

# Harmonization effort for OTC monograph in Taiwan

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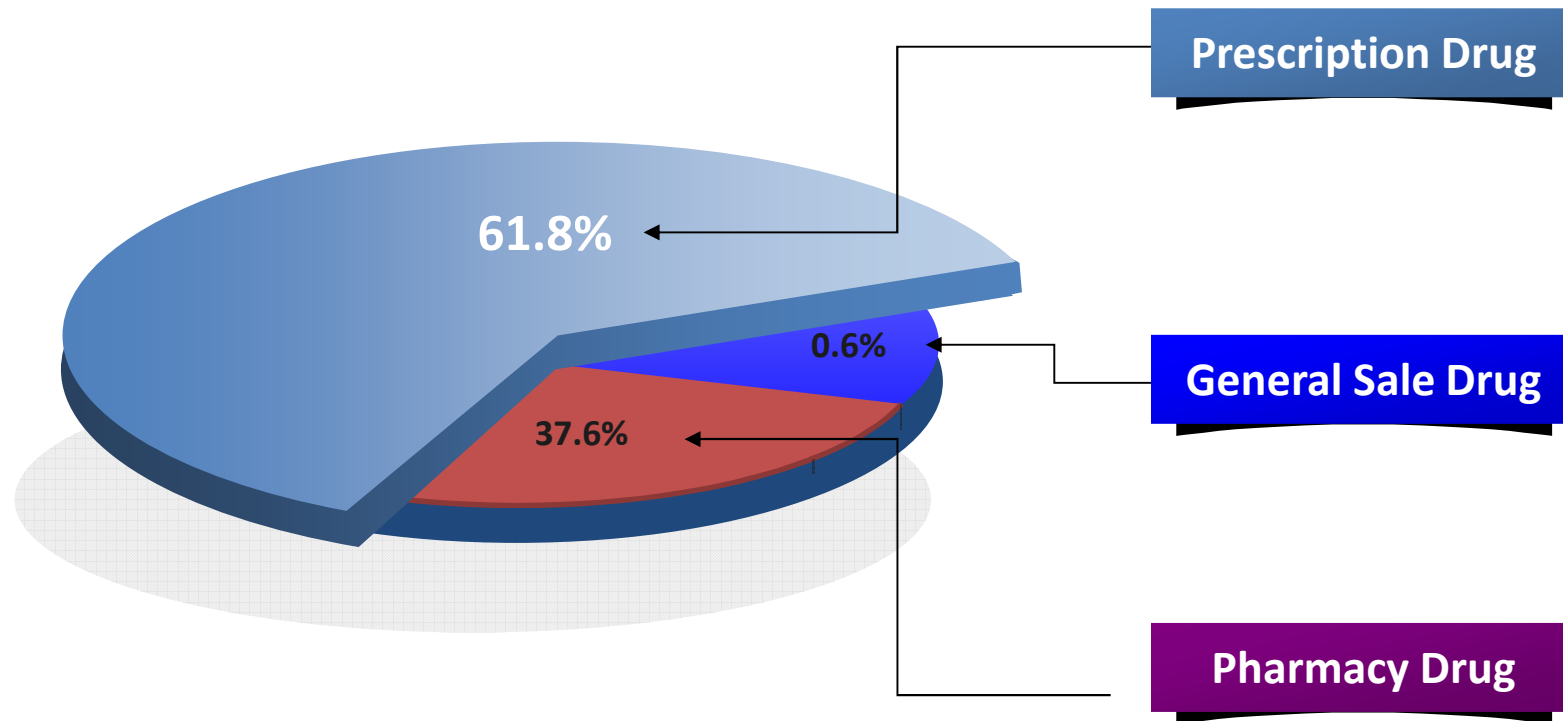
# Outline

- Background
- OTC drug registration
- OTC monographs
- Future directions

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# Distribution of Pharmaceutical Licenses



# Regulations for different drug categories

	Prescription Drugs	Pharmacy Drugs	General Sale Drug
<b>License required</b>	v	v	v
<b>Distribution</b>			
Hospital/Clinic	v	v	v
Pharmacy	v	v	v
General distribution	x	x	v
<b>sold on the Internet</b>	<b>x</b>	<b>x</b>	<b>v</b>
<b>Advertisement</b>			
Pre-approval	v	v	v
Mass media	x	v	v

# Differences between Non-prescription vs Prescription Drugs

## Non-Prescription Drugs

- To relieve symptom, prevent life-style diseases and improve/maintain health
- Mostly combination active ingredient products
- Physicians and pharmacists play consulting roles
- Packaged with varieties and in Layman language



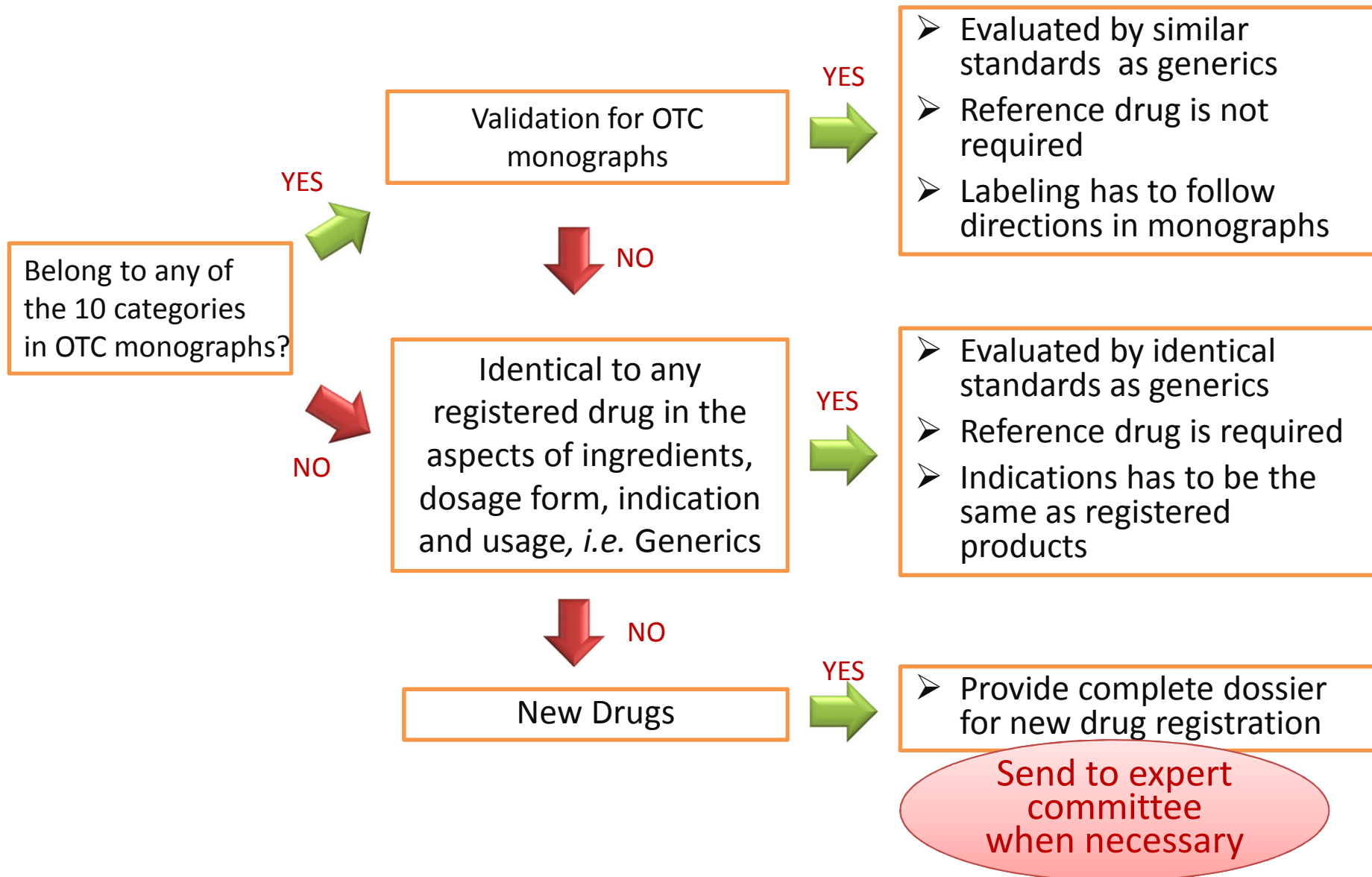
## Prescription Drugs.

- To treat disease
- Prescribed by physicians
- Mostly single active ingredient products
- Mostly single ingredient preparations
- Packaged in professional language

# Outline

- Background
- **OTC drug registration**
- OTC monographs
- Future directions

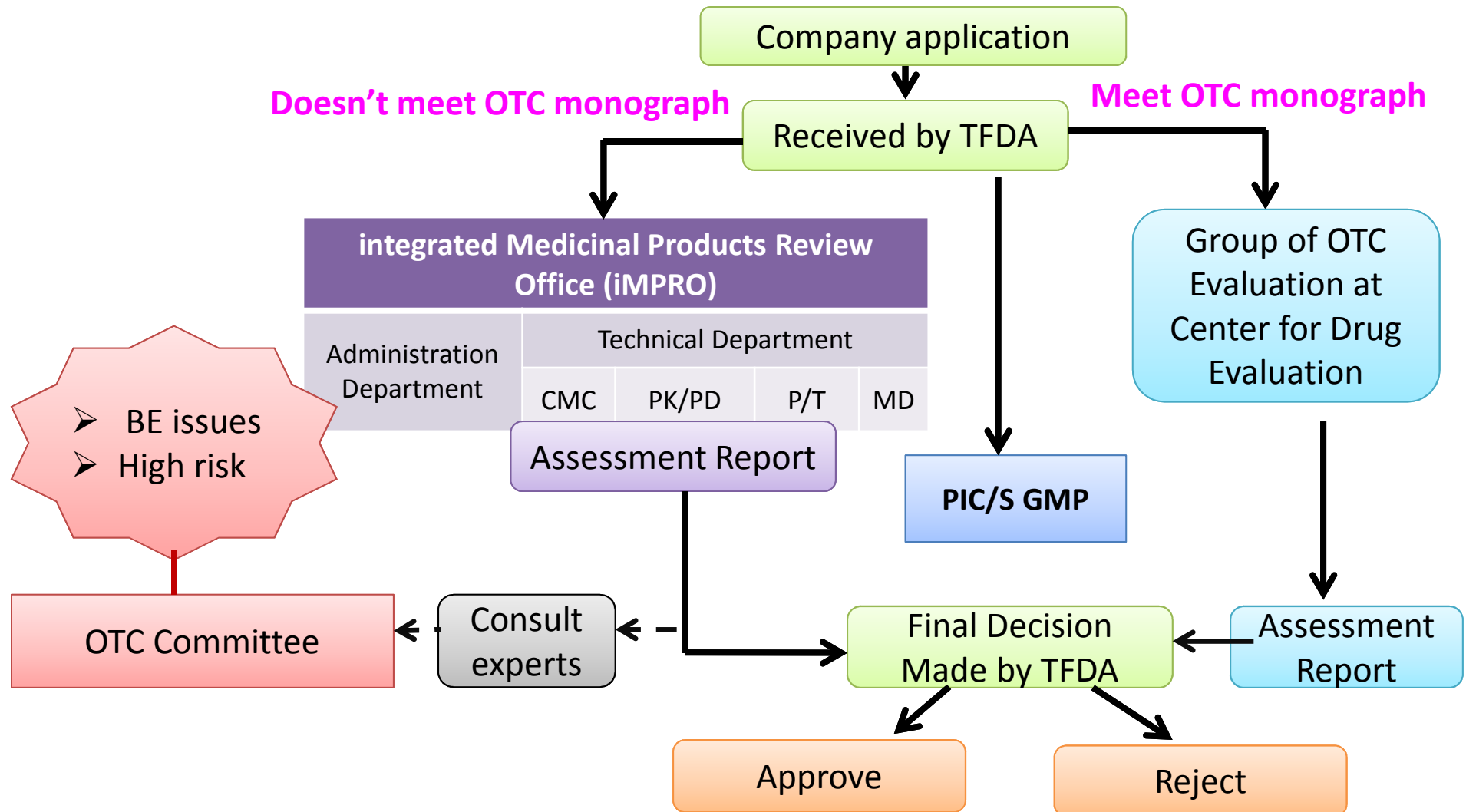
# Review Process in OTC Drug Registration



# Dossier Requirement

Evaluation	NDA	ANDA	OTC Monograph Drug Application
Reference drug	Not required	Required	Complied with Monograph
Safety Efficacy	<ul style="list-style-type: none"> <li>Pharm / Tox</li> <li>PK/PD/BA/BE</li> <li>Clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Bioequivalence (BE) as a surrogate to clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Bioequivalence (BE) requirement may be needed in special cases</li> </ul>
Quality	<ul style="list-style-type: none"> <li>Chemistry, Manufacturing and Controls(CMC)</li> <li>PIC/s GMP</li> <li>GLP, GCP</li> </ul>		
Labeling	<ul style="list-style-type: none"> <li>Labeling(direction of use )</li> </ul>		

# OTC Registration Process



# Outline

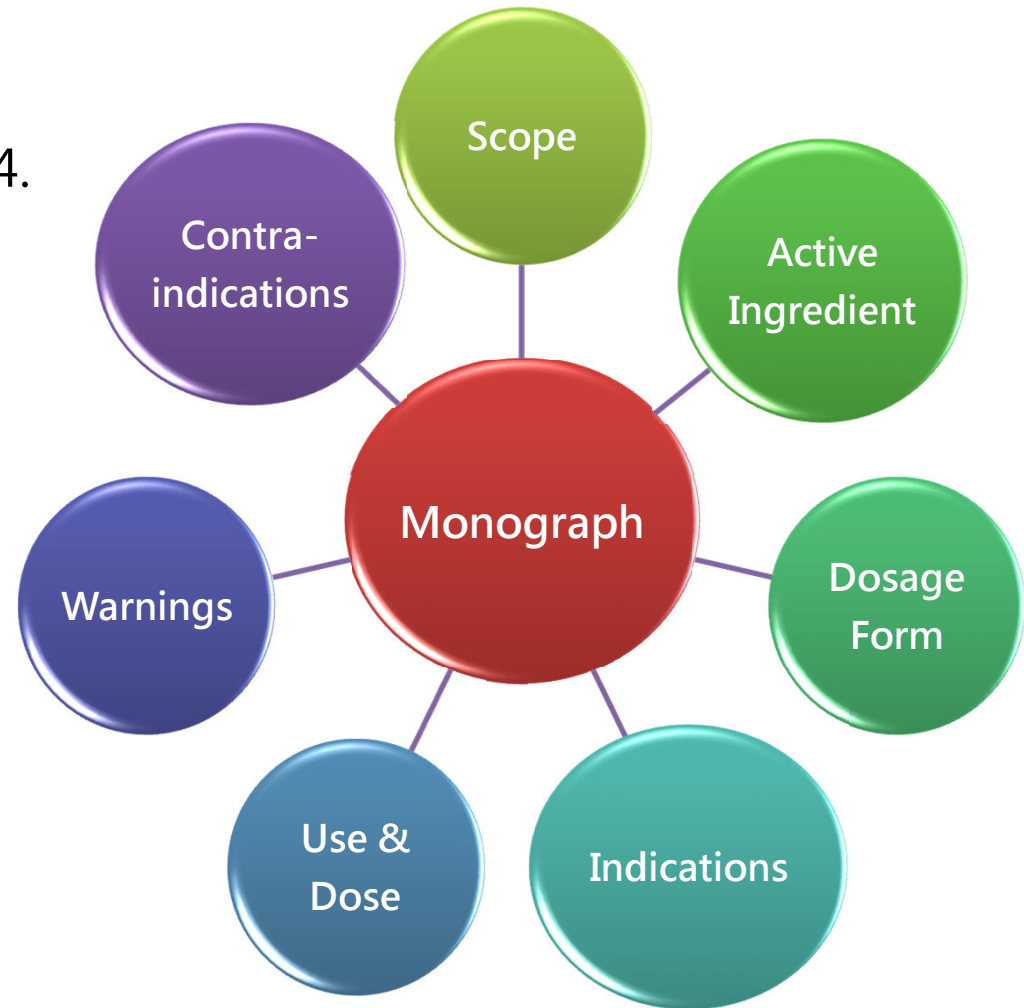
- Background
- OTC drug registration
- **OTC monographs**
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# Comparisons for OTC Monographs

	Taiwan	Japan	USA	Australia
<b>Category</b>	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—7 categories	OTC Medicine Monograph—14 categories
<b>Evaluation</b>	Evaluated by TFDA, with similar standards as generics	Evaluated by local agencies	Registration is not required, but OTC drugs will be inspected after marketing	Evaluated by federal agency, with similar standards as generics
<b>Classification</b>	By therapeutic classes	By therapeutic classes	By therapeutic classes, a few based on specific ingredients	By therapeutic classes
<b>Formulation</b>	Mostly combination active ingredient products. Single active ingredient products for specific categories.	Mostly combination active ingredient products with complicated formulations	Combination or Single active ingredient products are decided based on categories. Formulations are relatively simple.	Depend on individual ingredient

# 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 marketed in Taiwan.



# Update for OTC monographs

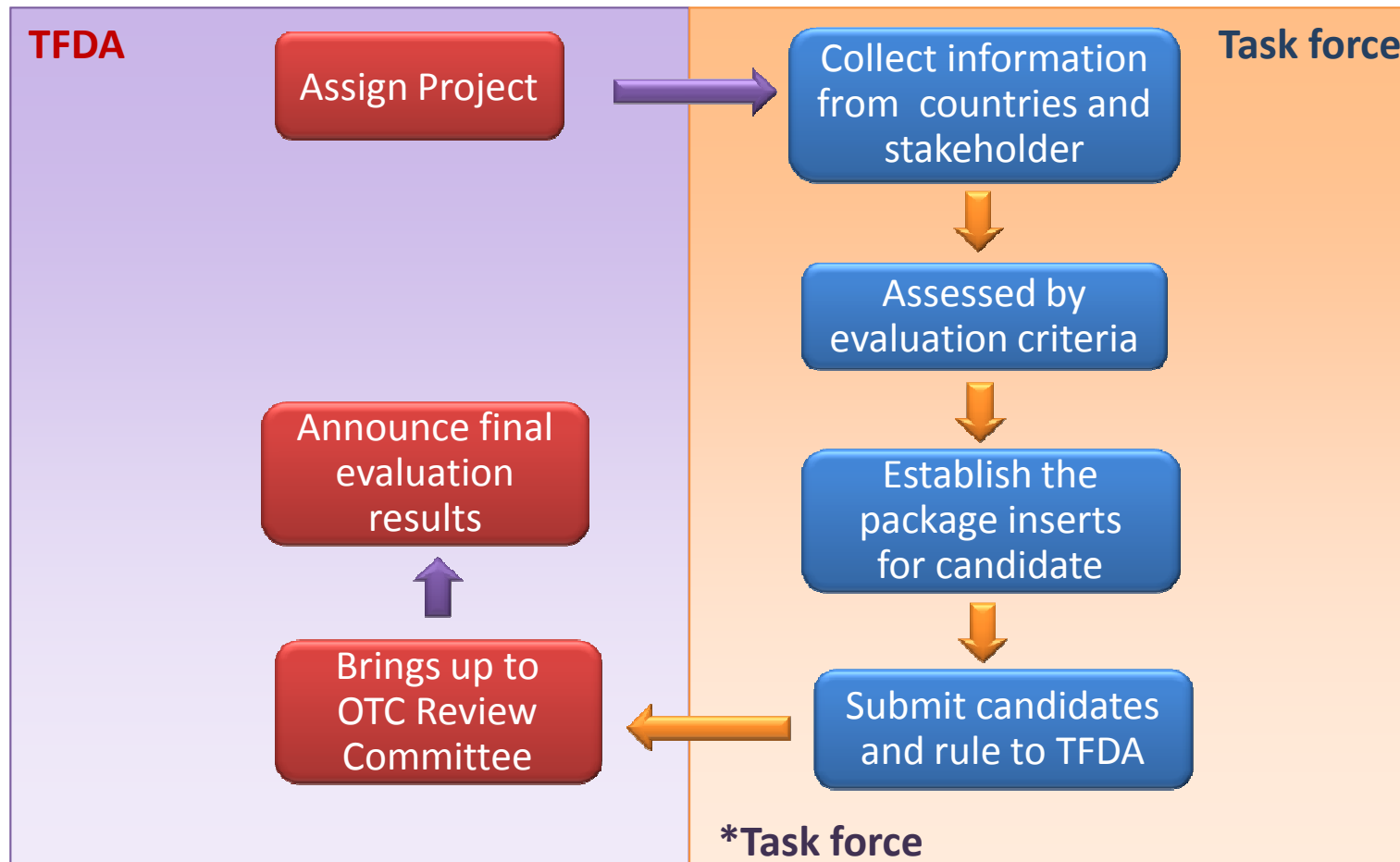


## Market demand and recommendations from OTC Committee

- **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
- Therapeutic Goods Administration (TGA) regulations
- Association of the European Self-Medication Industry (AESGP) website
- Other official formulary (Non-prescription Drugs)

# Update for OTC monographs



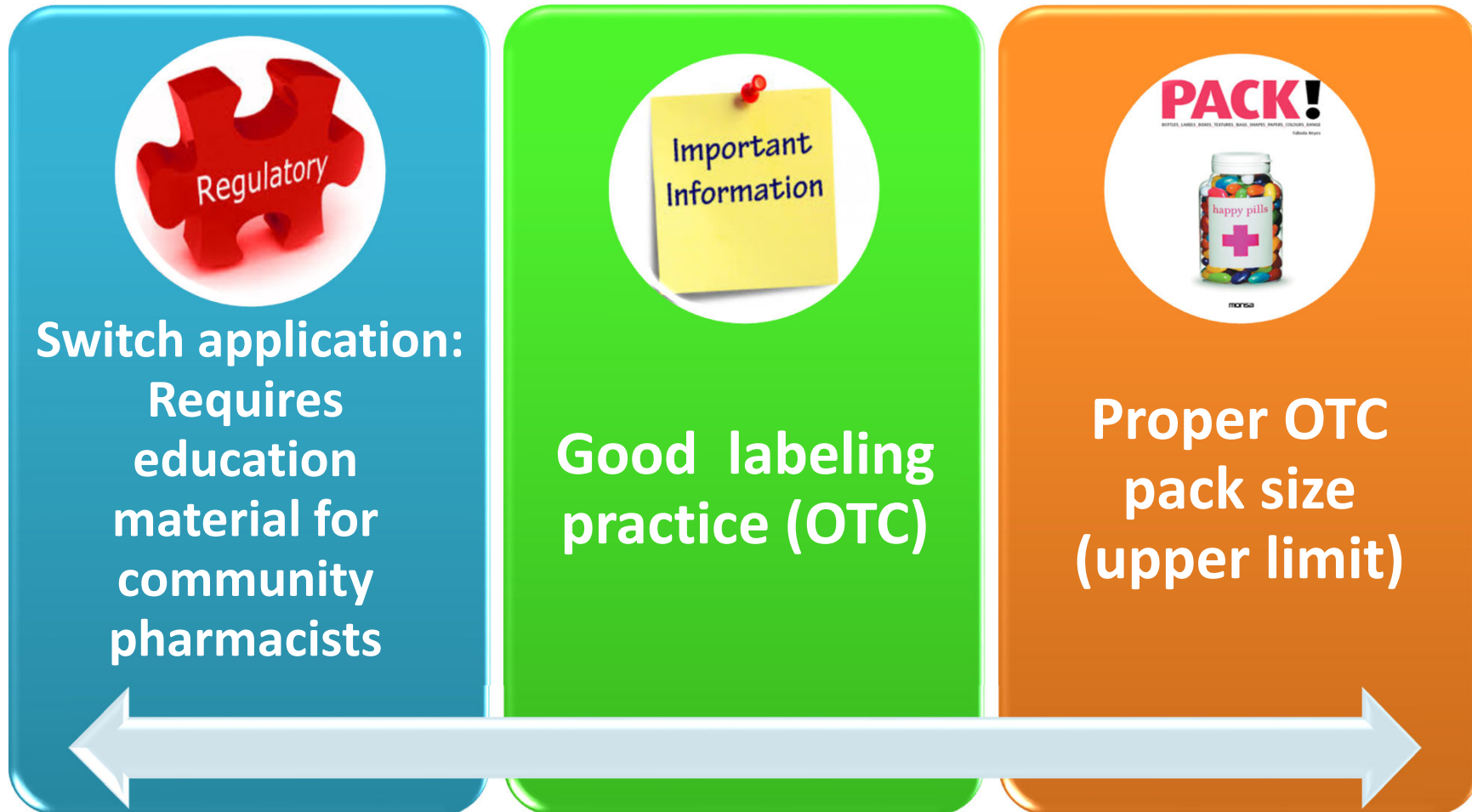
\*Task force

(Industry+ Regulators+ Pharmacist association)

# 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

# Continue efforts in OTC Product registration



# Continue efforts in pharmaceutical care



**Continue  
efforts in  
GPP**



**Strengthen  
pharmacist  
consultation  
for the public**



**Public  
education**



# Monograph for Antipyretic Analgesics

- The scope of preparations subject to these standards covers oral medicines and suppositories intended to alleviate pain or fever.

# Active ingredient listed in the Approval Standard

Classification		Active Ingredient	Maximum single dose(mg)		Maximum daily dose(mg)	
			Group I	Group II	Group I	Group II
Column A	1	Acetaminophen	325	1000 (500) *	1600	4000
	2	Aspirin	500	1000 (500) *	1600	4000
	3	Ethenzamide	500	-	1500	-
	4	Salicylamide	325	-	1600	-
Column B	1	Caffeine	120		300	
	2	Caffeine Anhydrous	120		300	

# Active ingredient listed in the Approval Standard

Classification	Active Ingredient	Maximum daily dose(mg)
Column C	1 Vitamin B <sub>2</sub> , its derivatives, and their salts	1.8-30
	2 Vitamin B <sub>2</sub> , its derivatives, and their salts	2.25-10
	3 Vitamin C, its derivatives, and their salts	82.5-500

Classification	Active Ingredient	Maximum daily dose(g)	
		Extract	Powder
Column D	Glycyrrhizae radix	5	1.5
	Cinnamomi cortex	5	1
	Zingiberis rhizoma	3	1
	Paeoniae radix	5	2

- **Active Ingredients**

- Group I preparation : In Column A, at least one active ingredient, and do not contain up to three active ingredients.
- Group II preparation : In Column A1 or A2, at least one active ingredient and do not contain up to two active ingredients.
- Other rules of combination and quantity are described for each classifications.

- **Dosage Forms**

- The dosage forms should be tablets, film-coated tablet, sugar-coated tablet, capsules, soft capsules, oral solution, suspension, syrups, powders and granules.
- If medicines contain the salicylate ingredient could be manufactured to enteric dosage form.
- Single ingredient medicines of Acetaminophen, Aspirin or Salicylamide could be manufactured to suppository.

- **Indications**

- Relief fever and pain (headache, toothache, sore throat, joint pain, muscular pain, menstrual pain, neuralgia).

- **Directions**

- Group I preparation : take medication if needed or with fever , and if symptoms are continuous, take the medicine every 4 to 6 hours, do not take more than 4 times in 24 hours.
- Group II preparation : take medication if needed or with fever , and if symptoms are continuous , take ○~  
○ tablets (units) with 4-6 interval period between dose, not more than ○ times in 24 hours. Use the minimum of dosage at the beginning.

Age group	Coefficient
12 years old and over	1
6- under 12 years old	1/2
3- under 6 years old	1/4
Under 3 years old	Diagnosis and treatment by a physician



Products



Healthcare



**Thank you for your attention!**