Supplementary protection certificate for medicinal products

2018/0161(COD) - 29/01/2019 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Legal Affairs adopted the report by Luis de GRANDES PASCUAL (EPP, ES) 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.

As a reminder, the Commission proposal aims to amend Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate (SPC) for medicinal products, with the aim of introducing the so-called 'export manufacturing waiver to SPC', thanks to which, in the future, EU-based companies will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the certificate, if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows.

Objective

The amendments introduced clarify that only exports to third countries outside the Union would be covered by the exception and define more precisely the objectives that this proposal should achieve, namely to promote the competitiveness of generics and biosimilars producers in the Union, to enhance growth and job creation in the internal market and to contribute to a wider supply of products under uniform conditions.

This should enable producers to compete effectively on third country markets where complementary protection does not exist or has expired and to ensure EU-Day1 Entry of generic and biosimilar medicines into the Union market after expiry of the relevant supplementary protection certificate.

The amending Regulation would aim to eliminate the unintentional effects of a supplementary protection certificate, but not to the detriment of any other patent or intellectual property right existing in a Member State, so as to allow making of generic products, biosimilars and active ingredients for the purpose of export to third countries and of entry into the Union market immediately after expiry of the relevant supplementary protection certificate.

Information to authorities and SCP holders

Manufacturers would be required to provide certain information to the authority that issued the SPC in the Member State where manufacture is to take place. The manufacturer established in the Union should check that there is no protection or that it has expired in the exporting country, or that it is subject to limitations or exemptions in that country. To this end, Members have inserted a new standard form for notification to the authority in Annex I of the proposal.

In order to ensure a more robust and transparent implementation of the safeguards provided for in the Commission’s proposal, Members introduced an additional requirement to inform directly the SPC holders of the intention to manufacture a product under the exception.

This obligation is without prejudice to the protection of confidential or commercially sensitive information and aims at ensuring that the SPC holders have access to the necessary information in order to assess whether the conditions to benefit from the exception are respected and there are no infringements of their intellectual property rights.

Manufacturing acts would only fall within the scope of the exception if the manufacturer (i) has sent a notification to the competent industrial property authority of the Member State of manufacture and (ii) has informed the holder of the issued supplementary protection certificate of the name and address of the manufacturer and the number of the certificate in the Member State at the latest three months before the date of commencement of manufacturing in the Member State concerned.

Combating diversion

Members specified that the Regulation should not affect the rules on the unique identifier provided for in Commission Delegated Regulation (EU) 2016/161.

In the case of products manufactured for export to third countries, the manufacturer should ensure that a logo, in accordance with the model set out in Annex - I bis, is affixed to the outer packaging of the product or medicinal product.

Application

The exception provided for in the Regulation should only apply to certificates for which the basic patent expired on or after 1 January 2021. The date in question takes into account the need to provide for a sufficiently long transitional period to ensure that holders of supplementary protection certificates are not deprived of their acquired rights. The Regulation should not have any retroactive effect.