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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (EXEMPTIONS) (AMENDMENT) ORDER 2021

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 (Exemptions) (Amendment) Order 2021 and comes into operation on 1 March 2021.

Amendment of paragraph 2

2. Paragraph 2 of the Health Products (Exemptions) Order 2016 (G.N. No. S 536/2016) (called in this Order the principal Order) is amended by inserting, immediately before the definition of "medical device", the following definitions:

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

"CTGT Products Regulations" means the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021);".

Amendment of paragraph 3

3. Paragraph 3 of the principal Order is amended by inserting, immediately after sub-paragraph (2), the following sub-paragraph:

"(3) The exemptions relating to CTGT products are set out in the Third Schedule.".

Amendment of First Schedule

4. Paragraph 1(2) of the First Schedule to the principal Order is amended by deleting the words "Therapeutic Products as".

New Third Schedule

5. The principal Order is amended by inserting, immediately after the Second Schedule, the following Schedule:

"THIRD SCHEDULE

Paragraph 3(3)

EXEMPTIONS RELATING TO CTGT PRODUCTS

CTGT products used in clinical research

1.—(1) Sections 12(3), 13(3) and 14(2) of the Act do not apply to a manufacturer, an importer or a supplier by wholesale of a CTGT product, if the CTGT product is manufactured, imported or supplied by wholesale (as the case may be) as clinical research material.

(2) In sub-paragraph (1), "clinical research material" has the same meaning as in regulation 2(1) of the Health Products (Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016).

Advertisement of CTGT products where intended purpose not registered

2.—(1) Section 19(1)(*b*) of the Act does not apply to a person who advertises, or causes to be advertised, any registered CTGT product —

(*a*) in the form of an article in a medical or scientific journal, review or publication;

(*b*) in the course of the person providing or exchanging medical or scientific information at, and in accordance with the published programme or agenda of, a scientific conference or scientific forum that is a private event; or

(*c*) at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum that is a private event, provided that —

(i) the intended purpose of the CTGT product (as advertised) is one for which the CTGT product is approved, registered or licensed in at least one other country; and

(ii) the advertisement contains a statement that the intended purpose of the CTGT product (as advertised) is different from the intended purpose for which the CTGT product is registered in Singapore.

(2) In this paragraph, "private event" means an event —

(*a*) that is not open to attendance by the general public; and

(*b*) at which the CTGT product, which is the subject of the advertising, is not sold or offered for sale, and is not given out or offered as a sample.

Adverse effects from use of CTGT products not resulting in serious adverse reaction

3.—(1) Section 42(1)(*b*) of the Act does not apply to a manufacturer, an importer or a supplier or registrant of a CTGT product if the adverse effect that has arisen or can arise from the use of the CTGT product does not result in a serious adverse reaction.

(2) In this paragraph, "serious adverse reaction" has the meaning given by regulation 36(3) of the CTGT Products Regulations.

Out-of-specifications CTGT products

4.—(1) In this paragraph —

"out-of-specifications CTGT product" or "OOS CTGT product" means a CTGT product that —

(*a*) is not a result of only minimal manipulation of cell or tissue;

(*b*) is autologous and contains viable human cells or tissue; and

(*c*) is unwholesome because of section 2(2)(*d*)(i) or (ii) of the Act;

"requesting qualified practitioner", for any OOS CTGT product, means a qualified practitioner who —

(*a*) intends to administer an OOS CTGT product —

(i) to a patient under his or her care; or

(ii) to a subject within a clinical trial where the qualified practitioner is an investigator in that clinical trial; and

(*b*) makes a request to the manufacturer or the importer of that OOS CTGT product (as the case may be), directly or indirectly, for the intended supply to the requesting qualified practitioner of that OOS CTGT product.