STATUTORY INSTRUMENTS

2006 No. 1928

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

Amendment of regulation 13 of the principal Regulations

8. In regulation 13 of the principal Regulations (supply of investigational medicinal products for the purpose of clinical trials), in paragraph (2), in sub-paragraph (b), for head (i) substitute—

"(i) the product has been manufactured, assembled or imported—

(aa) in accordance with the terms of a manufacturing authorisation,

(bb) in accordance with the terms of an authorisation referred to in Article 13 of the Directive granted by a competent authority of an EEA State other than the United Kingdom, or

(cc) in the case of assembly only, under the exemption in regulation 37, and".