Vice President Jyrki Katainen
Jobs, Growth, Investments and Competitiveness
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Vice President Valdis Dombrovskis
Euro & Social Dialogue
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Commissioner Elżbieta Bieńkowska
Internal Market, Industry, Enterprenuership and SMEs
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Vice President Andrus Ansip
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Brussels, 28 September 2017

Dear Vice Presidents, Dear Commissioner,

As you know, the European generic and biosimilar medicines industries need urgent action from the European Commission to introduce an SPC manufacturing Waiver which will create high skilled jobs and economic growth in Europe, as outlined in the Single Market Strategy of the European Commission in October 2015 and confirmed in the inception impact assessment "*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*".

As announced last Wednesday 27 September, at the event 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, which is very imminent.

In this context, over the next few days, a structured dialogue with the Chairs of the European Parliamentary committees is taking place, where you will agree the legislative procedures together to be discussed in the months ahead. In particular, tomorrow, Tuesday morning 3rd October, the dialogue of the cluster "Internal market" will take place in Strasbourg.

Medicines for Europe kindly requests that you urgently bring to the attention of the Chairs of the Committees Internal Market and Consumers Protection (IMCO), Industry, Research and Energy (ITRE) and Legal Affairs (JURI), [redacted] and [redacted] respectively, to insert the SPC Manufacturing Waiver in the future legislative procedures that the European Commission will present to the European Parliament and to the Council, and that will be concluded before the end of the mandate of the current European Commission.

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As recognised on several occasions by the Commission, the introduction of the SPC manufacturing wavier would facilitate investments in high skill jobs in several European countries and would allow European manufacturers to compete fairly with other global players, while at the same time keeping the same high level of SPC protection in the EU. Boosting investments in European manufacturing is even more fundamental when other world powers are putting industry at the top of their political agendas.

We cannot afford to lose concrete investments in Europe today. 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. Therefore, we urge the Commission to include the SPC Manufacturing Waiver in the future legislative procedures that the European Commission will present to the European Parliament and to the Council. Rapidity is vital for a stronger European industry.

Yours sincerely,

[redacted]

Adrian van den Hoven
Director General
Medicines for Europe

MEDICINES FOR EUROPE
Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Our vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Our 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. They include pharmaceutical companies with headquarters in Europe and National Associations.