



# 2<sup>nd</sup> APSMI Board of Directors Meeting

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18<sup>th</sup> October 2012

COEX Intercontinental Hotel

Seoul



# Today's Agenda

- 1. Confirmation of minutes of 1<sup>st</sup> APSMI Board of Directors Meeting, 7<sup>th</sup> October 2011**
- 2. Membership development**
- 3. Activities and Accounting Report in 2012**
- 4. 9<sup>th</sup> WSMI AP Regional conference & 1<sup>st</sup> APSMI GA**
- 5. Activities and the budget in 2013**
- 6. The 2<sup>nd</sup> APSMI General Assembly Meeting**
- 7. Topics from member associations**
- 8. Announcement**
- 9. Others**

# Member Replacement

## ***Board Member, National Association***

### ***KPMA***

[Ms. Han Byul \(Kristeen\) Jhung](#), team leader of international affairs: Succeeded Ms. Heeha Kim

### ***TPMMA***

[Ms. Sylvia Tsai](#), Vice Director of OTC Committee, Succeeded Ms. Iris Wang

### ***TSMIA***

[Ms. Malinee Uditananda](#), President, Succeeded Dr. Noppadon Adjimatera

## ***Board Member, Corporate***

### ***Daiichi-Sankyo HC***

[Mr. Yoshiki Nishii](#), new President of Daiichi-Sankyo HC Succeeded Mr. Toshio Takahashi

# Chairperson Election

## **New Chairperson of APSMI**

### **Ms. Eun Sun Kim**

Chairperson of Boryung Pharmaceutical Co. Ltd.  
Chairman, OTC Drug Promotion Committee of KPMA  
Vice-Chairperson of APSMI

## **Nominated new Vice- Chairperson**

### **Mr. Seiichi Sato**

President & CEO of Sato Pharmaceutical Co. Ltd.  
Vive-Chairman of WSMI, Vice-Chairman of JSMI  
Chairperson of APSMI

# **APSMI Activities in 2011, 2012**

# APSMI's Objective

**APSMI shall contribute the development of consumer healthcare industries, especially OTC industries in Asia-Pacific region with the consensus of the members to promote the responsible Self-Medication in Asia Pacific region, and with the exchanging and sharing information**

**Regulation** (including Rx-to-OTC Switching) and **Self-Medication** were selected as projects for exchanging and sharing information, and Mutual understanding.

**Promote the development of consumer healthcare industries, especially OTC industry, and revitalize OTC market through enhancing each country's Self-Medication and optimizing OTC regulation in the Asia-Pacific region.**



# Expected Outcome of Projects

- Promotion of consumer's health by carrying forward Self-Medication
- Improvement and optimization of OTC regulation in each country
- Quick launch of OTC medicines necessary for consumers including switch OTCs on the market
- Improvement of the access to OTC medicines and revitalization of OTC market
- Reduction of the healthcare expenditure covered by health insurance

# Tasks to be Achieved

- **Gaining the understanding by healthcare professionals and health authorities for promoting Self-Medication and using OTC medicines including switch OTCs**
- **Gaining the understanding by each regulatory authority for the optimization of OTC regulation**
- **Consultation with relevant parties including regulatory authorities for implementation of optimized OTC regulation in Asia-Pacific region**

# **Action Plan and Schedule (1)**

## **1. Short term (2011-2012)**

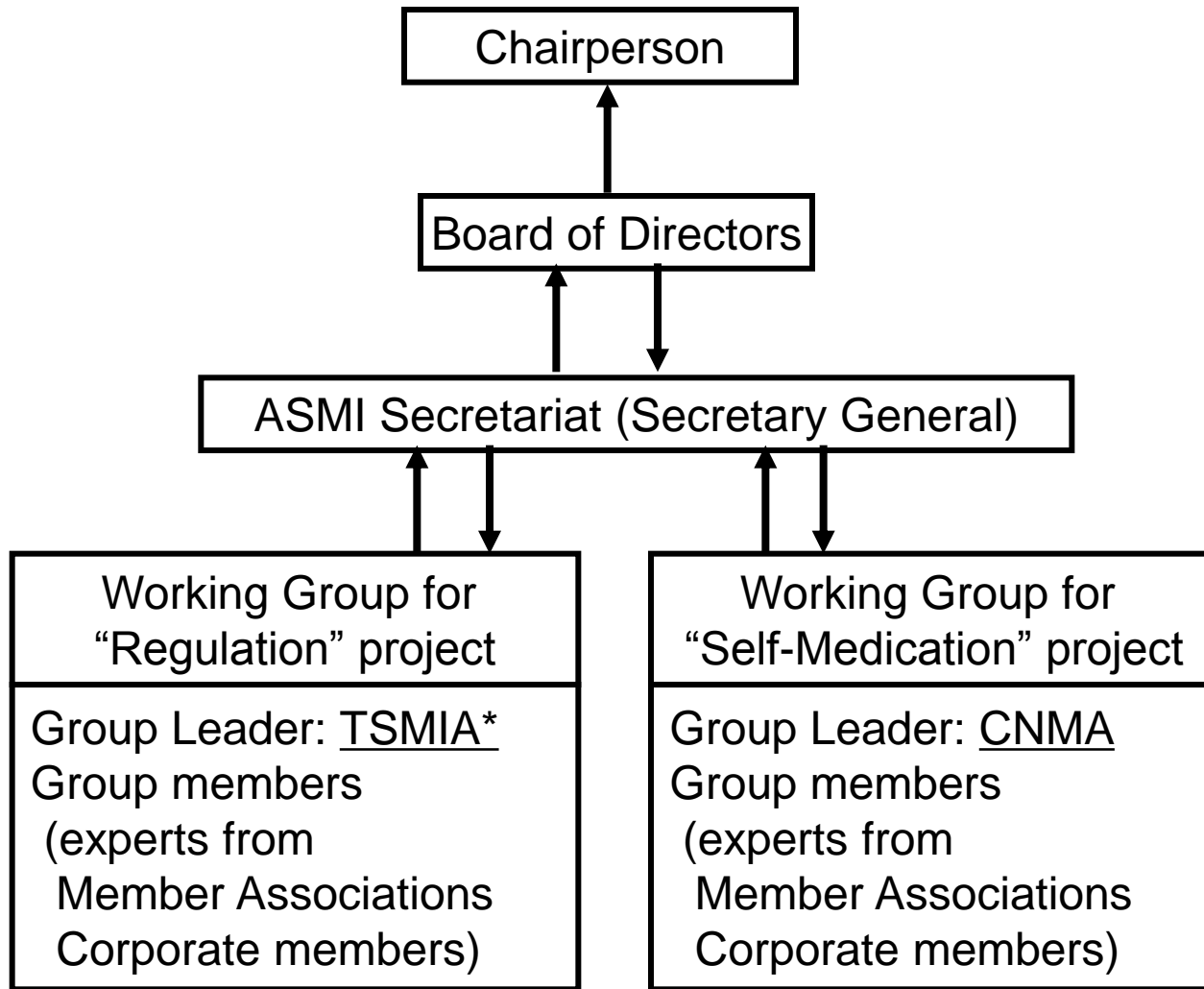
- Advancing – projects-, for “Self-Medication” and “Regulation”, and sharing the project results and mutual understanding within members**
- Reporting at 1st APSMI GAM**

## **2. Mid Term (2013-2014)**

- Pick up common problems & country specific issue**
- Starting the challenges for the solution of problems picked up from each project**
- Selection of new projects**

## **3. Long term**

- Clarifying the significance of OTC medicines**
- Achieving the healthy development and activation of healthcare industries and OTC industries**



\*Successor: JSMI, TPMMA

## **Step I (2011-2012)**

Collecting information on OTC regulation

- Classification and approval system of OTC in each country
- Regulation for OTC marketing, selling and advertisement
- Regulation for OTC quality

Summarization and share of the survey results

## **Step I (2011-2012)**

Survey of Self-Medication status in each member country

- OTC market/status of users
- Environment for self-medication
- Circumstances and cases of self-medication enlightenment activities

Summarization and share of the survey results

# Activities in 2012

- 1. Progress of projects**  
**Survey, Reports by WG**
- 2. 1<sup>st</sup> APSMI General Assembly**  
**with 9<sup>th</sup> WSMI Asia-Pacific Regional**  
**Conference, hosted by KPMA**
- 3. Publication of APSMI Country**  
**Report**
- 4. Introduce APSMI to non-member**  
**association**
- 5. Communication with WSMI**



**Theme: Future Horizons for Self-Care**

**Date: 19<sup>th</sup> Thursday, 20<sup>th</sup> Friday, October, 2012**

**Venue: COEX, Seoul, Korea**

**Host Association: KPMA**

# **Results of APSMI Activities**

## **APSMI Country Report**

**Self-Medication  
Working Group**

**Regulation  
Working Group**

**Information sharing**



**Reporting at the 1st APSMI General Assembly**



## **APSMI country report 2012**

- Survey report by APSMI Working groups
- OTC Market Review in Asia Pacific Region by Nicholas Hall & company, ASMI, CNMA, JSMI

# Country Report Index

- 1. Chairperson's Foreword**
- 2. Message from Nicholas Hall**
- 3. APSMI Profile and Activities**
- 4. Self-Medication Status Survey Report**
- 5. Regulation Survey Report**
- 6. Working Group Member**
- 7. OTC market in Asia-Pacific Region**
  - 1) Global View**
  - 2) Asia Pacific Review**
  - 3) Country/ Region Reports**

## Current Regulatory Status Survey

### - Focus Points -

- 1. Registration hurdle of OTC medicines**
- 2. Regulation for OTC marketing, selling and advertisement**
- 3. Quality and manufacturing control for OTC medicines**

## Items of the Survey

- 1. OTC classification**
- 2. Example of OTC products**
- 3. License requirement for OTC products**
- 4. Application type of OTC medicines registration**
- 5. Required document of OTC registration**
- 6. Lead time for OTC registration (in month)**
- 7. Problem about OTC classification and approval**
- 8. Advertising channel for OTC products**
- 9. Country's problem about regulation for OTC marketing, selling and advertisement**
- 10. Quality Standard/Regulation for OTC products**
- 11. Country's problem about regulation for OTC quality and manufacturing control**

## The Conclusion of Results

- 1. Registration hurdle of China and Thailand is higher than other countries.**
- 2. Japan does not have an Authority pre approval system for OTC Advertisement.**
- 3. Chinese Taipei has a local PIC/S GMP. On the other hand, Thailand GMP will be up-graded to PIC/S in 2015.**

## **Current Self-Medication Status Survey**

### **- Focus Points –**

**1. OTC market/status of users**

**2. Environment for Self-Medication**

**3. Circumstances and cases of Self-Medication enlightenment activities**



## **Main items of the Survey**

- 1. Recognition of Self-Medications**
- 2. Recognition ratio of OTC Medications**
- 3. Favorable counselor for Health Problems**
- 4. Access to OTC medicines**
- 5. Influence of health care system in each countries**
- 6. Benefits of OTC medicines**
- 7. Promotional activities on Self-Medication**
- 8. Cooperative organization for promotion of Self-Medication**
- 9. Multilateral activities to promote the Responsible Self-Medication with other associations**

## **The Conclusion of a Results**

- 1. There is a difference in degree for recognition of Self-Medication and OTC medicines.**
- 2. Physician is the largest number of answers for “favorable counselor for health problems”. Others are Pharmacist and Consumers themselves.**
- 3. National health care system is a one of barriers for promoting Self-Medication.**
- 4. Advertising by media, event for consumer, publication of Self-Medication booklets are popular for “promotional activities on Self-Medication.**

# **APSMI Activity Plan For 2013**

## Step II (2013)

Investigating and planning action plan for optimization of OTC regulation throughout Asia-Pacific region

- Analyzing problems of each country and pick up common challenges in the region
- Drawing schemes for common challenges and prioritizing them
- Breaking down the schemes for each association to achieve challenges in Asia-Pacific region

Meeting with Authorities, other Stakeholders

# Member of Regulation WG

Member	Name	Title
CNMA	Ms. Ruby HE Hong	Representative, CNMA
	Ms. Linda SUN Ling	Representative, CNMA
	Ms. Ruby SUN Yu	Representative, CNMA
JSMI	Mr. Kosei Iriyama	International Affair Committee, JSMI
	Mr. Kenji Ukita	
KPMA	Ms. Kristeen Jhung	Team Leader of Int'l Affairs Team, KPMA
TPMMA	Ms. Sylvia Tsai	Vice Director of OTC Committee, TPMMA
TSMIA		
APSMI	Mr. Yasuhiro Tagashira	Secretary General

## Step II (2013)

Verification of the survey results and planning and implementation of specific enlightenment activities

- Identification of problems common to all countries and those specific for certain countries/regions
- Discussion about actions to solve the common problems, regions where actions are taken, cost, expected outcome, etc.
- Implementation of enlightenment activities (by each association)

Collecting the successful examples of Self-Medication in member associations

# Member of Self-medication WG

Member	Name	Title
CNMA	Mr. James Fan Qun	Executive Director, CNMA
	Mr. Wenhui ZHANG	Representative, CNMA
	Ms. Ruby Sun	
	Ms. Nina Liu	
	Ms. Zheng Bo	International Affair Department, CNMA
JSMI	Mr. Masatoshi Nakamura	International Affair Committee, JSMI
	Mr. Shin Inoue	
KPMA	Ms. Kristeen Jhung	Leader of International Affairs Team, KPMA
TPMMA	Mr. Arthur Su	Assistant Director of OTC Committee, TPMMA
TSMIA		
APSMI	Mr. Yasuhiro Tagashira	Secretary General
Novartis CH	Mr. Rodney Hannington	Head of Marketing, Novartis

## **More communication within members**

- What supports members want**
- What information members want**

## **More Contact Stakeholders**

**e.g. International organization**

**Authorities**

**Healthcare Professionals**



# Our Goal

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**Through the solution of problems**

**Develop the OTC Market in AP region  
through enhancing Self-Medication  
by exchanging information, sharing  
information and mutual understanding**

**For saving National Health Cost**

**Account report in 2012  
&  
Proposed Budget in 2013**

# Account Repot in 2012

## Income

Item	Note	Budget		Income, actual		Difference	
		in US\$	in JPY	in US\$	in JPY	in US\$	in JPY
Annual Due		71,295	5,489,715	71,295	<b>5,532,872</b>	0	43,157
Carry Over		20,712	1,594,858	37,250	<b>2,890,608</b>	16,538	1,295,750
Interest etc.				10	<b>785</b>	10	785
Total		92,007	7,084,573	108,555	<b>8,424,265</b>	16,548	1,339,692
Exchange Rate	1US\$		77JPY		<b>77.6JPY</b>		77.6JPY

## Expenditure

Item	Note	Budget		Expenditure, estimated		Difference	
		in US\$	in JPY	in US\$	in JPY	in US\$	in JPY
Office Rental		4,675	360,000	4,639	<b>360,000</b>	0	0
Phone & Postage		2,727	210,000	2,335	<b>181,222</b>	-371	-28,778
Internet	Equipments	65	5,000	0	<b>0</b>	-64	-5,000
Web HP	Suporting Fee	649	50,000	1,289	<b>100,000</b>	644	50,000
Equipment	Seal, Stanp, etc.	260	20,000	257	<b>20,000</b>	0	0
Stationery		195	15,000	110	<b>8,543</b>	-83	-6,457
Consumable	Ink Tonaer etc.	649	50,000	320	<b>24,830</b>	-324	-25,170
Printing	Business Card etc.	758	58,400	4,436	<b>344,200</b>	3,683	285,800
Travel Fee	WSMI, KPMA, PhAMA etc	30,519	2,350,000	26,696	<b>2,071,587</b>	-3,588	-278,413
Transportation	Shipping Charge	0	0	1,933	<b>150,000</b>	1,932	150,000
Miscellaneous	Bank Charge etc.	91	7,000	39	<b>3,050</b>	-51	-3,950
Meeting Fee	APSMI Board Meeting (Oct.)	12,987	1,000,000	12,887	<b>1,000,000</b>	0	0
	APSMI GAM (Oct.)	12,987	1,000,000	12,887	<b>1,000,000</b>	0	0
Project Cost	Printing	12,987	1,000,000	12,887	<b>1,000,000</b>	0	0
	Others	6,494	500,000	6,443	<b>500,000</b>	0	0
Total Expenditure		86,044	6,625,400	87,158	<b>6,763,432</b>	1,779	138,032
Amount of Carry Over		5,963	459,173	21,402	<b>1,660,833</b>	15,486	1,201,660
Total		92,007	7,084,573	108,560	<b>8,424,265</b>	17,264	1,339,692
Exchange Rate	1US\$		77JPY		<b>77.6JPY</b>		77.6JPY

# Proposed Budget in 2013

## Income

Item	Note	Budget in 2013		Estimate in 2012		Difference	
		in US\$	in JPY	in US\$	in JPY	in US\$	in JPY
Annual Due		71,295	<b>5,561,010</b>	71,295	5,532,872	0	28,138
Carry Over	From 2012	21,292	<b>1,660,833</b>	37,250	2,890,608	-15,958	-1,229,775
Interest etc.				10	785	-10	-785
Total		92,587	<b>7,221,843</b>	108,555	8,424,265	-15,968	1,202,422
Exchange Rate	1US\$		<b>78JPY</b>		77.6JPY		77.6JPY

## Expenditure

Item	Note	Budget in 2013		Expenditure in 2012		Difference	
		in US\$	in JPY	in US\$	in JPY	in US\$	in JPY
Office Rental		4,615	<b>360,000</b>	4,639	360,000	0	0
Phone & Postage		2,945	<b>230,000</b>	2,335	181,222	629	48,778
Internet	Equipment	64	<b>5,000</b>	0	0	64	5,000
Web HP	Supporting Fee	1,282	<b>100,000</b>	1,289	100,000	0	0
Equipment	Seal, Stanp, etc.	64	<b>5,000</b>	257	20,000	-193	-15,000
Stationery		128	<b>10,000</b>	110	8,543	19	1,457
Consumable	Ink Tonaer etc.	385	<b>30,000</b>	320	24,830	67	5,170
Printing	Business Card etc.	54	<b>4,200</b>	4,436	344,200	-4,381	-340,000
Travel Fee	WSMI, KPMA, PhAMA etc	26,923	<b>2,100,000</b>	26,696	2,071,587	366	28,413
Transportation	Shipping Charge	385	<b>30,000</b>	1,933	150,000	-1,546	-120,000
Miscellaneous	Bank Charge etc.	38	<b>3,000</b>	39	3,050	-1	-50
Meeting Fee	APSMI Board Meeting	12,821	<b>1,000,000</b>	12,887	1,000,000	0	0
	Other Meeting	12,821	<b>1,000,000</b>	12,887	1,000,000	0	0
Project Cost	Printing	6,410	<b>500,000</b>	12,887	1,000,000	-6,443	-500,000
	Others	6,410	<b>500,000</b>	6,443	500,000	0	0
Total Expenditure		75,349	<b>5,877,200</b>	87,158	6,763,432	-11,421	-886,232
Amount of Carry Over		17,239	<b>1,344,643</b>	21,402	1,660,833	-4,075	-316,190
Total		92,587	<b>7,221,843</b>	108,560	8,424,265	-15,495	-1,202,422
Exchange Rate	1US\$		<b>77JPY</b>		77.6JPY		77.6JPY

- 1. Shared the cost of APSMI activities by each members**
- 2. The Rule of contribution in Finance is based on market size**

## **Association Member**

**Equivalent of 50% WSMI annual fee in previous year**

## **Corporate Member**

**US\$ 3,000**

# Annual Due in 2013

	WSMI(CHF)		APSMI(US\$)	
	2010	2011	2011	2012
CNMA	3,770	15,660	1,885	1,885
JSMI	75,390	78,330	37,695	37,695
KPMA	7,540	7,830	3,770	3,770
TPMMA	1,890	1,970	945	945
TSMIA	1,890	1,970	0	0
Corporate Member*			27,000	27,000
Total	90,480	105,760	71,295	71,295

1CHF: equivalent to 1US\$(2010)

\*Nine corporate members

**Not decide the venue and date now**

## **The 2<sup>nd</sup> APSMI General Assembly Meeting will be planned as follows;**

**Host: TSMIA ( 1<sup>st</sup> Condidate)**

**Venue: Thailand**

**Date: Autumn 2014**

**TSMIA is considering the host for the 2<sup>nd</sup> GAM with 10<sup>th</sup> WSMI Asia-Pacific Regional Conference.**



**If you have topics, please inform us.**

**CNMA**

**JSMI**

**KPMA**

**TPMMA**

**TSMIA**

**ASMI**

**G. P. Farmasi**

**PhAMA**

**WSMI**

## **APSMI secretariat will move in December**

### **New Address**

**Itopia Iwamotocho 1 Cho-me bldg, 8-15,  
1 Cho-me, Iwamotocho, Chiyoda-ku  
Tokyo, Japan**

**After it moves, APSMI will announce  
detail, e.g. the new telephone number etc.**