



Biro Pengawalan Farmaseutikal Kebangsaan  
National Pharmaceutical Control Bureau  
**KEMENTERIAN KESIHATAN MALAYSIA**  
MINISTRY OF HEALTH MALAYSIA

Our ref: Bil ( 1 ) dlm.SemRK/JPP/2013  
Date : **26 FEB 2013**

Dear Sir/Madam,

**NATIONAL REGULATORY CONFERENCE (NRC) 2013 ADVERTISING PROGRAM**

The National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia in collaboration with various organisations will be hosting the **NATIONAL REGULATORY CONFERENCE (NRC) 2013** from 7 - 9 May 2013.

2. The conference will be held in Hotel Istana, Kuala Lumpur and an estimated 300 people comprising regulators, industry representatives and academia from Malaysia and ASEAN region are expected to attend.

The objectives of this 3-day conference are:

- To update on developments and challenges in the evolving regulatory landscape
- To strengthen collaboration and understanding among stake holders
- To enhance competitiveness through regulatory transformation

3. This letter serves as a request for your support in participating in the programme book that will be distributed to all participants attending this conference. The conference will be officiated by the Hon. Minister of Health Malaysia and the keynote address will be delivered by the Director General of Health Malaysia. The tentative programme is attached for your information.

4. If you would like to participate in the programme book, please indicate your preference in the form attached.

5. On behalf of the Organising Committee, we thank you in advance for your support. If you have any questions, please contact the Programme and Publicity Committee (details listed in the advertising form).

Yours sincerely,

  
**TAN ANN LING**

**Chairman,  
Organising Committee  
National Regulatory Conference 2013**

\*NATIONAL REGULATORY CONFERENCE 2013 is in collaboration with:

Malaysian Association of Pharmaceutical Suppliers (MAPS)  
Malaysian Biotechnology Corporation (BiotechCorp)  
Malaysian Dietary Supplement Association (MADSA)  
Malaysian Organisation of Pharmaceutical Industries (MOPI)  
Malaysian Pharmaceutical Society (MPS)  
Pharmaceutical Association of Malaysia (PhAMA)

*ce* The Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFA)

# NATIONAL REGULATORY CONFERENCE 2013

## Tentative Programme

<b>DAY 1: 7 May 2013 (TUESDAY)</b>			
<b>MORNING PLENARY SESSION</b>			
<i>Chairperson: Dr. Tajuddin Akasah, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH) Malaysia</i>			
7.30am – 9.00am	Registration		
9.00am – 9.15am	Welcoming Remarks <i>Y. Bhg. Dato' Eisah A. Rahman</i> <i>Senior Director of Pharmaceutical Services, Ministry of Health Malaysia</i>		
9.15am – 9.30am	Opening Ceremony <i>Y.B. Dato' Sri Liow Tiong Lai</i> <i>Minister of Health Malaysia</i>		
9.30am – 10.00am	Key Note Address <i>Y. Bhg Datuk Dr. Noor Hisham Abdullah</i> <i>Director General of Health, Ministry of Health Malaysia</i>		
10.00am – 10.30am	COFFEE BREAK		
10.30am – 11.30am	<b>Plenary 1:-</b> Updates on Current and Future Regulatory Developments in Malaysia <i>Mr. Tan Ann Ling</i> <i>Director, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH) Malaysia</i>		
11.30am – 12.30pm	<b>Plenary 2:-</b> ASEAN Economic Community 2015: The Integration of the Healthcare Sector - Current Status and Updates <i>Ms. Shirley V Ramesh</i> <i>Senior Officer ASEAN Secretariat</i>		
12.30pm – 2.00pm	LUNCH		
<b>AFTERNOON TRACK SESSIONS</b>			
	<b>Track 1: Traditional Medicines, and Health Supplements (TMHS)</b> <i>Chairperson: Ms. Mazli Muhammad NPCB</i>	<b>Track 2: Pharmaceutical Products</b> <i>Chairperson: Mr. Rad zmi Rahmat Malaysian Association of Pharmaceutical Suppliers (MAPS)</i>	<b>Track 3: Biologic Products</b> <i>Chairperson: Ms. June Oi Pharmaceutical Association of Malaysia (PhAMA)</i>
2.00pm – 2.30pm	Herbal Product Development in Malaysia <i>To be confirmed</i> <i>Ministry of Agriculture (MOA)</i>	The Way Forward for Local Pharmaceutical Industries <i>Mr. Jamaludin Elis</i> <i>Pharmaniaga Manufacturing Berhad</i>	US Regulations of Follow-on Biologics <i>Dr. Frank A. Scappaticci</i> <i>Genentech/Roche</i>
2.30pm – 3.00pm	Helping SME industries to go global <i>To be confirmed</i> <i>Malaysia External Trade Development Cooperation (MATRADE)</i>	Quality Risk Management <i>Mr. Steve Slater</i> <i>Traque Asia, Singapore</i>	Global Development of Biosimilars with focus on MABs <i>Dr. Frank A. Scappaticci,</i> <i>Genentech/Roche</i>
3.00pm – 3.30pm	Integration of Traditional Medicine into Allopathic Healthcare System <i>Dr. Zalilah Abdullah</i> <i>Traditional &amp; Complimentary Medicine Division, MOH</i>	Updates on Implementation of Bioequivalence Study for Generic Medicines in Malaysia <i>Ms. Mazuwin Zainal Abidin</i> <i>NPCB</i>	Cell and Tissue Therapies: Current Trend and Challenges <i>Prof Dr. Ruszymah Hj Idrus</i> <i>Tissue Engineering Centre, UKM Medical Centre</i>
3.30pm – 4.00pm	Guidelines on Higher Claims for Complementary Medicine <i>Datin Shantini Thevendran</i> <i>NPCB</i>	Design in Bioequivalence Study <i>Dr. Lee Toong Chow</i> <i>Info Kinetics Sdn. Bhd.</i>	Malaysian Vaccine Programme (MVP) <i>Mr. Jay Padasian, Malaysian Malaysian Biotechnology Corporation (BiotechCorp)</i>
4.00pm – 4.30pm	Q & A	Q & A	Q & A
4.30pm – 5.00pm	ADJOURN & COFFEE		
7:30pm	OFFICIAL DINNER		

**DAY 2: 8 May 2013 (WEDNESDAY)**

**MORNING PLENARY SESSION**

*Chairperson: Dr. Kamaruzaman Saleh, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH) Malaysia*

8.30am – 9.15am	<b>Plenary 3:-</b> Regulatory Framework: Cell and Gene Therapy Products in Malaysia <i>Ms. Arpah Abas</i> <i>Head of Biologic &amp; Complementary Section, NPCB, MOH</i>
9.15am – 10.00am	<b>Plenary 4:-</b> Global Regulatory Trends: Challenges and Implications – Is Asia Breaking Out of the Age of Innocence? <i>Mr. Chew Kwee Tat</i> <i>Director, Regulatory Strategist, Strategic Drug Development Asia, Quintiles Singapore.</i>
10.00am – 10.30am	COFFEE BREAK
10.30am – 11.15am	<b>Plenary 5:-</b> Malaysia Adherence to Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practice (GLP) Mutual Acceptance of Data (MAD) System <i>Dr. Hasenah Ali</i> <i>Head of GLP Section, NPCB, MOH</i>
11.15am – 12.00am	<b>Plenary 6:-</b> Challenges in Supply Chain Management <i>Mr. Steve Slater</i> <i>Director, Traque Asia, Singapore</i>
12.00am – 12.45pm	<b>Plenary 7:-</b> Current Global Landscape of Pharmacovigilance <i>Dr. Pia Carduff-Janosa</i> <i>Chief Medical Officer, Uppsala Monitoring Centre(UMC), Sweden</i>
12.45pm – 2.00pm	LUNCH

**AFTERNOON TRACK SESSIONS**

	<b>Track 1:</b> <b>Traditional Medicines, and Health Supplements (TMHS)</b> <i>Chairperson: Dato' Dr Rajen M Malaysian Dietary Supplement Association (MADSA)</i>	<b>Track 2:</b> <b>Pharmaceutical Products</b> <i>Chairperson: Mr. Jimmy Piong Malaysian Organisation of Pharmaceutical Industries (MOPI)</i>	<b>Track 4:</b> <b>Cosmetic Products</b> <i>Chairperson: Mr. Seng San Bing Federation of Malaysian Manufacturers-Malaysian Cosmetics and Toiletries Industry Group (FMM-MCTIG)</i>
2.00pm – 2.30pm	Standardization of Herbal Extract <i>Prof. Zhari Ismail</i> <i>Universiti Sains Malaysia (USM)</i>	Nano Medicines in Pharmaceuticals <i>Assoc. Prof. Shahrurum Shamsuddin</i> <i>Universiti Sains Malaysia (USM)</i>	New Breakthrough in Cosmetic Formulation (nanoparticle/nanotechnology) <i>To be confirmed</i>
2.30pm – 3.00pm	Non-Clinical Studies for herbal products <i>Dr. Zakiah Ismail</i> <i>Institute Medical Research (IMR), MOH</i>	Risk Benefit Assessment and Risk Management <i>Dr. Pia Carduff-Janosa</i> <i>UMC, Sweden</i>	Safety Assessment of Cosmetics <i>Mr. Mohd Helme Mohd Helan,</i> <i>SIRIM Berhad</i>
3.00pm – 3.30pm	Global Regulatory Trends in Health Supplements <i>Ms. Michelle Stout</i> <i>Amway Corporation, CA, USA</i>	Importation and Exportation of Human Remains, Human Tissues and Pathogenic Organisms or Substances for Trial Purposes <i>Dr. Norhayati Rusli</i> <i>Disease Control Division, MOH</i>	Cosmetic Advertising & Product Claim <i>Ms. Zuraida Abdullah</i> <i>NPCB</i>
3.30pm – 4.00pm	Global Trending of Adulteration – Adverse Drug Reactions (ADR) in TMHS Products <i>Ms. Basmiah Md. Isa</i> <i>NPCB</i>	Updates on Malaysian Variation Guidelines <i>Mr. Chai Che Leong</i> <i>NPCB</i>	Product Information File (PIF) Audit: What to expect? <i>Ms. Nik Shamsiah Nik Salleh</i> <i>NPCB</i>
4.00pm – 4.30pm	Q & A	Q & A	Q & A
4.30pm – 5.00pm	ADJOURN & COFFEE		

**DAY 3: 9 May 2013 (THURSDAY)****PLENARY SESSION***Chairperson: Mr. Sulaiman Hj Ahmad, National Pharmaceutical Control Bureau (NPCB), Ministry of Health (MOH) Malaysia*

8.30am – 9.15am	<b>Plenary 8:-</b> Updates on National Medicines Policy (DUNAS) <i>Dr. Salmah Bahri</i> <i>Director of Pharmacy Practice and Development, Pharmaceutical Services Division, MOH</i>
9.15am – 10.00am	<b>Plenary 9:</b> Halal Pharmaceuticals <i>Dr. Tajuddin Akasah</i> <i>Deputy Director, NPCB, MOH</i>
10.00am – 10.45am	<b>Plenary 10:-</b> Pharmacy Legislative Transformation <i>Mr. Mohd. Hatta Ahmad</i> <i>Director of Pharmacy Enforcement, Pharmaceutical Services Division, MOH</i>
10.45am – 11.15am	COFFEE BREAK
11.15am – 12.00pm	<b>Plenary 11:-</b> Advertisement: Self-Regulation versus Enforcement <i>Mr. Muhammad Lukmani Ibrahim</i> <i>Secretary of Medicine Advertisement Board, MOH</i>
12.00pm – 12.45pm	<b>Plenary 12:-</b> Regulation of Medical Devices in Malaysia <i>Mr. Zamane Abd Rahman</i> <i>Chief Executive Officer, Medical Device Bureau, MOH</i>
12.45pm – 1.15pm	<b>Plenary 13:-</b> QUEST 3+: Issues and Challenges <i>Ms. Siti Aida Abdullah</i> <i>Deputy Director, NPCB, MOH</i>
1.15pm – 1.30pm	<b>Closing remarks</b> <i>Mr. Tan Ann Ling</i> <i>Director, National Pharmaceutical Control Bureau (NPCB), MOH</i>
1.30pm	LUNCH

**NATIONAL REGULATORY CONFERENCE 2013**  
**“REGULATORY INNOVATION TOWARDS TRANSFORMATION”**  
7 - 9 May 2013  
Hotel Istana, Kuala Lumpur, Malaysia

## **PROGRAMME ADVERTISING RATE AND SCHEDULE**

**Programme Booklet:**

The Programme Booklet is a comprehensive guide to all educational and social activities offered during the NATIONAL REGULATORY CONFERENCE 2013, and will be distributed to all attendees. The scientific programme, social event information and other conference features will be included in the Programme Booklet. The content will be developed and the publication will be produced by the Programme and Publicity Committee along with the other relevant committees.

**Circulation:**

Over 500 copies of the Programme Booklet will be printed and distributed during the conference.

**Dateline:**

Return contract by : 11-March-2013  
Advertisement graphics due : 15-March-2013

**Advertising Rates (per publication, per page)**

<b>Advertisement</b>	<b>Amount (MYR)</b>
Outside back cover	5,000
Inside back cover	4,000
Page facing inside back cover	4,000
Inside front cover	5,000
1 full page (inside)	2,000

**Specifications:**

All advertisements must be provided in electronic format. Film negatives will not be accepted.  
File format: TIFF, EPS, PDF (high resolution only)  
Include a 100% hard copy proof that matches the electronic file.  
Include all fonts used in all pages, illustrations, images, logos and artwork.

**Delivery:**

Please send all graphics and instructions to: Programme and Publicity Committee  
(Details listed at the end of the space contract).

**Advertisement Acceptance:**

The organising committee reserves the right to reject, for any reason any advertising submission, or to require revision at its discretion. If payment has been made for an advertisement which is subsequently rejected, the secretariat will refund such payment to the advertiser and shall have no further responsibility to the advertiser.

All advertisement submissions must be in final form; requests to make alterations will not be granted. All advertising materials submitted will become the property of the organising committee and, at its discretion, discarded unless the advertiser requests the return of the same in writing no later than 30 days after printing.

**Statement of Purpose:**

This activity is for scientific and educational purpose only and will not promote the company's products, directly or indirectly.

**NATIONAL REGULATORY CONFERENCE 2013**  
**"REGULATORY INNOVATION TOWARDS TRANSFORMATION"**

7 - 9 May 2013

Hotel Istana, Kuala Lumpur, Malaysia

## PROGRAMME ADVERTISING SPACE CONTRACT

We wish to take part in the National Regulatory Conference 2013 in the following manner:

Conference Programme Book (500 copies)		Cost (MYR)	No. of pages	Subtotal
<input type="checkbox"/>	• Outside back cover	RM 5,000		
<input type="checkbox"/>	• Inside back Cover	RM 4,000		
<input type="checkbox"/>	• Page facing inside back cover	RM 4,000		
<input type="checkbox"/>	• Inside front cover	RM 5,000		
<input type="checkbox"/>	• 1 full page (inside)	RM 2,000		

*Full payment is due with the delivery of the advertisement. All payments must be made in Malaysian Ringgit (MYR).*

We enclose here a cheque (No: \_\_\_\_\_) amounting to MYR \_\_\_\_\_

All cheques must be made payable to **Malaysian Pharmaceutical Society**.

**Account No:** 0-14271-31967-2 **Bank:** Maybank

Company: \_\_\_\_\_

Address: (or rubberstamp) \_\_\_\_\_

Tel no: \_\_\_\_\_ Fax no: \_\_\_\_\_ Email: \_\_\_\_\_

Name (Dr/Mr/Ms): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Authorisation

The Programme and Publicity Committee is hereby authorised to insert our advertisement(s) in the publication indicated above, in accordance to the Final Programme advertising schedule. This contract cannot be cancelled after the advertisement copy dateline. The Publication and Programme Committee is not responsible for any loss or damage sustained due to any misprint in an advertisement or the failure of an advertisement to appear in this publication; in such event, the advertiser's remedy is limited to recover of the amount paid for the publication of the advertisement.

Authorised signature: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name and Title: \_\_\_\_\_

### For NRC 2013 Use:

We hereby acknowledge receipt of your sponsorship.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### PLEASE RETURN COMPLETED FORM WITH PAYMENT TO:

Programme and Publicity Committee  
National Regulatory Conference 2013  
National Pharmaceutical Control Bureau  
Lot 36, Jalan Universiti,  
46200 Petaling Jaya, Selangor, Malaysia.  
(attention : Pn. Rosilawati Ahmad / Pn. Chew Huei Min )

Tel: +603 7883 5400 (Pn. Rosilawati ext. 8424 or Pn. Chew ext. 5503)

Email: [rosilawati@bpfk.gov.my](mailto:rosilawati@bpfk.gov.my) or [chew@bpfk.gov.my](mailto:chew@bpfk.gov.my)

Fax: +603 7958 1312