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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2018

In exercise of the powers conferred by sections 45 and 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 2018 and come into operation on 1 June 2018.

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 inserting, immediately after the words "described in" in the definition of "clinical purpose", the words "paragraph (*a*) of the definition of "Medical device" in";

(*b*) by inserting, immediately after the definition of "field safety corrective action", the following definition:

" "Good Distribution Practice Standard for Medical Devices" means any of the following:

(*a*) before 9 November 2020, the Authority's Good Distribution Practice for Medical Devices — Requirements (TS-01) as published on the Authority's website;

(*b*) the Singapore Standard for Good Distribution Practice for Medical Devices — Requirements (SS 620);

(*c*) any other good distribution practice standard for medical devices that is approved by the Authority and is specified on the Authority's website;";

(*c*) by inserting, immediately after the definition of "intended use" or "intended purpose", the following definitions:

" "ISO 13485" means the 2003 or 2016 edition of the publication ISO 13485, Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes, published by the International Organization for Standardization;

"laboratory-developed test" means a medical device in the form of an *in vitro* assay or test for clinical diagnostic use that is —

(*a*) manufactured based on basic scientific principles; or

(*b*) developed or manufactured based on reputable scientific sources,

but excludes a medical device that is modified or adapted from an *in vitro* assay or test manufactured or supplied by another person;";

(*d*) by deleting the definition of "refurbished medical device"; and

(*e*) by deleting the full-stop at the end of the definition of "trade description" and substituting a semi-colon, and by inserting immediately thereafter the following definition:

" " "trained user only" medical device" means a medical device that is to be used only by an individual who has undergone such training on

the safe and efficacious use of the medical device as is necessary.".

New Part IA

3. The principal Regulations are amended by inserting, immediately after regulation 2, the following Part:

"PART IA

MANUFACTURE AND IMPORT OF MEDICAL DEVICES

Requirements for issue of manufacturer's licence

2A. For the purposes of section 24(2)(*a*)(i) of the Act, the requirements that must be satisfied for the issue, to an applicant, of a manufacturer's licence for a medical device are that —

(*a*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities as are necessary for carrying out the manufacture of the medical device to be authorised by the licence;

(*b*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling, storage and distribution of the medical device as are necessary to prevent the deterioration of the medical device while it is in the applicant's ownership, possession or control;

(*c*) the applicant is able to conduct all manufacturing operations in such a way as to ensure that the medical device is not wrongly labelled as another type of medical device; and

(*d*) the applicant is able to comply with the requirements of ISO 13485 in relation to the manufacture of the medical device.

Requirements for issue of importer's licence

2B.—(1) For the purposes of section 24(2)(*a*)(i) of the Act, the requirements that must be satisfied for the issue, to an applicant, of an importer's licence for a medical device are that —

(*a*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the medical device as are necessary to prevent the deterioration of the medical device while it is in the applicant's ownership, possession or control; and

(*b*) the medical device —

(i) is an unregistered medical device that is imported for the purpose of the supply of that medical device by the applicant in accordance with regulation 7 or 10;

(ii) is an unregistered medical device that is imported for the purpose of the supply of the medical device by, or procured by, either of the following persons in accordance with regulation 8:

(A) a qualified practitioner;

(B) a private hospital, medical clinic or clinical laboratory licensed under the Private Hospitals and Medical Clinics Act (Cap. 248);

(iii) is an unregistered medical device that is imported for the purpose of the supply of the medical device on behalf of, or procured on behalf of, either of the following persons in accordance with regulation 8:

(A) a qualified practitioner;

(B) a private hospital, medical clinic or clinical laboratory licensed under the Private Hospitals and Medical Clinics Act;

(iv) is an unregistered medical device that is imported solely for the purpose of re-export in accordance with regulation 9;

(v) is intended to be supplied for use on a ship, and the medical device is one that is required to be carried on board the ship under the Merchant Shipping (Medical Stores) Regulations (Cap. 179, Rg 3), the Merchant Shipping (Maritime Labour Convention) (Medicines and Medical Equipment) Regulations 2014 (G.N. No. S 181/2014) or any other written law, for the treatment of persons on board the ship;

(vi) is intended to be supplied for use on an aircraft, and the medical device forms part of the medical supplies required under the Air Navigation Order (Cap. 6, O 2) or any other written law for the treatment of persons on board the aircraft;

(vii) is a registered medical device that is authorised for import by the registrant of the medical device; or

(viii) is in all respects the same as a registered medical device, the registrant of which has not authorised the applicant to import the registered medical device.

(2) In addition to the requirements in paragraph (1) —

(*a*) an applicant who intends to import a medical device under paragraph (1)(*b*)(iii) or (vii) must be able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485; and