OVERVIEW OF PHARMACEUTICAL PRICING AND REIMBURSEMENT REGULATION IN EUROPE[1]

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1. Introduction

The fundamental nature of national regulation on pharmaceutical products reflects the underlying national attitudes towards the provision and financing of healthcare. The main approaches and specific measures are the result of traditional attitudes of governments and their *ad hoc* responses to medical or financial crises. For example, countries that control the price at which medicines may be sold often have a tradition of direct government involvement in economic activity, including, until recently, that of controlling prices in a wide range of sectors. The above approaches are supplemented by differences in policy priorities and objectives between different government departments. This leads to the dilemma of health *versus* industrial policy in a number of member states.

Understandably, the pharmaceutical industry is not like most other industries. Apart from the manufacturer and final consumer of a new medicine, several other 'third parties', are involved, responsible for the distribution, payment and availability of medicines onto the marketplace:

(a) Third-party payers (governments, statutory health insurance funds, private insurers) are responsible for the payment of medicines. They act on behalf of consumers or patients and take part in reimbursement decisions;

(b) Wholesalers are responsible for distributing pharmaceuticals from source to retail outlets (ie pharmacies), and in doing so they are interested in acquiring pharmaceuticals from the cheapest source;

[1] This brief is based on information supplied by pharmaceutical experts or regulators in ministries of health of the 15 EU Member States. It forms part of a project sponsored by the European Commission – DG Enterprise, on the current status of national pricing and reimbursement regulations in the member states. The document reflects the state-of-the-art in pharmaceutical pricing and reimbursement regulation, as of February 2001.

(c) Prescribing physicians make decisions on behalf of their patients, since the latter have neither the knowledge nor the information to decide which is the most suitable medicine for their condition;

(d) Dispensing pharmacists usually follow physicians' instructions on what to dispense, but their dispensing behaviour can be influenced by the incentive structure of their payment method; the latter being directly related to the type of products they dispense;

(e) Finally, Ministries of Finance often levy VAT (usually at a lower than the standard rate) or any applicable consumption tax on prescribed and consumed medicines.

Therefore, each of the above agents has a vested interest in the pharmaceutical industry and its products.

2. National systems

Total pharmaceutical expenditure in a country is the sum of drugs dispensed, multiplied by their price. Costs increase when prices increase, volumes grow or the mix of products dispensed changes. Gross demographic factors result in volume demand for healthcare and especially for pharmaceuticals, increasing faster than population growth. Hence even if prices remained constant, expenditure would increase. Although the prices of drugs post-launch have not generally increased, the unit price of medicines at launch is increasing in real terms and the product mix is changing towards newer and more expensive products. Overall, growth in demand for medicines is strong.

National governments and their competent authorities have implemented a series of measures, both controls and incentives to influence supply of and demand for pharmaceuticals. Some countries have given greater emphasis to supply others to demand.

The supply-side controls are aimed at limiting the cost of reimbursed medicines to the authorities, by controlling their price and/or reimbursement (**Table 1**) and by limiting their availability through the use of positive and negative lists (**Table 3**).

Table 1

National controls for pharmaceutical products on the supply-side

	PRICING	***Reimbursement***
Austria	a) Price-contracting with price/volume agreements b) Rebate on excess sales	a) Positive list following price-volume agreements b) Contractual relationship of physician with *Krankenkassen* monitoring prescribing
Denmark	a) There is no policy of price control b) Price agreement between the industry and the Ministry of Health, [price reductions]: February 1998 – 30 March 2000	a) Positive list b) Reference Pricing for 'analogous' (generics) products c) Generic substitution ("G" scheme) d) European price comparisons e) Economic data in reimbursement (voluntary agreement)
Netherlands	Maximum price fixing (twice per year) through European price comparisons (reference countries are Germany, France, Belgium, UK)	a) Therapeutic Reference Pricing b) Positive list c) Promotion of dispensing parallel imports d) Explicit use of pharmaco-economic studies for reimbursement
Germany	Price freedom for new products	a) Reference price for off-patent sector (products subjected to generic competition; reference price for identical molecule only) b) Drug budgets with caps re-introduced in 1999 c) Negative list d) Positive list (proposed)
UK	a) PPRS: Agreement with industry on profit control, renewed on July 13th, 1999, for a five-year period b) Price cut, as part of PPRS, of 4.5% c) Free price modulation from 1.1.01	d) Negative list e) Homogeneous budget given to PCGs f) Practice guidelines g) Guidance on cost-effectiveness by NICE, influences prescribing
Ireland	a) Maximum authorised wholesale price is average of Danish, French, Dutch, German and UK prices b) Agreement with the industry (from August 1st, 1997, to July 31st, 2001) c) Price freeze for duration of above agreement d) Review of price freeze with international price comparisons e) Wholesale prices are the same but retail prices differ due to different pharmacy margins on GMS and private sales f) Price modulation permitted in exceptional cases	a) Positive list b) Indicative drug budget for doctors contracted into the GMS scheme c) Use of economic data in reimbursement decisions
Finland	Control through reimbursement system (manufacturer can launch at desired price, but needs to seek reimbursement)	a) Acceptance of a "reasonable" wholesale price by Ministry of Social Affairs and Health; this is the maximum price for the product; same rules for generics b) All new products remain in basic reimbursement category (50%) for two years c) Prices of existing products should be re-evaluated within 2 years

		d) Submission of pharmaco-economic data necessary when companies apply for a 'reasonable' price e) Control of prescribing in certain product categories f) Positive list (if the price is reasonable)
Sweden	a) Price control if reimbursement is sought b) Reimbursement price takes into account price in 10 European countries; exchange rates used for conversion c) Price should be lower than Denmark, the Netherlands, Germany, Switzerland and similar to those in Norway and Finland d) Annual negotiations between the industry and the National Social Insurance Board for price revisions	a) Reference price at pharmacy buying-in level b) Health economic evaluation if price premium is requested (for innovative products) c) Price-volume agreement for innovative products d) Positive list e) Negative list (OTCs)
Belgium	a) Price control with price comparisons and weights given to R&D b) Regular price cuts/freezes especially for older products	a) Positive list b) Prescribing control through Pharmanet c) Controls on specific categories of drugs (antibiotics, NSAIs) d) Controls on the veracity of reimbursement claims by pharmacists e) Generics must be at least 20% cheaper than branded product to qualify for reimbursement
France	a) Price fixing through negotiation (product's medical value, prices of comparable medicines, volume sales, conditions used) b) Comparisons with other European countries for 'innovative' products c) Periodic price reductions for new and expensive products	a) Comite Economique du medicament decides on reimbursable prices on advice from Transparency committee b) Positive List c) Medical references d) Targets for 'gate-keeping' GPs e) Pharmaco-economic guidelines under development f) Prices of generics 30% lower than those of the original
Italy	a) Average European Price (all EU countries) for "old" products and products registered with the national procedure; AEP is calculated on ex-manufacturer's price (excl. VAT), of top five selling equivalents, including generics. b) Price negotiation (contractual model) for new and innovative products (for drugs registered with EMEA or for those for which AEP cannot be calculated) c) Price freedom for non-reimbursable drugs d) Generics are priced at least 20% below the original e) Frequent use of price cuts/freezes	a) Positive list b) Reference pricing and 'same prices for same drugs' principle for off-patent drugs c) Formal requirement for economic evaluation during price negotiations d) Guidelines and protocols defined and managed at local level e) Official earmarked budget for innovative drugs introduced in 1998, representing 1% of national drug budget
Greece	a) Price Fixing for imported medicines (lowest EU price for the same molecule) b) Basic Cost formula for locally	a) Positive list b) Clustering (reference price) for calculating the average daily treatment cost c) Requirement to be included in reimbursement

	produced pharmaceuticals c) Cannot grant a price unless product is marketed in one European country	lists of 3 of the following countries: France, Germany, Switzerland, UK, USA, Sweden
Portugal	a) Two step process with Ministry of Finance agreeing to the maximum price for every new medicinal product and, subsequently, INFARMED processes reimbursement applications b) Price Control (Average pricing of Spain, France and Italy); additional restrictive criteria apply c) Price increases in 1998 and 1999 below the rate of inflation d) Generics priced at least 20% below equivalent branded product	a) Positive list b) Submission of 'cost-benefit' data
Spain	a) Price Control through negotiation on a cost-plus basis b) International price comparisons c) Price-volume agreement for expensive products	a) Positive list b) Negative list c) Reference pricing for estimating maximum reimbursement for multi-source products

Source: Author's compilations from national sources.

3. Regulation of supply

3.1. Price and rate of return controls

Control over price is exerted directly or indirectly; directly, by determination of the price on the market, through a pricing methodology (see below), and, indirectly, by controlling the rate of return on capital invested or return on sales. The former scheme is in operation in the majority of EU member states, in one form or another and for some segments of the pharmaceutical market, whereas the latter applies only to the UK case. **Table 1**, summarises the discussion of this section on supply-side measures.

Price controls limit the price at which a product may be sold on the market, irrespective of whether it is reimbursed and whom it is sold to. The amounts to be paid by health funds and patients are determined on the basis of an interplay between price, reimbursement and co-payment. As a result, there is an obvious motivation to control the amount that has to be reimbursed.

A multiplicity of price control variations exists. In some countries, there is a set maximum amount for reimbursement. This is usually calculated on the basis of the actual price of a drug, or in relation to the prices of other similar drugs on the market, or, indeed by taking prices of neighbouring countries as comparators either explicitly (average pricing) or implicitly. Patients must pay any difference between this amount and the price of the drug. In other EU countries, a reimbursement price must be obtained if a drug is to be reimbursed. This usually becomes the price in that market, as regulations in most countries stipulate that a medicine may only be sold at a single price and that market access without reimbursement is severely restricted. If drugs are fully reimbursed, controlling the price is the only way of limiting the amount paid by health insurance. There is also the possibility of two different pricing systems operating in parallel in a single country. Italy, for instance, applies a system of Average European Price for old products and a contractual model for newer medicines. Greece applies an external reference methodology (the lowest EU price) for imported pharmaceuticals and a full-cost approach for domestically produced ones.

Price is also important in countries where patients pay the difference between this and a maximum reimbursement amount. Authorities have an incentive to ensure that patients are not

charged more than what they are prepared to pay, on grounds of public health, social solidarity and economic efficiency. In a market where the normal constraints of supply and demand do not operate, price control may seem justified.

Countries that control the prices of prescription pharmaceutical products can be divided into three groups:

(a) In the first group, price control is partly a remnant of a time when governments interfered much more extensively in national economies. Belgium and Spain, for instance, require a price to be negotiated with national authorities before a prescription medicine can be marketed. The basis of price setting is supposed to be the cost and, to a lesser extent, the value of a product; this is a notoriously difficult calculation for medicines. Also taken into consideration are the prices of similar products on the national market, and of the same product in other European markets. Negotiations provide authorities with an opportunity to reward companies that have made, or promise to make, a positive contribution to the national economy. It is expected that the comparative pricing elements in these systems will achieve greater emphasis, thus diminishing the discretionary power of individuals.

(b) The second group only consists of the UK, where the prices of all branded drugs must be set so as to ensure that the overall of return on capital is within the authorised boundary. Given that negotiations and the allowed return on capital are confidential between the authorities and pharmaceutical companies, there is considerable scope for incentives, rewards and favouritism.

(c) In the third group, which includes Greece, Ireland, the Netherlands Portugal, and, partly, Italy, the maximum retail price of a product is determined in relation to the price of the same product in neighbouring countries, using a published formula. Disputes may arise as to which products in the reference countries can or cannot be included, and these can be settled in the courts of law.

3.2. Price revisions

The process of obtaining a revised price is traditionally based on the same principles as those that determine the initial price or reimbursement price. However, in the last few years, almost

every European country has negotiated or enacted a price freeze or price reduction on prescription drugs. In some countries, a fixed percentage price decrease is applied to all products. In other countries, some degree of latitude is granted to pharmaceutical companies to modulate a price reduction among products in their portfolio, as long as the overall reduction in costs is at least as much.

3.3. Price-volume agreements

When a reimbursement price is granted, the pricing and reimbursement authorities enter into a commitment to pay for a drug as long as it is prescribed appropriately. In the past, this was an open-ended commitment. Now, increasingly, price-volume agreements are negotiated which stipulate the volume that may be sold, based on forecast sales included in the application. If the sales volume is exceeded, the supplier is penalised usually by having the price of the product reduced. This situation arises from a suspicion that pharmaceutical companies supplied deliberately low volume forecasts for new drugs so as to obtain a higher price, and a desire to improve the likely reliability of forecasting the future cost of treatments. Although this has been characterised as a penalty on success, it may be seen more fairly as a penalty for inadequate market research and poor forecasting. Finally, some member states have formally (e.g. Italy) or informally earmarked parts of their pharmaceutical budgets for new and expensive medicines, or, indeed, enforce periodic price reductions (e.g. France), in exchange for fast access to market at a preferential price.

3.4. Price comparisons

Price comparisons could be either explicit, in that some kind of average is taken to be the price in the relevant market, or implicitly, in that decision makers require information about neighbouring countries' prices, without meaning that these will form the basis for the calculation of the price in the relevant market. The former is the *Average Pricing* variation, whereas the later is the *International Price Comparisons* variation.

Average pricing usually relies on taking the average of prices in three or four neighbouring countries, converted into local currency using exchange rates (**Table 2**). There are variations: Greece takes cheapest price of the same molecule in Europe; Portugal takes the cheapest of three set countries; Italy used to convert prices of four countries to Italian lira by using

Purchasing Power Parities (PPPs), although this has now changed to all EU prices being taken into consideration and conversion being done through the use of exchange rates. In the majority of cases where cross-country comparisons are taking place, reference countries usually comprise two high-price countries and two low-price countries.

Table 2
Pricing of pharmaceutical products: reference countries and basis of calculation

Country	Reference countries	Basis of calculation	Prices re-calculated	Conversion
Greece	Lowest price in Europe	Lowest price in Europe	No	Exchange rates
Ireland	Denmark, France, Germany, Netherlands, UK	Lowest of average and UK price	No	Exchange rates
Italy[1]	All EU countries	Average	Yes	Exchange rates
Netherlands	Belgium, France, Germany, UK	Average	Yes	Exchange rates
Portugal	France, Italy, Spain	Lowest	No	Exchange rates

Note: [1]Used for pricing some products only. For new and innovative products, the price is set through negotiation.
Source: Compiled from national sources.

In about half of the cases, only the initial prices are calculated. In the other half, prices in the reference countries are monitored and the maximum price re-calculated periodically. In each country, the detailed procedure for reaching the maximum price is published. The main elements covered are:

- Which products to select in each reference country;
- How to calculate the price of different forms (if allowed) or different pack sizes;
- How to reach the price to apply, especially if there are several products; and
- How to convert reference country prices into national currency.

3.5. Health economic evaluations

In all countries, reimbursement is negotiated on the basis of a variety of criteria. The therapeutic benefits of a product vis-à-vis those of its competitors are frequently cited. If a product is unquestionably superior in therapeutic terms, it will be reimbursed irrespective of the outcome of any health economic evaluation. Conversely, if it is of only marginal

therapeutic benefit, it will be difficult to justify a price premium relative to its competitors, and a health economic evaluation is unlikely to be of major help.

A number of countries in Europe have started to incorporate health economic evaluations in the decision-making process, either as an additional tool to determine the reimbursement price (the Netherlands, Finland), or even as a mechanism to guide prescribers (NICE in the UK). More countries are joining this league and have set up working parties to draft pharmaco-economic guidelines to be used in the decision-making process (France, Italy). In the meantime, cost-effectiveness criteria form part of the submission dossier and are taken into consideration (France, Ireland, Italy). In other member states, evidence on cost-efficacy is used in negotiations when a price premium is requested (Denmark, Sweden). Finally, other member states have announced that health economic criteria would be beneficial in the reimbursement process, but have not taken action in establishing such criteria (Greece).

Health economic evaluations are not likely to persuade doctors to prescribe one medicine in favour of another where clinical arguments have failed, and there are no financial implications for the doctor or the patient. If there are financial implications, this will help sway the prescriber who must, in turn, persuade the patient that the additional therapeutic benefits or improvement in the quality of life offered by the drug in question are worth the price premium. When patients decide between drugs suggested by doctors, they are balancing the clinical benefits, quality of life and cost to themselves. Health economic evaluations may well have a role if they are accessible to patients and can address doctors' and patients' concerns.

4. Regulation of demand

Pharmaceutical therapy prescribed by primary care doctors is generally recognised as a cost-effective method of providing healthcare in the majority of patients. Authorities are aware of the possibility that if the range of reimbursed treatments is too narrow, or the cost to the patient too high, there will be public health repercussions and cost implications as more patients seek admission to hospitals. **Table 3** summarises some key elements of demand-side policies in the member states.

4.1. Influencing the prescriber

Doctors prescribe medicines on behalf of their patients. In Europe, the primary criterion that applies in drug selection is therapeutic need, and the freedom to choose is jealously guarded. There are few restrictions as to which medicines may be prescribed, although not all medicines may be reimbursed. Usually, the length of prescription and sometimes the number of items allowed are regulated. Patients are not usually involved in the decision making, although in some countries this is becoming more frequent especially when alternative therapies involve significant financial implications for the patient, or when the doctor considers that the additional benefits obtained with the best drug do not outweigh its higher cost to the social health fund.

Three categories of measures influence prescribing (**Table 3**). The combination of two is common, and in some countries all three are used. The most fundamental category is the restriction of drugs that may be prescribed or those that will be reimbursed by the use of positive and negative lists. The second, more diffuse, category is that of issuing guidelines which are based primarily on therapeutic considerations; these guidelines influence what medications doctors prescribe and, in some countries, how prescriptions are written. The last category involves budgets that motivate doctors to take costs into consideration when selecting between alternative treatments.

Table 3
Prescribing, dispensing and consumption

Country	Positive list	Negative list	Budget	Guidelines/monitoring	Generic prescribing	Substitution	Incentives	Co-payment
Austria	Yes	No	No	Yes	No	No	No	Flat
Belgium	Yes	No	No	Yes	Potentially	In exceptional circumstances	No	%
Denmark	Yes	No	No	Yes	Yes	Yes		% + flat fee
Finland	Yes	No	No	Yes	Some	Yes	No	% + flat fee
France	Yes	No	Yes	Yes	Yes (gatekeepers)	Yes	Yes (gatekeepers)	%
Germany	No (but planned)	Yes	Yes	Yes	Yes	Yes	Yes	Flat fee
Greece	Yes	No	No	No	No	No	No	%
Ireland	Yes	No	Yes[1]	Yes	Yes	No	No	Deductible
Italy	Yes	No	Yes[2]	Yes	No	Yes	No	% + flat fee
Netherlands	Yes	No	No	Yes	Yes	Yes	Yes	Flat fee + Deductible
Portugal	Yes	No	No	Yes	No	No	No	%
Spain	Yes	Yes	No	Yes	Yes	No	No	% up to a max per item
Sweden	Yes	Yes	No	Yes	Yes	Some[3]	No	Deductible
UK	No	Yes	Yes	Yes	Yes	No	Yes	Flat

Source: compiled from national sources.
Note: [1] *For doctors contracted to the GMS.*
[2] *Pilot project in 30 ASLs starting in 1997.*
[3] *With doctor's approval for generics.*

where no data are given, this indicates that data are not applicable or available.

4.2. Positive and negative lists

By definition, all medicines require regulatory approval before they can be marketed. However, marketing approval is not synonymous with being covered by the social healthcare system. All member states operate restrictive lists (see **Table 3**). National reimbursement regulations are framed in an inclusive or exclusive mould. In countries where the inclusive system operates, drugs that receive marketing approval are, by default, reimbursed (of course that does not necessarily guarantee that they will be prescribed; e.g. in the UK); those excluded from reimbursement are said to be on the 'negative list'. In countries where the exclusive system operates, pharmaceutical companies have to apply for reimbursement status for their drugs; if granted, the drugs are placed on the 'positive list'.

The criteria through which pharmaceutical products are excluded from reimbursement (placed on the negative list), and the mechanism by which they are evaluated for reimbursement status (placed on the positive list), vary between countries. Some countries with positive lists are thought to delay the approval process for new drugs as a means of containment of pharmaceutical expenditure. Usually, therapeutic benefit is the most important consideration, although cost-effectiveness relative to products already reimbursed is growing in popularity, as was mentioned in section 3.5.

When a drug loses its reimbursement status, its prescription sales fall and often the pharmaceutical company attempts to have it re-classified as an OTC drug. Doctors often switch much of their prescribing to alternative, usually more powerful and more expensive medications that are reimbursed, especially for patients who are exempt from co-payment.

4.3. Prescribing guidelines, treatment protocols and rational prescribing

Physicians are encouraged in several ways to prescribe effective and (cost) efficient medicinal products (e.g. the Netherlands, UK). Prescribing guidelines and treatment protocols, with a focus on indications are published by competent authorities and medical associations/royal colleges of physicians. Independent sources of information on medicines is also distributed among general practitioners and pharmacists in bulletins (for instance the Bulletin of Medicines in the Netherlands or the Bandolier in the UK).

The aims of prescribing guidelines are to encourage doctors to prescribe rationally and consistently according to the medicine's indications and therapeutic needs of their patients. The main outcomes should be greater consistency in the drugs and length of treatment prescribed for each condition, and a reduction in the volume of drugs prescribed as redundant or duplicate ones are eliminated. Rational prescribing also means that the cheapest drugs are favoured among those that are medically interchangeable for a given condition. When guidelines are first applied, savings may be noticed. Thereafter, sales volumes will depend on the changing morbidity of the population and variations in the guidelines.

Best practice guidelines or protocols are usually issued in association with the medical establishment. They recommend how particular conditions should be treated and the drugs that should be prescribed, although in France guidelines operate through negative recommendations. Guidelines are available for a range of conditions in several countries. For serious conditions, the key recommended treatments are common across different countries. In a few countries, medical practice computer systems are in operation. These use therapeutic protocols that guide doctors towards selecting one of the recommended treatment options based on the diagnosis entered.

Monitoring of prescribing practices is increasing, both to assess how doctors apply prescribing guidelines and how their treatment costs compare to the average. Evidently, the results are more meaningful in systems where patients are registered with a single doctor who acts as a 'gatekeeper'. Information on doctors' spending by therapeutic class can be collated from the systems used to reimburse pharmacists. Comparisons can also be made to highlight any significant variations in treatment costs between individual doctors and the average for the region. As most prescriptions do not record the diagnosis, it is not possible to determine whether a patient was treated cost-effectively.

Peer reviews are the primary method of determining whether doctors adhere to prescribing guidelines and treat their patients cost-effectively. These also provide an opportunity for doctors to justify any spending above average. Practices to be reviewed are generally selected at random or on a rotating basis, except where there has been excessive spending. The introduction of patient smartcards and generalised use of medical practice computer systems will make it easier to determine the effectiveness of guidelines, and to carry out more

sophisticated analyses of whether and how individual doctors are performing. In some countries, such systems may be in breach of their very strong laws on privacy.

Doctors are sensitive about their freedom to prescribe. They are encouraged to avoid waste and to make decisions in accordance with the latest scientific consensus of best practice. Guidelines are in place primarily to inform and assist doctors in making better decisions. Hence, peer reviews are crucial.

4.4. Prescribing budgets

Doctors decide whether to treat a patient or refer that patient to a specialist or hospital. The range of conditions that can be treated in primary care is constantly increasing. However, budgets which only cover treatments in the surgery and prescription medicines may provide an incentive for doctors to refer their more 'costly' patients to specialists and hospitals. As doctors largely determine which types and what quantities of medicines are consumed, it may be surprising that so little emphasis has been placed on how prescribing can be influenced. This fact may be a reflection of doctors' political influence or an indication of the professional esteem in which they are held.

In some member states, doctors are allocated prescription budgets; in others, a practice budget will include prescription medicines. Prescription budgets are meant to encourage doctors to consider cost when selecting treatments, whilst allowing them the discretion of prescribing expensive treatments in individual cases. Managing a budget is much easier if it is set for an individual doctor or group practice, such as in the UK, rather than collectively for all doctors in a region, as in Germany. In most cases, budgets are not absolute and prescribing does not cease when their limits are reached. However, to make budgets effective, sanctions or rewards can be used. For example, in Germany, prior to 1997, penalties were rarely applied, despite numerous cases of overspending. In the UK, again prior to the December 1997 reform that established Primary Care Groups, doctors were rewarded when they spend less than their budget, by being allowed to use a proportion of the nominal saving to enhance their practice.

Ireland and Italy have been experimenting with budgets combined with incentives for a number of years now. In Ireland, doctors contracted to the GMS are allocated indicative drug budgets. The scheme started in July 1993, and entitles prescribers to retain up to 50% of any

savings. These savings can be used to improve services provided to patients or a specified aspect of the practice. The remainder are used by general practice units of each health board area to fund overall improvements in practice development. In Italy, local health authorities (ASL's) and doctors are starting to experiment with cost-containment projects in which doctors agree to curb their prescribing in return for a percentage of the savings due to the prescribing change. In 1997, about 30 ASLs in a number of regions signed agreements with the Finmg, one of the main bodies representing doctors. The projects vary from one area to another, but in most, the ASL sets a savings target for prescribing costs, and agrees jointly with doctors on a number of mechanisms for achieving this target. These include local therapeutic protocols, lists of cheaper equivalent products, and limited lists in certain therapeutic areas such as antihypertensives or antibiotics.

Unless doctors are able to monitor the cost of prescribing in relation to their budgets, and to forecast the likelihood of under- or overspending, there will be significant variations in the cost of treatment prescribed at different times in the budget cycle. Typically, patients presenting towards the end of a financial year may be prescribed less expensive treatments. Budgets provide an incentive for rational prescribing where the least expensive drug can be selected among those that are interchangeable. However, budgets can also lead to sub-optimal treatment and increase referral patterns; patients may be referred to specialists or hospitals if these costs are outside the prescriber's budget.

From a theoretical point of view, there should be a mechanism of assessing alternative forms of treatment and comparing them within a single budget. However, in practical terms, to include all levels of treatment within a doctor's budget would increase the complexity and cost of administration enormously, and would also potentially undermine the concept of solidarity amongst doctors.

4.5. Altering the system of paying physicians

Moving from a fee-for-service and freedom of access to any physician/specialist policy, towards a more restrictive gate-keeper paid on a capitation basis policy, has been another way of controlling the authorising behaviour of practising physicians. For instance, a significant step forward in the French health care reforms was made when the general practitioner union, MG-France, signed its contract with the national health insurance agency (CNAM). The

contract brought about significant changes in the delivery of health services in the ambulatory sector. At present, there is freedom of choice and patients can see any number of doctors as often as they want, whether GPs or specialists. Fees charged by specialists are usually higher than those of GPs, as are their prescribing levels. This is generally agreed to be a major contributor to France's high per capita drug consumption compared with other EC countries. In addition, GPs may not know which drugs a specialist has prescribed, and vice-versa, leaving the way open to drug interactions.

Under the agreement, GPs get a yearly allowance per registered patient (payment by capitation), and agree to ensure that 15% of the value of their prescriptions is for cheaper products, including 5% of generics. GPs also agree to take part in training programmes, play a bigger role in disease prevention, respect prescribing and other guidelines, and transmit treatment forms to the insurers electronically. They will have to ensure that their spending is in line with the annual health care insurance spending target (ONDAM). The contract is part of a wider drive by the government to have more control over how doctors operate; its signing came after protracted bargaining between GPs and insurers. The essence of the scheme is that patients can register with a "reference" GP, whom they will consult initially for their medical care. In return for registering with a GP, a patient will only have to pay FFr33 of the standard fee of FFr110. Registration with a GP will be voluntary, and patients can change GP or opt out at any time. They can also consult another doctor or specialist but then they will not benefit from the pre-payment exemption. Doctors will also receive an annual payment per patient, which had been set at FFr 150 for 1998.

4.6. Pharmacy dispensing

EU directives specify that a qualified pharmacist must be present when prescription medicines are dispensed, and that dispensing may only be through licensed pharmacies. National authorities have to decide what other products pharmacists may sell, who else may sell prescription medicines, how pharmacists' remuneration is set, and what pharmacists may dispense on the basis of a prescription. The degree of latitude that pharmacists have in what they can dispense depends on how prescriptions are written and on the right of substitution. When therapeutic substitution or substitution of similar drugs is permitted, the right of substitution may include a range of options that extend beyond those outlined in the International Non-proprietary Name (INN) designation.

Most prescriptions in Europe are written using a brand name. Some also have the name of the supplier. Only in a few cases are prescriptions written using the INN designation. Doctors only prescribe using the INN designation of a drug if trained to do so. The effectiveness of training is limited by the pressure of pharmaceutical promotion and the greater ease with which some brand names can be written and remembered. In some countries, computer software used by doctors prints the prescription using the INN designation of the drug(s) selected, unless overwritten by the doctor.

Generally, pharmacists must dispense exactly what is prescribed. In most European countries, substitution is not allowed except in an emergency or other exceptional circumstances, and even then the prescribing doctor's agreement may be required. When substitution is allowed, doctors almost always need to mark their consent (tick-in), rather than substitution being allowed unless the doctor forbids it (tick-out). The pharmacist then decides which drug to dispense. In Denmark, the patient must be consulted and agree to the substitution. No country gives doctors a direct incentive to allow pharmacists to substitute. Where substitution is allowed, pharmacists are not penalised financially for substituting a cheaper drug. In a few cases, a financial incentive is offered – usually a share in the price difference between the cost of the product prescribed and of that dispensed.

4.7. Does the distribution chain influence demand?

EU directives specify the conditions under which a pharmaceutical wholesaler may operate and impose public service requirements. National authorities regulate the distribution margins. In some cases, both the wholesale and retail margins are specified, while in others the overall distribution margin is specified. Regressive margins have been introduced in a number of countries, especially for pharmacists, to reduce the disincentive to dispense cheaper medicines. Discounts from manufacturer to wholesaler and on to the pharmacist are legal in most member states. These are largely determined by commercial considerations, but there may be limitations. In Belgium, some pharmacists offer discounts to patients.

In all EU countries, the wholesalers' gross income is the difference between their selling and buying prices; this is funded mainly by national social health funds. Authorities have no incentive in allowing wholesalers a greater margin than they need. This merely adds to the

costs they must reimburse; wholesalers have very limited influence on the choice or volume of drugs prescribed, and none on their price.

4.8. Remuneration of pharmacists

Healthcare authorities determine what pharmacists may dispense when presented with a prescription and how pharmacists' remuneration is set. In most member states, the bulk of pharmacists' income is derived from their margins (progressive, flat, or digressive) on dispensed prescription medicines, although pharmacists may typically receive dispensing fees and discounts by wholesalers or pharmaceutical companies. Whatever the system, a pharmacist's income is largely covered through social health funds.

Authorities need to strike a balance between their desire to contain costs by reducing the distribution margins, and ensuring that these are sufficient to fulfil their objectives in public service policy. For instance, in the Netherlands, a part of the pharmacist 's income is formed by discounts given by the producers or wholesalers. A clawback of 6.82% to a maximum of F15.00 is in operation to account for the difference between official and real selling prices. The clawback is a reflection of the government's disapproval of such differences and is based on an inquiry into the level of discounts received by pharmacists. The compensation for dispensing costs in the form of a yearly fixed tariff for each prescription is the result of negotiations between the Health Care Tariff Board, pharmacists and insurance companies (the tariff for 2000 was set at F12.55).

In some cases, pharmacists can determine, or at least influence, which drug is dispensed through increased substitution rights (see **Table 3**). In such cases, they may well become influenced by the difference in income from alternatives. In order to favour particular medicines, pharmacists may receive incentives from authorities, pharmaceutical companies or wholesalers.

4.9. Generics and generic policies as part of the demand-side

The size of the generic market in different member states varies immensely. This can be seen in **Table 4** which shows the size of generic markets in different countries in 1997 by value. In

terms of volume, the generic market usually occupies a larger percentage of the pharmaceutical market.

The variation in market size is largely an effect of differential policies on generics followed by the different member states. In some member states, generics are promoted and are seen as a tool to contain rising pharmaceutical costs (UK, Germany, the Netherlands, Denmark). In others, where prices are low, generic products are not actively promoted by health insurance organisations (Spain, Greece, Italy, France). There is, nevertheless, a shift in national policies in some of these countries to promote generic prescribing as part of overall health care reforms, whereby physicians who sign up to an agreement with social insurance are required to prescribe cheaper medicines, a proportion of which must be generics (e.g. France).

Doctors are also urged to use the generic name instead of brand names. Furthermore, the use of electronic prescription systems is strongly promoted in some countries, for instance, the Netherlands and Denmark. In Denmark, pharmacies are obliged to report each sale of a medicinal product to a central database electronically. For each sale of a medicinal product the pharmacies are obliged to report the specific identification number of the product sold. For prescription only products the pharmacy must report the specific number of the prescribing doctor and the number of the person who the product is prescribed for.

The issue of generic markets and generic competition is fairly complicated as it requires integrated action by policy makers on different types of agents, namely doctors and pharmacists, and is associated with the provision or not of incentives to either of these agents. Prescribing physicians raise ethical questions if substitution rights are awarded to pharmacists, and the latter will not have an incentive to substitute, unless their fee structure encourages them to do so.

Table 4
Generic markets in EU countries

Country	Pharmacy market (%)	Value (US$ million)
Austria	5-6%	88
Belgium	6%	360
Denmark	22-40%	197-359
Finland	Na	Na
France	3-4%	365-545
Germany	41.3%	4600
Greece	Na	Na
Ireland	Na	Na
Italy	1%	88
Netherlands	12.2%[1]	276
Norway	Na	Na
Portugal	~1%[2]	8.8
Spain	~1%[2]	51
Sweden	39%	1061
Switzerland	3%	84
UK	22%	1435

Notes: [1]1996; [2]Share is greater for copy products (20% in Portugal and 30% in Spain.
Source: Author's compilation from national source.

5. Demand side

5.1. Role of the patient

In most EU countries, the patient's role in contributing towards the total cost of medicines is very limited. Patients are intimately concerned with the outcome of the prescribed therapy, and have to contribute towards the cost of it. Yet, during consultations they defer to their doctor, rarely asking about alternative treatments or whether the higher cost of some drugs is warranted by greater therapeutic benefits. At the pharmacy, they are dispensed the medication prescribed, but have, at best, a limited say in its selection, even when substitution is allowed. Patients are not 'consumers' in the sense that applies in most markets.

The structure of some pricing and reimbursement systems, notably those where a patient's co-payment is fixed or nil irrespective of what is prescribed, gives the patient no incentive to become involved. Patients may become more involved as their contribution increases. In countries with reference prices, if doctors prescribe a drug above the reference price, they are obliged to advise patients that an alternative, cheaper product exists. A reluctance to raise

financial issues during a consultation has meant that products priced above the reference price lose the bulk of their market share.

Patients develop a familiarity with the physical characteristics of their medication, and therefore need reassurance from the pharmacist if the drug dispensed seems to differ from that to which they are used. Patients may complain when they are dispensed direct source drugs, because they had become accustomed to a different parallel trade product; however, this type of complaint is difficult to quantify. In any case, patients are only rarely allowed to influence which product is dispensed to them.

5.2. Patient co-payments

Patient co-payments are levied according to four mechanisms:

(a) a fixed fee (per item, per prescription, or according to pack size);
(b) a percentage of the value of the prescribed drug;
(c) a deductible up to a certain limit; and
(d) a combination of the above, usually a fixed fee or a deductible plus a percentage of the value of the drug.

Table 5 provides a summary of patient co-payment measures in all EU countries.

In addition to statutory patient co-payments, there are considerable exemptions. Thus, serious or chronic conditions, more effective drugs, disadvantaged social groups or patients in certain age groups attract a greater percentage subsidy, or are altogether exempt from paying any co-payment.

In a capped system, increasing the level of patient co-payments would be an obvious way of reducing the cost of healthcare and raising finance. However, despite efforts made in the past few years with the use of information systems and technology, the relatively low level of communication between prescribers, dispensers and patients means that such a strategy may have only a limited effect on the volume or choice of drugs dispensed, and would merely transfer the burden of funding to patients. In addition, exemptions mean that the role of co-payments in containing overall costs and reducing frivolous use is at best limited. For

instance, approximately 80% of the total number of prescriptions in the UK are co-payment free.

Table 5
Patient co-payments in EU countries, end-2000

Country	Type of co-payment
Austria (1999)	Flat fee of ATS43 per item and an additional ATS50 for each treatment
Belgium	Percentage up to a maximum of medicines' price for certain categories
Denmark	a) No reimbursement for persons over 18 years if expenditure on reimbursable pharmaceuticals does not exceed 500 DKK within a year.; If expenditure >500 DKK but <1200 DKK within a year, 50% of the expenditure between 500 and 1200 DKK is reimbursed; If yearly expenditure is >1200 and <2800 DKK, 75% of the amount exceeding 1200 DKK will be reimbursed; If expenditure >2800 DKK, the amount exceeding 2800 will be reimbursed at the rate of 85%. Persons under 18 years of age are not covered by the lower limit of 500 DKK. For children and young people the reimbursement is 50% of expenditures up to 500 DKK. In the case of expenditures over 500 DKK, the reimbursement rate is similar to the reimbursement rate for persons over 18. In the case of persons with a large, continued and professionally documented need for pharmaceuticals, there is an expenditure ceiling of 3600 DKK per person per year. b) A dispensing fee applies to POMs; it is DKK 6.15 exclusive of VAT per item prescribed
Finland	a) Flat fee per prescription b) There are three categories of reimbursement: basic refund of 50% of the price in excess of FIM 50 per purchase and, in the case of certain severe, long-term diseases, reimbursements of either 75% or 100% of the price in excess of FIM 25 per purchase. The diseases conferring a right to these two higher rates of reimbursement as well as the medicines are specified by the Council of State. Its decision is based on such factors as the nature of the illness, the necessity and economy of the drug and its therapeutic value in use and as demonstrated by research. Special reimbursement may be paid for a drug only after it has been within the scope of basic reimbursements for at least two years. Exceptions to this two-year requirement are possible if there are special reasons. A total of 35 diseases are currently included on the 100% reimbursement list (e.g. diabetes, severe psychotic disorders, hypothyroidism, glaucoma, epilepsy, cancer), while 9 diseases in all are on the 75% reimbursement list (including hypertension, coronary hearth disease, asthma). To qualify for either of these two higher reimbursement rates, patients must present a medical certificate proving the severity of the illness and necessity of continuing drug treatment. Additional refunds are paid to patients whose post-reimbursement drug expenditure exceeds a fixed annual amount (FIM 3283 in 1999). The extra reimbursement is paid if it exceeds FIM 100 in one calendar year. The extra reimbursement may be completely or in part withheld if the insured person has acted fraudulently when applying for reimbursement.
France	Percentage: 0%, 35%, 65% depending on type of condition
Germany	Flat fee per pack, depending on size: DM8, DM9, DM10
Greece	Percentage: 0%, 10% 25%
Ireland	• GMS: Individuals covered by the GMS must register with a doctor and do not pay for consultations. All authorised reimbursable medicines prescribed by their physician are free of charge. • DPS: This scheme covers non-GMS patients. This scheme replaced the DRS and DCSS schemes in July 1999. Under this Scheme , no individual or family has to pay more than IR£42.00 in a calendar month for approved drugs, medicines or appliances. Such patients pay their pharmacist for their expenditure up to IR£42.00 per month. Costs above this figure are reclaimed by the pharmacists from the State. • LTI: no prescription charge for 15 named chronic illnesses (named in 1975 and never updated since – HIV/AIDS not included) • A High-Tech Medicines Scheme also exists and is available to all categories of patients and schemes. Category Two patients, however, must pay the first IR£42.00 cost per month. These items include medicines such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or growth hormones. • Patients may claim tax relief on their own spending on prescription medicines if this is more than IR£100.00 for an individual or IR£200.00 for a family. The cost of medicines

	prescribed to non-GMS patients accounts for about 22% of total pharmaceutical expenditure that is reimbursed by the State. There is not any information available on private expenditure as private dispensing that costs below £42.00 per month per family or per person is not reimbursable.
Italy	• 1st item ITL3000; for larger amount of products, the total fee is ITL6000 • 100% reimbursement for drugs with documented efficacy for severe and chronic illness (Class A) and for hospital-only drugs requiring specialist supervision (Class H) • 50% reimbursement for other drugs of documented efficacy [of 'therapeutic relevance'] and drugs not listed in category A due to a high cost–benefit ratio • 0% reimbursement for drugs without proven efficacy and drugs with proven efficacy for minor diseases [drugs not assigned to A or B]
Netherlands	No official co-payment policy other than patient paying the difference between price of medicine and the price limit (reference price)
Portugal	• Percentage: 0%, 20%, 40% 70%, and 100% • For pensioners, an additional 15% is reimbursed of the non-fully reimbursed categories, i.e. 35%, 55% and 85% • Reimbursement rates for generics are 30%, 50%, 80%, and 100%
Spain	Percentage: 0%, 10% (up to a max of PTE439 per item, for drugs indicated for chronic conditions) and 40% (pharmaceuticals in general); (different co-payments apply for civil servant who opt-out of Insalud)
Sweden	• 0 per cent of the amount when the total cost falls below SEK 900 • 50 per cent of the amount above SEK 900 but less than SEK 1700 • 75 per cent of the amount above SEK 1700 but less than SEK 3300 • 90 per cent of the amount above SEK 3300 but less than SEK 4300 • 100 per cent of the total cost in excess of SEK 4300 • The different reimbursement levels are reached when out of pocket spending exceed 900, 1300, 1700 and 1800 SEK, respectively. Thus 1800 SEK is the maximum patient spending in a year. Any additional prescribed medicinal products are free-of-charge to the patient. However, patient spending can exceed 1800 SEK if the patient is prescribed a product that is within the reference pricing system and has a price above the reference price. In such situations the patient has to pay the difference between these two prices every time the drug is dispensed. Costs for all children under 18 years of age within a family unit may be added together. Liability for other health service costs in a 12-month period is limited to SEK 900. • No patient group is exempt from co-payment. The only exemption from co-payment is for insulin that is fully reimbursed.
UK	Flat rate at UK£6.10 per item; exemptions apply for pregnant women, children, the elderly and patients suffering from defined conditions

Source: Author's compilations from national sources.

5.3. Taxation

The rate of VAT on pharmaceutical products varies. Usually OTC products attract the standard VAT rate (one exception, is Greece, where the VAT rate both for POMs and OTCs is 8%), whereas prescription-only medicines (POMs) usually attract a lower VAT rate (e.g. the Netherlands it is 6%, in France it is 4%; in Finland it is 8%), although exceptions exist (e.g. Denmark applies 25%; Ireland applies 21%). In Ireland, prescription drugs administered orally are exempt whilst all other types are taxed. In the UK, prescription-only medicines are VAT exempt.

Pharmacists are paid or reimbursed the public price of drugs, which includes VAT. The greatest part of total pharmaceutical expenditure is covered by social health insurance funds. Thus, taxes on reimbursed drugs increase their costs. In recognition of this, many countries levy VAT at a reduced rate on prescription drugs.

Taxes on publicly funded goods and services are a transfer of funds from one public body to the central treasury. Deficits in the healthcare budget can be reduced by lowering the VAT rate. Additional taxes unique to the pharmaceutical industry include taxes on advertising expenditure or those occasionally imposed on pharmaceutical sales of reimbursable products as part of restrictive cost-containment policies. An example of the latter policy is Belgium: in August 1997, a tax (3%) was introduced on reimbursed sales and increased it to 4% for 1999. The publicity surrounding the introduction of taxes may increase prescribers' sensitivity to the importance of drug costs, but is unlikely to sway their choice between drugs.

6. Other policy segments

6.1. Parallel trade

Parallel traded products are identical medicines sold in another market. There can be no difference between their medical characteristics, although their SPC, indications, brand name and packaging may vary. As labelling and inserts are in the language of the country of origin, they have to be substituted. A single European brand name is now required for new medicines

authorised through the centralised procedure and, increasingly, multilingual inserts are being used.

European law does not allow discrimination on the grounds of country of origin within the EC, hence parallel trade is legal in all EEA countries. However, this is not legal in Switzerland. In all European countries, parallel trade of patented medicines from outside the EC may be prevented. In countries where prices are set, they are generally set low and, in consequence, tend to be the source of parallel exports. In countries where prices are higher, encouragement to parallel imports is provided as a way of promoting price competition and hence efficiency. The subsidy paid to pharmacists is usually less than that for the direct source product, which saves public funds; however, pharmacists are also allowed to gain more from parallel imports. As patients' co-payments become linked to the actual price of the drug dispensed, patients will benefit more from parallel trade. Parallel trade will only continue as long as price differences between EC member states provide a commercial opportunity for importers.

6.2. Hospital products

Hospital products typically account for 15% of the total pharmaceutical market in European countries. In most countries, hospitals are allocated a global budget within which they set their own budget for medicines. In most countries, hospitals freely negotiate the purchase price of the medicines they dispense.

Medication is considered an integral part of hospital treatment which is typically free. Reimbursement of individual drugs does not arise. When drugs are bought directly, prices are negotiated and this usually leads to substantial discounts. Even in countries where hospital prices are set by the authorities, price discounting to hospitals is commonplace, although in most cases it is unofficial. By contrast, in Italy, the official government policy is that prices of hospital drugs are determined in practically the same way as primary care drugs. Drugs prescribed and consumed within hospitals are subject to a statutory minimum discount of 50% of the public price. Of course, manufacturers can give additional discounts of 10-15%, especially in tenders.

The alternative method of purchasing is by tender. The European Directive on Public Procurement, which applies to most hospitals, is largely ignored by the healthcare sector in most member states.

In all countries, hospitals treat ambulatory patients for certain conditions, but there are different ways of delivering treatment:

- hospital treatment is compulsory in the absence of treatment protocols and therapy involves innovative, costly drugs;
- the hospital must initiate treatment;
- hospital treatment is the patient's choice.

In the first two examples, the role of hospitals is to regulate supply and prevent waste through over-prescribing.

6.3. The role of information systems

The role of information systems has increased considerably in the past few years. A number of European countries are increasingly monitoring prescribing and prices through integrated networks that are being put in operation. Such networks facilitate the flow of information between providers (in particular, prescribers and hospitals), dispensers, payers and patients, and allow close monitoring of what is consumed, on what patient and for what condition.

A few examples of segmented policies in individual European countries, include:

- Establishment of Pharmanet in Belgium, a census collection of drug utilisation data on all the prescriptions for reimbursed medicines in ambulatory care covering the entire territory of Belgium.

- Introduction of the '*Carte Vitale*' in France, a smartcard which, among others, allows the electronic transmission of prescribing data from pharmacies to insurers. Similar schemes operate in Germany (Krankenversicherten Karte), and there is a smart card project in Catalunya.

- Expansion of PRODIGY in the UK, which provides general practitioners with a course of action in prescribing *vis-à-vis* a given condition.

- An Information Technology (IT) network that monitors tender prices in 150 hospitals in Italy, operated by the Italian society of hospital pharmacists.

6.4. Over-The-Counter (OTC) medicines

OTC medicines are safe and are sold to treat minor, self-limiting illnesses and conditions. They are not important to the health of the patient, although they may improve well-being. The state rarely reimburses these drugs, even when they are prescribed by a doctor; hence, there is no reason to regulate their prices or include non-reimbursed ones within the scope of the pricing and reimbursement system. In Sweden, for example, OTCs can be reimbursed when there are deemed necessary for the treatment of lingering illnesses i.e. when continuous treatment for at least a year or when repeated treatments of at least three months duration are needed. In this case products like antacids, bulk laxatives, vitamins, skin moisteners, expectorants can be reimbursed provided that a reimbursement price has been granted.

The pricing of non-prescription medicines is free throughout the EU, with the exception of Belgium and Greece. As with pricing, there is no uniformity regarding the sale of OTC products. In some countries, these products are available in pharmacies, general stores and/or authorised drugstores, whereas in others they are available only in pharmacies (**Table 6**).

Healthcare authorities see the moving of drugs from prescription to OTC status as a way of limiting public expenditure on drugs which may also reduce the number of medical consultations. This varies considerably among countries, depending on differences in attitude towards the level of patient responsibility in the delivery of medical treatment. The public expenditure consequences of switching the status of a drug from prescription to OTC are limited where a prescribed drug is still reimbursed or patients are exempt from any co-payment.

Table 6
Availability of OTC products in EU countries, 2000

Countries	Type of outlet
Austria	Available from pharmacies and general-sale stores
Denmark	
Finland	
Germany	
Ireland	
UK	
The Netherlands	Available from pharmacies and authorised druggists
Belgium	Available from pharmacies only
France	
Greece	
Italy	
Luxembourg	
Portugal	
Spain	
Sweden	

Source: Author's compilations from national sources.