Commissioner Elżbieta BIEŃKOWSKA
Internal Market, Industry, Entrepreneurship and SMEs
European Commission
Rue de la Loi 200 / Wetstraat 200
1040 Bruxelles / Brussel

Brussels, 09th October 2017

URGENT MEETING REQUEST: Supplementary Protection Certificate (SPC) Manufacturing Waiver

Dear Commissioner Bieńkowska,

On Tuesday 10th October Medicines for Europe will formally nominate Marc Alexander Mahl as new President. Mr. Mahl is the Executive Vice President Business Unit for Generic Drugs at Fresenius Kabi, a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition.

President Mahl would be honoured to urgently meet you to discuss, among other crucial dossiers for our sector, the major priority for European generic and biosimilar manufacturers. As you know, the European generic and biosimilar medicines industry needs urgent action from the European Commission to introduce an SPC Manufacturing Waiver.

As outlined in the Single Market Strategy of the European Commission in October 2015 and confirmed in the inception impact assessment (February 2017) "*Optimising the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations*" the SPC Manufacturing Waiver is a key element of the Roadmap. A public consultation has been announced in the first half of 2017 and it was clearly stated that a legislative proposal could follow a final impact assessment in Q4 2017.

As announced last Wednesday 27 September by Lowri Evans, Director General for Internal Market, Industry, Entrepreneurship and SMEs, at the breakfast organized by the Small and Medium Enterprises Intergroup of the European Parliament on "Boosting SMEs through the Supplementary Protection Certificate (SPC) Manufacturing Waiver", the event can be considered a pre-consultancy phase as the official Public Consultation on the SPC manufacturing waiver, that is very imminent.

The introduction of the SPC manufacturing wavier would fix the unintended effects of the SPC Regulation and facilitate investments in high skill jobs in several European countries and would allow European manufacturers to compete fairly with other global players. Boosting investments in European manufacturing is even more fundamental when world powers around are putting industry at the top of their political agendas.

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We cannot afford to lose concrete investments in Europe today. As announced in the recent Industrial Policy strategy of the European Commission, Europe needs more job opportunities and real economic growth. We believe that the SPC manufacturing waiver, without eroding SPC protection in Europe, would stimulate the European generic and biosimilar medicines industry to invest in the development of medicines in Europe in order to provide treatments to patients in unprotected markets from our countries rather than from abroad. Rapidity is vital for a stronger European industry.

I thank you in advance for the attention that you would pose in my request and I remain at your disposal for any further information you may need.

Yours sincerely,

Adrian van den Hoven
Director General
Medicines for Europe

Medicines for Europe

Medicines for Europe (formerly EGA) represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation.