



## News/Photo

### Scenario Planning Workshop for Pharmaceutical Sector

Following up from the series of workshops held at MiGHT on the 2nd, 10th and 11th September 2024 organised by Pharmacy Policy & Strategic Planning Division of the Pharmacy Services Program, MAPS was invited again on the scenario planning from the outcome of the earlier series. (Scroll down for the earlier workshop titled Focus Group Discussion for Pharmaceutical Sector)

This workshop, scheduled for 30 September 2024 at the Function Room, MiGHT Partnership Hub, Jalan IMPACT, 63000 Cyberjaya was attended by MAPS' Vice President, En Shamsul Baharin.



### MOPI Regulatory Plus Conference 19-20 September 2024

Some MAPS members attended the MOPI Regulatory plus conference on 19 to 20 September 2024 organised by Pharmacy Policy & Strategic Planning Division of the Pharmacy Services Program. Below are some of the information presented:

Key note presentation by Dato Sri Norazman Ayob mentioned that cost of medicine has grown by 7.3% from 2014 to 2018. Therefore, there's co-payment scheme of 5% moving towards 10% in future. Shortage of Human Insulin triggered the reduced dependency on single source suppliers. Local tender volume will be split to 2 to ensure medicine security. Future EU FTA is in line. MOH Healthcare budget of RM41.2 Billion increased by 13.46% this year. RM6 billion will be on pharmaceuticals, 17% to public health clinic (Klinik Kesihatan) only.

Latest MOPI Statistic on the local manufacturing industry: Data from Matrade , IQVIA. Total Pharma industry RM12 billion. Prescription products 53% , generics 26%, OTC 21% by value. Prescription 16%, Generics 47% OTC 37% by volume. Total generics RM3 billion. 64% local, 36% imported. Government 52%, Private 48%. Export RM3 billion in 2023.



## **Budget 2025 Townhall Discussion with the Health Ministry**

The 2025 Budget Townhall on the 9th of Sept 2024 was held at the Everly Hotel in Putrajaya. Present were 3 representatives from Maps ; Mr Matthew, Ms Pei Leng, Mr Dharshen. The representatives from the MoH Top Management were (seated L-R)

- Datuk Dr Muhammad Radzi bin Abu Hassan  
Ketua Pengarah Kesihatan | KPK
- YB Dato Lukanisman bin Awang Sauni  
Timbalan Menteri Kesihatan Malaysia
- YB Datuk Seri Dr. Haji Dzulkefly Ahmad  
Menteri Kesihatan Malaysia
- Dato' Sri Suriani binti Dato' Ahmad  
Ketua Setiausaha | KSU
- Dato' Sri Norazman Ayob  
Timbalan Ketua Setiausaha Kewangan | TKSU (K)

The Townhall started at 2.45pm with two key areas of focus as shared by the Honourable Minister of Health, YB Datuk Seri Dr. Haji Dzulkefly Ahmad, which are:

- i) Healthcare Financing
- ii) Digital Health Transformation

As shared by the Minister, based on the 2024 budget, an allocation of 10.47 % of the total government budget of RM 393.8 billion was made for the MoH (i.e. RM 41.22 billion\*). MOH's share of total budget, was 1.1 % higher than its share in the 2023 budget. \*RM 35.15 billion comprised on management budget and RM 6.07 billion was allocated for development budget.

The allocation for 2024 also represented an increase of about 13.5 per cent from RM36.3 billion allocated in Budget 2023. This increment (RM4.89 billion) also marks the biggest percentage of increase for MOH's budget since 2014, and is the highest in absolute terms.

As the MOH continues to hold the position of the second-largest allocation in the federal budget after the Ministry of Education, currently for 2025, the Ministry is keen to obtain suggestions from various stakeholders

for value based models (such as subscription and consumption models) for a more sustainable operations for the MoH to reduce its opex.

This may be a good starting point for MAPS to initiate a dialogue with the MoH to champion our agendas to promote equitable access to healthcare.



## Focus Group Discussion for Pharmaceutical Sector

This focus group discussion was organised by Pharmacy Policy & Strategic Planning Division of the Pharmacy Services Program. It was hosted in the MIGHT(Malaysian Industry-Government Group for High Technology) building, Cyberjaya on 10 Sep 2024.

All the industry associations were invited, in addition to many government agencies and healthcare provider associations. MAPS was represented by the President. Four focus groups sat separately and produced many inputs for further deliberation by the policy makers.



## **Joint-Industry Discussion on Product Labelling Requirements**

MAPS RA Committee attended a joint-industry discussion on Product labelling requirement pertaining to animal origin finished product including packaging primer; on 2 Sept 2024 2pm via zoom; with PhAMA, MOPI and MMDA. Discussion includes the following:

- The practical impact of the new labelling requirements
- Feasibility and cost implications of compliance, including DNA PCR testing
- Challenges related to packaging and shared packs

Further a joint industry task force for this new requirement has been formed moving forward to seek for clarifications from NPRA.

## **Malaysia PV Community Inspection Readiness Networking Session**

MAPS RA committee attended Malaysia PV community inspection readiness networking session held on 16 Aug 2024. Sharing session by 3 companies that has underwent PV inspection (Sanofi, AZ and Duopharma). NPRA audit cover GVP , GDP and DRGD requirements (on post approval).



## **2nd Technical Committee Meeting for DUNas Component 3: Access to Medicines**

MAPS attended the DUNAS meeting component Access of Medicines on 26 August at the Delima Meeting Hall of Program Perkhidmatan Farmasi. The meeting was chaired by Puan Wan Noraimi binti Wan Ibrahim, Director of Pharmacy Practise and Development. The meeting discussed and reviewed the strategies and various initiatives under each plan.

### **Strategy: Sustaining access to drugs as per the demand of the country**

Some initiatives have been working on for strategy 1, such as encouraging the product registration process without compromising quality, safety and efficacy. Besides, there are initiatives to develop a Traditional & Complementary Medicines Formulary.

### **Strategy: Strengthen the supply chain value for optimal, effective and sustainable supply of medicines**

The studies conducted on the 33 types of medicines, namely SDG Basket Group, in various sectors, from government to private, were also presented at the meeting. However, the suitabilities of these 33 medicines need to be reviewed to reflect the appropriate situation in Malaysia.

The participants shared the challenges of when to get in the supply, especially for tender, as well as the progress of patent linkage, which the generic players are able to get in the generic medicines timely when patents expire.

**Strategy: To ensure the affordability and accessibility of medicines in both private and government**

For this strategy 4, a town hall on price tagging for private hospitals and general practitioners was conducted. Price transparency is one of the initiatives under this strategy 4.

**Strategy: Encourage usage of generic medicines in both government and private**

More GMAP (Generic Medicine Awareness Program) should be conducted for private hospitals, as current practices show that most private hospitals still prefer the usage of proprietary.



**2nd Technical Committee Meeting for DUNas Component 1: Good Governance for Medicines (GGM)**

The captioned meeting was held on 16th August 2024 morning at the Pharmacy Services Program, Jalan Prof. Diraja Ungku Aziz, Petaling Jaya, which was chaired by Puan Siti Aisah binti Bahari, Director of Pharmacy Policy and Strategic Planning. MAPS was represented physically by the President, Assistant Secretary and Board Director.

The achievements of the milestones outlined in the Master Plan of GGM component of the DUNas 4th term were tabled. Also tabled was the draft GGM module. The module will soon be shared with the associations for adaptations and modifications relevant to the industry. MAPS proposed that the Pharmacy Board consider accreditation modules by the association. If this is accepted, the association will work on producing the modules.



## **Engagement Session on Proposal for Implementation of Medicine Price Tagging Initiative at Private Healthcare Facilities and Community Pharmacies**

MAPS attended an engagement meeting on 13 August 2024 9am regarding the proposal to initiate price tagging in all retailer outlets including community pharmacies, private hospitals and GP clinics. This meeting was chaired by TKSU (K) YBhg. Dato'Sri Norazman Ayob. The session was held on site and on-line, with over 500 participants. Full implementation is expected to be by 2025.



## **NPRA-MAPS Dialogue 2024**

On 31 July 2024, NPRA had a yearly dialogue with MAPS with a fruitful discussion whereby both parties sought to understand issues at hand and tried to solve some of the outstanding issues like screening rejection etc. A workshop will be planned in November 2024 to address this issue. This meeting was chaired by Pn Rosilawati, Director of NPRA which was conducted in hybrid online and on-site manner.



## **National Bioeconomy Showcase 2024**

National Bioeconomy Showcase event was held at the World Trade Centre Kuala Lumpur from 17 to 18 July. This event was jointly organised by the Bioeconomy Corporation and Ministry of Science, Technology and Innovation (MOSTI). This showcased the latest bio-based technologies, innovations, services, and products in Malaysia. One of the key sectors is in healthcare.

The Prime Minister YAB Dato' Seri Anwar Ibrahim delivered the keynote address and launched the event at Dewan Tun Hussein Onn, WTC. MAPS President attended the launch ceremony.





## Dialogue with Deputy Secretary General (Finance), Ministry of Health

A few MAPS members were invited to and attended a dialogue with TKSU(K) Tan Sri Norazman Ayob on 5 July 2024 9am at Putrajaya. MOH will start to award tender on a fairer basis and wants the contracts to be spread to more companies and not award contract to a few selected companies to level the playing field. Companies are encouraged to register with MOF. MOH also wants the MIH Megatrends Oct 2024 to be the flagship event for MOH.

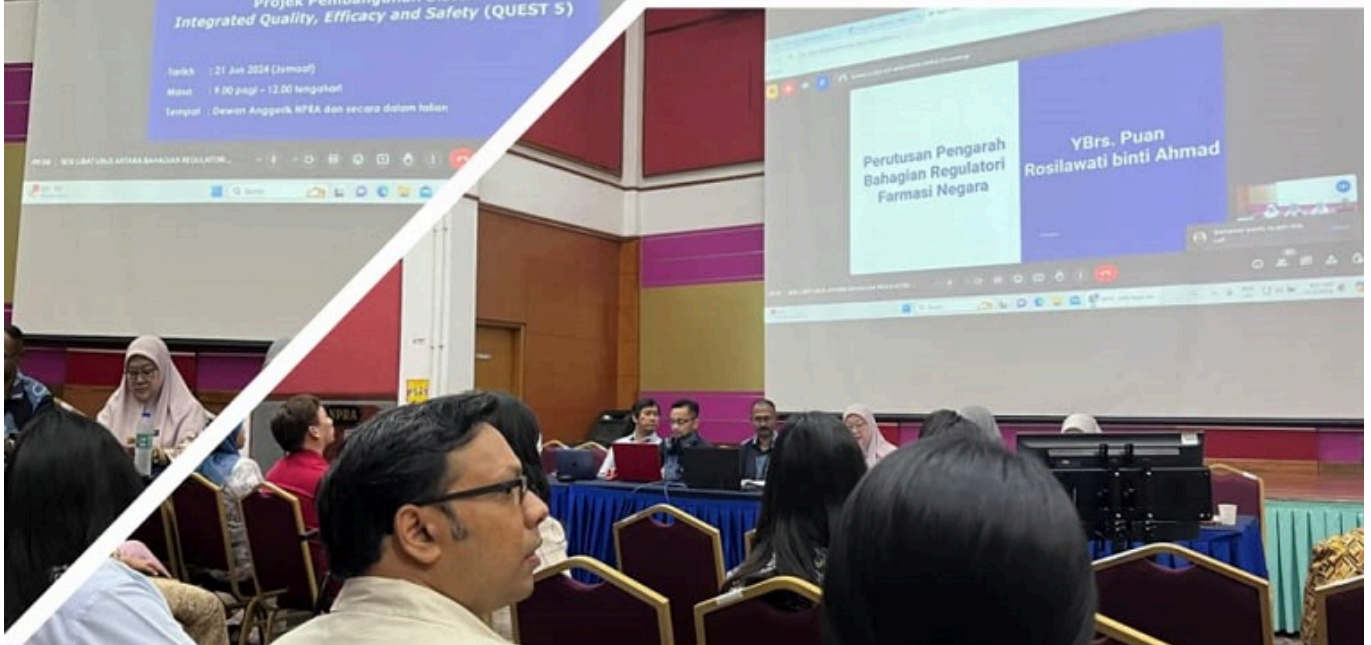
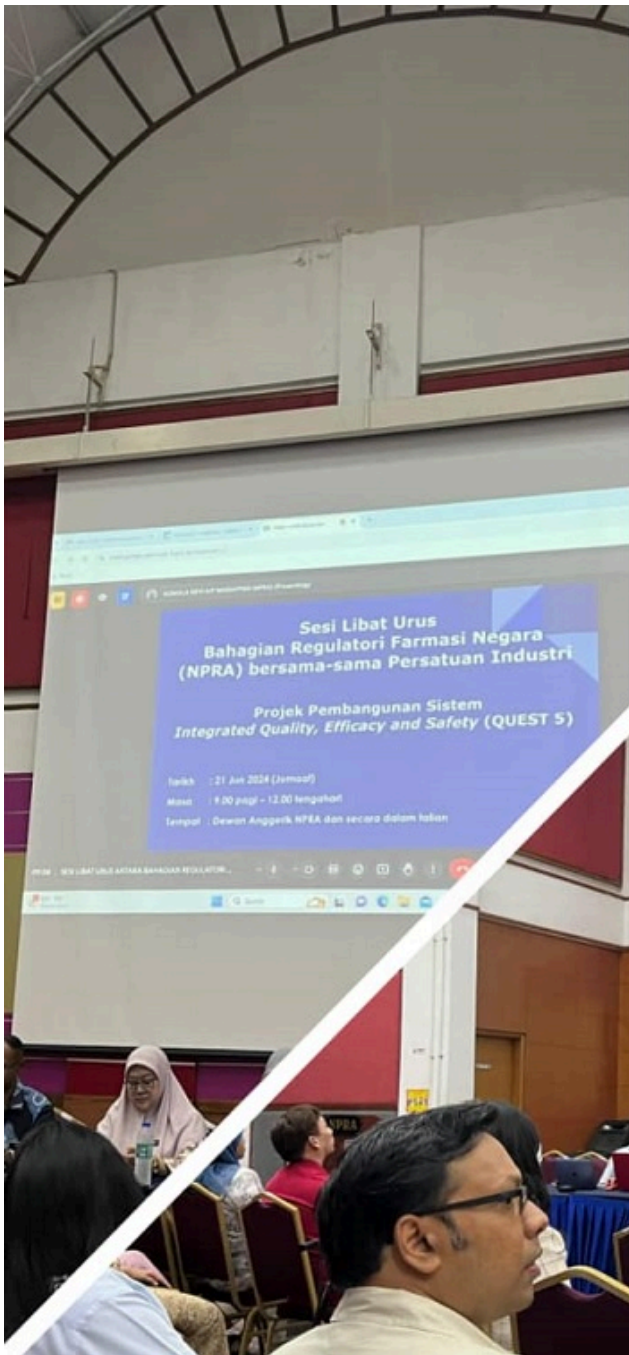


## 7th meeting of Pharmaceutical Product Working Group (PPWG), ASEAN

On 21 June 24 9am-12pm, MAPS attended a Quest 5 dialogue with NPRA. It was revealed that they have received a budget of RM17 million for Quest 5 setup. From the RM17 million, RM8 million is allocated to develop the system itself while the rest of it would go to maintenance of the system which includes the equipment, etc. Pn Rosilawati, the Pengarah of NPRA chaired the meeting. The timeline for the launching of Quest 5 is as below:

### **Timeline Action**

2024	Receive budget
Q1 2025	To receive the 'Surat Setuju'
Q4 2027	Go live with cosmetic module first (first release)
Q1 2028	Final release – full implementation of Quest 5 (second release)



## 7th meeting of Pharmaceutical Product Working Group (PPWG), ASEAN

MAPS participated as an observer in the 37th meeting of Pharmaceutical Product Working Group (PPWG), ASEAN, which was held on 6-7 June 2024 via video conference. This meeting was chaired by Director of NPRA Malaysia.

27:46

Chat 39 People Raise React View More Camera Mic Share Leave

37PPWG Doc 01 Ag 1 Draft Annotated Agenda.37PPWG\_2024 05 28 cleaned - Word

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THE THIRTY-SEVENTH MEETING OF THE PHARMACEUTICAL PRODUCT WORKING GROUP (PPWG)

6-7 June 2024 (Video Conference)

PROVISIONAL ANNOTATED AGENDA

AGENDA ITEM 1: ADOPTION OF AGENDA

The Meeting may wish to adopt the Provisional Agenda.

AGENDA ITEM 2: BUSINESS ARRANGEMENT

The ASEAN Secretariat may wish to inform the business arrangement.

Lusia Horwahyu

1/2

N NPRA-MAL... View all

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## 26th Meeting of the Implementation Working Group, ASEAN

MAPS participated as an observer in the 26th meeting of the Implementation Working Group (IWG), ASEAN, which was held on the 5-6 June 2024 through Video conferencing. Objective of meeting is to seek greater harmonization within ASEAN.

10:30

Chat 48 People Raise React View More Camera Mic Share Leave

37PPWG Doc 01 Ag 1 Draft Annotated Agenda.37PPWG\_2024 05 28 cleaned - Word

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37th Meeting of Pharmaceutical Product Working Group (PPWG) and Its Related Meetings

5-7 June 2024  
Video Conference Meeting  
Time Zone: Jakarta Time (GMT + 07:00)

TENTATIVE PROGRAMME OF ACTIVITIES (PoA)

5 June 2024 – The 26th IWG Meeting

Time	Meeting
08:30-09:00	Preparation for connection Opening Ceremony for 26th IWG Meeting
09:00 – 09:15	<ul style="list-style-type: none"> <li>Welcome Remarks by Chair</li> <li>Roll Call of each AMS</li> <li>Group Photo</li> <li>Admin Brief &amp; Familiarisation with MS Team tools</li> </ul>
09:15 -10:30	The 26th IWG Meeting

Yasinta Zulakha

You've been muted. You have been muted. Unmute

IM Rosito de S... View all

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## Committee of Inquiry for breach of ethic #1/2024

On 16 May 2024, MAPS participated in the Committee meeting of Inquiry for breach of ethic case held by Pharmacy Board. Further meeting will be held on 10 June 2024.



## E-Labeling Bil 2nd Meeting 2024

On 26 Mar 2024, 9am, MAPS attended another E-labelling Discussion on the proposal to conduct a study on "Impact of E-labelling implementation on Pharmaceutical on the Public, Healthcare Professionals & Industries" by DR June Choon from Center for Drug Policy and Health Economic research (CDPHER) Faculty of pharmacy, University Teknologi Mara. This study has been extended to cover public over the age of 18 years old, Health Care Providers (HCP), Associations like MMA, MPS and Malaysian Nursing Association plus industry's Regulatory Affairs personnel.

A video has been produced which will be launched soon to educate public and HCP on how to scan the QR code to retrieve the E-labelling. This meeting was chaired by YBrs. Puan Rosilawati binti Ahmad, Chairman of committee for e-Labeling.



## Training on Government Procurement Policy by MOF

On 21 Mar 2024, 2pm a training has been conducted on Government Procurement Policy by En Wan Azwar Zaihan bin Wan Ahmad, from Government procurement International Negotiation Section under Government Procurement Division, Ministry of Finance; pertaining to CPTPP (Comprehensive and Progressive Agreement for Trans-pacific Partnership). A total of 51 staff from among our members attended the training. This training was made possible following our engagement with the Deputy Secretary General (Finance) of the Ministry of Health, Dato Sri Norazman Ayob.



## Annual General Meeting 2024

The 13th AGM was held in the morning of 21st March 2024 with a quorum of 26 companies (70%). The Board of Directors for the term 2024 (21 March) – 2027 was also elected. Members present received and approved the Annual Report and Statement of Account, 2023. Issues and challenges affecting the Industry were also discussed. The President urged members to have active discussions within the company when received email notifications from MAPS. Please visit the "[About MAPS](#)" page and scroll down for the latest board members.

The Board and President thanks all members who attended the AGM and their unwavering support. The Board also thanks our gracious host Medispec and Dr Choe for his many years of service as Executive Director guiding us from strength to strength.



## Partnership and Collaboration for the Healthcare Industry Component of DUNas technical committee meeting

MAPS attended DUNas component 5: Partnership and Collaboration for the Healthcare Industry on 19 March 2024 9am to 12 pm. The Deputy Director of NPRA, Dr Azuana binti Ramli chaired this meeting. The status of 8 strategies and 9 initiatives were updated. The Pharmacy Services Program may call for a mid-term review sometime in quarter 3 this year.

# PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

Strategic partnership and collaboration among stakeholders shall be invigorated to support and foster the implementation of current and future goals in the healthcare sector

### Theme Focus

Knowledge Sharing	Technical Collaboration	Pharmaceutical Services Collaboration	Partnership In Digitalization Of Healthcare	Regional Collaborative Strategy
<b>STRATEGY 1</b> Encouraging research and development among stakeholders (1 initiative) (3 indicators)	<b>STRATEGY 3</b> Drug disposal management for healthy environment (1 initiative) (1 indicator)	<b>STRATEGY 5</b> Improving patient access to pharmacy services through public private partnership (1 initiative) (1 indicator)	<b>STRATEGY 7</b> Evaluation of conducive environment for digitalization information sharing between public and private sector (1 initiative) (1 indicator)	<b>STRATEGY 8</b> Initiating regional collaboration to promote equitable access to medicines (1 initiatives) (1 indicators)
<b>STRATEGY 2</b> Intensifying knowledge sharing in research and quality improvement (2 initiatives) (3 indicators)	<b>STRATEGY 4</b> Optimise human resource capacity in the community pharmacy to ensure continuous service delivery (1 initiative) (1 indicator)	<b>STRATEGY 6</b> Enhancing multi-sectoral technical engagement towards better health service delivery (1 initiative) (1 indicator)		
<b>8 STRATEGIES, 9 INITIATIVES, 12 INDICATORS</b>				

## New Deal for Business Validation meeting

Following the engagement session with the Economy minister, a validation session was held on March 15th at Zenith Hotel, Putrajaya. The first item on the agenda was the validation of the pharmaceutical industry on Quest 5 and formulary.





### **Quality Use of Medicine Component of DUNas technical committee meeting**

MAPS attended DUNas component 4: Quality Use of Medicine on 14 March 2024 9am to 10am. This meeting was chaired by En Mohd Zawawi bin Abdullah, Director of Pharmacy Enforcement. 4 strategies, 11 initiatives and 14 indicators were presented. The 4 over-arching strategies are on:

1. Prescribing & dispensing
2. Pharmaceutical care practices
3. Community Empowerment
4. Combating antimicrobial resistance

### **Engagement session with Economy Minister on the New Deal for Business**

The Government is in working towards increasing investor confidence, trade and competitiveness as well as stimulating economy through the implementation of the New Deal For Business (NDFB).



The main purpose of NDFB is to simplify business transactions and support the national digital transformation. This is expected to directly increase the country's productivity and position Malaysia among the 12 most competitive nations in the world.

NDFB will focus on structural reforms and improving the processes and procedures to counter bureaucracy, inefficient regulations and inappropriate bureaucratic burdens for investors and businesses.

For more information on this do visit this [report](#).

The President and Vice President attended this engagement session with the Economy Minister, YB Rafizi Ramli at Palm Garden Hotel, IOI City, Putrajaya on the afternoon of March 13 2004.



### **Assess to Medicines Component of DUNas technical committee meeting**

On 8 March 2024, MAPS attended DUNas meeting on Assess to Medicines (component 3), chaired by Puan Wan Noraimi binti Wan Ibrahim (Director, Pharmacy Practice and Development). 5 Strategies, 15 Initiatives and 17 Indicators were presented. Budget for Quest 5 has been released end of last year and NPRA will proceed to working on Quest 5 with MAMPU (MALAYSIAN ADMINISTRATION MODERNIZATION AND MANAGEMENT PLANNING UNIT, PRIME MINISTER'S DEPARTMENT) first then only with the industry later in early 2025.

### **Quality, Safety, Efficacy Component of DUNas technical committee meeting**

On 5 March 2024, DUNas meeting component 2: Quality, Safety & Efficacy meeting was held and chaired by Puan Rosilawati, Director of the National Pharmaceutical Regulatory Agency. 25 Strategies, 53 Initiatives and 80 indicators were presented. Most of the indicators were achieved, with the exception of:

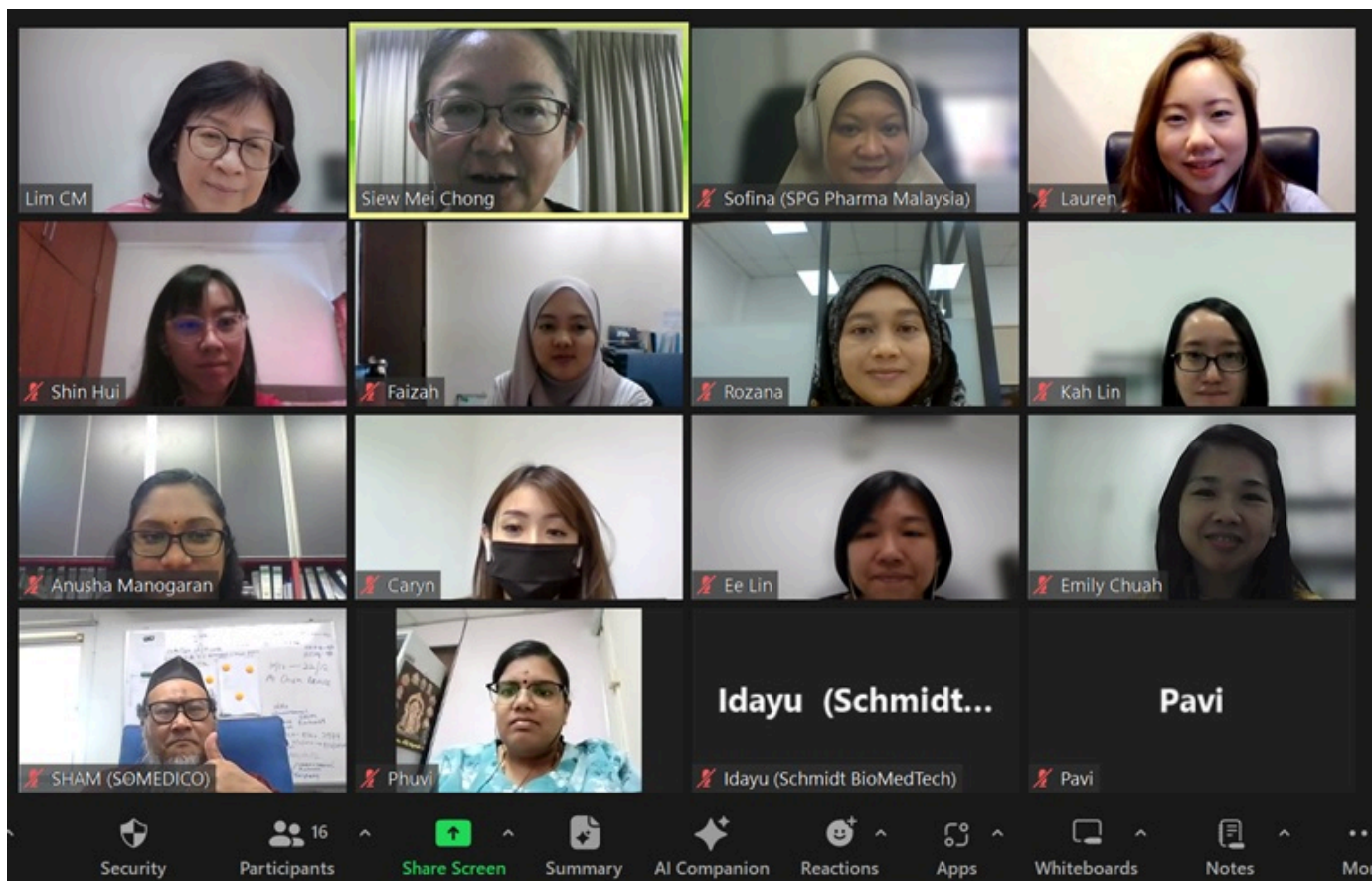
1. ICH status - Unable to fulfill 2x per year of meeting and unable to pay the membership fee of RM200k
2. NPRA to be a statutory body. This is awaiting confirmation from MOH if policy allowed.



### **Pre-meeting with NPRA Generics unit**

On the 4th March 2024, below issues were discussed and MAPS are to come out with a proposal or comment by 5 April to NPRA. 28 MAPS RAs attended the virtual discussion. The issues in this meeting are

1. Review on Small Label Criteria
2. In-use Stability for Multi Dose Liquid Preparation
3. Container Closure System for Dangerous/Cytotoxic Drug
4. Elemental Impurities in Pharmaceutical Products
5. Technical Summary Report (TSR)/ Public Assessment Report for Generics/hybrid
6. Updates on the use of TiO<sub>2</sub>



## Governance in Medicines Component of DUNas technical committee meeting

The Technical Committee for component 1 of DUNas Term 4, met on 26th February 2024. The achievements laid out in the Master Action Plan for the component of Governance in Medicines was presented. It was chaired by the Pharmacy Services Program Director of Policy and Strategy, Puan Siti Aisah binti Bahari. MAPS was represented by the President at this meeting.

Dasar Ubat Nasional (DUNas) or the National Medicines Policy is the Government and stakeholders' commitment towards achieving the medium and long term goals of pharmaceuticals in the nation. DUNas is in its' fourth term (2022-2026) and the Master Action Plan has been developed, approved by the DG of Health and is being implemented.

This component has 4 strategies, which are implemented via 6 initiatives. The strategies are

1. To foster a culture of ethical behaviour
2. To encourage transparency, accountability and ethical practices among health care professionals
3. To strengthen laws and regulations
4. To improve the capacity and capability of human capital

For a more comprehensive understanding of the National Medicines policy, do download it [here](#). Do note that this document is only in Bahasa Malaysia. Please discuss it with your staff if you need to understand it further in English.



Pembentangan Pencapaian Pelan Tindakan Induk (PTI) DUNas Penggal Keempat bagi Komponen Governance in Medicines

## Patent Linkage Meeting 23 Feb 2024

On 23 Feb 2024 9am, 5 Regulatory Committees of MAPS were represented in the discussion on Patent Linkage together with MOPI and TWN (Third World Network). This meeting is chaired by Puan Rosilawati. The industry and TWN reinforced that according to article 18.53 of CPTPP agreement stated that

1. a system to provide notice to a patent holder prior to the marketing [and not prior to registration] is needed. Therefore there should not be a time frame of 18 months stated in the guidelines to register a generic. Time frame should be open or not to have timeline at all.
2. There should not be a rush to implement patent linkage by July 2025, when in fact we are given 4.5 years to implement patent linkage.
3. Since notification is required before marketing, there is no need for generics players to fill in form 1 to 3 prior to screening and obtain acknowledgement from patent holders.

Generics industry is given a time frame until 29 March 2024 to come out with a different proposal than what has been agreed earlier with PhAMA.



## Malaysian National Medicines Policy Implementation Committee Meeting

DUNas or the Malaysian National Medicines Policy was drafted to prioritize the medium to long-term goals for the pharmaceutical sector.

In summary, Pn Norhaliza, Director of Pharmacy Service Program chaired the meeting for the 4th Term of DUNas (2022-2026) , to keep abreast of the developments/ implementation of the action plan to ensure that policy is on the right track.

There are 5 components are as below and includes various initiatives to encourage the equitable access of medicines as well as the rational use of medicines that are safe, efficacious, of high quality and affordable to improve health outcomes of the population.

1. Governance in Medicines
2. Quality Safety and Efficacy in Medicines
3. Access to Medicines
4. Quality Use of Medicines
5. Partnership and Collaboration for the Healthcare Industry

These topics can be good starting points for discussions to align MAPS interest to ensure our common goals are met.



## **ENGAGEMENT SESSION ON THE DOCUMENT DEVELOPMENT FOR THE NEW DEAL FOR BUSINESS (NDFB)**

As a follow up meeting with the MPC 2 days earlier, a larger meeting of associations across multiple sectors was called. This was hosted by PEMUDAH at Putrajaya. The purpose of this engagement was towards the formulation of the document for New Deal for Business (NDFB) which is aimed at improving business confidence, increasing productivity and competition, stimulating economic expansion and supporting the nation's digital transformation. The implementation of NDFB will impact investments, both foreign and domestic, create jobs and increasing the GDP. NDFB is aligned with the MADANI economy to position Malaysia among the 12 top competitive markets worldwide.

The NDFB shows the commitment of the government in solving issues to improve the business environment by managing structural and situational challenges. Focus on structural reform to address bureaucracy, efficient rules and inappropriate regulatory burdens. The 10 pain-points identified based on the World Bank

study, to be addressed are shown below.

**Figure 4. Overview of BEE Topics and Cross-cutting Themes**



The detailed methodology handbook is available for download by following [this link](#).

### **Malaysia Productivity Corporation meeting for New Deal for Business**

On 31 Jan 2024, MAPS met up with Malaysia Productivity Corporation to discuss issues and challenges with regards to doing pharmaceutical business in Malaysia. MPC will be setting up a Nexus to improve the productivity and efficiency of the industry. Following this meeting, MAPS was invited to an engagement session with MPC on 2 Feb 2024 to formulate New Deal for Business (NDFB) to increase confidence to do business, to improve productivity and competitiveness, to stimulate economical growth and enhance digitalization transformation in the country.



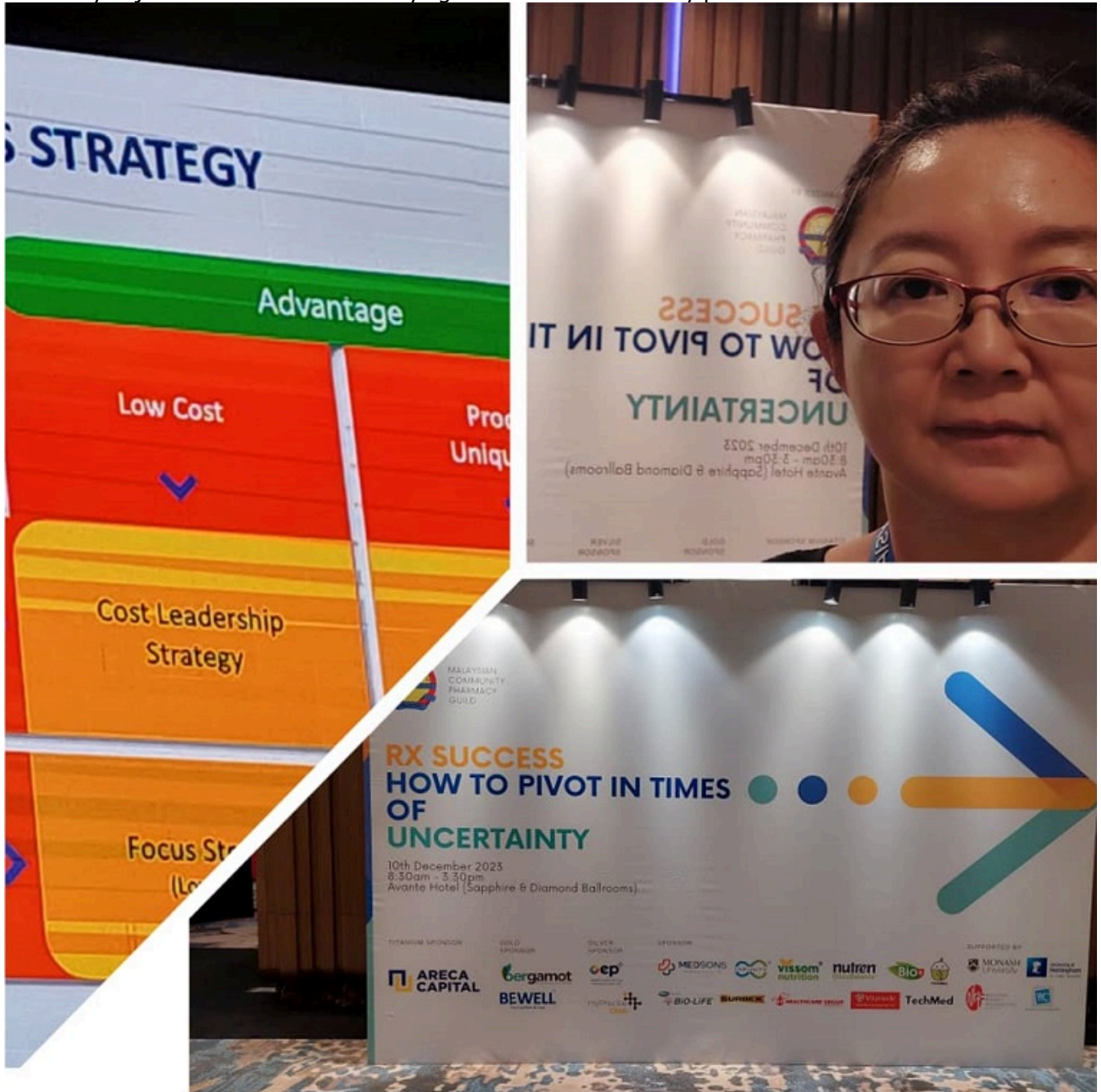
### **Video Conference with Pharmaniaga Higher Management Team**

On 30 Jan 2024 3pm, MAPS BOD has a video conference with Pharmaniaga higher management team on the new APPL contract's new Clause 4.9.2 2 Return of Products with Shelf life and Clauses 11.2.2 & 11.2.3 Invoice and Payment of the Products. MAPS sought for priority in payment and highlighting the difficulties MAPS members faced and the financial pressure should these clauses be imposed. Pharmaniaga assures that these clauses are meant for pandemic related products and not for normal pharmaceutical products and they





necessary adjustment to thrive in this trying times for all community pharmacists.



## **GUIDANCE DOCUMENT AND GUIDELINES FOR REGISTRATION OF BIOSIMILARS IN MALAYSIA (second edition, 2023) - Virtual Meeting**

MAPS RAs attended the virtual meeting on Biosimilars guidance documents on 25 Oct 2023. Feedback and responses from NPRA were presented, as well as highlights on issues with regard to biosimilars that require

further discussion. New guideline will be implemented by Dec 2023.

The image shows a Zoom meeting interface. The main window displays a presentation slide with the following text:

**NPRA RESPONSES TO COMMENTS BY INDUSTRY**

**GUIDANCE DOCUMENT AND GUIDELINES FOR REGISTRATION OF BIOSIMILARS IN MALAYSIA**  
Second Edition (2023)

25 October 2023, 2.15pm (virtual meeting)

The slide is presented by **TAN YUN MIN (NPRA) (Presenting)**. The meeting controls at the bottom show the time as 14:15 and the meeting ID as eqg-sqk-jep. The participant grid on the right includes:

- NORAI SYAH BI...
- Alice Chee
- Stephanie (Ph...
- NORA ASHIKI...
- TAN YUN MIN (...)
- KP Soh
- Akalliy Sofina ...
- 14 others
- Chong Siew Mei

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