STATUTORY INSTRUMENTS

2006 No. 1928

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

Amendment of regulation 44 of the principal Regulations

23. In regulation 44 of the principal Regulations (variation of manufacturing authorisation)—

(a) in paragraph (2), in sub-paragraph (a)—

(i) substitute "change—" for "change the—"

(ii) after head (ii), insert the following head—

"(iia) the manufacturing process,",

(iii) in head (iv), after "facilities,", insert "or", and

(iv) after head (iv), insert the following head—

"(v) the staff, including the qualified person,"; and

(b) for paragraph (8), substitute the following paragraph—

"(8) In this regulation—

"any relevant fee" means, in relation to an application to vary a manufacturing authorisation, any fee which may be payable in connection with that application under the Medicines (Products for Human Use—Fees) Regulations 1995(**1**); and

"valid application" means an application—

(a) made to the licensing authority,

(b) in writing and signed by or on behalf of the applicants,

(c) specifying the variation requested by the applicant,

(d) accompanied by—

(i) such particulars as are necessary to enable the licensing authority to consider the application, and

(ii) unless arrangements have been made with the licensing authority for the payment of any relevant fee other than at the time of the application, any such fee, and

(e) where the application, and any accompanying material, is in the English language.".

(**1**) S.I.1995/1116; relevant amending instruments are S.I. 2004/1157 and 2006/494.