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No. S 388

HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (SUMMIT BETWEEN THE UNITED STATES OF AMERICA AND THE DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA — EXEMPTION FOR US DELEGATION) ORDER 2018

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In exercise of the powers conferred by section 70 of the Health Products Act, the Health Sciences Authority makes the following Order:

Citation and commencement

1. This Order is the Health Products (Summit between the United States of America and the Democratic People's Republic of Korea — Exemption for US Delegation) Order 2018 and is deemed to have come into operation on 3 June 2018.

Definitions

2. In this Order, unless the context otherwise requires —

"exemption period" means the period between 3 June 2018 and 2 July 2018 (both dates inclusive);

- "medical professional" means a doctor or any other healthcare professional, but does not include a veterinary surgeon;
- "Summit meeting" means the series of meetings between representatives of the United States of America and the Democratic People's Republic of Korea taking place in Singapore between 10 June 2018 and 14 June 2018 (both dates inclusive), and includes any lead-in and lead-out activities and social events connected with the Summit meeting;

"US delegate" means an individual from the United States of America who is —

- (a) participating in the Summit meeting;
- (b) providing secretarial, administrative or professional support to delegates in paragraph (a); or
- (c) involved in any preparatory work in Singapore for the Summit meeting.

Exemption from import requirements

- **3.** A medical professional who is a US delegate who, during the exemption period, imports any therapeutic product for
 - (a) the use or intended use by the medical professional to manage or treat a condition of any US delegate arising in Singapore during the exemption period; or
 - (b) the use or intended use by any US delegate during the exemption period,

is exempt from sections 13(1), (2), (3) and (4), 42(1) and 44(1) of the Act, and regulation 6 of the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016), if the medical professional satisfies the conditions in paragraph 5.

Exemption from supply requirements

4. A medical professional who is a US delegate who, during the exemption period, supplies any therapeutic product imported by the medical professional under paragraph 3 to any US delegate is exempt

from sections 15, 17, 18, 42(1) and 44(1) of the Act if the medical professional satisfies the conditions in paragraph 5.

Conditions of exemption

- **5.** The exemptions in paragraphs 3 and 4 for a medical professional who is a US delegate are subject to the following conditions:
 - (a) the medical professional must, during the exemption period, maintain a list specifying the name and quantity of every therapeutic product the medical professional imports;
 - (b) the quantity of each therapeutic product imported by the medical professional must not exceed the quantity assessed by the medical professional as necessary to manage or treat all US delegates in Singapore for one month, having regard to the usage instruction recommended by the manufacturer or product owner of the therapeutic product (if any);
 - (c) no therapeutic product imported by the medical professional may be supplied to a person who is not a US delegate;
 - (d) the medical professional must, during the exemption period, ensure the proper control of the supply of every imported therapeutic product to any US delegate, and the proper safekeeping of every imported therapeutic product;
 - (e) any imported therapeutic product unused or unconsumed at the end of the exemption period must be exported from Singapore by the medical professional not later than —
 - (i) when the medical professional leaves Singapore; or
 - (ii) at the end of the exemption period,

whichever is earlier.

Exemption from wholesale licence requirements on supply by export

6. A medical professional who is a US delegate is exempt from section 14 of the Act, and regulation 8 of the Health Products

(Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016), when supplying any therapeutic product by export in accordance with paragraph 5(e).

Made on 8 June 2018.

KANDIAH SATKUNANANTHAM

Chairman, Health Sciences Authority, Singapore.

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