



# EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Innovation and Advanced Manufacturing  
Intellectual Property and Fight Against Counterfeiting  
Head of Unit

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Dear Mr Mahl,

Thank you for your letter of 5 February 2018 addressed to First Vice-President Timmermans, Vice-President Katainen and Commissioner Bieńkowska related to the assessment of the Supplementary Protection Certificate (SPC) manufacturing waiver. I am pleased to respond to you on their behalf.

The European Commission services are aware of the interest expressed by pharmaceutical stakeholders in relation to the impact that an SPC manufacturing waiver could have on innovation, manufacturing and access to medicines in the EU.

A public consultation on the patent and SPC exemptions ended in January 2018, and a number of studies on those matters are in the process of being concluded as well. The Commission is currently in the process of assessing appropriate follow-up.

Yours sincerely,

[REDACTED]

cc:

[REDACTED], Cabinet of First Vice-President Timmermans  
[REDACTED] Cabinet of Vice-President Katainen  
[REDACTED] Cabinet of Commissioner Bieńkowska