SCHEDULE 7 Regulation 40(4)

STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 1

INTERPRETATION

In this Schedule, "product specification" means—

(a) in the case of an investigational medicinal product manufactured before a request for authorisation to conduct the clinical trial involving those products has been made in accordance with regulation 17 or any equivalent provisions in any EEA State other than the United Kingdom, the specification for that product provided by the person who is to act as the sponsor of the proposed clinical trial,

(b) in the case of an investigational medicinal product manufactured for the purpose of export, the specification for that product provided by the person to whose order the products are manufactured, or

(c) in any other case, the specification for an investigational medicinal product contained in the investigational medicinal product dossier for that product.

PART 2

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE MANUFACTURE OR ASSEMBLY OF INVESTIGATIONAL MEDICINAL PRODUCTS

1. The holder of the authorisation shall—

(a) provide and maintain such staff, premises and plant (including technical equipment) as are necessary for the carrying out, in accordance with his authorisation and the product specification, of such stages of the manufacture and assembly of the investigational medicinal products as are undertaken by him; and

(b) not carry out any such manufacture or assembly except at the premises specified in his manufacturing authorisation.

2. The holder of the authorisation shall—

(a) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the investigational medicinal products which he handles, stores or distributes under his authorisation as are necessary to maintain the quality of the investigational medicinal products;

(b) not use for such purposes premises other than those specified in the authorisation or which may be approved from time to time by the licensing authority; and

(c) ensure that any arrangements he makes with a person for the storage and distribution of the investigational medicinal products are adequate to maintain the quality of those products.

3. The holder of the authorisation shall place the quality control system referred to in Article 11(1) of Commission Directive 2003/94/EC under the authority of the person notified to the licensing authority in accordance with paragraph 6(3) of Schedule 6 as being responsible for quality control.

4. The holder of the authorisation may use a contract laboratory pursuant to Article 11(2) of Commission Directive 2003/94/EC if operated by a person approved by the licensing authority.

5. The holder of the authorisation shall provide such information as may be requested by the licensing authority for the purposes of these Regulations or the Act—

(a) about the products currently being manufactured or assembled under his authorisation; and

(b) of the operations being carried out in relation to such manufacture or assembly.

6. The holder of the authorisation shall—

(a) inform the licensing authority before making any material alteration in the premises or plant used under his authorisation, or in the operations for which they are used; and

(b) inform the licensing authority of any change that he proposes to make in any personnel named in his authorisation as respectively—

(i) responsible for supervising the production operations, or

(ii) responsible for quality control of the investigational medicinal products being manufactured or assembled including the person named as the qualified person for the purposes of regulation 43 and paragraph 14.

7. The holder of the authorisation shall—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive 2003/94/EC; and

(b) permit the person authorised to take copies or make extracts from such documentation.

8. The holder of the authorisation shall keep readily available for examination by a person authorised by the licensing authority the samples of each batch of bulk formulated products referred to in Article 11(4) of Commission Directive 2003/94/EC.

9. Where the holder of the authorisation has been informed by the licensing authority that any batch of any investigational medicinal product to which his authorisation relates has been found not to conform as regards strength, quality or purity with—

(a) the specification of the relevant product; or

(b) the provisions of these Regulations, the Act or any regulations under the Act that are applicable to the investigational medicinal product,

he shall, if so directed, withhold such batch from distribution for use in clinical trials, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

10. The holder of the authorisation shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture shall, except so far as the conditions of the product specification for that product otherwise provide, be applied to samples taken from the investigational medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the licensing authority.

11. Where the authorisation relates to the assembly of an investigational medicinal product, and the holder of the authorisation supplies that investigational medicinal product at such a stage of assembly that does not fully comply with the provisions of the product specification that relate to labelling, that holder of the authorisation shall communicate the particulars of those provisions to the person to whom that investigational medicinal product has been so supplied.

12. Where—

(a) the manufacturing authorisation relates to the assembly of an investigational medicinal product;

(b) that investigational medicinal product is not manufactured by the holder of the authorisation; and

(c) particulars as to the name and address of the manufacturer of, or of the person who imports, that investigational medicinal product had been given by the holder of the authorisation to the licensing authority,

the holder of the authorisation shall forthwith notify the licensing authority in writing of any changes in such particulars.

13. The holder of the authorisation, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any authorisation or licence granted under these Regulations or Part II of the Act;

(b) amending the clinical trial authorisation in accordance with regulation 23 or 24; or

(c) suspending or terminating any clinical trial in accordance with regulation 31,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the authorisation, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for an authorisation or licence.

14. The holder of the authorisation shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal pursuant to regulation 43(1) to carry out the duties referred to in regulation 43(2).

PART 3

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

1. The holder of the authorisation shall—

(a) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the investigational medicinal products which he handles, stores or distributes under his authorisation as are necessary to avoid deterioration of the investigational medicinal products;

(b) not use for such purposes premises other than those specified in the authorisation or which may be approved from time to time by the licensing authority; and

(c) ensure that any arrangements he makes with a person for the storage and distribution of the investigational medicinal products are adequate to maintain the quality of those products.

2. The holder of the authorisation may use a contract laboratory pursuant to Article 11(2) of Commission Directive 2003/94/EC if operated by a person approved by the licensing authority.

3. The holder of the authorisation shall provide such information as may be requested by the licensing authority concerning the type and quantity of any investigational medicinal products which he imports.

4. The holder of the authorisation shall—

(a) inform the licensing authority before making any structural alterations to, or discontinuance of the use of, premises to which his authorisation relates; and

(b) inform the licensing authority if he changes the person named as the qualified person for the purposes of regulation 43 and paragraph 9.

5. The holder of the authorisation shall—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive 2003/94/EC; and

(b) permit the person authorised to take copies or make extracts from such documentation.

6. Where the holder of the authorisation has been informed by the licensing authority that any batch of any investigational medicinal product to which his authorisation relates has been found not to conform as regards strength, quality or purity with—

(a) the specification of the relevant product; or

(b) the provisions of these Regulations, the Act or any regulations under the Act that are applicable to the investigational medicinal product,

he shall, if so directed, withhold such batch from distribution for use in clinical trials, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

7. If the holder of the authorisation is not the sponsor of the clinical trial for which the investigational medicinal product is manufactured or assembled, he shall comply with the provisions of the product specification that relates to the supply of that investigational medicinal product for use in the trial.

8. The holder of the authorisation, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any authorisation or licence granted under these Regulations or Part II of the Act;

(b) amending the conduct of a clinical trial in accordance with regulation 23 or 24; or

(c) suspending or terminating any clinical trial in accordance with regulation 31,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the authorisation, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for an authorisation or licence.

9. The holder of the authorisation shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal pursuant to regulation 43(1) to carry out the duties referred to in regulation 43(2).