STATUTORY INSTRUMENTS

2013 No. 2593

The Human Medicines (Amendment) (No. 2) Regulations 2013

Amendment of regulation 196 of the 2012 Regulations

7.—(1) Regulation 196 of the 2012 Regulations (urgent action) is amended as follows.

(2) For paragraphs (1) and (2) substitute the following paragraphs—

"(1) The licensing authority must initiate the Section 4 procedure by informing the specified bodies where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities,—

(a) it considers suspending or revoking an authorisation or registration of a medicinal product or class of medicinal products;

(b) it considers prohibiting the supply of a medicinal product or class of medicinal products;

(c) it considers refusing the renewal of an authorisation or registration of a medicinal product; or

(d) it is informed by a holder that, on the basis of safety concerns, the holder has—

(i) interrupted the sale or supply, or offer of sale or supply, of the product,

(ii) taken action to have the product's authorisation or registration cancelled or intends to do so, or

(iii) not applied for the renewal of the product's authorisation or registration.

(2) The licensing authority must inform the specified bodies where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, it considers it necessary to vary an authorisation or registration or a class of authorisations or registrations to include—

(a) a new contra-indication,

(b) a reduction to the recommended dose, or

(c) a restriction to the therapeutic indications.

(2A) The information provided under paragraph (2) must outline the action considered and the reasons for the action.

(2B) Where the licensing authority considers urgent action is necessary in relation to the information provided under paragraph (2), it must initiate the Section 4 procedure.

(2C) The information required to be provided under paragraph (1) or (2) must be provided by the end of the day on which the consideration arose under paragraph (1)(a) to (c) or (2) or the information was received under paragraph (1)(d) (as the case may be)."

(3) In paragraph (3) after "paragraph" insert "(1) or".

(4) In paragraph (4)—

(a) for "paragraph (1)" substitute "paragraph (1) or (2)"; and

(b) for "paragraph (2)" substitute "paragraph (1) or (2) (as the case may be)".

(5) In paragraph (5) for "paragraph (1)", both times it appears, substitute "paragraph (1) or (2)".

(6) In paragraph (7)—

(a) after "inform" insert "the specified bodies"; and

(b) omit from "the following" to the end of the paragraph.

(7) For paragraph (8) substitute—

"(8) In this regulation—

"EU urgent action procedure" means the procedure under Articles 107j and 107k of the 2001 Directive;

"Section 4 procedure" means the procedure under Section 4 of Chapter 3 of Title IX of the 2001 Directive; and

"specified bodies" means—

(a) the competent authority of each EEA State other than the United Kingdom,

(b) the EMA, and

(c) the European Commission."