

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

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

(Codified version)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ⁽³⁾ has been substantially amended several times ⁽⁴⁾. In the interests of clarity and rationality the said Regulation should be codified.

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

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

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

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

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

(8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

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

⁽¹⁾ OJ C 77, 31.3.2009, p. 42.

⁽²⁾ Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 6 April 2009.

⁽³⁾ OJ L 182, 2.7.1992, p. 1.

⁽⁴⁾ See Annex I.

- (10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.
- (11) Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,

HAVE ADOPTED THIS REGULATION:

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 Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use ⁽¹⁾.

Article 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽²⁾ or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ⁽³⁾ may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Article 3

Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

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 authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

Article 5

Effects of the certificate

Subject to the provisions of Article 4, 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.

Article 6

Entitlement to the certificate

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

⁽¹⁾ OJ L 378, 27.12.2006, p. 1.

⁽²⁾ OJ L 311, 28.11.2001, p. 67.

⁽³⁾ OJ L 311, 28.11.2001, p. 1.

*Article 7***Application for a certificate**

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

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within 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 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 first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

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

(c) if the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication;

(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 in Article 36(1) of Regulation (EC) No 1901/2006;

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

2. Where an application for a certificate is pending, an application for an 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.

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

Article 9

Lodging of an application for a certificate

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

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

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

- (a) the name and address of the applicant;
- (b) the number of the basic patent;
- (c) the title of the invention;
- (d) the number and date of the authorisation to place the product on the market, referred to in Article 3(b), and the product identified in that authorisation;
- (e) where relevant, the number and date of the first authorisation to place the product on the market in the Community;
- (f) where applicable, an indication that the application includes an application for an extension of the duration.

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

Article 10

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

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

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, 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.

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

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

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

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

Article 11

Publication

1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least the following information:

- (a) the name and address of the holder of the certificate;
- (b) the number of the basic patent;
- (c) the title of the invention;
- (d) the number and date of the authorisation to place the product on the market referred to in Article 3(b) and the product identified in that authorisation;
- (e) where relevant, the number and date of the first authorisation to place the product on the market in the Community;
- (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 authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).

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

Article 12

Annual fees

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

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 Community, 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 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.

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.

Article 14

Expiry of the certificate

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 annual fee laid down in accordance with Article 12 is not paid in time;

- (d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC. The authority referred to in Article 9(1) of this Regulation may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate

1. The certificate shall be invalid 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 body responsible under national law for the revocation of the corresponding basic patent.

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 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 body responsible under national law for the revocation of the corresponding basic patent.

Article 17

Notification of lapse or invalidity

1. If the certificate lapses in accordance with point (b), (c) or (d) of Article 14, or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9(1).
2. If the extension of the duration is revoked in accordance with Article 16, notification thereof shall be published by the authority referred to in Article 9(1).

*Article 18***Appeals**

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

*Article 19***Procedure**

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

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

*Article 20***Additional provisions relating to the enlargement of the Community**

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

- (a) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate was lodged within six months from 1 January 2007;
- (b) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained:
 - (i) in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;
 - (ii) in the Community not earlier than six months prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;
- (c) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Estonia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six months provided for in the Patents Act of October 1999;
- (d) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Cyprus prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;
- (e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Latvia prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;
- (f) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004;
- (g) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate was lodged within six months from 1 May 2004;
- (h) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Malta prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;

- (i) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate was lodged within six months starting no later than 1 May 2004;
- (j) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 January 2007;
- (k) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovenia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004, including in cases where the period provided for in Article 7(1) has expired;
- (l) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date.

Article 21

Transitional provisions

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

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

2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to 1 May 2004 and the national legislation of Romania prior to 1 January 2007.

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*.

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

Done at Strasbourg, 6 May 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
J. KOHOUT

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)

Regulation (EEC) No 1768/92	This Regulation
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