DRAFT STATUTORY INSTRUMENTS

2019 No.

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 11

Amendment of Part 11 (Pharmacovigilance)

Substitution of regulation 196 (urgent action)

156. For regulation 196(**1**) and the italic heading immediately preceding it substitute—

"Major safety review

Major safety review by the licensing authority

196.—(1) The licensing authority may conduct a major safety review where—

(a) on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities it considers—

(i) suspending or revoking a UK marketing authorisation or traditional herbal registration of a medicinal product or in respect of a class of medicinal products,

(ii) prohibiting the supply of a medicinal product or a class of medicinal products,

(iii) refusing the renewal of a UK marketing authorisation or traditional herbal registration, or

(iv) action is necessary to vary a UK marketing authorisation or traditional herbal registration or a class of such authorisations or registrations, including to impose new conditions; or

(b) 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 to which a UK marketing authorisation or traditional herbal registration relates,

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

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

(2) If the licensing authority conducts a review under paragraph (1), it must—

(a) announce the initiation of that review on the UK web-portal as soon as reasonably practicable;

(**1**) Regulation 196 was amended by S.I. 2013/2593.

(b) include in that announcement—

(i) an outline of its reasons for conducting a major safety review, the medicinal products concerned and, where applicable, the active substances concerned, and

(ii) the proposed structure and time-scale of the review;

(c) notify a holder if the product to which that holder's authorisation or registration relates is within the scope of the review; and

(d) publish the outcome of that review, including any recommendations it is making, or action it is proposing to take, as soon as reasonably practicable after the conclusion of that review.

(3) A holder who is notified under paragraph (2)(c)—

(a) must provide to the licensing authority such information as the licensing authority notifies that holder it requires, within such time period as the licensing authority specifies; and

(b) may, where such information contains confidential data relevant to the subject matter of the review, because the data relates to a manufacturing process or trade secret, notify the licensing authority that that data is provided in confidence.

(4) Where the licensing authority proposes that action should be taken in respect of any UK marketing authorisation or traditional herbal registration—

(a) during the conduct of the major safety review, because urgent action is necessary to protect public health; or

(b) upon the conclusion of such a review,

it may exercise its powers under Part 5 or 7 (as the case may be) in relation to that authorisation or registration.".