STATUTORY INSTRUMENTS

# 2004 No. 1031

# The Medicines for Human Use (Clinical Trials) Regulations 2004

## PART 1

INTRODUCTORY PROVISIONS

### Citation and commencement

**1.** These Regulations may be cited as the Medicines for Human Use (Clinical Trials) Regulations 2004 and shall come into force on 1st May 2004.

### 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;

"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;

**[**[F5]"Commission Directive 2003/94/EC" , other than in Parts 2 and 3 of Schedule 7, means—

(a) in the case of an investigational medicinal product manufactured or assembled in, or imported into, Great Britain—

(i) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use, as modified by Schedule 2A to the 2012 Regulations, or

(ii) if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations, and have come into force, those Regulations;

(b) in the case of an investigational medicinal product manufactured or assembled in, or imported into, Northern Ireland, Commission Directive 2003/94/EC 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;

**[**F7" country " means a country or territory;**]**

"dentist" means a person registered in the dentists register under the Dentists Act 1984 F8F9...;

**[**F10"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;**]**

**[**F11"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 F12;

**[**F13"EAMS medicinal product" means a medicinal product that—

(a) has been included in the Early Access to Medicines Scheme by means of the licensing authority issuing an EAMS scientific opinion in respect of it; and

(b) remains in the scheme by virtue of the EAMS scientific opinion not ceasing to have effect in respect of it by virtue of regulation 167D of the 2012 Regulations;**]**

**[**F13"EAMS scientific opinion" is to be construed in accordance with regulation 167C(2)(b) of the 2012 Regulations;**]**

**[**F13"Early Access to Medicines Scheme" means the scheme of that name established and operated under regulation 167C(1) of the 2012 Regulations;**]**

**[**F14"EEA State" means a Member State, Norway, Iceland or Liechtenstein;**]**

F15 ... F16F17

**[**F18"electronic signature" means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign;**]**

"European Economic Area" means the European Economic Area created by the EEA Agreement;

**[**F19"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 [F20], or

(c) the Gene Therapy Advisory Committee;

"export" means export to **[**[F21]another country from the United Kingdom**]**, whether by land, sea or air;

[F22]...

"the Gene Therapy Advisory Committee" means the Gene Therapy Advisory Committee appointed by the Secretary of State[F23]...;

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972 [F24];

"Health Board" means a Health Board established under the National Health Service (Scotland) Act 1978 [F25];

"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) **[**[F26]a person registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989, [F27]...**]**

(f) a person registered in a register established and maintained under article 5 of **[**[F28]Health Professions Order 2001**]**,

(g) a registered osteopath as defined by section 41 of the Osteopaths Act 1993 [F29], or

(h) a registered chiropractor as defined by section 43 of the Chiropractors Act 1994 [F30];

"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 [F31]... Health Board or Health and Social Services Board,

(b) a Special Health Authority, [F32]... **[**[F33]integrated care board**]** or Local Health Board established under the National Health Service Act 1977,

(ba) **[**[F34]**[**[F35]NHS England**]** ,**]**

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

(ca) **[**[F36]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 [F37],

(e) [F38]...

(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 [F39] 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 [F40], or

(j) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991 [F41];

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

**[**[F42]"import", except in regulation 13 and Schedule 13, means import, or attempt to import—

(a) into Great Britain other than from Northern Ireland, or

(b) into Northern Ireland from a country other than an EEA State,

whether by land, sea or air and "imported" is to be construed accordingly;**]**

"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) [F43],

(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) [F44], or

(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) [F45], 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 **[**F46regulation 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);

**[**F47" marketing authorization " means—

(a) a UK marketing authorization,

(b) an EU marketing authorisation (as defined in the 2012 Regulations), or

(c) an authorization granted by a regulatory body responsible for licensing medicinal products in a country that is included in the list referred to in regulation 2A(1);**]**

**[**F48"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) **[**F49in relation to Great Britain, a person registered as a pharmacist in Part 1 F50... 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;

"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;

**[**F51"signatory" means a natural person who creates an electronic signature;**]**

"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 F52;

"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

(b) without receiving any treatment or product, as a control;

F53...

"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;

**[**F54" UK marketing authorization " —

(a) has the same meaning as "UK marketing authorisation" in the 2012 Regulations (and references to "UKMA(UK)", "UKMA(GB)" and "UKMA(NI)" in these Regulations should be construed in accordance with that definition); and

(b) includes a product licence granted by the licensing authority for the purposes of section 7 of the Medicines Act 1968;**]**

"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 **[**F55, or equivalent document,**]** 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** Words in reg. 2(1) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 1(a)**); 2020 c. 1, Sch. 5 para. 1(1)
**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** Words in reg. 2(1) inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(3)**; 2020 c. 1, Sch. 5 para. 1(1)
**F8** 1984 c. 24.
**F9** 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**
**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(a)**
**F11** 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)**
**F12** *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).
**F13** Words in reg. 2(1) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **16** (with reg. 19)
**F14** 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)**
**F15** 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)**
**F16** OJ No. L1, 3.1.1994, p.3.
**F17** OJ No. L1, 3.1.1994, p.572.
**F18** Words in reg. 2(1) substituted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 2(a)**
**F19** 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**
**F20** 2000 asp. 4; *see*S.S.I. 2002/190.
**F21** Words in reg. 2(1) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(4)**; 2020 c. 1, Sch. 5 para. 1(1)
**F22** Words in reg. 2(1) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(5)**; 2020 c. 1, Sch. 5 para. 1(1)
**F23** 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)**
**F24** S.I. 1972/1265 (N.I. 14).
**F25** 1978 c. 29.
**F26** 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**
**F27** Words in reg. 2(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 5 para. 19** (with reg. 12A, Sch. 5 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 13); 2020 c. 1, Sch. 5 para. 1(1)
**F28** Words in reg. 2(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 3 para. 8**; S.I. 2019/1436, reg. 2(b)
**F29** 1993 c. 21.
**F30** 1994 c. 17.

**F31** 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)**

**F32** 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)**

**F33** Words in Regulations substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), reg. 1(2), Sch. para. 1(1)**(3)** (with Sch. para. 1(2))

**F34** 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)**

**F35** Words in Regulations substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), reg. 1(1), **Sch. para. 1**

**F36** 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**

**F37** S.I. 1990/247 (N.I.3)

**F38** 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**

**F39** 1990 c. 19.

**F40** 2003 c. 43.

**F41** S.I. 1991/194 (N.I.1).

**F42** Words in reg. 2(1) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(6)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 1(b)**); 2020 c. 1, Sch. 5 para. 1(1)

**F43** 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).

**F44** 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).

**F45** S.I. 1991/194 (N.I. 1).

**F46** 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)

**F47** Words in reg. 2(1) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(8)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 1(d)**); 2020 c. 1, Sch. 5 para. 1(1)

**F48** 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)

**F49** 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)

**F50** Words in reg. 2(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 36(a)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

**F51** Words in reg. 2(1) inserted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 2(b)**

**F52** *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).

**F53** Words in reg. 2(1) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(10)**; 2020 c. 1, Sch. 5 para. 1(1)

**F54** Words in reg. 2(1) inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(11)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 1(f)**); 2020 c. 1, Sch. 5 para. 1(1)

**F55** Words in reg. 2(1) inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **3(12)**; 2020 c. 1, Sch. 5 para. 1(1)

### [F56List of countries for the purpose of the definition of "marketing authorization"

**2A.**—(1) The licensing authority must publish a list of countries for the purpose of the definition of "marketing authorization".

(2) In order to determine whether a country should be included in the list referred to in paragraph (1), the licensing authority may, in particular, take into account the regulatory equivalence of that country to the United Kingdom in assessing the safety, quality and efficacy of medicinal products.

(3) The licensing authority must—

(a) review the countries it has included in the list referred to in paragraph (1) to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(b) undertake such a review at least every three years beginning with the date on which that country is included in that list.**]**

**Textual Amendments**

**F56** Reg. 2A inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **4**; 2020 c. 1, Sch. 5 para. 1(1)

### Sponsor of a clinical trial

**3.**—(1) In these Regulations, subject to the following paragraphs, "sponsor" means, in relation to a clinical trial, the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

(2) If two or more persons take responsibility for the matters specified in paragraph (1) in relation to a clinical trial, those persons may—

(a) take joint responsibility for carrying out the functions of the sponsor of that trial under these Regulations; or

(b) allocate responsibility for carrying out the functions of the sponsor of that trial in accordance with paragraphs (4) to (10).

(3) If two or more persons take joint responsibility in accordance with paragraph (2)(a)—

(a) any reference to the sponsor in these Regulations shall, in relation to that trial, be construed as a reference to those persons; and

(b) paragraphs (4) to (10) shall not apply.

(4) One of the persons referred to in paragraph (2) shall be responsible for carrying out the functions of a sponsor under Part 3 (authorisation for clinical trials and ethics committee opinion) and shall make the request for authorisation to conduct the trial in accordance with regulation 17.

(5) The request for authorisation referred to in regulation 17 shall specify—

(a) who, in accordance with paragraph (4), is responsible for carrying out the functions of the sponsor under Part 3;

(b) who is to be responsible for carrying out the functions of the sponsor under Part 4 (good clinical practice and the conduct of clinical trials); and

(c) who is to be responsible for carrying out the functions of the sponsor under Part 5 (pharmacovigilance).

(6) After the clinical trial has been authorised by the licensing authority in accordance with regulation 18, 19 or 20, a different person may be specified as responsible for carrying out the functions of the sponsor under Part 3, 4 or 5 by making a substantial amendment to the terms of a clinical trial authorisation in accordance with regulations 24 to 26.

(7) Where a person is responsible for carrying out the functions of the sponsor under Part 3 by virtue of paragraph (5), or is specified in accordance with paragraph (6) as responsible for those functions, any reference to the sponsor in—

(a) that Part, except regulation 15,

(b) Parts 2 to 4 of Schedule 3,

(c) Schedule 5, in so far as it relates to decisions of the licensing authority under Part 3, and

(d) Schedule 12,

shall, in relation to the trial, be construed as a reference to that person.

(8) Where a person is specified in accordance with paragraph (5) or (6) as responsible for carrying out the functions of the sponsor under Part 4, any reference to the sponsor in—

(a) that Part, except regulation 28(1), or

(b) Schedule 5, in so far as it relates to notices under regulation 31(1),

shall, in relation to the trial, be construed as a reference to that person.

(9) Where a person is specified in accordance with paragraph (5) or (6) as responsible for carrying out the functions of the sponsor under Part 5, any reference to the sponsor in that Part shall, in relation to the trial, be construed as a reference to that person.

(10) Any reference to the sponsor in—

(a) regulations 15 and 28(1),

(b) Parts 2 and 6 to 9, and

(c) Schedules 1 and 7, and Part 1 of Schedule 3,

shall, in relation to the trial, include a reference to a person specified in accordance with paragraph (5) or (6).

(11) A person who is a sponsor of a clinical trial in accordance with this regulation must—

(a) be established in **[**F57the United Kingdom or a country that is included in the list referred to in paragraph (11A)**]**, or

(b) have a legal representative who is so established.

**[**F58(12) A person who is a sponsor of a clinical trial in accordance with this regulation may delegate any or all of his functions under these Regulations to any person but any such arrangement shall not affect the responsibility of the sponsor.**]**

**[**F59(11A) The licensing authority must publish a list of countries where a sponsor of a clinical trial, or their legal representative, may be established for the purpose of paragraph (11).

(11B) In order to determine whether a country should be included in the list referred to in paragraph (11A), the licensing authority may, in particular, take into account—

(a) the mechanisms that the country has in place to assist the licensing authority in contacting, or obtaining information in respect of, a sponsor or legal representative that is established there; and

(b) the country's ability to assist the licensing authority in any action it may need to take in respect of a sponsor or legal representative that is established there.

(11C) The licensing authority must—

(a) review the countries it has included in the list referred to in paragraph (11A) to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(b) undertake such a review at least every three years beginning on the date on which that country is included in that list.**]**

**Textual Amendments**

**F57** Words in reg. 3(11)(a) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **5(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F58** Reg. 3(12) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **3(b)**

**F59** Reg. 3(11A)-(11C) inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **5(3)**; 2020 c. 1, Sch. 5 para. 1(1)

### **[F60Sponsor's responsibility for the investigator's brochure**

**3A.** The sponsor of a clinical trial shall—

(a) ensure that the investigator's brochure for that trial, and any update of that brochure, presents the information it contains in a concise, simple, objective, balanced and non-promotional form that enables a clinician or potential investigator to understand it and make an unbiased risk-benefit assessment of the appropriateness of the proposed clinical trial; and

(b) validate and update the investigator's brochure at least once a year.**]**

**Textual Amendments**

**F60** Reg. 3A inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **4**

### **Responsibility for functions under the Directive**

**F61 4.** . . . . . .

**Textual Amendments**

**F61** Reg. 4 omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **6**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:**
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 1.