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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT)
REGULATIONS 2016

In exercise of the powers conferred by section 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Medical Devices) (Amendment) Regulations 2016 and come into operation on 1 November 2016.

Amendment of regulation 2

2. Regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (called in these Regulations the principal Regulations) is amended —

(*a*) by deleting the words "as may be updated from time to time" in the definition of "Authority's website";

(*b*) by inserting, immediately after the definition of "body orifice", the following definitions:

" "clinical purpose" means any of the specific purposes described in the second column of item 1 of the First Schedule to the Act;

"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);";

(*c*) by inserting, immediately after the definition of "*in vitro* diagnostic product", the following definition:

" "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 (Act 29 of 2015) comes into operation, is appointed under that Act;";

(*d*) by inserting, immediately after the definition of "registered pharmacist", the following definition:

" "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);"; and

(*e*) by inserting, immediately after the definition of "specimen receptacle", the following definition:

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

New regulation 3A

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

"**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.".

New regulations 4B and 4C

4. The principal Regulations are amended by inserting, immediately after regulation 4A, the following regulations:

"**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 (Cap. 262); and

(*b*) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

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 (Cap. 176) before 1 November 2016 for the import on or after that date.".

New regulations 5A and 5B

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

"**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 (Cap. 262) for that activity; and

(*b*) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

Wholesaling of medical device for use in clinical research

5B. 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*) 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.".

Deletion and substitution of regulation 10A

6. Regulation 10A of the principal Regulations is deleted and the following regulation substituted therefor:

"**Exception for clinical research**

10A. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product 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*) 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.".

New regulation 13A

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