

10th WSMI AP Regional Conference & 2nd APSMI General Assembly Meeting

21-22 October 2014 Phuket, Thailand









Maximize Self-Care Potential Through Asia Regulatory Harmonization

21-22 October 2014 Phuket, Thailand

First time in Thailand and South East Asia

The 10th WSMI AP Regional Conference & 2nd APSMI General Assembly Meeting entitled "Maximize Self-Care Potential Through Asia Regulatory Harmonization" is scheduled to take place during 21–22 October 2014 in Phuket, Thailand. The Conference is hosted by Thai Food and Drug Administration (Thai FDA) and Thai Self-Medication Industry Association (TSMIA) in collaboration with World Self-Medication Industry (WSMI) and Asia-Pacific Self-Medication Industry (APSMI).

Objective

Self-care development is a shared responsibility among multiple healthcare stakeholders. The Conference is initiated with the aim to present self-care challenges to health regulators and industry to ensure appropriate regulation needed to allow products to be made available to patients in a safe, timely and publicly accessible manner. The Conference provides a dynamic international forum to keep pharmaceutical stakeholders up-to-date on the latest relevant regulatory developments, legislative initiatives, and recent measures adopted at national and regional levels.





21-22 October 2014 Phuket. Thailand



Who Should Attend?

The Conference is aimed for all stakeholders involved in or interested in the aspects surrounding Self-Care and Self-Medication convergence initiatives.

In particular those involved in:

- Government authorities
- · Healthcare policymakers
- Healthcare professionals
- Executives and professionals from pharmaceutical industry (e.g. Marketing, Regulatory, Business Development, Government Affairs, Legal, R&D)
- Academia

Conference Fee and Registration

Registration is now open.



Fee: US\$ 800

Now until 30 August 2014

• Standard Registration

Fee: US\$ 1,000

1 September 2014 until 15 October 2014

• Late/ On-Site Registration

Fee: US\$ 1,200

After 15 October 2014

(Some conference materials may not be available upon registration.)



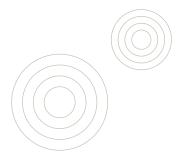


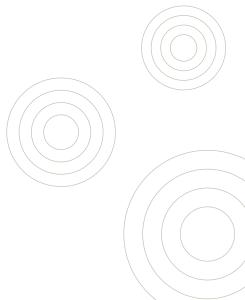


Thai Self-Medication Industry Association (TSMIA) was established and registered as trade association in 2009. TSMIA aims to support and promote the health industry in non-prescription medicines (OTC), herbal/ traditional medicines, and health supplements in Thailand. Other objectives are to promote the engagement of the enterprises related to non-prescription drugs, herbal medicines, and other health products, so that such products in good quality are available and distributed through appropriate channels, and to promote the rights of the people and medical personnel in Thailand for their opportunities to select non-prescription drugs, herbal medicines, and other health products for prevention and initial treatment of diseases.

TSMIA realizes that the responsible self-medication concept would benefit the country. Thus, it has brought this idea to a wider audience and invited all in OTC business in Thailand to consider the establishment of their own Association and have their own agenda to improve the self-care and self-medication concept in Thailand, which is one way to support and encourage sustainable good health for Thai people.







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PROVISIONAL PROGRAMME

Day 1: Tuesday 21 October 2014

08.30 - 09.00	Registration
Session 1:	Opening Session
09.00 - 09.20	Welcome Remarks, Opening Speech "Maximizing Self-Care Potential in Thailand"
	Dr. Boonchai SOMBOONSOOK, M.D., M.T.H.
	Secretary General, Thai Food and Drug Administration, Ministry of Public Health, Thailand
09.20 - 09.40	Welcome Remarks, Opening Speech "The Role of Self-Care and OTCs in Healthcare"
	Ms. Erica MANN
	Chairperson, World Self-Medication Industry, France
	Ms. Eun Sun KIM
	Chairperson, Asia-Pacific Self-Medication Industry, Korea
	Ms. Malinee UDITANANDA
	President, Thai Self-Medication Industry Association, Thailand
09.40 - 10.00	Official Conference Photograph
10.00 - 10.15	Coffee Break
10.15 - 10.40	Keynote Speech: Set the Scene for the Conference - "Maximize Self-Care Potential Through Asia
	Regulatory Harmonization"
	Mr. Roberto FUNARI
	Executive Vice President - Latin America and Asia Pacific, Reckitt Benckiser, Singapore

Session 2: Asia Self-Medication Market Trends, Health Policy, and Consumer Practice

10.40 - 12.00 Asia Pacific Health Policy on Self-Care

Chairperson: Dr. Gerald DZIEKAN, M.D., M.Sc.

Director General, World Self-Medication Industry, France

• Asia Pacific Consumer Practice in Self-Care: Market Trends

Mr. Vivek DHAWAN

CEO & Chief Coach, Mega Lifesciences Public Company Limited, Thailand

• China Healthcare Reform and Its Impact on Self-Care

Mr. Carl REN

Director, The Study Center of the Chinese Pharmaceutical Retailing, the Chinese Pharmaceutical Enterprise Management Association, People's Republic of China

• Reform of Self-Care with New Malaysia Pharmacy Bill

Mr. Muhammad Lukmani Bin IBRAHIM

Deputy Director Enforcement, Pharmaceutical Services Division, and Secretary, Medicines Advertisement Board, Ministry of Health, Malaysia



• Impact of Indonesia Universal Healthcare Coverage in Self-Care

Mr. Rachmadi JOESOEF

Director, PT Konimex, Indonesia

Discussion

12.00 - 13.00 Lunch Break

Session 3: Regional Economics, Industry, and Cooperation

13.00 - 13.40 Global Perspectives on Asia Pacific OTC Industry

Chairperson: Mr. Seiichi SATO

Vice-Chairman, Asia-Pacific Region, World Self-Medication Industry &

Vice-Chairperson, Asia-Pacific Self-Medication Industry

• Asia Pacific OTC Market - Trends and Proposals for Further Growth

Mr. Nicholas HALL

Chairman & CEO, Nicholas Hall Group of Companies, Nicholas Hall & Company, UK

• APSMI - Country and Regional Cooperation Update & APSMI Activities

Mr. Yasuhiro TAGASHIRA

Secretary General, Asia-Pacific Self-Medication Industry, Japan

• The Future of OTC in Asia: Growth through Innovation

Mr. Andy TISMAN

Global Senior Principal, Consumer Health, IMS Health, United Kingdom

Session 4: Realization & Implementation of ASEAN Healthcare Harmonization in 2015 and Beyond

13.40 - 15.20 Chairperson: Dr. Yuppadee JAVROONGRIT, Ph.D.

Senior Expert on Pharmaceutical Standard, Thai Food and Drug Administration, Ministry of Public Health, Thailand

• ASEAN Regulatory Harmonization Scheme Overview

Dr. Yuppadee JAVROONGRIT, Ph.D.

Senior Expert on Pharmaceutical Standard, Thai Food and Drug Administration,

Ministry of Public Health, Thailand

• ASEAN Pharmaceutical Regulatory Harmonization Update

Dr. Yuppadee JAVROONGRIT, Ph.D.

 $Senior\ Expert\ on\ Pharmaceutical\ Standard, Thai\ Food\ and\ Drug\ Administration,$

Ministry of Public Health, Thailand

• ASEAN Traditional Medicines and Health Supplements Regulatory Harmonization Update

Ms. Sukanya JIARAPONG

Senior Expert on Drug Safety and Efficacy, Thai Food and Drug Administration,

Ministry of Public Health, Thailand

• ASEAN Medical Devices Regulatory Harmonization Update

Ms. Yuwadee PATANAWONG

Senior Expert on Medical Device Safety, Thai Food and Drug Administration,

Ministry of Public Health, Thailand

• ASEAN Cosmetics Regulatory Harmonization Update

Dr. Sumalee PORNKITPRASARN, Ph.D.

Director, Bureau of Cosmetic and Hazardous Substances Control,

Thai Food and Drug Administration, Ministry of Public Health, Thailand

• 1st Self-CARER Meeting Update

Dr. Noppadon ADJIMATERA

South East Asia Regional Regulatory and Medical Affairs Director,

Reckitt Benckiser, Thailand

15.20 - 15.35 Coffee Break

Session 5: Value and Potential of OTC

15.35 - 16.00

• Experience with Measuring the Economic and Public Health Value of OTC:

Examples from the EU and US

Dr. Hubertus CRANZ

Director General, Association of the European Self-Medication Industry

Session 6: Communication, Education, and Partnership in Self-Care

16.00 - 17.30 Self-Care Advertising in Asia Pacific Countries

Chairperson: Dr. Noppadon ADJIMATERA

South East Asia Regional Regulatory and Medical Affairs Director,

Reckitt Benckiser, Thailand

• Comparison and Analysis of Various Global Regulatory Models: Pros and Cons of Each Model

Dr. Gideon SCHOOMBIE

Executive Director, Australian Self Medication Industry, Australia

Advertising Challenges in China

Mr. James Fan QUN

Executive Director, China Non-Prescription Medicines Association & President,

JOWIN (China) Group Co., Ltd., People's Republic of China

Advertising Challenges in Taiwan

Ms. Sylvia TSAI

Vice Director, OTC Committee, Taiwan Pharmaceutical Marketing & Management Association, Republic of China

• Advertising Challenges in Korea

Mr. Jae-Kook LEE

Managing Director, Communication Department,

Korea Pharmaceutical Manufacturers Association, Korea

• OTC Advertising Regulation in Japan

Mr. Motohito NISHIZAWA

Senior Advisor, Japan Self-Medication Industry, Japan

• Advertising Challenges in Malaysia

Mr. Muhammad Lukmani Bin IBRAHIM

Deputy Director Enforcement, Pharmaceutical Services Division,

and Secretary, Medicines Advertisement Board, Ministry of Health, Malaysia

18.30 - 19.00 Cocktail Reception

19.00 - 21.00 Gala Dinner





Day 2: Wednesday 22 October 2014

Session 6: Communication, Education, and Partnership in Self-Care (continue)

09.00 - 09.45 Experience in Consumer Education and Information Sharing in Self-Care

Chairperson: Dr. David WEBBER

President, International Self-Care Foundation, United Kingdom

• Consumer Education and Community Pharmacy in Japan

Mr. Toshiaki YOSHINO

Chairman, Japan Self-Medication Industry, Japan

• Self-Care Day in China

Dr. David WEBBER

President, International Self-Care Foundation, United Kingdom

• Aor Yor Noi: Example of Health Education Program in Thailand

Mr.Nirat TIASUWAN

Expert on Consumer Protection on Health Products System Development,

Thai Food and Drug Administration, Ministry of Public Health, Thailand

Session 7: Regulatory Challenges and Opportunities in OTC Industry

09.45 - 11.05 Optimizing OTC Regulatory Processes in Asia Pacific for Better Access

Chairperson: Mr. Vinit USAVAKIDVIREE, B.Sc. (Pharm), LL.B.

Senior Advisor in Safety, Effectiveness and Advisory in Safety and Efficacy of Health Products, Thai Food and Drug Administration, Ministry of Public Health, Thailand

• Challenges with ASEAN Pharmaceutical Regulation Scheme

Mr. Rachmadi JOESOEF

Director, PT Konimex, Indonesia

• Challenges with New Drug Regulations in OTC Innovation Registration in Asia

Dr. Takatoshi NAKAMURA, Ph.D.

Director of Office of OTC/Generic Drug,

Pharmaceuticals and Medical Devices Agency, Japan

• Process Simplification in OTC Registration: Abridged Application

Mr. Cheng Tiang NG

Asia Regional OTC RA Director, Teva Pharmaceutical Investments Singapore Pte Ltd., Singapore

• Review of Monographed OTC in Asia Pacific

Dr. Noppadon ADJIMATERA

South East Asia Regional Regulatory and Medical Affairs Director, Reckitt Benckiser, Thailand

11.05 - 11.20 Coffee Break



Rx to OTC Switches & Borderline Products Session 8: 11.20 - 11.40 Global Trends in Switching • The Case of Proven Economic and Social Benefit: Nicotine Switching Mr. Ian ADAMS Vice President, Regulatory Affairs and Quality – APLAM (Asia-Pacific, Latina, Africa & Middle East), GSK Consumer Healthcare, Australia 11.40 - 12.20 Managing Through Diversity of Product Classification • Similarity & Difference in OTC Classification and their Borderlines among Asia Pacific Dr. Noppadon ADJIMATERA South East Asia Regional Regulatory and Medical Affairs Director, Reckitt Benckiser, Thailand • Border of Asia OTC Devices VS Medicines: Reality Check Ms. Chadaporn TANAKASEMSUB Head of Regulatory Affairs, Asia Pacific and Russia, Alcon Asia Pacific, Thailand 12.20 - 13.20 Lunch Break Session 8: Rx to OTC Switches & Borderline Products (continue) 13.20 - 13.45 UK Guidelines on Switch and the Benefit-Risk Model Ms. Sheila KELLY Consultant, World Self-Medication Industry 13.45 - 15.20 Asia Pacific OTC Switching Regulation & Practices Chairperson: Ms. J.S. Sunitha Devi SHANMUGAM Regulatory Affairs & Quality Director - Asia, GlaxoSmithKline Consumer Healthcare, Malaysia • China Experience in OTC Switching Ms. Qing HAN Director of Regulatory Affairs, Xian Janssen Pharmaceuticals Ltd., People's Republic of China • Experience in OTC Switching in Taiwan Ms. Li-Ling LIU Director, Division of Medicinal Products, Taiwan FDA, Ministry of Health and Welfare, Republic of China • Korea's GSL Medicines Initiative Update Mr. Seog-Kyu YOON The official conference Team Manager, International Affairs Team, Pharmaceutical Policy Division, language is English. Korea Pharmaceutical Manufacturers Association, Korea

All conference presentations will be available only in the electronic format which will be uploaded onto the conference website.

The conference participants will have access to all presentations in two weeks prior to the Conference and the access will be available during and after the Conference.

Mr. Vinit USAVAKIDVIREE, B.Sc. (Pharm), LL.B.
Senior Advisor in Safety, Effectiveness and Advisory in
Safety and Efficacy of Health Products, Thai Food and Drug Administration,
Ministry of Public Health, Thailand

Regulatory Compliance Director, J&J Asia Pacific, Singapore

• Experience in Development of Thailand OTC Switching Guidelines

15.20 - 15.40 Introduction of Next WSMI & APSMI Meetings
 15.40 - 16.00 Closing: Phuket Communiqué Declaration
 16.00 End of Conference & Coffee Break

Mr. Roy SHYNG

• Singapore OTC Switching Regulation

Venue Of The Conference

The Conference will take place at:

Indigo Pearl Hotel

Nai Yang Beach and National Park, Thalang, Phuket 83110, Thailand

Tel: +66 (0) 76 327 006 **Fax:** +66 (0) 76 327 338–9 http://www.indigo-pearl.com

Accommodation and Room Rates

Rooms for participants of the Conference are at the following rates:

Premium Pearl Bed Suite
 D-Buk Suite
 Pool Pavilion
 THB 4,600 Net per room per night
 THB 6,300 Net per room per night
 THB 7,800 Net per room per night

The rates quoted are inclusive of 18.7% prevailing government taxes, service charge and daily American breakfast for 2 persons per room per night. These rates are applicable for stay during 19-22 October 2014 and valid for reservations made until 30 August 2014 only. Extending stay applied best available rate.

About Phuket

Phuket is Thailand's largest island and is widely known as a tourist attraction. The wealth of natural beauty on the island includes white sandy beaches and turquoise blue sea. It is regarded as the tourism hub of the Andaman coast.







O CONFERENCE REGISTRATION

I agree to attend the 10th WSMI AP Regional Conference & 2nd APSMI GAM entitled 'Maximize Self-Care Potential Through Asia Regulatory Harmonization' during 21–22 October 2014.

(Please complete a separate registration for each conference participant. For queries, please contact conference@tsmia.or.th)

1. FULL NAME				
Prefix				
First Name		Last Name		
Job Position				
2. ADDRESS (Will appear on office	ial receipt)			
Company / Organization				
Street Address				
E-mail		Phone	Fax Number	
3. CONFERENCE FEE PER DELEGA (Please choose one)	ΙΤΕ			
Registration Payment				
Early Bird	US\$ 800	Now until 30 August 2	2014	
Standard Registration	US\$ 1,000	1 September 2014 un	ntil 15 October 2014	
Late/On-Site Registration US\$ 1,200		After 15 October 2014 (Some conference materials may not be available upon registration.)		
			ingrak, Bangkok 10500, Thailand	

Important Notes

- $\bullet \ Please \ e-mail \ the \ bank \ transfer \ slip \ along \ with \ this \ conference \ registration \ form \ duly \ completed \ to \ conference @tsmia.or.th \ and \ we \ will \ determined \ and \ respectively. \\$ confirm your seat by sending an e-mail to you.
- We do not receive credit card payment.
- For on-site payment, please pay in US dollars at the exact amount.
- Should you be unable to attend, a substitute delegate is welcome at no extra charge.





Please submit one form for each room required. Kindly send the room reservation form to reservations@indigo-pearl.com, Tel: +66 (0) 76 327 006, Fax: +66 (0) 76 327 338-9.

1. ROOM Prefix	OCCUPANT: Name First Name	es of All Occupant	s Last Nam	ne		Passport No.	Nationality
Prefix	First Name		Last Nan	 Last Name		Passport No.	- Nationality
Prefix	First Name		Last Nan	ne		Passport No.	- Mationality
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Street Add	lress						
E-mail				Phone		Fax Number	
3. DATES			071105 - :			CT	
ARRIVAL D		DEPA	RTURE DATE :	/ 2014	Number o	of Total Nights:	
 Date	/ / 2014 Month	 Da	te Mont	/ 2014		-	
• Rooms a are avail. • Rooms b	ooked after 30 August ROOM um Pearl Bed Suite Suite	tay date during 19–2 lity basis. It will be	22 October 201 more favorable ed by availabili TYPE OF O Single	4 only. Extending step to all guests if both ty. BED O Double O So	tay applied best a pokings are mad ollywood Twin*	e early to ensure PREFERENCE Smoking Non Smoking	that the rooms
_	avilion ped: THB 1,800 net per		_		person	*Hollywood Twir style bed (share separate mattres	basement and
Airport tra	SPORTATION Insfer is available at TH vise flight detail with n		-		charge to one ac	•	
ARRIVALT	IME:	FLIGH	IT NUMBER :		Number o	of Guests :	
DEPARTURE TIME: FLIGHT N		IT NUMBER :	IUMBER: Number		of Guests:		
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signature	:				Mo	nth /	Year

7. CANCELLATION POLICY

- All cancellation must be made by written confirmation.
- Cancellation received by the hotel less than twenty one (21) days prior to the arrival date will affect one night penalty.
- $\bullet \textbf{Cancellation received by the hotel less than fourteen (14) days prior to the arrival date will affect penalty for the whole period of booking (100\%). } \\$





We invite Members of WSMI, APSMI, TSMIA, and also Non-Members to support this event and showcase their organization by taking up one of the many sponsorship opportunities below.

SPONSORSHIP AGREEMENT

Job Title

Company / Organization (as shown on official receipt)

Street Address (as shown on official receipt)	
Contact Person	

E-mail	Phone	Fax Number

Sponsorship Opportunities	Platinum THB 250,000 US\$ 8,333	Gold THB 150,000 US\$ 5,000	Silver THB 100,000 US\$ 3,333
Company name acknowledged in Welcome Remarks and Opening Speech	/	/	/
Company logo and name on the conference website with hyperlink to own site	/	✓	/
Company logo and name on display signs and backdrop in the event	/	✓	/
One company top executive entitled to participate in Welcome Reception and Gala Dinner as honoured guest	/	✓	/
Distribution of promotional materials in conference bags or other materials offered to delegates	/	✓	-
Number of free registration for company representatives	4	3	2
Free advertisement in the programme book	Free color ad on back cover or inner front cover or inner back cover	Free color ad on inner front cover.	Free color ad on inner back cover.

Bank transfer

Bank Name : Siam Commercial Bank Public Company Limited

Address: Abdulrahim Branch, 990 G Floor, Abdulrahim Place, Rama IV Road, Silom, Bangrak, Bangkok 10500, Thailand

SWIFT Code: SICOTHBK

Account Name: Thai Self-Medication Industry Association

Account No.: 153-212131-0

Important Notes

- Please e-mail the bank transfer slip along with this sponsorship form duly completed to conference@tsmia.or.th and we will confirm receipt by e-mail.
- If the Conference is cancelled due to force majeure, we will refund the sponsorship amount to you. (Please expect the deduction of bank charges.)

Visas and Customs Information

- 1. Generally, a foreign citizen who wishes to enter the Kingdom of Thailand is required to obtain a visa from a Royal Thai Embassy or a Royal Thai Consulate-General. However, nationals of certain countries do not require a visa if they meet visa exemption requirements as follows:
 - (1) they are nationals of countries which are exempted from visa requirements when entering Thailand for tourism purposes. Such nationals will be permitted to stay in the Kingdom for a period of not exceeding 30 days. For more information, please visit http:// www.mfa.go.th/main/en/services/123/15396-Tourist-Visa-Exemption.html
 - (2) they are nationals of countries which hold bilateral agreements with Thailand on the exemption of visa requirements. For more information, please visit http://www.mfa.go.th/main/en/services/123/15383-List-of-countries-which-have-concluded-Agreements.html
- 2. Nationals of certain countries may apply for visa upon arrival in Thailand. Travellers with this type of visa are permitted to enter and stay in Thailand for a period of not exceeding 15 days. For more information, please visit http://www.mfa.go.th/main/en/services/123/15393-Visa-on-Arrival.html
- 3. Travellers travelling from/through countries which have been declared Yellow Fever Infected Areas must acquire an International Health Certificate verifying the receiving of a Yellow Fever vaccination. For more information, please visit http://www.mfa.go.th/main/en/services/123/15384-List-of-countries-which-are-declared-Yellow-Fever.html
- 4. Nationals of certain countries are required to apply for a visa only at the Royal Thai Embassy or the Royal Thai Consulate-General in the applicant's country of residence, or at the Royal Thai Embassy which has jurisdiction over his or her country of residence. Travellers are advised to enquire about authorised office for visa issuance at any Royal Thai Embassy or Royal Thai Consulate-General before departure. Contact details and locations of Royal Thai Embassies and Royal Thai Consulates-General are available at http://www.thaiembassy.org/main

In the case that an invitation letter for applying a visa is required, please contact conference@tsmia.or.th



For more information, Please refer http://www.mfa.go.th/ main/en/services/123



