



on demand

Different combinations of measures are in place across Europe to control prescribing

Governments recognise that pharmaceuticals are a cost-effective method of providing treatment to most patients. If the range of reimbursed treatments is too narrow or the cost to the patient too high, there will be public health repercussions and an increase in costly hospital admissions. Demand for pharmaceuticals is regulated by efforts to influence prescribers and by co-payments and these affect both doctors' and patients' willingness to use a particular therapy.

INFLUENCING THE PRESCRIBER

In Europe, therapeutic need is the primary criterion used by doctors in selecting drugs. There are a few restrictions on which medicines may be prescribed, although not all medicines may be reimbursed. Usually, countries regulate the length of prescription, the product and sometimes the number of items allowed. Traditionally, patients were not involved in the decision-making, although in some countries this is changing, especially when alternative therapies may place a significant financial burden on the patient.

There are three categories of measures that may influence prescribing:

- 1) The use of positive and negative lists to specify which drugs may be prescribed or reimbursed
- 2) Guidelines to influence which drugs doctors prescribe - and, in some countries, how prescriptions are written - based on therapeutic and economic considerations
- 3) Budgets that oblige doctors to take costs and volumes into consideration when selecting particular treatments.

Different countries use different combinations of measures to control the prescribing, dispensing and consumption of pharmaceuticals. Approaches used in key European markets are summarised below.

AUSTRIA

- Positive and negative list
- No budget imposed
- Has guidelines/monitoring
- Generic prescribing is actively promoted
- Substitution is not allowed
- No incentives
- Co-payment - flat fee per prescription item, currently €4.25 for brand-name drugs and €2.80 for generics.

FINLAND

- Positive and negative list
- No budget imposed, but doctors receive capitated (set fee per patient) payments
- Has guidelines/monitoring
- Generic prescribing allowed
- Substitution is allowed, but doctor can forbid it
- Partially capitated doctor budgets
- Co-payment - deductible with additional 50, 25 or 0 per cent co-insurance up to an annual maximum ceiling.

FRANCE

- Positive list, but no negative list
- Budgets with ceiling for drug spend involving paybacks, target budgets for GPs
- Guidelines/monitoring - RMO system/non-compliance may carry penalties for GPs
- Generic prescribing encouraged, particularly among GPs who must prescribe at least 15 per cent generics per year
- Substitution extended, but doctors can override this
- Incentives through doctors' 'gate-keeping' role
- Co-payment co-insurance (0/35/65 per cent).

GERMANY

- No positive list, but negative list
- Budgets - target volumes for individual practices negotiated at regional level
- Guidelines/monitoring - IQWiG (an independent scientific assessor of therapies) plays a major role in issuing guidance
- Generic prescribing is indirectly encouraged through reference pricing classes
- Substitution is mandatory unless the doctor opposes it
- Incentives - target volumes for individual practices
- Co-payment - 10 per cent with a minimum of €5 and a maximum of €10 per pack.

ITALY

- No positive list, but a negative list
- Budgets are set by ASLs (local health authorities) at regional level and consequently there are regional variations
- Guidelines/monitoring - there is a National Guidelines Plan
- There is some generic prescribing through reference pricing
- There are limited substitution rights
- Incentives are offered through doctor budget systems at regional level
- Co-payments - patients pay the excess over reference price and there are regional co-payment schemes.

NORWAY

- Positive list, no negative list
- Budgets at central level
- Guidelines/monitoring defined by Board of Health
- Generic prescribing is allowed but limited
- Substitution allowed with the doctor's consent
- No incentives but statutory prescribing requirements
- Co-payment on a percentage of price up to a maximum of 70 per cent.

SPAIN

- Positive and negative lists
- There are drug budgets subject to fixed growth rates and paybacks
- Guidelines/monitoring have limited impact
- Generic prescribing encouraged and rising (with regional variations); doctors may only prescribe certain products generically
- Substitution allowed with doctor's agreement; also part of reference price
- Some incentives with doctors rewarded for spending below budget
- Co-payment at 0/10/40 per cent and co-insurance up to a maximum per item.

SWEDEN

- Positive and negative list
- Some counties use prescribing budgets
- Guidelines/monitoring
- Doctors are required to inform patients

- of generic alternatives when available
- Substitution allowed unless doctor overrides this
 - Some incentives; capitation schemes
 - Co-payment - deductible and tiered co-insurance up to a maximum per year.

UK

- No positive list, but health authorities and primary care trusts (PCTs) may have their own formulary. Has negative list
- PCTs in the UK are given a global budget to cater for the needs of their patients; specific budgets are given for particular indications such as hepatitis C vaccine
- Guidelines/monitoring
- Generic prescribing - doctors prescribe by the international non-proprietary name (INN)
- Substitution only allowed if doctor has prescribed by INN generic substitution within Pharmaceutical Price Regulation Scheme (PPRS) 2009
- Incentives - Yes; PCT budgets encourage generic prescribing
- Co-payment - £7.20 flat fee per prescription item (from 1 April 2009); exemptions apply.

CHANGING ROLE OF PATIENTS

In most European countries, the patient's role is very limited. Patients are concerned with the outcome of their prescribed therapies and must contribute to covering the cost. Yet, during consultations, they defer to their doctors, rarely asking about alternative treatments or questioning whether the higher cost of some drugs is warranted by greater therapeutic benefits.

At the pharmacy, patients receive their prescribed medications, but have, at best, a limited say in the selection process, even when substitution is allowed. Thus patients are not consumers in the same sense they are in other markets.

There is some circumstantial evidence, however, that patients do become more involved in their treatment selections when they are faced with differing co-payments levels. Their involvement is also likely to increase, as they become better informed through their own sources, such as the internet. There are at least two major obstacles to overcome, however, if patients are to become actively involved as effective demand-side regulators.

First, the structure of some pricing and reimbursement systems - notably those where co-payments are fixed or are set at nothing regardless of what the doctor prescribes - gives the patient little incentive to become involved. Patients may well become more engaged in prescribing decisions as their financial contribution increases.

In countries with reference pricing, if doctors prescribe a drug above the reference price, they must advise patients that an alternative,

cheaper product exists. They may even be obliged to prescribe the less expensive option. A reluctance to raise financial issues during consultations has meant that products priced above the reference price lose the bulk of their market share. Recent suggestions in the UK for top-up payments may open the possibility of patients playing a more active role in treatment decisions.

Patients develop a familiarity with the physical characteristics of their medications. Therefore, they need reassurance from their pharmacists if the drug dispensed seems to look different from what they are used to taking.

MARKET ACCESS

Patients may gain greater influence over market access. Payers and market access agencies are likely to shift more cost-control measures to patients by introducing new and higher co-payments. Potentially, patients may gain the option to stay with lower-cost alternative therapies or 'buy-in' to more expensive treatments. This ability to choose may encourage patients to become better informed healthcare consumers and more active players in demand-side regulation.

New schemes to regulate demand might include a new responsibility that payers place on the industry for making treatments available, if they are launched within a scheme that has direct impact on the use of health service resources.

One guiding example is that of Pfizer and Florida Medicaid. Together, they created a risk arrangement in which Pfizer guaranteed Medicaid savings. Pfizer promised to achieve savings of \$33m through a disease management programme in return for the inclusion of all of its products on a new restrictive formulary.

Pfizer focused on disease management, including hiring nurses, for high users who have chronic conditions such as diabetes, asthma or heart disease. The company is taking the complete financial risk that the disease management programme will contribute to reduced healthcare expenditures.

FUTURE PHARMA INVOLVEMENT

The next step in supply- and demand-side controls might include the delegation of responsibilities for health service delivery to the industry. These responsibilities could include providing treatment packages, increasingly financed by private sources on the basis of choice, and health system infrastructure investments provided by traditional players, such as public payers.

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