

STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 5

PHARMACOVIGILANCE

Notification of suspected unexpected serious adverse reactions

33.—(1) A sponsor shall ensure that all relevant information about a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial in the United Kingdom and is fatal or life-threatening is—

- (a) recorded; and
- (b) reported as soon as possible to—
 - (i) the licensing authority,
 - ^{F1}(ii)
 - (iii) the relevant ethics committee,

and in any event not later than 7 days after the sponsor was first aware of the reaction.

(2) A sponsor shall ensure that within 8 days of a report in accordance with paragraph (1)(b), any additional relevant information is sent to the persons or bodies listed in that paragraph.

(3) A sponsor shall ensure that a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial in the United Kingdom, other than those referred to in paragraph (1), is reported as soon as possible to—

- (a) the licensing authority;
- ^{F2}(b)
- (c) the relevant ethics committee,

and in any event not later than 15 days after the sponsor is first aware of the reaction.

^{F3}(4)

(5) A sponsor shall ensure that, in relation to each clinical trial in the United Kingdom for which he is the sponsor, the investigators responsible for the conduct of a trial are informed of any suspected unexpected serious adverse reaction which occurs in relation to an investigational medicinal product used in that trial, whether that reaction occurs during the course of that trial or another trial for which the sponsor is responsible.

- (6) The licensing authority shall—
 - (a) keep a record of all suspected unexpected serious adverse reactions relating to an investigational medicinal product which are brought to its attention, whether pursuant to paragraphs (1) or (3) or otherwise; and
 - ^{F4}(b)

Changes to legislation: There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 33. (See end of Document for details)

Textual Amendments

- F1** Reg. 33(1)(b)(ii) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **14(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Reg. 33(3)(b) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **14(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Reg. 33(4) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **14(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Reg. 33(6)(b) and word omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **14(5)**; 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 33.