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)

I[F1] Article 5

Effects of the certificate

1 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.

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 third countries; or

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

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

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

b the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) in the Member State in which that making is to take place, and informs the certificate holder, of the information listed in paragraph 5 of this Article no later than three months before the start date of the making in that Member State, 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 a certificate, whichever is the earlier;

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

d in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -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 9 of this Article and, if applicable, with Article 12(2).

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 Union 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;

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

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

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

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

7 Failure to comply with the requirements of point (e) of paragraph 5 with regard to a third country shall only affect exports to that country, and those exports shall, therefore, not benefit from the exception.

8 The maker shall ensure that medicinal products made pursuant to point (a)(i) of paragraph 2 do not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161[(1)].

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.**]**

Textual Amendments

F1 Substituted by Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (Text with EEA relevance).

(1) **[**[F1]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).**]**

Textual Amendments

F1 Substituted by Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (Text with EEA relevance).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 469/2009 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Art. 5(1) words inserted by S.I. 2020/1471 Sch. para. 13(a)
- Art. 5(3) words substituted by S.I. 2020/1050 Sch. para. 3(f)
- Art. 5(6) word inserted by S.I. 2020/1471 Sch. para. 13(c)(i)
- Art. 5(6) word substituted by S.I. 2020/1050 Sch. para. 3(h)(i)
- Art. 5(6) words omitted by S.I. 2020/1471 Sch. para. 13(c)(ii)
- Art. 5(6) words substituted by S.I. 2020/1050 Sch. para. 3(h)(ii)
- Art. 5(7) word omitted by S.I. 2020/1050 Sch. para. 3(i)(i)
- Art. 5(7) words inserted by S.I. 2020/1050 Sch. para. 3(i)(ii)
- Art. 5(8) omitted by S.I. 2020/1050 Sch. para. 3(j)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Annex -1 omitted by S.I. 2020/1050 Sch. para. 6
- Annex -1a omitted by S.I. 2020/1050 Sch. para. 6
- Signature words omitted by S.I. 2019/801 reg. 68
- Art. 1(e) words substituted by S.I. 2019/801 reg. 52(2)
- Art. 1(f)-(j) inserted by S.I. 2019/801 reg. 52(3)
- Art. 1(g) substituted in earlier amending provision S.I. 2019/801, reg. 52(3) by S.I. 2020/1050 reg. 34(a)
- Art. 1(j) words inserted in earlier amending provision S.I. 2019/801, reg. 52(3) by S.I. 2020/1050 reg. 34(b)
- Art. 1(k) words renumbered as Art. 1(k) by S.I. 2020/1050 Sch. para. 2(d)
- Art. 1(l) inserted by S.I. 2020/1471 Sch. para. 11(b)
- Art. 1(ja)(jb) inserted by S.I. 2020/1471 Sch. para. 11(a)
- Art. 1A inserted by S.I. 2019/801 reg. 53 (This amendment not applied to legislation.gov.uk. Reg. 53 omitted immediately before IP completion day by virtue S.I. 2020/1050, regs. 1(2), 35)
- Art. 2(b) words inserted in earlier amending provision S.I. 2019/801, reg. 54 by S.I. 2020/1471 reg. 3(4)
- Art. 3(b) words inserted in earlier amending provision S.I. 2019/801, reg. 54 by S.I. 2020/1471 reg. 3(5)(a)
- Art. 3(d) words inserted in earlier amending provision S.I. 2019/801, reg. 54 by S.I. 2020/1471 reg. 3(5)(b)(i)
- Art. 3(d) words inserted in earlier amending provision S.I. 2019/801, reg. 54 by S.I. 2020/1471 reg. 3(5)(b)(ii)
- Art. 5(1a)(1b) inserted by S.I. 2020/1471 Sch. para. 13(b)
- Art. 5(2)(a)(i) word omitted by S.I. 2020/1050 Sch. para. 3(a)(i)(aa)
- Art. 5(2)(a)(i) words inserted by S.I. 2020/1050 Sch. para. 3(a)(i)(bb)
- Art. 5(2)(a)(iii) words substituted by S.I. 2020/1050 Sch. para. 3(a)(iii)(aa)
- Art. 5(2)(a)(iii) words substituted by S.I. 2020/1050 Sch. para. 3(a)(iii)(bb)
- Art. 5(2)(a)(ii) words substituted by S.I. 2020/1050 Sch. para. 3(a)(ii)
- Art. 5(2)(a)(iv) words substituted by S.I. 2020/1050 Sch. para. 3(a)(iv)
- Art. 5(2)(b) word substituted by S.I. 2020/1050 Sch. para. 3(b)(i)
- Art. 5(2)(b) word substituted by S.I. 2020/1050 Sch. para. 3(b)(iii)
- Art. 5(2)(b) words substituted by S.I. 2020/1050 Sch. para. 3(b)(ii)
- Art. 5(2)(c) word substituted by S.I. 2020/1050 Sch. para. 3(c)
- Art. 5(2)(d) word omitted by S.I. 2020/1050 Sch. para. 3(d)(i)
- Art. 5(2)(d) words inserted by S.I. 2020/1050 Sch. para. 3(d)(ii)

- Art. 5(2)(d) words substituted by S.I. 2020/1050 Sch. para. 3(d)(iii)
- Art. 5(2)(e) words omitted by S.I. 2020/1050 Sch. para. 3(e)
- Art. 5(5)(c) omitted by S.I. 2020/1050 Sch. para. 3(g)(i)
- Art. 5(5)(d) word omitted by S.I. 2020/1050 Sch. para. 3(g)(ii)
- Art. 5(5)(e) word omitted by S.I. 2020/1050 Sch. para. 3(g)(iii)(aa)
- Art. 5(5)(e) words inserted by S.I. 2020/1050 Sch. para. 3(g)(iii)(bb)
- Art. 5(11)(12) inserted by S.I. 2020/1050 Sch. para. 3(k)
- Art. 8(1)(a)(v) words inserted in earlier amending provision S.I. 2019/801, reg. 55(2) by S.I. 2020/1471 reg. 3(6)(b)(i)
- Art. 8(1)(a)(v) words inserted in earlier amending provision S.I. 2019/801, reg. 55(2) by S.I. 2020/1471 reg. 3(6)(b)(ii)
- Art. 8(1)(a)(ii) words substituted by S.I. 2020/1471 Sch. para. 15(a)
- Art. 8(1)(a)(iv)(v) substituted for Art. 8(1)(a)(iv) by S.I. 2019/801 reg. 55(2)
- Art. 8(1)(a)(iv) substituted in earlier amending provision S.I. 2019/801, reg. 55(2) by S.I. 2020/1471 reg. 3(6)(a)
- Art. 8(1)(b)(c) substituted for Art. 8(1)(b)(c) by S.I. 2019/801 reg. 55(3)
- Art. 8(1)(b) words inserted in earlier amending provision S.I. 2019/801, reg. 55(3) by S.I. 2020/1471 reg. 3(7)(a)(i)
- Art. 8(1)(b) words inserted in earlier amending provision S.I. 2019/801, reg. 55(3) by S.I. 2020/1471 reg. 3(7)(a)(ii)
- Art. 8(1)(c) words inserted in earlier amending provision S.I. 2019/801, reg. 55(3) by S.I. 2020/1471 reg. 3(7)(b)(i)
- Art. 8(1)(c) words inserted in earlier amending provision S.I. 2019/801, reg. 55(3) by S.I. 2020/1471 reg. 3(7)(b)(ii)
- Art. 8(1)(d)(i) words substituted by S.I. 2019/801 reg. 55(4)(a)
- Art. 8(1)(d)(ii) inserted by S.I. 2020/1471 Sch. para. 15(b)
- Art. 8(1)(d)(ii) omitted by S.I. 2019/801 reg. 55(4)(b)
- art. 9(2)(d)(e) substituted by S.I. 2019/801 reg. 56(4)
- Art. 9(2)(d) substituted in earlier amending provision S.I. 2019/801, reg. 56(4) by S.I. 2020/1471 reg. 3(8)(a)
- Art. 9(2)(e) words substituted in earlier amending provision S.I. 2019/801, reg. 56(4) by S.I. 2020/1471 reg. 3(8)(b)
- Art. 9(2)(g) inserted by S.I. 2020/1471 Sch. para. 16
- Art. 10(7) inserted by S.I. 2019/801 reg. 57(7)
- Art. 10(7) omitted in earlier amending provision S.I. 2019/801, reg. 57(7) by S.I. 2020/1471 reg. 3(9)
- Art. 11(1)(d) substituted by virtue of S.I. 2019/801, reg. 58(3)(a) (as amended) by S.I. 2020/1471 reg. 3(10)(a)
- Art. 11(1)(d) word inserted by S.I. 2019/801 reg. 58(3)(a)
- Art. 11(1)(e) substituted by S.I. 2019/801 reg. 58(3)(b)
- Art. 11(1)(e) words substituted in earlier amending provision S.I. 2019/801, reg. 58(3)(b) by S.I. 2020/1471 reg. 3(10)(b)
- Art. 11(3a) inserted by S.I. 2020/1471 Sch. para. 17
- Art. 13(5) inserted by S.I. 2020/1471 Sch. para. 18
- Art. 13A13B inserted by S.I. 2020/1471 Sch. para. 19
- Art. 14(1) Art. 14 renumbered as Art. 14(1) by S.I. 2019/801 reg. 61(2)
- Art. 14(1)(c)(d) substituted by S.I. 2019/801 reg. 61(3)
- Art. 14(1)(c) word inserted in earlier amending provision S.I. 2019/801, reg. 61(3) by S.I. 2020/1471 reg. 3(11)(a)
- Art. 14(1)(d) words substituted in earlier amending provision S.I. 2019/801, reg. 61(3) by S.I. 2020/1471 reg. 3(11)(b)
- Art. 14(2) inserted by S.I. 2019/801 reg. 61(4)
- Art. 14(2)(3) inserted by S.I. 2020/1471 Sch. para. 20