Health Products (Clinical Trials) Regulations 2016

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No. S 331

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (CLINICAL TRIALS) REGULATIONS 2016

In exercise of the powers conferred by section 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 Trials) Regulations 2016 and come into operation on 1 November 2016.

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 the CTGT product as an active constituent; and

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

[S 107/2021 wef 01/03/2021]

"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 product which is related to any dose administered to that subject;

[S 107/2021 wef 01/03/2021]

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

[S 107/2021 wef 01/03/2021]

"amendment" means an amendment to —

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

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

"applicable CTGT product" means a CTGT product that is treated as a Class 2 CTGT product under the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021);

[S 107/2021 wef 01/03/2021]

"appropriate non-proprietary name", in relation to an active ingredient of a therapeutic product or an active substance in an applicable 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 107/2021 wef 01/03/2021]

"authorisation" means an authorisation for a clinical trial referred to in regulation 7(2)(*a*)(i);

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

[*Deleted by S 107/2021 wef 01/03/2021*]

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

[S 107/2021 wef 01/03/2021]

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

[S 107/2021 wef 01/03/2021]

"clinical trial in an emergency situation" means a clinical trial to determine the safety or efficacy of the investigational 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;

[S 107/2021 wef 01/03/2021]