

Supplementary protection certificates and paediatric extensions

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A medicine rarely reaches the market until many years after the patent on its active substance has been filed, because the clinical trials and the authorisation procedure take a long time. The effective period of exclusivity is therefore much shorter than the nominal patent term of twenty years. To compensate for this loss, the European Union introduced supplementary protection certificates for medicinal products in 1992. Switzerland followed with an amendment of the Patents Act that entered into force in 1995.¹ A certificate extends protection for the authorised product for a period that corresponds to the time between the filing of the patent and the first marketing authorisation in Switzerland, minus five years, with a maximum duration of five years.

The Swiss certificate regime follows the European model closely. As a consequence, the extensive case law of the Court of Justice of the European Union on concepts such as the "product" and the "basic patent" is influential in Switzerland, although it is not binding. The Federal Supreme Court has on several occasions aligned Swiss practice with European case law, for example on the question of when a product is "protected" by a basic patent, while reserving its own interpretation where the Swiss text differs.² The underlying policy reason is plain: the Basel groups apply for certificates throughout Europe on the basis of the same authorisation data. Divergent outcomes would complicate their planning of loss of exclusivity.

The revision of the Therapeutic Products Act and the Patents Act that entered into force on 1 January 2019 introduced a paediatric extension. A company that has conducted the studies required by an agreed paediatric investigation plan can obtain a six-month extension of its certificate, or alternatively a stand-alone paediatric certificate where no ordinary certificate exists.³ The extension is intended to reward the conduct of clinical studies in children, which are costly and ethically demanding and

which companies would otherwise often avoid. For a medicine with large sales, six months of additional exclusivity can be worth several hundred million francs, which explains why the paediatric rules are carefully monitored by investors and analysts.

The European Union has been working for several years on a reform of its pharmaceutical legislation and of the certificate regime, including a unitary certificate linked to the Unitary Patent and a centralised examination procedure. The Commission's proposals of 2023 also provided for a modulation of regulatory data protection depending on whether a company launches the medicine in all member states.⁴ Switzerland would not participate in a unitary certificate for the same reasons that keep it outside the Unitary Patent. Swiss law would nevertheless come under pressure to adapt if the substance of European protection periods changed, because the industry and Swissmedic share a strong interest in synchronised timetables.

1 Notes

1. Art. 140a–140z PatG on supplementary protection certificates for medicinal products, in force since 1 September 1995, modelled on Council Regulation (EEC) No 1768/92, now Regulation (EC) No 469/2009. To be verified. ↩
2. On the reception of the case law of the Court of Justice of the European Union on supplementary protection certificates by the Federal Supreme Court and the Federal Institute of Intellectual Property, see the commentaries on Art. 140b PatG and the decisions of the Federal Supreme Court since about 2017. To be verified. ↩
3. Art. 140n–140s PatG on the six-month extension of the supplementary protection certificate and the paediatric certificate, introduced with the revision of the Therapeutic Products Act in force since 1 January 2019. To be verified. ↩
4. European Commission, proposals of 2023 for a reform of the EU pharmaceutical legislation and for a unitary supplementary protection certificate; the legislative procedure was still ongoing at the time of writing. Status to be verified. ↩

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