[redacted]

From: [redacted]
Sent: mardi 18 septembre 2018 16:36
To: SEYCHELL Martin (SANTE)
Cc: [redacted]
Subject: Concerns of innovative SMEs regarding the Commission's proposal on SPC manufacturing waiver
Attachments: EBE-SPC-waiver-position-2018-08-02-final.pdf

Dear Mr Seychell,

The European Biopharmaceutical Enterprises (EBE) represents the voice of biopharmaceutical companies of all sizes (small, medium and large) in Europe.

Speaking for innovative SMEs, we are deeply concerned with the European Commission's legislative proposal to introduce a manufacturing waiver for supplementary protection certificate (SPC) for medicinal products. This proposal is likely to reduce the funding that innovative SMEs can secure from investors and reduce their viability. Furthermore, we believe that the proposal will send a negative signal to the rest of world regarding the importance of IP rights in Europe, which are being diminished by this proposal.

Strong IP protection including patents and SPCs are the lifeblood of the innovative biopharmaceutical industry, which largely consists of SMEs. IP protection is critical in ensuring a steady stream of capital invested in biopharmaceutical companies that develop innovative medicines. This is essential to ensure that inventions developed in a lab successfully reach patients. The majority of biopharmaceutical companies are SMEs at pre-profit stage (no marketed product), and thus their research and development activities rely on very large amounts of private sector investment and indeed often public sector investments over many years. Without an economic and institutional environment in Europe that is conducive to entrepreneurship and innovation - including a strong, predictable, and enforceable protection for patented inventions - investors will shy away from investing in biopharmaceutical innovation in the EU, reducing the ability of SMEs to provide solutions for the most pressing medical challenges facing Europe and the world. This comes at a time when biopharmaceutical innovation increasingly relies on the innovation delivered by SMEs.

At EBE we feel very strongly that an SPC manufacturing waiver would create uncertainties in terms of market potential for innovative biopharmaceutical SMEs, making it more difficult for them to access financing. Furthermore, EBE believes that allowing generic and biosimilar drug makers to manufacture for export before the SPC expires would negatively impact competitiveness of innovative biopharmaceutical SMEs. While the waiver may have a limited positive impact for the biosimilar and generic industry, it will be detrimental to the biopharmaceutical innovation in the EU on the long term.

On behalf of our President, Dr [redacted], who has already spoken up on the topic, please find attached our full considerations, available on our website at https://www.ebe-biopharma.eu/publication/ebe-view-on-the-spc-manufacturing-waiver/ respectively https://www.ebe-biopharma.eu/wp-content/uploads/2018/08/EBE-SPC-waiver-position-2018-08-02-final.pdf.

We would value an opportunity to discuss these important considerations with you at your earliest convenience, in order to maintain a European environment that is conducive to research and innovation through innovative small and medium-sized biopharmaceutical companies for the benefit of patients and European citizens in general.

We look forward to your response and remain,

Faithfully yours.

Best regards,

[redacted]
Executive Director
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