
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.