
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 1

INTRODUCTORY PROVISIONS

Interpretation

2.—(1) In these Regulations—

[^{F1}“the 2012 Regulations” means the Human Medicines Regulations 2012;]

“the Act” means the Medicines Act 1968 ^{F2};

“adult” means a person who has attained the age of 16 years;

“adverse event” means any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product;

“adverse reaction” means any untoward and unintended response in a subject to an investigational medicinal product which is related to any dose administered to that subject;

“authorised health professional” means—

- (a) a doctor,
- (b) a dentist,
- (c) a nurse, or
- (d) a pharmacist;

[^{F3}“appropriate committee” for the purposes of any provision of these Regulations under which a function falls to be performed means whichever the licensing authority considers to be appropriate of—

- (a) the Commission on Human Medicines; or
- (b) an expert committee appointed by the licensing authority;]

“assemble”, in relation to an investigational medicinal product, means—

- (a) enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or used in a clinical trial, or
- (b) where the product (with or without other medicinal products of the same description) is already contained in the container in which it is to be sold or supplied, or used in a clinical trial, labelling the container before the product is sold or supplied, or used in a clinical trial, in that container,

and “assembly” has a corresponding meaning;

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“business”, except in Schedule 2, includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate;

“chief investigator” means—

- (a) in relation to a clinical trial conducted at a single trial site, the investigator for that site, or
- (b) in relation to a clinical trial conducted at more than one trial site, the authorised health^{F4}... professional, whether or not he is an investigator at any particular site, who takes primary responsibility for the conduct of the trial;

“clinical trial” means any investigation in human subjects, other than a non-interventional trial, intended—

- (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
- (b) to identify any adverse reactions to one or more such products, or
- (c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products;

“Commission Directive 2003/94/EC” means Commission Directive 2003/94/EC^{F5} laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use;

[^{F6}“the Commission on Human Medicines” means the Commission on Human Medicines within the meaning of regulation 9 of the 2012 Regulations;]

“conditions and principles of good clinical practice” means the conditions and principles specified in Schedule 1;

“conducting a clinical trial” includes—

- (a) administering, or giving directions for the administration of, an investigational medicinal product to a subject for the purposes of that trial,
- (b) giving a prescription for an investigational medicinal product for the purposes of that trial,
- (c) carrying out any other medical or nursing procedure in relation to that trial, and
- (d) carrying out any test or analysis—
 - (i) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of the investigational medicinal products administered in the course of the trial,
 - (ii) to identify any adverse reactions to those products, or
 - (iii) to study absorption, distribution, metabolism and excretion of those products,

but does not include any activity undertaken prior to the commencement of the trial which consists of making such preparations for the trial as are necessary or expedient;

“container”, in relation to an investigational medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

“dentist” means a person registered in the dentists register under the Dentists Act 1984^{F7F8} ...;

[^{F9}“the 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;]

[^{F10}“Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;]

“doctor” means a registered medical practitioner ^{F11};

[^{F12}“EEA State” means a Member State, Norway, Iceland or Liechtenstein;]

^{F13} ^{F14}^{F15}
...

“electronic signature” means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication;

“European Economic Area” means the European Economic Area created by the EEA Agreement;

[^{F16}“the European Medicines Agency” means the European Medicines Agency established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;]

“ethics committee” means—

- (a) a committee established or recognised in accordance with Part 2,
- (b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000 ^{F17}, or
- (c) the Gene Therapy Advisory Committee;

“export” means export to a third country from an EEA State, whether by land, sea or air;

[^{F18}“the GCP Directive” means Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products;]

“the Gene Therapy Advisory Committee” means the Gene Therapy Advisory Committee appointed by the Secretary of State^{F19} ...;

“Health and Social Services Board” means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972 ^{F20};

“Health Board” means a Health Board established under the National Health Service (Scotland) Act 1978 ^{F21};

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

“health care professional” means—

- (a) a doctor,
- (b) a dentist,
- (c) a nurse,
- (d) a pharmacist,
- (e) [^{F22}a person registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989, or in the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act,]

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(f) a person registered in a register established and maintained under article 5 of ^{F23}Health and Social Work Professions Order 2001, other than a social worker registered in Part 16],

(g) a registered osteopath as defined by section 41 of the Osteopaths Act 1993 ^{F24}, or

(h) a registered chiropractor as defined by section 43 of the Chiropractors Act 1994 ^{F25};

“health centre” means a health centre maintained under section 2 or 3 of the National Health Service Act 1977, section 36 of the National Health Service (Scotland) Act 1978 or Article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972;

“health service body” means—

(a) a ^{F26}... Health Board or Health and Social Services Board,

(b) a Special Health Authority, ^{F27}... [^{F28}clinical commissioning group] or Local Health Board established under the National Health Service Act 1977,

(ba) [^{F29}the National Health Service Commissioning Board,]

(c) a Special Health Board established under the National Health Service (Scotland) Act 1978,

(ca) [^{F30}Healthcare Improvement Scotland established under the National Health Service (Scotland) Act 1978,]

(d) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 ^{F31},

(e) ^{F32}...

(f) the Scottish Dental Practice Board or the Common Services Agency for the Scottish Health Service established under the National Health Service (Scotland) Act 1978,

(g) the Northern Ireland Central Services Agency for the Health and Social Services established under the Health and Personal Social Services (Northern Ireland) Order 1972,

(h) a National Health Service trust established under the National Health Service and Community Care Act 1990 ^{F33} or the National Health Service (Scotland) Act 1978,

(i) an NHS foundation trust within the meaning of section 1(1) of the Health and Social Care (Community Health and Standards) Act 2003 ^{F34}, or

(j) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991 ^{F35};

“hospital” includes a clinic, nursing home or similar institution;

“import”, other than in regulation 13 and Schedule 3, means import into the United Kingdom from a third country, whether by land, sea or air;

“informed consent” shall be construed in accordance with paragraph 3 of Part 1 of Schedule 1;

“insurance or indemnity” includes provision for meeting losses or liabilities—

(a) under a scheme established under—

(i) section 21 of the National Health Service and Community Care Act 1990 (schemes for meeting losses and liabilities etc. of certain health service bodies in England and Wales) ^{F36},

(ii) section 85B of the National Health Service (Scotland) Act 1978 (schemes for meeting losses and liabilities etc. of certain health service bodies in Scotland) ^{F37}, or

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- (iii) Article 24 of the Health and Personal Social Services (Northern Ireland) Order 1991 (schemes for meeting losses and liabilities etc. of certain health service bodies in Northern Ireland) ^{F38}, or
- (b) in accordance with guidance issued by—
 - (i) the Secretary of State,
 - (ii) the Scottish Ministers,
 - (iii) the National Assembly for Wales, or
 - (iv) the Department for Health, Social Services and Public Safety,as to the arrangements to be adopted by health service bodies for meeting the costs arising from clinical negligence (known as NHS Indemnity);

“investigational medicinal product” means a pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorization but is, for the purposes of the trial—

- (a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorization,
- (b) used for an indication not included in the summary of product characteristics under the authorization for that product, or
- (c) used to gain further information about the form of that product as authorised under the authorization;

“investigational medicinal product dossier” means, in relation to an investigational medicinal product, the dossier relating to that product which accompanies a request for authorisation to conduct a trial in which that product is or is to be used, in accordance with paragraph 11 of Schedule 3;

“investigator” means, in relation to a clinical trial, the authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team;

“investigator’s brochure” means a document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects;

“labelling”, in relation to an investigational medicinal product, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and “label” has a corresponding meaning;

“legal representative”, other than in regulation 3 and Parts 2 to 4 of Schedule 3, has the meaning given by Part 1 of Schedule 1;

“licensing authority” shall be construed in accordance with [^{F39}regulation 6 of the 2012 Regulations];

“manufacture”, in relation to an investigational 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 it or mixing it with, some other substance used as a vehicle for the purposes of administering it;

“manufacturing authorisation” has the meaning given by regulation 36(1);

“marketing authorization” means—

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- (a) [^{F40}a UK marketing authorisation granted by the licensing authority under the 2012 Regulations,]
- (b) a marketing authorization issued by the competent authority of an EEA State, other than the United Kingdom, in accordance with Directive [2001/83/EC](#),
- (c) a marketing authorization granted by the European Commission under Council Regulation ([EEC](#)) [2309/93](#)^{F41} [^{F42}or Regulation ([EC](#)) No. [726/2004](#) of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency], or
- (d) a product licence granted by the licensing authority for the purposes of section 7 of the Medicines Act 1968 ^{F43},

[^{F44}“medicinal product” means a medicinal product within the meaning of regulation 2(1) of the 2012 Regulations.]

“minor” means a person under the age of 16 years;

“non-interventional trial” means a study of one or more medicinal products which have a marketing authorization, where the following conditions are met—

- (a) the products are prescribed in the usual manner in accordance with the terms of that authorization,
- (b) the assignment of any patient involved in the study to a particular therapeutic strategy is not decided in advance by a protocol but falls within current practice,
- (c) the decision to prescribe a particular medicinal product is clearly separated from the decision to include the patient in the study,
- (d) no diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question, and
- (e) epidemiological methods are to be used for the analysis of the data arising from the study;

“nurse” means a registered nurse or registered midwife;

“pharmaceutical form of an active substance” includes any substance or article to which these Regulations have effect by virtue of an order under section 104 or 105 of the Act (which relate to the application of Act to certain articles and substances which are not medicinal products);

“Pharmaceutical Society” in relation to Great Britain means the Royal Pharmaceutical Society of Great Britain, and in relation to Northern Ireland means the Pharmaceutical Society of Northern Ireland;

“pharmacist” means—

- (a) [^{F45}in relation to Great Britain, a person registered as a pharmacist in Part 1 or 4 of the register maintained under article 19 of the Pharmacy Order 2010, and]
- (b) in relation to Northern Ireland, a person registered in the register of pharmaceutical chemists for Northern Ireland made out and maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

“Phase I trial” means a clinical trial to study the pharmacology of an investigational medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial;

“the principles and guidelines of good manufacturing practice” means the principles and guidelines of good manufacturing practice set out in Commission Directive [2003/94/EC](#);

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“protocol” means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial;

“qualified person” means—

- (a) a person who as respects qualifications and experience satisfies the requirements of Article 49 or 50 of Directive 2001/83/EC, or
- (b) a person who, without satisfying the requirements referred to in paragraph (a)—
 - (i) has been engaged in activities equivalent to those to be performed in accordance with regulation 43(2) in respect of investigational medicinal products for a period of at least 6 months prior to 1st May 2004,
 - (ii) has, in accordance with paragraph 6(1) of Schedule 6, been named as a qualified person in a valid application for a manufacturing authorisation made prior to 1st May 2006, and
 - (iii) is—
 - (aa) a member of the Institute of Biology, the Pharmaceutical Society, the Royal Society of Chemistry, or such other body as may appear to the licensing authority to be an appropriate body for the purpose of this paragraph, or
 - (bb) the holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, which the licensing authority have stated in a notice in writing to that person to be qualifications sufficient for the purpose of performing the functions of a qualified person;

“relevant ethics committee”, in relation to a clinical trial, means—

- (a) in a case where an ethics committee has given a favourable opinion in relation to that trial and paragraph 13 of Schedule 2 applies, the ethics committee which is the relevant ethics committee for that trial by virtue of sub-paragraph (5) of that paragraph;
- (b) in a case where an ethics committee has given an unfavourable opinion in relation to that trial but a favourable opinion has been given by an appeal panel in accordance with paragraph 4(4) of Schedule 4, that committee, or
- (c) in any other case, the ethics committee which has given a favourable opinion in relation to that trial in accordance with regulation 15;

“serious adverse event”, “serious adverse reaction” or “unexpected serious adverse reaction” means any adverse event, adverse reaction or unexpected adverse reaction, respectively, that—

- (a) results in death,
- (b) is life-threatening,
- (c) requires hospitalisation or prolongation of existing hospitalisation,
- (d) results in persistent or significant disability or incapacity, or
- (e) consists of a congenital anomaly or birth defect;

“sponsor” shall be construed in accordance with regulation 3;

“Strategic Health Authority” means a Strategic Health Authority established under the National Health Service Act 1977^{F46};

“subject” means, in relation to a clinical trial, an individual, whether a patient or not, who participates in a clinical trial—

- (a) as a recipient of an investigational medicinal product or of some other treatment or product, or

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- (b) without receiving any treatment or product, as a control;
- “third country” means a country or territory outside the European Economic Area;
- “trial site” means a hospital, health centre, surgery or other establishment or facility at or from which a clinical trial, or any part of such a trial, is conducted;
- “unexpected adverse reaction” means an adverse reaction the nature and severity of which is not consistent with the information about the medicinal product in question set out—
- (a) in the case of a product with a marketing authorization, in the summary of product characteristics for that product,
- (b) in the case of any other investigational medicinal product, in the investigator’s brochure relating to the trial in question.

(2) Any reference in these Regulations to the holder of a manufacturing authorisation shall be construed as a reference to the holder of such an authorisation which is for the time being in force.

(3) Any reference in these Regulations to an application, request or other document that is signed includes a reference to an application, request of other document that is signed with an electronic signature.

Textual Amendments

- F1** Words in reg. 2(1) inserted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 53(a)** (with Sch. 32)
- F2** 1968 c. 67.
- F3** Words in reg. 2(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 53(b)** (with Sch. 32)
- F4** Word in reg. 2 omitted (29.8.2006) by virtue of [The Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **2(a)**
- F5** OJ No. L262, 14.10.2003, p.22.
- F6** Words in reg. 2(1) inserted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 53(c)** (with Sch. 32)
- F7** 1984 c. 24.
- F8** Words in reg. 2(1) omitted (3.12.2007) by virtue of [The European Qualifications \(Health and Social Care Professions\) Regulations 2007 \(S.I. 2007/3101\)](#), regs. 1(2), **154**
- F9** Words in reg. 2(1) substituted (1.5.2008) by [The Medicines for Human Use \(Clinical Trials\) and Blood Safety and Quality \(Amendment\) Regulations 2008 \(S.I. 2008/941\)](#), regs. 1(1), **2(a)**
- F10** Words in reg. 2(1) substituted (1.5.2008) by [The Medicines for Human Use \(Clinical Trials\) and Blood Safety and Quality \(Amendment\) Regulations 2008 \(S.I. 2008/941\)](#), regs. 1(1), **2(b)**
- F11** *See* Schedule 1 of the [Interpretation Act 1978 \(c. 30\)](#), as amended by paragraph 18 of Schedule 5 to the [Medical Act 1983 \(c. 54\)](#).
- F12** Words in reg. 2 substituted (29.8.2006) by [The Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **2(b)**
- F13** Words in reg. 2 omitted (29.8.2006) by virtue of [The Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **2(c)**
- F14** OJ No. L1, 3.1.1994, p.3.
- F15** OJ No. L1, 3.1.1994, p.572.
- F16** Words in reg. 2(1) substituted (1.1.2005) by [The Medicines \(Marketing Authorisations and Miscellaneous Amendments\) Regulations 2004 \(S.I. 2004/3224\)](#), regs. 1, **9**
- F17** 2000 asp. 4; *see* S.I. 2002/190.
- F18** Words in reg. 2 inserted (29.8.2006) by [The Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **2(d)**
- F19** Words in reg. 2(1) omitted (1.5.2008) by virtue of [The Medicines for Human Use \(Clinical Trials\) and Blood Safety and Quality \(Amendment\) Regulations 2008 \(S.I. 2008/941\)](#), regs. 1(1), **2(c)**

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- F20** S.I. 1972/1265 (N.I. 14).
- F21** 1978 c. 29.
- F22** Words in reg. 2(1) substituted (3.12.2007) by The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **201**
- F23** Words in reg. 2(1) substituted (1.8.2012) by The Health and Social Care Act 2012 (Consequential Provision Social Workers) Order 2012 (S.I. 2012/1479), art. 1(2), **Sch. para. 39**
- F24** 1993 c. 21.
- F25** 1994 c. 17.
- F26** Words in reg. 2(1) omitted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), arts. 1(2), 11, **Sch. 2 para. 66(2)(a)**
- F27** Words in reg. 2(1) omitted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), arts. 1(2), 11, **Sch. 2 para. 66(2)(b)**
- F28** Words in reg. 2(1) inserted (1.10.2012) by The NHS Commissioning Board Authority (Abolition and Transfer of Staff, Property and Liabilities) and the Health and Social Care Act 2012 (Consequential Amendments) Order 2012 (S.I. 2012/1641), art. 1(2)(b), **Sch. 3 para. 8(2)(a)**
- F29** Words in reg. 2(1) inserted (1.10.2012) by The NHS Commissioning Board Authority (Abolition and Transfer of Staff, Property and Liabilities) and the Health and Social Care Act 2012 (Consequential Amendments) Order 2012 (S.I. 2012/1641), art. 1(2)(b), **Sch. 3 para. 8(2)(b)**
- F30** Words in reg. 2(1) inserted (28.10.2011) by The Public Services Reform (Scotland) Act 2010 (Consequential Modifications of Enactments) Order 2011 (S.I. 2011/2581), art. 1(2)(b), **Sch. 2 para. 40**
- F31** S.I. 1990/247 (N.I.3)
- F32** Words in reg. 2(1) omitted (1.4.2006) by virtue of The General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006 (S.I. 2006/562), art. 1(1), **Sch. 2 para. 5**
- F33** 1990 c. 19.
- F34** 2003 c. 43.
- F35** S.I. 1991/194 (N.I.1).
- F36** 1990 c. 19; section 21 was amended by paragraph 79 of Schedule 1 to the Health Authorities Act 1995 (c. 17) and paragraph 81 of Schedule 4 to the Health Act 1999 (c. 8).
- F37** 1978 c. 29; section 85 was inserted by section 41 of the National Health Service and Community Care Act 1990 (c. 19) and was amended by paragraph 56 of Schedule 4 to the Health Act 1999 (c. 8).
- F38** S.I. 1991/194 (N.I. 1).
- F39** Words in reg. 2(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 53(d)** (with Sch. 32)
- F40** Words in reg. 2(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 53(e)** (with Sch. 32)
- F41** OJ No. L214, 24.8.1993, p.1.
- F42** Words in reg. 2(1) inserted (20.11.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(b), **Sch. para. 17(b)**
- F43** Section 7 does not apply to “relevant medicinal products” within the meaning given by S.I. 1994/3144.
- F44** Words in reg. 2(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 53(f)** (with Sch. 32)
- F45** Words in reg. 2(1) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 43** (with Sch. 5); S.I. 2010/1621, art. 2(1)
- F46** See section 8 of the National Health Service Act 1977 (c. 49) as substituted by section 1(2) of the National Health Service Reform and Health Care Professions Act 2002 (c. 17).

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