STATUTORY INSTRUMENTS

2006 No. 1928

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

Insertion of regulation 3A of the principal Regulations

4. After regulation 3 of the principal Regulations (sponsor of a clinical trial) insert the following regulation—

"**Sponsor's responsibility for the investigator's brochure**

3A. The sponsor of a clinical trial shall—

(a) ensure that the investigator's brochure for that trial, and any update of that brochure, presents the information it contains in a concise, simple, objective, balanced and non-promotional form that enables a clinician or potential investigator to understand it and make an unbiased risk-benefit assessment of the appropriateness of the proposed clinical trial; and

(b) validate and update the investigator's brochure at least once a year.".