STATUTORY INSTRUMENTS

# 2006 No. 2984

# MEDICINES

## The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006

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| *Made - - - -* | *15th November 2006* |
| *Laid before Parliament* | *21st November 2006* |
| *Coming into force - -* | *12th December 2006* |

The Secretary of State makes the following Regulations in exercise of the powers conferred upon her by section 2(2) of the European Communities Act 1972(**a**). She has been designated for the purposes of that section in relation to medicinal products(**b**).

**Citation, commencement and interpretation**

**1.**—(1) These Regulations may be cited as the Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 and shall come into force on 12th December 2006.

(2) In these Regulations, the "Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004(**c**).

**Amendment of the Clinical Trials Regulations**

**2.** In Schedule 1 to the Clinical Trial Regulations (conditions and principles of good clinical practice and for the protection of clinical trial subjects), in Part 1 (application and interpretation), in paragraph 1—

(a) in sub-paragraph (4), for "If" substitute "Subject to sub-paragraphs (6) and (7), if"; and

(b) after sub-paragraph (5), insert the following sub-paragraphs—

"(6) Sub-paragraph (7) applies if treatment is being, or is about to be, provided for a subject who is an incapacitated adult as a matter of urgency and, having regard to the nature of the clinical trial and of the particular circumstances of the case—

(a) it is also necessary to take action for the purposes of the clinical trial as a matter of urgency; but

(b) it is not reasonably practicable to meet the conditions set out in paragraphs 1 to 5 of Part 5.

(7) Where this sub-paragraph applies, paragraphs 1 to 5 of Part 5 shall not apply in relation to the subject if the action specified in sub-paragraph (6) is carried out in accordance with a procedure approved by an ethics committee or by an appeal panel appointed under Schedule 4 at the time it gave its favourable opinion.".

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(**a**) 1972 c.68.
(**b**) S.I. 1972/1811.
(**c**) S.I. 2004/1031; as amended by S.I. 2005/2754 and 2759 and 2006/1928.

**Amendment of the Adults with Incapacity (Scotland) Act 2000**

**3.** In section 51 of the Adults with Incapacity (Scotland) Act 2000(**a**) (authority for research) in subsection (3A)—

(a) omit "and" at the end of paragraph (a); and

(b) after paragraph (b), insert—

"(c) without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

(i) treatment is being, or is about to be, provided for an adult who is incapable in relation to a decision about participation in the research as a matter of urgency;

(ii) having regard to the nature of the clinical trial and of the particular circumstances of the case it is necessary to take action for the purposes of the clinical trial as a matter of urgency;

(iii) it has not been reasonably practicable to obtain the consent of any such person;

(iv) it has not been reasonably practicable to obtain the consent of any of the persons mentioned in paragraph (b)(ii)(A) or (B); and

(v) the action to be taken is carried out in accordance with a procedure approved by the Ethics Committee or any other ethics committee or by an appeal panel appointed under Schedule 4 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) at the time it gave its favourable opinion in relation to the clinical trial.".

Signed by authority of the Secretary of State for Health

*Andy Burnham*
Minister of State
Department of Health

15th November 2006

(**a**) 2000 asp 4; section 51 was amended by paragraph 21 of Part 1 of Schedule 10 to S.I. 2004/1031.

## 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**).

Regulation 28(1) of, and Schedule 1 to, the Clinical Trials Regulations implement, among other provisions, article 5(a) of that Directive, which requires that an incapacitated adult cannot be included in a clinical trial of a medicine without the consent of his legal representative.

Regulation 2 amends Schedule 1 to creates an exception to the general rule that an incapacitated adults cannot be included in a clinical trial unless the conditions in paragraphs 1 to 5 of Part 5 of Schedule 1 have been met; in particular that the adult's legal representative (as defined) has given informed consent. The exception applies only when the following conditions are met: (i) treatment is required urgently; (ii) the nature of the trial also requires urgent action; (iii) it is not reasonably practicable to meet the conditions in paragraphs 1 to 5 of Part 5 (obtaining consent etc); and (iv) an ethics committee has given approval to the procedure under which the action is taken.

Regulation 3 amends the Adults with Incapacity (Scotland) Act 2000 consequentially.

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.

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

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