Mauritius

Clinical Trials Act

Act 8 of 2011

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Clinical Trials Act
Contents

Part I – Preliminary 1
1. Short title 1
2. Interpretation 1
Part II – Clinical Research Regulatory Council 3
3. Clinical Research Regulatory Council 3
4. Functions and powers of Council 4
5. Meetings of Council 5
6. Secretary and other officers of Council 5
Part III – Ethics Committee 6
7. Ethics Committee 6
8. Functions of Ethics Committee 6
Part IV – Pharmacovigilance Committee 7
9. Pharmacovigilance Committee 7
10. Functions of Pharmacovigilance Committee 8
Part V – Trial licence 8
11. Trial licence 8
12. Application for trial licence 8
13. Grant of application 9
14. Refusal of application 10
15. Amendment of trial licence 10
16. Suspension or cancellation of trial licence 10
Part VI – Conduct of clinical trials 11
17. Good clinical practice 11
18. The sponsor 11
19. The investigator 12
20. Protection of subjects 12
21. Emergency measures 13
22. Strict liability of sponsor 13
23. Trial master file and archiving 13
24. Progress and completion of clinical trial reports 14
25. Completion and discontinuance of clinical trial 14
Part VII – Inspections 14
26. Verification of compliance 14
Part VIII – Pharmacovigilance 14

27. Record of adverse event or reaction 14
28. Notification of serious adverse event or reaction 14
Part IX – Register of clinical trials 15
29. Register of clinical trials 15
Part X – Offences 15
30. Offences 15
Part XI – Miscellaneous provisions 15
31. Annual report 15
32. Powers of Minister 16
33. Disclosure of interest 16
34. Protection from liability 16
35. Regulations 16
36. *** 16

Mauritius

Clinical Trials Act

Act 8 of 2011

Commenced on 1 September 2011

[This is the version of this document at 30 June 2017.]

Part I – Preliminary

1. Short title

This Act may be cited as the Clinical Trials Act.

2. Interpretation

In this Act—

"**administer**" means give or apply a substance or test article, in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle, to a human being—

(a) orally, by injection, by introduction into the body or in any other way; or

(b) by external application, whether by direct contact with the body or not;

"**adverse event**" means any untoward medical occurrence in a patient or a subject to whom a medicinal product is administered which does not necessarily have a causal relationship with the treatment;

"**adverse reaction**" means any untoward and unintended response to an investigational medicinal product administered in any dose to a subject;

"**Certificate of Good Manufacturing Practice (GMP)**" means a certificate which purports to show that a manufacturer has effectively implemented a set of international standards aimed at ensuring that an investigational medicinal product or medicinal product is consistently manufactured and controlled to the quality standards appropriate to their intended use;

"**Certificate of Pharmaceutical Product (COPP)**" means a certificate issued in a format recommended by the World Health Organisation by a drug regulatory authority and purporting to—

(a) indicate that a manufacturer has submitted its manufacturing site to regular GMP inspections; and

(b) provide details about the product and its manufacture, including, but not limited to, the marketing authorisation holder, the active ingredients and excipients, the manufacturing and packaging sites and whether or not the product is placed on the market in the country of origin;

"**clinical trial**" means an investigation in a subject intended—

(a) to discover or verify the clinical or pharmacological effect of an investigational medicinal product;

(b) to identify any adverse reaction to such a product; or

(c) to study the absorption, distribution, metabolism and excretion of such a product,

for the purpose of ascertaining the safety or efficacy of the product, after its administration to the subject;

"**conditions and principles of good clinical practice**" means the conditions and principles having their origin in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects;

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"**Council**" means the Clinical Research Regulatory Council referred to in section 3;

"**Ethics Committee**" means the Ethics Committee referred to in section 7;

"**guidelines**"—

(a) means guidelines which the Council considers applicable to the conduct of clinical trials in Mauritius;

(b) includes, but is not limited to, existing international standards such as the good clinical practice guideline (ICH E6) of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use;

"**health personnel**" includes any person who works in a technical or scientific capacity in a hospital, dispensary, clinic, laboratory or medical research centre;

"**investigational medicinal product**"—

(a) means the pharmaceutical form of a substance, test article or placebo being tested or used as a reference in a clinical trial;

(b) includes a medicinal product, the importation of which is permitted in an authorised form and which—

(i) is used, formulated or packaged in a different way;

(ii) is used for an unauthorised indication; or

(iii) is used to gain further information about the authorised form;

"**investigator**" means a medical practitioner, or other health professional acceptable to the Council, who is designated by a sponsor to be responsible for the conduct of a clinical trial;

"**investigator's brochure**" means a compilation of the clinical and nonclinical data on an investigational medicinal product which are relevant to the study of the product in a subject;

"**law practitioner**" has the same meaning as in the Law Practitioners Act;

"**manufacture**" has the same meaning as in the Pharmacy Act;

"**medical practitioner**" means a person registered as a general practitioner or a specialist under the Medical Council Act;

"**medicinal product**" means a substance which is manufactured, sold, supplied, imported or exported for use, wholly or mainly, in any of the following ways—

(a) by being administered to a human being for a medicinal purpose;

(b) as an ingredient in the preparation of a substance or article which is to be administered to a human being or an animal for a medicinal purpose;

"**medicinal purpose**" means—

(a) treating or preventing disease;

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

(c) contraception;

(d) inducing anaesthesia; or

(e) preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way;

"**Minister**" means the Minister to whom responsibility for the subject of health is assigned;

"**nursing officer**" means a person registered as a general nurse or a mental health nurse under the Nursing Council Act;

"**officer**" means an officer of the Council designated under section 6 and includes the Secretary;

"**pharmacist**" has the same meaning as in the Pharmacy Act;

"**pharmacovigilance**" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems;

"**Pharmacovigilance Committee**" means the Pharmacovigilance Committee referred to in section 9;

"**protocol**" means a document which describes the objective, design, methodology, statistical consideration and organisation of a clinical trial;

"**Register**" means the register of clinical trials referred to in section 29;

"**Secretary**" means the Secretary of the Council designated under section 6;

"**serious adverse event**" or "serious adverse reaction" means any adverse event or adverse reaction which —

(a) results in death;

(b) is life-threatening;

(c) requires hospitalisation or prolongation of existing hospitalisation;

(d) results in persistent or significant disability or incapacity; or

(e) consists of a congenital anomaly or birth defect;

"**site**" means a place approved by the Council for the conduct of a clinical trial;

"**sponsor**" means a person who assumes responsibility for the initiation, management and financing of a clinical trial;

"**subject**" means a human being to whom an investigational medicinal product is administered for the purposes of a clinical trial;

"**supervising officer**" means the supervising officer of the Ministry responsible for the subject of health;

"**test article**" means any drug (including a biological product for human use), human food additive, colour additive or other substance intended for administration to a human being;

"**Trade and Therapeutics Committee**" has the same meaning as in the Pharmacy Act;

"**trial licence**" means a licence issued under section 13;

"**trial master file**" means the file referred to in section 23.

Part II – Clinical Research Regulatory Council

3. Clinical Research Regulatory Council

(1) There shall be for the purposes of this Act a Clinical Research Regulatory Council.

(2) The Council shall consist of—

(a) a Chairperson;

(b) 3 medical practitioners, who shall include a paediatrician, a specialist in internal medicine and a specialist in public health, 2 of whom shall be public officers;

(c) 2 pharmacists, one of whom shall be a public officer;

(d) a representative of the University of Mauritius, having experience in biomedical research involving human beings;

(e) a biostatistician or a statistician having not less than 5 years' experience in health matters;

(f) a law officer designated by the Attorney-General;

(g) a person having wide experience in the field of pharmacology;

(h) a person having wide experience in the field of clinical trials.

(3) The Chairperson and every other member, other than an *ex officio* member, shall—

(a) be appointed by the Minister on such terms and conditions as he thinks fit; and

(b) hold office for a period of 2 years and be eligible for reappointment.

(4) Every member shall be paid such fees or allowances as the Minister may determine.

(5) The Council may, where it deems it necessary, co-opt other members but any co-opted member shall have no right to vote.

4. Functions and powers of Council

The functions and powers of the Council shall be to—

(a) consider and grant or refuse applications for a trial licence;

[Para. (a) came into operation on 24 September 2011.]

(b) issue, amend, extend, review, suspend or cancel trial licences;

[Para. (b) came into operation on 24 September 2011.]

(c) examine and approve the qualifications of every investigator;

[Para. (c) came into operation on 24 September 2011.]

(d) exercise control over licensees and on sites by inspection, examination of any reports received and such other means as may be appropriate;

[Para. (d) came into operation on 24 September 2011.]

(e) consult regularly with, and consider reports and recommendations from, the Ethics Committee, the Pharmacovigilance Committee and the Trade and Therapeutics Committee;

[Para. (e) came into operation on 24 September 2011.]

(f) prepare or approve guidelines for the safe and ethical operation of clinical trials;

(g) provide for the health, welfare, safety and protection of subjects;

[Para. (g) came into operation on 24 September 2011.]

(h) keep the Register;

[Para. (h) came into operation on 24 September 2011.]

(i) keep a record of all published material relating to clinical trials conducted in accordance with this Act;

[Para. (i) came into operation on 24 September 2011.]

(j) examine and act on any adverse report or complaint received from a sponsor, an investigator, an officer, the Pharmacovigilance Committee or any other person;

[Para. (j) came into operation on 24 September 2011.]

(k) arrange, where appropriate, for the training or continued training of investigators;

[Para. (k) came into operation on 24 September 2011.]

(l) appoint officers whose role includes, but is not limited to, verification of compliance with good clinical practice and pharmacovigilance provisions of this Act through inspections;

[Para. (l) came into operation on 24 September 2011.]

(m) perform such other duties, not inconsistent with this Act, as may be entrusted to it in writing by the Minister.

5. Meetings of Council

(1) The Council shall meet—

(a) at least once every month; and

(b) whenever a request for a meeting is made by the Chairperson or by not less than 5 members.

(2) Where the Chairperson is absent from any meeting, the members present shall elect from amongst themselves a member to preside at the meeting.

(3) At a meeting of the Council, 6 members shall constitute a quorum, of whom one shall be a medical practitioner.

(4) A decision of the Council shall be by a simple majority of the members present and voting and, in the event of an equality of votes, the Chairperson shall have a casting vote.

(5) Subject to this Act, the Council may conduct its meetings and proceedings in such manner as it thinks fit.

6. Secretary and other officers of Council

(1) The supervising officer shall designate a public officer to be the Secretary of the Council.

(2) The Secretary shall be—

(a) a medical practitioner;

(b) a pharmacist; or

(c) a nursing officer holding a BSc degree in Nursing or an equivalent qualification.

(3) The Secretary shall—

(a) make necessary entries in the Register;

(b) carry out such duties as may be assigned to him by the Council;

(c) in the exercise of his functions, act in accordance with such directions as he may receive from the Council.

(4) The supervising officer shall designate such number of public officers as the Council may require to assist it in the performance of its functions and in the exercise of its powers.

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Part III – Ethics Committee

[Part III came into operation on 24 September 2011.]

7. Ethics Committee

(1) There shall be an Ethics Committee which shall consist of—

(a) a Chairperson, who shall be a law practitioner of not less than 5 years' standing;

(b) a specialist in public health;

(c) a specialist in internal medicine;

(d) a person having experience in the conduct of biomedical research involving human beings;

(e) a social scientist;

(f) a clinical psychologist;

(g) 2 persons to represent civil society.

(2) The persons referred to in subsection (1) shall—

(a) be appointed by the Minister on such terms and conditions as he thinks fit;

(b) hold office for a period of 2 years and be eligible for reappointment; and

(c) be paid such fees or allowances as the Minister may determine.

(3) Where the Chairperson is absent from any meeting, the members present shall elect from amongst themselves a member to preside at the meeting.

(4) At a meeting of the Ethics Committee, 5 members, one of whom shall be a person referred to in subsection (1) (b) or (c), shall constitute a quorum.

(5) A decision of the Ethics Committee shall be by a simple majority of the members present and voting and, in the event of an equality of votes, the Chairperson shall have a casting vote.

(6) Subject to this Act, the Ethics Committee may conduct its meetings and proceedings in such manner as it thinks fit.

(7) The supervising officer may designate such number of public officers as the Ethics Committee may require to assist it in the performance of its functions.

8. Functions of Ethics Committee

(1) The functions of the Ethics Committee shall be to—

(a) give its opinion on every application for a trial licence or an amendment to a trial licence, submitted to it by the Council;

(b) advise the Council on the health, welfare, safety and protection of subjects in clinical trials;

(c) ensure that ethical values and international scientific standards are complied with and that local community values and customs are respected;

(d) prepare and adopt statements of general principles on which to base its evaluations;

(e) keep records of all its proceedings in relation to a clinical trial for a period of at least 15 years following the completion of the clinical trial.

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(2) For the purpose of giving its opinion under subsection (1) (a), the Ethics Committee shall take such factors as it thinks fit into consideration, including—

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

(b) the suitability of any investigator;

(c) the anticipated benefits and risks of the clinical trial;

(d) the adequacy of the measures to be taken for the health, welfare, safety and protection of subjects;

(e) the adequacy of the insurance cover to be contracted for the protection of subjects.

(3) The Ethics Committee shall establish and follow its own standard operating procedures.

Part IV – Pharmacovigilance Committee

[Part IV came into operation on 24 September 2011.]

9. Pharmacovigilance Committee

(1) There shall be a Pharmacovigilance Committee which shall consist of—

(a) a Chairperson, who shall be a specialist in internal medicine and a public officer;

(b) a specialist in paediatrics;

(c) a specialist in dermatology;

(d) a clinical pharmacologist or a senior lecturer in pharmacology at the University of Mauritius;

(e) 2 hospital pharmacists, who shall be public officers;

(f) an occupational physician;

(g) a nursing officer holding a BSc degree in Nursing or an equivalent qualification;

(h) the Chief Pharmacy Dispenser.

(2) The Chairperson and every other member, other than an *ex officio* member, shall—

(a) be appointed by the Minister on such terms and conditions as he thinks fit; and

(b) hold office for a period of 2 years and be eligible for reappointment.

(3) Every member shall be paid such fees or allowances as the Minister may determine.

(4) The Pharmacovigilance Committee may, where it deems necessary, co-opt other members but any co-opted member shall have no right to vote.

(5) (a) Where the Chairperson is absent from any meeting, the members present shall elect from amongst themselves a member to preside at the meeting.

(b) At a meeting of the Pharmacovigilance Committee, 5 members shall constitute a quorum.

(c) A decision of the Pharmacovigilance Committee shall be by a simple majority of the members present and voting and, in the event of an equality of votes, the Chairperson shall have a casting vote.

(d) Subject to this Act, the Pharmacovigilance Committee may conduct its meetings and proceedings in such manner as it thinks fit.

(6) The supervising officer may designate such number of public officers as the Pharmacovigilance Committee may require to assist it in the performance of its functions.

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10. Functions of Pharmacovigilance Committee

(1) The functions of the Pharmacovigilance Committee shall be to—

(a) collect all available information on adverse events and adverse reactions, in Mauritius or elsewhere, particularly in relation to subjects involved in clinical trials;

(b) analyse and classify any such information and communicate it to the health personnel and to the public and, where appropriate, to the relevant division of the World Health Organisation;

(c) liaise with the Trade and Therapeutics Committee for the purpose of recommending measures, by means of legislation or otherwise, to minimise the risk of adverse events and adverse reactions;

(d) ensure that health personnel are given adequate training in the collection and analysis of adverse events and adverse reactions;

(e) depute any of its members, where it deems necessary, to conduct an inspection in accordance with section 26;

(f) advise the Council and the Ethics Committee on any matter specified in this section.

(2) The Pharmacovigilance Committee shall establish and follow its own standard operating procedures.

Part V – Trial licence

[Part V came into operation on 24 September 2011.]

11. Trial licence

(1) No person shall conduct or cause or permit to be conducted a clinical trial unless he is—

(a) the holder of a trial licence; or

(b) an investigator acting on behalf of a sponsor who is the holder of a trial licence,

in relation to that clinical trial.

(2) No person shall conduct or cause or permit to be conducted a clinical trial except in accordance with the terms and conditions of a trial licence.

12. Application for trial licence

(1) A sponsor who wishes to obtain a trial licence shall make a written application to the Council in such form and manner as may be prescribed.

(2) An application under subsection (1) shall be accompanied by the prescribed application fee and—

(a) a protocol;

(b) an investigator's brochure;

(c) a brief curriculum vitae of every investigator;

(d) a Certificate of Good Manufacturing Practice (GMP) and a Certificate of Pharmaceutical Product (COPP) in relation to every investigational medicinal product from its country of origin; and

(e) the separate and different forms to be used for the purposes of patient and subject information, informed consent, recruitment of subjects, adverse event reports and adverse reaction reports.

(3) The sponsor shall also provide—

(a) information as to the quantity of every investigational medicinal product to be used in the clinical trial;

(b) information relating to the measures to be taken for the health, welfare, safety and protection of subjects;

(c) information relating to financial aspects of the clinical trial, in particular—

(i) sources of funding for the clinical trial and information on the financial or other interests of the sponsor relevant to the clinical trial;

(ii) the arrangements for the reimbursement of expenses incurred by the subjects;

(iii) any provision for compensation in the event of injury or death resulting from the clinical trial, including details of any insurance cover to be contracted for the protection of subjects;

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

(v) summary details of any financial arrangements between—

(A) the sponsor and the investigator; and

(B) the sponsor and the owner or occupier of the site;

(d) information relating to the anticipated benefits and risks of the clinical trial;

(e) information relating to the location, structure and amenities of any site where the clinical trial is to be conducted; and

(f) such other information as the Council may require.

(4) Where the Council receives an application under subsection (1), it shall refer the application and such other documents as it thinks fit to the Ethics Committee for an opinion.

13. Grant of application

(1) The Council may, after consideration of the opinion of the Ethics Committee, grant an application made under section 12 where it is satisfied that—

(a) the measures to be taken for the health, welfare, safety and protection of subjects are adequate;

(b) the anticipated benefits of the clinical trial outweigh its risks;

(c) the insurance cover to be contracted for the protection of subjects is adequate;

(d) the investigator is a suitably qualified person;

(e) the site for the clinical trial is suitable;

(f) the sponsor and the investigator will at all times comply with this Act and any regulations made under it; and

(g) the clinical trial is to be conducted in compliance with the guidelines referred to in section 4 (f).

(2) The Council may, when considering an application made under section 12, require the sponsor to furnish such additional information as may be necessary, within such time as it may determine.

(3) On granting an application under subsection (1), the Council shall issue a trial licence to the sponsor on such terms and conditions as it thinks fit and on payment of the prescribed licence fee.

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14. Refusal of application

(1) The Council may, after consideration of the opinion of the Ethics Committee, refuse an application made under section 12—

(a) where it considers that—

(i) any requirement set out under section 13 (1) is not satisfied;

(ii) the health, welfare, safety or protection of a subject is likely to be compromised; or

(iii) the proposed trial is of limited or no scientific benefit; or

(b) for any other good cause.

(2) Where the Council refuses an application under subsection (1), it shall give written notice of its decision to the sponsor.

15. Amendment of trial licence

(1) Where a sponsor, after having been issued with a trial licence, wishes to amend the protocol or any other document submitted under section 12, he shall make a written application to the Council in such form and manner as may be prescribed, accompanied by the prescribed application fee.

(2) The Council shall refer any application made under subsection (1) to the Ethics Committee for an opinion.

(3) The Council may, after consideration of the opinion of the Ethics Committee, grant or refuse the application.

(4) On approving the application, the Council may, where it considers it appropriate, issue an amended trial licence to the sponsor on such terms and conditions as it thinks fit and on payment of the prescribed fee.

(5) No sponsor shall implement any amendment referred to in subsection (1) unless it is approved by the Council.

16. Suspension or cancellation of trial licence

(1) Subject to subsection (2), the Council may, after giving the sponsor and the investigator written notice of its intention and allowing them not less than 14 days to make representations to the Council, suspend or cancel a trial licence and order the suspension or the termination of a clinical trial where—

(a) the clinical trial has not started within 12 months of the date on which the trial licence was issued;

(b) the clinical trial has started and has been suspended for more than 6 months;

(c) the sponsor or the investigator has, in connection with the clinical trial, trial licence or application for the licence, given false or misleading information;

(d) the clinical trial is not being conducted in accordance with this Act or any condition imposed under section 13; or

(e) there has been such change in the scientific reasons or circumstances that the clinical trial is no longer justified.

(2) (a) The Council may, where it is satisfied that the health, welfare, safety or protection of a subject is being or is likely to be compromised, forthwith suspend a trial licence and order the suspension of a clinical trial.

(b) The Council shall, where it has made an order under paragraph (a)—

(i) forthwith give written notice of its decision to the sponsor and the investigator;

(ii) invite them to make representations on the matter within 7 days; and

(iii) not later than 14 days after the receipt of any representations or, if no representations have been received, within 14 days of the issue of the notice under subparagraph (i), determine whether or not the trial licence shall be cancelled and the clinical trial terminated.

(3) The Council shall cause to be published in the *Gazette* and on the website of the Ministry such particulars as it thinks fit of any trial licence which is suspended or cancelled.

(4) Where a clinical trial is discontinued under section 25 (2), or is suspended or terminated under this section, its sponsor shall incur the cost of—

(a) any treatment which a subject of the clinical trial may require;

(b) any insurance cover to be contracted for the subject.

Part VI – Conduct of clinical trials

[Part VI came into operation on 24 September 2011.]

17. Good clinical practice

(1) Clinical trials shall be conducted in accordance with the conditions and principles of good clinical practice.

(2) The rights, safety and well-being of a subject shall prevail over the interests of science and society.

(3) Every sponsor shall ensure that any person involved in conducting a clinical trial is qualified by education, training and experience to perform his tasks.

(4) Every sponsor and investigator shall comply with guidelines prepared or approved by the Council.

18. The sponsor

(1) Subject to the approval of the Council, a sponsor and an investigator may be the same person.

(2) Every sponsor shall comply with the terms and conditions of any trial licence issued to him.

(3) Every sponsor shall designate an investigator who shall be based in Mauritius and be responsible for the conduct of the trial within Mauritius.

(4) Every sponsor shall be responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures.

(5) A sponsor of a clinical trial shall notify the Council in writing of any serious breach of—

(a) the conditions and principles of good clinical practice in connection with that trial; or

(b) the trial licence issued by the Council.

(6) For the purpose of this section, "serious breach" means a breach which is likely to affect to a significant degree—

(a) the safety or physical or mental integrity of a subject; or

(b) the scientific value of a clinical trial.

19. The investigator

Every investigator shall—

(a) be qualified by education, training and experience to assume responsibility for the proper conduct of a clinical trial;

(b) conduct a clinical trial in compliance with—

(i) the terms and conditions of the trial licence;

(ii) the protocol;

(iii) the conditions and principles of good clinical practice; and

(iv) the provisions of this Act and any regulations made under it.

20. Protection of subjects

(1) No sponsor or investigator shall use a human being as a subject unless—

(a) where the subject is of the age of 18 or over, he gives his written consent thereto;

(b) where the subject is of the age of 18 or over but incapable of giving his consent—

(i) his spouse, parent or guardian gives written consent thereto;

(ii) his participation in the clinical trial is essential; and

(iii) the clinical trial relates directly to the condition from which he is suffering;

(c) where the subject is under the age of 18—

(i) his responsible party gives written consent thereto; and

(ii) in case he is capable of forming an opinion, the sponsor and investigator are satisfied of his willingness to participate in the clinical trial.

(2) For the purposes of subsection (1), an investigator shall, before a clinical trial is conducted, give a full and reasonable explanation of the nature and object of the clinical trial and the risks involved, if any—

(a) where the subject is of the age of 18 or over, to the subject;

(b) where the subject is of the age of 18 or over but incapable of giving his consent, to his spouse, parent or guardian;

(c) where the subject is under the age of 18—

(i) to his responsible party; and

(ii) to the subject himself according to his capacity of understanding.

(3) A subject may, at any time, withdraw from a clinical trial without incurring any liability.

(4) No medical practitioner shall induce—

(a) a patient whom he is treating to consent to be a subject; or

(b) the responsible party of a patient whom he is treating to consent to the patient being a subject.

(5) Subject to subsection (6), no person shall, by means of any threat, coercion or reward, compel or induce another person to be a subject.

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(6) Subsection (5) shall not apply to a sponsor who compensates a subject for his participation in a clinical trial.

(7) The Council shall publish guidelines on informed consent requirements which every sponsor and investigator shall comply with.

(8) In this section—

"responsible party" means the person who exercises parental authority over a subject under the Code Civil Mauricien.

21. Emergency measures

(1) A sponsor and an investigator may take appropriate emergency measures in order to protect a subject against any immediate hazard to his health or safety.

(2) Where emergency measures are taken under subsection (1), the sponsor shall forthwith, and in any event within a period of 3 days, give written notice to the Council of those measures and the circumstances giving rise to them.

22. Strict liability of sponsor

(1) A sponsor shall be strictly liable for any damage or injury suffered by a subject as a direct or indirect result of a clinical trial.

(2) Any provision of a contract between a sponsor and a subject purporting to limit the sponsor's liability under subsection (1) shall be null and void.

(3) Before commencing a clinical trial, a sponsor shall enter into an insurance contract which covers the liability under subsection (1).

(4) A sponsor shall be responsible for the costs of treatment of a subject for any damage or injury suffered by the subject as a result of a clinical trial.

(5) Where the treatment under subsection (4) is not available in Mauritius, the sponsor shall, subject to the approval of the Council, make such treatment available in another country.

23. Trial master file and archiving

(1) Every sponsor shall keep a trial master file for a clinical trial in respect of which he holds a trial licence.

(2) A sponsor shall make the trial master file readily available at all reasonable times for inspection by the Council or any person appointed by the sponsor to audit the arrangements for the clinical trial.

(3) The trial master file shall at all times comprise documents which—

(a) enable both the conduct of the clinical trial and the quality of the data produced to be evaluated;

(b) show whether the clinical trial has been conducted in compliance with—

(i) this Act and regulations made under it; and

(ii) the guidelines referred to in section 4 (f); and

(c) contain information specific to each phase of the clinical trial.

(4) A sponsor shall keep, for not less than 15 years after the completion of a clinical trial, the trial master file which shall be—

(a) readily available at all reasonable times to the Council; and

(b) complete and legible.

24. Progress and completion of clinical trial reports

Every sponsor shall furnish to the Council a written report on the progress of a clinical trial, containing such particulars as the Council deems necessary, not later than 6 months after—

(a) the date on which the trial licence is issued;

(b) the end of every subsequent period of 6 months; and

(c) the completion of the clinical trial.

25. Completion and discontinuance of clinical trial

(1) A sponsor shall, not later than 90 days after a clinical trial is completed, notify the Council of the completion.

(2) Where a clinical trial is discontinued, its sponsor shall forthwith notify the Council in writing of the discontinuance and the reasons therefor.

Part VII – Inspections

[Part VII came into operation on 24 September 2011.]

26. Verification of compliance

A member or an officer of the Council, or a member of the Pharmacovigilance Committee, may, at all reasonable times, enter and inspect a site so as to enquire about the conduct of a clinical trial and shall, at the conclusion of his inspection, submit a written report to the Council or the Pharmacovigilance Committee, as the case may be, and provide a copy of the report to the investigator and the sponsor.

Part VIII – Pharmacovigilance

[Part VIII came into operation on 24 September 2011.]

27. Record of adverse event or reaction

(1) A sponsor shall keep detailed records of any adverse event, serious adverse event, adverse reaction or serious adverse reaction, which—

(a) arises during a clinical trial;

(b) comes to his knowledge from reports of similar clinical trials conducted elsewhere; or

(c) is reported to him by the investigator.

(2) The sponsor shall submit the records referred to in subsection (1) to the Council and Pharmacovigilance Committee on each anniversary of the clinical trial or upon request by the Council or Pharmacovigilance Committee, as the case may be.

28. Notification of serious adverse event or reaction

(1) An investigator shall, within 24 hours of becoming aware of a serious adverse event or serious adverse reaction, inform the sponsor of the event or reaction.

(2) Where the sponsor receives information under subsection (1), it shall, within 24 hours, notify the Council and Pharmacovigilance Committee in writing of the serious adverse event or serious adverse reaction.

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(3) A sponsor shall provide such follow-up information relating to the serious adverse event or serious adverse reaction as the Council or Pharmacovigilance Committee may require.

Part IX – Register of clinical trials

[Part IX came into operation on 24 September 2011.]

29. Register of clinical trials

(1) There shall be a Register, in such form as the Council thinks fit, in which the Secretary shall, in accordance with such instructions as may be given to him by the Council, keep a record of—

(a) every trial licence issued under this Act;

(b) particulars relating to every clinical trial in respect of which a trial licence has been applied for, issued, amended or refused;

(c) such other particulars as the Council thinks fit.

(2) The Council shall cause to be published in the *Gazette* and on the website of the Ministry, not later than 15 days after the issue of a trial licence, the particulars of that licence.

(3) Any person may, at all reasonable times and on good cause shown, inspect the Register on payment of the prescribed fee.

Part X – Offences

[Part X came into operation on 24 September 2011.]

30. Offences

Any person who—

(a) initiates, manages or conducts, or assists another person in, a clinical trial in respect of which no trial licence is in force;

(b) for the purposes of this Act, gives information which is false or misleading;

(c) fails to comply with an order requiring the suspension or termination of a clinical trial;

(d) fails to comply with a term or condition of a trial licence; or

(e) contravenes this Act or any regulations made under it,

shall commit an offence and shall, on conviction, be liable to a fine not exceeding 500,000 rupees and to penal servitude for a term not exceeding 8 years.

Part XI – Miscellaneous provisions

31. Annual report

(1) The Council shall submit to the Minister an annual report on its activities.

(2) The Council shall, in respect of its activities, furnish to the Minister such information in such manner and at such time as the Minister thinks fit.

[S. 31 came into operation on 24 September 2011.]

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32. Powers of Minister

The Minister may give such general directions to the Council, not inconsistent with this Act, as he considers necessary in the public interest and the Council shall comply with those directions.

33. Disclosure of interest

(1) Where any member of the Council, Pharmacovigilance Committee or Ethics Committee, or any person related to him by blood or marriage, has a financial or other material interest in relation to any matter before the Council, Pharmacovigilance Committee or Ethics Committee, as the case may be, that member—

(a) shall disclose the nature of the interest at or before the meeting convened to discuss the matter; and

(b) shall not take part in any deliberations of the Council, Pharmacovigilance Committee or Ethics Committee, as the case may be, relating to the matter.

(2) Where any member of the Council, Pharmacovigilance Committee or Ethics Committee has or acquires any financial interest in any clinical trial in Mauritius or elsewhere, he shall inform the Council, Pharmacovigilance Committee or Ethics Committee, as the case may be, in writing, of such interest.

34. Protection from liability

No liability, civil or criminal, shall be incurred by the Minister, the supervising officer, the Council or any of its members or officers, the Pharmacovigilance Committee or any of its members, or the Ethics Committee or any of its members, in respect of any act done or omitted in good faith in the execution of his or its functions or exercise of his or its powers under this Act.

35. Regulations

(1) The Minister may make such regulations as he thinks fit for the purposes of this Act.

(2) Regulations made under subsection (1) may provide for the payment of fees and the levying of charges.

36. ***