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DRAFT STATUTORY INSTRUMENTS

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**2019 No.**

**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—

“(7) The Ministers may by regulations amend paragraphs (4) to (6).

(8) The Ministers may only exercise the power in paragraph (7) if they consider that it is necessary to do so because of new scientific evidence.”.

**Amendment of regulation 103 (application for certificate of registration)**

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

(2) In paragraph (4), for “European Union” substitute “United Kingdom”.

(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”.

**Amendment of regulation 104 (consideration of application)**

**100.** Omit regulation 104(5) and (6).

**Amendment of regulation 108 (application for renewal of certificate)**

**101.** In regulation 108(2), for “European Union” substitute “United Kingdom”.

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

**102.**—(1) Regulation 110(1) is amended as follows.

(2) In paragraph (7), for “European Union” substitute “United Kingdom”.

(3) Omit paragraph (10).

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

103. Omit regulation 111.

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

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

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

105. In regulation 113(3A)(2), omit “in accordance with article 123(2) of the 2001 Directive”.

**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”.

**Amendment of regulation 116 (obligation in relation to product information)**

107. In regulation 116(2) for “European” to the end substitute “UK web-portal established in accordance with regulation 203(1).”

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(2) Paragraph (3A) was inserted by [S.I. 2013/2593](#).