SCHEDULE 1 Regulation 2(1)

CONDITIONS AND PRINCIPLES OF GOOD CLINICAL PRACTICE AND FOR THE PROTECTION OF CLINICAL TRIAL SUBJECTS

PART 1

APPLICATION AND INTERPRETATION

1.—(1) The conditions and principles specified in Part 2 apply to all clinical trials.

(2) If any subject of a clinical trial is—

(a) an adult able to give informed consent, or

(b) an adult who has given informed consent to taking part in the clinical trial prior to the onset of incapacity,

the conditions and principles specified in Part 3 apply in relation to that subject.

(3) If any subject of a clinical trial is a minor, the conditions and principles specified in Part 4 apply in relation to that subject.

(4) If any subject—

(a) is an adult unable by virtue of physical or mental incapacity to give informed consent, and

(b) did not, prior to the onset of incapacity, give or refuse to give informed consent to taking part in the clinical trial,

the conditions and principles specified in Part 5 apply in relation to that subject.

(5) If any person—

(a) is an adult unable by virtue of physical or mental incapacity to give informed consent, and

(b) has, prior to the onset of incapacity, refused to give informed consent to taking part in the clinical trial,

that person cannot be included as a subject in the clinical trial.

2. In this Schedule—

"Declaration of Helsinki" means the Declaration of Helsinki adopted by the World Medical Assembly in June 1964, as amended by the General Assembly of the Association in October 1975, October 1983, September 1989 and October 1996;

"guardian" shall be construed in accordance with section 51(8) of the Adults with Incapacity (Scotland) Act 2000 [F1];

"legal representative" means, in relation to a minor or to an adult unable by virtue of physical or mental incapacity to give informed consent, and who is, or is being considered as, a subject for a clinical trial—

(a) in relation to adults and minors in England, Wales and Northern Ireland, and minors in Scotland—

(i) a person, other than a person involved in the conduct of the trial, who—

(aa) by virtue of their relationship with that adult or that minor, is suitable to act as their legal representative for the purposes of that trial, and

(bb) is available and willing to so act for those purposes, or

(ii) if there is no such person, a person, other than a person connected with the conduct of the clinical trial, who is—

(aa) the doctor primarily responsible for the medical treatment provided to that adult, or

(bb) a person nominated by the relevant health care provider; and

(b) in relation to adults in Scotland—

(i) any guardian or welfare attorney who has power to consent to the adult's participation in research, or

(ii) if there is no such guardian or welfare attorney, the adult's nearest relative, or

(iii) if it is not reasonably practicable to contact a guardian or welfare attorney or the adult's nearest relative before the decision to enter the adult as a subject of the clinical trial is made, a person, other than a person connected with the conduct of the clinical trial, who is—

(aa) the doctor primarily responsible for the medical treatment provided to that adult, or

(bb) a person nominated by the relevant health care provider;

"nearest relative" has the meaning given by section 87(1) of the Adults with Incapacity (Scotland) Act 2000;

"parental responsibility"—

(a) in relation to England and Wales, has the same meaning as in the Children Act 1989 [F2],

(b) in relation to Scotland, has the same meaning as in the Children (Scotland) Act 1985 [F3], and

(c) in relation to Northern Ireland, has the same meaning as in the Children (Northern Ireland) Order 1995 [F4];

"person connected with the conduct of the trial" means—

(a) the sponsor of the trial,

(b) a person employed or engaged by, or acting under arrangements made with, the sponsor and who undertakes activities in connection with the management of the trial,

(c) an investigator for the trial,

(d) a health care professional who is a member of an investigator's team for the purposes of the trial, or

(e) a person who provides health care under the direction or control of a person referred to in paragraphs (c) and (d) above, whether in the course of the trial or otherwise;

"relevant health care provider" means—

(a) in relation to a person receiving services in pursuance of the National Health Service Act 1977 [F5], the National Health Service (Scotland) Act 1978 [F6], or the Health and Personal Social Services (Northern Ireland) Order 1972 [F7]—

(i) in a case where a health service body is providing those services, that body, or

(ii) in any other case, the health service body which entered the arrangements under which those services are provided, or

(b) in relation to any other person receiving health care, the person primarily responsible for providing that health care; and

"welfare attorney" shall be construed in accordance with section 51(8) of the Adults with Incapacity (Scotland) Act 2000.

Textual Amendments

F1 2000 asp 4.
F2 1989 c. 41; *see*, in particular, sections 3(1) and 5(6).
F3 1995 c. 36; *see*, in particular, sections 1(3) and 7(5).
F4 S.I. 1995/755 (N.I.2); *see*, in particular, article 6.
F5 1977 c. 49.
F6 1978 c. 29.
F7 S.I. 1972/1265 (N.I. 14).

3.—(1) For the purposes of this Schedule, a person gives informed consent to take part, or that a subject is to take part, in a clinical trial only if his decision—

(a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and

(b) either—

(i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or

(ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.

(2) For the purposes of this Schedule, references to informed consent—

(a) shall be construed in accordance with paragraph (1); and

(b) include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity.

PART 2

CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

Principles based on International Conference on Harmonisation GCP Guideline [F8]

1. Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with good clinical practice and the requirements of these Regulations.

Textual Amendments

F8 *See* Section 2 of the Note for Guideline on Good Clinical Practice (CPMP/ICH/135/95) published by the European Agency for the Evaluation of Medicinal Products in July 2002.

2. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The rights, safety, and well-being of the trial subjects are the most important considerations and shall prevail over interests of science and society .

4. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the clinical trial.

5. Clinical trials shall be scientifically sound, and described in a clear, detailed protocol.

6. A trial shall be conducted in compliance with the protocol that has a favourable opinion from an ethics committee.

7. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

8. Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s).

9. Subject to the other provisions of this Schedule relating to consent, freely given informed consent shall be obtained from every subject prior to clinical trial participation.

10. All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

11. The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules in accordance with the requirements of the Data Protection Act 1998 and the law relating to confidentiality.

12. Investigational medicinal products used in the trial shall be—

(a) manufactured or imported, and handled and stored, in accordance with the principles and guidelines of good manufacturing practice, and

(b) used in accordance with the approved protocol.

13. Systems with procedures that assure the quality of every aspect of the trial shall be implemented.

Conditions based on Article 3 of the Directive

14. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

15. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

16. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.

PART 3

CONDITIONS WHICH APPLY IN RELATION TO AN ADULT ABLE TO CONSENT OR WHO HAS GIVEN CONSENT PRIOR TO THE ONSET OF INCAPACITY

1. The subject has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

2. The subject has been informed of his right to withdraw from the trial at any time.

3. The subject has given his informed consent to taking part in the trial.

4. The subject may, without being subject to any resulting detriment, withdraw from the clinical trial at any time by revoking his informed consent.

5. The subject has been provided with a contact point where he may obtain further information about the trial.

PART 4

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO A MINOR

Conditions

1. Subject to paragraph 6, a person with parental responsibility for the minor or, if by reason of the emergency nature of the treatment provided as part of the trial no such person can be contacted prior to the proposed inclusion of the subject in the trial, a legal representative for the minor has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

2. That person or legal representative has been provided with a contact point where he may obtain further information about the trial.

3. That person or legal representative has been informed of the right to withdraw the minor from the trial at any time.

4. That person or legal representative has given his informed consent to the minor taking part in the trial.

5. That person with parental responsibility or the legal representative may, without the minor being subject to any resulting detriment, withdraw the minor from the trial at any time by revoking his informed consent.

6. The minor has received information according to his capacity of understanding, from staff with experience with minors, regarding the trial, its risks and its benefits.

7. The explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in the previous paragraph to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator.

8. No incentives or financial inducements are given—

(a) to the minor; or

(b) to a person with parental responsibility for that minor or, as the case may be, the minor's legal representative,

except provision for compensation in the event of injury or loss.

9. The clinical trial relates directly to a clinical condition from which the minor suffers or is of such a nature that it can only be carried out on minors.

10. Some direct benefit for the group of patients involved in the clinical trial is to be obtained from that trial.

11. The clinical trial is necessary to validate data obtained—

(a) in other clinical trials involving persons able to give informed consent, or

(b) by other research methods.

12. The corresponding scientific guidelines of the European Medicines Agency are followed.

Principles

13. Informed consent given by a person with parental responsibility or a legal representative to a minor taking part in a clinical trial shall represent the minor's presumed will.

14. The clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development.

15. The risk threshold and the degree of distress have to be specially defined and constantly monitored.

16. The interests of the patient always prevail over those of science and society.

PART 5

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO AN INCAPACITATED ADULT

Conditions

1. The subject's legal representative has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

2. The legal representative has been provided with a contact point where he may obtain further information about the trial.

3. The legal representative has been informed of the right to withdraw the subject from the trial at any time.

4. The legal representative has given his informed consent to the subject taking part in the trial.

5. The legal representative may, without the subject being subject to any resulting detriment, withdraw the subject from the trial at any time by revoking his informed consent.

6. The subject has received information according to his capacity of understanding regarding the trial, its risks and its benefits.

7. The explicit wish of a subject who is capable of forming an opinion and assessing the information referred to in the previous paragraph to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator.

8. No incentives or financial inducements are given to the subject or their legal representative, except provision for compensation in the event of injury or loss.

9. There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the subject outweighing the risks or produce no risk at all.

10. The clinical trial is essential to validate data obtained—

(a) in other clinical trials involving persons able to give informed consent, or

(b) by other research methods.

11. The clinical trial relates directly to a life-threatening or debilitating clinical condition from which the subject suffers.

Principles

12. Informed consent given by a legal representative to an incapacitated adult in a clinical trial shall represent that adult's presumed will.

13. The clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.

14. The risk threshold and the degree of distress have to be specially defined and constantly monitored.

15. The interests of the patient always prevail over those of science and society.

SCHEDULE 2

Regulations 7(1)(b), 8(a) and 9

ADDITIONAL PROVISIONS RELATING TO ETHICS COMMITTEES

1. In this Schedule—

"appointing authority" means—

(a) in relation to an ethics committee established under regulation 6, the Authority,

(b) in relation to an ethics committee recognised by the Authority after an application in accordance with regulation 7(1), the person who applied for recognition, or

(c) in relation to an ethics committee recognised without an application for recognition being submitted in accordance with regulation 7(3), the Authority;

"expert member" means a member of an ethics committee who—

(a) is a health care professional,

(b) has professional qualifications or experience relating to the conduct of, or use of statistics in clinical trials, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment, or

(c) is not a health care professional, but has been a registered medical practitioner or a person registered in the dentists register under the Dentists Act 1984;

"financial year" means the twelve months ending with 31st March; and

"lay member" means a member of an ethics committee, other than an expert member.

2.—(1) The provisions of this Schedule shall not apply in relation to the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000.

(2) The provisions of this Schedule, other than paragraph 13, shall not apply before 1st May 2005 in relation to an ethics committee established or recognised solely for the purpose of considering Phase I trials.

Membership

3.—(1) An ethics committee shall consist of—

(a) expert members; and

(b) lay members.

(2) An ethics committee shall have no more than 18 members.

(3) Subject to paragraph 7, the members of an ethics committee shall be appointed by the appointing authority.

(4) A person shall not be eligible for appointment as a lay member of an ethics committee if, in the course of his employment or business, he—

(a) provides medical, dental or nursing care, or

(b) conducts clinical research.

(5) An appointing authority shall, in relation to an ethics committee, exercise their power under sub-paragraph (3) so as to ensure that—

(a) at least one third of the total membership shall be lay members; and

(b) at least half of the lay members must be persons who are not, or who never have been—

(i) health care professionals,

(ii) persons involved in the conduct of clinical research, other than as a subject of such research, or

(iii) a chairman, member or director of—

(aa) a health service body, or

(bb) a body, other than a health service body, which provides health care.

4. A member of an ethics committee shall hold and vacate office as a member in accordance with the terms of the instrument appointing him as a member.

5.—(1) The appointing authority shall appoint—

(a) one of the members of each ethics committee to be chairman of the committee;

(b) another member to be vice-chairman; and

(c) another member to be alternate vice-chairman.

(2) The members appointed as chairman, vice-chairman and alternate vice-chairman shall each be appointed for such period, not exceeding the remainder of his term as a member, as the appointing authority may specify on appointing him.

(3) Any member so appointed may at any time resign from the office of chairman, vice-chairman or alternate vice-chairman.

(4) Where the chairman has died or has ceased to hold office, or where he is unable to perform his duties as chairman owing to illness, absence or any other cause, references to the chairman in this Schedule shall, so long as there is no chairman available to perform his duties, be taken to include references to—

(a) the vice-chairman;

(b) if the vice-chairman is also is unable to perform his duties, the alternate vice-chairman; or

(c) if all three individuals are unavailable, a member appointed by the appointing authority for the purposes of acting as chairman until one of those individuals is available to perform his duties.

6.—(1) An ethics committee may—

(a) appoint sub-committees consisting of members of the committee; and

(b) make arrangements for the exercise, on behalf of the committee, of any of its functions by such a sub-committee,

in accordance with the standing orders and operating procedures adopted under sub-paragraph (3).

(2) Subject to sub-paragraph (4), the meetings and proceedings of an ethics committee and its sub-committees shall be conducted in accordance with the standing orders made, and standing operating procedures adopted, under sub-paragraph (3).

(3) An ethics committee—

(a) shall, subject to approval by the Authority, make standing orders, and adopt standing operating procedures, for the regulation of its proceedings and business; and

(b) may, subject to approval by the Authority, vary or revoke such orders or procedures,

including provision for the suspension of the standing orders or operating procedures or any of them.

(4) No business shall be transacted at a meeting of an ethics committee, or a sub-committee of an ethics committee, to determine, in accordance with regulation 15, the opinion of an ethics committee in relation to a clinical trial, unless at least seven members of the committee (including any members co-opted under paragraph 8) are present, including at least—

(a) one lay member who is not and never has been—

(i) a health care professional, or

(ii) a chairman, member, director, officer or employee of a health service body; and

(b) one expert member.

Deputies and co-opted members

7.—(1) An ethics committee may appoint a person to act as the deputy of an expert member or a lay member provided that the person would be eligible for appointment as an expert member or, as the case may be, a lay member.

(2) A deputy shall hold and vacate office as a deputy member in accordance with the terms of the instrument appointing him as a deputy.

(3) A deputy may vote as a member of the committee only if the member for which he acts as deputy is absent.

(4) A deputy member and the member for which he is deputy shall count as one member for the purposes of paragraphs 3(2) and (4) and 6(4).

8.—(1) At any meeting of an ethics committee, the committee may co-opt up to 2 additional members for the purposes of that meeting.

(2) At any meeting of a sub-committee of an ethics committee, the sub-committee may co-opt an additional member for the purposes of that meeting.

(3) Subject to sub-paragraph (4), a person shall be eligible to be co-opted as a member only if he is or has been a member of an ethics committee.

(4) Paragraph (3) shall not apply in relation to the Gene Therapy Advisory Committee.

(5) A co-opted member shall hold office only in relation to the meeting for which he is co-opted.

(6) A member co-opted under this paragraph shall not count as a member for the purposes of paragraphs 3(2) and (4).

9.—(1) The appointing authority shall make arrangements for the appointment of such administrative and other staff for an ethics committee as they consider necessary to enable the committee to perform its functions.

(2) The appointing authority shall—

(a) secure the provision to an ethics committee of such accommodation and facilities as they consider necessary to enable the committee to perform its functions; and

(b) secure that arrangements are made for such administration, maintenance, cleaning and other services as may, in their opinion, be necessary for such accommodation and facilities.

(3) To enable an ethics committee to perform its functions, a health service body may make staff, premises and facilities available to an ethics committee under arrangements made with the appointing authority.

Expenses

10.—(1) The appointing authority shall, in respect of each financial year, pay to an ethics committee sums equal to the amount approved as the amounts of expenditure which they consider may be reasonably incurred by the committee in that year for the purpose of performing its functions.

(2) An ethics committee shall not incur expenses in excess of the amounts approved for that committee by the appointing authority under this paragraph.

11. The appointing authority may pay to members of ethics committees such travelling and other allowances as the authority may determine.

12.—(1) Within the period six months from the end of each financial year, every ethics committee shall prepare a report on the committee's activities during that year, which shall include a list of—

(a) the applications made to the committee in accordance with regulation 14; and

(b) the decisions made by the committee in relation to those applications.

(2) The ethics committee shall send a copy of the report to the Authority and, if the Authority is not the appointing authority for that committee, to its appointing authority.

13.—(1) This paragraph applies where—

(a) recognition of an ethics committee is revoked in accordance with regulation 8; or

(b) an ethics committee is abolished or ceases operation.

(2) If the person who was the appointing authority before revocation, abolition or the ceasing of operation of the committee ("the old committee") is the Authority, that person may nominate another ethics committee as responsible for the work of the committee.

(3) If the person referred to in sub-paragraph (2) was not the Authority, that person may only nominate an ethics committee with the approval of the Authority.

(4) If the person referred to in sub-paragraph (2) no longer exists or if that person fails to nominate another ethics committee, the Authority shall nominate such a committee.

(5) Where an ethics committee is nominated in accordance with the preceding sub-paragraphs—

(a) that committee shall consider any applications made to the old committee in accordance with regulation 14, if the old committee had not given an opinion before the date of revocation, abolition or ceasing of operation;

(b) that committee shall be the relevant ethics committee for any clinical trial in relation to which the old committee had given a favourable opinion in accordance with regulation 15.

SCHEDULE 3 Regulation 14(6), 17(2), 24(9) and 27(3)

PARTICULARS AND DOCUMENTS THAT MUST ACCOMPANY AN APPLICATION FOR AN ETHICS COMMITTEE OPINION, A REQUEST FOR AUTHORISATION, A NOTICE OF AMENDMENT AND A NOTIFICATION OF THE CONCLUSION OF A TRIAL

PART 1

APPLICATION FOR ETHICS COMMITTEE OPINION

1. An application document including the following information or, in each case, an explanation of why that information is not being provided—

(a) the reference number of the ethics committee to which the application is made;

(b) particulars identifying the trial including—

(i) the number allocated to the trial on the European database referred to in Article 11 of the Directive, and

(ii) full and short titles of the trial;

(c) the following particulars relating to the trial design—

(i) a summary of the trial, including justification and relevance, and the methodology to be used,

(ii) the primary, and any secondary, research hypothesis,

(iii) statistical analysis and justification for the numbers of subjects to be recruited for the trial, and

(iv) details of the process for peer review of the scientific value of the trial;

(d) brief details of any plans to conduct the trial outside the UK and any authorisation given in relation to the trial by a competent authority of an EEA State in accordance with Article 9 of the Directive;

(e) the name and address of the sponsor;

(f) details of any arrangements under which the sponsor has delegated any of his responsibilities in relation to the proposed trial;

(g) the financial arrangements for the trial, in particular—

(i) sources of funding for the trial and information on financial or other interests of the applicant relevant to the trial,

(ii) the arrangements for remuneration of, or re-imbursement of expenses incurred by, subjects,

(iii) any provision for compensation in the event of injury or death attributable to the trial,

(iv) details of any insurance or indemnity to cover the liability of the sponsor and investigator, and

(v) summary details of any financial arrangements between—

(aa) the sponsor or person funding the trial and the investigator, and

(bb) the sponsor or person funding the trial and the owner or occupier of the trial site;

(h) arrangements for the recruitment of subjects, including the materials to be used;

(i) the criteria for inclusion and exclusion of patients, including justification for recruiting from vulnerable groups;

(j) in the case of Phase I trials, methods for recording and verifying health status for healthy volunteers;

(k) procedures for checking simultaneous or recent involvement of potential subjects in other trials;

(l) details of any relationship between subject and investigator which may be relevant for the purposes of an ethical opinion;

(m) details of—

(i) any proposed additional investigational procedures or other interventions over and above those required for normal clinical care, and

(ii) any aspect of normal clinical care to be withheld or other deviation from normal treatment, and

(iii) the plan for treatment or care of subjects once their participation in the trial has ended;

(n) the procedures for—

(i) providing information to potential subjects, including a contact point where additional information can be obtained about the trial and the rights of trial subjects,

(ii) providing subjects with updated information during and (where relevant) after the trial, and

(iii) obtaining informed consent;

(o) details of the arrangements for access to confidential data about the subjects and the arrangements to protect subjects' privacy;

(p) the rules for terminating or concluding the trial before—

(i) the date for the conclusion of the trial specified in the protocol, or

(ii) the event specified in the protocol as the event which indicates that the end of the trial has occurred;

(q) any agreement on—

(i) the access by the investigator or his team to the data produced by the trial, and

(ii) the policy for publication of that data;

(r) an assessment of the ethical issues relating to the trial, including—

(i) the importance of the trial and of the new knowledge to be gained,

(ii) an assessment of the potential benefits, and

(iii) an assessment of the possible risks for the subjects;

(s) details relating to the chief investigator and each investigator, including—

(i) experience in conducting research, and

(ii) any potential conflicts of interest; and

(t) details of any proposed trial site and its suitability for conducting the trial.

2. A document containing the particulars specified in paragraphs 1 to 4 and 6 to 9 of Part 2 of this Schedule.

3. The following documents or, in each case, an explanation of why that document is not being provided—

(a) the protocol;

(b) the investigator's brochure for the proposed trial or, where the investigational medicinal product has a marketing authorisation and the product is to be used in accordance with the terms of that authorisation, the summary of product characteristics relating to that product;

(c) any document providing evidence of any insurance to cover the liability of the sponsor and investigator;

(d) copies of the advertisement material for recruitment of research participants;

(e) in the case of advertising contained on video or audio cassettes, a copy of the script for that advertising;

(f) a copy of any letter inviting a subject to participate in the trial;

(g) a copy of any questionnaire, diary or sample card to be completed by the subject in writing;

(h) a copy of all written information to be given to a potential subject or their legal representative prior to seeking informed consent;

(i) a copy of the form to be used to record the consent of a subject or their legal representative;

(j) a copy of any letters or other written information to be sent to any person who normally provides a subject's clinical care;

(k) a summary curriculum vitae for the chief investigator and each investigator.

PART 2

REQUEST FOR AUTHORISATION

1. The name and address of—

(a) the sponsor,

(b) if the sponsor is not established in the European Community, his legal representative,

(c) if any person has been authorised by the sponsor to make the request on his behalf, that person,

(d) if the persons taking responsibility for the initiation, management and financing (or arranging the financing) of the clinical trial have allocated responsibility in accordance with regulation 3(4), any person responsible for carrying out the functions of the sponsor under Part 4 or 5 of these Regulations, and

(e) any other person to whom the sponsor has delegated any of his responsibilities in relation to the proposed trial.

2. If any person is specified as a person responsible for the duties of the sponsor under regulation 28(2) and (3) in relation to the trial—

(a) the name and address of that person; and

(b) the trial sites in relation to which they are so responsible.

3. The address of each trial site and the names and address of the investigator responsible for the conduct of the trial at each site.

4. Where the trial is to be conducted at trial sites in another EEA State, a list of the competent authorities to which a request for authorisation has been made.

5. A copy of the ethics committee opinion in relation to that trial, if available.

6. A description of any investigational medicinal product to be used in the trial.

7. The name and address of the person responsible for the manufacture or importation of any finished investigational medicinal product to be used in the trial and the details of any authorisation referred to in Article 13 of the Directive held by that person.

8.—(1) The address of any premises at which any batch of finished investigational medicinal products to be used in the clinical trial has been, or is to be, checked in accordance with Article 13(3) of the Directive.

(2) If an investigational medicinal product to be used in the clinical trial has been, or is to be, imported from a third country, a statement from the qualified person at the disposal of the person holding the authorisation referred to in Article 13 of the Directive in relation to that importation specifying—

(a) the address of any premises outside the European Economic Area at which the product was manufactured or assembled; and

(b) the manufacturing or assembling operations performed at those premises.

9. A description of the proposed clinical trial.

10. The protocol for the proposed trial.

11.—(1) Subject to sub-paragraph (7), a dossier on each investigational medicinal product to be used in the trial ("investigational medicinal product dossier"), compiled in accordance with the following sub-paragraphs.

(2) In all cases the dossier must contain a summary assessment of the potential risks and benefits of the use of the product in the proposed trial.

(3) In the case of an investigational medicinal product, other than a product referred to in sub-paragraphs (4) to (7), the dossier must contain—

(a) summaries of the chemical, pharmaceutical and biological data on the active substance and the finished product;

(b) summaries of the non-clinical pharmacology and toxicology data on that product, if available; and

(c) summaries of the available data from previous clinical trials of, and human experience with, that product.

(4) In the case of an investigational medicinal product which has a marketing authorization, the dossier must contain—

(a) a copy of the summary of product characteristics;

(b) if there has been a change—

(i) to the process of manufacture of the product or its active substance, or

(ii) of manufacturer of that product or substance,

the summaries referred to in sub-paragraph (3)(a);

(c) if the product is to be used in the trial after it has been blinded, the summaries referred to in sub-paragraph (3)(a), in so far as they relate to the blinded product; and

(d) if the product is to be used other than in accordance with the terms of the summary of product characteristics under that authorization, the summaries referred to in sub-paragraphs (3)(b) and (c), in so far as that data relates to such use.

(5) In the case of an investigational medicinal product which does not have a marketing authorization, but where—

(a) another pharmaceutical form or strength of that product has a marketing authorization; and

(b) the investigational medicinal product is supplied by the holder of that authorization,

the dossier must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to the finished product to be used in the trial, and the summaries referred to in sub-paragraph (3)(b) and (c), in so far as they relate to the product to be used in the trial.

(6) In the case of an investigational medicinal product which does not have a marketing authorization, but where—

(a) another medicinal product containing the same active substance has a marketing authorization; and

(b) the investigational medicinal product is supplied by the manufacturer of that other product,

the dossier must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to that other product, and the summaries referred to in sub-paragraph (3)(b) and (c), in so far as they relate to the product to be used in the trial.

(7) Where the investigational medicinal product is a placebo, the dossier must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to that product.

(8) A dossier relating to an investigational medicinal product is not required if—

(a) the product has been used in a clinical trial that has been authorised, or is to be treated as having been authorised, by the licensing authority for the purposes of these Regulations; and

(b) the sponsor of that trial authorises the licensing authority to refer to the dossier submitted in relation to that trial.

12. A description or sample of the labelling which is to appear on each investigational medicinal product when supplied to a subject in the trial.

PART 3

NOTICE OF AMENDMENT

1. The name and address of—

(a) the sponsor,

(b) if the sponsor is not established in the European Community, his legal representative, and

(c) if any person has been authorised by the sponsor to send the notice on his behalf, that person.

2. Particulars identifying the trial, including—

(a) the title of the trial; and

(b) the number allocated to the trial on the European database referred to in Article 11 of the Directive.

3. A description of the proposed amendment.

4. A statement of the reasons for proposing that amendment.

5. A copy of the proposed changes to—

(a) the clinical trial protocol; or

(b) any other particulars or documents accompanying the request for authorisation or the application for an ethics committee opinion.

6. Summaries of—

(a) any data submitted in support of the proposed amendment; and

(b) any change to the assessment referred to in paragraph 11(2) of Part 2.

PART 4

NOTIFICATION OF CONCLUSION OF A CLINICAL TRIAL

1. The name and address of—

(a) the sponsor, and

(b) if the sponsor is not established in the European Community, his legal representative.

2. Particulars identifying the trial, including—

(a) the title of the trial; and

(b) the number allocated to the trial on the European database referred to in Article 11 of the Directive.

3. The investigational medicinal product tested in the trial.

4.—(1) The date on which the trial ended in the United Kingdom.

(2) If the trial was conducted at more than one trial site in the United Kingdom, the dates on which the trial was ended at those sites, if different from the date referred to in sub-paragraph (1).

(3) If the trial was conducted at any trial sites outside the United Kingdom, a statement as to whether the trial has ended at any of those sites and, if so, the date on which the trial was so ended.

5. If the trial is terminated as specified in regulation 27(2), the reasons for terminating the trial early.

SCHEDULE 4

Regulation 16(6)

APPEAL AGAINST UNFAVOURABLE ETHICS COMMITTEE OPINION

1.—(1) Subject to the following sub-paragraphs, where the United Kingdom Ethics Committee Authority ("the Authority") receive a notice pursuant to regulation 16(3) or (7) that a chief investigator wishes to appeal against an ethics committee opinion which is not favourable, the Authority shall, subject to sub-paragraph (2)—

(a) direct that the application for that opinion may be considered by another ethics committee specified in the direction; or

(b) appoint a panel in accordance with paragraph 3 ("an appeal panel") and refer the opinion to that panel.

(2) Subject to sub-paragraph (4), the Authority may refuse to give a direction or appoint a panel pursuant to sub-paragraph (1) where it considers that the grounds for appealing against the opinion are unfounded.

(3) Where the Authority refuse to give a direction or appoint a panel pursuant to sub-paragraph (1), the Authority shall send a notice to the chief investigator setting out their reasons for refusal.

(4) Where the opinion was given by the Gene Therapy Advisory Committee, the Authority must appoint a panel in accordance with paragraph 3 and refer the opinion to that panel.

2. Where a direction is given in accordance with paragraph 1(1)(a)—

(a) the ethics committee which gave the unfavourable opinion shall—

(i) send the application for that opinion, and

(ii) any additional information provided by the chief investigator,

to the ethics committee specified in the direction; and

(b) that committee shall consider the application in accordance with regulation 15.

3.—(1) An appeal panel appointed pursuant to paragraph 1(1)(b) shall consist of a chairman and at least 6 other members.

(2) One of the members shall be a person who is not—

(a) a health care professional,

(b) a person having professional qualifications or experience relating to the conduct of, or use of statistics in, clinical trials, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment, or

(c) a person who, although not a health care professional, has been a registered medical practitioner or a person registered in the dentists register under the Dentists Act 1984.

4.—(1) An appeal panel shall consider an ethics committee opinion referred to it in accordance with the following sub-paragraphs.

(2) The appeal panel shall consider—

(a) the opinion;

(b) the application for that opinion;

(c) the particulars and documents accompanying that application;

(d) the matters specified in regulation 15(6);

(e) any representations set out in the notice to the Authority; and

(f) in a case where the opinion has been confirmed by the Gene Therapy Advisory Committee on a review pursuant to regulation 16(5), the reasons given by the Committee for that confirmation.

(3) The panel may, if the chief investigator so requests, hold a hearing to consider the opinion, at which the chief investigator may make oral representations.

(4) The panel shall within 30 days of the opinion being referred to the panel, or such extended period as the Authority may in any particular case allow, either confirm the opinion or give a favourable opinion.

5. If an appeal panel gives a favourable opinion, the condition specified in regulation 11(3)(a) shall be deemed to have been satisfied.

6. The Authority may pay to members of an appeal panel such travelling and other allowances as the Authority may determine.

[F9SCHEDULE 5

Regulations 26(2) and 31(8)

PROCEDURAL PROVISIONS RELATING TO THE REFUSAL OR AMENDMENT OF, OR IMPOSITION OF CONDITIONS RELATING TO, CLINICAL TRIAL AUTHORISATIONS AND THE SUSPENSION OR TERMINATION OF CLINICAL TRIALS

Textual Amendments

F9 Sch. 5 substituted (30.10.2005) by The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 5**

Hearing before the appropriate committee

1.—(1) Where the licensing authority are notified of the wish of a sponsor or investigator to make representations in accordance with regulation 26(1) or 31(7), the authority shall inform the appropriate committee and the committee shall give the sponsor or investigator an opportunity to make such representations in accordance with sub-paragraphs (2) to (5).

(2) Subject to sub-paragraph (3), the sponsor or investigator shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(3) If the sponsor or investigator so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (2), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (1).

(4) The sponsor or investigator may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (2) and (3) has expired, except with the permission of the appropriate committee.

(5) If the sponsor or investigator gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (3), arrange for the sponsor or investigator to make such representations at a hearing before the committee.

(6) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this paragraph; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

2.—(1) In the case of a decision not to accept a request for authorisation to conduct a clinical trial or an amendment to the clinical trial authorisation, the licensing authority shall, after considering the report of the appropriate committee—

(a) confirm that they have grounds for not accepting the request or amendment; or

(b) accept the request for authorisation or amendment to the clinical trial authorisation, subject to such conditions as the licensing authority may consider appropriate.

(2) In the case of a decision to impose a condition following a request for authorisation to conduct a clinical trial or a notice of amendment to a clinical trial authorisation, the licensing authority shall, after considering the report of the appropriate committee—

(a) confirm their decision; or

(b) remove or alter the condition in question.

(3) In the case of a notice to suspend or terminate a trial, the licensing authority shall, after considering the report of the appropriate committee, confirm or revoke the notice.

(4) The licensing authority shall give notice to the sponsor or investigator of—

(a) the findings and advice of the appropriate committee and the reasons for it;

(b) their decision in accordance with sub-paragraph (1), (2) or (3).

Right to be heard by a person appointed

3.—(1) Subject to sub-paragraph (2), if a sponsor or investigator to whom notice is given under paragraph 2(4) is dissatisfied, he may, within 28 days or such longer period as the licensing authority may in any particular case allow, of the notice being given—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the decision referred to in the notice.

(2) Sub-paragraph (1)(a) shall not apply where—

(a) the sponsor or investigator had not made any representations in accordance with paragraph 1(2) to (5); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

(3) If the sponsor or investigator to whom notice is given under paragraph 2(4) makes written representations in accordance with sub-paragraph (2)(b), the licensing authority shall take those representations into account before deciding whether to confirm or alter their decision.

Hearing before person appointed

4.—(1) If a sponsor or investigator gives notice under paragraph 3(1)(a) of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the sponsor or investigator to have an opportunity of appearing before the person appointed by the licensing authority.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the sponsor or investigator shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the sponsor or investigator so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the sponsor or investigator fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or be heard by the person appointed; and

(b) the licensing authority shall decide whether to confirm or alter their decision.

(6) The sponsor or investigator may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the sponsor or investigator and the licensing authority may make representations.

(8) If the sponsor or investigator so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to confirm or alter their decision.

(10) The licensing authority shall then—

(a) notify the sponsor or investigator of their decision;

(b) if the sponsor or investigator so requests, provide him with a copy of the report of the person appointed.**]**

SCHEDULE 6

Regulation 38(3)

PARTICULARS THAT MUST ACCOMPANY AN APPLICATION FOR A MANUFACTURING AUTHORISATION

1. The name and address of the applicant, and, where the applicant is not the proposed holder of the authorisation, the name and address of the proposed holder.

2. A statement of the types of investigational medicinal products in respect of which the authorisation is required.

3. A statement of the manufacturing, assembling or importation operations to which the authorisation is to relate, including a statement whether they include one or more of the following—

(a) the manufacture of investigational medicinal products;

(b) the assembly of investigational medicinal products; or

(c) the importation of investigational medicinal products.

4.—(1) The address of each of the premises where the manufacturing, assembling or importation operations to which the application relates, including any testing associated with manufacture, assembly or import, are or are to be carried out.

(2) The address of each of the premises where the proposed holder of the authorisation proposes to store investigational medicinal products or from which he proposes to distribute them.

(3) A statement indicating the facilities and equipment available at each of the premises referred to in sub-paragraphs (1) and (2), for storing the investigational medicinal products on, and distributing them from or between, such premises.

(4) A separate statement in respect of each of the premises referred to in sub-paragraphs (1) and (2), of the manufacturing, assembling or importation operations capable of being carried out at those premises with their existing facilities. Each statement shall specify the classes of investigational medicinal products to which the operations are relevant.

(5) A separate statement in respect of each of the premises referred to in sub-paragraphs (1) and (2), of the facilities and equipment available at those premises for carrying out each stage of the manufacturing, assembling or importation operations described in sub-paragraph (4) of this paragraph.

5. A statement of any manufacturing operations, other than those to which the manufacturing authorisation is to relate, that are carried on by the proposed authorisation holder on or near each of the premises referred to in paragraph 4, and of the substances or articles which are the subject of any such operation.

6.—(1) The name and address and qualifications and experience of the qualified person who is to carry out the duties referred to in regulation 43(2).

(2) In the case of an authorisation relating to manufacture or assembly, the name and qualifications and experience of the production manager or other person whose duty it will be to supervise the production operations at each of the premises referred to in paragraph 4 of this Schedule, and the name and function of the person to whom he is responsible.

(3) In the case of an authorisation relating to manufacture or assembly—

(a) the name and degrees, diplomas or other qualifications and experience of the person to be in charge of quality control over all the premises referred to in paragraph 4 of this Schedule;

(b) the extent of the authority to be delegated to him to reject unsatisfactory batches of investigational medicinal products, and

(c) the name and function of the person to whom he is responsible.

7. A description of the arrangements for the identification and storage of materials and ingredients before and during manufacture and for the storage of investigational medicinal products after manufacture, assembly or importation.

8. A description of the arrangements at each of the premises where the holder of the authorisation stores or proposes to store investigational medicinal products for ensuring, so far as practicable, whether by maintaining records or other means, a satisfactory turn-over of stocks of investigational medicinal products.

9. A description of the arrangements—

(a) for maintaining production or importation records;

(b) for maintaining records of analytical and other testing procedures applied in the course of manufacture, assembly or importation for ensuring compliance of materials used in the manufacture of any investigational medicinal products with the specification of such materials or medicinal products; and

(c) for keeping reference samples of materials used in the manufacture of any investigational medicinal products and of the investigational medicinal products.

SCHEDULE 7 Regulation 40(4)

STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 1

INTERPRETATION

In this Schedule, "product specification" means—

(a) in the case of an investigational medicinal product manufactured before a request for authorisation to conduct the clinical trial involving those products has been made in accordance with regulation 17 or any equivalent provisions in any EEA State other than the United Kingdom, the specification for that product provided by the person who is to act as the sponsor of the proposed clinical trial,

(b) in the case of an investigational medicinal product manufactured for the purpose of export, the specification for that product provided by the person to whose order the products are manufactured, or

(c) in any other case, the specification for an investigational medicinal product contained in the investigational medicinal product dossier for that product.

PART 2

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE MANUFACTURE OR ASSEMBLY OF INVESTIGATIONAL MEDICINAL PRODUCTS

1. The holder of the authorisation shall—

(a) provide and maintain such staff, premises and plant (including technical equipment) as are necessary for the carrying out, in accordance with his authorisation and the product specification, of such stages of the manufacture and assembly of the investigational medicinal products as are undertaken by him; and

(b) not carry out any such manufacture or assembly except at the premises specified in his manufacturing authorisation.

2. The holder of the authorisation shall—

(a) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the investigational medicinal products which he handles, stores or distributes under his authorisation as are necessary to maintain the quality of the investigational medicinal products;

(b) not use for such purposes premises other than those specified in the authorisation or which may be approved from time to time by the licensing authority; and

(c) ensure that any arrangements he makes with a person for the storage and distribution of the investigational medicinal products are adequate to maintain the quality of those products.

3. The holder of the authorisation shall place the quality control system referred to in Article 11(1) of Commission Directive 2003/94/EC under the authority of the person notified to the licensing authority in accordance with paragraph 6(3) of Schedule 6 as being responsible for quality control.

4. The holder of the authorisation may use a contract laboratory pursuant to Article 11(2) of Commission Directive 2003/94/EC if operated by a person approved by the licensing authority.

5. The holder of the authorisation shall provide such information as may be requested by the licensing authority for the purposes of these Regulations or the Act—

(a) about the products currently being manufactured or assembled under his authorisation; and

(b) of the operations being carried out in relation to such manufacture or assembly.

6. The holder of the authorisation shall—

(a) inform the licensing authority before making any material alteration in the premises or plant used under his authorisation, or in the operations for which they are used; and

(b) inform the licensing authority of any change that he proposes to make in any personnel named in his authorisation as respectively—

(i) responsible for supervising the production operations, or

(ii) responsible for quality control of the investigational medicinal products being manufactured or assembled including the person named as the qualified person for the purposes of regulation 43 and paragraph 14.

7. The holder of the authorisation shall—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive 2003/94/EC; and

(b) permit the person authorised to take copies or make extracts from such documentation.

8. The holder of the authorisation shall keep readily available for examination by a person authorised by the licensing authority the samples of each batch of bulk formulated products referred to in Article 11(4) of Commission Directive 2003/94/EC.

9. Where the holder of the authorisation has been informed by the licensing authority that any batch of any investigational medicinal product to which his authorisation relates has been found not to conform as regards strength, quality or purity with—

(a) the specification of the relevant product; or

(b) the provisions of these Regulations, the Act or any regulations under the Act that are applicable to the investigational medicinal product,

he shall, if so directed, withhold such batch from distribution for use in clinical trials, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

10. The holder of the authorisation shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture shall, except so far as the conditions of the product specification for that product otherwise provide, be applied to samples taken from the investigational medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the licensing authority.

11. Where the authorisation relates to the assembly of an investigational medicinal product, and the holder of the authorisation supplies that investigational medicinal product at such a stage of assembly that does not fully comply with the provisions of the product specification that relate to labelling, that holder of the authorisation shall communicate the particulars of those provisions to the person to whom that investigational medicinal product has been so supplied.

12. Where—

(a) the manufacturing authorisation relates to the assembly of an investigational medicinal product;

(b) that investigational medicinal product is not manufactured by the holder of the authorisation; and

(c) particulars as to the name and address of the manufacturer of, or of the person who imports, that investigational medicinal product had been given by the holder of the authorisation to the licensing authority,

the holder of the authorisation shall forthwith notify the licensing authority in writing of any changes in such particulars.

13. The holder of the authorisation, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any authorisation or licence granted under these Regulations or Part II of the Act;

(b) amending the clinical trial authorisation in accordance with regulation 23 or 24; or

(c) suspending or terminating any clinical trial in accordance with regulation 31,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the authorisation, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for an authorisation or licence.

14. The holder of the authorisation shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal pursuant to regulation 43(1) to carry out the duties referred to in regulation 43(2).

PART 3

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

1. The holder of the authorisation shall—

(a) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the investigational medicinal products which he handles, stores or distributes under his authorisation as are necessary to avoid deterioration of the investigational medicinal products;

(b) not use for such purposes premises other than those specified in the authorisation or which may be approved from time to time by the licensing authority; and

(c) ensure that any arrangements he makes with a person for the storage and distribution of the investigational medicinal products are adequate to maintain the quality of those products.

2. The holder of the authorisation may use a contract laboratory pursuant to Article 11(2) of Commission Directive 2003/94/EC if operated by a person approved by the licensing authority.

3. The holder of the authorisation shall provide such information as may be requested by the licensing authority concerning the type and quantity of any investigational medicinal products which he imports.

4. The holder of the authorisation shall—

(a) inform the licensing authority before making any structural alterations to, or discontinuance of the use of, premises to which his authorisation relates; and

(b) inform the licensing authority if he changes the person named as the qualified person for the purposes of regulation 43 and paragraph 9.

5. The holder of the authorisation shall—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive 2003/94/EC; and

(b) permit the person authorised to take copies or make extracts from such documentation.

6. Where the holder of the authorisation has been informed by the licensing authority that any batch of any investigational medicinal product to which his authorisation relates has been found not to conform as regards strength, quality or purity with—

(a) the specification of the relevant product; or

(b) the provisions of these Regulations, the Act or any regulations under the Act that are applicable to the investigational medicinal product,

he shall, if so directed, withhold such batch from distribution for use in clinical trials, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

7. If the holder of the authorisation is not the sponsor of the clinical trial for which the investigational medicinal product is manufactured or assembled, he shall comply with the provisions of the product specification that relates to the supply of that investigational medicinal product for use in the trial.

8. The holder of the authorisation, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any authorisation or licence granted under these Regulations or Part II of the Act;

(b) amending the conduct of a clinical trial in accordance with regulation 23 or 24; or

(c) suspending or terminating any clinical trial in accordance with regulation 31,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the authorisation, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for an authorisation or licence.

9. The holder of the authorisation shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal pursuant to regulation 43(1) to carry out the duties referred to in regulation 43(2).

SCHEDULE 8

Regulations 40(5) and 44(6)

PROCEDURAL PROVISIONS RELATING TO PROPOSALS TO GRANT, REFUSE TO GRANT, VARY, SUSPEND OR REVOKE MANUFACTURING AUTHORISATIONS

1. In this Schedule—

"authorisation" means a manufacturing authorisation; and

"time allowed" means the period of 28 days or such extended period as the licensing authority may in any particular case allow.

2. Subject to paragraph 6, if the licensing authority propose—

(a) not to grant an authorisation;

(b) to grant an authorisation other than in accordance with the application; or

(c) to revoke, vary or suspend an authorisation,

the licensing authority shall notify the applicant or holder accordingly.

3. Any notification given under paragraph 2 shall include a statement of the proposals of the licensing authority and of the reasons for them.

[F10 4.—(1) Subject to sub-paragraph (2), the applicant or holder to whom notice is given under paragraph 2 may, within the time allowed after the notification was given—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the decision referred to in the notice.

(2) If the applicant or holder to whom notice is given under paragraph 2 makes written representations in accordance with sub-paragraph (1)(b), the licensing authority shall take those representations into account before deciding whether to—

(a) grant the authorisation,

(b) revoke, vary or suspend the authorisation, or

(c) confirm or alter their decision,

as the case may be.**]**

Textual Amendments

F10 Sch. 8 paras. 4, 5 substituted (30.10.2005) by The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 6**

[F10 5.—(1) If the applicant or holder gives notice under paragraph 4(1)(a) of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant or holder who gave notice to have an opportunity of appearing before the person appointed by the licensing authority.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the applicant or holder shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the applicant or holder fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or be heard by the person appointed; and

(b) the licensing authority shall decide whether to grant the authoriSation, revoke, vary or suspend the authorisation or confirm or alter their decision, as the case may be.

(6) The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations.

(8) If the applicant or holder so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to grant the authorisation, revoke, vary or suspend the authorisation or confirm or alter their decision, as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant or holder of their decision;

(b) if the applicant or holder so requests, provide him with a copy of the report of the person appointed.**]**

Textual Amendments

F10 Sch. 8 paras. 4, 5 substituted (30.10.2005) by The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 6**

6.—(1) Paragraph 2 shall not apply to the suspension of an authorisation where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorisation with immediate effect for a period not exceeding 3 months.

(2) If, after the suspension has taken effect, it appears to the licensing authority that the authorisation should be further suspended or revoked, the licensing authority shall proceed in accordance with the provisions of paragraphs 2 to 5.

SCHEDULE 9

Regulation 47(1)

MODIFICATIONS OF THE ENFORCEMENT PROVISIONS OF THE ACT SUBJECT TO WHICH THOSE PROVISIONS ARE APPLIED FOR THE PURPOSES OF THESE REGULATIONS

1. The modifications of the Act mentioned in regulation 47 are as follows.

2.—(1) Amendments in section 107 (validity of decisions and related proceedings) as follows.

(2) In subsection (1), for "Part II of this or of a Minister under section 75 of this Act, and the validity of any licence or certificate" substitute " the Clinical Trials Regulations, and the validity of any authorisation ".

(3) In subsections (2)(a) and (3)(b), for "this Act" substitute " the Clinical Trials Regulations ".

(4) In subsection (2)(b), for "this Act or of any regulations made under this Act" substitute " the Clinical Trials Regulations ".

(5) In subsection (4) (effect of quashing a decisions) substitute—

"(4) Subsections (4A) and (4B) of this section apply where a decision—

(a) to grant or issue an authorisation, or

(b) to give notice accepting a request for an authorisation, is quashed under this section.

(4A) Any authorisation granted or issued, or notice given, in pursuance of the decision shall be void.

(4B) Any proceedings on the application, or request, for the authorisation may be continued as if not such decision had been made.".

3. For section 108 (enforcement in England and Wales) substitute—

"(1) It shall be the duty of the Secretary of State to enforce in England, or to secure the enforcement in England of, the provisions of the Clinical Trials Regulations.

(2) It shall be the duty of the National Assembly for Wales to enforce in Wales, or to secure the enforcement in Wales of, the provisions of the Clinical Trials Regulations".

4. In section 109 (enforcement in Scotland), for subsections (1) to (3), substitute—

"(1) It shall be the duty of the Scottish Ministers to enforce in Scotland, or to secure the enforcement in Scotland of, the provisions of the Clinical Trials Regulations.".

5. For section 110 (enforcement in Northern Ireland) substitute—

"It shall be the duty of the Department for Health, Social Services and Public Safety to enforce in Northern Ireland, or to secure the enforcement in England and Wales of, the provisions of the Clinical Trials Regulations.".

6.—(1) Amendments in section 111 (rights of entry) as follows.

(2) In subsection (1)(a) (entry to ascertain whether Act etc. contravened), for the words after "contravention" substitute " of any provisions of the Clinical Trials Regulations, or ".

(3) In subsection (1)(b) (entry for purposes of functions under the Act etc.), for "this Act or any such regulations or order" substitute " those Regulations or any of the provisions of this Act applied by regulation 47 or those Regulations ".

(4) In subsection (2)(a) (right to enter craft), for the words from "this Act or of any regulations" onwards substitute " the Clinical Trials Regulations; ".

(5) In subsection (3) (rights to enter premises conferred on persons authorised by licensing authority)—

(a) for "an applicant for a licence under Part II of this Act" substitute " a person applying for or requesting an authorisation under the Clinical Trials Regulations ", and

(b) for "application for the licence or certificate" substitute " application or request for the authorisation ".

7.—(1) Amendments in section 112 (power to inspect, take samples and seize goods and documents) as follows.

(2) In subsection (1) (inspection for purpose of ascertaining whether Act etc. contravened), for the words before paragraph (a) substitute— " For the purposes of ascertaining whether there is or has been a contravention of the Clinical Trials Regulations, any person duly authorised in writing by an enforcement authority shall have a right to inspect— ".

(3) In subsection (2) (items of which samples may be taken), before the word "or" at the end of paragraph (a) insert—

"(aa) a medicinal product used or intended to be used in a clinical trial,".

(4) In subsection (3) (right to require production etc. of books and documents), after paragraph (a) insert—

"(a) to require—

(i) the sponsor of a clinical trial,

(ii) any person who, under arrangements made with the sponsor of a clinical trial, carries out functions of the sponsor of the trial,

(iii) an investigator for a trial,

(iv) any person, other than an investigator, who conducts a trial,

(v) any person occupying premises at which a clinical trial is being conducted, or

(vi) any person who, in the courses in the course of their employment with a person of a description specified in any of sub-paragraphs (i) to (v) of this paragraph, undertakes activities in connection with a clinical trial,

to produce any books or documents relating to the clinical trial which are in his possession or under his control;".

(5) In subsection (3)(b) (powers to take copies of documents produced), for "the preceding paragraph" substitute " paragraph (a) or (aa) of this subsection; ".

(6) In subsection (3), after paragraph (b) insert—

"(c) to take possession of any book or document produced under paragraph (a) or (aa) of this subsection.".

(7) In subsection (4) (right to seize items and documents), for "offence under this Act is" substitute—

"offence—

(a) under the Clinical Trials Regulations, or

(b) under section 114, 118 or 123 of this Act,

is. "

(8) In that subsection, for "under this Act" (in the second place) substitute " under those Regulations or under any of the provisions of this Act applied by regulation 47 of those Regulations ".

(9) In subsection (5) (opening of containers), for "this Act and any regulations or order made thereunder" substitute " the Clinical Trials Regulations ".

(10) In subsection (7) (rights of persons authorised by licensing authority)—

(a) for "a licence or certificate under Part II of this Act" substitute " an authorisation under the Clinical Trials Regulations ", and

(b) for "the application for the licence or certificate" substitute " the application or request for the authorisation ".

(11) In subsection (9) (Schedule 3 to have effect in relation to samples obtained for purposes of the Act), for "this Act" (in the second place) substitute " the Clinical Trials Regulations ".

(12) After subsection (9) insert—

"(10) In this section "clinical trial", and "investigator" and "sponsor" in relation to a clinical trial, have the meaning given by the Clinical Trials Regulations."

8.—(1) Amendments in section 115 (analysis of samples) as follows.

(2) In subsection (7) (certificate to be in prescribed form and signed), for "form prescribed by the Ministers" substitute " prescribed form ".

(3) Omit subsection (9) (regulations under subsection (5) to be made by the Ministers).

9.—(1) Amendments in section 116 (liability to forfeiture under the Customs and Excise Management Act 1979) as follows.

(2) For "this Act" (in both places) substitute " the Clinical Trials Regulations ".

(3) After subsection (3) insert—

"(4) In this section "the Ministers" means the Secretary of State and the Department for Health, Social Services and Public Safety, acting jointly.".

10. In section 118(1)(b) (restrictions on disclosing of information obtained in pursuance of the Act), for "this Act" substitute " the Clinical Trials Regulations or any provision of this Act applied by regulation 47 of those Regulations ".

11.—(1) Amendments in section 119 (protection for officers of enforcement authorities) as follows.

(2) In each of subsections (1) and (2) (relief from personal liability and power of authority to indemnify officer)—

(a) for "this Act" (in the first place) substitute " relevant legislation ", and

(b) for "this Act" (in the second place) substitute " that legislation ".

(3) In subsection (3) (meaning of "officer"), for "this Act" substitute " relevant legislation ".

(4) After subsection (3) insert—

"(4) In this section "relevant legislation" means—

(a) the Clinical Trials Regulations, or

(b) any provision of this Act applied by regulation 47 of those Regulations."

12.—(1) Amendments in section 121 (contravention due to fault of other person) as follows.

(2) In subsection (1) (where a person is guilty of an offence due to act or default of another, the other is also guilty of the offence), for "to which this section applies constitutes an offence under this Act" substitute " of the Clinical Trials Regulations constitutes an offence under those Regulations ".

(3) In subsection (2) (defence of due diligence where contravention due to act or default of another), for "this Act in respect of a contravention of a provision to which this section applies" substitute " the Clinical Trials Regulations in respect of a contravention of a provision of those Regulations ".

(4) Omit subsection (4) (provisions to which section applies).

13.—(1) Amendments in section 122 (warranty as defence) as follows.

(2) In subsection (1), for "this Act in respect of a contravention of a provision to which this section applies" substitute " the Clinical Trials Regulations in respect of a contravention of regulation 46 of those Regulations ".

(3) Omit subsection (2) (provisions to which section applies).

14.—(1) Amendments in section 124 (offences by bodies corporate) as follows.

(2) In subsection (1), for "this Act" substitute " the Clinical Trials Regulations, or under section 114, 118 or 123 of this Act, ".

(3) After subsection (2) insert—

"(2A) In subsections (1) and (2) of this section "body corporate" includes a Scottish partnership and "director", in relation to such a partnership, includes any of its partners."

15.—(1) Amendments in section 125 (prosecutions) as follows.

(2) In each of subsections (1) and (2) (time limits in England and Wales, and in Scotland), for "under this Act" substitute " under the Clinical Trials Regulations, or for an offence under section 114, 118 or 123 of this Act, ".

(3) Omit subsections (3) to (7).

16. In section 127 (service of documents)—

(a) for "any provision of this Act" substitute " relevant legislation ", and

(b) at the end add—

"In this section "relevant legislation" means any provision of the Clinical Trials Regulations or any provision of this Act applied by regulation 47 of those Regulations."

17.—(1) Amendments in section 129 (orders and regulations) as follows.

(2) Omit subsection (1) (powers to make regulations exercisable by the Ministers where not expressed to be otherwise exercisable).

(3) In subsection (2) (powers to make orders and regulations under the Act exercisable by statutory instrument), for the words from "this Act (other" to "section 120 of this Act)" substitute " any provision of this Act applied by regulation 47 of the Clinical Trials Regulations ".

(4) In subsection (3) (instruments which are subject to negative procedure), for paragraphs (a) to (c) substitute " an order or regulations made under any provision of this Act applied by regulation 46 of the Clinical Trials Regulations ".

(5) In subsection (4) (powers to make orders that include power to revoke or vary), for the words from ", other than" to 69(3), of this Act" substitute " of this Act applied by regulation 47 of the Clinical Trials Regulations ".

(6) In subsection (5) (powers to make regulations include power to make differential provision etc.), for "this Act" substitute " any provision of this Act applied by regulation 47 of the Clinical Trials Regulations ".

(7) In subsection (6) (duty to consult), for the words from the beginning to "effect) the Ministers" substitute— " Before making any regulations or order under any provision of this Act applied by regulation 47 of the Clinical Trials Regulations, the persons. "

(8) Omit subsections (6A) and (7) (which apply only in relation to veterinary products or instruments made otherwise than under Part 8 of the Act).

18.—(1) Amendments in section 131 (meaning of "wholesale dealing" and "retail sale" etc).

(2) Omit subsection (1) (meaning of "wholesale dealing").

(3) In subsection (2) (purposes referred to in subsections (1) and (3)), for "the preceding subsection" substitute " subsection (3) of this section ".

(4) In subsection (3) (meaning of "retail sale"), for "In this Act" substitute " In the provisions of this Act applied by regulation 47 of the Clinical Trials Regulations, ".

(5) Omit subsection (4) (meaning of "supply in circumstances corresponding to retail sale").

19.—(1) Amendments in section 132(1) (interpretation) as follows.

(2) At the beginning, for "In this Act," substitute " In the provisions of this Act applied by regulation 47 of the Clinical Trials Regulations, ".

(3) In the definition of "enforcement authority", for the words from "power" to "or under" substitute " to enforce the provisions of the Clinical Trials Regulations is imposed by ".

(4) After the definition of "manufacture" insert—

""medicinal product" means—

(a) anything that is a medicinal product within the meaning given by Article 1 of Directive 2001/83/EC, and

(b) anything that is an investigational medical product for the purposes of the Clinical Trials Regulations;".

(5) Omit the definition of "offence under this Act".

(6) For the definition of "prescribed" substitute—

""prescribed" means prescribed by regulations made by the Secretary of State and the Department for Health, Social Services and Public Safety, acting jointly;".

20.—(1) Amendments in Schedule 3 (sampling) as follows.

(2) In paragraph 1(1)(a), for the words from "this Act or of any regulations" onwards substitute " the Clinical Trials Regulations, or ".

(3) In paragraph 1(1)(b), for the words from "of their functions" onwards substitute " (in this Schedule referred to as "the relevant enforcement authority") of their functions under those Regulations or under any provision of this Act applied by regulation 47 of those Regulations, ".

(4) In paragraph 16, omit "the relevant enforcement officer is a Minister or the Pharmaceutical Society, and".

(5) Omit paragraph 17.

(6) In paragraph 19(3), for "form prescribed by the Ministers" substitute " prescribed form ".

(7) Omit paragraph 20(2).

(8) In each of paragraphs 21 and 22, for "under this Act" substitute " under the Clinical Trials Regulations, or under section 114, 118 or 123 of this Act, ".

(9) In paragraph 24(1), for "under this Act," substitute " under the Clinical Trials Regulations or under section 114, 118 or 123 of this Act, ".

(10) In paragraph 27 (power to apply Schedule with modifications), for "Ministers" substitute " Secretary of State and the Department for Health, Social Services and Public Safety, acting jointly, ".

SCHEDULE 10 Regulation 54

CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

PART 1

ACTS OF PARLIAMENT

The Act

1.—(1) Section 3 of the Act (general functions of the Medicines Commission) [F11] is amended as follows—

(2) In subsection (1), for the words from "advice" to "products, where" substitute—

"advice on matters—

(a) relating to the execution of this Act,

(b) relating to the exercise of any power conferred by this Act,

(c) relating to the execution of the Clinical Trials Regulations,

(d) relating to the exercise of any power conferred by those regulations, or

(e) otherwise relating to medicinal products,

where. "

(3) In subsection (2), after "by or under this Act" insert " or the Clinical Trials Regulations ".

(4) For subsection (2)(d) substitute—

"(d) to advise the licensing authority in cases where the authority—

(i) are required by the provisions of Part II of this Act, or by the provisions of the Clinical Trial Regulations, to consult the Commission with respect to any matter arising under those provisions; or

(ii) without being required to do so, elect to consult the Commission with respect to any matter arising under any of those provisions."

Textual Amendments

F11 Section 3 has effect as if any reference to the Act included a reference to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) ("the 1994 Regulations"); *see* regulation 9(1) of the 1994 Regulations.

2. In section 4 of the Act (establishment of committees) [F12], in subsection (2), for the words from "connected with" onwards substitute—

"connected with—

(a) the execution of this Act or the Clinical Trials Regulations, or

(b) the exercise of any power conferred by this Act or those regulations,

either generally or in relation to any particular class of substances or articles to which any provision of this Act or those regulations applies.".

Textual Amendments

F12 Section 4 has effect as if any reference to the Act included a reference to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) ("the 1994 Regulations"); *see* regulation 9(1) of the 1994 Regulations

3. In section 7 of the Act (restrictions as to dealings with medicinal products) [F13], after subsection (3), insert the following subsection—

"(3A) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is an investigational medicinal product within the meaning of the Clinical Trials Regulations.".

Textual Amendments

F13 Section 7 does not apply to "relevant medicinal products" within the meaning of regulation 1(2) of the 1994 Regulations; *see* regulation 9(2) of the 1994 Regulations.

4.—(1) Section 8 of the Act (provisions as to manufacture and wholesale dealing) shall be amended as follows.

(2) At the beginning of subsection (2), insert " Subject to subsection (2A) of this section ".

(3) After subsection (2) insert the following subsections—

"(2A) In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by subsection (2) of this section only apply—

(a) if the product has a product licence or marketing authorization, and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that licence or authorization.

(2B) In subsection (2A) of this section—

"investigational medicinal product" has the meaning given by the Clinical Trials Regulations; and

"marketing authorization" means—

(a) a marketing authorization issued by a competent authority in accordance with Directive 2001/83/EC, or

(c) a marketing authorization granted by the European Commission under Council Regulation (EEC) 2309/93[F14].".

(4) In subsections (3) and (3A) [F15], for "subsection (3C)", in both places those words appear, substitute " subsections (3C) and (3D) ".

(5) After subsection (3C), insert the following subsection—

"(3D) The restrictions imposed by subsections (3) and (3A) of this section do not apply where the product concerned is an investigational medicinal product within the meaning given by the Clinical Trials Regulations.".

Textual Amendments

F14 OJ No. L214, 24.8.1993, p.1.

F15 Subsections (3A) to (3C) of section 8 were inserted by regulation 2(4) of S.I. 1993/834

5.—(1) Section 23 of the Act (special provisions as to the effect of manufacturer's licence) [F16] shall be amended as follows.

(2) In subsection (1)—

(a) omit "clinical trials and";

(b) for paragraph (b), substitute the following paragraph—

"(b) the products are manufactured or assembled to the order of—

(i) a person who is the holder of such a product licence, or

(ii) if the products are to be used for the purposes of a clinical trial, the sponsor of that trial,".

(3) After subsection (5), insert the following subsection—

"(6) In this section, "clinical trial" and "sponsor", in relation to a clinical trial, have the meaning given by Clinical Trials Regulations.".

Textual Amendments

F16 Section 23 of the Act has effect as if any reference in subsection (1) to a product licence included a reference to a marketing authorization; *see* regulation 9(1) of the 1994 Regulations.

6. Section 31 of the Act shall be omitted

7.—(1) Section 35 of the Act (supplementary provisions as to clinical trials and medicinal test on animals) shall be amended as follows.

(2) In subsection (1), omit "a clinical trial certificate or".

(3) In subsection (2), omit paragraph (a).

(4) In subsection (4), omit the words from the beginning to "; and".

(5) In subsection (5)—

(a) omit "a clinical trial or";

(b) for paragraph (a), substitute the following paragraph—

"(a) an animal test certificate has been issued and is for the time being in force in respect of that test, and the test is to be carried out in accordance with that certificate, and;"

(c) in paragraph (b), omit "trial or".

(6) In subsection (7)—

(a) for "sections 31 and 32" substitute " section 32 ";

(b) omit "of a clinical trial or"; and

(c) in paragraph (a), omit "trial or".

(7) In subsection (8), omit paragraph (a).

(8) In subsection (10), omit "any of the provisions of subsections (5) to (8) of section 31 of this Act, or".

8. In section 36 of the Act (application for, and issue of, certificate)—

(a) in subsection (1), omit "a clinical trial certificate or";

(b) in subsection (2), omit "clinical trial or";

(c) in subsection (3), omit "clinical trial certificates or".

9.—(1) Section 37 of the Act (transitional provisions as to clinical trials and medicinal tests on animals) shall be amended as follows.

(2) In subsection (1), omit "31, ".

(3) In subsection (2), for "sections 31 and 32" substitute " section 32 ".

(4) In subsection (3)—

(a) omit paragraph (a);

(b) for "section 31 or section 32 of this Act do not apply to anything done in relation to medicinal products of that description or (as the case may be)" substitute " section 32 of the Act do not apply to anything done ".

(5) In subsection (4)—

(a) omit "a clinical trial certificate or";

(b) in paragraph (a), for the words from the beginning to "so specified" substitute " substances or articles specified in the application ".

10. In section 38 of the Act (duration and renewal of certificate)—

(a) in subsections (1) and (4), omit "clinical trial certificate or";

(b) in subsections (5) and (6), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ".

11. In section 39 of the Act (suspension, revocation or variation of certificate)—

(a) in subsections (1), (3) and (4), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ";

(b) in subsection (2)(c) and (e), omit "clinical trial or".

12. In section 44 of the Act (provision of information to licensing authority), in subsections (1) and (2), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ".

13. In section 45 of the Act (offences under Part II)—

(a) in subsections (1) and (2), omit "section 31,";

(b) in subsection (3), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ".

14. In section 46 of the Act (special defences under section 45), for "a clinical trial certificate or animal test certificate" (in each place) substitute " an animal test certificate ".

15. In section 47 of the Act (standard provisions for licences or certificates), in subsection (2) and (4), omit "clinical trial certificate or".

16. In section 50 of the Act (certificates for exporters of medicinal products), after paragraph (b) insert

", and

(c) to the provisions of the Clinical Trials Regulations and to any authorisation granted or other thing done by virtue of those regulations.".

17. In section 104 of the Act (application of Act to certain articles and substances), in subsection (1), after "such provisions of this Act" insert " , or the Clinical Trials Regulations, ".

18. In section 105 of the Act (application of Act to certain other substances which are not medicinal products), in subsection (1), after "such provisions of this Act" insert " , or the Clinical Trials Regulations, ".

19. In section 132 of the Act (general interpretation provisions)—

(a) in subsection (1)—

(i) omit the entry defining "clinical trial" and "clinical trial certificate", and

(ii) before the definition of "the Commission" insert the following definition—

""the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004;"; and

in subsection (3), omit "a clinical trial certificate or".

20. In section 1 of the Medicines Act 1971 (fees payable for the purposes of Part II of the Act) [F17] after subsection (2) insert the following subsection—

"(2A) In subsections (1) and (2)(b) above, any reference to a licence under Part II of the principal Act shall be taken to include a reference to a manufacturing authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004.".

Textual Amendments

F17 Section 1 of the Medicines Act 1971 has effect as if any reference in subsection (1) to any application in pursuance of the Act for a licence under Part II of the Act (or for the variation or renewal of such a licence) included a reference to any application under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) for a marketing authorization (or for the variation or renewal of such an authorization) and any reference in subsection (2)(b) to a licence under Part II of the Act included a reference to a marketing authorization; *see* regulation 9(12) of the those Regulations.

21. Section 51 of the Adults with Incapacity (Scotland) Act 2000 [F18] (authority for research) shall be amended as follows—

(a) in subsection (2), at the beginning of paragraph (b) insert " Subject to subsection (3A), ";

(b) after subsection (3), insert the following subsection—

"(3A) Where the research consists of a clinical trial of a medicinal product, the research may be carried out—

(a) without being approved by the Ethics Committee, if a favourable opinion on the trial has been given by an ethics committee, other than the Ethics Committee, in accordance with regulation 15 of the Medicines for Human Use (Clinical Trials) Regulations 2004; and

(b) without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

(i) it has not been practicable to contact any such person before the decision to enter the adult as a subject of the clinical trial is made, and

(ii) consent has been obtained from a person, other than a person connected with the conduct of the clinical trial, who is—

(A) the doctor primarily responsible for the medical treatment provided to that adult, or

(B) a person nominated by the relevant health care provider."; and

(c) at the end insert the following subsection—

"(9) In this section—

"clinical trial on a medicinal product" means a clinical trial as defined by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004;

"an ethics committee" has the meaning given by that regulation;

"person connected with the conduct of the trial" and "relevant health care provider" have the meanings given by Schedule 1 to those regulations.".

Textual Amendments

F18 2000 asp 4.

PART 2

ORDERS AND REGULATIONS

1. In the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 [F19]—

(a) in regulation 2 (interpretation), in the definition of "clinical trial certificate of right"and "animal test certificate of right,"omit " "clinical trial certificate of right" and";

(b) in regulation 3 (standard provisions for licences and certificates), omit paragraph (2); and

(c) in Schedule 1, omit Part II (standard provisions for clinical trial certificates and clinical trial certificates of right).

Textual Amendments

F19 S.I. 1971/972; regulation 3(3) and Part III of Schedule 1 are revoked insofar as they apply to animal test certificates by S.I. 2003/3309.

2. In the Medicines (Surgical Materials) Order 1971 [F20], in article 3, for the words from ", the provisions contained in Parts I and II of the Act" to the end substitute—

"(a) the provisions contained in Parts I and II of the Act, sections 62, 64, 65 and 67 of Part III of the Act, and the provisions contained in Parts V, VI and VIII of the Act shall have effect in relation to the said articles or substances described in the Schedule to this Order, as those provisions have effect in relation to medicinal products; and

(b) the provisions of the Clinical Trials Regulations shall have effect in relation to the said articles or substances.".

Textual Amendments

F20 S.I. 1971/1267, as amended by S.I. 1994/3119.

3.—(1) In the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 [F21], article 4 shall be amended as follows.

(2) In paragraph (1)—

(a) for "sections 7, 31(2) and 32" substitute " sections 7 and 32 ";

(b) in subparagraph (a), omit "a clinical trial, or, as the case may be,".

(3) In paragraph (2)—

(a) in subparagraph (i)—

(i) in paragraph (a), omit "a clinical trial, or, as the case may be,",

(ii) in paragraph (b), omit "clinical trial or";

(b) in subparagraph (iii)—

(i) omit "the clinical trial or, as the case may be,",

(ii) omit the words from "the doctor or dentist" to "as the case may be,";

(c) in subparagraph (iv)—

(i) omit the words from "that the doctor or dentist" to "as the case may be,",

(ii) omit the words "the trial, or, as the case may be".

(4) Omit paragraph (3).

Textual Amendments

F21 S.I. 1972/1200.

4. In the Medicines (Dental Filling Substances) Order 1975 [F22], in article 2, in paragraph (1), for the words from "the following provisions of the Act" to the end substitute—

"(a) the provisions contained in Parts I, II, III, V, VI and VIII of the Act shall have effect in relation to dental filling substances as those provisions have effect in relation to medicinal products; and

(b) the provisions of the Clinical Trials Regulations shall have effect in relation to those substances.".

Textual Amendments

F22 S.I. 1975/533, as amended by S.I. 1994/3119.

5. In the Medicines (Specified Articles and Substances) Order 1976 [F23], in article 2, in paragraph (1), for the words from "the provisions of the Act" to the end substitute—

"(a) the provisions of the Act set out in Part I of the said Schedule 2 shall have effect in relation to such articles or substances as those provisions have effect in relation to medicinal products; and

(b) the provisions of the Clinical Trials Regulations shall have effect in relation to those articles or substances.".

Textual Amendments

F23 S.I. 1976/968, as amended by S.I. 1994/3119.

6.—(1) The Medicines (Labelling) Regulations 1976 [F24] shall be amended as follows.

(2) In regulation 1 (citation and scope) [F25], after "apply", insert " or a medicinal product which is an investigational medicinal product within the meaning of the Medicines for Human Use (Clinical Trials) Regulations 2003 ".

(3) In regulation 2 (commencement), in paragraph (b), in sub-paragraph (i), omit ", clinical trial certificate".

(4) Omit regulation 6 (clinical trials).

(5) In regulation 10 (surgical materials), omit the words from ", except that" to the end.

(6) In regulation 16 (provisions in licences, clinical trial certificates and animal test certificates)—

(a) in paragraph (1), for "a clinical trial certificate or animal test certificate " substitute " an animal test certificate ";

(b) in paragraph (2), omit ", clinical trial certificate".

(7) Omit Schedule 2 (particulars required in the labelling of containers and packages of medicinal products for clinical trials).

Textual Amendments

F24 S.I. 1976/1726; the Regulations were revoked in so far as they relate to the labelling of containers and packages of medicinal products for administration in certain medicinal tests on animals by S.I. 1996/2194.

F25 As amended by S.I. 1994/3144.

7. In the Medicines (Fluted Bottles) Regulations 1978 [F26], in regulation 3 (exceptions)—

(a) after paragraph (e), insert the following paragraph—

"(ee) where medicinal products are investigational medicinal products within the meaning given by the Medicines for Human Use (Clinical Trials) Regulations 2004;"; and

(b) in paragraph (g), omit "clinical trial certificate or".

Textual Amendments

F26 S.I. 1978/40; regulation 3 was amended by S.I. 1994/3142 and 3144.

8. In Schedule 1 to the Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989 [F27], after paragraph 9A [F28] insert the following paragraph—

"**9B.** Functions of the licensing authority which are functions of theirs by virtue of the Medicines for Human Use (Clinical Trials) Regulations 2004 and the functions of any person appointed under Schedule 5 or 8 to those Regulations.".

Textual Amendments

F27 S.I. 1989/684.

F28 Paragraph 9A was inserted by S.I. 1995/871.

9. In the Medicines Act 1968 (Application to Radiopharmaceutical-Associated Products) Regulations 1992 [F29], in the Schedule—

(a) in the entry relating to section 44 of the Act, for " ", or of a clinical trial certificate or animal test certificate,"" substitute " , or of an animal test certificate, ";

(b) in the entry relating to section 45 of the Act, omit "section 31,", in both places those words appear;

(c) in the entry relating to section 46 of the Act, for " "or of a clinical trial certificate or animal test certificate"" substitute " or of an animal test certificate "; and

(d) in the entry relating to section 47 of the Act—

(i) for " "any clinical trial certificate or animal test certificate"" substitute " any animal test certificate ", and

(ii) for " ", or any clinical trial certificate or animal test certificate,"" substitute " , or any animal test certificate, ".

Textual Amendments
F29 S.I. 1992/605.

10. In the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 [F30], in Schedule 4 (application of the provisions of the Act)—

(a) in the entry relating to section 23 of the Act, omit "clinical trials and";

(b) in the entry relating to section 44 of the Act, for "a clinical trial certificate or animal test certificate", in both places those words appear, substitute " an animal test certificate ";

(c) in the entry relating to section 45 of the Act—

(i) omit "section 31,", and

(ii) for " "or of a clinical trial certificate or animal test certificate"" substitute " or of an animal test certificate "; and

(d) in the entry relating to section 46 of the Act, for " "or of a clinical trial certificate or animal test certificate"" substitute " or of an animal test certificate ".

Textual Amendments
F30 S.I. 1994/105.

11. In the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994 [F31], in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of "medicinal product"—

(a) for sub-paragraph (ii), substitute the following sub-paragraph—

"(ii) which is an "investigational medicinal product" within the meaning of regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003, or"; and

(b) omit sub-paragraph (iii).

Textual Amendments
F31 S.I. 1994/2844; regulation 1(2) was substituted by S.I. 1996/2635.

12. In the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 [F32]—

(a) in regulation 1—

(i) in paragraph (2), after the definition of "the Act" insert the following definition—

""the Clinical Trials Directive" means Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;",

(ii) in paragraph (5), omit "and except in the case of "clinical trial,"";

(b) in Schedule 1, in paragraph 2, for sub-paragraph (e) [F33] substitute the following sub-paragraph—

"(e) the relevant medicinal product—

(i) is manufactured, assembled or imported by the holder of an authorization referred to in Article 40 of the 2001 Directive which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; or

(ii) has been manufactured, assembled or imported as an investigational medicinal product by the holder of an authorization referred to in Article 13 of the Clinical Trials Directive"; and.

Textual Amendments

F32 S.I. 1994/3144.

F33 Paragraph 2(e) of Schedule 1 was amended by SI 2002/236.

13. In the Prescription Only Medicines (Human Use) Order 1997 [F34]—

(a) in article 1 (citation, commencement and interpretation), in paragraph (2), for the definition of "clinical trial exemption" substitute the following definition—

""clinical trial" has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003;"; and

(b) in article 3B (prescribing and administration by supplementary prescribers), in paragraph (3), in sub-paragraph (b), in head (ii), for the words from "and—" to the end substitute " which has been authorised, or is to be treated as having been authorised, by the licensing authority in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2003 ".

Textual Amendments

F34 S.I. 1997/1830; the relevant amending instrument is S.I. 2003/696.

14. In the Ionising Radiation (Medical Exposure) Regulations 2000 [F35], in regulation 2 (interpretation), in paragraph (1), after the definition of "ionising radiation", insert the following definition—

""Local Research Ethics Committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004,

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

(c) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State, the National Assembly for Wales or Scottish Ministers;".

Textual Amendments

F35 S.I. 2000/1059.

15. In the Private and Voluntary Health Care (England) Regulations 2001 [F36], in regulation 24 (research), for paragraph (2) substitute the following paragraph—

"(2) For the purposes of paragraph (1)(a), "appropriate Research Ethics Committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004; or

(b) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State;".

Textual Amendments

F36 S.I. 2001/3968.

16. In the Misuse of Drugs Regulations 2001 [F37], in regulation 18 (marking of bottles and other containers), for paragraph (3) substitute the following paragraph—

"(3) In this regulation—

"clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2003;

"medicinal test on animals" has the same meaning as in the Medicines Act 1968.".

Textual Amendments

F37 S.I. 2001/3998.

17. In the Health Service (Control of Patient Information) Regulations 2002 [F38], in regulation 1 (citation, commencement, interpretation and extent), in paragraph (2), for the definition of "research ethics committee" substitute the following definition—

""research ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, or

(b) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State or the National Assembly for Wales;".

Textual Amendments

F38 S.I. 2002/1438.

18. In the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002 [F39], in regulation 2 (interpretation), in paragraph (1), for the definition of "research ethics committee" substitute the following definition—

""research ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, or

(b) any other committee established to advise on the ethics of research investigations on human beings and recognised for that purpose by or on behalf of the Secretary of State;".

Textual Amendments

F39 S.I. 2002/2375.

SCHEDULE 11

Regulation 55

REVOCATIONS

Regulations and orders	*S.I. number*	*Extent of revocation*
The Medicines (Standard Provisions for Licence and Certificates) Regulations 1971	S.I. 1971/972	The whole Regulations in so far as they relate to clinical trial certificates
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971	S.I. 1971/973	The whole Regulations in so far as they relate to applications for clinical trial certificates
The Medicines (Exemption from Licences) (Clinical Trials) Order 1974	S.I. 1974/498	The whole Order
The Medicines (Renewal Applications for Licences and Certificates) Regulations 1974	S.I. 1974/832	The whole Regulations in so far as they relate to renewal applications for clinical trial certificates
The Medicines (Exemption from Licences) (Clinical Trials) Order 1995	S.I. 1995/2808	The whole Order
The Medicines (Exemption from Licences and Certificates) (Clinical Trials) Order 1995	S.I. 1995/2809	The whole Order
The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential Etc Provisions) Regulations 2002	S.I. 2002/2469	Schedule 1, Part 2, paragraph 67.

SCHEDULE 12

Regulation 56

TRANSITIONAL PROVISIONS

1.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004;

(b) no ethics committee has given a favourable opinion in relation to that trial in accordance with regulation 15; and

(c) a committee established or recognised for the purpose of advising on the ethics of research investigations on human beings has before 1st May 2004 given a favourable ethical opinion in relation to that trial.

(2) Subject to the following sub-paragraphs, where sub-paragraph (1) applies—

(a) the trial shall be treated for the purposes of these Regulations as if an ethics committee has given a favourable opinion in relation to that trial in accordance with regulation 15;

(b) regulations 12, 24(3) and 29 shall apply in relation to the trial with the modification that references to the application for an ethics committee opinion shall be read as references to the application for approval made to the committee referred to in sub-paragraph (1)(c); and

(c) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee referred to in sub-paragraph (1)(c).

(3) This sub-paragraph applies where the committee referred to in sub-paragraph (1)(c) has not been recognised by the Authority in accordance with regulation 7—

(a) for the area in which the trial sites are situated, or

(b) for the description or class of clinical trial into which the trial falls,

before 1st September 2004.

(4) Where sub-paragraph (3) applies—

(a) the sponsor of the clinical trial may make an application to an ethics committee established or recognised by the Authority in accordance with Part 2—

(i) for the area in which the trial sites are situated, or

(ii) for the description or class of clinical trial into which the trial falls,

for an amendment to the protocol for the trial within the meaning of Part 3 of these Regulations; or

(b) the chief investigator may make an application to an ethics committee in accordance with regulation 14.

(5) Where an ethics committee receives an application for an amendment in accordance with sub-paragraph (4)(a), it shall consider the amendment as if it was a valid notice of amendment under regulation 24.

(6) Where an ethics committee gives a favourable opinion in relation an application for amendment made pursuant to sub-paragraph (4)(a)—

(a) sub-paragraph (2)(c) shall cease to apply; and

(b) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee which gave that favourable opinion.

(7) Where an ethics committee gives a favourable opinion in relation to an application pursuant to sub-paragraph (4)(a), sub-paragraph (2) shall cease to apply in relation to that trial

(8) Where sub-paragraph (3) applies and before 1st May 2006 no favourable opinion has been given as specified in sub-paragraphs (6) and (7), sub-paragraph (2) and (4) shall cease to apply from that date.

(9) If the committee referred to in sub-paragraph (1)(b) is abolished or ceases operation before 1st May 2006—

(a) the Authority shall nominate an ethics committee as responsible for the work of the committee which is abolished or which ceases operation; and

(b) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee so nominated.

2.—(1) This sub-paragraph applies where a person has made an application for an ethical opinion in relation to a clinical trial before 1st May 2004 to a committee established or recognised for the purpose of advising on the ethics of research investigations on human beings.

(2) Where—

(a) sub-paragraph (1) applies;

(b) the committee has not given its opinion before 1st May 2004; and

(c) the committee has been recognised by the Authority in accordance with regulation 7 for the area in which the trial sites are situated, or for the description or class of clinical trial into which the trial falls,

the committee shall consider the application as if it had been made in accordance with regulation 14.

Clinical trial exemptions or notifications prior to 1st May 2004

3.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004; and

(b) immediately before 1st May 2004, a clinical trial certificate was in force and the trial was being conducted in accordance with that certificate.

(2) Where sub-paragraph (1) applies—

(a) the trial shall be treated for the purposes of these Regulations as having been authorised by the licensing authority;

(b) regulations 17 to 21 shall not apply in relation to the trial; and

(c) regulations 11, 24(2), 29, 31 and 45(1), and Schedule 7, shall apply in relation to the trial with the modification that references to the request for authorisation shall be read as references to the application for the clinical trial certificate.

4.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004; and

(b) immediately before 1st May 2004, the exemption conferred by article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 [F40] applied in respect of the sale or supply of medicinal products for the purposes of that trial.

(2) Where sub-paragraph (1) applies—

(a) the trial shall be treated for the purposes of these Regulations as having been authorised by the licensing authority;

(b) regulations 17 to 21 shall not apply in relation to the trial; and

(c) regulations 11, 24(2), 29, 31 and 45(1), and Schedule 7, shall apply in relation to the trial with the modification that references to the request for authorisation shall be read as references to the notice to the licensing authority specified in article 4(1)(a) of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 .

Textual Amendments
F40 S.I. 1995/2808.

5.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004;

(b) the investigational medicinal product used in the trial is a product with a marketing authorization;

(c) the trial has before 1st May 2004 been notified to the licensing authority by the person supplying the product for the purposes of that trial; and

(d) the licensing authority has before 1st May 2004 notified that person that—

(i) the trial appeared to fall within the terms of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 [F41], and

(ii) the authority agreed to the trial proceeding.

(2) Where sub-paragraph (1) applies—

(a) the trial shall be treated for the purposes of these Regulations as having been authorised by the licensing authority;

(b) regulations 17 to 21 shall not apply in relation to the trial; and

(c) regulations 11, 24(2), 29, 31 and 45(1), and Schedule 7, shall apply in relation to the trial with the modification that references to the request for authorisation shall be read as references to the notification referred to in sub-paragraph (1)(c).

Textual Amendments
F41 S.I. 1974/498.

6.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted 30th April 2004; and

(b) immediately before 1st May 2004, the exemption conferred by article 2(2) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 [F42] applied in respect of the sale or supply of medicinal products for the purposes of that trial.

(2) Where sub-paragraph (1) applies—

(a) the trial shall be treated for the purposes of these Regulations as having been authorised by the licensing authority;

(b) regulations 17 to 21 shall not apply in relation to the trial; and

(c) regulations 11, 24(2), 29, 31 and 45(1), and Schedule 7, shall apply in relation to the trial with the modification that references to the request for authorisation shall be read as references to the notification to the licensing authority specified in article 2(3)(c) or (4)(a) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972.

Textual Amendments

F42 S.I. 1972/1200.

7.—(1) This sub-paragraph applies where—

(a) an application for a clinical trial certificate has been made in accordance with section 36 of the Act and the licensing authority has not before 1st May 2004 determined whether to issue a certificate;

(b) the licensing authority has received a notice pursuant to article 4(1)(a) of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 and on 1st May 2004—

(i) the specified period within the meaning of article 4(2) of that Order has not expired, and

(ii) the authority has not given or sent a notice pursuant to article 4(1)(b); or

(c) the licensing authority has received a notice pursuant to article 4(2)(iv) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 and on 1st May 2004—

(i) the period specified in article (2)(v) of that Order has not expired, and

(ii) the authority has not given a direction pursuant to that article.

(2) Where sub-paragraph (1) applies the licensing authority shall treat the application or notice as a valid request for authorisation to conduct the clinical trial to which the application or notice relates under regulation 17.

Status:
Point in time view as at 30/10/2005.

Changes to legislation:
The Medicines for Human Use (Clinical Trials) Regulations 2004 is up to date with all changes known to be in force on or before 28 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.