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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (ADVERTISEMENT OF THERAPEUTIC PRODUCTS) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by section 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Advertisement of Therapeutic Products) Regulations 2016 and come into operation on 1 November 2016.

Definitions

2. In these Regulations, unless the context otherwise requires —

"enrolled nurse" means an individual who is enrolled as a nurse under the Nurses and Midwives Act (Cap. 209);

"licensee", in relation to a therapeutic product, means a holder of a manufacturer's licence, an importer's licence or a wholesaler's licence for the therapeutic product;

"non-public sector person" means a person other than —

(*a*) a public authority established by a public Act for a public purpose; or

(*b*) a person authorised by the Minister;

"pharmacy-only medicine" means a therapeutic product registered under the classification of "pharmacy-only medicine" in the Register of Health Products;

"prescription-only medicine" means a therapeutic product registered under the classification of "prescription-only medicine" in the Register of Health Products;

"publish", in relation to the advertisement of a therapeutic product, includes to distribute, show, display, exhibit, issue, disseminate or broadcast by any form of communication or in any manner;

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174); or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

"registered midwife" means an individual who is registered as a midwife under the Nurses and Midwives Act;

"registered nurse" means an individual who is registered as a nurse under the Nurses and Midwives Act;

"registered pharmacist" means an individual who is registered as a pharmacist under the Pharmacists Registration Act (Cap. 230);

"relevant health professionals" means individuals within any class of persons specified in the First Schedule;

"sales promotion" means any advertisement of a therapeutic product in the form of a sales campaign (including door-to-door sales), exhibition, competition or any other activity meant to introduce, publicise or raise the profile or public awareness or visibility of the therapeutic product for the purpose of promoting the sale or use of the therapeutic product;

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

Requirements for advertisement of therapeutic products

3. For the purposes of section 21(1) of the Act, an advertisement of a therapeutic product must, subject to the modifications in regulation 11, 12, 13 or 14 —

(*a*) comply with regulations 4, 5 and 6; and

(*b*) be undertaken in accordance with regulations 7, 8, 9 and 10.

Matters to be excluded in advertising therapeutic products

4. An advertisement of a therapeutic product must not —

(*a*) be likely to lead to a consumer of the therapeutic product self-diagnosing or inappropriately treating any serious disease by himself or herself;

(*b*) give the impression that advice from a registered pharmacist or qualified practitioner on the use of the therapeutic product is not necessary;

(*c*) give the impression that a medical consultation or surgical operation is not necessary if the therapeutic product is used;

(*d*) encourage, or be likely to encourage, inappropriate or excessive use of the therapeutic product;

(*e*) mislead, or be likely to mislead, directly or by implication or through emphasis, contrast or omission, any person with regard to the quality or efficacy of the therapeutic product;

(*f*) compare or contrast the therapeutic product with any other named therapeutic product or a brand thereof;

(*g*) exploit the lack of knowledge of consumers, or contain any language or image that causes or is likely to cause fear, alarm or distress to the public in respect of any disease or condition;

(*h*) claim or suggest that the therapeutic product is infallible, unfailing, magical or miraculous, or that the effect of taking the therapeutic product is certain, guaranteed or a sure cure;

(*i*) claim or suggest that the therapeutic product is not accompanied by any side effects;

(*j*) be likely to arouse unwarranted or unrealistic expectations of the effectiveness of the therapeutic product;

(*k*) offer to fully or partially refund the purchase price of the therapeutic product, or guarantee or suggest that a full or partial refund of the purchase price of the therapeutic product will be given to any purchaser or user of the therapeutic product;

(*l*) falsely claim or suggest that the use of the therapeutic product is promoted or endorsed by the Government or any public authority;

(*m*) be directed, or contain any material that is directed, principally at any person below the age of 14 years; or

(*n*) contain, or give the impression of, any endorsement or recommendation of the therapeutic product by —

(i) any healthcare professional; or

(ii) any person who, because of the person's celebrity, social or professional status, is likely to encourage the use of the therapeutic product.

Requirement for substantiation of assertions of uniqueness and prominence

5. Where an advertisement of a therapeutic product contains any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the therapeutic product from any other competing or similar therapeutic product, the statement, assertion, certification, award or feature must be substantiated by facts or evidence.

Restriction on promoting therapeutic products for specified diseases and conditions

6.—(1) An advertisement by a non-public sector person of a therapeutic product must not expressly or implicitly claim, indicate or suggest that the therapeutic product —

(*a*) will prevent, alleviate or cure any specified disease or condition;

(*b*) will prevent or alleviate any sign or symptom clinically attributable to any specified disease or condition; or

(*c*) has similar properties or characteristics to, or works as well as, a product that is commonly used for the purpose of treating any specified disease or condition.

(2) In this regulation, "specified disease or condition" means any disease or medical condition falling within any of the classes of diseases or medical conditions specified in the Second Schedule.

Prohibition against advertisement of prescription-only medicines

7. No advertisement of a therapeutic product by a non-public sector person may relate to a prescription-only medicine.

Requirement for advertisement of pharmacy-only medicines

8. An advertisement of a pharmacy-only medicine by a non-public sector person must prominently display an advisory or a warning statement required by the Authority to be displayed in connection with advertisements for that medicine.

Requirements for advertisement of unregistered therapeutic products

9.—(1) An advertisement of a therapeutic product that is not registered under the Act must —

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

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

(*c*) be made at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum that is a private event, for a therapeutic product that is approved, licensed or registered in at least one country outside Singapore, and contain a statement that the therapeutic product is not registered in Singapore.

(2) In addition, any advertisement of a therapeutic product that is not registered under the Act may contain a representation concerning the intended purpose or efficacy of the therapeutic product, provided that the representation has been verified by objective evidence.

(3) In paragraph (1), a reference to a private event is a reference to 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 paragraph (1), is not sold or offered for sale, and is not given out or offered as a sample.

Sales promotions

10.—(1) A person conducting any sales promotion involving a therapeutic product must not, in the course of that sales promotion, offer —

(*a*) any prize as an inducement to purchase the therapeutic product;

(*b*) together with the therapeutic product —

(i) any other health product; or

(ii) any medicinal product; or

(*c*) any sample of the therapeutic product.

(2) A person must not distribute or give, or cause to be distributed or given, or assist in the distribution or giving of, any free sample of a therapeutic product to the public or any section of the public.

(3) To avoid doubt, paragraph (2) does not prohibit a qualified practitioner, or a person acting in accordance with the instructions of a qualified practitioner, from giving, or causing to be given, a sample of a therapeutic product to any patient of that qualified practitioner.

(4) In this regulation, "medicinal product" has the same meaning as in the Medicines Act (Cap. 176).

Professional or scientific information advertising

11. Regulations 4(*f*), 6(1), 7 and 8 do not apply to an advertisement of a therapeutic product that —

(*a*) is directed at, or is contained in any means for conveyance of information that is intended for publication to, one or more of the classes of relevant health professionals; or

(*b*) is published only at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum that is not open to attendance by the general public.

Reference and trade advertisements

12.—(1) Regulations 6(1), 7 and 8 do not apply to a reference advertisement or a trade advertisement.

(2) In this regulation —

"reference advertisement" means a form of advertisement of a therapeutic product —

(*a*) containing a brief description of the therapeutic product, its intended purpose, and any contraindications or warnings relating to its use; and

(*b*) appearing in a publication consisting mainly of such forms of advertisement where the publication is published by a person, who is not the manufacturer, supplier, retailer, importer or exporter of the therapeutic product, to one or more of the classes of relevant health professionals;

"trade advertisement" means a form of advertisement of a therapeutic product which —

(*a*) is published by means of a catalogue, price list or other document for the purpose of supplying the therapeutic product by wholesale; and

(*b*) does not contain any recommendation relating to the use of the therapeutic product, other than as part of the name of the therapeutic product or as part of any heading or subheading indicating a therapeutic classification.

Informational statements

13.—(1) Regulations 6(1), 7 and 8 do not apply to an informational statement about a therapeutic product published —

(*a*) on the corporate website of the registrant or licensee of the therapeutic product;

(*b*) as part of a product launch event that is not accessible to any member of the general public other than an invited guest; or

(*c*) in the form of a press or media release,

provided that —

(i) any representation concerning the intended purpose and efficacy of the therapeutic product can be verified by objective evidence; and

(ii) in the case of a corporate website, no discussion board or forum relating to the therapeutic product is held on the corporate website.

(2) In this regulation, "corporate website" means an Internet website of a company that is accessible by the public and through which the public may obtain information about the company and its products.

Sales promotions involving registered therapeutic products

14.—(1) Regulation 10(1)(*b*) and (*c*) does not apply to any sales promotion involving a registered therapeutic product, if the therapeutic product —

(*a*) is supplied to a qualified practitioner or a registered pharmacist; or

(*b*) is supplied by wholesale by a person holding a valid wholesaler's licence.

(2) Regulation 10(1)(*c*) and (2) does not apply to the distribution of samples of a registered therapeutic product to one or more of the classes of relevant health professionals at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum that is not open to attendance by the general public.

Power of Authority to require copies of advertisements

15.—(1) The Authority may require, by written notice, any person who advertises, causes to be advertised, or is about to advertise or cause to be advertised, a therapeutic product to furnish to the Authority, within the time specified in the notice, such number of copies of any document or material containing the advertisement as the Authority may specify in the notice.

(2) Any person who fails to comply with a written notice under paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

FIRST SCHEDULE

Regulation 2

RELEVANT HEALTH PROFESSIONALS

1. Qualified practitioners
2. Registered pharmacists
3. Enrolled nurses, registered nurses and registered midwives
4. Persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, enrolled nurses, registered nurses or registered midwives

SECOND SCHEDULE

Regulation 6(2)

SPECIFIED DISEASES OR CONDITIONS

1. Blindness
2. Cancer
3. Cataract
4. Conception and pregnancy
5. Deafness
6. Diabetes
7. Drug addiction
8. Epilepsy or fits
9. Frigidity
10. Hypertension
11. Impotency
12. Infertility
13. Insanity
14. Kidney diseases

SECOND SCHEDULE — *continued*

15. Leprosy
16. Menstrual disorders
17. Paralysis
18. Sexual function
19. Tuberculosis

Made on 14 July 2016.

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(To be presented to Parliament under section 72(5) of the Health Products Act).