DRAFT STATUTORY INSTRUMENTS

2019 No.

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

Insertion of Schedule 13 (transitional provisions in relation to EU Exit)

26. After Schedule 12 insert—

"SCHEDULE 13 Regulation 56

Transitional provisions relating to EU Exit

List of countries for the purpose of the definition of "marketing authorization" on exit day (regulation 2A)

1.—(1) For the purpose of regulation 2A, during the transitional period, the licensing authority must include each EEA State in the list referred to in paragraph (1) of that regulation.

(2) Notwithstanding regulation 2A(3), the licensing authority must not, before the end of the transitional period, remove an EEA State from the list referred to in regulation 2A(1).

(3) In this paragraph, "transitional period" is the period of two years beginning with exit day.

List of countries where a sponsor of a clinical trial, or their legal representative, may be established on exit day (regulation 3(11A))

2.—(1) For the purpose of regulation 3, the licensing authority must include each EEA State in the list referred to in paragraph (11A) of that regulation.

(2) Notwithstanding regulation 3(11C), the licensing authority must not, before the end of the transitional period, remove an EEA State from the list referred to in regulation 3(11A).

(3) In this paragraph, "transitional period" is the period of two years beginning with exit day.

Import of investigational medicinal products from EEA States during the transitional period

3.—(1) The condition in regulation 13(2)(b) and the restriction in regulation 36(1) do not apply to an investigational medicinal product that is imported from an EEA State before the end of the transitional period, provided that the production batch of investigational medicinal products of which the product is a part has been checked and certified by a qualified person pursuant to Article 13(3) and (4) of the Directive.

(2) In this paragraph, "transitional period" is the period of one year beginning with exit day.

Approved country for import list on exit day (regulation 43A)

4.—(1) For the purpose of regulation 43A, during the transitional period, the licensing authority must include each EEA State in the list referred to in paragraph (1) of that regulation.

(2) Notwithstanding regulation 43A(3), the licensing authority must not, before the end of the transitional period, remove an EEA State from the list referred to in regulation 43A(1).

(3) In this paragraph, "transitional period" is the period of two years beginning with exit day.".