(Unofficial translation)

People's Democratic Republic

Peace Independence Democracy Unity Prosperity

Ministry of Health
Food and Drug Department
Tel: 021 243657

Ref no.2660/16.DFD
Vientiane Capital, dated 16 June 2016

Notification

To: Directors of Drug Production Factories and Import-Export Drug and Medical Equipment Companies.

Subject: Document compilation for import license of raw materials, packaging tools, medicines and medical equipment used in the production and for the distribution.

- With reference to the national drug policy ensuring quality of medical products to meet the international standards.
- With reference to the Law on Drug and Medical Products (Revised Version) No.7/NA, dated 21 December 2011.
- With reference to regulations or legal documents under the laws related to drug and medical products.

To ensure that drug and medical products produced and distributed in Lao PDR have good quality, efficiency, safety, and reasonable prices and being used in the vaccination and health treatment of the patients effectively.

The Department of Food and Drug would like to notify to all drug production factories and imported-exported drug and medical equipment companies nationwide about documents required for obtaining an import license of raw materials, packaging tools, drugs, and medical equipment used in the production and distribution as follows:

I. <u>The documents requesting for import consist of:</u>

1. An application for import license of raw materials as required by the Food and Drug department, signed by the technical officer and the director of the factories/companies.
2. Purchase order from the factories or companies (3 copies).

3. An invoice specified number of a production set, production date, and the expiry date (name of the product must be written clearly and to be the same name as the one registered, only abbreviation or code of the product will not be accepted) (3 copies).
4. Packing list (3 copies).

II. <u>Certified documents being additionally attached:</u>

Apart from the document listed in I (1,2,3, and 4) to be submitted for the import license, there are some other technical documents to be attached in order to ensure quality of the distribution circle as detailed below:

- **<u>For importation of raw materials:</u>**
  - The Good Manufacturing Practice Certificate of the production factories issued by the administrative authority of a country that produce raw material or WHO Prequalification.
  - The certificate of analysis for the production set requested for import.
- **<u>For packaging tools:</u>**
  - The packaging tools requested for import must be an item that will be packed as products already been registered, if it is not a registered item it must be approved to produce a sample drug.
- **<u>For Vaccin:</u>**
  - The certificate of lot released of the product set being imported issued by the drug administrative authority of the producing country.
  - The Good Manufacturing Practice (GMP) Certificate from the producer/manufacturer and/or WHO Prequalification Certificate.
- **<u>For medical equipment:</u>**
  - The ISO 13485 certificate certified by the administrative authority of the producing country or institutes being approved by the government.
  - The certificate of a quality analysis (for consumable devices) based on the standard of analysis of the WHO.
  - The second hand (used) medical equipment is not allowed to be imported.

The operation of drug production companies, import-export drug and medical equipment companies, and the wholesale companies in the country especially the suppliers of the raw materials and finished products must have a contract with supplier on the basis of being responsible for the quality, efficiency, and safety of the users. If the certified documents are not an original copy, they must be stamped by the concerned company.

This notification is effective for implementing 30 days upon the signature date.

Therefore, this notification is for your acknowledgement and cooperation for the implementation.

Director General of Food and Drug Department
(Signed and sealed)

Dr. Somthavy Charngvisommith