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

Brussels, 3rd October 2018

OBJECT: URGENT CALL TO SUPPORT A COMPREHENSIVE SPC MANUFACTURING WAIVER

Dear Commissioner Bieńkowska,

I am writing this letter to draw your attention to the recent proposal of the European Commission to amend the Regulation (EC) No 469/2009 concerning the Supplementary Protection Certificate for medicinal products by introducing an SPC manufacturing waiver. As stated in several legal and economic studies published by the European Commission, this proposal would have a significant impact on European patients and the entire European Pharmaceutical ecosystem, if applied correctly.

The generic and biosimilar industry, while welcoming the proposal and its rapid approval, has regretfully noticed that the current text proposed by the European Commission will not deliver any of the results announced by all the independent studies published by the European Commission itself, since the waiver would hardly be used.

Indeed, it is essential to amend the text with the following three key points. It is fundamental to bear in mind that all three topics are linked and only by enabling them all together can the SPC manufacturing waiver have the positive effects described by the European Commission.

* *Introduce "Day-1 launch" to produce in Europe for Europe*
* *Remove anti-competitive, unjustified and unnecessary anti-diversion measures*
* *Immediate Applicability while ensuring predictability*

The current text proposed by the European Commission covers only an Export waiver without providing the possibility to European manufacturers to be ready on the so called "**Day-1 launch"**, after the expiry of the SPC protection, to put their products on the European market. The Day-1 provision is an essential condition to resolve the problems created by unintended effects of the 1992 SPC regulation as stated also by the studies published by the European Commission.

As the European Commission asserts, both in the Impact Assessment and in the Explanatory Memorandum that accompany the proposal for generic and biosimilar companies, it is essential to be the first one on the market once competition is open from Day-1:

"These problems faced by EU-based generics and biosimilars manufacturers are aggravated by the dynamics of the generics/biosimilars markets where frequently only the first products to enter markets in a timely way after protection expires capture a significant market share and are financially viable. In the EU, generic firms entering one year after the first generic entrant only capture 11% of the first entrant's market share. Even though the decline in prices for biosimilars is not as steep as in the case of generics, there is a race in this market to launch first, since later entrants have difficulty in gaining market share without a further reduction in prices. For biosimilars, studies show that in 2016, the first biosimilars to reach the market captured over 70% market share (biosimilar volume). Second and third biosimilar entrants captured respectively 30-40% and 5-22% market share."

Without the inclusion of the "Day-1 launch", in order to remain competitive in the European market, European manufacturers would be still forced to delocalise, this would jeopardize the whole purpose of the SPC manufacturing waiver. Where it is not a European company entering the market on Day-1, it will be a Chinese, Indian or US company. SMEs will be always penalised, because they do not have the capacity to delocalise their production.

Furthermore, as legal studies demonstrate with strong evidence, in the context of Supplementary Protection Certificates ("SPCs"), "**Day-1 launch"** is in accordance not only with the applicable EU legislative framework but also with existing Free Trade Agreements ("FTAs") that the European Union negotiated with third countries, particularly the EU-Canada Comprehensive Economic and Trade Agreement ("CETA").

Europe needs to sustain its industry by creating prosperous conditions to boost European manufacturing and incentivise competitiveness when the European market is legitimately open. The current proposal has **huge potential but if the text is not amended, unfortunately, it will not have any positive impact.**

I take advantage of this letter to request an urgent meeting to further discuss with you the content of the proposal.

I remain at your disposal for any information you may need.

Yours sincerely,

[redacted]

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.