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Guidelines for Implementation of medical device regulatory system

APPLICATION FOR MEDICAL DEVICE ADVERTISEMENT APPROVAL - 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 guidance document for Code of Advertisement (COA).

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

ADVERTISEMENT FOR MEDICAL DEVICE - REQUIREMENTS

0 INTRODUCTION

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.

1 Scope

This guideline specifies the requirements for advertisement of medical devices that require approval and no approval required.

The following materials are controlled through self-regulation, and shall comply with the Codes of Advertisement (as specified in MDA/GD/0032) and do not require approval:

a) All medical device advertisements aimed at:

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

   These advertisements shall not be advertised to the general public.

b) materials that only contain product pictorial representation, brand and/or company name and/or logo that do not consist of any product claims or descriptions including catalogs, brochures, flyers, and etc.

c) materials which only contain exact replica of the packaging (not size but shape and content) as approved by the Authority during medical device registration.

d) Advertorial, disease awareness and health education campaigns, contests and competitions, sponsorship.

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 Healthcare professional

Medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional as listed in the 2nd Schedule of Allied Health Professions Act 2016 (Act 774).

[Source: Private Healthcare Facilities and Services Act 1998 (Act 586)].

2.5 Medical device

As defined in Section 2 of ACT 737.

2.6 Home use medical device

A home use medical device is a medical device labelled for use in any environment outside a professional healthcare facility and intended for use by healthcare professionals and/or lay persons. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes.

Note 1: Lay person includes patient (care recipient), caregiver (includes non-healthcare professionals), or family member that directly uses the device or provides assistance in using the device.

Note 2: A home use medical device requires adequate labelling for the user and may require training for the user by a healthcare professional in order to be used safely and effectively.

2.7 Editorial changes

Editorial changes are simple clarifications that do not alter the substantive meaning of the

advertising material. Editorial changes include punctuation changes, grammar corrections, reordering existing material, rephrasing sentences that does not alter the content and adding headers for ease of use.

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

All advertisements to be posted, displayed or broadcasted shall include the following information:

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

b) medical device registration number; and

c) In the case of advertisements that require approvals (refer 4.1) the advertisement approval number shall be included.

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

All advertisement shall comply with guidance document of Code of Advertisement (COA)-MDA/GD/0032.

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** in hardcopy by hand or via post/courier.

4.2.2 Two copies (colored version) of advertisement and/or advertisement script shall be submitted together with the application form. For applications that consist of a recording or video, the applicants shall submit story board (frame by frame). However, applicant shall submit appropriate media (e.g. thumb drive, flash drive, etc) if requested by the Authority.

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

4.2.4 Conditions for application

a) Application of approval for advertisement with the same content to be advertised in multiple languages and in any media can be made in one application. The same advertisement that consists of sound/video recordings in TV, radio and internet advertisements shall be made in separate application.

b) Sound and video advertisement with same script in TV/radio or other media, can be made in one application.

c) Advertisement may contain up to 5 medical devices. However application for approval is depending on content type.
    a. Advertisement application for multiple medical devices are limited to 5 medical devices per application.
    b. Advertisement application for multiple medical devices under the same grouping can be made in one application.

4.2.5 Translations

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 the Authority, such as Malaysian Institute of Translation and Books (ITBM), Malaysian Translators Association (MTA), Professional translators, Court translator and embassy translators.

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:

CHIEF EXECUTIVE
Medical Device Authority (MDA)
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC

63000 Cyberjaya, Selangor, MALAYSIA

c) Name, telephone number of the applicant and the statement. “Application for Medical Device Advertisement” shall be written at the back of the bank draft but not in the table section.

d) The processing fee is non-refundable.

4.3 Issuance of approval for medical device advertisement

If the Authority is satisfied with the advertisement application, the authority will issue an approval number for the particular advertisement.

The advertisement to be posted, displayed or broadcasted shall be the same as that approved by the Authority.

The advertisement approval will automatically be invalid upon expiry of the medical device registration. Advertisement approval for multiple medical devices will automatically be invalid upon the expiry of the earliest medical device registration. If there are changes in the claims of the medical device as per the registration information (in the case of change notifications), the advertisement will also be no longer valid and a new application needs to be submitted.

4.4 Changes after approval

4.4.1 Any change in the content of advertisements or any new issuance of the same advertisement using other languages requires for a new application for approval.

4.4.3 The following changes do not require a new application:

a) editorial changes; and

b) change of picture(s).

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

ANNEX A
(normative)

Application form for medical device advertisement

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

For office use only

CHECKLIST FOR MEDICAL DEVICE ADVERTISING
In accordance with Medical Device (Advertising) Regulations 2019

Please tick (√) in the box if the document(s) is/are available.

			Applicant	For Office Use
1.	Complete application form			
2.	Copy of proposed advertisement for the registered medical device (such as story board/art work)			
3.	RM1000 Bank Draft payable to '**KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN**'			
4.	Appointment/Authorisation Letter from the manufacturer or AR			
5.	Copy of translated advertisement (if the advertisement is in other language apart from Bahasa Malaysia and English)			
6.	Supporting documents (where applicable):			
	For contents with:	**Supporting document**		
	i) Testimonials	Consent letter from the user using the medical device to be advertised		
	ii) Celebrity Endorsement	Endorsement/Consent letter form the celebrity		
	iii) Test, trials or scientific reference	approval or permission letter from the sponsor/investigator (hospital) and data/reports/evidence of claims		
7.	Attestation & Declaration			

Acknowledgment of Receipt

Date of Receipt: _____

Application Ref. No.: _____

Applicant's Name: _____

Company Name: _____

Payment Status: _____ Bank Draft No.: _____

Application Status: ☐ Complete ☐ Processing
☐ Incomplete ☐ Reject

Acknowledged by: _____

Officer's Name: _____

Designation: _____

Date: _____

APPLICATION FORM FOR MEDICAL DEVICE ADVERTISING

In accordance with Medical Device (Advertising) Regulations 2019

1. APPLICANT'S DETAILS

Name of Applicant: Note. Applicant will be the person responsible for the advertisement.		I.C./Passport number:
Designation:		
Phone No.:	Email Address:	
Company name & registration number (if applicable):		
Address:		
Postcode:	City:	State:
Company's Phone No.:	Company Email Address:	

Role of Applicant: (Please tick one only)

☐ Establishment (Please state the Establishment License Number:……)

Type:
- ☐ Manufacturer
- ☐ Authorized Representative (AR)
- ☐ Distributor
- ☐ Importer

☐ Advertising agency/ service provider

☐ Other (Please specify:……)
e.g: Retailer, Healthcare Service Provider, Online Selling Platform Provider, etc.

2. MEDICAL DEVICE DETAILS

Name of Medical Device	Brand	Registration Number	Establishment License number

3. ADVERTISEMENT DETAILS

Has this advertisement been approved before?

- ☐ Yes
  (Please provide approval number:……)
- ☐ No

4. CONTENT TYPE (TICK 1 ONLY)

- ☐ Text/Infographic/Pictorial presentation (without video/audio recording)
- ☐ Visual recording/Audio visual recording
- ☐ Audio recording

4. PROPOSED MEDIA FOR ADVERTISEMENT	
Broadcast Media ☐ TV ☐ Radio ☐ Others (please state)	Internet/Social Media ☐ Company Webpage/portal ☐ Youtube ☐ Facebook ☐ Instagram ☐ Other Online selling platform (please state)
Name of program/slot:	URL:
Printed Media ☐ Newspaper ☐ Magazine ☐ Book ☐ Catalogue ☐ Brochure ☐ Poster/Flyer ☐ Others (please state) Name of publication:	External Media ☐ Billboard ☐ Signage ☐ Moving signage (Bus/Taxi/Car/etc) ☐ Others (please state)
Note. Please provide two copy of proposed advertisement for the registered medical device (such as story board/art work/video/script/dialog)	

5. PROPOSED LANGUAGE(S) FOR ADVERTISEMENT			
☐ Malay ☐ English	☐ Mandarin	☐ Tamil	☐ Other language (Please specify: ……)
Note.: Please provide translated format of advertisement in language other than Malay or English			

6. ADVERTISEMENT CONSIST OF:	
☐ Testimony	☐ Celebrity endorsement
☐ Information on tests, trials, scientific reference	
Note: Please provide supporting documents for the above, e.g: consent/endorsement/approval letter from the relevant individual/organization and data/report/evidences.	

6. ATTESTATION & DECLARATION

I, …… (name of person responsible), I/C/Passport no. …… , as the applicant of this advertisement, hereby declare that:

i. This advertisement complies with Medical Device (Advertising) Regulations 2019; and,

ii. Medical device(s) in this advertisement has/have been registered under sSection 5 of Act 737.

I, the undersigned, hereby attest that the information and documents provided in this application are true, accurate, correct, complete and current to this date. I understand that any declaration made by me in this application that is untrue, inaccurate or misleading is an offence under section 76(1) Act 737 and shall, upon conviction be liable to a fine not exceeding RM100,000.00 or to imprisonment for a term not exceeding 2 years or to both.

Signature: Company stamp:

Applicant's Name:
Date:

ANNEX B
(normative)

SUBMISSION AND PAYMENT INSTRUCTIONS FOR Medical Device Advertising

FORM FILLING INSTRUCTION

1. Please complete all information requested in this form. Incomplete application will be rejected and returned to the applicant.
2. Please complete the Checklist form to indicate all documents have been provided for the application.
3. Please send your application in hardcopy by hand or via post/courier.

FORMAT OF PROPOSED ADVERTISEMENT

1. The format of the video shall be in .MP4 or .AVI.
2. The size of the copy of the proposed advertisement (e.g: advertisement write-up/story board/artwork/script/dialog must shall be not more than 300 Mb per document.

PAYMENT INSTRUCTION:

1. Processing fee shall be paid during submission.
2. All payments shall be made through **bank draft.** Cash and online payment are **NOT** accepted. We will not be responsible for the cash sent or brought to our office.
3. The bank draft shall be made payable to "**KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN**".
4. Information of **the name and phone no. of the applicant** shall be written at the back of the bank draft.
5. Payment of the processing fee for multiple applications for advertisement **CAN** be combined in one bank draft.
6. The advertisement approval shall be given only after acceptance of the bank draft.
7. The bank draft will be returned to the applicant if payment information is inaccurate.
8. A receipt of payment will be issued once the bank draft is accepted. The receipt shall be kept as proof of payment.
9. Processing fee is non-refundable regardless of the outcome of the application.

Annex C
(normative)

Letter of Authorisation for Advertisement

[To be printed on Manufacturer or AR letterhead]

Medical Device Authority, Malaysia
Date:

Dear Sir/Madam,

Subject: Letter of Authorisation for ……..

We, (name of manufacturer or AR) as the manufacturer/authorised representative of the medical device listed in application for advertisement as attached, hereby authorise (company name and ROC number) to prepare and submit applications for advertisement of medical devices listed below, to the Medical Devices Authority on our behalf.

Name of Medical Device	**Registration Number**

We also authorise (company name) to make declarations and to submit relevant documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Medical Device Act 2012 (Act 737)-

We undertake to provide all the necessary support and assistance to the (company name) as may be required in relation to any matter involving the medical devices listed. We acknowledge that any non-compliance with any registration condition issued by the Medical Device Authority under Act 737 or deviations from that submitted for approval in relation to the advertisement may result in the suspension or cancellation of the advertisement.

We agree to furnish and assist the Medical Device Authority with any request for information on the application.

Yours sincerely,

(……(Signature)……)
Name:
Designation:
Company stamp:

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