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COVER NOTE

From:	European Economic and Social Committee
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
Subject:	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 - Opinion of the European Economic and Social Committee

Delegations will find attached above mentioned Opinion.

European Economic and Social Committee

INT/865
Supplementary protection certificate for medicinal products

OPINION

European Economic and Social Committee

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 – 2018/0161 (COD)]

Rapporteur working alone: **János WELTNER**

Referral	Council, 21/06/2018 European Parliament, 02/07/2018
Legal basis	Article 114 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted in section	04/09/2018
Adopted at plenary	20/09/2018
Plenary session No	537
Outcome of vote (for/against/abstentions)	167/2/7

1. **Conclusions and recommendations**

1.1 The EESC takes note of the fact that the Commission, in its Staff Working Document (SWD), has analysed four options to deal with the current problems arising from the present status of the Supplementary Protection Certificate (SPC).

1.2 The EESC agrees with the European Commission's (EC) conclusion, which proposes modifications in line with Option 4[1], i.e. legislation on both export and stockpiling waivers by amending Regulation 469/2009.

1.3 The EESC welcomes the fact that this proposal leaves SPC protection intact as regards placing products on the EU market.

1.4 The EESC also welcomes the market exclusivity of EU SPC holders in the Member States during the full period of SPC protection.

1.5 The EESC deems it to be most important that, on those non-EU markets where protection does not exist or has expired, there be fair competition for EU-based manufacturers who bring generics and biosimilars to these markets.

1.6 The EESC strongly supports those safeguards that ensure transparency and protect against a possible diversion onto the Union market of generics and biosimilars (G/Bs) in respect of which the original product is protected by an SPC.

1.7 The EESC supports the Commission's stance on SMEs, since they play an important role in manufacturing generics and developing biosimilars. SMEs will be better able to plan their market activities if the new SPC comes into force.

1.8 The EESC supports the Commission's plan for an evaluation of orphan and paediatric legislation, with further analysis in 2018-2019.

1.9 The EESC understands the Commission's position that, although it would be advantageous, the Commission will not be tabling a proposal for a unitary SPC at the moment, as the unitary patent package has not yet come into force.

1.10 The EESC supports the amendment of Regulation (EC) No 469/2009, as it is set out in document COM(2018) 317. At the same time, the EESC recommends that the Commission could propose to amend Regulation (EC) No 469/2009, as it is set out in document COM(2018) 317, to ensure that an SPC manufacturing waiver can be immediately applied.

[1] SWD(2018) 240 final, p. 29.

2. **Background**

2.1 An SPC will extend the period of effective protection for patents on new medicinal products, where an authorisation is required for them to be placed on the market.

2.2 The holder of both a patent and an SPC benefits from a maximum of 15 years of protection from the moment the product in question first obtains authorisation to be placed on the market in the EU.

2.3 The benefits of an SPC for its holder are significant. Since an SPC confers the same rights as a basic patent, the monopoly resulting from the basic (reference) patent is extended and enables its holder to prevent competitors from making use of the invention (manufacturing the medicine, offering it for sale, storing it, etc.) in those Member States in which an SPC has been granted.

2.4 An SPC serves as compensation for the investment put into research. It should also compensate for further research, monitoring and waiting in the period between the patent application being filed and authorisation to place such a product on the market being received.

2.5 In the EU, an SPC can be granted under the following conditions:

2.5.1 On the date of application for supplementary protection the product is protected by a basic patent;

2.5.2 The product has not already been the subject of a certificate;

2.5.3 A valid and first administrative authorisation to place the product on the market as a medicinal product has been granted.

2.6 The Stakeholders' Views[2] indicate that today's SPCs place EU-based manufacturers of generics and biosimilars (G/Bs) at a disadvantage vis-à-vis manufacturers capable of producing G/Bs outside the EU.

2.7 In its current form, the EU SPC increases reliance on imports of drugs and pharmaceuticals outside the EU.

2.8 The global pharmaceutical market has changed. Fast-growing economies (pharmerging) combined with ageing populations in the traditional industrialised regions have driven a massive demand for medicines. Total global spending on medicines increased from EUR 950 billion in 2012 to EUR 1.1 trillion in 2017 (USA 40%, China 20% and the EU less than 15%). Biologics will represent 25% of the pharmaceutical market value by 2022. This is being accompanied by a shift towards an ever-greater market share for G/Bs, which could represent 80% of medicines by volume by 2020 and about 28% of global sales.

2 SWD(2018) 242 final.

2.9 According to Medicines for Europe, 56% of medicines by volume currently supplied in the EU are G/Bs.

2.10 The Bolar[3] exemption has eliminated an unintended side effect of strong patent protection, based on the rationale that free competition should be allowed as soon as protection expires. It is a manufacturing waiver for testing and clinical trials purposes, and was intended to ensure that a generic could enter the market as soon as possible after the expiry of patent/SPC protection.

2.11 Regarding the SPC manufacturing waiver, EU firms are facing a situation similar to the pre-Bolar one. While the legitimate purpose of an SPC is to prevent the manufacturing of competing products for the purpose of marketing on the EU market while the SPC is in effect, it has two unintended and unforeseen consequences, namely:

2.11.1 Preventing G/Bs from being manufactured in the EU and exported to third countries (where no legal protection applies) during the EU SPC term; and

2.11.2 Preventing them from being manufactured in the EU (and then stored) early enough to be placed on the EU market immediately as of day-1.

2.12 Manufacturers of G/Bs (based in a Member State where the application of a SPC for the reference medicine has been applied) face the following problems:

2.12.1 During the period of protection covered by the certificate of the reference medicine in the EU, manufacturers cannot manufacture that medicine for any purpose, including for export outside the EU to countries where SPC protection for the reference medicine has expired or never existed, while manufacturers based in those third countries can do so.

2.12.2 Immediately upon expiry of the certificate: they are not ready to enter the EU market on day-1, since the EU SPC system does not allow manufacturing in the EU until then. By contrast, manufacturers based in third countries where SPC protection for the reference medicine has expired earlier, or never existed at all, can be ready to enter the EU market as of day-1, via exports, and thus gain a considerable competitive advantage.

2.13 The G/B sector now accounts for 160 000 jobs in the EU (Medicines for Europe). The loss of jobs, especially of highly skilled jobs, loss of know-how and a brain drain to non-EU countries, notably to Asia, must be prevented by an urgent change in the regulation of SPCs.

3 Directive 2001/83/EC and Directive 2001/82/EC.

2.14 The EU was a pioneer in the development of regulatory procedures to approve biosimilars: the EMA authorised the first biosimilar in 2006, while the FDA did so only in 2015. However, there are clear signs that Europe is now losing its competitive edge, with its trade partners catching up. Therefore there is an urgent need for the EU to restore the competitiveness of EU-based manufacturers of G/Bs. Doing nothing or postponing an initiative would further weaken the EU industry and unravel the EU's pioneering effect and competitive advantage in the biosimilar sector in particular.

2.15 In accordance with the Single Market Strategy, a targeted recalibration of certain aspects of SPCs is needed, aiming to tackle the following problems:

2.15.1 Loss of export markets in unprotected third countries;

2.15.2 Day-1 entry onto Member States' markets for EU-based manufacturers of G/Bs by introducing an "SPC manufacturing waiver" in the EU SPC legislation, allowing the manufacture of G/Bs within the EU during the SPC term;

2.15.3 Fragmentation resulting from the uneven implementation of the current SPC regime in the Member States that could be solved in connection with the upcoming unitary patent, and the possible creation thereafter of a unitary SPC title;

2.15.4 Fragmented implementation of the Bolar research exemption.

3. **General comments**

3.1 What can we expect from the new regulation?

3.1.1 Strengthening and retaining manufacturing capacity and know-how in the EU, thereby reducing unnecessary relocation/outsourcing.

3.1.2 Strengthening EU patients' access to medicines by diversifying geographical sources of supply and thus strengthening home production.

3.1.3 Removing obstacles to starting generic and biosimilar businesses in the EU, especially for SMEs that have more difficulties in overcoming obstacles and which may have difficulties if they have to face non-EU competition.

3.1.4 As manufacturing capacity established for export purposes can, prior to expiry of the certificate, be used with a view to supplying the EU market from day-1, it is also expected to boost, to some extent, access to medicines in the Union by enabling G/Bs to enter the market more quickly after the certificates have expired, thus ensuring the availability of a wider choice of affordable medicines once the period of patent and SPC protection has passed. This should have a positive effect on national health budgets.

3.1.5 The proposal will, to some extent, make medicines more accessible to EU patients, especially in those Member States in which access to some reference medicines (e.g. certain biologics) is difficult, by creating the conditions to help related G/Bs gain more rapid entry into the Union market once the relevant certificates have expired. It will also diversify the geographical origin of medicines available in the EU, thus strengthening the supply chain and security of supply.

4. **Specific comments**

4.1 The EC may find some way to use EU funds to support the building of manufacturing capacity in Member States for export purposes during the SPC term. This may, for certain products, allow a quicker scale-up of production for entering the EU market on day-1.

4.2 The Commission may support the activities of interested NGOs for developing indicators for monitoring and evaluating the new SPCs for the future development of the EU market share of EU-manufactured generics and biosimilars.

Brussels, 20 September 2018

Luca JAHIER
The president of the European Economic and Social Committee