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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.