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No. S 169

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT NO. 2)
REGULATIONS 2012

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, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) (Amendment No. 2) Regulations 2012 and shall come into operation on 1st May 2012.

Amendment of regulation 2

2. Regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (referred to in these Regulations as the principal Regulations) is amended by inserting, immediately after the definition of "specimen receptacle", the following definition:

" "sterile state", in relation to a medical device, means a state free of viable micro-organisms;".

Deletion and substitution of regulation 10A and new regulation 10B

3. Regulation 10A of the principal Regulations is deleted and the following regulations substituted therefor:

"**Exception for clinical trials**

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 shall not apply to the supply of a

medical device for the purpose of a clinical trial in accordance with the Medicines (Clinical Trials) Regulations (Cap. 176, Rg 3).

Exception for certain Class A medical devices

10B.—(1) 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 shall not apply to the supply of a Class A medical device —

(*a*) that is intended by its product owner to be supplied other than in a sterile state; and

(*b*) that is —

(i) manufactured under a valid manufacturer's licence;

(ii) imported by the supplier under a valid importer's licence; or

(iii) obtained by the supplier from a wholesaler who holds a valid wholesaler's licence.

(2) For the purposes of paragraph (1), a medical device shall be treated as a Class A medical device if it would have been assigned to Class A according to regulation 24 had the medical device been registered.".

Amendment of regulation 11

4. Regulation 11(1) of the principal Regulations is amended by inserting, immediately after the words "medical device" in sub-paragraph (*b*), the words "(but not an unregistered Class A medical device supplied on or after 1st May 2012 in accordance with the requirements specified in regulation 10B)".

New regulation 35A

5. 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 35, the following regulation:

"**Duty of supplier of unregistered Class A medical devices to furnish information**

35A. Where a medical device would have been assigned to Class A according to regulation 24 had it been registered and the medical device is supplied without being registered in accordance with the requirements specified in regulation 10B, the Authority may, under section 41(1) of the Act, by notice in writing, require the supplier of the medical device to furnish to the Authority, within such time as may be specified in the notice, the name, address and licence number of the manufacturer or wholesaler, as the case may be, from whom the supplier obtained the medical device.".

Amendment of regulation 49

6. Regulation 49 of the principal Regulations is amended by inserting, immediately after paragraph (6), the following paragraph:

"(7) For the avoidance of doubt, any reference to a change or proposed change referred to in paragraph (1)(*a*) does not include any such change by reason only of the registered medical device ceasing to be registrable by virtue of regulation 10B.".

Deletion of Sixth Schedule

7. The Sixth Schedule to the principal Regulations is deleted.

Savings and transitional provisions

8.—(1) Nothing in these Regulations shall affect the validity of any of the following:

(*a*) the registration, before 1st May 2012, of any previously registrable medical device;

(*b*) any notification under regulation 49(1) of the principal Regulations (being a notification given in respect of a previously registrable medical device) that is processed by the Authority before 1st May 2012;

(*c*) any approval given, before 1st May 2012, by the Authority under regulation 49(3) of the principal Regulations in respect

of any change made to a previously registrable medical device that may affect the safety, quality or efficacy of the medical device.

(2) Where any application under section 30(1) of the Act to register a previously registrable medical device is pending immediately before 1st May 2012, the Authority may —

(*a*) refuse to register the medical device; and

(*b*) refund the application fee for that application.

(3) Where the processing by the Authority of any notification under regulation 49(1) of the principal Regulations (being a notification given in respect of a previously registrable medical device) is pending immediately before 1st May 2012, the Authority may —

(*a*) refuse to process that notification; and

(*b*) refund the notification fee for that notification.

(4) Where any application, under regulation 49(4) of the principal Regulations for the Authority's approval to make any change to a previously registrable medical device that may affect the safety, quality or efficacy of the medical device, is pending immediately before 1st May 2012, the Authority may —

(*a*) refuse to process that application; and

(*b*) refund the application fee for that application.

(5) In this regulation, "previously registrable medical device" means a medical device —

(*a*) that is assigned to Class A according to regulation 24, or would have been assigned to Class A according to regulation 24 had it been registered;

(*b*) that is intended by its product owner to be supplied other than in a state free of viable micro-organisms; and

(*c*) that is —

(i) manufactured under a valid manufacturer's licence;

(ii) imported by the supplier under a valid importer's licence; or

(iii) obtained by the supplier from a wholesaler who holds a valid wholesaler's licence.

Made this 30th day of April 2012.

JOHN WONG
Chairman,
Health Sciences Authority,
Singapore

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