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

No. S 334

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT)
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:

Citation and commencement

1. These Regulations are the Health Products (Medical Devices) (Amendment) Regulations 2016 and come into operation on 1 November 2016.

Amendment of regulation 2

2. Regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (called in these Regulations the principal Regulations) is amended —

(*a*) by deleting the words "as may be updated from time to time" in the definition of "Authority's website";

(*b*) by inserting, immediately after the definition of "body orifice", the following definitions:

" "clinical purpose" means any of the specific purposes described in the second column of item 1 of the First Schedule to the Act;

"clinical research" has the same meaning as in regulation 2(1) of the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016);";

(*c*) by inserting, immediately after the definition of "*in vitro* diagnostic product", the following definition:

" "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;";

(*d*) by inserting, immediately after the definition of "registered pharmacist", the following definition:

" "regulated clinical trial" means any clinical research 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);"; and

(*e*) by inserting, immediately after the definition of "specimen receptacle", the following definition:

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

New regulation 3A

3. The principal Regulations are amended by inserting, immediately after regulation 3, the following regulation:

"**Manufacture of medical device for use in clinical research**

3A. A person may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the planned use for the medical device is a clinical purpose in any clinical research.".

New regulations 4B and 4C

4. The principal Regulations are amended by inserting, immediately after regulation 4A, the following regulations:

"**Import of medical device licensed under Radiation Protection Act**

4B. A person may import, without holding an importer's licence as required under section 13(1) of the Act, any medical device —

(*a*) in respect of which a licence to import the medical device is granted under the Radiation Protection Act (Cap. 262); and

(*b*) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

Import of medical device for use in clinical research

4C. A person may import, without holding an importer's licence as required under section 13(1) of the Act, any medical device if —

(*a*) the planned use for the medical device is a clinical purpose in any clinical research; and

(*b*) the person imports the device —

(i) after the person has given notice to the Authority of the import in accordance with regulation 51; or

(ii) in accordance with a permission given by the licensing authority under the Medicines Act (Cap. 176) before 1 November 2016 for the import on or after that date.".

New regulations 5A and 5B

5. The principal Regulations are amended by inserting, immediately after regulation 5, the following regulations:

"**Wholesaling of medical device licensed under Radiation Protection Act**

5A. A person may carry out any activity that is a supply by wholesale, without holding a wholesaler's licence as required under section 14(1) of the Act, in relation to any medical device —

(*a*) in respect of which a licence is granted under the Radiation Protection Act (Cap. 262) for that activity; and

(*b*) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

Wholesaling of medical device for use in clinical research

5B. A person may supply by wholesale, without holding a wholesaler's licence as required under section 14(1) of the Act, any medical device if —

(*a*) the planned use for the medical device is a clinical purpose in any clinical research; and

(*b*) where the person is the manufacturer of the medical device, the person gives the Authority notice in accordance with regulation 51 of the supply by wholesale before so supplying the medical device.".

Deletion and substitution of regulation 10A

6. Regulation 10A of the principal Regulations is deleted and the following regulation substituted therefor:

"**Exception for clinical research**

10A. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product by a person does not apply to the supply of a medical device if —

(*a*) the planned use for the medical device is a clinical purpose in any clinical research; and

(*b*) where the person is the manufacturer of the medical device, the person gives the Authority notice of the supply in accordance with regulation 51 before supplying the medical device.".

New regulation 13A

7. The principal Regulations are amended by inserting, immediately after regulation 13, the following regulation:

"**Supply of medical devices for use in clinical research**

13A.—(1) A person who manufactures a medical device under regulation 3A, imports a medical device under regulation 4C, or is supplied with a medical device under regulation 5B or 10A, may only supply the medical device —

(*a*) as one whose planned use is a clinical purpose in any clinical research; or

(*b*) as a medical device for some other purpose that the Authority has allowed and no other.

(2) To avoid doubt, as from the time that the Authority has allowed the supply mentioned in paragraph (1)(*b*), the medical device ceases to be a medical device whose planned use is a clinical purpose in any clinical research for the purposes of these Regulations; but continues to be subject to any applicable law relating to medical devices (including these Regulations).

(3) Any person who contravenes paragraph (1) shall be guilty of an offence and 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.".

Amendment of regulation 34

8. The principal Regulations are amended by renumbering regulation 34 as paragraph (1) of that regulation, and by inserting immediately thereafter the following paragraph:

"(2) Paragraph (1)(*c*) does not apply to the import of any medical device under regulation 4C.".

New regulation 36A

9. The principal Regulations are amended by inserting, immediately after regulation 36, the following regulation:

"**Duties of sponsor, etc.**

36A.—(1) This regulation applies in relation to any medical device manufactured under regulation 3A, imported under regulation 4C or supplied under regulation 5B or 10A.

(2) Without prejudice to regulation 13A, a person must not use the medical device, and the sponsor must ensure that no person involved in the clinical research uses the medical device except —

(*a*) for a clinical purpose in the research, and where the research requires approval of an institutional review board, with the approval of that board; or

(*b*) for some other use that the Authority has allowed and no other.

(3) To avoid doubt, as from the time that the Authority has allowed the other use mentioned in paragraph (2)(*b*), the medical device ceases to be a medical device whose planned use is, or which must be used, for a clinical purpose in any clinical research for the purposes of these Regulations; but continues to be subject to any applicable law relating to medical devices (including these Regulations).

(4) Unless the Authority otherwise allows, the sponsor must ensure that, within 6 months after the conclusion or termination of the clinical research, any unused medical device for that research is disposed of or exported.

(5) Any person who contravenes paragraph (2) or (4) shall be guilty of an offence and 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.

(6) In this regulation, "unused medical device" means any medical device referred to in paragraph (1) that —

(*a*) is not used in the clinical research (including where the medical device cannot or can no longer be used in the research); or

(*b*) is reusable after the conclusion or termination of the clinical research.".

Amendment of regulation 39

10. Regulation 39 of the principal Regulations is amended by inserting, immediately after paragraph (4), the following paragraph:

"(5) This regulation does not apply to a medical device which is supplied for a clinical purpose in any clinical research.".

New regulations 39A and 39B

11. The principal Regulations are amended by inserting, immediately after regulation 39, the following regulations:

"**Duty to maintain records of receipt and supply in relation to medical devices for clinical research**

39A.—(1) Every person who supplies any medical device whose planned use is for a clinical purpose in any clinical research (including a person who manufactures or imports the medical device, and supplies the medical device) must —

(*a*) maintain a record relating to every receipt (where applicable) and every supply by the person of the medical device; and

(*b*) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) A person referred to in paragraph (1) must ensure that every record referred to in that paragraph —

(*a*) contains, in relation to (where applicable) each receipt, and each supply, by the person of the medical device, all of the following information:

(i) the proprietary name or description of the medical device;

(ii) the date on which the medical device was received and supplied;

(iii) the name and address of the person from whom and to whom the medical device was received and supplied;

(iv) the quantity of the medical device received and supplied; and

(v) the identification number or mark (including the control number, lot number, batch number or serial number) of the medical device received and supplied; and

(*b*) is retained for the following periods:

(i) for any registered medical device used in a regulated clinical trial or any medical device used in any clinical research that is not a regulated clinical trial, the longer of the following periods:

(A) the projected useful life of the medical device;

(B) 2 years after the date on which the medical device is supplied;

(ii) for any unregistered medical device used in a regulated clinical trial, the period for which records 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.

(3) Any person who contravenes paragraph (1) or (2) shall be guilty of an offence and 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.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and 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.

Duty to maintain records of use and disposal, etc., in relation to medical devices for clinical research

39B.—(1) The sponsor referred to in regulation 36A(2) or (4) must —

(*a*) maintain a record of the putting to some other use, disposal or export of a medical device under that provision; and

(*b*) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) The sponsor referred to in paragraph (1) must ensure that every record referred to in that paragraph —

(*a*) contains all of the following information in relation to each medical device which is put to some other use, disposed of or exported:

(i) the proprietary name or description of the medical device;

(ii) the date on which the medical device was put to the other use, disposed of or exported;

(iii) the name and address of the person responsible for the putting to the other use, disposal or export, of the medical device;

(iv) the quantity of the medical device put to the other use, disposed of or exported;

(v) the identification number or mark (including the control number, lot number, batch number or serial number) of the medical device; and

(*b*) is retained —

(i) for any registered medical device used in a regulated clinical trial or any medical device used in any clinical research that is not a regulated clinical trial, for 2 years after the time when the

medical device is put to some other use, is disposed of or is exported, as the case may be; or

(ii) for any unregistered medical device used in a regulated clinical trial, for the period for which records 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.

(3) Any person who contravenes paragraph (1) or (2) shall be guilty of an offence and 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.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and 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.".

New regulation 51

12. The principal Regulations are amended by inserting, immediately before regulation 52 in Part X, the following regulation:

"**Notices to Authority**

51.—(1) A notice to be given to the Authority under these Regulations must be given in the form and manner, and within the time, specified on the Authority's website.

(2) Any person who, for the purposes of giving any notice to the Authority under these Regulations, furnishes the Authority with any particulars, information or document which the person knows is false or misleading shall be guilty of an offence and 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.".

[G.N. Nos. S 542/2011; S 140/2012; S 169/2012; S 370/2012; S 426/2012; S 646/2012]

Made on 14 July 2016.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[HSA 401:04/05-000; HSA/LPPD/711:12/58-000;
AG/LEGIS/SL/122D/2015/3 Vol. 1]

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