



## News/Photo

### 6th Healthcare + Expo, Taiwan

MAPS President was invited to the 6th Healthcare + Expo, Taiwan. The event was officially launched by the Taiwan President, Dr Tsai Ing-wen. The event took place at the Nangang Exhibition Centre, Taipei from December 1st to 4th.



### MOPI Webinar 3/2022 - Strengthening the Sustainability of Medicine Supply During National Health Crisis

MAPS participated in the webinar entitled Strengthening the Sustainability of Medicine Supply During National Health Crisis , on 23 November 2022.

Topics presented are :

1. Lessons learn from the disruption of global supply chain during the pandemic in ensuring the sustainability of medicine supply.
2. Covid19: Global trend and policies around the world in strengthening medicine supply.
3. Medicines supply sustainability.

### Engagement session on Licensing Activities

With the passing of the Poisons Amendment Act (2022), the Pharmacy enforcement division engaged stakeholders on the changes that will have an impact on the activities for poison licence holders. MAPS attended "SESI LIBAT URUS AKTIVITI PELESENAN" For Acta Racun Pindaan 2022 on 14 October 2022 8am to 12.30pm, together with other industry players.

Significantly, the roles of registered and licensed pharmacists are mentioned. A brief email has been sent out to all members. If you wish to have a copy of the actual act you can download it from the AG Chambers' website [here](#)



MASA	AGENDA
8.00 pagi	<ul style="list-style-type: none"> <li>• Pendaftaran peserta</li> <li>• Minum pagi</li> </ul>
8.30 pagi	<ul style="list-style-type: none"> <li>• Bacaan doa</li> <li>• Kata-kata aluan Pengerusi</li> </ul>
8.45 pagi	<ul style="list-style-type: none"> <li>• Sesi Pembentangan – Perubahan Dalam Aktiviti Pelesenan Bagi Penguatkuasaan Akta Racun (Pindaan) 2022</li> </ul>
9.45 pagi	<ul style="list-style-type: none"> <li>• Sesi Perbincangan</li> </ul>
11.45 pagi	<ul style="list-style-type: none"> <li>• Rumusan &amp; penutup sesi</li> </ul>
12.15 tengahari	<ul style="list-style-type: none"> <li>• Bersurai</li> <li>• Makan tengahari</li> </ul>



## MAPS CEO and Senior Managers Networking 1.0 2022

After over 2 years of various stages of MCO's plus with the lowering case load and and severity, and aided by high vaccination rates, MAPS Social and Sport committee has organised a luncheon for the members and guests to come together for networking. Many changes have taken place in the business environment under the new normal, and this event was aimed at being an opportunity to catch up to discuss the challenges so as to get ideas on how to better manage the business in the new environment. Of course also a time to enjoy some unique food as we talk informally.

For this MAPS CEO Networking lunch held on 12 October 2022, total participation of 30 CEOs & Senior Managers from 20 companies attended the Networking lunch. Issues are being discussed in an informal and lively manner. It is hoped that there will be more opportunities for such networking sessions, and potential members are welcome to join us.





## BEDE Dialogue with NPRA

A joint industry MAPS & MOPI dialogue with BEDE department of NPRA was held from 2:30pm to 4:30pm on 27 September to discuss on issues faced with regards to Bioequivalence Desktop evaluations matters.

The screenshot shows a Google Meet interface with a presentation window displaying a table of BEDE issues. The table is divided into two sections: 'BEDE issues from MAPS' and 'BEDE issues from MOPI'. Each section contains columns for BEDE Ref No., Date of application submission, Date of receipt after submission, Date of acceptance for Evaluation, and Remarks/Current status.

BEDE issues from MAPS				
BEDE Ref No.	Date of application submission ("handing hand in")	Date of receipt after submission ("of emd")	Date of acceptance for Evaluation / Screening Approval	Remarks/ Current status
1	BEDE-0409	21/7/2022	19/7/2022	Application approved on 17/10/2022 (Excluded screening approval)
2	BEDE-0430	06/7/2022	06/7/2022	Application approved on 12/10/2022 (Excluded screening approval)
3	BEDE-0431	06/7/2022	06/7/2022	Pending evaluation approval (Excluded screening approval)
4	BEDE-0528	27/7/2022	1/8/2022	Screening completed. Applicant to provide response for 2 <sup>nd</sup> screening remarks (Excluded screening approval)

BEDE issues from MOPI				
BEDE Ref No.	Date of application submission ("handing hand in")	Date of receipt after submission ("of emd")	Date of acceptance for Evaluation / Screening Approval	Remarks/ Current status
1	BEDE-0396	21/7/2021	21/7/21, 20/7/21, 5/11/21, 23/11/2021	12/9/2021 Pending evaluation
2	BEDE-0434	10/9/2021	13/9/2021	07/09/2021 Pending evaluation
3	BEDE-0435	08/09/21	11/09/21	7/09/21 Pending for evaluation approval
4	BEDE-0436	08/09/21	27/09/21	27/09/21 Pending for evaluation approval
5	BEDE-0437	30/09/20	5/03/21	19/09/20 Application approved on 5-Mar-21
6	BEDE-0490	30/09/20	5/03/21	23/03/21 Application approved on 23-Mar-21
7	BEDE-0498	11/09/21	23/09/21	21/09/21 Pending for evaluation approval
8	BEDE-0499	1/09/21	18/09/21	20/09/21 Application approved on 1-Sep-21
9	BEDE-0499	2/09/21	08/09/21	03/09/21 Application approved on 3-Sep-21
10	BEDE-0497	2/09/21	29/09/21	17/09/21 Pending for evaluation approval
11	BEDE-0495	2/09/21	29/09/21	17/09/21 Application approved on 5-Aug-21

## Launch of the National Biotechnology Policy 2.0 (DBN 2.0)

The National Biotechnology Policy 2.0 was officially launched on 12 September 2022 (Monday) by the Prime Minister of Malaysia, YAB Dato' Sri Ismail Sabri bin Yaakob at the World Trade Center Kuala Lumpur.

DBN 2.0 is an extension of the National Biotechnology Policy 2005-2020 which focuses on 3 main sectors which are Agriculture Biotechnology & Food Security, Industrial Biotechnology & Circular Economy and Healthcare Biotechnology & Wellness. The DBN 2.0 was attended by more than 300 representatives from the Ministry/agencies, industry, academia. MAPS president attended the event.







## **24th International Generic and Biosimilar Association - Malaysian Association Organisation of Pharmaceutical Industry Conference 2022**

MAPS attended the 24th IGBA-MOPI Conference held on 7-9 September 2022, with topic ranging from Generic and biosimilar medicines, from central to patient health to global healthcare policies.

The IGBA-MOPI Conference 2022 has been organized by the Malaysian Organisation of Pharmaceutical Industries (MOPI), an associate member of IGBA from 7th - 9th September 2022 @ Royale Chulan Kuala Lumpur.

The Conference brought together around 250 experts and leaders from the manufacturing industry, government agencies, NGOs, academia and other stakeholders to participate in vibrant discussions and knowledge-exchange sessions on issues, trends and policies that shape the off-patent industry today.



### **MESYUARAT CADANGAN TAKRIF AMALAN FARMASI**

The Pharmacy Act 1951 must be reviewed and updated accordingly as the Practice of Pharmacy has evolved and transformed since then. The Act must anticipate the positive changes of the profession, practise and behaviour of the healthcare demands. It must be made relevant for now and the future. It will have the impact on the total healthcare system for the well being of the Rakyat and Nation. Mr TC Lim and Dr Choe Tong Seng were both invited to be part of this meeting held at the Pharmacy Services Program premise.



## MESYUARAT MEMBINCANGKAN CADANGAN TAKRIF 'AMALAN FARMASI' – 29 OGOS 2022



Duduk dari kiri : Alice Chee Seat Mee, Dr. Choe Tong Seng, Prof. Dato' Dr. Abu Bakar Majeed, Akmalayatul Kamal binti Kamaruddin, Amrani bin Buang, Prof. Dr. Habibah A. Wahab, Lim Teng Chyuan

Berdiri dari kiri baris 1: Nurul Adha bin Othman, Hanisah binti Shafie, Zurainy binti A. Samah, Nurulfajar binti Mohd. Jamid, Umikalsom binti Ibrahim, Ung Liew Ean, Norhana binti Nawawi Suri

Berdiri dari kiri baris 2: Harpreet Kaur, Nurul Afifah binti Osman, Siti Nurul Fathimah binti Baharudin, Mejar Nurul Syazfeeza binti Samsudin

Berdiri dari kiri baris 3: Nurulbaikis@Zubaidah Anum bin Hamdan, Jamilatul Wahidah binti Jamal Radzi, Hazimah binti Hashim, Nur Syahrina binti Ishak

Berdiri dari kiri baris 4: Lt Kol. Mohd Halif bin Mohd Yusuf, Chan Lin Yee, Jason Tang Kar Seng, Indra Shahril bin Abdul Hamid.

### Health Policy Summit 15-16 Aug 2022

There is an increasing momentum on the formulation of the Health White Paper, which saw a major two day summit held at the Putra World Trade Center. The Prime Minister officiated this summit, while the Health Minister also took part in presentations, and panel discussions over both days. MAPS was invited and participated in this summit from 15-16 August 2022, which discussed about :

1. Health System Resilience- Innovation, Equity and Sustainability
2. Bridging "Health" back to healthcare
3. Health and healthcare throughout the age spectrum
4. Towards sustainable healthcare financing
5. Human resources for health
6. Realizing the call for "Whole of Society" in health outcome
7. Digital transformation: reimagining healthcare
8. The future of our healthcare, key area for reform: Service delivery & access, Financing , Governance.

Eventually all feedbacks will be collated and presented to the top policymakers. This white paper seeks to reimagine healthcare and is expected to set the landscape for the next 15 years, at least.



## **MAPS - MOPI discussion on common issues - 29 Jul 22**

After a long break due to the pandemic, delegates from MAPS and MOPI met again in a face to face event hosted at MOPI's secretariat. It was fruitful meeting where we discussed many issues:

- Proposal to MOH on price for tender items in view of weakened currency or increase in global raw materials
- Late delivery penalty charges imposed in view of current shortages
- Extension of length of time to supply MOH
- Release of production and business data to MOH
- APPL list be opened up to more players in the light of the shortage of medicines
- To discuss on the Nitrosamine Impurity issue
- General price control and "patent evergreening" issues
- Grandfather products for re-registration
- Hologram/QR code





### **Mesyuarat Kekurangan Bekalan Ubat-ubatan di Fasiliti Kesihatan Primer**

MAPS was invited to attend and give our opinions during " Mesyuarat Kekurangan Bekalan Ubat-ubatan di fasiliti Kesihatan Primer". MAPS being a key player in the supply chain of medicines in Malaysia, our views and support is sought after by MOH at a time like this. This meeting was held on 14 July 2022 at 1.30pm to 2.30pm at Bilik Gerakan, Block E7, KKM , Putrajaya with the Health Minister.



### **Workshop on Access to Affordable Treatment in Malaysia, 5 to 6 July 2022**

A two-day workshop was organised by Third World Network at AVANTÉ Hotel, Bandar Utama on Access to Affordable Treatment in Malaysia. MAPS was represented by the President, Secretary and Assistant Secretary. Participants comprised Officials from Ministry of Health, Ministry of Domestic Trade and Consumer Affairs, Malaysian Competition Commission, patient support & advocacy groups, civil society organisations, Drugs for Neglected Diseases Initiative and academia.

The Senior Director of Pharmacy Services Program, Pn. Norhaliza binti A Halim, represented the DG of health in delivering the opening speech. Many topics were covered in this intense workshop, even with speakers joining via weblink from Cairo including:

- Malaysia's Hepatitis C Journey
- Access to Cancer Medicines: Issues and Challenges
- Sustaining the national HIV programme
- Patents Act amendments: implications for access to affordable medicines
- Lessons from COVID-19 for pharmaceuticals regulation
- Progressing Sponsored Clinical Research in Malaysia
- From a WTO TRIPS Waiver to the 17 June 2022 TRIPS Decision: An assessment
- Regulatory requirements for biosimilars, including WHO Guidelines review
- Using Competition Law to Promote Access to Health Technologies in Low- and Middle-Income Countries
- Anti-competition behaviour in the market and remedies
- Price transparency and affordable pricing
- A domestic industry perspective



## **MAPS Regulatory Zoom Meeting - 28 June 2022**

A regulatory meeting was held via Zoom on 28 June at 3pm. With a total participants of 30 Regulatory Affairs staff participating, the agenda discussed included Product Renewal Market Survey, e-Labeling Costing Impact Survey, Product Marketing Status Survey, Nitrosamine Impurities and drug shortage. 3 Sub-committees were



formed to address these matters.



## **BIO-BASED ACCELERATOR PROGRAMme LAUNCH, 16HB JUNE 2022**

MAPS, via the President attended the Bioeconomy Corporation hosted launch of the Bio-Based Accelerator programme on June 16 at the Marriot Putrajaya. The Minister of Agriculture and Food Industries, YB Datuk Seri Dr Ronald Kiandee officiated the launch.



The newly introduced Bio-based Accelerator (BBA) programme helps bio-based companies to become innovative and tech savvy by facilitating them to infuse science, technology and automation in their business operations. This enables bio-based companies in the agriculture, industrial and **healthcare** sectors to progressively move up the value chain to become more efficient and competitive. This programme identifies gaps in skills, technology adoption, financial, regulatory and product marketability. For more information about this do visit their [website](#), which can be beneficial to members who need the facilitation provided by the Bioeconomy Corporation.

## Patents Laws Amendments Webinar 17 May 2022

MAPS participated at Patents Laws Amendments involving pharmaceutical industry webinar organized by MOPI on 17 May 2022. Summary and slides have been shared with all members of MAPS. Do check your email, in case you missed it.



## SESI DIALOG BERKENAAN PELAKSANAAN PERMIT IMPORT PERANTI PERUBATAN DI BAWAH PERINTAH KASTAM (LARANGAN MENGENAI IMPORT) 2017



A dialogue had been conducted on 13 May 2022 between Malaysia Medical Device Authority (MDA) with MAPS, MOPI and PhAMA, regarding the implementation of E-permit for each shipment of medical devices, to curb illegal importations of Medical Devices.



### **Bengkel Hala Tuju Pendidikan Farmasi Malaysia**

This focus group organised by the Malaysian Council of Pharmacy Deans was held at Zenith Hotel, Putrajaya on May 18th. Stakeholders from academia, pharmacy services, industry and military were invited to provide feedbacks to help in formulating the future direction of pharmacy education in Malaysia. MAPS was



represented by the President.



## 11th Annual General Meeting

MAPS 11th AGM was held on 22nd March 2022 at the Secretariat. There were 23 participants. Annual Financial and Committees Reports were presented. Much time was taken in the discussion for the Regulatory Report. It is important that CEOs are “on-top” of Regulatory issues as there will be financial impact for any delay, new requirements etc in the Regulatory process. It is strongly recommended that CEOs have regular engagements with their respective regulatory personnel, from time to time, for them to understand the impact in financials as well.

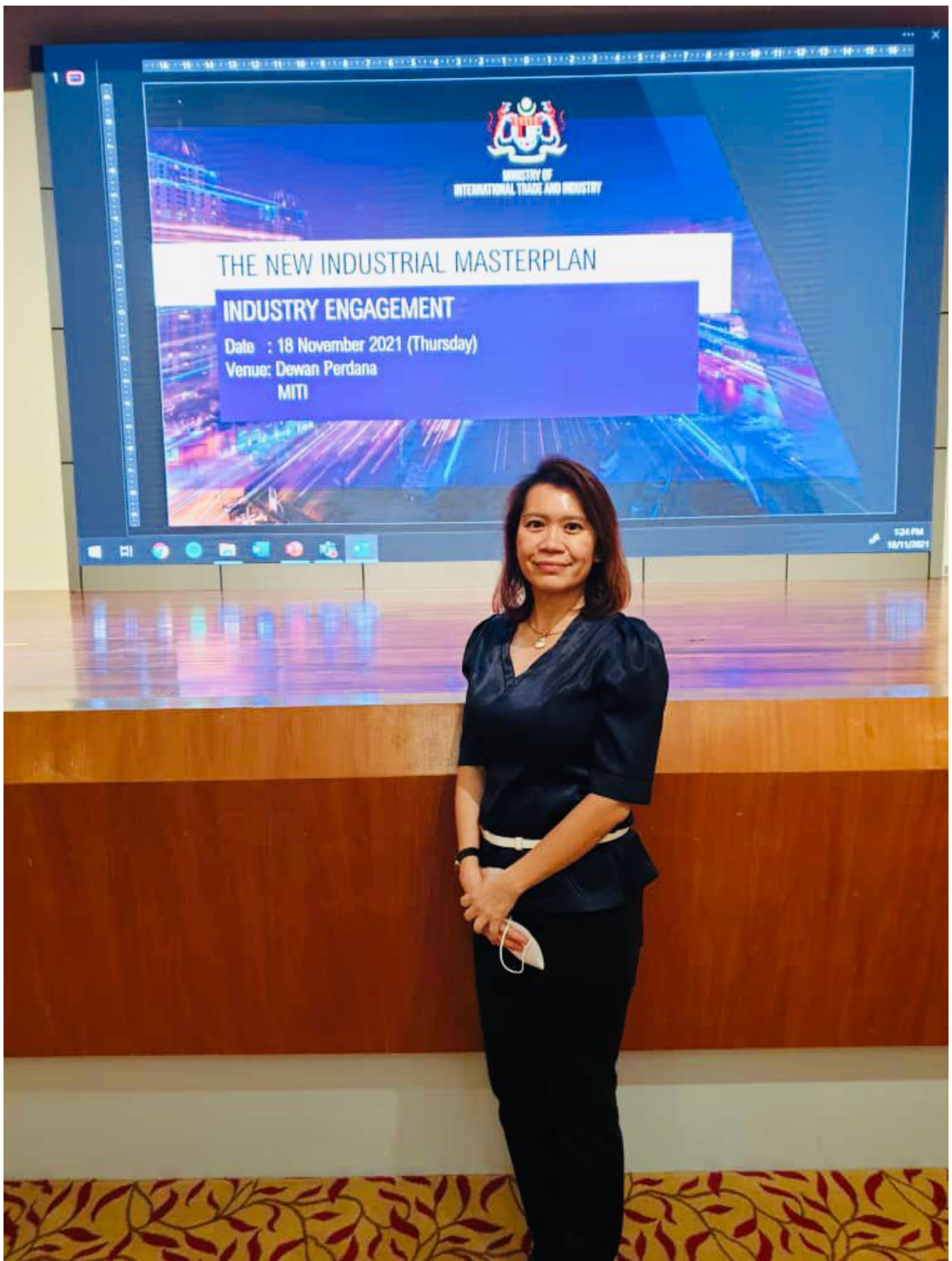




## **New Industrial Masterplan Industry Engagement**

The MITI organised an engagement session on the New Industrial Masterplan(NIMP) at the MITI building on 18th November 2021.

MITI is conducting a study to develop the NIMP which is currently at the draft final report stage. The NIMP will replace the Industrial Master Plan 3 (IMP3) and will set the strategic direction for the manufacturing and the services sectors from now till 2030.



At this stage, strategies and action plans at the national and industry level have been formulated covering approximately 23 industries, of which the Medical Devices and Pharmaceuticals are part of. MAPS was invited to provide feedback and views on the proposed strategies and action plans to help develop a holistic approach to grow and propel.

MAPS provided a formal response via an email in addition to the attendance of the workshop.

### **M&A and ERP System & Processes Talks, 1st April 2021**



Ten member companies sent over 30 delegates who attended this event. Two topics covered in this session are

Topic 1) Corporate Development Strategies: Maximise value or an exit strategy on the following 2 options - Mergers & Acquisitions (M&A) or Initial Public Offering (IPO)

Topic 2) An effective ERP system for businesses: The tested and proven ERP System and Handheld Palm Order System. It highlighted Data Analytics, MES Integration, Smart Warehouse, Portal, Web and accounting software.



## **National Covid 19 Vaccination Follow-Up Briefing 26th March 2021**

A Web Meeting was held as a follow-up to the earlier briefing by the Minister of MOSTI, YB Khairy Jamaluddin. The meeting was informed that the vaccination program for economic frontliners will be accelerated via a Private Public Partnership. Companies and associations that can gather large numbers will be given priority in this program. To qualify for this program companies need to achieve 80% sign-up rate. Via this the Ministry of Health will send the vaccine teams to specific sites to administer the vaccine. The cost of the team and vaccines will be borne by the government and the cost of setting up the external vaccination centres will be borne by the private partners. More details will ensue.

Other new considerations are for business travellers and students with overseas enrolment to be given priority vaccination, and vaccine choice will be allowed for this group if the country to be visited or enrolled requires a certain vaccine. Business travelers will need to provide proof of business travel and students will need to provide proof of enrolment.



## 10th AGM 18th March 2021

The 10th AGM was held in the MAPS Secretariat on 18th March 2021. There were 18 member Companies present. Tight and stringent SOPs were enforced. The new Board of Directors were voted in for a new term of March 2021/2024. The President expressed his desire to have more members participating in the activities of MAPS.



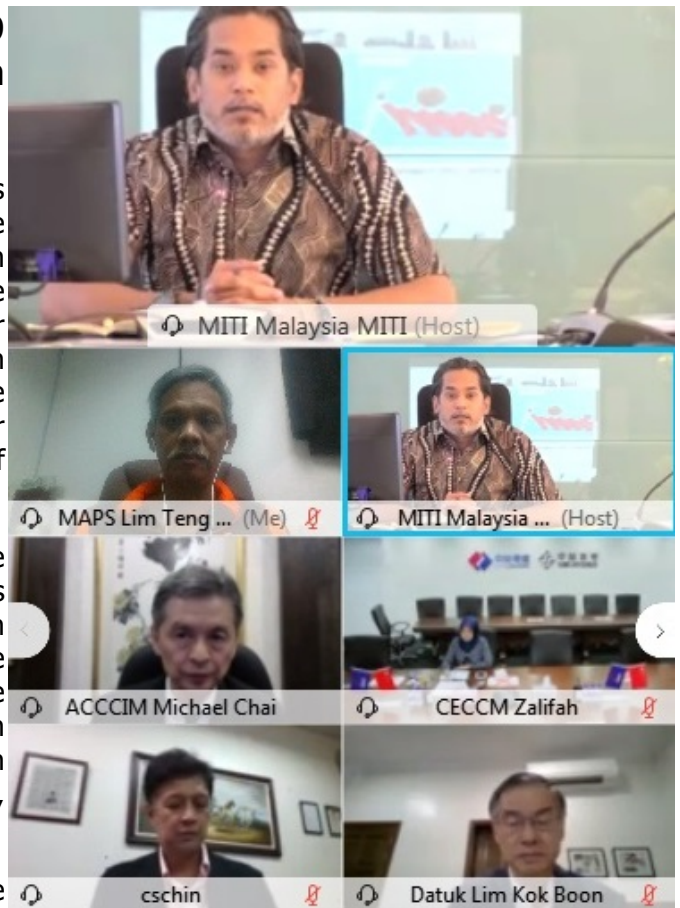


## Briefing On The National Covid-19 Immunisation Programme - 4 March 2021

With the arrival of the Covid-19 vaccine, the nation's largest vaccination programme has been rolled out since late February, and registration for the vaccination program was opened via various channels including the Mysejahtera app. This briefing was given by the Minister of Science, Technology and Innovation himself, YB Tuan Khairy Jamaluddin to industry leaders. At the time of the briefing, the number vaccinated has reached over 80,000 individuals, and registration has reached 7% of the population.

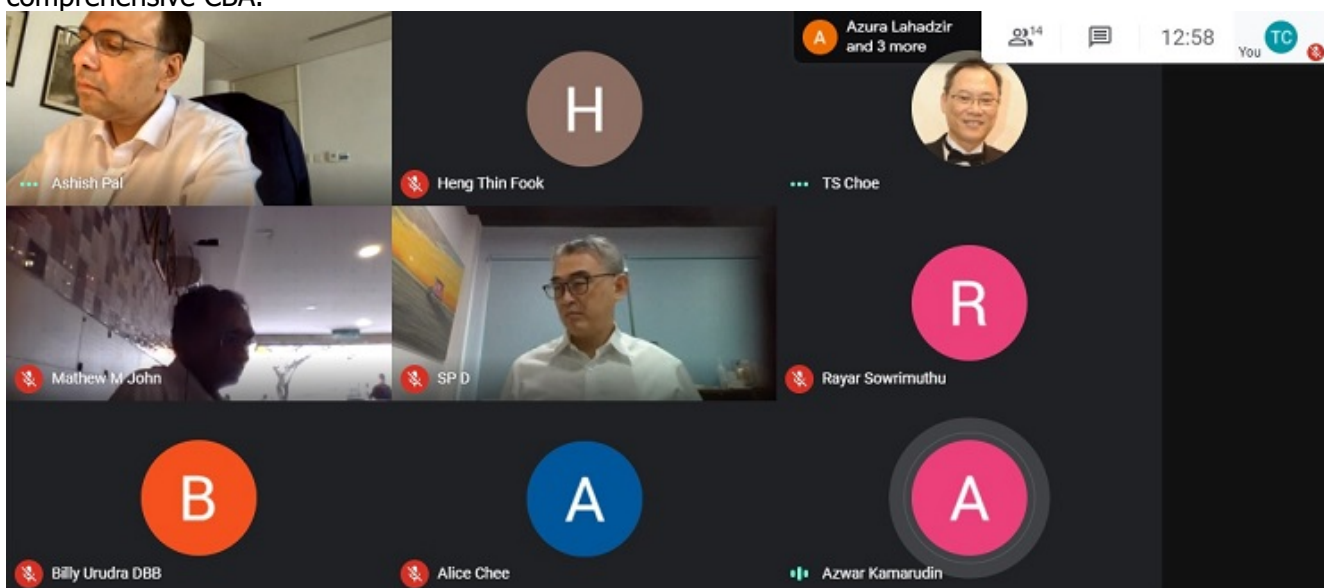
The program will be conducted at 4 stages, firstly the frontliners comprising the healthcare practitioners followed by the support frontliners such as those in security. The second stage will be rolled out to those who are at high risk of morbidity and mortality from the infection. Next comes the general eligible population (including foreign workers). Finally the vaccination program will be deployed in managing high risk areas, eg in areas of severe outbreaks

The vaccination program is targeted at 70 - 80% of the population in order to achieve herd immunity. This is projected to be achieved within 1 year of the vaccination program, subject to vaccine supply being consistent.



## Meeting with Malaysian Productivity Corporation on the CBA 16 Feb 2021

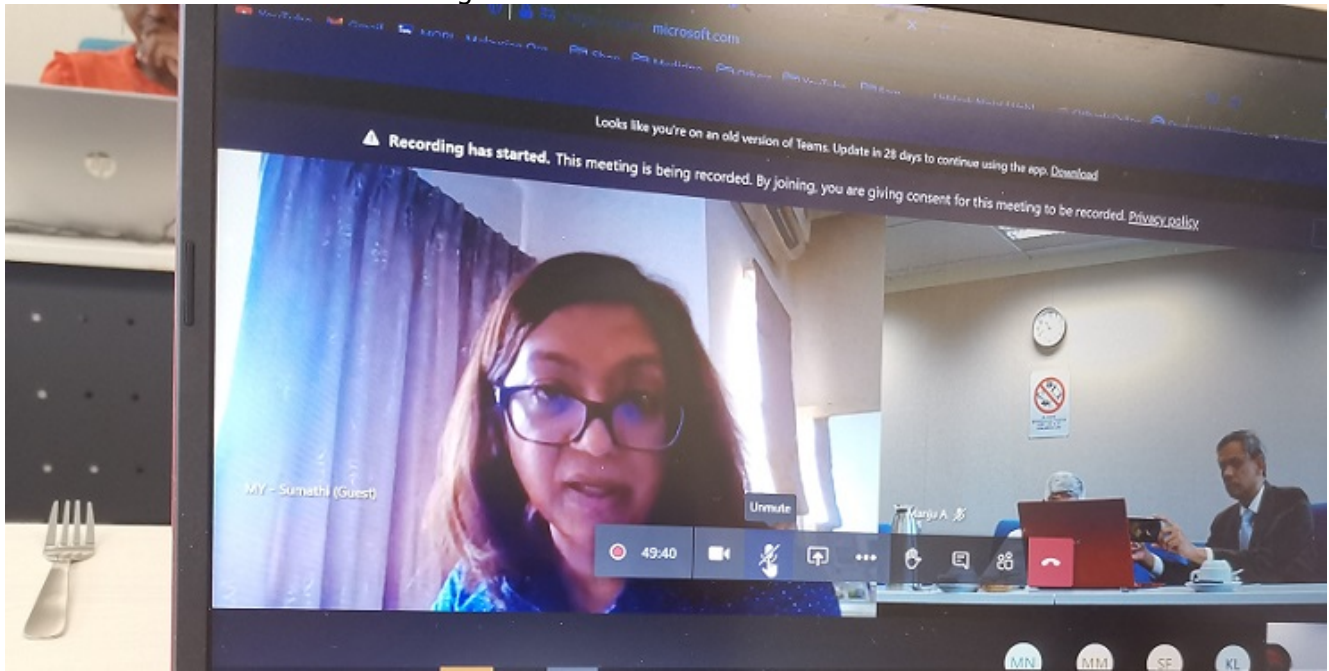
Following a series of joint industry meetings, it was agreed that the joint industry comprising MAPS, MOPI and PhAMA would meet with the MPC to discuss the way forward following the Cost Benefit Analysis (CBA) for the medicine price control proposal. We are pleased to note that the MPC is agreeable to conducting a more comprehensive CBA.



## Meeting with MITI on waiver Proposal by India & South Africa - 11 Jan 2021

The Ministry of International Trade and Industry (MITI) reached out to MAPS, MOPI and MMDA on a proposal by India & South Africa's proposal paper on "Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19". MAPS was represented by the President and Vice

President at this closed door meeting.



## Engagement session on Medicine Price Control and Cost Benefit Analysis - 5 Jan 2021

The pharmaceutical industry was invited by the Pharmacy Practice and Development department of the Pharmacy Services Program to an engagement session on Medicine Price Control. The Malaysian Productivity Corporation also did a presentation on the Cost Benefit Analysis that they performed at the engagement session. Following the session a few weeks was given for feedback on the matter via the government's United Public Consultation website. MAPS thanks all members who gave feedback.



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