REGULATION (EC) NO 469/2009

CONCERNING THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

KEELING SCHEDULE

SHOWING CHANGES WHICH WOULD BE EFFECTED BY THE SUPPLEMENTARY PROTECTION CERTIFICATES (AMENDMENT) (EU EXIT) REGULATIONS 2020, LAID ON 15 OCTOBER 2020

This schedule has been prepared by the Intellectual Property Office. It is intended for illustrative purposes only to assist the reader in understanding the changes to be made to Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (as currently amended) by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 when these come into force (subject to Parliamentary approval).

Note

When text is **omitted** by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020:

- Text is struck through and presented in red text.

When new text is **inserted** by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020

- Text is surrounded with square brackets and inserted in red text.

When existing text is **substituted** by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020

- Text to be replaced is struck through and presented in red text. The text replacing it is presented straight afterwards enclosed with square brackets and also in red text.

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

(Retained EU law version)

As amended by

Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019

and

The Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801)*

and

The Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1050)*

showing changes which would be effected by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020, laid on 15 October 2020

*Note that the changes introduced by the Patents (Amendment) (EU Exit) Regulations 2019 and the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 take effect at 11PM on 31 December 2020

Article 1

Definitions

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

(a) '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;

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

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

(d) 'certificate' means the supplementary protection certificate;

(e) 'application for an extension of the duration' means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and regulation 58A(3) of the Human Medicines Regulations 2012;

(f) 'comptroller' means the Comptroller-General of Patents, Designs and Trade Marks;

(g) 'court' means—

(i) as respects England and Wales, the High Court;

(ii) as respects Scotland, the Court of Session; and

(iii) as respects Northern Ireland, the High Court in Northern Ireland;

(h) "EEA authorisation" means an authorisation to place a medicinal product on the market which has effect in an EEA state in accordance with Directive 2001/83/EC or Directive 2001/82/EC;

(i) 'patent' means a patent which has effect in the United Kingdom;

(j) 'UK authorisation' means, in relation to a product, an authorisation to place that product on the market [in the United Kingdom] as a medicinal product granted or having effect as if granted in accordance with—

(i) Part 5 of the Human Medicines Regulations 2012; or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013.

[(ja) "GB authorisation" means, in relation to a product, an authorisation to place that product on the market in England and Wales and Scotland as a medicinal product granted or having effect as if granted in accordance with—

(i) Part 5 of the Human Medicines Regulations 2012; or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013 as they have effect in England and Wales and Scotland;

(jb) "NI authorisation" means, in relation to a product, an authorisation to place that product on the market in Northern Ireland as a medicinal product granted or having effect as if granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC as they have effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement;]

(k) 'maker' means the person, established in the United Kingdom, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to countries

outside the United Kingdom, the Isle of Man, and the Member States of the European Union or for the purpose of storing, is carried out.

[(l) "prescribed" means prescribed by rules under section 123 of the Patents Act 1977.]

Article 2

Scope

Any product may, under the terms and conditions provided for in this Regulation, be the subject of a certificate if it is—

(a) protected by a patent; and

(b) the subject of a UK[, GB or NI] authorisation prior to being placed on the market as a medicinal product.

Article 3

Conditions for obtaining a certificate

Where an application is submitted under Article 7, a certificate shall be granted if, at the date of submission of that application—

(a) the product is protected by a basic patent in force;

(b) there is a valid UK[, GB or NI] authorisation to place the product on the market;

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

(d) the authorisation referred to in point (b) is the first UK[, GB or NI] authorisation to place the product on the market as a medicinal product [in the territory of the United Kingdom, the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be].

Article 4

Subject matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the [UK, GB or NI] 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 [in the United Kingdom] before the expiry of the certificate.

Article 5

Effects of the certificate

1. Subject to the provisions of Article 4 [and paragraphs 1a and 1b], the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

[1a. The protection conferred by a certificate in accordance with paragraph 1 shall extend only to the territory in respect of which a valid, UK, GB or NI authorisation has been issued and where the authorisation—

(a) is the first authorisation for the product in the territory in accordance with Article 3(b) and (d), and

(b) has been issued before the certificate takes effect in accordance with Article 13(1).

1b. Where after the submission of an application for a certificate in accordance with Article 7(1) or (2) and before the certificate takes effect in accordance with Article 13(1), a GB or NI authorisation is granted in respect of the same product and the authorisation would have met the requirements of Article 3(b) and (d) had it been granted on the date of submission of the application, the protection conferred by a certificate in accordance with paragraph 1 shall extend to the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be.]

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

(a) the acts comprise:

(i) the making of a product, or a medicinal product containing that product, for the purpose of export to countries outside the United Kingdom, the Isle of Man and the Member States of the European Union; or

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

(iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the United Kingdom, in order to place that product, or a medicinal product containing that product, on the market of the United Kingdom, the Isle of Man or one or more Member States of the European Union after the expiry of the corresponding certificate; or

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

(b) the maker, through appropriate and documented means, notifies the comptroller, and informs the certificate holder, of the information listed in paragraph 5 of this Article no later than three months before the start date of the making in the United Kingdom, or no later than three months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by that certificate, whichever is the earlier;

(c) if the information listed in paragraph 5 of this Article changes, the maker notifies the comptroller 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 countries outside the United Kingdom, the Isle of Man and the Member States of the European Union, the maker ensures that the words 'UK export' are affixed so as to be sufficiently clear and visible to the naked eye to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 9 of this Article.

3. The exception referred to in paragraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the United Kingdom merely for the purpose of repackaging, re-exporting or storing.

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

5. The information to be provided by the maker for the purposes of point (b) of paragraph 2 shall be as follows:

(a) the name and address of the maker;

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

(d) the number of the certificate; and

(e) for medicinal products to be exported to countries outside the United Kingdom, the Isle of Man and the Member States of the European Union, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each country of export, as soon as it is publicly available.

6. For the purposes of notification to the comptroller under points (b) and (c) of paragraph 2, the maker shall use the standard [prescribed] form ~~for notification prescribed by rules made under section 123 of the Patents Act 1977( )~~.

7. Failure to comply with the requirements of point (e) of paragraph 5 with regard to a country outside the United Kingdom, the Isle of Man and the Member States of the European Union shall only affect exports to that country, and those exports shall, therefore, not benefit from the exception.

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

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

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

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

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

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

11. The Secretary of State may by regulations make further provision as to the manner and form (including design and colour) of affixing the words "UK export" to the outer packaging of the product, or the medicinal product containing that product, referred to in paragraph 2(a)(i) of this Article, and, where feasible, to its immediate packaging.

12. Those regulations are to be made by statutory instrument which is subject to annulment pursuant to a resolution of either House of Parliament.

Article 6

Entitlement to the certificate

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

Article 7

Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the [UK, GB or NI] authorisation referred to in Article 3(b) [and (d)] to place the product on the market as a medicinal product was granted. [Where more than one such authorisation is granted before the application for a certificate is lodged, the application shall be lodged within six months of the date of grant of the earliest of such authorisations.]

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

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

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

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

Article 8

Content of the application for a certificate

1. The application for a certificate shall contain:

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

(i) the name and address of the applicant;

(ii) if ~~he~~ [the applicant] has appointed a representative, the name and address of the representative;

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

~~(iv) the number and date of the UK authorisation as referred to in Article 3(b); and~~

[(iv) the number and date of the UK, GB or NI authorisation, or where there is more than one such authorisation, of each authorisation as referred to in Article 3(b) and (d);]

(v) the number and date of the earliest of any EEA authorisation, the granting of which predates the granting of the UK[, GB or NI] authorisation [as referred to in Article 3(b) and (d)];

b) a copy of the UK[, GB or NI authorisation or, where there is more than one such authorisation, of each] authorisation to place the product on the market, as referred to in Article 3(b) [and (d)], 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, Article 14 of Directive 2001/82/EC, Part 2 to Schedule 8 of the Human Medicines Regulations 2012 or Part 1 of Schedule 1 to the Veterinary Medicines Regulations 2013;

(c) where the product is the subject of one or more EEA authorisations granted prior to the UK[, GB or NI] authorisation referred to in Article 3(b) [and (d)], the applicant must provide in relation to the earliest of any such EEA authorisations—

(i) information regarding the identity of the product thus authorised;

(ii) information regarding the legal provision under which the authorisation procedure took place; and

(iii) a copy of the notice publishing the authorisation in the appropriate official publication;

(d) where the application for a certificate 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 regulation 58A(2)(a) of the Human Medicines Regulations 2012;

[(ii) details of the territory in respect of which the statement referred to in sub-paragraph (i) has been made.]

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

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

Article 9

Lodging of an application for a certificate

1. An application for a certificate (or an extension of the duration of a certificate) shall be lodged with the comptroller.

2. Notification of the application for a certificate shall be published by the comptroller. The notification shall contain at least the following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

~~(d) the number and date of the UK authorisation and the product identified in that authorisation;~~

[(d) the number and date of the UK, GB or NI authorisation or, where there is more than one such authorisation, each authorisation provided under Article 8(1)(b), the product identified in the authorisation or each authorisation and the territory in respect of which the authorisation has been granted or has effect as if granted;]

(e) where there are authorisations granted in the EEA before ~~the UK authorisation~~ [any UK, GB or NI authorisation provided under Article 8(1)(b)], the number and date of the earliest EEA authorisation;

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

[(g) where an indication is given in accordance with sub-paragraph (f), details of the territory in respect of which an extension has been applied for.]

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

Article 10

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

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the comptroller shall grant the certificate.

2. The comptroller shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation or any prescribed fee is not paid.

3. Where the application for a certificate does not meet the conditions laid down in Article 8 or the prescribed fee relating to the application has not been paid, the comptroller shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

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

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

~~7. References in this Article to a "prescribed fee" are to a fee prescribed under section 123 of the Patents Act 1977~~

Article 11

Publication

1. Notification of the fact that a certificate has been granted shall be published by the comptroller. The notification shall contain at least the following information:

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

(b) the number of the basic patent;

(c) the title of the invention;

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

[(d) the number and date of the UK, GB or NI authorisation or, where there is more than one such authorisation, of each authorisation provided under Article 8(1)(b) or Article 13A(1), the product identified in the authorisation and the territory in respect of which the authorisation has been granted or has effect as if granted;]

(e) where there are EEA authorisations granted before ~~the UK authorisation~~ [any UK, GB or NI authorisation provided under Article 8(1)(b)], the number and date of the earliest EEA authorisation;

(f) the duration of the certificate.

2. Notification of the fact that the application for a certificate has been rejected shall be published by the comptroller. The notification shall contain at least the information listed in Article 9(2).

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

[3a. Where notification is made that an extension of the duration of a certificate has been granted, the notification shall specify the territory in respect of which the extension has been granted.]

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

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the area comprising the European Economic Area and the United Kingdom, reduced by a period of five years.

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

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where regulation 58A of the Human Medicines Regulations 2012 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

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

[5. An extension of the duration of a certificate in accordance with paragraph 3 in respect of—

(a) a UK authorisation shall apply in the United Kingdom,

(b) a GB authorisation shall apply in only England and Wales and Scotland, and

(c) a NI authorisation shall apply in Northern Ireland only,

on condition that the territorial protection conferred by the extension does not exceed that conferred by the certificate.]

[Article 13A

Authorisation granted after submission of an application for a certificate

1. Where after the date of submission of an application under Article 7(1) or (2), but before the grant of a certificate under Article 10(1) in relation to a NI authorisation, a valid UK or GB authorisation is granted which, at its date of grant, is the first authorisation to place the product on the market as a medicinal product in the territory of the United Kingdom or the territory of England and Wales and Scotland as the case may be, the applicant shall notify the comptroller of the grant of the authorisation, within six months of its date of grant and before the certificate takes effect under Article 13(1), and provide the details set out in Article 8(1)(a)(iv) and (b) on the prescribed form.

2. Where after the submission of an application under Article 7(1) or (2), but before the grant of a certificate under Article 10(1) in relation to a UK or GB authorisation, a valid NI authorisation is granted which, at its date of grant, is the first authorisation to place the product on the market as a medicinal product in the

territory of Northern Ireland, the applicant shall notify the comptroller of the grant of the authorisation, within six months of its date of grant and before the certificate takes effect under Article 13(1), and provide the details set out in Article 8(1)(a)(iv) and (b) on the prescribed form.

3. Where after the grant of a certificate under Article 10(1) in relation to a UK or GB authorisation, but before expiry of the basic patent, a valid NI authorisation is granted which, at its date of grant, is the first authorisation to place the product on the market as a medicinal product in the territory of Northern Ireland, the certificate holder shall notify the comptroller of the grant of the authorisation, within six months of its date of grant and before the certificate takes effect under Article 13(1), and provide the details set out in Article 8(1)(a)(iv) and (b) on the prescribed form.

4. Where after the grant of a certificate under Article 10(1) in relation to a NI authorisation, but before expiry of the basic patent, a valid UK or GB authorisation is granted which, at its date of grant, is the first authorisation to place the product on the market as a medicinal product in the territory of the United Kingdom or the territory of England and Wales and Scotland as the case may be, the certificate holder shall notify the comptroller of the grant of the NI authorisation, within six months of its date of grant and before the certificate takes effect under Article 13(1), and provide the details set out in Article 8(1)(a)(iv) and (b) on the prescribed form.

5. If the applicant or the certificate holder fails to notify the comptroller of the grant of an authorisation in accordance with paragraph 1, 2, 3 or 4 the protection conferred by a certificate granted under Article 10 shall not extend to any additional territory covered by that authorisation.

6. On receipt of a notification under any of paragraphs 1 to 4, the comptroller shall publish:

(a) the number and date of the authorisation,

(b) the product identified in that authorisation, and

(c) the territory in respect of which the authorisation has been granted or has effect as if granted.

Article 13B

Extension of the duration of a certificate

1. Where after an application for an extension of the duration of a certificate in accordance with Article 7(3) or (4) has been made in respect of a GB authorisation, but before the application is granted, an application is also made for an extension of the duration of the certificate in respect of a NI authorisation in accordance with Article 7(3) or (4), the duration of the certificate, if the extension is granted, shall be extended in accordance with Article 13(3) and (5) to include the territory of Northern Ireland.

2. Where after an application for an extension of the duration of a certificate in accordance with Article 7(3) or (4) has been made in respect of a NI authorisation, but before the application is granted, an application is also made for an extension of the duration of the certificate in respect of a GB authorisation in accordance with Article 7(3) or (4), the duration of the certificate shall be extended in accordance with Article 13(3) and (5) to include the territory of England and Wales and Scotland.

3. Where after the grant in accordance with Article 10(6) of an application for an extension of the duration of a certificate in respect of a GB authorisation, an application is made, in accordance with Article 7(4), for an extension of the certificate in respect of an NI authorisation, the duration of the certificate shall be extended in accordance with Article 13(3) and (5) to include the territory of Northern Ireland.

4. Where after the grant, in accordance with Article 10(6) of an application for an extension of the duration of a certificate in respect of a NI authorisation, an application is made, in accordance with Article 7(4), for an extension of the certificate in relation to a GB authorisation, the duration of the certificate shall be extended in accordance with Article 13(3) and (5) to include the territory of England and Wales and Scotland.]

Article 14

Expiry of the certificate

1. The certificate shall lapse:

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

(b) if the certificate holder surrenders it;

(c) if the prescribed annual fee is not paid in time; [or]

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of ~~the appropriate authorisation or~~ [all UK, GB and NI] authorisations to place on the market. The comptroller may decide on the lapse of the certificate either of the comptroller's own motion or at the request of a third party.

~~2. In this Article, "prescribed" means prescribed by rules made under section 123 of the Patents Act 1977.~~

[2. Where a UK authorisation is withdrawn and replaced simultaneously with a GB authorisation and a NI authorisation, the certificate granted in respect of the UK authorisation shall not lapse.

3. Where a UK, GB or NI authorisation is withdrawn, but one or more such authorisations remain valid, the protection conferred by the certificate shall, as from the date of withdrawal, no longer extend to the territory covered by the authorisation withdrawn but shall continue in respect of the territory covered by any remaining authorisation.]

Article 15

Invalidity of the certificate

1. The certificate shall be invalid if:

(a) it was granted contrary to the provisions of Article 3;

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

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

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the comptroller or the court.

Article 16

Revocation of an extension of the duration

1. The extension of the duration may be revoked if it was granted contrary to the provisions of regulation 58A(3) of the Human Medicines Regulations 2012.

2. Any person may submit an application for revocation of the extension of the duration to the comptroller or the court.

Article 17

Notification of lapse or invalidity

1. If the certificate lapses in accordance with point (b), (c) or (d) of Article 14[(1)], or is invalid in accordance with Article 15, [or if the territorial extent of the certificate is limited in accordance with Article 14(3),] notification thereof shall be published by the comptroller.

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

Article 19

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable to the corresponding basic patent (as modified by section 128B of, and Schedule 4A to, the Patents Act 1977) shall apply to the certificate.

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

Article 22

Repeal

Regulation (EEC) No 1768/92, as amended by the acts listed in Annex I, is repealed.

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

Article 23

Entry into force

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

ANNEX I

REPEALED REGULATION WITH LIST OF ITS SUCCESSIVE AMENDMENTS

(referred to in Article 22)

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

ANNEX II

CORRELATION TABLE

Regulation (EEC) No 1768/92	**This Regulation**
—	Recital 1
Recital 1	Recital 2
Recital 2	Recital 3

Recital 3	Recital 4
Recital 4	Recital 5
Recital 5	Recital 6
Recital 6	Recital 7
Recital 7	Recital 8
Recital 8	Recital 9
Recital 9	Recital 10
Recital 10	—
Recital 11	—
Recital 12	—
Recital 13	Recital 11
Article 1	Article 1
Article 2	Article 2
Article 3, introductory wording	Article 3, introductory wording
Article 3, point (a)	Article 3, point (a)
Article 3, point (b), first sentence	Article 3, point (b)
Article 3, point (b), second sentence	—
Article 3, points (c) and (d)	Article 3, points (c) and (d)
Articles 4 to 7	Articles 4 to 7
Article 8(1)	Article 8(1)
Article 8(1a)	Article 8(2)
Article 8(1b)	Article 8(3)
Article 8(2)	Article 8(4)
Articles 9 to 12	Articles 9 to 12
Article 13(1), (2) and (3)	Article 13(1), (2) and (3)
Articles 14 and 15	Articles 14 and 15
Article 15a	Article 16
Articles 16, 17 and 18	Articles 17, 18 and 19
Article 19	—

Article 19a, introductory wording	Article 20, introductory wording
Article 19a, point (a), points (i) and (ii)	Article 20, point (b), introductory wording, points (i) and (ii)
Article 19a, point (b)	Article 20, point (c)
Article 19a, point (c)	Article 20, point (d)
Article 19a, point (d)	Article 20, point (e)
Article 19a, point (e)	Article 20, point (f)
Article 19a, point (f)	Article 20, point (g)
Article 19a, point (g)	Article 20, point (h)
Article 19a, point (h)	Article 20, point (i)
Article 19a, point (i)	Article 20, point (k)
Article 19a, point (j)	Article 20, point (l)
Article 19a, point (k)	Article 20, point (a)
Article 19a, point (l)	Article 20, point (j)
Article 20	Article 21
Article 21	—
Article 22	Article 13(4)
—	Article 22
Article 23	Article 23
—	Annex I
—	Annex II