STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

Modifications etc. (not altering text)
C1 Pt. 12 modified (E.W.) (1.10.2015) by The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 (S.I. 2015/895), regs. 1(3), **4(2)**

CHAPTER 1

Interpretation

Interpretation

213.—(1) In this Part—

[F1"approved country health professional" means a person who is practising in a profession included in the list published under regulation 214(6A) in a country that is included in that list in relation to that profession;**]**

[F2"clinical commissioning group" means a body established under section 14D of the National Health Service Act 2006;**]**

"the Common Services Agency" means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978 M1;

F3. . . . . .

"the dental care professionals register" means the register established and maintained under section 36B of the Dentists Act 1984 M2;

[F4"Council Directive 2005/36/EC" means Council Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications;**]**

F5...

F6. . . . . .

F7. . . . . .

"food" includes—

(a) beverages;

(b) confectionery;

(c) articles and substances used as ingredients in the preparation of food; and

(d) any manufactured substance—

(i) to which there has been added any vitamin, and

(ii) which is advertised as available and for sale to the general public as a dietary supplement;

"health authority" means—

(a) F8. . . . . .

(b) in relation to Wales, a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006 M3;

(c) in relation to Scotland, a Health Board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978 M4; and

(d) in relation to Northern Ireland, the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 M5;

"health care" means services for or in connection with the prevention, diagnosis or treatment of disease;

"health prescription" means a prescription issued by a doctor, dentist, supplementary prescriber, nurse independent prescriber, optometrist independent prescriber, **[**F9pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**]**[F10, paramedic independent prescriber**]** or community practitioner nurse prescriber under—

(a) in England, the National Health Service Act 2006;

(b) in Wales, the National Health Service (Wales) Act 2006;

(c) in Scotland, the National Health Service (Scotland) Act 1978; and

(d) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972 M6;

F11. . . . . .

"independent clinic"—

(a) in relation to England, means an establishment of either of the following kinds—

(i) a walk-in centre, in which one or more medical practitioners provides services of a kind which, if provided in pursuance of the National Health Services Act 2006, would be provided as primary medical services under Part 4 of that Act, or

(ii) a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the National Health Services Act 2006 provides medical services of any kind (including psychiatric treatment), except where such medical services are provided only under arrangements made on behalf of the patients by—

(aa) their employer,

(bb) a government department or any executive agency of any government department,

(cc) a prison or other establishment in which patients are held under custody, other than pursuant to any provision under the Mental Health Act 1983 M7, or

(dd) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity,

and where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting

room at different times, each of the medical practitioners shall be regarded as carrying on a separate independent clinic unless they practise together;

(b) in relation to Wales, has the meaning given by section 2(4) of the Care Standards Act 2000 [M8];

(c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Service (Scotland) Act 1978 [M9]; and

(d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 [M10];

"independent hospital"—

(a) in relation to England, means a hospital as defined by section 275 of the National Health Service Act 2006 that is not a health service hospital as defined by that section;

(b) in relation to Wales, has the meaning given by section 2(2) of the Care Standards Act 2000;

(c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Act 1978; and

(d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

"independent medical agency"—

(a) in relation to England, means an undertaking (not being an independent hospital) which consists of or includes the provision of services by medical practitioners, and the term "undertaking" in this definition includes any business or profession and—

(i) in relation to a public or local authority includes the exercise of any functions of that authority, and

(ii) in relation to any other body of persons, whether corporate or unincorporated, includes any of the activities of that body;

(b) in relation to Wales, has the meaning given by section 2(5) of the Care Standards Act 2000;

(c) in relation to Scotland means an undertaking which is neither an independent clinic nor an undertaking comprised in a hospital and which consists of or includes the provision of services, other than in pursuance of the National Health Service (Scotland) Act 1978, by a medical practitioner; and

(d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

[[F12]"local authority" has the same meaning as in section 2B of the National Health Service Act 2006;**]**

[[F13]"Maritime and Coastguard Agency" means the executive agency of that name of the Department for Transport;**]**

"maximum daily dose" or "MDD", in relation to a product for internal use, means the maximum quantity of the substance contained in the amount of the product that it is recommended should be taken or administered in any period of 24 hours;

"maximum dose" or "MD", in relation to a product for internal use, means the maximum quantity of the substance contained in the amount of the product that it is recommended should be taken or administered at any one time;

"NHS body" means—

(a) the Common Services Agency;

(b) a health authority;

(c) a special health authority;

(ca) **[**F14a clinical commissioning group;

(cb) the National Health Service Commissioning Board;**]**

(d) F15. . . . . .

(e) an NHS trust; or

(f) an NHS foundation trust;

"NHS foundation trust" has the meaning given by section 30(1) of the National Health Service Act 2006;

"NHS trust"—

(a) in relation to England, means an NHS trust established under section 25(1) of the National Health Service Act 2006;

(b) in relation to Wales, means an NHS trust established under section 18(1) of the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, means an NHS trust established under section 12A of the National Health Service (Scotland) Act 1978 M11; and

(d) in relation to Northern Ireland, means a Health and Social Care trust established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991 M12;

"nursing home" has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 M13;

"parenteral administration" means administration by breach of the skin or mucous membrane;

"patient group direction" or "PGD" means a written direction that relates to the sale or supply and to the administration of a description or class of medicinal product and that—

(a) is signed—

(i) by a doctor or dentist and by a pharmacist, and

(ii) by any other person who may be required to sign it in the circumstances specified for its use in any provision of this Part; and

(b) relates to sale or supply and to administration to persons generally (subject to any exclusions that may be specified in the PGD);

F16. . . . . .

"prison service" means—

(a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952 M14);

(b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989 M15); and

(c) in relation to Northern Ireland, the Department of Justice exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953 M16);

[F17"product subject to special medical prescription" means a prescription only medicine that has been designated as subject to special medical prescription in accordance with paragraph (3);**]**

[[F18]"Public Health Agency" means the Regional Agency for Public Health and Social Well-being established by section 12 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

"Public Health England" means the executive agency of that name of the Department of Health **[**[F19]and Social Care**]**;**]**

"registered chiropodist" means a person who is registered in Part 2 of the Health and Care Professions Council register;

"registered dental hygienist" means a person registered under that title in the dental care professionals register;

"registered dental therapist" means a person registered under that title in the dental care professionals register;

[F20] . . . . . .

"registered dispensing optician" means a person whose name is entered in the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989 [M17] or the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b) [M18] of that Act;

"registered occupational therapist" means a person who is registered in Part 6 of the Health and Care Professions Council register;

"registered orthoptist" means a person who is registered in Part 7 of the Health and Care Professions Council register;

"registered orthotist and prosthetist" means a person who is registered in Part 10 of the Health and Care Professions Council register;

[F21] . . . . . .

[F22] . . . . . .

[F23] . . . . . .

"registered provider"—

(a) in England, in relation to an independent hospital, independent clinic, an independent medical agency, a dental clinic or a dental practice means the person who is registered as a service provider under Chapter 2 of Part 1 of the Health and Social Care Act 2008 [M19] in respect of regulated activities (within the meaning of that Part) carried on in that hospital, clinic, agency, dental clinic or dental practice;

(b) in Wales, in relation to an independent hospital, an independent clinic or an independent medical agency, means the person who is registered under Part 2 of the Care Standards Act 2000 as the person who carries on the hospital, clinic or agency;

(c) in Scotland, in relation to an independent hospital, an independent clinic or an independent medical agency, means the person who is registered under section 10P of the National Health Service (Scotland) Act 1978 [M20]; and

(d) in Northern Ireland, in relation to an independent hospital, an independent clinic, a nursing home or an independent medical agency, means the person who is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person who carries on the hospital, clinic, nursing home or agency;

[F24] . . . . . .

"registered speech and language therapist" means a person who is registered in Part 12 of Health and Care Professions Council register;

"relevant manager"—

(a) in England, means—

(i) a person, other than the registered provider, who is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 as the manager of an independent hospital, independent clinic, an independent medical agency, a dental clinic or a dental practice, or

(ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic, agency, dental clinic or dental practice, that person;

(b) in Wales, means—

(i) a person, other than the registered provider, who is registered under Part 2 of the Care Standards Act 2000 as the manager of an independent hospital, an independent clinic or an independent medical agency, or

(ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic or agency, that person;

(c) in Scotland, means a person, other than the registered provider, who was identified as an individual who is to manage an independent hospital, an independent clinic or an independent medical agency on the application for registration of that clinic, hospital or agency under section 10P of the National Health Service (Scotland) Act 1978; and

(d) in Northern Ireland, means—

(i) a person, other than the registered provider, who is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of an independent hospital, an independent clinic, a nursing home or an independent medical agency, or

(ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic, nursing home or agency, that person;

"relevant prescriber" means any of the following—

(a) a doctor;

(b) a dentist;

(c) a supplementary prescriber;

(d) a nurse independent prescriber;

(e) a pharmacist independent prescriber;

(f) a community practitioner nurse prescriber;

(fa) **[**[F25]a physiotherapist independent prescriber;

(fb) a podiatrist independent prescriber;

(fc) a therapeutic radiographer independent prescriber;**]**

(fd) **[**[F26]a paramedic independent prescriber;**]**

(g) an optometrist independent prescriber; and

(h) an **[**[F27]approved country health professional**]**;

"repeatable prescription" means a prescription that contains a direction that it may be dispensed more than once;

[[F28]"school" means—

(a) a maintained school (as defined in section 20(7) of the School Standards and Framework Act 1998);

(b) a maintained nursery school (as defined in section 22(9) of the School Standards and Framework Act 1998);

(c) an independent school (as defined in section 463 of the Education Act 1996) entered on a register of independent schools kept under section 158 of the Education Act 2002;

(d) an independent educational institution (as defined in section 92(1) of the Education and Skills Act 2008) entered on a register of independent educational institutions kept under section 95 of that Act;

(e) a school approved under section 342 of the Education Act 1996 (non-maintained special schools);

(f) a pupil referral unit (as defined in section 19 of the Education Act 1996);

(g) an alternative provision Academy (as defined in section 1C(3) of the Academies Act 2010);

(h) a school as defined in section 135(1) of the Education (Scotland) Act 1980; and

(i) a school as defined in Article 2(2) of the Education and Libraries (Northern Ireland) Order 1986.**]**

"sell" means sell by retail (and "sale" has a corresponding meaning);

"special health authority" means—

(a) in relation to England, a Special Health Authority established under section 28 of the National Health Service Act 2006;

(b) in relation to Wales, a Special Health Authority established under section 22 of the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, a Special Health Board constituted under section 2(1)(b) of the National Health Service (Scotland) Act 1978 [M21]; and

(d) in relation to Northern Ireland, a special health and social care agency established under Article 3 of the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 [M22];

"supply" means supply in circumstances corresponding to retail sale;

"unit preparation" means a preparation, including a mother tincture, that—

(a) is prepared by a process of—

(i) solution,

(ii) extraction, or

(iii) trituration,

with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert dilutent; and

(b) is used—

(i) in that diluted form, or

(ii) where applicable, by impregnating tablets, granules, powders or other inert substances,

for the purpose of being administered to human beings.

(2) In this Part—

(a) a reference to a product being sold or supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a person includes a reference to it being supplied in accordance with such directions; and

(b) a reference to a product being sold or supplied for the purpose of being administered in accordance with a patient group direction includes a reference to it being supplied in accordance with a patient group direction.

[[F29](3) In this Part any substance or product for the time being specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations 2001 or in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002 is designated as a product subject to special medical prescription.**]**

Textual Amendments

F1 Words in reg. 213(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **179(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in reg. 213(1) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(a)** (with Sch. 3 para. 28)

F3 Words in reg. 213(1) omitted (E.W.S.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(i)** and words in reg. 213(1) omitted (N.I.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(i)**

F4 Words in reg. 213(1) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(ii)** and words in reg. 213(1) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(ii)**

F5 Words in reg. 213(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **179(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 213(1) omitted (E.W.S.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(iv)** and words in reg. 213(1) omitted (N.I.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(iv)**

F7 Words in reg. 213(1) omitted (1.10.2017) by virtue of The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **6** and words in reg. 213(1) omitted (N.I.) (1.10.2017) by virtue of The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **6**

F8 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(b)** (with Sch. 3 para. 28)

F9 Words in reg. 213(1) substituted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(a)** and words in reg. 213(1) substituted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(a)**

F10 Words in reg. 213(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **5(2)(a)** and words in reg. 213(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **5(2)(a)**

F11 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(c)** (with Sch. 3 para. 28)

F12 Words in reg. 213(1) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(d)** (with Sch. 3 para. 28)

F13 Words in reg. 213(1) inserted (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **3(2)(a)** and words in reg. 213(1) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **3(2)(a)**

F14 Words in reg. 213(1) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(e)(i)** (with Sch. 3 para. 28)

F15 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(e)(ii)** (with Sch. 3 para. 28)

F16 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(f)** (with Sch. 3 para. 28)

F17 Words in reg. 213(1) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(v)** and words in reg. 213(1) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(v)**

F18 Words in reg. 213(1) inserted (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **3(2)(b)** and words in reg. 213(1) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **3(2)(b)**

F19 Words in reg. 213(1) inserted (11.4.2018) by The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018 (S.I. 2018/378), art. 1(2), **Sch. para. 20(w)** (with art. 14)

F20 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(b)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(b)**

F21 Words in reg. 213(1) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **5(2)(b)** and words in reg. 213(1) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **5(2)(b)**

F22 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(c)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(c)**

F23 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(d)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(d)**

F24 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(e)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(e)**

F25 Words in reg. 213(1) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(f)** and words in reg. 213(1) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(f)**

F26 Words in reg. 213(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **5(2)(c)** and words in reg. 213(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **5(2)(c)**

F27 Words in reg. 213(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **179(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in reg. 213(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **22(b)** and words in reg. 213(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **22(b)**

F29 Reg. 213(3) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(b)** and reg. 213(3) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(b)**

Marginal Citations

M1 1978 c.29. Section 10(1) was amended by the Health Services Act 1980 (1980 c.53), Schedule 6 paragraph 2. There are other amendments not relevant to these Regulations.

M2 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.

M3 2006 c.42.

M4 1978 c.29. Section 2(1)(a) was amended by section 28(a)(i) of the National Health Service and Community Care Act 1990 (1990 c.19) and section 14(2) of, and paragraph 1 of Schedule 7 to, the Health and Social Services and Social Security Adjudications Act 1983 (1983 c.41).
M5 2009 c.1 (N.I.).
M6 S.I. 1972/1265 (N.I. 14).
M7 1983 c.20.
M8 2000 c.14.
M9 1978 c.29. Section 10F was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).
M10 S.I. 2003/431 (N.I. 9).
M11 1978 c.29. Section 12A was inserted by section 31 of the National Health Service and Community Care Act 1990 (1990 c.19), and amended by section 46(1)(a) of the Health Act 1999 (1999 c.8).
M12 S.I. 1991/194 (N.I. 1), Health and Social Services trusts were renamed Health and Social Care trusts by section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I.)). There are other amendments not relevant to this regulation.
M13 References to a nursing home in these Regulations concern Northern Ireland only.
M14 1952 c.52.
M15 1989 c.45.
M16 1953 c.18 (N.I.). Functions transferred by article 6(1) of, and Schedule 4 to, S.I. 2010/976.
M17 1989 c.44; section 7 was amended by S.I. 2005/848, articles 2 and 7(1).
M18 Section 8B was inserted by S.I. 2007/3101, regulations 178 and 180.
M19 2008 c.14.
M20 1978 c.29. Section 10P was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).
M21 Section 2(1)(b) was inserted by section 28(a) of the National Health Service and Community Care Act 1990 (1990 c.19).
M22 S.I. 1990/247 (N.I. 3). Special Health and Social Services Agencies were renamed Special Health and Social Care Agencies by section 1(4) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I.)).

CHAPTER 2

Sale and supply of medicines

Prescription only medicines

Sale or supply of prescription only medicines

214.—(1) A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.

(2) A person may not parenterally administer (otherwise than to himself or herself) a prescription only medicine unless the person is—

(a) an appropriate practitioner other than an **[**F30approved country health professional**]**; or

(b) acting in accordance with the directions of such an appropriate practitioner.

(3) The following are appropriate practitioners in relation to any prescription only medicine—

(a) a doctor;

(b) a dentist;

(c) a supplementary prescriber;

(d) a nurse independent prescriber; and

(e) a pharmacist independent prescriber.

(4) A community practitioner nurse prescriber is an appropriate practitioner in relation to a prescription only medicine specified in Schedule 13.

(5) An optometrist independent prescriber is an appropriate practitioner in relation to any prescription only medicine other than—

(a) a medicinal product that is a **[**F31product subject to special medical prescription**]**; or

(b) a medicinal product that is for parenteral administration.

[F32(5A) A podiatrist independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a **[**F33product subject to special medical prescription**]** other than—

(a) Dihydrocodeine: or

(b) Temazepam.

(5B) A physiotherapist independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a **[**F34product subject to special medical prescription**]** other than—

(a) Dihydrocodeine;

(b) Fentanyl;

(c) Morphine;

(d) Oxycodone; or

(e) Temazepam.**]**

[F35(5C) A therapeutic radiographer independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a product subject to special medical prescription other than—

(a) Codeine;

(b) Fentanyl;

(c) Midazolam;

(d) Morphine;

(e) Oxycodone;

(f) Temazepam; or

(g) Tramadol.**]**

[F36(5D) A paramedic independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a product subject to special medical prescription other than—

(a) Codeine;

(b) Fentanyl;

(c) Midazolam; or

(d) Morphine.**]**

(6) An **[**F37approved country health professional**]** is an appropriate practitioner in relation to any prescription only medicine other than a **[**F38product subject to special medical prescription**]**.

[F39(6A) The licensing authority must publish a list of approved countries and professions for the purposes of the definition of "approved country health professional".

(6B) In order to determine whether a country or profession should be included in the list published under paragraph (6A), the licensing authority may, in particular, take into account—

(a) the country's standards of professional qualification;

(b) the country's system for ensuring that qualified professionals have undergone training which meets the requirements that apply in that country;

(c) the effectiveness of enforcement of professional standards;

(d) the mechanisms the country has in place to assist members of the public in obtaining information in respect of a qualified professional who is established there; and

(e) the regularity and rapidity of information provided by that country relating to non-compliant professionals.

(6C) The licensing authority must—

(a) review a country or profession it has included in the list published under paragraph (6A) to determine if it is still satisfied that they should remain on the list, and if it is not so satisfied, remove it from that list; and

(b) undertake such a review at least every 3 years beginning with the date on which that country or profession was included in that list.**]**

(7) This regulation is subject to Chapter 3 (exemptions).

Textual Amendments

F30 Words in reg. 214(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **180(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in reg. 214(5)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(5)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F32 Reg. 214(5A)(5B) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **26**

F33 Words in reg. 214(5A) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(5A) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F34 Words in reg. 214(5B) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(5B) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F35 Reg. 214(5C) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **9** and reg. 214(5C) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **9**

F36 Reg. 214(5D) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **6** and reg. 214(5D) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **6**

F37 Words in reg. 214(6) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **180(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F38 Words in reg. 214(6) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(6) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F39 Reg. 214(6A)-(6C) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **180(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Prescribing and administration by supplementary prescribers

215.—(1) A supplementary prescriber ("S") may not give a prescription for a prescription only medicine unless S meets conditions A and C.

(2) A supplementary prescriber ("S") may not—

(a) parenterally administer a prescription only medicine; or

(b) give directions for the parenteral administration of a prescription only medicine,

unless S meets conditions B and C.

(3) Condition A is that S is acting in accordance with the terms of a clinical management plan that—

(a) relates to the patient to whom the product is prescribed;

(b) has effect when the prescription is given; and

(c) includes the particulars specified in Schedule 14.

(4) Condition B is that S is acting in accordance with the terms of a clinical management plan that—

(a) relates to the patient to whom the product is, or is to be, administered;

(b) has effect when the product is administered or (as the case may be) the direction is given; and

(c) includes the particulars specified in Schedule 14.

(5) Condition C is that S has access to health records that—

(a) are the health records of the patient to whom the plan relates; and

(b) are used by any doctor or dentist who is a party to the plan.

(6) This regulation is subject to regulation 216.

(7) In this regulation—

"clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates;

(b) the doctor or dentist who is a party to the plan; and

(c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

"health record" has the meaning given by section 68(2) of the Data Protection Act 1998 [M23].

Marginal Citations

M23 1998 c.29.

Exceptions to regulation 215

216.—(1) Regulation 215 does not apply if—

(a) S is a community practitioner nurse prescriber; and

(b) the prescription only medicine prescribed or administered, or in respect of which S gives directions for administration, is specified in Schedule 13.

(2) Regulation 215(2) does not apply if S is acting in accordance with the directions of another person who is an appropriate practitioner (other than a supplementary prescriber or an **[**[F40]approved country health professional**]**) in relation to the prescription only medicine in question.

Textual Amendments

F40 Words in reg. 216(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **181**; 2020 c. 1, Sch. 5 para. 1(1)

Requirements for prescriptions: general

217.—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner unless the following conditions are met.

(2) Condition A is that the prescription is signed in ink by the appropriate practitioner giving it.

(3) Condition B is that the prescription—

(a) is written in ink or otherwise so as to be indelible; or

(b) in the case of a health prescription which is not for a **[**[F41]product subject to special medical prescription**]**, is written as described in sub-paragraph (a) or by means of carbon paper or similar material.

(4) Condition C is that the prescription contains the following particulars—

(a) the address of the appropriate practitioner giving it;

(b) the appropriate date;

(c) an indication of the kind of appropriate practitioner giving it;

(d) the name and address of the person for whose treatment it is given; and

(e) if that person is under 12, that person's age.

(5) Condition D is that the prescription—

(a) is not dispensed after the end of the period of six months beginning with the appropriate date; or

(b) in the case of a repeatable prescription—

(i) it is not dispensed for the first time after the end of that period, and

(ii) it is dispensed in accordance with the directions contained in the prescription.

(6) Condition E is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—

(a) it is not dispensed on more than two occasions, or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the appropriate date.

(7) In this regulation "appropriate date" means, subject to paragraph (8)—

(a) in the case of a health prescription, whichever is the later of—

(i) the date on which it was signed by the appropriate practitioner giving it, or

(ii) a date indicated by the appropriate practitioner as the date before which it should not be dispensed; and

(b) otherwise, the date on which the prescription was signed by the appropriate practitioner giving it.

(8) This regulation—

(a) does not apply to a prescription given by an **[**F42approved country health professional**]** (as to which see regulation 218); and

(b) is subject to regulation 219 (electronic prescriptions).

Textual Amendments

F41 Words in reg. 217(3)(b) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(b)** and words in reg. 217(3)(b) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(b)**

F42 Words in reg. 217(8)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **182**; 2020 c. 1, Sch. 5 para. 1(1)

[F43**Requirements for prescriptions to be dispensed in an EEA state** F44**...**

217A.—(1) In this regulation—

"B" means a person who is an appropriate practitioner for the purposes of regulation 214(3) to (5B);

"P" means a person who is the patient of B.

(2) The information specified in paragraph (3) is to be included in any prescription where—

(a) P requests a prescription that is to be dispensed in an EEA state F45...; and

(b) B determines that such a prescription is appropriate.

(3) The specified information is—

(a) the patient's—

(i) surname,

(ii) first names written out in full, and

(iii) date of birth;

(b) the issue date of the prescription;

(c) B's—

(i) surname,

(ii) first names written out in full,

(iii) professional qualification,

(iv) direct contact details including—

(aa) email address,

(bb) telephone or fax number with the appropriate international prefix,

(v) work address,

(vi) confirmation that B works as a health professional in the UK, and

(vii) electronic signature or a signature written in ink;

(d) details about the prescribed product, including where applicable the—

(i) common name of the product as defined by Article 1 of the 2001 Directive,

(ii) brand name if—

(aa) the prescribed product is a biological medicinal product, or

(bb) B deems it medically necessary for that product to be dispensed and B's reasons justifying the use of the branded product,

(iii) pharmaceutical formulation (tablet, solution, etc.),

(iv) quantity,

(v) strength of the medicinal product as defined in Article 1 of the 2001 Directive, and

(vi) dosage regimen.

(4) A prescription under this regulation may only be issued by B in relation to those products that B is authorised to prescribe under regulation 214(3) to (5B).**]**

Textual Amendments

F43 Reg. 217A inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **6** and reg. 217A inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **6**

F44 Words in reg. 217A heading omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **183(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F45 Words in reg. 217A(2)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **183(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Requirements for prescriptions: [F46approved country health professional]

218.—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner who is an **[**F47approved country health professional**]** unless the following conditions are met.

[F48(2) Condition A is that—

(a) the prescription is issued in a **[**F49country included in the list published under regulation 214(6A)**]**; and

(b) the prescribing **[**F47approved country health professional**]** is legally entitled to issue a prescription of that kind in the country in which the prescription is issued.**]**

[F50(3) Condition B is that the prescription is signed in ink by the prescribing **[**F47approved country health professional**]**.**]**

(4) Condition C is that the prescription is written in ink or otherwise so as to be indelible.

[F51(5) Condition D is that the prescription contains—

(a) the patient's—

(i) surname,

(ii) first names written out in full, and

(iii) date of birth;

(b) the issue date of the prescription;

(c) the prescribing **[**F52approved country health professional's**]**—

(i) surname,

(ii) first names written out in full,

(iii) professional qualification,

(iv) direct contact details including—

(aa) email address, and

(bb) telephone or fax number with the appropriate international prefix,

(v) work address, and

(vi) name of the relevant member State in which that **[**F47approved country health professional**]** works; and

(d) details about the prescribed product, including where applicable the—

(i) common name of the product,

(ii) brand name if—

(aa) the prescribed product is a biological medicinal product, or

(bb) the prescribing **[**F47approved country health professional**]** deems it medically necessary for that product to be dispensed and the **[**F53approved country health professional's**]** reasons justifying the use of the branded product,

(iii) pharmaceutical formulation (tablet, solution, etc.),

(iv) quantity,

(v) strength of the medicinal product as defined in Article 1 of the 2001 Directive, and

(vi) dosage regimen.**]**

(6) Condition E is that the prescription—

(a) is not dispensed after the end of the period of six months beginning with the date on which it is signed by the **[**F47approved country health professional**]**; or

(b) in the case of a repeatable prescription—

(i) it is not dispensed for the first time after the end of that period, and

(ii) it is dispensed in accordance with the directions contained in the prescription.

(7) Condition F is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—

(a) it is not dispensed on more than two occasions; or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the date on which it is signed by the **[**F47approved country health professional**]**.

(8) This regulation is subject to regulation **[**F54219A (electronic prescriptions: EEA health professionals)**]**.

Textual Amendments

F46 Words in reg. 218 heading substituted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(2)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F47 Words in reg. 218 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F48 Reg. 218(2) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **23** and reg. 218(2) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **23**

F49 Words in reg. 218(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F50 Reg. 218(3) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **7(3)** and reg. 218(3) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **7(3)**

F51 Reg. 218(5) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **7(4)** and reg. 218(5) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **7(4)**

F52 Words in reg. 218(5)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F53 Words in reg. 218(5)(d)(ii)(bb) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F54 Words in reg. 218(8) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **3** and words in reg. 218(8) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **3**

Electronic prescriptions

219.—(1) This regulation applies to a prescription that is not a health prescription for a **[**[F55]substance or product for the time being specified in Schedule 1 to the Misuse of Drugs Regulations 2001 or in Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002**]**.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an appropriate practitioner other than an **[**[F56]approved country health professional**]** if—

(a) conditions A and B in regulation 217 are not met; but

(b) the conditions in paragraph (4) of this regulation and conditions C to E in regulation 217 are met.

[F57](3) . . . . . .

(4) The conditions mentioned in **[**[F58]paragraph (2)(b)**]** are that the prescription is—

(a) created in electronic form;

[[F59](b) signed with an advanced electronic signature; and

(c) sent to the person by whom it is dispensed—

(i) as an electronic communication (whether or not through one or more intermediaries), and

(ii) via the electronic prescription service, if it is for a substance or product for the time being specified in Schedule 2 or 3 to the Misuse of Drugs Regulations 2001 or in Schedule 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002.**]**

[[F60](5) In this regulation—

[[F61]"advanced electronic signature" has the meaning given within Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market;**]**

"electronic prescription service" means the service of that name which is managed by the Health and Social Care Information Centre established under section 252 of the Health and Social Care Act 2012 (the Health and Social Care Information Centre).**]**

Textual Amendments

F55 Words in reg. 219(1) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(2)** and words in reg. 219(1) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(2)**

F56 Words in reg. 219(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **185**; 2020 c. 1, Sch. 5 para. 1(1)

F57 Reg. 219(3) omitted (E.W.S.) (1.7.2015) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(3)** and reg. 219(3) omitted (N.I.) (1.7.2015) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(3)**

F58 Words in reg. 219(4) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(4)(a)** and words in reg. 219(4) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(4)(a)**

F59 Reg. 219(4)(b)(c) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(4)(b)** and reg. 219(4)(b)(c) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(4)(b)**

F60 Reg. 219(5) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(5)** and reg. 219(5) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(5)**

F61 Words in reg. 219(5) substituted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 8(2)**

[F62Electronic Prescriptions: [F63approved country health professionals]

219A.—(1) This regulation applies to a prescription that is not a health prescription for a product subject to special medical prescription.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an **[**F64approved country health professional**]** if—

(a) conditions B and C in regulation 218 are not met; but

(b) the conditions in paragraph (3) of this regulation and conditions A and D to F in regulation 218 are met.

(3) The conditions mentioned in paragraph (2)(b) are that the prescription is—

(a) created in electronic form;

(b) signed with an electronic signature; and

(c) sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries).**]**

Textual Amendments

F62 Reg. 219A inserted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **5** and reg. 219A inserted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **5**

F63 Words in reg. 219A heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **186(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F64 Words in reg. 219A(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **186(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Medicines not subject to general sale

Sale or supply of medicinal products not subject to general sale

220.—(1) Unless paragraph (2) applies, a person ("P") may not sell or supply, or offer for sale or supply, a medicinal product that is not subject to general sale.

(2) This paragraph applies if—

(a) P is a person lawfully conducting a retail pharmacy business;

(b) the product is sold, supplied, or offered for sale or supply, on premises that are a registered pharmacy; and

(c) P or, if the transaction is carried out on P's behalf by another person, that other person is, or acts under the supervision of, a pharmacist.

(3) This regulation is subject to Chapter 3.

General sale medicines

Sale or supply of medicinal products subject to general sale

221.—(1) A person ("P") may not sell or supply, or offer for sale or supply, a medicinal product that is subject to general sale elsewhere than at a registered pharmacy unless the following conditions are met.

(2) Condition A is that the place at which the medicinal product is sold, supplied, or offered for sale or supply, consists of premises of which P is the occupier and which P is able to close so as to exclude the public.

(3) Condition B is that—

(a) the medicinal product was made up for sale in its immediate and outer packaging elsewhere than at the place at which it is sold, supplied, or offered for sale or supply; and

(b) the immediate and outer packaging has not been opened since the product was made up for sale in it.

(4) Condition C is that, if the medicinal product is of a kind specified in Schedule 15, it is presented for sale in accordance with the requirements specified in that Schedule for a product of that kind.

(5) This regulation is subject to Chapter 3.

Sale of medicinal products from automatic machines

222. A person may not sell or offer for sale a medicinal product by means of an automatic machine if the product is not subject to general sale.

CHAPTER 3

Exemptions

Exemptions relating to supply in specific circumstances

Exemptions for doctors and dentists etc

223.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a doctor or dentist to a patient of that doctor or dentist.

(2) Regulations 220 and 221 do not apply to the sale, offer for sale, or supply of a medicinal product by a doctor or dentist—

(a) to a patient of the doctor or dentist, or

(b) to a person under whose care such a patient is.

(3) Regulations 220 and 221 do not apply to the sale, offer for sale or supply of a medicinal product in the course of the business of a hospital or health centre, where—

(a) the product is sold, offered for sale or supplied for the purposes of being administered to a person (whether in the hospital or health centre or elsewhere) in accordance with directions relating to that person; and

(b) those directions have been given by—

(i) a doctor,

(ii) a dentist,

(iii) a supplementary prescriber,

(iv) a pharmacist independent prescriber,

(v) an optometrist independent prescriber,

[F65(vi) a nurse independent prescriber,

(vii) a community practitioner nurse prescriber,

(viii) a podiatrist independent prescriber, F66...

(ix) a physiotherapist independent prescriber**]**F67...

[F68(x) a therapeutic radiographer independent prescriber**][**F69, or

(xi) a paramedic independent prescriber.**]**

(4) Regulations 220 and 221 do not apply to the sale or supply of a medicinal product to which paragraph (5) applies where—

(a) the product is sold or supplied by a registered midwife in the course of the registered midwife's professional practice; or

(b) the product is delivered or administered by a registered midwife on being supplied the product under arrangements made by the Secretary of State or the Minister for Health, Social Services and Public Safety.

(5) The products to which this paragraph applies are—

(a) medicinal products that are not prescription only medicines;

(b) prescription only medicines which by virtue of an exemption conferred under regulation 235(1) and 235(3) and Part 1 of Schedule 17 may be sold or supplied by a registered midwife otherwise than in accordance with a prescription given by a doctor or a dentist; and

(c) prescription only medicines which by virtue of an exemption conferred under regulation 235(3) and Part 3 of Schedule 17 may be administered by a registered midwife or a student midwife otherwise than in accordance with a prescription given by a doctor or a dentist.

Textual Amendments

F65 Reg. 223(3)(b)(vi)-(ix) substituted for reg. 223(3)(b)(vi)(vii) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **27**

F66 Word in reg. 223(3)(b)(viii) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **10(2)(a)** and word in reg. 223(3)(b)(viii) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **10(2)(a)**

F67 Word in reg. 223(3)(b)(ix) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **7(2)(a)** and word in reg. 223(3)(b)(ix) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **7(2)(a)**

F68 Reg. 223(3)(b)(x) and preceding word inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **10(2)(b)** and reg. 223(3)(b)(x) and preceding word inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **10(2)(b)**

F69 Reg. 223(3)(b)(xi) and preceding word inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **7(2)(b)** and reg. 223(3)(b)(xi) and preceding word inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **7(2)(b)**

Emergency sale etc by pharmacist: prescriber unable to provide prescription

224.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A to E are met.

(2) Condition A is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a relevant prescriber who by reason of an emergency is unable to provide a prescription immediately.

(3) Condition B is that the relevant prescriber has undertaken to provide the person lawfully conducting the retail pharmacy business with a prescription within the period of 72 hours beginning with the sale or supply.

(4) Condition C is that the prescription only medicine is sold or supplied in accordance with the directions of the relevant prescriber.

(5) Condition D is that the prescription only medicine is not a **[**[F70]product subject to special medical prescription**]**, other than a prescription only medicine that—

(a) consists of or contains phenobarbital or phenobarbital sodium; and

(b) is sold or supplied for use in the treatment of epilepsy.

(6) Condition E is that an entry is made in the record kept under regulation 253 within the time specified in that regulation stating the particulars required under paragraph 2 of Schedule 23.

Textual Amendments

F70 Words in reg. 224(5) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(d)** and words in reg. 224(5) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(d)**

Emergency sale etc by pharmacist: at patient's request

225.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A to E are met.

(2) Condition A is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting it and is satisfied—

(a) that there is an immediate need for the prescription only medicine to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay;

(b) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person requesting it; and

(c) as to the dose which in the circumstances it would be appropriate for that person to take.

(3) Condition B is that for a prescription only medicine shown in column 1 of the following table, the quantity of the product that is sold or supplied does not exceed that shown in column 2 for that prescription only medicine—

Prescription only medicine	***Maximum quantity***
A prescription only medicine that— (a) is a preparation of insulin, an aerosol for the relief of asthma, an ointment or cream, and (b) has been made up for sale in a package elsewhere than at the place of sale or supply.	The smallest pack that the pharmacist has available for sale or supply.
An oral contraceptive.	A quantity sufficient for a full treatment cycle.
An antibiotic for oral administration in liquid form.	The smallest quantity that will provide a full course of treatment.
A controlled drug within the meaning of Schedule 4 or 5 of the Misuse of Drugs Regulations 2001 or Schedule 4 or 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002.	Five days' treatment.
Any other prescription only medicine.	30 days' treatment.

(4) Condition C is that the prescription only medicine—

(a) does not consist of or contain a substance specified in Schedule 18; and

(b) is not a **[**[F71]product subject to special medical prescription**]**, other than a prescription only medicine that—

(i) consists of or contains phenobarbital or phenobarbital sodium, and

(ii) is sold or supplied for use in the treatment of epilepsy.

(5) Condition D is that an entry is made in the record kept under regulation 253 within the time specified in that regulation stating the particulars required under paragraph 4 of Schedule 23.

(6) Condition E is that the inner or outer packaging of the prescription only medicine is labelled to show—

(a) the date on which the prescription only medicine is sold or supplied;

(b) the name, quantity and (unless apparent from the name) the pharmaceutical strength of the prescription only medicine;

(c) the name of the person requesting the prescription only medicine;

(d) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied; and

(e) the words “Emergency Supply”.

(7) In this regulation “aerosol” means a product that is dispersed from its container by a propellant gas or liquid.

Textual Amendments

F71 Words in reg. 225(4)(b) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(e)** and words in reg. 225(4)(b) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(e)**

Emergency sale etc by pharmacist: pandemic diseases

226.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A and B are met.

(2) Condition A is that the supply is made whilst a disease is, or in anticipation of a disease being imminently,—

(a) pandemic; and

(b) a serious risk, or potentially a serious risk, to human health.

(3) Condition B is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied—

(a) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and

(b) as to the dose which in the circumstances it would be appropriate for that person to take.

[F72Sale etc by a pharmacist in accordance with a serious shortage protocol

226A.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.

(2) Condition A is that the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol (SSP).

(3) Condition B is that the requirements of the SSP are satisfied in respect of to whom, and subject to what conditions, the prescription only medicine may be sold or supplied for the purpose of being administered.

(4) Condition C is that the sale or supply of the prescription only medicine is by or under the supervision of a pharmacist who is of the opinion, in the exercise of his or her professional skill and judgement, that—

(a) in a case to which paragraph (5)(b)(i) applies, the sale or supply of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form of the prescription only medicine ordered by the prescriber is reasonable and appropriate; or

(b) in a case to which paragraph (5)(b)(ii) applies, the sale or supply of—

(i) a prescription only medicine other than the prescription only medicine ordered by the prescriber is reasonable, and

(ii) the substituted prescription only medicine, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this regulation, a SSP is a written protocol that—

(a) is issued by the Ministers (either of them acting alone or both of them acting jointly) in circumstances where the United Kingdom or any part of the United Kingdom is, in the opinion of the Ministers (either of them forming the opinion alone or both of them forming

the opinion jointly), experiencing or may experience a serious shortage of a prescription only medicine or prescription only medicines of a specified description;

(b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP—

(i) of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form ordered by the prescriber, or

(ii) of a prescription only medicine other than the prescription only medicine ordered by the prescriber;

(c) provides, in a case to which sub-paragraph (b)(ii) applies, that the other prescription only medicine is to be—

(i) a generic version of the prescription only medicine being substituted, or that both products are generic versions of another prescription only medicine,

(ii) in the case of a biological medicinal product, a similar medicinal product to the prescription only medicine being substituted, or that both products are similar medicinal products to another biological medicinal product, or

(iii) a prescription only medicine that has a similar therapeutic effect to the prescription only medicine being substituted; and

(d) specifies the period for which, and the parts of the United Kingdom (which may be all of the United Kingdom) in which, the protocol is to have effect.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol issued under this regulation has effect, the Ministers must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

Textual Amendments

F72 Reg. 226A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **9** and reg. 226A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **9**

Exemption for sale or supply in hospitals

227.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine—

(a) in the course of the business of a hospital; and

(b) for the purpose of being administered (in the hospital or elsewhere) to a particular person in accordance with directions that meet the conditions in paragraph (2).

(2) Those conditions are that the directions—

(a) are in writing;

(b) relate to the particular person to whom the prescription only medicine is to be administered; and

(c) are given by a person who is an appropriate practitioner in relation to that prescription only medicine.

(3) But such directions may be given by a supplementary prescriber only where the supplementary prescriber complies with regulations 215 (prescribing and administration by supplementary prescribers) and 216 (exceptions to regulation 215) in relation to the directions as if they were a prescription.

(4) This regulation applies regardless of whether the directions comply with regulation 217 (requirements for prescriptions).

Exemptions relating to prescriptions given by certain health professionals

228.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a pharmacist where—

(a) the sale or supply is in accordance with a prescription given by a person listed in paragraph (2) who is not an appropriate practitioner in relation to that prescription only medicine; but

(b) the pharmacist, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.

(2) Those persons are—

(a) another pharmacist;

(b) a registered nurse;

(c) a registered midwife;

(d) a person whose name is entered in the part of the Health and Care Professions Council register relating to—

(i) chiropodists and podiatrists,

(ii) physiotherapists, [F73]...

(iii) radiographers: diagnostic or therapeutic; or

[[F74](iv) paramedics; or**]**

(e) a registered optometrist.

(3) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a pharmacist where—

(a) the sale or supply is in accordance with a prescription given by a supplementary prescriber; and

(b) the pharmacist, having exercised all due diligence, believes on reasonable grounds that the supplementary prescriber has complied with regulation 215.

Textual Amendments

F73 Word in reg. 228(2)(d)(ii) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **8(2)(a)** and word in reg. 228(2)(d)(ii) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **8(2)(a)**

F74 Reg. 228(2)(d)(iv) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **8(2)(b)** and reg. 228(2)(d)(iv) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **8(2)(b)**

Exemption for supply by national health service bodies [F75and local authorities]

229.—(1) Regulations 214(1) **[**F76and (2)**]**, 220 and 221 do not apply to the supply of a medicinal product in accordance with condition A or B by—

(a) the Common Services Agency;

(b) a health authority or special health authority;

(c) an NHS trust;

(d) an NHS foundation trust;

[F77(da) a local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006); F78...**]**

[F79(db) Public Health England;

(dc) Public Health Agency; or**]**

F80(e) . . . . . .

(f) a person who is not a doctor, dentist or person lawfully conducting a retail pharmacy business, where the person supplies the product pursuant to an arrangement with **[**F81a clinical commissioning group, the National Health Service Commissioning Board or**]** one of the persons specified in paragraphs (a) **[**F82to **[**F83(dc)**]]**.

(2) Condition A is that the product is supplied for the purpose of being administered to a person in accordance with the written directions of a doctor, dentist, nurse independent prescriber, optometrist independent prescriber **[**F84, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**F85, paramedic independent prescriber**]** or pharmacist independent prescriber relating to that person, regardless of whether the directions comply with regulation 217 (requirements for prescriptions).

[F86(2A) In relation to a medicinal product that is for parenteral administration, condition A only applies if the person who has given the written directions is an appropriate practitioner in relation to that medicinal product.**]**

(3) Condition B is that—

(a) the product is supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD");

(b) the PGD relates to the supply of a description or class of medicinal product by the person by whom the medicinal product is supplied and has effect at the time at which it is supplied;

(c) the PGD contains the particulars specified in Part 1 of Schedule 16;

(d) the PGD is signed on behalf of the person specified in column 2 of the table in Part 2 of that Schedule ("the authorising person") against the entry in column 1 of that table for the class of person by whom the product is supplied;

(e) the individual who supplies the product—

(i) belongs to one of the classes of individual specified in Part 4 of that Schedule, and

(ii) is designated in writing, on behalf of the authorising person, for the purpose of the supply or administration of products under the PGD; and

[F87(f) when the product is supplied **[**F88, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(i) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), **[**F89or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(ii) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

[F90](4) . . . . . .

Textual Amendments

F75 Words in reg. 229 heading inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(a)** (with Sch. 3 para. 28)

F76 Words in reg. 229(1) inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **5(a)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **5(a)**

F77 Reg. 229(1)(da) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(b)** (with Sch. 3 para. 28)

F78 Word in reg. 229(1)(da) omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **4(2)(a)** and word in reg. 229(1)(da) omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **4(2)(a)**

F79 Reg. 229(1)(db)(dc) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **4(2)(b)** and reg. 229(1)(db)(dc) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **4(2)(b)**

F80 Reg. 229(1)(e) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(c)** (with Sch. 3 para. 28)

F81 Words in reg. 229(1)(f) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(d)(i)** (with Sch. 3 para. 28)

F82 Words in reg. 229(1)(f) substituted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(d)(ii)** (with Sch. 3 para. 28)

F83 Word in reg. 229(1)(f) substituted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **4(2)(c)** and word in reg. 229(1)(f) substituted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **4(2)(c)**

F84 Words in reg. 229(2) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **11** and words in reg. 229(2) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **11**

F85 Words in reg. 229(2) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **9** and words in reg. 229(2) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **9**

F86 Reg. 229(2A) inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **5(b)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **5(b)**

F87 Reg. 229(3)(f) substituted (31.12.2020) by S.I. 2019/775, **reg. 187** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 141**)

F88 Words in reg. 229(3)(f) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **5(c)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **5(c)**

F89 Words in reg. 229(3)(f)(i) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **17**

F90 Reg. 229(4) omitted (31.3.2022) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **5**

Exemption for supply etc under a PGD to assist doctors or dentists

230.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product by an individual belonging to one of the classes specified in Part 4 of Schedule 16 where—

(a) the individual supplies or (as the case may be) administers the product to assist a doctor in the provision of NHS primary medical services or a dentist in the provision of NHS primary dental services;

(b) the product is supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD"); and

(c) the following conditions are met.

(2) Condition A is that the PGD relates to the supply or (as the case may be) administration of a description or class of medicinal product in order to assist the doctor or dentist in providing the services (whether or not it relates to such supply in order to assist any other doctor or dentist).

(3) Condition B is that the PGD has effect at the time at which the product is supplied or (as the case may be) administered.

(4) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(5) Condition D is that the PGD is signed—

(a) by the doctor or dentist; or

(b) where it also relates to supply or administration to assist one or more other doctors or dentists, by one of those doctors or dentists.

(6) Condition E is that the PGD is signed—

(a) in the case of—

(i) NHS primary medical services, or

(ii) NHS primary dental services in England or Wales,

on behalf of the health authority**[**F91, local authority or National Health Service Commissioning Board**]** with which a contract or agreement for the provision of those services has been made or which provides those services;

(b) in the case of dental services in Scotland under the National Health Service (Scotland) Act 1978 M24, or general dental services in Northern Ireland, on behalf of the health authority with which an arrangement for the provision of those services has been made; and

(c) in the case of personal dental services provided under a pilot scheme in Scotland or Northern Ireland, on behalf of the health authority which is a party to the pilot scheme.

(7) Condition F is that the individual supplying the product is designated in writing for the purpose of the supply or (as the case may be) administration of medicinal products under the PGD—

(a) by the doctor or dentist; or

(b) where it also relates to supply to assist one or more other doctors or dentists, by one of those doctors or dentists.

[F92(8) Condition G is that when the product is supplied or (as the case may be) administered **[**F93, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), **[**F94or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

Textual Amendments

F91 Words in reg. 230(6)(a) substituted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(4)** (with Sch. 3 para. 28)

F92 Reg. 230(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 188** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 142**)

F93 Words in reg. 230(8) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **6** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **6**

F94 Words in reg. 230(8)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **18**

Marginal Citations

M24 1978 c.29.

Exemption for supply etc under a PGD by independent hospitals etc

231.—(1) Regulations 214, 220 and 221 do not apply to the sale or supply, or administration, of a medicinal product in accordance with the following conditions by—

(a) an independent hospital;

(b) an independent clinic;

(c) an independent medical agency; or

(d) a nursing home (in Northern Ireland).

(2) Condition A, which applies only to England, is that the registered provider at the hospital, clinic or agency is registered in compliance with section 10 of the Health and Social Care Act 2008 M25 in respect of one or more of the following regulated activities M26—

(a) treatment of disease, disorder or injury;

(b) assessment or medical treatment of persons detained under the Mental Health Act 1983;

(c) surgical procedures;

(d) diagnostic and screening procedures;

(e) maternity and midwifery services; and

(f) family planning.

(3) Condition B is that the product is sold or supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD").

(4) Condition C is that the PGD—

(a) relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person by whom the medicinal product is sold or supplied or administered; and

(b) has effect at the time at which it is sold or supplied.

(5) Condition D is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(6) Condition E is that the PGD is signed—

(a) by or on behalf of the registered provider; and

(b) if there is a relevant manager for the independent hospital, clinic or medical agency, or nursing home, by that manager.

(7) Condition F is that the individual who sells or supplies or (as the case may be) administers the product—

(a) belongs to one of the classes of individual specified in Part 4 of Schedule 16; and

(b) is designated in writing for the purpose of the sale or supply or (as the case may be) administration of products under the PGD—

(i) by or on behalf of the registered provider, or

(ii) if there is a relevant manager for the independent hospital, clinic or medical agency, or nursing home, by that manager.

[F95(8) Condition G is that when the product is supplied **[**F96, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK) **[**F97or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

Textual Amendments

F95 Reg. 231(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 189** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 143**)

F96 Words in reg. 231(8) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **7** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **7**

F97 Words in reg. 231(8)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **19**

Marginal Citations

M25 2008 c.14.

M26 Regulated activities for the purposes of section 10 are defined in section 8 of that Act and set out in regulation 3 of, and Schedule 1 to, S.I. 2010/781.

Exemption for supply etc under a PGD by dental practices and clinics: England and Wales

232.—(1) Regulations 214, 220 and 221 do not apply to the sale or supply, or administration, of a medicinal product in accordance with the following conditions by—

(a) a dental practice in England and Wales to which paragraph (2) applies; or

(b) a dental clinic in England and Wales to which paragraph (2) applies.

(2) This paragraph applies to a dental practice or dental clinic —

(a) in England, in respect of which the registered provider is registered in compliance with section 10 of the Health and Social Care Act 2008 in respect of one or both of the following regulated activities—

(i) treatment of disease, disorder or injury, or

(ii) diagnostic and screening procedures;

(b) in Wales, in which dental services are provided by private dentists and those dentists are registered with Healthcare Inspectorate Wales in accordance with the Private Dentistry (Wales) Regulations 2008 [M27], in relation to the services provided by those dentists.

(3) Condition A is that the product is sold or supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD").

(4) Condition B is that the PGD—

(a) relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person by whom the medicinal product is sold or supplied or administered; and

(b) has effect at the time at which it is sold or supplied.

(5) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(6) Condition D is that the PGD is signed—

(a) in England—

(i) by or on behalf of the registered provider, and

(ii) if there is a relevant manager for the practice or clinic, by that manager;

(b) in Wales—

(i) by the private dentist who is treating the person, and

(ii) if there is a manager for the practice or clinic, by that manager.

(7) Condition E is that the individual who sells or supplies or (as the case may be) administers the product—

(a) belongs to one of the classes of individual specified in Part 4 of Schedule 16; and

(b) is designated in writing for the purpose of the sale or supply or (as the case may be) administration of products under the PGD—

(i) in England—

(aa) by or on behalf of the registered provider, or

(bb) if there is a relevant manager for the practice or clinic, by that manager, or

(ii) in Wales, by the private dentist who is treating the person.

[[F98](8) Condition F is that when the product is supplied, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK) is in force in relation to it.**]**

(9) In relation to Wales, in this regulation "manager" means—

(a) a person who carries on the dental practice or dental clinic; or

(b) if there is no such person, a person who manages the practice or clinic.

Textual Amendments

F98 Reg. 232(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 190** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 144**)

Marginal Citations

M27 2008 No. 1976 (W. 185).

Exemption for supply etc under a PGD by person conducting a retail pharmacy business

233.—(1) Regulation 214 does not apply to the sale or supply, or administration, of a prescription only medicine by a person lawfully conducting a retail pharmacy business where—

(a) the person sells, supplies or (as the case may be) administers the prescription only medicine pursuant to an arrangement for the supply or administration of prescription only medicines with—

(i) the Common Services Agency,

(ii) a health authority or special health authority,

(iii) an NHS trust,

(iv) an NHS foundation trust,

[F99(iva) a clinical commissioning group,

(ivb) the National Health Service Commissioning Board,

(ivc) a local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006),**]**

[F100(ivd) Public Health England,

(ive) Public Health Agency,**]**

F101(v) . . . . . .

(vi) a police force in England, Wales or Scotland,

(vii) the Police Service of Northern Ireland,

(viii) a prison service,

(ix) Her Majesty's Forces, or

(x) an authority or person carrying on the business of an independent hospital, an independent clinic, an independent medical agency or, in Northern Ireland, a nursing home;

(b) the prescription only medicine is sold or supplied for the purpose of being supplied or (as the case may be) is administered to a person in accordance with a patient group direction ("PGD"); and

(c) the following conditions are met.

(2) Condition A is that the PGD relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person lawfully conducting a retail pharmacy business who sells or supplies or (as the case may be) administers the prescription only medicine.

(3) Condition B is that the PGD has effect at the time at which the prescription only medicine is sold or supplied or (as the case may be) administered.

(4) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(5) Condition D is that the PGD is signed—

(a) in the case of an arrangement with a body referred to in paragraph (1)(a)(i) **[**F102to (ive) (health bodies), by or on behalf of the person specified in column 2 of Part 2 of Schedule 16 against the entry in column 1 for that body**]**;

(b) in the case of an arrangement with a police force in England, Wales or Scotland or with the Police Service of Northern Ireland—

(i) by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body, and

(ii) by a doctor who is not employed or engaged by, and does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;

(c) in the case of an arrangement with a prison service, by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body;

(d) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for Her Majesty's Forces;

(e) in the case of an arrangement with an authority or person referred to in paragraph (1)(a)(x) (independent hospitals etc)—

(i) by or on behalf of the registered provider, and

(ii) if there is a relevant manager for the establishment or agency in question, by that manager.

(6) Condition E is that, where the prescription only medicine is administered by the person lawfully conducting a retail pharmacy business, the person belongs to one of the classes of individual specified in Part 4 of Schedule 16 and is designated in writing for the purpose of the administration of medicinal products under the PGD—

(a) in the case of an arrangement with a body referred to in paragraph (1)(a)(i) to (v) (health bodies), on behalf of that body;

(b) in the case of an arrangement with a body referred to in paragraph (1)(a)(vi) to (ix) (a police force, the Police Service of Northern Ireland, a prison service and Her Majesty's Forces), by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body; and

(c) in the case of an arrangement with an authority or person referred to in paragraph (1)(a)(x) (independent hospitals etc)—

(i) by or on behalf of the registered provider, or

(ii) if there is a relevant manager for the establishment or agency in question, by that manager.

[F103(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered **[**F104, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK) **[**F105or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

[F106(8) Regulation 220 does not apply to the supply, or administration, of a prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus where paragraph (1)(a) and (b) applies and conditions A to F are met.

F107(9) . . . . . .**]**

Textual Amendments

F99 Reg. 233(1)(a)(iva)-(ivc) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(5)(a)(i)** (with Sch. 3 para. 28)

F100 Reg. 233(1)(a)(ivd)(ive) inserted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **7(2)** and reg. 233(1)(a)(ivd)(ive) inserted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **7(2)**

F101 Reg. 233(1)(a)(v) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(5)(a)(ii)** (with Sch. 3 para. 28)

F102 Words in reg. 233(5)(a) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **7(3)** and words in reg. 233(5)(a) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **7(3)**

F103 Reg. 233(7) substituted (31.12.2020) by S.I. 2019/775, reg. 191 (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 145**)

F104 Words in reg. 233(7) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **8(a)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **8(a)**

F105 Words in reg. 233(7)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **20**

F106 Reg. 233(8)(9) inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **8(b)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **8(b)**

F107 Reg. 233(9) omitted (31.3.2022) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **6**

Exemption for supply etc of products under a PGD to assist the police etc

234.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product by an individual belonging to one of the classes specified in Part 4 of Schedule 16 in accordance with the following conditions.

(2) Condition A is that the individual supplies or (as the case may be) administers the product to assist the provision of health care by, on behalf of, or under arrangements made by, one of the following bodies ("the relevant body")—

(a) a police force in England and Wales or in Scotland;

(b) the Police Service of Northern Ireland;

[F108(c) a prison service;

(d) Her Majesty's Forces; or

(e) a contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency.**]**

(3) Condition B is that the product is supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD").

(4) Condition C is that the PGD relates to the supply or (as the case may be) the administration of a description or class of medicinal product to assist the provision of health care by, on behalf of, or under arrangements made by, the relevant body.

(5) Condition D is that the PGD has effect at the time at which the product is supplied or (as the case may be) administered.

(6) Condition E is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(7) Condition F is that the PGD is signed—

(a) by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for the relevant body; and

(b) where the relevant body is a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland.

(8) Condition G is that the individual who supplies the product is designated in writing by or on behalf of the relevant body for the purpose of the supply or (as the case may be) the administration of medicinal products under the PGD.

[F109(9) Condition H is that when the product is supplied **[**F110, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), **[**F111or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

Textual Amendments

F108 Reg. 234(2)(c)-(e) substituted for reg. 234(2)(c)(d) (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **5(2)** and reg. 234(2)(c)-(e) substituted for reg. 234(2)(c)(d) (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **5(2)**

F109 Reg. 234(9) substituted (31.12.2020) by S.I. 2019/775, **reg. 192** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 146**)

F110 Words in reg. 234(9) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **9** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **9**

F111 Words in reg. 234(9)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **21**

Exemption for sale, supply or administration by certain persons

235.—(1) Regulation 214(1) does not apply to the sale or supply by a person of a prescription only medicine if—

(a) the person is listed in column 1 of Part 1 of Schedule 17;

(b) the prescription only medicine is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(2) Regulation 214(1) does not apply to the supply by a person of a prescription only medicine if—

(a) the person is listed in column 1 of Part 2 of Schedule 17;

(b) the prescription only medicine is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(3) Regulation 214(1) does not apply to the administration by a person of a prescription only medicine if—

(a) the person is listed in column 1 of Part 3 of Schedule 17;

(b) the product is a prescription only medicine for parenteral administration listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(4) Regulation 220 does not apply to the sale, supply or offer for sale or supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 4 of Schedule 17;

(b) the product is a prescription only medicine or pharmacy medicine listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(5) Regulation 220 does not apply to the supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 5 of Schedule 17;

(b) the product is a prescription only medicine or pharmacy medicine listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(6) Regulation 221 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 4 of Schedule 17;

(b) the product is a medicinal product subject to general sale that is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(7) Regulation 221 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 5 of Schedule 17;

(b) the product is a medicinal product subject to general sale that is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

F112(8) . . . . . .

Textual Amendments

F112 Reg. 235(8) omitted (31.3.2022) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **7**

Exemptions in relation to specific kinds of product

Products consisting of or containing aloxiprin, aspirin or paracetamol

236. Regulation 214(1) does not apply to a medicinal product that is a prescription only medicine by virtue of paragraph 1(e) of Schedule 1 (non-effervescent aloxiprin, aspirin or paracetamol) if the quantity of the product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.

Products consisting of or containing pseudoephedrine salts or ephedrine base or salts

237.—(1) Regulation 214(1) does not apply to a medicinal product that is a prescription only medicine by virtue of paragraph 1(f) of Schedule 1 (products consisting of or containing pseudoephedrine salts or ephedrine base or salts) if conditions A and B are met.

(2) Condition A is that the product is not sold or supplied at the same time as another medicinal product that consists of or contains—

(a) in the case of pseudoephedrine salts, ephedrine base or salts; or

(b) in the case of ephedrine base or salts, pseudoephedrine salts.

(3) Condition B is that the medicinal products sold or supplied to a person at any one time do not in total contain more than—

(a) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts; or

(b) in the case of ephedrine base or salts, 180mg ephedrine base or salts.

Administration of certain medicines in an emergency

238. Regulation 214(2) does not apply to the administration of a prescription only medicine specified in Schedule 19 where this is for the purpose of saving life in an emergency.

Administration of smallpox vaccine

239.—(1) Regulation 214(2) does not apply to the administration of smallpox vaccine if condition A or B is met.

(2) Condition A is that—

(a) the vaccine has been supplied by, on behalf of, or under arrangements made by—

(i) the Secretary of State,

(ii) the Scottish Ministers,

(iii) the Welsh Ministers,

(iv) the Department of Health, Social Services and Public Safety, or

(v) an NHS body; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom.

(3) Condition B is that—

(a) the vaccine has been supplied by, on behalf of, or under arrangements made by, Her Majesty's Forces; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus to members of Her Majesty's Forces or other persons employed or engaged by them.

[F113Radioactive medicinal products

240.—(1) Regulation 214(2) does not apply to—

(a) a radioactive substance, administration of which results in a medical exposure; or

(b) any other prescription only medicine if it is being administered in connection with a medical exposure,

if Conditions A to E are met.

(2) Condition A is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to—

(a) in England and Wales and Scotland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2017 which apply to the exposure;

(b) in Northern Ireland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 which apply to the exposure.

(3) Condition B is that the medical exposure has been authorised by—

(a) an IRME practitioner; or

(b) where it is not practical for an IRME practitioner to authorise the exposure, an operator acting in accordance with written guidelines issued by an IRME practitioner.

(4) Condition C is that—

(a) in England and Wales and Scotland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.

(5) Condition D is that the prescription only medicine is not a product subject to special medical prescription.

(6) Condition E is that, in the case of a prescription only medicine that is not a radioactive substance, it is specified in the protocols referred to in paragraph (2).

(7) In this regulation—

"IRME practitioner" means—

(a) in relation to a medical exposure in England and Wales and Scotland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in relation to a medical exposure in Northern Ireland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;

"medical exposure" has the same meaning—

(a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;

"radioactive substance" has the same meaning—

(a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.**]**

Textual Amendments

F113 Reg. 240 substituted (6.2.2018) by The Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322), reg. 1, **Sch. 4 para. 2(3)** (as substituted (6.2.2018) by S.I. 2018/121, regs. 1(2), **2(4)(b)(ii)**)

Exemptions in respect of certain herbal remedies

241.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("A") of a herbal medicinal product if—

(a) the product does not contain a substance listed in Part 1 of Schedule 20;

(b) the product does not contain a substance listed in column 1 of Part 2 of that Schedule, unless the product is sold or supplied—

(i) in the case of a product for which there is a corresponding entry in column 2 of that Part, in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in that entry, and

(ii) in the case of a product for which there is a corresponding entry in column 3 of that Part, with the percentage of the substance in the product not exceeding that specified in that entry;

(c) the sale or supply, or offer for sale or supply, takes place on premises occupied by A and from which A can exclude the public; and

(d) the product is for administration to a person ("B") and A has been requested by or on behalf of B and in B's presence to use A's judgment as to the treatment required.

(2) A reference in this regulation to a substance listed in either Part of Schedule 20 is a reference to a substance that is obtained from any botanical source listed in either Part.

Exemption for medicinal products at high dilution

242.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) the medicinal product is neither for parenteral administration nor a **[**F114product subject to special medical prescription**]**;

(b) paragraph (2) applies to the medicinal product; and

(c) P has been requested by or on behalf of a particular person and in that person's presence to use P's own judgment as to the treatment required.

(2) This paragraph applies to a medicinal product that consists solely of one or more unit preparations of—

(a) any substance where the unit preparation has been diluted to at least one part in a million (6x);

(b) any substance that is listed in Part 1 of Schedule 21 where the unit preparation has been diluted to at least one part in a thousand (3x); or

(c) any substance that—

(i) is the active substance of a medicine that is subject to general sale;

(ii) is listed in Part 3 of Schedule 21; or

(iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

where the unit preparation has been diluted to at least one part in ten (1x).

(3) Regulation 220 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the medicinal product is neither for parenteral administration nor a **[**F115product subject to special medical prescription**]**;

(b) paragraph (4) applies to the medicinal product; and

(c) the conditions in regulation 221 are met.

(4) This paragraph applies to a medicinal product that consists solely of one or more unit preparations of—

(a) any substance where the unit preparation has been diluted to at least one part in a million million (6c);

(b) any substance that is listed in Part 2 of Schedule 21 where the unit preparation has been diluted to at least one part in a million (6x); or

(c) any substance that—

(i) is the active substance of a medicine that is subject to general sale;

(ii) is listed in Part 3 of Schedule 21; or

(iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

where the unit preparation has been diluted to at least one part in ten (1x).

Textual Amendments

F114 Words in reg. 242(1)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(g)** and words in reg. 242(1)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(g)**

F115 Words in reg. 242(3)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(g)** and words in reg. 242(3)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(g)**

Exemption for certain homoeopathic medicinal products

243.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) a certificate of registration is in force in relation to the product;

(b) the product is not an excluded product; and

(c) P has been requested by or on behalf of a particular person and in that person's presence to use P's own judgment as to the treatment required.

(2) Regulation 220 does not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) a certificate of registration is in force in relation to the product;

(b) the product is not an excluded product; and

(c) the conditions in regulation 221 are met.

(3) In this regulation "excluded product" means a product that is promoted, recommended or marketed—

(a) for use as an anthelmintic;

(b) for parenteral administration;

(c) for use as eye drops;

(d) for use as an eye ointment;

(e) for use as an enema;

(f) for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum; or

(g) for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

Other exemptions

Exemption in cases involving another's default

244.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person if the person, having exercised all due diligence, believes on reasonable grounds that the product is not a prescription only medicine.

(2) Regulation 220 does not apply to the sale or supply, or offer for sale or supply of a medicinal product by a person if—

(a) the person, having exercised all due diligence, believes on reasonable grounds that the product is subject to general sale;

(b) that belief is due to the act or default of another person; and

(c) the conditions in regulation 221 are met in relation to the sale or supply, or offer for sale or supply of the product.

Exemption in case of forged prescription

245. Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a forged prescription if the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.

Exemption where requirements for prescriptions not met

246. Regulation 214(1) does not apply to the sale or supply of a prescription only medicine otherwise than in accordance with a prescription given by an appropriate practitioner if—

(a) the sale or supply is otherwise than in accordance with such a prescription because a condition in regulation 217, 218**[**F116, 219 or 219A**]** is not met; and

(b) the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that the condition is met.

Textual Amendments

F116 Words in reg. 246(a) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **6** and words in reg. 246(a) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **6**

Exemption for supply in the event or anticipation of pandemic disease

247.—(1) Regulations 214(1), 220 and 221 do not apply to the supply of a medicinal product that meets the following conditions.

(2) Condition A is that the supply is made whilst a disease is, or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk, or potentially a serious risk, to human health.

(3) Condition B is that the supply is accordance with a protocol that—

(a) is approved by the Ministers **[**F117or an NHS body**]**;

(b) specifies **[**F118how the medicinal product is to be used for the prevention of or as a**]** treatment for the disease; and

(c) contains requirements as to the recording of—

(i) the name of the person who supplies the product to the person to be treated ("the patient") or to a person acting on the patient's behalf, and

(ii) evidence that the product was supplied to the patient or to a person acting on the patient's behalf.

[F119(4) A function of the Ministers under this regulation may be exercised by either of them acting alone or both of them acting jointly (and the reference in this regulation to "the Ministers" is to be read accordingly).**]**

Textual Amendments

F117 Words in reg. 247(3)(a) substituted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(6)(a)** (with Sch. 3 para. 28)

F118 Words in reg. 247(3)(b) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **13** and words in reg. 247(3)(b) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **13**

F119 Reg. 247(4) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(6)(b)** (with Sch. 3 para. 28)

[F120Protocols relating to coronavirus and influenza vaccinations and immunisations

247A.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus (of any type) that meets the following conditions.

(2) Condition A is that the supply is made, or the medicinal product is administered, while a disease (which may be neither coronavirus disease nor influenza) is, or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially serious risk to human health.

(3) Condition B is that the supply or administration is in accordance with the requirements of a protocol that is approved by the Secretary of State, the Scottish Ministers, the Welsh Ministers or the Minister of Health in Northern Ireland.

(4) Condition C is that the protocol specifies (amongst other matters)—

(a) the classes of persons permitted to administer medicinal products under the protocol;

(b) the process by which a person of the specified class is designated, and by whom, as a person authorised to administer medicinal products under the protocol;

(c) requirements as to the recording of the name of a person who, on any particular occasion, administers a medicinal product under the protocol; and

(d) requirements, where appropriate, for the supervision of a person who, on any particular occasion, administers a medicinal product under the protocol.

(5) Condition D is that when the medicine is supplied, there is in force in relation to it—

(a) an authorisation by the licensing authority on a temporary basis under regulation 174;

(b) before 1st January 2021, a marketing authorisation; or

(c) on and after 1st January 2021, a UK marketing authorisation **[**F121(including in Northern Ireland if supply is in accordance with regulation 167A)**]** or, in Northern Ireland, an EU marketing authorisation.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol approved under this regulation has effect, the Secretary of State must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

Textual Amendments

F120 Reg. 247A inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **14** and reg. 247A inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **14**

F121 Words in reg. 247A(5)(c) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **22**

Exemption for certain collection and delivery arrangements

248.—(1) Regulations 220 and 221 do not apply to the supply of a medicinal product on premises that are not a registered pharmacy where the supply—

(a) is in accordance with a prescription issued by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber**[**F122, physiotherapist independent prescriber,

podiatrist independent prescriber, therapeutic radiographer independent prescriber**]**[F123, paramedic independent prescriber**]** or optometrist independent prescriber; and

(b) forms part of a collection and delivery arrangement used by a person who lawfully conducts a retail pharmacy business.

(2) In this regulation "collection and delivery arrangement" means an arrangement whereby a person may—

(a) take or send a prescription given by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber**[**F124, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**]**[F125, paramedic independent prescriber**]** or optometrist independent prescriber to premises other than a registered pharmacy and which are capable of being closed by the occupier to exclude the public; and

(b) collect or have collected on his or her behalf from such premises a medicinal product prepared or dispensed in accordance with such a prescription at a registered pharmacy by or under the supervision of a pharmacist.

Textual Amendments

F122 Words in reg. 248(1)(a) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **12(2)** and words in reg. 248(1)(a) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **12(2)**

F123 Words in reg. 248(1)(a) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **10(2)** and words in reg. 248(1)(a) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **10(2)**

F124 Words in reg. 248(2)(a) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **12(3)** and words in reg. 248(2)(a) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **12(3)**

F125 Words in reg. 248(2)(a) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **10(3)** and words in reg. 248(2)(a) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **10(3)**

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 **[**F126UK**]** marketing authorisation;

[F127(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

F126 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)

F127 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.

[[F128](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

F128 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.

[F129(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

F129 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 [M28] (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 [M29] (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 **[**F130product 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

F130 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

M28 S.S.I. 2004/115

M29 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 **[**F131imposed 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

F131 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.

[F132Enforcement 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, **[**F133in 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

F132 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**

F133 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**)

[F132Exception 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 **[**F134in 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

F132 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**

F134 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**)

[F132Offences 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

F132 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**

Disqualification

Disqualification on conviction

256.—(1) A court before which a person ("P") is convicted of any offence under regulation 255(8) may order that P is disqualified from using the premises where that offence was committed for a period not exceeding 2 years if the following conditions are met.

(2) Condition A is that the offence was committed in a retail pharmacy business.

(3) Condition B is that the period of disqualification relates to the future use of the premises as a retail pharmacy business.

(4) Condition C is that the enforcement authority has made an application to the court for such an order.

(5) Condition D is that the court thinks it appropriate to grant an order having regard—

(a) to the gravity of the offence of which P has been convicted as mentioned in the preceding subsection;

(b) to the unsatisfactory nature of the premises; or

(c) to any offences under regulation 255(8) of which P has previously been convicted.

(6) Condition E is that the enforcement authority has not less than 14 days before the date of the hearing given P notice in writing of their intention to apply for such an order.

(7) If P uses the premises in respect of which an order under this regulation is in force for the purposes of a retail pharmacy business, P shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(8) At any time after the end of the period of six months beginning with the date on which an order under this regulation comes into force, P may apply to the court to revoke the order or to vary it by reducing the period of disqualification.

(9) On any application made under paragraph (8) of this regulation the court may—

(a) revoke or vary the order if it thinks it proper to do so having regard to all the circumstances of the case, including in particular the conduct of the applicant and any improvement in the state of the premises to which the order relates; or

(b) refuse to revoke or vary the order.

(10) If an application made by P under paragraph (8) is refused, no further application under that paragraph may be made within the period of three months beginning with the date of the refusal.

(11) The court determining an application under this regulation shall have power to order the applicant to pay the whole or any part of the costs of the application.

(12) In the application of this regulation to Scotland, for reference to an enforcement authority and to costs there shall be substituted respectively references to the procurator fiscal and to expenses.

Status:
Point in time view as at 31/03/2022.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 12.