DIRECTOR FOREWORD MEDICAL EQUIPMENT ASSESSMENT AND HOUSEHOLD HEALTH SUPPLIES

Currently, there are many medical devices and home health supplies ladders that are circulated and used in the community. Government issue a marketing authorization on the product to guarantee safety, quality and efficacy of medical devices and supplies domestic and imported household health in circulation in society.

Products that already have a distribution permit can be advertised in accordance with advertising ethics, considering health risk factors and public safety and the provisions of laws and regulations invitation. In order to protect the public from the influence of advertising which is not objective, incomplete and misleading, it is necessary guidelines for approval of medical equipment advertisements, *in vitro* diagnostic medicine and PKRT.

We thank all those who have contributed to the development of this manual. We realize that this book still needs improvement, For that, suggestions and input as an effort to improve are very much our expect.

Jakarta, October 2018
Director of Assessment of Medical Devices and PKRT
Indonesian Ministry of Health

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DIRECTOR GENERAL FOREWORD PHARMACEUTICAL AND MEDICAL DEVICES MINISTRY OF HEALTH

With great gratitude I welcome the publication
Guidebook on Procedures for Granting Medical Devices Advertising Approval,
In Vitro Diagnostic Medical Devices and PKRT which is a reference for
obtain approval for advertisements for medical devices and PKRT that already have
marketing authorization.

Society needs to be protected from the adverse effects of
showing advertisements for medical devices and home health supplies
stairs that are not objective, incomplete and misleading, then
the administration of advertisements for medical devices, *in vitro* diagnostic medical devices and PKRT must
in accordance with advertising ethics and the provisions of laws and regulations
invitation.

Finally, I hope that with the publication of the guidelines
this can make it easier and understand how to submit
application for approval of medical equipment advertisements, *in vitro* diagnostic medical devices and
PKRT for stakeholders, ad assessment team and any
entrepreneurs who want to advertise their products.

Jakarta, October 2018
Director General of Pharmacy and Medical Devices
Indonesian Ministry of Health

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Glossary of terms and abbreviations

1. Alkes : Medical devices
2. PKRT : Household Health Supplies
3. PS : Public service announcements
4. NGOs : Non-governmental organization
5. PNBP : Non-Tax State Revenue Fee

DRAFTING TEAM

Guidelines for Granting Medical Devices Advertising Approval,
In Vitro Diagnostic Medical Devices and PKRT

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F. Definition

A. Background

Health Law No. 36 of 2009 mandates
that getting the right health information
is a community right that must be fulfilled, one of the
the way is through advertising. The ads that are displayed
Of course, it must meet the rules in accordance with
Health Law No. 36 of 2009, namely the objective,
honest or true, complete, not misleading, not excessive
and clear.

Advertising directs people's minds so that they
pay attention, evaluate positively or do something
support, such as buying a product. Because of
Therefore, every business actor must choose the right way to
inform their products, one of which is by
how to issue advertisements about medical equipment, *in vitro* diagnostic medicine
and PKRT that attracts attention so that people will
use the product. People will select
medical equipment, *in vitro* diagnostic equipment and PKRT desired through
available information.

Advertising is an activity that is used as a way
business actors communicate with the public. However
advertising has both positive and negative impacts on life
Public. The following is an example of a positive impact such as advertising
help people understand information about goods,
services, and ideas offered by advertisers; advertising change

public behavior in a good direction, such as advertisements about wash your hands or brush your teeth. While examples of negative impacts Among other things, advertisements can cause wrong perceptions or misleading about a product.

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All ads have a specific purpose, but not all intend to make a profit. There is a purposeful advertisement to change people's way of thinking or behavior for the sake of the interests of society itself. The ad is referred to as Public Service Advertising (PSA). Not like product ads commercial, PSAs do not sell products for the public to buy, but he sells ideas that society wants to accept, for example advertisement about washing hands with soap. Generally PSAs are made by the government, NGOs (Non-Governmental Organizations) or other non-profit organizations and institutions commercial.

Currently, many medical devices, *in vitro* diagnostic equipment and PKRT are available circulated and used in society. The government publishes marketing authorization on the product to ensure safety, quality and benefit of imported and domestic products circulating in the community.

Products that already have a distribution permit can be advertised accordingly with advertising ethics, considering the risk factors public health and safety as well as provisions laws and regulations. In order to protect society from the influence of advertising that is not objective, no complete and misleading, then guidelines are needed granting approval of medical equipment advertisements, *in vitro* diagnostic medical devices and PKRT.

B. Legal Basis

1) Law No. 8/1999 on Consumer Protection (State Gazette of the Republic of Indonesia Indonesia of 1999 Number 42, Supplement to the Gazette Republic of Indonesia Number 3821);

2) Law Number 32 of 2002 concerning
Broadcasting (State Gazette of the Republic of Indonesia Year
2002 Number 139, Supplement to the State Gazette of the Republic of Indonesia
Indonesia Number 4252);

3) Law Number 36 Year 2009 concerning
Health (State Gazette of the Republic of Indonesia Year
2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia
Indonesia Number 5063);

4) Law Number 23 of 2014 concerning
Regional Government (State Gazette of the Republic of Indonesia
Indonesia Year 2014 Number 244, Supplement to the Gazette
Republic of Indonesia State Number 5587) as
has been amended several times, most recently by Law
Law Number 9 of 2015 concerning the Second Amendment
on Law Number 23 of 2014 concerning
Regional Government (State Gazette of the Republic of Indonesia
Indonesia Year 2015 Number 58, Supplement to the Gazette
Republic of Indonesia Number 5679);

5) Government Regulation Number 72 of 1998 concerning
Security of Pharmaceutical Preparations and Medical Devices
(State Gazette of the Republic of Indonesia of 1998 Number
138, Supplement to the State Gazette of the Republic of Indonesia
Number 3781);

6) Government Regulation Number 21 of 2013 concerning
Types and Tariffs of Non-Tax State Revenues
Applicable to the Ministry of Health (Gazette
Republic of Indonesia Year 2013 Number 56,
Supplement to the State Gazette of the Republic of Indonesia Number
5408);

7) Presidential Regulation Number 35 of 2015 concerning Ministry of Health (State Gazette of the Republic of Indonesia Indonesia Year 2015 Number 59);

8) Regulation of the Minister of Health Number 1189/Menkes/Per/VIII/2010 concerning Production of Medical Devices and Household Health Supplies (State News Republic of Indonesia Year 2010 Number 399);

9) Regulation of the Minister of Health Number 1191/Menkes/Per/VIII/2010 concerning Permit for Distribution of Medical Devices (Berita Republic of Indonesia Year 2010 Number 401);

10) Regulation of the Minister of Health Number 76 of 2013 about Advertisement of Medical Devices and Medical Supplies Household (State Gazette of the Republic of Indonesia Year 2014 Number 192);

11) Regulation of the Minister of Health Number 64 of 2015 about the Organization and Work Procedures of the Ministry of Health (State Gazette of the Republic of Indonesia of 2015 Number 1508);

12) Regulation of the Minister of Health Number 62 of 2017 regarding Circulation Permit of Medical Devices, Medical Devices *In Vitro* Diagnostics and Home Health Supplies Stairs (State Gazette of the Republic of Indonesia Year 2018 Number 82);

13) Regulation of the Minister of Finance Number 32/PMK.05/2014 about the Electronic State Revenue System (State Gazette of the Republic of Indonesia of 2014 Number 200);

14) Regulation of the Minister of Agriculture Number 107/Permentan/SR.140/9/2014 concerning Pesticide Control (Berita Republic of Indonesia Year 2014 Number 1274);

15) Regulation of the Minister of Agriculture Number 39/Permentan/SR.330/7/2015 concerning Pesticide Registration (News

Republic of Indonesia Year 2015 Number 1047);

C. Purpose

1) Protecting the public from the influence of medical equipment advertisements, medical equipment non-objective *in vitro* diagnostics and PKRT, no complete and misleading.

2) Provide a reference for the ad assessment team in order to the process of evaluating medical equipment advertisements, *in vitro* diagnostic medical devices and PKRT to comply with advertising ethics and regulations legislation.

4) Provide a reference for business actors to apply application for approval of medical equipment advertisements, diagnostic medical devices *in vitro* and PKRT.

D. Target

1) Stakeholders who need information related to procedures for granting medical equipment advertisement approval, *in vitro* diagnostic equipment and PKRT.

2) The Advertising Assessment Team as an evaluator in conducting assessment of application for approval of medical equipment advertisements, medical equipment *in vitro* diagnostics and PKRT.

3) Business actors in the field of Medical Devices, *in vitro* diagnostic medical equipment and PKRT that require approval of medical equipment advertisements, *in vitro* diagnostic equipment and PKRT.

E. Scope

The guidelines for granting ad approval include includes general criteria, provisions, service processes (flow and description, administrative requirements, time and cost), and assessment guide.

F. Definition

1) **Advertising** is information of a commercial nature and
public services regarding the availability of services, goods and services
ideas that can be utilized by the audience by
or without compensation to broadcasters who
concerned.

2) **Commercial** advertisements are advertisements that aim to
support marketing or promote a
products produced by the company/industry.

3) **Public Service Advertisements** are advertisements that aim to
to change people's way of thinking or behavior
in the interests of society itself.

4) **Media** are all forms and channels used
to convey information or messages.

5) **Visual** media is media that can be seen, read
and touched. This media relies on the sense of sight
and feeler. For example: photos, pictures, comics, pictures

sticks, posters, magazines, books, miniatures, props and
so.

6) **Audio** media is media that can be heard only.
use the sense of the ear as a channel.
Examples: sound, music and songs, musical instruments, broadcasts
radio and sound cassettes or CDs and so on.

7) **Audio-visual** media are media that can be heard
and viewed at the same time. This media moves
senses of hearing and sight simultaneously.
For example: drama, staging, film, television and media
VCDs. The internet is included in the form of audio-visual media,
but more complete and unifies all kinds of formats
media, called Multimedia because various formats exist
in the internet.

8) **Circulation Permit** is a license for Medical Devices, Medical Devices
In Vitro Diagnostics and PKRT produced by
Producers, and/or imported by PAK or importers who
will be circulated in the territory of the Republic of Indonesia,
based on an assessment of safety, quality, and

benefit.

9) **Medical Devices** are instruments, apparatus, machines and/or or implants that do not contain the drugs used to prevent, diagnose, cure and relieve disease, treat the sick, restore health in humans, and/or form structures and improve body function.

10) ***In Vitro*** **Diagnostic Medical** ***Device*** is any reagent, reagent products, calibrators, control materials, kits, instruments, apparatus, equipment or system, whether used alone or in combination with other reagents, products

reagents, calibrators, control materials, kits, instruments, apparatus, equipment or system expected by owner of the product for use *In Vitro* for examination of any specimen, including blood or tissue donors derived from the human body, solely eyes or basically for the purpose of giving information by taking into account the physiological state or pathological or congenital abnormalities, to determine safety and suitability of each blood or donor network with potential recipients, or to monitor therapeutic measures and contain specimens.

11) Next **Household Health Supplies** abbreviated as PKRT is a tool, material, or mixture of materials for maintenance and care for health humans, intended for home use stairs and public facilities.

12) **Production Certificate** is a certificate for producing Medical Devices, *In Vitro* Diagnostic Medical Devices and PKRT.

13) **Medical Device Distributors** , hereinafter referred to as PAK is a company in the form of a legal entity in the form of Limited Liability Company or Cooperative that has a license for procurement, storage, and distribution of tools Health and *In Vitro* Diagnostic Medical Devices .

14) **Marking** is objective, complete, and information

not misleading in the form of images, colors, text or a combination of or all three or any other form included in the package or included in the packaging, or is part of a container and/or the packaging.

15) **Assessment Team** is a team appointed by the Director General consisting of related main units in the Ministry Health and advertising expert.

16) **Days** are Working days

17) The **Ministry of Health** is the ministry that has the task of carrying out government affairs in the field of health.

18) **Minister** is the minister who organizes the affairs of government in the health sector.

CHAPTER

2

PROCEDURE FOR GIVING AGREEMENT ALKES ADVERTISING, ALKES DIAGNOSTIC *IN VITRO* AND PKRT

A. Good Advertising Rules

B. Terms

C. Service Process

D. Assessment Guide

A. Good Advertising Rules

For approval of medical equipment advertisements, *in vitro* diagnostic medical devices and PKRT can be given, of course, must meet the advertising rules that universally applicable, including:

- **Objective, honest, or true** . Here the ad must be contain information that is in accordance with reality which are actually. For medical equipment advertisements, diagnostic medical devices *in vitro* and PKRT, must provide correct information according to the distribution permit and must not deviate from the nature of safety, quality and usability.
- **Complete** . That is, ads can't hide or does not provide information that is important to known to the public. For medical equipment advertisements, diagnostic equipment *in vitro* and PKRT, advertisements must provide information regarding the benefits, contraindications, side effects and/or other information that must be considered in product use.
- **Not misleading** . Here ads may not cause wrong image or perception in society or raise concerns over a problem health. For medical equipment advertisement, *in vitro* diagnostic medicine and PKRT must be honest, accurate, responsible and should not take advantage of the public's concerns over health problems.
- **No exaggeration** . Ads containing information that giving effect above the reasonable limit is advertising excessive. For medical equipment, *in vitro* diagnostic equipment and PKRT, for example, should not overestimate its effectiveness or the safety, quality and usefulness of the product or make claims that make a perfect impression or guarantee to provide certainty of healing.

- **Obviously** , using Indonesian, Arabic numerals, and Latin letters that are easy to understand and do not cause double interpretation. Use of language, numbers and letters other than Indonesian, Arabic numerals and Latin letters allowed as long as there is no equivalent.

- **Products must be legally registered and advertising materials must be approved by the competent authority** (for medical equipment, *in vitro* diagnostic equipment and PKRT must be approved by the Ministry of Health).
- **Protect and respect the audience, no demeaning religion, culture, country, and class, and does not conflict with applicable law.**

B. Terms

In the case of applying for approval of medical equipment advertisements, diagnostic medical devices *in vitro* and regulated HOME are **creatives** with the following conditions:

1. Medical devices, *in vitro* diagnostic medical devices and PKRT that can be used advertised are those who **already have permission approval Circular that is still valid from the Ministry of Health.**
2. Advertisements for medical devices, *in vitro* diagnostic medical devices and PKRT **only can be loaded or displayed** on advertising media **after obtain approval** from the Directorate of Appraisal Tools Health and PKRT, Directorate General of Pharmacy and Medical Devices, Ministry of Health.
3. Advertisements for medical devices, *in vitro* diagnostic medical devices and PKRT which **obtain approval** from the Directorate of Appraisal Tools Health and PKRT, Directorate General of Pharmacy

and Medical Devices, Ministry of Health is **advertising commercially according to the approved marking on distribution permit**

4. The validity period of the advertisement is up to the distribution permit validity period finished.
5. **Only used** *in vitro* diagnostic equipment and medical supplies **by professionals should not be advertised to general public.**
6. **Advertiseable** *In Vitro* Diagnostic Medical Devices and Medical Devices must **meet administrative/technical requirements** and

the following **criteria** :

- **The product can be used by the community itself public (without the help of professionals) and does not require special skills, for** example:
  blood pressure meter, weighing scale, pads
  woman, toothbrush, contact lens, contact lens cleaner,
  wound dressings, adult diapers, thermometers,
  condoms, lubricants, spa galvanics, breast pumps, and *teethers* .
- **The product does not pose a high risk of consequences its use** , for example : massage chair and *heating pad* .
- **The product does not pose a high risk of consequences misinterpretation of examination results** , for example:
  pregnancy test strips and fast blood sugar meter,

7. PKRT that can be advertised by fulfilling administrative/technical requirements and criteria are PKRT products (according to the attachment of the Minister of Health No. 62 years) 2017) **except for** feeding bottles and/or pacifiers.

8. Application for approval of medical equipment advertisements, diagnostic medical devices *in vitro* and PKRT proposed based **on advertising media** , namely:

a. **Audio Media** : for example, radio advertisements, advertisements in the media information technology that is only in the form of voice, and etc

b. **Visual Media** : for example, advertising in the form of media print, magazine, brochure, banner, leaflet, external media soundless space, and/or other media (including information technology media) that utilize design images and text without sound

b. **Audio Visual Media** : for example, television commercials and/or or advertisements on other media (including media information technology) in the form of a combination video image, text and sound design.

9. The following is each **reference** to determine Is the application for approval of medical equipment advertising, medical equipment? *in vitro* diagnostics and PKRT **submitted in 1 (one) application** :

a) media and content (in this case in the form of claims) that

same

b) media and content (in this case a claim)
the same but with a different duration
(attach a *story board* for each duration
in the ad)

c) media and content (in this case a claim)
the same but with a different variant
(attach each distribution permit number).

d) media and content (in this case in the form of claims) and
the same trade name/product brand as
at the end of the *story board* displays 1 (one)

different frame types, different product variants
(attach each distribution permit number)

10. The following is each **reference** to determine
Is the application for approval of medical equipment advertising, medical equipment?
in vitro diagnostics and PKRT **submitted in more than 1**
(one) application :

a) media and content (in this case a claim)
different

b) different media but content (in this case
in the form of the same claim

c) the same media but content (in this case
in the form of a different claim

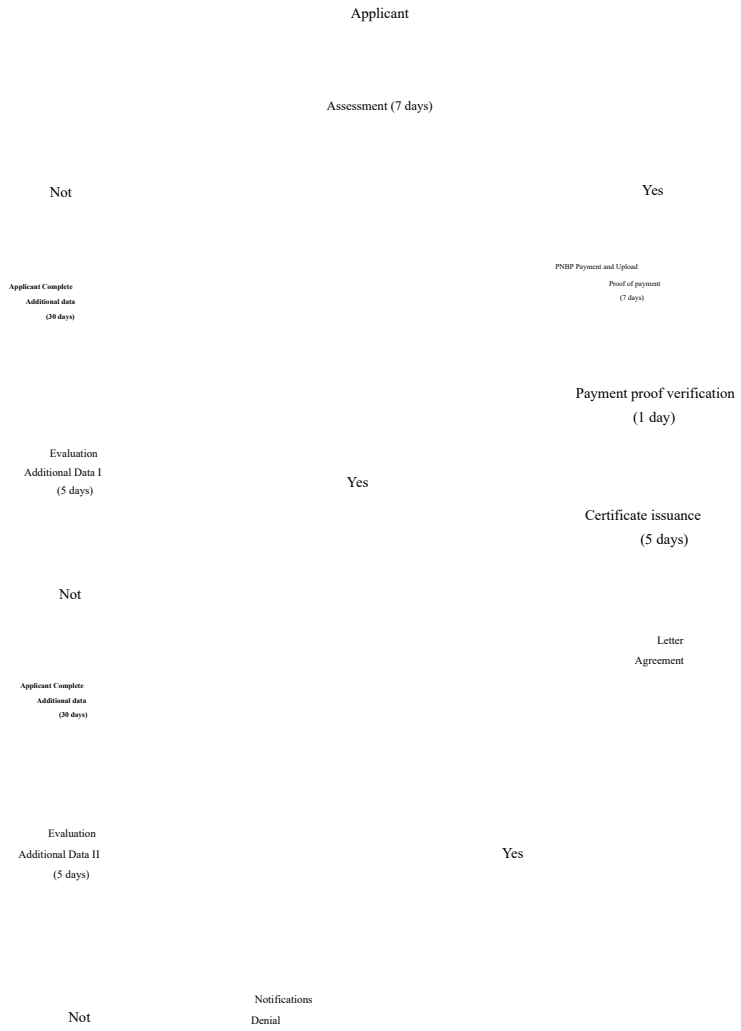
d) the same media content (in this case in the form of
claim) the same but the dosage form
different.

11. Advertisement of Medical Devices, *in vitro* diagnostic medical devices and PKRT before
broadcast on 3 (three) media (audio, visual and video)
audio-visual) must obtain approval from
Directorate of Assessment of Medical Devices and PKRT, while
supervision of advertisements is carried out by the Directorate of
Supervision of Medical Devices and PKRT, Ministry of
RI Health.

12. Business actors who display medical equipment advertisements, medical equipment *in vitro* diagnostics and PKRT as opposed to applicable provisions will be subject to appropriate sanctions with statutory regulations.

C. Service Process

Alkes Ad Approval Flow, *In Vitro* Diagnostic Medical Devices and PKRT.



Service Flow Description

a. The applicant submits an advertisement approval application online
online through the web address http://regalkes.kemkes.go.id and
upload requirements;

b. For applications that are declared complete, both in
administrative or technical, then the applicant will receive
code for payment of PNBP fees and given time
no later than 7 (seven) days to make payments and
upload proof of payment.

c. Proof of payment that has been uploaded by the applicant will be done
verification (1 day)

d. Ad approval can be received no later than 5 (five) days
after verification of proof of payment.

f. If there is an improvement in the ad design or
completeness of other requirements, the applicant is given 2 (two)
times the opportunity for improvement (additional data) and will
re-evaluated.

g. If in 2 (two) times additional data
the applicant has not been able to meet the applicable requirements,
then the application will be rejected.

Administration Requirements

1) Application letter addressed to the Director General
Pharmaceutical and Medical Devices cq Director of Appraisal Tools
Health and PKRT signed by the Leader
the company that owns the Marketing Permit of the advertised product

2) Photocopy of Production Certificate (for domestic products)

3) Photocopy of PAK Permit

4) Copy of distribution permit

5) Photocopy of the approved marking/label and if any approved brochure

6) **The design of the advertisement** where the **sound** , **image and text must be clear and easy to read** in a form adapted to advertising media as follows:

a. **Audio media** , such as radio, advertising design delivered in the form of a **script and audio recording**

b. **Visual media** , such as newspapers, magazines, tabloids, *leaflets* , *booklets* , brochures, silent *billboards* , banners, standing banners, etc. then the ad design is submitted in the form of **a printed design**

c. **Audio Visual media** , such as television, online portals and social media advertising design then submitted in the form of ***storyboards*** **and videos** .

7) **Special advertising in audio and audio visual media** , after the ad design is approved, the applicant submits it to **Counter 3 Integrated Service Unit of the Ministry of Health** as much as 3 (three) copies with the following form:

a. Audio media: submit audio recordings in the form of CD that has been given an identity.

b. Audio visual media: submit video on CD who have been identified.

Cost

Non-Tax State Revenue (PNBP) application for approval advertisements in accordance with applicable laws and regulations.

D. Assessment Guide

The following is an approval assessment guide form

advertisement for medical devices, *in vitro* diagnostic medical devices and PKRT:

General Rating

1) Using Indonesian, Arabic numerals, and Latin letters
which is easy to understand and does not lead to double interpretation.
Use of language, numbers, and letters other than Indonesian, numbers
Arabic and Latin letters are allowed as long as there are no equivalents.
2) Advertising claims must show the benefits/efficacy of the main formula
product.
3) The advertising material must meet the conditions according to the claim that
approved at the time of product registration.
4) The use of the word "halal" can only be done after the product
have an official certificate from the MUI or an authorized institution.
5) The use of asterisks is not used to hide,
misleading, confusing, deceiving audiences about
the actual quality, performance or price of the advertised product
or about the unavailability of a product.
6) The use of asterisks to give a more detailed explanation
or the source of a marked statement.
The inclusion of the explanation must be made in such a way,
so that it can be easily read by the public.
7) The inclusion of the price of a product in the advertisement must be shown
clearly, so that consumers know what to expect
obtained at that price.
8) If the product comparison displays research data, the methodology,
the source and time of the research must be clearly disclosed
and has obtained approval or verification from the organization
the research organizer.

9) The inclusion of price comparisons can only be made to
efficiency and usefulness of using the product and must be accompanied by
adequate explanation or reasoning.
10) Inclusion of a guarantee or quality assurance of a product in advertisements
must be able to account for the basics of the guarantee.
11) Ads that show scenes of results or effects of using
products within a certain period of time, must clearly disclose
adequate time span.
12) Ads that solely show children under 5
(five) years in any form must be accompanied by parents /
adults except for children under the age of

5 (five) years.

13) Advertisements containing or relating to certain professions must comply with the professional code of ethics.

14) The use of animated characters as imitation of a character or something popular character, must be with the permission of the person concerned or the owner of the rights to the character.

15) Ads featuring dramatization must include the words "This scene is dramatized".

16) Ads featuring dangerous scenes must include warning “dangerous scene”, “Do not imitate”.

17) For audio-visual advertising media, warning spots include writing that is clearly legible and proportional and displayed for at least 3 seconds. Written visualization must meet the following requirements: terms of contrast and clarity.

18) For audio advertising media, ad warning spots are read out at the end advertisement clearly and in a firm tone of voice.

19) Advertising for certain products such as condoms and products for the purpose of intimate is only broadcast to the audience at the appropriate time i.e after 22.00.

20) Advertisements for certain products such as condoms, sanitary napkins, tests pregnancy, intimate products and household pesticides must be adapted to the special provisions for the product and pay attention to appropriateness.

21) The use of the word “free” may not be included in the advertisement, if it turns out that consumers have to pay other costs.

22) Do not use superlative words such as “most”, “very”, “number one”, “only”, “top”, “potent”, “super”, “superior”, “amazing”, “magic”, “perfect” or words starting with 'ter', and/or or the same meaning that explains these advantages.

23) Contains no claims, representations or impressions that the product it's perfect, magical (*infallible, unfailing, magical, miraculous*) and/or mean the same.

24) Contains no claims, representations or impressions that the product safe, its use will not cause harm or not cause side effects.

25) May not directly or indirectly encourage excessive and unnecessary use of the product.

26) Comparison of products may not mention other brands.

27) Ads should not be compared directly with other products of the same type unless they are produced by the same manufacturer, the aspects the technical aspects of the product are the same, and the exact criteria are the same.

28) Product comparisons should not mislead the audience.
29) Advertising does not demean competitors' products directly or indirect.
30) Product advertisements must not intentionally imitate competitors' product advertisements in all aspects in such a way as to demean competing products, or misleading or confusing audience.
31) Ads must not imitate pre-existing icons or distinctive attributes used by something advertising a competitor's product and is still being used until the last two years.
32) Advertisements must not misuse scientific and statistical terms to mislead the audience, or create the impression that exaggerated.

33) Advertisements should not take advantage of ignorance and credulity society by including scientific data that cannot be validated and verified.
34) Ads must not contain the words “while stocks last” there” or other words with the same meaning.
35) Advertisements must not exploit eroticism or sexuality by any way, and for any purpose or reason.
36) Advertisements may not involve children in scenes that are harmful, misleading or inappropriate by children child.
37) Advertisements must not involve children as advocates for use of a product that is not intended for children.
38) Ads must not show power exploiting scenes whining (*pester power*) of children with the intention of forcing the parents to grant their children's wish will related products.
39) Advertisements must not harass, exploit, objectify, or ornamenting women so that they give the impression that degrading their nature, dignity and worth.
40) Ads must not contradict or bias equality *gender* rights in all aspects of daily life.
41) Ads must not give a derogatory or mocking impression people with disabilities.
42) Ads must not display inappropriate treatment of animals, mainly from protected and domesticated species.
43) Advertisements are prohibited from loading or displaying health workers or

actors who act as health workers or use identity or attributes of health workers, both clearly and disguised.

44) Advertisements may not use demonstrations of health workers or other similar to health workers, religious leaders and state officials.

45) Advertisements may not use names, initials, logos, symbols, and/or or references indicating suggested use from institutions or organizations engaged in the health sector.

46) Advertisements may not use recommendations from a laboratory, Government agencies, health or beauty professional organizations and/or health workers.

47) Animated characters should not be displayed in a scary or excessively disgusting.

48) The advertisement does not contain any claims, statements or implications which inappropriate, unreasonable, safe or cannot cause danger or side effects at all.

49) Advertising does not cause harmful misperceptions.

50) Ads may not use testimonials.

51) Advertisements may not use medical jargon/slogans that confusing.

52) Advertisements must not create fear or exploit myths that exist in society.

53) Scenes that are not entirely suitable for consumption by toddlers and children must include the words “Parental Guidance” or symbols that mean the same

54) Does not display percentages or other statements for state the effectiveness of the product.

55) Do not use the words “moisturize skin”, “soften” skin” and/or other words with the same meaning

Assessment of Medical Devices and Diagnostic Medical Devices Advertising *In Vitro*

1) Ads may not contain words, sentences or illustrations that claiming or impressing can cure a disorder or disease.

2) Ads may not suggest directly or indirectly
directly that the product can prevent, slow down or
restore physiological changes and degenerative conditions that
relating to or relating to the aging process.
3) Advertisements must not contain any claims or impressions that
the product is perfect, guarantees will provide certainty
recovery.
4) Ads must not ignore the main treatment/treatment,
offer specific advice, diagnosis or treatment for
serious and chronic disease.
5) Advertisements may not encourage use for immoral purposes and
must be in accordance with aesthetics and propriety and accompanied by spots
"FOLLOW THE INSTRUCTIONS FOR USE".
6) Product advertisements must not encourage purposeful use
to establish the diagnosis and must be accompanied by a warning spot
“PRODUCT IS FOR INITIAL INSPECTION AND MONITORING ONLY.
CONSULT FURTHER TO THE DOCTOR ”

PKRT Ad Rating

1) Household pesticides must include the recommendation “Avoid”
use in children under 6 years of age” for anti
mosquito pesticide *spray* and *repellant* in direct contact
with skin; or “Avoid use on minors
2 years” for anti-mosquito pesticide *patch products* (attached to
skin).
2) Advertisement of certain household health supplies such as preparations
antiseptic/disinfectant, household pesticide, laundry bleach
and cleaners, there must be a spot: "FOLLOW THE INSTRUCTIONS FOR USE,
WARNINGS, AND HOW TO COMPLETE IF THEY HAPPEN
ACCIDENT

3) Do not use words such as “germ-free”, “mosquito-free”, “safe”, “eliminate”, “potent”, “harmless”, “aromatherapy”, “anti-aging”, “treat”, “prevent dengue fever”, “anti-virus”, “relaxation”, “recommended by a doctor”, and/or other words that mean the same.

4) Antiseptics and disinfectants should not recommend the use exaggeration, e.g. removing bacteria, using claims which seems to function as a therapeutic treatment.

5) Household Pesticides should not be advertised as products Cosmetics and other household health supplies so that could be misinterpreted for its safety.

6) Do not use the words “family”, “kids”, “baby”, “soft”, “natural”, “natural”, “natural”, and/or other meaningful words the same for household pesticide products.

7) Do not use “insect repellent” claims and/or other words which means the same except for household pesticide products and camphor.

CHAPTER

3

CLOSING

With the preparation of this guide, there is a reference that can be
can be used by relevant stakeholders and business actors
in the field of medical equipment, *in vitro* diagnostic equipment and PKRT in making
advertising that is objective, honest or true, complete, not misleading,
not redundant and clear.

This guide is one of the media to improve performance
and ensure the quality of the advertising assessments that have been carried out
as well as being a reference for the advertising assessment team in order to
assessment of medical equipment advertisements, *in vitro* diagnostic medical devices and PKRT.

This guideline is expected to improve public services so that
better, transparent and accountable in accordance with applicable regulations.

ATTACHMENTS

Application Letter Format

COMPANY LETTERHEAD

Number	:	Date month Year
attachment	:	
Matter	: Ad Approval Application	

The honorable,
Director of Assessment of Medical Devices and PKRT
Directorate General of Pharmacy and Medical Devices
Indonesian Ministry of Health
Jl. HR. Rasuna Said Blok X5 Kav. 4-9
Jakarta 12950

Through this letter we apply for the issuance of approval advertisements for medical devices/ *in vitro* diagnostic medical devices /PKRT, with details as following :

Name of medical device/ *in vitro* diagnostic medical device /PKRT :
Distribution Permit Number :
Preparation Form :
Ad Format :
Ad Version :
Previous application number (if any):

Thus this application letter is submitted, for your attention, Mr. / Mrs
We would like to express our gratitude.

Best regards,

TTD+company stamp

Leader Name

Advertising Approval Letter Format

Number : ..... Date month Year
Attachment : .....
Regarding : ……

Dear,
Leader ……..
Address……..

In connection with the application for approval of advertisements for *in vitro* diagnostic medical devices / medical equipment / PKRT number …….. for the following products:

Name of medical device/ *in vitro* diagnostic medical device / PKRT : ……..
Distribution permit number : ……..
Advertising Media : ……..
Ad Version : ……..

Evaluation has been carried out and the results **can be approved** with the following conditions:
1. Advertisements displayed must be in accordance with the attached design
2. The attached ad design is an integral part
   of this agreement
3. This Agreement may be reviewed in accordance with the provisions
   apply
4. The validity period of the advertisement is until the distribution permit expires

This is conveyed to be understood.

director
Assessment of Medical Devices and PKRT
TTD+stamp
Name
NIP

Copy:
Director of Supervision of Medical Devices and PKRT

Advertising CD Label Format

Company name :

Name of medical device/ *in vitro* diagnostic medical device /PKRT :

Ad Version :

No. Application :