Medical Device Product, Regulatory Update in Lao PDR

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The Food and Drug Department is implementing Action plan No.8 of Ministry of Health (consumer health's protection)

- **Vision**

To ensure good quality, safety and efficacy of drugs and medical products including medical devices as well as their rational use for Lao people

Mission

- Develop and implement strategy, Policy, law and regulation
- Enforcement of law and regulation governing drug and medical devices
- Pre-marketing and Post marketing surveillances of drugs, medical devices and cosmetic product
- Strengthening of drugs and medical product quality assurance system including quality control
- Provide education and information on the use of drugs and medical products for both public and private sector
- Promote rational use of drugs.

Organization Chart

Food and Drug Department

- Administration Div.
- Food Control Div.
- Drug Control Div.
- Narc.,Chem. and Cos. Control Div.
- Traditional Med, RDF Div.
- Public Pharm. Control. Div.
- Inform. Edu. & Com. Div.
- Provincial Food & Drug Unit

- → Bureau of Food and Drug Inspec.
- → Food and Drug Quality Control Center
- → Medical Product Supply Center
- → Traditional Medicine Research Center
- → Pharmaceutical Factory N.2
- → Pharmaceutical Factory N.3

Legislative concerned

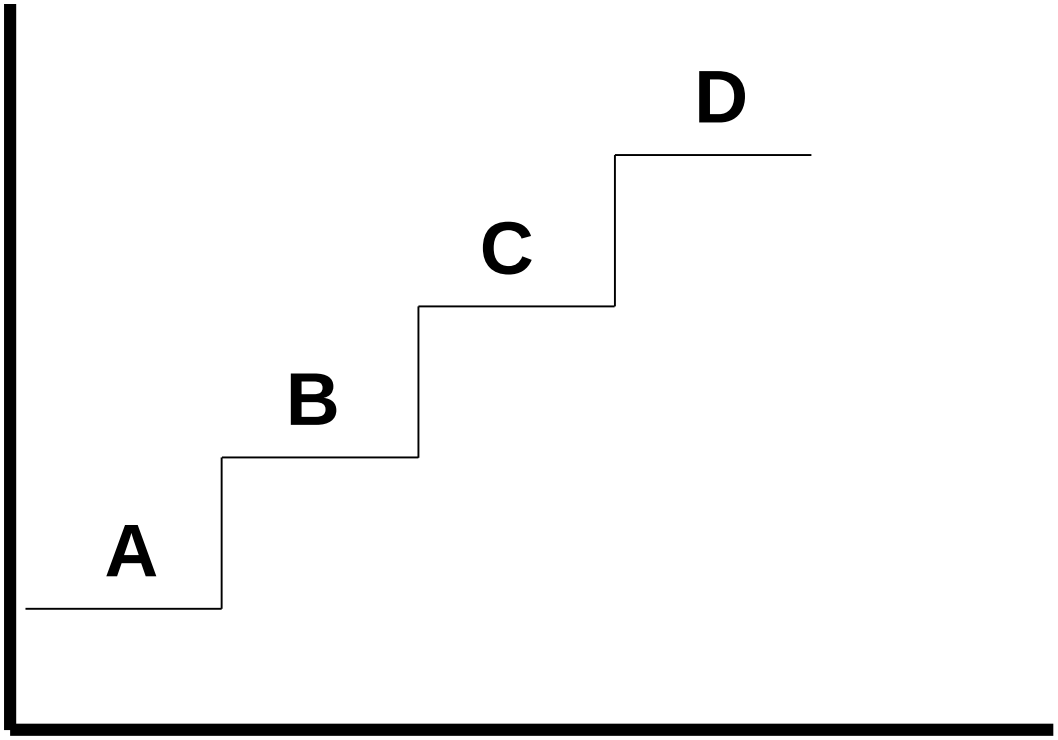
- Drug and medical product law enacted since April 2000, the first revision is completed and endorsed by National Assembly in end of 2011
- Regulation regarding drug and medical product company establishment No. 1442 dated 13 August 2003 (Importer or Distributor authorization) the authorization is included medical device import control
- The medical device not yet require to be registered
- Supervision and monitoring tools based on the Good Wholesaling Practice (GWP), the 10 indicators have been used for inspection practices
- Medical devices in distribution chain were took samples, tested and enforced (Condom).

General Situation

- Drug and medical product law enacted since April 2000, the first amendment is completed , endorsed by National Assembly (2011)
- In Laos there are 62 Import drug-medical device companies, who are representative for local distribution. There are 28 companies run for medical devices business.
- Lao PDR imports arround 98% of Medical device products for its consumption.
- The medical device placed in some health facilities such as central hospital or some provincial hospital is under the Public Private Partnership
- Most of medical device products are imported, (Program and Trade)
- The importation of medical device product is not yet required for Registration
- The FDD issued import license certificate based on importation request submission. (single use of import license)

Medical Device Product Control System

The Medical Device definition is included in the amended Law on Drug and Medical Product (2011) based on ASEAN Medical Device Directive (AMDD)



Device classes (risk based)

Medical Device Product Control System (cont')

- Requirement for importation based on the Drug and Medical Product Law
- The application for import (Import license issued by FDD)
- The documents requested to be submitted for import as follow:

  - Request letter from licensed company (authorized distributor)

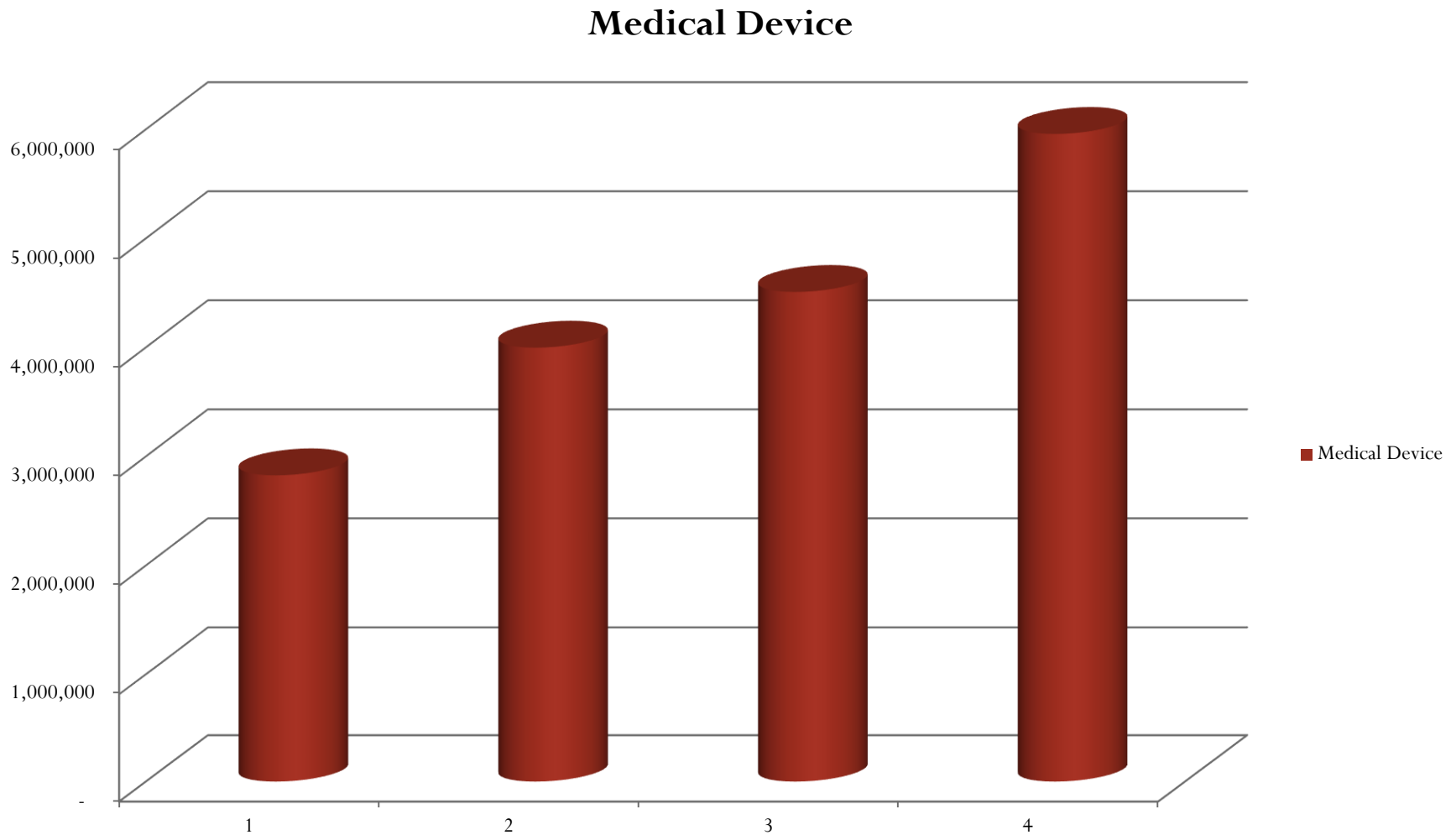
  - Purchase order

  - Invoices

  - Packing list

  - ISO 13485, Certificate of analysis, WHO prequalification for Consumable device

Importation record: MDP imported to Laos 2012-2015 (USD)



Medical Device Product Control System (cont')

- The AMDD is used as a reference for the steps forward of the control system, the AMDD has ratified on 25 May 2015
- The AMDD is in process in transition to the law and regulation in Laos
- The MoH has established the medical device control committee
- The medical device list and the level of use in health facility has been established by the Medical Product Supply Centre in collaboration with FDD.
- All medical equipments which equipped in central hospitals and provincial hospitals were recorded in to the ID system

Medical device control limitation

- Quality assurance system just only in the preliminary level
- Lack of experiences in MD classification
- Lack of medical device product quality testing skill and laboratory equipment
- Take time for setting up the Medical device registration regulation

Medical device registration regulation (draft)

- The definition of medical device is referred to AMDD
- Medical device has classified in A, B, C and D
- The registration will be required for class B, C and D.
- For class A will be required to notification
- The ASEAN Common Submission Dossier Template will be required for class C and D registration
- The medical device import for national Health Program will be required for fast tract registration
- The registration fees will be required in difference class of the device (50 – 200 USD).

Lesson learn and needs

- Enhancement of MD control system based on regional and international level
- Quality Assurance system needs to be established in near future (Pre market and Post market Control)
- Capacity building among staffs including testing skill
- Learning the ASEAN Regonised ISO, Classification, Quality assurance,Conformity assessment

THANK YOU