STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 7

LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS

Labelling

46.—(1) An investigational medicinal product shall be labelled in accordance with Article 15 of Commission Directive 2003/94/EC(**1**).

(2) Paragraph (1) shall not apply where the investigational medicinal product is—

(a) for use in a clinical trial with the characteristics specified in the second paragraph of Article 14 of the Directive;

(b) dispensed to a subject in accordance with a prescription given by an authorised health care professional; and

(c) labelled in accordance with the requirements of Schedule 5 to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**2**) that apply in relation to dispensed relevant medicinal products.

(**1**) OJNo. L262, 14.10.2003, p.22.
(**2**) S.I. 1994/3144; Schedule 5 was amended by S.I. 1998/3105, 2000/292 and 2002/542; "dispensed relevant medicinal product" is defined in paragraph 1 of Schedule 5.