Health Products (Clinical Research Materials) Regulations 2016

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No. S 332

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (CLINICAL RESEARCH MATERIALS) REGULATIONS 2016

In exercise of the powers conferred by sections 71 and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

PART 1

GENERAL

Citation and commencement

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

[S 108/2021 wef 01/03/2021]

Definitions

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

"active substance", in relation to a CTGT product, means a substance that —

(*a*) is usable in the manufacture of a CTGT product as an active constituent; and

(*b*) achieves its intended action by pharmacological, immunological, physiological, metabolic or physical means;

[S 108/2021 wef 01/03/2021]

"administer", in relation to any clinical research material, means to give or apply to a human being, whether —

(*a*) orally;

(*b*) by injection or by introduction into the body in any other way; or

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

"appropriate non-proprietary name", in relation to an active ingredient of a therapeutic product or an active substance in a CTGT product, means —

(*a*) the name or a synonym of the active ingredient or the active substance (as the case may be) described in the relevant monograph appearing in the latest edition of any specified publication; or

(*b*) in any other case, its international non-proprietary name or the accepted scientific name or other name descriptive of the true nature of the active ingredient or the active substance, as the case may be;

[S 108/2021 wef 01/03/2021]

"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 of the following that is manufactured, 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:

(*a*) a therapeutic product;

(*b*) a CTGT product that is treated as a Class 1 CTGT product under the

CTGTP Regulations and for which no notice has been submitted under regulation 4, 7 or 10 (as the case may be) of the CTGTP Regulations;

(*c*) a CTGT product that is treated as a Class 2 CTGT product under the CTGTP Regulations;

(*d*) a placebo;

[S 108/2021 wef 01/03/2021]

[*Deleted by S 730/2021 wef 01/10/2021*]

"CTGT product" means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;

[S 108/2021 wef 01/03/2021]

"CTGTP Regulations" means the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021);

[S 108/2021 wef 01/03/2021]

"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;

"international non-proprietary name", for an active ingredient of a therapeutic product or an active substance in a CTGT product, means a name which has been selected by the World Health Organization as a recommended international non-proprietary name for the active ingredient or the active substance, as the case may be;

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

"in-store pharmaceutical officer" means —

(*a*) a qualified pharmacist engaged or employed to provide pharmacy services at or from a licensed retail pharmacy; or