VIETNAM PHARMACEUTICAL REGISTRATION AND APPROVAL

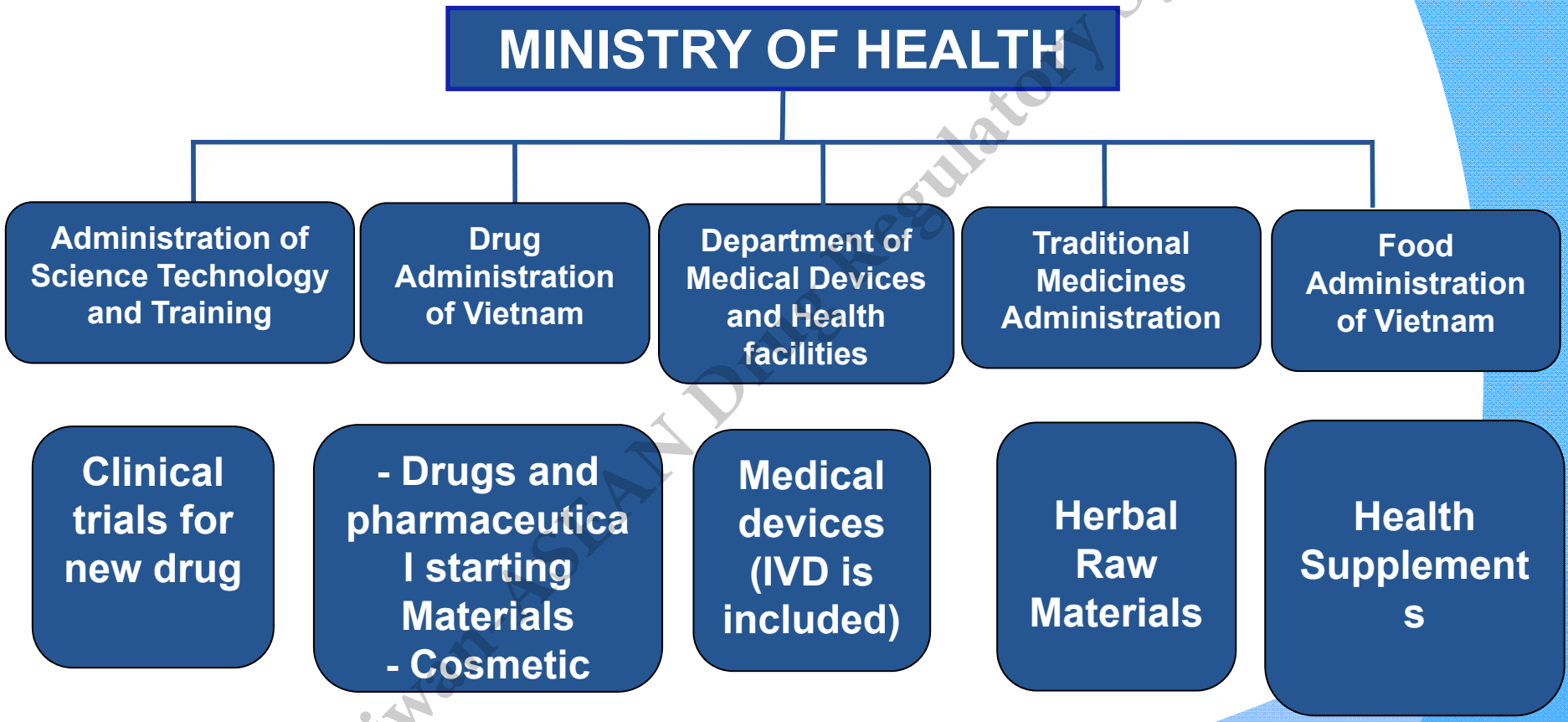
TU VIET LAN
DRUG ADMINISTRATION OF VIETNAM
MINISTRY OF HEALTH

Agenda

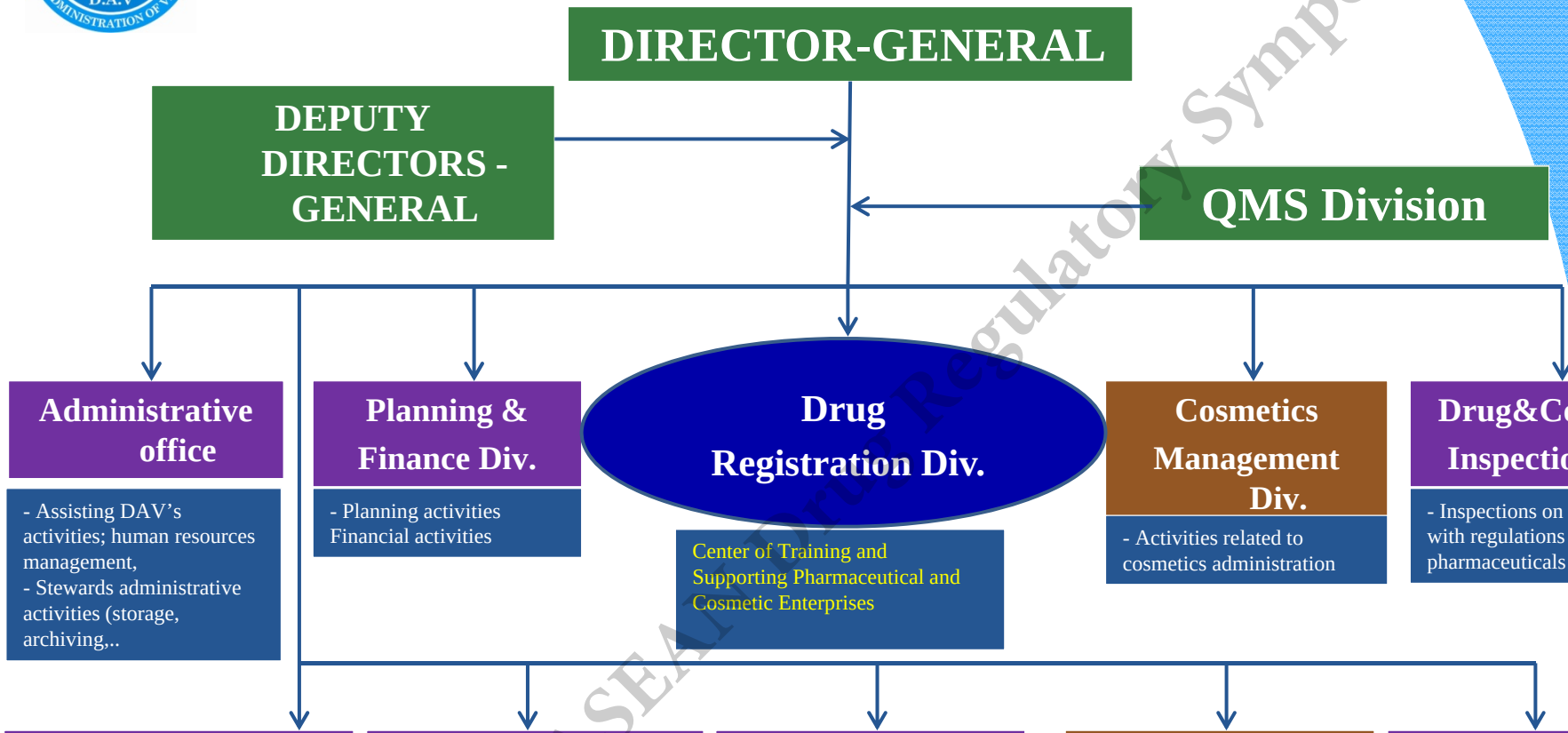
1. Pharmaceutical Governmental Management
2. Drug Marketing Authorization (Technique Requirement)
3. Notes from 1st Jan 2017

Part I
Pharmaceutical Governmental Management

Health products management system



DAV organizational chart



Introduction of DAV

- Established: in August 1996
- Belong to Ministry of Health
- Organization: 10 divisions and 2 assisting organizations
- Total staff: 140 has educational background on pharmaceutical and medical sciences and other scientific areas
- DAV relies on a significant support of external highly qualified experts (300) from universities, hospitals and research centers

Scope of DAV management

1. Drugs for human use, which include:
- Chemical drugs
- Traditional drugs, herbal drugs
- Medicinal starting materials (except herb materials)
- Vaccines
- Biologics (except in-vitro biologics)

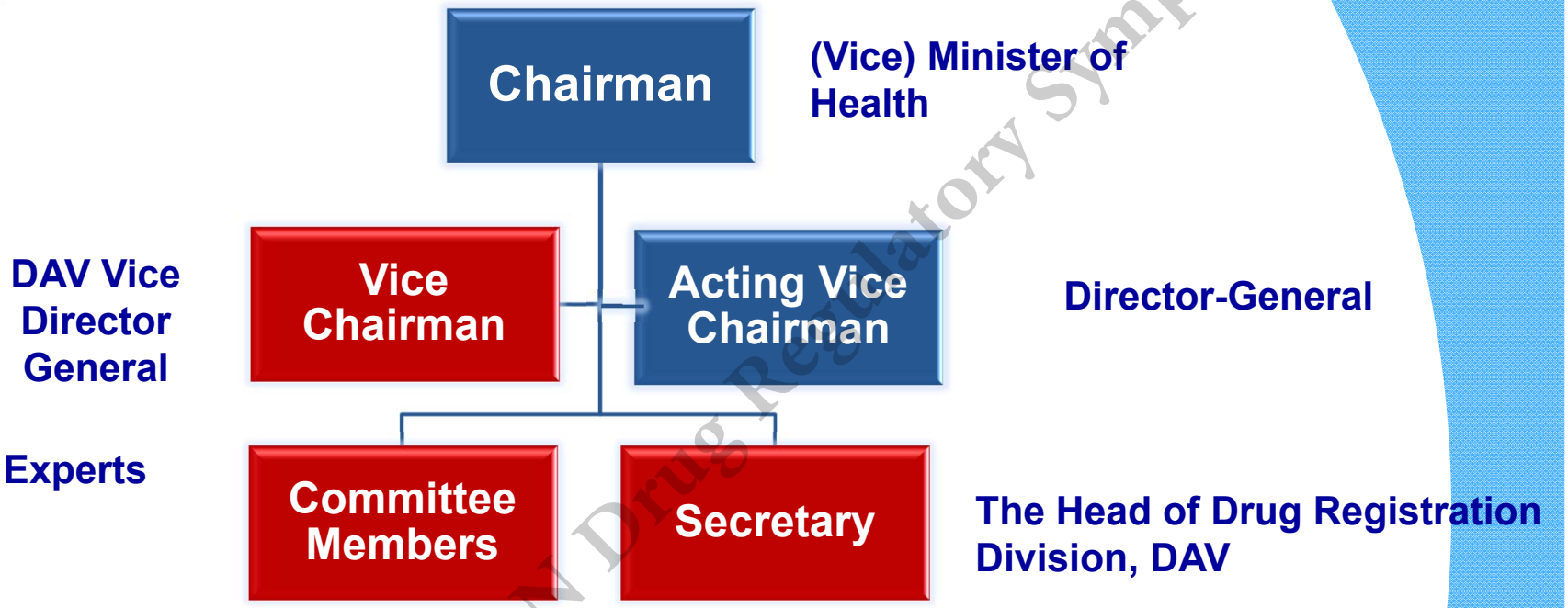
2. Cosmetics

Note:
- DAV regulates production, quality, storage, distribution, import, export related to drugs for human use
- DAH (Department of Animal Health - Ministry of Agriculture and Rural Development): Veterinary products

DAV- Functions and Missions

1. Development of policies and legal documents;
2. Drug registration and marketing authorization;
3. Proposal to the MOH for making decision on clinical trial of drugs to be registered, imported to Viet Nam;
4. Management over drug business and pharmaceutical practices;
5. Drug quality management;
6. Management over drug information and advertising, pharmacovigilance, rational and safe use of drugs;
7. Drug price and drug bidding management;
8. Management over traditional and herbal drugs;
9. Being the focal point in provision of direction, implementation of adequate drug supply for the hospital;
10. Cosmetic management;
11. Technical direction, inspection.

Advisory Committee for Drug MA



The task of Advisory Committee: offering advices for Ministry of Health

- To give the recommendations for Drug MA
- To propose the policies for registration regulation harmonization;
- To propose the policies about Drug Manufacturing, Importation and Circulation in Vietnam.

Part II
Drug Marketing Authorization

General requirements about registration dossiers

1. **Language:**

- Registratrion dossiers: English or in Vietnamese.
- Package Insert, Summary of product characterities, Label: Vietnamese.

2. **Common Technical Document Format:**

- ASEAN CTD or
- ICH CTD (for new chemical drugs, vaccines, biological products).
- Herbal Drugs: Not yet required.

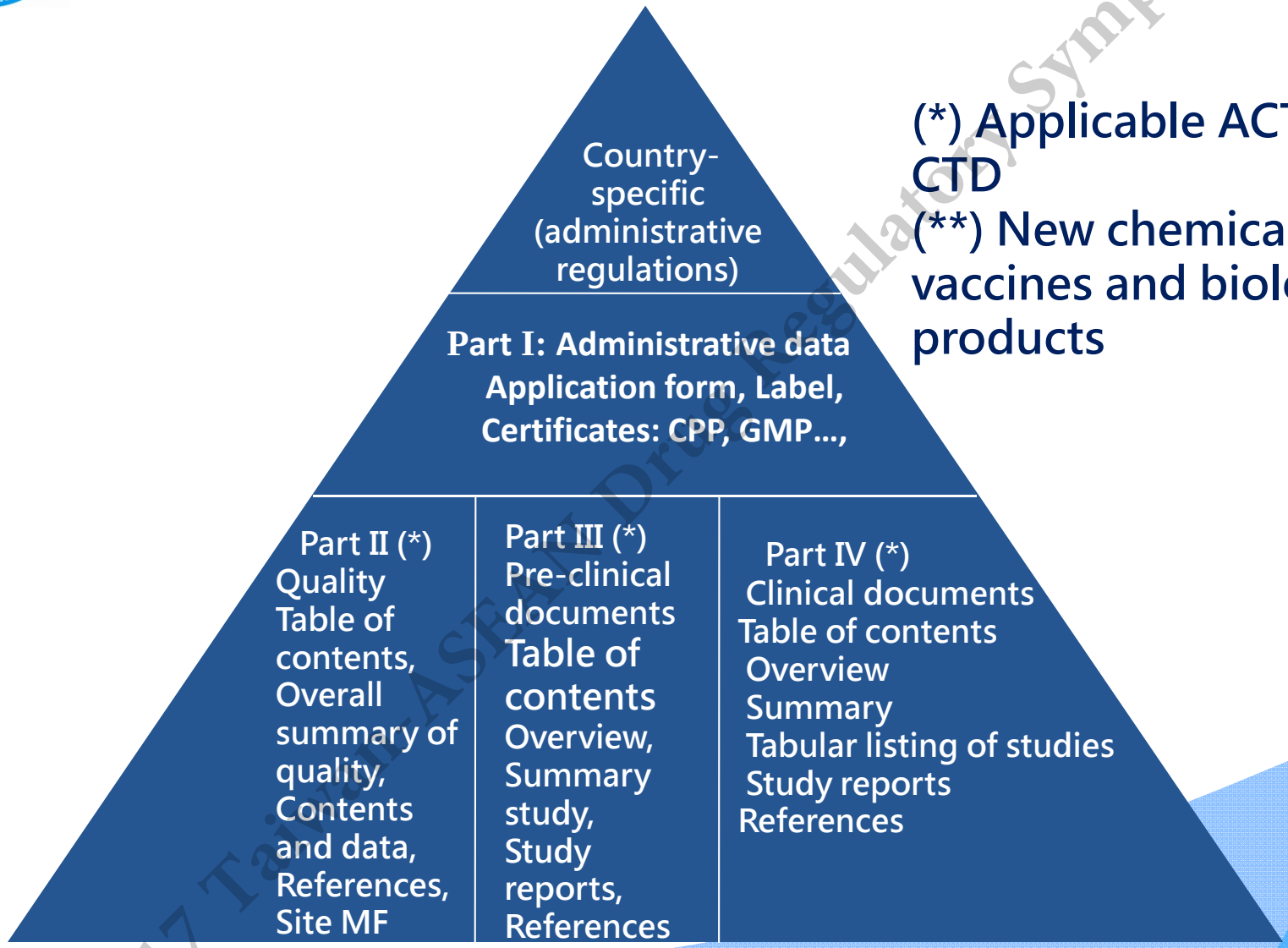
3. **Certificate of Analysis:**

- GMP complied Manufacturers or Authorised Labs.

4. **Clinical Trials**

- Only New Drug is required.

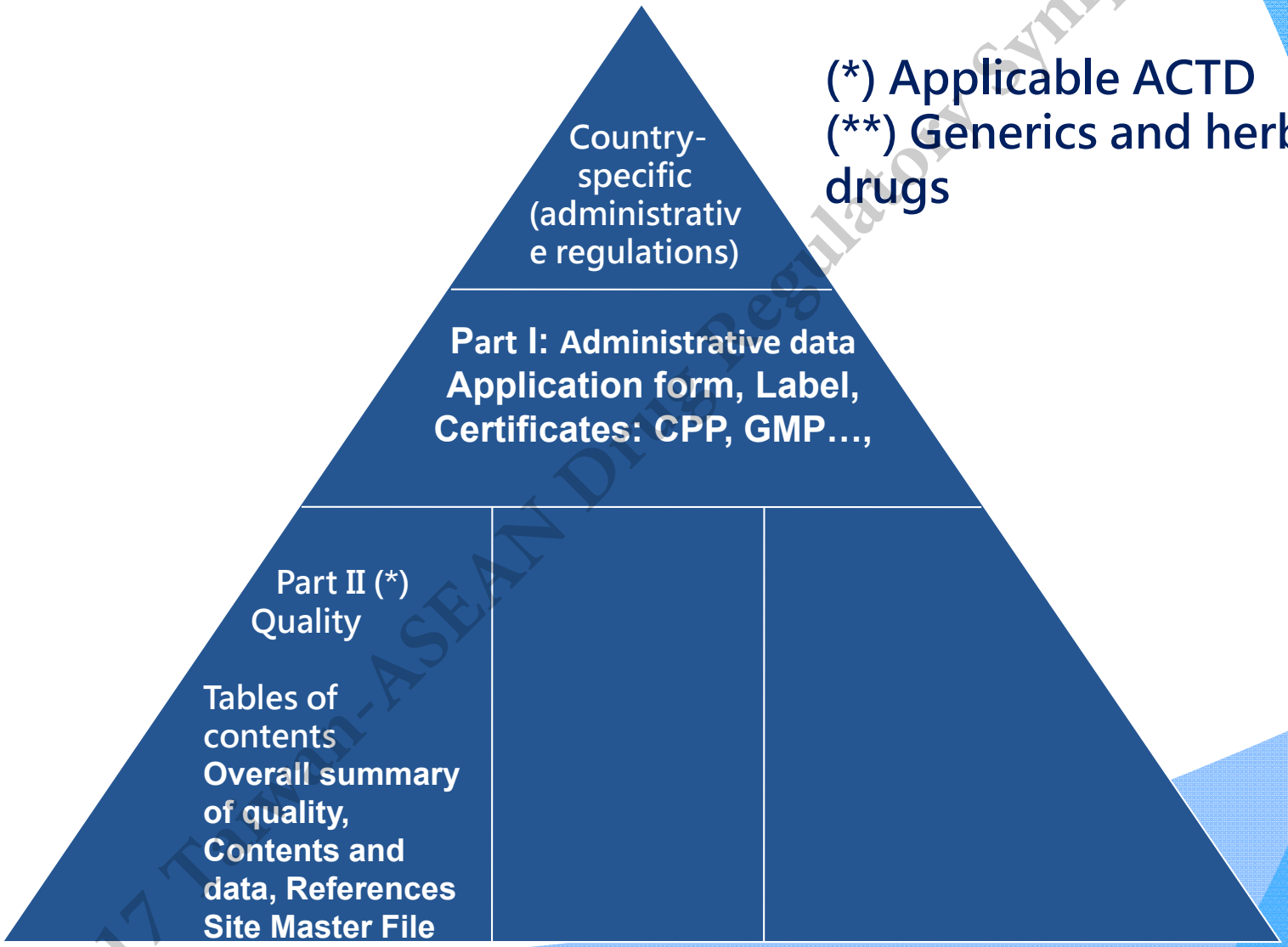
New drug application **



(*) Applicable ACTD, ICH-CTD

(**) New chemical drugs, vaccines and biological products

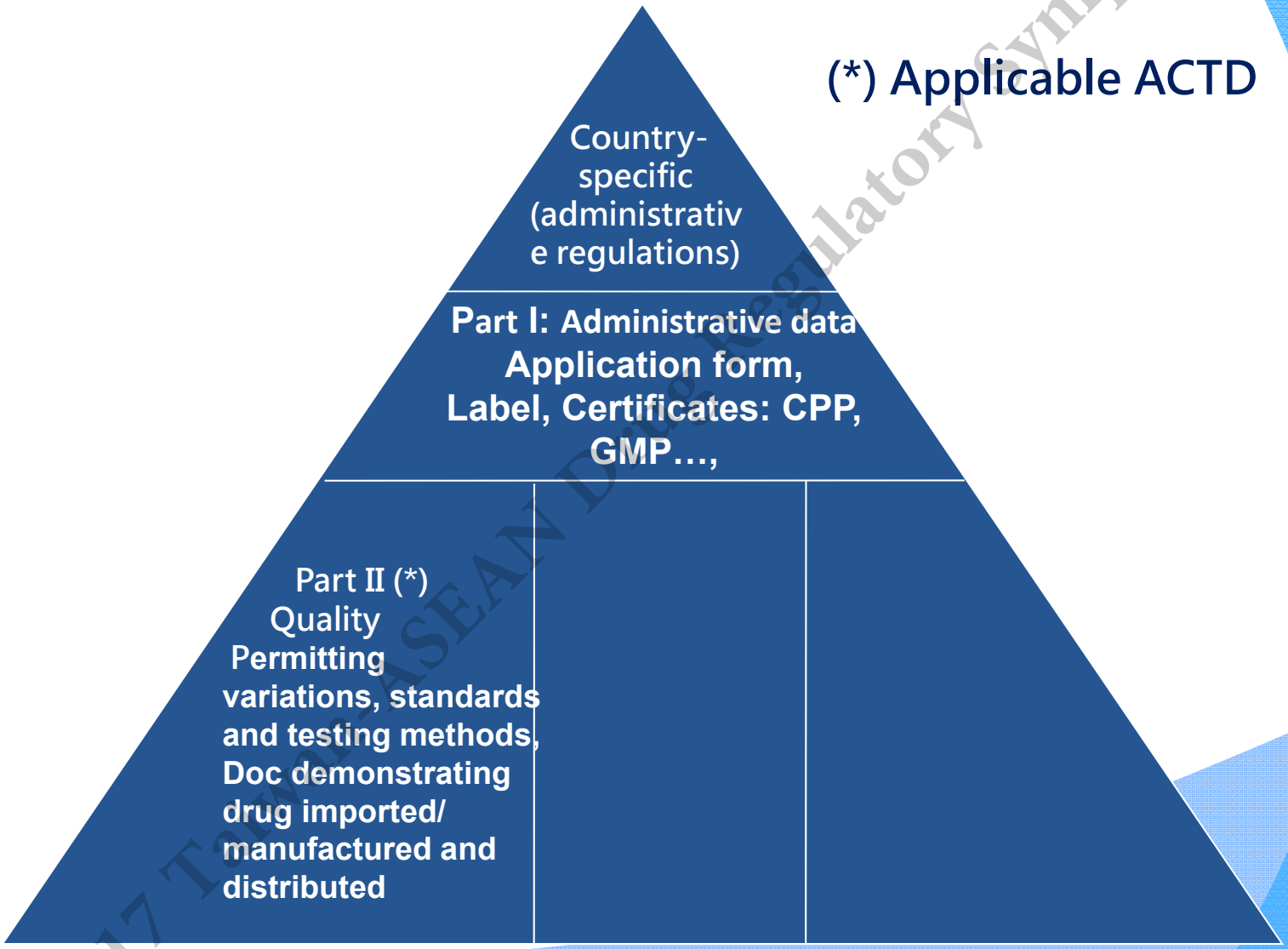
Generic application (**)



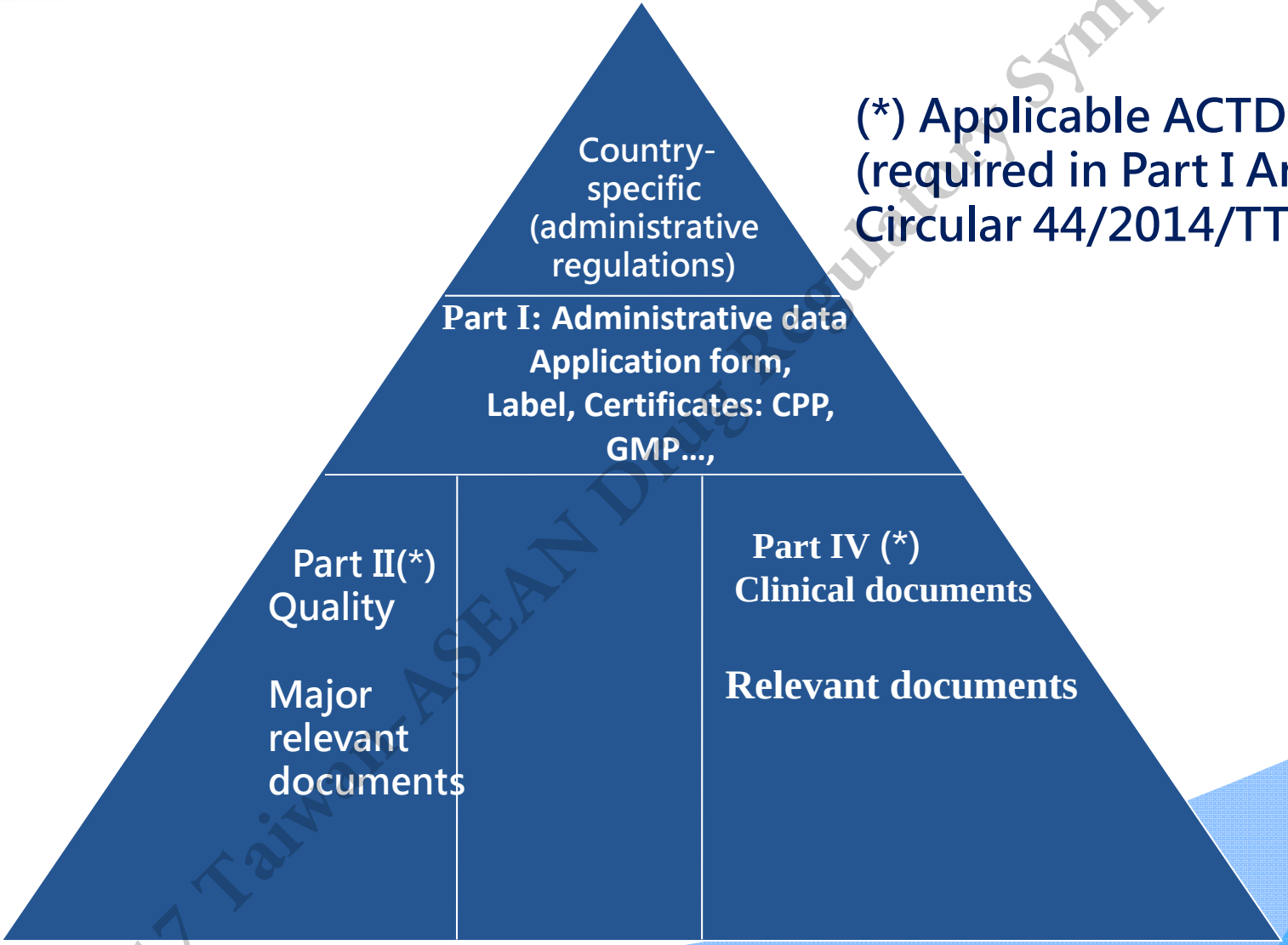
(*) Applicable ACTD
(**) Generics and herbal drugs

Extension application

(*) Applicable ACTD

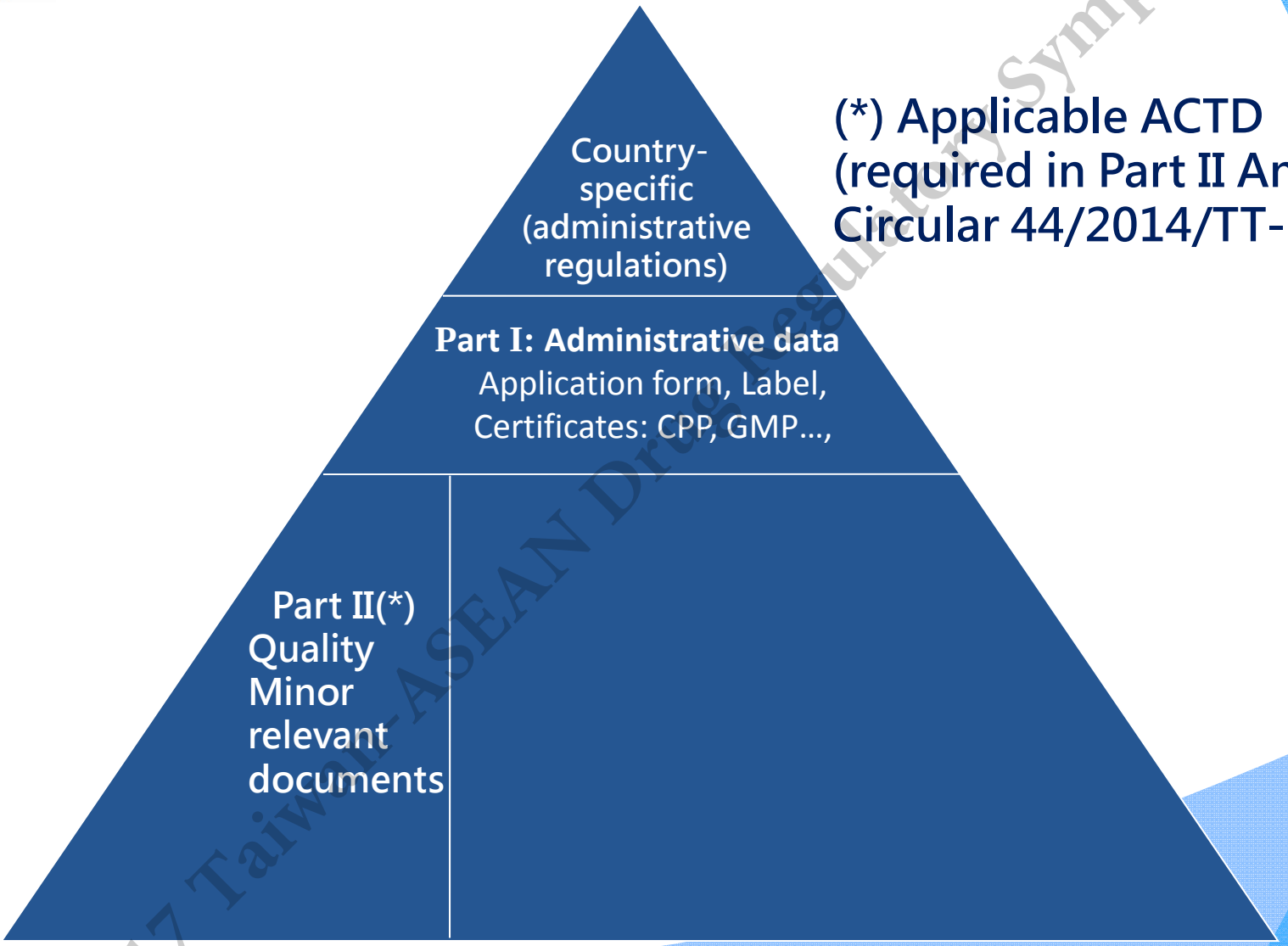


Major variations application



(*) Applicable ACTD (required in Part I Annex II Circular 44/2014/TT-BYT)

Minor variations application



(*) Applicable ACTD (required in Part II Annex II Circular 44/2014/TT-BYT)

Specific requirements of Administrative data (1)

1. Table of contents;
2. Report on safety and efficacy of drugs after circulation, made according to a set form;
3. Summary of Product, made according to a set form;
4. Power of attorney (if any), made according to a set form;
5. Application form, made according to a set form;
6. Cover page, made according to a set form;
7. Summary of history of drug for extension, made according to a set form;
8. Certificate of eligibility for drug trading relating to Vietnamese drug-trading establishment;
9. License for ref.office issued by the foreign competent agency regarding the foreign applicant;
10. CPP made according to a set form pertaining to foreign drugs;

Specific requirement of Administrative data (2)

11. GMP certificate of the foreign drug manufacturer if the CPP certification does not certify the GMP requirements. In case there are many manufacturers involving in the drug manufacturing process, the applicant submits the GMP certificates of all applicants involving in the finished drug manufacturing process;

12. Drug label according to Circular 06/2016/TT-BYT;

13. Drug information Patient information leaflets (06/2016/TT-BYT);

14. Summary of Product Characteristics pertaining to new chemical drugs, vaccines and biologicals, made according to a set form (the extension is not required);

15. Under-licensing agreement or contract for under-licensed drugs. Toll manufacturing contracts for toll-manufactured drugs;

16. Certificates, patents and relevant contracts of industrial property ownership transfer (if any);

17. Other legal documents (if any).

Specific requirement of Quality Dossier of herbal medicines (1)

1. Manufacturing Process:

a) Raw Materials: The manufacturing process is not required for excipient and materials named in the pharmacopoeia and materials manufactured by other manufacturers. In other cases, the process of manufacturing materials must be described in full and detail.

b) Finished Products:

- **Formula for the smallest unit of packing; content or concentration of each material; materials' applicable standards. If manufactured from extract, the quantity of medicinal materials must be indicated;**
- **Formula for a lot or batch of manufacture; weight or volume of each material;**
- **Diagram of the manufacturing process, including all stages;**
- **Description of the manufacturing process: full and detail each stage;**
- **List of equipments and instruments used: names of equipment, specifications and use purposes;**
- **Control in the manufacturing process: to describe in full and detail the criteria for inspection and control in the manufacturing process.**

Specific requirement of Quality Dossier of herbal medicines (2)

2. Quality Specification and Testing methods

a) For drug materials named in the pharmacopoeia, to indicate the name of the pharmacopoeia and year of publication. For those not named in the pharmacopoeia, to describe in full and detail the testing criteria and methods.

b) Finished products:

- Formula for the smallest unit of packing; content or concentration of each material; materials' applicable standards. If manufactured from bone glue, the quantity of medicinal materials must be indicated;

- Finished-product standards: to describe in full and detail the finished products' testing criteria and methods.

c) Packaging materials standards: to describe in full and details the testing criteria and methods.

d) Certificate of analysis: by manufacturer of competent labs.

e) Stability data:

- **Stability study protocol, Stability data;**
- **Stability research conclusions**

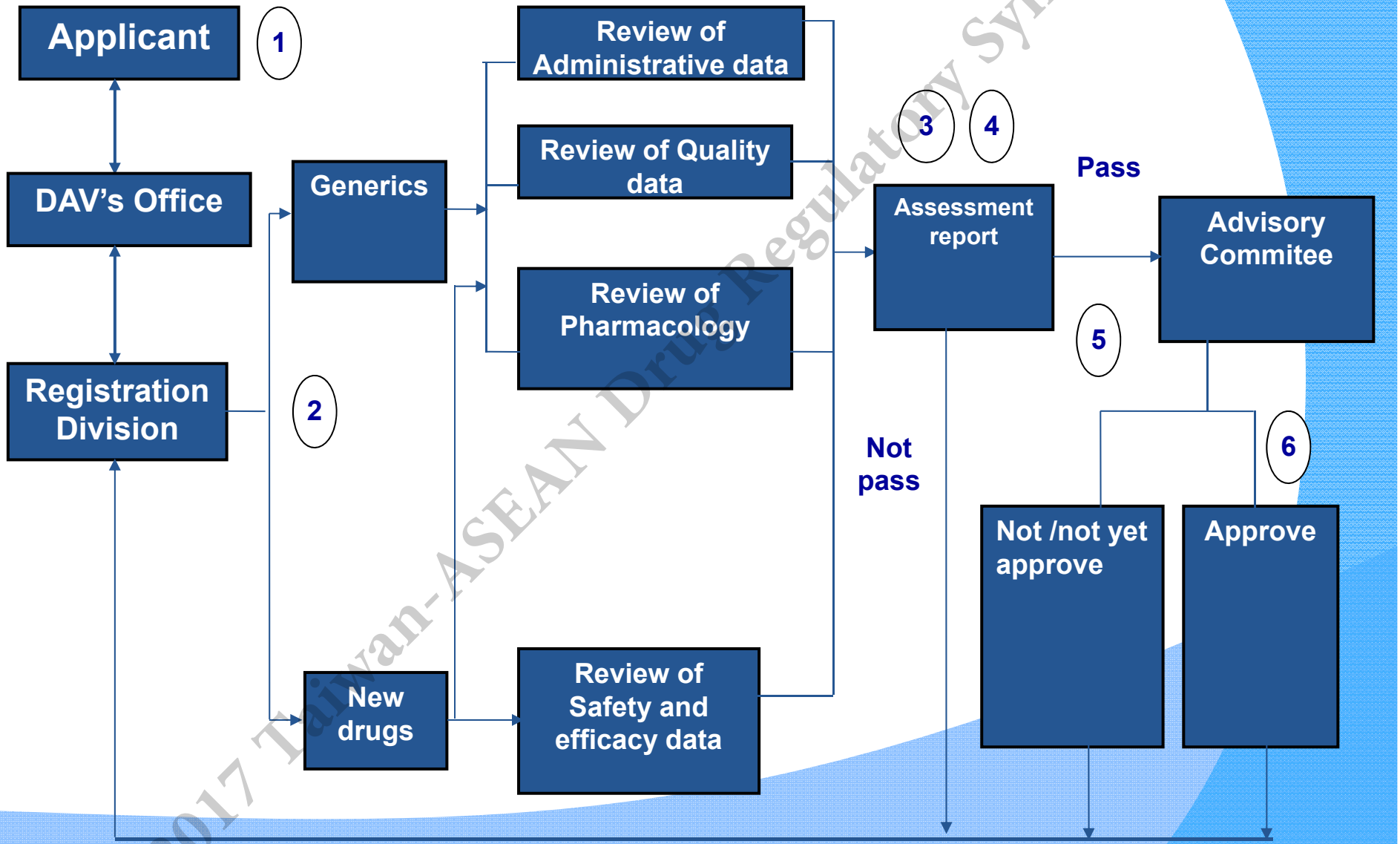
Priority Review

Priority will be given by the MOH to issuing MA or written notification before the time limit in the cases:

1. **Drugs meeting needs for ad-hoc treatments belong to the List of Orphan Drugs;**
2. **Drugs meeting needs for treatments in emergencies, disasters, epidemics;**
3. **Local drugs manufactured in new GMP-compliant production lines ≤18 months;**
4. **Vaccines passing WHO's pre-qualification and being considered as eligible for fast-track approval as per the procedure established and published by the DAV.**

(The applicants are required to indicate clearly their request for priority on the application form)

Drug Registration Process



Registration Fee

	Fee/Drug (1,000 VND)
1. Renewal and New Registration	
- New Registration dossier	5,500 (~ 270 USD)
- Extension Registration dossier	3,000 (~150 USD)
2. Major and Minor Variation Registration	1,000 (~ 50 USD)

MA revoke

1. Manufactured in contravention of application approved
2. 02 manufacturing lots not meeting quality standards or 01 time of violation but serious
3. Manufacturer or applicant applies for revocation
4. Product withdrawal in the country of origin
5. Contains active ingredients unsafe for users
6. Infringes intellectual property rights
7. Applicant is not changed after 02 months, from the day the applicant stopped operation

General information on pharmaceutical manufactures

1. Vietnamese pharmaceutical market value: around USD 3.4 billion (2016)

2. Manufacturers
   - GMP-WHO Manufacturers: 176
     - ⊙ Western drugs: 131
     - ⊙ Herbal drugs: 56
   - Vaccines GMP-WHO Manufacturers: 07

General information on drug marketing authorization

1. Number of valid drug MA: 19,413

- Domestic drugs: 12,405
- Imported drugs: 7,008

In which drugs from Taiwan manufacturers: 115 products

2. Number of valid MA for vaccines: 56

3. Number of valid MA for biologics: 333

Note: The vaccine NRA of Viet Nam was certified as functional by WHO in 06/2015

List of APIs required to be supported by BE data (still in revising)

TT	API
1	Amlodipin
2	Azithromycin
3	Carbamazepin
4	Cefixim
5	Cefuroxim Axetil
6	Clarithromycin
7	Glibenclamid
8	Gliclazid
9	Metformin
10	Metoprolol
11	Nifedipin
12	Rifampicin

Part III

Notes from 1st Jan 2017

(Pharmaceutical Law 2016 has come into effect from 1st Jan 2017)

Pharmaceutical Law 2016:

Chapter V: Registration, Circulation and Recall of Finished pharmaceutical Products, API

Section 1: Registration of finished pharmaceutical products and APIs

Decree No 54/2017/ND-CP: promulgating some articles and implementations of Pharmaceutical Law 2016

Chapter 5: Registration of Herbal Materials, Excipients, capsules and Inspection of Foreign manufacturing site.

Subjects and Requirements of Drug Registration

- Drugs to be circulated in Vietnam, excluding:

+ Drug dispensed in Pharmacies upon Prescription and to be supplied for customers of these pharmacies

+ Non-registered drugs imported by special quota import license for some specific purposes (Article No 60 Point 2).

+ Traditional medicines processed in the traditional hospitals to be used in the these hospitals (Article 70)

- API, excluding:

+ API to produce registered drugs according to approved registration dossiers

+ Non-registered API imported by special quota importation in some specific cases (Point 3 Article 60)

Applicant/MA Holder

- Applicants/MA Holders:

  + Local Pharmaceutical Companies: Manufacturers/Importer/Distributors

  + For Foreign Pharmaceutical Companies: Companies which are conducting pharmaceutical activities in Vietnam and having Representative Office in Vietnam

  + Applicants/MA Holders for Herbal Materials: above companies and others which collect and agriculture herbal materials

Rights and Responsibilities Of the Applicants/MA holders

+ To be guided of Drug registration, to be updated with the registration reviewing and approval process

+ To submit to Drug Authority for withdrawal of registered drugs which they are the applicants/MA holders

+ To report to DaV about variations on registered Drugs

+ To archive the submitted registeration dossiers and submit when required by authorities

+ To comply with the manufacturing site inspection requirements when required by competent authorities

Requirements on Drugs and Manufacturers

- Requirements of Drugs to be granted MA
  + To have proper Safety and Efficacy
  + To be produced in the manufacturer which meet requirements
  + To be produced from API and by process which are meet the required standards (Article 102, 103)
- GMP Inspection of foreign manufacturing sites
  + Dossier Inspection
  + Mutual Recognition of GMP Inspection results between Drug Authorities
  + Site GMP Inspection

Drug registration types

Drug registration types	Cases
New MA	- Having no MA in Vietnam - Having MA but there is variations of API, Strength, Dosage form, Rout of administration, manufacturer.
MA Extension	- Expired MA (change on Administrative data is acceptable)
MA variations	- Valid MA and having variations other than variations requested to apply for New MA.

Drug Registration Dossier

- **Administrative dossier:**
  + Application
  + Rep Office license (for foreign companies) / Manufacturer/Distributor/Wholesaler ' License
  + CPP, original label in the country of origin
  + Tentative label for Vietnam circulations, Drug Information
  + For Herbal Material registration: Business license is acceptable
- **Technical Dossier**
  + Quality dossier
  + Clinical dossier (New drug, reference drug
  + Biosimilar dossier (Biosimilar)

MA Variation/extension dossier

- **MA extension dossier:**
  - + Application
  - + Rep Office License (Foreign company) / Manufacturer, wholesaler, distributor license
  - + CPP (imported drug)
  - + Circulation report, report on safety and efficacy (upon request)
- **MA variation:**
  - + Application
  - + Technical dossiers related to variation
  - + Current MA

Herbal Material Registration

- Herbal Material (HM) required to have MA:
  + HM in the HM toxic list and to be used first time in Vietnam
  + HM having risk of falcified use and sub-standard quality
  + HM in the list to be agriculted to meet the supply requirements
  + Bulk HM (excluding Bulk HM for Herbal Medicine production of that manufacturer
- HM required Quality Specification Declaration:
  + HM that are not belong to above cases

Excipient/Capsule registration

- Excipient required to have MA

  + Excipient which comply with manufacturer's specification
  + Excipient is not included in recognized Pharmacopoieas
  + Excipient to produce drugs having valid MA is exempted

- Capsule registration

  + Capsule must to be registered.
  + Capsule using to produce drugs having valid MA is exempted

Importation of finished Drug products, API and primary packaging materials

**+ Finished Drug products, API and herbal materials that granted MA, are allowed to import into Vietnam without import licences, excluding special Control drugs (Narcotics, Psychotropics, Precursors, toxic drugs,
Donation…). The quantities is not limited.**

+ Finished drug products without MA, herbal materials, excipients, primary packaging materials and some drugs (orphan drugs, drugs for epidemic, National Health Program drugs) can be considered to grand import lisences under specific requirements.

+ API of registered drugs could be imported freely after notified by MoH

Importation dossier requirements

1. Drugs with MA:

- **Marketing Authorization (MA)**
- **Legal dossiers of MA holder (Business license, Rep Office license.**

2. Drugs without MA: depends on drug types:
Eg: Drugs for emergency, Orphan Drugs: Application form, Official demand from hospitals

3. Notified pharmaceutical starting materials

Thank you
for your attention