



Council of the
European Union

Brussels, 28 April 2023
(OR. en)

8869/23

**Interinstitutional File:
2023/0127(COD)**

PI 54
PHARM 66
COMPET 381
MI 349
IND 203
IA 87
CODEC 741

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 222 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

Delegations will find attached document COM(2023) 222 final.

Encl.: COM(2023) 222 final



Brussels, 27.4.2023
COM(2023) 222 final

2023/0127 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

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

EXPLANATORY MEMORANDUM

CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend the 20-year term of patents for medicinal or plant protection products (PPPs) by up to 5 years¹. They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner².

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

Regulation (EC) No 469/2009 provides for SPCs for medicinal products (both human and veterinary medicinal products), at a national level, to be granted by national patent offices on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 1610/96 provides for SPCs for plant protection products. Together these two measures constitute the EU's SPC regime.

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

The Commission's intellectual property action plan of November 2020 (COM(2020) 760 final), which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system. The plan noted that, for medicinal products and PPPs, SPC protection is only available at national level. At the same time, there is a centralised procedure for granting European patents and a centralised procedure for obtaining marketing authorisations for medicinal products.

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

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

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

In the same vein, the pharmaceutical strategy for Europe (COM(2020) 761 final) emphasised the importance of investing in R&D to create innovative medicines. The strategy stressed, however, that the differences between Member States in the implementation of intellectual property regimes, especially for SPCs, lead to duplications and inefficiencies that affect the competitiveness of the pharmaceutical industry. Both the Council⁴ and the European Parliament⁵ have called on the Commission to correct these deficiencies.

Additionally, there is a clear need to complement the unitary patent ('European patent with unitary effect') by a unitary SPC. Indeed, while a unitary patent may be extended by national SPCs, this approach is not optimal in the sense that the unitary protection conferred by a unitary patent would then, after patent expiry, be complemented by a plurality of legally independent national SPCs, without any unitary dimension anymore.

The grant of a unitary SPC could be requested by filing an application that would then be subjected to the same centralised examination procedure also applicable to 'centralised SPC applications' defined in a parallel proposal (COM(2023) 231) with a view to the grant of national SPCs in the Member States designated in the centralised applications. An applicant will have the possibility of filing a 'combined' centralised SPC application in which he/she would request the grant of both a unitary SPC (for those Member States in which the basic patent has unitary effect) and national SPCs (for other Member States).

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

The core substantive provisions applicable to the unitary certificates to which this proposal relates – i.e. the conditions for obtaining a unitary certificate – are the same as those of the existing SPC regime, while this proposal creates a unitary SPC to be granted following examination by a central authority, which relies on the same substantive rules, with minor modifications, as the centralised procedure for the grant of national certificates established in the parallel proposal COM(2023) 231. This ensures consistency across the whole SPC reform package, especially in the event of a 'combined' application requesting the grant of both a unitary certificate and national certificates, as explained below.

In addition to this proposal, parallel proposals are being made to create a centralised procedure for the grant of national certificates for medicinal products (COM(2023) 231), a centralised procedure for the grant of national certificates for plant protection products (COM(2023) 223), and a unitary certificate for plant protection products (cf. COM(2023) 221). Applications for all of these certificates would undergo the same centralised examination procedure described in this proposal, especially in the event of 'combined' applications that request both a unitary certificate and national certificates, as explained below. This ensures complete consistency across the whole SPC reform package.

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

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

This table explains the purposes of the four related proposals:

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

The proposed creation of a unitary SPC will be fully compatible with the unitary patent system, under Regulation (EU) No 1257/2012 and the Agreement on a Unified Patent Court (UPCA).

In addition, as this was already the case for Regulation (EC) No 469/2009, this proposal is compatible with the pharmaceutical EU legislation, including Regulation 1901/2006 on medicinal products for paediatric use, which provides for a possible ‘paediatric extension’ of SPCs for medicinal products, under specific conditions.

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

- **Consistency with other Union policies**

The COVID-19 pandemic has underlined the importance of having a strong and balanced IP system to provide the necessary incentives to develop new treatments and vaccines that patients will have access to. It has also highlighted the need for transparent and easily accessible information on the status of IP rights, including SPCs, to facilitate potential collaborations, licensing and freedom-to-operate analyses⁶. Patents and SPCs are key to supporting the EU in its efforts to build a European Health Union and to other related initiatives such as the new European Health Emergency Preparedness and Response Authority (HERA)⁷, EU FAB⁸ and the pharmaceutical strategy for Europe.

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

⁶ Discussions in this regard have been taken to the World Intellectual Property Organisation (WIPO), where national/regional patent offices were invited to share information on their collaborations with publicly accessible databases of patent status information concerning medicines and vaccines, such as MedsPaL. See: WIPO, Standing Committee on the Law of Patents, 32nd session, SCP/32/7, 2020.

⁷ European Commission, Commission Communication – HERA Incubator: Anticipating together the threat of COVID-19 variants, COM/2021/78, 2021.

⁸ European Commission, ‘Questions and answers : HERA incubator – Anticipating together the threat of COVID-19 variants’, 2021 (https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_642).

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

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The current proposal is based on the first subparagraph of Article 118 of the Treaty on the Functioning of the European Union, which is the only treaty provision suitable for the creation of unitary IP rights as it allows for measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.

Article 118 was introduced by the Treaty on the Functioning of the European Union (TFEU) and provides an express legal base for EU-wide intellectual property rights. It is also the legal basis for Regulation (EU) No 1257/2012 of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection.

Together with the parallel proposal relating to a centralised procedure for the grant of national certificates (COM(2023) 231), this proposal addresses the fragmentation of the existing SPC regime, implemented at a purely national level: despite the fact that SPCs are already harmonised – and indeed defined – by EU law, there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or been granted with a different scope. SPC applicants thus face diverging decisions across the EU on the same product, while incurring costs for applying and maintaining SPCs in several Member States. Consequently, further EU action is needed to address these issues and can, unlike national intervention by Member States, ensure a consistent EU-wide framework, and reduce the total costs and burden of fees to be paid in multiple Member States. Further EU-level action would strengthen the integrity of the single market by providing a centralised, balanced and transparent SPC system across the EU, and mitigate the negative consequences of redundant and potentially diverging procedures that applicants face⁹. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the single market for innovative medicinal products that are subject to marketing authorisations. EU-level action would also allow innovative and follow-on manufacturers to reap the benefits of an efficient intellectual property framework in the relevant product markets.

• Subsidiarity

EU action is necessary to provide a unitary SPC for the unitary patent. An EU IP right (such as a unitary SPC) can only be created by the EU. National legislation cannot achieve this objective, as it is not able to provide for unitary protection, and the objectives underlying this proposal can thus only be achieved at Union level. The Union-wide approach implemented by the centralised procedure for the grant of national certificates and unitary SPCs will ensure that the applicable rules and procedures are consistent across the Union — at least insofar as the Member States participating in the unitary patent system are concerned —, ensuring legal certainty for all relevant market participants. Moreover, the unitary SPC is an autonomous IP right, applying independently of any national system. Consequently, EU action is needed to create a new unitary SPC complementing the unitary patent.

⁹ Case C-58/08 ECLI:EU:C:2010:321.

- **Proportionality**

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

- **Choice of the instrument**

The instrument choice is an EU regulation establishing a unitary SPC. No other instrument can be envisioned for creating a unitary IP right.

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

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

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

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

- **Stakeholder consultations**

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

Most of the respondents to the Allensbach survey consultation (conducted by the Allensbach Institute and included in the 2018 study by the Max Planck Institute (MPI))¹⁰ and to the public consultation organised by the Commission endorse the creation of a Unitary SPC. Answers to Question 69 of the Allensbach survey show that there is wide support for a unitary SPC, and that from all categories of respondents. The same can be said of the replies to the questions relating to the unitary SPC included in the public consultation 'on Supplementary Protection

¹⁰ <https://ec.europa.eu/docsroom/documents/29524>

Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations' that was conducted from 12 October 2017 to 4 January 2018¹¹.

Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence¹². For further information, see Annex 2 of the Impact Assessment.

- **Collection and use of expertise**

The study¹³ carried out in 2018 by the Max Planck Institute on the legal aspects of SPCs in the EU (especially Chapter 22) provides key findings on the operation of the current SPC regime (for medicinal products). In particular that study included a survey among stakeholders in the EU Member States (2017), conducted by the Allensbach Institute¹⁴, which included several questions relating to a possible unitary SPC in addition to the many questions relating to the operation of the current (national) SPC regimes.

- **Impact assessment**

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

The following options were identified:

- Option 0: No policy change.
- Option 1: Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the Court of Justice of the European Union (CJEU). These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.
- Option 2: Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.
- Option 3: Centralised filing and examination of SPC applications, resulting in a non-binding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.
- Option 4: Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, but NPOs would have to follow the opinion. Therefore, while decisions on granting SPC protection would still be taken by national offices, the outcome of these decisions would be determined by a central authority.

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

¹² https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Medicinal-plant-protection-products-single-procedure-for-the-granting-of-SPCs_en

¹³ <https://ec.europa.eu/docsroom/documents/29524>

¹⁴ <https://ec.europa.eu/docsroom/documents/29524/attachments/4/translations/en/renditions/native>

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

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

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

Option 1, on guidelines for examining national SPC applications, would not be sufficient alone to overcome discrepancies between national practices, as the guidance would be non-binding. Nevertheless, in the context of the preferred options 4 and 5, EUIPO should develop guidelines that reflect its practice. These guidelines would be of practical use both to officials in charge of the SPC-related procedures and to their users, including professional advisers who assist applicants (e.g. by offering examples). This guidance would take stock of the practices developed by the examination panels, especially since they will include examiners from several different Member States, to improve consistency between examination practices under the new centralised procedure. Moreover, national offices may also benefit from guidelines developed by the examination authority for their own (national) examination procedures.

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

- **Regulatory fitness and simplification**

Enabling unitary patent holders to obtain through a single procedure a unitary SPC able to be enforced centrally in all relevant Member States represents a considerable simplification compared to the current situation in which national SPCs need to be applied for and enforced separately in each Member State, while noting that SPCs based on European patents (also non-unitary ones) will be able to be enforced before the Unified Patent Court (‘UPC’) once it is operating¹⁵.

- **Fundamental rights**

This proposal will have no impact on fundamental rights, especially since it is not proposed to alter the substantive features of the existing SPC regimes (e.g. conditions for grant, scope, effects). The initiative is consistent with the Charter of Fundamental Rights, as it offers greater legal certainty to applicants for unitary certificates, and where necessary for third

¹⁵ To some extent at least, during the transitional period during which non-unitary European patents will still be able to be litigated before national courts.

parties, by providing for the procedural conditions for the examination, opposition, appeal and invalidity actions before the centralised authority.

In particular, where a centralised examination opinion is negative, the applicant may file an appeal before the Boards of Appeal of the EUIPO.

Moreover, examiners from national offices will play a key role in the centralised examination procedure and participate in the substantive examination of the application, as well as may take part in opposition and invalidity proceedings.

On the other hand, third parties will be able to submit observations during the examination of a centralised application, and to initiate an opposition against an examination opinion. After a unitary SPC is granted by the Office, third parties will also be able to challenge its validity before the Office. Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State.

4. BUDGETARY IMPLICATIONS

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

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

Moreover it may be expected that only some medicinal products will be eligible for a unitary certificate in the first years of operation of the unitary patent system, considering that not all European patents will have unitary effect (which will be a prerequisite for applying for a unitary certificate).

5. OTHER ELEMENTS

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

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

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

Overall structure of the proposal

The proposal is structured similarly to the current SPC Regulations and in particular to a parallel proposal relating to the unitary certificate for plant protection products (COM(2023) 221). It first sets out general provisions on SPCs followed by procedural provisions. It also ensures alignment with certain provisions of the corresponding proposal relating to plant protection products (COM(2023) 223), derived from Regulation (EC) No 1610/96.

Furthermore, this proposal would amend:

- Regulation (EU) 2017/1001, that lays down the tasks carried out by the Office (see below under ‘Examination/granting authority’), to ensure that the Office will be able to implement the procedures envisaged in the context of the present reform of the SPC regime,
- Regulation (EC) No 1901/2006, to ensure that the paediatric extension it established will also be applicable in respect of unitary SPCs for medicinal products; and
- Regulation (EU) No 608/2013, to ensure that the customs measures it established will also be applicable in respect of unitary SPCs (for medicinal products under this proposal, and for plant protection products under the parallel proposal for plant protection products).

Coherence with the parallel proposal relating to plant protection products

This proposal is extremely similar to the one presented in parallel regarding the unitary SPC for plant protection products (COM(2023) 221), with a limited number of changes directly linked to the intrinsic differences between medicinal products and plant protection products, regarding in particular marketing authorisations (as there are no centralised marketing authorisations for plant protection products). The ‘SPC manufacturing waiver’ introduced into Regulation (EC) No 469/2009 by Regulation (EU) 2019/933 only applies to SPCs for medicinal products and therefore needs to be reflected in this new Regulation, but not in the above-mentioned parallel proposal regarding unitary SPCs for plant protection products.

Basic patent

It is proposed that a unitary SPC must be based on a European patent with unitary effect only (as the ‘basic patent’), which would ensure that its claims are identical for all Member States it covers, and would avoid the risk of the basic patent being revoked, or lapsing, for one or some of these Member States. In this respect it should be noted that paragraph 21 of the explanatory memorandum of the first proposal for a Council Regulation concerning the creation of a supplementary protection certificate for medicinal products (COM(90)101) already envisaged that ‘*when use is made of the European procedure to obtain a Community patent, it will likewise be necessary that the certificate can apply equally to medicinal products protected by a Community patent*’ (now referred to as a ‘European patent with unitary effect’ or, more informally, a ‘unitary patent’).

Allowing unitary SPCs to be based on national patents, or even on non-unitary European patents, would be more demanding insofar as the examination of such applications would be concerned, as it would be required to examine separately, for each of the Member States concerned, if the product concerned is indeed protected. This would also raise language issues, and affect legal certainty.

Examination/granting authority

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

After assessing the formal admissibility of the unitary SPC application, the central examination authority would entrust the substantive examination of the application to a panel. This panel would be made up of a member of that central authority and two qualified examiners, experienced in SPC matters, from two different national patent offices in Member

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

Examination procedure and remedies

After examining the application, the central examination authority will issue an examination opinion stating whether the application fulfils the applicable criteria (and in the first place those defined in Article 3). The applicant can file an appeal against a negative opinion (as further explained below).

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

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

On the basis of the examination opinion (as possibly amended following an opposition), the EUIPO will either grant a unitary SPC, or reject the application for it, subject to the outcome of any appeal before the Boards of Appeal of the .

After the grant of a unitary SPCs, third parties will be able to initiate invalidity proceedings (actions for a declaration of invalidity) before the Office. Here as well, related decisions may be appealed to the Boards of Appeal, and may end up before the General Court.

Counterclaims for a declaration of invalidity could be raised in the competent court of a Member State (including the Unified Patent Court where the applicable conditions are met, subject to a suitable amendment of the UPCA).

Marketing authorisations concerned

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

Substantive features of the SPC regime

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

- the case law¹⁶ on SPCs is progressively but effectively converging, and steadily reducing uncertainty about the interpretation of the SPC regime¹⁷, while further amendments might trigger new fluctuations and uncertainty as regards the proper interpretation of the amended rules;
- respondents to the Allensbach survey did not call for Article 3 of the SPC Regulations to be amended (question 48) even if they consider that the case law is unclear in some respects (question 46).

That being said, considering that there are national discrepancies in the interpretation of the rule defining the duration of a European patents, which may result in a one-day difference, there is a need to clarify that rule insofar as its application to unitary SPCs is concerned.

New recitals

Certain recitals concern the conditions set out in Article 3 for the grant of SPCs, and incorporate the case law of the Court of Justice. The aim is to ensure consistency. In particular the judgements in cases C- 121/17 and C-673/18 interpret Article 3(a) and 3(d) of Regulation (EC)No 469/2009, respectively, and should be considered settled case law. This is also the case for judgement C471/14, whereby the date of the first marketing authorisation in the Union, within the meaning of Article 13, is the date on which notification of the decision granting the authorisation was given to the addressee of the decision.

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

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

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

¹⁶ For a full list of cases, see Table 5.5. of the second MPI study.

¹⁷ Further clarifications are, however, necessary in certain areas as indicated by two referrals in 2022, cases C-119/22 and C-149/22.

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

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

Language regime

This Regulation envisages the possibility of filing a centralised SPC application in any official EU language. In this regard, the amount of text in an SPC application is extremely small, especially compared to patents and this would not present a burden for applicants. Certain matters would not require any translation, such as the identification of the basic patent and the relevant marketing authorisation, the relevant dates, and the identification of the applicant(s) and the product concerned. The translation costs are, therefore, expected to be considerably lower than would be the case for patent applications. See the impact assessment (SWD(2023) 118) for an exact calculation.

Appeals

Decisions of the central examination authority are subject to appeal. This also applies to a negative examination opinion issued by the central examination authority, against which the applicant may file an appeal. This also applies to other decisions of that authority; for instance, the decision relating to an opposition may be appealed by any of its parties. An appeal may result in the examination opinion being amended.

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

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

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

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

An application fee and possibly other procedural fees, such as the fee for an appeal, and annual (renewal) fees, will have to be paid by applicants to the central examination authority. The level of fees to be paid to the central examination authority will be set in an implementing act.

It would be appropriate that a fraction of the renewal fees paid by unitary SPC holders be transferred to the national patent offices¹⁸ of the Member States in which unitary SPCs have legal effect (as already planned in respect of renewal fees for unitary patents). At the same

¹⁸ Or any other national authority competent for the grant of SPCs.

time, it is necessary to ensure that those national offices that participate in the new procedure as regards the substantive examination of unitary SPC applications are properly remunerated for their participation.

Litigation

It is intended that a unitary SPC will be able to be litigated before the body responsible under national law for the revocation of the corresponding basic patent. It is expected that the definition of SPCs present in the UPCA will be amended to include unitary SPCs as well. Such amendment may be based on Article 87(2) of the UPCA.

Extension of unitary SPCs for paediatric medicinal products

Unitary SPC applicants/holders should be able to apply before the central examination authority for extensions of unitary SPCs for paediatric medicinal products, under the conditions currently provided for by Regulation (EC) No 1901/2006 – which, therefore, needs to be amended so as to ensure that it also applies to unitary SPCs in addition to national SPCs.

Centralised procedure for the grant of national SPCs

A parallel proposal (COM(2023) 231) is intended to create a centralised procedure for the filing and examination of ‘centralised SPC applications’, able to result in the grant (at a national level) of national SPCs in the Member States designated in that application. This procedure would be available potentially for all Member States, and only on the basis of a European patent as basic patent.

It is proposed that the procedure for the filing and examination of unitary SPC applications would be the same (*mutatis mutandis*) as the centralised procedure defined in the above-mentioned parallel proposal. In this manner, a ‘combined’ SPC application could possibly include both a request for the grant of a unitary SPC (for the Member States covered by the basic patent) and a request for the grant of national SPCs in other Member States. That ‘combined’ application would undergo a single examination procedure, ruling out any discrepancies, and considerably reducing costs and administrative burden for applicants.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(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 118, first paragraph, 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 Committee¹⁹,

Having regard to the opinion of the Committee of the Regions²⁰,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) 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.
- (2) 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.
- (3) Uniform patent and supplementary certificate protection within the internal market, or at least a significant part thereof, should feature amongst the legal instruments which pharmaceutical undertakings have at their disposal.
- (4) In its Communication of 25 November 2020 entitled ‘Making the most of the EU’s innovative potential – An intellectual property action plan to support the EU’s recovery and resilience’²¹, the Commission highlighted the need to tackle the remaining fragmentation of the Union’s intellectual property system. In that Communication, the Commission noted that, for medicinal products and plant protection products, supplementary protection is only available at national level. At the same time, there is a centralised procedure for granting European patents, as well

¹⁹ OJ C [...], [...], p. [...].

²⁰ OJ C [...], [...], p. [...].

²¹ COM(2020)760 final.

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 Council²² enters into force in June 2023 in respect of the Member States having ratified the Agreement on a Unified Patent Court ('UPC').

- (5) Regulation (EU) No 1257/2012 has created the possibility to provide unitary patents. However, Regulation (EU) No 1257/2012 does not provide for a unitary supplementary protection certificate ('unitary certificate').
- (6) In the absence of a unitary certificate, a unitary patent could only be extended by applying for several national certificates in each Member State where protection is sought, preventing the holder of a unitary patent from obtaining unitary protection during the whole combined protection period conferred by that unitary patent and subsequently by these certificates. Therefore, a unitary certificate for medicinal products should be created, that would allow a unitary patent to be extended in a unitary manner. Such a unitary certificate should be applied for on the basis of a unitary basic patent and a centralised authorisation; it would have the same legal effects as national certificates in all Member States in which that basic patent has unitary effect. The main feature of such a unitary certificate should be its unitary character.
- (7) A unitary certificate should provide uniform protection and have equal effect in all Member States where the basic patent it relies upon has unitary effect. Consequently, a unitary certificate should only be transferred or revoked, or expire, in respect of all those Member States.
- (8) Regulation [COM(2023) 231] replaces Regulation (EC) No 469/2009 of the European Parliament and of the Council²³, and includes new provisions establishing a centralised procedure for the examination of supplementary protection certificates for medicinal products.
- (9) Considering that products authorised under procedures other than the centralised one should still be able to enjoy supplementary protection, and that certain Member States have not yet joined the unitary patent system, certificates granted by national patent offices should remain available.
- (10) To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, and distortions of the internal market, the same substantive rules should apply, with appropriate adaptations, to certificates under Regulation [COM(2023) 231] and to unitary certificates, in particular as regards the conditions for grant of a certificate, as well as the duration and effects of a certificate.
- (11) In particular, the duration of the protection granted by a unitary certificate should be identical to the duration provided for as regards national certificates under Regulation [COM(2023) 231]; namely, the holder of both a unitary patent and a unitary certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time

²² 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).

²³ 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).

the medicinal product in question first obtains an authorisation to be placed on the market in the Union. Since the unitary certificate would take effect at the expiry of the basic patent, and in order to take into account discrepancies in national practices regarding the date of expiry of a patent which may result in 1-day differences, this Regulation should clarify when exactly the protection conferred by a unitary certificate should take effect.

- (12) Regulation (EU) No 2017/1001 of the European Parliament and of the Council²⁴ has established, under its Article 2, a European Union Intellectual Property Office ('the Office'). In the interest of the internal market, and due to the autonomous nature of the unitary certificate, its examination and grant procedure should be carried out by a single examining authority. This can be achieved by the Office being given the task of examining both applications for unitary certificates in accordance with this Regulation and Regulation [COM(2023) 221] and centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223]. To ensure consistency with this Regulation, Regulation (EU) No 2017/1001 should be amended.
- (13) A unitary certificate for a medicinal product should be based only on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council²⁵ or Regulation (EU) 2019/6 of the European Parliament and of the Council²⁶ only. 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 this would thus facilitate the examination of applications for unitary certificates.
- (14) An applicant should also be allowed to lodge a 'combined application' that would also include the designation of Member States, other than those in which the basic patent has unitary effect, in which the grant of national certificates would be requested as set out in Regulation [COM(2023) 231]. Such a combined application should undergo a single examination procedure.
- (15) In such an event, double protection by both a unitary certificate and a national certificate – whether obtained on the basis of a national application or of a centralised application – should be excluded in any Member State.
- (16) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims. Or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims provided that each of them is specifically identifiable in the light of all the information disclosed by that patent.
- (17) 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.

²⁴ 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).

²⁵ 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).

²⁶ 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).

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.

- (18) Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary 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 unitary certificate.
- (19) To ensure balanced protection, however, a unitary certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the unitary 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 unitary certificate. There is therefore a need to consider that the protection conferred by the unitary certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.
- (20) 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.
- (21) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all therapeutically equivalent products having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.
- (22) Regulation [COM(2023) 231] provides for an exception according to which, under narrowly defined circumstances and subject to various safeguards, the protection conferred by a national supplementary protection certificate for medicinal products does not extend to a product that would be manufactured in the Union by a person other than the holder of that certificate, where it is manufactured for the purpose of being exported to a third country, or of being stored in the Union in view of its entry into the Union market upon expiry of the certificate. To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, similar rights and limitations should be conferred by certificates under Regulation [COM(2023) 231] and by unitary certificates, and therefore that exception should also be available in respect of unitary certificates. The reasons for the introduction for the waiver and the conditions for its application should be applicable for unitary certificates.

- (23) To ensure alignment with the rules applicable to unitary patents, a unitary certificate as an object of property should be dealt with, in its entirety and in all Member States in which it has effect, as a national certificate of the Member State determined in accordance with the law that applies to the basic patent.
- (24) To avoid discrimination between applicants for national certificates under Regulation [COM(2023) 231] and applicants for unitary certificates under this Regulation, an extension of the duration of a certificate as defined by Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council²⁷ should also be available for unitary certificates. For this purpose that Regulation should be amended.
- (25) 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 unitary certificate 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 subsequent invalidity proceedings before the Office. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.
- (26) The examination of an application for a unitary certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the procedure, in particular as regards qualification and conflicts of interest.
- (27) The Office should examine the application for a unitary certificate and issue an examination opinion. That opinion should state the reasons for which it is positive or negative.
- (28) 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.
- (29) After the completion of the examination of a unitary certificate 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 Office should implement the examination opinion by granting a unitary certificate or rejecting the application, as applicable.
- (30) 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

²⁷ 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).

case of a combined application including the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

- (31) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.
- (32) Any person may challenge the validity of a unitary certificate by lodging with the Office an application for a declaration of invalidity.
- (33) The Office should have the possibility to charge a fee for the application for a unitary certificate and for an application for the extension of duration of a unitary certificate in the case of paediatric medicinal products, as well as other procedural fees such as those for oppositions, appeals and invalidity. The fees charged by the Office should be laid down by an implementing act.
- (34) Annual fees in respect of unitary certificates (also known as renewal fees) should be paid to the Office, which should retain a part of them to cover the expenses generated by carrying out tasks in relation to the grant of unitary certificates while the remaining part would be shared with those Member States in which unitary certificates have effect.
- (35) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted unitary certificates and their status. The register should be available in all official languages of the Union.
- (36) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union, to enable actors across the Union to easily apply for unitary certificates or submit third party observations and result in optimal transparency for all stakeholders across 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.
- (37) Financial provision should be made to ensure competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.
- (38) 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.
- (39) To ensure that Regulation (EU) No 608/2013 of the European Parliament and of the Council²⁸ also covers unitary certificates, that Regulation should be amended.
- (40) 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

²⁸ 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.

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 2016.²⁹ 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.

- (41) 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 Council³⁰.
- (42) The Commission should regularly report on the operation of this Regulation, in coordination with that required in Regulation [COM(2023) 231]. The Commission should regularly evaluate the impact of unitary supplementary protection on access to medicines.
- (43) 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 also applies to the above-mentioned exception, which maintains the core rights of the certificate, by being limited 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 does not go beyond what is necessary and appropriate in the light of its overall objective, which is to promote the

²⁹ 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).

³⁰ 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).

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.

- (44) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the autonomous nature of the unitary certificate being independent from national systems, 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.
- (45) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725³¹ and delivered an opinion on XXX [OP, please add reference once available].
- (46) Provision should be made for appropriate arrangements to facilitate a smooth implementation of the rules provided for in this Regulation. To allow for sufficient time for the Office to prepare the operational set-up and launch of the procedure to be used for the grant of unitary certificates, as set out in this Regulation, the application of this Regulation should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down rules on the unitary supplementary protection certificate ('unitary certificate') for medicinal products protected by a European patent with unitary effect and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in 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;

³¹ 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).

- (3) 'European patent' means a patent granted by the European Patent Office ('EPO') under the rules and procedures laid down in the European Patent Convention³² ('EPC');
- (4) '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;
- (5) 'basic patent' means a unitary 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 unitary certificate;
- (6) 'application for an extension of the duration' means an application for an extension of the duration of a unitary certificate pursuant to Article 20(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006;
- (7) '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;
- (8) 'centralised application' means an application made before the European Union Intellectual Property Office ('the Office') pursuant to Chapter III of Regulation [COM(2023) 231] with a view to the grant of certificates, for the product identified in the application, in the designated Member States;
- (9) '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.

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled:
 - (a) the product is protected by that basic patent in force;
 - (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;
 - (c) the product has not already been the subject of a certificate, nor of a unitary certificate;
 - (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.
2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State.

³² Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000.

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable.

Article 4

Scope of the protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary 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 unitary certificate.

Article 5

Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States in which the basic patent has unitary effect.
2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may only be limited, transferred or revoked, or lapse, in respect of all those Member States.
3. By way of derogation from paragraph 1, the unitary certificate shall not confer protection against certain acts which would otherwise require the consent of the unitary certificate holder, if all of the following conditions are met:
 - (a) the acts comprise any of the following:
 - (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries;
 - (ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export;
 - (iii) the making, no earlier than 6 months before the expiry of the unitary 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;
 - (iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than 6 months before the expiry of the unitary certificate.
 - (b) the maker, through appropriate and documented means, notifies the Office, and the competent industrial property office of the respective Member State, and informs the unitary certificate holder, of the information referred to in paragraph 6 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 unitary certificate, whichever is the earlier;
- (c) if the information referred to in paragraph 6 of this Article changes, the maker notifies the Office and the competent industrial property office of the respective Member State, 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 I, 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 10 of this Article and, if applicable, with Article 31(4).
4. Paragraph 3 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.
 5. The information provided to the unitary certificate holder for the purposes of paragraph 3, 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.
 6. For the purposes of paragraph 3, 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 unitary certificate having effect in the Member State of making, and the number of the certificate or unitary 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.
 7. For the purposes of the notifications to the Office and to the competent industrial property office referred to in paragraph 3, points (b) and (c), the maker shall use the standard form for notification set out in Annex II.
 8. Failure to provide the information referred to in paragraph 6, 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 3.

9. The maker shall ensure that medicinal products made pursuant to paragraph 3, point (a)(i), do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161³³.
10. 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 3, point (a), is fully informed and aware of all of the following:
 - (a) that those acts are subject to paragraph 3;
 - (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 3, point (a)(i), or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(iii), could infringe the unitary certificate referred to in that paragraph where, and for as long as, that certificate applies.

Article 6

Entitlement to the unitary certificate

1. The unitary 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 unitary certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

Article 7

The unitary certificate as an object of property

A unitary certificate or an application for a unitary certificate as an object of property shall be treated in its entirety, in each Member State in which the basic patent has unitary effect, in accordance with the national law applicable to the basic patent as an object of property.

Article 8

Application for a unitary certificate

1. The application for a unitary 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 unitary effect is attributed to the basic patent, the application for a unitary certificate shall be lodged within 6 months of the date on which unitary effect is attributed to the basic patent.
3. The application for an extension of the duration may be lodged at the same time when lodging the application for a unitary certificate or when the application for the

³³ 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).

unitary certificate is pending and the appropriate requirements of Article 9(1), point (d), or Article 9(2), respectively, are fulfilled.

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

Article 9

Content of the application for a unitary certificate

1. The application for a unitary certificate shall contain the following:
 - (a) a request for the grant of a unitary certificate, stating the following information:
 - (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 of the European Parliament and of the Council³⁴ 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 unitary 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

³⁴ 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).

authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

2. Where an application for a unitary certificate is pending, an application for an extension of the duration in accordance with Article 8(3) shall include the documents referred to in paragraph 1, point (d) of this Article and a reference to the application for a certificate already lodged.
3. The application for an extension of the duration of a unitary certificate already granted shall contain the documents referred to in paragraph 1, point (d), and a copy of the certificate already granted.
4. The applications referred to in this Article shall be filed by using specific application forms.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 10

Lodging of an application for a unitary certificate

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, shall be lodged with the Office.

Article 11

Examination of the admissibility of an application for a unitary certificate

1. The Office shall examine the following:
 - (a) whether the application for a unitary certificate complies with Article 9;
 - (b) whether the application complies with Article 8;
 - (c) whether the application fee referred to in Article 31(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 for a unitary certificate.

Article 12

Publication of the application

If the application for a unitary certificate complies with Article 11(1), or if an application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall publish the application in the Register.

Article 13

Examination of the application for a unitary certificate

1. The Office shall assess the application on the basis of all the conditions in Article 3(1), for all Member States in which the basic patent has unitary effect.
2. Where the application for a unitary certificate and the product to which it relates comply with Article 3(1) for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.
3. Where the application for a unitary certificate and the product to which it relates does not comply with Article 3(1) in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.
4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.
5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine applications for unitary certificates 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 55.

Article 14

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 in which the basic patent has unitary effect.
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 application in the Register.
4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.
5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 15

Opposition

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

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.
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 unitary certificate application against which opposition is filed, the name of its holder, and the identification of the product;
 - (b) the particulars of the opponent and, where applicable, of its representative;
 - (c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based.
5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 17. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application.
6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate this to opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.
7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the unitary certificate application, together with a copy of the notice of opposition.
8. 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.
9. 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.
10. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.
11. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.
12. 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.
13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 16

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 applications for unitary certificates.
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 examination of applications for unitary certificates.
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, opposition and invalidity proceedings. Each such competent national authority shall update that list in the event of a change.

Article 17

Examination panels

1. The assessments under Articles 13, 15, 19 and 23 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 16(1) from two different participating competent national authorities, under supervision of the Office.
2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.
3. When setting up an examination panel, the Office shall ensure the following:
 - (a) geographical balance amongst the participating offices;
 - (b) the respective workload of the examiners is taken into account;
 - (c) no more than one examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].
4. The Office shall publish a yearly an overview of the number of procedures, including those for examination, opposition, appeal and invalidity, 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 55.

Article 18

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

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 take one of the following decisions:

- (a) where the examination opinion is positive, the Office shall grant a unitary certificate;
- (b) where the examination opinion is negative, the Office shall reject the application for a unitary certificate.

Article 19

Grant of an extension of the duration of a unitary certificate

1. After ensuring that the application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall assess that application on the basis of the conditions laid down in Article 36 of Regulation (EC) No 1901/2006.
2. Third parties may also submit observations in respect of an application for an extension of the duration of a unitary certificate.
3. Where the application for an extension of the duration complies with the conditions referred to in paragraph 1, the Office shall grant an extension of the duration of the unitary certificate.
4. Where the application for an extension of the duration does not comply with the conditions referred to in paragraph 1, the Office shall reject that application.

Article 20

Duration of the unitary certificate

1. The unitary certificate shall take effect at the end of the lawful term of the basic patent, namely on the twentieth anniversary of the filing date of the application for that patent, for a period equal to the period which elapsed between the date on which the application for the 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. The duration of the unitary certificate may not exceed 5 years from the date on which it takes effect.
3. The periods laid down in paragraphs 1 and 2 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 this Article may be extended only once.

Article 21

Expiry of the unitary certificate

The unitary certificate shall lapse in any of the following events:

- (a) at the end of the period provided for in Article 20;
- (b) if the unitary certificate holder surrenders it;
- (c) if the annual fee laid down in accordance with Article 31(3) is not paid in time;
- (d) if and as long as the product covered by the unitary certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation to place on the market in accordance with Regulation (EC) No 726/2004 or Regulation (EU) 2019/6.

For the purposes of the first subparagraph, point (d), the Office may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 22

Invalidity of the unitary certificate

The unitary certificate shall be invalid in any of the following events:

- (a) the certificate was granted contrary to Article 3;
- (b) the basic patent has lapsed before its lawful term expires;
- (c) the basic patent is revoked or limited to the extent that the product for which the unitary 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.

Article 23

Application for a declaration of invalidity

1. Any person may file with the Office an application for a declaration of invalidity of a unitary certificate.
2. An application for a declaration of invalidity may only be filed on the grounds that one or more of the conditions set out in Article 22 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.
3. An application for a declaration of invalidity 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 related fee has been paid.
4. The application for a declaration of invalidity shall contain:
 - (a) the references of the unitary certificate against which that application is filed, the name of its holder, and the identification of the product;
 - (b) the particulars of the person referred to in paragraph 1 ('applicant') and, where applicable, of its representative;
 - (c) a statement of the grounds on which the application for a declaration of invalidity is based.

5. The application for a declaration of invalidity shall be examined by an invalidation panel set up by the Office in accordance with the rules applicable to examination panels. However, the invalidation panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application, nor, the case being, any examiner involved in possible related opposition proceedings, nor in related appeal proceedings.
1. An application for a declaration of invalidity shall be inadmissible where an application relating to the same subject matter and cause of action, and involving the same parties, has been adjudicated on its merits, either by the Office or by a competent court as referred to in Article 24, and the decision of the Office or that court on that application has acquired the authority of a final decision.
7. If the invalidation panel notes that the application for a declaration of invalidity does not comply with paragraphs 2, 3 or 4, it shall reject that application as inadmissible, and communicate this to applicant.
8. The decision to reject an application for a declaration of invalidity as inadmissible shall be communicated to the holder of the unitary certificate, together with a copy of that application.
9. Where the application for a declaration of invalidity is not rejected as inadmissible, the Office shall promptly transmit that application to the holder of the unitary certificate, and shall publish it in the Register. If several applications for a declaration of invalidity have been filed, the Office shall promptly communicate them to the other applicants.
10. The Office shall issue a decision on the application for a declaration of invalidity within 6 months, unless the complexity of the case requires a longer period.
11. If the examination of the application for a declaration of invalidity reveals that the one or more of the conditions set out in Article 22 are met, the unitary certificate shall be declared invalid. Otherwise the application for a declaration of invalidity shall be rejected. The outcome shall be mentioned in the Register.
12. The unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation, to the extent that it has been declared invalid.
13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure governing the declaration of invalidity.

Article 24

Counterclaim for the invalidity of a certificate

1. A counterclaim for a declaration of invalidity may only be based on the grounds for invalidity set out in Article 22.
2. The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the Office relating to the same subject matter and cause of action and involving the same parties has already become final.
3. If the counterclaim is brought in a legal action to which the holder of the unitary certificate is not already a party, that holder shall be informed thereof and may be joined as a party to the action in accordance with the conditions applicable before the competent court.

4. The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the Office of the date on which the counterclaim was filed. The Office shall record that information in the Register. If an application for a declaration of invalidity of the unitary certificate had already been filed before the Office before the counterclaim was filed, the court shall be informed thereof by the Office and stay the proceedings until the decision on the application is final or the application is withdrawn.
5. Where the competent court of a Member State has given a judgment which has become final on a counterclaim for a declaration of invalidity of a unitary certificate, a copy of the judgment shall be sent to the Office without delay, either by the court or by any of the parties to the national proceedings. The Office or any other interested party may request information about such transmission. The Office shall mention the judgment in the Register and shall take the necessary measures to comply with its operative part.
6. The competent court hearing a counterclaim for a declaration of invalidity may stay the proceedings on application by the holder of a unitary certificate and after hearing the other parties and may request the defendant to submit an application for a declaration of invalidity to the Office within a time limit which it shall determine. If the application is not made within the time limit, the proceedings shall continue; the counterclaim shall be deemed withdrawn. Where the competent court of a Member State stays the proceedings it may order provisional and protective measures for the duration of the stay.

Article 25

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

1. The Office may revoke an extension of the duration 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 to the Office.

Article 26

Notification of lapse or invalidity

1. Where the unitary certificate lapses in accordance with Article 21, point (b), (c) or (d), or is invalid in accordance with Article 22 and 23, the Office shall promptly publish a notification thereof.
2. Where the extension of the duration is revoked in accordance with Article 25, the Office shall promptly publish a notification thereof.

Article 27

Conversion

1. Where the unitary effect of the basic patent is revoked while the application for a unitary certificate is still pending, the holder of that application may, subject to a fee,

request the conversion of that application into a centralised application for certificates.

2. Where the unitary effect of the basic patent is revoked after the unitary certificate has been granted, the holder of that certificate may, subject to a fee, request the conversion of that unitary certificate into national certificates.
3. A request for conversion may be filed with the Office within 3 months after notification of the revocation of the unitary effect of the basic patent.
4. A request for conversion, as well as its outcome, shall be published in the Register.
5. The Office shall check whether the conversion requested fulfils the conditions set out in this Article, together with the formal conditions specified in the implementing act adopted pursuant to paragraph 8. If the conditions governing the request are not fulfilled, the Office shall notify the applicant of the deficiencies. If the deficiencies are not remedied within a period to be specified by the Office, the Office shall reject the request for conversion. Where the conversion fee has not been paid within the relevant period of 3 months, the Office shall inform the applicant that the request for conversion is deemed not to have been filed.
6. Where a request under paragraph 1 complies with paragraph 5, the Office shall convert the application for a unitary certificate into a centralised application for certificates designating the Member States in which the basic patent had unitary effect. In the event of a combined application, the designation of the Member States in which the basic patent had unitary effect shall be added to the designation of other Member States already included in the combined application.
7. Where a request under paragraph 2 complies with paragraph 5, the Office shall transmit the request for conversion to the competent national authorities of each Member State in which the basic patent had unitary effect and for which the request has been found admissible. The competent national authorities shall take decisions accordingly.
8. The Commission shall adopt implementing acts specifying the details to be contained in a request for conversion of the for a unitary certificate or unitary certificate into a centralised application for certificates or national certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 28

Appeals

1. Any party to proceedings under this Regulation, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.
2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.
3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out

the grounds of appeal shall be filed within 4 months of the date of notification of the decision.

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.
5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards may annul or alter the opinion.
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 54 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 29

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 25(1).
2. A Board of Appeal in matters regarding unitary 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 referred to in Article 165(2), (3) and (4), and Article 167(2) of Regulation (EU) 2017/1001 in matters regarding unitary 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 unitary certificates shall be appointed in accordance with Article 166(5) of Regulation (EU) 2017/1001.

Article 30

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to unitary certificates under this Regulation.

Article 31

Fees

1. The Office shall charge a fee for an application for a unitary certificate, and for an application for the extension of the duration of a unitary certificate.
2. The Office shall charge a fee for appeals, for oppositions, for applications for a declaration of invalidity and for conversions.
3. The unitary certificate shall be subject to the payment of annual maintenance fees to the Office.
4. The notifications referred to in Article 5(3), points (b) and (c), shall be subject to the payment of a fee to the Office.
5. The Commission is empowered to adopt implementing acts determining the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which they are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 32

Combined applications

An application for a unitary certificate may be included in a combined centralised application in which the applicant also requests the grant of national certificates, in the designated Member States, in accordance with the centralised procedure under Regulation [COM(2023) 231]. In that case, Article 39 of that Regulation shall apply.

Article 33

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 1³⁵.

³⁵ Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

Article 34

Communications to the Office

1. Communications addressed to the Office may be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically.
2. The Commission is empowered to adopt delegated acts in accordance with Article 54 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 35

Register

1. As regards applications for unitary certificates for medicinal products, the Register set up under Article 35 of Regulation [COM(2023) 231]³⁶ shall include, for each unitary certificate, or application for a unitary certificate, or application for an extension of the duration of a unitary certificate, the following information, as applicable:
 - (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 38(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 number of the basic patent;
 - (g) an identification of the product for which a unitary certificate is requested;
 - (h) 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;
 - (i) the number and date of the first authorisation to place the product on the market in the Union;
 - (j) the date and a summary of the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;
 - (k) where applicable, the number and the duration of the unitary certificate;
 - (l) where applicable, the date and a summary of the examination opinion relating to an application for an extension of the duration of a unitary certificate;

³⁶ Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products [COM(2023) 231].

- (m) where applicable, the filing of an opposition, and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;
 - (n) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;
 - (o) where applicable, a mention that a certificate has lapsed or was declared invalid;
 - (p) where applicable, the filing of an application for a declaration of invalidity and, once available, the outcome of the related proceedings;
 - (q) where applicable, information relating to a request for conversion, and its outcomes;
 - (r) information on the payment of annual fees.
2. The Register shall contain changes to the information in paragraph 1, including transfers, each accompanied by the date of recording of such entry.
 3. The Register and information referred to in paragraphs 1 and 2 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.
 4. The Executive Director of the Office may determine that information other than those referred to in paragraphs 1 and 2 shall be entered in the Register.
 5. The Office shall collect, organise, make public and store the information referred to in paragraphs 1 and 2, including any personal data, for the purposes laid down in paragraph 7. The Office shall keep the Register easily accessible for public inspection.
 6. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.
 7. The processing of the data concerning the entries set out in paragraphs 1 and 2, including any personal data, shall take place for the purposes of the following:
 - (a) administering the applications and unitary certificates in accordance with this Regulation 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.
 8. All the data, including personal data, concerning the entries in paragraphs 1 and 2 shall be considered to be of public interest and may be accessed by any third party. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

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, 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 unitary 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 Council³⁷ shall apply to documents held by the Office.
2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.
3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

³⁷ 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).

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 Council³⁸.

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 this Regulation, other than the filing of an application for a unitary certificate.
2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the Union 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

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division ('SPC Division') shall be set up within the Office and, in addition to the responsibilities under Regulations [COM(2023) 231] and [COM(2023) 223], shall be responsible for implementing the tasks set out in this Regulation and in Regulation [COM(2023) 221], including in particular:

- (a) receiving and supervising the examination of applications for unitary certificates, applications for an extension of the duration of unitary certificates, appeals and observations by third parties;
- (b) adopting examination opinions on behalf of the Office in relation to applications for unitary certificates, as well as in relation to applications for an extension of the duration of unitary certificates;

³⁸ 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).

- (c) deciding on oppositions against examination opinions;
- (d) deciding on applications for a declaration of invalidity;
- (e) processing conversion requests;
- (f) maintaining the register and the database.

Article 40

Decisions and communications of the Office

1. Decisions of the Office under this Regulation 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 Regulation 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 Regulation 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 28. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Article 41

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, opposition panel or invalidity panel shall not be public.
3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.
4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 42

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:
 - (a) hearing the parties;
 - (b) requests for information;
 - (c) the production of documents and items of evidence;
 - (d) hearing witnesses;
 - (e) opinions by experts;
 - (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.
2. The relevant panel may commission one of its members to examine the evidence adduced.
3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.
4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.
5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.
6. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 43

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 Regulation or of acts adopted pursuant to this Regulation, 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 54 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 44

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 54 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 45

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 46

Restitutio in integrum

1. The applicant for or holder of a unitary certificate, or any other party to proceedings before the Office under this Regulation, 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 Regulation, 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 15(1) and (3).

Article 47

Interruption of proceedings

1. Proceedings before the Office under this Regulation 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 39, 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 54 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 48

Costs

1. The losing party in opposition proceedings and proceedings for a declaration of invalidity, 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 55.
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 259/68³⁹. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 49

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.
2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality
3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.
4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 50

Amendment to Regulation (EU) 2017/1001

Regulation (EU) 2017/1001 is amended as follows:

- (1) Article 151(1) is amended as follows:
 - (a) point (c) is replaced by the following:

‘(c) promoting convergence of practices and tools in the fields of trade marks and designs as well as supplementary protection certificates, in cooperation with the central industrial property offices in the Member States, including the Benelux Office for Intellectual Property’;
 - (b) the following points (f) and (g) are added:

‘(f) the tasks referred to in Chapter III of Regulation [COM(2023) 231] and in Chapter III of Regulation [COM(2023) 223] as well as in Regulations [COM(2023) 222] and [COM(2023) 221];

(g) on the basis of requests for participation in the centralised examination procedure, and after giving the Commission an opportunity to comment on

³⁹ 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.)’

them, appointing, by concluding an agreement, those competent national authorities whose examiners will be able to participate in the centralised examination of centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223], including opposition proceedings, and of applications for unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221], including opposition and invalidity proceedings';

- (2) in Article 152(1), the first subparagraph is replaced by the following:

‘The Office and the central industrial property offices of the Member States and the Benelux Office for Intellectual Property shall cooperate with each other to promote convergence of practices and tools in the field of trade marks, designs, and supplementary protection certificates.’.

Article 51

Amendment to Regulation (EU) No 608/2013

Article 2(1) of Regulation (EU) No 608/2013 is amended as follows:

- (1) points (f) and (g) are replaced by the following:

‘(f) a supplementary protection certificate for medicinal products as provided for in Regulation [COM(2023) 231] of the European Parliament and of the Council of ddddd concerning the supplementary protection certificate for medicinal products⁴⁰ [OP, please insert the No and date of COM(2023) 231 once adopted, as well as its O.J. reference in the footnote];

(g) a supplementary protection certificate for plant protection products as provided for in Regulation [COM(2023) 223] of the European Parliament and of the Council of ddddd concerning the creation of a supplementary protection certificate for plant protection products⁴¹ [OP, please insert the No and date of COM(2023) 223 once adopted, as well as its O.J. reference in the footnote];’;

- (2) the following points (m) and (n) are inserted:

‘(m) a unitary supplementary protection certificate for medicinal products as provided for in Regulation [COM(2023) 222] of the European Parliament and of the Council of ddddd on the unitary supplementary protection certificate for medicinal products and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013⁴² [OP, please insert the No and date of COM(2023) 222 once adopted, as well as its O.J. reference in the footnote];

(n) a unitary supplementary protection certificate for plant protection products as provided for in Regulation [COM(2023) 221] of the European Parliament and of the Council of ddddd on the unitary supplementary protection certificate for plant protection products⁴³ [OP, please insert the No and date of COM(2023) 221 once adopted, as well as its O.J. reference in the footnote].’.

⁴⁰ O.J. reference to be inserted

⁴¹ O.J. reference to be inserted

⁴² O.J. reference to be inserted

⁴³ O.J. reference to be inserted

Article 52

Amendment to Regulation (EC) No 1901/2006

Regulation (EC) No 1901/2006 is amended as follows:

- (1) in Article 2, point (4) is replaced by the following:

‘(4) ‘paediatric use marketing authorisation’ means a marketing authorisation granted in respect of a medicinal product for human use which is not protected by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or by a patent which qualifies for the grant of the supplementary protection certificate, covering exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product.’;
- (2) in Article 8, the first paragraph is replaced by the following:

‘In the case of authorised medicinal products which are protected either by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or by a patent which qualifies for the grant of the supplementary protection certificate, Article 7 of this Regulation shall apply to applications for authorisation of new indications, including paediatric indications, new pharmaceutical forms and new routes of administration.’;
- (3) Article 36 is amended as follows:
 - (a) in paragraph 1, the first subparagraph is replaced by the following:

‘Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate or unitary supplementary protection certificate shall be entitled to a six-month extension of the periods referred to in Articles 13(1) and 13(2) of Regulation [COM(2023) 231] or Article 20(1) and 20(2) of Regulation [COM(2023) 222].’;
 - (b) in paragraph 4, the first sentence is replaced by the following:

‘Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or under a patent which qualifies for the grant of the supplementary protection certificate.’.

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 it by applicants and by a fraction of the annual fees paid by the holders of unitary certificates, while the remainder of the annual fees shall be shared with the Member States in accordance with the number of unitary certificates having legal effect in each of them. The fraction of the annual fees to be shared with Member States shall

initially be set at a certain value but shall be reviewed every 5 years, in such a manner as to achieve financial sustainability for the activities carried out by the Office under this Regulation as well as under Regulations [COM(2023) 231], [COM(2023) 223] and [COM(2023) 221].

2. For the purposes of paragraph 1, the Office shall keep an account of the annual fees paid to it by holders of unitary certificates in force in the respective Member States.
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 those 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 55.
5. Article 12 of Regulation (EU) No 1257/2012 shall apply to the annual fees due in respect of unitary certificates.

Article 54

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 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(3) shall be conferred on the Commission for an indeterminate period of time from XXX [*OP please insert the date = date of entry into force*].
3. The delegation of power referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(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 Article 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) or 47(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 55

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. 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 56

Evaluation

By xxxxxx [*OP, please insert: five years after the date of application*], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation.

Article 57

Entry into force and application

This Regulation shall enter into force on XXX [*OP – please insert the date - the 20th day following its publication in the Official Journal of the European Union*].

It shall apply from xxxxx [*OP please insert first day of the 12th month after the date of entry into force*].

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President