HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (ADVERTISEMENT OF SPECIFIED HEALTH PRODUCTS) (CONSOLIDATION) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

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Citation

1. These Regulations are the Health Products (Advertisement of Specified Health Products) (Consolidation) Regulations 2016.

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;

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

Prepared and Published by

THE LAW REVISION COMMISSION UNDER THE AUTHORITY OF THE REVISED EDITION OF THE LAWS ACT 1983

26.4.2024

"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;

"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;

"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;

"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;

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

"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.

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.

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.

Notification of supply of clinical research material by manufacturer

6.—(1) Regulation 3(3) and (4) applies to a supply of clinical research material by a person who manufactures the material (called in these Regulations a manufacturer) only if the manufacturer gives the Authority notice of the supply before the manufacturer supplies the material.

(2) The notice must be given in the form and manner, and within the time specified, on the Authority's website.

(3) This regulation does not apply if the manufacture of the clinical research material being supplied comprises solely of the packaging or labelling of the material.

FIRST SCHEDULE

Regulation 2

RELEVANT HEALTH PROFESSIONALS

1. Qualified practitioners
2. Registered pharmacists
3. Enrolled nurses, registered nurses and registered midwives

FIRST SCHEDULE — *continued*

4. Persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, enrolled nurses, registered nurses or registered midwives

SECOND SCHEDULE

Regulation 2

SPECIFIED HEALTH PRODUCTS

1. Therapeutic products
2. CTGT products

THIRD 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
15. Leprosy
16. Menstrual disorders
17. Paralysis
18. Sexual function

THIRD SCHEDULE — *continued*

19. Tuberculosis