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.