

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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GUIDANCE FOR INDUSTRY

GUIDE ON ADVERTISEMENTS AND SALES PROMOTION OF MEDICINAL PRODUCTS



PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

REVISION HISTORY

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1 INTRODUCTION

1.1 Introduction

The objective of advertisement controls for medicinal products is to ensure that accurate and factual information about the products is disseminated and to ensure that the advertisements and sales promotion activities do not mislead consumers or induce unnecessary purchase or consumption of the products. This is essential in helping both the public and healthcare professionals to make informed decisions in their choice of the products.

This Guidance provides the requirements on the conduct of advertisements and sales promotion activities for medicinal products and is intended to complement the provisions prescribed under the Medicines Act and its subsidiary legislation, the Medicines (Medical Advertisement) Regulations.

Anyone who advertise any medicinal product are required to comply with the requirements in this Guidance and the relevant legislation.

The examples highlighted in this Guidance are not exhaustive and may be updated periodically.

1.2 Legislation

The requirements for the advertisements and sales promotion activities of medicinal products are prescribed in the following legislation:

- Medicines Act - Part VI Promotion of Sales of Medicinal Products and Medical Advertisements
- Medicines (Medical Advertisements) Regulations

1.3 Definitions

“**Advertisement**” as defined in Part VI of Medicines Act, includes every form of advertising, whether in a publication, or by the display of any notice or signboard, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents, or by words inscribed on any article, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting or television, or in

any other way, and any reference to the issue of an advertisement shall be construed accordingly.

“Medical advertisement” as defined in Part VI of Medicines Act, means an advertisement relating or likely to cause any person to believe that it relates to any medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose.

“Sales promotion” as defined in the Medicines (Medical Advertisements) Regulations means any medical advertisement in the form of a sales campaign (including door-to-door sales and price discounts), an exhibition, a competition or any other activity meant to introduce, publicise or raise the profile, or public awareness or visibility, of the medicinal product.

“Medicinal Products” as referred to in the Medicines Act includes (not exhaustive):

- (a) Chinese Proprietary Medicines (CPM)
- (b) Traditional Medicines (TM)
- (c) Homeopathic Medicines (HM)
- (d) Quasi-medicinal products e.g. medicated soaps / plasters / beverages / toothpastes, vitamin and mineral preparations
- (e) Medicated Oil and Balms

2 MEDICAL ADVERTISEMENT AND SALES PROMOTION PERMIT REQUIREMENTS

All advertisements and sales promotion activities of medicinal products directed to the general public are subject to advertisement and sales promotion permit controls by the Authority.

Prior to issuing any medical advertisements or conducting any sales promotion activities directed to the general public, you must ensure all of the following requirements are met:

- (a) the advertisement or sales promotion has a valid permit from HSA;
- (b) the permit number appears in the advertisement or sales promotion materials, or script for radio advertisement, where applicable;
- (c) the advertisement or sales promotion is published or conducted in accordance with the permit and has not been amended without prior approval by HSA.

2.1 Types of advertisements

The following describes the different types of advertisements for submission of permit applications.

2.1.1 Advertisement using light and sound projection

Includes any advertisement with light and sound effects, e.g. television commercials, cinema advertisements, videos, videos on the Internet.

2.1.2 Any other advertisement

Includes any advertisement not using light and sound effects, i.e. still advertisement, sound advertisement. (This does not include advertisements in the form of sales promotions see 2.1.3)

(a) Still

Includes any advertisement in print media, e.g. newspapers, magazines, brochures, posters, wobblers, stickers, display stands, lighted-boxes, mail order announcements, calendars, or static displays on the Internet

(b) Sound

Includes any advertisement broadcast over radio, any audio recordings, audio recordings on the Internet

2.1.3 Sales promotion

Includes any activity with the purpose of introducing, publicising or promoting the sale or use of a medicinal product using any modes of projection. For example (not exhaustive): price discounts, multiple packs offer.

2.2 Application for medical advertisement and sales promotion permits

You must submit all applications for medical advertisement and sales promotion permits via the Pharmaceutical Regulatory Information System (PRISM) which is available on HSA's website.

Each permit is valid for 1 year from the date of issuance of permit. You may renew your permit on a yearly basis.

Please refer to Appendix 1 and 2 for more information on types of applications, permit application procedures and fees.

2.3 Exception for trade, business or profession

You do not need to apply for a permit for the following types of medical advertisements and sales promotion activities:

- (a) Medical advertisements or sales promotion activities which are directed exclusively at a person who may lawfully sell or supply any medicinal product in the course of his trade, business or profession (e.g. healthcare professionals); and not accessible to the general public.
- (b) “Reference advertisement” which contains a brief description of a medicinal product, its use, any contra-indications and warnings appearing in a publication where the publication is sent or delivered to practitioners or pharmacists by a person who is not involved in the sale of or dealings in that medicinal product as a manufacturer, supplier, retailer, importer or exporter.
- (c) “Trade advertisement” which is issued in a catalogue, price list or other document for the purpose of supplying the medicinal product by wholesale, but which does not contain any recommendation relating to the use of the product other than as part of the name of the product or as part of any heading or sub-heading indicating a therapeutic classification.

3 REQUIREMENTS AND GUIDELINES FOR MEDICAL ADVERTISEMENT AND SALES PROMOTION ACTIVITIES

All medical advertisement and sales promotion applications will be evaluated upon submission for alignment to the requirements and appropriateness for advertising to the general public.

This section highlights the requirements and principles for the conduct of medical advertisements and sales promotion activities, and serves as a guide for companies to aid in their submission of advertising and promotion materials.

3.1 False or misleading advertisements and representations

You must ensure that all advertised information is correct and truthful. Any claims relating to a particular medicinal product must be aligned with the approved uses of the product or label recommendations, as well as with any prevailing guidance for that category of medicinal product.

You must not make any false or misleading advertisement or representation relating to medicinal products of a particular description to a practitioner, patient or person for the purpose of inducing him to prescribe / supply / request for / purchase the product of that description.

An advertisement will be taken to be false or misleading if:

- (a) it falsely describes the description of medicinal products, or
- (b) it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects

3.2 Prohibited diseases and conditions

You must not publish or cause to be published any medical advertisements directed to the general public that claim, indicate or suggest, whether directly or indirectly, that the medicinal product will prevent, alleviate or cure any disease or condition specified in the First Schedule to the Medicines Act.

The diseases and conditions specified in the First Schedule are:

1. Blindness
2. Cancer
3. Cataract
4. Drug addiction
5. Deafness
6. Diabetes
7. Epilepsy or fits
8. Hypertension
9. Insanity
10. Kidney diseases
11. Leprosy
12. Menstrual disorders

13. Paralysis
14. Tuberculosis
15. Sexual functions
16. Infertility
17. Impotence
18. Frigidity
19. Conception and pregnancy

This prohibition does not apply to any advertisement which is distributed only to, or is contained in a publication (e.g. journal articles) intended for circulation mainly among one or more of the following classes of persons:

- (a) practitioners;
- (b) pharmacists;
- (c) nurses and midwives;
- (d) persons undergoing training with a view to becoming practitioners, pharmacists or nurses and midwives

3.3 Further guidelines for conduct of medical advertisements

(a) Truthfulness

Advertisements should truthfully state the nature, quality and properties of the medicinal product. Your advertisements must not directly or indirectly mislead the reader or give rise to any unrealistic expectations with regard to the safety, quality or properties of the medicinal product by:

- implication,
- through emphasising certain information
- omitting information,
- being ambiguous,
- making exaggerated claims e.g. “the only”, “longest lasting”, “works the fastest”, or
- by comparison with other categories of products

Recommendations relating to the use of the medicinal product must be accurately stated and should be relevant to their properties.

(b) Substantiation of assertions of uniqueness and prominence

All claims made in the advertisement must be substantiated. Any text, emphasis, certification, award or unique feature or prominence of the advertised product must be substantiated by facts or robust objective evidence from credible sources, such as, articles published in peer-reviewed journals.

Information must be presented in a balanced, objective and accurate manner and must be referenced by reflecting the appropriate citations (where relevant).

You must ensure that claims such as “most popular”, “number one sales” are substantiated by market data from credible sources, for example, recognised third party research companies. Supporting data must be available and must be provided upon request. You must also indicate the source of reference, including the identity of the certifying or awarding body, and the date of the study or award in the advertisement.

Requirements for substantiation also apply to the publication of any testimonials. Testimonials include “user experience” or “user review”. Testimonials must be current, genuine, authenticated, for example, via signed testimonials, and be of a typical experience. “Typical experience” would mean the result obtained from the use of a medicinal product, which would likely to be attained by the average user of the product. You must present supporting evidence for the testimonials upon request.

(c) Comparative Claims

Medical advertisements must not denigrate or attack unfairly any other products, goods or services or other sectors of the industry. You must ensure that advertisements directed to the general public do not contain comparative claims against another named product or brand e.g. “works faster and better than Brand xxx”. However, comparison among medicinal products within the same brand by the same company to highlight differences between the products is allowable.

(d) Language

Medical advertisements directed to the public should be in simple-to-understand language, easily comprehensible and should avoid confusing medical jargons. Scientific jargons and irrelevancies should not be used to make claims appear to have a scientific basis they do not possess. Any scientific terminologies used should be in a manner that is readily understood by the targeted audience.

You must not directly or indirectly cause fear, alarm, distress to the consumers or abuse the trust, exploit the lack of knowledge of any consumer in advertisements by using eye catching words, e.g. 'danger', 'caution', 'beware', or any repulsive or disturbing words or images that cause fear, alarm or distress to the public.

(e) Use of Scientific Data

Advertisements should not exploit the ignorance and credulity of the public by including scientific data that the general public cannot verify or validate. Your advertisements for a medicinal product must not misuse research results or make unnecessary quotations from technical and scientific publications.

(f) Superlatives and exaggerating terms

Medical advertisements should not overly use superlatives or exaggerating terms which imply or suggest a usage or property which the medicinal product does not possess. Examples of terms that amount to superlative or exaggerative: 'miracle', '100% safe', 'instant cures', 'clinically proven', 'increase memory power', 'improve study grades'.

(g) Encouraging inappropriate or excessive use

Advertisements should not directly or indirectly encourage indiscriminate, unnecessary or excessive use of a medicinal product.

You must not suggest or offer trial use of a medicinal product with phrases such as "try product", "free" or "complimentary".

(h) Guaranteed results and side effects

Advertisements must not contain any claim or statement suggesting that the medicinal product advertised is magical or infallible or the results from taking it are guaranteed and extraordinary.

All medicinal products have the potential to cause side-effects as each individual respond differently. You must not claim or suggest that the product does not cause or is free from any side effects.

(i) Discourage from medical advice

Advertisements should not in any way discourage the public from seeking the advice of a medical professional.

You must not directly or indirectly, cause the reader to self-diagnose or self-treat any serious diseases¹ in advertisements for the medicinal product. They must not suggest that with the use of the product, the consumer would not need to consult a physician or a pharmacist.

Examples of serious diseases which are not allowed for direct to consumer advertisements: Cardiovascular disease, Dengue, Hepatitis, Neuralgia, Osteoporosis, Fatty liver diseases.

(j) Recommendations and endorsements

You must not include any recommendation by any healthcare professional in your advertisement. You must avoid the perception of professional endorsement in advertisements, for example, the feature of models in "white coats" or with stethoscopes.

You must ensure that advertisements of CPM / TM directed to the general public do not contain recommendations or endorsement from a celebrity or give the impression of advice or support from a celebrity.

In this context, "recommendations" can include testimonials, support and endorsements which would include, but is not limited to any compliment, accolade or positive assessment. "Celebrity" includes persons of all fields, not limited to media, sports, politics, and culinary personalities with or without identifying the celebrity in the advertisements.

(k) Endorsement by Government or public authority

You must not publish any advertisements reflecting false or erroneous claims indicating or suggesting that the use of a product is promoted, supported or endorsed by the Government or any public authority.

¹ Serious diseases refer to chronic / life-threatening diseases / conditions, which cannot be self-diagnosed / managed and where a delay in treatment would lead to death, hospitalisation, serious injury or irreversible deterioration of the disease / condition.

(l) Logos, Initials and Trademarks

Advertisements should not make use of names, initials, logos and / or trade service marks of other firm, company or institution. You must have written permissions from the concerned firm, company or institution on the use of their names, initials, logos and / or trade service marks before use.

The names and / or logos of HSA and any of its professional groups must not be used for advertisement and sales promotion of a product in any media.

(m) Refund

You should not make any offer to refund money, either in full or partial, to users of the product.

(n) Guidelines for specific groups of products

In certain instances, additional requirements or advisories may be required for identified groups of products. Please see examples below:

Product group / type	Requirements
Vitamins and Minerals Preparations	Advertisements of products containing vitamins and minerals should not suggest that there is evidence of general widespread vitamin deficiency.
Medicinal products containing Red Yeast Rice	Advertisements for products containing red yeast rice products should provide an advisory that any person with existing medical conditions or taking other medicines should consult physician before consumption. Example: Please consult your physician if you are taking other medications.
Weight Management Products	Advertisements for products intended for weight management should contain an advisory for maintenance of good health. Example: Use in conjunction with a balanced diet and regular exercise.

3.4 Further guidelines for conduct of sales promotion

All sales promotion mechanics are evaluated upon application submission to ensure that the proposed activity is appropriate, do not induce unnecessary purchase or consumption of the medicinal product. In general, sales promotion activities directed at the general public should not (not exhaustive):

- (a) Offer a medicinal product free-of-charge with the purchase of a non-medicinal product
- (b) Offer prizes through lucky draw, contest or membership with purchase of the product with terms such as “win a prize” or “get a lucky draw” and equivalent
- (c) Use terms such as “free” or “complimentary” (免费或附送), “get a gift” (赠品) and equivalent.
- (d) Distribute samples² of Chinese Proprietary Medicines / Traditional Medicines / Homeopathic Medicines.

² Distribution of samples refers to the distribution of unit(s) / portion of a product to a recipient without charge.

APPENDIX 1 – TYPES OF APPLICATIONS

This Appendix describes the types of permit applications for New, Amendment and Renewal application submissions. If you have doubts on which application form to submit, please contact us at hsa_ma_appl@hsa.gov.sg.

1 New application

A new application is an application for an advertisement and sales promotion permit.

(a) Advertisement

If a single copy of advertisement comes in more than one language, only one application is required.

If an advertisement comes in more than one copy, each in a different language, separate applications will be required. For example, two applications will be required for a leaflet that comes in two separate copies, one in English and one in Chinese.

An additional application for a sale promotion permit will be required if the advertisement also contains a sales promotion announcement.

(b) Sales Promotion

Sales promotion activities for multiple products (up to a maximum of five products) can be submitted under one application.

The Sales Promotion Mechanics is to be submitted as an attachment in the application in PRISM using the following format:

1. Name of Product(s)
2. Promotion Method (e.g. quantum of price discount)
3. Press Advertisement, if any (to provide a draft artwork as an attachment)
4. Promotion Materials (e.g. shelf-talker, wobblers), if any (to provide as an attachment)
5. Promotion Venue (e.g. retail pharmacy, roadshows)

2 Amendment application

An amendment is an application for a minor alteration made to an approved advertisement or sales promotion.

Minor alterations may include change of text, inclusion or omission of some words, and / or change in the visuals, and the changes are along the same concept of the approved advertisement or sales promotion.

If the alterations proposed are major, applicants would need to submit an application for a new permit. Amendment fees are not refundable.

Amendment applications are not required for changes which do not affect the product claims. For example:

- (a) re-arranging the text and / or visual
- (b) updating company's contact details, e.g. address and telephone numbers
- (c) updating retailer's logo
- (d) updating the product's usual selling price.

Amendment of company and applicant particulars for an issued permit can be submitted via amend@prism:

- Amend Company Information
- Amend Applicant's Details

3 Renewal

A renewal is an application for an advertisement whose permit is nearing its expiry date and you wish to renew the permit.

A system generated renewal notification and reminder will be sent to the company via the selected mode of contact indicated in the permit (e.g. email or fax), 60 days and 45 days, respectively, before the expiry date of a permit.

- a) For GIRO linked companies:

The permit will be automatically renewed unless the company opts out from the renewal by the given date stated in the renewal notification.

You must use the online 'Auto Renewal Preference' function to opt out of auto-renewal. (Note: If the opt out is successful, an acknowledgment statement will be displayed after clicking the Save button, i.e. 'The record is updated successfully'.)

b) For non-GIRO linked companies:

The permit will not be renewed unless the company submits a renewal application before the expiry date of the permit. The permit will expire and invalid if it is not renewed before its expiry date.

You must use the online 'Renew Advertisement and Sales Promotion Permit' to submit a renewal application for the permit.

APPENDIX 2 – ADVERTISEMENT AND SALES PROMOTION PERMIT APPLICATION PROCEDURES AND FEES

If this is the first time that you are applying for a license / permit with the HSA, you are required to submit a one-time CRIS registration via CRIS - 'Client Registration and Identification Service' function under e-Services on the HSA's website (cris@hsa).

Please login the PRISM online system to submit your application. The modes of payment include GIRO and credit card.

Procedures to Apply for Advertisement and Sales Promotion Permit

1. Go to prism@hsa under e-Services on HSA's website.
(<http://www.hsa.gov.sg/prism>)
2. Select 'Advertisements and Sales Promotion'.
3. Go to 'Make an application – apply@prism'.
4. Click [View guide] to preview the online application form in plain text.
5. Click 'Apply for Advertisements and Sales Promotion Permit' to submit a new application.
6. Complete the form with the required information and submit.
7. Upon successful submission of an application, an acknowledgement with an application number will be generated. The application number is not a permit number. You may use the application number for enquiry before the approval of the application.

Note:

8. The processing time for each application is **14** working days, excluding time taken by applicant to make required changes.
9. If the application is approved, a permit number will be issued with an endorsed copy of the approved specimen, i.e. 'MAHPxxxxxxx' for approved advertisement, 'MAHSxxxxxxx' for approved sales promotion.

You may contact us at hsa_ma_appl@hsa.gov.sg if you need any assistance on your application.

Fees

Effective Date: 2 Apr 2019

1 Application for a permit for ---		
(a)	A medical advertisement using light & sound projection	\$206
(b)	Any other medical advertisement that is not a sales promotion	\$103
	(i) A medical advertisement using still projection	
	(ii) A medical advertisement using sound projection	
(c)	a sales promotion	\$103
2 Permit for ---		
(i) the first year for ---		
(a)	A medical advertisement using light & sound projection	\$103
(b)	Any other medical advertisement that is not a sales promotion	\$103
	(i) A medical advertisement using still projection	
	(ii) A medical advertisement using sound projection	
(c)	a sales promotion	\$103
(ii) each subsequent year for ---		
(a)	A medical advertisement using light & sound projection	\$309
(b)	Any other medical advertisement that is not a sales promotion	\$206
	(i) A medical advertisement using still projection	
	(ii) A medical advertisement using sound projection	
(c)	a sales promotion	\$206
3 Application to amend a permit		\$52
4 Transfer of medical advertisement / sales promotion permit		\$16

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

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