Health Products (Exemptions) Order 2016

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No. S 536

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (EXEMPTIONS) ORDER 2016

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.

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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.

(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

(*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.

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.

(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: