STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 6

MANUFACTURE AND IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

Qualified persons

43.—(1) Subject to paragraphs (4) and (5), the holder of a manufacturing authorisation must have at his disposal the services of at least one qualified person who is responsible for carrying out the duties referred to in paragraph 2.

(2) A qualified person shall be responsible for carrying out the duties specified in Article 13(3) and (4) of the Directive, in accordance with that Article, in respect of the investigational medicinal products manufactured, assembled or imported in accordance with the authorisation in question.

(3) A qualified person shall perform his functions under these Regulations in accordance with the Code of Practice for Qualified Persons in the Pharmaceutical Industry, published jointly by the Institute of Biology, the Royal Pharmaceutical Society of Great Britain and the Royal Society of Chemistry in March 2004(**1**).

(4) If the holder of the authorisation satisfies the requirements as to qualifications and experience specified in paragraph (a) or (b) of the definition of "qualified person" in regulation 2(1), he may act as the qualified person in accordance with paragraph (2) for the purposes of that authorisation.

(5) For the purposes of this paragraph, but without prejudice to paragraph (6) below, the holder of the authorisation may regard a person as satisfying the provisions of the said Article 49 or 50, as respects formal qualifications if he produces evidence that—

(a) he is a member of—

(i) the Institute of Biology,

(ii) the Pharmaceutical Society,

(iii) the Royal Society of Chemistry, or

(iv) such other body as may appear to the licensing authority to be an appropriate body for the purpose of this paragraph; and

(b) he is regarded by the body of which he is a member as so satisfying those provisions.

(6) Where, after giving the holder of the authorisation and the person acting as a qualified person the opportunity of making representations to them (orally or in writing), the licensing authority are of the opinion that—

(**1**) A copy of the Code of Practice may be obtained by writing to the Institute of Biology, 20 Queensbury Place, London SW7 2DZ, the Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN or the Royal Society of Chemistry, Burlington House, Piccadilly, London W1V 0BN.

(a) the person so acting does not satisfy—

(i) the provisions of the said Articles 49 and 50 of Directive 2001/83/EC as respects qualifications and experience, or

(ii) the requirements as to qualifications and experience specified in paragraph (b) of the definition of "qualified person" in regulation 2(1); or

(b) he is failing to carry out the duties referred to in paragraph (2) adequately or at all,

and have notified the holder of the authorisation accordingly in writing, the holder of the authorisation shall not permit that person to act as a qualified person.