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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2017

In exercise of the powers conferred by sections 71(1) and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Medical Devices) (Amendment) Regulations 2017 and come into operation on 15 August 2017.

Amendment of regulation 26

2. Regulation 26 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) is amended —

(*a*) by deleting the word "or" at the end of paragraph (1)(*a*)(i) and (ii);

(*b*) by inserting, immediately after sub-paragraph (ii) of paragraph (1)(*a*), the following sub-paragraphs:

"(iii) a full evaluation process; or

(iv) a priority full evaluation process; or";

(*c*) by inserting, immediately after paragraph (3A), the following paragraphs:

"(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.

(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.

(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 Fourth Schedule is paid.";

(*d*) by deleting paragraph (5);

(*e*) by inserting, immediately after the definition of "competent regulatory agency" in paragraph (6), the following definitions:

" "infectious disease" has the same meaning as in the Infectious Diseases Act (Cap. 137);

"novel medical device" means a medical device that —

(*a*) is intended for the purposes of the diagnosis, prevention, monitoring,