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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for medicinal products (recast)

(Text with EEA relevance)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

EXPLANATORY MEMORANDUM

CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend the 20-year term of patents for medicinal or plant protection products (PPPs) by up to 5 years[1]. They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner[2].

This proposal aims to simplify the EU's SPC system as regards national SPCs for medicinal products, as well as improve its transparency and efficiency. This initiative was announced in the Commission work programme for 2022 as initiative number 16 under Annex II (REFIT initiatives)[3].

Regulation (EC) No 469/2009 provides for SPCs for medicinal products (both human and veterinary medicinal products) to be granted at a national level on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 1610/96 provides for SPCs for plant protection products. Together these two measures constitute the EU's SPC regime. As Regulation (EC) No 469/2009 has been amended several times, and since further amendments are to be made, that Regulation should, in the interest of clarity, be recast, which is the **first objective of this proposal** (and of the parallel proposal on PPPs (COM(2023) 223).

As confirmed by the evaluation carried out in 2020 (SWD(2020)292 final), today's purely national procedures for granting SPCs involve separate examination proceedings (in parallel or subsequent) in Member States. This entails duplication of work, resulting in high costs and more often discrepancies between Member States in decisions to grant or refuse SPCs including in litigation before national courts. Inconsistency between Member States in decisions to grant or refuse SPCs is the single reason most often cited by national courts for preliminary references to the Court of Justice of the European Union on the application of the EU's SPC regime. The current purely national procedures, therefore, lead to significant legal uncertainty.

The Commission's intellectual property action plan of November 2020 (COM(2020) 760 final), which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system. The plan noted that, for medicinal

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1 An additional 6-month period of protection is available, subject to specific conditions, for medicinal products for use in the paediatric population, as defined by Regulation (EC) 1901/2006.

2 The unitary patent (UP) is a legal title that will provide uniform protection across all participating countries on a one-stop-shop basis. As of April 2023, 17 Member States are expected to participate in the UP system. For updates and more information, see: https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en.

3 European Commission, Annexes to Commission communication – Commission work programme 2022, COM(2021) 645 final, 2021, p. 9 (https://eur-lex.europa.eu/resource.html?uri=cellar%3A9fb5131e-30e9-11ec-bd8e-01aa75ed71a1.0001.02/DOC_2&format=PDF#page=9).

products and PPPs, SPC protection is only available at national level. At the same time, there is a centralised procedure for granting European patents and a centralised procedure for obtaining marketing authorisations for medicinal products. In the same vein, the pharmaceutical strategy for Europe (COM(2020) 761 final) emphasised the importance of investing in R&D to create innovative medicines. The strategy stressed, however, that the differences between Member States in the implementation of intellectual property regimes, especially for SPCs, lead to duplications and inefficiencies that affect the competitiveness of the pharmaceutical industry. Both the Council[4] and the European Parliament[5] have called on the Commission to correct these deficiencies.

Therefore, a **second objective of this proposal** is to introduce a centralised procedure for granting SPCs for medicinal products. This would allow applicants to obtain SPCs in the respective designated Member States subject to marketing authorisations having been granted in/for each of them, by filing a single 'centralised SPC application' that would undergo a single centralised examination procedure.

While that examination would be conducted by a centralised authority, the actual grant of SPCs would be done by the respective national offices of the designated Member States, based on a positive opinion from the central examination authority. The opinion of the central examination authority would be binding upon the national offices of the designated Member States.

A parallel proposal (COM(2023) 223), with similar provisions to this one for medicinal products[6], concerns SPCs for PPPs.

- **Consistency with existing policy provisions in the policy area**

The core substantive features of the proposed centralised procedure – i.e. the conditions for obtaining certificates, as well as their legal effect – are the same as those of the existing SPC regime. This proposal introduces new procedural provisions as regards the centralised examination and is not intended to modify the scope nor the effect of the rights conferred by national SPCs currently granted according to Regulation (EC) No 469/2009. The same new procedural provisions are also inserted in the above-mentioned parallel proposal on SPCs for PPPs (COM(2023) 223).

At the same time, parallel proposals are being made to create unitary certificates for medicinal products (cf. COM(2023) 222) and for PPPs (cf. COM(2023) 221). Applications for these unitary certificates would undergo the same centralised examination procedure described in this proposal, especially in the event of 'combined' applications that request both a unitary certificate and national certificates, as explained below. This ensures complete consistency across the whole SPC reform package.

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4 Council conclusions on intellectual property policy of 10 November 2020 https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf.

5 European Parliament, Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)), https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html.

6 Human and veterinary medicinal products.

This table explains the purposes of the four related proposals:

Medicinal products		**Plant protection products**
PROPOSAL 1 Regulation on the SPC for medicinal products (recast)	← Art. 114 TFEU →	**PROPOSAL 2** Regulation on the SPC for plant protection products (recast)
PROPOSAL 3 Regulation on the unitary SPC for medicinal products	← Art. 118 TFEU →	**PROPOSAL 4** Regulation on the unitary SPC for plant protection products

Moreover, it should be noted that nothing will prevent national SPCs as defined in Regulation (EC) No 469/2009 and in Chapter II of this proposal from being granted on the basis of a unitary patent as the basic patent.

Finally, this proposal is part of the 'EU patent package' announced in 2023 which, besides the revision, modernisation and introduction of a system for unitary supplementary protection certificates, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

- **Consistency with other Union policies**

The COVID-19 pandemic has underlined the importance of having a strong and balanced IP system to provide the necessary incentives to develop new treatments and vaccines that patients will have access to. It has also highlighted the need for transparent and easily accessible information on the status of IP rights, including SPCs, to facilitate potential collaborations, licensing and freedom-to-operate analyses[7]. Patents and SPCs are key to supporting the EU in its efforts to build a European Health Union and to other related initiatives such as the new European Health Emergency Preparedness and Response Authority (HERA)[8], EU FAB[9] and the pharmaceutical strategy for Europe.

The proposed centralised procedure is therefore fully consistent with the existing pharmaceutical legislation and with other relevant legislation, in particular the European patent with unitary effect ('unitary patent') as set out in Regulation (EU) No 1257/2012, and the related Agreement on a Unified Patent Court (UPCA). The unitary patent system will enter into force on 1 June 2023.

In addition, this proposal is fully compatible with Regulation (EC) No 1901/2006 on medicinal products for paediatric use, which provides for a possible 'paediatric extension' of SPCs for medicinal products under specific conditions.

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7 Discussions in this regard have been taken to the World Intellectual Property Organisation (WIPO), where national/regional patent offices were invited to share information on their collaborations with publicly accessible databases of patent status information concerning medicines and vaccines, such as MedsPaL. See: WIPO, Standing Committee on the Law of Patents, 32nd session, SCP/32/7, 2020.

8 European Commission, Commission Communication – HERA Incubator: Anticipating together the threat of COVID-19 variants, COM/2021/78, 2021.

9 European Commission, 'Questions and answers : HERA incubator – Anticipating together the threat of COVID-19 variants', 2021 (https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_642).

Moreover, this proposal complements the pharmaceutical strategy for Europe and its intention to promote both innovation in medicines and better access to them, including the related legislative changes that are contemplated as regards regulatory protections (*[OP, please add a reference to the ongoing reform of the pharmaceutical legislation]*).

Finally, the SPC reform and the other initiatives listed in the intellectual property action plan contribute to the broader innovation strategy of the EU.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

This proposal is based on Article 114(1) of the Treaty on the Functioning of the European Union on the single (or 'internal') market. This is the same legal basis used for Regulations (EC) No 469/2009 and (EC) No 1610/96 (previously Articles 100a, and then 95, respectively, of the Treaty establishing the European Community, as it then was). It is once again necessary to have recourse to Article 114 to adapt the EU SPC regime in the light of how the existing system has been applied. Even though SPCs are already harmonised, there are still cases where some Member States have granted SPCs while identical applications have been refused in others or been granted with a different scope. SPC applicants thus face diverging decisions across the EU on the same product, while incurring costs for applying and maintaining SPCs in several Member States. Consequently, further EU action is needed to address these issues and can, unlike national intervention by Member States, ensure a consistent EU-wide framework, and reduce the total costs and burden of fees to be paid in multiple Member States. Further EU-level action would strengthen the integrity of the single market by providing a centralised, balanced and transparent SPC system across the EU, and mitigate the negative consequences of redundant and potentially diverging procedures that applicants face[10]. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the single market for innovative medicinal products that are subject to marketing authorisations. EU-level action would also allow innovative and follow-on manufacturers to reap the benefits of an efficient intellectual property framework in the relevant product markets.

• Subsidiarity

The objectives underlying the proposal can only be achieved at Union level. The Union-wide approach implemented by the centralised procedure envisaged in this proposal will ensure that the applicable rules and procedures are consistent across the Union, ensuring legal certainty for all relevant market participants.

• Proportionality

This initiative does not go beyond what is necessary to achieve the identified objectives. Its scope is limited to those aspects that Member States cannot achieve satisfactorily on their own and where EU action can produce better results, e.g. in terms of consistent decisions on SPC applications to reduce administrative burdens and costs, and improve transparency and legal certainty.

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10 Case C-58/08 ECLI:EU:C:2010:321.

- **Choice of the instrument**

As the current SPC legislation is only governed by regulations, no other instrument can be envisioned for recasting the existing EU SPC legislation (Regulations (EC) No 469/2009 and (EU) No 2019/933) and introducing a centralised procedure.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations and fitness checks of existing legislation**

An evaluation of the SPC regime was carried out in 2020 (SWD(2020) 292). It found that SPCs promote innovation and the availability of new medicines and PPPs because they help companies recoup their R&D investments. Although the SPC Regulations provide a common framework within the EU, they are administered at national level. This fragmentation leads to high costs and imposes an administrative burden on applicants (especially SMEs) and national administrations. It also leads to legal uncertainty, as the scope of protection can differ across the EU. This has a negative impact on SPC users and makers of generics. These negative effects are amplified by a lack of transparency, especially from a cross-border perspective, making it difficult to trace what SPC protection exists for which products in which Member States. This affects both SPC holders and generics manufacturers.

An evaluation of the SPC manufacturing waiver, which is an exception introduced by Regulation (EU) 2019/933, which amended Regulation (EC) No 469/2009, and is included in this proposal, will be undertaken in the near future (as foreseen in Article 21a of Regulation (EC) No 469/2009).

- **Stakeholder consultations**

The Commission conducted a public consultation during the evaluation of the SPC regime (between 12 October 2017 and 4 January 2018)[11]. In addition, the Max Planck Institute study mentioned below included a survey of stakeholders in the Member States, conducted in 2017 by the Allensbach Institute ('the Allensbach survey'), which included several questions on the operation of the current (national) SPC regimes. Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence. For further information, see Annex 2 of the impact assessment (SWD(2023) 118).

- **Collection and use of expertise**

The study[12] carried out in 2018 by the Max Planck Institute on the legal aspects of SPCs in the EU (especially Chapter 22) provides key findings on the operation of the current SPC regime (for medicinal products). The additional Max Planck Institute study completed in 2022[13] provides a deeper analysis of the design of a centralised procedure.

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11 https://ec.europa.eu/docsroom/documents/29464

12 https://ec.europa.eu/docsroom/documents/29524

13 https://op.europa.eu/en/publication-detail/-/publication/94cb20ea-2ff0-11ed-975d-01aa75ed71a1/language-en

- **Impact assessment**

An impact assessment was carried out and submitted to the Regulatory Scrutiny Board in late 2022 and, after resubmission, received a positive opinion on 16 December 2022 (SWD(2023) 118).

The following options were identified:

– Option 0: No policy change.

– Option 1: Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the Court of Justice of the European Union (CJEU). These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.

– Option 2: Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.

– Option 3: Centralised filing and examination of SPC applications, resulting in a non-binding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.

– Option 4: Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, but NPOs would have to follow the opinion. Therefore, while decisions on granting SPC protection would still be taken by national offices, the outcome of these decisions would be determined by a central authority.

– Option 5: A ‘unitary SPC’ complementing the unitary patent. The central authority, in addition to examining applications, would grant a ‘unitary SPC’ to applicants with a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (initially 17) Member States party to the UPCA.

These options would not replace national SPCs, but would provide alternative routes to obtaining SPC protection across the EU.

A combination of options 4 and 5 constitutes the preferred choice. It would provide for a centralised procedure that could result in the grant of national SPCs in some or all Member States, and/or of a unitary SPC (covering those Member States in which the basic unitary patent has effect). When deciding on who should act as the examination authority, several criteria were considered: accountability (in particular, to the European Parliament), alignment with the EU’s overarching political values and current policy priorities, and experience with substantive SPC assessment. It is therefore proposed that the EU Intellectual Property Office (EUIPO) should become the central examination authority, supported by national offices.

Option 1, on guidelines for examining national SPC applications, would not be sufficient alone to overcome discrepancies between national practices, as the guidance would be non-binding. Nevertheless, in the context of the preferred options 4 and 5, EUIPO should develop guidelines that reflect its practice. These guidelines would be of practical use both to officials in charge of the SPC-related procedures and to their users, including professional advisers

who assist applicants (e.g. by offering examples). This guidance would take stock of the practices developed by the examination panels, especially since they will include examiners from several different Member States, to improve consistency between examination practices under the new centralised procedure. Moreover, national offices may also benefit from guidelines developed by the examination authority for their own (national) examination procedures.

Option 2 may not provide enough predictability, as some reference offices could be more lenient than others, thus leading to 'forum shopping', while Option 3 alone would allow offices to re-examine the SPC application, and has thus the potential to result in divergences on the decision to grant or refuse an SPC, leading to further fragmentation in the single market.

- **Regulatory fitness and simplification**

Enabling holders of European patents to obtain several (national) SPCs across the EU through a centralised procedure would represent a considerable simplification compared to the current situation in which national SPCs need to be applied for and granted separately in each Member State. The proposed new centralised procedure is expected to result in significant reductions in costs and administrative burden for applicants, and in improved legal certainty and transparency, including for third parties (e.g. makers of generics).

In addition, as regards medicinal products, this proposal will result in a single SPC Regulation instead of three, as would have resulted from proposing the creation of a centralised procedure through a stand-alone Regulation while leaving the existing Regulation (EC) No 469/2009 (as amended by Regulation (EU) 2019/933) unaffected. In other words, this proposal – that will recast and repeal Regulation (EC) No 469/2009, which was amended by Regulation (EU) No 2019/933 – will achieve a 'one in, two out' outcome.

- **Fundamental rights**

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects). The initiative is consistent with the Charter of Fundamental Rights as it offers greater legal certainty to applicants for the grant of an intellectual property right and where necessary for third parties, by providing for the procedural conditions for the examination, opposition and appeal before the centralised authority.

In particular, where a centralised examination opinion is negative, the applicant may file an appeal before the Boards of Appeal of the EUIPO. Oppositions to applications may also be filed by third parties.

In addition, a national office may decide to not grant an SPC, despite a positive examination opinion, in certain narrowly defined situations, namely where material circumstances in that Member State have changed since the filing of the centralised application (such as the basic patent being no longer in force). Moreover, examiners from national offices will play a key role in the centralised examination procedure and participate in the substantive examination of the application, as well as may take part in opposition proceedings.

On the other hand, third parties will be able to submit observations during the examination of a centralised application, and to initiate an opposition against an examination opinion. Where national SPCs are granted by national offices on the basis of a positive opinion, third parties will also be able to challenge their validity before the respective national courts or other competent bodies, as already possible today pursuant to Regulation (EC) No 469/2009.

As further explained below under 'Basic patent', legal certainty concerns call for closing the national route when SPC protection is sought for a given product, where the conditions are fulfilled for the centralised procedure – i.e., in such a case, the filing of separate national applications before national offices should be prohibited. This is intended to avoid divergences between national decisions as such divergences would be avoided by using the centralised procedure, and to prevent users from filing national SPC applications only before national offices whose examination practice is less rigorous. This practice is akin to forum shopping and undermines the SPC system. Applicants may seek to file weak applications at national level in the hope of receiving SPCs from more lenient offices.

Conversely, as further explained below under 'Unitary SPC', this proposal does not exclude centralised SPC applications designating one or more Member States participating in the unitary patent system, potentially resulting in national SPCs being granted in these Member States, as long as double protection is excluded, even where the conditions are met for the grant of a unitary SPC.

A comparison of these two proposed measures does not show any unjustified difference of treatment. Indeed, there may be cases where an applicant, while holding a unitary patent, has no interest in obtaining SPCs in all the Member States which that patent covers, and therefore that applicant should not be forced to apply for a unitary SPC, even if the conditions thereof were fulfilled. On the other hand, the closing of the national route for the centralised procedure never creates an obligation to designate all Member States for which the centralised procedure can be used in given circumstances, as the applicant is free to choose which Member States should be designated.

4. BUDGETARY IMPLICATIONS

This proposal will have no impact on the EU budget, since the system will remain fully self-funded by applicants' fees, as is already the case for the existing SPCs regimes governed by Regulations (EC) No 469/2009 and (EC) No 1610/96, and will be implemented by the examination authority, the EUIPO. The necessary set-up costs of the tasks conferred to the EUIPO, including the costs of new digital systems, will be financed from the EUIPO's accumulated budgetary surplus. A breakdown of the budgetary impact on the examination authority is provided in Annex 5D of the impact assessment.

The financial impacts on Member States (national offices) will also remain low. Indeed, while the number of SPCs applied for each year is likely to increase, it is quite low for the time being, even in large Member States. For instance, in 2017, 70 SPC applications were filed in Germany and 72 in France. The largest number of applications (95) were filed in Ireland. The average cost varies by country. Based on current average coverage (20 Member States) and duration (3.5 years), SPC protection for a given product would cost around EUR 98 500 on average. In order to cover all 27 Member States for 5 years one would pay nearly EUR 192 000 in total (not including any fees charged by patent lawyers). For a breakdown of the costs, see Annex 5B of the impact assessment (SWD(2023) 118).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

It is envisaged that an evaluation will be carried out every 5 years.

- **Detailed explanation of the specific provisions of the proposal**

Overall structure of the proposal

Chapter I of the proposal includes definitions and other general provisions.

Chapter II of the proposal includes most of the existing provisions of Regulation (EC) No 469/2009 regarding national applications for certificates, filed at national offices[14] (as amended by Regulation (EU) 2019/933), without changing their substance, except for minor technical adaptations that bring the recast regulation up to current drafting standards and ensure better alignment with certain provisions of the corresponding proposal on plant protection products (COM(2023) 223), derived from Regulation (EC) No 1610/96.

Chapter III includes new provisions defining the new centralised procedure.

Chapter IV contains final provisions, including the repeal of Regulation (EC) No 469/2009.

Basic patent

The existing SPC Regulations do not impose any limitation on the types of ('basic') patents on which a national SPC application must rely, which may thus be: (1) a national patent resulting from either a national patent application or from a European patent application; or (2) a unitary patent (a 'European patent with unitary effect'). To remove any residual legal uncertainty, the option to rely on this second type of patent will be clarified through minor amendments, in the recitals of this proposal, that explicitly refer to unitary patents. In this respect it should be noted that paragraph 21 of the explanatory memorandum of the first proposal for a Council Regulation concerning the creation of a supplementary protection certificate for medicinal products (COM(90)101) envisaged that '*when use is made of the European procedure to obtain a Community patent, it will likewise be necessary that the certificate can apply equally to medicinal products protected by a Community patent*' (now referred to as a 'European patent with unitary effect' or, more informally, a 'unitary patent').

It is proposed that applications for SPCs filed under the new centralised procedure (Chapter III of this proposal) must be based on European patents only as 'basic patents', including a European patent with unitary effect. This will facilitate the examination of centralised SPC applications because the filing and examination of a European patent application, if positive, results in the grant of a European patent having, with a few exceptions, identical claims for all designated countries, which is required for unitary patents.

Moreover, today most inventions, and in particular medicinal products, patented in the EU are protected by European patents, which are granted only as the result of a thorough examination procedure, and not by national patents, which in several Member States are not subject to an in-depth substantive examination.

Therefore, under the proposed centralised procedure, allowing centralised SPC applications to be based on national patents would be more demanding as regards the examination of such applications, as it would be necessary to examine separately, for each of the designated Member States, whether the product concerned is indeed protected by each of the respective national patents in force, which will not necessarily have the same claims. This may also affect legal certainty.

[14] More precisely, filed with the competent industrial property office of the Member State concerned, unless another authority was designated for that purpose.

A requirement that the claims of the basic (European) patent must be identical for all Member States designated in a centralised SPC application would make it easier to examine the application. However, the cases where a European patent includes two or more sets of claims for different Member States are quite rare, and it is very exceptional that there are more than two sets of claims. For this reason, this proposal does not include a requirement that the claims of the basic patent must be identical for all Member States designated in a centralised SPC application.

In those situations where a centralised application could be filed, namely where the basic patent is a European patent and the marketing authorisation is a centralised one, the choice could have been made to also allow applicants to file national SPC applications. Based on the findings of the evaluation completed in 2020, which revealed discrepancies between the granting practices of various national offices, this might have resulted, however, in applicants applying for certificates in Member States with less strict examination standards, to avoid filing a centralised application that may be rejected due to a stricter examination. Such a situation would be detrimental to consistency and legal certainty, could promote forum shopping, and would result in a higher total workload across the EU from examining applications. To avoid these drawbacks, it is considered preferable to examine applications under the centralised procedure in all cases where the conditions for using this procedure are met. Accordingly, this proposal requires that a national SPC application, filed in a Member State, be rejected where the requirements for filing a centralised application are fulfilled (‘closing of the national route’).

Examination/granting authority

Under the proposed centralised procedure, a central examination authority will carry out a substantive examination of a centralised SPC application, especially as regards the conditions for grant defined in Article 3 of the existing SPC Regulations. The Commission proposes that the EUIPO should be the central examination authority, in particular because it is an EU agency and therefore part of the EU legal order.

After assessing the formal admissibility of the centralised SPC application, the central examination authority would entrust the substantive examination of the application to a panel. This panel would be made up of a member of that central authority and two qualified examiners, experienced in SPC matters, from two different national patent offices in Member States. Before designating examiners qualified to examine SPC issues, these national patent offices will have agreed, through an ad hoc agreement with the central examination authority, to participate in this centralised examination system. Competencies and skills in SPC matters are scarce and qualified SPC examiners can be found today in national patent offices. Moreover, the relatively low number of products for which SPC applications are made each year (less than 100) justifies making recourse to existing qualified examiners in Member States, as opposed to creating an entirely new body of experts. During the examination, third parties may submit their observations on the validity of a certain centralised SPC application after its publication.

Examination procedure and remedies

After examining the centralised SPC application, the central examination authority will issue an examination opinion stating, for each of the designated Member States, whether a national SPC fulfilling the applicable criteria (and in the first place those defined in Article 3) should be granted or refused. The applicant can file an appeal against a negative or partly negative opinion (as further explained below).

In order to account for the need to have a complete system of remedies and avoid the need for third parties challenging a positive examination opinion in national courts which would then in turn have to make reference to the EU Courts, third parties will be able to challenge a positive (or partly positive) opinion by initiating an opposition procedure during 2 months after the publication of the examination opinion. Such an opposition may result in the examination opinion being amended.

Challenges against the examination opinion can be appealed to the Boards of Appeal, and subsequently to the General Court and, possibly, ultimately before the Court of Justice subject to the system of leave to appeal under Articles 170a and following of the Rules of Procedure of the Court of Justice, or under the review procedure in accordance with Article 256, paragraph 2, TFEU, Article 62 of the Statute of the Court and Articles 191 and following of the Rules of Procedure of the CJEU.

The opinion (including where amended following an opposition) will then be transmitted to the national offices of each of the designated Member States. Where the opinion is positive the designated Member States will grant a national SPC in accordance with their national rules, e.g. as regards publication, registration in relevant databases and the payment of annual (renewal) fees, unless circumstances have changed, such as the basic patent no longer being in force in a certain Member State. Subject to the outcome of any appeal before the Boards of Appeal or the EU courts, if the examination opinion is negative, the national office concerned must reject the application.

After the grant of SPCs at a national level, third parties will still be able to initiate invalidity proceedings before the body responsible under national law for the revocation of the corresponding basic patents, or the competent courts of the Member States, including the Unified Patent Court, as applicable. The same applies to a possible counterclaim for a declaration of invalidity of an SPC.

Marketing authorisations concerned

It is proposed that only a centralised marketing authorisation (as defined in Regulation (EC) No 726/2004 and in Regulation (EU) No 2019/6) could serve as the basis for a centralised SPC application for medicinal products made under the centralised procedure proposed in Chapter III. Today, most medicinal products are authorised under that centralised marketing authorisation procedure. A centralised SPC application based on national marketing authorisations, such as those granted under the decentralised or mutual recognition procedures, would have significant drawbacks. These would include a bigger examination workload, potential differences between the various national marketing authorisations granted for the product concerned in different Member States, including language issues.

Substantive features of the SPC regime

This reform does not intend to modify, nor further clarify in view of the relevant case law of the Court of Justice, the substantive features currently laid down in Regulation (EC) No 469/2009 for the existing national SPC regimes or the new centralised procedure, since:

– the case law[15] on SPCs is progressively converging, and steadily reducing uncertainty about the interpretation of the SPC regime[16], while further amendments

[15] For a full list of cases, see Table 5.5. of the second MPI study.

[16] Further clarifications are, however, necessary in certain areas as indicated by two referrals in 2022, cases C-119/22 and C-149/22.

might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;

– respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the case law is unclear in some respects (question 46).

New recitals

It was noted that there were no relevant recitals in Regulation (EC) No 469/2009 that could assist in interpretation of Article 3. Accordingly, certain recitals concern the conditions in Article 3 for the grant of SPCs, and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C-121/17 and C-673/18 interpret Article 3(a) and 3(d) of Regulation (EC)No 469/2009, respectively, and should be considered settled case law. This is also the case for judgement C-471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

The requirement that the product should be protected by the basic patent means that the product should fall within the scope of one or more claims of that patent, as properly interpreted at the basic patent's filing date. This also includes situations where the product corresponds to a general functional definition used by one of the claims of the basic patent, and necessarily comes within the scope of the invention covered by that patent, even if it is not indicated in individualised form as a specific embodiment in the patent, provided that it is specifically identifiable from the patent.

Many general objectives set out in the Explanatory Memorandum of the proposal (COM(90)101) for what became Council Regulation 1768/92/EEC, i.e. the predecessor of Regulation (EC) No 469/2009, remain fully relevant today and should continue to be used as a guide to interpretation, where relevant. This includes the objective that *only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate*.

Furthermore, as regards the rights conferred by a certificate, *the certificate confers the same protection as the basic patent, but only protects the product covered by the authorisation, for all pharmaceutical uses authorised, until the expiry of the basic patent.*

As regards the rights conferred by a certificate, and in line with the earlier statements regarding derivatives, it could be appropriate to consider that the protection conferred by a certificate on a product extends to the therapeutically equivalent derivatives of the product.

For biological products, the application of the rules, both as regards the conditions for grant and the effects of a certificate, should take into account the fact that minor differences may be unavoidable between a subsequent biosimilar and the product initially authorised, given the nature of biological products.

Language regime

This Regulation envisages the possibility of filing a centralised SPC application in any official EU language. In this regard, the amount of text in an SPC application is extremely small, especially compared to patents and this would not present a burden for applicants. Certain matters would not require any translation, such as the identification of the basic patent and the relevant marketing authorisation, the relevant dates, and the identification of the applicant(s)

and the product concerned. The translation costs are, therefore, expected to be considerably lower than would be the case for patent applications. See the impact assessment (SWD(2023) 118) for an exact calculation.

Appeals

Decisions of the central examination authority are subject to appeal. This also applies to a negative (or partly negative) examination opinion issued by the central examination authority, an appeal could be filed by an applicant before the central examination authority, during a limited period after the issuance of the examination opinion. This also applies to other decisions of that authority; for instance, the decision relating to an opposition may be appealed by any of its parties. An appeal may result in the examination opinion being amended.

In the event of a 'combined' SPC application as referred to below – namely an SPC application which requests the grant of a unitary SPC and also of national SPCs –, such an appeal would also be applicable to the (common) examination opinion relating to the combined SPC application.

The appeal would take place before the Boards of Appeal of the EUIPO. Members from the Boards of Appeal should be appointed in accordance with Article 166 (5) of Regulation 2017/1001. These members may also be national examiners, but they may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates.

In terms of workload, SPC applications are made for less than 100 products each year on average, for medicinal products and PPPs together, and introducing third-party observations should help keep the number of appeals at a very low level.

Fees

An application fee and possibly other procedural fees, such as the fee for oppositions and appeals, will have to be paid to the central examination authority. For national SPCs granted under the centralised procedure, renewal fees would have to be paid to the national patent offices of all the Member States where such certificates have been granted. This would differ, however, for unitary certificates granted under the parallel proposals COM(2023) 222 and COM(2023) 221, whereby the examination authority shall charge application and annual (renewal) fees. The level of fees to be paid to the central examination authority will be set in an implementing act.

Financial transfers between the central authority and national patent offices (NPOs)

As the procedural fees paid by applicants to the central examination authority may not be sufficient to cover the costs incurred by that authority under the new centralised procedure, it is necessary to ensure that a fraction of the renewal fees collected by national offices for SPCs granted on the basis of the centralised procedure will be transferred to the central examination authority. This already happens between national patent offices and the European Patent Office (EPO) in respect of renewal fees for European patents. At the same time, it is necessary to ensure that those national offices that participate in the new centralised procedure as regards the substantive examination of centralised SPC applications are properly remunerated for their participation.

Litigation

Whether it was obtained under today's current national procedures or under the newly proposed centralised procedure, an SPC based on an European patent, including a unitary patent, will be able to be litigated before the body responsible under national law for the

revocation of the corresponding basic patent, which is typically a national court, and may also, for those Member States participating in the unitary patent system (i.e. that have ratified the UPCA), be the Unified Patent Court ('UPC') where the applicable conditions are fulfilled (cf. Article 3(b) of the UPCA, together with Article 2(g) and Article 32)[17].

National aspects

As the proposed centralised procedure results in the grant of national certificates (SPCs), many existing national requirements and procedures, currently applicable to the SPCs applied for nationally, will be equally applicable to the certificates granted under the proposed centralised procedure. This relates in particular to publication requirements, national registers, the payment of renewal fees and the SPC manufacturing waiver introduced by Regulation (EU) 2019/933 and the paediatric extension defined in Regulation (EC) No 1901/2006.

No changes are proposed to the judicial procedures applicable to nationally granted SPCs, whether granted on the basis of a national application or of a centralised application, e.g. as regards revocation and enforcement, subject to the provisions of the UPCA, for its parties, where applicable. In other words, invalidity actions and infringement actions may be brought before the UPC also in respect of a nationally granted SPC based on a European patent, subject to the applicable conditions, in particular the requirement that neither the patent nor the SPC has been opted-out from the jurisdiction of the UPC.

Extension of SPCs for paediatric medicinal products

SPC applicants and holders should be able to use the centralised SPC granting procedure to apply for extensions of SPCs for paediatric medicinal products, under the conditions currently provided for by Regulation (EC) No 1901/2006.

Unitary SPCs

A parallel proposal (COM(2023) 222) is intended to create a unitary SPC for medicinal products. This unitary certificate would be available only on the basis of a European patent with unitary effect ('unitary patent'), as a basic patent, and would exert its effects uniformly in all the Member States in which the basic patent has unitary effect (17 initially).

The procedure for the centralised filing and examination of applications for such unitary certificates would be the same *mutatis mutandis* as the centralised procedure set out in this proposal. In this manner, a 'combined' SPC application could possibly include both a request for the grant of a unitary SPC (for the Member States covered by the basic patent) and a request for the grant of national SPCs in other Member States. This 'combined' application would undergo a single examination procedure, ruling out any discrepancies, and considerably reducing costs and the administrative burden for applicants. For the sake of clarity, this proposal does not exclude centralised SPC applications designating one or more Member States participating in the unitary patent system, as long as no unitary SPC is simultaneously requested in such a case.

[17] Where the related basic patent or the SPC itself has not been opted-out from the competence of the UPC and where no action has already been brought before a national court (as far as those Member States in which the patent has unitary effect are concerned).

↓ 469/2009 (adapted)

2023/0130 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for medicinal products (recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~ ⌦ on the Functioning of the European Union ⌫, and in particular Article ~~95~~ ⌦ 114(1) ⌫ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[18],

Having regard to the opinion of the Committee of the Regions[19],

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ 469/2009 recital 1 (adapted)

~~Council Regulation (EC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products has been substantially amended several times[20]. In the interests of clarity and rationality the said Regulation should be codified.~~

⇩ new

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[21] has been substantially amended[22]. Since further amendments are to be made, that Regulation should be recast in the interests of clarity.

18 OJ C […], […], p. […].

19 OJ C […], […], p. […].

20 ~~See Annex I.~~

21 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

↓ 469/2009 recital 2

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

↓ 469/2009 recital 3 (adapted)

(3) Medicinal products, ~~especially~~ ⌦ in particular ⌫ those that are the result of long, costly research will not continue to be developed in the ~~Community~~ ⌦ Union ⌫ ~~and in Europe~~ unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

↓ 469/2009 recital 4 (adapted)

(4) ~~At the moment,~~ T~~t~~he period that elapses between the filing of an application for a patent for a new medicinal product and ⌦ the ⌫ authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

↓ 469/2009 recitals 5 and 6 (adapted)

(5) ⌦ That ⌫ ~~This~~ situation leads to a lack of protection which penalises pharmaceutical research ⌦ and there is ⌫ ~~. There exists~~ a risk ~~of~~ ⌦ that ⌫ research centres situated in the Member States ⌦ relocate ⌫ ~~relocating~~ to countries that offer greater protection.

↓ 469/2009 recital 7 (adapted)

(6) A uniform solution at ~~Community~~ ⌦ Union ⌫ level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the ~~Community~~ ⌦ Union ⌫ and thus directly affect the functioning of the internal market.

[22] See Annex I.

↓ 469/2009 recital 8 (adapted)
⇨ new

(7) Therefore, the provision of a supplementary protection certificate ⌦ (‘certificate’) ⌫ granted, under the same conditions, by each of the Member States at the request of the holder of a national ⌦ patent ⌫ or European patent ⇨, with or without unitary effect, ⇦ relating to a medicinal product for which marketing authorisation has been granted is necessary. ~~A regulation is therefore the most appropriate legal instrument.~~ ⇨ The certificate should provide its holder with an adequate additional period of effective protection subsequent to the expiry of the basic patent. An application for such a certificate should be filed with the competent industrial property office (‘competent national authority’) of the Member State concerned. ⇦

⇩ new

(8) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims. Or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims, provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.

(9) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any therapeutically equivalent derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, either alone or in combination with one or more additional active ingredients, whether for the same therapeutic indication or for a different one.

(10) Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate should extend only to the product, namely the active ingredient or combinations thereof, covered by the authorisation to place it on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

(11) To ensure balanced protection, however, a certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the certificate but also therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars, even where such derivatives are not explicitly mentioned in the product description on the certificate. There is therefore a need to consider that the protection conferred by the certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(12) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product

should be allowed to be granted to each of those holders, where they can demonstrate that they are not economically linked. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

(13) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all therapeutically equivalent products having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.

(14) In order to ensure maximum flexibility and not unduly discriminate between holders of different types of patents, there should be no limitation on the type of patent on which a national certificate can be applied for before a competent national authority. Therefore, this should continue to be possible on the basis of a national patent or of a European patent and, in particular, this should also be possible in respect of a European patent with unitary effect ('unitary patent').

↓ 469/2009 recital 9 (adapted)

(15) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains ⌦ an ⌫ authorisation to be placed on the market in the ~~Community~~ ⌦ Union ⌫.

↓ 469/2009 recital 10 (adapted)
⇨ new

(16) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For ~~this~~ ⌦ that ⌫ purpose, ⌦ it should not be possible to grant a ⌫ ~~the~~ certificate ~~cannot be granted~~ for a period exceeding ⌦ 5 ⌫ years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the ⌦ Union ⌫ market as a medicinal product. ⇨ In addition, the timely entry of generics and biosimilars into the Union market is also important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines. ⇦

↓ 469/2009 recital 11

~~Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law.~~

⇩ new

(17) In order to promote the development of paediatric medicinal products, it should be possible to extend the period of overall maximum exclusivity of 15 years and the maximum period of validity of the certificate of 5 years where the paediatric extension provided for in Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[23] applies.

(18) Since the creation of supplementary protection, certificates were only applied for and granted nationally, thus requiring several similar applications to be filed and examined in parallel in a number of Member States. This has resulted in duplication of work for both applicants and competent industrial property offices ('competent national authorities') conducting separate examination proceedings in respect of a given product, as well as in occasional discrepancies in the decisions taken by the competent national authorities in different Member States. Such differences usually pertain to the conditions for the grant or refusal of a certificate and include the grant of a certificate in one Member State but the refusal in another Member State regarding the same product or differences in the application of the conditions that apply to prior marketing authorisation or whether the product has already been the subject of a supplementary protection certificate. This leads to legal uncertainty and is inconsistent with the aims of the internal market.

(19) There is a centralised procedure for granting European patents, as well as a centralised procedure for obtaining marketing authorisations for medicinal products. In addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012 of the European Parliament and of the Council[24] is to enter into force in June 2023 in respect of the Member States having ratified the Agreement on a Unified Patent Court ('UPC').

(20) Therefore, it is necessary to complement the existing national procedures for the grant of certificates for medicinal products with a centralised procedure. That procedure should make it possible, where the basic patent is a European patent, including a unitary patent, to request the grant of national certificates for two or more designated Member States through the filing and examination of a single 'centralised' application. Following the grant of certificates under the centralised procedure, those certificates should be equivalent to the certificates granted under national procedures and be subject to the same rules.

(21) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[25] has established, under its Article 2, a European Union Intellectual Property Office ('the Office'). In the interest of the internal market, the centralised procedure should be carried out by a single examining authority. This can be achieved by the Office being

[23] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

[24] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

[25] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

given the task of examining applications for certificates under the centralised procedure in accordance with this Regulation.

(22) In order to provide for a simplified examination of a centralised application, its filing should be available only on the basis of a European patent, including a unitary patent. The centralised application should not be available on the basis of a set of independent national patents, as their claims are likely to be different, resulting in greater complexity in examination compared to the situations where the basic patent is a European patent.

(23) The centralised procedure should apply only to a medicinal product that is based on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council[26] or Regulation (EU) No 2019/6 of the European Parliament and of the Council[27]. These authorisations refer to human medicinal and veterinary medicinal products respectively. Such an authorisation, unlike national authorisations, relates to the same medicinal product throughout the Union, and will facilitate the examination of centralised applications.

(24) The Office should have the possibility to charge a fee for the centralised application for a certificate and for an application for the extension of duration of certificates in the case of paediatric medicinal products, as well as other procedural fees such as a fee for opposition or appeal. The fees charged by the Office should be laid down by an implementing act.

(25) To ensure consistency amongst the certificates granted based on the same basic patent and for the same product in Member States, to reduce the global examination workload, and to ensure an appropriate application of the conditions for grant in all Member States where protection is sought for a given product, it is necessary that the centralised procedure be the only option available as regards those Member States for which the related requirements are fulfilled, namely that the basic patent be a European patent, including a unitary patent, and that the marketing authorisation be a centralised one. To this end, a national application for a certificate filed with a competent national authority, should be rejected by that national office where the requirements to use the centralised procedure are met. This measure is proportionate considering the risk of divergences, and does not apply to those situations where those requirements do not apply, in which case national applications may still be filed.

(26) An applicant should also be allowed to lodge a 'combined application' that would include an application for a unitary certificate as set out in Regulation [COM(2023) 222]. Such a combined application should undergo a single examination procedure.

(27) In order to avoid double protection, it should not be possible to grant certificates – whether national certificates or unitary certificates – for the same product in the same Member State based on both a national application and a centralised application.

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[26] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[27] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

(28) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the centralised application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate invalidity proceedings before the body responsible under national law for the revocation of the corresponding basic patent. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

(29) The Office should examine the centralised application for certificates and issue an examination opinion. That opinion should state the reasons for which it is positive or negative in respect of each of the designated Member States.

(30) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.

(31) Where the Office finds that the conditions for grant of a certificate are fulfilled in one or more of the Member States designated in a centralised application, but are not fulfilled in one or more of the other ones, including where in one of the designated Member States the basic European patent has different claims which do not cover the product, the Office should issue a positive opinion for those designated Members States in which the conditions for obtaining a certificate are fulfilled, and a negative opinion for those in which the conditions are not fulfilled.

(32) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

(33) After the completion of the examination of a centralised application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the opinion should be transmitted to the respective national patent offices of the designated Member States.

(34) Where the examination opinion is positive for one or several Member States, the respective competent national authorities should grant a certificate in accordance with the applicable domestic rules, in particular as regards publication, registration in relevant databases and the payment of annual fees.

(35) Where the examination opinion is negative for one or several Member States, the respective competent national authorities should reject the application in accordance with the applicable domestic rules.

(36) For the sake of coherence and legal certainty, the same substantive provisions should apply to national applications and to centralised applications regarding in particular the scope, the conditions for obtaining certificates, the subject-matter of protection and effect of certificates, and their publication. The centralised procedure would result in

the grant of national certificates fully identical to those granted on the basis of national applications.

(37) Since certain competent national authorities may have limited administrative capacity to conduct a full substantive examination of applications for certificates, competent national authorities should remain able to not verify all the conditions for granting a certificate on the basis of a national application. However, to ensure the quality and uniformity of the certificates granted under the centralised procedure, the Office should examine all of the conditions for grant of a certificate under the centralised procedure.

(38) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may be filed.

(39) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

(40) Any person may challenge the validity of a certificate granted following the centralised procedure before a competent court of a Member State, which includes the Unified Patent Court where the conditions are met.

(41) To reduce administrative burden and costs for certificate holders, there is a need for the centralised procedure to provide for a swift way of applying for, and granting, an extension of the duration of a set of equivalent certificates for a given medicinal product, granted under the new centralised procedure, in accordance with Regulation (EC) No 1901/2006. As for certificates, such extensions should be granted by competent national authorities, subject to a positive examination of the centralised application for an extension of the duration.

(42) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council[28] from the protection granted to holders of supplementary protection certificates for medicinal products. It noted the absence of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third country markets in which protection does not exist or has expired or for the purpose of storing with a view to day-one placement on the Union market entry. Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The reasons for the introduction for the waiver and the conditions for its application remain applicable at the present time.

[28] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (OJ L 153, 11.6.2019, p. 1).

↓ 2019/933 recital 5 (adapted)

(43) ~~Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The Union should strike~~ A~~a~~ balance ⌦ should be struck ⌫ between restoring a level playing field between ~~those~~ makers ⌦ of generics and biosimilars established in the Union and makers based in third countries that offer less or no protection ⌫ and ensuring that the essence of the exclusive rights of holders of certificates ('certificate holders') is guaranteed in relation to the Union market.

↓ 2019/933 recital 8 (adapted)

(44) ~~The aim of this Regulation is to promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of generics and biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets.~~ ~~This Regulation should also allow such~~ M~~m~~akers ⌦ of generics and biosimilars established in the Union should be allowed ⌫ to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired ('EU day-one entry'). ~~This Regulation should also complement the efforts of the Union's trade policy to ensure open markets for makers of products, or medicinal products containing those products, established in the Union. Over time, this Regulation should benefit the entire pharmaceutical sector in the Union by allowing all players, including newcomers, to reap the benefits of the new opportunities opening up in the fast-changing global pharmaceutical market. Furthermore, the general interest of the Union would be promoted given that, by reinforcing Union-based supply chains for medicines and by allowing storing with a view to entry into the Union market upon expiry of the certificate, medicines would become more accessible to patients in the Union after the expiry of the certificate.~~

↓ 2019/933 recital 9 (adapted)

(45) In those specific and limited circumstances, and in order to create a level playing field between makers established in the Union and third-country makers, it is appropriate to provide for an exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or of storing, and any related acts in the Union strictly necessary for that making or for the actual export or the actual storing ⌦ ('related acts') ⌫, where such acts would otherwise require the consent of ⌦ the ⌫ ~~a~~ certificate holder~~ ('related acts')~~. For instance, such related acts could include~~:~~ ⌦ the ⌫ possessing~~,~~ offering to supply~~,~~ supplying~~,~~ importing~~,~~ using or

synthesising ⌦ of ⌫ an active ingredient for the purpose of making a medicinal product.~~; or~~ ⌦They could also consist of ⌫ temporary storing or advertising ⌦ of the product ⌫ for the exclusive purpose of export to third-country destinations. ~~That~~ ⌦ The ⌫ exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker.

🡻 2019/933 recital 10 (adapted)

(46) The exception should apply to a product, or a medicinal product containing that product, protected by a certificate~~. It~~ ⌦ and ⌫ should cover the making of the product protected by ⌦ the ⌫ ~~a~~ certificate in the territory of a Member State and the making of the medicinal product containing that product.

🡻 2019/933 recital 11

(47) The exception should not cover placing a product, or a medicinal product containing that product, which is made for the purpose of export to third countries or of storing with a view to EU day-one entry, on the market of a Member State where a certificate is in force, either directly or indirectly after export, nor should it cover re-importation of such a product, or medicinal product containing that product, into the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity carried out for the purpose of import of products, or medicinal products containing those products, into the Union merely for the purposes of repackaging and re-exporting. In addition, the exception should not cover any storing of products, or medicinal products containing those products, for any purposes other than those set out in this Regulation.

🡻 2019/933 recital 12 (adapted)
⇨ new

(48) By limiting the scope of the exception to ⌦ the ⌫ making ⌦ of a product, or a medicinal product containing that product, ⌫ for the purpose of export outside the Union or to making for the purpose of storing, and to acts strictly necessary for such making or for the actual export or the actual storing, the exception ~~provided for in this Regulation~~ ~~should~~ ⇨ will ⇦ not conflict with the normal exploitation of the product, or the medicinal product containing that product, in the Member State in which the certificate is in force, namely with the core exclusive right of the certificate holder to make that product for the purpose of placing it on the Union market during the term of the certificate. In addition, that exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.

🡻 2019/933 recital 13 (adapted)

(49) Effective and proportionate safeguards should apply in relation to the exception in order to increase transparency, to help the ~~holder of a~~ certificate ⌦ holder to ⌫

enforce its protection in the Union and check compliance with ~~the conditions set out in~~ this Regulation, and to reduce the risk of illicit diversion onto the Union market during the term of the certificate.

↓ 2019/933 recital 14 (adapted)
⇨ new

(50) ~~This Regulation should~~ ⇨ To ensure better transparency and legal certainty, it is necessary to ⇦ impose an information obligation on the maker, namely the person established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export or storing, is carried out. ~~It is possible that the maker directly carries out the making~~ ⌦ That obligation should apply also where the making is directly carried out by the maker ⌫. ~~That information obligation should consist of requiring the maker to provide certain information to the competent industrial property office, or another designated authority, which granted the certificate ('the authority') in the Member State where the making is to take place. A standard form for notification should be provided for this purpose. The information should be provided before the making of a product, or a medicinal product containing that product, starts for the first time in that Member State, or before any related act prior to that making, whichever is the earlier. The information should be updated as and when appropriate. The making of a product, or a medicinal product containing that product, and the related acts, including those performed in Member States other than the one of making in cases where the product is also protected by a certificate in those other Member States, should only fall within the scope of the exception where the maker has sent the notification to the authority of the Member State of making, and where the maker has informed the holder of the certificate granted in that Member State. Where making takes place in more than one Member State, a notification should be required in each of those Member States. In the interests of transparency, the authority should be required to publish, as soon as possible, the information received, together with the date of notification of that information. Member States should be allowed to require that notifications, and updates to notifications, be subject to the payment of a one-off fee. That fee should be set at a level which does not exceed the administrative cost of processing notifications and updates.~~

↓ 2019/933 recital 18

(51) ~~For reasons of proportionality, failure to comply with the requirement regarding a third country should only affect exports to that country, and exports to that country should, thus, not benefit from the exception provided for in this Regulation.~~ It should be the responsibility of the maker established in the Union to verify that protection does not exist or has expired in a country of export, or whether that protection is subject to any limitations or exemptions in that country.

↓ 2019/933 recital 20 (adapted)
⇨ new

(52) ~~This Regulation should impose e~~Certain due diligence requirements ⌦should be imposed⌫ on the maker as a condition to use the exception ⇨ , so as to ensure better transparency and legal certainty ⇦. ~~The maker should be required to inform persons within its supply chain in the Union, including the exporter and the person carrying out the storing, through appropriate and documented means, in particular contractual means, that the product, or the medicinal product containing that product, is covered by the exception provided for in this Regulation and that the making is intended for the purpose of export or storing. A maker who fails to comply with those due diligence requirements should not benefit from the exception, nor should any third party performing a related act in the Member State of making or in a different Member State in which a certificate conferring protection for the product is in force.~~ The holder of the relevant certificate ⌦ will ⌫ ~~would~~, therefore, be entitled to enforce its rights under the certificate, while having due regard to the general obligation, provided for in Directive 2004/48/EC of the European Parliament and of the Council[29], not to engage in abusive litigation.

↓ 2019/933 recital 21 (adapted)

(53) ~~This Regulation should impose labelling requirements on the maker in respect of products, or medicinal products containing those products, to be exported, in order to facilitate, by means of a logo, identification of such products or such medicinal products as being exclusively intended for the purpose of export to third countries. Making for the purpose of export and related acts should only fall within the scope of the exception if the product, or the medicinal product containing that product, is labelled in the manner provided for in this Regulation.~~ ~~That l~~Labelling ~~obligation~~ ⌦ in this Regulation ⌫ should be without prejudice to labelling requirements of third countries.

↓ 2019/933 recital 22

(54) Any act not covered by the exception provided for in this Regulation should remain within the scope of the protection conferred by a certificate. Any diversion onto the Union market, during the term of the certificate, of any product, or any medicinal product containing that product, made under the exception, should remain prohibited.

[29] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

↓ 2019/933 recital 23
⇨ new

(55) This ~~Regulation~~ ⇨ exception ⇦ is without prejudice to other intellectual property rights that could protect other aspects of a product, or a medicinal product containing that product. This ~~Regulation~~ ⇨ exception ⇦ does not affect the application of Union acts that aim to prevent infringements, and facilitate enforcement, of intellectual property rights, including Directive 2004/48/EC and Regulation (EU) No 608/2013 of the European Parliament and of the Council[30] ~~(7)~~.

↓ 2019/933 recital 24
⇨ new

(56) This ~~Regulation~~ ⇨ exception ⇦ does not affect the rules on the unique identifier, provided for in Directive 2001/83/EC of the European Parliament and of the Council[31]. The maker should ensure that any medicinal product made for the purpose of export~~, pursuant to this Regulation,~~ does not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161[32] ⇨ , to ensure that such a product may be identified if it were illicitly re-imported into the Union ⇦. However, under that Delegated Regulation, the requirement to carry such an active unique identifier applies to medicinal products intended to be placed on the market of a Member State upon expiry of the corresponding certificate ⇨ ; accordingly, the prohibition of a unique identifier does not apply to such products ⇦.

↓ 2019/933 recital 25
⇨ new

(57) This ~~Regulation~~ ⇨ exception ⇦ does not affect the application of Directive~~s~~ ~~2001/82/EC and~~ 2001/83/EC and Regulation (EU) 2019/6, in particular the requirements relating to the manufacturing authorisation of medicinal products made for export. This includes compliance with the principles and guidelines of good manufacturing practices for medicinal products and using only active substances which have been manufactured in accordance with good manufacturing practices for active substances and distributed in accordance with good distribution practices for active substances.

30 Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 (OJ L 181, 29.6.2013, p. 15).

31 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

32 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

↓ 2019/933 recital 26 (adapted)
⇨ new

(58) To safeguard the rights of certificate holders, the exception provided for in this Regulation should not apply to a certificate that ~~has~~ ⌦ had ⌫ already taken effect at the date of entry into force of ~~this~~ Regulation ⌦ (EU) 2019/933 of the European Parliament and of the Council ⌫. ~~In order t~~To ensure that the rights of certificate holders are not excessively restricted, the exception should apply to certificates that are applied for on or after the date of entry into force of ~~this~~ Regulation ⌦ (EU) No 2019/933 ⌫. Given that a certificate takes effect at the end of the lawful term of the basic patent, which can be a relatively long time after the date of filing of the application for the certificate, ~~and in order to achieve the aim of this Regulation,~~ it is justified that ⇨ the exception set out in ⇦ this Regulation also ~~cover~~ ⌦ covers ⌫, over a certain period of time, a certificate that was applied for before the date of entry into force of ~~this~~ Regulation ⌦ (EU) No 2019/933 ⌫, but ~~has~~ ⌦ had ⌫ not yet taken effect before that date, irrespective of whether or not that certificate was granted before that date. The exception ⌦ applied ⌫ ~~should apply~~, therefore, from 2 July 2022 to a certificate that ~~takes~~ ⌦ took ⌫ effect from the date of entry into force of ~~this~~ Regulation ⌦ (EU) No 2019/933⌫. The concept of 'certain period of time' for each individual certificate that takes effect after the date of entry into force of ⌦ that ⌫ ~~this~~ Regulation should ensure that the exception ~~is~~ ⌦ be ⌫ applied, on a progressive basis, to such a certificate, depending on the date on which it ~~takes~~ ⌦ took ⌫ effect and on its duration. Such application of the exception would allow the holder of a certificate that ~~has~~ ⌦ had ⌫ been granted, but that ~~has~~ ⌦ had ⌫ not yet taken effect by the date of the entry into force of ~~this~~ Regulation ⌦ (EU) 2019/933 ⌫, a reasonable period of transition to adapt to the changed legal context, while at the same time ensuring that makers of generics and biosimilars can benefit effectively, without excessive delay, from the exception.

↓ 2019/933 recital 27 (adapted)

(59) ~~Typically, an applicant for a certificate files an application at approximately the same date in each Member State of filing. However, due to differences in national procedures for the examination of applications, the date of grant of the certificate might vary significantly from one Member State to another, thereby creating disparities in the legal situation of the applicant in the Member States in which the certificate was applied for. Introducing t~~The exception ⌦ should apply ⌫ on the basis of the date of the filing of the application for a certificate ~~would, therefore~~, ⌦ in order to ⌫ promote uniformity and limit the risk of disparities.

⇩ new

(60) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for certificates under the centralised procedure, including on certificates granted on that basis by competent national authorities, which should share with the Office any related information. The register should be available in all official languages of the Union.

(61) Regulation [COM(2023) 222][33] creates a unitary supplementary protection certificate for medicinal products, which may be requested for those Member States in which the basic patent has unitary effect. The request for such a unitary certificate may be made in a combined application for a certificate under the centralised procedure covered by this Regulation. In such a case, the combined application including both requests should be subject to a single centralised examination procedure. Double protection by both a unitary certificate and a certificate granted pursuant to this Regulation should be excluded.

(62) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union. The Office should accept verified translations, into one of the official languages of the Union, of documents and information. The Office may, if appropriate, use verified machine translations.

(63) Financial provision should be made to ensure that competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.

(64) The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, should be financed from the Office's accumulated budgetary surplus.

(65) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of: (i) specifying the content and form of the notice of appeal and the content and the form of the Boards of Appeal's decision, (ii) specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates, (iii) specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office, (iv) setting out the detailed arrangements for oral proceedings, (v) setting out the detailed arrangements for the taking of evidence, (vi) setting out the detailed arrangements for notification, (vii) specifying the details regarding the calculation and duration of time limits and (viii) setting out the detailed arrangements for the resumption of proceedings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[34] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards: (i) the application forms to be used; (ii) rules on procedures relating to the filing, and

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[33] Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

[34] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office, (iii) the criteria in the ways the examination panels are to be set up, and the criteria for the selection of examiners, (iv) the amounts of the applicable fees to be paid to the Office, (v) specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party, and (vi) rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[35].

↓ 2019/933 recital 28 (adapted)
⇨ new

(67) The Commission should carry out a regular evaluation of this Regulation ⇨, in particular in order to assess the impact on the exception on the competitiveness of the pharmaceutical sector of the Union⇦. ~~Pursuant to the Interinstitutional Agreement of 13 April 2016 on Better Law-Making, that evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures.~~ That evaluation should take into account, on the one hand, exports to outside the Union, and on the other ⌦ hand ⌫, the effects of storing on the swifter entry of generics and especially biosimilars into markets in the Union as soon as possible after a certificate expires. Such regular evaluation should also address the effects of this ~~Regulation~~ ⇨ exception ⇦ on the making of generics and biosimilars in the Union by makers of generics and biosimilars established in the Union. In that context, it ⌦ is ⌫~~would be~~ important to ascertain whether making that was previously taking place outside of the Union ~~would be~~ ⌦ are being ⌫ moved to within Union territory. In particular, ⌦ the ⌫ ~~that~~ evaluation should review the effectiveness of the exception in the light of the aim to restore a global level playing field for makers of generics and biosimilars in the Union. ⌦ The evaluation ⌫ ~~It~~ should also study the impact of the exception on research and production of innovative medicines in the Union by certificate holders and consider the balance between the different interests at stake, in particular as regards public health, public expenditure and, in ⌦ that ⌫ ~~this~~ context, access to medicines within the Union. It should also study whether the period provided for as regards the making of generics and biosimilars for the purpose of storing is sufficient to achieve the objective of EU day-one entry, including its effects on public health. ⇨ The Commission should also regularly evaluate the centralised procedure. ⇦

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[35] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

↓ 2019/933, recital 30 (adapted)
⇨ new

(68) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union ('the Charter'). ⇨ The rules in this Regulation should be interpreted and applied in accordance with those rights and principles. ⇦ In particular, this Regulation seeks to ensure full respect for the right to property and the right to health care ⇨ and the right to an effective remedy ⇦ ~~set out respectively~~ in Articles 17 and 35 ⇨ and 47 ⇦ of the Charter. This Regulation should maintain the core rights of the certificate, by limiting the exception provided for in this Regulation to the making of a product, or a medicinal product containing that product, only for the purpose of export outside the Union or for the purpose of storing for a limited period of time with a view to entry into the Union market upon expiry of the protection, and to the acts strictly necessary for such making or for the actual export or the actual storing. In the light of those fundamental rights and principles, the exception provided for in this Regulation does not go beyond what is necessary and appropriate in the light of the overall objective of this Regulation, which is to promote the competitiveness of the Union by avoiding relocation and allowing makers of generics and biosimilars established in the Union to compete, on the one hand, on fast-growing global markets where protection does not exist or has already expired, and on the other, on the Union market upon expiry of the certificate. ~~Indeed, it is necessary to benefit from the positive economic effects arising from the exception, as otherwise the Union would risk substantially weakening its position as a hub for pharmaceutical development and manufacturing. It is, therefore, appropriate to introduce that exception in order to increase the competitive position of makers of generics and biosimilars established in the Union in third countries whose markets are in any event open to competition, whilst leaving the scope and duration of the protection granted by the certificate in the Union untouched. The appropriateness of the measure is further ensured by providing for appropriate safeguards regulating the use of the exception. This Regulation should allow sufficient time for public authorities to put in place the necessary arrangements to receive and publish notifications.~~ ⇨ In addition, the removal of the possibility to file a national application for a certificate with a competent national authority, where the requirements to use the centralised procedure are met, is proportionate in the light of the risk of divergences. Where the requirements do not apply, national applications may still be filed. ⇦

⇩ new

(69) The establishment of a centralised procedure for the grant of certificates should not affect in any manner the national applications for certificates still pending before competent national authorities, nor the certificates granted on the basis of national applications.

(70) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, with a view to ensuring that the applicable rules and procedures are consistent across the Union, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality

as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(71) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[36] and delivered an opinion on XXX *[OP, please add reference once available]*.

(72) Appropriate arrangements should be made to facilitate a smooth transition from the rules provided for in Regulation (EC) No 469/2009 to the rules laid down in this Regulation. To allow for sufficient time for the Office to implement and launch the centralised procedure, the provisions on centralised applications should apply from *[OP – insert the date - one year after the entry into force of this Regulation]*,

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↓ 469/2009 (adapted)
⇨ new

HAVE ADOPTED THIS REGULATION:

CHAPTER I

⌦ GENERAL PROVISIONS ⌫

Article ~~2~~ 1

~~*Scope*~~ ⌦ *Subject matter* ⌫

~~Any product~~ ⌦ This Regulation lays down rules on the supplementary protection certificate ('certificate') for medicinal products ⌫ protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC ~~of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use~~[6] ⇨ , Regulation (EC) No 726/2004 ⇦ or ~~Directive 2001/82 of the European Parliament and of the Council 6 November 2001 on the Community code relating to veterinary medicinal products (7)~~ Regulation (EU) 2019/6 ~~may, under the terms and conditions provided for in this Regulation, be the subject of a certificate~~.

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[36] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

↓ 469/2009 (adapted)

Article ~~1~~ 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(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;

(2) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;

(3) ‘basic patent’ means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

~~‘certificate’ means supplementary protection certificate;~~

(4) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006 ~~of 12 December 2006 on medicinal products for paediatric use~~ [37];

↓ 2019/933 Art. 1 pt. 1

(5) ‘maker’ means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out.

⇩ new

(6) ‘national application’ means an application for a certificate made before a competent national authority pursuant to Article 9;

(7) ‘centralised application’ means an application made before the Office pursuant to Article 20 with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

[37] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1) OJ L 378, 27.12.2006, p. 1.

(8) ‘centralised application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 30 of this Regulation and Article 36 of Regulation (EC) No 1901/2006;

(9) ‘designated Member State’ means a Member State for which a certificate is sought under the centralised examination procedure laid down in Chapter III, as identified in a centralised application for a certificate;

(10) ‘European patent’ means a patent granted by the European Patent Office (EPO) under the rules and procedures laid down in the European Patent Convention (‘EPC’)[38];

(11) ‘unitary patent’ means a European patent which benefits from unitary effect in those Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

(12) ‘competent national authority’ means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates, as referred to in Article 9(1).

CHAPTER II
NATIONAL APPLICATIONS FOR A CERTIFICATE

↓ 469/2009 ⇨ new

Article 3

Conditions for obtaining a certificate

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application ⇨ , all of the following conditions are fulfilled ⇦:

   (a) the product is protected by a 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 Directive 2001/83/EC, ⇨ Regulation (EC) No 726/2004 ⇦ or ~~Directive 2001/82/EC~~ Regulation (EU) 2019/6, as appropriate;

   (c) the product has not already been the subject of a certificate;

   (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

[38] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000

⇩ new

2. By way of derogation from paragraph 1, a certificate shall not be granted under this Chapter, in a Member State, on the basis of a national application where the requirements of Article 20(1) are fulfilled for the filing of a centralised application in which that Member State would be designated.

3. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked.

🡻 469/2009 (adapted)

Article 4

⌦ Scope ⌫ ~~Subject matter of~~ ⌦ the ⌫ protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

🡻 933/2019 Art. 1 pt. 2 (adapted)

Article 5

Effects of the certificate

1. ~~Subject to the provisions of Article 4,~~ T~~t~~he certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

2. By way of derogation from paragraph 1, the certificate ~~referred to in paragraph 1~~ shall not confer protection against certain acts which would otherwise require the consent of the ~~holder of the certificate (~~'the certificate holder'~~)~~, if ⌦ all of ⌫ the following conditions are met:

   (a) the acts comprise ⌦ any of the following ⌫:

      (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; ~~or~~

      (ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; ~~or~~

      (iii) the making, no earlier than ⌦ 6 ⌫ ~~six~~ months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the

market of Member States after the expiry of the corresponding certificate; ~~or~~

(iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than ⌦ 6 ⌫ ~~six~~ months before the expiry of the certificate.

(b) the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) in the Member State in which that making is to take place, and informs the certificate holder, of the information ⌦ referred to ⌫ ~~listed~~ in paragraph 5 ~~of this Article~~ no later than ⌦ 3 ⌫ ~~three~~ months before the start date of the making in that Member State, or no later than ⌦ 3 ⌫ ~~three~~ months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(c) if the information ⌦ referred to ⌫ ~~listed~~ in paragraph 5 of this Article changes, the maker notifies the authority referred to in Article 9(1) and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex ~~Ia~~ II, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).

3. ~~The exception laid down referred to in p~~Paragraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

4. The information provided to the certificate holder for the purposes of paragraph 2, points (b) and (c), ~~of paragraph 2~~ shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

5. ~~The information to be provided by the maker f~~For the purposes of paragraph 2, point (b), ~~of paragraph 2~~ ⌦ the maker shall provide all of the following information ⌫ ~~shall be as follows~~:

(a) the name and address of the maker;

(b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

(d) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; ~~and~~

(e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

6. For the purposes of notification to the authority under paragraph 2, points (b) and (c), ~~of paragraph 2,~~ the maker shall use the standard form for notification ~~contained~~ ⌦ set out ⌫ in Annex ~~Ia~~ III.

7. Failure to ~~comply with the requirements of~~ ⌦ provide the information referred to in ⌫ paragraph 5, point (e), ~~of paragraph 5~~ with regard to a third country shall only affect exports to that ⌦ third ⌫ country, and those exports shall~~, therefore,~~ not benefit from the exception ⌦ laid down in paragraph 2 ⌫.

8. The maker shall ensure that medicinal products made pursuant to paragraph 2, point (a) (i), ~~of paragraph 2~~ do not bear an active unique identifier within the meaning of ~~Commission~~ Delegated Regulation (EU) 2016/161[39].

9. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker ~~who~~ ⌦that⌫ performs acts falling under paragraph 2, point (a), ~~of paragraph 2~~ is fully informed and aware of ⌦ all of ⌫ the following:

(a) that those acts are subject to paragraph 2;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(i), ~~of paragraph 2~~ or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(iii), ~~of paragraph 2~~ could infringe the certificate referred to in ⌦ that ⌫ paragraph ~~2~~ where, and for as long as, that certificate applies.

10. Paragraph 2 shall apply to certificates that are applied for on or after 1 July 2019.

Paragraph 2 shall also apply to certificates that have been applied for before 1 July 2019 and that take effect on or after that date. Paragraph 2 shall only apply to such certificates from 2 July 2022.

Paragraph 2 shall not apply to certificates that have taken effect before 1 July 2019.

⬇ 469/2009 (adapted)
⇨ new

Article 6

Entitlement to the certificate

1. The certificate shall be granted to the holder of the basic patent or ~~his~~ ⌦ to the ⌫ successor in title ⌦ of that holder ⌫.

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[39] ~~Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).';~~

⇩ new

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

🡻 469/2009 (adapted)
⇨ new

Article 7

Application for a certificate

1. The application for a certificate shall be lodged within ⌦ 6 ⌫ ~~six~~ months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within ⌦ 6 ⌫ ~~six~~ months of the date on which the patent is granted.

3. The application for an extension of the duration may be ~~made~~ ⌦ lodged at the same time ⌫when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1), point (d), or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than ⌦ 2 ⌫ ~~two~~ years before the expiry of the certificate.

~~Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.~~

Article 8

Content of the application for a certificate

1. The application for a certificate shall contain ⌦ the following ⌫:

   (a) a request for the grant of a certificate, stating in particular:

      (i) the name and address of the applicant;

      (ii) if ⌦ the applicant ⌫ ~~he~~ has appointed a representative, the name and address of ⌦ that ⌫ ~~the~~ representative;

      (iii) the number of the basic patent and the title of the invention;

      (iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3⌦ (1), point ⌫(b), and, if this authorisation is not the first authorisation for placing the product on the market in the ⌦ Union ⌫ ~~Community~~, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 35 ~~14~~ of ~~Directive 2001/82/EC~~ Regulation (EU) 2019/6;

(c) ⌦ where ⌫ ~~if~~ the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the ⌦ Union ⌫ ~~Community~~, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication ⇨ or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised ⇦;

(d) where the application for a certificate for a medicinal product includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

2. Where an application for a certificate is pending, an application for an extension of the duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1, point (d), of this Article and a reference to the application for a certificate already filed.

3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1, point (d), and a copy of the certificate already granted.

4. Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

Article 9

Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(1), point (b), to place the product on the market was obtained, unless the Member State designates another authority for ⌦ that ⌫ ~~the~~ purpose.

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain ~~at least~~ ⇨ all of ⇦ the following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorisation to place the product on the market, referred to in Article 3(1), point (b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the ⌦ Union ⌫ ~~Community~~;

(f) where applicable, an indication that the application includes an application for an extension of the duration.

3. Paragraph 2 shall apply to the notification of the application for an extension of the duration of a certificate already granted or where an application for a certificate is pending. The notification shall additionally contain an indication of the application for an extended duration of the certificate.

Article 10

Grant of the certificate or rejection of the application for a certificate

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Chapter~~Regulation~~, the authority referred to in Article 9(1) shall grant the certificate.

2. The authority referred to in Article 9(1) shall, subject to paragraph 3 ⌦ of this Article ⌫, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Chapter~~Regulation~~.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(1), points (c) and (d), are met.

6. Paragraphs 1 to 4 shall apply *mutatis mutandis* to the application for an extension of the duration.

Article 11

Publication

1. ⌦ The authority referred to in Article 9(1) shall publish, as soon as possible, ⌫ n~~N~~otification of the fact that a certificate has been granted ~~shall be published by the authority referred to in Article 9(1)~~. The notification shall contain ~~at least~~ ⇨ all of ⇦ the following information:

(a) the name and address of the holder of the certificate;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorisation to place the product on the market referred to in Article 3 (1), point (b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the ⌦ Union ⌫ ~~Community~~;

(f) the duration of the certificate.

2. ⌦ The authority referred to in Article 9(1) shall publish, as soon as possible, ⌫ nNotification of the fact that the application for a certificate has been rejected ~~shall be published by the authority referred to in Article 9(1)~~. The notification shall contain at least the information listed in Article 9(2).

3. Paragraphs 1 and 2 shall apply to the notification of the fact that an extension of the duration of a certificate has been granted or of the fact that the application for an extension has been rejected.

↓ 2019/933 Art. 1 pt. 3

4. The authority referred to in Article 9(1) shall publish, as soon as possible, the information listed in Article 5(5), together with the date of notification of that information. It shall also publish, as soon as possible, any changes to the information notified in accordance with Article 5(2), point (c) ~~of Article 5(2)~~.

↓ 933/2019 Art. 1 pt. 4 (adapted)

Article 12

Fees

1. Member States may require that the certificate be subject to the payment of annual fees.

2. Member States may require that the notifications to in Article 5(2), points (b) and (c), ~~of Article 5(2)~~ be subject to the payment of a fee.

↓ 469/2009 (adapted)
⇨ new

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the ⌦ Union ⌫ ~~Community~~, reduced by a period of ⌦ 5 ⌫ ~~five~~ years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed ⌦ 5 ⌫ ~~five~~ years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 ⌦ of this Article ⌫ shall be extended by ⌦ 6 ⌫ ~~six~~ months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of ⌦ that ⌫ ~~this~~ Article may be extended only once.

~~Where a certificate is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.~~

Article 14

Expiry of the certificate

The certificate shall lapse ⌦ in any of the following events ⌫:

(a) at the end of the period provided for in Article 13;

(b) if the certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or ~~Directive 2001/82/EC~~ Regulation (EU) 2019/6.

⇨ For the purposes of point (d), ⇦ ~~T~~the authority referred to in Article 9(1) ~~of this Regulation~~ may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate

1. The certificate shall be invalid ⌦ in any of the following events ⌫ ~~if~~:

(a) ⌦ the certificate ⌫ ~~it~~ was granted contrary to ~~the provisions of~~ Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent ⇨ , or before a competent court of a Member State ⇦.

Article 16

Revocation of an extension of the duration of a certificate for a medicinal product

1. The extension of the duration may be revoked if it was granted contrary to ~~the provisions of~~ Article 36 of Regulation (EC) No 1901/2006.

2. Any person may submit an application for revocation of the extension of the duration ⌦ granted under this Chapter ⌫ to the body responsible under national law for the revocation of the corresponding basic patent.

Article 17

Notification of lapse or invalidity

1. If the certificate lapses in accordance with ~~point (b), (c) or (d) of~~ Article 14, points (b), (c) or (d), or is invalid in accordance with Article 15, ⌦ the authority referred to in Article 9(1) shall publish ⌫ notification thereof ~~shall be published by the authority referred to in Article 9(1)~~.

2. If the extension of the duration is revoked in accordance with Article 16, ⌦ the authority referred to in Article 9(1) shall publish ⌫ notification thereof ~~shall be published by the authority referred to in Article 9(1)~~.

Article 18

Appeals

1. The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Article 15(2) and Article 16(2) taken under this ~~Regulation~~ Chapter shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

⇩ new

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Union, contained in the application for a certificate as provided for in Article 8, is incorrect.

🡻 469/2009 (adapted)

Article 19

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates.

2. Notwithstanding paragraph 1, the procedure for opposition to the grant~~ing~~ of a certificate shall be excluded.

⇩ new

CHAPTER III
CENTRALISED PROCEDURE FOR CERTIFICATES

Article 20

Scope of the centralised application

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.

2. When the conditions under paragraph 1 are met, the filing of national applications shall be prohibited, in respect of the same product, in those Member States in which that basic patent is in force.

3. A centralised application shall be lodged with the European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office').

4. Articles 1 to 7 and 13 to 18 shall apply to centralised applications.

5. The centralised application shall be lodged by using a specific application form.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used to lodge a centralised application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 21

Content of the centralised application

The centralised application shall contain the following:

(a) designation of the Member States in which certificates are sought under the centralised procedure;

(b) the information referred to in Article 8(1).

Article 22

Examination of the admissibility of a centralised application

1. The Office shall examine the following:

(a) whether the centralised application complies with Article 21;

(b) whether the centralised application complies with Article 7;

(c) whether the application fee referred to in Article 34(1) has been paid within the prescribed period.

2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.

3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.

4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application.

Article 23

Publication of the centralised application

If the centralised application complies with Article 22, or if an application for an extension of the duration of certificates complies with Article 33(2), the Office shall publish the application, without undue delay, in the Register.

Article 24

Examination of the centralised application

1. The Office shall assess the application on the basis of all the conditions in Article 3(1) for each of the designated Member States.

2. Where the centralised application for a certificate and the product to which it relates comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 25

Observations by third parties

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates in one or more of the Member States designated therein.

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the centralised application in the Register.

4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 26

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of a centralised application, any person ('opponent') may file with the Office a notice of opposition to that opinion.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the designated Member States.

3. Opposition shall be filed in writing, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the opposition fee has been paid.

4. The notice of opposition shall contain:

   (a) the references of the centralised application against which opposition is filed, the name of its holder, and the identification of the product;

   (b) the particulars of the opponent and, where applicable, of its representative;

   (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 28. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the centralised application.

6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the centralised application, together with a copy of the notice of opposition.

A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

8. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.

11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall mention this in the Register.

12. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 27

Role of competent national authorities

1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications.

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

   The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the centralised examination procedure.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination and opposition proceedings. Each such competent national authority shall update that list in the event of a change.

Article 28

Examination panels

1. The assessments under Articles 24, 26 and 33 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 27(1) from two different participating competent national authorities.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

   (a) geographical balance amongst the participating offices;

(b) the respective workload of the examiners is taken into account;

(c) no more than one examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

4. The Office shall publish a yearly overview of the number of procedures, including those for examination, opposition and appeal, each competent national authority participated in.

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up, and the criteria for the selection of examiners. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 29

Appeals

1. Any party to proceedings under this Chapter, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within 4 months of the date of notification of the decision.

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards may annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 30

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible for deciding on appeals against decisions of the Office taken on the basis of Article 29(1).

2. A Board of Appeal in matters regarding centralised applications for certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referenced in Article 165 (2), (3) and 4, as well as Article 167 (2) of Regulation (EU) 2017/1001 in matters regarding centralised applications for certificates. Decisions taken by a single member as under Article 165 (2) of Regulation (EU) 2017/1001 shall not be possible.

4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

Article 31

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates under this Regulation.

Article 32

National implementation of a centralised examination opinion

1. After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall transmit the examination opinion and its translations to the competent national authority of each designated Member State.

2. In respect of a centralised application, where a positive examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall grant a certificate in accordance with applicable national rules and procedures.

3. By way of derogation from paragraph 2, a Member State may decide not to grant a certificate, where material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions laid down in Article 15(1), points (b) or (c), or Article 14, first paragraph, point (d).

In such a case that Member State shall reject the application insofar as that Member State is concerned.

4. A certificate granted by a competent national authority under this Article shall be subject to Articles 4, 5, 11 and 12 to 19, and to the applicable national legislation.

5. Where a negative examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall issue a rejection decision according to its applicable national rules and procedures.

Article 33

Centralised application for an extension of the duration of certificates

1. Where certificates for a given medicinal product have been granted through the centralised procedure, their holder may request an extension of the duration of those certificates by filing a centralised application for an extension of the duration of those certificates with the Office. That centralised application shall specify the designation of the Member States for which the extension is requested.

2. The centralised application for an extension of the duration of certificates shall be filed in accordance with Article 7(3) and (4), Article 8(1), point (d), Article 8(2), (3) and (4).

3. Articles 10, 11 and 17 shall apply, whereby references to 'the authority referred to in Article 9(1)' shall be understood as references to the Office.

4. Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.

Article 34

Fees

1. The Office shall charge a fee for a centralised application for certificates, and for a centralised application for the extension of the duration of a certificate.

2. The Office shall charge a fee for an appeal, and for an opposition.

3. The Commission is empowered to adopt implementing acts to determine the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which those fees are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

4. Article 12 shall apply to certificates granted under this Chapter.

Article 35

Register

1. The Office shall develop, keep and maintain an electronic Register, providing up-to-date information regarding the status of all published centralised applications, and of all centralised applications for an extension of the duration of certificates.

2. The Register shall include, for each centralised application or certificate, all of the following information:

(a) the name and address of the applicant or certificate holder;

(b) the name and business address of the representative, other than a representative as referred to in Article 37(3);

(c) the application as well as its date of lodging and date of publication;

(d) whether the application relates to a medicinal product or to a plant protection product;

(e) where applicable, an indication that the application includes an application for an extension of the duration;

(f) the designated Member States;

(g) the number of the basic patent;

(h) an identification of the product for which certificates are requested;

(i) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified therein;

(j) the number and date of the first authorisation to place the product on the market in the Union;

(k) the date and a summary of the examination opinion in respect of each of the designated Member States;

(l) where applicable, the duration of the certificates to be granted;

(m) where applicable, the date and a summary of the examination opinion relating to an application for an extension of the duration of a certificate;

(n) where applicable, the filing of an opposition, and its outcome, including where applicable a summary of the revised examination opinion;

(o) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

(p) where applicable and available, the particulars of the certificates granted in each of the designated Member States;

(q) where applicable, a mention that the centralised application was rejected in one or more of the designated Member States;

(r) where applicable, a mention that a certificate has lapsed or was declared invalid;

(s) information on the payment of annual fees, as provided by the relevant competent national authorities.

3. The Register shall contain changes to the information in paragraph 2, including transfers, each accompanied by the date of recording of such entry.

4. The Register and information referred to in paragraphs 2 and 3 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the Register.

5. Competent national authorities shall promptly share with the Office information relating to the grant, lapse, invalidity or transfers of certificates and to the rejection of applications under Chapters II and III, and to the payment of related annual fees.

6. The Executive Director of the Office may determine that information other than those referred to in paragraphs 2 and 3 shall be entered in the Register.

7. The Office shall collect, organise, make public and store the information referred to in paragraphs 2 and 3, including any personal data, for the purposes laid down in paragraph 10. The Office shall keep the Register easily accessible for public inspection.

8. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

9. The processing of the data concerning the entries set out in paragraphs 2 and 3, including any personal data, shall take place for the purposes of the following:

(a) administering the applications in accordance with this Chapter and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

10. All the data, including personal data, concerning the entries in paragraphs 2 and 3 shall be considered to be of public interest and may be accessed by any third party free of charge. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

11. The Register set up under this Article shall also be used to publish information relating to certificates for plant protection products under Regulation [COM(2023) 223], and relating to unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221].

Article 36

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

(a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

(b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

(c) communicating with the applicants and other third parties;

(d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred

to in paragraph 2 of this Article but including those listed in Article 35(3), may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 37

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[40] shall apply to documents held by the Office.

2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.

3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

4. The processing of personal data by the Office shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council[41].

Article 38

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area shall be represented before the Office in accordance with this Article in all proceedings provided for by Chapter III of this Regulation, other than the filing of a centralised application.

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the European Economic Area may be represented before the Office by an employee.

An employee of a legal person may also represent other legal persons which are economically linked with the legal person being represented by that employee.

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[40] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

[41] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office.

Article 39

Combined applications

1. A centralised application may also include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 222][42] ('combined application').

2. The combined application shall undergo a single centralised examination procedure, as well as a single opposition or appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application.

3. The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.

Article 40

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and shall be responsible for implementing the tasks set out in Chapter III of this Regulation and in Chapter III of Regulation [COM(2023) 223], as well as in Regulations [COM(2023) 222] and [COM(2023) 221], including in particular:

(a) receiving and supervising the examination of centralised applications for certificates, centralised applications for an extension of the duration of certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to centralised applications for certificates, as well as in relation to centralised applications for an extension of the duration of certificates;

[42] Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

(c) deciding on oppositions against examination opinions;

(d) maintaining the register and the database.

Article 41

Languages

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.

2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[43].

Article 42

Communications to the Office

1. Communications addressed to the Office may be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically.

2. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

Article 43

Decisions and communications of the Office

1. Decisions of the Office under this Chapter shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified in writing to the parties.

2. Any decision, opinion, communication or notice from the Office under this Chapter shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

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[43] Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

3. Decisions of the Office under this Chapter which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed in writing at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 29. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Article 44

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

2. Oral proceedings before an examination panel or opposition panel shall not be public.

3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.

4. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 45

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:

   (a) hearing the parties;

   (b) requests for information;

   (c) the production of documents and items of evidence;

   (d) hearing witnesses;

   (e) opinions by experts;

   (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. The relevant panel may commission one of its members to examine the evidence adduced.

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.

4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.

5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.

6. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 46

Notification

1. The Office shall, as a matter of course, notify those concerned of decisions, including opinions, summonses and of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Chapter or of acts adopted pursuant to this Chapter, or of which notification has been ordered by the Executive Director.

2. Notification may be effected by different means, including electronic means. The details regarding electronic means shall be determined by the Executive Director.

3. Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.

4. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 47

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The Executive Director shall determine, before the commencement of each calendar year, the days on which the Office is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the Office is located.

3. The Executive Director shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the Office is located or, in the case of an actual interruption of the Office's connection to admitted electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster or strike, interrupts or interferes with proper communication from the parties to the proceedings to the Office or vice-versa, the Executive Director may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the Executive Director, shall extend until a date to be determined by the Executive Director. When determining that date, the Executive Director shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the Office, such determination of the Executive Director shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 48

Correction of errors and manifest oversights

1. The Office shall correct any linguistic errors or errors of transcription and manifest oversights in its decisions, including opinions, or technical errors in publishing information in the Register, of its own motion or at the request of a party.

2. Where the Office has made an entry in the Register or taken a decision which contains an obvious error attributable to the Office, it shall ensure that the entry is cancelled or the decision is revoked. The cancellation of the entry in the Register or the revocation of the decision shall be effected within 1 year of the date on which the entry was made in the Register or that decision was taken, after consultation with the parties to the proceedings.

3. The Office shall keep records of any such corrections or cancellations.

4. Corrections and cancellations shall be published by the Office.

Article 49

Restitutio in integrum

1. The applicant or any other party to proceedings before the Office under this Chapter, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Chapter, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed in writing within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, or in Article 26(1) and (3).

Article 50

Interruption of proceedings

1. Proceedings before the Office under this Chapter shall be interrupted:

(a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative

appointed under Article 38, proceedings shall be interrupted only on application by such representative;

(b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office;

(c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office.

2. Proceedings before the Office shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 51

Costs

1. The losing party in opposition proceedings, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[44]. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 52

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.

2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality

3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.

4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

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[44] Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Commission and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1.).

Article 53

Financial provisions

1. The expenses incurred by the Office in carrying out the additional tasks given to it in accordance with this Regulation shall be covered by the procedural fees to be paid to the Office by applicants and, if needed, by a fraction of the annual fees paid to competent national authorities by the holders of certificates granted under Chapter III. That fraction shall initially be set at a certain value but shall be reviewed every 5 years, with the objective of achieving financial sustainability for the activities carried out by the Office under this Regulation as well as Regulations [COM(2023) 223], [COM(2023) 222] and [COM(2023) 221], insofar as expenses incurred by the Office are not covered by fees under these Regulations.

2. For the purposes of paragraph 1, each competent national authority shall keep an account of the annual fees paid to it by holders of certificates granted under this Chapter.

3. The expenses incurred by a competent national authority participating in proceedings under this Chapter shall be covered by the Office and shall be paid annually, on the basis of the number of proceedings in which that competent national authority was involved during the preceding year.

4. The Commission is empowered to adopt implementing acts laying down rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

↓ 469/2009 (adapted)

~~*Article 20*~~

~~*Additional provisions relating to the enlargement of the Community*~~

~~Without prejudice to the other provisions of this Regulation, the following provisions shall apply:~~

~~(a) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate was lodged within six months from 1 January 2007;~~

~~(b) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained:~~

~~(i) in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;~~

~~(ii) in the Community not earlier than six months prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was~~

~~lodged within six months of the date on which the first market authorisation was obtained;~~

~~(e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Estonia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six months provided for in the Patents Act of October 1999;~~

~~(d) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Cyprus prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;~~

~~(e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Latvia prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;~~

~~(f) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004;~~

~~(g) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate was lodged within six months from 1 May 2004;~~

~~(h) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Malta prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;~~

~~(i) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate was lodged within six months starting no later than 1 May 2004;~~

~~(j) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying~~

~~for a certificate shall be open for a period of six months starting no later than 1 January 2007;~~

~~(k) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovenia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004, including in cases where the period provided for in Article 7(1) has expired;~~

~~(l) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date.~~

↓ 2012 Act of Accession (adapted)

~~(m) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months from the date of accession.~~

↓ 469/2009 (adapted)

Article 54~~21~~

Transitional provisions

~~1. This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before 2 January 1993 or to applications for a certificate filed in accordance with that legislation before 2 July 1992.~~

~~With regard to Austria, Finland and Sweden, this Regulation shall not apply to certificates granted in accordance with their national legislation before 1 January 1995.~~

↓ 2012 Act of Accession (adapted)

~~2.~~ This Regulation shall apply to ~~supplementary protection~~ certificates granted in accordance with the national legislation of ⌦ Czechia ⌫ ~~the Czech Republic~~, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession.

⇩ new

CHAPTER IV
FINAL PROVISIONS

Article 55

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 26(13), 29(8), 31, 42(2), 44(4), 45(6), 46(4), 47(5) and 50(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 26(13), 29(8), 31, 42(2), 44(4), 45(6), 46(4), 47(5) and 50(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 26(13), 29(8), 31, 42(2), 44(4), 45(6), 46(4), 47(5) and 50(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 56

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

↓ 2019/933 Art. 1 pt. 5 (adapted)

Article 57~~21a~~

Evaluation

1. No later than five years after the date referred to in Article 5(10), and every ~~five~~ ⌦ 5 ⌫ years thereafter, the Commission shall carry out an evaluation of Article 5(2) to (9) and Article 11 in order to assess whether the objectives of those provisions have been achieved, and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. In addition to evaluating the impact of the exception of making for the purpose of export, special account shall be taken of the effects of making for the purpose of storing in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate on access to medicines and on public health expenditure, and of whether the waiver and in particular the period provided for in Article 5(2), point (a)(iii), ~~of Article 5(2)~~ is sufficient to achieve the objectives referred to in Article 5, including public health.

⇩ new

2. By *[OP, please insert: five years after the date of application]*, and every 5 years thereafter, the Commission shall also carry out an evaluation of the application of Chapter III.

Article 58

Transitional provisions for pending applications

Article 20(2) shall not apply to national applications for certificates that are pending before competent national authorities on the xxxxxx *[OP – please insert the date of application of this Regulation]* and that meet the conditions under Article 20(1).

↓ 469/2009 (adapted)

Article 59~~22~~

Repeal

Regulation ⌦ (EC) No 469/2009 ⌫ ~~(EEC) No 1768/92, as amended by the acts listed in Annex I,~~ is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex IV~~II~~.

↓ (adapted)

Article 60~~23~~

Entry into force ⌦ and application ⌫

This Regulation shall enter into force on the ~~20th~~ ⌦ twentieth ⌫ day following its publication in the *Official Journal of the European Union*.

⇩ new

Articles 20 to 53 and 55 to 57 shall apply from xxxxx *[OP: please insert: the first day of the 12th month after the entry into force]*.

↓ 469/2009

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 231 final

ANNEXES 1 to 2

ANNEXES

to the

Proposal for a Regulation of the European Parliament and of the Council

on the supplementary protection certificate for medicinal products (recast)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

↓ 469/2009 (adapted)

ANNEX I

Repealed Regulation with ~~list of its successive amendments~~ ⌦ the amendment thereto ⌫

~~• Council Regulation (EEC) No 1768/92~~ ~~• (OJ L 182, 2.7.1992, p. 1)~~	• =
~~• Annex I, point XI.F.I, of the 1994 Act of Accession~~ ~~• (OJ C 241, 29.8.1994, p. 233)~~	• =
~~• Annex II, point 4.C.II, of the 2003 Act of Accession~~ ~~• (OJ L 236, 23.9.2003, p. 342)~~	• =
~~• Annex III, point 1.II, of the 2005 Act of Accession~~ ~~• (OJ L 157, 21.6.2005, p. 56)~~	• =
~~• Regulation (EC) No 1901/2006 of the European Parliament and of the Council~~ ~~• (OJ L 378, 27.12.2006, p. 1)~~	• ~~Only Article 52~~

⌦ Regulation (EC) No 469/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 1) ⌫	
⌦ Regulation (EU) 2019/933 of the European Parliament and of the Council (OJ L 153, 11.6.2019, p. 1) ⌫	
⌦ 2012 Act of Accession (OJ L112, 24.2.2012, p. 21) ⌫	⌦ Only Annex III, point 1(2)(II)(2) ⌫

↓ 2019/933 Art. 1 pt. 6

ANNEX II~~I~~

Logo

This logo shall appear in black and in such a size as to be sufficiently visible.

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EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 231 final

ANNEX 3

ANNEX

to the

Proposal for a Regulation of the European Parliament and of the Council

on the supplementary protection certificate for medicinal products (recast)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

↓ 2019/933 Art. 1 pt. 6

ANNEX III ~~Ia~~

Standard form for notification pursuant to Article 5(2), points (b) and (c).

Tick the appropriate box		□ New notification □ Update of an existing notification	
(a)	Name and address of the maker	…	
(b)	Purpose of making	□ Export □ Storing □ Export and storing	
(c)	Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place	Member State of making	
		(Member State of first related act (if any))	
(d)	Number of certificate granted in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making	Certificate of Member State of making	
		(Certificate of Member State of first related act (if any))	
(e)	For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export		

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ANNEX 4

ANNEX

to the

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on the supplementary protection certificate for medicinal products (recast)

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

↓ 469/2009

ANNEX IV~~II~~

Correlation table

Regulation 469/2009	This Regulation
Article 1, introductory wording	Article 2, introductory wording
Article 1, points (a) to (c)	Article 2, points (1) to (3)
Article 1, point (d)	-
Article 1, point (e) and (f)	Article 2, points (4) and (5)
-	Article 2, points (6) to (12)
Article 2	Article 1
Article 3	Article 3(1)
-	Article 3(2) and (3)
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6(1)
-	Article 6(2)
Article 7(1) to (4)	Article 7(1) to (4)
Article 7(5)	-
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
Article 11	Article 11
Article 12	Article 12
Article 13(1), (2) and (3)	Article 13(1), (2) and (3)
Article 13(4)	-
Article 14	Article 14
Article 15	Article 15
Article 16	Article 16
Article 17	Article 17
Article 18	Article 18(1)
-	Article 18(2)
Article 19	Article 19
-	Article 20
-	Article 21
-	Article 22
-	Article 23
-	Article 24
-	Article 25
-	Article 26
-	Article 27
-	Article 28
-	Article 29
-	Article 30
-	Article 31

-	Article 32
-	Article 33
-	Article 34
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-	Article 40
-	Article 41
-	Article 42
-	Article 43
-	Article 44
-	Article 45
-	Article 46
-	Article 47
-	Article 48
-	Article 49
-	Article 50
-	Article 51
-	Article 52
-	Article 53
Article 20	-
Article 21(1)	-
Article 21(2)	Article 54
-	Article 55
-	Article 56
Article 21a	Article 57(1)
-	Article 57(2)
-	Article 58
Article 22	Article 59
Article 23	Article 60
Annex 1	Annex I
Annex -I	Annex II
Annex -Ia	Annex III
-	Annex IV