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[F1].

(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 **[**[F2]a**]** health care professional; and

(c) labelled in accordance with the requirements of **[**[F3]Part 13 of the 2012 Regulations that apply in relation to medicinal products sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner within the meaning of regulation 214(3) to (6) of those Regulations**]**.

Textual Amendments

F1 OJ No. L262, 14.10.2003, p.22.

F2 Word in reg. 46(2)(b) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **24**

F3 Words in reg. 46(2)(c) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 56** (with Sch. 32)

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 7.