STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[[F1]Manufacture and distribution of medicinal products and active substances**]**

[[F1]CHAPTER 2**]**

Manufacturing and wholesale dealing

Miscellaneous and offences

Certification of manufacturer's licence

31.—(1) The licensing authority must issue a certificate in accordance with the following paragraphs of this regulation in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products if requested to do so by—

(a) subject to paragraph (5), the holder of the licence;

(b) a person who intends to export a medicinal product manufactured or assembled by the holder under the licence; or

(c) the competent authorities of a country other than **[**[F1]the United Kingdom**]** into which a medicinal product manufactured or assembled under the licence is, or is proposed to be, imported.

(2) The certificate must contain —

(a) information sufficient to identify the holder of the manufacturer's licence;

(b) details of the medicinal products that may be manufactured or assembled under the licence; and

(c) any other information concerning the holder, the product or the licence that the licensing authority thinks it appropriate to include, including information relating to clinical trials.

(3) If—

(a) a request is made—

(i) under paragraph (1)(a) in relation to the export or the proposed export of a product, or

(ii) under paragraph (1)(b) or (c); and

(b) there is a **[**[F2]UK marketing authorisation, EU marketing authorisation, Article 126a authorisation**]** or a traditional herbal registration in force for any product to which the licence relates,

the certificate must be accompanied by the summary of the product characteristics relating to that product.

(4) The licensing authority may restrict the information provided under sub-paragraphs (2)(a) and (b) and paragraph (3) to information relating to the specific medicinal products mentioned in the request made under paragraph (1).

(5) A licence holder who makes a request under paragraph (1) must—

(a) produce to the licensing authority a **[**F3UK marketing authorisation, EU marketing authorisation, Article 126a authorisation**]**, certificate of registration or traditional herbal registration in relation to any product to which the certificate is to relate; or

(b) make a declaration to the licensing authority explaining why no **[**F4UK marketing authorisation, EU marketing authorisation, Article 126a authorisation**]**, certificate of registration or traditional herbal registration is available.

(6) The licensing authority must have regard to the prevailing administrative arrangements of the World Health Organisation when issuing the certificate.

Textual Amendments

F1 Words in reg. 31(1)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in reg. 31(3)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 31(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Words in reg. 31(5)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 16**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 31.