
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.

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(1) 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

(1) 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.

(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.

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⁽²⁾;

“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;

(2) 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).

“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(3),
 - (ii) the Health and Personal Social Services (Northern Ireland) Order 1972(4) and the Health and Social Care (Reform) Act (Northern Ireland) 2009(5),
 - (iii) the National Health Service (Wales) Act 2006(6),
 - (iv) the National Health Service (Scotland) Act 1978(7);

“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(8);

“the Clinical Trials Regulations” means the Medicines for Human Use (Clinical Trials) Regulations 2004(9);

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

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

(3) 2006 c.41.

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

(5) 2009 c.1 (N.I.).

(6) 2006 c.42.

(7) 1978 c.29.

(8) 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).

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

(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⁽¹⁰⁾;

“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](#)⁽¹¹⁾;

“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⁽¹²⁾;

“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⁽¹³⁾; or

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

⁽¹⁰⁾ [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.

⁽¹¹⁾ OJ No L 33, 8.2.2003, p. 30.

⁽¹²⁾ OJ No L 102, 7.4.2004, p. 48.

⁽¹³⁾ [2003 c.21](#).

“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(14);

“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(15);

“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(16);
- (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(17);
- (i) a registered chiropractor as defined in section 43 of the Chiropractors Act 1994(18);
- (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(19), other than a social worker, in the Health and Care Professions Council register; or

(14) OJ L 91, 30.3.2004, p.25.

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

(16) S.I. 2010/231.

(17) 1993 c.21. Section 41 was amended by S.I. 2007/3101 regulations 206 and 214.

(18) 1994 c.17.

(19) 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).

(k) a person registered in the dental care professionals register established and maintained under section 36B of the Dentists Act 1984⁽²⁰⁾ as a member of a profession complementary to dentistry specified by regulation 2 of the General Dental Council (Professions Complementary to Dentistry) Regulations 2006⁽²¹⁾;

“health centre” means a health centre maintained under—

- (a) section 2 or 3 of the National Health Service Act 2006⁽²²⁾;
- (b) section 2 or 3 of the National Health Service (Wales) Act 2006⁽²³⁾;
- (c) section 36(1)(b) of the National Health Service (Scotland) Act 1978⁽²⁴⁾; or
- (d) article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972⁽²⁵⁾;

“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);

⁽²⁰⁾ 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.

⁽²¹⁾ S.I. 2006/1440, Schedule.

⁽²²⁾ 2006 c.41.

⁽²³⁾ 2006 c.42.

⁽²⁴⁾ 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.

⁽²⁵⁾ 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).

“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 30th March 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(26); 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(27);

“NHS primary medical services” means—

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

(26) 1997 c.46.

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

- (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⁽²⁸⁾;

“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⁽²⁹⁾; 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

⁽²⁸⁾ 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) .

⁽²⁹⁾ S.I. 2010/231.

a relevant European State maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽³⁰⁾;

“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⁽³¹⁾;

“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

⁽³⁰⁾ S.I. 1976/1213 (N.I. 22), as amended by S.R. 2008 No. 192.

⁽³¹⁾ S.I. 2002/253, as amended by S.I. 2009/1182.

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⁽³²⁾ or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a)⁽³³⁾ 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⁽³⁴⁾; and
- (b) in relation to Northern Ireland, premises entered in the register required to be kept under section 75⁽³⁵⁾ 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⁽³⁶⁾;

“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⁽³⁷⁾;

“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⁽³⁸⁾;

“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

⁽³²⁾ 1989 c.44; section 7(a) was amended by S.I. 2005/848, articles 2 and 7(1).

⁽³³⁾ Section 8B was inserted by S.I. 2007/3101, regulations 178 and 180.

⁽³⁴⁾ 1968 c.67. Sections 74A and 74J were inserted by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231.

⁽³⁵⁾ Section 75 was amended by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231

⁽³⁶⁾ 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).

⁽³⁷⁾ OJ No L 324, 10.12.2007, p.121.

⁽³⁸⁾ OJ No L 334, 12.12.2008, p.7.

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.

PART 2

Administration

Commission on Human Medicines

9.—(1) There is to continue to be a body known as the Commission on Human Medicines (referred to in these Regulations as “the Commission”).

(2) The Commission is to perform the functions conferred on it by these Regulations.

(3) The Commission is to have at least eight members.

(4) The members of the Commission are to be appointed by the Ministers.

(5) The Ministers must appoint one of the members of the Commission to chair it.

(6) The Ministers must consult the Scottish Ministers before exercising their functions under paragraphs (4) and (5).

Functions of the Commission

10.—(1) The Commission must give advice to either or both of the Ministers in relation to the matters listed in paragraph (2) if—

(a) the Minister, or Ministers, request it; or

- (b) the Commission considers it appropriate to give it.
- (2) The matters mentioned in paragraph (1) are matters—
 - (a) relating to the execution of any duty imposed by these Regulations or the Clinical Trials Regulations;
 - (b) relating to the exercise of any power conferred by these Regulations or the Clinical Trials Regulations; or
 - (c) otherwise relating to medicinal products.
- (3) Without prejudice to paragraphs (1) and (2), or to any other functions conferred on the Commission by or under these Regulations, the Commission must—
 - (a) give advice with respect to the safety, quality and efficacy of medicinal products; and
 - (b) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given.
- (4) The Commission must also advise the licensing authority if—
 - (a) the licensing authority is required under Schedule 11 (advice and representations) or the Clinical Trials Regulations to consult the Commission about any matter arising under those provisions; or
 - (b) the licensing authority consults the Commission about any matter arising under those provisions.

British Pharmacopoeia Commission

- 11.**—(1) There is to continue to be a committee called the British Pharmacopoeia Commission (referred to as “the BPC” in this regulation).
- (2) The BPC is to continue to have the following functions—
 - (a) the preparation under regulation 317(1) of editions of the British Pharmacopoeia;
 - (b) the preparation of compendia under regulation 317(3);
 - (c) the preparation under regulation 318 (which provides for the preparation and publication of lists of names to be used as headings to monographs in the British Pharmacopoeia) of lists of names; and
 - (d) the preparation of any other document under regulation 319.
 - (3) The BPC is to have at least eight members.
 - (4) The members of the BPC are to be appointed by the Ministers.
 - (5) The Ministers must appoint one of the members of the BPC to chair it.
 - (6) The Ministers must consult the Scottish Ministers before exercising their functions under paragraphs (4) and (5).
 - (7) In this regulation, a reference to preparation includes revision or amendment.

Reporting to Ministers

- 12.**—(1) In this Part “advisory body” means—
- (a) the Commission, or
 - (b) the British Pharmacopoeia Commission.
- (2) Each advisory body must give a report to the Ministers each year about—
- (a) the performance of its functions; and

- (b) the performance of the functions of any expert advisory group appointed by it under regulation 14 (including any expert advisory group appointed jointly with the other advisory body).
- (3) Each advisory body must give its report to the Ministers at the time specified by the Ministers.
- (4) The Secretary of State must lay a copy of each report before Parliament.

Co-option of additional members of advisory bodies

13.—(1) An advisory body may co-opt one or more additional members for the purposes of a meeting.

(2) A person co-opted as a member of an advisory body for the purposes of a meeting ceases to be a member at the end of the meeting.

Appointment of expert advisory groups

14.—(1) An advisory body, or the advisory bodies acting jointly, may with the approval of the licensing authority appoint one or more sub-committees, to be known as expert advisory groups.

(2) The licensing authority may direct an advisory body to appoint an expert advisory group to advise on the matters specified in the direction.

(3) An expert advisory group may include, or consist of, persons who are not members of the advisory body or bodies which appointed the expert advisory group.

(4) The advisory body or bodies which appointed the expert advisory group must appoint a member of the group as its chair.

(5) The chair of an expert advisory group may co-opt additional members of the group for the purposes of a meeting.

(6) Before co-opting additional members under paragraph (5) the chair of the group must consult the chair of the advisory body or bodies which appointed the group.

(7) A person co-opted as a member of an expert advisory group for the purposes of a meeting ceases to be a member of the group at the end of the meeting.

Delegation of functions to expert advisory groups

15.—(1) An advisory body may delegate any of its functions, other than the functions specified in paragraph (2), to an expert advisory group.

(2) The functions which may not be delegated are functions of providing advice to the licensing authority in any case where the licensing authority is required to consult the advisory body under—

- (a) Schedule 11 (advice and representations); and
- (b) the Clinical Trials Regulations.

(3) But an advisory body may arrange for an expert advisory group to provide advice to the advisory body in relation to the performance of a function referred to in paragraph (2).

Further provision about advisory bodies and expert advisory groups etc

16. Schedule 2 (which makes further provision about advisory bodies and expert advisory groups, and provision about payment and expenses of expert committees appointed by the licensing authority) has effect.

PART 3

Manufacturing and wholesale dealing

Grant etc of licences

Manufacturing of medicinal products

- 17.**—(1) A person may not except in accordance with a licence (a “manufacturer’s licence”)—
- (a) manufacture, assemble or import from a state other than an EEA State any medicinal product; or
 - (b) possess a medicinal product for the purpose of any activity in sub-paragraph (a).
- (2) Paragraph (1) is subject to paragraphs (3) to (5).
- (3) Paragraph (1) applies in relation to an investigational medicinal product only—
- (a) if the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration; and
 - (b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that authorisation, certificate or registration.
- (4) In paragraph (3), “marketing authorisation” means—
- (a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or
 - (b) an EU marketing authorisation.
- (5) Paragraph (1) does not apply to a person who, in connection with the importation of a medicinal product from a state other than an EEA State—
- (a) provides facilities solely for transporting the product; or
 - (b) acting as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer’s licence authorising the importation of the product.
- (6) Paragraph (1) does not apply to a person who imports a medicinal product for administration to himself or herself or to any other person who is a member of that person’s household.

Wholesale dealing in medicinal products

- 18.**—(1) A person may not except in accordance with a licence (a “wholesale dealer’s licence”)—
- (a) distribute a medicinal product by way of wholesale dealing; or
 - (b) possess a medicinal product for the purpose of such distribution.
- (2) Paragraph (1) is subject to paragraphs (4) to (6) and regulation 19.
- (3) Distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, is not to be taken to be in accordance with a wholesale dealer’s licence unless the distribution is carried on, or as the case may be the product held, at premises specified in the licence.
- (4) Paragraph (1) does not apply to anything done in relation to a medicinal product by the holder of a manufacturer’s licence in respect of that product.
- (5) Paragraph (1) does not apply where the product concerned is an investigational medicinal product.
- (6) Paragraph (1) does not apply if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source.

(7) In these Regulations a reference to distributing a product by way of wholesale dealing is a reference to—

- (a) selling or supplying it; or
- (b) procuring or holding it or exporting it to another EEA State for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (8).

(8) Those purposes are—

- (a) selling or supplying the product; or
- (b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(9) A wholesale dealer's licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, unless a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product (but this is subject to the exceptions in regulation 43(6)).

(10) In paragraph (9), “marketing authorisation” means—

- (a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or
- (b) an EU marketing authorisation.

Exemptions from requirement for wholesale dealer's licence

19.—(1) Regulation 18 does not apply to the sale or offer for sale of a medicinal product by way of wholesale dealing, or possession for the purpose of such sale or offer, where paragraph (2) applies and the person selling or offering the product for sale is—

- (a) the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration, (an “authorisation”) which relates to the product, including a holder of an authorisation who manufactured or assembled the product; or
- (b) a person who is not the holder of an authorisation in relation to the product but manufactured or assembled the product to the order of a person who is the holder of an authorisation relating to the product.

(2) This paragraph applies if—

- (a) until the sale, the medicinal product has been kept on the premises of the person who manufactured or assembled the product (in this regulation referred to as “authorised premises”); and
- (b) those premises are premises authorised for use for manufacture or assembly by that person's manufacturer's licence.

(3) For the purposes of this regulation, a medicinal product is regarded as having been kept on authorised premises at a time when—

- (a) it was being moved from one set of authorised premises to another, or from one part of authorised premises to another part; or
- (b) it was being moved from authorised premises by way of delivery to a purchaser.

(4) Regulation 18 does not apply to a person who in connection with the importation of a medicinal product—

- (a) provides facilities solely for transporting the product; or

- (b) acting as an import agent, handles the product where the product is imported solely to the order of another person who intends to sell the product or offer it for sale by way of wholesale dealing or to distribute it in any other way.

(5) Regulation 18 does not apply to the distribution of a medicinal product by way of wholesale dealing, or to the possession of a medicinal product for the purpose of such distribution, if the distribution or possession is solely for the purpose of exporting the product to states other than EEA States.

Mixing of medicines

20.—(1) Regulation 17(1) (manufacturing of medicinal products) does not apply to the mixing of medicines by—

- (a) a nurse independent prescriber;
- (b) a pharmacist independent prescriber;
- (c) a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient;
- (d) a person acting in accordance with the written directions of a—
 - (i) doctor,
 - (ii) dentist,
 - (iii) nurse independent prescriber, or
 - (iv) pharmacist independent prescriber; or
- (e) a person acting in accordance with the written directions of a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient.

(2) In this regulation “mixing of medicines” means the combining of two or more medicinal products together for the purposes of administering them to meet the needs of an individual patient.

Application for manufacturer’s or wholesale dealer’s licence

21.—(1) An application for a grant of a licence under this Part must—

- (a) be made to the licensing authority;
- (b) be made in the way and form specified in Schedule 3; and
- (c) contain or be accompanied by the information, documents, samples and other material specified in that Schedule.

(2) An application must indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.

Factors relevant to determination of application for manufacturer’s or wholesale dealer’s licence

22.—(1) In dealing with an application for a manufacturer’s licence the licensing authority must in particular take into consideration—

- (a) the operations proposed to be carried out under the licence;
- (b) the premises in which those operations are to be carried out;
- (c) the equipment which is or will be available on those premises for carrying out those operations;

- (d) the qualifications of the persons under whose supervision the operations will be carried out; and
 - (e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.
- (2) In dealing with an application for a wholesale dealer's licence the licensing authority must in particular take into consideration—
- (a) the premises on which medicinal products of the descriptions to which the application relates will be stored;
 - (b) the equipment which is or will be available for storing medicinal products on those premises;
 - (c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and
 - (d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

Grant or refusal of licence

23.—(1) Subject to the following provisions of these Regulations, on an application to the licensing authority for a licence under this Part the licensing authority may—

- (a) grant a licence containing such provisions as it considers appropriate; or
- (b) refuse to grant a licence if having regard to the provisions of these Regulations and any European Union obligation it considers it necessary or appropriate to do so.

(2) The licensing authority must grant or refuse an application for a licence under this Part within the period of 90 days beginning immediately after the day on which it receives the application.

(3) Paragraph (2) applies to an application only if the requirements of Schedule 3 have been met.

(4) If a notice under regulation 30 requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (2).

(5) In paragraph (4), the “information period” means the period—

- (a) beginning with the day on which the notice is given, and
- (b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(6) The licensing authority must give the applicant a notice stating the reasons for its decision in any case where—

- (a) the licensing authority refuses to grant an application for a licence; or
- (b) the licensing authority grants a licence otherwise than in accordance with the application and the applicant requests a statement of its reasons.

Standard provisions of licences

24.—(1) The standard provisions set out in Schedule 4 may be incorporated by the licensing authority in a licence under this Part granted on or after the date on which these Regulations come into force.

(2) The standard provisions may be incorporated in a licence with or without modifications and either generally or in relation to medicinal products of a particular class.

Duration of licence

25. A licence granted under this Part remains in force until—
- (a) the licence is revoked by the licensing authority; or
 - (b) the licence is surrendered by the holder.

General power to suspend, revoke or vary licences

26.—(1) The licensing authority may in accordance with the procedure specified in regulation 27—

- (a) suspend a licence under this Part for such period as the authority thinks fit;
 - (b) revoke a licence under this Part; or
 - (c) vary the provisions of a licence under this Part.
- (2) The suspension or revocation of a licence may be—
- (a) total;
 - (b) limited to medicinal products of one or more descriptions; or
 - (c) limited to medicinal products manufactured, assembled or stored on specified premises or a specified part of any premises.
- (3) The powers conferred by this regulation may not be exercised in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the grounds specified in—
- (a) paragraph (4) (in relation to either a manufacturer's licence or a wholesale dealer's licence);
 - (b) paragraph (5) (in relation to a manufacturer's licence); or
 - (c) paragraph (6) (in relation to a wholesale dealer's licence).
- (4) Those grounds are that—
- (a) the information in the application as a result of which the licence was granted was false or incomplete in a material respect;
 - (b) a material change of circumstances has occurred in relation to any of the matters stated in the application;
 - (c) the holder of the licence has materially contravened a provision of it; or
 - (d) the holder of the licence has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the licence relates when required to do so under regulation 30(2).
- (5) In relation to a manufacturer's licence, the powers conferred by this regulation may also be exercised on either or both of the following grounds—
- (a) that the holder of the manufacturer's licence has manufactured or assembled medicinal products to the order of a person who holds a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") and has habitually failed to comply with the provisions of that authorisation; or
 - (b) that the holder of the manufacturer's licence does not have appropriate facilities to carry out processes of manufacture or assembly authorised by the licence.
- (6) In relation to a wholesale dealer's licence, the powers conferred by this regulation may also be exercised on the grounds that the equipment and facilities available to the holder of the licence for storing or distributing medicinal products are inadequate to maintain the quality of medicinal products of one or more descriptions to which the licence relates.

Procedure where licensing authority proposes to suspend, revoke or vary licence

- 27.**—(1) This regulation applies where—
- (a) the provisions of regulation 28 do not apply; and
 - (b) the licensing authority proposes to suspend, vary or revoke a licence under regulation 26.
- (2) The licensing authority must notify the licence holder in writing of—
- (a) its proposal;
 - (b) the reasons for it; and
 - (c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, revocation or variation should take effect.
- (3) The licence holder may before the date specified in the notice—
- (a) make written representations to the licensing authority with respect to the proposal; or
 - (b) notify the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations.
- (4) If the licence holder makes written representations in accordance with paragraph 3(a) the licensing authority must take those representations into account before making a decision in the matter.
- (5) If the licence holder notifies the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations in accordance with paragraph 3(b), Schedule 5 has effect.
- (6) If the licensing authority proceeds to suspend, revoke or vary a licence in accordance with the provisions of regulation 26 it must give a notice to the licence holder.
- (7) The notice must—
- (a) give particulars of the suspension, revocation or variation; and
 - (b) give reasons for the decision to suspend, revoke or vary the licence.
- (8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

Suspension of licence in cases of urgency

- 28.**—(1) Notwithstanding anything in the preceding provisions of this Part, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under this Part with immediate effect, the licensing authority may do so for a period not exceeding three months.
- (2) This paragraph applies where—
- (a) a licence has been suspended under paragraph (1); and
 - (b) it appears to the licensing authority that it is necessary to consider whether the licence should be further suspended, revoked or varied.
- (3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 27 (but this is subject to paragraphs (4) and (5)).
- (4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 27 and any proceedings under that regulation have not been finally disposed of before the end of the period for which the licence was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 27 to suspend, vary or revoke the licence is made on an application to the High Court under regulation 322(4) paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a).

Variation of licence on the application of the holder

29.—(1) This regulation applies if the holder of a licence under this Part applies to the licensing authority for a variation of the licence.

(2) The application must—

- (a) be in writing;
- (b) specify the variation requested;
- (c) be signed by or on behalf of the applicant;
- (d) be accompanied by such information as may be required to enable the licensing authority to consider the application; and
- (e) be accompanied by the required fee (if any).

(3) The licensing authority must consider an application made in accordance with this regulation.

(4) If paragraph (5) applies, the licensing authority must vary the licence or refuse to vary it before the end of the period allowed for considering the application.

(5) This paragraph applies to a variation which would have the effect of altering—

- (a) the types of medicinal product in respect of which the licence was granted;
- (b) any operation carried out under the licence; or
- (c) any premises, equipment or facilities in respect of which the licence was granted.

(6) The period allowed for consideration of an application under this regulation is—

- (a) in a case where the licensing authority considers that it is necessary to inspect premises to which the licence relates, 90 days beginning with the day after the date when the licensing authority receives the application; and
- (b) in any other case 30 days beginning with that day.

(7) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application.

(8) If a notice under paragraph (7) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (6).

(9) In paragraph (8), the “information period” means the period—

- (a) beginning with the day on which the notice is given; and
- (b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority’s satisfaction that the applicant is unable to provide it.

(10) Nothing in this regulation affects the powers conferred by regulation 26.

Provision of information

30.—(1) Where an application has been made to the licensing authority for a licence under this Part, the licensing authority may, before determining the application, require the applicant to

provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(2) The licensing authority may give a notice to the holder of a licence under this Part, requiring the holder to provide information of a kind specified in the notice within the period specified in the notice.

(3) A notice under paragraph (2) may not be given to the holder of a licence unless it appears to the licensing authority, or representations are made to the licensing authority by the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, that it is necessary for the licensing authority to consider whether the licence should be varied, suspended or revoked.

(4) A notice under paragraph (2) may specify information which the licensing authority, or the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, thinks necessary for considering whether the notice should be varied, suspended or revoked.

Miscellaneous and offences

Certification of manufacturer's licence

31.—(1) The licensing authority must issue a certificate in accordance with the following paragraphs of this regulation in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products if requested to do so by—

- (a) subject to paragraph (5), the holder of the licence;
- (b) a person who intends to export a medicinal product manufactured or assembled by the holder under the licence; or
- (c) the competent authorities of a country other than an EEA State into which a medicinal product manufactured or assembled under the licence is, or is proposed to be, imported.

(2) The certificate must contain —

- (a) information sufficient to identify the holder of the manufacturer's licence;
- (b) details of the medicinal products that may be manufactured or assembled under the licence; and
- (c) any other information concerning the holder, the product or the licence that the licensing authority thinks it appropriate to include, including information relating to clinical trials.

(3) If—

- (a) a request is made—
 - (i) under paragraph (1)(a) in relation to the export or the proposed export of a product, or
 - (ii) under paragraph (1)(b) or (c); and
- (b) there is a marketing authorisation or a traditional herbal registration in force for any product to which the licence relates,

the certificate must be accompanied by the summary of the product characteristics relating to that product.

(4) The licensing authority may restrict the information provided under sub-paragraphs (2)(a) and (b) and paragraph (3) to information relating to the specific medicinal products mentioned in the request made under paragraph (1).

(5) A licence holder who makes a request under paragraph (1) must—

- (a) produce to the licensing authority a marketing authorisation, certificate of registration or traditional herbal registration in relation to any product to which the certificate is to relate; or
 - (b) make a declaration to the licensing authority explaining why no marketing authorisation, certificate of registration or traditional herbal registration is available.
- (6) The licensing authority must have regard to the prevailing administrative arrangements of the World Health Organisation when issuing the certificate.

Sale and supply of starting materials

- 32.** A person must not sell or supply an active substance if the active substance—
- (a) has not been manufactured or assembled in accordance with the principles and guidelines for good manufacturing practice applicable to starting materials and set out in the Good Manufacturing Practice Directive; and
 - (b) is sold or supplied to a person for use in the manufacture of a medicinal product, except where—
 - (i) the product is a special medicinal product, or
 - (ii) regulation 17(1) (manufacturing of medicinal products) does not apply to the manufacture of the product by virtue of any provision of section 10 of the Medicines Act 1968.

Offence concerning data for advanced therapy medicinal products

33.—(1) A person who is, or immediately before its revocation or suspension was, the holder of a manufacturer's licence relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

- (a) keep the data referred to in Article 15(1) of Regulation (EC) No 1394/2007 in accordance with the requirements of Article 15(4) of that Regulation; or
- (b) transfer the data referred to in Article 15(1) to the licensing authority in the event of that person's bankruptcy or liquidation,

but this is subject to paragraphs (2) and (3).

- (2) Sub-paragraph (1)(b) does not apply if—
 - (a) the person is bankrupt or in liquidation and has transferred the data to another person; or
 - (b) the period for which the person was required to keep the data in accordance with the requirements of Article 15(4) mentioned in sub-paragraph (1)(a) has expired.

(3) It is a defence for a person charged with an offence under paragraph (1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Offences: breach of regulations and false information and defence concerning starting materials

34.—(1) A person is guilty of an offence if the person contravenes the provisions of regulation 17(1), 18(1) or 32.

(2) A person is guilty of an offence if the person knowingly gives false information in response to a notice under regulation 30(1).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 30(2).

(4) The defence in paragraph (5) applies to a person who is charged under paragraph (1) with an offence of contravening regulation 17(1) (prohibition on manufacturing a medicinal product except in accordance with a licence) by virtue of a breach of regulation 37(2)(b) (requirement that active substances used as starting materials are manufactured or assembled in accordance with the Good Manufacturing Practice Directive).

(5) It is a defence for the person to show that the person could not, by taking all reasonable precautions and exercising all due diligence, have discovered that an active substance was not manufactured in accordance with regulation 37(2)(b).

Penalties

35.—(1) A person guilty of an offence under regulation 33(1) or regulation 34(1) or (2) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 34(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Conditions for holding a manufacturer's licence

Conditions for manufacturer's licence

36.—(1) Regulations 37 to 41 apply to the holder of a manufacturer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products).

(2) Those provisions are regulations 37(2)(b), 38, 39(6)(a) and (8), 40 and 41.

(3) The requirements of Part 1 of Schedule 6 apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

Manufacturing and assembly

37.—(1) This regulation applies in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The licence holder must—

- (a) comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive; and
- (b) use active substances as starting materials only if those substances have been manufactured or assembled in accordance with the principles and guidelines mentioned in paragraph (a), in so far as those principles and guidelines relate to starting materials (but see paragraph (3)).

(3) The requirement in paragraph (2)(b) does not apply in relation to the manufacture or assembly of special medicinal products.

(4) The licence holder must maintain such staff, premises and equipment as are necessary for the stages of manufacture and assembly of medicinal products undertaken by the licence holder in accordance with—

- (a) the manufacturer's licence; and
- (b) the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applying to the medicinal products.

(5) The licence holder must not manufacture or assemble medicinal products, or classes of medicinal products, other than those specified in the licence.

(6) The licence holder must not manufacture or assemble medicinal products on premises other than those specified in the licence as approved by the licensing authority for the purpose.

(7) The licence holder must ensure that blood, or blood components, imported into the United Kingdom and used as a starting material or raw material in the manufacture of a medicinal product meet—

- (a) the standards of quality and safety specified in Commission Directive [2004/33/EC](#) of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components⁽³⁹⁾; or
- (b) equivalent standards.

Imports from states other than EEA States

38.—(1) This regulation applies in relation to a manufacturer's licence relating to the import of medicinal products.

(2) The licence holder must comply with the conditions set out in this regulation in relation to the import of medicinal products from a state other than an EEA State.

(3) The licence holder must—

- (a) comply with the principles and guidelines on good manufacturing practice in the Good Manufacturing Practice Directive in so far as they are relevant to the import of medicinal products; and
- (b) ensure that active substances have been used as starting materials in the manufacture of medicinal products, other than special medicinal products, imported from a state other than an EEA State only if those substances have been manufactured or assembled in accordance with the principles and guidelines mentioned in paragraph (a), in so far as those principles and guidelines relate to starting materials.

Further requirements for manufacturer's licence

39.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of medicinal products under the licence as are appropriate in order to maintain the quality of the medicinal products.

(3) The licence holder must ensure that any arrangements made for the handling, control, storage and distribution of medicinal products are adequate to maintain the quality of the products.

(4) The licence holder must not handle, control, store or distribute medicinal products on any premises other than those specified in the licence as approved by the licensing authority for the purpose.

(39) OJ L 91, 30.3.2004, p.25.

(5) The licence holder must inform the licensing authority before making a material alteration to the premises or facilities used under the licence, or to the purposes for which those premises or facilities are used.

(6) The licence holder must inform the licensing authority of any proposed change to—

- (a) the qualified person; and
- (b) any person named in the licence as having responsibility for quality control.

(7) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority to do anything that the licensing authority could have done for the purposes of verifying a statement made in an application for a licence.

(8) In distributing a medicinal product by way of wholesale dealing, the licence holder must comply with regulations 43(1), (2) and (5) and 44(2) and (3) as if the licence holder were the holder of a wholesale dealer's licence.

Obligation to provide information relating to control methods

40.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licensing authority may require the licence holder to provide the authority with proof of the control methods employed by the holder in relation to a medicinal product.

Requirements as to qualified persons

41.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must ensure that there is at the disposal of the holder at all times at least one qualified person who is responsible for carrying out, in relation to medicinal products manufactured, assembled or imported under the licence, the duties specified in Part 3 of Schedule 7.

(3) If the licence holder satisfies the requirements of Part 1 or 2 of Schedule 7 the licence holder may act as a qualified person.

(4) A qualified person may be treated by the licence holder as satisfying the requirements of Part 1 or 2 of Schedule 7 if that person produces evidence that he or she—

- (a) is a member of a body specified in paragraph (5); and
- (b) is regarded by that body as satisfying those requirements.

(5) Those bodies are—

- (a) the Society of Biology;
- (b) the Royal Pharmaceutical Society;
- (c) the Pharmaceutical Society of Northern Ireland;
- (d) the Royal Society of Chemistry; and
- (e) such other body as may be specified by the licensing authority for the purpose of this paragraph.

(6) Where the qualified person changes, the licence holder must give the licensing authority advance notification of—

- (a) that change; and
- (b) the name, address and qualifications of the new qualified person.

(7) The licence holder must not permit any person to act as a qualified person other than the person named in the licence or another person notified to the licensing authority under paragraph (6).

(8) Paragraph (9) applies if the licensing authority thinks, after giving the licence holder and a person acting as a qualified person the opportunity to make representations (orally or in writing), that the person—

- (a) does not satisfy the requirements of Part 1 or 2 of Schedule 7 in relation to qualifications or experience;
- (b) does not satisfy paragraph (b) of the definition of “qualified person” in regulation 8; or
- (c) is failing to carry out the duties referred to in paragraph (2) adequately or at all.

(9) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a qualified person.

(10) The licence holder must at all times provide and maintain such staff, premises and equipment as are necessary to enable the qualified person to carry out the duties referred to in paragraph (2).

(11) The licence holder is not obliged to meet the requirements of this regulation in relation to any activity under the licence which relates to special medicinal products or to products authorised on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc).

Conditions for holding a wholesale dealer’s licence

Conditions for wholesale dealer’s licence

42.—(1) Regulations 43 to 45 apply to the holder of a wholesale dealer’s licence (referred to in those regulations as “the licence holder”) and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a wholesale dealer’s licence insofar as the licence relates to exempt advanced therapy medicinal products).

(2) Those provisions are regulations 43(2), (5) and (8) and 44.

(3) The requirements in Part 2 of Schedule 6 apply to the holder of a wholesale dealer’s licence insofar as the licence relates to exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

Obligations of licence holder

43.—(1) The licence holder must comply with the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive.

(2) The licence holder must ensure, within the limits of the holder’s responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met.

(3) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of medicinal products under the licence as are necessary—

- (a) to maintain the quality of the products; and
- (b) to ensure their proper distribution.

(4) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(5) Subject to paragraph (6), the licence holder must not sell or supply a medicinal product, or offer it for sale or supply, unless—

- (a) there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an “authorisation”) in force in relation to the product; and

- (b) the sale or supply, or offer for sale or supply, is in accordance with the authorisation.
- (6) The restriction in paragraph (5) does not apply to—
 - (a) the sale or supply, or offer for sale or supply, of a special medicinal product;
 - (b) the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration by virtue of legislation adopted by that State under Article 5(1) of the 2001 Directive; or
 - (c) the sale or supply, or offer for sale or supply, of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of the product under regulation 174.
- (7) The licence holder must—
 - (a) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the withdrawal or recall from sale of medicinal products in accordance with paragraph (b);
 - (b) maintain an emergency plan to ensure effective implementation of the recall from the market of a medicinal product where recall is—
 - (i) ordered by the licensing authority or by the competent authority of any EEA State, or
 - (ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for, the product; and
 - (c) keep records, in relation to the receipt and dispatch of medicinal products, of—
 - (i) the date of receipt,
 - (ii) the date of despatch,
 - (iii) the name of the medicinal product,
 - (iv) the quantity of the product received or dispatched, and
 - (v) the name and address of the person from whom the products were received or to whom they are dispatched.
- (8) The licence holder must notify the licensing authority and the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an “authorisation”) in relation to a medicinal product if the licence holder intends to import the product from another EEA State and is neither—
 - (a) the holder of an authorisation in relation to the product; nor
 - (b) acting on behalf of the holder of an authorisation.
- (9) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).
- (10) In this regulation, “marketing authorisation” means—
 - (a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or
 - (b) an EU marketing authorisation.

Requirement for wholesale dealers to deal only with specified persons

- 44.—**(1) The licence holder may not obtain supplies of medicinal products from anyone except—

- (a) the holder of a manufacturer's licence or wholesale dealer's licence in relation to products of that description; or
 - (b) a person who holds an authorisation granted by another EEA State authorising the manufacture of products of that description or their distribution by way of wholesale dealing.
- (2) The licence holder may distribute medicinal products by way of wholesale dealing only to—
- (a) the holder of a wholesale dealer's licence relating to those products;
 - (b) the holder of an authorisation granted by the competent authority of another EEA State authorising the supply of those products by way of wholesale dealing;
 - (c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale; or
 - (d) a person who may lawfully administer those products.
- (3) Where a medicinal product is supplied to a person pursuant to paragraph (2)(c), the licence holder must enclose with the product a document stating—
- (a) the date on which the supply took place;
 - (b) the name and pharmaceutical form of the product supplied;
 - (c) the quantity of product supplied; and
 - (d) the name and address of the licence holder.
- (4) The licence holder must—
- (a) keep a record of information supplied in accordance with paragraph (3) for at least five years beginning immediately after the date on which the information is supplied; and
 - (b) ensure that the record is available to the licensing authority for inspection.

Requirement as to responsible persons

- 45.**—(1) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the “responsible person”) who in the opinion of the licensing authority—
- (a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate to carry out the functions mentioned in paragraph (2); and
 - (b) has adequate experience relating to those activities and procedures.
- (2) Those functions are—
- (a) ensuring that the conditions under which the licence was granted have been, and are being, complied with; and
 - (b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applicable to those products.
- (3) The licence holder must notify the licensing authority of—
- (a) any change to the responsible person; and
 - (b) the name, address, qualifications and experience of the responsible person.
- (4) The licence holder must not permit any person to act as a responsible person other than the person named in the licence or another person notified to the licensing authority under paragraph (3).

(5) Paragraph (6) applies if, after giving the licence holder and a person acting as a responsible person the opportunity to make representations (orally or in writing), the licensing authority thinks that the person—

- (a) does not satisfy the requirements of paragraph (1) in relation to qualifications or experience; or
- (b) is failing to carry out the functions referred to in paragraph (2) adequately or at all.

(6) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a responsible person.

PART 4

Requirement for authorisation

Requirement for authorisation

46.—(1) A person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product.

(2) A person may not sell or supply, or offer to sell or supply, a medicinal product otherwise than in accordance with the terms of—

- (a) a marketing authorisation;
- (b) a certificate of registration;
- (c) a traditional herbal registration; or
- (d) an Article 126a authorisation.

(3) A person may not possess an unauthorised medicinal product if the person knows or has reasonable cause to believe that the product is intended to be sold or supplied to another person within the European Economic Area.

(4) A person may not in the circumstances mentioned in paragraph (5)—

- (a) manufacture or assemble a medicinal product; or
- (b) procure the sale, supply, manufacture or assembly of a medicinal product.

(5) Those circumstances are that the person knows or has reasonable cause to believe that the medicinal product has been or is intended to be sold or supplied contrary to paragraph (1).

(6) For the purposes of this regulation a medicinal product is unauthorised if none of the following 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.

(7) This regulation is subject to—

- (a) Part 10 (exceptions to requirement for marketing authorisation etc); and
- (b) Article 83 of Regulation (EC) No 726/2004 (authorisation of placing on the market of medicinal product for compassionate reasons).

(8) A medicinal product is not unauthorised for the purposes of this regulation if—

- (a) it is sold or supplied, or offered for sale or supply, for export to an EEA State; and

(b) the product may lawfully be sold or supplied in that state by virtue of legislation adopted by that state in compliance with the 2001 Directive.

(9) Paragraphs (1) and (2) do not apply to the sale, supply, or offer for sale or supply, of a medicinal product to a person outside the European Economic Area.

(10) Paragraphs (1) and (2) do not apply to the sale, supply, or offer for sale or supply, of an investigational medicinal product to a person specified in regulation 13(1) of the Clinical Trials Regulations for the purposes of administering that product in a clinical trial, provided that the conditions specified in regulation 13(2) of those Regulations are satisfied.

(11) Paragraph (3) does not apply to possession of an investigational medicinal product by a person who knows or has reasonable cause to believe—

- (a) that the investigational medicinal product is intended to be sold or supplied within the European Economic Area; and
- (b) that paragraph (10) will apply to the sale or supply.

Breach of requirement

47.—(1) A person who breaches regulation 46 is guilty of an offence.

(2) A person guilty of an offence under this regulation is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine, to imprisonment not exceeding two years or to both.

(3) It is to be presumed for the purposes of regulation 46(3) that, if a person (“P”) knows or has reasonable cause to believe that a medicinal product is intended to be sold or supplied to another person, P knows or has reasonable cause to believe that the other person is within the European Economic Area.

(4) Paragraph (3) does not apply if P proves that P did not know or have reasonable cause to believe that the person was within the European Economic Area.

(5) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (4), the court or jury must assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

(6) Paragraph (7) applies if the holder of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation is charged with an offence under this regulation in respect of anything that—

- (a) has been manufactured or assembled to the holder’s order by another person; and
- (b) has been so manufactured or assembled as not to comply with the terms of the authorisation, certificate or registration.

(7) Where this paragraph applies, it is a defence for the holder to prove that—

- (a) the holder communicated the terms of the authorisation, certificate or registration to the other person; and
- (b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

PART 5

Marketing authorisations

Application of this Part

48.—(1) This Part applies to relevant medicinal products.

(2) In this Part—

“generic medicinal product” has the meaning given in Article 10(2)(b) of the 2001 Directive;

“relevant medicinal product” means a medicinal product that is not—

(a) a registrable homoeopathic medicinal product; or

(b) a traditional herbal medicinal product; and

“reference medicinal product” has the meaning given in Article 10(2)(a) of the 2001 Directive.

Application for UK marketing authorisation

Application for grant of UK marketing authorisation

49.—(1) The licensing authority may, subject to regulation 58, grant a UK marketing authorisation for a relevant medicinal product in response to an application made in accordance with this Part.

(2) A marketing authorisation granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The applicant must be established in the European Union.

(4) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.

(6) The application and any accompanying material must be in English.

(7) The application must include a statement indicating whether the product to which the application relates should be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(8) The application must include a statement indicating—

(a) whether any terms of the authorisation are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and

(b) if so, what terms are proposed.

Accompanying material

50.—(1) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide the material specified in Schedule 8 in relation to the product.

(2) An applicant for the grant of a UK marketing authorisation for a radionuclide generator must, in addition, provide—

- (a) a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nucleid preparation; and
- (b) qualitative and quantitative particulars of the eluate or the sublimate.

(3) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for dealing with the application.

(4) If any of the medicinal products to which the application relates is liable to be imported from a country other than an EEA State, the material or information referred to in paragraph (3) may include an undertaking from the manufacturer of the product to comply with the matters set out in Schedule 9.

(5) Material that is submitted under this regulation must be submitted in accordance with the applicable provisions of Annex I to the 2001 Directive.

(6) This regulation is subject to—

- (a) regulation 51 (applications relating to generic medicinal products);
- (b) regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc);
- (c) regulation 53 (applications relating to certain biological medicinal products);
- (d) regulation 54 (applications relating to products in well-established medicinal use);
- (e) regulation 55 (applications relating to new combinations of active substances);
- (f) regulation 56 (applications containing information supplied in relation to another medicinal product with consent); and
- (g) Schedule 10 (applications relating to national homoeopathic products).

Applications relating to generic medicinal products

51.—(1) An applicant for a UK marketing authorisation for a relevant medicinal product that is a generic medicinal product may provide information in relation to the application in accordance with Article 10(1), (5) and (6) of the 2001 Directive.

(2) If the licensing authority grants a UK marketing authorisation for the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in the United Kingdom before the time at which it may be placed on the market in accordance with—

- (a) Article 10(1) of the 2001 Directive; or
- (b) in a case where the application for the marketing authorisation for the reference medicinal product referred to in the application was submitted on or before 30th October 2005, Article 10(1) of the 2001 Directive as it stood before it was amended by Article 1(8) of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending the 2001 Directive⁽⁴⁰⁾ (“Directive 2004/27/EC”), in accordance with Article 2 of Directive 2004/27/EC .

(40) OJ No L 136, 30.4.2004, p. 34.

Applications relating to certain medicinal products that do not qualify as generic etc

52.—(1) This regulation applies where—

- (a) an application is made for a UK marketing authorisation in respect of a product by reference to another medicinal product as reference medicinal product; and
- (b) one or more of the circumstances listed in Article 10(3) of the 2001 Directive applies in respect of the application.

(2) The applicant must provide information in accordance with Article 10(3) and (6) of the 2001 Directive.

(3) Regulation 51(2) shall apply to the application as it applies in relation to an application made in accordance with regulation 51(1).

Applications relating to similar biological medicinal products

53.—(1) This regulation applies if an applicant for a UK marketing authorisation for a biological medicinal product is not able to show that it meets a condition for its being a generic version of a similar medicinal product because of any of the reasons described in Article 10(4) of the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10(4) and (6) of the 2001 Directive.

(3) Regulation 51(2) shall apply to the application as it applies in relation to an application made in accordance with regulation 51(1).

Applications relating to products in well-established medicinal use

54.—(1) This regulation applies if an applicant for a UK marketing authorisation for a relevant medicinal product is able to demonstrate that the active substances of the product have been in well-established medicinal use within the European Union for at least 10 years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I to the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10a of the 2001 Directive.

Applications relating to new combinations of active substances

55.—(1) This paragraph applies to an application for a UK marketing authorisation for a relevant medicinal product that contains active substances that—

- (a) have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations, the 2001 Directive or Regulation (EC) No 726/2004; but
- (b) have not been used in that combination for therapeutic purposes.

(2) The applicant must provide information in accordance with Article 10b of the 2001 Directive.

Applications containing information supplied in relation to another product with consent

56.—(1) This regulation applies to an application for a UK marketing authorisation for a relevant medicinal product where—

- (a) the product that is the subject of the application (“product A”) has the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as a product (“product B”);
- (b) product B is the subject of a UK marketing authorisation; and

(c) the holder of the marketing authorisation for product B has allowed use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on product B with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

(2) The documentation referred to in paragraph (1)(c) in relation to product B may be used in relation to the application in relation to product A, in accordance with Article 10c of the 2001 Directive.

Obligation to update information supplied in connection with application

57.—(1) The applicant for a UK marketing authorisation must update information supplied in accordance with paragraphs 18 to 21 of Schedule 8 (material to accompany an application for a UK marketing authorisation) in connection with the application.

(2) The applicant must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(3) Updated information within paragraphs (1) or (2) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.

Consideration of application

Consideration of application

58.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a UK marketing authorisation before the end of 210 days beginning immediately after the day on which the application for the authorisation is submitted in accordance with regulations 49 to 55.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

- (a) beginning with the date on which the request is made; and
- (b) ending with the date on which the information or material is provided.

(3) If the licensing authority requests the applicant to give an oral or written explanation of the application, the period referred to in paragraph (1) is suspended for the period—

- (a) beginning with the date on which the request is made; and
- (b) ending with the date on which the explanation is provided.

(4) The licensing authority may grant the application only if, having considered the application and the accompanying material, the authority thinks that—

- (a) the applicant has established the therapeutic efficacy of the product to which the application relates;
- (b) the positive therapeutic effects of the product outweigh the risks to the health of patients or of the public associated with the product;
- (c) the application and the accompanying material complies with regulations 49 to 55; and
- (d) the product's qualitative and quantitative composition is as described in the application and the accompanying material.

(5) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a UK marketing authorisation.

- (6) This regulation does not apply to an application that—
- (a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or
 - (b) has been referred to the Committee for Medicinal Products for Human Use established under Regulation (EC) No 726/2004 for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(7) An application to which paragraph (6) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

Conditions of UK marketing authorisation: general

59.—(1) The licensing authority may—

- (a) grant a UK marketing authorisation subject to one or more of the conditions in paragraph (2); or
- (b) vary or remove a condition in paragraph (2) to which the UK marketing authorisation is subject.

(2) Those conditions are—

- (a) to take certain measures for ensuring the safe use of the medicinal product and include them in the risk management plan;
- (b) to conduct post-authorisation safety studies;
- (c) to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Part 11;
- (d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;
- (e) the existence of an adequate pharmacovigilance system; and
- (f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed.

(3) An obligation to conduct such studies as are referred to in paragraph (2)(f) must be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive, while taking into account the scientific guidance referred to in Article 108a of the 2001 Directive.

(4) The marketing authorisation must lay down deadlines for the fulfilment of the conditions in paragraph (2) where necessary.

(5) The licensing authority must notify the EMA of any marketing authorisation that it has granted subject to a condition included in accordance with this regulation.

(6) The holder of the authorisation must incorporate any condition included in a marketing authorisation in accordance with this regulation into the risk management system for the product.

(7) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject.

Conditions of UK marketing authorisation: exceptional circumstances

60.—(1) The licensing authority may—

- (a) grant a UK marketing authorisation subject to conditions in accordance with the following paragraphs of this regulation; or
- (b) vary or remove such a condition to which the UK marketing authorisation is subject.

(2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the authorisation or (as the case may be) its holder.

(3) The power in paragraph (1)(a) to grant an authorisation subject to conditions may be exercised only—

- (a) in exceptional circumstances; and
- (b) when the applicant can show that the applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use.

(4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.

(5) The conditions may, in particular, relate to the safety of the product to which the authorisation relates.

(6) The conditions may, in particular, require that, where there is a serious adverse reaction relating to the use of the product—

- (a) the reaction must be reported to the licensing authority; and
- (b) such other action as may be specified in the conditions must be taken.

(7) The licensing authority must keep under review—

- (a) the conditions under this regulation to which a UK marketing authorisation is subject; and
- (b) the holder's compliance with those conditions.

(8) The licensing authority must consider those matters no less frequently than—

- (a) at the end of the period of one year beginning with the date on which the authorisation was granted; and
- (b) at the end of each subsequent period of one year.

(9) The licensing authority must notify the EMA of any marketing authorisation that it has granted subject to a condition included in accordance with this regulation.

(10) The holder of the authorisation must incorporate any condition included in a marketing authorisation in accordance with this regulation into the risk management system for the product.

(11) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject.

Conditions of UK marketing authorisation: new obligations post-authorisation

61.—(1) After the granting of a UK marketing authorisation, the licensing authority may impose an obligation on the holder of the authorisation in accordance with either or both of—

- (a) paragraph (4), in a case where paragraph (2) applies; or
- (b) paragraph (5), in a case where paragraph (3) applies.

(2) This paragraph applies if there are concerns about the risks of a medicinal product that is the subject of a marketing authorisation.

(3) This paragraph applies if the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly.

(4) The obligation in this paragraph is to conduct a post-authorisation safety study.

(5) The obligation in this paragraph is to conduct a post-authorisation efficacy study.

(6) If concerns as described in paragraph (2) apply to more than one medicinal product, the licensing authority shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study.

(7) The obligation under paragraph (5) shall be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive while taking account of the scientific guidance referred to in Article 108a of the 2001 Directive.

(8) Where the licensing authority imposes an obligation under paragraph (4) or (5), it must without delay give written notice to the holder of —

- (a) the imposition of the obligation;
- (b) the justification for the imposition;
- (c) the objectives and timeframe for submission and conduct of the study; and
- (d) the opportunity to present written observations in accordance with paragraph (9) and the time limit specified for doing so.

(9) Where the holder so requests within the period of thirty days beginning on the day after the receipt by the holder of the notice referred to in paragraph (8), the licensing authority must provide the holder of the authorisation with an opportunity to present written observations in response to the imposition of the obligation within the time limit specified by the licensing authority in the notice.

(10) Where the holder presents written observations under paragraph (9), the licensing authority must withdraw or confirm the imposition of the obligation under paragraph (4) or (5) on the basis of the written observations as soon as is reasonably practicable.

(11) Paragraph (12) applies where the licensing authority—

- (a) imposes an obligation under paragraph (4) or (5) and the holder does not present written representations under paragraph (9); or
- (b) confirms the imposition of an obligation under paragraph (10).

(12) Where this paragraph applies, the licensing authority must vary the marketing authorisation to include the obligation as a condition of the marketing authorisation as if it were a condition imposed under regulation 59 (conditions of UK marketing authorisations: general).

(13) The licensing authority must notify the EMA that the marketing authorisation is subject to a condition included in accordance with paragraph (12).

(14) The holder of the authorisation must incorporate any condition included in a marketing authorisation in accordance with paragraph (12) into the risk management system for the product.

(15) Schedule 11, which makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject, shall apply in relation to the variation or removal of a condition included in a marketing authorisation in accordance with paragraph (12).

Classification of UK marketing authorisation

62.—(1) A UK marketing authorisation must include a term that the product to which the authorisation relates is to be available—

- (a) only on prescription;
- (b) only from a pharmacy; or
- (c) on general sale.

(2) In making a determination under paragraph (1), the licensing authority must have regard to the following in relation to the product—

- (a) the maximum single dose;
- (b) the maximum daily dose;
- (c) the strength of the product;
- (d) its pharmaceutical form;

- (e) its packaging; and
- (f) such other circumstances relating to its use as the licensing authority considers relevant.

(3) A UK marketing authorisation must be granted subject to a condition that the product to which the authorisation relates is to be available only on prescription if the licensing authority considers that the product—

- (a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist;
- (b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;
- (c) contains substances, or preparations of substances, of which the activity requires, or the side effects require, further investigation; or
- (d) is normally prescribed by a doctor or dentist for parenteral administration.

(4) In deciding whether paragraph (3) applies to a product, the licensing authority must take into account whether the product—

- (a) contains a substance listed in any of Schedules I, II or IV to the Narcotics Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention);
- (b) contains a substance listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention);
- (c) is likely, if incorrectly used—
 - (i) to present a substantial risk of medicinal abuse,
 - (ii) to lead to addiction, or
 - (iii) to be used for illegal purposes;
- (d) contains a substance that, by reason of its novelty or properties, might fall within paragraph (c), but as to which there is insufficient information available to determine whether it does so fall;
- (e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments that can only be followed in a hospital;
- (f) is used in the treatment of conditions that must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or
- (g) is intended for outpatients but may produce very serious side effects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.

(5) A UK marketing authorisation may include a term that the product to which the authorisation relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Frequency of periodic safety update reports

63.—(1) The licensing authority must, if paragraph (2) applies, include in a UK marketing authorisation a term that specifies the frequency, calculated from the date on which the authorisation is granted, with which the holder of the authorisation must submit periodic safety update reports in accordance with regulation 191(8) (obligation on holder to submit periodic safety update reports: general requirements).

(2) This paragraph applies in the case of a medicinal product in relation to which regulation 191(8) applies by virtue of regulation 191(1).

Duties of licensing authority in connection with determination

64.—(1) This regulation applies if the licensing authority grants a UK marketing authorisation.

(2) The licensing authority must inform the holder of the authorisation of the summary of the product characteristics as approved by the authority.

(3) The licensing authority must ensure that the summary of the product characteristics continues to match the version it has approved, subject to any changes it approves.

(4) As soon as is reasonably practicable after granting the marketing authorisation, the licensing authority must make available publicly—

- (a) the marketing authorisation;
- (b) the package leaflet;
- (c) the summary of the product characteristics;
- (d) any conditions established in accordance with Articles 21a, 22 and 22a of the 2001 Directive; and
- (e) any deadlines for the fulfilment of those conditions.

(5) The licensing authority must draw up an assessment report and make comments on the file as regards—

- (a) the results of the pharmaceutical and pre-clinical tests, the clinical trials, the risk management system and the pharmacovigilance system of the product to which the authorisation relates; or
- (b) in the case of a national homoeopathic medicinal product within the meaning of Schedule 10, the information submitted under paragraphs 3 to 5 of that Schedule.

(6) The licensing authority must—

- (a) revise the assessment report whenever new information becomes available that is of importance for the evaluation of the quality, safety or efficacy of the medicinal product;
- (b) make the assessment report publicly available (with the omission of information of a commercially confidential nature) as soon as is reasonably practicable after it has been prepared or revised; and
- (c) include in the assessment report a summary, written in a manner that is understandable to the public, that contains, in particular, a section relating to the conditions of use of the medicinal product.

(7) The assessment must be provided separately for each indication that is authorised.

Validity of UK marketing authorisation

Validity of UK marketing authorisation

65.—(1) Subject to the following paragraphs, a UK marketing authorisation remains in force—

- (a) for an initial period of five years beginning with the date on which it is granted; and
- (b) if the authorisation is renewed in accordance with regulation 66, for an unlimited period after its renewal.

(2) The licensing authority may, on the first application for renewal of an authorisation, determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients

to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

- (3) In that event the authorisation remains in force—
 - (a) for a further period of five years beginning with the date on which it is first renewed; and
 - (b) if the authorisation is further renewed under regulation 66, for an unlimited period after its further renewal.
- (4) If an application for the renewal or further renewal of an authorisation is made in accordance with regulation 66 the authorisation remains in force until the licensing authority notifies the applicant of its decision on the application.
- (5) This regulation is subject to—
 - (a) regulation 67 (failure to place on the market etc); and
 - (b) regulation 68 (revocation etc of marketing authorisations).

Application for renewal of authorisation

66.—(1) The licensing authority may renew a UK marketing authorisation in response to an application made in accordance with this regulation.

- (2) The applicant must be established in the European Union.
- (3) The application must be—
 - (a) made in writing;
 - (b) signed by or on behalf of the applicant; and
 - (c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.
- (4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.
- (5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (as the case may be) (3)(a) of regulation 65 (initial and further period of validity).
- (6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy, including—
 - (a) the evaluation of data contained in suspected adverse reaction reports and periodic safety update reports submitted in accordance with Part 11; and
 - (b) all amendments made since the authorisation was granted.
- (7) The licensing authority may renew a UK marketing authorisation only if, having considered the application and the material accompanying it, the authority thinks that the positive therapeutic effects of the product to which the authorisation relates outweigh the risks of the product to the health of patients or of the public.
- (8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a UK marketing authorisation.

Failure to place on the market etc

67.—(1) A UK marketing authorisation ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom during the period of three years beginning immediately after the day on which it was granted.

(2) A UK marketing authorisation for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

- (a) in response to an application in writing by the holder of the UK marketing authorisation; or
- (b) by the licensing authority of its own motion.

(5) An exemption may be granted only—

- (a) in exceptional circumstances; and
- (b) on public health grounds.

(6) An exemption—

- (a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and
- (b) may be renewed or further renewed.

Revocation, variation and suspension of marketing authorisation

Revocation, variation and suspension of UK marketing authorisation

68.—(1) The licensing authority may revoke, vary or suspend a UK marketing authorisation if any of the following conditions is met.

(2) Condition A is that the licensing authority thinks that—

- (a) the product to which the authorisation relates is harmful;
- (b) the positive therapeutic effects of the product do not outweigh the risks of the product to the health of patients or of the public;
- (c) the product lacks therapeutic efficacy, in that therapeutic results cannot be obtained from the product; or
- (d) the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the application or the material supplied with it is incorrect.

(4) Condition C is that the licensing authority thinks that there has been a breach of—

- (a) a term of the authorisation; or
- (b) a requirement imposed by Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that a condition to which the authorisation is subject by virtue of regulations 59 (conditions of UK marketing authorisations: general), 60 (conditions of UK marketing authorisations: exceptional circumstances) or 61 (conditions of UK marketing authorisations: new obligations post-authorisation) has not been fulfilled.

(6) Condition E is that the licensing authority thinks that the holder of the authorisation has not complied with regulation 75(1) to (3) (requirements to provide information).

(7) Condition F is that the holder of the authorisation has ceased to be established in the European Union.

(8) Condition G is that—

- (a) the product to which the authorisation relates is manufactured in the United Kingdom; and
 - (b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with regulations 37 (manufacturing and assembly), 38 (imports from states other than EEA States), 39 (further requirements for manufacturer's licence), 40 (obligation to provide information relating to control methods) or 41 (requirements as to qualified persons).
- (9) Condition H is that—
- (a) the product to which the authorisation relates is manufactured in a member State other than the United Kingdom; and
 - (b) the licensing authority thinks that the licensee under the manufacturer's licence for the product has failed to comply in relation to the product with provision giving effect to Article 41 of the 2001 Directive (requirements relating to manufacturing authorisations) in that member State.
- (10) Condition I is that the licensing authority thinks that urgent action to protect public health is necessary, in which case it—
- (a) may suspend the authorisation; and
 - (b) must notify the suspension to the EMA, the European Commission, and all other member States by the end of the next working day following the day on which the suspension comes into force.
- (11) Condition J is that—
- (a) the holder applies to vary the authorisation; and
 - (b) the licensing authority thinks that the application should be granted.
- (12) Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a UK marketing authorisation, other than a proposal to vary an authorisation on the application of its holder.
- (13) This regulation is subject to regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive).

Suspension of use etc of relevant medicinal product

69.—(1) The licensing authority may, if any of the following conditions are met, suspend the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a UK marketing authorisation relates.

- (2) Condition A is that the licensing authority thinks that—
- (a) the product to which the authorisation relates is harmful;
 - (b) the positive therapeutic effects of the product do not outweigh the risks of the product to the health of patients or of the public;
 - (c) the product lacks therapeutic efficacy, in that therapeutic results cannot be obtained from the product; or
 - (d) the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it.
- (3) Condition B is that the licensing authority thinks that the holder of the authorisation has not complied with regulation 75(7) (requirements to provide proof of controls on manufacturing process).
- (4) Condition C is that the licensing authority thinks that there has been a breach of—
- (a) a term of the authorisation; or

- (b) a requirement imposed by Part 13 (packaging and leaflets).
- (5) Condition D is that the licensing authority thinks that paragraph (4) or (5) of regulation 26 (power to revoke, suspend or vary manufacturers' licences) applies in relation to the manufacturer's licence for the product to which the authorisation relates.
- (6) A suspension under this regulation may relate to batches of the product.
- (7) The licensing authority must give notice in writing of a suspension under this regulation to the holder of the UK marketing authorisation.
- (8) The licensing authority must provide in the notice that the suspension—
 - (a) is to take effect immediately or from a date specified in the notice; and
 - (b) is to apply for the period specified in the notice.
- (9) Where a medicinal product is the subject of a suspension under this regulation, the licensing authority may—
 - (a) in exceptional circumstances; and
 - (b) for such a transitional period as the licensing authority may determine,allow the supply of the medicinal product to patients who are already being treated with the medicinal product.
- (10) This regulation is subject to regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive).

Authorisations granted under Chapter 4 of Title III of the 2001 Directive

- 70.**—(1) Regulations 68 and 69 do not apply in relation to a UK marketing authorisation that—
- (a) was granted in accordance with the provisions of Chapter 4 of Title III of the 2001 Directive (mutual recognition procedure and decentralised procedure);
 - (b) was granted before 1st January 1995 in accordance with Article 4 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology⁽⁴¹⁾; or
 - (c) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorisation.
- (2) A proposal by the licensing authority to vary, suspend or revoke a marketing authorisation within paragraph (1), or an application by the holder of such an authorisation to vary or revoke it, is to be determined in accordance with Chapter 4 of Title III of the 2001 Directive.

Withdrawal of medicinal product from the market

- 71.**—(1) This regulation applies if—
- (a) under regulation 68, regulation 70(2), Article 34(3) of the 2001 Directive or Regulation (EC) No 726/2004 the licensing authority or the European Commission revokes or suspends a marketing authorisation, or
 - (b) under regulation 69 or Article 20(4) of Regulation (EC) No 726/2004 the licensing authority suspends the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a marketing authorisation relates.

⁽⁴¹⁾ OJ No L 15, 17.1.1987. p.38.

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the authorisation requiring that person to comply with both of the following requirements.

(3) Requirement A is to take all reasonably practicable steps to inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of the product to which the authorisation relates of—

- (a) the revocation or suspension;
- (b) the reasons for the revocation or suspension; and
- (c) any action to be taken to restrict or prevent further use, sale, supply or offer for sale or supply of the product.

(4) Requirement B is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

- (a) the product; or
- (b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

Sale etc of suspended medicinal product

72.—(1) This regulation applies if the use, sale, supply or offer for sale or supply of a medicinal product is suspended in accordance with regulation 69 or 70(2) or Article 20(4) of Regulation (EC) No 726/2004.

(2) A person must not—

- (a) sell, supply or offer to sell or supply the product; or
- (b) procure the sale, supply or offer for sale or supply of the product,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

Obligations of holder of marketing authorisation

Obligation to notify placing on the market etc

73.—(1) The holder of a UK marketing authorisation must notify the licensing authority of the date on which the product to which the authorisation relates is placed on the market in the United Kingdom, taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a UK marketing authorisation must notify the licensing authority if the product to which the authorisation relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

(6) The licensing authority may require the holder of a UK marketing authorisation to provide—

- (a) information relating to the volume of sales in the United Kingdom of the product to which the authorisation relates; or

- (b) information of which the holder is aware relating to the volume of prescriptions in the United Kingdom for the product.
- (7) The holder of a UK marketing authorisation must provide the licensing authority with information that it requires under paragraph (6)—
 - (a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or
 - (b) otherwise, as soon as is reasonably practicable after receipt of the request.

Obligation to take account of scientific and technical progress

74.—(1) The holder of a UK marketing authorisation must keep under review the methods of manufacture and control of the product to which the authorisation relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the marketing authorisation to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

Obligation to provide information relating to safety etc

75.—(1) The holder of a UK marketing authorisation must provide the licensing authority with any new information that might entail the variation of the authorisation.

(2) The holder must, in particular, provide the licensing authority with the following information—

- (a) information about any prohibition or restriction imposed in relation to the product to which the authorisation relates by the competent authority of any country in which the product is on the market;
- (b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation;
- (c) data on the use of the medicinal product where such use is outside the terms of the marketing authorisation; and
- (d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

(3) Information within paragraph (1) or (2) must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a UK marketing authorisation to provide the authority with information that—

- (a) is specified by the licensing authority; and
- (b) demonstrates that the positive therapeutic effects of the product to which the authorisation relates continue to outweigh the risks of the product to the health of patients or of the public.

(5) The information that may be required under paragraph (4) includes information arising from use of the product—

- (a) in a country which is not an EEA State; or
- (b) outside the terms of the marketing authorisation, including use in clinical trials.

(6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the UK marketing authorisation, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.

(7) The licensing authority may require the holder of a UK marketing authorisation to provide the authority with proof of the control methods employed by the manufacturer of the product to which the authorisation relates.

(8) The holder of a UK marketing authorisation must provide the licensing authority with information it requests under paragraphs (4) or (7)—

- (a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or
- (b) otherwise, as soon as is reasonably practicable after receipt of the request.

Obligation in relation to product information

76.—(1) The holder of a UK marketing authorisation for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

Record-keeping obligations

77. The holder of a marketing authorisation must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of any product to which the authorisation relates.

Obligation to ensure appropriate and continued supplies

78. The holder of a marketing authorisation must take all reasonable steps to ensure appropriate and continued supplies of the product to which the authorisation relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

Offences relating to specific requirements

Failure to provide information on marketing authorisations to EMA

79.—(1) The holder of a marketing authorisation is guilty of an offence if the holder—

- (a) has not submitted information to the EMA as required by Article 57(2)(b) of Regulation (EC) No 726/2004 (information on all existing medicinal products for human use authorised or registered in the EU) in relation to any medicinal product that is the subject of a marketing authorisation granted before 2nd July 2012; and
- (b) fails to do so as soon as is reasonably practicable after the coming into force of these Regulations.

(2) The holder of a marketing authorisation is guilty of an offence if the holder fails to submit information to the EMA as required by Article 57(2)(c) of Regulation (EC) No 726/2004 (information on any new or varied authorisations granted in the EU) in relation to any medicinal product that is the subject of a marketing authorisation granted on or after 2nd July 2012 as soon as is reasonably practicable after the grant of the authorisation.

Urgent safety restrictions

- 80.** The holder of a marketing authorisation is guilty of an offence if the holder —
- (a) fails to inform the licensing authority or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008 that the holder has taken urgent safety restrictions on the holder's own initiative;
 - (b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority or the European Commission under Article 22(2) of that Regulation; or
 - (c) fails to submit an application for variation of the marketing authorisation to the licensing authority or the European Commission in accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—
 - (i) the taking under Article 22(1) or, as the case may be,
 - (ii) the imposition under Article 22(2),of that Regulation of an urgent safety restriction.

Offences relating to EU marketing authorisations

Obligation to update information supplied in connection with EU application

81. An applicant for an EU marketing authorisation is guilty of an offence if that person fails to supply updated information to the EMA in accordance with Article 8(3) of the 2001 Directive as applied by Article 6(1) of Regulation (EC) No 726/2004.

EU marketing authorisations: failure to notify placing on market etc

82.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to notify the EMA in accordance with—

- (a) the first paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify date of placing of product on the market); or
- (b) the second paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify that product is to be withdrawn from the market).

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide the EMA with information that it requires under the third paragraph of Article 13(4) of Regulation (EC) No 726/2004 (information as to sales and prescriptions)—

- (a) where the period within which the information must be provided is specified in a written notice given to the holder by the EMA, before the end of that period; or
- (b) otherwise, as soon as is reasonably practicable after receipt of the request.

EU marketing authorisations: failure to take account of technical and scientific progress

83. The holder of an EU marketing authorisation is guilty of an offence if the holder fails to apply to vary the marketing authorisation as required by Article 16(1) of Regulation (EC) No 726/2004 (obligation to take account of scientific and technical progress).

EU marketing authorisations: failure to provide information as to safety etc

84.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide information to the EMA, the Commission or the licensing authority as required by Article 16(2) of Regulation (EC) No 726/2004 (new information which might entail amendment

of particulars or documents) as soon as is reasonably practicable after becoming aware of the information.

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide the EMA with information that it requests as required by the first paragraph of Article 16(4) of Regulation (EC) No 726/2004 (data on risk-benefit balance).

EU marketing authorisations: failure to update product information

85.—(1) The holder of an EU marketing authorisation for a medicinal product is guilty of an offence if the holder fails to ensure that the product information relating to the product is kept up to date with current scientific knowledge, as required by Article 16(3) of Regulation (EC) No 726/2004.

(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

EU marketing authorisations: breach of pharmacovigilance condition etc

86.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to comply with—

- (a) any obligation to which the marketing authorisation is subject by virtue of Articles 10a(1) or 14(7); or
- (b) any condition to which the authorisation is subject by virtue of Article 14(8),

of Regulation (EC) No 726/2004.

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to incorporate into the risk management system for the product as required by Article 14a of Regulation (EC) No 726/2004—

- (a) any recommendation referred to in Article 9(4)(c), (ca), (cb) or (cc);
- (b) any obligation to which the authorisation is subject by virtue of Articles 10a(1) or 14(7); or
- (c) any condition to which the marketing authorisation is subject by virtue of Article 14(8),

of Regulation (EC) No 726/2004.

Offences relating to advanced therapy medicinal products

Offences in connection with risk management systems and traceability systems

87.—(1) The holder of an EU marketing authorisation for an advanced therapy medicinal product is guilty of an offence if the holder fails to—

- (a) submit an additional report evaluating the effectiveness of a risk management system and the results of studies within the period of 21 days beginning on the day following receipt of a request made under the second sub-paragraph of Article 14(2) of Regulation (EC) No 1394/2007, or such longer period as the EMA may specify; or
- (b) include in any periodic safety update report referred to in Article 28(2) of Regulation (EC) No 726/2004 an evaluation of the effectiveness of a risk management system or of the results of any study performed pursuant to the first sub-paragraph of Article 14(2) of Regulation (EC) No 1394/2007, as required by the third sub-paragraph of Article 14(2).

(2) A person who is, or who immediately before its revocation or withdrawal was, the holder of an EU marketing authorisation for an advanced therapy medicinal product is guilty of an offence if the person fails to—

- (a) establish and maintain a traceability system in accordance with the requirements set out in Article 15(1) of Regulation (EC) No 1394/2007;
- (b) where the product contains human cells or tissues, to ensure that the traceability system is complementary to and compatible with the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC, as regards human cells and tissues other than blood cells, and Articles 14 and 24 of Directive 2002/98/EC, as regards blood cells; or
- (c) to keep the data to which the traceability system relates in accordance with the requirements of Article 15(4) of Regulation (EC) No 1394/2007.

Offence concerning data for advanced therapy medicinal products

88.—(1) A person who is, or immediately before its revocation or suspension was, the holder of an EU marketing authorisation relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

- (a) keep the data referred to in Article 15(1) of Regulation (EC) No 1394/2007 in accordance with the requirements of Article 15(4) of that Regulation; or
- (b) transfer the data referred to in Article 15(1) to the EMA in the event of that person's bankruptcy or liquidation in accordance with Article 15(5),

but this is subject to paragraph (2).

(2) Paragraph (1)(b) does not apply if—

- (a) the person is bankrupt or in liquidation and has transferred the data to another person; or
- (b) the period for which the person was required to keep the data in accordance with the requirements of Article 15(4) mentioned in paragraph (1)(a) has expired.

Offences relating to the Paediatric Regulation

Offences in connection with withdrawal of product from the market

89.—(1) This regulation applies to a person (“H”) if—

- (a) H is the holder of a UK marketing authorisation;
- (b) H has benefited from one or more rewards or incentives under any of Articles 36, 37 and 38 of the Paediatric Regulation in relation to the product to which the authorisation relates, and
- (c) all of the periods of protection provided pursuant to those Articles have expired in relation to H.

(2) H is guilty of an offence if H ceases to supply the product without previously in accordance with Article 35 of the Paediatric Regulation —

- (a) transferring the UK marketing authorisation to another person who has declared an intention to continue to supply the product; or
- (b) allowing such a person to use the pharmaceutical, pre-clinical and clinical documentation contained in the file on that product as provided for in regulation 56.

(3) H is guilty of an offence if H—

- (a) ceases to supply the product; and
- (b) does not in accordance with Article 35 of the Paediatric Regulation inform the EMA of H's intention to do so before the beginning of the period of six months ending immediately before the day on which H does so.

Failure to place on the market taking account of paediatric indication

90.—(1) A person (“P”) is guilty of an offence if—

- (a) P is the holder of a UK marketing authorisation;
- (b) P obtains a paediatric indication in respect of the product to which the authorisation relates following completion of an agreed paediatric investigation plan;
- (c) the product was placed on the market for other indications before P obtained that paediatric indication; and
- (d) P fails to place the product on the market taking account of the paediatric indication in accordance with Article 33 of the Paediatric Regulation before the end of the period of two years beginning immediately after the day on which the paediatric indication is authorised.

(2) In this regulation “paediatric indication” means a term of the marketing authorisation enabling the product to which it relates to be used by or administered to persons under the age of 18 years.

Failure to notify results of third country clinical trials

91.—(1) This regulation applies to a person (“P”) if—

- (a) a decision by the EMA in respect of a paediatric investigation plan is addressed to P;
- (b) the plan refers to clinical trials carried out in third countries (“third country clinical trials”); and
- (c) P is established in the United Kingdom.

(2) P is guilty of an offence if P does not enter into the database referred to in Article 11 of the Clinical Trials Directive the details set out in that Article in relation to the third country clinical trials in accordance with Article 41(1) of the Paediatric Regulation within whichever is the later of—

- (a) the period of one month beginning after the day on which the decision was received; or
- (b) the period of one month beginning after the day on which the necessary permission to conduct the clinical trial was received from the competent authorities in the country where the clinical trial is to take place.

(3) P is guilty of an offence if P does not submit the results of those clinical trials to the EMA in accordance with Article 41(2) of the Paediatric Regulation within the period of—

- (a) six months, if P is the holder of a marketing authorisation for the medicinal product concerned; or otherwise
- (b) twelve months,

beginning with the day on which the last of those trials ended.

(4) Paragraph (3) does not apply, and regulation 93(3) shall apply, in the case of a clinical trial that forms part of a paediatric study to which regulation 93 applies.

Failure of sponsor of UK paediatric clinical trial to notify results of trial

92.—(1) This regulation applies to the sponsor (“S”) of a paediatric clinical trial in the United Kingdom in respect of a medicinal product if—

- (a) the product has a UK marketing authorisation but S is not the holder of the authorisation; or
- (b) the product does not have a marketing authorisation.

(2) S is guilty of an offence if S does not submit the results of the clinical trial to the EMA in accordance with Article 41(2) of the Paediatric Regulation within the period of twelve months beginning with the day on which the trial ended.

Failure to notify results of paediatric study

93.—(1) This regulation applies to a person (“H”) if—

- (a) H is the holder of a UK marketing authorisation; and
- (b) H sponsors a paediatric study in respect of the product to which the authorisation relates.

(2) H is guilty of an offence if H does not submit the results of the study to the licensing authority in accordance with Article 46(1) of the Paediatric Regulation within the period of six months beginning with the day on which the study ended.

(3) H is guilty of an offence if H does not submit the results of any clinical trial that forms part of that study to the EMA in accordance with Article 41(2) of the Paediatric Regulation within the period of six months beginning with the day on which the trial ended.

Failure to submit report to EMA

94. The holder of a marketing authorisation is guilty of an offence if the holder fails to submit an annual report to the EMA as required by Article 34(4) of the Paediatric Regulation.

General provisions relating to offences

Offences in connection with application

95. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a marketing authorisation for a relevant medicinal product, the person—

- (a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product;
- (b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular;
- (c) fails to provide the EMA with any information that is relevant to the evaluation of the safety, quality or efficacy of the product as required by paragraph (7) or (11) in the “Introduction and general principles” of Annex 1 to the 2001 Directive as applied by Article 6(1) of Regulation (EC) No 726/2004; or
- (d) provides to the EMA any information of the kind described in sub-paragraph (c) that is false or misleading in a material particular.

Provision of false or misleading information

96.—(1) The holder of a marketing authorisation is guilty of an offence if the holder provides any information to which paragraph (2) applies that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product but that is false or misleading in a material particular to—

- (a) the licensing authority;
- (b) the EMA; or
- (c) the competent authorities of other EEA States.

(2) This paragraph applies to information about the product that is supplied pursuant to the obligations in—

- (a) these Regulations; or
- (b) Regulation (EC) No 726/2004.

(3) This regulation is without prejudice to the operation of regulation 95.

Breach of pharmacovigilance condition

97. The holder of a marketing authorisation is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation is subject by virtue of any of regulations [59](#) (conditions of UK marketing authorisation: general), [60](#) (conditions of UK marketing authorisation: exceptional circumstances) or [61](#) (conditions of UK marketing authorisation: new obligations post-authorisation).

General offence of breach of provision of this Part

98.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

- (a) failure by the holder of a marketing authorisation to comply with any requirement or obligation in this Part;
- (b) contravention by any person of any prohibition in this Part; or
- (c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Penalties

99.—(1) A person guilty of an offence under this Part, other than a breach of regulation [79](#) (failure to provide information on marketing authorisations to EMA), is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

(2) A person guilty of a breach of regulation [79](#) is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine.

Persons liable

100. If a breach of regulation [95](#) (offences in connection with application) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

101.—(1) Paragraph (2) applies if the holder of a marketing authorisation is charged with an offence under this Part in respect of anything that—

- (a) has been manufactured or assembled to the holder's order by another person; and
- (b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

(2) It is a defence for the holder to prove that—

- (a) the holder communicated the terms of the authorisation to the other person; and
- (b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulations 73(3) or 78, or an offence under any of regulations 88 to 93, 95 and 96, to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 6

Certification of homoeopathic medicinal products

Application of Part

Application of Part

102.—(1) This Part applies to a homoeopathic medicinal product (a “registrable homoeopathic medicinal product”) that meets the following conditions.

(2) Condition A is that the product is administered orally or externally.

(3) Condition B is that no specific therapeutic indication appears—

- (a) on the labelling of the product; or
- (b) in any information supplied with the product.

(4) Condition C is that—

- (a) the product contains no more than one part per 10,000 of the mother tincture; and
- (b) in a case where the product’s active substance is a relevant allopathic substance, the product contains no more than 1/100th of the smallest concentration of that substance used in allopathy.

(5) In this regulation “relevant allopathic substance” means an active substance whose presence in an allopathic medicinal product means that the product is only available on prescription.

(6) For this purpose—

- (a) “allopathic medicinal product” means a medicinal product other than a homoeopathic medicinal product; and
- (b) “allopathy” means treatment using an allopathic medicinal product.

Application for certificate of registration and consideration of application

Application for certificate of registration

103.—(1) The licensing authority may, subject to regulation 104, grant an application for a certificate of registration for a registrable homoeopathic medicinal product in response to an application made in accordance with this Part.

(2) A certificate granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The application may relate to two or more homoeopathic medicinal products derived from the same homoeopathic stock or the same combination of homoeopathic stocks.

(4) The applicant must be established in the European Union.

(5) The application must be—

- (a) made in writing;
 - (b) signed by or on behalf of the applicant; and
 - (c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.
- (6) An application is treated as signed for the purposes of paragraph (5)(b) if it is signed with an electronic signature.
- (7) The application and any accompanying material must be in English.
- (8) The applicant must provide each of the following for each product to which the application relates—
- (a) a statement of the scientific name, or other name given in a pharmacopoeia, of the homoeopathic stock or stocks from which the product is derived;
 - (b) a statement of the routes of administration, pharmaceutical forms and degree of dilution of the product;
 - (c) a dossier describing how the homoeopathic stock or stocks are obtained and controlled and justifying their homoeopathic use on the basis of an adequate bibliography;
 - (d) a manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation of the product;
 - (e) evidence that each manufacturer of the medicinal product is authorised to manufacture it (which, in the case of a product manufactured in the United Kingdom or another EEA State, means the manufacturer's licence or (as the case may be) its equivalent in that EEA State);
 - (f) where an authorisation to place the product on the market has been granted by another member State, a copy of the authorisation;
 - (g) a mock-up of the outer and immediate packaging of the product; and
 - (h) data concerning the stability of the product.
- (9) This material, taken as a whole, must be such as to demonstrate the pharmaceutical quality and batch to batch homogeneity of each product to which the application relates.
- (10) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for considering the application.

Consideration of application

104.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a certificate of registration before the end of the period of 210 days beginning immediately after the day on which an application for the certificate is submitted in accordance with regulation 103.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

- (a) beginning with the date on which the request is made; and
- (b) ending with the date on which the information or material is provided.

(3) The licensing authority may grant a certificate only if, having considered the application and the accompanying material, the authority thinks that—

- (a) the risks to the health of patients or of the public associated with the product do not outweigh any beneficial effects of the homoeopathic medicinal product in question;
- (b) the application and the accompanying material complies with regulation 103; and

- (c) the product's qualitative or quantitative composition is as described in the application and the accompanying material.
- (4) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a certificate of registration.
- (5) This regulation does not apply to an application that—
 - (a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or
 - (b) has been referred to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.
- (6) An application to which paragraph (5) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

Conditions of certificate of registration

- 105.**—(1) The licensing authority may—
- (a) grant a certificate of registration subject to conditions; or
 - (b) vary or remove a condition to which the certificate of registration is subject.
- (2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the certificate or (as the case may be) its holder.
- (3) The power in paragraph (1)(a) to grant an authorisation subject to conditions may be exercised only—
- (a) in exceptional circumstances; and
 - (b) when the applicant can show that the applicant is unable to provide comprehensive data on the safety of the medicinal product under normal conditions of use.
- (4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.
- (5) The conditions may, in particular, relate to the safety of the product to which the certificate relates.
- (6) The conditions may, in particular, require that, where there is an incident relating to the use of the product—
- (a) the incident must be reported to the licensing authority; and
 - (b) such other action as may be specified in the conditions must be taken.
- (7) The licensing authority must keep under review—
- (a) the conditions to which a certificate of registration is subject; and
 - (b) the holder's compliance with those conditions.
- (8) The licensing authority must consider those matters no less frequently than—
- (a) at the end of the period of one year beginning with the date on which the certificate was granted; and
 - (b) at the end of each subsequent period of one year.
- (9) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a certificate of registration is subject.

Classification of certificate of registration

- 106.**—(1) A certificate of registration must include a term that the product to which the certificate relates is to be available—

- (a) only from a pharmacy; or
- (b) on general sale.

(2) A certificate of registration may include a term that the product to which the certificate relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Validity of certificate of registration

107.—(1) Subject to the following paragraphs, a certificate of registration remains in force—

- (a) for an initial period of five years beginning with the date on which it is granted; and
- (b) if the authorisation is renewed under regulation 108 for an unlimited period after its renewal.

(2) The licensing authority may, on the first application for renewal of a certificate, determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event, the certificate remains in force—

- (a) for a further period of five years beginning with the date on which it is first renewed; and
- (b) if the authorisation is further renewed under regulation 108 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a certificate is made in accordance with regulation 108 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

- (a) regulation 109 (failure to place on the market etc); and
- (b) regulation 110 (revocation etc of certificate of registration).

Application for renewal of certificate

108.—(1) An application for the renewal of a certificate of registration must be made to the licensing authority.

(2) The applicant must be established in the European Union.

(3) The application must be—

- (a) made in writing;
- (b) signed by or on behalf of the applicant; and
- (c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (as the case may be) (3)(a) of regulation 107 (initial and further period of validity).

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy (including all amendments made since the authorisation was granted).

(7) The licensing authority may renew a certificate only if, having considered the application and the material accompanying it, the authority thinks that the risks to the health of patients or of the

public associated with the homoeopathic medicinal product to which the certificate relates do not outweigh any beneficial effects of the product.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a certificate of registration.

Failure to place on the market etc

109.—(1) A certificate of registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom during the period of three years beginning immediately after the day on which it was granted.

(2) A certificate of registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

- (a) in response to an application in writing by the holder of the certificate of registration; or
- (b) by the licensing authority of its own motion.

(5) An exemption may be granted only—

- (a) in exceptional circumstances; and
- (b) on public health grounds.

(6) An exemption—

- (a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and
- (b) may be renewed or further renewed.

Revocation, variation and suspension of certificate of registration

Revocation, variation and suspension of certificate of registration

110.—(1) The licensing authority may revoke, vary or suspend a certificate of registration if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

- (a) the product to which the certificate relates is harmful;
- (b) the risks of the product to the health of patients or of the public outweigh any beneficial effects of the product; or
- (c) the product's qualitative or quantitative composition is not as described in the application for the certificate or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the application or the material accompanying it is incorrect.

(4) Condition C is that the licensing authority thinks that there has been a breach of—

- (a) a term of the certificate; or
- (b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that a condition to which the certificate is subject by virtue of regulation 105 (conditions of certificate or registration) has not been fulfilled.

(6) Condition E is that the licensing authority thinks that the holder of the certificate has not complied with regulation 115(1) to (3) (requirements to provide information).

(7) Condition F is that the holder of the certificate has ceased to be established in the European Union.

(8) Condition G is that—

(a) the holder applies to vary the certificate; and

(b) the licensing authority thinks that the application should be granted.

(9) Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a certificate of registration, other than a proposal to vary a certificate on the application of its holder.

(10) This regulation is subject to regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive).

Certificates granted under Chapter 4 of Title III of the 2001 Directive

111.—(1) Regulation 110 does not apply in relation to a certificate of registration that was granted in accordance with the provisions of Chapter 4 of Title III of the 2001 Directive (mutual recognition procedure and decentralised procedure).

(2) A proposal by the licensing authority to vary, suspend or revoke a certificate of registration within paragraph (1), or an application by the holder of such a certificate to vary or revoke it, is to be determined in accordance with Chapter 4 of Title III of the 2001 Directive.

Withdrawal of homoeopathic medicinal product from the market

112.—(1) This regulation applies if under regulation 110 or regulation 111(2) the licensing authority revokes or suspends a certificate of registration.

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the certificate requiring the holder to comply with the following requirement.

(3) That requirement is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product to which the certificate relates; or

(b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

(4) The notice must specify the grounds for giving the notice.

Obligations of holder of certificate of registration

Obligation to notify placing on the market etc

113.—(1) The holder of a certificate of registration must notify the licensing authority of the date on which the product to which the certificate relates is placed on the market in the United Kingdom taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a certificate of registration must notify the licensing authority if the product to which the certificate relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

(6) The licensing authority may require the holder of a certificate of registration to provide information relating to the volume of sales in the United Kingdom of the product to which the certificate relates.

(7) The holder of a certificate of registration must provide the licensing authority with information that it requires under paragraph (6)—

- (a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or
- (b) otherwise, as soon as is reasonably practicable after receipt of the request.

Obligation to take account of scientific and technical progress

114.—(1) The holder of a certificate of registration must keep under review the methods of manufacture and control of the product to which the certificate relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the certificate of registration to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

Obligation to provide information relating to safety etc

115.—(1) The holder of a certificate of registration must provide the licensing authority with any new information that might entail the variation of the certificate.

(2) The holder must, in particular, provide the licensing authority with the following information—

- (a) information about any prohibition or restriction imposed in relation to the product to which the certificate relates by the competent authority of any country in which the product is on the market;
- (b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the certificate of registration;
- (c) data on the use of the product where such use is outside the terms of the certificate of registration; and
- (d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

(3) Information within paragraph (1) or (2) must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a certificate of registration to provide the authority with information that—

- (a) is specified by the licensing authority; and
- (b) demonstrates that the risks of the product to the health of patients or of the public do not outweigh any beneficial effects of the product to which the certificate relates.

(5) The information that may be required under paragraph (4) includes information arising from use of the product—

- (a) in a country which is not an EEA State; or
 - (b) outside the terms of the certificate of registration.
- (6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the certificate of registration, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.
- (7) The licensing authority may require the holder of a certificate of registration to provide the authority with proof of the control methods employed by the manufacturer of the product to which the certificate relates.
- (8) The licensing authority may notify the holder of a certificate of registration that it requires the holder to provide to the licensing authority information of any description specified in the notice, within the period specified in the notice, subject to paragraph (9).
- (9) A notice under paragraph (8) must not be served unless it appears to the licensing authority, or it is represented to the licensing authority by the Commission or by an expert committee appointed by the licensing authority—
- (a) that circumstances exist by reason of which it is necessary to consider whether the certificate of registration should be varied, suspended or revoked; and
 - (b) that the information required by the notice is needed to consider that question.
- (10) The holder of a certificate of registration must provide the licensing authority with information that it requires under paragraphs (4) or (7)—
- (a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or
 - (b) otherwise, as soon as is reasonably practicable after receipt of the request.

Obligation in relation to product information

116.—(1) The holder of the certificate of registration for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

Record-keeping obligation

117. The holder of a certificate of registration must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of the product to which the certificate relates.

Obligation to ensure appropriate and continued supplies

118. The holder of a certificate of registration must take all reasonable steps to ensure appropriate and continued supplies of the product to which the certificate relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

Provisions relating to offences

Offences in connection with applications

119. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a certificate of registration for a registrable homeopathic medicinal product, the person—

- (a) fails to provide the licensing authority with any information that is relevant to an evaluation of the quality of the product; or
- (b) provides to the licensing authority any information that is relevant to an evaluation of the quality of the product that is false or misleading in a material particular.

Provision of false or misleading information

120.—(1) The holder of a certificate of registration for a medicinal product is guilty of an offence if the person provides the licensing authority with any information that is relevant to the quality of the product but that is false or misleading in a material particular.

(2) Paragraph (1) is without prejudice to the operation of regulation 119.

General offence of breach of provision of this Part

121.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

- (a) failure by the holder of a certificate of registration to comply with any requirement or obligation in this Part;
- (b) contravention by any person of any prohibition in this Part; or
- (c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Penalties

122. A person guilty of an offence under this Part is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

Persons liable

123. If an offence under regulation 119 (offences in connection with applications) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

124.—(1) Paragraph (2) applies if the holder of a certificate of registration is charged with an offence under this Part in respect of anything that—

- (a) has been manufactured or assembled to the holder's order by another person; and
- (b) has been so manufactured or assembled as not to comply with the terms of the certificate.

(2) It is a defence for the holder to prove that—

- (a) the holder communicated the terms of the certificate to the other person; and
- (b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulation 113(3) or 118 or an offence under regulation 119 or 120 to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 7

Traditional herbal registrations

Application of Part

Traditional herbal medicinal products

125.—(1) This Part applies to a herbal medicinal product (a “traditional herbal medicinal product”) if the following conditions are met.

(2) Condition A is met if by virtue of its composition and indications the product is appropriate for use without the need for a medical practitioner to—

- (a) diagnose the condition to be treated by the product;
- (b) prescribe the product; or
- (c) monitor the product’s use.

(3) Condition B is met if the product is intended to be administered at a particular strength and in accordance with a particular posology.

(4) Condition C is met if the product is intended to be administered externally, orally or by inhalation.

(5) Condition D is met if—

- (a) the product has been in medicinal use for a continuous period of at least 30 years, and
- (b) the product has been in medicinal use in the European Union for a continuous period of at least 15 years.

(6) It is immaterial for the purposes of condition D whether or not during a period mentioned in that condition—

- (a) the sale or supply of the product has been based on a specific authorisation; or
- (b) the number or quantity of the ingredients (or any of them) has been reduced.

(7) Condition E is met if there is sufficient information about the use of the product as mentioned in condition D (referred to in this Part as its “traditional use”), so that (in particular)—

- (a) it has been established that the traditional use of the product is not harmful; and
- (b) the pharmacological effects or efficacy of the product are plausible on the basis of long-standing use and experience.

Addition of vitamins or minerals

126. The addition to a traditional herbal medicinal product of a vitamin or mineral does not prevent a traditional herbal registration from being granted for the product if—

- (a) there is well-documented evidence of the safety of the vitamin or mineral; and

- (b) the action of the vitamin or mineral is ancillary to the action of the product's active herbal ingredients in connection with the use authorised by the traditional herbal registration.

Application for traditional herbal registration

Application for grant of traditional herbal registration

127.—(1) The licensing authority may, subject to regulation 130, grant an application for a traditional herbal registration for a traditional herbal medicinal product in response to an application made in accordance with this Part.

(2) A registration granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The applicant must be established in the European Union.

(4) The application must be—

- (a) made in writing;
- (b) signed by or on behalf of the applicant; and
- (c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.

(6) The application and any accompanying material must be in English.

(7) The application must include a statement indicating whether the product to which the application relates should be available—

- (a) only from a pharmacy; or
- (b) on general sale.

(8) The application must include a statement indicating—

- (a) whether any terms of the registration are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and
- (b) if so, what terms are proposed.

Accompanying material

128.—(1) The applicant for the grant of a traditional herbal registration must provide the material specified in Schedule 12 in relation to the product.

(2) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for considering the application.

(3) If the application relates to a product that is contained in the list referred to in Article 16f(1) of the 2001 Directive—

- (a) the applicant does not need to provide the material referred to in paragraphs 16 to 20 of Part 1 of Schedule 12; and
- (b) paragraph (2) of this regulation does not apply.

(4) Material that is submitted under this regulation must be submitted in accordance with Annex I to the 2001 Directive, so far as applicable to traditional herbal medicinal products.

Obligation to update information supplied in connection with application

129.—(1) The applicant for a traditional herbal registration must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(2) Updated information within paragraph (1) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.

*Consideration of application***Consideration of application**

130.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a traditional herbal registration before the end of the period of 210 days beginning immediately after the day on which an application for the registration is submitted in accordance with regulation 128.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

- (a) beginning with the date on which the request is made; and
- (b) ending with the date on which the information or material is provided.

(3) If the licensing authority requests the applicant to give an oral or written explanation of the application, the period referred to in paragraph (1) is suspended for the period—

- (a) beginning with the date on which the request is made; and
- (b) ending with the date on which the explanation is provided.

(4) The licensing authority may grant the application only if, having considered the application and the accompanying material, the authority thinks that—

- (a) the product complies with conditions A to E of regulation 125 (conditions for a product to be a traditional herbal medicinal product);
- (b) the product to which the application relates is not harmful under normal conditions of use;
- (c) the application and the accompanying material complies with the requirements of this Part;
- (d) the product's qualitative and quantitative composition is as described in the application and the accompanying material; and
- (e) the product's pharmaceutical quality has been satisfactorily demonstrated.

(5) The licensing authority need not take into account any updated information supplied in connection with the application under regulation 129 (obligation to update information supplied in connection with application), unless it thinks that the information is unfavourable in respect of the safety, quality or efficacy of the product concerned

(6) The licensing authority may refuse the application on the ground that it is more appropriate to consider whether to authorise the placing of the product on the market in response to an application for a marketing authorisation or certificate of registration for the product.

(7) Paragraph (4)(a) is subject to Article 16c(4) of the 2001 Directive (procedure where product has been used in the European Union for less than 15 years).

(8) If the application relates to a herbal medicinal product that is contained in the list referred to Article 16f(1) of the 2001 Directive—

- (a) paragraph (4)(a) applies as if it referred to conditions A to D of regulation 125; and
- (b) paragraph (4)(b) does not apply.

(9) Where Article 16d(1) of the 2001 Directive (products to which the mutual recognition procedure and decentralised procedure apply) does not apply to the product, the licensing authority must, in considering the application, take into account any registrations granted by other member States in accordance with Chapter 2a of Title III of the 2001 Directive.

(10) The licensing authority must take into account—

- (a) any herbal monograph of the kind referred to in Article 16h(3) of the 2001 Directive that the authority thinks relevant to the application; or
- (b) if no relevant monograph within sub-paragraph (a) has been established, such other monographs, publications or data as the authority thinks relevant.

(11) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a traditional herbal registration.

(12) This regulation does not apply where Article 16d(1) applies to the product and the application—

- (a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or
- (b) has been referred to the Committee for Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(13) An application to which paragraph (12) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

Classification of traditional herbal registration

131.—(1) A traditional herbal registration must include a term that the product to which the registration relates is to be available—

- (a) only from a pharmacy; or
- (b) on general sale.

(2) A traditional herbal registration may include a term that the product to which the registration relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Validity of traditional herbal registration

Validity of traditional herbal registration

132.—(1) Subject to the following paragraphs, a traditional herbal registration remains in force—

- (a) for an initial period of five years beginning with the date on which it is granted; and
- (b) if the registration is renewed under regulation 133 for an unlimited period after its renewal.

(2) The licensing authority may on the first application for renewal of a registration determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event, the registration remains in force—

- (a) for a further period of five years beginning with the date on which it is first renewed; and
- (b) if the registration is further renewed under regulation 133 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a registration is made in accordance with regulation 133 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

- (a) regulation 134 (failure to place on the market); and
- (b) regulation 135 (revocation etc of traditional herbal registration).

Application for renewal of registration

133.—(1) An application for the renewal of a traditional herbal registration must be made to the licensing authority.

(2) The applicant must be established in the European Union.

(3) The application must be—

- (a) made in writing;
- (b) signed by or on behalf of the applicant; and
- (c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (3)(a) of regulation 132 (initial and further period of validity), as the case may be.

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy including—

- (a) the evaluation of data contained in suspected adverse reaction reports and periodic safety update reports submitted in accordance with Part 11; and
- (b) all variations introduced since the traditional herbal registration was granted.

(7) The licensing authority may renew a traditional herbal registration only if, having considered the application and the material accompanying it, the authority thinks that the positive therapeutic effects of the product to which the registration relates outweigh the risks of the product to the health of patients or of the public.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a traditional herbal registration.

Failure to place on the market etc

134.—(1) A traditional herbal registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom during the period of three years beginning immediately after the day on which it was granted.

(2) A traditional herbal registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

- (a) in response to an application in writing by the holder of the traditional herbal registration;
- or

- (b) by the licensing authority of its own motion.
- (5) An exemption may only be granted only—
 - (a) in exceptional circumstances; and
 - (b) on public health grounds.
- (6) An exemption—
 - (a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and
 - (b) may be renewed or further renewed.

Revocation, variation and suspension of traditional herbal registration

Revocation, variation and suspension of traditional herbal registration

135.—(1) The licensing authority may revoke, vary or suspend a traditional herbal registration if any of the following conditions are met.

- (2) Condition A is that the licensing authority thinks that—
 - (a) the product to which the registration relates is harmful;
 - (b) the pharmacological effects or efficacy of the product are no longer plausible; or
 - (c) the product’s qualitative or quantitative composition is not as described in the application for the registration or the material accompanying it.
- (3) Condition B is that the licensing authority thinks that the application or the material supplied with it is incorrect.
- (4) Condition C is that the licensing authority thinks that there has been a breach of—
 - (a) a term of the registration; or
 - (b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).
- (5) Condition D is that the licensing authority thinks that the holder of the registration has not complied with regulation 145(1) to (3) (requirement to provide information that may entail amendment of authorisation).
- (6) Condition E is that the holder of the registration has ceased to be established in the United Kingdom.
- (7) Condition F is that—
 - (a) the product to which the registration relates is manufactured in the United Kingdom; and
 - (b) the licensing authority thinks that the holder of the manufacturer’s licence for the product has failed to comply in relation to the product with regulations 37 (manufacturing and assembly), 38 (imports from states other than EEA States), 39 (further requirements for manufacturer’s licence), 40 (obligation to provide information relating to control methods) or 41 (requirements as to qualified persons).
- (8) Condition G is that—
 - (a) the product to which the registration relates is manufactured in an EEA State other than the United Kingdom; and
 - (b) the licensing authority thinks that the holder of the manufacturer’s licence for the product has failed to comply in relation to the product with provision giving effect to Article 41 of the 2001 Directive (requirements relating to manufacturing authorisations) in that member State.

(9) Condition H is that the licensing authority thinks that urgent action to protect public health is necessary, in which case it—

- (a) may suspend the registration; and
- (b) must notify the suspension to the EMA, the European Commission, and all other member States by the end of the next working day following the day on which the suspension comes into force.

(10) Condition I is that—

- (a) the holder applies to vary the registration; and
- (b) the licensing authority thinks that the application should be granted.

(11) This regulation is subject to regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive).

Revocation by licensing authority: further provisions

136.—(1) The licensing authority must revoke a traditional herbal registration if—

- (a) the application for the registration was submitted in accordance with regulation 128(3) on the basis that the herbal medicinal product to which it relates was contained in the list referred to Article 16f(1) of the 2001 Directive; and
- (b) the product ceases to be contained in that list.

(2) Paragraph (1) does not apply if within the period of three months beginning immediately after the day on which product ceases to be contained on the list the holder—

- (a) submits to the licensing authority the material specified in Schedule 12 (including that referred to in paragraphs 16 to 20 of Part 1 of that Schedule) in relation to the product; and
- (b) provides the licensing authority with any material or information that the licensing authority reasonably considers necessary for considering the application and requests the holder to provide.

(3) This regulation is subject to regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive).

Procedures for revocation, variation or suspension

137. Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a traditional herbal registration, other than a proposal to vary a registration on the application of its holder.

Suspension of use etc of traditional herbal medicinal product

138.—(1) The licensing authority may suspend the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a traditional herbal registration relates if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

- (a) the product is harmful;
- (b) the pharmacological effects or efficacy of the product are no longer plausible; or
- (c) the product's qualitative or quantitative composition is not as described in the application for the registration or the material accompanying it.

(3) Condition B is that the licensing authority thinks that the holder has not complied with regulation 145(7) (requirements to provide proof of controls on manufacturing process).

- (4) Condition C is that the licensing authority thinks that there has been a breach of—
- (a) a term of the registration; or
 - (b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).
- (5) Condition D is that the licensing authority thinks that paragraph (4) or (5) of regulation 23 (power to revoke, suspend or vary manufacturers' licences) applies in relation to the manufacturer's licence for the product.
- (6) A suspension under this regulation may relate to batches of the product.
- (7) The licensing authority must give notice in writing of a suspension under this regulation to the holder of the registration.
- (8) The licensing authority must provide in the notice that the suspension—
- (a) is to take effect immediately or from a date specified in the notice; and
 - (b) is to apply for the period specified in the notice.
- (9) Where a medicinal product is the subject of a suspension under this regulation, the licensing authority may—
- (a) in exceptional circumstances; and
 - (b) for such a transitional period as the licensing authority may determine,
- allow the supply of the medicinal product to patients who are already being treated with the medicinal product.
- (10) This regulation is subject to regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive).

Registrations granted under Chapter 4 of Title III of the 2001 Directive

- 139.**—(1) Regulations 135 to 138 do not apply in relation to a traditional herbal registration that—
- (a) was granted in accordance with the provisions of Chapter 4 of Title III of the 2001 Directive (mutual recognition procedure and decentralised procedure); or
 - (b) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the registration.
- (2) A proposal by the licensing authority to vary, suspend or revoke a traditional herbal registration within paragraph (1), or an application by the holder of such a registration to vary or revoke it, is to be determined in accordance with Chapter 4 of Title III of the 2001 Directive.

Withdrawal of traditional herbal medicinal product from the market

- 140.**—(1) This regulation applies if—
- (a) under regulation 135, 136, 139(2) or Article 34(3) of the 2001 Directive the licensing authority revokes or suspends a traditional herbal registration; or
 - (b) under regulation 138 the licensing authority suspends the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a traditional herbal registration relates.
- (2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the registration requiring the holder to comply with both of the following requirements.

(3) Requirement A is to take all reasonably practicable steps to inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of the product to which the registration relates of—

- (a) the revocation or suspension;
- (b) the reasons for the revocation or suspension; and
- (c) any action to be taken to restrict or prevent further use, sale, supply or offer for sale or supply of the product.

(4) Requirement B is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

- (a) the product; or
 - (b) the batches of the product specified in the notice,
- within the time and for the period specified in the notice.

Sale etc of suspended traditional herbal medicinal product

141.—(1) This regulation applies if the use, sale, supply or offer for sale or supply of a traditional herbal medicinal product is suspended in accordance with regulation 138 or 139(2).

(2) A person must not—

- (a) sell, supply or offer to sell or supply the product; or
- (b) procure the sale, supply or offer for sale or supply of the product,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

Obligations of holder of traditional herbal registration

Obligation to notify placing on the market etc

142.—(1) The holder of a traditional herbal registration must notify the licensing authority of the date on which the product to which the registration relates is placed on the market in the United Kingdom taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a traditional herbal registration must notify the licensing authority if the product to which the registration relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

(6) The licensing authority may require the holder of a traditional herbal registration to provide information relating to the volume of sales in the United Kingdom of the product to which the registration relates.

(7) The holder of a traditional herbal registration must provide the licensing authority with information that it requires under paragraph (6)—

- (a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

- (b) otherwise, as soon as is reasonably practicable after receipt of the request.

Obligation to take account of scientific and technical progress

143.—(1) The holder of a traditional herbal registration must keep under review the methods of manufacture and control of the product to which the registration relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the traditional herbal registration to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

Obligation following new herbal monograph

144. Where a new herbal monograph of the kind referred to in Article 16h(3) of the 2001 Directive is established the holder of a traditional herbal registration for a product to which the monograph relates must as soon as is reasonably practicable—

- (a) consider whether to modify the registration dossier; and
- (b) notify any modification to the licensing authority.

Obligation to provide information relating to safety etc

145.—(1) The holder of a traditional herbal registration must provide the licensing authority with any new information that might entail the variation of the registration.

(2) The holder must, in particular, provide the licensing authority with the following information—

- (a) information about any prohibition or restriction imposed in relation to the product to which the registration relates by the competent authority of any country in which the product is on the market;
- (b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the traditional herbal registration;
- (c) data on the use of the product where such use is outside the terms of the traditional herbal registration; and
- (d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

(3) Information within paragraph (1) or (2) must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a traditional herbal registration to provide the authority with information that—

- (a) is specified by the licensing authority; and
- (b) demonstrates that the positive therapeutic effects of the product to which the registration relates outweigh the risks of the product to the health of patients or of the public.

(5) The information that may be required under paragraph (4) includes information arising from use of the product—

- (a) in a country which is not an EEA State; or
- (b) outside the terms of the traditional herbal registration,

including use in clinical trials.

(6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the traditional herbal registration, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.

(7) The licensing authority may require the holder of a traditional herbal registration to provide the authority with proof of the control methods employed by the manufacturer of the product to which the registration relates.

(8) The holder of a traditional herbal registration must provide the licensing authority with information that it requires under paragraph (4) or (7)—

- (a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or
- (b) otherwise, as soon as is reasonably practicable after receipt of the request.

Obligation in relation to product information

146.—(1) The holder of the traditional herbal registration for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

Record-keeping obligations

147. The holder of a traditional herbal registration must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of any product to which the registration relates.

Obligation to ensure appropriate and continued supplies

148. The holder of a traditional herbal registration must take all reasonable steps to ensure appropriate and continued supplies of the product to which the registration relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

Offences relating to traditional herbal registrations

Urgent safety restrictions

149. The holder of a traditional herbal registration is guilty of an offence if the holder—

- (a) fails to inform the licensing authority or the European Commission in accordance with Article 22(1) of Regulation (EC) No. 1234/2008 that the holder has taken urgent safety restrictions on the holder’s own initiative;
- (b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority or the European Commission under Article 22(2) of that Regulation; or
- (c) fails to submit an application for variation of the traditional herbal registration to the licensing authority or the European Commission in accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—
 - (i) the taking under Article 22(1) or, as the case may be,
 - (ii) the imposition under Article 22(2),of that Regulation of an urgent safety restriction.

Offences in connection with applications

150. A person is guilty of an offence if in the course of an application for the grant, renewal or variation of a traditional herbal registration for a traditional herbal medicinal product the person—

- (a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or
- (b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product that is false or misleading in a material particular.

Provision of false or misleading information

151.—(1) The holder of a traditional herbal registration is guilty of an offence if the holder provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a traditional herbal medicinal product but that is false or misleading in a material particular.

- (2) Paragraph (1) is without prejudice to regulation 150.

General offence of breach of provision of this Part

152.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

- (2) A breach of a provision in this Part includes any—
 - (a) failure by the holder of a traditional herbal registration to comply with any requirement or obligation in this Part;
 - (b) contravention by any person of any prohibition in this Part; or
 - (c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Penalties

153. A person guilty of an offence under this Part is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

Persons liable

154. If an offence under regulation 150 (offences in connection with applications) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

155.—(1) Paragraph (2) applies if the holder of a traditional herbal registration is charged with an offence under this Part in respect of anything that—

- (a) has been manufactured or assembled to the holder's order by another person; and
- (b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

- (2) It is a defence for the holder to prove that—
- (a) the holder communicated the terms of the registration to the other person; and
 - (b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.
- (3) It is a defence for a person charged with an offence consisting of a breach of regulation 142(3) or 148 or an offence under regulation 150 or 151 to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.
- (4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 8

Article 126a authorisations

Article 126a authorisations

156.—(1) The licensing authority may grant an Article 126a authorisation for a medicinal product if the following conditions are met.

(2) Condition A is that no United Kingdom marketing authorisation, certificate of registration or traditional herbal registration is in force for the product.

(3) Condition B is that no application is pending in the United Kingdom for a marketing authorisation, certificate of registration or traditional herbal registration for the product.

(4) Condition C is that the licensing authority considers that the placing of the product on the market in the United Kingdom is justified for public health reasons.

(5) Condition D is that the product is imported from another member State that has, in accordance with the 2001 Directive, authorised the placing on the market of the product in that member State.

(6) Condition E is that the person to whom the authorisation is granted is established in the European Union.

(7) Before granting an Article 126a authorisation, the licensing authority must notify the authorisation holder in the member State mentioned in paragraph (5) of the proposal to grant the Article 126a authorisation.

(8) Before granting an Article 126a authorisation, the licensing authority may request the competent authority in the member State mentioned in paragraph (5) to provide in accordance with Article 126a(3)(b) of the 2001 Directive a copy of—

- (a) the assessment report for that product as mentioned in Article 21(4) of the 2001 Directive; and
- (b) the authorisation in force for that product.

(9) An Article 126a authorisation remains in force for the period specified in it unless revoked before the end of that period.

(10) That period may be specified by reference to the occurrence or non-occurrence of a particular event or events.

Requests from other member States

157.—(1) Paragraph (2) applies where the licensing authority is requested by the competent authority of another member State to provide in accordance with Article 126a(3)(b) of the 2001 Directive a copy of—

- (a) the assessment report for a medicinal product as mentioned in regulation 64(5) (duties of licensing authority in connection with determination); and
- (b) the marketing authorisation in force for that product.

(2) The licensing authority must supply those documents to the competent authority before the end of the period of thirty days beginning on the day after the request is received.

Application of these Regulations

158. The following provisions of Part 5 (marketing authorisations) apply to an Article 126a authorisation as they apply to a marketing authorisation—

- (a) regulation 62 (classification of marketing authorisation);
- (b) regulation 63 (frequency of periodic safety update reports);
- (c) regulation 68 (revocation etc of marketing authorisation) and Schedule 11 (advice and representations in connection with revocations etc) so far as relating to that regulation;
- (d) regulation 69 (suspension of use etc of medicinal product);
- (e) regulation 71 (withdrawal of medicinal products from the market);
- (f) regulation 72 (sale etc of suspended medicinal product);
- (g) regulation 80 (urgent safety restrictions); and
- (h) regulations 98 (general offence of breach of provision of this Part), 99 (penalties) and 101(1) and (2) (defences), so far as relating to the regulations mentioned in subparagraphs (a) and (e) to (f).

PART 9

Borderline products

Provisional determination

159.—(1) This regulation applies if the licensing authority thinks that a product without a marketing authorisation, traditional herbal registration, certificate of registration or Article 126a authorisation is a medicinal product.

(2) The licensing authority may give a notice in writing (a “provisional determination notice”) to any person (the “recipient”)—

- (a) who has sold or supplied the product, or has offered to sell or supply it; or
- (b) whom the licensing authority thinks may sell or supply the product.

(3) The provisional determination notice must—

- (a) advise the recipient that the licensing authority has made a provisional determination that the product is a medicinal product;
- (b) give reasons for the provisional determination;
- (c) advise the recipient of the recipient’s rights to challenge the provisional determination in accordance with regulation 160 and

- (d) specify a period of at least six weeks beginning immediately after the date on which the provisional determination notice is given to the recipient (in this Part “the determination date”) within which any written representations in accordance with regulation 160(2)(a) must be made to the licensing authority.

Challenge to provisional determination

160.—(1) A recipient of a provisional determination notice may, within the period of four weeks beginning immediately after the determination date, give notice in writing to the licensing authority requesting the authority to submit the provisional determination to review.

- (2) If the recipient gives such notice the recipient must—
 - (a) within the period specified in the provisional determination notice, make written representations to the licensing authority explaining why the recipient thinks the product is not a medicinal product; or
 - (b) within the period of four weeks beginning immediately after the determination date, inform the licensing authority in writing that the recipient wants to make oral representations explaining why the recipient thinks the product is not a medicinal product.
- (3) If—
 - (a) the recipient has informed the licensing authority that the recipient wants to make written representations in accordance with paragraph (2)(a); and
 - (b) the licensing authority thinks that, because of exceptional circumstances or the nature or complexity of the issues involved, additional time is needed for the preparation of written representations,

the licensing authority may alter the period for making written representations.

- (4) The licensing authority must inform the recipient in writing of an alteration under paragraph (3) and of the reasons for it.

Written representations procedure

161.—(1) If a recipient makes written representations in accordance with regulation 160(2)(a) the licensing authority must appoint a panel of at least two persons (“the reviewers”) to advise on the provisional determination.

- (2) The licensing authority must provide the reviewers with—
 - (a) the recipient’s written representations; and
 - (b) any written representations of the licensing authority.
- (3) The reviewers must advise the licensing authority on the authority’s provisional determination taking account of—
 - (a) the written representations; and
 - (b) any other evidence submitted to them.
- (4) The licensing authority must take into account the reviewers’ advice and make a final determination as to whether the product is a medicinal product.
- (5) The licensing authority must—
 - (a) inform the recipient in writing of its final determination and of the reasons for it; and
 - (b) if the licensing authority disagrees with the reviewers’ advice, inform the recipient in writing of the reasons for that disagreement.

Oral representations procedure

162.—(1) If a recipient informs the licensing authority in accordance with regulation 160(2)(b) that the recipient wants to make oral representations, the licensing authority must—

- (a) appoint a panel of at least two persons (“the reviewers”) to conduct the review; and
- (b) after consultation with the recipient set a date for the hearing.

(2) The licensing authority may alter the date of the hearing at the request of the recipient or of its own motion if it thinks that because of exceptional circumstances or the nature or complexity of the issues involved additional time is needed for preparation for the hearing.

(3) The licensing authority must inform the recipient in writing of any alteration under paragraph (2) and of the reasons for it.

(4) The recipient and the licensing authority may make oral representations at the hearing.

(5) The reviewers must advise the licensing authority on the authority’s provisional determination, taking account of—

- (a) the oral representations made and any other evidence submitted by the recipient at the hearing;
- (b) any oral representations made or other evidence submitted by the licensing authority at the hearing; and
- (c) any other evidence heard by the review panel.

(6) The licensing authority must take into account the reviewers’ advice and make a final determination as to whether the product is a medicinal product.

(7) The licensing authority must—

- (a) inform the recipient in writing of its final determination and of the reasons for it; and
- (b) if the licensing authority disagrees with the reviewers’ advice, inform the recipient in writing of the reasons for that disagreement.

Final determination without representations

163.—(1) This regulation applies if the recipient—

- (a) does not give notification to the licensing authority that the recipient wishes to challenge its provisional determination within the period of four weeks beginning immediately after the determination date;
- (b) gives such notification, but fails to make written representations to the licensing authority within the period for making those representations; or
- (c) gives such notification, but fails to make oral representations at a hearing before the reviewers appointed for the purposes of advising on the provisional determination.

(2) The licensing authority must—

- (a) make a final determination as to whether the product is a medicinal product; and
- (b) inform the recipient in writing of its final determination and of the reasons for it.

Effect of final determination

164.—(1) If the licensing authority makes a final determination that a product is a medicinal product, it may give a notice to any person—

- (a) who has sold or supplied the product, or has offered to sell or supply it; or
- (b) whom the licensing authority thinks may sell or supply the product.

- (2) The notice must require the person—
- (a) to cease to sell, supply or offer to sell or supply the product from the date specified in the notice until a marketing authorisation, traditional herbal registration, certificate of registration or Article 126a authorisation is granted in respect of the product; or
 - (b) not to sell, supply or offer to sell or supply the product unless a marketing authorisation, traditional herbal registration, certificate of registration or Article 126a authorisation is granted in respect of the product.

Determination in other cases

165. Nothing in this Part prevents the licensing authority from determining that a product is a medicinal product without following the procedures in this Part when it thinks it appropriate.

Offences relating to borderline products

- 166.**—(1) A person is guilty of an offence if that person sells or supplies, or offers to sell or supply a product in breach of a notice under regulation 164(1) imposing a requirement under—
- (a) regulation 164(2)(a); or
 - (b) regulation 164(2)(b).
- (2) A person guilty of an offence under this regulation is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

PART 10

Exceptions to requirement for marketing authorisation etc

Exceptions

Supply to fulfil special patient needs

- 167.**—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product (a “special medicinal product”) if—
- (a) the medicinal product is supplied in response to an unsolicited order;
 - (b) the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;
 - (c) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and
 - (d) the following conditions are met.
- (2) Condition A is that the medicinal product is supplied—
- (a) to a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber; or
 - (b) for use under the supervision of a pharmacist in a registered pharmacy, a hospital or a health centre.

(3) Condition B is that no advertisement relating to the medicinal product is published by any person.

(4) Condition C is that—

- (a) the manufacture and assembly of the medicinal product are carried out under such supervision; and
- (b) such precautions are taken,

as are adequate to ensure that the medicinal product meets the specification of the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber who requires it.

(5) Condition D is that written records of the manufacture or assembly of the medicinal product in accordance with condition C are maintained and are available to the licensing authority or to the enforcement authority on request.

(6) Condition E is that if the medicinal product is manufactured or assembled in the United Kingdom or imported into the United Kingdom from a country other than an EEA State—

- (a) it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or
- (b) it is manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorisation granted by the licensing authority for the purposes of regulation 36 of the Clinical Trials Regulations.

(7) Condition F is that if the product is imported from an EEA State—

- (a) it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State; or
- (b) it is manufactured or assembled as an investigational medicinal product in that State by the holder of an authorisation in relation to its manufacture or assembly in accordance with Article 13 of the Clinical Trials Directive as implemented in that State.

(8) Condition G is that if the product is distributed by way of wholesale dealing by a person (“P”), who has not, as the case may be, manufactured, assembled or imported the product in accordance with paragraph (6)(a) or (7)(a), P must be the holder of a wholesale dealer's licence in relation to the product in question.

(9) In this regulation “publish” has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Use of non-prescription medicines in the course of a business

168.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply to anything done in relation to a medicinal product if the following conditions are met.

(2) Condition A is that the medicinal product is not a prescription only medicine.

(3) Condition B is that the medicinal product is sold or supplied to a person who is a health care professional (“P”) exclusively for use by P—

- (a) in the course of a business carried on by P, and
- (b) for the purposes of administering it or causing it to be administered otherwise than by selling it.

(4) Condition C is that the medicinal product is—

- (a) manufactured and assembled in accordance with the specification of P; and

- (b) for use by a patient for whose treatment P is directly responsible in order to fulfil the special needs of that patient
- (5) Condition D is that if sold or supplied through the holder of a wholesale dealer's licence the medicinal product is sold or supplied to such a person and for such use as mentioned in condition B.
- (6) Condition E is that no advertisement relating to the medicinal product is published by any person.
- (7) Condition F is that the sale or supply of the medicinal product is in response to an unsolicited order.
- (8) Condition G is that if the medicinal product is —
 - (a) manufactured or assembled in the United Kingdom or imported into the United Kingdom from a country other than an EEA State, it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or
 - (b) imported from an EEA State, it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State.
- (9) In this regulation “publish” has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Mixing of general sale medicinal products

169.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply to a medicinal product (“the product”) in respect of which the following conditions are met.

(2) Condition A is that the product is manufactured by the mixing of authorised medicinal products with other authorised medicinal products, or with substances that are not medicinal products.

(3) Condition B is that any authorised medicinal product that is so mixed is subject to general sale.

(4) Condition C is that the product is manufactured by a person (“H”) who is the holder of a manufacturer's licence that—

- (a) relates specifically to the manufacture of medicinal products in accordance with this regulation; and
- (b) was granted or renewed not more than five years before the date on which the product is sold or supplied in accordance with paragraphs (5) and (6),

and that the product is manufactured in accordance with the terms of that licence.

(5) Condition D is that the product is sold or supplied by H to a person (“P”) for administration to P or to a member of P's household.

(6) Condition E is that P is present and asks H to use H's judgment as to the treatment required.

(7) Condition F is that no advertisement relating to the product is published by any person.

(8) Condition G is that written records of the manufacture of the product and of the sale or supply of the product are maintained and are made available to the licensing authority or to the enforcement authority on request.

(9) In this regulation, “authorised medicinal product” means a medicinal product that is the subject of—

- (a) a marketing authorisation;
- (b) a certificate of registration; or
- (c) a traditional herbal registration.

Record-keeping requirements

170.—(1) Where the sale or supply of a medicinal product relies on the exemptions under regulations 167, 168 or, subject to paragraph (4), 169, the person who sells or supplies the product must maintain for at least five years a record showing—

- (a) the source from which and the date on which the person obtained the product;
- (b) the person to whom and the date on which the sale or supply was made;
- (c) the quantity of the sale or supply;
- (d) the batch number of the batch of that product from which the sale or supply was made; and
- (e) details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware.

(2) The person must make the records available for inspection by the licensing authority on request.

(3) The person must notify the licensing authority of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

(4) In the case of a medicinal product that is sold or supplied in reliance on the exemption in regulation 169—

- (a) the reference in paragraph (1)(a) to “the product” means all the medicinal products that were mixed in the course of the manufacture of the product; and
- (b) paragraph (1)(d) shall not apply.

Exempt advanced therapy medicinal products

171.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to an advanced therapy medicinal product (an “exempt advanced therapy medicinal product”) if the following conditions are met.

(2) Condition A is that the product is prepared—

- (a) on a non-routine basis;
- (b) in the United Kingdom; and
- (c) according to specific quality standards equivalent to those provided for advanced therapy medicinal products authorised under Regulation (EC) No 726/2004.

(3) Condition B is that the product is used—

- (a) in a hospital in the United Kingdom;
- (b) under the exclusive professional responsibility of a doctor; and
- (c) in order to comply with an individual medical prescription for a product made to order for an individual patient.

(4) Condition C is that no advertisement relating to the medicinal product is published by any person.

(5) Condition D is that the sale or supply of the medicinal product is in response to an unsolicited order.

(6) In this regulation “publish” has the meaning given in regulation 277(1) (interpretation Part 14 advertising).

Parallel import licences

172.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not prevent—

- (a) the holder of a parallel import licence from placing the medicinal product to which the licence relates on the market; or
 - (b) the sale or supply, or offer for sale or supply, of a medicinal product to which a parallel import licence relates, in accordance with the terms of that licence.
- (2) In this regulation “parallel import licence” means a licence that—
- (a) is granted by the licensing authority in compliance with the rules of European Union law relating to parallel imports; and
 - (b) authorises the holder to place on the market a medicinal product imported into the United Kingdom from another EEA State.

Exemption for certain radiopharmaceuticals

173. Regulation 46 (requirement for authorisation) does not apply where a radiopharmaceutical is prepared—

- (a) at the time when it is intended to be administered;
- (b) in accordance with the manufacturer’s instructions and by the person by whom it is to be administered;
- (c) from radionuclide generators, radionuclide kits and radionuclide precursors in respect of which a marketing authorisation is in force; and
- (d) for administration in accordance with regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978(42).

Supply in response to spread of pathogenic agents etc

174. The prohibitions in regulation 46 (requirement for authorisation) do not apply where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis in response to the suspected or confirmed spread of—

- (a) pathogenic agents;
- (b) toxins;
- (c) chemical agents; or
- (d) nuclear radiation,

which may cause harm to human beings.

Offences

Offences relating to exceptions

175.—(1) A person to whom this paragraph applies is guilty of an offence if the person provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product that is false or misleading in a material particular.

(2) Paragraph (1) applies to any person who for the purposes of regulation 167 (special patient needs)—

- (a) sells or supplies the product; or
- (b) provides a specification for the product.

(42) *S.I. 1978/1006*, as amended by *S.I. 1995/2147* and *S.I. 2006/2806*; there are other amendments not relevant to these Regulations.

- (3) A person is guilty of an offence if the person fails to—
- (a) maintain any record required by regulation 170(1) (records in connection with special medicinal products etc);
 - (b) make any record available as required by regulation 170(2); or
 - (c) notify the licensing authority of any suspected serious adverse reaction as required by regulation 170(3).

Penalties and supplementary provision about offences

- 176.**—(1) A person guilty of an offence under regulation 175 is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.
- (2) It is a defence for a person charged with an offence under regulation 175(1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.
- (3) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (2), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 11

Pharmacovigilance

Application of this Part and interpretation

- 177.**—(1) This Part and Schedule 33 apply, except to the extent set out in paragraph (4)(b), in relation to medicinal products that are the subject of—
- (a) a UK marketing authorisation;
 - (b) a traditional herbal registration; or
 - (c) an Article 126a authorisation.
- (2) References in this Part to a “holder” are to the holder of—
- (a) a UK marketing authorisation;
 - (b) a traditional herbal registration; or
 - (c) an Article 126a authorisation,
- and, in relation to such references, “product” means the product to which the authorisation or registration relates.
- (3) References to an “authorisation or registration” in this Part and in Schedule 33 are references to—
- (a) a UK marketing authorisation;
 - (b) a traditional herbal registration; or
 - (c) an Article 126a authorisation

and “authorised or registered” is to be read accordingly.

- (4) The following provisions of this Part and Schedule 33 apply in relation to medicinal products that are the subject of an EU marketing authorisation—

- (a) regulation 206 (infringement notices); and
 - (b) regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004), and paragraphs 2 and 4 of Schedule 33 (transitional arrangements: pharmacovigilance), but that regulation and those paragraphs do not apply in relation to the medicinal products specified in paragraph (1).
- (5) In this Part and in Schedule 33—
- “co-ordination group” means the group of that name established under Article 27 of the 2001 Directive;
- “Eudravigilance database” means the database and data-processing network set up and maintained by the EMA under Article 24 of Regulation (EC) No 726/2004;
- “infringement notice” has the meaning given to it in regulation 206 (infringement notices);
- “relevant competent authorities” means the competent authority of each EEA state other than the United Kingdom which has granted in relation to a medicinal product—
- (a) an authorisation in accordance with Chapter 1 of Title III to the 2001 Directive (marketing authorization);
 - (b) an authorisation in accordance with Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure);
 - (c) a registration in accordance with Chapter 2a of Title III to the 2001 Directive (traditional use registration for herbal medicinal products); or
 - (d) an authorisation in accordance with Article 126a of the 2001 Directive;
- “relevant post-authorisation safety study” means a post-authorisation safety study which—
- (a) is non-interventional;
 - (b) is initiated, managed or financed by the holder voluntarily or pursuant to conditions imposed under regulation 59 (conditions of a UK marketing authorisation: general) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation); and
 - (c) involves the collection of safety data from patients or health care professionals; and
- “UK web-portal” has the meaning given in regulation 203 (obligations on licensing authority in relation to national medicines web-portal).

Obligations on licensing authority in relation to pharmacovigilance

General obligations of the licensing authority

- 178.** The licensing authority must—
- (a) take all appropriate measures to encourage the reporting to it of suspected adverse reactions;
 - (b) facilitate reporting through the provision of alternative reporting formats in addition to web-based formats;
 - (c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;
 - (d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner, through publication on the UK web-portal, and through other means of publicly available information as necessary; and

- (e) ensure that all appropriate measures are taken to identify any biological medicinal product (including name and batch number) prescribed, dispensed or sold in the United Kingdom which is the subject of a suspected adverse reaction report through—
 - (i) the methods for collecting data, and
 - (ii) where necessary, the follow up of suspected adverse reaction reports.

Obligation on licensing authority to operate pharmacovigilance system

179.—(1) The licensing authority must operate a pharmacovigilance system.

(2) The pharmacovigilance system must in particular enable the collection of information on the risks that medicinal products present to patients' health or public health, including information on—

- (a) adverse reactions in humans arising from use of a medicinal product (irrespective of whether the use was within the terms of an authorisation or registration); and
 - (b) adverse reactions associated with occupational exposure.
- (3) The licensing authority must on an ongoing basis—
- (a) evaluate scientifically the information collected under the pharmacovigilance system;
 - (b) consider options for minimising and preventing risks presented by medicinal products; and
 - (c) take appropriate regulatory action, if any.

Obligation on licensing authority to audit pharmacovigilance system

180.—(1) The licensing authority must perform a regular audit of its pharmacovigilance system and report the results of that audit to the European Commission.

(2) The results of the audit referred to in paragraph (1) must be reported to the European Commission—

- (a) on the first occasion no later than 21st September 2013; and
- (b) every two years after the first occasion.

Delegation of obligations under this Part

181.—(1) The licensing authority may delegate any of its obligations under this Part to another EEA State where the conditions in paragraph (2) are met.

(2) The conditions in this paragraph are that the EEA State to whom the obligations are to be delegated—

- (a) has given its written agreement to the delegation; and
- (b) is not performing delegated obligations under this Part on behalf of another EEA State.

(3) Where the licensing authority has delegated any of its obligations under paragraph (1), it must—

- (a) inform the European Commission, the EMA and all other EEA States in writing of the delegation as soon as is reasonably practicable; and
- (b) make the delegation public as soon as is reasonably practicable.

(4) The licensing authority may agree to carry out any of the obligations of another EEA State under Title IX of the 2001 Directive on a delegated basis, but may carry out obligations under that Title only for one EEA State at any time.

Obligations on holders in relation to pharmacovigilance system

Obligation on holder to operate pharmacovigilance system

- 182.**—(1) The holder must operate a pharmacovigilance system.
- (2) The holder must (as part of its pharmacovigilance system)—
- (a) have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance who resides and operates in the EU and is responsible for the establishment and maintenance of the pharmacovigilance system;
 - (b) maintain and make available on the request of the licensing authority a pharmacovigilance system master file;
 - (c) operate a risk management system for the product in accordance with the risk management plan (if any) for the product (subject to regulation 183);
 - (d) monitor the outcome of the risk minimisation measures which are contained in the risk management plan (if any) for the product or which are laid down as conditions of the authorisation of the product under regulations 59 to 61 (conditions of UK marketing authorisation); and
 - (e) update the risk management system for the product and monitor pharmacovigilance data to determine whether in relation to the product—
 - (i) there are new risks,
 - (ii) risks have changed, or
 - (iii) there are changes to the risk-benefit balance.
- (3) The holder must keep the licensing authority and the EMA informed of the name and contact details of the appropriately qualified person mentioned in paragraph (2)(a) at all times.
- (4) The holder must use its pharmacovigilance system to—
- (a) evaluate scientifically all information relevant to the product;
 - (b) consider options for minimising and preventing the risk presented by the use of the product; and
 - (c) take appropriate measures as soon as is reasonably practicable to—
 - (i) investigate the potential risks of the product,
 - (ii) communicate the risks, and
 - (iii) implement actions for minimising and preventing the risks, including updating the risk management system for the product.
- (5) Where the licensing authority requests that the pharmacovigilance system master file is made available under paragraph (2)(b), the holder must submit a copy of the pharmacovigilance system master file to the licensing authority before the end of the period of 7 days beginning on the day after the day when the request was made.
- (6) This regulation is subject to regulation 212 (transitional arrangements).

Exception to obligation to operate risk management system

- 183.**—(1) The holder is not required to operate a risk management system under regulation 182(2)(c) in relation to a medicinal product which has an authorisation or registration that was granted before 21st July 2012.

(2) The licensing authority may impose an obligation on the holder to operate a risk management system in relation to a medicinal product referred to in paragraph (1) if there are concerns about new or changed risks affecting the risk-benefit balance of that product.

(3) Paragraphs (4) to (6) apply where the licensing authority imposes an obligation to operate a risk management system on the holder under paragraph (2).

(4) The licensing authority must without delay notify the holder in writing of—

- (a) the imposition of the obligation;
- (b) the justification for the obligation;
- (c) the timeframe for submission of the detailed description of the risk management system required under paragraph (8)(a); and
- (d) the opportunity to present written observations in accordance with paragraph (5).

(5) Where the holder so requests before the end of the period of thirty days beginning on the day after the receipt by the holder of the notice referred to in paragraph (4), the licensing authority must provide the holder with an opportunity to present written observations in response to the imposition of the obligation within such a time limit as the licensing authority may specify.

(6) Where a holder presents written observations under paragraph (5), the licensing authority must withdraw or confirm the imposition of the obligation under paragraph (2), having regard to the written observations, as soon as is reasonably practicable.

(7) Paragraphs (8) and (9) apply where the licensing authority—

- (a) imposes an obligation under paragraph (2) and the holder does not present written obligations under paragraph (5); or
- (b) confirms the imposition of the obligation under paragraph (2) pursuant to paragraph (6).

(8) The holder must—

- (a) submit to the licensing authority in writing a detailed description of the risk management system which it intends to introduce for the product in accordance with the timeframe set out in the notification under paragraph (4); and
- (b) comply with the obligation to operate a risk management system.

(9) Where the imposition relates to a product with a UK marketing authorisation, the licensing authority must vary the authorisation to include the measures to be taken as part of the risk management system as conditions of the authorisation as if they were conditions imposed under regulation 59 (conditions of UK marketing authorisations: general).

Obligation on holder to audit pharmacovigilance system

184.—(1) The holder must—

- (a) perform a regular audit of its pharmacovigilance system;
- (b) place a note concerning the main findings of each audit on the pharmacovigilance system master file on completion of each audit; and
- (c) ensure that an appropriate corrective action plan is prepared and implemented as soon as is reasonably practicable after completion of each audit.

(2) The holder may remove the note placed on the pharmacovigilance system master file under paragraph (1)(b) when all the measures in the corrective action plan under paragraph (1)(c) have been fully implemented.

*Recording, reporting and assessment of pharmacovigilance data***Recording obligations on the licensing authority**

185. The licensing authority must record all suspected adverse reactions to medicinal products that—

- (a) occur in the United Kingdom; and
- (b) are reported to it by a patient or a patient's carer, a health care professional, a coroner or a procurator fiscal.

Reporting obligations on the licensing authority

186.—(1) The licensing authority must—

- (a) when it receives a suspected adverse reaction report from a person mentioned in regulation 185(b), follow up the report with that person as appropriate;
- (b) ensure that reports of suspected adverse reactions in the United Kingdom may be submitted to it, whether by the UK web-portal or by other means;
- (c) collaborate with the EMA and the holders of authorisations or registrations in the detection of duplicates of suspected adverse reaction reports;
- (d) submit reports of serious suspected adverse reactions that it has recorded under regulation 185 electronically to the Eudravigilance database before the end of the period of 15 days beginning on the day following the day on which the report was received; and
- (e) submit reports of non-serious suspected adverse reactions it has recorded under regulation 185 electronically to the Eudravigilance database before the end of the period of 90 days beginning on the day following the day on which the report was received.

(2) Paragraph (3) applies where the licensing authority has received a report of a suspected adverse reaction arising from an error associated with the use of a medicinal product.

(3) The licensing authority must (in addition to meeting the requirements in paragraph (1) in respect of the report) ensure that the report is made available to any statutory body with functions in relation to patient safety within the United Kingdom.

(4) This regulation is subject to regulation 212 (transitional arrangements).

Recording obligations on holders

187.—(1) Subject to paragraph (2), the holder must record all suspected adverse reactions to the product occurring in the EEA or in third countries which are brought to its attention irrespective of whether the reaction—

- (a) is reported spontaneously by patients or health care professionals; or
- (b) occurred in the context of a post-authorisation study.

(2) Paragraph (1) does not apply where the suspected adverse reaction occurred in the context of a clinical trial within the meaning of the Clinical Trials Regulations.

(3) The holder must not refuse to consider reports of suspected adverse reactions to the product received electronically or by any other appropriate means from patients or from health care professionals.

(4) The holder must ensure that reports recorded under paragraph (1) are accessible (electronically or physically) at a single point within the EEA.

Reporting obligations on holders

- 188.**—(1) Subject to paragraph (2), the holder must in relation to the product—
- (a) submit electronically to the Eudravigilance database a report on all serious suspected adverse reactions that occur in the EEA and third countries before the end of the period of 15 days beginning on the day following the day on which the holder gained knowledge of the reaction;
 - (b) submit electronically to the Eudravigilance database a report on all non-serious suspected adverse reactions that occur in the EEA before the end of the period of 90 days beginning on the day following the day on which the holder gained knowledge of the reaction;
 - (c) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;
 - (d) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the Eudravigilance database by way of an update to the original report within the specified time period; and
 - (e) collaborate with the EMA and the competent authorities of the EEA States in the detection of duplicates of suspected adverse reaction reports.
- (2) The holder is not required to submit a report of a suspected adverse reaction to the product under paragraph (1)(a) or (b), or to provide follow-up information under paragraph (1)(d), where—
- (a) the suspected adverse reaction relates to a medicinal product which contains a monitored active substance; and
 - (b) the suspected adverse reaction is recorded in a monitored publication.
- (3) Paragraph (4) applies to medicinal products containing a monitored active substance.
- (4) The holder must—
- (a) monitor medical literature other than the monitored publications for reports of suspected adverse reactions to the product; and
 - (b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1).
- (5) In this regulation—
- “monitored active substance” means an active substance on the list of active substances being monitored by the EMA published under Article 27 of Regulation (EC) No 726/2004;
- “monitored publication” means a publication on the list of publications being monitored by the EMA published under Article 27 of Regulation (EC) No 726/2004; and
- “the specified time period” means—
- (a) in the case of serious adverse reactions, the period of 15 days beginning on the day following the day on which the follow up information became known to the holder; and
 - (b) in the case of non-serious adverse reactions, the period of 90 days beginning on the day following the day on which the follow up information became known to the holder.
- (6) This regulation is subject to regulation 212 (transitional arrangements).

Signal detection

Signal detection: licensing authority obligations

- 189.**—(1) The licensing authority must in relation to each medicinal product—

- (a) monitor the data in the Eudravigilance database to determine whether there are any relevant changes;
 - (b) assess updates to the risk management system for the product;
 - (c) monitor the outcome of risk minimisation measures contained in the risk management plan (if any); and
 - (d) monitor the outcome of conditions imposed under regulations 59 to 61 (conditions of UK marketing authorisations) (if any).
- (2) The licensing authority must collaborate with the EMA in carrying out its functions under paragraph (1).
- (3) The licensing authority must inform the bodies specified in paragraph (4) without delay if it detects any relevant changes in relation to a medicinal product.
- (4) The bodies specified in this paragraph are—
- (a) the EMA; and
 - (b) the relevant competent authorities.
- (5) In this regulation “relevant changes” in relation to a medicinal product means—
- (a) new risks;
 - (b) risks that have changed; or
 - (c) changes to the risk-benefit balance.

Signal detection: holder obligation

- 190.**—(1) The holder must inform the EMA and the licensing authority without delay if it detects any relevant changes in relation to the product.
- (2) In this regulation, “relevant changes” has the meaning given in regulation 189(5).

Periodic Safety Update Reports

Obligation on holder to submit periodic safety update reports: general requirements

- 191.**—(1) The holder must submit reports known as periodic safety update reports (“PSURs”) in relation to the product to the EMA in accordance with this regulation, or in a case where paragraph (2) applies, in accordance with regulation 192.
- (2) This paragraph applies to—
- (a) a marketing authorisation granted pursuant to regulations 51 (applications for UK marketing authorisations relating to generic medicinal products) or 54 (application relating to products in well-established medicinal use); or
 - (b) a traditional herbal registration.
- (3) In the following paragraphs of this regulation—
- “authorisation” means a UK marketing authorisation or an Article 126a authorisation;
- “the holder” means the holder of a UK marketing authorisation or an Article 126a authorisation; and
- “product” means a product to which a UK marketing authorisation or Article 126a authorisation relates.
- (4) Each PSUR must contain—

- (a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the authorisation for the product;
 - (b) a scientific evaluation of the risk-benefit balance of the product; and
 - (c) all data relating to the volume of sales of the product and any data the holder has relating to the volume of prescriptions, including an estimate of the population exposed to the product.
- (5) For the purposes of paragraph (4)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation for the product.
- (6) Each PSUR must be submitted electronically.
- (7) PSURs must be submitted to the EMA with the frequency and on the dates as set out in paragraphs (8) to (10).
- (8) In the case of an authorisation granted on or after 21st July 2012, the holder must submit PSURs with the frequency as specified in the authorisation for the product, with the dates of submission being calculated from the date of authorisation.
- (9) In the case of an authorisation granted before 21st July 2012 which specifies the frequency and dates of submission of PSURs, the holder must submit PSURs with the frequency and on the dates as specified in the authorisation for the product.
- (10) In the case of an authorisation granted before 21st July 2012 which does not specify the frequency and dates of submission of PSURs, the holder must submit a PSUR—
- (a) immediately upon the request of the licensing authority;
 - (b) where the product has not yet been placed on the market within the EEA, at least every six months following authorisation until the placing on the market within the EEA; and
 - (c) where the product has been placed on the market within the EEA—
 - (i) at least every six months during the first two years following the initial placing on the market,
 - (ii) once a year for the following two years, and
 - (iii) every three years after that.
- (11) This regulation is subject to regulation [212](#) (transitional arrangements).

Obligation on holder to submit periodic safety update reports: derogation from general requirements

- 192.**—(1) This regulation applies in relation to medicinal products granted—
- (a) a marketing authorisation pursuant to regulations [51](#) (applications for UK marketing authorisations relating to generic medicinal products) or [54](#) (application relating to products in well-established medicinal use); or
 - (b) a traditional herbal registration.
- (2) In the following paragraphs of this regulation—
- “authorisation or registration” means a marketing authorisation to which paragraph (1)(a) applies or a traditional herbal registration;
- “the holder” means the holder of a marketing authorisation to which paragraph (1)(a) applies or of a traditional herbal registration; and
- “product” means a product to which a marketing authorisation referred to in paragraph (1)(a) or a traditional herbal registration relates.

- (3) The holder must submit PSURs in relation to the product to the EMA in accordance with paragraph (5)—
- (a) where requested to do so by the licensing authority in accordance with paragraph (4); or
 - (b) in the case of a product to which paragraph (1)(a) applies, where it is a condition to which the marketing authorisation for the product is subject by virtue of regulations 59 (conditions of UK marketing authorisation: general) or 60 (conditions of UK marketing authorisation: exceptional circumstances) to do so.
- (4) The licensing authority may request the holder to submit PSURs where—
- (a) it has concerns relating to the product’s pharmacovigilance data; or
 - (b) it considers there is a lack of PSUR data relating to an active substance of the product after the authorisation or registration is granted.
- (5) The submission of PSURs under paragraph (3) must be in accordance with—
- (a) where the PSUR is submitted pursuant to a request under paragraph (3)(a), the terms of the request; and
 - (b) where the PSUR is submitted pursuant to a condition under paragraph (3)(b), the terms of the condition.
- (6) Each PSUR must contain—
- (a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the authorisation or registration for the product;
 - (b) a scientific evaluation of the risk-benefit balance of the product; and
 - (c) all data relating to the volume of sales of the product and any data the holder has relating to the volume of prescriptions, including an estimate of the population exposed to the product.
- (7) For the purposes of paragraph (6)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation or registration for the product.
- (8) Each PSUR must be submitted electronically.
- (9) Where the licensing authority requests submission of PSURs under paragraph (3)(a), it must communicate a PSUR assessment report to the EMA as soon as is reasonably practicable after each report is received.
- (10) In this regulation “PSUR assessment report” means a report which evaluates the information provided in a PSUR.
- (11) This regulation is subject to regulation 212 (transitional arrangements).

Harmonisation of PSUR frequency or date of submission

- 193.**—(1) Where products that are subject to different authorisations or registrations contain the same active substance or the same combination of active substances, the frequency and dates of submission may be amended and harmonised in accordance with—
- (a) Article 107c(4) of the 2001 Directive; or
 - (b) paragraphs (2) to (4).
- (2) The holder may, where one or more of the grounds in paragraph (3) is met, submit a request in relation to the product to the EMA—
- (a) to determine an EU reference date; or
 - (b) to change the frequency of submission of the PSUR.

- (3) The grounds in this paragraph are—
 - (a) reasons relating to public health;
 - (b) in order to avoid duplication of the assessment; or
 - (c) in order to achieve international harmonisation.

(4) The second paragraph of Article 107c(6) of the 2001 Directive has effect in relation to the submission and determination of a request under paragraph (2).

(5) Where the frequency or dates of submission of a PSUR are changed in accordance with Article 107c(4) or Article 107c(6) of the 2001 Directive, the holder must apply to vary the product's authorisation or registration to reflect the new frequency or date of submission before the end of the period of six months beginning on the day after the change is made public by the EMA.

- (6) In this regulation, “EU reference date” in relation to a product means—
 - (a) the date of the first marketing authorisation in the EEA of a medicinal product containing the same active substance or the same combination of active substances as that product; or
 - (b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations in the EEA for a medicinal product containing the same active substance or the same combination of active substances as that product.

Responding to a single assessment of PSUR under Article 107e of the 2001 Directive

194.—(1) This regulation applies where PSURs relating to a medicinal product have been assessed under the EU single assessment procedure.

- (2) The licensing authority must implement—
 - (a) the necessary measures that are consequent upon any agreement reached under Article 107g(2) of the 2001 Directive as part of the EU single assessment process, in accordance with the implementation timetable determined in the agreement; or
 - (b) any decision adopted under Article 107g(4)(a) of the 2001 Directive before the end of the period of 30 days beginning on the day after the day on which the licensing authority received notification of the decision.
- (3) Paragraph (4) applies where—
 - (a) an agreement reached under Article 107g(2) of the 2001 Directive requires a variation to be made to an authorisation or registration; and
 - (b) the terms of the agreement are known to the holder of that authorisation or registration.

(4) A holder of an authorisation or registration referred to in paragraph (3)(a) must submit to the licensing authority in accordance with the implementation timetable determined in the agreement an appropriate application for a variation, including—

- (a) an updated summary of the product characteristics; and
- (b) an updated package leaflet.

(5) In this regulation, “EU single assessment procedure” means the single assessment procedure laid down in Article 107e of the 2001 Directive, which covers—

- (a) medicinal products that are authorised in more than one member State; and
- (b) medicinal products that contain the same active substance or the same combination of active substances and for which a harmonised EU reference date and frequency of submission of PSURs have been established under Article 107c of the 2001 Directive.

Obligation on licensing authority to assess PSURs where EU single assessment procedure does not apply

195.—(1) This regulation applies where PSURs relating to a medicinal product have not been assessed under the EU single assessment procedure because—

- (a) the medicinal product to which the PSUR relates has not been authorised to be placed on the market in accordance with the 2001 Directive in an EEA State other than the United Kingdom; and
- (b) a harmonised EU reference date and frequency of submission of PSURs have not been established for that product under Article 107c of the 2001 Directive.

(2) The licensing authority must assess the PSURs to determine whether there are any relevant changes.

(3) Where the licensing authority has assessed a PSUR under paragraph (2) it must—

- (a) consider whether any action concerning the authorisation or registration of the product to which the PSUR relates is necessary; and
- (b) vary, suspend, or revoke the authorisation or registration as appropriate.

(4) In this regulation—

“EU reference date” has the meaning given in regulation 193(6);

“EU single assessment procedure” has the meaning given in regulation 194(5); and

“relevant changes” in relation to a medicinal product means—

- (a) new risks,
- (b) risks that have changed, or
- (c) changes to the risk-benefit balance.

Urgent action

Urgent action

196.—(1) This regulation applies where the licensing authority forms the view that as a result of the evaluation of data resulting from pharmacovigilance activities urgent action is necessary in connection with—

- (a) suspending or revoking an authorisation or registration of a medicinal product or class of medicinal products;
- (b) prohibiting the supply of a medicinal product or class of medicinal products;
- (c) refusing the renewal of an authorisation or registration of a medicinal product;
- (d) receiving information from the holder that, on the basis of safety concerns, the holder has interrupted the sale or supply, or offer for sale or supply, of the product or that the holder has taken action to have the product’s authorisation or registration cancelled or that the holder intends to do so; or
- (e) considering whether the terms of the authorisation or registration of a medicinal product or class of medicinal products should be varied to include a new contra-indication, an alteration of a recommended dose or a restriction to the therapeutic indications.

(2) The licensing authority must provide information about the urgent action it considers necessary by the end of the day following the day on which the view under paragraph (1) was formed to—

- (a) the competent authorities of the EEA States other than the United Kingdom;

- (b) the EMA; and
 - (c) the European Commission.
- (3) When informing the EMA under paragraph (2), the licensing authority must make available to the EMA in relation to the medicinal product or class of medicinal products—
- (a) all relevant scientific information at its disposal; and
 - (b) any assessment it has carried out.
- (4) Where the EU urgent action procedure does not apply in relation to the medicinal product or class of medicinal products referred to in paragraph (1), the licensing authority—
- (a) must inform the holder that it has taken action under paragraph (2); and
 - (b) may take such steps as it sees fit to address the safety concerns.
- (5) Where the EU urgent action procedure does apply in relation to the medicinal product or class of medicinal products referred to in paragraph (1), the licensing authority may where the conditions in paragraph (6) are met—
- (a) suspend the authorisation or registration of the medicinal product or the authorisations and registrations for the class of medicinal products referred to in paragraph (1) (as the case may be); or
 - (b) prohibit its or their use within the United Kingdom.
- (6) The conditions in this paragraph are that—
- (a) urgent action is necessary to protect public health; and
 - (b) an agreement under Article 107k of the 2001 Directive in respect of the medicinal product or class of medicinal products has not been reached.
- (7) Where the licensing authority takes action under paragraph (5), it must by the end of the next working day after the day on which the action is taken inform of the reasons for the action the following—
- (a) the European Commission;
 - (b) the EMA; and
 - (c) the competent authority of each EEA State other than the United Kingdom.
- (8) In this regulation “the EU urgent action procedure” means the procedure under Articles 107j and 107k of the 2001 Directive.

EU urgent action procedure

- 197.**—(1) Where the EU urgent action procedure is initiated in relation to a medicinal product or class of medicinal products, the licensing authority—
- (a) may publicly announce the initiation of the EU urgent action procedure on the UK web-portal; and
 - (b) must implement the measures set out in any agreement reached under Article 107k of the 2001 Directive in relation to the medicinal product or class of medicinal products in accordance with the implementation timetable determined in the agreement.
- (2) Paragraph (3) applies where an agreement under Article 107k of the 2001 Directive in relation to a medicinal product or class of medicinal products requires a variation to be made to one or more authorisation or registration.
- (3) Each holder of an authorisation or registration covered by the agreement referred to in paragraph (2) must submit to the licensing authority in accordance with the terms of the agreement (including its implementation timetable) an application for a variation in respect of the authorisation or registration including—

- (a) an updated summary of the product characteristics; and
 - (b) an updated package leaflet.
- (4) In this regulation, “EU urgent action procedure” has the same meaning as it is given in regulation 196(8).

Post-authorisation safety studies

Post-authorisation safety studies: general provisions

198.—(1) A relevant post-authorisation safety study—

- (a) may not be conducted where the act of conducting the study promotes the use of a medicinal product; and
- (b) may not provide for payments to health care professionals for participating in the study except in compensation for time and expenses incurred.

(2) The licensing authority may require the holder for the product which is the subject of a relevant post-authorisation safety study to submit the protocol and progress reports for the study to the competent authorities of the EEA States in which the study is conducted.

(3) The holder for the product which is the subject of a relevant post-authorisation safety study must—

- (a) comply with a requirement imposed by the licensing authority under paragraph (2) (if any);
- (b) while the study is being conducted—
 - (i) monitor the data generated, and
 - (ii) consider its implications for the risk-benefit balance of the product which is the subject of the study;
- (c) communicate to the relevant competent authorities any new information that arises at any point during the study which might influence the evaluation of the risk-benefit balance for that product as soon as is reasonably practicable after it becomes known to the holder; and
- (d) send the final report on the study to the competent authorities of the EEA States in which the study was conducted before the end of the period of 12 months beginning on the day after the day on which data collection for the study ended.

(4) This regulation is subject to regulation 212 (transitional arrangements).

Submission of draft study protocols for required studies

199.—(1) This regulation applies to a relevant post-authorisation safety study that is to be conducted pursuant to a condition of a UK marketing authorisation imposed under regulation 59 (conditions of a UK marketing authorisation: general) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation).

(2) The holder for the product which is the intended subject of the study must submit a draft protocol for the study to the body specified in paragraph (3) before the study is commenced.

(3) The body specified in this paragraph is—

- (a) where the study is to be conducted in the United Kingdom only, the licensing authority; or
- (b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (5) applies where a draft protocol is submitted to the licensing authority under paragraphs (2) and (3)(a).

(5) Where this paragraph applies, the licensing authority, before the end of the period of 60 days beginning on the day after the day on which the draft protocol is submitted, must issue—

- (a) a letter endorsing the draft protocol;
- (b) a letter objecting to the draft protocol on the grounds that—
 - (i) it considers that the conduct of the study promotes the use of a medicinal product, or
 - (ii) it considers that the design of the study does not fulfil the study objectives; or
- (c) a letter notifying the holder for the product which is the intended subject of the study that the study is a clinical trial within the meaning of the Clinical Trials Regulations.

(6) A study may not commence unless a letter endorsing the draft protocol has been issued by—

- (a) the licensing authority under paragraph (5)(a); or
- (b) the Pharmacovigilance Risk Assessment Committee under Article 107n(2) of the 2001 Directive.

(7) Paragraph (8) applies where a letter endorsing the draft protocol has been issued by the Pharmacovigilance Risk Assessment Committee under Article 107n(2) of the 2001 Directive.

(8) Where this paragraph applies, the holder for the product which is the intended subject of the study must forward the protocol to the competent authorities of the EEA States in which the study is to be conducted before commencing the study.

(9) In this regulation, “a letter” includes email correspondence.

(10) This regulation is subject to regulation 212 (transitional arrangements).

Amendment to study protocols for required studies

200.—(1) This regulation applies where a study to which regulation 199 applies has been commenced.

(2) The holder for the product which is the subject of the study must submit any substantial amendments to the study protocol to the body specified in paragraph (3) before their implementation.

(3) The body specified in this paragraph is—

- (a) where the study is being conducted in the United Kingdom only, the licensing authority; or
- (b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (5) applies where a proposed amendment to a study protocol is submitted to the licensing authority under paragraphs (2) and (3)(a).

(5) Where this paragraph applies, the licensing authority must as soon as is reasonably practicable—

- (a) assess the amendment; and
- (b) inform the holder of its endorsement of, or objection to, the proposed amendment.

(6) Paragraph (7) applies where the proposed amendment to a study protocol is submitted to the Pharmacovigilance Risk Assessment Committee under paragraphs (2) and (3)(b).

(7) Where this paragraph applies, the holder who submitted the amendment must inform the competent authorities of the EEA States in which the study is being conducted of any amendment to the study protocol approved by the Pharmacovigilance Risk Assessment Committee as soon as is reasonably practicable.

(8) This regulation is subject to regulation 212 (transitional arrangements).

Submission and evaluation of final study reports for required studies

201.—(1) This regulation applies where a study to which regulation 199 applies has been completed.

(2) Subject to paragraph (4), the holder for the product which is the subject of the study must submit electronically, before the end of the period of 12 months beginning on the day after the day on which data collection for the study ended, to the body specified in paragraph (3)—

- (a) a final study report; and
- (b) an abstract of the study results.

(3) The body specified in this paragraph is—

- (a) where the study was conducted in the United Kingdom only, the licensing authority; or
- (b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (2) does not apply where a written waiver has been granted by the licensing authority for reports falling under paragraph (3)(a), or by the Pharmacovigilance Risk Assessment Committee for reports falling under paragraph (3)(b).

(5) The holder must without delay—

- (a) evaluate whether the results of a final study report submitted under paragraph (2) have an impact on the authorisation or registration of the medicinal product to which the report relates; and
- (b) if necessary, submit an application to vary the authorisation or registration for the product.

(6) This regulation is subject to regulation 212 (transitional arrangements).

Follow-up of final study reports

202.—(1) This regulation applies where—

- (a) the Pharmacovigilance Risk Assessment Committee has made recommendations concerning an authorisation or registration or a class of authorisations or registrations based on a final study report under Article 107q(1) of the 2001 Directive; and
- (b) an agreement on the action to be taken in respect of the authorisation or registration or the class of authorisations or registrations has been reached by the co-ordination group under the procedure laid out in Article 107q(2) of the 2001 Directive (“the agreement”).

(2) The licensing authority must implement the measures set out in the agreement in accordance with the implementation timetable determined in the agreement.

(3) Paragraph (4) applies where—

- (a) the agreement requires a variation to be made to one or more authorisation or registration; and
- (b) the terms of the agreement are known to the holder or holders for the product or products which is, or which are, the subject of the agreement.

(4) Where this paragraph applies, each holder must submit to the licensing authority in accordance with the terms of the agreement (including its implementation timetable) an application for a variation including—

- (a) an updated summary of the product characteristics; and
- (b) an updated package leaflet.

(5) This regulation is subject to regulation 212 (transitional arrangements).

Transparency and communications

Obligations on licensing authority in relation to national medicines web-portal

203.—(1) The licensing authority must set up and maintain a national medicines web-portal (“the UK web-portal”) linked to the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004 (“the EU web-portal”).

(2) The licensing authority must make available publicly by means of the UK web-portal the following (at a minimum)—

- (a) the assessment reports prepared or revised by the licensing authority under regulation 64(5) and (6) (duties of licensing authority in connection with determination), each with a summary;
- (b) the summary of the product characteristics for the medicinal products concerned;
- (c) the package leaflet for the medicinal products concerned;
- (d) a summary of the risk management plan (if any) for the medicinal products concerned;
- (e) the list of medicinal products that are subject to additional monitoring referred to in Article 23 of Regulation (EC) No 726/2004; and
- (f) information on the different ways of reporting suspected adverse reactions to medicinal products to the licensing authority by patients or their carers, health care professionals, coroners or procurators fiscal (including by way of the web-based structured forms referred to in Article 25 of Regulation (EC) No 726/2004).

Obligation on licensing authority in relation to public announcements

204.—(1) This regulation applies where the licensing authority intends to make a public announcement relating to information on pharmacovigilance concerns.

(2) Subject to paragraph (4), the licensing authority must inform the bodies specified in paragraph (3) not less than 24 hours prior to making the public announcement.

(3) The bodies specified in this paragraph are—

- (a) the EMA;
- (b) the European Commission; and
- (c) the competent authority of each EEA State other than the United Kingdom.

(4) Paragraph (2) does not apply if the information in the announcement needs to be made public urgently for the protection of public health.

Obligations on holders in relation to public announcements

205.—(1) This regulation applies where the holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal product.

(2) The holder must inform the bodies listed in paragraph (3) of its intention to make the public announcement—

- (a) as soon as is practicable once it forms that intention; and
- (b) in any event no later than at the same time as, or before, the public announcement is made.

(3) The bodies listed in this paragraph are—

- (a) the licensing authority;
- (b) the EMA; and
- (c) the European Commission.

- (4) The holder must ensure that the information in the public announcement—
- (a) is presented objectively; and
 - (b) is not misleading.

Enforcement

Infringement notices

206.—(1) If an enforcement authority has objective grounds for considering that any person (“P”) has contravened any provision of this Part, or of Chapter 3 of Title II of Regulation (EC) No 726/2004, it may serve upon P a notice in writing (referred to in this Part as an “infringement notice”)—

- (a) informing P of the authority’s grounds for considering that P has contravened one or more provision of this Part or of that Chapter;
- (b) specifying the relevant provision of this Part or of that Chapter;
- (c) specifying the measures which P must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;
- (d) requiring P to take those measures, within such period as may be specified in the notice;
- (e) specifying the further action (if any) that the enforcement authority may take.

(2) An infringement notice may include directions as to the measures to be taken by P to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(3) If an enforcement authority serves an infringement notice in accordance with paragraph (1), it shall as soon as is reasonably practicable inform—

- (a) the EMA; and
- (b) the European Commission.

Offences

207.—(1) A person is guilty of an offence if the person commits a breach of a provision in this Part, other than regulation 199(2) or (6) (submission of draft study protocols for required studies).

(2) A breach of a provision in this Part includes any—

- (a) failure by a holder to comply with any requirement or obligation in this Part; or
- (b) contravention by any person of any prohibition in this Part.

False and misleading information

208. A person is guilty of an offence if the person provides information to the licensing authority or the EMA, pursuant to an obligation in this Part, but that information is false or misleading in a material particular.

Penalties

209.—(1) Subject to paragraph (2), a person guilty of an offence under regulation 207 or 208 is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(2) A person guilty of an offence under regulation 207 which relates to a breach of a provision listed in paragraph (3) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine.

(3) Those provisions are regulations—

- (a) 182(2)(a) and (b), (3) and (5);
- (b) 183(8)(a);
- (c) 184(1)(a) and (b);
- (d) 187(4);
- (e) 188(1)(c) and (e);
- (f) 193(5);
- (g) 198(1) and (3)(a) and (d);
- (h) 199(8); and
- (i) 200(7).

Offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004

210.—(1) A person is guilty of an offence if the person—

- (a) commits a breach of a provision of Regulation (EC) No 726/2004 listed in paragraph (3); or
- (b) provides information which is false or misleading in a material particular to the licensing authority or the EMA pursuant to an obligation in Chapter 3 of Title II of Regulation (EC) No 726/2004.

(2) A breach of a provision listed in paragraph (3) includes any—

- (a) failure to comply with any requirement or obligation contained in any of those provisions;
- (b) contravention of any prohibition contained in any of those provisions; or
- (c) failure to comply with any requirement imposed by the licensing authority or the EMA pursuant to any of those provisions.

(3) Those provisions are—

- (a) Article 16(4), second paragraph(43);
- (b) Article 20(8)(44);
- (c) Article 21(1) and (2)(45);
- (d) Article 22(46);
- (e) Article 28(1), (2) and (5)(47);

(43) Article 16(4), second paragraph, of Regulation (EC) No 726/2004 (“the Regulation”) imposes an obligation identical to that set out in Article 23(4), second paragraph, of the 2001 Directive; Article 23(4), second paragraph, of the 2001 Directive is transposed at regulation 182(5).

(44) Article 20(8) of the Regulation applies Article 107i of the 2001 Directive, which in turn applies Articles 107j and 107k of the 2001 Directive; Article 107k(2) second paragraph is implemented in regulation 197(3).

(45) Article 21(1) of the Regulation, first paragraph, cross-refers to obligations set out in Article 104 of the 2001 Directive, implemented in regulation 182 and 185; Article 21(1), second paragraph, and 21(2) of the Regulation are similar in effect to Article 104a of the 2001 Directive, implemented in regulation 183.

(46) Article 22 of the Regulation cross-refers to obligations set out in Article 106a(1) of the 2001 Directive; Article 106a(1) is implemented in regulation 205.

(47) Article 28(1) and (2) of the Regulation cross-refers to obligations set out in Articles 107, 107a, 107b and 107c of the 2001 Directive; those Articles are implemented in regulations 185, 186, 187, 188, 191, 192 and 193; Article 28(5) of the Regulation applies Articles 107e to 107g of the 2001 Directive; Article 107g of the 2001 Directive is implemented in regulation 194.

- (f) Article 28a(3)(48); and
 - (g) Article 28b(1)(49), except insofar as it imposes an obligation under Article 107n(1), or the first paragraph of Article 107n(3), of the 2001 Directive.
- (4) Subject to paragraph (5), a person guilty of an offence under this regulation is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.
- (5) A person guilty of an offence under this regulation in relation to a provision of Regulation (EC) No 726/2004 listed in paragraph (6) is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to a fine.
- (6) Those provisions are—
- (a) Article 16(4), second paragraph;
 - (b) Article 21(1) insofar as it relates to obligations set out in—
 - (i) the second paragraph of Article 104(2) of the 2001 Directive save the obligation regarding preparing and implementing a corrective action plan,
 - (ii) Article 104(3)(a) of the 2001 Directive,
 - (iii) Article 104(3)(b) of the 2001 Directive, or
 - (iv) the second paragraph of Article 104(3) of the 2001 Directive;
 - (c) Article 21(2) insofar as it relates to the obligation to submit a detailed description of a risk management system;
 - (d) Article 28(1) insofar as it relates to obligations set out in—
 - (i) the second paragraph of Article 107(1) of the 2001 Directive,
 - (ii) the first sentence of Article 107(4) of the 2001 Directive, or
 - (iii) Article 107(5) of the 2001 Directive;
 - (e) Article 28(2) insofar as it relates to the obligation set out in the third paragraph of Article 107c(4) of the 2001 Directive; and
 - (f) Article 28b(1) insofar as it relates to prohibitions or obligations set out in—
 - (i) Article 107m(3) to (6) of the 2001 Directive,
 - (ii) the second paragraph of Article 107n(3) of the 2001 Directive, or
 - (iii) the last sentence of Article 107o of the 2001 Directive.
- (7) This regulation is subject to regulation 212 (transitional arrangements).

Persons liable

211. If an offence under regulation 207(1) (offences) or regulation 210(1)(a) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

(48) Article 28a(3) of the Regulation imposes an obligation identical to that set out in the first sentence of Article 107h(3) of the 2001 Directive; Article 107h(3) first sentence is implemented in regulation 190.

(49) Article 28b(1) of the Regulation cross-refers to prohibitions and obligations set out in Articles 107m, 107n, 107o, 107p and 107q of the 2001 Directive; those Articles are implemented in regulations 198, 199, 200, 201 and 202; Article 107n(1) and the first paragraph of Article 107n(3), implemented in regulation 199(2) and (6), are excluded as they are enforced otherwise than by way of criminal offence.

Transitional arrangements

Transitional arrangements

212. Regulations 182, 186, 188, 191, 192, 198, 199, 200, 201, 202 and 210 are subject to the transitional provisions set out in Schedule 33 (transitional arrangements: pharmacovigilance).

PART 12

Dealings with medicinal products

CHAPTER 1

Interpretation

Interpretation

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⁽⁵⁰⁾;

“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⁽⁵¹⁾ or in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations (Northern Ireland) 2002⁽⁵²⁾, 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⁽⁵³⁾;

“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⁽⁵⁴⁾), 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

⁽⁵⁰⁾ 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.

⁽⁵¹⁾ 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.

⁽⁵²⁾ 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.

⁽⁵³⁾ 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.

⁽⁵⁴⁾ 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**(55)**;
- (b) in relation to Wales, a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006**(56)**;
- (c) in relation to Scotland, a Health Board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978**(57)**; 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**(58)**;

“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**(59)**;

“Health Protection Agency” means the body of that name established under section 1 of the Health Protection Agency Act 2004**(60)**;

“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

(55) 2006 c.41.

(56) 2006 c.42.

(57) 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).

(58) 2009 c.1 (N.I.).

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

(60) 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⁽⁶¹⁾, 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⁽⁶²⁾;
- (c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Service (Scotland) Act 1978⁽⁶³⁾; 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⁽⁶⁴⁾;

“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;

⁽⁶¹⁾ 1983 c.20.

⁽⁶²⁾ 2000 c.14.

⁽⁶³⁾ 1978 c.29. Section 10F was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).

⁽⁶⁴⁾ 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⁽⁶⁵⁾; 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⁽⁶⁶⁾;

“nursing home” has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003⁽⁶⁷⁾;

“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—

⁽⁶⁵⁾ 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).

⁽⁶⁶⁾ 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.

⁽⁶⁷⁾ 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⁽⁶⁸⁾);
- (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989⁽⁶⁹⁾); 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⁽⁷⁰⁾);

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

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

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

“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⁽⁷¹⁾ or the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b)⁽⁷²⁾ 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

⁽⁶⁸⁾ 1952 c.52.

⁽⁶⁹⁾ 1989 c.45.

⁽⁷⁰⁾ 1953 c.18 (N.I.). Functions transferred by article 6(1) of, and Schedule 4 to, S.I. 2010/976.

⁽⁷¹⁾ 1989 c.44; section 7 was amended by S.I. 2005/848, articles 2 and 7(1).

⁽⁷²⁾ 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⁽⁷³⁾ 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⁽⁷⁴⁾; 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—

⁽⁷³⁾ 2008 c.14.

⁽⁷⁴⁾ 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⁽⁷⁵⁾; 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⁽⁷⁶⁾;

“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

⁽⁷⁵⁾ Section 2(1)(b) was inserted by section 28(a) of the National Health Service and Community Care Act 1990 (1990 c.19).

⁽⁷⁶⁾ 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.

CHAPTER 2

Sale and supply of medicines

Prescription only medicines

Sale or supply of prescription only medicines

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

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

- (a) an appropriate practitioner other than an EEA health professional; or
- (b) acting in accordance with the directions of such an appropriate practitioner.

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

- (a) a doctor;
- (b) a dentist;
- (c) a supplementary prescriber;
- (d) a nurse independent prescriber; and
- (e) a pharmacist independent prescriber.

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

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

- (a) a medicinal product that is a controlled drug; or
- (b) a medicinal product that is for parenteral administration.

(6) An EEA health professional is an appropriate practitioner in relation to any prescription only medicine other than a controlled drug.

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

Prescribing and administration by supplementary prescribers

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

(2) A supplementary prescriber (“S”) may not—

- (a) parenterally administer a prescription only medicine; or
- (b) give directions for the parenteral administration of a prescription only medicine,

unless S meets conditions B and C.

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

- (a) relates to the patient to whom the product is prescribed;
- (b) has effect when the prescription is given; and

- (c) includes the particulars specified in Schedule 14.
- (4) Condition B is that S is acting in accordance with the terms of a clinical management plan that—
 - (a) relates to the patient to whom the product is, or is to be, administered;
 - (b) has effect when the product is administered or (as the case may be) the direction is given; and
 - (c) includes the particulars specified in Schedule 14.
- (5) Condition C is that S has access to health records that—
 - (a) are the health records of the patient to whom the plan relates; and
 - (b) are used by any doctor or dentist who is a party to the plan.
- (6) This regulation is subject to regulation 216.
- (7) In this regulation—
 - “clinical management plan” means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—
 - (a) the patient to whom the plan relates;
 - (b) the doctor or dentist who is a party to the plan; and
 - (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;
 - “health record” has the meaning given by section 68(2) of the Data Protection Act 1998(77).

Exceptions to regulation 215

- 216.**—(1) Regulation 215 does not apply if—
- (a) S is a community practitioner nurse prescriber; and
 - (b) the prescription only medicine prescribed or administered, or in respect of which S gives directions for administration, is specified in Schedule 13.
- (2) Regulation 215(2) does not apply if S is acting in accordance with the directions of another person who is an appropriate practitioner (other than a supplementary prescriber or an EEA health professional) in relation to the prescription only medicine in question.

Requirements for prescriptions: general

- 217.**—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner unless the following conditions are met.
- (2) Condition A is that the prescription is signed in ink by the appropriate practitioner giving it.
 - (3) Condition B is that the prescription—
 - (a) is written in ink or otherwise so as to be indelible; or
 - (b) in the case of a health prescription which is not for a controlled drug, is written as described in sub-paragraph (a) or by means of carbon paper or similar material.
 - (4) Condition C is that the prescription contains the following particulars—
 - (a) the address of the appropriate practitioner giving it;
 - (b) the appropriate date;

- (c) an indication of the kind of appropriate practitioner giving it;
 - (d) the name and address of the person for whose treatment it is given; and
 - (e) if that person is under 12, that person's age.
- (5) Condition D is that the prescription—
- (a) is not dispensed after the end of the period of six months beginning with the appropriate date; or
 - (b) in the case of a repeatable prescription—
 - (i) it is not dispensed for the first time after the end of that period, and
 - (ii) it is dispensed in accordance with the directions contained in the prescription.
- (6) Condition E is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—
- (a) it is not dispensed on more than two occasions, or
 - (b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the appropriate date.
- (7) In this regulation “appropriate date” means, subject to paragraph (8)—
- (a) in the case of a health prescription, whichever is the later of—
 - (i) the date on which it was signed by the appropriate practitioner giving it, or
 - (ii) a date indicated by the appropriate practitioner as the date before which it should not be dispensed; and
 - (b) otherwise, the date on which the prescription was signed by the appropriate practitioner giving it.
- (8) This regulation—
- (a) does not apply to a prescription given by an EEA health professional (as to which see regulation 218); and
 - (b) is subject to regulation 219 (electronic prescriptions).

Requirements for prescriptions: EEA health professionals

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

- (2) Condition A is that it is an EEA prescription.
- (3) Condition B is that the prescription is signed in ink by the EEA health professional giving it.
- (4) Condition C is that the prescription is written in ink or otherwise so as to be indelible.
- (5) Condition D is that the prescription contains the following particulars—
 - (a) the address of the EEA health professional giving it;
 - (b) the date on which it is signed by the EEA health professional;
 - (c) an indication of whether the EEA health professional is a doctor or dentist; and
 - (d) the name of the person for whose treatment it is given.
- (6) Condition E is that the prescription—
 - (a) is not dispensed after the end of the period of six months beginning with the date on which it is signed by the EEA health professional; or
 - (b) in the case of a repeatable prescription—

- (i) it is not dispensed for the first time after the end of that period, and
 - (ii) it is dispensed in accordance with the directions contained in the prescription.
- (7) Condition F is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—
- (a) it is not dispensed on more than two occasions; or
 - (b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the date on which it is signed by the EEA health professional.
- (8) This regulation is subject to regulation 219 (electronic prescriptions).

Electronic prescriptions

219.—(1) This regulation applies to a prescription that is not a health prescription for a controlled drug.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an appropriate practitioner other than an EEA health professional if—

- (a) conditions A and B in regulation 217 are not met; but
- (b) the conditions in paragraph (4) of this regulation and conditions C to E in regulation 217 are met.

(3) A prescription only medicine is also sold or supplied in accordance with a prescription given by an EEA health professional if—

- (a) conditions B and C in regulation 218 are not met, but
- (b) the conditions in paragraph (4) of this regulation and conditions A and D to F in regulation 218 are met.

(4) The conditions mentioned in paragraphs (2)(b) and (3)(b) are that the prescription is—

- (a) created in electronic form;
- (b) signed with an advanced electronic signature; and
- (c) sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries).

(5) In this regulation “advanced electronic signature” means an electronic signature that is—

- (a) uniquely linked to the person (“P”) giving the prescription;
- (b) capable of identifying P;
- (c) created using means that P can maintain under P’s sole control; and
- (d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable.

Medicines not subject to general sale

Sale or supply of medicinal products not subject to general sale

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

(2) This paragraph applies if—

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

- (b) the product is sold, supplied, or offered for sale or supply, on premises that are a registered pharmacy; and
 - (c) P or, if the transaction is carried out on P's behalf by another person, that other person is, or acts under the supervision of, a pharmacist.
- (3) This regulation is subject to Chapter 3.

General sale medicines

Sale or supply of medicinal products subject to general sale

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

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

(3) Condition B is that—

- (a) the medicinal product was made up for sale in its immediate and outer packaging elsewhere than at the place at which it is sold, supplied, or offered for sale or supply; and
- (b) the immediate and outer packaging has not been opened since the product was made up for sale in it.

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

(5) This regulation is subject to Chapter 3.

Sale of medicinal products from automatic machines

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

CHAPTER 3

Exemptions

Exemptions relating to supply in specific circumstances

Exemptions for doctors and dentists etc

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

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

- (a) to a patient of the doctor or dentist, or
- (b) to a person under whose care such a patient is.

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

- (a) the product is sold, offered for sale or supplied for the purposes of being administered to a person (whether in the hospital or health centre or elsewhere) in accordance with directions relating to that person; and
 - (b) those directions have been given by—
 - (i) a doctor,
 - (ii) a dentist,
 - (iii) a supplementary prescriber,
 - (iv) a pharmacist independent prescriber,
 - (v) an optometrist independent prescriber,
 - (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—

<i>Prescription only medicine</i>	<i>Maximum quantity</i>
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(78), 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⁽⁷⁹⁾ in respect of one or more of the following regulated activities⁽⁸⁰⁾—

- (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

⁽⁷⁹⁾ 2008 c.14.

⁽⁸⁰⁾ 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) 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;

(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⁽⁸¹⁾, 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

⁽⁸¹⁾ 2008 No. 1976 (W. 185).

(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,

(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.

Exemptions in relation to specific kinds of product

Products consisting of or containing aloxiprin, aspirin or paracetamol

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

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

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

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

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

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

- (a) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts; or
- (b) in the case of ephedrine base or salts, 180mg ephedrine base or salts.

Administration of certain medicines in an emergency

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

Administration of smallpox vaccine

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

(2) Condition A is that—

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

(i) the Secretary of State,

(ii) the Scottish Ministers,

(iii) the Welsh Ministers,

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

(v) an NHS body; and

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

(3) Condition B is that—

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

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

Radioactive medicinal products

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

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

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

if the following conditions are met.

(2) Condition A is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000(82) which apply to the exposure.

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

(a) an IRME practitioner; or

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

(4) Condition C is that the IRME practitioner mentioned in paragraph (a) or (b) of paragraph (3) is the holder of a certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978(83).

(5) Condition D is that the prescription only medicine is not a controlled drug.

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

(82) S.I. 2000/1059, as amended by S.I. 2006/2523.

(83) S.I. 1978/1006.

(7) In this regulation—

“IRME practitioner” means, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000;

“medical exposure” has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000; and

“radioactive medicinal product” means a medicinal product which consists of, contains or generates a radioactive substance so that, when the product is administered, the radiation it emits may be used.

Exemptions in respect of certain herbal remedies

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

- (a) the product does not contain a substance listed in Part 1 of Schedule 20;
- (b) the product does not contain a substance listed in column 1 of Part 2 of that Schedule, unless the product is sold or supplied—
 - (i) in the case of a product for which there is a corresponding entry in column 2 of that Part, in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in that entry, and
 - (ii) in the case of a product for which there is a corresponding entry in column 3 of that Part, with the percentage of the substance in the product not exceeding that specified in that entry;
- (c) the sale or supply, or offer for sale or supply, takes place on premises occupied by A and from which A can exclude the public; and
- (d) the product is for administration to a person (“B”) and A has been requested by or on behalf of B and in B’s presence to use A’s judgment as to the treatment required.

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

Exemption for medicinal products at high dilution

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

- (a) the medicinal product is neither for parenteral administration nor a controlled drug;
- (b) paragraph (2) applies to the medicinal product; and
- (c) P has been requested by or on behalf of a particular person and in that person’s presence to use P’s own judgment as to the treatment required.

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

- (a) any substance where the unit preparation has been diluted to at least one part in a million (6x);
- (b) any substance that is listed in Part 1 of Schedule 21 where the unit preparation has been diluted to at least one part in a thousand (3x); or
- (c) any substance that—
 - (i) is the active substance of a medicine that is subject to general sale;
 - (ii) is listed in Part 3 of Schedule 21; or

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

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

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

- (a) the medicinal product is neither for parenteral administration nor a controlled drug;
- (b) paragraph (4) applies to the medicinal product; and
- (c) the conditions in regulation 221 are met.

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

- (a) any substance where the unit preparation has been diluted to at least one part in a million million (6c);
- (b) any substance that is listed in Part 2 of Schedule 21 where the unit preparation has been diluted to at least one part in a million (6x); or
- (c) any substance that—
 - (i) is the active substance of a medicine that is subject to general sale;
 - (ii) is listed in Part 3 of Schedule 21; or
 - (iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

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

Exemption for certain homoeopathic medicinal products

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

- (a) a certificate of registration is in force in relation to the product;
- (b) the product is not an excluded product; and
- (c) P has been requested by or on behalf of a particular person and in that person’s presence to use P’s own judgment as to the treatment required.

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

- (a) a certificate of registration is in force in relation to the product;
- (b) the product is not an excluded product; and
- (c) the conditions in regulation 221 are met.

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

- (a) for use as an anthelmintic;
- (b) for parenteral administration;
- (c) for use as eye drops;
- (d) for use as an eye ointment;
- (e) for use as an enema;
- (f) for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum; or
- (g) for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

Other exemptions

Exemption in cases involving another's default

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

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

- (a) the person, having exercised all due diligence, believes on reasonable grounds that the product is subject to general sale;
- (b) that belief is due to the act or default of another person; and
- (c) the conditions in regulation 221 are met in relation to the sale or supply, or offer for sale or supply of the product.

Exemption in case of forged prescription

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

Exemption where requirements for prescriptions not met

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

- (a) the sale or supply is otherwise than in accordance with such a prescription because a condition in regulation 217, 218 or 219 is not met; and
- (b) the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that the condition is met.

Exemption for supply in the event or anticipation of pandemic disease

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

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

- (a) pandemic; and
- (b) a serious risk, or potentially a serious risk, to human health.

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

- (a) is approved by the Ministers, an NHS body or the Health Protection Agency;
- (b) specifies the symptoms of and treatment for the disease; and
- (c) contains requirements as to the recording of—

- (i) the name of the person who supplies the product to the person to be treated (“the patient”) or to a person acting on the patient’s behalf, and
- (ii) evidence that the product was supplied to the patient or to a person acting on the patient’s behalf.

Exemption for certain collection and delivery arrangements

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

- (a) is in accordance with a prescription issued by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or optometrist independent prescriber; and
- (b) forms part of a collection and delivery arrangement used by a person who lawfully conducts a retail pharmacy business.

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

- (a) take or send a prescription given by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or optometrist independent prescriber to premises other than a registered pharmacy and which are capable of being closed by the occupier to exclude the public; and
- (b) collect or have collected on his or her behalf from such premises a medicinal product prepared or dispensed in accordance with such a prescription at a registered pharmacy by or under the supervision of a pharmacist.

CHAPTER 4**Miscellaneous provisions, offences and disqualification***Miscellaneous provisions***Restrictions on persons to be supplied with medicinal products**

249.—(1) The holder of an authorisation of the kind referred to in paragraph (2) may not sell a prescription only medicine or a pharmacy medicine by way of wholesale dealing to a person who does not fall within a class specified in Schedule 22.

(2) Those authorisations are—

- (a) a marketing authorisation;
- (b) a certificate of registration;
- (c) a traditional herbal registration; and
- (d) an Article 126a authorisation.

(3) A person may not, in the course of a business consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing, sell a prescription only medicine or a pharmacy medicine by way of wholesale dealing to a person who does not fall within a class specified in Schedule 22.

(4) This regulation is subject to regulation 250.

Exceptions to regulation 249

250.—(1) This regulation makes provision for exceptions to regulation 249.

(2) A person may sell by way of wholesale dealing a pharmacy medicine which is for the purpose of being administered to human beings in the course of a business to any person carrying on such a business.

(3) A person may sell by way of wholesale dealing a pharmacy medicine to which a general sale exemption applies to any person who by virtue of that exemption may sell the pharmacy medicine

by retail, or supply it in circumstances corresponding to retail sale, otherwise than by or under the supervision of a pharmacist.

(4) In paragraph (3) “general sale exemption” means an exemption from regulation 220 conferred by a provision of Chapter 3.

(5) A person may sell by way of wholesale dealing to a person specified in column 1 of Parts 1 to 3 of Schedule 17 a prescription only medicine specified in relation to that person in column 2 of Parts 1 to 3 of that Schedule.

(6) A person may sell by way of wholesale dealing to a registered optometrist a product that is a prescription only medicine by reason only that it contains one or more of the following substances—

- (a) amethocaine hydrochloride;
- (b) lidocaine hydrochloride;
- (c) oxybuprocaine hydrochloride; or
- (d) proxymetacaine hydrochloride.

(7) A person may sell by way of wholesale dealing to an additional supply optometrist a product that is a prescription only medicine by reason only that it contains thymoxamine hydrochloride.

(8) A person may sell by way of wholesale dealing to a registered dispensing optician a prescription only medicine that—

- (a) is required for use by a registered optometrist or doctor attending the optician’s practice; and
- (b) contains one or more of the following substances—
 - (i) amethocaine hydrochloride,
 - (ii) chloramphenicol,
 - (iii) cyclopentolate hydrochloride,
 - (iv) fusidic acid,
 - (v) lidocaine hydrochloride,
 - (vi) oxybuprocaine hydrochloride,
 - (vii) proxymetacaine hydrochloride, and
 - (viii) tropicamide.

(9) A person may sell by way of wholesale dealing to a registered dispensing optician a prescription only medicine that—

- (a) is required for use by the optician in the course of a professional practice as a contact lens specialist; and
- (b) contains one or more of the following substances—
 - (i) lidocaine hydrochloride,
 - (ii) oxybuprocaine hydrochloride, and
 - (iii) proxymetacaine hydrochloride.

(10) In this regulation—

“additional supply optometrist” means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;

“contact lens specialist” means a person who is a registered dispensing optician and against whose name particulars of the contact lens speciality have been entered in—

- (a) the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989; or
- (b) the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b) of that Act.

Compliance with standards specified in certain publications

251.—(1) A person may not sell a medicinal product that has been demanded by the purchaser by, or by express reference to, a particular name if—

- (a) the name is a name at the head of the relevant monograph; and
- (b) the product does not comply with the standard specified in that monograph.

(2) A person may not sell or supply a medicinal product in pursuance of a prescription given by a doctor or dentist in which the product required is described by, or by express reference to, a particular name if—

- (a) the name is a name at the head of the relevant monograph; and
- (b) the product does not comply with the standard specified in that monograph.

(3) A person may not sell or supply a medicinal product that has been offered or exposed for sale by, or by express reference to, a particular name if—

- (a) the name is a name at the head of the relevant monograph; and
- (b) the product does not comply with the standard specified in that monograph.

(4) If the particular name referred to in paragraph (1), (2) or (3) is that of an active ingredient of the product, the product does not comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with that standard.

(5) See regulation 252 for the meaning of certain expressions used in this regulation.

Compliance with standards specified in certain publications: supplementary

252.—(1) Where, together with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, there was specified a particular edition of a particular publication, “the relevant monograph” in that paragraph means—

- (a) the monograph (if any) headed by the name in that edition; or
- (b) if there is no such monograph, the appropriate current monograph (if any) headed by that name.

(2) Where, together with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, there was specified a particular publication, but not an edition of that publication, “the relevant monograph” in that paragraph means—

- (a) the monograph (if any) headed by the name in the current edition; or
- (b) if there is no monograph of the kind mentioned in sub-paragraph (a), the appropriate current monograph (if any) headed by that name; or
- (c) if there is no monograph of the kinds mentioned in sub-paragraphs (a) or (b), the monograph headed by that name in the latest edition of the specified publication that contained a monograph headed by that name.

(3) Where no publication was specified with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, “the relevant monograph” in that paragraph means the appropriate current monograph (if any).

(4) In this regulation “publication” means—

- (a) the British Pharmacopoeia; or
 - (b) a compendium published under Part 15 (British Pharmacopoeia).
- (5) In this regulation “current” means current at the time when the medicinal product is demanded, described in a prescription or offered or exposed for sale (as the case may be).
- (6) In this regulation “the appropriate current monograph”, in relation to a particular name, means—
- (a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia; or
 - (b) if there is no such monograph, the monograph (if any) headed by that name in the current edition of a compendium published under Part 15 (British Pharmacopoeia).
- (7) For the purposes of regulation 251 and this regulation, any monograph in an edition of a publication must be construed in accordance with any general monograph or notice, or any appendix, note or other explanatory material, that is contained in that edition and applies to that monograph.

Pharmacy records

253.—(1) A person lawfully conducting a retail pharmacy business must, in respect of every sale or supply of a prescription only medicine, make or cause to be made an entry in a written or computerised record kept for that purpose.

- (2) An entry required by paragraph (1)—
- (a) must state the particulars specified in Schedule 23; and
 - (b) subject to paragraph (3), must be made—
 - (i) on the day of the sale or supply, or
 - (ii) if that is not reasonably practicable, on the day following that day.
- (3) Where the sale or supply is made under regulation 224 (emergency sale etc by pharmacist: prescriber unable to provide prescription), the particulars specified in paragraph 2(e) and (f) of Schedule 23 may be entered on the day that the prescription is received.
- (4) Paragraphs (1) to (3) do not apply if any of the following apply—
- (a) the sale or supply is in pursuance of a health prescription or a prescription for oral contraceptives;
 - (b) a separate record of the sale or supply is made in accordance with the Misuse of Drugs Regulations 2001 or the Misuse of Drugs Regulations (Northern Ireland) 2002;
 - (c) the sale is by way of wholesale dealing and the order or invoice relating to the sale or a copy of the order or invoice is retained by the person lawfully conducting the retail pharmacy business who makes the sale;
 - (d) in Scotland, the sale or supply is to a doctor for use in the circumstances referred to in paragraph 45 of Schedule 5 to the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004⁽⁸⁴⁾ (provision of drugs, medicines and appliances for immediate treatment or personal administration);
 - (e) in Northern Ireland, the sale or supply is to a doctor for use in the circumstances referred to in paragraph 47 of Schedule 5 to the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004⁽⁸⁵⁾ (provision of drugs, medicines and appliances for immediate treatment or personal administration).

⁽⁸⁴⁾ S.S.I. 2004/115

⁽⁸⁵⁾ S.R. (NI) 2004 No. 140.

- (5) A person lawfully conducting a retail pharmacy business must preserve for a period of two years beginning immediately after the relevant date—
- (a) the record kept under paragraphs (1) to (3);
 - (b) a prescription in pursuance of which a prescription only medicine has been sold or supplied other than—
 - (i) a health prescription, or
 - (ii) a prescription for a controlled drug;
 - (c) an order or invoice referred to in paragraph (4)(c) or a copy of the order or invoice; and
 - (d) orders referred to in column 3 of Parts 1 to 3 of Schedule 17, except orders referred to in paragraph 3 of Part 1 of that Schedule.
- (6) In paragraph (5) “the relevant date” means—
- (a) in relation to sub-paragraph (a), the date on which the last entry is made in the record;
 - (b) in relation to sub-paragraphs (b), (c) and (d)—
 - (i) where the prescription only medicine was sold or supplied in accordance with a repeatable prescription, the date of the final sale or supply pursuant to that prescription, and
 - (ii) otherwise, the date on which the prescription only medicine was sold or supplied.

Prohibitions concerning traceability of treatment with advanced therapy medicinal products

254.—(1) A person may not treat a patient with an advanced therapy medicinal product if there is not a system in place for patient and product traceability in relation to such treatment containing sufficient detail to enable the linking of the product to the patient who received it and vice versa.

(2) A person may not treat a patient with an advanced therapy medicinal product if the treatment involves a product which contains human cells or tissues and the traceability system referred to in paragraph (1) is not complementary to, and compatible with, the requirements laid down in—

- (a) Articles 8 and 14 of Directive 2004/23/EC, as regards human cells and tissues other than blood cells; and
- (b) Articles 14 and 24 of Directive 2002/98/EC, as regards blood cells.

(3) It is a defence to an offence of breach of paragraph (1) or, as the case may be, paragraph (2) if the person who treats a patient was assured in writing before the treatment was given that a system of traceability as described in paragraph (1) or, as the case may be, paragraph (2) was in place in relation to the treatment given by that person.

(4) A person may not give an assurance in writing to a person (“P”) who treats a patient with an advanced therapy medicinal product that a system of traceability as described in paragraph (1) or paragraph (2) is in place in relation to treatment with an advanced therapy medicinal product given by P if no such system is in place.

Offences relating to dealings with medicinal products

255.—(1) A person is guilty of an offence if the person breaches any of the following provisions of this Part—

- (a) regulation 214(1) (prohibition on sale etc of prescription only medicine otherwise than in accordance with prescription from appropriate practitioner);
- (b) regulation 214(2) (prohibition on parenteral administration of prescription only medicine otherwise than by or under directions of appropriate practitioner);

- (c) regulation 220 (prohibition on sale etc of medicinal product not subject to general sale otherwise than by or under supervision of pharmacist);
 - (d) regulation 249 (prohibition on sale of prescription only medicine or pharmacy medicine by way of wholesale dealing to person not within Schedule 22);
 - (e) regulation 251 (compliance with standards specified in certain publications); or
 - (f) regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products).
- (2) A person is guilty of an offence if the person—
- (a) is an appropriate practitioner by virtue of regulation 214; and
 - (b) gives a prescription or directions in respect of a medicinal product in relation to which the person is not an appropriate practitioner.
- (3) A person is guilty of an offence if the person gives a prescription or directions or administers a medicinal product without meeting the conditions for doing so that apply to that person by virtue of regulation 215 (conditions to be met by supplementary prescriber).
- (4) A person (“P”) is guilty of an offence if—
- (a) P has in P’s possession a medicinal product to which regulation 214(1) applies; and
 - (b) P intends to supply it otherwise than in accordance with a prescription of an appropriate practitioner.
- (5) A person guilty of an offence under any of paragraphs (1) to (4) is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.
- (6) A person is guilty of an offence if the person breaches—
- (a) regulation 221 (prohibition on sale of medicinal product subject to general sale otherwise than in accordance with that regulation); or
 - (b) regulation 222 (prohibition on sale by automatic machine of medicinal product not subject to general sale).
- (7) A person guilty of an offence under paragraph (6) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.
- (8) A person is guilty of an offence if the person breaches regulation 253 (record-keeping requirements for persons carrying on a retail pharmacy business).
- (9) A person guilty of an offence under paragraph (8) is liable on summary conviction to a fine not exceeding £400.

Disqualification

Disqualification on conviction

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

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

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

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

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

- (a) to the gravity of the offence of which P has been convicted as mentioned in the preceding subsection;
- (b) to the unsatisfactory nature of the premises; or
- (c) to any offences under regulation 255(8) of which P has previously been convicted.

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

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

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

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

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

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

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

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

PART 13

Packaging and leaflets

CHAPTER 1

Requirements for packaging and package leaflets relating to medicinal products

Packaging requirements: general

257.—(1) The information specified in Part 1 of Schedule 24 must appear—

- (a) on the outer packaging of a medicinal product; and
- (b) on the immediate packaging of the product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to immediate packaging if the packaging is in the form of a blister pack and is placed in outer packaging which complies with the requirements of Part 1 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 1 of Schedule 24.

(4) The information specified in Part 2 of Schedule 24 must appear on immediate packaging to which paragraph (2) applies.

(5) The information specified in Part 3 of Schedule 24 must appear on immediate packaging to which paragraph (3) applies.

(6) Information included on the packaging of a product in accordance with this regulation, regulation 261 and Schedule 24 must be easily legible, comprehensible and indelible.

(7) Nothing in this regulation or Schedule 24 applies to a registrable homoeopathic medicinal product.

Packaging requirements: specific provisions

258.—(1) In addition to other information required by this Part, the information specified in Part 1 of Schedule 25 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner for the purposes of regulation 214(3) to (6), whether or not the medicinal product in question is a prescription only medicine.

(2) The requirements of paragraph 4 or 6 of Schedule 25, as the case may be, are satisfied in relation to a package containing a number of packages of medicinal products of the same description if the information specified in paragraph 4 or 6 of that Schedule is shown on one or more of those packages.

(3) The information specified in Part 2 of that Schedule must appear on a package which contains a number of packages of medicinal products of the same description, other than special medicinal products, for the purpose of transport, delivery or storage.

(4) But paragraph (3) does not apply to a packing case, crate or other covering used solely for the purposes of transport or delivery of packages of medicinal products, each of which is labelled in accordance with the other requirements of this Part.

(5) In addition to the other information required by this Part, the information specified in Parts 3 and 4 of Schedule 25 must appear on the outer packaging and the immediate packaging of products of the kind specified in those Parts of that Schedule.

(6) Nothing in this regulation or Schedule 25 requires information to appear on—

- (a) a package containing a medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of the package;
- (b) a paper bag or similar wrapping in which a package that contains a medicinal product and bears information in accordance with the requirements of this regulation and that Schedule is placed at the time of sale or supply;
- (c) a package enclosing a package of a medicinal product for export;
- (d) an ampoule or other container of not more than 10 millilitres' nominal capacity which is enclosed in a package on which information appears in accordance with the requirements of this regulation and that Schedule; or
- (e) a blister pack or similar packaging enclosed in a package on which information appears in accordance with the requirements of Parts 3 and 4 of Schedule 25.

(7) Nothing in this regulation or Schedule 25 applies to a medicinal product—

- (a) which is an anti-viral medicine in the form of a solution to be used for the treatment of a child under the age of one year;
- (b) on the container of which appears—
 - (i) the name of the person to whom the product is to be administered,

- (ii) the date on which the product is sold or supplied, and
- (iii) the necessary instructions for proper use; and
- (c) which is sold or supplied for the purpose of treating a disease which is—
 - (i) a serious risk to human health, or potentially a serious risk to human health, and
 - (ii) pandemic or imminently pandemic.

(8) Nothing in this regulation or Schedule 25 applies to a traditional herbal medicinal product or a registrable homoeopathic medicinal product.

Packaging requirements: information for blind and partially sighted patients

259.—(1) The name of a medicinal product must also be expressed in Braille format on the outer packaging of the product (or, if there is no outer packaging, on the immediate packaging of the product).

(2) The holder of a marketing authorisation, Article 126a authorisation or traditional herbal registration for a medicinal product must ensure that the package leaflet is made available on request in formats suitable for blind and partially-sighted persons.

(3) Nothing in this regulation applies to a registrable homoeopathic medicinal product.

Package leaflets

260.—(1) A package leaflet for a medicinal product must—

- (a) be drawn up in accordance with the summary of the product characteristics; and
- (b) contain all the information specified in Schedule 27 in the order specified in that Schedule.

(2) A package leaflet must be included in the packaging of a medicinal product unless all the information required by Part 1 of Schedule 27 (and, where the product contains paracetamol, the information required by Part 2 of that Schedule) is conveyed on the outer packaging or the immediate packaging of the product.

(3) A package leaflet relating to a medicinal product must be legible, clear and easy to use, and the applicant for, or holder of, a marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product must ensure that target patient groups are consulted in order to achieve this.

(4) Regulation (5) applies in a case where a package leaflet is not provided under paragraph (2) because all the information required by Schedule 27 is conveyed on the outer packaging or the immediate packaging of the product.

(5) Where this paragraph applies, any requirement of these Regulations that is expressed by reference to a package leaflet shall be taken to refer to the outer packaging or, as the case may be, the immediate packaging of the product.

(6) Nothing in this regulation or Schedule 27 applies to a registrable homoeopathic medicinal product.

Use of pictures and symbols etc

261.—(1) The outer packaging and the package leaflet of a medicinal product may include—

- (a) symbols, diagrams or pictures designed to clarify information mentioned in Part 1 of Schedule 24 or in Schedule 27; and
- (b) other information, compatible with the summary of the product characteristics, which is useful to the patient.

(2) Symbols, diagrams, pictures or additional information included in accordance with this regulation must not include any element of a promotional nature.

(3) Nothing in this regulation applies to a registrable homoeopathic product.

Labelling requirements for radionuclides

262.—(1) Where a medicinal product contains radionuclides—

- (a) the carton and the container of the product must be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency; and
- (b) the labelling on the shielding and the vial must comply with the remaining provisions of this regulation.

(2) The label on the shielding must—

- (a) include the information specified in Part 1 of Schedule 24;
- (b) explain in full the codings used on the vial;
- (c) indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial; and
- (d) indicate the number of capsules or, for liquids, the number of millilitres per container.

(3) The label on the vial must include—

- (a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;
- (b) the batch identification and expiry date of the product;
- (c) the international symbol for radioactivity;
- (d) the name and address of the manufacturer; and
- (e) the amount of radioactivity; as mentioned in paragraph 2(c).

Leaflets relating to radionuclides

263.—(1) The licensing authority must ensure that a detailed instruction leaflet is enclosed with—

- (a) radiopharmaceuticals;
- (b) radionuclide generators;
- (c) radionuclide kits; or
- (d) radionuclide precursors.

(2) The leaflet must include the information specified in Schedule 27.

(3) The leaflet must also include—

- (a) any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product; and
- (b) special precautions for the disposal of the packaging and its unused contents.

Homoeopathic medicines

264.—(1) The outer packaging and immediate packaging and, where a package leaflet is included, the package leaflet of a homoeopathic medicinal product must clearly include the words “homoeopathic medicinal product”.

(2) The outer packaging and immediate packaging and, where a package leaflet is included, the package leaflet of a registrable homoeopathic medicinal product must also include the information

specified in paragraph (1) and Part 1 of Schedule 28 and no other information (unless paragraph (5) or (6) applies).

(3) Regulation (4) applies in a case where a package leaflet is not included with a registrable homoeopathic medicinal product.

(4) Unless the context requires otherwise, any requirement of these Regulations that is expressed by reference to a package leaflet shall be taken to refer to—

- (a) the outer packaging or the immediate packaging of the product; or
- (b) in a case to which paragraph (5) or paragraph (6) applies, the outer packaging of the product.

(5) Where the immediate packaging of a registrable homoeopathic medicinal product is in the form of a blister pack and is placed in outer packaging which complies with the requirements of this regulation and Part 1 of Schedule 28, the immediate packaging must include the information specified in this regulation and Part 2 of Schedule 28.

(6) Where the immediate packaging of a registrable homoeopathic medicinal product is too small to display the information required by Part 1 of Schedule 28, the immediate packaging must include the information specified in this regulation and Part 3 of Schedule 28.

Additional requirements for traditional herbal medicinal products

265.—(1) Schedule 29 imposes additional requirements in relation to traditional herbal medicinal products.

(2) Nothing in this regulation or Schedule 29 requires information to appear on—

- (a) a package containing a traditional herbal medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of the package;
- (b) a paper bag or similar wrapping in which a package that contains a traditional herbal medicinal product and bears information in accordance with the requirements of this regulation and that Schedule is placed at the time of sale or supply;
- (c) a package enclosing a package of a traditional herbal medicinal product for export;
- (d) an ampoule or other container of not more than 10 millilitres' nominal capacity which is enclosed in a package on which information appears in accordance with the requirements of this regulation and that Schedule; or
- (e) a blister pack or similar packaging, enclosed in a package labelled in accordance with the requirements of this regulation and that Schedule.

Language requirements etc

266.—(1) Information given in accordance with the requirements of this Part must be given in English unless either or both of paragraphs (2) and (3) applies.

(2) This paragraph applies in the case of a medicinal product that has been designated as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products⁽⁸⁶⁾ where—

- (a) any information specified in paragraph (1) is given in a language of an EEA State other than English; and
- (b) the licensing authority accedes to a reasoned request that the information need not be given in English.

⁽⁸⁶⁾ OJ No L 18, 22.1.2000, p.1, as amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14.

(3) This paragraph applies in the case of a product for which the licensing authority grants an Article 126a authorisation where the licensing authority decides that the information need not be given in English.

(4) In a case where paragraph (5) applies, the licensing authority may grant either or both of—

- (a) an exemption from the obligation that certain particulars should appear on the outer and immediate packaging and in the package leaflet of the medicinal product in accordance with this Part; and
- (b) a full or partial exemption from the obligation that the information included on the outer and immediate packaging and in the package leaflet for the product must be given in English in accordance with paragraph (1).

(5) This paragraph applies—

- (a) when a medicinal product is not intended to be delivered directly to the patient; or
- (b) where there are severe problems in respect of the availability of the medicinal product.

(6) The licensing authority may make the grant of an exemption in accordance with paragraph (4) subject to measures that it considers necessary to safeguard human health

(7) Information given in English in accordance with this regulation may be given in several languages in addition to English, provided that the same particulars appear in all the languages used.

Submission of mock-ups of packaging and leaflets to licensing authority

267.—(1) At the time when a person applies for a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, the person must submit to the licensing authority—

- (a) one or more mock-ups of the outer packaging and immediate packaging proposed for the product; and
- (b) a draft package leaflet.

(2) If the application is for a marketing authorisation, Article 126a authorisation or traditional herbal registration, the person must also provide to the licensing authority the results of assessments of the packaging and package leaflet carried out in co-operation with target patient groups.

(3) The licensing authority must refuse the application for a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration if—

- (a) the packaging or the package leaflet does not comply with the requirements of this Part; or
- (b) (in relation to an application for a marketing authorisation, Article 126a authorisation or traditional herbal registration) the information on the packaging or the package leaflet does not accord with the particulars listed in the summary of the product characteristics.

(4) If the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a product wishes to make changes to the packaging or the package leaflet (other than a change connected with the summary of the product characteristics), the proposed change must be submitted to the licensing authority in accordance with paragraph (5).

(5) In the circumstances in paragraph (4) the holder must submit to the licensing authority such of the following as are affected by the proposed change—

- (a) one or more mock-ups of the outer packaging and immediate packaging of the product showing the proposed change; and
- (b) a draft package leaflet showing the proposed change.

(6) If the licensing authority has not refused a proposed change within the period of 90 days beginning with the date of the submission, the applicant may make the change.

Enforcement and offences

Offence relating to packaging and package leaflets: holder of authorisation etc

268.—(1) This regulation applies to the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product who sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, a medicinal product to which the authorisation, certificate or registration relates.

- (2) A person to whom this regulation applies is guilty of an offence if—
- (a) a package or package leaflet relating to the product does not comply with the applicable requirements of this Part or Article 28 or 32 of the Paediatric Regulation; or
 - (b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.

Offences relating to packaging and package leaflets: other persons

269.—(1) This regulation applies to a person, other than the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply.

- (2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, knowing or having reasonable cause to believe—
- (a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part or Article 28 or 32 of the Paediatric Regulation; or
 - (b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.

Non-compliance with requirements of this Part

270.—(1) If the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration fails to comply with a requirement imposed by this Part in relation to a medicinal product, the licensing authority may give a notice to the holder requiring compliance within three months or such other period (which may be less than three months) as may be specified in the notice.

(2) If the holder fails to comply with the notice, the licensing authority may suspend the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration until the holder complies with the requirements of this Part.

- (3) A person who fails to comply with a notice under this regulation is guilty of an offence.

Offences: penalties

- 271.** A person who is guilty of an offence under regulation 268, 269 or 270 is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years, or to both.

CHAPTER 2

Requirements relating to child safety

Interpretation

272. In this Chapter—

“appropriate practitioner” means any of the persons described as appropriate practitioners in relation to any prescription only medicine in regulation 214(3), (5) and (6);

“regulated medicinal product” means a medicinal product containing aspirin, paracetamol or more than 24mg of elemental iron, in the form of tablets, capsules, pills, lozenges, pastilles, suppositories or oral liquids, but does not include—

- (a) effervescent tablets containing not more than 25% of aspirin or paracetamol by weight;
- (b) medicinal products in sachets or other sealed containers which hold only one dose;
- (c) medicinal products which are not intended for retail sale or for supply in circumstances corresponding to retail sale; or
- (d) medicinal products which are for export only.

Child resistant containers for regulated medicinal products

273.—(1) Regulated medicinal products sold or supplied otherwise than in accordance with regulation 274 may be sold only in containers which are—

- (a) opaque or dark tinted; and
- (b) child resistant.

(2) For the purposes of these Regulations, containers which are not reclosable are child resistant if they have been evaluated in accordance with, and comply with the requirements of—

- (a) British Standard EN 14375:2003 published by the British Standards Institution on 18th April 2005; or
- (b) any equivalent or higher technical specification for non-reclosable child resistant packaging recognised for use in the European Economic Area.

(3) For the purposes of these Regulations, containers which are reclosable are child resistant if they have been evaluated in accordance with, and comply with the requirements of—

- (a) British Standard EN ISO 8317:2004 published by the British Standards Institution on 11th May 2005; or
- (b) any equivalent or higher technical specification for reclosable child resistant packaging recognised for use in the European Economic Area.

Exemptions from regulation 273

274.—(1) Regulation 273 does not apply to the retail sale, or supply in circumstances corresponding to retail sale, of regulated medicinal products in accordance with paragraph (2).

(2) Sale or supply is in accordance with this paragraph if the sale or supply is carried out—

- (a) by or under the supervision of a pharmacist;
- (b) on premises which are a registered pharmacy; and
- (c) either—

- (i) in accordance with a prescription given by an appropriate practitioner where it is not reasonably practicable to provide the regulated medicinal products in containers that are both opaque or dark tinted and child resistant, or
 - (ii) at the request of a person who is aged 16 or over and specifically requests that the regulated medicinal products not be contained in a child resistant container.
- (3) Regulation 273 also does not apply to the sale or supply of regulated medicinal products—
- (a) by a doctor or dentist to a patient, or the patient’s carer, for the patient’s use;
 - (b) by a doctor or dentist to a person who is an appropriate practitioner, at the request of that person, for administration to a patient of that person; or
 - (c) in the course of the business of a hospital or health centre, where the sale or supply is for the purposes of administration, whether in the hospital or health centre or elsewhere, in accordance with the directions of an appropriate practitioner.

Colouring of aspirin and paracetamol products for children

275. The sale or supply of a medicinal product containing aspirin or paracetamol of any colour other than white is prohibited if—

- (a) it is a product for children aged 12 or under; and
- (b) in the case of paracetamol, it is in a solid form (including tablets, capsules, pills, lozenges, pastilles or suppositories).

Offences

276.—(1) A person is guilty of an offence if, in the course of a business, the person sells or supplies, or possesses for the purposes of sale or supply—

- (a) a regulated medicinal product in a container which does not comply with the requirements of regulation 273, unless the sale or supply is or would be exempt from those requirements under regulation 274; or
 - (b) a medicinal product containing aspirin or paracetamol the sale or supply of which is prohibited under regulation 275.
- (2) A person guilty of an offence under this regulation is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding 2 years, or to both.

PART 14

Advertising

CHAPTER 1

General

Interpretation

277.—(1) In this Part—

“court” means the High Court or, in Scotland, the Court of Session;

“injunction” (except in regulation 313) includes an interim injunction;

“OFCOM” means the Office of Communications;

“person qualified to prescribe or supply medicinal products” includes—

- (a) persons who, in the course of their profession or in the course of a business, may lawfully—
 - (i) prescribe medicinal products,
 - (ii) sell medicinal products by retail, or
 - (iii) supply medicinal products in circumstances corresponding to retail sale; and
- (b) employees of such persons;

“publication”, in relation to an advertisement, means the dissemination or issue of that advertisement—

- (a) orally;
- (b) in writing;
- (c) by means of an electronic communications network within the meaning of the Communications Act 2003⁽⁸⁷⁾; or
- (d) in any other way,

and includes causing or procuring such publication by or on behalf of another person, and “publish” has a corresponding meaning.

(2) In the application of this Part to Scotland—

- (a) references to an injunction are to be read as references to an interdict; and
- (b) references to an interim injunction are to be read as references to an interim interdict.

Functions of the Ministers

278. A function of the Ministers under this Part may be exercised by either of them acting alone or both of them acting jointly (and references in this Part to “the Ministers” are to be read accordingly).

CHAPTER 2

Requirements relating to advertising

General

Products without a marketing authorisation etc

279. A person may not publish an advertisement for a medicinal product unless one of the following 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.

(87) 2003 c.21.

General principles

280.—(1) A person may not publish an advertisement for a medicinal product with a marketing authorisation, traditional herbal registration or Article 126a authorisation unless the advertisement complies with the particulars listed in the summary of the product characteristics.

(2) A person may not publish an advertisement for a medicinal product unless the advertisement encourages the rational use of the product by presenting it objectively and without exaggerating its properties.

(3) A person may not publish an advertisement for a medicinal product that is misleading.

Duties of authorisation holders and registration holders

281.—(1) This regulation applies to a person who holds—

- (a) a marketing authorisation for a medicinal product;
- (b) a certificate of registration for a medicinal product;
- (c) a traditional herbal registration for a medicinal product; or
- (d) an Article 126a authorisation for a medicinal product.

(2) The person must establish a scientific service to compile and collate all information relating to the product (whether received from medical sales representatives employed by that person or from any other source).

(3) The person must ensure that any medical sales representative who promotes the product is given sufficient training, and has sufficient scientific knowledge, to enable the representative to provide information about the product that is as precise and complete as possible.

(4) The person must retain—

- (a) a sample of any advertisement for which the person is responsible relating to the product; and
- (b) a statement indicating the persons to whom the advertisement is addressed, the method of its publication and the date when it was first published.

(5) The person must, if required to do so by notice given to the person by the Ministers, within the period specified in that notice—

- (a) provide a copy of the sample and statement mentioned in paragraph (4) to the Ministers;
- (b) supply such other information as the Ministers may request for the purposes of their functions under this Part; or
- (c) provide such assistance as the Ministers may request for those purposes.

Advertising to the public

Application of regulations 283 to 292

282. Regulations 283 (products for the purpose of inducing abortions) to 292 (exception for approved vaccination campaigns) apply to advertisements wholly or mainly directed at members of the public

Products for the purpose of inducing abortions

283. A person may not publish an advertisement that is likely to lead to the use of a medicinal product for the purpose of inducing an abortion.

Prescription only medicines

284.—(1) A person may not publish an advertisement that is likely to lead to the use of a prescription only medicine.

(2) This regulation is subject to regulation [292](#) (exception for approved vaccination campaigns).

Narcotic and psychotropic substances

285.—(1) A person may not publish an advertisement relating to a medicinal product that—

- (a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or
- (b) contains a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

(2) This regulation is subject to regulation [292](#) (exception for approved vaccination campaigns).

Material relating to diagnosis

286.—(1) A person may not publish an advertisement relating to a medicinal product that states, or implies, that a medical consultation or surgical operation is unnecessary.

(2) A person may not, in particular, publish an advertisement relating to a medicinal product that offers to provide a diagnosis or suggest a treatment by post or by means of an electronic communications network within the meaning of the Communications Act 2003.

(3) A person may not publish an advertisement relating to a medicinal product that might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.

Material about effects of medicinal product

287.—(1) A person may not publish an advertisement relating to a medicinal product that suggests that the effects of taking the medicinal product—

- (a) are guaranteed;
- (b) are better than or equivalent to those of another identifiable treatment or medicinal product; or
- (c) are not accompanied by any adverse reaction.

(2) A person may not publish an advertisement relating to a medicinal product that uses in terms that are misleading or likely to cause alarm pictorial representations of—

- (a) changes in the human body caused by disease or injury; or
- (b) the action of the medicinal product on the human body.

(3) A person may not publish an advertisement relating to a medicinal product that refers in terms that are misleading or likely to cause alarm to claims of recovery.

(4) A person may not publish an advertisement relating to a medicinal product that suggests that—

- (a) the health of a person who is not suffering from any disease or injury could be enhanced by taking the medicinal product; or
- (b) the health of a person could be affected by not taking the medicinal product.

(5) Paragraph (4)(b) is subject to regulation [292](#) (exception for approved vaccination campaigns).

Material about status of medicinal product

288. A person may not publish an advertisement relating to a medicinal product that suggests that—

- (a) it is a foodstuff, cosmetic or other consumer product that is not a medicinal product; or
- (b) its safety or efficacy is due to the fact that it is natural.

Recommendations by scientists etc

289. A person may not publish an advertisement relating to a medicinal product that refers to a recommendation by—

- (a) scientists;
- (b) health care professionals; or
- (c) persons who because of their celebrity could encourage use of the medicinal product.

Advertisements directed at children

290. A person may not publish an advertisement relating to a medicinal product that contains any material that is directed principally at children.

Form and content of advertisement

291.—(1) A person may not publish an advertisement relating to a medicinal product unless it is presented so that—

- (a) it is clear that it is an advertisement; and
- (b) the product is clearly identified as a medicinal product.

(2) A person may not publish an advertisement relating to a medicinal product unless it includes—

- (a) the name of the medicinal product;
- (b) if the medicinal product contains only one active ingredient, the common name of the active ingredient;
- (c) the information necessary for the correct use of the medicinal product; and
- (d) an express and clear invitation to read carefully the instructions on the package or in the package leaflet (as the case may be).

(3) This regulation is subject to regulation [296](#) (exception for advertisements intended as a reminder).

(4) Paragraph (2) is subject to regulation [301](#) (advertisements for registered homoeopathic medicinal products).

Exception for approved vaccination campaigns

292. Regulations [284](#) (prescription only medicines), [285](#) (narcotic and psychotropic substances) and [287\(4\)\(b\)](#) (material about effects of medicinal products) do not apply to an advertisement as part of a vaccination campaign that—

- (a) relates to a medicinal product that is a vaccine or serum; and
- (b) has been approved by the Ministers.

Prohibition of supply to the public for promotional purposes

Prohibition of supply to the public for promotional purposes

293.—(1) The holder of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.

(2) A person who carries on a medicines business may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.

(3) This regulation applies regardless of whether the promotional purpose is that of the seller or supplier or of a third party.

(4) In this regulation “medicines business” means a business that consists in whole or in part of manufacturing, selling or supplying medicinal products.

Advertising to persons qualified to prescribe or supply etc

General requirements

294.—(1) This regulation applies to an advertisement that—

- (a) relates to a medicinal product; and
- (b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not publish an advertisement to which this regulation applies unless—

- (a) subject to paragraph (3), it contains the particulars set out in paragraphs 1 to 8 of Schedule 30; and
- (b) in the case of a written advertisement, it is in accordance with paragraph 9 of that Schedule.

(3) In the case of an advertisement that is not a written advertisement, those particulars may alternatively be made available in written form to all persons to whom the advertisement is made available.

(4) This regulation—

- (a) does not apply to an advertisement to which regulation 295 (abbreviated advertisements) applies;
- (b) does not apply to oral representations made by medical sales representatives to which regulation 299 (medical sales representatives) applies; and
- (c) is subject to regulations 296 (exception for advertisements intended as a reminder) and 301 (advertisements for registered homoeopathic medicinal products).

Abbreviated advertisements

295.—(1) This regulation applies to an abbreviated advertisement that—

- (a) relates to a medicinal product; and
- (b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not issue an abbreviated advertisement to which this regulation applies unless it contains—

- (a) the particulars set out in paragraphs 2 to 6 of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply);
- (b) the statement “Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:”; accompanied by

- (c) a web site address that corresponds to that statement; and
 - (d) the name and address of the holder of the marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation for the medicinal product, or the business name and address of the part of the holder's business that is responsible for its sale or supply.
- (3) The web site at the address mentioned in sub-paragraph (2)(c) must make available—
- (a) the particulars set out in Schedule 30; or
 - (b) a copy of the summary of the product characteristics.
- (4) In this regulation, “abbreviated advertisement” means an advertisement, other than a loose insert, that—
- (a) does not exceed 420 square centimetres in size; and
 - (b) appears in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply medicinal products.
- (5) This regulation is subject to regulation 301 (advertisements for registered homoeopathic medicinal products).

Exception for advertisements intended as a reminder

296. Regulations 291 (form and content of advertisement) and 294 (general requirements) do not apply to an advertisement relating to a medicinal product if the advertisement is intended solely as a reminder of the product and consists solely of—

- (a) in the case of a product other than a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name or trademark; and
- (b) in the case of a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name, invented name or trademark or the scientific name of the stock or stocks from which it is derived.

Written material accompanying promotions

297.—(1) A person may not as part of the promotion of a medicinal product send or deliver any written material to a person qualified to prescribe or supply medicinal products unless the material—

- (a) contains particulars in accordance with all the paragraphs of Schedule 30; and
- (b) states the date on which it was drawn up or last revised.

(2) A person may not include any information in written material to which paragraph (1) applies unless it—

- (a) is accurate;
- (b) is up-to-date;
- (c) can be verified; and
- (d) is sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the product to which it relates.

(3) A person may not include any illustrative material in written material to which paragraph (1) applies unless—

- (a) the illustrative material is accurately reproduced; and
- (b) the written material indicates the precise source of the illustrative material.

(4) In this regulation “illustrative material” means a quotation, table or any other illustrative material taken from a medical journal or other scientific work.

Free samples for persons qualified to prescribe or supply medicinal products

298.—(1) A person (“the supplier”) may not supply a free sample of a medicinal product to another person (“the recipient”) unless the following conditions are met.

- (2) Condition A is that the recipient—
 - (a) is qualified to prescribe medicinal products; and
 - (b) receives the sample for the purpose of acquiring experience in dealing with the product in question.
- (3) Condition B is that the sample is supplied to the recipient—
 - (a) on an exceptional basis; and
 - (b) in response to a request from, and signed and dated by, the recipient.
- (4) Condition C is that, taking the year in which the sample is supplied as a whole, only a limited number of samples of the product in question are supplied to the recipient in that year.
- (5) Condition D is that the sample—
 - (a) is no larger than the smallest presentation of the product that is available for sale in the United Kingdom;
 - (b) is marked “free medical sample – not for resale” or bears a similar description; and
 - (c) is accompanied by a copy of the summary of the product characteristics.
- (6) Condition E is that the sample does not contain—
 - (a) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or
 - (b) a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).
- (7) Condition F is that the supplier maintains an adequate system of control and accountability in relation to the supply of free samples.

Medical sales representatives

299.—(1) This regulation applies in relation to the promotion by a medical sales representative of medicinal products to persons qualified to prescribe or supply such products.

(2) During each visit for promotional purposes the representative must give to, or have available for, each person visited a copy of the summary of the product characteristics for each product promoted.

(3) The representative must report all information, with particular reference to any adverse reactions, that—

- (a) is received from persons visited for promotional purposes; and
- (b) relates to the use of a product promoted,

to the scientific service established in accordance with regulation [281\(2\)](#) by the holder of the marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation for the product.

Inducements and hospitality

300.—(1) A person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer, or promise any gift, pecuniary advantage or benefit unless it is—

- (a) inexpensive; and
 - (b) relevant to the practice of medicine or pharmacy.
- (2) A person may not provide hospitality at a meeting or event held for the purposes of the promotion of a medicinal product unless—
- (a) the hospitality is strictly limited to the main purposes of the meeting or event; and
 - (b) the person to whom it is provided or offered is a health care professional.
- (3) Nothing in this regulation shall prevent any person providing hospitality at an event held for purely professional or scientific purposes provided that—
- (a) the hospitality is strictly limited to the main scientific objective of the event; and
 - (b) the person to whom it is provided or offered is a health care professional.
- (4) A person qualified to prescribe or supply medicinal products may not solicit or accept any gift, pecuniary advantage, benefit or hospitality that is prohibited by this regulation.
- (5) In this regulation “hospitality” includes—
- (a) sponsorship of a person’s attendance at a meeting or event; and
 - (b) the payment of travelling or accommodation expenses.
- (6) This regulation does not apply in relation to measures or trade practices relating to prices, margins or discounts that were in existence on 1st January 1993.

Homoeopathic medicinal products

Advertisements for registered homoeopathic medicinal products

301.—(1) A person may not publish an advertisement relating to a homoeopathic medicinal product to which a certificate of registration relates unless the advertisement meets the following conditions.

- (2) Condition A is that the advertisement does not mention any specific therapeutic indications.
- (3) Condition B is that the advertisement does not contain any details other than those mentioned in Schedule 28 (labelling requirements for registrable homoeopathic medicinal products).
- (4) Nothing in regulation 291(2) (form and content of advertisement), 294 (general requirements) or 295 (abbreviated advertisements) requires an advertisement relating to a homoeopathic medicinal product to which a certificate of registration relates to contain any detail not specified in Schedule 28.

Traditional herbal medicinal products

Advertisements for traditional herbal medicinal products

302. A person may not publish an advertisement relating to a herbal medicinal product to which a traditional herbal registration relates unless it contains—

- (a) the words “Traditional herbal medicinal product for use in”; followed by
- (b) a statement of one or more therapeutic indications for the product consistent with the terms of the registration; followed by
- (c) the words “exclusively based on long standing use”.

Offences

Offences

303.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Chapter.

(2) A breach of a provision in this Chapter includes any—

- (a) contravention by any person of any prohibition in this Chapter; and
- (b) failure by any person to comply with any requirement or obligation in this Chapter.

(3) A person guilty of an offence under this regulation other than one to which paragraph (4) applies is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(4) This paragraph applies to an offence consisting of a breach of—

- (a) regulation 298(1) (free samples);
- (b) regulation 299(2) or (3) (medical sales representatives); or
- (c) regulation 300(4) (solicitation or acceptance of inducements or hospitality).

(5) A person guilty of an offence to which paragraph (4) applies is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

CHAPTER 3

Monitoring of Advertising

Scrutiny by Ministers

Requirement to provide copy advertisement

304.—(1) The Ministers may give a notice in writing under paragraph (2) or (3) to any person appearing to them to be concerned or likely to be concerned with the publication of advertisements relating to medicinal products.

(2) A notice under this paragraph is a notice that requires the person to whom it is given to provide the Ministers within a specified period with a copy of any advertisement that, as at the date of service of the notice, the person has published or proposes to publish and that relates to—

- (a) a specified medicinal product; or
- (b) medicinal products of a specified class or description.

(3) A notice under this paragraph is a notice that requires the person to whom it is given to provide the Ministers with a copy of any advertisement that the person proposes to publish during a specified period and that relates to—

- (a) a specified medicinal product; or
- (b) medicinal products of a specified class or description.

(4) The period specified in a notice under paragraph (3) must not exceed 12 months.

(5) A notice under paragraph (3) must specify the number of days before the proposed publication date of any advertisement by which a copy of the advertisement must be provided to the Ministers.

(6) A notice under paragraph (3) may be withdrawn by the Ministers before the expiry of the specified period.

(7) A notice under paragraph (2) or (3) may require the person to whom it is given not to publish, or further publish, during a specified period any advertisement a copy of which the person is required by the notice to provide to the Ministers.

(8) A notice under paragraph (2) or (3) must give the Ministers' reasons for giving the notice and (if appropriate) for imposing a requirement under paragraph (7).

(9) In this regulation "specified" means specified in the notice.

Invitation to make representations about compatibility

305.—(1) This regulation applies if, having considered an advertisement a copy of which is obtained by them pursuant to a notice given under regulation 304 or by some other means, the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2.

(2) The Ministers may give a notice in writing under this regulation to any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement.

(3) A notice under this regulation must—

- (a) state that the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2;
- (b) give the reasons why they are minded to make the determination;
- (c) state that the person to whom it is given may make written representations to the Ministers within the period of 21 days beginning immediately after the date of the notice as to why the advertisement is compatible with the prohibitions imposed by Chapter 2; and
- (d) refer to the action that may be taken by the Ministers under regulation 306.

(4) A notice under this regulation may require the person to whom it is given not to publish, or to cease to publish, the advertisement.

Decision about compatibility

306.—(1) This regulation applies if the Ministers have given a notice under regulation 305 ("the original notice") to a person.

(2) After the end of the period of 21 days referred to in that regulation, the Ministers must give a further notice in writing ("the new notice") to that person of their determination whether the advertisement is compatible with the prohibitions imposed by Chapter 2.

(3) In making that determination, the Ministers must take account of any representations made in accordance with that regulation.

(4) If—

- (a) the Ministers make a determination that the advertisement is compatible with the prohibitions imposed by Chapter 2; and
- (b) the original notice imposed a requirement under regulation 305(4),

the new notice must provide that the requirement no longer applies.

(5) The following provisions apply if the Ministers make a determination that the advertisement is incompatible with the prohibitions imposed by Chapter 2.

(6) The new notice must give the Ministers' reasons for the determination.

(7) If the original notice imposed a requirement under regulation 305(4), the new notice may provide—

- (a) that the requirement is to continue to apply; or

(b) that the requirement no longer applies.

(8) If the original notice did not impose a requirement under regulation 305(4), the new notice may require the person to whom it is given not to publish, or to cease to publish, the advertisement.

Corrective statement

307.—(1) This regulation applies if the new notice—

- (a) maintains the application of a requirement imposed under regulation 305(4) to cease to publish the advertisement that is the subject of the notice; or
- (b) imposes a requirement to cease to publish that advertisement.

(2) The new notice may require the person to whom it is given to publish—

- (a) the Ministers' reasons for making the determination that the advertisement was incompatible with the prohibitions imposed by Chapter 2, either in full or in part; and
- (b) a corrective statement concerning the advertisement.

(3) A requirement imposed under paragraph (2)—

- (a) must specify the time within which publication must take place; and
- (b) may specify the form of publication.

Offences

308.—(1) A person is guilty of an offence if that person fails to comply with a requirement imposed by a notice given to that person under—

- (a) regulation 304(2) or (3);
- (b) regulation 305(4) (including such a notice as maintained under regulation 306(7)); or
- (c) regulation 306(8).

(2) A person guilty of an offence under paragraph (1) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(3) A person is guilty of an offence if that person fails to comply with a requirement imposed on that person under regulation 307(2).

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Complaints to Ministers

Complaints to Ministers: duty to consider

309.—(1) This regulation applies if a person makes a complaint to the Ministers that an advertisement that has been published, or that is proposed to be published, is incompatible with the prohibitions imposed by Chapter 2.

(2) Subject to the following provisions of this regulation and to regulation 310, the Ministers must consider the complaint unless it appears to the Ministers to be frivolous or vexatious.

(3) The Ministers are not under any duty to consider a complaint if either OFCOM or a body that appears to the Ministers to be a self-regulatory body that deals with complaints about advertisements of the type in question is already dealing with the same complaint.

- (4) If the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306) they—
- (a) may consider the complaint; but
 - (b) are not under any duty to do so.
- (5) If the complaint is one that OFCOM would be under a duty to consider if it had been made to OFCOM (see regulation 314) the Ministers must—
- (a) investigate the complaint; or
 - (b) seek the agreement of the complainant to the complaint being referred to OFCOM.
- (6) If, within a reasonable time of being approached by the Ministers, the complainant agrees to the complaint being referred to OFCOM the Ministers must refer the complaint to OFCOM.
- (7) If, within a reasonable time of being approached by the Ministers, the complainant does not agree to the referral of the complaint, the Ministers must consider the complaint.
- (8) The Ministers must also consider the complaint if, having referred it to OFCOM, OFCOM—
- (a) decides not to consider the complaint because it appears to OFCOM to be frivolous or vexatious; or
 - (b) fails to deal adequately with the complaint within a reasonable time of the referral being made.

Complaints to Ministers: power to refer

- 310.**—(1) This regulation applies if—
- (a) a person (“the complainant”) makes a complaint within paragraph (2) to the Ministers that an advertisement that has been published, or that it is proposed be published, is incompatible with the prohibitions imposed by Chapter 2; and
 - (b) the complaint does not appear to the Ministers to be frivolous or vexatious.
- (2) A complaint is within this paragraph if—
- (a) it is a complaint that the advertisement contains material prohibited by any of regulations 286 to 290, but is not a complaint that OFCOM would be under a duty to consider if it had been made to OFCOM (see regulation 314); or
 - (b) it is a complaint that the advertisement is incompatible with any of the prohibitions imposed by regulations 294 to 300.
- (3) The Ministers may—
- (a) select a body that appears to them to be a self-regulatory body that deals with complaints about advertisements of the type in question (“the appropriate body”); and
 - (b) seek the agreement of the complainant to the complaint being referred to the appropriate body.
- (4) If within a reasonable time of being approached by the Ministers the complainant agrees to the complaint being referred to the appropriate body, the Ministers must refer the complaint to that body.
- (5) If within a reasonable time of being approached by the Ministers the complainant does not agree to the referral of the complaint, the Ministers must consider the complaint.
- (6) The Ministers must also consider the complaint if, having referred it to the appropriate body—
- (a) the appropriate body decides not to consider the complaint because it appears to the body to be frivolous or vexatious; or
 - (b) the Ministers think that the appropriate body has failed to deal adequately with the complaint within a reasonable time of the referral being made.

(7) But if the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306)—

- (a) the duties in paragraphs (4) to (6) do not apply; and
- (b) each of those paragraphs has effect as if it conferred a power on the Ministers to act as mentioned in that paragraph.

Injunctions

Application for injunction

311.—(1) This regulation applies—

- (a) if the Ministers consider that an advertisement that has been published, or that is proposed to be published, is incompatible with the prohibitions imposed by Chapter 2; and
- (b) whether or not a complaint has been made to the Ministers or to any other person.

(2) The Ministers may apply to the court for an injunction against any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement.

(3) On the making of an application under paragraph (2), the court may grant an injunction prohibiting the publication, or further publication, of the advertisement.

(4) An injunction granted under paragraph (3) may also prohibit the publication, or further publication, of any advertisement in similar terms or likely to convey a similar impression.

(5) The court may not refuse to grant an injunction for lack of evidence that—

- (a) the publication, or proposed publication, of the advertisement has given rise to loss or damage to any person; or
- (b) the person responsible for the advertisement intended it to be incompatible with the prohibitions imposed by Chapter 2 or failed to exercise proper care to prevent it from being so incompatible.

(6) The court must give its detailed reasons in writing for its decision to grant or refuse an injunction.

(7) Where the court grants an injunction, the Ministers must as soon as is reasonably practicable provide the following in writing to each person against whom the injunction has been granted—

- (a) the court's reasons for granting the injunction;
- (b) any remedy available in the court; and
- (c) the time limit to be met for any remedy to be available.

Application for injunction: accuracy of factual claim

312.—(1) This regulation applies if—

- (a) an application for an injunction is made under regulation 311; and
- (b) the advertisement in question makes a factual claim about the medicinal product to which it relates.

(2) The court may require any person appearing to it to be responsible for the advertisement to provide evidence as to the accuracy of the factual claim.

(3) The court may impose a requirement under paragraph (2)—

- (a) on the application of any party to the proceedings for the injunction; or
- (b) of its own motion.

(4) In deciding whether or not to impose a requirement under paragraph (2) the court must have regard to the interests of any person who would be subject to, or affected by, the requirement.

(5) A requirement imposed under paragraph (2) must specify the time within which the evidence must be provided.

(6) If the person on whom a requirement is imposed under paragraph (2) fails to comply with it the court may infer that the factual claim is inaccurate.

(7) A person may fail to comply with a requirement imposed under paragraph (2) by—

- (a) not providing any evidence; or
- (b) providing evidence that the court considers inadequate.

Grant of injunction: publication of decision and corrective statement

313.—(1) This regulation applies if the court grants an injunction under regulation 311, other than an interim injunction, in respect of an advertisement that has been published.

(2) The Ministers may by notice in writing require any person against whom the injunction has been granted to publish—

- (a) all or part of the court’s decision; and
- (b) a corrective statement concerning the advertisement in respect of which the application for the injunction was made.

(3) A requirement imposed under paragraph (2)—

- (a) must specify the time within which publication must take place; and
- (b) may specify the form of publication.

(4) If a person (“P”) fails to comply with a requirement imposed under paragraph (2) the Ministers may certify that failure to the court and the court may enquire into the matter.

(5) If the court enquires into the matter it must as part of its enquiry—

- (a) hear any witnesses produced against or on behalf of P; and
- (b) consider any statement offered in P’s defence.

(6) If having conducted its enquiry the court is satisfied that P failed without reasonable excuse to comply with a requirement imposed under paragraph (2) it may deal with P as if P were in contempt of court.

Complaints to OFCOM

Complaints to OFCOM

314.—(1) This regulation applies if OFCOM—

- (a) receives from a person a complaint that an advertisement that contains material prohibited by any of regulations 286 to 290 (“prohibited material”) has been included in—
 - (i) a licensed service, or
 - (ii) S4C Digital or a service provided by the Welsh Authority under section 205 of the Communications Act 2003(88) (“the 2003 Act”); or
- (b) has a complaint as described in sub-paragraph (a) referred to it by the Ministers under regulation 309(5) and (6).

(2) OFCOM must consider the complaint unless—

- (a) the complaint appears to it to be frivolous or vexatious; or
 - (b) paragraph (3) applies.
- (3) If the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306) OFCOM—
- (a) may consider the complaint; but
 - (b) is not subject to any duty to do so.
- (4) If, having considered the complaint, OFCOM considers that the advertisement contains prohibited material it may—
- (a) in the case of an advertisement that has been included in a licensed service, give to the person who is the holder of the licence in respect of that service a direction to exclude the advertisement from the licensed service; and
 - (b) in the case of an advertisement that has been included in S4C Digital or a service provided by the Welsh Authority under section 205 of the 2003 Act, give to the Welsh Authority a direction to exclude the advertisement from S4C Digital or the service provided under section 205 of the 2003 Act.
- (5) If OFCOM gives a direction under paragraph (4), it may also give a direction to the licence holder or (as the case may be) the Welsh Authority to exclude from the service any advertisement in similar terms or likely to convey a similar impression.
- (6) In deciding whether or not to exercise its power to give a direction under paragraph (4), OFCOM must disregard any lack of evidence that—
- (a) the publication of the advertisement has given rise to loss or damage to any person; or
 - (b) the person responsible for the advertisement intended it to be incompatible with the prohibitions imposed by Chapter 2 or failed to exercise proper care to prevent it from being so incompatible.
- (7) A direction given under this regulation to a licence holder is to be treated for the purposes of the 2003 Act as a direction with respect to a matter mentioned in section 325(5) of that Act.
- (8) A direction given under this regulation to the Welsh Authority is to be treated for the purposes of the Communications Act 2003 Act as a direction with respect to a matter mentioned in paragraph 14(2) of Schedule 12 to that Act.
- (9) If OFCOM gives a direction under this regulation, it must inform the licence holder or (as the case may be) the Welsh Authority in writing of its reasons for doing so.
- (10) In this regulation—
- “licensed service” means a service in respect of which OFCOM has granted a licence under Part 1 or 3 of the Broadcasting Act 1990(89) or Part 1 or 2 of the Broadcasting Act 1996(90);
- “S4C Digital” means the television service provided in digital form and known as S4C Digital; and
- “Welsh Authority” means the authority whose name is, by virtue of section 56(1) of the Broadcasting Act 1990(91), Sianel Pedwar Cymru.

(89) 1990 c.42.

(90) 1996 c.55.

(91) Section 56(1) was amended by section 406(7) of and Schedule 19(1) to the Communications Act 2003.

General

Public interest etc

315. In exercising the functions conferred on them by this Chapter, the Ministers, the court and OFCOM must have regard, in particular, to the public interest.

Civil proceedings

316. In exercising the functions conferred on them by this Chapter, the Ministers may institute civil proceedings in their own name.

PART 15

British Pharmacopoeia

British Pharmacopoeia and compendia

317.—(1) The British Pharmacopoeia Commission (in this Part referred to as “the BPC”) must, at such intervals as it thinks appropriate, prepare or cause to be prepared editions of the British Pharmacopoeia, containing such relevant information relating to substances, combinations of substances and articles falling within paragraph (2) as the BPC thinks appropriate.

(2) The substances, combinations of substances, and articles falling within this paragraph are—

- (a) substances, combinations of substances and articles (whether medicinal products or not) which are or may be used in the practice of medicine or surgery (other than veterinary medicine or veterinary surgery), dentistry or midwifery; and
- (b) substances, combinations of substances and articles used in the manufacture of anything falling within paragraph (a).

(3) The BPC may also, at such intervals as it thinks appropriate, prepare or cause to be prepared—

- (a) a compendium (other than the British Pharmacopoeia) containing such relevant information relating to substances, combinations of substances and articles within paragraph (2) as the BPC thinks appropriate; and
- (b) a compendium containing such relevant information as the BPC thinks appropriate in relation to—
 - (i) substances, combinations of substances and articles (whether veterinary medicinal products or not) which are or may be used in the practice of veterinary medicine or veterinary surgery; and
 - (ii) substances, combinations of substances and articles used in the manufacture of anything falling within sub-paragraph (i).

(4) The Ministers must arrange for the publication of anything prepared or caused to be prepared by the BPC under this regulation.

(5) In this Part—

- (a) a reference to preparing a thing or causing it to be prepared includes amending it, or causing it to be amended;
- (b) a reference to publication includes publication by electronic means; and
- (c) “relevant information”, in relation to a substance, combination of substances or article, means information consisting of descriptions of, standards for, or notes or other matter relating to the substance, combination of substances or article.

Lists of names

318.—(1) The BPC must, at such intervals as it thinks appropriate, prepare or cause to be prepared a list of names which appear to it to be suitable—

- (a) to be used as the names of substances, combinations of substances or articles falling within regulation 317(2) or (3)(b); and
- (b) to be placed at the head of monographs relating to those substances, combinations of substances or articles in any edition of the British Pharmacopoeia or in a compendium prepared under that regulation.

(2) Where a list has been prepared in accordance with paragraph (1), the Ministers must cause it to be published.

Other documents

319.—(1) The BPC must, at such intervals as it thinks appropriate, prepare or cause to be prepared other documents (in addition to those falling within regulation 317 or 318) containing such relevant information relating to substances, combinations of substances or articles falling within regulation 317(2) or (3)(b) as the BPC thinks appropriate.

(2) Where a document has been prepared in accordance with paragraph (1), the Ministers may cause it to be published.

Supplementary provisions

320.—(1) Anything published in accordance with a provision of this Part (other than regulation 319 (“a publication”)) must specify the date on which it is to take effect.

(2) The Ministers must give notice of the date mentioned in paragraph (1) by notices published in the London, Edinburgh and Belfast Gazettes not less than 21 days before that date.

(3) Where in any proceedings an enforcement authority produces a copy of a publication, it shall be presumed that the copy is a true copy of the edition of that publication that was in force at the time when the events that are the subject of the proceedings took place, unless evidence is adduced to the contrary.

Specified publications

321.—(1) In this regulation “specified publication” means any of the following—

- (a) the European Pharmacopoeia;
- (b) the British Pharmacopoeia;
- (c) the Cumulative List of Recommended International Nonproprietary Names;
- (d) a compendium prepared and published under regulation 317; or
- (e) a list of names prepared and published under regulation 318.

(2) Paragraph (3) applies if an authorisation refers to a specified publication, but not to a particular edition of the publication.

(3) Where this paragraph applies, in order to determine whether anything done at a time when the authorisation is in force is done in accordance with the authorisation, the reference to a specified publication is to be construed as a reference to the edition of the specified publication in force at that time, unless the authorisation expressly provides otherwise.

(4) In paragraph (3) the reference to the edition of a specified publication in force at a particular time is a reference to the edition of that publication in force, under whatever title, at that time.

(5) In this regulation “authorisation” means any of the following—

- (a) a manufacturer's licence;
- (b) a wholesale dealer's licence;
- (c) a marketing authorisation;
- (d) an Article 126a authorisation;
- (e) a certificate of registration; or
- (f) a traditional herbal registration.

PART 16

Enforcement

Validity of decisions and proceedings

322.—(1) The validity of a decision of the licensing authority under Parts 3 (manufacturing and wholesale dealing), 5 (UK marketing authorisations), 6 (certification of homoeopathic medicinal products), 7 (traditional herbal medicinal products) or 8 (Article 126a authorisations) is not to be questioned in any legal proceedings.

(2) The validity of a licence, authorisation, certificate or registration granted or issued, or other thing done, in pursuance of a decision of a kind mentioned in paragraph (1) is not to be questioned in any legal proceedings.

(3) Paragraphs (1) and (2) are subject to the following provisions of this regulation.

(4) A person to whom notice of the decision is given may make an application to the High Court to challenge the validity of the decision on the grounds that—

- (a) the decision is not within the powers conferred on the licensing authority; or
- (b) a requirement of these Regulations in connection with the matter to which the decision relates has not been complied with.

(5) An application under paragraph (4) must be made within the period of three months beginning immediately after the day on which notice of the decision is given to the applicant.

(6) On an application under paragraph (4) the High Court may—

- (a) make an interim order suspending the operation of the decision to which the application relates until the final determination of proceedings; or
- (b) quash the decision, if satisfied that—
 - (i) the decision is not within the powers conferred by these Regulations, or
 - (ii) the interests of the applicant have been substantially prejudiced by a failure to comply with a requirement under these Regulations.

(7) If a decision to grant a licence, authorisation, certificate or registration is quashed under this regulation—

- (a) a licence, authorisation, certificate or registration granted in pursuance of the decision is void; and
- (b) the application process for the grant of the licence, authorisation, certificate or registration may be continued as if the decision had not been made.

(8) In the application of this regulation to Scotland, references to the High Court are to be construed as references to the Court of Session.

Enforcement in England, Wales and Scotland

323.—(1) The Secretary of State must enforce or secure the enforcement of these Regulations and the relevant EU provisions in England, Wales and Scotland.

(2) The Secretary of State may make arrangements for either or both of—

(a) the General Pharmaceutical Council; or

(b) in respect of each area for which there is a drugs authority, the drugs authority for the area, to enforce the provisions of these Regulations listed in paragraph (3) to the extent specified in the arrangements.

(3) The provisions referred to in paragraph (2) are—

(a) regulations 251 (compliance with standards specified in certain publications) and 255(1)(e) (offences relating to dealings with medicinal products: compliance with standards specified in certain publications);

(b) Part 13 (packaging and leaflets); and

(c) Part 14 Chapter 2 (requirements relating to advertising).

(4) Arrangements made with the General Pharmaceutical Council under paragraph (2)(a) in relation to Part 14 Chapter 2 are to be limited to the enforcement of those provisions in respect of—

(a) advertisements displayed or representations made on or in any premises where medicinal products are sold by retail or supplied in circumstances corresponding to retail sale;

(b) advertisements displayed on any web site associated with such premises; and

(c) advertisements displayed on, or in close proximity to, a vending machine in which medicinal products are offered or exposed for sale.

(5) The General Pharmaceutical Council must continue to enforce—

(a) regulations 214 (sale or supply of prescription only medicines) and 220 (sale or supply of medicines not subject to general sale); and

(b) in their application to or in relation to premises that are registered pharmacies, the provisions of these Regulations to which paragraph (7) applies.

(6) In each area for which there is a drugs authority, that drugs authority must continue to enforce the provisions of these Regulations to which paragraph (7) applies in their application to or in relation to premises that are not registered pharmacies.

(7) This paragraph applies to regulations 221 (sale or supply of medicinal products subject to general sale) and 222 (sale of medicinal products from automatic machines).

(8) Functions conferred by virtue of paragraphs (2), (5) and (6) are to be exercised concurrently with the Secretary of State.

(9) Nothing in this regulation confers a function on a person in relation to—

(a) a hospital (except so much of the hospital as is a registered pharmacy); or

(b) so much of any premises as is used as a doctor's or dentist's practice.

(10) In this regulation "drugs authority" means—

(a) in England—

(i) in relation to a non-metropolitan county, metropolitan district or London borough, the council of that county, district or borough, and

(ii) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London;

(b) in Wales, the council of a county or county borough; and

(c) in Scotland, a council constituted in relation to a local government area under section 2 of the Local Government etc (Scotland) Act 1994⁽⁹²⁾.

(11) In this Part “premises” includes—

- (a) any place; and
- (b) a ship, aircraft, hovercraft or vehicle.

(12) Nothing in this regulation is to be construed as authorising any person other than the Lord Advocate or a procurator fiscal to institute proceedings in Scotland for an offence.

Enforcement in Northern Ireland

324.—(1) The Minister for Health, Social Services and Public Safety (in this regulation referred to as “the Minister”) must enforce or secure the enforcement of these Regulations and the relevant EU provisions in Northern Ireland.

(2) The Minister may make arrangements for a district council to enforce the provisions of these Regulations listed in paragraph (3) in its district to the extent specified in the arrangements.

(3) Those provisions are—

- (a) regulations 221 (sale or supply of medicinal products subject to general sale), 222 (sale of medicinal products from automatic machines) and 255(6) (certain offences relating to dealings with medicinal products);
- (b) regulations 251 (compliance with standards specified in certain publications) and 255(1)(e) (certain offences relating to dealings with medicinal products);
- (c) Part 13 (packaging and leaflets); and
- (d) Part 14 Chapter 2 (requirements relating to advertising).

(4) Functions conferred by virtue of paragraph (2) are to be exercised concurrently with the Minister.

(5) Regulation 323(9) has effect in relation to functions conferred by this regulation as it has effect in relation to functions conferred by regulation 323.

(6) In this regulation, “district council” means a council established under the Local Government Act (Northern Ireland) 1972⁽⁹³⁾.

Rights of entry

325.—(1) An inspector may at any reasonable time enter premises—

- (a) in order to determine whether there has been a contravention of a provision of these Regulations which the enforcement authority is required or empowered to enforce by virtue of regulations 323 and 324;
- (b) in order to verify whether the data submitted in respect of an active substance used as a starting material in order to obtain a conformity certificate issued by the European Directorate for the Quality of Medicines and Healthcare (“EDQM”) comply with the monographs of the European Pharmacopoeia, if the EDQM asks the enforcement authority to do so; and
- (c) for the purposes of any other function of the enforcement authority under these Regulations.

(2) A person may not exercise a right of entry under this regulation in relation to premises used only as a private dwelling unless 24 hours’ notice has been given to the occupier.

⁽⁹²⁾ 1994 c.39. There is an amendment to section 2(1) that is not relevant to this regulation.

⁽⁹³⁾ 1972 c.9 (N.I.).

(3) A person exercising, or attempting to exercise, a right of entry under this regulation must produce identification on request.

Application for warrant

326.—(1) In a case where this regulation applies, a justice of the peace may issue a warrant authorising an inspector to enter premises, by force if necessary.

(2) This regulation applies if, on sworn information in writing, the justice of the peace is satisfied that—

- (a) there are reasonable grounds for entering the premises by virtue of the enforcement authority's functions under these Regulations;
- (b) an inspector has a right to enter them by virtue of regulation 325; and
- (c) a condition specified in paragraph (3) is satisfied.

(3) Those conditions are—

- (a) that—
 - (i) admission to the premises has been refused or is expected to be refused, and
 - (ii) notice of the intention to apply for a warrant has been given to the occupier;
- (b) that a request for admission, or the giving of notice, would defeat the object of the entry;
- (c) that the case is one of urgency; or
- (d) that the premises are unoccupied or the occupier is temporarily absent.

(4) In relation to a ship, aircraft, hovercraft or vehicle, references in this Part to the occupier of premises are to be read as references to the master, commander or other person in charge of the ship, aircraft, hovercraft or vehicle.

(5) A warrant granted under this regulation continues in force for a period of 30 days beginning with the day on which the warrant is granted.

(6) In the application of this regulation to England, references to a justice of the peace include a reference to a district judge (magistrates' courts).

(7) In the application of this regulation to Scotland, references to a justice of the peace are to be read as references to a sheriff, stipendiary magistrate or justice of the peace.

(8) In the application of this regulation to Northern Ireland, references to a justice of the peace are to be read as references to a lay magistrate or a district judge (magistrates' courts).

Powers of inspection, sampling and seizure

327.—(1) An inspector may inspect anything mentioned in paragraph (2)—

- (a) in order to determine whether there has been a contravention of any provision of these Regulations which the enforcement authority must or may enforce by virtue of regulations 323 and 324;
- (b) for the purpose described in regulation 325(1)(b) (verification of data at the request of the European Directorate for the Quality of Medicines and Healthcare); or
- (c) in order to verify any statement made by an applicant for a manufacturer's or wholesale dealer's licence, marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation in an application under Parts 3 or 5 to 8.

(2) The things mentioned in paragraph (1) are—

- (a) a substance or article appearing to the inspector to be a medicinal product;
- (b) an article appearing to the inspector to be—

- (i) a container or package used or intended to be used to contain a medicinal product, or
 - (ii) a label or leaflet used or intended to be used in connection with a medicinal product;
 - (c) plant or equipment, including computer equipment, appearing to the inspector to be used or intended to be used in connection with the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products;
 - (d) any process of manufacture or assembly of medicinal products;
 - (e) the way in which medicinal products, or the materials used in the manufacture of medicinal products, are tested at any stage in the process of manufacture or assembly; and
 - (f) information and documents relating to the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products;
 - (g) information and documents relating to the safety of medicinal products, including information and documents relating to compliance with—
 - (i) conditions imposed under any of regulations [59](#) (conditions of UK marketing authorisation: general), [60](#) (conditions of UK marketing authorisation: exceptional circumstances), [61](#) (conditions of UK marketing authorisation: new obligations post-authorisation) or [105](#) (conditions of certificate of registration),
 - (ii) the requirements of Part 11 (pharmacovigilance),
 - (iii) obligations and conditions under Articles 10a(1), 14(7) or 14(8) of Regulation (EC) [No 726/2004](#), and
 - (iv) the requirements of Chapter 3 (pharmacovigilance) of Title II of Regulation (EC) [No 726/2004](#).
- (3) The inspector may for the purposes specified in paragraph (1) take or purchase a sample of a substance or article which appears to the inspector to be—
- (a) a medicinal product which is, or is intended to be, sold or supplied; or
 - (b) a substance or article used, or intended to be used, in the manufacture of a medicinal product.
- (4) The inspector may for the purposes specified in paragraph (1) require a person carrying on a business which consists of or includes the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products, or a person employed in connection with such a business, to produce information or documents relating to the business which are in the person's possession or under the person's control.
- (5) The inspector may take copies of information or documents—
- (a) inspected under sub-paragraph (2)(f) or (g); or
 - (b) produced under paragraph (4).
- (6) The inspector may seize and retain a substance or article appearing to the inspector to be a medicinal product if the inspector reasonably believes that an offence under these Regulations is being or has been committed in relation to, or by means of, that substance or article.
- (7) The inspector may, if the inspector reasonably believes that it may be required as evidence in proceedings, seize and retain—
- (a) any document; or
 - (b) anything inspected, or discovered in the course of an inspection, under paragraph (1).
- (8) The inspector may, if necessary, require a person who has the authority to do so—
- (a) to open a container or package;
 - (b) to open a vending machine; or

(c) to allow the inspector to open a container, package or vending machine, for the purpose of enabling the inspector to seize a substance, article, document or other thing under paragraph (6) or (7).

(9) The information and documents referred to in this regulation include any that are stored electronically.

Regulation 327: supplementary

328.—(1) Where an inspector seizes a substance, article, document or other thing under regulation 327(6) or (7) (powers of inspection, sampling and seizure) the inspector—

- (a) must, where practicable, inform—
 - (i) the person, if any, from whom it was seized, and
 - (ii) the occupier of the premises from which it was seized; or
- (b) in relation to anything seized from a vending machine, must inform—
 - (i) the person whose name and address are stated on the machine to be those of the machine’s owner, or
 - (ii) if no name and address are stated, the occupier of the premises on which the machine stands or to which it is affixed.

(2) An inspector exercising, or attempting to exercise, a right under regulation 327 must produce identification on request.

(3) The provisions of Schedule 31 have effect in relation to samples obtained by inspectors on behalf of enforcement authorities.

Application of sampling procedure to substance or article seized under this Part

329.—(1) This regulation applies where an inspector seizes a substance or article under regulation 327 (powers of inspection, sampling and seizure).

- (2) On request in accordance with paragraph (3), the inspector must either—
 - (a) set aside a sample of the substance or article seized; or
 - (b) treat the substance or article as a sample,

whichever seems more appropriate having regard to the nature of the substance or article.

- (3) A request is made in accordance with this paragraph if—
 - (a) it is made by a person (“P”) who is entitled to be informed of the seizure under regulation 328; and
 - (b) it is made either at the time of the seizure or within the period of 21 days beginning with the day immediately after the day on which P is informed of the seizure.

(4) An inspector is not required by paragraph (2) to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.

- (5) An inspector must—
 - (a) divide a sample under paragraph (2) into three parts;
 - (b) mark each part;
 - (c) seal or fasten each part; and
 - (d) supply one part to P.

(6) Paragraphs 10 to 12 and 15 to 26 of Schedule 31 apply to a sample under this regulation as they apply to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if—

- (a) references to the preceding provisions of that Schedule were references to the preceding provisions of this regulation;
- (b) references to a sampling officer were references to an inspector who seized a substance or article under regulation 327 (powers of inspection, sampling and seizure); and
- (c) a reference to the relevant enforcement authority were a reference to the authority by which the inspector is authorised.

Analysis of samples: other cases

330.—(1) This regulation applies where a person other than an inspector or a person authorised by an enforcement authority has purchased a medicinal product.

(2) The person may submit a sample of the medicinal product for analysis to the public analyst for the area in which the product was purchased or, if for the time being there is no public analyst for the area, to the public analyst for another area.

(3) Paragraphs 2 to 13 of Schedule 31 have effect, in relation to a person proposing to submit a sample in pursuance of paragraph (2), as if in that Schedule references to the sampling officer were references to that person.

(4) A public analyst to whom a sample is submitted under this regulation must analyse the sample, or cause it to be analysed, as soon as practicable (but this is subject to the following provisions of this regulation).

(5) If the public analyst to whom a sample is submitted thinks that a proper analysis cannot be carried out for any reason, the public analyst must send it to the public analyst for some other area, who must as soon as practicable analyse the sample, or cause it to be analysed (subject to paragraph 6).

(6) A public analyst to whom a sample is submitted or sent under this regulation may demand payment in advance of the required fee, and if payment in advance is demanded may refuse to carry out the analysis until the fee is paid.

(7) A public analyst who has analysed a sample or caused it to be analysed must issue a certificate specifying the result of the analysis to the person by whom the sample was submitted under paragraph (2).

(8) Paragraphs 21 to 23 of Schedule 31 have effect in relation to a certificate issued under this regulation as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.

(9) In this regulation “public analyst”—

- (a) in relation to England and Wales and Scotland has the meaning given by section 27 of the Food Safety Act 1990⁽⁹⁴⁾; and
- (b) in relation to Northern Ireland has the meaning given by Article 27(1) of the Food Safety (Northern Ireland) Order 1991⁽⁹⁵⁾.

Findings and reports of inspections

331.—(1) If the outcome of the inspection of things referred to in regulation 327(2)(g) (powers of inspection, sampling and seizure: information and documents relating to safety etc) is that

⁽⁹⁴⁾ 1990 c.16. Section 27 was amended by the Local Government etc (Scotland) Act 1994 section 180(1) and Schedule 18 paragraph 163(3), the Food Standards Act 1999 section 40(1) and Schedule 5 paragraphs 7 and 8, the Local Government (Wales) Act 1994 section 22(3) and Schedule 9 paragraph 16(2), S.I. 1994/865 regulation 24, and the Local Government and Public Involvement in Health Act 2007 sections 22 and 241, Schedule 1 Part 2 paragraph 17, and Schedule 18 Part 1.

⁽⁹⁵⁾ 1991 No. 762 (N.I. 7). There are amendments not relevant to these Regulations.

the holder of a marketing authorisation or traditional herbal registration does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file, or any provision of Part 11 (pharmacovigilance), the enforcement authority must—

- (a) bring the deficiencies to the attention of the holder;
 - (b) give the holder the opportunity to submit comments; and
 - (c) inform the other EEA States, the EMA and the European Commission.
- (2) Paragraph (1) is without prejudice to paragraphs (3) and (5).
- (3) After every inspection carried out in accordance with regulations 325 (rights of entry) and 327 (powers of inspection, sampling and seizure) in connection with medicinal products other than registrable homoeopathic medicinal products, the enforcement authority must report on whether the activities to which the inspection relates comply with such of the provisions mentioned in paragraph (4) as apply to those activities.
- (4) Those provisions are—
- (a) the Good Manufacturing Practice Directive and any principles or guidelines of good manufacturing practice referred to in Article 47 of the 2001 Directive;
 - (b) the guidelines on good distribution practice referred to in Article 84 of the 2001 Directive; and
 - (c) in the case of the holder of a marketing authorisation or traditional herbal registration—
 - (i) Part 11 (pharmacovigilance), and
 - (ii) Chapter 3 (pharmacovigilance) of Title II (authorisation and supervision of medicinal products for human use) of Regulation (EC) No 726/2004.
- (5) The enforcement authority must before adopting the report —
- (a) communicate the content of the report to the person to whose activities the inspection relates; and
 - (b) give that person the opportunity to submit comments.

Restrictions on disclosure of information

332.—(1) A person (“P”) must not disclose to another person, otherwise than in the performance of P’s functions—

- (a) any information relating to a manufacturing process or trade secret obtained by P on premises which P has entered by virtue of regulation 325 or of a warrant under regulation 326; or
 - (b) any information obtained by P or given to P in pursuance of these Regulations.
- (2) Paragraph (1) does not apply if—
- (a) P is, or is acting on behalf of, a public authority for the purposes of the Freedom of Information Act 2000(96); and
 - (b) the information is not held by the authority on behalf of another person.

Protection for inspectors

333.—(1) An inspector is not personally liable in respect of any act done in the execution, or purported execution, of a function under these Regulations and within the scope of the inspector’s employment by an enforcement authority (or, where the inspector is not employed by the authority,

(96) 2000 c.36.

the scope of the inspector's authorisation), provided that the act was done in the honest belief that these Regulations required or permitted it.

(2) Where an action is brought against an inspector in respect of an act falling within paragraph (1), the enforcement authority may indemnify the inspector against any damages, costs or expenses incurred, if the authority is satisfied that the inspector honestly believed that these Regulations required or permitted the act.

(3) Paragraph (2) applies in a case where the person is not legally entitled to require an indemnity from the enforcement authority.

(4) A reference to an inspector in this regulation includes a reference to an employee of the licensing authority who accompanies an inspector pursuant to regulation 334(1).

Supplementary provisions and offences

334.—(1) An inspector entering any premises by virtue of regulation 325 or of a warrant under regulation 326 may be accompanied by such persons, and take such equipment, as the inspector thinks appropriate.

(2) Where an inspector enters premises in pursuance of a warrant under regulation 326, the inspector must, if the property is unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespass as they were before the inspector entered.

(3) It is an offence for a person—

- (a) intentionally to obstruct an inspector;
- (b) intentionally to fail to comply with a requirement properly made under regulation 327 by an inspector; or
- (c) without reasonable cause, to fail to give an inspector any other assistance or information which the inspector may reasonably require in order to perform a function under these Regulations.

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(5) A person who knowingly makes a false statement in giving information as mentioned in paragraph (3)(c) is guilty of an offence.

(6) A person who breaches the prohibition in regulation 332(1) (restrictions on disclosure of information) is guilty of an offence.

(7) A person who is guilty of an offence under paragraph (5) or (6) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

(8) Nothing in this regulation is to be read as requiring a person to answer a question or to give information if doing so might incriminate that person or the spouse or civil partner of that person.

(9) In this regulation “occupier”, in relation to a ship, aircraft, or vehicle, is to be read in accordance with regulation 326(4).

PART 17

Miscellaneous and general

Provisions relating to offences

Contravention due to fault of another person

335.—(1) This regulation applies where—

- (a) a contravention of a provision referred to in paragraph (6) constitutes an offence; and
- (b) a person (“A”) contravenes the provision by reason of the act or omission of another person (“B”).

(2) B may be charged with and convicted of the offence, whether or not proceedings are also brought against A.

(3) If B is convicted B is liable to the same punishment as would have been imposed on A if A had been convicted of the offence.

(4) If A is charged with the offence it is a defence for A to prove on the balance of probabilities that—

- (a) A exercised all due diligence to avoid contravening the provision; and
- (b) the contravention was due to the act or omission of B.

(5) A may not rely on the defence in paragraph (4) unless not later than seven clear days before the date of the hearing A serves on the prosecutor a notice in writing of any information held by A which identifies, or assists in identifying, B.

(6) The provisions mentioned in paragraph (1) are—

- (a) regulation 251 (compliance with standards specified in certain publications);
- (b) regulations 268 and 269 (offences relating to packaging and package leaflets);
- (c) regulation 273 (child resistant containers for regulated medicinal products);
- (d) regulation 275 (colouring of aspirin and paracetamol products for children);
- (e) any prohibition or requirement in Chapter 2 of Part 14 (advertising); and
- (f) regulations 305(4) and 306(7) and (8) (notices not to publish, or to cease to publish, an advertisement).

Warranty as defence

336.—(1) This regulation applies where proceedings are brought against a person (“the defendant”) for an offence under these Regulations in respect of a contravention of a provision mentioned in paragraph (3).

(2) It is a defence for the defendant to prove that—

- (a) the substance or article to which the contravention relates (the “relevant substance or article”) was sold to the defendant in the United Kingdom as—
 - (i) a substance or article which could be lawfully sold, supplied or offered for sale or supply, or
 - (ii) a substance or article which could be lawfully sold, supplied or offered for sale or supply under the name or description or for the purpose under or for which it was sold;

- (b) the relevant substance or article was sold with a written warranty certifying a matter specified in paragraph (a), and that if the warranty were true the alleged offence would not have been committed;
 - (c) at the time of the commission of the alleged offence the defendant had no reason to believe that the matter certified in the warranty was otherwise; and
 - (d) at the time of the commission of the alleged offence the relevant substance or article was in the same state as when the defendant purchased it.
- (3) The provisions are—
- (a) regulation 251 (compliance with standards specified in certain publications);
 - (b) regulations 268 and 269 (offences relating to packaging and package leaflets);
 - (c) regulation 273 (child resistant containers for regulated medicinal products); and
 - (d) regulation 275 (colouring of aspirin and paracetamol products for children).
- (4) A warranty is not to be a defence under this regulation unless, no later than three clear days before the date of the hearing, the defendant sends to the prosecutor, and to the person who gave the warranty to the defendant—
- (a) a copy of the warranty;
 - (b) a notice stating that the defendant intends to rely on it; and
 - (c) the name and address of the person from whom the defendant received the warranty.
- (5) Where the defendant is an employee of the person who purchased the substance or article under the warranty, the defendant is entitled to rely on the provisions of this regulation in the same way as the employer.
- (6) The person by whom the warranty is alleged to have been given is entitled to appear at the hearing and to give evidence.
- (7) The court may adjourn the hearing in order to enable a person to appear and give evidence in accordance with paragraph (6).
- (8) For the purposes of this regulation, a name or description entered in an invoice is to be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description without contravening a provision mentioned in paragraph (3).
- (9) In the application of this regulation and regulation 337 to Scotland, references to the defendant are to be construed as references to the accused.

Offences in relation to warranties and certificates

337.—(1) It is an offence for a defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336 (3)—

- (a) intentionally to apply a warranty given in relation to one substance or article to a different substance or article; or
 - (b) intentionally to apply to one substance or article a certificate issued under regulation 330 or paragraph 19 of Schedule 31 in relation to a sample of a different substance or article.
- (2) A person who intentionally or recklessly gives a purchaser a false warranty certifying a matter specified in regulation 336(2)(a) is guilty of an offence.

(3) If the defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336(3) relies successfully on a warranty given to the defendant or to the defendant's employer, proceedings for an offence under paragraph (2) may be brought in accordance with paragraph (4).

- (4) Proceedings may be brought, as the prosecutor chooses—
 - (a) before a court which has jurisdiction in the place where a sample of the substance or article to which the warranty relates was taken; or
 - (b) before a court which has jurisdiction in the place where the warranty was given.
- (5) A person guilty of an offence under this regulation is liable—
 - (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

Offences by bodies corporate and partnerships

338.—(1) If an offence under these Regulations committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, an officer of the body corporate, or a person purporting to act as an officer of the body corporate, that officer or person (as well as the body corporate) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(2) If the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and omissions of a member in connection with the member's functions of management as it applies to an officer of the body corporate.

(3) If an offence under these Regulations is—

- (a) committed by a Scottish partnership; and
- (b) proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, a partner of the partnership,

the partner (as well as the partnership) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(4) In this regulation “officer” in relation to a body corporate means a director, secretary or other similar officer of the body corporate.

Prosecutions

Prosecutions

339.—(1) A magistrates' court in England or Wales may try an information for an offence under these Regulations that is triable only summarily if the information was laid at any time within the period of twelve months beginning with the commission of the offence.

(2) Summary proceedings in Scotland for an offence triable only summarily under these Regulations may be commenced at any time within the period of twelve months beginning with the commission of the offence (and section 136(3) of the Criminal Procedure (Scotland) Act 1995(97) applies for the purposes of this paragraph as it applies for the purposes of that section).

(3) A magistrates' court in Northern Ireland may hear and determine a complaint for an offence punishable on summary conviction under these Regulations, other than an offence which is also triable on indictment, if the complaint was made at any time within the period of twelve months beginning with the commission of the offence.

(4) A body referred to in regulation 323(2) (enforcement in England, Wales and Scotland) may not institute proceedings for an offence under these Regulations in relation to a contravention of a provision which it may or must enforce by virtue of arrangements made under that regulation unless

it has given no less than 28 days' notice of its intention to do so, together with a summary of the facts on which the charges are founded, to the Secretary of State.

(5) A district council (as defined in regulation 324 (enforcement in Northern Ireland)) may not institute proceedings for an offence under these Regulations in relation to a contravention of a provision which it may or must enforce by virtue of arrangements made under regulation 324(2) unless it has given no less than 28 days' notice of its intention to do so, together with a summary of the facts on which the charges are founded, to the Minister for Health, Social Services and Public Safety.

(6) A certificate of the Secretary of State or of the Minister for Health, Social Services and Public Safety that the requirements of paragraph (4) or, as the case may be, (5) have been complied with is to be conclusive evidence that the requirements have been complied with, and a document purporting to be such a certificate is to be presumed to be such a certificate unless the contrary is proved.

General

Presumptions

340.—(1) Paragraph (2) applies for the purposes of proceedings under these Regulations for an offence consisting of offering a medicinal product for sale by retail in contravention of regulation 220 (sale or supply of products not subject to general sale) or 221 (sale or supply of products subject to general sale).

(2) If it is proved that the medicinal product in question was found on a vehicle from which medicinal products are sold, it is to be presumed, unless the contrary is proved, that the person in charge of the vehicle offered the medicinal product for sale.

(3) Paragraph (4) applies for the purposes of proceedings under these Regulations for an offence consisting of a contravention of a provision within paragraph (5), where it is proved that the medicinal product in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products.

(4) It is to be presumed, unless the contrary is proved, that the person charged possessed the medicinal product for the purpose of sale or supply.

(5) The provisions within this paragraph are regulations 268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons) and 276 (offences: requirements relating to child safety) to the extent that they establish an offence based on possession of a medicinal product for the purpose of sale or supply.

Decisions under these Regulations

341.—(1) Where the licensing authority notifies a person of a decision under these Regulations, it must—

- (a) state its reasons for the decision; and
- (b) inform the person of any action the person may take under these Regulations to challenge that decision and of the time for taking that action.

(2) Paragraph (1) is without prejudice to any other provision of these Regulations concerning notification by the licensing authority.

(3) The licensing authority must publicise any decision under these Regulations to which paragraph (4) applies in such manner as it thinks fit.

(4) Those decisions are—

- (a) a decision to grant or revoke a marketing authorisation;

- (b) a decision to grant or revoke a certificate of registration; and
- (c) a decision to grant or revoke a traditional herbal registration.

Time limits for provision of information etc

342.—(1) This regulation applies if—

- (a) by any provision of these Regulations a person is required to provide—
 - (i) any information or document to the licensing authority or to the Ministers, or
 - (ii) any assistance to the licensing authority or to the Ministers; and
- (b) no time is specified in that provision within which the obligation must be performed.

(2) The obligation must be performed within such time as may be specified in a written notice given to the person by the licensing authority or the Ministers (as the case may be).

Service of documents

343.—(1) A notice or other document required or authorised by any provision of these Regulations to be served on a person, or to be given or sent to a person, may be served, given or sent—

- (a) by delivering it to the person;
- (b) by sending it by post to the person’s usual or last known residence or place of business in the United Kingdom;
- (c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or by sending it by post to the secretary or clerk of the body corporate at that office; or
- (d) in the case of a Scottish partnership by delivering it to a partner or by sending it by post to the address of the principal office of the partnership; or
- (e) if the person consents in writing to the use of electronic communication, by a means of electronic communication.

(2) Where a notice or other document is sent by means of electronic communication it is treated for the purposes of these Regulations as received on the day on which it is sent, unless the contrary is proved.

Payment of expenses by Ministers

344.—(1) If a person enforces a provision of these Regulations in accordance with functions conferred under Part 16 (enforcement), the relevant Minister must pay such amounts as the person may reasonably require in respect of expenses incurred in the course of enforcement.

(2) In paragraph (1) “the relevant Minister” means—

- (a) in relation to enforcement in England, Wales, and Scotland, the Secretary of State; and
- (b) in relation to enforcement in Northern Ireland, the Minister for Health, Social Services and Public Safety.

Immunity from civil liability

Immunity from civil liability

345.—(1) This regulation applies where the licensing authority makes a recommendation or requirement to which paragraph (2) applies in response to the suspected or confirmed spread of—

- (a) pathogenic agents;
- (b) toxins;
- (c) chemical agents; or
- (d) nuclear radiation,

which may cause harm to human beings.

(2) This paragraph applies to a recommendation or requirement—

- (a) for the use of a medicinal product without an authorisation; or
- (b) for the use of a medicinal product with an authorisation, but for a therapeutic indication that is not permitted under the authorisation.

(3) None of the following are to be subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement—

- (a) any holder of an authorisation for the product;
- (b) any manufacturer of the product;
- (c) any officer, servant, employee or agent of a person within paragraph (a) or (b); or
- (d) any health care professional.

(4) This regulation does not apply in relation to liability under section 2 (liability for defective products) of the Consumer Protection Act 1987⁽⁹⁸⁾ or article 5 of the Consumer Protection (Northern Ireland) Order 1987⁽⁹⁹⁾.

(5) In this regulation “authorisation” means a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation.

Review

Review

346.—(1) The Secretary of State must from time to time carry out a review of the provisions listed in paragraph (2).

(2) Those provisions are—

- (a) Part 11;
- (b) regulations—
 - (i) 59,
 - (ii) 60(3)(b), (9) and (10),
 - (iii) 61,
 - (iv) 63,
 - (v) 64(4)(b), (d) and (e), (5)(a) and (6)(c),
 - (vi) 65(2),
 - (vii) 66(5) and (6),
 - (viii) 68(2)(a) and (b) and (5),
 - (ix) 69(2)(a) and (b), (5) and (10),
 - (x) 75(2)(b) and (c),

⁽⁹⁸⁾ 1987 c.43. Section 2(4) was repealed in relation to England and Wales by S.I. 2000/2771 article 2(1) and (3) and in relation to Scotland by S.S.I. 2001/265 article 2(1) and (3).

⁽⁹⁹⁾ S.I. 1987/2049 (N.I. 20), as amended by 2001 c.13 (NI).

- (xi) 76,
 - (xii) 79,
 - (xiii) 85,
 - (xiv) 86,
 - (xv) 97,
 - (xvi) 105(3)(b),
 - (xvii) 107(2),
 - (xviii) 108(5),
 - (xix) 115(2)(b) and (c),
 - (xx) 132(2),
 - (xxi) 133(5) and (6),
 - (xxii) 266(4) and (5),
 - (xxiii) 327(2)(g),
 - (xxiv) 331, and
 - (xxv) regulation 349 insofar as it repeals section 10(7) of the Medicines Act 1968; and
- (c) Schedules —
- (i) 8 paragraphs 12, 13, 19, and 23,
 - (ii) 12 paragraph 21, and
 - (iii) 27 paragraphs 14 and 15.
- (3) The Secretary of State must
- (a) set out the conclusions of a review carried out in accordance with paragraph (1) in a report; and
 - (b) publish the report.
- (4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the 2001 Directive and Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community Code relating to medicinal products for human use(100) are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).
- (5) The report must in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these Regulations that implement those Directives in relation to the subject matter of the provisions mentioned in paragraph (2)(a), (b)(i) to (xxiv) and (c);
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (6) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
- (7) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Transitional provisions, savings, amendments, repeals and revocations

Transitional provisions and savings

347. Schedule 32 contains transitional provisions and savings.

Amendments to existing law

348. Schedule 34 contains amendments to existing law.

Repeals and revocations

349. Schedule 35 contains repeals and revocations.

Signed by authority of the Secretary of State for Health.

9th July 2012

19th July 2012

Earl Howe
Parliamentary Under-Secretary of State
Department of Health
Edwin Poots
Minister for Health, Social Services and Public
Safety