EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Clinical Trials) Regulations 2004 (the Clinical Trials 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 for human use(**1**) (the Clinical Trials Directive).

Regulation 2(a) and (b) update the definition of the Clinical Trials Directive and Directive 2001/83/EC respectively to take account of the subsequent amendment of those Directives by Community Regulations. Regulations 2(c) amends the definition of the Gene Therapy Advisory Committee (GTAC).

Regulations 3(a) and (b), 5 and 6 amend provisions relating to ethics committees. Regulation 3(a) and (b) enables ethics committees to give favourable opinions subject to conditions. Regulation 5 has the effect of (i) bringing those with experience and/or knowledge of clinical research within the definition of an "expert member"; (ii) allowing ethics committees to delegate the determination of final opinions to the Chair or a sub-committee; (iii) transferring the power to appoint deputy members from the ethics committee to the appointing authority; and (iv) altering the eligibility and terms of appointment of co-opted members. Regulation 6 amends the particulars and documents that need to accompany an application for an ethics committee opinion.

Regulation 3(c) enables GTAC to notify the United Kingdom Ethics Committee Authority (UKECA) that a clinical trial application does not merit an opinion from GTAC; the outcome of serving such a notice is that the obligation on GTAC to review the application is lifted, whilst UKECA becomes obliged to transfer the application to another ethics committee who in turn become obliged to provide an opinion.

Regulation 4 amends Schedule 1 to the Clinical Trials Regulations to qualify the application of the requirements listed in paragraphs 1 to 5 of Part 4 of Schedule 1 to minors participating in trials. The amendment has the effect that the meeting of those requirements can be deferred whilst (i) the minor requires urgent treatment; (ii) urgent action is required for the purposes of the trial; and (iii) meeting the requirements is not reasonably practicable, provided that an ethics committee has given its approval. The requirements in paragraphs 1 to 5 include the requirement of informed consent to be given by a person with parental responsibility for, or a legal representative of, the minor.

Regulations 7, 8 and 9 make amendments to the Blood Safety and Quality Regulations 2005 (the Blood Regulations) in order to rectify errors in the Blood Safety and Quality (Amendment) Regulations 2006, which amended the Blood Regulations.

The amendment to regulation 9(1) of the Blood Regulations (effected by regulation 8 of these Regulations) brings the duty to retain records that is established by that regulation and applies to hospital blood banks in to line with the similar duty that is established by regulation 7(1) and applies to blood establishments. The amendments effected by regulation 7 and 9 of these Regulations address minor drafting errors.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business 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.

(**1**) OJ No. L121, 1.5.2001, p.34.