DRAFT STATUTORY INSTRUMENTS

2019 No.

The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

Amendment of regulation 43 (qualified persons)

18. In regulation 43, for paragraph (2) substitute—

"(2) Subject to paragraphs (2A) and (2C), the qualified person is responsible for ensuring that—

(a) in the case of an investigational medicinal product manufactured in the United Kingdom, each production batch has been manufactured and checked in compliance with—

(i) the requirements of these Regulations;

(ii) the principles and guidelines of good manufacturing practice;

(iii) the product specification, as defined in Part 1 of Schedule 7; and

(iv) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(b) in the case of an investigational medicinal product manufactured in a country other than the United Kingdom, each production batch has been manufactured and checked in accordance with—

(i) standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 2003/94/EC;

(ii) the product specification, as defined in Part 1 of Schedule 7; and

(iii) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used.

(2A) The qualified person is not responsible for carrying out the controls in paragraph (2) where—

(a) the product is imported from a country that is included on the list referred to in regulation 43A ("approved country for import"); and

(b) the qualified person ensures that there is appropriate evidence to confirm that each production batch has been certified as provided for in Article 13 of the Directive, or such equivalent certification procedure as applies in the approved country for import.

(2B) The licensing authority must publish guidance on the evidence that it considers to be appropriate for the purposes of paragraph (2A)(b).

(2C) The qualified person is not responsible for carrying out the controls in paragraph (2) where—

(a) an investigational medicinal product which has a marketing authorization, or has been approved for marketing in another country, is imported as a comparator product; and

(b) documentation cannot be obtained certifying that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 2003/94/EC.

(2D) Where paragraph (2) does not apply by virtue of paragraph (2C), the qualified person is responsible for ensuring that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the request, particulars and documents submitted to the licensing authority under to regulation 17.

(2E) The qualified person is responsible for ensuring, in relation to an investigational medicinal product, that documentary evidence is produced that each batch of the product satisfies the provisions of paragraph (2), (2A) or (2D) (as the case may be).

(2F) The documentary evidence referred to in paragraph (2E) must be—

(a) kept up to date as operations are carried out; and

(b) available for inspection by the licensing authority for a period of at least five years beginning with the date on which the documentary evidence is produced.”.