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Paediatric extensions – Switzerland to follow suit as of January 2019

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In order to provide adequate incentives for the research and development of high-quality medicinal products adapted for paediatric needs, special rewards, such as a 6-month paediatric extension of the term of a Supplementary Protection Certificate (SPC) have been made available in the EU since 2007.

Switzerland, which participates in the EU's single market and traditionally has adapted its IP provisions to those of the EU, will now follow suit.

In line with this, the Swiss Patent Act and Patent Ordinance have been amended so as to provide for an additional 6-month paediatric extension of proprietary protections, by either extending the term of a pending or granted SPC or by way of a new paediatric certificate, which is linked directly to the term of the basic patent.

These amendments to the Swiss Patent Act and Patent Ordinance, which are based on a revision of the Therapeutic Products Act, mandating the need to carry out appropriate clinical trials in the paediatric population, will come into force as of 1 January 2019.

In order to apply for a paediatric extension, paediatric trials in compliance with an agreed paediatric investigation plan (PIP) must have been completed. Moreover, the application for a paediatric authorization in Switzerland must be submitted no later than six months after the corresponding application for authorization in the European Economic Area.

A request for a paediatric extension for an SPC must be filed at the earliest together with the SPC request and no later than two years before the expiry of the SPC, whereas a paediatric extension on the basis of a patent (i.e., in the absence of an SPC) must be filed at least two years prior to the expiry of the patent.

Dr. Alexa von Uexküll and Oswin Ridderbusch, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the new handbook “European SPCs Unravelled: A Practitioner’s Guide to Supplementary Protection Certificates in Europe” published by Wolters Kluwer.

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