Press Release

Comprehensive SPC manufacturing waiver key for patient access to medicines, jobs and growth in Europe.

For Immediate Release

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Summary

- Today the European Commission launched a legislative proposal for a Supplementary Protection Certificate (SPC) Manufacturing Waiver which is essential for patient access to medicines and pharmaceutical manufacturing in Europe.
- As outlined in the CRA independent study for the Commission and impact assessment, only a comprehensive and usable SPC manufacturing waiver, covering export and production for immediate launch in the EU after SPC expiry, will create thousands of high skill jobs, open new opportunities for SMEs and most importantly ensure medicines are readily available and accessible for patients in Europe at opening of competition.
- Medicines for Europe calls on the European Parliament and European Council to rapidly adopt the SPC manufacturing waiver with the right to produce for export and 'day 1 launch' for European patients.

Medicines for Europe commends the European Commission for proposing an SPC manufacturing waiver which will have a positive impact on the export of European generic and biosimilar medicines, particularly for small and medium enterprises (SMEs).

Nonetheless, we are concerned that the legislative proposal does not fully address the unintended effects of the SPC Regulation, specifically production for 'day 1 launch' in Europe after SPC expiry, as was clearly announced in the European Commission **Single Market Strategy for Europe in 2015**. The Commission published the Charles River Associates (CRA) study which showed the importance of allowing generic and biosimilar manufacturers to prepare for launch in Europe at SPC expiry – with thousands of manufacturing jobs and lower national government drugs bills at stake (see addendum below). This is underlined in the Explanatory Memorandum of today's proposal which surprisingly is not included the draft legislative amendment. The draft also contains a few anomalies that undermine its stated intentions and give limited practical effect to the amendment for SMEs which hope to benefit from this opportunity.

In multiple reports and resolutions, the European Parliament has called on the European Commission to introduce a comprehensive SPC manufacturing waiver, covering both export and 'day 1 launch', to level the playing field between European and non-EU manufacturers.

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Legislators (Parliament and Council) now have the possibility of improving the Commission proposal by including manufacturing for 'day 1 launch' and correcting the anomalies that limit its effective use for SMEs. Only a comprehensive and usable SPC manufacturing waiver would address the unintended effect of the SPC regulation that has forced European generic and biosimilar manufacturers to delocalise manufacturing outside the EU.

Marc Alexander Mahl, President of **Medicines for Europe** commented that "*the launch of the SPC manufacturing waiver legislative proposal is a very positive step to create manufacturing jobs in Europe, and to boost competitiveness by allowing EU companies to compete on a level playing field. However, this proposal should allow companies – especially SMEs - to prepare for 'day 1 launch' after expiry in Europe. Without this, European patients will not get timely access to European manufactured generic and biosimilar medicines.*

For products with large investments in development and manufacturing infrastructure, like biosimilar medicines, EU `day 1 launch´ capability is a key criteria for localisation in Europe. Imported biosimilar and complex medicines from non-SPC markets will be available on 'day 1', while EU-based manufacturers would be specifically blocked from competing in the critical phase of market formation.

Our call now is on the European Parliament and Council to rapidly adopt the proposal with the right to produce for launch in Europe, which will increase access to medicines for patients, lower drug costs for national health budgets and benefit a dynamic European industry.

We have also gathered the key documents and resources pertaining to the SPC manufacturing waiver on the newly-launched website www.spcwaiver.com. This website aims to gather concrete and legitimate information about current SPC protection and the complete SPC manufacturing waiver for medicinal products in the EU and its consequences, as well as appropriate ways to strengthen the European economy."

Addendum

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.

Data in support of a comprehensive and usable SPC manufacturing waiver (CRA study)

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.

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 **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 1 launch'**: 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 1 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.

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