Supplementary protection certificate for medicinal products

2018/0161(COD) - 17/04/2019 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 572 votes to 63, with 22 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

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

The amendments to Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the Supplementary Protection Certificate (SPC) for medicinal products shall aim to boost the competitiveness of European producers of generic medicinal products and biosilimar products by introducing an exception for manufacturing for export purposes (manufacturing waiver) to the protection granted to an original medicine by a supplementary protection certificate (SPC).

Thanks to the waiver, EU-based makers of generics and biosimilars will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

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').

Information to authorities and SPC holders

The exception shall apply if:

- generics or biosimilars are produced exclusively for export to third countries where protection of the original medicine does not exist or has expired or for storage purposes during the last six months before the expiry of the certificate;

- the maker has provided the information required by the regulation to both the authorities of the member state of production and to the holder of the SPC at least three months in advance;

- the maker has duly informed all those involved in the commercialisation of the product covered by the exception that the product can be put on the market only outside the EU;

- the maker has affixed to the packaging of the product the specific logo provided for by the regulation indicating clearly that it is only for export.

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;

- 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.

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.