DRAFT STATUTORY INSTRUMENTS

2019 No.

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

Insertion of regulation 43A (approved country for import)

19. After regulation 43 insert—

"**Approved country for import**

43A.—(1) The licensing authority must publish a list of countries which it is satisfied have a regulatory framework applicable to investigational medicinal products exported to the United Kingdom that is equivalent to the regulatory framework in the United Kingdom, in that the respective control and enforcement activities in those countries ensure an equivalent level of protection of public health.

(2) In order to determine whether a country should be included in the list referred to in paragraph (1), the licensing authority may, in particular, take into account—

(a) the country's system for ensuring that each batch of an investigational medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of the clinical trial in which the product is to be used;

(b) the country's rules for good manufacturing practice;

(c) the regularity of inspections to verify compliance with good manufacturing practice;

(d) the effectiveness of enforcement of good manufacturing practice;

(e) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers of investigational medicinal products;

(f) any on-site review of that country's regulatory system undertaken by the licensing authority;

(g) any on-site inspection of a manufacturing site in that country observed by the licensing authority; and

(h) any other relevant documentation available to the licensing authority.

(3) The licensing authority must—

(a) review the countries it has included in the list referred to in paragraph (1) to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(b) undertake such a review at least every three years beginning with the date on which that country is included in that list.".