Press Release

Commission sponsored study shows Supplementary Protection Certificate (SPC) Manufacturing Waiver will create Jobs, strengthen the pharmaceutical sector and reduce medicine costs

For Immediate Release

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Summary

- The European Commission Public Consultation on the Supplementary Protection Certificate (SPC) Manufacturing Waiver is essential for pharmaceutical manufacturing in Europe.
- The SPC manufacturing waiver will create thousands of high skill jobs and open new opportunities for SMEs in Europe.
- The waiver will ensure that Europe maintains its technological leadership and capacity in the manufacturing and supply of essential medicines and contribute to more competition on medicine costs.

On Thursday 12 October, the Directorate-general for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) launched a public consultation on the Supplementary Protection Certificate (SPC) Manufacturing Waiver and the Bolar exemption. Medicines for Europe calls for a swift introduction of the SPC manufacturing waiver in EU legislation and for a wide definition of Bolar. These measures would create a more competitive industry as demonstrated in the CRA study sponsored by the European Commission "Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe". According to the report, the SPC manufacturing waiver would:

- Create 20,000 to 25,000 additional manufacturing jobs in Europe by 2025;
- Increase the net sales for the EU based pharmaceutical industry by €7.3 to €9.5 billion by 2025;
- Ensure faster entry of generic & biosimilar competition in the EU after SPC expiry – thus, improving access for patients;
- Enable savings in pharmaceutical expenditures of €1.6 to €3.1 billion thanks to competition;
- Generate, together with a broader Bolar exemption, additional EU active pharmaceutical ingredient (API) sales of €211.8 to €254.3 million by 2030 creating an additional 2000 jobs in that sector.

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The SPC compensates originator drug manufacturers for regulatory approval delays by extending their monopoly for up to 5 years after patent expiry. Whilst our industry does not challenge the principle of compensation for delays, the application of the SPC forces generic and biosimilar manufacturers to manufacture outside of Europe for export to countries without SPCs or whose SPC expires earlier than in Europe. With the SPC manufacturing waiver European medicine manufacturers will be able to re-invest in high skill jobs in Europe. To improve access to life saving medicines for patients, the SPC manufacturing waiver complements the Bolar provision and enable European manufacturers to bring competition at the date of SPC expiry and without unnecessary delays.

As proposed by the European Commission and confirmed in several studies, the SPC manufacturing waiver will not affect originator drug manufacturers as they will continue to benefit from the longest period of monopoly protection globally for most drugs.

Adrian van den Hoven, Director General at **Medicines for Europe** commented that "*the CRA study shows the huge benefits that the SPC Manufacturing Waiver and Bolar harmonisation offer Europe in terms of jobs, manufacturing and a lower overall medicines bill. The Commission must now legislate to make this a reality.*"

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. Its 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. **Medicines for Europe** member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.

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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 5 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 **Bolar exemption,** provided for in Directive (2004/27), enables generic and biosimilar medicine developers to undertake R&D in order to obtain regulatory approval for their products.
- 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.