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PREFACE

The present publication has its origins in our report submitted, in the spring of 2000, to the Working Group on the Reimbursement of Medical Expenses 2000, which had been appointed by the Ministry of Social Affairs and Health in Finland. The report describes the drug reimbursement systems in the EU Member States, Iceland and Norway. The tasks of the Working Group on the Reimbursement of Medical Expenses 2000 included the evaluation of the functionality and appropriateness of the Finnish drug reimbursement system as compared with the other European reimbursement systems. The present publication contains an updated and expanded version of the report submitted to the Working Group.

Data on the drug reimbursement systems in the various countries were obtained both from conventionally published research reports and newspaper articles as well as from the Internet pages of various authorities and organisations. Data was also obtained from the news bulletins of international medical journals. Several international colleagues have also provided us with background information and explanatory comments.

The staff at the Research Department of the Social Insurance Institution of Finland have offered us both help and support during our work. Research secretary Hilkka Ruuska has assisted us in finding the relevant data and has been responsible for listing all source material. The English translations are by Brian Fleming, Ulla Brady and Diana Tullberg from the English Centre and Maarit Green. Office secretaries Ritva Salavirta, Eeva-Kaisa Keinänen and Petra Niilola have completed the layout of the publication and have, together with editor Tarja Hyvärinen, prepared the report for publication.

We would like to extend our warmest thanks to all concerned.

February 2003 The authors

INTRODUCTION

Of all available treatments, drug treatments are not only the most commonly used but also perhaps the most rapidly changing and developing. Drug treatments are now available to treat an increasing number of illnesses and drugs are safer and more effective today than ever before. Drugs are also now being used for disease prevention and for the treatment of increasingly less significant ailments and symptoms.

As a general rule, new drug treatments are more expensive than the earlier ones. An extra cost is acceptable when the treatment adds years or quality to life, or if it has other benefits, such as savings in other health care costs. However, this is not always the case. The effects of new drugs are always surrounded by uncertainty and questions which will not be answered until the drug has entered into wider use in routine health care.

It is easy to understand why the managing and development of various systems to reimburse drug costs have required a continuous flow of resources throughout Europe. The drug reimbursement systems in the EU Member States differ, for example, as far as their coverage, range of reimbursable drugs and the size of reimbursement are concerned. Some of the systems have been introduced recently, but most have developed into their present form over a long time period. They are all an inseparable part of the social welfare and health care systems of each country. Considering drug reimbursement systems on their own does not give a complete picture of the total health care costs incurred by the patient in each country. However, a study of the drug reimbursement systems does offer an understanding of how the systems have been developed in response to challenges imposed by increasing costs and new drug treatments.

The present report describes the drug reimbursement systems used in the EU Member States, Iceland and Norway in 2001. Major changes during the 1990s and the early years of the new millennium have also been included.

THE PROPORTION OF OUTPATIENT DRUG COSTS OF TOTAL HEALTH CARE COSTS

The proportion of outpatient drug costs of total health care drug costs varies greatly from country to country. Of the countries reviewed, at the end of the 1990s the proportion was lowest in Denmark, i.e. 9.0%, and the highest in Portugal, i.e. 25.8%, according to the latest statistics from the OECD (Table 1). The corresponding figure for Finland was 15.1%, which is near the average of the countries.

Table 1. The proportion (%) of outpatient drug costs of total health care costs in 1980, 1985, 1990, 1993, 1996 and 1999.

Country	*1980*	*1985*	*1990*	*1993*	*1996*	*1999*
Belgium	17.4	15.7	15.5	17.4	15.4	16.1[1]
Denmark	6.0	6.6	7.5	8.5	8.9	9.0
Finland	10.7	9.7	9.4	12.3	14.4	15.1
France	15.9	16.2	20.0	20.9	21.1	22.9
Germany	13.4	13.8	14.3	12.4	12.4	12.7[2]
Greece	18.8	-	14.5	17.8	17.9	14.7[2]
Iceland	15.9	16.6	15.7	14.4	16.6	15.4
Ireland	10.9	9.9	11.1	9.8	9.5	9.9[2]
Italy	13.7	17.8	21.2	19.9	21.1	22.1
Luxembourg	14.5	14.8	14.9	-	11.5	11.7
Netherlands	7.4	8.6	9.1	10.4	10.4	11.0
Norway	8.7	9.1	7.2	9.6	9.0	9.1[1]
Portugal	19.9	25.4	24.9	25.6	26.3	25.8[2]
Spain	21.0	20.3	17.8	18.7	20.1	20.5[1]
Sweden	6.5	7.0	8.0	10.7	12.9	12.8[1]
United Kingdom	12.8	14.1	13.6	14.9	15.7	16.3[1]

[1] Data from 1997.
[2] Data from 1998.
No data available from Austria.
Source: OECD Health Data 2001.

The average proportion of outpatient drug costs of total health care costs has increased during the last twenty years. In 1980, the average proportion of outpatient drug costs of total health care costs in the EU Member States, Iceland and Norway was 13.3%. The corresponding figure at the end of the 1990s had increased to 15.3%. However, the increase is not evident in all countries and the outpatient drug cost proportion in Belgium, Spain, Ireland, Iceland, Greece, Luxembourg and Germany was smaller at the end of the 1990s than it had been in 1980. In Finland, the proportion of outpatient drug costs of total health care costs has grown comparatively quickly. The figure has grown not only because of the rapid increase in drug costs but also because of the simultaneous decrease of the other health care costs. During the economic slump of the early 1990s, significant cuts were applied to inpatient care, outpatient care other than drug treatments and investment, and the subsequent economic recovery has not seen the return of the previous level of spending.

OVERVIEW OF DRUG REIMBURSEMENT SYSTEMS IN EU COUNTRIES, ICELAND AND NORWAY

Criteria of reimbursability

Price

In Norway, Iceland and all the EU Member States with the exception of the United Kingdom and Germany reimbursable drugs are currently required to be reasonably priced. Official regulations for establishing this vary from country to country.

In many countries the price of a drug is compared with the price of the same product in other European countries. In the Netherlands, for example, the price is based on the average price of the product in Belgium, Germany and France. In Ireland, the factory price of a drug cannot exceed the lowest price of the product in the United Kingdom or the average price in Denmark, France, Germany, the Netherlands and the United Kingdom. In Finland, one of the criteria for assessing the reasonableness of the price is the price of the product in the other countries in the European Economic Area.

In assessing prices, the authorities also take general account of the domestic prices of comparable products, the benefits of the drug and the level of innovation it represents. Health economics studies which allow the measurement and comparison of the costs and benefits of different treatment alternatives are becoming increasingly common in assisting price assessments and particularly decisions on reimbursability. In Finland since 1998 such studies have been mandatory in price applications for drugs containing a new medicinal substance. In Italy, France, Spain and Sweden, too, similar studies can be used in pricing decisions. But they are more often used when making the actual decision on reimbursability.

The United Kingdom does not set prices for individual drugs; with the exception of generic drugs, each producer can freely set the prices for its own products. However, the authorities negotiate a profit framework with the producer. If the profit turns out to be greater than agreed, the company either returns the surplus to the government, reduces the price of its drugs or postpones planned price rises.

Reference price system

Under a reference price system, a specific group of drugs is allocated a reference price, which is used as the basis for calculating the reimbursement. Such a drug group can consist of products containing the same medicinal substance, products containing medicinal substances that belong chemically to the same group or drugs having the same effect in treatment. The price of an individual drug can be higher than the reference price set for the group, but a patient purchasing it is reimbursed solely on the basis of the reference price. The difference between the reference price and the actual price is borne entirely by the patient. The reference price system is intended to encourage the prescription and use of cheaper generic drugs and thus reduce costs for both the patient and society.

The reference price system is in use in the Netherlands, Belgium, Spain, Iceland, Italy, Sweden and Germany. With the exception of Germany, these countries also operate a

price setting procedure. Norway abandoned its reference price system at the beginning of 2001. The decision was preceded by an extensive study which showed the system had been unable to foster more rational prescription practices and its running costs were greater than the savings achieved.

In 2001, Denmark abandoned use of the term *reference price*, replacing it with *reimbursement price*. In practice, the system based on reimbursement price operates on the same principles as the reference price system. Under the latter, Denmark had reviewed its reference prices every two weeks, but nowadays the reimbursement prices of all drugs are set for at least six months at a time. In line with the principle applied under the reference price system, the customer pays the difference between the reimbursement price and the actual price for drugs for which there are generic products on the market.

Other criteria of reimbursability

In Finland, setting the wholesale price of a drug also means that the drug is accepted onto the list of basic reimbursement drugs from the date the price comes into force. In most European countries merely approving the price of a drug does not automatically lead to its approval as a reimbursable drug; the decision on this is taken separately. The price of a drug can also be renegotiated when deciding on its reimbursability.

There are both positive lists (lists of reimbursable drugs) and negative lists (lists of non-reimbursable drugs) in use. Only Ireland and Sweden approve almost all drugs on the market for reimbursement. The most common drugs to be classed as non-reimbursable are products intended for short periods of self-care use. This is the case in, for example, Finland, the Netherlands, the United Kingdom, Spain, Denmark and Luxembourg. Greater demands of effectiveness and cost-effectiveness have also begun to be placed on reimbursable prescription drugs. Among others, Belgium, Italy, Spain, the Netherlands and Denmark have removed the less important prescription drugs from their reimbursement systems. In France, all reimbursable drugs have been classified for the purposes of reassessing their reimbursability. The aim is to gradually remove ineffective drugs from the system altogether. Portugal has also begun to classify drug products on the basis of their effectiveness.

Many EU countries have sought to define the reimbursability of new, expensive drugs in such a way as to restrict reimbursement only to those patients who will benefit most from treatment. In Finland, a number of drugs, including certain drugs for treating multiple sclerosis, Alzheimer's and erection disorders, have since the beginning of 1999 been reimbursable only in closely defined situations. In Italy, drugs including beta interferon, growth hormone and preparations for treating infertility are reimbursable only if the treatment has been considered necessary by a specialist. In Denmark, drugs including the bisphosphonates used in treating osteoporosis, drugs for Alzheimer's and drugs for treating erection disorders all require a separate application on behalf of each patient. In some countries only the hospitals can supply patients with expensive drugs.

In Greece, which has several different systems of insurance, a drug is reimbursable only if it has been prescribed by a physician working for the system concerned. In Spain, a drug is only reimbursable if the doctor prescribing it works within the public health care system.

Table 2. Principles of drug reimbursement systems.

Country	The proportion of drug cost payable by patient	Basis of reimbursement calculation	Reimbursement affected by severity of illness or effectiveness of medicinal product	Reimbursement to children different from reimbursement to adults	Patient's wealth affects reimbursement	System recognises other special groups	Ceiling set to patient's payments	Reference price system
Austria	fixed	package	no	no	yes	no	no	no
Belgium	percentage	prescription	yes	yes	no	yes	yes[1]	yes
Denmark	percentage	drug purchase costs over 12 months	yes	yes	no	yes	yes	yes
Finland	fixed + percentage	drug costs of one purchase	yes	no	no	no	yes	no
France	percentage	prescription	yes	no	no	no	no	no
Germany	fixed	package size	no	yes	yes	yes	yes	yes
Greece	percentage	prescription	yes	yes	no	yes	no	no
Iceland	fixed + percentage	prescription	yes	no	no	no	yes	yes
Ireland	fixed	monthly costs of family	yes	no	yes	no	yes	no
Italy[2]	-	-	yes	no	no	no	-	yes
Luxembourg	percentage	prescription	yes	no	no	no	no	no
Netherlands[3]	-	-	-	-	-	-	-	yes
Norway	percentage	prescription	yes	yes	yes	yes	yes	no
Portugal	percentage	prescription	yes	no	yes	yes	no	no
Spain	percentage	prescription	yes	no	no	yes	yes	yes
Sweden	percentage	drug purchase costs over 12 months	no[4]	yes	no	no	yes	yes
United Kingdom	fixed	prescription	no	yes	yes	yes	yes	no

1 For some drugs.
2 No deductibles in Italy at present.
3 No deductible under public insurance, variable deductibles under private insurance.
4 Except insulin

Method of calculation and size of reimbursement

The proportion of the price of a drug payable by the patient is determined in three different ways in the countries reviewed here. In Finland and Iceland the patient's share includes a fixed deductible plus a percentage of the rest of the price. In Finland, all drugs purchased at the same time are included in the calculation, which means the patient pays just the one fixed deductible irrespective of the number of separate drugs purchased. In Iceland, the fixed deductible is charged separately on each drug purchased.

In the United Kingdom, Ireland and Austria, the sum payable by the patient is completely independent of the price of the drug; it is always the same fixed sum. In Germany, too, patients pay a fixed sum, although here this varies according to the size of the drug package.

Reimbursement is most commonly calculated as a percentage of the cost of the drug. Such percentage-based systems, and systems that include a combination of a fixed component and a percentage-based component, often have several different reimbursement categories. Drugs belong to the different reimbursement categories based on their effectiveness and how essential they are. Another possible criterion is if the illness is particularly serious or chronic in nature. The more serious and chronic an illness is, the larger the reimbursable proportion of the costs of the drug will generally be.

A new sort of graduated system of reimbursement has been introduced in Sweden and Denmark. This is based on the idea that there is no need to reimburse the costs of patients who seldom use drugs or who use only a small amount; instead, reimbursement should be directed primarily to people who have to make major outlays on drugs. In a graduated system, reimbursement only begins once the patient's costs have crossed a certain threshold sum; thereafter, the higher the overall costs rise, the higher the proportion reimbursed. The system makes no distinction between drugs based on their effectiveness or on how necessary they are. A graduated system was introduced in Sweden at the beginning of 1997 and in Denmark in 2000.

Major outlays on drugs

In most of the countries reviewed, some sort of ceiling has been placed on the amount patients are expected to contribute to the costs of their own drugs, but the principles for calculating the ceiling vary from country to country. In Spain, Iceland and Norway a ceiling is set for each separate purchase of a medicine, while in Sweden, Finland and Belgium the ceiling applies to the costs of medicines purchased throughout the year. In Sweden and Norway, adults can add the costs of drugs for children in the family to the accumulated total for their own drugs costs. In Belgium, only deductibles for drugs in the highest

reimbursement categories are taken into account. In contrast, consumers in the United Kingdom can purchase a *season ticket* for four months or a year in advance to cover all their prescription charges for that period. In Germany, the ceiling is determined according to income, while in Norway the ceiling covers all health care costs.

Table 3. Reimbursement categories in some European countries

Country	Reimbursement categories	Reimbursable drugs or illnesses
Belgium	100%	Vital drugs, e.g. insulin and cancer drugs
	75%	Therapeutically significant drugs, e.g. antibiotics, antiasthmatics, antihypertensives
	50%	Therapeutically less significant drugs, e.g. spasmolytics and antiemetics
	40%	Drugs used in certain chronic illnesses, e.g. drugs used in coronary heart disease
	20%	Includes contraceptive preparations and products which have not yet been allocated to a reimbursement group etc.
	0%	Includes hypnotics, small packets of analgesics etc.
Finland	100%	Essential drugs in chronic illnesses where the drug restores or replaces normal bodily functions, e.g. antidiabetic and cancer drugs
	75%	Essential drugs in chronic illnesses, e.g. antihypertensives, antiasthmatics and drugs to treat cardiac insufficiency
	50%	Other drugs
France	100%	Essential and particularly expensive drugs, e.g. drugs to treat diabetes, AIDS and cancer. Drugs used in certain chronic illnesses
	65%	Important drugs, e.g. antibiotics
	35%	Drugs to treat acute illnesses etc.
Greece	90%	Drugs used in certain chronic illnesses
	75%	The most common reimbursement category
Iceland	100%	Vital drugs, e.g. antidiabetic drugs and antipsychotics
	35%	Therapeutically important drugs used in chronic illnesses, e.g. antiasthmatics and cardiac drugs
	20%	The majority of drugs belong to this category
	0%	Includes some antimicrobials, hypnotics and anxiolytics etc.
Luxembourg	100%	Vital and expensive drugs used in chronic illnesses
	78%	The majority of drugs belong to this category
	40%	Less significant drugs
Portugal	100%	Essential drugs used in chronic illnesses, e.g. antidiabetic and cardiac drugs and antituberculous drugs
	70%	Includes antiasthmatics, and cardiovascular drugs etc.
	40%	Includes vaccines and immunoglobulins etc.
	20%	New products the therapeutic value of which is not yet proven.
Spain	90%	Drugs used in chronic illnesses, e.g. antiasthmatics, antidiabetic drugs, antiepileptics and antihypertensives
	60%	All other drugs

Drug reimbursement for special groups

The reimbursement systems in many European countries recognize special groups whose drug costs are reimbursed over and above the general principles for reimbursement, or who do not have to pay for their drugs at all. Special principles normally pertain to children, the elderly or pensioners. For example, in the United Kingdom, Spain and Greece the elderly or pensioners are exempted entirely from payment, while in Iceland their deductible is smaller than that of other age groups. People on low incomes constitute a special category in, for example, the United Kingdom, Portugal and Germany. The benefits for the chronically ill and people with disabilities differ from the rest of the population in, for example, Belgium, the United Kingdom, Spain, Ireland, Iceland, Greece, France, Germany and Denmark. Special groups more rarely taken into account are pregnant women, the mothers of small children, widows and orphans. These special groups can account for a considerable proportion of the population: in Austria 18%, Spain 20%, Ireland 38% and Germany 40% of the population get their medicines free of charge. In the United Kingdom, in as many as 85% of drug purchases the patient does not have to pay the prescription charge.

Public financing of drug costs

Drug reimbursement systems are often compared internationally by looking at the share of out-patient drug costs covered out of the public purse. OECD statistics show the level varies considerably from country to country. The shares are lowest in Italy, Denmark, Belgium and Finland, in all of which the contribution by public financing is under 50% of total costs. In Ireland and Luxembourg the figure is over 80%. However, it is not possible to interpret and compare these figures unambiguously without more precise knowledge of what the figures from the different countries are based on. In the first place, for the figures to be comparable, all the countries would have to include the same costs under the heading of drug costs. The classifications used can differ in, for example, whether vitamins, health foods and nutritional preparations are included or not. In the second place, the figures for the total cost of drugs and the level of public financing should include details of all parties involved in selling and reimbursing the cost of medicines. For example, the OECD's figures for Finland do not include social assistance paid by the local municipal authorities towards the cost of drugs, nor the drug costs taken into account in calculating the level of support paid to pensioners, children and people with disabilities. The comparability of the statistics is further weakened by the fact that it is also possible to share out drug costs retrospectively. Among others, the authorities in Belgium, Spain, the United Kingdom, Ireland, Italy and France have entered into agreements with the pharmaceutical industry whereby producers return some of their profits to the reimbursement system. Belgium and France have also imposed special taxes on the industry in an attempt to offset the costs of the reimbursement system.

Table 4. Proportion (%) of public financing of outpatient drug costs in 1980, 1985, 1990, 1993, 1996 and 1999.

Country	1980	1985	1990	1993	1996	1999
Belgium	57	51	47	44	45	45[1]
Denmark	50	45	34	49	48	47
Finland	47	45	47	44	47	49
France	65	-	57	56	56	59
Germany	74	72	73	71	72	69[2]
Greece	60	-	70	72	71	70
Iceland	51	62	71	63	66	64
Ireland	53	61	65	73	81	82[2]
Italy	71	68	63	51	38	41
Luxembourg	86	86	85	-	81	81
Netherlands	67	63	67	91	63	64
Norway	42	43	79	60	59	60[1]
Portugal	69	65	62	62	65	66[1]
Spain	64	63	72	72	76	77[1]
Sweden	72	70	72	69	71	71[1]
United Kingdom	68	64	67	64	63	64[1]

[1] Data from 1997.
[2] Data from1998.
No data available from Austria.
Source: OECD Health Data 2001

Development of reimbursement systems and measures to slow the growth in costs

Drug reimbursement systems have been used in a variety of ways in attempts to damp down the growth in the costs of drugs. The most common methods have been to tighten the price controls on drugs and restrict the number of drugs approved for reimbursement. Reimbursement of the costs of expensive drugs often requires a separate decision for each patient. Efforts have also been made to shift responsibility for payment more towards the patient. The increases in deductibles have mainly been small, but there have also been a number of more substantial increases. In 1992, Belgium introduced two new categories of reimbursement (20% and 40%), while Luxembourg transferred some drugs from the 80% to the 40% category. In Sweden, the deductibles in the new graduated reimbursement system introduced in 1997 already had to be increased in 1999 due to the high costs. Even so, the regulation of patient deductibles would no longer seem to be the primary means of controlling rising costs.

Efforts have also been made to slow rising costs using methods outside the reimbursement system. Most EU countries have reviewed the margins of retail pharmacists and drug wholesalers and reduced or frozen the prices of drugs. Like the increases in the patient deductible, experience suggests that these steps do not have a lasting impact on rising drug costs. They have been unable to alter the background factors behind the rising costs, and the cost growth curve has continued to rise at almost the same pace as before.

Influencing doctors' prescription practices is nowadays seen as an important tool for controlling costs. Methods include doctors' budgets, feedback systems and education. A variety of ancillary measures are being used to encourage the prescribing of cheaper products. One of these is a system of reference prices; this has become more popular in recent years particularly in the countries of southern Europe, although some countries that have previously employed reference prices are now abandoning the system.

Efforts have also been made to increase the use of generic drugs through generic prescribing and generic substitution. Generic prescribing involves the doctor prescribing a drug using the name of the required medicinal substance; the pharmacist then selects the cheapest product containing the prescribed substance. Generic prescribing is possible in Finland, although it is very rarely used here. In contrast, it is very common in the United Kingdom, where 70% of drugs are prescribed in this way.

Generic substitution is a procedure in which the doctor prescribes a specific product, but the pharmacist is free to change it for a cheaper generic product. Generic substitution is possible in the Netherlands, Spain, Italy, France and Denmark. In Germany and the Netherlands the pharmacist can also substitute another product containing a different medicinal substance that has the same

effect in treatment. This is known as therapeutic substitution. In Portugal, the prescription of cheaper generic drugs has also been supported by paying a higher level of reimbursement for generic drugs.

The pharmaceutical companies have also been brought in more than before to bear responsibility for growing costs and to share the uncertainty that surrounds new drugs. In practice, responsibility has been shared through agreements between the companies and the public authorities. These can, for example, agree in advance on what would be an acceptable rise in costs, at the same time agreeing appropriate action if the agreed limits are either exceeded or not reached. Agreements of this sort have been concluded in, for instance, the United Kingdom, Spain, Italy, Portugal and Denmark.

Table 5. Practices in operation to increase the use of cheaper generic products

Country	Generic prescribing	Generic substitution	Therapeutic substitution
Austria	no	no	no
Belgium	no	no	no
Denmark	no	yes	no
Finland	yes	no	no
France	no	yes	no
Germany	no	yes	yes[1]
Greece	no	no	no
Iceland	yes	no	no
Ireland	yes	no	no
Italy	no	yes	no
Luxembourg	yes	no	no
Netherlands	no	yes	yes[1]
Norway	no	yes	no
Portugal	no	no	no
Spain	no	yes	no
Sweden	no	yes[2]	no
United Kingdom	yes	no	no

1 Only in certain drug groups.
2 Sweden plans to introduce generic substitution in the autumn of 2002.

DRUG REIMBURSEMENT SYSTEMS COUNTRY BY COUNTRY

The drug reimbursement systems are described as they were at the turn of 2001/2002. Any planned changes and reorganisations to the systems are also included wherever appropriate.

The conversion of the national currencies into euros was carried out by using the exchange rates issued by the European Central Bank on 8 March 2002 (Appendix).

Austria

In Austria, health insurance is managed by 28 sickness funds with the *Hauptverband der Österreichischer Sozialversicherungsträger* as an umbrella organisation. The operations are monitored by the *Bundesministerium für Arbeit, Gesundheit und Soziales* (BMAGS). The statutory health insurance covers approximately 99% of the population.

Pricing

In Austria, the prices of all drugs, including over-the-counter medicines, were controlled until 1998. The ministry responsible for social affairs and health, BMAGS, used to set a maximum price for a product. Pricing had to take into account the interests of the national economy, the manufacturer and the patient. Prices were determined on the basis of prices in the other EU Member States and the manufacturing country, prices of comparable products in Austria and proven costs submitted by the company filing the price application. The price approved by the ministry was a maximum price, which often had to be lowered by the marketing authorisation holder when seeking reimbursement status for the product. In practice, price negotiations first took place with the ministry and then again with the social insurance institute. According to the pharmaceutical industry, prices usually had to be reduced 5–30% from the prices approved by the ministry. The industry felt that the Austrian method was the most regulated in Europe.

In 1998, a new system was proposed in Austria in which the pricing of over-the-counter medicines was to be unregulated. For the pricing of prescription drugs, the industry could choose from three alternatives. The marketing authorisation holder could decide whether to accept the price proposed by the social insurance institute or to relate the price to a certain sales volume. In the latter case the price would be lowered if the volume is
exceeded. The marketing authorisation holder could also choose to make a repayment to the sickness fund on any excess sales. The proposal did not come into force and the previous process remained operational for another year.

In September 1999, a Price Notification System was officially introduced in Austria. The pricing of drugs by the pharmaceutical industry is unregulated, but the authorities may intervene whenever they consider a price too high. The marketing authorisation holder must inform the ministry of the price six weeks prior to market entry. The price notification must bear information about the domestic prices of corresponding products. The price level of new drugs must not exceed that in the other EU countries.

Both the wholesaler and pharmacist margins are controlled. The margin for both is degressive. A limit has been set to the wholesaler margin. Pharmacies are

required to give discounts to the social insurance institutes, the size of the discount is related to the size of the pharmacy. In 1997 and 1998, the discount was an average of 7.5%

There is no Value Added Tax for pharmaceuticals reimbursed by health insurance. Value Added Tax for other pharmaceuticals is 20%.

Criteria for reimbursement

The introduction of the Price Notification System on 1 September 1999 did not alter the principles of drug reimbursement. The reimbursement status of a drug continues to be based on a separate approval. The criteria considered include the cost of the drug, therapeutic value and funds available. If a health economic evaluation is available it will be used in decision making.

The reimbursement system divides drugs into two groups. Some of the drugs are always reimbursed when prescribed by a doctor. These drugs are listed in a list called *Heilmittelverzeichnis.* New drugs are added to the list several times a year. An estimated 60% of all drugs are included in this list. The generic products on the list are approximately 10–15% cheaper than the original product.

Drugs not included in the *Heilmittelverzeichnis* list are reimbursed only after a special assessment. In order to obtain reimbursement for such medication the patient must receive a prescription from a doctor eligible to make a decision on the necessity of the drug. Many new innovative and very costly drugs are included in this category.
When making decisions about the reimbursability, a positive approach is taken towards new products for currently untreatable diseases. Products which are priced lower than products already on the market are also favoured as are those which offer lower treatment costs than alternative products.

Size of reimbursement

The patient only pays a fixed sum per package for reimbursable drugs. The sum was increased in October 2000 from ATS 45 (EUR 3.27) to ATS 55 (EUR 4.00). If the actual price of the drug is lower than the fixed sum payable, the patient may purchase the drug him/herself. Drugs prescribed by a private doctor attract a surcharge of 15%, added at the pharmacy. Pharmacies collect the prescription charge for the reimbursable drugs and pass it on to the insurers. Approximately 18% of the population are exempt from prescription charges on social grounds.

In January 1997, a treatment fee of ATS 50 (EUR 3.63) was introduced, payable every calendar quarter. The patient pays the fee in association with a medical

consultation and the issuing of a prescription. The fee has resulted in somewhat reduced numbers of prescriptions written.

Doctors' prescribing habits

In order to promote effective and economic prescribing habits, the authorities issue treatment guidelines to doctors. The guidelines contain information about less costly drug treatments etc. The prescription behaviour of doctors is monitored and a doctor who repeatedly writes more prescriptions than average may – at least in theory - be asked to refund the excess, or his contract with the sickness fund may be terminated.

Changes in the drug reimbursement system and drug prices

The first measures to contain drug costs were not introduced until 1995 in Austria.

1995
The wholesale margin was changed from a fixed margin to a degressive margin.

1996
Prescription charge was increased more than the usual annual increase, i.e. from ATS 35 to ATS 42 (from EUR 2.54 to EUR 3.05).

Approximately 600 prescription drugs were made into over-the-counter medicines.

A collective project of the social insurance institute, the pharmaceutical industry, doctors, pharmacies and patients, to promote rational prescribing, was initiated.

The review of the status of all reimbursed drugs was commenced. The task was completed in 1997. Approximately 50 products were delisted from the reimbursement system.

1997
The factory prices of drugs (including generic products) were reduced.

The wholesaler and pharmacist margins were reduced.

A treatment fee, associated with a prescription, was introduced.

1999
The Price Notification System was introduced.

2000
In order to curb the increase in drug costs, a proposal was made to reduce the factory prices of certain drugs and to increase the use of generic products. The first measures were introduced in the autumn of 2000.

The wholesaler and pharmacist margins were reduced.

Prescription charge was increased from ATS 45 to ATS 55 (from EUR 3.27 to EUR 4.00).

Latest changes, proposals and discussion topics

The pharmaceutical industry and the authorities have differed in their opinion as to how to renew the Austrian system to increase transparency. The view of the pharmaceutical industry is that drugs registered through the centralised procedure should automatically be accepted for reimbursement. Other prescription drugs should always be reimbursed when the price does not exceed the average price of the product in the EU countries.

Belgium

Almost all Belgians are covered by statutory health insurance. Health insurance is paid either from a public sickness fund or by five non-profit making insurance companies. *Institut Nationale d'Assurance Maladie et d'Invalidité* (INAMI) regulates the distribution of available funds.

Belgians consume large quantities of medicines and almost all consultations with a physician generate a prescription.

Pricing and reimbursability

Prices are near the European average. Until the end of 2001, the Pricing Committee of the *Ministére des Affaires Economique* was in charge of setting a maximum approved price for all drugs entering the market. At the same time the ministry responsible for social affairs and health assessed the therapeutic value of the product by comparing it to products already on the market. Representatives from the public sickness fund, industry and wholesalers, pharmacies and consumers took part in the pricing negotiations. When determining the price the following criteria were considered: the development and production costs, the price of the product in the manufacturing country and in the other EU countries, as well as other products already on the market.

The ministry responsible for social affairs and health, *Ministére des Affaires Sociales*, used to be responsible for deciding whether a drug should be eligible for reimbursement or not. A drug could only become reimbursable if its price did not exceed that of generic alternatives or therapeutically equivalent products already on the market. In other words, the price of earlier products acted as a reference price for products to be introduced later on. However, it was also possible to give a therapeutically superior product a higher price than that of a product already on the market, but a percentage limit was set to the price increase. The price of a pharmaceutical with an innovative nature belonging to a new drug group could exceed the price of products already marketed. Price comparisons were made by using the defined daily dose (DDD) of the medical substances. In practice, the reimbursable price was often lower than the price set by the *Ministére des Affaires Economique.*

A generic product became eligible for reimbursement only if its price was at least 16% lower than that of the original product.

The processing of pricing and reimbursements in Belgium changed in early 2002. The previous system was slow, since a price had to be accepted first and the reimbursability of the drug was decided only subsequently. The new system aims to reduce the decision making from the previous nearly 600 days to 180 days. Under the new system, whilst the price is being assessed by the *Comission de*

Prix pour les Spécialités Pharmaceutiques, the clinical value of the product is being assessed by external professionals. A 22-member *Comission de Remboursement des Mèdicaments* (CRM) will then process the assessments. The commission has representatives from the insurance companies as well as independent professionals and medical and pharmaceutical members. The ministry responsible for health makes the final decision. If no decision is issued within 180 days, the price proposed by the manufacturer will be valid. The prices of all new reimbursable drugs are re-evaluated after 1.5–3 years.

In June 2001, a reference price system was introduced in Belgium with the aim to increase the use of generic products; generic products account for only 1–2% of the total drug sales. The system covers only about 300 products. The reference price is set about 16% lower than that of the original product. Before the introduction of the reference price system, the manufacturers of the original products reduced their prices. It has been agreed that if the price of the original product has been reduced, the reference price will not be automatically set lower.

The wholesaler and pharmacist margins for reimbursable drugs are regulated. The wholesaler margin for generic products is fixed at 22.5%, and for other products it is 13% of the factory price. However, the margin must not exceed BEF 88 (EUR 2.18) per package. There is no regulation on the margin for over-the-counter medicines. It is common for the wholesalers to give discounts to pharmacies.

Likewise, the pharmacist margin for reimbursable drugs is also fixed: 38.7% for generic products, and for other products 31.0% of the factory price. However, the margin must not exceed BEF 300 (EUR 7.44) per package. It is common for pharmacies to use the same calculation method for the margin for non-reimbursable drugs. Many pharmacies give discounts to customers.

Value Added Tax for all pharmaceuticals is 6%.

Criteria for reimbursement

When deciding upon the reimbursability of a drug its evidence-based efficacy, economic implications and social importance are considered.

Size of reimbursement

Belgium used to have only three reimbursement categories: groups A, B and C. Two more groups, i.e. groups Cs and Cx, were introduced in 1992 as a cost saving measure. Group D contains non-reimbursable drugs.

Group A contains drugs essential for life, such as insulin and medication used in cancer treatment. Drugs in this group are reimbursed in full.

Group B contains therapeutically significant drugs, such as antibiotics, antiasthmatics and antihypertensives. The cost of Group B drugs is reimbursed 75%. However, there is a ceiling for the amount to be borne by the patient. In 2000, the ceiling was set at BEF 375 (EUR 9.30) per prescription. When Group B drugs are prescribed to children, widows, disabled persons, pensioners and orphans (so-called VIPO patients) 85% of the cost is reimbursed. In 2000, VIPO patients paid the maximum of BEF 250 (EUR 6.20) per prescription.

Group C contains therapeutically less significant drugs, such as spasmolytics and antiemetics. The cost of Group C drugs is reimbursed 50%. In 2000, the maximum amount payable by the patient per prescription for drugs in this group was BEF 375 (EUR 9.30) for the VIPO patients and BEF 625 (EUR 15.49) for other patients.

The cost of Group Cs drugs is reimbursed 40%. This group consists of drugs used in certain chronic illnesses, such as coronary heart disease. There is no set limit to the amount payable by the patient.

Group Cx contains, for example, contraceptive preparations and products which have been granted official reimbursement status, but which have not yet been allocated to a reimbursement group. The cost of Group Cx drugs is reimbursed 20%.

Drugs in group D are not reimbursed at all. Drugs in this group include over-the-counter medicines, small packets of analgesics, certain hypnotics and cough medicines.

In principle, a doctor who wishes to prescribe drugs in Groups B or C, and have them reimbursed, must obtain permission from the national sickness fund. For example, drugs to lower blood cholesterol can only be reimbursed if dietary and other treatment methods have been ineffective. In practice the permission is almost always granted.

A pharmaceutical may belong to several groups simultaneously depending on how important it is considered socially. For example, an antibiotic might be reimbursed in full when it is used to treat tuberculosis but only 75% in less significant infections.

In 1996, Group A encompassed 8% of all pharmaceuticals, Group B 64%, Groups C and Cs 2%, Group Cx 13% and Group D 13%.

Belgian pharmacies still prepare many pharmaceuticals. A medicine prepared in the pharmacy costs the patient either BEF 40 or 80 (EUR 0.99 or EUR 1.98).

Some medicines prepared in the pharmacy are free for the VIPO patients, and the maximum they will have to pay is BEF 80 (EUR 1.98).

Changes in the drug reimbursement system and drug prices

1992
Drug Groups Cs, Cx and D were introduced.

1993
Drug prices were frozen until the end of 1993.

An extra 2% tax was imposed on the pharmaceutical industry, based on the sales of reimbursable drugs.

1995
Several changes were proposed for the drug pricing and reimbursement system. The proposals included price reductions of 20% for products no longer covered by patent and price limits for expensive drugs. It was proposed that products with no therapeutic value should become non-reimbursable. Some of the proposals came into force with immediate effect.

1996
A limit was set to the wholesaler and pharmacist margins.

Prices were reduced by 2% in June.

Drug prices were initially frozen until the beginning of 1997.

The pharmaceutical industry was required to return 3% of the value of the 1995 sales.

All pharmaceuticals prepared in a pharmacy used to be reimbursed, even though the same pharmaceutical might have been non-reimbursable when sold as a registered drug. This regulation was unified; a product would be reimbursed in the same way whether it was dispensed in a package or prepared by a pharmacy.

1997
The prices of reimbursable drugs, which had been on the market for over 15 years, were reduced twice. The reductions were explained by the fact that the research and development costs of the drug would have been recovered over the 15 year period. The total of the price reductions amounted to 8%.

The price of a generic product had to be at least 16% lower than that of the original product.

Several tens of products were removed from the list of reimbursable drugs.

1999
The prices of drugs, which had been on the market for over 15 years, were reduced again, this time by 4–8%. The price freeze relating to all pharmaceutical products continued.

Monitoring of doctors' prescribing habits commenced and feedback was given to prescribers, through the Pharmanet system.

2000
The ministry responsible for health, and the pharmaceutical industry, agreed that the industry will return 65% of any drug reimbursement spending exceeding the budget for 2001. Any sum to be returned would be divided between the pharmaceutical companies, and the amounts payable would be proportional to the market share of each company. This was meant to be a one-off procedure, but it has become a permanent practice.

The prices of drugs, which had been on the market for over 15 years, were reduced by 12%.

The price of medicine packages, meant for treatment of over a month's duration, was reduced.

2001
The reference price system was introduced.

Widespread campaigns were organised, targeting doctors and pharmacists, aiming at rationalising the prescribing habits and the use of analgesics and antimicrobial agents.

2002
The pricing and reimbursement process was changed.

Latest changes, proposals and discussion topics

In Belgium, attempts to curb increased drug costs have included changes in the drug prices, an additional sales-based tax levied on the pharmaceutical industry, attempts to influence both the use of medicines and the amount to be borne by the patient. At the end of 2001, the ministry responsible for social affairs and health proposed to introduce further measures: a price reduction of approximately 12% for drugs that had been on the market for a long time, an increase in the use of generic products, a re-evaluation of the wholesaler and pharmacist margins and changes to the doctor's prescribing habits, e.g. through education.

According to the latest information, instead of the price reduction proposed by the ministry, Belgium is planning price reductions for drugs that have been reimbursable for over 10 years. An association representing the Belgian pharmaceutical industry has approved the proposal. The association has also approved a 1.5% increase in the annual repayment for 2002.

The ministry has proposed the expansion of the reference price system as well as the delisting of ineffective products from the reimbursement system. It has been proposed that the reference price should be set 20%, rather than the current 16%, below the price of the original product. There are also plans to make the proportion payable by the patient relative to the drug package size, i.e. the patient would have to pay more for larger packages and less for smaller ones. However, larger packages would remain relatively cheaper than smaller ones. This practice is proposed to come into effect in April 2002. There are plans to abolish the discounts given by pharmacies to customers. Restrictions are also planned to the visits by representatives from pharmaceutical companies and their dispensing of free samples. The introduction of health economic evaluations relating to pharmaceuticals is being prepared.

Denmark

In Denmark, health care services are mainly offered and financed by the public sector. The public health care system also manages the health insurance system, which covers the entire population. The reimbursement system is implemented regionally. Drug reimbursements are also paid in accordance with the Social Pensions Act, Social Welfare Act and through private insurers. A significant number of the Danes hold a private insurance policy.

Pricing

Drug prices in Denmark have for a long time been higher than average in Europe. Denmark does not enforce a specific policy of price control and the manufacturers do not require an approval for their prices. The manufacturers are, however, required to notify the authorities (*Lægemiddelstyrelsen)* of the prices every six months. The notified price is binding.

A reference price system has been used in Denmark since 1993. It covers approximately 500 pharmaceutical products. The reference price used to be determined according to the average price of the two cheapest products. The reference price was then reviewed every two weeks. In 2001, the term “reference price” was removed from the legislation and replaced with the term “reimbursement price” (*tilskudspris*). At the same time, the basis for reimbursement calculations was changed. When the product is to be marketed only in Denmark, the reimbursement price is based on the price of the cheapest generic product available. If the product is also for sale in the other EU countries, the price approved for the reimbursable product must not exceed the average price in 11 EU countries, Norway, Liechtenstein and Iceland. When calculating the average price, the prices in Greece, Portugal, Spain and Luxembourg are ignored. The price used for calculation purposes is the price approved for the product in the particular EU member state, on market entry. If the product is subsequently introduced to the market in a country where it has not been for sale previously, the manufacturer must inform the authorities of the matter. If the product belongs to a group of interchangeable drugs, and it is for sale in several countries, its reimbursement price is determined according to the average price of the cheapest products in the reference countries. If the product is marketed only in Denmark, the reimbursement price is set according to the cheapest generic alternative.

The wholesaler margin is not controlled, but is based on an agreement between the manufacturer and the wholesaler. *Sundhedsministeriet* makes decisions regarding the pharmacist margin, which is degressive. Value Added Tax for pharmaceuticals is 25%.

Criteria for reimbursement

The majority of pharmaceuticals are reimbursable. Decisions regarding the reimbursability of a drug take into consideration the therapeutic value of the drug and, at an increasing frequency, its financial implications. The reimbursement decision may be based on a health economic evaluation. Between May 1998 and October 2001 fifteen health economic evaluations were assessed in Denmark.

A proportion of the drug reimbursements are paid via a special assessment process. A patient may be eligible for reimbursement of drugs not covered by the public reimbursement system. To obtain reimbursement, the patient must submit an application which includes a doctor's certificate stating the necessity of the drug treatment. In 1998, approximately 60,000 such applications were submitted; one in four for lipid-lowering drugs. In 1999, the regulations were changed so that lipid-lowering drugs were included, with certain criteria, in the public reimbursement system. This special application process is also applicable for bisphosphonates used in osteoporosis, antiasthmatics, sex hormones, cough medicines, drugs used in Alzheimer's disease, obesity and erectile dysfunction and certain new antidiabetic drugs. Since 1999, quinolone antibiotics have not been covered by the public reimbursement system.

Terminally ill patients may receive all medication free through the special assessment process. With a medical certificate, patients with a chronic illness may obtain extra assistance towards their drug costs when their annual expenditure exceeds a certain sum (in 2002, DEK 3,735, i.e. EUR 502.52). The extra assistance is granted by *Lægemiddelstyrelsen.* Patients with chronic illnesses used to be able to apply for additional reimbursement from their local authority. Local authorities retain the power to pay additional reimbursement to those on a low income and to the disabled.

The special assessment process is also applied, for example, when patients with allergies need drug reimbursement. If the patient cannot tolerate, due to an allergy or other therapeutic reason, the lowest priced generic products in accordance with the substitution regulations, the drug prescribed by the doctor will be reimbursed.

Over-the-counter medicines generate reimbursement only if certain criteria are fulfilled. They can be reimbursed to pensioners, the disabled and to those with a chronic illness or on a low income. A prescription is required to qualify for reimbursement.

Some drugs with particularly high treatment costs, such as interferon beta, are issued to patients treated in outpatient care via hospitals.

Size of reimbursement

Until early 2000, drugs were divided into three reimbursement categories:

1. Insulin was the only pharmaceutical product receiving a 100 % reimbursement.

2. Drugs used to treat severe illnesses received a 74.7% reimbursement.

3. Drugs used to treat less severe illnesses received a 49.8% reimbursement. Drugs in this category could not include those which presented a potential danger of abuse.

In March 2000, the drug reimbursement system was changed from the percentage based system into a *need-dependent* system, i.e. into a system resembling that used in Sweden, a system of gradually increasing reimbursement. The size of the tiers is changed annually, but in 2002 the following apply: patients aged 18 and over will receive drug reimbursement payments only after their annual expenditure reaches DKK 515 (EUR 69.29). The reimbursement percentage is 50 when the patient's drug expenditure is DKK 515–1,240 (EUR 69.29–166.83). The reimbursement percentage is 75 if the expenditure is over DKK 1,240 (EUR 166.83) but below DKK 2,900 (EUR 390.18). The reimbursement percentage is 85 if the expenditure is over DKK 2,900 (EUR 390.18). The maximum amount payable by patients with a chronic illness is DKK 3,735 (EUR 502.52). Patients under the age of 18 receive a 50% reimbursement for expenditure below DKK 515 (EUR 69.29). The pharmacies and doctors have access to updated data of the patient's total drug expenditure. This allows them to inform the patient of the cost of the new medication.

The reimbursement of generic products is based on the reimbursement price. The patient pays the difference between the actual price and the reimbursement price.

Substitution

The sale of generic products and parallel imports is significant in Denmark. In 1997, the sale of generic products amounted to just below 40% of all sales in Denmark, when the corresponding average figure in Europe was approximately 15%. Parallel import products amounted to 11% of the sales. The parallel import company Paranova, was the fourth largest pharmaceutical company in Denmark in 1997.

Generic substitution has been allowed since 1991. Initially the pharmacies were allowed to substitute the drug with the cheapest generic alternative only if the

doctor had marked the prescription with a “G”. The practice of marking the prescription was uncommon; it was used in less than 5% of the prescriptions.

In 1997, the regulations were changed so that substitution was allowed unless the prescriber had explicitly forbidden it with a marking “Ej G”. In 2001, products costing less than DKK 100 (EUR 13.45) had to be substituted with a cheaper product if the cheaper product was priced at least DKK 5 (EUR 0.67) less than the prescribed product. Products costing more than DKK 100 (EUR 13.45) had to be substituted if the cheaper product was priced 5% less, and products costing over DKK 400 (EUR 53.82) if the cheaper product was priced at least DKK 20 (EUR 2.69) less. The O-substitution was introduced in 1997. This means that the prescribed product can be substituted with a lower priced parallel import product. The prescribing doctor was able to forbid the substitution by adding the name of the manufacturer next to the brand name of the product. Adding the words ”Ej S” meant that the product must not be substituted either with a generic alternative or a parallel import product. Doctors were against the new rules, and during the first year 40% of all prescriptions contained the words ”Ej S” or ”Ej G”. However, substitution was more prevalent than it had been before 1997.

In June 2001, the rules governing substitution were simplified. The patient will be dispensed the cheapest product amongst all equally-named products (parallel and direct import products) and generic alternatives. Alternatively, the patient may be dispensed a product whose price differs from the lowest price within the following limits: if the cheapest product costs up to DKK 100 (EUR 13.45), the price of the dispensed product may differ up to DKK 5 (EUR 0.67) from the cheapest price. If the cheapest product costs more than 100 DKK (EUR 13.45) but less than DKK 400 (EUR 53.82), the price of the dispensed product may differ up to 5% of the cheapest price. If the cheapest product costs more than 400 (EUR 53.82), the price of the dispensed product may differ up to DKK 20 (EUR 2.69). Of all the substitution markings, only the marking ”Ej S” remains in use, but even in this case the pharmacy may dispense the cheapest parallel import product. If the doctor wishes the patient to be dispensed with a particular manufacturer’s product, he/she must add the product number, or the name of the manufacturer, in addition to the brand name of the product. Substitution is now so prevalent that only about 10% of prescriptions bear the marking “Ej S”.

Agreements between the pharmaceutical industry and the authorities

The pharmaceutical industry and the authorities have made several agreements in order to contain cost developments. The first one came into force in 1994. It was then decided that the prices of reimbursable drugs would not be increased between the time period of January 1994 and March 1995. In 1995, the savings target set for reimbursement costs was DKK 82 million (EUR 11 million). For this purpose the prices of reimbursable drugs were decreased 5%, and it was agreed

with the industry that prices would be frozen for the time being. In 1997, it was agreed to freeze the prices until March 1998.

In 1998, *Sundhedsministeriet* and the pharmaceutical industry made an agreement stating that the increase in reimbursement costs would be limited to 0.8% in 1998, and to 3% in 1999. If the growth should exceed the set limits, the exceeding sum would be the liability of the industry. The situation was monitored on a monthly basis by comparing the drug reimbursement costs and companies' income with the corresponding figures from the previous year. If the total growth of drug reimbursement costs was more than 0.8% and the turnover of the company, relating to drugs covered by the agreement, had increased by more than the allowed 0.8%, the company would reduce its prices for the next three months. If an individual company should not be able to compensate for the increase in the drug reimbursement costs, the other pharmaceutical companies partaking in the agreement would take part in the compensation. According to the agreement, price reduction was not required if it would effect an over 10% change in the company's turnover, or if the prices would fall below the European average. When calculating the European average price, ten EU member states were used as reference countries; Greece and Italy were excluded.

If a price of a product fell significantly below that of the European average, whilst the agreement was in force, it was possible to increase the price. On the other hand, the price of a new product entering the market had to be lower than the average price in the European reference countries. The manufacturer had to inform the authorities of any price changes in the reference countries.

In accordance with the agreement the authorities were banned, during the agreement period, from introducing other measures with a bigger than the agreed effect on the turnover of the pharmaceutical company. Measures not included in the agreement included the reference price system, generic substitution, the acceptance of drugs into the reimbursement system, reimbursement percentages and the retail pharmacist margin.

The average annual increase in the drug reimbursement costs between 1991 and 1997 was 6%. In practice, the agreement introduced a price freeze to the level of prices in January 1998. In 1998, the increase in the drug reimbursement costs was 7.1% as compared with the previous year. In June-August 1998, the prices of 1,800 pharmaceutical products were reduced by 12-14%. The prices of some products were reduced up to 50%.

The Danish trade competition authorities requested the opinion of the European Union Commission on the agreement between the pharmaceutical industry and the ministry. The commission felt that the agreement did not encourage free competition between the pharmaceutical companies. Both the ministry and the pharmaceutical industry accepted the opinion of the commission, and the agreement was not continued after March 2000.

As the agreement no longer was valid and pricing became unregulated, pharmaceutical companies increased the prices of several products. In July 2000, the prices of pharmaceutical products were 3.6% higher than they had been in the previous July. This led to the introduction of a new price freeze in November 2000. It was in force until June 2001. It was decided, after the price freeze, that the Danish prices must not exceed the price level of November 2000 or the price level in 11 EU countries, Norway and Iceland. The ruling applies to both new and old products.

Changes in the drug reimbursement system and drug prices

1990
The deductible of DKK 800 (EUR 107.64) was abandoned 18 months after it was introduced. In 1 July 1989 a deductible, payable by the patient, of DKK 800 (EUR 107.64) had been introduced to curb the increase in drug costs. Drug reimbursements were paid only after the patient had paid the full amount of deductibles. However, the system proved difficult to implement and met with political problems.

1991
The regulation of the wholesaler margin was abandoned.

Generic substitution became possible.

1993
The reference price system was introduced.

1994
An agreement was made with the pharmaceutical industry to freeze prices until March 1995.

1995
The industry voluntarily reduced the prices of reimbursable drugs by 5% and those of other products by 2%.

A new, voluntary price freeze agreement was signed until April 1997.

1996
The reimbursement percentage for antibiotics was reduced from 75 to 50.

To cover insurance costs for drug damages the reimbursement percentages were reduced from 75 to 74.7 and from 50 to 49.8.

1997
Competition was encouraged through price comparisons. It became possible to delist a drug from the reimbursement system if its therapeutic value did not correspond with its price. The average European price was introduced to price evaluations.

The substitution system was reformed.

The pharmacist margin was reduced.

Authorities and pharmaceutical industry agreed on an acceptable increase of reimbursement costs.

1998
Some drugs were delisted from the reimbursement system.

2000
A new drug reimbursement system was introduced in March.

Prices were frozen from November 2000 until June 2001.

2001
New pricing criteria were introduced. The ending of the price freeze increased price levels.

With the reform of the Medicines Act the sale of over-the-counter medicines was allowed from outlets other than pharmacies. However, pharmaceutical products cannot be displayed on the supermarket shelves.

The rules governing substitution were simplified.

Latest changes, proposals and discussion topics

Several plans to contain the increase of drug reimbursement costs have been introduced in Denmark. In 1996, it was proposed that the reimbursement system should be changed so that it consists of only one category instead of the present three. The number of reimbursable drugs was proposed to be reduced and drugs would be accepted into the reimbursement system for a fixed period only, e.g. for four years. After the fixed period the cost benefit ratio of the drug would be re-evaluated by comparing it with therapeutically equivalent products. It was proposed that more drugs should be included in the substitution system and more over-the-counter medicines should be delisted from the reimbursement system. The aim of the working group behind the proposals was not to increase the proportion of drug costs to be borne by the patient but to produce a more

economic and effective system that is easier to manage. However, the changes were not implemented in the proposed form.

The introduction of therapeutic substitution has been discussed since 1997. The substitution by the pharmacist should not be limited to products containing the same active ingredient but therapeutically equal products could also be used. A list would be provided of the interchangeable products. The proposal was planned to be introduced as soon as possible. However, therapeutic substitution was not introduced since the industry and authorities could not agree on prices.

The committee which proposed the current drug reimbursement system evaluated the functionality of the entire drug distribution chain. The committee felt that competition in the drug market should be increased. The efficacy of pharmacies should be improved and it was proposed that it might be appropriate to abolish the principle of the same prices for the same drugs. Drug prices, then amongst the highest in Europe, should be reduced so that they would not exceed the average prices in Europe. The committee also proposed the introduction of therapeutic substitution and thought it was important to increase the amount of drug information.

The new Medicines Act of 2000, defined pharmacies as a part of the health care system. According to the new Act, a qualified pharmacist may own up to four pharmacies and private hospitals can found their own pharmacies. There are no regulations regarding pharmacy opening hours.

Finland

Each inhabitant of Finland is covered by public health insurance. The health insurance is managed by the Social Insurance Institution (*Kansaneläkelaitos, Kela*).

Pricing

In Finland, the pricing of pharmaceutical products by the marketing authorisation holder is unregulated. Drug reimbursement is a part of the overall public health insurance scheme, and the reasonableness of the drug price is one of the prerequisites of a reimbursement. Pricing is the responsibility of the Pharmaceuticals Pricing Board (*Lääkkeiden hintalautakunta*), which operates under the auspices of the Ministry of Social Affairs and Health. In addition to representatives from the Ministry of Social Affairs and Health, the Board also has representatives from the Ministry of Finance, *Kela*, the National Agency for Medicines and the National Research and Development Centre for Welfare and Health (*STAKES*).

When deciding on what constitutes a reasonable price, the Pharmaceuticals Pricing Board takes into account the cost of the drug therapy as well as the benefits to be gained from its use, as compared with alternative treatments, by the patient and by the social and health care services, from the perspective of total expenditure. The Board will also consider the prices of corresponding products in Finland and the price of the same pharmaceutical product in other EU countries. Manufacturing, research and development costs are also taken into consideration when deciding on the price. Since 1998, a health economic evaluation has been a compulsory addition to a price application for a product containing a new active ingredient. *Kela* will also submit their formal statement to the Board on the reasonableness or fairness of the suggested price.

The decisions are made for a fixed period only, and prices are valid for up to five years. The decisions made for products with a new active ingredient will remain valid for up to three years. In the past, prices were issued on a ”valid until further notice” basis and the Board was unable to reduce prices even when the criteria for the reasonableness of the price had changed. Since 1998, the prices set by the Board have been issued for a fixed period only. In 1998–1999 the Board reviewed all prices and converted previously issued prices from the indefinite to fixed-term validity. The price of a drug was reduced if its indications had been significantly expanded, if the same pharmaceutical product was available for a significantly lower price or if the price of the drug was significantly lower in the other Nordic countries or in the EU member states.

The wholesaler margin is not controlled. The pharmacist margin is degressive. Pharmacies are also paid a fee of FIM 2.48 (EUR 0.42) for any drugs dispensed.

Pharmacies in Finland pay a special tax, known as a pharmacy fee. The pharmacy fee is calculated from the pharmacy's turnover. The average pharmacy fee is approximately 7% of turnover. Value Added Tax for pharmaceuticals is 8%.

Criteria for reimbursement

In Finland, a drug must have an approved "reasonable wholesale price" to be eligible for reimbursement. After the reasonable wholesale price has been approved the product will automatically qualify for reimbursement under the Basic Refund Category.

Drugs used to treat certain serious and chronic illnesses attract more than the basic reimbursement, i.e. they are reimbursed under the Special Refund Categories. The Council of State makes decisions regarding both the illnesses justifying special refunds and drugs eligible for such a reimbursement. The following are considered: the nature of the illness, the necessity and cost implications of the drug and the therapeutic value of the drug as shown in clinical practice and research. The reimbursability of individual products is confirmed by *Kela*. In order to receive reimbursement under the Special Refund Category the patient must submit a doctor's certificate to *Kela* stating the illness, its severity and the medication needed to treat it.

The Council of State also makes decisions regarding the "significant and expensive" drugs, and illnesses which justify their reimbursement. The sub-group of "significant and expensive drugs" was introduced at the beginning of 1999. Drugs in this group are reimbursed only if the illness fulfils certain criteria. To qualify for reimbursement

the patient must submit a doctor's certificate to *Kela* or, in certain cases, the prescription must bear an appropriate marking. The reason for creating the sub-group was to target and limit reimbursement to patients who, based on existing knowledge and clinical evidence, are likely to gain most from these expensive treatments. *Kela* retains the right to decide at what stage or level of the illness the product becomes reimbursable. Moreover, *Kela* will decide what proof is to be submitted regarding the illness, to qualify for reimbursement. The "significant and expensive drugs" include drugs to treat the relapsing-remitting form of MS, Alzheimer's disease causing significant functional disability, severe erectile dysfunction caused by severe underlying disease and morbid obesity.

Over-the-counter medicines usually only qualify for reimbursement if used for long-term treatment. The Ministry of Social Affairs and Health makes decisions regarding the reimbursability of over-the-counter medicines.

Size of reimbursement

The reimbursement system contains a Basic Refund Category with a sub-group for “significant and expensive drugs” and two Special Refund Categories.

The patient pays a fixed deductible of FIM 50 (EUR 8.41) per purchase for drugs in the Basic Refund Category. Of the balance remaining, the patient pays 50%.

The Higher Special Refund Category includes 36 chronic illnesses. The patient pays a fixed deductible of FIM 25 (EUR 4.20) per purchase for drugs used to treat these illnesses. The category covers illnesses where drug treatment is necessary and effective to maintain the patient’s health status and where the drug restores or replaces normal bodily functions. Drugs used to treat diabetes and cancer are examples of drugs belonging to the Higher Special Refund Category.

The Lower Special Refund Category consists of ten chronic illnesses. The patient pays a fixed deductible of FIM 25 (EUR 4.20) per purchase for drugs used to treat these illnesses. Of the balance remaining, the patient pays 25%. The category includes illnesses where drug treatment is necessary to maintain the patient’s health status. The Lower Special Refund Category includes, for example, drugs to treat long-term hypertension, asthma and cardiac insufficiency.

A ceiling has been set to the annual sum payable by the patient. In 2002, this ceiling is EUR 594. The patient is entitled to an Additional Refund when his/her payments exceed the ceiling by FIM 100 (EUR 16.82).

Changes in the drug reimbursement system and drug prices

1990
The fixed deductible per purchase for drugs in the Basic Refund Category was increased from FIM 30 to FIM 35 (from EUR 5.05 to EUR 5.89).

1992
The fixed deductible per purchase for drugs in the Basic Refund Category was increased from FIM 35 to FIM 45 (from EUR 5.89 to EUR 7.57). The reimbursement percentage for drugs in the Basic Refund Category was reduced from 50% to 40%. The reimbursement percentage for the Lower Special Refund Category was reduced from 90% to 80%. Some over-the-counter medicines were delisted from the reimbursement system.

1993
The Working Group on the Reimbursement of Medicine Costs submitted its memorandum. Some of the proposals were introduced in 1994.

Generic substitution became operational.

1994
A fixed deductible, payable per purchase, was also introduced into the Special Refund Categories. The reimbursement percentage for the Lower Special Refund Category was reduced from 80% to 75%. The fixed deductible of the Basic Refund Category was increased from FIM 45 to FIM 50 (from EUR 7.57 to EUR 8.41) and the reimbursement percentage from 40% to 50%. An Additional Refund became payable only after the annual ceiling set to the patient's own payments was exceeded by FIM 100 (EUR 16.82).

Direct price monitoring was abolished. *Lääkekorvauslautakunta* (now *Lääkkeiden hintalautakunta*) became responsible for setting the wholesale price, on which reimbursement is based.

Turnover Tax for pharmaceuticals was abolished, and Value Added Tax for pharmaceuticals was set at 12%. The change increased prices by about 7%.

1996
Generic substitution was abandoned. Generic prescription was introduced.

1997
The Working Group on Medicine Costs submitted its memorandum. The Working Group put forward several proposals regarding, for example, pricing and the drug reimbursement system. A significant proportion of the proposals were implemented.

1998
The criteria for new drugs to become eligible for Special Refunds were reviewed.

Value Added Tax for pharmaceuticals was reduced to 8%.

The compulsory stockpiling surcharge was abolished.

The pharmacist margin was made more degressive.

Wholesale prices, which are the basis for reimbursement, were set for a fixed term only. Previous wholesale prices, which had been the basis for reimbursement, were reviewed and rationalised.

The *Rohto* programme was initiated. The aim of the *Rohto* programme is to guide doctor's prescribing habits towards a more rational direction.

1999
The sub-group of "significant and expensive drugs" was introduced.

2001
The Working Group on the Reimbursement of Medical Expenses 2000 submitted its concluding report.

Latest changes, proposals and discussion topics

The Working Group on the Reimbursement of Medical Expenses 2000, appointed by the Ministry of Social Affairs and Health, concluded its task in the spring of 2001. The task of the Working Group was to evaluate the functionality and appropriateness of the drug reimbursement system taking into consideration the cost-effectiveness, current treatment practices, the international development of the medical sector and European reimbursement practices.

According to the Working Group the current reimbursement system is ready for reform but the Working Group failed to present a unanimous proposal for a new system. The reform could be either based on the current system or could be a cost-based, single reimbursement category system. The model based on the current system gained more support among the Working Group members. In the single reimbursement category system the patient would pay a fairly high deductible per product, but the reimbursement percentage for the balance remaining would be high.

The Working Group felt that in the future a group of medical experts should assess, for example, which drugs could be left non-reimbursable and which should be included in the sub-group of “significant and expensive drugs”. The group of experts should also evaluate the functionality and appropriateness of the Special Refund Categories as well as the possibilities to increase the use of more economically priced generic products.

The Ministry of Social Affairs and Health appointed, without delay, an administrator for further examination of the proposals. His task is to present, by the summer of 2002,

- a reclassification of the pharmaceutical products that remain outside the current reimbursement system, the drugs in the Basic Refund Category and the illnesses and drugs in the Special Refund Categories. The reclassification should be done in such a manner as to create a reimbursement system with one Basic Refund Category, one Special Refund Category and possibly a Nil Refund Category.

- proposals for the prerequisites, and the evaluation methods thereof, required of a drug to be included in the Special Refund Category.

- the definition of “significant and expensive drugs” and proposals for the reimbursement of rarely used drugs.

France

The French population is covered almost universally by health insurance. Health insurance is managed by various sickness funds, the members of which include various professional groups and their family members. A large proportion of the population also has additional insurance to cover charges not paid for by public health insurance.

Pricing

The pricing of drugs by the manufacturers is unregulated. However, the prices of reimbursable drugs must be approved. Once the marketing authorisation has been obtained, the holder will submit a price application both to the *Comité Economique des Produits de Santé* (CEPS, formerly CEM) and the *Commission de Transparence.*

The *Commission de Transparence* will assess the therapeutic value of the product and will issue an opinion on the reimbursability of the product. The commission consists of medical and pharmaceutical representatives as well as representatives from the health insurance organisation, industry and other professions. The commission assesses whether the drug should be included in the reimbursement system (known as the SMR classification) and what is the added value of the drug as compared with existing drug treatments (ASMR classification). The ASMR classification includes five levels:

1. Major therapeutic progress.

2. Products with great improvement in terms of efficacy, or reduction of adverse events, as compared with existing products.

3. Products with modest improvement in terms of efficacy, or reduction of adverse events, as compared with existing products.

4. Products with minor improvement in terms of benefits as compared with existing products. These benefits could include, for example, user-friendliness or a smaller interaction risk.

5. Products with no therapeutic improvement as compared with existing products but are considered a justified addition.

   The sixth class includes products with no achievable benefits and they will be classified as non-reimbursable.

The classification is mainly based on therapeutic values; economic issues are considered only for the first two levels. The ASMR level is re-assessed every three years.

The price is set in negotiations between CEPS and the manufacturer. CEPS consists of representatives from the ministries responsible for finance, social affairs and health. The price setting takes into account the ASMR level, expected sales, the research and marketing costs of the drug and funds available for health care. In practice, products with an ASMR level 1–4 can be set a price that is higher than that of alternative products. This does not always take place automatically if it is estimated that the sales will be sufficient to provide the manufacturer with an adequate profit margin. The price of products at level 5 cannot exceed that of existing products. If a new product is expected to increase the drug consumption of the entire group, a price that is lower than that of the existing products might be requested.

The price of a generic product has to be 30% lower than that of the original product.

The wholesaler and pharmacist margins for reimbursed drugs are regulated, but they can set their own margins for other products. The calculation of the margins was simplified in 1999. The wholesaler margin for lower priced drugs is proportionately larger than that for more expensive drugs. The six-tiered pharmacist margin was changed to a three-tiered system in 1999. The margin is regressive. Pharmacies are also paid a delivery fee for any dispensed reimbursable drugs. In 2002, the fee is FRF 3.50 (EUR 0.53) per drug. The fee is FRF 5.50 (EUR 0.84) for certain drugs which require special advice given by the pharmacist.

Value Added Tax for reimbursable pharmaceuticals is 2.1% and for other pharmaceuticals 5.5%. France has been reprimanded twice by the European Commission for the reduction of Value Added Tax payable for reimbursable pharmaceuticals. The tax is considered too low and therefore discriminatory towards other products.

The French drug prices have for long been among the lowest in Europe. Due to the low prices the industry has sought compensation through higher sales volumes. Drug consumption per inhabitant in France is one of the highest in Europe.

Criteria for reimbursement

Approximately 7,700 pharmaceuticals are marketed in France, and less than 40% are prescription drugs. A little over half of the products, i.e. 4,200, are included in the reimbursement system.

Two lists for reimbursable drugs, i.e. positive lists, are operational in France: one for outpatient care and one for hospital use. CEPS makes decisions regarding the reimbursability and the actual reimbursement category of a drug. The level of reimbursability is determined according to the efficacy, adverse effects, the severity and duration of illness, existing treatments available and issues relating to public health. A reimbursable drug must have an approved price.

The reimbursement of some very expensive drugs requires a prior decision for each individual patient.

Size of reimbursement

There are three reimbursement categories:

- The 100% reimbursement category which includes essential and particularly expensive drugs, such as drugs to treat diabetes, AIDS and cancer as well as drugs used in certain chronic illnesses (approximately 30 illnesses are listed).

- The 65% reimbursement category which includes important drugs, such as antibiotics.

- The 35% reimbursement category which includes drugs to treat acute illnesses. The majority of reimbursable drugs belong to this category.

- There is no fixed deductible in any of the categories, but a percentage payment is calculated from the total cost. Certain patient groups, i.e. those with a chronic illness, are exempt from any deductibles. Approximately 40% of all reimbursed prescriptions are dispensed free of charge to the patient.

Agreements with the pharmaceutical industry

The price setting procedure is based on agreements between the pharmaceutical industry and the State. The previous agreement, between CEM and the Central Organisation for the pharmaceutical industry, came to an end towards the end of 1996. The new agreement did not emerge until 1999, after lengthy discussions. The new agreement has been signed separately with each pharmaceutical company. It sets limits both to the total sales growth of different therapy groups and to the sales of individual companies. If the limits are exceeded the industry will pay back a part of the overspent sum to the State. For this repayment, a percentage will be calculated separately for each therapeutic group. The repayments for the various therapeutic groups will partly be the joint liability of the industry and partly of individual companies. It is possible to make the

repayment through price reductions. Products classified as ASMR level 1 are exempt from the repayments for three years and products at the level 2 for two years. Generic products do not generate repayments.

The agreement included a statement according to which new innovative drugs will be priced in France in such a manner that no parallel import will be generated. The validity period of prices and reimbursement decisions was also shortened. CEPS (CEM) and representatives of the industry keep each other informed at regular intervals on any changes in training, prescribing habits and drug reimbursements.

The agreement was signed by 97% of pharmaceutical companies. The sum to be repaid by the companies which did not sign the agreement will be calculated according to total drug sales, and they will not have the opportunity to make the repayment through price cuts.

Generic substitution

The proportion of generic product sales has been very small in France. The introduction of generic substitution was discussed for several years. In 1998, pharmacies agreed to substitute an out of stock item with a generic equivalent. Generic substitution was introduced properly in early 1999. It is only possible to substitute a generic product with a cheaper generic product, and only with the customer's approval. The doctor may prohibit substitution by marking the prescription with "NS". In 1999, a new, more extensive substitution list was introduced with the aim to encourage the use of more economically priced products. The list has been updated several times since then. The introduction of substitution has not increased the use of generic products and the anticipated savings have not been reached.

Changes in the drug reimbursement system and drug prices

1990
Turnover Tax for reimbursable drugs was reduced from 5.5% to 2.1%.

1993
A 9% Marketing Tax was levied on reimbursable drugs.

1994
The reimbursement percentage was reduced from 70% to 65% and from 40% to 35%.

The first price agreement with the pharmaceutical industry came into force.

1995
The pharmaceutical industry paid a “solidarity sum” of FRF 2.5 billion (EUR 0.4 billion).

1996
Marketing Tax was increased to 14%.

1998
The pricing practices for generic products were tightened: the price of a generic product had to be 30% lower than the original product.

1999
Generic substitution was introduced.

Prices in certain drug groups were reduced by 3–5.5%.

The calculations of the wholesaler and pharmacist margins were made simpler.

A new price agreement with the pharmaceutical industry came into force.

A re-classification of all reimbursed drugs was commenced.

2000
The first change was introduced to the reimbursement categories as a result of the re-classification. The reimbursement percentage of vasodilators was reduced from 65% to 35%. However, the decision had to be rescinded due to faulty administrative procedures.

2001
The delivery fee payable to pharmacies was changed.

The re-classification of reimbursed drugs was completed.

The prices of drugs deemed ineffective during the re-classification were reduced.

The prices of some market successes (e.g. proton pump inhibitors and lipid-lowering drugs) were reduced by 2–15%.

In December, a list was published containing approximately 200 products whose reimbursement percentage was to be reduced from 65% to 35% (e.g. sucralfate, cortisone, neomycin, leuprorelin, buserelin).

Latest changes, proposals and discussion topics

Several attempts have been endeavoured in France to contain the increasing drug costs. Generic substitution was introduced in 1999, and to promote generic substitution the government has promised cuts in the Marketing Tax for manufacturers who market generic products. Pharmacies are encouraged to practise generic substitution through discounts. Pharmaceutical companies are allowed to give discounts of up to 10.7% to pharmacies for generic products, when the maximum discount for other products is 2.5%. However, the sale of generic products has remained low; in 2001 it was only approximately 3% of total sales. Proposals have lately been put forward to increase the price difference between generic and original products from the present 30% to 40%.

CEPS has re-classified the drugs within the reimbursement system for the purposes of evaluating their reimbursement status. In addition to the efficacy of the drug, the re-classification took into account the adverse effects, indications and value of the drug as compared with other drugs in the same therapeutic group. The drugs were divided into four levels: effective, moderately effective, slightly effective and ineffective. Of the total of 4,200 products assessed, 63% were categorised as effective or moderately effective, 19% as slightly effective and 19% as ineffective. The re-classification has been presented to the marketing authorisation holders who are given an opportunity to respond. It is not

known as yet what will be the approach taken towards the products classified as ineffective. The proposal to render them non-reimbursable without delay has been abandoned since many of these products are manufactured by small French companies, and the removal of them from the reimbursement system could lead to job losses. It is likely that their prices will be cut and the reimbursement category lowered, and they will gradually be phased out from the system over the next three years.

In 2001, a new type of price agreement was made in France with the manufacturers of the two COX 2 inhibitors, celecoxib and rofecoxib. At the time of price setting it was agreed that after a certain time the manufacturers would reduce the prices. The manufacturer of Celebrex, which contains celecoxib, has agreed to reduce the price by 18% in 2004. The price of Vioxx, which contains rofecoxib, will be reduced twice. In 2003, the price of the higher strength product will be reduced by 13.3%, and in 2005 the price of the higher strength product will be further reduced by 20% and that of the lower strength product by 16%. Similar agreements are expected to be made in France in the future, in connection with price approvals for products containing new medicinal substances.

French doctors prescribe three times as many antipsychotic drugs as German doctors and twice as many antimicrobials as UK doctors. The government set a target to reduce the consumption of antidepressants and antimicrobials by 10%

by 2000. The prescription of antimicrobials was to be reduced though information and training aimed at doctors. However, these measures had no significant effect.

At the moment discussions are held with pharmacies on the maximum wholesaler discounts acceptable, without them affecting the calculation method for the pharmacist margin. It has also been proposed that the delivery fee for generic drugs should be increased and that for other products decreased.

Germany

The health insurance system in Germany is managed by hundreds of sickness funds, the majority of which are employees' sickness funds. Those with high earnings may choose between a private insurer and statutory health insurance. The majority are covered by statutory health insurance, based on their earnings. Children are usually covered by a private insurer.

Pricing

Drug prices in Germany are higher than the average European prices. Pricing by the marketing authorisation holder is unregulated. A notification of the price to the authorities is the only requirement. Even though drug prices are officially unregulated in Germany, the authorities have tried to influence them through the introduction of a reference price system, negative lists and budgets allocated to individual doctors.

A reference price system has gradually been introduced since 1989. The system covers drugs which have generic alternatives and therapeutically equal products on the market. The *Bundesausschuss der Artze und Krankenkasse* (BAK), which consists of doctors and representatives of sickness funds, classifies drugs into three categories for the purposes of setting the reference price:

1. Pharmaceuticals with the same medicinal substance.

2. Pharmaceuticals with a comparable medicinal substance and which are therapeutically equal.

3. Pharmaceuticals which are therapeutically equal, particularly combination products.

The reference price is set for a so-called standard package. A package with a size and strength available in the range provided by several manufacturers is chosen as a standard package. If several suitable package sizes and strengths are available, the most sold one is chosen as the standard package. The prices of other packages are defined in relation to the standard package.

When defining the reference price the differences in price, set savings targets and the manufacturer's interest are considered. The aim is to set a reference price which will also allow price competition between products priced below the reference price. The price should be in the upper limits of the lowest third of the appropriate price band.

Until 2001, the sickness funds' umbrella organisation *Spitzenverbände der Krankenkassen* (SK) made the final decision on reference prices. From 2002

until 2003 the ministry responsible for health is temporarily setting the reference prices. So far, it is not yet clear how the setting of reference prices will be managed after 2003. Reference prices are reviewed once a year.

The sale of drugs covered by the reference price system accounts for over 70% of the total sale of reimbursable drugs. Drugs not covered by the system include patented drugs, drugs prepared at pharmacies and vaccines.

The wholesaler and pharmacist margins are regulated. Both margins are degressive. Pharmacies are required to give discounts to the sickness funds. The discount used to be 5%, but as a part of savings measures introduced in early 2002 the discount was increased to 6% for the duration of 2002 and 2003.

Until April 1998, Value Added Tax for pharmaceuticals was 15%, after this it was increased to 16%.

Criteria for reimbursement

Approximately 70,000 pharmaceutical products are marketed in Germany, which is the highest number in the EU region. Several homeopathic products and natural remedies are classified as pharmaceutical products. All pharmaceutical products are included in the public reimbursement system, except those on the negative list. There are two negative lists. The first one was introduced in 1983 and the second in 1991. The lists include products with only slight therapeutic value. These products include, for example, combination products containing three or more active ingredients and products with controversial efficacy. Several drugs, used for the treatment of the common cold and digestive symptoms, are reimbursed only to patients below the age of 18. Drugs in the negative list can be reimbursed on a named patient basis.

Size of reimbursement

For drugs in the reference price system, the sickness fund pays the cost up to the reference price, and the patient pays the excess. The patient also has to pay a fixed package fee. When purchasing drugs not included in the reference price system, the patient will only pay a package fee. The fee is calculated according to the package size. In 2001, the fee was DEM 8 (EUR 4.09) for small packages, DEM 9 (EUR 4.60) for medium-sized packages and DEM 10 (EUR 5.11) for large packages. Whether a package is considered large or small is also dependent on the pharmaceutical form and the illness being treated. A package containing 20 tablets intended for the treatment of a chronic illness may be considered small, but the package may be considered large or medium-sized if used to treat an acute illness. The proportion payable by the patient must not exceed the actual

price of the medicine, i.e. if the actual price is lower than the package fee the patient will only pay the actual price.

A limit has been set to the sum payable by the patient: the deductibles must not exceed 2% of the patient's net earnings. The limit is lower for those suffering from chronic illnesses, i.e. 1% of net earnings. Some patient groups are exempt from deductibles altogether, for example, children, pregnant women, those in receipt of social welfare, the unemployed and those on a low income. Forty per cent of the population was exempt from paying deductibles in 1998. In 1999, the rules were changed so that those with a chronic illness became exempt from the payments 12 months after diagnosis.

Generic substitution

Generic substitution was previously allowed only with the permission of the prescriber. In February 2002, new substitution legislation came into force but its introduction is going to be gradual. According to the new legislation, the pharmacy must dispense the patient with one of the five cheapest generic products available, unless forbidden by the prescribing doctor. However, the pharmacy is not allowed to substitute the product if the doctor has already chosen a product from the lowest third of the price band. As compared with other European countries, a large amount of generic products are currently sold in Germany.

Drug expenditure budgets

In 1993, a drug expenditure budget was introduced. The budget defined the funds available for sickness funds. The plan was for any budgetary excess to be the liability of both the doctors and the pharmaceutical industry. However, the full budget was not spent in 1993. In 1994, the pharmaceutical industry was released from its liability and doctors were allocated regional budgets. In 1998, instead of regional budgets, budgets were issued for each surgery. The system of regional budgets was resumed the following year. In theory, slight overspending will generate a warning, but more serious consequences may follow overspending of more than 25%. In practice, a repayment has not so far been requested. The introduction of an individual budgetary ceiling for each doctor is currently being discussed again in Germany. When setting the budgetary ceiling the number of patients, their age and morbidity would be taken into account. Should the doctor exceed the ceiling he/she could be banned from prescribing or his/her prescribing habits would be monitored during a probation period. The measures taken would be dependent on the seriousness of the case. Doctors who do not reach their budgetary ceiling could be awarded benefits.

Very little research has been done into the effect of drug budgets on drug costs. There is evidence that budgets have rationalised prescribing habits. On the other hand, it has also been reported that towards the end of the year, when funds available are scarce, patients do not receive the treatment they need and that treatment costs are transferred to be paid by other health care sectors. Particularly expensive drugs are prescribed privately.

Changes in the drug reimbursement system and drug prices

1989
The reference price system was introduced.

1991
The negative list was expanded. The list contained 3,000 products.

1992
Prescription charge was increased from DEM 2 to DEM 3 (from EUR 1.02 to EUR 1.53)

Prescription charge was removed from drugs in the reference price system.

1993
The first drug expenditure budget.

Prices of prescription drugs not in the reference price system were reduced by 2.5–5%, and prices were frozen until 1995.

A prescription charge was reintroduced for drugs in the reference price system. The charge was tied to the price of the drug: DEM 3 (EUR 1.53) for products priced up to DEM 30 (EUR 15.34), DEM 5 (EUR 2.56) for products priced up to DEM 50 (EUR 25.56) and DEM 7 (EUR 3.58) for products priced over DEM 50 (EUR 25.56).

The reference price system was simplified.

Value Added Tax for pharmaceuticals was increased from 14% to 15%.

Pharmacies were required to dispense a generic alternative, if it was priced at least 10% lower (DEM 1, i.e. EUR 0.51) than the original product. The ruling was not followed in practice and was abolished in 1995.

1994
Prescription charge was tied to the package size and no longer to the price of the drug (DEM 3, DEM 5,DEM 7; EUR 1.53, EUR 2.56, EUR 3.58).

1997
Prescription charges were increased in January (DEM 4, DEM 6, DEM 8; EUR 2.05, EUR 3.07, EUR 4.09).

Changes in reimbursement payments were tied to the prescription charge, i.e. should the proportion of drug costs reimbursed by health insurance increase by 0.1% the prescription charge would be increased by DEM 1 (EUR 0.51), or the equal percentage.

Regional drug budgets were replaced by budgets allocated to individual doctors or the surgeries.

Prescription charges were increased in July (DEM 9, DEM 11, DEM 13; EUR 4.60, EUR 5.62, EUR 6.65).

The reference price system was reviewed. The changes implemented reduced the prices of drugs in the system. Prices of other drugs increased.

1998
Value Added Tax for pharmaceuticals was increased to 16%.

The wholesaler and pharmacist margins were reduced for the most expensive drugs.

1999
Prescription charges were reduced (DEM 8, DEM 9, DEM 10; EUR 4.09, EUR 4.60, EUR 5.11).

The practice of issuing regional budgets was resumed.

2000
The negative list was expanded.

The reference price system was expanded with the addition of 55 new drugs.

2001
New, reviewed reference prices were introduced.

2002
Several savings measures were introduced. Changes were made, for example, to the substitution rules and the drug discounts given to the sickness funds.

Latest changes, proposals and discussion topics

BAK, which acts as the professional body for doctors and sickness funds, decides on the measures to be taken to ensure appropriate and economical health care to the German population. It has provided guidelines of the duties and commitments of those prescribing drugs. These guidelines also contain the principles of when to instigate drug treatment.

According to the guidelines the doctor must consider the necessity of a drug treatment before prescribing one. There is no need to prescribe a drug if its use is not medically founded, if the same treatment result can be achieved with a drug-free approach or if there is no evidence of the benefit of the drug. The doctor should choose the most economic product. When prescribing a drug the doctor must be aware of the treatment guidelines issued for the particular illness and of the approved indications of the drug. If the drug is prescribed for long-term use, arrangements must always be made for follow-up appointments. The joint organisation for doctors and sickness funds issues doctors instructions regarding drugs which are therapeutically equivalent, regardless of their active ingredients. The aim of these instructions is to guide prescribing habits so that the expensive drugs would only be prescribed when they are therapeutically superior.

It is not usually possible to investigate the efficacy of different drugs at the sickness funds' expense. However, in exceptional cases the fund may give permission for such a trial. It has been proposed that the doctor should write down the ICD-10 code on the prescription to facilitate the monitoring of prescribing habits.

An introduction of a positive list is once again being proposed in Germany. Similar proposals were made in 1993-1995. A draft of a new positive list, drawn up by a broad based panel of experts, is currently being circulated to the authorities. Drugs with only minor therapeutic benefit or poor cost effectiveness have not been included.

In 2002, the manufacturers of original products were required to pay the State a one-off payment of EUR 204.5 million. The sum is to be divided between the sickness funds. Another savings measure discussed is the reduction of Value Added Tax for pharmaceuticals.

Changes have been proposed to the deductibles so as to discourage the purchase of large packages. The proposed deductible is 15–20% of the price of the drug, but a ceiling would be set to the deductibles of particularly expensive drugs. The sums payable by the patient would be income related.

An electronic citizen's health card is planned to be introduced in Germany with information about the patient's illnesses and medication. The introduction of the card is anticipated to reduce the amount of paperwork and improve

communication between different health care departments as well as reduce the likelihood of prescribing interacting drugs.

Greece

Many insurance systems operate in Greece. The *Institutous Kinonikis Asfalias* (IKA), which is the largest insurance company, covers almost half of the population. Farmers (OGA) have their own large insurance company as do merchants, manufacturers and small businessmen (TEVE). These three offer insurance to 90% of the population. The rest are insured by over 70 different insurers. Approximately 40 of these are involved in health insurance.

Pricing

In Greece, the prices of both prescription drugs and over-the-counter medicines are monitored. Price levels are among the lowest in Europe and drug consumption is relatively high. Due to the low prices, patented drugs are exported from Greece.

Prices are set by a body which operates under the Ministry of Development with representatives from other ministries, IKA, pharmacies and the pharmaceutical industry.

Before 1997, the prices in Greece were based on the average of the three lowest European prices. Today, the approved price is based on the lowest price of the product in the other European countries and on the calculated, theoretical price of the product. The theoretical price of an imported product consists of its price in the country of origin plus import etc. costs. The theoretical price of a product manufactured in Greece consists of manufacturing, distribution etc. costs. The lowest European price is then compared with the theoretical price and the lower of the two is set as the maximum price for the product. The reasonableness of the price should be checked annually, but this has not happened in practice. The price of a generic product has to be at least 20% lower than that of the original product.

A price can generally only be set for imported products if the product is for sale in at least two other European countries, of which at least one uses price regulation. This ruling is not applied to drugs deemed essential for health care.

The drug can only be marketed after its price has been announced in an official journal. The notification should be published every 90 days, but, in practice, the time difference between publications may be almost a year. This causes discontent, particularly among the pharmaceutical industry.

A fixed percentage margin is set for wholesalers and pharmacists. Wholesalers may give discounts to pharmacies, but the discounts for prescription drugs must not exceed 5%. To support the work of rural pharmacies the wholesalers give them extra discounts. Value Added Tax for pharmaceuticals is 8%.

Criteria for reimbursement

The first national positive list was introduced in 1998. It included mainly generic products. When the list was being compiled the efficacy of the product and its cost, as compared with products within the same drug group, were taken into consideration as well as its availability in France, Germany, Sweden, Switzerland, the UK and USA. Drugs included in the positive list must be for sale in at least three of the above countries. All drugs costing less than GRD 400 (EUR 1.17) and drugs considered essential, such as cancer drugs and antidepressants, are included in the list. Approximately 25% of drugs are not included. The list should be renewed every other year, but this has not always happened.

Only drugs prescribed by a doctor working within an insurance system will be reimbursed.

Size of reimbursement

Insurance companies usually pay 75% of the drug costs, but there are some exceptions. Certain patient groups, such as pensioners, children and patients with some chronic illnesses, e.g. diabetes or cancer, are exempt from any payment. In some chronic illnesses, the patient pays 10% of the drug costs. These illnesses include Parkinson's disease, Paget's disease and Crohn's disease.

Changes in the drug reimbursement system and drug prices

1993
Drug prices were increased 1-5% per product (an average of 2.75%).

IKA approved a positive list.

1994
Prices of drugs were frozen for three years. Prices were not increased between 1994 and 1997, and no new products were accepted into the reimbursement system from June 1996 to June 1997.

1995
IKA started to use the price of a generic drug as the basis for reimbursing original products.

1996
Drug price setting was changed.
The wholesaler and pharmacist margins were reduced.

1997
The following proposals were put forward: the reduction of the pharmacist margin from 35% to 34%, the reduction of the wholesaler margin from 8.4% to 7.4%, the introduction of a negative list and a reference price system, the setting of prices to 63% of the European average and an introduction of a system which would allow the sickness funds to negotiate prices directly with the manufacturers. The plans did not come into force in the proposed form.

A new price setting procedure was introduced, which takes into account the lowest price in Europe and the calculated theoretical price of the product.

1998
In April, a national list of reimbursable drugs was introduced.

2000
A list containing 200 proposals to improve the health care system was published.

Latest changes, proposals and discussion topics

According to the Greek Supreme Court decision made at the end of 2001, the current drug pricing procedure in Greece is illegal. The repercussions of the decision are not yet known. The Ministry and the pharmaceutical industry are discussing ways to make necessary alterations to the pricing method. The aim of the industry is to return the pricing method to the pre-1997 state.

Iceland

The entire Icelandic population is covered by health insurance, which is managed by the *Tryggingastofnun rikisins* (TR).

Pricing

The pricing of over-the-counter medicines by the manufacturer is unregulated. The maximum wholesale and retail prices for all prescription drugs, however, are set by the ministry responsible for social affairs and health (*Heilbrigdis- og tryggingamalaraduneytid*). Drug regulatory authorities are also consulted. Issues relating to pricing are discussed within a pricing committee (*Lyfjaverdsnefnd rikisins*) which operates under the ministry.

A reference price system was introduced in Iceland in 1995. A reference price is set for each drug group by adding 5% to the price of the cheapest product. The prices are checked every calendar quarter.

The wholesaler and pharmacist margins are regulated.

Value Added Tax for pharmaceuticals is 24.5%.

Criteria for reimbursement

The ministry responsible for social affairs and health and the TR make decisions regarding the reimbursability of drugs. The criteria considered include the therapeutic value of the drug and funds available for reimbursement. A health economic evaluation for new pharmaceutical products is required at an increasing frequency.

Size of reimbursement

The reimbursement rules were simple in Iceland, until the end of 1991. All patients only paid a fixed prescription charge for their medication. Patients were rarely aware of the sums involved and no price competition between products existed. In 1990, the social insurance paid on average 82% of all drug costs.

According to the Nordic Statistics on Medicines 1987–89, the average drug costs per inhabitant in Iceland were 50% higher than those in the other Nordic countries. When the matter was investigated it became apparent that the consumption of antimicrobials and anti-ulcerative drugs was far more prevalent in Iceland than in the other Nordic countries. The average wholesaler and pharmacist margins were also higher.

In 1992, the drug reimbursement system was changed and the fixed prescription charge was replaced with a payment consisting of a fixed deductible component and a percentage-based component. In the new system, drugs are divided into four groups. Reimbursability is based on the ATC class and the therapeutic indication of the drug. As a result of the reform, the proportion of a patient's drug costs reimbursed by the social insurance fell to 68%.

The majority of pharmaceutical products belong to Group E. In 2002, patients pay 80% of the cost exceeding ISK 1,700 (EUR 19.28) for drugs in this group, up to ISK 4,950 (EUR 56.14) per prescription. Pensioners and the disabled pay 50% of the cost exceeding ISK 600 (EUR 6.81), up to ISK 1,375 (EUR 15.59).

For drugs in Group B, patients pay 65% of the cost exceeding ISK 1,700 (EUR 19.28), up to ISK 3,400 (EUR 38.56). Pensioners and the disabled pay 50% of the cost exceeding ISK 600 (EUR 6.81), up to ISK 1,050 (EUR 11.91). This group includes, for example, drugs to treat cardiovascular diseases as well as antidepressants and antiasthmatics.

The deductible, payable by the patient, has been increased almost annually for the drugs in Group B or E.

The patient pays the total cost of drugs in Group O. This group includes almost all over-the-counter medicines, some antimicrobials, a significant proportion of hypnotics, sedatives and some anxiolytics.

Patients receive drugs for diabetes, some antipsychotics, hormone preparations and drugs to treat glaucoma free of charge. Since the beginning of 2001, most cancer drugs, immunoglobulins, new antirheumatic drugs, erythropoietin and coagulation factors have been classified as hospital products.

For drugs belonging to the reference price system, the patient pays the amount exceeding the reference price.

Expensive drugs are reimbursed after an individual assessment carried out for each patient.

Drugs for up to 100 days' treatment can be reimbursed per one purchase. For some drugs, e.g. anti-ulcerative drugs, only a 30 days' supply can be reimbursed.

Changes in the drug reimbursement system and drug prices

1990
Doctors were issued with a list of lower priced products (the *Best Buy* list). It allowed price comparison between drugs within the same group. If the doctor chose the lowest priced product from the list the patient also benefited, in the

form of a lower prescription charge; the prescription charge for drugs included in the *Best Buy* list was ISK 550 (EUR 6.24) and that for other drugs ISK 750 (EUR 8.51).

1991
Cough medicines, all preparations used for the common cold, laxatives, sedatives, hypnotics and some oral antimicrobials were delisted from the reimbursement system.

The fixed prescription charge was increased from ISK 750 to ISK 850 (from EUR 8.51 to EUR 9.64). The prescription charge for products in the *Best Buy* list was reduced from ISK 550 to ISK 500 (from EUR 6.24 to EUR 5.67).

1992
Lipid-lowering drugs were reimbursed only after individual assessment of each patient.

Generic substitution was introduced. It became possible to substitute the prescribed drug with a cheaper one if the prescription bore the marking ”S”. If the prescription bore the marking “R” substitution was not possible.

The fixed prescription charge payable by the patient was replaced with a payment consisting of a fixed deductible component and a percentage-based component. In the new system, the patient paid 25% of the cost exceeding ISK 500 (EUR 5.67) for drugs in Group E, up to ISK 3,000 (EUR 34.03). Those over 67 years of age paid 10% of the cost exceeding ISK 150 (EUR 1.70), up to ISK 700 (EUR 7.94). For drugs in Group B, the patient paid 12.5% of the cost exceeding ISK 500 (EUR 5.67), up to ISK 1,500 (EUR 17.01). Pensioners and the disabled paid 5% of the cost exceeding ISK 150 (EUR 1.70), up to ISK 400 (EUR 4.54).

The proportion payable by the patient increased on average by 13%. The proportion payable by the elderly and the disabled decreased by 8.7%.

1993
The deductible, payable by the patient, was increased.

The ATC class of the drug became the basis for reimbursement.

1994
Drug legislation was changed. The pharmacy licence holder must carry the professional responsibility, but the proprietor of the pharmacy may be someone other than a pharmacist. One of the aims of the reform was to increase competition between pharmacies.

Unregulated pricing was introduced for over-the-counter medicines.

Restrictions were applied to the amount of drugs reimbursed per purchase.

1995
The reference price system was introduced.

The pharmacy staff were required to inform customers of cheaper alternatives whenever the prescription did nor bear the marking “R” (no substitution).

The deductible, payable by the patient, was increased.

1996
Restrictions to establish a pharmacy were lifted. The pharmacist must still hold the qualification of a Master of Science (Pharmacy).

The deductible, payable by the patient, was increased.

1997
The maximum wholesale and retail prices were reviewed. Prices of drugs costing over ISK 3,100 (EUR 35.16) were increased. The prices of all other drugs were reduced. In October 1997, the maximum retail prices were on average 6.6% lower than in January 1996. The prices of the twenty most sold products were reduced by 14%, on average.

The deductible, payable by the patient, was increased.

1998
The deductible, payable by the patient, was increased.

1999
The deductible, payable by the patient, was increased.

2000
The deductible, payable by the patient, was increased twice during the year.

Latest changes, proposals and discussion topics

Iceland has tried various ways to reduce drug consumption and costs, i.e. regulations regarding the drug reimbursement system have changed, distribution margins have been reduced and the reimbursement list has seen the introduction of the *Best Buy* list, as well as lists containing reimbursable and non-reimbursable drugs. Furthermore, generic substitution has been approved and attempts have been made towards rationalising prescribing habits.

The deductibles have been increased nine times during the last nine years. In 2002, yet another increase came into force. Iceland planned a changeover to a gradual reimbursement system, as in Sweden and Denmark. So far these plans have not been implemented and lately “a different” system to the ones in Sweden and Denmark has been discussed. Details of the plan have not been published. Most concern appears to be around the issue of how to ensure drug treatment to those who receive it free of charge under the present system.

Other topics of recent discussions have included increasing the use of generic products, more extensive use of health economic evaluations and the introduction of a prescription register. The register would allow the monitoring of the prescribing and consumption of medicines.

Ireland

The entire Irish population is covered by health insurance. Those on a low income, i.e. about 30% of the population, are eligible for free health care and medicines through a system called the *General Medical Services* (GMS). The remainder pay a proportion of any health care services they receive. Almost half of these people are covered by a voluntary, additional insurance to cover any out-of-pocket expenses.

Pricing

In principle, there is no regulation of prices for drugs entering the market. Since 1972, the ministry responsible for social affairs and health and the pharmaceutical industry, i.e. the *Irish Pharmaceutical Healthcare Association (IPHA),* have signed a succession of agreements on the supply and price of drugs within the GMS system. The latest agreement is from 1997, and it was signed for five years. According to this agreement, the maximum factory price in Ireland must not exceed the lowest price of a corresponding product in the UK nor the average price in Denmark, France, Germany, the Netherlands and the UK. If the product is not available in these reference countries, the price will be negotiated. In practice, the prices set are also applicable to drugs other than the GMS-reimbursed prescription drugs. In Ireland, health economic evaluations may be required.

The pricing of over-the-counter medicines by the manufacturer is unregulated.

The wholesaler margin is usually 15–17% of the factory price. The margin for high technology medicines is lower than that for other medicines. Wholesalers often give discounts to pharmacies.

The pharmacist margin is regulated, and it varies according to the reimbursement system. The pharmacies are reimbursed, by the GMS, a fixed sum of IEP 1.93 (EUR 2.45) for any reimbursable drugs dispensed. Under the *Long Term Illness* (LTI) scheme and the *Drug Payment Scheme* (DPS), pharmacists are paid a 50% margin for reimbursed drugs and a fixed dispensing fee of IEP 1.68 (EUR 2.13). Pharmacists are paid a monthly fee of IEP 31.52 (EUR 40.02) for dispensing high technology medicines. There is no regulated margin for other medicines, but the principles of the LTI and DPS schemes are often applied by the pharmacists.

There is no Value Added Tax for oral medication. Value Added Tax for all other pharmaceuticals is 21%.

Criteria for reimbursement

The *Department of Health,* which operates under the ministry for social affairs and health, is responsible for making decisions on the reimbursability of drugs. Reimbursable drugs are listed in a positive list (called the *Code Book*) which is updated annually. Practically all drugs marketed are reimbursable. According to the agreement of 1997, drugs will not be removed from the list for the duration of the agreement.

A negative list was introduced in Ireland in 1982. The list includes over-the-counter medicines, analgesics and antacids.

Size of reimbursement

Drugs, prescribed by a doctor contracted to the GMS, are free to a patient covered by the GMS system. In 1999, drug purchases made by these patients accounted for 78% of all drug expenditure.

Patients diagnosed as suffering from certain chronic and serious illnesses, such as diabetes, haemophilia, epilepsy, MS, Parkinson's disease and acute leukaemia receive medication, to treat these illnesses, free of charge through the *Long Term Illness* (LTI) scheme. The conditions were selected in 1975 and have not been updated.

Until June 1999, the *Drug Cost Subsidisation System* (DCSS) was operational in Ireland. The scheme covered patients requiring regular, expensive medication and who were not eligible for reimbursement through the GMS or LTI schemes. Under the DCSS system, the patient would pay the maximum of IEP 32 (EUR 40.63) for his/her medication per month.

Patients not covered by the GMS, LTI or DCSS schemes paid the maximum of IEP 90 (EUR 114.28) in a calendar quarter for their medication, or IEP 360 (EUR 457.11) in a calendar year (DRS system).

In July 1999, the DPS scheme replaced the DCSS and DRS systems. Under the DPS scheme no individual or family has to pay more than IEP 42 (EUR 53.33) for drugs in a calendar month.

Drug budgets

Since 1993, doctors contracted to the GMS have been allocated individual drug budgets. The scheme is similar to that in the UK. There are no sanctions for exceeding the budget, but the doctor may retain 50% of any savings and use it to improve the services provided. Information on prescribing patterns is provided to

doctors on a monthly basis. They prescribe branded generic products more often than their UK counterparts. Generic prescription is operational in Ireland.

Changes in the drug reimbursement system and drug prices

1993
A three-year agreement with the pharmaceutical industry came into force. Prices were reduced by 3%, and prices were frozen for four years. Prices of new drugs were to be priced according to prices in Germany, Denmark, the UK, the Netherlands and France. Prices of new drugs were to be reviewed every two years. According to the agreement, the pharmaceutical industry would return, each year, 5% of the value of drugs reimbursed by the GMS.

The ministry responsible for social affairs and health tried to encourage the prescription of generic products.

1994
A communal drug budget was allocated to general practitioners.

1997
A new five-year agreement with the pharmaceutical industry came into force. In accordance with the agreement, prices were frozen until July 2002. A right to review the prices was retained in the eventuality of significant currency fluctuations. The agreement also stipulates that the industry should, each month, return 4% of the sales value of drugs prescribed through the GMS system.

1998
The proportion of the sales value of drugs, prescribed through the GMS system, to be repaid by the industry each month was reduced to 3%.

1999
The drug reimbursement system was simplified by abandoning the DCSS and DRS schemes and replacing them with the DPS scheme.

Latest changes, proposals and discussion topics

The Irish government would like to increase research into the operations of health care. They believe that this would also have beneficial repercussions on the research and development carried out in the industry. As compared with other countries very few clinical drug trials are carried out in Ireland. To increase research-based activity, a new separate department will be appointed to function under the ministry responsible for social affairs and health.

Italy

In Italy, health care services and costs are managed by the *Servizio Sanitario Nazionale* (SSN). The SSN is also responsible for health insurance. Approximately 10% of Italians are covered through private insurers.

The Italian drug market is the third largest in Europe and the consumption of drugs is high.

Pricing

Drugs prices in Italy are approximately 30% lower than the European average. The prices of reimbursable drugs have been regulated since 1994. Before this, prices were based on production cost figures presented by the manufacturers. The price of drugs registered through the national procedure – and, until 1997, through a mutual recognition procedure – is set according to the average price in other countries. The *Comitato Interministeriale per la Programmazione Economica* (CIPE) is responsible for the system. The calculations to set prices have varied. Previously, a product price in Italy could not exceed the average price in the reference countries, i.e. France, Spain, Germany and the UK. In 1996, the European Commission requested a clarification of the Italian pricing policies. The Commission's concern was the possible violation of the principle of the free movement of goods by keeping prices too low so as to discourage imports into Italy. In July 1998, the Italian pricing policies were altered under pressure from the European Commission. The methodology of the European average price was introduced. The Italian price was not allowed to exceed this price. The calculation took into account the prices in 12 EU countries. Comparisons used sales-weighted factory prices. At the same time, purchasing power parity was replaced with actual exchange rates. The prices of products already on the market had to be adjusted to the level of the European average price. If the existing price was higher than the European average price, it had to be reduced with immediate effect. If the existing price was lower, it was possible to increase it to the level of the average price within the next five years. The new pricing policies did not comply with EU regulations either, and since 1999 it has been possible for companies not satisfied with prices set through the average price system to negotiate the reasonableness of prices with the CIPE.

Prices for products registered through the EU centralised procedure have been negotiated with the marketing authorisation holder since 1998, and this procedure continues today. Until 2001, the negotiations were carried out with the *Commissione Consultative Unica del Farmacon* (CUF) but a new, broader based body has now been introduced. The actual setting of prices is still carried out by CUF. The pricing by CUF is based on the therapeutic value and innovativeness of the product, prices in other countries, sales forecasts in Italy, as well as economic commitments of the manufacturer and the SSN. The negotiation

process was temporarily expanded, between 1998 and 2000, to cover drugs registered through the mutual recognition procedure.

In September 2001, a reference price system was introduced in Italy. Initially the reference price was based on the average price of products whose price was at least 20% lower than the original product. Already in November 2001, the lowest price set for a product became the reference price. A reference price is set for products which contain the same medicinal substance and with identical pharmaceutical dosage form and package size. Reference prices are reviewed every six months.

The prices of non-reimbursable drugs have not been controlled since 1990. Since 1998, it has been possible to apply price increases to non-reimbursable drugs only once a year, and any increases are notifiable to the authorities.

The wholesaler and pharmacist margins for reimbursable drugs are regulated. The margin for drugs registered through the EU centralised procedure is degressive, and that for the others linear.

Value Added Tax for pharmaceuticals was 4.6% until 1996, and thereafter 10%.

Criteria for reimbursement

In 1999, the number of registered drugs in Italy was approximately 29,000, but only about 9,400 were marketed. Of these, approximately 4,000 were eligible for reimbursement. The list of reimbursable drugs, *Prontuario*, was renewed in 1994. The number of reimbursable drugs fell by 12%. A drug must have an approved price before it can become reimbursable.

Some drugs are reimbursed only according to certain criteria. These include interferon beta which is reimbursed only to patients aged between 16 and 50, the growth hormone, products used for infertility, some cancer medication and erythropoietin. The antipsychotic drugs, risperidone and olanzapine, are reimbursed in full to patients who have not responded to other treatment. The newest antihypertensives (losartan, valsartan, candesartan) are reimbursed if the patient cannot tolerate ACE inhibitors. A reimbursement may also require an evaluation of the necessity of the drug, issued by a specialist or a university hospital. The reimbursability criteria have been criticised in that they restrict the doctors' prescribing behaviour. The CUF has stated that the purpose of the criteria is not to restrict prescribing but to target reimbursements according to the best available medical knowledge. However, due to its bureaucratic nature, the system of restricted reimbursements was relaxed in 2001.

Size of reimbursement

Until the end of 2000, Italy employed three reimbursement categories. The reimbursability and the reimbursement category were decided upon before the start of the registration process. The efficacy and cost of the drug were considered during categorising. Drugs in Group A were reimbursed in full. This group contained drugs vital for life and drugs for the treatment of chronic illnesses. In 1999, these drugs amounted to 92% of all drug reimbursements. Group B consisted of drugs considered to have therapeutic relevance. The patient paid 50% of the cost of drugs in Group B, but only up to ITL 70,000 (EUR 36.15) per purchase per drug. All other drugs were classified as belonging to Group C. Drugs in Group C were non-reimbursable.

Patients below 6 and over 65 years of age as well as pensioners, those with low income, pregnant women and the disabled did not have to pay the deductible for drugs in the 50% category. Also those aged between 60 and 64 and unemployed were given certain concessions.

The patient paid a prescription charge of ITL 3,000 (EUR 1.55) for the purchase of one drug and ITL 6,000 (EUR 3.10) for the purchase of two or more drugs.

In early 2001, the reimbursement categories were abolished in anticipation of the reference price system. Drugs were re-classified as either being reimbursable (former Group A and part of Group B, based on the therapeutic efficacy) or non-reimbursable (former Group C and part of Group B). The prescription charge was also abolished. Today, the patient receives reimbursable drugs free of charge, except those included in the reference price system if the price exceeds the reference price. In this case the patient pays the difference between the actual price and the reference price.

Drug expenditure budgets

The Italian drug expenditure budget specifies the sum available annually for drug expenditure. A working group, with representatives from the CUF, pharmaceutical industry, wholesalers and pharmacies, monitors the development of costs. It will take necessary measures should year-end overspending be anticipated. In case of budget overspending the deficit should be borne by the SSN and the medical companies.

Agreements were made regarding the overspending during 1998 and 1999; the pharmaceutical industry, wholesalers and pharmacies would pay approximately 60% of the overspending by the end of April 2000, the final 40% would be borne by the State. However, the agreement was nullified in 2001 at the introduction of the reference price system and an agreement of drug price reductions.

Generic substitution

Generic substitution has been possible in certain situations since 1999, for example, if the pharmacy has run out of the prescribed medication. In 2001, pharmacies were required to dispense the cheapest alternative unless explicitly forbidden by the prescriber. Information about the advantages of generic products has been conveyed to patients and doctors though various campaigns. The sales of generic products did show an increase of several per cent in 2001 as compared with the previous year.

Changes in the drug reimbursement system and drug prices

1992
Prescription charge was increased to ITL 1,500 (EUR 0.77), and the maximum deductible for partially reimbursed drugs was set at ITL 40,000 (EUR 20.66).

The wholesaler margin was reduced.

1993
Prescription charge was increased to ITL 4,000 (EUR 2.07), and the maximum deductible for partially reimbursed drugs to ITL 50,000 (EUR 25.82).

Those on a low income were made exempt from paying a deductible.

1994
The drug expenditure budget was introduced.

Prescription charge was increased to ITL 5,000 (EUR 2.58).

New classification of reimbursable drugs was introduced.

To off-set reductions in drug prices, 260 new products were included in the 100% reimbursement group.

The basis for prescription charges was changed. The charge for one purchase of one drug was reduced to ITL 3,000 (EUR 1.55), and the charge for one purchase of several drugs remained unchanged at ITL 5,000 (EUR 2.58).

The list of reimbursable drugs was renewed.

European average price was introduced to the pricing of drugs.

1995
The drug expenditure budget was reduced and it was decided to keep it at this level until 1997.

The prescription charge for a purchase containing new drugs was increased to ITL 6,000 (EUR 3.10).

Children and the elderly were made exempt from paying a deductible.

The prices of manufacturers, whose sales increased by more than 10% from the preceding year, were reduced by 2.5%.

Value Added Tax for pharmaceuticals was reduced to 4.6 %. The previous tax had been 19% for over-the-counter medicines and 9% for all other pharmaceuticals.

1996
A new, larger drug expenditure budget was approved in January.

In principle, only the cheapest generic alternative was reimbursed. This restriction was applied only rarely in practice.

Almost 700 products, including non-steroidal anti-inflammatory drugs, were delisted from the reimbursement system.

Drug expenditure budget was increased in July.

Drug prices were reduced by an average of 3.1%.

Doctors were instructed to favour generic products.

Drug expenditure budget was increased in October.

Drug expenditure budget was increased in December.

1997
Value Added Tax for pharmaceuticals was increased from 4.6% to 10%.

1998
Price increases of non-reimbursable drugs became notifiable to the authorities.

The calculation criteria to obtain the European average price was changed.

1999
Negotiations also became possible when making decisions on prices of drugs registered through the national procedure.

The prices of some products were reduced by 15%.

Generic substitution was approved, under strict criteria.

2001
The reference price system was introduced.

Reimbursement categories and the prescription charge were abolished.

The prices of drugs whose patent had expired were reduced by 5%.

A new body was appointed for price negotiations regarding drugs registered through the centralised or mutual recognition procedure. At the same time, criteria for price setting was reformed.

The generic substitution right of pharmacies was expanded.

Latest changes, proposals and discussion topics

The review of products within the reimbursement system, initiated in 1993, is still in progress in Italy. The next products to have their reimbursability criteria checked are the 1,000 products that were introduced to the market over 10 years ago.

When the prescription charges were abolished in early 2001, almost a year before the introduction of the reference price system, drug costs increased by 25-30%. As a result of the escalating costs, the ministry responsible for health set a working group (*Commissione per la Spesa Farmaceutica*) to discuss possible countermeasures. The working group completed its task in 2001. It proposed, for example, the expansion of the reference price system to cover specific drug groups (e.g. ACE inhibitors) and an annual price decrease of 5%, for four years, for drugs whose patent has expired. The working group also proposed the return of a deductible, payable by the patient, and the building of
the reimbursement system around the severity of the illness as well as the refusal of direct reimbursement for the high earners. The proposals further included the provision of independent drug information for doctors, a closer monitoring of prescribing habits and the delisting of some drug groups from the reimbursement system. The working group included representatives from the ministry responsible for health, the ministry of finance, CUF, the pharmaceutical industry as well as wholesalers and pharmacists. The government approved the proposals in December 2001.

The various regions of Italy may now make independent decisions on the reimbursability of drugs which are not considered essential. These drugs include certain drugs for the treatment of migraine, allergies and asthma and analgesics.

Luxembourg

The entire population of Luxembourg is covered by statutory health insurance. The insurance is managed by various sickness funds, the members of which are various professional groups with their family members.

Pricing

A maximum allowed retail price is set for all drugs entering the market in Luxembourg. The price is set by the ministry responsible for financial affairs. The price is based on the price of the product in the country of origin and in the country from where it is imported to Luxembourg. Of all pharmaceutical products, 99% are import products, mainly from France, Germany and Belgium.

The price (with VAT) for products imported from Belgium is 98.44% of the Belgian price (with VAT). The price (without tax) of products imported from the other European countries is the price (without tax) of the product in the country of origin minus 0.62%. When determining the price for products imported from outside Europe, the price of the product in Belgium, France and Germany is taken into account. The price (without tax) will be the lowest price (without tax) in the reference countries minus 0.62%. The price of products which belong to several of the above-mentioned groups will be set at the level of the lowest price.

The wholesaler margin is 15.21% of the purchase price. A limit has been set to the margin for expensive drugs. A fixed percentage margin is set for pharmacists. The margin for drugs imported from Belgium is 53.8%, and 57.84% for the others. However, a limit has been set to the margin for expensive drugs. Pharmacies are required to give discounts to the social insurance institutes.

Value Added Tax for pharmaceuticals is 3%.

Criteria for reimbursement

Luxembourg operates a negative list. The list includes approximately a quarter of all drugs marketed, mainly over-the-counter medicines. Until 1997, all drugs not in the negative list were reimbursed.

In early 1998, a new positive list was introduced including drugs which are eligible for reimbursement only in approved indications.

Generic products which are more expensive than the original product are not reimbursed.

Size of reimbursement

Drugs are divided into three reimbursement categories. The category is decided when the product enters the market. Drugs which are vital for life, as well as expensive drugs for the treatment of chronic illnesses, are reimbursed in full. The majority of drugs belong to the 78% reimbursement category. Some drugs deemed less significant are reimbursed 40%.

The amount of drugs reimbursed at one purchase is limited. A doctor may prescribe up to three reimbursable drugs during one consultation. When prescribing expensive drugs the doctor must follow special instructions. A pharmacy may dispense up to two packages of any one particular drug at a time. Some products attract even stricter restrictions, e.g. only four doses of sumatriptan, used in migraine, can be reimbursed each month.

Generic prescribing

Generic prescribing is permitted in Luxembourg. If a generic substance has been prescribed, the pharmacy must dispense the lowest priced product. For this purpose doctors and pharmacists have a list, known as a transparency list, of exchangeable products at their disposal. These lists are compiled by the ministry responsible for health issues. Generic substitution is permitted only in certain situations.

Monitoring of prescription behaviour

The sickness funds have been sending feedback to doctors on their prescribing habits since 1995. Even though the ministry does in principle have powers to issue financial claims on doctors for their prescribing habits, these measures are employed rarely. In individual cases the ministry has requested an explanation of a particular doctor's prescribing habits.

Changes in the drug reimbursement system and drug prices

1994
Some products were transferred from the 80% reimbursement category to the 40% category.

1998
A positive list was introduced.

Some products were transferred from the 80% reimbursement category to the 40% category.

1999
The 80% reimbursement category was changed into a 78% category.

Latest changes, proposals and discussion topics

Proposals have been made in Luxembourg not to include drugs of which there is insufficient data in the reimbursement system, and the same applies for drugs which generate treatment costs in excess of those achieved with alternative products.

Netherlands

The health insurance system in the Netherlands is a mixture of private and public insurance schemes. Public insurance is statutory to pensioners and to those whose income does not exceed a certain limit. In 2001, this limit was NLG 64,300 (EUR 29,178). Almost 65% of the Dutch population is covered by public health insurance. This insurance is paid for by an employer–employee shared contribution, related to the employee's income. Those with a higher income may purchase private health insurance, should they wish to do so. Approximately one third of the Dutch population is covered through private insurers.

Doctors work primarily through private practices. Patients register with a particular doctor. The public sector pays the doctors according to the number of treated patients whereas the private insurance companies pay according to the services provided.

The consumption of drugs per inhabitant is lower in the Netherlands than in most other European countries.

Pricing

The pricing of drugs was uncontrolled in the Netherlands until 1996. However, the reference price system introduced in 1991 had an indirect effect on the prices.

A reference price is allocated to a cluster of drugs deemed to be therapeutically equivalent. The clustering of drugs is based on their mode of action, therapeutic indication, method of administration and adverse effects. The reference price is set slightly below the average price within the cluster. The introduction of the system has reduced price differences between pharmaceutical products. Two years after the system came into force, 90% of all products had been re-priced to the level of, or below, the reference price. Likewise, the prices of many products which had been lower than the reference price had been increased to the reference level.

Despite the reference price system, and the general 5% price reduction and freezing of prices in the summer of 1994, drug costs continued to soar in the Netherlands and the price level was one of the highest in Europe. To curb the increasing costs a maximum wholesale price policy was introduced in 1996. This encompasses all reimbursable drugs, both those protected by a patent and generic. The price is set by the ministry responsible for social affairs and health, and it is based on the average price of the drug in Belgium, Germany, France and the UK. These reference countries represent about 60% of the total EU population. Initially only Belgium, Germany and the UK were proposed as the reference countries, but the price level attained with the prices from these

countries alone was considered too high. The pharmaceutical products from the reference countries are considered comparable when they contain the same active ingredient and have equal strength and pharmaceutical dosage form. The prices are reviewed twice a year.

The margin for wholesalers is not controlled. The profit made by the pharmacy is not dependent on the price of a medicine; their income is based partly on the pharmaceutical work carried out and partly on the discounts given by wholesalers. The institutions responsible for the insurance system pay pharmacies a fixed tariff for each prescription they dispense (NLG 2.55, i.e. EUR 1.16, in 2000). The tariff is reviewed annually. If the patient is covered by public health insurance the pharmacy will receive no prescription tariff. However, a fixed annual sum is paid to the pharmacies, based on the number of customers covered by public insurance. It is common and legal for pharmacies to offer discounts. However, the amount of the discount is restricted. As a further incentive to encourage the sale of generic and other cheaper products, the pharmacies are entitled to one third of the sum saved when a cheaper product is dispensed to the patient. The sales of generic and parallel import products are high in the Netherlands.

Value Added Tax for both prescription drugs and over-the-counter medicines is 6%.

Criteria for reimbursement

Until 1991, all prescribed drugs were eligible for reimbursement. The drug reimbursement system was changed greatly by the introduction of the reference price system and the positive list in 1991.

Only pharmaceutical products with a marketing authorisation are added to the positive list. The ministry responsible for social affairs and health (*Ministerie van Volksgezondheit*, *Welzijn en Sport*) and the department responsible for the reimbursement system (*College voor Zorgverzekeringen*) make joint decisions regarding drug reimbursements. Products with a reference price are listed in *annex 1a.* If a reference price cannot be allocated to a product it will be placed in *annex 1b*. When deciding about the reimbursement of products in *annex 1b* the therapeutic value of the product is considered together with its efficacy, any possible adverse effects and the method of administration. So far, only the costs relating to the use of the product have been evaluated. If the therapeutic value of a product is low it will not be considered eligible for reimbursement. Some drugs in the positive list are classified into *annex 2*. These drugs are reimbursed only if certain criteria are fulfilled. The criteria could be, for example, that the prescription must be written by a specialist physician.

The positive list was frozen in the mid-1990s in order to contain increasing costs. This rendered several new expensive drugs non-reimbursable for many years. The idea was to initially restrict the use of new drugs to hospitals and, only when more information on their cost effectiveness was available, extend their use to outpatient care. In 1996, there were 35 new pharmaceutical products in the Netherlands that were non-reimbursable in outpatient care. Some of these products have later been added to the positive list.

After September 1999, over-the-counter medicines for short-term treatment, even when prescribed, have not been eligible for reimbursement. These include, among others, some antiviral and antifungal drugs. Some over-the-counter medicines, such as cough medicines and nicotine preparations, had already become non-reimbursable earlier.

It is, however, possible to receive reimbursement for about 60 over-the-counter medicines if the product has an approved therapeutic indication needing long-term treatment, and if the prescriber has indicated such use in the prescription. Long-term treatment refers to treatment of at least three months' duration. Even in this case, the patient has to pay the cost of the first 15 treatment days. This enables the reimbursement of, for example, paracetamol products, antihistamines and calcium preparations for the treatment of osteoporosis.

Drugs prepared at a pharmacy are almost always reimbursable.

Size of reimbursement

There have been attempts from time to time to transfer a proportion of the drug therapy costs to the patient. These experiments have never been long lasting. At present, the patient pays the difference between the reference price and the actual price of the drug, for drugs in the reference price system. All other drugs in the reimbursement system are free for the patient.

Generic substitution

A pharmacy may substitute a drug with a cheaper product if the prescribed drug is more expensive than a competitive product (generic substitution). Usually the prescriber will approve the substitution by marking the prescription accordingly. Therapeutic substitution, where a pharmacist may substitute the prescribed drug with a therapeutically equivalent drug but which has a different medicinal substance, is also possible in certain cases.

Changes in the drug reimbursement system and drug prices

1991
The reference price system was introduced. Positive list was introduced at the same time.

1992
The statutory insurance for high-earners was reduced.

1993
Negative lists were introduced.

1994
Certain over-the-counter medicines were removed from the reimbursement system.
Prices were reduced by 5% and frozen until 1996.

The present health insurance system was introduced.

1996
Maximum wholesale prices were allocated for reimbursable drugs.

127 drugs were delisted from the positive list (e.g. certain antidepressants and analgesics).

1999
The criteria for reimbursing over-the-counter medicines were changed.

Latest changes, proposals and discussion topics

Reductions in drug costs and preparation for future cost developments are central discussion topics in the Netherlands. A committee report presented in 1999 proposed, among other things, that the drug reimbursement system should be changed so that each insurance company could have more latitude than at present when deciding which drugs to reimburse. The insurance companies would negotiate the drug prices, distribution and costs with the industry, wholesalers and pharmacies. However, they would not be able to refuse to reimburse costs according to the nature of the patient's illness or perceived risk factors. The aim of the reform would be to increase competition on the drug market, and between the insurance companies, as well as to improve the services offered by insurance companies to their customers. These reforms would be the most extensive seen in the Netherlands for fifty years, and would also have repercussions for the other European countries. The proposals have received widespread political support and they are expected to be implemented in one form or another by 2005.

In 1999, detailed guidelines were published on how to carry out a health economic evaluation on those drugs proposed to be included in the reimbursement system. At present, the evaluation remains voluntary. It is planned that in February 2002 the guidelines will be trialed for drugs in the *annex 1b* group.

To promote rational prescribing doctors have been issued with national treatment guidelines. Electronic prescribing is also possible, and computer programmes, which suggest reasonably priced generic alternatives, have been developed. Data relating to the sales of individual pharmacies are collected and used to monitor the development of sales. Data relating to an individual patient, doctor or pharmacy are not allowed to be published. However, each doctor receives a brief amount of feedback of his/her own prescribing habits.

Norway

The entire Norwegian population is covered by public health insurance.

Pricing

The pricing of over-the-counter medicines by manufacturers is unrestricted in Norway. However, all prescription drugs, including those not included in the reimbursement system, must have an approved price. A new central office, known as *Statens legemiddelverk,* sets the prices. The price is determined on the basis of the prices in Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden and the UK. The price in Norway must not exceed the average price of the three countries with the lowest price. All comparisons are done at unit level, since different package sizes are not comparable. Whether the unit price was calculated using a small or large package is also taken into account when assessing the reasonableness of the price. The prices are not usually re-assessed more often than once a year, but after the launch of a new product the price is checked every six months for two years. If one of the reference countries removes the product from the market, the price may be re-assessed.

Until the end of 2000, generic products were included in the reference price system. Since 1998, the reference price system was also applied to patented products which had parallel import products on the market. The reference price was based on the lowest price and it was possible to alter it twice a year. The reference price system was abandoned when it became apparent that the running costs of the system outweighed the savings made. The reference price system also failed to raise doctors' price awareness in the way expected.

Wholesalers can negotiate their margin with the manufacturers. The wholesaler margin is one of the lowest in Europe. The drugs sold by pharmacies have been set a pharmacy purchase price and a pharmacy retail price. The pharmacy profit consists of a percentage margin based on the wholesale price and a fixed sum per package. The margin based on the drug price is 8% for the first NOK 200 (EUR 25.91) and 5% for the price exceeding this sum. The majority of the profit is generated through the fixed sum payable for each package. The pharmacy charges NOK 20.50 (EUR 2.66) per package. Pharmacies may add an extra NOK 10 (EUR 1.30) per package to the retail price (without tax) of some drugs with CNS effects. If a pharmacy purchases drugs, e.g. generics or parallel imports, at a lower price than the set purchase price, it is allowed to keep 50% of the saving made. The pharmacist margin was lowered three times during 2000 and 2001. Value Added Tax for pharmaceuticals is 24%.

Criteria for reimbursement

Prescription drugs are divided into reimbursable drugs, written on a blue prescription sheet, and non-reimbursable drugs, written on a white prescription sheet. The *Rikstrygdeverket* or *Statens legemiddelkontroll* (SLK) used to be in charge of making decisions about reimbursements, and in some cases the issue was processed through the ministry responsible for social affairs and health. The *Riskstrygdeverket* made decisions regarding products for which there already was a therapeutically and financially comparable product on the market. The *Riskstrygdeverket* was also able to consult the SLK. The SLK made decisions regarding products which contained a new medicinal substance and when no corresponding drug was previously included in the reimbursement system. To support its decision it was possible for the SLK to request a health economic evaluation.

Since 2000, reimbursement decisions have been made at the *Statens legemiddelverk* . The duration and severity of the illness as well as the economic aspects of the drug are included in the decision-making criteria.

In principle, only drugs used for long-term treatment of at least three months duration are reimbursed. Patients must pay themselves for any drug treatment intended to treat a short-term illness or for drugs used for prophylaxis. In 2002, there are a total of 43 illness groups in which the medication is reimbursable. Each illness has its own positive list. A reimbursable drug must have an approved price.

There are four different methods to reimburse a drug:

A. Drugs which are prescribed to treat an approved indication, and are included in the positive list, are always reimbursed. Over 90% of drug reimbursements are paid for drugs in this group.

B. An individual decision may be made on the reimbursability of drugs in illnesses that are not included in the positive list, or in situations where the illness is listed but the drug not. A specialist physician must be able to justify the need of the drug in the treatment of the patient. This method makes it possible to reimburse, for example, montelukast in asthma and interferon beta in MS.

C. Drugs to treat infectious diseases, such as tuberculosis, syphilis and HIV, are provided free of charge.

D. Patients whose drug spending is high may receive a contribution towards their costs on social grounds. The contribution is considered separately for each patient. Of expenditure exceeding NOK 1,200

(EUR 155.44) 90% is reimbursed. This method enables the reimbursement of drugs that are not included in the positive list.

Size of reimbursement

The reimbursement in groups A and B is dependent on the age of the patient. Patients under the age of 7 are exempt from any payments. Anyone older than this will pay 36% of the cost; however, only up to NOK 360 (EUR 46.63) per prescription. Drugs in group C are provided free of charge.

A ceiling has been set to the patient's annual drug and other health care costs. In 2002, this limit is NOK 1,350 (EUR 174.87). Two-thirds of any costs exceeding the limit are reimbursed. Any drug costs incurred by a patient under the age of 16 can be included when calculating the parents' limit. The proportion payable by the patient is reviewed annually.

Prescriptions and substitution

Since 1999, doctors have been required to prescribe the generic product with the lowest price, from the therapeutically equivalent alternatives on the market. Exceptions to this rule are possible only on strict medical grounds.

Parallel import products can be dispensed to the patient, unless explicitly forbidden by the prescriber. Parallel imports are encouraged by allowing the pharmacies to keep a proportion of the saving made when dispensing a parallel import product. At least half of the saving must go to the payer of the drug, i.e. to the patient or the social insurance institute. In 1998, the sales value of parallel import products was 7% of all drug sales.

Generic substitution was introduced in 2001. The *Statens legemiddelverk* keeps a list of interchangeable products. The list is updated every three months.

Changes in the drug reimbursement system and drug prices

1990
Patients paid 20% of the cost of reimbursable drugs, up to the maximum of NOK 175 (EUR 22.67) per prescription. The previous maximum amount per prescription had been NOK 150 (EUR 19.43). The amount payable by children and pensioners was 10% of the cost, up to the maximum of NOK 75 (EUR 9.72).

1991
Children under 7 years of age were made exempt from a deductible.
Rules regarding the prescription of an available product with the lowest price were tightened. The doctor had to indicate on the prescription sheet whether he/she had chosen the lowest priced alternative, and if not, had he/she done it for medical reasons. In certain drug groups the maximum reimbursement paid was 10% more than the price of the cheapest generic product.

1992
The reimbursement limit for generic products was set 5% higher than the price of the cheapest product.

The proportion payable by the patient for reimbursable drugs was increased from 20% to 30% and the maximum amount per prescription from NOK 175 (EUR 22.67) to NOK 300 (EUR 38.86). There were no changes to the deductibles payable by pensioners and children aged 7–16.

1993
The reference price system was introduced.

1994
The *icke-behov* principle was abandoned. Until 1994, only products considered medically necessary by the authorities were granted marketing authorisation (*icke-behov* principle). The product was not always granted marketing authorisation if there was already a corresponding product on the market. The situation changed when the EEA agreement came into force.

The monopoly of the state-owned wholesaler was ended.

Parallel importation was approved.

1995
The pricing of over-the-counter medicines became unregulated.

The pharmacist margin was reduced.

A pharmacist-owned organisation called *Apokjeden* was founded. The organisation buys drugs in bulk for its member companies.

1996
A health economic department was founded by a drug regulatory authority.

1997
The proportion payable by the patient for reimbursable drugs was increased from 30% to 36% and the maximum amount per prescription from NOK 300 (EUR 38.86) to NOK 330 (EUR 42.75). The deductibles payable by pensioners and

children aged 7–16 were increased to 12% of the drug cost, up to the maximum of NOK 110 (EUR 14.25) per prescription.

The report "Rammevilkår for omsetning av legemidler" (NOU 1997:6) by the Strøm committee was published. The report discusses the drug industry as a whole, price setting, prescribing habits, questions relating to health economics and pharmacies.

The report "Piller, prioritering og politikk" (NOU 1997:7) by the Grund committee was published. The report discusses the functionality of the drug reimbursement system from the point of view of the patient and society and any reforms needed to the system.

The pharmacist margin was reduced.

1998
Original products with parallel import products on the market were included in the reference price system. The reimbursement was based on the lowest price within the group.

Proposals were published regarding, for example, the freeing of pharmacy licences, establishing pharmacies and the introduction of generic substitution.

1999
The pharmacist margin was reduced.

The deductibles payable by pensioners and children aged 7–16 were increased to 36%
of the drug cost.

Doctors were required to principally prescribe generic products with the lowest price.

Representatives from the government and pharmaceutical industry prepared guidelines for carrying out health economic evaluations.

Drug price setting was changed. The price of the product was compared to that in ten reference countries.

2000
The maximum amount payable by the patient per prescription was increased from NOK 330 (EUR 42.75) to NOK 340 (EUR 44.04). The annual ceiling set to drug and other health care costs was increased from NOK 1,320 (EUR 170.98) to NOK 1,370 (EUR 117.46).

Prices of prescription drugs were reduced by 5% and those of over-the-counter medicines were increased by 2.5%.

Guidelines for carrying out health economic evaluations were published.

2001
The maximum amount payable by the patient per prescription was increased from NOK 340 (EUR 44.04) to NOK 360 (EUR 46.63). The annual ceiling set to drug and other health care costs was increased from NOK 1,370 (EUR 117.46) to NOK 1,450 (EUR 187.82).

The reference price system was abandoned.

The restrictions on ownership of pharmacies were lifted, and the majority joined to form three separate pharmacy chains.

Generic substitution was introduced.

The *Statens legemiddelverk* became operational.

2002
The annual ceiling set to drug and other health care costs was reduced from NOK 1,450 (EUR 187.82) to NOK 1,350 (EUR 174.87).

The pharmacies were required to grant the social insurance institute a NOK 1 (EUR 0.13) discount for each reimbursed prescription written on a blue prescription sheet.

Latest changes, proposals and discussion topics

The pricing and reimbursement of pharmaceuticals are discussed keenly in Norway. The pharmaceutical industry feels that the current system is too favourable towards generic products.

A register is proposed which would contain data on reimbursed prescriptions. If the proposed legislation is approved during 2002, the register would be introduced in 2003. The register data could be used to target reimbursement payments towards patients who would, according to available evidence, gain the most benefit from the treatment.

Patients over the age of 67 will be made exempt from paying the deductible as from October 2002.

Portugal

In Portugal, the national health care system called *Servico Nacional de Sáude* (SNS) provides health care services and manages health insurance. It covers approximately 90% of the population. The remaining 10% are insured either by private insurers or insurance offered by employers.

Pricing

Drug prices in Portugal are among the lowest in Europe. The prices of prescription and generic drugs are regulated through a two-step process. On market entry, the pharmaceutical company and the *Direccao-General do Comércio e da Concorrencia* (DGCC), which operates under the ministry responsible for trade and industry, negotiate the price. At this stage, prices of corresponding products in Spain, Italy and France are used as reference prices. The average of the two highest prices from the reference countries used to be set as the price. Currently, the price of a pharmaceutical in Portugal must not exceed the lowest price in the reference countries. If the lowest price is 30% lower than the average price in the two cheapest reference countries, the price is set using the lowest price plus a sum corresponding to one third of the average price in the two cheapest reference countries. If the product is marketed in only one of the reference countries, the lowest price of the identical or similar product in that country is applied in Portugal. If the product is not marketed in any of the reference countries, but there is such a product on the Portuguese market, the price of the existing product is applied. If the product is not marketed in any of the reference countries the price of the product in the country of origin will be applied. For the price comparison the medicinal substance, strength, pharmaceutical form and package size must be identical. If the marketed package sizes differ, the smallest is used. If the strengths differ, all the strengths in the reference countries are taken into account, and their unit prices are used when calculating a price for the strength to be marketed in Portugal.

The prices are reviewed once a year. If the product enters the market of a reference country at a later stage, the pricing calculations are reviewed, taking into account the new reference price and the Portuguese price is changed if necessary. In such a case, the price change will be spread over several years so that an annual price reduction or increase does not exceed 10%.

A price on which reimbursement is based is accepted separately. This is processed by the *Instituto Nacional de Farmácia e do Medicamento* (INFARMED), which operates under the ministry responsible for health. When setting the price the following criteria are considered: treatment costs as compared with corresponding products, the social significance of the illness and the duration of the illness. The price on which reimbursement is based is usually 20–30% lower than the one approved by the DGCC. Previously, the price of a

generic product could be up to 80% of the price of the original product. In 2001, the rule was tightened to 65%.

Since the end of 1998, it has been possible to lower the price of a reimbursable product which is over 20% more expensive than an equivalent generic product with a market share of at least 10%. After the introduction of the legislation, the prices of over 70 products were reduced during the first year. Moreover, 14 products were delisted from the reimbursement system after the manufacturer refused to lower the price.

Manufacturers may price over-the-counter medicines themselves. However, the DGCC monitors the market and may, if necessary, ask a manufacturer to re-assess the price. In practice, the occurrence of this is rare.

The wholesaler and pharmacist margins for prescription drugs have a percentage limit. There is no regulation on the margin for over-the-counter medicines.

Value Added Tax for pharmaceuticals is 5%.

Criteria for reimbursement

INFARMED decides which drugs to include in the reimbursement system. The reimbursable product must fulfil one of the following criteria:

- The product is innovative. Corresponding products are not marketed in Portugal or the efficacy or tolerability of the product is superior to previous products.

- The product exhibits a favourable cost-benefit ratio.

- The product shows economic benefit as compared with existing alternatives.

- The product is a combination product, the components of which are already marketed separately. The combination of the separate components should produce therapeutic benefits and make the use of one product more economic than two.

- The product is a combination product, the components of which are not marketed separately. The combination of the separate components should have therapeutic benefits.

For a product to be reimbursable, it must have a price approved by INFARMED. Since 1999, a health economic evaluation has been requested when applying for reimbursement status. Since 2000, INFARMED has entered into agreement with

pharmaceutical companies whereby the reimbursement decision is tied to the sales of the drug. Should the reimbursement costs stated in the agreement be exceeded, the company must either lower the price of the product or its reimbursement category.

INFARMED consults external authorities in decision-making. A Unit for Economic Evaluation, founded to work alongside INFARMED, provides information relating to health economic issues.

Size of reimbursement

The reimbursable drugs have been divided into four groups:

Drugs in Group A are reimbursed in full. This group includes essential drugs to treat chronic illnesses, such as cancer drugs and drugs used in diabetes and tuberculosis. Group A contains 5% of all pharmaceutical products.

The cost of drugs in Group B is reimbursed 70%. Drugs in this group include antiasthmatics and cardiovascular drugs. Group B contains 37% of all pharmaceutical products.

The cost of drugs in Group C is reimbursed 40%. This group includes vaccines and immunoglobulins. Group C contains 58% of all pharmaceutical products.

Group D was added in 2000. The cost of drugs in Group D is reimbursed 20%. The group is intended for new products the therapeutic value of which is not yet proven.

In the case of pensioners whose income is not higher than the national minimum wage, an extra 15 percentage units is reimbursed for the cost of drugs in the Groups B, C and D.

Since September 2000, the reimbursement for generic products has been 10 percentage units higher than that of a normal reimbursement.

Agreements with the pharmaceutical industry

In 1997, the government made an agreement with the industry to freeze prices. The agreement also covered price rises in subsequent years. According to the agreement, the price increase in 1998 could be 75% of the inflation rate of 1997. Subsequently, prices were increased on average by 1.65% in 1998. The increase for 1999 was correspondingly agreed to be 80% of the inflation rate of 1998. The agreement further stipulated that the maximum annual increase in reimbursement payments is 4%. Should reimbursement payments increase more

that this in 1997 the pharmaceutical companies would repay the State approximately 64% of the exceeded sum to the maximum of PTE 6.3 billion (EUR 31 million). A similar agreement was drawn up for 1998 and 1999. The pharmaceutical companies contributed towards the sum to be repaid by paying an amount proportional to their market share. The agreement ended at the end of 1999.

A new agreement was signed in October 2001. This agreement also states the annual limit to reimbursement costs. In 2001, the costs could increase up to 6.5%, in 2002 up to 5% and in 2003 up to 4%. If the costs increase more than the figures stated the pharmaceutical companies will repay the State 64.5% of the exceeded sum. If drug costs increase more than 10.5% during the first year, 10.0% the year after and 9.5% the year after that, the agreement will be reviewed annually. According to the agreement, in December 2001 the companies may increase the prices of the products which have been frozen since 1999. These increases will stay valid throughout 2002 and the increases will vary from 1% to 2% so that the prices of manufacturers with lower prices can be increased more. Price increases for 2003 will be decided separately. The agreeing parties also agreed to promote the sales of generic products.

Changes in the drug reimbursement system and drug prices

1992
The reimbursement levels of the reimbursement categories were changed. The reimbursement percentage in Group B was reduced from 80% to 70% and that in Group C from 50% to 40%.

Prices were increased by approximately 8%.

1993
Prices were increased by approximately 2.5%.

1994
Prices were reduced by 0–8%, depending on their price level.

1995
Prices were increased by 1%.

1996
Prices were increased by 8%.

1997
Drug prices were frozen. At the same time, agreements were made on price increases for the following years.

1998
Rules regarding the price and reimbursability of drugs were tightened.

1999
During the latter half of the year, neurological drugs prescribed by specialists were moved from Group C to Group A and antidepressants from Group C to Group B.

Health economic evaluations became compulsory for reimbursement applications.

2000
The prices of 39 drugs were reduced.

INFARMED published a drug list for the use of doctors; the list described the benefits and adverse effects of 4,000 prescription drugs. The published list also included the prices, reimbursement information and economic evaluation of the products. The aim of the list is to improve prescribing habits and to contain the increase in drug costs.

The reimbursement level of generic products was improved.

The reimbursement group D was introduced.

2001
A new agreement was signed by the pharmaceutical industry and the government.

The ministry published a list of original drugs and the corresponding generic products.

The price of a generic product had to be at least 35% lower than that of the original product.

The reimbursability of neurological drugs was no longer tied to the speciality of the prescribing doctor.

The review of reimbursable drugs was commenced.

Latest changes, proposals and discussion topics

In Portugal, the proportion of drug costs of total health care costs is one of the highest in the OECD countries, 26.3% in 1997. Proposals to curb the increased drug costs have included the introduction of budgets to individual doctors, generic substitution and a reference price system to promote the sales of generic

drugs. In 1998, actual generic products accounted for less than 1% of drug reimbursements expenses, and several opinions prevail on the influence of generic substitution on expenditure. The introduction of a reference price system has been proposed several times before, but so far the plans have not been put into action. It had been planned that during 2002 generic substitution, based on the active ingredient of the drug, would be introduced. However, the reform has not come into force, at least during early 2002.

Electronic drug databases and an electronic drug pricelist are being prepared in order to increase doctors' price awareness. The appropriateness of the package sizes is also discussed. It has been proposed that the patient should be dispensed exactly the amount of medication prescribed. This would reduce the amount of wasted medication and avoid unnecessary costs.

In 2001, a re-evaluation of the rationality of the drugs chosen to be reimbursed was initiated in Portugal. The aim is to delist drugs, with no proven benefits, from the system.

Spain

Ninety-eight per cent of the Spanish population is covered by public health insurance. The insurance is managed by the *Instituto Nacional de la Salud* (INSALUD).

Pricing

Until the end of 1997, all drug prices were regulated in Spain. The pricing of over-the-counter medicines and non-reimbursable drugs is now unregulated.

The pricing of reimbursable prescription drugs is carried out by a pricing commission (*La Comisión de Precios de los Medicamentos)* which operates under the ministry responsible for health. Representatives from three different ministries sit on the commission. In price setting the criteria assessed are: the therapeutic value of a drug, its expected sales and the prices of similar drugs in Spain and other European countries. In practice, the price is usually set according to product development and production costs. The aim is to set a price that would generate a return of approximately 12-18% on the company's investment. Should the sales exceed expectations the price may be subsequently reduced.

In early 2000, the Spanish government approved a dual pricing system according to which drugs can be priced differently dependent on whether they are intended for sale in Spain or for export. Price regulations apply to drugs intended for domestic sale, but pharmaceutical companies may price export products without restriction. The aim of this change was to control the parallel trade from Spain. Due to its low price levels, Spain is one of the most important parallel trade countries. The value of parallel trade has been estimated at 25–60 billion pesetas (EUR 150–361 million) annually. The European Commission is deliberating the legality of dual pricing. Glaxo Wellcome already started to apply similar pricing policies in Spain in early 1998. The Commission intervened, and such policies were considered contrary to legislation regarding price competition.

After several years of planning, Spain introduced a reference price system in December 2000. Reference prices are set 10–50% below the prices of original products. Products with at least one competitive product on the market are included in the system. With the introduction of the reference price system, the number and sales of generic products have increased. At the end of 1997, only 50 generic products were offered for sale, but by the end of 2001 the number had increased to almost a thousand. The prices of the original products have also come down which has led to further reductions in the generic product prices.

The wholesaler margin is 9.6% for drugs costing below ESP 13,035 (EUR 78.34) and a fixed sum of ESP 1,384 (EUR 8.32) for more expensive drugs. The

pharmacist margin is 33% for generic drugs costing below ESP 13,035 (EUR 78.34) and 27.9% for other products. The margin for drugs costing over ESP 13,035 (EUR 78.34) is a fixed sum of ESP 5,580 (EUR 33.54). Pharmacies may give customers discounts of up to 10% for over-the-counter medicines.

Value Added Tax for pharmaceuticals is 4%.

Criteria for reimbursement

The *Dirección General de Farmacia y Productos Sanitarios* (DGFPS) makes decisions about reimbursable drugs. When making a decision the following criteria are considered: the nature of the illness, the therapeutic value of the drug, its efficacy, price and total cost as compared to corresponding products, as well as costs incurred by the drug to public health insurance.

Spain operates a negative list. The list was introduced in 1994 and contained, for example, cough medicines, laxatives, antacids and creams. A proposal was made in 1997 to expand the list by about 900 products. The proposed products included antimicrobials, corticosteroids, diuretics and vitamins. The new list came into force in 1998, but was significantly shorter than the one proposed.

Drugs are reimbursed only when prescribed by a doctor working in the public sector. Drugs prescribed by a private doctor must be paid by the patient him/herself.

Size of reimbursement

Generally, 60% of the cost of a drug is reimbursed. Patients pay 10% for drugs used in the treatment of chronic illnesses, such as asthma, diabetes, epilepsy and hypertension; however the maximum amount to be borne by the patient is ESP 439 (EUR 2.64)

Among others, pensioners and the disabled are exempt from any drug payments. Approximately 20% of the Spanish population obtain their medication free of charge, and these drugs account for approximately 70% of all drug costs.

Generic substitution

Pharmacies may practise generic substitution, i.e. they may substitute the prescribed drug with a cheaper generic alternative, unless the doctor has specifically forbidden substitution.

Changes in the drug reimbursement system and drug prices

1991
Drug prices were increased by 3.2%, on average. This was the first price increase since 1988. The increase did not cover products which had entered the market after 1987. The increase varied according to the price of the product.

1993
The deductible in chronic illnesses was increased from ESP 5 to ESP 400 (from EUR 0.03 to EUR 2.40).

The automatic inclusion of new drugs to the reimbursement system was stopped.

It became possible to remove products from the reimbursement system if new products, which are comparable or better but cheaper, enter the market.

Value Added Tax for pharmaceuticals was reduced from 6% to 3%.

1994
The negative list was introduced. Over 800 products were removed from the reimbursement system .

Prices were reduced by 3%, and frozen until 1997.

The pharmacist margin was reduced by 2%.

1995
The pharmaceutical manufacturers and the Spanish government agreed that should the annual drug reimbursement costs increase by more than 7%, the manufacturers would return 57% of the excess to the State. Moreover, manufacturers would repay 1% of the sales value of reimbursed drugs to the State. Similar repayment schemes have been applied before. The amount of the repayments have fluctuated from 1 to 3.5% depending on the agreement.

Value Added Tax for pharmaceuticals was increased from 3% to 4%.

1996
A new 40% reimbursement category was proposed by the pharmaceutical industry. The proposal was rejected.

Discussions on a reference price system were initiated.

1997
The wholesaler margin was reduced by 1% and the pharmacist margin by 2%.

Generic drugs were given legal status.

1998
A reference price system was planned. It was based on proposals brought forward during the previous years.

Pharmaceutical manufacturers were required to pay ESP 65 billion (EUR 391 million) to the State regardless of the sales figures during 1998–2000.

The negative list was expanded.

A draft law was published on a reference price system.

1999
The wholesaler margin was reduced by 1.4%.

In September, the prices of all reimbursable drugs were reduced by approximately 6% (4-10% depending on the price of the drug).

Plans to introduce a reference price system continued.

2000
The reference price system was introduced.

The government proposed that pensioners should pay an average of 10% of their drug costs. The amount payable would be linked to the earnings of the pensioner. The proposal was later abandoned.

2001
A price reduction of 15% was applied to products with a higher price than the average of three cheaper, corresponding products. The price reduction was applicable to about 150 products. As a result of the price reduction, the prices of some products dropped below the reference price.

Andalucia introduced a reference price system applicable to all drugs. At the same time, they introduced generic prescription; the doctor prescribes using the generic name and the pharmacy dispenses the lowest priced product available.

Latest changes, proposals and discussion topics

Drug prices in Spain are among the lowest in Europe. Despite this, prices were reduced between 1996 and 1999 by an average of 11%. As a result of the reference price system, and the price reductions in 2001, prices have continued to fall.

In 1999, drug costs increased in Spain by almost 10%. In July 1999, the Spanish government announced that should costs keep on escalating by more than 8%,

the industry must pay an extra repayment to the State, in addition to the already agreed repayments. The legality of the repayments was deliberated on for a long time. In 2001, the industry agreed to pay the requested sum.

In 2001, the government and the pharmaceutical companies signed a stability pact; the industry will try to contain drug costs during 2002–2004 and the government will not impose any financial constraints on the industry. The agreement also defined a sum which the industry may use for research and development. Almost half of this sum is to be allocated to research institutes outside the industry.

More price cuts are on the way in early 2002. The reductions will be 10% on average, up to the maximum of 40%. At the same time, the prices of some products will be increased. In 2002, more drugs are to be included in the reference price system. A reward system is planned for doctors who use generic prescription in over 6% of their prescriptions.

To contain drug costs the government has proposed that wholesalers should repay the State ESP 8 billion (EUR 48 million) and pharmacies ESP 40 billion (EUR 240 million) over a three year period.

Sweden

In Sweden, health services and their costs are primarily the responsibility of the public sector. The system is heavily decentralised. The health insurance system is managed by the *Riksförsäkringsverket* (RFV), which operates under the ministry responsible for social affairs and health, the *Socialdepartementet.* The entire population is covered by the public health insurance system.

Pricing

The pricing of pharmaceutical products by the marketing authorisation holder is unregulated. However, if the product is to be covered by the reimbursement system an agreement has to be achieved with the RFV regarding its price. The price application can be submitted before the marketing authorisation has been granted. When deciding on a reasonable price, the criteria considered include the following: the therapeutic and health economic value of the product, the effect of the product on reimbursement costs, the price of corresponding products in Sweden and other countries as well as the research and manufacturing costs. The price negotiations are usually brief and end in a positive result. County councils are also given the opportunity of deliberations with the RFV, but the RFV will make the final decision.

Sweden uses a reference price system. The reference price is decided by the RFV. It is set 10% higher than the price of the cheapest generic alternative. When the reference price has been set the drug will automatically be included in the reimbursement system. The reference prices are reviewed four times a year.

Over-the-counter medicines may be priced by the manufacturers without restriction; these are not included in the reimbursement system.

Wholesalers and pharmacists have fixed percentage margins. However, the pharmacist margin for expensive products must not exceed SEK 200 (EUR 22.06). Pharmacies are not privately owned, but drug dispensing is carried out by the state-owned *Apotek Ab,* which has 900 sales outlets.

Prescription drugs are exempt from Value Added Tax. Value Added Tax for over-the-counter medicines is 25%.

Criteria for reimbursement

About 3,500 pharmaceutical products are marketed in Sweden. Out of these, 90% are reimbursable. A reimbursable drug must have a price which has been approved by the RFV or it must belong to the reference price system. When the price has been set, the drug is added to the positive list. In addition to the RFV,

other authorities dealing with reimbursement issues are *Läkemedelsverket* and *Socialstyrelsen.* Before the decision is made regarding the reimbursability, the manufacturer may be asked to provide a health economic evaluation. In principle, almost all prescription drugs are reimbursed. An exception to this are drugs used to treat obesity, erectile dysfunction and baldness. Nicotine products and some cough medicines are also non-reimbursable.

When over-the-counter medicines are prescribed for the treatment of some chronic illnesses they may be reimbursed. To be eligible for reimbursement the drug must have a price approved by the RFV.

Parallel import products are reimbursed only if their price is at least 10% below that of the original product.

Size of reimbursement

Before 1997, the reimbursable drugs were divided into two reimbursement categories. The treatment of approximately 30 illnesses was free for the patient, and for the rest of the drugs the patient paid a fixed deductible. In 1996, the deductible for the most expensive drugs of one purchase was SEK 170 (EUR 18.75) and the deductible for the rest of the drugs, during the same purchase, was SEK 70 (EUR 7.72) per drug. There was a limit to the sum payable by the patient for drug and other health care costs. In 1996, this limit was SEK 2,200 (EUR 242.62). When the patient's payments reached the set limit the patient was issued a so-called "free card" which entitled the owner to receive drugs free of charge for the remainder of the 12-month period. In 1990, five per cent of the population was in possession of the card, and in 1996 the figure had risen to 10%.

A new drug reimbursement system was introduced at the beginning of 1997. The size of reimbursement is no longer dependent on the nature of the illness but is based on the total cost of products purchased by the beneficiary in the course of 12 months. The children under 18 years of age within a family unit are considered as one beneficiary and their costs are pooled together. If the total drug costs during 12 months fall below SEK 900 (EUR 99.26), the patient pays the total sum. When the costs are between SEK 901 and 1,700 (EUR 99.37–187.48) the patient pays 50% of the costs, between SEK 1,701 and 3,300 (EUR 187.59–363.94) the patient pays 25% and between 3,301 and 4,300 (EUR 364.05–474.22) the patient pays 10%. Drugs purchased after the SEK 4,300 (EUR 474.22) limit has been reached are dispensed free of charge to the patient. The maximum amount payable by the patient, during 12 months, is SEK 1,800 (EUR 198.51). Costs not counting towards the maximum sum payable include: over-the-counter medicines, prescribed vitamins, drugs not included in the reimbursement system and drugs whose price is above the reference price; in these situations the patient has to pay the difference between the two prices.

Insulin forms an exception, and it is always dispensed free of charge. As was the case under the previous system, under the new system approximately 10% of the population receive their drugs free of charge, after they have reached the annual limit of SEK 4,300 (EUR 474.22).

The current reimbursement ranges have been in force since June 1999. At the time of the introduction of the system, reimbursements were paid for drug costs exceeding SEK 400 (EUR 44.11) and the limit set to the patient's own contribution was SEK 1,300 (EUR 143.37).

Development and distribution of drug costs

The increase of drug reimbursement costs has fluctuated in Sweden according to the changes introduced. In 1995, drug costs increased by 11%. A few months before the introduction of the reimbursement reform patients bought large amounts of drugs to store away, and in 1996 drug reimbursement costs increased by almost 20%. The reimbursement costs for 1997 were lower than those for the previous year, but in 1998 the reimbursement costs increased again by 21%. In 1999, the increase in reimbursement costs slowed down to 10%, as a result of the changes made to the reimbursements ranges. In 2001, drugs delisted from the reimbursement system included those for the treatment of obesity and erectile dysfunction. The increase in drug costs was only 6.5% during that year.

The aim of the drug reimbursement reform was to increase the proportion of drug costs payable by the patients from 20% to approximately 25%. However, this was not achieved and in 1998 the proportion paid by the patients was 21%. In 2001, patients paid 23% of the cost of reimbursable drugs.

Changes in the drug reimbursement system and drug prices

1990
The deductible, payable by the patient, was increased from SEK 65 (EUR 7.17) to SEK 75 (EUR 8.27) per drug.

1991
The deductible, payable by the patient, was increased to SEK 90 (EUR 9.93) per drug.

1992
Some over-the-counter medicines were delisted from the reimbursement system (negative list).

The deductible, payable by the patient, was increased. The deductible for the most expensive drug of one purchase was SEK 120 (EUR 13.23) and the deductible for the rest of the drugs was SEK 10 (EUR 1.10) per drug.
A limit of SEK 1,500 (EUR 165.43) per 12 months was set to all health care costs payable by the patient.

1993
Some prescription drugs were changed to over-the-counter medicines.

Some previously reimbursable drugs were delisted from the reimbursement system.

The reference price system was introduced.

1994
The pharmacist margin for prescription drugs was reduced and that for over-the-counter medicines was increased by 2.5%.

Generic substitution became operational, on the approval of the prescribing doctor.

1995
The deductibles, payable by the patient, were increased to SEK 125 and SEK 25 (EUR 13.79 and EUR 2.76).

The deductibles, payable by the patient, were increased to SEK 160 and SEK 60 (EUR 17.65 and EUR 6.62). A limit of SEK 1,800 (EUR 198.51) per 12 months was set to all health care costs payable by the patient.

1996
The deductibles, payable by the patient were increased to SEK 170 and SEK 70 (EUR 18.75 and 7.72). A limit of SEK 2,200 (EUR 242.62) was set to all health care costs payable by the patient.

1997
The drug reimbursement system was reformed. A limit of SEK 1,300 (EUR 143.37) was set to drug costs payable by the patient.

1999
The proportion payable by the patient towards the reimbursement costs was increased.

The pharmacist margin for products with a wholesale price in excess of SEK 2,000 (EUR 220.57) was reduced.

2000
The pharmacist margin for all drug packages was reduced by SEK 2.60 (EUR 0.29).

The committee reviewing the new reimbursement system submitted its report.

2001
Drugs used for the treatment of obesity and erectile dysfunction were delisted from the reimbursement system. Reimbursement can be paid towards purchases of these products only in very rare situations.

The pharmacist margin for each drug package was increased.

Latest changes, proposals and discussion topics

Since 1996, several reports have been submitted in Sweden regarding the drug distribution system and the increased drug costs. According to one of the reports, the profits made by *Apoteket Ab* were excessive. Based on this report, *Apoteket Ab* was required to enter SEK 400 million (EUR 44 million) into their accounts as income for 1997 and save SEK 300 million (EUR 33 million) in 1998. In order to make the necessary savings *Apoteket Ab* closed some of the smaller outlets and reduced staff numbers. The abolishment of the pharmacy monopoly held by *Apoteket Ab* has been deliberated over several years. In mid-March 1999, the Swedish government declared that the monopoly of *Apoteket Ab* as the owner of the pharmacy outlets and the distributor of drugs is to remain.

In autumn 2000, the committee set to assess the current drug reimbursement system and analyse the cost developments from various point of view completed its task. The criticism of the current system has included the fact that it is difficult for patients to understand and the problems encountered when implementing reimbursements for high expenditures.

The task of the committee was to consider the effect of prescribing habits, generic substitution and parallel import products on cost developments. It was also to evaluate the effect of the ”free cards” on patients’ drug purchases. Approximately 800,000 Swedes are in the possession of the card, and this was considered to be one of the reasons for the continuing growth. At the time of setting up the committee, the so-called lifestyle drugs were reimbursable and their costs accounted for approximately a quarter of the increase seen in drug costs. One of the tasks of the committee was to determine the situations under which the lifestyle drugs should be reimbursed and whether their reimbursement would pose problems with prioritisation.

In its report the committee made several proposals for reforms. One of the proposed reforms was to change the reimbursement system by abolishing the

tiered reimbursements, and the patient would pay all drug costs up to SEK 1,800 (EUR 198.51) for a 12 month period and SEK 40 (EUR 4.41) per drug thereafter, to the maximum of SEK 1,000 (EUR 110.28). To avoid excessive financial burden, the initial SEK 1,800 could also be paid in instalments. It would still be possible to add the drug costs of all the family's children together, but the initial payment would then be SEK 900 (EUR 99.26). It was envisaged that the proportion of the costs payable by the patient would be 28–32%.

In order to curb the increase in drug costs the committee suggested an increased use of starter packs in drug treatments and the utilisation of computers during consultations with a doctor. The committee did not recommend the introduction of generic substitution or generic prescribing.

The committee suggested the introduction of a new department for the purposes of drug reimbursement and pricing decisions. Almost all drugs are currently reimbursed in Sweden which, according to the committee, cannot be considered appropriate. The committee feels that the first task of the new department would be to review the range of drugs eligible for reimbursements. The committee was unwilling to name any particular drug groups, the reimbursement status of which it considered inappropriate. However, it was generally considered that the removal of drugs used to treat obesity and erectile dysfunction from the reimbursement system in 2001 was a result of the committee's wish to rationalise the range of drugs eligible for reimbursement.

Despite the views of the committee, generic substitution is planned to be introduced during 2002. The substitution of a drug with another product containing the same medicinal substance would be possible, unless explicitly forbidden by the prescriber. The patient would have to pay the difference between the actual price and the reference price for the more expensive drugs. At present substitution is allowed only with the doctor's approval. The sale of generic products has been low and has only succeeded in certain districts after agreements between doctors and pharmacies.

In 1996, it was decided in Sweden that county councils should become responsible for drug costs and take overall responsibility for drug treatments. Decentralisation would make it easier to take local conditions and needs into consideration and to improve cost management. Despite expectations the reform did not take place in 2001, and a new date has been set for 2002. Equal targeting of funding has proved to be problematic. The transfer of pricing and reimbursement decisions to the county councils has also been discussed for a long time. According to a proposal published in 2001, a totally new national board will be established in Sweden to make decisions regarding drug pricing and reimbursement.

It has been proposed that the prescribing doctor's place of work should be marked on each prescription. A workplace-specific code would assist the monitoring of drug costs and regional comparisons.

United Kingdom

The health services in the United Kingdom are primarily offered by the *National Health Service (NHS).* To be eligible for the NHS services the patient must register with a NHS doctor. To obtain hospital treatment or services from a specialist the patient must be referred by his/her own NHS doctor.

Pricing

The pricing of pharmaceutical products by the marketing authorisation holder is unregulated. In order for the drug to be reimbursable under the NHS it must be included in the *Pharmaceutical Price Regulation Scheme* (PPRS)*.* The PPRS does not set individual drug prices, but the *Department of Health (DoH)* which operates under the *Secretary of State* negotiates a profit framework with the manufacturer. The manufacturer may then freely set the price within this framework. A pharmaceutical company may set the prices, particularly for new products, with considerable latitude for the five years following market entry. However, the annual sales of the new product must not exceed GBP 20 million (EUR 32 million) and the pharmaceutical company's profit must not exceed the set framework. The negotiations with the PPRS are based on the profit and loss account of the pharmaceutical company. An actual profit of approximately 20% is accepted. However, if the profit percentage is higher than the figure approved, the company either returns the surplus to the NHS, reduces the price of its drugs or postpones any planned price rises. The approved profit may be exceeded by up to 50% if the profit is the result of introducing a new product to the market or increasing the efficiency of the company. The market authorisation holder may freely reduce prices but will require permission for price increases.

Over-the-counter medicines and generic products are not included in the PPRS. The prices for generic products, which are to be reimbursed by the NHS, are set by the DoH. The prices were previously based on the weighted average of the main manufacturers' prices. In 1999, the prices of generic products increased by almost 50% due to the shortage of generic products. The price increase caused an extra expenditure of approximately GBP 200 million (EUR 325 million) for the NHS. In August 2000, a statutory maximum price was set for the most used generic products reimbursable by the NHS. The maximum price was set according to the price level at the turn of 1998/1999. The maximum prices are going to be reviewed every 15 months. The system of maximum prices is going to be in force for the time being, until a long-term and sustainable solution is found for the pricing of generic products. The proposed alternatives include: the development of the current system, the introduction of a reference price system or centralised purchasing by the NHS of all necessary generic products.

There is no upper price limit for over-the-counter medicines.

Wholesalers pay less than the factory prices for drugs covered by the NHS reimbursement scheme. The wholesalers will then in return usually give discounts to pharmacies.

Pharmacies are financed by the payments from the NHS. The NHS pays the pharmacy the wholesale price for any drugs dispensed, with a deduction of an estimated discount given by the wholesaler. If the discount given to the pharmacy was in fact larger than estimated by the authorities, the pharmacy may keep the difference. Pharmacies are therefore keen to obtain products from the wholesalers as cheaply as possible. Pharmacies may set their own margin for over-the-counter medicines.

There is no Value Added Tax for pharmaceuticals covered by the reimbursement scheme, but the tax for other pharmaceuticals is 17.5%.

Criteria for reimbursement

About 14,000–15,000 pharmaceutical products are marketed in the United Kingdom. These are divided into three groups:

The *General Sales List* (GSL) contains drugs which can be purchased without prescription, including purchases from outlets other than pharmacies, and several generic products. Drugs in this group are not reimbursed.

The *Pharmacy-Only List* (P) contains drugs which do not require a prescription but may only be sold through pharmacies. These drugs may be reimbursed in certain cases, e.g. for the treatment of long-term illness, for patients under the age of 16 and on social grounds.

Prescription-Only Medicines (POM) require a prescription. All drugs in this group are reimbursed 100%, excluding drugs in the negative list. The negative list was introduced in 1985 and it had only about 600 products. Today the list is considerably more extensive and it lists about 2,000 products. The negative lists contains, for example, antacids, analgesics, cough medicines, laxatives, anxiolytic drugs, vitamins and asthma medication. Drugs in the negative list are not reimbursable in any situation.

A reimbursable drug must be included in the PPRS.

Size of reimbursement

The patient only pays a prescription charge for each drug purchase. The prescription charge is reviewed annually. In 2002, the prescription charge is GBP 6.20 (EUR 10.06). In practice, 85% of drug purchases do not generate a

prescription charge. The groups exempt from paying a prescription charge include patients aged under 18 or over 60, pregnant women, mothers with children aged under 1 year, patients with low income or those suffering from a chronic illness. Neither is there a prescription charge for the contraceptive pill. Drug consumers may buy an advance "season ticket" for four or twelve months to cover all prescription charges for that time period. In 2002, a four month season ticket costs GBP 32.90 (EUR 53.39) and one for twelve months GBP 89.00 (EUR 144.43).

A significant number of drugs reimbursed by the NHS are cheaper than the prescription charge and when purchasing these products the patient is required to pay more than the actual value of the drug. These products include, for example, most generic products.

Doctor's budgets

The NHS doctors belong to one of two groups which have different responsibilities for their budget. Some doctors are *fundholders* and have been allocated a total budget which they manage themselves. With the allocated funds they organise primary health care services for their own patients. These funds will also go towards personnel costs, prescription drugs and certain hospital services. Funds are allocated according to the number of patients registered with the doctor and the structure of the local population. The fundholder may keep any surplus funds, but, by the same token, the fundholder is not refunded any budgetary excess. If the fundholder is unable to function within the framework of the allocated budget, the budget may be withdrawn.

The majority of the NHS doctors do not hold a budget (*non-fundholders*) and their salary is determined, among other things, on the basis of the number of registered patients and the services offered. However, doctors in this group must also budget for their own drug expenditure, but it is not possible to require a strict adherence to this budget.

Should a doctor exceed the drug budget by more than 25%, he/she will be invited to discuss possibilities to reduce the drug expenditure. Doctors are usually encouraged to prescribe by using generic names instead of proprietary names, and the pharmacy is required to dispense the cheapest alternative available.

A drug budget alone has not been found to be enough to curb drug costs. However, the drug expenditure of fundholders has been more restrained. There has been discontent amongst the primary care physicians about them being held responsible for the increasing drug costs even though expensive treatments are usually initially prescribed by specialist doctors. A significant proportion of drug expenditure is accounted for by the continued primary care use of drugs initially introduced during a hospital stay.

The United Kingdom is planning to stop allocating budgets to individual fundholders; this is to be replaced with a system where a group of approximately 50 doctors, i.e. a *Primary Care Group*, is responsible for a regional budget.

Generic products

In 1985, approximately 35% of all prescriptions were written using a generic name. This had increased to 63% by 1998 and half of the products dispensed to patients were generic products. It was then estimated that the proportion of generic products would be as high as 80% if pharmacies dispensed a generic product whenever possible. A target was set by the NHS to have 72% of all prescriptions written using generic names by March 2002. The containment of drug costs and improved efficiency were cited as criteria for the target. The target has almost been achieved: 71% of all prescriptions were written using generic names by 2000 and 52% were also dispensed as generic products. Approximately 80% of prescriptions for antimicrobials were written with generic names.

Changes in the drug reimbursement system and drug prices

1990
Prescription charge was increased from GBP 2.80 to GBP 3.05 (from EUR 4.54 to EUR 4.95).

1991
Prescription charge was increased from GBP 3.05 to GBP 3.40 (from EUR 4.95 to EUR 5.52).

1992
Glaxo introduced a new delivery system which reduced the wholesaler costs.

Prescription charge was increased from GBP 3.40 to GBP 3.75 (from EUR 5.52 to EUR 6.09).
The negative list was expanded.

1993
Some prescription only medicines were made available without prescription.
Prescription charge was increased from GBP 3.75 to GBP 4.25 (from EUR 6.09 to EUR 6.90).

The factory prices of drugs were reduced by 2.5% and the prices were frozen for three years. PPRS reduced the approved profit margins for pharmaceutical manufacturers.

1994
Prescription charge was increased from GBP 4.25 to GBP 4.75 (from EUR 6.90 to EUR 7.71).

1995
Prescription charge was increased from GBP 4.75 to GBP 5.25 (from EUR 7.71 to EUR 8.52).

1996
Prescription charge was increased from GBP 5.25 to GBP 5.50 (from EUR 8.52 to EUR 8.93).

The negative list was expanded.

1997
Prescription charge was increased from GBP 5.50 to GBP 5.65 (from EUR 8.93 to EUR 9.17).

1998
Prescription charge was increased from GBP 5.65 to GBP 5.80 (from EUR 9.17 to EUR 9.41).

The prices of drugs included in the PPRS were reduced by 4.5%. An agreement was made to freeze the prices until the end of 2000 and even after this any price increase could not be more than 20% of the prices in August 1999.

1999
Prescription charge was increased from GBP 5.80 to GBP 5.90 (from EUR 9.41 to EUR 9.57).
A new PPRS was introduced in October.

2000
Prescription charge was increased from GBP 5.90 to GBP 6.00 (from EUR 9.57 to EUR 9.74).
Maximum prices were introduced to the generic products reimbursed by the NHS.
In 2000, the average price reduction was 30%.
One prescription in eight was dispensed as a parallel import product.

2001
Prescription charge was increased from GBP 6.00 to GBP 6.10 (from EUR 9.74 to EUR 9.90)
Pharmacy delivery fees were reduced.

2002
Prescription charge was increased from GBP 6.10 to GBP 6.20 (from EUR 9.90 to EUR 10.06).

Latest changes, proposals and discussion topics

According to international price comparisons, in 1999 drug prices in the United Kingdom were high as compared to many other European countries. The latest PPRS agreement of 1 October 1999, between the ministry and the pharmaceutical industry, advised on a price reduction. According to the agreement, the pharmaceutical industry reduced the prices of all drugs other than generic products by 4.5% and prices were frozen for 15 months. The companies themselves chose which prices to reduce. The agreement is advantageous to manufacturers with several patented products on the market, since the agreement allows new products to be priced with considerable latitude.

The price reductions have particularly affected products which have equivalent parallel import products on the market. Companies marketing parallel imports are afraid that the agreement will diminish the need for parallel importation and make competition impossible. They are considering legal action. Due to the criticism, the Department of Health and the pharmaceutical industry plan to clarify the competitiveness of the drug markets in the United Kingdom.

The PPRS has long been criticised for the lack of openness, and the new agreement offers no improvement in this regard. However, the NHS feels that one benefit offered by the new agreement is that it is not as strict as the previous ones.

It has been forecast that the new agreement will not actually be able to contain the NHS drug costs but they will continue at the current annual rate of approximately 9%.

The new lifestyle drugs have generated much discussion in the United Kingdom and it has been suggested that patients should bear more of the costs than hitherto. It has been suggested that the fixed prescription charges give patients wrong perceptions over drug costs and lead to irrational drug choices. It has also been proposed that the United Kingdom should adopt a system like the one used in Sweden, i.e. the proportion payable by the patient is linked to the amount of drug consumption.

There is also much discussion about the operations of the *National Institute for Clinical Excellence* (NICE). NICE, which operates under the NHS, was founded in early 1999. It produces, for example, assessments relating to health technology as well as treatment guidelines for various illnesses and symptoms, for the use of patients and doctors. By providing quick information about the cost

effectiveness of new treatments, NICE strives to guide NHS expenditure in a more effective direction and create opportunities to unify treatment practices throughout the nation. NICE has carried out assessments on the clinical value and cost effectiveness of certain new drugs, including those used in the treatment of MS and a drug indicated for the treatment of influenza. NICE updates the validity of its assessments every 1–3 years.

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APPENDIX

Exchange rates published on 8 March 2002 by the European Central Bank

Currencies	currency/euro exchange rate
Austrian schilling (ATS)	13.7603
Belgian franc (BEF)	40.3399
Danish krone (DKK)	7.4325
Dutch guilder (NLG)	2.20371
English pound sterling (GBP)	0.61620
Finnish mark (FIM)	5.94573
French franc (FRF)	6.55957
German mark (DEM)	1.95583
Greek drachma (GRD)	340.750
Icelandic krona (ISK)	88.17
Irish punt (IEP)	0.787564
Italian lira (ITL)	1936.27
Luxembourg franc (LUF)	40.3399
Norwegian krone (NOK)	7.7200
Portuguese escudo (PTE)	200.482
Spanish peseta (ESP)	166.386
Swedish krona (SEK)	9.0675