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STATUTORY INSTRUMENTS

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**2004 No. 1031**

The Medicines for Human Use  
(Clinical Trials) Regulations 2004

PART 6

MANUFACTURE AND IMPORTATION OF  
INVESTIGATIONAL MEDICINAL PRODUCTS

**Obligations of manufacturing authorisation holder**

- 42.** The holder of a manufacturing authorisation shall comply with—
- (a) the principles and guidelines of good manufacturing practice; and
  - (b) the provisions referred to in regulation 40(3).