

Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity

Ministry of Health

No 937/MOH
Vientiane Capital, date 12 July 2004

**Regulation on
Drug and Medical Products Production**

- Reference to: Drug and Medical Products Law No 01/NA, dated 08 April 2000;
- Reference to: Prime Minister Decree on Ministry of Health Organization and Action No 020/PM, dated 19 March, 1999;
- Reference to: Prime Minister Decree on the Adoption on National Drug Policy of Lao PDR No 49/PMO, dated 13 March 1993;
- Reference to: Food and Drug Department Request and Study of Macro Departments and Leaders of Ministry of Health;

**Minister of Ministry of Health agrees to issue
Regulation on Drug and Medical Products Production as follows:**

**Group I
General Provisions**

Article 1: Objective and Target.

- 1.1. Objective:** To manage the action of the factory on drug and medical products having proper order in running business in compliance with rules of Law and professional principles in order to ensure the good quality and safety of drug and medical products and highly effective for consumers, contributing to the economic and social development of the nation.
- 1.2. Target:** To encourage the drug and medical products factory in achieving its target in accordance with defined conditions, rules, principles and standard of related sectors.

Article 2. Definition

- 2.1. Drug and medical products factory:** is the facility producing drug and Medical products, establishing under specific rules approved by Ministry of Health.
- 2.2. Drug, modern drug or traditional medicine, medical products, pharmacist:** (See the definition mentioning in the Law on Drug and Medical Products in articles 8, 9, 10, 15, and 16).
- 2.3. Raw material:** means every material, despite of active and inactive Ingredients or sustainably unchanged, so that all these materials are used for drug and medical products production.
- 2.4. Production:** means all activities related to drug and medical products

Production, including manufacturing process, formula development, processing, Packing, labeling, packaging, introducing of use, cleaning, storage and Inspection.

- 2.5. **Manufactured lot:** means number of any product completely processed, where the important factor of manufactured lot is its uniform characteristic.
- 2.6. **Good Manufacturing Practice:** is part of the quality assurance, where the Manufacturer must use and strictly apply in accordance with Good Manufacturing Practice components approving by Ministry of Health.
- 2.7. **Lot number:** means number or letter or code representing the certified manufacturing lot in order to carry out the monitoring and inspection.
- 2.8. **Use:** means indication on the method of drug and medical product to be used In correct dosage mentioning in the medical prescription.

Group II

The Establishment Procedure on Drug and Medical products Factory

Article 3: Conditions of authorized person in establishing the drug and medical products factory

- 3.1. It shall be pharmacist with Lao citizen holding Diploma or Certificate on Pharmaceutical Profession Success Education, approved by Ministry of Health and shall carry out professional working experiences in at least 5 years in his/her belonging agency, who will be the professional staff for individual or organization, which will run this business field.
- 3.2. If it is a foreigner pharmacist with Diploma or Certificate on Pharmaceutical Profession Success Education, shall be approved and certified by related Institution and Ministry of Health of Lao PDR.
- 3.3. It shall be the person with no sanction period and no position escape or No disciplinary penalty due to the pharmaceutical profession mistakes.
- 3.4. It shall be person with good health without mental health diseases, no addiction and no other communicable diseases.

Article 4: Conditions of location to build the drug and medical products factory

- 4.1. **The selection the place to build the factory:** the place where to build the Factory shall be located in the areas without the contamination from outside and other environments such as: it should not be built nearby the insecticide factory, cement factory, factory easily making the contamination to environment, nearby dusty road, crowded place and other inappropriate places.
- 4.2. **Building design and structure:** room arrangement to be parts of factory shall ensure in preventing the easy contamination starting from entrance gates, offices, meeting rooms, toilets, hand wash sink, drug production rooms and exit gates

in order to facilitate the quality assurance and the safety of drug products and staff working in production lines.

4.3. The facilities using for the assurance of Good Manufacturing Practice standard issued by Ministry of Health: floor, ceiling, walls, ventilation system, water system, waste disposal system and storage warehouse for raw materials, finished products, packaging materials and waste shall be standardized, avoiding the damage from outside (air, humidity, heating, temperature, dirty, dust ...), no affecting to worsen environment and people health.

4.4. It shall be equipped with alert system, especially against burning that maybe occurred, voice, lighting and odor controlling system and dust filter to do not affecting to the health of employees and workers within and people surrounding the factory. Employees and workers shall put on the clothes, which can protect the contamination and to be source of microbes causing the illness.

4.5. Quality analysis laboratory: Factory on drug and medical products shall have its own specific analysis laboratory with skilled and experienced analysts and appropriate and sufficient analysis equipment in order to meet its all testing targets, quality assurance during production processes and after production.

4.6. Warehouse and storage facility: it shall have separate storage area for Quarantine (specimen drug) to inspect, monitor and to be evidence after delivery from the storage area for finished products and other materials; it shall be written clear texts or numbers (storage area for controlled drug or narcotic drug).

General standard of warehouse: warehouse and storage facility shall have large Area, enough lighting, equipped by appropriate lift machine; inside of warehouse, It shall be clean and dry, having temperature and humidity measuring equipment and can be measured all time in line with determined standard; it shall have standard plates and shelves; it shall be protected from thieves, stolen, damage from insects, rodents and shall have burning protection system.

Warehouse for inflammable and other toxic substances: inflammable substances, Substances risk to be fired; easily explosive substances shall be stored in a separated room. For high toxic, narcotic and other dangerous substances shall be stored in the special room, robust enough and should be installed the alert system when some event occurring.

Storage room for non-standard drug and materials waiting for destroying: this room is used to store non-standard drug and materials waiting for destroying only. It is strictly prohibited to store standard drug and materials.

Article 5. Documents, important and necessary information to accompany the License request for its consideration are as follows:

The compiling on documents to request the License on establishing authorization of drug and medical products production and its renewal:

5.1. The compiled documents to request License on establishing of drug and medical product factory:

1. The personal brief history with photo (not more than 1 year);

2. Diploma;
3. Retirement Certificate or Service Release Certificate;
4. Health Check Certificate (not more than 3 months);
5. Certificate on professional working service performance;
6. Current Address Certificate with photo;
7. Photo in size 4x6 = 3 (not more than 1 year);
8. Location map of factory;
9. The Certificate on residence ownership;
10. Penalty Declaration Certificate;
11. Citizen Declaration Certificate (if foreigner);
12. Map of room arrangement inside of factory;
13. If the foreigner, it shall have Certificate on residence and correct residential permission in line with rules of Lao PDR.

5.2. The compiling on documents to renew License on establishing of drug and medical product factory:

1. The application form for renewal;
2. Health Check Certificate;
3. Factory ownership Certificate;
4. The annual report in last 1 year and next year plan.

Article 6. Consideration method on License approval on Drug and Medical Products Production.

6.1. The application form submission on drug and medical products factory establishment: person intending to run the business on drug and medical products production shall submit the application form to Provincial/Capital and Special Zone Health Departments through Industry and Commerce Sector, where the factory will be located, in order to consider and make comments and then forward to Food and Drug Department, Ministry of Health to consider in issuing the Professional License. (Timeframe for documents consideration is about 45 days).

The Professional License has its validity in 03 years, before its expiry date, the request should be submitted for its renewal.

6.2. The running business on drug and medical products production: after releasing the Professional License by Food and Drug Department, Industry and Commerce Sector will consider to issue the Business License.

6.3. The temporary closing or cancellation on running business on drug and medical products production: the running business on drug and medical products production shall be temporarily closed or cancelled depending on each case as follows:

- Professional Staff has passed-away.
- In case, warning and fining have been carried out over than 03 times.
- In case, there is mistake or violation against rules of Law.
- There is complaint from effecting and damage victims or rendered decision by

court.

Article 7. Liability of the factory owner

In running business on drug and medical products production, the factory owner shall be directly responsible against the Laws.

When inspectors visit the factory, the factory owner shall definitely cooperate and facilitate their field work.

Group III

Procedure on Running Business on Drug and Medical products Production

Article 8. Request permission on essay production on Drug and Medical Products.

The person running the business shall submit the application form to Ministry of Health to request the permission on essay production in line with Form P.D.1 which composed by:

1. Labels and containers in all size (2 sets).
2. Complete documents related to the production (2 sets).
3. Drug samples.

Article 9. Registration on drug and medical products

After receiving the permission on essay production on drug and medical products in line with Form P.D.1, the manufacturer shall continue to compile application form to request the formula registration in line with Form P.D.2 which composed by:

1. Drug analysis Certificate, indicating on analysis technique and documents using for analysis (2 sets).
2. Copy of Quality Assurance Certificate on raw materials using in producing drug samples (2 sets).
3. Documents or reference papers certifying on the quality of drug (information on the essay) (2 sets).
4. Documents related to the production technique (1 set).
5. Information on the study on the self-live experiment.
6. Labels and documents on drug use (1 set).
7. Drug samples for inspection and monitoring the quality.

Article 10. Production, distribution on drug and medical products

Every drug and medical product item, before its production and distribution, shall be correctly registered and stamped in line with rules issued by Ministry of Health.

Group IV

The Quality Assurance

Article 11. Production Staff Health

Staff working in the production lines shall be good health, without communicable diseases, infection and dermatology diseases. Every staff shall perform health check and holding the Health Check Certificate issued by defined official hospitals on at least twice a year basis.

Article 12. Education level and staff capacity

Staff working on production lines shall have appropriate education and capacity level for the production performance work and continuously be trained, especially on Good Manufacturing Practice.

Article 13. Staff clothing

Staff working in the production area shall put on clean clothes and appropriate protection gowns in line with Good Manufacturing Practice principles for each production area such as: cap, gloves, mouth and nose masks, shoes and others...

Article 14. Contamination and mixing up protection shall apply as follows:

1. Determined specific room for production.
2. Arranging machines and equipment appropriately using for production work in line with objectives and room area size.

Article 15. Good Manufacturing Practice

To ensure the quality and safety of drug product, every production process on drug and medical product shall apply Good Manufacturing Practice (GMP) principles issued by Ministry of Health.

Group V

Rewards for good performance person and measures against violators

Article 16. Rewards for good performance person

Any individual or organization having excellent performance on the implementation of this regulation shall be rewarded and some given privilege considering by Ministry of Health.

Article 17. Prohibition

Since the drug is “special goods”, the factory shall strictly implement the prohibition as follows:

- It is prohibited to give its ownership, sale or rend the Pharmaceutical Profession License ;
- It is prohibited to produce the banned drug, dangerous drug, counterfeited drug, sub-standard drug, narcotic drug and psychotropic drug which are not allowed by Ministry of Health.
- It is prohibited to move the factory, without the permission from Ministry of Health.
- No individual or juristic person produce drug without permission and registration at Food and Drug Department, Ministry of Health.

Article 18. Measures against violators

Individual or juristic person who is the factory owner, violating against Law and this regulation:

- 1st time: shall be educated, fined one fold of market goods value and recorded in the legal action filing of Food and Drug Department.
- 2nd time: shall be seized, fined two fold of market goods value. In case, refusing to take action in line with the officer inspection decision, the business shall be closed in period of 6 months and recorded in the legal action filing of Food and Drug Department.
- 3rd time: shall be seized, fined four fold of market goods value, the business shall be permanently closed and prosecuted to the court.

Group VI Final Provisions

Article 19. Implementation

The Food and Drug Department shall be responsible to implement this regulation, in cooperation with Provincial/Capital/Special Zone Health Departments and other related sectors in the whole country.

All regulations, rules, directives previously promulgated and contradicted against the provisions of this regulation shall be entirely cancelled.

Article 20. This regulation shall get into force since the date of signature.

Minister of Ministry of Health

Signed and sealed

Dr PoneMek DALALOY

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No 937/MOH
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