Medicines (Clinical Trials) Regulations

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MEDICINES ACT
(CHAPTER 176, SECTIONS 18 AND 74)

MEDICINES (CLINICAL TRIALS) REGULATIONS

Rg 3

G.N. No. S 54/1978

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Citation

1. These Regulations may be cited as the Medicines (Clinical Trials) Regulations.

Definitions

2. In these Regulations, unless the context otherwise requires —

"certificate" means a certificate issued under regulation 5;

"holder of a certificate" means a doctor or dentist to whom a certificate has been issued under regulation 5;

"legal representative", in relation to a person who is to be used as a subject in a clinical trial, means an individual or judicial or other body authorised under the

law to consent on behalf of that person to his participation in the clinical trial;

"principal investigator" means a doctor or dentist, as the case may be, specified in a certificate as the person responsible for the conduct and supervision of a clinical trial;

"sponsor" means an individual, company, institution or organisation which takes responsibility for the initiation, management or financing of a clinical trial;

"subject" means a person to whom the test material is to be administered in a clinical trial;

"test material" means any medicinal product administered to a subject in a clinical trial;

"window period" means the period, determined based on scientific evidence, within which the test material must be administered to a subject on a clinical trial for it to have the intended potential direct benefit to the subject.

Clinical trial

3. No clinical trial shall be conducted except in accordance with these Regulations.

Exclusions

4. Sections 5 and 6 of the Act shall not apply to any clinical trial conducted under these Regulations.

Application for certificate for clinical trial

5.—(1) No person shall conduct or cause or permit to be conducted a clinical trial except in accordance with a certificate issued by the licensing authority.

(2) An application for a certificate shall be in such form as the licensing authority may require.

(3) A certificate may be issued subject to such terms and conditions as the licensing authority may think fit to impose, including any condition requiring the sponsor of a clinical trial to obtain and maintain insurance to provide compensation in the event of injury or loss arising from the conduct of the clinical trial on such terms as the licensing authority may approve.

(4) The licensing authority may, without assigning any reason, refuse to issue a certificate or may suspend or revoke any certificate already issued.

(5) Any person aggrieved by such refusal, suspension or revocation may appeal to the Minister whose decision shall be final.

Period of validity of clinical trial certificate

6. Any certificate issued shall be valid for a period of 2 years with effect from the date on which it was issued.

Principal investigator to supervise clinical trial

7. Every clinical trial shall be conducted under the charge and supervision of a principal investigator.

Clinical trial confined to place specified

8. No clinical trial shall be conducted except at such place as may be specified in the certificate.

Discontinuance of clinical trial

9. Where a clinical trial is discontinued, the holder of a certificate shall forthwith inform the licensing authority of the discontinuance and the reasons therefor.

Change of principal investigator

10. Where there is a change of principal investigator during a clinical trial, the holder of a certificate shall forthwith notify the licensing authority of the change and shall furnish to the licensing authority particulars of the new principal investigator.

Consent required to use person as subject in clinical trial

11.—(1) Subject to paragraphs (2) and (3), a holder of a certificate shall not use a person as a subject in a clinical trial unless the following conditions are satisfied:

(*a*) in the case of a person of or above the age of 21 years, or a person below the age of 21 years who is married, with the consent of that person;

(*b*) in the case of a person below the age of 21 years who is not married, with the consent of that person and —

(i) that person's parent or guardian (if there is no parent); and

(ii) if different from sub-paragraph (*i*), that person's legal representative.

(2) The consent of a person below the age of 21 years who is not married shall not be required under paragraph (1) if —

(*a*) that person lacks sufficient understanding to give such consent; and

(*b*) there is a reasonable prospect that participation in the clinical trial will

directly benefit that person.

(3) The consent of a person who is unconscious or incapable of exercising rational judgment shall not be required under paragraph (1) if —

(*a*) the principal investigator and a doctor who is not otherwise participating in the clinical trial certify in writing that —

(i) that person is unconscious or incapable of exercising rational judgment; and

(ii) it is not likely that that person will regain consciousness and be capable of exercising rational judgment within the window period;

(*b*) consent thereto has been obtained from —

(i) that person's spouse, parent, guardian (if there is no parent) or any other person having charge of him; and

(ii) if different from sub-paragraph (*i*), that person's legal representative; and

(*c*) there is a reasonable prospect that participation in the clinical trial will directly benefit that person.

(4) Subject to paragraph (5), consents obtained for the purposes of these Regulations shall be —

(*a*) in written form approved by the licensing authority and signed and dated by the person giving his consent; or

(*b*) if the person giving his consent is unable to sign the written form, in any other form and manner as the licensing authority may approve.

(5) If the person giving his consent for the purposes of these Regulations is unable to read, the consent form referred to in paragraph (4) shall be read and explained to him in the presence of an impartial witness who shall sign and date the consent form to attest that the form was accurately explained to that person and that his consent thereto was freely given.

(6) Any person making a decision for the purposes of paragraph (1)(*b*)(i) or (ii) or paragraph (3)(*b*)(i) or (ii) or regulation 12(8) shall act in the best interests of the person to be used as a subject in the clinical trial and have regard, so far as ascertainable, to the subject's past and present wishes and feelings and any factors which the subject would consider if he were able to do so.