

# HEALTH SCIENCES AUTHORITY

## REGULATORY GUIDANCE

December 2013

# MEDICAL DEVICE GUIDANCE

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

Revision 1



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## 1. INTRODUCTION

This guidance document is intended to complement the provisions of the Health Products Act (*Act*), Health Products (Medical Devices) Regulations 2010 (*Regulations*) and the Singapore Code of Advertising Practice (SCAP) relating to the advertisement and sales promotion of medical devices for any person in local public media or intended for the information of the general public.

Advertisements and sales promotion of medical devices currently do not require prior approval from the Health Sciences Authority (HSA). It is the responsibility of the advertiser to ensure compliance with prevailing legislations and guidelines.

## 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](#) for details of these legislations.

### 3. DEFINITION

- “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.
  
- 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

### 4. PROHIBITED ADVERTISEMENTS

Pursuant to *Regulations* 21 and 22, advertisements relating to the following are prohibited from advertising to the general public.

- “Professional Use only” medical devices

No person shall advertise any registered “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.

(Note: 'Qualified Practitioners' refers to registered medical practitioners or registered dentists)

- Disease or condition specified in the Second Schedule of the *Regulations*

An advertisement relating to a medical device shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any disease or condition specified in the Second Schedule, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among the qualified practitioners, registered pharmacists, registered nurses and registered midwives, and persons undergoing training with a view of becoming qualified or registered as the aforementioned groups.

Second Schedule:

1. Blindness (失明)
2. Cancer (癌症)
3. Cataract (白内障)
4. Drug addiction (毒癮)
5. Deafness (耳聾)
6. Diabetes (糖尿病)
7. Epilepsy or fits (癲癇或抽搐)
8. Hypertension (高血压)
9. Insanity (精神错乱)

10. Kidney diseases (肾病)
11. Leprosy (麻风)
12. Menstrual disorders (月经不调)
13. Paralysis (瘫痪症)
14. Tuberculosis (结核病)
15. Sexual functions (性功能)
16. Infertility (不育症)
17. Impotence (阳痿)
18. Frigidity (性冷感)
19. Conception and pregnancy (受孕或怀孕)

## **5. CLAIMS GUIDELINES**

- (a) Registered medical devices
  - i. Claims concerning the intended use and efficacy of the medical device must be aligned with the Authority's approved indications.
  - ii. Advertisements shall not contain any statement which expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the Authority.
- (b) Non-sterile Class A medical devices exempt from product registration
  - i. 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.

- ii. Please refer to Appendix A for a reference list of acceptable claims for some examples of non-sterile Class A medical devices.

(c) Advertisement Claims

- i. Product claims presented in advertisements must be truthful and well supported by scientific evidence.
- ii. Claims of market prominence or uniqueness (e.g. 'No. 1'; '1st in the market') must be substantiated with independent third party research data.
- iii. The use of superlatives or exaggerated claims should be avoided. e.g. miraculous, 100% safe.

(d) Medical devices with supply restrictions

Advertisements of medical devices with supply restriction must feature the restrictions on the face of the advertisements. Some examples are provided below.

- 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.
- Medical devices intended for supervised supply by specified healthcare professionals should feature advisories like 'Consult your pharmacist' as applicable.

(e) Additional notes for certain medical device categories

The Singapore Code of Advertising Practice (SCAP) stipulates specific requirements including the feature of caveats for certain product

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categories. Some examples and their references in SCAP are provided below.

- Condoms - SCAP Appendix F clause 6.7.3 pg. 32
- Hearing aids - SCAP Appendix F clauses 6.15 and 6.16 pg. 34
- Slimming products - SCAP Appendix H pg. 41
- Hair and scalp products - SCAP Appendix I pg. 47



## 6. GENERAL PRINCIPLES

The following general principles 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.

(a) Truthfulness

Advertisements should truthfully state the nature, quality and properties of the medical device. Advertisements should not mislead in any way by ambiguity, exaggeration, omission or otherwise. Unqualified superlatives must not be used.

(b) Substantiation

All claims made in the advertisement must be substantiated with scientific studies.

(c) Accuracy

Recommendations relating to the use of the medical device should be accurately stated in moderate terms and should be relevant to their properties.

(d) Comparisons

Advertisements should not contain comparisons with other products unless scientifically proven. All comparative advertisements should be so designed that they are clear and fair, without denigrating other products.

(e) Indiscriminate Use

Advertisements should not directly or indirectly encourage indiscriminate, unnecessary or excessive use of the medical device.

(f) 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.

(g) Fear and Superstition

Advertisements should not arouse fear in the minds of the public nor should they exploit the public's superstition.

(h) Language

Medical advertisements should be in simple-to-understand language, easily comprehensible and should avoid confusing medical jargon. Scientific jargon and irrelevancies should not be used to make claims appear to have a scientific basis they do not possess.

(i) Endorsements and Testimonials from Healthcare Professionals

Advertisers should not give the impression of advice or support from healthcare professionals, i.e. visual and/or audio presentation of doctors/dentists/pharmacists or nurses on the medical device.

Advertisements should not carry testimonials or recommendations by healthcare professionals.

(j) User Testimonials

Testimonials featured in advertisements should reflect the typical experience of an average user of the medical device. Product claims therein should also be aligned with the medical device's intended purpose. Particular care should be taken to ensure that testimonials

based on fictitious characters are not framed to give the impression that real people are involved.

(k) Logos, Initials and Trademarks

Advertisements should not make use of names, initials, logos and/or trade service marks of any firm, company or institution without written permission from the concerned firm, company or institution.

The names and logos of the Health Sciences Authority and any of its professional groups cannot be used for any medical device advertisements and sales promotion in any media (printed or static, sound and light & sound).

(l) Cure

There should not be any words, phrases, or illustrations in advertisements which claim or imply the cure of any ailment, illness or disease other than from the relief of its symptoms. E.g. Complete cures, cure when other treatment fails, instant cure.

(m) Anti-ageing

There should not be direct or indirect suggestion that the medical device can prevent, retard or reverse the physiological changes and degenerative conditions brought about by or associated with ageing.

(n) Reference to Sexual Function

There should not be any implication that the medical device can induce sexual virility or they are effective in treating sexual weakness or sexual excess and conditions such as premature ejaculation, erectile dysfunction.

(o) Guaranteed

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Advertisements should not contain any claim, statement or implication that the medical device is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure.

(p) Claims of Safety

There should not be any claim, statement or implication that the medical device is 100% safe, has no side effects and that their use will not cause harm.

(q) Discourage from Medical Advice

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

(r) Research use only product

Products that are meant for research use only should not be advertised or promoted to the general public.

(s) Conformance with SCAP

All medical advertisements must also comply with the Singapore Code of Advertising Practice (SCAP) administered by the Advertising Standards Authority of Singapore (ASAS) to the Consumers Association of Singapore (CASE).

## APPENDIX A

A reference list of acceptable product claims for some examples of Class A medical devices that are non-sterile and 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](#).

- 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 non-sterile Class A medical devices*	Acceptable product claims
1.	Adhesive bandage / dressing / strip / tape	<ul style="list-style-type: none"> <li>• cover and protect intact skin or wounds</li> <li>• approximate the skin edges of a wound</li> <li>• support an injured part of the body</li> <li>• fix dressings to skin</li> <li>• bind/attach/secure objects to the skin/body part</li> <li>• additional properties where substantiated e.g. waterproofing</li> </ul>
2.	Adhesive tape remover	<ul style="list-style-type: none"> <li>• remove adhesive tape and its residue from the skin or other surfaces</li> </ul>
3.	Nasal aspirator, manual	<ul style="list-style-type: none"> <li>• enable gentle suction and clearing of excessive mucus from the nasal passages to facilitate easier breathing</li> </ul>
4.	Ice bag/collar	<ul style="list-style-type: none"> <li>• provide dry cold therapy to a limited external surface area of the body</li> <li>• alleviate pain and/or promote healing in minor injuries of the body</li> </ul>
5.	Bandage, self-adherent	<ul style="list-style-type: none"> <li>• secure a dressing</li> <li>• maintain pressure over a compress</li> <li>• immobilise a limb or other body part</li> </ul>
6.	Bandage, clavicle	<ul style="list-style-type: none"> <li>• maintain fixation and longitudinal extension of the clavicle during a period of treatment</li> </ul>

	Examples of non-sterile Class A medical devices*	Acceptable product claims
7.	Bandage, elastic	<ul style="list-style-type: none"> <li>provide support or local pressure to a part of the body, especially a joint, while allowing movement</li> </ul>
8.	Bandage, gauze	<ul style="list-style-type: none"> <li>cover and protect wounds</li> </ul>
9.	Bandage, gauze, roller	<ul style="list-style-type: none"> <li>bandage heads, limbs, and difficult to dress wounds (e.g., burns, plastic surgery, or orthopaedic wounds)</li> </ul>
10.	Bandage, traction	<ul style="list-style-type: none"> <li>assist in exerting desirable tensile (pulling) forces on the body</li> </ul>
11.	Bedpan	<ul style="list-style-type: none"> <li>receptacle for urine and faeces</li> </ul>
12.	Abdominal / ankle / breast / chest / sternum / wrist binder	<ul style="list-style-type: none"> <li>support relaxed abdominal walls/ ankle joint/ breasts/ribs and chest/sternum/ wrist joint</li> </ul>
13.	Blanket, general purpose	<ul style="list-style-type: none"> <li>wrap or cover a person for warmth and comfort</li> </ul>
14.	Bottle, heating / cooling	<ul style="list-style-type: none"> <li>filled with either hot or cold water or ice for the purpose of applying heat or cold therapy to an area of the body</li> </ul>
15.	Contact lens case	<ul style="list-style-type: none"> <li>for the storage of contact lenses when the lenses are not being used</li> </ul>
16.	Chair, bath / shower	<ul style="list-style-type: none"> <li>to be sat upon by a person who is either bathing, showering, or using some washing facility</li> </ul>
17.	Chair, toilet	<ul style="list-style-type: none"> <li>allows an immobilised person/patient to utilise a standard stationary toilet without leaving the chair</li> </ul>
18.	Compression dressing	<ul style="list-style-type: none"> <li>compress a local area, e.g., to stop bleeding, prevent oedema</li> <li>provide support for varicose veins or ostomy aids</li> </ul>
19.	Compression garment	<ul style="list-style-type: none"> <li>fit over and apply pressure to a specific body part(s) (e.g., thighs, hips, buttocks)</li> <li>may aid in the readjustment of overlying skin, after significant subcutaneous tissue removal (e.g., fat removal after liposuction)</li> </ul>
20.	Cotton ball	<ul style="list-style-type: none"> <li>apply medications to or remove liquid from various parts of the body</li> </ul>
21.	Cover, thermometer	<ul style="list-style-type: none"> <li>prevent cross-contamination between patients and/or environmental exposure</li> </ul>
22.	Gloves, examination	<ul style="list-style-type: none"> <li>prevent contamination between patient and examiner</li> </ul>
23.	Heat/ cold pack	<ul style="list-style-type: none"> <li>provide cold/hot therapy to body surface and/or underlying tissue, e.g. muscle</li> </ul>
24.	<i>Mask, Face</i>	<ul style="list-style-type: none"> <li>prevent contamination to patient/ health care personnel</li> </ul>
25.	Pressure alleviation pad	<ul style="list-style-type: none"> <li>prevent pressure sores, e.g. bed sores or decubitus ulcers occurring on the parts of the patient's body which are prone to this</li> </ul>
26.	Finger protector	<ul style="list-style-type: none"> <li>protect an injured finger from further trauma during the healing process</li> </ul>

	Examples of non-sterile Class A medical devices*	Acceptable product claims
27.	Protector, foot (e.g. <i>Bunion/Callus/Corn protectors, pads, plasters</i> )	<ul style="list-style-type: none"> <li>protect that part of the foot from friction against surfaces and knocks against objects</li> <li>may have additional properties (e.g. waterproof, lubricating, hypoallergenic) where substantiated</li> </ul>
28.	Patient restraint	<ul style="list-style-type: none"> <li>temporarily secure the arm or leg of an adult patient to prevent injury or hazards. when anchored to a fixture or furniture part (e.g., a bedrail)</li> <li>restrict movement of the patient and prevent the patient from interfering with treatment</li> </ul>
29.	Restraint, fingers	<ul style="list-style-type: none"> <li>restrict finger mobility and prevent potential injury</li> </ul>
30.	Restraint, body	<ul style="list-style-type: none"> <li>secure a patient's arms to the torso to prevent self-inflicted injury</li> </ul>
31.	Self-exam pad, breast	<ul style="list-style-type: none"> <li>used as an aid in performing breast self-examination</li> </ul>
32.	Orthotic shoe	<ul style="list-style-type: none"> <li>support, align, prevent, or correct deformities of the feet to help improve their function</li> </ul>
33.	Cast boot	<ul style="list-style-type: none"> <li>boot-like cover for a foot enclosed in a leg cast</li> </ul>
34.	Shoe, Cast	<ul style="list-style-type: none"> <li>protect the cast material and provide support</li> </ul>
35.	Sling	<ul style="list-style-type: none"> <li>support and limit the range of motion of an injured limb during the healing period</li> <li>support and limit the range of motion of a body in transport</li> </ul>
36.	Splint	<ul style="list-style-type: none"> <li>immobilise an injured body or body part</li> </ul>
37.	Splint, nasal, external	<ul style="list-style-type: none"> <li>immobilisation of parts of the nose typically after a fracture or treatment</li> <li>may function as a truss-like support on the outside of the nose</li> </ul>
38.	Cast stockinette	<ul style="list-style-type: none"> <li>used as padding under a cast or splint</li> </ul>
39.	Stocking, stockinette	<ul style="list-style-type: none"> <li>hold bandages in place</li> <li>place uniform pressure on a leg, finger, arm, or other part of an extremity</li> <li>pad the area under a cast or splint</li> <li>cover a stump when a prosthesis is worn</li> </ul>
40.	Stocking, medical support	<ul style="list-style-type: none"> <li>support, correct, prevent deformity, or to align body structures for functional improvement</li> </ul>
41.	Tourniquet strap	<ul style="list-style-type: none"> <li>compress the arteries and regulate the blood flow</li> </ul>
42.	Transfer aid, person	<ul style="list-style-type: none"> <li>assist in the physical transfer of a person/patient, e.g. ill, disabled or infirm, from one position to another</li> </ul>
43.	Walking crutch / frame / table / stick	<ul style="list-style-type: none"> <li>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</li> </ul>

	<b>Examples of non-sterile Class A medical devices*</b>	<b>Acceptable product claims</b>
44.	Wheel Chair	<ul style="list-style-type: none"><li>• wheeled personal mobility device for a disabled user not having the full capacity to walk by him or herself</li></ul>



# HEALTH SCIENCES AUTHORITY

Health Products Regulation Group  
Blood Services Group  
Applied Sciences Group

[www.hsa.gov.sg](http://www.hsa.gov.sg)

## **CONTACT INFORMATION**

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