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Little-known pitfall in application for paediatric extensions or paediatric SPCs

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Introduction

As is well known, Switzerland is not a member state of the European Union. For this reason, Switzerland also has a separate and independent system when it comes to the approval of medicinal products. A pharmaceutical company wishing to obtain a marketing authorisation (MA) for a medicinal product in the European Union and Switzerland must therefore file separate applications with the European Medicines Agency (EMA) and with the Swiss Therapeutic Products Agency (Swissmedic). The MA procedure before Swissmedic is governed by Swiss regulatory law and is therefore independent from the procedure before the EMA. Therefore, from a regulatory point of view, it is usually not necessary that the applications for MAs in Switzerland and the European Union are coordinated in any particular way (although of course such coordination makes sense from a commercial and strategic perspective).

Against this background, it is important to note that there is a connection between Swiss MA applications and MA applications in the European Union or the European Economic Area (EEA), respectively, when it comes to paediatric extensions or paediatric supplementary protection certificates (SPCs) in Switzerland. This nexus – which will be explained in detail below – is not always known and can have daunting consequences on patent or SPC protection if not taken into account at an early stage.

Paediatric SPCs and paediatric extensions

The application for and the grant of Swiss SPCs in general is regulated in the Swiss Patent Act (PatA). In Switzerland, SPCs are granted upon respective request by the Swiss Institute of Intellectual Property (IPI). As of 1 January 2019, it is also possible to obtain paediatric SPCs or paediatric extensions of existing SPCs for a duration of six months. While paediatric extensions are well-known in the European Union, paediatric SPCs are a protective right that is only available in Switzerland. A paediatric SPC is basically the same as a paediatric extension, the only difference being that it is not based on an existing SPC but on the basic patent alone. In other words, paediatric SPCs can be obtained by patent owners that do not have an SPC in Switzerland but still wish to extend patent protection for six months based on their paediatric indications.

Conditions for grant of paediatric SPCs or paediatric extensions

Article 140n(1) and article 140t(1) of the PatA state the requirements that must be met in order to obtain a paediatric extension or a paediatric SPC in Switzerland. The wording of article 140n(1) of the PatA (concerning paediatric extensions) is as follows (article 140t(1) of the PatA has identical wording with respect to paediatric SPCs):

> *The IPI shall extend the term of protection (Art. 140e) of certificates issued by six months if the authorisation (Art. 9 TPA) of a medicinal product containing the product:*
>
> > *a. contains confirmation that the information on the medicinal product reflects the results of all studies performed in accordance with the paediatric test concept (Art. 11 para. 2 let. a no 6 TPA) considered in the authorisation process; and*
> >
> > b. *was applied for no later than six months after the application for initial authorisation in the European Economic Area of a medicinal product containing the product in which the corresponding medicinal product information reflects the results of all studies performed in accordance with the paediatric test concept considered for the authorisation.*

The first condition is rather straightforward: the grant of a paediatric extension or a paediatric SPC in Switzerland requires a granted Swiss MA for the paediatric indication as a basis.

As a second condition, this Swiss MA must contain a confirmation that the information on the authorised medicinal product reflects the results of all studies performed in accordance with the paediatric test concept.[(1)] An MA holder in Switzerland must file a paediatric test concept that was either created specifically for Switzerland or already approved by the EMA, the US Food and Drug Administration or a similar foreign authority. Usually, MA holders submit the paediatric investigation plan (PIP) agreed by the EMA also in Switzerland.

The third condition for the grant of a paediatric extension or a paediatric SPC requires specific attention. According to this requirement, the Swiss MA that is the basis for the paediatric extension or the paediatric SPC must have been applied for with Swissmedic within six months after the first application for an MA, reflecting all of the studies according to the paediatric test concept, has been filed in the EEA. In other words, a pharmaceutical company wishing to apply for a paediatric extension or a paediatric SPC in Switzerland must make sure that the application for the Swiss MA for the paediatric indication was filed within six months after the filing of the first respective MA application in the EEA. As there is no exemption to this third condition, the Swiss IPI will not grant a paediatric extension or a paediatric SPC in Switzerland if this requirement is not fulfilled.

Finally, the Swiss Patent Act contains further deadlines with respect to the filing of an application for a paediatric SPC or a paediatric extension: an application for a paediatric SPC must be filed, at the latest, two years before the expiry of the basic patent. Applications for a paediatric extension can be filed along with the application for the SPC at the earliest and must be filed two years before the expiry of

the SPC at the latest.

Thus, the right timing is of essence when considering the filing of an application for a paediatric extension or a paediatric SPC in Switzerland.

Key recommendations

For pharmaceutical companies that wish to benefit from either a paediatric extension or a paediatric SPC in Switzerland, it is recommended to take the six-month deadline between the MA application in the EEA and the MA application in Switzerland (or the application for an MA extension) into account at an early stage. In order to meet this deadline, it makes sense to file an MA application or an application for MA extension concerning the paediatric indication in Switzerland roughly at the same time as such application (reflecting all studies according to the EU-PIP) is submitted to the EMA for the first time.

The deadlines for the filing of the application for a paediatric extension or a paediatric SPC with the Swiss IPI must also be kept in mind. This requires effective coordination and alignment of the work streams within the pharmaceutical company and a close cooperation between the teams responsible for regulatory applications in the European Union and regulatory applications in Switzerland, as well as the responsible team for patents/SPCs in Switzerland.

If the Swiss peculiarities are ignored after the filing of an MA application for the paediatric indication in the EEA, a pharmaceutical company runs the risk that its patent or SPC protection, respectively, expires earlier in Switzerland than in the European Union. This undesirable consequence can be avoided by taking into account the described nexus between the first MA application for the paediatric indication in the European Union/EEA and the MA application for such paediatric indication, as well as the other applicable deadlines for the filing of an application for paediatric extensions and paediatric SPCs in Switzerland.

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Endnotes

(1) The unofficial English translation of the Swiss Patent Act uses the term "pediatric test concept" while Swissmedic prefers the term "pediatric investigation plan", which is also common in the European Union.