. Indeed, there is no obvious reason to link the remuneration of distribution chains to the price of medicines. If some products require particular storage features, their management could be paid accordingly. On the other hand, the definition of caps may foster competition between distributors and finally reduce retail prices, at least if the final purchaser benefits from a part of the savings.

Conclusions

While access to medicines in the OECD countries studied appears to be at a very high level, there is room for improvement. This is possible without sacrificing cost control. Efforts to improve value for money in public spending on pharmaceuticals could do a lot to free up resources that could be better spent enhancing the availability, accessibility and appropriate use of effective medicines. Many, if not all countries have some room for improvement in this respect. They could good get better value for their money by maximising use of generic alternatives to off-patent original products, fostering generic price erosion through competition, ensuring efficient distribution systems for prescription and OTC products, and becoming more sophisticated in their reimbursement pricing strategies.

Notes

1. The Transparency Directive (Directive 89/105/EEC) adopted by the Council of the European Union in 1989, sets maximum delay periods for pricing and reimbursement decisions to EU member countries (90 days after manufacturers' application for reimbursement and 90 days for reimbursement, which makes a total of 180 days) and calls for the use of more transparent criteria in decision-making.
2. Some NHS primary care trusts have delayed reimbursement for some drugs that were being assessed by NICE by as much as 32 months. This so-called "NICE blight" applies to a relatively small number of drugs (Cohen *et al.*, 2007).
3. Agreement signed between the French pharmaceutical industry association and the Economic Committee on health products (*www.leem-media.com/leem-image/leem/document/412.pdf*, accessed 1 August 2007).
4. Lanjouw (2005) analysed a sample of 836 new pharmaceuticals, launched in 68 countries over 20 years (1986-2002). She measured the probability of entry in each country (within two years and within ten years) against a set of variables representing the level of IPR protection, the existence and scope of price control (depending on whether some or all of the market was regulated), market opportunities (population size and structure), economic variables (GDP/capita, and other variables), demand-side regulation (adoption of an essential drug list, use of national formulary, of national guidelines), and potential for imitative competition (share of total R&D expenditure in GDP).
5. The study utilised 133 pharmacologic quality-of-care indicators developed by experts for use with data collected through survey interviews and medical record reviews.
6. For example, the comparator countries for international benchmarking of pharmaceuticals prices in Canada were selected as ones that had or aspired to have a strong national presence of the pharmaceutical industry (Paris and Docteur, 2006).
7. See, for example, the 2004 testimony of US Centers for Medicare and Medicaid Services Administrator Mark McClellan before the US Finance Committee, in which he argued that "using competition to drive price negotiation will maximize savings on drug prices, as well as, or better than when government does direct price negotiation".
8. The bargaining power of Medicare prescription drug plans (PDPs) was weakened by a provision of the Medicare Modernization Act requiring PDPs to offer drugs within each therapeutic category and class (Atlas, 2004). This provision was interpreted as requiring PDPs to list "more than one drug" in each therapeutic class. The US Pharmacopeia (USP) is in charge of defining the relevant therapeutic classes, in consultation with stakeholders, to help PDPs to structure formularies and curtail them from "skewing formularies away from the drugs needed by beneficiaries with the costliest conditions". The definition of therapeutic classes is important as the bargaining power of PBMs decreases as the number of classes increases. The USP defined 146 classes in 2004, while PBMs were asking for no more than 90 and manufacturers for more than 200 classes (Atlas, 2004).
9. The rebate is computed for a "normalised brand prescription", *i.e.* adjusted for differences in length/size of prescriptions among studies PBMs. We were not able to compute how much this represents in PBMs total expenditures.
10. Consistency was defined as having the difference between the country's pharmaceutical price level and its economy-wide price level less than one standard deviation from the OECD average.
11. France's pharmaceutical price level may overstate the prices paid, to the extent that they do not take into account confidential rebates negotiated with manufacturers. Manufacturers may be willing to grant such concessions to France because of its high volume of drug consumption and because lack of transparency ensures that the low prices in France will not influence the prices manufacturers are able to obtain in other markets.
12. It is likely that the original products include both on-patent and off-patent originals. Furthermore, some countries may have reported prices for original products that were still patent protected, whereas the price for the same product in another country may have been reported for an off-patent original. The extent to which this is a problem is not known.
13. This similarity may be partly explained by the fact that 75% of products in the master list for which prices were sought are original products. However, data correspondents were instructed to report prices for a mix of products representative of the mix of products sold in the country.
14. Canada also uses the United States – whose economy-wide price levels are close to Canada's – as a reference country in its patented medicine price regulation.

15. Companies with branded prescription drugs with NHS sales exceeding 1 million GBP in 2004 were required to reduce prices by 7% from 1 January 2005.

16. The authors note that savings from parallel trade in Germany were exceptionally low in 2004 due to other cost-containment measures adopted the same year, which made parallel trade less attractive.

17. NICE in the United Kingdom adopts the payer perspective, considering the net cost to the National Health Service associated with a net benefit obtained by the patient.

18. The LFN in Sweden, on the other hand, adopts a broader social perspective, taking into account net costs and benefits that accrue to society and not only the health service (Moïse and Docteur, 2007b).

19. Sweden's pharmaceutical pricing agency (LFN) has undertaken retrospective class reviews for products approved for reimbursement prior to the LFN's inception in October 2002.

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ANNEX 4.A1

The Relationship between Retail Pharmaceutical Price Levels and Economy-wide Price Levels in OECD Countries

It is possible to examine the relative price levels of pharmaceuticals using price indices prepared by OECD and Eurostat as input to the development of economy-wide purchasing power parities (PPPs), which are used to convert nominal expenditure levels to real expenditures by adjusting for differences in the price levels and currency exchange rates (see Box 1.2 for more details).

This annex provides a detailed comparison of economy-wide price levels with the level of retail pharmaceutical prices. The comparison begins with an overall assessment, then considers price levels for original and generic products.

Retail pharmaceutical price levels compared with economy-wide price levels

A comparison of retail pharmaceutical price levels and economy-wide price levels reveals some interesting findings (Table 4.A1.1).

Pharmaceutical price levels roughly correspond with economy-wide price levels in most countries

Two-thirds of OECD countries' pharmaceutical price levels[1] are consistent with their relative economy-wide price levels – consistency being defined as the difference between pharmaceutical price levels in a country and its economy-wide price levels being at least one standard deviation away from the OECD average. For instance, Belgium's economy-wide price level in 2005 – when converted to USD PPP – was about 5% above the OECD average and its pharmaceutical price level was about 9% above the average.[2] Similarly, Portugal had an economy-wide price level and a pharmaceutical price level that were both slightly below the OECD average.

Switzerland's pharmaceutical prices are even higher than prices overall

Switzerland has the third highest economy-wide price level in the OECD (140% of the OECD average) and the highest pharmaceutical price level (185% of OECD average), but it is notable that the margin on the pharmaceutical side is significantly greater than that for prices overall.[3] Even when taking into account high prices across the board, Swiss pharmaceutical prices are still notably high. Differential tax treatment may contributes somewhat to the difference – reimbursed medicines are subject to a 2.4% tax rather than

Table 4.A1.1. **Economy-wide price levels and retail price levels for pharmaceuticals, 2005**

	GDP-PPP comparative price level (OECD = 100)	Pharmaceutical comparative price level (OECD = 100)	Difference between pharmaceutical and economy-wide price level
Iceland	153	159	6
Denmark	143	120	–23
Switzerland	140	185	46
Norway	138	119	–19
Ireland	127	118	–9
Sweden	126	94	–32
Finland	123	111	–12
Japan	118	118	–1
Luxembourg	116	103	–13
United Kingdom	115	92	–23
France	114	91	–23
Germany	112	127	15
Netherlands	112	109	–3
Austria	110	106	–4
Belgium	109	105	–4
Italy	109	117	8
Australia	107	81	–27
New Zealand	105	113	8
Canada	105	134	29
United States	102	130	28
Spain	97	77	–20
Portugal	89	94	4
Greece	88	73	–15
Korea	75	71	–4
Mexico	70	106	36
Turkey	67	69	2
Hungary	64	73	9
Czech Republic	60	71	11
Poland	58	68	9
Slovak Republic	56	70	14
Standard deviation			19.2

Note: Price levels are expressed as a percentage of the OECD average price level, which is computed as a geometric mean. Countries that were more than one standard deviation away from the OECD average: pharmaceutical price level less than economy-wide price level – Denmark, Sweden, the United Kingdom, France, Australia and Spain; pharmaceutical price level greater than economy-wide price level – Switzerland, Canada, the United States and Mexico.
Source: Eurostat–OECD Purchasing Power Parity Programme, 2007.

the 7.6% tax applied to most other goods. However, the tax differential is small compared to the price gap and compared to other European countries with a minimum VAT of 15%.

Denmark's pharmaceutical prices are relatively high, but not as high as general prices in its economy

Denmark has relatively high overall prices, standing at 143% of the OECD average, and relatively high pharmaceutical prices, at 120% of the OECD average. Differential taxes are not a factor as Denmark's 25% VAT applies to pharmaceuticals as well as other goods and services.

In some countries, relative pharmaceutical prices deviate from economy-wide prices

Mexico has very low economy-wide prices and average pharmaceutical prices

Mexico's economy-wide prices are just 70% of the OECD average. Its pharmaceutical price level stands at 106%, however, suggesting that drugs in Mexico are much more expensive, relative to other goods and services sold in Mexico, than they are elsewhere. Danzon and Furukawa (2003 and 2008) found the same result in two separate, but similar studies comparing pharmaceutical ex-manufacturer prices.

Canada and the United States have average economy-wide prices and high pharmaceutical prices

The United States had an economy-wide price level that was 102% of the OECD average, while its public pharmaceutical price level was relatively high at 130% of the OECD average.[4] The situation is similar in Canada, with an economy-wide price level that was 5% above the OECD average and a pharmaceutical price level 34% greater than the OECD average.

Australia and Spain had average economy-wide prices and low pharmaceutical prices

Australia stands out in the other direction, with economy-wide prices that exceeded those of the OECD average by 7%, but with pharmaceutical prices at just 81% of the OECD average. Differential taxes may account for some of the difference, but the tax rate is too low to account for all of the difference; prescription medicines as well as OTC medicines are exempted under certain circumstances from the standard Goods and Services Tax (VAT) of 10%. At 97%, the economy-wide price level in Spain was not significantly different from the OECD average, but the pharmaceutical price level was 77%, much lower than the OECD average.

Sweden, France and the United Kingdom have high economy-wide prices and low pharmaceutical prices

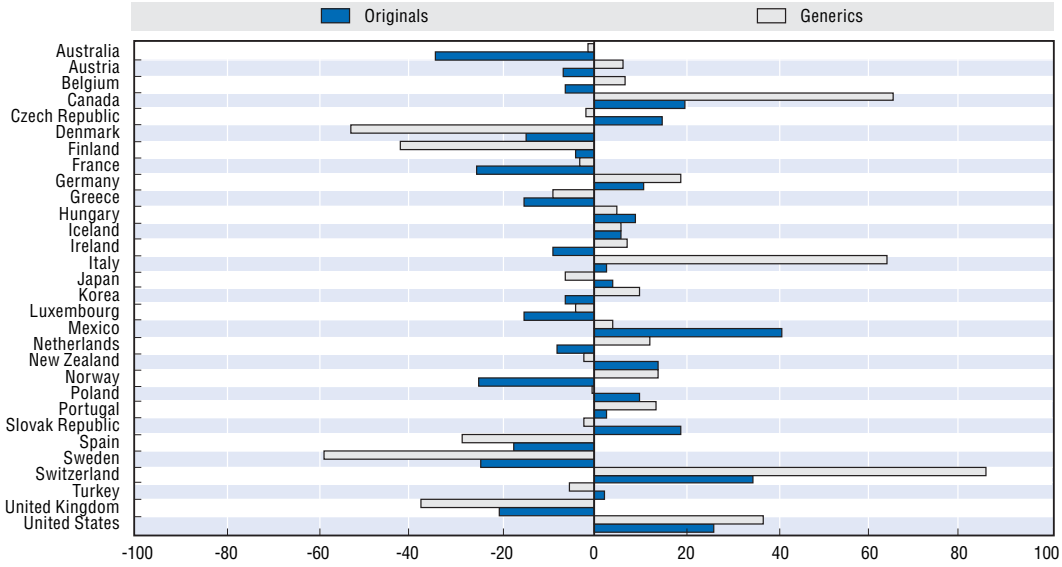
Sweden stands out in having economy-wide prices that were 126% of the OECD average, but pharmaceutical prices that were only 94% of the OECD average. France and the United Kingdom were similar, but the difference between economy-wide prices and pharmaceutical prices was less pronounced.

In all three cases, a differential treatment of pharmaceuticals in application of VAT may explain much of the variation between the pharmaceutical and economy-wide price levels. France applies a 2.1% VAT for reimbursed pharmaceuticals and a 5.5% VAT for non-reimbursed pharmaceuticals, compared to a 19.6% standard VAT. The United Kingdom has no VAT for pharmaceuticals furnished at National Health Service pharmacies; its 17.5% standard VAT applies to OTC and hospital medicines. Sweden exempts prescription-only medicines from its 25% VAT, but this is charged for OTC drugs. All of these tax rates reflect the situation in 2006 (PPRI, forthcoming).

Pharmaceutical price levels for original and generic products

Figure 4.A1.1 reveals a mix of patterns in relative price levels for original and generic products in OECD countries.

Figure 4.A1.1. **Retail price – economy-wide price level differentials for original and generic pharmaceuticals, 2005**



Note: Price levels are expressed as a percentage of the OECD average price level, which is computed as a geometric mean. The light (dark) shaded area represents original(generic) – economy wide price level differentials that fall within one standard deviation of the OECD average.

Source: Eurostat–OECD Purchasing Power Parity (PPP) Programme, 2007.

Pharmaceutical price levels roughly correspond with economy-wide price levels in most countries

Overall, most OECD countries' original and generic price levels do not differ substantially from their economy-wide price levels. Twenty-one countries had original price levels consistent – defined similarly to overall retail price levels – with their economy-wide price levels. Slightly more countries (22) had generic price levels consistent with their economy-wide price levels, although this is likely a statistical artefact due to the higher variability in generic price levels.

In some countries, relative original and pharmaceutical prices deviate from economy-wide prices

Sweden's and the United Kingdom's original and generic price levels are much lower than their economy-wide price levels

Sweden had the fifth lowest generic price level of any country, 67% lower than the OECD average price level for generics. This result is in large part due to Sweden's generic substitution policy. Although its original price level was the same as the OECD average, this was still substantially lower than its economy-wide price level. In both cases, the exemption from VAT for prescribed medicines contributes significantly to the price differentials with economy-wide prices.

Both original and generic retail prices in the United Kingdom were lower than the OECD average, especially generics (77% of the OECD average). The government pays the standard VAT (17.5%) for prescription medicines dispensed in retail pharmacies, essentially an exemption from VAT for prescription medicines. It is likely, therefore, that differences in

VAT applicability explain a significant portion of the difference between original and generic price levels with economy-wide prices.

Three countries have original and generic price levels that are much greater than their economy-wide price levels

Price levels for both original products and generics were considerably higher than economy-wide price levels in Canada, Switzerland and the United States. Switzerland in particular, had price levels that were substantially greater than the OECD average; the price level for originals was 74% greater than the OECD average, whereas that for generics was 125% greater. Despite the fact these high prices reflect Switzerland's standing *vis-à-vis* other OECD countries regarding economy-wide prices, the difference with its economy-wide prices are notable. In part the differential with economy-wide price levels reflects the exemption from VAT afforded to prescription medicines, but it also reflects Switzerland's pricing policies (Paris and Docteur, 2007).

In Canada's case generic pharmaceutical price levels are a more of an outlier than are original price levels; generic prices are 70% greater than the OECD average compared to 25% for originals (Canada's economy-wide price level is virtually equal to the OECD average). These results confirm the findings from the case study for Canada, especially with regards to generics (Paris and Docteur, 2006).

On one level the finding for the United States is not surprising considering it is generally acknowledged as having one of the highest pharmaceutical price levels among OECD countries (at least for ex-manufacturer prices) and economy-wide price levels that are almost identical to the OECD average. However, it is somewhat surprising to find that US generic prices are 39% greater than the OECD average. Several studies have shown that, although original prices in the United States are among the highest in the world, price levels for generics tend to be much lower (ITA, 2004; PMPRB, 2006; Danzon and Furukawa, 2008).

Original price levels in Australia, France and Norway are lower than their economy-wide price levels

Original price levels in Australia are fourth lowest among OECD countries even though its economy-wide price level is slightly above the OECD average. There is no VAT for prescription medicines in Australia, which may explain some of the difference with economy-wide price levels. However, differential VAT rates may be less of a factor in explaining why the original – economy-wide price level difference is greater than for most other OECD countries, since the standard rate of VAT (10%) is lower than most OECD countries.

France is similar to Australia, although its original and economy-wide price levels are slightly greater. In France, the VAT for prescription-only medicines is lower than it is for other goods, which at 19.6% is almost double the rate in Australia.

The reason why original prices in Norway are significantly lower than economy-wide prices is probably due to the relatively high overall prices in Norway. The price level for original products in Norway is slightly above the OECD average, but economy-wide price are the fourth highest in the OECD. Furthermore, the standard VAT rate is applicable to prescription medicines ruling differential VAT rates as a possible explanation.

Original prices in Mexico are larger than economy-wide prices

Mexico has an economy-wide price level that is significantly lower than the OECD average, but a price level for original drugs that is greater than the OECD average. With generic prices that are in-line with its economy-wide price level, the relatively high price of originals in Mexico can explain much of the the difference between original prices and economy-wide prices observed earlier in this Annex.

Generic price levels in Denmark and Finland are lower than economy-wide price levels

The difference between generic prices and economy-wide prices in Finland is lower than all countries except Sweden and Denmark. A significantly lower VAT rate for prescription medicines than for all other goods offers a partial explanation. This is not the case in Denmark, where the standard VAT rate applies to prescription medicines.

Italy has a much higher generic price level than its economy-wide level

Italy's generic price level was second highest among OECD countries. With only an above average economy-wide price level, the difference with the generic price level was third largest, being roughly the same as for Canada. The VAT rate in Italy for all goods is double the rate for prescription medicines.

Notes

1. It is important to note that the price levels being considered are retail prices, which include the price received by the manufacturer plus wholesale and retail mark-up, plus any VAT or other tax paid by the final purchaser. A presentation of the average prices received by manufacturers would result in different relative rankings across countries.
2. Note that price levels should be used to provide a rough estimate of where a country stands relative to its peers. They are not sufficiently precise to be reliable in distinguishing ranking of countries with similar price levels.
3. The very low level of penetration of generic products in the Swiss market, compared to other countries offering high ex-manufacturer prices for patented medicines (*e.g.*, the United States, Canada and Germany), likely contributes to Switzerland's relatively very high retail price level.
4. The 2005 prices reported by US officials from the Bureau of Labor Statistics (BLS) were below those in the 2007 US Federal Supply Schedule, widely considered to be among the lowest US prices. According to BLS officials, the data were obtained from a check of several Internet pharmacies.

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Pharmaceutical Pricing Policies in a Global Market

Glossary

Active ingredient: the chemical substance contained in a *pharmaceutical* which is responsible for its therapeutic effect. Some pharmaceuticals contain more than one active ingredient (combination product).

Active substance: see *active ingredient*.

Anatomic Therapeutic Chemical (ATC) classification system: in this WHO classification system *pharmaceuticals* are divided into different groups according to the organ or system on which they act and/or their chemical, pharmacological and therapeutic properties. The ATC Classification system is divided into five levels. ATC 4 level defines a *therapeutic group*, whereas ATC 5 level defines a single *active ingredient* or a fixed combination of active ingredients. A medicinal product can be given more than one ATC code if it is available in two or more strengths or formulations with clearly different therapeutic uses.

Bioequivalent pharmaceuticals: are considered to be bioequivalent if they contain the same molecule (in the same form, dosage type and strength) and are released into, and absorbed by, the body at the same rate. See *generic*.

Brand: the trade or marketing name**.** Brand names used to designate a particular *pharmaceutical* product may differ across countries.

Brand name: see *brand*.

Claw back: a scheme under which *third-party payers* recoup (part of the) *discounts/rebates* granted between various parties to *pharmaceutical* sales transactions, *e.g.* wholesalers and *pharmacists*.

Co-insurance: *cost sharing* in the form of a set proportion of the cost of a service or product.

Compound: see *active ingredient*.

Compulsory license: a license to use a patent, copyright, or other exclusive right that a government forces the holder to grant to others. Compulsory licensing allows generic *manufacturers* to make and sell *generic* versions of *on-patent pharmaceuticals* before patent expiry, in exchange for royalty payments to patent holders.

Co-payment: insured patients' contribution towards the cost of a medical service covered by the insurer. Can be expressed as a percentage of the total cost of the service (also known as co-insurance) or as a fixed amount.

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

Cost sharing: terms of coverage by a *third-party payer* specifying how the patient's share of the costs of health care will be calculated. Cost-sharing mechanisms include

co-payments (known as user fees in tax-financed coverage systems), *deductibles* and co-insurance.

Cross-border trade: the act of importing *pharmaceuticals* into one country (the "import" country) from another (the "export" country) for the purpose of personal consumption in the import country.

Cross-country referencing: see *external price referencing*.

Data exclusivity: protection of an originator pharmaceutical company's data preventing other parties from using these data for a commercial purpose. Concretely, this protection prevents *generic* product *manufacturers* from proceeding to clinical trials and health authorities from evaluating generic product *market authorisation* applications during this period. In the European Union, this period was harmonised to eight years in 2004.

Deductible: patient's share in the form of a fixed amount which must be paid for a service or of total cost incurred over a defined period by a covered person before a *third-party payer* covers all or a percentage of the rest of the cost.

Defined Daily Dose (DDD): the assumed average maintenance dose per day for a *pharmaceutical* used for its main indication in adults.

De-listing: dropping a *pharmaceutical* from a pharmaceutical list (*e.g. positive list*), often resulting in exclusion from *reimbursement*.

Direct-to-consumer advertising (DTCA): the advertising of aimed directly at the public.

Discount: a price reduction granted to specified purchasers of a *pharmaceutical*.

Dispensing fee: payment of the *pharmacist* for the service of dispensing a *pharmaceutical*.

Distributor: a *pharmaceutical* company that sells products it does not produce itself under a licence obtained from the *manufacturer*. Also refers to all actors in the pharmaceutical distribution chain, such as wholesalers or retailers.

Drug: see *pharmaceutical*.

Effectiveness: the extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do.

Efficacy: the extent to which an intervention produces a beneficial result under ideal conditions.

Efficiency: a measure of the extent to which health care resources are being used so as to maximisevalue for money.

Evergreening: strategies employed by an originator pharmaceutical company (see *original product*) to extend the patent life of an original product by applying for patents for various attributes of the product on a sequential, rather than simultaneous basis.

Ex-factory price: the *manufacturer's* posted price, in some countries also referred to as list price. Discounts or other incentives offered by *manufacturers* result in an effective price that is lower than the ex-factory price.

External price referencing: the practice of comparing *pharmaceutical* prices across countries. There are various methods applied and different country baskets used.

Formulary: list of products reimbursed or paid for by a *third-party payer*. See also *open formulary*.

Framework agreement: agreement between social health insurers, national health services or ministries with pharmaceutical *manufacturers* establishing guidelines for policies relating to *pharmaceuticals*. Framework agreements may include provisions relating to *pricing*, promotion, etc. They are used in countries such as France and Spain.

Free pricing: a policy under which *manufacturers* are free to set prices at the level or levels which the market will bear, free from government intervention.

Generic: bioequivalent version of an *original product*. There are branded and *unbranded generics* on the market. Branded generics also have a specific trade name, whereas unbranded generics use the *international non-proprietary name*.

Generic name: see International Non-proprietary Name.

Generic substitution: practice of *pharmacists* substituting a *generic* pharmaceutical, either a branded or *unbranded generic*, for a branded *pharmaceutical*.

Health technology assessment (HTA): the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.

Internal reference pricing: a method to compare prices of products in a country with the price of identical (ATC-5 level) or similar products (ATC-4 level). Often performed in the course of a *reference pricesystem*.

Internal price referencing: see *internal reference pricing*.

International Non-proprietary Name (INN): Identifies *pharmaceutical* substances and *active ingredients*. Each INN is a unique name that is globally recognised and is public property.

International price benchmarking: see *external price referencing*.

List price: see *ex-factory price*.

Manufacturer: a pharmaceutical company that produces *pharmaceuticals* and very often also searches for and develops new drugs. See also *distributor*.

Manufacturer price: see *ex-factory price*.

Market(ing) authorisation: a licence issued by a regulatory agency approving a pharmaceutical for market use based on a determination by authorities that the *pharmaceutical* meets the requirements of quality, safety and efficacy for human use in therapeutic treatment. Also known as a sanitary license.

Me-too: an *original product* that is approved subsequent to another product that is comparable or similar in composition and in therapeutic effect to the me-too product.

Medicinal product: see *pharmaceutical*.

Medicine: see *pharmaceutical*.

Negative list: list of *pharmaceuticals* not covered by a *third-party payer* (see also *positive list*).

New chemical entity (NCE): a drug approved for *marketing authorisation* with an *active ingredient* not present in any drug previously approved by a regulatory agency.

New molecular entity (NME): see *new chemical entity*.

Non-prescription medicine: see *over-the-counter pharmaceutical*.

Off-patent pharmaceutical: *original product* whose patent has expired.

Off-patent product: see *off-patent pharmaceutical*.

On-patent pharmaceutical: an *original product* whose patent is still in force.

Open formulary: a *pharmaceutical* benefit design that provides coverage for drugs on the *formulary* (if any) as well as other drugs not specifically listed.

Original preparation: see *original product*.

Original product: the first version of a *pharmaceutical*, developed and patented by an originator pharmaceutical company which receives exclusive rights to market the product for a specified period of time. An original product has one or more trade names used for marketing purposes, its so-called *brand* names.

Original substitution: see *generic substitution*.

Orphan drug: a *pharmaceutical* which only has a limited target population or which treats a rare disease thus limiting its commercial and financial potential.

Out-of-pocket payments: payments made by a health-care consumer that are not reimbursed by a *third-party payer*. This includes all forms of *co-payments*, co-insurance and deductibles as well as payments for non-covered services and informal payments for health-care services.

Over-the-counter pharmaceutical (OTC): *pharmaceuticals* which may be dispensed without a doctor's prescription being submitted and which are in some countries available via self-service in pharmacies and/or other retail outlets (*e.g.* drug stores, supermarkets).

Parallel import: see *parallel trade*.

Parallel trade: the act of importing *pharmaceuticals* into one country (the "import" country) from another (the "export" country) and placing them on the market outside the formal channels authorised by the product's *manufacturer* or licensed distributors.

Pharmaceutical: any *active ingredient* or a combination of two or more active ingredients in a product which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a pharmaceutical.

Positive list: see *formulary*.

Pharmaceutical form: the pharmaceutical-technological form in which an *active substance* is made available. *Pharmaceuticals* may be administered in solid form (*e.g.* tablets, powders), in semi-liquid form (*e.g.* ointments, pastes), in liquid form (*e.g.* drops, injectables, infusions) or in gaseous form (inhalation).

Pharmaco-economics: see *pharmaco-economic evaluation*.

Pharmaco-economic evaluation: assessment of the relationship between costs and outcomes for a given product, and, possibly, comparisons to costs and outcomes of alternative treatments, pharmaceutical or not.

Pharmacist: a person trained and licensed to prepare and distribute medicines and to give information about them.

Pharmacy margin: the gross profit of pharmacies expressed as a percentage of the *retail price*.

Pharmacy mark-up: the gross profit of pharmacies expressed as a percentage of the *pharmacy purchasing price*.

Pharmacy purchasing price: the price charged by wholesalers to the retailers (usually pharmacies). It includes any *wholesale mark-up*.

Positive list: see *formulary*.

Preferred drug list (PDL): a term sometimes used as an alternative to *formulary*, but more precisely refers to a list of preferred medicines within selected drug classes on a formulary for which a patient's co-payment is lower and/or prior authorisation is not required.

Prescribing budget: the maximum amount of money to be spent on *pharmaceuticals* in a specific region or for an individual physician or a group of physicians, for a specified period of time, fixed ex-ante. Prescribing budgets are a cost-containment measure used by *third-party payers*.

Prescription Fee/Charge: a set amount to be paid by a patient for each item prescribed by a physician and dispensed at the expense of a *third-party payer*, *i.e.* a form of fixed *co-payment*.

Prescription-only-medicines (POM): *pharmaceuticals* that may be dispensed only on a doctor's prescription.

Price-volume agreement: the price of a pharmaceutical is agreed to between a *third-party payer* and a pharmaceutical *manufacturer* based on a forecasted volume of sales. If the actual sales volume exceeds the forecast, the price of the *pharmaceutical* may be revised downwards or the manufacturer asked to pay a *rebate*.

Pricing: the act of setting a price for a *pharmaceutical*.

Pricing policy: plan or course of actions used by government authorities, or *third-party payers,* to influence the amount paid by purchasers or the amount received by sellers (*e.g. free pricing*, regulated pricing – see *regulated price*).

Prior authorisation: formal agreement from a *third-party payer* for the *reimbursement* of a treatment, prior to the purchase of the treatment.

Procurement: the act of purchasing a *pharmaceutical* by a public authority.

Product life-cycle management: refers to a range of practices used by *manufacturers* of *originalproducts*, including but not limited to patent-related strategies, intended to limit or delay competition by *generics*.

Rebate: a partial refund following a purchase.

Reference price: a maximum *reimbursed amount* set by a *third-party payer* for a defined group of *pharmaceuticals* judged to be similar. Usually, one reference price is set for all products in a given *ATC*-4 and/or *ATC*-5 level group. See *reference price system*.

Reference price system: a scheme used by *third-party payers* to set a common *reimbursement price* for a defined group of *pharmaceuticals* judged to be similar. Patients buying a pharmaceutical that is part of a group for which a *reference price* has been set must pay the difference between that price and the *retail price* of the pharmaceutical in question, in addition to any fixed or percentage *co-payments*.

Registration: see *market(ing) authorisation*.

Reimbursement: the share of costs (for a service or a *pharmaceutical*) which the *third-party payer* pays. One-hundred per cent reimbursement means that the third-party payer accepts 100% of the costs for a *pharmaceutical* or healthcare service.

Reimbursed amount: the actual sum paid by a *third-party payer* to an insured person or seller of a *pharmaceutical*. May be equivalent to the full *reimbursement price* (as in Austria) or set as a percentage share of the reimbursement price (as in Denmark).

Reimbursement level: the share of total charges for a service or a *pharmaceutical* which the *third-party payer* pays. For example, an 80% *reimbursement level* means that the third-party payer assumes 80% of the costs for a pharmaceutical or healthcare service.

Reimbursement price: the basis for *reimbursement* of pharmaceuticals in a health care system, *i.e.* the maximum amount that a *third-party payer* will pay for a particular *pharmaceutical*. See *reimbursed amount*.

Retail price: the price charged by retail *pharmacists* or other retailers to the general public.

Switch: reclassification of the dispensing status of a *pharmaceutical* from *prescription-only* to *over-the-counter*.

Supplementary Protection Certificate (SPC): gives originators (see *original product*) a complementary period of market exclusivity beyond patent expiry to compensate for delays of marketing in the *pharmaceutical* sector. SPCs are available in EU countries. Similar protection exists in other countries.

Therapeutic group: *pharmaceuticals* from the same pharmacological class, such as statins.

Therapeutic referencing: see *internal reference pricing*.

Third-party payer: any entity, public or private, that pays or insures health or medical expenses on behalf of beneficiaries or recipients of the coverage.

Unbranded generic: see *generic*.

Value-added tax (VAT): a tax levied on the sale of goods and services (compulsory for EU Member States). The VAT rate for pharmaceuticals in the EU is often lower than the standard minimum VAT-rate of 15%.

Wholesale margin: gross profit of wholesalers, expressed as a percentage of the *pharmacy purchasing price*.

Wholesale mark-up: gross profit of wholesalers, expressed as a percentage of the *ex-factory price*.

Wholesale price: see pharmacy purchasing price.

Various sources were used to compile this glossary. The following sources were consulted most frequently or were used to extract a verbatim definition:

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List of Abbreviations

ADR	Adverse Drug Reactions
AMP	Average Manufacturer Price
ANAFAM	Asociación Nacional de Fabricantes de Medicamentos
ASMR	Amélioration du Service Médical Rendu
ATC	Anatomic Therapeutic Chemical Classification
BP	Best Price
BPAs	Blanket Purchase Agreements
CBO	Congressional Budget Office
CBS	Centraal Bureau voor de Statistiek (Netherlands)
CEPS	Economic Committee for Health Products
CME	Continuing Medical Education
CP	Centralised Procedure
DALY	Disability Adjusted Life Year
DDD	Defined Daily Dose
DoH	Department of Health
DP	Drugs Payment
DP	Decentralised Procedure
DRA	Deficit Reduction Act
DRG	Diagnostic-Related Group
DTC	Drug and Therapeutic Committees
DTCA	Direct-to-Consumer Advertising
DTI	Department of Trade and Industry
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industry Associations
EGA	European Generics Manufacturers Association
EMEA	European Medicines Evaluation Agency
EPC	European Patent Convention Treaty
EPO	European Patent Office
EU	European Union
FDA	Food and Drug Administration
FSS	Federal Supply Schedule
FTC	Federal Trade Commission
GAO	General Accounting Office
GDP	Gross Domestic Product
GP	General Practitioner
HD	Health Data
IOM	Institute of Medicine
IPR	Intellectual Property Rights

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LFN	Sweden's Pharmaceutical Pricing Agency
LOOP	Law of One Price
LTI	Long Term Illness
MAGR	Mean Annual Growth Rate
MCC	Marginal Cost of Capital
MPA	Medical Products Agency
MRP	Mutual Recognition Procedure
MRR	Marginal Rate of Return
NAS	New Active Substances
NCE	New Chemical Entities
NCU	National Currency Unit
NHS	National Health Services
NICE	National Institute of Clinical Excellence
NME	New Molecular Entities
ÖBIG	Austrian Health Institute
OOP	Out-of-pocket
OTC	Over-the-counter (non-prescription) drugs
PBAC	Pharmaceutical Benefits Advisory Committee
PBM	Pharmaceutical Benefits Management
PDL	Preferred Drug List
PDP	Prescription Drug Plan
PICTF	Pharmaceutical Industry and Competitiveness Task Force
PMPRB	Prescription Medicine Prices Review Board
POM	Prescription-only medicine
PPP	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information
PPRS	Pharmaceutical Price Regulation Scheme
R&D	Research and Development
RBP	Rémunération basée sur les prestations
ROI	Return on Investment
SKK	Slovak koruna
SPC	Supplementary Protection Certificate
TRIPS	Trade-Related Aspects of Property Rights
USC	Uniform System of Classification
USP	US Phamacopeia
VA	Veterans Affairs
VAT	Value Added Tax
VFA	Verband Forschender Arzneimittelhersteller e.V.
VHA	Veterans Health Administration
VISN	Veteran Integrated Service Network

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