

REGULATORY GUIDANCE

01 NOVEMBER 2016

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



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. GENERAL INTRODUCTION

1.1 Introduction

The objective of advertisement controls for health products ("HP") is to ensure that accurate and truthful 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 HP. This is essential in helping both the public and healthcare professionals to make informed decisions in their choice of HP.

This Guidance 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 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. Anyone who advertise or cause any product to be advertised as a TP are required to comply with the HPA and the Regulations.

1.2 Definitions

"**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. The forms of media include but are not limited to:

- (a) Newspapers, flyers, banners and lightboxes
- (b) LCD (liquid crystal display)/ LED (light emitting diodes) display panels.
- (c) Internet advertisements including those on digital communication channels e.g. Facebook and Blogs
- (d) Press releases and materials used in product launch events which are not open to the general public.

Feature of the name, identity, pack shot, tagline or 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.

"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:

- 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.

Examples of medicinal products include Chinese Proprietary Medicines ("CPM"), quasi medicinal products (vitamin and mineral preparation, medicated plasters, sweets for relieving cough and throat irritation), Traditional Medicines ("TM"), and medicated oils and balms.

"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 contraindications and warning 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 Schedule¹.

"**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 TP 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.

"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

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.

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 cause any product to be advertised as a TP is 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 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 <u>Annex 1</u> for a summary of requirements for advertisement of TPs that are directed to the public, to the relevant health professionals and for trade purposes.

2.2 General rules for advertisements of therapeutic products

Advertisements for TP 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 First Schedule to the HPA. <u>Advertisements of TPs must</u> <u>be aligned with the intended uses (indications) as per registered with the</u> <u>Authority</u>. 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.

Advertisement of TPs must not give any false information concerning the TP or create any erroneous impression regarding the formulation, composition, specification, quality, safety, efficacy or uses of the TP. Representation relating to a TP's safety, efficacy and quality are to be furnished to and verified by the Authority prior to advertising e.g. through an application to register the TP or an application for minor / major variations. Please see Guidance on Therapeutic Product Registration available on HSA website for more information.

You must ensure that advertisements of TPs also comply with any relevant conditions of registration that may be imposed. For example, a TP may be approved for certain uses, but its conditions may prohibit the advertisement of these approved uses to the 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 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 terminologies used should be in a manner that is readily understood by the targeted 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 include "user experience' or "user review" e.g. "*After using this product, my condition improved within 3 weeks, I am so pleased with the results*". Testimonials must be current, genuine, authenticated, for example, via signed testimonials, 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. You must present supporting evidence for the testimonials upon request.

You must ensure that claims such as "most popular", "number one sales" are verified and substantiated by market data from credible sources, e.g. recognised third party research companies. Supporting data must be available and 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.

(See: HP(Advert of TP) 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 the reader to self-diagnose or self-treat any serious diseases². Your advertisements must not suggest that with the use of the TP, the consumer would not need to consult a physician or a 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 TP) Reg 4(a), 4(b), 4(c))

2.4.2 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 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 .

² Serious diseases refer to chronic / life-threatening diseases / conditions, which cannot be selfdiagnosed / managed and where a delay in treatment would lead to death, hospitalisation, serious injury or irreversible deterioration of the disease / condition.

Advertisers should balance between meeting customers' needs and 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 do not encourage inappropriate or excessive use.

For illustration, a multiple pack offer of 100 tablets (10 x 10's tablets / box) of analgesic will not be appropriate as such a mechanic may lead to unnecessary purchase or consumption, increasing the chances of an accidental or deliberate overdose.

- (b) any TP offered without charge via distribution of samples³, or any suggestion or offer for trial use of TP with phrases such as "try product", "free / complimentary / trial use"
- (c) any advertisements or sales promotion of TP that involves the giving away of prizes⁴ (including lucky draws, lucky dips and contests) with the purchase of a TP.

(See: HP(Advert of TP) 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:

• implication,

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

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

- through emphasising certain information,
- omitting information,
- being ambigious,
- making exaggerated claims e.g. "the only", "longest lasting", "works the fastest", or
- comparison with other categories of products.

(See: HPA Sn 20, HP(Advert of TP) 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:

- implication,
- omitting information,
- being ambigious, or
- making exaggerated claims e.g. "the only", "longest lasting", "works the fastest",

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) eye catching words and phrases like
 - "danger";
 - "caution";
 - "Beware"
- (b) emphasising 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.

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

2.4.5 Guaranteed results and side effects

The content of any advertisement featuring a TP must 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 each individual respond differently. You must not feature in an advertisement of TP, any claim or statement suggesting that the TP is totally safe and does not cause or is free from any side effects.

(See: HP(Advert of TP) Reg 4(h); 4(i))

2.4.6 Refunds

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

(See: HP(Advert of TP) 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.

(See: HP(Advert of TP) Reg 4(I))

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 TP) 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, "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.

You should avoid the perception of professional endorsement for the TP in advertisements, for example, the feature of models in "white coats" or with stethoscopes. You are advised to exercise care when featuring pharmacies, healthcare institutions or scenes of surgical procedures as it may give rise to a perception of an endorsement by a healthcare professional.

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

3 FURTHER REQUIREMENTS FOR ADVERTISEMENTS DIRECTED TO THE PUBLIC

In addition to the requirements listed in Section 2, advertisements of TPs directed to the public must 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 members of the public do not contain comparative claims against another named TP or brand e.g. "works faster and more effective than Brand xxx". However, comparison among products within the same brand by the same company to highlight differences between the products is allowable.

You may feature comparative claims among drug classes or categories, or generic claims without comparison to other brands e.g. 'works faster', if supported by objective evidence. The basis of comparison should be similar for all comparative claims, for example, products compared should be intended for the same purpose.

However, please note that any comparative statements featured must not mislead the public about the product being advertised or about any product which it is compared with.

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

3.2 **Prohibition of certain materials and advertisements**

You must not advertise to the public any advertisements that 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 Schedule⁵; or
- (b) will prevent or alleviate any sign or symptom clinically attributable with any disease or condition specified in the Second 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.

Advertisements of prescription only medicines (POM) directed to the general public is prohibited. Hence, these advertisements must not be made available in any publicly accessible areas including waiting areas of hospitals and clinics.

(See: HP(Advert of TP) Reg (6), Reg (7))

3.3 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)
- (b) Appropriate statements advising consumers to consult their healthcare professionals on the use of the medicine or if symptoms persist

The advisories must be clearly and prominently reflected on the advertisement. As a general rule, the statements have to be placed prominently and legible to the unaided eye of the target view.

⁵ Specified diseases and 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.

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 pharmacy only (P) medicines. The requirement(s) for specific advisories will be communicated to you as product registrants individually by the Authority either at the time of registration of the TP, or through any written notice or directive 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 TP) Reg (8))

3.4 Sales promotion activities directed to the public

You must not conduct the following sales promotion to the public:

The offer of:

- (a) of any prize e.g. through lucky draws, dips and contest as an inducement to purchase the TP;
- (b) of any health / medicinal product with a TP;
- (c) of any sample of the TP

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 TP) Reg 10(1))

3.5 Advertising on the Internet

The definition of 'advertisement' under the HPA includes advertisements on the Internet such as e-commerce sites, microsites and will also include those presented using digital communication channels e.g. Facebook and Blogs.

If you wish to advertise TPs on such channels to the public, please note that these advertisements will be subject to all requirements in the HPA and the Regulations.

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 the general public.

You must ensure that advertisements of TPs featured on Internet and social media pages designed specifically for persons specified in the First Schedule are restricted in order to prevent access by the members of the public. A disclaimer or statement reflected on a freely accessible page, indicating the target audience, is **not** acceptable.

(See: HP(Advert of TP) Reg 6, 7)

4.2 Advertisements of prohibited diseases and Prescription only medicines

Reference to the diseases and conditions specified in the Second 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 opened to the 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 opened to the general public.

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

(See: HP(Advert of TP) 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 Second Schedule. Such information, are still subject to controls under Sections 19 & 20 of the HPA and Regulations 4 & 5 of the Regulations, and may include non-promotional information⁶ (i.e. not containing promotional elements for the

⁶ Examples of non-promotional information includes, but is not limited to, patient information leaflets, package inserts, information on product use(s), mechanism of action, contra-indications and warnings.

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 provides information about the company. Such websites must not carry any discussion forums on the TP, or similar platforms / testimonials, as these discussions generally stem from individual's experience and may inadvertently provide non-factual information regarding the TP.

(See: HP (Advert of TP) 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 opened 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.

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 at scientific conferences and forums, as part of the official scientific program or through scientific or medical journal articles. Information relating to unregistered TPs or unapproved uses conveyed for such purposes must be substantiated by objective scientific evidence.

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

4.5 Sales promotion activities directed at healthcare professionals or healthcare institutions

Medicinal and other health products 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 to each instituition'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 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 with unapproved uses. You must also not offer any prize as an inducement for the wholesale purchase of a registered TP.

(See: HP(Advert of TP) Reg14)

5 CORRECTIVE MEASURES IN RELATION TO CONTRAVENING ADVERTISEMENTS

As part of compliance review and investigation, you may be required to furnish copies of TP advertisements which have been advertised or about to be advertised to the Authority within a specified time. When required, the Authority will communicate with the advertiser by a written notice on the submission.

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

5.1 Corrective measures

If you have advertised any TP or cause 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 per specified by the Authority, which may include, but 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 the corrective advertisement is to be published / broadcast

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 reasonable 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 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 original 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 Unit at <u>HSA_MA@hsa.gov.sg</u>.

To facilitate reviews and follow-ups, all complaints and feedback should 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 noncompliance including the clause / provision / prescribed requirements referred to should be provided.

Annex 1

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	Applicable to	Applicable to
		in	Direct-to-	advertisements
		guidance	consumer	directed to
			advertisements	relevant health
				professionals
				and trade
1	Substantiation of assertions of uniqueness	2.3		
	and prominence			
2	Advertisement of TP must	2.4.1	\checkmark	
	not discourage reader from			
	medical or professional advice			
3	Advertisement of TP must	2.4.2	\checkmark	
	not encourage			
	inappropriate or excessive			
	use			
4	Advertisements of TP must	2.4.3	\checkmark	
	be truthful and must not			
	mislead the readers			
5	Advertisements of TP must	2.4.4	\checkmark	
	not cause fear and alarm			

			1	,
6	Advertisements of TP must	2.4.5	\checkmark	
	not claim or imply that the			
	results from taking the TP			
	is guaranteed results and			
	that the TP is free from			
	side effects			
7	Advertisements of TP must	2.4.6	\checkmark	
	not offer any monetary			
	refunds			
8	Advertisements of TP must	2.4.7	\checkmark	
	not contain any			
	endorsement by			
	Government or Public			
	Authority			
9	Advertisements of TP must	2.4.8	\checkmark	
	not be directed principally			
	at children			
10	Advertisements of TP must	2.4.9	\checkmark	
	not contain any			
	recommendations or			
	endorsement by healthcare			
	professionals or celebrities			
11	Advertisements of TP must	3.1		
	not contain comparative			
	claims involving another			
	named TP or brand			
12	Prohibition of	3.2		
	advertisements of TP			
	relating to the specified			
	diseases and conditions			
	listed in the Second			
	Schedule			
13	Prohibition of	3.2		
	advertisements of			
	Prescription Only			
	Medicines (POM)			
14	Mandatory advisories for	3.3	\checkmark	
	Advertisements of			
	Pharmacy-only medicines			
	(P-medicines)			
L			1	1

15	Prohibited sales promotion activities	3.4	
16	Advertisements of prohibited diseases and	4.2	
	Prescription only medicines		
17	Advertisements on	4.3	
	corporate websites		
18	Advertisements of	4.4	
	unregistered TPs or		
	unapproved uses		
19	Sales promotions intended	4.5	
	for healthcare		
	professionals or healthcare		
	institutions		



Health Products Regulation Group Blood Services Group Applied Sciences Group

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HEALTH SCIENCES AUTHORITY - HEALTH PRODUCTS REGULATION GROUP