CONFÉDÉRATION DES PME

Le Président

Elżbieta Bieńkowska
Commissioner for Internal Market, Industry,
Entrepreneurship and SMEs
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels, Belgium

Puteaux, January 23, 2018

Dear Commissioner Bienkowska,

The European Commission published a consultation which aims to establish an exemption for the production of products under the protection of a Supplementary Protection Certificate in order to build up stocks for commercialization as soon as the CPC falls or for purposes to markets where the specialty is not protected by a CCP.

CPME believes that in line with the plan set in the inception impact assessment of February 2018, and as requested several times by the European Parliament, a legislative amendment introducing the SPC manufacturing waiver should be proposed by the European Commission as soon as possible in order to allow the European small and medium enterprises (SMEs) to invest in Europe and seize the upcoming opportunities driven by SPC expiries worldwide.

We think that this proposal will create new opportunities for European SMEs.

An SPC manufacturing waiver would enable the European SMEs to compete effectively with global competitors, by increasing manufacturing and R&D in Europe, creating new high skill job opportunities, boosting contract manufacturers and developers of medicines.

As recognized in the study published by the European Commission with the public consultation, the SPC manufacturing waiver would create a level playing field for EU-based developers of generic and biosimilar medicines vis-à-vis non-EU countries (both for export and for EU-market entry purposes), while at the same time keeping a high level of SPC protection in the EU. We understand that the SPC manufacturing waiver is not intended and would not have the effect of undermining the compensation that originator pharmaceutical companies seek for marketing approval delays in Europe. As shown in the study published by the Commission, the extremely positive benefits of an SPC manufacturing waiver would include EUR9.5 Billion additional net sales for the EU pharma industry, 25.000 new direct jobs in

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Europe, EUR3.1 billion savings for EU healthcare budgets deriving from increased competition. Most importantly, the SPC manufacturing waiver would particularly benefit those SMEs that lack resources to manufacture outside Europe before the SPC expiry. With the SPC manufacturing waiver, contract manufacturing would no longer be outsourced.

With no resultant cost to holders of European SPCs, the only practical change would be the insourcing of manufacturing and development in the European Union. Forbidding manufacturing and export during the SPC period does not benefit SPC holders in Europe and prevents faster and bigger access to European medicines in developing and less developed countries.

As stressed at the Competitiveness Council meeting of 29 May 2017, Europe needs a strong industrial policy stimulating manufacturing in Europe and it is appreciated that the European Commission has adopted most of the announced measures of the Single Market Strategy of 2015 and is committed to deliver the remaining initiatives by the end of 2017.

We hope to see rapid progress in the next few months in the introduction of an SPC manufacturing waiver to boost SMEs in Europe.

Yours sincerely,

François Asselin