Supplementary protection certificate for medicinal products

2018/0161(COD) - 28/05/2018 - Legislative proposal

PURPOSE: to amend Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: a **supplementary protection certificate** (SPC) is an intellectual property right available in EU Member States that extends by up to five years the legal effects of a reference patent on a medicinal product that has been authorised by national or European regulatory authorities. A harmonised SPC system is sought to compensate for the loss of effective patent protection due to the time required in order to obtain marketing authorisation (including research and clinical trials). The EU legislation applicable to SPCs on medicinal products is Regulation (EC) No 469/2009.

Reliance on SPC protection is significant and increasing. At the same time however, EU and global pharmaceutical markets are undergoing profound changes. Global demand for medicines has increased massively.

Alongside this, there is a shift towards an ever-greater market share for generics and biosimilars.

Although the EU has been a hub for pharmaceutical research and development (R&D) and production, its competitive position is under threat today. While Europe's trading partners are increasingly involved in the manufacturing of generics and biosimilars, EU-based manufacturers of generics and/or biosimilars face a significant problem: during the SPC period of protection of the product in the EU, they cannot manufacture for any purpose, including export outside the EU to countries where SPC protection has expired or does not exist, while manufacturers based in those non-EU countries can do so.

This competitive disadvantage entails a risk of delocalisation of manufacturing outside of Europe, loss of investment opportunities, and a brake on further innovation and job creation in Europe. The certificate also makes it more difficult for EU manufacturers to enter the EU market immediately after its expiry, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed.

The Commission proposed to amend the Union's legislation on Supplementary Protection Certificates for medicinal products by introducing a so-called **manufacturing exemption for export purposes** (manufacturing waiver).

In its resolution of 26 May 2016 on the single market strategy, the European Parliament endorsed the need to take action on the EU SPC regime and urged the Commission to introduce and implement by 2019 **an SPC manufacturing waiver** to boost the competitiveness of the generics and biosimilars sector, but without undermining the market exclusivity granted under the SPC regime in protected markets.

IMPACT ASSESSMENT: the preferred option is the introduction of a targeted and narrow exception to Regulation (EC) No 469/2009. This option is expected to enhance the competitiveness of EU-based

generic and biosimilars manufacturers in terms of exports during the SPC term, resulting in additional net sales of EU pharmaceuticals of up to EUR 1 billion per year. EU patients and health authorities would benefit from a strengthened and more timely supply of medicines (e.g. in terms of diversification of the supply). Additional savings to public spending in Member States on pharmaceuticals, potentially of the order of upwards of 4%, could materialise from increased competition between generics and biosimilars manufacturers in EU markets following SPC expiry in the Union.

CONTENT: the Commission proposes a targeted amendment to Regulation (EC) No 469/2009 on the supplementary protection certificate for medicinal products.

Concretely, the proposal:

- **it introduces an exception**, to enable manufacturers of generics and biosimilars to manufacture such medicines for the purpose of exporting them outside the EU during the SPC protection term. This waiver will remove the competitive disadvantages EU-based manufacturers of generics and biosimilars are currently facing. This proposal leaves SPC protection fully intact as regards placing products on the EU market. SPC holders will keep their market exclusivity in Member States during the full SPC protection term;
- **provides for 'anti-diversion' safeguards**, notably a requirement to notify, *ex ante*, such manufacturing to independent national public bodies (which will hold the relevant information in a publicly accessible register) along with labelling requirements for products that are exported and due diligence requirements on the manufacturer vis-à-vis persons in its supply chain;
- **makes the exception subject to the following conditions**: the exception will apply only to SPCs that have not yet been granted, and only after a transitional period to accommodate pending applications. This transition will allow market players to take account of the new situation when making investment decisions. It will also give national authorities enough time to set up their arrangements for receiving notifications of the intention to make use of the manufacturing waiver.