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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products

Delegations will find attached document SWD(2018) 241 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products

{COM(2018) 317 final} - {SEC(2018) 246 final} - {SWD(2018) 240 final} - {SWD(2018) 242 final}

Executive Summary Sheet

Impact assessment on a Proposal for a Regulation of the European Parliament and of the Council amending Regulation 469/2009 concerning the supplementary protection certificate for medicinal products.

A. Need for action

Why? What is the problem being addressed?

The problem relates to the existing EU regime (Regulation (EC) No 469/2009) concerning the supplementary protection certificate (SPC) for medicinal products, which was introduced in 1992 and provides for additional (patent-like) protection for pharmaceutical products subject to market authorisation, by up to 5 years after patent expiry (5.5 years in case a paediatric extension is granted). While the benefits of an SPC for its holder are significant, the SPC system, as a result of significant changes in pharmaceutical markets, is now having unintended side effects on the competitiveness of EU-based manufacturers of generics and/or biosimilars ('G/Bs'). The main problems are: (1) during the SPC term, they cannot manufacture with a view to exporting G/Bs to third countries where protection has expired; and (2) immediately upon SPC expiry, they are not ready to place G/Bs on the EU market. EU-based G/B manufacturers thus risk foregoing significant export opportunities and crucial lead-time to enter the market in Member States, and this at the time where significant new opportunities are opening up (cf. major patent cliff from 2020 onwards). Unless action is taken now, European manufacturers risk foregoing significant opportunities, and this will in turn have a negative impact on jobs, on patients (increased import supply dependency, higher prices through limited competition) and on research for biosimilars.

What is this initiative expected to achieve?

This initiative intends to restore the level playing field between EU-based G/B manufacturers and non-EU-based ones, which would be beneficial for the competitiveness of the former and the European economy as a whole, while maintaining the current high level of IP protection in the EU. Although views differ about the exact magnitude of the benefits of the initiative, it is estimated that the envisaged solution (the introduction of an export waiver, cf. infra) could result in net additional export sales of EU-made pharmaceuticals of between EUR 0.6bn and EUR 1bn per year (for a sample of molecules representing 32% of the relevant medicines). The initiative should also be beneficial for patients (due to speedier access upon SPC expiry to more affordable medicines) and for health systems, and should confirm EU's position as a hub for pharmaceutical innovation, in particular in the biosimilars sector.

What is the value added of action at the EU level?

Only action at EU level would be effective. Action by Member States is conceivable (and national solutions based on voluntary agreements have actually been tested at a small scale, but did not prove effective), but would go against the core objective of Regulation 469/2009, which is to provide for a uniform regime across the internal market. Moreover, the existing Regulation places strict limits on the possibility for individual Member States to address, in a unilateral manner, the problems identified.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

Various options have been considered. Some options were discarded at an early stage, notably (i) relying only on the (on-going) efforts of the Union to convince its international trade partners to align their IPR regimes with the EU one, (ii) expanding the Bolar exemption, (iii) introducing new ad-hoc licensing measures systems and (iv) cutting down the maximum duration of SPCs. Options that were considered include, apart from the status quo option, a soft law approach (fostering voluntary, industry-led agreements); introducing a manufacturing waiver for export purposes only and/or for export and stockpiling purposes; and introducing a manufacturing waiver accompanies by safeguard measures. Various timing option for entry into effect of a waiver were considered.

The preferred option is to amend the existing SPC regime (Regulation (EC) No 469/2009) to introduce a 'waiver' allowing G/Bs to be manufactured in the EU during the SPC term for export purposes. To ensure a balanced approach, better protection of SPC holders in the EU, and transparency, this waiver would be accompanied by various safeguard measures, such as labelling and notification requirements. With regard to supplying the EU market shortly after expiry of the SPC, manufacturers taking advantage of this export waiver would, to a certain extent, also be ready for EU day-1 entry upon SPC expiry as they would have already operative manufacturing capacity.

Who supports which option?

EU-based manufacturers of generics and biosimilars – as well as, to some extent, patient groups and healthcare

stakeholders – support the preferred option.
SPC holders ('originators') support the status quo, as they fear additional competition in export markets (from G/Bs manufacturers based in the Union) and increased IP infringements. Regarding the former concern, it should be noted that the waiver might lead to a slight reduction in sales for some, but this reduction will be largely offset by the expected benefits the proposal will bring and might occur in any event, due to increasing competition from manufacturers based outside the Union. As regards the latter concern, it should be noted that the preferred option includes various anti-diversion measures that will work to the benefit of SPC holders.
In the public consultation, some Member States expressed support for an export waiver and none expressed explicit opposition to the idea. Most Member States took the view they might support the initiative, subject to convincing evidence being presented in terms of net economic impact. The European Parliament has underlined, in several Resolutions, its support for the preferred option.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The preferred option would boost the competitiveness of EU-based G/B manufacturers in respect of export during the SPC term and of timely entry on to the EU market upon SPC expiry. This is expected to results in net additional exports of EU-made pharmaceuticals nearing EUR 1bn per year (based on a limited sample covering only 32% of the relevant market), with all of the obvious beneficial consequences in terms of job creation (estimated around 20-25 000 direct jobs, based on the same limited sample) and reduced relocation. Even if some studies contest the magnitude of these positive benefits, no study denies them altogether. In addition, the preferred option includes effective, but not cumbersome or costly, anti-diversion measures (taking special consideration of the SME angle), which will lead to a better protection against infringement of SPCs in the Union. Finally, the preferred option could bring positive results for patients and healthcare systems (better access to medicines) and would boost R&D in the Union, for biosimilars in particular.

What are the costs of the preferred option (if any, otherwise main ones)?

The preferred option may cause a slight reduction in the sales of SPC holders ('originators'), due to increased competition they would face from EU-based G/B manufacturers in export markets during the SPC term (in 'non-SPC' third countries, which are anyway fully open to international competition). This possible erosion of sales (which may also impact on jobs) is estimated to be around 10 times lower than the estimated benefits for EU-based G/B manufacturers, and might occur in any event (due to increasing competition based outside Europe).
Virtually no administrative, compliance or other implementation costs are envisaged, although the anti-diversion measures proposed will imply some administrative work, but this should be largely offset by the fact that IP rights will be better protected. No other costs (e.g. environmental costs) have been identified.

How will businesses, SMEs and micro-enterprises be affected?

The IA includes an SME test which looks at the potential impact of the preferred option as regards various categories of SMEs engaged in either R&D or manufacturing, of either so-called 'original' products or generic and biosimilar products. It concludes that the preferred option would be highly beneficial to EU-based SMEs manufacturing generics and biosimilars, as it is more difficult for them than for larger companies to set up manufacturing facilities outside the EU in order to side step the increasing unintended effects of the EU SPC regime. The proposal will also create new R&D and manufacturing opportunities for SMEs and start-ups in highly lucrative and fast-growing sectors, in particular as regards biosimilars (where there is intensive investment in R&D). The initiative would be beneficial for dynamism of the whole EU pharmaceutical ecosystem (start-up creation, etc.).
As explained above, the preferred option might lead to a loss of potential sales of SPC holders given that the latter will face increased competition in export markets, from G/B manufacturers within the EU. However, given that such competition might occur in any event and given that the preferred option leaves the core of IP SPC protection in Europe intact, the limited risk of losses of sales will have a very limited effect on the possibility for SMEs engaging in R&D to gain a return on their investments. This effect is largely offset by the beneficial effects of the proposal on the EU as a hub for pharmaceutical R&D at large.

Will there be significant impacts on national budgets and administrations?

Impacts on health systems are expected to be positive, given that the preferred option will foster more competition in European markets and is likely to facilitate the switching to cheaper medicines after the lapse of SPC protection. Increased R&D and manufacture in the EU will result in better access to medicines at a more affordable price. It will also lead to better security and quality of supply (less counterfeits, less uncertainty due to import reliance).

Will there be other significant impacts?

As mentioned above, the preferred option would be beneficial in terms of global competitiveness and trade, and

it will also entail positive effects for patients. The EU research community is expected to gain from this initiative (as R&D in biosimilars often happens at the same place where manufacturing takes place), which would help prevent the relocation of related research.
D. Follow up
When will the policy be reviewed?
Yes, the actual impact of the amended SPC regime will be monitored, on the basis of pre-defined criteria.