
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 8

ENFORCEMENT AND RELATED PROVISIONS

Offences

49.—(1) Any person who contravenes any of the following provisions—

- (a) regulation 12(1) and (2);
- (b) regulation 13(1);
- (c) regulation 27;
- (d) regulation 28(1) to (3);
- (e) regulation 29;
- (f) regulation 30(2);
- (g) regulation 32(1), (3), and (5) to (9)
- (h) regulation 33(1) to (5)
- (i) regulation 34
- (j) regulation 35(1);
- (k) regulation 36(1);
- (l) regulation 42; and
- (m) regulation 43(1) and (6),

shall be guilty of an offence.

(2) Any person who has in his possession a medicinal product for the purpose of selling or supplying it in contravention of regulation 13(1) shall be guilty of an offence.

(3) Any person who fails to comply with a notice of suspension or termination served on him under regulation 31, unless that notice has been withdrawn or revoked by the licensing authority, shall be guilty of an offence.

(4) Where an investigational medicinal product is manufactured, assembled or imported in contravention of regulation 36(1), any person who sells or supplies the product for the purposes of a clinical trial knowing or having reasonable cause to suspect that it was so manufactured, assembled or imported shall be guilty of offence.

(5) Where an investigational medicinal product is imported in contravention of regulation 36(1), any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under these Regulations, the Act or any other enactment, is in possession of the product knowing or having reasonable cause to suspect that it was so imported shall be guilty of offence.

(6) Any sponsor who sells or supplies, or procures the sale or supply, of an investigational medicinal product—

(a) to a subject for the purposes of a clinical trial; or

(b) to a person for the purpose of administering the product to such a subject, the labelling of which does not comply with regulation 46, shall be guilty of an offence.

(7) Any person who sells or supplies an investigational medicinal product—

(a) to a subject for the purposes of a clinical trial; or

(b) to a person for the purpose of administering the product to such a subject, the labelling of which does not comply with regulation 46, knowing, or having reasonable cause to believe, that the labelling does not so comply, shall be guilty of an offence.