STATUTORY INSTRUMENTS

# 2019 No. 775

# 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 ".

**Commencement Information**

**I1** Reg. 108 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

**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.".

**Commencement Information**

**I2** Reg. 109 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 125 (traditional herbal medicinal products)**

**110.** In regulation **[**F1125(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.**]**

**Textual Amendments**

**F1** Words in reg. 110 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. 82**

**Commencement Information**

**I3** Reg. 110 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 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.".

**Commencement Information**

**I4** Reg. 111 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

**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 **[**F2for which a THR(GB) may be granted**]**.

(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.".

**Textual Amendments**

**F2** Words in reg. 112 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. 83**

**Commencement Information**

**I5** Reg. 112 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 127 (application for grant of traditional herbal registration)**

**[**F3**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—

(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.".**]**

**Textual Amendments**

**F3** Reg. 113 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. 84**

**Commencement Information**

**I6** Reg. 113 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 128 (accompanying material)

**[**[F4]**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)".**]**

**Textual Amendments**

**F4** Reg. 114 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. 85**

**Commencement Information**

**I7** Reg. 114 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 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—

**[**F5(a) after "Article 23 of Regulation (EC) No 726/2004" insert "or regulation 202A, as the case may be";**]**

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

(c) before "This", insert " ▼ ".

**Textual Amendments**

**F5** Reg. 115(3)(a) 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. 86**

**Commencement Information**

**I8** Reg. 115 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 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), **[**F6for "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."**]**

(4) In paragraph (8), **[**F7after "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)**]**

**[**F8(5) In paragraph (9), after "Where" insert ", in relation to an application for a THR(NI) or THR(UK),".**]**

(6) In paragraph (10)(a) **[**F9for "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**]**

**[**F10(7) In paragraph (12), after "This regulation does not apply where" insert ", in relation to an application for a THR(NI) or THR(UK),".**]**

**[**F11(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 licencing 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**

**F6** Words in reg. 116(3) 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. 87(a)**

**F7** Words in reg. 116(4) 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. 87(b)**

**F8** Reg. 116(5) 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. 87(c)**

**F9** Words in reg. 116(6) 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. 87(d)**

**F10** Reg. 116(7) 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. 87(e)**

**F11** Reg. 116(8) 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. 87(f)**

**Commencement Information**

**I9** Reg. 116 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

### 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 **[**F12THR(GB) (other than an application under the unfettered access route)**]** 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.".

**Textual Amendments**

**F12** Words in reg. 117 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. 88**

**Commencement Information**

**I10** Reg. 117 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 133 (application for renewal of registration)**

**118.** In regulation 133(2), **[**F13for "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."**]**."

**Textual Amendments**

**F13** Words in reg. 118 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. 89**

**Commencement Information**

**I11** Reg. 118 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

**[F14Amendment 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)".**]**

**Textual Amendments**

**F14** Reg. 118A 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. 90**

**Commencement Information**

**I12** Reg. 118A 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 135 (revocation, variation and suspension of traditional herbal registration)**

**119.**—(1) Regulation 135 [M1] is amended as follows.

**[F15**(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.".**]**

(2) In paragraph (7)(b), **[F16**after "states other than EEA states" insert "/ countries other than approved countries for import".**]**

**[F17**(3) In paragraph (8)(a) omit "other than the United Kingdom".**]**

(4) In paragraph (9), **[F18**in sub-paragraph (b), at the beginning insert "in the case of a THR(NI) or THR(UK),".**]**

**[F19**(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.".**]**

(5) Omit paragraph (11).

**Textual Amendments**

**F15** Reg. 119(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. 91(a)**

**F16** Words in reg. 119(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. 91(b)**

**F17** Reg. 119(3) 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. 91(c)**

**F18** Words in reg. 119(4) 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. 91(d)**

**F19** Reg. 119(4A) 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. 91(e)**

**Commencement Information**

**I13** Reg. 119 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 135 was amended by S.I. 2013/1855.

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

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

(2) In paragraph (1)(a), **[**[F20]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"**]**

(3) Omit paragraph (3).

**Textual Amendments**

**F20** Words in reg. 120(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. 92**

**Commencement Information**

**I14** Reg. 120 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 138 (suspension of use etc of traditional herbal medicinal product)

**121.** Omit regulation 138(10).

**Commencement Information**

**I15** Reg. 121 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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

**122.** Omit regulation 139.

**Commencement Information**

**I16** Reg. 122 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 140 (withdrawal of traditional herbal medicinal product from the market)

**123.** In regulation **[**[F21]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"**]**

**Textual Amendments**

**F21** Words in reg. 123 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. 93**

**Commencement Information**

**I17** Reg. 123 in force on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

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

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

**Commencement Information**

**I18** Reg. 124 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 142 (obligation to notify placing on the market etc)

**125.** **[**[F22]In regulation 142(5C), for "traditional herbal registration" substitute "THR(NI) or THR(UK)**]**[M2].

**Textual Amendments**

**F22** Words in reg. 125 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. 94**

**Commencement Information**

**I19** Reg. 125 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** Regulation 142 was amended by S.I. 2013/2593.

**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 **[**[F23]to be placed on the market in Great Britain**]**.

(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 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.".

**Textual Amendments**

**F23** Words in reg. 126 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. 95**

**Commencement Information**

**I20** Reg. 126 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

**[**[F24]**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.".**]**

**Textual Amendments**

**F24** Reg. 127 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. 96**

**Commencement Information**

**I21** Reg. 127 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 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 ".

**Commencement Information**

**I22** Reg. 128 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 146 (obligation in relation to product information)

**[**[F25]**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).".**]**

**Textual Amendments**

**F25** Reg. 129 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. 97**

**Commencement Information**

**I23** Reg. 129 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 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.".

**Commencement Information**

**I24** Reg. 130 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

**[F26Substitution 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 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.”.**]**

**Textual Amendments**

**F26** Reg. 131 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. 98**

**Commencement Information**

**I25** Reg. 131 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 7.