

# The Regulation of Cosmetics in Japan

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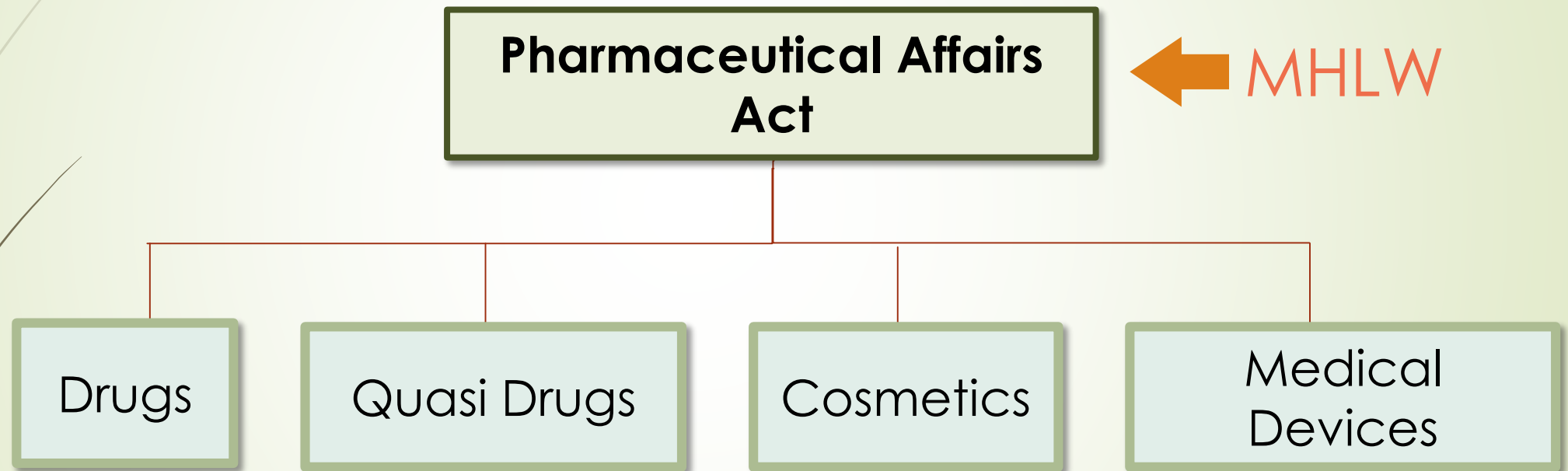
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1. Overview

1.1 The regulation by the Pharmaceutical Affairs Act

**[Fig. 1]** Coverage of pharmaceutical Affairs Act



1. Overview

1.1 The regulation by the Pharmaceutical Affairs Act

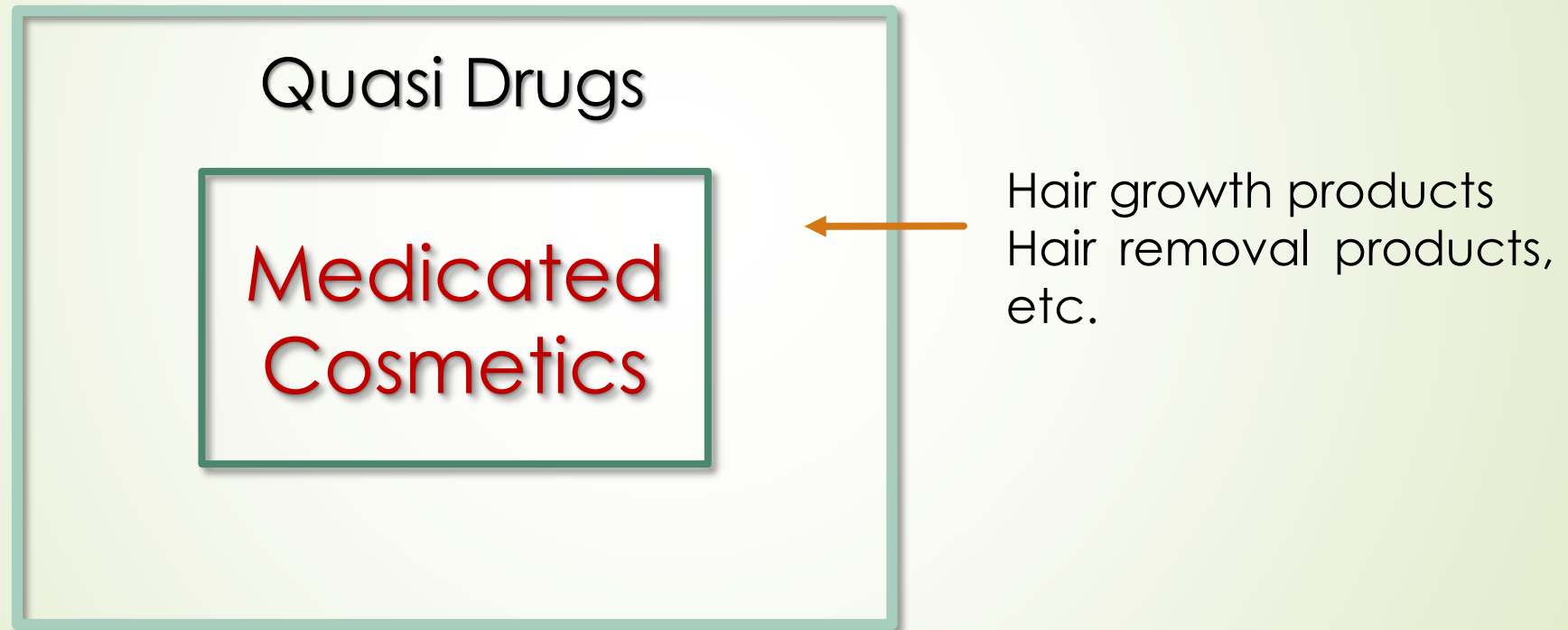
**[Fig. 2]** Two types of Cosmetics



## 1. Overview

### 1.1 The regulation by the Pharmaceutical Affairs Act

#### **[Fig. 3]** Composition of Quasi Drug category




# 1. Overview

## 1.1 The regulation by the Pharmaceutical Affairs Act



### **[Fig. 4]** Regulation history

2001



Abolition of approval system  
Implementation of self-responsibility system

2005

Implementation of primary distribution system  
Introduction of GQP and GVP

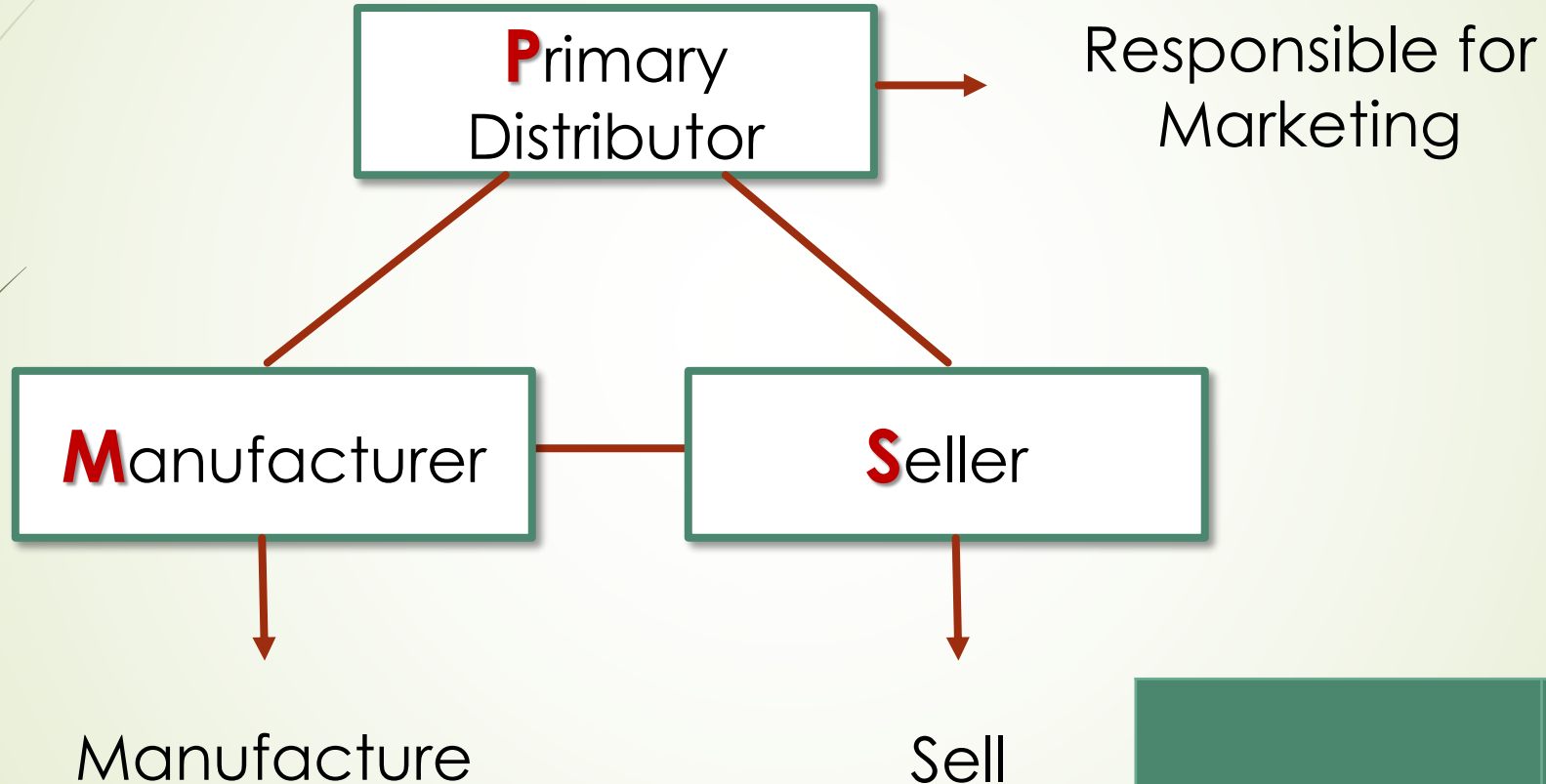
**[Fig. 5]** Definition of Cosmetics

*Any item having mild effects on the human body that is rubbed, spread, or otherwise applied in a similar manner for the purpose of cleansing, beautifying, or enhancing the attractiveness of the human body, to change physical appearance, or to maintain skin or hair in a healthy condition.*

## 2. Cosmetics

### 2.1 What is Cosmetics?

**[Fig. 6]** Key 3 roles of cosmetic company



	Governmental Approval
Primary Distributor	○
Manufacturer	○
Seller	×

## 2. Cosmetics

### 2.1 What is Cosmetics?

**[Fig. 7]** Role-playing patterns of cosmetic company

	<b>P</b> Primary Distributor	<b>M</b> anufacturer	<b>S</b> eller
<b>1</b>	Company A	Company A	Company A
<b>2</b>	Company A	Company A	Company B
<b>3</b>	Company A	Company B	Company C



## 2. Cosmetics

### 2.1 What is Cosmetics?

**[Fig. 8]** General requirements of Primary Distributor and Manufacturer

<b>Requirements</b>	
<b>Primary Distributor</b>	<b>Manufacturer</b>
Personnel requirements (applicant and general manager of P)	Personnel requirements (applicant and head technical)
GQP/GVP conformity: Execution of operations for quality control and post-manufacturing/sales safety management, and appropriate management of manuals and records.	Physical requirements (buildings and facilities of manufacturing plant)

## 2. Cosmetics

### 2.1 What is Cosmetics?

#### **[Fig. 9]** Must-dos for GQP/GVP

GQP	GVP
Sufficient staff having the capability to appropriately and smoothly execute operations	Sufficient staff having the capability to appropriately and smoothly execute operations
Duties of general manager of manufacturing and sales	Duties of general manager of manufacturing and sales
Assignment of quality assurance officer	Assignment of safety management officer
Duties of quality assurance officer	Duties of safety management officer
Preparation of procedure manuals for quality control	Implementation of duties for safety management
Implementation of duties for quality control	Record keeping
Management of documents and records	

## 2.2 The requirements for product launch

- 1) Three types of key person
- 2) Registration to the government
- 3) Product name

### **[Fig. 10]** Prohibited cases of product naming

1	The same name as that of Drugs or Quasi Drugs
2	A name which leads to misrepresentation
3	A name which suggests Drug-like efficacy
4	A name which includes ingredients name
5	A name which is composed of only by the Roman alphabet

...etc.

## 2.2 The requirements for product launch

### 4) Ingredients

#### **[Fig. 11]** Types of list for ingredients

Preservatives, UV absorbers, Tar colors	Positive list
Others	Negative list

## 2.2 The requirements for product launch

### 4) Ingredients

#### **[Fig. 12]** A list of 30 prohibited ingredients

1	6-Acetoxy-2,4-dimethyl-m-dioxane
2	Antihistamines except those of aminoether type (such as diphenhydramine)
3	Hormones and those derivatives except estradiol, estrone and ethinylestradiol
4	Vinyl chloride monomer
5	Methylene chloride
6	Bismuth compounds other than bismuth oxychloride
7	Hydrogen peroxide
8	Cadmium compounds
9	Sodium perborate
10	Chloroform
11	Progrenolone acetate
12	Dichlorophene
13	Mercury and its compounds
14	Strontium compounds
15	Sulfamide and its derivatives
16	Selenium compounds
17	Nitrofurantoin type compounds
18	Hydroquinone monobenzylether
19	Halogenated salicylanilide
20	Vitamin L1 and Vitamin L2
21	Bithionol
22	Pilocarpin
23	Pyrogallol
24	Inorganic fluorine compounds
25	Pregnanediol
26	Local anesthetics such as procaine
27	Hexachlorophen
28	Boric acid
29	Formalin
30	Methyl alcohol

## 2.2 The requirements for product launch

### 4) Ingredients

#### **[Fig. 13]** Additional Prohibition

Additional  
Prohibition

#1 Medical drug  
ingredients

#2 Ingredients that do not  
meet the standards  
for Biological Materials

## 2.2 The requirements for product launch

### 4) Ingredients

#### **[Fig. 14]** DHC, CoQ10's case

CoQ10 → Not among 30 negative ingredients



DHC: Launch cosmetic with CoQ10



MHLW suspended due to medical drug  
ingredient theory

## 2.2 The requirements for product launch

### 5) Time Required

**[Fig. 15]** Time required for approval

The local government accepts the application usually within one week.



## 2.3 Marketing Regulation

### 1) Scope of effectiveness

#### [Fig.16] Scope of recognized cosmetic effects

**Govt. approval is not required**

1	Cleansing hair and scalp	29	Soften skin
2	Using fragrance to reduce unpleasant hair and scalp odors	30	Give gloss to skin
3	Keep hair and scalp healthy	31	Give luster to skin
4	Give moisture and sheen to hair	32	Make skin smooth
5	Moisturize hair and scalp	33	Make beards easier to shave
6	Keep hair and scalp moist	34	Condition skin after shaving
7	Make hair supple	35	Prevent rashes
8	Make hair easier to brush	36	Prevent sunburn
9	Keep hair lustrous	37	Prevent skin splotches and freckles resulting from sunburn
10	Give luster to hair	38	Impart fragrance
11	Stop dandruff and itching	39	Protect nails
12	Control dandruff and itching	40	Keep nails healthy
13	Supplement and maintain hair moisture and oil content	41	Moisten nails
14	Prevent hair breakage and frizzing	42	Prevent chapped lips
15	Improve and maintain hair pattern	43	Fill in lip creases
16	Prevent hair static electricity	44	Moisten lips
17	Cleanse dry skin (that has become dry as a result of cleansing)	45	Keep lips healthy
18	Prevent blemishes and rashes (by cleansing) (facial wash)	46	Protect lips, prevent dryness
19	Condition skin	47	Prevent lip roughness caused by dryness
20	Combat skin wrinkles	48	Make lips smooth
21	Keep dry skin supple	49	Prevent cavities (brushing teeth with toothpaste)
22	Prevent skin chapping	50	Whiten teeth (brushing teeth with toothpaste)
23	Tighten skin	51	Remove plaque (brushing teeth with toothpaste)
24	Moisten skin	52	Cleanse the mouth (toothpaste)
25	Supplement and preserve skin moisture and oil content	53	Prevent bad breath (toothpaste)
26	Keep skin soft	54	Remove tooth film (brushing teeth with toothpaste)
27	Protect the skin	55	Prevent plaque deposits (brushing teeth with toothpaste)
28	Protect skin dryness	56	Making fine wrinkles due to dryness less noticeable

Note 1: Parenthesized text refers to aspects of physical form during usage, not to the effect itself.

Note 2: #56 should be based on the Guidelines for the Method of Evaluating the Functions of Cosmetic Products (2011, Japanese Cosmetic Science Society)

**[Fig.17]** Scope of recognized cosmetic effects

MHLW — The Act

Appropriate advertising standard  
for Drugs, Quasi Drugs, Cosmetics  
and Medical Devices

➔ Mainly Efficacy

➔ Other methods  
besides efficacy

**[Fig. 18]** Prohibition in cosmetic advertising

1	Testimonials should not be used besides feeling of use
2	Before-After comparison should not be used
3	Clinical trial data should not be showed
4	Recommendation of medical experts such as a medical doctor is prohibited

...etc.

### 3. Medicated Cosmetics

#### 3.1 What is Medicated Cosmetics?

## **[Fig. 19]** Important effectiveness for Medicated Cosmetics

Practically important effectiveness as Medicated Cosmetics

<b>1</b>	Skin-whitening or to prevent sun spots and freckles
<b>2</b>	To prevent acne
<b>3</b>	Sterilization by soap
<b>4</b>	Wrinkle improvement

### 3.2 The Requirements for product launch

1) Tree types of key person ~ 4) Ingredients

#### [Fig. 20] Approved ingredients for Medical Cosmetics

1	Ascorbic acid/derivatives
2	Placental Extracts
3	Kojic Acid (Obtained by Sansho Seiyaku Co., Ltd. in 1988)
4	Arbutin (Obtained by Shiseido Co., Ltd. in 1989)
5	Ellagic Acid (Obtained by the Lion Corporation in 1996)
6	Chamomilla Extract (Obtained by the Kao Corporation in 1998)
7	4-n-Butylresorcinol (Rucinol <sup>®</sup> ) (Obtained by POLA in 1998)
8	Linoleic Acid (Obtained by Sunstar Inc. in 2001)
9	Tranexamic Acid (Obtained by Shiseido Co., Ltd. in 2002)
10	4-Methoxy Potassium Salicylate (4MSK) (Obtained by Shiseido Co., Ltd. in 2003)
11	Adenosine Monophosphate Disodium Salt (Obtained by Otsuka Pharmaceutical Co., Ltd. in 2004)
12	5,5'-Dipropyl-biphenyl-2,2'-diol (Magnolignan <sup>®</sup> ) (Obtained by Kanebo Cosmetics Inc. in 2005)
13	4-(4-Hydroxyphenyl)-2-butanol (4-HPB) (Obtained by Kanebo Cosmetics Inc. in 2007)
14	Tranexamic Acid Cetyl Ester Hydrochloride (Obtained by CHANEL .KK in 2009)

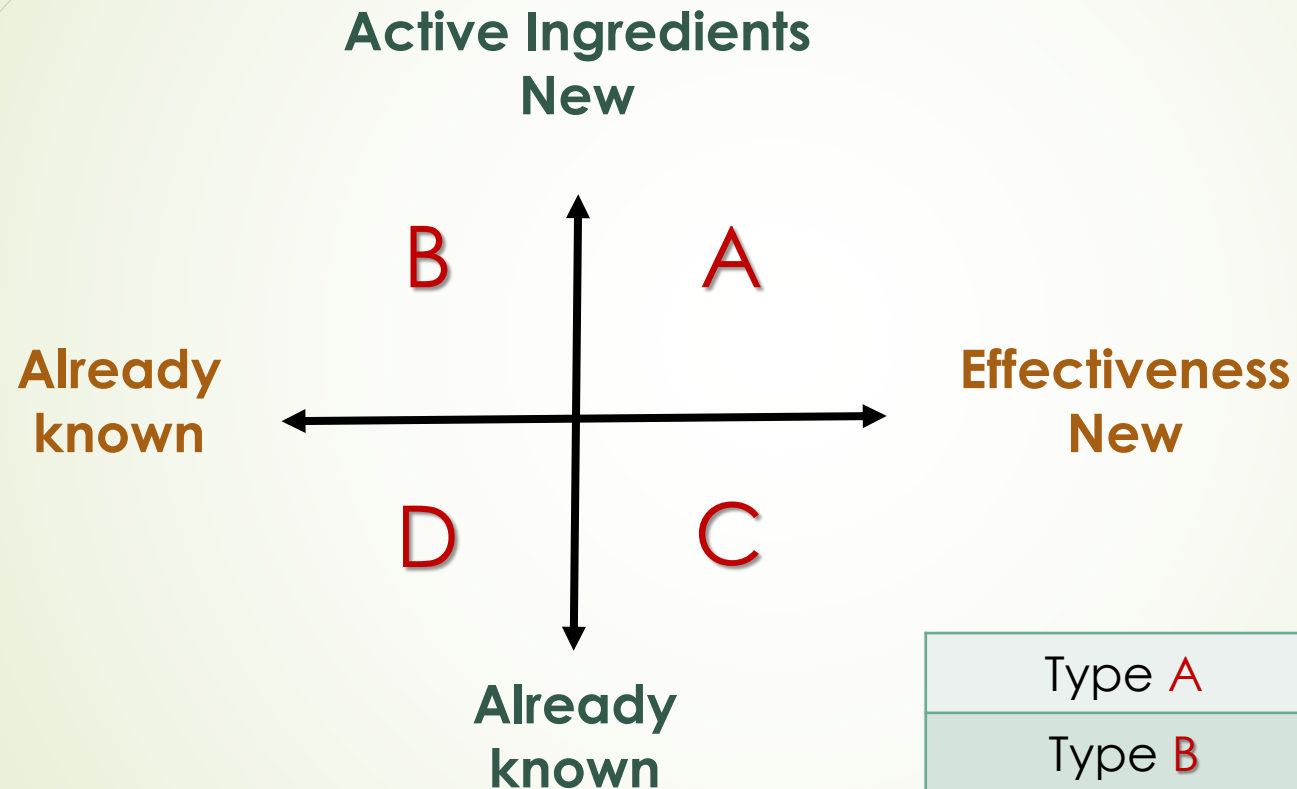
...etc.

### 3.2 The Requirements for product launch

5) Scope of effectiveness

6) Time required

**[Fig. 21]** Matrix chart: Active ingredients vs Effectiveness



Type A	extraordinary difficult
Type B	very difficult
Type C	very difficult
Type D	easy

### 3.3 Marketing regulation

#### 1) Scope of claim

**[Fig. 22]** Scope of claim

Drugs > **Medicated Cosmetics** > Cosmetics

### 3.3 Marketing regulation

#### 1) Scope of claim

**[Fig. 23]** Scope of claim for acne

<b>Drugs</b>	cure acne
<b>Medicated Cosmetics</b>	prevent acne
<b>Cosmetics</b>	prevent acne by facial wash (soap)



#### 4. Quick look of the regulatory requirements for exporting cosmetics to Japan

**[Fig. 24]** Business flow of exporting cosmetics to Japan

