

Notification of the Ministry of Public Health

Regulations, methods and conditions for direct medical device advertising
To exempt medical and public health practitioners who do not need advertising
permission
B.E. 2556

For and to facilitate advertisers of medical devices with the characteristics and methods of Direct advertising to medical and public health practitioners is exempt from Therefore, they have to set up rules, procedures and conditions for advertising of medical devices directly.

To exempt medical and public health practitioners who do not need advertising permission by virtue of Section 5, paragraph one of the Medical Devices Act, 2008 and Section 57 paragraph four of the Medical Device Act B.E.

Additional by the Medical Devices Act (No. 2), B.E. 2562 (2019) Minister of Public Health with the advice of the Medical Device Committee issued the announcement as follows:

Article 1 of this announcement

“Direct advertising” means the conveying of messages, whether from person to person, to group of people Or a group of people to a group of people For the benefit of trade and includes sales promotion as well "direct advertising to medical and public health practitioners" means advertising of the medical device through any advertising medium of the nature and method limited to only in medical and public health practitioners
Clause 2. This notification shall apply to the advertisement of medical devices as follows:

(1) obtaining permission to produce, import or sell

(2) being exempt from production Import or sale under Section 27 (1) (2) (3) (5) and (8).

Of the Medical Device Act B.E. 2551 (2008) and Section 27 (4) and (6) of the Act Medical Devices B.E. 2551 (2008) as amended by the Medical Devices Act (No. 2) B.E.

(3) is in the process of working Conducted research under Section 27 (5) of the Medical Devices Act.

B.E. 2551 (2008)

Clause 3. Advertising materials must be of the following medium that can restrict access only:

Practitioners in medical and public health only

- (1) Publications
- (2) video
- (3) telephone
- (4) digital

Clause 4 Advertisers who are exempt from requesting permission to advertise under this announcement must advertisement without violation under Section 59 of the Medical Device Act B.E. 2551 (2008) and show the text or sound in the media used in advertising that "Direct advertising to medical professionals and public health exempt without permission "to clearly and inform such advertisements. According to form Jor. Attached to this announcement By electronic means of Food committee and medicine as the main In the event that this cannot be done, it shall be submitted by other means to the Secretary-General of the Committee. Food and Drug Administration
Announcement Clause 5 This Notification shall come into force as from the date of its publication in the Government Gazette.

Notified on 26 August B.E.
Anutin Charnwirakul
Minister of Health

Form Jor.
Notification form for direct advertisement of medical device
Medical and public health practitioners
Who are exempt from requesting permission

Write at
Date

I located at
..... Village Soi / Alley
Road Sub-district / Sub-district
District / District Province.....
Phone / Fax
With Is
the owner / authorized person Power of juristic person

We would like to notify the direct advertisement of the medical device to exempt medical and public health practitioners. Request for permission from the Food and Drug Administration Which has details as follows

1. Name (product) is a medical device that
- Permission to produce, import or sell
 - Being exempted from production, import or sale under Section 27 (1) (2) (3) (4) (5) (6) or (8) of the Act.
- Medical devices 2008 and as amended
- In the process of research under Section 27 (5) of the Medical Devices Act B.E. 2008

2. Advertising materials
- Type publication Journal / book Leaflet Decal Nameplate Poster
 - video
 - Phone
 - Digital (specify)

3. Place and timing of advertising media distribution
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4. Methods for limiting direct access to advertising materials to medical and public health practitioners
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.....

5. Attach evidence of advertising directly to the medical and public health practitioner, ie the message that is used in advertising In the case of the act In lieu of substitution, attach a power of attorney to act on behalf of a certified copy of the certificate. Registration of the company or partnership, as the case may be.

6. I certify that

6.1 The above statement is true in all respects. And get to know the rules, methods and conditions of advertising Medical devices directly to medical and public health practitioners who are exempt from applying for permission

6.2 Such advertising materials Is a medium that can Access is restricted to medical professionals and Public health only

6.3 Not to act in violation of Section 59 of the Medical Devices Act B.E. 2008

Signature Informant
(.....)