No. S 000

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (ADVERTISEMENTS FOR THERAPEUTIC PRODUCTS) REGULATIONS 2015

ARRANGEMENT OF REGULATIONS

Regulation

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, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Advertisements for Therapeutic Products) Regulations 2015 and shall come into operation on 2015.

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" means a holder of a manufacturer's licence, an importer's licence or a wholesaler's licence;

"pharmacy-only medicine" means a therapeutic product that is registered by the Authority and entered into the Register of Health Products under the classification of "pharmacy-only medicine";

"prescription-only medicine" means a therapeutic product that is registered by the Authority and entered into the Register of Health Products under the classification of "prescription-only medicine";

"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);

"therapeutic product" means a product falling within the category of health products called therapeutic products in the First Schedule to the Act.

Requirements for advertisements for therapeutic products

3. For the purposes of section 21(1) of the Act, an advertisement for a therapeutic product must comply with regulations 4, 5 and 6, and the issue or publication of the advertisement must be undertaken in accordance with regulations 7, 8 and 9, unless that advertisement is excepted under regulation 10 or 11.

Requirements on excluded matters in advertisements for therapeutic products

4.—(1) An advertisement for 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 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, or guarantee or suggest that a full or partial refund of, the purchase price of the therapeutic product will be given to dissatisfied users 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.

(2) Paragraph (1)(*f*) does not apply to an advertisement —

(*a*) that is distributed only to, or is contained in any means for conveyance of information that is intended for circulation among, one or more of the classes of persons specified in the First Schedule; or

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

(3) An advertisement for a therapeutic product that is intended for direct use by the general public must not contain any representation

concerning the intended use and efficacy of the therapeutic product unless —

(*a*) that representation has been verified by objective evidence; and

(*b*) that objective evidence has been furnished to the Authority at the time of the application to register the therapeutic product, if paragraph (4) does not apply.

(4) Paragraph (3)(*b*) does not apply to an advertisement for an unregistered therapeutic product at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum —

(*a*) that is not open to attendance by the public; and

(*b*) at which none of the following takes place:

(i) the sale or offer for sale of the unregistered therapeutic product;

(ii) the giving out or offering of samples of the unregistered therapeutic product.

Requirement for substantiation of assertions of uniqueness and prominence

5. Where an advertisement for 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 advertisements promoting therapeutic products for specified diseases and conditions

6.—(1) An advertisement for 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, or works as well as, a product that is commonly used for the purpose of treating any specified disease or condition.

(2) Paragraph (1) does not apply to an advertisement —

(*a*) that is distributed only to, or is contained in any means for conveyance of information that is intended for circulation among, one or more of the classes of persons specified in the First Schedule; or

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

(3) 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.

Advertisements for prescription-only medicines

7. A person who advertises any prescription-only medicine may do so only if the advertisement —

(*a*) is distributed only to, or is contained in any means for conveyance of information that is intended for circulation among, one or more of the classes of persons specified in the First Schedule; or

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

Advertisements for pharmacy-only medicines

8. A person who advertises to the public any pharmacy-only medicine may do so only if the advertisement prominently displays any advisory or warning statement required to be displayed by the Authority, as communicated by the Authority at the time of

registration of the pharmacy-only medicine or through any written notice or directive issued by the Authority.

Sales promotions

9.—(1) A person conducting any sales promotion of 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*) as a gift, with the purchase of the therapeutic product —

(i) any other therapeutic product;

(ii) any medicinal product other than a therapeutic product; or

(iii) any medical device;

(*c*) any sample of the therapeutic product; or

(*d*) any discount or price reduction conditional upon a minimum quantity of the therapeutic product purchased.

(2) Paragraph (1)(*c*) does not apply to the distribution of samples of a registered therapeutic product at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum that is not open to attendance by the public.

(3) Paragraph (1)(*b*), (*c*) and (*d*) does not apply to the purchase of a therapeutic product by a qualified practitioner, or to the wholesale supply of a therapeutic product by a person holding a valid wholesaler's licence, at the sales promotion.

(4) In this regulation —

"medical device" means a medical device referred to in the First Schedule to the Act;

"medicinal product" has the same meaning as in the Medicines Act (Cap. 176);

"sales promotion" means any advertisement 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 any therapeutic product for the purpose of promoting the sale or use of the therapeutic product.

Exception for reference and trade advertisements and public authorities

10.—(1) Regulations 6(1), 7 and 8 do not apply to —

(*a*) a reference advertisement or a trade advertisement; or

(*b*) any advertisement issued or published by the Government or any public authority, or by any person authorised by the Minister to issue or publish such advertisement.

(2) In this regulation —

"reference advertisement" means an advertisement —

(*a*) containing a brief description of a therapeutic product, its use, any contra-indications and warnings relating to its use; and

(*b*) appearing without charge in a publication consisting mainly of such advertisements where the publication is sent or delivered by a person who is not the manufacturer, supplier, retailer, importer or exporter of the therapeutic product to one or more of the persons specified in the First Schedule;

"trade advertisement" means an advertisement for a therapeutic product which is issued by means of a catalogue, price list or other document for the purpose of supplying the therapeutic product by wholesale, but which 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 sub-heading indicating a therapeutic classification.

Exception for informational statements

11.—(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 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 use 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.

Power of Authority to require copies of advertisements

12.—(1) If the Authority requires by written notice, the advertiser or publisher of an advertisement for a therapeutic product (whether or not a manufacturer, an importer, a supplier or a registrant of the therapeutic product) must furnish to the Authority, within such time as may be specified in the notice, such number of copies specified in the notice of every advertisement for the therapeutic product that the person has issued, or has caused to be issued.

(2) Any person who fails to comply with a notice given by the Authority 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

Regulations 4(2), 6(2), 7 and 10(2)

SPECIFIED PERSONS

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(3)

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
15. Leprosy
16. Menstrual disorders
17. Paralysis

18. Sexual function
19. Tuberculosis