

**THE MINISTRY OF
HEALTH**

No. 09/2015/TT-BYT

**THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness**

Hanoi, May 25, 2015

CIRCULAR

Providing for the certification of advertising contents for special products, goods and services under the management of the Ministry of Health^(*)

Pursuant to the June 21, 2012 Law on Advertising;

Pursuant to the June 17, 2010 Law on Food Safety;

Pursuant to the November 23, 2009 Law on Medical Examination and Treatment;

Pursuant to the November 21, 2007 Chemical Law;

Pursuant to the June 14, 2005 Pharmacy Law;

Pursuant to the Government's Decree No. 181/2013/ND-CP of November 14, 2013, detailing a number of articles of the Law on Advertising;

Pursuant to the Government's Decree No. 100/2014/ND-CP of November 6, 2014, providing for the trading in and use of nutritious products for infants, feeding bottles and teats;

Pursuant to the Government's Decree No. 63/2012/ND-CP of August 31, 2012, defining the functions, duties, powers and organizational structure of the Ministry of Health;

At the proposal of the Director of the Legal Department;

The Minister of Health promulgates the Circular providing for the certification of advertising contents for special products, goods and services under the management of the Ministry of Health.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular provides for the conditions, competence, dossiers and procedures for certification of advertising contents for special products, goods and services under the management of the Ministry of Health, including:

1. Drugs not banned from advertising as prescribed in Clause 5, Article 7 of the Law on Advertising.

2. Cosmetics.

3. Food and food additives under the management of the Ministry of Health, including:

a/ Functional food;

^(*) *Công Báo Nos 609-610 (20/6/2015)*

- b/ Food fortified with micronutrients;
- c/ Natural mineral water;
- d/ Bottled drinking water;
- dd/ Food additives and food processing aids.

4. Chemicals, insecticides and disinfectants for household and medical use.

5. Medical equipment.

6. Milk and nutritious products for children under the management of the Ministry of Health which are not banned from advertising as prescribed in Clause 4, Article 7 of the Law on Advertising.

7. Medical examination and treatment services.

Article 2. Subjects of application

This Circular applies to organizations and individuals involved in the certification of advertising contents for special products, goods and services under the management of the Ministry of Health in the territory of Vietnam.

Article 3. Appraisal charge and fee for grant or re-grant of written certifications of advertising contents for special products, goods and services under the management of the Ministry of Health

1. The requester for certification of advertising contents shall pay an appraisal charge and a fee for grant or re-grant of written certification of advertising contents to the agency receiving the request for certification of advertising contents as prescribed by law.

2. An advertisement design to be regarded as a dossier of request for certification of advertising contents that is liable to appraisal charge and certification fee shall be determined as follows:

a/ The following shall be regarded as a dossier of request for certification of advertising contents:

- An advertisement design for a product, goods or service for a single target user;
- An advertisement design for a product, goods or service for a single target user used for different forms of advertising (e.g., leaflet, poster, book, newspaper).

b/ The following shall not be regarded as a dossier of request for certification of advertising contents:

- Different advertisement designs for a product, goods or service for a single target user. In this case, each advertisement design shall be regarded as a dossier;

- An advertisement design showing different products, goods or services for a single target user. In this case, each goods, product or service shall be regarded as a dossier.

c/ Drug advertising:

The following shall be regarded as a dossier of request for certification of drug advertising contents:

- The advertisement designs specified at Point a, Clause 2 of this Article;

- An advertisement design for a drug having one content and one form of preparation for a single target user;

- An advertisement design for two or more drugs of the same manufacturer having the same active element but different contents, forms of preparation and routes of administration for a single target user.

d/ Cosmetic advertising:

The following shall be regarded as a dossier of request for certification of cosmetic advertising contents:

- The advertisement designs specified at Point a, Clause 2 of this Article;

- An advertisement design for two or more products corresponding to one cosmetic announcement sheet having a receipt number.

dd/ Advertising of food and food additives:

- The following shall be regarded as a dossier of request for certification of advertising contents for food and food additives:

+ The advertisement designs specified at Point a, Clause 2 of this Article;

+ An advertisement design for two or more products of food and food additives having the same uses and target users.

- The following shall not be regarded as a dossier of request for certification of advertising contents for food and food additives:

+ The advertisement designs specified at Point b, Clause 2 of this Article;

+ An advertisement design for two or more products of food and food additives having different uses and target users. In this case, each product shall be regarded as a dossier.

Chapter II

CONDITIONS, COMPETENCE, DOSSIERS AND PROCEDURES FOR CERTIFICATION OF ADVERTISING CONTENTS FOR SPECIAL PRODUCTS, GOODS AND SERVICES UNDER THE MANAGEMENT OF THE MINISTRY OF HEALTH

Article 4. General conditions for certification of advertising contents

1. Advertising contents must comply with the law on advertising and do not fall in the prohibited cases prescribed in Article 8 of the Law on Advertising.

2. Voices, texts and images in an advertisement must be short, common and compliant with Article 18 of the Law on Advertising. The smallest font size used in an advertisement must be readable under normal conditions and must not be smaller than the proportion corresponding to VnTime or Times New Roman font size 12 on A4 paper.

Article 5. Conditions for certification of drug advertising contents

Drugs must fully satisfy the advertising conditions specified at Point a, Clause 4, Article 20 of the Law on Advertising, and Article 3 of the Government's Decree No. 181/2013/ND-CP of November 14, 2013, detailing a number of articles of the Law on Advertising (below referred to as Decree No. 181/2013/ND-CP); and comply with the following specific provisions:

1. Drugs are permitted for advertising prescribed in Clause 1, Article 1 of this Circular, including:

a/ Drugs which are on the list of non-prescription drugs and are not restricted from use or are not recommended to be used under physician's supervision by competent state agencies;

b/ For drugs to be advertised on radio or television, their main active elements must be on the list of drugs' active elements and *materia medica* permitted to be advertised on radio and television as prescribed in Appendix No. 02 to this Circular.

2. Drugs have a valid registration number for sale in Vietnam and have a package insert approved by the Ministry of Health.

3. Drugs have a complete dossier as prescribed in Article 14 of this Circular.

4. The requester for certification of advertising contents is the unit named in the product sale registration certificate or is the Vietnam-based representative office of such unit or is a unit with legal person status authorized in writing by such unit.

5. Drug advertising contents must:

a/ Be consistent with the documents specified in Clause 1, Article 3 of Decree No. 181/2013/ND-CP;

b/ Contain all the information specified in Clause 2, Article 3 of Decree No. 181/2013/ND-CP, and the following information:

- For advertisements on books, newspapers, magazines or leaflets: precautions, dosage and administration;

- For advertisements on radio or television, the contents specified in Clause 3, Article 3 of Decree No. 181/2013/ND-CP, indications and contraindications, or recommendations for special users shall all be clearly read aloud;

- For advertisements on online newspapers, websites or advertising screens:

+ Audio advertisements must contain the information like those on radio or television;

+ Non-audio advertisements must contain the information like those on books, newspapers, magazines or leaflets;

If there are multiple advertising pages/scenes, they must appear consecutively and pause for an interval long enough for viewers to read through the information appearing on such pages; the page/scene with product information must be still for viewers to read through the information.

c/ Contain all the information specified in Clause 4, Article 3 of Decree No. 181/2013/ND-CP, for outdoor advertisements.

d/ May not include indications which are:

- Specified in Clause 5, Article 3 of Decree No. 181/2013/ND-CP;

- For treatment of viral hepatitis or new strange diseases.

dd/ May not include:

- Information and images specified in Clause 6, Article 3 of Decree No. 181/2013/ND-CP;

- Information and images that overstate the status of diseases or uses of drugs;

- Images of animals and plants that need protection;
- Information and images that may mislead that the drug can be used without physician's prescription or is entirely harmless, without any side-effects and contraindication, and is 100% effective.

Article 6. Conditions for certification of cosmetic advertising contents

1. Cosmetics must fully satisfy the advertising conditions specified at Point b, Clause 4, Article 20 of the Law on Advertising.

2. Advertising contents must comply with Article 4 of Decree No. 181/2013/ND-CP and the following provisions:

a/ The use of images, uniforms, names, mails or pieces of writing of health establishments, physicians, pharmacists or other health workers is not permitted;

b/ The features and uses of products must conform to the nature and classification of the products and the features and uses already announced in accordance with law.

3. Advertising contents shall be accompanied by a complete dossier specified in Article 15 of this Circular.

4. The requester for certification of advertising contents is the unit named in the product announcement sheet or its Vietnam-based representative office or is a unit with legal person status that is authorized in writing by the unit named in the product announcement sheet.

Article 7. Conditions for certification of advertising contents for food and food additives

1. Food and food additives are accompanied by written certifications of conformity with food safety regulations (for products for which no national technical regulations are available) or receipts of regulation conformity announcements issued by a competent state agency.

2. Advertising contents must comply with Article 5 of Decree No. 181/2013/ND-CP and the following provisions:

a/ For contents other than the announced ones, there must be lawful and scientific documents as proof and sources of reference materials cited in advertising layouts and scripts; for products with special usage and preservation instructions, such shall be specified in their advertisements;

b/ For advertisements on billboards, signboards, posters or product shelves, or with texts appearing at the foot of the television screen, on other articles, or on aerial, underwater or mobile objects, not all the information on usage, effects and preservation shall be presented, but the advertising contents must comply with the contents announced to be conformable with technical regulations or with food safety regulations;

c/ Not to advertise food in the form of pieces of writing of physicians, pharmacists or health workers that describe the food as having treatment effects;

d/ Not to use images, uniforms, names or mails of health establishments, physicians, pharmacists or health workers, or thank-you letters of patients to advertise food.

3. Advertising contents shall be accompanied by a complete dossier specified in Article 16 of this Circular.

4. The requester for certification of advertising contents is the unit named in the receipt of regulation conformity announcement or the written certification of conformity with food safety regulations (for products for which no national technical regulations are available) or a unit with legal person status authorized in writing by the unit named in such receipt or written certification.

Article 8. Conditions for certification of advertising contents for chemicals, insecticides and disinfectants for household and medical use

1. The products must fully satisfy the advertising conditions specified at Point c, Clause 4, Article 20 of the Law on Advertising.

2. Advertising contents must comply with Article 6 of Decree No. 181/2013/ND-CP.

3. Advertising contents shall be accompanied by a complete dossier specified in Article 17 of this Circular.

4. The requester for certification of advertising contents is the unit named in the product sale registration certificate or a unit with legal person status authorized in writing by the unit named in the product sale registration certificate.

Article 9. Conditions for certification of advertising contents for medical equipment

1. The products must fully satisfy the advertising conditions specified at Point g, Clause 4, Article 20 of the Law on Advertising.

2. Advertising contents must comply with Article 7 of Decree No. 181/2013/ND-CP.

3. Advertising contents shall be accompanied by a complete dossier specified in Article 18 of this Circular.

4. The requester for certification of advertising contents is the unit named in the sale registration certificate, for home made products, or in the import permit, for imported products, or its Vietnam-based representative office or a unit with legal person status authorized in writing by the unit named in the sale registration certificate or the import permit.

Article 10. Conditions for certification of advertising contents for milk and nutritious products for children

1. The products must fully satisfy the advertising conditions specified at Point d, Clause 4, Article 20 of the Law on Advertising and shall be accompanied by a receipt of regulation conformity announcement or written certification of conformity with food safety regulations (for products no technical regulations are available) issued by a competent state agency.

2. Advertising contents must comply with Article 8 of Decree No. 181/2013/ND-CP and Clause 2, Article 6 of the Government's Decree No. 100/2014/ND-CP of November 6, 2014, for the trading in and use of nutritious products for infants, feeding bottles and teats.

3. Advertising contents shall be accompanied by a complete dossier specified in Article 16 of this Circular.

4. The requester for certification of advertising contents is the unit named in the receipt of regulation conformity announcement or the written certification of conformity with food safety regulations (for products no technical regulations are available), or a unit with legal person status authorized in writing by the unit named in such receipt or written certification.

Article 11. Conditions for certification of advertising contents for medical examination and treatment services

1. The services must fully satisfy the advertising conditions specified at Point c, Clause 4, Article 20 of the Law on Advertising, specifically as follows:

- a/ Having a medical examination and treatment license, for health establishments;
- b/ Having a medical examination and treatment practice certificate, for practitioners required by the law on medical examination and treatment to possess a practice certificate.

2. Advertising contents must comply with Article 9 of Decree No. 181/2013/ND-CP.

3. Advertising contents shall be accompanied by a complete dossier specified in Article 19 of this Circular.

4. The requester for certification of advertising contents is the unit named in the medical examination and treatment license or a unit with legal person status authorized in writing by the unit named in such license.

Article 12. Competence to issue written certifications of advertising contents in the fields under the management of the Ministry of Health

1. Organizations under the Ministry of Health have competence to issue written certifications of advertising contents as follows:

a/ The Drug Administration of Vietnam, for the drugs specified in Clause 1, Article 1 of this Circular;

b/ The Food Safety Administration, for functional food, food fortified with micronutrients, and milk and nutritious products for children as prescribed in Clause 6, Article 1 of this Circular;

c/ The Medical Examination and Treatment Management Department, for medical examination and treatment services using modern medical methods provided by health establishments having operation licenses granted and lists of technical professional operations approved by the Minister of Health;

d/ The Traditional Medicine and Pharmacy Management Department, for medical examination and treatment services using traditional medical methods provided by health establishments having operation licenses granted and lists of technical professional operations approved by the Minister of Health;

dd/ The Health Environment Management Department, for chemicals, insecticides and disinfectants for household and medical use;

e/ The Medical Equipment and Works Department, for medical equipment (by order of the Minister of Health).

2. Provincial-level Health Departments shall issue written certifications of advertising contents for:

a/ Cosmetics of units named in cosmetic announcement sheets and headquartered in geographical areas under their management. In case of advertising cosmetics at conferences, workshops or other events, provincial-level Health Departments of localities where such conferences, workshops or events are expected to be held shall issue written certifications of advertising contents;

b/ Medical examination and treatment services provided by health establishments with operation licenses granted and lists of technical professional operations approved by directors of provincial-level Health Departments.

3. Food Safety and Hygiene Branches under provincial-level Health Departments have competence to:

a/ Issue written certifications of advertising contents for natural mineral water, bottled drinking water, food additives and food processing aids;

b/ Issue written certifications of advertising contents in case of advertising at conferences, workshops or events held in geographical areas under their management to introduce food and food additives as prescribed in Clause 3, Article 1 of this Circular;

c/ Give feedbacks on food that is advertised to have effects on human health when consulted by competent agencies assigned to issue written certifications of, or appraise, advertising contents for food under the management of the Ministry of Industry and Trade or the Ministry of Agriculture and Rural Development.

Article 13. General requirements on a dossier of request for certification of advertising contents for products, goods and services under the management of the Ministry of Health

1. A dossier shall be made in one set.

2. A dossier must comprise:

a/ A written request for certification of advertising contents as specified in Appendix No. 01 to this Circular;

b/ The enterprise's business registration certificate or the foreign trader's representative office establishment license;

c/ Advertising contents requested for certification:

- For radio or television advertisements, there must be one audio or visual disc or electronic file of to-be-advertised contents enclosed with 3 scripts of the advertisement, clearly describing the contents and medium of advertising, images (for television advertisements), texts and music;

- For advertisements in media other than radio or television, there must be 3 color advertising layouts enclosed with an electronic file of advertising contents;

- For advertisements at conferences, workshops or events, in addition to the materials specified at this Point, there must also be a valid advertisement design approved by a competent agency and used in the agenda (in case the advertisement design has been approved), the agenda specifying the contents of reports, time (date) and venue (address) of the the conference/workshop/event; contents of the reports to be presented at the conference/workshop/event and documents to be distributed to participants; list of names, academic titles and professional qualifications of speakers (speakers must possess diplomas and professional qualifications relevant to to-be-advertised products, goods or services. For drug advertising, speakers must possess a pharmacy diploma; for advertising of medical examination and treatment services, speakers must possess a medicine diploma; for advertising of food, food additives and food processing aids, speakers must possess medicine and pharmacy diploma or a university or higher degree in a relevant discipline).

d/ Label designs or approved label designs in case approval by a competent health agency is required by law.

3. Other documents:

a/ In case the requester for certification of advertising contents is an authorized unit, the following papers are required:

- The valid paper of authorization;
- The authorized unit's business registration certificate or the license for establishment of the foreign trader's representative office.

b/ Reference documents proving or certifying information in the advertising contents:

- Documents in English shall be translated into Vietnamese and enclosed with the English originals. The Vietnamese translations shall be appended with the seal of the requester;
- Documents in a foreign language other than English shall be translated into Vietnamese and enclosed with the original documents in that language. The Vietnamese translations shall be notarized in accordance with law.

c/ The papers in the dossier shall be clearly printed and arranged in the order specified in this Circular, and must have a cover and a list of papers; different parts of the dossier shall be separated with color sheets;

d/ The papers in the dossier must remain valid and may be certified copies or copies appended with the seal of the requester. These papers must each have the requester's seal, and every two adjoining pages shall be appended with such seal;

dd/ An advertisement design shall be presented on an A4-size paper; a large-size outdoor advertisement design shall be presented on an A3-size paper or a paper of another size, with a scale showing its actual size.

4. Requirements on dossiers submitted to agencies providing level-4 online public services:

Dossiers shall be converted into electronic files (single file) and must comply with the guidance of agencies providing level-4 online public services.

Article 14. Dossier of request for certification of drug advertising contents

1. The papers specified in Article 13 of this Circular.
2. The package insert approved by the Drug Administration of Vietnam under the Ministry of Health.
3. The product sale permit granted or drug registration number-issuing decision issued by the Drug Administration of Vietnam.

Article 15. Dossier of request for certification of cosmetic advertising contents

1. The papers specified in Article 13 of this Circular.
2. The cosmetic announcement sheet having the receipt number issued by a competent agency.
3. Valid documents proving the features and uses of the product, in case the cosmetic advertising contents mention the product's features and uses not stated in the above announcement sheet.

Article 16. Dossier of request for certification of advertising contents for food, food additives, and milk and nutritious products for children

1. The papers specified in Article 13 of this Circular.
2. The regulation conformity announcement receipt or the written certification of conformity with food safety regulations (for products for which no technical regulations are available) issued by a competent state agency.
3. A sheet of detailed information on the products, certified by a competent state agency.
4. Valid documents proving the features and uses of and information on the products, in case the advertising contents mention the products' features, uses and information not stated in the sheet of detailed information.

Article 17. Dossier of request for certification of advertising contents for chemicals, insecticides and disinfectants for household and medical use

1. The papers specified in Article 13 of this Circular.
2. The sale registration certificate for chemicals, insecticides and disinfectants.

Article 18. Dossier of request for certification of advertising contents for medical equipment

1. The papers specified in Article 13 of this Circular.
2. The import permit or sale registration certificate for medical equipment.

Article 19. Dossier of request for certification of advertising contents for medical examination and treatment services

1. The papers specified in Article 13 of this Circular.
2. The medical examination and treatment license of the service provider, granted by the Minister of Health or the director of the provincial-level Health Department, and the list of technical professional operations approved by the Minister of Health or the director of the provincial-level Health Department.
3. The medical examination and treatment practice certificate of the service provider, in case such certificate is required by law.

Article 20. Procedures for issuance of written certifications of advertising contents

1. The requester for certification of advertising contents shall submit a dossier to a competent agency defined in Article 12 of this Circular (below referred to as dossier-receiving agency).

2. For an invalid dossier, within 5 working days from the date of receipt based on the dossier-receiving agency's mark of incoming official letters, this agency shall notify such to the requester for completion of the dossier. The time limit for the requester to complete the dossier is 90 days after receiving the written notice from the dossier-receiving agency. Past this time limit, the dossier will become invalid.

3. Within 10 working days from the date of receipt of a complete and valid dossier based on the dossier-receiving agency's mark of incoming official letters, the competent state agency shall issue a written certification of advertising contents, made according to the form provided in Appendix No. 03 to this Circular. In case of refusal, it shall issue a written reply clearly stating the reason.

4. The dossier-receiving agency shall publicize on its portal the list of products, goods and services under its management for which written certifications of advertising contents have been issued and of which written certifications of advertising contents have expired.

5. Advertising at conferences, workshops or events:

a/ At least 2 working days before advertising, the organization or individual that has special products, goods or services under the management of the Ministry of Health for which a competent agency of the Ministry of Health has issued the written certification of advertising contents at conferences, workshops or other events shall notify in writing the form, time and place of advertising, enclosed with copies of such written certification and approved advertisement design or advertising script to the provincial-level Health Department of the locality where advertising will be conducted, for inspection or examination when necessary;

b/ If the venue and time of the conference, workshop or event are changed as compared to the written certification of advertising contents, the organization or individual having products, goods or services advertised shall notify such change to the provincial-level Health Department of the locality where the conference, workshop or event will be held at least 2 working days before advertising is conducted.

6. Procedures for registration of certification of advertising contents shall be carried out again in the following cases:

a/ The requester for certification of advertising contents modifies or supplements the dossier in contravention of the dossier-receiving agency's notice for dossier completion;

b/ The requester for certification of advertising contents fails to modify or supplement the dossier within the time limit specified in Clause 2 of this Article.

7. The dossier-receiving agency shall not receive dossiers of request for certification of advertising contents from a unit that has committed a violation of the law on advertising until the unit has completely served the sanctioning decision issued by a competent agency or person.

Article 21. Re-issuance of written certifications of advertising contents

1. A written certification of advertising contents may be re-issued when it is lost or damaged, as follows:

a/ The unit named in the written certification or the authorized unit shall send a written request for re-issuance of the written certification of advertising contents, made according to the form provided in Appendix No. 04 to this Circular, to the competent agency that has issued such written certification;

b/ Within 5 working days from the date of receipt of the written request based on the dossier-receiving agency's mark of incoming official letters, the agency competent to certify advertising contents shall re-issue the written certification of advertising contents to the unit. In case of refusal, it shall issue a written reply clearly stating the reason.

2. A written certification of advertising contents shall be re-issued in case it expires under Point a, Clause 1, Point a, Clause 2, Point a, Clause 3, Point a, Clause 4, or Point a, Clause 5, Article 23 of this Circular, and there is no change in advertising contents:

a/ The unit named in the written certification or the authorized unit shall send a dossier

of request for re-issuance of the written certification of advertising contents to the competent agency that has issued such written certification. Such dossier must comprise:

- The written request for re-issuance of the written certification of advertising contents, made according to the form provided in Appendix No. 04 to this Circular;

- One of the following papers which remains valid, proving the products, goods or services requested for certification of advertising contents:

- + The product sale permit granted or drug registration number-issuing decision made by the Drug Administration of Vietnam, for drug advertising;

- + The cosmetic-product announcement sheet having the receipt number issued by a competent state agency, for cosmetic advertising;

- + The regulation conformity announcement receipt or the written certification of conformity with food safety regulations (for products for which no technical regulations are available) issued by a competent state agency; the sheet of detailed information on the products; and designs of main labels approved by a competent state agency, for advertising of food or food additives;

- + The sale registration certificate for chemicals, insecticides or disinfectants, for advertising of chemicals, insecticides or disinfectants for household and medical use;

- + The import permit or sale registration certificate for medical equipment, for advertising of medical equipment.

- The expired written certification of advertising contents, enclosed with approved designs or scripts of advertisements.

b/ Within 5 working days from the date of receipt of a written request based on the dossier-receiving agency's mark of incoming official letters, the agency competent to certify advertising contents shall re-issue the written certification of advertising contents to the requester. In case of refusal, it shall issue a written reply clearly stating the reason.

3. Re-issuance of a written certification of advertising contents which remains valid but the name or address of the organization or individual responsible for marketing products, goods and services is changed while the advertising contents are not changed:

a/ The unit named in the written certification of advertising contents or the authorized unit shall send a dossier of request for re-issuance of the written certification of advertising contents to the competent agency that has issued such written certification. The dossier must comprise:

- The written request for re-issuance of the written certification of advertising contents, made according to the form provided in Appendix No. 04 to this Circular;

- The issued written certification of advertising contents, enclosed with the approved design or script of the advertisement;

- The competent agency's document proving the change of the name or address of the organization or individual responsible for marketing products, goods and services.

b/ Procedures for re-issuance of written certifications of advertising contents must comply with Clauses 2, 3, 4 and 5, Article 20 of this Circular.

4. Re-issuance of a written certification of advertising contents in case it expires under Article 23 of this Circular but does not fall in the case specified in Clause 2 of this Article, and

the cases of changing or adding advertising contents which are not mentioned in Clause 3 of this Article:

An enterprise shall make a dossier and carry out procedures for registration of the certification of advertising contents exactly as in the case of first-time registration.

5. A dossier of request for re-issuance of a written certification of advertising contents must comply with Clause 3, Article 13 of this Circular.

Article 22. Method of writing serial numbers of written certification of advertising contents

1. For written certifications of advertising contents issued by organizations under the Ministry of Health, a serial number shall be written as follows: serial number/year of issuance/XNQC-abbreviated name of the issuer. For example: 123/2015/XNQC-ATTP.

2. For written certifications of advertising contents issued by provincial-level Health Departments or Food Safety and Hygiene Branches, a serial number shall be written as follows: serial number/year of issuance/XNQC-abbreviated names of the issuer and province or centrally run city. For example: 123/2015/XNQC-YTHN or 123/2015/XNQC-ATTPHN.

Article 23. Cases of expiration of written certifications of advertising contents

1. Cases of expiration of a written certification of drug advertising contents:

- a/ The drug's registration number expires;
- b/ The drug's registration number is withdrawn or the drug is recommended by a competent state agency to be restricted from use;
- c/ There are changes in the information on indications, contraindications or dosage of the drug.

2. Cases of expiration of a written certification of cosmetic advertising contents:

- a/ The receipt number of the cosmetic-product announcement sheet expires;
- b/ The cosmetic is banned from sale or is recalled or the receipt number of its announcement sheet is withdrawn;
- c/ There are changes in information affecting the safety and quality of the cosmetic.

3. Cases of expiration of a written certification of advertising contents for food, food additives or milk and nutritious products for children:

- a/ The receipt of the regulation conformity announcement or the written certification of conformity with food safety regulations expires;
- b/ The enterprise's food safety and hygiene eligibility certificate is revoked;
- c/ The components or uses of the products or goods are changed;
- d/ The products or goods are banned from sale or are recalled.

4. Cases of expiration of a written certification of advertising contents for chemicals, insecticides or disinfectants for household and medical use:

- a/ The sale registration certificate for chemicals, insecticides or disinfectants for household and medical use expires;
- b/ The products or goods are banned from sale or recalled;

c/ The components or uses of or other information on the products or goods are changed or added, affecting their safety, as compared to the sale registration certificate granted by the Ministry of Health which remains valid.

5. Cases of expiration of a written certification of advertising contents for medical equipment:

a/ The import permit or sale registration certificate for the products or goods expires;

b/ The products or goods are banned from sale or recalled.

6. Cases of expiration of a written certification of advertising contents for medical examination and treatment services:

a/ The health establishment's operation license is revoked or it is suspended from operation;

b/ The health establishment's right to use its operation license is deprived under the law on handling of administrative violations;

c/ The health establishment is re-granted the operation license as a result of a change in the scope of professional operations related to the advertised medical examination and treatment services.

7. Other cases as provided for by law.

Chapter III

IMPLEMENTATION PROVISIONS

Article 24. Effect

1. This Circular takes effect on July 16, 2015.

2. From the effective date of this Circular, the following documents and provisions shall be annulled:

a/ The provisions on drug advertising in the Minister of Health's Circular No. 13/2009/TT-BYT of September 1, 2009, guiding the information on and advertising of drugs;

b/ The provisions on drug advertising in the Minister of Health's Circular No. 45/2011/TT-BYT of December 21, 2011, amending and supplementing a number of articles of the Minister of Health's Decision No. 1570/2000/QD-BYT of May 22, 2000, on the application of Good Laboratory Practices principles; the Minister of Health's Decision No. 2701/2001/QD-BYT of June 29, 2001, on the application of Good Storage Practices principles; the Ministry of Health's Circular No. 06/2004/TT-BYT of May 28, 2004, guiding the subcontracting production of drugs; the Ministry of Health's Decision No. 3886/2004/QD-BYT of November 13, 2004, on the application of Good Manufacturing Practices principles according to the World Health Organization's recommendations; the Ministry of Health's Circular No. 13/2009/TT-BYT of September 1, 2009, guiding the information on and advertising of drugs; the Ministry of Health's Circular No. 22/2009/TT-BYT of November 24, 2009, on drug registration; and Circular No. 47/2010/TT-BYT of December 29, 2010, guiding the import and export of drugs and packings in direct contact with drugs;

c/ The Ministry of Health's Circular No. 42/2010/TT-BYT of December 15, 2010, promulgating the list of drugs' active elements and *materia medica* eligible to be registered to be advertised on radio or television;

d/ The provisions on cosmetic advertising in the Minister of Health's Circular No. 06/2011/TT-BYT of January 25, 2011, on cosmetic management;

dd/ The Minister of Health's Circular No. 08/2013/TT-BYT of March 13, 2013, guiding the advertising of food under the management of the Ministry of Health.

Article 25. Reference provisions

1. In case the documents referred to in this Circular are amended, supplemented, replaced or annulled, the amending, supplementing or replacing documents shall be complied with.

2. In case certificates, licenses, receipts, written certifications, announcement sheets, or decisions issuing drug registration numbers mentioned in this Circular are modified, supplemented, or replaced with other papers or otherwise named under legal documents issued by competent state agencies, the names of the papers prescribed in such legal documents shall be used.

Article 26. Transitional provisions

1. Organizations and individuals that have submitted advertising registration dossiers for special products, goods and services under the management of the Ministry of Health and obtain the dossier receipts from competent state agencies before the effective date of this Circular may continue advertising such products, goods and services until such receipts expire.

2. For products, goods and services eligible for online issuance of written certifications of advertising contents, competent agencies shall issue written certifications of advertising contents pursuant to this Circular and relevant regulations.

Article 27. Implementation responsibility

1. The heads of the agencies competent to issue written certifications of advertising contents specified in Article 12 of this Circular shall organize the implementation of this Circular in their assigned fields and examine and supervise advertising activities after issuing such written certifications.

2. Requesters for certification of advertising contents shall take responsibility for the legality and accuracy of the information and documents in the dossiers of request for certification of advertising contents and of the advertising contents.

3. The Director of the Legal Department, the Chief of the Office, the Chief Inspector, and directors and general directors of departments, administrations and general departments under the Ministry of Health; directors of provincial-level Health Departments and heads of provincial-level Food Safety Branches, and related organizations and individuals shall implement this Circular.

Any problems arising in the course of implementation of this Circular should be reported to the Ministry of Health for study and settlement.-

For the Minister of Health
Deputy Minister
PHAM LE TUAN

** All appendices to this Circular are not translated.*