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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 12**

**Dealings with medicinal products**

**CHAPTER 1**

**Interpretation**

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**213.**—(1) In this Part—

“the Common Services Agency” means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978(1);

“controlled drug” means any substance or product for the time being specified in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001(2) or in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations (Northern Ireland) 2002(3), except where the context requires otherwise;

“the dental care professionals register” means the register established and maintained under section 36B of the Dentists Act 1984(4);

“EEA health professional” means—

- (a) a doctor who is lawfully engaged in medical practice in an EEA State other than the United Kingdom or in Switzerland; or
- (b) a dentist who is lawfully engaged in dental practice in an EEA State other than the United Kingdom or in Switzerland (including a person whose formal qualifications as a doctor are recognised for the purposes of the pursuit of the professional activities of a dental practitioner under Article 37 of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications(5)),

and who is not otherwise a doctor or a dentist for the purpose of these Regulations;

“EEA prescription” means a prescription given in an EEA State other than the United Kingdom or in Switzerland;

“external use” in relation to a medicinal product—

- (a) means its use by application to the skin, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal in circumstances where local action only is necessary and systematic absorption is unlikely to occur; but

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

(2) S.I. 2001/3998. Schedule 1 has been amended by S.I. 2005/1653, 2009/3136, 2010/1144 and 1799. Schedule 2 has been amended by S.I. 2003/1432 and 2009/3136. Schedule 3 has been amended by S.I. 2007/2154.

(3) S.R. 2002 No. 1. Schedule 1 has been amended by S.R. 2005 No. 360 and S.R. 2010 Nos. 148 and 247. Schedule 2 has been amended by S.R. 2003 No. 314 and S.R. 2009 No. 390. Schedule 3 has been amended by S.R. 2007 No. 348.

(4) 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.

(5) OJ No L 255, 30.9.2005, p.22, as last amended by Commission Regulation (EU) No 213/2011 (OJ No L 59, 4.3.2011, p.4).

- (b) does not include its use by means of a throat spray, nasal spray, nasal inhalation or teething preparation or by means of throat pastilles, throat lozenges, throat tablets or nasal drops;

“food” includes—

- (a) beverages;
- (b) confectionery;
- (c) articles and substances used as ingredients in the preparation of food; and
- (d) any manufactured substance—
- (i) to which there has been added any vitamin, and
  - (ii) which is advertised as available and for sale to the general public as a dietary supplement;

“health authority” means—

- (a) in relation to England, a Strategic Health Authority established or continued under section 13 of the National Health Service Act 2006(6);
- (b) in relation to Wales, a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006(7);
- (c) in relation to Scotland, a Health Board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978(8); and
- (d) in relation to Northern Ireland, the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009(9);

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

“health prescription” means a prescription issued by a doctor, dentist, supplementary prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist — independent prescriber or community practitioner nurse prescriber under—

- (a) in England, the National Health Service Act 2006;
- (b) in Wales, the National Health Service (Wales) Act 2006;
- (c) in Scotland, the National Health Service (Scotland) Act 1978; and
- (d) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(10);

“Health Protection Agency” means the body of that name established under section 1 of the Health Protection Agency Act 2004(11);

“independent clinic”—

- (a) in relation to England, means an establishment of either of the following kinds—
- (i) a walk-in centre, in which one or more medical practitioners provides services of a kind which, if provided in pursuance of the National Health Services Act 2006, would be provided as primary medical services under Part 4 of that Act, or

(6) 2006 c.41.

(7) 2006 c.42.

(8) 1978 c.29. Section 2(1)(a) was amended by section 28(a)(i) of the National Health Service and Community Care Act 1990 (1990 c.19) and section 14(2) of, and paragraph 1 of Schedule 7 to, the Health and Social Services and Social Security Adjudications Act 1983 (1983 c.41).

(9) 2009 c.1 (N.I.).

(10) S.I. 1972/1265 (N.I. 14).

(11) 2004 c.17.

- (ii) a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the National Health Services Act 2006 provides medical services of any kind (including psychiatric treatment), except where such medical services are provided only under arrangements made on behalf of the patients by—
  - (aa) their employer,
  - (bb) a government department or any executive agency of any government department,
  - (cc) a prison or other establishment in which patients are held under custody, other than pursuant to any provision under the Mental Health Act 1983<sup>(12)</sup>, or
  - (dd) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity,

and where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical practitioners shall be regarded as carrying on a separate independent clinic unless they practise together;

- (b) in relation to Wales, has the meaning given by section 2(4) of the Care Standards Act 2000<sup>(13)</sup>;
- (c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Service (Scotland) Act 1978<sup>(14)</sup>; and
- (d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003<sup>(15)</sup>;

“independent hospital”—

- (a) in relation to England, means a hospital as defined by section 275 of the National Health Service Act 2006 that is not a health service hospital as defined by that section;
- (b) in relation to Wales, has the meaning given by section 2(2) of the Care Standards Act 2000;
- (c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Act 1978; and
- (d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

“independent medical agency”—

- (a) in relation to England, means an undertaking (not being an independent hospital) which consists of or includes the provision of services by medical practitioners, and the term “undertaking” in this definition includes any business or profession and—
  - (i) in relation to a public or local authority includes the exercise of any functions of that authority, and
  - (ii) in relation to any other body of persons, whether corporate or unincorporated, includes any of the activities of that body;

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<sup>(12)</sup> 1983 c.20.

<sup>(13)</sup> 2000 c.14.

<sup>(14)</sup> 1978 c.29. Section 10F was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).

<sup>(15)</sup> S.I. 2003/431 (N.I. 9).

- (b) in relation to Wales, has the meaning given by section 2(5) of the Care Standards Act 2000;
- (c) in relation to Scotland means an undertaking which is neither an independent clinic nor an undertaking comprised in a hospital and which consists of or includes the provision of services, other than in pursuance of the National Health Service (Scotland) Act 1978, by a medical practitioner; and
- (d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

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

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

“NHS body” means—

- (a) the Common Services Agency;
- (b) a health authority;
- (c) a special health authority;
- (d) a Primary Care Trust;
- (e) an NHS trust; or
- (f) an NHS foundation trust;

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

“NHS trust”—

- (a) in relation to England, means an NHS trust established under section 25(1) of the National Health Service Act 2006;
- (b) in relation to Wales, means an NHS trust established under section 18(1) of the National Health Service (Wales) Act 2006;
- (c) in relation to Scotland, means an NHS trust established under section 12A of the National Health Service (Scotland) Act 1978<sup>(16)</sup>; and
- (d) in relation to Northern Ireland, means a Health and Social Care trust established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991<sup>(17)</sup>;

“nursing home” has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003<sup>(18)</sup>;

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

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

- (a) is signed—

<sup>(16)</sup> 1978 c.29. Section 12A was inserted by section 31 of the National Health Service and Community Care Act 1990 (1990 c.19), and amended by section 46(1)(a) of the Health Act 1999 (1999 c.8).

<sup>(17)</sup> S.I. 1991/194 (N.I. 1), Health and Social Services trusts were renamed Health and Social Care trusts by section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I.)). There are other amendments not relevant to this regulation.

<sup>(18)</sup> References to a nursing home in these Regulations concern Northern Ireland only.

- (i) by a doctor or dentist and by a pharmacist, and
  - (ii) by any other person who may be required to sign it in the circumstances specified for its use in any provision of this Part; and
- (b) relates to sale or supply and to administration to persons generally (subject to any exclusions that may be specified in the PGD);

“Primary Care Trust” means a Primary Care Trust established or continued under section 18 of the National Health Service Act 2006;

“prison service” means—

- (a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952<sup>(19)</sup>);
- (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989<sup>(20)</sup>); and
- (c) in relation to Northern Ireland, the Department of Justice exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953<sup>(21)</sup>);

“registered chiroprapist” means a person who is registered in Part 2 of the Health and Care Professions Council register;

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

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

“registered dietitian” means a person who is registered in Part 4 of the Health and Care Professions Council register;

“registered dispensing optician” means a person whose name is entered in the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989<sup>(22)</sup> or the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b)<sup>(23)</sup> of that Act;

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

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

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

“registered paramedic” means a person who is registered in Part 8 of the Health and Care Professions Council register;

“registered physiotherapist” means a person who is registered in Part 9 of the Health and Care Professions Council register;

“registered podiatrist” means a person who is registered in Part 2 of the Health and Care Professions Council register;

“registered provider”—

- (a) in England, in relation to an independent hospital, independent clinic, an independent medical agency, a dental clinic or a dental practice means the person who is registered as

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(19) 1952 c.52.

(20) 1989 c.45.

(21) 1953 c.18 (N.I.). Functions transferred by article 6(1) of, and Schedule 4 to, S.I. 2010/976.

(22) 1989 c.44; section 7 was amended by S.I. 2005/848, articles 2 and 7(1).

(23) Section 8B was inserted by S.I. 2007/3101, regulations 178 and 180.

a service provider under Chapter 2 of Part 1 of the Health and Social Care Act 2008<sup>(24)</sup> in respect of regulated activities (within the meaning of that Part) carried on in that hospital, clinic, agency, dental clinic or dental practice;

- (b) in Wales, in relation to an independent hospital, an independent clinic or an independent medical agency, means the person who is registered under Part 2 of the Care Standards Act 2000 as the person who carries on the hospital, clinic or agency;
- (c) in Scotland, in relation to an independent hospital, an independent clinic or an independent medical agency, means the person who is registered under section 10P of the National Health Service (Scotland) Act 1978<sup>(25)</sup>; and
- (d) in Northern Ireland, in relation to an independent hospital, an independent clinic, a nursing home or an independent medical agency, means the person who is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person who carries on the hospital, clinic, nursing home or agency;

“registered radiographer” means a person who is registered in Part 11 of the Health and Care Professions Council register;

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

“relevant manager”—

- (a) in England, means—
  - (i) a person, other than the registered provider, who is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 as the manager of an independent hospital, independent clinic, an independent medical agency, a dental clinic or a dental practice, or
  - (ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic, agency, dental clinic or dental practice, that person;
- (b) in Wales, means—
  - (i) a person, other than the registered provider, who is registered under Part 2 of the Care Standards Act 2000 as the manager of an independent hospital, an independent clinic or an independent medical agency, or
  - (ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic or agency, that person;
- (c) in Scotland, means a person, other than the registered provider, who was identified as an individual who is to manage an independent hospital, an independent clinic or an independent medical agency on the application for registration of that clinic, hospital or agency under section 10P of the National Health Service (Scotland) Act 1978; and
- (d) in Northern Ireland, means—
  - (i) a person, other than the registered provider, who is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of an independent hospital, an independent clinic, a nursing home or an independent medical agency, or
  - (ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic, nursing home or agency, that person;

“relevant prescriber” means any of the following—

<sup>(24)</sup> 2008 c.14.

<sup>(25)</sup> 1978 c.29. Section 10P was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).

- (a) a doctor;
- (b) a dentist;
- (c) a supplementary prescriber;
- (d) a nurse independent prescriber;
- (e) a pharmacist independent prescriber;
- (f) a community practitioner nurse prescriber;
- (g) an optometrist independent prescriber; and
- (h) an EEA health professional;

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

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

“special health authority” means—

- (a) in relation to England, a Special Health Authority established under section 28 of the National Health Service Act 2006;
- (b) in relation to Wales, a Special Health Authority established under section 22 of the National Health Service (Wales) Act 2006;
- (c) in relation to Scotland, a Special Health Board constituted under section 2(1)(b) of the National Health Service (Scotland) Act 1978<sup>(26)</sup>; and
- (d) in relation to Northern Ireland, a special health and social care agency established under Article 3 of the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990<sup>(27)</sup>;

“supply” means supply in circumstances corresponding to retail sale;

“unit preparation” means a preparation, including a mother tincture, that—

- (a) is prepared by a process of—
  - (i) solution,
  - (ii) extraction, or
  - (iii) trituration,with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert diluent; and
- (b) is used—
  - (i) in that diluted form, or
  - (ii) where applicable, by impregnating tablets, granules, powders or other inert substances,for the purpose of being administered to human beings.

(2) In this Part—

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

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<sup>(26)</sup> Section 2(1)(b) was inserted by section 28(a) of the National Health Service and Community Care Act 1990 (1990 c.19).

<sup>(27)</sup> S.I. 1990/247 (N.I. 3). Special Health and Social Services Agencies were renamed Special Health and Social Care Agencies by section 1(4) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I.)).

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