Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016

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No. S 336

MEDICINES ACT
(CHAPTER 176)

MEDICINES (MEDICINAL PRODUCTS AS CLINICAL RESEARCH MATERIALS) REGULATIONS 2016

In exercise of the powers conferred by sections 18, 34, 44 and 74 of the Medicines Act, the Minister for Health makes the following Regulations:

PART 1

GENERAL

Citation and commencement

1. These Regulations are the Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016 and come into operation on 1 November 2016.

Definitions

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

"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 CRM" means any clinical research material that is used for the needs of any clinical research as described in the protocol, but not as the material to be tested or used as a reference in the research;

"clinical research" means any research involving human beings (whether or not a regulated clinical trial);

"clinical research material" means any medicinal product or placebo, that is not specified in the First Schedule, that is manufactured, assembled, imported or supplied for the purpose of being used in any clinical research by way of administration to a subject in accordance with the protocol for the research;

"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 CRM" means any clinical research material that is to be tested or used as a reference in any clinical research;

"proprietary name" means a word or words used in connection with the supply of a medicinal product for the purpose of indicating that it is the product of a particular person who manufactures, selects the name of, certifies or deals with the medicinal product, or offers it for supply;

"protocol" means a document that describes the objectives, design, methodology, statistical considerations and organisation of any clinical research;

"regulated clinical trial" means a clinical trial that is —

(*a*) issued with a certificate under regulation 8 of the Medicines (Clinical Trials) Regulations 2016 (G.N. No. S 335/2016); or

(*b*) authorised by the Authority, or notified to the Authority and the notification accepted by the Authority, under regulation 8 or 9 of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016);

"sponsor" means a person who takes responsibility for the initiation, management or financing of any clinical research;

"subject" means a human being, whether or not a patient, who participates in any clinical research —

(*a*) as a recipient of the clinical research material to which the research relates, or of some other treatment or procedure in that research; or

(*b*) as a control, without receiving any such clinical research material, or any such treatment or procedure.

PART 2

EXEMPTIONS FOR CLINICAL RESEARCH MATERIALS

Exemptions from Act

3.—(1) Subject to paragraphs (2), (3) and (4), sections 5 and 6 of the Act do not apply to any medicinal product that is not specified in the First Schedule, and that —

(*a*) is manufactured, assembled, imported or supplied as clinical research material; or

(*b*) is exported under regulation 7(5).

(2) Paragraph (1) applies to the import by a person (called in these Regulations an importer) of the clinical research material only if the importer gives the Authority notice of the import before importing the product.

(3) Where a person who manufactures (called a manufacturer in these Regulations) the clinical research material supplies the material, paragraph (1) applies to the supply only if the manufacturer gives the Authority notice of the supply before supplying the product.

(4) A notice under this regulation must be given in the form and manner, and within the time, specified on the Authority's website.

(5) A notice of the import mentioned in paragraph (2) is not required if —

(*a*) before 1 November 2016 —

(i) the clinical research material was a medicinal product under the Act; and

(ii) the import of the product was permitted by the licensing authority under the Act in connection with any clinical trial regulated under the Medicines (Clinical Trials) Regulations (Rg 3) in force immediately before 1 November 2016; and

(*b*) the clinical research material is imported in accordance with the permission.

PART 3

MANUFACTURE, ASSEMBLY AND IMPORT OF CLINICAL RESEARCH MATERIALS

Manufacture, assembly and import of clinical research materials

4.—(1) A manufacturer of any clinical research material, or an importer of such material, must ensure that the material is of the correct identity and conforms with the