

Regulatory Optimization on self-care medicines' regulation in ASIAN Countries [Self-CARER Activities]



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Risk-based categorization of medicines

Characteristics

Cost of Medication

New Drug

- Unknown efficacy and safety
- High work load for Reviewer
- Expensive Cost (with high cost for medical doctor)

Generic Drug

- Relatively known efficacy and safety
- Moderate work load for Reviewer
- Relatively low Drug Cost (with high cost for medical doctor)

Self-care Medicine*

- Known efficacy and safety
- Low work load for Reviewer
- Low Cost (without cost for medical doctor)

Covered by
Health Insurance
(Certain portion)

Responsibility by
the individual

*Self-care medicine:

almost same meaning as OTC, i.e. "Medicinal products which can be used by consumers to treat self-recognized and minor disorders/ symptoms/ illness and be available without prescription".

Under the different regulation, neutral term "**self-care medicines**" was preferred in Self-CARER.

Rational for “Self-Medication”

[Macroscopic view]

- As country’s economy develops, the cost of health insurance for innovative medicine/medical device increases.
- National Health system is covered by national budget. When health insurance expense increased, budget assignment in the country is critically discussed, especially, from the viewpoint of the assignment balance between prescription drugs and self-care medicines.

[Microscopic view]

- self-care medicines is categorized separately from prescription drug which does not need to be paid from national budget
- self-care medicines is used from “self-decision” by self-funding
(Self-Medication)
- Accumulated experience exists in the use of self-care medicines to patients (this means safety profile is different from prescription drug)

Japan's efforts up to the present

(as Example case on OTC pharmaceuticals)

1. Revision of sales regulation of non-prescription drugs
2. Development of healthy longevity increasing industry
3. Reviewing the roles of OTC pharmaceuticals
4. Clarifying the roles of parties involved
5. Simplification of approval assessment
6. Enrichment of safety measures
7. Promoting Rx-to-OTC switch
8. Establishment of Self-medication tax system (special exemption of medical cost)

OTC pharmaceuticals (about 11,000 items)

Approved by the minister

- ⊖ Pharmaceuticals not applicable to the standards for approval by the governor

Approved by the governor

- ⊖ Pharmaceuticals applicable to the standards for approval by the governor
- ⊖ Standards for approval by the governor are prepared for the following efficacy groups (15 efficacy groups):
 - n Cold remedy
 - n Antipyretic and analgesic
 - n Antitussive and expectorant
 - n Gastrointestinal medicine
 - n Laxative
 - n Antivertiginous drugs
 - n Ophthalmologic drugs
 - n Preparations with vitamin as primary agent
 - n Enema agent
 - n Anthelmintic
 - n Nasal drug for rhinitis
 - n Oral agent for rhinitis
 - n External agent for hemorrhoids
 - n Drugs for athlete's foot and ringworm
 - n Antipruritic and anti-inflammatory

(about 4,500 items)

Period required for approval assessment

Due to the approval standard, the assessment period is shorter than the period of approval by the minister.

- ∅ Approval by the minister : 7.0 months
- ∅ Approval by the governor : 2 to 3 months

Expansion and review of items approved by the governor

<Advantages>

- ∅ Citizens : Expansion of items that meet the needs
- ∅ PMDA : Faster assessment of items in new areas due to reductions in the assessment of OTC pharmaceuticals
- ∅ Companies : Reduction in burden of development, faster product making

Promoting Rx-to-OTC switch

“Japan Revitalization Strategy” revised in 2014 – challenges for the future – (June 24, 2014)

Second part: Three action plans

2. Strategic market creation plan

Theme 1: Prolongation of “healthy longevity” of the citizens

(3) Specific measures to be newly considered

ii) Activating the service industry not covered by public insurance

(iii) Promoting transfer from ethical pharmaceuticals to OTC pharmaceuticals (Rx-to-OTC switch)

The following measures will be taken to accelerate the transfer of pharmaceuticals (including diagnostic drugs) from ethical to general use (Rx-to-OTC switch) for promotion of self-medication:

...

- Mechanisms that reflect the opinions of more diverse bodies, such as the industries and consumers, will be established within this fiscal year with reference to examples overseas (e.g., USA).

Basic policies in economic/financial management and reform (outline) 2014 (June 24, 2014)

Chapter 3: Positive cycle of economic revitalization and financial restoration

2. Idea on the priority and efficiency in primary areas of expenditure

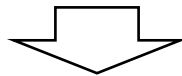
(1) Social security reform

(Reform of drug prices and pharmaceuticals)

In order to promote self-medication, efforts for accelerating the transfer of pharmaceuticals (including diagnostic drugs) from ethical to general use (Rx-to-OTC switch) should be implemented with the setting of specific goals.

Problems on current regulations of self-care medicines

Currently, many global and regional harmonization initiatives evolve, but almost no attentions are paid for self-care medicines area as a target of regulatory optimization.

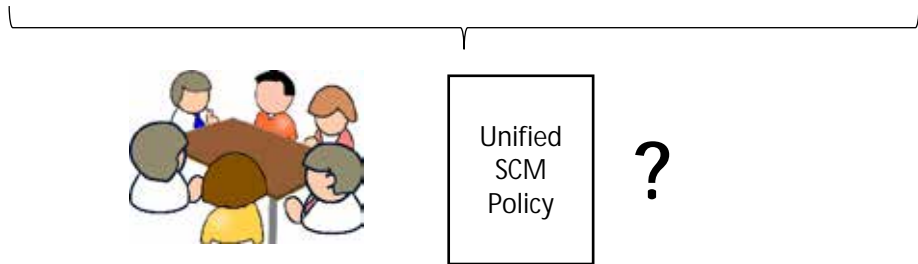


As a result, it happens that

- Review requirement and process for self-care medicines are the same as for new drugs and generic drugs in many countries including Asian region, and
- Optimized regulatory system is not available for self-care medicines.

Disadvantages raised from deficiency of harmonization on Self-care medicine (SCM)

- No platform to share knowledge and review policy of SCM reviewers.
- Lack of unified review policy may lead un-optimized regulatory resource allocation.



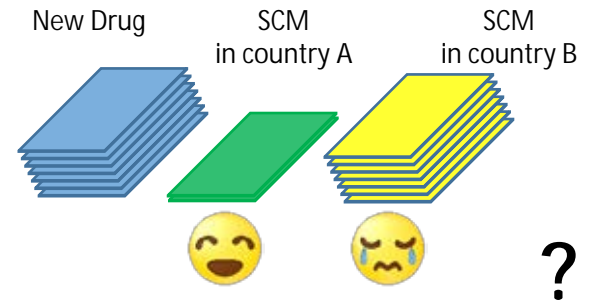
- SCM is not categorized as stand alone review category.
- Applicants need to submit same amounts of data as new drugs.
- Burdensome to both applicants and reviewers

- Same medicine is sold as Rx in one country and as SCM in other country.
- Information item on labelling is different in each country.
- Such situation makes confusion of traveler.

Country A
Rx



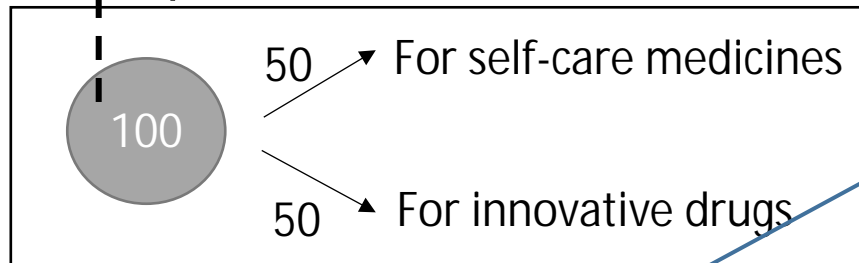
Country B
SCM



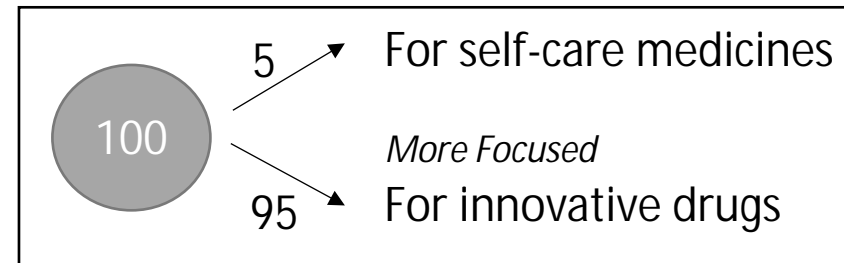
Benefit of optimization on regulatory system of self-care medicines

Amount of regulatory resource

Equal resource allocation



Optimized resource allocation



Optimization by utilizing known efficacy and safety profiles and/or other countries experiences on the basis of mutual reliance

Seek WHO's input regarding *Good Reliance Practice*

Through harmonization/optimization,

- resource of a regulatory agency for self-care medicines can be allocated to the resource for more innovative drugs
- self medication policy can be promoted in national citizens

Discussion place “Self-CARER”

“Self-Medication Collaborative Asian Regulator Expert Roundtable (Self-CARER)” is an **unique platform** for the regulatory optimization of self-care medicines in Asia.

[Past Meetings]

1st Meeting : in 2014 (Phuket, Thailand)

2nd Meeting : in 2015 (Bangkok, Thailand)

3rd Meeting: in 2016 (Nagoya, Japan)

[Next Meeting]

4th Meeting: Mar. 20-22, 2018 in Taiwan

[Character of Self-CARER]

- no legal bounding
- expert-based discussion
- learning development
- mutual reliance

3rd Meeting

- Date: 12-13 October, 2016
- Place: Nagoya (Japan)
- Participants:

Cambodia, Chinese Taipei, Indonesia, Japan, Korea, Lao P.D.R., Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

- Guest: Dr. Lembit Rägo (CIOMS)
- Chair: PMDA (Japan), Co-Chair: Thai FDA (Thailand)



3rd Meeting Achievements

Topics	Achievement	Future issue
Increasing efficiency on registration/review process	<u>Safety and efficacy data were exempted from submission in many countries. Many regulators prioritized review of quality data.</u>	<u>Have more technical discussion. Japan will lead this effort.</u>
Ingredient directory	<i>The Meeting recognized that although many regulators have their own database, it is difficult to share such database mostly by the language used. Possibility to utilize existing database will be explored.</i>	<i>Facilitate continuous information sharing. Therefore, there is no appointed authority to lead this.</i>
Switch/Re-classification	<u>The Meeting recognized that information sharing of existing guidelines would be beneficial to the countries who do not have guideline.</u>	<u>Share information regarding different regulatory authorities' switch/reclassification systems. Thailand will lead information gathering efforts.</u>
Others	<i>The Meeting selects Self-CARER logo.</i>	<i>Continue information sharing while searching for an appropriate training provider</i>

Support from Industry

Self-CARER activity is supported by industry association APSMI (Asia-Pacific Self-Medication Industry) especially in terms of logistic arrangements and suggestions for technical topics.

APSMI-participating associations

China	China Nonprescription Medicines Association (CNMA)
Philippines	Consumer Healthcare Industry Association of the Philippines, Inc. (CHAP)
Indonesia <i>NEW</i>	Gabungan Perusahaan Farmasi Indonesia (G.P. Farmasi Indonesia)
Japan	Japan Federation of Self-Medication Industries (JFSMI)
Korea	Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)
Chinese Taipei	Taiwan Pharmaceutical Marketing & Management Association (TPMMA)
Thailand	Thai Self-Medication Industry Association (TSMIA)

Self-CARER initiative is recognized by WHO as one of the unique regulatory networks in a global perspective

An article entitled “The Self-medication Collaborative Asian Regulator Expert Roundtable (Self-CARER)” has been published in WHO Drug Information Vol. 31, Number 1 (2017).

<http://www.who.int/medicines/publications/druginformation/en/>



Thank you very much!!

