EUROPEAN COMMISSION

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Dear Chair,

The Commission would like to thank the Poslanecká sněmovna for its Opinion 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 {COM(2015) 317 final}.

In proposing this measure, the Commission has made good on its promise in the October 2015 Single Market Strategy, an initiative that was endorsed by the European Parliament in the COMI report of May 2016. In its report, the European Parliament called for an supplementary protection certificate waiver to be put in place by 2019, without undermining the market exclusivity granted under the supplementary protection certificate regime in protected markets.

As stressed by the Commission when coming forward with this proposal, the Commission remains fully committed to strong intellectual property rights and supplementary protection certificate protection and enforcement both in the Single Market and in third countries.

The main objective of the proposal is to remove the current competitive disadvantage faced by EU-based manufacturers of generics and biosimilars vis-à-vis non-EU based manufacturers, and thus support the European Unions' companies in taking part in, and becoming leaders of, the expanding global market for these products. The Commission proposal does not affect in any way the market exclusivity that supplementary protection certificate holders enjoy in the Single Market during the term of the certificate.

The Commission believes that this objective is fully compatible with maintaining Europe as an attractive location for research and innovation for innovative medicines. The proposal is expected to result in additional sales of EU-made pharmaceuticals (ca. 1 billion EUR/year) and create an estimated 20,000 to 25,000 jobs.

Mr Ondřej BENEŠÍK
Chair of the Committee for
European Affairs of the
Poslanecká sněmovna
Sněmovní 4
CZ – 118 26 PRAGUE 1

cc *Mr Radek VONDRÁČEK*
President of the
Poslanecká sněmovna
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In response to the more specific comments in the Opinion, the Commission would like to refer the Poslanecká sněmovna to the enclosed annex.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Poslanecká sněmovna and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Frans Timmermans
First Vice-President

Elżbieta Bieńkowska
Member of the Commission

ANNEX

The Commission has carefully considered the issues raised by the Poslanecká sněmovna and would like to offer the following observations:

*The Commission takes good note of the opposition of the Poslanecká sněmovna to the proposal (**Conclusion 2**) and of its support for the Czech Government's framework position (**Conclusion 3**).*

*As mentioned in the Explanatory Memorandum to the proposal, the appropriate legal base (**Conclusion 4**) for this initiative is Article 114 of the Treaty on the Functioning of the European Union, i.e. the legal basis of the instrument being amended, namely Regulation (EC) No 469/2009. The Impact Assessment accompanying the proposal further explains that, while the envisaged action does have an effect on the trade relations between the European Union and third countries, the centre of gravity of the proposal is the competitiveness of manufacturers of medicines within the internal market.*

*The Commission considers the proposal to be a balanced, proportionate and well-calibrated adjustment to the current supplementary protection certificate system, which keeps intact the exclusive rights that supplementary protection certificate holders enjoy in respect of the marketing of innovative medicines in the European Union during the supplementary protection certificate term. The Commission listened carefully to the expectations and concerns of stakeholders, and believes that the final text represents a fair balance between the different interests at stake, notably due to the limited scope of the waiver. The proposal also includes strong and robust safeguards against possible abuse or risk of infringement of certificates (**Conclusion 5**), which the Poslanecká sněmovna has rightly signalled as being important to adequately address. In this context, the proposal – and the Impact Assessment – pay specific attention to recalling that there are no derogations from any applicable EU rules on intellectual property rights enforcement and medicinal products.*

*The Commission considers that protection of intellectual property rights – and the incentive to innovation it provides – is of crucial importance for the the European Union's pharmaceutical industry, and thus fully agrees with the Poslanecká sněmovna on the importance of allowing innovative firms to recoup investments made for research and development of authentic medicines (**Conclusion 6**). In the options considered in the Impact Assessment, the impact of the waiver on all stakeholders, in particular originator firms, on the competitiveness of the European Union as a whole and on innovation, delocalisation/relocalisation, small and medium-sized entreprises and patients was thoroughly assessed. The Impact Assessment showed that the overall benefit to the European Union's pharmaceutical ecosystem could be upwards of EUR 1 billion per year over ten years, delivering 20-25,000 extra jobs within the European Union. The proposal also complements the efforts of the Union's trade policy to ensure free and fair trade, which strives to ensure equivalent supplementary protection in as many of our trade partners as possible.*

*It is worth recalling that the European Union's supplementary protection certificate system is arguably the strongest such regime in the world, and this proposal – which is essentially a fine-tuning of the current system – does not change the core of the supplementary protection certificate system, nor the duration of the protection provided by supplementary protection certificates, which, as the Poslanecká sněmovna rightly points out, is only one of the criteria taken into consideration in the choice of the place of production of generic and biosilimar medicinal products (**Conclusion 7**).*

The points made above are based on the initial proposal presented by the Commission, which is currently in the legislative process involving both the European Parliament and the Council.