STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 7

Traditional herbal registrations

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herbal registration must notify the licensing authority if the product to which the registration relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).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(3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.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the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

(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.

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.

Obligation following new herbal monograph

144. Where a new herbal monograph of the kind referred to in Article 16h(3) of the 2001 Directive is established the holder of a traditional herbal registration for a product 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.

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 which is not an EEA State; 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.

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.

(2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

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.