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No. S 536

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (EXEMPTIONS) ORDER 2016

ARRANGEMENT OF PARAGRAPHS

Paragraph

1. Citation and commencement
2. Definitions
3. Exemptions
4. Revocation

The Schedules

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) Order 2016 and comes into operation on 1 November 2016.

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;

[S 110/2021 wef 01/03/2021]

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

[S 110/2021 wef 01/03/2021]

"medical device" means a health product categorised as a medical device in the First Schedule to the Act;

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act;

"Therapeutic Products Regulations" means the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016).

Exemptions

3.—(1) The exemptions relating to therapeutic products are set out in the First Schedule.

(2) The exemptions relating to medical devices are set out in the Second Schedule.

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

[S 110/2021 wef 01/03/2021]

Revocation

4. The following Orders are revoked:

(*a*) Health Products (Medical Devices) (Exemption) Order 2012 (G.N. No. S 170/2012);

(*b*) Health Products (Medical Devices) (Exemption No. 2) Order 2012 (G.N. No. S 427/2012).

FIRST SCHEDULE

Paragraph 3(1)

EXEMPTIONS RELATING TO THERAPEUTIC PRODUCTS

Therapeutic products used in clinical research

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

FIRST SCHEDULE — *continued*

(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).

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Presentation of therapeutic products in certain circumstances

2.—(1) Regulation 20(1) of the Therapeutic Products Regulations (read with section 18(1) of the Act) does not apply to a supplier of a therapeutic product, if the supplier dispenses the therapeutic product in accordance with regulation 17 of those Regulations.

(2) Regulation 20(1)(*c*) and (*d*) and (2) to (5) of the Therapeutic Products Regulations (read with section 18(1) of the Act) does not apply to a supplier of a therapeutic product, if the therapeutic product is supplied under any of the following circumstances:

(*a*) the therapeutic product, being a therapeutic product imported under regulation 52 of those Regulations, is supplied solely for the personal use of any member of the supplier's family;

(*b*) the therapeutic product is supplied solely for the purpose of scientific education or research and development, or for a non-clinical purpose;

(*c*) the therapeutic product is supplied solely for export in accordance with regulation 53 of those Regulations.

(3) In this paragraph, "dispense" and "non-clinical purpose" have the same meanings as in regulation 2(1) of the Therapeutic Products Regulations.

Advertisement of therapeutic products where intended purpose not registered

3.—(1) Section 19(1)(*b*) of the Act does not apply to a person who advertises, or causes to be advertised, any registered therapeutic product in such a way as to represent that the intended purpose of the therapeutic product is different from the intended purpose for which the therapeutic product is registered under the Act, if the advertisement is —

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

(*b*) made in the course of 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

FIRST SCHEDULE — *continued*

(*c*) made 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 therapeutic product, as advertised, is one for which the therapeutic 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 therapeutic product, as advertised, is different from the intended purpose for which the therapeutic 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 therapeutic product, which is the subject of the advertisement mentioned in sub-paragraph (1), is not sold or offered for sale, and is not given out or offered as a sample.

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

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

(2) In this paragraph, "serious adverse reaction" has the same meaning as in regulation 34(3) of the Therapeutic Products Regulations.

SECOND SCHEDULE

Paragraph 3(2)

EXEMPTIONS RELATING TO MEDICAL DEVICES

Medical devices used in clinical research

1.—(1) Sections 12(3), 13(3) and 14(2) of the Act do not apply to a manufacturer, importer or supplier by wholesale of a medical device, if the medical device is used for a clinical purpose in any clinical research.

(2) In this paragraph —

"clinical purpose" means any of the specific purposes described in the second column of item 1 of the First Schedule to the Act;

"clinical research" means any research involving human beings.

SECOND SCHEDULE — *continued*

Dealing in medical devices licensed under Radiation Protection Act

2.—(1) Sections 13(3) and 14(2) of the Act do not apply to an importer or a supplier by wholesale of a medical device, if —

(*a*) the import or supply by wholesale, as the case may be, of the medical device is licensed under the Radiation Protection Act (Cap. 262); and

(*b*) the medical device is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

(2) In this paragraph, "Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg.

Unregistered medical device supplied in certain circumstances

3.—(1) Sections 12(2) and 13(2) of the Act do not apply to a manufacturer or an importer of a medical device, if the medical device is an unregistered medical device that is supplied in accordance with regulation 10B of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010).

(2) Section 13(2) of the Act does not apply to an importer of a medical device, if the medical device is an unregistered medical device that is supplied in accordance with regulation 8 of the Health Products (Medical Devices) Regulations 2010.

Adverse effects from use of medical devices not resulting in serious adverse reaction

4.—(1) Section 42(1)(*b*) of the Act does not apply to a manufacturer, an importer, a supplier or a registrant of a medical device, if the defect in the medical device, or adverse effect that has arisen from the use of the medical device, does not relate to —

(*a*) any defect or adverse effect that represents a serious threat to public health;

(*b*) an incident that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person; or

(*c*) an incident a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person.

SECOND SCHEDULE — *continued*

(2) In this paragraph, "a serious threat to public health" has the same meaning as in regulation 42(2) of the Health Products (Medical Devices) Regulations 2010.

[S 321/2018 wef 01/06/2018]

Wellness devices

5.—(1) Section 12(1) and (2) of the Act and the Health Products (Medical Devices) Regulations 2010 do not apply to a manufacturer of a wellness device, if the manufacturer satisfies the requirements in sub-paragraph (4).

(2) Section 13(1) and (2) of the Act and the Health Products (Medical Devices) Regulations 2010 do not apply to an importer of a wellness device, if the importer satisfies the requirements in sub-paragraph (4).

(3) Section 14(1) of the Act and the Health Products (Medical Devices) Regulations 2010 do not apply to a supplier by wholesale of a wellness device, if the supplier satisfies the requirements in sub-paragraph (4).

(4) The requirements mentioned in sub-paragraphs (1), (2) and (3) are that the manufacturer, importer or supplier by wholesale (as the case may be) of the wellness device must ensure —

(*a*) that the wellness device is supplied with the clarification statement; and

(*b*) that any advertisement of the wellness device includes the clarification statement.

(5) In this paragraph —

"clarification statement" means the following text or any statement in English that conveys the same meaning:

"This device or software is intended for use only for general wellbeing purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose (such as the detection, diagnosis, monitoring, management or treatment of any medical condition or disease). Any health-related information provided by this device or software should not be treated as medical advice. Please consult a physician for any medical advice required.";

"wellness device" means a device or software which is intended by its manufacturer —

(*a*) to be used only to enable or encourage the user of the device or software to adopt or maintain a healthy lifestyle, or for the user's general wellbeing; but

SECOND SCHEDULE — *continued*

(*b*) not to be used for any of the following purposes:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices;

(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body.

[S 321/2018 wef 01/06/2018]

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

THIRD SCHEDULE — *continued*

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 —

THIRD SCHEDULE — *continued*

(*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.

THIRD SCHEDULE — *continued*

(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;

THIRD SCHEDULE — *continued*

(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.

THIRD SCHEDULE — *continued*

(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.

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KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

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