



Bulgarian Generic Pharmaceutical Association

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

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

Dear Prime Minister,

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 studies¹.

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

rights pursuant to the Charter of fundamental rights of the European Union while achieving a better balance with the other fundamental rights of access to health care and to conduct a business.

The second study, presented by Pinsent Masons, focuses on the anti-competitive effect of **unjustified and unnecessary disclosure of confidential information**. As currently drafted, the notification requirement imposes the public disclosure of commercially sensitive and confidential information (CCI) which is part of a business plan of a company and the publication of which would hinder competition in the market. The disclosure of confidential business information to the SPC holder and/or other competitors (both generic and originator competitors) would act against the interests of the manufacturer concerned as this information could be misused to limit generic or biosimilar competition and will strongly question and limit the intended use of the waiver, acting against the spirit of this legislation.

If the text of the proposal remains as it is now, without taking into account all these three key elements, the manufacturing waiver will not be usable for generic and biosimilar medicine manufacturers and it would not generate the promised economic value and expected healthcare savings.

As co-legislator in the Council, your country will play a key role in ensuring that this measure delivers for Europe. We kindly request that you support a comprehensive and usable SPC manufacturing waiver with the inclusion of Day1 launch, the immediate applicability of the proposal and the removal of the requirement to disclose commercially sensitive business information within the priorities of your national position on this proposal.

Enclosed you will find the Medicines for Europe position paper and the two legal studies developed respectively by Crowell and Moring and Pinsent Masons. We remain at your disposal for any further clarification on this crucial issue for the generic and biosimilar medicines industry.

We thank you again for your support which is vital for the competitiveness of our industry and its ability to supply European patients with affordable quality medicines and contribute to a vibrant manufacturing sector in Europe.

Yours faithfully,

Nikolay Hadjidenchev
Chairman
BGPharma

