OTC Accessibility to Consumer and Expansion of Monograph in Taiwan

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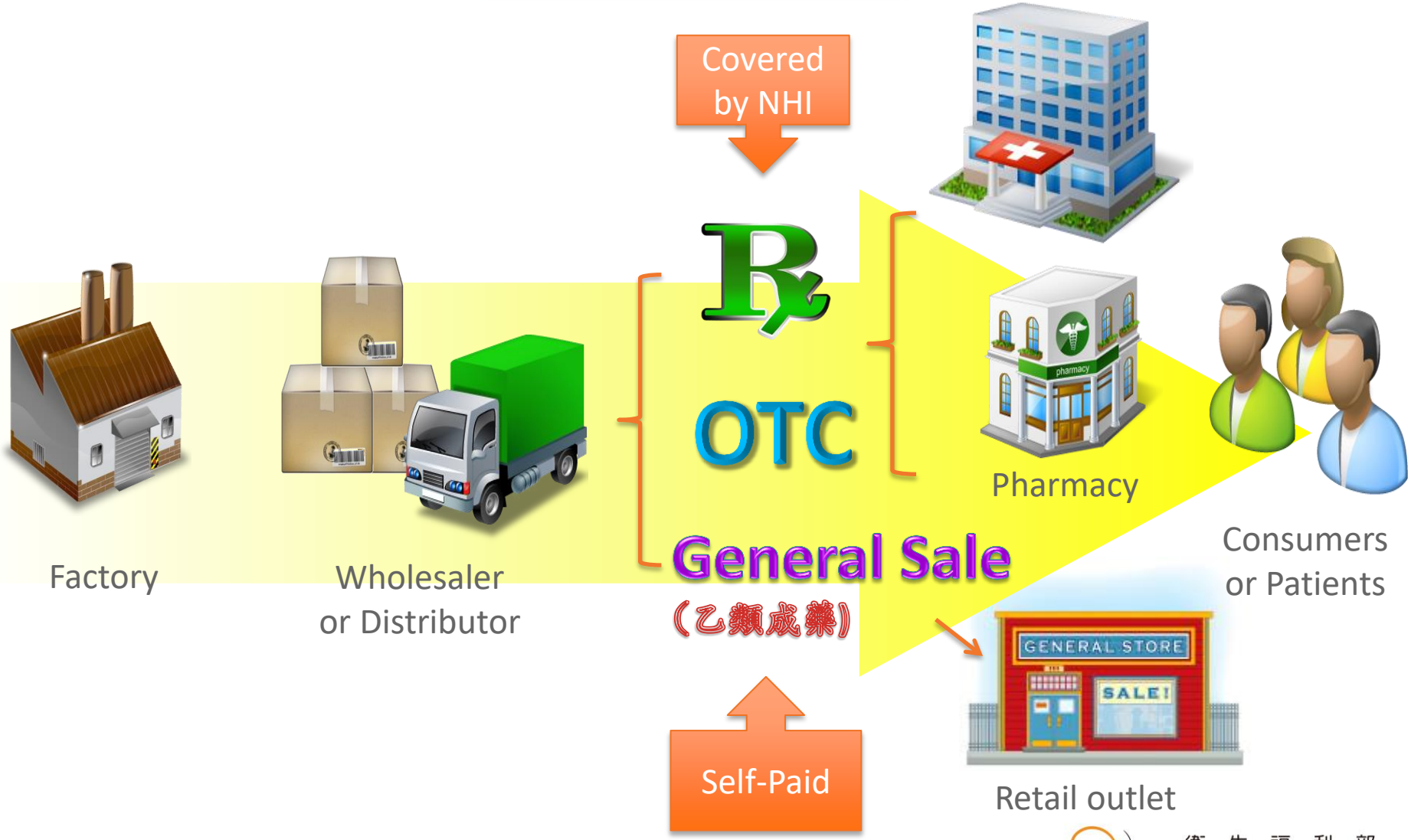
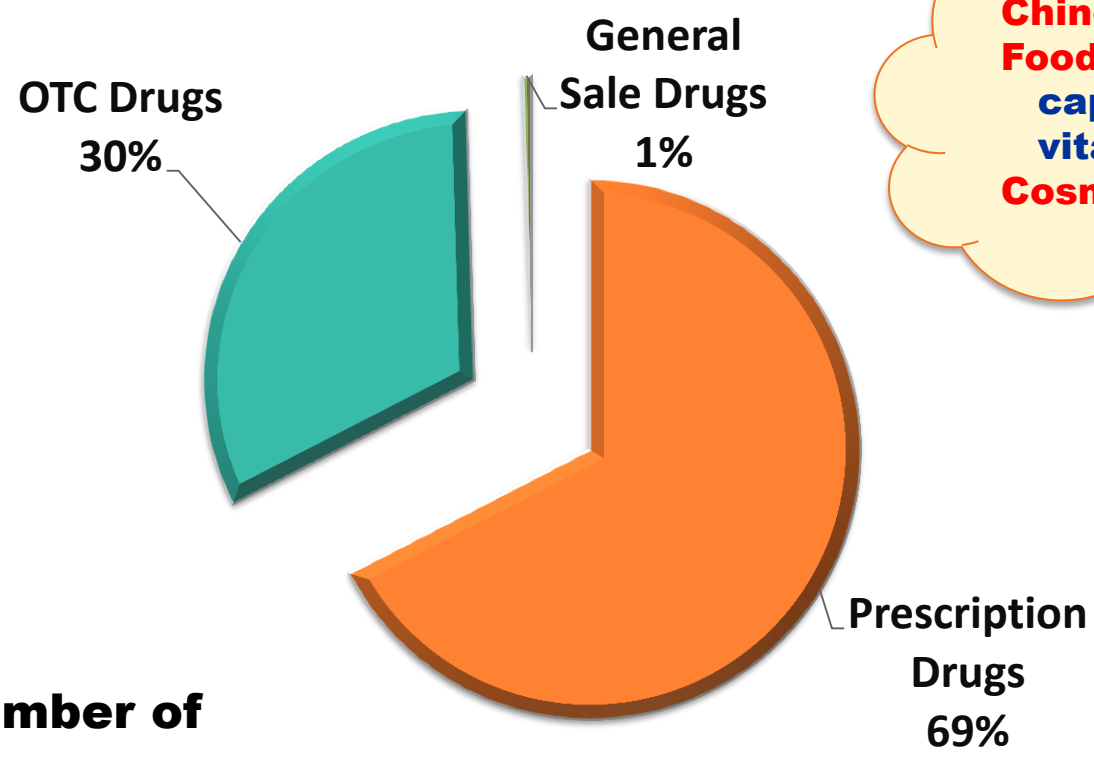
Outline

- Drug classification in Taiwan
- OTC expansion
  - Expansion of monograph
  - Rx switch to OTC
- OTC accessibility to consumer
  - Distribution (internet sale)
  - Advertisement regulation
  - Promotion for safe use of drugs
- Future perspectives

Drug Classification



Distribution Chart of Drug License by Category



Chinese Medicine, Foods in tablet or capsule form (e.g. vitamin products), Cosmetics

Total number of drug licenses (excluding the API) ~22,000

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Milestones of Non-Prescription Drug Regulation

1970 1980 1990 2000 2010 2020

- Pharmaceutical Affairs Act 1970
- Pharmaceutical Affairs Act Enforcement Rules 1973
- Regulations for Registration of Medicinal Products 1975
- OTC Monograph (10 groups) 1996
- Online Sales for General Sale Drugs 2015
- Labeling Revision (Colloquial) 2016
- OTC Monograph (16 groups) 2018

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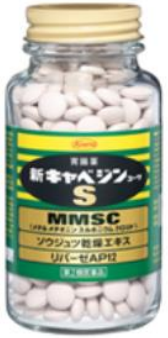
Taiwan Non-Prescription Drug Market

- The non-prescription drug market in Taiwan has a turnover of around 265 million US dollars per year. 50% of the non-prescription drugs are imported from Japan, Europe, US, and other developed countries. Some famous Japanese pharmacies like Tomod's and Japan Medical have entered the market since 2012. Until May 2018, there were 84 stores in total.
- Some famous pharmacies in Taiwan are Watsons and Cosmed. Until May 2018, there were 970 stores in total.



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OTC Expansion

Expansion of Monograph: 16 Groups

(Announced in Oct. 2018)

- Antipyretic and analgesic
- Cold remedy
- Antitussive and Expectorant
- Ophthalmologic
- Anti-allergy
- Gastrointestinal
- Motion sickness
- Anthelmintic
- Laxative
- Anti-fungal
- Antibiotic and disinfectant
- Antipruritic and anti-inflammatory
- Anti-acne
- Diaper rash
- Dry skin
- Dermatological—others

Dermatological

Expansion of Dermatological Medicines Group

Before		After expansion	
Monograph	Ingredient	Monograph	Ingredient
Dermato-logical	28	Anti-fungal	23
		Antibiotic and disinfectant	23
		Antipruritic and anti-inflammatory	40
		Anti-acne	5
		Diaper rash	13
		Dry skin	12
		Dermatological-others (not belong to above 6 groups)	6

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Requirement of Registration

Evaluation	NDA	ANDA	OTC monograph drug application
Reference drug	Not required	Required	Complied with monograph
Safety Efficacy	• Pharm/Tox • PK/PD/BA/BE • Clinical trials	Bioequivalence (BE)	Not required
Quality	• Chemistry, Manufacturing and Controls (CMC) • PIC/S GMP • GLP, GCP		
Labeling	Labeling (direction of use)		

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DMF Exemption

(Announced on May 9, 2018)

- According to the Regulations for Registration of Medicinal Products, technical documents of active pharmaceutical ingredients (Drug Master File, DMF) are required.

- Announcement dated May 9, 2018:
  - Non-prescription drugs which are not new ingredients or under pharmacovigilance
  - API source complied with GMP
  - DMF documents could be surrogated by an outline of synthesis route / manufacturing process, testing specifications, methods and results of active ingredients

Rx Switch to OTC

(Announced on Nov. 16, 2017)

- To encourage Rx switch to OTC, TFDA announced a checklist of Rx switch to OTC application

- Documents for submission:
  - Application form
  - Drug safety profile, clinical literature, or contents in pharmacopoeia
  - Draft of packaging inserts
  - Education plan for pharmacists

Please download from:
http://www.fda.gov.tw/tc/siteContent.aspx?sid=9593

Checklist for Applicant

檢附資料	廠商自我審核
1. 藥品變更登記申請書 類別變更 適應症變更 用法用量變更 其他：	 □有 □無 □有 □無 □有 □無 □有 □無
2. 藥品許可證正本 (如涉及需換證者，應另附查驗登記申請書正本)	□有 □無
3. 轉類之安全性試驗、臨床文獻及十大醫藥先進國家藥典或醫藥品集收載情形	□有 □無
4. 如係輸入藥品，應另附原廠變更通知函	□是 □否
5. 如係輸入藥品，應另附經中央衛生主管機關認可國家所核准該適應症、用法用量之證明該證明並應經我國駐外館處簽證。(涉及適應症、用法用量變更)	□是 □否
6. 標籤仿單外盒 6.1 原核准並蓋有中央衛生主管機關騎縫章之外盒、仿單、標籤黏貼表。 6.2 標仿單擬稿各二份。 6.3 如係申請遺失補發者，應另附遺失切結書。	□有 □無 (申請核定本遺失補發者，免附。) □有 □無 □有 □無
7. 藥師教育訓練計畫	□有 □無
8. 項次1-7之電子檔案，並以光碟燒錄(一式二份)	□有 □無
9. 審查費(100,000元)	□有 □無

OTC Accessibility to Consumer

Regulations for Different Categories

	Prescription Drugs	OTC Drugs	General Sale Drugs
Distribution			
Hospital/Clinic	v	v	v
Pharmacy	v	v	v
Supermarket Grocery shop	x	x	v
Internet	x	x	v
Advertisement			
Pre-approval	v	v	v
Academic medical journal	v	v	v
Mass media	X	v	v

Online Sales for General Sale Drugs

(Announced on June 30, 2015)

- Qualification: Pharmaceutical dealers, pharmacies, supermarkets, grocery shops, and hospitality industries
- Disclosure at conspicuous places on the webpages:
  - Information of the above-mentioned dealers:
    - ✓ Name, address, dedicated consultation hotline, service hours, establishment permit document, and searchable link
  - Drug information:
    - ✓ Product name, indication, pharmaceutical dealer name, manufacturer name, manufacturer address, product license number, side effect, contraindication, precaution, photo of product package/insert and searchable link
    - ✓ Reminder note that ”Consumers shall carefully read the drug insert prior to use”

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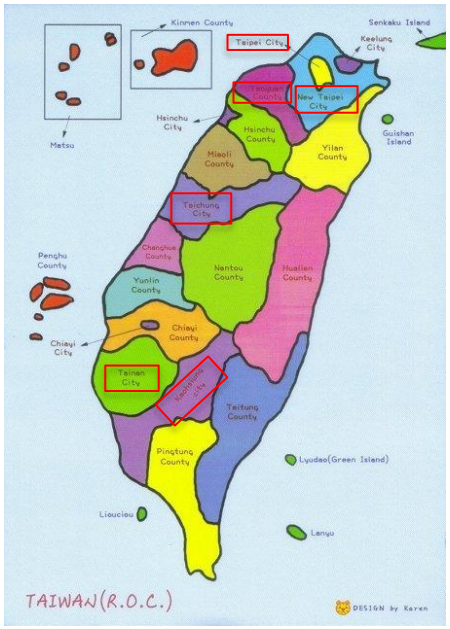
Regulation of Advertisement

Publish or broadcast drug advertisement

Pharmaceutical Dealers

PAA §65:
Persons other than pharmaceutical dealers are not allowed to make advertisements for medicaments.



PAA §66 and PAA Enforcement Act §44
Before publishing or broadcasting an advertisement, pharmaceutical firms that are license holders shall apply for approval with central or municipal competent health authority.

Drugs

PAA §69:
No pictorial or literal description or propaganda regarding the medical efficacy of any product other than the medicaments defined in this Act shall be made.

Prescription Drugs

PAA §67:
For medicaments requiring prescriptions of physicians, publish only in academic medical journals

Non-Prescription Drugs

No restriction:
- Movie, TV, radio station, internet, press (poster, leaflet, newspaper, journal, magazine, billboard, car body)
- Academic medical journals

Friendly Package

Scan for audio descriptions

Name of product, indication, usage & dosage, dosage form and shape, consultation number

Labeling requirement: Prints of "chemical drug" or "chemical drug with botanic herbal" on the package

Promotion for Safe Use of Drugs

(Multiple Channels)

(Pharmacy)

(Campus)

(Community)

(Press Conference)

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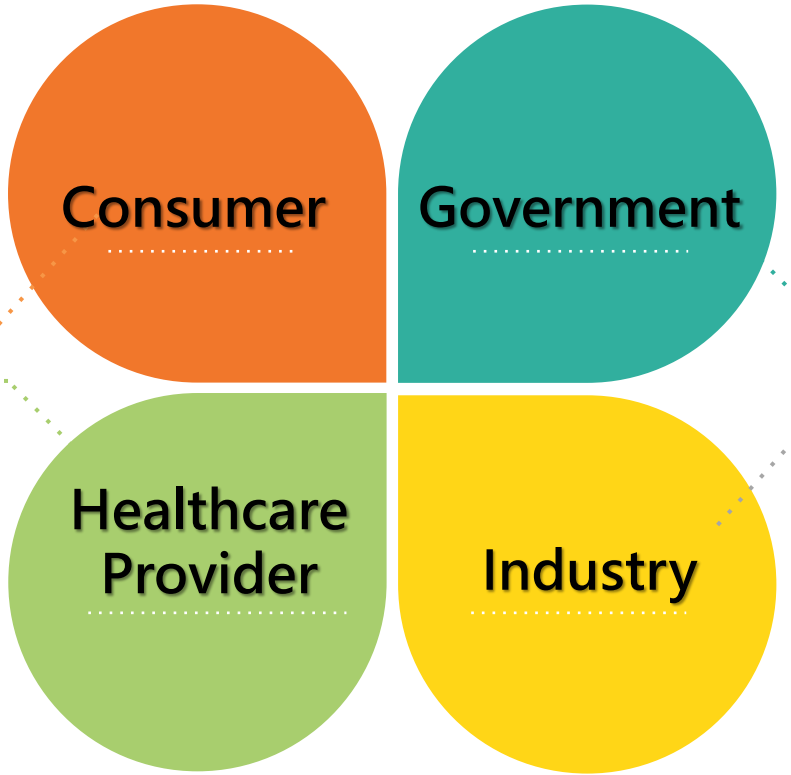
Future Perspectives

(Quadruple-Win Scenario)

- Be responsible for self-care & self-medication

- Approve a wider range of safe and effective self-medication products



- Provide high quality service to the public

- Develop and invest in self-medication products

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Thank You for Your Attention!

For more information, please visit

http://www.fda.gov.tw