STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 1

INTRODUCTORY PROVISIONS

[F1List of countries for the purpose of the definition of "marketing authorization"

2A.—(1) The licensing authority must publish a list of countries for the purpose of the definition of "marketing authorization".

(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 the regulatory equivalence of that country to the United Kingdom in assessing the safety, quality and efficacy of medicinal products.

(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.**]**

Textual Amendments

F1 Reg. 2A inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **4**; 2020 c. 1, Sch. 5 para. 1(1)

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 2A.