

Regulation of Boundary Products in Taiwan

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**Section of Generic Drugs
Division of Medicinal Products**



衛 生 福 利 部
食 品 藥 物 管 理 署
Food and Drug Administration

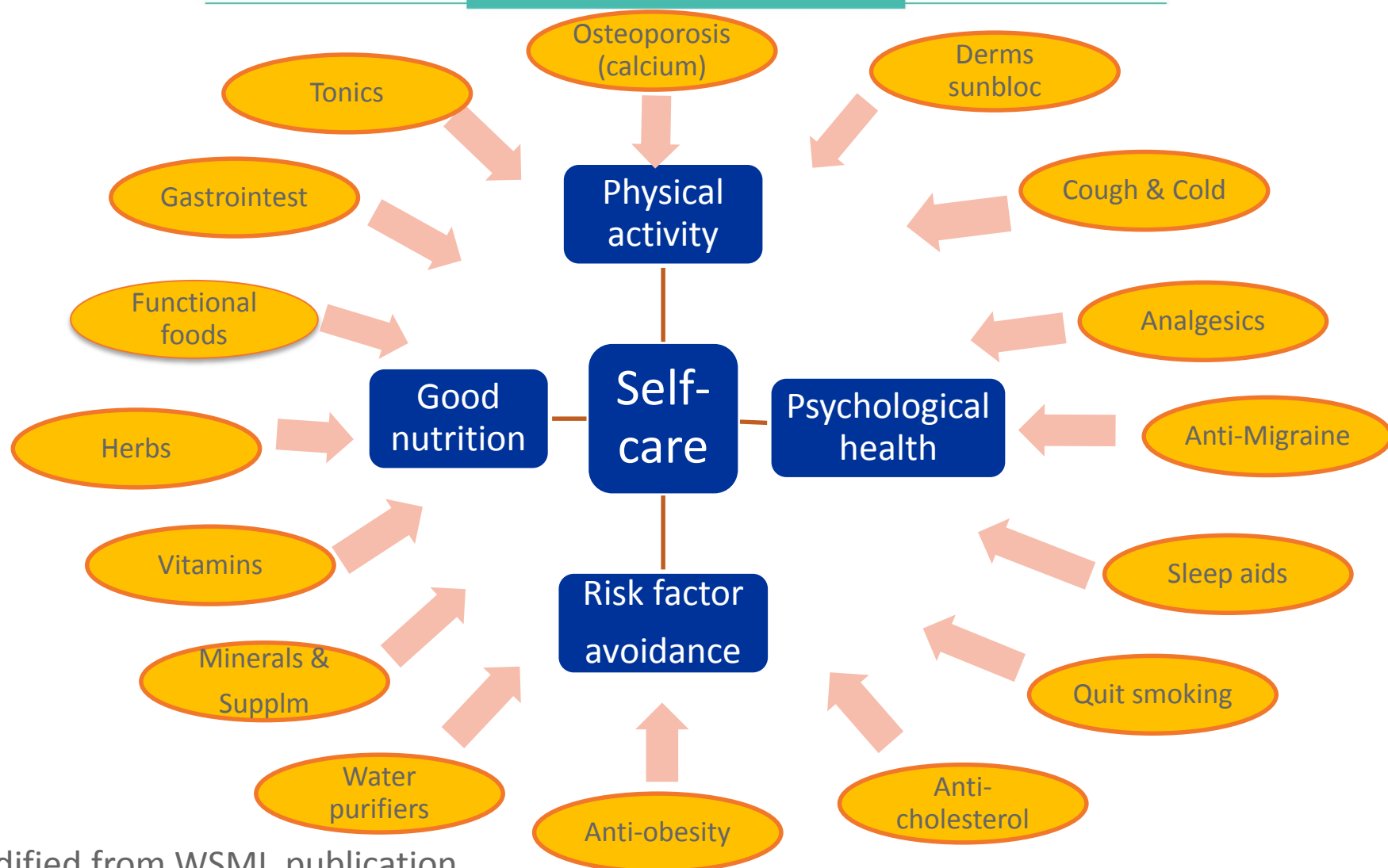
<http://www.fda.gov.tw/>

Taiwan Profile

- Population: 23.4 million
- Area: about 36,000 sq.km.
(14,400 sq. m.)
- Capital: Taipei City
- 99.8% citizen covered by NHI
 - A single payer national health insurance system
- Pharmaceutical market:
 - US\$ 5.6 billion in 2016
 - Aging population

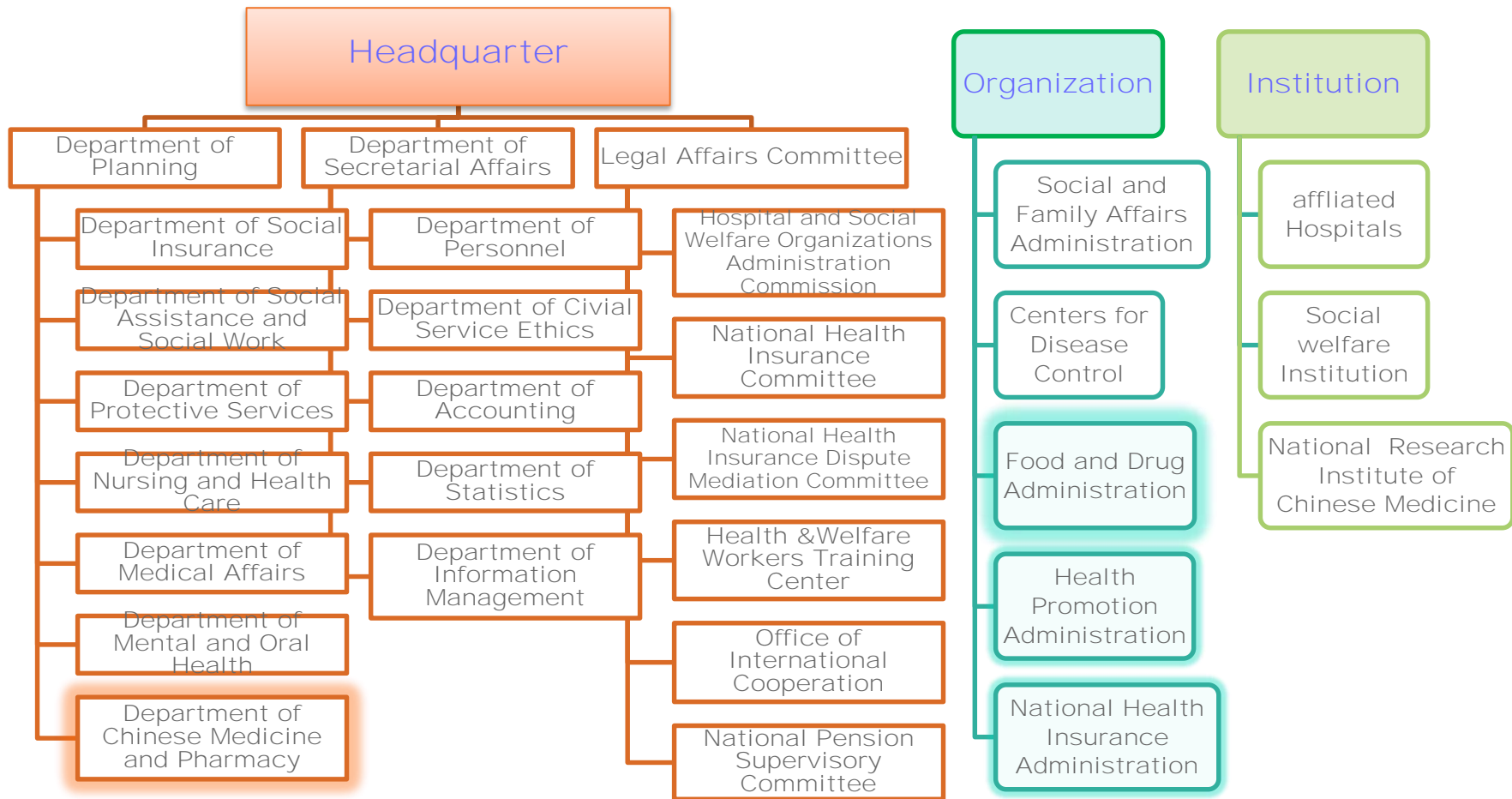


Nonprescription Products are Tools

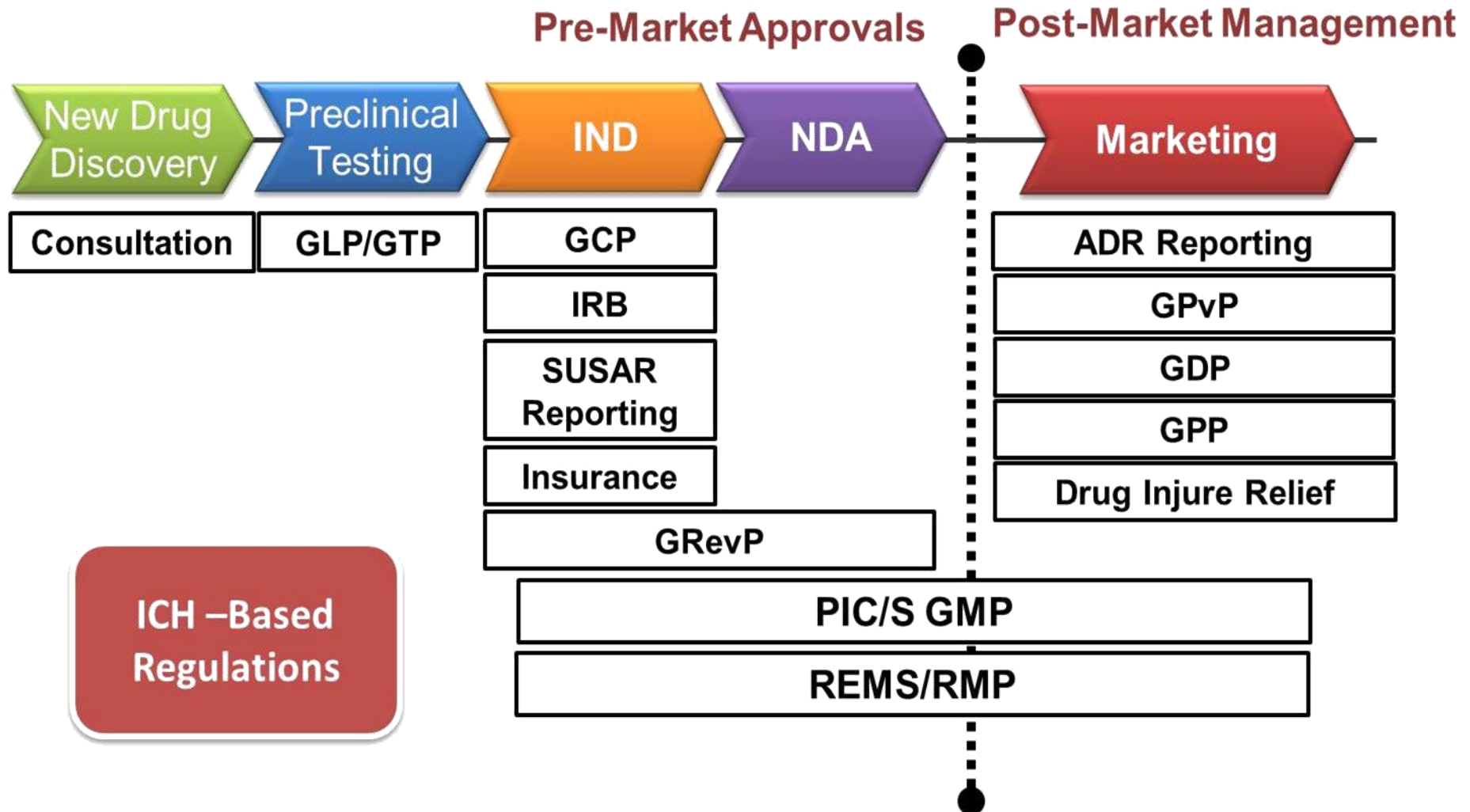


Modified from WSMI publication
Better regulation of nonprescription medicine

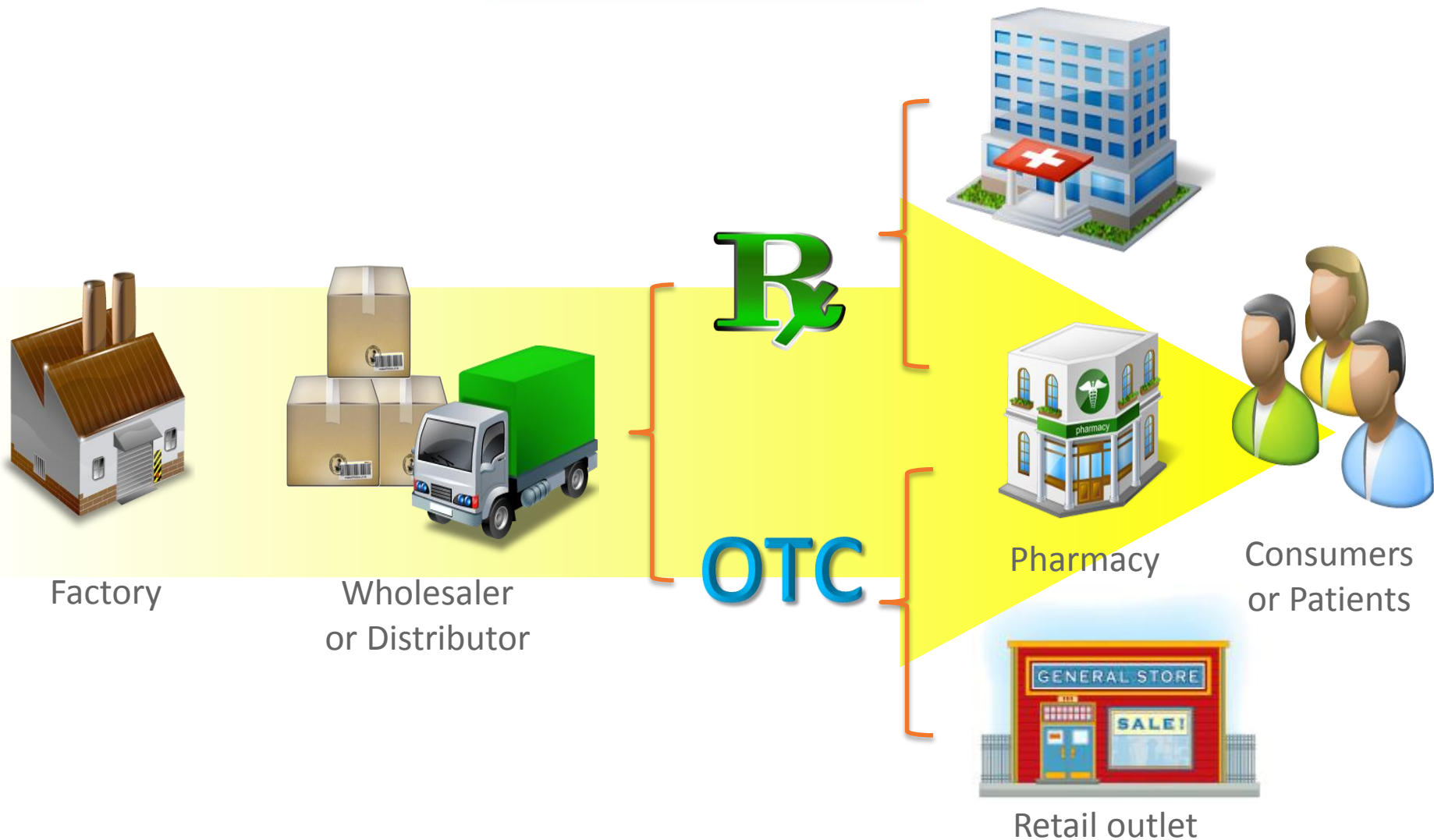
Ministry of Health and Welfare (MOHW) Organization Chart



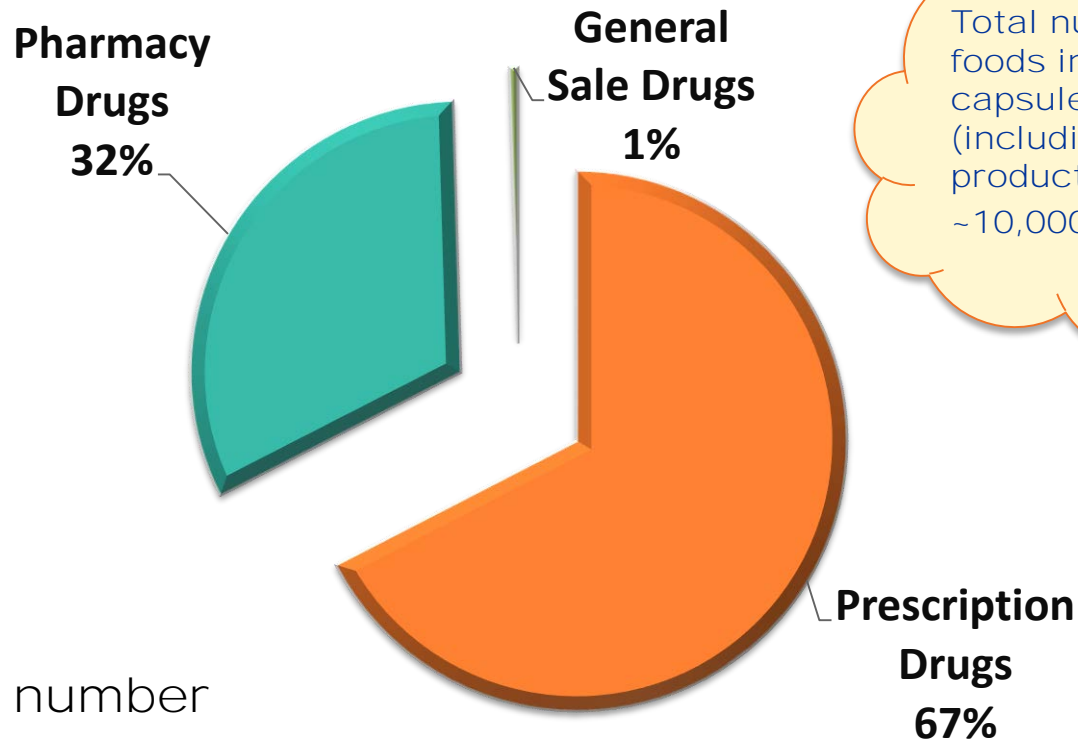
Life Cycle Management of Medicinal Products



Classification and Retail Distribution



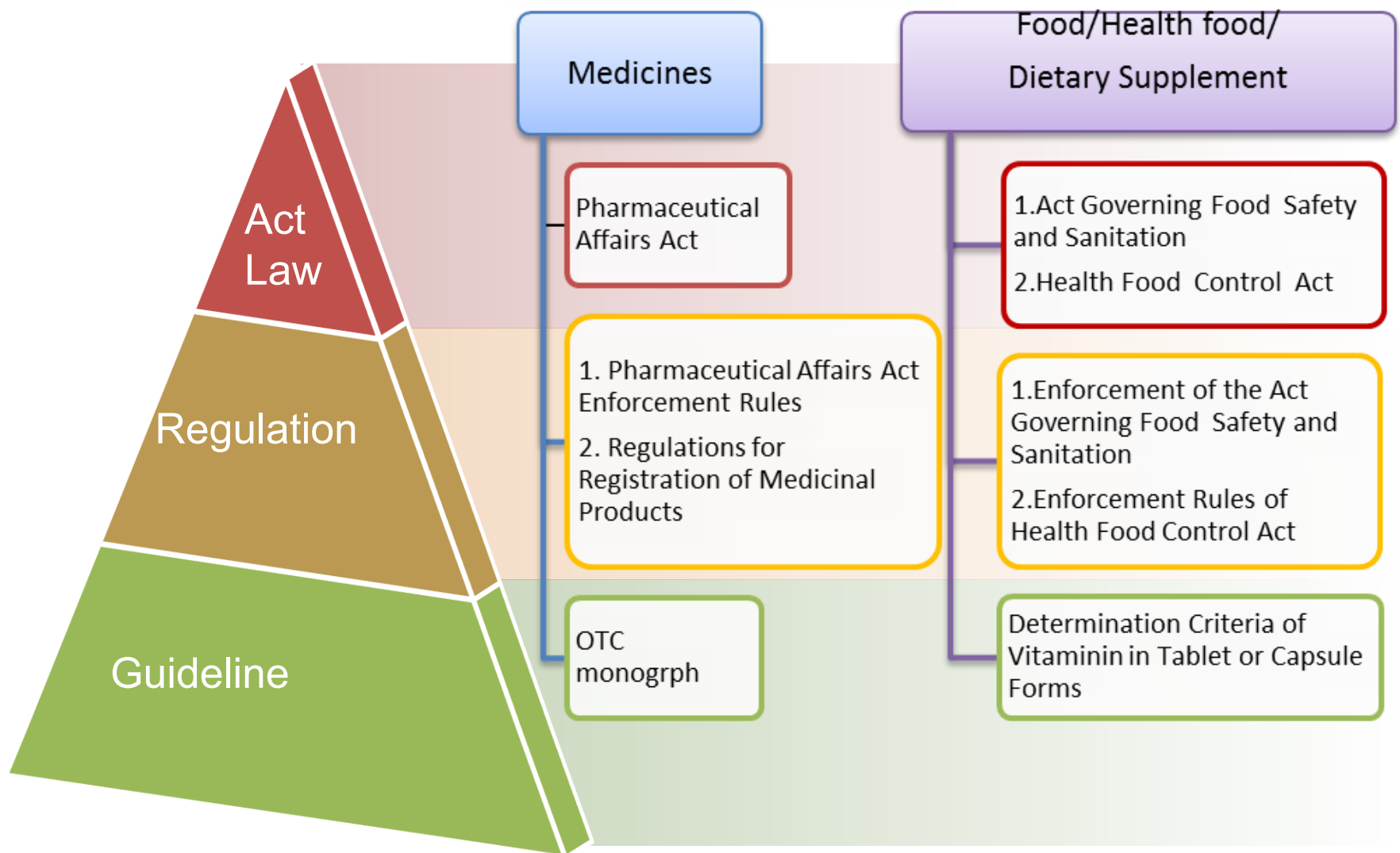
Distribution Chart of Drug Licenses



Total number of foods in tablet or capsule form (including vitamin products)
~10,000

The total number of drug licenses (including the API)
~25,000

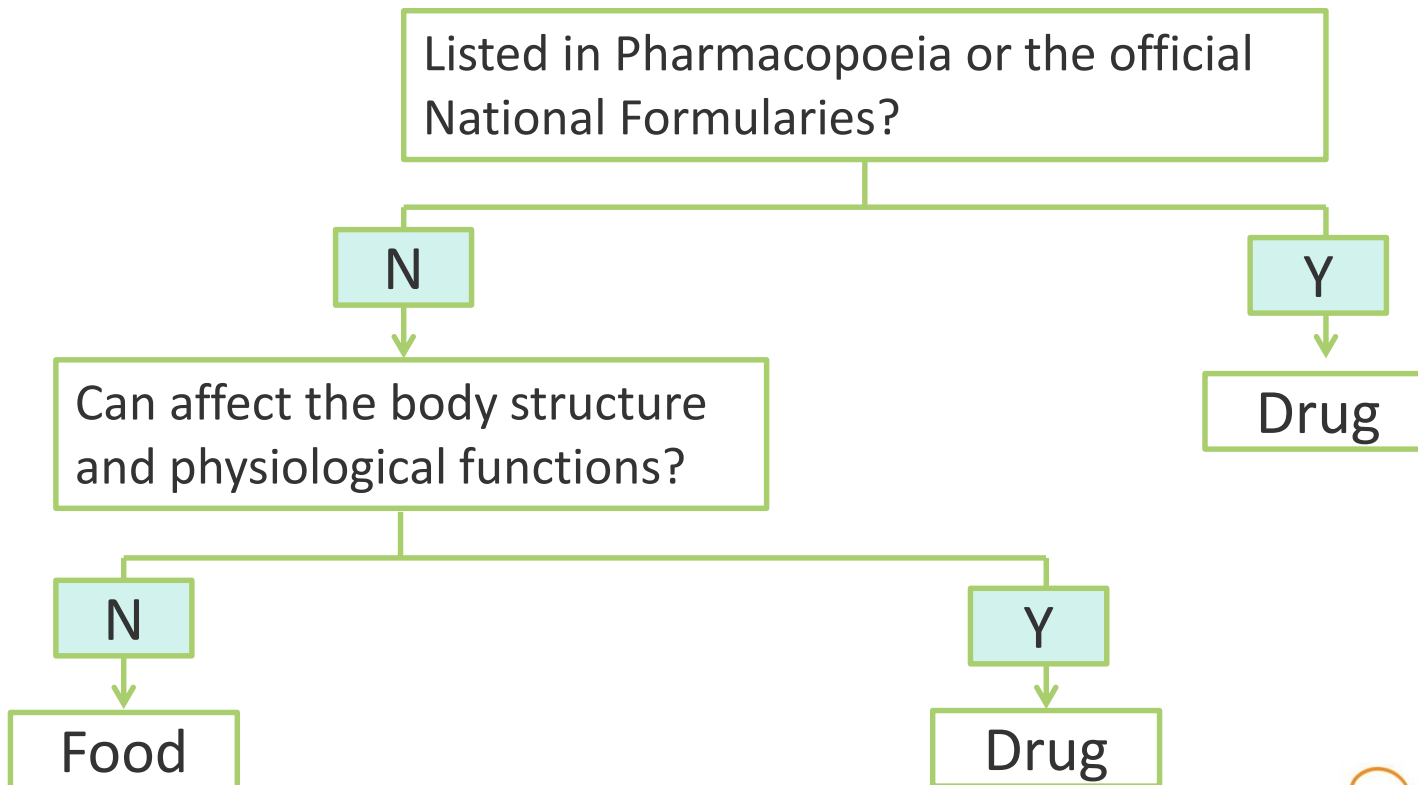
Regulatory Framework



Classification of Capsule and Tablet Products

- Considerations

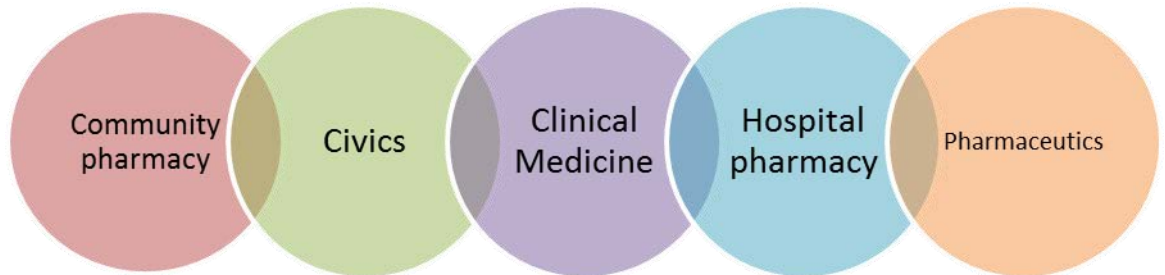
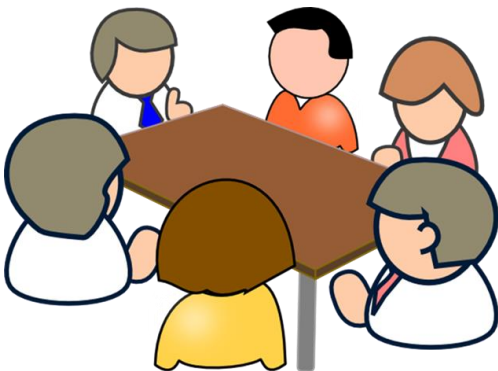
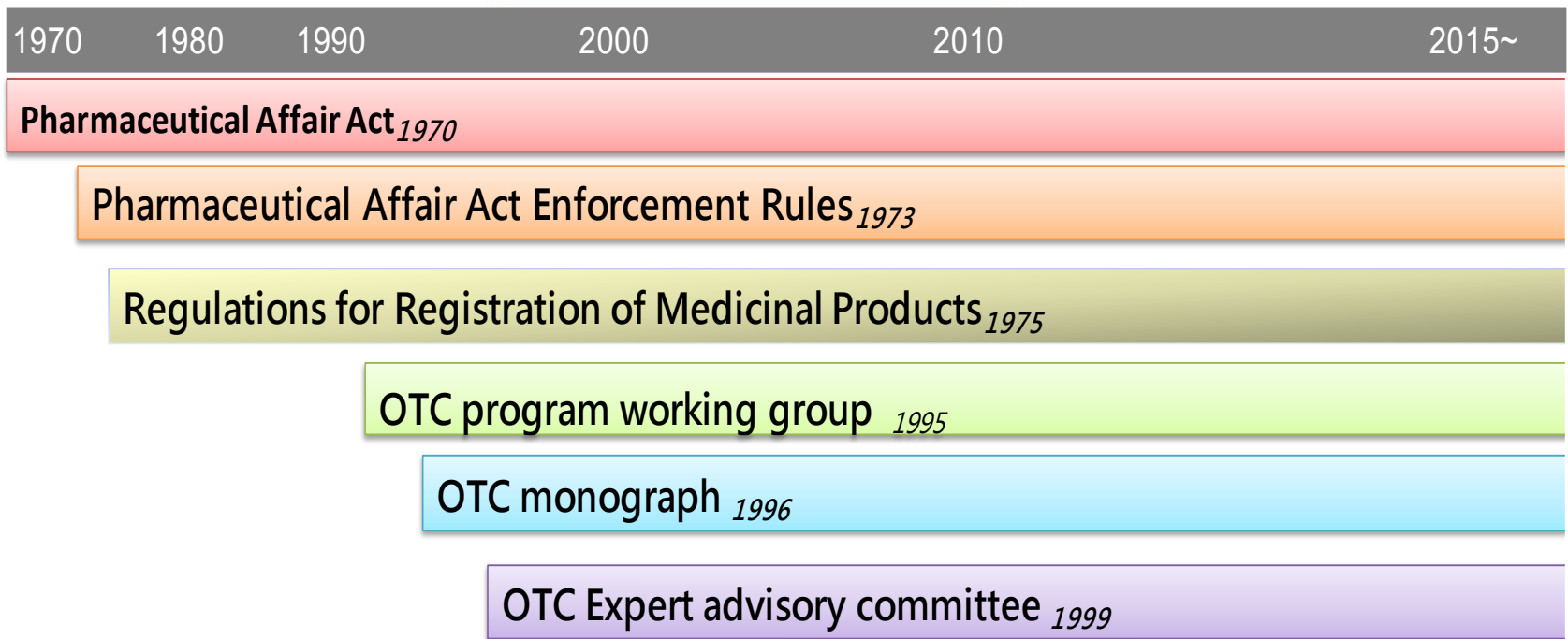
- ✓ Ingredients and Contents
- ✓ Dosage and Usage
- ✓ Intended use



Determination Criteria for Vitamins in Tablet or Capsule Form

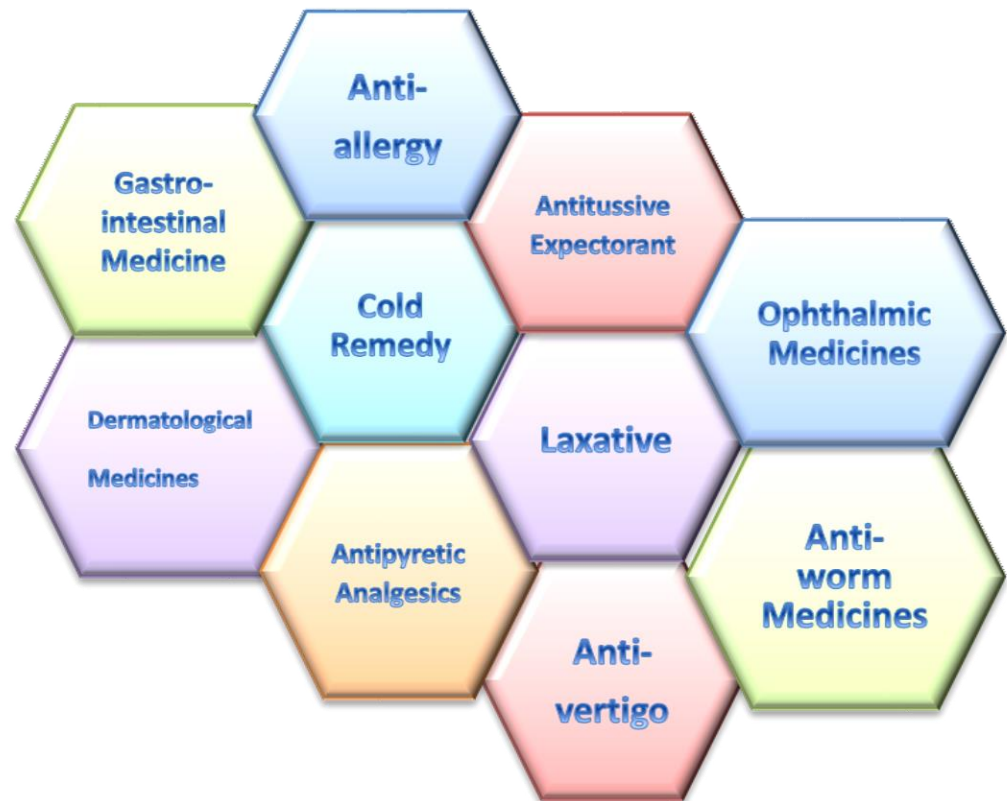
items	「Standard for specification, Scope, Application and Limitation of Food additives」 Upper limit in daily dosage	Dietary Reference Intake 150%
Vit. A	10000 I.U. (3000 μg)	1050 μg
Vit. B ₁	50 mg	1.95 mg
Vit. B ₂	100 mg	2.25 mg
Vit. B ₆	80 mg	2.1 mg
Vit. B ₁₂	1000 μg	3.6 μg
Vit. C	1000 mg	150 mg
Vit. D	800 I.U. (20 μg)	15 μg
Vit. E	400 I.U. (268 mg)	18 mg
Vit. K	500 μg	140 μg
Nicotinic Acid	100 mg	25.5 mg
Folate	800 μg	600 μg

Milestones

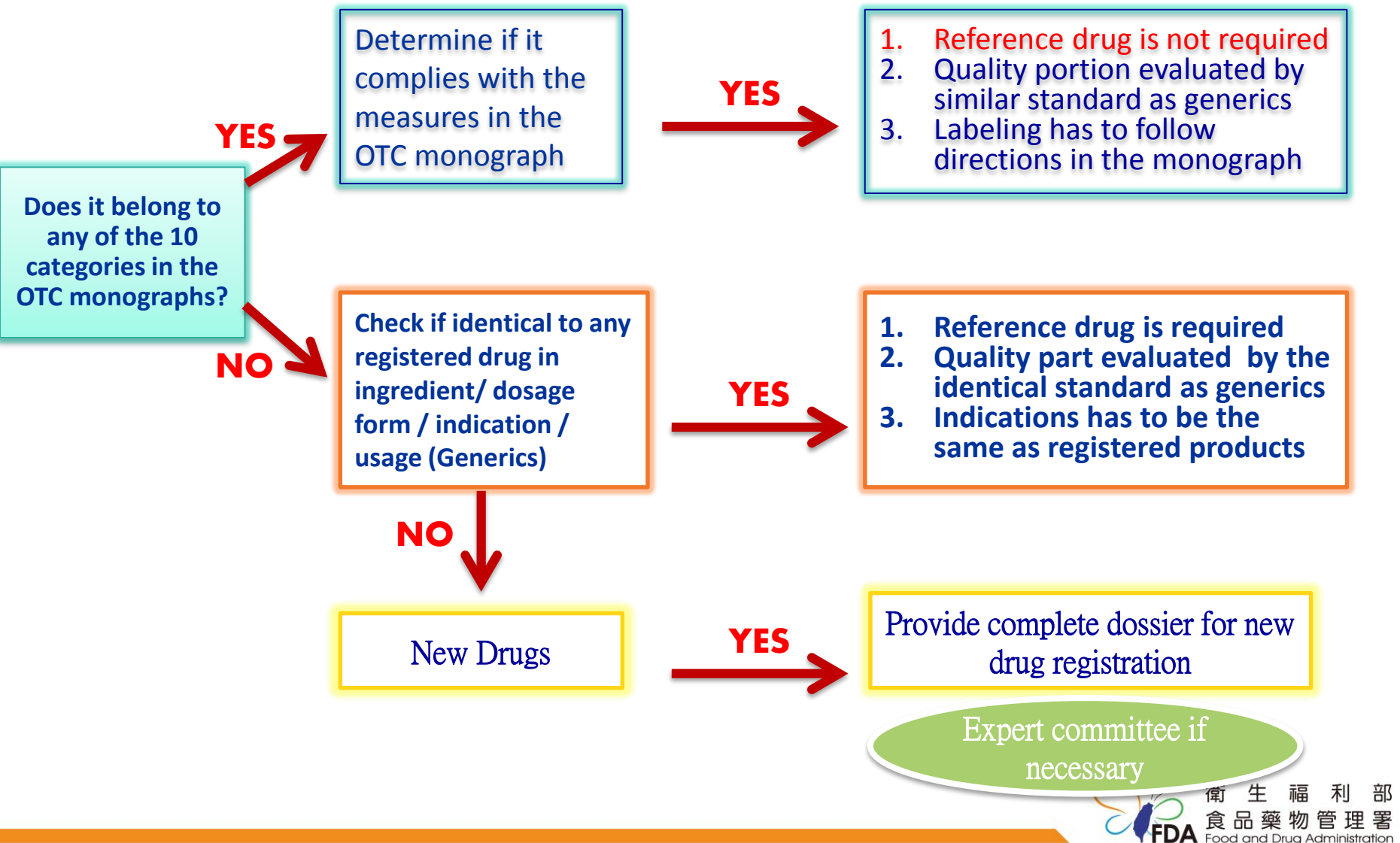


OTC Monographs

- For drugs commonly used to alleviate mild symptoms, monographs with active ingredients and dosage range were developed.
- Manufacturers can design formulas within the scope of the monograph, and not be subject to the limitations of the reference drugs.
- It's easy to follow standard usage, precautions, warnings and labeling, to provide people with convenience and safety.



OTC Medicines Registration



Dossier Requirement

Evaluation	NDA	Generics	OTC Monograph Drug Application
Reference Drug	Not required	Required	Compiled with Monograph
Safety Efficacy	<ul style="list-style-type: none">Pharm/ToxPK/PD/BA/BEClinical trials	Bioequivalence (BE) as a surrogate to clinical trial	BE may be required in some cases
Quality	<ul style="list-style-type: none">Chemistry, Manufacturing and Controls(CMC)PIC/S GMPGLP, GCP,		
Labeling	Labeling (direction of use)		

Labeling Revision

【Ingredients】

Active Ingredients and contents

Inactive ingredients (excipients)

【Uses (indications)】

【Precautions】

- ✓ Do not use if...
- ✓ Seek for doctor diagnosis and treatment before use if...
- ✓ Consult a doctor/pharmacist before use if...
- ✓ Other precautions

【Directions】

【Warnings】

- ✓ Stop using and consult a doctor or pharmacist with this instruction if the following symptoms occur (shown in tables)
- ✓ Stops using and receive doctor diagnosis and treatment if the following symptoms occur

【Package】

Consumer Language

Begin with the Must-Know Before-Use information

Follow with the Direction

Follow with *What-to-Do* when uncomfortable symptoms occur after taking the medicine



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Package Revision

~QR Code

Easy to read by using
a smart phone
scanning



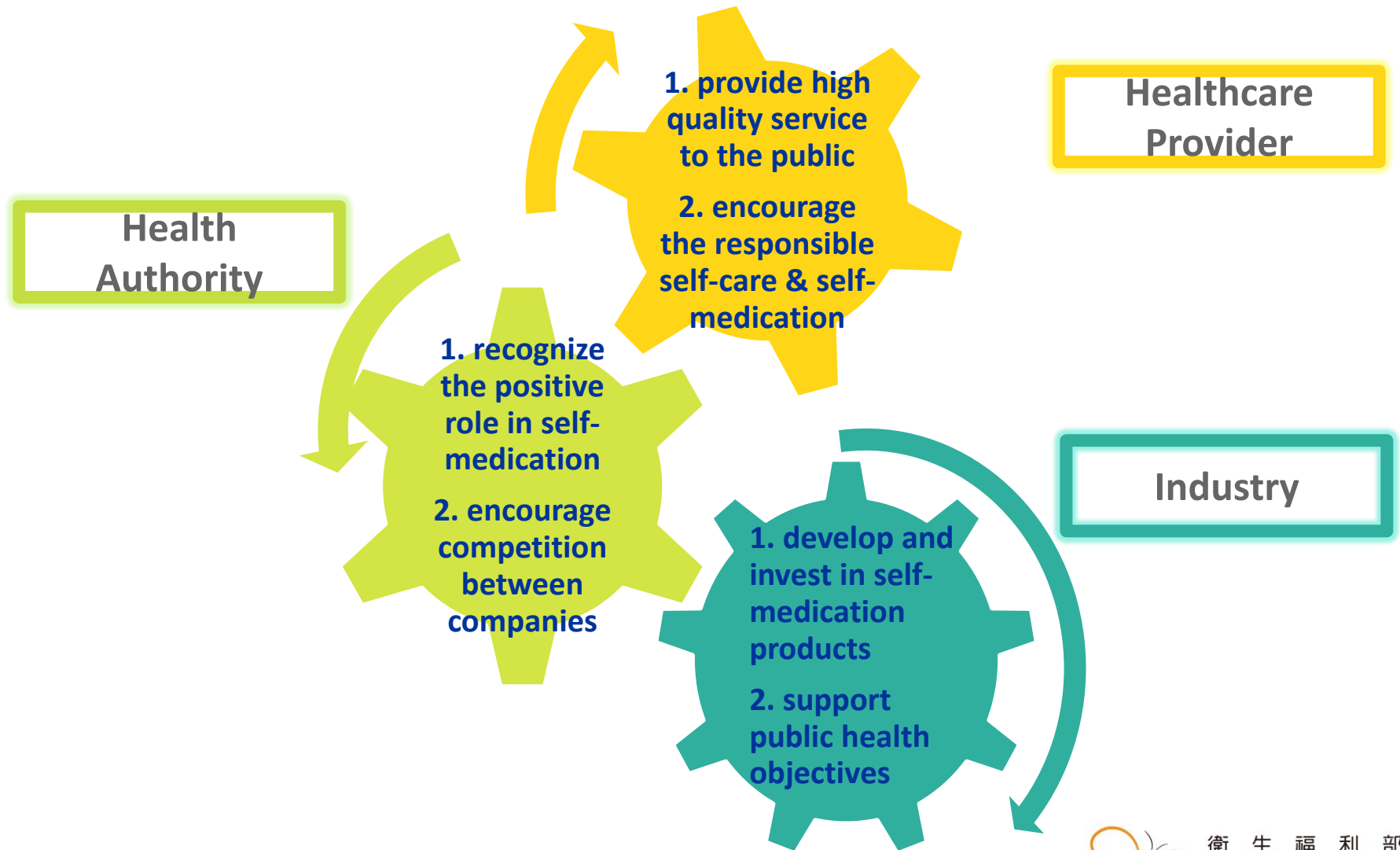
Name of the product,
use (indications),
usage & dosage,
dosage form and
shape, consultation
phone



Regulations for Different Categories

	Prescription Drugs	Pharmacy Drugs	General Sale Drugs
License required			
Pre-approval	v	v	v
Distribution			
Hospital/Clinical	v	v	v
Pharmacy	v	v	v
General distribution	x	x	v
Internet	x	x	v
Advertisement			
Pre-approval	v	v	v
Mass media	X	v	v

Perspectives





The 4th Self-CARER Annual Meeting

Date: March 20 – 22, 2018

Venue: National Taiwan University Hospital (NTUH) International Convention Center, Taipei (to be confirmed)

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Thank You for Your Attention!



For more information, please visit
<http://www.fda.gov.tw>



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