STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

Manufacturing and wholesale dealing

Conditions for holding a manufacturer's licence

Conditions for manufacturer's licence

36.—(1) Regulations 37 to 41 apply to the holder of a manufacturer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products).

(2) Those provisions are regulations 37(2)(b), 38, 39(6)(a) and (8) , 40 and 41.

(3) The requirements of Part 1 of Schedule 6 apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

Manufacturing and assembly

37.—(1) This regulation applies in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The licence holder must—

(a) comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive; and

(b) use active substances as starting materials only if those substances have been manufactured or assembled in accordance with the principles and guidelines mentioned in paragraph (a), in so far as those principles and guidelines relate to starting materials (but see paragraph (3)).

(3) The requirement in paragraph (2)(b) does not apply in relation to the manufacture or assembly of special medicinal products.

(4) The licence holder must maintain such staff, premises and equipment as are necessary for the stages of manufacture and assembly of medicinal products undertaken by the licence holder in accordance with—

(a) the manufacturer's licence; and

(b) the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applying to the medicinal products.

(5) The licence holder must not manufacture or assemble medicinal products, or classes of medicinal products, other than those specified in the licence.

(6) The licence holder must not manufacture or assemble medicinal products on premises other than those specified in the licence as approved by the licensing authority for the purpose.

(7) The licence holder must ensure that blood, or blood components, imported into the United Kingdom and used as a starting material or raw material in the manufacture of a medicinal product meet—

(a) the standards of quality and safety specified in Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components(**1**); or

(b) equivalent standards.

Imports from states other than EEA States

38.—(1) This regulation applies in relation to a manufacturer's licence relating to the import of medicinal products.

(2) The licence holder must comply with the conditions set out in this regulation in relation to the import of medicinal products from a state other than an EEA State.

(3) The licence holder must—

(a) comply with the principles and guidelines on good manufacturing practice in the Good Manufacturing Practice Directive in so far as they are relevant to the import of medicinal products; and

(b) ensure that active substances have been used as starting materials in the manufacture of medicinal products, other than special medicinal products, imported from a state other than an EEA State only if those substances have been manufactured or assembled in accordance with the principles and guidelines mentioned in paragraph (a), in so far as those principles and guidelines relate to starting materials.

Further requirements for manufacturer's licence

39.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of medicinal products under the licence as are appropriate in order to maintain the quality of the medicinal products.

(3) The licence holder must ensure that any arrangements made for the handling, control, storage and distribution of medicinal products are adequate to maintain the quality of the products.

(4) The licence holder must not handle, control, store or distribute medicinal products on any premises other than those specified in the licence as approved by the licensing authority for the purpose.

(5) The licence holder must inform the licensing authority before making a material alteration to the premises or facilities used under the licence, or to the purposes for which those premises or facilities are used.

(6) The licence holder must inform the licensing authority of any proposed change to—

(a) the qualified person; and

(b) any person named in the licence as having responsibility for quality control.

(7) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised

(**1**) OJ L 91, 30.3.2004, p.25.

in writing by the licensing authority to do anything that the licensing authority could have done for the purposes of verifying a statement made in an application for a licence.

(8) In distributing a medicinal product by way of wholesale dealing, the licence holder must comply with regulations 43(1), (2) and (5) and 44(2) and (3) as if the licence holder were the holder of a wholesale dealer's licence.

Obligation to provide information relating to control methods

40.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licensing authority may require the licence holder to provide the authority with proof of the control methods employed by the holder in relation to a medicinal product.

Requirements as to qualified persons

41.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must ensure that there is at the disposal of the holder at all times at least one qualified person who is responsible for carrying out, in relation to medicinal products manufactured, assembled or imported under the licence, the duties specified in Part 3 of Schedule 7.

(3) If the licence holder satisfies the requirements of Part 1 or 2 of Schedule 7 the licence holder may act as a qualified person.

(4) A qualified person may be treated by the licence holder as satisfying the requirements of Part 1 or 2 of Schedule 7 if that person produces evidence that he or she—

(a) is a member of a body specified in paragraph (5); and

(b) is regarded by that body as satisfying those requirements.

(5) Those bodies are—

(a) the Society of Biology;

(b) the Royal Pharmaceutical Society;

(c) the Pharmaceutical Society of Northern Ireland;

(d) the Royal Society of Chemistry; and

(e) such other body as may be specified by the licensing authority for the purpose of this paragraph.

(6) Where the qualified person changes, the licence holder must give the licensing authority advance notification of—

(a) that change; and

(b) the name, address and qualifications of the new qualified person.

(7) The licence holder must not permit any person to act as a qualified person other than the person named in the licence or another person notified to the licensing authority under paragraph (6).

(8) Paragraph (9) applies if the licensing authority thinks, after giving the licence holder and a person acting as a qualified person the opportunity to make representations (orally or in writing), that the person—

(a) does not satisfy the requirements of Part 1 or 2 of Schedule 7 in relation to qualifications or experience;

(b) does not satisfy paragraph (b) of the definition of "qualified person" in regulation 8; or

(c) is failing to carry out the duties referred to in paragraph (2) adequately or at all.

(9) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a qualified person.

(10) The licence holder must at all times provide and maintain such staff, premises and equipment as are necessary to enable the qualified person to carry out the duties referred to in paragraph (2).

(11) The licence holder is not obliged to meet the requirements of this regulation in relation to any activity under the licence which relates to special medicinal products or to products authorised on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc).