STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 1

INTRODUCTORY PROVISIONS

Responsibility for functions under the Directive

4.—(1) For the purposes of the Directive, the competent authority of the United Kingdom shall be the licensing authority.

(2) Subject to paragraph (3), the licensing authority shall perform, as respects the United Kingdom, the functions of the Member State under the Directive.

(3) Paragraph (2) shall not apply in so far as any functions fall to be performed by the exercise of any powers or duties which are conferred by any provision of these Regulations, or by any provision of the Act as applied by these Regulations, on a person or body other than the licensing authority.