

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)

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	Signature

ANNEX I

ANNEX -I

Logo

This logo shall appear in black and in such a...

ANNEX -Ia

Standard form for notification pursuant to points (b) and (c)...

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. (See end of Document for details) [View outstanding changes](#)*

ANNEX II

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. (See end of Document for details) View outstanding changes*

- (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.

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. 1 word omitted by [S.I. 2020/1050 Sch. para. 2\(b\)](#)
- Art. 1 words inserted by [S.I. 2020/1050 Sch. para. 2\(c\)](#)
- Art. 1 words inserted in earlier amending provision [S.I. 2019/801, reg. 52\(3\)](#) by [S.I. 2020/1471 reg. 3\(3\)](#)
- Art. 1 words substituted by [S.I. 2020/1050 Sch. para. 2\(a\)](#)
- Art. 2 substituted by [S.I. 2019/801 reg. 54](#)
- Art. 3 substituted by [S.I. 2019/801 reg. 54](#)
- Art. 4 words inserted by [S.I. 2020/1471 Sch. para. 12\(a\)](#)
- Art. 4 words inserted by [S.I. 2020/1471 Sch. para. 12\(b\)](#)
- 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\(j\)](#)
- Art. 7(1) words inserted by [S.I. 2020/1471 Sch. para. 14\(a\)](#)
- Art. 7(1) words inserted by [S.I. 2020/1471 Sch. para. 14\(b\)](#)
- Art. 7(1) words inserted by [S.I. 2020/1471 Sch. para. 14\(c\)](#)
- Art. 8(4) omitted by [S.I. 2019/801 reg. 55\(5\)](#)
- Art. 9(1) substituted by [S.I. 2019/801 reg. 56\(2\)](#)
- Art. 9(2) words substituted by [S.I. 2019/801 reg. 56\(3\)](#)
- Art. 10(1)-(3) words substituted by [S.I. 2019/801 reg. 57\(2\)](#)
- Art. 10(2) words inserted by [S.I. 2019/801 reg. 57\(3\)](#)
- Art. 10(3) words inserted by [S.I. 2019/801 reg. 57\(4\)](#)
- Art. 10(4) words substituted by [S.I. 2019/801 reg. 57\(5\)](#)
- Art. 10(5) omitted by [S.I. 2019/801 reg. 57\(6\)](#)
- Art. 11(1) words substituted by [S.I. 2019/801 reg. 58\(2\)](#)
- Art. 11(2) words substituted by [S.I. 2019/801 reg. 58\(2\)](#)
- Art. 11(4) word substituted by [S.I. 2020/1050 Sch. para. 4\(a\)](#)
- Art. 11(4) words substituted by [S.I. 2020/1050 Sch. para. 4\(b\)](#)
- Art. 12 omitted by [S.I. 2019/801 reg. 59](#)
- Art. 13(1) words substituted by [S.I. 2019/801 reg. 60\(2\)](#)
- Art. 13(3) words substituted by [S.I. 2019/801 reg. 60\(3\)](#)
- Art. 15(2) word omitted in earlier amending provision [S.I. 2019/801, reg. 62](#) by [S.I. 2020/1050 reg. 36](#)
- Art. 15(2) words substituted by [S.I. 2019/801 reg. 62](#)
- Art. 16(1) words substituted by [S.I. 2019/801 reg. 63\(2\)](#)
- Art. 16(2) words substituted by [S.I. 2019/801 reg. 63\(3\)](#)
- Art. 17 words substituted by [S.I. 2019/801 reg. 64](#)
- Art. 17(1) word inserted by [S.I. 2020/1471 Sch. para. 21\(a\)](#)
- Art. 17(1) words inserted by [S.I. 2020/1471 Sch. para. 21\(b\)](#)
- Art. 18 omitted by [S.I. 2019/801 reg. 65](#)
- Art. 19(1) substituted by [S.I. 2019/801 reg. 66](#)
- Art. 20 omitted by [S.I. 2019/801 reg. 67](#)
- Art. 21 omitted by [S.I. 2019/801 reg. 67](#)
- Art. 21a omitted by [S.I. 2020/1050 Sch. para. 5](#)

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](#)