STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 7

Traditional herbal registrations

[F1 Interpretation and application of Part]

Textual Amendments

F1 Pt. 7 cross-heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **108**; 2020 c. 1, Sch. 5 para. 1(1)

[F2 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.**]**

Textual Amendments

F2 Reg. 124A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **109**; 2020 c. 1, Sch. 5 para. 1(1)

Traditional herbal medicinal products

125.—(1) This Part applies to a herbal medicinal product (a "traditional herbal medicinal product") if the following conditions are met.

(2) Condition A is met if by virtue of its composition and indications the product is appropriate for use without the need for a medical practitioner to—

(a) diagnose the condition to be treated by the product;

(b) prescribe the product; or

(c) monitor the product's use.

(3) Condition B is met if the product is intended to be administered at a particular strength and in accordance with a particular posology.

(4) Condition C is met if the product is intended to be administered externally, orally or by inhalation.

(5) Condition D is met if—

(a) the product has been in medicinal use for a continuous period of at least 30 years, and

[F3(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.]

(6) It is immaterial for the purposes of condition D whether or not during a period mentioned in that condition—

(a) the sale or supply of the product has been based on a specific authorisation; or

(b) the number or quantity of the ingredients (or any of them) has been reduced.

(7) Condition E is met if there is sufficient information about the use of the product as mentioned in condition D (referred to in this Part as its "traditional use"), so that (in particular)—

(a) it has been established that the traditional use of the product is not harmful; and

(b) the pharmacological effects or efficacy of the product are plausible on the basis of long-standing use and experience.

Textual Amendments

F3 Reg. 125(5)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 110** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 82**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F4List 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.]

Textual Amendments

F4 Reg. 125A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **111**; 2020 c. 1, Sch. 5 para. 1(1)

Addition of vitamins or minerals

126. The addition to a traditional herbal medicinal product of a vitamin or mineral does not prevent a traditional herbal registration from being granted for the product if—

(a) there is well-documented evidence of the safety of the vitamin or mineral; and

(b) the action of the vitamin or mineral is ancillary to the action of the product's active herbal ingredients in connection with the use authorised by the traditional herbal registration.

[F5 List of herbal substances, preparations and combinations for use in traditional herbal medicinal products

Textual Amendments

F5 Reg. 126A and cross-heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **112** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 83**); 2020 c. 1, **Sch. 5 para. 1(1)**

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 for 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.**]**

Application for traditional herbal registration

Application for grant of traditional herbal registration

127.—(1) The licensing authority may, subject to regulation 130, grant an application for a traditional herbal registration for a traditional herbal medicinal product in response to an application made in accordance with this Part.

[F6(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.**]**

(2) A registration granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The applicant **[**[F7], 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) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

[[F8](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.**]**

(5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.

(6) The application and any accompanying material must be in English.

(7) The application must include a statement indicating whether the product to which the application relates should be available—

(a) only from a pharmacy; or

(b) on general sale.

(8) The application must include a statement indicating—

(a) whether any terms of the registration are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and

(b) if so, what terms are proposed.

Textual Amendments

F6 Reg. 127(1A)(1B) inserted (31.12.2020) by S.I. 2019/775, **reg. 113(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**)

F7 Reg. 127(3)(a)-(c) substituted for words in reg. 127(3) (31.12.2020) by S.I. 2019/775, **reg. 113(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**)

F8 Reg. 127(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 113(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**)

Accompanying material

128.—[[F9](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.**]**

(2) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for considering the application.

(3) If the application relates to a product that is contained in the list referred to in Article 16f(1) of the 2001 Directive **[**[F10]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)**]**—

(a) the applicant does not need to provide the material referred to in paragraphs 16 to 20 of Part 1 of Schedule 12; and

(b) paragraph (2) of this regulation does not apply.

(4) Material that is submitted under this regulation must be submitted in accordance with Annex I to the 2001 Directive, so far as applicable to traditional herbal medicinal products.

Textual Amendments

F9 Reg. 128(1)(1A) substituted for reg. 128(1) (31.12.2020) by S.I. 2019/775, **reg. 114(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 85**)

F10 Words in reg. 128(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 114(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 85**)

Obligation to update information supplied in connection with application

129.—(1) The applicant for a traditional herbal registration must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(2) Updated information within paragraph (1) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.

Consideration of application

Consideration of application

130.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a traditional herbal registration before the end of the period of 210 days beginning immediately after the day on which an application for the registration is submitted in accordance with regulation 128.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the information or material is provided.

(3) If the licensing authority requests the applicant to give an oral or written explanation of the application, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the explanation is provided.

(4) The licensing authority may grant the application only if, having considered the application and the accompanying material, the authority thinks that—

(a) the product complies with conditions A to E of regulation 125 (conditions for a product to be a traditional herbal medicinal product);

(b) the product to which the application relates is not harmful under normal conditions of use;

(c) the application and the accompanying material complies with the requirements of this Part;

(d) the product's qualitative and quantitative composition is as described in the application and the accompanying material; and

(e) the product's pharmaceutical quality has been satisfactorily demonstrated.

(5) The licensing authority need not take into account any updated information supplied in connection with the application under regulation 129 (obligation to update information supplied in connection with application), unless it thinks that the information is unfavourable in respect of the safety, quality or efficacy of the product concerned

(6) The licensing authority may refuse the application on the ground that it is more appropriate to consider whether to authorise the placing of the product on the market in response to an application for a **[**[F11]UK**]** marketing authorisation or certificate of registration for the product.

(7) Paragraph (4)(a)

[[F12](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.**]**

(8) If the application relates to a herbal medicinal product that is contained in the list referred to Article 16f(1) of the 2001 Directive **[**[F13]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)**]**—

(a) paragraph (4)(a) applies as if it referred to conditions A to D of regulation 125; and

(b) paragraph (4)(b) does not apply.

(9) Where **[**[F14], in relation to an application for a THR(NI) or THR(UK),**]** Article 16d(1) of the 2001 Directive (products to which the mutual recognition procedure and decentralised procedure apply) does not apply to the product, the licensing authority must, in considering the application, take into account any registrations granted by other member States in accordance with Chapter 2a of Title III of the 2001 Directive.

(10) The licensing authority must take into account—

(a) any herbal monograph of the kind referred to **[**[F15]—

(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**]**

(b) if no relevant monograph within sub-paragraph (a) has been established, such other monographs, publications or data as the authority thinks relevant.

(11) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a traditional herbal registration.

(12) This regulation does not apply where **[**[F16], in relation to an application for a THR(NI) or THR(UK),**]** Article 16d(1) applies to the product and the application—

(a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or

(b) has been referred to the Committee for Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(13) An application to which paragraph (12) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

[[F17](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

F11 Word in reg. 130(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **116(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Reg. 130(7)(a)(b) substituted for words in reg. 130(7) (31.12.2020) by S.I. 2019/775, **reg. 116(3)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 130(8) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(b)**) 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 130(9) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(5)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(c)**)

F15 Reg. 130(10)(a)(i)(ii) substituted for words in reg. 130(10)(a) (31.12.2020) by S.I. 2019/775, **reg. 116(6)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Words in reg. 130(12) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(7)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(e)**)

F17 Reg. 130(14)(15) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(8)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(f)**)

[F18 Procedure where less than 15 years use of traditional herbal medicinal product

130A.—(1) Where an application for a THR(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

F18 Reg. 130A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **117** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 88**); 2020 c. 1, **Sch. 5 para. 1(1)**

Classification of traditional herbal registration

131.—(1) A traditional herbal registration must include a term that the product to which the registration relates is to be available—

(a) only from a pharmacy; or

(b) on general sale.

(2) A traditional herbal registration may include a term that the product to which the registration relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Validity of traditional herbal registration

Validity of traditional herbal registration

132.—(1) Subject to the following paragraphs, a traditional herbal registration remains in force—

(a) for an initial period of five years beginning with the date on which it is granted; and

(b) if the registration is renewed under regulation 133 for an unlimited period after its renewal.

(2) The licensing authority may on the first application for renewal of a registration determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event, the registration remains in force—

(a) for a further period of five years beginning with the date on which it is first renewed; and

(b) if the registration is further renewed under regulation 133 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a registration is made in accordance with regulation 133 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

(a) regulation 134 (failure to place on the market); and

(b) regulation 135 (revocation etc of traditional herbal registration).

Application for renewal of registration

133.—(1) An application for the renewal of a traditional herbal registration must be made to the licensing authority.

(2) The applicant **[**[F19], 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.**]**

(3) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (3)(a) of regulation 132 (initial and further period of validity), as the case may be.

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy including—

(a) the evaluation of data contained in suspected adverse reaction reports and periodic safety update reports submitted in accordance with Part 11; and

(b) all variations introduced since the traditional herbal registration was granted.

(7) The licensing authority may renew a traditional herbal registration only if, having considered the application and the material accompanying it, the authority thinks that the positive therapeutic effects of the product to which the registration relates outweigh the risks of the product to the health of patients or of the public.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a traditional herbal registration.

Textual Amendments

F19 Reg. 133(2)(a)-(c) substituted for words in reg. 133(2) (31.12.2020) by S.I. 2019/775, **reg. 18** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 89**); 2020 c. 1, **Sch. 5 para. 1(1)**

Failure to place on the market etc

134.—(1) A traditional herbal registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom **[**[F20](or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)**]** during the period of three years beginning immediately after the day on which it was granted.

(2) A traditional herbal registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom **[**[F21](or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)**]** for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

(a) in response to an application in writing by the holder of the traditional herbal registration; or

(b) by the licensing authority of its own motion.

(5) An exemption may only be granted only—

(a) in exceptional circumstances; and

(b) on public health grounds.

(6) An exemption—

(a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and

(b) may be renewed or further renewed.

Textual Amendments

F20 Words in reg. 134(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 118A(2)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 90**)

F21 Words in reg. 134(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 118A(3)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 90**)

Revocation, variation and suspension of traditional herbal registration

Revocation, variation and suspension of traditional herbal registration

135.—(1) The licensing authority may revoke, vary or suspend a traditional herbal registration if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the registration relates is harmful;

(b) the pharmacological effects or efficacy of the product are no longer plausible; or

(c) the product's qualitative or quantitative composition is not as described in the application for the registration or the material accompanying it.

(3) Condition B is that the licensing authority thinks that the application or the material supplied with it is incorrect.

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the registration; or

(b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that the holder of the registration has not complied with regulation 145(1) to (3) (requirement to provide information that may entail amendment of authorisation).

[[F22](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.**]**

(7) Condition F is that—

(a) the product to which the registration relates is manufactured in the United Kingdom; and

(b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with regulations 37 (manufacturing and assembly), 38 (imports from states other than EEA States **[**[F23]/ countries other than approved countries for import**]**), 39 (further requirements for manufacturer's licence), 40 (obligation to provide information relating to control methods) or 41 (requirements as to qualified persons).

(8) Condition G is that—

(a) the product to which the registration relates is manufactured in an EEA State [F24]...; and

(b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with provision giving effect to Article 41 of the 2001 Directive (requirements relating to manufacturing authorisations) in that member State.

(9) Condition H is that the licensing authority thinks that urgent action to protect public health is necessary, in which case it—

(a) may suspend the registration; and

(b) **[**[F25]in the case of a THR(NI) or THR(UK),**]** must notify the suspension to the EMA, the European Commission, and all other member States by the end of the next working day following the day on which the suspension comes into force.

(10) Condition I is that—

(a) the holder applies to vary the registration; and

(b) the licensing authority thinks that the application should be granted.

[[F26](10A) Condition J is that the manufacture of the product to which registration relates is not carried out in compliance with the particulars provided under paragraphs 5 and 9 of Schedule 12.**]**

[[F27](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.**]**

[F28](11) . . . . . .

Textual Amendments

F22 Reg. 135(6) substituted (31.12.2020) by S.I. 2019/775, **reg. 119(1A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(a)**)

F23 Words in reg. 135(7)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 119(2)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 Words in reg. 135(8)(a) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 119(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(c)**)

F25 Words in reg. 135(9)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 119(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 Reg. 135(10A) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **20**

F27 Reg. 135(10B) inserted (31.12.2020) by S.I. 2019/775, **reg. 119(4A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(e)**)

F28 Reg. 135(11) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **119(5)**; 2020 c. 1, Sch. 5 para. 1(1)

Revocation by licensing authority: further provisions

136.—(1) The licensing authority must revoke a traditional herbal registration if—

(a) the application for the registration was submitted in accordance with regulation 128(3) on the basis that the herbal medicinal product to which it relates was contained in

[[F29](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**]**

(b) the product ceases to be contained in that list.

(2) Paragraph (1) does not apply if within the period of three months beginning immediately after the day on which product ceases to be contained on the list the holder—

(a) submits to the licensing authority the material specified in Schedule 12 (including that referred to in paragraphs 16 to 20 of Part 1 of that Schedule) in relation to the product; and

(b) provides the licensing authority with any material or information that the licensing authority reasonably considers necessary for considering the application and requests the holder to provide.

[F30](3) . . . . . .

Textual Amendments

F29 Reg. 136(1)(a)(i)(ii) substituted for words in reg. 136(1)(a) (31.12.2020) by S.I. 2019/775, **reg. 120(2)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 92**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Reg. 136(3) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **120(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Procedures for revocation, variation or suspension

137. Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a traditional herbal registration, other than a proposal to vary a registration on the application of its holder.

Suspension of use etc of traditional herbal medicinal product

138.—(1) The licensing authority may suspend the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a traditional herbal registration relates if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

(a) the product is harmful;

(b) the pharmacological effects or efficacy of the product are no longer plausible; or

(c) the product's qualitative or quantitative composition is not as described in the application for the registration or the material accompanying it.

(3) Condition B is that the licensing authority thinks that the holder has not complied with regulation 145(7) (requirements to provide proof of controls on manufacturing process).

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the registration; or

(b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that paragraph (4) or (5) of regulation 23 (power to revoke, suspend or vary manufacturers' licences) applies in relation to the manufacturer's licence for the product.

(6) A suspension under this regulation may relate to batches of the product.

(7) The licensing authority must give notice in writing of a suspension under this regulation to the holder of the registration.

(8) The licensing authority must provide in the notice that the suspension—

(a) is to take effect immediately or from a date specified in the notice; and

(b) is to apply for the period specified in the notice.

(9) Where a medicinal product is the subject of a suspension under this regulation, the licensing authority may—

(a) in exceptional circumstances; and

(b) for such a transitional period as the licensing authority may determine,

allow the supply of the medicinal product to patients who are already being treated with the medicinal product.

[F31](10) . . . . . .

Textual Amendments

F31 Reg. 138(10) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **121**; 2020 c. 1, Sch. 5 para. 1(1)

Registrations granted under Chapter 4 of Title III of the 2001 Directive

[F32]**139.** . . . . . .

Textual Amendments

F32 Reg. 139 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **122**; 2020 c. 1, Sch. 5 para. 1(1)

Withdrawal of traditional herbal medicinal product from the market

140.—(1) This regulation applies if—

[[F33](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**]**

(b) under regulation 138 the licensing authority suspends the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a traditional herbal registration relates.

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the registration requiring the holder to comply with both of the following requirements.

(3) Requirement A is to take all reasonably practicable steps to inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of the product to which the registration relates of—

(a) the revocation or suspension;

(b) the reasons for the revocation or suspension; and

(c) any action to be taken to restrict or prevent further use, sale, supply or offer for sale or supply of the product.

(4) Requirement B is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product; or

(b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

Textual Amendments

F33 Reg. 140(1)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 123** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 93**); 2020 c. 1, **Sch. 5 para. 1(1)**

Sale etc of suspended traditional herbal medicinal product

141.—(1) This regulation applies if the use, sale, supply or offer for sale or supply of a traditional herbal medicinal product is suspended in accordance with regulation 138 [F34]....

(2) A person must not—

(a) sell, supply or offer to sell or supply the product; or

(b) procure the sale, supply or offer for sale or supply of the product,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

Textual Amendments

F34 Words in reg. 141(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **124**; 2020 c. 1, Sch. 5 para. 1(1)

Obligations of holder of traditional herbal registration

Obligation to notify placing on the market etc

142.—(1) The holder of a traditional herbal registration must notify the licensing authority of the date on which the product to which the registration relates is placed on the market in the United Kingdom taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a traditional herbal registration must notify the licensing authority if the product to which the registration relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

[[F35](5A) The holder of a traditional herbal registration must notify the licensing authority forthwith if the holder takes action to—

(a) request the cancellation of the registration;

(b) not apply for the renewal of the registration; or

(c) withdraw the product to which the registration relates from the market in a third country (whether temporarily or permanently) and the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5B) A notification under paragraph (3) or (5A) must include the reasons for the action, in particular declaring if the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5C) The holder of a **[**[F36]THR(NI) or THR(UK)**]** must notify the EMA forthwith where the action which is the subject of a notification by the holder under paragraph (3) or (5A) is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.**]**

(6) The licensing authority may require the holder of a traditional herbal registration to provide information relating to the volume of sales in the United Kingdom of the product to which the registration relates.

(7) The holder of a traditional herbal registration must provide the licensing authority with information that it requires under paragraph (6)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F35 Reg. 142(5A)-(5C) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **6**

F36 Words in reg. 142(5C) substituted (31.12.2020) by S.I. 2019/775, **reg. 125** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 94**); 2020 c. 1, **Sch. 5 para. 1(1)**

Obligation to take account of scientific and technical progress

143.—(1) The holder of a traditional herbal registration must keep under review the methods of manufacture and control of the product to which the registration relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the traditional herbal registration to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

[[F37]Establishment of herbal monographs

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

F37 Reg. 143A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **126** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 95**); 2020 c. 1, **Sch. 5 para. 1(1)**

Obligation following new herbal monograph

[[F38]**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

F38 Reg. 144 substituted (31.12.2020) by S.I. 2019/775, **reg. 127** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 96**)

Obligation to provide information relating to safety etc

145.—(1) The holder of a traditional herbal registration must provide the licensing authority with any new information that might entail the variation of the registration.

(2) The holder must, in particular, provide the licensing authority with the following information—

(a) information about any prohibition or restriction imposed in relation to the product to which the registration relates by the competent authority of any country in which the product is on the market;

(b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the traditional herbal registration;

(c) data on the use of the product where such use is outside the terms of the traditional herbal registration; and

(d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

(3) Information within paragraph (1) or (2) must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a traditional herbal registration to provide the authority with information that—

(a) is specified by the licensing authority; and

(b) demonstrates that the positive therapeutic effects of the product to which the registration relates outweigh the risks of the product to the health of patients or of the public.

(5) The information that may be required under paragraph (4) includes information arising from use of the product—

(a) in a country **[**[F39]other than the United Kingdom**]**; or

(b) outside the terms of the traditional herbal registration,

including use in clinical trials.

(6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the traditional herbal registration, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.

(7) The licensing authority may require the holder of a traditional herbal registration to provide the authority with proof of the control methods employed by the manufacturer of the product to which the registration relates.

(8) The holder of a traditional herbal registration must provide the licensing authority with information that it requires under paragraph (4) or (7)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F39 Words in reg. 145(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **128**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation in relation to product information

146.—(1) The holder of the traditional herbal registration for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

[[F40](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

F40 Reg. 146(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 129** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 97**)

Record-keeping obligations

147. The holder of a traditional herbal registration must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of any product to which the registration relates.

Obligation to ensure appropriate and continued supplies

148. The holder of a traditional herbal registration must take all reasonable steps to ensure appropriate and continued supplies of the product to which the registration relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

[[F41]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.**]**

Textual Amendments

F41 Reg. 148A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **130**; 2020 c. 1, Sch. 5 para. 1(1)

Offences relating to traditional herbal registrations

Urgent safety restrictions

[[F42]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

F42 Reg. 149 substituted (31.12.2020) by S.I. 2019/775, **reg. 131** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 98**)

Offences in connection with applications

150. A person is guilty of an offence if in the course of an application for the grant, renewal or variation of a traditional herbal registration for a traditional herbal medicinal product the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product that is false or misleading in a material particular.

Provision of false or misleading information

151.—(1) The holder of a traditional herbal registration is guilty of an offence if the holder provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a traditional herbal medicinal product but that is false or misleading in a material particular.

(2) Paragraph (1) is without prejudice to regulation 150.

General offence of breach of provision of this Part

152.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

(a) failure by the holder of a traditional herbal registration to comply with any requirement or obligation in this Part;

(b) contravention by any person of any prohibition in this Part; or

(c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Penalties

153. A person guilty of an offence under this Part is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

Persons liable

154. If an offence under regulation 150 (offences in connection with applications) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

155.—(1) Paragraph (2) applies if the holder of a traditional herbal registration is charged with an offence under this Part in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

(2) It is a defence for the holder to prove that—

(a) the holder communicated the terms of the registration to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulation 142(3) or 148 or an offence under regulation 150 or 151 to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 7.