EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Clinical Trials) Regulations 2004 (the principal Regulations) which implement Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products in human use(**1**). In particular, they implement Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (the GCP Directive)(**2**) and make other miscellaneous amendments.

Regulations 2(d), 3(b), 4, 5, 9(a) and (b), 14, 18, 20 to 22, 23(a), 25(a) and (c), 26(b) and (d), 27(3), 28(b) and 31 implement the GCP Directive. In particular they amend the principal Regulations so as to make provision for the following matters:

(a) delegation of functions by the sponsor (regulation 3(b));

(b) imposition of new requirements on sponsors/investigators in relation to the investigator's brochure and trial documentation (regulation 4, 18, 25(a) and (c) and 26(b) and (d));

(c) functions of the Member State and the competent authority under the GCP Directive to be exercised by the licensing authority, unless the functions fall to be performed by the exercise of powers and duties conferred on another person or body under or by virtue of the principal Regulations (regulation 2(d) and 5);

(d) changes to the obligations of ethics committees (regulation 9(b) and 28(b));

(e) the sharing of information between ethics committees and the licensing authority (regulation 14);

(f) amendment of the provisions on the scope of, and procedures for, manufacturing authorisations and the obligations of the holders of such authorisations (regulations 20 to 22, 23(a) and 31); and

(g) a revision of the conditions and principles of good clinical practice which apply to all trials (regulations 9(a) and 27(3)).

Regulations 11, 13, 19 and 23(b) remove the requirement that the appropriate fee must accompany applications for clinical trial authorisations, applications to amend clinical trial authorisations, applications for manufacturing authorisations and applications to amend manufacturing authorisations, where the applicant has made arrangements with the licensing authority for the payment of the fee at a different time.

Regulation 16 makes provision for a new requirement that serious breaches of good clinical practice or the trial protocol must be notified to the licensing authority.

Regulation 25 extends the application of the infringement notices regime in the principal Regulations to a) breaches of the sponsor's responsibilities for the investigator's brochure; b) the requirement not to start or conduct a clinical trial without a clinical trial authorisation or a favourable opinion from an ethics committee; c) the requirement of the sponsor to report serious breaches of good clinical practice or the trial protocol; and d) the requirements relating to the trial master file and archiving.

(**1**) OJNo. L121, 1.5.2001, p.34.
(**2**) OJ No. L91, 9.4.2005, p.13.

Regulation 26 makes the following a criminal offence: a) breach of the sponsor's responsibility for the investigator's brochure; b) breach of the requirement on a sponsor to report serious breaches of good clinical practice or the trial protocol; and c) breach of the trial master file and archiving requirements.

Regulations 2(a) to (c), 3(a), 6 to 8, 9(c), 10, 12, 15, 17, 24, 27(2) and (4), 28(a) and (c), 29, 30, 32 and 33 correct various errors in the principal Regulations.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business and a Transposition Note is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ and copies have been placed in the library of both Houses of Parliament.