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 2017, generics accounted for more than three-quarters of the volume of pharmaceuticals sold in the United Kingdom, Chile, Germany and New Zealand, but less than one-quarter in Luxembourg and Switzerland (Figure 10.10). Differences in market structures (notably the number of off-patent medicines) and prescribing practices explain some crosscountry differences, but generic uptake also depends on policies (OECD, 2018[1]; Socha-Dietrich, James and Couffinhal, 2017[2]). In Austria, for example, generic substitution by pharmacists is still not allowed. In Luxembourg, generic substitution by pharmacists is set by law but 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 GPs 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 between the originator and a generic, but with responsibility for any difference in price. In Greece, patients choosing originator over generic drugs are also required to directly pay the difference.

Biological medicines contain active substances from a biological source, such as living cells or organisms. When such medicines no longer have monopoly protection, 'copies' ("biosimilars") of these products can be approved. Biosimilars have increased price competition and improved affordability. In 2017, biosimilars accounted for more than 70% of the volume of the 'accessible market' for erythropoietin (used to treat anaemia) in Finland, Germany, the Slovak Republic and Greece (Figure 10.11). In most European countries, prices of erythropoietin fell between 30% and 80% after biosimilar entry. In Norway and Denmark, known for their effective procurement policies, data show zero or small biosimilar uptake and no price reduction in 2017. In Denmark, the tender process had already triggered competition between originator products, leading to price reductions with which biosimilars could not compete. In Norway, the originator product won the nationwide tender in 2017, with confidential rebates that affected the list price. These examples highlight the inherent problems of lack of price transparency.

For tumour necrosis factor (TNF) inhibitors (used to treat autoimmune and immune-mediated disorders), biosimilars have over 90% of the accessible market in Denmark and Norway, but less than 10% in Switzerland, Ireland and Greece (Figure 10.11). Price reductions since biosimilar entry are more modest than for erythropoietin, ranging from 4% in Switzerland to 45% in Poland. For both biosimilars, actual price reductions may be higher than what appears in figures, which only report list prices.

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.

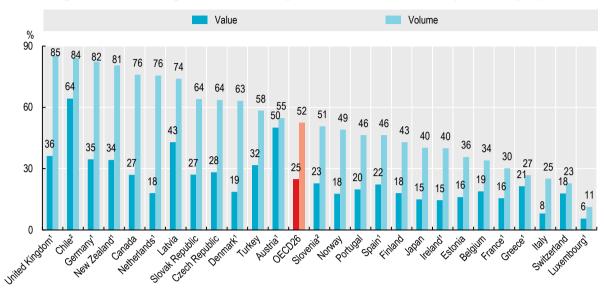
Biosimilar market shares and changes in prices are measured for the 'accessible market', i.e. the market composed of originator products that are no longer protected and their biosimilars. Market share is computed as biosimilar treatment days as a share of the total volume of biosimilar and referenced product(s). Price change is measured as the difference between prices in 2017 and in the year before entry of the first biosimilar.

References

- [1] OECD (2018), "Strategies to reduce wasteful spending: Turning the lens to hospitals and pharmaceuticals", in Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris, https://dx.doi.org/10.1787/health_glance_eur-2018-5-en.
- [3] QuintilesIMS (2017), The Impact of Biosimilar Competition in Europe, QuintilesIMS Institute, Parsippany, http:// www.quintilesims.com.
- [2] Socha-Dietrich, K., C. James and A. Couffinhal (2017), "Reducing ineffective health care spending on pharmaceuticals", in Tackling Wasteful Spending on Health, OECD Publishing, Paris, https://dx.doi.org/ 10.1787/9789264266414-7-en.

212 HEALTH AT A GLANCE 2019 © OECD 2019

Figure 10.10. Share of generics in the total pharmaceutical market, 2017 (or nearest year)



 $1. \, Re imbursed \, pharmaceutical \, market. \, 2. \, Community \, pharmacy \, market. \, Source: \, OECD \, Health \, Statistics \, 2019.$

StatLink https://doi.org/10.1787/888934018165

Figure 10.11. Biosimilar market share in treatment days for anti-TNF alfas and erythropoietin vs accessible market, 2017 (or nearest year), in European countries



Source: IQVIA MIDAS MAT December 2017.

StatLink https://doi.org/10.1787/888934018184



From: Health at a Glance 2019 OECD Indicators

Access the complete publication at:

https://doi.org/10.1787/4dd50c09-en

Please cite this chapter as:

OECD (2019), "Generics and biosimilars", in *Health at a Glance 2019: OECD Indicators*, OECD Publishing, Paris.

DOI: https://doi.org/10.1787/d58d7923-en

This work is published under the responsibility of the Secretary-General of the OECD. The opinions expressed and arguments employed herein do not necessarily reflect the official views of OECD member countries.

This document, as well as any data and map included herein, are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area. Extracts from publications may be subject to additional disclaimers, which are set out in the complete version of the publication, available at the link provided.

The use of this work, whether digital or print, is governed by the Terms and Conditions to be found at http://www.oecd.org/termsandconditions.

