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No. S 969

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) (AMENDMENT) REGULATIONS 2020

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 (Therapeutic Products) (Amendment) Regulations 2020 and come into operation on 1 December 2020.

Amendment of regulation 32

2. Regulation 32(1) of the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016) is amended by deleting the words "or 58(1)(*a*), (*b*) or (*d*)" in sub-paragraph (*b*) and substituting the words ", 58(1)(*a*), (*b*) or (*d*) or 60A(3) or (4)".

New Part 8A

3. The Health Products (Therapeutic Products) Regulations 2016 are amended by inserting, immediately after regulation 60, the following Part:

"PART 8A

EXCEPTION — EMERGENCY THERAPEUTIC PRODUCTS

Manufacture, import and supply of emergency therapeutic product

60A.—(1) For the purposes of section 12(1) of the Act and without prejudice to regulations 30, 31, 33, 34 and 35, the manufacture of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the manufacture of a therapeutic product without a licence.

(2) For the purposes of section 13(1) of the Act and without prejudice to regulations 30, 33, 34 and 35, the import of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the import of a therapeutic product without a licence.

(3) For the purposes of section 14(1) of the Act and without prejudice to regulations 30, 32, 34 and 35, the supply by wholesale of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply by wholesale of a therapeutic product without a licence.

(4) For the purposes of section 15(1) of the Act and without prejudice to regulations 30, 32, 34 and 35, the supply of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply of a therapeutic product 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 (Cap. 42);

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

(*a*) the therapeutic product is needed —

(i) to treat 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 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 therapeutic product has the potential —

(A) to treat 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 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 therapeutic product outweigh the known risks of the therapeutic product, to a person on whom the therapeutic product is used;

"infectious disease" has the meaning given by section 2 of the Infectious Diseases Act (Cap. 137).".

[G.N. Nos. S 219/2017; S 119/2018; S 92/2019]

Made on 27 November 2020.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

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