STATUTORY INSTRUMENTS

2024 No. 1075

PATENTS

The Supplementary Protection Certificates (Amendments Relating to the Windsor Framework) Regulations 2024

Made - - - -	*28th October 2024*
Laid before Parliament	*31st October 2024*
Coming into force - -	*1st January 2025*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8C(1) and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Supplementary Protection Certificates (Amendments Relating to the Windsor Framework) Regulations 2024 and come into force on 1st January 2025.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of Regulation (EC) No 469/2009

2. 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(**b**) is amended in accordance with regulations 3 to 10.

Amendment to Article 1

3. In Article 1 (definitions)—

(a) after point (g) insert—

"(ga)"Windsor Framework" means the part of the EU withdrawal agreement known as the Windsor Framework by virtue of Joint Declaration No. 1/2023 of 24 March 2023 made between the European Union and the United Kingdom in the Joint Committee established by the EU withdrawal agreement;";

(**a**) 2018 c. 16. Section 8C was inserted by section 21 of the European Union (Withdrawal Agreement) Act 2020 (c. 1) and was amended by section 55(3) of the United Kingdom Internal Market Act 2020 (c. 27); paragraph 21 of Schedule 7 was amended by paragraph 8 of Schedule 2 to the Retained EU Law (Revocation and Reform) Act 2023 (c. 28), and paragraphs 38 and 53 of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020.

(**b**) EUR 469/2009 was amended by S.I. 2019/801, S.I. 2020/1050 and S.I. 2020/1471.

(b) in point (h), for "Directive 2001/83/EC or Directive 2001/82/EC" substitute "Directive 2001/83/EC(**a**), Directive 2001/82/EC(**b**) or Regulation (EU) No 2019/6(**c**)";

(c) after point (ja) insert—

"(jaa)"transitioned-UK authorisation" means a GB authorisation for a medicinal product in force immediately before 1 January 2025 which, pursuant to Schedule 33B to the Human Medicines Regulations 2012(**d**) , has effect on and after that date as a UK authorisation;";

(d) in point (jb), substitute for "or Directive 2001/82/EC" to the end with ", Directive 2001/82/EC or Regulation (EU) No 2019/6 as they have effect by virtue of the Windsor Framework;";

(e) after point (jb) insert—

"(jc) "former NI authorisation" means a NI authorisation for a medicinal product for human use that is prohibited from being placed on the market in Northern Ireland by Article 4(1) of Regulation (EU) No 2023/1182(**e**) of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC;".

Amendment to Article 5

4. In Article 5 (effects of the certificate)—

(a) in paragraph 1b, insert "UK," before "GB or NI authorisation";

(b) in paragraph 1b, after "shall extend to" insert "the territory of the United Kingdom,";

(c) after paragraph 1b, insert—

"1c. Where after the submission of an application for a certificate in accordance with Article 7(1) or (2) in respect of a GB authorisation and before the certificate takes effect in accordance with Article 13(1), that authorisation becomes a transitioned-UK authorisation, the protection conferred by a certificate in accordance with paragraph 1 shall extend to the territory of England and Wales, Scotland and Northern Ireland.".

Amendment to Article 7

5. In Article 7 (application for a certificate), after paragraph 2 insert—

"2a. Where an application for a certificate lodged before 1 January 2025 in accordance with paragraph 1 or 2 contains a NI authorisation granted pursuant to Regulation (EU) No 2019/6, that authorisation shall be treated on and after 1 January 2025 as if it were a valid NI authorisation for the purpose of Article 3(b) and (d) at the time the application was lodged.".

Amendment to Article 8

6. In Article 8 (content of the application for a certificate), in paragraph 1(b), after "Article 14 of Directive 2001/82/EC," insert "Article 35 of Regulation (EU) No 2019/6,".

(**a**) OJ L311, 28.11.2001, p. 67.
(**b**) OJ L311, 28.11.2001, p. 1.
(**c**) OJ L4, 7.1. 2019, p. 43.
(**d**) S.I. 2012/1916. Schedule 33B was inserted by regulation 146 of S.I. 2024/832.
(**e**) OJ L157, 20.6.2023, p. 1.

Amendment to Article 13A

7. In Article 13A (authorisation granted after submission of an application for a certificate), in paragraph 4, after "the comptroller of the grant of the" omit "NI".

Amendment to Article 13B

8. In Article 13B (extension of the duration of a certificate)—

(a) in paragraph 2, after "the certificate in respect of a" insert "UK or";

(b) after paragraph 2 insert—

"2a. 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, the GB authorisation becomes a transitioned-UK authorisation, 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 England and Wales, Scotland and Northern Ireland.";

(c) in paragraph (4) after "the certificate in relation to a" insert "UK or";

(d) after paragraph (4) insert—

"5. 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, the authorisation becomes a transitioned-UK 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, Scotland and Northern Ireland.".

Insertion of Article 19A

9. After Article 19 (procedure) insert—

"Article 19A

Transitional provisions

Annex III contains transitional provisions concerning the implementation of the Windsor Framework that apply to applications and certificates in relation to medicinal products for human use.".

Insertion of Annex III

10. After Annex II (correlation table) insert—

"ANNEX III

Article 19A

Transitional provisions in relation to applications and certificates for medicinal products for human use concerning the implementation of the Windsor Framework

New applications

1.—(1) This paragraph applies to applications lodged under Article 7 on or after 1 January 2025.

(2) For applications lodged in accordance with Article 7(1)—

(a) a NI authorisation under Article 3(b) and Article 3(d) includes a former NI authorisation granted as a NI authorisation during the period commencing on 1 July 2024 and ending on 31 December 2024; and

(b) any certificate granted under Article 10 in relation to a former NI authorisation of the type referred to in sub-paragraph (a) shall only have effect if a UK authorisation for the same product has been notified to the comptroller in accordance with Article 13A or a copy of such a UK authorisation is contained in the application.

(3) For applications lodged in accordance with Article 7(2), a former NI authorisation that was granted as a NI authorisation for the product specified in the application shall not be considered, for the purpose of Article 3(d), to be the first authorisation to place the product on the market as a medicinal product in the territory of the United Kingdom.

Certificates in effect in Northern Ireland

2. Where a certificate granted solely on the basis of a NI authorisation was in effect before 1 January 2025, and a GB authorisation for the same product—

(a) was granted on or after the date on which the certificate took effect but before 1 January 2025,

(b) is in effect on or before 31 December 2024 but a valid notification has not been made to the comptroller in accordance with Article 13A, and

(c) becomes a transitioned-UK authorisation,

the certificate shall continue, on and after 1 January 2025, to have effect solely in the territory of Northern Ireland on the basis of the transitioned-UK authorisation for that product.

Notification of authorisations

3. For the purposes of Article 13A, the applicant or the certificate holder—

(a) shall notify the comptroller of the grant of a NI authorisation granted before 1 January 2025 in accordance with paragraphs 2 and 3 of Article 13A notwithstanding that it becomes a former NI authorisation on and after 1 January 2025;

(b) shall not be required to notify the comptroller where before the certificate takes effect a GB authorisation becomes a transitioned-UK authorisation.

Lapse or withdrawal of certificates

4. For the purposes of Article 14—

(a) where a NI authorisation in respect of a product becomes a former NI authorisation and a GB authorisation for the same product becomes a transitioned-UK authorisation, a certificate based upon the NI and GB authorisations before 1 January 2025 shall not lapse;

(b) any reference to the withdrawal of a NI authorisation under Article 14 includes a case where a NI authorisation becomes a former NI authorisation, and in such a case, the authorisation shall be treated as being withdrawn in relation to the territory of Northern Ireland on 1 January 2025.

Paediatric extensions

5.—(1) This paragraph applies to—

(a) an application for an extension of the duration of a certificate, lodged in accordance with Article 7(3) or (4) but not determined before 1 January 2025; and

(b) an extension of the duration of a certificate granted in accordance with Article 10—

(i) before 1 January 2025; or

(ii) on or after 1 January 2025, pursuant to an application falling within sub-paragraph (a).

(2) Where this paragraph applies, regulation 58A(3) of the Human Medicines Regulations 2012(**a**) applies without the amendments made by The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024.

(3) This paragraph applies only to an application for an extension of the duration of a certificate which has not been determined before 1 January 2025 where—

(a) the condition set out in sub-paragraph (a) or (b) in regulation 58A(3) of the Human Medicines Regulations 2012 was met before 1 January 2025; or

(b) the period for lodging an application for an extension of the duration of a certificate in Article 7(4) expires before 1 January 2025.".

Peter Kyle
Secretary of State
28th October 2024 Department for Science, Innovation and Technology

(**a**) S.I. 2012/1916.

EXPLANATORY NOTE

(This note is not part of the Regulations)

Overview

In accordance with Decision No 1/2023 of the Joint Committee established by the Agreement of the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 24 March 2023 laying down arrangements relating to the Windsor Framework, the United Kingdom ("UK") and the European Union ("EU") agreed to the Windsor Framework in March 2023. The Northern Ireland Protocol as amended is referred to as the Windsor Framework.

The Windsor Framework includes new arrangements in relation to the grant of marketing authorisations for medicinal products for human use in Great Britain and Northern Ireland ("NI") to come into effect on 1st January 2025.

These Regulations 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 ("the SPC Regulation") to reflect those new arrangements.

These Regulations also amend the SPC Regulation to reflect new arrangements under the Windsor Framework for the grant of marketing authorisations for medicinal products for veterinary use under Regulation (EU) No 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ("the EU Veterinary Medicines Regulation").

Medicinal products for human use

Regulation 3 amends Article 1 to insert a new definition of "transitioned-UK authorisation" to reflect a GB authorisation in force immediately before 1st January 2025 that becomes a UK authorisation from that date. Regulation 3 also inserts a new definition of "former NI authorisation" to reflect a NI authorisation for a medicinal product for human use which is prohibited by Regulation (EU) No 2023/1182 from being placed on the market in NI.

Regulation 4 amends Article 5(1b) to insert a reference to a UK authorisation such that for an application previously filed on the basis of a NI authorisation, a later UK authorisation (whether a transitioned-UK authorisation or a new UK-wide authorisation) may trigger the extension of the territorial scope of the SPC to cover the remainder of the UK (subject to notification under Article 13A).

Regulation 4 also inserts a new paragraph (1c) into Article 5, and along with Regulation 8, addresses the territorial scope of the certificate or its paediatric extension, respectively, extending to the whole of the UK where, in respect of an application involving a GB authorisation, that authorisation becomes a transitioned-UK authorisation.

Regulation 10 inserts a new Annex III which sets out transitional provisions applying to applications and certificates relating to medicinal products for human use.

Medicinal products for veterinary use

Regulation 3 amends the definitions of "EEA" and "NI authorisation" in Article 1(h) and (jb), respectively, to insert a reference to the EU Veterinary Medicines Regulation and also inserts a reference to the Windsor Framework in Article 1(jb).

Regulation 5 inserts a new paragraph (2a) in Article 7 to recognise that, for the purpose of assessing applications after 1st January 2025, applications submitted before 1st January 2025 based on authorisations granted under the EU Veterinary Medicines Regulation have a valid legal basis.

Regulation 6 amends Article 8 to insert a reference to the EU Veterinary Medicines Regulation in relation to the content of an application for a certificate based on an authorisation for veterinary medicines under that legislation.

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

Details of the Windsor Framework are available at www.gov.uk/government/publications/the-windsor-framework or from the Cabinet Office, 100 Parliament Street, London, SW1A 2BQ

A copy of this instrument and the Explanatory Memorandum are available from the Intellectual Property Office at Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ. The Explanatory Memorandum is also available alongside this instrument on the Legislation UK website at www.legislation.gov.uk.

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