Press Release

For Immediate Release
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SPC manufacturing waiver moves a step closer as influential European Parliament ENVI Committee supports reform

SPC waiver will deliver more affordable medicines, savings in healthcare budget and job creation across the E.U.

Access to affordable medicines essential to European patient wellbeing

Medicines for Europe welcomes the European Parliament's Committee on Environment, Public Health and Food Safety's ('ENVI') support for an SPC manufacturing waiver.

ENVI voiced its support in its Draft Opinion on the proposal which was published by the Committee on 13 September last.

The ENVI Committee Rapporteur, MEP Tiemo Wölken (S&D, Germany), welcomed the proposal to amend Regulation (EC) No 469/2009 which provides a supplementary protection to medicinal products. Mr. Wölken acknowledged that the amendment proposal was in line with the European Parliament's commitment to improve access to medicines for patients.

Currently, as a result of the existing SPC regulation, EU-based generic and biosimilar medicine manufactures face restrictions which limit their capacity to manufacture and export to countries outside the EU where no SPC applies. This places these companies at a competitive disadvantage to those outside of the EU.

The existing manufacturing restriction also denies European patients access to more affordable medicines from the first day on which the SPC expires, due to the long lead-in times required to produce medicines.

Mr. Wölken acknowledged the need to "*restore the level playing field between EU-based generic and biosimilar manufacturers and non-EU based ones, boosting the competitiveness of EU manufacturers….as well as facilitating Day-1 entry within the Union*."

He also pointed to the need to "*reduce barriers to access to medicines*", noting that "*producing within the EU can lead to enhanced security and quality of supply, reduced counterfeits and uncertainty due to import reliance*".

Medicines for Europe Director General Adrian van den Hoven welcomed the draft opinion of ENVI, stating:

"*ENVI's draft opinion is a significant one. It ensures that the introduction of an SPC manufacturing waiver now moves a step closer to being realised. The extensive consideration given to this proposal by ENVI, including its Rapporteur MEP Tiemo Wölken and others such as MEP Cabezon Ruiz (S&D, Spain), must be acknowledged. ENVI's amendments to the Commission's original proposal, including the need for Day-1 launch and the removal of the disclosure of some commercially sensitive information enhance the proposal further. At the same time,*

some additional improvements to the proposal can be achieved, especially with regard to the need for applying the SPC manufacturing waiver as soon as possible in order for it to serve the purposes it is meant for, as well as making sure that the system can function, notably getting rid of the disclosure of some of the commercial sensitive and confidential information within the notification requirement.

"ENVI recognises the important, and much needed, reforms which this proposal will deliver for European patients and for the competitiveness of European pharmaceutical manufacturers. The Committee's Draft Opinion acknowledges the SPC waiver's key public health benefits – faster access to affordable medicines, enhanced security and quality of supply, improved competitiveness for EU-based generic and biosimilar manufacturers, whilst reinforcing the EU's position as a hub for pharma innovation and manufacturing.

ENVI have been unequivocal in their support of this proposal in the past, and MEP Tiemo Wölken has confirmed this in its Draft Opinion. Medicines for Europe now urges the other ENVI rapporteurs and European Parliament committees, JURI and INTA, as well as the other policymakers – at national and European level – to support this line and prioritise the introduction of this proposal", added Mr. van den Hoven.

ENDS.

Note for editors

A comprehensive and workable SPC manufacturing waiver will generate huge opportunities for Europe as highlighted in the Charles Rivers Associates study - the only independent study on this issue commissioned and published by the European Commission:

1) Net additional sales for the EU based pharmaceutical industry of €7.3 to €9.5 billion by 2025;
2) 20,000 to 25,000 additional direct jobs in Europe by 2025;
3) Faster entry of generic & biosimilar competition in EU after SPC expiry – thus, better access for patients;
4) Savings in pharmaceutical expenditures of €1.6 to €3.1 billion;
5) Additional EU APIs sales of €211.8 to €254.3 million by 2030;
6) Additional 2000 EU API-related jobs by 2030.

Link to ENVI draft opinion: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-627.040%2b01%2bDOC%2bPDF%2bV0%2f%2fEN

Definitions

- The **Supplementary Protection Certificate** (SPC), governed by Regulation (EC) No 469/2009, is a European incentive that extends the protection of patented medicines by up to five years to compensate the time lost in obtaining regulatory approval of the medicine. During this period, European manufacturers of generic and biosimilar medicines cannot produce their medicines in the EU.
- The **SPC Manufacturing Waiver** is a proposal to fix an unintended side effects of the SPC by allowing developers of generic and biosimilar medicines to produce during the SPC period in order to supply unprotected markets as soon as possible after protections expire.
- '**Day-1launch'**: This term refers to the presence of generic and/or biosimilar medicines on the market immediately after the expiry of the SPC. Currently European based generic and biosimilar industries

cannot be on the market on the first day after the expiry of the SPC because they can only start manufacturing on day one after SPC expiry. This forces generic and biosimilar companies to delocalise to be on the market on day 1 to avoid losing competitiveness to foreign manufacturers.

About Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU. For information on the SPC manufacturing waiver, please see www.spcwaiver.com.