
STATUTORY INSTRUMENTS

2006 No. 1928

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

Amendment of regulation 15 of the principal Regulations

9. In regulation 15 of the principal Regulations (ethics committee opinion), in paragraph (5)—
- (a) in sub-paragraph (b), for “paragraph 2” substitute “paragraph 10”;
 - (b) in sub-paragraph (e), after “investigator’s brochure” insert “ or, where the investigational medicinal product has a marketing authorization and the product is to be used in accordance with the terms of that authorization, the summary of product characteristics relating to that product”; and
 - (c) in sub-paragraph (h)—
 - (i) after “include” insert “ minors or”, and
 - (ii) for “Part 5” substitute “Part 4 or Part 5 respectively”.