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(**1**);

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).

(**1**) 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.

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 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(**2**) 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),".

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

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) 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(**3**); or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013(**4**) 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(**5**).".

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

(**3**) S.I. 2012/1916. Regulation 58A is inserted by S.I. 2019/775, reg. 64.
(**4**) S.I. 2013/2033.
(**5**) 1977 c. 37; section 123 was last amended by the Patents Act 2004 c. 16.

(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.

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),".