First published in the Government *Gazette*, Electronic Edition, on 25 May 2018 at 5 pm.

No. S 321

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (EXEMPTIONS)
(AMENDMENT) ORDER 2018

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 2018 and comes into operation on 1 June 2018.

Amendment of Second Schedule

2. The Second Schedule to the Health Products (Exemptions) Order 2016 (G.N. No. S 536/2016) is amended by inserting, immediately after paragraph 3, the following paragraphs:

"**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.

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

(*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.".

Made on 17 May 2018.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[HSA/Legal/2018:15; AG/LEGIS/SL/122D/2015/4 Vol. 1]