

Welcome to

2nd APSMI General Assembly Meeting

EUN-SUN, KIM

Chairperson of APSMI

The Role of Self-Medication and OTC in Healthcare



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- 1. Definition of Self-Medication**
- 2. Self-Medication Development in Korea**
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1. Definition of Self-Medication

Self-Cure or Self-Treatment that patients treat minor ailments by themselves.

Know how to use medicines correctly

Continuous health care in daily life

Obtaining correct information on the medicines

Cultivating a habit to check health and lifestyle

- **Decrease of medical expenses**
- **Extension of healthy life span**
- **Prevention of serious diseases**

2. Self-Medication Development in Korea

Previous recognition (Negative)

- ✓ Medicines have risks.
- ✓ It's better not to take medicines as much as possible.
- ✓ In case the Symptom becomes worse, should go to hospital.



Changing recognition (Positive)

- ✓ Medicines can be muchly effective if properly used.
- ✓ Self-Medication is practicable if acquiring the correct knowledge of medicines.



2. Self-Medication Development in Korea

Future consumer education



'How to correctly use medicines' Puppet Show in 2014

- Date: May 30th, 2014
- Venue: Geumcheon-Gu Community Center, Seoul
- Audience: over 500 children

2. Self-Medication Development in Korea

Educational Programs for Consumers

1st Step

2014

Program for children

2nd Step

2015

Introduction to official curriculum
(primary/middle/high school)

3rd Step

2016~

Development of nationwide education program

3. Review on APSMI activities in Asia

● **Sharing Self-Medication Activities**

- Exchange of detailed activities
- Exchange of successful cases

● **Boosting the Optimization of OTC regulation in Asia**

- Support the 1st OTC regulatory authorities roundtable meeting at Phuket (Oct 20th, 2014)
- Suggest 『The Future Perspectives on OTC Regulation in Asia』

● **Publish APSMI Country Report 2014**

- APSMI activities and results

3. Review on APSMI activities in Asia

The Future Perspectives on OTC Regulation in Asia

The Future Perspectives on OTC Regulation in Asia

"To expedite the launch of high-quality OTC medicines for Asian consumers"

1. Active ingredients of OTC medicines must have the experience/evidence of safe and efficacious use in prescription or OTC medicines, and the safety and efficacy of OTC medicines must be confirmed. Considering the lower level of risk in OTC medicines, the assessment process for OTC approval should be different from the assessment process of new ethical medicines.
2. The Investigation of the registration requirements should be conducted to optimize the data required for OTC medicines approval in each country, and avoid the unnecessary repetition of data generation to support the registration, particularly clinical studies.
3. OTC medicines which active ingredients are listed in the monograph and/or have the experience/evidence of use in other countries, which active ingredients have evidences of safety and efficacy, and which active ingredients do not exceed the dosage and application in other countries, should be regarded as the "well-established OTC medicines" and the minimum approval requirements should be adopted by the regulatory authority (e.g. ANDA or generic drug application, instead of NDA or new drug application).
4. The appropriate use of Brand names in OTC medicines should be authorized, given it help in communicating the characteristics of OTC medicines, and avoiding the misapplication use.
5. Tabular list of ingredients/dosages approved for OTC medicines in each country (Asian version monograph) should be established, and health authorities should explore the harmonization possibility to allow the common classifications, ingredients, doses etc. in OTC medicines within Asia.
6. Efforts should be made to achieve optimization of OTC approval assessment through interaction between regulatory authorities of individual countries, and ultimately the cooperation between authorities in driving the regulatory optimization or harmonization in OTC registration across Asia.

1. Simplify OTC product approval procedures
2. Optimize the required dossiers for the product approval.
3. Appropriate use of brand names
4. Tabulate Asian monograph
5. Exchange information between regulatory authorities

3. Review on APSMI activities in Asia

Publish APSMI Country Report 2014 (APSMI activities and results)



✓ Self-Medication activities in each country

✓ Information on OTC regulation in each country

✓ The Future Perspectives on OTC Regulation in Asia

✓ OTC market information for Asia-Pacific area

Thank You