STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Authorisation procedure for clinical trials involving medicinal products with special characteristics

20.—(1) This regulation applies to clinical trials—

(a) involving medicinal products—

[F1(i) which do not have a marketing authorization and are developed by means of one of the following biotechnological processes—

(aa) recombinant DNA technology,

(bb) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,

(cc) hybridoma and monoclonal antibody methods, or**]**

(ii) which have an active ingredient—

(aa) that is a biological product of human or animal origin,

(bb) containing biological components of human or animal origin, or

(cc) the manufacturing of which requires such components,

other than products falling within regulation 19; or

(b) where the licensing authority, within 7 days from the date of receipt of a valid request for authorisation of the trial, issues a notice to the sponsor specifying that by virtue of the special characteristics of the medicinal product to which the trial relates, written authorisation for that trial is required.

(2) The licensing authority may, within the period of 30 days from the date of receipt of a valid request for authorisation of a clinical trial to which this regulation applies—

(a) issue a written authorisation to the sponsor; or

(b) give a notice in writing to the sponsor setting out the grounds for not authorising the trial.

(3) Where a sponsor is given a notice in accordance with paragraph (2)(b), he may, within the period of 14 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration.

(4) The licensing authority shall consider a valid amended request and, not later than 60 days from the date on which the original request was received—

(a) issue a written authorisation to the sponsor; or

(b) give a notice in writing to the sponsor setting out the grounds for not accepting the request.

(5) A written authorisation issued under this regulation may contain such conditions as the licensing authority consider appropriate.

Textual Amendments

F1 Reg. 20(1)(a)(i) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **9**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 20.