
STATUTORY INSTRUMENTS

2004 No. 1031

MEDICINES

The Medicines for Human Use
(Clinical Trials) Regulations 2004

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THE MEDICINES FOR HUMAN USE
(CLINICAL TRIALS) REGULATIONS 2004

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SCHEDULE 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...
2. In this Schedule— “Declaration of Helsinki” means the Declaration of...
3. (1) For the purposes of this Schedule, a person gives...

PART 2 — CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

1. Principles based on International Conference on Harmonisation GCP Guideline
2. Before the trial is initiated, foreseeable risks and inconveniences have...
3. The rights, safety, and well-being of the trial subjects are...
4. The available non-clinical and clinical information on an investigational medicinal...
5. Clinical trials shall be scientifically sound, and described in a...
6. A trial shall be conducted in compliance with the protocol...
7. The medical care given to, and medical decisions made on...
8. Each individual involved in conducting a trial shall be qualified...
9. Subject to the other provisions of this Schedule relating to...
10. All clinical trial information shall be recorded, handled, and stored...
11. The confidentiality of records that could identify subjects shall be...
12. Investigational medicinal products used in the trial shall be—
13. Systems with procedures that assure the quality of every aspect...
14. Conditions based on Article 3 of the Directive
15. The rights of each subject to physical and mental integrity,...
16. Provision has been made for insurance or indemnity to cover...

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...

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2. The subject has been informed of his right to withdraw...
3. The subject has given his informed consent to taking part...
4. The subject may, without being subject to any resulting detriment,...
5. The subject has been provided with a contact point where...

PART 4 — CONDITIONS AND PRINCIPLES WHICH APPLY IN
RELATION TO A MINOR

1. Conditions
2. That person or legal representative has been provided with a...
3. That person or legal representative has been informed of the...
4. That person or legal representative has given his informed consent...
5. That person with parental responsibility or the legal representative may,...
6. The minor has received information according to his capacity of...
7. The explicit wish of a minor who is capable of...
8. No incentives or financial inducements are given—
9. The clinical trial relates directly to a clinical condition from...
10. Some direct benefit for the group of patients involved in...
11. The clinical trial is necessary to validate data obtained—
12. The corresponding scientific guidelines of the European Medicines Agency are...
13. Principles
14. The clinical trial has been designed to minimise pain, discomfort,...
15. The risk threshold and the degree of distress have to...
16. The interests of the patient always prevail over those of...

PART 5 — CONDITIONS AND PRINCIPLES WHICH APPLY IN
RELATION TO AN INCAPACITATED ADULT

1. Conditions
2. The legal representative has been provided with a contact point...
3. The legal representative has been informed of the right to...
4. The legal representative has given his informed consent to the...
5. The legal representative may, without the subject being subject to...
6. The subject has received information according to his capacity of...
7. The explicit wish of a subject who is capable of...
8. No incentives or financial inducements are given to the subject...
9. There are grounds for expecting that administering the medicinal product...
10. The clinical trial is essential to validate data obtained—
11. The clinical trial relates directly to a life-threatening or debilitating...
12. Principles
13. The clinical trial has been designed to minimise pain, discomfort,...
14. The risk threshold and the degree of distress have to...
15. The interests of the patient always prevail over those of...

SCHEDULE 2 — ADDITIONAL PROVISIONS RELATING TO ETHICS
COMMITTEES

1. Interpretation
2. Application of provisions of the Schedule
3. Membership
4. A member of an ethics committee shall hold and vacate...
5. Chairman, vice-chairman and alternate vice-chairman
6. Committees, meetings and proceedings
7. Deputies and co-opted members
8. (1) At any meeting of an ethics committee, the committee...
9. Staff, premises and facilities
10. Expenses

11. The appointing authority may pay to members of ethics committees...
12. Annual report
13. Transfer of functions

SCHEDULE 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...
2. A document containing the particulars specified in paragraphs 1 to...
3. The following documents or, in each case, an explanation of...

PART 2 — REQUEST FOR AUTHORISATION

1. The name and address of— (a) the sponsor,
2. If any person is specified as a person responsible for...
3. The address of each trial site and the names and...
4. Where the trial is to be conducted at trial sites...
5. A copy of the ethics committee opinion in relation to...
6. A description of any investigational medicinal product to be used...
7. The name and address of the person responsible for the...
8. (1) The address of any premises at which any batch...
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...
12. A description or sample of the labelling which is to...

PART 3 — NOTICE OF AMENDMENT

1. The name and address of— (a) the sponsor,
2. Particulars identifying the trial, including— (a) the title of the...
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—
6. Summaries of— (a) any data submitted in support of the...

PART 4 — NOTIFICATION OF CONCLUSION OF A CLINICAL TRIAL

1. The name and address of— (a) the sponsor, and
2. Particulars identifying the trial, including— (a) the title of the...
3. The investigational medicinal product tested in the trial.
4. (1) The date on which the trial ended in the...
5. If the trial is terminated as specified in regulation 27(2),...

SCHEDULE 4 — APPEAL AGAINST UNFAVOURABLE ETHICS COMMITTEE OPINION

1. (1) Subject to the following sub-paragraphs, where the United Kingdom...
2. Where a direction is given in accordance with paragraph 1(1)(a)—...
3. (1) An appeal panel appointed pursuant to paragraph 1(1)(b) shall...
4. (1) An appeal panel shall consider an ethics committee opinion...
5. If an appeal panel gives a favourable opinion, the condition...
6. The Authority may pay to members of an appeal panel...

SCHEDULE 5 — PROCEDURAL PROVISIONS RELATING TO THE REFUSAL OR AMENDMENT OF, OR IMPOSITION OF CONDITIONS RELATING TO, CLINICAL TRIAL AUTHORISATION AND THE SUSPENSION OR TERMINATION OF CLINICAL TRIALS

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1. (1) Where the licensing authority are notified of the sponsor's...
2. (1) If a person to whom a notice is given...
3. (1) If a decision notified in accordance with paragraphs 1(6)...

SCHEDULE 6 — PARTICULARS THAT MUST ACCOMPANY AN APPLICATION FOR A MANUFACTURING AUTHORISATION

1. The name and address of the applicant, and, where the...
2. A statement of the types of investigational medicinal products in...
3. A statement of the manufacturing, assembling or importation operations to...
4. (1) The address of each of the premises where the...
5. A statement of any manufacturing operations, other than those to...
6. (1) The name and address and qualifications and experience of...
7. A description of the arrangements for the identification and storage...
8. A description of the arrangements at each of the premises...
9. A description of the arrangements— (a) for maintaining production or...

SCHEDULE 7 — STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 1 — INTERPRETATION

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...
2. The holder of the authorisation shall— (a) provide and maintain...
3. The holder of the authorisation shall place the quality control...
4. The holder of the authorisation may use a contract laboratory...
5. The holder of the authorisation shall provide such information as...
6. The holder of the authorisation shall— (a) inform the licensing...
7. The holder of the authorisation shall— (a) keep readily available...
8. The holder of the authorisation shall keep readily available for...
9. Where the holder of the authorisation has been informed by...
10. The holder of the authorisation shall ensure that any tests...
11. Where the authorisation relates to the assembly of an investigational...
12. Where— (a) the manufacturing authorisation relates to the assembly of...
13. The holder of the authorisation, for the purpose of enabling...
14. The holder of the authorisation shall at all times provide...

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...
2. The holder of the authorisation may use a contract laboratory...
3. The holder of the authorisation shall provide such information as...
4. The holder of the authorisation shall— (a) inform the licensing...
5. The holder of the authorisation shall— (a) keep readily available...
6. Where the holder of the authorisation has been informed by...
7. If the holder of the authorisation is not the sponsor...
8. The holder of the authorisation, for the purpose of enabling...
9. The holder of the authorisation shall at all times provide...

SCHEDULE 8 — 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...
2. Subject to paragraph 6, if the licensing authority propose—
3. Any notification given under paragraph 2 shall include a statement...
4. A person to whom notification has been given under paragraph...
5. (1) Where an applicant or the holder gives notice under...
6. (1) Paragraph 2 shall not apply to the suspension of...

SCHEDULE 9 — 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...
2. (1) Amendments in section 107 (validity of decisions and related...
3. For section 108 (enforcement in England and Wales) substitute—
4. In section 109 (enforcement in Scotland), for subsections (1) to...
5. For section 110 (enforcement in Northern Ireland) substitute— It shall...
6. (1) Amendments in section 111 (rights of entry) as follows...
7. (1) Amendments in section 112 (power to inspect, take samples...
8. (1) Amendments in section 115 (analysis of samples) as follows...
9. (1) Amendments in section 116 (liability to forfeiture under the...
10. In section 118(1)(b) (restrictions on disclosing of information obtained in...
11. (1) Amendments in section 119 (protection for officers of enforcement...
12. (1) Amendments in section 121 (contravention due to fault of...
13. (1) Amendments in section 122 (warranty as defence) as follows...
14. (1) Amendments in section 124 (offences by bodies corporate) as...
15. (1) Amendments in section 125 (prosecutions) as follows.
16. In section 127 (service of documents)— (a) for “any provision...
17. (1) Amendments in section 129 (orders and regulations) as follows...
18. (1) Amendments in section 131 (meaning of “wholesale dealing” and...
19. (1) Amendments in section 132(1) (interpretation) as follows.
20. (1) Amendments in Schedule 3 (sampling) as follows.

SCHEDULE 10 — CONSEQUENTIAL AND OTHER AMENDMENTS OF
ENACTMENTS

PART 1 — ACTS OF PARLIAMENT

1. The Act
2. In section 4 of the Act (establishment of committees), in...
3. In section 7 of the Act (restrictions as to dealings...
4. (1) Section 8 of the Act (provisions as to manufacture...
5. (1) Section 23 of the Act (special provisions as to...
6. Section 31 of the Act shall be omitted
7. (1) Section 35 of the Act (supplementary provisions as to...
8. In section 36 of the Act (application for, and issue...
9. (1) Section 37 of the Act (transitional provisions as to...
10. In section 38 of the Act (duration and renewal of...
11. In section 39 of the Act (suspension, revocation or variation...
12. In section 44 of the Act (provision of information to...
13. In section 45 of the Act (offences under Part II)—...
14. In section 46 of the Act (special defences under section...
15. In section 47 of the Act (standard provisions for licences...
16. In section 50 of the Act (certificates for exporters of...
17. In section 104 of the Act (application of Act to...
18. In section 105 of the Act (application of Act to...

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19. In section 132 of the Act (general interpretation provisions)—
 20. The Medicines Act 1971
 21. The Adults with Incapacity (Scotland) Act 2000
- PART 2 — ORDERS AND REGULATIONS
1. In the Medicines (Standard Provisions for Licences and Certificates) Regulations...
 2. In the Medicines (Surgical Materials) Order 1971, in article 3,...
 3. (1) In the Medicines (Exemption from Licences) (Special Cases and...
 4. In the Medicines (Dental Filling Substances) Order 1975, in article...
 5. In the Medicines (Specified Articles and Substances) Order 1976, in...
 6. (1) The Medicines (Labelling) Regulations 1976 shall be amended as...
 7. In the Medicines (Fluted Bottles) Regulations 1978, in regulation 3...
 8. In Schedule 1 to the Medicines (Fixing of Fees Relating...
 9. In the Medicines Act 1968 (Application to Radiopharmaceutical-Associated Products) Regulations...
 10. In the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations...
 11. In the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994,...
 12. In the Medicines for Human Use (Marketing Authorisations Etc.) Regulations...
 13. In the Prescription Only Medicines (Human Use) Order 1997—
 14. In the Ionising Radiation (Medical Exposure) Regulations 2000, in regulation...
 15. In the Private and Voluntary Health Care (England) Regulations 2001,...
 16. In the Misuse of Drugs Regulations 2001, in regulation 18...
 17. In the Health Service (Control of Patient Information) Regulations 2002,...
 18. In the National Health Service (Functions of Strategic Health Authorities...

SCHEDULE 11 — REVOCATIONS

SCHEDULE 12 — TRANSITIONAL PROVISIONS

1. Ethical approval given before 1st May 2004
2. Applications for ethical approval prior to 1st May 2004
3. Clinical trial exemptions or notifications prior to 1st May 2004
4. (1) This sub-paragraph applies where— (a) a clinical trial is...
5. (1) This sub-paragraph applies where— (a) a clinical trial is...
6. (1) This sub-paragraph applies where— (a) a clinical trial is...
7. Applications for clinical trial exemptions or notifications prior to 1st May 2004

Explanatory Note