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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

**Exemption for hospitals and health centres**

**37.**—(1) The restriction imposed by regulation 36(1) shall not apply to the assembly of an investigational medicinal product where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to in paragraph (1) are that—

(a) the assembly is carried out in—

(i) in a hospital or health centre, and

(ii) by a doctor, a pharmacist or a person acting under the supervision of a pharmacist;  
and

(b) the investigational medicinal products are assembled exclusively for use in—

(i) that hospital or health centre, or

(ii) any other hospital or health centre which is a trial site for the clinical trial in which the product is to be used.

**Changes to legislation:**

There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 37.