Medicines (Clinical Trials) (Amendment) Regulations 1998

Table of Contents

No. S 250

MEDICINES ACT
(CHAPTER 176)

MEDICINES (CLINICAL TRIALS) (AMENDMENT)

REGULATIONS 1998

In exercise of the powers conferred by sections 18 and 74 of the Medicines Act, the Minister for Health hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Clinical Trials) (Amendment) Regulations 1998 and shall come into operation on 1st August 1998.

Amendment of regulation 2

2. Regulation 2 of the Medicines (Clinical Trials) Regulations (Rg 3) (referred to in these Regulations as the principal Regulations) is amended —

(*a*) by deleting the definition of "director";

(*b*) by inserting, immediately after the definition of "holder of a certificate", the following definitions:

" "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;"; and

(*c*) by deleting the full-stop at the end of the definition of "test material" and substituting a semi-colon and, by inserting immediately thereafter the following definition:

" "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.".

Amendment of regulation 5

3. Regulation 5(3) of the principal Regulations is amended by inserting, immediately after the word "impose", the words ", 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".

Amendment of regulation 7

4. Regulation 7 of the principal Regulations is amended —

(*a*) by deleting the word "director" and substituting the words "principal investigator"; and

(*b*) by deleting the word "Director" in the marginal note and substituting the words "Principal investigator".

Amendment of regulation 10

5. The principal Regulations are amended by deleting the word "director" wherever it appears in regulation 10 and in the marignal note and substituting in each case the words "principal investigator".

Deletion and substitution of regulation 11, and new regulation 11A

6. Regulation 11 of the principal Regulations is deleted and the following regulations substituted therefor:

"**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, except with the consent of that person;

(*b*) in the case of a person below the age of 21 years who is not married, except 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; or

(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 11A(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.

(7) Paragraphs (2) and (3) and regulation 11A shall not apply if the clinical trial can practicably be carried out using only subjects who have given their own consent under paragraph (1).

(8) Paragraphs (2) and (3) and regulation 11A shall operate subject to any advance medical directive made under the Advance Medical Directive Act (Cap. 4A).

(9) For the purposes of paragraphs (2)(*b*) and (3)(*c*), a clinical trial shall not be taken to hold out any reasonable prospect of direct benefit to the subject unless —

(*a*) appropriate animal and other pre-clinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the proposed use of the test material to provide a direct benefit to the subject; and

(*b*) risks associated with the clinical trial are reasonable in relation to what is known about the medical condition of the subject, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed use of the test material.

Clinical trials in emergency situations

11A.—(1) No person shall conduct a clinical trial under this regulation except with the prior approval of the licensing authority given under paragraph (2).

(2) The licensing authority shall not give its approval for any clinical trial to be conducted under this regulation unless the principal investigator and 2 specialists who are not otherwise participating in the clinical trial certify in writing that —

(*a*) the clinical trial needs to be conducted on subjects who are in a life-threatening situation to determine the safety and effectiveness of the test material;

(*b*) available treatments are unproven or unsatisfactory;

(*c*) there is a reasonable prospect that participation in the clinical trial will directly benefit the subjects because —

(i) the subjects are facing a life-threatening situation that