

Introduction of OTC Regulations in Taiwan

藥求安全 食在安心

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衛生福利部食品藥物管理署

Food and Drug Administration,
Ministry of Health and Welfare

<http://www.fda.gov.tw/>

Outline

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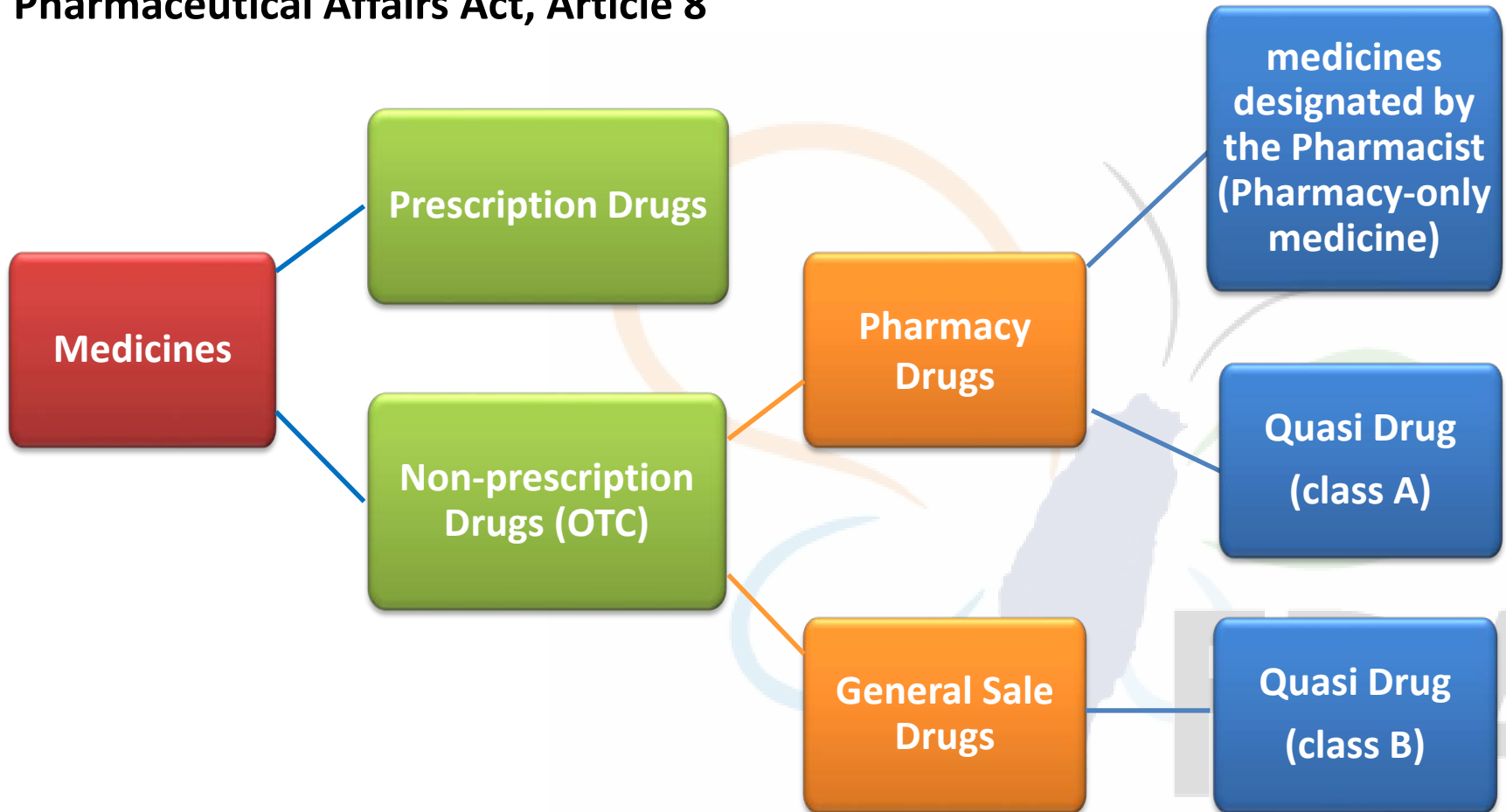
- Background
- Amendments of OTC monographs
- Latest policy on OTC labeling
- Future missions



Drug Categories

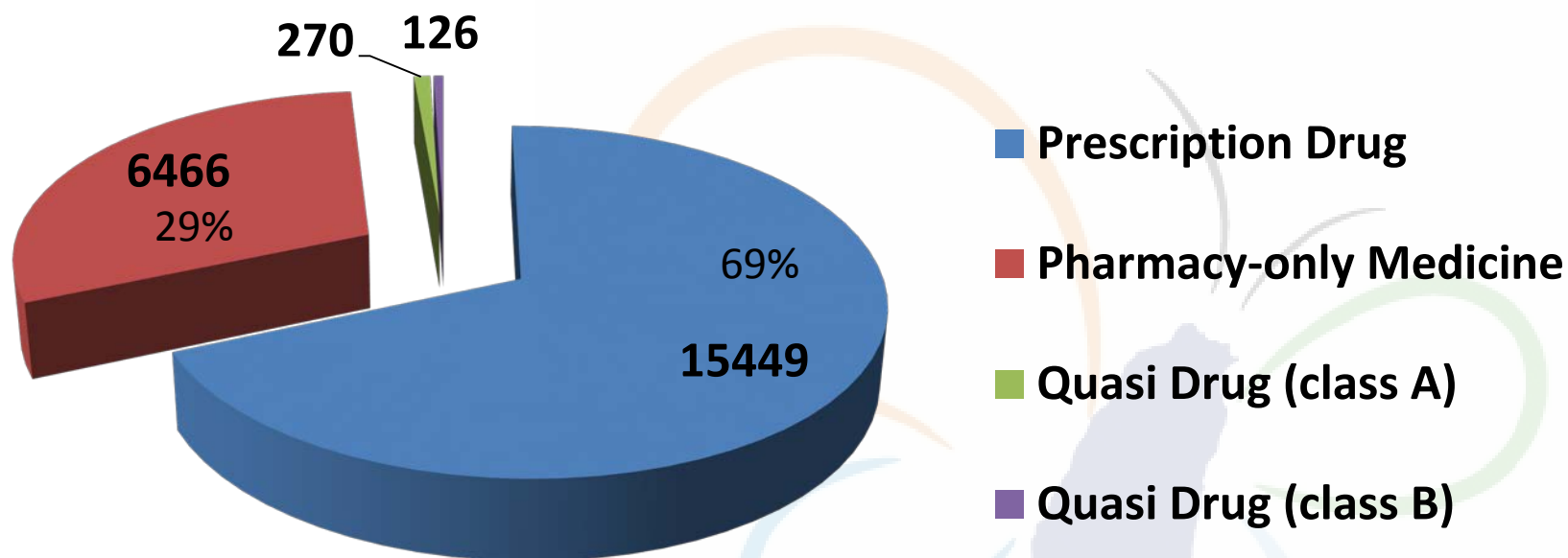
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Pharmaceutical Affairs Act, Article 8



Distribution of Pharmaceutical Licenses

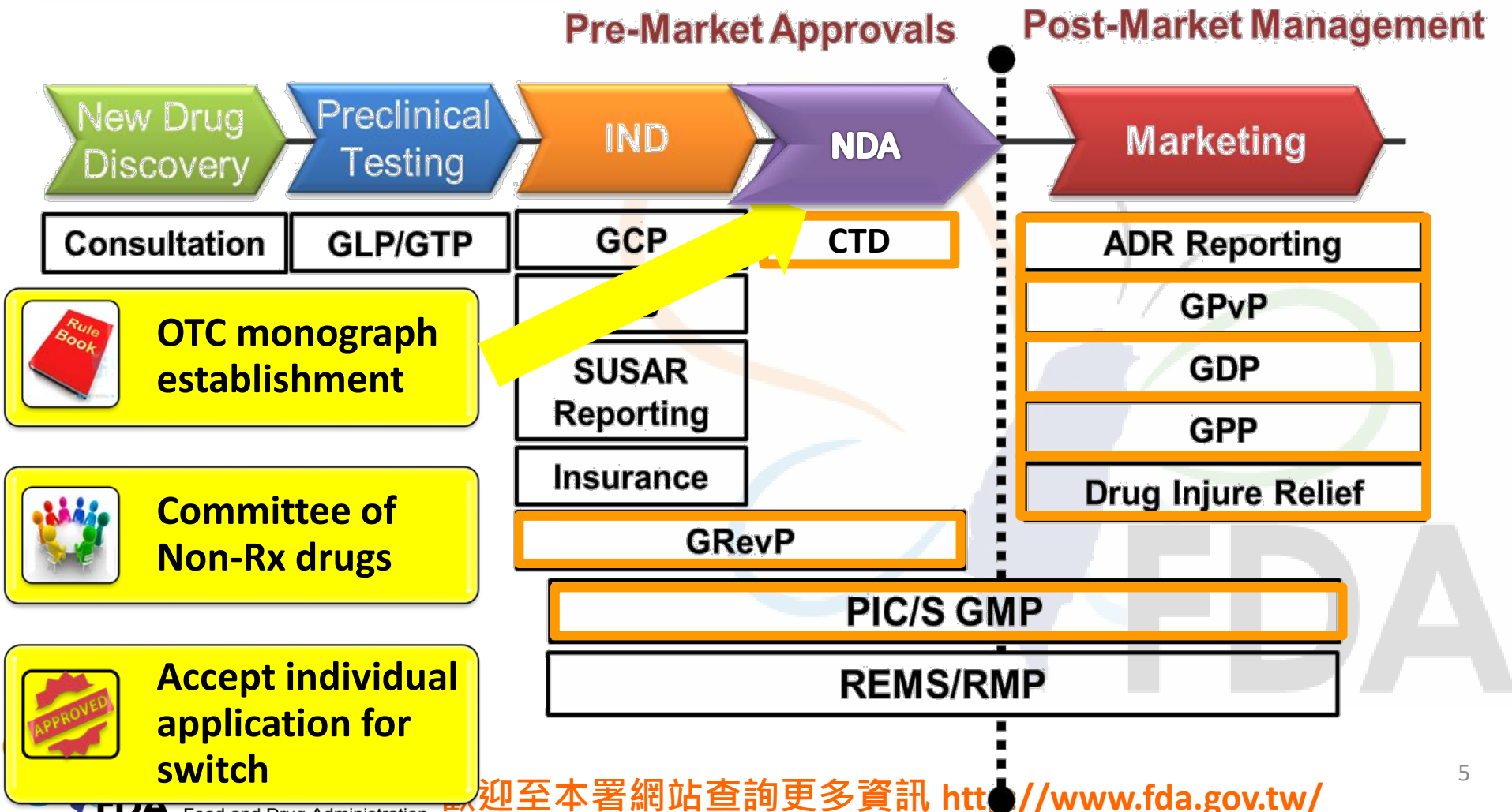
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Pharmaceutical Regulation in Taiwan

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Life cycle management of medicinal products



Comparisons for listing items in monographs

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Listing Items	Taiwan	JAPAN
Scope of category	○	○
Types of active ingredients	○	○
Quantities of active ingredients (including maximum daily doses)	○	○
Dosage forms	○	○
Dosage and administration	○	○
Indications	○	○
Notice and warnings	○	×
Packaging units	×	○

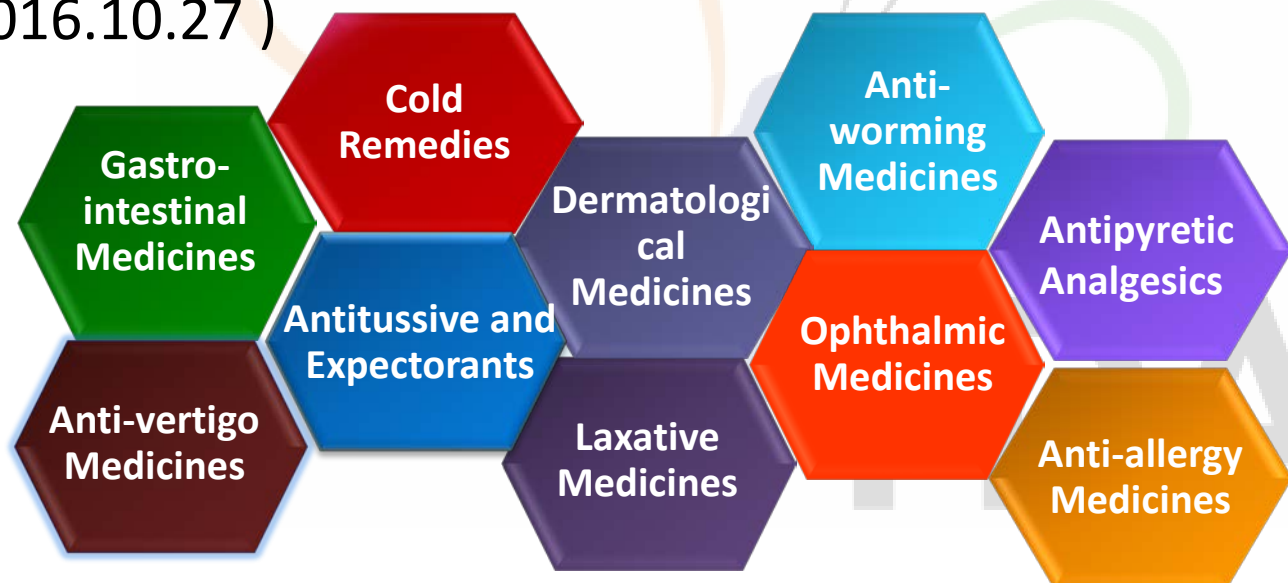
The monograph requesting list including 25 items from Japan part is still in evaluation process.



OTC Monographs

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- **Monograph for Ophthalmic Medicines (2015.08.03)**
- **Monograph for Dermatological Medicines (2016.10.27)**
Removed 8 ingredients : Betamethasone Dipropionate 、 Betamethasone Valerate (0.1% cream & 0.05% lotion) 、 Hydrocortisone Butyrate 、 Hydrocortisone Valerate 、 Triamcinolone Acetonide 、 Desonide 、 Fluocinolone Acetonide
- **All OTC Monograph (Colloquial revision for Precautions & Warnings on 2016.10.27)**



Latest policy for better regulation in non-prescription products in Taiwan



Pharmaceutical Affairs Act

Article 75 (104.12.2)

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The labels, use instructions and packages of medicaments shall indicate the following particulars as approved:

1. Name and address of the manufacturer;
2. Name of the medicament and permit license number;
3. Lot number;
4. Date of manufacture and period of validity or shelf-life;
5. Major ingredients, dosage and method of administration;
6. Major medical efficacy, functions, and indications;
7. Reactions, counter-indications and other warnings; and
8. Other particulars as required by relevant regulations.

The particulars in Subparagraph 4 or the preceding Paragraph may be omitted, if such omission has been publicly announced by the central competent health authority.

For the medicaments announced by the central competent health authority, the labels, use instructions, and packages shall **provide supplementary measures such as Braille characters or other sufficient information** for reading along with the regulations prescribed in Paragraph 1; The indicated items, indicate methods and other requirements shall be established by the central competent health authority.

Format of Package Insert



【Ingredients】

Active Ingredients and amount

Inactive ingredients (excipients)

【Uses (indications)】

【Precautions】

- Do not use if you have
- Ask a doctor before use if you have
- Ask a doctor or pharmacist before use if you are
- others

【Directions】

【Warnings】

- After taking the drug, stops use and consult a doctor or pharmacist if the following symptoms occur
- After taking the drug, stops use and accepts the physician diagnosis and treatment if the following symptoms occur

【Package】

Package Format

Item	【Drug Information】
1	Name and permit license number
2	QR Code
3	Name and address of the manufacturer
4	Lot number
5	Date of manufacture and period of validity or shelf-life
6	Active ingredients (name and amount) Inactive ingredients (excipients)
7	Uses (indications)
8	Limitations
9	Directions
10	Classification
11	Consultation Hotline

QR Code

- Requirements

- * Use durable stickers or printed tags and present in fixed location
- * Print at the lower right corner on the largest space below the opening of the package
- * Use smart phone or any mobile instrument to scan QR Code. The image must be able to be decoded into text recognizable by text-to-speech apps.
- * Provide essential information includes product name , uses (indications), directions, dosage form, consultation hotline and other information

Future Missions





Thank You for Your Attention

Chiang Kai-shek Memorial Hall



Taipei 101



Yehliu Geopark



Sun Moon Lake



North-East coast
of Taiwan



Pingxi Flying Lanterns



Penghu



Night Markets



Temples