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Transparency Register ID:
917393784-81

Deutsche Sozialversicherung
Europavertretung | DSV

Opinion from German Social Insurance, issued 19th September 2023

Commission Proposal for a Regulation on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

Commission Proposal for a Regulation on the supplementary protection certificate for medicinal products (recast)

Commission Proposal for a Regulation on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006

Content

I. Preliminary remark

On April 27, 2023, the European Commission made proposals to reform intellectual property rights for medicines. These include proposed regulations on standard essential patents, mandatory licensing of patents in crisis situations, and the revision of the legislation on Supplementary Protection Certificates (SPCs). Thus, a unitary European certificate is to be established to complement the unitary European patent already introduced by Regulations (EU) No. 1257/2012 and (EU) No. 1260/2012 and due to start in 2023. In addition, a centralized procedure is to be established at EU level to obtain supplementary protection certificates in all designated member states. The new rules are intended to complement the unitary European patent system, which will be applied from June 1, 2023, provide greater transparency and ensure fair access to innovation even in emergency situations.

A study commissioned by the European Commission shows that for 61 percent of the medicines considered, the longest effective protection of new medicines from generic competition is provided by patent protection or an SPC. Consequently, regulatory market protection under pharmaceutical law only takes effect in a good third of all cases. This underscores the importance of patent law regulations for the position of drugs on the market and must be taken into account elsewhere, namely in the revision of European pharmaceutical law proposed by the European Commission on April 26, 2023. There, the legal design of patent protection significantly influences the balance between incentives for the development of new medicines on the one hand and, because of its competitive implications, the long-term financial stability of healthcare systems on the other. If the goals set by the European Commission with the pharmaceutical package regarding access, availability and affordability of medicinal products are to be achieved, a shortening of exclusivity periods must be worked towards both in pharmaceutical law and in patent law.

The DSV supports the envisaged uniform European granting of SPCs if it promotes competition, leads to more transparency, effectiveness and legal certainty and thus contributes to more efficient care. However, it must be ensured that patent owners must also use a centralized procedure for granting SPCs in all cases that are eligible for a centralized procedure. In this respect, it must be ruled out that national application procedures can be used specifically in individual cases to raise the hurdles for a legal attack on the SPC by providers of generics or biosimilars. Furthermore, the granting of the SPC should be limited to the primary patent (original active ingredient patent independent of references to dosage forms, indications, etc.). A "patent thicket" consisting of a multitude of secondary patents, which serves to shield a product from competition, must be counteracted.

From the point of view of the DSV, the simpler and less expensive application for SPCs will foreseeably lead to greater use. In order to ensure the objectives of the European Commission within the framework of pharmaceutical legislation and, in particular, the affordability and availability of new medicinal products, a shortening of the protection period of SPCs would be necessary as compensation. These goals are also served by strengthening transparency through the establishment of a digital database for drug-related property rights, which must be made available to providers of generics and biosimilars as well as to health authorities and payers.

The draft regulation on the granting of compulsory licenses for crisis management is intended to create the possibility of granting compulsory licenses for crisis-relevant products on a uniform European basis in the event of an identified crisis or emergency situation in the Union. Relevant emergency situations are also to include a public health emergency at Union level pursuant to Article 23 of Regulation (EU) 2022/2371. The DSV also supports the extension of the national to include European uniform regulations for compulsory licenses. The procedure for European uniform compulsory licenses under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) should be extended to all cases where there is an overriding public interest across the Union.

In the following sections, concrete proposals are made for the implementation of supplementary protection certificates and compulsory licensing.

II. Opinion

1 _ Proposals for amendments to the draft Regulation on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation ((EU) No 608/2013

The draft regulation [COM(2023) 222 final] aims to simplify the EU system of supplementary protection certificates and make it more transparent and efficient by creating a single certificate for medicinal products.

Amendment

	Text proposed by the Commission		Amendment
Art. 2 Par. 1	(1) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;	>	(1) 'medicinal product' means any substance or combination of substances ~~presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;~~***that fulfils at least one of the following conditions:*** ***(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; or*** ***(b) any substance or combination of substances that may be used in or ademinstered to human beings with a view to either resstoring, correcting or***

			modifying physiological functions by exerting a pharmacological, immonological or metabolic action, or to making a medical diagnosis;

Justification

Article 2 contains the necessary definitions. Paragraph 1 contains the definition of a ‘medicinal product’.

In view of DSV it remains unclear why the definition used here differs from the definition used in the proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC. Because of the close connection between the two proposals in the field of patent law and the pharmaceutical sector, and for reasons of legal clarity, the definition of the term from the pharmaceutical legislation should be used here with identical wording.

The proposed amendment reflects the wording of the draft Directive on medicinal products for human use.

Amendment

	Text proposed by the Commission		**Amendment**
Art. 3 Par. 1 Subpar. 2 new	A unitary certificate shall be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled: (a) the product is protected by that basic patent in force; (b) a valid authorisation to place the product on the market as a	>	A unitary certificate shall be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled: (a) the product is protected by that basic patent in force; (b) a valid authorisation to place the product on the market as a

medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;	medicinal product has been granted in accordance with ***Directive 2001/83/EC,*** Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004, ***as appropriate***;
(c) the product has not already been the subject of a certificate, nor of a unitary certificate;	(c) the product has not already been the subject of a certificate, nor of a unitary certificate;
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.	(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.
	When the conditions under Subparagraph 1 are met, the centralised application procedure under Article 20 of Regulation [COM(2023) 231] shall be mandatory and a 'unitary certificate' shall be issued.

Justification

The current proposal of the European Commission in Article 3 paragraph 1 provides that - even in the case of a unitary European basic patent - the applicant can choose whether to apply for a European unitary SPC or for SPCs in the national procedure when a medicinal product covered by a European patent has not been authorised through the centralised procedure under Regulation (EC) No 726/2004.

There are concerns that in cases qualifying for a centralised procedure, patent proprietors could specifically use national application procedures in individual cases to raise the hurdles for a legal attack on the SPC by suppliers of generic or biosimilar products. This would be contrary to the concern of the legislation to resolve the fragmentation of the system in favour of improved efficiency and transparency. It should therefore be considered, in analogy to the centralised authorisation procedure for medicinal products for human use to make the unitary certificate and the centralised application procedure compulsory under the conditions of Article 3 paragraph 1.

The proposed amendment for a sub-paragraph 2 sets out an obligation for the unitary certificate and the centralised application procedure under the above conditions.

Amendment

	Text proposed by the Commission	Amendment
Art. 3 Par. 2	The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State. Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable.	The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State. ***The granting of the certificate or unitary certificate is to be limited to the primary patent.*** ~~Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable~~.

Justification

The clarification in Article 3 paragraph 2, that a patent holder can only be granted a supplementary protection certificate for a product once - as has been the case up to now - is understandable in principle and is also supported. However, in the opinion of the DSV, the regulation does not go far enough: the granting of the SPC should be limited to the primary patent.

Secondary patents are often applied for and granted for medicinal products beyond the primary patent on the use of a chemical substance (class) as an active ingredient. Secondary patents concern partial developments in relation to the product, such as its manufacture, pharmaceutical composition or use for certain indications. On average, seven secondary patents are granted for a product, but considerably more for individual products. The strategy of shielding a product from competition through a multitude of secondary patents is known as a "patent thicket". The use of secondary patents in this way creates legal uncertainty and an artificial barrier to market entry for generics and biosimilars. They are used to extend the monopoly position of the product sometimes far beyond the protection period of the primary patent, sometimes to well over 20 years. If the patent proprietor has the choice of applying for a supplementary protection certificate also for a secondary patent, this could be used in some cases to circumvent the duration of the protective effect of the SPC determined in Article 20.

Finally, the exception in subparagraph 2 is not comprehensible. It describes that two suppliers of the same product, each of which holds a patent on this product, can be granted an SPC independently of each other, provided they are not economically linked. First of all, it should be noted that in this case there is always a licence agreement between the companies anyway, since the product is usually protected by an active substance patent. However, this already constitutes an economic link. Moreover, it is not evident why the circumstance of parallel distribution of a product by several suppliers should justify an effectively longer monopoly position for one of the products (depending on the date of grant of the respective basic patents) than in the case of a single supplier. This is because no innovation worth protecting is associated with this. On the contrary, it is to be feared that this regulation will be exploited strategically. The regulation should therefore be deleted without replacement.

Amendment

	Text proposed by the Commission		**Amendment**
Art. 5 Par. 3 Subpar. 2 new		>	***This Article, particularly with regard to (iii) and (iv), is without prejudice to the conditions of Article 10 paragraph 6 of Directive 2001/83/EG.***

Justification

Article 5 sets out the effects of the unitary certificate.

The DSV expressly supports exemptions from the protection of the SPC for the purpose of a faster nationwide market entry of generics and biosimilars after the expiry of the protection period. With regard to Article 5 (3) et seq., however, the interaction with Article 85 of the Commission's draft directive on medicinal products for human use [COM(2023) 192 final] should be taken into account. The exceptions described under Article 5 paragraph 3 point (a), (iii) and (iv), are already covered by Article 85 of the Draft Directive concerning the pharmaceutical legislation. In this respect, it must be ensured in Article 5 paragraph 2 et seq. for suppliers of generic medicinal products or biosimilars that they are not subject to any further obligations or restrictions compared to Article 85 of revised Directive 2001/83/EC.

The supplementary subparagraph ensures that the obligations of the addressed pharmaceutical suppliers do not go beyond the scope of Art. 85 of revised Directive 2001/83/EC.

Amendment

	Text proposed by the Commission		**Amendment**
Art. 20 Par. 2	The duration of the unitary certificate may not exceed 5 years from the date on which it takes effect.	>	The duration of the unitary certificate may not exceed ~~5~~ four years from the date on which it takes effect.

Justification

Article 20 deals with the duration of the unitary certificate. Paragraph 2 says that this can be a maximum of five years from the date it takes effect.

In order to achieve the goals pursued with the pharmaceutical revision, in particular better affordability and availability of new medicinal products, a shortening of the exclusivity periods in pharmaceutical law and patent law must be brought about in the same way. With regard to supplementary protection certificates, this means in concrete terms that in return for the facilitation of the use of SPCs and the desired shortening of the processing times of the marketing authorisation, a shortening of their period of protection should necessarily be associated. An SPC extends the

effective patent protection from the time of authorisation to a maximum of 15 years, but not by more than five years. This means that in certain cases - namely if the medicinal product is approved between year 10 and year 20 of patent protection - a faster approval can lead to effectively longer protection periods. This runs counter to the aforementioned intention to shorten exclusivity periods.

In order to account for the aforementioned consequences and prevent an extension of the effective exclusivity protection by an SPC, we propose a reduction to a maximum duration of four years instead of five.

Amendment

	Text proposed by the Commission		Amendment
Art. 36 Par. 6 new		>	***The Office shall cooperate closely with the European Medicines Agency in order to establish and maintain, on the basis of the existing registers and the obligation to maintain a database pursuant to paragraph 1, an product-related central database in which all European and national patent and regulatory protection rights granted under medicinal products law are recorded.***

Justification

Article 36 obliges the Office to populate a database in addition to keeping a register of Unitary Protection Certificates issued. This database shall be used for communication with applicants and third parties as well as for the administration of applications for the grant of a protection certificate.

Generics and biosimilars come onto the market when the patent or SPC for the reference product expires. The establishment of a digital database for medicinal product-related property rights thus also improves planning security and competitive opportunities for suppliers of generics and biosimilars. The relevant information should also be made available to health authorities and payers so that they can take

it into account in their national supply planning and procurement procedures. The improved plannability of the contractual relationships of the health insurance funds with generic and biosimilar suppliers that can be achieved in this way also contributes to improving the security of supply.

As a result, the proposed register and database, together with the European Patent Register, should be expanded into a central, digital information platform at EU level, in which all (also national) patent and regulatory protection rights for medicinal products are listed on a product-related basis and in which reference is also made to pending proceedings in this regard. In this way, the transparency necessary for the smooth functioning of the internal market and the respective national health systems could be efficiently ensured.

Paragraph 6 new is intended to ensure that the information from the registers and the new database for unitary protection certificates is available for the establishment of a database for information on regulatory and patent protection periods pursuant to Article 138 of the draft Regulation [COM(2023) 193 final] and Article 82a new of the draft Directive [COM(2023) 192 final].

Amendment

	Text proposed by the Commission		Amendment
Art. 42 Par. 3	If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.	>	If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. ***Where an expert is summoned, the Office ensures that the person concerned is able to give an independent opinion and that there is no conflict of interest.*** The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

Justification

Article 42 regulates the procedure for taking evidence in appeal cases.

Here, provisions should be added to ensure that experts are independent and that conflicts of interest are taken into account when they are consulted.

The insertion in paragraph 3 obliges the Office, when inviting experts, to verify their independence and to exclude conflicts of interest.

2 _ Proposals for amendments to the draft Regulation on the supplementary protection certificate for medicinal products (recast)

The draft Regulation [COM(2023) 231 final] aims to establish a centralised procedure at EU level to obtain national supplementary protection certificates in all designated Member States.

Amendment

	Text proposed by the Commission		Amendment
Art. 20 Par. 1	Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.	>	Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted ***in accordance with Directive 2001/83/EC,*** through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, ***as appropriate,*** the procedure in this Chapter shall apply.

Justification

The European Commission's current proposal in Article 3 paragraph 1 and in Article 20 of the draft regulation provide that the applicant can choose whether to apply for SPCs in a centralised procedure under the present draft Regulation or in a national procedure, when a medicinal product covered by a European patent has not been authorised through the centralised procedure under Regulation (EC) No. 726/2004.

The DSV is concerned that in cases principally eligible for a centralised procedure under Article 20 because of a European basic patent, patent proprietors could specifically use national application procedures in individual cases to raise the hurdles for a legal attack on the SPC by generic or biosimilar providers. This would run counter to the legislator's concern to overcome the fragmentation of the system in favour of more efficiency and transparency.
Consideration should therefore be given to making the centralised application procedure compulsory in the cases of medicinal products that are covered by a European patent.

In that regard, a reference to Directive 2001/83/EC is introduced in Paragraph 1.

In addition, the following further amendments proposed by the DSV to the draft Regulation on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No608/2013, are to be transferred by analogy to the draft Regulation on the supplementary protection certificate for medicinal products (recast) COM(2023) 231 final:

Further Amendments

As a consequence of the comments of the DSV on the draft Regulation [COM(2023) 222 final] in Opinion Part II. 1, some proposed amendments are to be included in the draft Regulation on the supplementary protection certificate for medicinal products (recast) [COM(2023) 231 final]:

- In Article 2, paragraph 1, the definition of medicinal product from Article 2, paragraph 1 [COM(2023) 222],
- in Article 3, paragraph 3, the limitation to the primary patent as the basic patent and the deletion of the rule for multiple separate SPCs in the case of multiple applications from Article 3, paragraph 2 [COM(2023) 222],-
- in Article 5, paragraph 2, new second subparagraph, the interaction with the Bolar exception from Article 5, paragraph 3, new second subparagraph [COM(2023) 222],
- in Article 13, paragraph 2, the duration of the allowance from Article 20, paragraph 2 [COM(2023) 222],
- in Article 36, paragraph 6 new, the database on exclusivity rights from Article 36(6) [COM(2023) 222],
- in Article 45, paragraph 3, the conflicts of interest of experts from Article 42(3) [COM(2023) 222].

3 _ Proposal for an amendment to the draft regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

The draft regulation [COM(2023) 224 final] aims to ensure that, on the one hand, balance and incentives for innovation are maintained in times of crisis and, on the other hand, rapid access to critical products and technologies is ensured even if there are no voluntary licensing agreements.

Amendment

	Text proposed by the Commission		Amendment
Art. 4	The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.	>	The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex ***or where the Commission formally recognised an overriding public interest throughout the Union by means of an implementing act.***

Justification

Article 4 provides the legal basis for the granting of compulsory Union licences in crisis or emergency situations.

The DSV is in favour of extending the national regulations to include uniform European regulations for compulsory licences. The procedure for European uniform compulsory licences under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) should be extended to all cases where there is an overriding public interest throughout the Union. This is the purpose of the proposed amendment.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and longterm care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance, pension insurance and accident insurance offer effective protection against the consequences of major risks to life.