Notification of the Food and Drug Administration
Re: Prescription of Rules, Procedures and Conditions for Advertising Medical Devices
B.E. 2553 (2010)[1]

Whereas it is expedient to prescribe rules, procedures and conditions for the advertisement of medical devices to ensure propriety, accuracy and efficiency of advertisement so as to promote the proper use of medical devices and not cause misconceptions or deceptions of consumers;

By virtue of section 57 paragraph two, section 57 paragraph three and section 58 paragraph two of the Medical Device Act B.E. 2551 (2008), being a law with certain provisions in relation to the restriction of rights and liberties of persons which section 29 in conjunction withsection 33, section 41, section 43 and section 45 of the Constitution of the Kingdom of Thailand so permit by virtue of law, the Secretary-General of the Food and Drug Administration, in the capacity of the licensor under the Medical Device Act B.E. 2551 (2008), hereby issues the following Notification:

Clause 1. In this Notification:

"advertisement" means an act by any means which causes the public to see, hear or acknowledge content for commercial purposes and shall include a sales promotion campaign;

"content" includes the display of letter, shape, artificial mark, picture, motion picture, light, sound, mark or any act which causes the public to understand a meaning;

"sales promotion campaign" means the offer of information, persuasion or an act by any means which induces a sale;

"advertisement medium" means an object used as a medium for advertisement, such as:

(1) printed matters (e.g. pamphlet, flier, book, newspaper, magazine, journal, medical journal, billboard, poster, decal, etc.);

(2) radio transmitter, loudspeaker, television;

(3) radio broadcast, projector or film, cable television, fax, video recording;

(4) digital medium (e.g. internet, mobile phone, etc.);

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[1] This translation has been prepared by the Legal Research Institute Foundation (LRIF) for information purposes only. Whilst LRIF has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

(5) advertisement on an object or vehicle;

(6) other materials and media.

Clause 2. This Notification applies to advertisements of medical device, as follows:

2.1 A person who wishes to advertise a medical device must receive a medical device advertising licence from the licensor and must comply with other conditions prescribed by the licensor. A medical device advertising licence shall be valid for a period not exceeding three years from the date of issue of licence. An application for a medical device advertising licence (Form KhorPhor. 1) and the medical device advertising licence (Form KhorPhor. 2) shall in accordance with the documents appended to this Notification.

2.2 In the case where a medical device advertising licence is lost, destroyed or damaged, the medical device advertising licensee shall submit an application for a substitute licence within fifteen days from the date of knowledge of the loss, destruction or damage. The new medical device advertising licence (Form KhorPhor. 2) shall state the prior licence number with the word "substitute" marked on top and the day, month and year of issue of the advertising licence substitute shall be specified along with the signature of the licensor. An application for a substitute medical device advertising licence (Form KhorPhor. 3) shall be in accordance with the document appended to this Notification. The grant of licence shall be shown at the end of the application for substitute advertising licence along with the issue of a substitute advertising licence.

2.3In the case where there is a wish to change, amend or revise a non-essential particular in the medical device advertising licence, e.g. relocation, change of sale representative telephone number, etc., the medical device advertising licensee shall submit an application to amend a particular in the medical device advertising licence (Form KhorPhor. 4) in accordance with the document appended to this Notification. The grant of amendment may be endorsed on the reverse side of the medical device advertising licence or by the affixation of a signature in the appendix to the medical device advertising licence or by the affixation of a signature in the end of the application to amend.

2.4 Before submitting an application for a licence and receiving a medical device advertising licence, the licence applicant must pay a licence application free and medical device advertising licence fee in accordance with the rates prescribed by Ministerial Regulation.

Clause 3. The following advertisements of medical devices are prohibited.

3.1 Advertisement of a medical device subject to a ban on manufacture, import or sale.

3.2 Advertisement of the following medical devices:

3.2.1 counterfeit medical device;

3.2.2 substandard medical device;

3.2.3 poor quality medical device;

3.2.4 unsafe medical device;

3.2.5 medical device manufactured or imported not in accordance with a licence or medical device notification certificate;

3.2.6 medical device in regard to which a licence or medical device notification certificate has been revoked.

3.3 Advertisement of benefits, quality, quantity, standard, composition or origin of medical device which is false or exaggerated, in whole or in part, or has the characteristics of deceiving or concealment of facts, regardless of whether or not there is a use or reference to an academic report, statistic or any other exaggerated or false material, such as:

3.3.1 boastful or deceptive advertisement, e.g. use of words such as “top”, “supreme”, “special”, “magnificent”, “excellent”, “best”, “absolute”, “complete cure”, “worry-free”, “immediate”, “instant”, “holy”, “miracle”, “safe”, “safest”, “most suitable”, “number one”, “first”, “most”, “certain”, “better”, “overcome serious diseases”, “peace of mind”, “confident”, “rare opportunity”, “non-allergic”, “no side effects”, or the use of other words, terms, pictures or sounds having a similar meaning;

3.3.2 advertisement showing more details than specified in the label or manufacturer’s medical device documentation, unless supported by evidence or a reliable academic publication, but such advertisement must not relate to details on the indication or purpose of medical device use.

3.4 Advertisement which shows endorsement or praise of medical device benefits by a person, whether directly or indirectly.

3.5 Advertisement which offers a chance to receive a prize by any means.

3.6 Advertisement which shows benefits on the ability to prevent, cure, relieve, treat a disease or symptoms of a disease which is banned by Notification of the Minister.

3.7 Advertisement showing a content which is deceptive in regard to the essence of the medical device.

3.8 Advertisement of a medical device name which is boastful, false, deceptive, misleading or contrary to good morals and Thai tradition.

3.9 Advertisement which is impolite to the public or directly or indirectly supports an illegal act or an act contrary to good morals and Thai tradition, or leads to a deterioration of national culture, or could cause detriment to society as a whole.

3.10 Advertisement which could cause disharmony or disunity among the people.

3.11 Advertisement which induces a consumer to receive services or overuse a medical device repeatedly more than necessary or unsuitably, such that there could be harm from the use or understanding that regular use is suitable.

3.12 Advertisement conducted by a method which could be harmful to health, body or mind or could cause annoyance for consumers.

3.13 Advertisement which discredits or compares to a medical device of another operator, except for comparisons to one's own products or academic comparisons, and in any event the name of medical device or product technology of other persons must not be mentioned.

Clause 4. Conditions for medical device advertisement:

4.1 The use of language, including extracts from foreign languages, must comply with proper Thai usage with proper spelling pursuant to the Notification of the Office of the Prime Minister or the Royal Institute Dictionary. In the case of an advertisement in other foreign languages, excluding English, the advertising licence applicant shall prepare a translation of all contents in Thai or English with a certification of the translation from a state agency or private agency approved by the state.

4.2 The name of medical device shall be properly specified at least once or in one location. The name specified may be the common name or trade name consistent with the licence or medical device notification certificate or certificate of medical device import or label or manufacturer's medical device documentation, as the case may be.

4.3 An advertisement of benefits, quality, quantity, standard, composition or origin of medical device must be true or consistent with the licence or specifications declaration receipt or label or manufacturer's medical device documentation, as the case may be.

4.4 The origin or source of medical device shall be shown, which may be the source of manufacture, import or sale, as the case may be, together with the address and telephone number. In the case of a medical device manufactured under the copyright of a foreign company or a hire for manufacture, the source of manufacture and country of manufacture shall be clearly specified.

4.5 An advertisement of medical device for which a licence or medical device notification certificatehas been granted shall specify the licence number medical device notification certificate number, as the case may be.

4.6 An advertisement of a new product shall be used for a medical device that has begun distribution in Thailand for a period of no more than 1 year.

4.7 An advertisement which creates an understanding that a medical device is sold worldwide must be accompanied by evidence of distribution in at least 20 countries and at least 3 continents.

4.8 An advertisement of instructions for use must be clear and easily understandable so as to enable the consumer or user of medical device to comply properly.

4.9 An advertisement of medical device which contains or requires a warning, prohibited use or precaution in the label or medical device documentation must contain the text “please read the warning in the label or medical device documentation before use” and the details of the warning, prohibited use and necessary precaution, as the case may be, shall be shown (e.g. risk of ineffectiveness or harm or side effect) in a way which a consumer can read, acknowledge or understand easily or clearly. The advertisement must be appropriate to the advertising media for which a licence is sought. The following conditions shall be complied with:

4.9.1 printed and internet media without sound, the text shall be shown in a font colour which contrasts the background, a shape and size which is easily legible, clear, a font size of no less than 1 in 4 of the font size of the essential substance which must not be less than 2 millimetres;

4.9.2 billboard, the font size shall be clear and easily legible, has a contrasting colour from the background and has a size of no less than 1 in 3 of the largest fonts;

4.9.3 radio broadcast, the sound of every syllable in the advertisement must be clearly audible using the same speed and tempo of speech as the content of the advertisement;

4.9.4 television broadcast, visual projection, film and internet media with sound, the sound of every syllable in the advertisement must be clearly audible and the content shall be shown as a super font for a period of at least 5 seconds; the content must be shown in a font colour in contrast to the background, a shape and size which is easily legible and clear, and a font size of at least 1 in 25 of the screen’s height;

4.9.5 other media for trade purposes, the content must be shown in accordance with clause 4.9.1 or 4.9.2 or 4.9.3 or 4.9.4, as appropriate as the case may be.

A content which shows additional conditions shall also comply with clause 4.9.1 or 4.9.2 or 4.9.3 or 4.9.4 as the case may be.

4.10 An advertisement of medical device which is related to other laws, such as the law relating to consumer protection, medical practice, medical centres, medical professions or an advertisement of a medical device which incorporates other products such as food, drugs, cosmetics or hazardous substances must be licensed or comply with all relevant laws, as the case may be.

4.11 Reference to an academic publication, research study, statistic, endorsement by any institute and confirmation of any fact in support of the advertisement must be in accordance with international principles and show acceptable and reliable academic evidence, as follows:

4.11.1 reference as proof or support of content used in the advertisement must be in accordance with academic principles and such reference must specify the researcher and sponsor (if any);

4.11.2 a reference may be:

(1) an academic publication, e.g. article, research study, experiment result or result of a standard quality assessment conducted on a medical device by a government agency or educational institution specializing in the relevant technical branch as approved by the Food and Drug Administration, or that has been published in an acceptable and reliable book or journal but such document must not contain a specific praise for the advertised medical device; or

(2) a certificate issued by a state agency or private institution accredited by the state, or a domestic or foreign specialist approved by the Food and Drug Administration.

4.12 Scientific data advertised must be accurate, complete, balanced and not cause misconception. The data must be appropriate and clearly and comprehensibly communicated.

4.13 Advertisement of a mark or any endorsement, e.g. industrial product standard mark, production quality certification, etc., must be accompanied by evidence of actual endorsement. The use of a mark or logo of any agency in an advertisement must be accompanied by evidence of such agency's consent in the application.

4.14 Advertisement on free tokens or souvenirs (gimmicks) shall display only the name of the medical device which may also contain the name or mark or logo of the company.

4.15 Advertisement of privileges must clearly specify the conditions and details of the privileges, such as specification of the place, commencement and

termination date of such privileges, price of product/service or privilege offered, and must be in compliance with relevant laws.

Clause 5. Duties of the advertising licensee.

5.1 Advertisement of only the licensed content, any deviations thereof would render the whole advertisement as unlicensed.

5.2 The advertising licence number must be shown clearly in all licensed advertising media, except on free tokens or souvenirs.

5.3 An advertisement may be displayed for a period of not more than 3 years from the licence date or otherwise specified on the licence, except:

5.3.1 In the case of an amendment to a particular in the licence, medical device notification certificate or medical device import certificate, e.g. changes to the label or medical device documentation, or having details different in the essence to the extent that use of licensed advertising content is no longer possible, etc, the validity period of the advertisement licence shall expire from the date of such amendment.

5.3.2 In the case where a manufacturing licence, import licence, sale licence, medical device notification certificate or medical device import licence, or establishment registration certificate is revoked, the validity period of the advertising licence shall expire from the revocation date of such document.

5.3.3 In the case where a medical device sale licence under section 6(3) expires, the advertising licence shall expire from the expiry date of such medical device sale licence.

5.3.4 In the case where a quality certification or mark expires, is annulled or revoked, the medical device advertising licence shall expire from the expiration, annulment or revocation of such document, as the case may be.

5.4 Advertisement licensed for dissemination to medical personnel shall be published only in media which communicates directly to medical practitioners, health practitioners, nursing and midwifery practitioners, dental practitioners, medical technology practitioner, physiotherapy practitioner, veterinary practitioner or other medical and public health practitioners.

5.5 Advertising conditions shall include media type restrictions, time and place of advertisement, as well as restrictions on the type of medical device and description of medical device advertisement which is inappropriate or banned from advertisement in public media.

5.6 Compliance with other conditions as specified in the advertising content documents or as specified by the licensor specifically for the medical device.

Clause 6. The Food and Drug Administration reserves the right to revoke this advertisement licence if there is a reasonable cause or necessity in accordance with the law on administrative procedures.

Clause 7. In the case where there is a violation of prescriptions relating to the advertisement of medical device pursuant to the Medical Device Act B.E. 2551 (2008), the licensor shall have the power to issue one of the following orders:

7.1 amend the content or method of advertisement;

7.2 prohibit the use of certain content or method appearing in the advertisement;

7.3 suspend the advertisement.

The licensor may order the publication of the correct data along with an order under 7.1, 7.2 or 7.3.

Clause 8. The submission of an application under this Notification of the Food and Drug Administration in Bangkok shall be submitted at the Food and Drug Administration, Ministry of Public Health. In other provinces, a submission shall be made at the Provincial Public Health Office of the locality where the advertising media is situated and the licence shall be deemed as a licence for all areas covered by such advertising media.

Clause 9. An advertisement licensed prior to the effective date of this Notification may continue to be advertised for the period specified in the medical device advertisement licence.

Clause 10. This Notification shall come into force from the day following the date of its publication in the Government Gazette[2].

Given on the 22nd of November B.E. 2553 (2010)

PipatYingsaree

Secretary-General of the Food and Drug Administration

[2] Published in the Government Gazette, Volume 127, Part 143d, Page 13 on 15th December B.E. 2553 (2010).

Form Khor Phor.1

Application for Medical Device Advertising Licence

Ref No..... Date ..... Time ..... Receiving Official .....
Reviewing Official ..... Date .....

Written at .....
Date .....

I (company/business/shop) ..... situated at number ..... Soi/Trok ..... Street ..... Tambon/Khwaeng ..... Amphoe ..... Province ..... Telephone/Fascimile ..... with ..... as the owner/authorized representative of the juristic person hereby submits an application for advertising licence to the Food and Drug Administration pursuant to the following particulars:

1. Name (product) .....
   Licence/medical device notification certificate/import Certificate number.....
   Name of manufacturer/importer .....
   Name of product owner .....
2. Advertising media ❑ printed matter, type ❍ newspaper ❍ magazine ❍ journal/book ❍ pamphlet ❍ decal ❍ signboard ❍ poster ❍ other (please specify) .....
   ❑ radio broadcast ❑ loudspeaker for a duration of ..... minutes
   ❑ television broadcast ❑ video recording ❑ film for a duration of .. minutes
   ❑ other (please specify) .....
3. Advertisement target ❑ public ❑ medical and public health practitioners ❑ other .....
4. The following documents in support of the advertising licence application have been attached herewith:

❑ Evidence identifying the owner or representative of the owner of the advertised goods

❍ In the case of a juristic person: copy of certificate of registration of the company or limited partnership, power of attorney, copy of the identification cards of the grantor and grantee of the power of attorney (if any), or

❍ In the case of a natural person: copy of commercial registration/business registration certificate, copy of identification card and house registration.

❑ Content of advertisement and a copy thereof, a total of ..... pages

❍ sketch and content ❍ advertisement script ❍ sketch, subtitle and sound ❍ other .....

❑ Copy of medical device manufacturing/importing establishment registration certificate (if any)

❑ Copy of licence/medical device notification certificate/import certificate, as the case may be

❑ Copy of label and medical device documentation (or operating manual) from the manufacturer

❑ References (if any): ❍ academic publication, total of ..... pages
❍licence and previously licensed advertising content ..... subject/..... pages

❑Other, ...

Signature..... Licence Applicant
( )

Form Khor Phor.2

[Garuda]

Medical Device Advertising Licence

Licence No. KhorPhor.

This Licence has been granted to

.....

represented by .....

address/no. ..... Moo .....

Soi ..... Street .....

Tambon/Khwaeng ..... Amphoe/District .....

Province ..... Telephone .....

as the licensee for the advertisement of medical device products:

.....

.....

.....

.....

.....

by way of the following media: .....

.....

pursuant to application receipt no. ..... dated .....

Advertising is permitted in accordance with the advertising content attached to this licence, ... pages, subject to the conditions stated on the reverse side of this licence.

This licence is valid until ..... month ..... year.....

Given on ..... month ..... Year .....

(signature) .....

Position .....

Licensor

The conditions of advertisement are as follows:

1. Approval is granted only to the content and pictures not crossed out.
2. Not to be valid for more than 3 years from the licence date.
3. To be valid for the period preceding any change in establishment registration certificate, licence, medical device notification certificate, medical device import certificate, label and accompanying document which affects the advertising content or picture.
4. Advertising content and picture must be consistent with the licence. If an advertisement is inconsistent with this licence, the entire content and picture will be deemed as unlicensed.
5. The advertising licence number shall be displayed in printed matter, television broadcast and internet media.
6. The Food and Drug Administration reserves the right to revoke this licence if reasonable and necessary causes are found pursuant to the Administrative Procedures Act B.E. 2539 (1996).
7. Other conditions shall be as stated in the advertising content document.

Medical Device Division
Telephone 0-2590-7148
Fascimile 0-2591-8445

FDA No.:

The conditions of advertisement are as follows:

1. Approval is granted only to the content and pictures not crossed out.
2. Not to be valid for more than 3 years from the licence date.
3. To be valid for the period preceding any change in establishment registration certificate, licence, medical device notification certificate, medical device import certificate, label and accompanying document which affects the advertising content or picture.
4. Advertising content and picture must be consistent with the licence. If an advertisement is inconsistent with this licence, the entire content and picture will be deemed as unlicensed.
5. The advertising licence number shall be displayed in printed matter, television broadcast and internet media.
6. The Food and Drug Administration reserves the right to revoke this licence if reasonable and necessary causes are found pursuant to the Administrative Procedures Act B.E. 2539 (1996).
7. Other conditions shall be stated in the advertising content document.
8. Advertisement may be shown only in media distributed directly to medical and public health practitioners.

Medical Device Division
Telephone 0-2590-7148
Fascimile 0-2591-8445

FDA No.:

Form Khor Phor.3

Ref No..... Date ..... Time .....
Reviewing Official ..... Date .....

Application for Substitute Medical Device Advertising Licence

Written at .....

Date .....

1. I (company/business/shop) ..... situated at number ..... Soi/Trok ..... Street ..... Moo ..... Tambon/Khwaeng ..... Amphoe/District ..... Province .....Poscode ..... Telephone ..... with ..... as the owner/authorized representative of the juristic person, age ..... years residing at house no. ..... Tambon/Khwaeng ..... Amphoe/District ..... Province ..... Postcode ..... Telephone .....

2. I wish to apply for a substitute for medical device advertising licence no. ..... issued on ..... month ..... year ..... licence expiry date ..... month ..... year ..... for medical devices named .....
.....
.....
due to the original licence being ❑ lost ❑destroyed ❑ damaged ❑ other .....

3. I have attached herewith the following documents and evidence:

(1) Receipt of a report of medical device advertising licence loss filed at the local police station where the licence was lost in the case of a lost licence.

(2) Remaining medical device advertising licence in the case of a partially destroyed or essentially damaged licence.

(3) other relevant documents (please specify) .....

Signature..... Applicant
( )

Note: Insert the mark / in the box □ preceding the required text.

No. Sor Thor 1002. Food and Drug Administration

Date .....

❑granted ❑ issue of substitute medical device advertising licence denied

❑other .....

(signature) .....

Position .....

Form Khor Phor.4

Ref No..... Date ..... Time .....
Reviewing Official ..... Date .....

Application for Amendment Particulars in the Medical Device Advertising Licence

Written at .....

Date .....

1. I (company/business/shop) ..... situated at number ..... Soi/Trok ..... Street ..... Moo ..... Tambon/Khwaeng ..... Amphoe/District ..... Province .....Poscode ..... Telephone ..... with ..... as the owner/authorized representative of the juristic person, age ..... years residing at house no. ..... Tambon/Khwaeng ..... Amphoe/District ..... Province ..... Postcode ..... Telephone .....

2. I wish to amend particulars in medical device advertising licence no. ..... issued on ..... month ..... year ..... licence expiry date ..... month ..... year ..... pursuant to the following details .....
.....
.....
.....

3. I have attached herewith the following documents and evidence:
   (1) Copy of medical device advertising licence (KhorPhor. 2)
   (2) Details of changes relating to the medical device
   (3) other relevant documents (please specify) .....
.....
.....

Signature..... Applicant
( )

Note: Insert the mark / in the box ☐ preceding the required text.

No. Sor Thor 1002. Food and Drug Administration

Date .....

❑granted ❑amendment to particulars in the medical device advertising licence denied

❑other .....

(signature) .....

Position .....