

Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity

Ministry of Health

No 2579/MOH
Vientiane Capital, date: 12 /11/2003

**Regulation on
Drug and Medical Products Donation**

- Reference to: Drug and Medical Products Law No 01/NA, dated 08 April 2000;
- Reference to: Prime Minister Decree No 020/PM, dated 19/03/99 on Ministry of Health Organization and Action;
- Reference to: National Drug Policy No 6.31 on Drug Donation;
- Reference to: Food and Drug Department Request;

Minister of Ministry of Health issues Regulation:

**Group I
General Provisions**

Article 1: Objective and Target

1.1 Objective

To control the drug and medical products donation in order in getting the highest benefit of donor intention and able to use them in health care in line with receiver's need.

1.2 Target

Such donated Drug and Medical Products shall be in good quality, quickly reached to places or individual who needs them and in good condition.

**Group II
Donation Principles**

Article 2: Drug and Medical Products Donation

Drug and Medical Products Donation composed by Number or Sets, which are intended to be freely used in the health care and do not in the commercial form; and generally it has been donated from both local and international public, private organizations.

Article 3: Donation reception

The Donation can be done when it is agreed between donors and health Sector only.

Article 4: Agreement Contents

Such agreement mentioned in the article 3 of this regulation shall be Mentioned as follows:

a. Name of Drug and Medical Products

For drug holding its brand name and INN and Medical Products or others, It shall be described its general characteristic and its brand name (e.g.: X-Ray Equipment for Dental use "Philips" or "Dentogram")

- b. Quality or Number of each product item provided
- c. Drug and dosage form (such as tablet 50 mg, ampoule 100 mg and etc.)
Or goods special technical specification (X-Ray film Kodak type XR 245)
- d. Unit package (such as box or sack 1000 tablets, personal box and etc..)
- e. Expiry date for each drug item or product holding its short self-life (e.g.: film, diagnostic sets)
- f. Expected time and route to transport the goods arriving to Lao PDR or its final destination.
- g. Other issues raising by donors or receivers such as:
Documents showing that such products can officially be sold in its original country.

Article 5: Importation and Inspection

Agreed local or international donation shall be allowed to import to Lao PDR, unless upon the agreement mentioned in article 4 of this regulation. When such drug and medical products arriving at Lao PDR entry port, They shall be inspected by health authorities.

**Group III
Donation obligation**

Article 6: Donation obligation

6.1 Donation preparation

Such donated drug and medical products shall have their self-life in at least more than 12 months when arriving to Lao PDR (in exception for specific case). Some medical equipment can be used in several years, if they are the second hand medical equipments, they shall be certified that these products are in good condition and can be used. Donors shall only provide the products which could be found their accessories and repairable.

6.2 Labeling or label on bulk container

- Labeling should be clearly mentioned on the product characteristic, especially its manufacturer and expiry date.
- When drug or medical product containing in small pack unit, but they are re-packed in big container; it shall be labeled in English version or French version on out-side of the container.
- When provided drug containing in special patient unit, each drug unit shall be labeled in Lao version; the best choice.
- When providing the medical products, this provision shall ensure the availability of its using Manual and such products are still be effectively used and repairable.

6.3 Lot number

Donated drug shall be produced in the same lot number.

6.4 Packaging

Donated drug and medical product shall be well- packed in order to protect the shocking, the humidity or sun shine to ensure the quality of drug and medical product when arriving to consumers.

Drug and some products are necessarily packed in special containers and stored in special condition e.g. Diagnostic reagents and vaccines shall be

stored at low temperature and their label shall be clearly mentioned the storage and transport condition.

6.5 Accessories

If donated items are medical equipments, to ensure their long usage self-life, it shall be provided with necessary accessories.

Article 7: Donor obligation

- 7.1 It shall follow the agreement provisions;
- 7.2 Donated items shall be sent to targeted donation places;
- 7.3 The duty free and official tax fee shall be ensured its free of charge (in case of the international donation)
- 7.4 The report to donors shall be done, after receiving the donation within 90 days.

Article 8: Donation focal point

Donation focal point in Lao PDR is The Food and Drug Department, Ministry of Health.

**Group IV
Rewards and sanctions**

Article 9: Rewards

Individual, juridical person or local and International organizations having good deeds in implementing this regulation, shall be appropriately rewarded and privileged.

Article 10: Measures towards violation

Individual, juridical person or organizations violating against this regulation, shall be educated and responsible for the donation damage.

**Group V
Implementation**

Article 11: The Food and Drug Department, the Curative Department, Provincial, Capital and Special Zone Health Departments and related sectors shall promulgate its detail provisions and effectively implement this regulation.

Article 12: This regulation shall get into force from the date of signature.

The regulations and Notices previously promulgating and contradicting against this regulation are hereby canceled.

Minister of Ministry of Health
Signed and Sealed

Dr. PoneMek Dalaloy

