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DRAFT CHAPTER FOR PRIORITIES PUBLICATION ON PHARMACEUTICAL POLICIES

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NOTE BY THE SECRETARIAT

1. This document contains the draft Chapter 6 for the 'Health System Priorities when Money is Tight' publication. It draws on the 2008 OECD report on Pharmaceutical Pricing, but also discusses new policies and approaches that have been introduced by countries since then.

2. Some parts of the analysis are yet to be completed. Where this is the case, the relevant discussion is indicated in [square brackets].

3. Delegates are invited to:

- **COMMENT** on the draft Chapter, and
- **SUGGEST** additional analysis and evidence that should be added to the Chapter.

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CHAPTER 6
DRAWING ALL THE BENEFITS FROM PHARMACEUTICAL SPENDING

Introduction

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

5. Countries have adopted different approaches to reconcile these objectives, in line with the general organisation of their health system. 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?", "at what price (for the insurer and for the patient)?"

6. This chapter presents recent trends in pharmaceutical policies. The first section provides updated data on pharmaceutical spending, funding and growth. The second section describes briefly the main instruments used by OECD countries to regulate pharmaceutical reimbursement and pricing. The third section looks at recent experiences with innovative pricing agreements, which are developing in some countries. The last section presents recent policy initiatives aiming to get more value for money from off-patent markets.

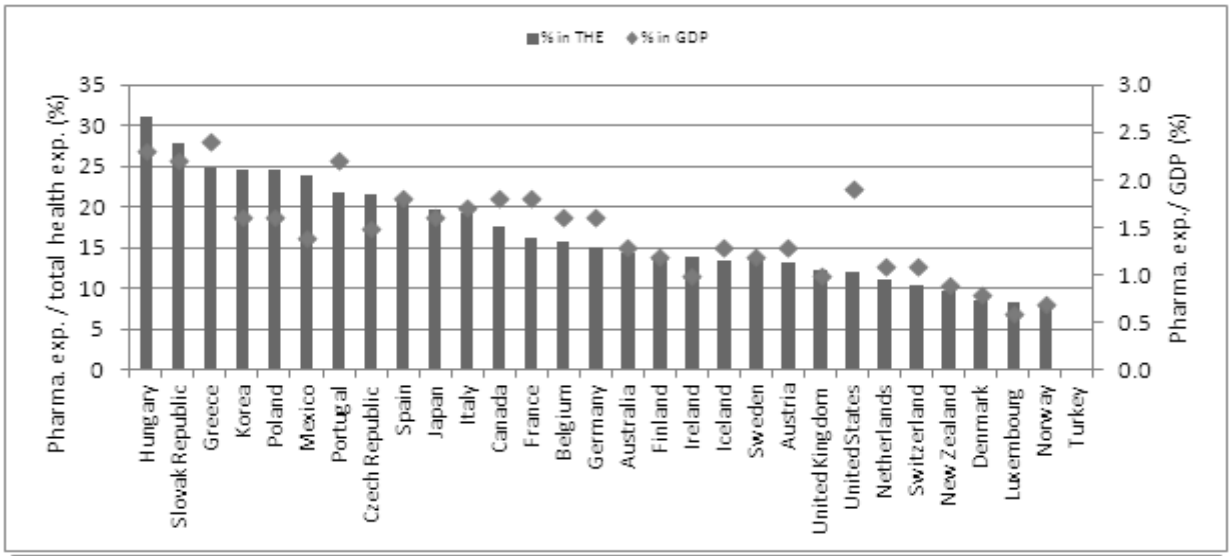
Pharmaceutical spending in OECD countries

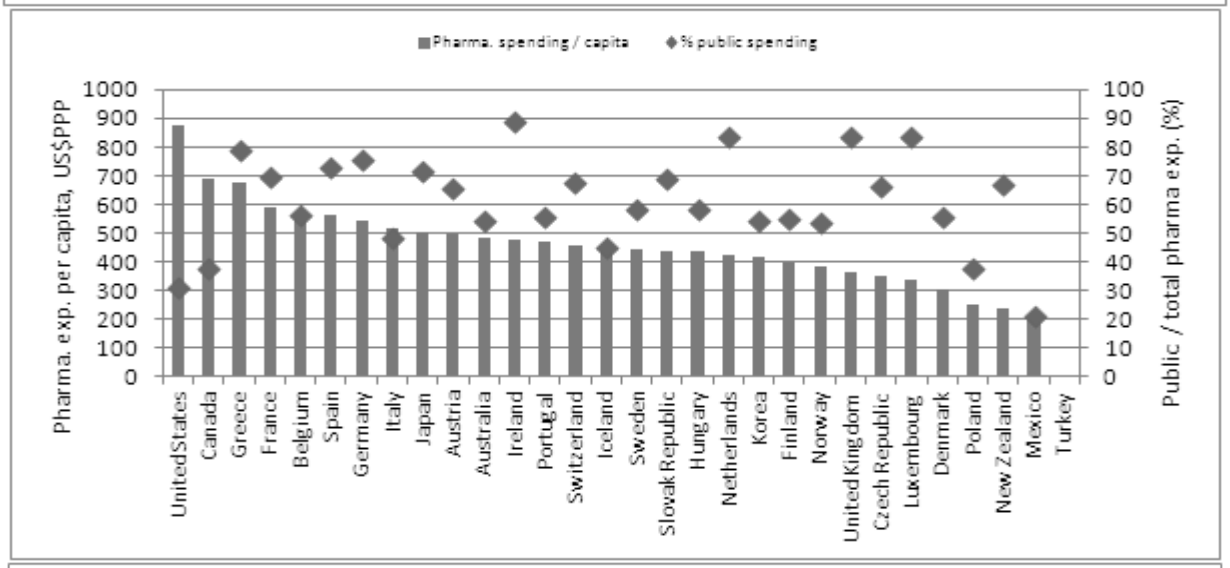
7. Pharmaceutical spending[1] accounts for 17% of total health spending and 1.5% of GDP on average in OECD countries (Figure 1.A.). However, the dispersion around these averages is high: pharmaceutical spending accounts for only 8% of total health expenditures in Norway, while it absorbs 31% of health spending in Hungary, and more than 24% in the Slovak Republic, Greece, Korea, Poland and Mexico. Per capita spending, expressed in US$PPP ranges from 198 in Mexico to 878 in the United States, reflecting large differences in volumes and prices of pharmaceuticals (OECD, 2008).

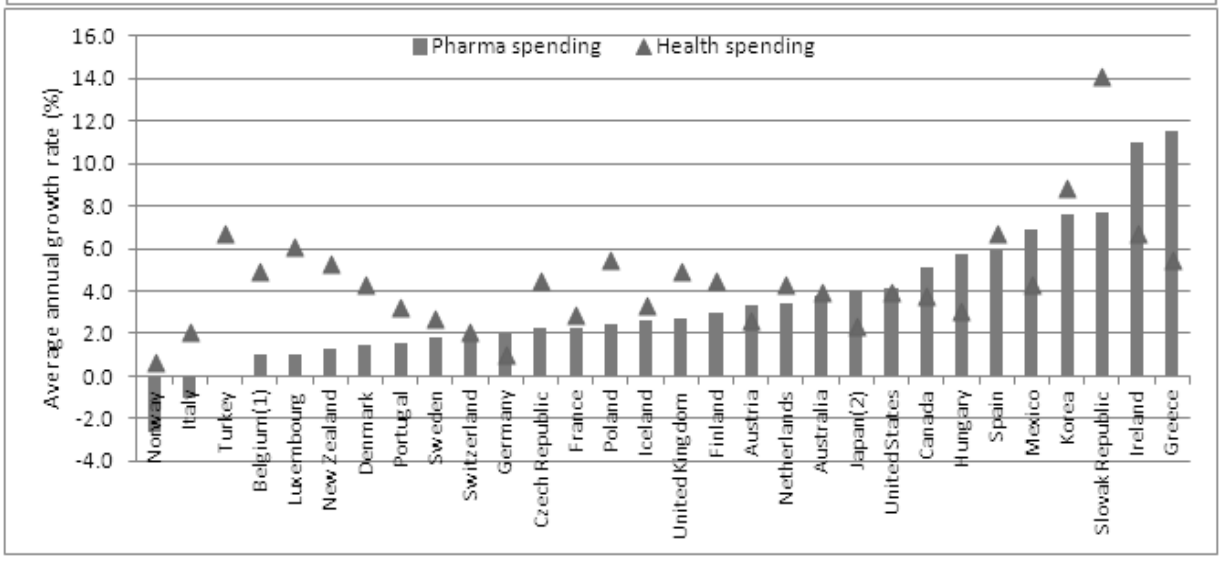
8. In the past, pharmaceutical spending has risen at a faster pace than total health spending (THE) in developed countries. This trend has now reversed: between 2002 and 2007, real pharmaceutical expenditure has grown by 3.5% per year on average in OECD countries, while total health spending has increased by 4.5%. Over this period, growth in pharmaceutical spending surpassed growth in THE in only nine OECD countries: Germany, Austria, Japan, the United States, Canada, Hungary, Mexico, Ireland and Greece. In Norway and Italy, real growth of pharmaceutical spending was even negative.

[1] In Health Accounts, « pharmaceutical expenditure » refers to expenditures for pharmaceuticals dispensed to out-patients care. It does not include spending for pharmaceuticals dispensed in inpatient care, which have been increasing at a faster pace.

Figure 1. Pharmaceutical spending 2007, and growth 2002-2007







9. 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 does not always coincide with a decline in expenditures [IMS data need to be analysed more closely].

10. Some governments confronted with high fiscal pressure have adopted drastic measures to curb pharmaceutical expenditure growth in the past months. In Ireland for instance, where pharmaceutical spending was growing at a very high pace, the government agreed with the Irish Pharmaceutical Health Care Association (representing international research-based companies) 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 (0.50€ per prescription, capped at 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.

11. In May 2010, Greece enforced regulations aiming to achieve an average pharmaceutical price cut of 21.5%, Spain announced price cuts of 23% for patented drugs and 25% for generic drugs; the United States announced an immediate increase from 15.1% to 23.1% in the discount for drugs sold to the Medicaid programme. In 2009, Hungary blocked the introduction of any new innovative medicine in the positive list to respond to fiscal constraint. Some further examples of recent actions to cut public expenditure on pharmaceuticals are described in Box 1.

Box 1. Recent pharmaceutical pricing developments

Denmark:	Price freeze or cut for hospital drugs
France:	Pricing of new drugs to be more strictly related to value
Germany:	The compulsory rebate of 6% of the price for patented drugs to be increased to 16%; pricing of new drugs to be related to value.
Greece:	Reductions of up to 27% for patented drugs; generics to be priced 30% lower than the main brand, subject to reference pricing with other countries.
Hungary:	No new drugs eligible for reimbursement, temporarily.
Ireland:	Up to 40% cut in the price of some generics.
Spain:	Reductions of up to 16% in price of patented drugs, and 25% reductions in prices of generics.
Sweden:	Reduction of prices of €200m over 3 years
UK:	Reductions of 5% of the price of patented drugs; greater use of generics. Public discussion of move to "value-based pricing"
US:	Increase in the discount for drugs covered in the Medicare program, from 15.1% to 23.1%

Source: Financial Times, 2 June 2010, and communication with countries.

[2] http://www.who.int/medicines/areas/policy/imsreport/en/index.html, accessed on May 18, 2010.

12. 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%; Italy distributed social vouchers to vulnerable people (€40 per months) for the purchase of primary goods or pharmaceuticals (Council of the European Union, 2009).

13. Beyond short term policies, OECD country 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.

Reimbursement and pricing policies in OECD countries

14. Pharmaceutical expenditures are predominantly financed by public schemes in all OECD countries but the United States, Canada, Iceland, Poland and Mexico. Public funding exceeds 80% of pharmaceutical spending in a few countries: Ireland, the Netherlands, the United Kingdom and Luxembourg (See Figure 1).

15. The vast majority of OECD countries establish a list of drugs eligible for reimbursement ("positive list") at the national level. Only five countries have adopted other policies: Canada and the United States, where private and public health insurers develop their own positive lists (formularies); Germany and the United Kingdom, where "negative lists" are established instead; and Greece, where a positive list will be prepared. Pharmaceutical coverage generally entails user charges, with exemptions for some segments of the population and/or categories of drugs.

16. Most OECD countries regulate the price or the reimbursement price of outpatient pharmaceuticals reimbursed by third-party payers at the national level[3]. Only a few countries do not directly regulate the price of new pharmaceuticals at market entry, among which Germany, the United Kingdom and the United States.

17. OECD countries use three main instruments to regulate pharmaceutical prices: international benchmarking, therapeutic benchmarking and economic assessment. Some of them actually use a mix of those instruments, applying to different market segments. The OECD report on pharmaceutical pricing policies, published in 2008, described policy employed by Member countries and shed some light on their impact on prices and availability of pharmaceuticals (OECD, 2008).

International benchmarking

18. Twenty-four OECD countries use international benchmarking to define the price (or a maximum price) of pharmaceuticals[4]: they look at prices paid by a set of comparator countries to determine a maximum price for a new drug.

19. International benchmarking has been used by OECD countries for different reasons. In Canada, a Federal Board checks that pharmaceutical companies do not abuse from their monopoly power in setting the prices of all patented drugs (reimbursed or not). Within the European Union, governments and the industry promoted international benchmarking with the idea that pharmaceutical prices should vary within

[3] The prices of drugs not eligible for reimbursement and drugs purchased by hospitals are most often not regulated.

[4] Only Denmark, Germany, Korea, Sweden, the United Kingdom and the United States do not use international benchmarking at all.

a "corridor" to reduce incentives for parallel trade[5]. Finally, many countries adopted international benchmarking as a practical guide in negotiating prices with manufacturers.

20. The list of "comparator countries" is naturally 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 Greece, Hungary, Poland and Portugal, while France refers to Germany, Italy, Spain and the United Kingdom. Canada selected a set of countries with a 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.

21. 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 Federal Board controls *a posteriori* that the price proposed to consumers and payers is not higher than the median price in comparator countries (as stipulated by the regulation) and asks rebates from the manufacturer if this is not the case. 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).

22. 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 and 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, will not guarantee that the price set will reflects the country-specific value of a pharmaceutical product.

23. 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

24. *When using therapeutic referencing*, countries regulate the price of new entrants by comparison with the price 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.

[5] So-called "parallel trade" (import/export of pharmaceuticals outside the formal channels organised by the product's manufacturer or licensed distributor) is authorised in the EU. Parallel trade is likely to take place when the price differential between two countries is higher that 15%. It represents a loss for manufacturers, to the benefit of other stakeholders.

25. Canada, Belgium, France, 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 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.

26. "*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. 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 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).

27. 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 do claim to achieve this, and are discussed in the next section.

Pharmaco-economic assessment

28. 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 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.

29. 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.

30. Pharmaco-economic assessment is, in many ways, be 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 high cost end-of-life medicines or orphan drugs[6] (less likely to meet the cost-effectiveness thresholds) and have adapted their policy to take into account the specificities of those products.

31. Beside the three main instruments described above, OECD countries use a variety of other instruments to regulate pharmaceutical prices: Spain uses a cost-plus regulation; the United Kingdom caps the profit of pharmaceutical companies; and several countries have developed product-specific pricing agreements. Those 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 paper.

Price regulation and price levels

32. The discussion above describes briefly the benefits and drawbacks of the main policy instruments used by OECD countries. 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 price regulation at market entry, such as the United Kingdom, had relatively low prices. Pharmaceutical prices are somewhat related to GDP per capita, though variations in income were found to explain only 1/5 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

33. 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.

Recent developments in reimbursement and pricing policies

34. 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 health care services to be forgone to fund it.

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[6] "Orphan drugs" basically refers 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 1/1,500 people in the United States, less than 1/2,000 people in the European Union and less than 1/2,500 in Japan. Beyond this, 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 defined criteria to be met by a medicine to be granted an "orphan drug status". In the EU, those criteria are: the severity of the disease; the fact that it serves an unmet need; and either prevalence below 1/2,000 or a negative expected return on investment.

35. Media coverage of negative reimbursement decisions –especially 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 as assessed by bodies in charge of economic evaluation, and have been forced to find ways to circumvent their own cost-effectiveness thresholds (Raftery, 2008).

36. 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 sufficient. Treatments which fail to meet efficiency thresholds may be seen as desirable to the public because they extend life or relieve severe symptoms. Apparently, "rational choice", as defined by economists, does not seem to coincide with collective preferences.

37. We could argue that citizens are not well informed about the real costs and benefits of treatments, potential adverse effects, uncertainty, and opportunity costs. We could also mention 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 [find opinion polls?]. Still, decisions have to be made. What should decision-makers do?

38. 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 effective treatments for economic reasons and do want to provide incentives to develop drugs for small population groups with severe diseases.

39. 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 2).

Box 2. Strategies to cope with high-price medicines in pluralistic systems

[To Be completed]

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 incentivize the use of cheaper alternative through differential copayments 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 copayments. Traditionally, private plans have been using three-tiered copayments: monthly copayments of $5 to $0 for generic drugs, $20 to $30 for brand-name medicines with moderate prices and $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 et al., 2008). For drugs whose price can exceed $50,000 a year, co-insurance represents out-of-pocket payments of more than $10,000.

In Canada, two-third of the population are covered by private health plans for pharmaceutical consumption. Except in Québec, where private plans are required to provide the same benefits than public plans, private insurers can define their own formularies [to be completed].

Source : Lee et al., 2008; Faden *et al.*, 2009

Economic evaluation and drugs with poor cost-effectiveness

40. In many OECD countries, clinical effectiveness is the main criteria 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, 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).

41. In general, price regulations and rules for reimbursement are lighter for drugs used in hospital settings than for drugs used in outpatient 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 programs to fund high-cost drugs on top of payment per case (e.g. Germany, France). In other countries, access to inpatient expensive drugs is unequal and linked to the ability and willingness to pay of hospitals.

42. Countries which consider cost-effectiveness to make reimbursement decisions have tried to provide explicit answers to trade-offs between results of economic evaluation 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.

43. Sweden was the first country to make 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 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 €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.

44. In the United Kingdom, institutes in charge of economic appraisal have adapted their guidance to take into account those 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 3). Similarly, in Scotland the Scottish

Medicines Consortium takes other criteria than ICER into account to make decisions, such as the fact 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).

Box 3. Social values and economic assessment

The cost-effectiveness incremental 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 outpatient 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 prioritized over people with less severe conditions;
- The *cost-effectiveness principle*: the costs of using a medicine should be reasonable from a medical, humanitarian and social-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 Clinical Excellence and Public Health (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 £30,000/QALY. The supplementary guidance applies to the following:

- Treatments indicated for patients with a *short life expectancy*, normally less than 24 months;
- There is sufficient evidence that the treatment offers an extension to life, normally *at least 3 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 on 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.

Notes:

(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 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.

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

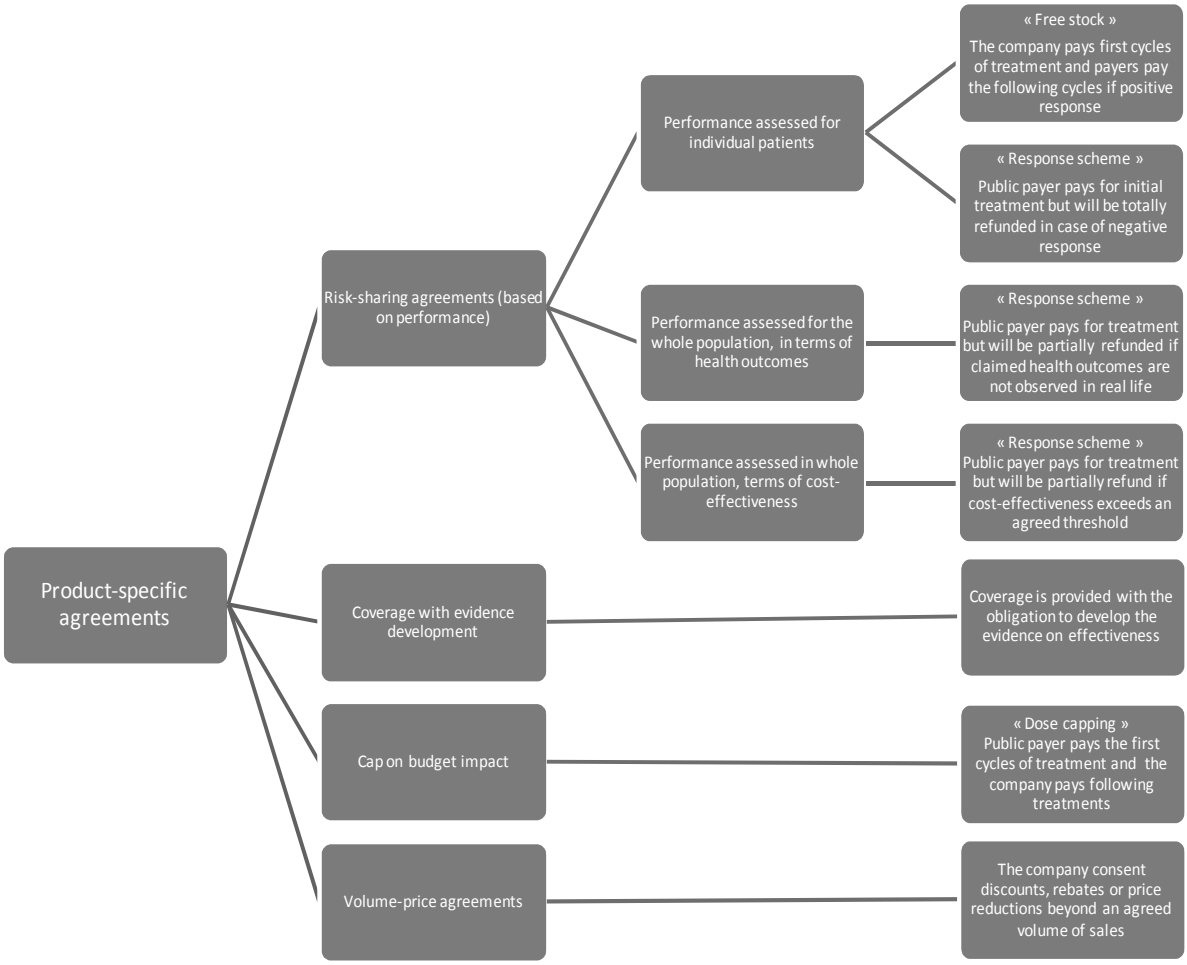
45. Beyond adaptations of criteria for decision-making, those countries have been using product-specific agreements for drugs with poor cost-effectiveness ratio or high budget impact.

Product-specific pricing agreements

46. Payers and pharmaceutical companies have developed *pricing agreements* to enhance access to medicines with high costs or high budget impact (IMS, 2009; Carlson, 2010). These agreements between third-party payers and pharmaceutical companies, either seek to link the "value" brought by a new products in terms of health gain, to the unit price or, more basically, to limit budget impact. Several typologies have already been developed to classify those 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 Chart 2).

47. In *volume-price agreements*, the unit price of a product is linked to volumes of sales, so that it declines when volumes increase. It is consistent with the idea that the 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. Volume price agreements do not really allow third-party payers to control spending but just to extract a share of companies' rent.

Figure 2. Typology of product-specific reimbursement and pricing agreements



48. *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 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.

49. *Coverage with evidence development (CED) schemes* have been adopted in the United Kingdom, the United States, and Sweden (Carlson et al., 2009). 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 UK, 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). The overall objective of CED schemes is thus to improve knowledge about the product's impact on health.

50. *Risk-sharing agreements* are 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.

51. Risk-sharing agreements can take several forms. Outcomes to be assessed can be set 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 again, companies producing treatments for multiple sclerosis agreed to reduce the price of their products in order to maintain an *average* cost/QALY at £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.

Box 4. 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 3 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 equalize 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 common 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

52. 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 about 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.

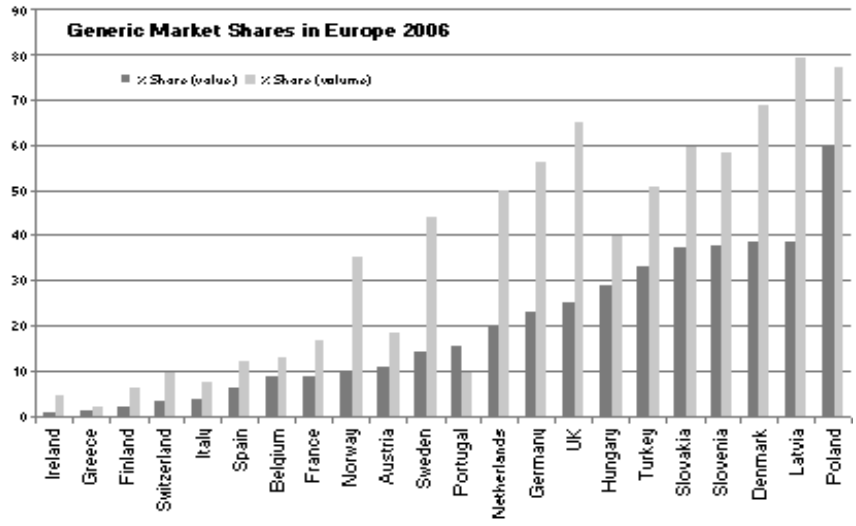
53. Product-specific agreements could well prove to be a useful new instrument in promoting patient access to innovative treatments while linking public funding to therapeutic value. However, as yet, there is insufficient evidence to be confident in their utility. As these agreements are developing quickly 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.

Efforts to develop generic markets

54. All OECD countries see the development of generic market as a good opportunity to increase efficiency in pharmaceutical spending, by offering cheaper products than on-patent drugs to consumers and third-party payers and allowing a re-allocation of scarce funds to innovative medicines. Most OECD countries have implemented policies to promote generic use (see Table 1). However, generic market shares in pharmaceutical sales show wide variations across OECD countries (Figure 3).

Figure 3. Generic market shares in 2007

This figure will be updated and completed with non EU OECD countries



Source: EGA website

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

56. 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[7,8] 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].

57. 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). 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 the pharmacist decide for product-specific cases.

58. 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 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 Japan for instance, generic prices are set at 70% of the originator's price (see table 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.

7 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.

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

Table 1. Policies to promote generic use [TBCompleted]

	Prescription in INN			Generic substitution			Incentives			P & R policy	
	Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory	Incentives for pharmacists	Incentives for patients	Incentives for physicians	Reference price system	Price linkage
Australia					x						
Austria	x			x						N	
Belgium		x		x						O	
Canada											
Chile											
Czech Republic		x			x					O	
Denmark	x					x				O	
Finland		x				x					
France		x			x					O	45%
Germany		x				x				O	
Greece	x			x							
Hungary		x			x					O	
Iceland											
Ireland		x		x						N	
Italy		x			x					O	
Japan											70%
Korea											
Luxembourg				x						N	
Mexico											
Netherlands		x			x					O	
New Zealand											
Norway		x			x						
Poland		x			x					O	
Portugal			x		x					O	
Slovak Republic		x				x				O	
Spain					x					O	
Sweden	x					x					
Switzerland											
Turkey	x				x						80%
United Kingdom		x		x						N	
United States											
Estonia			x		x					O	
Israel											
Slovenia					x					O	
Russia											

Notes: “Price linkage. Figures represent prices set for generics at market entry, as a proportion of the originator’s price.
Sources: Vogler *et al.* (2009, Vogler *et al.* (2009)

59. 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 prescribed products[9] (see Table 1). However, professional behaviour is not only shaped by laws. If 80% of prescriptions are written in INN in the UK, whereas this is only the case of 12% of prescriptions in France (PPRI, 2008). Similarly, pharmacists may be allowed to substitute generics to brand-name drugs, without doing it in practice [find appropriate examples in PPRI reports]. 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 3), including Poland and the United Kingdom.

60. 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 1990's 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 [Develop the French P4P example]. 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 cheap medicines.

61. 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 copayment is a co-insurance rate (expressed as a % of the price), when fixed copayments are lower for generics ("tiered" copayments) 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). [Summarise differential impact of different copayment schemes, see where policy measures have provided good results]

62. 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).

63. 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).

[9] Naturally, « substitution rights » are useless or implicit when doctors prescribe in INN.

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). 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

64. 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 outpatient 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 harmful according to recent studies. Careful design is needed to use contracting to achieve better value-for-money in pharmaceutical spending.

65. In the United States, health insurers and Pharmacy Benefit Managers (PBM) have been contracting with pharmaceutical companies since the 1980s. They have obtained discounts or confidential rebates from manufacturers in exchange for "listing", "preferred drug status", or even exclusive listing[10] in their formularies for both patented and off-patent drugs sold to outpatients (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 outpatient sector in a small number of countries. (Leopold *et al.*, 2008, Kanavos, 2009).

66. 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.

67. 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 2007-2008, 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 outpatient pharmaceuticals (Maarse, 2009: Kanavos, 2009).

68. The total initial savings of the tendering practices in the Netherlands were substantial (€ 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 and, which were not passed on to health insurers, threatening the financial

[10] « Listing » means that the drug is covered by the plan. Under « preferred drug » status, a drug benefits from lower copayments 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.

sustainability of many of them. To compensate this loss, the dispensing fee for pharmacists was increased from €6 to €8.25, generating an additional income of €200 million (Kanavos, 2009).

69. 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.

70. 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[11]. Health insurance funds tender for two types of contracts: contracts for the purchase of a specific active ingredient or contracts for a product-portfolio.

71. 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 (Panavos, 2009).

72. In Canada, British Columbia and Ontario have issued tenders since 2007 for the purchase of a small number of top-selling molecules by their public plans. In both cases, the winner is the company offering the highest confidential rebate. The winner 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).

73. All these experiences show that tendering processes allow short-term savings, obtained both by drastic price reductions and, in some case, 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[12]. 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.

Conclusion

74. 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.

75. To cope with the economic crisis and address unprecedented budget deficits, several OECD countries recently implemented drastic policies to cut pharmaceutical spending or, at least, contain their

11 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.

12 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.

growth. These emergency measures, however, should not distract policy-makers from the long-term objectives of pharmaceutical policies: ensuring access to affordable medicines to their citizens; getting good value-for-money from pharmaceutical spending; and encouraging future innovation. This Chapter provided a brief review of current pharmaceutical reimbursement and pricing policies in OECD countries, focusing 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.

76. Several countries are trying to make decisions about the pricing of new pharmaceutical products more 'rational' in order to maximize the value-for-money of pharmaceutical spending. Cost-effectiveness and/or budgetary impact are sometimes now taken into account explicitly when making decisions about coverage of new drugs. Meanwhile, pharmaceutical companies have developed products for the treatment of severe rare conditions (orphan diseases, some cancers). Due to the uncertainty surrounding health benefits claimed by companies, or simply to the high reservation prices (justified by the companies because the population targeted is so small), these drugs do not always meet cost-effectiveness criteria and are sometimes excluded from benefit packages for this reason. These decisions are 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 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 will remain out until more firm evidence has been collected, it appears that some of these arrangements may well be useful new policy tools to be added to the armory of payers for health services in their attempt to get good value-for-money without taking on too great an amount of financial risk.

77. 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 if the result is not also to be supply shortages and excessive market concentration in the longer term.

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