HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-08: Guidance on Medical Device Advertisements and Sales Promotion

Revision 2

HSA
Health Sciences Authority

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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 Medical Devices ("MD") set out in the Health Products Act ("HPA") and the Health Products (Medical Device) 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 MD are required to comply with the HPA and the Regulations.

2. LEGISLATION

The relevant legislative control for the advertisement of medical devices is included in the following legislation:

 Health Products Act
- Part V Advertisement of Health Products, Sections 19-23.
- Any person who contravenes the provisions of section 19, 20, 21 or 23 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

 Health Products (Medical Devices) Regulations 2010
- Part V Advertisement of Medical Devices, Regulations 19-23.
- Every offence under these Regulations may be compounded in accordance with section 65 of the Act.
- Any person who contravenes the Regulations shall be guilty of an offence and shall be liable to a fine not exceeding $5,000.

Please refer to our website (www.hsa.gov.sg) for details of these legislation.

3. DEFINITIONS

"**Advertisement**" in relation to a health product, means the publication, dissemination or conveyance of any information for the purpose of promotion, whether directly or indirectly, the sale or use of that health product by any means or in any form, 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:

(i) Flyers, banners and lightboxes
(j) LCD (liquid crystal display) / LED (light emitting diodes) display panels.
(k) Advertisements on digital interactive media or social media channels e.g. Facebook, Blogs, Instagram
(l) Press releases and materials used in product launch events

Feature of the name, identity, pack shot, tagline or logo associated with the MD, with the intent or purpose of promoting the MD and its use shall be deemed as an advertisement for purpose of the HPA and the Regulations.

An advertisement shall include a sales promotion which means any sales campaign (including door to door sales), exhibition, competition or any other activity meant to introduce, publicise or raise the profile or public awareness or visibility of any medical device for the purpose of promoting the sale or use of the medical device

"**Professional use only medical device"** refers to a medical device that is to be used on an individual solely by, or under the supervision of, a qualified practitioner.

"**Qualified Practitioner**" refers to a registered medical practitioner under the Medical Registration Act; or a registered dentist under the Dental Registration Act whose name appears in the first division of the Register of Dentists.

4. REQUIREMENTS FOR ADVERTISEMENTS OF MEDICAL DEVICES

4.1 Introduction

Anyone who advertises or cause any product to be advertised as a MD 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 advertisement controls are set out in sections 19 and 20 of the HPA and regulations 19 to 23 of the Regulations.

4.2 Rules for advertisements of Medical Devices

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

In general, no product should be advertised as a MD or that it can function as a MD, if it is not a MD as defined in First Schedule to the HPA. Advertisement of MDs must not give any false information concerning the MD or create any erroneous impression regarding the components, composition, specification, quality, safety, efficacy or uses of the MD. Any representation relating to a MD must be factual and substantiated by objective evidence.

Where the MD is a registered MD, you must ensure that all advertised claims are aligned to the indications and instructions for use (IFU) as registered with the HSA. Information that has not been registered or which may potentially or indirectly extend the usage of a registered MD must not be included in advertisements. This is to ensure information provided in the advertisement falls within the scope of the approved use of the MD.

Advertisements of MD exempted from registration i.e. Class A medical devices, must be aligned and not deviate from the product owner's specifications.

You must also ensure that advertisements of MDs comply with any relevant conditions of registration that may be imposed.

4.3 Substantiation of assertions of uniqueness and prominence

Any text, emphasis, certification, award or unique feature or prominence of the advertised MD must be substantiated by facts or robust objective evidence from credible sources.

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, which includes "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 relevant market data. 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.

4.4 Prohibited Advertisements

4.4.1 Advertisements relating to the following are prohibited from advertising to the general public.

(a) A registered "Professional Use only" medical devices; or

(b) an unregistered "professional use only" medical device that is supplied in accordance with Regulation 8 or 10 of the Regulations

No person shall advertise any "professional use only" medical device, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, qualified practitioners.

4.4.2 An advertisement relating to a MD shall not expressly or implicitly claim, indicate or suggest that the MD will prevent, alleviate or cure any disease or condition specified in the Second Schedule[1], unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among the following classes of people:

(a) qualified practitioners
(b) registered pharmacists
(c) registered nurses and registered midwives
(d) persons undergoing training with a view of becoming qualified or registered as the aforementioned groups.

5 GENERAL PRINCIPLES FOR ADVERTISEMENTS OF MEDICAL DEVICES

Advertisers are encouraged to adhere to the following general principles so as to ensure that advertisement claims do not convey misleading messages that could lead to inappropriate use of the product or bring about undue harm to the public.

5.1 Discourage from medical or professional advice

Advertisements of MDs should not directly or indirectly, cause the reader to self-diagnose or self-treat any serious diseases[2]. Advertisements must not suggest that with the use of the MD, the consumer would not need to consult a doctor.

Advertisements should not offer to diagnose, or suggest that medical interventions, e.g. surgical operations, are not required by using the MD featured in the advertisements.

5.2 Truthfulness

All product claims presented in advertisements must be well supported by scientific evidence. You must truthfully state the nature, quality and properties of the MD 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 MD in the advertisements by:

[1] 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.

[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.

- implication,
- 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.

The use of superlatives or exaggerated claims should be avoided. E.g. miraculous, 100% safe.

5.3 Inappropriate or Indiscriminate Use

Advertisements should not directly or indirectly encourage inappropriate, indiscriminate, unnecessary or excessive use of the MD.

5.4 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. Advertisements should not misuse research results or make unnecessary quotations from technical and scientific publications.

5.5 Comparative Claims

Advertisements should also not denigrate or attack unfairly any other products, goods or services or other sectors of the industry.

Any comparative statements featured must not mislead the public about the product being advertised or about any product which it is compared with.

5.6 Causing fear and alarm

You should 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

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

(a) words 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 that cause fear, alarm or distress to the public.

5.7 Guaranteed results and claims of safety

Advertisement of MD should not contain any claim or statement suggesting that the results from using the MD are guaranteed, extraordinary or is better than or equivalent to any identifiable treatment. There should not be any claim, statement or implication that the MD is 100% safe, has no side effects or that its use will not cause harm.

5.8 Recommendations and 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 MD is promoted, supported or endorsed by the Government or any public authority including the Health Sciences Authority (HSA).

The names and logos of HSA and any of its professional groups cannot be used for any medical device advertisements and sales promotion in any media.

5.9 Recommendations and endorsements by healthcare professionals

You should not include any recommendation by any healthcare professional 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.

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.

5.10 Advertisements of specific categories of MD

5.10.1 Class A medical devices exempted from product registration

(a) Dealers shall be mindful and exercise due diligence in making product claims and advertising for their products. Presentations and advertisements for the intended use of a medical device must not deviate from the Product Owners' specifications.

(b) Please refer to Appendix A for a reference list of acceptable claims for some examples of Class A medical devices.

5.10.2 Medical devices with supply restrictions

Advertisements of medical devices with supply restriction should feature relevant advisories on the advertisements. Some examples are provided below.

(a) Contact lenses must be supplied via registered optometrists and in accordance with the Optometrists & Opticians Act. Advisories e.g. 'visit/consult your optometrist' should be featured.

(b) Medical devices intended for supervised supply by specified healthcare professionals should feature advisories like 'Consult your doctor/physician' as applicable.

5.10.3 Specific requirements under the Singapore Code of Advertising Practice (SCAP)

The Singapore Code of Advertising Practice (SCAP) administered by the Advertising Standards Authority of Singapore (ASAS) stipulates specific requirements including the feature of caveats for certain products which may include MD, provided below.

- Condoms
- Hearing aids
- Slimming products
- Hair and scalp products

Please access the SCAP (www.asas.org.sg) for further details.

6 CORRECTIVE MEASURES IN RELATION TO CONTRAVENING ADVERTISEMENTS

As part of compliance review and investigation, you may be required to furnish copies of MD 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.

6.1 Corrective measures

If you have advertised any MD or cause any MD 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

This is in addition to the penalities 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 reasonable incurred.

6.2 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 MD's safety, efficacy and quality which may lead to inappropriate prescribing or use of the product, e.g. advertising unapproved indications of a MD.

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.

7 FEEDBACK ON ADVERTISEMENTS

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

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 non-compliance including the clause / provision / prescribed requirements referred to should be provided.

APPENDIX A

A reference list of acceptable product claims for some examples of Class A medical devices that are exempted from product registration*.

*(*The classification of Class A medical devices should be in accordance with relevant Guidance Documents e.g. GN-13 or GN-14. The examples given below should not be used as a reference for classification of medical devices.*

For information on classification of medical devices, please refer to other Guidance Documents available on our website (www.hsa.gov.sg).

- *GN-13 Guidance on Risk Classification of General Medical Devices*
- *GN-14 Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices*
- *GN-22 Guidance for Dealers on Class A Medical Devices exempted from Product Registration)*

	Examples of Class A medical devices*	**Acceptable product claims**
1	Adhesive bandage / dressing / strip / tape	• cover and protect intact skin or wounds • approximate the skin edges of a wound • support an injured part of the body • fix dressings to skin • bind/attach/secure objects to the skin/body part • additional properties where substantiated e.g. waterproofing
2	Adhesive tape remover	• remove adhesive tape and its residue from the skin or other surfaces
3	Nasal aspirator, manual	• enable gentle suction and clearing of excessive mucus from the nasal passages to facilitate easier breathing
4	Ice bag / collar	• provide dry cold therapy to a limited external surface area of the body • alleviate pain and/or promote healing in minor injuries of the body
5	Bandage, self-adherent	• secure a dressing • maintain pressure over a compress • immobilise a limb or other body part
6	Bandage, clavicle	• maintain fixation and longitudinal extension of the clavicle during a period of treatment
7	Bandage, elastic	• provide support or local pressure to a part of the body, especially a joint, while allowing movement
8	Bandage, gauze	• cover and protect wounds
9	Bandage, gauze, roller	• bandage heads, limbs, and difficult to dress wounds (e.g., burns, plastic surgery, or orthopaedic wounds)
10	Bandage, traction	• assist in exerting desirable tensile (pulling) forces on the body

	Examples of Class A medical devices*	Acceptable product claims
11	Bedpan	• receptacle for urine and faeces
12	Abdominal / ankle / breast / chest / sternum / wrist binder	• support relaxed abdominal walls / ankle joint / breasts / ribs and chest / sternum / wrist joint
13	Blanket, general purpose	• wrap or cover a person for warmth and comfort
14	Bottle, heating / cooling	• filled with either hot or cold water or ice for the purpose of applying heat or cold therapy to an area of the body
15	Contact lens case	• for the storage of contact lenses when the lenses are not being used
16	Chair, bath / shower	• to be sat upon by a person who is either bathing, showering, or using some washing facility
17	Chair, toilet	• allows an immobilised person/patient to utilise a standard stationary toilet without leaving the chair
18	Compression dressing	• compress a local area, e.g., to stop bleeding, prevent oedema • provide support for varicose veins or ostomy aids
19	Compression garment	• fit over and apply pressure to a specific body part(s) (e.g., thighs, hips, buttocks) • may aid in the readjustment of overlying skin, after significant subcutaneous tissue removal (e.g., fat removal after liposuction)
20	Cotton ball	• apply medications to or remove liquid from various parts of the body
21	Cover, thermometer	• prevent cross-contamination between patients and/or environmental exposure
22	Gloves, examination	• prevent contamination between patient and examiner
23	Heat / cold pack	• provide cold/hot therapy to body surface and/or underlying tissue, e.g. muscle
24	Mask, Face	• prevent contamination to patient/ health care personnel
25	Pressure alleviation pad	• prevent pressure sores, e.g. bed sores or decubitus ulcers occurring on the parts of the patient's body which are prone to this
26	Finger protector	• protect an injured finger from further trauma during the healing process
27	Protector, foot (e.g. *Bunion / Callus / Corn protectors, pads, plasters)*	• protect that part of the foot from friction against surfaces and knocks against objects • may have additional properties (e.g. waterproof, lubricating, hypoallergenic) where substantiated
28	Patient restraint	• temporarily secure the arm or leg of an adult patient to prevent injury or hazards. when

	Examples of Class A medical devices*	Acceptable product claims
		anchored to a fixture or furniture part (e.g., a bedrail) • restrict movement of the patient and prevent the patient from interfering with treatment
29	Restraint, fingers	• restrict finger mobility and prevent potential injury
30	Restraint, body	• secure a patient's arms to the torso to prevent self-inflicted injury
31	Self-exam pad, breast	• used as an aid in performing breast self-examination
32	Orthotic shoe	• support, align, prevent, or correct deformities of the feet to help improve their function
33	Cast boot	• boot-like cover for a foot enclosed in a leg cast
34	Shoe, Cast	• protect the cast material and provide support
35	Sling	• support and limit the range of motion of an injured limb during the healing period • support and limit the range of motion of a body in transport
36	Splint	• immobilise an injured body or body part
37	Splint, nasal, external	• immobilisation of parts of the nose typically after a fracture or treatment • may function as a truss-like support on the outside of the nose
38	Cast stockinette	• used as padding under a cast or splint
39	Stocking, stockinette	• hold bandages in place • place uniform pressure on a leg, finger, arm, or other part of an extremity • pad the area under a cast or splint • cover a stump when a prosthesis is worn
40	Stocking, medical support	• support, correct, prevent deformity, or to align body structures for functional improvement
41	Tourniquet strap	• compress the arteries and regulate the blood flow
42	Transfer aid, person	• assist in the physical transfer of a person/patient, e.g. ill, disabled or infirm, from one position to another
43	Walking crutch / frame / table / stick	• assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person
44	Wheel Chair	• wheeled personal mobility device for a disabled user not having the full capacity to walk by him or herself

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

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