STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 6

Certification of homoeopathic medicinal products

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of registration must notify the licensing authority if the product to which the certificate relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

[[F1](3A) A notification under paragraph (3) must include the reasons for the withdrawal [F2]....**]**

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(3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.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the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.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

F1 Reg. 113(3A) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **5**

F2 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 **[**F3other 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

F3 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.

[[F4](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

F4 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.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Obligations of holder of certificate of registration.