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

Grant etc of licences

Manufacturing of medicinal products

17.—**[**[F1](1) A person may not except in accordance with a licence (a "manufacturer's licence")—

(a) manufacture a medicinal product,

(b) assemble a medicinal product,

(c) import a medicinal product into Great Britain from a country other than—

(i) Northern Ireland, or

(ii) an approved country for import,

(d) import a medicinal product into Northern Ireland from a country other than an EEA State, or

(e) possess a medicinal product for the purpose of any activity in sub-paragraphs (a) to (d).**]**

(2) Paragraph (1) is subject to **[**[F2]paragraphs (3) to (9)**]** .

(3) Paragraph (1) applies in relation to an investigational medicinal product only—

(a) if the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration; and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that authorisation, certificate or registration.

(4) In paragraph (3), "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or

[[F3](aa) a UK marketing authorisation; or**]**

(b) an EU marketing authorisation.

(5) Paragraph (1) does not apply to a person who, in connection with the importation of a medicinal product [F4]...—

(a) provides facilities solely for transporting the product; or

(b) acting as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.

(6) Paragraph (1) does not apply to a person who imports a medicinal product for administration to himself or herself or to any other person who is a member of that person's household.

[[F5](7) Paragraph (1) does not apply to imports into Northern Ireland from Great Britain of—

(a) special medicinal products, and

(b) medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(8) For the purposes of paragraph (7) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.**]**

[[F6](9) Paragraph (1)(d) does not apply to the importation of a medicinal product into Northern Ireland from Great Britain by the holder of a wholesale dealer's licence, where the following conditions are met—

(a) the medicinal product has undergone—

(i) in an EEA State, the quality control testing provided for by Article 51 of the 2001 Directive, or

(ii) in the United Kingdom, checks in accordance with these Regulations and the requirements of the marketing authorisation relating to the product and that these are appropriately certified;

(b) the batch release of the medicinal product has been undertaken—

(i) in Northern Ireland or an EEA State, by a qualified person in accordance with Article 51(1) of the 2001 Directive, and it is accompanied by the appropriate control reports, or

(ii) in Great Britain, by a qualified person applying equivalent standards;

(c) the medicinal product has a UKMA(UK) or UKMA(NI);

(d) the importation of the medicinal product is with a view to its sale or supply in Northern Ireland only; and

(e) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive, that the features specified in paragraph 18A of Schedule 24 are affixed on the packaging.**]**

Textual Amendments

F1 Reg. 17(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **14(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 9(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 17(2) substituted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **3(2)**

F3 Reg. 17(4)(aa) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **14(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 9(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Words in reg. 17(5) omitted (31.12.2020) by virtue of S.I. 2019/775, reg. 14(5) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(d)**)

F5 Reg. 17(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **14(6)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 9(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Reg. 17(9) inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **3(3)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 17.