SCHEDULE 1

CONDITIONS AND PRINCIPLES OF GOOD CLINICAL PRACTICE AND FOR THE PROTECTION OF CLINICAL TRIAL SUBJECTS

PART 4

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO A MINOR

Conditions

1. Subject to paragraph 6, a person with parental responsibility for the minor or, if by reason of the emergency nature of the treatment provided as part of the trial no such person can be contacted prior to the proposed inclusion of the subject in the trial, a legal representative for the minor has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

2. That person or legal representative has been provided with a contact point where he may obtain further information about the trial.

3. That person or legal representative has been informed of the right to withdraw the minor from the trial at any time.

4. That person or legal representative has given his informed consent to the minor taking part in the trial.

5. That person with parental responsibility or the legal representative may, without the minor being subject to any resulting detriment, withdraw the minor from the trial at any time by revoking his informed consent.

6. The minor has received information according to his capacity of understanding, from staff with experience with minors, regarding the trial, its risks and its benefits.

7. The explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in the previous paragraph to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator.

8. No incentives or financial inducements are given—

(a) to the minor; or

(b) to a person with parental responsibility for that minor or, as the case may be, the minor's legal representative,

except provision for compensation in the event of injury or loss.

9. The clinical trial relates directly to a clinical condition from which the minor suffers or is of such a nature that it can only be carried out on minors.

10. Some direct benefit for the group of patients involved in the clinical trial is to be obtained from that trial.

11. The clinical trial is necessary to validate data obtained—

(a) in other clinical trials involving persons able to give informed consent, or

(b) by other research methods.

12. The corresponding scientific guidelines of the European Medicines Agency are followed.

Principles

13. Informed consent given by a person with parental responsibility or a legal representative to a minor taking part in a clinical trial shall represent the minor's presumed will.

14. The clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development.

15. The risk threshold and the degree of distress have to be specially defined and constantly monitored.

16. The interests of the patient always prevail over those of science and society.

Status:
Point in time view as at 01/05/2004.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 4.