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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT NO. 4)
REGULATIONS 2012

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, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) (Amendment No. 4) Regulations 2012 and shall come into operation on 1st September 2012.

New regulation 4A

2. The Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (referred to in these Regulations as the principal Regulations) are amended by inserting, immediately after regulation 4, the following regulation:

"**Import of medical devices for personal use**

4A. A person may import, without holding an importer's licence as required under section 13(1) of the Act, any medical device for his personal use or for the personal use of any member of his family, subject to —

(*a*) such conditions; and

(*b*) such limits on quantity, not exceeding a total quantity of usage of the medical device for 3 months,

as the Authority thinks fit, based on the usage instructions recommended by the manufacturer or product owner of the medical device.".

Amendment of regulation 11

3. Regulation 11(1) of the principal Regulations is amended —

(*a*) by deleting the word ''and'' at the end of sub-paragraph (*e*); and

(*b*) by deleting the full-stop at the end of sub-paragraph (*f*) and substituting a semi-colon, and by inserting immediately thereafter the following sub-paragraphs:

''(*g*) the supply on or after 1st September 2012 of an unregistered Class A or B medical device, not being an unregistered Class A medical device supplied in accordance with the requirements in regulation 10B, which is listed on the Class A or B Medical Device Transition List as published on the Authority's website; and

(*h*) the supply on or after 1st September 2012 of an unregistered Class C or D medical device which is listed on the Class C or D Medical Device Transition List as published on the Authority's website.''.

Deletion and substitution of regulations 25 and 26

4. Regulations 25 and 26 of the principal Regulations are deleted and the following regulations substituted therefor:

''**Requirement for registration of medical device**

25. For the purposes of section 30(2)(*a*)(iii) of the Act, the prescribed requirements for the registration of a medical device are the safety and performance requirements for the medical device specified in the First Schedule.

Evaluation process

26.—(1) For the purposes of section 33 of the Act, the Authority may, upon an application for the registration of a medical device —

(*a*) evaluate the medical device under —

(i) an abridged evaluation process; or

(ii) an expedited abridged evaluation process; or

(*b*) immediately register the medical device.

(2) A medical device may qualify for evaluation under an abridged evaluation process, if —

(*a*) any competent regulatory agency of a foreign jurisdiction has granted approval for the supply of the medical device in that jurisdiction;

(*b*) the approval by the competent regulatory agency is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

(3) A medical device may qualify for evaluation under an expedited abridged evaluation process, if —

(*a*) at least one reference regulatory agency of a foreign jurisdiction has granted approval for the supply of the medical device in that jurisdiction;

(*b*) the approval by the reference regulatory agency is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

(4) The Authority may immediately register a medical device, if —

(*a*) at least 2 reference regulatory agencies, each of a foreign jurisdiction, have granted approval for the supply of the medical device in their jurisdictions;

(*b*) the approval by each of the reference regulatory agencies is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

(5) A medical device which does not qualify for evaluation under an abridged evaluation process or expedited abridged evaluation process referred to in paragraph (2) or (3) respectively, or for immediate registration under paragraph (4), shall be evaluated under a full evaluation process.

(6) In this regulation —

''competent regulatory agency'' means any body or organisation which —

(*a*) exercises a legal right to control the use or sale of medical devices within a country or territory outside Singapore;

(*b*) may take enforcement action to ensure that medical devices advertised or supplied within that country or territory outside Singapore comply with the legal requirements applicable in that country or territory outside Singapore; and

(*c*) is recognised by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device;

''reference regulatory agency'' means a competent regulatory agency specified on the Authority's website at the time of the application for the registration of the medical device for the purpose of an expedited abridged evaluation process under paragraph (3) or immediate registration under paragraph (4).''.

Deletion of regulations 27, 28 and 29

5. Regulations 27, 28 and 29 of the principal Regulations are deleted.

Amendment of regulation 30

6. Regulation 30 of the principal Regulations is amended by deleting paragraph (1) and substituting the following paragraph:

''(1) The Authority may, on the application of a person who intends to export a medical device and upon receiving the relevant fee specified in the Fourth Schedule, issue to the person a certificate containing such statement relating to the medical device as the Authority may consider appropriate having regard to any applicable requirements (whether having the force of law or not) in the country to which the medical device is to be exported.''.

Amendment of regulation 50

7. Regulation 50 of the principal Regulations is amended by inserting, immediately after paragraph (3), the following paragraph:

"(4) The Authority may, in any particular case or class of cases, waive or refund the whole or any part of any fee paid or payable under these Regulations.".

Amendment of First Schedule

8. The First Schedule to the principal Regulations is amended by deleting the Schedule reference and substituting the following Schedule reference:

"Regulations 11(1), 15, 25, 33, 34 and 36".

Amendment of Third Schedule

9. The Third Schedule to the principal Regulations is amended —

(*a*) by deleting the word "or" at the end of paragraph 13(3)(*e*);

(*b*) by deleting the full-stop at the end of sub-paragraph (*f*) of paragraph 13(3) and substituting the word "; or", and by inserting immediately thereafter the following sub-paragraph:

"(*g*) to have a biological effect."; and

(*c*) by deleting paragraph 20 and substituting the following paragraph:

"**Medical devices incorporating medicinal products**

20. A medical device shall be assigned to Class D, if it incorporates as an integral part a substance which —

(*a*) is liable to act on a human body with an action ancillary to that of the medical device; and

(*b*) is subject to the licensing requirements of section 5 or 6 of the Medicines Act (Cap. 176).".

Amendment of Fourth Schedule

10. The Fourth Schedule to the principal Regulations is amended —

(*a*) by deleting the words ''27 to'' in the Schedule reference;

(*b*) by deleting item 2 and substituting the following item:

''2. Application fee for evaluation of a medical device for registration, in a case where the medical device is proposed to be classified as —	
(*a*) a Class A medical device, by verification of the presentation of, and the conformity declaration for, the medical device	Nil
(*b*) a Class B medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$1,800
(ii) by evaluation under an expedited abridged evaluation process referred to in regulation 26(3)	$900
(iii) which is immediately registered under regulation 26(4)	$900
(iv) by evaluation under a full evaluation process	$3,500
(*c*) a Class C medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$3,500
(ii) by evaluation under a full evaluation process	$5,700
(*d*) a Class D medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$5,700
(ii) by evaluation under a full evaluation process	$11,400

(*e*) a medical device that contains a medicinal product —		
	(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$10,000
	(ii) by evaluation under a full evaluation process	$75,000''; and

(*c*) by deleting item 12 and substituting the following item:

''12.	Processing fee in relation to a certificate under regulation 30(1) for a medical device intended for export (for one medical device and addressed to one country)	$50.''.

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

Made this 31st day of August 2012.

JOHN WONG
Chairman,
Health Sciences Authority,
Singapore.

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