Supplementary Protection Certificate (SPC) Manufacturing Waiver

Benefits & Myths

The benefits

as shown in the study published by the European Commission[1]

- ✓ High skill pharma R&D and manufacturing back into the EU & avoid relocation of production capacities
- ✓ €9.5 billion additional net sales for the EU pharmaceutical industry
- ✓ Create high skill jobs in Europe → 25.000 additional direct jobs (100.000 indirect)
- ✓ Increase competition and supply in Europe → Savings to EU pharmaceutical spending of €3.1 billion
- ✓ €254.3 million additional sales of EU Active Pharmaceutical Ingredients (API) → 2000 new direct jobs
- ✓ Boost particularly European SMEs: reduce costs - spur growth
- ✓ Develop & strengthen EU manufacturing science
- ✓ Increase the EU trade balance: more export, less reliance on foreign production
- ✓ Ensure high quality and continuity of supply of medicines in third countries: faster & increased access
- ✓ Create economic growth in Europe → Boost the opportunity to compete for global leadership

Myths to be dispelled

Is the SPC Manufacturing Waiver (MW) inconsistent with the EU objective to maintain its global leadership in the pharmaceutical sector?

The pharmaceutical sector as a strategic sector which includes the EU generic, biosimilar and value added medicine industries, tries to compete to be one of the strongest globally. Any stimulus to strengthen the EU sector can only increase EU global leadership, especially if it has no impact on the originator industry, as the SPC MW evidence shows. As the study published by the Commission shows, the waiver would be beneficial to the whole EU pharmaceutical sector, also including the Active Pharmaceutical Ingredients (API) industry.

An SPC MW will particularly benefit European SMEs as contractors & sub-contractors, instead of forcing EU companies to rely on non-EU SMEs.

Does the SPC MW change the European Intellectual Property Right (IPR) system? With an SPC MW, would the SPC compensation be reduced or limited?

The SPC MW does *not* erode or change IP protection in any way. The study published by the Commission strongly confirms this point. The monopoly on the market that the originators enjoy in the EU or abroad during the SPC period will remain as it is now, until the very end of the SPC protection.

The SPC MW would only allow the EU generic and biosimilar medicines industries to be ready for marketing once all protections expire. The only difference is that instead of marketing from abroad, it would be done from EU.

Is the SPC MW detrimental for R&D activities in the pharmaceutical sector?

Not at all, quite the contrary. The SPC MW would have no negative impact on R&D, it would actually attract *more* R&D in Europe. The EU is still a leader on R&D for complex generic, biosimilar and value added medicines. Pharma

[1] https://publications.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en

companies prefer to keep R&D and manufacturing in the same location. In fact, despite the objective of the SPC Regulation being to attract manufacturing and R&D to Europe, the SPC unintendedly forces delocalisation of both manufacturing and R&D. Another study published by the Commission with the Public Consultation shows that of the SPCs filed in Europe, 44% come from US-based companies, and only 30% from EU-based companies.[2]

Is the SPC MW applied in any major developed country?

Yes, Canada has just introduced the SPC MW in its legislation, which of course represents a huge competitiveness advantage for the Canadians if the EU does not follow within a very short-term period.

Would the SPC MW increase the risks of generic and biosimilar medicines entering EU markets before SPCs expire? And in non-EU markets?

No. The rules in place today to avoid that this happens will *not change* at all with an SPC MW. The study published by the Commission strongly confirms this point. All EU countries have all the necessary legal tools to block and seize infringing pharmaceuticals before they reach the market (*e.g.* preliminary injunctions), and this will not change. The same applies in non-EU markets.

The SPC MW is only about entering the market and creating competition immediately *after* SPCs expire. European companies today cannot do it. Either they produce abroad, or they enter the EU market over 6-9 months after SPCs expire.

Would the SPC MW have any implications for other sectors as well?

Yes, *positive* implications for other sectors: as confirmed in the study published by the Commission, the Active Pharmaceutical Ingredient sector has also been forced to delocalise outside Europe in the past years. The SPC MW would benefit them significantly, especially in countries where production of API has always been important.

It will also benefit EU contractors & sub-contractors that manufacture for both originator and generic companies, instead of forcing them to rely on non-EU third party manufacturers.

Would an SPC MW be negative if it creates more competition for originators on EU and non-EU markets, and especially in pharma-emerging markets?

Commercially speaking there is absolutely *no difference* for originator companies. They face competition immediately after protection expiry in any case: if not from Europe, competition comes from non-EU developers. The SPC MW intends to allow European producers to compete on a level-playing-field with non-EU competitors.

Any legislation or argumentation preventing exports of high quality generic and biosimilar medicines to developed or pharma-emerging countries is against access to medicines and to the detriment of patients.

Legally speaking, once SPCs expire, markets are legally *open to competition* and *no obstacle* for companies to compete should exist or be created. Any delay, whatever the cause, is anti-competitive.

Are there other barriers that prevent generic companies from entering the market after protection expiries?

In general, at midnight on the day of protection expiry, generic medicines (necessarily produced abroad) are ready at borders to enter the market. If in some countries there are national rules delaying generic entry even when competition should be open for generic competitors, these barriers are anti-competitive and should be removed.

The SPC MW would remove the unintended barrier that prevents European companies from producing in Europe while competing on a level-playing-field with non-EU competitors.

[2] https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en