STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 6

MANUFACTURE AND IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

Grant or refusal of manufacturing authorisation

40.—(1) The licensing authority shall grant a manufacturing authorisation only if—

(a) the applicant—

(i) has complied with the requirements of regulation 38,

(ii) has at his disposal suitable and sufficient premises, technical equipment and control facilities complying with the requirements of Commission Directive 2003/94/EC, as regards the manufacture or import, and control, of the products to which the authorisation relates and the storage of such products,

(iii) has at his disposal the services of at least one qualified person, and

(iv) if a notice has been given under regulation 39(2), has provided the information requested by the licensing authority; and

(b) they have established that the particulars supplied pursuant to regulation 38(3) are accurate.

(2) Subject to paragraph (1), the licensing authority may grant a manufacturing authorisation in respect of any or all of—

(a) the descriptions of investigational medicinal products;

(b) the manufacturing, assembling or importation operations; or

(c) the premises,

specified in the application made pursuant to regulation 38.

(3) The licensing authority may grant a manufacturing authorisation containing—

(a) any provisions to be incorporated in the authorisation in accordance with paragraph (4); or

(b) such other provisions as the licensing authority consider appropriate.

(4) The provisions specified—

(a) in the case of a manufacturing authorisation relating to the manufacture or assembly of investigational medicinal products, in Part 2 of Schedule 7; and

(b) in the case of a manufacturing authorisation relating to the importation of investigational medicinal products, in Part 3 of Schedule 7,

may be incorporated by the licensing authority in any manufacturing authorisation, with or without modifications and either generally or in relation to investigational medicinal products of any particular class.

(5) The provisions of Schedule 8 shall have effect where the licensing authority propose—

(a) to refuse to grant a manufacturing authorisation; or

(b) to grant a manufacturing authorisation otherwise than in accordance with the application.

(6) Where the licensing authority—

(a) refuse to grant a manufacturing authorisation; or

(b) grant a manufacturing authorisation otherwise than in accordance with the application,

and the applicant requests the authority to state their reasons, the licensing authority shall give the applicant a notice in writing stating the reasons for their decision.