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

Conditions for holding a wholesale dealer's licence

Obligations of licence holder

43.—**[**[F1](1) The licence holder must comply with the guidelines on good distribution practice—

(a) in the case of a licence holder in Great Britain, published under, or that apply by virtue of, regulation C17;

(b) in the case of a licence holder in Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive.**]**

(2) The licence holder must ensure, within the limits of the holder's responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met.

(3) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of medicinal products under the licence as are necessary—

(a) to maintain the quality of the products; and

(b) to ensure their proper distribution.

(4) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(5) Subject to paragraph (6), the licence holder must not sell or supply a medicinal product, or offer it for sale or supply, unless—

[[F2](a) in the case of a product for sale or supply—

(i) in Great Britain, there is a UKMA(GB), UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation"), or

(ii) in Northern Ireland, there is a UKMA(NI), UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), and EU marketing authorisation or an Article 126a authorisation (an "authorisation"),

in force in relation to the product; and**]**

(b) the sale or supply, or offer for sale or supply, is in accordance with the authorisation.

(6) The restriction in paragraph (5) does not apply to—

(a) the sale or supply, or offer for sale or supply, of a special medicinal product **[**F3in the United Kingdom**]**;

[F4(aa) the supply, or offer for supply, of an unauthorised EAMS medicinal product in the United Kingdom;**]**

(b) the export **[**F5from Northern Ireland**]** to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration by virtue of legislation adopted by that State under Article 5(1) of the 2001 Directive; F6...

[F7(ba) the export from Great Britain to an approved country for import, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that country without—

(i) a marketing authorisation, certificate of registration or traditional herbal registration within the meaning of the 2001 Directive, by virtue of legislation adopted by that country under Article 5(1) of that Directive, where the approved country for import is an EEA State, or

(ii) such equivalent authorisation, certificate or registration in the approved country for import, under legislation in that country that makes provision that is equivalent to Article 5(1) of the 2001 Directive, where the approved country for import is not an EEA State.**]**

(c) the sale or supply, or offer for sale or supply, of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of the product under regulation 174; **[**F8or

[F9(d) the wholesale distribution of medicinal products—

(i) from Northern Ireland to a person in a country other than Great Britain or a country other than an EEA State; or

(ii) from Great Britain to a person in a country other than Northern Ireland or a country other than an approved country for import.**]**

(7) The licence holder must—

(a) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the withdrawal or recall from sale of medicinal products in accordance with paragraph (b);

(b) maintain an emergency plan to ensure effective implementation of the recall from the market of a medicinal product where recall is—

[F10(i) ordered by the licensing authority or—

(aa) in the case of a licence holder in Great Britain, by an appropriate authority for the licensing of medicinal products in an approved country for import;

(bb) in the case of a licence holder in Northern Ireland, by the competent authority of any EEA State, or**]**

[F11(ii) carried out in co-operation with the manufacturer of, or the holder of—

(aa) in the case of a product for sale or supply in Great Britain, the UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration, or

(bb) in the case of a product for sale or supply in Northern Ireland, the UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

for, the product; and**]**

[F12(c) keep records in relation to the receipt, dispatch or brokering of medicinal products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the date of brokering,

(iv) the name of the medicinal product,

(v) the quantity of the product received, dispatched or brokered,

(vi) the name and address of the person from whom the products were received or to whom they are dispatched,

(vii) **[**F13where the receipt, dispatch or brokering of medicinal products takes places in Northern Ireland,**]** the batch number of medicinal products bearing safety features referred to in point (o) of Article 54 of the 2001 Directive.***/***

[F12(8) A licence holder **[**F14in Northern Ireland**]** ("L") who imports from another EEA State a medicinal product in relation to which L is not the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or a traditional herbal registration shall—

(a) notify the intention to import that product to the holder of the authorisation and—

(i) in the case of a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004, to the EMA; or

(ii) in any other case, the licensing authority; and

(b) pay a fee to the EMA in accordance with Article 76(4) of the 2001 Directive or the licensing authority as the case may be, in accordance with the Fees Regulations,

but this paragraph does not apply in relation to the wholesale distribution of medicinal products to a person in a **[**F15country other than an EEA State**].]**

[

F16(8A) Paragraph (8B) applies to a person ("P") who—

(a) imports into Great Britain a medicinal product, other than for the sole purpose of wholesale distribution of that product to a person in a country other than the United Kingdom; but

(b) is not the holder of a UK marketing authorisation, certificate of registration or traditional herbal registration in respect of that product.

(8B) Where this paragraph applies, P must—

(a) notify—

(i) the holder of any authorisation, certificate or registration, granted by an authority in the country from which the product is exported, to sell or supply that product in that country, and

(ii) the licensing authority,

of the intention to import that product; and

(b) pay a fee to the licensing authority in accordance with the Fees Regulations.**]**

(9) 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 in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).

[F17(10) The holder **[**F18of a licence relating to wholesale dealings in Northern Ireland**]** ("L") must verify in accordance with paragraph (11) that any medicinal products received by L that are required by Article 54a of the Directive to bear safety features are not falsified but this paragraph does not apply in relation to the distribution of medicinal products received from a third country by a person to a person in a third country.

(11) Verification under this paragraph is carried out by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted under Article 54a(2) of the 2001 Directive.

(12) The licence holder must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

(13) The licence holder must immediately inform the licensing authority and, where applicable, the **[**F19UK marketing authorisation holder or EU marketing authorisation holder**]**, of medicinal products which the licence holder receives or is offered which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified.

(14) **[**F20Where the medicinal product is obtained through brokering—

(a) a licence holder in Great Britain must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b);

(b) a licence holder in Northern Ireland must verify that the broker involved is validly registered with the licensing authority or the competent authority of an EEA State.**]**

(15) In this regulation **[**F21as it applies in the case of a product for sale or supply in Northern Ireland**]**, "marketing authorisation" means—

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

(b) an EU marketing authorisation.**]]**

Textual Amendments

F1 Reg. 43(1) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(a)**)

F2 Reg. 43(5)(a) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(b)**)

F3 Words in reg. 43(6)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Reg. 43(6)(aa) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **7** (with reg. 19)

F5 Words in reg. 43(6)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(aa)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Word in reg. 43(6)(b) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **6(2)(a)** and word in reg. 43(6)(b) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **6(2)(a)**

F7 Reg. 43(6)(ba) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(d)(i)(ii)(aa)(bb)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Reg. 43(6)(d) and preceding word inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **6(2)(b)** and reg. 43(6)(d) and preceding word

inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **6(2)(b)**

F9 Reg. 43(6)(d) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(c)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F10 Reg. 43(7)(b)(i) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(5)(a)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(f)(i)**)

F11 Reg. 43(7)(b)(ii) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(5)(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(f)(ii)**)

F12 Reg. 43(7)(c)(8) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **14(a)**

F13 Words in reg. 43(7)(c)(vii) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(5)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 43(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(5A)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Words in reg. 43(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(5A)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Reg. 43(8A)(8B) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(i)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F17 Reg. 43(10)-(15) substituted for reg. 43(10) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **14(b)**

F18 Words in reg. 43(10) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(7)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(j)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F19 Words in reg. 43(13) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(8)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(k)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 Reg. 43(14) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(9)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(l)**)

F21 Words in reg. 43(15) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(10)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(l)**); 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 43.