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## News

### Bengkel Penyediaan Garis Panduan Pengendalian “Orphan Drugs”

2-4th December 2014

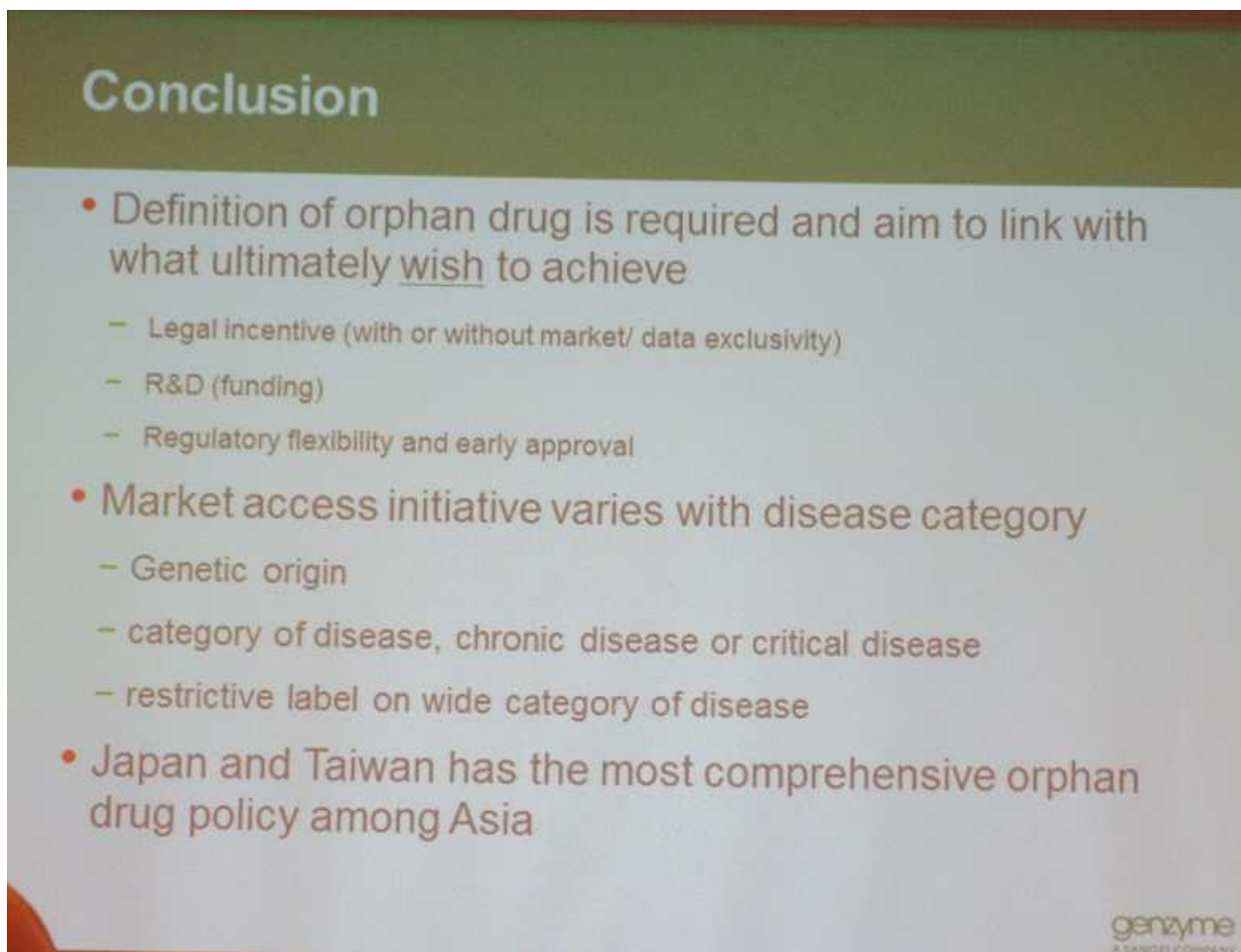
Klana Resort, Seremban

There were 35 participants from the MOH and the Private sector.

Orphan Drugs are currently classified as (1) drugs, vaccines and diagnostic agents that are used for the prevention, treatment and diagnosing of Rare Diseases and (2) drugs that are not economically viable to be supplied, treated and diagnosed a disease or condition.

The objective of the Bengkel is to have a “Malaysian Act/Policy Guideline for Orphan Drugs”, which is also one of the elements under the Malaysian National Medicine Policy 2012 (2nd Edition), to be ready by late 2015 or 2016.

INCENTIVES						
COUNTRY	Market exclusivity (years)	Fast track approval	Regulatory fee waivers	Tax credit	Pricing	Reimbursement
US	7	✓	✓	✓	Market-driven	✓
EUROPE	10	✓	✓	managed by member states		✓
AUSTRALIA	-	✓	✓	No information		✓
JAPAN	10	✓	✓	✓	Price negotiation	For certain diseases
S. KOREA	6		No information			✓
TAIWAN	-	✓	No information			70% -100%
SINGAPORE			No information			



## MAPS Inaugural Dinner

It was a highly anticipated event which culminated on the 28th November 2014 at Glenmarie Holiday Inn.

About 300 gorgeously decked persons descended on the Grand Ballroom as early as 6.30 that evening despite the challenges presented by the rain against these brave souls, ie Major traffic jams, risk of soaking their garments and ruining of their deftly applied make-up. Yet they all look gorgeous and appear unperturbed, and even more excited for the evening to come.



Old friends who have not seen each other for years caught up with one another and took opportunity for photo ops.

When all was ready, the Board and specially invited guests were led in by the dance troupe to the dinner event themed Glamorous Nite.



Thereafter, the MC welcomed all guests after the special guests have taken their seats.

Guests were introduced to MAPS by way of a video presentation.

As dinner progressed MAPS President, En Radzmi Rahmat delivered a speech elaborating on the quick progress made by such a young association.

(Right: En Radzmi Rahmat, President of MAPS delivering the inaugural speech)



Dr Nour Hanah represented Datuk Eisah for the Pharmaceutical Services Division in delivering her speech.

(Bottom: Dr Nour Hanah, Deputy Director Pharmaceutical Services Division delivering the speech)



In between dishes, guests were entertained by the dance team and also the band. If you missed the giant peacock, you have really missed something.



Some of the guests were also invited to sing along, although none, for good reason, were invited to take part in the high energy dances... albeit there being many suppliers of analgesics and potent muscle rubs.

Some of the dance moves had the dancers stacked 3-persons high.

(Left: En Shamsul goes Sha-la-la-la-la-la, as Mr Saravanan looks on)



Further participation saw 6 contestants picked for the "Best Dressed" male and female categories.

(Picture above: Candidates for the best dressed for the evening).

Lucky draws were picked by Mr Heng, MAPS Secretary of the Board and En Radzmi. A total of 10 prizes were distributed to the lucky winners with the grand prize being a 42 inch LG Smart LED TV set.

As the night rolled on, and the dinner came to a close, many stayed on to catch up on news about their friends. All in all the event was very successful and enjoyed by the guests.

### **Here's to many more annual dinners for MAPS!**

*Note: Members can download high resolution photos from the event by logging into the Members section. Forgot how to log in? Contact the MAPS secretariat.*



### **Malaysian Productivity Corporation dialogue with MAPS Board**

The Board of Directors started a meeting earlier in the day on 28th October 2014 at the MAPS Secretariat. After the Board meeting, some of the Board Directors met with Consultants from the Malaysian Productivity Corporation (MPC) at the same premise in the afternoon.

The MPC delegation was led by En Mohd Alamin Rehan with Mr Goh Swee Seang as the attending fellow and supported by Farah and Ilyana. As an introduction to MAPS, the delegates were given a preview of the video presentation prepared for the upcoming inaugural dinner(See you there, OK?). The delegation had previously met with PhAMA.



The MPC delegates shared with the Board that the MPC has been recently tasked with looking into government regulations which have the potential of impeding competitiveness and business friendliness. In the dialogue, the delegation was researching on the existence of such regulations. In the 2 hour dialogue, board members raised some issues which have been viewed to impact or have the potential to impact our industry.



## Analytical Method Validation and Process Validation Seminar



This seminar held from 24 to 25 September 2014 at Eastin Hotel, Petaling Jaya was jointly organised by the Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI) and Malaysian Association of Pharmaceutical Suppliers (MAPS) in collaboration with the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia.

A total of 251 Participants attended the seminar.

Participants breakdown:

- PhAMA: 66
- MOPI:87
- MAPS:29
- OTHER:29
- NPCB:40
- **Total:251**



The purpose of this seminar has been achieved which is to enhance the regulatory knowledge and competency of product registration holders in the pharmaceutical industry on Analytical Method Validation and Process Validation requirements.



NPCB experts provided the latest updates on these requirements. They also provided in-depth clarification and more specific interpretation of the requirements detailed in the Drug Registration Guidance Document (DRGD) with sharing on common problems encountered with these sections in registration applications as part of the learning process for the industry.

NPCB applauded the industry and specifically the 3 associations involved for jointly organizing the seminar. They hope that more similar collaborations can be done in the near future.



## Medicine Pricing and Reimbursement Workshop 2014

This event took place from 25 - 27 October at the Concorde Inn KLIA organised by the Drug Pricing Unit of Pharmacy Services Division. About 30 participants took part in this event. They were from:

- Pharmacy Services Division
- NPCB
- Health Financing Unit of MOH
- Ministry of Education
- Mindef
- KPDNKK
- FPMPAM
- MPS
- MCPG
- MOPI
- PhAMA
- MAPS







(Photo: Participants from MAPS, MOPI, PhAMA, MPS and Mindef)

Participants deliberated on the inputs by WHO Consultant before engaging in looking for an equitable pricing mechanism for the benefit of the Rakyat. One of the outcomes was each pharmaceutical association would encourage its members to share wholesale pricing with the Drug Pricing Unit to enable the unit in understanding the pricing of pharmaceuticals in the country. With this understanding, the unit would be more effective in ensuring that medicines remain affordable.

### **MAPS Board of Directors and Regulatory sub-committee meeting with NPCB Director**

A delegation comprising some Board Members of MAPS and the regulatory sub-committee had a meeting with the Director of the NPCB, En Tan Ann Ling on the 3rd July 2014 on regulatory issues and challenges viz:

1. Timeline for Variation Application
2. Timeline for New Product Registration
3. Clarification on Zone IVb Stability Data Requirement for Renewal
4. Quest 3: Online Registration Challenge
5. Renewal of Registration (for Products requiring BE and PIC/s)



(Above)En Tan making a point during the discussion

(Below)Participants in the meeting



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