STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[F1Manufacture and distribution of medicinal products and active substances]

[F1CHAPTER 2]

Manufacturing and wholesale dealing

Textual Amendments

F1 Pt. 3 Ch. 2 heading inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **4**

Grant etc of licences

Manufacturing of medicinal products

17.—[F2(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 [F3paragraphs (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

[F4(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 [F5]...—

(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.

[[F6](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.**]**

[[F7](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

F2 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)**

F3 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)**

F4 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)**

F5 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)**)

F6 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)**

F7 Reg. 17(9) inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **3(3)**

[F8Wholesale dealing in medicinal products

18.—(1) A person may not except in accordance with a licence (a "wholesale dealer's licence")—

(a) distribute a medicinal product by way of wholesale dealing; F9...

(b) possess a medicinal product for the purpose of such **[**F10distribution; F11...**]**

[F12(c) import a medicinal product into Great Britain from an approved country for import**][**F13; or

(d) supply a listed NIMAR product from Great Britain to Northern Ireland.**]**

(2) Paragraph (1)—

(a) does not apply—

(i) to anything done in relation to a medicinal product by the holder of a manufacturer's licence in respect of that product,

(ii) where the product concerned is an investigational medicinal product, or

(iii) if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source; and

(b) is subject to regulation 19.

[F14(2A) Paragraph (1)(c) does not apply to imports into Great Britain from an EEA State of medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(2B) For the purposes of paragraph (2A) 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.**]**

(3) Distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, is not to be taken to be in accordance with a wholesale dealer's licence unless the distribution is carried on, or as the case may be the product held, at premises located in the UK and specified in the licence.

(4) In these Regulations a reference to distributing a product **[**F15(including a listed NIMAR product)**]** by way of wholesale dealing is a reference to—

(a) selling or supplying it; or

(b) procuring or holding it or exporting it for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (5).

(5) Those purposes are—

(a) selling or supplying the product; or

(b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

[F16(6) A wholesale dealer's licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession of a medicinal product for the purpose of such distribution, unless—

(a) in the case of a product for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration is in force in respect of the product, F17...

(b) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product, **[**F18or

(c) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) is in force in respect of the product,**]**

but this is subject to the exceptions in regulation 43(6).**]**

(7) In **[**F19paragraph (6)(b)**]**, "marketing authorisation" means—

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

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

Textual Amendments

F8 Reg. 18 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **5**

F9 Word in reg. 18(1)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in reg. 18(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Word in reg. 18(1)(b) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(a)(i)**

F12 Reg. 18(1)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(c)** (as amended S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(a)(i)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Reg. 18(1)(d) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(a)(ii)**

F14 Reg. 18(2A)(2B) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Words in reg. 18(4) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(b)**

F16 Reg. 18(6) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(3)** (as substituted by (S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F17 Word in reg. 18(6)(a) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(c)(i)**

F18 Reg. 18(6)(c) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(c)(ii)**

F19 Words in reg. 18(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F20Approved country for import

18A.—(1) The licensing authority must—

(a) publish a list of countries from which medicinal products may be imported under a wholesale dealing licence ("approved country for import list"); and

(b) only include in that list a country which is included in the approved country for batch testing list.

(2) In order to determine whether a country should be included in the approved country for import list, the licensing authority may, in particular, take into account—

(a) the country's system for ensuring that each batch of a medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of that product;

(b) the country's rules for good distribution practice;

(c) the regularity of inspections to verify compliance with good distribution practice;

(d) the effectiveness of enforcement of good distribution practice;

(e) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers and distributers of medicinal products;

(f) any on-site review of that country's regulatory system undertaken by the licensing authority;

(g) any on-site inspection of a manufacturing site in that country observed by the licensing authority; and

(h) any other relevant documentation available to the licensing authority.

(3) The licensing authority must—

(a) remove a country from the approved country for import list if that country is removed from the approved country for batch testing list;

(b) in any event review the countries it has included in the approved country for import list to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(c) undertake that review at least every three years beginning with the date on which that country is included in that list.**]**

Textual Amendments

F20 Reg. 18A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **16**; 2020 c. 1, Sch. 5 para. 1(1)

Exemptions from requirement for wholesale dealer's licence

19.—(1) Regulation 18 does not apply to the sale or offer for sale of a medicinal product by way of wholesale dealing, or possession for the purpose of such sale or offer, where paragraph (2) applies and the person selling or offering the product for sale is—

[F21(a) the holder of—

(i) in the case of a product for sale or supply in Great Britain **[**F22(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)**]**, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation") which relates to the product, or

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation") which relates to the product,

including a holder of an authorisation who manufactured or assembled the product; or**]**

(b) a person who is not the holder of an authorisation in relation to the product but manufactured or assembled the product **[**F23in the United Kingdom**]** to the order of a person who is the holder of an authorisation relating to the product.

(2) This paragraph applies if—

(a) until the sale, the medicinal product has been kept on the premises of the person who manufactured or assembled the product (in this regulation referred to as "authorised premises"); and

(b) those premises are premises authorised for use for manufacture or assembly by that person's manufacturer's licence.

(3) For the purposes of this regulation, a medicinal product is regarded as having been kept on authorised premises at a time when—

(a) it was being moved from one set of authorised premises to another, or from one part of authorised premises to another part; or

(b) it was being moved from authorised premises by way of delivery to a purchaser.

(4) Regulation 18 does not apply to a person who in connection with the importation of a medicinal product—

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

(b) acting as an import agent, handles the product where the product is imported solely to the order of another person who intends to sell the product or offer it for sale by way of wholesale dealing or to distribute it in any other way.

[F24(4A) Regulation 18 does not apply in connection with the distribution by way of wholesale dealing of a medicinal product to be used for vaccination or immunisation against coronavirus or influenza virus, where the person distributing the medicinal product—

(a) was supplied with the medicinal product for the purposes of the administration of it under relevant arrangements;

(b) is supplying the medicinal product for the purposes of the administration of it by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements; and

(c) is authorised by the body making the arrangements to supply the medicinal product as mentioned in sub-paragraph (b) under the relevant arrangements.

(4B) Regulation 18 does not apply in connection with the distribution by way of wholesale dealing of a medicinal product to be supplied or administered in accordance with a protocol of the type mentioned in regulation 247, where the person distributing the medicinal product—

(a) was supplied with the medicinal product for the purposes of the supply or administration of it to a patient under relevant arrangements;

(b) is supplying the medicinal product for the purposes of the supply or administration of it to a patient by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements; and

(c) is authorised by the body making the arrangements to supply the medicinal product as mentioned in sub-paragraph (b) under the relevant arrangements.

(4C) In this regulation, "relevant arrangements" means—

(a) arrangements for the provision of services as part of—

(i) in England, the health service as defined by section 275(1) of the National Health Service Act 2006,

(ii) in Scotland, the health service as defined by section 108(1) of the National Health Service (Scotland) Act 1978,

(iii) in Wales, the health service as defined by section 206(1) of the National Health Service (Wales) Act 2006, and

(iv) in Northern Ireland, the system of health and social care promoted under section 2(1) of the Health and Social Care (Reform) Act (Northern Ireland) 2009; or

(b) arrangements for the provision of services (otherwise than as mentioned in sub-paragraph (a)) as part of the medical services of Her Majesty's Forces.

(4D) Paragraphs (4A) to (4C) cease to have effect on 1st April **[**F25 2026**].]**

F26 (5) . . . . . .

[F27 (6) Regulation 18 does not apply to a person ("P") who imports a medicinal product into Great Britain from an approved country for import for administration to P or to any other person who is a member of P's household.**]**

Textual Amendments

F21 Reg. 19(1)(a) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **17(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 11(a)**)

F22 Words in reg. 19(1)(a)(i) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **6**

F23 Words in reg. 19(1)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **17(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F24 Reg. 19(4A)-(4D) inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **4** and reg. 19(4A)-(4D) inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **4**

F25 Word in reg. 19(4D) substituted (E.W.S.) (31.3.2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024 (S.I. 2024/344), regs. 1(2), **4** and (N.I.) (31.3.2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024 (S.R. 2024/68), regs. 1(2), **4**

F26 Reg. 19(5) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **6**

F27 Reg. 19(6) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **17(4)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 11(b)**)

Mixing of medicines

20.—(1) Regulation 17(1) (manufacturing of medicinal products) does not apply to the mixing of medicines by—

(a) a nurse independent prescriber;

(b) a pharmacist independent prescriber;

(c) a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient;

[F28(ca) physiotherapist independent prescriber;

(cb) podiatrist independent prescriber;]

[F29(cc) a therapeutic radiographer independent prescriber;]

[F30(cd) a paramedic independent prescriber;]

(d) a person acting in accordance with the written directions of a—

(i) doctor,

(ii) dentist,

(iii) nurse independent prescriber, F31...

[F32(iv) pharmacist independent prescriber,

(v) physiotherapist independent prescriber, F33...

(vi) podiatrist independent prescriber; or]

[F34(vii) therapeutic radiographer independent prescriber; or]

[F35(viii) paramedic independent prescriber; or]

(e) a person acting in accordance with the written directions of a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient.

(2) In this regulation "mixing of medicines" means the combining of two or more medicinal products together for the purposes of administering them to meet the needs of an individual patient.

Textual Amendments

F28 Reg. 20(1)(ca)(cb) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **7(a)**

F29 Reg. 20(1)(cc) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **5(2)(a)** and reg. 20(1)(cc) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **5(2)(a)**

F30 Reg. 20(1)(cd) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **4(2)(a)** and reg. 20(1)(cd) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **4(2)(a)**

F31 Word in reg. 20(1)(d)(iii) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **7(b)**

F32 Reg. 20(1)(d)(iv)-(vi) substituted for reg. 20(1)(d)(iv) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **7(c)**

F33 Word in reg. 20(1)(d)(v) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **5(2)(b)(i)** and word in reg. 20(1)(d)(v) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **5(2)(b)(i)**

F34 Reg. 20(1)(d)(vii) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **5(2)(b)(ii)** and reg. 20(1)(d)(vii) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **5(2)(b)(ii)**

F35 Reg. 20(1)(d)(viii) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **4(2)(b)** and reg. 20(1)(d)(viii) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **4(2)(b)**

Application for manufacturer's or wholesale dealer's licence

21.—(1) An application for a grant of a licence under this Part must—

(a) be made to the licensing authority;

(b) be made in the way and form specified in Schedule 3; and

(c) contain or be accompanied by the information, documents, samples and other material specified in that Schedule.

(2) An application must indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.

Factors relevant to determination of application for manufacturer's or wholesale dealer's licence

22.—(1) In dealing with an application for a manufacturer's licence the licensing authority must in particular take into consideration—

(a) the operations proposed to be carried out under the licence;

(b) the premises in which those operations are to be carried out;

(c) the equipment which is or will be available on those premises for carrying out those operations;

(d) the qualifications of the persons under whose supervision the operations will be carried out; and

(e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.

(2) In dealing with an application for a wholesale dealer's licence the licensing authority must in particular take into consideration—

(a) the premises on which medicinal products of the descriptions to which the application relates will be stored;

(b) the equipment which is or will be available for storing medicinal products on those premises;

(c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and

(d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

Grant or refusal of licence

23.—(1) Subject to the following provisions of these Regulations, on an application to the licensing authority for a licence under this Part the licensing authority may—

(a) grant a licence containing such provisions as it considers appropriate; or

(b) refuse to grant a licence if having regard to the provisions of these Regulations [F36]... it considers it necessary or appropriate to do so.

(2) The licensing authority must grant or refuse an application for a licence under this Part within the period of 90 days beginning immediately after the day on which it receives the application.

(3) Paragraph (2) applies to an application only if the requirements of Schedule 3 have been met.

(4) If a notice under regulation 30 requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (2).

(5) In paragraph (4), the "information period" means the period—

(a) beginning with the day on which the notice is given, and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(6) The licensing authority must give the applicant a notice stating the reasons for its decision in any case where—

(a) the licensing authority refuses to grant an application for a licence; or

(b) the licensing authority grants a licence otherwise than in accordance with the application and the applicant requests a statement of its reasons.

Textual Amendments

F36 Words in reg. 23(1)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **19**; 2020 c. 1, Sch. 5 para. 1(1)

Standard provisions of licences

24.—(1) The standard provisions set out in Schedule 4 may be incorporated by the licensing authority in a licence under this Part granted on or after the date on which these Regulations come into force.

(2) The standard provisions may be incorporated in a licence with or without modifications and either generally or in relation to medicinal products of a particular class.

[[F37](3) In Schedule 4, in relation to a licence holder in Great Britain, references to the principles and guidelines set out in the Good Manufacturing Practice Directive are to those principles and guidelines as they apply under or by virtue of regulation B17.**]**

Textual Amendments

F37 Reg. 24(3) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **19A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 13**)

Duration of licence

25. A licence granted under this Part remains in force until—

(a) the licence is revoked by the licensing authority; or

(b) the licence is surrendered by the holder.

General power to suspend, revoke or vary licences

26.—(1) The licensing authority may in accordance with the procedure specified in regulation 27—

(a) suspend a licence under this Part for such period as the authority thinks fit;

(b) revoke a licence under this Part; or

(c) vary the provisions of a licence under this Part.

(2) The suspension or revocation of a licence may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the grounds specified in—

(a) paragraph (4) (in relation to either a manufacturer's licence or a wholesale dealer's licence);

(b) paragraph (5) (in relation to a manufacturer's licence); or

(c) paragraph (6) (in relation to a wholesale dealer's licence).

(4) Those grounds are that—

(a) the information in the application as a result of which the licence was granted was false or incomplete in a material respect;

(b) a material change of circumstances has occurred in relation to any of the matters stated in the application;

(c) the holder of the licence has materially contravened a provision of it; or

(d) the holder of the licence has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the licence relates when required to do so under regulation 30(2).

(5) In relation to a manufacturer's licence, the powers conferred by this regulation may also be exercised on either or both of the following grounds—

[F38(a) that the holder of the manufacturer's licence has manufactured or assembled medicinal products to the order of a person who holds—

(i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation"), F39...

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI) or a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation"), **[**F40or

(iii) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) (an "authorisation"),**]**

and has habitually failed to comply with the provisions of that authorisation; or**]**

(b) that the holder of the manufacturer's licence does not have appropriate facilities to carry out processes of manufacture or assembly authorised by the licence.

(6) In relation to a wholesale dealer's licence, the powers conferred by this regulation may also be exercised on the grounds that the equipment and facilities available to the holder of the licence for storing or distributing medicinal products are inadequate to maintain the quality of medicinal products of one or more descriptions to which the licence relates.

Textual Amendments

F38 Reg. 26(5)(a) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **21** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 15**)

F39 Word in reg. 26(5)(a)(i) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **7(a)**

F40 Reg. 26(5)(a)(iii) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **7(b)**

Procedure where licensing authority proposes to suspend, revoke or vary licence

27.—(1) This regulation applies where—

(a) the provisions of regulation 28 do not apply; and

(b) the licensing authority proposes to suspend, vary or revoke a licence under regulation 26.

(2) The licensing authority must notify the licence holder in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, revocation or variation should take effect.

(3) The licence holder may before the date specified in the notice—

(a) make written representations to the licensing authority with respect to the proposal; or

(b) notify the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations.

(4) If the licence holder makes written representations in accordance with paragraph 3(a) the licensing authority must take those representations into account before making a decision in the matter.

[[F41](5) If the licence holder notifies the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations in accordance with paragraph (3)(b)—

(a) Schedule 5 has effect; and

(b) the licence holder must pay a fee for a review upon oral representations in accordance with the Fees Regulations.**]**

(6) If the licensing authority proceeds to suspend, revoke or vary a licence in accordance with the provisions of regulation 26 it must give a notice to the licence holder.

(7) The notice must—

(a) give particulars of the suspension, revocation or variation; and

(b) give reasons for the decision to suspend, revoke or vary the licence.

(8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

Textual Amendments

F41 Reg. 27(5) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **8**

Suspension of licence in cases of urgency

28.—(1) Notwithstanding anything in the preceding provisions of this Part, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under this Part with immediate effect, the licensing authority may do so for a period not exceeding three months.

(2) This paragraph applies where—

(a) a licence has been suspended under paragraph (1); and

(b) it appears to the licensing authority that it is necessary to consider whether the licence should be further suspended, revoked or varied.

(3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 27 (but this is subject to paragraphs (4) and (5)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 27 and any proceedings under that regulation have not been finally disposed of before the end of the period for which the licence was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 27 to suspend, vary or revoke the licence is made on an application to the High Court under regulation 322(4) paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a).

Variation of licence on the application of the holder

29.—(1) This regulation applies if the holder of a licence under this Part applies to the licensing authority for a variation of the licence.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant;

(d) be accompanied by such information as may be required to enable the licensing authority to consider the application; and

(e) be accompanied by the required fee (if any).

(3) The licensing authority must consider an application made in accordance with this regulation.

(4) If paragraph (5) applies, the licensing authority must vary the licence or refuse to vary it before the end of the period allowed for considering the application.

(5) This paragraph applies to a variation which would have the effect of altering—

(a) the types of medicinal product in respect of which the licence was granted;

(b) any operation carried out under the licence; [F42]...

(c) any premises, equipment or facilities in respect of which the licence was **[**[F43]granted; or**]**

[[F44](d) the responsible person (import) under regulation 45AA.**]**

(6) The period allowed for consideration of an application under this regulation is—

(a) in a case where the licensing authority considers that it is necessary to inspect premises to which the licence relates, 90 days beginning with the day after the date when the licensing authority receives the application; and

(b) in any other case 30 days beginning with that day.

(7) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application.

(8) If a notice under paragraph (7) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (6).

(9) In paragraph (8), the "information period" means the period—

(a) beginning with the day on which the notice is given; and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(10) Nothing in this regulation affects the powers conferred by regulation 26.

Textual Amendments

F42 Word in reg. 29(5)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **23(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F43 Words in reg. 29(5)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **23(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F44 Reg. 29(5)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **23(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Provision of information

30.—(1) Where an application has been made to the licensing authority for a licence under this Part, the licensing authority may, before determining the application, require the applicant to provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(2) The licensing authority may give a notice to the holder of a licence under this Part, requiring the holder to provide information of a kind specified in the notice within the period specified in the notice.

(3) A notice under paragraph (2) may not be given to the holder of a licence unless it appears to the licensing authority, or representations are made to the licensing authority by the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, that it is necessary for the licensing authority to consider whether the licence should be varied, suspended or revoked.

(4) A notice under paragraph (2) may specify information which the licensing authority, or the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, thinks necessary for considering whether the notice should be varied, suspended or revoked.

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 **[**F45the 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 **[**F46UK 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 **[**F47UK 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 **[**F48UK 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

F45 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)

F46 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)**

F47 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)**

F48 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)**

Sale and supply of starting materials

[F49]32. . . . . . .

Textual Amendments

F49 Reg. 32 revoked (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **35**

Offence concerning data for advanced therapy medicinal products

33.—(1) A person who is, or immediately before its revocation or suspension was, the holder of a manufacturer's licence relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) keep the data referred to in **[**[F50]paragraph 8 of Schedule 6**]** in accordance with the requirements of **[**[F51]paragraph 9 of that Schedule**]**; or

(b) transfer the data referred to in **[**[F52]paragraph 8**]** to the licensing authority in the event of that person's bankruptcy or liquidation,

but this is subject to paragraphs (2) and (3).

(2) Sub-paragraph (1)(b) does not apply if—

(a) the person is bankrupt or in liquidation and has transferred the data to another person; or

(b) the period for which the person was required to keep the data in accordance with the requirements of **[**[F53]paragraph 9**]** mentioned in sub-paragraph (1)(a) has expired.

(3) It is a defence for a person charged with an offence under paragraph (1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Textual Amendments

F50 Words in reg. 33(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F51 Words in reg. 33(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in reg. 33(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F53 Words in reg. 33(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Offences: breach of regulations and false information and defence concerning starting materials

34.—(1) A person is guilty of an offence if the person contravenes the provisions of regulation 17(1) **[**[F54]or 18(1)**]**.

(2) A person is guilty of an offence if the person knowingly gives false information in response to a notice under regulation 30(1).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 30(2).

(4) The defence in paragraph (5) applies to a person who is charged under paragraph (1) with an offence of contravening regulation 17(1) (prohibition on manufacturing a medicinal product except in accordance with a licence) by virtue of a breach of regulation **[**F55 37(3)**]** (requirement that active substances used as starting materials are manufactured or assembled in accordance with the Good Manufacturing Practice Directive).

(5) It is a defence for the person to show that the person could not, by taking all reasonable precautions and exercising all due diligence, have discovered that an active substance was not manufactured in accordance with regulation **[**F55 37(3)**]**.

Textual Amendments

F54 Words in reg. 34(1) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **9(a)**

F55 Word in reg. 34(4)(5) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **9(b)**

Penalties

35.—(1) A person guilty of an offence under regulation 33(1) or regulation 34(1) or (2) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 34(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

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 **[**F56 37(3)**]**, 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.

[F57(4) **[**F58Where a manufacturer's licence relates to the manufacture or assembly of a medicinal product in, or import of a medicinal product into, Northern Ireland, the requirements**]** and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were **[**F59provisions of that**]** licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

(a) Article 4 (composition of the unique identifier);

(b) Article 5 (carrier of the unique identifier);

(c) Article 6 (quality of the printing of the two-dimensional barcode);

(d) Article 7 (human-readable format);

(e) Article 10 (verification of the safety features) insofar as it relates to manufacturers;

(f) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to manufacturers;

(g) Article 12 (unique identifiers which have been decommissioned);

(h) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to manufacturers;

(i) Article 14 (verification of the two-dimensional barcode);

(j) Article 15 (record keeping);

(k) Article 16 (verifications to be performed before removing or replacing the safety features);

(l) Article 17 (equivalent unique identifier); and

(m) Article 18 (actions to be taken in case of tampering or suspected falsification).

(6) In distributing a medicinal product by way of wholesale dealing **[**F60in Northern Ireland**]**, the requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (7) shall apply to the holder of a manufacturer's licence and have effect as if they were provisions of the licence.

(7) The provisions mentioned in paragraph (6) are—

(a) Article 20 (verification of the authenticity of the unique identifier by wholesalers), subject to the exemption contained in Article 21 (derogations from Article 20(b));

(b) Article 22 (decommissioning of unique identifiers by wholesalers); and

(c) Article 24 (actions to be taken by wholesalers in case of tampering or suspected falsification).**]**

Textual Amendments

F56 Word in reg. 36(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **10**

F57 Reg. 36(4)-(7) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **4** and reg. 36(4)-(7) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **4**

F58 Words in reg. 36(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **27(a)(i)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F59 Words in reg. 36(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **27(a)(ii)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F60 Words in reg. 36(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **27(b)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 17**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F61**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 comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive **[**F62which apply under or by virtue of regulation B17**]**.

(3) Unless paragraph (10) applies, the licence holder shall use active substances as starting materials only if—

(a) those substances have been manufactured in accordance with good manufacturing practice for active substances; and

(b) those substances have been distributed in accordance with the guidelines on good distribution practice for active substances.

(4) The licence holder shall verify—

(a) that the manufacturer or distributor of an active substance used by the licence holder has complied with the requirements of good manufacturing practice and good distribution practice for active substances by means of audits performed—

(i) directly by the licence holder, or

(ii) by a person acting on behalf of the licence holder under a contract;

[F63(b) that unless the active substance is imported into Great Britain from a country other than an approved country for import or into Northern Ireland from a country other than an EEA State from a third country, any manufacturers, importers or distributors supplying active substances to the licence holder—

(i) in the case of a product imported into Great Britain, are registered with the appropriate authority for the registration of such persons in the approved country for import, and

(ii) in the case of a product imported into Northern Ireland, are registered with the competent authority of a member State in which they are established; and**]**

(c) the authenticity and quality of the active substance.

(5) The licence holder shall ensure that—

(a) excipients are suitable for use in a medicinal product by—

(i) ascertaining what the appropriate good manufacturing practice is, and

(ii) ensuring that the ascertained good manufacturing practice is applied;

(b) the suitability of the excipient is ascertained on the basis of a formalised risk assessment as described **[**F64in the case of a product for sale or supply in Great Britain **[**F65(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)**]**, in the guidelines which apply under or by virtue of regulation C17 and, in the case of a product for sale or supply in Northern Ireland,**]** in paragraph 5 of Article 47 of the 2001 Directive;

(c) the assessment under sub-paragraph (b) takes account of—

(i) the source,

(ii) requirements under other quality systems,

(iii) intended use of the excipients, and

(iv) previous instances of quality defects,

(d) the authenticity and quality of any excipient used is verified; and

(e) the measures taken under this paragraph are documented by the licence holder.

(6) 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; F66...

[F67(aa) in the case of a product for supply as an EAMS medicinal product, the conditions attached to the EAMS scientific opinion in respect of the product; and**]**

(b) **[**F68in the case of a product for sale or supply—

(i) in Great Britain **[**F69(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)**]**, the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK), or

(ii) in Northern Ireland, the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisations or Article 126a authorisations,

applying to the medicinal products.**]**

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

(8) 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.

(9) 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 **[**F70the Blood Quality and Safety Regulations 2005**]**; or

(b) equivalent standards.

(10) The requirements in paragraphs (3) to (5) do not apply in relation to the manufacture or assembly of special medicinal product to which regulation 167 (supply to fulfil special needs) applies **[**F71or an EAMS medicinal product to which regulation 167E(1) to (4) (EAMS medicinal product: manufacture, assembly, importation, distribution and supply) applies**]**.

(11) The licence holder must immediately inform the **[**F72licensing authority**]** and, where applicable, the **[**F73UK**]** marketing authorisation holder, of medicinal products which come within the scope of manufacturing authorisation which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified.**]**

Textual Amendments

F61 Reg. 37 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **11**

F62 Words in reg. 37(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(1A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 18(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F63 Reg. 37(4)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **28(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(b)**)

F64 Words in reg. 37(5)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 18(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F65 Words in reg. 37(5)(b) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **8**

F66 Word in reg. 37(6)(a) omitted (15.4.2022) by virtue of The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **5(2)(a)** (with reg. 19)

F67 Reg. 37(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), **5(2)(b)** (with reg. 19)

F68 Reg. 37(6)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **28(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(d)**)

F69 Words in reg. 37(6)(b)(i) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **8**

F70 Words in reg. 37(9)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F71 Words in reg. 37(10) 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), **5(3)** (with reg. 19)

F72 Words in reg. 37(11) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F73 Word in reg. 37(11) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Imports from states other than EEA States [F74/ countries other than approved countries for import]

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 **[**F75from—

(a) in the case of an import into Great Britain, a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country 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 **[**F76, in the case of an import into Great Britain, a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State**]** only if those substances have been manufactured or assembled in accordance with **[**F77good manufacturing practice for active substances**]**.

Textual Amendments

F74 Words in reg. 38 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **29(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 19(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F75 Reg. 38(2)(a)(b) substituted for words in reg. 38(2) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **29(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 19(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F76 Words in reg. 38(3)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **29(4)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 19(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F77 Words in reg. 38(3)(b) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **4** and words in reg. 38(3)(b) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **4**

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 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.

[F78(8) In distributing a medicinal product by way of wholesale dealing, the licence holder must comply with the following as if they are a holder of a wholesale dealer's licence—

(a) regulations 43(1), (2) and (5), 43ZA and 44(5) and (6), and

(b) regulation 43A, if applicable, where the product is being distributed in NI.**]**

Textual Amendments

F78 Reg. 39(8) substituted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **9**

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 **[**F79, unless conditions attached in accordance with regulation 174A(1) provide otherwise,**]** to products authorised on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc).

[F80(12) The licence holder is not obliged to meet the requirements of this regulation in relation to any activities under the licence which relate to EAMS medicinal products, unless the conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) provide otherwise.**]**

Textual Amendments

F79 Words in reg. 41(11) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **5** and words in reg. 41(11) inserted (N.I) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **5**

F80 Reg. 41(12) 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), **6** (with reg. 19)

Conditions for holding a wholesale dealer's licence

Conditions for wholesale dealer's licence

42.—(1) Regulations 43 to 45 **[**F81(not including regulation 43ZA)**]****[**F82(in the case of a wholesale dealer's licence held in Northern Ireland) or regulations 43 to 45AA **[**F83(including regulation 43ZA)**]** (in the case of a wholesale dealer's licence held in Great Britain)**]** apply to the holder of a wholesale dealer'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 wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products).

[F84(2) Those provisions are regulations 43(2) and (8) and 44.**]**

(3) The requirements in Part 2 of Schedule 6 apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

[F85(4) **[**F86Where a wholesale dealer's licence relates to wholesale dealings in Northern Ireland, the requirements**]** and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were **[**F87provisions of that**]** licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

(a) Article 10 (verification of the safety features) insofar as it relates to wholesalers;

(b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to wholesalers;

(c) Article 12 (unique identifiers which have been decommissioned);

(d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to wholesalers;

(e) Article 20 (verification of the authenticity of the unique identifier), subject to the exemption contained in Article 21 (derogations from Article 20(b));

(f) Article 22 (decommissioning of unique identifiers); and

(g) Article 24 (actions to be taken in case of tampering or suspected falsification).**]**

[F88(6) Paragraph (4) does not apply in relation to listed NIMAR products in Northern Ireland.**]**

Textual Amendments

F81 Words in reg. 42(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **10(a)(i)**

F82 Words in reg. 42(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **31(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 21(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F83 Words in reg. 42(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **10(a)(ii)**

F84 Reg. 42(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **13**

F85 Reg. 42(4)(5) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **6** and reg. 42(4)(5) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **6**

F86 Words in reg. 42(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **31(3)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 21(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F87 Words in reg. 42(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **31(3)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 21(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F88 Reg. 42(6) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **10(b)**

Obligations of licence holder

43.—**[**F89(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—

[F90(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 **[**F91in the United Kingdom**]**;

[F92(aa) the supply, or offer for supply, of an unauthorised EAMS medicinal product in the United Kingdom;**]**

(b) the export **[**F93from 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; F94...

[F95(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; **[**F96or

[F97(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—

[F98(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**]**

[F99(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**]**

[F100(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) **[**F101where 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.***/***

[F100(8) A licence holder **[**F102in 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 **[**F103country other than an EEA State**]**.**]**

[

F104(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).

[F105(10) The holder **[**F106of 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 **[**[F107]UK 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) **[**[F108]Where 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 **[**[F109]as 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

F89 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)**)

F90 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)**)

F91 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)

F92 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)

F93 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)**

F94 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)**

F95 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)**

F96 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)**

F97 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)**

F98 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)**)

F99 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)**)

F100 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)**

F101 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)**

F102 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)**

F103 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)**

F104 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)**

F105 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)**

F106 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)**

F107 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)**

F108 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)**)

F109 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)**

[F110Obligations of licence holder in Great Britain supplying listed NIMAR products to Northern Ireland

43ZA.—(1) This regulation applies only to licence holders in Great Britain supplying listed NIMAR products to Northern Ireland.

(2) A licence holder must comply with the guidelines on good distribution practice, published under, or that apply by virtue of, regulation C17.

(3) So that the needs of patients in Northern Ireland are met, the licence holder must ensure, within the limits of the holder's responsibility, the continued supply of listed NIMAR products to—

(a) registered pharmacies in Northern Ireland;

(b) any person who may lawfully sell those products by retail sale or may lawfully supply them in circumstances corresponding to retail sale in Northern Ireland;

(c) any person who may lawfully administer prescription only medicines in Northern Ireland.

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

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

(b) to ensure their proper distribution.

(5) 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.

(6) The licence holder must not sell or supply, or offer for sale or supply, listed NIMAR products to a person in Northern Ireland, unless—

(a) there is a UKMA(UK) or UKMA(GB) in force in relation to that product; and

(b) the sale or supply is in accordance with that authorisation (except for the fact the product will be in Northern Ireland).

(7) The licence holder must—

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

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

(i) ordered by the licensing authority or

(ii) carried out in co-operation with the manufacturer of, or the holder of the corresponding UKMA(GB) or UKMA(UK) for the product; and

(c) keep records in relation to the receipt, dispatch or brokering of listed NIMAR products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the date of brokering,

(iv) the name of the listed NIMAR 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; and

(d) provide the records in sub-paragraph (c) to the licensing authority on request.

(8) 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).

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

(10) The licence holder must immediately inform the licensing authority 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.

(11) Where the listed NIMAR product is obtained through brokering, a licence holder must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b).**]**

Textual Amendments

F110 Reg. 43ZA inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **11**

[F111Requirement for wholesale dealers to decommission the unique identifier

43A.—(1) This regulation applies only to medicinal products that are required to bear safety features pursuant to Article 54a of the 2001 Directive.

(2) Before supplying a medicinal product to a person **[**F112in Northern Ireland**]** who falls within one of the classes specified in paragraph (3), the licence holder must verify the safety features and decommission the unique identifier of that medicinal product in accordance with the requirements laid down in Commission Regulation 2016/161.

(3) The classes of person mentioned in paragraph (2) are—

(a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;

(b) persons who receive the product for the purpose of selling, supplying or administering it as a veterinary medicinal product;

(c) dentists;

(d) registered optometrists or registered dispensing opticians;

(e) registered paramedics;

(f) persons who are members of Her Majesty's armed forces;

(g) F113... the Police Service of Northern Ireland;

(h) government institutions maintaining stocks of medicinal products for the purposes of civil protection or disaster control;

(i) universities or other institutions concerned with higher education or research, other than healthcare institutions;

(j) a prison service;

(k) persons carrying on the business of a school;

(l) **[**F114nursing**]** homes;

(m) hospices.**]**

Textual Amendments

F111 Reg. 43A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **7** and reg. 43A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **7**

F112 Words in reg. 43A(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **34(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F113 Words in reg. 43A(3)(g) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **34(b)(i)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F114 Word in reg. 43A(3)(l) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **34(b)(ii)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F115Requirement for wholesale dealers to deal only with specified persons

44.—F116(1) . . . . . .

(2) **[**F117The**]** licence holder must not obtain supplies of medicinal products from anyone except—

(a) the holder of a manufacturer's licence or wholesale dealer's licence in relation to products of that description;

(b) the person who holds an authorisation granted by **[**F118an approved country for import (in the case of a licence holder in Great Britain) or by an EEA State (in the case of a licence holder in Northern Ireland)**]** authorising the manufacture of products of the description or their distribution by way of wholesale dealing; **[**F119or**]**

[F120(c) where the medicinal product is directly received—

(i) in the case of a licence holder in Great Britain, from a country that is not an approved country for import ("A"), for export to a country that is not an approved country for import ("B"), and

(ii) in the case of a licence holder in Northern Ireland, from a country other than an EEA State ("A") for export to another country other than an EEA State ("B"),

the supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.**]**

F121(d) . . . . . .

(3) Where a medicinal product is obtained in accordance with paragraph F122... (2)(a) or (b), the licence holder must verify that—

(a) the wholesale dealer who supplies the product complies with the principles and guidelines of good distribution practices; or

(b) the manufacturer or importer who supplies the product holds a manufacturing authorisation.

F123(4) . . . . . .

(5) **[**F124The**]** licence holder may distribute medicinal products by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence relating to those products;

[F125(b) the holder of an authorisation granted by—

(i) in the case of a licence holder in Great Britain, the appropriate authority of an approved country for import;

(ii) in the case of a licence holder in Northern Ireland, the competent authority of an EEA State,

that is responsible for authorising the supply of those products by way of wholesale dealing;**]**

(c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale;

(d) a person who may lawfully administer those products; or

[F126(e) in relation to supply—

(i) in the case of a licence holder in Great Britain to persons in countries other than approved countries for import, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country to which the product is supplied;

(ii) in the case of a licence holder in Northern Ireland to persons in a country other than an EEA State, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country other than an EEA State concerned.**]**

(6) Where a medicinal product is supplied to a person who is authorised or entitled to supply medicinal products to the public in accordance with paragraph F127... (5)(c) or (e), the licence holder must enclose with the product a document stating the—

(a) date on which the supply took place;

(b) name and pharmaceutical form of the product supplied;

(c) quantity of product supplied; **[**F128and**]**

(d) name and address of the licence holder; and

(e) batch number of the medicinal products bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive **[**F129, in the case of a licence holder in Northern Ireland.**]**

(7) The licence holder must—

(a) keep a record of information supplied in accordance with paragraph (6) for at least five years beginning immediately after the date on which the information is supplied; and

(b) ensure that the record is available to the licensing authority for inspection.**]**

[F130(8) A licence holder in Great Britain may only obtain a medicinal product in respect of which a UKMA(GB) was granted under the unfettered access route if the product satisfies the definition of qualifying Northern Ireland goods.

(9) Paragraph (2)(c) does not apply to—

(a) in the case of a licence holder in Great Britain, products received from Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products received from Great Britain.

(10) Paragraph (5)(e) does not apply to—

(a) in the case of a licence holder in Great Britain, products supplied to Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products supplied to Great Britain.**]**

Textual Amendments

F115 Reg. 44 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **15**

F116 Reg. 44(1) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(2)** and reg. 44(1) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(2)**

F117 Word in reg. 44(2) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(a)** and word in reg. 44(2) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(a)**

F118 Words in reg. 44(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 25(a)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F119 Word in reg. 44(2) inserted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(b)** and word in reg. 44(2) inserted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(b)**

F120 Reg. 44(2)(c) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(a)(ii)**)

F121 Reg. 44(2)(d) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(d)** and reg. 44(2)(d) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(d)**

F122 Word in reg. 44(3) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(4)** and word in reg. 44(3) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(4)**

F123 Reg. 44(4) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(5)** and reg. 44(4) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(5)**

F124 Word in reg. 44(5) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(6)** and word in reg. 44(5) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(6)**

F125 Reg. 44(5)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(b)**)

F126 Reg. 44(5)(e) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(c)**)

F127 Word in reg. 44(6) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **7** and word in reg. 44(6) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **7**

F128 Word in reg. 44(6)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F129 Words in reg. 44(6)(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(5)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 25(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F130 Reg. 44(8)-(10) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **35(6)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(e)**)

Requirement as to responsible persons

45.—(1) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person") who in the opinion of the licensing authority—

(a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate to carry out the functions mentioned in paragraph (2); and

(b) has adequate experience relating to those activities and procedures.

[[F131](1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.**]**

(2) Those functions are—

(a) ensuring that the conditions under which the licence was granted have been, and are being, complied with; and

[[F132](b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of—

(i) in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations, and

(ii) in the case of a licence holder in Northern Ireland, the marketing authorisations, **[**[F133]requirements of regulation 167A,**]** Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products.**]**

(3) The licence holder must notify the licensing authority of—

(a) any change to the responsible person; and

(b) the name, address, qualifications and experience of the responsible person.

(4) The licence holder must not permit any person to act as a responsible person other than the person named in the licence or another person notified to the licensing authority under paragraph (3).

(5) Paragraph (6) applies if, after giving the licence holder and a person acting as a responsible person the opportunity to make representations (orally or in writing), the licensing authority thinks that the person—

(a) does not satisfy the requirements of paragraph (1) in relation to qualifications or experience; or

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

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

Textual Amendments

F131 Reg. 45(1A) inserted (31.12.2022) The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **36(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 26(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F132 Reg. 45(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **36(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 26(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F133 Words in reg. 45(2)(b)(ii) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **12**

[[F134]Requirement as to responsible persons where licence holder imports from an approved country for import

45AA.—(1) Subject to paragraph (2), this regulation applies to a licence holder in Great Britain where the licence holder imports a medicinal product from an approved country for import under a wholesale dealer's licence.

(2) The requirements of this regulation do not apply where an unlicensed medicinal product falling under paragraph (1) is imported—

(a) from an approved country for import for the sole purpose of distribution by way of wholesale dealing as a special medicinal product; or

(b) for the sole purpose of wholesale distribution of that product to a person in a country other than an approved country for import.

(3) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person (import)") whose name is included in the register established under regulation 45AB.

(4) A responsible person (import) must—

(a) carry out the functions under regulation 45(2), unless a responsible person under regulation 45 is performing those functions in respect of the licence; ...

(b) ensure that there is appropriate evidence to confirm that each production batch of a medicine imported from an approved country for import under the licence has been certified as provided for in Article 51 of the 2001 Directive, or such equivalent certification procedure as applies in the approved country for import; and

(c) ensure that each production batch of a medicinal product that is subject to the batch testing condition and that is imported into Great Britain from an approved country for import has been certified as being in conformity with the approved specifications in the UK marketing authorisation by—

(i) the appropriate authority, or

(ii) where the batch testing exemption applies, a laboratory in a country that has an agreement with the United Kingdom to the effect that the appropriate authority will recognise that certificate in place of the appropriate authority's own examination.

(5) The licensing authority must publish guidance on the documentation that it considers to be appropriate evidence for the purposes of paragraph (4)(b).

(6) Guidance published under paragraph (5) may be taken into account by the licensing authority in determining whether it considers there has been a failure to comply with this regulation.

(7) The licence holder must apply to vary the licence if a change is proposed to the responsible person (import).

(8) The licence holder must not permit any person to act as a responsible person (import) other than the person named in the licence.

(9) Paragraph (10) applies if—

(a) the person acting as responsible person (import) in respect of the licence is no longer included in the register under 45AB;

(b) the licensing authority thinks, after giving the licence holder and a person acting as a responsible person (import) the opportunity to make representations (orally or in writing), that the responsible person (import) is failing to carry out the functions referred to in paragraph (4) adequately or at all.

(10) Where this paragraph applies the licensing authority—

(a) must notify the licence holder in writing that the person is not permitted to act as a responsible person (import) in respect of that licence; and

(b) may, subject to regulation 45AB(3)(b), remove that person's name from the register under regulation 45AB.

(11) In this regulation, "unlicensed medicinal product" means a medicinal product in respect of which—

(a) there is no marketing authorisation, within the meaning of the 2001 Directive, in any EEA State in respect of that product, where the product is imported from an approved country for import that is an EEA State; or

(b) there is no licence or authorisation in respect of that product as regards its sale or supply in the approved country for import, where the product is imported from an approved country for import that is not an EEA State.

Textual Amendments

F134 Regs. 45AA, 45AB inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **37** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 27**); 2020 c. 1, **Sch. 5 para. 1(1)**

Register for responsible persons (import)

45AB.—(1) The licensing authority must maintain a register of persons ("the responsible person (import) register") who may carry out the role of responsible person (import) under regulation 45AA.

(2) The licensing authority may only include a person's name in the responsible person (import) register if that person—

(a) holds—

(i) a diploma, certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, or

(ii) such other qualification as the licensing authority is satisfied is equivalent;

(b) is a member of—

(i) the Royal Society of Biology,

(ii) the Royal Pharmaceutical Society,

(iii) the Pharmaceutical Society of Northern Ireland,

(iv) the Royal Society of Chemistry, or

(v) such other body as may be specified by the licensing authority for the purpose of this paragraph; and

(c) has a minimum of 2 years' experience in performing the functions of a responsible person under regulation 45, or in performing such other functions that appear to the licensing authority to be equivalent.

(3) The licensing authority—

(a) may remove a person's name from the responsible person (import) register if it no longer considers that the person satisfies the requirements of paragraph (2); but

(b) it may not exercise that power unless it has given that person the opportunity to make representations to it (orally or in writing).]

Textual Amendments

F134 Regs. 45AA, 45AB inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **37** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 27**); 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, CHAPTER 2.