GOVERNMENT OF THE REPUBLIC OF THE UNION OF MYANMAR

Ministry of Health
Department of Food and Drug Administration

Registration Procedures of Biopharmaceuticals and Medical Devices

Aye Thet Wai

Control Officer (Drug)

Country Profile

- Republic of the Union of Myanmar – a sovereign state in Southeast Asia bordered by Bangladesh, India, China, Laos and Thailand which enjoys tropical climate
- Capital city – Naypyidaw
- Largest city – Yangon


MYANMAR
Hkakabo Razi (5889m)
CHINA
INDIA
BANGLADESH
Ayeyarwady Ry
Mekong Ry
Bagan
Mandalay
Kengtung
Kyaingtong)
VIETNAM
Nay Pyi Taw
Mrauk U
(Myohaung)
LAOS
Bay of Bengal
Pyay
(Prome)
Taungoo
Bago (Pega)
Pathein
(Bassein)
Thaton
0 200 km
0 120 miles
Yangon
(Rangoon)
Mawlamyine
(Moulmein)
THAILAND
Three Pagodas Pass
Mouth of the Ayeyarwady
Andaman Islands (INDIA)
CAMBODIA
Myeik
Myeik Archipelago
ANDAMAN SEA
Gulf of Thailand

Organization and functions of Ministry of Health

- Ministry of Health – taking the responsibility of providing comprehensive health care services covering activities for promoting health, preventing diseases, providing effective treatment and rehabilitation to raise the health status of the population
- Major source of finance for health care services – provided by government

- Six Departments exist under Ministry of Health

1. Department of Medical Care
2. Department of Public Health
3. Department of Medical Research
4. Department of Human Resource Development and Management
5. Department of Traditional Medicine
6. Department of Food and Drug Administration

Evolutional history and Structure of MFDA

- Food control works conducted by Food and Water Division of National Health Laboratory (NHL) situated at Municipal Laboratory, Yangon
- Drug Control Laboratory at NHL including Pharmacognosy
- Food and water laboratory moved to NHL in 1990

- Food and Drug Supervisory Committees formed in 1990
- Started enforcement works since 1993 after establishing Enforcement Section
- Formation of Food and Drug Administration in 1995 (upgrading of Food and Drug Laboratory Division of NHL)
- 2000 – FDA branch(upper Myanmar) – formed
- Moved to NPT in November 2009

- 2013- Became a separate Department under the Ministry of Health

- MFDA – Five Divisions headed by Director General
  1. Administrative Division
  2. Food Control Division
  3. Drug Control Division
  4. Cosmetic and Medical Device Control Division
  5. Laboratory Division

Objective – To ensure safer food, drug, cosmetics and medicals devices utilized by Myanmar people

Regulatory activities carried ou / MFDA

- Food Control Activities – in line with policy guidelines from Ministry of Health, Myanmar Food and Drug Board of Authority and implemented according to National Food Law
- Pre-market assessment – conducted for locally produced food and imported ones and also for exported food

- Issues Health Recommendation for locally produced food with the approval of Central Food and Drug Board of Authority
- Approved establishments – good manufacturing facilities in place and products conform with standard safety and quality parameters
- Issues Import Recommendation for Imported food and Health Certificate for imported consignments

- Safety and quality parameters assessed based on Codex Alimentarius Commission (joint FAO and WHO organization) guidelines for both local and imported food
- Post-market assessment – also regularly performed by MFDA to ensure the safety of food marketed in domestic trade
- Risk assessment also being done to prioritize high risk food

- MFDA also participating in developing Myanmar Food Standards together with other related departments
- Drug Control Activities include

  1.Marketing authorization for new products, Renewal Registration and variation of existing authorization

  2. Good manufacturing practice inspection and licensing of manufacturers

3. Good Storage & Good distribution Practice

Inspection of Importer

4. Post market Surveillance

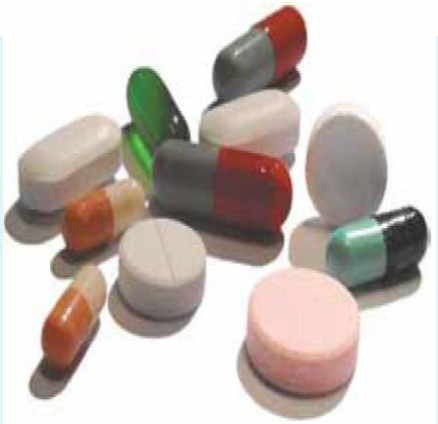
5. Adverse drug reaction monitoring and

6. Training and Health Education to public

- MFDA also notify to public and health care professional for counterfeit and unregistered medicine as alert notice

- MFDA issues the notification and import recommendation for medical devices, acknowledgement of cosmetic notification and import recommendation for oral hygiene products
- Also conducts the Good Manufacturing Practices inspection and issues Manufacturer License for disposable syringes and Certificate of Cosmetic manufacturer
- Also performs Post Market Surveillance of cosmetic and medical devices

Pharmaceutical Administration in Myanmar



- To protect the public from unsafe drugs

  1992- National Drug Law

  2014- Amendment of NDL

  1993- Notifications for registration, manufacturing, importation, sale and distribution, labeling and advertisement

Drug Registration Process in Myanmar

- Drug registration procedures and requirement are in line with ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirement (ACTR).

- Department of Food and Drug Administration has already published the ‘A Guideline on Drug Registration Application in April, 2014’.

Drug registration Process

For new application

(1) remitting the assessment Fees. (300000 Kyats/product)

(2) Apply for import sample permit

(3) Submission of drug sample

(4) Submission of document

* all the complete documents and good shelf life of samples must be submitted to Department of Food and Drug Administration within 6months from assessment fees.

(5) remitting of Laboratory Fees. (For analysis)

(6) Checking evaluation of Document
(time interval 1-2 months)

(7) If complete., DCS will issue the preview.

(8) Submission of lists of application to Drug Advisory Committee, Approval/ Reject

When the drug is approved for registration, the applicant will be notified to remit 500000 Kyats as Registration Fees.

After remit Registration Fees., Department of Food and Drug Administration issue the DRC

Time interval - For Generic products & Over The Counter } **10 months to 1year & 2months**

- For New products for Myanmar } **more than 1 year**

Documents required for Registration of Vaccines

I. Administrative data and product information same as Pharmaceuticals

- Batch release certificate of regulatory authority
- COPP
- Summary of product characteristic

II. Manufacturing and Quality

III. Report on pre-clinical studies

IV. Report on Clinical Trials

For Medical Device

– Regulatory process are according to technical guidance from ASEAN Medical Device Directive(AMDD)

Ministry of Health is processing to implement AMDD

(already signed the agreement of AMDD in ASEAN Summit - 2014)

- Before complete transposition of AMDD, DFDA mainly regulates on high risk products (such as disposable medical devices and important test kits in public health concern)

Regulatory Services

For importation of medical devices

- import recommendation and
- Notification of products

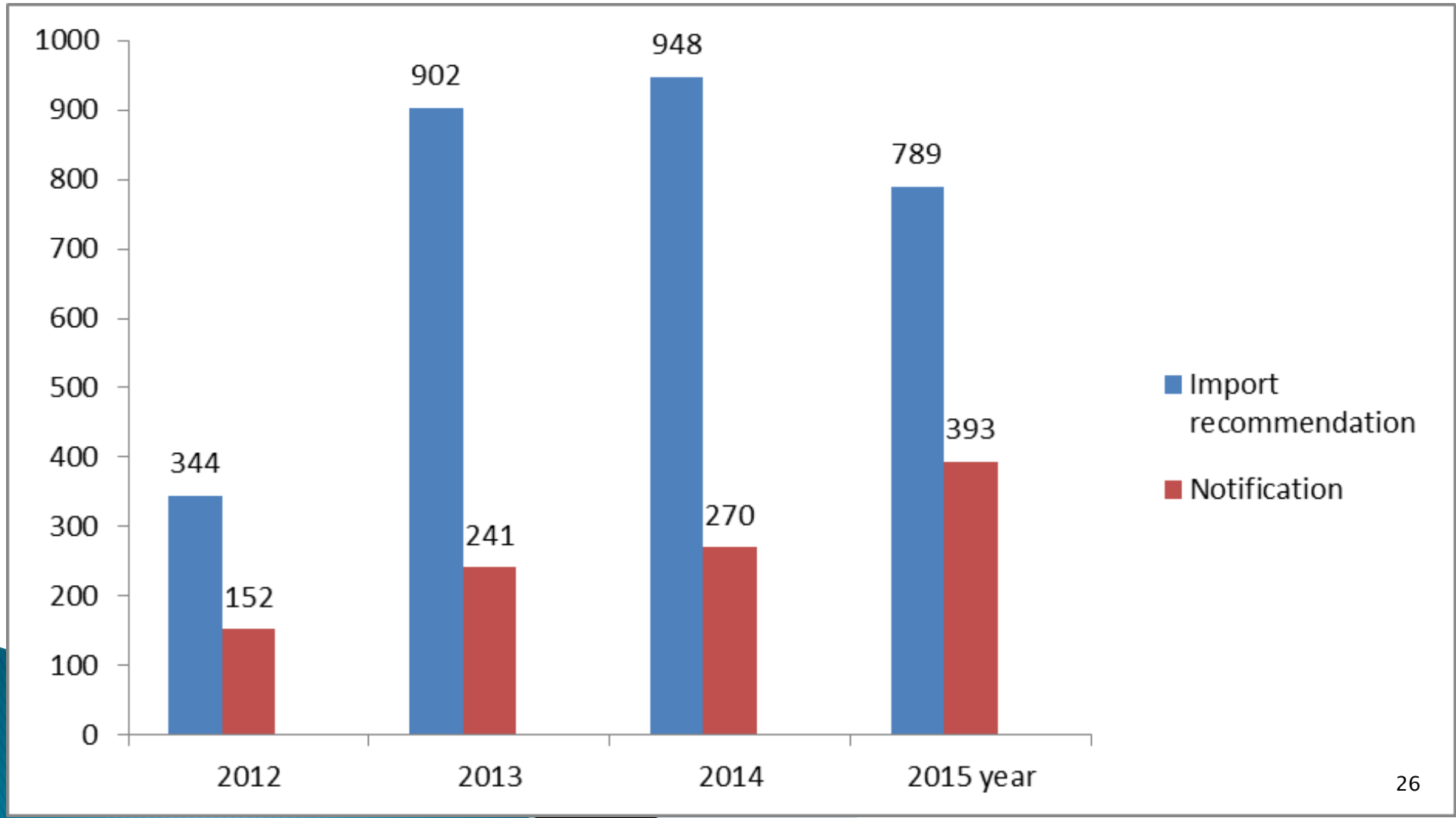
For local production of medical devices,

- Provision of manufacture license according to good manufacturing practice (GMP)

Documents required for Import Recommendation/Notification of Medical Devices

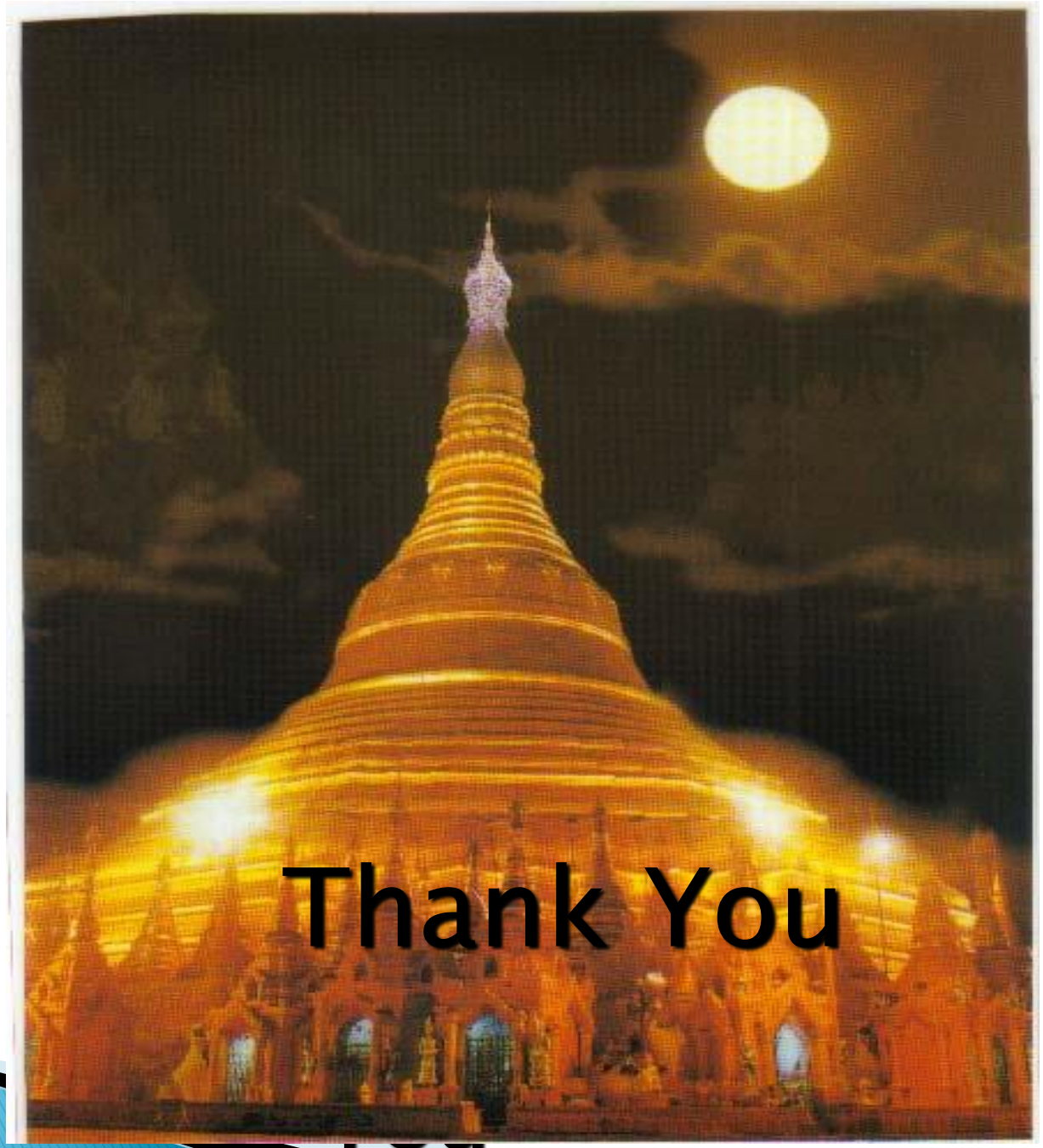
- Letter of Authorization from owner or manufacturer
- Free Sale or Export Certificate
- Manufacturing License or GMP Certificate copy
- ISO Certificate copy
- Manufacturing flow chart
- Sterilization method for sterile products
- Certificate of Analysis for reference sample
- Copy of business license of the local company or certificate of incorporation

No. of Medical Device Import Recommendation and Notification (2012-2015)



Challenges for Regulation

- Inexistence of Medical Device law in current status
- Requirement of capacity building for regulators
- Scarcity of international funding resources for capacity development
- Knowledge and awareness of manufacturers and importers on ASEAN Medical Device Directive (AMDD)


Thank You