STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 5

PHARMACOVIGILANCE

Notification of adverse events

32.—(1) An investigator shall report any serious adverse event which occurs in a subject at a trial site at which he is responsible for the conduct of a clinical trial immediately to the sponsor.

(2) An immediate report under paragraph (1) may be made orally or in writing.

(3) Following the immediate report of a serious adverse event, the investigator shall make a detailed written report on the event.

(4) Paragraphs (1) to (3) do not apply to serious adverse events specified in the protocol or the investigator's brochure as not requiring immediate reporting.

(5) Adverse events, other than those to which paragraphs (1) to (3) apply, that are identified in the protocol as critical to evaluations of the safety of the trial shall be reported to the sponsor in accordance with the reporting requirements, including the time periods for such reporting, specified in that protocol.

(6) The reports made under paragraphs (1), (3) and (5) shall identify each subject referred to in the report by a number assigned to that subject in accordance with the protocol for the trial.

(7) The number assigned to a subject in accordance with the protocol must be different from the number of any other subject in that trial, including any subject at a trial site outside the United Kingdom.

(8) Where the event reported under paragraph (1) or (5) consists of, or results in, the death of a subject, the investigator shall supply—

(a) the sponsor; and

(b) in any case where the death has been reported to the relevant ethics committee, that committee,

with any additional information requested by the sponsor or, as the case may be, the committee.

(9) The sponsor shall keep detailed records of all adverse events relating to a clinical trial which are reported to him by the investigators for that trial.

(10) The licensing authority may, by sending a notice in writing to the sponsor, require him to send the records referred to in paragraph (9), or copies of such records, to the authority.

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.

Clinical trials conducted in third countries

34. If a clinical trial is being conducted at a trial site in a third country in addition to sites in the United Kingdom, the sponsor of that trial shall ensure that all suspected unexpected serious adverse reactions occurring at that site are entered into the European database established in accordance with Article 11 of the Directive.

Annual list of suspected serious adverse reactions and safety report

35.—(1) As soon as practicable after the end of the reporting year, a sponsor shall, in relation to each investigational medicinal product tested in clinical trials in the United Kingdom for which he is the sponsor furnish the licensing authority and the relevant ethics committees with—

(a) a list of all the suspected serious adverse reactions which have occurred during that year in relation to—

(i) those trials, whether at trial sites in the United Kingdom or elsewhere, or

(ii) any other trials relating to that product which are conducted outside the United Kingdom and for which he is the sponsor,

including those reactions relating to any investigational medicinal product used as a placebo or as a reference in those trials; and

(b) a report on the safety of the subjects of those trials.

(2) In paragraph (1), "reporting year", in relation to an investigational medicinal product, means the year ending on the anniversary of—

(a) in the case of a product which has a marketing authorization, the earliest date on which any such authorization relating to that product was granted or issued; or

(b) in any other case, the earliest date on which any clinical trial—

(i) relating to that product, and

(ii) for which the person responsible for making the report was the sponsor,

was authorised in an EEA State.

(3) For the purposes of paragraph (2)(b), the date on which a clinical trial was authorised in an EEA State is—

(a) in the case of the United Kingdom, the date on which the trial was authorised by the licensing authority in accordance with these Regulations, or

(b) in the case of any other EEA State, the date on which the trial was authorised by the competent authority of that EEA State in accordance with the Directive.