First published in the Government *Gazette*, Electronic Edition, on 15th July 2016 at 5:00 pm.

No. S 332

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS AS CLINICAL RESEARCH MATERIALS) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

PART 1

GENERAL

Regulation

1. Citation and commencement
2. Definitions

PART 2

EXCEPTIONS FOR MANUFACTURE, IMPORT AND SUPPLY OF CLINICAL RESEARCH MATERIALS

3. Exceptions from Act
4. Notification of import of clinical research material
5. Approval for import of consignments of clinical research materials containing psychotropic substances
6. Approval for export of consignments of certain clinical research materials
7. Notification of supply of clinical research material by manufacturer

PART 3

MANUFACTURE AND IMPORT OF CLINICAL RESEARCH MATERIALS

8. Manufacture and import of clinical research materials

PART 4

SUPPLIES OF CLINICAL RESEARCH MATERIALS

Regulation

9. Supply only as clinical research material
10. Supply to subject of codeine cough preparations
11. Supply to subject of prescription-only or pharmacy-only medicine
12. Supply to subject by administration of prescription-only medicine
13. Supply of clinical research material properly labelled

PART 5

DUTIES RELATING TO
CLINICAL RESEARCH MATERIALS

Division 1 — Use and disposal, etc., of clinical research materials

14. Dealing with clinical research materials

Division 2 — Keeping of records

15. Records of manufacture
16. Records of receipt and supply
17. Records of dealings with clinical research materials
18. Production of and time for keeping of records

Division 3 — Reports to Authority

19. Notifications of unexpected serious adverse drug reactions
20. Recall of clinical research material

PART 6

MISCELLANEOUS

21. Certificate of manufacturing standard of clinical research materials
22. Certificate of distribution standard of clinical research materials
23. Enforcement requirements
24. Offences

The Schedules

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 (Therapeutic Products as Clinical Research Materials) Regulations 2016 and come into operation on 1 November 2016.

Definitions

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

"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, 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 therapeutic product or placebo 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;

"codeine cough preparation" means a therapeutic product that —

(*a*) is in liquid form;

(*b*) contains codeine; and

(*c*) is intended by the person who manufactured the product for the treatment of cough;

"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;

"in-store pharmaceutical officer" means —

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

(*b*) a person acting under the supervision of the qualified pharmacist mentioned in paragraph (*a*) when providing pharmacy services at or from the licensed retail pharmacy;

"licensed retail pharmacy" means the premises specified in a pharmacy licence;

"pharmacy licence" means a licence issued under the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

"pharmacy-only medicine" means a therapeutic product registered under the classification of "pharmacy-only medicine" in the Register of Health Products;

"prescription-only medicine" means a therapeutic product registered under the classification of "prescription-only medicine" in the Register of Health Products;

"proprietary name" means a word or words used in connection with the supply of a therapeutic 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 therapeutic product, or offers it for supply;

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