
STATUTORY INSTRUMENTS

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.