MEDICINE ASSESSMENT AND REGISTRATION OF PHARMACEUTICAL DRUG IN OUR COUNTRY

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Purpose and objectives of the training

Training objectives

- Train and equip participants with knowledge and skills in dossier assessment to enable them to evaluate data for registration of medicines.
- Support Rwanda FDA in retreat sessions to evaluate dossier submitted for registration.

Learning objectives

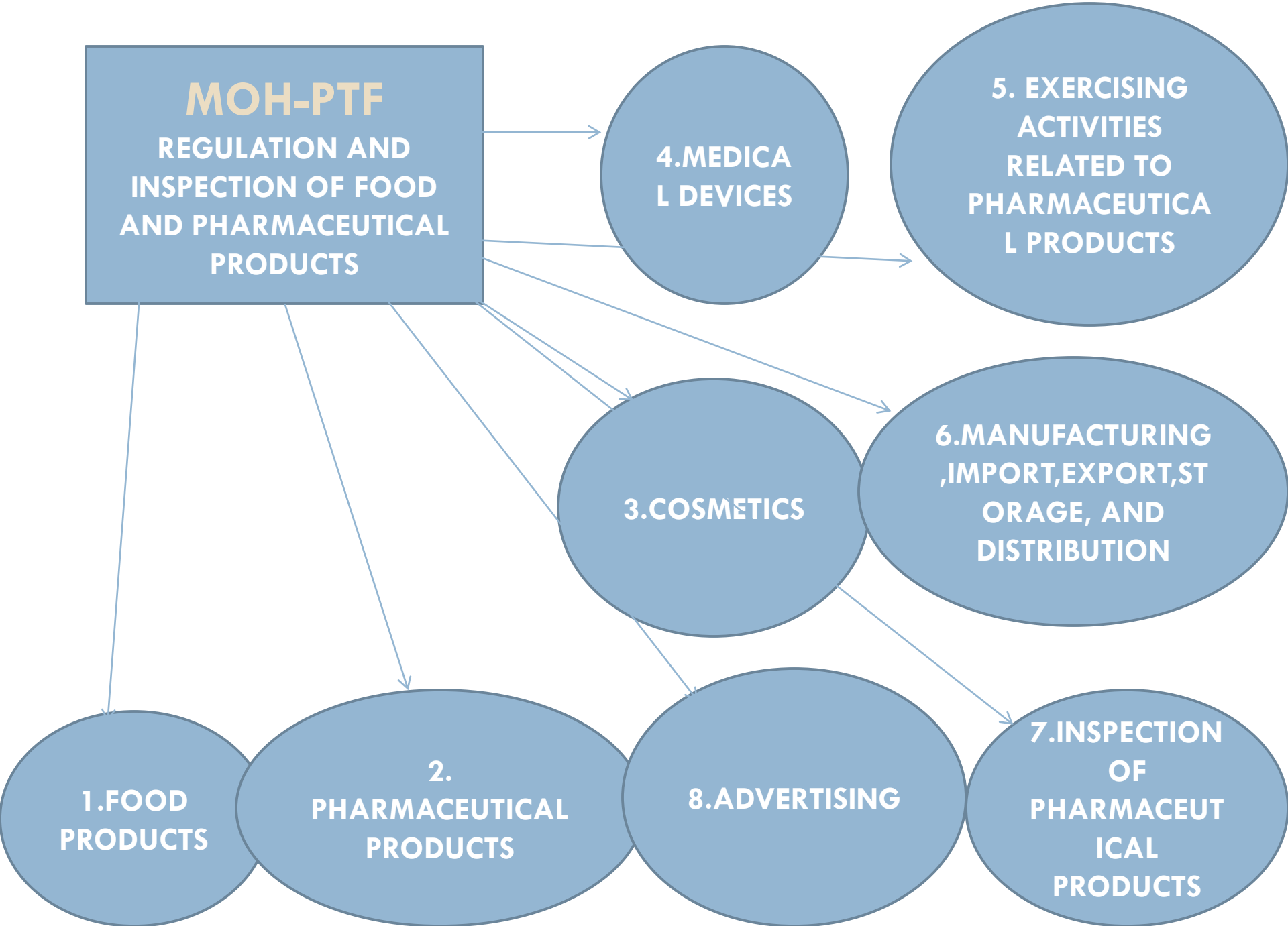
- Recognize and articulate the scientific & regulatory basis and assumptions for demonstration of completeness of dossier content.
- Demonstrate knowledge, understanding and application of key principles of ethics in dossier assessment.
- Analyze and draw conclusions on available data to demonstrate completeness based on application of relevant requirements in applicable regulatory guidelines
- Review and write a scientific assessment report on data submitted on application for registration of a medicine in accordance with applicable regulatory guidelines.

Introduction

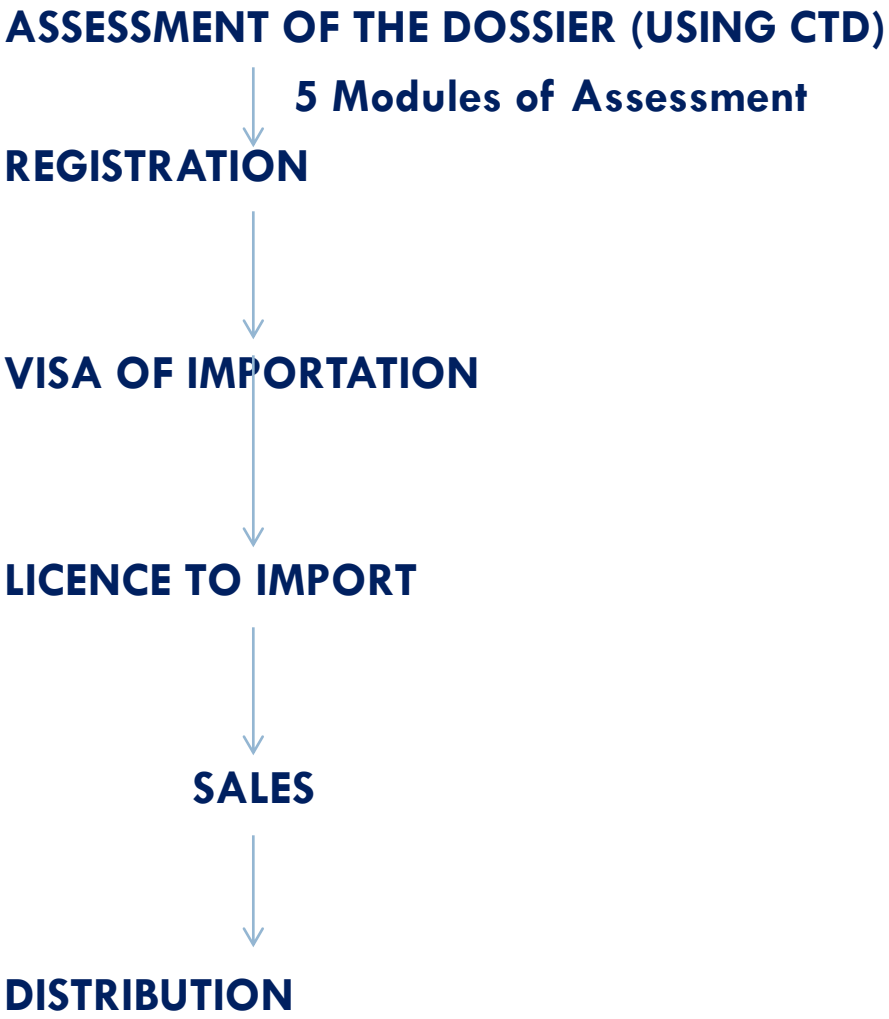
- The Ministry of Health/Pharmacy Task Force (PTF) is responsible for ensuring that medicines distributed in the country are safe, efficacious and of good quality.
- The Law 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products requires for registration of pharmaceutical products and medical devices.
- The Medicine Available in our market need to be safe, effective and assured quality.

What do PTF focus on for regulation and inspection?

- 1. Food Products
- 2. Pharmaceutical Products
- 3. Cosmetics
- 4.Medical Devices
- 5. Exercising Activities related to Pharmaceutical Products and Medical Devices
- 6.Manufacturing ,Import, Export, Storage and Distribution of Items regulated Under this law
- 7. Inspection of Pharmaceutical products
- 8. Advertising


MOH-PTF
REGULATION AND INSPECTION OF FOOD AND PHARMACEUTICAL PRODUCTS
4.MEDICAL DEVICES
5. EXERCISING ACTIVITIES RELATED TO PHARMACEUTICAL PRODUCTS
3.COSMETICS
6.MANUFACTURING ,IMPORT,EXPORT,STORAGE, AND DISTRIBUTION
1.FOOD PRODUCTS
2. PHARMACEUTICAL PRODUCTS
8.ADVERTISING
7.INSPECTION OF PHARMACEUTICAL PRODUCTS

Regulation flow



Objectives

- Effective medicines regulation promotes and protects public health by ensuring that:
  - Medicines are of the required quality ,safety and efficacy
  - Medicines are appropriately manufactured, stored distributed and dispensed.
  - Illegal manufacturing, and trade are detected and adequately sanctioned.
  - Health professional and patients have the necessary information to enable them to use medicines rationally.
  - Promotion and adverting is fair, balanced and aimed at rational drug use.

MoH Approuved Guideline

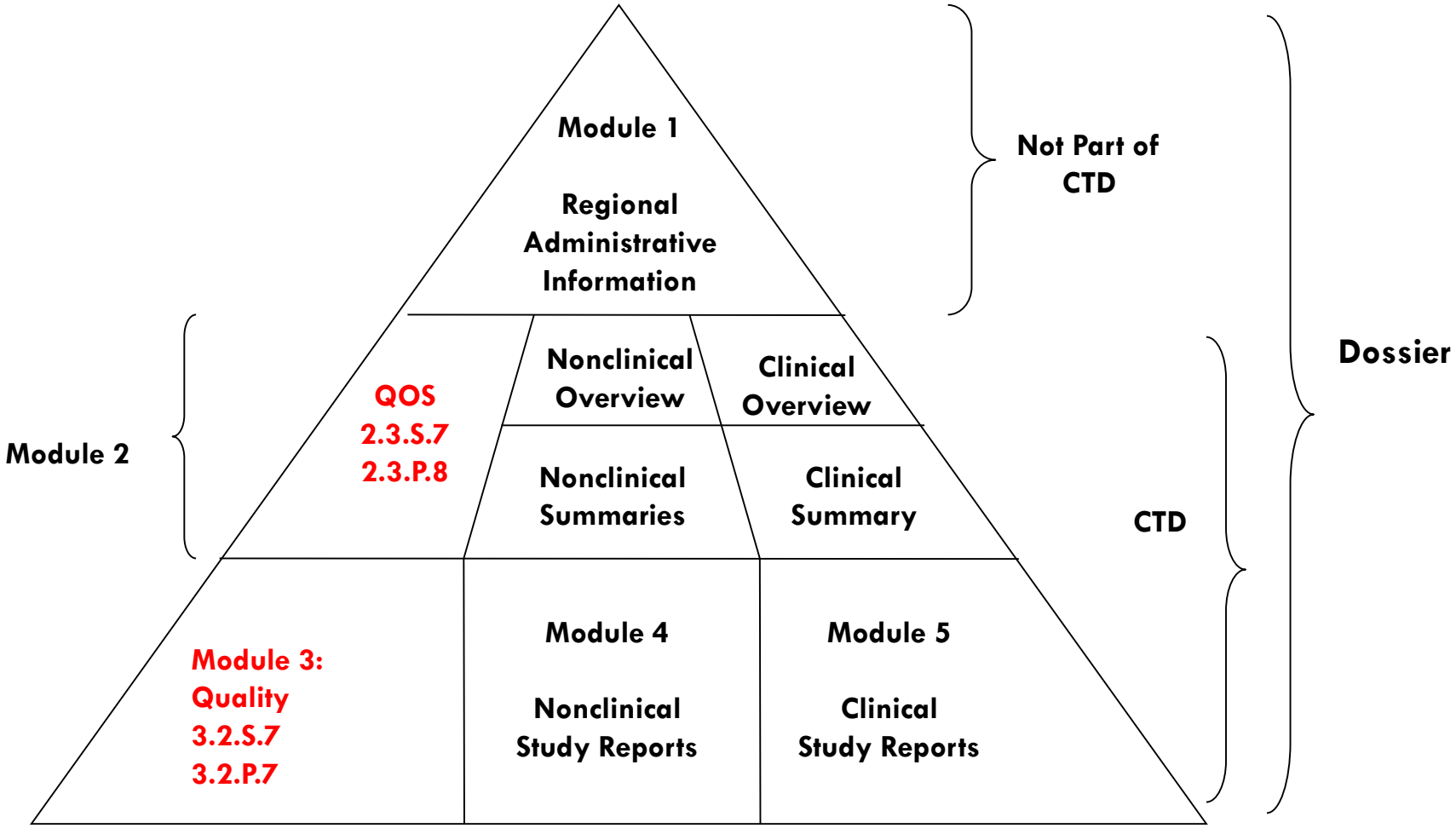
- The guideline of assessment and registration of human pharmaceutical products provide guidance (procedures and requirements) for applicant/manufacturer who want to register their pharmaceutical products.
- The document is called **CTD**= **Common Technical Document** for the Registration of Medicines for Human Use for submission to the MOH.

Assessment of the drug for registration

- The assessment of the new drug in the market is based on the evaluation of the five Module of the applicant dossier referred to the Approved MOH Guidelines .
  - Module 1: Administrative Information and Prescribing Information requirement
  - Module 2: Quality Overall Summaries
  - Module 3: Quality of Pharmaceutical Product
  - Module 4: Non-Clinical Product
  - Module 5: Clinical

  Common Technical Document
  - In every assessed pack, sample of pharmaceutical product must be inside.

Section in the dossier



MOH Guidelines

- Module 1: Administrative information and Product Information (SmPC, Container labelling,PIL Patient Information leaflet, Sample…….)
- Module 2: QOS (Quality Overall Summary: sufficient information from each section to provide the quality assessor an overview of Module 3)

Moh Guidelines

- Module 3: Quality (API and FPP)
  - From the nomenclature, structure, manufacture, manufacturing process, process control,…….. Container closure system, stability of the API.
  - FPP : description, composition, pharmaceutical development, component of the FPP, FPP, manufacturing process development, container closure system,……

CTD

- The general objective of the CTD guidelines is :
  - to provide harmonized medicines registration procedures ---------- improve access to essential medicines for prevention and treatment.
  - Pre-marketing evaluation, marketing authorization/registration and post-marketing review
- The assessment and registration of the drugs contribute to the quality of pharmaceutical products available in the market of our country.
- Ensure also the pharmaceutical products are safe, efficacious and of a good quality.
- Minimize the counterfeit medicine in the market

Assessment of the dossier

- We use many references :
  - Approved MOH Guidelines on submission of documentation for registration of human pharmaceutical products.
  - International Pharmacopeia
  - European Pharmacopeia
  - US Pharmacopeia
  - ICH Guidelines (International Conference on Harmonisation)

Result of assessment of the dossier

- The assessment of the dossier is based on the API (Active Pharmaceutical Ingredient: general information, manufacture, characterization, control of the API, reference standards and stability) and FPP (Final Pharmaceutical Product: description and composition ,pharmaceutical development, manufacture , control of excipient, control of FPP, container-closure system and stability)

- After assessing the applicant dossier using the five modules of the Common Technical Document ,and evaluate the sample given and write the comment and queries in every section for the first assessor, the second assessor verify all the dossier and take the decision if the drug is going to be **registered** or not depending on how the assessment was going on!

Conclusion

- The assessment and registration of the pharmaceutical products ensure the quality, safety and efficacy of the products in the market.
- Pharmaceutical products are a key input for health service delivery in national, district, health center and , health post .