EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

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European Commission
Ms. Elżbieta Bieńkowska
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The European Commission's work on the SPC legislation

Dear Commissioner Bieńkowska,

We are following up on our letter of 24 January 2018 in which we have expressed our growing concerns regarding the potential introduction of a waiver for Supplementary Protection Certificates (SPC).
We had to learn recently that, prior to taking a decision on the way forward, you appear to have given representatives of the large pharmaceutical companies extra time to provide additional data to substantiate the Commission's policy choice. Against the background of good policy-making practice and under consideration that we have voiced our severe concerns on this matter in the above mentioned letter, we feel that this privileges the input of a certain market segment to the detriment of others, in particular small-to-mid-sized companies. It also calls the entire formal consultation process into question.

We therefore have a number of requests:

- First, we would like a clear indication of how the data provided during the consultation was dealt with and how it is being integrated into the final policy choice. It is astonishing to see that a consultation process of 12 weeks was apparently insufficient, yet a policy change will likely be put forward in the coming days or weeks.

- Furthermore, we would like to understand which additional data was requested and which data you feel is missing in order to determine the policy choice. We have on numerous occasions stated that the data, notably the CRA study, was by no means sufficiently solid to justify making such a major policy change and that it would create incoherence within the IP framework as well as between the SPC legislation and other policy fields.

- In relation to the previous points, EUCOPE should be granted at least the same opportunity to provide additional information. You are surely aware that gathering solid data requires time, in particular when compiled by small and mid-sized companies with their very limited resources. We trust, however, that you aim to treat all parts of the pharmaceutical industry equally and do not forego the additional input of small and mid-sized companies for the sake of rushing a policy decision.

We would like to remind you again that the small and mid-sized industry is recognised as the backbone of Europe's economy and to be key in ensuring not only economic growth and job creation but also innovation in the EU. Further development and innovation by our small-to-mid-sized members need to be incentivised with stringent IP protection. Only a a robust legal framework can foster growth and job generation.

Yours sincerely

Dr. Alexander Natz
Secretary General

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