

EXTENSIONS TO SUPPLEMENTARY PROTECTION CERTIFICATES ARISING FROM PAEDIATRIC TRIALS

On 26 January 2007, Regulation (EC) No. 1901/2006 came into force. This Regulation sets out the new legislative framework to promote the development of medicinal products for use in the paediatric population. Amongst the incentives introduced by Regulation No. 1901/2006 is the possibility of an extension to the duration of a Supplementary Protection Certificate (SPC) covering a marketed medicinal product.

Supplementary Protection Certificates

SPCs provide additional protection, beyond patent expiry, for products (medicinal or plant protection) that require a marketing authorisation.

Extension of SPC Duration

Before Regulation (EC) No. 1901/2006 came into force, the maximum duration of an SPC was 5 years.

Now, under the provisions of the new Regulation, an SPC covering a product may be extended (beyond the term that it would otherwise be afforded) by a period of 6 months. This extension of term applies to *all* of the authorised indications for the product (including the non-paediatric indications).

The SPC duration extension may apply if the results of a Paediatric Investigation Plan (PIP) agreed with the European regulators (the EMEA) are included in an application for Marketing Authorisation for:

- (a) a product not previously authorised (Articles 7 and 36(1)); or
- (b) a new indication (including paediatric indication), new pharmaceutical form or a new route of administration of a previously-authorized product (Article 8 and 36(1)).

The extension of duration may be available even if the data from the PIP fail to lead to the authorisation of a paediatric indication. However, in this situation, the results of the paediatric studies must at least be reflected in the Summary of Product Characteristics (SmPC) for the medicinal product concerned (Article 36(1)). There are also some particular circumstances in which the extension of duration is not available.

An application for extension of the duration of an SPC can be made:

- (i) when applying for an SPC;
- (ii) when an SPC application is pending; or, at the latest
- (iii) 2 years prior to the expiry of an existing SPC.

However, prior to 26 January 2012, it will be possible to file such an application for extension up to 6 months before the expiry of an existing SPC.

An extension of SPC duration may be based upon paediatric studies on a marketed product that have been completed by 26 January 2007 (not in accordance with an agreed PIP). However, the extension may only be granted if those studies are submitted by 26 January 2008 *and* additional significant studies contained in an agreed PIP are completed after 26 January 2007.

Action Point

If you are conducting (or are considering conducting) clinical trials on a product that is protected by a patent or SPC, and would like to know whether an extension of SPC duration could apply to your product, then please contact us for advice. We can also provide information on the general SPC system.

If you require any further information, please contact Mike Snodin or John Miles at our Nottingham office.

The information in this Newsletter was correct at the date of release. More up to date information is available by contacting Eric Potter Clarkson LLP. All comments contained here are of a general nature and full professional advice should be sought on any specific problem.

Please note that all our Newsletters can be found on our website at www.eric-potter.com.

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