Chapter 6

Drawing all the Benefits from Pharmaceutical Spending

OECD countries' pharmaceutical policies generally focus on three main objectives: making medicines accessible and affordable to patients; containing public spending growth, and providing incentives for future innovation. This chapter provides a brief review of current pharmaceutical reimbursement and pricing policies in OECD countries, as well as short-term measures adopted in response to the economic crisis. It then focuses in particular on two important issues: decisions pertaining to the coverage of new products with high costs and/or uncertain benefits, and the development of generic markets.

1. Introduction

OECD countries' pharmaceutical policies seek to balance three broad objectives: make medicines accessible and affordable to patients; contain public spending growth, and provide incentives for future innovation.

Countries have adopted different approaches to reconciling these objectives, in line with the general organisation of their health systems. The vast majority of OECD countries regulate pharmaceutical coverage at the central level to offer a standardised drug benefit package to their population, as for other health benefits. They also regulate the prices (or reimbursement prices) of pharmaceutical products covered by public schemes. In other countries, individual private or public insurers design drug cost reimbursement packages for their enrolees, in a more or less regulated environment. In all circumstances, payers have to make decisions about which drug should be covered, and at what price (for the insurer and for the patient).

To foster innovation in the pharmaceutical sector, countries use a range of policies, such as public investments in basic R&D, tax credits for private R&D expenditures, education and training of a high-skilled workforce and protection of intellectual property rights. As discussed in the OECD Innovation Strategy (OECD, 2010b), countries could do more to strengthen innovation, which is an essential contributor to economic growth and societies' well-being. This chapter, however, does not address innovation policies *per se* and concentrates on reimbursement and pricing policies.

The main goal of this chapter is to present recent trends in pharmaceutical policies. Section 1 provides updated data on pharmaceutical spending, and funding sources. Section 2 provides an overview of pharmaceutical reimbursement and pricing policies in OECD countries. Section 3 looks at recent experiences with innovative pricing agreements and Section 4 presents recent policy initiatives aiming to get more value for money from off-patent markets.

2. Pharmaceutical spending in OECD countries

Pharmaceutical spending[1] accounts for 17% of total health spending and 1.5% of GDP on average in OECD countries (Figure 6.1). However, the dispersion around these averages is high: pharmaceutical spending accounts for only 8% of total health expenditures in Norway, while it absorbs 32% of health spending in Hungary, and more than 25% in Turkey, the Slovak Republic and Mexico. Per capita spending (in USD PPPs) ranges from 132 in Chile to 897 in the United States, reflecting large differences in the volume and prices of pharmaceuticals (Figure 6.2; and OECD, 2008).

Expenditures for out-patient pharmaceuticals are predominantly financed by public schemes in all countries but seven (Italy, Iceland, Estonia, Canada, Poland, the United States and Mexico). Public funding accounts for more than three-quarter of pharmaceutical spending in a few countries: Germany, Greece, the Netherlands, the United Kingdom and Luxembourg (see Figure 6.3). Private health insurance plays a significant role in the financing of out-patient medicines in the United States (30%), Canada (30%),

Figure 6.1. **Pharmaceutical spending as a share of total health expenditure and GDP, 2008**

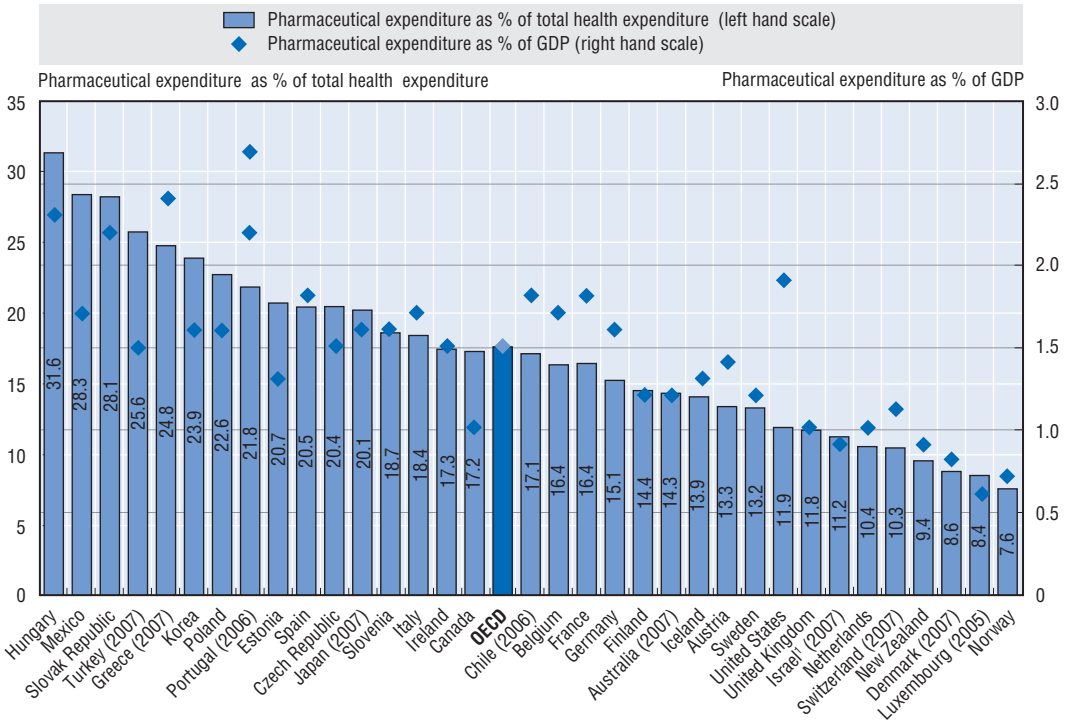

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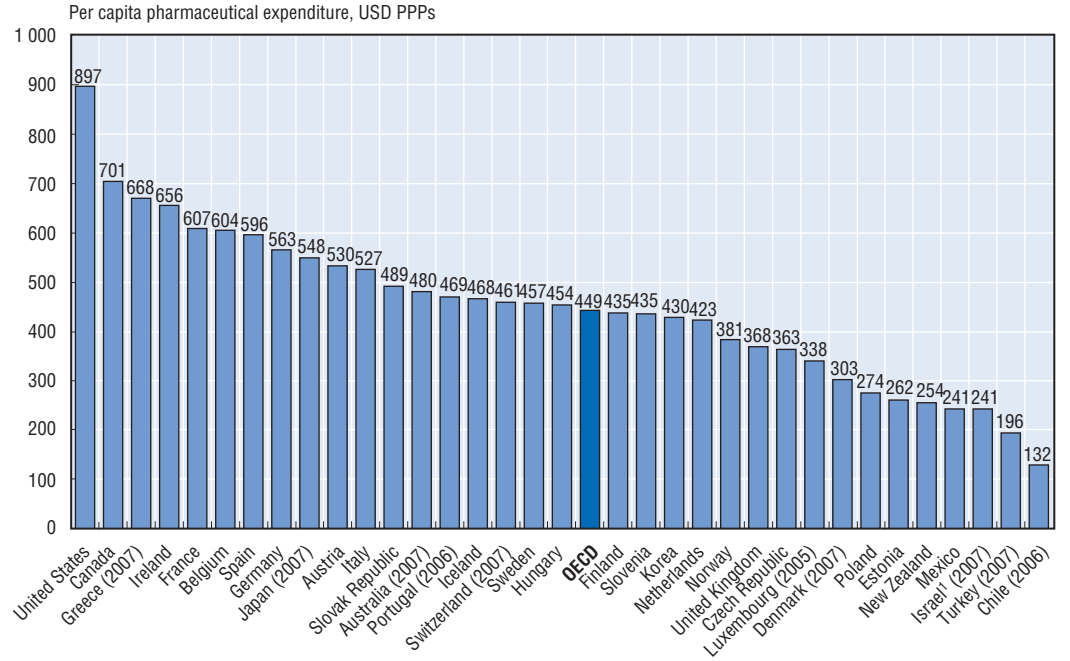
Figure 6.2. **Per capita pharmaceutical spending 2008**



1. The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

Source: OECD (2010a), *WHO-NHA Database* and OECD Secretariat's estimates.

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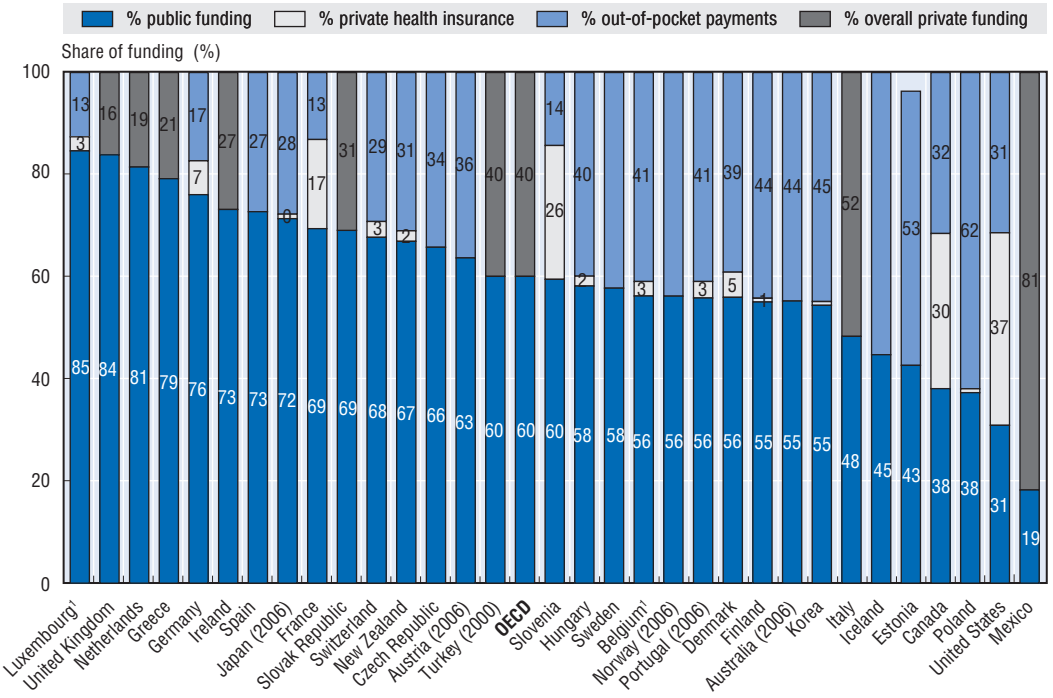
Figure 6.3. **Pharmaceutical spending, by funding sources, 2007**



Note: In Estonia, 4% of pharmaceuticals spending is funded by corporations in private sector (other than health insurance).
1. Luxembourg and Belgium do not include any estimate for over-the-counter drugs – *i.e.* prescription only.
Source: System of Health Accounts 2009, OECD (2010a) and OECD Secretariat's estimates.

StatLink http://dx.doi.org/10.1787/888932319611

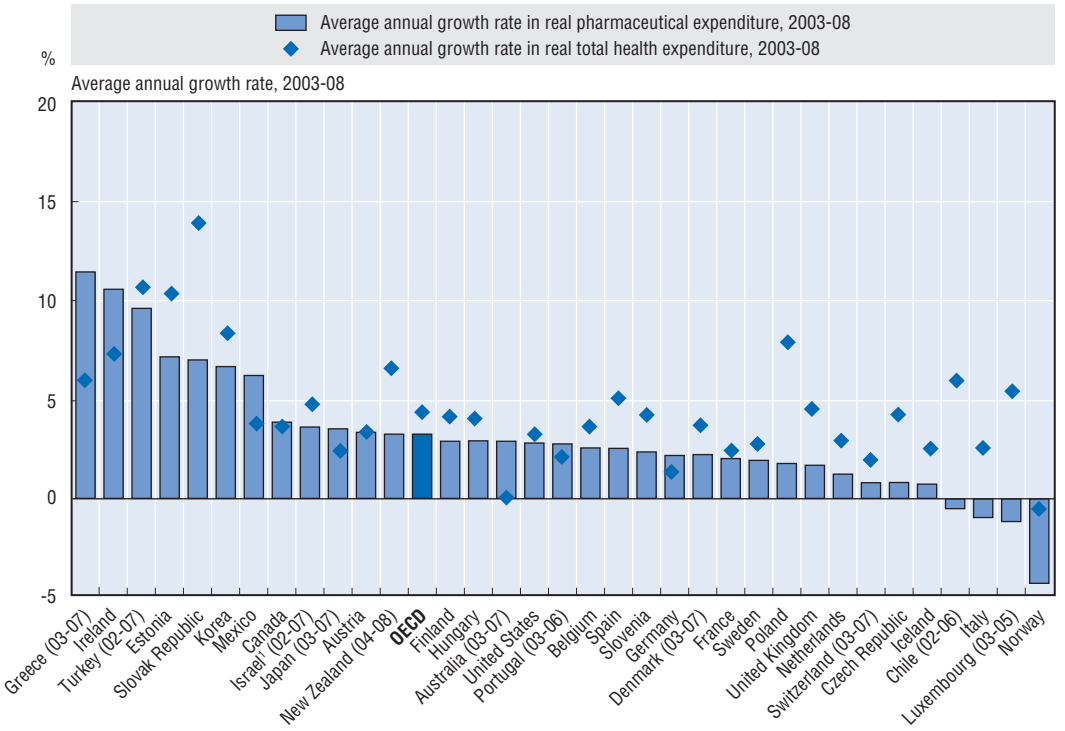
Slovenia (26%) and France (17%) through different mechanisms though. In the United States and Canada, private health insurance offers primary coverage for drug consumption to a significant share of the population (see Box 6.2), while in France, it only covers co-payments left after coverage by social health insurance.

In the past, pharmaceutical spending has risen at a faster pace than total health spending in developed countries. This trend has now reversed: between 2003 and 2008, real pharmaceutical expenditure has grown by 3.1% per year on average in OECD countries, while total health spending has increased by 4.5% (see Figure 6.4). Over this period, growth in pharmaceutical spending surpassed growth in total heath expenditure in only nine OECD countries: Greece, Ireland, Mexico, Japan, Australia, Portugal, and Germany. In Norway, Luxembourg, Italy and Chile, real growth of pharmaceutical spending was even negative.

The economic crisis that hit the world in 2008 has already affected pharmaceutical markets. IMS data on market trends, monitored quarter by quarter from Q1 2008 to Q4 2009 for the World Health Organisation[2] show that a few countries have experienced a significant decline in consumption (ranging from 12% to 25%) in at least one quarter (by comparison with the same quarter in the previous year): the Czech Republic, Estonia, Slovenia, and public schemes in Russia. However, decline in consumption cannot be unambiguously attributed to the crisis. In the Czech Republic for instance, the decline is likely due to changes in pharmaceutical policies which preceded the recession.

Some governments confronted with high fiscal pressure have adopted drastic measures to curb pharmaceutical expenditure growth in 2009 or 2010. In Ireland and Greece, for

Figure 6.4. **Pharmaceutical spending growth, 2003 to 2008**



1. The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

Note: Spending is deflated using an economy-wide (GDP) price index.

Source: OECD (2010a), *WHO-NHA Database* and OECD Secretariat's estimates.

StatLink http://dx.doi.org/10.1787/888932319573

instance, where pharmaceutical spending was growing at a very rapid pace, governments enforced emergency measures – mainly sharp price reductions – and announced the implementation of more structural policies (see Box 6.1). In other countries, such as France, Germany or the United Kingdom, price reductions or rebates on pharmaceuticals have often been used as adjustment variables to contain health spending growth (France), tackle health insurance funds deficits (Germany) or cap profits made by companies on NHS sales (the United Kingdom).

On the other hand, some countries reacted to the crisis by adopting measures to ensure access to health care and medicines. For instance, Austria cut the VAT rate on pharmaceuticals from 20 to 10% and Italy distributed social vouchers to vulnerable people (EUR 40 per month) for the purchase of primary goods or pharmaceuticals (Council of the European Union, 2009).

Beyond short-term policies, OECD countries will continue to pursue long-term goals of obtaining good value for money without discouraging innovation. The following paragraphs describe briefly current reimbursement and pricing policies and present recent developments.

3. Reimbursement and pricing policies in OECD countries

In the majority of OECD countries, the entire population is either entitled to coverage for health risks (tax-funded systems) or covered by compulsory health insurance (social

Box 6.1. **Examples of recent pharmaceutical pricing developments**

In the **Czech Republic**, prices and reimbursement were reduced by 7% in 2009 for all drugs not affected by revisions that occurred in 2008.

In **Germany**, the Minister of Health announced a bundle of short-term and structural measures in April 2010. Manufacturers' rebates on pharmaceutical prices (for drugs not subject to reference prices) were increased from 6% to 16% and prices frozen until December 2013. From 2011, pharmaceutical companies will be required to provide information to the Joint Federation of physicians and health insurance funds (G-BA) on the therapeutic benefit of new products, through comparison with existing competitors. The G-BA will assess the product, assisted by the Institute for Quality and Efficiency in Health Care (IQWiG) if needed. If the product has no added therapeutic value, it will be clustered in a group of reference prices. If the product has an added-value, the manufacturer will be invited to negotiate a rebate with the umbrella organisation of health insurance funds. If the two parties cannot reach an agreement, a central authority will set a rebate, using international price benchmarking. Health insurer funds are allowed to negotiate further rebates with the manufacturer, individually or in group.

In **Greece**, prices of pharmaceuticals were reduced in March 2010 anywhere from 3 to 27%, depending on their initial price. Beyond this emergency measure, Greece is revising its reimbursement and pricing policy: a positive list will be established; the three lowest prices in the European Union will be used as benchmark for price at market entry; "dynamic pricing" will be used after market entry (annual increase in sales exceeding 5% will lead to a 2.5% price reduction); and a stepped-price model will be used for generic pricing.

In **Ireland**, the government and the Irish Pharmaceutical Health Care Association (representing international research-based companies) agreed on price cuts of 40% on nearly 300 widely prescribed medicines, as well as an increase in the annual rebate paid by manufacturers to the Health Service Executive on sales under public schemes (from 3.53 to 4%, raised on a wider base). The government decided to introduce a prescription charge (EUR 0.50 per prescription, capped at EUR 10 per month and per family) and announced the implementation of reference prices (maximum reimbursement amounts for clusters of products) and right of pharmacists to substitute cheaper but equivalent products where possible.

In **Spain**, the government has proposed two modifications of the Guarantees Act for Medicines (Ley 29/2006) in order to modify the price of pharmaceuticals. First, the price of generic medicines will be reduced by 25%. Second, a general 7.5% rebate is applicable since July 2010 for all medicines prescribed by NHS physicians and to pharmaceutical inputs bought by NHS hospitals.

In **Switzerland**, the prices of reimbursed medicines was re-examined to be in line with six comparator countries (Austria, Denmark, France, Germany, the Netherlands and the United Kingdom), with a 4% tolerance margin in order to compensate for shifts in currency changes. This change is expected to save about CHF 400 million. Measures recently implemented include a periodic re-examination of prices every 3 years as well as a systematic review of the price of products for which a new indication has been approved by the Swiss Drug Agency.

In **the United Kingdom**, the new Pharmaceutical Pricing Regulation Scheme (PPRS) signed in December 2008 for five years aims to introduce value-based pricing for drugs purchased by the NHS. The government and the industry have agreed on the principle of "flexible pricing", which means that companies will be allowed to increase the price of their products after market entry, if new evidence has been produced about the benefits of their drug (as assessed by NICE, see Section 4 of this chapter). The NHS has implemented "patient access schemes" to provide access to drugs not judged cost-effective by NICE. In the meantime, the PPRS imposed price cuts of 3.9% in 2009 and 1.9% in 2010, as well as measures to increase the use of generics.

Box 6.1. **Examples of recent pharmaceutical pricing developments** *(cont.)*

In the **United States**, the health reform introduced several measures to expand coverage of pharmaceuticals and to contain related costs. A set of measures aims to progressively abolish the coverage Gap[1] for enrollees in Medicare Part D drug plans with standard benefits by 2020. Since January 2010, beneficiaries falling in the coverage gap have received a rebate of USD 250 from their insurer, and from July 2010, they should get a 50% mandatory discounts on the costs of their medications from manufacturers who want their products to be listed in Medicare Part D drug plans. The Medicaid drug rebate percentage increased to 23.1% of average manufacturer price for brand name drugs, to 17.1% for clotting factors and drugs approved exclusively for pediatric use, and to 13% for non-innovator, multiple source drugs. The reform also imposes an annual fee on manufacturers and importers of branded pharmaceuticals. The fee was set at USD 2.5 billion for 2010 and is shared between companies according to their volume of sales. It is planned to increase up to USD 4.1 in 2018 and decrease afterwards.

1. In standard Medicare drug benefits, beyond a certain level of out-of-pocket payments – USD 2 850 in 2010 –, patients have to pay the full cost of prescription drugs until their out-of-pocket payments reach USD 4 550. Then, they are entitled to catastrophic coverage.

Source: Communication from national authorities; Germany: *www.bmg.bund.de* (Press release of 28 April 2010); Greece: *www.sfee.gr/en/price-determination*; United States: *www.kff.org/healthreform/upload/8061.pdf*; Ireland: *http://debates.oireachtas.ie/DDebate.aspx?F=DAL20100119.xml&Node=3052#N3052*, consulted on 29 June 2010; United Kingdom: *www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825*.

insurance-based systems). In these cases, entitlements to health benefits are most often defined at the central level with different degrees of explicitness and detail (Paris *et al.*, 2010). Out-patient pharmaceuticals are most often included in the standard benefit package covered by public or social schemes.[3] In a few countries, patients obtain out-patient drug coverage through a variety of schemes, with possible variations in the range of benefits covered (see Box 6.2).

Countries with universal and uniform entitlements generally establish a list of drugs eligible for reimbursement or public funding ("positive list") at the national level, with the exception of Germany[4] and the United Kingdom, where "negative lists" are established instead; and Greece, where a positive list is in preparation. Pharmaceutical coverage generally entails user charges, with exemptions for some segments of the population and/or categories of drugs.

All OECD countries employ some form of price regulation for at least some market segments

In terms of pharmaceutical price regulation, two general rules apply to the majority of OECD countries. First, in general, countries do not regulate the prices of over-the-counter (OTC) medicines not covered by health insurance, either because they do not consider OTC drugs as merit goods, to which access should be guaranteed for all residents, or because they rely on consumer demand price sensitivity to drive price competition. Second, by contrast, most OECD countries regulate the price or reimbursement price of out-patient prescription drugs covered by health insurance to address well-known market failures.[5, 6]

There are however several exceptions to these general rules. Canada and Mexico, for instance, regulate the prices of *all* patented medicines (whether covered or not) to protect consumers from potential abuse of monopoly power of sellers and ensure that the price of patented drugs are not excessive: Canada sets maximum ex-factory prices, though purchasing

Box 6.2. **Countries with pluralistic systems for pharmaceutical coverage**

In a few OECD countries, out-patient pharmaceuticals are covered by multiple schemes and the range of benefits covered is not uniform: Canada, Chile, Mexico, Turkey and the United States.

In **Canada**, while drugs administered in hospitals are fully covered through the universal, publicly financed Medicare programme, out-patient prescription drugs are not included among the insured benefits guaranteed by the *Health Canadian Act*. Provinces and territories and the federal government provide coverage to about one-third of Canadian residents through publicly financed programmes targetting some populations (seniors, social assistance beneficiaries, indigenous persons, veterans, etc.). Provinces and territories and the federal government make coverage decisions and establish formularies for each of the public plan they manage. About two-third of Canadian residents are covered for prescription drugs by private insurance (employer-based or individual contracts). Private plans establish their own formularies and tend to be more inclusive than public plans though some of them mirror public plans coverage. In Québec, all plans are required to offer coverage at least equal to the public formulary (Paris and Docteur, 2006).

In **Mexico**, more than half of the population is covered through social security; 20% by the Seguro Popular, a publicly-subsidised voluntary scheme targeting the population without access to social security, and 1% by voluntary private coverage. All these schemes provide coverage for out-patient prescription drugs, often with cost sharing. The uninsured can obtain health care services through the Ministry of Health or state health authorities. Social security agencies and public authorities purchase medicines using two formularies (one for primary care and one for secondary and tertiary levels), defined at the central level (Moïse and Docteur, 2007).

In the **United States**, people obtain drug coverage from a variety of sources. In 2008, 58% of American residents obtained prescription drug coverage through employer-sponsored private plans, 9% through individually-purchased private plans, Another 9% are enrolled in *Medicare Part D* plans, a voluntary programme for seniors, subsidised by the federal government and run by private health insurers. About 20% of the population is covered by *Medicaid*, the joint federal-state programme for low-income people. Private health insurers may offer a choice between several drug plans, with different formularies, cost sharing and premiums. Only Medicare Part D drug plans are somewhat constrained by law in terms of formulary design. In Medicaid, prescription drug is an optional service but all state programmes cover drugs, with big interstate differences in formularies, co-payments and limits in the number of prescriptions which can be filled (Kaiser Family Foundation, 2010).

prices can be further negotiated by purchasers, while Mexico limits the retail prices paid by consumers who purchase drugs in pharmacies without social insurance coverage.

Also, a few countries allow manufacturers to set their prices at market entry for out-patient prescription pharmaceuticals: Denmark, Germany, the United Kingdom and the United States. In Denmark, manufacturers can freely set their prices at market entry. However, the price of a product, in relation with its therapeutic value, is a major criterion in coverage decision making (PPRI, 2008a).

In Germany, pharmaceutical companies have been free to set their prices at market entry until recent reforms, even for drugs reimbursed by social health insurance. A broad

system of reference prices (see below) puts downward pressure on prices when therapeutic alternatives exist since even new patented products can be clustered with low-priced products, including generics. Until now, health insurance funds have, however, essentially been "price-takers" for truly innovative drugs. The 2007 reform has therefore mandated the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the cost effectiveness of new innovative products to help health insurance funds to set maximum reimbursement prices. This measure will be applicable from 2011.

In the United Kingdom, pharmaceutical companies can freely set entry prices for their products, including those covered by the National Health Service. However, they face some constraints: first, the Pharmaceutical Pricing Regulation Scheme (PPRS) imposes an annual cap on profits made by companies on NHS sales and companies are required to modulate the price of their products to not exceed this cap. Second, price increases are subject to authorisation and must be justified. Third, the National Institute for Health and Clinical Excellence (NICE) assesses the cost effectiveness of medicines with high costs or high budget impact and/or uncertain or low benefits to decide whether the product should or not be funded by the NHS. Though this last feature is not direct price regulation, it can however put some pressure on prices, especially when therapeutic alternatives are available.

In the United States, pharmaceutical prices are not subject to direct price regulation. Pharmaceutical companies can set the price of their drugs at market entry. In the private sector, Pharmacy Benefit Management companies and health insurance plans use formulary management tools to negotiate prices with manufacturers. When therapeutic alternatives are available, third-party payers are able to obtain price discounts or rebates from manufacturers in exchange for listing or status of "preferred drug" (lower co-payment) in their plan's formulary. In other cases, their purchasing power is weaker. Prices of drugs purchased by federal authorities (*e.g.* the Veterans Health Administration) or for Medicaid programmes are more regulated. For instance, manufacturers are required to enter in national rebate agreements with federal authorities if they want their product to be listed in Medicaid formularies. The price they charge to Medicaid cannot exceed the average manufacturer price (price paid to the manufacturer for the drug in all states by wholesalers for drugs sold in pharmacies, after discounts) reduced by a rebate percentage, recently increased to 23% for on-patent drugs.

OECD countries which regulate the price or reimbursement prices of out-patient pharmaceuticals use three main instruments: international benchmarking, therapeutic benchmarking and economic assessment. Some of them actually use a mix of these instruments, applying to different market segments (*e.g.* Canada, France and Switzerland use both international and therapeutic benchmarking though for different purposes). The OECD report on pharmaceutical pricing policies, published in 2008, described in more detail the policies employed by member countries and shed light on their impact on prices and availability of pharmaceuticals (OECD, 2008).

International benchmarking

Twenty-four OECD countries use international benchmarking to define the price (or a maximum price) of pharmaceuticals: they look at prices paid by a set of comparator countries to determine a maximum price for a new drug.

The list of "comparator countries" is obviously a key element of this policy tool. Members of the European Union typically refer to each other, and usually select a subset of countries with a similar income level. For instance, the Czech Republic refers to Estonia, France, Greece, Hungary, Italy, Lithuania, Portugal and Spain, while France refers to Germany, Italy, Spain and the United Kingdom. In Canada, the federal Patented Medicine Prices Review Board (PMPRB) uses international benchmarking as one means to ensure that the prices of patented medicines are not excessive (whether reimbursed or not). The PMPRB refers to a set of comparator countries that were selected in part for their perceived commitment to promote pharmaceutical innovation (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States), with the idea that Canada should make a "fair contribution" to global R&D costs. Mexico refers to the prices paid in the six countries with the highest market shares for the product considered.

In general, international benchmarking takes place during the pricing and reimbursement process, before market entry. This is not the case in Canada, however, where the PMPRB regulate *a posteriori* the ex-factory prices of patented medicines, often limiting them to the median price of the comparator countries. In addition, the PMPRB ensures that the price of each patented product does not exceed the highest international price of the comparator countries. If the domestic price is considered excessive, the Board may order the patentee to offset the excess revenue accumulated, by reducing the price of the drug or the price of another drug, or by making payments to the federal government. Some countries define strictly in the regulation that the price must be "equal to the lowest price" in comparator countries or something similar (*e.g.* the Slovak Republic sets its price cap 10% above the average price of the three lowest-price countries among those referenced), while other countries are less prescriptive (in France, the price must be "consistent" with prices observed in comparator countries).

International benchmarking has several drawbacks. First, it is likely to influence companies launch strategies and subsequently delay or even compromise launch in low-price countries (to avoid any reference to them). Second, it has encouraged a disconnection between "list prices" and actual prices paid by third-party payers, often obtained through rebates consented in confidential agreements with manufacturers. This fact is in turn likely to blur price comparisons and benchmarking. Economists and policy makers generally agree on the fact that cross-country price discrimination for patented pharmaceuticals is a win-win situation in which companies earn the revenues they need to invest in R&D while people in lower-income countries access the medicines they would not access at a high price. From the payer's point of view, medicines may have different value, depending on the ability and willingness to pay, the epidemiological context of the country and the costs of other inputs. However, international benchmarking, by itself, does not guarantee that the price set will reflects the country-specific value of a pharmaceutical product.

In fact, several countries use international benchmarking for a limited market segment – the most innovative products – and prefer therapeutic referencing for other parts of the market.

Internal or therapeutic referencing

When using therapeutic referencing, countries regulate the price of new entrants by comparison with the prices of competing drugs in the market. They first assess the therapeutic advantage of the new drug over existing competitors and then determine a

"price premium" in relation to the level of innovativeness of the new product. Under this policy, a product with no added therapeutic value will be priced at the same level or at a lower level than existing competitors. This practice mirrors pricing strategies employed by companies in markets with free pricing, where non-innovative products are priced at a lower level than competitor products at market entry in order to gain market shares.

Canada, Belgium, France, Italy, Japan and Switzerland use therapeutic referencing for products which are not "breakthrough" innovations. The assessment of the therapeutic "added value" of the new entrant is, however, applied in different ways: while in France, a Transparency Committee assesses the added therapeutic value on a 1 to 5 scale, Switzerland has a less formalised process leaving more room to negotiation. In Italy, an algorithm was established to evaluate the innovativeness of a product. In all cases, the price premium is set or negotiated on a case-by-case basis with no predefined rules, and often takes other parameters into account, such as expected volumes of sales.

"*Reference price*" policies, which set maximum reimbursement prices for clusters of products with identical properties, can be seen as a variant of therapeutic referencing, with one crucial difference: under such policies, the product's price – either freely set by the company or negotiated – can remain above the maximum reimbursement price, if patients are ready to pay for its "added value" even if this is merely brand loyalty. Reference price policies have been adopted by more than one-third of OECD countries but the scope of such policies varies enormously (Habl *et al.*, 2008). Most countries define clusters of bio-equivalent products (with the same active ingredient or combination of active ingredient, administered in the same way) but a few countries define wider groups of "therapeutically equivalent" products (Germany, the Czech Republic, the Netherlands, New Zealand and the Slovak Republic). As a result, the market share subject to maximum reimbursement prices varies widely, ranging from 5% of total pharmaceutical market in France to 60% in Germany (by volume).

With therapeutic referencing, the price of a new entrant very much depends on the value attached by regulating authorities to incremental innovation (the "added value" of the new product). Experience has shown that the criteria adopted to assess the advantages of a new drug are very different across countries. In addition, the price of the new product is based on the prices set for competitors in the past, not always revised to reflect the current value of therapeutic products. Finally, although therapeutic referencing ensures price consistency *within* therapeutic classes, it does not guarantee price consistency *across* therapeutic classes. Economic tools may help to achieve this, and are discussed in the next section.

Pharmaco-economic assessment

More than half of OECD countries take into account pharmaco-economic assessment (PEA) to make reimbursement decisions given the price proposed by the manufacturer. PEA is thus not directly used to regulate prices but can provide incentives for manufacturers to lower their price in order to meet the requirements for reimbursement. Only a few countries systematically use PEA for all products applying for inclusion in the positive list: Australia, the Netherlands, New Zealand and Sweden. In the United Kingdom, only products with high costs, high budget impact and/or a high level of uncertainty on clinical effectiveness are evaluated to determine whether they should be funded by the NHS or not. In Canada, the intergovernmental Common Drug Review, part of the Canadian Agency for Drugs and Technologies in Health, systematically assesses the cost effectiveness of products with new active substances to inform coverage decisions of public drug schemes. In Italy, PEA is used

in the negotiation process in order to support pricing and reimbursement decisions. In Germany and France, new provisions (in 2007 and 2008) state that new innovative pharmaceuticals should undergo economic assessment but how this will be done is still being determined. Korea recently introduced PEA in coverage decision making.

Most often, agencies responsible for economic assessment compute an incremental cost-effectiveness ratio (ICER) to measure added costs per QALY (quality-adjusted life year) gained, by comparison with therapeutic alternatives. They usually adopt a public payer perspective, which means that they consider only costs and potential savings for the public coverage schemes. By contrast, Sweden and Norway have adopted a societal perspective, in which both benefits and costs are estimated at the society level (for third-party payers, but also for patients, their family, employers and the government). ICER thresholds (beyond which a drug is unlikely to be funded) are generally not explicitly defined but can be inferred from past decisions.

Pharmaco-economic assessment is, in many ways, the most rational tool to make reimbursement decisions since it guarantees that costs to society of a new medicine are proportionate to its clinical benefits. It also sends signals to the industry about the type of benefits which are the more valued and payers' willingness to pay. On the other hand, performing such assessments requires expertise and means which are not available in all OECD countries. Moreover, it is not widely accepted by the public, the industry, nor the medical profession, especially when it is perceived as a rationing tool rather that an instrument to improve efficiency of pharmaceutical spending. Finally, countries using ICER thresholds have already been confronted with ethical questions raised by expensive end-of-life medicines or orphan drugs[7] (less likely to meet the cost-effectiveness thresholds) and have adapted their policy to take into account the specificities of those products.

Beside the three main instruments described above, OECD countries use a variety of other instruments to regulate pharmaceutical prices. For instance, Italy negotiates prices as well as individual caps for each pharmaceutical company on revenues drawn from NHS sales, beyond which companies will have to pay rebates. Spain uses a cost-plus regulation; the United Kingdom caps the profit of pharmaceutical companies; and several countries have developed product-specific pricing agreements. These agreements have gained attention of policy makers as interesting tools to promote efficiency in pharmaceutical spending. They are reviewed in the Section 4 of this chapter.

Price regulation and price levels

The discussion above describes briefly the benefits and possible drawbacks of the main policy instruments used by OECD countries to regulate pharmaceutical prices. However, an important conclusion has to be emphasised: price regulation does not necessarily lead to low prices (OECD, 2008). Retail prices of pharmaceuticals ranged from 68% below to 185% above the OECD average in 2005 and some countries with price regulation had high prices (Switzerland, Canada), while countries without direct price regulation at market entry, such as the United Kingdom, had relatively low prices. Pharmaceutical prices are partly related to GDP per capita, though variations in income were found to explain only one-fifth of variations in retail prices; and to economy-wide price levels (variations in which explain more than half of the variations in drug prices). This should not be surprising: in fact, regulators do not always try to obtain the cheapest price and do not exhaust their purchasing power. Their efforts to improve static efficiency of pharmaceutical spending are counterbalanced by their wish to maintain incentives for R&D investments and future innovation (dynamic efficiency). Moreover, the

price is not the whole story: efficiency of pharmaceutical spending also depends on appropriate prescription and use of pharmaceuticals and an efficient distribution chain.

This conclusion is not to say that current pharmaceutical pricing policies are ideal and ensure value-for-money for pharmaceutical spending. Efforts have to be made to better link the price of pharmaceuticals to their "value" and some countries have already taken steps to get more value-for-money. Recent initiatives are reviewed below.

4. Recent developments in reimbursement and pricing policies

Policy makers sometimes have to make hard decisions, especially when manufacturers propose new high-priced products for the treatment of fatal or disabling diseases. Confronted with constrained financial resources, they have to weigh the costs and benefits of the new treatment against the benefits of other health care services to be forgone to fund it.

Media coverage of negative reimbursement decisions – for example NICE decisions in England and Wales – indicates how sensitive the population is to "treatment denial". Opponents to the recent US health reform actively raised the spectre of rationing, though the current situation in the United States is far from ensuring access to high cost medicines to anyone who need them (Faden *et al.*, 2009). In the past, England, Australia and New Zealand have often found it to be politically difficult to refuse funding for drugs with poor cost effectiveness and have been forced to find ways to circumvent their own cost-effectiveness thresholds (Raftery, 2008).

Indeed, policy makers face a real dilemma. Cost-effectiveness studies provide scientific information about the benefits and costs (including opportunity costs) of new treatments. However, the general public does not always find appeals to rationality convincing. Treatments which fail to meet efficiency thresholds may be seen as desirable because they extend life or relieve severe symptoms. Apparently in some cases, "rational choices", as defined by economists, do not seem to coincide with collective preferences.

It could be argued that citizens are not well informed about the real costs and benefits of treatments, potential adverse effects, uncertainty, and opportunity costs. Or that the same citizens who oppose rationing are not necessarily ready to increase their contributions to the health care system or to lose current benefits. How then to arrive at a good compromise on what treatments to fund?

Medicines with small population targets, such as orphan drugs and end-of-life medicines, are the most likely to raise this type of problems: manufacturers have a very high reservation price (to compensate for small volumes) and policy makers, on their side, do not like to deny treatments for economic reasons while they do want to provide incentives to develop drugs for small population groups with severe diseases.

In an attempt to respond to all these concerns, policy makers have adapted some of their policy instruments and criteria for decision making. The paragraphs below describe some of these adaptations. This discussion mainly focuses on public policies, since almost all OECD countries regulate the reimbursement and prices of medicines covered by public schemes at the central level. However, other systems are not immune to problems raised by high-cost medicines. In the United States, for instance, strategies have been adopted by public and private payers to cope with high-priced medicines (Box 6.3).

Box 6.3. **Strategies used by private insurers in the United States to cope with high-price medicines**

In the United States, some public and private insurers have been using pharmaco-economic assessment (PEA) to design pharmaceutical benefits. Most often, PEA has been used to compare alternative treatments in order to negotiate prices with manufacturers, to incentivise the use of cheaper alternative through differential co-payments or, more rarely, to exclude drugs from coverage in the more restricted formularies. Many insurers, however, do not exclude treatments without alternative from their formularies. The funding of new expensive treatments is thus provided by increasing premiums or cost shifting to patients.

Some private health plans have recently introduced a fourth tier for co-payments. Traditionally, private plans have used three-tiered co-payments to promote the use of the cheapest drugs: monthly co-payment typically ranges from USD 5 to USD 10 for generic drugs, USD 20 to USD 30 for brand-name medicines with moderate prices and USD 50 for high priced brand-name drugs. To respond to cost-pressure imposed by costly medicines, private plans have introduced a "fourth tier" under the form of a 20% to 30% co-insurance. Tier 4 systems have been introduced into 86% of Medicare drug plans and 10% of commercial drug plans with drug benefits (Lee and Emanuel, 2008). For drugs whose price can exceed USD 50 000 a year, co-insurance represents out-of-pocket payments of more than USD 10 000.

Source: Lee and Emanuel (2008); Faden *et al.* (2009).

Economic evaluation and drugs with poor cost effectiveness

In many OECD countries, clinical effectiveness is an essential criterion considered when deciding whether there should be public funding. Even high-cost new drugs usually end up being reimbursed by public programmes, so long as effectiveness is proven and benefits are high, though sometimes with severe restrictions and/or prior authorisation required to limit budget impact. In Australia, for instance, the Pharmaceutical Benefits Advisory Committee may recommend the use of medications within special programmes, with access restricted to patients with the greatest capacities to benefit from treatments (Nikolentzos *et al.*, 2008).

In general, price regulations and rules for reimbursement are lighter for drugs used in hospital settings than for drugs used in out-patient care. In most cases, drugs are purchased by hospitals and funded through payments made by third-party payers and patients. Hospitals are usually under budget constraints and payment schemes will determine the capacity to use high-cost drugs. Global budgets and payments per case, which are now widely used in OECD countries, provide few incentives to use new high-cost medicines, especially when their costs are not yet included in standard average costs per case which serve to establish prices. To overcome this difficulty, several countries have introduced special programmes to fund high-cost drugs on top of payments per case (*e.g.* Germany, France). In other countries, access to in-patient expensive drugs is unequal and linked to the ability and willingness of hospitals to pay.

Countries which consider cost effectiveness to make reimbursement decisions have tried to provide explicit answers to trade-offs between results of economic evaluations and population expectations. First of all, a common feature of coverage decisions based on cost effectiveness is that no country has defined an explicit and definitive ICER threshold beyond which a new drug has no chance to be funded. Instead, countries accept that other

criteria need to be taken into account, and use flexible thresholds, beyond which a drug is simply less likely to be funded.

Sweden made explicit the criteria to be taken into account beyond cost effectiveness in coverage decisions. The "need and solidarity principle" states that serious diseases must be given a higher level of priority when making decisions (Box 6.3). To comply with this requirement, the Pharmaceutical Benefits Board use different cost-effectiveness thresholds, linked to the severity of the treated ailment. As a result, it has in the past funded treatments with costs per QALY exceeding EUR 90 000 (Garau and Mestre-Ferrandiz, 2009). In addition, in Sweden, the consideration of "budget impact" in the assessment process plays in favour of high-cost medicines with small target population, such as orphan drugs: decision makers are more likely to fund medicines with high cost per QALY when expected budget impact remains reasonable.

In the United Kingdom, institutes in charge of economic appraisal have adapted their guidance to take into account these problems. In England and Wales, NICE revised its guidance for the appraisal of life-extending and end-of-life treatments in July 2009 (see Box 6.4). Similarly, in Scotland, the Scottish Medicines Consortium takes other criteria than

Box 6.4. **Social values and economic assessment**

The incremental cost-effectiveness ratio (ICER) is widely used to assess the value of a new product and recommend or make coverage decisions. However, ICER are generally not considered in isolation from "social values".

Social values and criteria for coverage decisions in Sweden

The Pharmaceutical Benefits Board[1] makes coverage decisions for medicines used in out-patient care. Decisions are based on three criteria:

The human value principle: equality of human beings and the integrity of every individual should be respected. Coverage decision should not discriminate between people because of their age, sex, race, etc.

The *need and solidarity principle*: those in greatest need take precedence for reimbursement decisions, *i.e.* people with more severe diseases are prioritised over people with less severe conditions.

The *cost-effectiveness principle*: the costs of using a medicine should be reasonable from a medical, humanitarian and socio-economic perspective.

In Sweden, cost effectiveness is assessed with a societal perspective, which means that all costs and benefits are considered, regardless of who pays (third-party payers and patients) and who benefits from health gains (patients, employers, central or local governments).

NICE's new guidance for the appraisal of life-extending, end-of-life treatment

Since 1999, the National Institute for Health and Clinical Excellence (NICE) has been assessing the cost effectiveness of health strategies to recommend their use or otherwise in the England and Wales National Health Systems. In 2008, NICE published a report on the consideration of social values in its appraisal process and explicitly excluded the "rule of rescue"[2] as a relevant decision criteria (NICE, 2008). More recently, however, NICE revised its guidance for the appraisal of life-extending, end-of-life treatments to allow funding of such treatments whose ICER is above the usual GBP 30 000/QALY threshold. The supplementary guidance applies to the following:

Treatments indicated for patients with a *short life expectancy*, normally less than 24 months.

Box 6.4. **Social values and economic assessment** *(cont.)*

There is sufficient evidence that the treatment offers an extension to life, normally *at least three additional months*, compared to current NHS treatments;

The treatment is licensed or otherwise indicated, for *small patient population*.

In these circumstances, the appraisal committee is expected to consider the impact of giving greater weight to QALYs achieved in the later stages of terminal diseases in the ICER and to assess the magnitude of the additional weight needed to fall within the current threshold range. Any guidance produced using this supplementary advice should be reviewed within two years.

1. Created in 2002, the Pharmaceutical Benefit Board (LFN) is now part of the Dental and Pharmaceutical Benefits Agency (Swedish acronym TLV).
2. The "rule of rescue" refers to the fact that any available means should be employed to attempt to save someone from a severe threat, at any cost (like is done for people lost in mountains). This rule is mentioned by some analysts to justify the unrestricted use of high-cost medicines for serious conditions.

Source: LFN (2007); Mason and Drummond (2009); NICE (2008, 2009).

ICER into account to make decisions, such as whether the drugs treats a life-threatening disease, substantially increases life expectancy or quality of life, or bridges a gap to a "definitive" therapy (Garau and Mestre-Ferrandiz, 2009).

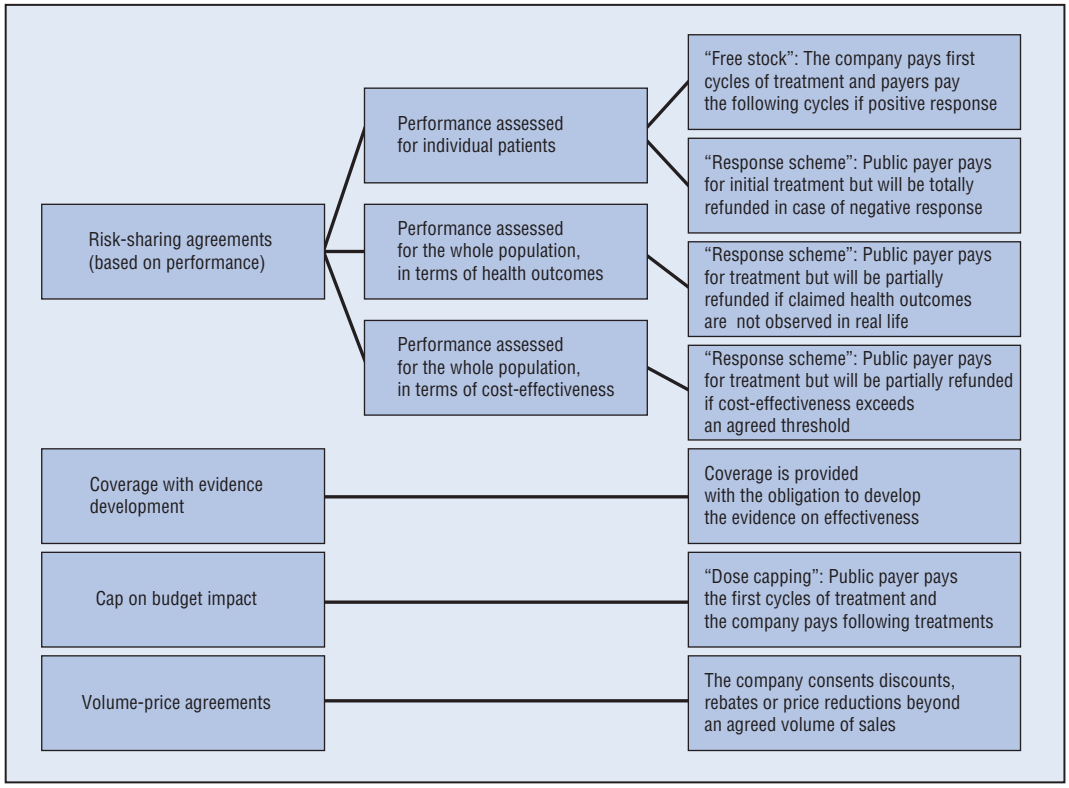
Beyond adaptations of criteria for decision making, these countries have been using product-specific agreements for drugs with poor cost-effectiveness ratio or high budget impact.

Product-specific pricing agreements

Payers and pharmaceutical companies have developed product-specific *pricing agreements* to enhance access to medicines with high costs or high budget impact (IMS, 2009; Carlson *et al.*, 2010). These agreements between third-party payers and pharmaceutical companies, either seek to link the "value" brought by a new product in terms of health gain, to the unit price or, more basically, to limit budget impact. Several typologies have already been developed to classify these agreements (IMS, 2008; Carlson *et al.*, 2010). An alternative typology is used here, which distinguishes agreements according to their objectives: to extract a share of companies' rent beyond an agreed level of revenues; to limit impact on public budgets; to improve the evidence about effectiveness or cost effectiveness, or to share the risks of uncertain benefits (see Figure 6.5).

In *volume-price agreements*, the unit price of a product is linked to volumes sold, so that it declines when volumes increase. It is consistent with the idea that a seller is willing to reduce its reservation price in exchange for higher volumes. Price reductions most often take the form of confidential discounts or rebates, agreed between manufacturers and third-party payers. Volume-price agreements have been widely used by private insurers and Pharmacy Benefit Managers in the United States, who used to negotiate discounts or rebates in exchange for formulary listing or listing with a "preferred drug" status (*i.e.* a lower prescription charge for consumers). In France, volume-price agreements are signed by the regulating authority when there is a risk of inappropriate use likely to generate volumes greater than those expected at the time of price negotiation. Australia also uses two types of agreements with the same logic, with price reductions beyond an agreed volume of sales or manufacturers' rebates beyond an expenditure cap. Volume-price

Figure 6.5. **Typology of product-specific reimbursement and pricing agreements**



Source: OECD Secretariat.

agreements do not really allow third-party payers to control spending but just to extract a share of companies' rent.

Agreements to limit budget impact simply preclude public payers from spending more than a fixed amount per patient. Such agreements have been concluded between NICE and pharmaceutical companies in "dose capping" Patient Access Schemes (see Box 6.4). For instance, the NHS agreed to pay for the first two years of multiple myeloma treatment by lenalidomide provided that costs after two years will be borne by the manufacturer.

Coverage with evidence development (CED) schemes have been adopted in Italy, the United Kingdom, the United States, and Sweden (Carlson *et al.*, 2010) and will be used in certain circumstances in Australia from 2011. They link coverage to data collection by the company to inform payers about health outcomes achieved either in new clinical trials or in "real life". CED schemes are adopted when there is a high level of uncertainty in the clinical evidence produced by the manufacturer in its application for funding. Typically, in the United Kingdom, CED schemes provide coverage only for patients included in clinical trials. In Sweden, these schemes provide coverage in exchange for information on the actual use of the product (*e.g.* obesity treatments), on long-term effects on morbidity and mortality (*e.g.* cholesterol products), on quality of life (*e.g.* insulin detemir), and/or on cost effectiveness (*e.g.* treatment for Parkinson's disease, vaccine for cervical cancer). In Italy, web-based "Registries" have been developed, for instance for innovative oncologic and orphan drugs, with the aim to collect information about rational and appropriate use of specific medicines in a single database; to monitor the related consumption and

expenditure; and to provide information needed for risk-sharing agreements. The overall objective of CED schemes is thus to improve knowledge about the product's impact on health.

Risk-sharing agreements are also signed when there is a high level of uncertainty about the benefits claimed by the manufacturer. When health benefits are potentially high, the third-party payer agrees to fund the new treatment but will ask to be (at least partly) refunded by the company if claimed benefits are not observed in the real life. The agreement signed by the English NHS with several manufacturers in 2002 for multiple sclerosis treatments is the most famous example.

Risk-sharing agreements can take several forms. Outcomes to be assessed can be defined in terms of *clinical benefits* (*e.g.* clinical response, improvement in quality of life) or in terms of *cost effectiveness* (the cost/QALY gained should not exceed a certain threshold). The outcomes can be assessed at the *individual level* (*i.e.* for each patient treated), or at the *aggregate level*, considering the whole population treated. For instance, in Germany, a health insurance fund signed an agreement with Novartis to obtain a refund of a patient's treatment for osteoporosis if an osteoporosis-related fracture occurs. In England, Janssen Cilag agreed to refund treatment of multiple myelomia for patients who do not respond positively after four cycles of treatments. In England also, companies producing treatments for multiple sclerosis agreed to reduce the price of their products in order to maintain an average cost/QALY at GBP 36 000 (IMS, 2009). In France, the coverage of a treatment for schizophrenia claimed to improve compliance was approved under the condition that the company monitors compliance in real life and will refund a part of social security spending if compliance targets are not met. In Italy, two types of agreements exist: in so-called "risk-sharing" agreements, manufacturers are required to pay back a percentage of NHS spending for patients not responding to the treatment, while in "payment by results", manufacturers will pay back all costs for patients that do not respond to the treatment.

Many of these agreements are too recent to be evaluated. In terms of process, they are likely to increase administration costs and R&D costs (not least, the costs incurred by generating evidence) but their benefits are expected to offset their costs. Carlson *et al.* (2010) reviewed the available evidence on CED and performance-based agreements concluded in the past decade. They found that several drugs initially funded under CED agreements were successfully approved for general or restricted coverage after the CED period, though this was not always the case. They found only two studies which evaluated risk-sharing agreements. In England, an agreement between Pfizer and the North Staffordshire region's health authority on an anti-cholesterol product ended with positive health outcomes (the population treated met cholesterol level targets) and no refund from the company. The results of the UK NHS agreement on multiple sclerosis are more mixed: in spite of positive health outcomes, the cost effectiveness of the treatment could not be assessed with certainty.

Product-specific agreements could well prove to be a useful new instrument in promoting patient access to innovative treatments while linking public funding to therapeutic value. However, as yet, there is insufficient evidence to be confident in their utility. As these agreements are developing quickly in OECD countries, their results in terms of benefits and costs need to be assessed. The assessment should focus on their design (are all agreements workable?) as well as on their final outcomes.

Box 6.5. **Patient Access Schemes in the United Kingdom**

The 2009 Pharmaceutical Price Regulation Scheme introduced Patient Access Schemes (PAS) in order to enhance access to innovative treatments whose cost effectiveness was too high to meet NICE standards for NHS funding. PAS take several forms:

Under *free stock* agreements, the company provides the first cycles of treatments for free and the NHS bears the costs of following cycles if the clinical response to first cycles is positive. For instance, UCB agreed to provide at no cost the first 12 weeks of its treatment for moderate to severe rheumatoid arthritis (certolizumab pegol) and the NHS will continue to fund the treatment if the clinical response is positive.

Under *dose capping* agreements, the NHS pays for the first cycles of treatments and the company bears the costs of following treatments. For instance, the NHS pays for the first 14 doses (per eye) of treatment for acute wet-macular degeneration by ranibizumab and Novartis will cover following injections, up to three years.

Discount agreements provide a simple minimum discount to the NHS (which can be further negotiated by local purchasers), which differs from usual confidential agreements concluded between pharmaceutical companies and public or private payers in other OECD countries in that it is public and, in some circumstances, caps the cost of the whole treatment for an individual. For instance, Roche has agreed to discount by 14.5% the price of its treatment for non-small cell lung cancer (erlotinib) in order to equalise its price to a cheaper competitor until definitive results of head-to-head clinical trials are available and a new NICE appraisal.

A recent survey on PAS implementation in the United Kingdom concluded that refunds received by hospitals according to two of these schemes were not passed on to Primary Care Trusts, who ultimately pay for health services delivered to their patients. In addition, hospitals complained about the lack of staff to manage PAS and recuperate funds from companies. The new NICE's PAS Liaison Unit is likely to facilitate implementation, which would also benefit from the production of standard templates for local PAS (Williamson, 2010).

Source: NICE website; Williamson (2010), Pharmaceutical Price Regulation Scheme, 2009 (*www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825*).

5. Efforts to develop generic markets

All OECD countries see the development of generic markets as a good opportunity to increase efficiency in pharmaceutical spending, by offering cheaper products than on-patent drugs and allowing a reallocation of scarce funds to innovative medicines. Most OECD countries have implemented policies to promote generic use (see Table 6.1). However, generic market shares in pharmaceutical sales show wide variations across OECD countries (Figure 6.6).

Since generic entry often entails a dramatic fall in revenues for original products, pharmaceutical companies have developed a set of strategies aimed at maximising the period of market exclusivity for their product and/or countering generic entry (OECD, 2008). In a huge inquiry on practices used by pharmaceutical companies to delay generic entry in 27 EU countries between 2000 and 2007, the European Commission identified legitimate and less legitimate strategies, among which: patent filing strategies (multiply sequential patents related to a single product to increase uncertainty about patent expiry); undue patent litigation; and settlements with generic companies to restrict or delay market entry

Table 6.1. **Policies to promote the use of generic drugs**

	Prescription in INN			Generic substitution			Incentives to prescribe/ dispense/ purchase generics (or cheap drugs)			Pricing and reimbursement policy	
	Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory	Incentives for pharmacists	Incentives for patients	Incentives for physicians	Reference price system	Price linkage (discount for 1st generic entrant/ originator's price)
Australia		X			X		F	F	–	Y	–12.5%[1]
Austria	X			X			N	n.a.	NF	N	–48%,–15%+S
Belgium		X		X			NF	F	F&NF	Y	–30%
Canada[2]		X[2]	X[2]		X[2]	X[2]	F[2]	F[2]	[2]	Y/N[2]	[2]
Chile			X[3]		X		N	F	NF[3]	N	N
Czech Republic	X				X		n.a.	F	F	Y	–20%
Denmark	X					X	NF	F	NF	Y	N
Finland		X				X	NF	F	NF	Y	–40%
France		X			X		NF	F	NF&F	Y	–55%+S
Germany		X				X	NF	F	F	Y	N
Greece	X			X			N	F	N	Y	–20%+S
Hungary		X			X		NF	F	N	Y	–30%,-10%,–10%
Iceland					X		n.a.	F	n.a.	Y	n.a.
Ireland		X			X[4]		N	F	NF	Y[4]	S
Italy		X			X		F	F	NF	Y	–20%
Japan		X			X		F	F	[5]	n.a.	–30%[5]
Korea		X			X		F	F	n.a.	n.a.	–32%,–15%
Luxembourg		X		X			n.a.	n.a.	NF	N	n.a.
Mexico			X		X			F	NF	N	N
Netherlands		X			X		F	F	n.a.	Y	N
New Zealand		X			X[6]		F	F	NF	n.a.	n.a.
Norway		X			X		F	F	NF	N	S
Poland		X			X		NF	F	N	Y	–25%, –25%
Portugal			X		X		N	F	N	Y	–35%
Slovak Republic		X				X	NF	F	NF	Y	N
Spain		X				X	NF&F[7]	F	NF&F[7]	Y	–30%
Sweden		X				X	NF&F	F	NF	N	N
Switzerland		X			X		F	F	N	N	–20% to –50%[8]
Turkey	X				X			F	–	Y	–20%
United Kingdom		X		X			F	N	NF	N	N
United States[9]							F[9]	F[9]	N	N	N

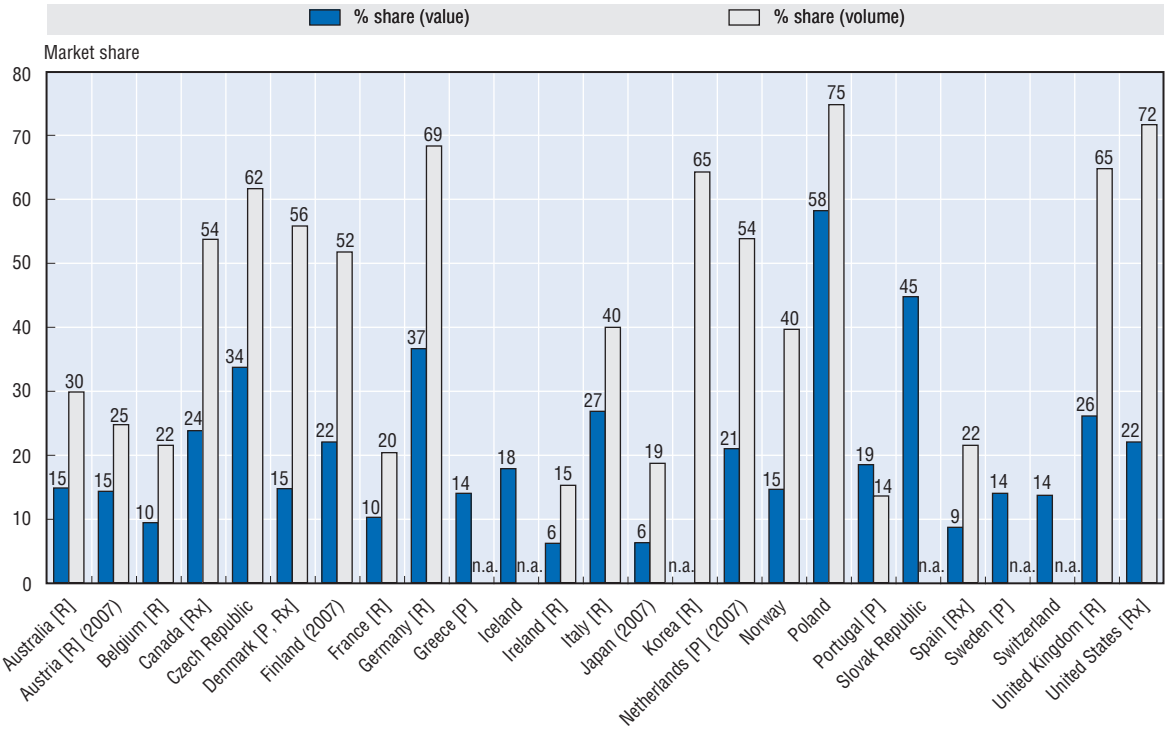
Note: INN= International Non-proprietary Name; F= Financial incentive; N= No; n.a.= not available; NF= Non financial incentives; S= Stepped price model (prices of both originators and generics are reduced after an initial period); Y= Yes. For pharmacists, this table only considers incentives provided by drug coverage schemes. Market incentives (such as rebates from manufacturers, vertical integration, etc.) are not reported. Price linkage: pricing policy linking the (maximum) price of the first generic entrant (and followers in some cases) to the price of the original drug. Pricing dynamics may differ across countries afterwards.

1. The price reduction applies to the generic and the originator product.
2. In Canada, the regulation of prescription and generic substitution differs across provinces and territories. Incentives for doctors, pharmacists and patients vary across drug plans. Reference prices are only used by some drug plans.
3. Only in the public sector.
4. To be implemented.
5. In Japan, there is no direct incentive for physicians, but an incentive for medical institutions exists. Generic prices are revised after market entry.
6. If the pharmacist has a substitution arrangement with the prescriber.
7. In some regions.
8. Depending on originator's market sales.
9. Legislation on prescription in INN and substitution is not uniform across states. Incentives for pharmacists, patients and doctors vary across drug plans. Patients' co-payments are generally lower for generics.

Source: Various sources, including PPRI country profiles (*http://ppri.oebig.at*, in press) and personal communications.

StatLink http://dx.doi.org/10.1787/888932319839

Figure 6.6. **Generic drug market shares in 2008**



n.a. = not available; P = Community pharmacy market; R = Reimbursable market (out-patient); Rx = Prescription drug market. Otherwise: total market.

Source: National sources and EFPIA (2010).

StatLink http://dx.doi.org/10.1787/888932319630

(European Commission, 2008). The European Commission concluded that compliance with Competition Law needed to be more closely scrutinised and that the European Union would benefit from the creation of Community patents and a unified litigation system.

However, it would be wrong to conclude that it is primarily the actions of the pharmaceutical industry which alone are holding back the development of generic markets. Many public policies continue to hinder their development too. "Patent linkage", for instance, may impose undue delays to generic entry: according to this rule, the authority in charge of marketing authorisation is expected to check whether a patent has expired before granting marketing authorisation. Most OECD countries have adopted a "Bolar type" provision allowing drug agencies to assess generic applications and deliver market authorisations before patent expiry[8, 9] so that generics can enter the market as soon as the patent expires. However, a few countries continue to link the delivery of marketing authorisation to patent expiry (*e.g.* the Slovak Republic, Mexico).

In addition, in many countries, pricing and reimbursement processes impose further delays to generic entry. With regards to the specificity of generic products, procedures could certainly be shortened or accelerated to speed up generic penetration (EGA, 2009; European Commission, 2008). In Australia, for instance, the recent agreement between the government and the major pharmaceutical industry association plans for a parallel assessment of new products by authorities in charge of marketing authorisation and reimbursement policy from 2011. On top of marketing authorisation and reimbursement and pricing procedures, some countries add another step to restrict substitution

opportunities by defining groups of "interchangeable products" which can be substituted for each other by pharmacists. Countries may consider the costs and benefits of this procedure and see whether it could be replaced by a general procedure setting the rules for interchangeability and substitution at a more general level once and for all and letting pharmacists decide for product-specific cases.

Reference price policies and "price linkage" may reduce generic price competition in some circumstances. In reference price policies, payers set a maximum reimbursement price (MRP) for clusters of products, most often by reference to the price(s) of the cheapest generic(s). Consumers have to pay any difference between the price and this reimbursement amount. This policy does not provide much incentive for generic manufacturers or pharmacists to sell generic drugs below the MRP and may well reduce price competition in the long run, especially if reference prices are not frequently updated. On the other side, reference price policies unambiguously favour generic penetration of the pharmaceutical market, which is still a high priority for several countries.

Many countries regulate the prices of generics in relation to the originator's price, with a fixed discount – a practice known as "price linkage". In France, generic prices are set 55% below the originator's price (see Table 6.1). For third-party payers, this policy does not guarantee good "value-for-money": once a patent has expired, there is no reason for them to pay a higher price for a brand-name drug than for bio-equivalent products. A unique reimbursement price for the cluster offers better value-for-money to third-party payers, with the possibility for individual providers to set prices above this amount if they can benefit from brand loyalty. In addition, price linkage may reduce dynamic price competition in generic markets: in markets with free pricing, generic prices will likely decrease when the number of competitors increases. Some countries have introduced "stepped pricing models", in which prices of originators (and sometimes generics) are reduced after an initial period with the wish to mirror off-patent market dynamics (*e.g.* Austria, France, Norway). However, this approach does not guarantee that generic prices will be as low as they could be in a freer market.

A majority of OECD countries have allowed physicians to prescribe in International Non-proprietary Names (INN) and/or pharmacists to substitute (cheaper) equivalent medicines to brand-name prescribed products[10] (see Table 6.1). However, professional behaviour is not only shaped by laws. If 80% of prescriptions are written in INN in the United Kingdom, this is only the case of 12% of prescriptions in France (PPRI, 2008b). Similarly, pharmacists may be allowed to substitute generics for brand-name drugs, without doing it in practice. A few countries still do not allow prescription in INN or generic substitution in pharmacies, including Greece, where the generic market share is exceptionally low. In another small number of countries, generic substitution by the pharmacist is mandatory (*e.g.* Denmark, Sweden). However, this does not seem to be a necessary condition to ensure high generic penetration, since generics have high market shares in several countries without mandatory substitution (see Figure 6.6), including Poland and the United Kingdom.

Financial incentives for physicians, pharmacists and patients have been created to foster the development of generic markets. Physicians have been provided financial incentives to prescribe cheaper alternatives in different ways: they may receive per capita funding for their patients and be allowed to keep any savings achieved through economic prescribing, as it was the case for some physician groups in the United States in the 1990s

or GP fundholders in the United Kingdom. They may be financially rewarded by extra payments if they reach targets in terms of generic prescription, as defined in pay-for-performance schemes. For instance, the French Contracts for improvements of individual practices (CAPIs), signed on a voluntary basis by primary care doctors, link bonus payments to targets in the share of generic prescription for a few generic groups (see Chapter 4). On the contrary, they can be penalised if they have average prescription costs above the average of a peer group. This option has been used in Germany. Though it proved very difficult to penalise physicians, the incentive encouraged the prescription of cheaper medicines.

Incentives for patients depend on out-of-pocket payments. The way user charges are designed is likely to influence generic take-up, when patients have a choice. Patients have a financial interest to choose cheaper drugs when the co-payment is a co-insurance rate (expressed as a percentage of the price), when fixed co-payments are lower for generics ("tiered" co-payments) or in "reference price" systems. Some countries have supplemented existing incentives to further encourage generic use. For instance, in 2006 Switzerland increased the co-insurance rate for brand-name drugs for which cheaper interchangeable generics are available from 10 to 20%. France decided in 2008 that patients had to pay in advance for their drugs and be reimbursed later when they refuse generic substitution (while the usual rule is direct payment of the pharmacist by third-party payer).

Incentives for pharmacists generally consist in correcting the disincentive inherent in pharmacists' remuneration schemes in the vast majority of OECD countries: pharmacists margins are set in relation to the price of medicines and are therefore higher (in absolute terms) for more expensive products. With such an incentive, pharmacists are penalised when they substitute a generic for a more expensive drug. Several countries have reversed or at least neutralised this incentive (*e.g.* France). Other countries have created positive incentives: in Switzerland for instance, pharmacists receive a fee for generic substitution. In several countries (*e.g.* Hungary, Norway, Poland), pharmacists have the obligation to inform patients about the possibility of a cheaper alternative, which acts as a non-financial incentive to encourage generic substitution.

Another important feature of the distribution chain is the ability of manufacturers to negotiate rebates and discounts with wholesalers and/or pharmacists in order to gain market shares over generic competitors. Since pharmacists are generally free to pick up any generic when they substitute a generic for an original drug, generic manufacturers are ready to negotiate high rebates or discounts on their products to gain market shares. Fierce competition has led to big rebates in some countries, enhancing pharmacists' revenues. However, a common concern for countries with regulated prices or maximum reimbursement prices for generics is that third-party payers and consumers do not benefit from generic price competition that occurs at the pharmacy level. In Canada, for instance, rebates and allowances given by manufacturers to pharmacies were estimated at 40% of payers' generic drug costs (Competition Bureau Canada, 2008).

To ensure that payers benefit from these rebates, OECD countries have adopted different strategies. Some countries have capped manufacturers' rebates (France, the Canadian Province of Ontario for its public drug benefit).

In 2007, Australia commenced implementing a new policy of "price disclosure". Under this new arrangement, the "weighted average disclosed price (WADP)" is computed on a regular basis for drugs subsidised by the Pharmaceutical Benefits Scheme (PBS) across all products with the same active ingredient(s) and the same mode of administration, for a

period of 12 months, taking into account manufacturers' discounts. When the gap between the current PBS ex-factory price and the WADP is 10% or more, the PBS price is adjusted to the new calculated price. In Japan, the drug prices are regularly (usually biennially) revised to be brought closer to actual market prices as measured by the government's drug price survey. With such arrangements, payers and consumers can benefit from generic price competition.

Other countries have developed direct contracting between health insurers and manufacturers. The discussion below presents these recent developments, as well as the evidence on their impact.

Contracting, tendering, procurement and competition in generic markets

Contracting, tendering and public procurement policies have been used for decades in some market segments in OECD countries. In the past four years, several countries developed contracting opportunities to extend those practices with the aim to foster generic price competition in the out-patient sector. Though huge price reductions have been obtained in some cases, the long-term impact on generic markets is unclear, and could even prove harmful according to recent studies. Careful design is needed to use contracting to achieve better value-for-money in pharmaceutical spending.

In the United States, health insurers and pharmacy benefit managers have been contracting with pharmaceutical companies since the 1980s. They have obtained substantial discounts or confidential rebates from manufacturers in exchange for "listing", "preferred drug status", or even "exclusive listing"[11] in their formularies for both patented and off-patent drugs sold to out-patients (US Federal Trade Commission, 2005). New Zealand introduced competitive tendering for generic drugs subsidised by the public drug plan for out-patients in 1997. The tendering process resulted in significant price reductions: 40% on average in 1997/98 and 60% in 1999/2000. For some products, price reductions reached 84% to 96% in five years (OXERA, 2001). In other countries, contracting has mainly been used in the hospital sector, as well as for the purchase by public authorities of specific medicines (mainly vaccines) and has only recently been developed in the out-patient sector in a small number of countries (Leopold *et al.*, 2008; Kanavos, 2009).

In the Netherlands, health insurers are allowed to select one or more products, within a cluster of products with the same active ingredient, to be eligible for reimbursement. They contract with pharmaceutical companies to obtain discounts or rebates on prices in exchange for the exclusivity of the reimbursement status, for a given period of time. Under this policy, patients have to pay out-of-pocket the price of non-selected products, unless a doctor has confirmed a medical need for a specific product.

Dutch health insurers have been using both collective and individual tendering. In 2005, seven private health insurers in the Netherlands, covering about 70% of the population, decided to tender jointly for the purchase of three high-selling off-patent active ingredients (simvastatin, pravastatin and omeprazole). Manufacturers offering the lowest price (or no more than 5% above) were selected and their drugs were supplied to patients free of charge, while other drugs were not reimbursed at all. Following an agreement between the Health Insurance Board, the generic association and the pharmacists' association for 2007-08, collective tendering has not been extended to other active ingredients. However, 33 substances were listed for potential tenders, led by individual health insurers. Insurers can use additional incentives: one insurer decided for

instance to exempt patients who use preferred drugs from the annual deductible for out-patient pharmaceuticals (Maarse, 2009; Kanavos, 2009).

The total initial savings of the tendering practices in the Netherlands were substantial (EUR 355 million): price reduction reached 90% in some cases and generic substitution increased. However, pharmacies experienced a dramatic loss of the revenues they previously earned from the discounts granted by generic manufacturers which were not passed on to health insurers, threatening the financial sustainability of many of them. To compensate this loss, the dispensing fee for pharmacists was increased from EUR 6 to EUR 8.25, which generated an additional income of EUR 200 million for pharmacists but also offset part of the savings achieved by health insurance funds (Kanavos, 2009).

However, according to generic manufacturers, the current tendering practice puts excessive price pressure on the generic market, and compromises the generic market in the long term, as companies may be tempted to leave the Dutch market.

In Germany, the 2007 Health Insurance Competition Enhancing Act designed a set of incentives to foster health insurance funds' contracting opportunities. According to the new law, when health insurance funds contract with a pharmaceutical company (in practice mainly generic companies) to obtain price reductions, pharmacists are obliged to substitute the "preferred" drug for the initial prescription, unless a doctor has formally excluded substitution.[12] Health insurance funds tender for two types of contracts: contracts for the purchase of a specific active ingredient or contracts for a product portfolio.

These provisions were challenged by pharmaceutical companies with the German antitrust agency and examined by the European Court of Justice, who finally ruled that German health insurance companies have to comply with European regulations for public procurement (Kanavos, 2009).

In Canada, British Columbia, Ontario and Saskatchewan issue tenders for the purchase of a small number of top-selling molecules by their public plans. The winner is the company offering the highest confidential rebate and receives exclusive listing for a set period of time. The size of confidential rebates gained through this practice is not known. However, in one case, the government of Ontario dropped a tender process for a drug (ranitidine) because the brand manufacturer reduced its formulary price by 75%, which suggests that potential price reductions are likely to be of this magnitude (Competition Bureau Canada, 2008; Hollis, 2009).

All these experiences show that tendering processes allow short-term savings, obtained both by drastic price reductions and, in some cases, by an increase in generic market penetration. However, they also tend to increase market concentration, with the risk of lower price competition in the longer term if some generic providers decide to exit the market. In some cases, bid winners also failed to supply the market and countries experienced shortages.[13] A careful design of tendering processes is therefore needed to guarantee both that winning companies will be able to supply adequately the market or otherwise risk enforceable penalties, and prevent competing companies from abandoning national markets.

6. Conclusions

Policy makers have continuously adapted pharmaceutical policies to respond to new challenges posed by market dynamics and medical progress, with the objectives of ensuring access to affordable medicines to their citizens, containing spending growth

and sustaining R&D efforts. The impact of these policies on national markets and innovation capacities need to be monitored in order to make adjustments when necessary.

To cope with the economic crisis and address unprecedented budget deficits, several OECD countries have recently implemented drastic policies to cut pharmaceutical spending or, at least, contain their growth. Several countries are trying to make decisions about the pricing of new pharmaceutical products more "rational" in order to maximise the value-for-money of pharmaceutical spending. Cost-effectiveness and/or budgetary impact are sometimes taken into account explicitly when making decisions about coverage of new drugs. Restricting coverage is unpopular and decision makers are torn between "economic rationality" (to maximise the efficiency of public spending) and the pressure to respond to people's expectations.

To deal with this dilemma, some countries have amended the criteria to be taken into account for coverage decisions. Other countries have developed innovative pricing agreements linking public spending to health outcomes obtained. Although the jury is still out until more evidence has been collected, it appears that some of these arrangements may well be useful new policy tools for payers of health services in their attempt to get good value-for-money without taking on too great financial risk.

Another strategy for increasing value-for-money in pharmaceutical spending is to expand the market for generic drugs. OECD countries have implemented policies to promote generic uptake: physicians have been given the possibility to prescribe in INN, and pharmacists the right to substitute generics for brand-name products in almost all countries. However, in several OECD countries, generic markets remain underdeveloped, suggesting that appropriate economic incentives for providers, physicians, pharmacists and patients are lacking. Moreover, in several countries, price competition has been weak or has not benefitted consumers and third-party payers. More aggressive use of tendering processes, for instance in Germany and the Netherlands, has led to immediate and sometimes huge price reductions. However, the approach is not without risks: experience shows that calls for tender need to be carefully designed in order to avoid the problem of supply shortages and excessive market concentration in the longer term.

Notes

1. In the system of health accounts, "pharmaceutical expenditure" refers to expenditures for pharmaceuticals and other medical non-durables dispensed to out-patients. It includes prescribed medicines, over-the-counter medicines, as well as a range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices. It does not include spending for pharmaceuticals dispensed in in-patient care. The latter accounts for 5% to 15% of total spending on pharmaceuticals in countries for which data are available.
2. *www.who.int/medicines/areas/policy/imsreport/en/index.html,* accessed on 18 May 2010.
3. Drugs used in hospitals are generally covered by public and social schemes through "hospital benefits".
4. In Germany, 10% of residents are covered by private health insurance. Though private health insurers have some latitude to define their benefit package, they most often cover the same pharmaceutical products than statutory health insurers.
5. The main market failures in the market for out-patient prescription drugs are the following: low consumer price sensitivity (due to insurance coverage); manufacturers' monopoly position for on-patent drugs, especially when there is no therapeutic alternative; and separation of the decision to

purchase (by the doctor, generally not sensitive to price) from the responsibility to bear the cost (patients and third-party payers). In countries where drug insurance is mainly provided by social or public schemes, the need to contain health spending growth and spend efficiently is another justification for the regulation of reimbursement prices.

6. There is no clear trend regarding price regulation for medicines used in hospitals: many countries set maximum list prices while others do not regulate prices at all. The common feature is that purchasing processes generally allow price negotiations. Hospitals under budget constraint are sensitive to price and use their purchasing power to negotiate prices whenever possible.

7. "Orphan drugs" basically refer to medicines developed for rare conditions. Countries use different thresholds to consider that a disease is rare: "rare conditions" are those which affect less than one in 1 500 people in the United States, less than one in 2 000 people in the European Union and less than one in 2 500 people in Japan. The United States and the European Union have implemented policies to encourage private investments in R&D for rare diseases (*e.g.* increased market exclusivity) and have consequently defined criteria to be met by a medicine to be granted an "orphan drug status". In the European Union, those criteria are: the severity of the disease; the fact that it serves an unmet need; and either prevalence below one in 2 000 or a negative expected return on investment.

8. Drug agencies cannot assess generic application before the end of the "data exclusivity period", which lasts 5 years in the United States and 8 to 11 years in the European Union.

9. "Patent expiry" is used in this text as a synonym for expiry of patents and supplementary protection certificates which exist in many OECD countries.

10. "Substitution rights" are useless or implicit when doctors prescribe in INN.

11. "Listing" means that the drug is covered by the plan. Under "preferred drug" status, a drug benefits from lower co-payments than its competitors. "Exclusive listing" means that the drug is the only product covered by the drug plan in its therapeutic class or for a given molecule.

12. To ensure consistency with policies aiming to encourage efficient prescription by physicians, "preferred drugs" are excluded from statistics used to monitor physicians' prescription targets and impose financial penalties when necessary.

13. According to Carradinha (2009), both Netherlands and New Zealand experienced shortages because the bid winner was unable to fulfil its commitment. In both cases, a solution was found because competitors were ready to supply the product.

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