STATUTORY INSTRUMENTS

2020 No. 1471

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

Transitional provisions

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

(a) Directive 2001/83/EC(**1**) 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(**2**) 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(**3**) 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.

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(4) Where on or after IP completion day a UK authorisation granted or having effect before IP completion day is withdrawn and replaced with a GB authorisation and a NI authorisation, any certificate granted in respect of the UK authorisation does not lapse.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

(**1**) OJ L311, 28.11.2001, p.67.
(**2**) OJ L311, 28.11.2001, p.1.
(**3**) OJ L309, 24.11.2009, p.1.

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.