efpia
European Federation of Pharmaceutical Industries and Associations

To: Commissioner Elżbieta BIEŃKOWSKA
Internal Market, Industry, Entrepreneurship and SMEs
European Commission
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Cc: Lowri Evans, Director General, DG Grow
Antti Peltomäki, Deputy Director-General, DG Grow
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Subject: EFPIA response to request for information on the SPC Manufacturing Exemption impact

Brussels, 13 February 2018

Dear Commissioner Bieńkowska,

We would like to follow-up on the discussion that we had together with our EFPIA President, Mr. Stefan Oschmann, and a delegation of our Board members on 30th January this year. During that meeting and in our subsequent letter to you, we raised the concern that introducing an SPC manufacturing exemption risks harming the innovative pharmaceutical industry in Europe, and that a further structural and holistic analysis of the innovative, biosimilar and generic industries is necessary to accurately consider the impact of an SPC exemption. We are happy to comply with your request for further information on the impact that the proposed SPC manufacturing exemption may have on the EU's trade balance and took note of your reflections on the so-called "first mover" advantage for Canadian generics. You asked that any further submission of information be made within two weeks.

With regard to the European trade balance, we have reviewed various studies published in relation to a potential SPC manufacturing exemption and our conclusion is that the impact of an SPC manufacturing exemption on the EU trade balance remains uncertain or could even be negative. Existing evidence - the Pugatch Consilium, in their study *"Unintended and Unattended Consequences: The Opportunity Costs of Reducing Exclusivity Rights for Intellectual Property",* estimates that the impact on EU export sales would be negative as the European innovative biopharmaceutical industry could stand to lose between € 1.09 bn (USD 1.34 bn) and €1.85 bn (USD 2.27 bn). This negative effect on the trade balance is further illustrated by the QuintilesIMS study on *"Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU"* which shows that the SPC manufacturing exemption could result in replacing more high-value innovative exports with lower value generics. Consequently, this would cause a worsening in the EU's trade balance. The conclusions drawn in the abovementioned studies have also been confirmed in the Office of Health Economics (OHE) report, which we have shared as part of our response to the Consultation.

With regard to the proposed "first mover" advantage, based on the published studies, it can be concluded that such an advantage for small molecules would depend on the market to which generics would be exported and that for biosimilars there is no evidence of a first mover advantage. For example, generics exports to Russia and Turkey (two markets identified as potential export targets) would face a range of trade barriers, price levels,


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ability to manage local commercial relations and local incentives that give local generic companies a significant advantage. In Canada, Certificates for Supplementary Protection (CSPs) were introduced via Canadian legislation in September 2017, following CETA's provisional entry into force. The export exemption under CETA will however not have effect for nearly 10 years, since the newly introduced SPC-like protection will only start at the end of the patent life of certain products launched in Canada after September 2017. Even then, any "advantage" would depend on a variety of other factors beyond the exemption.

EFPIA and its membership remain highly concerned that numerous uncertainties and gaps remain in the analysis of the short and long-term impact of a legislative provision such as a potential SPC manufacturing exemption. We have analysed the different reports and studies on the SPC manufacturing exemption, and conclude that key questions that could inform the actual impact of the issue at hand, are left unexplored and unanswered such as the (non)treatment of innovation and innovation-related incentives and the lack of analysis of any displacement effects of an exemption. We attach a gap analysis on the issues that we believe need to be further examined before an informed and balanced decision can be taken on an SPC manufacturing exemption. These issues would need to be addressed in the spirit of ensuring evidence-based policy-making that takes account of all available information and respects the Innovation Principle. Better Regulation would also suggest that where uncertainties or unknown elements remain, these elements need further exploration.

EFPIA therefore strongly recommends that the Commission undertake a robust analysis of the full eco-system of the pharmaceutical sector that can address the questions in the attached gap analysis to ensure that any decision on an SPC manufacturing exemption promotes the global competitiveness of the EU, creates jobs and growth, and ensures a continued contribution of the EU pharmaceutical industry to a positive EU trade balance, in line with the Commission's Industrial Policy Strategy. Furthermore, we believe that such an analysis should assess any potential inconsistencies with existing EU legislation and policy on the overarching incentives system. Finalising the assessment of all policy elements as indicated by the Commission in its roadmap of February 2017 remains crucial. More importantly, all elements of the incentives evaluation should be considered to find a balanced solution for all EU-based manufacturers in support of sustainable innovation.

Thank you for your consideration and for the opportunity to provide you with this information. EFPIA and its members remain at your full disposal for any additional information you may require and continue to be fully committed to delivering on our commitment to patients, society and a strong European economy.

Best wishes,

[redacted]

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Director General

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