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,

(ii) the competent authorities of any EEA State, other than the United Kingdom, in which the trial is being conducted, and

(iii) the relevant ethics committee,

and in any event not later that 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;

(b) the competent authorities of any EEA State, other than the United Kingdom, in which the trial is being conducted; and

(c) the relevant ethics committee,

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

(4) For the purposes of paragraphs (1) to (3), the sponsor may fulfil his obligations to report or provide information to the licensing authority and the competent authorities of any EEA State, other than the United Kingdom, by entering the report or information in the European database established in accordance with Article 11 of the Directive.

(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

(b) ensure that the details of those reactions are entered in the European database established in accordance with Article 11 of the Directive, whether by the sponsor or the authority.