
STATUTORY INSTRUMENTS

2020 No. 1471

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

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

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(1) 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)—

(1) EUR 2009/469, as amended by S.I. 2019/801 and S.I. 2020/1050. 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>

- (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) 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.