

## Six-month SPC term extensions under Regulation (EC) No 1901/2006

Regulation 1901/2006 provides valuable incentives, including six-month SPC term extensions, to reward pharmaceutical companies for meeting various requirements.

### Background

The paediatric Regulation – Regulation (EC) No 1901/2006<sup>1</sup> imposes a number of requirements on pharmaceutical companies and, in return, sets out *incentives* for meeting the requirements and *penalties* for non-compliance.

Since 1997, US law has provided marketing incentives to manufacturers who conduct studies of drugs in children. Regulation 1901/2006 aims to provide similar incentives in Europe, with the broad aim of encouraging research into and the dissemination of information about medicinal products for use in the paediatric population (children of up to 18 years of age).

### Regulation 1901/2006 is relevant to medicinal products in general.

Although Regulation 1901/2006 is ostensibly related to medicinal products for paediatric use, it is in fact relevant to all medicinal products, not just those specifically designed for paediatric use. Regulation 1901/2006 also relates

to both authorised and unauthorised medicinal products, irrespective of whether they are covered by intellectual property rights.

### Requirements imposed by Regulation 1901/2006

Among the requirements imposed by Regulation 1901/2006 are the following.

#### 1. Marketing authorisation applications<sup>2</sup>

Data on the paediatric use of a medicinal product from an agreed paediatric investigation plan (PIP) must now be provided at the time of applying for a marketing authorisation in respect of any medicinal product that has not previously received marketing authorisation in the EU.

The requirement to include data from a PIP may, however, be waived for medicines unlikely to benefit children. Additionally, there is a deferral system which ensures that medicines are tested in children only when it is safe to do so and which prevents delays in the authorisation of medicines for adults.

#### 2. Applications to vary or to extend existing marketing authorisations to new indications, pharmaceutical forms or routes of administration<sup>3</sup>

Data on the paediatric use of a medicinal product from an agreed PIP must now also be provided at the time of applying to vary or to extend an existing marketing authorisation to any new indication, pharmaceutical form or route of administration. The data must

cover both existing and new indications, pharmaceutical forms and routes of administration. This requirement applies to authorised medicinal products which are protected by an SPC, or by a patent which qualifies for the grant of an SPC. As under paragraph 1 above, there will be waiver and deferral systems.

### Incentives offered by Regulation 1901/2006

Regulation 1901/2006 offers the following incentives for complying with the above requirements.

#### 1. SPC terms extended by six months<sup>4</sup>

If all the data from a PIP is provided at the time of applying for a marketing authorisation or at the time of applying to vary or extend an existing marketing authorisation (see above), SPCs (supplementary protection certificates) relating to the product will have their terms extended by six months.

The outcome of the paediatric studies is irrelevant.

SPCs will have their terms extended whatever the outcome of the paediatric studies, provided that the data from the PIP is incorporated into the marketing authorisation documentation. The SPC term extension will apply to all authorised indications for the product and will not be limited to the paediatric indications.

To obtain an SPC term extension, the product must be authorised in all Member States.<sup>5</sup> In the UK, the Court of



Appeal has indicated that it is possible for an SPC term extension to be granted even if the product is not authorised in all Member States at the time of applying for the SPC term extension provided that the product subsequently becomes authorised in all Member States.<sup>6</sup>

An application to obtain an SPC term extension can be made when filing the SPC application, during prosecution of the SPC application and after the SPC has been granted. However, an application to extend an SPC must be filed not later than two years before the normal expiry of the SPC. This deadline is extended to six months before the normal expiry of the SPC during a transitional period which ends on 26th January 2012.<sup>7</sup>

**In contrast to the situation in the US, the term extension applies *only to SPCs*.**

Some states, however, have been prepared to grant negative term SPCs (i.e. SPCs with a term of from -6 to 0 months) or zero term SPCs which, by themselves, are of no value but have the potential to be extended by virtue of Regulation 1901/2006. For example, an SPC with a term of -3 months would lead to an aggregate extension of +3 months if the SPC were extended by 6 months under Regulation 1901/2006.

Although negative term SPCs have been granted in some states (e.g. the UK<sup>8</sup>),

they have been refused in a number of other states (e.g. Germany). The issue of whether or not such negative term SPCs are allowable has been referred to the Court of Justice<sup>9</sup>, and so we should receive clarification soon.

### **2. Orphan medicines<sup>10</sup>**

Orphan medicines may benefit from two years of market exclusivity in addition to the ten years currently awarded under the EU orphan medicines Regulation.<sup>11</sup>

### **3. Off-patent products<sup>12</sup>**

Regulation 1901/2006 envisages a new type of marketing authorisation for medicinal products not protected by SPCs or SPC-qualifying patents, the "paediatric use marketing authorisation" (PUMA) which is awarded for exclusively therapeutic indications which are relevant for use in the paediatric population. A PUMA may provide periods of data (for 8 years) and market exclusivity (for 10 to 11 years), in accordance with the well-known 8+2+1 rules.

## **Implications of Regulation 1901/2006**

Regulation 1901/2006 affects pharmaceutical companies in both the research-based and generic sectors. Research-based pharmaceutical companies will benefit from SPC term extensions whilst generic pharmaceutical companies, in particular, will benefit from the availability of PUMAs when developing paediatric formulations of off-patent medicines.

The obligations to generate and collect paediatric data will increase the cost of bringing new products to market for research-based pharmaceutical firms. Other obligations imposed by Regulation 1901/2006 (which are beyond the scope of this note) will increase the costs of maintaining certain existing products on the market. It has been suggested that some research-based pharmaceutical companies may seek to specialise in products exempt from Regulation 1901/2006 so as to avoid the costs of additional clinical trials.

**It may sometimes be necessary to choose between *alternative types* of extended protection.**

Companies will sometimes need to choose between the alternative forms of extended protection available. For example, SPC term extensions will not be available if, under existing EC legislation, a marketing authorization holder has gained an additional year of marketing exclusivity for a new paediatric indication on the grounds that the new paediatric indication brings significant clinical benefit compared with existing therapies.<sup>13</sup>

## **How this may affect you at the moment**

Regulation 1901/2006 can be used to extend SPCs by six months (or to provide the other incentives mentioned above).

If you have performed, or are considering performing, *clinical trials* on a product that is protected by a patent or an SPC and would like to know whether an SPC term *extension* might be available, we suggest that you contact us for advice. We would also be happy to advise you on what measures, if any, can be taken to extend SPCs that you already own.

The UK Court of Appeal has clarified that there is considerable scope for correcting irregularities in SPC term extension applications after they have been filed.<sup>14</sup> It may therefore sometimes be worth applying for an SPC term extension even though, at the time of making the application, you are unable to meet all the requirements of Regulation 1901/2006.

Regulation 1901/2006 imposes a number of obligations on marketing authorisation holders in addition to those discussed above and sets out various penalties for companies that do not abide by the Regulation. Each EU member state is responsible for determining suitable penalties but is obliged to inform the commission of any action instigated for infringement of Regulation 1901/2006.

The European Commission will make public the names of infringers and the details of any financial penalties imposed. The European Commission can also impose penalties directly.<sup>15</sup> **We therefore suggest that you ensure that your regulatory affairs department is fully aware of the requirements imposed by Regulation 1901/2006.**

This note provides a brief overview of some of the aspects of Regulation 1901/2006 and is by no means comprehensive. Moreover, Regulation 1901/2006 has only recently come into force and so there will be additional

developments as applications are made and the Regulation becomes better understood.

There is already some variation in how different EC member states are interpreting the requirements necessary to obtain SPC extensions under Regulation 1901/2006 and, as mentioned above, there have been diverging practices on the issue of negative term SPCs which will shortly be addressed by the Court of Justice.

The above discussion is intended solely to draw your attention to some of the changes, particularly those relating to SPCs, and should not be taken as legal advice tailored to your business. We would, however, be happy to provide further information and to advise you on potential SPC filing strategies.

## Need advice?

For further information please contact:  
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<sup>1</sup> Amendments made by Regulation 1901/2006 have been incorporated into the codified medicinal product SPC Regulation (EC/469/2009). Additionally, Regulation 1901/2006 amends Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

<sup>2</sup> Regulation (EC) No 1901/2006, Article 7

<sup>3</sup> Regulation (EC) No 1901/2006, Article 8

<sup>4</sup> Regulation (EC) No 1901/2006, Article 36

<sup>5</sup> Regulation (EC) No 1901/2006, Article 36(3)

<sup>6</sup> *E I du Pont Nemours & Co v UK Intellectual Property Office (UKIPO)* [2009] EWCA Civ 966. The Court of Appeal allowed the appeal against the UKIPO's decision to refuse the application, thereby bringing the outcome in the UK into line with that in other states where the corresponding SPC term extensions have been granted.

<sup>7</sup> Regulation (EC) No 1901/2006, Article 52(2)

<sup>8</sup> UK Intellectual Property Office decision BL/O/108/08

<sup>9</sup> By the German Federal Patent Court in *Sitagliptin* (15 W (pat) 36/08) - session of 28th January 2010.

<sup>10</sup> Regulation (EC) No 1901/2006, Article 37

<sup>11</sup> Regulation (EC) No 141/2000, Article 8

<sup>12</sup> Regulation (EC) No 1901/2006, Article 38

<sup>13</sup> Regulation (EC) No 1901/2006, Article 36(5)

<sup>14</sup> *E I du Pont Nemours & Co v UK Intellectual Property Office (UKIPO)* [2009] EWCA Civ 966

<sup>15</sup> Regulation (EC) No 1901/2006, Article 49