STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[F1Manufacture and distribution of medicinal products and active substances]

[F1CHAPTER 4

Importation, manufacture and distribution of active substances

[F1Criteria for importation, manufacture or distribution of active substances

45M.—(1) A person may not—

(a) import;

(b) manufacture; or

(c) distribute,

an active substance unless that person is registered with the licensing authority in accordance with regulation 45N and the requirements in regulation 45O are met.

(2) Paragraph (1) applies in relation to an active substance which is to be used in an investigational medicinal product only—

[F2(a) if—

(i) in the case of a product for sale or supply in Great Britain, the product has a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in the case of a product for sale or supply in Northern Ireland, the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration, and]

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

(3) Paragraph (1)(a) does not apply to a person who, in connection with the importation of an active substance F3...—

(a) provides facilities solely for transporting the active substance; or

(b) acting as an import agent, imports the active substance solely to the order of another person who holds a certificate of good manufacturing practice issued by the licensing authority.]

Textual Amendments

F1 Pt. 3 Chs. 3, 4 inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **16**

F2 Reg. 45M(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **42(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 31**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 45M(3) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **42(3)**; 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 45M.