Supplementary protection certificate for medicinal products

2018/0161(COD) - 11/06/2019 - Final act

PURPOSE: to stimulate the competitiveness of European producers of generic medicines and biosilimentaires products.

LEGISLATIVE ACT: Regulation (EU) 2019/933 of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

CONTENT: this Regulation amends Regulation (EC) No 469/2009 in order to remove the competitive disadvantages faced by generic and biosimilar manufacturers established in the EU compared to manufacturers established outside the EU on world markets.

Supplementary Protection Certificates (SPCs) are intellectual property rights that extend (by a maximum of five years) the patent protection of medicines that require extensive testing and clinical trials before they are allowed to be placed on the EU market. SPCs may put producers of generic and biosimilars medicines established in Europe at a disadvantage compared to companies established in third countries, which undermines innovation and job creation in Europe.

Indeed, during the SPC period of protection of the product in the EU, EU-based manufacturers of generic and/or biosimilar-related products cannot currently manufacture for any purpose, including export outside the EUto countries where SPC protection has expired or does not exist, while manufacturers based in those non-EU countries can do so.

Derogation for the supplementary protection certificate for medicinal products (SPC)

The Regulation introduces an exception to the protection granted to an original medicinal product by a protection certificate for export and/or storage purposes.

The aim of this Regulation is to promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of generics and biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets.

This Regulation shall also allow such makers to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired (‘EU day-one entry’).

Effects of the certificate

Waivers shall only apply if:

- generics or biosimilars are produced exclusively for export to third countries where the protection of the original medicinal product does not exist or has expired or for storage purposes during the last six months of the CCP's validity;

- the maker, through appropriate and documented means, notifies the authority in the Member State in which that making is to take place, and informs the certificate holder, of the required information no later than three months before the start date of the making in that Member State,

- the maker has duly informed all parties involved in the marketing of the product;

- the maker has affixed to the packaging of the product the specific logo provided for in the Regulation, which clearly indicates that the product is intended solely for export to third countries

Information to be provided

The information to be provided by the maker shall be as follows:

- the name and address of the maker;

- an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

- the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

- the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; and

- for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

The information provided to the certificate holder shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

Member States may require that the certificate be subject to the payment of annual fees.

Application

Until 1 July, 2022, the amending regulation will affect only SPCs that are applied for on or after the date of entry into force of the regulation. From then on, the regulation will also affect SPCs applied for before the entry into force of the regulation, but which have become effective after the entry into force of the regulation.

ENTRY INTO FORCE: 31.6.2019.