

OTC Switch in Taiwan



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Outline

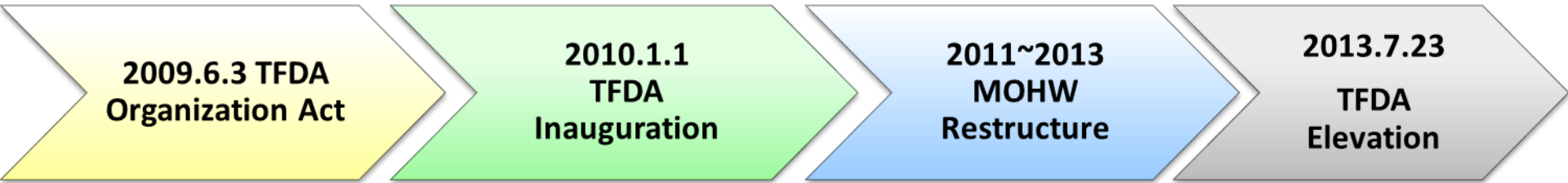
- Taiwan Profile
- Overview of Pharmaceutical situation
- Two pathways of Rx-to-OTC Switch
- Initiative for Rx to OTC switch
- Future Missions

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)
- Pharmaceuticals Market:
NT\$ 82.4 Billion(US\$ 2.75 Billion) in 2013



History of TFDA



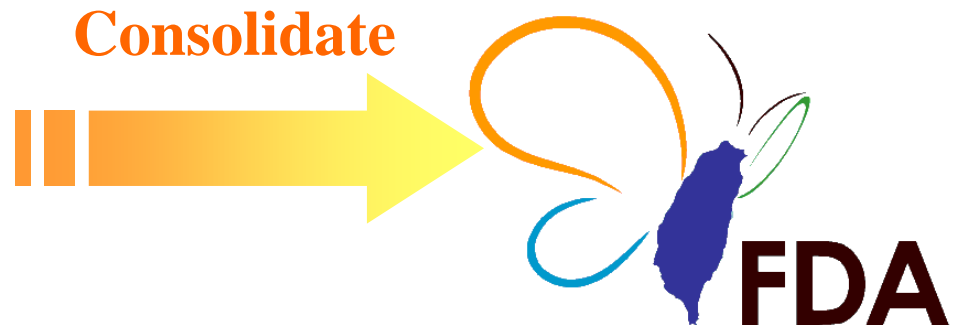
Bureau of...

Food Safety

Pharmaceutical Affairs

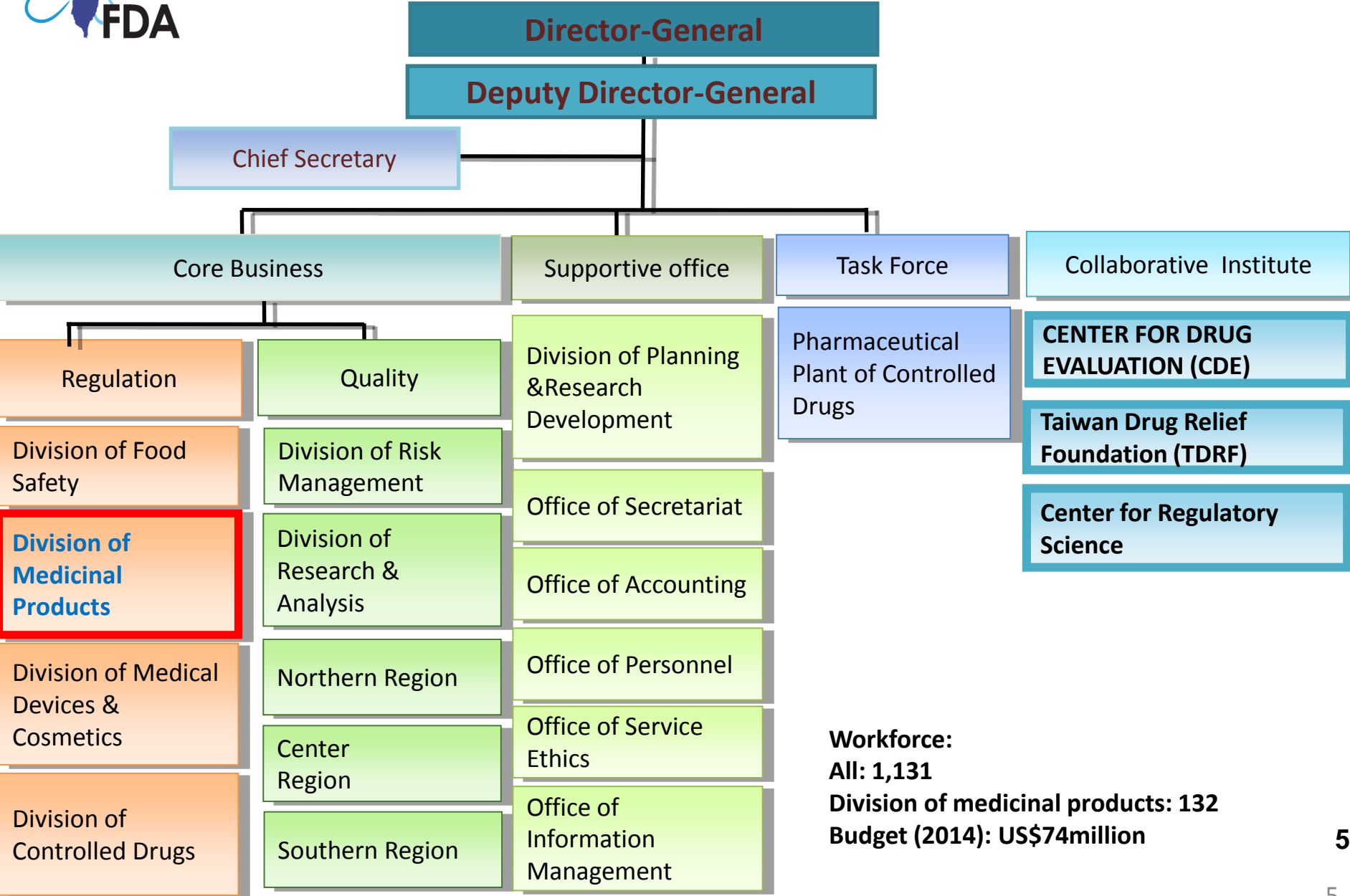
Food and Drug Analysis

Controlled Drugs





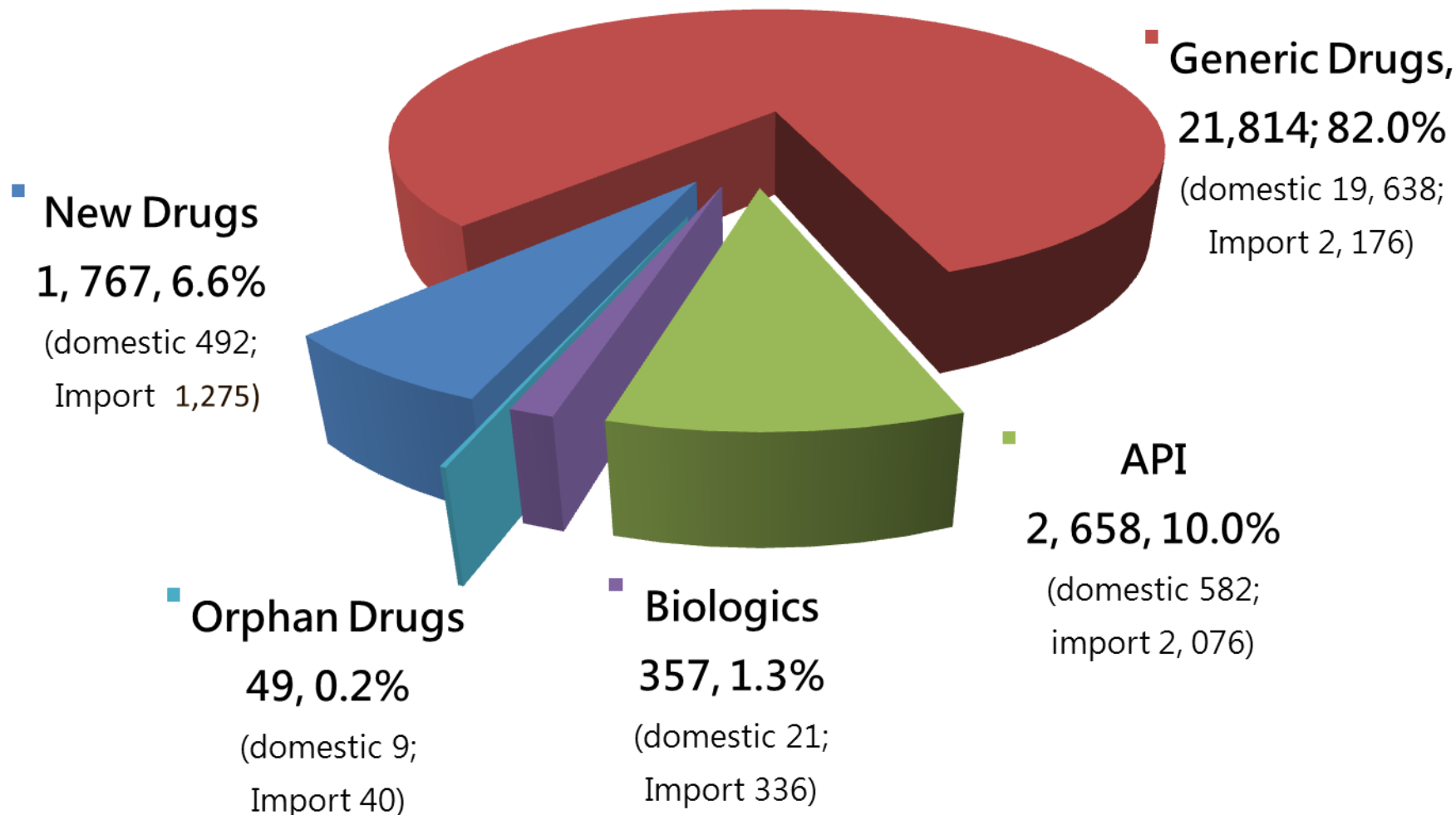
TFDA Organization Chart



Overview of Pharmaceutical Situation

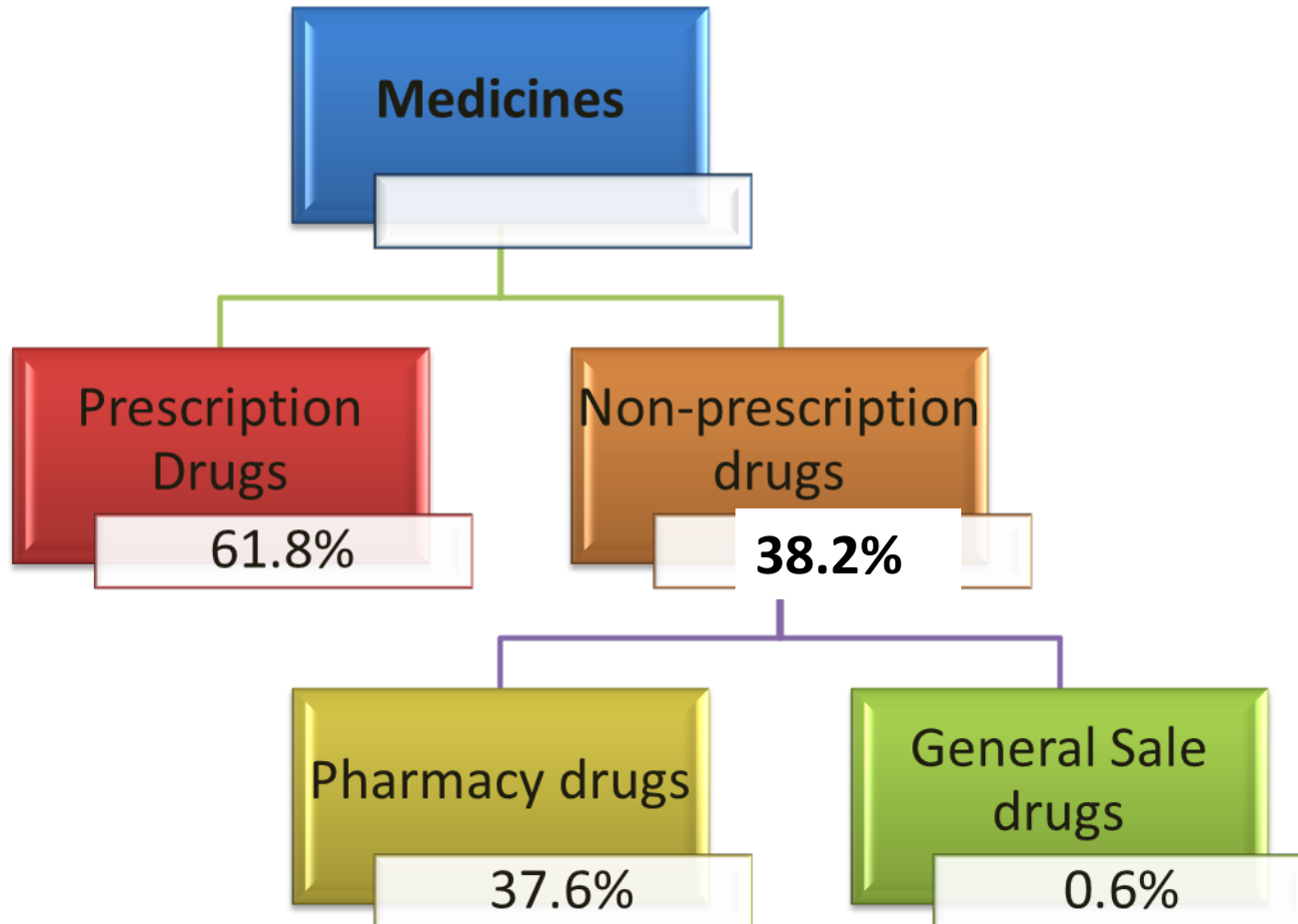
Distribution of Pharmaceutical Licenses

<26,654>



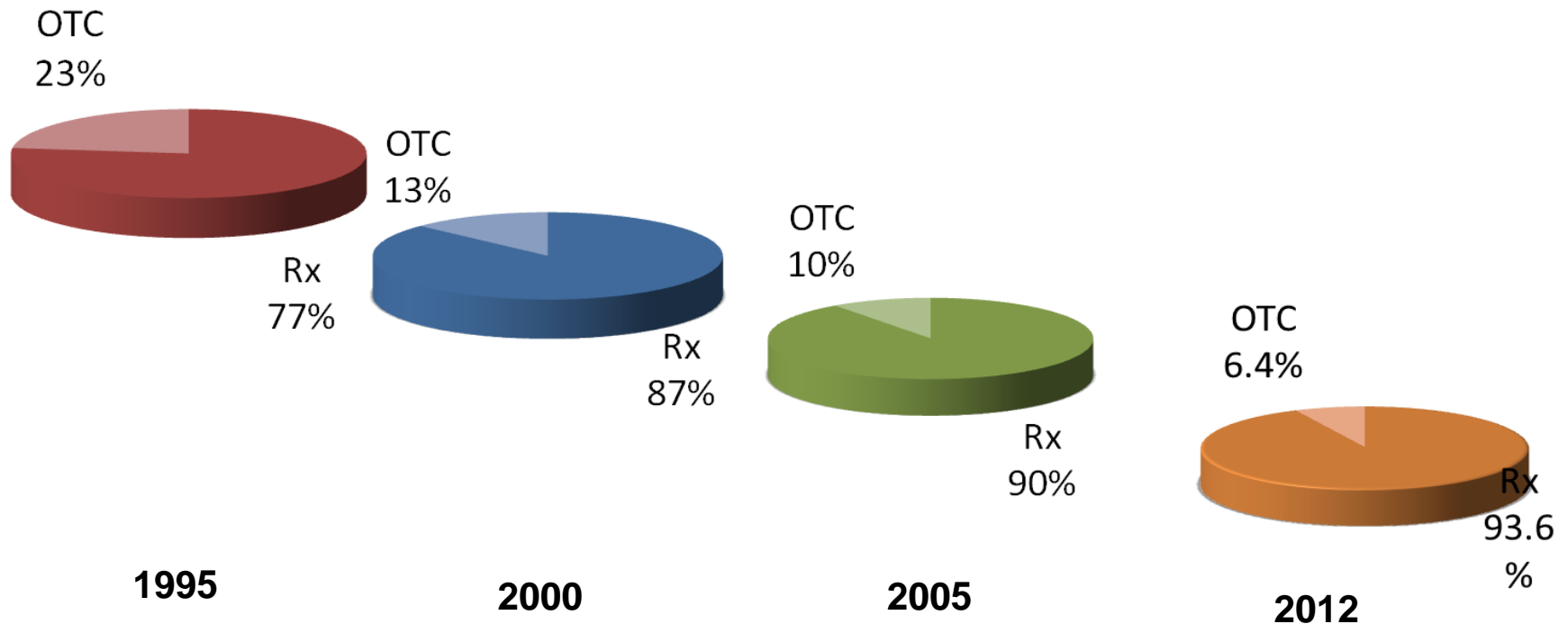
Medicines Classifications

Pharmaceutical Affairs Act, Article 8



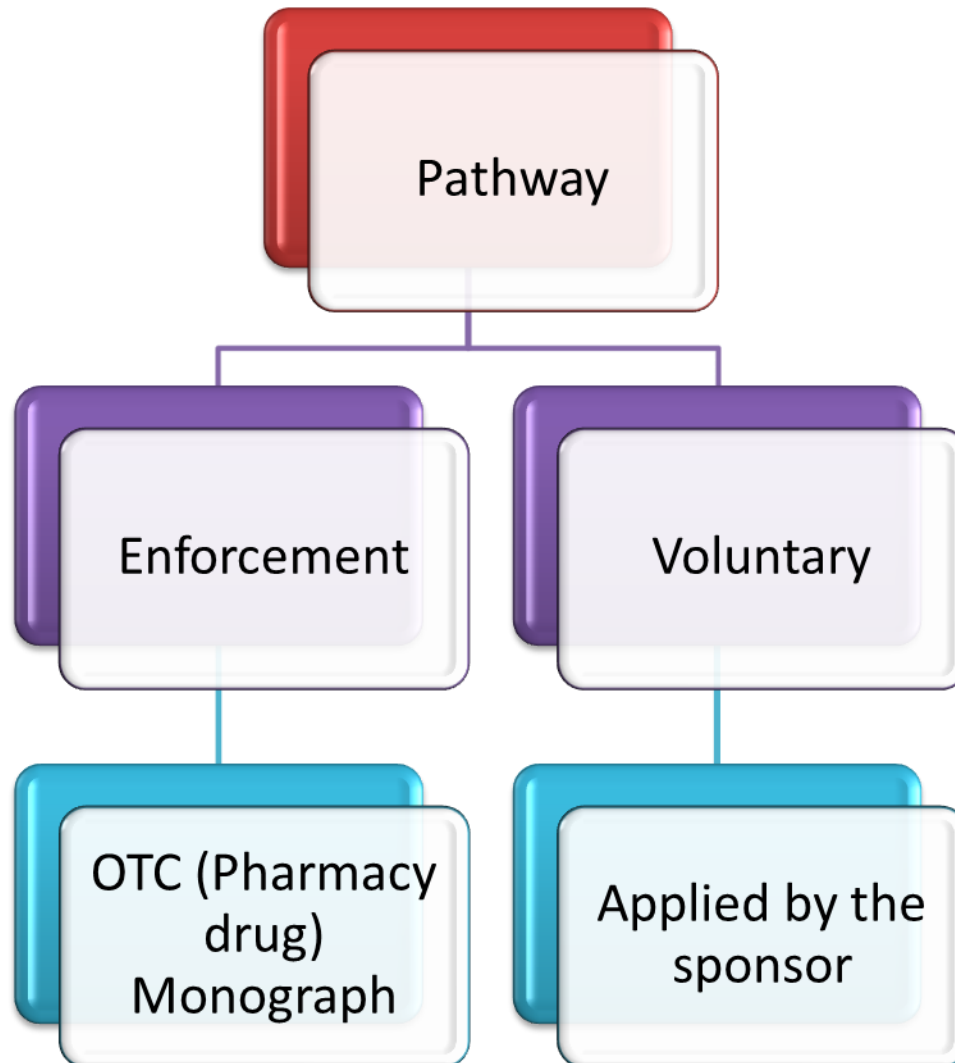
OTC Market Trend

- After NHI implementation, market share of prescription drug increases from 77% to 93.7% and market share of non-prescription drug decreases from 23% to 6.3%.
- Non-prescription drugs are not reimbursed by National Health Insurance.



Two Pathways of Rx-to-OTC Switch

Rx to OTC Switch



Switch by License Holder (Voluntary)

- Applied by the sponsor
- The documents required for application :
 - Safety test,
 - Clinical references
 - Pharmacopoeia or formularies of the A10 countries

*A10 Countries : Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, UK, US

Rx to OTC Switch Products

(Voluntary)

List of switching products from 2009~2014

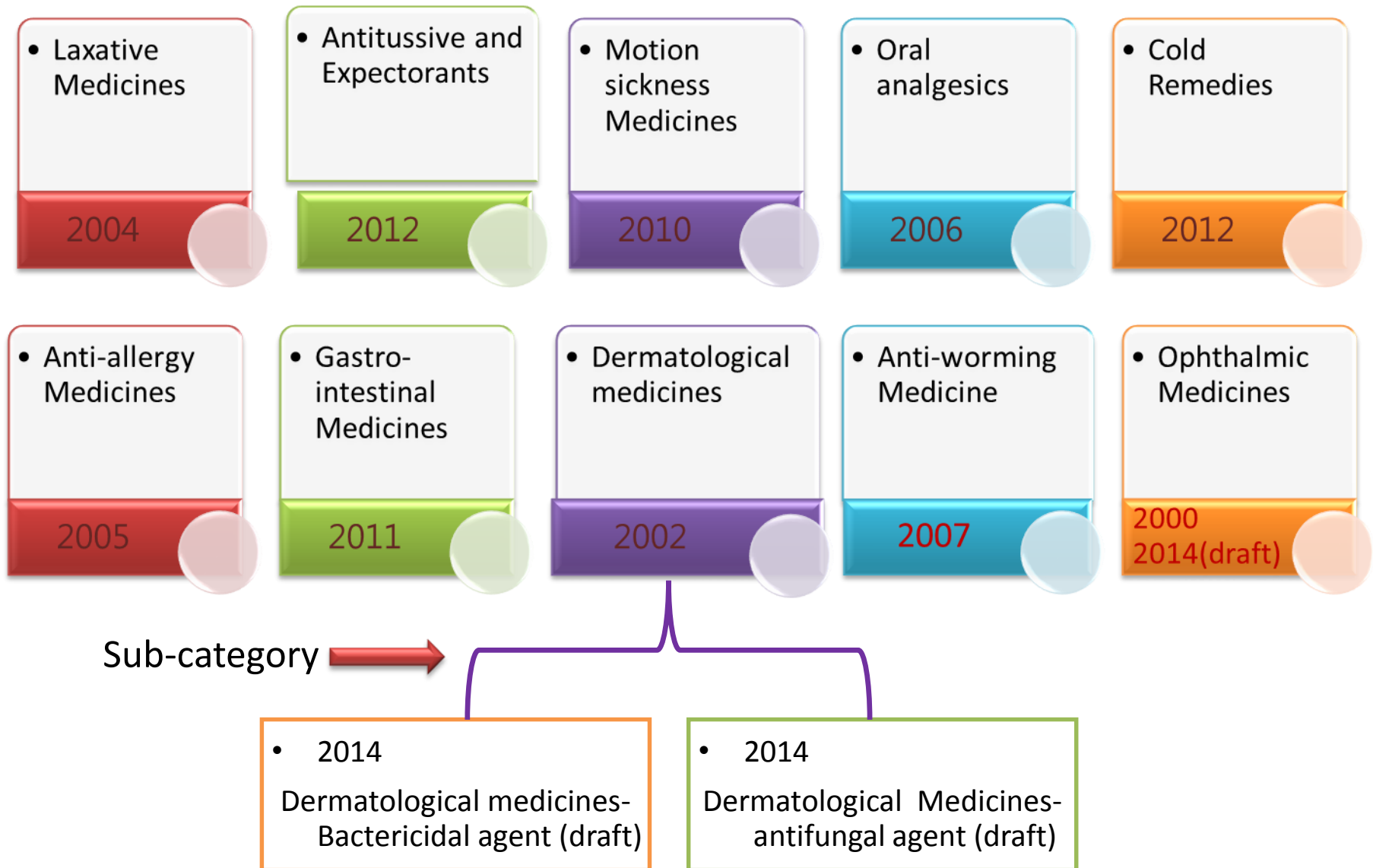
Products	Dose
Amorolfine HCl Cream	5mg
Bifonazole Ointment	1%
Silymarin Tablets	150mg
Horse-Chestnut Extract SR Tablets	262.5mg
Loratadine Tablets	10mg
Enoxolone/Rongalite Gingival Paste	Cernitin-GBX 60gm ; Cernitin T60 3mg
Clotrimazole Vaginal Tablets	500mg
Cernitin-GBX, Cernitin T60 Tablets	Cernitin-GBX 60gm ; Cernitin T60 3mg

Switch by the Government

(enforcement)

- To establish OTC monograph for 10 categories
- Continue to update more ingredients and categories to allow more OTC in the monograph
- Listed ingredients increased from 159 to 389 between 2000 to 2012.
- Safety test and clinical references are not required for registration if product complies with OTC monograph.

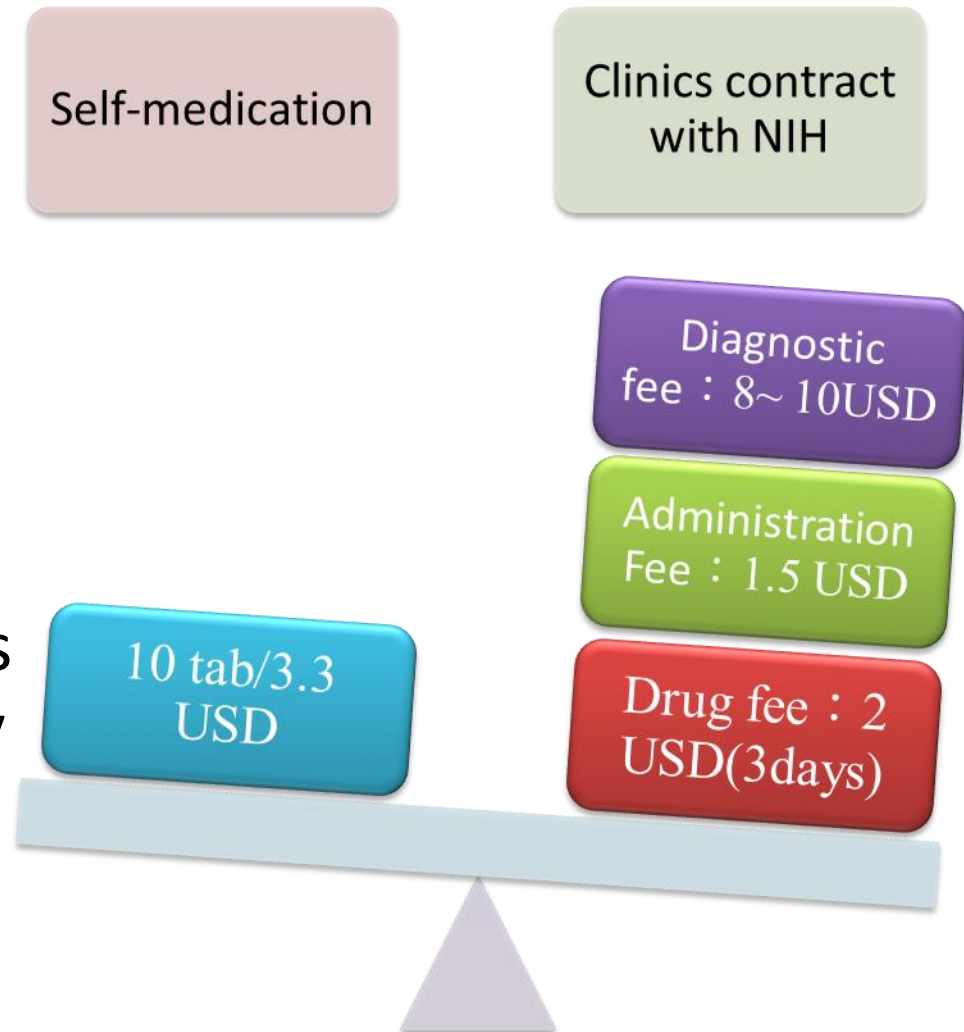
OTC Monographs



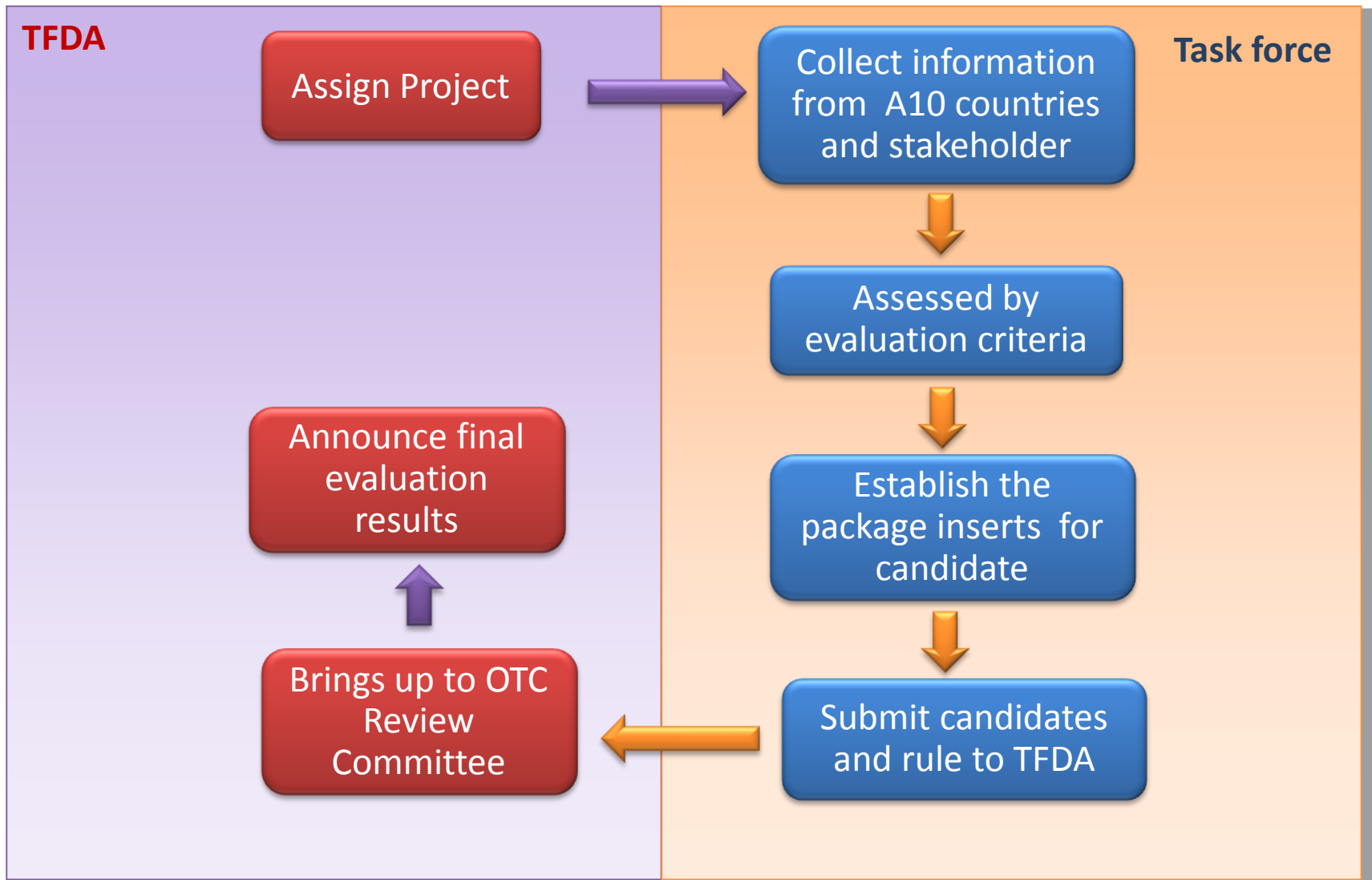
Initiative for Rx to OTC switch

Driving Forces

- Improving access for patients
- Relieve costs pressure in NIH system
- Increasing items for Community Pharmacy
- New business opportunities for pharmaceutical industry
- Worldwide trend for self-medication



Steps of Selecting Candidates



***Task force**

(Industry+ Regulators+ Pharmacist association)

Evaluation Criteria

- Prevent and treat minor symptoms and ailments that do not require medical consultation
- Be used for more than ten years and without serious ADR reports
- Be used as non-prescription drug at least three of A10 Countries for more than a year, and used in Taiwan with similar indication.

Evaluation Results in 2014

Candidates (draft):

Cetirizine HCl

Triamcinolone

Benzydamine

Omeprazole

Miconazole
(Vaginal agents)

Pantoprazole

Fexofenadine

Azelastine

Ketotifen
(Ophthalmic
solution)

Triamcinolone
(Nasal spray)

Aspirin
(Low dose)

Package inserts(draft):

Cetirizine hydrochloride 1mg/ml or 10mg/Tablet

【成分】

Cetirizine hydrochloride 1mg/ml 或 10mg/Tablet。
(國內目前無核准 5mg/Tablet)

【適應症】

緩解過敏性鼻炎、枯草熱所引起之相關症狀(流鼻水、打噴嚏、眼睛及喉部搔癢)及過敏所引起之搔癢、皮膚癢疹。

【用法用量】

成人及 6 歲以上兒童：一次 10mg (10ml 或一錠)，一天一次，於晚餐後伴隨開水服用。

6 歲以下之兒童，請諮詢醫師診治。

65 歲以上長者或患有肝腎疾病患者，請諮詢醫師診治。

【類別】醫師藥師藥劑生指示藥品

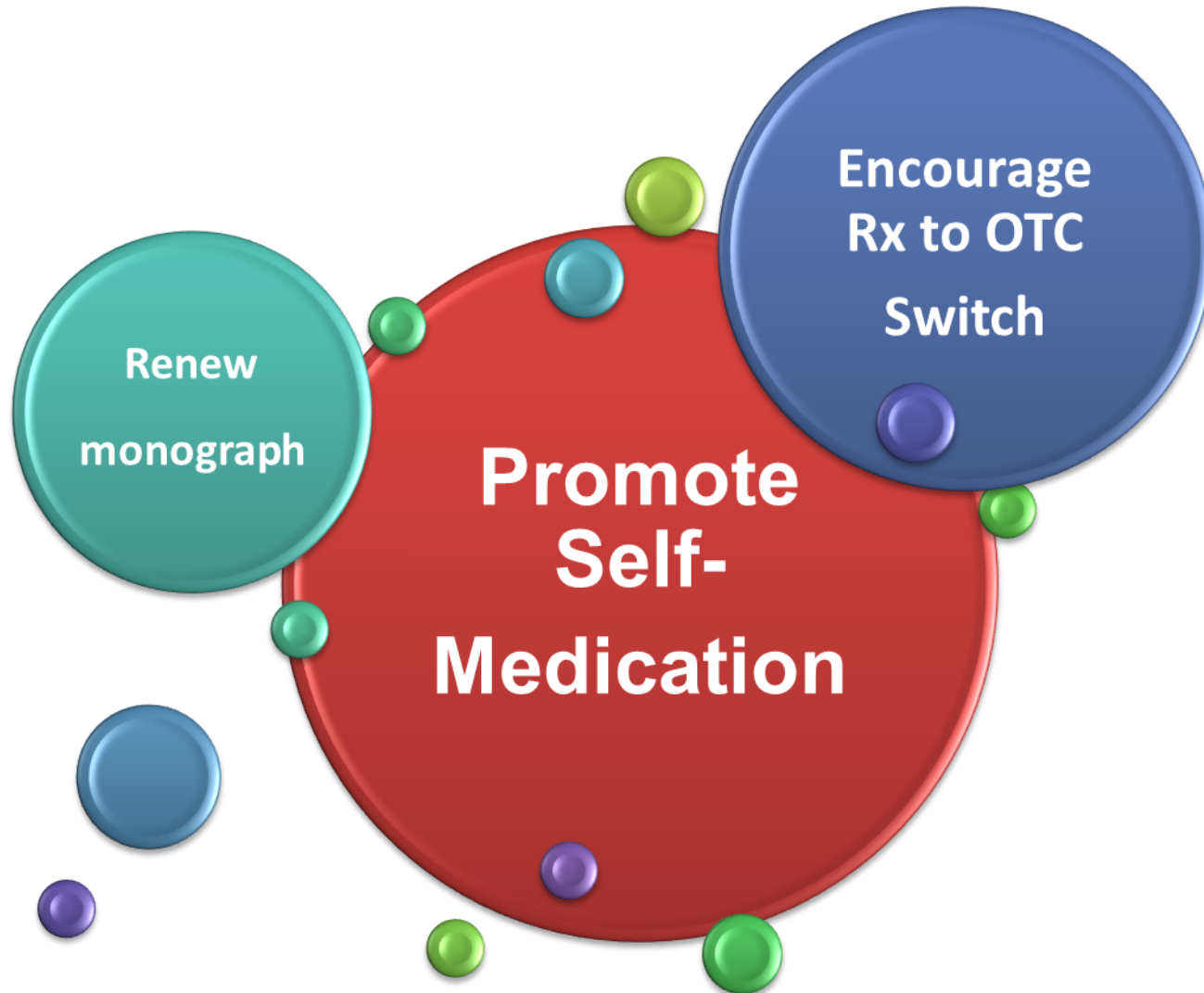
【注意事項】

- 一、為防止兒童誤食請妥善保管。
- 二、避免陽光直射，宜保存於陰涼之處。
- 三、孕婦需經醫師處方，不得自行服用。
- 四、Cetirizine 會被排泄至乳汁中，因此授乳婦不可使用本藥。
- 五、勿超過建議劑量，若有不適情況產生，應立即停藥就醫。
- 六、液劑使用前須振搖均勻，並使用廠商所附量器量取藥量。

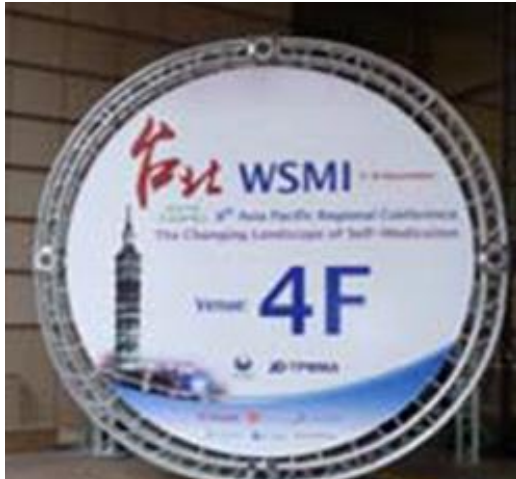
【警語】

- 一、服用本藥後，可能會發生輕微、短暫性副作用，如頭痛、眩暈、嗜眠、精神激昂、口乾、胃腸道不適，偶有視覺上之困擾，偶見興奮反應。

Future Missions



40th Anniversary of WSMI in Taipei



THE STORY OF SELF-CARE AND SELF-MEDICATION
40 years of progress, 1970-2010



APSMI was established on 5th November 2010 in Taipei





Thank You for Your Attention

