Introduction of OTC Regulations in Taiwan

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Outline

- Background
- OTC drug registration
- OTC monographs
- Rx-to-OTC switch
- Future missions

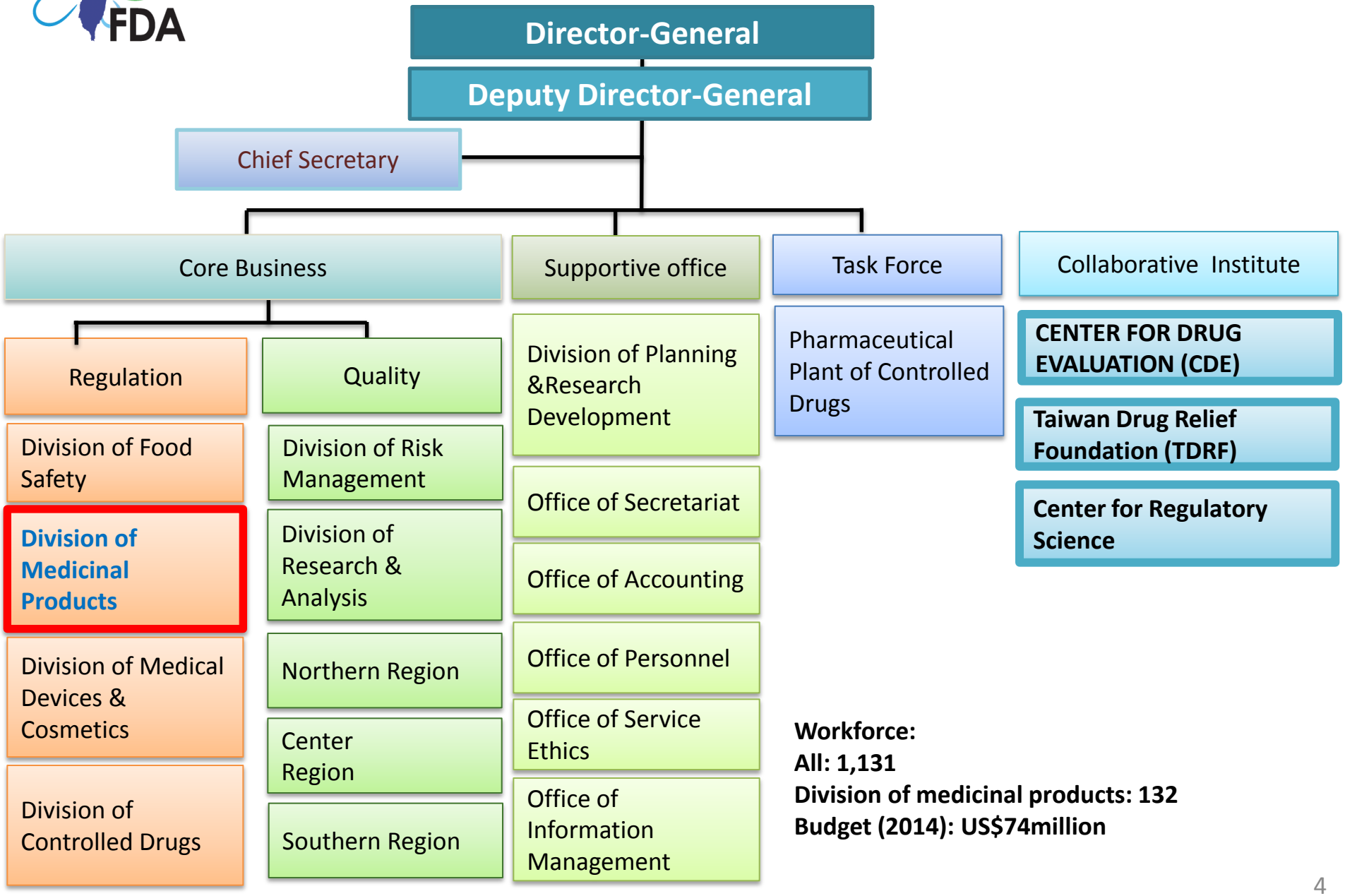
Taiwan Profile

- Area: about 36,000 sq.km.
  (14,400 square miles)
- Capital: Taipei City
- Population: 23 million
- 99.8% Citizen Covered by NHI
  – a Single Payer and Single Database (IC Card)





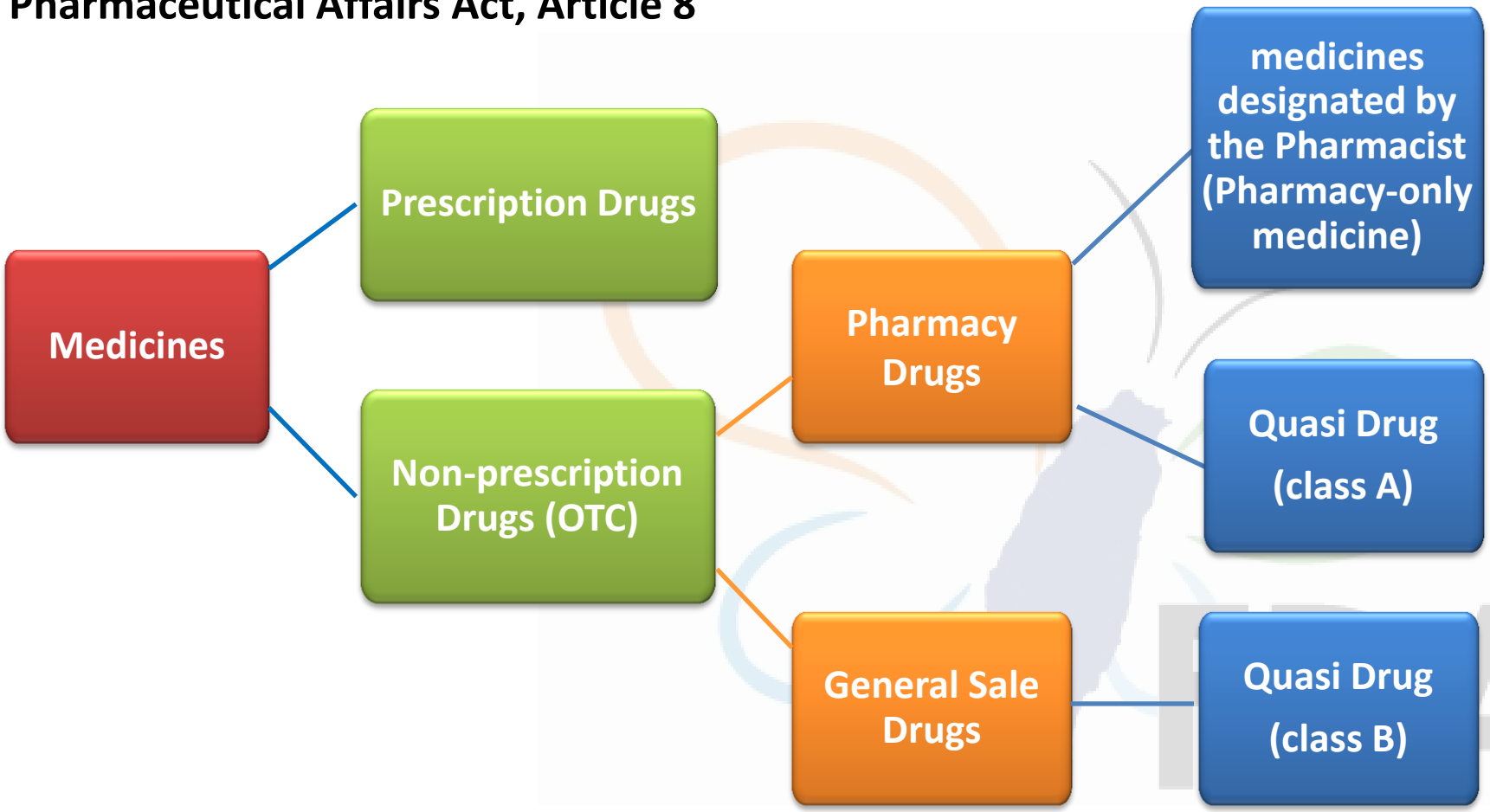
TFDA Organization Chart



Workforce:
All: 1,131
Division of medicinal products: 132
Budget (2014): US$74million

Drug Categories

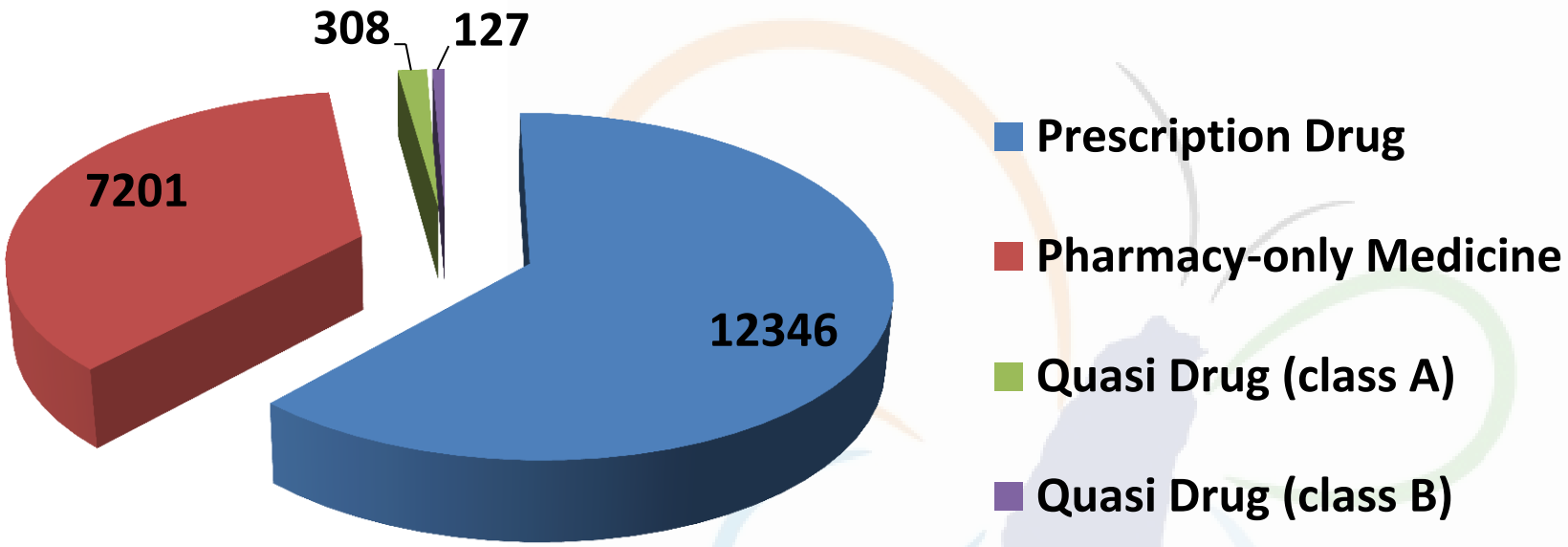
Pharmaceutical Affairs Act, Article 8



Regulations for different drug categories

	Prescription Drugs	Pharmacy only medicine/ Class A Quasi Drugs	Class B Quasi Drugs
Manufacturing/ Import registration			
Pre-approval	v	v	v
Distribution			
Hospital/Clinic	v	v	v
Pharmacy	v	v	v
General sale	x	x	v
Advertisement			
Pre-approval	v	v	v
Mass media	X	v	v

Distribution of Pharmaceutical Licenses



Differences between Non-prescription vs Prescription Drugs

Non-Prescription Drugs	Prescription Drugs
To relieve symptom, prevent life-style diseases and improve/maintain health	To treat disease
Self-medication	Prescribed by physicians
Mostly compound preparations	Mostly single ingredient preparations
Physicians and pharmacists play consulting roles	Prescribed by physicians and prepared by pharmacists
Packaged with varieties and in consumer language	Packaged in professional language

Validation Process in OTC Drug Registration

Belong to any of the 10 categories in OTC monographs?

YES → Validation for OTC monographs

- YES → ➢ Evaluated with similar standards as to generics
  ➢ Formulation basis is not required
  ➢ Labeling has to follow directions in monographs
- NO ↓

NO → Identical to any registered drug in the aspects of ingredients, dosage form, indication and usage, *i.e.* Generics

- YES → ➢ Evaluated with the same standards as for generics
  ➢ Formation basis is required
  ➢ Indications has to be the same as registered products
- NO ↓

New Drugs

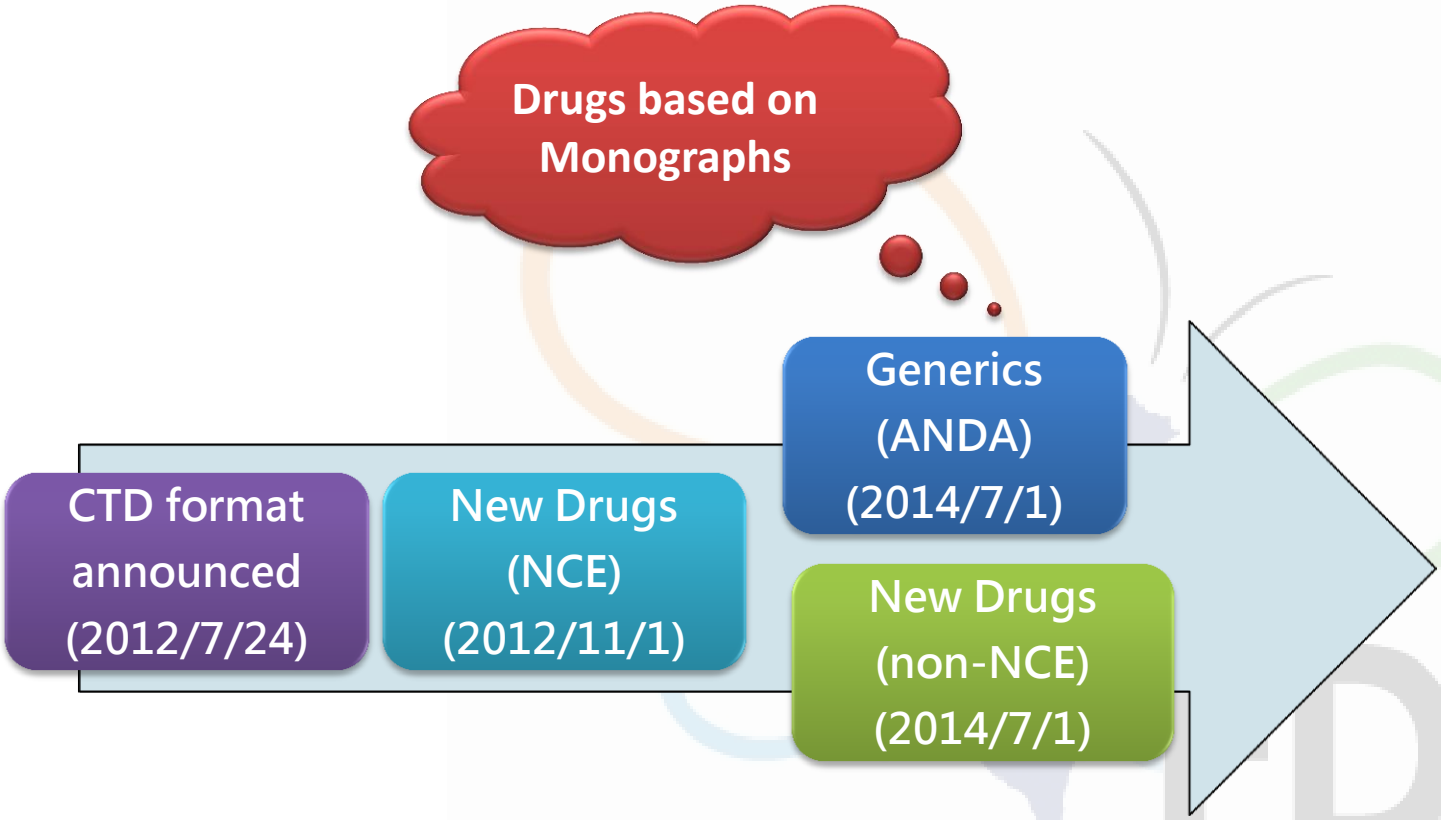
- YES → ➢ Provide complete dossier for new drug registration

Send to expert committee when necessary

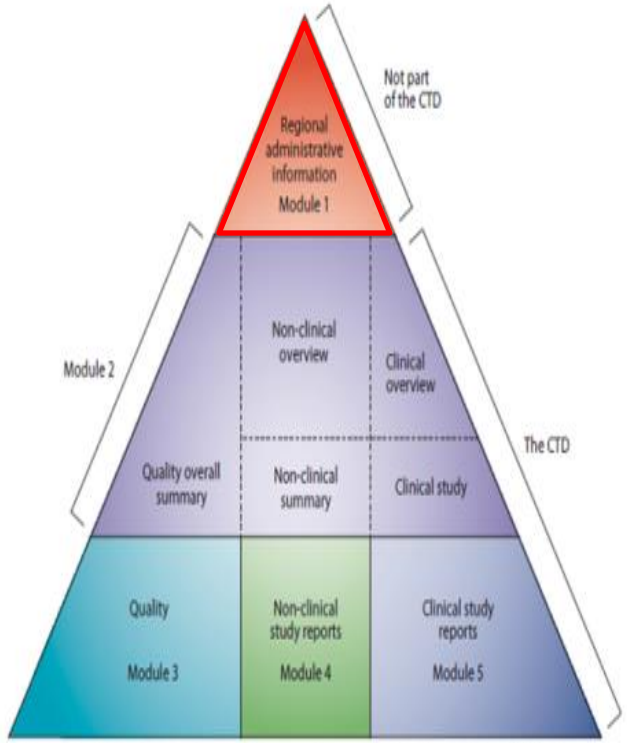
Comparisons in Dossier Preparation

Evaluation	NDA	ANDA	OTC Drug Application
Formulation basis	Not required	Required	Not required
Safety Efficacy	• Pharm / Tox • PK/PD/BA/BE • Clinical trials	• Bioequivalence (BE) as a surrogate to clinical trial	• Bioequivalence (BE) as a surrogate to clinical trial
Quality	• Chemistry, Manufacturing and Controls, CMC • GLP, GCP, cGMP		
Labeling	• Labeling(direction of use)		

Drug Registration Format



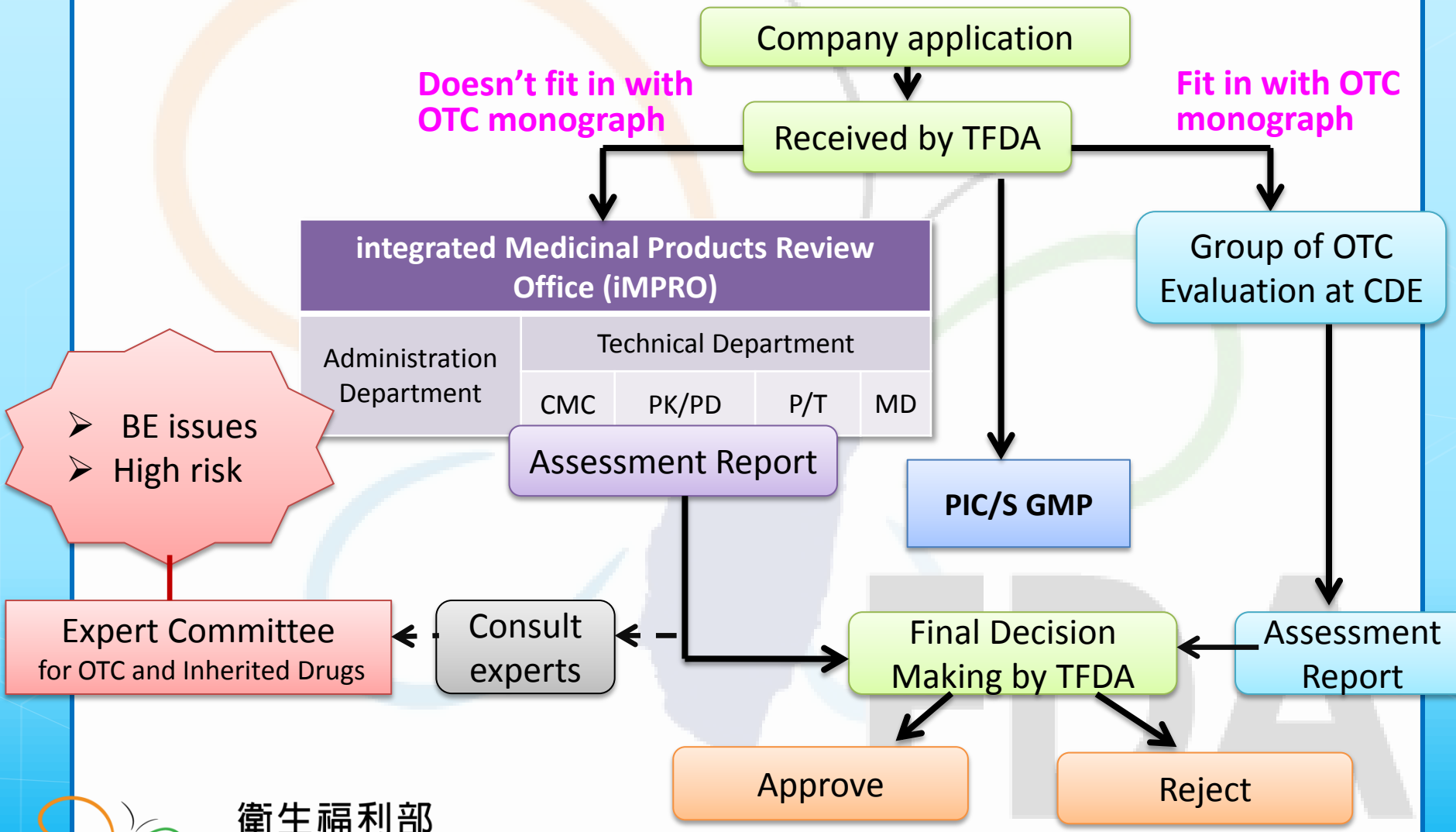
CTD Format



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

Module	Description
Module I Regional Administrative Information	Administrative documents that are required by local agencies
Module 2 Summaries	Summaries of quality, non-clinical and clinical study reports.
Module 3 Quality	CMC information for drug substance and drug product
Module 4 Non-clinical Study Reports	Pharmaco-toxicological data
Module 5 Clinical Study Reports	Data from clinical trials, human PK/PD studies

OTC Registration Process



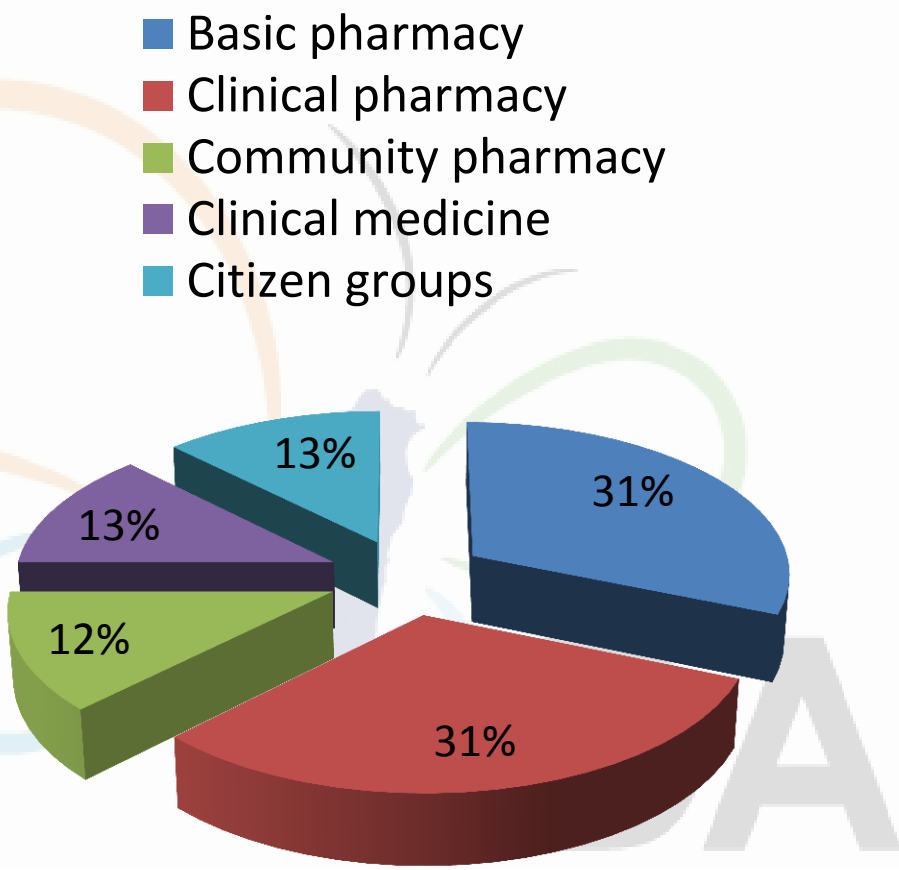
OTC Evaluation Guidelines

- Is there any specific or unique pharmacotoxicity related to this drug category?
- Does the drug have a wide safety margin?
- Is the dosing interval a safety concern?
- Does this drug have a long administration experience?
- Is the safety for high dosage clearly identified?
- Is there complete risk assessment? What is the result?
- Is the study in pharmacodynamics complete?
- Does reference evaluation fully support the administration and labeling in the application?
- Has all the possibilities of drug-drug interaction been fully analyzed?
- What is the Rx-to-OTC experience in other countries?

Expert Committee (Non-prescription drug)

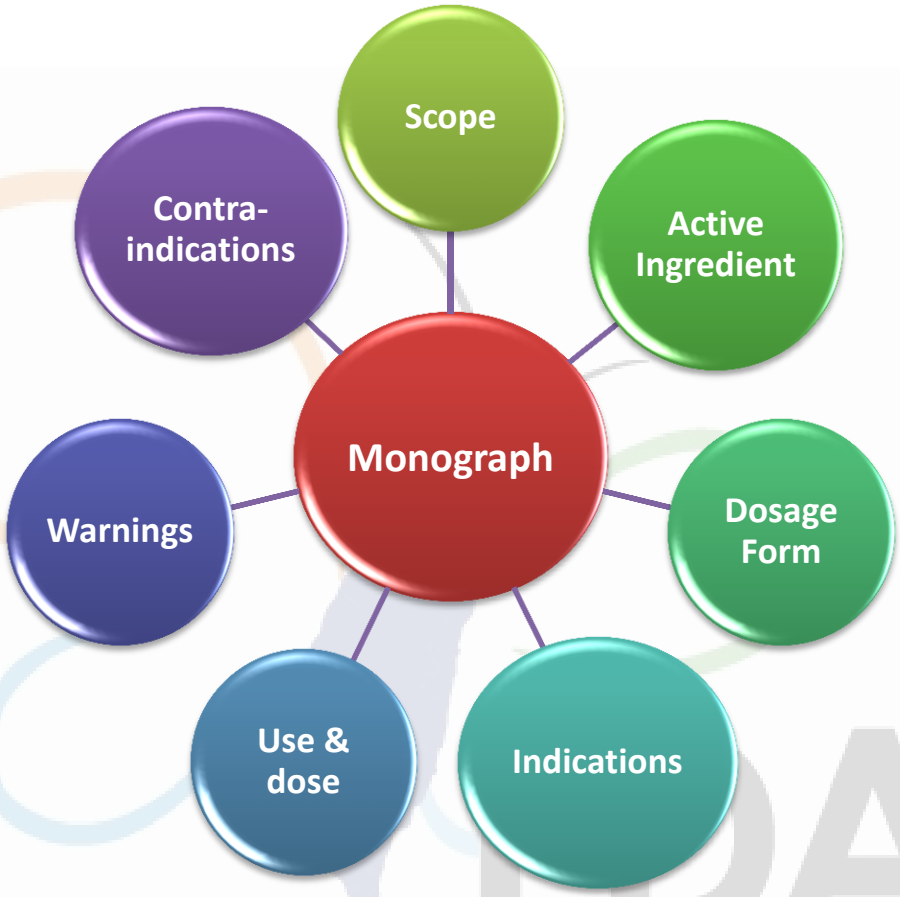
Purpose

- Consultation/suggestions for regulations and standards for non-prescription drugs
- Consultation/suggestions for regulations and standards for high-risk OTC drugs
- Consultation/suggestions for other related issues.



OTC Monographs

- OTC monographs was prepared with assistance from related associations since 1994.
- OTC monographs with 10 categories was published in 4/12/1994.
- Update annually for each categories in the OTC monographs since 2000.
- Taking OTC monographs from Japan as its skeleton and the A10 countries as its content, Taiwan OTC monographs collect ingredients that are mostly administrated in Taiwan.



A10 countries include Germany, US, UK, France, Japan, Switzerland, Canada, Australia, Belgium, and Sweden.

Update for OTC monographs

- **References：**
  - Current OTC monographs and registered drugs
  - OTC monographs, Japan
  - Code of Federal Regulation, USA
  - OTC Directory, UK
  - Regulation in labeling and components, Health Canada
  - TGA regulations
  - World Self-Medication Industry Website
  - Other official formulary (Non-prescription Drugs)

Comparisons for OTC Monographs

	Taiwan	Japan	USA	Canada	Australia
Name	OTC monographs with 10 categories	OTC monographs with 15 categories for pharmacy-only drugs and 11 categories for general-sale drugs	Code of Federal Regulation Title 21	Nonprescription drug labeling standard—27 items	OTC Medicine Monograph—6 items
Evaluation	Evaluated by federal agency, with similar standards as to generics	Evaluated by state agencies	Registration is not required, but OTC drugs will be inspected after marketing	unknown	Evaluated by federal agency, with similar standards as to generics
Category	By therapeutic classes	By therapeutic classes	By therapeutic classes, a few based on specific ingredients	By therapeutic classes, a few based on specific ingredients	Mostly single ingredient preparations
Formula-tion	Mostly compound preparations. Single ingredient preparations for specific categories and ingredients.	Mostly compound preparations with complicated formulations	Compound or single ingredient preparation are decided based on categories. Formulations are relatively simple.	Compound or single ingredient preparation are decided based on categories. Formulations are relatively simple.	Depend on individual ingredient

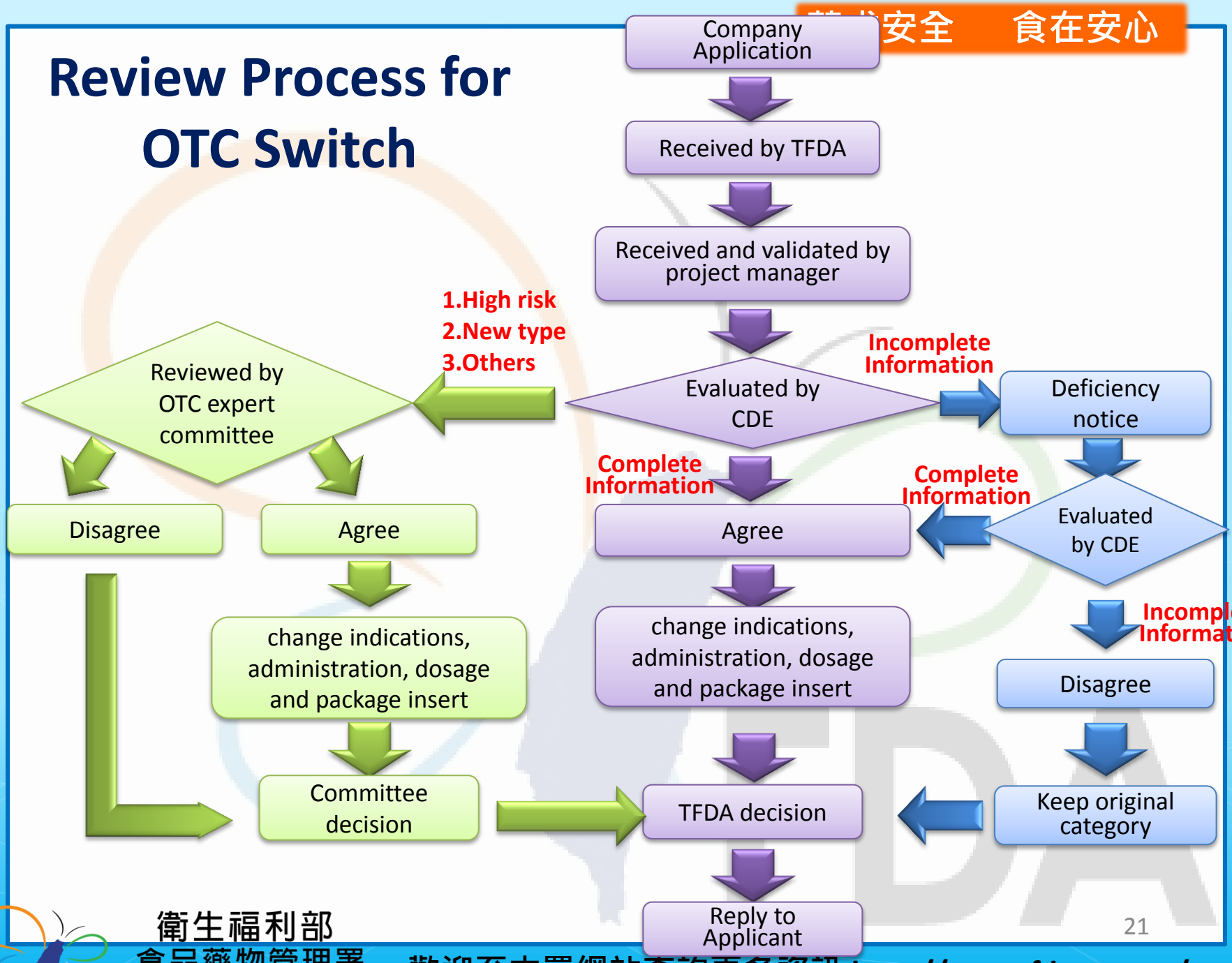
OTC Monographs

- Laxative Medicines
- Antitussive and Expectorants
- Anti-vertigo Medicines
- Antipyretic Analgesics
- Cold Remedies
- Anti-allergy Medicines
- Gastro-intestinal Medicines
- Anti-worming Medicines
- Ophthalmic Medicines
- Dermatological Medicines

Rx-to-OTC Switch

- Points for consideration:
  - Industry may have different needs for drug distribution, commercial or NIH-pricing.
  - Lower impact on prescribing behavior due to OTC switch.
  - Worldwide trend for self-medication.
- Differentiated by indications, and may limit package size if necessary.
- Descriptions on boxes, labels and inserts should be in consumer language in order to make drug information more accessible and understandable to the general public.

Review Process for OTC Switch



Future Missions

Future Cooperation

- Regulatory harmonization
  (1) Information exchange
  (2) Bilateral discussion on regular basis
- Exchange experiences in public education for self-medication

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Thank your for your attention!