EUROPEAN COMMISSION

SEC(2018) 246

REGULATORY SCRUTINY BOARD OPINION

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}
{SWD(2018) 240}
{SWD(2018) 241}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels, 9.3.2018
Ares(2018)1327984

Opinion

Title: Impact Assessment / SPC manufacturing waiver

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Context

The EU Supplementary Protection Certificates (SPC) system is one element of the overall EU Intellectual Property Rights framework for medicinal products. It can extend patent-like protection for up to 5.5 years beyond the date when the original patent expires. It partly compensates patent holders for loss of effective patent protection time between the granting of the patent and the authorisation to market.

This initiative aims to address unintended consequences of the existing SPC system. During the SPC period, EU-based manufacturers of generics (G) or biosimilars (B) cannot produce either for export or for storage. They thus lose export opportunities to third countries and are unable to enter the EU market immediately when the SPC expires. This puts EU-based G/B manufacturers at a disadvantage vis-à-vis others based outside the EU. The initiative would aim to "level the playing field" by granting a manufacturing waiver for export and stockpiling purposes. The EU SPC-holders oppose this initiative. They claim that it is likely to harm their sales by shortening the effective patent protection time.

(B) Main considerations

The Board notes the stakeholder consultation as well as the various studies used to underpin the analysis.

However, the report still contains significant shortcomings that need to be addressed. As a result, the Board expresses reservations and gives a positive opinion only on the understanding that the report shall be adjusted in order to integrate the Board's recommendations on the following key aspects:

(1) The report does not sufficiently reflect the views and concerns of relevant stakeholder groups, including SPC holders and SMEs.

(2) The report does not elaborate all relevant options and their key dimensions, in particular regarding the timing of the waivers.

(C) Further considerations and adjustment requirements

(1) The different parts of the report (problem description, objectives, impacts) should more systematically reflect the concerns of all stakeholder groups, including the SPC holders. In this regard, it could be useful to revise the objectives in order to better reflect the importance of the continued protection of patent rights.

(2) The analysis should better reflect the strengths and weaknesses of the key studies. In addition, it should clarify the robustness of the cost and benefit estimates.

(3) The set of options should be more complete and detailed. The main report should include the options for the timing of the introduction of the manufacturing waiver. This is currently analysed in an annex. The report further needs to consider differentiating the options on the duration of the stockpiling waiver in comparison with the duration of the export waiver. It should also consider the accompanying use of a soft-law approach for some options.

(4) The report should better explain the potential impacts of the manufacturing (notably of the stockpiling) waiver with regard to the EU's trade policy and to the compatibility with WTO-TRIPS provisions.

(5) The impact assessment should include a more comprehensive analysis of costs and benefits of the proposed options for SMEs. It should also better reflect SME views on the different options and their potential impacts.

(6) The report should include a proportionate evaluation of the specific effects of the SPC legislation, covering both the origins of the SPC legislation as well as the intended and unintended consequences of it. It should also explain the timing of the more comprehensive evaluation of the Intellectual Property Rights framework for medicinal products. In addition, it should clarify the REFIT dimension of the initiative, i.e. examine potential for simplification and burden reduction.

The Board takes note of the quantification of the various costs and benefits associated to the preferred option of this initiative, as assessed in the report considered by the Board and summarised in the attached quantification tables.

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

(D) RSB scrutiny process

The lead DG shall ensure that the report is adjusted in accordance with the recommendations of the Board prior to launching the interservice consultation.

The attached quantification tables may need to be adjusted to reflect any changes in the choice or the design of the preferred option in the final version of the report.

Full title	Supplementary Protection Certificates manufacturing waiver
Reference number	2017/GROW/051
Date of RSB meeting	07/03/2018

ANNEX: Quantification tables extracted from the draft impact assessment report submitted to the Board on 12/02/2018

(N.B. The following tables present information on the costs and benefits of the initiative in question. These tables have been extracted from the draft impact assessment report submitted to the Regulatory Scrutiny Board on which the Board has given the opinion presented above. It is possible, therefore, that the content of the tables presented below are different from those in the final version of the impact assessment report published by the Commission as the draft report may have been revised in line with the Board's recommendations.)

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	Amount	Comments
Direct benefits		
Exports of EU-made generics/ biosimilars during the SPC term, under a waiver that would at least cover export purposes – evidently the benefits would be even larger if the waiver also covered stockpiling with a view to day-1 entry onto the EU market (for which no estimations are available)	Increase of the EU pharmaceutical trade balance by EUR 6 -10 bn over 10 years for a sample of 134 molecules (32% of the relevant medicines) Amount above revised down to EUR 2-3 bn	CRA study, section 3.4 OHE-EFPIA
Increased employment by EU-based manufacturers of generics/biosimilars	> 20,000 additional jobs Revised down to 3,000 to 9,400 jobs	CRA study, S. 3.4 OHE-EFPIA
Savings for Member States' national health systems	~ 4-8 % savings	CRA study
Indirect benefits		
Improvement of the whole EU pharmaceutical ecosystem (also beneficial to originators)	Impossible to quantify – A healthy, vibrant EU pharma ecosystem will clearly be beneficial not only for generics/biosimilars manufacturers but also for originators and research organisations, as well as for the creation and growth of start-ups.	

II. Overview of costs – Preferred option							
		EU-based generics/biosimilars manufacturers		EU-based SPC holders (originators)		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Waiver for export and stockpiling purposes	Direct costs	Possible loss of employ-_ment by origina-tors[1]	0	/	Possible decrease in sales (1) in export markets during the SPC term and (2) in the EU immediately after SPC expiry. This impact is estimated to be low considering that these two market situations are anyway fully open to inter-national competition. Available estimations include: • 139 - 278 M€ (CRA study, S. 3.4) • 191 - 573 M€ (OHE-EFPIA)	/	0
	Indirect costs	/	Minor logistical costs relating to specific labelling (for export) and to reporting/notifi-cation (depending on the anti-diversion measures finally decided). The related costs could be around 10 k€ per product per year[2].	/	0	/	Minor administrative costs may be incurred by that/those administration(s) that will receive notifications (depending on the anti-diversion measures finally decided).

[1] The Pugatch study mentions a range of 4,500-7,700 direct job losses. However, this study seriously overestimates the consequences of a waiver on SPC holders (see section 6.3)

[2] Considering that the evaluation of *Regulation 953/2003 to avoid trade diversion into the EU of certain key medicines* found that a pharmaceutical company incurred in a costs of a few EUR 100.000s between 2003 and 2015 for adding a logo on its packs and for getting regulatory authorities to amend/extend marketing authorisations for the medicines due to a change of packaging.