STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 6

Amendment of Part 6 (certification of homoeopathic products)

Amendment of regulation 102 (regulation-making power to amend regulation 102(4) to (6))

98. In regulation 102 (application of Part 6), at the end insert—

[[F1]"(7) The Secretary of State may make regulations in respect of Great Britain to amend paragraphs (4) to (6).

(8) The Secretary of State may only exercise the power in paragraph (7) if the Secretary of State considers that it is necessary to do so because of new scientific evidence."**]**.

Textual Amendments

F1 Words in reg. 98 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 75**

Commencement Information

I1 Reg. 98 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 103 (application for certificate of registration)

99.—(1) Regulation 103 is amended as follows.

[[F2](1A) After paragraph (1) insert—

"(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part ("under the unfettered access route") and grant a COR(GB) only where—

(a) there is already in place, or will be at the time the COR(GB) is granted, a certificate of registration in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in paragraph (5B), and

(c) the registrable homoeopathic medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A certificate of registration must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that certificate of registration being "in force" is limited to that territory.".**]**

(2) In paragraph (4), **[**F3for "must be established in the European Union" substitute—

, where it is applying for—

(a) a COR(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a COR(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a COR(UK), must be established in the United Kingdom.**]**

[F4(2A) After paragraph (5) insert—

"(5A) The application must include a statement indicating whether the certificate sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.

(5B) The applicant for the grant of a COR(GB) under the unfettered access route must provide—

(a) the application form submitted in connection with the granting of the COR(NI) which authorises the sale or supply of the product in Northern Ireland;

(b) a copy of all material submitted in support of the application for the COR(NI) which authorises the sale or supply of the product in Northern Ireland; and

(c) a copy of the COR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in paragraph (8) which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.".**]**

(3) In paragraph (8)—

(a) in sub-paragraph (e)—

(i) omit "or another EEA State", and

(ii) for "that EEA State" substitute " a country other than the United Kingdom "; and

(b) in sub-paragraph (f), for "another member state" substitute " a country other than the United Kingdom ".

Textual Amendments

F2 Reg. 99(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(a)**

F3 Words in reg. 99(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(b)**

F4 Reg. 99(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(c)**

Commencement Information

I2 Reg. 99 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 104 (consideration of application)

[[F5]**100.**—(1) Regulation 104 (consideration of application) is amended as follows.

(2) After paragraph (6) insert—

"(7) In the case of an application under the unfettered access route, the licensing authority may grant a COR(GB) (notwithstanding paragraph (3)) where the licensing authority—

(a) has considered the application under the unfettered access route and the accompanying material,

(b) is satisfied that the applicant has complied with the application requirements, and

(c) is satisfied that the conditions in regulation 103(1A) will continue to be met.

(8) The licensing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.".**]**

Textual Amendments

F5 Reg. 100 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 77**

Commencement Information

I3 Reg. 100 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 108 (application for renewal of certificate)

101. In regulation 108(2), **[**[F6]for "must be established in the European Union" substitute—

", where it is applying for renewal of—

(a) a COR(NI) and originally granted—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a COR(GB) and originally granted—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) in the whole United Kingdom, must be established in the United Kingdom."**]**

Textual Amendments

F6 Words in reg. 101 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 78**

Commencement Information

I4 Reg. 101 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F7Amendment of regulation 109 (failure to place on the market etc.)

101A.—(1) Regulation 109 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after "in the United Kingdom" insert "(or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)".

(3) In paragraph (2) after "in the United Kingdom" insert "(or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)".**]**

Textual Amendments

F7 Reg. 101A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 79**

Commencement Information

I5 Reg. 101A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 110 (revocation, variation and suspension of certificate of registration)

102.—(1) Regulation 110 [M1] is amended as follows.

[[F8](2) In paragraph (7) for "established in the European Union" substitute—

"established in—

(a) the United Kingdom; or

(b) in relation to a COR(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.".**]**

[[F9](2A) After paragraph (8A) insert—

"(8B) Condition I is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.".**]**

(3) Omit paragraph (10).

Textual Amendments

F8 Reg. 102(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(a)**

F9 Reg. 102(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(b)**

Commencement Information

I6 Reg. 102 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 Regulation 110 was amended by S.I.2013/1855.

Omission of regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive)

103. Omit regulation 111.

Commencement Information

I7 Reg. 103 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 112 (withdrawal of homoeopathic medicinal product from the market)

104. In regulation 112(1), omit "or regulation 111(2)".

Commencement Information

I8 Reg. 104 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 113 (obligation to notify placing on the market etc)

105. In regulation 113(3A) [M2], omit "in accordance with article 123(2) of the 2001 Directive".

Commencement Information

I9 Reg. 105 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 Paragraph (3A) was inserted by S.I. 2013/2593.

Amendment of regulation 115 (obligation to provide information relating to safety etc)

106. In regulation 115(5)(a) for "which is not an EEA State" substitute " other than the United Kingdom ".

Commencement Information

I10 Reg. 106 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F10Amendment of regulation 116 (obligation in relation to product information)

107. For regulation 116(2), substitute—

"(2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product authorised by a COR(NI) or COR(UK)—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product authorised by a COR(GB), the UK web-portal established in accordance with regulation 203(1).".**]**

Textual Amendments

F10 Reg. 107 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 81**

Commencement Information

I11 Reg. 107 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, PART 6.