#### THE MINISTRY OF HEALTH

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# SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

No: 06/2011/TT-BYT Hanoi, January 25, 2011

# CIRCULAR PROVIDING COSMETIC MANAGEMENT

#### THE MINISTRY OF HEALTH

Pursuant to the Government's Decree No 188/2007/ND-CP of December 27, 2007 regulation about functions, duties, powers and obligation, and organizational structure of the Health Ministry; Pursuant to the Government's Decree No 188/2007/ND-CP of December 27, 2008 detailing implementation some articles of the Goods and Products Quality Law;

Pursuant to the Government's Decree No 24/2003/ND-CP on March 13, 2003 detailing implementation the Advertising Ordinance;

Pursuant to the Government's Decree No 89/2006/ND-CP of August 30, 2006 regulation on labeling of goods:

Pursuant to the Government's Decree No 12/2006/ND-CP of January 23, 2006 detailing implementation the Commercial Law in the international trade activities as well as activities which are agency for sale and purchase, processing and transit of with foreign country;

Pursuant to the Government Prime Minister's Decision No 10/2010/QD-TTg of February 10, 2010 regulation about the certification of free sale for the export or import goods and products; To carry out the Combination Convention in the cosmetic management which has been signed by

countries are member of the Association of Southeast Asian Nations on September 2, 2003 (commonly called ASEAN Cosmetic Convention),

The Minister of Health promulgates on cosmetic management as the following:

#### Chapter I

### **GENERAL REGULATION**

# Article 1: The scope of regulation and objects of application

- 1. This circular regulates the management of cosmetic products which is domestic produced, import cosmetic to sale in the scope of Vietnam territory, involving: cosmetic product announcement; product information dossier; request of product safety; product labeling; cosmetic advertising; cosmetic exporting or importing; collecting cosmetic pattern for quality inspection, verifying, investigation, and settling violations; duties of organizations, individuals in cosmetic production, trade, import and consumers' right.
- 2. This circular is applied for the cosmetic state management agencies, organizations, individuals conduct operations related to the cosmetic product declaration, the information, the advertising, the export, the import, the production, the trade of cosmetic products in Vietnam.

# **Article 2: Term Interpretation**

In this Circular, the following terms shall be construed as follows

1. Cosmetic product is a substance or a preparation which is used for touch with outside parts of human body (skin, hair system, finger nails, toenails, lip, and outside reproduction organ) or teeth and mouth mucous membrane with main purpose in order to cleanse, aromatize, change the outward characteristics, form, adjust body's smell, safeguard body, or maintain the human body in good condition.

- 2. Cosmetic name is the title which is given to a cosmetic product; it can be a new one named by itself together with brand or name of the producer. Letters which composes the product name must be Latin letters.
- 3. Organizations, individuals who are responsible for putting products on market are organizations, individuals have name written in the cosmetic product announcement dossier and be responsible for cosmetics product in the market.
- 4. The receipt number of Cosmetic product proclamation is a number issued by the competent state management agency, when receiving the cosmetic product announcement dossier. The announcement receipt number is useful in order to prove cosmetic product have been declared by organizations, individuals who are responsible for circulation products in market, just about cosmetic shall be circulated in market, are not value to certify that such product have been guaranteed of the safety, the effectiveness, and meeting all requirements of the ASEAN Cosmetic Association and the Annexes attached.
- 5. Cosmetic Product Owner is an organization or individual which owns formulas, process of production, standards of the product quality.
- 6. *Product stability* is the stable capacity of product when preserved in the appropriate condition still remains its initial quality; especially, still guarantees requirements of products safe.
- 7. Quantitative of goods is the amount of cosmetic shown with the absolute weight or the true volume in meter or in meter and British measurement system.
- 8. *Cosmetic label* is writing, print, drawing, photocopy of words, drawings, pictures which are pasted, printed, enclosed, casted, engraved, carved directly on goods, trade packing of goods, or other materials affixed with goods, trade packing of goods.
- 9. Label writing is showing basic, necessary content of cosmetic in label for customer to acknowledge, to rely on to choice, and use exactly, for producers to advertise goods and to base for functional agencies in inspection and supervisory.
- 10. Original label is the label which shown at the first time of affixing on trade packing of cosmetic.
- 11. *Auxiliary-label* is the label shows compulsory contents which is translated the cosmetic's original label from in the foreign language to in Vietnamese and supplement compulsory contents provided in this Circular which the original cosmetic label still lacks.
- 12. *Trade packing of cosmetic* is the packing contains cosmetic inside and traffic together with the cosmetic. The trade packing of cosmetic has two kinds: the direct packing and the outside packing.
- a. Direct packing is the packing contains goods, directly contacts with goods, makes into cube or tightly covers in cube of goods.
- b. Outside package is the packing used for packing one or a set of goods organizations which had direct packing before.
- 13. *Cosmetic circulation* is the display operation, transportation, and saving of goods in the goods selling or buying process, except case of transportation import goods of organizations, individuals from border gate to storehouse.
- 14. The number of lot of produced cosmetic is a signal in number or letter, or combination of number and letter in order to realize the lot of products and allow inquiring whole of source of a lot of product including of all steps of the manufacture process, quality inspection, and delivery lot of that product.
- 15. Cosmetic manufacturing date is the time mark of completed manufacture, processing, packing or other ways to perfect the last step of the product lot.
- 16. Expiry date of cosmetic is the time mark appointed for a lot of cosmetic which after this time-limit, the cosmetic shall not permitted for delivering or using
- 17. Best using period date is the time mark which the producers advise the customers for using when the quality of product is gaining at the most effective level.

- 18. *Cosmetic goods origin* is the country or territory area where products all of cosmetic or where implements the end basic processing step regarding to cosmetic in case of many countries or territory areas involved in the cosmetic manufacturing processing.
- 19. Certificate of free sale (CFS) is a certify issued by an authority agency in the export country for the export domestics trader stated in CFS to confirms that the cosmetic is freely produced and sold in the export country.
- 20. *Usage Introduction* is necessary information to guide the cosmetic user be safe and suitable. The usage introduction may be printed on the direct packing or in an attached document with the trade packing of cosmetic in which have instructions for usage and other information as regulated.
- 21. Cosmetic advertising is cosmetic introductory and broadcast activities to promote the process of cosmetic manufacture, sale, and usage.
- 22. Seminar, cosmetic introduction event is a meeting to introduce or special subject discuss with consumers about deep professional knowledge involving cosmetic.
- 23. Advertiser is organizations, individuals who have demand to advertise cosmetics produced or delivered by themselves.
- 24. Advertisement publisher is organizations, individuals transmit the cosmetic advertising product to consumers, includes the newspaper; telecommunication; television agencies; publishers; internet network management organizations; exhibition, fair, culture or sport program organizer; and organizations, individuals applying other advertising ways.
- 25. ASEAN Cosmetic Association is the representative agency of ASEAN member countries for following, decision and dealing conflicts related to the implementation of ASEAN Cosmetic Convention.

### Chapter II

### **COSMETIC PRODUCT PROCLAMATION**

# Article 3: The cosmetic product proclamation regulation

- 1. Organizations or individuals which are responsible of putting the cosmetic product on the market just permitted selling cosmetic when be issued the number of cosmetic product proclamation receiving by the authority agencies as well as responsible for safety, effectiveness, and quality of product. The authority agencies shall carry out after-sales inspection when the product has been being sold in the market.
- 2. Cosmetic product proclamation fee is implemented in accordance with the regulations in force.
- 3. Organizations or individuals who are responsible for putting the products on the market must have the function of cosmetic business in Vietnam.
- 4. Cosmetic product feature proclamation (the cosmetic usage purpose) must satisfy the ASEAN's instruction of the cosmetic product feature proclamation (Appendix No 3-MP).

### Article 4: The cosmetic proclamation dossier

The cosmetic proclamation dossier includes the following documents:

- 1. Cosmetic product proclamation report (02 versions) with the proclamation data (soft version of proclamation report);
- 2. Copy of business registration certificate of organizations, individuals who are responsible for circulation products into the market (with the enterprise's signature and seal). In case the cosmetic domestic produced, but organizations, individuals who be responsible for putting products on the market are not the manufacturer must have a copy of business registration certificate of the producer (have legal notarized);
- 3. Original or notarized copy of letter of attorney from the producers or the owners of products authorized for organizations, individuals are responsible of putting products on the market in Vietnam

(applied to the import or domestic cosmetic of which organizations or individuals are responsible of putting products on the market, be not the manufacturer). For the import product, the letter of attorney must be a copy notarized sign and consul legalized as provisions of law, except for being exempted of the consul legalization in regard to international treaties in which Vietnam is a member. The letter of attorney must satisfy requirements regulated at the Article 6 of this Circular.

- 4. Certificate of free sale (CFS) is only applied for import cosmetic product proclamation which satisfies the following requirements:
- a. CFS which is issued by the current territory must have been original or legally notarized and still in the day of validity. In case CFS is not provided of the expiry day, it must be a certificate which has just been issued within 24 months.
- b. CFS must be consul legalized according to provisions of the law, except consul legalization immunity case according to the international treaties in which Vietnam is a member.

# Article 5: The manner to establish the cosmetic product proclamation report and the proclamation data

- 1. The proclamation report:
- a. The cosmetic product report is set up in accordance with the form in appendix No 01-MP. The proclamation report must be signed by the representative under laws and with the seal of the organizations or individuals who are responsible for sale products in the market at the positions of report's paper margins. The manner to write contents in the cosmetic product report shall followed the instruction in the appendix No 02-MP
- b. Every cosmetic product proclaimed in a proclamation report.

Cosmetic product which perfect produced in every different enterprises shall be proclaimed separately. In case there are more than one company, taking part in the manufacturing process in order to product a complete product, may joint make a proclamation report and clear state each companies' name and full address.

Products have the same owners in one of the following situations is permitted to proclaim in one proclamation report:

- Products are packed with a joint name and sold out in form of a product set.
- Products have same name, same product line with similar formulas but different in color or smell. For products of hair dye, perfume, must be separate proclaimed with each color, each smell.
- Other kinds will be decided by the department of Medicine management the Health Ministry based on the ASEAN Cosmetic Association's decision.
- c. The manner to write component of formula which are composed in the cosmetic product:
- Components in the product formula must be efficiently listed in descending order of content. Components of perfume, aroma causing substances and their materials can be written in word "flavoring" (perfume, fragrance, flavor, and aroma). Components with less than 1% content can be listed in whatever order after components with more than 1%. Color causing substances can be listed in whatever order after other components in accordance with the color index (CI) or by names mentioned in the Appendix 4 (Annex IV) of the ASEAN Cosmetic Treaty. The cosmetic products for making up under different colors, the producer can list all color causing substances in "containable" section or "+/-".
- Having full percentages of components provided of limit of concentration and content according to the Appendix (Annexes) of the ASEAN Cosmetic Treaty. Between the unit position and decimal position shall be marked with a comma (",").
- Ingredient's name must be written in the International law name Nomenclature of Cosmetic Ingredients INCI is regulated in the latest publications: The International Cosmetic Ingredient Dictionary, the British Pharmacopoeia, the United States Pharmacopoeia, the Chemical Abstract Services, the Japanese Standard Cosmetic Ingredient, and the Japanese Cosmetic Ingredients

Codex. Plant title and the fluid is extracted from plant must be written in the scientific title which involves the limb and species (the limb title can be shortened). Ingredients from the animal need accurately writing in the scientific name of that animal.

The following substances are not subject to be considered as the cosmetic Ingredient:

- Impurities in materials used.
- Auxiliary materials used for the technology purpose but absent from the end-product.
- Exerted materials used with a necessary mount such as solvent or the bearer of scent-causing ingredients.
- d. The language in the proclamation report may be in Vietnamese or English. Contents which are mentioned in section 3 (the usage purpose), section 7 (the information of organization, individual who are responsible for putting products on the market), section 8 (information of enterprise's representative under the law), section 9 (information of import company) in the proclamation report must be written in Vietnamese or in Vietnamese and English.
- 2. The proclamation data (the soft version of the proclamation report): Organizations, individuals can submit the proclamation data according to clause 1, article 4 of this Circular by one of two following ways:
- a. Direct declaration: Organizations or individuals, who signed on the cosmetic product proclamation, must send the text to the Medicine Management department under the Ministry of Health to be issued an entry account to access the cosmetic management database, and fill in forms in the database directly. The proclamation report which is submitted to the competent state management agency must be printed out from that database.
- b. Access the Medicine Management department's electronic information page (website), download the database of the cosmetic product report (Appendix 01-MP), fill all the information into the database according to the law regulation, save to the electronic device (USB, CD-ROM, etc.). The proclamation report which is to be submitted to the Government's Management Office must be printed from that database.

The organization or the individual, whose name is on the cosmetic proclamation, must completely be responsible for the propriety of content of the cosmetics product proclamation report (signed and sealed version) compare with the proclamation data (soft version) declared or submitted to the Management Office.

#### Article 6: Provisions of the authorization certificate

- 1. The presenting language must be Vietnamese or English or bilingual Vietnamese and English.
- 2. The authorization certificate must have sufficient the following contents:
- a. The producer's name and address; in case the delegating party is the owner of product, must clearly state name and address of the owner of product, and name and address of the producer as well;
- b. The name and address of authorized organizations, individuals;
- c. The scope of authorization (undersigned on the proclamation and circulation product in Vietnam);
- d. The label or name of authorized product;
- e. The time-limit of authorization:
- f. The commitment of the producer or the owner of product to provide sufficient product information file (PIF) for organizations or individuals who are responsible for putting product on market;
- g. Name, position, and the signature of the delegating party's representative.

### Article 7: Procedure of receiving and solving proclamation dossier

- 1. The collecting and solving cosmetic product proclamation dossier is packed up into one set, submitted directly or posted to the following competent state management agency:
- a. Regarding to the export cosmetic: organizations or individuals who are responsible for bringing product into market apply the cosmetic product proclamation dossier at the Medicine Management Bureau the Ministry of Health.
- b. Regarding to the cosmetic produced by domestic organizations, individuals: organizations or individuals who are responsible for putting product on market apply the cosmetic product proclamation dossier at the Department of Health in which have production factory. The cosmetic products which are produced, packed from the import semi finished products shall be considered domestic produced products.
- c. Regarding to the cosmetic trading in the scope of industrial trading area of Moc Bai border gate economic area in Tay Ninh province implement of the proclamation at the Moc Bai border gate Economical Area Management Board; the cosmetic trading in the scope of Lao Bao special economic -trade area in Quang Tri province implement of the proclamation at the Economic Area Management Board of Quang Tri province.

The transporting cosmetic from the industrial trade area of Moc Bai border gate economic area in Tay Ninh province into other function areas in Moc Bai border gate economic area of Tay Ninh province or into the domestic market for trading; transporting cosmetic from the Lao Bao special economic -trade area in Quang Tri province into the domestic market for trading must implement of the proclamation at the Medicine Management Department— the Health Ministry in accordance with regulations of this Circular (organizations or individuals, who undersign on the cosmetic proclamation, must have function to trade on cosmetic in Vietnam, and not located in two these areas).

- 2. Handling the cosmetic product proclamation dossier:
- a. Within 03 working days since receiving the regular proclamation dossier and proclamation fee as provided competent state management agencies are obligated to issue the number of receiving the cosmetic product proclamation report.
- b. In case the proclamation dossier which still does not satisfy provisions of this Circular, within 05 working days since receiving dossier, the dossier receiving agency must announce in writing for organizations or individuals of contents, which having not satisfied yet, to fix, amend dossier (figuring out unsatisfied contents in details).

The amending dossier includes:

- A document explains amending and supplementing of the organization or the individual whose name is on the cosmetic proclamation;
- The cosmetic product proclamation report with the proclamation data (soft copy of the proclamation report) or other amended and supplemented documents;

Within 05 working days since receiving the supplementing dossier satisfying the regulations in this circular, competent state management agencies are obligated to issue the receipt number of the product proclamation report.

In case the amending and supplementing dossier does not satisfy this circular's regulation, within 05 working days since receiving the supplementing dossier, the dossier receiving agency must announce organizations or individuals in a text document of not issuing the receipt number of the product proclamation report.

c. Within 03 months since the announcement document is issued as provided at point b of this clause; if competent state management agency still does not receive any supplementing dossier from organizations or individuals whose name are on the cosmetic proclamation, the proclamation dossier shall be invalid. In this case, if organizations or individuals want to continue the proclamation, they must submit a new dossier and pay a new fee according to the regulations.

# Article 8: The regulation on writing the receipt number of cosmetic product proclamation report

The receipt number of cosmetic product proclamation report is regulated as follows: issued order number + forward slash + issued year (two end numbers) + forward slash + CBMP + hyphen + abbreviated name notation of province, city, the Economical Area Management Board or the Medicine Management Department (QLD) in accordance with Appendix 04-MP.

For example, 135/11/CBMP-HN means that the receipt number of cosmetic product proclamation report is 135 and issued in 2011 by Hanoi Medicine Department.

## Article 9: The change of proclaimed contents

Regarding to cosmetic products have already been declared and issued the receipt number of cosmetic product proclamation report, when have any change of content provided at Appendix 05-MP, organizations or individuals who are responsible for putting product on the market must establish a document to suggest supplementing (regarding to content which don't need make a new proclamation), attached with data related to the supplementing content and must be permitted in writing by competent state agency or implement a new proclamation in regard to the regulation (regarding to contents need make a new proclamation).

### Article 10: The effect time of the receipt number of cosmetic product proclamation report

The receipt number of cosmetic product proclamation report shall be valid for 05 years since issuing day. After 05-year-expiry, if organizations or individuals want to continue selling product in the market, they must make a proclamation again before the expiry of the receipt number of cosmetic product proclamation report and pay a regulated cost fee.

### Chapter III

### **COSMETIC PRODUCT INFORMATION DOSSIER**

## Article 11: The general regulation of cosmetic product information dossier

Every cosmetic product must get a Product Information File (PIF) when delivered to the market in accordance with ASEAN's instruction which is saved at the address of organizations or individuals who are responsible for putting the product on the market.

#### **Article 12: The Content of the Product Information File**

- 1. The Product Information File involves of the following 04 parts:
- a. Part 1: Administrative documents and a summary of product;
- b. Part 2: Material quality;
- c. Part 3: Product quality;
- d. Part 4: Safety and efficiency.

The details of the product information file are regulated in Appendix 07-MP.

2. Part 1 of the Product Information File must immediately be presented to the agency of Consideration, Investigation when required; others, if inefficiently, must be presented within 15-60 days since the consideration day in regard to the Functional agency's request.

### Chapter IV

# **COSMETIC PRODUCT SAFETY REQUIREMENTS**

### Article 13: The cosmetic safety requirements

The organization or the individual which delivers the product to the market must guarantee that its product shall be harmless for people's health when exerted in normal or appropriate conditions instructed, propriety for the composed form, information on the label, instruction, special carefulness, and else which are supplied by the producer or the owner.

The producer or the owner must evaluate the safety property of every cosmetic product in accordance with the ASEAN safety property norm. The heavy metal limit and the microorganisms in

the cosmetic must satisfy the ASEAN's requirements regulated in Appendix No 06-MP. The cosmetic Ingredients must satisfy the Appendix requirements (Annexes) – new version of the ASEAN Cosmetic Treaty (website: www.dav.gov.vn or www.aseansec.org).

# Article 14: The prohibited Ingredients, the regulated Ingredients of concentration, content and use condition limit in the cosmetic product formula

Organizations or individuals are not banned to deliver the cosmetic product which is composed with:

- 1. Prohibited substances in the cosmetic with conditions followed from Appendix II (Annex II).
- 2. Listed Ingredients in part I from Appendix III (Annex III), with the concentration, the content exceeds the permissible limit or condition.
- 3. Other color substances listed in Appendix IV (Annex IV), part 1, except the cosmetic which is used for dying hair.
- 4. Color substances listed in Appendix IV (Annex IV), part 1, is exerted outside mentioned conditions.
- 5. Maintenance substances outside the section of Appendix VI (Annex VI), part 1.
- 6. Maintenance substances listed in Appendix VI (Annex VI), part 1, with the concentration, the content exceeds the permissible limit or condition, except these which are used in special purposes unrelated to the maintenance substances effect.
- 7. Substances for filtering the ultraviolet ray which is not involved in the section from Appendix VII (Annex VII), part 1.
- 8. Substances for filtering the ultraviolet ray in Appendix VII (Annex II), the content exceeds the permissible limit or condition.

The present substances referred in Appendix II (Annex II) with the mark content is still acceptable if it is unavoidable technical errors in "perfecting that cosmetic product" and still satisfies the product safety requirements in the article 13 of this circular

# Article 15: Cosmetic products contain the following Ingredients are still allowed to be putting on the market

- 1. Ingredients or materials listed in Appendix III (Annex III), part 2, in mentioned limits and conditions until the marked schedule in (g) column of this Appendix.
- 2. Color substances listed in Appendix IV, part 2, in mentioned limits and conditions until the marked schedule in this Appendix.
- 3. Maintenance substances listed in Appendix 2, part 2, in the permissible limit and condition, until the day which is mention in (f) column from this Appendix. However, some Ingredients in this amount can be applied to other contents in specific purposes and presented fully in the product display form.
- 4. Substances for filtering the ultraviolet ray is regulated in part 2 of Appendix VII (Annex VII), in the permissible limit and condition, until the mentioned day in column (f) of this Appendix.

Regulation about using substances which are involved in Appendix (Annexes) above can be adjusted in accordance with the ASEAN Cosmetic Associate's decision. This regulation shall automatically update and come valid in Vietnam.

### Chapter V

#### WRITINGS ON THE COSMETIC LABEL

#### Article 16: The label location

1. The cosmetic label must be glue on the commodity, package of commercial article on a location which is easy be seen of full regulated contents without disconnecting details or parts of the commodity.

2. In case, the outward package is not permitted or impossible to open, there must be the label with the required information on the package.

### Article 17: The size, the appearance, and the content of label

- 1. The organization or the individual who are responsible for putting products on the market may identify the size of cosmetic product label but must assure that the information writing on the label must be readable by the ordinary eyes. The content of the label or the auxiliary label (if any) must be honest, clear, accurate, and reflect of exact product's quality.
- 2. The color of letter, numeral, drawing, sign, symbol which are displayed on the label must be clear. The color of letter and numeral must have contrast to the colored background of the label.

### Article 18: The content required to write on the label

- 1. The cosmetic product's label must be suitable for requirements for the cosmetic label writing set by The ASEAN. The following contents must be presented on the label:
- a. The product's name and function, unless the presented form of product has been displayed clearly the product's function;
- b. The usage instruction, unless the presented form clearly been displayed the product's using manner;
- c. The full formula ingredients: must write clearly ingredients according to the international nomenclature regulated for latest printed forms mentioned at point c, clause 1, Article 5 of this Circular (unnecessary to write the percent rate of ingredients);
- d. The country where the product was made;
- e. The name and the address of organizations or individuals who are responsible for putting products on market (written fully in Vietnamese according to the business registration certificate or the investment permission certificate);
- e. Quantification is presented with weight or volume, in regard to the meter system or the meter system and the British system;
- f. The manufacture lot number;
- g. The manufacture day or the expiry must be clearly presented (i.e.: day/month/year). The date writing way must clearly be presented and involved of month/year or day/month/year in right order. The "expiry" or "the best using before date" can be exerted, if necessary, can add the instructed condition needs obey to make sure of the product's stability.

Referring to products with the stability below 30 months, the writing of expiry day is compulsory;

- h. Warning about safety for usage; especially, warnings in the "usage condition and required alarms are compelled to be printed the product's label" column is referred in Appendices of ASEAN Cosmetic Treaty; these alarms are compelled to be printed on the label.
- 2. In case, the size, the form, or the package material can not be fully printed information which is regulated in charter 1 of this Circular on the original label, these required contents have to be printed on the auxiliary label attached with the cosmetic product and on the original label must figure out the position in which these contents are printed.

The following information is compelled to be printed on the original label of product's the direct packing:

- a. The product's name;
- b. The product lot number.

### Article 19: The presented language on the cosmetic label

Contents regulated in the article 18 from this Circular must be written in English or Vietnamese; specifically, information in part b, e, and h in clause 1 of the Article 18 must be written in Vietnamese.

### Article 20: The other information is presented on the cosmetic label

The organization or the individual is allowed to write other contents on the label. The added information is not opposite to the law regulation and must guarantee the honesty, the accuracy, the true reflection of the product's quality without causing the imperative content on the cosmetic label hidden and deviated.

## **Chapter VI**

### **COSMETIC ADVERTISING**

### Article 21: The regulation on advertising cosmetic

- 1. The cosmetic advertising is implemented on the public device for such is the television, the radio, the electronic information pages (id: internet, website), book, newspaper, magazine, pamphlet, pano, poster, air body, water body, or the other advertising means which are implemented or supported or authorized by the cosmetic enterprise organization as well as the seminar, the information, the product introduction activities.
- 2. Organizations are allowed to advertise or organize the seminar and the cosmetic product introduction event when have the receipt of permission file of advertising, operation seminar, cosmetic introduction event according to the law regulations.
- 3. The cosmetic advertising content must be appropriate to evident materials which affirm the safety and the efficiency of the cosmetic and be obedient to the ASEAN's instruction of declaring quality of the cosmetic product.

# Article 22: The content of cosmetic advertising, seminar, and cosmetic introduction event

The content of cosmetic advertising, seminar, and cosmetic introduction event must be enough the following information:

- 1. The cosmetic' name;
- 2. The quality, the efficiency (list the cosmetic' functions, essential effects if not presented on the product's name);
- 3. The name and the address of the organization or the individual who is responsible for putting product on the market;
- 4. The warning of use (if any).

## Article 23: The cosmetic advertising on the television, the radio device

If the cosmetic advertising is implemented on the television or the radio, clauses 1, 3, 4 in the Article 22 must be read loudly clearly. In case, presenting words on the screen, contents above must be shown with appropriately transmitted and the advertising letters' size must be big enough in order to sure clear, readable content.

#### Article 24: The advertising on newspaper or pamphlet

If the advertising is on newspaper or pamphlet, the ending part of the first page of advertisement document must print: (a) the advertising registration file receipt No of the Health Service; (b) day...month...year... of receiving the regular file printed on the file receipt.

# Article 25: The registration dossier of cosmetic advertising, seminar organization, cosmetic introduction event

- 1. The registration dossiers of cosmetic advertising, seminar organization, and cosmetic introduction event are inclusive of the following documents:
- a. The registration applying of cosmetic advertising, seminar organization, and cosmetic introduction event (Appendix 10-MP);
- b. The copy of the issued cosmetic product proclamation report (sealed by organization or individual who registers to advertise);

- c. The copy of the business registration certificate of organization or individual who registers to advertise (sealed by organization or individual who registers to advertise);
- d. The authorization letter of organization or individual who proclaims cosmetic for organization or individual who registers for advertisement, cosmetic introduction event, seminar operation (in case, organization or the individual who registers for advertisement, cosmetic introduction event, seminar operation is not organization or individual who proclaims cosmetic);
- e. The subtitles materials of the product's properties and utilities in case the advertised content and the presented content at the seminar or the cosmetic introduction event show the cosmetic's properties and utilities which are outside the presented content in the cosmetic product proclamation report;
- f. 02 advertisement scenarios (scenario must clearly describe the picture, callouts and music which are going to be put into the advertisement) or 02 advertising models which are going to be published (applied to the cosmetic advertisement registration file) or documents intend to show, publish in the seminar, cosmetic introduction event (applied to the cosmetic introduction event, seminar operation registration file). The file must get the joint pages stamp of organization or the individual who registers for advertisement, cosmetic introduction event, and seminar operation.
- 2. The manner to set up registration file for cosmetic advertising, cosmetic introduction event, seminar operation:
- a. The cosmetic advertising registration file can be established for one or many products, which are advertised in many different public information means.

The cosmetic advertisement or the advertising sceneries can be set up for one or many different products.

b. The cosmetic introduction event, seminar operation registration file can be set up for one or many products, operated at one or many locations in cities or provinces.

# Article 26: The authority of receiving and handling registration file of cosmetic advertising, cosmetic introduction event, and seminar organization

- 1. Before advertising of cosmetic, organizations, individuals have to send 01 set of cosmetic advertisement registration file according to the current provisions to the Health Department of place where the main office of organizations, individual proclaiming cosmetic products is located. The file envelop must clearly be written on with "the cosmetic advertising registration file".
- 2. Before operating seminar, cosmetic introduction event, organizations, individuals have to send 01 set of applying file according to the current provisions to the Health Department of location where operate seminar, cosmetic introduction event. The file envelop must clearly be written on with "the seminar, cosmetic introduction event operation registration file".
- 3. The Health Departments of centrally-affiliated cities and provinces (except advertising forms which are implemented according to the February 28, 2007 Joint Circular No 06/2007/TTLT/BVHTT-BYT-BXD of the Ministry of Culture and Information, the Ministry of Health, the Ministry of Agricultural and Rural Development, the Ministry of Construction on guiding the one-stop shop procedures for the grant of advertisement permits) receive and solve the registration dossier of cosmetic advertising, cosmetic seminar organization, and cosmetic introduction event.

# Article 27: The order and procedure of issuing the registration dossier receipt of cosmetic advertising, seminar organization, and cosmetic introduction event

1. After receiving the registration file of cosmetic advertising seminar organization and cosmetic introduction event which are regular in accordance with provisions of this Circular and the fee as current provisions, the Health Department sends to file applying organizations the receipt of cosmetic advertising seminar organization and cosmetic introduction event registration file (Appendix 11-MP) with the advertising pattern or the sceneries meet requirements (applied to the cosmetic advertising registration file). The date printed on the file receipt is the date when the Health department has received the full regular file. After 10 working days, since the day of received file, if the Health

department does not require any amending or supplementing in writing, those organizations shall be permitted to make advertisement, operate seminar, cosmetic introduction event in regard to the registered content.

- 2. In case the file is irregular to this Circular's provisions, the Health department shall notify the organization with an announcement in writing to supplement, complete the dossier.
- a. In the announcement, must be stated clearly, in detailing of amending and supplementing documents and contents.
- b. The organization has to amend and supplement according to the mentioned contents in the required amending and supplementing document and send back to the Health department. When the organization has yet supplemented the file fully, the Health department shall send a file receipt, the date printed on the file receipt is the date when Health department has received the full supplemented file. After 10 working days, since the day of receiving the supplemented advertisement content, if the Health department does not send out a amending and supplementing requirement in writing, the organization shall be permitted to advertise, operate seminar, cosmetic introduce event in regard to the amended content.
- c. In case, the supplemented file cannot rightly satisfy the referred contents in the amending and supplementing document, the Health department shall notify to the organization not to advertise, operate seminar, cosmetic introduce event as registered contents. Therefore, if the organization wants to continue to advertise, operate seminar, cosmetic introduce event, have to apply the file again, order of the file registration and consideration shall be implemented from the beginning and pay the fee as provided.
- d. In 02 months, since the Health department sends a document on contents need be supplemented to the file applying organization, if the Health department does not receive any document attached with the supplementing file, the registration file of advertisement, seminar, cosmetic introduce event operation shall be invalid.

### Article 28: The advertising information content evaluating fee

- 1. The cosmetic advertising content evaluating fee of an applying file collect/pay according to the current provisions which is calculated upon the products in 01 cosmetic product proclamation report issued the receipt number (independent from public telecommunication devices used for advertisement).
- 2. The cosmetic introduction event, seminar operation file evaluating fee (the advertising information content evaluating fee) collect/pay according to the current provisions which is calculated upon the products in 01 cosmetic product proclamation report issued the receipt number (independent from the number of cosmetic introduction event, seminar operation times).

### Article 29: The cosmetic advertising in other local areas

After receiving the file receipt of cosmetic advertising registering, if the organization wants to advertise on other advertising devices under local authorities of places different from the place where send advertisement registration file, must send an announcement in writing with the notarized copy of the regular cosmetic registration file receipt and all registered equivalent advertising content (the advertising sceneries or the advertising pattern) to the Local Health department where the advertising is going to be put into process before advertisement implementation at least 03 working days.

# Article 30: Changing and supplementing the content of advertising, seminar organization, and cosmetic introduction event

- 1. The organization who registers advertising, seminar, cosmetic introducing event operation must submit a supplementation registration file to the Health department where issues the file receipt when change one of the following contents:
- a. Name, address of organization or individual who are responsible for putting product on the market without changing the business registration certificate number or the investment certificate number;

- b. Name, address of organization who registers advertising, seminar, cosmetic introduction event operation without changing the business registration certificate number or the investment certificate number;
- c. Location and formal time of seminar, cosmetic introduction event operation compared to the registered estimation.
- 2. The supplementing file involves: the suggesting document for changing and supplementing, as well as documents in related to changing and supplementing content.
- 3. Other changes or supplementations out of contents referred at charter 1 of this Article, the organization who registers advertising, seminar, cosmetic introduction event operation must implement new registration as prescribed.
- 4. The Health department is obligated to deal supplementing files in 10 working days, since receiving enough regular file.

# Article 31: The invalid cases of cosmetic advertising content, seminar organization content, and cosmetic introduction event

- 1. The content of cosmetic advertising, seminar organization, and cosmetic introduction event is invalid in the following cases:
- a. The Cosmetic which has circulation registration number, cosmetic quality standard proclamation receipt number, cosmetic product proclamation receipt number is invalid.
- b. The cosmetic which is recommended not to be consumed or is withdrew by the state authority management agency.
- c. There are changes about the information affecting the safety and quality of cosmetic.
- 2. The organization that has advertising content, seminar organization content, and cosmetic introduction event be invalid, is compelled to communicate with related agencies, the advertisement publisher in order to stop publishing the cosmetic advertising information.

### Chapter VII

### **EXPORT OR IMPORT OF COSMETIC**

#### **Article 32: Export of cosmetic**

Export of cosmetic must be implemented at the Customs agency in accordance with the current law regulation and the import country's requirements.

# Article 33: The file, procedure of issuing the Certificate of Free Sale (CFS) in regard to the cosmetic which has been domestic produced for export

- 1. The CFS issuing request file includes:
- a. The CFS issuing request applying (Appendix IV of the February 10, 2010 Decision No 10/2010/QD-TTg of the Prime Minister, on providing the certificate of free sale for the export or import commodities, products) must be fully regularly enumerated;
- b. The copy of the cosmetic product proclamation report has been issued the receipt No (the copy sealed by trader who suggest for the CFS granting).
- 2. The issuing of the Certificate of Free Sale (CFS) for cosmetics which are domestic produced for export must be implemented according to regulations in Chapter II of the February 10, 2010 Decision No 10/2010/QD-TTg of the Prime Minister, providing the certificate of free sale for export or import commodities, products; moreover:
- a. The domestic cosmetic for export purpose is issued the CFS when it is issued the cosmetic product proclamation receipt number by competent state management agency.
- b. The export trader must register the trader file at the Health department where have cosmetic manufacturing plant and make CFS issuing procedure for export cosmetic goods.

- c. Every CFS is issued for 01 or many products (CFS pattern in regard to Appendix 12-MP) and become effective in next 02 years since issued day.
- 3. The cost or the fee for the CFS issuing is implemented according to the current regulation (The cost or the fee for the CFS issuing is calculated on product in 01 cosmetic product proclamation report with issued receipt number).
- 4. The Health department in central-affiliated cities and provinces are competent agencies in issuing and managing CFS of export cosmetics which are manufactured in that area (where the manufacturing plant is placed).

# Article 34: The file, the procedure of issuing the certificate of organization satisfying principles and norms of the "cosmetic good manufacture practice" of the ASEAN Association (CGMP-ASEAN), which serves for the export demand

- 1. The manufacturing organization which has demand to be issued the certificate of organization satisfying principles and norms of the "cosmetic good manufacture practice" of the ASEAN Association (CGMP- ASEAN), which serves for the export demand, sends the consideration registration file to the Medicine Management department the Health Ministry. The file is inclusive of:
- a. The consideration registration applying of "cosmetic good manufacture practice" (Appendix No 13-MP);
- b. The copy of Business Registration Certificate of the Investment license;
- c. The organization chart and human of organization (the organization chart must clearly presents the name, job title, technical, professional level of officers who are in charge of parts), the working process and experiences in the assigned fields of the officers who are in charge of parts (manufacture, quality check, quality guarantee, storehouse);
- d. The training program, assessment results of training the "cosmetic good manufacture practice" at organization;
- e. The location chart and design of factory (includes: the general background chart, the worker's way chart, way chart of material, package, semi-finished product, finished product, waste-treating system chart);
- f. The list of factory's current equipments (involves manufacturing equipments and cosmetic quality-checking equipments) has to clearly states name, manufacture year, manufacture country and situation of equipment);
- g. The list of goods which are being manufactured or estimated produced (state clearly the product form);
- h. The self-investigation minutes of "the cosmetic good manufacturing practice" (the self-investigation minutes must clearly states investigation time, element of self-investigation delegation, self-investigation purpose, self-investigation results and time proposals and contemporary problem-solving means).
- 2. The authority of receiving and handling file:

The Medicine Management department – the Ministry of Health is obligated to consider files, plan and make decision to establish investigation delegation, inform to organization at least 10 days before implementing investigation.

- 3. The certificate of organization satisfying principles and norms of the "cosmetic good manufacture practice" is valid in 03 years since the issuing day.
- 4. The manufacture organization (the GMP registration organization for short) must pay the fee for evaluating of cosmetic manufacture standards and conditions, in accordance with the current regulations.

### Article 35: Import of cosmetic

- 1. Cosmetic products which have been issued the valid cosmetic product proclamation receipt number by the Medicine Management department the Health Ministry, permitted to import in Vietnam. The import procedure is implemented at the Customs agency according to the current regulations. When implementing the import procedure, enterprise presents to the Customs agency the cosmetic product proclamation report which has been issued the receipt number by the Medicine Management department the Health Ministry.
- 2. Import of cosmetic in some special situations (not obligated to implement the cosmetic product proclamation according to this Circular's regulation);
- a. Organization or individual who imports cosmetic in order to study and experiment must send the cosmetic import bill used for studying and experiment to the Medicine Management department the Ministry of Health (Appendix No 14-MP). The maximum amount for each product is 10 patterns.

The cosmetic import bill which is used for studying and experiment is made into 03 versions. After approved, 02 versions are saved at the Medicine Management department, 01 version is sent back to the organization. The version which is sent back to the organization shall be sealed with "the version for sending to enterprise" in order to present to the customs agency when make customs clearance procedure.

The cosmetic products which are imported for studying, experiment have to be used in the right purpose and not to permit to put on the market.

b. The organizations, individuals who receive cosmetic as gifts must implement the import procedure at the customs agency as the regulations. The overall value of each gift receiving time is not to exceed the cargo quantum which is exempted of the imposed tax in the current regulations.

The import cosmetic patterns such as gifts shall be not permitted to put on the market.

c. The organizations, individuals who imports cosmetic for displaying at fair, gallery and other temporary import for re-export situations must implement procedure of applying for temporary import for re-export license of the Ministry of Industry and Trade in accordance with the current regulations.

## **Chapter VIII**

#### COSMETIC SAMPLING FOR THE QUALITY CHECK

### Article 36. The principle of sampling

- 1. Cosmetic sampling for quality checking or supervision must follow the principle of sampling random pattern and take pattern at different positions of the product lot.
- 2. The amount of pattern which is necessary to collect for analysis and archives basing on the checking requirement, quality standard, test method, but at least enough for the three-time-analysis or enough for implementation experiment which guarantee result accurate and trustworthy.
- 3. The pattern for analysis and archives must be put into the cover, tightly soldered, and labeled. The label of thing cover pattern must clearly state the product's name, the name of the organization or the individual responsible for putting product on market, the lot number, the expiry of using, place of sampling, and date of sampling.
- 4. Make the minutes of cosmetic sampling in accordance with Appendix 09-MP: The cosmetic sampling minutes must clearly state the product's name, the manufacture lot number, date of sampling, place of sampling, records of abnormal in sampling process, the signature and name of sampling person, the sampled organization's representative, the seer (if necessary). The minutes is made into 03 versions: One version saved at organization of collecting pattern, one version saved at the consideration agency, one version saved at the cosmetic quality checking management agency.

#### Article 37. The rights and obligations of sampling officer

1. Presenting the card of investigator or the quality controller or the introduction letter or decision on establishing the check delegation signed by the head of the cosmetic quality inspection agency when implementing his duty.

- 2. Asking organization having the pattern to present dossiers or the materials related to source, quantity, quality of the sampling cosmetic lot; giving out the method of sampling, quantity of patterns for analysis and archives samples from the cosmetic lot in the sampling process.
- 3. Checking and sampling any pattern packaged from the cosmetic lot when have any suspicion of product's quality and safety.
- 4. Being responsible for the technical manipulation, the legal procedure in the process of sampling, transportation and transfer samples to the analyze agency.

### Article 38. The transportation and transfer samples

- 1. After finishing the sampling, the sampling officer must send samples with the cosmetic sampling minutes attached and hand over to the analyze agency. In special cases, the sample can be posted to the analyze agency.
- 2. The cosmetic samples must be packed up inside the appropriate cover and transported by the suitable means to make sure that the samples are maintained in accordance with the regulation, avoid spoiling, damage during transportation process.

# Article 39: The conclusion of the cosmetic samples quality checking

- 1. The cosmetic samples which are collected by the quality checking authority state agency guarantee the representative property for the whole cosmetic lot and are implemented to analyze in the recognized laboratories; for which the conclusion of the quality checking result shall be legal valid regard to the whole product lot.
- 2. All cosmetic samples which are sent to the quality checking state agency by organizations or individuals in order to analyze the quality; for which the checking result shall be just legal valid regard to the sent samples.

### Article 40: The sampling and analyzing fee for the cosmetic quality check

- 1. The cosmetic sampling fee and the cosmetic sample analyzing cost for the cosmetic quality check in manufacturing, composing, and putting on the market will be paid by the quality checking agency who decides on sampling and analyzing sample in accordance with the regulation of the March 3, 2010 Joint-Circular No 28/2010/TTLT-BTC-BKHCN by the Joint-Ministries of Finance, Science, and Technology, on guiding budget management and spending in relation to state checking operation of the commodity product quality.
- 2. In case, the analyzed sample is unsatisfied the quality standard which concluded by the cosmetic quality checking agency, organizations, individual who are responsible for putting the product on the market must pay for the whole fee of collecting pattern, analyzing cosmetic pattern to the quality checking agency in accordance with Article 10, Article 12, Article 14, Article 16, and Article 41 of the Product Quality Law in 2007, the March 3, 2010 Joint-Circular No 28/2010/TTLT-BTC-BKHCN of the Joint-Ministries of Finance, Science, and Technology on guiding budget management and spending in relation to state checking operation of the commodity product quality, and related law documents.
- 3. In case, the cosmetic is complained and accused of the quality; however, the quality checking agency conclusive that the complaint, accusation of product quality are not right, the person, who complaint, accuse, must pay for the whole fee of sampling, analyzing cosmetic sample to the quality checking agency regulated in charter 1 of this Article.
- 4. The cosmetic sampling payment for quality checking, the cosmetic sample analyzing payment are organized in the operation budget estimate of the cosmetic quality checking state agency, according to the regulations in the March 3, 2010 Joint-Circular No 28/2010/TTLT-BTC-BKHCN of the Joint-Ministries of Finance, Science, and Technology on guiding budget management and spending in relation to state checking operation of the commodity product quality, and related law documents.

## Chapter IX

### CHECKING, INVESTIGATING, AND HANDLING OF VIOLATIONS

Article 41: The state checking on the cosmetic quality

- 1. The cosmetic quality checking agency:
- a) The Cosmetic Quality Checking Central agency is the Medicine Management department the Ministry of Health. The Medicine Management department directs the checking-system in the whole country. In the cosmetic quality checking state activities, the Medicine Management department coordinates with the inspector of the Health Ministry, the Medicine Analyzing Central Institute, the Medicine Analyzing Institute of Ho Chi Minh City, Medicine departments of centrally-affiliated cities and provinces in order to carry out and supervise the post-sale promotion activities regard to the cosmetic products.

On the cosmetic analyzing result of the analyzing state agencies, the Medicine Management department – the Ministry of Health is the agency who conclusive cosmetic quality in limit of whole country.

- b. The local cosmetic quality-checking agency is the Health department of centrally-affiliated cities and provinces. The Health departments of centrally-affiliated cities and provinces organize to carry out the post-sale promotion activities on the domestic cosmetic, the import cosmetic which is delivered in their area, and handle problems in relation to the cosmetic quality according to the law regulations; follow and statistic of the cosmetic quality management situation in their localities; conclude the cosmetic quality on the cosmetic-analyzing result of the cosmetic quality analyzing state agency in their localities.
- 2. The cosmetic analyzing state system involves:
- a. In the Central: The Central Medicine-Analyzing Institute, the Medicine-Analyzing Institute of Ho Chi Minh City.
- b. In the Locality: The Medicine and Cosmetic Analyzing Centers in centrally-affiliated cities and provinces.
- 3. The Heads of cosmetic quality analyzing state agencies are responsible for the conclusion of cosmetic quality-checking result before the law.

# Article 42: The checking and inspecting form

- 1. The scheduled check and inspection: The scheduled check and inspection shall be warned for the checked organization in order to prepare being inspected before implementing of checking, inspecting activities.
- 2. The sudden check and inspection: The sudden check and inspection shall be made when discovering the products which are unqualified product, don't obey provisions of putting on the market, or because of the customer's complaints. In urgent cases, the authority agencies have the right of check and inspection without warning.

### Article 43: The content of checking and inspecting

- 1. Checking and inspecting the obedience of laws on the cosmetic production and the trading:
- a. The obedience of principles and standards of "cosmetic good manufacturing practice" of the Asian Southeast Association Nations (CGMP-ASEAN) or equivalence which are admitted by the ASEAN Cosmetic Association;
- b. The label writing;
- c. The Product Information File (PIF) regulated by the ASEAN;
- d. The cosmetic advertising.
- 2. The check and the inspection of solving the dispute, the complaint, the denouncement on the quality and other contents related to the cosmetic (if any).
- 3. The check and the inspection of implementing announcement of confiscation the cosmetic in regard to the regulation (if any).

### Article 44: The priority order in checking and supervising the post sale-promotion

The check and the inspection of the cosmetic post sale-promotion need to get together at the import, delivery, manufacturing organizations. The priority in checking and supervising the cosmetic post-promotion is dependent on the product's kind, origin source, label, company's brand name, formula Ingredients according to the ASEAN's instruction on checking and supervising the post sale-promotion (Appendix No 08-MP).

### Article 45: Suspending the cosmetic circulation and confiscation

- 1. The cosmetic which is suspended circulation and confiscated when one in two following situations happens:
- a. The cosmetic which is put into the market has not yet been issued with a cosmetic proclamation receipt No by the Government's Authority Office;
- b. The cosmetic which is unqualified or unsafe for the consumer;
- c. The delivered cosmetic gets the formula which is written not exact as the proclaimed one in the file.
- d. The cosmetic which contains the prohibited substance, or the concentration, the content exceeds the permissible level;
- dd. The circulation of cosmetic which gets a inappropriate usage label compared to the proclamation file or is unsatisfying the regulation in writing on the label of this Circular; dependent on the level of violation, the product can be suspended of circulation and confiscated;
- e. The circulation of cosmetic is produced at a factory which is unsatisfying the regulation, "cosmetic good manufacturing practice" standard of the Asian Southeast Association Nations (CGMP-ASEAN) or the ASEAN Cosmetic Association equivalent admits; dependent on the level of violation, the product can be suspended of deliver and confiscated.
- f. The expired or over-expired cosmetic in accordance with the producer's warning;
- g. The false, illicitness-imported, unclear-sourced, origin, and imperfection-packaged product;
- h. The cosmetic is voluntarily confiscated in written by organization or individual who is responsible for putting it on the market.
- 2. The authority of making decisions to confiscate the cosmetic:
- a. The Medicine Management Department the Ministry of Health gives out a decision to confiscate the cosmetic from the whole country.
- b. The Provincial or Central Cities Health Service, the Management Board of the Moc Bai Entry Economical Area (Tay Ninh Province) or the Management Board of the Economical Area, in Quang Tri Province implement the Medicine Management department the Ministry of Health's announcement of confiscating the law-breaking cosmetic in accordance with the law regulation in the region and report to the Medicine Management department.

### Article 46: Confiscating the cosmetic product proclamation receipt number

- 1. The cosmetic product proclamation receipt number is confiscated in one of the following situations:
- a. The circulated cosmetic gets two unqualified lots which are concluded by the Government's Cosmetic Quality Management Office;
- b. The circulated cosmetic gets the formula which is not exact as the proclaimed one in the file;
- c. The circulated cosmetic gets the label in which the origin and the source are written erroneously;
- d. The circulated cosmetic gets the label in which the cosmetic existing properties are written erroneously;
- e. The cosmetic unsafe for the consumer;
- f. The cosmetic which contains the prohibited substance, or the concentration, the content exceeds the permissible level;

- g. The cosmetic which is concluded of breaking the intellectual ownership right or falsifying another delivery-permissible product's label.
- h. The product which is prohibited in the current country;
- i. The organizations or the individuals who put the cosmetic to the market gives out a request document of confiscating the cosmetic product proclamation receipt No;
- j. No Product Information File (PIF) for presenting to the Authority Office in accordance with the Article 12 of this Circular;
- k. Forging the document, using fake seal or forging the signature, the seal of the Authority Office of Vietnam or foreign country, of the manufacturer or the product owner;
- I. Dishonest declaring about contents referred in the cosmetic proclamation receipt.
- 2. The authority of giving out a decision to confiscate the cosmetic product receipt number:
- a. The Medicine Management department the Ministry of Health make decision to confiscate the domestics-manufactured product proclamation receipt Number issued by the Medicine Management department before April 25, 2009, for the imported products in the whole country.
- b. The Provincial and Central Cities Service of Health make decision to confiscate the local manufactured product proclamation receipt number issued by their organization.
- c. The Management Department of the Moc Bai Entry Economical Area (Tay Ninh Province), the Management Department of the Quang Tri Province Economical Area decides to confiscate the local manufactured product proclamation receipt No issued by their organization.

# Article 47: Suspension situations of receiving the cosmetic product proclamation file, the cosmetic advertising registration file, the seminar organization file, the cosmetic introduction event

- 1. The Government's Management Office shall suspend considering and receiving the cosmetic product proclamation file in 06 months in regarding to the organizations or the individuals which has one of the following behaviors:
- a. Trading on the illicitly imported cosmetic, the false cosmetic, the unclear-sourced origin cosmetic;
- b. Trading on the cosmetic which is not yet issued the cosmetic product proclamation receipt No by state management authorities;
- c. Disobeying the implementation of confiscating the law-breaking cosmetic in accordance with the state authority office's announcement;
- d. Producing or business cosmetic at a factory which is unsatisfying the regulation, "cosmetic good manufacturing practice" standard of the Asian Southeast Association Nations (CGMP-ASEAN) or the ASEAN Cosmetic Association equivalent admits;
- e. Producing or business cosmetic which contains the prohibited substance, or the concentration and the content exceeds the permissible level;
- f. Using the cosmetic manufacturing materials which have been declared not to putting on the market by the manufacturing country;
- g. Importing and trading on the cosmetic or the cosmetic product materials which have been declared not to deliver in the market by the manufacturing country;
- h. Manufacturing and trading cosmetic whose formula is not exact as the content in the cosmetic product proclamation file;
- i. Forging the document, using fake seal or forging the signature, the seal of the Authority Office of Vietnam or foreign country, of the manufacturer or the product owner;
- k. Dishonestly confessing about contents referred in the cosmetic proclamation receipt;

- I. Owning no Product Information File (PIF) for saving at the enterprise in according to the regulation.
- 2. The Government's Management Office shall suspend considering and receiving the registration file of cosmetic advertisement, seminar, and cosmetic introduction event, in 06 months in regarding to the organizations or the individuals who has one of the following behaviors:
- a. Advertising the cosmetic, holding the cosmetic seminar, and the cosmetic introducing when have not issued the cosmetic advertising registration file receipt, the cosmetic seminar-holding registration file receipt, the cosmetic introducing event registration file receipt by the state competent office according to the law regulations;
- b. Advertising, holding the seminar, and introducing the event of the cosmetic which is not issued with the cosmetic product proclamation receipt Number;
- c. Advertising the cosmetic which is possible to make the consumer misunderstand that the cosmetic is a tablet; advertising the cosmetic which is used of the title, the symbol, the image, the letter of the Healthcare organization or the Pharmacy organization of Health officers; advertising the cosmetic on property and efficiency which are not enough for the scientific base.
- 3. The state competent office shall consider suspending receiving the cosmetic advertising registration file, the cosmetic seminar-holding registration file, the cosmetic introducing event registration file from the organizations or the individuals who do not submit the annual trading manufacturing activity results report in regard to provisions.

When the suspension time period for considering and collecting the file comes to an end, after the organization has already overcome all law-breakings and submitted report, the state competent office shall continue to consider and collecting the cosmetic advertising registration file, the cosmetic seminar-holding registration file, the cosmetic introducing event registration file of the organization.

### Chapter X

# THE OBLIGATION OF THE ORGANIZATION, THE INDIVIDUAL WHO MANUFACTURE, TRADE, AND IMPORT THE COSMETIC AND THE CONSUMER'S RIGHT

# Article 48: The obligation of the organization, the individual who manufacture, trade, and import the cosmetic in order to put on the Vietnam market

- 1. The organization, the individual, who are responsible for putting cosmetic on the market, must be responsible for all contents declared in the cosmetic product proclamation report, for the safety, the efficiency, and the quality of the product; as well as guarantee that the circulated products satisfy all requirements of the ASEAN Cosmetic Treaty and the attached Appendix .
- 2. The organizations, the individuals who put the cosmetic on the market must be responsible to follow, to discover, and to confiscate immediately the unqualified cosmetic, as well as implement the confiscation announcement from the state authority office and inform to the state authority office about the confiscation; punctually deal with the consumer's complaints of the cosmetic's quality and compensate for consumer's loss in accordance with the regulation; refund to the buyer the produced cost in the maintenance, transportation, and circulation process.
- 3. In case finding side-effects which are serious and able to damage the consumer's life because of the cosmetic product's quality, the organizations, the individuals who put the cosmetic on the market must report to the Medicine Management department the Health Ministry within 07 days since the day or receiving the first feedback from this side-effect in accordance with the version at Appendix No 18-MP. The announcement in detail on this serious side-effect must be sent back to the Medicine Management department the Health Ministry within next 08 days.
- 4. The organizations, the individuals who put the cosmetic on the market must save the Product Information File (PIF) in at least 03 years since the latest manufacture lot is put on the market and presented to the checking and inspecting Functional Office when is requested.
- 5. The organizations which manufacture the cosmetic must deploy to apply and satisfy principles, the "cosmetic good manufacturing practice" standard of the Asian Southeast Association Nations (CGMP-ASEAN)

- 6. The organizations, the individuals who business on the cosmetic must conduct requirements of state competent offices about checking and inspecting the cosmetic quality, confiscating the violation cosmetics, and be entitle to complain about the conclusion and the law-breaking judgment form in accordance with the law regulation on the complaint and the denouncement.
- 7. The organizations, the individuals who put the cosmetic on the market must obey the Vietnamese Regulation and Law on the intellectual ownership. When having the conclusion of the state competent offices on the intellectual-ownership law-breaking label and industrial-style, The organizations, the individuals must stop manufacturing, trading, and importing in order to conduct of changing the label and the industrial style as provided, and be responsible for refunding and resolving all damages (if any).

### Article 49: The cosmetic consumer's right

The consumer has right to be informed about the cosmetic, to complain, to sue, and to ask the cosmetic-trading organization to refund damage in regard to the law regulation incase of consuming the circulated cosmetic which is unqualified and unsafe.

### Chapter XI

### THE IMPLEMENTING ORGANIZATION

# Article 50: The information and the report

- 1. The Medicine Management department the Ministry of Health is responsible to update and deploy regulations related to the ASEAN Cosmetic Treaty in the electronic information page of the Medicine Management department (website address: www.dav.gov.vn). Frequently popularize the changes on the technical criterion which have been decided by the ASEAN Cosmetic Association for relative organizations and cosmetic-trading organizations, as well as collaborate to carry out those changes and decisions in Vietnam. All decisions of managing the cosmetic which are accepted by the ASEAN Cosmetic Association are applied in Vietnam.
- 2. The Medicine Management department, the Provincial and Center Cities department of Health, the Management Board of Moc Bai Entry Economical Area (Tay Ninh Province), and the Management Board of Quang Tri Province Economical Area, in accordance with the authority, are obligated to up cosmetic violation handling results in the electronic information page of the office in order to serve checking, inspecting, and supervising of after-sale.
- 3. Periodically annually on June 30 and December 31, the Provincial and Central Cities department of Health, the Management Board of Moc Bai Entry Economical Area (Tay Ninh Province), and the Management Board of Quang Tri Province Economical Area send the report of quality management situation and the cosmetic after-checking work in the local region, report of issuance of the cosmetic product receipt (Appendix 15-MP) and report of issuance of the registration file receipt of cosmetic advertising, cosmetic seminar-holding, and cosmetic introducing event (Appendix No 16-MP) to the Medicine Management department the Ministry of Health.
- 4. Periodically annually on January 30, the organization, the individuals who are responsible for putting the cosmetic on the market must send their previous year business activity result report to the Medicine Management department the Ministry of Health and the department of Health (Appendix 17-MP).

### Article 51: The forms and the appendixes attached with the Circular

- 1. The cosmetic product proclamation receipt form: Appendix No 01-MP.
- 2. The document guides on proclaiming the cosmetic product: Appendix No 02-MP.
- 3. The ASEAN's instruction on proclaiming the cosmetic product's property: Appendix No 03-MP.
- 4. The abbreviation treaty of the central province name, city name and some Management Board of Economical Areas: Appendix 04-MP.
- 5. The changes after proclaiming the cosmetic product: Appendix No 05-MP.

- 6. ASEAN's regulation on the heavy metal limit and the micro-organism in the cosmetic product: Appendix No 06-MP.
- 7. The product information file: Appendix No 07-MP.
- 8. The document guide of ASEAN on checking the cosmetic post-promotion: Appendix No 08-MP.
- 9. The cosmetic sampling minute form: Appendix No 09-MP.
- 10. The registration dossier receipt form of cosmetic advertising, seminar organization, cosmetic event: Appendix 10-MP.
- 11. The registration dossier receipt form of cosmetic advertising, seminar organization, cosmetic event: Appendix 11-MP.
- 12. The Certificate of Free Sale (CFS) form: Appendix No 12-MP.
- 13. The "cosmetic good manufacturing practice" examination registration receipt form: Appendix No 13-MP.
- 14. The import order form for studying and testing: Appendix No 14-MP.
- 15. The report form of the list of cosmetics which have been issued the cosmetic product proclamation receipt Number: Appendix No 15-MP.
- 16. The report form of the list of cosmetics which have been issued the registration dossier receipt of cosmetic advertising, seminar organization, cosmetic event: Appendix No 16-MP.
- 17. The cosmetic business manufacturing activity result report form: Appendix No 17-MP.
- 18. The cosmetic disadvantageous side-effects announcement form: Appendix No 18-MP.

### **Article 52: The transfer regulation:**

- 1. Since the effective day of this Circular, all organizations, individuals who put the cosmetic product on the Vietnam market must implement the cosmetic product proclamation in regard to the regulation of this Circular.
- 2. Regarding to the products which have been declared since March 10, 2008 (in accordance with the provisions in the Cosmetic Management Regulation promulgated together with the December 31, 2007 Decision No 48/2007/QD-BYT of the Minister of the Ministry of Health) and issued with a valid cosmetic product proclamation receipt number which satisfies the provisions of this Circular shall be permitted to continue to manufacture (regarding to the domestic cosmetic), import (regarding to the foreign product) until the end of limit time of the cosmetic product proclamation receipt.
- 3. Cosmetic products which put on the market without satisfying the cosmetic product safety requirement in accordance with the regulation in Chapter IV of this Circular; organizations, individuals who are responsible for putting the cosmetic on the market must confiscate all products and implement fully provisions in this Circular.
- 4. For the cosmetic products, which were putted on the market in the valid period of the permission, if they satisfy the product safety requirement in regard to the regulations in Chapter IV of this Circular shall be still putted on the market until the expiry date of products.

### Article 53: The implementation effect

- 1. This Circular takes effect from April 1, 2011.
- 2. Canceling the December 31, 2007 Decision No 48/2007/QD-BYT of the Minister of Health on adoption the Cosmetic Management Regulation, the December 26, 2008 Decision No 40/2008/QD-BYT of the Minister of Health on devolving the state management on the Vietnam domestic cosmetic, the July 2, 2008 Decision No 22/2008/QD-BYT from the Health Ministry on authorizing the Management Board of Moc Bai Entry Economical Area, Tay Ninh Province to implement the cosmetic management function; the September 21, 2010 Decision No 3450/QD-BYT of the Health Ministry on

authorizing the Management Board of Quang Tri Province Economical Area to implement the cosmetic management function.

- 3. The Heads of units under the Ministry of Health; the units directly under the Ministry of Health; director of Provincial and Central Cities department of Health, and related organizations or individuals are obligated to fulfill implement this Circular.
- 4. During the implementation deploying process; if there are any difficulties or problems, the organizations, individuals may send report to the Ministry of Health (Medicine Management Department, 138A Giang Vo, Ba Dinh, Ha Noi) for consideration and solution./.

FOR THE MINISTER DEPUTY MINISTER

**Cao Minh Quang**