HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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EXPLANATORY GUIDANCE TO THE HEALTH PRODUCTS (ADVERTISEMENT OF SPECIFIED HEALTH PRODUCTS) REGULATIONS 2016

- For Therapeutic Products Advertisements -

HSA
Health Sciences Authority

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.

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1 GENERAL INTRODUCTION

1.1 Introduction

The objectives of regulating advertisements of health products ("HP") are (i) to ensure that accurate and truthful information about the products is disseminated and (ii) to ensure that the advertisements and sales promotion activities do not mislead consumers or induce unnecessary purchase or consumption of the HP. These controls are essential in helping both the general public and healthcare professionals to make informed decisions when selecting HP.

This guidance document aims to clarify the principles of advertisement controls for Therapeutic Products ("TP") set out in the Health Products Act ("HPA") and the Health Products (Advertisement of Specified Health Products) Regulations ("the Regulations"), and should be read in conjunction with the HPA and the Regulations.

The examples highlighted in this guidance document are not exhaustive and may be updated periodically. Anyone who advertises or causes any product to be advertised as a TP is required to comply with the HPA and the Regulations.

1.2 Definitions

"**Advertisement**" as defined in Section 2 of the 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. Examples include:

- Electronic Direct Mailers,
- Websites, social media channels / platforms,
- Press releases and materials used in product launch events which are not open to the general public.

Information containing any reference to a specific HP, named or otherwise, with the intent or purpose of promoting the HP and its use shall be deemed as an advertisement for purpose of the HPA and the Regulations. This includes, but is not limited to, features of the name, identity, pack shot, tagline, description or logo associated with the HP.

Indirect references to a specific HP promoting their sale or use are also considered advertisements. This includes the use of any acronyms, misspellings, creative wording or designs intended to refer to the specific HP.

"Medicinal product" as referred to in this guidance, 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:

(a) use by being administered to one or more human beings 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.

"Publish" in relation to an advertisement, includes to distribute, show, display, exhibit, issue, disseminate or broadcast by any form of communication or in any manner.

"**Reference advertisement**" means an advertisement –

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

(b) appearing in a publication consisting mainly of such advertisements where the publication is published or issued by a person who is not the manufacturer, supplier, retailer, importer or exporter of the therapeutic product to one or more relevant health professionals specified in the First Schedule[1].

"**Sales Promotion**" means any advertisement in the form of a sales campaign (including door-to-door sales), exhibition, competition or any activity meant to introduce, publicise or raise the profile or public awareness or visibility of any therapeutic product for the purpose of promoting the sale or use of the product.

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

[1] Relevant health professionals 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.

"**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 REQUIREMENTS FOR ADVERTISEMENTS OF THERAPEUTIC PRODUCTS

2.1 Introduction

Anyone who advertises or causes any product to be advertised as a TP must comply with Part 5 of the HPA, and the Regulations. The principles set out in the HPA and the Regulations allow information and / or advertisements to be disseminated 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 14 of the Regulations.

Please refer to Annex 1 for a summary of requirements for advertisements of TPs that are directed to the general public, to the relevant health professionals and for trade purposes.

2.2 General rules for advertisements of therapeutic products

Advertisements of TPs do not require prior approval by the Authority. However, you have to ensure that the advertisements comply with the principles and requirements as stated in the HPA and the Regulations.

In general, no product should be advertised as a TP or that it can function as a TP, if it is not a TP as defined in the First Schedule to the HPA. **Advertisements of TPs must be aligned with the intended uses (indications) as per registered with the Authority**. Advertisements of unregistered TPs or unapproved uses of a registered TP (unregistered

indications) are not allowed. For example, an advertisement depicting a baby / infant when the TP was not indicated for them would be in breach of this provision.

Advertisements of TPs must not give any false information concerning the TPs or create any erroneous impression regarding the formulation, composition, specification, quality, safety, efficacy or uses of the TPs. You must ensure that any representation relating to a TP is factual, substantiated and aligned with that registered with the HSA. Advertisements must not include information that has not been registered with HSA or information which may potentially or indirectly extend the usage of a TP. This is to ensure information provided in the advertisement falls within the scope of the approved use of the TP.

You must ensure that advertisements of TPs also comply with any relevant conditions of registration that may be imposed. For example, whilst a TP may be approved for certain uses, its registration conditions may prohibit the advertisement of these approved uses to the general public.

(See: HPA Sn 19, Sn 20)

2.3 Substantiation of assertions of uniqueness and prominence

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

Information must be presented in a balanced, objective and accurate manner and must be referenced by reflecting the appropriate citations (where relevant). Any scientific terminology used should be in a manner that is readily understood by the target audience.

Requirements for substantiation also apply to the publication of any testimonials, whether directly or through linkages to third-party websites or advertising platforms. Testimonials, which include user experiences and reviews, e.g., "*After using this product,*

my condition improved within 3 weeks, I am so pleased with the results", must be current, genuine and authenticated (such as through signed testimonials), and representative of typical user experiences. 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" refers to results that an average user of the product would likely achieve. You must present supporting evidence for the testimonials upon request.

You must ensure that claims such as "most popular", "number one sales", "number one selling" are substantiated by relevant and verified market data. Supporting data must be available and provided upon request. You should 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.

(See: HP (Advert of SHP) Reg 5)

2.4 Further requirements for advertisements of TPs

2.4.1 Discourage from medical or professional advice

Advertisements of TPs must not directly or indirectly, cause readers to self-diagnose or self-treat any serious diseases[2]. Your advertisements must not suggest that using the TP eliminates the need to consult a physician or pharmacist.

You must not offer to diagnose, or suggest that medical interventions, e.g., surgical operations, are not required by using the TP featured in the advertisements.

(See: HP (Advert of SHP) Reg 4(a), 4(b), 4(c))

2.4.2 Encouraging inappropriate or excessive use

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

Advertisements of TPs must not encourage inappropriate or excessive use of the TP. Examples of content or manner of advertisements that will amount to "encouraging inappropriate or excessive use of the TP" include, but not limited to the following:

(a) Excessive multiple packs offered for sales promotion purposes.

Advertisers must balance customers' needs against the potential for over-consumption or inappropriate purchase of the TP when planning promotional activities. You should take into consideration the TP's intended use, appropriate duration for self-medication, the risk of accidental overdose etc. to ensure that the advertisement or sales promotion does not encourage inappropriate or excessive use.

For illustration, a multiple pack offer of 100 tablets (10 packs of 10 tablets) of analgesics will not be appropriate, as this may lead to unnecessary purchase or consumption, increasing the risk of accidental or deliberate overdose.

(b) Conditional promotions

Promotional activities with conditions on minimum purchases, e.g., activities requiring consumers to purchase a minimum quantity of TP within a limited period so as to receive additional benefits, will also not be appropriate. Such mechanics may encourage unnecessary purchase or consumption of the TP and may lead to consumers inappropriately managing serious conditions without seeking medical advice.

(c) any TP offered without charge via distribution of samples[3], or any suggestion or offer for trial use of TP with phrases such as "try product", "free / complimentary / trial use".

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

(d) any advertisements or sales promotion of TP that involves the giving away of prizes[4] (including lucky draws, lucky dips and contests) with the purchase of a TP.

(See: HP (Advert of SHP) Reg 4(d),10(a), 10(c))

2.4.3 Truthfulness

You must truthfully state the nature, quality and properties of the TP in your advertisements and must not directly or indirectly mislead the reader or give rise to any unrealistic expectations with regard to the safety, quality or efficacy of the TP in the advertisements by:

(a) implication,
(b) selective emphasis of information,
(c) omitting information,
(d) being ambiguous,
(e) making exaggerated claims, e.g., "the only", "longest lasting", "works the fastest", or
(f) comparison with other product categories.

(See: HPA Sn 20, HP (Advert of SHP) Reg 4(e), 4(j))

2.4.4 Causing fear and alarm

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:

(a) implication,
(b) omitting information,
(c) being ambiguous, or
(d) making exaggerated claims, e.g., "the only", "longest lasting", "works the fastest."

[4] A prize is something offered or striven for in competitions or in contests of chance.

You must not induce fear or unjustified concern that the reader is suffering, or without using the TP 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" include, but not limited to, the following:

(a) attention grabbing words and phrases like "danger”, “caution”, “beware”;
(b) emphasising without substantiation that a large majority of the population may be or are susceptible to a certain disease / condition;
(c) any repulsive or disturbing images or words that cause fear, alarm or distress to the public.

(See: HP (Advert of SHP) Reg 4(g))

2.4.5 Guaranteed results and side effects

Advertisements of TPs must not contain any claims or statements suggesting that the TP is magical or infallible, or that the results from taking the TP are guaranteed, extraordinary or better than or equivalent to any identifiable treatment.

All TPs have the potential to cause side effects as each individual responds differently. You must not include in an advertisement of TP any claims or statements suggesting that the TP is totally safe, does not cause side effects or is free from any side effects.

(See: HP (Advert of SHP) Reg 4(h), 4(i))

2.4.6 Refunds

You must not offer to refund money, either in full or partial to purchasers or users in advertisements of TPs.

(See: HP (Advert of SHP) Reg 4(k))

2.4.7 Endorsement by Government or Public Authority

You must not publish any advertisements reflecting false or erroneous claims indicating or suggesting that the use of the TP is promoted, supported or endorsed by the Government or any public authority. The use of HSA's name and / or logo in advertisements is not allowed.

(See: HP (Advert of SHP) Reg 4(l))

2.4.8 Advertising to children

You must ensure that there is no material (language or images) that is directed exclusively or principally at children under 14 years old in advertisements of TPs.

(See: HP (Advert of SHP) Reg 4(m))

2.4.9 Recommendations and endorsements

You must not include any recommendation by any healthcare professional, or any person who, because of the person's celebrity, social or professional status, is likely to encourage the use of the TP, in your advertisement.

In this instance, "recommendation" can include testimonials, support and endorsements which include, but are 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. It also includes persons of social or professional status such as influencers or key opinion leaders whose testimonials or support is likely to encourage the use of the TP.

You should avoid creating any perception of professional endorsement for the TP in advertisements, such as featuring models in "white coats" or with stethoscopes. You are advised to exercise care when featuring pharmacies, healthcare institutions or scenes of surgical procedures as these may create a perception of an endorsement by a healthcare professional.

(See: HP (Advert of SHP) Reg 4(n))

3 FURTHER REQUIREMENTS FOR ADVERTISEMENTS DIRECTED TO THE GENERAL PUBLIC

In addition to the requirements listed under Section 2, advertisements of TPs directed to the public must also comply with the requirements stipulated under Section 3 of this guidance.

3.1 Comparative Claims

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 TP or brand, e.g., “works faster and more effective than Brand xxx”. However, comparisons among products within the same brand by the same company to highlight differences between the products are allowable.

However, please note that any comparative statements featured must not mislead the general public about either the product advertised or the products being compared.

(See: HP (Advert of SHP) Reg 4(f))

3.2 Prohibition of certain materials and advertisements

You must not publish any advertisement to the public that claims, indicates or suggests, whether expressly or implicitly, that the TP

(a) will prevent, alleviate or cure any specified disease or condition specified in the Third Schedule[5]; or

(b) will prevent or alleviate any sign or symptom clinically attributable to any disease or condition specified in the Third Schedule; 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 specified in the Third Schedule.

(See: HP (Advert of SHP) Reg 6)

3.3 Prohibition on advertisement of prescription only medicines (POM) to the general public

Advertisements of prescription only medicines (POM) directed to the general public are prohibited. This includes all means and forms as described under section 1.2 above. These advertisements must not be made available in public places.

(See: HP (Advert of SHP) Reg 7)

3.4 Advertisements of pharmacy only medicines (P-medicines)

The safe use of some medicines depends on compliance with certain warnings and cautionary statements. You are required to prominently display the following advisories for all direct-to-consumers advertisements of pharmacy only medicines (P-medicines):

(a) Appropriate statements advising consumers to read the Patient Information Leaflet (PIL) or the Product Insert (PI); and

(b) Appropriate statements advising consumers to consult their healthcare professionals on the use of the medicine or if symptoms persist.

[5] Specified diseases and conditions listed in the Third 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.

As a general rule, the statements have to be placed prominently and be legible to the unaided eye of the target viewer.

You are not required to reflect the advisories on reminder advertisements which only feature the names and / or logos of the TP.

Specific advisories or warning statements may be required for advertisements of specific P-medicines. The requirement(s) for specific advisories will be communicated to product registrants individually by the Authority either at the time of TP registration, or through written notices or directives issued by the Authority.

Examples of specific advisory or warning statements may include:

(a) Known serious side effects,

(b) Contraindications,

(c) Precautions,

(d) Age restrictions.

(See: HP (Advert of SHP) Reg 8)

3.5 Sales promotion activities directed to the general public

You must not include the following in sales promotion activities directed to the general public:

The offer of:

(a) of any prize, e.g., through lucky draws, dips and contests as an inducement to purchase the TP;

(b) of any health / medicinal product[6] with a TP;

(c) of any sample of the TP.

[6] Examples of medicinal products include (non-exhaustive) complementary health products such as Chinese Proprietary Medicines, quasi-medicinal products (vitamin and mineral preparation, medicated plasters, sweets for relieving cough and throat irritation), Traditional Medicines, and medicated oils and balms.

You are also reminded that all sales promotion activities should not induce excessive use of the TP, as detailed in Section 2.4.2 of this guidance.

(See: HP (Advert of SHP) Reg 10(1))

3.6 Advertising on the Internet and digital platforms

The definition of 'advertisement' under the HPA includes advertisements on all media which include those published on the Internet such as corporate websites, e-commerce platforms, microsites as well as mobile applications and advertisements presented on digital interactive platforms, social media channels / platforms and blogs.

If you plan to advertise TPs on such channels to the general public, these advertisements must comply all the requirements in the HPA and the Regulations.

3.7 Provision of non-promotional information on diseases and their management e.g. Disease Education / Awareness Campaigns

Information on diseases and their management, such as Disease Education / Awareness Campaigns, is intended to educate the general public and provide information about specific conditions and treatment approaches. They shall not be used as indirect advertisements promoting the sale or use of specific TPs.

In providing information on diseases and their management or conducting Disease Education / Awareness Campaigns, companies should adhere to the following:

(a) References to specific HP, whether direct or indirect, are not allowed when providing information on treatment options involving HP. Information on treatment options should be presented in the context of a balanced overview consisting of the relevant disease information, the full range of treatment options with no reference to any specific HP and provide information on their associated risks and benefits. Where HPs are mentioned, the information shall be limited to

therapeutic class, active ingredients, or generic terms relating to the technology and / or treatments.

(b) Where treatment options are limited and may potentially draw attention to a single product, the focus should be on the disease rather than the product.

(c) Emphasis should not be placed on any single product, for example, by mention of the brand name, use of large font or employing promotional terms such as (non-exhaustive), 'breakthrough technology', 'revolutionary', 'game-changing', 'cutting-edge therapy', 'unparalleled efficacy', 'state of the art', 'pioneering approach', 'unmatched effectiveness' or 'exceptional outcomes'.

(d) Direct or indirect therapeutic or safety comparative claims with the intent to solicit the uptake of any single product should not be made between specific ingredients or treatment options.

(e) Patients should be directed to speak to a healthcare professional to seek further advice.

Any information that does not align with the criteria above and focuses on or draws attention to a specific HP may be considered an advertisement under the HPA, subject to the prevailing requirements.

4 FURTHER REQUIREMENTS FOR ADVERTISEMENTS DIRECTED TO RELEVANT HEALTH PROFESSIONALS SPECIFIED IN THE FIRST SCHEDULE AND FOR TRADE

In addition to the general requirements listed under Section 2 of this guidance, you must ensure that advertisements of TPs directed to the healthcare professionals or for trade purposes comply with the additional requirements stipulated under Section 4 of this guidance.

4.1 Advertisements intended for persons specified in the First Schedule

The relevant health professionals specified in the First Schedule of the Regulations include:

(a) Qualified practitioners,
(b) Registered pharmacists,
(c) Enrolled nurses,
(d) Registered nurses and registered midwives, and
(e) Persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, enrolled nurses, registered nurses or registered midwives.

You must ensure that advertisements intended solely for these classes of persons are restricted in circulation and are not freely available to or accessible by the general public.

You must ensure that advertisements of TPs featured on the Internet, social media pages and digital platforms designed specifically for persons specified in the First Schedule are restricted in order to prevent access by the general public. Adequate measures (e.g., authentication, password protection) should be put in place to ensure that access to the information is restricted to authorised individuals.

(*See: HP (Advert of SHP) Reg 6, 7)*

4.2 Advertisements of prohibited diseases and Prescription only medicines

Reference to the diseases and conditions specified in the Third Schedule as well as reference to POMs are allowed in the following instances:

(a) For advertisements distributed to relevant health professionals specified in the First Schedule to the Regulations (see Section 4.1).
(b) For reference or trade advertisements.
(c) For the purpose of information published on corporate websites (see Section 4.3), press releases and product launch events that are not open to the general public.

(d) For advertisements distributed at pharmaceutical trade fairs / exhibitions or scientific conferences / forums which are restricted in attendance to medical / scientific professionals, and not open to the general public.

Care must be taken to ensure that these advertisements are not distributed to the general public.

(See: HP (Advert of SHP) Reg 11, Reg 12, Reg 13)

4.3 Corporate websites

Local corporate websites belonging to TP registrants and licensees may include factual information about their TPs, including information on POM and diseases specified in the Third Schedule. Such information is still subject to controls under Sections 19 & 20 of the HPA and Regulations 4 & 5 of the Regulations, and may include non-promotional information[7] (i.e., not containing promotional elements for the purpose of inducing sale / usage) 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 provide information about the company. Such websites must not include any discussion forums or testimonials on the TP, , as these discussions generally stem from individual's experience and may inadvertently give non-factual information regarding the TP.

(See: HP (Advert of SHP) Reg 13)

4.4 Advertisements of unregistered TPs or unapproved uses

You may disseminate advertising materials relating to unregistered TPs or unapproved uses of registered TPs only at pharmaceutical trade fairs / exhibitions or scientific conferences / forums, where attendance is not open to the general public, e.g., restricted to the medical / scientific professionals, provided that the unregistered TP or the unapproved use has been registered / licensed elsewhere globally.

[7] Examples of non-promotional information include, but are not limited to, patient information leaflets, package inserts, information on product use(s), mechanism of action, contra-indications and warnings.

You must ensure that the information presented is not false and misleading, is substantiated by objective scientific evidence and that the materials clearly and prominently indicate that the TP or its use is not approved locally. You are prohibited from the sale or supply of unregistered TPs or TPs with unapproved uses at these events.

The controls, however, are not intended to restrict the exchange of scientific or medical information through:

(a) peer-reviewed scientific or medical journal articles; or

(b) scientific conferences and forums, as part of the official scientific program.

Information relating to unregistered TPs or unapproved uses conveyed for such purposes should be balanced (e.g. limitations of the data and of the TP are adequately discussed) and must be substantiated by objective scientific evidence.

(See: HP (Advert of SHP) Reg 9)

4.5 Sales promotion activities directed at healthcare professionals or healthcare institutions

Medicinal products and other HPs, e.g., as banded offers, may be offered as part of sales promotion activity involving a registered TP if the TP is intended to be supplied to a qualified practitioner or a registered pharmacist or is intended to be supplied by wholesale.

You may also distribute samples of registered TPs to qualified healthcare professionals, i.e., qualified practitioners / registered pharmacists at their institution of practice in accordance with each institution's policies. Samples of registered TPs may also be distributed to the qualified professionals, e.g., prescribers at pharmaceutical trade fairs / exhibitions, scientific conferences / forums, where there is no attendance by the general public. However, you should ensure that any distribution of samples is

conducted appropriately, e.g., samples of POM should only be distributed to qualified practitioners.

You are prohibited from the sale, offer for sale and distribution of samples of unregistered TPs or TPs for unapproved uses. You must also not offer any prize as an inducement for the wholesale purchase of a registered TP.

(See: HP (Advert of SHP) Reg 14)

5 CORRECTIVE MEASURES IN RELATION TO CONTRAVENING ADVERTISEMENTS

As part of compliance review and investigation, you may be required to provide the Authority with copies of TP advertisements that have been published or are pending publication, within a specified timeframe. When required, the Authority will inform you by a written notice regarding the submission.

(See: HP (Advert of SHP) Reg 15)

5.1 Corrective measures

If you have advertised any TP or caused any TP to be advertised in contravention of the HPA and its Regulations, the Authority may order you to do any or all of the following:

(a) Stop the advertisement with immediate effect.

(b) Take reasonable measures to remove the offending advertisements that have been published / distributed.

(c) Publish a corrective advertisement in a manner and containing information as specified by the Authority, which may include, but is not limited to:

- The content of the corrective advertisement.
- The medium where the corrective advertisement is to be published / broadcast.

- The duration for which the corrective advertisement is to be published / broadcast.

This is in addition to the penalties which may be imposed under the HPA. If you fail to comply with the order issued, the Authority may take such steps as it thinks reasonable and necessary to implement the requirements of the order and recover the cost and expenses reasonably incurred.

(See: HPA Sn 23)

5.2 Required content for corrective advertisements

In certain cases of contraventions, a corrective advertisement will be considered if it is assessed that the content of the offending advertisement provides inaccurate information pertaining to a TP's safety, efficacy and quality which may lead to inappropriate prescribing or use of the product, e.g., advertising unapproved indications of a TP.

In instances where a corrective advertisement is assessed to be necessary, the Authority will communicate the requirements including the content, size and placement and duration of the corrective advertisement to the affected companies via a written notice. In general, corrective advertisements are to be targeted at the audience who saw the offending advertisement and should adhere to the following content and format:

(a) **An expression of regret and apology**

(b) **Opening statement**

This should clearly indicate that this is a corrective statement issued at the order of the HSA and the product concerned, e.g., "*The HSA has ordered xxx to issue a corrective advertisement regarding the promotion of xxx*".

(c) **Statement on the breach**

This should outline how the advertisement was in breach of the Act / Regulations and give a description of the correct facts.

(d) **Description of the case**

When and where the offending advertisement was placed.

(e) **Contact information**

Details of the company contact should readers have any further questions about these matters or about the product.

6 FEEDBACK ON ADVERTISEMENTS

All complaints and feedback should be directed to the Medical Advertisements & Compliance Monitoring Unit at HSA_MA@hsa.gov.sg.

HSA values all feedback received and ensures strict confidentiality of the information provided. Compliance and / or enforcement actions will be taken where necessary. Our review process and subsequent actions are prioritised based on evidence and risk assessment, considering factors such as the severity of the alleged non-compliance, potential risk or harm to patients and consumers, and the advertiser's compliance history. This assessment determines the urgency and extent of our response. Please note that information pertaining to our reviews and investigations is not disclosed to third parties.

To facilitate review and follow-up of the complaint or feedback, please provide the following information:

(a) Details of where and when the advertisement was published (a copy or image of the advertisement to be provided).

(b) Details of the concerns identified with the advertisement. The identified non-compliance including the clause / provision / prescribed requirements referred to should be provided.

7 ANNEX

Summary of requirements for direct-to-consumer advertisements of therapeutic products (TPs) and advertisements of TPs directed to relevant health professionals and for trade

In addition to the general rules prescribed under the HPA, all TP advertisements must comply with the following requirements prescribed in the Regulations. For further explanation on the individual specific requirements for all TP advertisements intended for the general public, please refer to Sections 2 and 3 of this Explanatory Guidance. For further explanation on the individual specific requirements for all TP advertisements directed at relevant health professionals and trade, please refer to Sections 2 and 4 of this Explanatory Guidance.

S/N	Prescribed requirements	Section in guidance	Applicable to Direct-to-consumer advertisements	Applicable to advertisements directed to relevant health professionals and trade
1	Substantiation of assertions of uniqueness and prominence	2.3	√	√
2	Advertisements of TP must not discourage reader from medical or professional advice	2.4.1	√	√
3	Advertisements of TP must not encourage inappropriate or excessive use	2.4.2	√	√
4	Advertisements of TP must be truthful and must not mislead the readers	2.4.3	√	√
5	Advertisements of TP must not cause fear and alarm	2.4.4	√	√
6	Advertisements of TP must not claim or imply that the	2.4.5	√	√

	results from taking the TP is guaranteed results and that the TP is free from side effects			
7	Advertisements of TP must not offer any monetary refunds	2.4.6	√	√
8	Advertisements of TP must not contain any endorsement by Government or Public Authority	2.4.7	√	√
9	Advertisements of TP must not be directed principally at children	2.4.8	√	√
10	Advertisements of TP must not contain any recommendations or endorsement by healthcare professionals or celebrities	2.4.9	√	√
11	Advertisements of TP must not contain comparative claims involving another named TP or brand	3.1	√	
12	Prohibition of advertisements of TP relating to the specified diseases and conditions listed in the Third Schedule	3.2	√	
13	Prohibition of advertisements of Prescription Only Medicines (POM)	3.2	√	
14	Mandatory advisories for Advertisements of Pharmacy-only medicines (P-medicines)	3.3	√	
15	Prohibited sales promotion activities	3.4	√	

16	Advertisements of prohibited diseases and Prescription only medicines	4.2		√
17	Advertisements on corporate websites	4.3		√
18	Advertisements of unregistered TPs or unapproved uses	4.4		√
19	Sales promotions intended for healthcare professionals or healthcare institutions	4.5		√

HEALTH SCIENCES AUTHORITY

Applied Sciences Group
Blood Services Group
Enforcement Group
Integrated Health Regulation Group

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