

## Generics and biosimilars

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The value of a patent becomes visible when it expires. After loss of exclusivity, sales of a small-molecule medicine can fall by most of their volume within months as generic manufacturers enter the market at a fraction of the price. Basel is home both to originators and to one of the largest generics companies in the world. Sandoz, formerly the generics division of Novartis, was spun off and listed on the SIX Swiss Exchange in October 2023. It has its headquarters in Basel.<sup>1</sup> The separation reflected the view of Novartis's management that innovative medicines and generics require different business models and attract different investors.

Biological medicines, which make up a growing share of the portfolios of Roche and Novartis, follow a different pattern. Because biological products are produced in living cells, a competitor can only produce a similar product whose comparability with the original must be demonstrated through analytical and clinical studies. These biosimilars require greater investment than generics and enter the market more slowly, so that originators of biological medicines lose their market share more gradually.<sup>2</sup> Roche experienced this transition after the expiry of the patents on its large antibody medicines in oncology, which had been at the heart of its growth during the first decade of the century.

In Switzerland the market share of generics and biosimilars has remained lower than in many other European countries, partly because of the incentives created by the distribution margins and partly because of the habits of doctors and patients. The higher co-payment for originals where a cheaper generic exists, introduced and later raised by the Federal Department of Home Affairs, is intended to change these habits.<sup>3</sup> For the industry of Basel the generics question is ambivalent: Sandoz profits from higher generic penetration, while the originators prefer pricing rules that preserve the value of their brands after expiry.

## 1 Notes

1. Spin-off of Sandoz Group AG from Novartis AG by distribution of shares to Novartis shareholders and listing on SIX Swiss Exchange on 4 October 2023. To be verified. ↩
2. On the regulatory requirements for biosimilars in Switzerland, see Swissmedic's guidance on the authorisation of biosimilars, which follows the approach of the European Medicines Agency. To be verified. ↩
3. On the differentiated co-payment (Selbstbehalt) of 20 or 40 per cent for original preparations where generics are available, in the KLV, and its amendments in 2024. Figures to be verified. ↩

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