

The European Union: pharma package and Critical Medicines Act

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The European Union remains the second pillar of the Basel groups' business and the immediate economic environment of the Basel region. Its pharmaceutical policy has moved in two directions since 2023. The first is the reform of the general pharmaceutical legislation proposed by the Commission in April 2023, which aims to improve access to medicines across the member states, to address shortages and antimicrobial resistance, and to recalibrate the incentives for innovation.¹ The most contested element was the protection of regulatory data, which the Commission proposed to reduce in its baseline and to make partly conditional on launch in all member states.

After lengthy negotiations, the Council and the European Parliament reached a political agreement, the compromise text of which was published in March 2026. According to practitioner analyses, the compromise keeps eight years of data protection and reduces the baseline market protection from two years to one, with the possibility of regaining a year for products addressing an unmet medical need under further conditions. A total period comparable to the existing one thus remains available for qualifying products.² Formal adoption and publication were expected in the course of 2026, with application about two years later. The reform will therefore take full effect towards the end of the decade, within the horizon of the scenarios in this chapter.

The second direction is industrial policy. In March 2025 the Commission proposed a Critical Medicines Act, which is intended to strengthen the security of supply of medicines considered critical, many of them older off-patent products, by supporting manufacturing in the Union, by using public procurement criteria that reward supply security and by coordinating stockpiling.³ For the originator groups of Basel the act is of secondary importance, because their innovative products are rarely in

short supply. Sandoz, by contrast, as a producer of generics and biosimilars with manufacturing in Austria, Slovenia and elsewhere in Europe, may benefit from procurement rules that favour European production. The act also reflects a broader European shift towards strategic autonomy in which Switzerland participates only indirectly, through its bilateral agreements and its market access.

Switzerland's relationship with the European Union, the subject of Chapter IV of this Part, is relevant here in one specific respect. The agreement on mutual recognition in relation to conformity assessment, which allowed Swiss manufacturers to sell medical devices in the European Union on the basis of Swiss certificates, ceased to be updated for medical devices in 2021 after the Federal Council broke off negotiations on an institutional framework agreement. Medicines continued to benefit from the mutual recognition of good manufacturing practice inspections and batch release.⁴ The package of agreements concluded politically in December 2024 provides for the updating of this agreement. Its fate is therefore one of the variables that determine whether Basel remains embedded in the European regulatory space.

1 Notes

1. European Commission, proposal for a Directive on the Union code relating to medicinal products for human use, COM(2023) 192, and proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM(2023) 193, both of 26 April 2023. To be verified. ↩
2. Compromise text of the EU pharmaceutical package published on 6 March 2026, summarised e.g. by Sidley Austin, "EU Pharma Package: Compromise Text Published – Best Efforts Required", May 2026: eight years of regulatory data protection, baseline market protection reduced from two years to one, with an additional year available for products meeting unmet medical need and further conditions; formal adoption expected in 2026 and application about 24 months after entry into force. Status to be verified. ↩
3. European Commission, proposal for a Regulation laying down a framework for strengthening the availability and security of supply of critical medicinal products (Critical Medicines Act), COM(2025) 102, of 11 March 2025; status of the legislative procedure in the European Parliament and the Council to be verified. ↩

4. Agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessment of 21 June 1999 (SR 0.946.526.81), chapter 15 on good manufacturing practice for medicinal products; non-update of chapter 4 on medical devices from 26 May 2021. Status to be verified. ↩

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