

Data exclusivity under the Therapeutic Products Act

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Patent protection is supplemented by a separate right that is often of equal commercial importance: the protection of the documentation submitted to obtain marketing authorisation. The Federal Act on Medicinal Products and Medical Devices of 2000, usually called the Therapeutic Products Act, regulates the authorisation of medicines by Swissmedic, the Swiss Agency for Therapeutic Products in Bern.¹ Under the act, a generic manufacturer may refer to the documentation of the originator only after the expiry of a protection period, which is ten years for a medicine with a new active substance. This protection runs independently of patents, so that it can secure a period of exclusivity even when no patent protection exists or the patent has expired early.

The 2019 revision extended and differentiated these periods. A new indication, a new route of administration or a new dosage form can attract three years of protection. The period can rise to ten years if the new indication brings a significant clinical benefit and is supported by extensive clinical studies. Medicines developed for children can obtain ten years for the paediatric documentation. For medicines against rare diseases the period is fifteen years.² The orphan period of fifteen years exceeds the ten-year market exclusivity for orphan medicines in the European Union. It reflects a deliberate policy decision to make Switzerland attractive for the development of treatments for rare diseases.

Being small in comparison with the American Food and Drug Administration or the European Medicines Agency, Swissmedic has sought to compensate for its size through international cooperation. It participates in the Access Consortium with the regulators of Australia, Canada, Singapore and the United Kingdom, and in Project Orbis, an initiative of the Food and Drug Administration for the concurrent review of cancer medicines.³ Since 2019 the agency may also take into account the results of a foreign authorisation procedure in a simplified procedure,

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which shortens the time to market in Switzerland for products already approved by recognised regulators.⁴ For the pharmaceutical groups of Basel, a fast Swiss approval is of limited commercial importance in itself, because the Swiss market accounts for a very small share of their global sales. It matters more as a signal and as a reference point for the prices paid in other countries.

1 Notes

1. Bundesgesetz über Arzneimittel und Medizinprodukte (Heilmittelgesetz, HMG) of 15 December 2000, SR 812.21, in force since 1 January 2002; Swissmedic as the federal agency for therapeutic products. To be verified. ↩
2. Art. 11a, 11b and 11c HMG on document protection (ten years for new active substances, three years for new indications, routes of administration or dosage forms, up to ten years for significant clinical benefit, ten years for paediatric use and fifteen years for orphan medicinal products), as revised with effect from 1 January 2019. To be verified. ↩
3. On Swissmedic's participation in the Access Consortium (with Australia, Canada, Singapore and the United Kingdom) and in Project Orbis, see Swissmedic's annual reports. To be verified. ↩
4. Art. 13 HMG on the consideration of authorisations by countries with comparable control of medicinal products, and the implementing provisions on the simplified authorisation procedure. To be verified. ↩

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