



**EXPLANATORY
GUIDANCE TO THE
HEALTH PRODUCTS
(ADVERTISEMENTS OF
THERAPEUTIC
PRODUCTS)
REGULATIONS
2015**

Table of Contents

1. General Introduction

1.1 Introduction 2

1.2 Definitions 2

2. Explanatory notes relating to the content and manner of advertisements for Therapeutic Products

2.1 Introduction 5

2.2 General rules for advertisements of therapeutic products..... 5

2.3 Substantiation of assertions of uniqueness and prominence 6

2.4 Prohibition of certain materials 7

2.5 Advertisements of Pharmacy medicines 9

2.6 Principles and requirements for advertisements of TPs

2.6.1 Discourage from medical or professional advice 9

2.6.2 Encouraging inappropriate or excessive use 10

2.6.3 Truthfulness 10

2.6.4 Comparative Claims 11

2.6.5 Causing fear and alarm..... 11

2.6.6 Guaranteed results and side effects 12

2.6.7 Refunds 12

2.6.8 Recommendations and endorsements 12

2.6.9 Endorsement by Government or Public Authority 13

2.6.10 Advertising to children..... 13

2.7 Advertising on the Internet..... 13

2.8 Sales promotion activities 14

3. Contact Information

3.1 Contact details 15

1. GENERAL INTRODUCTION

1.1 Introduction

The objective of advertisement controls for Therapeutic Products (“TP”) is to ensure that the TP which is advertised or promoted for sale do not adversely affect public health, mislead consumers or induce unnecessary consumption of the TP.

The controls on the advertising and promotion of health products is critical as accurate and truthful information about a health product is essential in helping both the public and healthcare professionals to make informed decisions in their choice of health products.

This Guidance aims to clarify some of the principles set out in the Health Products Act (“HPA”) and the Health Products (Advertisements of Therapeutic Products) Regulations (“the Regulations”), and should be read in conjunction with the HPA and the Regulations. The examples highlighted in this Guidance are not exhaustive and may be updated periodically. All persons who advertise or cause any product to be advertised as a TP are required to comply with this Guidance, HPA and the Regulations. Persons who advertise or cause any product to be advertised as a TP are responsible for all advertisements associated with the product advertised.

1.2 Definitions

Therapeutic Product¹ (TP) is a category of health products that will be regulated under the HPA and will be defined in the First Schedule of the HPA. A TP is intended for a therapeutic, preventive, palliative or diagnostic purpose, and its scope includes chemical and biologic drugs.

Medicinal product means any substance or article which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways:

¹ The finalised legal definition of ‘Therapeutic Product’ under the First Schedule to the HPA, will be provided at a later date.

- (a) use by being administered to one or more human beings or animals for a medicinal purpose;
- (b) use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

“a medicinal purpose” will include any one or more of the following purposes:

- (a) treating or preventing disease;
- (b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- (c) contraception;
- (d) inducing anaesthesia;
- (e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

Examples of medicinal products include chinese proprietary medicines, quasi medicinal products, traditional medicines, medicated oil and balm, as well as health supplements.

“Advertisement” as defined in section 2 of HPA, in relation to a health product means the publication, dissemination or conveyance of any information for the purpose of promoting whether directly or indirectly, the sale or use of that health product by any means or in any forms, including the following:

- (a) publication in a newspaper, magazine, journal or other periodical;
- (b) display of posters or notices;
- (c) circulars, handbills, brochures, pamphlets, books or other documents;
- (d) letters addressed to individuals, or bodies corporate or unincorporate;
- (e) photographs or cinematograph films;
- (f) sound broadcasting, television, the Internet or other media;
- (g) public demonstration of the use of the health product; and
- (h) offer of trials of the health product to members of the public.

The definition of advertisement is broad and includes all forms of advertisement in any media including media such as billboards, lightboxes, digital media boxes, LCD / LED panels, or banners.

Digital communication channels e.g. Facebook and Blogs are considered as Internet medium. Advertisements of TPs directed at consumers which are set up by companies and posted on such channels, will be subject to all requirements in the HPA and the Regulations.

The definition of 'advertisement' will also include press releases and materials used in product launch events which are not open to the general public. They are expected to comply with Sections 19 & 20 of the HPA, and Regulations 4 & 5 of the Regulations.

For avoidance of any doubt, any feature of the name / identity, pack shot and/or tagline / logo associated with the TP, with the intent or purpose of promoting the TP and its use shall be deemed as an advertisement for purpose of the HPA and the Regulations.

"Reference advertisement" means an advertisement –

- (a) containing a brief description of a therapeutic product, its use, any contra-indications and warning 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 relating to 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.

2. EXPLANATORY NOTES RELATING TO THE CONTENT AND MANNER OF ADVERTISEMENTS FOR THERAPEUTIC PRODUCTS

2.1 Introduction

All persons who advertise or cause any product to be advertised as a TP are required to comply with Part V of the HPA and the Regulations. The principles set out in the HPA and the Regulations allow information and/or advertisements to be disseminated to the public for the purpose of creating awareness and enabling consumers to take better ownership of their own health choices. The principles of advertisement controls are set out in sections 19 and 20 of the HPA and regulations 4 to 9 of the Regulations.

2.2 General rules for advertisements of therapeutic products

Advertisements for any TP will no longer require a permit. However, persons who advertise a TP have to ensure that the advertisements comply with the principles and requirements as stated in the HPA and the Regulations.

In general, no product can be advertised as a TP or that it can function as a TP, if the product is not a TP, as defined in First Schedule to the HPA.

Advertisements must not promote any unregistered TP or unregistered indications of a registered TP unless the advertisement is confined to pharmaceutical trade fairs/exhibitions or scientific conferences/forums that are not opened to the public, and where information presented is not false and misleading and is substantiated by objective scientific evidence. Sale or sampling of unregistered TPs at these events is strictly prohibited.

An advertisement cannot promote any TP for use by a patient group for which it is not indicated. For example, an advertisement depicting a baby/infant when the TP was not indicated for children would be in breach of this provision.

All advertisements of TPs must comply with any relevant product registration licence conditions that may be imposed. E.g. a TP may be approved for use in certain therapeutic indications, but its product registration conditions may prohibit the advertisement of any of these approved indications to the public.

2.3 Substantiation of assertions of uniqueness and prominence

Any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the advertised TP from other competing or similar TP in advertisements must be substantiated by facts or objective evidence.

All claims must be substantiated by robust objective evidence from credible sources. E.g. studies reported in articles published in peer-reviewed journals, scientific journals, literature of established sources such as those published by government agencies.

Literature references, information, findings or conclusions from independent research, surveys or scientific studies must be presented in a balanced, objective and accurate manner. If the advertisement makes reference to any published paper, appropriate citations must be provided in the advertisement.

Any scientific terminologies used should be in a manner that is readily understood by the audience to whom it is directed.

This requirement also applies to the publication of any testimonials, whether directly or through linkages to third party websites or advertising platforms. Testimonials include "user experience" or "user review". Testimonials must be current, genuine, authenticated e.g. via signed testimonials of a real consumer, and be of a typical experience. In this context, "current" would mean that the featured testimonial must be up to date and hold true at the time of the publication of the advertisement. "Typical experience" would mean the result obtained from the use of a product, which would likely to be attained by the average user of the product. Evidence must

be available to show that the testimonials reflect the typical experience of ordinary users.

Usage of superlatives, including but not limited to "best" and "only" are not allowed. Claims such as "most popular", "number one sales" require verification by a credible source e.g. market survey conducted independently by a recognised third party research company. The source of reference, including the identity of the certifying/awarding body, and the date of the award must be indicated in the advertisement.

2.4 Prohibition of certain materials

The Regulations prohibits advertisements of TPs which claims, indicates or suggests, whether expressly or implicitly, that the TP

- (a) will prevent, alleviate or cure any specified disease or conditions specified in the Second Schedule²; or
- (b) will prevent or alleviate any sign or symptom clinically attributable with any disease or condition specified in the Second Schedule. For example:
 - claims relating the reduction/regulation of blood sugar/glucose level which is attributable to 'Diabetes'
 - claims relating to the reduction/regulation of blood pressure which is attributable to 'Hypertension' ; 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.

This prohibition does not apply to advertisements that are:

² Specified diseases/conditions listed in the Second Schedule to the Regulations include: Blindness, Cancer, Cataract, Conception and pregnancy, Deafness, Diabetes, Drug addiction, Epilepsy or fits, Frigidity, Hypertension, Impotency, Infertility, Insanity, Kidney diseases, Leprosy, Menstrual disorders, Paralysis, Sexual function and Tuberculosis.

- (a) distributed only to the classes of persons specified in the First Schedule³ to the Regulations; or
- (b) contained in reference or trade advertisements; or
- (c) contained in information published on corporate websites, information distributed at product launch events which are not open to the public or press releases; or
- (d) distributed at pharmaceutical trade fairs, pharmaceutical trade exhibitions, scientific conferences or scientific forums which are not open to the public.

The Regulations also prohibits the advertisement of prescription only medicines (POM), unless the advertisement is

- (a) distributed to only to the classes of persons specified in the First Schedule to the Regulations; or
- (b) contained in reference or trade advertisements; or
- (c) contained in information published on corporate websites, information distributed at product launch events which are not open to the public or press releases; or
- (d) distributed at pharmaceutical trade fairs, pharmaceutical trade exhibitions, scientific conferences or scientific forums which are not open to the public

Advertisements of POMs shall not be directed to the general public. Placement of such advertisements in any publicly accessible areas such as waiting areas of hospitals and clinics are prohibited.

Internet and social media pages designed specifically for persons specified in the First Schedule must be accessible only via log-in access and be password protected to prevent access by the members of the public.

³ Classes of persons specified in the First Schedule to the Regulations include: Qualified Practitioners, Registered pharmacists, Enrolled nurses, registered nurses and registered midwives and persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, enrolled nurses, registered nurses or registered midwives.

2.5 Advertisements of Pharmacy medicines

The safe use of some medicines depends on compliance with certain warnings and cautionary statements. All direct to consumers advertisements of pharmacy only (P) medicine are required to prominently display advisories or warning statements as communicated by the Authority at the time of registration of the therapeutic product or through any written notice or directive issued by the Authority; The advisories or warning statements shall be clearly and prominently reflected on the advertisement.

Examples of warning or advisory statements may include:

- (a) Known serious side effects
- (b) Contraindications
- (c) Precautions
- (d) Age restrictions
- (e) Appropriate statements advising consumers to read the Patient Information Leaflet (PIL)
- (f) Appropriate statements advising consumers to consult their healthcare professionals on the use of the medicine

2.6 Principles and requirements for advertisements of TPs

2.6.1 Discourage from medical or professional advice

Advertisement directed to the general public shall not, directly or by implication cause the reader to self diagnose or self-treat any serious diseases. Advertisements shall not suggest that with the use of the TP, the consumer would not need to consult a physician or a pharmacist.

Advertisements shall not contain any offer to diagnose, or suggest that medical interventions e.g. surgical operations, are not required by using the TP featured.

2.6.2 Encouraging inappropriate or excessive use

Advertisements of TPs must not encourage inappropriate or excessive use of the TP.

Examples of content or manner of advertisements that amount to “encouraging inappropriate or excessive use of the therapeutic product” would include, but not limited to the following:

- (a) discounts offered with a minimum quantity purchase of the TP.

Direct discounts offered on a single unit of the TP are allowed, but any discounts or price reductions offered with a minimum purchase of the TP is not allowed as it can induce unnecessary purchase and consumption.

For illustrations, a TP priced at a regular price of \$8 can be sold at \$4. However, a package deal of 2 boxes at a price of \$8 is not allowed as this requires the consumer to buy 2 boxes in order to enjoy the discount, encouraging unnecessary or excessive use of the product. A promotional offer of a TP with any other medicinal product, at a reduced price is also not allowed.

- (b) any TP offered free of charge via distribution of samples, or any suggestion or offer for trial use with phrases such as "try product", "free/complimentary/trial use"
- (c) any advertisements or sales promotion of TP that involves the giving away of prizes (including lucky draws, lucky dips and contests).

2.6.3 Truthfulness

Advertisements should truthfully state the nature, quality and properties of the TP and must not directly, indirectly, imply, omit, be ambiguous, make exaggerated claims e.g. “the only”, “longest lasting”, “works the fastest”, or by comparison with other

categories of products, mislead the reader or give rise to any unrealistic expectations with regard to the safety, quality or efficacy of the TP.

2.6.4 Comparative Claims

Advertisements shall not denigrate or attack unfairly any other products, goods or services or other sectors of the industry. No comparative advertisements against another named TP or brand, e.g. “works faster and more effective than Brand xxx” should be featured for advertisements that are directed to the members of the public. Comparative claims among drug classes or categories, supported by objective evidence are allowed. Any comparative statements featured must not mislead the general consumers about the product being advertised or about any product with which it is compared.

2.6.5 Causing fear and alarm

Advertisements must not directly, indirectly, imply, omit, be ambiguous, make exaggerated claims or by comparison with other categories of products, cause fear, alarm, distress, abuse the trust, or exploit the lack of knowledge of any consumer.

Advertisement shall not in any way induce fear or unjustified concern that the reader is suffering, or without using the product being advertised, may suffer or suffer more severely, from any disease or condition.

Examples of content or manner of advertisement that amounts to “exploit the lack of knowledge of consumers, or cause or is likely to cause fear, alarm or distress to the public” would include, but not limited to, the following:

- (a) eye catching words and phrases like
 - "danger";
 - “caution”;
 - “Beware”

- (b) emphasizing that a large majority of the population may be or are susceptible to a certain disease / condition without substantiation.
- (c) any repulsive or disturbing images or words that cause fear, alarm or distress to the public.

2.6.6 Guaranteed results and side effects

The content of any advertisement featuring a TP shall not contain any claim or statement suggesting that the TP is magical or infallible or the results from taking the TP are guaranteed, extraordinary or is better than or equivalent to any identifiable treatment.

All TPs have the potential to cause side-effects as individuals respond differently to the medications consumed. The content of any advertisement featuring a TP shall not contain any claim or statement suggesting that the TP does not cause or is free from any side effects.

2.6.7 Refunds

Advertisements of TPs should not contain any offer to refund money, either in full or partial, to users.

2.6.8 Recommendations and endorsements

Advertisements of TPs must not contain any recommendation by any healthcare professional; or any person who, because of the person's celebrity or social/professional status, is likely to encourage the use of the therapeutic product.

"Recommendations" include testimonials, support and endorsements which would include, but is not limited to any compliment, accolade or positive assessment given by any person.

"Celebrity" includes persons of all fields, including but not limited to media, sports, politics, culinary personalities with / without identifying the celebrity in the advertisements.

Particular care is needed to avoid the perception of professional endorsement for the TP. E.g. when models in "white coats" or models with stethoscopes are featured. Care is also advised regarding features of pharmacies, healthcare institutions or surgeries as it gives rise to an implied perception of an endorsement by a healthcare professional.

2.6.9 Endorsement by Government or Public Authority

A false/erroneous claim indicating or suggesting that the use of the TP is promoted, supported or endorsed by the Government or any public authority is not allowed.

Advertisements featuring a registered TP are only allowed to use the term "registered", "注册", "berdaftar", "பதிவு" in describing its registration status as granted by the HSA under section 30 of the HPA.

The feature of HSA's logo in advertisements is also prohibited.

2.6.10 Advertising to children

Advertisements of TPs shall not contain any material that is directed exclusively or principally at children under 14 years old.

2.7 Advertising on the Internet

The definition of 'advertisement' under the HPA will include advertisements on the Internet, including those presented using digital communication channels e.g. Facebook and Blogs.

Such channels set up by companies containing advertisements of TPs that are directed at the consumers, will be subject to all requirements in the HPA and the Regulations

Corporate websites of registrants and licensee that may include, but not limited to the following information, are subject to controls under Sections 19 & 20 of the HPA and Regulations 4 & 5 of the Regulations:

- (a) patient information leaflets, factual information and reports about their products;
- (b) other non-promotional information about the TP, supported by robust evidence and any risk-benefit profile.

Corporate websites in this context refer to Internet websites of registrants or licensees that provides information about the company. Such websites must not carry any discussion forums, or similar platforms, as these discussions generally stem from individual's experience and may inadvertently provide non-factual information regarding the TP.

2.8 Sales promotion activities

The Regulations prohibits the following sales promotion mechanics relating to a TP. The offer:

- (a) of any prize as an inducement to purchase the TP;
- (b) of a gift with the purchase of the TP —
 - any other therapeutic product; or
 - any medicinal product; or
 - any medical device;
- (c) of any sample of the therapeutic product;
- (d) of any discount or price reduction conditional upon a minimum quantity of the therapeutic product purchased.

The offer of prizes for the purchase of TPs through activities such as lucky draws, dips and contests is prohibited. Offering discounts upon minimum purchase e.g.

purchase 2 packs at 50% off, purchase a bundled pack of TP and any medicinal product is not allowed.

The prohibitions (b), (c) and (d) does not apply to any sales promotion activities conducted for the purpose of wholesale dealings.

Distribution of samples of registered TPs is not allowed unless the distribution is conducted at and restricted to pharmaceutical trade fairs/exhibitions, scientific conferences/forums, and is not directed at the public. The sale, offer for sale and distribution of samples of unregistered TPs is strictly prohibited in all instances.

3. CONTACT INFORMATION

Please use the prescribed feedback template provided to submit your feedback to us.

The feedback template may be submitted via:

- (a) Email – hsa_feedback@hsa.gov.sg ; or
- (b) Fax – 6478 9076

All feedback should be submitted by 23 November 2014.

For any further clarifications, please contact:

Medical Advertisements Unit
Vigilance, Compliance & Enforcement Division
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg

T: 6866 3478

F: 6478 9038

Email: hsa_ma@hsa.gov.sg