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 2

REQUEST FOR AUTHORISATION

8.—(1) The address of any premises at which any batch of finished investigational medicinal products to be used in the clinical trial has been, or is to be, checked in accordance with Article 13(3) of the Directive.

(2) If an investigational medicinal product to be used in the clinical trial has been, or is to be, imported from a third country, a statement from the qualified person at the disposal of the person holding the authorisation referred to in Article 13 of the Directive in relation to that importation specifying—

(a) the address of any premises outside the European Economic Area at which the product was manufactured or assembled; and

(b) the manufacturing or assembling operations performed at those premises.