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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.

(2) Section 13(5)(*d*) of the Act does not apply to a person who imports, or procures or arranges for the import, of an OOS CTGT product if —

(*a*) the import is by or on behalf of a requesting qualified practitioner for the OOS CTGT product who intends to administer that OOS CTGT product in the course of treating a patient of the requesting qualified practitioner; and

(*b*) a risk assessment has been conducted by the manufacturer of that OOS CTGT product.

(3) Section 16(1)(*d*) of the Act does not apply to a person who supplies, or procures or arranges for the supply of, an OOS CTGT product (called the supplier) if —

(*a*) the supply is pursuant to a request by a requesting qualified practitioner who intends to administer or apply the OOS CTGT product to a subject within a clinical trial or to a patient of the requesting qualified practitioner;

(*b*) the supply is to the sponsor of the clinical trial, the requesting qualified practitioner or other person connected with the requesting qualified practitioner (called the intermediary);

(*c*) a risk assessment has been conducted by the manufacturer of that OOS CTGT product (who may or may not be the same person as the supplier); and

(*d*) the results of that risk assessment have been provided by the manufacturer of that OOS CTGT product (directly or indirectly) before the supply starts to the following, whichever is applicable:

(i) in the case of a clinical trial, the sponsor of the clinical trial;

(ii) in any other case, the requesting qualified practitioner or the intermediary, as the case may be.

(4) Section 16(1)(*d*) of the Act does not apply to a sponsor of a clinical trial who supplies, or procures or arranges for the supply of, an OOS CTGT product if —

(*a*) the supply is to a requesting qualified practitioner who is an investigator of the clinical trial and pursuant to a request by the requesting practitioner for the purpose of the clinical trial;

(*b*) a risk assessment has been conducted by the manufacturer of that OOS CTGT product; and

(*c*) the results of that risk assessment have been provided (directly or indirectly) to that requesting qualified practitioner before the OOS

CTGT product is administered or applied to any person who is the subject of the clinical trial.

(5) Section 16(1)(*d*) of the Act does not apply to a requesting qualified practitioner who supplies, or procures or arranges for the supply of, an OOS CTGT product by administration or application to any person who is the subject of a clinical trial if —

(*a*) the requesting qualified practitioner is an investigator of the clinical trial;

(*b*) a risk assessment has been conducted by the manufacturer of that OOS CTGT product; and

(*c*) the requesting qualified practitioner does all of the following before the OOS CTGT product is administered or applied to the subject of the clinical trial:

(i) evaluated the risks of administering that OOS CTGT product to the subject of the clinical trial based on the results of the risk assessment conducted by the manufacturer;

(ii) determined that the benefits of administering that OOS CTGT product to that subject outweigh the risks to the subject's health of not doing so;

(iii) notified the relevant institutional review board of the intended administration of that OOS CTGT product in accordance with the requirements of that board;

(iv) informed the subject, or the subject's legal representative, that the OOS CTGT product is unwholesome and explained the risks associated with the administration or application of that OOS CTGT product;

(v) has the written consent from the subject, or the subject's legal representative, to have that OOS CTGT product administered or applied to the subject.

(6) Section 16(1)(*d*) of the Act does not apply to a requesting qualified practitioner who supplies, or procures or arranges for the supply of, (by administration or application) to a patient of the requesting qualified practitioner an OOS CTGT product in the course of treating the patient if —

(*a*) the requesting qualified practitioner made a request to the manufacturer or the importer of that OOS CTGT product (as the case may be), either directly or through a registrant, for the intended supply of that OOS CTGT product;

(*b*) a risk assessment has been conducted by the manufacturer of that OOS CTGT product; and

(*c*) the requesting qualified practitioner does all the following before starting to administer or apply that product to that patient:

(i) evaluate the risks of administering or applying that OOS CTGT product to the patient based on the results of the risk assessment conducted by the manufacturer of that product;

(ii) determine that administering that OOS CTGT product is necessary as the risk of a failure to treat the patient with the OOS CTGT product would be greater than the risk associated with administering or applying the OOS CTGT product to that patient;

(iii) obtains a consensus from the Clinical Ethics Committee of the licensed healthcare institution at which the requesting qualified practitioner is carrying out the treatment, and a written endorsement from a relevant specialist who is not involved in the care or treatment of the patient, supporting the administration or application of that OOS CTGT product to that patient;

(iv) informs the patient that the OOS CTGT product is unwholesome and explains the risks associated with the administration or application of that OOS CTGT product to that patient;

(v) has the written consent from the patient to have that OOS CTGT product administered or applied to the patient.

(7) Any word or expression in this paragraph that is defined in regulation 2 of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016) or the CTGT Products Regulations has the meaning given to it by those Regulations.".

[G.N. No. S 321/2018]

Made on 15 February 2021.

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