STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the Human Medicines Regulations 2012.

(2) These Regulations come into force on 14th August 2012.

Medicinal products

2.—(1) In these Regulations "medicinal product" means—

(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or

(b) any substance or combination of substances that may be used by or administered to human beings with a view to—

(i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or

(ii) making a medical diagnosis.

(2) These Regulations do not apply to—

(a) whole human blood; or

(b) any human blood component, other than plasma prepared by a method involving an industrial process.

Modifications etc. (not altering text)

C1 Reg. 2 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Scope of these Regulations: special provisions

3.—(1) Regulation 17(1) (manufacturing of medicinal products: requirement for licence) shall not apply in circumstances where paragraph (4) applies.

(2) Regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) shall not apply in circumstances where paragraph (5) or (6) applies.

(3) These Regulations do not apply where paragraph (7) applies.

(4) This paragraph applies where a medicinal product is assembled by a registered nurse or a registered midwife if—

(a) the nurse or midwife is acting in the course of his or her profession; and

(b) the conditions in paragraphs (8) and (9) are met.

(5) This paragraph applies where a medicinal product is manufactured or assembled by a doctor or dentist and the conditions in paragraphs (8) and (9) are met.

(6) This paragraph applies where a herbal medicinal product is manufactured or assembled by a person ("A") if—

(a) the manufacture or assembly takes place on premises occupied by A and from which A can exclude the public;

(b) 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;

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

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

(i) in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in column 2 of that Part, or

(ii) in the case of a product for external use only, with a percentage of the substance in the product that does not exceed the percentage specified in column 3 of that Part; and

(e) the condition in paragraph (9) is met.

(7) This paragraph applies where the product is a radionuclide that is in the form of a sealed source.

(8) This condition is that the medicinal product is supplied—

(a) to a patient in the course of the treatment of that patient; or

(b) in a case to which paragraph (5) applies, to a patient of another doctor or dentist who is a member of the same medical or dental practice.

(9) This condition is that the medicinal product is not manufactured or, as the case may be, assembled—

(a) on a large scale; or

(b) by an industrial process.

(10) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products) does not apply to a medicinal product that is sold or supplied in circumstances where paragraph (11) or (12) applies in relation to the product, except to the extent set out in paragraph (14), but the requirements of paragraph (13) shall apply.

(11) This paragraph applies where a medicinal product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of paragraph (5) or (6).

(12) This paragraph applies in the case of a medicinal product where—

(a) the product is the result of a process of assembly of an authorised medicinal product;

(b) regulation 17(1) does not apply to the process of assembly by virtue of paragraph (4) or (5);

(c) the process of assembly results in a change in the presentation of the authorised medicinal product; and

(d) by reason of that change the product so assembled is not sold or supplied in accordance with the terms of—

(i) the marketing authorisation,

(ii) the certificate of registration,

(iii) the traditional herbal registration, or

(iv) the Article 126a authorisation,

that relates to the authorised medicinal product.

(13) The information specified in Part 1 of Schedule 26 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product that is sold or supplied in circumstances—

(a) where paragraph (11) applies to the product, except in the case of a product manufactured in accordance with paragraph (6); or

(b) where paragraph (12) applies in relation to the product.

(14) Regulations 269 (offences relating to packaging and package leaflets: other persons) and 271 (offences: penalties) shall have effect in relation to paragraph (13) as if that paragraph were a requirement of Part 13.

(15) For the purposes of this regulation and regulation 4 (special provisions for pharmacies etc), a medicinal product is authorised if there is in force for the product—

(a) a marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

Special provisions for pharmacies etc

4.—(1) Regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) do not apply where any provision of section 10 of the Medicines Act 1968 [M1] so provides.

(2) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products) does not apply to a medicinal product that is sold or supplied in circumstances where paragraph (3) or (4) applies in relation to the product, except to the extent set out in paragraph (6), but the requirements of paragraph (5) shall apply.

(3) This paragraph applies in a case where a medicinal product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of any provision of section 10 of the Medicines Act 1968.

(4) This paragraph applies in the case of a medicinal product where—

(a) the product is the result of a process of assembly of a medicinal product that is an authorised medicinal product within the meaning of regulation 3(15);

(b) regulation 17(1) does not apply to the process of assembly by virtue of any provision of section 10 of the Medicines Act 1968;

(c) the process of assembly results in a change in the presentation of the authorised medicinal product; and

(d) by reason of that change the product so assembled is not sold or supplied in accordance with the terms of—

(i) the marketing authorisation,

(ii) the certificate of registration,

(iii) the traditional herbal registration, or

(iv) the Article 126a authorisation,

that relates to the authorised medicinal product.

(5) The information specified in Part 2 of Schedule 26 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product that is sold or supplied in circumstances where paragraph (3) or (4) applies in relation to the product.

(6) Regulations 269 (offences relating to packaging and package leaflets: other persons) and 271 (offences: penalties) shall have effect in relation to paragraph (5) as if that paragraph were a requirement of Part 13.

Marginal Citations

M1 Section 10(1) was amended by paragraph 10(a) of Part 1 of Schedule 8 to S.I. 2006/2407, **paragraph 5(a)** of Schedule 3 to the Regulation of Care (Scotland) Act 2001, and article 3 of S.I. 1971/1445. Section 10(2) was repealed by paragraph 10(b) and (3)(b) was repealed by paragraph 10(c) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(4) was amended and section 10(5) and (6) inserted by article 3 of S.I. 1971/1445. Section 10(6A) was repealed by paragraph 10(d) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(7) was inserted by article 3 of S.I. 1971/1445, and amended by regulation 3 of S.I. 1993/834. Section 10(7A) to (7C) was inserted by the Health Act 2006 section 26(1), and section 10(7A) was amended by paragraph 10(e) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(8) was inserted by S.I. 1971/1445 article 3. Section 10(9) was inserted by paragraph 5(a) of Schedule 3 to the Regulation of Care (Scotland) Act 2001.

Classification of medicinal products

5.—(1) In these Regulations references to a medicinal product subject to general sale are to a product that is not a prescription only medicine or a pharmacy medicine but is—

(a) a product that is covered by an authorisation of which it is a term that the product is to be available on general sale; or

(b) a product that—

(i) is covered by an EU marketing authorisation, and

(ii) is not classified in the authorisation as a prescription only medicine, and

(iii) the licensing authority has determined should be available on general sale.

(2) In paragraphs (1)(a) and (5)(a) "authorisation" means—

(a) a UK marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

(3) In these Regulations references to a prescription only medicine are to any of the following—

(a) a medicinal product that is covered by an authorisation of which it is a term that the product is to be available only on prescription;

(b) a medicinal product that—

(i) is covered by an EU marketing authorisation, and

(ii) is classified in the authorisation as a prescription only medicine;

(c) a medicinal product that is a prescription only medicine by virtue of Part 1 of Schedule 1; or

(d) a medicinal product that is the result of—

(i) the assembly, or

(ii) the reformulation (including the combining with other substances),

of a medicinal product that is a prescription only medicine by virtue of sub-paragraph (a) or (b).

(4) In paragraph (3)(a) "authorisation" means—

(a) a UK marketing authorisation; or

(b) an Article 126a authorisation.

(5) In these Regulations references to a pharmacy medicine are to a medicinal product that is not a prescription only medicinal product or a medicinal product subject to general sale but is—

(a) covered by an authorisation of which it is a term that the product is to be available only from a pharmacy;

(b) a product that—

(i) is covered by an EU marketing authorisation, and

(ii) is not classified in the authorisation as a prescription only medicine,

other than a product to which paragraph (1)(b)(iii) applies;

(c) available only from a pharmacy by virtue of Part 2 of Schedule 1; or

(d) the result of—

(i) the assembly, or

(ii) the reformulation (including the combining with other substances),

of a medicinal product that is a pharmacy medicine by virtue of sub-paragraph (a) or (b).

The licensing authority and the Ministers

6.—(1) The licensing authority is responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under these Regulations.

(2) In these Regulations "the licensing authority" means either or both of the Ministers.

(3) Any function that—

(a) is conferred on "the licensing authority" by these Regulations; or

(b) is a function within paragraph (4),

may be exercised by either of the Ministers acting alone or by both of them acting jointly.

(4) The functions of a member State, or of the competent authority of a member State, under any of the relevant EU provisions are to be exercised by the licensing authority if—

(a) they relate to medicinal products; and

(b) they are to be exercised by, or by any authority of, the United Kingdom.

(5) Paragraph (4) does not apply to any function that is conferred by these Regulations on a person or body other than the licensing authority.

(6) In these Regulations "the Ministers" means—

(a) the Secretary of State; and

(b) the Minister for Health, Social Services and Public Safety.

(7) Any function that is conferred on "the Ministers" by these Regulations is to be exercised by the Ministers acting jointly.

(8) Paragraph (7) does not apply where these Regulations provide for a function of the Ministers to be exercised by either of them acting alone or both of them acting jointly.

Advertisements relating to medicinal products

7.—(1) In these regulations "advertisement", in relation to a medicinal product, includes anything designed to promote the prescription, supply, sale or use of that product.

(2) This includes, in particular, the following activities—

(a) door-to-door canvassing;

(b) visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;

(c) the supply of samples;

(d) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except where the intrinsic value of such inducements is minimal;

(e) the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and

(f) the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including the payment of their travelling and accommodation expenses in that connection.

(3) But references in these Regulations to an "advertisement" do not include any of the following—

(a) a medicinal product's package or package leaflet;

(b) reference material and announcements of a factual and informative nature, including—

(i) material relating to changes to a medicinal product's package or package leaflet,

(ii) adverse reaction warnings,

(iii) trade catalogues, and

(iv) price lists,

provided that no product claim is made; or

(c) correspondence, which may be accompanied by material of a non-promotional nature, answering a specific question about a medicinal product.

(d) In this regulation "person qualified to prescribe or supply medicinal products" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

General interpretation

8.—(1) In these Regulations (unless the context otherwise requires)—

"the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use [M2];

"administer" means administer to a human being—

(a) orally, by injection, or by introduction into the body in any other way; or

(b) by external application (whether or not by direct application to the body),

and any reference in these Regulations to administering anything is to administering it in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, a substance used as a vehicle;

"advanced therapy medicinal product" means a medicinal product described in Article 2(1)(a) of Regulation (EC) No 1394/2007;

"adverse reaction" means a response to a medicinal product that is noxious and unintended;

"advisory body" has the meaning given by regulation 12(1);

"appropriate practitioner" means an appropriate practitioner within the meaning of regulation 214;

"Article 126a authorisation" means an authorisation granted by the licensing authority under Part 8 of these Regulations;

"assemble" in relation to a medicinal product includes the various processes of dividing up, packaging and presentation of the product, and "assembly" has a corresponding meaning;

"biological medicinal product" and "biological substance" have the meaning given in the third indent of paragraph 3.2.1.1.(b) of Annex I to the 2001 Directive;

"blood component" means any of the following—

(a) red cells;

(b) white cells;

(c) platelets; and

(d) plasma;

"the British Pharmacopoeia" means the British Pharmacopoeia referred to in regulation 317;

"business" includes—

(a) a professional practice;

(b) any activity carried on by a body of persons whether corporate or unincorporated; and

(c) the provision of services by or on behalf of the Secretary of State, the Minister for Health, Social Services and Public Safety, the Welsh Ministers or the Scottish Ministers as the case may be under the following enactments—

(i) the National Health Service Act 2006 [M3],

(ii) the Health and Personal Social Services (Northern Ireland) Order 1972 [M4] and the Health and Social Care (Reform) Act (Northern Ireland) 2009 [M5],

(iii) the National Health Service (Wales) Act 2006 [M6],

(iv) the National Health Service (Scotland) Act 1978 [M7];

"certificate of registration" means a certificate of registration granted by the licensing authority under Part 6 of these Regulations;

"clinical management plan" means a written plan relating to the treatment of an individual patient and agreed by—

(a) the patient;

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

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

"clinical trial" has the meaning given by regulation 2 of the Clinical Trials Regulations;

"the Clinical Trials Directive" means Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [M8];

"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004 [M9];

"the Commission" has the meaning given by regulation 9(1);

"common name" in relation to a medicinal product, active substance or excipient means—

(a) its international non-proprietary name recommended by the World Health Organisation; or

(b) if such a name does not exist, its usual common name;

"community practitioner nurse prescriber" means a person—

(a) who is a registered nurse or a registered midwife; and

(b) against whose name is recorded in the professional register an annotation signifying that the person is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary;

"contravention" includes failure to comply (and "contravene" has a corresponding meaning);

"cosmetic" means any substance or preparation intended to be applied to the surfaces of the human body (including the epidermis, pilary system and hair, nails, lips and external genital organs), or the teeth or buccal mucosa, wholly or mainly for the purpose of—

(a) perfuming them;

(b) cleansing them;

(c) protecting them;

(d) caring for them or keeping them in condition;

(e) modifying their appearance (for aesthetic purposes or otherwise); or

(f) combating body odours or normal body perspiration;

"dentist" means a person registered in the dentists register under section 14 of the Dentists Act 1984 [M10];

"Directive 2002/98/EC" means Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[M11];

"Directive 2004/23/EC" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [M12];

"disease" includes any injury, ailment or adverse condition, whether of body or mind;

"doctor" means a registered medical practitioner;

"effervescent", in relation to a tablet or capsule, means containing not less than 75 per cent, by weight of the tablet or capsule, of ingredients included wholly or mainly for the purpose of releasing carbon dioxide when the tablet or capsule is dissolved or dispersed in water;

"electronic communication" means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

(a) by means of an electronic communications network within the meaning of section 32(1) of the Communications Act 2003 [M13]; or

(b) by other means but while in an electronic form;

"the EMA" means the European Medicines Agency established by Regulation (EC) No 726/2004;

"enactment" includes primary and secondary legislation of the devolved administrations in Wales, Scotland and Northern Ireland;

"enforcement authority" means the Secretary of State, the Minister for Health, Social Services and Public Safety or a person on whom a function of enforcing a provision of these Regulations has been conferred by virtue of regulations 323 or 324;

"EU marketing authorisation" means a marketing authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004;

"European Economic Area" or "EEA" means the European Economic Area created by the EEA agreement;

"the European Pharmacopoeia" means the European Pharmacopoeia published by the European Directorate for the Quality of Medicines;

"exempt advanced therapy medicinal product" has the meaning given in regulation 171;

"expert advisory group" has the meaning given by regulation 14(1);

"export" means export, or attempt to export, from the United Kingdom, whether by land, sea or air, and "import" has a corresponding meaning;

"the Good Manufacturing Practice Directive" means Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use [M14];

"the Health and Care Professions Council register" means the register established and maintained by the Health and Care Professions Council under article 5 of the Health and Social Work Professions Order 2001 [M15];

"health care professional" means—

(a) a doctor;

(b) a dentist;

(c) a pharmacist;

(d) a pharmacy technician registered in Part 2 or 5 of the Register of pharmacists and pharmacy technicians established and maintained under article 19(2) of the Pharmacy Order 2010 [M16];

(e) a registered nurse;

(f) a registered midwife;

(g) a registered optometrist;

(h) a registered osteopath as defined in section 41 of the Osteopaths Act 1993 [M17];

(i) a registered chiropractor as defined in section 43 of the Chiropractors Act 1994 [M18];

(j) a person registered as a member of a relevant profession within the meaning of article 2 and paragraph 1 of Schedule 3 to the Health and Social Work Professions Order 2001 [M19], other than a social worker, in the Health and Care Professions Council register; or

(k) a person registered in the dental care professionals register established and maintained under section 36B of the Dentists Act 1984 [M20] as a member of a profession complementary to dentistry specified by regulation 2 of the General Dental Council (Professions Complementary to Dentistry) Regulations 2006 [M21];

"health centre" means a health centre maintained under—

(a) section 2 or 3 of the National Health Service Act 2006 [M22];

(b) section 2 or 3 of the National Health Service (Wales) Act 2006 [M23];

(c) section 36(1)(b) of the National Health Service (Scotland) Act 1978 [M24]; or

(d) article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972 [M25];

"herbal medicinal product" means a medicinal product whose only active ingredients are herbal substances or herbal preparations (or both);

"herbal preparation" means a preparation obtained by subjecting herbal substances to processes such as extraction, distillation, expression, fractionation, purification, concentration or fermentation, and includes a comminuted or powdered herbal substance, a tincture, an extract, an essential oil, an expressed juice or a processed exudate;

"herbal substance" means a plant or part of a plant, algae, fungi or lichen, or an unprocessed exudate of a plant, defined by the plant part used and the botanical name of the plant, either fresh or dried, but otherwise unprocessed;

"homoeopathic medicinal product" means a medicinal product prepared from homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by—

(a) the European Pharmacopoeia; or

(b) in the absence of such a description in the European Pharmacopoeia, in any pharmacopoeia used officially in an EEA State;

"hospital" includes a clinic, nursing home or similar institution;

"immediate packaging" in relation to a medicinal product means the container or other form of packaging immediately in contact with the medicinal product;

"inspector" means a person authorised in writing by an enforcement authority for the purposes of Part 16 (enforcement) (and references to "the enforcement authority", in relation to an inspector, are to the enforcement authority by whom the inspector is so authorised);

"intermediate product" means a substance which—

(a) has been manufactured for use in the manufacture of medicinal products; and

(b) is intended for further processing by a manufacturer of such products;

"investigational medicinal product" has the meaning given in regulation 2(1) of the Clinical Trials Regulations;

"labelling" in relation to a container or package of medicinal products means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents (and "label" has a corresponding meaning);

"the licensing authority" has the meaning given by regulation 6(2);

"manufacture", in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, a substance used as a vehicle for the purpose of administering it;

"manufacturer's licence" has the meaning given by regulation 17(1);

"marketing authorisation" means—

(a) a UK marketing authorisation; or

(b) an EU marketing authorisation;

"medicinal product subject to general sale" has the meaning given in regulation 5(1) (classification of medicinal products);

"the Ministers" is to be construed in accordance with regulation 6(6) to (8);

"name" in relation to a medicinal product means—

(a) where the product has a UK marketing authorisation or traditional herbal registration, the name—

(i) as approved by the licensing authority in granting the authorisation or registration, or

(ii) where that name has been varied since that approval, as so amended;

(b) where the product has an EU marketing authorisation, the name—

(i) as approved by the European Commission in granting the authorisation, or

(ii) where that name has been varied since that approval, as so amended; and

(c) where the product has an Article 126a authorisation, the name—

(i) as approved by the licensing authority to appear on the packaging and any package leaflet of the product under the authorisation, or

(ii) where that name has been varied since that approval, as so amended;

"the Narcotic Drugs Convention" means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30thMarch 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972;

"NHS primary dental services" means—

(a) in relation to England, primary dental services under the National Health Service Act 2006;

(b) in relation to Wales, primary dental services under the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, dental services under the National Health Service (Scotland) Act 1978 or personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997 [M26]; and

(d) in relation to Northern Ireland, general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972 or personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997 [M27];

"NHS primary medical services" means—

(a) in relation to England, primary medical services under the National Health Service Act 2006;

(b) in relation to Wales, primary medical services under the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, primary medical services under the National Health Service (Scotland) Act 1978; and

(d) in relation to Northern Ireland, primary medical services under the Health and Personal Social Services (Northern Ireland) Order 1972;

"nurse independent prescriber" means a person who—

(a) is a registered nurse or registered midwife; and

(b) is noted in the professional register as qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent / supplementary prescriber;

"optometrist independent prescriber" means a person—

(a) who is a registered optometrist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

"outer packaging" in relation to a medicinal product means any packaging into which the immediate packaging of the medicinal product is placed;

"package" in relation to a medicinal product, includes—

(a) a container of the product;

(b) any box, packet or other article in which one or more containers of the product are or are to be enclosed; and

(c) any box, packet or other article in which a box, packet or other article mentioned in paragraph (b) or this paragraph is or is to be enclosed;

"package leaflet" in relation to a medicinal product, means a leaflet that accompanies the product and contains information for the user of the product;

"paediatric clinical trial" means a clinical trial conducted in whole or in part on persons under the age of 18 years;

"paediatric investigation plan" means a research and development programme with the purpose of generating data determining the conditions in which a medicinal product may be authorised to treat persons under the age of 18 years;

"the Paediatric Regulation" means Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[M28];

"periodic safety update report" or "PSUR" has the meaning given in regulation 191 (obligation on holder to submit periodic safety update reports: general requirements);

"pharmacist" means—

(a) in relation to Great Britain a person registered in Part 1 or 4 of the Register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010 [M29]; and

(b) in relation to Northern Ireland a person registered in the register of pharmaceutical chemists for Northern Ireland or the register of visiting pharmaceutical chemists from a relevant European State maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 [M30];

"pharmacist independent prescriber" means a person who—

(a) is a pharmacist; and

(b) is noted in the relevant register as qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"the Pharmacovigilance Risk Assessment Committee" means the committee of the EMA established by Article 56(1)(aa) of Regulation (EC) No 726/2004;

"pharmacovigilance system" means a system used by the holder of a marketing authorisation, traditional herbal registration or Article 126a authorisation, or by the licensing authority, to fulfil the tasks and responsibilities set out in Part 11 and designed to monitor the safety of authorised or registered medicinal products and detect any change to their risk-benefit balance;

"pharmacovigilance system master file" means a detailed description of the pharmacovigilance system used by the holder of a marketing authorisation, traditional herbal registration or Article 126a authorisation with respect to one or more authorised or registered medicinal products;

"pharmacy medicine" has the meaning given in regulation 5(5) (classification of medicinal products);

"post-authorisation efficacy study" means any study relating to a medicinal product to which a marketing authorisation relates that is conducted with the aim of considering the efficacy of that product;

"post-authorisation safety study" means any study relating to a medicinal product to which a marketing authorisation, traditional herbal registration or Article 126a authorisation relates that is conducted with the aim of—

(a) identifying, characterising or quantifying a safety hazard;

(b) confirming the safety profile of the medicinal product; or

(c) measuring the effectiveness of risk management measures;

"prescription only medicine" has the meaning given in regulation 5(3) (classification of medicinal products);

"product information" in relation to a medicinal product means—

(a) the summary of the product characteristics;

(b) the immediate and outer packaging; and

(c) the package leaflet;

"the professional register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001 [M31];

"the Psychotropic Substances Convention" means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971;

"qualified person", except in relation to the expression "appropriately qualified person", means—

(a) a person who satisfies the requirements specified in Part 1 or 2 of Schedule 7; or

(b) where an application for a licence is made before 30th April 2013, in so far as the application relates to activities in respect of traditional herbal medicinal products, a person who has been engaged in activities in respect of traditional herbal medicinal products equivalent to those in Part 3 of Schedule 7 on or before 30th April 2011 and continues to be so engaged at the time when the application is made;

"radionuclide" means a radioactive isotope;

"radionuclide generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

"radionuclide kit" means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration;

"radionuclide precursor" means any radionuclide produced for the radio-labelling of another substance prior to administration, other than a radionuclide that is incorporated in or produced from a generator or is included in a radiopharmaceutical;

"radiopharmaceutical" means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

"registered midwife" means a person registered in the Midwives Part of the professional register;

"registered nurse" means a person registered in the Nurses Part or the Specialist Community Public Health Nurses Part of the professional register;

"registered optometrist" means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989 [M32] or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) [M33] of that Act;

"registered pharmacy" means—

(a) in relation to Great Britain, premises entered in the register required to be kept under article 19 of the Pharmacy Order 2010 for the purposes of sections 74A and 74J of the Medicines Act 1968 [M34]; and

(b) in relation to Northern Ireland, premises entered in the register required to be kept under section 75 [M35] of the Medicines Act 1968;

"registrable homoeopathic medicinal product" means a homoeopathic medicinal product to which regulation 102 applies;

"Regulation (EC) No 726/2004" means Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [M36];

"Regulation (EC) No 1394/2007" means Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004[M37];

"Regulation (EC) No 1234/2008" means Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products [M38];

"the relevant EU provisions" means the provisions of legislation of the European Union relating to medicinal products for human use, except to the extent that any other enactment provides for any function in relation to any such provision to be exercised otherwise than by the licensing authority;

"relevant European State" means an EEA State or Switzerland;

"relevant medicinal product" has the meaning given by regulation 48;

"the relevant register" means—

(a) in relation to a pharmacist—

(i) in Great Britain, Part 1 of the Register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010, or

(ii) in Northern Ireland, the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

(b) in relation to a registered nurse or registered midwife, the professional register;

(c) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989 or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act; and

(d) in relation to a chiropodist or podiatrist, a physiotherapist or a radiographer, the part of the Health and Care Professions Council register relating to—

(i) chiropodists and podiatrists,

(ii) physiotherapists, or

(iii) radiographers;

"retail pharmacy business" means a business (other than a professional practice carried on by a doctor or dentist) which consists of or includes the retail sale of medicinal products that are not subject to general sale;

"risk management plan" means a detailed description of the risk management system;

"risk management system" means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including an assessment of the effectiveness of those activities and interventions;

"serious adverse reaction" means an adverse reaction that—

(a) results in a person's death;

(b) threatens a person's life;

(c) results in a person being hospitalised as an inpatient or prolongs a person's existing stay in hospital;

(d) results in a person's persistent or significant disability or incapacity; or

(e) results in a congenital anomaly or birth defect;

"special medicinal product" means a product within the meaning of regulation 167 or any equivalent legislation in an EEA State other than the United Kingdom;

"substance" means any matter regardless of its origins and includes—

(a) human substances (such as human blood and human blood products);

(b) animal substances (such as micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts and blood products);

(c) vegetable substances (such as micro-organisms, plants, parts of plants, vegetable secretions and extracts);

(d) chemical substances (such as elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis); and

(e) gases and vapours;

"the summary of the product characteristics" in relation to a medicinal product means—

(a) where the product has a UK marketing authorisation or traditional herbal registration, the summary of the product characteristics—

(i) as approved by the licensing authority in granting the authorisation or registration, or

(ii) where the summary has been varied since that approval, as so amended; or

(b) where the product has an EU marketing authorisation, the summary of the product characteristics—

(i) as approved by the European Commission in granting the authorisation, or

(ii) where the summary has been varied since that approval, as so amended;

"supplementary prescriber" means a person who is noted in the relevant register as qualified to order drugs, medicines and appliances as a supplementary prescriber (or, in the case of a registered nurse or registered midwife, as a nurse independent/supplementary prescriber) and is—

(a) a pharmacist;

(b) a registered midwife;

(c) a registered nurse;

(d) a chiropodist, podiatrist, physiotherapist or radiographer; or

(e) a registered optometrist;

"suspected" in relation to an adverse reaction means that there is at least a reasonable possibility of there being a causal relationship between a medicinal product and an adverse event;

"third country" means a country or territory outside the EEA:

"traditional herbal medicinal product" means a herbal medicinal product to which regulation 125 applies;

"traditional herbal registration" means a traditional herbal registration granted by the licensing authority under these Regulations;

"UK marketing authorisation" means a marketing authorisation granted by the licensing authority under—

(a) Part 5 of these Regulations; or

(b) Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure);

"vaccine" means an antigenic substance which consists wholly or partly of—

(a) any micro-organisms, viruses or other organisms in any state;

(b) any toxins of microbial origin which have been detoxified (toxoids); or

(c) any extracts or derivatives of any micro-organisms or of any viruses,

being substances which, when administered to human beings, are used for the prevention of specific diseases;

"wholesale dealer's licence" has the meaning given by regulation 18(1).

(2) In these Regulations, references to distribution of a product by way of wholesale dealing are to be construed in accordance with regulation 18(7) and (8).

(3) In these Regulations, references to selling by retail, or to retail sale, are references to selling a product to a person who buys it otherwise than for a purpose specified in regulation 18(8).

(4) In these Regulations, references to supplying anything in circumstances corresponding to retail sale are references to supplying it, otherwise than by way of sale, to a person who receives it otherwise than for a purpose specified in regulation 18(8);

(5) References in these Regulations to the terms of—

(a) a marketing authorisation include the information supplied in relation to the authorisation in accordance with—

(i) regulation 50 and Schedule 8, and

(ii) (if appropriate) Schedule 10 (national homoeopathic products),

as updated in accordance with regulation 57, as approved upon grant under regulation 49 and as varied under regulation 68;

(b) a certificate of registration include the information supplied in relation to the certificate in accordance with regulation 103, as approved upon grant under regulation 103 and as varied under regulation 110; and

(c) a traditional herbal registration include the information supplied in relation to the registration in accordance with regulation 128 and Schedule 12, as updated in accordance with regulation 129, as approved upon grant under regulation 127 and as varied under regulation 135.

(6) References in these Regulations to a condition of—

(a) a marketing authorisation is to a condition to which the authorisation is subject by virtue of regulation 59(1) or 60(1); and

(b) a certificate of registration is to a condition to which the certificate is subject by virtue of regulation 105(1).

(7) For the purposes of these Regulations medicinal products are of the same description if—

(a) they are manufactured to the same specification, and

(b) they are in the same pharmaceutical form.

Modifications etc. (not altering text)

C2 Reg. 8(1) applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M2 OJ No L 311, 28.11.2001, p.67. Directive 2001/83/EC was last amended by Directive 2010/84/EU (OJ No L 348, 31.12.2010, p.74).

M3 2006 c.41.

M4 S.I. 1972/1265 (N.I. 14).

M5 2009 c.1 (N.I.).

M6 2006 c.42.

M7 1978 c.29.

M8 OJ No L 121, 1.5.2001, p.34. Directive 2001/20/EC was last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).

M9 S.I. 2004/1031, to which there are amendments not relevant to these Regulations.

M10 1984 c.24. Section 14 was substituted by the Dentists Act 1984 (Amendment) Order 2005 (S.I. 2005/2011) articles 2 and 6 and further amended by the European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), **regulations 109** and 111. Other amendments of the Dentists Act are not relevant to these Regulations.

M11 OJ No L 33, 8.2.2003, p. 30.

M12 OJ No L 102, 7.4.2004, p. 48.

M13 2003 c.21.

M14 OJ L 91, 30.3.2004, p.25.

M15 S.I. 2002/254, as amended by S.I. 2009/1182. There are other amendments that are not relevant.

M16 S.I. 2010/231.

M17 1993 c.21. Section 41 was amended by S.I. 2007/3101 regulations 206 and 214.

M18 1994 c.17.

M19 S.I. 2002/254. Relevant amendments were made by S.I. 2004/2033, **S.I**. 2009/1182, S.I. 2010/233 and the Health and the Social Care Act 2012 (2012 c.7).

M20 1984 c.24. Section 36B was inserted by S.I. 2005/2011, **articles 2(1)** and 29.

M21 S.I. 2006/1440, **Sch**edule.

M22 2006 c.41.

M23 2006 c.42.

M24 1978 c.29. Concurrent functions under section 36(1) were transferred to the National Waiting Times Board by article 4(2)(c) and (4) of S.S.I. 2002/305.

M25 S.I. 1972/1265 (N.I. 14), as amended by S.I. 1984/1158 (N.I. 8), **S.I**. 1986/595 (N.I. 4) and 2004/311 (N.I. 2).

M26 1997 c.46.

M27 S.I. 1997/1177 (N.I. 7).

M28 OJ No L 378, 27.12.2006, p.1. Regulation (EC) No 1901/2006, as amended by Regulation (EC) No 1902/2006 (OJ No L 378, 27.12.2006, p.20) .

M29 S.I. 2010/231.

M30 S.I. 1976/1213 (N.I. 22), as amended by S.R. 2008 No. 192.

M31 S.I. 2002/253, as amended by S.I. 2009/1182.

M32 1989 c.44; section 7(a) was amended by S.I. 2005/848, **articles 2** and 7(1).

M33 Section 8B was inserted by S.I. 2007/3101, **regulations 178** and 180.

M34 1968 c.67. Sections 74A and 74J were inserted by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231.

M35 Section 75 was amended by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231

M36 OJ No L 136, 30.4.2004, p.1. Regulation (EC) No 726/2004 was last amended by Regulation (EU) No 1235/2010 (OJ No L348, 31.12.2010, p.1).

M37 OJ No L 324, 10.12.2007, p.121.

M38 OJ No L 334, 12.12.2008, p.7.

Status:
Point in time view as at 14/08/2012.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 1.