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STATUTORY INSTRUMENTS

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**2006 No. 1928**

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

**Amendment of Schedule 1 to the principal Regulations**

27. Schedule 1 to the principal Regulations (conditions and principles of good clinical practice and for the protection of clinical trial subjects) shall be amended as follows.

- (1) In Part 1 (application and interpretation), in paragraph 2—
  - (i) in the definition of “legal representative”, in paragraph (a)—
    - (aa) in sub-paragraph (i), for “involved in” substitute “connected with”, and
    - (bb) in sub-paragraph (ii), in head (aa), after “adult” insert “or that minor”; and
  - (ii) in the definition of “parental responsibility”, in paragraph (b), for “1985” substitute “1995”.
- (2) For Part 2 (conditions and principles which apply to all clinical trials), substitute the following—

“PART 2

CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

**Principles based on Articles 2 to 5 of the GCP Directive**

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.
2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.
3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.
4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.
6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.
7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.
8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

**Conditions based on Article 3 of the Directive**

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.”

(3) In Part 4 (conditions and principles which apply in relation a minor), in paragraph 1, for “Subject to paragraph 6, a” substitute “A”.