European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2024)0099

Supplementary protection certificate for medicinal products (recast)

European Parliament legislative resolution of 28 February 2024 on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (COM(2023)0231 – C9-0146/2023 – 2023/0130(COD))

(Ordinary legislative procedure – recast)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0231),

– having regard to Article 294(2) and Article 114(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0146/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 27 September 2023[1],

– having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts[2],

– having regard to Rules 110 and 59 of its Rules of Procedure,

– having regard to the report of the Committee on Legal Affairs (A9-0022/2024),

A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the

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1 OJ C, C/2023/865, 08.12.2023, ELI: http://data.europa.eu/eli/C/2023/865/oj.
2 OJ C 77, 28.3.2002, p. 1.

Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;

1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2023)0130

Position of the European Parliament adopted at first reading on 28 February 2024 with a view to the adoption of Regulation (EU) 2024/... 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 on the Functioning of the European Union , and in particular Article 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[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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1 OJ C, C/2023/865, 08.12.2023, ELI: http://data.europa.eu/eli/C/2023/865/oj.

2 OJ C [...], [...], p. [...].

Whereas:

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[3] has been substantially amended[4]. Since further amendments are to be made, that Regulation should be recast in the interests of clarity.

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health. ***Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research. However, it is difficult to establish a direct link between such favourable rules and Union competitiveness because while such rules make Union markets more attractive, medicines' geographical origin and authorised medicines from third countries are equally eligible to receive all Union incentives, just as Union based innovative companies can equally benefit from incentives in third countries.*** **[Am. 1]**

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3 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).

4 See Annex I.

~~(3) Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research.~~ **[Am. 2]**

(4) The 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.

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

(6) A uniform solution at 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 Union and thus directly affect the functioning of the internal market.

(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. 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.

(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~~***in light of*** the description ***and drawings*** of the patent***, on the basis of that person’s general knowledge in the relevant field and of the prior art at the*** ~~on its~~ filing date ***or priority date of the basic patent***. 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~~***active ingredient*** is specifically identifiable in the light of all the information disclosed by that patent***, on the basis of the prior art at the filing date or priority date of the basic patent***. **[Am. 3]**

(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. **[Am. 4]**

(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~~***biosimilar*** 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. **[Am. 5]**

(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’).

(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 Union .

(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 that purpose, it should not be possible to grant a certificate 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.

(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[5] 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.

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5 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).

(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[6] 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.

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6 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).

(21) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[7] 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 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.

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7 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).

(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[8] or Regulation (EU) No 2019/6 of the European Parliament and of the Council[9]. 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 ***in accordance with Article 86 of Directive (EU) .../... [2023/0132(COD)],*** 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. **[Am. 6]**

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8 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).

9 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).

(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.

(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 ***and related patent*** matters, located today at national offices only. To ensure an optimal quality of the examination, ***the Office and the competent national authorities should make sure that designated examiners have the relevant expertise and sufficient experience in the assessment of supplementary protection certificates. Additional*** 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.
[Am. 7]

(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.

(32a) To guarantee an effective protection of innovation, in certain urgent situations, including where the expiry of the basic patent is imminent, an expedited examination procedure might be necessary, notwithstanding the possibility for third parties to submit observations and make use of other remedies provided for in this Regulation. Therefore, a mechanism for applicants to request an expedited examination procedure should be provided. **[Am. 8]**

(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. ***The Office shall ensure the transmission takes place within a timeframe allowing national patent offices to grant the certificate or reject the application, as applicable, before the expiry of the basic patent.*** **[Am. 9]**

(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) ***To safeguard procedural rights and ensure a complete system of remedies,*** 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. **[Am. 10]**

(39) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their ***relevant expertise, independence and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account. **[Am. 11]**

(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.

(41a) The timely entry of generics and biosimilars onto the Union market is important, in particular to increase competition, to reduce prices and to ensure both the sustainability of national healthcare systems and better access to affordable medicines for patients in the Union. The importance of such timely entry was underlined by the Council in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States. On the other hand, it should be borne in mind that intellectual property rights remain one of the cornerstones of innovation, competitiveness and growth in the internal market. **[Am. 12]**

(42) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council[10] 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.

(43) A balance should be struck between restoring a level playing field between 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.

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10 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).

(44) Makers 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’).

(45) In those specific and limited circumstances, and in order to create a level playing field between ***Union-based*** makers ~~established in the Union and third-country~~***and third country*** makers, ~~it is appropriate to provide for an exception to~~ the protection conferred by a ***supplementary protection*** certificate ***in accordance to Regulation (EU) 2019/933 should be restricted,*** so as to allow ~~the~~ making ~~of a product, or a medicinal product containing that product,~~ for the ***exclusive*** 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’)~~ ***itself***, where such acts would otherwise require the consent of ~~the~~ ***a*** certificate holder***(‘related acts’)***. For instance, ~~such~~ related acts could include ~~the possessing~~ ***the, possession, supply***, offering to supply, ~~supplying, importing, using or synthesising of~~ ***import, use or synthesis of*** an active ingredient for the purpose of making a medicinal product~~. They could also consist of~~ ***containing that product, or*** temporary ~~storing~~***storage of the product*** or advertising ~~of the product~~ for the exclusive purpose of export to ~~third-country~~***third country*** destinations. The exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker. **[Am. 13]**

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

(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.

(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 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.

(49) Effective and proportionate safeguards should apply in relation to the exception in order to increase transparency, to help the certificate holder to enforce its protection in the Union and check compliance with this Regulation, and to reduce the risk of illicit diversion onto the Union market during the term of the certificate.

(50) 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. That obligation should apply also where the making is directly carried out by the maker .

(51) 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.

(52) 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 holder of the relevant certificate will , 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[11], not to engage in abusive litigation.

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11 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).

(53) Labelling in this Regulation should be without prejudice to labelling requirements of third countries.

(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.

(55) This 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 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[12] .

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[12] 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).

(56) This 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[13]. The maker should ensure that any medicinal product made for the purpose of export does not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161[14] , 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 .

(57) This exception does not affect the application of Directive 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.

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13 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).

14 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).

(58) To safeguard the rights of certificate holders, the exception provided for in this Regulation should not apply to a certificate that had already taken effect at the date of entry into force of Regulation (EU) 2019/933 of the European Parliament and of the Council . 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 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, it is justified that the exception set out in this Regulation also covers , over a certain period of time, a certificate that was applied for before the date of entry into force of Regulation (EU) No 2019/933 , but had not yet taken effect before that date, irrespective of whether or not that certificate was granted before that date. The exception applied , therefore, from 2 July 2022 to a certificate that took effect from the date of entry into force of 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 Regulation should ensure that the exception be applied, on a progressive basis, to such a certificate, depending on the date on which it took effect and on its duration. Such application of the exception would allow the holder of a certificate that had been granted, but that had not yet taken effect by the date of the entry into force of 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.

(59) The exception should apply on the basis of the date of the filing of the application for a certificate , in order to promote uniformity and limit the risk of disparities.

(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. ***However, the information provided in the register should not be used in regards to practices of patent linkage and no regulatory or administrative decisions related to generics or biosimilars, such as marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the SPC, should be based on information provided for in the register.*** **[Am. 14]**

(61) Regulation [COM(2023) 222][15] 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.

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

(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.[16] 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.

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16 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).

(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 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[17].

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17 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).

(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. 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 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 important to ascertain whether making that was previously taking place outside of the Union are being moved to within Union territory. In particular, the 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 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 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.

(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 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. 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.

(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[18] and delivered an opinion on XXX [OP, please add reference once available].

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18 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).

(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],

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter

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 , Regulation (EC) No 726/2004 or Regulation (EU) 2019/6 .

Article 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;

(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 [19];

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19 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).

(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.

(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;

(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’)[20];

(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).

(12a) ‘economically linked’ means, in respect of different holders of two or more basic patents protecting the same product, that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder. **[Am. 15]**

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

Chapter II

National applications for a certificate

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~~***.../... [2023/0132(COD)]***,Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, as appropriate; **[Am. 16]**

(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.

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. ***The same principle shall apply mutatis mutandis to applications submitted by the holder concerning the same product for which one or more certificates or unitary certificates have been previously granted to other different holders of different patents.*** **[Am. 17]**

Article 4

Scope 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.

Article 5

Effects of the certificate

1. The 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, ***and in accordance with Regulation (EU)…/… [2023/0130(COD)],*** the certificate shall not confer protection against certain acts which would otherwise require the consent of the ~~the~~ certificate holder, if all of the following conditions are met: **[Am. 18]**

   (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*** **[Am. 19]**

(ii) any related act that is strictly necessary for ~~the~~***that*** making~~,~~ in the Union~~, referred to in point (i),~~ or for the actual export ***itself***; ***or*** **[Am. 20]**

(iii) ~~the~~ making, no earlier than 6 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*** **[Am. 21]**

(iv) any related act that is strictly necessary for the making~~,~~ in the Union~~,~~ ***as*** referred to in point (iii), or for the actual storing ***itself***, provided that such related act is carried out no earlier than 6 months before the expiry of the certificate. **[Am. 22]**

(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 in paragraph 5 no later than 3 months before the start date of the making in that Member State, or no later than 3 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 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 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. 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), 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. For the purposes of paragraph 2, point (b), the maker shall provide all of the following information :

(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;

(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), the maker shall use the standard form for notification set out in Annex III.

7. Failure to provide the information referred to in paragraph 5, point (e), with regard to a third country shall only affect exports to that third country, and those exports shall 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), do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161.

9. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker that performs acts falling under paragraph 2, point (a), 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), or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(iii), could infringe the certificate referred to in that paragraph 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.

Article 6

Entitlement to the certificate

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

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.

Article 7

Application for a certificate

1. The application for a certificate shall be lodged within 6 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 months of the date on which the patent is granted.

3. The application for an extension of the duration may be 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 years 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 has appointed a representative, the name and address of that 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 , 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 of Regulation (EU) 2019/6;

(c) where 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 , 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;

(da) if applicable, the consent of the third party referred to in Article 6(2) of this Regulation; **[Am. 23]**

(db) information on any direct public financial support received for research related to the development of the product. **[Am. 24]**

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 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 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 ;

(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, 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.

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~~***without undue delay***, notification of the fact that a certificate has been granted. The notification shall contain all of the following information: **[Am. 25]**

(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 ;

(f) the duration of the certificate.

(fa) information on any direct public financial support received for research related to the development of the product. **[Am. 26]**

2. The authority referred to in Article 9(1) shall publish, as soon as possible, notification of the fact that the application for a certificate has been rejected . 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.

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) .

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), be subject to the payment of a fee.

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 , reduced by a period of 5 years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed 5 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 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 Article may be extended only once.

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 Regulation (EU) 2019/6.

For the purposes of point (d), the authority referred to in Article 9(1) 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 :

(a) the certificatewas granted contrary to Article 3 ***or 6(2)***; **[Am. 27]**

(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 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 ***or before a competent court of a Member State***. **[Am. 28]**

Article 17

Notification of lapse or invalidity

1. If the certificate lapses in accordance with 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 .

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 .

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 Chapter shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

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.

2a. Full transparency shall be ensured throughout the whole appeal proceeding, which shall be open, whenever possible, to public participation. **[Am. 29]**

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 of a certificate shall be excluded.

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***, as appropriate, in accordance with Directive .../... [2023/0132(COD)],*** through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply. **[Am. 30]**

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, ***in the Register*** without undue delay~~, in the Register~~***and no later than five working days after***.
[Am. 31]

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) ***and (3) and Article 6(2)*** ~~Article 3(1)~~ for each of the designated Member States. **[Am. 32]**

2. Where the centralised application for a certificate and the product to which it relates comply with Article 3(1) ***and (3) and Article 6(2)*** 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 ***and publish the opinion on the dedicated register without undue delay***. **[Am. 33]**

3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) ***and (3) and Article 6(2)*** 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 ***and publish the opinion on the dedicated register without undue delay***. **[Am. 34]**

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.

5a. The Office shall adopt an examination opinion within 6 months after publication of the centralised application in the Register. Without prejudice to Articles 25, 26 and 28 of this Regulation, whenever duly justified for reasons of urgency, the applicant may submit a request for an expedited procedure. Where the request for an expedited examination procedure is deemed justified, the Office shall adopt an examination opinion within 4 months from the publication of the application for a unitary certificate.
[Am. 35]

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.

3a. Whenever the expedited procedure applies in accordance with to Article 24 (5a), observations shall be submitted within six weeks after publication of the application in the Register. **[Am. 36]**

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 ***or 6*** are not fulfilled for one or more of the designated Member States. **[Am. 37]**

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.

   (ca) any evidence the opponent relies on in support of the opposition. **[Am. 38]**

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~~***its decision as well as the reasoning for its decision to the*** opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1. **[Am. 39]**

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 ***including a detailed reasoning for that decision*** within 6 months, unless the complexity of the case requires a longer period. **[Am. 40]**

9a. In cases where several oppositions have been filed against an examination opinion, the Office shall deal with the oppositions jointly and issue one single decision in regards to all oppositions filed. **[Am. 41]**

10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition ***and notify the opponent of its decision,*** and the Office shall mention this in the Register. **[Am. 42]**

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.

12a. Full transparency shall be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation. **[Am. 43]**

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***, on the basis of their relevant expertise and of their experience in the field***.
[Am. 44]

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~~***relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates***; **[Am. 45]**

(aa) where possible, geographical balance amongst the participating offices; **[Am. 46]**

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

(c) ***that there is*** no ~~more than one~~ examiner employed by a competent national authority making use of the exemption ~~laid down~~***set out*** in Article 10(5) ***of this Regulation***.
[Am. 47]

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***, including corresponding evidence relied on,*** shall be filed within 4***3*** months of the date of notification of the decision. **[Am. 48]**

3a. Any reply to statement of the grounds of appeal shall be submitted in writing within three months from the date of the notification of the statement of the grounds of appeal. Where applicable, the Office shall set a date for an oral hearing within three months after the filing of the reply to the grounds of appeal or within six months of the filing of grounds of appeal, whichever is earlier. The Office shall issue a written decision within three months of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable. **[Am. 49]**

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~~***shall*** annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States. **[Am. 50]**

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.***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.*** **[Am. 51]**

4a. Article 166(9) of Regulation (EU) 2017/1001 shall apply to Boards of Appeal in matters regarding centralised applications for certificates. **[Am. 52]**

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.

Such transmission shall take place without undue delay within a timeframe allowing the competent national authorities of each designated Member State to grant or reject a certificate, as applicable, according to applicable national procedures, before the expiry of the basic patent. **[Am. 53]**

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.

5a. The competent national authority shall inform the applicant of its decision without undue delay. **[Am. 54]**

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 ***or an opposition*** in respect of a centralised application for an extension of the duration of certificates. **[Am. 55]**

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***,*** ***searchable and public*** 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. **[Am. 56]**

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;

(ja) information on any direct public financial support received for research related to the development of the product; **[Am. 57]**

(k) the date and ~~a summary of~~ the examination opinion in respect of each of the designated Member States; **[Am. 58]**

(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, ***its status*** and its outcome, including where applicable a summary of the revised examination opinion; **[Am. 59]**

(o) where applicable, the filing of an appeal, ***its status*** and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion; **[Am. 60]**

(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].

11a. By way of derogation of Article 35(9)(b) public authorities shall not use the information provided for in the register for practices of patent linkage and no regulatory or administrative decisions related to generics or biosimilar shall be based on information provided for in the register and be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisation, pricing and reimbursement decisions or tender bids. **[Am. 61]**

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[21] 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.

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21 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).

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[22].

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.

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22 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).

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.

   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][23] (‘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.

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

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;

(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[24].

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.

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

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.

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.~~ **[Am. 62]**

3. Oral proceedings before ***an examination panel, an opposition panel or*** the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the ***examination panel, the opposition panel or the*** Boards of Appeal decide otherwise in cases where admission of the public ***to all or a part of the oral proceedings*** could have serious and unjustified disadvantages, in particular for a party to the proceedings. **[Am. 63]**

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. ***Where an expert is summonsed, the Office or the relevant panel, as applicable, shall verify that the person is free of any conflict of interest.*** The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.
[Am. 64]

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[25]. 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.

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25 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.).

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.

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.

Article 54

Transitional provisions

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

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.

Article 57

Evaluation

1. No later than five years after the date referred to in Article 5(10), and every 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), is sufficient to achieve the objectives referred to in Article 5, including public health.

2. By ***…*** [~~OP,~~***OJ:*** 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***, and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee***. ***The evaluation should assess in particular whether the objectives of the provisions in that Chapter have been achieved.*** **[Am. 65]**

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).

Article 59

Repeal

Regulation (EC) No 469/2009 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.

Article 60

Entry into force and application

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

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].

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

Done at …,

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

Annex I

Repealed Regulation with the amendment thereto

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)

Annex II

Logo

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

Annex III

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

<table>
<tr><td>Tick the appropriate box</td><td colspan="2">☐ New notification ☐ Update of an existing notification</td></tr>
<tr><td>(a) Name and address of the maker</td><td colspan="2">…</td></tr>
<tr><td>(b) Purpose of making</td><td colspan="2">☐ Export ☐ Storing ☐ Export and storing</td></tr>
<tr><td rowspan="2">(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</td><td>Member State of making</td><td></td></tr>
<tr><td>(Member State of first related act (if any))</td><td></td></tr>
<tr><td rowspan="2">(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</td><td>Certificate of Member State of making</td><td></td></tr>
<tr><td>(Certificate of Member State of first related act (if any))</td><td></td></tr>
<tr><td rowspan="3">(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</td><td colspan="2"></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2"></td></tr>
</table>

Annex IV

Correlation table

Regulation (EC) No 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

Regulation (EC) No 469/2009	This Regulation
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

Regulation (EC) No 469/2009	This Regulation
-	Article 28
-	Article 29
-	Article 30
-	Article 31
-	Article 32
-	Article 33
-	Article 34
-	Article 35
-	Article 36
-	Article 37
-	Article 38
-	Article 39
-	Article 40
-	Article 41
-	Article 42
-	Article 43
-	Article 44
-	Article 45
-	Article 46

Regulation (EC) No 469/2009	This Regulation
-	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

Regulation (EC) No 469/2009	This Regulation
Annex -Ia	Annex III
-	Annex IV