

Statutory Instrument 2006 No. 2984

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

Coming into force 12th December 2006

EXPLANATORY NOTE:

Regulation 2 amends Schedule 1 to create an exception to the general rule that an incapacitated adult 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.