

# CHAPTER 2

## Pharmaceutical policies

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### THE GENERIC MEDICINES MARKET IN EUROPE



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The European experience demonstrates that supply-side policies need to be supplemented by demand-side policies, with incentives for physicians, pharmacists and patients to use generic medicines. This would lead to a sustainable generic medicines market and substantial healthcare savings.

**W**hen the 20-year patent on an originator medicine expires in the European Union, less expensive versions of the medicine can enter the market.

In the case of a conventional (a small, chemical-ly derived molecule) originator medicine, patent expiry may be accompanied by the introduction of generic medicines. In addition to conventional medicines, pharmaceutical companies are marketing biopharmaceuticals, i.e. large and complex molecules derived from living organisms using biotechnology. When the patent on a biopharmaceutical expires, biosimilar medicines can enter the market. Generic and biosimilar medicines are cheaper than originator medicines due to lower costs of research and development. In this way, generic/biosimilar medicines support the sustainability of healthcare provision and contribute to controlling pharmaceutical expenditure.

Pharmacoeconomic aspects of generic medicines are discussed by focusing on:

- the economic analysis of generic medicines policy
- the economic evaluation of generic medicines
- the savings from generic medicines use.

#### ECONOMIC ANALYSIS OF GENERIC MEDICINES POLICY

A comparative study examined the impact of generic medicines policies on the development of generic medicines markets in Europe [1]. The experience of European countries shows that there is no single approach towards developing a generic medicines market. For instance, the demand for generic medicines in mature markets (see Figure 1) such as those in Denmark and The Netherlands is driven by generic substitution by the pharmacist, in Poland by a favourable attitude of physicians towards generic medicines and by physician budgets in Germany and UK.

However, the development of a generic medicines market needs to be actively sustained by a generic medicines policy. Countries have often used supply-side policies, which relate to the pricing and reimbursement of drugs, to develop their generic medicines market. However, limiting such policies to supply-side measures only, as is the case in Austria, is not enough to help realise the full potential of a generic medicines market. Supply-side measures also need to be supplemented by so-called demand-side policies, as these create incentives for physicians to prescribe, pharmacists to dispense and patients to use generic medicines.

The ability of the generic medicines industry to deliver competitive prices can only be achieved and sustained if it is ensured a high volume of the pharmaceutical market. This high volume is dependent on demand-side policies. On the one hand, countries with mature generic medicines markets have in place incentives for physicians, pharmacists and/or patients to make use of generic medicines. On the other hand, there are often few incentives to stimulate generic medicines consumption in countries with developing generic medicines markets. For example, in Italy and Spain, the generic medicines market is small (see Figure 1), which when combined with the low cost of medicines, has undermined the economic viability of the generic medicines market.

Reference-pricing systems appear to have aided the development of national generic medicines markets by imposing a patient co-payment on originator medicines priced above the level of the reference price. However, if the reference-pricing system is accompanied by price reductions of originator medicines to the level of the reference price, the system does not aid the development of the generic medicines market. Evidence of such a pricing strategy of originator medicine companies

# The development of a generic medicines market needs to be actively sustained by a generic medicines policy.

in the context of a reference-pricing system was found for France and Italy. A reference-pricing system tends to be more successful in markets characterised by a developed generic medicines segment, substantial price differences between medicines within a group, and higher medicine prices.

Physician budgets appear to have created a stimulus to prescribe generic medicines in Germany and UK, but rewards and sanctions for budget surpluses and deficits, respectively, are a necessary condition for making budgets effective. Initiatives to promote prescribing by international non-proprietary name provide impetus for generic medicines use only if regulation specifying which medicine pharmacists need to dispense and the system of pharmacist remuneration favour the delivery of generic medicines.

Generic substitution aids generic medicines use if it is financially attractive to pharmacists to substitute generic for originator medicines. However, the remuneration system of pharmacists in the majority of selected countries provides a financial disincentive to dispense generic medicines. Belgian and French remuneration systems that guarantee the same absolute margin on originator and generic medicines provide a neutral financial incentive to pharmacists, but increase the price of generic medicines relative to originator medicines. Few countries have in place systems that financially reward pharmacists for substituting generic for originator medicines. In countries where companies compete by

offering discounts to pharmacists, healthcare payers and patients do not capture the potential savings from generic medicines use.

Patient co-payment seems to play a role in stimulating demand for generic medicines in Poland and Portugal. This incentive does not exist in France where co-payments tend to be covered by private insurance. Many countries have launched advertising campaigns to inform patients of generic medicines, but the effectiveness of such campaigns has not been evaluated.

## ECONOMIC EVALUATION OF GENERIC MEDICINES

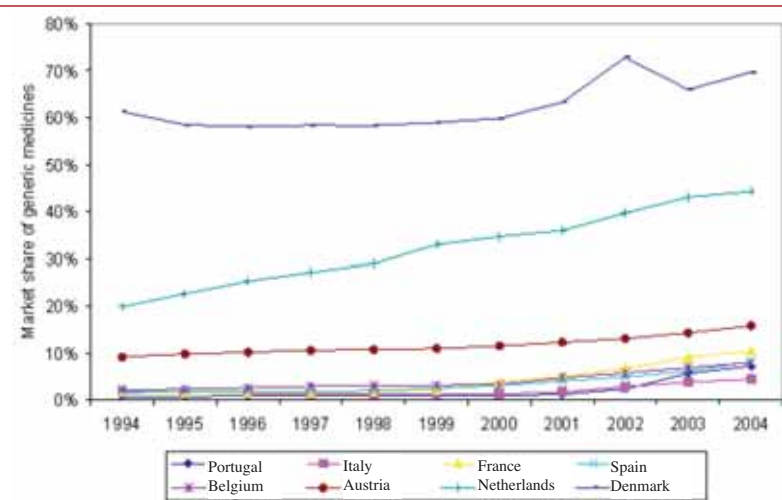
An economic evaluation calculates the incremental cost-effectiveness ratio of a medicine relative to an appropriate comparator. The need to perform an economic evaluation depends on the interchangeability of off-patent medicines: are generic/biosimilar medicines comparable to originator medicines [2]?

To enter the European market, national medicine agencies and the EMA assess the safety, quality and efficacy of generic medicines. In accordance with Directive 2004/27/EC, a generic medicine needs to be essentially similar to the originator medicine, meaning that the generic medicine has the same qualitative and quantitative composition of active substances, the same pharmaceutical form and the same bioavailability as the originator medicine as demonstrated by appropriate studies. In other words,

medicine agencies verify and validate that generic medicines have the same safety, quality and efficacy as originator medicines. However, concerns have emerged about the interchangeability of generic and originator medicines. For instance, a literature review comparing generic with originator clozapine found conflicting evidence about the bioequivalence of generic and originator clozapine [3]. Furthermore, generic substitution may reduce patient compliance with medicine therapy and undermine continuity of care.

There is inherent variation between biopharmaceuticals because they are derived from living organisms. This variation also extends to biosimilar medicines. Biosimilar medicines are agents that are similar, but not identical to the originator biopharmaceutical. From a pharmacoeconomic

**Figure 1: Market share of generic medicines by volume**



Source: IMS Health

Note: Data relate to ambulatory care, except for Denmark (hospital and ambulatory care)

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perspective, the question arises whether inherent differences between biopharmaceuticals and biosimilar medicines produce differences in safety, effectiveness and costs. To date, this question is unresolved.

If generic/biosimilar and originator medicines are interchangeable, generic substitution will maintain effectiveness at reduced costs, and can be recommended. If generic/biosimilar and originator medicines are not interchangeable, the costs in addition to the effectiveness of therapy may be affected: a lower effectiveness of a generic/biosimilar medicine may result in the need for additional therapy or hospitalisation and may entail that the patient needs to take more time off work. In this case, an economic evaluation needs to be performed to assess the pharmacoeconomic value of the generic/biosimilar medicine.

### SAVINGS FROM GENERIC MEDICINES USE

Savings from increased generic substitution in EU countries can be substantial. One study calculated savings from generic substitution for the top 10 active substances by public expenditure on originator medicines in 11 countries [4]. For each active substance, average price levels, weighted by volume of sales of medicines belonging to the group of originator medicines and to the group of generic medicines, were calculated. The price difference between the originator and generic medicines was multiplied by the volume of originator medicines to be substituted. The analysis considered that, following generic substitution, 5% of market volume for each active substance would be made up by originator medicines and 95% by generic medicines.

Increased generic substitution for the top 10 active substances generated total potential savings of around Euros 3

billion per year. Increased generic substitution would be expected to reduce public expenditure on originator medicines containing these active substances by at least 20% in each country. Countries that pursue the development of their domestic generic medicines market, therefore, can expect to gain substantial savings from increased generic substitution.

### CONCLUSION

Generic medicines create savings for healthcare systems. However, variation in the development of domestic generic medicines markets indicates that the European Union is not maximising its full potential in generic medicines. The European experience demonstrates that supply-side policies need to be supplemented by demand-side policies (such as incentives for physicians, pharmacists and patients to use generic medicines) to lead to a successful and sustainable generic medicines market. Such policies, when implemented successfully, can save billions of Euros on pharmaceutical expenditure without affecting the quality of care, thus contributing to sustainable and affordable medical care.

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