Generics and biosimilars

All OECD countries view generic and biosimilar markets as an opportunity to increase efficiency in pharmaceutical spending, but many do not fully exploit their potential. In 2019, generics accounted for more than three-quarters of the volume of pharmaceuticals sold in Canada, Chile, Germany, the Netherlands, New Zealand and the United Kingdom, but less than one-quarter in Luxembourg and Switzerland (Figure 9.7). By value, generics accounted for more than two-thirds of the pharmaceuticals sold in Chile in 2019, but on average less than one-quarter in OECD countries. Differences in market structures (notably the number of off-patent medicines) and prescribing practices explain some cross-country differences, but generic uptake also depends on policies (OECD, 2018[9]; Socha-Dietrich, James and Couffinhal, 2017[10]). In Austria, for example, generic substitution by pharmacists is not permitted. In Luxembourg, generic substitution by pharmacists is limited to selected medicines.

Many countries have implemented incentives for physicians, pharmacists and patients to boost generic markets. Over the last decade, France and Hungary, for example, have introduced incentives for general practitioners to prescribe generics through pay-for-performance schemes. In Switzerland, pharmacists receive a fee for generic substitution; in France, pharmacies receive bonuses if their substitution rates are high. In many countries, third-party payers fund a fixed reimbursement amount for a given medicine, allowing the patient a choice of the originator or a generic, but with responsibility for any difference in price (Socha-Dietrich, James and Couffinhal, 2017[10]).

Biologicals are a class of medicines manufactured in, or sourced from, living systems such as microorganisms, or plant or animal cells. Most biologicals are very large, complex molecules or mixtures of molecules. Many are produced using recombinant DNA technology. When such medicines no longer have market exclusivity, “biosimilars” – follow-on versions of these products – can be approved. The market entry of biosimilars creates price competition, thereby improving affordability.

In 2019, biosimilars accounted for more than 80% of the volume of the “accessible market” (see the “Definition and comparability” box) for erythropoietins (used to treat anaemia) in Finland, Greece, Italy and Poland (Figure 9.8). In most European countries, the list prices of erythropoietins fell by between 30% and 80% following biosimilar market entry. The impact of biosimilar competition has led to both originator and biosimilar manufacturers of erythropoietins lowering their prices.

For tumour necrosis factor (TNF) inhibitors also known as anti-TNF alfas (used to treat a range of autoimmune and immune-mediated disorders), biosimilars had over 80% of the accessible market in Denmark, but less than 10% in Greece and Hungary in 2019 (Figure 9.8). Price reductions since biosimilar entry have been more modest than for erythropoietins, and prices have even appeared to increase in some countries. However, for both drug classes, actual price reductions are greater than those appearing in the figures shown here: these data are based on list prices, and do not take into account any confidential discounts or rebates, which can be substantial.

Definition and comparability

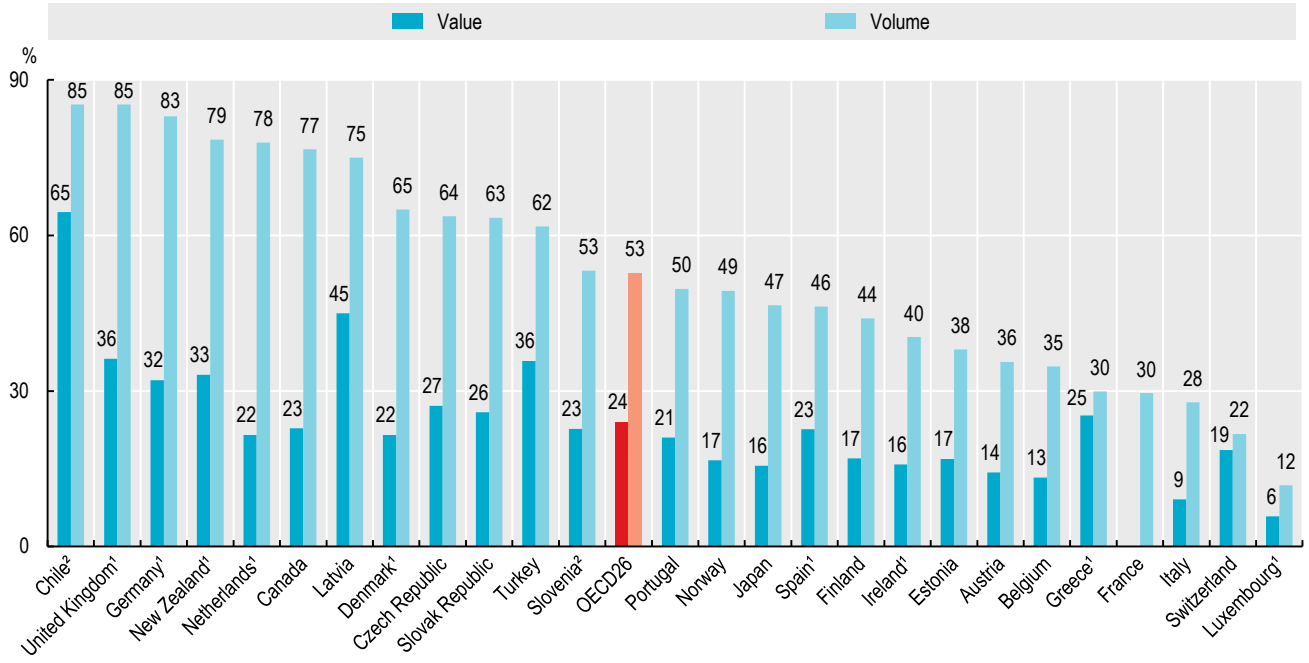
A generic medicine is defined as a pharmaceutical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference product, and whose bioequivalence with the reference product has been demonstrated. Generics may be either branded (generics with a specific trade name) or unbranded (identified using the international non-proprietary name and the name of the company).

Countries were requested to provide data for the whole of their respective markets. However, many countries provided data covering only the community pharmaceutical market or the reimbursed pharmaceutical market (see figure notes). The share of generic market expressed in value can be the turnover of pharmaceutical companies, the amount paid for pharmaceuticals by third-party payers or the amount paid by all payers (third-party and consumers). The share of the generic market by volume can be expressed in DDDs or as a number of packages/boxes or standard units.

A biosimilar medicinal product (a biosimilar) is a product granted regulatory approval by demonstrating sufficient similarity to the reference medicinal product (biological) in terms of quality characteristics, biological activity, safety and efficacy.

Biosimilar market shares and changes in prices are measured with respect to the “accessible market”, which is the market comprising originator products that no longer have market exclusivity, and their biosimilars. The accessible market for biosimilars is highly dynamic due to the progressive loss of exclusivity of biological medicines over time. Market share is computed as the number of biosimilar treatment days as a proportion of the accessible market treatment days. Price changes are measured as the differences between prices per treatment day in 2019 and in the year before entry of the first biosimilar. The tumour necrosis factor inhibitor accessible market includes adalimumab, infliximab and etanercept. The erythropoeitin accessible market includes darbepoetin alfa, and epoetin alfa, beta, delta, theta and zeta.

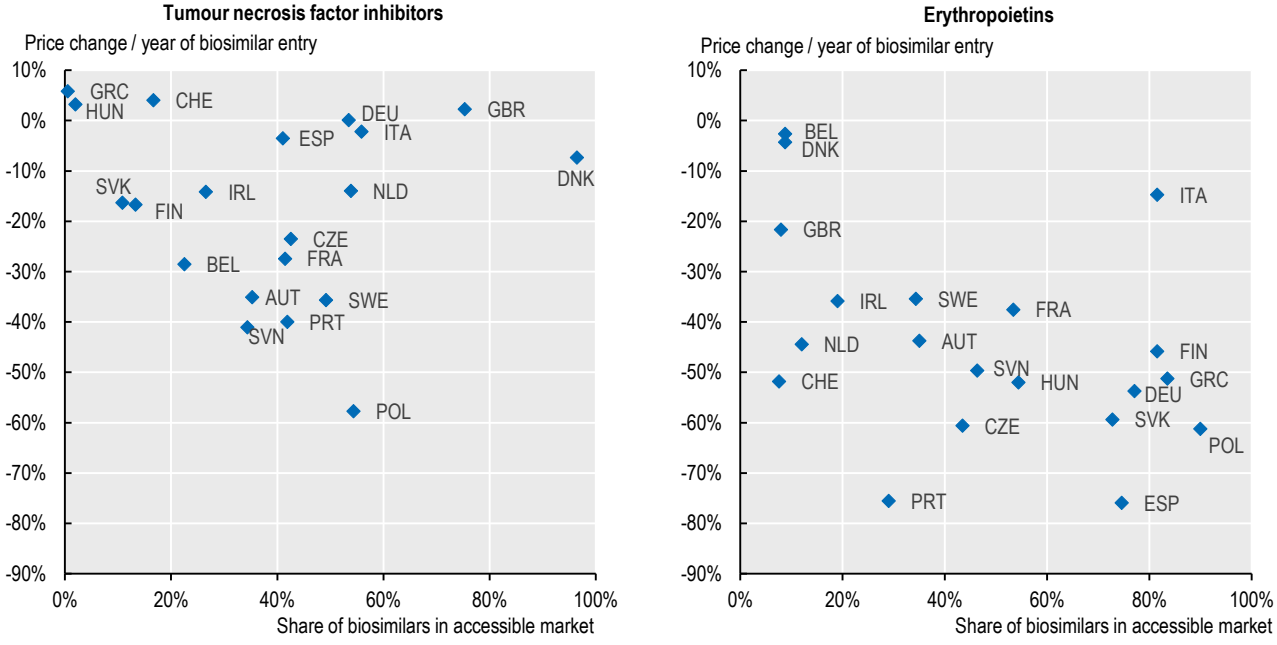
Figure 9.7. **Share of generics in the total pharmaceutical market, 2019 (or nearest year)**



1. Reimbursed pharmaceutical market, i.e. the sub-market in which a third party payer reimburses medicines. 2. Community pharmacy market.
Source: OECD Health Statistics 2021.

StatLink https://stat.link/uyjgok

Figure 9.8. **Biosimilar market share in treatment days for tumour necrosis factor inhibitors and erythropoietins vs. accessible market, 2019 (or nearest year)**



Source: IQVIA MIDAS® MAT December 2019. Data for Greece reflect only retail panel data.

StatLink https://stat.link/pgh5qj