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The European Commission's work on the SPC legislation

Dear Secretary General Selmayr,

On behalf of EUCOPE, which gives voice to innovative small and medium-sized enterprises in the pharmaceutical and biotech sector, I wish to express our deepest concerns regarding the potential legislative proposal introducing a manufacturing waiver of Supplementary Protection Certificates (SPCs) for generic and biosimilar companies.

A key ingredient of the EU's framework for protecting intellectual property rights (IPR), the SPC allows the normal patent period to be extended by a further 5 years. Likewise, similar rights are granted in other jurisdictions outside Europe, such as Australia, Japan, South Korea and the United States. As a result, developers of new pharmaceutical products can compensate for delays associated with clinical trials and regulatory approval, thereby guaranteeing return on their investment. Small and mid-sized companies in the biotech sector in particular are very dependent on tools like the SPC, due to the resources they must devote to research and development.

In February 2017, the European Commission launched an impact assessment to explore the possibility of reforming the SPC framework by introducing an exemption or 'waiver' which would allow EU-based manufacturers of generics or biosimilars to already manufacture their products within the period of European SPC patent protection with a view to exporting their products to third countries that have no SPC protection. The belief – which we dispute strongly – is that such a waiver might stimulate speedier entry to the European market for generics and biosimilars, thus improving patients' accessibility to medicines and generating savings in health budgets.

As the impact assessment is in its final stages, we are extremely worried about the knock-on impact of a potential reform on the overall incentives framework for new medicines. An SPC manufacturing waiver could fundamentally undermine and unbalance a proven system that is delivering new life-changing medicines year upon year.

As a trade association representing small and mid-sized businesses, our role in the system is to find new medicines for patients with life-altering and life-threatening diseases. Weakening IP incentives for innovative SMEs weakens Europe's ability to deliver new medicines and compete on innovation. As highlighted at our Breakfast event on 13 March on the topic of SME involvement in EU policy-making, particularly in the context of the possible SPC revision, between 50 to 80% of return on investments is only achieved during the SPC period. While 'big pharma' can divest away from high-risk disease areas to adapt to new regulatory regimes, a legislative measure that seriously undermines SPC protection such as the manufacturing waiver means small and mid-sized companies and start-up biotechs will struggle to gain the start-up capital needed to get their operations off the ground. In the discovery business, small and mid-sized companies are responsible for a high percentage of new molecules developed, which are then commercialized by larger companies. A dilution of the SPC protection will be perceived by potential investors as the starting point of a major curtailment of the incentives system. Consequently, companies will move away from high-risk R&D activities, leaving tens of thousands of European citizens without treatments or cures.The Commission has not taken sufficient account of the impact on jobs that a manufacturing waiver would entail, particularly as regards the possibility of geographical displacement, while over-estimating the alleged benefits of a waiver for European generics and biosimilars, especially given the reality that much of generics manufacturing is moving to developing countries.

In addition to the major detrimental impact on innovation and small and mid-sized companies this initiative may have, we must firmly object to the way the impact assessment has been handled by the Commission. The process has been rushed, lacks thorough analysis of impacts, creates policy incoherence and in which our

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voice was inadequately taken into account, despite numerous letters to the relevant Directorate General and its political hierarchy.

In particular, we must highlight the following defects in the process:

- **DG GROW has conducted consultations in a very rushed fashion that suggests it is using stakeholder input simply to validate a pre-determined position**. This is totally incompatible with the standards of consultation set out in the Better Regulation Guidelines.
- In particular, the Commission has shown **a fundamental disregard for the interests of small and mid-sized businesses**. Despite indications that innovative small and mid-sized companies would be profoundly affected by the introduction of an SPC manufacturing waiver, DG GROW has neglected to apply the SME test required by the Better Regulation Guidelines in order to establish the extent to which a proposal would affect the competitiveness of small and mid-sized companies, their business environment and innovation at large. Worse still, it appears to be discriminating against such companies by prioritising the input of larger market players.
- DG GROW has failed to take account of the **risks of incoherence with other EU policies**, particularly in the area of trade where it has consistently promoted SPC frameworks and the importance of robust IPR protection. It has also **failed to give due consideration to alternative, more proportionate policy options** that have already been implemented in Member States such as France; regrettably, a soft law option for the SPC waiver was excluded from the outset in the relevant Inception Impact Assessment[1] and in the subsequent public consultation.

Given the seriousness of the issues set out above as well as the very restricted timeframe, we would appreciate the opportunity to discuss this key file with you, from both a policy and 'Better Regulation' point of view. Please find attached for your consideration two annexes, one explaining in more detail the Better Regulation principles that have not been respected during this process and the other detailing the substantive questions the Commission has not answered in its analysis of the SPC issue. Any supplementary information you may require we will gladly provide.

We sincerely hope that our arguments will be taken on board and that the European Commission does not take any hasty decision on the matter without thoroughly analysing the effects which would generate catastrophic consequences for small and mid-sized companies.

Yours sincerely

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Cc: Commissioner Elżbieta Bieńkowska,
First Vice President Frans Timmermans
Vice President Jyrki Katainen
Commissioner Vytenis Andriukaitis
Commissioner Cecilia Malmström

[1] The Inception Impact Assessment of February 2017 explicitly excluded non-legislative instruments as an option for regulating the issue 3.1 : "*The policy objectives sought by options 3.2, 3.3 and 3.4 could be partially achieved by the non-legislative options described*"