STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

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,

[F1(vi) a nurse independent prescriber,

(vii) a community practitioner nurse prescriber,

(viii) a podiatrist independent prescriber, F2...

(ix) a physiotherapist independent prescriber**]**F3...

[F4(x) a therapeutic radiographer independent prescriber**][**F5, 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

F1 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**

F2 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)**

F3 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)**

F4 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)**

F5 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 **[**F6product 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

F6 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	Five days' treatment.

Misuse of Drugs Regulations (Northern Ireland) 2002.	
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 **[**F7product 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

F7 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.

[F8Sale 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

F8 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, [F9]...

(iii) radiographers: diagnostic or therapeutic; or

[[F10](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

F9 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)**

F10 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 [F11and local authorities]

229.—(1) Regulations 214(1) **[**[F12]and (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;

[[F13](da) a local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006); [F14]...**]**

[[F15](db) Public Health England;

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

[F16](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 **[**[F17]a clinical commissioning group, the National Health Service Commissioning Board or**]** one of the persons specified in paragraphs (a) **[**[F18]to **[**[F19](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 **[**[F20], physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**]****[**[F21], paramedic independent prescriber**]** or pharmacist independent prescriber relating to that person, regardless of whether the directions comply with regulation 217 (requirements for prescriptions).

[F22(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

[F23(f) when the product is supplied **[**F24, 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), **[**F25or, 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.**]**

F26(4) . . . . . .

Textual Amendments

F11 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)

F12 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)**

F13 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)

F14 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)**

F15 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)**

F16 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)

F17 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)

F18 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)

F19 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)**

F20 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**

F21 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**

F22 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)**

F23 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**)

F24 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)**

F25 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**

F26 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**[**F27, 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 M1, 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.

[F28(8) Condition G is that when the product is supplied or (as the case may be) administered **[**F29, 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), **[**F30or, 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

F27 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)

F28 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**)

F29 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**

F30 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

M1 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 [M2] in respect of one or more of the following regulated activities [M3]—

(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.

[[F31](8) Condition G is that when the product is supplied **[**[F32], 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) **[**[F33]or, 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

F31 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**)

F32 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**

F33 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

M2 2008 c.14.

M3 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 [M4], 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.

[F34(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

F34 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

M4 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,

[F35(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),**]**

[F36(ivd) Public Health England,

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

[F37](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) **[**[F38]to (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.

[F39(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered **[**F40, 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) **[**F41or, 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.**]**

[F42(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.

F43(9) . . . . . .**]**

Textual Amendments

F35 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)

F36 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)**

F37 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)

F38 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)**

F39 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**)

F40 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)**

F41 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**

F42 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)**

F43 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;

[F44(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.

[F45(9) Condition H is that when the product is supplied **[**F46, 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), **[**F47or, 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

F44 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)**

F45 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**)

F46 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**

F47 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.

F48(8) . . . . . .

Textual Amendments

F48 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.

[F49Radioactive 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

F49 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 **[**[F50]product 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 **[**[F51]product 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

F50 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)**

F51 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**[**F52, 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

F52 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 **[**F53or an NHS body**]**;

(b) specifies **[**F54how 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.

[F55(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

F53 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)

F54 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**

F55 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)

[F56Protocols 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 **[**F57(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

F56 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**

F57 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**[**F58, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**F59, 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**[**F60, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**F61, 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

F58 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)**

F59 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)**

F60 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)**

F61 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)**

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, CHAPTER 3.