SCHEDULE 3

PARTICULARS AND DOCUMENTS THAT MUST ACCOMPANY AN APPLICATION FOR AN ETHICS COMMITTEE OPINION, A REQUEST FOR AUTHORISATION, A NOTICE OF AMENDMENT AND A NOTIFICATION OF THE CONCLUSION OF A TRIAL

PART 4

NOTIFICATION OF CONCLUSION OF A CLINICAL TRIAL

1. The name and address of—

(a) the sponsor, and

(b) if the sponsor is not established in the European Community, his legal representative.

2. Particulars identifying the trial, including—

(a) the title of the trial; and

(b) the number allocated to the trial on the European database referred to in Article 11 of the Directive.

3. The investigational medicinal product tested in the trial.

4.—(1) The date on which the trial ended in the United Kingdom.

(2) If the trial was conducted at more than one trial site in the United Kingdom, the dates on which the trial was ended at those sites, if different from the date referred to in sub-paragraph (1).

(3) If the trial was conducted at any trial sites outside the United Kingdom, a statement as to whether the trial has ended at any of those sites and, if so, the date on which the trial was so ended.

5. If the trial is terminated as specified in regulation 27(2), the reasons for terminating the trial early.