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Similarity & Difference in OTC Classification and their Borderlines among Asia Pacific

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- Legal status of medicines
- Medicine classification in Asia Pacific
 - Pharmacy & General Sales List medicines
 - Conventional & Novel medicines
- OTC borderline products
 - Medicines vs Medical devices
 - Medicines vs Health supplements
 - Medicines vs Cosmetics/Biocides
 - Medicines vs Traditional medicines

Why classification is important?



Indication to use

Registration route

Product placement

R&D studies

Product advertising

Product size limitation etc



When we should start to think of product classification?

At the earliest stage of product development

Legal status of medicines

- Legal Status is the status the Authorities grant in a licence
- Legal Status governs:
 - Whether it needs prescription or not
 - Where it can be sold
 - If it can be advertised
 - Whether there is price control
- Legal Status of a product is guided by
 - Its active
 - Its concentration
 - The safety profile of the product / time in market
 - The indication / claim for which it is intended

Legal status of medicines

- Legal Status varies by Country
- Legal Status varies across the Brands' range of products
- Where it can be sold:
 - a) Prescription (Rx, Prescription Only Medicine = POM)
 - b) Pharmacy
 - Pharmacy Non Self-Select – behind the Counter
 - Pharmacy Self-Select – in front of the Counter
 - c) General Sales List (GSL)
 - Pharmacy Self-Select
 - Grocery, Traditional Trade
 - Gas Stations & Vending Machines

OTC medicines – common classification



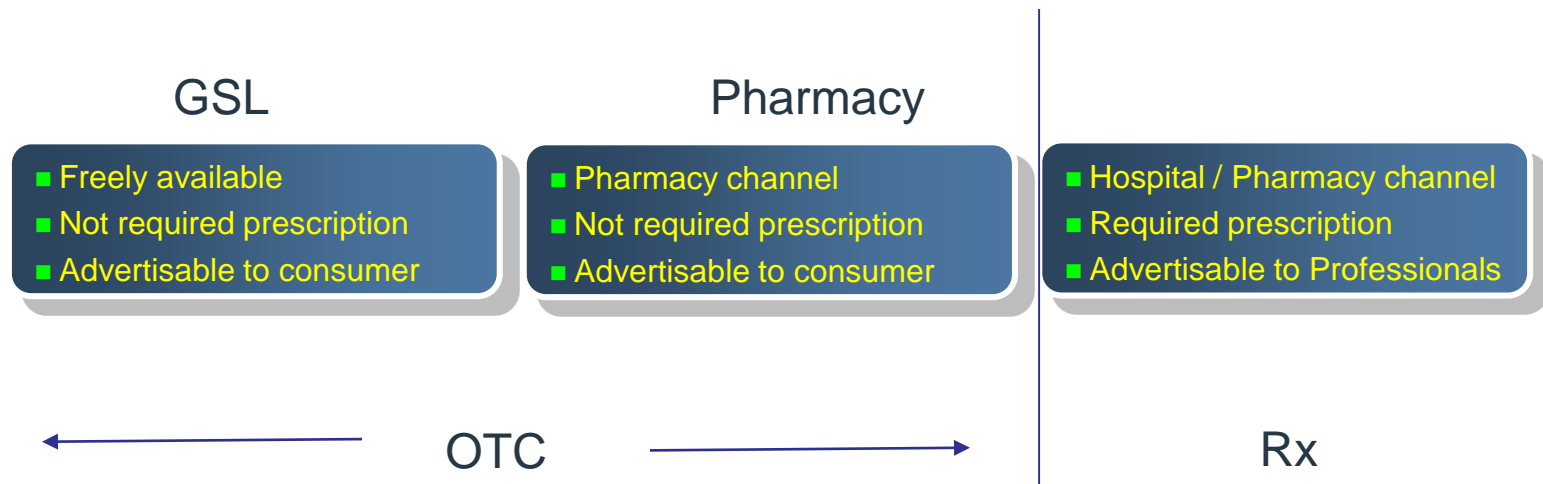
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UK		Classification	Supply controls	Record keeping	Level of control	RoW	
Rx	CD	Misuse of Drug Act schedules	Special supply regulations apply	Records in controlled drugs register and routine records	Most professional control – least patient control. Hardest to access	Rx	
	POM	Prescription only medicine	Prescribed by specified health care professional	Record kept			
OTC	P	Pharmacist supervised sale	Sold by or under the supervision of a pharmacist	Record rarely kept		OTC	Scheduled medicine, Dangerous drugs, special OTC, etc
	GSL	General Sales List medicine	Available from any retail outlet	Record never kept			Non-scheduled medicine, Non-dangerous drugs, Quasi-drug Household medicine, etc
	Herbal	New regulations imminent	Available from any retail outlet and some self appointed specialist shops	Record never kept	Most patient control – least professional control. Easiest to access		Ayurvedic medicines, Health supplement, functional food, etc.

Ref: Christine Bond, The over-the-counter pharmaceutical market – policy and practice (2008), Eurohealth 14 (3)

Pharmacy & GSL as OTC (non-prescription)

- Medicinal products can be accessed without prescription, with good risk-benefit profile in treating minor illness and self-manageable diseases/symptoms
- OTC definitions are not harmonized and named differently around the world.
- OTC cover both Pharmacy medicines and GSL (General Sales List)



Medicine classification in Asia Pacific



Medical Product Classification in East Asia

Country

- Freely available
- Not required prescription
- Advertised

- Pharmacy channel
- Not required prescription
- Advertised

- Hospital / Pharmacy channel
- Required prescription
- No advertising

UK	GSL	P	POM
USA	OTC	-	Rx
Hong Kong	GSL	P	POM
Korea	Quasi-Drug	OTC	Rx
China	OTC-Green	OTC-Red	Rx
Japan	Quasi-Drug OTC#2,3	OTC#1	Rx
Taiwan	OTC-Class1	IR	Rx
Philippines	DRHR	OTC	Rx
Vietnam	-	OTC	Rx
Thailand	HHR	Dangerous drug (DD) Non dangerous drug (NDD)	Rx
Malaysia	GSL	Poison C non-Poison	Rx
Indonesia	OTC-Green dot	OTC-Blue dot	Rx-Red dot
Singapore	GSL	P	Rx
India	Ayurvedic medicine Exempted medicines	Schedule drug Non-schedule drug	Rx

Example of product classification diversity



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Lack of Harmonized Medicine Classification System

Low
Level of control



High
Level of control

General sale list- advertisable	Pharmacy advertisable	Pharmacy non-advertisable	Prescription non-advertisable
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	Thailand	Malaysia	Singapore	Philippines	Indonesia
Ibuprofen 200 mg tab	Pharmacy- non- advertisable	Pharmacy- non- advertisable	Pharmacy- advertisable	Pharmacy- advertisable	Pharmacy advertisable
Cetirizine HCl 10 mg tab	Pharmacy- non- advertisable	Pharmacy- non- advertisable	Pharmacy- advertisable	Pharmacy- advertisable	Prescription non- advertisable
Ambroxol 15mg/5ml syrup	Pharmacy- advertisable	General sale list advertisable	General sale list advertisable	Pharmacy- advertisable	Pharmacy advertisable

Classification of medicines

Conventional vs Novel medicines

- OTC medicine is regulated under the same regulatory framework as prescription medicines in most AP e.g.
 - Regulatory requirement (quality-efficacy-safety)
 - Registration dossier
 - Pricing control
- OTC could be classified as generic (conventional) or new (novel) drug differently in each country.
- New OTC medicines might be subject to NCE's requirement, if it is new to countries, and will typically given status as Rx initially.
 - New combination
 - New dosage/delivery route
 - New strength etc

ASEAN definition of new (novel) drug

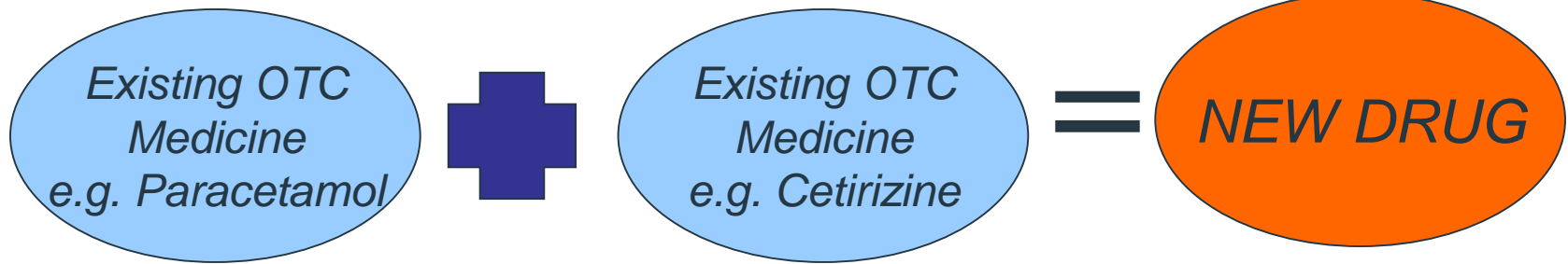
- New Chemical Entity
e.g. salts, esters form of OTC actives, new switched actives etc.
- New Combination
e.g. combination of OTC actives etc.
- New Route of Administration
e.g. topical products of OTC actives previously used as oral format etc
- New Dosage form
e.g. chewing gum, instant granule powder etc.
- New Strength
e.g. higher dose unit, metered dose etc.
- New Indication
e.g. new switched indication, extended indication etc.
- New Delivery System
e.g. Controlled release system of OTC actives etc.

Novel medicines – usually with Rx status as default

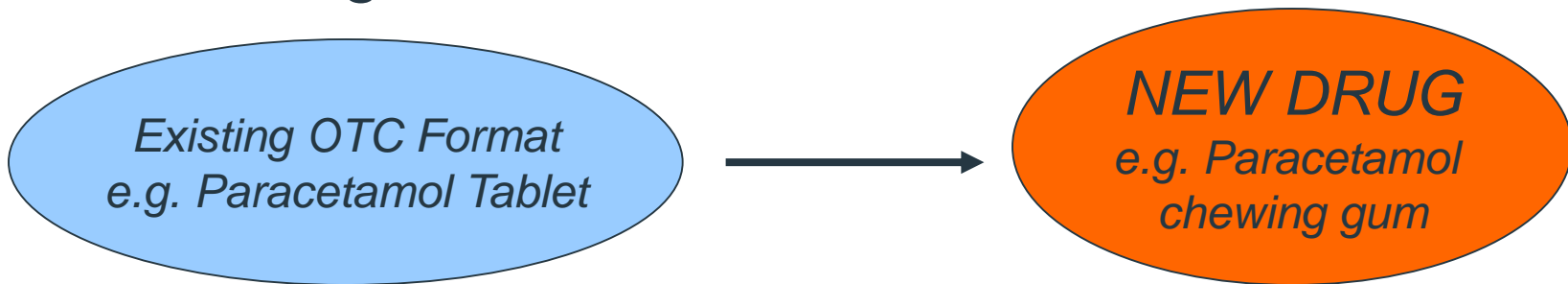


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New combination

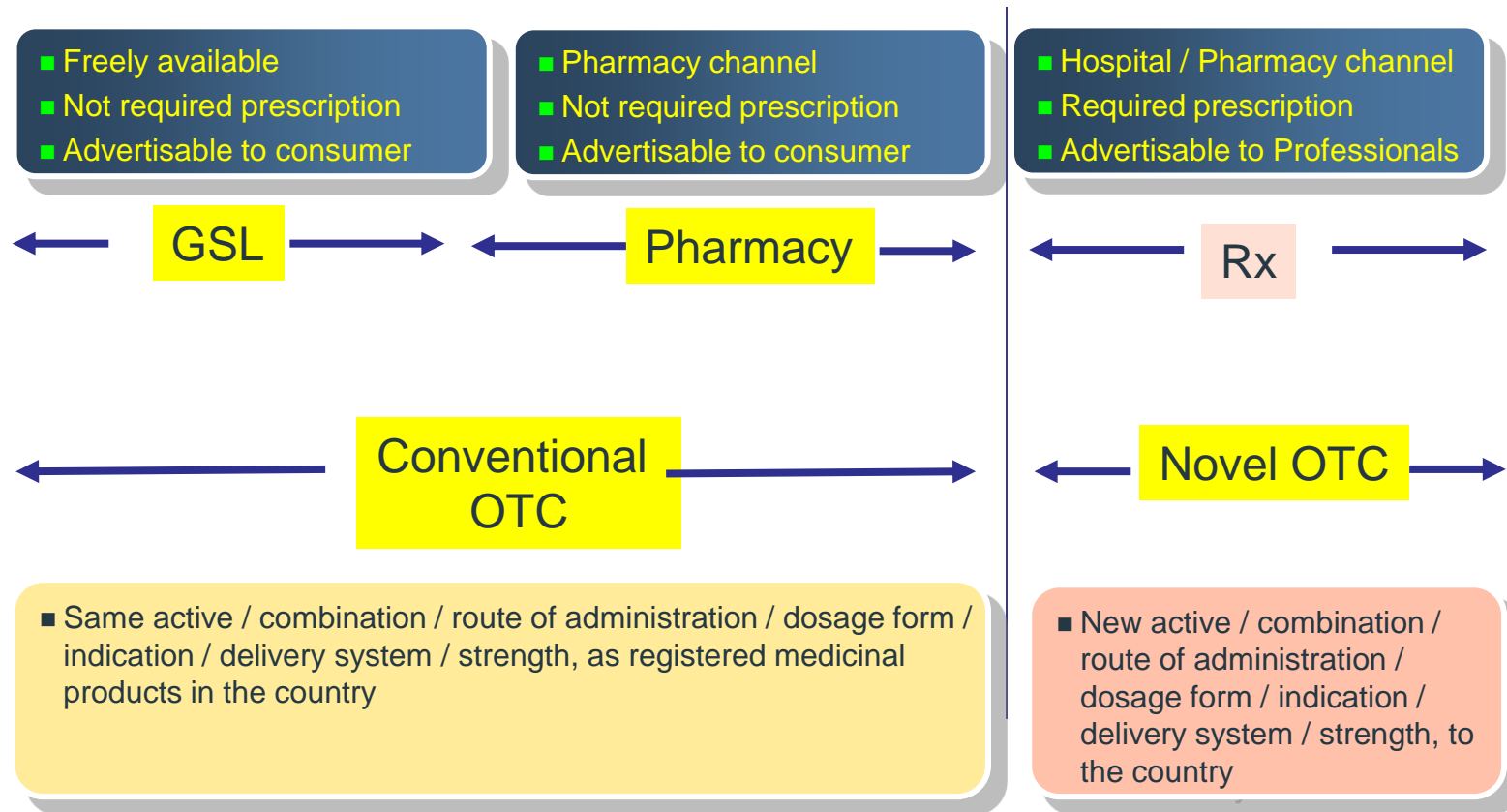


New Dosage form



- ✓ 12-24 months registration
- ✓ Require clinical study
- ✓ Likely to be in prescription classification

Combined framework of medicines classification



OTC Borderline products: legal definition



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Medicine:

- (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medical devices

- Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

OTC Borderline products: legal definition (cont)



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Traditional herbal medicines

- Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

Cosmetics

- Cosmetic products mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition

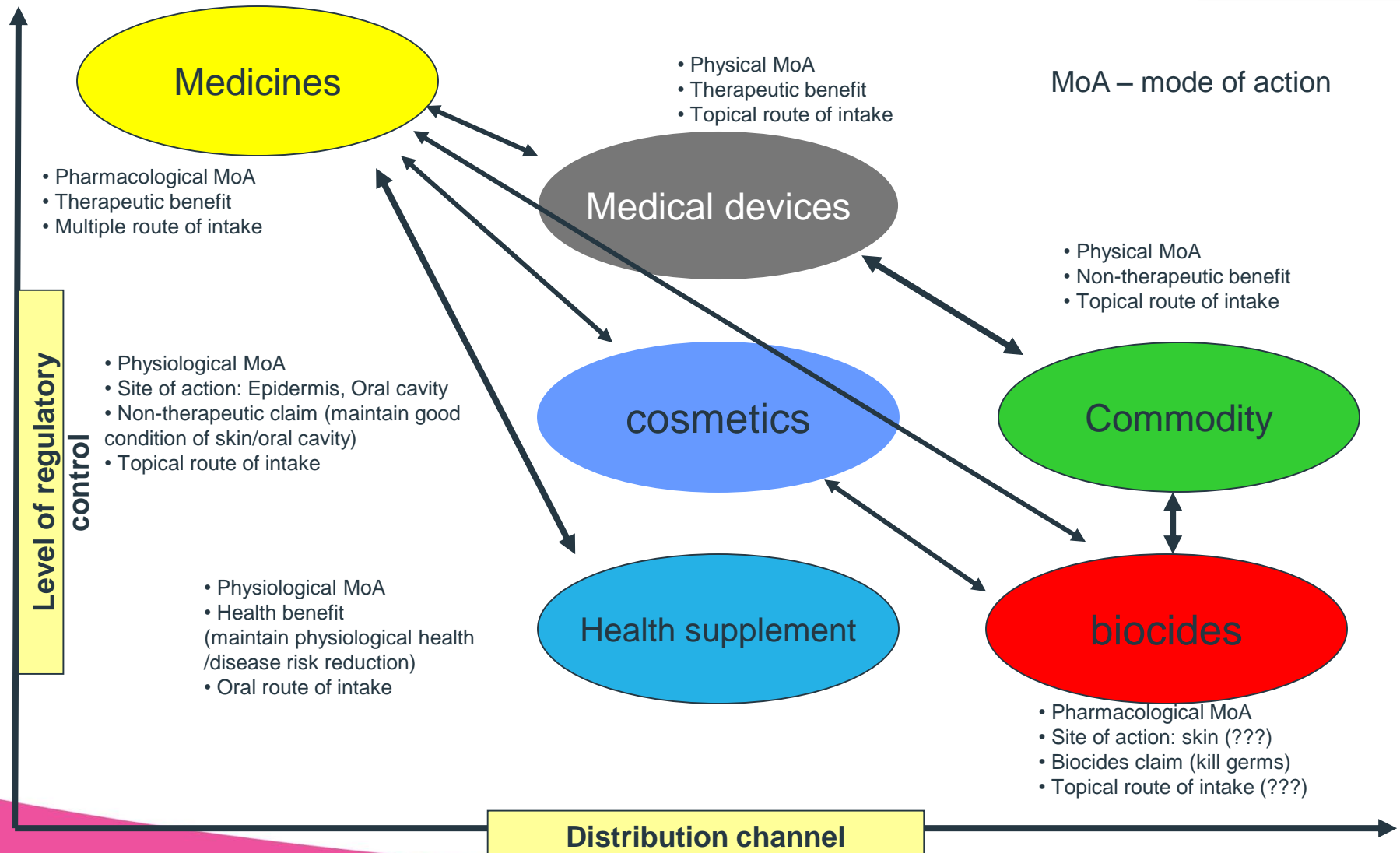
Food supplement

- foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

Borderline of OTC medicines



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Limited

Free sales

Example of possible classifications

- Modern medicine (e.g. **standardized ginger extract** with indication for dyspepsia & motion sickness, or topical anti-infective cream)
- Traditional medicine (e.g. **ginger extract** (non-standardized) with indication for traditionally uses in indigestion)
- Medical devices (e.g. plaster impregnated with **standardized ginger extract** for wound management)
- Cosmetics (e.g. **standardized ginger extract** for antibacterial body cream)
- Food supplement (e.g. **ginger root** capsules)

Factor governing the legal classification

Formulation ingredients
Indication/Intended Use/Claim
Quantity of “active” ingredients
Format and dose etc

Diversity in product classifications

Borderline product (medicine vs non-medicines)

	Thailand	Malaysia	Singapore	Philippines	Indonesia
1% Selenium Sulfide shampoo	Medicine	Cosmetic	Cosmetic	Cosmetic	Cosmetics
Boric acid Eye wash	Medicine	Medicine	Medical Device	Medicine	Medicine
Psyllium seed powder	Medicine	Medicine	Dietary supplement	Dietary supplement	Traditional medicine
Glucosamine	Medicine	Medicine	Dietary supplement	Dietary supplement	Dietary supplement

Summary



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- Classification of product should be determined at the earliest time of product development
- Product classification (Legal status) is important to OTC developments, as it impact the pathway of development & commercialization
- Legal status of medicines can be divided into 3 classification: POM (Rx), P (Pharmacy), GSL (General Sales List)
- Medicine classification also depends on the status of product – Conventional vs Novel medicines (typically granted as Rx initially)
- OTC can be overlapped with borderline products, such as Medical devices, Health supplements, Cosmetics, Traditional medicines

Thank you

ขอบคุณครับ