Paediatric Extensions to Supplementary Protection Certificates in the EU / EEA and UK

Introduction

Supplementary Protection Certificate (SPCs) for medicinal products are intellectual property rights intended to compensate patent holders for the loss in effective patent term that results from the time taken to receive marketing authorisations for such products. An SPC takes effect at the expiry of the normal term of the patent on which it is based, and expires at whichever is the earlier of (i) 15 years from the first marketing authorisation in the EU/EEA, and (ii) 5 years from the expiry of the basic patent.

Usually, therefore, the maximum term of an SPC is 5 years. However, the term of an SPC may be extended by six months in exchange for the provision of paediatric data. Such extensions are known as paediatric extensions.

To promote such research, the Paediatric Regulation requires all applicants for a new marketing authorisation to present the results of studies in children in accordance with an agreed paediatric investigation plan (PIP).

Equivalent provisions have been introduced by the UK Human Medicines Regulations following the UK's departure from the EU. Paediatric extensions are also available in Switzerland. Please contact your J A Kemp contact separately if you require advice regarding the Swiss procedure.

Procedure for obtaining a PIP compliance statement in the EU

The first step towards obtaining a paediatric extension is taken as part of the procedure for obtaining a marketing authorisation. This procedure requires an application for marketing authorisation to include a paediatric investigation plan (PIP). The expected contents of the PIP are defined in the Paediatric Regulation, and include details of the paediatric studies and their timelines. The PIP is submitted to the European Medicines Agency (EMA) through the Paediatric Committee, which then issues an opinion on the merits of the studies proposed in the PIP. There are essentially three possible outcomes:

(i) Positive opinion: the PIP is approved. The studies set out in the PIP should be performed. The results will ultimately be added to the application for marketing authorisation, and assessed to confirm compliance with the PIP.

(ii) Negative opinion: if it is not necessary or appropriate to develop the medicine in question in children. The Paediatric Committee may issue a waiver from the requirements to complete a PIP.

(iii) Deferral: for example if the Committee deem it is more appropriate first to conduct studies in adults only. The applicant can request a deferral.

A marketing authorisation will only issue if compliance with an approved PIP is confirmed, or if there is an active waiver or deferral. If compliance can be confirmed at the time of the original application for authorisation, then the summary of product characteristics (SmPC) will contain a statement to this effect and the results of the paediatric studies. However, waivers and deferrals are relatively common, and it is not unusual for a PIP to be completed only after the initial marketing authorisation is obtained. In those cases, the results of the PIP are submitted with a request for variation of the marketing authorisation. The results are again assessed for compliance with the PIP. If compliance is confirmed, the SmPC will be updated to contain a statement to this effect and the results of the paediatric studies.

Deadline to apply for a paediatric extension of SPCs in the EU

The procedure for requesting a paediatric extension will depend upon whether or not the initial marketing authorisations contains the PIP compliance statement.

If the initial marketing authorisation contains the PIP compliance statement, then the application for the paediatric extension should be made to the relevant national patent office(s) together with the application for the SPC itself.

If an SPC already exists, which will normally be the case if the initial marketing authorisation did not contain the PIP compliance statement, then the application for the paediatric extension will need to be made separately to the relevant national patent office(s). The deadline for doing so is two years before expiry of the SPC[1].

Requirements for grant of a paediatric extension of SPCs in the EU

A paediatric extension cannot be granted unless the PIP has been completed and an updated SmPC containing the PIP compliance statement and the results of the paediatric studies has been issued.

It is not necessary that the results from the PIP show that the product may be used in the paediatric population. Thus, there is no requirement for paediatric indications to be added to the SmPC in order for the paediatric extension to be granted: all that is needed is for the PIP to have been completed.

However, there are a number of further requirements for grant of a paediatric extension in the EU:

- An extension to SPC term is only available for a medicinal product that is authorised in all EU member states. This

requirement will be met if an EU authorisation is obtained using the centralised procedure available via the European Medicines Agency (EMA). However, if the EU's mutual recognition or decentralised procedures, whereby national offices rather than the EMA conduct the assessments, have been used, then demonstrating that the product is authorised in all EU member states poses a greater evidential burden[2]. Further, if the product has been authorised via national authorities in selected (i.e. not all) member states, then a paediatric extension will not be available.

- No paediatric extension is available for drugs designated as orphan medicinal products. However, a two-year extension to the ten-year market exclusivity provided by Regulation (EC) No 141/2000 on orphan medicinal products may be available for products for which a PIP has been completed. For further information on orphan medicinal products see our briefing here.
- A paediatric extension is not available for products for which a one-year extension to market protection is granted under Regulation (EC) No 726/2004 in connection with a new therapeutic indication which brings a significant clinical benefit in comparison with existing therapies. In effect, an applicant demonstrating a new paediatric indication that has significant clinical benefit in comparison with existing therapies will need to choose between (a) an additional six months of SPC term under the Paediatric Regulation, and (b) an extra year of market protection. For further information on data exclusivity and market protection see our briefing here.

Paediatric extension of SPCs in the UK

Applications for paediatric extensions in the UK that were filed before 1 January 2021 continue to be assessed according to the EU regime set out above. For applications filed from 1 January 2021, the UK Human Medicines Regulations apply instead.

The provisions introduced by the UK Human Medicines Regulations largely mirror those of the EU Paediatric Regulation. In particular, the UK still requires the provision of results obtained under an agreed PIP in order to obtain a PIP compliance statement, and any request for a paediatric extension must be filed at least two years before expiry of the SPC. However, the UK no longer requires that the medicinal product is authorised in all EU member states.

Therefore, a paediatric extension may now be available in the UK under circumstances where it previously would not have been.

In addition, SPCs in the UK based on applications filed after 1 January 2021 may now be granted with differing geographical scope, depending on the available marketing authorisation(s) when the application is filed. For example, an EU marketing authorisation will continue to have effect in Northern Ireland (NI) and so can form the basis for an SPC covering NI only. The rest of the UK (Great Britain / GB) is free to diverge from EU law, and will therefore require a marketing authorisation issued by the MHRA which can form the basis for an SPC covering GB only. The resulting SPC will have geographical scope corresponding to the marketing authorisation(s) upon which it is based. However, any "missing" scope can be added later, provided the relevant additional marketing authorisation is obtained before the SPC enters into force.

Similar complexity applies to any request for paediatric extension of SPCs in the UK. If granted, the extension will only apply in those parts of the UK for which the marketing authorisation(s) contains the necessary paediatric data. Should the requirements for a paediatric extension later be met in another part of the UK, it is possible to make a separate request for the paediatric extension to apply also in that part. Any such request must be made no later than two years before expiry of the SPC.

Footnotes

1. This deadline cannot be extended. If the PIP has not been completed by two years before SPC expiry but completion is expected before SPC expiry, then a request for a paediatric extension can be filed by the deadline without the PIP compliance statement. Most patent offices allow applicants to cure the irregularity of the missing PIP compliance statement by filing the PIP compliance statement when it becomes available.
2. Many patent offices require that the national authorisations from each member state have been updated to include the PIP compliance statement before granting the paediatric extension. The process for updating marketing authorisations to include the PIP compliance statement can be lengthy in some countries, and poses a further logistical burden on applicants.

For more information, please contact:

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