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HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS 2010

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Regulation

In exercise of the powers conferred by sections 45, 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:

PART I

PRELIMINARY

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) Regulations 2010 and shall come into operation on 10th August 2010.

Definitions

2. In these Regulations, unless the context otherwise requires —

"active implantable medical device" means any active medical device that is intended by its product owner —

(*a*) to be introduced, either —

(i) by surgical or medical intervention, wholly or partially into the body of a human being; or

(ii) by medical intervention, into a body orifice; and

(*b*) to remain in place after the procedure;

"active medical device" means any medical device —

(*a*) the operation of which depends on a source of electrical energy or any source of power other than that directly generated by a human body or gravity; and

(*b*) which acts by converting that energy,

but does not include any medical device intended to transmit any energy, substance or other element between that medical device and a patient without any significant change to that energy, substance or element;

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

[S 334/2016 wef 01/11/2016]

"body orifice" means any natural opening in a human body, the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy;

"clinical purpose" means any of the specific purposes described in paragraph (*a*) of the definition of "Medical device" in the second column of item 1 of the First Schedule to the Act;

[S 334/2016 wef 01/11/2016]

[S 318/2018 wef 01/06/2018]

"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);

[S 334/2016 wef 01/11/2016]

"custom-made medical device" means a medical device that —

(*a*) is made at the request of a qualified practitioner and in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device;

(*b*) is intended to be used only in relation to a particular individual; and

(*c*) is not adapted from a mass-produced medical device;

"Fees Regulations" means the Health Products (Fees) Regulations 2022 (G.N. No. S 450/2022);

[S 456/2022 wef 01/07/2022]

"field safety corrective action" means any action taken to reduce the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device, including —

(*a*) the return of the medical device to its product owner;

(*b*) the replacement or destruction of the medical device;

(*c*) any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;

(*d*) the clinical management of any patient who has used the medical device;

(*e*) the modification of the medical device;

(*f*) the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;

(*g*) the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or

(*h*) any upgrade to any software used with the medical device, including any such upgrade carried out by remote access;

"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;

[S 318/2018 wef 01/06/2018]

"harm" means any physical injury or damage to the health of a person, or any damage to property or the environment;

"hazard" means any potential source of harm;

"implantable medical device" means any medical device which is intended by its product owner —

(*a*) to be wholly introduced into a human body, or to replace a human epithelial surface or the surface of a human eye, by surgical intervention, and to remain in place after the surgical intervention; or

(*b*) to be partially introduced into a human body by surgical intervention, and to remain in place for at least 30 days after the surgical intervention,

and includes any such medical device that is wholly or partially absorbed by the human body, epithelial surface or eye;

"*in vitro* diagnostic product" —

(*a*) means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used *in vitro* for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information —

(i) concerning a physiological or pathological state or a congenital abnormality;

(ii) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or

(iii) to monitor therapeutic measures; and

(*b*) includes a specimen receptacle;

"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 comes into operation, is appointed under that Act;

[S 334/2016 wef 01/11/2016]

[S 434/2023 wef 31/12/2021]

"intended use" or "intended purpose" , in relation to a medical device or its process or service, means the objective intended use or purpose, as the case may be, of the medical device, process or service, as reflected in the specifications, instructions and information provided by the product owner of the medical device;

"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;

[S 318/2018 wef 01/06/2018]

"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;

[S 318/2018 wef 01/06/2018]

"licensee" means a holder of any licence issued by the Authority under the Act;

"medical device" means a medical device referred to in the First Schedule to the Act;

"medicinal product" has the same meaning as in section 3 of the Medicines Act 1975;

[S 434/2023 wef 31/12/2021]

"non-viable", in relation to a biological entity, means that the entity is incapable of growth, development and reproduction;

"objective evidence" means information that can be proved to be true, based on facts obtained through observation, measurement, testing or any other means;

"product owner", in relation to a health product, means a person who —

(*a*) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(*b*) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf;

""professional use only" medical device" means a medical device that is to be used on an individual solely by, or under the supervision of, a qualified practitioner;

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act 1997, when acting in the course of providing medical treatment to a patient under his care; or

[S 434/2023 wef 31/12/2021]

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act, when acting in the course of providing dental treatment to a patient under his care;

[*Deleted by S 318/2018 wef 01/06/2018*]

"registered midwife" has the same meaning as in section 2 of the Nurses and Midwives Act 1999;

[S 434/2023 wef 31/12/2021]

"registered nurse" has the same meaning as in section 2 of the Nurses and Midwives Act 1999;

[S 434/2023 wef 31/12/2021]

"registered pharmacist" has the same meaning as in section 2 of the Pharmacists Registration Act 2007;

[S 434/2023 wef 31/12/2021]

"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);

[S 334/2016 wef 01/11/2016]

"risk" means a combination of the probability of occurrence of harm and the severity of that harm;

"serious deterioration in the state of health", in relation to a person, means —

(*a*) a life-threatening illness or injury suffered by that person;

(*b*) a permanent impairment of a bodily function of that person;

(*c*) any permanent damage to any part of that person's body; or

(*d*) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage;

"specimen" means a discrete portion of a body fluid or tissue, or of any other sample associated with a human body, which is taken for —

(*a*) examination;

(*b*) study; or

(*c*) analysis of one or more quantities or characteristics, in order to determine the character of the whole;

"specimen receptacle" means any receptacle, whether vacuum-type or not, intended by its product owner to be used for the primary containment of any specimen derived from a human body;

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

[S 334/2016 wef 01/11/2016]

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

[S 169/2012 wef 01/05/2012]

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act;

[S 538/2016 wef 01/11/2016]

"trade description" means any description, statement or indication which, directly or indirectly and by whatever means given, relates to any of the following matters in respect of a medical device:

(*a*) the quantity, length, width, height, area, volume, capacity or weight of the medical device;

(*b*) the method of manufacture, production, processing, modification, refurbishment or reconditioning of the medical device;

(*c*) the components or composition of the medical device;

(*d*) the fitness for purpose (including expiry date), strength, performance, behaviour or accuracy of the medical device;

(*e*) any physical or other characteristics of the medical device not referred to in paragraphs (*a*) to (*d*);

(*f*) the testing of the medical device by any person and the results thereof;

(*g*) the approval of the medical device by any person or its conformity with a description or class of medical devices approved by any person;

(*h*) the place or date of the manufacture, production, processing, modification, refurbishment or reconditioning of the medical device;

(i) the name of the person who manufactured, produced, processed, modified, refurbished or reconditioned the medical device;

(*j*) any other history, including any history of previous ownership or use, of the medical device;

[S 318/2018 wef 01/06/2018]

""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.

[S 318/2018 wef 01/06/2018]

PART IA

MANUFACTURE AND IMPORT OF MEDICAL DEVICES

[S 318/2018 wef 01/06/2018]

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.

[S 318/2018 wef 01/06/2018]

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, any of the following persons in accordance with regulation 8:

(A) a qualified practitioner;

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

[S 1080/2021 wef 03/01/2022]

(C) a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service;

[S 1080/2021 wef 03/01/2022]

[S 1080/2021 wef 03/01/2022]

(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, any of the following persons in accordance with regulation 8:

(A) a qualified practitioner;

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

[S 1080/2021 wef 03/01/2022]

(C) a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service;

[S 1080/2021 wef 03/01/2022]

[S 1080/2021 wef 03/01/2022]

(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 (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;

[S 434/2023 wef 31/12/2021]

(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 (O 2) or any other written law for the treatment of persons on board the aircraft;

[S 434/2023 wef 31/12/2021]

(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.

[S 318/2018 wef 01/06/2018]

PART II

MANUFACTURE AND IMPORT OF MEDICAL DEVICES WITHOUT LICENCE

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.

[S 318/2018 wef 01/06/2018]

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.

[S 334/2016 wef 01/11/2016]

Manufacture of laboratory-developed tests

3B.—(1) A person licensed under the Healthcare Services Act 2020 to provide any of the following licensable healthcare services 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 provision of that licensable healthcare service:

(*a*) a clinical laboratory service;

(*b*) a nuclear medicine assay service;

(*c*) a blood banking service;

(*d*) a cord blood banking service.

[S 1080/2021 wef 03/01/2022]

(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.

[S 318/2018 wef 01/06/2018]

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.

[S 318/2018 wef 01/06/2018]

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;

(*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.

[S 318/2018 wef 01/06/2018]

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.

[S 426/2012 wef 01/09/2012]

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 2007; and

[S 434/2023 wef 31/12/2021]

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

[S 318/2018 wef 01/06/2018]

[S 334/2016 wef 01/11/2016]

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 1975 before 1 November 2016 for the import on or after that date.

[S 334/2016 wef 01/11/2016]

[S 434/2023 wef 31/12/2021]

PART III

SUPPLY OF MEDICAL DEVICES

Division 1 — Wholesale supply

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).

[S 318/2018 wef 01/06/2018]

Wholesaling of self-manufactured medical devices

5. A licensed manufacturer who manufactures a medical device may supply that medical device by wholesale without holding a wholesaler's licence under section 14(1) of the Act.

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 2007 for that activity; and

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

[S 318/2018 wef 01/06/2018]

[S 334/2016 wef 01/11/2016]

Wholesaling of medical device for use in clinical research

5B.—(1) 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*) subject to paragraph (2), 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.

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

Division 2 — Unregistered medical devices

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.

[S 318/2018 wef 01/06/2018]

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.

[S 318/2018 wef 01/06/2018]

Exception for medical devices for patients' use

8.—(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 an unregistered medical device by or on behalf of, or procured by or on behalf of —

(*a*) a qualified practitioner for the use of a patient of that qualified practitioner;

[S 1080/2021 wef 03/01/2022]

(*b*) a private hospital or medical clinic licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) for the use of a patient of that private hospital or medical clinic;

[S 1080/2021 wef 03/01/2022]

(*c*) a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service, for the use of a patient of that person,

[S 1080/2021 wef 03/01/2022]

if paragraph (2) or (3) is satisfied.

[S 318/2018 wef 01/06/2018]

(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.

[S 318/2018 wef 01/06/2018]

(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.

[S 318/2018 wef 01/06/2018]

Exception for export or re-export

9. 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 that is manufactured solely for export or that is imported solely for re-export, if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for the purpose of export or re-export only.

Exception for non-clinical use

10.—(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 medical device that is imported, supplied or used for a non-clinical purpose, if the requirements in paragraph (1A) are satisfied.

[S 318/2018 wef 01/06/2018]

(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.

[S 318/2018 wef 01/06/2018]

(2) In paragraph (1), "non-clinical purpose" means any purpose other than a purpose described in paragraph (*a*) of the definition of "Medical device" in the second column of item 1 of the First Schedule to the Act.

[S 318/2018 wef 01/06/2018]

Exception for clinical research

10A.—(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 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*) subject to paragraph (2), 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.

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

Exception for Class A medical devices

10B.—(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.

[S 318/2018 wef 01/06/2018]

(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.

[S 169/2012 wef 01/05/2012]

[S 318/2018 wef 01/06/2018]

Exceptions for phased implementation of prohibition

11.—(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 —

(*a*) the supply no later than 31st December 2011 of an unregistered Class A or B medical device —

(i) which is not an implantable medical device;

(ii) which is not, or cannot be, licensed as a medicinal product under the Medicines Act 1975 before 10th August 2010; and

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(iii) in respect of which the Authority does not at any time receive any information concerning, and does not at any time become aware of, any defect or adverse effect under section 42(2) of the Act;

(*b*) the supply on or after 1st January 2012, but before 1st June 2018, of an unregistered Class A or B medical device (but not an unregistered Class A medical device supplied on or after 1st May 2012 in accordance with the requirements specified in regulation 10B) —

(i) which is listed on the Class A or B Medical Device Transition List as published on the Authority's website on or before 1st January 2012;

(ii) which qualifies for evaluation under an abridged evaluation process referred to in regulation 26;

(iii) which is not, or cannot be, licensed as a medicinal product under the Medicines Act 1975 before 10th August 2010;

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(iv) which complies with the First Schedule as in force immediately before 1 June 2018;

[S 318/2018 wef 01/06/2018]

(v) in respect of which the Authority does not at any time receive any information concerning, and does not at any time become aware of, any defect or adverse effect under section 42(2) of the Act; and

(vi) in respect of which the Authority receives, before 1st December 2011, and does not at any time reject, an application for registration as a Class A or B medical device;

[S 140/2012 wef 05/04/2012]

[S 169/2012 wef 01/05/2012]

[S 318/2018 wef 01/06/2018]

(*c*) the supply no later than 31st July 2011 of an unregistered Class C or D medical device —

(i) which is not an implantable medical device; and

(ii) in respect of which a licence to deal with the medical device has been granted under section 6 or 7 of the Radiation Protection Act 2007 and has not expired;

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(*d*) the supply at any time of an unregistered Class C or D medical device —

(i) which is listed on the Class C or D Medical Device Transition List as published on the Authority's website on or before 10th August 2010;

(ii) which qualifies for evaluation under an abridged evaluation process referred to in regulation 26;

(iii) which, if it is an implantable medical device, has been approved, before 1st January 2011, by at least 2

competent regulatory agencies referred to in regulation 26;

(iv) which complies with the First Schedule as in force immediately before 1 June 2018;

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(v) in respect of which the Authority does not at any time receive any information concerning, and does not at any time become aware of, any defect or adverse effect under section 42(2) of the Act; and

(vi) in respect of which the Authority receives, and does not at any time reject, an application for registration as a Class C or D medical device;

[S 140/2012 wef 05/04/2012]

(*e*) the retail supply, at any time, by a retail supplier of an unregistered medical device that the retail supplier has taken possession of before 10th August 2010;

[S 140/2012 wef 05/04/2012]

[S 426/2012 wef 01/09/2012]

(*f*) the retail supply, at any time, by a retail supplier of an unregistered Class A or B medical device that the retail supplier has taken possession of on or after 10th August 2010 but before 5th April 2012;

[S 140/2012 wef 05/04/2012]

[S 426/2012 wef 01/09/2012]

(*g*) the supply on or after 1st September 2012, but before 1st June 2018, 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

[S 426/2012 wef 01/09/2012]

[S 318/2018 wef 01/06/2018]

(*h*) the supply on or after 1st September 2012, but before 1st June 2018, 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.

[S 426/2012 wef 01/09/2012]

[S 318/2018 wef 01/06/2018]

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

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.

[S 318/2018 wef 01/06/2018]

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).

[S 318/2018 wef 01/06/2018]

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 the 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.

[S 318/2018 wef 01/06/2018]

Division 3 — Requirements for supply

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.

[S 318/2018 wef 01/06/2018]

Supply of "professional use only" medical devices

13.—(1) For the purposes of section 17(1) of the Act —

(*a*) no licensed wholesaler of medical devices shall supply any "professional use only" medical device to any person who intends to supply that medical device to others unless that person is —

(i) also a licensed wholesaler of medical devices; or

(ii) a qualified practitioner; and

[S 318/2018 wef 01/06/2018]

(*b*) no person shall supply, by way of administration or application to any other person, any "professional use only" medical device, unless the person administering or applying the medical device is, or acts under the supervision of, a qualified practitioner.

[S 318/2018 wef 01/06/2018]

[S 318/2018 wef 01/06/2018]

(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.

[S 318/2018 wef 01/06/2018]

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.

[S 334/2016 wef 01/11/2016]

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*.

[S 318/2018 wef 01/06/2018]

PART IIIA

EXCEPTION — EMERGENCY MEDICAL DEVICES

[S 968/2020 wef 01/12/2020]

Manufacture, import and supply of emergency medical devices

13C.—(1) For the purposes of section 12(1) of the Act and without prejudice to regulations 33, 38, 39, 41, 42, 44, 45, 46 and 47, the manufacture of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the manufacture of a medical device without a licence.

(2) For the purposes of section 13(1) of the Act and without prejudice to regulations 34, 39, 41, 42, 44, 45, 46 and 47, the import of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the import of a medical device without a licence.

(3) For the purposes of section 14(1) of the Act and without prejudice to regulations 31, 35, 39, 41, 42, 44, 45, 46 and 47, the supply by wholesale of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply by wholesale of a medical device without a licence.

(4) For the purposes of section 15(1) of the Act and without prejudice to regulations 31, 35, 39, 42, 44, 45, 46 and 47, the supply of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply of a medical device that is not registered.

(5) In this regulation —

"civil defence emergency" means a civil defence emergency declared under section 102(1) of the Civil Defence Act 1986;

[S 434/2023 wef 31/12/2021]

"emergency medical device" means a medical device that is for such time designated by the Minister as an emergency medical device for the purposes of this regulation, where —

(*a*) the medical device is needed —

(i) to treat or diagnose any medical condition resulting from a civil defence emergency;

(ii) to prevent the spread or possible outbreak of an infectious disease; or

(iii) to treat or diagnose an infectious disease or any medical condition associated with an infectious disease,

where the medical condition or infectious disease is potentially serious or life-threatening; and

(*b*) in the opinion of the Authority, there is —

(i) preliminary scientific evidence that the medical device has the potential —

(A) to treat or diagnose the medical condition resulting from the civil defence emergency;

(B) to prevent the spread or possible outbreak of the infectious disease; or

(C) to treat or diagnose the infectious disease or any medical condition associated with the infectious disease,

as the case may be; and

(ii) ongoing scientific evidence that the potential benefits of the medical device outweigh the known risks of the medical device, to a person on whom the medical device is used;

"infectious disease" has the meaning given by section 2 of the Infectious Diseases Act 1976.

[S 968/2020 wef 01/12/2020]

[S 434/2023 wef 31/12/2021]

PART IV

PRESENTATION OF MEDICAL DEVICES

Trade descriptions

14.—(1) For the purposes of section 18(1) of the Act, the presentation of a medical device shall comply with the following requirements:

(*a*) no trade description which is false or misleading, or which explicitly or implicitly suggests that the supply or use of the medical device is promoted or endorsed by the Authority, shall be applied to the medical device; and

(*b*) no change or modification made, or caused to be made, to the presentation of the medical device, for the purpose of promoting or demonstrating the use of the medical device, shall cause the medical device to depart from its product owner's specifications in relation to its intended purpose, design, components and method of installation or operation.

(2) For the purposes of paragraph (1)(*a*) —

(*a*) a trade description is false or misleading, if it —

(i) contains any false statement or information concerning the medical device; or

(ii) is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the medical device; and

(*b*) a person applies a trade description to a medical device, if he —

(i) affixes or annexes the trade description to, or in any manner marks it on or incorporates it in —

(A) the medical device; or

(B) any thing in or on the medical device or with which the medical device is supplied;

(ii) places the medical device in, on or with any thing which the trade description has been affixed or annexed to, marked on or incorporated in; or

(iii) makes any oral or written statement of the trade description, or uses the trade description in any other manner, which is likely to be understood as referring to the medical device.

(3) Where a medical device is supplied pursuant to a request in which a trade description is used, and it is reasonable in the circumstances to infer that any medical device so supplied will correspond to that trade description, the person supplying the medical device shall be deemed to have applied that trade description to the medical device.

Information to be provided with medical devices

15.—(1) For the purposes of section 18(1) of the Act, no person shall supply any medical device unless the following information accompanies the medical device when it is supplied:

(*a*) the trade or brand name of the medical device;

(*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;

[S 318/2018 wef 01/06/2018]

(*c*) [*Deleted by S 318/2018 wef 01/06/2018*]

(*d*) where the medical device is contained in a package and the contents of the package are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the medical device, such as the size, net weight, length, volume or number of units;

(*e*) the expiry date of the medical device, if the medical device has one, as determined by the product owner of the medical device on the basis of the component of the medical device that has the shortest projected useful life;

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

General provisions as to labelling

16.—(1) The Authority may stipulate —

(*a*) under section 24(5) of the Act, in the conditions attached to a licence in respect of a medical device; or

(*b*) under section 32 of the Act, in the conditions attached to the registration of a medical device,

a requirement to use a label, sticker or packaging insert or any other means for presenting any information accompanying the medical device.

(2) All information on the label of a medical device shall be provided in English, and may, in addition, be provided in any other language.

(3) All numbers, letters and symbols used to provide any information on the label of a medical device shall be legible, permanent and prominent in colour, size and positioning.

(4) If a symbol or code (whether in the form of a colour or otherwise) is used to provide any information on the label of a medical device, an explanation of the symbol or code shall be provided.

Substantiation of assertions of uniqueness and prominence in presentations

17.—(1) For the purposes of section 18(1) of the Act, where the presentation of a medical device includes any trade description containing any statement, assertion, certification, award or feature of

uniqueness or prominence differentiating the medical device from any other competing or similar medical device, the statement, assertion, certification, award or feature must be substantiated by facts or evidence.

(2) For the purposes of paragraph (1), the facts or evidence required for substantiation include —

(*a*) in relation to a certification or an award, the identity of the certifying or awarding body and the date the certification or award was granted; and

(*b*) in relation to any claim of historical precedence in the use or administration of the medical device for the purpose of medical treatment, information on the outcome of that use or administration of the medical device.

Corrective measures in relation to contravening trade descriptions

18.—(1) Where any manufacturer, importer, supplier or registrant of a medical device has applied a trade description in contravention of regulation 14 or 17, the Authority may order that manufacturer, importer, supplier or registrant, as the case may be, to do any or all of the following at the manufacturer's, importer's, supplier's or registrant's own cost:

(*a*) to stop the trade description with immediate effect;

(*b*) to take such measures as may be reasonable and necessary in the circumstances to discontinue or remove any trade description that may already have been disseminated, used or published;

(*c*) to disseminate, apply or publish a corrective trade description in such manner and containing such information as the Authority may require.

(2) If a person to whom an order under paragraph (1) is directed fails to comply with the order —

(*a*) he 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; and

(*b*) the Authority may take such steps as it thinks reasonable and necessary to implement the requirements of the order, and recover any costs and expenses reasonably incurred by it in so doing from that person.

PART V

ADVERTISEMENT OF MEDICAL DEVICES

Advertisement of medical device

19. For the purposes of section 21(1) of the Act, an advertisement of any medical device shall comply with the following requirements:

(*a*) if the medical device is intended for direct delivery to the general public or for direct use by the general public, the advertisement shall not contain any statement concerning the intended use and efficacy of the medical device, unless —

(i) such statement has been verified by objective evidence; and

(ii) where the medical device is a registered medical device, the objective evidence mentioned in sub-paragraph (i) has been furnished to the Authority at the time the application to register the medical device was made; and

[S 318/2018 wef 01/06/2018]

(*b*) an advertisement of a medical device —

(i) may, in the case of a registered medical device, include —

(A) a statement to the effect that the medical device is registered under the Act; and

(B) the registration number assigned to the medical device by the Authority; but

(ii) shall not contain any statement which expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the Authority.

Substantiation of assertions of uniqueness and prominence in advertisements

20.—(1) For the purposes of section 21(1) of the Act and without prejudice to regulation 19, where the advertisement of a medical device contains any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the medical device from any other competing or similar medical device, the statement, assertion, certification, award or feature must be substantiated by facts or evidence.

(2) For the purposes of paragraph (1), the facts or evidence required for substantiation include —

(*a*) in relation to a certification or an award, the identity of the certifying or awarding body and the date the certification or award was granted; and

(*b*) in relation to any claim of historical precedence in the use or administration of the medical device for the purpose of medical treatment, information on the outcome of that use or administration of the medical device.

(3) Any facts or evidence referred to in paragraph (2)(*a*) must be indicated on the face of the advertisement.

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.

[S 318/2018 wef 01/06/2018]

Restriction on advertisements promoting medical devices for specified diseases and conditions

22. For the purposes of section 21(1) of the Act and without prejudice to regulation 19, an advertisement relating to a medical device shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any disease or condition specified in the Second Schedule, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, one or more of the following classes of persons:

(*a*) qualified practitioners;

(*b*) registered pharmacists;

(*c*) registered nurses and registered midwives;

(*d*) persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, registered nurses or registered midwives.

Power of Authority to require copies of advertisements

23. For the purposes of section 41(1) of the Act, the Authority may require the manufacturer, importer, supplier or registrant of a medical device to furnish to the Authority, within such time as may be specified in the notice, such number of copies, as may be specified in the notice, of any advertisement relating to any medical device which the manufacturer, importer, supplier or registrant has issued, or has caused to be issued, within the period of 12 months immediately preceding the date the notice is served.

PART VI

REGISTRATION OF MEDICAL DEVICES

Assignment of medical devices into classes

24.—(1) For the purposes of section 29(2)(*a*) of the Act, the classes of medical devices shall be as specified in Part I of the Third Schedule.

[S 318/2018 wef 01/06/2018]

(2) For the purposes of assigning a medical device into a class of medical devices under section 29(2)(*b*) of the Act, the following principles shall apply:

(*a*) the Authority shall have regard to the intended purpose of the medical device;

(*b*) if the medical device may be assigned into 2 or more classes of medical devices, the Authority shall assign the medical device into such of those classes as represents the highest health risk posed to an end-user of the medical device;

(*c*) if the medical device is designed to be used in combination with another medical device, each of the medical devices shall be classified separately;

(*d*) if the medical device has 2 or more intended purposes, the medical device shall, subject to sub-paragraph (*b*), be assigned into a class of medical devices having regard to the most critical intended purpose of the medical device.

(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.

[S 318/2018 wef 01/06/2018]

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.

[S 318/2018 wef 01/06/2018]

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;

[S 444/2017 wef 15/08/2017]

(ii) an expedited abridged evaluation process;

[S 444/2017 wef 15/08/2017]

(iii) a full evaluation process; or

[S 444/2017 wef 15/08/2017]

(iv) a priority full evaluation process; or

[S 444/2017 wef 15/08/2017]

(*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 Class C 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.

[S 646/2012 wef 01/01/2013]

[S 318/2018 wef 01/06/2018]

(3A) A Class D medical device may qualify for evaluation under an expedited abridged evaluation process, 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.

[S 646/2012 wef 01/01/2013]

(3B) A medical device is to be evaluated under a full evaluation process where —

(*a*) the medical device does not qualify for evaluation under an abridged evaluation process mentioned in paragraph (2), for evaluation under an expedited abridged evaluation process mentioned in paragraph (3) or (3A), or for immediate registration under paragraph (4); or

(*b*) despite the medical device qualifying for an abridged evaluation process or expedited abridged evaluation process, an applicant who wishes to register the medical device under section 30 of the Act chooses to subject the medical device to a full evaluation process.

[S 444/2017 wef 15/08/2017]

(3C) A Class B, C or D medical device may qualify for evaluation under a priority full evaluation process if the medical device —

(*a*) is a medical device that is to be evaluated under a full evaluation process mentioned in paragraph (3B); and

(*b*) is, in the Authority's opinion, a novel medical device.

[S 444/2017 wef 15/08/2017]

(3D) Despite paragraph (3C), a Class B, C or D medical device that only satisfies the requirements of paragraph (3C)(*a*) may qualify for a priority full evaluation process if the appropriate fee specified in the Fees Regulations is paid.

[S 444/2017 wef 15/08/2017]

[S 456/2022 wef 01/07/2022]

(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.

(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.

[S 318/2018 wef 01/06/2018]

(5) In paragraph (4A), "standalone mobile application" means software that is designed to be used only with a mobile computing

device, and which is intended to be used to control or affect the operation of —

(*a*) the mobile computing device; or

(*b*) another medical device that is software.

[S 318/2018 wef 01/06/2018]

(5A) [*Deleted by S 318/2018 wef 01/06/2018*]

(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;

"infectious disease" has the same meaning as in the Infectious Diseases Act 1976;

[S 444/2017 wef 15/08/2017]

[S 434/2023 wef 31/12/2021]

"novel medical device" means a medical device that —

(*a*) is intended for the purposes of the diagnosis, prevention, monitoring, treatment or alleviation of diabetes, or any disease in a specified branch of medicine, that has no other means of being diagnosed, prevented, monitored, treated or alleviated; or

(*b*) represents new medical technology, as compared to other registered medical devices, that provides a

clinical advantage for the diagnosis, prevention, monitoring, treatment or alleviation of diabetes, or any disease in a specified branch of medicine;

[S 444/2017 wef 15/08/2017]

"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 (3A) or immediate registration under paragraph (4) or (4A);

[S 646/2012 wef 01/01/2013]

[S 426/2012 wef 01/09/2012]

[S 444/2017 wef 15/08/2017]

[S 318/2018 wef 01/06/2018]

"specified branch of medicine" means any cardiovascular disease, cancer, infectious disease or ophthalmic disease.

[S 444/2017 wef 15/08/2017]

Prescribed time for cancellation of registration of medical device for non-payment of retention fee

26A. For the purposes of section 37(2) of the Act, the prescribed time is 60 days after the anniversary of the date of the registration of the medical device.

[S 456/2022 wef 01/07/2022]

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.

[S 318/2018 wef 01/06/2018]

PART VII

CERTIFICATES

27. [*Deleted by S 426/2012 wef 01/09/2012*]

28. [*Deleted by S 426/2012 wef 01/09/2012*]

29. [*Deleted by S 426/2012 wef 01/09/2012*]

Certification of medical devices intended for export

30.—(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 Fees Regulations, 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.

[S 426/2012 wef 01/09/2012]

[S 456/2022 wef 01/07/2022]

(2) An application for a certificate under paragraph (1) shall be made in such form and manner as the Authority may specify on the Authority's website.

PART VIII

DUTIES AND OBLIGATIONS OF MANUFACTURERS, IMPORTERS, ETC., OF MEDICAL DEVICES

Duty of licensees, suppliers and registrants to comply with enforcement orders

31.—(1) A licensee, supplier or registrant of a medical device shall, if required by the Authority or an enforcement officer —

(*a*) produce his licence or certificate of registration, or such other document as the Authority or enforcement officer may specify for ensuring compliance with the Act, to the Authority or enforcement officer for inspection;

(*b*) furnish the Authority or enforcement officer with such information as the Authority or enforcement officer may require for ensuring compliance with the Act; and

(*c*) attend at such place as the Authority or enforcement officer may specify to produce that licence, certificate or other document or furnish that information.

(2) An enforcement officer may conduct routine inspections of —

(*a*) any premises that are being used for the manufacture, supply or storage of medical devices; and

(*b*) any conveyances that are being used for the transport of medical devices.

(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.

[S 318/2018 wef 01/06/2018]

(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.

[S 318/2018 wef 01/06/2018]

(4) A licensee, supplier or registrant of a medical device whose premises are being used for the manufacture, supply or storage of medical devices, or whose conveyances are being used for the transport of medical devices, shall allow an enforcement officer —

(*a*) to conduct routine inspections of those premises or conveyances; and

(*b*) to take, without payment, for testing, examination or analysis a sample of any medical device that is found pursuant to the inspection.

(5) Any person who contravenes paragraph (1) 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.

Duty to comply with conditions of licence or registration

32.—(1) A manufacturer, importer, supplier or registrant of any medical device shall comply with such conditions, for the grant to the manufacturer, importer, supplier or registrant of any licence in respect of that medical device, or for the registration of that medical device, as the Authority may impose.

(2) 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.

(3) Without prejudice to paragraph (2), the Authority may suspend or cancel the licence or registration, as the case may be, which the Authority has granted to a person, if that person contravenes paragraph (1).

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.

[S 318/2018 wef 01/06/2018]

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.

[S 318/2018 wef 01/06/2018]

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.

[S 318/2018 wef 01/06/2018]

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.

[S 169/2012 wef 01/05/2012]

Duty of registrant to ensure compliance with safety and performance requirements

36. A registrant of a medical device shall 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.

[S 318/2018 wef 01/06/2018]

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.

[S 334/2016 wef 01/11/2016]

Offence for contravention of duties

37. Any person who contravenes regulation 33, 34, 35 or 36 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 manufacture

38.—(1) A manufacturer of a medical device shall maintain records of —

(*a*) such information relating to the medical device and its manufacture or assembly as the Authority may specify; and

(*b*) the manufacture of each batch of the medical device and of the tests carried out thereon, in such manner as the Authority may specify.

(2) The manufacturer shall maintain the records referred to in paragraph (1) for the longer of the following periods:

(*a*) the projected useful life of the medical device; or

(*b*) 2 years after the date on which the medical device is supplied to another person.

(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 he 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 supply

39.—(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).

[S 318/2018 wef 01/06/2018]

(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.

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

(*a*) contains, in relation to each supply by him of the medical device, the following information:

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

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

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

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

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

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

(i) the projected useful life of the medical device; or

(ii) 2 years after the date on which the medical device is supplied to another person.

(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 he 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.

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

[S 334/2016 wef 01/11/2016]

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.

[S 334/2016 wef 01/11/2016]

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.

[S 334/2016 wef 01/11/2016]

Qualified practitioners to maintain records of implantable medical devices

40.—(1) A qualified practitioner who has introduced into the body of a person an implantable medical device listed in the Fifth Schedule shall maintain proper records of the following matters:

(*a*) the name, address and national registration identity card number (if any) of that person;

(*b*) the date on which the implantable medical device was introduced into the body of that person;

(*c*) the name and description of the implantable medical device;

[S 318/2018 wef 01/06/2018]

(*d*) the lot or batch number of the implantable medical device;

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

(2) Any person who contravenes paragraph (1) 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.

(3) Any person who in compliance or purported compliance with paragraph (1) —

(*a*) wilfully makes, or causes to be made, a false entry in any record required to be maintained under that paragraph; or

(*b*) wilfully omits to make an entry required to be made by him in any such record,

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 complaints

41.—(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).

[S 318/2018 wef 01/06/2018]

(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*) 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.

[S 318/2018 wef 01/06/2018]

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

[S 318/2018 wef 01/06/2018]

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

(*a*) contains the following information:

(i) the proprietary name or description of the medical device that is the subject of the complaint;

(ii) the date on which the complaint was received;

(iii) the name and address of the complainant or, if unavailable, a unique identifier for the complaint;

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

(v) the nature of the problem that is the subject of the complaint; and

(*b*) is retained for at least 5 years after the expiry of the projected useful life of the medical device.

(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 he 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.

Reporting of defects and adverse effects

42.—(1) For the purposes of section 42(1) of the Act, every manufacturer, importer, supplier or registrant of a medical device, whether registered or unregistered, shall, upon becoming aware of any defect in the medical device or any adverse effect that has arisen from the use thereof, inform the Authority of the defect or adverse effect within the following time delimited after the manufacturer, importer, supplier or registrant first becomes aware of the defect or adverse effect:

(*a*) within 48 hours, if the information relates to any defect or adverse effect that represents a serious threat to public health;

(*b*) within 10 days, if the information relates to an incident that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person; and

(*c*) within 30 days, if the information relates to an incident a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person.

(2) For the purposes of paragraph (1)(*a*), a defect in, or an adverse effect that has arisen from the use of, a medical device, represents a serious threat to public health if —

(*a*) it is a hazard arising from a systematic failure of the medical device that the manufacturer, importer, wholesaler or registrant of the medical device has become aware of;

(*b*) it may lead to the death of, or a serious injury to, any person;

(*c*) the existence or probable rate of occurrence of, or degree of severity of the harm caused by, the hazard was not

previously known or anticipated by the manufacturer or product owner of the medical device; and

(*d*) it is necessary for the manufacturer or product owner of the medical device to take prompt action (including the recall of the medical device) to eliminate, or reduce the risk of, the hazard.

Reporting of information adversely affecting quality, safety or efficacy of medical device

43.—(1) Every licensee or registrant of a medical device shall, within 15 days after receiving any information which adversely affects the validity of any data furnished by him to the Authority relating to the quality, safety or efficacy of any medical device to which his licence or registration relates, inform the Authority of such information.

(2) Any person who contravenes paragraph (1) 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.

(3) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any information which he 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.

Notification to Authority concerning recall

44.—(1) For the purposes of section 44(1) of the Act, every manufacturer, importer, supplier or registrant of a medical device who intends to recall the medical device shall notify the Authority of the intended recall at least 24 hours before the time of the intended recall.

(2) The notification referred to in paragraph (1) shall be made in such form and manner as the Authority may require.

(3) Where the Authority has been notified of the intended recall of a medical device under paragraph (1), the Authority may by notice in

writing require the manufacturer, importer, supplier or registrant of the medical device to do either or both of the following:

(*a*) inspect the medical device and provide a report of the findings of the inspection;

(*b*) take such other measures as the Authority thinks necessary.

(4) Any person who fails to comply with a notice given to him by the Authority under paragraph (3) 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.

Duty to furnish report on recall

45.—(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.

[S 318/2018 wef 01/06/2018]

(2) The report referred to in paragraph (1) shall be made in such form and manner, and shall contain such information relating to the recall, as the Authority may require.

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(3) Any person who contravenes paragraph (1) 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 with any report which he 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.

Notification to Authority concerning field safety corrective action

46.—(1) Every manufacturer, importer, supplier or registrant of a medical device shall, before carrying out any field safety corrective

action in relation to a medical device, notify the Authority of the intended field safety corrective action.

(2) The notification referred to in paragraph (1) shall be made in such form and manner as the Authority may require.

(3) Where the Authority has been notified of any intended field safety corrective action in relation to a medical device under paragraph (1), the Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of the medical device to do either or both of the following:

(*a*) issue or cause to be issued, to such persons as the Authority may specify or to the general public, a statement informing them of the field safety corrective action;

(*b*) take such other measures as the Authority thinks necessary.

(4) Any person who contravenes paragraph (1) or fails to comply with a notice given to him by the Authority under paragraph (3) 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.

(5) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any notification which he 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 furnish report on field safety corrective action

47.—(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.

[S 318/2018 wef 01/06/2018]

(2) The report referred to in paragraph (1) shall be made in such form and manner, and shall contain such information relating to the field safety corrective action, as the Authority may require.

[S 318/2018 wef 01/06/2018]

(3) Any person who contravenes paragraph (1) 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 with any report which he 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.

Changes affecting licence

48.—(1) Every licensee shall notify the Authority of —

(*a*) any change or proposed change to any particulars furnished by him to the Authority in relation to his application for his licence; and

(*b*) any change or proposed change that significantly affects the activities of the licensee that are authorised by his licence.

(2) A notification under paragraph (1) shall —

(*a*) be made in such form and manner as the Authority may require;

(*b*) be submitted within such time as the Authority may specify in the conditions of the licence;

(*c*) be accompanied by such particulars, information, documents and samples as the Authority may require;

(*d*) be accompanied by the relevant notification fee specified in the Fees Regulations, if any; and

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[S 456/2022 wef 01/07/2022]

(*e*) if required by the Authority, be accompanied by a statutory declaration by the licensee verifying any information contained in or relating to the notification.

(3) A licensee shall not, without the approval of the Authority, make any change that significantly affects the activities of the licensee that are authorised by his licence.

(4) An application for the Authority's approval under paragraph (3) shall be made in such form and manner as the Authority may specify on the Authority's website.

(5) For the purposes of paragraphs (1) and (3), a change that significantly affects the activities of a licensee that are authorised by his licence includes (but is not limited to) a change of one or more of the following:

(*a*) the premises where the licensee operates;

(*b*) the facilities and equipment used by the licensee;

(*c*) the operations and processes carried out by the licensee;

(*d*) the personnel responsible for supervising the operations and processes carried out by the licensee.

(6) Any licensee who contravenes paragraph (1) 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.

(7) Any licensee who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any notification under paragraph (1) which he knows is false or misleading; or

(*b*) contravenes paragraph (3),

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.

Changes concerning registered medical device

49.—(1) 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 —

(*a*) any change or proposed change to any particulars provided in relation to the registration of the medical device; and

(*b*) any change or proposed change that may affect the safety, quality or efficacy of the medical device.

[S 318/2018 wef 01/06/2018]

(2) An application for the Authority's approval under paragraph (1) shall —

(*a*) be made in such form and manner as the Authority may require;

(*b*) be submitted within such time as the Authority may specify in the conditions of the registration of the medical device;

(*c*) be accompanied by such particulars, information, documents and samples as the Authority may require;

(*d*) be accompanied by the relevant fee specified in the Fees Regulations; and

[S 318/2018 wef 01/06/2018]

[S 456/2022 wef 01/07/2022]

(*e*) if required by the Authority, be accompanied by a statutory declaration by the registrant verifying any information contained in or relating to the notification.

[S 318/2018 wef 01/06/2018]

(3) Where any change made to a registered medical device may affect the safety, quality or efficacy of the medical device, the registrant of the medical device shall ensure that the medical device is not supplied until after the Authority has given its approval for the change.

(4) [*Deleted by S 318/2018 wef 01/06/2018*]

(5) Any registrant of a registered medical device who contravenes paragraph (1) 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.

(6) Any registrant of a registered medical device who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any notification under paragraph (1) which he knows is false or misleading; or

(*b*) contravenes paragraph (3),

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.

(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.

[S 169/2012 wef 01/05/2012]

PART IX

[*Deleted by S 456/2022 wef 01/07/2022*]

PART X

MISCELLANEOUS

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.

[S 334/2016 wef 01/11/2016]

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.

[S 318/2018 wef 01/06/2018]

Revocation

52. The Health Products (Medical Devices) Regulations 2007 (G.N. No. S 563/2007) are revoked.

Savings and transitional provision

53. Notwithstanding regulation 52, anything done under any provision of the revoked Health Products (Medical Devices) Regulations 2007 shall continue to have effect as from 10th August 2010 as if it had been done under the corresponding provision of these Regulations.

FIRST SCHEDULE

[*Deleted by S 318/2018 wef 01/06/2018*]

SECOND SCHEDULE

Regulation 22

DISEASES AND CONDITIONS SPECIFIED FOR PURPOSES OF REGULATION 22

1. Blindness.
2. Cancer.
3. Cataract.
4. Drug addiction.

SECOND SCHEDULE — *continued*

5. Deafness.
6. Diabetes.
7. Epilepsy or fits.
8. Hypertension.
9. Insanity.
10. Kidney diseases.
11. Leprosy.
12. Menstrual disorders.
13. Paralysis.
14. Tuberculosis.
15. Sexual function.
16. Infertility.
17. Impotency.
18. Frigidity.
19. Conception and pregnancy.

THIRD SCHEDULE

Regulation 24(1)

ASSIGNMENT OF MEDICAL DEVICES INTO CLASSES

PART I

CLASSES OF MEDICAL DEVICES

1. The classes of medical devices, listed in ascending order of the health risk posed to an end-user of a medical device assigned to the class, are as follows:

(*a*) Class A (low risk);

(*b*) Class B (moderately low risk);

(*c*) Class C (moderately high risk); and

(*d*) Class D (high risk).

THIRD SCHEDULE — *continued*

PART II

GENERAL CRITERIA FOR RISK CLASSIFICATION OF MEDICAL DEVICES

Division 1 — Medical devices other than in vitro diagnostic products

1. 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;

"CTGT product" means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;

[S 111/2021 wef 01/03/2021]

"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.

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

THIRD SCHEDULE — *continued*

(*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, CTGT products or medicinal products;

[S 111/2021 wef 01/03/2021]

(*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 1975;

[S 434/2023 wef 31/12/2021]

(*h*) whether the medical device is manufactured from or incorporates any, or any combination of —

(i) cells or tissues of animal origin; or

(ii) derivatives of cells or tissues of animal, human or recombinant origin,

which are or have been rendered non-viable;

[S 111/2021 wef 01/03/2021]

(*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.

THIRD SCHEDULE — *continued*

Division 2 — In vitro diagnostic products

3. 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.

[S 318/2018 wef 01/06/2018]

FOURTH SCHEDULE

[*Deleted by S 456/2022 wef 01/07/2022*]

FIFTH SCHEDULE

Regulation 40(1)

IMPLANTABLE MEDICAL DEVICES

1. Heart valve.
2. Annuloplasty ring.
3. The following active implantable medical device systems:
   (*a*) all models of implantable pacemakers and leads;
   (*b*) all models of implantable defibrillators and leads;
   (*c*) artificial heart;
   (*d*) implantable ventricular support system; and
   (*e*) implantable drug infusion system.
4. All orthopaedic joint replacement implants.
5. The following neurological implantable devices:
   (*a*) neurological stents;
   (*b*) neurological implants;

FIFTH SCHEDULE — *continued*

(*c*) implantable neurostimulation devices and leads.

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6. Breast implant.

[S 318/2018 wef 01/06/2018]

7. Intraocular lens.

[S 318/2018 wef 01/06/2018]

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*.

[S 318/2018 wef 01/06/2018]

SIXTH SCHEDULE

[*Deleted by S 169/2012 wef 01/05/2012*]

Made this 5th day of August 2010.

EDISON LIU
Chairman,
Health Sciences Authority,
Singapore.

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