Health Products (Advertisement of Specified Health Products) Regulations 2016

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No. S 333

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (ADVERTISEMENT OF SPECIFIED HEALTH PRODUCTS) REGULATIONS 2016

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 Specified Health Products) Regulations 2016 and come into operation on 1 November 2016.

[S 109/2021 wef 01/03/2021]

Definitions

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

"CTGT product" means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;

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

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

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"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 specified health product registered under the classification of "prescription-only medicine" in the Register of Health Products;

[S 109/2021 wef 01/03/2021]

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

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"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 specified health 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 specified health product for the purpose of promoting the sale or use of the specified health product;

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"specified health product" means a health product specified in the Second Schedule;

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

Requirements for advertisement of specified health products

3. For the purposes of section 21(1) of the Act, an advertisement of a specified health 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 the following regulations:

(i) in the case of any specified health product — regulations 7, 9 and 10;

(ii) in the case of a therapeutic product only — regulation 8.

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Matters to be excluded in advertising specified health products

4. An advertisement of a specified health product must not —

(*a*) be likely to lead to a consumer of the specified health 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 specified health product is not necessary;

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

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

(*f*) compare or contrast the specified health product with any other named specified health 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 specified health product is infallible, unfailing, magical or miraculous, or that the effect of taking the specified health product is certain, guaranteed or a sure cure;

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

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

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

(*l*) falsely claim or suggest that the use of the specified health 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 specified health 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 specified health product.

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Requirement for substantiation of assertions of uniqueness and prominence

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

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Restriction on promoting specified health products for specified diseases and conditions

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