Medicines (Clinical Trials) Regulations 2016

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No. S 335

MEDICINES ACT
(CHAPTER 176)

MEDICINES (CLINICAL TRIALS)
REGULATIONS 2016

In exercise of the powers conferred by section 18 of the Medicines Act, the Minister for Health makes the following Regulations:

PART 1

GENERAL

Citation and commencement

1. These Regulations are the Medicines (Clinical Trials) Regulations 2016 and come

into operation on 1 November 2016.

Definitions

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

"adult" means a person who —

(*a*) is at least 21 years of age; or

(*b*) is below 21 years of age, and is or was married;

"adverse drug reaction" means any untoward and unintended response in a subject to an investigational medicinal product which is related to any dose administered to that subject;

"adverse event" means any untoward medical occurrence in a subject to whom an investigational medicinal product has been administered, including any occurrence which is not necessarily caused by or related to that product;

"amendment" means an amendment to —

(*a*) any term of an application for a clinical trial certificate to conduct a clinical trial; or

(*b*) any particulars or documents (including a protocol) accompanying such application;

"appropriate non-proprietary name", in relation to an active ingredient of a medicinal product, means —

(*a*) the name or synonym of the active ingredient described in the relevant monograph appearing in the latest edition of any of the following publications:

(i) the British Pharmacopoeia;

(ii) the European Pharmacopoeia;

(iii) the United States Pharmacopoeia and the National Formulary;

(*b*) where the active ingredient is not described in a monograph in any such publication, its international non-proprietary name; or

(*c*) where paragraph (*a*) or (*b*) is not applicable, the accepted scientific name or other name descriptive of the true nature of the active ingredient;

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"auxiliary medicinal product" means a medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational medicinal product;

"clinical trial certificate" means a certificate for a clinical trial referred to in regulation 7;

"clinical trial in an emergency situation" means a clinical trial to determine the safety or efficacy of the investigational medicinal product being tested in the trial on subjects where —

(*a*) the subjects are facing a life-threatening situation that necessitates intervention;

(*b*) the subjects are unable to consent to being subjects in the trial as a result of their medical condition; and

(*c*) it is not feasible to request consents from the legal representatives of the subjects within the window period;

"institutional review board" means an independent body which —

(*a*) is constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and wellbeing of subjects by, among other things, reviewing, approving and providing continuing review of the protocol, amendments, and the methods and materials to be used in obtaining and documenting informed consent of the subjects; and

(*b*) when Part 4 of the Human Biomedical Research Act 2015 (Act 29 of 2015) comes into operation, is appointed under that Act;

"investigational medicinal product" means —

(*a*) a medicinal product; or

(*b*) a placebo,

that is to be tested or used as a reference in a clinical trial;

"investigator" means an investigator of a clinical trial;

"investigator's brochure" means a document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product relevant to the study of the product in subjects;