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Market Access in European Union Countries: Pricing and Reimbursement of New Healthcare Technologies

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A major aim of health policy in most EU member countries is to regulate and control the price of, access to and the use of new and expensive medical technology. Despite this common objective, there are great differences in the means used to achieve it, because healthcare, pricing and reimbursement systems as well as domestic industry and economic status and priorities are different across countries.

This article classifies and presents the common practices and mechanisms employed in different member states to determine access to and use of new pharmaceutical and medical technology. Practices either aim at the supply side or the demand side of the medical market.

Supply-Side Practices

A commonly used measure is price control or regulation of medical technology. Prices may be set on the basis of production costs, the prices in other countries, of similar products within the country, the medical and economic benefits and the cost effectiveness of therapies under consideration. Another mechanism involves the direct control of healthcare expenditure where discounts, freezes, cuts and rebates are imposed on manufacturers. Often, agreements about price, volume and risk sharing are in place, where manufacturers pay back the state in cases where consumption is greater than a certain predefined level, or in cases where medical and economic benefits promised are not realised in real life. Other mechanisms involve the regulation and control of industry profit rates and tax obligations. Another group of measures involves the reimbursement policies applied. Often positive or negative lists, reference price systems and economic evaluations are employed to decide how to reimburse new pharmaceutical and medical technologies (see table 1).

Demand Side Measures

Demand side measures focus mainly on changing the behaviour of the parties determining the demand for healthcare technology including physicians, pharmacists and patients. Physician measures include the implementation of practice and prescription guidelines, the implementation of education, the provision of information, the monitoring of prescribing patterns, prescription quotas, implementation of budgets and financial incentives, all of which influence their choices and market behaviour. In terms of patient measures the main one includes cost sharing, either in the form of fixed or variable co-payments, co-insurance or deductibles. Lately, information and educational campaigns aim to guide and define patient behaviour. In terms of pharmacists, various incentives, schemes and discounts are used to promote substitution of expensive with cheaper drugs and technologies (see table 2).

Direct Price Control

Price control is the easiest and oldest measure aiming to limit private and public pharmaceutical and medical technology expenditure to ensure the affordability of patient treatment and the financial sustainability of the healthcare system. Price control is common for instance in countries such as Austria, Finland, France, Italy, Ireland, Latvia, Lithuania, Poland, Slovenia and Spain. Evidence suggests that where prices are not controlled, they may be higher compared to countries where there is more regulation.

Cost Sharing

Cost sharing is a commonly used approach to control access and expenditure even though it disproportionately affects low-income individuals. A form of splitting the cost of healthcare services in order to reduce public expenditure on the service, it aims to generate income or reduce expenditure for the third-party payer, to reduce administrative costs, to make users cost-conscious, to promote competition, to reduce abuse and inefficiency and to facilitate access where needed. Countries where this approach is used include Austria, Italy, UK, Belgium, France, Greece, Estonia, Finland, Latvia, Lithuania, Poland, Portugal, Slovakia, Slovenia, Spain, Cyprus, Germany, Norway, Denmark, Sweden and Ireland.

Reference Pricing

International price comparisons and reference pricing represent a new trend in EU countries. Price comparisons are used to set the price of the product in one country on the basis of other countries selected for this purpose. Reference pricing represents a mechanism for establishing a maximum level of third-party financing/ reimbursement for a group of products classified somehow with a therapeutically equivalent class.

A price above the reference price is borne by the consumer to generate and reinforce price competition and to reduce cost especially when generic products become available, while maintaining standard quality. To be implemented, products are first clus manufacturers tered in groups and then a formula is used to set the reference price.

Risk-Sharing Mechanisms

Payback and risk-sharing mechanisms control access and expenditures on new therapies. In this context, manufacturers are asked to return a certain part of their revenue to a purchaser or the state authority if sales exceed a previously determined maximum amount or in cases where medical benefits have not been realised in real life either at individual or at population level. It is used in countries like the UK, Spain, France and Norway to reduce deviations from a prospectively set budget and to guarantee that a fair relationship will be attained between expenditure and benefit and to reduce the risk for the payer.

Prescribing Incentives

Prescribing incentives involve the application of various explicit or implicit measures, which guide the choice and use of medical and pharmaceutical technology. The objectives tend to vary depending on the aims and priorities of those who establish them. Incentives are mainly aimed at maximising effectiveness and minimising risk and cost.

Use of Generic Equivalents

Generic use promotion is a priority in many countries. Measures include fast track and cheaper registration of generics, encouraged or mandatory prescribing by active pharmaceutical ingredient, incentives for substitution in favour of generics by physicians and pharmacists and consumers, selective financing of generics in positive lists, reference price systems, procurement by tendering, and favourable pricing policies. Obviously the main purpose of generic policies is to increase competition and access and to contain expenditure, without compromising quality and therapeutic equivalence.

Fast-track registration and/or lower registration fees are used in Austria, Finland, France, Hungary, Italy, the Netherlands, Portugal, Slovakia, and Sweden. Financial or other motives for doctors are provided in the UK, the Netherlands, Portugal, Romania, Italy and price control of generics is used in Austria, Cyprus, Finland, France, Hungary, Ireland, Italy, Portugal, and Slovenia. Generic substitution by the pharmacist is encouraged or imposed in Cyprus, Denmark, Italy, Sweden, Finland, France, Hungary, Malta, Romania Slovakia, Slovenia and the Netherlands.

Economic Evaluation

Finally, economic evaluation or otherwise cost-effectiveness analysis is also used in many countries either to set the price or the reimbursement level or to determine the prescription pattern of new technologies. This approach compares the extra cost and benefit of new products in relation to existing ones, to find out whether a fair premium is asked for the innovation. Nonetheless, it needs to be said that it raises issues as to what the threshold of fairness may be from one country to another.

Conclusions

EU countries are all trying to promote greater and more equitable access to new medical and pharmaceutical therapies, but they also share common concerns about limiting public expenditure. The mix of measures employed is determined by their economic and industry status and by the characteristics of their health policy and health care system.

In this context direct price regulation, international price comparisons, economic evaluation, cost sharing, reference pricing, generic use, rational prescription and pay back policies are used in different ways to achieve the above often conflicting objectives.

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