STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 6

Certification of homoeopathic medicinal products

Application of Part

Application of Part

102.—(1) This Part applies to a homoeopathic medicinal product (a "registrable homoeopathic medicinal product") that meets the following conditions.

(2) Condition A is that the product is administered orally or externally.

(3) Condition B is that no specific therapeutic indication appears—

(a) on the labelling of the product; or

(b) in any information supplied with the product.

(4) Condition C is that—

(a) the product contains no more than one part per 10,000 of the mother tincture; and

(b) in a case where the product's active substance is a relevant allopathic substance, the product contains no more than 1/100th of the smallest concentration of that substance used in allopathy.

(5) In this regulation "relevant allopathic substance" means an active substance whose presence in an allopathic medicinal product means that the product is only available on prescription.

(6) For this purpose—

(a) "allopathic medicinal product" means a medicinal product other than a homoeopathic medicinal product; and

(b) "allopathy" means treatment using an allopathic medicinal product.

[[F1](7) The Secretary of State may make regulations in respect of Great Britain to amend paragraphs (4) to (6).

(8) The Secretary of State may only exercise the power in paragraph (7) if the Secretary of State considers that it is necessary to do so because of new scientific evidence.**]**

Textual Amendments

F1 Reg. 102(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **98** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 75**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for certificate of registration and consideration of application

Application for certificate of registration

103.—(1) The licensing authority may, subject to regulation 104, grant an application for a certificate of registration for a registrable homoeopathic medicinal product in response to an application made in accordance with this Part.

[[F2](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 COR(GB) only where—

(a) there is already in place, or will be at the time the COR(GB) is granted, a certificate of registration in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in paragraph (5B), and

(c) the registrable homoeopathic medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A certificate of 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 certificate of registration being "in force" is limited to that territory.**]**

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

(3) The application may relate to two or more homoeopathic medicinal products derived from the same homoeopathic stock or the same combination of homoeopathic stocks.

(4) The applicant **[**[F3]where it is applying for—

(a) a COR(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 COR(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 COR(UK), must be established in the United Kingdom.**]**

(5) 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.

[[F4](5A) The application must include a statement indicating whether the certificate sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.

(5B) The applicant for the grant of a COR(GB) under the unfettered access route must provide—

(a) the application form submitted in connection with the granting of the COR(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 COR(NI) which authorises the sale or supply of the product in Northern Ireland; and

(c) a copy of the COR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in paragraph (8) which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.**]**

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

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

(8) The applicant must provide each of the following for each product to which the application relates—

(a) a statement of the scientific name, or other name given in a pharmacopoeia, of the homoeopathic stock or stocks from which the product is derived;

(b) a statement of the routes of administration, pharmaceutical forms and degree of dilution of the product;

(c) a dossier describing how the homoeopathic stock or stocks are obtained and controlled and justifying their homoeopathic use on the basis of an adequate bibliography;

(d) a manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation of the product;

(e) evidence that each manufacturer of the medicinal product is authorised to manufacture it (which, in the case of a product manufactured in the United Kingdom [F5]..., means the manufacturer's licence or (as the case may be) its equivalent in **[**[F6]a country other than the United Kingdom**]**);

(f) where an authorisation to place the product on the market has been granted by **[**[F7]a country other than the United Kingdom**]**, a copy of the authorisation;

(g) a mock-up of the outer and immediate packaging of the product; and

(h) data concerning the stability of the product.

(9) This material, taken as a whole, must be such as to demonstrate the pharmaceutical quality and batch to batch homogeneity of each product to which the application relates.

(10) 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.

Textual Amendments

F2 Reg. 103(1A)(1B) inserted (31.12.2020) by S.I. 2019/775, **reg. 99(1A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(a)**)

F3 Reg. 103(4)(a)-(c) substituted for words in reg. 103(4) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 99(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 76(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Reg. 103(5A)(5B) inserted (31.12.2020) by S.I. 2019/775, **reg. 99(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(c)**)

F5 Words in reg. 103(8)(e) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **99(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 103(8)(e) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **99(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in reg. 103(8)(f) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **99(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Consideration of application

104.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a certificate of registration before the end of the period of 210 days beginning immediately after the day on which an application for the certificate is submitted in accordance with regulation 103.

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

(a) the risks to the health of patients or of the public associated with the product do not outweigh any beneficial effects of the homoeopathic medicinal product in question;

(b) the application and the accompanying material complies with regulation 103; and

(c) the product's qualitative or quantitative composition is as described in the application and the accompanying material.

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

(5) This regulation does not apply to an application that—

(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 Medicinal Products for Human Use for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(6) An application to which paragraph (5) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

[[F8](7) In the case of an application under the unfettered access route, the licensing authority may grant a COR(GB) (notwithstanding paragraph (3)) 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 103(1A) will continue to be met.

(8) The licensing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.**]**

Textual Amendments

F8 Reg. 104(7)(8) inserted (31.12.20200 by S.I. 2019/775, **reg. 100(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 77**)

Conditions of certificate of registration

105.—(1) The licensing authority may—

(a) grant a certificate of registration subject to conditions; or

(b) vary or remove a condition to which the certificate of registration is subject.

(2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the certificate or (as the case may be) its holder.

(3) The power in paragraph (1)(a) to grant an authorisation subject to conditions may be exercised only—

(a) in exceptional circumstances; and

(b) when the applicant can show that the applicant is unable to provide comprehensive data on the safety of the medicinal product under normal conditions of use.

(4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.

(5) The conditions may, in particular, relate to the safety of the product to which the certificate relates.

(6) The conditions may, in particular, require that, where there is an incident relating to the use of the product—

(a) the incident must be reported to the licensing authority; and

(b) such other action as may be specified in the conditions must be taken.

(7) The licensing authority must keep under review—

(a) the conditions to which a certificate of registration is subject; and

(b) the holder's compliance with those conditions.

(8) The licensing authority must consider those matters no less frequently than—

(a) at the end of the period of one year beginning with the date on which the certificate was granted; and

(b) at the end of each subsequent period of one year.

(9) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a certificate of registration is subject.

Classification of certificate of registration

106.—(1) A certificate of registration must include a term that the product to which the certificate relates is to be available—

(a) only from a pharmacy; or

(b) on general sale.

(2) A certificate of registration may include a term that the product to which the certificate 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 certificate of registration

107.—(1) Subject to the following paragraphs, a certificate of 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 authorisation is renewed under regulation 108 for an unlimited period after its renewal.

(2) The licensing authority may, on the first application for renewal of a certificate, 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 certificate 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 authorisation is further renewed under regulation 108 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a certificate is made in accordance with regulation 108 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 109 (failure to place on the market etc); and

(b) regulation 110 (revocation etc of certificate of registration).

Application for renewal of certificate

108.—(1) An application for the renewal of a certificate of registration must be made to the licensing authority.

(2) The applicant **[**[F9], where it is applying for renewal of—

(a) a COR(NI) and originally granted—

(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 COR(GB) and originally granted—

(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) in the whole United Kingdom, 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 (as the case may be) (3)(a) of regulation 107 (initial and further period of validity).

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy (including all amendments made since the authorisation was granted).

(7) The licensing authority may renew a certificate only if, having considered the application and the material accompanying it, the authority thinks that the risks to the health of patients or of the public associated with the homoeopathic medicinal product to which the certificate relates do not outweigh any beneficial effects of the product.

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

Textual Amendments

F9 Reg. 108(2)(a)-(c) substituted for words in reg. 108(2) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 101** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 78**); 2020 c. 1, **Sch. 5 para. 1(1)**

Failure to place on the market etc

109.—(1) A certificate of registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom **[**F10(or, in the case of a COR(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 certificate of 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 **[**F11(or, in the case of a COR(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 certificate of registration; or

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

(5) An exemption may 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

F10 Words in reg. 109(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 101A(2)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 79**)

F11 Words in reg. 109(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 101A(3)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 79**)

Revocation, variation and suspension of certificate of registration

Revocation, variation and suspension of certificate of registration

110.—(1) The licensing authority may revoke, vary or suspend a certificate of 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 certificate relates is harmful;

(b) the risks of the product to the health of patients or of the public outweigh any beneficial effects of the product; or

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

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

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

(a) a term of the certificate; or

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

(5) Condition D is that the licensing authority thinks that a condition to which the certificate is subject by virtue of regulation 105 (conditions of certificate or registration) has not been fulfilled.

(6) Condition E is that the licensing authority thinks that the holder of the certificate has not complied with regulation 115(1) to (3) (requirements to provide information).

(7) Condition F is that the holder of the certificate has ceased to be **[**F12established in—

(a) the United Kingdom; or

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

in accordance with the requirements of these Regulations.**]**

(8) Condition G is that—

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

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

[F13(8A) Condition H is that the manufacture and control of the product to which the certificate relates is not in compliance with the particulars provided under regulation 103(8)(c) and (d).**]**

[F14(8B) Condition I 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.**]**

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

(10) This regulation is subject to regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive).

Textual Amendments

F12 Reg. 110(7)(a)(b) substituted for words in reg. 110(7) (31.12.2020) by S.I. 2019/775, **reg. 102(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(a)**)

F13 Reg. 110(8A) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **19**

F14 Reg. 110(8B) inserted (31.12.20200 by S.I. 2019/775, **reg. 102(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(b)**)

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

F15111. . . . . . .

Textual Amendments

F15 Reg. 111 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **103**; 2020 c. 1, Sch. 5 para. 1(1)

Withdrawal of homoeopathic medicinal product from the market

112.—(1) This regulation applies if under regulation 110 [F16]... the licensing authority revokes or suspends a certificate of registration.

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

(3) That requirement is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product to which the certificate relates; or

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

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

(4) The notice must specify the grounds for giving the notice.

Textual Amendments

F16 Words in reg. 112(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **104**; 2020 c. 1, Sch. 5 para. 1(1)

Obligations of holder of certificate of registration

Obligation to notify placing on the market etc

113.—(1) The holder of a certificate of registration must notify the licensing authority of the date on which the product to which the certificate 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 certificate of registration must notify the licensing authority if the product to which the certificate relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

[[F17](3A) A notification under paragraph (3) must include the reasons for the withdrawal [F18]....**]**

(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.

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

(7) The holder of a certificate of 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

F17 Reg. 113(3A) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **5**

F18 Words in reg. 113(3A) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **105**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation to take account of scientific and technical progress

114.—(1) The holder of a certificate of registration must keep under review the methods of manufacture and control of the product to which the certificate 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 certificate of registration to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

Obligation to provide information relating to safety etc

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

(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 certificate 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 certificate of registration;

(c) data on the use of the product where such use is outside the terms of the certificate of 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 certificate of registration to provide the authority with information that—

(a) is specified by the licensing authority; and

(b) demonstrates that the risks of the product to the health of patients or of the public do not outweigh any beneficial effects of the product to which the certificate relates.

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

(a) in a country **[**F19other than the United Kingdom**]**; or

(b) outside the terms of the certificate of registration.

(6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the certificate of 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 certificate of registration to provide the authority with proof of the control methods employed by the manufacturer of the product to which the certificate relates.

(8) The licensing authority may notify the holder of a certificate of registration that it requires the holder to provide to the licensing authority information of any description specified in the notice, within the period specified in the notice, subject to paragraph (9).

(9) A notice under paragraph (8) must not be served unless it appears to the licensing authority, or it is represented to the licensing authority by the Commission or by an expert committee appointed by the licensing authority—

(a) that circumstances exist by reason of which it is necessary to consider whether the certificate of registration should be varied, suspended or revoked; and

(b) that the information required by the notice is needed to consider that question.

(10) The holder of a certificate of registration must provide the licensing authority with information that it requires under paragraphs (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

F19 Words in reg. 115(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **106**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation in relation to product information

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

[[F20](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 authorised by a COR(NI) or COR(UK)—

(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 authorised by a COR(GB), the UK web-portal established in accordance with regulation 203(1).**]**

Textual Amendments

F20 Reg. 116(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 107** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 81**)

Record-keeping obligation

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

Obligation to ensure appropriate and continued supplies

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

Provisions relating to offences

Offences in connection with applications

119. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a certificate of registration for a registrable homoeopathic medicinal product, the person—

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

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

Provision of false or misleading information

120.—(1) The holder of a certificate of registration for a medicinal product is guilty of an offence if the person provides the licensing authority with any information that is relevant to the quality of the product but that is false or misleading in a material particular.

(2) Paragraph (1) is without prejudice to the operation of regulation 119.

General offence of breach of provision of this Part

121.—(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 certificate of 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

122. 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

123. If an offence under regulation 119 (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

124.—(1) Paragraph (2) applies if the holder of a certificate of 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 certificate.

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

(a) the holder communicated the terms of the certificate 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 113(3) or 118 or an offence under regulation 119 or 120 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 6.