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STATUTORY INSTRUMENTS

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**2004 No. 1031**

**MEDICINES**

The Medicines for Human Use  
(Clinical Trials) Regulations 2004

*Made* - - - - - *31st March 2004*  
*Laid before Parliament* *1st April 2004*  
*Coming into force* *1st May 2004*

THE MEDICINES FOR HUMAN USE  
(CLINICAL TRIALS) REGULATIONS 2004

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**Changes to legislation:** There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004. (See end of Document for details)

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**Changes to legislation:** There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004. (See end of Document for details)

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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 Articles 2 to 5 of the GCP Directive
- 2. Each individual involved in conducting a trial shall be qualified...
- 3. Clinical trials shall be scientifically sound and guided by ethical...
- 4. The necessary procedures to secure the quality of every aspect...
- 5. The available non-clinical and clinical information on an investigational medicinal...
- 6. Clinical trials shall be conducted in accordance with the principles...
- 7. The protocol shall provide for the definition of inclusion and...
- 8. The investigator and sponsor shall consider all relevant guidance with...
- 9. All clinical information shall be recorded, handled and stored in...
- 10. Conditions based on Article 3 of the Directive
- 11. The medical care given to, and medical decisions made on...

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12. A trial shall be initiated only if an ethics committee...
13. The rights of each subject to physical and mental integrity,...
14. 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...
    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. In this Schedule— “appointing authority” means— in relation to an...
2. (1) The provisions of this Schedule shall not apply in...
3. Membership

4. A member of an ethics committee shall hold and vacate...
5. (1) The appointing authority shall appoint— (a) one of the...
6. (1) An ethics committee may— (a) appoint sub-committees consisting of...
7. Deputies and co-opted members
8. (1) At any meeting of an ethics committee, the committee...
9. (1) The appointing authority shall make arrangements for the appointment...
10. Expenses
11. The appointing authority may pay to members of ethics committees...
12. (1) Within the period six months from the end of...
13. (1) This paragraph applies where— (a) recognition of an ethics...

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...

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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 AUTHORISATIONS AND THE SUSPENSION OR TERMINATION OF CLINICAL TRIALS

1. Hearing before the appropriate committee
2. Licensing authority decision
3. Right to be heard by a person appointed
4. Hearing before person appointed

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 describing the types of investigational medicinal product in...
3. A statement of the manufacturing, assembling or importation operations to...
- 3A Where the application relates to the inactivation of viral or...
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

In this Schedule— “ Commission Directive 2003/94/EC ” in relation...

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...
- 14A The holder of the authorisation shall only manufacture or assemble...

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...
- 9A The holder of the authorisation shall only import EAMS medicinal...

#### 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. (1) Subject to sub-paragraph (2), the applicant or holder to...
5. (1) If the applicant or holder gives notice under paragraph...
6. (1) Paragraph 2 shall not apply to the suspension of...

#### SCHEDULE 9 — MODIFICATIONS OF THE ENFORCEMENT PROVISIONS OF THE 2012 REGULATIONS SUBJECT TO WHICH THOSE PROVISIONS ARE APPLIED FOR THE PURPOSES OF THESE REGULATIONS

1. The modifications of the 2012 Regulations mentioned in regulation 47...
2. In regulation 2 (medicinal products)— (a) at the beginning of...
2. In regulation 8(1) (interpretation)— (a) the definition “assemble” is substituted...
3. In regulation 322(1) (validity of decisions and proceedings) omit “or”...
4. In regulation 325(1) (rights of entry) insert after sub-paragraph (b)...
5. (1) Regulation 327 (powers of inspection, sampling and seizure) is...

#### 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) ,...
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. In section 1 of the Medicines Act 1971 (fees payable...
21. Section 51 of 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. (1) In the Medicines (Exemption from Licences) (Special Cases and...
  4. In the Medicines (Dental Filling Substances) Order 1975 , in...
  5. In the Medicines (Specified Articles and Substances) Order 1976 ,...
  6. (1) The Medicines (Labelling) Regulations 1976 shall be amended as...
  7. In the Medicines (Fluted Bottles) Regulations 1978 , in regulation...
  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...
15. In the Private and Voluntary Health Care (England) Regulations 2001...
16. In the Misuse of Drugs Regulations 2001 , in regulation...
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. (1) This sub-paragraph applies where— (a) a clinical trial is...
2. (1) This sub-paragraph applies where a person has made an...
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. (1) This sub-paragraph applies where— (a) an application for a...

#### SCHEDULE 13 — Transitional provisions relating to EU Exit

1. List of countries for the purpose of the definition of “marketing authorization” on IP completion day (regulation 2A)
2. List of countries where a sponsor of a clinical trial, or their legal representative, may be established on IP completion day (regulation 3(11A))
3. Import of investigational medicinal products into Great Britain from EEA States during the transitional period
4. Approved country for import list on IP completion day (regulation 43A)

Explanatory Note



**Changes to legislation:**

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