Annexe K

International survey of pharmaceutical pricing and reimbursement schemes

February 2007

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1 OVERVIEW

1.1 As part of the market study of the PPRS, the OFT has undertaken ten case studies to learn about pricing and reimbursement schemes in other countries. The countries studied were: Australia, Canada, Finland, France, Germany, the Netherlands, Spain, Sweden, Switzerland and the US. Most of these case studies involved visits to the country, while for the US, discussions and meetings occurred in the UK.

1.2 Our objective in undertaking this exercise was to inform our thoughts on options for reform, by identifying the range of alternative approaches to pricing and reimbursement that exist in the world. As noted elsewhere in the report, international comparisons should be interpreted with caution. There are considerable challenges to be faced in attempting to compare outcomes in different countries and draw inferences from them about the relative effectiveness of different policy regimes, largely because outcomes are determined by the interaction of a number of different policy instruments and other country-specific factors. The focus of this annexe, rather, is on the practicality of different approaches and on understanding how and why they work in the context of the health system within which they are embedded.

1.3 The chapters that follow present summaries of the systems in each of the ten countries studied, and discuss the following main elements:

- an overview of the healthcare system, with a focus on expenditure on prescription pharmaceuticals and sources of funding
- the pharmaceutical supply chain
- government policies for the pricing and reimbursement of patented and generic drugs
- the views of industry organisations and companies we met, and
- key issues that we have identified as being of particular relevance to understanding the approach adopted in the country concerned.

1.4 This rest of this chapter comprises a summary of our general observations drawn from across the countries included in the case study exercise. It begins with a comparison of key statistics on each of the countries before presenting some of the high level findings from the case studies. The issues covered include:

- the importance of stability and transparency in drug pricing systems
- ex ante reimbursement and pricing controls, including
  - systems that set price in relation to therapeutic benefit relative to a substitute
  - price – volume agreements and rebates
- ex post controls, including
  - systematic cost effectiveness reviews
  - profit controls
- price cuts
  - the different varieties of co-payment regimes, and
  - generic drug policies.

Expenditure and sources of funding

1.5 The countries visited represent a very broad range of different healthcare systems and policies, exhibiting significant differences in market size and healthcare spending. The following two diagrams show differences in market size (pharmaceutical market value at ex factory prices) and per capita spending in each country.

Figure 1.1: Pharmaceutical market value at ex factory prices (€ million 2004)

Note: Medicinal products as defined by Directive 2001/83/EEC; Denmark, Finland, Sweden: pharmaceutical market value at pharmacy purchasing prices; Greece: Including parallel exports; France, Germany, Ireland, Italy, Spain: estimates.
Figure 1.2: Per capita pharmaceutical market value at ex factory prices (€ 2004)

Table 1.1: Sources of funding for pharmaceutical expenditure, 2004-2006

<table>
<thead>
<tr>
<th>Prescription pharmaceuticals</th>
<th>Public insurance</th>
<th>Private insurance</th>
<th>Out of pocket payments</th>
<th>OTC (of total pharmaceutical expenditure)</th>
<th>Generics share of sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>83.6%</td>
<td></td>
<td>16.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>46%</td>
<td>34%</td>
<td>20%</td>
<td>10%</td>
<td>17.7% *</td>
</tr>
<tr>
<td>Finland</td>
<td>67%</td>
<td></td>
<td>33%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>75%</td>
<td>20%</td>
<td>5%</td>
<td></td>
<td>7%</td>
</tr>
<tr>
<td>Germany†</td>
<td>87%</td>
<td></td>
<td>13%²</td>
<td>3%</td>
<td>34.6%</td>
</tr>
<tr>
<td>Netherlands†</td>
<td>99.7%</td>
<td></td>
<td>0.3%</td>
<td>11%</td>
<td>20.4% *</td>
</tr>
<tr>
<td>Spain</td>
<td>93.7%</td>
<td></td>
<td>6.3%</td>
<td></td>
<td>7.4%</td>
</tr>
<tr>
<td>Sweden</td>
<td>80%</td>
<td></td>
<td>20%</td>
<td></td>
<td>14%</td>
</tr>
<tr>
<td>Switzerland†</td>
<td>90%</td>
<td></td>
<td>10%</td>
<td>20%</td>
<td>5.9%</td>
</tr>
<tr>
<td>US</td>
<td>27.5%</td>
<td>47.6%</td>
<td>24.9%</td>
<td></td>
<td>51% *</td>
</tr>
<tr>
<td>UK</td>
<td>94.4%</td>
<td></td>
<td>5.6%</td>
<td></td>
<td>26.9% *</td>
</tr>
</tbody>
</table>

† Germany, the Netherlands and Switzerland have an obligatory insurance system where insurance is premium- (as opposed to tax-) funded. The government set the standards for those services that insurance has to reimburse.

1 Most data relate to 2005 and have been taken directly from our interactions with country officials. Some data relates to 2002, 2004 and 2006, please see *Notes for details.

2 About ten per cent of population are covered by private insurance and not by the Statutory Health Funds.

**Transparency, stability and credible institutions**

1.6 Transparency and stability of the rules of the system, as well as fairness and credibility of the institutions implementing the rules, are important factors for the efficient functioning of a pharmaceutical pricing system.

1.7 Stability is important in any pricing system. We found that companies generally favoured schemes where government measures are announced and discussed in advance. Most of the complaints we heard from industry organisations and companies related to what they described as opportunistic governmental behaviour and short term thinking, for example, unpredictable price cuts enforced at little notice.

1.8 We found that companies also favour systems based on clear, transparent rules, where they understand the risks to which they are being exposed and the incentives that arise from them. Companies also appeared to favour systems that allowed for constructive interactions and positive working relations between the government and industry.

1.9 The French system, for example, which is based on a framework agreement that is renegotiated every four years, was considered by companies to be a good approach to ensuring stability and predictability. However, price cuts outside the negotiated framework agreement are considered negatively because they undermine the predictability of the system and may affect companies’ ability to plan effectively for the long term.

1.10 Regarding institutions, independent bodies that implement pricing policies through a transparent approach seem to be particularly well received by companies we spoke to. Furthermore, several companies insisted that possibilities for interaction with the relevant bodies to discuss evaluations and pricing are very important. The LFN (Pharmaceutical Benefits Board) in Sweden is a good example of an institution that is recognised both nationally (by industry and government) and internationally for its coherent and well organised approach, as well as for the fair, pragmatic and transparent way it executed its tasks.

**Drug reimbursement and pricing systems**

1.11 Despite the complexity of the different reimbursement and pricing systems we analysed, it is possible to identify three basic approaches to the setting of prices and the determination of reimbursement levels for pharmaceuticals. These are:
approaches based on international reference pricing
profit controls, and
value-based approaches (a broad term comprising systems that set prices in relation to the benefits a drug produces compared to those of an appropriate comparator).

1.12 Many countries apply a mix of different measures and approaches to pricing and/or negotiating the reimbursement of pharmaceuticals. In almost all countries price discussions are linked to reimbursement in the sense that if no agreement on price is reached, the drug will not be reimbursed.

1.13 The following table shows a (simplified) overview of the different pricing and reimbursement systems in the countries we studied.

Table 1.2: Overview of the different systems

<table>
<thead>
<tr>
<th></th>
<th>Ex ante</th>
<th>Ex post</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>free pricing / immediate reimbursement</td>
<td>pricing relative to substitute</td>
</tr>
<tr>
<td>Australia</td>
<td>✓</td>
<td>✔️</td>
</tr>
<tr>
<td>Canada</td>
<td>✓**</td>
<td>✓**</td>
</tr>
<tr>
<td>Finland</td>
<td>✓</td>
<td>✔️</td>
</tr>
<tr>
<td>France</td>
<td>✓</td>
<td>✓**</td>
</tr>
<tr>
<td>Germany</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>✓</td>
<td></td>
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<tr>
<td>Spain</td>
<td>✓</td>
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<tr>
<td>Sweden</td>
<td>✓</td>
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<tr>
<td>Switzerland</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td></td>
<td>✓️</td>
</tr>
<tr>
<td>US</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*non-innovative drugs  ** innovative drugs

IRP: International Reference Pricing (see below)
PVA: Price Volume Agreements (see below)
Note: The US has a system where several actors determine pricing and reimbursement levels according to a variety of mechanisms. The main mechanisms used are those identified above.

**Ex ante controls**

1.14 In most European markets (except for Germany and the UK), pricing negotiations take place before the reimbursement of a drug is approved. Policies generally follow a two step process where first, a drug is accepted (or rejected) for reimbursement and

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3 Free pricing applies for New Active Substances only.
second, price negotiations are undertaken. As can be seen from the above table, the different approaches to determining prices are numerous and variable.

1.15 While most of these policies delay drug reimbursement in the respective markets, these delays vary substantially. Delays are generally seen as a negative feature by manufacturers as they prevent drugs from being used and reimbursed in the market and shorten the period of reimbursement while patent protection is in place.

1.16 In this respect, however, two points should be made. First, although entry onto the market may be delayed under the ex ante approach, subsequent take-up rates are typically faster than those observed in the UK, which has no ex ante controls. This may be related to the fact that clinicians feel more confident about prescribing new drugs if an independent body has examined the drug and formally accepted it on the reimbursement lists.4 Second, we observed shorter delays in cases where governments rely (in addition to ex ante analysis) on ex post pricing and reimbursement reviews (see below). This may be due to the fact that reviewers are aware that they can correct any inaccuracies and take new evidence into account during the later review and so don’t tend to feel that they are making a ‘once and for all’ decision.

1.17 There appears to be a wide ranging misunderstanding of pricing and reimbursement policies in the US. Several discussants appeared to suggest that access to the market in the US was ‘free’ in the sense of there being no requirement to agree a price before a product can be reimbursed. However, our study suggests that reimbursement of new drugs in the US does not happen automatically (as it does in the UK and Germany), but will be subject to negotiations with several intermediaries (PBMs) representing private insurance organisations. Thus, in contrast to common belief, there is also an element of delay for reimbursement of new drugs in the US, although this will vary by plan and delays are in general brief by international standards.

**Pricing relative to a therapeutic substitute**

1.18 The majority of countries take some account of relative therapeutic benefits when setting the public reimbursement prices of branded prescription medicines. The approaches taken vary widely in terms of methodology and aims, however. There are three main approaches: cost effectiveness pricing, therapeutic tendering and reference pricing.

1.19 Setting (maximum) prices on the basis of an assessment of cost effectiveness is an approach used by a variety of countries. Australia pioneered this approach but it has since been used by several countries including Sweden. Cost effectiveness assessments are also a key part in the reimbursement recommendations made by the Common Drugs Review in Canada.

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4 This factor may be especially important when clinical effectiveness is reviewed ex ante.
1.20 Many countries, including some of those we studied – notably Germany - use internal reference pricing to relate the price of a drug to similar drugs that exist on their formularies. This is generally done by introducing a flat reimbursement price for a group of 'similar' drugs. The concept of similar products may be interpreted in different ways depending on the preferences of the country concerned. Many of these policies are under attack from companies because they consider that they do not recognise the marginal benefits that certain drugs may have compared to others. Our view, as discussed in Annexe L, is that where incremental benefits can be demonstrated, these should be reflected in prices.

**Price volume agreements (PVAs) and rebates**

1.21 Price volume agreements are a common measure to limit drug pricing before a drug is launched on the market; they are used for example in both Australia and France. PVAs typically fix a price for an initial volume of sales of a drug and provide a reduced price for any additional volumes sold.

1.22 Rebate policies are used in several countries we studied. Germany, France, Australia and Spain all have regimes where rebates are agreed ex ante and are paid ex post. Rebates that have come to our attention vary between 3 to 16 per cent of the retail price. The US also has an extensive system of rebates. Transactions prices are typically the result of a complex system of rebates and discounts between multiple payers, manufacturers and intermediaries. A forthcoming academic study estimates that rebates in different drug classes may be as high as 13 to 47 per cent of list prices.\(^5\)

1.23 In the main report we have distinguished between approaches under which the price of a product changes after a certain volume is exceeded (which we have called ‘price volume agreements’) and those in which a payment or rebate is made between the payer and the manufacturer. In practice, companies often implement what they call price volume agreements through side payments rather than price changes. There is an important reason for adopting this approach (which for clarity we refer to as a rebate approach here and in the main report), relating to the international ramifications of price decisions, as discussed below.

1.24 For companies, rebates can be beneficial if they help protect global prices of major brands from being eroded by international reference pricing or parallel trade.\(^6\) Rebates can also help mitigate some of the potential disadvantages of parallel trade for low-

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\(^5\) In Annexe F, we note that ex manufacturer prices in the US are often characterised as being far higher than in the rest of the world, and up to twice as high as in the next most expensive countries. Due to the existence of rebates, we have reason to believe that many such price comparisons significantly overestimate the price level in the US.

\(^6\) If other countries reference their prices to, for example, Australian and French prices, companies will be reluctant to lower their prices in these countries so as not to influence prices abroad. Similarly, if parallel trade between two countries is possible, companies will be reluctant to agree to price reductions that will lead to prices in one country being significantly below prices in the other country. Rebates can limit those effects by allowing companies to charge high prices upfront and deliver ex post repayments.
priced countries. Such negative effects may, for example, include supply shortages if drug supplies for a national market are redirected to be sold abroad. As rebates are directly paid to government, companies are able to maintain list prices at levels that make it less attractive to parallel export goods from a market. This can be beneficial for government and manufacturers alike, as governments benefit from lower real prices while at the same time securing supplies, and manufacturers do not lose money to parallel traders.

1.25 For governments, rebates can also be a helpful tool where the value of a drug varies significantly by indication. In such cases, the population for which the drug is particularly cost effective can be estimated and a premium price paid for volumes prescribed up to that level, with prices reflecting differential cost effectiveness applied for subsequent volumes. This will help ensure value for money for the health service and reduce the incentive on companies to market their product intensively so as to expand volumes of sale beyond indications for which it is cost effective. France is an example of a country that has adopted an approach of this kind.

Ex post controls

Systematic cost effectiveness reviews

1.26 An interesting feature of different pricing and reimbursement policies are the systematic cost effectiveness (and formulary) reviews covering the full range of licensed medicines on a market. These reviews can incorporate data generated in clinical practice, in contrast to ex ante reviews, which are based solely on clinical trial data. Sweden’s LFN is carrying out such a process of reviews for all licensed medicines by group, with the objective of completing the reviews of all products by the end of 2009. Another country with a similar policy is Finland, where reviews were carried out over two years, covering a wide (but not complete) range of products on the market.

1.27 The objective of these reviews is to ensure that prices reflect developments in the market, such as new entry of similar drugs or generics in a drug group. We found the Swedish exercise particularly interesting because group reviews concentrated on relative cost effectiveness in drug classes and comprised a complete review of all drugs on the market, taking account of new developments in research or clinical practice. Furthermore the LFN appeared to be a credible institution in the eyes of many stakeholders, including pharmaceutical manufacturers. We consider that these systematic reviews of drugs can help create information on the relative effectiveness of a drug and secure value for money by reviewing prices and clinical value at regular intervals.

Profit controls

1.28 We found that the PPRS is the only example of an operational approach to profit control in the world. While systems in Spain and Australia refer in principle to costs and
profits as factors to be taken into account in deciding pricing and reimbursement, in neither country are these criteria used in practice.

**Price cuts**

1.29 Across the board price cuts are employed in a number of countries, including Finland, France, Spain the UK. We generally found them to be among the least popular measures among companies. This is largely because where they are imposed, they tend to be unpredictable, both in terms of their timing and magnitude and are not obviously related to factors that companies having any control over. Price cuts in the UK have avoided one of these characteristics – namely that their timing has been broadly predictable – but, as noted in Annexe J, when combined with up front freedom of pricing, this has the potential to create additional incentive problems.

1.30 In some countries, price cuts are applied to specific categories of products and at particular times. For example, in Australia, when a drug’s patent expires and the first generic enters, a 12.5 per cent cut is imposed on the originator product and all other products in the same therapeutic group.

1.31 In most countries, some form of price freeze is employed. Canada is a rare example of a country that does not adopt this approach – prices allowed by the PMPRB are uprated annually in line with inflation.7

**International reference pricing (IRP)**

1.32 IRP is generally used on an ex ante basis. Certain countries, such as Canada and Switzerland, also use it on an ongoing basis throughout the lifecycle of a product.

**Co-payments**

1.33 Co-payments (contributions by patients to the price of a drug or to certain drug categories) exist in some form in all of the countries we studied.8 The form they take varies significantly from country to country, however. In terms of their structure, they can take the form of flat rate payments that patients pay per prescription (the UK), a mix of flat and percentage rate co-payments on every drug dispensed (Germany and the US) and payments that are related to the total annual cost of an individual or family’s medicines (Sweden and Switzerland). Co-payments may also vary according to other dimensions as well, such as the type and severity of disease that the drug treats (Finland) or the therapeutic value of the drug compared to available alternatives (the US

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7 Provincial formularies sometimes impose price freezes, however.
8 Several countries also use co-payments for other services such as GP consultations and hospital treatments.
and Germany, for example). The latter category can have a significant effect on competitive pressures, particularly in generics markets, as discussed below.

1.34 In most countries, defined categories of patient are exempt from paying co-payments and drugs dispensed in hospitals do not attract a charge. In the UK, patient contributions are made through the flat rate prescription charge, although about 85 per cent of prescriptions are exempt of this charge. As can be observed from Figure 1.3 below, estimated out of pocket payments for reimbursed pharmaceuticals in other countries we have studied can be up to six times higher than those in the UK. Only the Netherlands has a lower overall level of patient contribution. France and Spain have similar levels of patient contribution to those in the UK.

Figure 1.3: Estimated costs paid by the patient in the total reimbursed pharmacy market value, 2005

![Costs paid by health insurance system and out of pocket payments](image)

Note: Australia June 2004 - June 2005; US data for 2004, out-of-pocket expenditure does not include expenditure on private health insurance (that accounts for 47.6 per cent of prescription drug spending), France: data refers to 2004; Source: EFPIA Annual Report (2005); Rapport d’activité, 2004, comité économie des produits de santé (CEPS) 2005; OFT analysis.

1.35 We found that some countries employ systems of co-payments not simply to ease the funding burden on the public sector but also in an attempt to give patients incentives to make efficient choices between drugs. For example, under a reference pricing system a

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9 In the US, formularies are typically divided into a three tier structure, in which generics attract the lowest levels of co-payment, followed by preferred brands – with whom the PBM has negotiated a favourable price of which have no therapeutic equivalent - and finally non-preferred and off-patent brands.

10 Contribution levels are likely to be underestimated in Australia as that data only relate to drugs the costs of which are partly met through the PBS. Expenditure on drugs the price of which falls below the flat rate patient contribution is therefore not included in this calculation.
patient may be fully reimbursed for a particular drug, but have discretion to choose a higher priced drug (which the reimbursement authority has deemed a close enough substitute) if he or she is willing to pay for it. Examples are Germany and Australia.

1.36 As noted by Danzon (2001),\textsuperscript{11} however, such choices will only be efficient if patients are sufficiently informed about the relative therapeutic benefits of the drugs between which they are asked to choose. In practice, this is more likely to be the case in the choice between an off-patent brand and a bioequivalent generic than between therapeutic substitutes. Variable co-payments can therefore be an important driver of competition in generics markets, as discussed in the section below.

1.37 In principle the facility to allow variable co-payments can bolster the bargaining position of the payer – if the threat of giving an unfavourable reimbursement status is perceived as more credible by the company than that of withdrawing reimbursement altogether. This effect should not be overstated, however. While a useful instrument to the public purchaser, co-payment systems are by no means necessary to implement the different approaches to pricing, including value-based approaches. Sweden is an example of a country that implements value-based pricing, but simply withdraws reimbursement for a product if the manufacturer is not prepared to accept the maximum price set. Moreover, in other countries (such as the Netherlands) patients are highly reluctant to make co-payments and thus the effect of a manufacturer setting the price of a new medicine above reimbursement value is similar to the effect of withdrawing reimbursement (in that very few patients get the benefit of the new medicine).

Generic drug policies

1.38 An important aspect of drug pricing and reimbursement policies is policy on generic drugs. Here, different policies can lead to large disparities in generics use and pricing between different countries. Generics policies also have a strong influence on the use of branded off-patent products in a market. It is possible to identify two sorts of generics policy: policies to increase the use of generics; and policies and other factors that influence the price of generics.

1.39 In relation to the use of generics, two sorts of mechanism are relevant:

- policies that influence doctors’ prescribing habits, and
- policies that allow – and sometimes require - pharmacists to engage in generic substitution (that is, dispense a generic against a branded prescription).

1.40 In countries where the generics policy is based on monetary incentives to doctors, we sometimes observed ambiguous effects. This may be due to the fact that incentives were not sufficiently strong, or to conflicting incentives.

In relation to generics prices, in most countries where pharmacies are privately owned they have strong incentives to negotiate competitive purchase prices for generics. Whether these are translated into reimbursement prices, however, depends on the particular policy regime adopted by the country. A variety of policies and factors can help to bring competitive pressures to bear on reimbursement prices for generics:

- centralised tendering for generics (typically only possible with a monopoly public purchaser as is the case in Sweden)
- decentralised purchasing with auditing arrangements allowing for average purchase prices to be reflected in reimbursement costs, preserving pharmacy incentives to purchase efficiently (as in the UK’s Scheme M), and
- monetary incentives for patients through co-payment systems as described above, combined with the ability of pharmacies to engage in generic substitution (such that patients have both the incentive and the ability to choose the cheapest generic, as in Finland).

All of these approaches require a competitive generics market – that is, actual (or potential) competition between manufacturers to supply a given drug.

In relation to the first type of measure, in Sweden the national pharmacy monopoly achieves very competitive generics prices through a monthly auction which tenders the supply of a certain generic to the supplier submitting the lowest price in that month. This creates a strong incentive for generic suppliers to compete on price and as a result Sweden has a highly competitive, low priced market for generic drugs.

Decentralised purchasing combined with average price ‘pass-through’ is an attractive arrangement in principle, retaining incentives for efficient procurement while allowing them to translate into savings for the health service. As discussed in Annexe A, it has been used effectively in the UK. We understand that there are proposals to move towards such an approach in Australia. The success of the approach depends crucially on the robustness of arrangements for auditing pharmacy purchase prices, however.

In countries where incentives are given to patients through significantly lower co-payments for generics than for branded drugs, the use of generics can increase and prices can fall, provided there is genuine competition between generics manufacturers for the products concerned.

The above policy can only work under a generic substitution regime, where pharmacists are able to substitute a generic for a branded product unless the doctor indicates otherwise on the prescription form. This approach seems to be used by several countries including Germany and to a certain extent Finland. Under such an approach generics use can increase significantly. Generic substitution – in some cases implying the obligation rather than the facility of dispensing the cheapest generic drug unless the Doctor specifically excludes this – can also be employed in conjunction with the other measures discussed above, such as centralised tendering (as happens in Sweden).
Other countries have had to use administrative measures in an attempt to secure savings to the healthcare system through generic entry. These include Australia, where price cuts are sometimes imposed on a group of products when the first generic enters the market. Such administrative approaches have generally been less successful in producing sustainable, competitive generics prices. As a result, countries are increasingly looking to move away from such policies.

Figure 1.5 provides an estimate of the share of generics in the pharmaceutical market.

**Figure 1.5: Share (estimate in %) accounted for by generics in pharmaceutical market sales value, 2005**

Pharmaceutical expenditure and sources of funding

2.1 Healthcare in Australia is delivered by a mix of public and, increasingly, private doctors and hospitals. However, all Australian residents are eligible for publicly funded insurance schemes run by the Commonwealth government. These are Medicare Australia (‘Medicare’) for general medical expenses and the Pharmaceutical Benefits Scheme (PBS) for prescription pharmaceuticals dispensed in primary care. Hospital prescriptions are usually charged as part of patients’ total hospital expenses and are covered by either Medicare or private insurance schemes.

2.2 The PBS has operated for over 50 years and is funded by general taxation. The scheme directly reimburses mainly prescriptions written in primary care but does also control

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12 State and Territory governments manage healthcare delivery, with different arrangements across the country. Most GPs are private but there is a more even mix between public and private provision in hospital services. The Commonwealth government directly operates and funds national subsidy schemes such as Medicare and the PBS.

13 Private insurance for general (non-pharmaceutical) healthcare expenditure is increasingly prevalent, and encouraged by the government through various tax incentives.
the supply and cost of many hospital drugs that are reimbursed by other public sources such as Medicare.

2.3 Around 80 per cent of all prescription medicines available in Australia are publicly reimbursed and most of those are listed on the PBS. Medicines listed on the PBS have to be accepted onto the scheme’s positive list, the Schedule of Pharmaceutical Benefits. Patients are not reimbursed for the full cost of listed drugs. Rather, they are liable for two forms of co-payments:

- a flat-rate Patient Contribution on all prescriptions, and
- premiums for numerous drugs that the PBS does not fully cover above the standard contribution (‘Brand Premiums’ and ‘Therapeutic Group Premiums’).

2.4 The Patient Contribution was AU$29.50 (approximately £11.6515) as of mid-2006 or AU$4.70 (£1.85) for concessional beneficiaries (children, the elderly, the unemployed and several other groups). There are also safety nets, whereby if a patient’s annual expenditure on the contributions reaches a threshold the rate drops to the concessional rate for general patients and zero for concession-holders. The Contributions and safety nets are indexed annually in line with the consumer price index. About 80 per cent of patient contributions (by value) are paid by concessional patients.

2.5 Product premiums vary in size, though most are AU$3.00 (£1.18) or less. A premium may be granted for a drug when the manufacturer and the Minister for Health and Ageing (in practice usually, but not always, PBS officials) cannot agree on the subsidised price – and only when at least one therapeutically equivalent alternative is available with no premium. The majority of such arrangements are Brand Premiums charged for off-patent branded drugs (about 350 products) where at least one generic is available without the premium. Therapeutic Group Premiums are payable on some chemicals within four major therapeutic classes (where a PBS committee deems all chemicals to be highly interchangeable at the patient level) and only where another chemical in the class is available at no extra cost to patients. Neither Therapeutic Group Premiums nor Brand Premiums count towards the patient safety net.

2.6 Some details of Government reimbursements paid for drugs listed on the PBS during the year to June 2005 are shown below. The figures include medicines dispensed by community pharmacies in primary care but not PBS-listed items prescribed in hospitals and covered by Medicare or other sources. The table also details the share of the primary care drugs bill borne by patients in the form of flat-rate Patient Contributions.

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14 Some public medicines are supplied outside the usual PBS/Medicare arrangements. There are special programmes for orphan drugs, mass immunisation vaccines, unapproved drugs (for experimental use in consenting patients) and a few other areas.

15 All subsequent currency exchanges to British Pounds were based on exchange rates from 31 January 2007 (1 AU$ = 0.394338 GBP). The numbers thus only give a rounded indication of values in pounds and were not period or purchasing power parity adjusted.

16 A few, however, are much larger. Pemetrexed (for lung cancer) carries a patient premium of around AU$400. However, the subsidised cost of the chemical is also high at around AU$3000.
Table 2.1: Government reimbursements paid for drugs June 2004-2005

<table>
<thead>
<tr>
<th>Category</th>
<th>Year to June 2005</th>
<th>Year to June 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Govt Cost AU$ millions</td>
<td>Pat Contribs AU$ millions</td>
</tr>
<tr>
<td>Concessions non Safety</td>
<td>3,077</td>
<td>444</td>
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<tr>
<td>Concessions Safety Net</td>
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</tr>
<tr>
<td>General non Safety Net</td>
<td>851</td>
<td>573</td>
</tr>
<tr>
<td>General safety Net</td>
<td>223</td>
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</tr>
<tr>
<td>Emergency supplies</td>
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<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5,305</strong></td>
<td><strong>1,041</strong></td>
</tr>
</tbody>
</table>

Note: excludes payments for war veterans\(^{17}\) of AU$466 million (circa £184 million) in the year to June 2005. 1 AU$ = 0.394338 GBP

Source: Department of Health and Ageing presentation to OFT.

2.7 In the year to June 2005 the Australian government spent AU$5.3 billion (circa £2.1 billion) on PBS reimbursements, with patients contributing another AU$1 billion (circa £395 million) in flat-rate co-payments. Government expenditure was up 6.1 per cent on the same period the year before.

Pharmaceutical supply chain

2.8 The pharmaceutical supply chain in Australia is similar to that in many other countries. In primary care, medicines are prescribed by GPs and dispensed by community pharmacies. Pharmacies provide medicines to patients at the flat-rate Patient Contribution with product premiums remitted directly to the manufacturer concerned. Pharmacies subsequently claim reimbursement from Medicare, which administers the day-to-day operations of the PBS. This gives patients and healthcare providers a single point of contact with the health service.

2.9 Margins for pharmacies and wholesalers are regulated. By convention, most drugs are listed on the PBS at pharmacy-purchase level. In such cases, the manufacturer receives around 90 per cent of the PBS reimbursement price (before any product premiums). Wholesalers receive around ten per cent of the PBS reimbursement price. Pharmacists are paid mark-ups proportional to drug purchase prices to retain as margin. Pharmacists also receive dispensing fees, plus miscellaneous allowances where applicable.

2.10 Not all items on the Schedule are listed at the pharmacy-purchase level. Exceptions include ‘Section 100’ items with special distribution arrangements (such as highly specialised drugs) which are priced at the ex manufacturer level. Prices are set at these levels for convenience (because, for example, pharmacies may not be involved in the distribution of Section 100 items).

\(^{17}\) War veterans are covered separately from the rest of the population by the 'Repatriation PBS' (RPBS) which levies no patient co-payments.
2.11 In secondary care, hospitals procure medicines from manufacturers and wholesalers on commercial terms and typically do not charge patients for them directly (instead consolidating charges into total hospital bills). Some hospitals are permitted to write PBS-reimbursed prescriptions.18

Institutions

2.12 The PBS is administered by the Australian Government Department of Health and Ageing. Prior to gaining listing on the PBS, a drug must first be assessed for its safety, efficacy and quality by the licensing authority, the Therapeutic Goods Administration (TGA).

2.13 If the TGA recommends that a drug should be available for sale in Australia, the manufacturer (or any other sponsor) can apply for a listing on the PBS. Listings are considered by two committees of the PBS: the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA). The Minister for Health and Ageing formally approves listings.

2.14 The PBAC assesses the evidence on a candidate drug’s clinical efficacy and likely cost effectiveness before advising the Minister if the drug should be listed on the PBS. The recommendation of the PBAC is then considered by the PBPA, which negotiates the PBS reimbursement price with the sponsor.

2.15 For drugs that are expected to cost the public purse more than AU$10 million (£ 3.95 million) net per annum, the final terms of pricing must be agreed by the Cabinet.

Ex ante pricing and reimbursement controls

2.16 PBS prices are set ex ante with reference to therapeutic value but are subject to frequent ex post reviews. Reviews (considered in detail below) focus on how clinical practice suggests that the true efficacy of drugs may be different from that implied by clinical trials data used to inform pricing at launch.

2.17 Sponsors seeking an initial listing on the PBS for a new chemical entity19 can decide on which of two bases to submit drugs to the PBAC. Sponsors can request:

- a ‘cost-minimisation’ listing (usually appropriate for drugs having reasonably close therapeutic substitutes) leading to the PBPA setting the reimbursement price by therapeutic group referencing, based on the PBAC’s assessment of the equivalent doses of similar chemicals

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18This policy was introduced in recent years to address ‘cost-shifting’ by hospitals, which are under growing financial pressures. Some hospitals had stopped prescribing for many cases (for example, patients near to discharge), passing the financial burden to primary care and the PBS. Reforms allow hospital doctors to write PBS prescriptions for many outpatients and discharged inpatients. The aim was that hospitals would use this facility responsibly and perhaps reduce waste by prescribing more accurately than GPs taking over cases with less background on their individual circumstances.

19The pricing of generics is explained in the section on ex post measures, below.
• a ‘cost effectiveness’ listing (usually appropriate for innovative drugs or products with clear advantages over similar chemicals) that, only if agreed by the PBAC, leads to the PBPA negotiating a price based on the PBAC’s assessment of incremental therapeutic benefits.

2.18 A sponsor pursuing a listing for a new chemical entity can do so on a cost effectiveness basis (CE basis, OFT abbreviation) for some indications and a cost-minimisation (C-Min) basis for others. When submissions on both C-Min and CE bases are successful at PBAC, the PBPA negotiates a composite price, taking the results of both assessments into account.

2.19 Over 80 per cent of requests for listing on a C-Min basis succeed, whereas only around 20 per cent of CE requests are passed on that basis. Drugs that fail to access the Schedule on a CE basis are often offered C-Min listings.20 Conversely, manufacturers offered only C-Min listings having submitted a dossier of clinical and economic evidence can justify inclusion on a CE basis if they revert to the PBAC with evidence of clinical superiority over apparently similar products. However, once minded that a C-Min listing is appropriate, the PBAC often holds firm and the exchanges required for drugs eventually to be listed have taken several years when manufacturers have disagreed with a PBAC view.

2.20 For drugs listed on a C-Min basis, therapeutic group referencing takes place within therapeutic groups approximating to ATC2 or ATC3 classifications used in many other jurisdictions.21 The lowest priced brand or chemical sets the benchmark price for the other brands of the same chemical, or the other chemicals, in the same group. Prices are set to be equal at equivalent doses. Examples of groups priced in this way include the calcium channel blockers and the ACE inhibitors (but, for example, combination products containing an ACE inhibitor and a diuretic are in a separate group).

2.21 The individual therapeutic groups used in C-Min pricing do not define the limits of the approach. When the PBAC considers that drugs in different groups have common indications, it may recommend linking their prices (through so called ‘therapeutic relativities’). Conversely, C-Min groups and therapeutic relativities do not dictate the price of all products falling within them. Drugs with CE listings are classified in C-Min groups – despite not being subject to reference pricing – so that the system can accommodate changes in the basis of listings.

2.22 Drugs only achieve CE listings successfully if they are innovative or have clear clinical advantages over similar medicines. To grant a CE listing for a drug, the PBAC often requires evidence from a head-to-head clinical trial against a next-best therapeutic alternative (except for breakthrough technologies lacking even distant equivalents).

20 Note that drugs listed on a C-Min basis are not necessarily cheap. Listing on a C-Min basis can occur simply because therapeutic alternatives are available, but all alternatives may be high-cost.
21 For a description of the Anatomical Therapeutic Chemical (ATC) please refer to the classification of the World Health Organisation. In the UK, BNF Paragraphs, which usually contain broadly substitutable drugs, approximate to ATC3. See Annexe A for further details.
2.23 If the PBAC grants a CE listing, the PBPA sets a price it deems appropriate. There is no public cost effectiveness threshold beyond which medicines will not be accepted, but there may be an implicit one of about AUS$90,000/QALY\(^{22}\) (£35,541). In setting a CE price, officials take account of various factors, including usually clinical efficacy, prices of the drug in other countries and, sometimes, social equity (so a high price may be granted to a drug expected to be needed in small total quantities against a rare condition). The PBPA does not in general consider costs of product development (R&D), though it may put some weight on production costs, for example when products are difficult to manufacture.

2.24 Both C-Min and CE prices are public reimbursement prices. However, as mentioned above, manufacturers may be able to negotiate a patient-payable premium for a drug where they wish to charge more than the government will subsidise. A Brand Premium can be applied to any product in any class (that is, an originator or branded generic) provided a bioequivalent generic is available to patients in the same form and strength at the benchmark price. Therapeutic Group Premiums can only be set if another chemical in the same therapeutic class is available in the same presentation at the benchmark price. Both Brand Premiums and Therapeutic Group Premiums can be set at any level that manufacturers think the market will bear.

2.25 As mentioned above, any listing on any terms for which total PBS reimbursements are expected to exceed AU$10 million (£3.95 million) net per annum must be approved by the Cabinet. Increasingly in such cases, the PBPA is asked to structure risk sharing agreements to contain aggregate costs. Currently 33 such mechanisms are in place, mainly price-volume agreements under which sponsors covenant to reduce prices (or pay rebates) on sales exceeding a specified volume threshold.

**Ex post pricing and reimbursement controls**

2.26 Risk sharing agreements are an increasingly important element in pricing. As well as standard price-volume mechanisms, a number of other risk sharing schemes have been put in place to contain costs:

- schemes establishing an annual cap (on expenditure or script volumes) for an individual drug, under which manufacturers rebate to government a proportion of excess over the cap
- schemes establishing a common annual sales cap for all drugs used to treat a particular condition, with excesses repaid by sponsors according to the market share of each.

2.27 The PBPA also reviews the prices of every product listed on the PBS at least once each year, in time for the publication of the latest Schedule of Pharmaceutical Benefits. All the elements of the ex ante pricing process can be reviewed, typically in the light of new clinical evidence brought to the attention of the PBAC.

\(^{22}\) Quality Adjusted Life Years
2.28 For C-Min listings, new information most commonly leads to therapeutic relativities between products being altered. When a product is found to be more or less effective against the benchmark than previously assumed, the PBAC revises the dose at which it is considered equivalent and the PBPA resets the prices of each dose to be equal to the benchmark (cheapest product). When any manufacturer requests a price cut during the year the affected drug becomes the benchmark in its group – by dint of becoming the cheapest. The prices of CE listings can also be revised if new information suggests that the drug’s efficacy, range of uses, convenience or any other distinguishing properties versus a next-best comparator have changed from previous assumptions.

2.29 Product premiums can also be adjusted every time the Schedule is re-released. Manufacturers simply notify the PBPA of their intention to change or introduce one.

2.30 Two other important ex post controls that have no direct corollaries at the ex ante pricing stage for new chemical entities are the treatment of generics and the Weighted Average Monthly Treatment Cost (WAMTC) review process for certain C-Min groups.

2.31 Generics (always marketed under brand names in Australia) are automatically listed on a C-Min basis. When a chemical’s patent expires and the first generic version appears, the prices of the originator and all other products in the same therapeutic group are automatically reduced by 12.5 per cent. This generally does not apply to CE listings. Generics are initially priced at parity to their group’s benchmark and are subsequently treated like any other product.

2.32 The WAMTC methodology is applied to seven of the therapeutic groups in which drugs are listed on a C-Min basis. Four of these are the Therapeutic Group Premium groups. The other three also contain products that are thought to be closely alike in action and effects – and the PBAC has not ruled out making them Therapeutic Group Premium groups in the future.

2.33 Each group is a major expenditure area. Because of this, the government is concerned that therapeutic reference pricing should reflect as accurately as possible the average doses at which drugs are actually prescribed, as opposed to the doses evaluated by clinical studies under controlled conditions. This is important because the C-Min procedure sets a drug’s price to be equal to its benchmark at equivalent doses (so that if 10mg of the drug is deemed equivalent to 20mg of its benchmark, 20mg of the drug will receive twice the 20mg price of the benchmark). Hence the outturn cost of two drugs priced identically at theoretically equivalent doses can be substantially different – even when the same number of packs is prescribed – if different doses are used in practice. In particular, if a drug turns out to be effective only at higher doses than had

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23The groups are: Angiotensin converting enzyme (ACE) inhibitors; Angiotensin II receptor antagonists; Calcium channel blockers; H2-receptor antagonists; Proton pump inhibitors; Selective serotonin reuptake inhibitors (SSRIs); Statins (simvastatin and pravastatin only), (the price of atorvastatin is linked to the price of simvastatin, at a constant 14 per cent premium).

24For most drugs, both price setting and ex post reviews are mainly informed by formal clinical studies. The WAMTC process, which rigorously assesses how clinical practice changes the picture given by trials, is a major exercise that would not be feasible for all drugs.
been implied by clinical trials, it could prove more expensive than predicted, potentially much more so in these seven heavily prescribed classes. In such a case the C-Min procedure would have failed in practice.

2.34 The WAMTC process seeks to address this issue by using clinical data\(^2\) to audit the prescribing of drugs in each group. Every year:

- the cost of an average month’s treatment with each drug is estimated by a statistical approach (assuming that some observed low- and high-dose prescribing is unusual and unlikely to persist)
- the cheapest drug in each group is set as the benchmark and price adjustments are negotiated on all other products, affecting various forms and strengths so that the expected average monthly treatment cost for all drugs in each group – as they are used in practice – is the same.

2.35 In each group, all products except the benchmark may then apply Brand Premiums and Therapeutic Group Premiums as appropriate and if manufacturers so desire. As with the standard C-Min procedure, drugs that have been granted CE listings are exempt from WAMTC reviews.

**Volume controls**

2.36 The PBS also implements some demand side controls. Many items listed on the Schedule of Pharmaceutical Benefits (nearly 30 per cent) are ‘restricted benefits’ which doctors must obtain authority to prescribe from Medicare. Furthermore, all items are listed on the Schedule with a maximum prescribable quantity (for a single script). Authority can be obtained to exceed the maximum in most but not all cases.

2.37 As PBS expenditures have grown in recent years, the government is gradually placing more emphasis on incentives and advice for patients and prescribers. National programmes promoting the ‘quality use’ of medicines to doctors, and offering education on new products, were developed in 2002 by the government working with representative bodies for GPs and pharmacists. Furthermore, in 2003 decisions of the PBAC to accept or reject PBS listings for medicines were made public for the first time in a bid to communicate the issues involved to the general public. Also, the reimbursed price of PBS medicines has appeared on labels when the full cost exceeds the Patient Contribution.

2.38 As mentioned earlier, co-payments (flat rate contributions and payable premiums whenever a drug exceeds agreed government funding) are used to make patients more cost-aware and to reduce spending. The flat-rate contributions themselves were increased (by over 20 per cent) to current levels in 2004.

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\(2\)There are various eligible sources of data, which sponsors are permitted to choose between. Sponsors may also submit their own evidence on how and why drugs are used in certain ways, for example to contend that high-dose prescribing reflects not a less effective product but rather clinicians’ preferences for using it in difficult cases such as drug-resistant patients.
Generics prescribing and penetration

2.39 As mentioned above, there are no ‘true’ generics in Australia: all bioequivalent versions of a chemical are marketed under different brand names. Doctors tend to prescribe by brand name, though pharmacists have substitution rights (with patient agreement and provided a doctor has not explicitly vetoed substitution).

2.40 Following the application of the 12.5 per cent price cut to all drugs in a therapeutic reference group when the first generic is listed, generics are treated identically to originator products. That is, generics remain within the reference group and any one can become the benchmark product if its manufacturer requests a price cut.

Industry views

2.41 Manufacturers inevitably had a range of views on PBS reflecting their different experiences of the system. Some manufacturers believe that the PBS prices branded drugs too aggressively while being too generous to generics. There are specific features of the regime that are felt to lead to this outcome, these are:

- the principle of therapeutic group reference pricing, including both brands and generics
- the 12.5 per cent therapeutic-group price cuts following genericisation of one product in the group, which cascade via therapeutic relativities to drugs in separate categories with common uses. Hence even new PBS listings can be marked down within a few months of appearing on the Schedule
- the stance of the PBAC and PBPA, which some companies see as being unduly sceptical of their products. Some claimed that the PBAC can be dismissive of therapeutic value that is difficult to quantify, such as benefits in subgroups (for example children) or conditions that have to be assessed subjectively (such as depression, Alzheimer’s, etc). These companies would prefer a fuller ex post assessment of such areas (above reconsideration of equivalent doses), to allow time for clinical data to give a fuller picture than is afforded by clinical trials, and
- the WAMTC methodology. Some companies feel that the focus on how medicines are dosed in practice compared to during clinical trials unfairly assumes that real clinical usage achieves the same outcomes as are seen in controlled conditions. In the view of one company, if a drug proves more effective than expected in the general population this is ignored in the subsequent price re-setting process. The company said that the data used for WAMTC reviews typically does not detail indications, which could lead to unexpected benefits of drugs being missed.

2.42 Companies have mixed views about the risk sharing (for example, price-volume) schemes. Some see such mechanisms as 'punishing success' insofar as the process assumes that the usefulness of a drug can be accurately inferred from its scale of use. Other manufacturers believe that risk sharing schemes can help protect global prices of major brands from being eroded by international reference pricing when other countries
monitor the Australian market. They reason that the schemes permit higher prices for a
given budgetary objective than would be acceptable to the government under uncapped
expenditure arrangements.

2.43 Perceiving the PBS as a rigorous regime by international standards, some companies
have asserted that it is ‘hard to do business’ in Australia, specifically that the scheme
makes an insufficient contribution to the global costs of R&D. The government has
implemented various explicit industrial policy measures to support innovation directly
rather than through the pricing system.26 Companies seem mostly positive about these,
albeit with reservations.

Key issues

Overview

2.44 Australia provides the longest standing experience of the use of cost effectiveness
assessment to inform pharmaceutical pricing decisions. The PBS is generally considered
to be a robust system that provides a sustainable mechanism for pricing both
breakthrough drugs and drugs for which close substitutes are available.

2.45 There is some suggestion that the efficiency of price signals can be improved through
such an approach. For example, while companies have suggested to us that for many
drugs, prices can be relatively low in Australia, there is some evidence to suggest that
for genuinely innovative drugs, relatively high prices may be possible.27

2.46 The PBS has also evolved mechanisms in a pragmatic way to deal with potential
problems – such as the use of price volume agreements to encourage drugs to be
prescribed in indications for which they are cost effective. An aspect of drug pricing
policy that has proved problematic, however – and is motivating reforms of the system
– is policy with respect to generics pricing. This is discussed further at the end of this
section.

AUSFTA

2.47 In part due to the application of therapeutic group reference pricing, the prices of
branded medicines listed on the PBS are low by international standards. But by some
opinions the Australian approach to drug pricing – and the competitive value for money

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26 The ‘Factor F’ programme in the 1980s was a series of tax breaks and other investment incentives aimed
specifically at research-intensive pharmaceutical manufacturers. Commentators agree that the
programme was generous and some claim that it discouraged manufacturers from withdrawing
investments from Australia when they would otherwise have done so. During the 1990s Factor F was
succeeded by the Pharmaceutical Industry Investment Programme, a similar but smaller package. The
latest initiative, P3, is not targeted specifically at the pharmaceutical industry – but also includes
biologics and other sectors.

The many methodological problems with conducting price comparisons are discussed in Annexe F.
it secures – has come under pressure from the 'Australia-United States Free Trade Agreement' (AUSFTA) that entered into force in January 2005.

2.48 In the agreement Australia undertakes to recognise the value of pharmaceuticals and importance of R&D. The exact meaning of these undertakings has been debated but some commentators suspect that the agreement was sought by the US to push for higher prices for branded products in Australia and tacitly refers to the stance of the PBAC and PBPA. However, the PBS is nowhere mentioned by name in AUSFTA and the agreement is broadly drafted and open to interpretation. The Australian government considers that AUSFTA is mainly relevant to procedural issues – to which it has recently made changes, increasing the openness of the PBAC and PBPA and creating new appeals procedures for negative decisions.

**Future reforms**

2.49 Within Australia, the industry is pursuing two high-level reforms to the PBS. Medicines Australia has campaigned for generics to be treated differently from brands in the pricing process. Many branded manufacturers maintain that allowing generics prices to be lower than the prices of equivalent brands could generate substantial savings that the government could channel towards future R&D.

2.50 The industry is also campaigning for changes to the way that the PBAC and PBPA evaluate cost effectiveness when deciding whether and how to list new products on the PBS. At present, evaluations do not take account of the indirect costs of illness that drugs may avert, such as lost productivity. But Medicines Australia has been asking for these to be routinely considered as benefits against which to weigh costs – and potentially to justify higher prices.

2.51 The Australian government will introduce some incremental changes to PBS from mid 2007, mainly to the pricing of drugs in therapeutic reference groups that contain generics.\(^{28}\) As far as we understand, the changes are aimed at securing more competitive reimbursement prices for generics in Australia (as Australia lacks a well developed generics market).

2.52 As part of these changes a system of 'price disclosure' will be introduced to control government costs more closely, particularly in relation to off-patent drugs. Although pharmacy margins are regulated in Australia, some suppliers offer pharmacies lower prices than are provided for in the regulations – effectively, extra margin – to encourage dispensing of certain products (since pharmacists have generic substitution rights). The government wishes to clawback these dispensing profits by reducing reimbursement prices. Accordingly, as a condition of listing on the PBS, suppliers will be required to disclose pharmacy sales prices from 2009 for brands where competition

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\(^{28}\) www.health.gov.au/
is judged to be low and from 2012 for brands (in Formulary 2 as discussed below) where competition is judged to be high.29

2.53 From 1 August 2007 onwards, PBS listed medicines will be listed on two separate formularies, with no ongoing price links (reference pricing) across (but only within) the formularies. We understand that Formulary 1 will comprise mainly on-patent branded medicines and Formulary 2 will mainly comprise branded medicines where generics are available as well as medicines with different active substances that are judged interchangeable. Formulary lists were not available to, but we understand that the new system will, for example, de-link the price of some of the statins but not the Proton Pump Inhibitors. We have not had access to analysis underlying these changes.

2.54 Furthermore, additional to the price cut by 12.5 per cent when the first generic appears in a group, from August 2008 onwards further price reductions will be required for all drugs in Formulary 2:

- a reduction of two per cent per year for three years for products where price competition is judged to be low (small rebates to pharmacies), and
- a one-off reduction of 25 per cent (on 1 August 2008) for products where price competition is judged to be high (rebates of 25 per cent and more to pharmacies).

2.55 Another change of note is the removal of restricted-benefit status for around 200 drugs in the Schedule of Pharmaceutical Benefits, meaning that doctors will no longer be required to telephone Medicare for authorisation to prescribe those items.

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29 In principle, this could allow introduction of a system with similar characteristics to those of Scheme M in the UK (see Annexe A).
Sources of health care funding

3.1 Instead of having a single federal plan, the Canadian health care system is based on a ‘national program that is composed of 13 interlocking provincial and territorial health insurance plans’. The 13 jurisdictions (10 provinces, 3 territories) are supported by Health Transfers from the Federal Government to provide ‘medically necessary services’, which comprises free hospital and primary care. The provinces are not, however, required to fund pharmaceuticals outside hospitals. The exact responsibilities of the provinces in health care service provision are regulated by the Canada Health Act.

3.2 At the national level, the Canadian Agency for Drugs and Technologies in Health (CADTH) provides Canada’s federal, provincial and territorial governments with evidence-based information about the effectiveness and cost-effectiveness of drugs and other health technologies. The Patented Medicines Price Review Board (PMPRB) has a dual role of regulating the maximum prices for patented drugs in Canada (to ensure they are not excessive), and reporting on pharmaceutical trends and R&D

30 www.hc-sc.gc.ca/hcs-sss/medi-assur/index_e.html
spending to help inform decisions by policymakers. It also carries out annual drug price reviews. Decisions relating to drug plan design (such as coverage criteria) are made by each jurisdiction. Each jurisdiction is also currently responsible for maintaining its own public formulary. Therefore, although there is a common basic standard of coverage for healthcare in Canada, the drugs reimbursed in each province may be subject to jurisdictional variation.

3.3 The Federal Government offers pharmaceutical coverage for people in the Armed Forces, the Royal Canadian Mounted Police, First Nations and Inuit peoples, veterans, federal inmates and refugee claimants. Each province and territory has established drug programmes which typically provide pharmaceuticals for senior citizens (those over 65), persons receiving social assistance and, in some provinces, people with high drug expenditure relative to their incomes. Only the province of Saskatchewan has a system of universal coverage for pharmaceuticals for its population.

3.4 Private drug insurance plans also play a significant role in Canada. About 1,000 private plans provide coverage for two-thirds of the Canadian population – the majority of these being financed via employer-sponsored programmes. The level of private insurance coverage varies across provinces, together with employment conditions. According to Luffman (2005), high wage and unionised workers are more likely to have access to employer-sponsored private insurance.

3.5 According to estimates for 2000, 98 per cent of the Canadian population has some form of public or private sector drug plan coverage. The two per cent of the population without drug insurance is concentrated in particular geographical areas, particularly in the Atlantic provinces. It is estimated that in 2000, one in four residents of the four Atlantic provinces had no public or private pharmaceutical coverage. Moreover, coverage for the great majority of Canadians (89 per cent) provides an overall protective cap on out-of-pocket costs, regardless of the severity of the drug expense.

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31 As an example, the Ontario drug program covers only very limited sub-sections of the population: senior citizens (65 and over); those on social assistance; residents of nursing homes and long-term care facilities; and those whose drug expenditure exceeds three to four per cent of their annual income (under the Trillium Drug Program). Coverage is also provided for certain disease categories (for example, Cancer care). In total, about 22 per cent of Ontario’s population receive drug benefits via the public system. With that said, public drug expenditure in Ontario accounts for about 45 per cent of the province’s total prescription drug expenditures. Private insurance (mainly through employers) covers the majority of the population, accounting for about 36 per cent of prescription drug costs. The remaining 20 per cent of expenditure is private out-of-pocket expenditures (typically in the form of co-payments and deductibles).


33 Fraser Group/Tristat Resources (2002), Drug expense coverage in the Canadian population: protection from severe drug expenses.

34 Newfoundland, Nova Scotia, New Brunswick and Prince Edward Island.
In 2005, public funds accounted for 46 per cent ($9.5 billion / £4.1 billion) of total prescription drug expenditure in Canada, 34 per cent ($7.1 billion / £3.07 billion) was paid by private insurance and 20 per cent ($4.0 billion / £1.73 billion) from out-of-pocket payments. OTC drugs constitute about 10 per cent ($2.2 billion / £0.95 billion) of total pharmaceutical expenditures.

Pharmaceutical supply chain

In 2005, 58 per cent of pharmaceutical sales by manufacturers were made to distributors and wholesalers, 30 per cent to self-distributing retail chains, and 12 per cent directly to retail pharmacies and hospitals. Canada has a large generic industry, which accounted for 44 per cent of all prescriptions filled in Canada and 17.7 per cent of total prescription drug expenditure in 2006.

There are differences in drug licences between the US and Canada, however, cross-border trade in pharmaceuticals between the US and Canada is not formally permitted. Thus, it is possible for US citizens to cross the border to have their prescriptions filled in Canada. In recent years, cross-border trade has been made easier with the existence of internet pharmacies. It is estimated that approximately 14 per cent of internet pharmacy sales are generic forms of drugs where the patent has expired in Canada, but not in the US.

Recently, growth in parallel trade has been limited by manufacturer imposed supply restrictions on participating pharmacies, disciplinary actions by Canadian professional medical and pharmacy associations to curb prescription 'co-signing' practices, and the introduction of US Medicare in 2006. In 2006, the total value of the Canada-US cross-border drug trade is estimated to have declined by 30 per cent – 50 per cent from its peak of between $CAN 1.0 – $ CAN 1.5 billion (£0.43 - £0.65 billion) in 2004.

Institutions

The CADTH is an independent non-governmental body that assesses health technology and publishes reports for the technical use of medical devices and drugs. The board of

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35 Currency exchanges to British Pounds were based on exchange rates from 31 January 2007 (1 CAN $ = 0.432296 GBP). The numbers thus only give an indication of values in pounds and were not period or purchasing power parity adjusted.
40 Filling prescriptions across the border is not formally prohibited – rather, certain conditions need to be satisfied before it can be permitted (for example, an American is able to fill a prescription in Canada so long as it is written by a Canadian physician. Also, a number of US states will accept a prescription written by a Canadian physician). These provisions exist primarily to accommodate potential health needs of foreign visitors.
41 See Brett Skinner, Price Controls, Patents and Cross-Border Internet Pharmacies. www.fraserinstitute.ca/admin/books/files/PriceControls&XborderPharmacies1.pdf
directors of the CADTH is appointed by the deputy health ministers of the provinces, territories and federal government.

3.11 The Common Drug Review (CDR) is part of the CADTH. It is funded, supported and led by the federal and provincial jurisdictions (except Quebec). 30 per cent of the funding for CDR comes from Health Canada and 70 per cent from the provincial drug plans. Since 2003 the CDR has reviewed the clinical effectiveness of drugs and gives recommendations to the provinces and federal plans on whether a new drug should be reimbursed. However, these recommendations are not binding for the drug plans. The CDR currently only reviews out-of-hospital drugs. In the future, the CDR also plans to review other drugs, such as oncology, and undertake some drug class reviews.42

3.12 The PMPRB is an arm’s length, quasi-judicial tribunal that determines the maximum non-excessive price for patented pharmaceuticals in the Canadian market and carries out semi-annual drug price reviews. The PMPRB starts its work when drugs are already sold on the Canadian market and then determines, following its guidelines (see 3.23), the maximum allowed price for a pharmaceutical. The maximum non-excessive price established by the PMPRB limits the pharmaceutical company’s price setting. The PMPRB Board consists of five members, chosen for their expertise in medicine, economics, law and pharmacy. Decisions of the Board have the status of a federal court decision. PMPRB staff are independent from the Board; they conduct investigations independently and only inform the Board Chair of recommendations to launch a hearing into an excessive drug price. Price reviews take place regularly following special Guidelines established by the Board.

3.13 Health Canada is the governmental body responsible for monitoring pharmaceutical licensing in the Canadian market. It also administers the federal insurance scheme for First Nations and Inuit peoples and plans general Canadian health strategy. Currently it works with provinces and territories (excluding Quebec) on a National Pharmaceuticals Strategy (NPS), designed to improve access, safety, effectiveness and appropriate use of drugs in the health care system.43

Ex ante pricing and reimbursement controls

Reimbursement

3.14 The CDR typically initiates a review based on a submission from a manufacturer, although the public drug plans may also initiate a CDR review.44

3.15 The CDR considers published and unpublished data when reviewing the cost-effectiveness of a drug. It then issues a recommendation for (or against)

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42 CDR underwent a formal review of its procedures last year that generated positive feedback. Future challenges of CADTH/CDR include increased collaboration between provincial drug plans to adopt CDR recommendations and pressure from the federal government to create a single national formulary.

43 Note that health policy planning is mainly under provincial jurisdiction.

44 All 12 provinces/territories (except Quebec) and federal drug plans are participating in the drug plan.
reimbursement, which the participating drug plans may choose to follow. The criteria for CDR reviews are:

- cost effectiveness
- safety (there might be more recent data available than at the time of the license decision), and
- effectiveness

3.16 When available, the CDR uses cost per Quality Adjusted Life Years (QALY) measures to evaluate the cost effectiveness of drugs.45 In general, an economic evaluation is submitted to the CDR by the manufacturer, which the CDR then reviews and critiques. For ‘me-too’ drugs the CDR looks at cost effectiveness relative to comparator drugs (this is referred to as a cost-minimisation review). At present, QALYs are not adjusted for equity concerns, but there are discussions over an orphan drug strategy at the national level. The cost per QALY calculation is a significant criterion in the CDR’s decision to recommend a drug for reimbursement. However, the CDR does not have a fixed cost per QALY threshold that would distinguish a ‘list’ from a ‘do not list’ recommendation.

3.17 During the CDR review, the manufacturer can submit new evidence and ‘stop the clock’ if it wants to prepare a new submission or change its price proposal. After the review, the manufacturer can only submit new clinical evidence, a new price or a new economic model that significantly changes the drug’s cost effectiveness.

3.18 If the CDR issues a negative decision on reimbursement, provinces usually agree with the result and do not include the drug in their formulary. In cases of positive CDR evaluations, each province may carry out their own evaluations (if they wish) and then consider entering price negotiations or refuse reimbursement. In Ontario, for example, the Drug Quality and Therapeutics Committee (DQTC) will evaluate the added value of a drug and issue its own recommendation to the provincial drug plan. Once each province has made a decision, the company is informed as to whether their drug will be reimbursed in that area.

**Pricing**

3.19 The PMPRB is responsible for determining the maximum ‘non-excessive’ price for all patented drugs in the Canadian market. The decision on reimbursement made by the CDR is completely independent from the decision on the maximum price, made by the PMPRB. There is also no fixed sequence between the CDR and the pricing review of the PMPRB; both processes run in parallel, and there is no obligatory information sharing. Both bodies do, however, have discussions, consultations and information sharing.

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45 In all other cases manufactures receive a cost minimisation review that evaluates and compares the cost of a new drug with an alternative existing treatment (generally for non-innovative drugs).
sharing on an informal basis. The 'price' of a drug for the CDR is the market price on review and not the maximum possible price determined by the PMPRB.

3.20 Manufacturers do not have to wait for a decision from the PMPRB before they can sell a product on the market. Free pricing is allowed after a manufacturer receives market authorisation. The pricing review officially starts when a new patented drug is first sold on the market. The PMPRB does not set prices, but reviews them to ensure that they are not excessive. If the PMPRB finds the market price of a product to be excessive, prices need to be adjusted. The company can agree to voluntarily reduce the price and payback excessive revenues, or the Chair of the PMPRB Board may decide to issue a Notice of Hearing to determine whether the price is excessive.

3.21 The Human Drug Advisory Panel (HDAP) of the PMPRB carries out scientific reviews based on the documentation sent by the companies and other available information.

3.22 The first step in the pricing review process requires the Human Drug Advisory Board, which comprises of three experts, to review the clinical evidence of the drug's efficacy and therapeutic improvement. The Panel may also call on clinical experts for advice if necessary. The Panel determines:

- the category of the new drug (see below)
- whether there are any comparable drugs sold in Canada, and
- where there are comparable drugs, what would be the comparable form or strength of comparators relative to the drug being reviewed.

3.23 The analysis which the PMPRB use to establish a maximum price depends on the category in which the drug is classified. The categories are:

- Category 1 (that is, line extension of an existing drug): The maximum price is calculated as based on existing strengths of comparable dosage form
- Category 2 (that is, breakthrough drugs): International reference prices (manufacturer list prices) from seven countries (France, Germany, Italy, Sweden, Switzerland, the UK and the United States) are used to calculate a median price which will be the maximum price in the Canadian market. If data are not available for all of these countries, an interim maximum non-excessive price will be set and this will be reviewed when the drug is sold in at least five countries or within three years, whichever comes first, and

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46 If the hearing finds that prices are indeed excessive re-payments or fines may be imposed. As a quasi-judicial tribunal the PMPRB has the powers to enforce these decisions.

47 A hearing panel will consist of at least two members; PMPRB staff will present the case against the manufacturer. All panel decisions on matters of process can be appealed to Canada’s federal courts. Third parties can be admitted to hearings; for instance Provinces and Territories are statutory parties and have a right to be heard. Since 1987 there have been 35 occasions where the PMPRB found 'excessive' pricing but reached a voluntary agreement with the company, eight hearings that were settled before it came to a panel, and three full hearings.

48 That is, a price that exceeds the maximum allowed reimbursement price. How the maximum reimbursement price is calculated is described below.
• Category 3 (that is, me toos): The highest price among therapeutically comparable drugs is used to set the maximum price. If no comparable products have been identified, international reference pricing (see above) is used to determine the maximum price.\(^{49}\)

3.24 The PMPRB’s main objective is consumer protection from excessive prices. It is important to note that the PMPRB ‘maximum price’ is only a ceiling price for the first sale by a manufacturer to a hospital, wholesaler, pharmacy or other customer; provincial governments can enter into price negotiations for reimbursement and might obtain lower prices. In about one fifth of all cases the PMPRB price ceiling will be the same as the provincial reimbursement price.

3.25 The PMPRB maximum non-excessive price may also differ from prices on the provincial formularies because of formulary price freezes introduced by some jurisdictions. As a result, although the PMPRB Guidelines do allow for annual price increments (limited to annual change in the Consumer Price Index), provinces may not accept such price increases for reimbursement purposes. As a result, manufacturers did not always choose to price as high as the maximum non-excessive price.

**Ex post pricing and reimbursement controls**

3.26 Price reviews of all patented drugs in the market take place on a six months basis. The price review, a purely mathematical exercise, determines whether actual prices in the market are exceeding the maximum non-excessive price determined by the PMPRB.

3.27 To complete the reviews, companies have to submit detailed sales and price data by province and ‘buyer-type’ every six months. Prices are allowed to increase according to the Consumer Price Index (CPI) but are never allowed to exceed the highest price among the seven reference countries. Each year in April, the PMPRB publishes an estimation of the CPI so that companies can calculate themselves how much their prices are allowed to increase without exceeding the maximum price.\(^{50}\) The PMPRB system is semi-automated and would automatically flag up a possible excessive price.

3.28 If the system finds prices to be ‘excessive’, companies have the opportunity to reduce prices and/or to make repayments equal to the excess revenues. In some cases they can also reduce the price of another drug or make a repayment to hospitals that equals the excess revenue. If, after a public hearing by the Board, a company is found to have followed a ‘policy of excessive pricing’ it can be ordered to repay up to double the amount of its excessive pricing.

\(^{49}\) In some hearings a price ‘premium’ has been attributed based on the argument that the drugs had received similar premiums in other countries. However, before this approach is formally applicable new guidelines have to be established by the Board.

\(^{50}\) After each year ‘Category 2’ drugs prices may, as a maximum, be equal to the median price of the reference countries and ‘Category 3’ drugs price may be equal to the highest price in the same therapeutic class, taking into account increases to the CPI. Due to the fact that prices are allowed to increase with the CPI, ‘me-too’ drugs may have higher prices than the international median.
3.29 Other price controls are carried out by provincial governments and include among others price freezes and price cuts: Ontario introduced price freezes from 1994 - 1998 and is contemplating the introduction a drug tendering model as well as reference pricing, British Columbia has introduced reference pricing policies for certain drug classes, and Saskatchewan introduced a 'drug tendering system' where manufacturers are given the opportunity to bid for a time limited period of exclusive supply rights for certain high volume generic drugs (see also Sweden).

Volume controls

3.30 Volume controls are also carried out by provincial governments and include GP monitoring and audit procedures as well as different generic substitution regimes. Every province has its own system and slightly different approach to these volume controls.

Generic pricing and penetration

3.31 Non-patented drug prices, including generics, are not subject to national price controls, such as those of the PMPRB for patented drugs. However, each jurisdiction is free to determine its own reimbursement and utilization policies for non-patented drugs.

3.32 One common problem on the Canadian generic market seems to be the small number of players. The generic market is dominated by Canadian companies that have 'locked in' all bigger retail chains. This deters further market entry. As a consequence of relatively rigid pricing policies for generics and tough competition for shelf-space, Canadian generic prices are relatively high on an international level.

3.33 In Ontario, prior to the introduction of Bill 102, a first generic entrant could only be reimbursed if its entry price is at least 30 per cent lower than the branded equivalent. Subsequent generic entrants reduce this overall generic price ceiling to 90 per cent of the first generics’ price.

3.34 Traditionally, generic manufacturers have competed fiercely for shelf space in pharmacies by offering discounts or added value services to pharmacists (discounts have been estimated at 20 to 40 per cent of retail generic prices). However, these discounts are not passed through to customers in the form of lower prices. A new provincial law contains provisions for a code of conduct for pharmacies that will ban rebates to pharmacies and oblige pharmacies to notify the government of any rebates received.

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51 Which often grants ‘automatic’ reimbursement if a generic enters the market at a certain percentage below the branded price. Later, most jurisdictions have ‘least cost alternative’ policies, which set a reimbursement cap equal to the cost of the lowest cost bioequivalent option (that is, interchangeable products) - these policies then do not discriminate between brand and generic. As an example, the Ontario Government has reduced the generic price ceiling to a flat 50 per cent of the price of the branded drug.
Industry view

3.35 The CDR was introduced in order to achieve more consistency in the provision of drugs and to streamline the drug review process for drug listing decisions. In practice however, companies felt concerned that the CDR delayed access to reimbursement by an additional six months without adding stability to the system. This is because each provincial drug plan may, after a CDR review, undertake a separate provincial review. Companies would favour more stability in the system either through a national formulary (which they consider rather unrealistic), a binding decision by the CDR, or a single review by each province. Although companies generally recognise the CDR as a competent body, some of them consider current CDR reviews too stringent (50 per cent negative recommendations) and would prefer a more transparent and flexible approach to QALYs and evaluation.

3.36 Companies would also favour a common federal strategy to value innovation and to promote research and development in pharmaceuticals. Quebec’s health care model is in this respect considered by industry to be very good as the Quebec Government is said to strike a balance between ‘giving incentives to invest and innovate’, cost containment, and value for money.

3.37 As regards the PMPRB, companies seem generally satisfied with the procedures in place but criticise the administrative burden of the obligatory price data submissions, claiming that companies incur high costs due to the collection of data.

Key issues

3.38 One key feature of the Canadian system is that health care delivery is decentralised (services delivered by jurisdictions to their respective populations). Although there are enforced national standards for medically necessary hospital and physician services (universal coverage), prescription drug coverage outside a hospital setting is not guaranteed by the Canada Health Act 1984. The federal government has no direct authority over provincial coverage decisions for pharmaceuticals. The result is varying levels of public drug coverage across jurisdictions.

3.39 Price differences are theoretically possible in this system but, as prices for drugs on the formularies are published routinely by each jurisdiction, the prices obtained across jurisdictions are known, and the best prices are demanded by all jurisdictions. It is therefore unlikely that official price differences could persist in the long run; effective price differences could probably only be sustained through rebates between provinces.

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52 Though it is not known in how many cases this happens. Government claims that separate reviews rarely happen.
53 The Quebec government has, for example, introduced preferential treatment for innovative drugs called the BAP15 initiative. This initiative gives innovative drugs, on average, an extra two to four years of ‘monopoly’ on the formulary after patent expiry. This is even after patent protection no generic product can access the formulary.
and companies. Often the two biggest provinces, Ontario and Quebec act as 'leaders' for setting prices.

3.40 Another feature closely linked to the 'Provincial system' is the fact that transactions costs for companies (to negotiate with each province) are high and that in negotiations with provincial, territorial and federal jurisdictions, immediate budgetary impacts and cost-containment might in some cases override long-term policies for innovation.

3.41 As a move towards common national standards of pharmaceutical coverage that meet objectives such as fairness, equal access and efficiency, the National Pharmaceutical Strategy (NPS), a joint federal, provincial and territorial initiative was developed by Canada’s First Ministers in 2004. The NPS consists of nine elements:

- enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem
- accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process
- accelerate access to non-patented drugs and achieve international parity on the prices for non-patented drugs
- establishing a common national formulary based on safety and cost effectiveness
- pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines
- develop, assess and cost options for catastrophic drug coverage for Canadians;
- strengthen evaluations of real-world drug safety and effectiveness
- broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record, and
- enhance analysis of cost-drivers and cost effectiveness, including best practices in drug plan policies.

3.42 The PMPRB is one of the few bodies to our knowledge that takes decisions on prices unrelated to drug reimbursement and enforces those decisions by statute. The PMPRB also operates one of the only schemes that allow for annual drug price increases (in line with inflation). Although industry has expressed concerns with the amount of data required by the PMPRB, companies comply with the provisions in practice.

3.43 Finally, manufacturers' pricing in Canada may to a certain extent be influenced by its proximity to the Unites States. As parallel trade between Canada and the US is possible, companies may fear trigger/reputation effects if Canadian prices are significantly below US prices. This may ultimately influence companies' pricing strategies in Canada. In the worst case scenario this may even lead to drugs not being launched (as it seems to have occurred in two cases).
Sources of health care funding

4.1 The Finnish health care system is universal and financed through general taxation. Finland has an exceptionally decentralised health care system with 431 independent municipalities providing health services for their residents through public health centres and doctors. The Finnish healthcare system is based on a two tier system in which municipalities finance most of the inpatient and outpatient care delivered through public centres and doctors. The use of prescribed medicines as well as private health care services (through private doctors), occupational health care and student health services are financed by the Social Insurance Institution (Kela).

4.2 The Finnish Government does not impose a limit to the general drug budget; its policy states that the costs of everything needed will be reimbursed. However, the government has set a 'growth target' for the period 2008-2011 announcing that growth in the budget for drug reimbursement should not exceed five per cent.
However, there is a fixed budget for new products in the special reimbursement category (€8.4 million (£5.57 million\textsuperscript{54}) /year).

4.3 The Finnish drug reimbursement system is based on a ‘positive list’.\textsuperscript{55} Currently 4750 products are reimbursable in the Finnish market, 55 per cent of those products are in a special reimbursement category (categories where a higher than normal percentage of the drug’s price is reimbursed). This excludes pure hospital drugs and all non-reimbursable drugs. Around 13-14 per cent of the total Finnish pharmaceutical market expenditure is on OTC products. Private sources (patients, private insurance) pay around 50 per cent of the total expenditure on drugs or 33 per cent of the total costs of reimbursed drugs (in 2005). If annual co-payments exceed a threshold of €617 (£409.13) per patient in 2006, drugs will be fully reimbursed except for a co-payment of €1.50 (£1) per drug. Private insurances exist but do not seem to be common.

Pharmaceutical supply chain

4.4 Finnish price setting controls the wholesale price of pharmaceuticals; the wholesaler margin is unregulated. Manufacturers and wholesalers negotiate their shares of the wholesale price set by manufacturers on the basis of the maximum regulated reasonable wholesale price. The final wholesale margin is estimated to be about two to four per cent of the wholesale price. There are only two wholesalers in the Finnish market.

4.5 The retail price equals the wholesale price plus a pharmacy margin that amounts to on average circa 31 per cent. The exact calculation can be seen in Table 4.1 below. The retail price includes an additional eight per cent VAT. Pharmacy margins are lower for expensive products and higher for less expensive products.

4.6 The maximum wholesale prices of reimbursable drugs are fixed. Non-reimbursable drugs are free to set prices and negotiate margins with wholesalers.

4.7 A pharmacy fee of on average seven per cent was introduced to ensure country-wide pharmacy coverage in Finland and to secure service in remote areas. The pharmacy fee is paid on sales volumes and amounts to zero – ten per cent of total sales. Very small pharmacies are exempted and large pharmacies pay a higher fee. Funds collected from the pharmacy fees go to the Ministry of Finance and seem to be reinvested in R&D activities in universities. The true pharmacy margin is thus circa 24 per cent.

\textsuperscript{54} All subsequent Euro currency exchanges to British Pounds are based on exchange rates from 31 January 2007 (1EUR = 0.662893 GBP). Any numbers shown only give a rounded indication of values in pounds and were not period or purchasing power parity adjusted.

\textsuperscript{55} No official positive list is published in Finland. However, PPB publishes a file on its website, which includes the names and prices of all reimbursable pharmaceuticals.
Table 4.1: Wholesale and retail margins in Finland

<table>
<thead>
<tr>
<th>Wholesale price (PPP56)</th>
<th>Retail price excluding VAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>€0 - 9.25</td>
<td>1.5 x PPP + €0.50</td>
</tr>
<tr>
<td>€9.26 - 46.25</td>
<td>1.4 x PPP + €1.43</td>
</tr>
<tr>
<td>€46.26 – 100.91</td>
<td>1.3 x PPP + €6.05</td>
</tr>
<tr>
<td>€100.92 – 420.47</td>
<td>1.2 x PPP + €16.15</td>
</tr>
<tr>
<td>above €420.47</td>
<td>1,125 x PPP + €47,68</td>
</tr>
</tbody>
</table>

Note: 1 EUR = 0.662893 GBP57

4.8 Retail prices are not permitted to vary between different pharmacies. Discounts given by any wholesaler to a pharmacy have to be given to any other pharmacy in the country, which leads to no price competition between pharmacies. This 'no discount' policy came into effect on 1 February 2006.

4.9 Drugs for hospitals are mostly bought through tendering processes and might achieve lower prices than the 'market price'. Hospitals are funded by municipalities which decide what services they will offer.

4.10 GPs can generally practice as private or public doctors. Some may chose to do both. Private doctors are funded through patient contributions, private health care funds and by Kela. Public doctors and health care centre services are financed by the municipality. Patients may choose freely which GP to consult and prescriptions are refunded whether the prescribing doctor is private or public.

Institutions

4.11 The National Agency for Medicines licenses drugs for the Finnish market and controls the number and location of pharmacies licensed to sell medicines.

4.12 The Pharmaceuticals Pricing Board (PPB) is an independent body that belongs to the Ministry of Social Affairs and Health and is regulated by law. Each one of the medical, pharmaceutical, legal and economic disciplines shall be represented by at least one member. In addition, PPB has an Independent Board of experts that serves a three year term (with possibility of re-nomination) and comprises doctors, pharmacologists, social insurance experts as well as health economists.

4.13 PPB controls pricing by accepting (what they define as the) reasonable maximum wholesale prices. Decisions are taken by the PPB Board, which meets at least once per month. PPB does not negotiate prices but takes a 'yes or no' decision based on the price submission by the company. Before a final negative decision, a draft decision is given to the applicant and the applicant may give his response (that is, providing more

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56 PPP: wholesale price to pharmacy;  
57 Currency exchanges to British Pounds based on exchange rates from 31 January 2007 (1 EUR = 0.662893 GBP). Any numbers shown only give an indication of values in pounds and were not period or purchasing power parity adjusted.
evidence or suggesting a lower price). In the event a 'no' is given, companies can reapply proposing a new price proposal; however, the administrative procedure will then start again at zero. Within the evaluation process, companies can stop the clock to provide new evidence or submit a new maximum price. Appeals to PPB’s decisions are possible. In the past five years there were around 30-40 appeals.

4.14 Kela is an independent body under public law that is directly responsible to the Parliament. Kela administers the health insurance scheme.

4.15 Finland has no expert body carrying out its own studies on cost-benefit, cost effectiveness and pharmaco-economics.

**Ex ante pricing and reimbursement controls**

**Pricing**

4.16 The PPB controls pricing as well as reimbursement by accepting reasonable maximum wholesale prices. Reasonable wholesale price refers to the maximum price at which the product may be sold to pharmacies and hospitals. All wholesale prices are set separately for original products, parallel trade and generics.

**Figure 4.1: Finnish price setting**

<table>
<thead>
<tr>
<th>Pharmaceuticals Pricing Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirms reasonable wholesale price and basic and special reimbursement status of medicinal products, clinical nutritional products, basic ointments.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secretariat of Pharmaceuticals Pricing Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presents the application to the PPB.</td>
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</table>

<table>
<thead>
<tr>
<th>Expert group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepares an opinion regarding applications of special reimbursement status and, when needed, basic/restricted reimbursement to the PPB</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kela</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepares an opinion regarding applications to the PPB</td>
</tr>
</tbody>
</table>

4.17 In the Finnish System, pricing and reimbursement are decided in parallel. This means that the PPB decides, based on an opinion by an expert group as well as Kela, first on the general acceptance of a drug for reimbursement and then on the reasonableness of the price proposed by the manufacturer.

4.18 Assessment of the reasonableness of the price is based on three criteria that are the same for the assessment of all products:

- an economic evaluation of the product compared to major competitors or prevailing treatment practices
• the wholesale price in Finland, prices of comparable drugs in Finland and the price of the product in other EU countries, and

• the budget impact of the new drug on the pharmacy budget based on a sales estimate by the manufacturer.

4.19 Additionally health economic studies are taken into account. Reimbursement and pricing decisions take up to 180 days.

4.20 Prices are generally (but not obligatorily) set for a certain period of time; however, these stability periods are no longer fixed but tend to be set in accordance with other drugs in the same group. This facilitates price reviews. A maximum stability period is five years. Price increases can be requested by manufacturers and are dealt with within 90 days.

4.21 For its international price comparisons, PPB includes the EU15 countries as well as Norway and Iceland. There is no formal calculation of averages. It seems that Finland predominantly aims at aligning its prices with the lower half of European prices. When new products are reviewed in Finland, the UK, Denmark and Germany will generally already have an established market price and can be used as a comparator. If drugs are likely to have a big budget impact, prices will be set more carefully. However there seems to be no clear cut-off point or mathematical formula for the consideration of international prices.

4.22 Refunds to pharmacies are not based on the level of the reasonable wholesale price, but instead on the basis of the actual wholesale prices that pharmacies are required to communicate every two weeks to Kela. In this way the government tries to benefit from manufacturer’s rebates in the system.

4.23 As mentioned earlier, an expert group comprised of clinical experts, health economists and social insurance experts as well as Kela give recommendations on a drug’s reimbursement status. The final decision on reimbursement is taken by the PPB.

4.24 To be admitted for basic reimbursement, a drug has to show a therapeutic value and must not be part of any of the following categories:

• a medicinal product that is used for the treatment of a disease of a temporary nature or with mild symptoms

• a medicinal product with minor therapeutic value

• a medicinal product used for purposes other than treatment of a disease, or

• a herbal medicinal product, a homeopathic product or an anthroposophic product.

Reimbursement

4.25 There are three reimbursement categories, each having its individual co-payment level and access restrictions. The reimbursement categories are graded according to medical
criteria based on the severity of the illness and the necessity of the drug treatment. Reimbursement categories are:

- basic refund of 42 per cent (of the full drug price) for all basic drugs found to have therapeutic value
- lower special refund of 72 per cent for severe and chronic diseases where medicinal products are necessary and indispensable, and
- higher special refund of 100 per cent for drugs treating severe and chronic diseases where medicinal products are necessary and indispensable and drugs have either replacement or remedial effects.

Examples of the latter group are drugs treating epilepsy, diabetes and cancer.

### Table 4.2: Refund categories in Finland

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic refund</td>
<td>42%</td>
<td>(co-payment 58%)</td>
</tr>
<tr>
<td>Lower special refund</td>
<td>72%</td>
<td>(co-payment 28%)</td>
</tr>
<tr>
<td>Higher special refund</td>
<td>100%</td>
<td>(co-payment €3 per medicine per purchase)</td>
</tr>
<tr>
<td>Additional refund</td>
<td></td>
<td>if the costs of reimbursable drugs paid by a patient exceed the defined annual limit (€616.72 year 2006 (£409.07)), all costs after the obligatory co-payment of €1.50 (£1) per medicine per purchase will be reimbursed in full</td>
</tr>
</tbody>
</table>

4.26 The reimbursement categories are graded according to medical criteria and a government decree defines which severe and chronic illnesses entitle the patients to reimbursement under the special refund categories. That means a medicinal product even for the same indication can belong in one or two or in all three reimbursement categories at the same time; that is because the refund categories also apply 'per patient'. Patients with a special chronic illness can receive a certain drugs under a special refund category whereas a 'normal' patient may be refunded the same drug only under the basic refund category.

4.27 Companies have to apply for each reimbursement status separately and it is the duty of the applicant to supply data that shows that their product is to be added to the special reimbursement category. Generally, a drug is only granted special reimbursement status after a two year period which leaves time to collect sufficient practical and research data on the therapeutic value, indispensability and replacement or remedial effect of a drug.58 There seem to be only a few examples where drugs immediately reached a special reimbursement status.

4.28 In order to receive reimbursement under the Special Refund Category (72 or 100 per cent) the patient must submit a doctor’s certificate to Kela stating the illness, its

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58 As a transfer of a product into the special refund categories increases the usage and the costs, the purpose of this two-year period is to test effectiveness in a real population and to test how useful and economical a chemical entity is in practice. Although exceptions can be made for major innovations, the aim is to improve resource allocation by targeting pharmacotherapy and reducing costs.
severity and the medication needed to treat it. If a special refund is not granted the patient usually receives a basic refund.

**Ex post pricing and reimbursement controls**

4.29 Due to recent changes in the law, PPB no longer commits to any formal stability period for the reimbursement price. This means that price reviews can take place anytime, on a group by group basis or on an individual basis.

4.30 In practice, price reviews of certain drugs or drug categories can be triggered if a product in a certain drug group goes off patent, if a product’s sales and reimbursement expenses significantly exceed the estimates accepted as the basis for the price confirmation decision, if a new product or generic enters the market or if a product expands its indications.

4.31 The last extensive review has taken two years (2003 to 2005) and has covered drugs with generic competitors and ‘me-too’ drugs on the Finnish reimbursement list. The review has focused among others on Proton Pump Inhibitors (PPIs) and Statins.

4.32 From 2006, PPB is also able to create a negative list of non reimbursable drugs which might be used for re-evaluated drugs. PPB must hear the marketing authorisation holders and Kela before deciding to put a drug on the negative list. PPB can terminate reimbursement at any time if it has carried out these prior inquiries.

4.33 As a final measure to control prices, the Finnish government recently reverted to a price cut of five per cent on maximum wholesale prices of all reimbursed drugs. The cut was implemented on 1 January 2006.

4.34 A government working group has been established to evaluate what would be the impact of a reference price system in Finland. This reference price system could be based on equal substances or therapeutic equivalents. The introduction of a reference price system could possibly ease any distortions created by the different reimbursement categories. The report of the Working Group is expected in February 2007.

**Volume controls**

4.35 Kela tries to influence prescribing habits by publishing information and feedback to doctors through the use of prescription registers. However, results are minimal. ROHTO – a recently established body – tries to encourage physicians to implement evidence based practices and to affect implementation and uptake of evidence based medicine. Results may be observed only in the future.

4.36 Cost containment in Finland seems to be achieved mainly through low reasonable maximum wholesale prices and co-payments. Private households’ out-of-pocket payments amount to 19 per cent of the total value of health expenditure, and 34 per
cent of the total expenditure on pharmaceuticals.\textsuperscript{59} This gives patients strong incentives for the reasonable use of drugs and an increase in the use of generic products.

**Generic pricing and penetration**

4.37 Until 1995 Finland had a 'process patent' system which allowed industries to copy (or invent around) European drug products. Government policy was focused on keeping patent protection weak and thus Finnish research-based pharmaceutical industries were scarce. As a result of this policy, Orion, a former Finnish generic drugs producer, still profits from a relatively large market share in the Finnish market.

4.38 Whereas price setting for normal drugs can be lengthy, generic drugs are able to access the market for reimbursed drugs if they propose a maximum wholesale price that is 40 per cent lower than the branded product’s price. The general secretariat of PPB will then automatically decide that the product price is reasonable. If the proposed price of a generic fails to be 40 per cent lower than the original, reimbursement will be decided by the PPB. Second or later generic products entering the market have to be priced equal to or lower than the first generic to be accepted and reimbursed.

4.39 Once a product goes off patent, price competition seems to work relatively well in parts of the Finnish market. Prices of generics seem to be up to 80 per cent lower than the accepted brand price. This is probably due to Finland’s generic substitution system. This system is based on a ‘price corridor’ and stimulates price competition among generics and branded drugs on the wholesale level. However, data suggests that for about 45 per cent of prescriptions there is no generic competition on the market, probably as a result of few generic competitors. This will significantly reduce the savings from generic substitution.

4.40 The obligatory generic substitution regime based on a ‘price corridor’ obliges pharmacies to dispense only cheap (generic or branded) products whose prices lie within a €2 (£1.33) or €3 (£2) price corridor depending on the price of the drug set by the lowest priced generic.\textsuperscript{60} Every three months this price corridor is updated. However, the prices of drugs can be changed every two weeks. Through this measure branded products closely mirror the price of generic products in order to secure market shares. Generics tend to compete for the lowest price and for consumers not willing to pay out of their pocket. The price corridor has shown to be effective in reimbursement categories where a patient’s share is bigger and also has a budgetary impact for both patients and social insurance if it concerns medicines that are widely used. However, in the higher special reimbursement category where a patient only pays a fixed-deductible of €3 per purchase per medicine the price corridor seems not to work. In such cases patients have no financial interest in substitution.

\textsuperscript{59} EFPIA, Annual report
\textsuperscript{60} A medicinal product is only marginally different from the least price if the difference in price to the least expensive substitutable product is less than €2 (£1.30), if the least expensive product costs less than €40 (£26.50), or less than €3 (£2), or if the least expensive product costs €40 (£26.50) or more.
4.41 Finnish generic prices seem to be among the lowest prices in the world, in part due to the introduction of the price corridor. A Canadian study from June 2006\textsuperscript{61} found Finnish generics prices to be half the level of Canadian generic prices, with New Zealand being the only other country included that had lower prices. The study also found that Finnish generics prices decreased by 23.9 per cent in 2005, thus being the second fastest to decline after the UK which is found to have price decreases of 32.4 per cent in 2005.

### Box 4.1: Price corridor

A patient that comes to a pharmacy with a generic prescription or a prescription for product D would be proposed products A, B and C. The patient would be able to freely choose which of the products A, B or C he wishes to buy (his co-payments will depend on the price of the drug that is dispensed). As long as he or his doctor do not insist on having product D, the patient would not be offered product D. Therefore, drugs that are not within the ‘price corridor’ set by the cheapest generic product will be rarely dispensed. The price corridor has shown to be effective in reimbursement categories where a patient’s co-payments are higher. In the higher special reimbursement category, where a patient only pays a fixed-deductible of €3 per purchase per medicine, the price corridor seems not to work.

### Industry view

4.42 We understand that companies find the Finnish system rather complicated and some complain that the government is very focused on keeping prices at a low level. It was also mentioned that there is a general feeling that the Finnish system is rather unpredictable.

4.43 We understand that there is also a feeling that different categories of reimbursement (of patients and of drugs) are not fair and create wrong incentives for doctors and patients. In some cases it may be advantageous to prescribe/buy a more expensive product because it is in a higher reimbursement category than a very similar, cheaper product. It might also lead to a husband and wife using the same product but being reimbursed at different levels (for example if the husband is more severely ill than the wife). Furthermore, healthy lifestyles such as losing weight and practising sports might, instead of being rewarded, be penalised by a drop from a special to a basic reimbursement category.

4.44 There was also criticism concerning the delays that occur for accessing the special reimbursement categories, a process which was described as opaque. The industry

\textsuperscript{61} PMPRB, “Non-Patented Prescription Drug Prices Reporting, Canadian and Foreign Price Trends”, June 2006.
organisation has filed a complaint on this issue at the European Commission’s DG Competition, challenging the practice that new products coming onto the market are being delayed before accessing to a higher reimbursement category. They argue that new products cannot compete on an equal level with products already admitted to special reimbursement categories, because the latter are preferred by doctors and patients for their lower co-payments.

Key issues

4.45 Finnish patients are known to be very aware of drug prices and generic usage is high on a European level. However, in the higher special reimbursement category where patients only pay a fixed-deductible sum of €3 (£2) per purchase per medicine the price corridor seems ineffective. In such a case a patient has no financial interest in substitution. A main driver of this seems to be the low reimbursement levels with average co-payments of 35 per cent on reimbursed drugs, which encourages patients to monitor their drug usage, discuss drug prescribing with their doctors and ask for cheaper alternatives in the pharmacy. However, it also implies large out of pocket costs increasing the financial burden of certain patients. An annual maximum co-payment that a patient is expected to pay on reimbursable medicines has been set. When the annual ceiling sum (€617 (£409) in 2006) is reached, the patient is entitled to an additional refund. Subsequent costs of reimbursable products are reimbursed in full after €1.50 (£1) co-payment per medicine per purchase.

4.46 Finnish prices can sometimes be found to be above average in international price comparisons. However, a common view among companies is that Finnish prices are among the lowest in Europe. We also found studies at ex manufacturers’ price levels suggesting that Finnish wholesale prices are rather low in comparison with the rest of Europe (see Annexe F for more details). This ambiguity may be due to a large gap between retail and manufacturer prices in Finland that may make comparisons misleading.

62 Along with basic topical ointments and clinical nutritional preparations.
FRANCE

Sources of health care funding

5.1 Health care is provided through a universal tax funded system. Private complementary insurance is used to top up public services and reimburse co-payments for prescription drugs. There are public top-up schemes for people on low income.

5.2 The government negotiates a Framework Agreement with manufacturers in order to control pharmaceutical pricing and reimbursement. This agreement is renewed every four years. It outlines the general lines of decision-making and the methodologies by which the government evaluates the therapeutic benefits of medicines. It also establishes annual price-volume agreements that are applied to most product groups and on the basis of which individual manufacturers pay an aggregate volume-based rebate or an individually agreed product-by-product rebate to the government. The current framework agreement expires at the end of 2006.

5.3 About 8,250 drug presentations are available on the French market. More than half of those are included in the government’s positive list of publicly reimbursable medicines.
Pharmaceutical supply chain

5.4 The French public health care system reimburses patients for prescription drugs at one of four levels: zero per cent, 35 per cent, 65 per cent or 100 per cent, depending on how the drug was evaluated by the Haute Autorité de Santé (HAS). The remaining costs are normally paid by private complementary insurance, which most French patients take out. In 2004, the government covered about 75 per cent of the value of all prescription drugs sold in French community pharmacies, with private top-up insurance making up most of the remainder, circa 20 per cent. Out-of-pocket payments only amounted to 5.3 per cent of prescription drugs sold in pharmacies.63

5.5 The private insurers directly deal with the pharmacist so that the patient does not incur any direct costs. This system of payment applies to about two thirds of drug purchases.

5.6 The French generic market is very small (due to low brand prices and weak incentives to dispense generics drugs) and thus generics only represent 13.4 per cent of the total market by volume and 7.0 per cent by value.64

Institutions

5.7 The HAS is responsible for determining whether a drug should be included on the French positive list and thus be eligible for reimbursement. The HAS stresses that its role is to make clinical assessments and not to conduct cost effectiveness analysis. The Transparency Commission within the HAS carries out the evaluations of the clinical benefits of medicines and rules on whether products submitted to it should be reimbursed. The HAS will actively recommend a product for reimbursement only if it provides benefits beyond those offered by existing treatments. Products that the Transparency Commission deems no better than existing alternatives are usually passed to the Comité Economique des Produits de Santé (CEPS) (see below) with a recommendation to list only if prices can be negotiated such that aggregate cost savings can be obtained.

5.8 The HAS also reviews reimbursable drugs on a regular basis and publishes ‘recommendations for use’ and ‘treatment guidance’ for certain drugs.

5.9 The CEPS is responsible for drug pricing. It negotiates prices, price-volume agreements and risk sharing schemes with companies. The CEPS is comprised of representatives of government and the main insurance groups, as well as an independent president and vice president. It is noteworthy that prices are only considered in the French system once a drug’s dossier is passed to the CEPS.

Ex ante pricing and reimbursement controls

5.10 In order to achieve reimbursement, manufacturers have been required to submit evidence of therapeutic benefits since October 1999. The Transparency Commission within the HAS initially evaluates this evidence in order to determine the absolute therapeutic benefits (‘medical service rendered’, abbreviated to SMR in French) of each drug as well as its benefits relative to therapeutic substitutes (‘improvement in the medical service rendered’, ASMR in French).

5.11 The level of reimbursement accorded to a product is determined formulaically by the SMR score that the Transparency Commission awards it as well as by the seriousness of the illness (‘serious conditions’ or ‘not usually serious conditions’). The SMR thus determines if a product’s service to the patient justifies it being reimbursement by the public insurance system.

Table 5.1: Establishing the SMR

<table>
<thead>
<tr>
<th>SMR (Medical service rendered)</th>
<th>Illness</th>
<th>serious conditions</th>
<th>conditions not usually of a serious nature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major or considerable</td>
<td>65%</td>
<td>35%</td>
<td></td>
</tr>
<tr>
<td>Moderate or low</td>
<td>35%</td>
<td>35%</td>
<td></td>
</tr>
<tr>
<td>Insufficient</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

Source: OFT discussion in France

5.12 The ASMR score that evaluates the additional benefit of a product over existing therapeutic equivalents is later used by the CEPS to inform price negotiations between the manufacturer and the CEPS. The ASMR is a formulaic basis to price negotiations but discretion is also applied.

5.13 A product having for example different benefits in different indications or patient subgroups can be awarded a separate ASMR score for each use. In such cases the CEPS nonetheless negotiates a single price for the drug, though a larger element of discretion may be involved.

5.14 ASMR scores are awarded by medical experts, taking a pragmatic view about the likely clinical effectiveness of new products and the proven benefits of older drugs under review. ASMR scores range from one (best) to five and take into consideration:

- the efficacy of the drug
- the severity of the disease treated
- available therapeutic alternatives, and
- the drug’s likely ‘place in the therapeutic strategy’ of the French system.
5.15 Broadly, drugs achieving each of the ASMR levels tend to have the following characteristics:

- **ASMR I** – Life-saving drugs. Only two or three products per year achieve this status.
- **ASMR II** – ‘Disease-modifying’ drugs that may change the general perception of an illness. This category is also very rare (awarded to perhaps five products per year) and contains mostly niche products (for example orphan drugs).
- **ASMR III** – Drugs offering a therapeutic breakthrough or clear value-added over existing therapies. This class comprises about 15 to 20 per cent of all products evaluated.
- **ASMR IV** – Most 'me-too' drugs that confer only slight additional benefits over existing drugs and therapies. Around half the drugs evaluated each year receive this status.
- **ASMR V** – Drugs with no incremental benefits over existing alternatives. A small number of new branded products are in this category, as well as all generics by definition.

5.16 Taking into account the ASMR, the CEPS uses two broad approaches to negotiate prices: one for products ranked ASMR I to III and another for drugs with an ASMR of IV or V.

5.17 For ASMR I-III drugs, manufacturers are granted ‘free’ pricing (under the 'dépôt de prix' system). This means that companies are permitted to select a price that lies within 'reasonable boundaries' and which the CEPS carries the burden of proof for refuting. Reasonable boundaries are defined as the average list price in Britain, Germany, Italy and Spain (or in whichever subset of those countries that a price is available). One principle aim of the 'dépôt de prix' arrangement has been to accelerate the listing process for important new drugs.

5.18 For each drug ranked ASMR IV or V, the CEPS negotiates a price as well as a price-volume agreement that generate aggregate savings should the drug be over-prescribed. All prices are set by the CEPS in agreement with drug manufacturers.

5.19 In some cases of ASMR V and VI products, a new form of pricing approach is used called a risk sharing agreement. These agreements can be especially important for ASMR IV or V products, where manufacturers disagree with the HAS over its therapeutic evaluation. In such cases, the CEPS may allow a company to charge a higher price than would otherwise be granted, on condition of sponsoring an empirical evaluation of the drug’s clinical benefits and lodging an upfront deposit from which compensation is deducted if the evaluation fails to confirm the company’s claims. This approach is commonly used for orphan drugs in particular.
5.20 On average, drugs take 152 days after first submission to the HAS to achieve reimbursement status (generics take an average of 93 days and brands 250 days). In the fast-track procedure (dépôt de prix) the average time taken is 76 days.

Ex post pricing and reimbursement controls

5.21 Ex post annual rebates (based on price-volume agreements) are regulated by law and are agreed during the initial listing process. The framework agreement sets out that manufacturers give a so-called aggregate rebate to the government if a class of drugs (as a whole) exceeds its agreed budget, average growth rates or agreed volume thresholds. The individual rebates given by each company are based on the sales growth of a company’s drug in the class and overall sales volumes of the company. Volume thresholds are systematically set for innovative but very expensive drugs. Here, an evaluation of the drug’s target population (based on indication) will define the volume thresholds and repayments.

5.22 Ex post annual rebates are eventually put in place for all drugs, although ASMR I and II drugs are exempt for three and two years respectively. The rebates constitute a (short-term) alternative to price cuts.

5.23 As well as standard price-volume agreements, the French government also negotiates special rebates for certain drugs where prescribing volumes in France are high compared to other countries, and/or for ASMR I to III products eligible for ‘free’ pricing where European prices are judged to be high. In 2004, total rebates (special and aggregate rebates) totalled around three per cent of the overall drugs bill, and were made up of:

- €250 million from agreements on specific products
- €420 million of reductions from aggregate rebates.

5.24 A drug awarded a high ASMR at listing but a lower ASMR on ex post review will not typically be granted a price increase. The parameters of price-volume agreements may, however, be changed; thus the manufacturer could reap benefits through greater volumes of prescribing. Price increases to products are generally not possible.

5.25 Price cuts have been applied regularly since 2001 to address the fact that actual expenditures for prescription drugs have exceeded predictions every year since then. For example, the 2001 savings plan (the plan d’économie des médicaments) was

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65 Classes of drugs are defined here as "markets with sufficient (economic) substitutability between products where drug companies are in direct competition".

66 Prices may only increase if the CEPS has committed a fault or if a (generally old but important) product is exploitable only with difficulty at a certain price.
targeted specifically at prescription drugs, included a price cut of seven to eight per cent\textsuperscript{67} as well as an agreement with GPs under which higher wages were offered in exchange for increases in the rate of generic prescribing. Furthermore, delistings from the formulary are taking place on a regular basis. These measures are taken outside the negotiated framework agreement and are thus not agreed by manufacturers.

5.26 The French system also achieves cost control on specific drugs by setting flat prices for the average daily cost of treatment for any patient. In order to achieve this it assesses how doses are used in practice and subsequently sets the price of all available presentations. The aim is to prevent manufacturers from gaming the system by pursuing high prices for certain presentations (for example on the grounds of benefits to specific subgroups) and promoting them for use in all patients.

5.27 Finally, French drug prices are reviewed by the CEPS at least every five years and a negative evaluation might lead to a delisting or price decrease.

**Volume controls**

5.28 Private insurers attempt to monitor GPs (in particular their adherence to guidance issued by the HAS) and encourage generic prescribing. However, insurers have no power to grant incentives to doctors, who themselves have little incentive to take prices into account when prescribing. This is because most doctors work in private practices and feel little obligation to adhere to guidance.

5.29 The French government attempted to increase generic prescribing by granting GPs higher wages in return for higher generic prescribing rates through the 2001 'plan d’économie des médicaments'. Results, however, were limited.

**Generic pricing and penetration**

5.30 The listing process for generics is much shorter than for brands. By custom and practice, generics manufacturers typically pitch prices 40 per cent below those of equivalent brands, whereupon prices are agreed automatically by the CEPS.

5.31 France has had an appreciable generics market only since 1995. However, due to opposition from doctors, generic penetration has remained low. Pharmacists have had generic substitution rights since 1999. In 2001, the government attempted to increase generic prescribing through wage incentives for GPs. Furthermore, generic dispensing has been encouraged by granting generics higher proportional margins than brands. However, generics still constitute only around seven per cent by value of the French prescription drug market.

\textsuperscript{67} Price cuts of on average 7 to 8 per cent were obtained from products with an insufficient SMR during the years 2000-2002. In April 2003, 617 drugs with a ‘moderate or low’ SMR were subject to a decrease in their reimbursement levels.

www.previade.fr/ebn.ebn?pid=23&domain=site&site=6&uid=documentsite_5236&rub=538
Industry view

5.32 Companies are generally satisfied with the framework agreement and overall architecture of the French system. However, many complain that the government has repeatedly used measures outside the agreement, such as across-the-board price cuts. Companies have been especially concerned about the scale of price cuts under the 'plan d’économie des médicaments'.

5.33 There are fears in the industry that it is becoming increasingly difficult to achieve ASMR I for new launches and thus that freedom of pricing is only granted to a very small number of drugs every year. A related worry is that the – very popular – fast-track procedure has been applied to only 12 products in the last four years. This means that delays for most drug launches are long and that the fast-track procedure cannot meet industry’s expectation of faster access to market.

5.34 The industry also believes that the French government does too little to support research and development or to provide good infrastructure for clinical trials. There have been calls for more public-private research clusters and investments in hospitals to be centres of excellence in clinical trials.

5.35 Industry sources fear that the government is poised to introduce more cost-containment measures in the next four-year framework agreement. It is thought that the government may push for branded products with ASMR IV-V to be priced at parity with generics once they appear (typically meaning a 40 per cent price cut when relevant generics are launched after patent expiry). It has also been suggested that the government may wish to make such price decreases effective up to three years before products lose patent protection.

Key issues

5.36 Historically, the French market has been typified by low prices and especially high volumes. France has one of the highest per capita pharmaceutical spending in Europe amounting to €480 (£318) per head\(^68\) (in 2002 – compared to €248 (£164.50) in the UK). Furthermore, French GPs have some of the highest prescribing rates in Europe and uptake of new drugs is very fast.\(^69\) The government is thus concerned that prices are increasing (in part because products are reference-priced to the UK and Germany) and that the budgetary impact could be explosive given the scale of use of many drugs in France. This may reinforce the government’s push for further price cuts.

5.37 Price-volume agreements are a central element of the French pricing system and rebates often cause effective prices to be substantially lower than official

\(^{68}\) Stichting Farmaceutische Kengetallen, Ministerie van Volksgezondheid, Welzijn an Sport; (study commissioned by the Dutch Ministry of Health, Welbeing and Sport), www.sfk.nl

\(^{69}\) It is not known whether this is because French physicians are more influenced by marketing or simply less risk-averse than their peers abroad.
reimbursement prices. Thus, even if French prices often appear to be in a medium range in international comparisons, real price might be substantially lower due to ex post (and hidden) rebates.

5.38 Price-volume and rebate agreements are pragmatic approaches that have proved acceptable to government and companies alike. As noted, in certain cases (where cost effectiveness differs significantly by indication) they can also help secure value for money for the public purchaser (by ensuring a premium payment is only paid for prescription volumes that reflect likely estimates of the clinically relevant population).
Sources of health care funding

6.1 Ninety per cent of the German population is insured by a Statutory Health Fund (SHF), of which there are 254 in Germany. SHFs are run by a number of different groups, including regions, companies or professional groups. Ten per cent of the population is insured through a private health insurance that is available for people with a high income or the self-employed. The state ensures public health care for the unemployed. Apart from this, the government does not add tax income or other benefits to the system.

6.2 Members of the SHF pay for their health care through obligatory employee and employer contributions. Fees are very similar among the different funds and amount to around 13.4 per cent of the patient’s income (paid as shared contribution by employer and employees). Family members can be insured by a parent or husband/wife.

6.3 Each of the SHFs manages its own budget, contributions and sets its fees. The funds all provide exactly the same services as defined either by law, statutory order, the G-
BA\textsuperscript{70} (Gemeinsamer Bundesausschuss) or the different umbrella organisations of the SHFs (referred to in the following the Statutory Health Insurer’s organisations (SHIs).\textsuperscript{71}

6.4 Private insurance covers the same services as the SHFs but normally provides additional benefits such as single bedrooms in hospitals and coverage for homeopathic medicine.

6.5 There is limited competition between different SHF; most patients rarely switch from one fund to another as services and fees are similar. Private insurance is under more pressure from competition as those patients that are eligible for private insurance can choose from the different providers and fees may vary.\textsuperscript{72}

6.6 The German drug bill amounts to approximately €30 billion (£19.9 billion), €26 billion (£17.3 billion) in outpatient care; three billion in hospitals and circa one billion in OTCs. About 12-13 per cent of expenditure on prescription drugs is paid ‘out-of-pocket’ (including co-payments and top-up payments). The remainder is covered by insurance. Each SHFs spends about 17 per cent of its total budget on pharmaceuticals.

Figure 6.1: Drug funding in outpatient care in Germany

![Diagram showing drug funding in outpatient care in Germany](image)


\textsuperscript{70} The G-BA is a joint committee comprised of doctors, dentists, hospital representatives and representatives of the SHIs and has a central responsibility in the field of drug provision for those with statutory health insurance.

\textsuperscript{71} Each SHF works in a defined region or for a defined company, that is, on a provincial level. All of those SHFs are, on the national level, organised in an umbrella organisation (SHI). That is, all company related SHFs are united in one national umbrella organisation the ‘organisation of the private sector statutory health funds’.

\textsuperscript{72} In order to be eligible for private insurance a person’s income has to exceed a certain minimum threshold.
Pharmaceutical supply chain

6.7 Wholesalers in the German market have a regulated maximum margin the size of which depends on the manufacturer’s price of a product. The margin is calculated as set out in the table below.

<table>
<thead>
<tr>
<th>Manufacturer price</th>
<th>Wholesale margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower level €</td>
<td>Upper level €</td>
</tr>
<tr>
<td>0.01</td>
<td>3.00</td>
</tr>
<tr>
<td>3.01</td>
<td>3.74</td>
</tr>
<tr>
<td>3.75</td>
<td>5.00</td>
</tr>
<tr>
<td>5.01</td>
<td>6.66</td>
</tr>
<tr>
<td>6.67</td>
<td>9.00</td>
</tr>
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<td>9.01</td>
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<td>11.57</td>
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<td>23.01</td>
<td>26.82</td>
</tr>
<tr>
<td>26.83</td>
<td>1200.00</td>
</tr>
<tr>
<td>1200.01 and more</td>
<td></td>
</tr>
</tbody>
</table>

Note: 1 EUR = 0.662893 GBP
Source: www.aponet.de/apotheke/ampreise/07_03_02_00_00_c_AMpreise_ebau.html

6.8 In 2002, 93 per cent of drugs were sold in pharmacies only seven per cent in supermarkets or other shops. In 2004 e-commerce has been allowed and internet pharmacies are starting to compete for dispensing of prescription drugs but mostly OTC products. Physicians however, are very rarely involved in dispensing medication.

6.9 For prescription-only drugs, pharmacists are paid through a fixed margin of three per cent plus a flat-rate payment of €8.10. (£5.37) The retail price includes VAT at 16 per cent. The pharmacy margin is calculated from the manufacturer’s price plus the relevant maximum margin for wholesalers excluding VAT (see below). Prices for prescription drugs are equal in all pharmacies. However for non-prescription drugs, the pharmacist is free to add a margin.
Table 6.2: Calculation of the retail price

<table>
<thead>
<tr>
<th>Manufacturer Price $^{73}$</th>
<th>€20.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Wholesale margin</td>
<td>€1.40</td>
</tr>
<tr>
<td>= Net Price</td>
<td>€21.40</td>
</tr>
<tr>
<td>+ Pharmacy margin</td>
<td>€8.74</td>
</tr>
<tr>
<td>= Net Pharmacy price</td>
<td>€30.14</td>
</tr>
<tr>
<td>+ VAT</td>
<td>€4.82</td>
</tr>
<tr>
<td>= Retail Price</td>
<td>€34.96</td>
</tr>
<tr>
<td>- Pharmacy Rebate to SHI</td>
<td>€2.00</td>
</tr>
<tr>
<td>= Price for SHI</td>
<td>€32.96</td>
</tr>
</tbody>
</table>

Note: 1 EUR = 0.662893 GBP
Source: www.aponet.de/apotheke/ampreise/07_03_02_00_00_c_AMpreise_ebau.html

6.10 For drugs used for in-patient care, hospitals may negotiate prices with wholesalers or manufacturers and often receive rebates of 50 per cent or more. Hospitals manage their own formularies and are very efficient in cost containment as they are paid 'flat rates' (daily averages) for therapies and surgeries by the SHI.$^{74}$ These flat rates vary depending on location and hospitals compete on their margin between real costs and the daily averages reimbursed. This leads to specialisation of hospitals in their areas of 'excellence'.

6.11 GPs invoice the sickness funds for their services but are not under direct control of the SHI. However, they are under the supervision of the SHI and are subject to some more or less binding constraints (see cost-containment measures).

6.12 Patients pay a co-payment for every drug dispensed as well as a one off payment of €10 (£6.60) (per quarter) when they see a doctor. In certain cases (discussed in detail later) they also pay a top-up payment if a drug is more expensive than the agreed reference price. A maximum threshold of payments is achieved if a patient has made co-payments that amount to two per cent of his or her total income.

Institutions

6.13 Licensing of pharmaceuticals is the responsibility of the Paul Ehrlich Institute and the Federal Institute for Pharmaceuticals and Medical Devices (BfArM).

6.14 The Ministry of Health (Bundesministerium fuer Gesundheit) sets the framework for health care interventions, approves measures taken within this framework, monitors the outcome of reforms and controls the work of the Statutory Sickness Funds. It is also the final decision-maker concerning reference pricing groups and reimbursement.

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$^{73}$ www.aponet.de/apotheke/ampreise/07_03_02_00_00_c_AMpreise_ebau.html

$^{74}$ Efficiencies arise from the incentive to beat the average flat rate prices paid subject to maintaining a given quality.
6.15 The G-BA (Gemeinsamer Bundesausschuss) is a joint committee comprised of doctors, dentists, hospital representatives and representatives of the SHIs. The G-BA has a central responsibility in the field of drug provision for those with statutory health insurance. It regulates reimbursement and restrictions on prescribing on efficiency grounds. Furthermore G-BA assesses new methods of medical examination and treatment, evaluates and classifies new drugs on the German market and is responsible for the publication of treatment guidelines (submitted for approval to the Federal Ministry of Health). Appeals to G-BA’s decisions are possible (on evidence as well as on legal grounds).

6.16 In 2004, the G-BA established an independent federal institute (IQWiG) for the evaluation of medical efficiency, quality and effectiveness. Its tasks are the evaluation of the effectiveness of drugs following a request of the G-BA or self-initiative of IQWiG. It then prepares non-binding recommendations to the G-BA. There is no formal cost effectiveness analysis in the system; this is however planned from 2007 onwards. IQWiG cooperates with NICE and HAS (the French expert body) on an informal basis to exchange basic information and scientific evidence.

6.17 The Social Insurance Organisation is responsible for administering and monitoring the Reference Price Groups. It calculates reference prices in the different groups following a predefined formula and updates reimbursement levels if necessary. Furthermore the organisation monitors doctors’ prescribing behaviour, sets doctors’ budget targets and tries to influence prescribing behaviour through information campaigns. Within the G-BA the social insurance organisation also takes part in reviewing the effectiveness of drugs.

**Ex ante pricing and reimbursement controls**

6.18 Factory prices are set by manufacturers without negotiations involving governmental agencies, direct price controls or profit controls. All drugs are available and fully reimbursed from the date of licensing until decided otherwise (see ex post evaluation).

**Ex post pricing and reimbursement controls**

6.19 Pricing is free in the German market. However, G-BA and SHIs may decide to reimburse drugs only to a certain extent. In those cases, patients have to cover the difference between a drug’s price and its reimbursement level (additionally to an obligatory co-payment).

6.20 Germany does not have a ‘positive list’ of reimbursable pharmaceuticals. Until 2003 most drugs that received a licence were automatically reimbursed. Today, drugs for ‘trivial’ diseases for the over 18s as well as lifestyle drugs and most OTCs for those over 12 years old are excluded from reimbursement. The Minister of Health is allowed to exclude ‘inefficient’ drugs from reimbursement and put them on a negative list.

6.21 When a new drug comes onto the market the G-BA is responsible for identifying and classifying it (if possible in an already existing or new reference price group). If
The 2004 health law re-introduced the possibility of including on-patent drugs in the reference price system. This means a single reference price group can include on-patent, off-patent as well as generic drugs for similar (but not necessarily equivalent) therapeutic usage. As a result of the 2004 law, the G-BA reviews the drug market to find suitable candidates to create new reference price groups. Statins and PPIs were some of the first drugs to be reviewed and reference priced due to their high sales volumes.

Other regulatory measures to control prices in the German system are obligatory rebates imposed on pharmacies and manufacturers. Those rebates are estimated to amount to €2 billion (£1.32 billion) in 2006.

Pharmacies are required to grant the social insurance institutions a rebate of two euros per prescription-only drug (and five per cent for OTCs) dispensed. Additionally pharmacies are obliged to generate seven per cent of their turnover with parallel imports in order to decrease costs for the public sickness funds.75

Manufacturers are required to grant the social insurance institutions a rebate of:

- six per cent for on-patent drugs that are not reference priced
- six per cent for generics without a reference price, and
- ten per cent for all drugs (generics and off-patent brands) where at least two generic copies are available.

Drugs exempted from rebates are on-patent drugs under the reference price system. Generic drugs that are not included in a reference price group pay a (cumulative) rebate of 16 per cent.

Recently, generic products have been made exempt from the ten per cent rebate if their price lies 30 per cent below the reference price.

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75 The SHIs have lists of drugs that are available for import for at least €15 (£10) less than in Germany. The SHIs then monitor the turnover of pharmacies that dispense products on the import lists. They then deduct seven per cent from what they would have reimbursed to those pharmacies.
Volume controls

6.27 SHIs try to influence GPs’ prescribing habits by setting specific target prescribing volumes. These targets (individual and local) are established by negotiation between the doctors association and the sickness funds. SHI also monitors prescribing and a federal information system is in place to inform GPS about SHI covered prescriptions.

6.28 On average target volumes amount to €34 (£22.5) per patient/quarter, but different rates apply for specialists or GPs with a high percentage of elderly patients. Targets are not strictly binding and thus exceeded regularly. If a doctor exceeds his personal target (regularly) he might be faced with an audit and formal re-payments could be imposed.

Box 6.1: Reference pricing revisited

The reference price system establishes an upper limit for sickness fund reimbursement on groups of drugs. That is health funds only reimburse pharmacies up to a predefined ceiling and patients pay the difference between the reference price and the market price if they prefer a more expensive drug (top-up payment). Co-payments have to be paid on every drug dispensed. 45 per cent of all sales by value on the German market are reference priced; about 70 per cent of all prescriptions.

The G-BA is still creating new reference groups but the percentage of prescriptions covered by reference priced drugs is not likely to increase above 80 per cent. There are currently about 440 reference groups of which 120 are reference groups that include both off and on-patent drugs.

After a new drug comes on the market two cases can apply:

1. If the new drug is known or supposed to be similar to an existing product, the GBA evaluates whether the drug has an additional benefit over existing products. If not, the drug will be included (if possible) in an existing reference group. If the evaluation is positive the drug will be exempted from grouping and fully reimbursed.

2. If the drug’s substance is not similar to an existing product, the GBA evaluates the clinical effectiveness of the drug. If there is an additional benefit of the drug for the health care system it will be fully reimbursed, IQWiG may be asked for advice on this issue.

The reference price is established as the price in the lower third of all prices of a group, at which at least 20 per cent of all prescriptions and 20 per cent of volume can be supplied. The SHI performs regressions to compare prices of products (and different strengths and pack sizes) within the reference group and calculates the reference price*. Only five per cent of the volume or two per cent of the turnover (for referenced priced drugs) is constituted by drugs that are more expensive than the reference price.

Reference prices are revised every year. This creates a strong downward pressure on companies to reduce branded drug prices to the reference price level (to avoid extra patient top-up payments) and generic prices to 30 per cent below the reference price level (to take advantage of the waiving of co-payments). Currently, however, the revision of reference prices is suspended as a result of the newly introduced waiving of co-payments.

*Initially, the SHI calculates the ‘lower third price’ (price at the 33 percentile); then it calculates whether 20 per cent of prescriptions and volume are available at this price; if not, it will increase the price until this condition is met. If more than 20 per cent of prescriptions and volume are available at the ‘lower third’ price, it will reduce the price to the level at which exactly 20 per cent of prescriptions and 20 per cent of volumes are available. The reimbursement price is proposed and discussed in a public hearing and afterwards decided by unanimous decision of SHIs. No final approval is needed from the Minister. The official reimbursement price is published in the official journal. This whole process takes about one year.
In practice this happens only in exceptional cases. Despite this, the audit system seems to be viewed as a threat and thus imposes a constraint on GPs' prescribing.

**Generic pricing and penetration**

6.29 The generic substitution regulation (aut-idem) obliges pharmacists to dispense lower priced generics unless the physician explicitly opposes substitution. In the rare event a patient insists on the branded product or the price of the drug dispensed is above the reference price, the patient must make up the difference between the product’s price and the reference price by means of a top-up payment.

6.30 To further increase the use of generics, co-payments for generics drugs in certain groups are now waived and some generics are exempt from the obligatory rebates. Furthermore, discounts from manufacturers and wholesalers to pharmacies have been prohibited to encourage competition on list prices rather than on discounts to pharmacies.

6.31 In the future, the Ministry wants to introduce more competition in the generic market by making generic manufacturers contract directly with SHFs. Under this scheme, pharmacies could only dispense the generic product that the patient’s sickness fund has contracted with.

**Industry view**

6.32 The main industry complaints relate to overregulation and what industry regards as a short-term, short-sighted approach to innovation in German health policy. Reference pricing for on-patent products is clearly opposed and companies would wish a more active discussion between the payers and Industry, especially during the evaluation of drugs.

**Key issues**

6.33 A clear driver of the German system and a unique approach in Europe to drug pricing is the German reference price groups system. In contrast to other countries, the German system can include chemically equivalent, therapeutically substitutable as well as broadly comparable on- and off-patent substances in one reference group and fix a common reimbursement price. Thus, a reimbursement price can be the same for drugs with small differences in clinical effectiveness.

6.34 The spirit of the system is that small improvements should not be covered by the state but can be paid for by the patient via ‘top-up’ payments. The German system thus only rewards new drugs that lead to significant improvements in medical end-points, mortality or to a significant decrease in side effects.

6.35 Current reform proposals concern the introduction of a 'public health fund' (with a fixed budget) from which sickness funds will receive payments according to their member (and risk) structure. In this structure patients would pay a fixed fee into the public fund
and each sickness fund could ask for additional fees from their members to cover extra costs up to a total maximum of five per cent of the SHFs budget. These additional fees would be directly out of pocket fees and are supposed to give patients more incentives to switch between funds.\textsuperscript{76}

6.36 It has been argued that Germany’s reference pricing system has been the source of a ‘flight’ of industry and R&D out of Germany. However, during our research it was suggested to us that the loss of pharmaceutical R&D in Germany over the last few years may in fact be due to a lack of public research funding and few networks between private research and universities. This view is supported by the fact that R&D levels in Germany have decreased before the reintroduction of reference pricing for on-patent products. It seems, therefore, unlikely that there is a strong link between Germany’s reference pricing and reduced levels of R&D.

\textsuperscript{76} A maximum threshold for those fees will be set at one per cent of a person’s income.
The Health Insurance Board (CVZ) decides whether a new drug is interchangeable with other medicines or not. Interchangeable drugs are known as Annex 1A drugs, non-interchangeable ones as Annex 1B drugs.

The Ministry of Health takes decisions on pricing and reimbursement. Annex 1A drugs are reimbursed based on a maximum reimbursement price for each cluster of interchangeable drugs. Annex 1B drug’s reimbursement price is evaluated on cost-effectiveness, budgetary impact and therapeutic value basis.

Off-patent

Price caps based on international reference pricing represent an upper limit for patient co-payments.

Licensing

Most generic products enter the market at the maximum reimbursement price and compete on discounts to pharmacies. In 2005, manufacturers agreed to reduce generics prices by 40%.

Reimbursement

Sources of health care funding

7.1 The Dutch health care system is a compulsory insurance scheme financed from taxes as well as patient contribution. This system was introduced on 1 January 2006 and from then on consumers have been able to choose between private sector insurers that purchase health services, including hospital and primary care services and pharmaceuticals. Health care providers are contracted by insurers based on performance and price.

7.2 There is a minimum package of insurance that is mandatory for everyone. On average this is about half funded by direct contributions from those insured and half funded by contributions paid by employers. Insurers are required to accept all applicants and expected health costs are shared between insurers through redistribution (based on the risk-profile of their customers).

7.3 The insurers pay both for hospital inpatient and for outpatient care and negotiate directly with hospitals on the quality and volume of outpatient and inpatient care as well as on the price of care. As regards inpatient medicines, hospitals negotiate prices with the pharmaceutical companies. The controls over insurers’ reimbursement of pharmacies for outpatient medicines are described below.
7.4 Since its introduction, the system has seen strong competition between insurers\textsuperscript{77} with premiums being about ten per cent below the level expected (in 2006 typically around €1,030 (£684) instead of €1,106 (£733)). For 2007, insurers have increased premiums by only eight per cent on average, less than the expected 10-12 per cent. However, this could reflect temporary reductions to attract as much business as possible at the start of the system. Around 25 per cent of consumers have switched between insurers. Switches are possible on an annual basis.

7.5 In the Netherlands about nine per cent of the total health care budget is spent on pharmaceuticals, €4.3 billion (£2.85 billion) in 2005 (including prescription fees).

**Pharmaceutical supply chain**

7.6 Pharmaceuticals are distributed through wholesalers and pharmacies. About half of pharmacies are owned by wholesalers and most of the rest by individuals. There are no large pharmacy chains independent of wholesalers. De Wolf \textit{et al}\textsuperscript{78} quote figures suggesting that in 2002 the net wholesale margin was about five per cent of list prices.

7.7 Pharmacies receive a prescription charge of €6 (£4) paid by the patient but reimbursed by the insurers. Pharmacies are reimbursed by the insurers at the lower list price and maximum reimbursement price less clawback of 6.82 per cent (maximum clawback per prescription is €6.80 (£4.5)).\textsuperscript{79} Pharmacy margins are high due to pharmacists receiving large discounts on generic medicines, as discussed below (under generic pricing and penetration).

7.8 The patient may be required to make a co-payment if the drug’s reimbursement price is below its list price. The total level of such co-payments in the Dutch market is low: around 0.3 per cent of the total value of outpatient prescription medicines for drugs with reimbursement prices below the list price and 2.0 per cent including non-reimbursable drugs such as Viagra. We were told that Dutch consumers were very reluctant to make co-payments.

7.9 In the Netherlands, 11 per cent of total pharmaceutical sales (11 per cent of €5.7 billion (£3.78 billion)) are OTC drugs or health products.

**Institutions**

7.10 A new regulator, the Netherlands Healthcare Authority (NZa), regulates the interaction between insurers and healthcare providers in non-liberalised sectors such as pharmaceutical care. The NZa also stimulates competition and supervises market behaviour in liberalised sectors.

\textsuperscript{77} However, there is no free entry to the Dutch insurance market.

\textsuperscript{78} \textit{Regulating the Dutch pharmaceutical market: improving efficiency or controlling costs?}, P. de Wolf, WBF Brouwer and FFH Rutten, International Journal of Health Planning and Management, 2005, 20, 351-374.

\textsuperscript{79} Numbers are for June 2006.
7.11 The Ministry of Health takes decisions on reimbursement of outpatient medicines on the advice of the CVZ (Health Insurance Board) and decides on pricing.

Ex ante pricing and reimbursement controls

7.12 Drugs in the Netherlands are divided between those which are 'interchangeable' with other medicines (known as Annex 1A) and those which are not (Annex 1B). When a new drug is licensed, a committee of the CVZ decides whether or not a drug is interchangeable with other medicines. Interchangeability is defined as: identical affliction (clinically relevant properties); identical mode of administering; identical age category; no clinically relevant differences in effects; no clinically relevant differences in side-effects.

7.13 The maximum reimbursement price (GVS) for each cluster of interchangeable drugs is based on a simple average of the October 1998 prices of each drug in the cluster at that time (WHO’s Defined Daily Doses are used to compare different drugs). There had been an intention to update these maximum reimbursement prices regularly but this has not yet occurred.

7.14 A manufacturer may set prices above the maximum reimbursement price but then the patient has to pay the difference. Dutch patients are disinclined to pay co-payments and manufacturers typically reduce prices to the reimbursement level. There are about 350 to 400 clusters of interchangeable drugs, accounting for about 85 per cent of turnover on prescription drugs. Although several major drugs have gone off-patent in recent years, this has not led to a reduction in maximum reimbursement prices because they have not been recalculated since 1998.

7.15 If a drug is considered to be non-interchangeable with other medicines (Annex 1B), the committee considers its therapeutic value, cost effectiveness and budgetary impact and then advises whether it should be reimbursed. The minister takes a decision on the basis of the advice of the committee. From 2005, it is mandatory to submit a pharmaco-economics dossier. Cost effectiveness analyses are available on the website of the CVZ. Due to budgetary limits, the Annex 1B route was closed between about 1996 and 2000 (except where no alternative treatment was available).

7.16 Annex 1A decisions are made within 90 days but Annex 1B decisions take longer, typically upwards of 120 days. For Annex 1B drugs, there may be some negotiation on price: a manufacturer may reduce the price if it results in the drug being reimbursed. For Annex 1A drugs, there is no possibility of price negotiation, although a manufacturer may decide not to market in the Netherlands.

7.17 Decisions may be appealed to a regular court, which has no special medical expertise and does not reconsider the merits of the decision.

Formally, the Minister of Health decides but we understand the Minister is obliged to follow the advice of the committee.
Ex post pricing and reimbursement controls

7.18 In addition to maximum reimbursement prices, the Netherlands has a system of caps on list prices (WTG) for all medicines (both Annex 1A and 1B). Price caps represent an upper limit on list prices. Unlike the maximum reimbursement prices based on drug clusters, the price cannot be increased through patient co-payments.

7.19 Price caps are based on a simple average of the prices in Belgium, France, Germany and (except for generics) the UK. For in-patent drugs, this just means taking the manufacturer’s price in each of the four countries and averaging it. UK prices are taken from *Chemist and Druggist*. For off-patent drugs, the price cap covers both branded and generic versions, so the calculation in principle includes generics as well as the originator brand. In practice this has not (so far) led to very low price caps for off-patent drugs. Reasons for this include lags in international reference pricing; limited
data sources, and high generic prices in comparator countries (the UK is excluded from such generic comparisons).

7.20 Price caps are imposed at the wholesale level and are updated twice per year. Price caps were introduced in 1996. We were told that, at that time, Dutch prices were 20 per cent above the European average and the goal was to get prices down to the European average: this goal has been achieved.

Volume controls

7.21 Choices between drugs are made by doctors and pharmacies. We were told that the insurers are trying to get influence over these choices (by offering incentives to prescribers). For example, an insurer may offer a payment if a practice prescribes more than 80 per cent simvastatin to new patients requiring statins. The insurer can monitor this through prescriptions. Insurers also work together with doctors and pharmacies to address issues such as over-prescription of some drugs and under-prescription of others.

7.22 We were told that one Dutch insurer arranged for groups of GPs to rank the drugs for the most important therapies. The choice between drugs was made using a system known as SOJA (System of Objectified Judgment Analysis) which also is the basis of the STEPS analysis used in Northern Ireland (see Box 4.4 in Annexe A). Under this approach, the GPs involved were committed to prescribing the top two or three drugs to at least 80 per cent of their patients, and received a financial incentive from the insurer for doing so. We were told that in practice around 90 per cent of prescriptions followed the SOJA recommendations.

Generic pricing and penetration

7.23 Pharmacists are able to substitute a brand for a generic unless the prescriber indicates otherwise. De Wolf et al. quote figures suggesting the market share of generics was 18 per cent by value in 2002. In 2005, the market share of generics was 20.4 per cent per cent by value (49.8 per cent by prescription).

7.24 As noted above, price caps are the same for generic and branded versions and maximum reimbursement prices for drug clusters are based on average prices in October 1998. The incentive therefore is for generic manufacturers to set a list price close to the maximum reimbursement price and compete on discounts to pharmacies. As major drugs came off-patent, pharmacies benefited substantially. We were told that, between 1997 and 2003, trade profits per pharmacy increased from about €100,000 (£66,300) to about €350,000 (£232,000). This level of profits was well in excess of

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81 We were told that UK category M prices had not been included as they were not shown in Chemist and Druggist although this is being corrected.
82 See reference above.
the level that underpinned the existing clawback of just below seven per cent of list prices (see above).

7.25 In 2004, an agreement was reached between government, health insurers, generics industry and pharmacists to reduce generics price by 40 per cent. In 2005, the main pharmaceutical companies joined the agreement and reduced off-patent branded pharmaceuticals prices by 40 per cent as well; they also agreed a price freeze on other products. This agreement only lasts until January 2008 and it is unclear what will replace it.

Industry view

7.26 In regards to the Annex 1A assessments, it was suggested to us that there had been improvements in the system but that the transparency of certain aspects of the decision-making process could still be improved.

7.27 Concern was also expressed that appeals on the substance of a decision were to a general court with no specific expertise on pharmaceuticals.

Key issues

7.28 An interesting development to observe will be what succeeds the current voluntary agreement which limits prices of generics and off-patent drugs when the current agreement expires in 2008.

7.29 Under the current Dutch system, insurers negotiate prices with providers of all aspects of health care except primary care medicines (which continue to be subject to complex reimbursement controls). A second issue would therefore be whether, in the longer run, insurers seek to move to a system where they negotiate outpatient reimbursement prices with drug suppliers.

7.30 Finally, the Netherlands is noteworthy as one of the only countries in the world with a lower overall level of patient contribution than the UK (approximately 0.3% of prescription pharmaceutical spend).
Sources of health care funding

8.1 The Spanish system is a health system with universal coverage funded by taxation. Financing of the system is centralised and funds are distributed by the National government to the Autonomous Communities according to a capitation formula. About 15 per cent of the Spanish population is covered by private (additional) health insurance.

8.2 Drug authorisation, pricing and reimbursement issues are decided nationally whereas the 17 Autonomous Communities have complete power over public health and healthcare services planning. Regional governments can add additional restrictions or cost-containment measures to the already existing criteria set by the government. These include issuing prescription guidance, setting a shadow reimbursement price, giving financial incentives to doctors and making use of health inspectors.

8.3 General health care is provided free of charge. For pharmaceuticals delivered outside hospitals, patients must contribute co-payments of between 10 and 40 per cent of the total drug value (ten per cent for drugs for chronic diseases, up to a maximum limit of
€2.64 (£1.75) per drug; 40 per cent for all other drugs\(^83\). Pensioners and the disabled do not make co-payments.

8.4 Despite this high level of co-payments average co-payments on prescription drugs amount to only 6.26 per cent\(^84\) of total prescription drug value (in 2005). The reason for these low levels of co-payments seems to be that many people receive drugs from hospitals where they are free of charge. In total, private households’ out-of-pocket payments on health care (not limited to pharmaceuticals) amount to circa 23 per cent of total health expenditure in the Spanish market.

**Pharmaceutical supply chain**

8.5 Over 100 wholesalers operate in the Spanish market. Traditionally, wholesalers focus on their own region and, as a result, the market is highly fragmented. The five largest wholesalers accounted for 50.4 per cent of the market in 2003.

8.6 The wholesale margin is a statutory fixed rate of 7.6 per cent of the wholesale price if the manufacturer price for a pharmaceutical is below €89.62 (see Table 8.1). If the manufacturer price is €89.62 or higher, the wholesale margin is a fixed sum of €7.37.

8.7 Pharmaceuticals (both prescription-only and non-prescription) can only be sold in pharmacies. There are rules concerning the opening of new pharmacies, taking into account geographic and demographic criteria. In 2005, there were 20,461 community pharmacies, each serving an average of 2,047 patients.

8.8 The pharmacist’s margin for pharmaceuticals with a manufacturer price below €89.62 (£59.47) is statutorily fixed at 27.9 per cent of the pharmacy retail price. If the manufacturer price is €89.62 (£59.47) or higher, the pharmacy margin is a fixed sum of €37.53 (£24.90) (see Table 8.1). These margins apply to all pharmaceuticals – reimbursable and non-reimbursable pharmaceuticals, branded pharmaceuticals, generics and OTCs. The VAT rate for pharmaceuticals is four per cent.\(^85\)

<table>
<thead>
<tr>
<th>Manufacturer price in € (excl. VAT)</th>
<th>Wholesale margin</th>
<th>Pharmacy margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>€0.00 – €89.62</td>
<td>7.6% of the wholesale price</td>
<td>27.9% of pharmacy retail price</td>
</tr>
<tr>
<td>&gt; €89.62</td>
<td>€ 7.37</td>
<td>€ 37.53</td>
</tr>
</tbody>
</table>

Note: 1 EUR = 0.662893 GBP
Source: Submission from the Spanish Ministry of Health

\(^{83}\) The category in which a certain drug falls is decided by the nature of the disease treated only.
\(^{84}\) 7.2 per cent in 2004 according to EFPIA, Annual report.
\(^{85}\) The standard VAT rate in Spain is 16 per cent.
8.9 Pharmacies and wholesalers may under certain conditions be able to secure discounts or rebates from pharmaceutical manufacturers. This will increase their profit margin beyond the official margins stated above. For the government, there is no formal mechanism to identify any such discounts and consequently for taking advantage of those rebates.

8.10 Primary care is provided through general practitioners, who usually have their practice in Primary Health Care Centres. Every neighbourhood has its own health centre. Doctors are employed by those health care centres and are therefore tied to decisions or measures taken by their community or region. Patients have the right to choose their physician within the health area.

8.11 Hospitals are managed by the autonomous regions and hospital drugs are provided free of charge from the regional budget.

Institutions

8.12 The Spanish Medicines Agency (Agencia Espanola del Medicamento y Productos Sanitarios, AEMPS) is responsible for the evaluation, authorisation, inspection, vigilance and control of pharmaceuticals. The Committee for the Evaluation of Medicinal Products for Human Use (CODEM) is the associate body of the Spanish Medicinal Products Agency responsible for advising on the technical and scientific issues involved in the authorisation of new medicines.

8.13 The General Subdirectorate of Quality of Medicines and Health Products conducts the analysis that informs pricing and reimbursement decisions but has no decision-making power. It produces an evaluation document on new drug entities, based on the submission by the manufacturer as well as therapeutic benefit and effectiveness of the drug and writes a proposal to the Interministerial Commission on Pharmaceuticals.

8.14 Within the Ministry of Health, the Directorate General of Pharmacy and Health Products (DGFPS) decides on the reimbursement of new drug products. The Interministerial Commission on Pharmaceutical Prices – a Commission made up of representatives from the Ministry of Health, the Ministry of Finance and the Ministry of Industry – determines the price of a drug based on a proposal prepared by the General Subdirectorate of Quality of Medicines and Health Products (for reimbursable prescription-only pharmaceuticals). The Health Minister has the final decision-making power.

8.15 The Ministry of Health may set a time period for which the acceptable price for reimbursement is valid, and prices may be revised due to technical, budgetary or health-related issues. However, there are no formal post-launch price reviews.

86 Comité de Evaluación de Medicamentos de Uso Humano CODEM
87 Subdirección General de Calidad de Medicamentos y Productos Sanitarios
88 Dirección General de Farmacia y Productos Sanitarios
89 Comisión Interministerial de Precios de los Medicamentos
A new health law has recently been introduced in Spain on 27 July 2006 (Ley 29/2006). Although the law introduces some new measures and establishes some general practice as law, all details of the changes are not yet fully known.

It is, however, nearly certain, that the new legislation will establish an expert body to carry out clinical evaluation on the ‘added-value’ of new products. It is not yet clear which evaluation criteria will be used in practice by this body but it has been suggested that Spain's autonomous regions will be able to refer scientific experts to this body and will thus receive a means of eventually influencing pricing and reimbursement decisions. However, it seems clear that the new body will only issue an unbinding evaluation for use in the General subcommittee although details of the interaction between the bodies are not clear. The new body will be placed within the Spanish Medicines Agency and will be independent from government.

**Ex ante pricing and reimbursement controls**

Reimbursement decisions precede pricing decisions. The reimbursement decision is based on health criteria only whereas pricing decisions seem to be based on economic criteria and concern only reimbursed products. However, there are no formal health economic criteria used such as QALYS and the submission of pharmaco-economic studies is not mandatory.

Manufacturers receive a preliminary resolution regarding the Interministerial Commission's proposed price. In case of disagreement, manufacturers can appeal and a final decision is released through a resolution. If such a resolution indicates that the pharmaceutical is not going to be reimbursed, the manufacturer is able to launch the product as a non reimbursed product.

Pricing criteria mentioned in the law and by government are:

- **therapeutic value added (over other drugs on the formulary):** no formal criteria seem to be set out to determine 'value added' but it is the general rule that a drug that is found to have an added value can receive a 10-20 per cent price premium (over other drugs on the formulary). In practice the Directorate calculates daily dosages and compares those to similar drugs on the market. If the drug has no added value concerning end-points, morbidity and other relevant factors, the drug’s price will be fixed at the price of the cheapest equivalent product in the market. Under the new law, a new body will be involved in this ‘added value’ evaluation and thus new criteria might be established

- **international reference pricing:** the General Subdirectorates considers prices in different European countries but focuses especially on France, Italy and Portugal (as those are the countries with similar health systems and relatively low prices). The lowest price in any of these markets seems to be the guideline for any price proposal in Spain. Industry confirms that in price negotiations the cheapest price elsewhere in Europe is generally used as a 'price-ceiling' that cannot be exceeded
• **costs of R&D, production costs and profits:** the Spanish law mentions that the pricing decision should be based on a calculation of the 'total cost' of a drug; including R&D costs, production costs and a certain level of profits (12 to 18 per cent). This 'profit level' was initially introduced to grant companies a sustained level of profitability. However, although it is still mentioned in the law, the evaluation of the 'profit cap' has not been applied since the 1990s (as was confirmed by both government and industry).

• **sales forecast:** companies have to submit a forecast of sales for new drugs. It is not exactly clear what happens if companies exceed those limits but there seem to be repayments based on total sales (not on per-drug sales).

8.21 Therapeutic value added over existing drugs and international reference prices seem to be the most important criteria in Spain and prices are based upon low-price European countries. Even if provided for by law, drug prices are unlikely to rise after introduction. The price setting delay is circa six months.

### Ex post pricing and reimbursement controls

8.22 There is no formal ex post evaluation. However, by law the government has the possibility to carry out such evaluations. In practice, an infrequent delisting from the national formulary take place based on criteria of effectiveness.

8.23 The most binding constraint on prices have recently been a series of price cuts of:

• on average six per cent (four to ten per cent depending on the price of the drug) in 1999

• 15 per cent in May 2002 for a very limited number of above average priced drugs, and

• 4.2 per cent in 2005 as well as two per cent in 2006 on non-reference priced products marketed for over ten years.\(^9^0\)

8.24 Under the new law, an obligatory 20 per cent price cut for non generically available products commercialised for more than ten years will be put in place (even if a product is still under patent protection).

8.25 Another binding constraint is the internal reference pricing system in place for off-patent groups of chemically identical substances. A reference price is introduced if at least three off-patent drugs with equal substances are available in the market. The reference price equals the average price of the cheapest three daily dosages available and is reviewed every year. The new law will also changes some details on the reference price system although such changes are unclear at present.

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\(^9^0\) Source: Document submitted by the Spanish Ministry of Health and prepared by OBIG/Austrian Health Institute
8.26 Another measure by the Spanish government is an obligatory rebate scheme for manufacturers and pharmacists depending on the value of sales to the National Health Service. The system generated on average €60 million (£40 million) of rebates from manufacturers every four months previous to the new law of July 2006. These revenues are supposed to decrease after the introduction of the new law.

**Volume controls**

8.27 At the regional level, authorities issue prescription guidance, offer incentives for compliance to doctors and monitor closely the prescriptions through information systems.

8.28 For certain (mostly expensive) drugs with restricted therapeutic indications or conditions for use, the Spanish government and the autonomous regions have introduced a system of ‘health inspectors’. If a patient wants to receive a certain drug he must see a health inspector who will review the patient’s files and ‘accept’ the use of the drug. It seems to us that this measure has initially been put in place to control the use of drugs with limited indications but has been extended for cost containment purposes. The new law seems to further extend the scope for putting new drugs on those special lists.

**Generic pricing and penetration**

8.29 As an unwritten rule, generic entry will happen at 30 per cent below the branded product’s price and generics will be immediately reimbursed. Despite this the use of generic drugs is rather low, although it is increasing. Generics represented 14.1 per cent of all units sold within the National Health System and a 7.35 per cent of total pharmaceutical expenditure in 2005. Government claims that this low usage occurs because average drug prices are already very low in Spain and patients seem to manifest a strong preference for branded drugs.

8.30 By law, generic products can be substituted if a prescription is written generically or if a prescribed branded drug is priced above the reference price in its reference group. In those cases a generic product priced below or equal to the reference price can be dispensed. The pharmacy will be reimbursed on the actual price of the product as opposed to the reference price.

8.31 Regional governments promote the use of cheap generic drugs by setting a regularly reviewed91 ‘shadow reimbursement price’ that is lower than the national reference price. The shadow reimbursement price is, for example, set at the level of the cheapest available generic. In the case of a generic prescription, pharmacies are then free to choose which generic they want to dispense and will only be reimbursed at the price of the cheapest generic. This practice seems to have fostered price competition among generic manufacturers, but also on pharmacy discounts. Thus, the new law declared

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91 Every 3 months.
discounts to pharmacies illegal; it remains to be seen if former discounts will be now passed through to consumer prices. Overall, however, as prices are seen to decrease sharply after generic entry, the shadow price policy seems to have fostered competition among generics (and brands).

8.32 Despite its achievements, the downside of the 'shadow reimbursement price' policy is that patients may receive a different kind of pill every time they go to the pharmacy. This may affect patients’ confidence.

Industry view

8.33 Industry criticises the unpredictability in the Spanish system which is said to be due to a lack of stability and transparency of the assessment criteria. The Spanish system is said to be based on too many different measures that make the system unstable. The price setting mechanism is considered to lack transparency and to be time-consuming. Industry also complains about a lack of a clear framework for R&D investment and links between private and public research that would improve research outcomes.

Key issues

8.34 Parallel trade of pharmaceuticals from the low priced Spanish market into the high priced European Countries such as the UK and Germany has increased over recent years. Although the Spanish government had already taken preliminary steps with the introduction of Article 100 in the previous health law, problems with shortages in certain pharmaceutical products arose. Currently Spain seems to be faced with shortages of drugs especially in certain rural areas; insulin products were one of those mentioned to us where availability was compromised temporarily.

8.35 In the new health law the government has re-stated in Article 90 that Spain seeks to regulate prices in their national territory only (emphasis added) and has also introduced a new provision under Article 87 on ‘traceability’. This is supposed to oblige wholesalers and manufacturers to communicate sales data to the government on all drugs sold for the public market. With this measure, the government wants to track and control when and where drugs are sold and in what quantities. This system will also guarantee security for the patient. The system might be put in place via a barcode system on drug boxes that identifies each drug by a code.

8.36 Industry is in favour of the ‘traceability of products’ but worries that manufacturers will have to carry the financial burden.

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92 Ley 25/1990, of 20 December 1990, Titulo VIII, Article 100(2), "El Ministerio de Sanidad y Consumo,..., establecerá el precio industrial máximo con carácter nacional, para cada especialidad farmacéutica ...", [emphasis added];

93 Ley 29/2006 of 26 July 2006, Article 87 'Garantías de trazabilidad';
In March 1998 Glaxo Wellcome (a Spanish subsidiary of GSK) adopted new General Sales Conditions that stipulated its medicines would be sold to Spanish wholesalers at prices differentiated according to the national insurance scheme which would reimburse them. In practice, medicines to be reimbursed by other Member States of the Community would be sold at a higher price than those to be reimbursed in Spain. That system was introduced in order to limit parallel trade in medicines between Spain and other Member States, in particular the United Kingdom, where prices were fixed at a higher level.

The measure was taken after the Spanish Health Law explicitly declared that Spain would only limit pharmaceutical pricing on its own national territory.

In May 2001, the European Commission decided that the General Sales Conditions were prohibited by Community competition law because they constituted an agreement that restricted competition. It also decided that GSK had failed to prove to the Commission that the conditions necessary to justify such an agreement were satisfied. It therefore ordered GSK to bring the practice to an end.

GSK requested the Court of First Instance (CFI) to annul the Commission decision, which it did in part in September 2006. The CFI’s view was that although the Commission was correct to state that GSK’s General Sales Conditions restrict competition by preventing the price and the cost of medicines from falling, the Commission did not sufficiently examine the question as to whether or not they might give rise to an economic advantage by contributing to the financing of innovation and should be permitted.

The CFI found the Commission was right to conclude that the General Sales Conditions constituted an agreement between undertakings. However, it found that the Commission’s main conclusion - that the General Sales Conditions had as their object the restriction of competition because they made provision for differentiated prices which sought to limit parallel trade in medicines - was incorrect. In particular, the Commission did not take into account the fact that the prices of medicines reimbursed by the National Insurance schemes are not freely determined by supply and demand, but rather set or controlled by the Member States. For that reason, it could not be presumed that parallel trade tends to reduce prices and increase the welfare of final consumers, as it would do in the absence of those special regulations.

The Court considered that GSK had not succeeded in invalidating the Commission’s subsidiary conclusion that the General Sales Conditions have as their effect the restriction of competition. Given the measures taken by certain Member States to recover a part of the profits made by parallel traders, for the benefit of the National Insurance schemes and patients, the CFI concluded that parallel trade permits a limited but real reduction in the price and the cost of medicines, in so far as they prevent that advantage from being produced, the General Sales Conditions diminish the welfare of final consumers.

Finally, the CFI found the theory that the General Sales Conditions might give rise to an economic advantage by contributing to innovation which plays a central role in the pharmaceutical sector, was not examined with sufficient thoroughness. The Commission did not take into account all the factual arguments and the relevant economic evidence, and did not sufficiently substantiate its conclusions.
The LFN decides about the reimbursement status and sets the price of reimbursed outpatient medicines. Decisions are made on cost-effectiveness grounds. There are no direct negotiation on price.

The LFN reviews all medicines on the Swedish markets (as of October 2002). This will be an ongoing process. Reviews are taking place in drug groups and will establish which drugs will be continued to be reimbursed and at which price (range). Drugs are compared to similar treatments and possible generic alternatives. Cost-effectiveness in different indications is considered.

Once a drug is off-patent, the pharmacy monopolist Apoteket AB issues monthly tenders for the supply of this drug. The supplier with the lowest price can supply the entire volume of the drug for the Swedish pharmacy market for a month.

Sources of health care funding

9.1 Sweden has a universal health care system that covers all inhabitants. Health care is funded by taxation (local and national) and provided through county councils. The private health care sector is very small. Medicines for in-patient care are funded directly by the county councils that negotiate with drug companies over prices. Medicines for outpatient care (whether prescribed in hospitals or clinics) are funded through patients’ payments (about 20 per cent of the total cost)\textsuperscript{96} and government grants to the county councils (about 80 per cent).

9.2 The government grant is based on factors such as population size and characteristics and is set in advance for three to four years. Within this period county councils have to fund any excess of actual expenditure\textsuperscript{97} but can keep any savings, at least until the

\textsuperscript{96} All patients pay the first SEK 900 (circa £66) of the cost of medicines per year, but above this amount patient payments are reduced on a sliding scale and the maximum payment per family is SEK 1800 (£132). There is no exemption for the elderly or those on low incomes. 1 SEK was approximately 0.073 GBP as of 2 February 2007.

\textsuperscript{97} Except in extreme cases of overspending, when the Government will help.
grant is reset. Hence county councils are encouraged to control spending on outpatient care and attempt to do so via their medicine committees which encourage cost effective prescribing practice, for example through formularies. These do, however, have limited ability to influence prescribing of individual physicians. On aggregate, the county councils were, in 2005, under-spending against grants, most likely due to larger than expected savings on generic drugs (although the positions of individual councils varies). The county councils are not able to negotiate discounts on outpatient medicines obtained via Apoteket AB (the state-owned pharmacy monopoly).

Pharmaceutical supply chain

9.3 Outpatient medicines are obtained by patients from branches of Apoteket AB. Apoteket AB obtains its supplies from two wholesalers (Tamro and Kronan), which receive a margin of about three per cent from the manufacturers. Apoteket AB also obtains supplies from parallel importers. Apoteket AB’s margin varies according to a sliding scale which gives a larger percentage margin for lower value items: we were told it averages about 17 per cent.

Institutions

9.4 The LFN (Pharmaceutical Benefits Board) sets reimbursement prices (see below). The LFN is a small agency with 30 employees, mainly pharmacists and economists. The SBU (Swedish Council on Technology Assessment in Health Care) carries out health technology appraisals. The SBU currently publishes three series of assessment reports on health technology. Its yellow reports are comprehensive reports covering a whole subject area, its alert reports are early assessments of single, new methods that are being developed and disseminated in health care and its white reports provide exploratory ‘state of the art’ information on topics that may need to be assessed.

Ex ante pricing and reimbursement controls

9.5 The LFN decides on the reimbursement status and sets the price of reimbursed outpatient medicines. The LFN has three criteria for its decisions:

- human value: respect for equality
- need and solidarity: those in greatest need take precedence, and
- cost effectiveness.

9.6 LFN carries out its cost effectiveness analysis from a societal perspective, that is, it tries to take account of all costs and benefits. If it is difficult to calculate QALYs, LFN may calculate benefits using patients’ average willingness to pay for treatments as a measure of benefit.

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98 It sets both wholesale and retail price, the difference representing Apoteket AB’s margin.
9.7 The LFN decides whether or not a medicine should be reimbursed for outpatient use at the price proposed by the manufacturer. It does not negotiate on price, although the manufacturer may withdraw a proposal and resubmit at a lower price. If the LFN concludes a medicine is not cost effective it does not say at what price it would judge the drug to be cost effective.

9.8 The LFN has a maximum of 180 days to make its decision, its administrative target is 120 days and the average time taken to make a final decision is 90 days.

9.9 Some decisions not to reimburse certain medicines have been appealed to an administrative court and have not yet come into force. The administrative court reassesses the LFN’s decision on its merits and is not limited to judicial review.

9.10 There is a simplified approach for the evaluation of parallel imports and generics. Those are approved as long as their price is not above that of similar medicines already approved for reimbursement.

**Ex post pricing and reimbursement controls**

9.11 Since the current Swedish pricing system started in October 2002, the LFN has started a process of revision of all licensed medicines. All medicines approved before October 2002 continue to be reimbursed at their existing price until reviewed by LFN. The LFN is reviewing existing medicines in groups: in June 2006 it finished reviews of two groups (migraine and stomach acids) and the reviews of a further 50 groups, covering around 2000 reimbursed medicines, are expected to be completed by the end of 2009 (the first six of these have been started).

9.12 The review of stomach acids covered proton pump inhibitors (PPIs), H2 antagonists and some other medicines and represents a useful example of its approach. LFN found that PPIs, with the exception of esomeprazole (see below), had similar effects to each other. LFN allowed continued reimbursement of PPIs as long as the price was no more than about 25 per above generic omeprazole. It discontinued reimbursement of more expensive PPIs. LFN stopped the reimbursement of all H2 antagonists and various other medicines on the grounds that they were only cost effective in treating milder forms of the disease and that the impact on patients’ quality of life of such milder forms was very small.

9.13 As regards esomeprazole, LFN considered that it by and large achieved similar results to other PPIs, but gave better treatment outcomes in the treatment of heartburn with ulcers on the oesophagus. As its treatment costs were higher, LFN limited reimbursement to patients where ulcers in the oesophagus had been diagnosed or where other PPIs had not achieved a satisfactory result. We were told that, after completion of the LFN’s review, the manufacturer of esomeprazole was fined SEK100,000 (£ 7,332) for issuing a notice to doctors that provided misleading advice on the continued reimbursement of esomeprazole. It is worth noting that, unlike in other countries, LFN has no facility to limiting premium reimbursement to a specific level of prescribing volumes.
Manufacturers may apply to increase or decrease the price of reimbursed medicines. Decreases are agreed routinely while increases may be considered in a similar way to the evaluation of new medicines. However, the LFN told us that it did not accept price increases unless there was a high risk of the medicine disappearing from the market and patients having a high need for it.

Manufacturers can appeal against a decision not to increase a price. Alternatively, the manufacturer can withdraw the medicine from the reimbursement system and make a new application for reimbursement.

**Volume controls**

For in-patient medicines, the county councils (rather than individual hospitals, which are mostly controlled by the county councils) negotiate with manufacturers for drug prices. Each county council will tend to include leading doctors in its region during negotiations over price. The councils tend to get better prices each year by playing manufacturers with substitutable medicines off against each other. A county council cannot guarantee volumes but they do work hard to get their list of preferred medicines used in hospitals. They have succeeded in moving away from specific price/volume trade-offs and towards getting a negotiated flat price. We were told the highest discounts averaged about 30 per cent although on more normal medicines they were about ten per cent (compared to the outpatient list price). No discounts were available on drugs without close substitutes, for example new oncology drugs.

Under the current system the county councils are not allowed to negotiate prices with manufacturers in outpatient care but instead have medicine committees which make recommendations to physicians on prescribing practice. We were told that each year the pharmacy boards make stronger and stronger recommendations and that compliance by prescribers was getting better.

**Generic pricing and penetration**

Sweden has a generic substitution regime. Apoteket AB substitutes a generic for a branded product unless the doctor indicates otherwise on the prescription form. This only happens in a small number of prescriptions. There are about 16 generic suppliers in Sweden, which account for 14 per cent of the wholesale market by value and 41 per cent by number of prescriptions.

LFN adjusts its price list of reimbursed medicines once per month. Since Apoteket AB takes the cheapest supply on about 96.5 per cent of prescriptions, the generic supplier submitting the lowest price in a particular month potentially gets nearly all of the outpatient business for the month. This creates a strong incentive for generic suppliers to price very low. Sweden thus has a highly competitive generic sector.

We were told that generic substitution was a main reason for the lower growth in expenditure on outpatient medicines since 2002. Expenditure had been increasing at about ten per cent per year in the 1990s but the rate of growth has reduced to eight
per cent in 2002. 2.3 per cent in 2003, 0.2 per cent in 2004 and 0.4 per cent in 2005.

Industry view

9.21 The industry was supportive of the LFN but concerned with the power of the county councils, some of which were underspending against their government grants. The industry also criticised the county councils’ medicine committees which it said were trying to reduce the take-up of new medicines.

9.22 Swedish industry had initially been opposed to using health technology analysis (HTA) to decide reimbursement issues but, having seen that HTA could support the reimbursement of expensive drugs, is now in favour. It also accepted generic substitution, which was working well. The industry’s view was that savings from generic substitution should be spent on new medicines.

9.23 The industry thought the LFN was transparent and keen to engage in a dialogue, for example brainstorming events have been held from time to time. The Swedish system was argued to be better than many other systems, in particular because of its transparency and because decisions were made according to objective criteria. Compared to some other countries, industry regarded it as positive that decisions were not based on negotiations between the authority and the manufacturer which were time consuming and led to game-playing.

9.24 The industry was pleased that the LFN’s assessments of new medicines had, in nearly every case, resulted in the new medicine being reimbursed. The industry was less happy with the reviews of existing medicines by therapy groups. In particular, it did not like the idea of groups including both in-patent and out-of-patent medicines.

Key issues

9.25 Sweden is notable for its coherent and well-organised approach to drug pricing and its competitive generic sector. The completion of the LFN’s reviews of all existing medicines on the Swedish market is a very interesting process to follow up. Sweden is one of the only countries that is undertaking such an extensive review of existing drug groups on its market. It will be also interesting to see how reviews already carried out will be updated periodically in the future.
Sources of health care funding

10.1 The Swiss health care system is a compulsory private system where patients pay a monthly variable fee a to registered health insurance fund. All insurers reimburse against a common national formulary. Patients generally make a co-payment of ten per cent on each service delivered, including not only pharmaceuticals but also treatment costs (doctors, physiotherapists, etc). Payments from these co-payments are limited to CHF700 (circa £289) per year. The Swiss government does not add funds to the insurance system.

10.2 Although fees can differ between insurers, patients do not often switch between insurers and active competition is therefore limited. Overall, insurance premiums have been rising at about five per cent per year.

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99 The monthly fee is variable. The reason for this is that the insured choose an 'excess' charge (similar to car insurance) where they pay the first 350 CHF – 2500 CHF (circa £144 - £1028) of health care cost out of pocket (in addition to their monthly premium and co-payments). Depending on the value of the 'excess' their monthly premium is fixed. Exchange rate: 1 CHF = 0.411087 GBP (10 February 2007).

100 This threshold payment is not based on a percentage of a patient’s income – like in many other countries – but is a fixed threshold.
Currently the Swiss positive list comprises approximately 2,500 drugs. Criteria for reimbursement are clinical effectiveness and economic efficiency. The BAG (Ministry of Health) is responsible for administering prices and reimbursement. Prices (for new products) are set based on the evaluation of the drug and the company’s price proposal. In some cases drugs may receive an innovation bonus of 10 to 20 per cent of the value of the drug should the drug show increased efficacy or a better risk profile than existing treatments. There is a formal appeal procedure against decisions made by the BAG.

Currently, 30 per cent of the drug volume and 20 per cent of the value of drugs sold in the Swiss market are OTC drugs. Out of pocket payments on pharmaceuticals amount to circa ten per cent of total drug expenditure.

**Pharmaceutical supply chain**

The BAG defines the ex manufacturer reimbursement price. Margins for retailers and wholesalers are composed of a fixed and a variable component. How the margin is distributed among those depends on negotiation and bargaining. The variable margin equals 15 per cent of manufacturer price for drugs costing below CHF 879.99 (circa £362). Above this the margin is ten per cent. Additionally there is an increasing fixed margin of CHF 4 to CHF 240 (circa £1.64 - £99) depending on the price of the drug.

In some cases wholesalers and retailers are vertically integrated and due to the rural character of Switzerland a significant number of doctors are allowed to dispense drugs.

Pharmacists and dispensing doctors receive a regressive margin determined by the retail price – the higher the price the smaller the margin in percentage terms. Nonetheless, pharmacists earn more from dispensing expensive, as opposed to lower cost, pharmaceuticals.

Hospitals can legally be supplied at prices lower than the maximum price determined by the BAG.

There have been complaints about hidden rebates given to pharmacies and dispensing doctors by manufacturers to influence dispensing. As those rebates were not passed through to the consumers, the Swiss government has decided to monitor pharmacies better in the future.

Parallel trade of patented products is not an issue in Switzerland as Switzerland is not a member of the European Union or the EEA. Parallel trade products can only enter the Swiss market once the patent protection for a product has expired.

**Institutions**

Swissmedic is responsible for registering drug products, drug licensing and drug surveillance.
10.12 BAG makes the decisions on reimbursement and pricing of all prescription drugs in the market which it takes three to four months to do. It also conducts regular price reviews of the drugs on the formulary.

10.13 The Federal Commission on drugs is a body assisting the BAG with expert advice. This Commission has 28 members and meets five times a year to discusses new drugs and drug indications that have applied for reimbursement. The Commission gives a recommendation for reimbursement as well as price (the latter in a less detailed form).

Ex ante pricing and reimbursement controls

10.14 After a license has been granted, new drugs that want to be taken onto the list of reimbursable drugs, have to apply to the BAG. The BAG pharmacists then prepare an evaluation of a drug’s clinical efficacy and cost effectiveness. The BAG presents its evaluation to the Federal Commission on drugs that gives a recommendation on reimbursement and pricing. There are clear guidelines on what evidence the Commission and the BAG expect to see in a manufacturer’s submission.

10.15 The BAG can (but need not) follow the recommendations of the Federal Commission. It generally follows the recommendations concerning reimbursement but has a relatively large leeway to decide pricing. Drugs can only be reimbursed in the Swiss market once a decision on pricing has been made.

10.16 There is a procedure for a fast track reimbursement access for innovative drugs. If Swissmedic recognises a product as ‘fast-track’, drug files can be submitted to the BAG before the official licensing decision, and the drug’s dossier will be sent by email to the Federal Commission on drugs. The BAG may abstain from a formal meeting and discussion with the Federal Commission and instead ask for a written statement. This shortens the decision process significantly.

10.17 Pricing decisions may include the following analysis:

- a comparison of the new drug with reimbursed and non reimbursed therapeutic equivalents. Those may be either within the Swiss market but may also include drugs that are only available outside Switzerland
- a cost effectiveness analysis (yet considered to be less important), and
- the drug’s price in Denmark, Germany, Great Britain and the Netherlands. The price in Switzerland should not lie above the average price of those four countries.

10.18 Overall, the pricing decision is not a very formal process following strict rules. If a new drug has a therapeutic equivalent it is assessed on its therapeutic benefits. QALYs are not used but in practice additional benefits do tend to translate into a price increase. For new drugs the BAG looks at reference countries but often Switzerland is one of the

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101 If one of those countries should not be available prices in France, Italy and Austria may be used as substitutes.
first countries to have a drug launched. Then the BAG tends to accept the price the company initially proposed knowing that a drug review will take place within 24 months time. The 24 months review thus accelerates the ex ante decision-making process.

10.19 At launch, the innovation bonus of 10 to 20 per cent - above the price of a similar product in the Swiss market - is granted if the Commission and the BAG find an additional, relevant market benefit in a product. After the first review, the bonus allows the product to still be 10 to 20 per cent more expensive than the average price in the European reference countries. There are no detailed criteria for innovation, but on average ten per cent of all new drugs on the market receive this bonus. After patent expiry the bonus expires and the price of the product has to equal the average reference price. Innovative drugs constitute 11 per cent of total health care costs on the Swiss market, which is relatively high compared to other countries such as, for example, France where only two to three drugs per year are recognised as innovative.

Ex post pricing and reimbursement controls

10.20 The Swiss system is based on a system of frequent (scheduled) price reviews and price cuts based on an international reference basket. Those reviews help to keep costs at a 'European level' but grant on the other hand sufficient flexibility upfront.

10.21 Initially, reimbursement prices are reviewed after 24 months. At this stage the price in the Swiss market is compared with the average price of the same drug in Denmark, Germany, the UK and the Netherlands. Manufacturers must re-pay any difference in revenue if the initial reimbursement price of a drug is considered inappropriate when reviewed by the Federal Drug Commission. Thus, should the price of the drug in the Swiss market exceed the reference countries' average price by more than three per cent or, should the difference in the drugs' revenues be higher than 20,000 CHF (£8,450), the surplus revenue is reclaimed and the price of the drug decreased. Through this mechanism Switzerland claims to ensure against paying excessive prices, despite being a first-launch market. The ex post mechanism also ensures that ex ante decisions can be made in a shorter time and with less rigidity.

10.22 Price increases are possible and can be requested every other year. They are dealt with by the BAG and decided within three to four months time. They are however very rarely granted.

10.23 Branded products which have been granted a new indication have an additional price review seven years after their market introduction. At this point, cost effectiveness is examined as well as the relative price of the drug compared to prices in the reference countries (see above).

102 France, Italy and Austria are used as a subsidiary basket.
At patent expiry or, at the latest, after 15 years, prices of the original branded drug are reviewed again and prices are lowered. Prices are adjusted to the lowest price in the four reference countries (Denmark, Germany, Great Britain, Netherlands). Cost effectiveness reviews are also undertaken. After a further two years, a drug’s price is reviewed again and eventually lowered depending on generic competition and new treatment methods available.

Volume controls

Swiss insurance companies monitor doctors through peer reviews and the threat of audit. There have never been cases of lawsuits but doctors seem to monitor their own spending because they consider that high spending could cause future disadvantages. Those disadvantages could for example arise if insurers were in the future allowed to select, contract or reimburse only certain doctors of their choice.103

Generic pricing and penetration

Generics are reimbursed if they enter the market at a price at least 30 per cent cheaper than the original product. After 24 months generics prices are again reviewed and maybe lowered.

A recent measure to make further savings on branded and generic drugs is that branded products have to lower their price by 30 per cent when going off-patent; otherwise patients will have to make a 20 per cent co-payment (instead of a ten per cent co-payment) when buying an off-patent branded product. To ensure further benefits from generics use, the BAG also plans to introduce a system where generics prices have to be reduced on an annual basis.

Pharmacies are obliged to inform patients about available generic alternatives. Since recently pharmacists are able to dispense a generic drug if doctors have not formally opposed substitution of the branded product. However, it seems that pharmacists do not have a clear incentive to dispense the lowest priced product as margins of branded and generic drugs are similar (see 10.5) or, indeed, even higher for brands. No reliable data is yet available to show how often generics are substituted. As co-payments are, relatively high in Switzerland and calculated as a percentage of the drug price, it might be that patients will from now on push pharmacists to dispense cheaper alternatives. Additionally, the new law that introduces higher co-payments for high priced branded off-patent drugs might increase the use of generics in general.

Currently, the Swiss generic market is, despite all efforts, relatively small; only 5.9 per cent of pharmaceuticals on the market are generics (EFPIA annual report). 23 per cent of all off-patent drugs are available as generics in the Swiss market.

103 Insurers would like to move to such a system where they could freely choose which hospital and doctor to reimburse.
Industry view

10.30 There seems to be much interaction between institutions, ministries and industry in Switzerland which creates a friendly and stable environment for discussion on both sides. Companies seem to value the positive approach of discussion and interaction between the different stakeholders in the Swiss system.

10.31 Companies value the relatively quick access to the Swiss market and the recognition of innovation for a relatively wide range of products. Prices are also relatively high in Switzerland, which largely explains companies’ positive views.

Key issues

10.32 In the view of both government and industry, the Swiss system provides a relatively quick and well organised access to the market despite its ex ante pricing and reimbursement system. This is achieved through fast-track arrangements and fast decision-making processes, which are themselves facilitated through the ex post review mechanism, which ensures ex ante decisions can be corrected if necessary. The fact that there is a review mechanism to adjust prices ex post gives decision-makers the leeway to make faster and more flexible decisions upfront.

10.33 It should be noted however that the Swiss system relies heavily on international reference pricing (IRP) – that is, on the judgements of other countries regarding the appropriate price of pharmaceuticals. Clearly such an approach could not be adopted by all countries. In particular, as discussed in Annexe L, we do not consider it to be a feasible option for the UK, given the important role of the UK in the IRP systems of other countries.

10.34 Finally, it should also be noted that there is a significant financial burden on patients for access to pharmaceuticals in Switzerland. This is largely incurred through high private insurance premiums.
11 **THE US**

The PBM (Pharmaceutical Benefit Manager) evaluates drug effectiveness and negotiates discounts with manufacturers and pharmacies. Scientific Pharmacy and Therapeutic Committees (within a PBM) carry out clinical effectiveness assessments and give a recommendation for inclusion on the formulary. The PBM manages the formulary (based on price and discounts) and takes decisions on co-payments based on a three tier structure.

The size of discounts a PBM receives from a manufacturer depends on the number of patients/plans a PBM represents.

Each drug plan decides if it wants (outside the PBM formulary) additional products to be reimbursed under its health plan.

Reimbursement

Off-patent

Licensing

The Medicaid statute requires rebates from the drug manufacturers. These obligatory rebates for the public system are based on average wholesale prices and are updated on a yearly basis.

Generic prices are negotiated between pharmacy chains/pharmacy buyer groups and manufacturers. As pharmacies have generic substitution rights they have buyer power and can negotiate large discounts.

PBM reimburse pharmacies on the level of a maximum allowable charge (MAC) – a flat price for all drugs with equal molecule and strength.

### Sources of health care funding

11.1 There are three main routes of access to health insurance in the United States. The first is through an employer or a family member’s employer health coverage (for adults under the age of 65 and children). The second route of access to healthcare is through a government programme (for those 65 and over or the poor) and the third route is the purchase of an individual private insurance policy.

11.2 It is estimated that approximately 85 per cent of the US population has health care/insurance coverage. Most citizens over 65 will have coverage either through government programmes such as Medicare, Medicaid and the Veterans Association (VA), or through a private individual healthcare package or a combination of both. For most citizens under the age of 65 their healthcare package is obtained through their employer or a family member’s employer package, or in some instances through the
purchase of individual insurance packages. However, about 15 per cent of citizens are uninsured.\textsuperscript{104}

Publicly-funded programmes

Publicly-funded programmes include the following:

- the Medicare programme,\textsuperscript{106} consisting of two parts (A&B), is a nationwide health insurance programme providing health insurance to people aged 65 or over, people entitled to Social Security disability payments for two years or more, and people with end-stage renal disease, regardless of income
  - Medicare Part A covers most Americans over 65 and provides hospital insurance coverage. It does not cover pharmaceuticals. Medicare provides coverage for approximately 40 million elderly (over 65) and disabled Americans\textsuperscript{106}
  - Medicare Part B is optional and provides supplementary medical coverage for doctors’ visits and diagnostic tests. It is heavily subsidised by the federal government\textsuperscript{107}
  - Medicare Part D is optional and beneficiaries receive prescription medication by purchasing subsidised\textsuperscript{108} coverage from a selected list of insurance plans that staff at the Center for Medicare & Medicaid Services (CMS) have approved

- the Medicaid programme\textsuperscript{109} is a nationwide health care programme that is operated and administered by the states, with Federal financial participation. Within certain broad federally determined guidelines, states decide who is eligible; the amount, duration, and scope of services covered; rates of payment for providers; and methods of administering the program. The programme, authorised by Title XIX of the Social Security Act, is designed for the poor. It does not cover all of the poor, but only persons who meet specified eligibility criteria. Medicaid provides coverage for approximately 50 million Americans. Medicaid covers young children, pregnant women and low-income adults whose family income is at or below 133 per cent of the federal poverty level.

\textsuperscript{104}This official number may in practice vary as some uninsured persons may be eligible for Health Care funding under the Medicaid program (see below) and on the other hand some people over the age of 65 might not be enrolled in the Medicare program.
\textsuperscript{105}Medicare is run by the US federal agency Center for Medicare & Medicaid Services (CMS).
\textsuperscript{106}Health insurance for people aged 65 or older, under 65 with certain disabilities, and any age with End-Stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).
\textsuperscript{107}Many Medicare beneficiaries also purchase Medicare Supplementary Insurance (Medigap) policies or have coverage from a former employer. Medigap policies are federally regulated and must include specified core benefits.
\textsuperscript{108}The public subsidy consists of a very low insurance premium (US$ 20-30 per month) for the patient and a re-insurance of the health plan that any payment exceeding US$ 5000 (per enrollee per year) would be covered by public funds.
\textsuperscript{109}Medicaid is run by the US federal agency Center for Medicare & Medicaid Services (CMS).
11.4 Other public programmes are:

- **State Children’s Health Insurance Program (SCHIP)** is an optional Federal/State partnership. Its main objective is to provide insurance to children whose families are not eligible for Medicaid and cannot afford private insurance.\(^{110}\)

- **TRICARE/CHAMPUS** is a military health care program for persons in active duty and retired members of uniformed services, their families, and survivors.

- **Veterans Association (VA)**, The Department of Veterans Affairs provides medical assistance to eligible veterans.

- **Indian Health Service (IHS)** provides medical assistance to eligible American Indian and Alaska Native people at IHS facilities.

**Privately funded programmes**

11.5 Privately funded health insurance is obtained either through an individual’s employer, their spouse’s employer or through self purchase healthcare plans. In most instances family members, including children, are covered through a company’s health care plan. However, this is not always the case.

11.6 Individual insurance policies are generally more expensive and less comprehensive than group policies. These individual policies can be purchased through insurance companies that provide managed care. It was estimated that in 1999 approximately seven per cent of the population under 65 obtained health insurance coverage through individually issued, non-group policies.

11.7 Companies provide health care insurance mostly in two ways, either by contracting directly with an insurance company (Managed Care Organizations (MCO)) or by creating an employers’ self-funded plan. Employers offering health care through an insurance company will negotiate for a package of benefits at a specified monthly premium per person or per family. Employers providing self-funded plans (self-insure) assume 100 per cent of the risk of expenses from their employees’ health care coverage. These self-funded plans are very common. Companies can also choose to provide a self-funded plan managed by insurance companies who administer and process claims, and provide access to a provider network.

11.8 For privately funded programmes like employment-based insurance and individual insurance, the federal government provides subsidies through the tax code. That means that employer contributions for health insurance coverage are deductible to employers, but are not considered taxable income to employees and retirees.

\(^{110}\)SCHIP provides grants to states to provide health insurance coverage for uninsured children. It is estimated that in 2003 5.8 million children were enrolled in SCHIP. Like Medicaid, SCHIP participants are enrolled in managed care and receive certain key health benefits.
11.9 Although the employer contributes to the cost of healthcare it offers, the employee ultimately pays for the majority of the cost of healthcare in monthly premiums, which are reflected in lower salaries and benefits. It should be noted that not all employers offer health care insurance and in some instances they will only insure those working full time.

Sources of funding

11.10 According to the Federal Trade Commission report on Improving Healthcare, the United States spent approximately 14 per cent of gross domestic product, or $1.6 trillion (circa £0.82 trillion\textsuperscript{111}) on health care services in the United States in 2002. Public Sector health care services (funded by federal, state, and local government) accounted for approximately 45 per cent of the total expenditure on healthcare. Private insurance and other private spending accounted for 40 per cent of total healthcare expenditure - 35 per cent by private insurance and five per cent by other private funds - while consumer out-of-pocket expenses accounted for about 14 per cent.\textsuperscript{112}

11.11 Expenditure on prescription drugs amounted to just under $190bn (circa £97.6 billion) in 2004, about 10.2 per cent of total health expenditure. Private expenditure accounted for over 70 per cent of this total (just under 50 per cent private insurance and about 25 per cent out of pocket expenditure). The breakdown in expenditure is shown in greater detail in the table below, which draws on data from CMS.\textsuperscript{113}

\begin{table}[h]
\centering
\begin{tabular}{lcccccc}
\hline
\textbf{Sources of funding} & \textbf{2004} & \textbf{2003} & \textbf{2002} & \textbf{2001} & \textbf{2000} \\
\hline
Prescription Drugs & $188,452 & $174,112 & $157,941 & $138,559 & $120,803 \\
Private Funds & 72.5\% & 73.5\% & 75.2\% & 76.2\% & 77.1\% \\
Out-of-pocket Payments & 24.9\% & 25.1\% & 25.3\% & 26.1\% & 27.7\% \\
Pvt Health Insurance & 47.6\% & 48.4\% & 49.8\% & 50.0\% & 49.4\% \\
Public Funds & 27.5\% & 26.5\% & 24.8\% & 23.8\% & 22.9\% \\
Federal Funds & 16.9\% & 16.1\% & 14.6\% & 13.9\% & 13.1\% \\
State and Local Funds & 10.6\% & 10.4\% & 10.2\% & 10.0\% & 9.8\% \\
\hline
\end{tabular}
\caption{Expenditure on prescription drugs in the US by source of funds}
\end{table}

\textsuperscript{111}All subsequent currency exchanges to British Pounds were based on exchange rates from 12 February 2007, 1 USD = 0.513739 GBP. The numbers thus only give a rounded indication of values in pounds and were not period or purchasing power parity adjusted.

\textsuperscript{112}\textit{Improving Health Care: A Dose of Competition} - A Report by the Federal Trade Commission and the Department of Justice July 2004

\textsuperscript{113}www.cms.hhs.gov/NationalHealthExpendData
It is noteworthy that almost 25 per cent of expenditure on prescription pharmaceuticals in the United States was paid out-of-pocket, that is directly met by patients. This is more than five times as much as patients in the UK pay and significantly more than citizens in many other European countries. These 25 per cent include payments for drugs made by uninsured citizens but exclude premium payment made by privately insured to their respective private insurance.

It should also be noted that the proportion of prescription drug expenditure met by Federal Funds will be expected to have increased in 2005, when Medicare Part D came into force. The proportion met by State and Local funds will be expected to have declined, due to relatively poor elderly people moving from state funded Medicaid programs to Medicare part D.

Institutions

The Center for Medicare & Medicaid Services (CMS)\textsuperscript{114} is a US federal agency which administers Medicare, Medicaid, and the State Children’s Health Insurance Program. It delivers healthcare to the over 65s and others with qualifying medical conditions, and to the poor. CMS does not contract for medicines (as it does not cover drugs under the general Medicare entitlement). CMS however receives statutory rebates for drugs under the Medicaid program.

Managed Care Organizations, (MCOs) are responsible for the financing and delivery of health care services. MCOs create networks of preferred providers (physicians, hospitals etc) or directly employ physicians to provide care. Managed care organizations thus create a network of practitioners that deliver health care services to their members. MCOs either offer insurance plans to employers or individuals directly, or provide their network to private employer plans. They may also handle claims processing for employer plans. MCOs are paid by employers or patient groups' contributions. The main (different) types of MCOs are health maintenance organizations (HMO), point of service plans (POS) and preferred provider organizations (PPOs).\textsuperscript{115}

Pharmaceutical Benefits Managers, (PBM) manage the pharmacy benefit, that is, all drugs available, for a group health plan. They are employed by HMO plans, self-insured employers, indemnity plans, labour union plans or plans covering public employees to

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\textsuperscript{114}Full name also the Department of Health and Human Services Centres for Medicare and Medicaid Services;

\textsuperscript{115}A HMO (Health Maintenance Organization) is a health plan that is involved in how health care is delivered. They coordinate health care with patients and providers that participate in the health plan. HMOs are the most common type of managed care and are typically owned by insurance companies.

POS (Point-of-service plans) allow patients to select a primary care gatekeeper; however they can use out-of-plan physicians for some services which then allows for more choice and flexibility.

PPOs (Preferred provider organizations) are similar to POS programs. A key difference is that they do not require a coordinating primary care physician. Instead, PPOs have a panel of 'preferred providers' who agree to accept discounted fees. Some physicians who wish to avoid managed care entirely have begun 'concierge practices', where they provide personalised care, including house calls, to patients willing and able to pay out of pocket for health care costs.
find the ‘best deals’ for pharmaceuticals. PBMs contract with pharmaceutical manufacturers on behalf of health care plans to obtain brand name and generic drugs for consumers. PBMs are regulated both by State and Federal law. These regulatory requirements apply directly or indirectly to discrete functions that are performed by PBMs, regardless of whether the PBM is an independent organization or an internalised function within a health plan.

### Pharmaceutical supply chain

11.17 PBMs manage the pharmacy benefit for both private and public access to pharmaceuticals to a large extent. The Pharmaceutical Care Management Association ‘PCMA’ estimates that about 70 PBMs manage approximately 80 per cent of all expenditure on prescription drugs in the U.S.

11.18 Private healthcare plans contract with PBMs to handle the pharmacy benefit for their enrollees and obtain discounts for prescription drugs. Similarly, Medicare Part D drugs prescription plans benefits are managed by PBMs.\(^{116}\) The Medicare prescription plan is outsourced to health insurance companies. It is these insurance companies/health care plans that contract with PBMs to negotiate prices directly with the pharmaceutical manufacturers based on volume of purchases. In essence the PBM cuts out the pharmacy from the negotiation process thus obtaining larger discounts for consumers entitled to Medicare and enrolled in the Part D program.

11.19 PBMs provide enrollees of health care plans or Medicare Part D access to pharmaceuticals in two ways; through mail order and retail pharmacies.

11.20 PBMs contract for drugs in two ways: through retail pharmacies and pharmaceutical manufacturers. With retail pharmacies they contract on the reimbursement amounts for drugs dispensed by the pharmacy and with pharmaceutical manufacturers they contract on the basis of discounts and fees.

11.21 PBMs establish networks of pharmacies that consumers can use and thus obtain better discounts for the plans they provide. PBMs have an ability to broker large discounts with pharmacies as they serve multiple healthcare plans. It is estimated that they tend to contract with 90 per cent of the pharmacies in the region they service. The ‘PCMA’ estimates that 70 per cent of all enrollees (lives) covered by PBMs are done so by the top five companies.

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\(^{116}\) Medicare Part D introduced a prescription drug plan enabling senior citizens and those qualifying for Medicare to access drugs at cheaper rates. This was in response to the public pressure as general Medicare does not cover prescription medicines. Medicare part D provides beneficiaries with a choice between 50 -60 insurance companies that all offer slightly different pharmaceutical coverage at different prices.
There are different prices in the US system that reflect the different distribution channels of drugs.

The AWP is the average wholesale price, an ‘official list price’ that does not reflect real prices in the system but is mainly used for negotiations between PBMs and manufacturers.\textsuperscript{117}

The AMP (average manufacturer price) is the average price at which manufacturers sell drugs to wholesalers for the retail market. It thus reflects all rebates paid by manufacturers to wholesalers and to retail pharmacies (who buy directly from the manufacturer). Manufacturers are required to report the AMP to the CMS. The AMP is not public but is estimated be on average about AWP minus two to three per cent. It is estimated that wholesale margins vary substantially between different buyers depending on buyer power and market shares of the buyers.

The average selling price is used by Medicare part B for drugs dispensed directly by physicians.

\textsuperscript{117}The definition of CBO (2007) says: ‘The AWP is a published list price for a drug sold by wholesalers to retail pharmacies and nonretail providers. However, in practice, the AWP is not what retail pharmacies and nonretail providers pay for drugs but, instead, is often used as a basis for payment to retail pharmacies by, for example the Medicaid program, PBMs and health plans. Those organisationis often pay pharmacies a price discounted off of the AWP’
MAC (maximum allowable cost) is a price used by PBMs to reimburse pharmacies for generic drugs. It is based on the lowest three real prices of generic drugs taking into account pharmacy discounts but allowing pharmacies a dispensing fee.

PBMs contract with manufacturers on the basis of fees and discounts (off-invoice discounts) based on the AWP. Discounts are directly transferred between manufacturer and PBM. Additionally, fees will be paid by the manufacturer to the PBM for administrative and promotional services provided by the PBMs. The size of discounts on drugs prices will be negotiated based on the following criteria:
- sales volumes or market share targets of the PBM
- preferred placement of certain drug products on the PBMs’ formulary
- or a combination of any of the above.

PBM reimbursement to a retail pharmacy is stated as a discount from a measure of the wholesale price plus a dispensing fee for the pharmacy. PBMs also negotiate the amount that a plan will pay the retail pharmacy per prescription of each drug and charges for basic PBM services.

PBMs contract with the pharmacies based on the following criteria:
- for branded drugs, the price discount formula is based on the ‘average wholesale price’ (AWP) as stated by the manufacturer, for example, ‘AWP – 10% + $2.00’. ($2 is equivalent to approximately £1)
- for generic drugs, the formula is based on the ‘maximum allowable cost’ (MAC) as specified by the PBM, for example, ‘MAC - 10% + $2.00’.

If the PBM network of consumer is vast the retail pharmacies will offer a better discount rate as they are likely to gain more customers.

PBMs contract with Health care plans to include the fee the plan will pay the retail pharmacy per prescription charge and fees for basic PBM services. The contract with health care plans is as follows:
- for branded drugs a discount on the ‘average wholesale price’ (AWP) plus an administration charge per prescription, for example, ‘AWP - 5% + $0.10’, and
- for generic drugs a discount from the ‘maximum allowable cost’ (MAC) as specified by the PBM.

When a consumer enrolled in an insurance plan purchases a drug at a pharmacy, they present the pharmacist with a health care plan card or drugs prescription card identifying the source of insurance coverage. The pharmacy will transmit the insurance coverage information to the PBM, which verifies coverage and determines if the plan covers the prescribed drug, what the plan owes as direct payment to the pharmacy, and what the consumer co-payment will be (if any). The PBM transmits this information back to the pharmacy, logs the payment information on its system, and transmits the billing information to health insurers. These insurers then remit payment to the PBM,
which forwards payment to the retailer. This process, known as claims adjudication, is handled electronically. 95 per cent of patients with prescription drugs insurance coverage receive their benefits through a PBM.

Ex ante pricing and reimbursement controls

11.33 Prescription drug prices are set through negotiation and bargaining between manufacturers, wholesalers, retailers, insurers, PBMs, consumers and government following the processes set out above. As in most other countries in the world, the major bargaining chip payers have in negotiating prices is through the reimbursement system – the possibility of not reimbursing a drug or, more commonly, requiring a high co-payment from patients for use of the drug.

11.34 Reimbursement depends on each patient’s healthcare package, including the prescription plan, and follows a formulary set out by the PBM. The formulary is the list of PBM-approved drugs for treating various diseases and conditions. The formulary enables the PBM to manage pharmacy benefits and control drugs prices that health plans and consumers pay. When deciding on the formulary a PBM will consider cost containment, access to medicines and generic substitution.

11.35 Pharmacy and Therapeutic (P&T) committees are used by the PBMs to evaluate individual drugs (by class of drugs) for clinical effectiveness. P&T committees will look at comparative effectiveness and depending on the size of the PBM use more or less sophisticated approaches. PBMs generally look at the cost effectiveness of a drug in their respective enrollee population. Here as well, the size of the PBM and its reputation (strict cost-containment or more open formulary) will influence the methods used.

11.36 The PBM will classify each drug as follows: 'include on the formulary'; 'exclude from the formulary'; or 'optional'. Those drugs classified as 'optional' are then looked at again and given a ranking on their clinical effectiveness and cost. Exclusions from the formulary are very rare, drugs are rather put on the 'non-preferred tier' (see explanation later). Key issues to be considered when deciding whether or not a drug is to be included in the formulary are generic substitutability and therapeutic interchangeability.

11.37 Although the PBM sets the formulary the group healthcare plans often amend it to satisfy the needs of the consumers enrolled in their plans.

11.38 The formulary will be divided into a three tier structure that defines the level of co-payments patients will have to make for their drugs. The tiered system of co-payments is as follows (see also Figure 11.2):

- the first tier of the formulary will only include generic drugs – co-payments for drugs in this category are very low
- the second tier includes selective 'preferred brands'. That is on-patent drugs for which the PBM has negotiated a favourable price or brand-name drugs with no therapeutic equivalent. As an example, if a drug class contains several products
with similar therapeutic value, the PBM might only include two to three products of the class, for which it has negotiated a very good price, into its second tier

- the third tier includes off-patent branded drugs with generic equivalent, lifestyle drugs and drugs with similar effects as another second-tier drug will be included in the third tier. To obtain drugs in the third tier, patients have to make higher co-payments (than for the other tiers) – up to US$35-40 (circa £18 - £20.5) per drug, and

- in some instances there is a fourth tier for other drug categories.

**Figure 11.2: Formulary and tier structure**

![Formulary and tier structure diagram]

11.39 Co-payments are a fixed or percentage fee per drug and increase according to its tier: the higher the ‘tier’, the higher the fee. Fixed co-payments allow insurers to contain costs by encouraging patients to use cheaper drugs but also allow PBMs to keep the real prices of their drugs (and discounts) confidential. Most plans now have an upper threshold for the maximum co-payments an enrollee will have to pay. This threshold varies but an average figure was said to be around US$ 1,000 (circa £514 per patient per year.

11.40 The co-payment structure also allows PBMs to achieve greater formulary compliance, that is, greater use of preferred brands. The greater compliance allows the PBMs to further negotiate with pharmaceutical manufacturers for better prices as compliance is an indication of the ability of the PBM to steer enrollees to certain drugs. Thus, the higher the formulary compliance and the more enrollees a PBM represents, the more bargaining power it has and the lower the prices for the enrollees.

**Ex post pricing and reimbursement controls**

11.41 For the Medicaid program, the Medicaid statute requires obligatory rebates from pharmaceutical manufacturers. The CMS who administers Medicaid does not negotiate these rebates (or any prices) but bases rebates on a formula contained in statute that says that Medicaid should either pay:

- Average Manufacturer Price (AMP) – 15.1per cent
• or the lowest price that any private buyer including hospitals receive\textsuperscript{118} ('best price').

That is, Medicaid receives at least a rebate of 15.1 per cent. In the event another player in the market receives a higher rebate (for example, 20 per cent), Medicaid profits from this and receives a rebate of exactly the same amount.\textsuperscript{119}

11.42 In order for this system to work, regular audits of rebates received in the market are undertaken and stiff penalties are imposed apply for misreporting.\textsuperscript{120}

11.43 The federally required rebates from the manufacturers directly go to the States participating in the scheme. However, the States (that administer Medicaid) can, in addition to the obligatory rebates, negotiate additional rebates with manufacturers.

11.44 The public Medicare Part D programme which provides drug plans for the elderly does not receive additional rebates from manufacturers. Here, the government solely relies on the Health plan/PBMs to negotiate low prices (see also 'sources of health care funding').

**Volume controls**

11.45 MCOs handle large networks of doctors, specialists and hospitals to provide health care to their members. In order to control costs MCOs engage in selective contracting based on price and limit their services through different 'cost containment' measures such as required pre-authorization (for certain treatments), restricted access to specialists, higher co-payments (and sometimes denial of coverage) for out-of-network care, practice guidelines, 'real-time' utilization reviews, restricted coverage of prescription drugs and disease management for chronic illnesses.

11.46 As some MCOs have their own hospitals and doctors which are employed directly (and exclusively) by the MCO. Thus the MCOs can easily enforce its cost-containment strategy.

**Generic pricing and penetration**

11.47 Prices for generic drugs are negotiated between manufacturers and pharmacies (mainly pharmacy chains or pharmacy groups). As pharmacies are able to substitute branded drugs for generics (as long as a doctor does not oppose this), pharmacy chains or groups have significant negotiating power, that is, they can offer large market shares

\textsuperscript{118}This methodology is applied for single source ('S category') drugs and innovator multiple source ('I category') drugs. For non-innovator multiple source drugs ('N category') the rebate is equal to 11 per cent of the Average Manufacturer Price (AMP).

\textsuperscript{119}The downside of this system is that manufacturers are well aware that any rebate higher than 15.1 per cent given to a market player will be automatically reported to CMS and thus the same rebate would have to be given to the (relatively large) Medicaid system.

\textsuperscript{120}Audits are undertaken by the Office of Inspector General within the HHS (Health and Human Services).
to a manufacturer if their generic is the preferred product dispensed and thus big pharmacy chains can negotiate very competitive prices.

11.48 As explained earlier, co-payments for generic drugs are significantly lower than for other drugs. The three tier formulary rewards patients who buy generics (for example, $5 (circa £2.60) co-payment for a generic drug compared to $35 (circa £18) for a non-preferred brand). Due to the three tier system, the use of originator off-patent drugs in the US market is negligible (eight per cent).

11.49 In addition to the tier formulary, pharmacies are only reimbursed for generics at the MAC price (maximum allowable cost121) which is a flat price for all similar molecules and strengths. Thus Pharmacies have an incentive to negotiate large rebates with generic manufactures.

11.50 Generics' share of the US prescription drug market was about 51 per cent (by volume) in 2002.

Key Issues

11.51 The US system of pharmaceutical pricing is different in some respects to those found in many developed countries, due largely to the higher proportion of expenditure met through private funds (out of pocket payments and private health insurance). However, we have found that some of the 'received wisdom' about the US is wrong and that there are stronger elements of commonality between the US and other systems than is commonly held to be the case.

11.52 First, it is sometimes claimed that US has a system of 'free pricing', which is contrasted with 'price control' systems found in Europe and elsewhere. As shown in this chapter, this is false. Payers and their intermediaries negotiate robustly on prices, using a variety of mechanisms to do so. While demand is more disaggregated than in other countries, individual payers – such as Kaiser Permanente, for example, an MCO that has just under ten million members - have considerable buyer power. Some public payers, such as the Veterans Association, have reputations for being particularly tough negotiators.

11.53 Another misconception is that reimbursement in the US is immediate and automatic, that is – in terms of the terminology we have been using in this report - there are no ex ante pricing and reimbursement controls. In reality, PBMs and health plans evaluate the therapeutic benefit of a drug against existing alternatives, negotiate prices with manufacturers and decide where (and whether or not) to include a drug on the formulary. As noted above, the bargaining power of payers in this process comes from the possibility of not reimbursing a drug or, more commonly, requiring a high co-payment from patients for use of the drug.

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121The MAC (calculated by PBMs) equals the average of the three lowest real market prices of one generic (taking into account pharmacy discounts) plus a small dispensing fee for the pharmacy.
This process of clinical evaluation is generally not as lengthy as in some other countries, such that drugs are available fairly rapidly for the insured in the US, but there is considerable variation between plans. For example, some plans will market themselves on the basis of strict cost-containment and low premiums while others will tend to have higher premiums and a more liberal formulary policy. Delays will be greater in the former than the latter. However, such delays do exist, which means that reimbursement of newly launched drugs is not immediate and automatic.

It is also generally believed that payers in the US do not carry out assessments of the cost effectiveness of drugs. It is true that the US has not experienced the extensive use of formal, cost effectiveness analysis seen in many of the other countries reviewed in this annexe. However, practices are changing in this respect. In making formulary decisions PBM P&T committees make an assessment of the clinical and cost effectiveness of drugs. Currently such assessments tend to focus on disease-specific outcome measures (for example, a surrogate such as change in total cholesterol), rather than generalisable (that is, non disease-specific) patient outcomes such as QALYs.

Finally, prices in the US are often characterised as being far higher than in the rest of the world. This certainly has an element of truth, but comparisons, such as those discussed in Annexe F, that suggest that US price levels are roughly twice those found in the next most expensive countries are probably over estimates. The reason is that, as discussed in this chapter, transactions prices in the US are the result of complex systems of rebates and discounts between multiple payers, manufacturers and intermediaries. Those rebates are not known to the public but are only reported to CMS (Medicaid) to allow the calculation of the obligatory ‘best price’ for the governmental buyer. Some of these rebates may not be captured in the official price comparisons.

A forthcoming study by Panos Kanavos et al. estimates those discrepancies between list prices (AWP) and actual reimbursement prices. Based on the Federal Supply Schedule (prices paid by the Medicare system), the study estimates that rebates in different drug classes may range between 13 and 47 per cent (of AWP price). Across all therapeutic categories the study finds an average discount of 32 per cent, reaching 39 per cent if weighted by volumes. The study even comes to the conclusion that ‘US public prices are comparable to and in many cases, lower than, prices in a number of European countries’.

A study of the US congressional budget office (CBO) finds that prices for single-source branded drugs for conventional retail pharmacies amount to circa 83 per cent of AWP and no more than 78 per cent for mail-order pharmacies. Additionally, another

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124The study was based on IMS Health data for the fourth quarter 2003 and a sample of 40 per cent of US sales prescription drugs in 2003.
study of Danzon and Furukawa (2003)\textsuperscript{125} states that health data for the United States, although maybe taking account of official rebates, do not reflect off-invoice manufacturer discounts given to managed care and government buyers. The authors estimate those off-invoice discounts to amount to an average of an additional eight per cent off manufacturer price.

11.59 This is not to say that high list prices such as the AWP are without any significance in the US. The 15 per cent of US citizens who are uninsured (or those with very minimal levels of insurance) will face prices close to the officially stated list prices, if they are able to access drugs at all.

11.60 We understand that CMS has recently announced that it intends to make greater use of formal effectiveness analysis in the future.\textsuperscript{126} Furthermore, there are potential legislative proposals to allow the federal government to intervene in drug price negotiations for Medicare Part D. The idea is that government would negotiate prices and use its buying power to drive drug costs down, instead of leaving it to competing private insurance plans to negotiate Medicare drug prices. Critical voices have suggested that government intervention could restrict access to drugs (through stricter formulary management and the provision of a single plan). At this stage it is unclear whether such legislation will be passed in the near future.

\textsuperscript{125} Patricia Danzon, Michael Furukawa, "Prices and availability of pharmaceuticals: Evidence from nine countries", Health Affairs Web Exclusive, October 2003;
\textsuperscript{126} www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=10
www.cms.hhs.gov/apps/media/press/release.asp