VIETNAM PHARMACEUTICAL REGISTRATION AND APPROVAL

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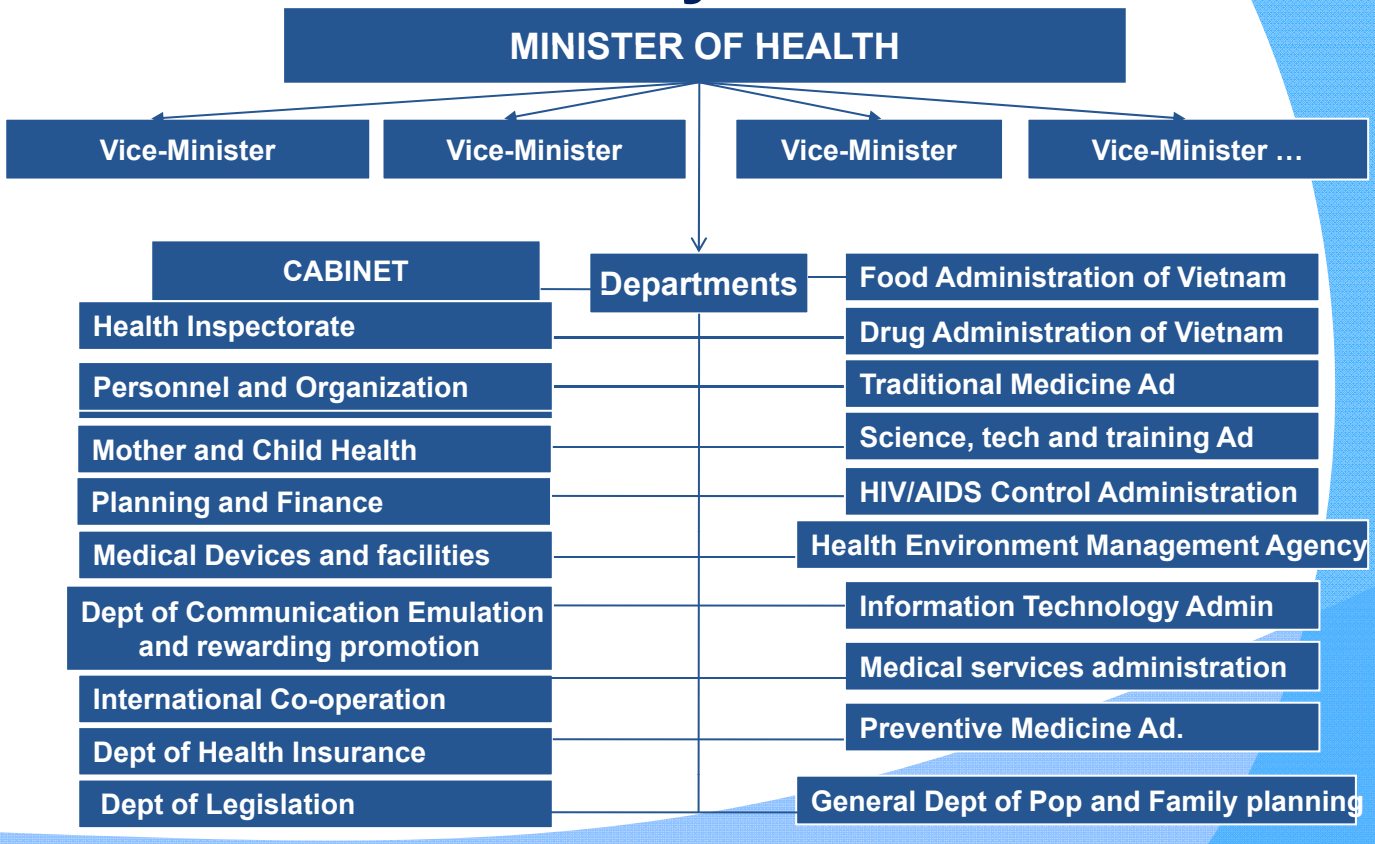
DRUG ADMINISTRATION OF VIETNAM
MINISTRY OF HEALTH

Agenda

1. Pharmaceutical Governmental Management
2. Drug marketing authorization
3. Some figures on pharmaceutical market
4. Notes from 1st Jan 2017

Part I
Pharmaceutical Governmental Management

Organizational Chart of the Ministry of Health



Health products management system

MINISTRY OF HEALTH

- Administration of Science Technology and Training
- Drug Administration of Vietnam
- Department of Medical Devices and Health facilities
- Traditional Medicines Administration
- Food Administration of Vietnam

- Clinical trials for new drug
- - Drugs and pharmaceutical starting Materials
  - Cosmetic
- Medical devices (IVD is included)
- Herbal Raw Materials
- Health Supplements

DAV organizational chart

DIRECTOR-GENERAL

DEPUTY DIRECTORS - GENERAL

QMS Division

Administrative office
- Assisting DAV's activities; human resources management,
- Stewards administrative activities (storage, archiving,..

Planning & Finance Div.
- Planning activities Financial activities

Drug Registration Div.
- Activities related to granting MA for drugs.
- Monitoring drug MA recalls
- …..

Cosmetics Management Div.
- Activities related to cosmetics administration

Drug&Cosmetic Inspection Div.
- Inspections on compliance with regulations on pharmaceuticals

Legislation & International Integration Div.
- Legislation-related activities
- Integration activities
- International cooperation

Drug Information and Advertising Management Div
- Administration related to drug safety and efficacy.
- Administration of drug advertising

Pharmaceutical Business Management Div.
- Administration related to pharmaceutical practices
- Administration of drug import

Drug Price Management Div.
- Drug price administration
- Stabilization of drug market.
- …

Drug Quality Management Div.
- Conducting GPs-related inspections
- Administration of drug recalls and suspensions
- Administration of drug quality

Introduction of DAV

- Established: in August 1996
- Belong to Ministry of Health
- Organization: 10 divisions and 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)

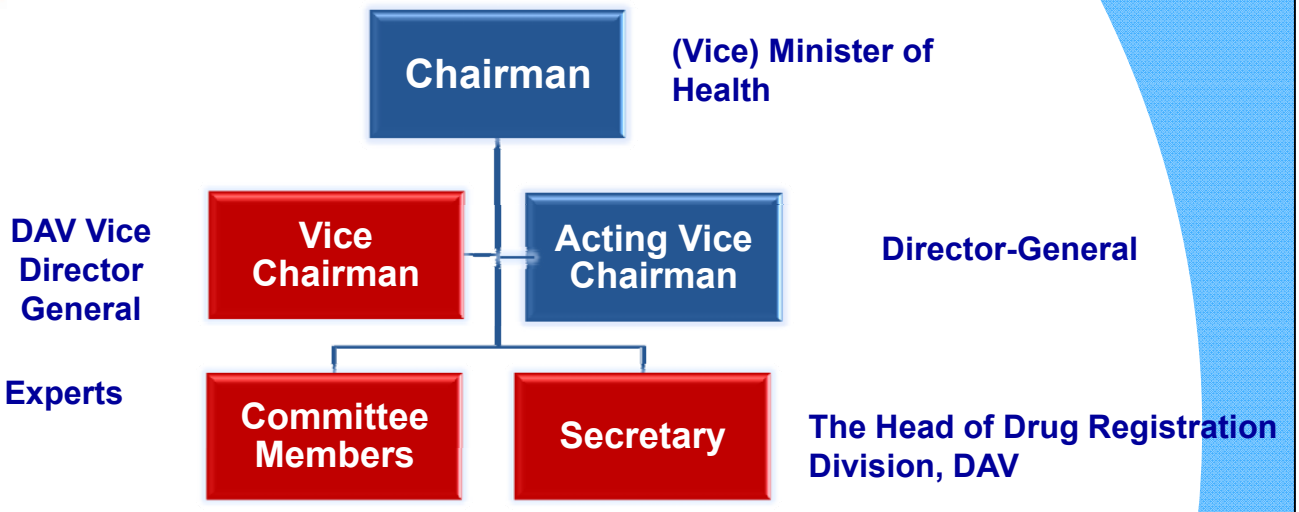
2. Cosmetics

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.

Drug Registration Consultative Committee



The task of Drug Registration consultative Committee:
offering advices for Ministry of Health on:
- Issuance of registration No;
- Making policies for registration regulation harmonization;
- Making policies about Drug Manufacturing, Importation and Circulation in Vietnam.

Part II
Drug Marketing Authorization

Legal documents

Legal ground:

1. Pharmaceutical Law No. 34/2005/QH11
2. Decree No. 176/2013/NĐ-CP dated 14/11/2013 on the administrative punishment in health sector

Guiding documents:

1. Circular No. 44/2014/TT-BYT dated 24/11/2014 on drug registration
2. Circular No. 23/2013/TT-BYT dated 13/8/2013 guiding drug toll manufacture
3. Circular No. 08/2010/TT-BYT dated 26/4/2010 guiding submission of BA/BE report.
4. Circular No. 06/2016/TT-BYT dated 08/3/2016 guiding drug labeling
5. Circular No 09/2010/TT-BYT dated 28/4/2010 on drug quality management
6. Circular No. 03/2012/TT-BYT dated 02/2/2012 guiding drug clinical trial
7. Circular No 05/2010/TT-BYT 01/03/2010 on data protection for drug registration
8. Circular No. 03/2013/TT-BTC dated 08/01/2013 on the fee

Drug Registration in Vietnam

1. Drugs to be circulated in the market must:

-Be granted registration number/MA or Import license issued by MoH;

-Meet quality standard registered with MoH;

-Have labels in Vietnamese and meet labelling regulation;

-Have price declared and be sold not higher than the declared price.

2. Registration No/MA is granted based on Assessment of Qualily, Safety and Efficacy of the product

Applicant/MA holder

1. Local Pharmaceutical Companies (Manufacturers/Importer/Distributors)

2. Foreign Pharmaceutical Companies:

- **Foreign Pharmaceutical Companies that have Representative Office in Vietnam;**
- **Foreign Pharmaceutical Companies that have License for conducting pharmaceutical activities in Vietnam granted before 15/1/2015.**

Applicant Responsibilities (1)

1. Assuring quality, safety, efficacy and consistency of drug marketing with the registration dossier;
2. Providing sufficiently and accurately all the data, reports and information related to the drug;
3. Updating information on quality, safety and efficacy of the respective drug;
4. Inform DAV in case the registered drug in VN is recalled in any country within 07 working days;
5. Collaborating with importers, manufacturers to withdraw the drugs failing to meet quality, safety, efficacy regulations;

Applicant Responsibilities (2)

6. Report on the 15th December every year to DAV the marketing of drug: are manufactured/imported or not.
7. Retaining full dossiers and providing the competent authorities when requested;
8. Cooperating and facilitating the performance of audits, assessments of manufacturing sites;
9. Changing the applicant within 01 month from the date of the applicant stopped operation;
10. Collaborating with manufacturer to carry out specific studies or providing additional information on request of regulatory authority.

General requirements about registration dossiers

1. **Language:**
- Registratrion dossiers: English or in Vietnamese.
- Package Insert, Drug Characteristics, 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.

Application Types

1. First-time application: new/generic application
- Drugs have not been granted registration No in VN;
- Drugs have been granted registration numbers in Viet Nam but subject to other variations;
- Drugs have been granted registration number in VN but not renewal or extension registration in the right time.

2. Renewal application

Drugs have been granted registration numbers but expired and cannot meet the requirement for extension.

3. Variations application: Major/Minor application

Drugs have been granted registration number but minor or major variations during valid period.

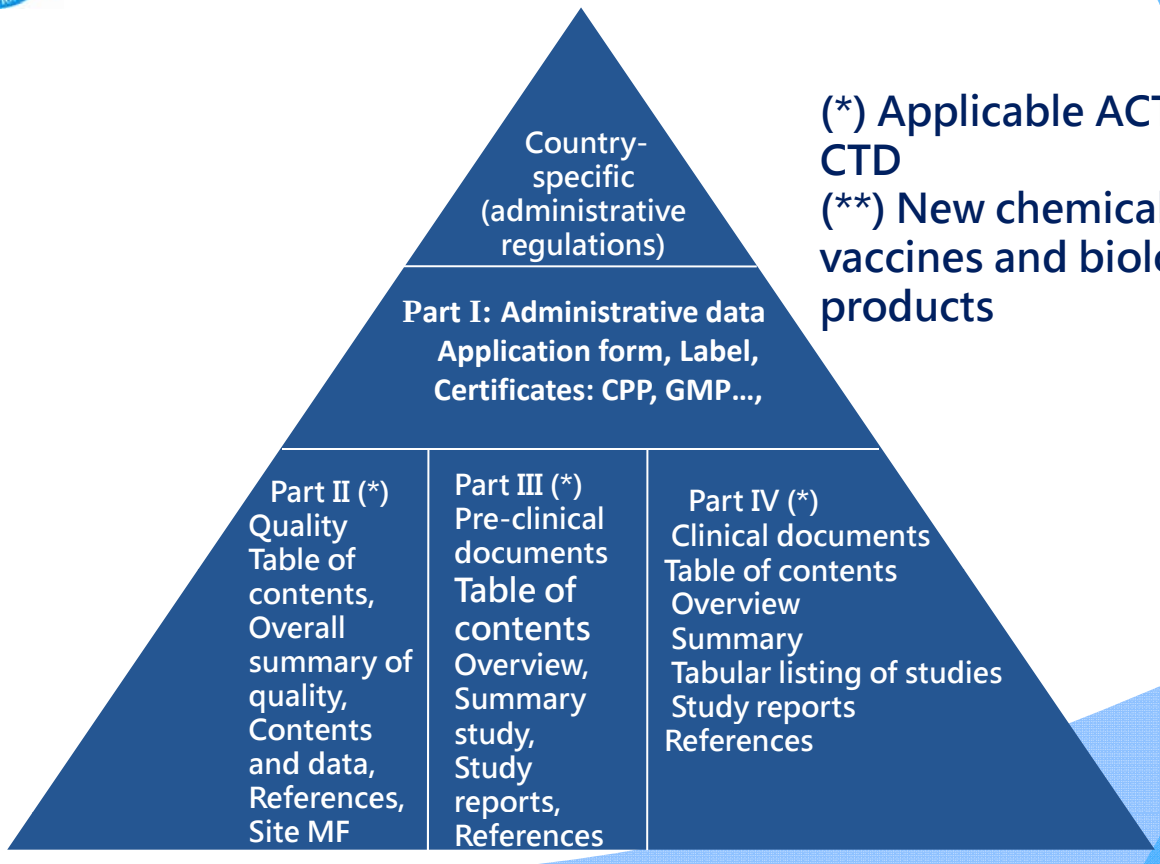
Application Types

4. Extension application

Drug granted registration No but expired and meet requirements:

- 5-year validity MA and marketed after registed;
- Privious registration dossiers complianced with ACTD or ICH-CTD and ASEAN CT guidelines for chemical drugs or with Circular 22 for others;
- Not subject to withdrawal or suspension of receiving applications or suspension of issuing registration No;
- Without any recommendations of WHO or DAV or foreign drug regulatory authorities on therapeutic efficacy during registration extended timeline;
- Without any variations or supplements at the point of submitting the extended dossier and during the process of reviewing extended registration dossiers.

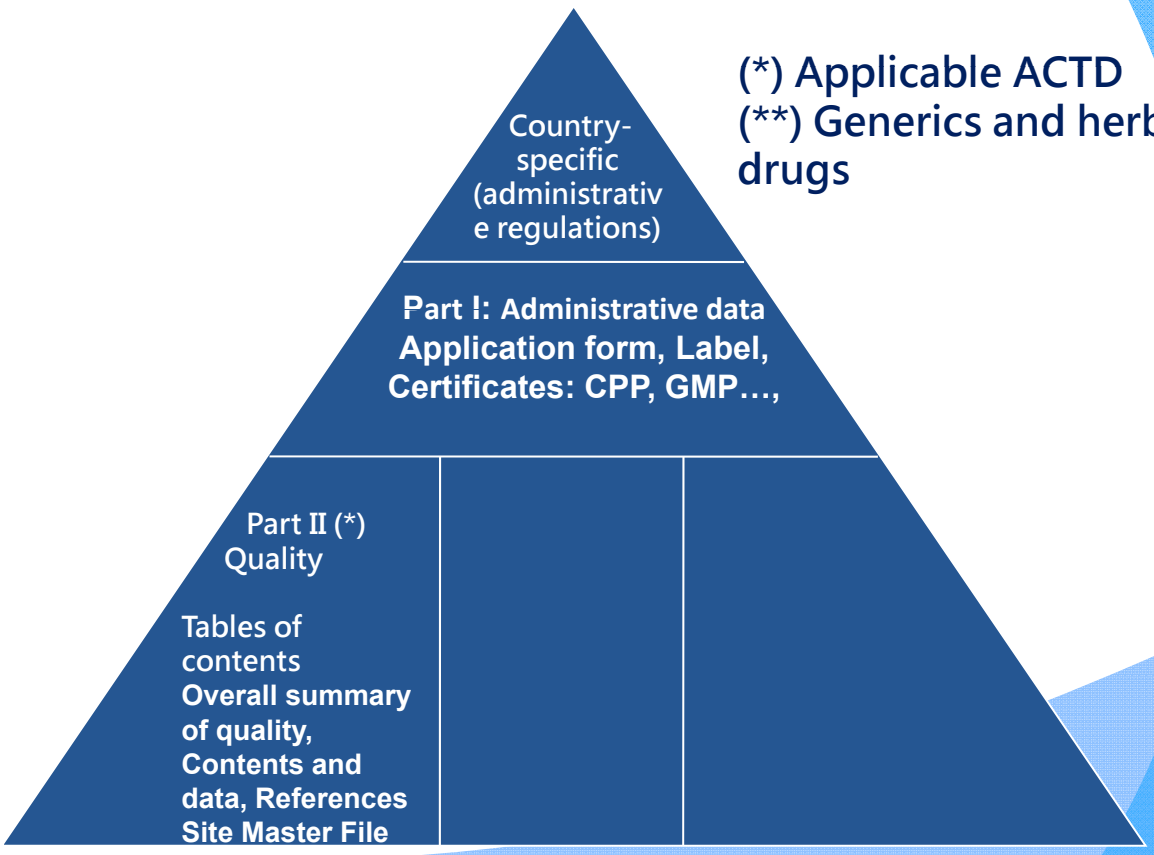
New drug application **



(*) Applicable ACTD, ICH-CTD

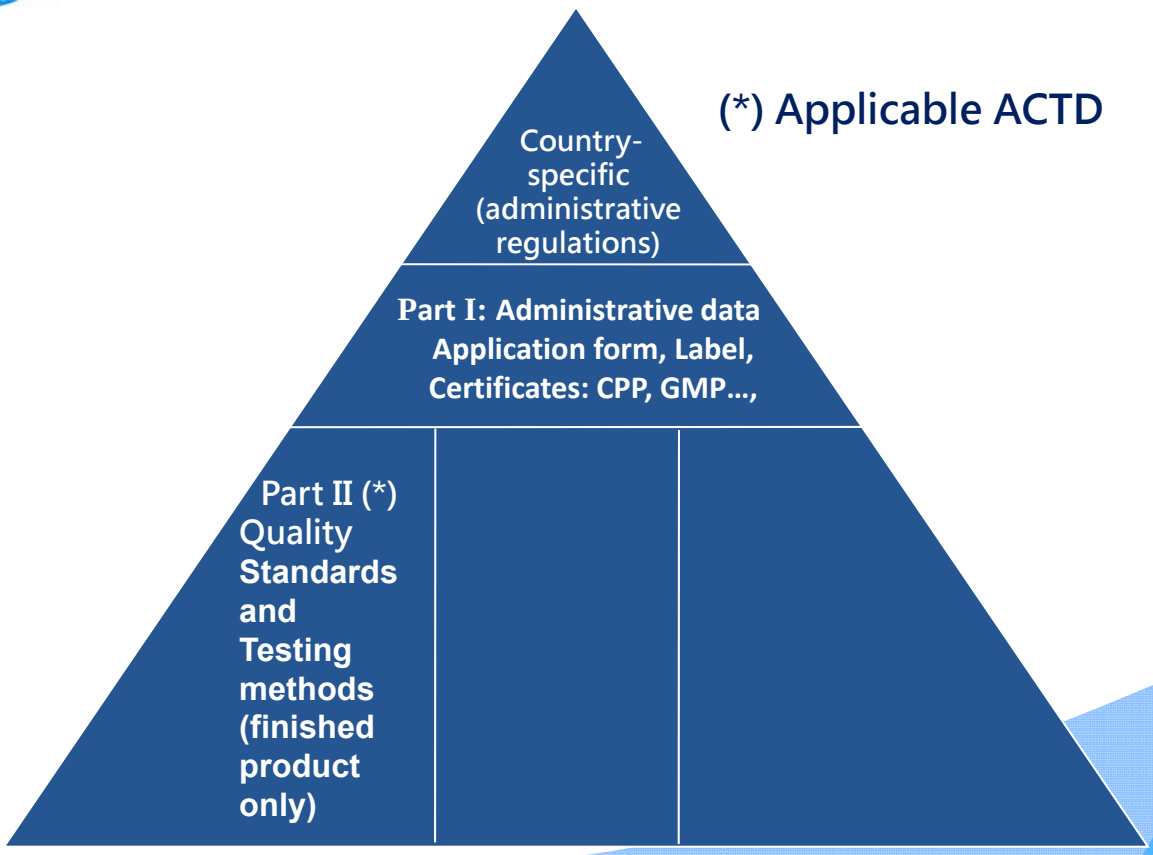
(**) New chemical drugs, vaccines and biological products

Generic application (**)



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

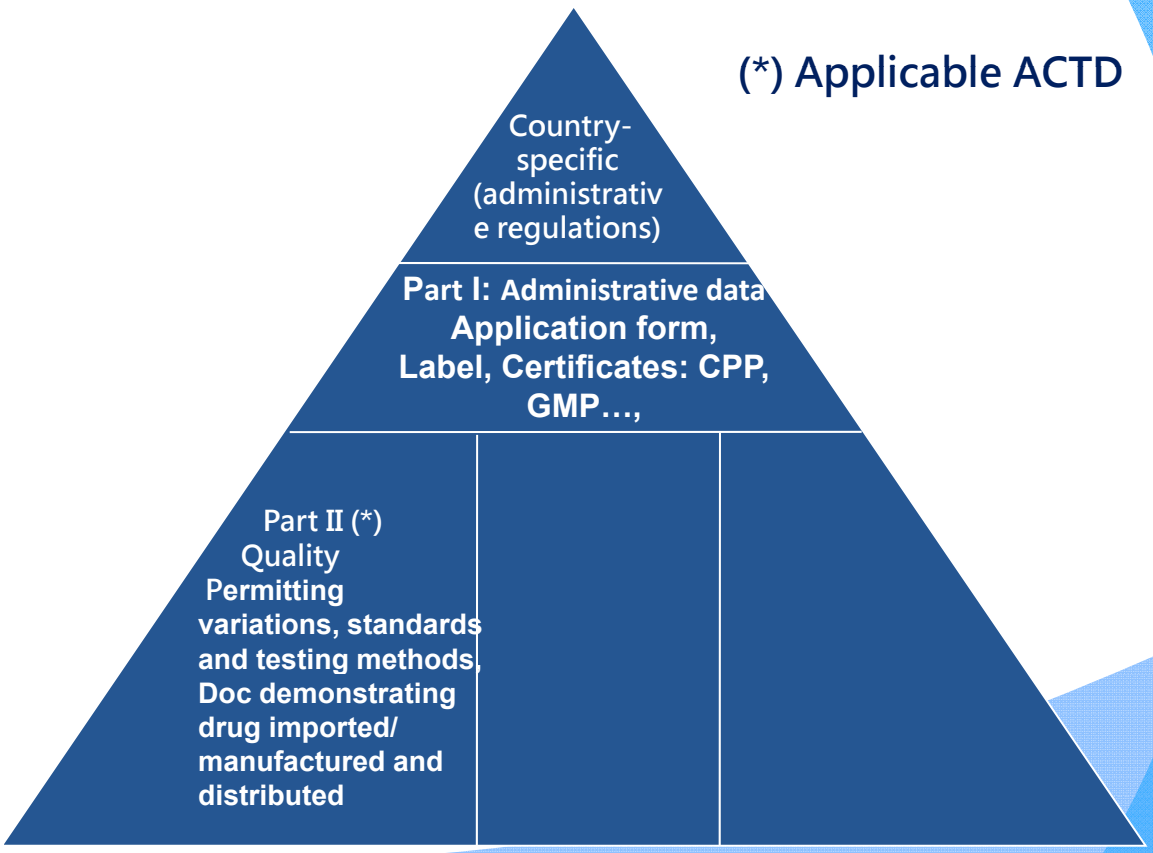
Renewal application



(*) Applicable ACTD

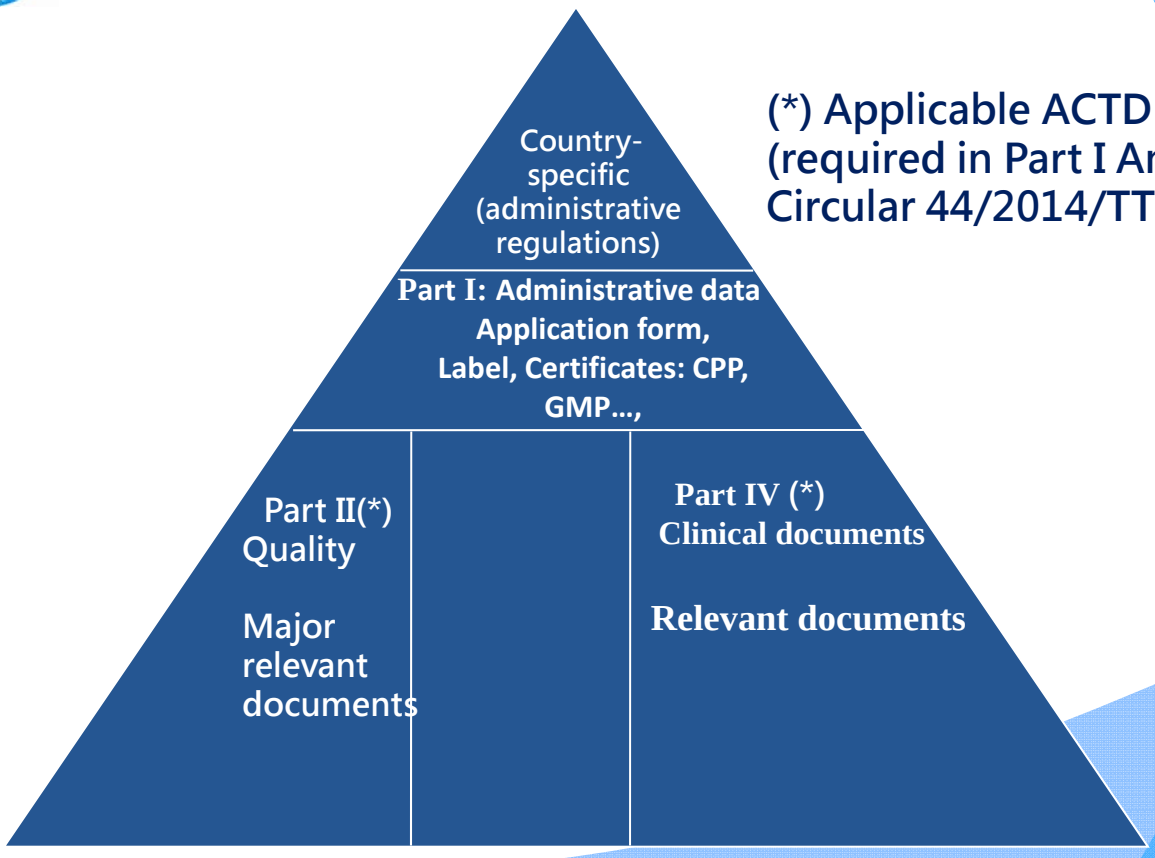
Extension application

(*) Applicable ACTD

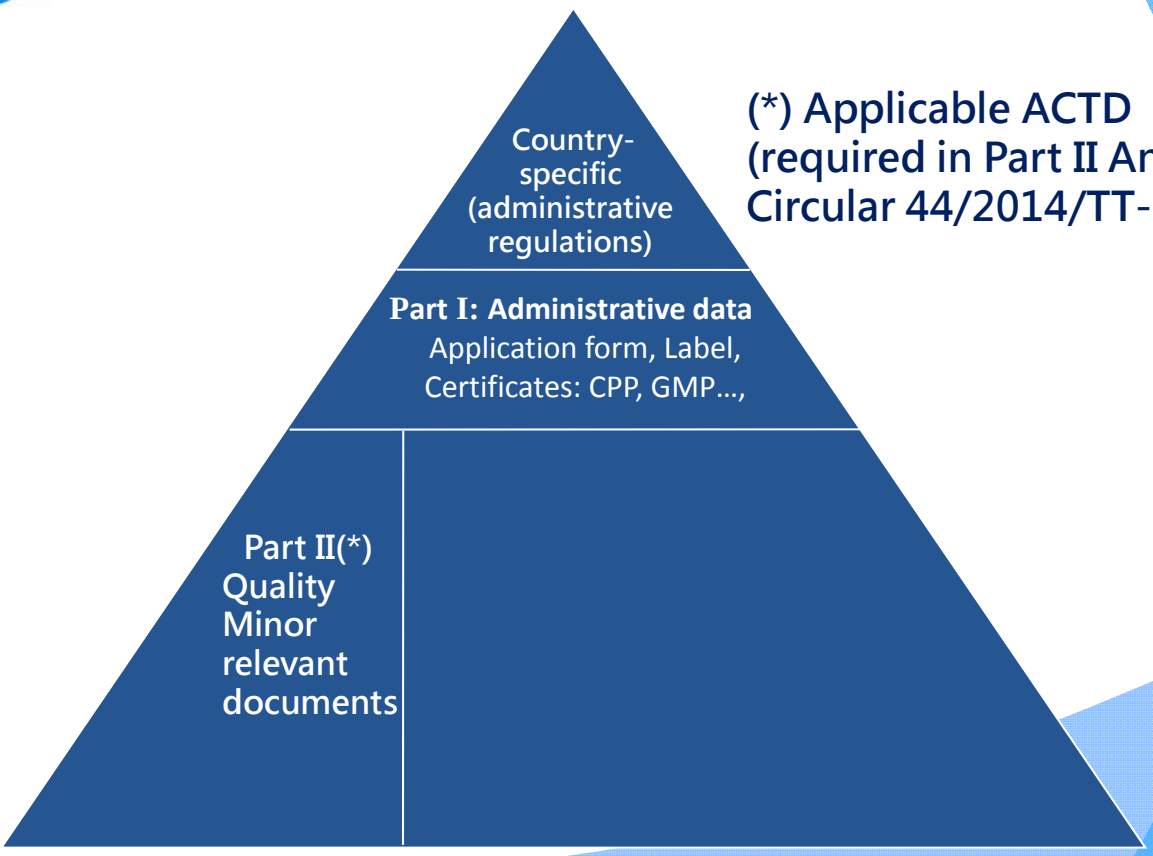


Major variations application

(*) 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. Report on drugs for renewal, made according to a set form;
8. Summary of history of drug for extension, made according to a set form;
9. Certificate of eligibility for drug trading relating to Vietnamese drug-trading establishment;
10. License for drug trading issued by the foreign competent agency regarding the foreign applicant;
11. CPP made according to a set form pertaining to foreign drugs;

Specific requirement of Administrative data (2)

12. 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;

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

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

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

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

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

18. 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 bone glue, 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

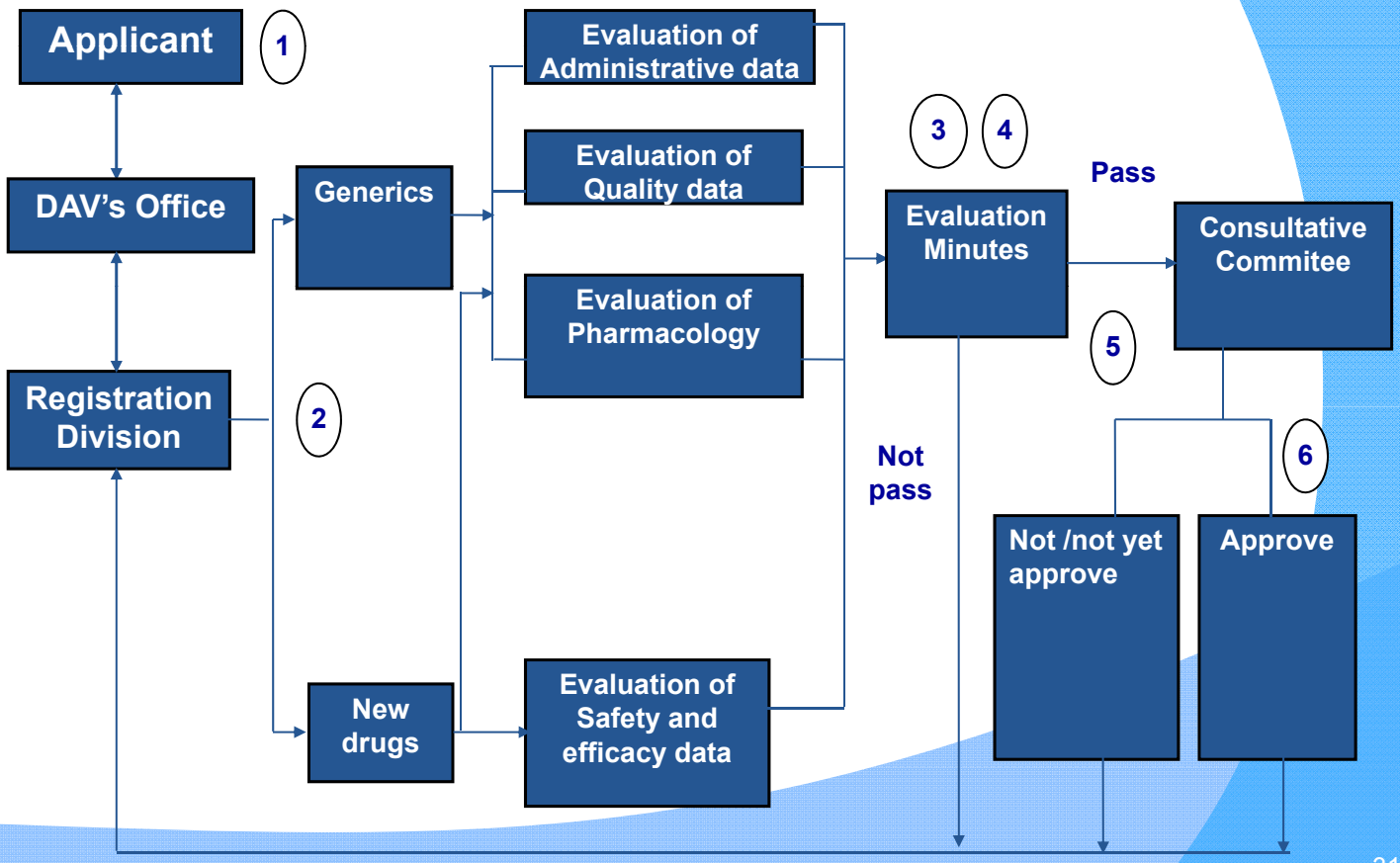
Priority Review

Priority will be given by the MOH to issuing registration No 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



Description of Process (1)

1. Receiving dossiers and collecting registration fee:

- Office of Administration receive drug registration dossiers, then forward these to the Drug Registration Division.

2. Classification and preparation of dossiers for appraisal:

- Dossiers are classified by: New drug; Vaccines, biological products; Generic drug and Herbal drug to be referred to relevant groups of experts of appraisal.

3. Appraisal of drug registration dossiers:

- New drugs; vaccines and biological products: Appraisal of Administrative data; Quality Profile; Product information; Profile of Safety and Efficacy - Information relating to rational use of drug.
- Generics, herbal drugs: Appraisal of administrative; Quality Profile; and Product information.

Description of Process (2)

4. Post appraisal dossiers:
- Focal expert classifies dossiers: Qualified; not yet qualified or not qualified.
- Qualified dossiers collected for meetings of the consultative Committee, not yet or not qualified, inform the applicant.

5. Preparation of contents and dealing with meeting minutes of the consultative Committee, Reporting and note taking of minutes of the Committee's meeting.

6. Preparation of the list and issuance of decisions on granting drug registration number.

Approval timeline

1. First-time registration, renewal: 6 months

2. Extension of MA: 3 months

3. Registration for variations:

- 01 major variation or 02 minor variations or more: 90 days
- 01 minor variation: 60 days
- Variations that need notification only: 20 days

Validity of registration number

1. Maximum 5 years

2. Drugs of which safety and efficacy are required for continued monitoring: maximum 3 years

Registration Fee

	Fee/Drug (1,000 VND)
1. Renewal and New Registration	
- Registration dossier with data protection	6,000 (~ 300 USD)
- Registration dossier with BE/BA Study	5,500 (~270 USD)
- Others	4,500 (~ 230 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

Part III
Some figures on pharmaceutical market

Total Drug Consumption

(* Unit: 1,000 USD)

Year	Total Drug Consumption*	Local Drugs*	Imported Drugs*	Drug Consumption per capita (US$)
2005	817,396	395,157	650,180	9.8
2006	956,353	475,403	710,000	11.2
2009	1,696.135	831,205	1,170,828	19.8
2010	1,913,661	919,039	1,252,572	22.2
2011	2,432,500	1,140,000	1,527,000	27.6
2012	2,600,000	1,200,000	1,750,000	29.5
2013	2,775,000	1,300,000	1.845.000	31.8
2014	3,120,000	1,390,000	1,870,000	34.38
2015	3,436,000	1,649,000	2,057,000	37.97

General information on Vietnamese pharmaceutical market

1. Vietnamese pharmaceutical market value: around USD 3.4 billion
2. Manufacturers (by 11/2016)
   - GMP-WHO Manufacturers: 163
   - GMP-PICS manufactures 08
     - ⊙ Western drugs: 124
     - ⊙ Herbal drugs: 49
   - Vaccines GMP-WHO Manufacturers: 05
3. Foreign companies holding business license in Viet Nam:
   - Total: 734 companies
   - Taiwan: 12 companies

General information on drug registration

By 11/2016

1. Number of valid drug MA: 15,054

- **Domestic drugs: 9,012**
- **Imported drugs: 6,042**

In which drugs from Taiwan manufacturers: 115 products

2. Number of valid MA for vaccines: 58

3. Number of valid MA for biologics: 274

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

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 IV

Notes from 1st Jan 2017

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

Types of application

1. First-time application

- Drugs have not been granted registration number in VN;
- Drugs have already been granted reg No in VN but changes to its active ingredients, herbal ingredients or concentrations thereof, dosage form, administration route, manufacturer (except for secondary packaging facility, releasing facility, or releasing location);
- Pharmaceutical materials already have been granted registration number in Viet Nam but change to its manufacturer (except for secondary packaging facility, releasing facility, or releasing location).

Types of application

2. Extension application

Drugs, Pharmaceutical materials have been granted registration number but variations during valid period except for the variation cases in Clause 1.

3. Variation application

Drugs, Pharmaeceutical materials have been granted registration numbers but expired, including changed administrative datas at the point of submitting the extended dossier.

Approval timeline

- 03 months for extension and variation application

- 12 months for first-time application

Assessing GMP Complied

When registering an imported drug or pharmaceutical material in Vietnam, foreign manufacturer must assess the fulfillment of GMP requirements as using any of the following ways:

1. Assessing documents about manufacturing conditions;
2. Mutual recognition of inspection results given by pharmacy authorities regarding the fulfillment of GMP requirements;
3. Inspection at the manufacturing facility.

Clinical Requirement for New Drugs

Not required 05 years of circulation in country of origin but need to be marketed at least in one or several countries and have full data available on the safety, efficacy to be exempted from clinical trial in VN (to facilitate quick access to new drugs).

Thank you
for your attention