Draft Regulations laid before Parliament under paragraph 8F(1) of Part 1A of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No. XXX

EXITING THE EUROPEAN UNION

PATENTS

The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020

Made - - - - ***

Coming into force in accordance with regulation 1(2)

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8C(1)(**a**) of the European Union (Withdrawal) Act 2018(**b**).

In accordance with paragraph 8F(1) of Part 1A of Schedule 7(**c**) to the European Union (Withdrawal) Act 2018, a draft of this instrument has been laid before Parliament and approved by resolution of each House of Parliament.

Citation and commencement

1.—(1) These Regulations may be cited as the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020.

(2) This regulation and regulations 2 and 3 come into force immediately before IP completion day and regulations 4 to 7 come into force on IP completion day.

Amendments to the Patents (Amendment) (EU Exit) Regulations 2019

2.—(1) Part 6 of the Patents (Amendment) (EU Exit) Regulations 2019(**d**) (supplementary protection certificates for plant protection products – amendments to Regulation (EC) No 1610/96) is amended as follows.

(2) In the following paragraphs, a reference to an Article or a paragraph is to that of Regulation (EC) 1610/96(**e**) and a reference to a regulation is to a regulation of the Patents (Amendment) (EU Exit) Regulations 2019.

(3) In Article 1 (definitions), as amended by regulation 20(3), omit paragraph 15.

(**a**) Section 8C was inserted by section 21 of the European Union (Withdrawal Agreement) Act 2020 c. 1.
(**b**) 2018 c. 16 as amended by the European Union (Withdrawal Agreement) Act 2020 c. 1.
(**c**) Paragraph 8F of Part 1A of Schedule 7 was inserted by section 41(4) of, and paragraph 5 of Schedule 5 to, the European Union (Withdrawal Agreement) Act 2020 c. 1.
(**d**) S.I. 2019/801, as amended by S.I. 2020/1050.
(**e**) EUR 1996/1610, as amended by S.I. 2019/801 and S.I. 2020/1050. This is a reference to the retained version of Regulation (EC) 1610/96. That retained version is online at http://www.legislation.gov.uk/eur/1996/1610/contents

(4) In Article 2(b) (scope), as inserted by regulation 22, for "UK", substitute "GB or NI".

(5) In Article 3(1) (conditions for obtaining a certificate), as amended by regulation 23—

(a) in sub-paragraph (b), for "UK", substitute "GB or NI".

(b) in sub-paragraph (d)—

(i) omit "UK";

(ii) insert at the end "in the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be".

(6) In Article 8 (content of the application for a certificate), as amended by regulation 24(2)—

(a) in paragraph 1(a)(iv)—

(i) for "UK authorization", substitute "GB or NI authorisation or both GB and NI authorisations";

(ii) after "3(1)(b)", insert "and (d)";

(b) in paragraph (1)(a)(v)—

(i) for "UK", substitute "GB or NI";

(ii) after "authorization", in the second place it occurs, insert "as referred to in Article 3(1)(b) and (d)".

(7) In Article 8, as amended by regulation 24(3)—

(a) in paragraph (b)—

(i) for "UK authorization", substitute "GB or NI authorisation or both GB and NI authorisations";

(ii) after "3(1)(b)", insert "and (d)";

(b) in paragraph (c)—

(i) for "UK", substitute "GB or NI ";

(ii) after "3(1)(b)", insert "and (d)".

(8) In Article 9 (lodging of an application for a certificate), as amended by regulation 25(4)—

(a) for paragraph 2(d), substitute—

"(d) the number and date of the GB or NI authorisation or both a GB and a NI authorisation provided under Article 8(1)(b), the product identified in the authorisation and the territory in respect of which the authorisation has been granted or has effect as if granted";

(b) in paragraph (e), for "the UK authorisation", substitute "any GB or NI authorisation provided under Article 8(1)(b)".

(9) In Article 10 (grant of the certificate or rejection of the application), as amended by regulation 26, omit paragraph 6.

(10) In regulation 27(3), omit sub-paragraph (a) of that regulation.

(11) In Article 11(1)(e), as amended by regulation 27(3), for "the UK authorization", substitute "any authorisation provided under Article 8(1)(b)".

(12) In Article 14(1) (expiry of the certificate), as amended by regulation 30—

(a) at the end of paragraph (c), insert "or";

(b) in paragraph (d), for "the appropriate authorization or" substitute "all".

(13) In regulation 30, omit paragraph 4 of that regulation.

3.—(1) Part 8 of the Patents (Amendment) EU Exit Regulations 2019 (supplementary protection certificates for medicinal products – amendments to Regulation (EC) No 469/2009) is amended as follows.

(2) In the following paragraphs, a reference to an Article or a paragraph is to that of Regulation (EC) 469/2009(**a**) and a reference to a regulation is to a regulation of the Patents (Amendment) (EU Exit) Regulations 2019.

(3) In Article 1, in the definition of "UK authorisation" in paragraph (j) inserted by regulation 52(3), after "market", insert "in the United Kingdom".

(4) In Article 2 (scope), in paragraph (b), as inserted by regulation 54, after "UK", insert ", GB or NI".

(5) In Article 3 (conditions for obtaining a certificate), as inserted by regulation 54—

(a) in sub-paragraph (b), after "UK", insert ", GB or NI";

(b) in sub-paragraph (d)—

(i) after "UK", insert ", GB or NI";

(ii) insert at the end "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".

(6) In Article 8 (content of the application for a certificate), as amended by regulation 55(2)—

(a) for paragraph 1(a)(iv), substitute—

"(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);";

(b) in paragraph (1)(a)(v)—

(i) after "UK", insert ", GB or NI";

(ii) after "authorisation", in the second place it occurs, insert "as referred to in Article 3(b) and (d)".

(7) In Article 8(1), as amended by regulation 55(3)—

(a) in paragraph (b)—

(i) after "UK", insert ", GB or NI authorisation or, where there is more than one such authorisation, of each";

(ii) after "3(b)" insert "and (d)";

(b) in paragraph (c)—

(i) after "UK", insert ", GB or NI";

(ii) after "3(b)" insert "and (d)".

(8) In Article 9 (lodging of an application for a certificate), as amended by regulation 56(4)—

(a) for paragraph 2(d), substitute—

"(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";

(b) in paragraph (e), for "the UK authorisation", substitute "any UK, GB or NI authorisation provided under Article 8(1)(b)".

(9) In Article 10 (grant of the certificate or rejection of the application for a certificate) as amended by regulation 57, omit paragraph 7.

(10) In Article 11 (publication), as amended by regulation 58(3)—

(a) for paragraph (d), insert—

"(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)

(**a**) EUR 2009/469, as amended by S.I. 2019/801 and S.I. 2020/xxx. This is a reference to the retained version of Regulation EUR 2009/469. That retained version is online at http://www.legislation.gov.uk/eur/2009/469/contents

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;";

(b) in paragraph (e), for "the UK authorisation", substitute "any UK, GB or NI authorisation provided under Article 8(1)(b)".

(11) In Article 14(1) (expiry of the certificate), as amended by regulation 61—

(a) at the end of sub-paragraph (c), insert "or";

(b) in sub-paragraph (d), for "the appropriate authorisation or" substitute "all UK, GB and NI".

(12) In regulation 61, omit paragraph (4) of that regulation.

Amendments to Regulation (EC) 1610/96

4. Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products is amended as set out in Part 1 of the Schedule.

Amendments to Regulation (EC) 469/2009

5. Regulation (EC) 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products is amended as set out in Part 2 of the Schedule.

Amendment to the Patents Rules 2007

6. In the Patents Rules 2007(**a**), in rule 116A, as inserted by regulation 42 of the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020(**b**)—

(a) the existing text is numbered as paragraph 1;

(b) after paragraph 1, insert—

"(2) Notifications under Article 13A of Regulation (EC) 1610/96 and Article 13A of Regulation (EC) 469/2009 must be made on Patents Form SP6.".

Transitional provisions

7.—(1) Where an application for an authorisation is made before IP completion day under—

(a) Directive 2001/83/EC(**c**) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,

(b) Directive 2001/82/EC(**d**) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, or

(c) Regulation (EC) No 1107/2009(**e**) of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market,

but the authorisation is not granted until on or after IP completion day, these Regulations apply to any application for a supplementary protection certificate made in respect of the authorisation.

(2) These Regulations apply to an application for a supplementary protection certificate made on or after IP completion day in respect of a UK authorisation granted or having effect as if granted before IP completion day.

(**a**) S.I. 2007/3291, as by S.I. 2011/2052; there are other amending instruments but none are relevant.
(**b**) S.I. 2020/1050.
(**c**) OJ L311, 28.11.2001, p.67.
(**d**) OJ L311, 28.11.2001, p.1.
(**e**) OJ L309, 24.11.2009, p.1.

(3) The former regulations continue to apply to an application for a supplementary protection certificate made, but not determined, before IP completion day in respect of a UK authorisation granted or having effect as if granted before IP completion day.

(4) Where on or after IP completion day a UK authorisation granted or having effect before IP completion day is withdrawn and replaced with a GB authorisation and a NI authorisation, any certificate granted in respect of the UK authorisation does not lapse.

(5) For the purposes of paragraphs (2), (3) and (4), "UK authorisation" means an authorisation granted or having effect as if granted under—

(a) 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,

(b) 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, or

(c) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market,

and references to a UK, GB or NI authorisation, where they occur in these Regulations (but not including this regulation) are to be treated as meaning a "UK authorisation" as defined in this paragraph.

(6) For the purposes of paragraphs (4) and (7)—

(a) "GB authorisation" has the meaning ascribed to it in paragraph 15 of Article 1 of Regulation (EC) 1610/96, as amended by regulation 4 of, and paragraph 2 of the Schedule to, these Regulations, and paragraph (ja) of Article 1 of Regulation (EC) 469/2009 as amended by regulation 5 of, and paragraph 9 of the Schedule to, these Regulations; and

(b) "NI authorisation" has the meaning ascribed to it in paragraph 16 of Article 1 of Regulation (EC) 1610/96, as amended by regulation 4 of, and paragraph 2 of the Schedule to, these Regulations and paragraph (jb) of Article 1 of Regulation (EC) 469/2009 as amended by regulation 5 of, and paragraph 9 of the Schedule to, these Regulations.

(7) For the purposes of paragraph (4), where the former regulations apply to a "UK authorisation" as defined in paragraph (5), the UK authorisation includes a GB authorisation and NI authorisation in combination.

(8) For the purposes of this regulation, "former regulations" means Regulation (EC) 1610/96 and Regulation (EC) 469/2009 without the amendments made by these Regulations but including the amendments made by the Patents (Amendment) (EU Exit) Regulations 2019 and the Intellectual Property (Amendment etc.) (EU Exit Regulations) 2020.

Name
Title
Date Department for Business, Energy and Industrial Strategy

SCHEDULE

Regulations 4 and 5

Amendments to Regulations on Supplementary Protection Certificates

PART 1

Amendments to Regulation (EC) 1610/96

Interpretation of Part 1

1. In this Part, a reference to an Article or a paragraph is to that of Regulation (EC) 1610/96.

Article 1: definitions

2. In Article 1, after the definition of "patent" in paragraph 14, as inserted by regulation 20(3) of the Patents (Amendment) (EU Exit) Regulations 2019, insert—

"**15.** "GB authorisation" means an authorisation, to place a plant protection product on the market in England and Wales and Scotland, granted or having effect as if granted under Regulation (EC) 1107/2009(**a**);

16. "NI authorisation" means an authorisation, to place a plant protection product on the market in Northern Ireland, granted or having effect as if granted in accordance with Regulation (EC) 1107/2009 as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement;

17. "prescribed" means prescribed by rules under section 123 of the Patents Act 1977.".

Article 4: subject matter of protection

3. In Article 4—

(a) for "authorizations", substitute "GB or NI authorisation or both GB and NI authorisations";

(b) after "authorized", insert "in the United Kingdom".

Article 5: effects of the certificate

4. In Article 5—

(a) the existing text is numbered as paragraph 1;

(b) in paragraph 1, after "Article 4", insert "and paragraphs 2 and 3";

(c) after paragraph 1, insert—

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

(a) is the first authorisation for the product in the territory in accordance with Article 3(1)(b) and (d), and

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

3. Where after the submission of an application for a certificate in accordance with Article 7 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

(**a**) EUR 2009/1107. This is a reference to the retained version of Regulation (EC) 2009/1107. That retained version is online at http://www.legislation.gov.uk/eur/2009/1107/contents.

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.".

Article 7: application for a certificate

5. In Article 7, paragraph (1)—

(a) before "authorization", insert "GB or NI";

(b) after "3(1)(b)", insert "and (d)";

(c) after the end of the sentence, insert—

"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.".

Article 11: publication

6. In Article 11, for paragraph (d), substitute:

"(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;";

Article 13A: authorisation granted after submission of an application for a certificate

7. After Article 13, insert—

"*Article 13A*

Authorisation granted after submission of an application for a certificate

1. Where after the submission of an application under Article 7(1), but before the grant of a certificate under Article 10(1) in relation to a 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 plant protection product in the territory of Northern Ireland, the applicant 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.

2. Where after the submission of an application under Article 7(1), but before the grant of a certificate under Article 10(1) in relation to a NI authorisation, a valid GB authorisation is granted which, at its date of grant, is the first authorisation to place the product on the market as a plant protection product in the territory of England and Wales and Scotland, the applicant shall notify the comptroller of the grant of the GB 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 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 plant protection product in the territory of Northern Ireland, the certificate holder shall notify the comptroller 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.

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 GB authorisation is granted which, at its date of grant, is the first authorisation to place the product on the market as a plant protection product in the territory of England and Wales and Scotland, the certificate

holder shall notify the comptroller of the grant of the GB 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 certificate holder fails to notify the comptroller of the grant of an authorisation in accordance with any of paragraphs 1 to 4, the protection conferred by a certificate granted under Article 10(1) 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 relevant territory in respect of which the authorisation has been granted or has effect as if granted."

Article 14: expiry of the certificate

8. In Article 14, after paragraph 1, insert—

"**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.

4. For the purposes of paragraphs 2 and 3, "UK authorisation" means an authorisation to place a plant protection product on the market in the United Kingdom, granted or having effect as if granted, prior to IP completion day, under Regulation (EC) 1107/2009(**a**) of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.".

Article 16: notification of lapse or invalidity

9. In Article 16—

(a) after "Article 14", insert "(1)";

(b) after "Article 15," insert "or if the territorial extent of the certificate is limited in accordance with Article 14(3),".

PART 2

Amendments to Regulation (EC) 469/2009

Interpretation of Part 2

10. In this Part, a reference to an Article or a paragraph is to that of Regulation (EC) 469/2009.

Article 1: definitions

11. In Article 1—

(**a**) OJ L309, 24.11.2009, p.1.

(a) after the definition of "UK authorisation" in paragraph (j), as inserted by regulation 52(3) of the Patents (Amendment) (EU Exit) Regulations 2019 and amended by regulation 3(3) of these Regulations, insert—

"(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(**a**); or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013(**b**) 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;";

(b) After paragraph (k), insert—

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

Article 4: subject matter of protection

12. In Article 4—

(a) before "authorisation", insert "UK, GB or NI";

(b) after "authorised", insert "in the United Kingdom".

Article 5: effects of the certificate

13. In Article 5—

(a) In paragraph 1, after "Article 4", insert "and paragraphs 1a and 1b";

(b) after paragraph 1, insert—

"**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.";

(c) in paragraph 6—

(i) insert "prescribed" before "form";

(ii) omit the words from "for" to the end.

(**a**) S.I. 2012/1916. Regulation 58A is inserted by S.I. 2019/775, reg. 64.
(**b**) S.I. 2013/2033.
(**c**) 1977 c. 37; section 123 was last amended by the Patents Act 2004 c. 16.

Article 7: application for a certificate

14. In Article 7, paragraph (1)—

(a) before "authorisation", insert "UK, GB or NI";

(b) after "3(b)", insert "and (d)";

(c) after the end of the sentence, insert—

"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.".

Article 8: content of the application for a certificate

15. In Article 8—

(a) in paragraph 1(a)(ii), for "he", substitute "the applicant";

(b) in paragraph 1(d), after sub-paragraph (i), insert—

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

Article 9: lodging of an application for a certificate

16. In Article 9, paragraph 2, after sub-paragraph (f), insert—

"(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.".

Article 11: publication

17. In Article 11, after paragraph 3, insert—

"**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.".

Article 13: duration of the certificate

18. In Article 13, after paragraph 4 insert—

"**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

19. After Article 13, insert—

"*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 a 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.".

20. In Article 14, after paragraph (1), insert—

"**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.".

21. In Article 17, in paragraph (1)—

(a) after "Article 14", insert "(1)";

(b) after "Article 15," insert "or if the territorial extent of the certificate is limited in accordance with Article 14(3),".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations deal with matters arising out of the Protocol on Ireland/Northern Ireland ("Protocol") in the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 19 October 2019. Union law which applies to the United Kingdom in respect of Northern Ireland under Article 5(4) of the Protocol includes the following EU Directives and Regulations on medicinal products and plant protection products in paragraphs 20 and 24 of Annex 2 to the Protocol:

— 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 (OJ L311, 28.11.2001, p.1);

— 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 L311, 28.11.2001, p.67);

— Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (OJ L378, 27.12.2006, p.1);

— Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L309, 24.11.2009, p.1).

The grant of a supplementary protection certificate in relation to these products may be dependent on marketing authorisations provided under these Directives and Regulations.

Regulations 2 and 3 amend the Patents (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/801) in relation to supplementary protection certificates for medicinal products and plant protection products. The Patents (Amendment) (EU Exit) Regulations 2019 come into force on IP

completion day. The changes made by these Regulations to the Patents (Amendment) EU Exit Regulations come into effect prior to IP completion day (Regulation 1(2)).

Regulation 4 and Part 1 of the Schedule amend Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

Regulation 5 and Part 2 of the Schedule amend 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.

Regulation 6 amends the Patents Rules 2007 (S.I. 2007/3291) to provide for a new form to notify the comptroller of any authorisations granted after submission of an application for a supplementary protection certificate. This change is effected by amending regulation 42 of the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1050).

Regulation 7 provides for transitional provisions.

Regulations 4 to 7 come into force on IP completion day.

Paragraph 2 of Part 1 of the Schedule amends Article 1 of Regulation (EC) No 1610/96 and paragraph 11 of Part 2 of the Schedule amends Article 1 of Regulation (EC) No 469/2009 to introduce new definitions of "GB authorisation" and "NI authorisation". A "GB authorisation" covers the territory of Great Britain (England and Wales and Scotland) and a NI authorisation covers the territory of Northern Ireland.

Paragraph 4 of Part 1 of the Schedule amends Article 5 of Regulation (EC) No 1610/96 and paragraph 13 of Part 2 of the Schedule amends Article 5 of Regulation (EC) No 469/2009 to provide that the protection conferred by a certificate extends only to the territory in respect of which a valid marketing authorisation has been granted.

Paragraph 7 of Part 1 of the Schedule inserts a new Article 13A in Regulation (EC) No 1610/96 and paragraph 19 of Part 2 of the Schedule inserts a new Article 13A in Regulation (EC) No 469/2009. These provisions deal with the situation where a marketing authorisation has been applied for or granted in respect of e.g. Great Britain (GB), and a later authorisation is applied for or granted for Northern Ireland (NI). In these circumstances, the comptroller must be notified of the later authorisation so that this may be published.

Paragraph 19 of Part 2 of the Schedule also inserts a new Article 13B in Regulation (EC) No 469/2009 to deal with extensions of the duration of certificates granted in respect of paediatric uses of medicinal products. An extension of the duration of a certificate in respect of a GB authorisation is extended, in certain circumstances, to include Northern Ireland and vice versa the extension of the duration of a certificate in respect of a NI authorisation is extended to include Great Britain.

The changes made by these Regulations supplement other changes made to UK law in relation to supplementary protection certificates by Parts 6 and 8 of the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 which come into force on IP completion day.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public and voluntary sectors is foreseen.

An explanatory memorandum is available alongside this instrument on the Legislation UK website at www.legislation.gov.uk.

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£6.90

UK202010141011 10/2020 19585

http://www.legislation.gov.uk/id/ukdsi/2020/9780348213645

ISBN 978-0-34-821364-5

9 780348 213645