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No. S 105

HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (EXISTING MANUFACTURERS OF CTGT PRODUCTS — EXEMPTION) ORDER 2021

ARRANGEMENT OF PARAGRAPHS

Paragraph

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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 period in force

1.—(1) This Order is the Health Products (Existing Manufacturers of CTGT Products — Exemption) Order 2021.

(2) This Order is in force for 2 years starting 1 March 2021.

Definitions

2. In this Order —

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

“minimal manipulation” has the meaning given by regulation 2(1) of the Health Products (Cell, Tissue and

Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021);

“relevant CTGT product” means a CTGT product that —

- (a) is not a result of minimal manipulation of any cell or tissue; and
- (b) is intended for clinical supply.

Exemption for continued manufacture

3. A person who, immediately before 1 March 2021, manufactures in the course of business any relevant CTGT product in any premises is exempt from section 12(1) of the Act with respect to the continued manufacture of that and any other relevant CTGT product in those premises.

Import for manufacture of relevant CTGT product

4. A person who is exempt from section 12(1) of the Act by virtue of paragraph 3 is also exempt from section 13(1) of the Act with respect to the import by the person of any health product for the purpose of manufacturing the relevant CTGT product which is the subject of and manufactured in accordance with the exemption.

Wholesale supply of relevant CTGT product

5. A person who is exempt from section 12(1) of the Act by virtue of paragraph 3 is also exempt from section 14(1) of the Act with respect to the supply by wholesale by the person of the relevant CTGT product which is the subject of and manufactured in accordance with the exemption.

Made on 15 February 2021.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

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