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

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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;

"psychotropic substance" means a substance specified in the First Schedule to the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016);

"qualified pharmacist" means a person who —

(*a*) is registered as a pharmacist under the Pharmacists Registration Act (Cap. 230);

(*b*) holds a valid practising certificate granted under section 23 of that Act; and

(*c*) is in active practice as defined in regulation 2 of the Pharmacists Registration (Practising Certificates) Regulations 2008 (G.N. No. S 438/2008);

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174); or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

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

(*a*) 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); or

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

"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;

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act.

(2) For the purposes of these Regulations, a prescription is valid only if the prescription —

(*a*) is written and signed by a qualified practitioner; and

(*b*) contains all of the following particulars:

(i) the date of the prescription;

(ii) the name and address of the qualified practitioner giving the prescription;

(iii) the name, identity card or other identification document number, and contact details, of the subject to whom the prescription relates;

(iv) the name and total amount of the prescribed clinical research material to be supplied to, and the dose to be taken by, the subject;

(v) where the qualified practitioner giving the prescription intends for the prescription to be repeated, an indication of the number of times, and the time period between which, the prescribed clinical research material may be supplied;

(vi) where the prescription is given by a dentist, a declaration by the dentist that the prescription is "for dental treatment only".

PART 2

EXCEPTIONS FOR MANUFACTURE, IMPORT AND SUPPLY OF CLINICAL RESEARCH MATERIALS

Exceptions from Act

3.—(1) Section 12(1) of the Act does not apply to the manufacture of any clinical research material.

(2) Subject to regulations 4 and 5, section 13(1) of the Act does not apply to the import of any clinical research material.

(3) Subject to regulations 6 and 7, section 14(1) of the Act does not apply to the supply by wholesale of any clinical research material.

(4) Subject to regulation 7, section 15(1) of the Act does not apply to the supply of any clinical research material.

Notification of import of clinical research material

4.—(1) Regulation 3(2) applies to the import of any clinical research material only if the person who imports the material (called in these Regulations an importer) gives the Authority notice of the import before importing the material.

(2) The notice must be given in the form and manner, and within the time, specified on the Authority's website.

(3) A notice of the import mentioned in paragraph (1) is not required if —

(*a*) before 1 November 2016 —

(i) the clinical research material was a medicinal product under the Medicines Act (Cap. 176); and

(ii) the import of the product was permitted by the licensing authority under that Act in connection with any clinical trial regulated under the Medicines (Clinical Trials) Regulations (Cap. 176, Rg 3); and

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

Approval for import of consignments of clinical research materials containing psychotropic substances

5.—(1) Despite regulation 3(2), an importer must not import any clinical research material that contains any psychotropic substance, except under and in accordance with a prior approval of the Authority for each consignment of the material to be imported.

(2) An application for an approval under paragraph (1) must —

(*a*) be made in the form and manner specified on the Authority's website;

(*b*) be accompanied by such particulars, information, documents and samples as the Authority may require; and

(*c*) be accompanied by the relevant fee specified in the First Schedule.

(3) Upon receiving an application under this regulation, the Authority may approve the application or refuse to approve the application.

(4) The Authority may subject its approval to such conditions as the Authority thinks necessary and may, from time to time, by notice in writing to the person granted the approval —

(*a*) modify or remove any condition of the approval; or

(*b*) impose any new condition on the approval.

(5) The conditions referred to in paragraph (4) may include a condition limiting the quantity which may be imported in the consignment under the approval, and different limits may be imposed under different approvals.

(6) The Authority may, at any time, suspend or revoke any approval.

(7) To avoid doubt, this regulation applies in addition to regulation 4.

(8) In this regulation, "prior approval of the Authority" includes a permission given before 1 November 2016 by the licensing authority under the Medicines Act (Cap. 176), for the importer to import a

consignment of the clinical research material on or after that date in accordance with the conditions of the permission (if any).

Approval for export of consignments of certain clinical research materials

6.—(1) This regulation applies to any clinical research material which —

(*a*) contains any psychotropic substance; or

(*b*) is a codeine cough preparation.

(2) Despite regulation 3(3), the person must not export the clinical research material except under and in accordance with a prior approval of the Authority for each consignment of the material to be exported.

(3) An application for an approval under paragraph (2) must —

(*a*) be made in the form and manner specified on the Authority's website;

(*b*) be accompanied by such particulars, information, documents and samples as the Authority may require; and

(*c*) be accompanied by the relevant fee specified in the First Schedule, if the material contains any psychotropic substance.

(4) Upon receiving an application under this regulation, the Authority may approve the application or refuse to approve the application.

(5) The Authority may subject its approval to such conditions as the Authority thinks necessary and may, from time to time, by notice in writing to the person granted the approval —

(*a*) modify or remove any condition of the approval; or

(*b*) impose any new condition on the approval.

(6) The Authority may, at any time, suspend or revoke any approval.

(7) In this regulation, "prior approval of the Authority" includes a permission given before 1 November 2016 by the licensing authority

under the Medicines Act (Cap. 176), for the person to export a consignment of the clinical research material on or after that date in accordance with the conditions of the permission (if any).

Notification of supply of clinical research material by manufacturer

7.—(1) Regulation 3(3) and (4) applies to a supply of clinical research material by a person who manufactures the material (called in these Regulations a manufacturer) only if the manufacturer gives the Authority notice of the supply before the manufacturer supplies the material.

(2) The notice must be given in the form and manner, and within the time specified, on the Authority's website.

(3) This regulation does not apply if the manufacture of the clinical research material being supplied comprises solely of the packaging or labelling of the material.

PART 3

MANUFACTURE AND IMPORT OF CLINICAL RESEARCH MATERIALS

Manufacture and import of clinical research materials

8.—(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 applicable standards of strength, quality and purity for the material.

(2) Despite paragraph (1), where the manufacturer of the clinical research material only packages or labels the material, the manufacturer need only ensure that the material is of the correct identity.

PART 4

SUPPLIES OF CLINICAL RESEARCH MATERIALS

Supply only as clinical research material

9.—(1) A person who manufactures, imports or is supplied with any clinical research material under regulation 3(1), (2), (3) or (4) must only supply the material for the purpose of being used in any clinical research in accordance with the protocol for the research.

(2) Despite paragraph (1), the person may supply the clinical research material for a purpose other than that specified in paragraph (1) if the Authority has allowed such supply.

(3) To avoid doubt, as from the time that the Authority has allowed the supply for a purpose other than that specified in paragraph (1) —

(*a*) the clinical research material in question ceases to be clinical research material; and

(*b*) nothing in these Regulations prevents the clinical research material which ceases to be such, from being subject to any law relating to therapeutic products.

Supply to subject of codeine cough preparations

10.—(1) This regulation applies to a supply of any clinical research material that is a codeine cough preparation to a subject in any clinical research that is not a regulated clinical trial.

(2) A person must not make the supply unless —

(*a*) the person is a qualified practitioner or a qualified pharmacist; and

(*b*) the person complies with all of the following requirements:

(i) the person does not supply more than a total of 240 ml of any one or more codeine cough preparations to any one subject on any one occasion;

(ii) the person does not supply any codeine cough preparation to the same subject more than once within a period of 4 days (including Sundays and public holidays);

(iii) if the person is a qualified pharmacist, on each occasion of the supply of the codeine cough preparation by the person to the subject, the person provides professional counselling on the use of the codeine cough preparation.

Supply to subject of prescription-only or pharmacy-only medicine

11.—(1) This regulation applies to a supply of any clinical research material that is prescription-only medicine or pharmacy-only medicine to a subject in any clinical research that is not a regulated clinical trial.

(2) A person must not make the supply unless —

(*a*) the person is specified in the first column of Part 1 of the Second Schedule; and

(*b*) the person makes the supply in the circumstances specified against the person in the second column of Part 1 of the Second Schedule.

Supply to subject by administration of prescription-only medicine

12. A person must not administer any clinical research material that is prescription-only medicine to a subject in any clinical research unless —

(*a*) the person is a qualified practitioner; or

(*b*) the person administers the material in accordance with the instructions of a qualified practitioner.

Supply of clinical research material properly labelled

13.—(1) For the purpose of section 18 of the Act, a person must not supply any clinical research material for the purpose of being used in any regulated clinical trial, unless it is labelled in accordance with the Second Schedule to the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016); except that paragraph 1(1)(*d*), (2)(*a*) to (*d*) and (*g*), (3)(*a*) to (*d*), (*g*) and (*j*)

and (4)(*a*), (*b*), (*e*) and (*h*) of that Schedule does not apply if the supply is by wholesale.

(2) For the purpose of section 18 of the Act, a person must not supply any other clinical research material unless it is labelled in accordance with the requirements set out in the Third Schedule.

PART 5

DUTIES RELATING TO CLINICAL RESEARCH MATERIALS

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

Dealing with clinical research materials

14.—(1) This regulation applies to any clinical research material manufactured in, imported into, or supplied in, Singapore under regulation 3.

(2) Without prejudice to regulation 9, a person must not use the clinical research material in any clinical research, and the sponsor must ensure that no person involved in the research uses the material —

(*a*) except in accordance with the protocol for the research; and

(*b*) where the research requires the approval of an institutional review board, only after the approval has been obtained.

(3) Despite paragraph (2) —

(*a*) the clinical research material need not be used as referred to in paragraph (2) if the Authority has allowed some other use of the material; and

(*b*) the sponsor must ensure that the material is put to the other use.

(4) To avoid doubt, as from the time that the Authority has allowed the other use under paragraph (3) —

(*a*) the clinical research material in question ceases to be clinical research material; and

(*b*) nothing in these Regulations prevents the clinical research material which ceases to be such, from being subject to any law relating to therapeutic products.

(5) Unless the Authority otherwise allows, the sponsor must ensure that, within 6 months of the conclusion or termination of the clinical research, any unused clinical research material obtained for the research is disposed of or (subject to regulation 6 in relation to any material that contains any psychotropic substance) exported.

(6) In paragraph (5), "unused clinical research material" means any clinical research material referred to in paragraph (1) which is not used in the clinical research for which the material was obtained (including where the material cannot or can no longer be used in the research).

Division 2 — Keeping of records

Records of manufacture

15. A manufacturer of any clinical research material must keep records of the manufacture, assembly and testing of the material.

Records of receipt and supply

16.—(1) A person who supplies any clinical research material (including a manufacturer or an importer of the material who supplies the material) must keep records relating to every receipt (where applicable) and every supply by the person of the material, in order to permit proper evaluation to be made of the accountability and traceability of the material.

(2) The records referred to in paragraph (1) include all of the following:

(*a*) the proprietary name or description of the clinical research material;

(*b*) the identification number of the clinical research material (including the control number, lot number, batch number or serial number);

(*c*) where applicable, details of each receipt of the clinical research material by the person (whether as a result of an import by, or a supply to, the person), namely —

(i) the date on which the material was received;

(ii) the quantity of the material received; and

(iii) the name and address of the person from whom the material was received;

(*d*) details of each supply of the clinical research material by the person, namely —

(i) the date on which the material was supplied;

(ii) the quantity of the material supplied; and

(iii) the name and address of the person to whom the material was supplied.

(3) In addition to any records required to be kept under this regulation, where the clinical research material is pharmacy-only medicine that is supplied to a subject, the person making the supply must also keep records of all of the following:

(*a*) the name, identity card or other identification document number, and contact details, of the subject;

(*b*) the strength of the material supplied;

(*c*) the dosage, and the frequency and purpose of the treatment for which the supply is made.

(4) In addition to any records required to be kept under this regulation, where the clinical research material is supplied to a subject against a valid prescription given by a qualified practitioner, the person making the supply must also keep records of all of the following:

(*a*) the name, identity card or other identification document number, and contact details, of the subject;

(*b*) if the material is supplied by a qualified pharmacist or a person acting under the supervision of a qualified pharmacist, the name and the address of the qualified practitioner who signed the prescription.

(5) The records referred to in paragraphs (3) and (4) must be made on the day of the supply to which the records relate or, if that is not reasonably practicable, the next day.

Records of dealings with clinical research materials

17.—(1) A sponsor must keep records relating to all clinical research materials that are put to some other use, disposed of or exported, as the case may be, under regulation 14, in order to permit proper evaluation to be made of the accountability and traceability of the material.

(2) The records referred to in paragraph (1) include all of the following:

(*a*) the proprietary name or description of the clinical research material;

(*b*) the identification number of the clinical research material (including the control number, lot number, batch number or serial number);

(*c*) the date on which the clinical research material was put to some other use, disposed of or exported;

(*d*) the quantity of the clinical research material put to some other use, disposed of or exported;

(*e*) the name and address of the person responsible for the putting to some other use, disposal or export, of the clinical research material.

Production of and time for keeping of records

18.—(1) A person who is required to keep any record under this Division must —

(*a*) keep the records for the applicable period specified in paragraph (2) or (3); and

(*b*) produce the records for inspection when required by the Authority at any reasonable time during the applicable period.

(2) For records relating to any manufacture, assembly and testing of clinical research material, the applicable period is the longer of the following periods:

(*a*) one year after the expiry date of the material;

(*b*) 5 years after the date of such manufacture, assembly and testing.

(3) For records relating to the receipt and supply of, or the putting to some other use, disposal or export, of clinical research material, the applicable period is as follows:

(*a*) where the clinical research is not a regulated clinical trial, the period of 2 years after the supply, putting to some other use, disposal or export, as the case may be;

(*b*) where the clinical research is a regulated clinical trial, the period for which records of the trial must be kept under regulation 23(2)(*c*) of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016) or regulation 23(2)(*c*) of the Medicines (Clinical Trials) Regulations 2016 (G.N. No. S 335/2016), as the case may be.

Division 3 — Reports to Authority

Notifications of unexpected serious adverse drug reactions

19.—(1) Where, during any clinical research that is not a regulated clinical trial, any USADR occurs in a subject that results in death or is life-threatening, then the sponsor must ensure that —

(*a*) all relevant information about the USADR is —

(i) recorded; and

(ii) reported to the Authority as soon as possible and in any event not later than 7 days after the sponsor first becomes aware of the event; and

(*b*) any additional relevant information about the USADR is —

(i) recorded; and

(ii) sent to the Authority within 8 days of the record referred to in sub-paragraph (i).

(2) Where, during any clinical research that is not a regulated clinical trial, any USADR that is not referred to in paragraph (1) occurs in a subject, the sponsor must ensure that all relevant information about the reaction is —

(*a*) recorded; and

(*b*) reported to the Authority as soon as possible and in any event not later than 15 days after the sponsor first becomes aware of the event.

(3) In this regulation —

"investigator's brochure" means a document of an investigator of any clinical research that is not a regulated clinical trial, containing a summary of the clinical and non-clinical data relating to the clinical research material relevant to the study of the material in subjects;

"serious adverse drug reaction" has the same meaning as in regulation 2(1) of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016);

"USADR" means an unexpected serious adverse drug reaction in a subject following the administration of any clinical research material to the subject, the nature and severity of which is not consistent with information about the material set out —

(*a*) in the case of material that is a registered health product, in the product information leaflet or the investigator's brochure relating to the material; and

(*b*) in the case of material that is not a registered health product, in the investigator's brochure relating to the material.

Recall of clinical research material

20.—(1) For the purposes of section 44(1) of the Act, where any person intends to recall any clinical research material which the person manufactured, imported or supplied pursuant to regulation 3, the person must immediately, but in any case no later than 24 hours before the start of the intended recall, notify the Authority of, and the reasons for, the intended recall.

(2) The notice in paragraph (1) must be made in such form and manner as the Authority may require.

(3) Where the Authority has been notified of the intended recall of any clinical research material under paragraph (1), the Authority may by written notice require the person to do either or both of the following:

(*a*) investigate the matter occasioning the recall of the clinical research material and provide a report of the findings of the investigation;

(*b*) take such other measures as the Authority thinks necessary.

(4) A person to whom a notice in paragraph (3) is given must comply with the notice at the person's own cost and within the time specified in the notice or, if no time is specified in the notice, within a reasonable time after the date of the notice.

PART 6

MISCELLANEOUS

Certificate of manufacturing standard of clinical research materials

21.—(1) The Authority may, on the application of a manufacturer of any clinical research material and on being satisfied, after completion of an assessment of conformity, that the manufacturer conforms to an applicable Good Manufacturing Practice Standard, issue a GMP Certificate to the manufacturer subject to any terms and conditions as the Authority thinks fit.

(2) Every GMP Certificate issued is valid for a period specified in the certificate, being not longer than 3 years starting on the date of commencement of the assessment mentioned in paragraph (1).

(3) An application for a GMP Certificate must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the First Schedule.

(4) In this regulation and the First Schedule —

"GMP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Manufacturing Practice Standard;

"Good Manufacturing Practice Standard" means the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products and any other good manufacturing practice standard approved by the Authority.

Certificate of distribution standard of clinical research materials

22.—(1) The Authority may, on the application of a person who distributes a therapeutic product and on being satisfied, after completion of an assessment of conformity, that the person conforms to an applicable Good Distribution Practice Standard, issue a GDP Certificate to the person subject to any terms and conditions as the Authority thinks fit.

(2) Every GDP Certificate issued is valid for a period specified in the certificate, being not longer than 3 years starting on the date of commencement of the assessment mentioned in paragraph (1).

(3) An application for a GDP Certificate must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the First Schedule.

(4) In this regulation and the First Schedule —

"GDP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Distribution Practice Standard;

"Good Distribution Practice Standard" means the Authority's Guidance Notes on Good Distribution Practice and any other good distribution practice standard approved by the Authority.

Enforcement requirements

23.—(1) An enforcement officer may conduct routine inspections of —

(*a*) any premises that are being used for the manufacture, supply or storage of any clinical research material; and

(*b*) any conveyances that are being used for the transport of any clinical research material.

(2) An enforcement officer conducting a routine inspection under paragraph (1) may —

(*a*) require any person having possession or control of any clinical research material that is found during the inspection to furnish, without charge, a sample of such material for the Authority's examination; and the person must comply with the requirement; and

(*b*) take or cause to be taken any photograph of —

(i) the premises or conveyances referred to in paragraph (1); or

(ii) any property or material found on the premises or in the conveyances.

Offences

24.—(1) A person shall be guilty of an offence if the person —

(*a*) contravenes regulation 5(1), 6(2), 8(1), 9(1), 10(2), 11(2), 12, 14(2), (3)(*b*) or (5), 15, 16(1), (3), (4) or (5), 17(1), 18(1), 19(1) or (2), 20(4) or 23(2)(*a*); or

(*b*) for the purposes of making an application or giving any notice or report to the Authority under these Regulations, furnishes the Authority with any particulars, information or document which the person knows is false or misleading, or any sample which the person knows is altered or adulterated.

(2) A person who is guilty of an offence for contravening regulation 15, 16(1), (3), (4) or (5), 17(1), 18(1)(*a*) or 19(1)(*a*)(i), (*b*)(i) or (2)(*a*) shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) A person who is guilty of an offence for contravening any other provision in paragraph (1)(*a*), or guilty of an offence under paragraph (1)(*b*), shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

FIRST SCHEDULE

Regulations 5(2)(*c*), 6(3)(*c*), 21(3) and (4) and 22(3) and (4)

FEES

1. Application fee for approval to import or export clinical research material containing psychotropic substances	$103 per consignment
2. Application fee for each of the following certificates or documents:	
(*a*) a GMP Certificate	$6,180
(*b*) each additional copy of a GMP Certificate	$206
(*c*) a GDP Certificate	$3,605

FIRST SCHEDULE — *continued*

(*d*) each additional copy of a GDP Certificate	$206

[S 94/2019 wef 02/04/2019]

SECOND SCHEDULE

Regulation 11(2)

PART 1

SUPPLY TO SUBJECT OF CERTAIN THERAPEUTIC PRODUCTS

First column	*Second column*
Person who may supply	*Circumstances of supply*
1. For prescription-only medicine	
(*a*) A qualified practitioner, or a person acting in accordance with the instructions of a qualified practitioner	The supply is to a subject under the care of the qualified practitioner
(*b*) An in-store pharmaceutical officer providing pharmacy services at or from a licensed retail pharmacy	Either — (i) the supply is in accordance with a valid prescription given by a qualified practitioner; or (ii) the supply is of prescription-only medicine specified in the list of prescription-only medicines exempted for limited sale and supply, and made under all of the following conditions: (A) the medicine is labelled to show a maximum daily dose not exceeding that specified in the list; (B) the medicine is supplied in a quantity that does not exceed the maximum supply specified in the list;

SECOND SCHEDULE — *continued*

First column	*Second column*
Person who may supply	*Circumstances of supply*
	(C) the medicine is supplied to a subject who is of or above any minimum age specified in the list;
	(D) the in-store pharmaceutical officer keeps a record of the supply of the medicine under regulation 16(4)
2. For pharmacy-only medicine	
(*a*) A qualified practitioner, or a person acting in accordance with the instructions of a qualified practitioner	The supply is to a subject under the care of the qualified practitioner
(*b*) An in-store pharmaceutical officer engaged or employed by the holder of a pharmacy licence for the licensed retail pharmacy	The supply is made at or from the licensed retail pharmacy

PART 2

DEFINITIONS

1. For the purposes of item 1(*b*)(ii) in Part 1, "list of prescription-only medicine exempted for limited sale and supply" or "list" means the list, as published on the Authority's website, of therapeutic products classified as prescription-only medicines that may be supplied at or from a licensed retail pharmacy without the need for a valid prescription.

THIRD SCHEDULE

Regulation 13(2)

LABELLING REQUIREMENTS

1.—(1) Clinical research materials supplied on or after 1 November 2017 must be labelled with information for all of the following purposes:

(*a*) to ensure protection of the subject and traceability;

(*b*) to enable identification of the material and the trial;

(*c*) to facilitate proper use and storage of the material;

(*d*) to ensure the reliability and robustness of data generated in the trial.

(2) Without limiting the generality of sub-paragraph (1), every unregistered investigational CRM, every registered investigational CRM which does not satisfy the requirements in sub-paragraph (5), and every unregistered auxiliary CRM must be labelled with all of the following information:

(*a*) the words "For clinical research use only" or similar wordings;

(*b*) a clinical research reference allowing identification of the trial, site, investigator and sponsor;

(*c*) the research subject identification number or treatment number and, where relevant, visit number;

(*d*) the name, address and telephone number of the main contact for —

(i) information on the clinical research material;

(ii) information on the research; and

(iii) emergency unblinding;

(*e*) the name of the substance used in the clinical research material and its strength or potency, as well as, in the case of blinded trials, the name of the comparator or placebo;

(*f*) the pharmaceutical form, route of administration and quantity of dosage units of the clinical research material;

(*g*) the directions for use of the clinical research material (which may be a reference to a leaflet or other explanatory document intended for use by the subject or person administering the material);

(*h*) the batch or code number identifying the contents and packaging operation of the clinical research material;

THIRD SCHEDULE — *continued*

(*i*) the period of use (which may be an expiry date or a retest date), in month and year format and in a manner that avoids any confusion as to which is the month and which is the year;

(*j*) the storage conditions.

(3) Without limiting the generality of sub-paragraph (1), every registered investigational CRM which satisfies the requirements of sub-paragraph (5) must be labelled with all of the following information:

(*a*) the words "For clinical research use only" or similar wordings;

(*b*) a clinical research reference allowing identification of the trial, site, investigator and sponsor;

(*c*) the name of the person to whom the clinical research material is to be administered or the research subject identification number;

(*d*) the name, address and any identification number or logo of the licensed healthcare institution, licensed retail pharmacy, or trial site where the clinical research material is supplied or dispensed;

(*e*) the name of the clinical research material, being the proprietary name and the appropriate non-proprietary name of the active ingredient in the clinical research material;

(*f*) where the appropriate non-proprietary name is included on the label of the product, the appropriate quantitative particulars of any active ingredient of the clinical research material;

(*g*) the directions for use of the clinical research material;

(*h*) an appropriate control number, such as a serial number, batch number or lot number;

(*i*) the expiry date of the clinical research material;

(*j*) the date that the clinical research material is dispensed;

(*k*) where the clinical research material is registered, the registration number assigned to the product by the Authority.

(4) Without limiting the generality of sub-paragraph (1), every registered auxiliary CRM must be labelled with all of the following information:

(*a*) the name of the person to whom the clinical research material is to be administered or the research subject identification number;

(*b*) the name, address and any identification number or logo of the licensed healthcare institution, licensed retail pharmacy, or trial site where the clinical research material is supplied or dispensed;

THIRD SCHEDULE — *continued*

(*c*) the name of the clinical research material, being the proprietary name and the appropriate non-proprietary name of the active ingredient in the clinical research material;

(*d*) where the appropriate non-proprietary name is included on the label of the product, the appropriate quantitative particulars of any active ingredient of the clinical research material;

(*e*) the directions for use of the clinical research material;

(*f*) an appropriate control number, such as a serial number, batch number or lot number;

(*g*) the expiry date of the clinical research material;

(*h*) the date that the clinical research material is dispensed;

(*i*) where the clinical research material is registered, the registration number assigned to the product by the Authority.

(5) The requirements for the purpose of sub-paragraphs (2) and (3) in relation to any investigational CRM are all of the following:

(*a*) the material is not used in the clinical trial in a blinded fashion;

(*b*) the material is not repackaged for use in the trial;

(*c*) the material is used in accordance with the terms of its registration (if registered).

(6) The information referred to in sub-paragraphs (2), (3) and (4) must be in English, and must be clearly legible and unambiguous.

(7) The address and telephone number referred to in sub-paragraph (2)(*d*) need not appear on the label if the subjects are given a leaflet or card providing such information and instructed to keep the leaflet or card in their possession at all times.

(8) The information referred to in sub-paragraph (2)(*b*), (*c*), (*d*) and (*f*) to (*i*) need not appear on the label if they are available by any other means, so long as —

(*a*) sub-paragraph (1) is complied with; and

(*b*) the reasons for the omission are set out in the protocol or such other document as the Authority may allow.

(9) Sub-paragraphs (1)(*d*), (2)(*a*) to (*d*) and (*g*), (3)(*a*) to (*d*), (*g*) and (*j*) and (4)(*a*), (*b*), (*e*) and (*h*) do not apply where the supply is by wholesale.

2. Clinical research materials supplied before 1 November 2017 must —

(*a*) be labelled in accordance with paragraph 1; or

THIRD SCHEDULE — *continued*

(*b*) have the following particulars written on its container:

(i) the proprietary name, reference number or other identification mark of each item of such material;

(ii) the name and address of the manufacturer;

(iii) the production batch number of the material;

(iv) the name or other identification mark of the subject for whom the material is intended;

(v) the date of manufacture and the expiry date of the material;

(vi) the storage conditions appropriate for each item of material as may be indicated by the manufacturer; and

(vii) the words "This product shall only be used under strict medical surveillance" or "This product shall only be used under strict dental surveillance", as the case may be.

Made on 14 July 2016.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[HSA 401:04/05-000; HSA/LPPD/711-12/57-000; AG/LEGIS/SL/122D/2015/2 Vol. 1]

(To be presented to Parliament under section 72(5) of the Health Products Act).