Boosting SMEs through the Supplementary Protection Certificate (SPC) Manufacturing Waiver

Board: Othmar Karas (EEP), Maria Grapini (S&D), Kay Swinburne (ECR), Michael Theurer (ALDE), Reinhard Bütikofer (Greens/EFA)

Dear MEPs, Dear Assistants, Dear Stakeholders,

On **Wednesday 27 September 2017** a breakfast was held at the European Parliament organised by Mrs. Maria Grapini, member of the European Parliament (S&D), Vice-President of the SME Intergroup, in collaboration with **Medicines for Europe** on "**Boosting SMEs through the Supplementary Protection Certificate (SPC) Manufacturing Waiver**".

The event was organised to highlight how the SPC manufacturing waiver can boost the growth of European SMEs, through a balanced debate between representatives from originator, generic and biosimilar manufacturers.

Around 60 people attended the event and the audience was composed of Members of the European Parliament and their assistants, Members of the Permanent Representation of Member States to the EU, Members of the European Commission and representatives from the pharmaceutical industry, originators as well as generic and biosimilar.

Keynote Opening

- **Maria GRAPINI**, MEP (S&D), Vice-President of the SME Intergroup

Statements

- ***"Fostering entrepreneurship and growth of small businesses"***
  Lowri EVANS, Director-General, DG GROW, European Commission

- ***"SMEs' voice"***
  Carsten BROCKMEYER, CEO, Formycon

  Ahmed BOUZIDI, CEO, Vaxeal group and Member, European Biopharmaceutical Enterprises (EBE) Board of Directors

- ***"SPC Manufacturing Waiver: Benefits and Myths"***
  Adrian VAN DEN HOVEN, Director General, Medicines for Europe

Please find below a summary of the SME Intergroup event:

The event was opened by Ms. **Maria Grapini** who introduced the four speakers: Ms. **Lowri Evans**, Director General for Internal Market, Industry, Entrepreneurship and SMEs (DG Grow) at the European Commission, Mr. **Ahmed Bouzidi**, CEO of Vaxeal group (for EFPIA), Mr. **Carsten Brockmeyer**, CEO of Formycon (a biosimilar medicine developer and potential manufacturer) and Mr. **Adrian van den Hoven**, Director General of Medicines for Europe.

According to the European Commission, the event can be considered a pre-consultancy phase as the official Public Consultation on the **SPC manufacturing waiver** is very **imminent**. Ms. Lowri Evans recognizes the **spectacular growth** over the past years of the generic and biosimilar sectors as well as the opportunities for export and for launch at expiry and the European Commission has confirmed that a **study** conducted specifically on these sectors is **about to be published**. Furthermore the Director General of DG Grow stated that the European Commission fully understands that the process for a potential introduction of the **SPC manufacturing waiver** needs to start **as soon as possible** in order to **seize the opportunity** for the SMEs as well as for generic and biosimilar sectors as a whole, to manufacture in the EU during the period of the SPC so as to have the possibility of exporting to countries where the SPC is not in force, or where the patent has expired before the EU, plus the chance to manufacture in the EU during the SPC in order to place the product on the market immediately after the expiration of the SPC. The DG also called for a balanced discussion and welcomed the opportunity to learn more from the generic and biosimilar industry and to understand if there were concerns from the originator industry.

Mr. Carsten Brockmeyer and Mr. Ahmed Bouzidi were invited as representatives of a biosimilar SME and an originator/biological SME respectively. While Mr. Bouzidi was a bit **sceptical** on the impact of the **SPC manufacturing waiver impact on manufacturing in Europe** because countries like India and China apply protectionist policies to prevent European companies from exporting there. He also expressed concerns that this **lower investment** in **R&D** for new chemical entities if the protection on the EU market would be shortened as a result of the waiver. For Mr. Brockmeyer the introduction of the SPC manufacturing waiver could represent a **concrete opportunity** for the **generic** and **biosimilar medicines industries** for investment in the EU without altering the actual SPC protection in Europe, which would remain unchanged. He underlined that his own company had the resources to invest in a manufacturing plant in Europe but that it could not do so without an SPC waiver.

Mr. Adrian van den Hoven concluded with some figures compiled by Medicines for Europe that show how the SPC manufacturing waiver could potentially create **thousands of high skill jobs in the generic**, **biosimilar** and **value added sectors**. He reiterated that the introduction of the SPC manufacturing waiver would not erode the SPC regulation in any way as the monopoly compensation for regulatory approval delays would continue unchanged and that it could really represent a boost for European manufacturing which could benefit both sides of the industry.