STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Ethics committee opinion

15.—**[**F1(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.

[F2(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.

[F3(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 **[**F4paragraph 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 **[**F5or, 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 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 **[**F6minors or**]** persons incapable of giving informed consent, whether the research is justified having regard to the conditions and principles specified in **[**F7Part 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 **[**[F8]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;

[[F9]"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

F1 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)**

F2 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)**

F3 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)**

F4 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)**

F5 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)**

F6 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)**

F7 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)**

F8 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)**

F9 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)**

Status:
Point in time view as at 19/08/2010. This version of this provision has been superseded.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 15.