PARLAMENT ČESKÉ REPUBLIKY
Poslanecká sněmovna
předseda výboru pro evropské záležitosti
Mgr. Ondřej B e n e š í k

Prague, 10th September 2018

Dear Mr. President,

I would like to inform you about the opinion of the Committee for European Affairs of the Chamber of Deputies of the Parliament of the Czech Republic

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(2018)317 final, Council Code 9485/18.

The respective document was included in the agenda of the 15th session of the Committee for European Affairs and was scrutinized on 5th September 2018. According to the Rules of Procedure of the Chamber of Deputies the President of the Office of Industrial Property was present at the session to introduce the preliminary Government's Framework Position.

After the hearing of the rapporteur's review and after the discussion the Committee has adopted the resolution No. 126 **in the context of the Political Dialogue** which is enclosed to this letter.

Yours sincerely

Enclosure

Mr. Jean-Claude Juncker
President of the European Commission
B r u s s e l s

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PARLIAMENT OF THE CZECH REPUBLIC
Chamber of Deputies
Committee for European Affairs

Resolution No. 126

15th Session on 5 September 2018

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(2018)317 final, Council Code 9485/18/

Conclusions of the Resolution:

Committee for European Affairs

1. **discussed** 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(2018)317 final, Council Code 9485/18;
2. **disagrees** with the Proposal for a Regulation in its current form;
3. **supports** the Czech Government's Framework position on the draft regulation;
4. **expresses** doubts whether Article 114 TFEU (it confers authority to EU to adopt measures for the establishment and functioning of the internal market) provides a sufficient legal basis for the adoption of the Proposal for a Regulation authorizing production exclusively for export to non-EU markets;
5. **is afraid** that despite the measures in the Proposal for a Regulation, the Proposal may increase the risk of infringement of the EU's supplementary protection certificate;
6. **thinks** that the legislation contained in the Proposal for a Regulation could complicate the return of investments spent on research and development of original medicines;
7. **is of the opinion** that the duration of protection provided by a supplementary protection certificate is only one of the criteria that manufacturers of generic and biologically-relevant medicines take into account when choosing their place of production, in addition to, for example, lower production costs in some third countries;
8. **authorizes** the Chairman of the Committee for European Affairs to forward this resolution to the President of the European Commission **in the context of the Political Dialogue**;
9. **submits** the documents along with their Resolution and the Government's Framework Position to the Committee on Health for Information.