STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Supply of investigational medicinal products for the purpose of clinical trials

13.—(1) Subject to paragraphs (3) and (4), no person shall, in the course of a business carried on by him, sell or supply any investigational medicinal product to—

(a) an investigator,

(b) a health care professional who is a member of an investigator's team,

(c) a person who provides or is to provide health care under the direction or control of a person referred to in sub-paragraphs (a) and (b), or

(d) a subject,

for the purpose of administering that product in a clinical trial, unless the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to in paragraph (1) are—

(a) the licensing authority has authorised the clinical trial for the purposes of which the product is sold or supplied;

(b) in the case of an investigational medicinal product manufactured or assembled in an EEA State, other than in accordance with the terms of a marketing authorization relating to that product, or imported into an EEA State—

(i) the product has been manufactured, assembled or imported in accordance with the terms of—

(aa) a manufacturing authorisation, or

(bb) an authorisation referred to in Article 13 of the Directive granted by a competent authority of an EEA State other than the United Kingdom, and

(ii) the production batch of investigational medicinal products of which the product is a part has been checked and certified by a qualified person pursuant to Article 13(3) and (4) of the Directive.

(3) If an investigational medicinal product has been manufactured or imported prior to 1st May 2004—

(a) the condition specified in paragraph (2)(b)(i) shall apply only in relation to any assembly of that product which takes place on or after that date; and

(b) the conditions specified in paragraph (2)(b)(ii) shall not apply.

(4) The restriction in paragraph (1) shall not apply to the sale or supply of a medicinal product in accordance with the terms of a marketing authorisation relating to that product, other than a marketing authorisation issued by the competent authority of an EEA State other than the United Kingdom.