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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SEC(2023)172 final
Subject:	Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products - REGULATORY SCRUTINY BOARD OPINION

Delegations will find attached document SEC(2023)172 final.

Encl.: SEC(2023)172 final

EUROPEAN COMMISSION

Brussels, 16.12.2022
SEC(2023) 172 final

REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products

{COM(2023) 221-223 final}
{COM(2023)231 final}
{SWD(2023) 117-119 final}

Ref. Ares(2022)8770499 - 16/12/2022

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: GROW Impact assessment / Revision of the legislation on supplementary protection certificates

Overall 2nd opinion: POSITIVE

(A) Policy context

The initiative aims to revise the legislation on supplementary protection certificates (SPCs). SPCs are specific Intelecutal Property (IP) rights that can extend up to five years the 20-year term of patents related to medicinal or plant protection products. They aim to offset the loss of effective patent protection companies incur due to the lengthy testing period required for the regulatory marketing authorisation of these products.

The initiative builds on the 2018 evaluation of the SPC system which identified several shortcomings such as the high costs for companies of seeking and maintaining SPC protection, the legal uncertainty in Member States related to the status of SPCs and the difficulty to monitor the legal situation of SPCs. This initiative aims to address these shortcomings by amongst other things considering the creation of a unitary SPCs that would provide a new IP-right at the EU level that would match the upcoming unitary patent.

(B) Summary of findings

The Board notes the improvements made to the report responding to the Board's previous opinion.

The Board gives a positive opinion. However, the Board considers that the report should further improve with respect to the following aspects:

(1) The report is not sufficiently clear about the drivers behind the divergences of national practices for SPCs.

(2) The report does not sufficiently justify the choice of the preferred option.

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 02/352. E-mail: regulatory-scrutiny-board@ec.europa.eu

(C) What to improve

(1) The revised report identifies the legal uncertainty related to SPCs and cumbersome monitoring as the main problem to be tackled. However, when it comes to the analysis of the problem drivers, it should be more explicit as to what precisely drives the divergence of national practices on SPCs: flexibility in the existing legislation, the lack of effective implementation or guidance, or rather a lack of resources.

(2) While the revised report compares a broader set of combinations of options, it should better justify the choice of the preferred combination of options in view of the results of the cost benefit analysis.

(3) The report should ensure the consistency of the figures throughout.

(4) The report should better explain how the improvement of SPCs will stimulate innovation and competitiveness of the agri-chemical sector in Europe.

(5) The report should better explain what success for this revised legislative initiative would look like and propose more specific monitoring indicators linked with SMART objectives.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The lead DG may proceed with the initiative.

The lead DG must take these recommendations into account before launching the interservice consultation.

Full title	Revision of the legislation on supplementary protection certificates (SPCs), Proposal for a Regulation of the European Parliament and the Council on supplementary protection certificates, creating a centralised examination procedure amending Regulations (EC) No 496/2009 and 1610/96 and Proposal for a Regulation of the European Parliament and the Council on the creation of a unitary supplementary protection certificate.
Reference number	PLAN/2020/9220
Submitted to RSB on	23/11/2022
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	*Amount*	*Comments*
Direct benefits		
Lower SPC maintenance fees for SPC holders	EUR 111 100	Savings per SPC holder for EU wide, five year long protection. Affecting up to 400 firms per year.
Saving on legal advice for SPC applicants	EUR 52 000	Savings per applicant. Due to dealing with one authority instead of 27 with different procedures and requirements. Affecting up to 100 firms per year.
Saving on translation cost for SPC applicants	EUR 4 000	Savings per applicant. As application can be in one of the official EU languages, instead of languages of each Member State. Affecting up to 100 firms per year.
Saving on SPC search cost for generic/biosimilar manufacturers and health sector	EUR 40 000	Saving per firm/healthcare authority. Concern identification of active SPC on a given territory. Based on cost of acquiring commercial database. Affecting up to 300 generic/biosimilar firms and at least 27 central pharmaceutical procurement bodies.
Indirect benefits		
Potentially higher investments in novel medicines	EUR 37 million	Estimated total annual additional income of originators due to extended territorial coverage of unitary SPC protection.
Administrative cost savings related to the 'one in, one out' approach *		
Saving on legal advice for SPC applicants	EUR 52 000	As above
Saving on translation cost for SPC applicants	EUR 4 000	As above

II. Overview of costs – Preferred option							
		Citizens/Consumers		**Businesses**		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Action (a)	Direct adjustment costs					EUR 1.4 million for the central authority	
	Direct administrative costs						EUR 1.8 million annually for central authority
	Direct regulatory fees and charges			Application fee potentially higher by EUR 30 000 per applicants in comparison to baseline			

	Direct enforcement costs						
	Indirect costs		EUR 37 million estimated total EU wide additional spending on medicines due to extended territorial coverage of unitary SPC protection.				
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs						
	Indirect adjustment costs						
	Administrative costs (for offsetting)						

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / Revision of the legislation on supplementary protection certificates

Overall opinion: NEGATIVE

(A) Policy context

The initiative aims to revise the legislation on supplementary protection certificates (SPCs). SPCs are specific IP-rights that can extend up to five years the 20-year term of patents related to medicinal or plant protection products. They aim to offset the loss of effective patent protection companies incur due to the lengthy testing period required for the regulatory marketing authorisation of these products.

The initiative builds on the 2018 evaluation of the SPC system which identified several shortcomings such as the high costs for companies of seeking and maintaining SPC protection, the legal uncertainty in Member States related to the status of SPCs and the difficulty to monitor the legal situation of SPCs. This initiative aims to address these shortcomings by amongst other things considering the creation of a unitary SPCs that would provide a new IP-right at the EU level that would match the upcoming unitary patent.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting and commitment to make changes to the report.

However, the Board gives a negative opinion because the report contains the following significant shortcomings:

(1) The report is neither sufficiently clear about the main problem that needs to be tackled nor how important it is.

(2) The report does not sufficiently explain the coherence between this initiative and the parallel revision of the general pharmaceuticals legislation.

(3) The net impacts of each option and combination of options are not sufficiently analysed. The comparison of options does not unequivocally allow the identification of the preferred option, including in terms of proportionality. The choice of the preferred examination authority is not sufficiently argued.

(4) The presentation of the views of different stakeholder categories is not sufficiently accurate or balanced throughout the report.

(C) What to improve

(1) The report should better justify why the existing SPC legislation needs to be revised. The argument of the cost reduction for obtaining SPC protection is not convincing, not least in view that more far-reaching cost-reduction solutions followed in third countries have been discarded. The alternative argument of enhancing legal certainty is also not sufficiently elaborated and supported with evidence nor has it been developed into the overall narrative of the report. The report should clearly indicate the focus of the initiative. It should better explain to what extent the cost of obtaining and maintaining SPC protection is a serious problem for companies concerned including by setting out more clearly the SME dimension. It should provide further evidence on how important SPCs are for companies' investment decisions and how the legal uncertainty affects generic new entrants and healthcare providers. It should also provide evidence on how an improvement of SPCs could stimulate innovation and competitiveness of the pharmaceutical and agri-chemical sectors in Europe. It should be clearer on the underlying problem drivers (e.g. divergent national procedures a result of the flexibility provided by the Regulation, lack of effective implementation, guidance or resources). It should be clearer on the link and potential synergies between the unitary patent and the unitary SPC.

(2) The report should better explain how this initiative dovetails with the revision of the general pharmaceuticals legislation which proposes to reduce the patent protection period. It should better show how coherence of policy objectives and measures will be ensured, particularly in terms of availability and affordability of medicines and in terms of the reduction of administrative burdens, increased competitiveness and innovation.

(3) The report should identify upfront combinations of options and assess them along with the individual options. It should be clear whether any of the discarded options received support from stakeholders or Member States.

(4) The costs and the benefits for the key stakeholder groups should be clearly set out under each (combination of) option(s). In order to allow a systematic comparison of options, the report should clarify the quantitative net impacts and the qualitative criteria and scores used. Effectiveness considerations should be clearly separated from efficiency issues. Based on the improved analysis of the net impacts, benefit-cost ratios and the qualitative comparison, the report should better explain the choice and proportionality of the preferred option. It should also better explain why only one combination of options was considered. The arguments supporting the choice of the EU Intellectual Property Office as the preferred examination authority should be better justified, including by adequately reflecting the views expressed by stakeholders.

(5) The report should be clearer on any budgetary implications and how administrative efficiency will be ensured. It should spell out explicitly how the options comply with the "do no significant harm" principle and the objectives set out in the European Climate Law.

(6) The presentation of the views of the different stakeholder categories should be presented more accurately and in a more balanced way throughout the report. The data limitations stemming from the lack of a public consultation, assumptions and other considerations with regard to the various sources of stakeholders' feedback should be more openly and systematically presented in the report, in particular what the different stakeholders categories expect from a unitary SPC.

(7) The report should describe what success would look like and present a set of monitoring indicators linked to the specific objectives. It should also explain how and when the monitoring will be performed. *Some more technical comments have been sent directly to the author DG.*

(D) Conclusion **The [lead] DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.**	
Full title	Revision of the legislation on supplementary protection certificates (SPCs), Proposal for a Regulation of the European Parliament and the Council on supplementary protection certificates, creating a centralised examination procedure amending Regulations (EC) No 496/2009 and 1610/96 and Proposal for a Regulation of the European Parliament and the Council on the creation of a unitary supplementary protection certificate.
Reference number	PLAN/2020/9220
Submitted to RSB on	23/09/2022
Date of RSB meeting	28/09/2022

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