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,

(vi) a nurse independent prescriber, or

(vii) a community practitioner nurse 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.

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 controlled drug, 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.

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 controlled drug, 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.

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.

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, or

(iii) radiographers: diagnostic or therapeutic; 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.

Exemption for supply by national health service bodies

229.—(1) Regulations 214(1), 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;

(e) a Primary Care Trust; or

(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 one of the persons specified in paragraphs (a) to (e).

(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 or pharmacist independent prescriber relating to that person, regardless of whether the directions comply with regulation 217 (requirements for prescriptions).

(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

(f) when the product is supplied, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in relation to it.

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 or Primary Care Trust 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(**1**), 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.

(8) Condition G is that when the product is supplied or (as the case may be) administered, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in relation to it.

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(**2**) in respect of one or more of the following regulated activities(**3**)—

(**1**) 1978 c.29.
(**2**) 2008 c.14.

(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.

(8) Condition G is that when the product is supplied, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in relation to it.

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;

(**3**) 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.

(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(**4**), 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.

(8) Condition F is that when the product is supplied, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration 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.

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,

(**4**) 2008 No. 1976 (W. 185).

(ii) a health authority or special health authority,

(iii) an NHS trust,

(iv) an NHS foundation trust,

(v) a Primary Care Trust,

(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) to (v) (health bodies), on behalf of 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.

(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in relation to it.

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;

(c) a prison service; or

(d) Her Majesty's Forces.

(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.

(9) Condition H is that when the product is supplied, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in relation to it.

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.