Memo

Summary of the CRA Study "*Assessing the economic impacts of changing exemption provision during patent and SPC protection in Europe*"

The CRA study commissioned and published by the European Commission concludes that an SPC manufacturing waiver would bring:

- **Net additional sales for the EU based pharmaceutical industry of €7.3 to €9.5 billion by 2025;**
- **20,000 to 25,000 additional direct jobs in Europe by 2025;**
- **Faster entry of generic & biosimilar competition in EU after SPC expiry – thus, further access for patients;**
- **Savings in pharmaceutical expenditures of €1.6 to €3.1 billion;**
- **Together with a broader "Bolar" exemption, additional EU APIs sales of €211.8 to €254.3 million by 2030;**
- **Additional 2000 EU API-related jobs by 2030**

Background

On 5th October 2017 the European Commission published a study entitled "*Assessing the economic impacts of changing exemption provision during patent and SPC protection in Europe*", the study was conducted by "Charles Rivers Associates" on the basis of data collected through different sources, such as IMS, EMA, CPA, and interviews with EFPIA and Medicines for Europe .

The study touches three topics: the "Bolar exemption", the "Unitary Patent Protection and Unified Patent Court" and the "SPC manufacturing waiver".

The "Bolar" Exemption was introduced in the EU law in 2004 by Article 10(6) of Directive 2004/27 amending Directive 2001/83 on the Community code relating to medicinal products for human use. Under this rule, conducting studies and trials necessary to gain regulatory approval for generic medicinal products and the consequential practical requirements do not constitute acts infringing patent rights or supplementary protection certificates for medicinal products.

In the current landscape in the EU, there is no harmonization in the transposition of the Directive 2001/83/EC within the Member States. Where in some cases there is a narrower Bolar exemptions, there is legal uncertainty and this puts companies running clinical trials or supplying Active Pharmaceutical Ingredients (API) at a risk of infringement.

The SPC provides similar protection to the one provided by the patent, therefore under the SPC term the production of the SPC protected medicine is not allowed, even if it is not destined for the domestic SPC protected market. This regulation creates disadvantage for generic and biosimilar manufacturers based in those countries where the SPC is in force compared to companies that have their manufacturer sites in countries where there is no SPC protection.

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The study also covers the effects of a wider or narrower Bolar in relation to the Unitary Patent Protection and the Unified Patent Court**.**

Scope of the study

The intent of the study is to analyze if and which kind of amendments could solve the issues related to the abovementioned topics and to do so, for each topic, the Commission explores different scenarios:

- Changes to the Bolar Exemption
- Changes to the SPC provisions introducing the SPC export exemption or manufacturing waiver
- Effect of the Bolar on the introduction of Unitary Patent Protection and Unitary Patent Court

Extending the scope of the Bolar Exemption to cover all medicines

With regard to extending the scope of the Bolar Exemption to cover all medicines, i) data collected shows how in countries with a wider Bolar scope there is no clear evidence so far of more clinical trials; ii) an extension of the Bolar in countries where the provision is narrower would save between €23-€34.2 million per year; iii) an extension of the Bolar to any medicines would affect positively incentives to innovate in the EU and it would remove legal uncertainty; iv) It is also stated how a wider and harmonised Bolar would increase the number of skilled jobs in countries that switch from a narrow to a wider Bolar; v) In addition, extending the scope of the Bolar would increase the number of countries where patients can be recruited to support marketing authorisations in any country since it would reduce clinical trial delays related with patient recruitment: vi) such amendment would also reduce the need to duplicate clinical trials, it has been estimated that savings would be between €647,406 to €1 million per case avoiding to run a clinical trial in one additional country and between €2.6 to €4.4 million avoiding to run it in four additional countries; vi) a wider Bolar would reduce the need to make early decisions about where to launch first.

The study collected evidence on how positive the effects of a wider and harmonised Bolar would be also for generic and biosimilar companies: i) it would reduce the need of additional bioequivalence tests to obtain marketing authorisation in other countries; ii) it would reduce legal risks and need to obtain legal advice by EU country as to what acts are covered by the Bolar in each Member States; iii) it would mean significant savings for biosimilars since the clinical trials for these kind of medicines are much more expensive compared to others.

Extending the scope of the Bolar Exemption to allow the supply of APIs within the EU

An extension directed also to APIs would mean higher share of APIs used by European generics producers to be sourced from European API suppliers rather than from non-EU countries. It has been estimated that costs of switching API suppliers could reach €4 million per case. This means that a change of supplier is unlikely.

A combination of the SPC manufacturing waiver with an extension of the Bolar exemption to cover the third party supply of APIs within Europe would mean a raise in EU APIs sales between €211.8 million and €254.3 million by 2030. The additional EU API sales would mean 1,160 to almost 2,000 additional jobs by 2030.

Effect of a wider/narrower Bolar on Unitary Patent Protection and Unified Patent Court

Companies wishing to use results of tests and clinical trials for marketing authorisation outside Europe would incur additional legal costs to determine whether they could be infringing, and this statement is valuable for innovators as well as for generics and biosimilars.

A narrow interpretation of the Bolar in the UPC could result in the duplication of clinical trials for innovative medicines and biosimilars to support marketing authorisation outside the EU and this would mean higher costs of development between €2.8 and €4.9 million per product. For biosimilars product these costs could be substantially higher.

For EU-based generic this amendment could also mean that Europe will become less attractive for bioequivalence tests and more tests would be conducted outside the EU.

Allowing manufacturing of SPC protected medicines in protected (domestic) markets for purposes of exporting to third countries where the corresponding patent or SPC has expired

An SPC export waiver could result in additional export sales by European generic of €7.6 billion. The study also considers the potential negative impact on export sales for European originator medicines, which is estimated to range from €138 to €278 million by 2025. Considering the impact on both EU based originators and generics and biosimilars, the study estimates net additional sales for the EU based pharmaceutical industry of €7.3 to €9.5 billion by 2025, which translated in other figures means between 6-18% of total generic and originator EEA non-biological export sales to the third countries.

For the biosimilar industry, the SPC export waiver could result in additional export sales of €2.97 billion in the best scenario and in the worst scenario €463 million by 2025. The net impact of the SPC export waiver on the European biological industry is estimated to be between €1.2 and €2.1 billion in additional sales by 2025.

The proposal does not enable generic and biosimilar companies competition *during* the patent protection or eventual SPC but only *after* protection has expired. Therefore, it cannot be expected to lead to a reduction in incentives to innovate relative to what was intended by the design of the patent and patent extension terms in Europe and other countries. The proposed measure could only negatively affect incentives to innovate if it resulted in generic and biosimilar products for export markets to leak into domestic European markets during the SPC protection. The risk of infringement stays really low as it is currently, since the risk of infringement is likely to dissuade companies from engaging in such activities.

The SPC export waiver would also bring between 20,000 and 25,000 additional jobs by 2025.

If the SPC export waiver results in generic entry right after protection expiry in the domestic market this would mean savings in pharmaceutical expenditures of €1.6 to €3.1 billion.

Allowing manufacturing of SPC protected medicines in protected (domestic) markets for purposes of selling to other EU Member States where the corresponding patent or SPC has expired

The net additional sales to EU-based generic manufacturers could be between €207.9 and €416 million by 2025. This estimation cannot be done for biosimilar industries since the study has no projection in this regard. The introduction of an SPC that allows to export in EU Member States where the SPC has already expired should not have any negative impact on incentives to innovate. The only risk could be an infringement by generic and biosimilar companies, but the fact that already today companies can stockpile in EU countries where no SPC is in place demonstrates that this risk is extremely low..

The estimation by 2025 is of about 548 and 1,095 additional jobs.

Allowing manufacturing of SPC protected medicines in protected (domestic) markets for purposes of preparing for entry in the domestic market (with minimal delay) subsequent to patent or SPC expiration i.e. stockpiling

A stockpiling exemption would benefit the European generic and biosimilar industry. The study states how generic and biosimilar manufacturer located in countries where the SPC is not foreseen or the patent expires in advance are in a position much facilitated compare to producers located in territory where the patent lasts longer or there is an SPC.

A stockpiling exemption would balance the situation and it would particularly increase incentives by generic and biosimilar manufacturers to invest in manufacturing and R&D production in the EU. Analyses in the study show how if generic entry was brought forward by 6 months this can be translated in savings on pharma expenditure around €1.1 billion over a three year period. If biosimilar entry was brought forward by 6 months, savings on expenditure would be over €15 million.

Conclusions

From the CRA study, it is clear that a wider and harmonised interpretation of the Bolar exemption would be beneficial for the pharmaceutical industry as a whole and for EU healthcare systems. The study shows that positive impacts strongly outweigh any negative effect.