No. S 000

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 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;";

(*b*) 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;";

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

(*d*) 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

(*b*) an applicant who intends to import a medical device under paragraph (1)(*b*)(viii) —

(i) must be able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485; and

(ii) must obtain the Authority's prior approval for each consignment of the medical device to be imported.

(3) An application for the Authority's approval under paragraph (2)(*b*)(ii) must be made in the form and manner specified on the Authority's website.".

Deletion and substitution of regulation 3

4. Regulation 3 of the principal Regulations is deleted and the following regulation substituted therefor:

"**Manufacture of medical devices**

3.—(1) A person that is a private hospital, medical clinic or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) (called in this regulation a healthcare institution) may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the medical device —

(*a*) is manufactured —

(i) at the request of a qualified practitioner practising at the healthcare institution; and

(ii) in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device; and

(*b*) is intended for the use of a particular patient of the healthcare institution.

(2) A person may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the manufacture is for the purpose of —

(*a*) fitting or adjusting the medical device to meet the requirements of the end user of the medical device; or

(*b*) enabling the continued use of the medical device by the end user for the purpose for which the medical device was originally provided to the end user.

(3) A healthcare institution mentioned in paragraph (1), or a person mentioned in paragraph (2), is subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42, 44, 45, 46 and 47.".

New regulations 3B and 3C

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

"**Manufacture of laboratory-developed tests**

3B.—(1) A person that is a clinical laboratory licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) may manufacture a laboratory-developed test without holding a manufacturer's licence under section 12(1) of the Act, if the person manufactures the laboratory-developed test solely for the use of that clinical laboratory.

(2) A person mentioned in paragraph (1) is subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42, 44, 45, 46 and 47.

Manufacture of Class A medical devices for charitable purposes

3C.—(1) A person may manufacture a Class A medical device without holding a manufacturer's licence under section 12(1) of the Act if the following requirements are satisfied:

(*a*) the Class A medical device is intended for the use of a citizen or permanent resident of Singapore who is unable to bear the cost of the medical device due to impecuniosity (called in this regulation the recipient);

(*b*) the person manufactures the Class A medical device at the request or instruction of the recipient, or another person that intends to supply the medical device to the recipient;

(*c*) the person obtains the prior approval of the Authority before manufacturing the Class A medical device;

(*d*) the person —

(i) does not solicit or receive any remuneration from any person for the manufacture of the Class A medical device; or

(ii) receives any payment only as reimbursement for any costs and expenses the person reasonably incurred under a contract or an arrangement with

another person for the manufacture of the Class A medical device.

(2) A person mentioned in paragraph (1) is subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42, 44, 45, 46 and 47.

(3) For the purposes of paragraph (1), a medical device is 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.

(4) In paragraph (1)(*d*)(i), "remuneration" includes any payment, commission, incentive, benefit or reward, in money or money's worth.".

Deletion and substitution of regulation 4

6. Regulation 4 of the principal Regulations is deleted and the following regulation substituted therefor:

"**Manufacture of medical devices by way of secondary assembly**

4.—(1) A person may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act if the following requirements are satisfied:

(*a*) the medical device is manufactured by way of secondary assembly;

(*b*) the person —

(i) holds an importer's licence under section 13(1) of the Act or a wholesaler's licence under section 14(1) of the Act; and

(ii) is able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485.

(2) A person mentioned in paragraph (1) is subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42, 44, 45, 46 and 47.

(3) A person that is —

(*a*) a private hospital, medical clinic or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248); or

(*b*) a retail pharmacy licensed under the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016),

may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the medical device is manufactured by way of secondary assembly solely for the purpose of supplying the medical device in packaging that is smaller in size than the original packaging of the medical device, or in a quantity smaller than the quantity in which the medical device is supplied to that person.

(4) A person mentioned in paragraph (3) must ensure that the secondary packaging of the medical device bears the following information:

(*a*) the expiry date or shelf life of the medical device that is consistent with the information on the label on the primary packaging of the medical device as approved by the Authority; and

(*b*) such other requirements as the Authority may require.

(5) A person mentioned in paragraph (1) or (3) must ensure that the information on any label of the secondary packaging of the medical device is consistent with the information on the label of the primary packaging of the medical device as approved by the Authority.

(6) In this regulation —

"original packaging", in relation to a medical device, means the outer packaging for the medical device used when the medical device is supplied to a person mentioned in paragraph (1) or (3);

"primary packaging", in relation to a medical device, means packaging that maintains the sterility or integrity of the medical device;

"secondary assembly" means the process of repackaging a medical device from its original packaging into secondary packaging, without any breach of the primary packaging, before the medical device is supplied;

"secondary packaging", in relation to a medical device, means the outer packaging for the medical device used in substitution for the original packaging.".

Amendment of regulation 4B

7. Regulation 4B of the principal Regulations is amended by deleting paragraph (*b*) and substituting the following paragraph:

"(*b*) which is registered under the Act.".

New regulation 4D

8. The principal Regulations are amended by inserting, immediately before regulation 5 in Part III, the following regulation:

"**Requirements for issue of wholesaler's licence**

4D.—(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 a wholesaler'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, 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; and

(*b*) subject to paragraph (2), the applicant is able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485.

(2) Paragraph (1)(*b*) does not apply if the applicant —

(*a*) returns an unregistered medical device which has undergone maintenance or repair to the person who owns the unregistered medical device in accordance with regulation 7;

(*b*) supplies by wholesale an unregistered medical device that is manufactured solely for export, or imported solely for re-export, in accordance with regulation 9;

(*c*) supplies by wholesale an unregistered medical device that is imported or supplied for a non-clinical purpose in accordance with regulation 10;

(*d*) supplies by wholesale a medical device to a ship, if the medical device is an unregistered medical device and is imported in accordance with the requirements in regulation 2B(1)(*b*)(v); or

(*e*) supplies by wholesale a medical device to an aircraft, if the medical device is an unregistered medical device and is imported in accordance with the requirements in regulation 2B(1)(*b*)(vi).".

Amendment of regulation 5A

9. Regulation 5A of the principal Regulations is amended by deleting paragraph (*b*) and substituting the following paragraph:

"(*b*) which is registered under the Act.".

Amendment of regulation 5B

10. Regulation 5B of the principal Regulations is amended —

(*a*) by inserting, immediately before the word "where" in paragraph (*b*), the words "subject to paragraph (2),"; and

(*b*) by renumbering the regulation as paragraph (1) of that regulation, and by inserting immediately thereafter the following paragraphs:

"(2) Paragraph (1)(*b*) does not apply if the person manufactures the medical device solely by way of secondary assembly.

(3) In paragraph (2), "secondary assembly" has the same meaning as in regulation 4(6).".

Deletion and substitution of regulations 6 and 7

11. Regulations 6 and 7 of the principal Regulations are deleted and the following regulations substituted therefor:

"**Exception for custom-made medical devices, etc.**

6. Despite any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product does not apply to the supply of —

(*a*) a medical device that is manufactured in accordance with regulation 3;

(*b*) a laboratory-developed test that is an unregistered medical device and is manufactured in accordance with regulation 3B; or

(*c*) a custom-made medical device that is an unregistered medical device.

Exception for medical devices which underwent maintenance or repair

7. Despite any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product does not apply to the return, after undergoing maintenance or repair, of an unregistered medical device to the person who owns that medical device.".

Amendment of regulation 8

12. Regulation 8 of the principal Regulations is amended —

(*a*) by deleting the words "if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for such use" and substituting the words "if paragraph (2) or (3) is satisfied"; and

(*b*) by renumbering the regulation as paragraph (1) of that regulation, and by inserting immediately thereafter the following paragraphs:

"(2) Where a person mentioned in paragraph (1) supplies, or procures the supply of, an unregistered medical device, the person —

(*a*) must —

(i) hold an importer's licence or a wholesaler's licence for the unregistered medical device; or

(ii) be 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 unregistered 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*) must not supply that unregistered medical device to another person except with the Authority's prior approval.

(3) Where a person (*P*) supplies, or procures the supply of, an unregistered medical device on behalf of a person mentioned in paragraph (1), *P* —

(*a*) must —

(i) hold an importer's licence or a wholesaler's licence for the unregistered medical device; or

(ii) be able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485; and

(*b*) must not supply that unregistered medical device to another person except with the Authority's prior approval.".

Amendment of regulation 10

13. Regulation 10 of the principal Regulations is amended —

(*a*) by deleting the words "if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for such purpose" in paragraph (1) and substituting the words "if the requirements in paragraph (1A) are satisfied";

(*b*) by inserting, immediately after paragraph (1), the following paragraph:

"(1A) The requirements mentioned in paragraph (1) are that the person who supplies the unregistered medical device —

(*a*) must —

(i) hold an importer's licence or a wholesaler's licence for the unregistered medical device; or

(ii) be 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 unregistered 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*) must not supply that medical device to another person except with the Authority's prior approval."; and

(*c*) by inserting, immediately after the words "described in" in paragraph (2), the words "paragraph (2) of".

Amendment of regulation 10A

14. Regulation 10A of the principal Regulations is amended —

(*a*) by inserting, immediately before the word "where" in paragraph (*b*), the words "subject to paragraph (2),"; and

(*b*) by renumbering the regulation as paragraph (1) of that regulation, and by inserting immediately thereafter the following paragraphs:

"(2) Paragraph (1)(*b*) does not apply if the person manufactures the medical device solely by way of secondary assembly.

(3) In paragraph (2), "secondary assembly" has the same meaning as in regulation 4(6).".

Amendment of regulation 10B

15. Regulation 10B of the principal Regulations is amended —

(*a*) by deleting paragraph (1) and substituting the following paragraph:

"(1) Despite any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product does not apply to the supply of a Class A medical device that is —

(*a*) manufactured under a valid manufacturer's licence or in accordance with regulation 3C;

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

(*c*) obtained by the supplier from a wholesaler who holds a valid wholesaler's licence."; and

(*b*) by deleting the word "certain" in the regulation heading.

Amendment of regulation 11

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

(*a*) by inserting, immediately after the words "1st January 2012" in sub-paragraph (*b*), the words ", but before [1 June 2018],";

(*b*) by inserting, immediately after the words "the First Schedule" in sub-paragraphs (*b*)(iv) and (*d*)(iv), the words "as in force immediately before [1 June 2018];"; and

(*c*) by inserting, immediately after the words "1st September 2012" in sub-paragraphs (*g*) and (*h*), the words ", but before [1 June 2018],".

New Division 2A of Part III

17. Part III of the principal Regulations is amended by inserting, immediately after regulation 11, the following Division:

"*Division 2A — Other exceptions*

Exception for import of medical device by licensed manufacturer without importer's licence

11A. The holder of a manufacturer's licence may import a medical device without holding an importer's licence, if the medical device is required for the purpose of carrying out the manufacture of another medical device in accordance with the conditions of the manufacturer's licence.

Exception for wholesale of medical devices to ships or aircraft by licensed importer without wholesaler's licence

11B.—(1) A person may supply by wholesale an unregistered medical device to a ship without holding a wholesaler's licence, if —

(*a*) the medical device is imported in accordance with the requirements in regulation 2B(1)(*b*)(v); and

(*b*) the person holds an importer's licence for the medical device.

(2) A person may supply by wholesale an unregistered medical device to an aircraft without holding a wholesaler's licence, if —

(*a*) the medical device is imported in accordance with the requirements in regulation 2B(1)(*b*)(vi); and

(*b*) the person holds an importer's licence for the medical device.

(3) Despite any other provision in these Regulations, the prohibition in section 15(1) of the Act against the supply of an

unregistered health product does not apply to the supply of an unregistered medical device —

(*a*) for use on a ship in accordance with paragraph (1); or

(*b*) for use on an aircraft in accordance with paragraph (2).

Previously registered medical devices

11C. A supplier of a registered medical device may continue to supply the medical device, by administration to a person or by retail sale, despite a cancellation of the registration of the medical device and despite the prohibition in section 15(1) of the Act against the supply of a health product that is not registered, if —

(*a*) the cancellation of the registration is either made by the Authority under section 37(2) of the Act or upon the application of the registrant under section 37(3) of the Act;

(*b*) the supplier has taken possession of the medical device before the cancellation of its registration; and

(*c*) the Authority does not direct a recall of the medical device from the market.".

Deletion and substitution of regulation 12

18. Regulation 12 of the principal Regulations is deleted and the following regulation substituted therefor:

"**Supply of Class A medical devices**

12.—(1) For the purposes of section 17(1) of the Act and without prejudice to regulation 35A, a person who supplies a Class A medical device in accordance with regulation 10B must furnish such information about the medical device as the Authority may require.

(2) The person mentioned in paragraph (1) must furnish the information within such time and in such manner as the Authority may specify.

(3) For the purposes of paragraph (1), a medical device is 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 13

19. Regulation 13 of the principal Regulations is amended —

(*a*) by deleting the word "registered" in paragraphs (*a*) and (*b*); and

(*b*) by renumbering the regulation as paragraph (1) of that regulation, and by inserting immediately thereafter the following paragraph:

"(2) In paragraph (1), "professional use only" medical device" means —

(*a*) a registered "professional use only" medical device; or

(*b*) an unregistered "professional use only" medical device supplied in accordance with regulation 8.".

New regulation 13B

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

"**Supply of "trained user only" medical devices**

13B.—(1) For the purposes of section 17(1) of the Act, a person must not supply a "trained user only" medical device to another person (*P*) unless the person, at or before the time the medical device is supplied to *P* —

(*a*) provides, or ensures the provision of, such training on the safe and efficacious use of the medical device as the manufacturer of the medical device determines is necessary, to every user of the medical device; or

(*b*) ensures that every user of the medical device has received the training mentioned in sub-paragraph (*a*).

(2) In paragraph (1) —

" "trained user only" medical device" means —

(*a*) a registered "trained user only" medical device; or

(*b*) an unregistered "trained user only" medical device supplied in accordance with regulation 8 or 10;

"user", in relation to a medical device, means an individual who is an employee or contractor of, or otherwise associated with, *P*.".

Amendment of regulation 15

21. Regulation 15 of the principal Regulations is amended —

(*a*) by deleting sub-paragraphs (*b*) and (*c*) of paragraph (1) and substituting the following sub-paragraph:

"(*b*) where the medical device is supplied for use in any investigational testing, the statement "For Clinical Trial Use" or any other statement in English that conveys the same meaning;";

(*b*) by deleting the word "and" at the end of paragraph (1)(*e*);

(*c*) by deleting sub-paragraph (*f*) of paragraph (1) and substituting the following sub-paragraphs:

"(*f*) the product owner's name or trading name, address, telephone number and electronic mail address;

(*g*) an appropriate control number, such as a batch code, lot number or serial number."; and

(*d*) by deleting paragraph (2) and substituting the following paragraph:

"(2) The information mentioned in paragraph (1) must be provided in the manner specified on the Authority's website.".

Amendment of regulation 19

22. Regulation 19 of the principal Regulations is amended by deleting the words "such objective evidence" in paragraph (*a*)(ii) and substituting the words "where the medical device is a registered medical device, the objective evidence mentioned in sub-paragraph (i)".

Deletion and substitution of regulation 21

23. Regulation 21 of the principal Regulations is deleted and the following regulation substituted therefor:

"**Advertisement of "professional use only" medical devices**

21. For the purposes of section 21(1) of the Act and despite regulation 19, a person must not advertise any of the following "professional use only" medical devices, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, qualified practitioners:

(*a*) a registered "professional use only" medical device;

(*b*) an unregistered "professional use only" medical device that is supplied in accordance with regulation 8 or 10.".

Amendment of regulation 24

24. Regulation 24 of the principal Regulations is amended —

(*a*) by deleting the words "the Third Schedule" in paragraph (1) and substituting the words "Part I of the Third Schedule"; and

(*b*) by inserting, immediately after paragraph (2), the following paragraph:

"(3) For the purpose of determining the health risk posed to an end user of a medical device under paragraph (2)(*b*), the Authority is to have regard to —

(*a*) the general criteria for risk classification of medical devices in Part II of the Third Schedule; and

(*b*) the risk classification rules for medical devices set out on the Authority's website.".

Deletion and substitution of regulation 25

25. Regulation 25 of the principal Regulations is deleted and the following regulation substituted therefor:

"**Requirements for registration**

25. For the purposes of section 30(2)(*a*)(iii) of the Act, the Authority may, after carrying out an evaluation under section 33 of the Act, register a medical device if the Authority is satisfied —

(*a*) that the overall intended benefits to an end user of the medical device outweigh the overall risks associated with the use of the medical device; and

(*b*) based on the conformity of the medical device with the safety and performance requirements for the medical device set out on the Authority's website, that the medical device is suitable for its intended purpose and that any risk associated with its use is minimised.".

Amendment of regulation 26

26. Regulation 26 of the principal Regulations is amended —

(*a*) by deleting the words "A medical device, not being a Class D medical device," in paragraph (3) and substituting the words "A Class C medical device";

(*b*) by inserting, immediately after paragraph (4), the following paragraphs:

"(4A) Despite paragraph (4), the Authority may immediately register a Class B medical device, or a Class B or C medical device that is a standalone mobile application, 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.

(4B) In paragraph (4A), "standalone mobile application" means software that is designed solely for use with a mobile computing device, and which is intended to be used to control or affect the operation of another medical device that is software.";

(*c*) by deleting paragraph (5A); and

(*d*) by inserting, immediately after the words "paragraph (4)" in the definition of "reference regulatory agency" in paragraph (6), the words "or (4A)".

New regulation 27

27. The principal Regulations are amended by inserting, immediately after regulation 26, the following regulation:

"**Disclosure of information on applications for registration**

27. For the purposes of section 66(2)(*d*) of the Act, the Authority may from time to time disclose, for the information of the public and in the manner determined by the Authority, such particulars of applications for the registration of medical devices which it receives as it may determine, provided that the particulars to be disclosed under this regulation exclude —

(*a*) any trade secret; and

(*b*) any information that has commercial value that would be, or would likely be, diminished by the disclosure.".

Amendment of regulation 31

28. Regulation 31 of the principal Regulations is amended by deleting paragraph (3) and substituting the following paragraphs:

"(3) An enforcement officer conducting an inspection under paragraph (2) may —

(*a*) require the person having possession or control of any medical device that is found during the inspection —

(i) to furnish, without charge, a sample of the medical device for the Authority's examination; or

(ii) to send, at the person's own cost, a sample of the medical device to a testing laboratory approved by the Authority to carry out such tests as the Authority may require within the time specified by the Authority or, if no time is specified, within a reasonable time; and

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

(i) the premises or conveyance mentioned in paragraph (2); or

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

(3A) Where a person having possession or control of a medical device is required to send a sample of the medical device for testing under paragraph (3)(*a*)(ii), the person must furnish a copy of the results of the test to the Authority within such time as the Authority may specify.".

Deletion and substitution of regulations 33, 34 and 35

29. Regulations 33, 34 and 35 of the principal Regulations are deleted and the following regulations substituted therefor:

"**Duty of manufacturer**

33. Despite any other provision in this Part, a manufacturer of a medical device —

(*a*) must ensure, and maintain objective evidence to establish, that the medical device complies with the safety and performance requirements for the medical device set out on the Authority's website;

(*b*) must 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 manufacturer's ownership, possession or control;

(*c*) if the manufacturer is the holder of a manufacturer's licence for the medical device —

(i) must ensure, and maintain objective evidence to establish, that the manufacture of the medical device complies with the requirements of ISO 13485;

(ii) must provide and maintain such staff, premises, equipment and facilities as are necessary for carrying out, in accordance with the licence, the manufacture of the medical device;

(iii) must not carry out the manufacture of the medical device in any premises other than the premises specified in the licence;

(iv) must not use, for the purposes of handling or storing the medical device, any premises other than the premises specified in the licence, or any other premises that the Authority may approve from time to time;

(v) must arrange, at the manufacturer's own cost, for a testing laboratory approved by the Authority to carry out such tests as are necessary to ensure the safety, quality and performance of the medical device, and that the medical device complies with the safety and performance requirements for the medical device mentioned in paragraph (*a*); and

(vi) must, if the Authority requires in writing, furnish a copy of the results of the tests mentioned in sub-paragraph (v) to the Authority within such time as the Authority may specify; and

(*d*) must 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.

Duty of importer

34.—(1) Despite any other provision in this Part, an importer of a medical device —

(*a*) must ensure, and maintain objective evidence to establish, that the medical device complies with the safety and performance requirements for the medical device set out on the Authority's website;

(*b*) must 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 importer's ownership, possession or control;

(*c*) if the importer is the holder of an importer's licence for the medical device —

(i) must, if required under these Regulations, ensure, and maintain objective evidence to establish that, the handling and storage of the medical device complies with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485; and

(ii) must not use, for any purpose mentioned in sub-paragraph (*b*), any premises other than the premises specified in the licence, or any other premises that the Authority may approve from time to time; and

(*d*) must import only medical devices that are authorised to be imported by —

(i) the registrant of the medical device;

(ii) the product owner of the medical device; or

(iii) any other person approved by the Authority.

(2) Paragraph (1)(*d*) does not apply to the import of any medical device in accordance with regulation 4C.

Duty of wholesaler

35. Despite any other provision in this Part, a wholesaler of a medical device —

(*a*) must supply the medical device by wholesale only to a person who may lawfully supply such medical devices in accordance with the Act and these Regulations;

(*b*) must 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 wholesaler's ownership, possession or control; and

(*c*) if the wholesaler is the holder of a wholesaler's licence for the medical device —

(i) must, if required under these Regulations, ensure, and maintain objective evidence to establish, that the handling, storage and distribution of the medical device complies with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485; and

(ii) must not use, for any purpose mentioned in paragraph (*b*), any premises other than the premises specified in the licence, or any other premises that the Authority may approve from time to time.".

Amendment of regulation 36

30. Regulation 36 of the principal Regulations is amended —

(*a*) by deleting the words "the First Schedule" and substituting the words "the safety and performance requirements for the medical device set out on the Authority's website"; and

(*b*) by deleting the words “First Schedule” in the regulation heading and substituting the words “safety and performance requirements”.

Amendment of regulation 39

31. Regulation 39 of the principal Regulations is amended by deleting paragraph (1) and substituting the following paragraphs:

“(1) A person who —

(*a*) is a manufacturer, an importer, a wholesaler or a registrant of a medical device;

(*b*) manufactures a medical device without holding a manufacturer’s licence under section 12(1) of the Act in accordance with regulation 3;

(*c*) supplies a custom-made medical device or laboratory-developed test that is an unregistered medical device in accordance with regulation 6;

(*d*) supplies a refurbished medical device mentioned in regulation 7 as in force immediately before [1 June 2018]; or

(*e*) supplies an unregistered medical device in accordance with regulation 7, 8, 9, 10 or 11,

must comply with the requirements in paragraph (1A).

(1A) The requirements mentioned in paragraph (1) are —

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

(*b*) to produce the record mentioned in sub-paragraph (*a*) for inspection by the Authority or an enforcement officer as and when the Authority or enforcement officer requires.

(1B) In paragraph (1)(*d*), “refurbished medical device” has the same meaning as in regulation 2 as in force immediately before [1 June 2018].”.

Amendment of regulation 40

32. Regulation 40(1) of the principal Regulations is amended —

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

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

"(*e*) the name of the manufacturer, product owner or supplier of the implantable medical device;

(*f*) the model number or catalogue number of the implantable medical device.".

Amendment of regulation 41

33. Regulation 41 of the principal Regulations is amended by deleting paragraph (1) and substituting the following paragraphs:

"(1) A person who —

(*a*) is a manufacturer, an importer, a wholesaler or a registrant of a medical device;

(*b*) manufactures a medical device without holding a manufacturer's licence under section 12(1) of the Act in accordance with regulation 3;

(*c*) supplies a custom-made medical device or laboratory-developed test that is an unregistered medical device in accordance with regulation 6;

(*d*) supplies a refurbished medical device mentioned in regulation 7 as in force immediately before [1 June 2018]; or

(*e*) supplies an unregistered medical device in accordance with regulation 7, 8, 9, 10 or 11,

must comply with the requirements in paragraph (1A).

(1A) The requirements mentioned in paragraph (1) are —

(*a*) to maintain a record of every complaint received by the person pertaining to the medical device; and

(*b*) produce the record mentioned in sub-paragraph (*a*) for inspection by the Authority or an enforcement officer as and when the Authority or enforcement officer requires.

(1B) In paragraph (1)(*d*), "refurbished medical device" has the same meaning as in regulation 2 as in force immediately before [1 June 2018].".

Amendment of regulation 45

34. Regulation 45 of the principal Regulations is amended —

(*a*) by deleting paragraph (1) and substituting the following paragraph:

"(1) Every manufacturer, importer, supplier or registrant of a medical device who recalls the medical device must furnish to the Authority a report on the recall no later than the 21st day after the date of the commencement of the recall, or such longer period as the Authority may allow in the particular case."; and

(*b*) by deleting the words "preliminary report and final" in paragraph (2).

Amendment of regulation 47

35. Regulation 47 of the principal Regulations is amended —

(*a*) by deleting paragraph (1) and substituting the following paragraph:

"(1) Every manufacturer, importer, supplier or registrant of a medical device who carries out any field safety corrective action in relation to the medical device must furnish to the Authority a report on the field safety corrective action no later than the 21st day after the date of the commencement of the field safety corrective action, or such longer period as the Authority may allow in the particular case."; and

(*b*) by deleting the words "preliminary report and final" in paragraph (2).

Amendment of regulation 48

36. Regulation 48(2) of the principal Regulations is amended by inserting, immediately after the words "Fourth Schedule" in paragraph (*d*), the words "(if any)".

Amendment of regulation 49

37. Regulation 49 of the principal Regulations is amended —

(*a*) by deleting the words "The registrant of a registered medical device shall notify" in paragraph (1) and substituting the words "A registrant of a registered medical device must, unless the change is of a type specified on the Authority's website to be one for which the Authority's approval is not required, obtain prior approval from the Authority before effecting";

(*b*) by deleting the words "A notification" in paragraph (2) and substituting the words "An application for the Authority's approval";

(*c*) by deleting the word "notification" in paragraph (2)(*d*); and

(*d*) by deleting paragraph (4).

Amendment of regulation 50

38. Regulation 50 of the principal Regulations is amended —

(*a*) by inserting, immediately after paragraph (2), the following paragraph:

"(2A) An evaluation fee for the registration of a medical device specified in the Fourth Schedule is payable upon the Authority's acceptance of the medical device for evaluation after the Authority has conducted an initial screening."; and

(*b*) by inserting, immediately after paragraph (3), the following paragraph:

"(3A) For the purposes of section 37(2) of the Act, the Authority may cancel the registration of a medical device if the retention fee is not paid within 60 days after the anniversary of the date of the registration of the medical device.".

New regulation 51A

39. The principal Regulations are amended by inserting, immediately after regulation 51, the following regulation:

"**Confidential information**

51A. For the purposes of section 66(2)(*d*) of the Act, the Authority may disclose any confidential information relating to the quality, safety or efficacy of a medical device, if —

(*a*) the disclosure is, in the opinion of the Authority, necessary to protect the health or safety of members of the public; or

(*b*) the disclosure is to a Government department or statutory body in order to enable the Government department or statutory body to perform its public functions.".

Deletion of First Schedule

40. The First Schedule to the principal Regulations is deleted.

Amendment of Third Schedule

41. Part II of the Third Schedule to the principal Regulations is deleted and the following Part substituted therefor:

"PART II

GENERAL CRITERIA FOR RISK CLASSIFICATION OF MEDICAL DEVICES

Division 1 — Medical devices other than in vitro diagnostic products

Definitions

2. In this Division —

"active diagnostic medical device" means an active medical device used, whether alone or in combination with any other medical device, to supply information for detecting, diagnosing or monitoring, or to provide support in the treatment of, any physiological condition, state of health, illness or congenital deformity;

"active therapeutic medical device" means an active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap;

"invasive medical device" means a medical device which, in whole or in part, penetrates inside a human body, either through a body orifice or through the surface of the body;

"long-term use", in relation to a medical device, means continuous use of the medical device for a period exceeding 30 days;

"non-invasive medical device" means a medical device other than an invasive medical device;

"short-term use", in relation to a medical device, means continuous use of the medical device for a period of between 60 minutes and 30 days;

"surgically invasive medical device" means an invasive medical device which penetrates into the body —

(*a*) through the surface of the body, with the aid or in the context of a surgical operation; or

(*b*) other than through a body orifice;

"transient use", in relation to a medical device, means continuous use of the medical device for a period not exceeding 60 minutes.

3. The general criteria for risk classification of medical devices, other than *in vitro* diagnostic products, are —

(*a*) the intended use, as identified by the product owner, of the medical device;

(*b*) the level of risk posed to users and other persons by or in relation to the use of the medical device;

(*c*) whether the medical device is an invasive medical device, a non-invasive medical device or a surgically invasive medical device;

(*d*) whether the medical device is for long-term use, short-term use or transient use;

(*e*) whether or not the medical device is an active medical device;

(*f*) where the medical device is an active medical device, whether the medical device is an active diagnostic medical device, active therapeutic medical device or active medical device used for administering or removing therapeutic products or medicinal products;

(*g*) whether the medical device incorporates, as an integral part, a substance that is liable to act on a human body with an action ancillary to that of the medical device, and the substance is —

(i) a therapeutic product; or

(ii) a medicinal product subject to the licensing requirements of section 5 or 6 of the Medicines Act (Cap. 176);

(*h*) whether the medical device is manufactured from or incorporates —

(i) any, or any combination of —

(A) cells or tissues of animal origin; or

(B) derivatives of cells or tissues of animal or human origin,

which are or have been rendered non-viable; or

(ii) any, or any combination of, cells, tissues or derivatives of cells or tissues of recombinant origin;

(*i*) whether the medical device is used for the sterilisation or disinfection of another medical device; and

(*j*) whether the medical device is used for contraception or the prevention of the transmission of a sexually transmitted disease.

Division 2 — In vitro diagnostic products

4. The general criteria for risk classification of medical devices that are *in vitro* diagnostic products are —

(*a*) the intended use, as identified by the product owner, of the medical device;

(*b*) the intended user, as identified by the product owner, of the medical device; and

(*c*) the significance, in relation to the diagnosis or treatment of a patient or foetus or to public health, of the information provided by or derived from the use of the medical device.".

Amendment of Fifth Schedule

42. The Fifth Schedule to the principal Regulations is amended by deleting items 4 and 5 and substituting the following items:

"4. All orthopaedic joint replacement implants.

5. The following neurological implantable devices:

(*a*) neurological stents;

(*b*) neurological implants;

(*c*) implantable neurostimulation devices and leads.

6. Breast implant.

7. Intraocular lens.

8. Cardiovascular stent in contact with the central circulatory system, including the following major internal blood vessels:

(*a*) *aorta abdominalis*;

(*b*) *aorta ascendens*;

(*c*) *aorta descendens* to the *bifurcatio aortae*;

(*d*) *aorta thoracica*;

(*e*) *arcus aorta*;

(*f*) *arteria carotis communis*;

(*g*) *arteria carotis externa*;

(*h*) *arteria carotis interna*;

(*i*) *arteriae cerebrates*;

(*j*) *arteriae coronariae*;

(*k*) *arteriae pulmonales*;

(*l*) *ilica communis*;

(*m*) *truncus brachiocephalicus*;

(*n*) *venae cava inferior*;

(*o*) *venae cava superior*;

(*p*) *venae cordis*;

(*q*) *venae pulmonales*.".

[G.N. Nos. S 542/2011; S 140/2012; S 169/2012; S 370/2012; S 426/2012; S 646/2012; S 334/2016; S 538/2016; S 444/2017]

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