Ministry of Health and Sports

Myanmar

Department of Food and Drug Administration

Drug Regulations in Myanmar

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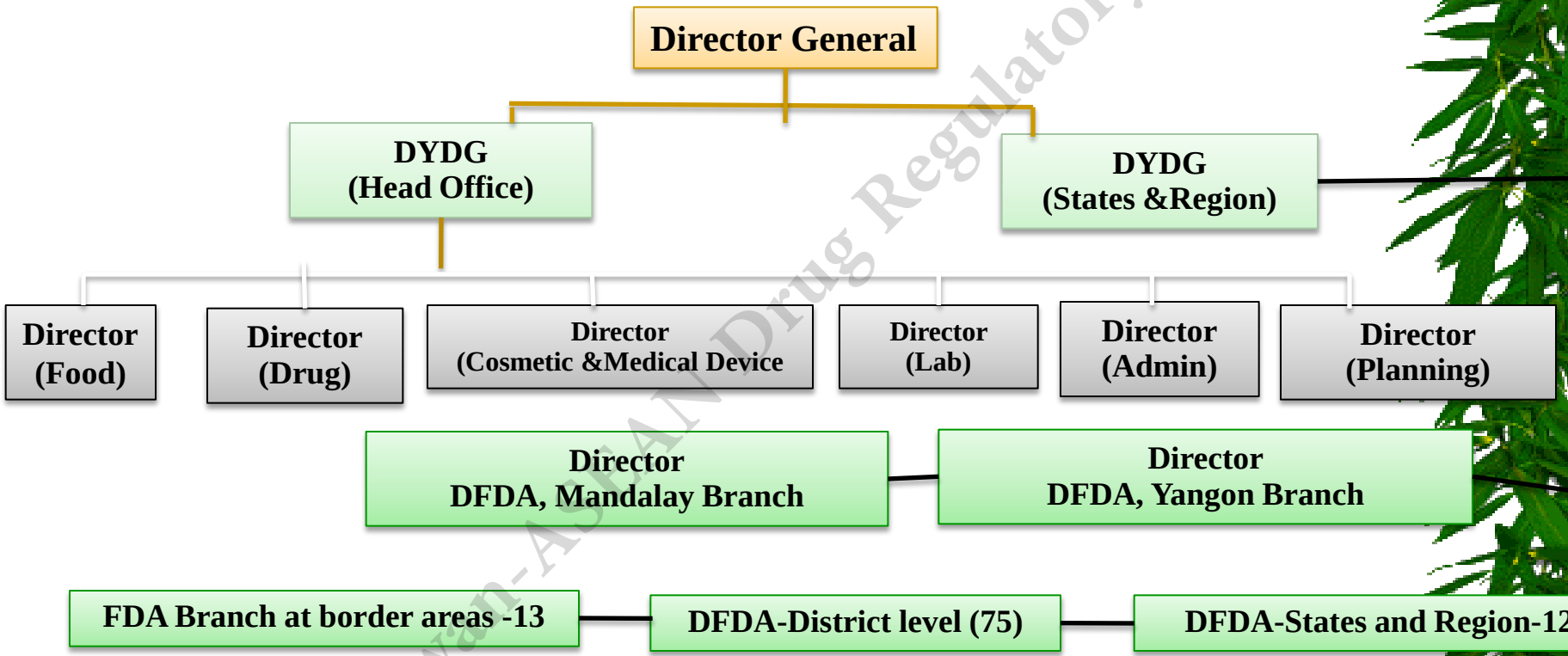
Myanmar

Departmental Profile of DFDA

- Under Ministry of Health and Sports
- FDA established in 1995 under Department of Health - upgraded from Food and Drug Quality Control Laboratory of National Health Laboratory,yangon-1990
- Expanded branches Mandalay(2000)
- Nay Pyi Taw(2010)
- Food and Drug Administration was upgraded to one of the department under MOH -very recently from 1st August 2013

  Expansion of set up to 2875 fr 665
- Branches at 12 States and Regions, district level
- 13 Border Stations – at Muse, Myawady, Tamu, Tacheileik, Myeik and Kawthaung

Organisation set-up of DFDA



Central

Drug Control Division

Registration

- Inspection &Licensing
  (Manufacturing, Import)
-PMS

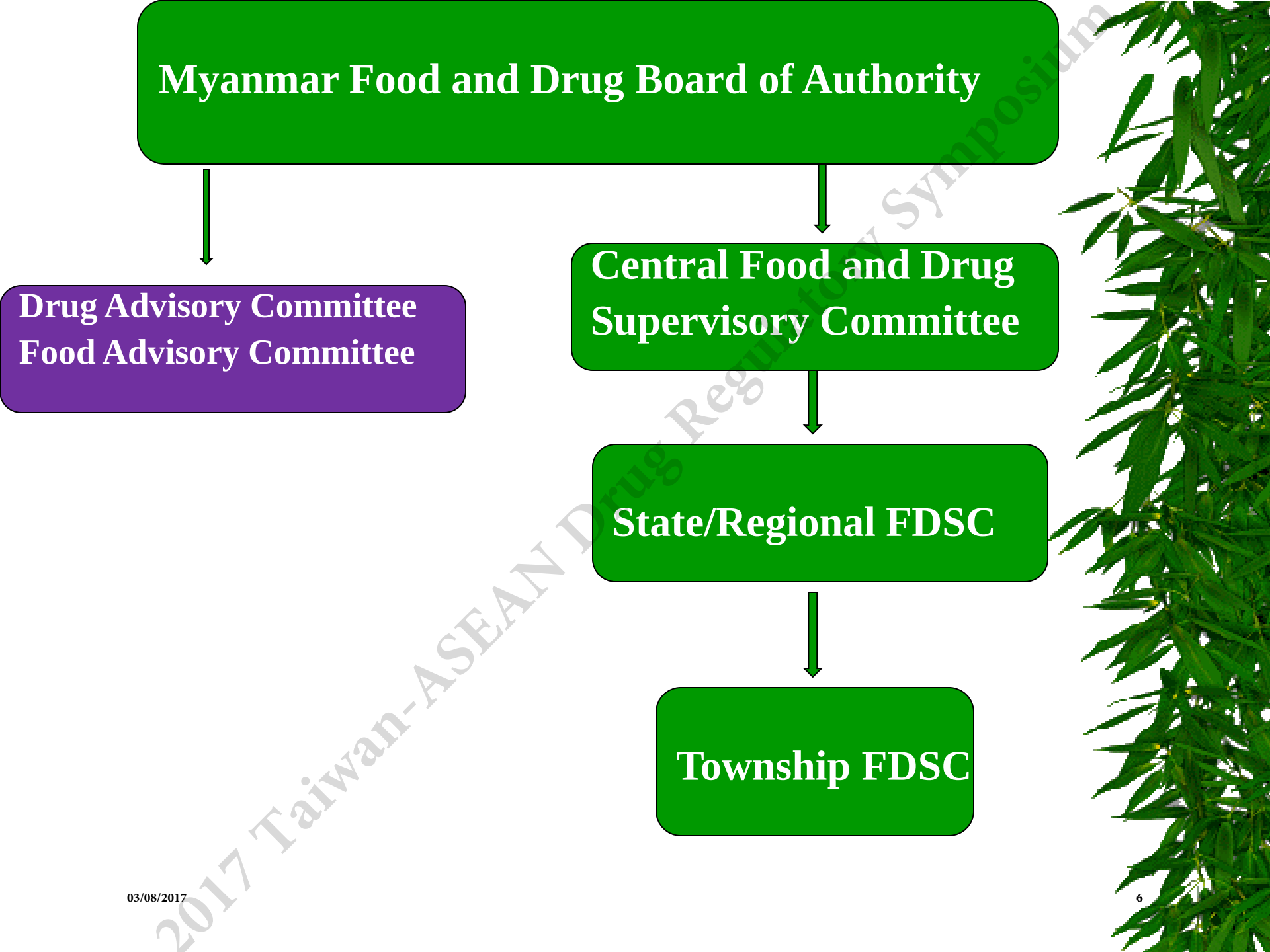
State & regional

Drug Control Division

- Inspection
  (Manufacturing, Import)
- PMS
(pharmacy inspection,
drug sample collection&
Analysis,ADR monitor)

Pharmaceutical Administration in Myanmar

- To protect the public from unsafe drugs-
- 1992 October - National Drug Law
- 1993 August Notifications --Registration, manufacturing, sales, distribution, importation, labelling and advertisement
- Administrative committee - MFDBA, CFDSC
- Technical committee - DAC



Types of Licences concerning with Pharmaceuticals

- National Drug Law - October 1992
  - Product Licence
    (Drug Registration Certificate)
  - Manufacturer's Licence
  - Importer's Licence
    (Import Approval Certificate)
  - Drug Seller's Licence
    (Retail, Wholesale)

Pharmaceuticals control activities

(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 for DIAC

(4) Post market Surveillance

(5) Adverse drug reaction monitoring

Registration Procedure in Myanmar

Notification concerned with registration in accordance with NDL

Flow Chart for Drug Registration

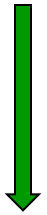
(According to Guideline for Registration Updated on April 2014)

Applicant

- authorized representative of product licence holder at country of origin
- Resident in myanmar
- Local company-representative-company employee technical competent person authorized to serve as contact person

LOA-letter of authorisation

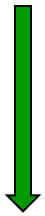
- Manufacturer to Local party



Registration Procedure in Myanmar

APPLICANT

- Getting a prescribed form for application(Form 1)
- Separate Form (1) for different kinds of drugs and dosage forms
- Entering a list of drugs,wished to be applied in register book at drug control section
- Get a letter of intimation issued by DCS for remittance of assessment fee
- Remit required payment to DFDA (assessment fee -300,000 kyats for each product)
- Getting DFDA approval for importation of sample drugs



Registration Procedure in Myanmar

Flow Chart for Drug Registration Application

APPLICANT

- Submission of Complete ACTD and Samples accompanied with COA(lab analysis, retention, clinical trial)

DFDA

- Check Samples of Labelling requirement ,shelf live
- Issue receipt
- Check completeness of documentary requirements
- For non-conforming dossier

  Submit DAC for rejection
- For conforming dossier

  Issue acknowledgement of receipt of Form 1 and dossiers

  Designate application number and date for future reference

Registration Procedure in Myanmar

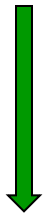
Previewing of documents

DFDA

- Adequate information provided-proceed to further stages of evaluation
- Inadequate-ask further information

APPLICANT

- Getting intimation (4 months from getting acknowledgement of receipt of dossier) to provide further information if it is needed
- Submit if required



Registration Procedure in Myanmar

- Review documents
- Conduct evaluation
- Confirmatory Clinical Trial (Only for New Products for Myanmar and New dosage form) and Getting Expert Opinion

Laboratory Analysis

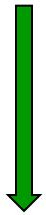
Prepare a list of complete and assessed applications

Submit to DAC Meeting for Submission and Consideration for Acceptance/Rejection

Registration Procedure in Myanmar

APPLICANT

- Enquire about approval
- Approximately **9months-1 yr (common established drug)** after Getting intimation (4 months from getting acknowledgement of receipt of dossier to provide further information if it is needed)
- **1½ yr or more (new product in myanmar)**



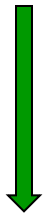
Registration Procedure in Myanmar

DFDA

•Issue letter of intimation to remit registration fee for approved drug

APPLICANT

•remit registration fee (500,000 kyats)within 90 days from date of intimation and get credit advice issued by DFDA upon remittance of registration fees



Registration Procedure in Myanmar

FDA

- issue registration certificate 2 week to 1 month after receiving credit advice

Registration Procedure in Myanmar

Fees Levied

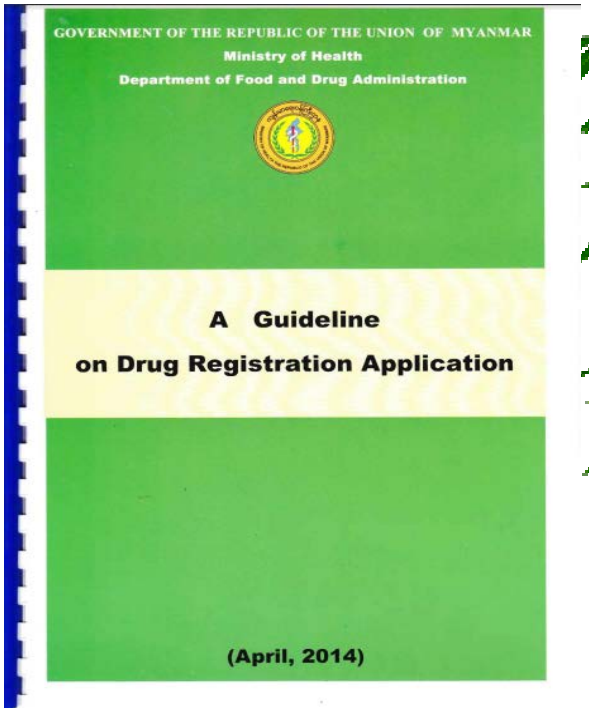
- 1.Registration Assessment Fees-300,000 (In Kyats)+Fees (in kyats)for Lab analysis
- 2.Registration Fees - 500,000(In Kyats)
- 3.Variation of Registration- 100 ,000(In Kyats) for each variation

Note: (1) & (2) are levied either for fresh registration or renewal of registration.

Registration Procedure in Myanmar

Dossier Requirements

- To implement the ASEAN common technical Dossier (ACTD) Starting January, 2009.
- Required dossiers can be available in our guideline on drug registration application (updated in 2014)
- Guideline can be available online website www.fdamyanmar.gov.mm



Drug Importation Approval Certificate

-Notification pertain to drug importation 5/93

-requirements of applicant- same as registration

-Case application forwarded by respective Company to FDA

- Prescribed Forms

- Documentary of storage premises and facilities, no of staffs and their duties, provision for protection of goods from contaminations .,etcs

- Inspection of warehouse (Good Storage & Good distribution Practice Inspection of Importer)

- Facilities of the warehouse complied with requirement

Drug Importation Approval Certificate

- **Case reports put up to** CFDSC for Consideration and Approval
- Considered and recommended to issue Drug Importation Approval Certificate to the Applicant(valid 3 years)
- No of importer-208

Manufacturer's license

- Notification pertain to drug manufacturing 4/93
- -evaluate description about factory by applicant-e,g layout plan, availability of water supply, equipments, HVAC system, waste disposal system,manufacturing process organization..etc),
- - visit plant inspection by FDA
- -issue notice - to correct some suggestion during inspection
- IF all requirements have been met,submitted to CFDSC for consideration
- -issue manufacturer's license
- -validity- 3 year
- -Number of pharmaceutical factory – 8 (including Government factory)

Private factory are now ongoing process

Food and Drug Control Activity
DFDA,Mandalay

Food and Drug Control Activity DFDA,Mandalay

- To enable the public to have quality and safe food efficacious drug- FDA (Mandalay Branch) is implementing the task complying with guidance from Ministry of Health, Myanmar Food and Drug Board of Authority and Department of Food and Drug Administration (Nay Pyi Taw).

Drug Control Activities

- Pre-market Assessment

Inspection-

Good manufacturing practice inspection –as a member together with central department for licensing of manufacturers.

Good Storage & Good distribution Practice Inspection of drug store together with township FDSC for licensing of Importer-DIAC.

Drug Control Activities

- Post-market Assessment

1-Sampling of drugs from the market

2-pharmacy inspection

3-ADR monitoring

1-Sampling of drugs from the market

- Random sampling from retail and wholesale drug shops
- Test at drug lab
- If spurious, sub-standards or counterfeit drugs were identified during surveillance, confirmed at central lab and then actions were taken according to NDL
- Announcement of unregistered drugs in public news paper
- Alert notification of counterfeit to State/Region FDSC to enforce selling of such drug in pharmacy

2-Pharmacy Inspection –

-licensing for drug sellers (OTC and POM)–issued by TFDSC according to NDL

-licensing for limited control drug(eg;benzodiazepam) selling-issued by TFDSC acc to Order related to control of narcotic and psychotropic promulgated in 2003

-substances for highly controlled drug selling- issued by CFDSC acc to Order related to control of narcotic and psychotropic promulgated in 2003

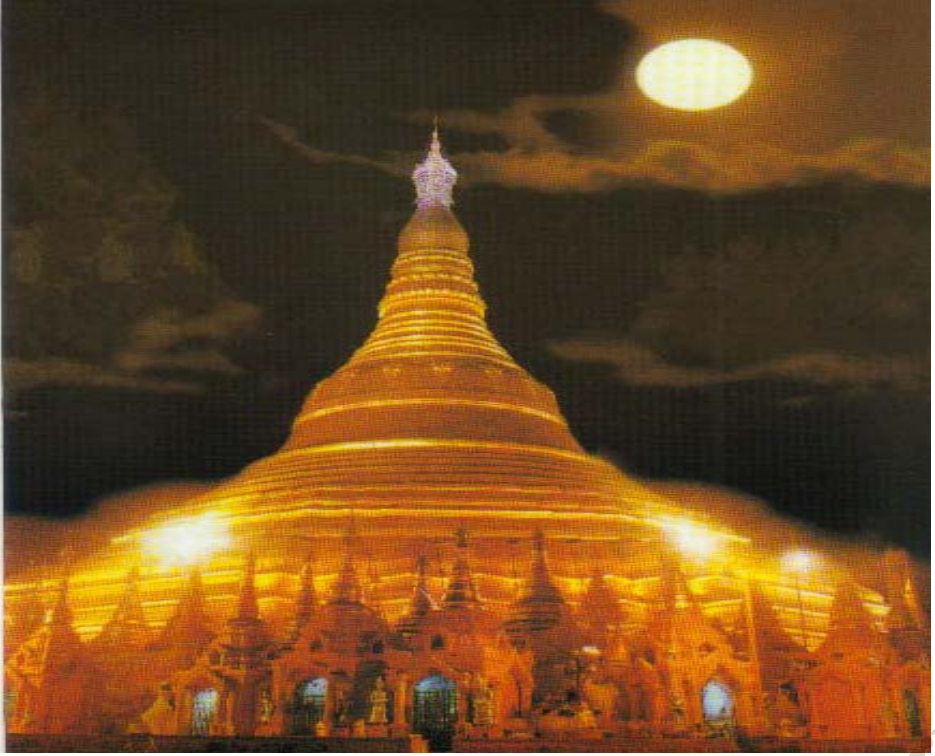
- -Pharmacy inspection together with TFDSC
- compliance with GSP, GPP
- Selling of unauthorized drugs

(unregistered drug, fake drug, substandard drug, deteriorated drugs, adulterated drugs, dangerous drug which is determined as not fit for utilization by MOH by notification/announcement)

- -to whom violate NDL, Take action according to NDL

3-ADR Monitoring

- DFDA distributes revised ADR form to Central/state/regional hospitals as well as health office and DAC members
- Regulator, health care professional and marketing authorization holder are mainly concerned with PV activity
- Spontaneous reporting
- Mandatory for pharma company to report safety report to DFDA acc to NDL



Thank You