EU Amending Regulation

EXEMPTION FROM SPC PROTECTION FOR MEDICINES

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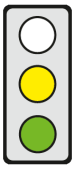
KEY ISSUES

Objective of the Regulation: An exemption from supplementary protection certificates is intended to permit the export of generic drugs and biosimilars to third countries where there is no patent or certificate protection. This aims to restore a level playing-field between manufacturers in the EU and those in third countries.

Affected parties: Manufacturers of generics and biosimilars, active substances and intermediary products; original manufacturers.



Pro: (1) The exemption reduces competitive disadvantages for European manufacturers of generics and biosimilars who are unable to relocate their manufacturing to third countries, e.g. SMEs.

(2) It increases the attractiveness of the EU for manufacturers of generics and biosimilars.

Contra: Its advantages are however limited because it does not permit manufacturing for stockpiling purposes, for protected EU markets, which means that a "day-1" market entry is still practically impossible for EU manufacturers. The Regulation should permit such manufacture ("stockpiling waiver").

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Proposal COM(2018) 317 of 28 May 2018 for a Regulation **amending Regulation** (EC) No 469/2009 **concerning the supplementary protection certificate for medicinal products**

Brief Summary

Note: Unless otherwise indicated, Article numbers refer to the Regulation that is subject to amendment (EC) No. 469/2009. Unless otherwise indicated, Recitals and page numbers refer to the proposal for an amendment COM(2018) 317.

- **Supplementary protection certificates**
  - For medicines, the time from patent application to market authorisation may often be more than eight years.
  - In order to compensate patent holders for the period in which a patent already applies but the corresponding medicine has not yet been authorised for sale, there are "supplementary protection certificates" (hereinafter: Supplementary Protection Certificates – SPCs) [Recitals 4, 5, 8 Regulation (EC) No. 469/2009, p. 2].
  - SPCs take effect after expiry of the patent protection period extending the protection – legal effect – of a patent for the active substance of a medicine as well as any use of the active substance as a medicine (hereinafter, for the sake of simplicity: medicine) by up to a maximum of five years [Art. 1 (b), Art. 4 (1), Art. 13 (2)].
  - Applications for an SPC may be made in any EU Member State for the Member State concerned [Recital 1].
  - SPCs prohibit competitors, in the Member States in which the SPC applies, from manufacturing and marketing the active substance and the corresponding medicine as well as any intermediary products [Recital 4, p. 3].

- **Context and objectives of the Proposal**
  - SPCs give rise to competitive disadvantages for manufacturers based in the EU – i.e. in Member States with SPC protection – that produce
    - replicas of original medicines (generics) and
    - replicas of original biotech medicines (biosimilars).
  - This is because – by contrast with competitors from third countries in which patent, SPC or other protection either does not exist or has already expired (hereinafter: "third countries without protection") – these manufacturers are not allowed to [Recitals 4 and 5, p. 1–4]
    - produce their generics and biosimilars for export to third countries without protection or
    - build up production capacity in order to supply EU Member States as soon as SPC protection has lapsed; this obstructs their timely ("day-1") market entry in those Member States.
  - "Manufacturers" are companies or parts of companies that manufacture products themselves on site. "EU-based manufacturers" or "EU manufacturers" thus manufacture in the EU.
  - The generics and biosimilars sector in the EU encompasses 350 manufacturing sites, over 160,000 jobs and exports to over 100 countries. In 2016, in quantitative terms, 56% of prescribed drugs in the EU were generics or biosimilars. (SWD(2018) 240, p. 9–10 and 11)

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– The Commission wants to reduce the existing competitive disadvantages, affecting export to third countries and "day-1" market entry after expiry of SPC protection, by way of a targeted exemption from SPC protection for export purposes [Recitals 8 and 9, p. 1, 3 and 4]. This is intended to [p. 2, 4, 6, 7, 10, 12]
  - initiate investment in the European generics and biosimilars industry and create jobs in the EU,
  - prevent further relocation of the manufacturing of generics and biosimilars to third countries and
  - improve the supply of medicines and relieve national healthcare budgets.
– The Commission also wants to [Recital 12, p. 5 and 8]
  - make reliance on this exemption "transparent" and
  - inter alia prevent the violation of SPC protection applicable in the EU, e.g. because the exemption allows medicines get onto the EU market illegally,

  by introducing duties of notification, labelling and care for those manufacturers who want to use the exemption.

► **Exemption for manufacturing for export**

– The exemption applies to manufacturers that are not SPC-holders and that manufacture [Art. 4 (2) (a) i)]
  - generics or biosimilars in the form of finished medicines or
  - only the SPC-protected active substances or intermediary products used for medicines

  (hereinafter for the sake of simplicity: "generics and biosimilars").
– In future, they will be able to manufacture generics and biosimilars in Member States where there is SPC protection, for the exclusive purpose of export to third-countries without protection and sell them in those countries. [Art. 4 (2) (a) i)]
– The exemption only applies to SPCs that are issued as of the start of the third calendar month following publication of the Regulation in the EU Official Journal [Art. 4 (5)],
– The exemption also applies to any act that is related to manufacture and is "strictly necessary" for that manufacture or for export [Art. 4 (2) (a) ii)]. This includes e.g. upstream or downstream acts carried out by the manufacturer itself or by contractually commissioned third parties [Recital 9, p. 7].
– The exemption only permits manufacture for the purpose of export to third-countries, not to EU Member States without SPC protection [Art. 4 (2) (a) i)].

► **Use of exemption subject to duty of notification, labelling and care**

– Manufacturers that are not SPC-holders must submit inter alia the following information to the competent authority, in each Member State in which a generic or biosimilar is to be manufactured, no later than 28 days prior to the start of manufacture [Art. 4 (2) (b), (3) (a)–(f), Recital 13]:
  - their name and address and that of the premises where manufacture is to take place in the Member State,
  - the number of the relevant SPC and
  - the intended start of manufacture in the Member State and an indicative list of the third countries to which the product is to be exported.
– The competent authority must publish this information within 15 days [Art. 11 (4)].
– Manufacturers must place a logo on the packaging indicating the export purpose [Art. 4 (2) (c)].
– The manufacturer must ensure by "appropriate, in particular contractual means" that contractually commissioned persons – such as third parties in a supply chain – who perform related acts are fully informed that [Art. 4 (2) (d) and (4), Recital 14]
  - the actions undertaken are subject to the exemption and its requirements and
  - placing the generics or biosimilars on the market in the EU as well as their import or reimport into the EU may breach the rights of the SPC-holder.

Main Changes to the Status Quo

Generics and biosimilars can be manufactured in EU Member States with SPC protection where they are for export to third countries without patent, SPC or other protection, provided the manufacturers comply with the associated duties.

Statement on Subsidiarity by the Commission

National exemptions from SPC protection would be detrimental to the internal market. Moreover, only a uniform EU exemption enables division of manufacturing work between several Member States with SPC protection [S. 7].

Policy Context

In its Communication on the Single Market Strategy [COM(2015) 550], the Commission announced "a targeted recalibration of certain aspects of patent and SPC protection" in order to strengthen the competitiveness of European companies. As well as the exemption from SPCs, uniform EU application of the "Bolar clause" – an additional exemption under patent law – is also planned. In addition to the recalibration, an EU unitary patent and a possible EU unitary SPC title are also at the planning stage. In 2016, the EU Parliament called on the Commission to introduce an exemption from SPCs until 2019 without undermining the SPC protection in those countries with protection [p. 1].

Legislative Procedure

28 May 2018	Adoption by the Commission
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Directorates General:	DG Internal Market, Industry, Entrepreneurship and SMEs (leading)
Committees of the European Parliament:	Legal Affairs (leading), Rapporteur: Luis de Grandes Pascual (EVP, ES)
Federal Ministries:	Justice and Consumer Protection (leading)
Committees of the German Bundestag:	Health (leading);
Decision-making mode in the Council:	Qualified majority (acceptance by 55% of Member States which make up 65% of the EU population)

Formalities

Competence:	Art. 114 TFEU (Internal Market)
Form of legislative competence:	Shared competence (Art. 4 (2) TFEU)
Procedure:	Art. 294 TFEU (ordinary legislative procedure)

ASSESSMENT

Economic Impact Assessment

The exemption from SPC protection for the manufacture of generics and biosimilars for export is a boost for manufacturers of generics and biosimilars based in the EU – or more precisely in Member States with SPC protection – because it means that, as soon as the period of protection of a medicine patent comes to an end, they can manufacture their products for export to third countries in which there is no SPC protection and where also no other protection is valid anymore. Manufacturers can thus open up export markets earlier than previously, from the EU. Target export markets are e.g. China, Russia and Brazil, which do not have SPC protection and whose imports of pharmaceutical products from the EU grew each year on average by 21.1%, 10.3% and 8.7% respectively between 2001 and 2016 (SWD(2018) 240, p. 81).

Manufacturers can also enter third-country markets, in which SPC protection expires earlier than in the EU, on the first day after expiry of local protection. In the USA, which is a major target country for EU pharmaceutical exports, protection often expires earlier. Thus, protection in the USA expired on average more than two years earlier than in the EU in the case of 93 active substances from a random sample of 109; it was a similar case in South Korea (SWD(2018) 240, p. 72).

The exemption thus, on the one hand, **reduces competitive disadvantages for European manufacturers of generics and biosimilars who are unable to relocate their manufacturing to third countries, e.g.** small and medium-sized enterprises (**SME**s). Because, until now, they have only been able to develop export markets much later than competitors from third countries without SPC or similar protection. **The exemption**, on the other hand, **increases the attractiveness of the EU for manufacturers of generics and biosimilars** because manufacture in the EU will generally become more lucrative as a result of earlier access to export markets in third countries.

These advantages are, however, limited because the exemption does not permit manufacturing by EU manufacturers **for SPC-protected EU markets** purely **for stockpiling purposes which means that a "day-1" market entry is still practically impossible for EU manufacturers** in these markets after expiry of the SPC protection. This is because, by contrast with competitors from third countries without protection, they will still only be able to start production for the EU market as of the first day following expiry of SPC protection and thus will not be able to supply it until – possibly much – later. Since, on the generics and biosimilars market, it is crucial to be one of the first suppliers on the market in order to secure market share, EU-based manufacturers are still at a substantial competitive disadvantage and the EU remains substantially less attractive for the generics and biosimilar industry.

This is all the more significant since third countries such as China and India enjoy additional advantages – such as when it comes to production costs. It is also likely that third countries – e.g. USA and Japan – will upgrade their legislation and introduce a similar exemption so that initial advantages for EU manufacturers as compared with the manufacturers in these countries, and an advantage to the EU as a business location, will only be short lived. Finally, the exemption does not permit export to EU Member States without SPC protection, which additionally weakens its beneficial effect. Consequently, the exemption will only have a limited ability to combat the migration of manufacturers of generics and biosimilars to third countries, or to encourage investment and create jobs. Similarly limited is thus the extent to which it can achieve the objectives of improving the supply of medicines and relieving national healthcare budgets as a result of lower prices from increased competition.

The Regulation should, if the EU really wants to improve competition conditions for European manufacturers of generics and biosimilars, as well as its attractiveness to the industry, **also permit manufacture for stockpiling purposes,**

for SPC-protected **EU markets,** to take place a reasonable time before the expiry of a corresponding SPC **("stockpiling waiver")**. This would enable EU-based manufacturers to gain timely ("day-1") market entry in EU Member States following expiry of the SPC and effectively remedy the regulatory disadvantages of the EU regarding competition and location.

The exemption applicable to manufacturing for export will reduce the profits of original manufacturers. Although it will not limit the market exclusivity of an SPC-protected medicine in the EU during the protection period of the SPC, it will intensify competition in third-country markets without protection in which original manufacturers are often present. This is particularly true where European manufacturers of generics and biosimilars have a better reputation for quality than their competitors from third countries and are therefore more popular. Although the exemption still does not allow "day-1" market entry to EU markets for European manufacturers of generics and biosimilars, it may speed up their access which means that original manufacturers will be subject to more intensive competition in the EU after expiry of SPC protection. From an ordoliberal perspective, however, reductions in profits for original manufacturers do not justify mandatory restrictions on competition in markets where SPC or other protection does not exist or has expired. Where reductions in profits mean that European original manufacturers cease their research activities, and investments stop, this may be counteracted by longer periods of protection for patents and SPCs.

The duties of notification, labelling and care make using the exemption more transparent. This facilitates the discovery and prevention of breaches and improves the evidence situation, both for original manufacturers and users of the exemption, in the event of dispute.

Legal Assessment

Legislative Competency

Although the exemption aims to strengthen the competitiveness of manufacturers of generics and biosimilars in third countries, it affects uniform EU legislation on SPC protection and thus the manufacture of active substances and medicines in the EU internal market. Thus, the power under Art. 114 TFEU on the functioning of the EU internal market applies.

Subsidiarity.

Unproblematic.

Compatibility with EU Law in other respects

The proposed amendment is proportionate in that it only enables manufacturers of generics and biosimilars to develop foreign markets without SPC protection and thus does not unreasonably restrict the rights of SPC-holders: the exclusivity rights under patents and SPCs are limited by territory and thus not directly affected by the exemption; the market exclusivity of SPC-holders remains intact. SPC-holders are only – indirectly – affected by the exemption where they themselves are competing, with their protected active substances and medicines, in third countries without protection or following expiry of the SPC, because then, in addition to the competitors from third countries who are active anyway, they will also be competing with those from the EU, which will potentially increase competition. The fact that manufacturers of generics and biosimilars currently cannot take part in this competition is a restriction of their freedom to conduct a business (Art. 16 CFR) even though SPCs – unless otherwise provided in international agreements – are not in fact supposed to provide economic protection against competition in third countries. Considering the possible increase in the competitiveness of manufacturers of generics and biosimilars, the restriction of SPC protection is reasonable.

The exemption is inappropriate for achieving the objective, also envisaged by the Commission, of making "day-1" market access in EU Member States easier for EU manufacturers on expiry of SPC protection, because, by contrast with their competitors from third countries, they are not allowed to start production for EU markets any earlier.

With regard to safeguarding the confidence of SPC-holders, the exemption is proportionate as it will only affect SPCs issued after entry into force of the Regulation.

Publication, by the competent authority, of the manufacturing locations of the active substances and medicines intended for export is not necessary; on the contrary, such publication may involve trade secrets of a manufacturer of generics or biosimilars.

Possible future follow-up measures by the EU

The EU will probably also introduce a "stockpiling waiver" after examination of the exemption.

Conclusion

The exemption reduces competitive disadvantages for European manufacturers of generics and biosimilars who are unable to relocate their manufacturing to third countries, e.g. SMEs. It increases the attractiveness of the EU for manufacturers of generics and biosimilars. These advantages are however limited because the exemption does not permit manufacturing for stockpiling purposes, for SPC-protected EU markets, which means that "day-1" market entry is still practically impossible for EU manufacturers. The Regulation should also permit such manufacture for stockpiling purposes ("stockpiling waiver").