STATUTORY INSTRUMENTS

2008 No. 941

MEDICINES

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008

Made - - - -	*31st March 2008*
Laid before Parliament	*7th April 2008*
Coming into force - -	*1st May 2008*

The Secretary of State makes the following Regulations in exercise of the powers conferred upon him by section 2(2) of the European Communities Act 1972(**a**). He has been designated for the purposes of that section in relation to medicinal products(**b**) and in relation to health protection measures regulating the use of material of human origin(**c**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 and shall come into force on 1st May 2008.

(2) In these Regulations—

"the Blood Regulations" means the Blood Safety and Quality Regulations 2005(**d**);

"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004(**e**).

Amendment of regulation 2 of the Clinical Trials Regulations

2. In regulation 2 of the Clinical Trials Regulations (interpretation), in paragraph (1)—

(a) for the definition of "the Directive" substitute the following definition—

""the Directive" means Directive 2001/20/EC of the European Parliament and of the Council 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(**f**);";

(b) for the definition of "Directive 2001/83/EC" substitute the following definition—

(**a**) 1972 c.68.
(**b**) S.I. 1972/1811.
(**c**) S.I. 2004/3037.
(**d**) S.I. 2005/50, as amended by S.I. 2005/1098, 2532 and 2898, 2006/2013, 2007/604 and 2008/525.
(**e**) S.I. 2004/1031, as amended by S.I. 2005/2754 and 2759 and 2006/1928 and 2984.
(**f**) OJ No. L121, 1.5.2001, p.34; this Directive has been amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ No. L378, 27.12.06, p.1).

""Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**a**); "; and

(c) in the definition of "the Gene Therapy Advisory Committee" omit the words from "to" to the end.

Amendment of regulation 15 of the Clinical Trials Regulations

3. In regulation 15 of the Clinical Trials Regulations (ethics committee opinion)—

(a) for paragraph (1), substitute the following paragraph—

"(1) Except as provided for in paragraph (4A) (which removes the requirement on the Gene Therapy Advisory Committee to give an opinion) and subject to paragraphs (3) and (4) (which suspend and disapply time limits respectively), an ethics committee shall give an opinion in relation to the clinical trial to which a valid application relates within the specified period beginning with the date of receipt of the valid application.";

(b) after paragraph (3) insert the following paragraphs—

"(3A) An ethics committee may give a favourable opinion subject to conditions specified in writing in relation to a clinical trial.

(3B) If an ethics committee gives a favourable opinion subject to conditions, the ethics committee is to be treated as having given a favourable opinion in relation to the clinical trial only if the specified conditions are satisfied."; and

(c) after paragraph (4), insert the following paragraphs—

"(4A) Where a notification under paragraph (4B) is received by the Authority—

(a) the Gene Therapy Advisory Committee shall not give an opinion in relation to the clinical trial to which the application subject to that notification relates;

(b) the Authority shall direct that the application be considered by another ethics committee specified in the direction;

(c) the Gene Therapy Advisory Committee shall send the application to the ethics committee specified in the direction immediately following the direction being given; and

(d) the ethics committee specified in the direction shall, subject to the application being valid, give an opinion in relation to the clinical trial to which that application relates within the specified period beginning with the date of the Gene Therapy Advisory Committee's receipt of the application.

(4B) The Chairman, vice-chairman or alternate vice-chairman of the Gene Therapy Advisory Committee may notify the Authority (instead of giving an opinion) within the specified period beginning with the date of the Committee's receipt of an application that the clinical trial to which that application relates does not merit an opinion from the Gene Therapy Advisory Committee.".

Amendment of Schedule 1 to the Clinical Trials Regulations

4.—(1) In Schedule 1 to the Clinical Trials Regulations (conditions and principles of good clinical practice and for the protection of clinical trial subjects), in Part 1 (application and interpretation), paragraph 1 shall be amended as follows.

(2) In sub-paragraph (3), for "If" substitute "Subject to sub-paragraphs (6) and (7), if".

(3) In sub-paragraph (6)—

(**a**) OJ No. L311, 28.11.01, p.67; the Directive has been amended by Directive 2002/98/EC of the European Parliament and of the Council (OJ No. L33, 8.2.2003, p.30), Commission Directive 2003/63/EC (OJ No. L159, 27.6.2003, p.46), Directive 2004/24/EC of the European Parliament and of the Council (OJ No. L136, 30.4.2004, p.85), Directive 2004/27/EC of the European Parliament and of the Council (OJ No. L136, 30.4.2004, p.34) and Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ No. L378, 27.12.06, p.1).

(a) after "a subject who is" insert "a minor or"; and

(b) for "Part 5" substitute "Part 4 in the case of a minor or paragraphs 1 to 5 of Part 5 in the case of an incapacitated adult".

(4) In sub-paragraph (7), for "Part 5" substitute "Part 4 in the case of a minor or paragraphs 1 to 5 of Part 5 in the case of an incapacitated adult".

Amendment of Schedule 2 to the Clinical Trials Regulations

5.—(1) Schedule 2 to the Clinical Trials Regulations (additional provisions relating to ethics committees) shall be amended as follows.

(2) In paragraph 1 (interpretation), in the definition of "expert member", in sub-paragraph (b), for "clinical trials" substitute "clinical research".

(3) In paragraph 3 (membership), in sub-paragraph (3), for "Subject to paragraph 7, the" substitute "The".

(4) In paragraph 6 (committees, meetings and proceedings)—

(a) in sub-paragraph (2), for "sub-paragraph (4)" substitute "sub-paragraphs (4) and (4A)";

(b) for sub-paragraph (4) substitute the following sub-paragraphs—

"(4) All valid applications for an ethics committee opinion must be considered by a full meeting of an ethics committee.

(4A) Where a full meeting of an ethics committee has considered a valid application and reached a provisional opinion, it may delegate the final determination of its opinion in accordance with regulation 15 to the Chairman of the ethics committee or a sub-committee of specified members."; and

(c) after sub-paragraph (5) insert the following sub-paragraph—

"(6) For the purposes of this paragraph, a "full meeting of an ethics committee" is one at which at least seven members of the committee (including any members co-opted under paragraph 8) are present, including at least—

(a) one lay member who is not and never has been—

(i) a health care professional, or

(ii) a chairman, member, director, officer or employee of a health service body; and

(b) one expert member.".

(5) In paragraph 7 (deputies and co-opted members), in sub-paragraph (1), for "An ethics committee" substitute "The appointing authority".

(6) In paragraph 8 (co-opted members)—

(a) in sub-paragraph (3) for "an ethics committee" substitute "a committee that advises or has advised on the ethics of research involving human subjects"; and

(b) for sub-paragraph (5) substitute the following sub-paragraph—

"(5) A co-opted member shall hold and vacate office in accordance with the ethics committee's standing orders and operating procedures adopted under paragraph 6(3).".

Amendment of Schedule 3 to the Clinical Trials Regulations

6. In Schedule 3 to the Clinical Trials Regulations (particulars and documents), in Part 1 (application for ethics committee opinion), in paragraph 2, for "paragraphs 1 to 4 and 6 to 9" substitute "paragraphs 1 to 3 and 6".

Amendment of regulation 7 of the Blood Regulations

7. In regulation 8 of the Blood Regulations (labelling of blood and blood components and traceability), in paragraph (3), after "sub-paragraph (a)" insert "of paragraph (2)".

Amendment of regulation 8 of the Blood Regulations

8. In regulation 9 of the Blood Regulations (hospital blood bank requirements), for sub-paragraph (f) of paragraph 1, substitute—

"(f) retain, for a period of at least 15 years, a record of any serious adverse events which may affect the quality or safety of blood and blood components;".

Amendment of regulation 12B of the Blood Regulations

9. In regulation 12B of the Blood Regulations (requirement to report serious adverse reactions and events), in paragraph (5), for "(3)(b)" substitute "(4)(b)".

Signed by authority of the Secretary of State for Health.

Dawn Primarolo
Minister of State
Department of Health

31st March 2008

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(**a**) (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.

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

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