DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 7

Amendment of Part 7 (Traditional Herbal Registrations)

Amendment of italic heading above regulation 125 (traditional herbal medicinal products)

108. For the italic heading "Application of Part", substitute "Interpretation and application of Part".

Insertion of regulation 124A (interpretation)

109. Before regulation 125 (traditional herbal medicinal products), insert—

"**Interpretation of this Part**

124A. In this Part, "relevant list" means—

(a) the list referred to in Article 16f(1) of the 2001 Directive, as that list may be amended from time to time; or

(b) if the licensing authority publishes a list under regulation 126A(1), that list.".

Amendment of regulation 125 (traditional herbal medicinal products)

110. In regulation 125(5)(b), for "European Union" substitute "United Kingdom or a country included in the list published under regulation 125A(1)".

Insertion of regulation 125A (list of approved countries for herbal medicinal products)

111. After regulation 125 insert—

"**List of approved countries for traditional use of a herbal medicinal product**

125A.—(1) The licensing authority may publish a list of countries for the purposes of regulation 125(5)(b) (condition D).

(2) In establishing the list under paragraph (1), the licensing authority may only include a country in that list if it is satisfied that—

(a) continuous use evidence in respect of that country can be sufficiently validated by the licensing authority; and

(b) the country has a level of pharmacovigilance that is equivalent to that in the United Kingdom to ensure that any safety issues in respect of the herbal medicinal product have been properly identified.

(3) The licensing authority must—

(a) review any list it publishes under paragraph (1) to determine if a country still satisfies the criteria for inclusion in the list specified in paragraph (2), and if it is not so satisfied, remove that country from the list; and

(b) undertake such a review at least every three years beginning with the date on which the country is included in that list.".

Insertion of new italic heading and regulation 126A (list of herbal substances, preparations and combinations for use in traditional herbal medicinal products)

112. After regulation 126 (addition of vitamins or minerals) insert—

"List of herbal substances, preparations and combinations for use in traditional herbal medicinal products

Licensing authority list as to herbal substances, preparations and combinations for use in traditional herbal medicinal products

126A.—(1) The licensing authority may establish, and publish a list of, herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.

(2) A list established under paragraph (1) must contain, with regard to each herbal substance—

(a) the indication;

(b) the specified strength and posology;

(c) the route of administration; and

(d) any other information necessary for the safe use of the herbal substance as a traditional medicinal product.

(3) The licensing authority may review and amend any list it publishes under paragraph (1) at such intervals as it considers appropriate.".

Amendment of regulation 127 (application for grant of traditional herbal registration)

113. In regulation 127(3), for "European Union" substitute "United Kingdom".

Amendment of regulation 128 (accompanying material)

114. In regulation 128(3), for "list referred to in Article 16f(1) of the 2001 Directive" substitute "relevant list".

Amendment of Schedule 12 (material to accompany an application for a traditional herbal registration)

115.—(1) Schedule 12 is amended as follows.

(2) In paragraphs 16 and 17, for "another member State or a third country" substitute "a country other than the United Kingdom".

(3) In paragraph 21—

(a) for "Article 23 of Regulation (EC) No 726/2004" substitute "regulation 202A";

(b) before "statement", insert "symbol and"; and

(c) before "This", insert "▼".

Amendment of regulation 130 (consideration of application)

116.—(1) Regulation 130 is amended as follows.

(2) In paragraph (6), insert "UK" before "marketing authorisation".

(3) In paragraph (7), for "Article" to the end substitute "regulation 130A.".

(4) In paragraph (8), for "list referred to in Article 16f(1) of the 2001 Directive" substitute "relevant list".

(5) Omit paragraph (9).

(6) In paragraph (10)(a) for "Article 16h(3) of the 2001 Directive" substitute "regulation 143A".

(7) Omit paragraphs (12) and (13).

Insertion of regulation 130A (procedure where less than 15 years use of traditional herbal medicinal product)

117. After regulation 130 (consideration of application) insert—

"**Procedure where less than 15 years use of traditional herbal medicinal product**

130A.—(1) Where an application for a traditional herbal registration has been made and the licensing authority considers that—

(a) the traditional herbal medicinal product does not satisfy regulation 125(5)(b) (Condition D); but

(b) otherwise satisfies the conditions in regulation 125,

the licensing authority may refer the matter to the appropriate committee for relevant advice, and the procedure in Part 3 of Schedule 11 applies (referral to the appropriate committee for traditional herbal registrations).

(2) In this regulation—

"appropriate committee" has the same meaning as in paragraph 2(4) of Schedule 11;

"relevant advice" means advice as to whether—

(a) the conditions in regulation 125, other than condition D, are met in relation to the application; and

(b) the licensing authority should exercise its powers under regulation 143A to establish a herbal monograph.".

Amendment of regulation 133 (application for renewal of registration)

118. In regulation 133(2), for "European Union" substitute "United Kingdom".

Amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration)

119.—(1) Regulation 135(**1**) is amended as follows.

(2) In paragraph (7)(b), for "from states other than EEA States" substitute "countries other than approved countries for import".

(3) Omit paragraph (8).

(4) In paragraph (9), omit sub-paragraph (b) (and the "and" immediately preceding it).

(**1**) Regulation 135 was amended by S.I. 2013/1855.

(5) Omit paragraph (11).

Amendment of regulation 136 (revocation by licensing authority: further provisions)

120.—(1) Regulation 136 is amended as follows.

(2) In paragraph (1)(a), for "list referred to in article 16f(1) of the 2001 Directive" substitute "relevant list".

(3) Omit paragraph (3).

Amendment of regulation 138 (suspension of use etc of traditional herbal medicinal product)

121. Omit regulation 138(10).

Omission of regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive)

122. Omit regulation 139.

Amendment of regulation 140 (withdrawal of traditional herbal medicinal product from the market)

123. In regulation 140(1)(a), for "regulation 135, 136, 139(2) or Article 34(3) of the 2001 Directive" substitute "regulation 135 or 136".

Amendment of regulation 141 (sale etc of suspended traditional herbal medicinal product)

124. In regulation 141(1), omit "or 139(2)".

Amendment of regulation 142 (obligation to notify placing on the market etc)

125. Omit regulation 142(5C)(**2**).

Insertion of new regulation 143A (establishment of herbal monographs)

126. After regulation 143 (obligation to take account of scientific or technical progress) insert—

"**Establishment of herbal monographs**

143A.—(1) The licensing authority may establish herbal monographs for herbal medicinal products and traditional herbal medicinal products.

(2) Subject to paragraph (3), the licensing authority must—

(a) consult the appropriate committee, within the meaning of paragraph 2(4) of Schedule 11, on a proposal to establish herbal monographs under paragraph (1); and

(b) take the advice of the appropriate committee into account in determining whether to proceed with that proposal.

(3) Where an application for a traditional herbal registration has been referred to the appropriate committee by the licensing authority under regulation 130A, the licensing authority must consider whether to exercise its powers under paragraph (1), taking into

(**2**) Regulation 142 was amended by S.I. 2013/2593.

account any relevant advice of the appropriate committee given under Part 3 of Schedule 11 in relation to that application.

(4) The licensing authority must publish a list of any herbal monographs established under this regulation.

(5) Until the licensing authority exercises the power under paragraph (1), the Community herbal monographs published from time to time under Article 16h(3) of the 2001 Directive continue to apply, and holders of a traditional herbal registration and the licensing authority must continue to take them into account in exercising any function or in relation to any obligation to which they are relevant under this Part.".

Amendment of regulation 144 (obligation following new herbal monograph)

127. In regulation 144, for "Article 16h(3) of the 2001 Directive" substitute "regulation 143A".

Amendment of regulation 145 (obligation to provide information relating to safety etc)

128. In regulation 145(5)(a), for "which is not an EEA State" substitute "other than the United Kingdom".

Amendment of regulation 146 (obligation in relation to product information)

129. In regulation 146(2), for "European" to the end substitute "the UK web-portal established in accordance with regulation 203(1)."

Insertion of regulation 148A (urgent safety restrictions)

130. After regulation 148 (obligation to ensure appropriate and continued supplies) insert—

"**Urgent safety restrictions**

148A.—(1) Where, in the event of a risk to public health, the holder of a traditional herbal registration takes urgent safety restrictions on its own initiative, it must inform the licensing authority immediately.

(2) If the licensing authority has not raised objections within 24 hours following receipt of that information, the urgent safety restrictions are deemed to be accepted by the licensing authority.

(3) In the event of a risk to public health, the licensing authority may impose urgent safety restrictions.

(4) Where an urgent safety restriction is taken by the holder of a traditional herbal registration, or imposed by the licensing authority, the holder must submit an application for variation of that registration in relation to that restriction within 15 days beginning with the date of the initiation of that restriction.".

Amendment of regulation 149 (urgent safety restrictions)

131.—(1) Regulation 149 is amended as follows.

(2) In the heading to regulation 149, at the end insert "**:** offences".

(3) In sub-paragraph (a), for "or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008" substitute "in accordance with regulation 148A(1)".

(4) In sub-paragraph (b), for "or the European Commission under Article 22(2) of that Regulation" substitute "in accordance with regulation 148A(2)".

(5) For sub-paragraph (c), substitute—

"(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.".