STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

CHAPTER 4

Miscellaneous provisions, offences and disqualification

Miscellaneous provisions

Restrictions on persons to be supplied with medicinal products

249.—(1) The holder of an authorisation of the kind referred to in paragraph (2) may not sell a prescription only medicine or a pharmacy medicine by way of wholesale dealing to a person who does not fall within a class specified in Schedule 22.

(2) Those authorisations are—

(a) a **[**[F1]UK**]** marketing authorisation;

[[F2](aa) an EU marketing authorisation;**]**

(b) a certificate of registration;

(c) a traditional herbal registration; and

(d) an Article 126a authorisation.

(3) A person may not, in the course of a business consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing, sell a prescription only medicine or a pharmacy medicine by way of wholesale dealing to a person who does not fall within a class specified in Schedule 22.

(4) This regulation is subject to regulation 250.

Textual Amendments

F1 Word in reg. 249(2)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **194(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 249(2)(aa) inserted (31.12.2020) by S.I. 2019/775, **reg. 194(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 148**)

Exceptions to regulation 249

250.—(1) This regulation makes provision for exceptions to regulation 249.

(2) A person may sell by way of wholesale dealing a pharmacy medicine which is for the purpose of being administered to human beings in the course of a business to any person carrying on such a business.

(3) A person may sell by way of wholesale dealing a pharmacy medicine to which a general sale exemption applies to any person who by virtue of that exemption may sell the pharmacy medicine by retail, or supply it in circumstances corresponding to retail sale, otherwise than by or under the supervision of a pharmacist.

(4) In paragraph (3) "general sale exemption" means an exemption from regulation 220 conferred by a provision of Chapter 3.

[F3(4A) A person may, in the course of a business consisting (wholly or partly) of manufacturing medicinal products or of selling products by way of wholesale dealing, sell by way of wholesale dealing a prescription only medicine to any person who by virtue of regulation 247 or 247A may supply or administer that medicine in accordance with a protocol of the types mentioned in those regulations.**]**

(5) A person may sell by way of wholesale dealing to a person specified in column 1 of Parts 1 to 3 of Schedule 17 a prescription only medicine specified in relation to that person in column 2 of Parts 1 to 3 of that Schedule.

(6) A person may sell by way of wholesale dealing to a registered optometrist a product that is a prescription only medicine by reason only that it contains one or more of the following substances—

(a) amethocaine hydrochloride;

(b) lidocaine hydrochloride;

(c) oxybuprocaine hydrochloride; or

(d) proxymetacaine hydrochloride.

(7) A person may sell by way of wholesale dealing to an additional supply optometrist a product that is a prescription only medicine by reason only that it contains thymoxamine hydrochloride.

(8) A person may sell by way of wholesale dealing to a registered dispensing optician a prescription only medicine that—

(a) is required for use by a registered optometrist or doctor attending the optician's practice; and

(b) contains one or more of the following substances—

(i) amethocaine hydrochloride,

(ii) chloramphenicol,

(iii) cyclopentolate hydrochloride,

(iv) fusidic acid,

(v) lidocaine hydrochloride,

(vi) oxybuprocaine hydrochloride,

(vii) proxymetacaine hydrochloride, and

(viii) tropicamide.

(9) A person may sell by way of wholesale dealing to a registered dispensing optician a prescription only medicine that—

(a) is required for use by the optician in the course of a professional practice as a contact lens specialist; and

(b) contains one or more of the following substances—

(i) lidocaine hydrochloride,

(ii) oxybuprocaine hydrochloride, and

(iii) proxymetacaine hydrochloride.

(10) In this regulation—

"additional supply optometrist" means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;

"contact lens specialist" means a person who is a registered dispensing optician and against whose name particulars of the contact lens speciality have been entered in—

(a) the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989; or

(b) the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b) of that Act.

Textual Amendments

F3 Reg. 250(4A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **15** and reg. 250(4A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349)

Compliance with standards specified in certain publications

251.—(1) A person may not sell a medicinal product that has been demanded by the purchaser by, or by express reference to, a particular name if—

(a) the name is a name at the head of the relevant monograph; and

(b) the product does not comply with the standard specified in that monograph.

(2) A person may not sell or supply a medicinal product in pursuance of a prescription given by a doctor or dentist in which the product required is described by, or by express reference to, a particular name if—

(a) the name is a name at the head of the relevant monograph; and

(b) the product does not comply with the standard specified in that monograph.

(3) A person may not sell or supply a medicinal product that has been offered or exposed for sale by, or by express reference to, a particular name if—

(a) the name is a name at the head of the relevant monograph; and

(b) the product does not comply with the standard specified in that monograph.

(4) If the particular name referred to in paragraph (1), (2) or (3) is that of an active ingredient of the product, the product does not comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with that standard.

(5) See regulation 252 for the meaning of certain expressions used in this regulation.

[[F4](6) In paragraph (1), (2) or (3) a product is to be treated as complying with the standard specified in the relevant monograph where—

(a) the product complies with the standard specified in a relevant marketing authorisation for the product concerned, and

(b) the standard specified in that marketing authorisation does not comply with the standard specified in the relevant monograph.

(7) In paragraph (6), "relevant marketing authorisation" means—

(a) an EU marketing authorisation;

(b) an authorisation granted by the licencing authority under Chapter 4 of Title III to the 2001 Directive; or

(c) a UKMA(GB) granted under the unfettered access route.**]**

Textual Amendments

F4 Reg. 251(6)(7) inserted (31.12.2020) by S.I. 2019/775, **reg. 194A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 149**)

Compliance with standards specified in certain publications: supplementary

252.—(1) Where, together with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, there was specified a particular edition of a particular publication, "the relevant monograph" in that paragraph means—

(a) the monograph (if any) headed by the name in that edition; or

(b) if there is no such monograph, the appropriate current monograph (if any) headed by that name.

(2) Where, together with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, there was specified a particular publication, but not an edition of that publication, "the relevant monograph" in that paragraph means—

(a) the monograph (if any) headed by the name in the current edition; or

(b) if there is no monograph of the kind mentioned in sub-paragraph (a), the appropriate current monograph (if any) headed by that name; or

(c) if there is no monograph of the kinds mentioned in sub-paragraphs (a) or (b), the monograph headed by that name in the latest edition of the specified publication that contained a monograph headed by that name.

(3) Where no publication was specified with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, "the relevant monograph" in that paragraph means the appropriate current monograph (if any).

(4) In this regulation "publication" means—

(a) the British Pharmacopoeia; or

(b) a compendium published under Part 15 (British Pharmacopoeia).

(5) In this regulation "current" means current at the time when the medicinal product is demanded, described in a prescription or offered or exposed for sale (as the case may be).

(6) In this regulation "the appropriate current monograph", in relation to a particular name, means—

(a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia; or

(b) if there is no such monograph, the monograph (if any) headed by that name in the current edition of a compendium published under Part 15 (British Pharmacopoeia).

(7) For the purposes of regulation 251 and this regulation, any monograph in an edition of a publication must be construed in accordance with any general monograph or notice, or any appendix, note or other explanatory material, that is contained in that edition and applies to that monograph.

Pharmacy records

253.—(1) A person lawfully conducting a retail pharmacy business must, in respect of every sale or supply of a prescription only medicine, make or cause to be made an entry in a written or computerised record kept for that purpose.

(2) An entry required by paragraph (1)—

(a) must state the particulars specified in Schedule 23; and

(b) subject to paragraph (3), must be made—

(i) on the day of the sale or supply, or

(ii) if that is not reasonably practicable, on the day following that day.

(3) Where the sale or supply is made under regulation 224 (emergency sale etc by pharmacist: prescriber unable to provide prescription), the particulars specified in paragraph 2(e) and (f) of Schedule 23 may be entered on the day that the prescription is received.

(4) Paragraphs (1) to (3) do not apply if any of the following apply—

(a) the sale or supply is in pursuance of a health prescription or a prescription for oral contraceptives;

(b) a separate record of the sale or supply is made in accordance with the Misuse of Drugs Regulations 2001 or the Misuse of Drugs Regulations (Northern Ireland) 2002;

(c) the sale is by way of wholesale dealing and the order or invoice relating to the sale or a copy of the order or invoice is retained by the person lawfully conducting the retail pharmacy business who makes the sale;

(d) in Scotland, the sale or supply is to a doctor for use in the circumstances referred to in paragraph 45 of Schedule 5 to the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 [M1] (provision of drugs, medicines and appliances for immediate treatment or personal administration);

(e) in Northern Ireland, the sale or supply is to a doctor for use in the circumstances referred to in paragraph 47 of Schedule 5 to the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004 [M2] (provision of drugs, medicines and appliances for immediate treatment or personal administration).

(5) A person lawfully conducting a retail pharmacy business must preserve for a period of two years beginning immediately after the relevant date—

(a) the record kept under paragraphs (1) to (3);

(b) a prescription in pursuance of which a prescription only medicine has been sold or supplied other than—

(i) a health prescription, or

(ii) a prescription for a **[**[F5]product subject to special medical prescription**]**;

(c) an order or invoice referred to in paragraph (4)(c) or a copy of the order or invoice; and

(d) orders referred to in column 3 of Parts 1 to 3 of Schedule 17, except orders referred to in paragraph 3 of Part 1 of that Schedule.

(6) In paragraph (5) "the relevant date" means—

(a) in relation to sub-paragraph (a), the date on which the last entry is made in the record;

(b) in relation to sub-paragraphs (b), (c) and (d)—

(i) where the prescription only medicine was sold or supplied in accordance with a repeatable prescription, the date of the final sale or supply pursuant to that prescription, and

(ii) otherwise, the date on which the prescription only medicine was sold or supplied.

Textual Amendments

F5 Words in reg. 253(5)(b)(ii) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(h)** and words in reg. 253(5)(b)(ii) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(h)**

Marginal Citations

M1 S.S.I. 2004/115

M2 S.R. (NI) 2004 No. 140.

Prohibitions concerning traceability of treatment with advanced therapy medicinal products

254.—(1) A person may not treat a patient with an advanced therapy medicinal product if there is not a system in place for patient and product traceability in relation to such treatment containing sufficient detail to enable the linking of the product to the patient who received it and vice versa.

(2) A person may not treat a patient with an advanced therapy medicinal product if the treatment involves a product which contains human cells or tissues and the traceability system referred to in paragraph (1) is not complementary to, and compatible with, the requirements **[**F6imposed pursuant to—

(a) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990;

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005; and

(c) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007**]**.

(3) It is a defence to an offence of breach of paragraph (1) or, as the case may be, paragraph (2) if the person who treats a patient was assured in writing before the treatment was given that a system of traceability as described in paragraph (1) or, as the case may be, paragraph (2) was in place in relation to the treatment given by that person.

(4) A person may not give an assurance in writing to a person ("P") who treats a patient with an advanced therapy medicinal product that a system of traceability as described in paragraph (1) or paragraph (2) is in place in relation to treatment with an advanced therapy medicinal product given by P if no such system is in place.

Textual Amendments

F6 Reg. 254(2)(a)-(c) and words substituted for words (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **195**; 2020 c. 1, **Sch. 5 para. 1(1)**

Offences relating to dealings with medicinal products

255.—(1) A person is guilty of an offence if the person breaches any of the following provisions of this Part—

(a) regulation 214(1) (prohibition on sale etc of prescription only medicine otherwise than in accordance with prescription from appropriate practitioner);

(b) regulation 214(2) (prohibition on parenteral administration of prescription only medicine otherwise than by or under directions of appropriate practitioner);

(c) regulation 220 (prohibition on sale etc of medicinal product not subject to general sale otherwise than by or under supervision of pharmacist);

(d) regulation 249 (prohibition on sale of prescription only medicine or pharmacy medicine by way of wholesale dealing to person not within Schedule 22);

(e) regulation 251 (compliance with standards specified in certain publications); or

(f) regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products).

(2) A person is guilty of an offence if the person—

(a) is an appropriate practitioner by virtue of regulation 214; and

(b) gives a prescription or directions in respect of a medicinal product in relation to which the person is not an appropriate practitioner.

(3) A person is guilty of an offence if the person gives a prescription or directions or administers a medicinal product without meeting the conditions for doing so that apply to that person by virtue of regulation 215 (conditions to be met by supplementary prescriber).

(4) A person ("P") is guilty of an offence if—

(a) P has in P's possession a medicinal product to which regulation 214(1) applies; and

(b) P intends to supply it otherwise than in accordance with a prescription of an appropriate practitioner.

(5) A person guilty of an offence under any of paragraphs (1) to (4) 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.

(6) A person is guilty of an offence if the person breaches—

(a) regulation 221 (prohibition on sale of medicinal product subject to general sale otherwise than in accordance with that regulation); or

(b) regulation 222 (prohibition on sale by automatic machine of medicinal product not subject to general sale).

(7) A person guilty of an offence under paragraph (6) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(8) A person is guilty of an offence if the person breaches regulation 253 (record-keeping requirements for persons carrying on a retail pharmacy business).

(9) A person guilty of an offence under paragraph (8) is liable on summary conviction to a fine not exceeding £400.

[F7Enforcement notices relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public

255A.—(1) This regulation applies to a person who, in the course of a business carried on by that person, sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, **[**F8in Northern Ireland,**]** a medicinal product that is required by Article 54a of the 2001 Directive to bear safety features.

(2) If an enforcement authority has objective grounds for considering that a person to whom this regulation applies has contravened a provision of Commission Regulation 2016/161 listed in

paragraph (4), the enforcement authority may serve upon that person a notice in writing (referred to in this Regulation as an "enforcement notice")—

(a) informing that person of the authority's grounds for considering that the person has contravened one or more of those provisions;

(b) specifying the relevant provisions;

(c) specifying the measures which the person must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;

(d) requiring the person to take those measures, within such period as may be specified in the notice;

(e) warning the person that that a failure to comply with the enforcement notice constitutes an offence under paragraph (5) and that further action may be taken in respect of the contravention unless the requirements specified in the notice are met.

(3) An enforcement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(4) The provisions mentioned in paragraph (2) are—

(a) Article 10 (verification of the safety features) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(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 persons authorised or entitled to supply medicinal products to the public;

(e) Article 25 (obligations of persons authorised or entitled to supply medicinal products to the public), subject to the exemptions contained in Article 26 (derogations from Article 25);

(f) Article 27 (obligations when applying the derogations);

(g) Article 28 (obligations when supplying only part of a pack);

(h) Article 29 (obligations in case of inability to verify the authenticity and decommission the unique identifier); and

(i) Article 30 (actions to be taken by persons authorised or entitled to supply medicinal products to the public in case of suspected falsification).

(5) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with an enforcement notice served upon them under paragraph (2).

(6) A person guilty of an offence under paragraph (5) is liable—

(a) on summary conviction to a fine; or

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

Textual Amendments

F7 Regs. 255A-255C inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **10** and regs. 255A-255C inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **10**

F8 Words in reg. 255A(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 196** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 150**)

[F7Exception to Article 25 of Commission Regulation 2016/161: health care institutions

255B. Article 25(1) of Commission Regulation 2016/161 does not apply to a person authorised or entitled to supply medicinal products to the public **[**F9in Northern Ireland**]** if—

(a) the person authorised or entitled to supply medicinal products to the public is operating within a healthcare institution;

(b) the person authorised or entitled to supply medicinal products to the public obtains the medicinal product bearing the unique identifier through a wholesaler belonging to the same legal entity as the healthcare institution;

(c) the wholesaler that supplies the product to the healthcare institution has verified the safety features and decommissioned the unique identifier in accordance with the requirements laid down in Commission Regulation 2016/161;

(d) no sale of the medicinal product takes place between the wholesaler supplying the product and that healthcare institution; and

(e) the medicinal product is supplied to the public within that healthcare institution.**]**

Textual Amendments

F7 Regs. 255A-255C inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **10** and regs. 255A-255C inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **10**

F9 Words in reg. 255B inserted (31.12.2020) by S.I. 2019/775, **reg. 196A** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 150**)

[F7Offences relating to Commission Regulation 2016/161: management of the repository system

255C.—(1) A legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161 is guilty of an offence if the legal entity fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).

(2) The provisions mentioned in paragraph (1) are—

(a) Article 31 (establishment of the repositories system);

(b) Article 32 (structure of the repositories system);

(c) Article 33 (uploading of information in the repositories system);

(d) Article 34 (functioning of the hub);

(e) Article 35 (characteristics of the repositories system);

(f) Article 36 (operations of the repositories system);

(b) Article 37 (obligations of legal entities establishing and managing a repository which is part of the repositories system);

(c) Article 38 (data protection and data ownership); and

(d) Article 39 (access by national competent authorities).

(3) A legal entity guilty of an offence under paragraph (1) is liable on summary conviction, or on conviction on indictment, to a fine.

(4) A person guilty of an offence under paragraph (1) by virtue of regulation 338 is liable—

(a) on summary conviction to a fine; or

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

Textual Amendments

F7 Regs. 255A-255C inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **10** and regs. 255A-255C inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **10**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Miscellaneous provisions.