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ADVERTISEMENT FOR MEDICAL DEVICE-REQUIREMENTS

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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PREFACE

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737),

b) Medical Device Regulations 2012; and

c) Medical Device (Advertising) Regulations 2019.

Other related authorities who may be consulted on queries regarding advertisements are listed in Annex D.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya
Selangor
MALAYSIA
Fax: (03) 8230 0200
Email: mdb@mda.gov.my
Website: http://www.mda.gov.my

OBJECTIVE

This Guidance Document on Advertisement for Medical Devices complements the provisions of Section 44 of Medical Device Act 2012 and Medical Device (Advertising) Regulations 2019 on advertisement and is intended to provide guidance in ensuring good marketing practices and advertising messages which promote the quality use of medical device in a socially responsible and ethical manner. Section 44 (1) states that "No person shall advertise medical device unless the medical device has been registered and complied with the requirements of the Act" and Section 44 (2) states that "No person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement".

Advertisements give notice and public information with the intent to draw attention and inform. As such, they attract consumers to buy medical devices and have a direct impact on business. Thus, advertisers may be guided by principles not to take undue advantage, whilst laws and regulations are in place to ensure that advertisements contain a high standard of information that is proper and reliable.

Advertising encompasses written or spoken words, and any pictorial representation or design, used or appearing to be used to promote the sale of medical devices, generally by highlighting the approved device claims.

ADVERTISEMENT FOR MEDICAL DEVICE- REQUIREMENTS

1 Scope

This guidance document specifies the requirements for advertisement of medical devices.

2 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations and the following apply:

2.1 Advertisement

Any statement, pictorial representation or design, by means of any document as defined under the Evidence Act 1950 [*Act 56*] or by any other means, which is intended or claimed whether directly or indirectly, to promote the use or supply of anything related to medical device. Advertisement includes announcement of a public nature whether for the sale or purchase of medical device or constituting of an invitation to participate in an activity and conveyed by or through any signage, image or sound disseminated through any medium for advertising purposes.

2.2 Advertiser

Any person who use any form or medium, whether printed or electronic, to advertise a medical device including journalists, publishers or public relations agencies, celebrities, web designer or web hosting.

2.3 Advertorial

A newspaper or magazine advertisement giving information about a product in the style of an editorial or objective journalistic article.

2.4 Children

A person under age of eighteen years. (Source: Child Act 2001, Act 611).

2.5 HealthCare professional includes a medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional and any other person involved in the giving of medical, health, dental, pharmaceutical or any other healthcare services under the jurisdiction of the Ministry of Health [Source: Private Healthcare Facilities And Services Act 1998 (Act 586)].

2.6 Medical device

As defined in ACT 737.

2.7 Senior citizen

A person aged 60 years and above.

[Source: Definition made in the "World Assembly on Ageing 1982" in Vienna]

2.8 Home use medical device

A medical device intended for users in any environment. This includes devices that are intended not only for use by healthcare professionals but also for use by lay persons.

a) A user is a patient (care recipient), caregiver, or family member that directly uses the device or provides assistance in using the device.

b) A qualified healthcare professional is a licensed or non-licensed healthcare professional with proficient skill and experience with the use of the device so that they can aid or train care recipients and caregivers to use and maintain the device.

3 Requirements

3.1 General requirements

Only medical devices registered with the Authority may be advertised. There shall be no misleading or fraudulent claims in respect of the medical device in any advertisement.

3.2 Responsible person

a) The responsible “person” for medical device advertisement, shall be the manufacturer or authorized representative of the medical device.

b) The manufacturer or authorized representative may assign advertisers consisting of a private individual or any third party, to advertise the medical device on their behalf, and ensure compliance with regulatory requirements.

c) A person who advertises a medical device shall have authorisation from the manufacturer or authorised representative.

3.3 Information required in advertisements

Each advertisement shall include the following information:

a) the statement, “Registered under Act 737”, and

b) medical device registration number.

Cautionary statements are encouraged for medical devices, and all required statements etc. should appear clearly in the advertisements.

3.4 Standards for the ethical advertising of medical device

Each advertisement shall comply with the guiding principles (**code of advertisement**) as stated under **Clause 5.**

4 Application for medical device advertisement approval

4.1 An application for approval to the authority shall be made for all advertisement of medical devices relating to:

a) home use medical devices; and

b) advertisement aimed for the general public.

4.2 Application procedure

4.2.1 Application shall be submitted by the advertiser to the Authority by using the 'Application Form for Medical Device Advertisement' in **Annex A** by email to Chief Executive Medical Device Authority at email address advertisement@mda.gov.my.

4.2.2 A copy of advertisement and/or advertisement script shall be submitted together with the application form.

4.2.3 The 'Application Form for Medical Device Advertisement' is published in the Authority website at www.mda.gov.my.

4.2.4 One application may be made for multiple medical devices within one advertisement with the same content. One application may also be made for all media with the same content except for TV, Radio and Internet advertisement with sound/video recordings.

4.2.5 For advertisement using other languages besides Bahasa Malaysia and English, a translated version shall be provided. Translated version shall be endorsed by a body recognised by Authority, such as Malaysian Institute of Translation and Books (ITBM) and Malaysian Translators Association.

4.2.6 Processing fee

Each application shall be submitted together with a RM 1,000.00 processing fee, with the following conditions:

a) Processing fee shall be paid through bank draft. CASH WILL NOT BE accepted.

b) The bank draft shall be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and sent to:

KETUA EKSEKUTIF
Medical Device Authority (MDA)
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor, MALAYSIA
U/P: UNIT KHIDMAT PENGURUSAN

c) Name, Telephone No. of the applicant and 'Application for Medical Device Advertisement' shall be written at the back of the bank draft but not in the table section.

4.3 Issuance of Approval for Medical Device Advertisement

If the Authority is satisfied with the advertisement application, the authority will issue the certificate of approval of the particular advertisement to the advertiser.

4.4 Changes after approval

4.4.1 Any change in the content of advertisements requires for a new application for approval.

4.4.2 The following changes do not require a new application:

a) editorial changes;

b) change of picture(s); and

c) translations.

However, if the changes are related to pictorial change that delivers a different message or claim, a new application shall be submitted.

4.5 Advertisements that require no approval

The following materials are controlled through self-regulation, and shall comply with the requirements of this guidance document. Manufacturers/ Authorised representatives are not required to apply for approval to the Authority for:

a) materials such as catalogues or pamphlets that only contain product pictorial representation, brand and/or company name and/or logo that do not consist of any product claims; and

b) materials which only contain exact replica of the packaging (not size but shape and content) approved by the Authority.

c) All medical device advertisements aimed at:

   i. Personnel that are directly involved in procurement, or administration in a healthcare facility; and
   ii. Healthcare professionals

5 Code of Advertisement (COA)

5.1 This COA promotes the standards for the ethical advertising of medical device. It does not seek to regulate the following activities:

a) Pricing or other trade terms for the supply of devices i.e. commercial policies and/or practices of medical device industry players.

b) Provision of non-promotional information such as:

   i. community messages;

   ii. clinical trial and investigational testing recruitment material. Any announcement that is intended to assist in the recruitment of patients or

clinical investigators for a clinical trial or investigational test concerning a health product may be considered non-promotional.

iii. Corporate Messages. A corporate message is defined as a communication (e.g., web site, brochure, published article, prospectus, annual report, etc.) that provides information about a health product manufacturer, or organization, concerning its philosophy, activities, product range (by name), financial details, area of future development or research, etc.

5.2 Advertising materials that would be covered by this COA include the following listed articles:

a) Internet Advertising such as:
- window advertising
- website and other internet materials including brand home pages, banner
- pay-per-click advertising
- direct mail materials
- viral marketing materials
- advertising and social media
- online advertising
- advertising on electronic ordering system

b) Marketing such as:
- telephone help lines (automated product promotional messages)
- brand reminders
- articles or advertorials in journals, magazines and newspapers
- point-of-sale materials
- vehicle wrappers
- touch screen advertising
- directories
- text messages
- on-pack statement
- consumers promoters
- talk shows
- display packs, giant mock-up boxes
- outdoor displays such as billboards, banners, bunting and posters
- aerial promotion such as hot air balloon
- indoor displays such as at airport, washroom, shopping centre
- light box advertising
- any other forms of advertising

c) Posters/Flyers such as:
- consumer brochures, booklets, leaflets, pamphlets and broadsheets
- bulletins and newsletters
- calendars
- catalogues

d) Sponsorship such as:
- sports, art and other sponsorship
- branded material relating to device sponsorship

e) TV/Radio such as:
- cinema, television and radio/audio commercials
- video recordings

5.3 Standards of promotion

An advertisement shall present information which is factually correct and not exaggerated. Advertisements should take into account peoples' legitimate desire for information and encourage the correct and proper use of a medical device and shall not be misleading.

An advertisement is deemed to be false or misleading if it falsely describes the medical device, misleads the nature or quality of the device, their uses or effects, or any reference to a false or misleading representation.

Claims made shall not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity. Promotional materials shall be accurate, objective and of high ethical standards.

5.4 Device claims

An advertisement shall comply with the intended purpose(s) of a registered device as approved in its registration by the Authority. An advertisement shall not promote a medical device outside its approved claim(s), nor promote a device for use by a patient group not indicated.

Advertisements shall not contain any statement or visual presentation which, whether directly or by implication, is likely to mislead the consumer about any device. Advertisements shall contain information that is reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date and be capable of substantiation. They shall not contain any misleading or unverifiable information that is likely to induce unjustifiable medical use or to give rise to undue risks.

It is important that advertisements do not abuse the trust or exploit the lack of knowledge among the general public. Advertisements shall not lead to self-diagnosis or inappropriate treatment of potentially serious diseases.

5.4.1 Therapeutic claims

There shall not be therapeutic claims in the form of any words, phrases or illustrations in advertisements which claim or imply the cure of any ailment, illness or disease as listed in Annex B, other than from the relief of its symptoms and according to the intended use and/or indication of the device.

5.4.2 Claims relating to ageing and premature ageing

Advertisements shall not suggest or imply a device will control, retard or reverse the physiological processes associated with ageing or premature ageing unless substantiated by evidence and in accordance with the intended purpose(s) of a registered device as approved in its registration by the Authority.

5.4.3 Claims concerning the brain, memory and concentration

Advertising shall not claim “improvement or enhancement of brain or memory functions”, “improving mental performance, IQ or intelligence” or “prolonging, improving or enhancing concentration”, unless substantiated by evidence and in accordance with the intended purpose(s) and/or indication(s) of a device as approved in its registration by the Authority.

5.4.4 Claims relating to immunity against specific disease(s)

Advertisements shall not claim to provide immunity against specific diseases.

5.4.5 Claims relating to stress

Advertisements shall not promote the use of a particular device to prevent or reduce the stress of modern living unless substantiated by evidence and in accordance with the intended purpose(s) and/or indication(s) of a device as approved in its registration by the Authority.

5.4.6 Claims relating to performance in sports and studies

Advertisements shall not imply that the use of a particular device can improve performance in sports and studies unless substantiated by evidence and in accordance with the intended purpose(s) and/or indication(s) of a device as approved in its registration by the Authority.

5.4.7 Claims concerning weight management

Advertisements for medical device indicated for weight loss, reduction or management shall have an appropriate balance between claims of device effectiveness and references to healthy diet and physical activity. There shall not be claims that a device offers quick weight loss results or physiological thermogenic (fat burning) activity. There shall be a statement in the advertisement encouraging “a well-balanced diet plan and exercise’’.

5.4.8 ‘Before’ and ‘after’ claims

If claims “after” and “before” are made, the advertiser should state the details clearly and fairly and do not mislead consumers.

Care should be given to ensure that all claims used are related to the approved device intended purpose(s) and/or indication(s) of a device as approved in its registration by the Authority. All claims shall not depict a more serious or exaggerated condition.

5.4.9 Claims related to device origin

There should not be over emphasis on the manufacturer or foreign country of origin in promoting the efficacy of a medical device.

5.4.10 Natural claims

Advertisements shall not suggest that the safety or effectiveness of a medical device is due to the fact that it is natural nor claim that a device is “natural” unless all of its components or materials are made with naturally-sourced forms.

5.4.11 Device novelty claims

Advertisements relating to novelty of the advertised medical device shall not be misleading and the medical device has been introduced in Malaysian market for not more than 18 months.

5.4.12 Safety claims

Claims pertaining to medical device safety shall not imply that the device is not associated with or free from any side effects. Phrases such as “no side effects”, “no harmful effects”, and “no toxic or adverse effects” shall not be used.

Any statement related to possible adverse effects shall be specific and based on data approved by the Authority or published data to which references are given.

5.5 Acts of violence or illegal activities

Advertisements shall not contain any statements or visual presentations which might lead to or support acts of violence, criminal or illegal activity or appear to condone such acts or activities.

5.6 Dangerous practices or disregard for safety

Advertisements shall not show or refer to dangerous practices or manifest a disregard for safety. Special care has to be taken in advertisements directed towards or depicting children.

5.7 Standard of morality or decency

Advertisements shall not contain statements or visual presentations which are likely to be offensive to the standard of morality or decency prevailing in Malaysian society or in any way defamatory or humiliating to any segment of the public.

5.8 Disparagement

Advertisements shall not:

a) contain any statement(s) which either explicitly or by implication disparages the medical profession; or the value of professional attention and treatment; or another medical device; or
b) discredit or unfairly attack other medical devices, advertisers or advertisements directly or by implication.

5.9 Substantiation

Advertisements shall not exploit the ignorance of the public by including scientific data that the general public cannot comprehend, verify, or validate.

All claims, descriptions, and comparisons which relate to matters of objectively ascertainable facts shall be capable of substantiation and held readily available upon request by the Authority.

5.10 Fear and superstition

Advertisements shall not:

a) be framed as to abuse the trust of the consumer or exploit his lack of experience or knowledge;

b) play on fear by containing any statement or illustration likely to induce fear on the part of the viewer or listener that he is suffering, or may, without diagnosis or treatment, suffer or suffer more severely, from diseases or conditions of the human body;

c) play on superstition or exploit the superstitious; or

d) directly, or by implication, exploit the religious requirement(s) or belief(s) of any community.

5.11 Advertising on the internet

Internet advertising of medical device is acceptable provided the material posted on the Internet does not contravene existing regulatory requirements or Guidelines. The identity of the responsible company and of the intended audience shall be readily apparent. The content and presentation (including links, etc.) should be appropriate and apparent to the intended audience. All information required in 3.3 shall be clearly visible. Members of the public shall not be encouraged to access information which is not intended for them.

Websites containing advertisements or information which nature and content are directed at healthcare professionals shall include a warning statement, “This webpage content is intended for Healthcare Professionals only, not for general public”.

5.12 Social responsibility

The advertiser for advertising of a medical device should observe a high standard of social responsibility to consumers and to the society. This section covers what is deemed ‘socially responsible’ advertising practices.

All endorsement and testimonials are not allowed to feature endorsement / testimonial without consent.

5.12.1 Celebrity endorsement

Advertisements may include a recommendation or endorsement by celebrities. A celebrity is an actual person who is very well known in public life who, because of their status, encourage the general public to use a medical device, but they shall be responsible and accountable for the advertisement.

5.12.2 Endorsement by health professionals

Advertisements shall not contain any visual or audio presentation or statement(s) of healthcare professionals including healthcare professional from overseas, scientists, or any other professionals which gives the impression of professional recommendation or endorsement.

There shall not be any visual or audio presentation or statement(s) giving the impression of professional endorsement or recommendation made by associations or persons who appear in the advertisements. In addition, the use of white coat, stethoscope, healthcare professional environment or any expression that provides undue authority that the device is recommended by a healthcare professional is not allowed.

Note. 5.12.2 is only applicable to advertisements of medical device to the general public.

5.12.3 User testimonials

Advertisement may not include testimonials unless it is genuine and related to the personal experience over a reasonable period of time of the person that giving it. Its testimonials shall refer to the approved intended purpose only and shall be supported by a consent letter of testimony.

5.12.4 Tests, trials and research references

Reference, whether directly or by implication, to tests, trials, research and the like may only be used if fully substantiated with evidence. Reference to tests or trials conducted in a named hospital, clinic, institute, laboratory or college or by named professional or official organisation is permissible only if authorised and approved by the relevant named hospital, clinic, institute, laboratory or college or by named professional or official organisation.

Research results, reference to or quotes from technical and scientific literature of conference, workshop, seminar etc. shall not be misused. Statistics presented shall be accurate and fair.

Graphs, tables and pictorial representations shall be relevant to the claims or comparisons being made and not be misleading.

5.12.5 Comparative advertising

Comparisons of medical devices shall be balanced, fair and capable of substantiation.

Comparative claims shall:

a) be made factual and fair. The intent advertisement should be to inform and not to discredit, disparage, degrade, or attack competitors, competing medical devices or services directly or by implication;

b) be unambiguous, accurate, fair and clearly understandable;

c) not make unjustifiable use of the name or initials of any establishment, nor take advantage of the trade name or symbol of another firm or its medical device(s) or the goodwill acquired by its advertising campaign;

d) not explicitly identify the competitive medical device, whether by name, brand name, company, or any form of identification that clearly exposes the identity of the competition;

e) not involve the selection of a subject matter of a comparison as to create an artificial advantage;

f) should not use or draw on partial results or stress insignificant results to mislead the consumer to draw an improper conclusion;

g) not involve the use of “baseless” hanging comparatives which merely claim that a medical device is e.g. “more accurate”, “faster”, “more versatile” etc.

5.12.6 Lifestyle and encouragement of unnecessary purchase or indiscriminate use

Advertising should not undermine healthy lifestyle advice or health promoting behaviour. Similarly, advertising should not promote behaviour which is damaging to health.

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

5.12.7 Superlatives

Superlatives shall not be used to imply, claim or infer the superiority of the advertised medical device. Consumers shall not be led to over-estimate the value of a medical device whether by exaggeration or unrealistic comparisons or statements.

The characteristics of the medical device shall not be exaggerated by improper use of words, phrases or methods of presentation.

Superlatives, words, and phrases which are not allowed are specified in Annex C.

5.12.8 Self-diagnosis and management

Advertisements shall not describe a range of symptoms that may be similar to conditions other than those for which the medical device is intended for, resulting in consumers making a wrongful self-diagnosis.

The advertisements should encourage consumers to share information with the health care providers to ensure the medical device is suitable for the intended user.

Advertisement for self-diagnostic medical devices shall include the following statement:

"Please consult your healthcare professional for the interpretation of result and diagnosis"

5.12.9 Unwarranted anxiety

Advertising shall not induce unwarranted anxiety among consumers about their condition by suggesting a greater severity than actual, and that the condition may deteriorate if the medical device or brand featured is not used.

5.13 Advertisement aimed at specific population

5.13.1 Pregnant or lactating women

Advertisements shall not suggest or recommend any medical device, for use by pregnant or lactating women unless the devices substantiated by evidence and in accordance with the intended purpose(s) and/or indication(s) of a device as approved in its registration by the Authority.

All such advertisements shall encourage a cautious approach before use and include a statement that women should consult their healthcare professional before use.

5.13.2 Children

Advertisement addressed to children, or likely to be seen by them, shall not contain anything, whether in illustrations or otherwise, which might result in harming them physically, mentally, morally; or which exploit their credulity, their lack of experience or their natural sense of loyalty.

Images depicting children below 12 years old handling medical device without supervision shall not be allowed.

The following cautionary statement shall be included in the advertisement:

"Children shall not use device without supervision"

5.13.3 Senior citizens

Advertisements for medical device used by senior citizens shall have a statement that regular supervision by healthcare professional is encouraged.

5.13.4 People with disabilities

Images depicting people with disabilities handling the medical devices shall not be over emphasized, and such advertisements are encouraged to mention the need to seek health professional advice and supervision to ensure proper device use.

5.14 Advertising of medical device for healthcare professional use only

Medical device intended for healthcare professional use only, shall not be advertised to the general public.

5.15 Terms and conditions

If an advertisement of a medical device requires the terms and conditions that should be made known to the consumers, the advertisers shall fulfill the following criteria:

a) the placement of the words, terms and conditions should be clear, easy to be seen and read by consumers;

b) the statement on the terms and conditions should be clear, brief and easy to understand by consumers. Usage of legal terms or language and slang which will confuse consumers shall be avoided; and

c) in case further information or details on the terms and conditions are not made available in the advertisement, the advertiser shall state the source where the information may be obtained, such as the advertiser's website.

Advertisers shall ensure that disclaimer placed in any advertisement is not contradicting with the claims as advertised, and it shall be valid and does not violate any laws.

In the case of online advertisements, a disclaimer should be placed on the same advertisement site and not in different sites.

5.16 Other promotional activities

5.16.1 Advertorials

Advertorials which describe the use, current research or innovation without reference to the device or brand name is allowed. The device brand name, pictorial representation or any reference to the device website shall not be included. Statements or disclaimers in such advertorials that the consumer should seek appropriate professional healthcare advice shall be included.

Advertisement in the advertorial form should be allowed but shall be in line with the approved medical device claim(s). Any advertisement featuring the registered medical devices linked to the advertorials shall not be placed on the same page, page before or page after the advertorial.

5.16.2 Disease awareness and health education campaigns

Campaigns providing information, promoting awareness and educating the public about health, diseases and their management are encouraged. The focus should be on health and disease education, and where to get appropriate advice. It shall not promote the use of a particular medical device. The medical device, its pictorial representation or any reference to the device shall not be included.

Restricting the range of management options described or drawing attention to the use of specific devices will be considered promotional in nature.

5.16.3 Press releases for medical device launches

Press releases for announcements of medical device launches is allowed on the condition that the information is factual, not misleading the general public, and not used as the sole purpose to promote the medical devices.

Relevant results in the context of alternative treatments and of current practices for the treatment of the indicated condition is allowed, provided there is no disparagement of other medical devices used for the same conditions.

The use of brand names, the tone and content of the press release shall be factual and not sensationalized.

Particular care should be taken by the company in providing information in response to direct approaches from the media where a company has little or no control over the final device press releases.

5.16.4 Contests and competitions

Contests and competitions linked to a brand and company is allowed without mention of specific devices. However, inducement of unnecessary purchase of medical devices via the use of contests and competitions is not allowed.

5.16.5 Sponsorship

Sponsorship linked to a brand and company is allowed without mention of specific devices.

5.16.6 Samples for promotional purposes

Advertisements shall not offer or describe any medical device as a sample to the general public (for example through newspapers, magazines, by post or through pharmacies and general retailers) except for home use medical device or any device prescribed by a healthcare professional that would not disturb cultural sensitivity.

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: mdb@mda.gov.my

For office use only
Submission ID No:
Date:

ANNEX A

APPLICATION FORM FOR MEDICAL DEVICE ADVERTISEMENT

In accordance with Medical Device (Advertising) Regulations 2019

Please complete all information requested on this form.

- One notification application may be made for multiple medical devices within one advertisement.
- One application may also be made for all media with the same content except for TV, Radio and Internet advertisement with sound/video recordings.
- All fields are mandatory unless stated otherwise.

1. ADVERTISER Details (e.g: Establishment, Retailer, Healthcare Service Provider, Online Selling Platform Provider, etc.)

Name of Advertiser:		
Company registration number (if applicable):		
Address:		
Postcode:	City:	State:
Type of advertiser (Please tick one only)	☐ Manufacturer	
		Please state the Establishment License Number:……
	☐	Authorized representative (AR)
		Please state the Establishment License Number :……
	☐	Retailer, Healthcare Service Provider, Online Selling Platform Provider, etc. Please state:……
Person responsible for advertiser:		
Identification Number/ Passport number:		
Address (as in IC/passport):		
Designation:		
Phone No. :	Email Address:	
Contact Person :		
Phone No. :	Email Address:	

2. MEDICAL DEVICE DETAILS			
Name of Medical Device	**Brand**	**Registration Number**	**Establishment license number**

3. ADVERTISEMENT DETAILS		
Has this advertisement been approved before?	☐ Yes	☐ No
Previous advertisement approval number if available		

4. PROPOSED MEDIA FOR ADVERTISEMENT			
☐	TV	☐	Radio
☐	Billboard	☐	Posters/Flyers
☐	Newspaper/Magazine	☐	Social Media
☐	Other (please specify)		

5. PROPOSED LANGUAGE(S) FOR ADVERTISEMENT			
☐	English	☐	Malay
☐	Mandarin (translated version)	☐	Tamil
☐	Other language: ……		

6. ANY OTHER REMARKS (E.G. JUSTIFICATION FOR ANY SPECIAL CLAIMS)

7. SUPPORTING DOCUMENTS ASSOCIATED WITH MEDICAL DEVICE ADVERTISEMENT(S)

Please provide following supporting document for this (these) advertisement for medical device(s):

i. Copy of proposed advertisement for the registered medical device (such as story board/art work)
ii. Payment (Bank Draft or FPX)
iii. Letter of appointment/ authorisation (if the advertisement is undertaken not by the manufacturer or AR)
iv. Copy of translated version (if the advertisement apart from Bahasa Malaysia and English)

Please send your application to advertisement@mda.gov.my .

4. ATTESTATION & DECLARATION

I, < NAME OF PERSON RESPONSIBLE >, ID < >, * ADVERTISER OF THIS (THIS) ADVERTISEMNT , HEREBY DECLARE THAT:

i. THIS ADVERTISEMENT COMPLIES WITH MEDICAL DEVICE (ADVERTISING) REGULATIONS 2019
ii. PRODUCT(S) IN THIS ADVERTISEMENT, MEET THE DEFINITION OF MEDICAL DEVICE AS IN SECTION 2, MEDICAL DEVICE ACT 2012 (ACT 737);AND HAS BEEN REGISTERED UNDER SECTION 5 OF ACT 737

I, THE UNDERSIGNED, HEREBY ATTEST THAT THE INFORMATION AND DOCUMENTS PROVIDED IN THIS NOTIFICATION ARE TRUE, ACCURATE, CORRECT, COMPLETE AND CURRENT TO THIS DATE. I UNDERSTAND THAT ANY DECLARATION BY ME IN THIS APPLICATION THAT IS UNTRUE, INACCURATE OR MISLEADING SHALL, UPON CONVICTION BE LIABLE TO A FINE NOT EXCEEDING RM 100,000.00 OR TO IMPRISONMENT FOR A TERM NOT EXCEEDING 2 YEARS OR TO BOTH. (SECTION 76(1) ACT 737)

ANY TRANSLATED VERSION- REFER TO ORIGINAL VERSION

*(STRIKETHROUGH ACCORDINGLY)

SIGNATURE:

PERSON RESPONSIBLE NAME:

DESIGNATION :

DATE :

COMPANY STAMP :

Annex B
(normative)

Diseases and conditions

There shall not be claims in the form of any words, phrases or illustrations in advertisements which claim or imply the cure of any the following diseases and conditions:

1. Arteriosclerosis
2. Asthma
3. Cancer
4. Chronic insomnia
5. Deafness
6. Diabetes and other metabolic/endocrine diseases
7. Diseases of the eye (e.g. blindness, cataract)
8. Diseases or defects of the heart or cardiovascular disease
9. Diseases or defects of the kidney
10. Drug addiction
11. Epilepsy or fits
12. Frigidity
13. Hernia or rupture
14. Hypertension
15. Impotency or impairment of sexual function
16. Infertility
17. Leprosy
18. Mental disorders, diseases and conditions (unless substantiated)
19. Miscarriage or abortion
20. Nervous debility, or other complaint or infirmity, arising from or relating to sexual intercourse
21. Paralysis
22. Practice of contraception
23. Serious infectious diseases including AIDS and HIV-related diseases
24. Tuberculosis
25. Venereal disease
26. Improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings

The above list is non-exhaustive and may be subject to change by the Authority.

Annex C
(normative)

Superlatives descriptors, words or phrases

Superlatives descriptors, words or phrases not allowed in advertisements:

1. Anti-ageing
2. Anti-stress
3. Aphrodisiac
4. Arousal
5. Complete cure
6. Enhancement of sexual organs
7. Fabulous, Fantastic
8. Guaranteed
9. Hormone releaser
10. Instant cure
11. Libido
12. Longevity
13. Miraculously, miracle, magic magical
14. Mythical
15. No. 1 (or similar to indicate sequence or superiority) (unless substantiated)
16. No side effect, no harmful effects, no toxic or adverse effects.
17. Perpetual youth
18. Saintly, heavenly
19. Sensational relief
20. Sexual powers
21. Superior
22. The ‘best’, ‘only’, ‘most’
23. Unique
24. World’s best
25. Any percentage (unless substantiated)
26. Effective (unless substantiated)
27. Any other superlatives, words or phrases which are synonymous to the above

This above list is non-exhaustive and may be subject to change by the Authority.

Annex D
(informative)

Other related Authorities

The following is a list of other related authorities who may be consulted on queries regarding advertisements:

Ministry of Domestic Trade and Consumer Affairs
No.13, Persiaran Perdana, Presint 2
Pusat Pentadbiran Kerajaan Persekutuan
62623 Wilayah Persekutuan Putrajaya
Tel No.: 03-8000 8000/ 1800 886 800
Fax No.: 03-8882 5762
Website: www.kpdnkk.gov.my
e-aduan: https://e-aduan.kpdnhep.gov.my/

Malaysia Consumer Claims Tribunal
Ministry of Domestic Trade and Consumer Affairs
Aras 5, Podium 2
13, Persiaran Perdana, Putrajaya
Tel No.: 03-8882 5822
Fax No.: 03-8882 5831
e-Tribunal: http://ttpm.kpdnkk.gov.my/etribunal
Website: https://www.kpdnhep.gov.my/en/corporate-info/department/tribunal-for-consumer-claims.html

Ministry of Information, Communication and Culture
Corporate Communication Chief
Corporate Communication Unit Ground Floor, Blok B
Kompleks Sultan Abdul Samad Jalan Raja
50610 Wilayah Persekutuan Kuala Lumpur
Tel No.: 03-2612 7320 / 7321 / 7322
Fax No.: 03-2691 2366
e-Complaint: eaduan@kpkk.gov.my
Website: www.kpkk.gov.my

Advertising Standards Authority Malaysia
Unit 706, Block B
Pusat Dagangan Phileo Damansara 1
9 Jalan 16/11, Off Jalan Damansara
46350 Petaling Jaya,
Selangor Darul Ehsan
Malaysia
Tel No.: 03-7660 8535
Fax No.: 03-7660 8532
Website: www.asa.org.my

For queries regarding electronic advertisements:

Malaysian Communications and Multimedia Commission
MCMC Tower 1
Jalan Impact, Cyber 6
63000 Cyberjaya,
Selangor Darul Ehsan,Malaysia
Tel No. : 03-8688 8000
Fax No. : 03-8688 1000
Email : scd@cmc.gov.my
e-Complaint : aduanskmm@cmc.gov.my
Complaint Hotline: 1-800-888-030
Website : www.mcmc.gov.my

Communications and Multimedia Content Forum (CMCF)
Unit 1206, Blok B
Pusat Dagangan Phileo Damansara
19, Jalan 16/11, Off Jalan Damansara
46350 Petaling Jaya
Selangor
Hotline : 1-800-88-CMCF (2623)
Tel No.: 03-7954 8105 / 7958 3690
Fax No.: 03-7954 1260
Email: secretariat@cmcf.my
Website: www.cmcf.my

Communications and Multimedia Content Forum (CFM)
6-02, Tingkat 6, Straits Trading Building
No. 2, Lebuh Pasar Besar
50050 Wilayah Persekutuan Kuala Lumpur
Hotline: 1-800-18-2222
Tel No.: 03-2692 3800
Fax No.: 03-2693 2288
Email: www.complaint.cfmorg.my
Website: www.cfm.org.my
Consumer Portal: www.consumerinfo.my

Radio Televisyen Malaysia (RTM)
Seksyen Aduan dan Perhubungan Awam
Bahagian Perhubungan Raya
Jabatan Penyiaran Malaysia Angkasapuri
50614 Wilayah Persekutuan Kuala Lumpur
Tel No.: 03-2282 5333
Fax No.: 03-2282 7146
Email: feedback@rtm.gov.my
Website: www.rtm.gov.my

Perbadanan Kemajuan Filem Nasional Malaysia (FINAS)
Bahagian Pelesenan dan Penguatkuasaan
Kompleks Studio Merdeka Jalan Hulu Kelang
68000 Ampang
Selangor Darul Ehsan
Tel No.: 03-4104 1300
Fax No.: 03-4104 1334
Website: www.finas.gov.my

For queries regarding pharmaceutical & healthcare services advertisements:

Pharmacy Enforcement Division
Ministry of Health
Lot 36, Jalan Universiti
46350 Petaling Jaya
Selangor Darul Ehsan
Tel No.: 03-7841 3200
Fax No.: 03-7968 2251
Email: pharmacy1@moh.gov.my
Website: www.pharmacy.gov.my

Medicine Advertisements Board
Pharmaceutical Services Division
Lot 36, Jalan Universiti 46350 Petaling Jaya
Selangor Darul Ehsan
Tel No.: 03-7841 3200
Fax No.: 03-7968 2251
Website: www.pharmacy.gov.my
(For medicines advertisement approval)

For queries regarding cosmetics advertisements:

National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health
Lot 36, Jalan Universiti
46350 Petaling Jaya
Selangor Darul Ehsan
Tel No.: 03-7883 5400
Fax No.: 03-7956 2924
Email: tal@bpfk.gov.my
Website: www.bpfk.gov.my

Any queries regarding film advertisements:

Kementerian Dalam Negeri
Blok D1 & D2, Kompleks D
Pusat Pentadbiran Kerajaan Persekutuan
62546 Wilayah Persekutuan Putrajaya
Tel No.: 03-8886 8000 / 3000
Fax No.: 03-8889 1613 / 03-8889 1610
Website: www.moha.gov.my

Lembaga Penapis Filem
Aras 2, Blok D2, Kompleks D
Pusat Pentadbiran Kerajaan Persekutuan
62546 Wilayah Persekutuan Putrajaya
Tel No.: 03-8886 3230
Fax No.: 03-8889 1685
(For advertisement film broadcasting)

Bahagian Kawalan Penerbitan Dan Teks Al-Quran
Kementerian Keselamatan Dalam Negeri
Aras 5 & 6, Blok D1, Kompleks D
Pusat Pentadbiran Kerajaan Persekutuan
62502 Wilayah Persekutuan Putrajaya
Tel No.: 03-8886 8047
Fax No.: 03-8889 1682
(For advertisement publication)

For queries regarding Halal logo:

Hub Halal Division
Jabatan Kemajuan Islam Malaysia
Aras Bawah, Blok 2200 Bangunan Enterprise 3
Persiaran APEC
63000 Cyberjaya
Selangor Darul Ehsan
Tel No.: 03-8315 0200
Fax No.: 03-8318 0744
Website: www.islam.gov.my

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: http://www.mda.gov.my