Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Medical Device Regulatory Update, Lao PDR.

Bounxou Keohavong Director General

Food and Drug Department, MoH, Lao PDR.

27th GHWP Annual Meeting and 27th GHWP TC Meeting, 27th - 30th Nov 2023
Shanghai International Convention Center

Lao PDR is Land-link country located in South East Asia

Capital city: Vientiane Capital

Population: 7 Million

Land area: 236,800 km^2

Administrative:

-1 Capital city

-17 provinces

-148 districts

-8,636 villages

Pharmaceutical Industries Profile:

-Pharmaceutical Manufacturers 12

* Most of them are generic drugs manufacturers

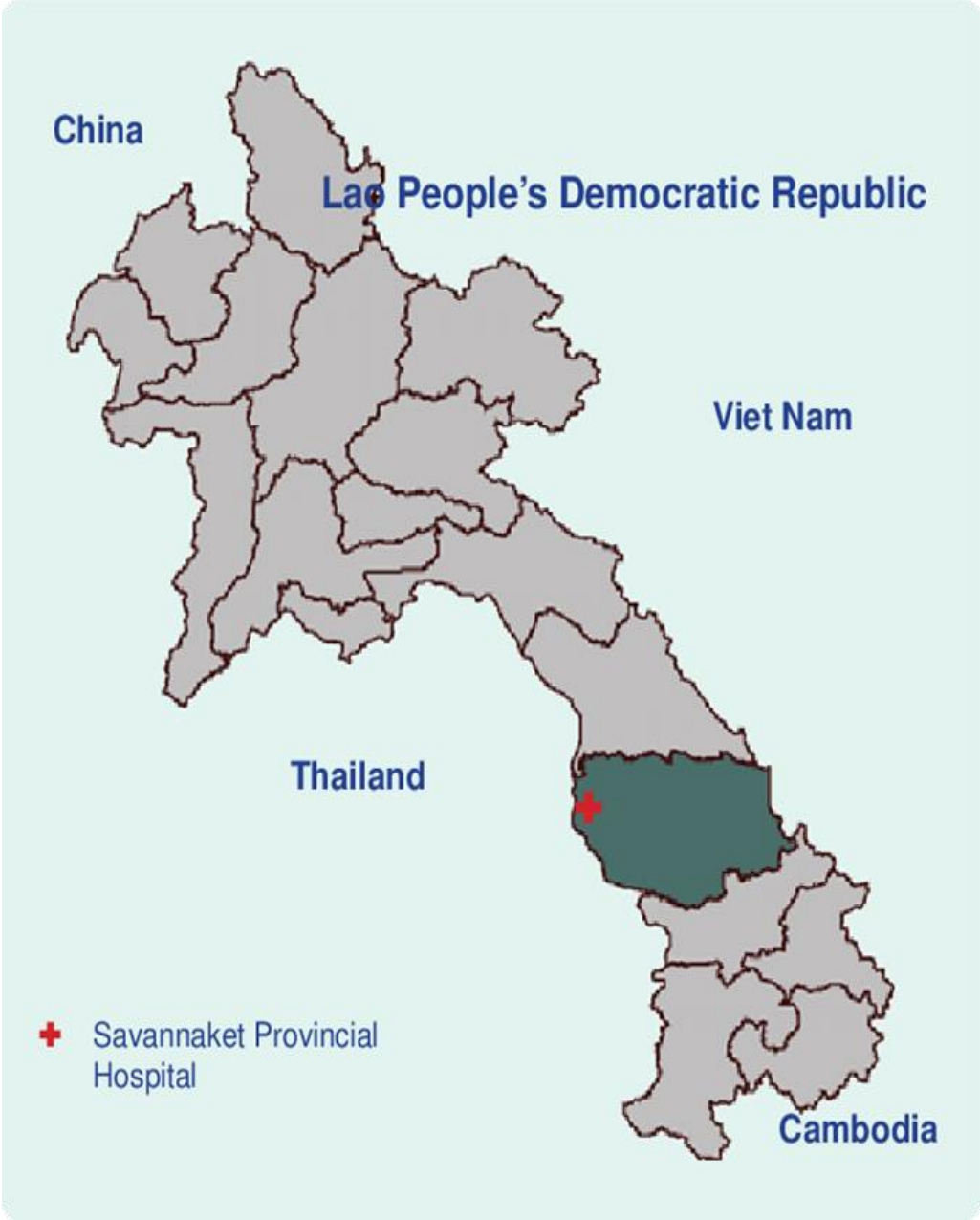
* Medical device is 100% rely on imports

* Some PPE and medical-face mask production available

- Pharmaceutical Companies 95

(representatives, Imports, exports, Distributors)

-Private pharmacy 3,600



Available Legislation tools

- National Drug Policy since 1993 (2003 revised)
- Drug and medical product law revised in 2011 (would be revised in 2024)
- Regulation on establishment of pharmaceutical company
- Regulation on establishment of pharmacy
- Regulation drug and medical products donation
- Regulation on drug and medical products donation
- Regulation on drug and medical products advertisement control
- Regulation on drug and medical products disposal
- Regulation on Medical Device Registration No. 1470/MoH, 11 July 2023.

Current Implementation

Establishment licensing

- Manufacturer's license
- Importer-Exporter's license
- Wholesaler
- Retailer

Registration

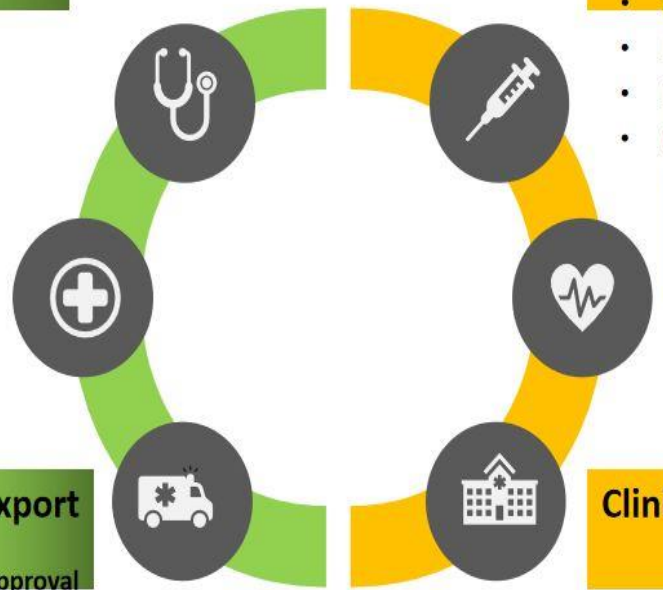
- Establishment registration

[The registration of MD class C and D will start in January 2024)

Import-Export

- Import-Export Approval

(Quality management system, Testing Lab ISO17025, Consencus standard)



Post-market control

- Report of AE and medical device malfunction
- Report of FSCA
- Importation and distribution records
- Complaint records

Control of Products Overclaim

- Pre-approval advertisement
- Prohibited products over claim by law

Clinical Performance Validation

- Laboratory

(Medical Face mask testing available)

Import and Distribution's data

Sources: (Top 10)

- Thailand
- China
- Korea
- India
- Viet Nam
- Japan
- Singapore
- Germany
- USA
- Switzerland

Amount:

- Three years data: 6 – 10 M USD

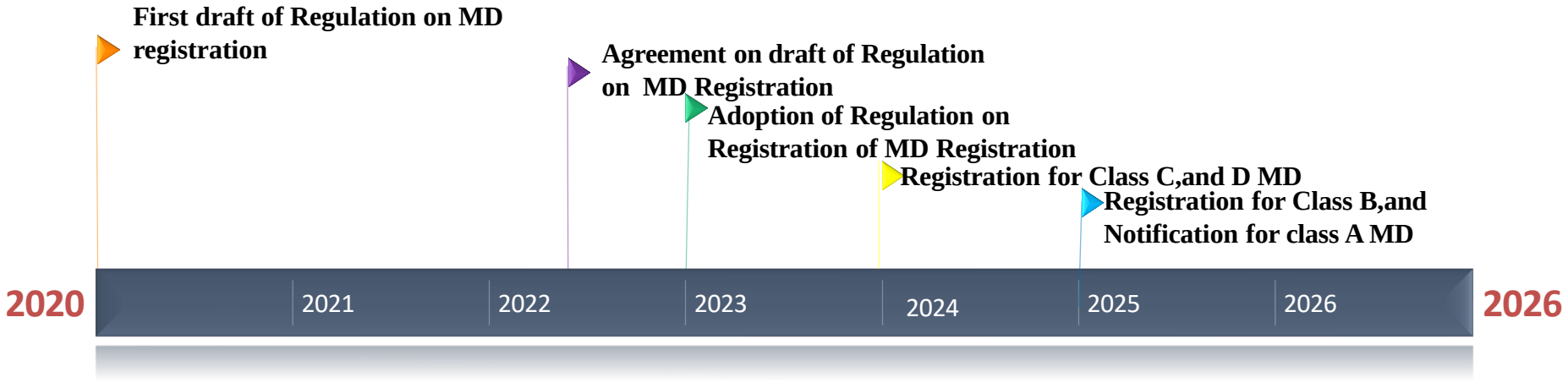
Some articles of Regulation on Medical Device Registration No.1470/MoH and its related application forms.

- **Article 3: Definition N.1 Definition of Medical Device**
- **Article 5: Risk classification of Medical Device (Class A, B, C & D)**
- **Article 13: Rules for risk classification of Medical Device (24)**
- **Form MD.1 for Medical Device Registration application (Class B, C, D)**
- **Form MD.2 for Medical Device Notification application (Class A)**
- **Form MD.3 for Medical Device Registration renew (renew every 5 years)**
- **Form MD.4 for Medical Device Post- registration Variation**

*** The Common Submission Dossier Template will be required for class C and D registration**

Available at FDD website
http://fdd.gov.la/content.php?contID=30

GANTT CHART FOR LAOS on MD Registration Implementation



Communication to industry
Communication to Regulators from Central and Province

Meeting was conducted by support of UNDP-China triangle project for COVID-19 response in Asia-Pacific

Meeting was conducted by support of UNDP-China triangle project for COVID-19 response in Asia-Pacific

Development of guidances and establishment of Reliance pathway

suppose to be with Thailand FDA and support from APACMED

Training (pre-market, post-market, dealers controls)

ASEAN priority activities with dialog partners

Issue and actions

- Human resource limitation
- Enhancement of MD control system.
- Quality Assurance system (Pre market and Post market Control)
- Learning the Essential Principle of safety and performance on MD, ASEAN Regonized ISO, Classification, Quality assurance , Conformity assessment Practices.
- Strengthening of PMAS

Thank you