Supplementary protection certificate for medicinal products

On 13 February 2019, Parliament and Council negotiators agreed on amending the EU rules on patent protection for generic and biosimilar medicines. Parliament is due to vote on the compromise text, approved by its Committee on Legal Affairs (JURI), at its second plenary session in April.

Background

Supplementary Protection Certificates (SPCs) are intellectual property rights that aim to offset the loss of effective patent protection for medicines that occurs owing to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval. The Commission found that the current EU SPC rules – granting patent protection to medicines in the testing and clinical trial phase – has a negative impact on EU-based manufacturers of generics and biosimilars, who are prohibited from manufacturing and exporting their products during the original medicine's SPC period of protection. This puts them at a major competitive disadvantage compared with manufacturers based in non-EU countries.

European Commission proposal

In May 2018, the Commission proposed to amend Regulation 469/2009 in order to introduce an exception to SPC protection for some medicinal products. The objective of the proposal is to provide EU-based companies with a way to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of validity of the supplementary protection certificate, providing this is done exclusively for export to a non-EU market where protection has expired or never existed. According to the Commission, this reform is necessary to boost the competitiveness of the EU's generic and biosimilar industries on global markets, and improve access to high quality and affordable medicines in the EU.

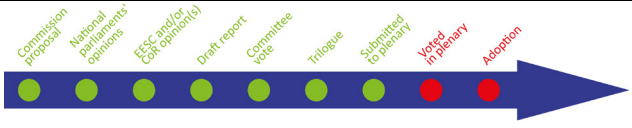
European Parliament position

The JURI committee adopted its report in January 2019. Following trilogue negotiations, the co-legislators agreed rapidly on a compromise text, on 14 February 2019. While the Commission initially proposed an exception for export purposes only, the compromise text introduces an exception for generics or biosimilars produced for export to third countries where protection of the original medicine does not exist or has expired, but also for stockpiling purposes (i.e. for supply on the first day when the patent protection expires). Makers of generics and biosimilars are subject to some notification requirements, and the regulation envisages a regular five-yearly evaluation.

The compromise, which has the support of the generic medicines industry, is expected to generate at least €1 billion per year in net additional export sales and to create new jobs in the pharmaceutical sector over the next 10 years. Furthermore, civil society organisations believe the new provision on stockpiling will allow for better access to quality and affordable medicines. Some stakeholders, however, stress that the measures proposed will have a significant impact on medical innovation, and warn that the political compromise on stockpiling will have adverse effects.

The agreement was endorsed by the JURI committee and by Coreper in February 2019, and is now subject to formal approval by the European Parliament and the Council.

First-reading report: 2018/0161(COD); Committee responsible: JURI; Rapporteur: Luis Grandes Pascual (EPP, Spain)



EPRS | European Parliamentary Research Service
Author: Tambiama Madiega, Members' Research Service
PE 637.902 – April 2019