Generics and biosimilars

All OECD countries view the development of generic markets as a good opportunity to increase efficiency in pharmaceutical spending, but many do not fully exploit the potential of generics (Figure 10.10). In 2015, generics accounted for more than three-quarters of the volume of pharmaceuticals sold in the United States, Chile, Germany, New Zealand and the United Kingdom, while they represented less than one-quarter of the market in Luxembourg, Italy, Switzerland and Greece.

Some of the differences in generic uptake can be explained by market structures, notably the number of off-patent medicines, and by prescribing practices, but generic uptake also depends on policies implemented by countries (EGA, 2011; Vogler, 2012). Several countries have expanded their efforts to encourage generic uptake since the onset of the economic crisis in 2008.

Financial incentives for physicians, pharmacists and patients have been implemented to boost the development of generic markets. For instance, France (in 2009 and 2012) introduced incentives for GPs to prescribe generics through a pay-for-performance scheme while in Japan (in 2012) payment bonuses also contributed to an increased share of generics in total prescribing. Pharmacies are often paid through mark-ups based on the price of medicines. This disincentive to substitute a generic for a more expensive drug has been addressed in some countries. France guarantees pharmacists an equivalent mark-up, while in Switzerland pharmacists receive a fee for generic substitution. Patients have a financial interest to choose cheaper drugs when their co-payment is lower for generic drugs than its equivalent. This is generally the case in all systems using reference prices (or fixed reimbursement amount) for clusters of products. In Greece, patients choosing originator over generic drugs are now required to pay for the difference.

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the "reference medicine"). Biological medicines contain active substances from a biological source, such as living cells or organisms. The rationale behind the introduction of biosimilars is to increase price competition, thereby reducing prices. There is large variation in the uptake for two biosimilars – Epoetin and Anti-Tumour Necrosis Factor (Anti-TNF) – across OECD countries (Figure 10.11). Biosimilars have 100% of the Epoetin market share in Finland, Hungary, Poland, the Slovak Republic and the Czech Republic, whereas it is 2% in Belgium and 6% in the United Kingdom. For Anti-TNF, biosimilars have 90% and 82% of the market share in Denmark and Norway respectively, while it is 2% in Switzerland and 5% in Belgium and Ireland.

Definition and comparability

A generic 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 can be classified in branded generics (generics with a specific trade name) and unbranded generics (which use the international non-proprietary name and the name of the company).

Countries were requested to provide data for the whole market. 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 generic market in volume can be expressed in DDDs or as a number of packages/boxes or standard units.

A Biosimilar Medicinal Product is the product granted regulatory approval, demonstrating similarity to the Reference Medicinal Product in terms of quality characteristics, biological activity, safety and efficacy. Referenced Medicinal Product is the original product, which was granted market exclusivity at the start of its life, but once exclusivity has expired the product has been categorised as *referenced*. The biosimilar market share is the number of biosimilar treatment days as a share of biosimilar and referenced product(s) volume. Volume is measured in Defined Daily Dose which is a measure of the average dose prescribed as defined by the WHO.

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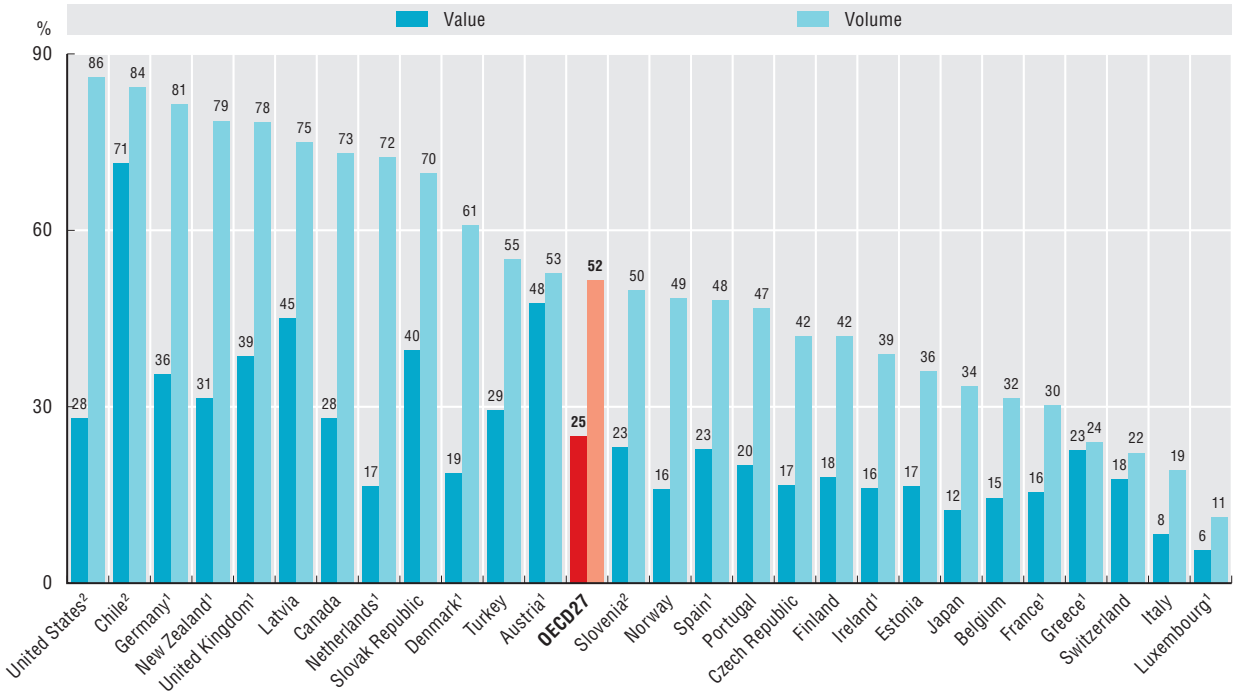
10.10. Share of generics in the total pharmaceutical market, 2015 (or nearest year)

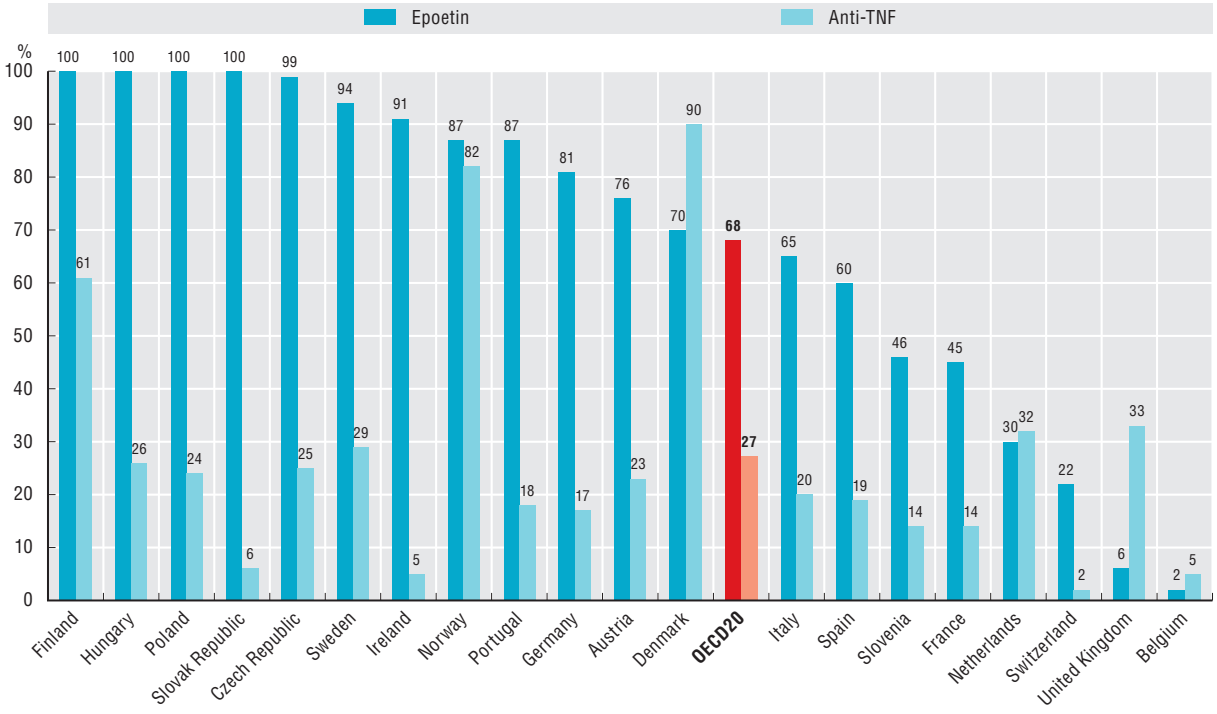


1. Reimbursed pharmaceutical market.
2. Community pharmacy market.

Source: OECD Health Statistics 2017.

StatLink http://dx.doi.org/10.1787/888933605559

10.11. Biosimilar market share (volume) for Epoetin and Anti-Tumour Necrosis Factor (Anti-TNF) vs reference product , 2015 (or nearest year)



Source: Quintiles IMS (2017), "The Impact of Biosimilar Competition in Europe", London.

StatLink http://dx.doi.org/10.1787/888933605578