

## Reducing Unnecessary Regulatory Burdens (RURB) in Pharmaceutical Industry: Engagement with Pharmaceutical Association of Malaysia (PhaMA)

30 October 2020, 3.30pm

### Attendees:

Mr. Mohd Hilmi Mohd Idris	MPC
Mrs. Anis Marina Abd Wahab	MPC
Mr. Ahmad Zaidi Abd. Wahab	MPC Associate
Dr. Yogesvari Sambasevam	MPC Associate
Ms. Alice Chee Seat Mee	PhaMA
Ms. Janice Tan	Novartis Corporation (M) Sdn. Bhd.
Ms. Ta Su May	DKSH Malaysia
Ms. Stephanie Ong	Sanofi-Aventis (Malaysia) Sdn. Bhd.
Ms. Long Siew Mei	Merck Sharp & Dohme (MSD) Malaysia
Ms. Nesha Armo	Merck Sharp & Dohme (MSD) Malaysia
Ms. Sebrina Su	AstraZeneca Sdn. Bhd.

Adalah dengan ini diperakuan perkhidmatan seperti berikut:-



Mohamad Azrol Md Dali  
Timbalan Pengarah  
Perbadanan Produktiviti Malaysia  
Tel: 03-7955 7266

RURB Study on Pharmaceutical Industry: Engagement with Industry

01:35:02 Request control Leave

### 6. Multiple Agency Approvals

Issue	Remarks	Suggestion
<u>Medical Device Authority (MDA) &amp; National Pharmaceutical Regulatory Agency (NPRA)</u>	Have to register the finished products with both NPRA and MDA.	Register only with NPRA
Registration for Medical Device-Drug (combined product)	Time consuming.	

**Questions**

- How many products/companies involved with the issue?
- Is there any other related products/process?
- Benchmark with other countries' best practices?
- Rationale for suggestion/recommendation?

Anis Marina Abd Wahab

Participants

- Yogesvari Sambasevam
- Alice (Guest)
- Anis Marina Abd Wahab
- ARMO, NESHA
- Long, Siew Mei
- Mohd Hilmi Mohd Idris
- Ong, Stephanie /MY
- Su, Sebrina
- Tan, Janice
- Zaidi (Guest)

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Zaidi (Guest) Tan, Janice Alice (Guest)