EU Commission releases proposal for pharma waiver to boost generic drug exports

The EU Commission has released a new proposal introducing a manufacturing waiver for exports. It aims at leveling the playfield for EU-based and non-EU-based manufacturers of generic and biosimilar medicinal products. The Commission believes this can help boost investments and create more than 20.000 new jobs in the EU over the next ten years in generics and biosimilars production.

In April 2017 the European Commission awarded Copenhagen Economics the task of carrying out a study entitled 'Study on the economic impact of supplementary protection certificates (SPC), pharmaceutical incentives and rewards in Europe'. Now the EU Commission has released their final report representing the results of the study. The study gives an insight into the economic impact of SPCs and the pharmaceutical incentives and rewards in the European Union. While the protection for medicinal products in the EU is one of the strongest worldwide, the study shows a decrease of the effective protection period from 15 to approximately 13 years since 1996. New products are often only available in larger and wealthier European countries and not at the same time.

But while SPCs were introduced to compensate for the loss of effective patent protection, they also restrict EU-based manufacturers from making products for countries outside the EU where SPC protection has expired or doesn´t exist. That issue shall be addressed by the proposed export manufacturing waiver.

This proposal does not compromise SPC protection itself but would enable EU-based manufacturers to compete with non-EU-based manufacturers on eye level. For better transparency and to avoid diversion onto the Union market, businesses intending to manufacture for export purposes will be under an obligation to notify the competent authorities, and the information will be made public.

Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe
https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf

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
https://ec.europa.eu/docsroom/documents/29462

Summary of the replies to the public consultation on supplementary protection certificates and patent research exemption for sectors whose products are subject to regulated market authorizations
https://ec.europa.eu/docsroom/documents/29464