Bulgarian Generic Pharmaceutical Association

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To
Mr. Boyko Borissov,
Prime Minster of the Republic of Bulgaria

OBJECT: LEGAL STUDIES IN SUPPORT OF A COMPRHENESIVE AND USABLE SPC MANUFACTURING WAIVER

Dear Prime Minster,

As you are already aware, on 28th May 2018, the European Commission launched a narrow and targeted legislative proposal for a **SPC manufacturing waiver** to correct the unintended effects of the SPC Regulation which forces generic and biosimilar medicine manufacturers to delocalise pharmaceutical production outside of Europe.

Bulgarian Generic Pharmaceutical Association (BGPharmA) together with Medicines for Europe welcome the long awaited European Commission proposal which outlines the huge potential benefits for Europe in terms of access to medicines for patients, 3,1 Billion € in savings for national healthcare budgets and opportunities to create 25.000 manufacturing direct jobs and boost SMEs. All these benefits are clearly stated in several European Commission official studies[1].

However, our members believe that the current proposal, as it stands today, will not harvest any of the benefits highlighted above. To ensure that Europe truly benefits from this proposal and to have a system which works and delivers on the promised jobs and growth in Europe, the following equally important improvements should be taken into account:

- Introduction of an "EU day-1 launch"
- Application of the waiver to current SPCs
- Remove the need to disclose commercially sensitive information

We are writing to you specifically to share two legal studies developed by two distinguished international law firms, respectively Crowell and Moring and Pinsent Masons.

The first study, presented by Crowell and Moring, considers whether, in the context of supplementary protection certificates ("SPCs"), **Day1 launch** (a stockpiling waiver) is in accordance not only with the applicable EU legislative framework but also with existing free trade agreements ("FTAs") that the European Union negotiated with third countries, particularly the EU-Canada Comprehensive Economic and Trade Agreement ("CETA"). This analysis concludes that the introduction of a SPC stockpiling waiver would not contravene either the applicable EU legislative framework or the European Union's obligations to its trading partners under negotiated FTAs. In addition, the study proves that the European Commission approach to exclude the **immediate applicability** of the SPC manufacturing is unwarranted. In fact, a full SPC manufacturing waiver, including stockpiling for export and EU day-1 launch without unnecessary and unjustified limitations, would ensure a high level of protection of IP

[1] "Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe" - Charles Rivers Associates Study
Impact Assessment accompanying the document 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