DRAFT STATUTORY INSTRUMENTS

2019 No.

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

Amendment of regulation 13 (supply of investigational medicinal products for the purpose of clinical trials)

7.—(1) Regulation 13 is amended as follows.

(2) For paragraph (2)(b)(**1**), substitute—

"(b) the product has been manufactured, assembled or imported—

(i) in accordance with the terms of a manufacturing authorisation, or

(ii) in the case of assembly only, under the exemption in regulation 37.".

(3) After paragraph (2), insert—

"(2A) The condition specified in paragraph (2)(b) does not apply to an investigational medicinal product that has been manufactured or assembled in accordance with the terms of a UK marketing authorization relating to that product.".

(4) Omit paragraph (3).

(5) In paragraph (4)—

(i) for "of a marketing authorisation" substitute "of a UK marketing authorization"; and

(ii) omit the words from ", other than a marketing authorisation" to the end.

(**1**) Paragraph (2)(b) was amended by S.I. 2006/1928.