STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Interpretation of Part 3

11. In this Part—

"amendment to the clinical trial authorisation" means an amendment to—

(a) the terms of the request for authorisation to conduct that trial or the application for an ethics committee opinion in relation to that trial,

(b) the protocol for that trial, or

(c) the other particulars or documents accompanying that request for authorisation or application for ethics committee approval;

"substantial amendment to the clinical trial authorisation" means an amendment to the clinical trial authorisation which is likely to affect to a significant degree—

(a) the safety or physical or mental integrity of the subjects of the trial,

(b) the scientific value of the trial,

(c) the conduct or management of the trial, or

(d) the quality or safety of any investigational medicinal product used in the trial;

"valid application" means an application for an ethics committee opinion which complies with the provisions of regulation 14; and

"valid request for authorisation" means a request to the licensing authority for authorisation to conduct a clinical trial which complies with the provisions of regulation 17, and "valid amended request" shall be construed accordingly.

Requirement for authorisation and ethics committee opinion

12.—(1) No person shall—

(a) start a clinical trial or cause a clinical trial to be started; or

(b) conduct a clinical trial,

unless the conditions specified in paragraph (3) are satisfied.

(2) No person shall—

(a) recruit an individual to be a subject in a trial;

(b) issue an advertisement for the purpose of recruiting individuals to be subjects in a trial,

unless the condition specified in paragraph (3)(a) has been satisfied.

(3) The conditions referred to in paragraphs (1) and (2) are—

(a) an ethics committee **[**F1to which an application in relation to the trial may be made in accordance with regulation 14**]** or an appeal panel appointed under Schedule 4 has given a favourable opinion in relation to the clinical trial; and

(b) the clinical trial has been authorised by the licensing authority.

(4) For the purposes of these Regulations, a clinical trial has been authorised by the licensing authority if—

(a) in the case of a trial to which regulation 18 relates—

(i) the trial is to be treated as authorised by virtue of regulation 18, or

(ii) the authority has accepted the request for authorisation in accordance with the procedure specified in Schedule 5; or

(b) in the case of a clinical trial to which regulation 19 or 20 applies—

(i) the authority has given a notice of authorisation in accordance with those regulations, or

(ii) the authority has accepted the request for authorisation in accordance with the procedure specified in Schedule 5.

Textual Amendments

F1 Words in reg. 12(3)(a) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **7**

Supply of investigational medicinal products for the purpose of clinical trials

13.—(1) Subject to paragraphs (3) and (4), no person shall, in the course of a business carried on by him, sell or supply any investigational medicinal product to—

(a) an investigator,

(b) a health care professional who is a member of an investigator's team,

(c) a person who provides or is to provide health care under the direction or control of a person referred to in sub-paragraphs (a) and (b), or

(d) a subject,

for the purpose of administering that product in a clinical trial, unless the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to in paragraph (1) are—

(a) the licensing authority has authorised the clinical trial for the purposes of which the product is sold or supplied;

[F2(b) in the case of—

(i) an investigational medicinal product manufactured or assembled in the United Kingdom, the product has been manufactured or assembled—

(aa) in accordance with the terms of a manufacturing authorisation, or

(bb) in the case of assembly only, under the exemption in regulation 37;

(ii) an investigational medicinal product imported into Northern Ireland from an EEA State—

(aa) the product has been manufactured, assembled or imported into an EEA State in accordance with the terms of an authorisation referred to in Article 13 of the Directive granted by a competent authority of an EEA State, and

(bb) the production batch of investigational medicinal products of which the product is a part has been checked and certified by a qualified person pursuant to Article 13(3) and (4) of the Directive;

(iii) an investigational medicinal product imported into Northern Ireland from a country other than an EEA State, the product has been imported into Northern Ireland in accordance with the terms of a manufacturing authorisation;

(iv) an investigational medicinal product imported into Great Britain other than from Northern Ireland, the product has been imported in accordance with the terms of a manufacturing authorisation.**]**

[F3(2A) The condition specified in paragraph (2)(b) does not apply to an investigational medicinal product that has been manufactured or assembled in accordance with the terms of a ... marketing authorization or marketing authorisation issued by the competent authority of an EEA State in accordance with Directive 2001/83/EC relating to that product.**]**

F4(3) . . . . . .

[F5(4) The restriction in paragraph (1) shall not apply to—

(a) the sale or supply of a medicinal product in Great Britain in accordance with the terms of a UKMA(GB) or UKMA(UK), and

(b) the sale or supply of a medicinal product in Northern Ireland in accordance with—

(i) the terms of a UKMA(NI) or UKMA(UK), or

(ii) an EU marketing authorisation (as defined in the 2012 Regulations).**]**

Textual Amendments

F2 Reg. 13(2)(b) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **7(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 2(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Reg. 13(2A) inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **7(3)** (as amended by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 2(b)(i)(ii)**); 2020 c. 1, Sch. 5 para. 1(1)

F4 Reg. 13(3) 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, **7(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Reg. 13(4) substituted (31.12.2020) by S.I. 2019/744, reg. 7(5) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 2(c)**)

Application for ethics committee opinion

14.—(1) An application for an ethics committee opinion in relation to a clinical trial shall be made by the chief investigator for that trial.

(2) A chief investigator for a trial shall make an application for an ethics committee opinion in relation to that trial to one ethics committee only, regardless of the number of trial sites at which the trial is to be conducted.

(3) Subject to paragraphs (4) and (5), the application for an ethics committee opinion in relation to a clinical trial shall be made to an ethics committee established or recognised—

(a) for—

(i) the entire United Kingdom, or

(ii) in relation to an area of the United Kingdom in which the chief investigator is professionally based; and

(b) in relation to a description or class of clinical trial into which the proposed trial falls.

(4) If a clinical trial—

(a) is conducted at one or more trial sites in Scotland;

(b) involves adults unable by virtue of physical or mental incapacity to give informed consent; and

(c) the chief investigator is professionally based at a hospital, health centre, surgery or other establishment or facility in Scotland,

the application for an ethics committee opinion in relation to that trial shall be made to the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000 [F6].

(5) An application for an ethics committee opinion in relation to a clinical trial involving medicinal products for gene therapy, other than a trial falling within paragraph (4), shall be made to the Gene Therapy Advisory Committee.

(6) An application shall be—

(a) in writing;

(b) signed by the chief investigator making the application; and

(c) accompanied by the particulars and documents specified in Part 1 of Schedule 3.

(7) The application and any accompanying material shall be supplied in the English language.

(8) For the purposes of this regulation, a chief investigator is professionally based at the hospital, health centre, surgery or other establishment or facility at or from which he primarily conducts his professional practice.

Textual Amendments

F6 2000 asp. 4; *see*S.S.I. 2002/190.

Ethics committee opinion

15.—**[**[F7](1) Except as provided for in paragraph (4A) (which removes the requirement on the Gene Therapy Advisory Committee to give an opinion) and subject to paragraphs (3) and (4) (which suspend and disapply time limits respectively), an ethics committee shall give an opinion in relation to the clinical trial to which a valid application relates within the specified period beginning with the date of receipt of the valid application.**]**

(2) Where following receipt of a valid application it appears to the committee that further information is required in order to give an opinion on a trial, the committee may, within the specified period and before giving its opinion, send a notice in writing to the applicant requesting that he furnishes the committee with that information.

(3) Where the committee sends a request in accordance with paragraph (2), the specified period shall be suspended pending receipt of the information requested.

[F8(3A) An ethics committee may give a favourable opinion subject to conditions specified in writing in relation to a clinical trial.

(3B) If an ethics committee gives a favourable opinion subject to conditions, the ethics committee is to be treated as having given a favourable opinion in relation to the clinical trial only if the specified conditions are satisfied.**]**

(4) If the clinical trial involves a medicinal product for xenogenic cell therapy, the time limits referred to in paragraphs (1) to (3) shall not apply and the ethics committee may give an opinion in relation to that trial or send a notice under paragraph (2) at any time after receipt of the valid application.

[F9(4A) Where a notification under paragraph (4B) is received by the Authority—

(a) the Gene Therapy Advisory Committee shall not give an opinion in relation to the clinical trial to which the application subject to that notification relates;

(b) the Authority shall direct that the application be considered by another ethics committee specified in the direction;

(c) the Gene Therapy Advisory Committee shall send the application to the ethics committee specified in the direction immediately following the direction being given; and

(d) the ethics committee specified in the direction shall, subject to the application being valid, give an opinion in relation to the clinical trial to which that application relates within the specified period beginning with the date of the Gene Therapy Advisory Committee's receipt of the application.

(4B) The Chairman, vice-chairman or alternate vice-chairman of the Gene Therapy Advisory Committee may notify the Authority (instead of giving an opinion) within the specified period beginning with the date of the Committee's receipt of an application that the clinical trial to which that application relates does not merit an opinion from the Gene Therapy Advisory Committee.**]**

(5) In preparing its opinion, the committee shall consider, in particular, the following matters—

(a) the relevance of the clinical trial and its design;

(b) whether the evaluation of the anticipated benefits and risks as required under **[**F10paragraph 10**]** of Part 2 of Schedule 1 is satisfactory and whether the conclusions are justified;

(c) the protocol;

(d) the suitability of the investigator and supporting staff;

(e) the investigator's brochure **[**F11or, where the investigational medicinal product has a marketing authorization and the product is to be used in accordance with the terms of that authorization, the summary of product characteristics **[**F12, or equivalent document,**]** relating to that product**]**;

(f) the quality of the facilities for the trial;

(g) the adequacy and completeness of the written information to be given, and the procedure to be followed, for the purpose of obtaining informed consent to the subjects' participation in the trial;

(h) if the subjects are to include **[**F13minors or**]** persons incapable of giving informed consent, whether the research is justified having regard to the conditions and principles specified in **[**F14Part 4 or Part 5 respectively**]** of Schedule 1;

(i) provision for indemnity or compensation in the event of injury or death attributable to the clinical trial;

(j) any insurance or indemnity to cover the liability of the investigator or sponsor;

(k) the amounts, and, where appropriate, the arrangements, for rewarding or compensating investigators and subjects;

(l) the terms of any agreement between the sponsor and the owner or occupier of the trial site which are relevant to the arrangements referred to in sub-paragraph (k); and

(m) the arrangements for the recruitment of subjects.

(6) If—

(a) any subject of the clinical trial is to be a minor; and

(b) the committee does not have a member with professional expertise in paediatric care,

it shall, before giving its opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of paediatric care which may arise in relation to that trial.

(7) If—

(a) any subject to the clinical trial is to be an adult incapable by reason of physical and mental incapacity to give informed consent to participation in the trial; and

(b) the committee does not have a member with professional expertise in the treatment of—

(i) the disease to which the trial relates, and

(ii) the patient population suffering that disease,

it shall, before giving its opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of that disease and patient population which may arise in relation to that trial.

(8) The ethics committee shall consider, and give an opinion on, any other issue relating to the clinical trial, if—

(a) the committee has been asked by the applicant to consider the issue;

(b) it is, in the committee's opinion, relevant to the other matters considered by the committee in accordance with this regulation.

(9) Where an ethics committee gives an opinion in accordance with this regulation, it shall publish a summary of that opinion.

(10) In this regulation—

"the specified period" means—

(a) in the case of a clinical trial involving a medicinal product for gene therapy or somatic cell therapy or a medicinal product containing a genetically modified organism **[**[F15]or a tissue engineered product**]**—

(i) where a specialist group or committee is consulted, 180 days, or

(ii) where there is no such consultation, 90 days; or

(b) in any other case, 60 days;

[[F16]"specialist group or committee" means a group or committee whose functions include the provision of advice on ethical or scientific issues in relation to—

(a) tissue engineered products;

(b) in the case of medicinal products for gene therapy or somatic cell therapy, the use of such therapies in the treatment of humans; or

(c) in the case of medicinal products containing genetically modified organisms, the administration of such products to humans.**]**

Textual Amendments

F7 Reg. 15(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), **3(a)**

F8 Reg. 15(3A)(3B) inserted (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), **3(b)**

F9 Reg. 15(4A)(4B) inserted (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), **3(c)**

F10 Words in reg. 15(5)(b) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **9(a)**

F11 Words in reg. 15(5)(e) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **9(b)**

F12 Words in reg. 15(5)(e) inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **8**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in reg. 15(5)(h) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **9(c)(i)**

F14 Words in reg. 15(5)(h) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **9(c)(ii)**

F15 Words in reg. 15(10) inserted (19.8.2010) by The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882), regs. 1(1), **9(2)(a)**

F16 Words in reg. 15(10) substituted (19.8.2010) by The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882), regs. 1(1), **9(2)(b)**

Review and appeal relating to ethics committee opinion

16.—(1) This regulation applies where a chief investigator for a trial has been notified by the ethics committee to which he made an application in accordance with regulation **[**[F17]14**]** that the committee's opinion in relation to that trial is not favourable.

(2) This regulation does not apply in relation to an opinion given by—

(a) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000; or

(b) an ethics committee pursuant to paragraph 2 of Schedule 4.

(3) Where the opinion was given by an ethics committee other than the Gene Therapy Advisory Committee, the chief investigator may within 90 days of being notified that the committee's opinion is not favourable, give a notice to the United Kingdom Ethics Committees Authority—

(a) stating his wish to appeal against the opinion; and

(b) setting out his representations with respect to that opinion.

(4) Where the opinion was given by the Gene Therapy Advisory Committee, the chief investigator may, within 14 days of being notified of that opinion—

(a) give a notice in writing to the Committee requiring the Committee to review its opinion; or

(b) give a notice in writing to the United Kingdom Ethics Committee Authority—

(i) stating his wish to appeal against the opinion; and

(ii) setting out his representations with respect to that opinion.

(5) Where the Gene Therapy Advisory Committee is required by a notice under paragraph (4) to review its opinion, it must do so within 60 days of receipt of the notice.

(6) On a review pursuant to paragraph (5), the Gene Therapy Advisory Committee may vary or confirm their opinion and shall give notice in writing to the chief investigator of the variation or confirmation.

(7) If the Gene Therapy Advisory Committee confirm their opinion pursuant to paragraph (6), a chief investigator may within the 14 days of being notified of the confirmation give notice in writing to the United Kingdom Ethics Committees Authority—

(a) stating his wish to appeal against the Committee's opinion; and

(b) setting out his representations with respect to that opinion

(8) Schedule 4 shall have effect to regulate the procedure where the Authority receives a notice in accordance with paragraph (3), (4) or (7).

Textual Amendments

F17 Word in reg. 16(1) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **10**

Request for authorisation to conduct a clinical trial

17.—(1) A request for authorisation to conduct a clinical trial shall be made to the licensing authority by the sponsor of the trial.

(2) **[**[F18]Subject to paragraph (2A), a**]** request shall—

(a) be in writing and signed by or on behalf of the sponsor; and

(b) be accompanied by—

(i) the particulars and documents specified in Part 2 of Schedule 3, and

(ii) any fee which may be payable in connection with that application under the **[**[F19]Medicines (Products for Human Use) (Fees) Regulations 2016**]**.

[[F20](2A) No fee need accompany a request where arrangements have been made with the licensing authority for payment of the fee referred to in paragraph (2)(b)(ii) other than at the time of request.**]**

(3) The request and any accompanying material shall be supplied in the English language.

Textual Amendments

F18 Words in reg. 17(2) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **11(a)**

F19 Words in reg. 17(2)(b)(ii) substituted (1.4.2016) by The Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190), regs. 1, **61(2)(a)**

F20 Reg. 17(2A) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **11(b)**

Authorisation procedure for clinical trials involving general medicinal products

18.—(1) This regulation applies to clinical trials involving medicinal products other than those to which regulations 19 and 20 apply.

(2) The licensing authority may, within the period of 30 days from the date of receipt of a valid request for authorisation of a clinical trial to which this regulation applies, give written notice to the sponsor—

(a) setting out the licensing authority's grounds for not accepting the request;

(b) stating that the licensing authority accepts the request for authorisation; or

(c) stating that the licensing authority accepts the request for authorisation, subject to the conditions specified in the notice.

(3) Subject to paragraph (4), if—

(a) a notice is given in accordance with paragraph (2)(b); or

(b) no notice is given in accordance with paragraph (2),

the clinical trial is to be treated as authorised.

(4) If a notice is given in accordance with paragraph (2)(c), the clinical trial is to be treated as authorised only if the conditions specified in the notice are satisfied.

(5) If the sponsor is given a notice in accordance with paragraph (2)(a) or (c), he may, within the period of 14 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration.

(6) The licensing authority shall consider a valid amended request and may, within the period of 60 days from the date on which the original request was received give a written notice to the sponsor—

(a) setting out the licensing authority's grounds for not accepting the amended request;

(b) stating that the licensing authority accepts the amended request; or

(c) stating that the licensing authority accepts the amended request, subject to the conditions specified in the notice.

(7) Subject to paragraph (8), if a valid amended request has been received and—

(a) a notice is given in accordance with paragraph (6)(b); or

(b) no notice is given in accordance with paragraph (6),

the clinical trial is to be treated as authorised.

(8) If a valid amended request has been received and a notice is given in accordance with paragraph (6)(c), the clinical trial is to be treated as authorised only if the conditions specified in the notice are satisfied.

(9) If—

(a) the licensing authority gives written notice to the sponsor of grounds for non-acceptance in accordance with paragraph (2)(a) and the sponsor does not submit an amended request in accordance with paragraph (5), or

(b) the sponsor has submitted an amended request in accordance with paragraph (5), but the licensing authority gives written notice to the sponsor of grounds for non-acceptance in accordance with paragraph (6)(a),

the request is to be treated as rejected and the authority shall not consider any further amendments to the request.

Authorisation procedure for clinical trials involving medicinal products for gene therapy etc.

19.—[[F21](1) This regulation applies to clinical trials involving—

(a) medicinal products for gene therapy and somatic cell therapy, including xenogenic cell therapy;

(b) medicinal products containing genetically modified organisms; or

(c) tissue engineered products.**]**

(2) Subject to the following provisions of this regulation, the licensing authority may, within the period of 30 days from the date of receipt of a valid request for authorisation of a clinical trial to which this regulation applies—

(a) issue a written authorisation to the sponsor; or

(b) give a notice in writing to the sponsor setting out the grounds for not accepting the request.

(3) The licensing authority shall not authorise a clinical trial involving products for gene therapy if the use of those products in that trial would result in modifications to any subject's germ line genetic identity.

(4) If the licensing authority considers that it is appropriate to do so, they may consult the relevant committee before deciding whether to authorise a clinical trial.

(5) Where the authority consults the relevant committee in accordance with paragraph (4), the period specified in paragraph (2) shall be extended by a further 90 days.

(6) Where a sponsor is given a notice in accordance with paragraph (2)(b), he may, within the period of 30 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration.

(7) The licensing authority shall consider a valid amended request and, not later than 90 days, or, in a case falling within paragraph (5), 180 days, from the date on which the original request was received—

(a) issue a written authorisation to the sponsor; or

(b) give a notice in writing to the sponsor setting out the grounds for not accepting the request.

(8) A written authorisation issued under this regulation may contain such conditions as the licensing authority consider appropriate.

(9) If the clinical trial involves a medicinal product for xenogenic cell therapy, the time limits set out in paragraphs (2), (5) and (7) shall not apply and the authority may issue an authorisation or notice under those paragraphs at any time after receipt of the request.

(10) In this regulation, "the relevant committee" means—

(a) the **[**F22Commission on Human Medicines F23...**]**; or

(b) such other body or committee as the licensing authority may consider appropriate in relation to the application under consideration.

Textual Amendments

F21 Reg. 19(1) substituted (19.8.2010) by The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882), regs. 1(1), **9(3)**

F22 Words in reg. 19(10)(a) substituted (30.10.2005) by The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 2**

F23 Words in reg. 19(10) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 55** (with Sch. 32)

Authorisation procedure for clinical trials involving medicinal products with special characteristics

20.—(1) This regulation applies to clinical trials—

(a) involving medicinal products—

[F24(i) which do not have a marketing authorization and are developed by means of one of the following biotechnological processes—

(aa) recombinant DNA technology,

(bb) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,

(cc) hybridoma and monoclonal antibody methods, or**]**

(ii) which have an active ingredient—

(aa) that is a biological product of human or animal origin,

(bb) containing biological components of human or animal origin, or

(cc) the manufacturing of which requires such components,

other than products falling within regulation 19; or

(b) where the licensing authority, within 7 days from the date of receipt of a valid request for authorisation of the trial, issues a notice to the sponsor specifying that by virtue of the special characteristics of the medicinal product to which the trial relates, written authorisation for that trial is required.

(2) The licensing authority may, within the period of 30 days from the date of receipt of a valid request for authorisation of a clinical trial to which this regulation applies—

(a) issue a written authorisation to the sponsor; or

(b) give a notice in writing to the sponsor setting out the grounds for not authorising the trial.

(3) Where a sponsor is given a notice in accordance with paragraph (2)(b), he may, within the period of 14 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration.

(4) The licensing authority shall consider a valid amended request and, not later than 60 days from the date on which the original request was received—

(a) issue a written authorisation to the sponsor; or

(b) give a notice in writing to the sponsor setting out the grounds for not accepting the request.

(5) A written authorisation issued under this regulation may contain such conditions as the licensing authority consider appropriate.

Textual Amendments

F24 Reg. 20(1)(a)(i) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **9**; 2020 c. 1, Sch. 5 para. 1(1)

Clinical trials conducted in [F25countries other than the United Kingdom]

21.—(1) If the licensing authority receives a valid request for authorisation relating to a clinical trial which is or is to be conducted in **[**F26another**]** country as well as the United Kingdom, the licensing authority may, if they think fit, require the production by the sponsor of any one or more of the following—

(a) an undertaking, given by the sponsor, to permit their premises in that country to be inspected by or on behalf of the licensing authority for the purpose of establishing whether the conditions and principles of good clinical practice are satisfied or adhered to in relation to that trial; or

(b) an undertaking, given by the owner or occupier of any premises in that country at which the clinical trial is or is to be conducted, to permit those premises to be inspected by or

on behalf of the licensing authority for the purpose of establishing whether the conditions and principles of good clinical practice are satisfied or adhered to in relation to that trial.

(2) If a sponsor fails to produce an undertaking required by the licensing authority in accordance with paragraph (1), that failure constitutes a ground for not accepting the request for authorisation, for the purposes of regulations 18 to 20.

Textual Amendments

F25 Words in reg. 21 heading substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **10(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F26 Word in reg. 21(1) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **10(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Amendments to clinical trial authorisation

22. Subject to regulation 30, an amendment to a clinical trial authorisation may be made—

(a) by the licensing authority, in accordance with regulation 23; or

(b) by the sponsor, in accordance with regulation 24 or 25.

Amendments by the licensing authority

23.—(1) Subject to paragraphs **[**F27(2) and (3)**]**, the licensing authority may make amendments to a clinical trial authorisation if it appears to the authority to be necessary to ensure—

(a) the safety or scientific validity of the clinical trial; or

(b) that the conditions and principles of good clinical practice are satisfied or adhered to in relation to the clinical trial.

(2) Where the licensing authority propose to make an amendment in accordance with paragraph (1), the authority shall, at least 14 days before the date on which it is proposed the amendment should take effect, serve a notice on the sponsor stating their proposal and the reasons for it.

(3) If, within 14 days of the date a notice is served in accordance with paragraph (2), the sponsor makes representations in writing to the licensing authority, the authority—

(a) shall take those representations into account before deciding whether to make the amendment; and

(b) may delay the date the proposed amendment is to take effect, in order to allow time for them to consider those representations.

Textual Amendments

F27 Words in reg. 23(1) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **12**

Amendments by the sponsor

24.—(1) A sponsor may make an amendment to a clinical trial authorisation, other than a substantial amendment, at any time.

(2) A sponsor shall—

(a) keep records of the amendments made in accordance with paragraph (1); and

(b) send those records, or copies of such records, to the licensing authority, where the authority send him a notice in writing requiring him to provide those records, or copies of such records.

(3) If the sponsor proposes to make a substantial amendment to a clinical trial authorisation which consists of, or includes, an amendment to—

(a) the terms of the request for authorisation of the clinical trial; or

(b) the particulars or documents that accompanied that request,

he shall send a valid notice of amendment to the licensing authority, whether or not he is also required to send a notice in accordance with paragraph (4).

(4) If the sponsor proposes to make a substantial amendment to a clinical trial authorisation which consists of, or includes, an amendment to—

(a) the terms of the application for an ethics committee opinion in relation to the clinical trial; or

(b) the particulars or documents that accompanied that application,

he shall send a valid notice of amendment to the relevant ethics committee, whether or not he is also required to send a notice in accordance with paragraph (3).

(5) The licensing authority may, within the period of 35 days from the date of receipt of a valid notice of amendment, give written notice to the sponsor—

(a) setting out the licensing authority's grounds for not accepting the proposed amendment; or

(b) stating that the licensing authority accepts the application for amendment, subject to any conditions which may be specified in the notice.

(6) A relevant ethics committee shall, within the period of 35 days from the date of receipt of a valid notice of amendment, give an opinion to the sponsor.

(7) Subject to paragraph (8), if the sponsor has sent a notice in accordance with paragraph (3), he may make the amendment only if—

(a) the licensing authority have given him a notice in accordance with paragraph (5)(b); or

(b) no notice has been given by the licensing authority in accordance with paragraph (5).

(8) If the sponsor has been given a notice in accordance with paragraph (5)(b), he may make the amendment subject to the conditions, if any, specified in the notice.

(9) If the sponsor has sent a notice in accordance with paragraph (4), he may make the amendment only if the relevant ethics committee has given a favourable opinion.

(10) In this regulation—

[[F28]"any relevant fee" means, in relation to a notice of amendment, any fee which may be payable in connection with that notice under the **[**[F29]Medicines (Products for Human Use) (Fees) Regulations 2016**]**; and**]**

"valid notice of amendment" means a notice that is—

((a)) in writing; and

((b)) accompanied by—

(i) the particulars specified in Part 3 of Schedule 3, and

(ii) **[**[F30]unless arrangements have been made with the licensing authority for the payment of any relevant fee other than at the time of the request, any such fee.**]**

Textual Amendments

F28 Words in reg. 24(10) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **13(a)**

F29 Words in reg. 24(10) substituted (1.4.2016) by The Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190), regs. 1, **61(2)(b)**

F30 Words in reg. 24(10) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **13(b)**

Modifying or adapting rejected proposals for amendment

25.—(1) Subject to the following provisions of this regulation, if—

(a) the ethics committee opinion on a proposed amendment to the protocol is not favourable; or

(b) the sponsor has been notified by the licensing authority of any grounds for non-acceptance of a proposed amendment to the protocol,

and it is possible to modify or adapt the proposed amendment in order to meet the concerns of ethics committee or the licensing authority as set out in the opinion or, as the case may be, the grounds for non-acceptance, the sponsor may amend the protocol accordingly.

(2) If a sponsor proposes to amend the protocol in accordance with paragraph (1), the sponsor shall, at least 14 days before the amendment is to be made, give a notice in writing to the licensing authority and the relevant ethics committee.

(3) The licensing authority may, within the period of 14 days from the date of receipt of a notice under paragraph (1), give written notice to the sponsor setting out the licensing authority's further grounds for not accepting the modified or adapted amendment.

(4) The relevant ethics committee may, within the period of 14 days from the date of receipt of a notice under paragraph (1), give a written notice to the sponsor stating that its opinion of the modified or adapted amendment is unfavourable.

(5) If—

(a) the sponsor receives a written notice under paragraphs (3) or (4), he may not make the amendment; and

(b) if he receives no such notice, he may make the modified or adapted amendment.

Reference to the appropriate committee or the Medicines Commission

26.—(1) If—

(a) a sponsor has been notified by the licensing authority that—

(i) there are grounds for not accepting a request for authorisation, or

(ii) in accordance with regulation 18(2) or (6), 19(8) or 20(5), the trial is authorised subject to specified conditions;

(b) the licensing authority has amended a clinical trial authorisation under regulation 23; or

(c) the sponsor [F31]... has been notified by the licensing authority in accordance with regulation **[**[F32]24(5)**]** or 25(3) that—

(i) the authority does not accept a proposed, modified or adapted amendment to the clinical trial authorisation, or

(ii) the authority accepts such an amendment subject to conditions,

the sponsor may, within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given, give notice in writing to the licensing authority of his wish to make written or oral representations to the appropriate committee [F33]....

(2) Schedule 5 shall have effect to regulate the procedure for reference to the appropriate committee [F34]... following receipt of a notice in accordance with paragraph (1).

Textual Amendments

F31 Word in reg. 26(1)(c) omitted (30.10.2005) by virtue of The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 3(a)(i)(aa)**

F32 Word in reg. 26(1)(c) substituted (30.10.2005) by The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 3(a)(i)(bb)**

F33 Words in reg. 26(1) omitted (30.10.2005) by virtue of The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 3(a)(ii)**

F34 Words in reg. 26(2) omitted (30.10.2005) by virtue of The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 3(b)**

Conclusion of clinical trial

27.—(1) Subject to paragraph (2), within 90 days of the conclusion of a clinical trial the sponsor shall notify the licensing authority and the relevant ethics committee in writing that the trial has ended.

(2) If a trial is terminated—

(a) before the date for the conclusion of the trial specified in the protocol for that trial, or

(b) before the event specified in the protocol as the event which indicates the end of the trial has occurred,

the sponsor shall notify the licensing authority and the relevant ethics committee in writing of the termination of the trial within 15 days of the date of termination.

(3) A notification made in accordance with paragraphs (1) or (2) shall contain the particulars specified in Part 4 of Schedule 3.

[F35Information sharing

27A. The licensing authority and an ethics committee may disclose to each other any information acquired in carrying out their respective functions under these Regulations where disclosing such information may assist the other body in carrying out its functions under these Regulations.**]**

Textual Amendments

F35 Reg. 27A inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **14**

[F36Publication of information

27B.—(1) Subject to paragraph (3), the licensing authority may make accessible to the public information contained in the items listed in paragraph (2) insofar as it relates to a clinical trial carried out, or being carried out, under these Regulations.

(2) The items listed in this paragraph are—

(a) the request for authorisation made under regulation 17;

(b) any amended request for authorisation made under regulation 18, 19 or 20;

(c) any amendment to the protocol made under regulation 23, 24 or 25;

(d) the favourable opinion of the ethics committee given in accordance with regulation 15 or the favourable opinion given by an appeal panel in accordance with paragraph 4 of Schedule 4;

(e) the notification of the end of the clinical trial made under regulation 27.

(3) Prior to making information available to the public under paragraph (1), the licensing authority must, after consulting such persons as the licensing authority considers appropriate, publish a list of the information which may be made accessible to the public under paragraph (1).**]**

Textual Amendments

F36 Reg. 27B inserted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **11**; 2020 c. 1, Sch. 5 para. 1(1)

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 3.