



LAO PEOPLE'S DEMOCRATIC REPUBLIC
Peace Independence Democracy Unity Prosperity

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Ministry of Health

No. 2580 /MOH
Vientiane Capital, Dated 12 November 2003

DECISION ON
THE QUALITY CONTROL OF COSMETIC PRODUCTS

- Pursuant to article 15 of the Law on drug and medicinal products No. 01/NA, dated 8 May 2000 and Presidential Decree issued No 13/LPDR, dated 22 May 2000;
- Pursuant to the Prime-Minister Decree No 020/PM, dated March 9, 1999 on the structure and function of the Ministry of Health;
- Pursuant to the request of the Food and Drug Department.

The Minister of Public Health issues this Decision as follows:

Part I General
Principles

Article 1. Objective

This Decision defines the principles, rules, measures to control and promote cosmetic products that are produced, imported, exported and distributed in Lao PDR in order to have such quality and standards so as to assure the safety of consumers.

Article 2. Outputs

The implementation of this decision will deliver safety to consumers. The operation of the businesses will be orderly and be the reference tool for relevant government staff at every level to manage and inspect cosmetic products.

Article 3. Definitions of the terms used by this decision:

Permit person: means the Food and Drug Department, Ministry of Health, the provincial public health office, Vientiane Capital and special area;

Cosmetic products: means substances used for brushing, massaging, spraying, sprinkling, with steam or any action aimed at any part of external human body for beauty or to enhance beauty

which include materials used as ingredients specifically for cosmetic production or other materials that have been classified by the Ministry of Health to be cosmetic products except the jewelry;

External human body: means skin, mouth, nails, hair and others;

Jewelry: means necklace, earrings, watches, clothes and others;

Packaging: means any material used for filling or packing cosmetic products;

Labeling: means pictures, or any message that gives instructions about the cosmetics that are contained or inserted in the packaging including documents or guidelines for use of those cosmetics;

Production: means the processing or the operation of mixing, processing, re-filling or changing the packaging;

Import: means the importation or placing an order to import into Lao PDR according to the permit of the competent authority;

Sale: means the sale, distribution or exchange for the benefit of the trade including storing it for sale;

Establishment: the location of a building or a part of a building including the area of the establishment used for the operation of the business;

Operator: means the person who has permission to operate the business of cosmetic products including the manager or the representative, individual that operates the business;

Control cosmetic: means the cosmetic products which contain control chemicals as ingredients as required by Ministry of Health.

Part II

Rights and function of authorized person

Article 4. The Competent authority

The authority for management and inspection the quality of cosmetic products consist 2 level :

- Central level: Food and Drug Department, Ministry of Health;
- Provincial level: Provincial public Health office, Vientiane Capital and special zone;

Article 5. Rights and function of the authority in each level

To manage and control the quality of cosmetic products to be effective and safe, the authorized bodies at each level have the following rights and functions as follow:

5.1 Central level:

1. issue regulations and standards, identify the List of cosmetic products, special controlled cosmetic, control and banned chemicals and issue notices;
2. registration of cosmetics;
3. issue permission for production, import-export and distribution;
4. monitoring and control of pre and post marketing and taking samples for analysis;
5. monitoring and inspecting the content of advertisements of cosmetic products;
6. withdrawal or cancellation of cosmetic products that present a danger to the consumer;
7. receive and consider complaints on quality issues of the cosmetic products.

5.2 Provincial level:

1. Issue permit for production, import-export and distribution according to designation from Ministry of Health;
2. monitoring and control of the quality pre and post marketing and taking samples;
3. control and inspection of the content of advertisements for cosmetic products;
4. Receive and consider complaints on quality issues of cosmetic products.

Part III

Business operation for cosmetic products

Article 6. Individuals or organizations that intend to operate the business of production, import and sale of cosmetic products should apply with an application form to get official permission from the public health sector and related agencies and should bring samples of what they intend to produce, import or sell to be registered by the Food and Drug Department, Ministry of Health.

Article 7. Requirements for operating the production of cosmetic products

Individuals or organizations that intend to establish and operate a business for the production of cosmetics, should fulfill following requirements:

1. have appropriate technical staff such as: pharmacy or chemist or technical staff experienced in this sector;
2. have the necessary facilities to ensure the application of Good Manufacturing Practices such as: availability of a production room, a storage room that complies with requirements and with the necessary equipment;
3. availability of a system for the protection and safety of the environment;
4. before conducting production of cosmetic products, they should apply from the Food and Drug Department, Ministry of Health with a list identifying the products accompanied by the formula and production steps.

Article 8. The importation of cosmetic

Individuals or organizations that intend to import cosmetic products should fulfill the following requirements:

1. the person or enterprise should have relevant experience and have a registered business;
2. request a permit from the public health sector for the importation of listed control cosmetics;
3. have conditions and facilities for storage and transport of cosmetic products such as to maintain their quality.

Special control cosmetics to be distributed in Lao PDR should be registered with the Food and Drug Department, Ministry of Health. Any import of cosmetic products is subject to inspection by the public health sector.

Article 9. Sale of cosmetic

Sale of cosmetic products can be done at pharmacies, barber shops or general supermarkets that have an official permit.

A business operator of cosmetic products should be responsible for the quality and safety of their product according to the law.

Article 10. Advertisement

Individuals or organizations that intend to advertise cosmetic products should obtain permission and comply with the advertisement control regulations of the Ministry of Health.

Advertising should use terms that are not misleading to the consumer and that do not have negative impact to the public.

Part IV Registration of Cosmetic products

Article 11. Registration of cosmetic products

11.1 Cosmetic products that are to be registered are products containing chemicals according to classification of the Ministry of Health.

11.2 Application for registration

Individuals or organization that intend to advertise cosmetic products, should submit an application for registration to the Food and Drug Department with the necessary documents and samples as follows:

1. letter of request (according to the form issued by the Food and Drug Department);
2. certificate of trade/business registration;
3. valid free sale certificate from the manufacturing country;
4. samples (as required) in the original package.

Article 12. Content of labeling

Cosmetic products that are to be registered, should have labeling in Lao or English language clearly and readable as follows:

1. Name of control cosmetic;
2. Name and amount of chemical that is the main ingredient of the product;
3. Registration number issues by the manufacturing country;
4. Name of manufacturer, address, lot, manufacturing date and expiry date;
5. Instruction for use or warning safety notices;
6. Size of packaging.

Article 13. Validity of registration certificates and cancellation

13.1 The validity of a registration certificate for a cosmetic product is valid for 5 years from the date of signature. 90 days before the expiry date, the owner of the products should submit an application form for renewal of the registration and, if not submitted within this period, the registration certificate will be cancelled.

13.2 Cosmetic products that have been registered may be cancelled, if it is found that the product has no benefit or is of poor quality or is unsafe for consumers as specified in the registration or in the case of the mother company being declared insolvent.

Part V

Payment of fees and professional service fee

Article 14. The operator of a cosmetic product should pay a fee and a professional service fee for their own account for analysis of their products, issuing of the certificate of registration and others as identified officially from time to time

14.1 The fee for registration according to the requirements of the Ministry of Finance;

14.2 The professional fee according to the Ministry of Health's rules.

Part VI

Prohibitions and measures against violators

Article 15. Prohibitions

1. It is prohibited for individuals or organizations to produce, import, export and sell cosmetic products without permission from the health sector and other related agencies;
2. It is prohibited for individuals or organizations to advertise by making claims in excess of reality about the quality of the product without permission by the public Health sector and related agency;
3. It is prohibited for individuals or organizations to sell adulterated cosmetic products as certified by the registration;
4. It is prohibited to use food additives over the limit officially defined;

5. It is prohibited to fake the formula, label as notified in the registration;
6. It is prohibited to advertise food by making claims that misrepresent the nature of food.

Article 16. Measures towards violators

Individuals or organizations that violate this regulation shall be educated, warned fined and punished, depending on the gravity of the case as follows:

16.1 Violation of article 8: will be educated, given warning and temporally closure will be proposed awaiting official permission;

16.2 Violation of Article 11: 1st violation – will receive education, warning, 2nd violation: shall be fined to the amount of the cost of an advertisement permit according to the advertisement control decision;

16.3 Violation of Article 12: 1st violation: shall be fined the same amount as the cost for registration of the cosmetic product. 2nd violation: shall be fines three times the cost of the registration of the cosmetic products and the business shall be closed.

Part VI Final provisions

Article 17. Implementation

All organizations including government and related private sector should cooperate and strictly implement this decision together.

Article 18. The Food and Drug Department is the central point responsible for implementing this regulation in order for it to be effective in the entire country.

Article 19. Effectiveness

This regulation is effective from the date of signature.

**Minister of Health
H.E. Ponemek DARALOY**