

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for Health

Brussels, SANTE/B5/ sante.ddg1.b.5(2018)5675036

By e-mail only

Dear Ms

Subject: Your e-mail dated 18 September 2018 - Concerns of innovative

SMEs regarding the Commission's proposal on SPC manufacturing

waiver

Thank you for sharing with me and other DG SANTE colleagues the European Biopharmaceutical Enterprises' position on the European Commission's legislative proposal for manufacturing waiver for supplementary protection certificate (SPC) for medicinal products.

DG GROW, as the DG responsible for this file, will respond to your letter. DG SANTE works closely with DG GROW on this file and we take note of your comments.

Yours sincerely,

Martin Seychell

(e signed)

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