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NOTE

From:	Presidency
To:	Council
No. Cion doc.:	9485/18 + ADD1 + ADD2 + ADD3 + ADD4
Subject:	Proposal for a Regulation concerning Supplementary Protection Certificates for Medicinal Products - Information from the Presidency on the state of play

Supplementary Protection Certificates (SPCs) are intellectual property rights that extend patent protection (for up to five years) for medicinal products that must undergo lengthy testing and clinical trials before being authorised to be placed on the EU market. The aim of SPCs is to avoid that the term of patent protection would in actuality be curtailed by the period that elapses between the date of filing of the patent application and the date of the authorisation to place the product on the market in the EU.

The current EU SPC rules may, however, have a negative impact on EU based manufacturers of generics and biosimilars since they cannot - during the SPC period of protection of the product in the EU - manufacture their products to countries where SPC protection has expired or does not exist, while manufacturers based in those non-EU countries can do so.

With a view to addressing this imbalance, the Commission submitted a proposal¹ on 28 May 2018, which was presented to the Competitiveness Council on the same day.

¹ Doc. 9485/18 + ADD1 + ADD2 + ADD3 + ADD4.

This Commission proposal proposes an **SPC manufacturing waiver for export purposes**, that would enable EU-based manufacturers to produce generics of the medicine protected by the SPC provided their production is only for export to non-EU countries. This measure aims at creating a level playing field between manufacturers of generic and biosimilar medicines based in the EU and their competitors based in third countries where SPC protection does not exist (Brazil, Russia, India and China). In 2020, when patents for a number of medicinal products are expected to expire and would become subject to competition by the generics/biosimilar industry.

On the side of the European Parliament, adoption of the report at Committee level (JURI) is pending and is expected to occur in January 2019.

On the basis of the intensive discussions held in the Council Working Party on Intellectual Property, the Austrian Presidency prepared several compromise proposals, the latest of which is set out in doc. 14647/18 and was submitted to the Intellectual Property Working Party for discussion at its meeting on 28 November 2018.

The Presidency compromise texts met with a large amount of support among delegations, but a few important issues are still unresolved.

The Presidency will now take on board the outcome of this latest meeting and consult closely with delegations and the Commission in order to determine the best way forward for this urgent and important file.
