STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 5

PHARMACOVIGILANCE

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.