SCHEDULE 6

Regulation 38(3)

PARTICULARS THAT MUST ACCOMPANY AN APPLICATION FOR A MANUFACTURING AUTHORISATION

1. The name and address of the applicant, and, where the applicant is not the proposed holder of the authorisation, the name and address of the proposed holder.

2. A statement of the types of investigational medicinal products in respect of which the authorisation is required.

3. A statement of the manufacturing, assembling or importation operations to which the authorisation is to relate, including a statement whether they include one or more of the following—

(a) the manufacture of investigational medicinal products;

(b) the assembly of investigational medicinal products; or

(c) the importation of investigational medicinal products.

4.—(1) The address of each of the premises where the manufacturing, assembling or importation operations to which the application relates, including any testing associated with manufacture, assembly or import, are or are to be carried out.

(2) The address of each of the premises where the proposed holder of the authorisation proposes to store investigational medicinal products or from which he proposes to distribute them.

(3) A statement indicating the facilities and equipment available at each of the premises referred to in sub-paragraphs (1) and (2), for storing the investigational medicinal products on, and distributing them from or between, such premises.

(4) A separate statement in respect of each of the premises referred to in sub-paragraphs (1) and (2), of the manufacturing, assembling or importation operations capable of being carried out at those premises with their existing facilities. Each statement shall specify the classes of investigational medicinal products to which the operations are relevant.

(5) A separate statement in respect of each of the premises referred to in sub-paragraphs (1) and (2), of the facilities and equipment available at those premises for carrying out each stage of the manufacturing, assembling or importation operations described in sub-paragraph (4) of this paragraph.

5. A statement of any manufacturing operations, other than those to which the manufacturing authorisation is to relate, that are carried on by the proposed authorisation holder on or near each of the premises referred to in paragraph 4, and of the substances or articles which are the subject of any such operation.

6.—(1) The name and address and qualifications and experience of the qualified person who is to carry out the duties referred to in regulation 43(2).

(2) In the case of an authorisation relating to manufacture or assembly, the name and qualifications and experience of the production manager or other person whose duty it will be to supervise the production operations at each of the premises referred to in paragraph 4 of this Schedule, and the name and function of the person to whom he is responsible.

(3) In the case of an authorisation relating to manufacture or assembly—

(a) the name and degrees, diplomas or other qualifications and experience of the person to be in charge of quality control over all the premises referred to in paragraph 4 of this Schedule;

(b) the extent of the authority to be delegated to him to reject unsatisfactory batches of investigational medicinal products, and

(c) the name and function of the person to whom he is responsible.

7. A description of the arrangements for the identification and storage of materials and ingredients before and during manufacture and for the storage of investigational medicinal products after manufacture, assembly or importation.

8. A description of the arrangements at each of the premises where the holder of the authorisation stores or proposes to store investigational medicinal products for ensuring, so far as practicable, whether by maintaining records or other means, a satisfactory turn-over of stocks of investigational medicinal products.

9. A description of the arrangements—

(a) for maintaining production or importation records;

(b) for maintaining records of analytical and other testing procedures applied in the course of manufacture, assembly or importation for ensuring compliance of materials used in the manufacture of any investigational medicinal products with the specification of such materials or medicinal products; and

(c) for keeping reference samples of materials used in the manufacture of any investigational medicinal products and of the investigational medicinal products.

Status:
Point in time view as at 01/05/2004.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, SCHEDULE 6.