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STATUTORY INSTRUMENTS

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**2004 No. 1031**

The Medicines for Human Use  
(Clinical Trials) Regulations 2004

PART 5

PHARMACOVIGILANCE

**Clinical trials conducted in third countries**

**34.** If a clinical trial is being conducted at a trial site in a third country in addition to sites in the United Kingdom, the sponsor of that trial shall ensure that all suspected unexpected serious adverse reactions occurring at that site are entered into the European database established in accordance with Article 11 of the Directive.