

SCHEDULES

SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 6

Amendment of Part 7 (amendment of Part 7 (Traditional Herbal Registrations))

82. In regulation 110 (amendment of regulation 125 (traditional herbal medicinal products)) for “125(5)(b)” to the end substitute—

“125(5) for sub-paragraph (b) substitute—

“(b) in relation to—

(i) a THR(NI) or THR(UK), the product has been in medicinal use in the European Union for a continuous period of at least 15 years;

(ii) a THR(GB), the product has been in medicinal use in the United Kingdom or a country included in the list published under regulation 125A(1) for a continuous period of at least 15 years.”.”.

Commencement Information

I1 Sch. 2 para. 82 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

83. In regulation 112 (insertion of new italic heading and regulation 126A (list of herbal substances, preparations and combinations for use in traditional herbal medicinal products)), in the inserted regulation 126A(1), after “traditional herbal medicinal products” insert “ for which a THR(GB) may be granted ”.

Commencement Information

I2 Sch. 2 para. 83 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

84. For regulation 113 (amendment of regulation 127 (application for grant of traditional herbal registration)) substitute—

“**113.**—(1) Regulation 127 (application for grant of traditional herbal registration) is amended as follows.

(2) 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 THR(GB) only where—

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- (a) there is already in place, or will be at the time the THR(GB) is granted, a traditional herbal registration in respect of the product authorising sale or supply in Northern Ireland,
 - (b) the applicant complies with the requirements in regulation 128(1A), and
 - (c) the traditional herbal medicinal product satisfies the definition of qualifying Northern Ireland goods.
- (1B) A traditional herbal 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 traditional herbal registration being “in force” is limited to that territory.”.
- (3) In paragraph (3) for “must be established in the European Union” substitute—
- “, where it is applying for—
- (a) a THR(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 THR (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 THR(UK), must be established in the United Kingdom.”.
- (4) After paragraph (4) insert—
- “(4A) The application must include a statement indicating whether the traditional herbal registration sought is for sale or supply of the product in—
- (a) the whole United Kingdom;
 - (b) Great Britain only; or
 - (c) Northern Ireland only.”.”.

Commencement Information

I3 Sch. 2 para. 84 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

85. For regulation 114 (amendment of regulation 128 (accompanying material)) substitute—

“**114.**—(1) Regulation 128 (accompanying material) is amended as follows.

(2) For paragraph (1) substitute—

“**128.**—(1) The applicant for the grant of a traditional herbal registration other than a THR(GB) under the unfettered access route must provide the material specified in Schedule 12 in relation to the product.

(1A) The applicant for the grant of a THR(GB) under the unfettered access route must provide—

- (a) the application form submitted in connection with the granting of the THR(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 THR(NI) which authorises the sale or supply of the product in Northern Ireland; and
- (c) a copy of the THR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in Schedule 12 which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.”.

(3) In paragraph (3), after “of the 2001 Directive” insert “ where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB) ”.”.

Commencement Information

I4 Sch. 2 para. 85 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

86. For regulation 115(3)(a) (amendment of Schedule 12 (material to accompany an application for a traditional herbal registration)) substitute—

“(a) after “Article 23 of Regulation [\(EC\) No 726/2004](#)” insert “ or regulation 202A, as the case may be ”.”.

Commencement Information

I5 Sch. 2 para. 86 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

87. In regulation 116 (amendment of regulation 130 (consideration of application))—

(a) in paragraph (3) for “for “Article” to the end substitute—

“for “is subject to” to the end substitute—

“(a) where the application is for a THR(NI) or THR(UK), is subject to Article 16c(4) of the 2001 Directive (procedure where product has been used in the European Union for less than 15 years);

(b) where the application is for a THR(GB), is subject to regulation 130A.”.”;

(b) in paragraph (4) for “for “list referred to” to the end substitute—

“after “of the 2001 Directive” insert “where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB) ”.”;

(c) for paragraph (5) substitute—

“(5) In paragraph (9), after “Where” insert “ , in relation to an application for a THR(NI) or THR(UK), ”.”;

(d) in paragraph (6) for “for “Article 16h(3)” to the end substitute—

“for “in Article 16h(3)” to the end substitute—

“(i) in Article 16h(3) of the 2001 Directive, where the application is for a THR(NI) or THR(UK);

(ii) in regulation 143A, where the application is for a THR(GB), that the authority thinks relevant to the application; or”.”;

(e) for paragraph (7) substitute—

“(7) In paragraph (12), after “This regulation does not apply where” insert “, in relation to an application for a THR(NI) or THR(UK), ”.”;

(f) after paragraph (7) insert—

“(8) After paragraph (13) insert—

“(14) In the case of an application under the unfettered access route, the licensing authority may grant a THR(GB) (notwithstanding paragraph (4)) 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 127(1A) will continue to be met.

(15) 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.”.”.

Commencement Information

I6 Sch. 2 para. 87 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

88. In regulation 117 (Insertion of regulation 130A (procedure where less than 15 years use of traditional herbal medicinal product)), in the inserted regulation 130A(1), for “traditional herbal registration” substitute “ THR(GB) (other than an application under the unfettered access route) ”.

Commencement Information

I7 Sch. 2 para. 88 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

89. In regulation 118 (amendment of regulation 133 (application for renewal of registration)) for “for “European Union”” to the end substitute—

“for “must be established in the European Union” substitute—

“, where it is applying for renewal of—

- (a) a THR(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 THR(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 THR(UK), must be established in the United Kingdom.”.”.

Commencement Information

18 Sch. 2 para. 89 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

90. After regulation 118 amendment of regulation 133 (amendment of regulation 133 (application for renewal of registration)) insert—

“Amendment of regulation 134 (failure to place on the market etc.)

118A.—(1) Regulation 134 (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 THR(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 THR(GB) granted after an application under the unfettered access route, in Great Britain) ”.”.

Commencement Information

19 Sch. 2 para. 90 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

91. In regulation 119 (amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration))—

(a) after paragraph (1) insert—

“(1A) For paragraph (6) substitute—

“(6) Condition E is that the holder of the registration has ceased to be established in—

(a) the United Kingdom; or

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

in accordance with the requirements of these Regulations.”.”;

(b) in paragraph (2), for “for “from states” to the end substitute “after “states other than EEA states” insert “ / countries other than approved countries for import ”.”;

(c) for paragraph (3) substitute—

“(3) In paragraph (8)(a) omit “other than the United Kingdom”.”;

(d) in paragraph (4) for “omit sub-paragraph” to the end substitute “ in sub-paragraph (b), at the beginning insert “in the case of a THR(NI) or THR(UK),”.”;

(e) after paragraph (4) insert—

“(4A) After paragraph (10A) insert—

“(10B) Condition K 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.”.”.

Commencement Information

110 Sch. 2 para. 91 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

92. In regulation 120(2) (amendment of regulation 136 (revocation by licensing authority: further provisions)) for “for “list referred to in” to the end substitute—

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“for “the list referred to in” to the end substitute—

- “(i) the list referred to in Article 16f(1) of the 2001 Directive, in the case of a THR(NI) or THR(UK);
- (ii) the list established under regulation 126A where the application is for a THR(GB); and”.

Commencement Information

I11 Sch. 2 para. 92 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

93. In regulation 123 (amendment of regulation 140 (withdrawal of traditional herbal medicinal product from the market) for “140(1)(a)” to the end substitute “140(1) for sub-paragraph (a) substitute—

“(a) under—

- (i) regulation 135 or 136, in the case of a THR(GB);
 - (ii) regulation 135 or 136 or Article 34(3) of the 2001 Directive, in the case of a THR(NI) or THR(UK),
- the licensing authority revokes or suspends the registration; or”.

Commencement Information

I12 Sch. 2 para. 93 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

94. In regulation 125 (amendment of regulation 142 (obligation to notify placing on the market etc)) for “Omit regulation 142(5C)” substitute “In regulation 142(5C), for “traditional herbal registration” substitute “ THR(NI) or THR(UK) ”.

Commencement Information

I13 Sch. 2 para. 94 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

95. In regulation 126 (insertion of new regulation 143A (establishment of herbal monographs)), in the inserted regulation 143A(1), after “traditional herbal medicinal products” insert “ to be placed on the market in Great Britain ”.

Commencement Information

I14 Sch. 2 para. 95 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

96. For regulation 127 (amendment of regulation 144 (obligation following new herbal monograph)) substitute—

“Substitution of regulation 144 (obligation following new herbal monograph)

127. For regulation 144 substitute—

“**144.**—(1) Paragraph (2) applies where a new herbal monograph of the kind referred to—

- (a) in the case of a THR (NI) or THR (UK), in Article 16h(3) of the 2001 Directive, or
 - (b) in the case of a THR (GB), in regulation 143A,
- is established.
- (2) Where this paragraph applies, the holder of the THR(GB), THR(NI) or THR(UK) to which the monograph relates must as soon as is reasonably practicable—
- (a) consider whether to modify the registration dossier; and
 - (b) notify any modification to the licensing authority.”.”.

Commencement Information

I15 Sch. 2 para. 96 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

97. For regulation 129 (amendment of regulation 146 (obligation in relation to product information)) substitute—

“**129.** For regulation 146(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 for sale or supply in Northern Ireland—
 - (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 for sale or supply in Great Britain only, the UK web-portal established in accordance with regulation 203(1).”.”.

Commencement Information

I16 Sch. 2 para. 97 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

98. In regulation 131 (amendment of regulation 149 (urgent safety restrictions)) substitute—

“**Substitution of regulation 149 (urgent safety restrictions)**

131. For regulation 149 substitute—

“**149.**—(1) The holder of a THR(NI) or a THR(UK) is guilty of an offence if the holder—

- (a) fails to inform the licensing authority or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008 that the holder has taken urgent safety restrictions on the holder's own initiative;
- (b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority or the European Commission under Article 22(2) of that Regulation; or
- (c) fails to submit an application for variation of the traditional herbal registration to the licensing authority or the European Commission in

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accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—

- (i) the taking under Article 22(1) or, as the case may be,
- (ii) the imposition under Article 22(2),

of that Regulation of an urgent safety restriction;

(2) The holder of a THR(GB) is guilty of an offence if the holder—

- (a) fails to inform the licensing authority in accordance with regulation 148A(1) that the holder has taken urgent safety restrictions on the holder's own initiative;
- (b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority in accordance with regulation 148A(2); or
- (c) fails to submit an application for variation of the traditional herbal registration to the licensing authority in accordance with regulation 148A(4) before the end of the period of 15 days beginning with the day after—
 - (i) the taking under regulation 148A(1), or
 - (ii) the imposition under regulation 148A(2),
 of an urgent safety restriction.”.”.

Commencement Information

I17 Sch. 2 para. 98 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

Changes to legislation:

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