



KEMENTERIAN KESIHATAN MALAYSIA

2024

**LAPORAN TAHUNAN
ANNUAL REPORT**

**BAHAGIAN REGULATORI FARMASI NEGARA
NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)**

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Misi

Mission

Menjamin kesihatan rakyat melalui kawalan regulatori ubat-ubatan dan kosmetik berlandaskan kecemerlangan saintifik

To safeguard the nation's health through scientific excellence in the regulatory control of medicinal products and cosmetics

Visi

Vision

Menjadi badan regulatori bagi ubat-ubatan dan kosmetik yang disegani dunia

To be an internationally renowned regulatory authority for medicinal products and cosmetics

Objektif

Objective

Memastikan bahawa bahan-bahan terapeutik yang dibenarkan di pasaran tempatan adalah selamat, berkesan dan bermutu, serta kosmetik yang telah dinotifikasi adalah selamat dan berkualiti

To ensure that therapeutic substances approved for the local market are safe, effective and of quality and also to ensure that natural products and cosmetics approved are safe and of quality

Visi, Misi, Objektif
Vision, Mission, Objective

PERUTUSAN PENGARAH

DIRECTOR'S FOREWORD



Hampir dua tahun dunia dibelenggu dengan situasi pandemik COVID-19 yang tercetus sejak Februari 2020. Justeru tahun 2021 merupakan permulaan baru untuk meningkatkan usaha mengekang penularan virus tersebut.

Program Imunisasi COVID-19 Kebangsaan (PICK) merupakan strategi utama negara dalam melindungi rakyat dari ancaman COVID-19 disamping menggiatkan pemulihan keadaan sosio-ekonomi. Antara usaha utama NPRA adalah dengan menyegerakan proses pendaftaran vaksin COVID-19 tanpa berkompromi dengan aspek kualiti, keselamatan, dan keberkesanan serta patuh kepada semua keperluan yang diperuntukkan dalam Peraturan-peraturan Kawalan Dadah dan Kosmetik (PKDK) 1984.

Sepanjang tahun 2021, sebanyak 13 vaksin COVID-19 telah didaftarkan secara bersyarat dan sebahagiannya telah digunakan dalam PICK. Syabas diucapkan kepada semua anggota NPRA atas usaha tidak berbelah bahagi dalam memastikan rakyat Malaysia mendapat akses segera kepada vaksin tersebut. Situasi pandemik ini seterusnya memberikan peluang kepada industri farmaseutikal di Malaysia untuk berkembang dengan dristik melalui kewujudan fasiliti pengilangan vaksin secara *fill and finish* yang pertama di Malaysia. Seperti yang dirancang dalam Pelan Pembangunan Vaksin

It has been almost two years the world was held back by the COVID-19 pandemic since the virus first appeared in February 2020. The year 2021 was meant to be a new beginning to step up efforts towards ending the pandemic.

The National COVID-19 Immunisation Programme (PICK) was the nation's main strategy to protect communities from the threat of the virus while also aiming to revive the socio-economic state of the nation. Efforts made by NPRA include expediting the registration process of COVID-19 vaccines without compromising its quality, safety and efficacy, while also ensuring the processes adhere to the requirements outlined in the Control of Drugs and Cosmetics Regulations (CDCR) 1984.

Throughout 2021, there were 13 COVID-19 vaccines granted conditional registration by the Drug Control Authority (DCA) and several of these are used in PICK. I would like to congratulate all NPRA staff for their endless contributions in ensuring Malaysians are able to gain immediate access to COVID-19 vaccines. The pandemic situation was also an opportune time for the local pharmaceutical industry to expand significantly with the establishment of the first vaccine manufacturing facility performing the fill and finish process in Malaysia. As strategized in the National Vaccine Development Roadmap (NVDR), it is

Negara (PPVN), Malaysia dijangka akan mempunyai lebih banyak fasiliti pengilangan vaksin di mana NPRA dijangka akan terus terlibat secara aktif bagi menyokong pelan negara ini.

Di kesempatan ini juga saya bagi pihak pengurusan tertinggi NPRA ingin merakamkan ucapan terima kasih kepada semua anggota yang terus memberikan perkhidmatan yang cemerlang sepanjang tempoh Perintah Kawalan Pergerakan (PKP). Ternyata arahan Bekerja Dari Rumah yang telah dikeluarkan melalui pekeliling Perkhidmatan Awam tidak menjelaskan produktiviti NPRA sebaliknya setiap anggota telah menunjukkan kemampuan masing-masing dalam mengimbangkan komitmen antara kerja dengan keluarga dengan baik sekali.

Walau bagaimanapun, haruslah diingatkan bahawa perjalanan kita belum berakhir di sini. Ini kerana pelbagai inisiatif perlu diusahakan untuk menyokong Pelan Pemulihan Negara serta persediaan untuk memasuki fasa endemik COVID-19.

Saya berharap kesungguhan yang ditunjukkan oleh NPRA sehingga kini dapat diteruskan dalam usaha mengukuhkan sistem regulatori selaras dengan matlamat NPRA untuk menjadi *World Health Organisation (WHO) Listed Authority*, dan seterusnya meningkatkan lagi kolaborasi dan kerjasama dengan agensi regulatori negara antarabangsa.

anticipated that more vaccine manufacturing facilities will be established in the long term. Therefore, NPRA will be expected to be actively involved to support the national roadmap.

On behalf of NPRA's top management, I would like to take this opportunity to express my heartiest appreciation to each NPRA staff for their excellent service during the Movement Control Order (MCO). It is obvious that the Work from Home directive issued through the Public Service circular has not affected NPRA's productivity. Instead, NPRA staff is able to demonstrate their ability in balancing their commitment towards work and family seamlessly.

Nevertheless, it must be reminded that our journey does not end here. There is still much work need to be done towards supporting the National Recovery Plan and preparation as we move into the COVID-19 endemic phase.

I sincerely hope the resilience shown by NPRA will continue to support efforts in strengthening the regulatory system. This is in line with our aim to become a World Health Organisation (WHO) Listed Authority, therefore allowing opportunities for more collaboration and cooperation with other regulatory authorities on the international level.

Pengurusan Tertinggi | Top Management



YBrs Dr. Roshayati Binti Mohamad Sani

Pengarah, Jusa B
Bahagian Regulatori Farmasi Negara

*Director, Jusa B
National Pharmaceutical Regulatory Agency*



YBrs. Puan Rosilawati Binti Ahmad

Timbalan Pengarah, Jusa C
Pusat Penilaian Produk & Kosmetik

*Deputy Director, Jusa C
Centre of Product & Cosmetic Evaluation*



YBrs. Puan Salwati Binti Abd. Kadir

Timbalan Pengarah, Jusa C
Pusat Koordinasi & Perancangan Strategik
Regulatori

*Deputy Director, Jusa C
Centre of Regulatory Coordination & Strategic
Planning*



YBrs. Dr. Noraida Binti Mohd Zainoor

Timbalan Pengarah, Jusa C
Pusat Komplians & Kawalan Kualiti

*Deputy Director, Jusa C
Centre of Compliance & Quality Control*



Puan Azlin Binti Ahmad

Penolong Pegawai Tadbir (Eksekutif) N36
Ketua Pusat Pentadbiran

*Assistant Administrative Officer
(Executive) N36
Head of Centre of Administration*

Pengenalan | *Introduction*

Bahagian Regulatori Farmasi Negara (NPRA) merupakan sebuah badan regulatori kerajaan di bawah Kementerian Kesihatan Malaysia yang bertanggungjawab dalam memastikan kualiti, keberkesanan dan keselamatan produk farmaseutikal serta kualiti dan keselamatan produk semulajadi dan kosmetik yang dipasarkan di Malaysia.

NPRA yang dahulunya dikenali sebagai Makmal Pengawalan Farmaseutikal Kebangsaan, telah ditubuhkan pada Oktober 1978. Institusi ini telah ditubuhkan untuk melaksanakan kawalan kualiti ke atas produk farmaseutikal. Infrastruktur dan kemudahan institusi ini direkabentuk bagi memenuhi keperluan aktiviti kawalan dan pengujian kualiti yang dijalankan.

Bermula tahun 1985, NPRA bertanggungjawab untuk memastikan kualiti, keberkesanan dan keselamatan produk farmaseutikal melalui penilaian data saintifik dan ujian makmal. Sistem untuk memantau produk-produk di pasaran juga telah ditubuhkan. Sejak itu, NPRA telah memperluaskan kawalan kualiti dan keselamatan ke atas produk-produk generik (racun berjadual dan bukan racun berjadual), semulajadi, kosmetik, veterinar, Bahan Aktif Farmaseutikal (API) dan seterusnya kawalan ke atas produk vaksin dan produk plasma melalui aktiviti *Lot Release*.

National Pharmaceutical Regulatory Agency (NPRA) is a government agency that is responsible in ensuring the quality, safety and efficacy of pharmaceutical products as well as the quality and safety of natural and cosmetic products marketed in the Malaysia.

NPRA, formerly known as the National Pharmaceutical Control Laboratory, was set up in October 1978. This institution was established to implement quality control on pharmaceutical products. The infrastructure and facilities were designed to meet the requirements for testing and quality control activities.

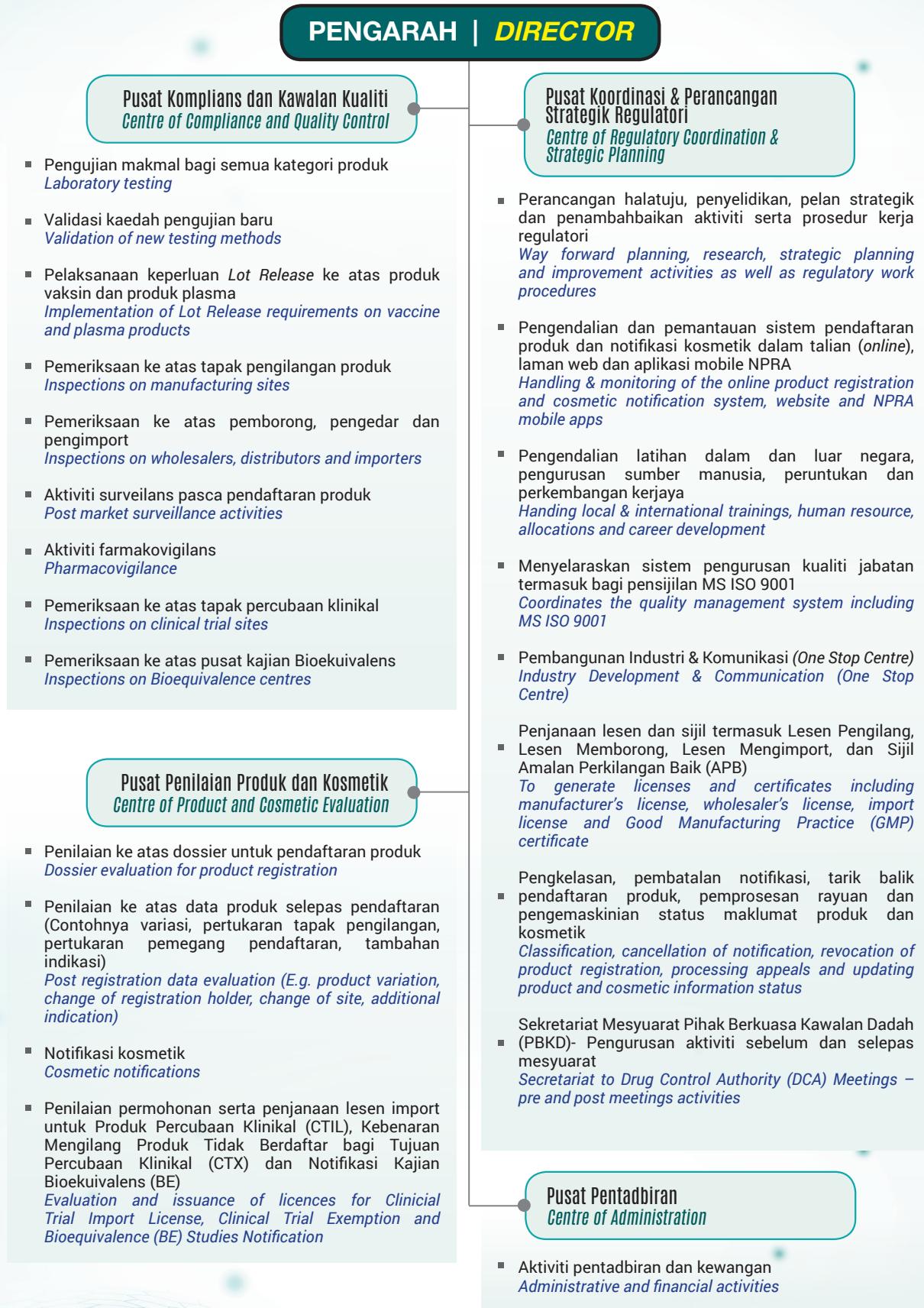
Starting from 1985, NPRA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through evaluation of scientific data and laboratory tests. A system to monitor products in the market was also established. Over the years, NPRA has extended the control of the quality and safety of generics (scheduled poison and non-scheduled posion), natural products, cosmetics, veterinary products, Active Pharmaceutical Ingredients (API) including the quality control of vaccine and plasma products through Lot Release activities.

Sejajar dengan perkembangan serta keperluan semasa, NPRA telah melaksanakan perubahan struktur organisasi melalui proses pengstrukturkan semula yang telah berkuat kuasa mulai 2 Disember 2019. Proses ini melibatkan perubahan utama di mana tujuh (7) pusat dalam NPRA telah disusun semula menjadi empat (4) pusat sahaja bagi menyelaras semua aktiviti utama NPRA berdasarkan fungsi pusat. Dengan pelaksanaan pengstrukturkan semula ini, NPRA dapat menambahbaik kualiti perkhidmatan yang diberikan bagi mencapai misi untuk menjamin kesihatan rakyat melalui kawalan regulatori ubat-ubatan dan kosmetik berlandaskan kecemerlangan saintifik.

In line with current developments, NPRA underwent a major restructuring process which came into effect on 2 December 2019, whereby the previous seven (7) centres have been rearranged to four (4) centres, and the main activities of NPRA have been streamlined according to the each centre's function. Through this restructuring exercise, the NPRA will continuously strive to improve the services provided as we seek to achieve our mission to safeguard the nation's health through scientific excellence in the regulatory control of medicinal products and cosmetics.

Carta Organisasi | Organisational Chart

Berikut merupakan empat (4) pusat di NPRA dengan tugasannya masing-masing:
Below are the four (4) centres in NPRA with respective responsibilities :-



PIAGAM PELANGGAN

PENDAFTARAN PRODUK	MASA
Penilaian Penuh	
<ul style="list-style-type: none"> Menilai permohonan pendaftaran Produk: <ul style="list-style-type: none"> o Ubat Generik Racun Berjadual o Ubat Generik Bukan Racun Berjadual o Ubat Baru dan Produk Biologik 	210 hari bekerja* 210 hari bekerja* 245 hari bekerja*
Penilaian Ringkas	
<ul style="list-style-type: none"> Menilai permohonan pendaftaran Produk Ubat Generik Bukan Racun Berjadual#, Produk Suplemen Kesihatan dan Produk Semulajadi yang mengandungi: <ul style="list-style-type: none"> o Bahan aktif tunggal o Dua (2) atau lebih bahan aktif Pengeluaran notifikasi kosmetik Keputusan permohonan pertukaran Pemegang Pendaftaran Keputusan permohonan pertukaran tapak pengilang 	116 hari bekerja* 136 hari bekerja*
	1 hari bekerja^ 45 hari bekerja*
	60 hari bekerja*
PELESENAN	MASA
<ul style="list-style-type: none"> Kelulusan lesen pengilang, pemborong dan pengimport Penilaian Permohonan Lesen Import untuk Percubaan Klinikal (CTIL) dan Kebenaran Mengilang untuk Percubaan Klinikal (CTX): <ul style="list-style-type: none"> o Bagi produk yang melibatkan Kajian Fasa I, Produk Biologikal, <i>Cell & Gene Therapy Products (CGTPs)</i> dan Produk Herba o Bagi produk-produk selain daripada yang disebutkan di atas 	4 hari bekerja* 45 hari bekerja* 30 hari bekerja*
PENSIJILAN	
<ul style="list-style-type: none"> Pengeluaran Sijil Penjualan Bebas (CFS) bagi: <ul style="list-style-type: none"> o Kosmetik o Produk Veterinar Pengeluaran Sijil Produk Farmaseutikal (CPP) 	15 hari bekerja* 15 hari bekerja* 15 hari bekerja*

* Setelah permohonan lengkap diterima

^ Bagi permohonan yang memenuhi keperluan yang ditetapkan

#Rujuk Drug Registration Guidance Document (DRGD) untuk senarai produk

CLIENT CHARTER

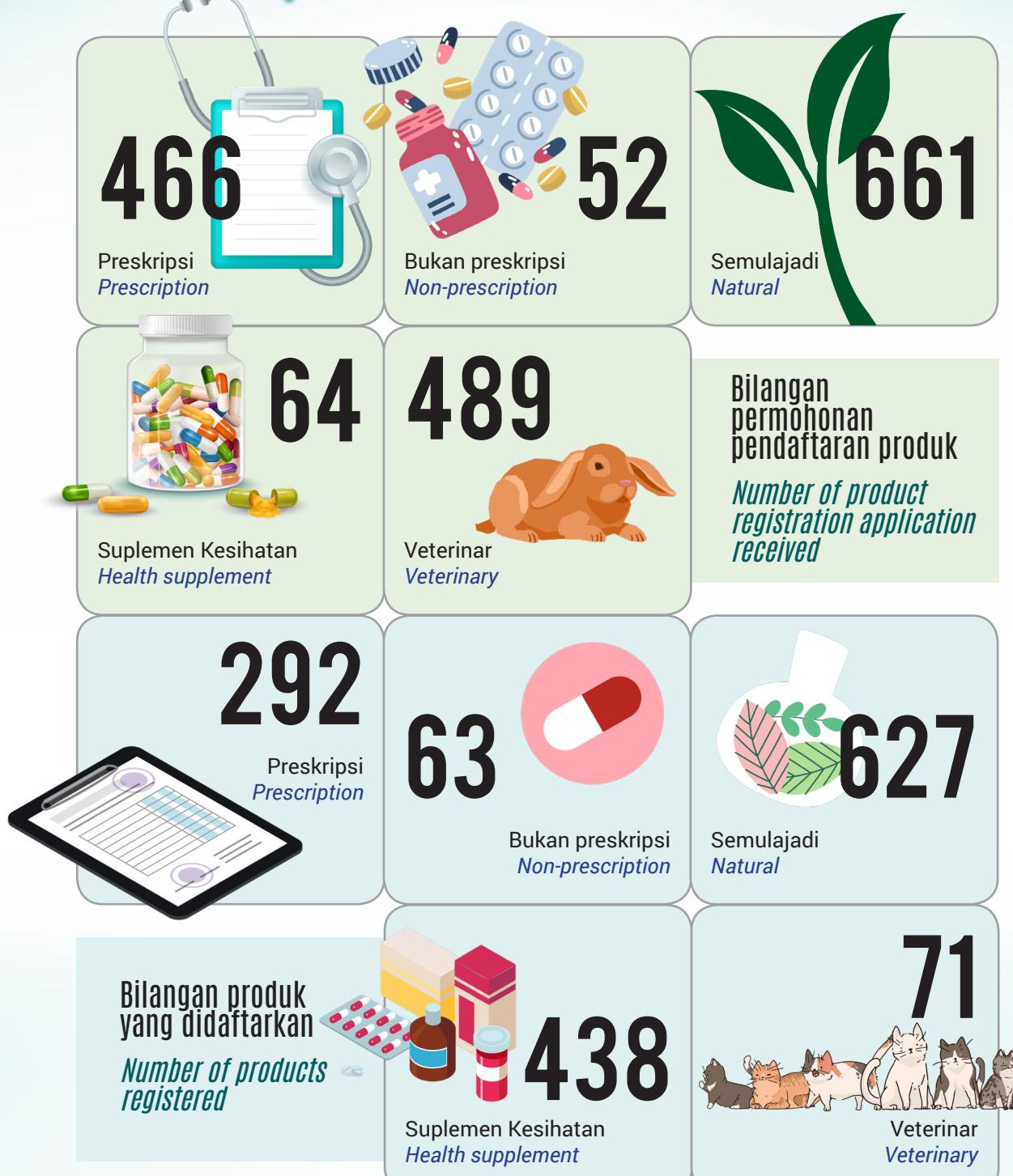
PRODUCT REGISTRATION	DURATION
<i>Full Evaluation</i>	
<ul style="list-style-type: none"> • To evaluate application for registration of: <ul style="list-style-type: none"> o Generic Product (Scheduled Poison) o Generic Product (Non-Scheduled Poison) o New Drug Product and Biologic Product 	<i>210 working days*</i> <i>210 working days*</i> <i>245 working days*</i>
<i>Abridged Evaluation</i>	
<ul style="list-style-type: none"> • To evaluate application for registration of Generic Product (Non-Scheduled Poison) #, Health Supplement and Natural Product containing: <ul style="list-style-type: none"> o Single active ingredient o Two (2) or more active ingredients • Issuance of cosmetic notification • Change of Registration Holder • Change of manufacturing site application 	<i>116 working days*</i> <i>136 working days*</i> <i>1 working day[^]</i> <i>45 working days*</i> <i>60 working days*</i>
LICENSING	DURATION
<ul style="list-style-type: none"> • Issuance of manufacturer's, wholesaler's and importer's license • Evaluation of import license application for Clinical Trial License (CTIL) and Clinical Trial Exemption (CTX): <ul style="list-style-type: none"> o For products involving Phase 1 Trial, Biological Products, Cell & Gene Therapy Products (CGTPs) and Herbal Products o For products other than stated above 	<i>4 working days*</i> <i>45 working days*</i> <i>30 working days*</i>
CERTIFICATION	
<ul style="list-style-type: none"> • Issuance of Certificate of Free Sale (CFS) for: <ul style="list-style-type: none"> o Cosmetic products o Veterinary products • Issuance of Certificate of Pharmaceutical Product 	<i>15 working days*</i> <i>15 working days*</i> <i>15 working days*</i>

*Upon receipt of complete application

[^]For applications fulfilling the stipulated requirements

Refer to Drug Registration Guidance Document (DRGD) for list of products

Statistik Ringkas | *Brief Statistics*



Bilangan lesen / sijil yang dikeluarkan
Number of licenses / certificates issued:

Lesen Pengilang
Manufacturer License

253



477

Lesen Pengimport
Importer License



1,084

Lesen Pemborong
Wholesaler License



2,487

Sijil Produk Farmaseutikal
Certificate of Pharmaceutical Products (CPP)



31

Sijil Penjualan Bebas Produk Veterinar
Certificate of Free Sale (CFS) for Veterinary Products



2,656

Sijil Penjualan Bebas Produk Kosmetik
Certificate of Free Sale (CFS) for Cosmetic Products

2,317

Sijil Lot Release
Vaksin
Vaccine Lot Release Certificate



127

Sijil Lot Release Produk
Plasma
Plasma Product Lot Release Certificate

54,927

Bilangan laporan Adverse Drug Reaction (ADR) yang diterima
Number of Adverse Drug Reaction (ADR) report received

1.1 Sila tandakan simptom yang anda alami.
Please tick the symptom you are experiencing.

Kesakitan di tempat suntikan/injection site pain
Bengkak di tempat suntikan/injection site swell
Kemerahan di tempat suntukan/injection site redness
Berasa lelah/Feeling of tiredness
Sakit kepala/Headaches
Sakit otot/Muscle pain

Report Date:	Ref ID:	Product Name:	Batch No.:
Report Type:	Date Received:	Manufacturing Date:	Expiry Date:
Patient Information:			
Name:	Age:	Gender:	Address:
Phone No.:	Relationship to patient:	Occupation:	Medical Condition:
Symptom Description:			
Other Information:			
Signature:			

4,135



Bilangan sampel yang diambil dalam PMS
(Program Pengawasan Pasca Pendaftaran)
Number of samples taken in PMS (Post Market Surveillance Programme)

42,302

Jumlah ujian yang
djalankan
Number of tests
performed



Bilangan Pemeriksaan Amalan
Perkilangan Baik (APB)
Number of Good Manufacturing Practice
(GMP) Inspections

369

4

Bilangan Pemeriksaan Amalan Klinikal Baik
Number of Good Clinical Practice (GCP)
Inspections



Bilangan Pemeriksaan Pusat Kajian
Bioekuivalens (BE)
Number of Bioequivalence (BE) Centres
inspections

1



Kesiapsiagaan dan Respon Bahagian Regulatori Farmasi Negara (NPRA) Semasa Pandemik COVID-19

*NPRA's Preparedness and Timely Response
to the COVID-19 Pandemic*

Susulan situasi COVID-19 pada tahun 2021 yang saban hari semakin membimbangkan, terdapat keperluan mendesak untuk mempercepatkan akses kepada vaksin COVID-19. Dengan itu NPRA telah menggiatkan usaha pendaftaran produk vaksin bagi menjayakan Program Imunisasi COVID-19 Kebangsaan (PICK).

Jawatankuasa Jaminan Akses Vaksin (JKJAV) yang dipengerusikan bersama oleh Yang Berhormat Menteri Kesihatan dan Yang Berhormat Menteri Sains, Teknologi dan Inovasi ditubuhkan pada 14 Oktober 2020 bagi menerajui usaha mempertingkatkan akses vaksin kepada rakyat dengan cepat tanpa mengabaikan aspek keselamatan, kualiti dan keberkesanan. Susulan itu beberapa jawatankuasa teknikal ditubuhkan. Task Force Pendaftaran Vaksin yang dipengerusikan Pengarah NPRA dipertanggungjawabkan untuk mengenalpasti mekanisme bagi menyegerakan akses kepada vaksin COVID-19.

Berikut adalah perkara-perkara yang dilaksanakan oleh NPRA:

a. Laluan Pendaftaran Bersyarat Vaksin COVID-19 oleh NPRA untuk pendaftaran vaksin COVID-19

i. Pendaftaran Fast Track Bersyarat untuk Produk Farmaseutikal semasa bencana

Pada akhir 2020, NPRA telah mengeluarkan Direktif mengenai Garis Panduan Pendaftaran Bersyarat Produk Farmaseutikal Semasa Bencana. Pelaksanaan ini adalah untuk menyegerakan penilaian vaksin COVID-19.

With the worsening of the COVID-19 situation, there was an urgent need for immediate access to COVID-19 vaccines. Measures were taken by NPRA to expedite the registration process in support of the National COVID-19 Immunisation Programme (PICK).

The COVID-19 Vaccine Supply Assurance Special Committee (JKJAV) co-chaired by the Minister of Health and the Minister of Science, Technology and Innovation was established on 14 October 2020 to ensure timely access to COVID-19 vaccines for the country without compromising its safety, quality and efficacy. Following this, several technical committees were established. The COVID-19 Vaccine Registration Task Force headed by the Director of NPRA was tasked to identify mechanisms to expedite access to COVID-19 vaccines.

The following are the measures taken by NPRA:

a. Conditional Registration Pathways by NPRA to expedite access to COVID-19 Vaccines

i. Conditional Fast Track Registration Pathway for Pharmaceuticals during disaster

At the end of 2020, NPRA issued a directive on the conditional fast-track registration for pharmaceutical products during disaster. This was to expedite the evaluation of COVID-19 vaccines.

ii. Pendaftaran Bersyarat secara *Recognition* berdasarkan WHO *Emergency Use Listing* bagi vaksin COVID-19 di bawah COVAX Facility

Dilaksanakan ke atas vaksin COVID-19 yang telah diberi kelulusan *World Health Organisation (WHO) Emergency Use Listing (EUL)* berdasarkan kriteria-kriteria yang ditetapkan. Mekanisme *recognition* ini dicadangkan bagi memudahkan cara pendaftaran vaksin yang tidak dikendalikan oleh sebarang Pemegang Pendaftaran Produk (PRH), berdasarkan situasi semasa tanpa mengabaikan aspek kualiti, keselamatan dan keberkesanannya.

iii. Pendaftaran Bersyarat Produk Farmaseutikal Semasa Bencana Secara *Recognition*

Mengambil kira bilangan vaksin COVID-19 yang mendapat kebenaran penggunaan kecemasan dan pendaftaran bersyarat oleh WHO dan Pihak Berkuasa negara rujukan yang semakin bertambah, prosedur *recognition* akan mempercepatkan proses pendaftaran produk dengan menggunakan *risk-based approach* tanpa mengabaikan kualiti, keselamatan dan keberkesanannya produk dengan memanfaatkan penilaian yang telah dilakukan oleh WHO atau pihak berkuasa *stringent*.

ii. Conditional Registration through Recognition based on WHO Emergency Use Listing for COVID-19 Vaccines under COVAX Facility

Implemented on all COVID-19 vaccines already granted World Health Organization (WHO) Emergency Use Listing (EUL) based on specified criteria. Recognition procedure is recommended to facilitate application for registration which is not submitted through a Product Registration Holder (PRH), without compromising the quality, safety and efficacy of the vaccines.

iii. Conditional Registration for Pharmaceutical Products During Disaster through Recognition

Taking into account the increasing number of COVID-19 vaccines granted Emergency Use Authorization (EUA) and conditional approval by WHO and Drug Control Authority's (DCA) reference countries, the recognition procedure will expedite the registration process by using a risk based approach without compromising the quality, safety and efficacy of vaccines by benefiting from the evaluation already performed by WHO or Stringent Regulatory Authorities (SRAs).

Rajah 1: Laluan Pendaftaran Vaksin COVID-19 Semasa Pandemik
Figure 1: COVID-19 Vaccine Registration Pathway During the Pandemic

1

Direktif No. 18/2020 (14 Disember 2020)

Pendaftaran *Fast Track* Bersyarat Produk Farmaseutikal Semasa Bencana:
Conditional Fast-Track Registration for Pharmaceutical Products During Disaster:

- Penilaian diberi keutamaan, *rolling submission*
Priority Review, rolling submission
- Tempoh Penilaian dikurangkan: 120 hari bekerja
Evaluation timeline reduced: 120 working days

2

Direktif No. 9/2021 (12 April 2021)

Pendaftaran Bersyarat secara *Recognition* berdasarkan WHO EUL bagi Vaksin COVID-19 di bawah Fasiliti COVAX
Conditional Registration through Recognition based on WHO EUL for COVID-19 Vaccines under COVAX Facility:

- Berdasarkan *recognition* WHO Emergency Use Listing (EUL)
This is based on recognition via WHO Emergency Use Listing (EUL)
- Tempoh penilaian: 20 hari bekerja
Evaluation timeline: 20 working days

3

Direktif No 15/2021 (12 Julai 2021)

Pendaftaran *Fast Track* Bersyarat Produk Farmaseutikal Semasa Bencana secara *Recognition*:

Conditional Registration for Pharmaceutical Products during Disaster through Recognition:

- *Recognition* berdasarkan kelulusan Emergency Use Authorization atau pendaftaran bersyarat oleh WHO atau negara rujukan PBKD
Recognition based on Emergency Use Authorization approval or conditional registration by WHO or DCA reference countries
- Tempoh Penilaian: 20 hari bekerja
Evaluation timeline: 20 working days

NPRA turut memudahcara pengimportan beberapa sumber vaksin COVID-19 yang berdaftar ke Malaysia berdasarkan undang-undang dan peraturan-peraturan sedia ada seperti berikut:

- Sumbangan vaksin dari kerajaan Amerika Syarikat, Jepun, China, United Kingdom, Singapura dan Kerajaan Emiriah Arab Bersatu (UAE)
- Penerimaan vaksin COVID-19 menggunakan saluran diplomatik untuk kegunaan kakitangan kedutaan negara asing di Malaysia

Additionally, NPRA also facilitated the importation of several registered COVID-19 vaccine sources into Malaysia, based on current laws and regulations as follows:

- Vaccine donations from the governments of United States of America, Japan, China, United Kingdom, Singapore and United Arab Emirates (UAE)
- Acceptance of COVID-19 vaccines via diplomatic channels for employees of foreign embassies in Malaysia

Imej 1: Malaysia menerima sumbangan vaksin dari Kerajaan United Kingdom
Image 1: Malaysia receives vaccine donation from the Government of United Kingdom



Sumber: BERNAMA
Source: BERNAMA

b.Penyelidikan Klinikal COVID-19

Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat kali ke-367 pada 13 Disember 2021 telah membuat keputusan untuk menerima permohonan Kebenaran Mengilang Produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal (CTX) bagi produk vaksin COVID-19 keluaran pengilang tempatan yang menjalankan penyelidikan dan

b.COVID-19 Clinical Trials

The Drug Control Authority (DCA) at its 367th meeting on 13 December 2021 has agreed to accept Clinical Trial Exemption (CTX) applications for COVID-19 vaccine product manufactured by local manufacturer that conducts research and development (R&D) in Malaysia involving First-in-Human (FIH) trials. CTX applications for this

pembangunan (R&D) di Malaysia yang melibatkan kajian *First-in-Human* (FIH). Permohonan CTX bagi kategori produk kajian tersebut akan diterima oleh NPRA berdasarkan prosedur sedia ada mulai 1 Januari 2022.

c. Aktiviti Lot Release

PBKD dalam mesyuaratnya kali ke-353 pada 5 Februari 2021 telah bersetuju untuk mengecualikan keperluan menjalankan ujian fizikal untuk aktiviti *Lot Release* bagi semua produk vaksin COVID-19 berdaftar yang diimport dan digunakan semasa situasi pandemik. Merujuk kepada vaksin COVID-19 yang diimport, keperluan aktiviti *Lot Release* adalah seperti berikut:

- Penilaian *Lot Summary Protocol*; dan
- Pemeriksaan rangkaian sejuk di gudang produk atau fasiliti kesihatan yang menerima vaksin terus dari pengilang

category of investigational product will be accepted by NPRA from 1 January 2022 based on existing procedures.

c. Lot Release Activity

The DCA at its 353rd meeting on 5 February 2021 agreed to exempt the requirement to conduct physical testing for Lot Release activity on all registered COVID-19 vaccines which are imported and are being used during the pandemic. In reference to imported COVID-19 vaccines, the requirements for Lot Release activity will include the following:

- *Lot summary protocol evaluation; and*
- *Cold chain inspection at warehouse or health facility which received the vaccines directly from manufacturer*

Imej 2: Pemeriksaan rangkaian sejuk *Lot Release* vaksin oleh Pegawai NPRA di klinik kesihatan

Image 2: Lot Release cold chain inspection by NPRA officers at a health facility



d.Rangkaian bekalan dan logistik Vaksin pengurusan COVID-19

Vaksin yang dikategorikan sebagai *Time and Temperature Sensitive Products* atau TTSP mempunyai keperluan penyimpanan yang berbeza. Tambahan dengan penggunaan sistem penyimpanan dan pengedaran bagi produk vaksin yang memerlukan suhu *ultra-low* serendah (-70 darjah celcius,) cabaran untuk mengelakkan penyimpangan suhu semasa transit adalah amat besar.

Untuk memudahkan cara proses pengedaran vaksin, model pengedaran vaksin telah dibangunkan berdasarkan persetujuan dengan pihak syarikat farmaseutikal/pengimport pembekal seperti berikut:

- Penghantaran terus ke fasiliti kesihatan oleh pengilang melalui syarikat penghantaran yang dilantik Pemegang Pendaftaran Produk (PRH); atau
- Penghantaran melalui pengedar tempatan yang dilantik oleh syarikat farmaseutikal atau Kerajaan Malaysia

Peranan NPRA adalah untuk memastikan aktiviti pengimportan dan pengedaran dilaksanakan oleh pihak yang dilesenkan di bawah Peraturan-peraturan Kawalan Dadah dan Kosmetik (PKDK) 1984.

d.Supply chain and logistical management of COVID-19 vaccines

Certain vaccines categorized as Time and Temperature Sensitive Product (TTSP) requires different storage and handling conditions, which requires an ultra-low temperature storage and distribution system (-70 degrees celcius). Temperature deviation was a great challenge at each point of supply.

To ease the distribution process, COVID-19 vaccine distribution model was developed in accordance with the mutual agreement of the pharmaceutical company/ importer/ supplier. There are 2 types of vaccine distribution models:

- *Direct delivery to health facilities from manufacturers through shipping companies appointed by the Product Registration Holder (PRH)*
- *Delivery through a local distributor warehouse appointed by the pharmaceutical company or the Government of Malaysia*

NPRA's role is to ensure the importation and distribution activities is conducted by licensed parties under the Control of Drugs and Cosmetics Regulations (CDCR) 1984.

Imej 3: Pengurusan logistik dan pengedaran vaksin
Image 3: Vaccine logistics and distribution



Sumber: BERNAMA
Source: BERNAMA

e. Pemantauan Vaksin

Strategi Farmakovigilans Kebangsaan untuk vaksin COVID-19 adalah seperti berikut:

- **Pra-pendaftaran:**
Keperluan untuk Pemegang Pendaftaran Produk (PRH) mengemukakan dokumen keselamatan termasuk *Pharmacovigilance System Summary (PVSS)* dan *Risk Management Plan (RMP)* dengan *Malaysian Specific Annex (MSA)* bagi tujuan mitigasi sebarang risiko vaksin yang dikenalpasti.
- **Pasca-pendaftaran:**
Pemantauan keselamatan dan pengurusan kesan advers susulan imunisasi (AEFI) bagi vaksin COVID-19 dilaksanakan melalui sistem sedia ada. Namun begitu penerima vaksin boleh melaporkan kesan sampingan melalui aplikasi MySejahtera yang membolehkan NPRA untuk memantau tren dan insiden kesan advers di kalangan penerima vaksin.

Keselamatan

e. Vaccine Safety Monitoring

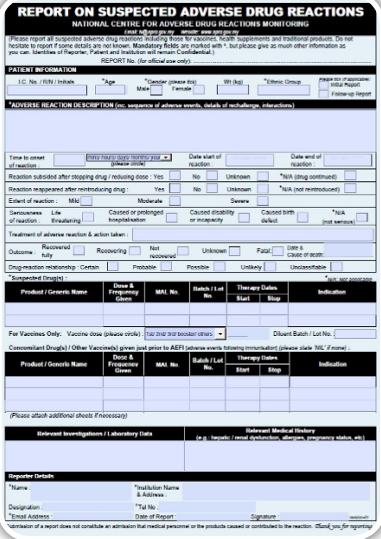
The national pharmacovigilance strategies for the COVID-19 vaccine are as follows:

- **Pre-registration:**
The Product Registration Holders (PRH) are required to provide safety-related documents including the company's Pharmacovigilance System Summary (PVSS) and the Risk Management Plan (RMP) with a Malaysian Specific Annex (MSA) to mitigate any identified and potential risks of the vaccines.
- **Post-registration:**
Safety monitoring and the management of adverse events following immunisation(AEFI) for COVID-19 vaccines are mainly anchored on the existing monitoring system. Vaccine recipients may also self-report mild to moderate adverse event in their MySejahtera Application which enables NPRA to monitor the incidence and trends of documented adverse events among vaccine recipients.

- Selain dari pengawasan pasif, surveilans aktif untuk events of special interest (AESI) turut dipantau sebagai projek kajian oleh Institut Penyelidikan Klinikal (*Institute of Clinical Research*).
- Apart from passive surveillance by NPRA, the Institute of Clinical Research (ICR), MOH also conducts active surveillance of selected events of special interest (AESI) as a research project.

Rajah 2: Kaedah pelaporan Kesan Advers Ubat (ADR)/ Kesan Advers Susulan Imunisasi (AEFI)
Figure 2: Adverse Drug Reaction (ADR)/ Adverse Events Following Immunisation (AEFI) reporting tools

1. NPRA website: npra.gov.my
mycovid.aefi@npra.gov.my



2. MySejahtera



1.1 Sila tandakan simptom yang anda alami.
*Please tick the symptoms you are experiencing. **

Kesakitan di tempat suntikan/Injection site pain	<input type="checkbox"/>
Bengkak di tempat suntikan/Injection site swelling	<input type="checkbox"/>
Kemerahan di tempat suntikan/Injection site redness	<input type="checkbox"/>
Berasa keletihan/Feeling of tiredness	<input type="checkbox"/>
Sakit kepala/Headaches	<input type="checkbox"/>
Sakit otot/Muscle pain	<input type="checkbox"/>

f. Mobilisasi anggota ke fasiliti COVID-19

Kemunculan gelombang COVID-19 ketiga pada tahun ini telah meningkatkan keperluan sumber manusia di pelbagai peringkat di Kementerian Kesihatan Malaysia. Dengan itu, anggota NPRA telah dimobilisasikan kepada beberapa fasiliti yang diwujudkan khas bagi mengatasi penularan COVID-19 seperti berikut:

- Pusat Pemberian Vaksin (PPV)
- Crisis and Preparedness Response Centre (CPRC)
- Bilik Gerakan COVID-19 Program Perkhidmatan Farmasi
- Hospital Angkatan Tentera Tuanku Mizan

f. Deployment of staff to COVID-19 Facilities

The emergence of the third COVID-19 wave this year has increased the human resource needs at different operational levels of the Ministry of Health. Hence, NPRA staff were deployed to the following facilities to assist in the fight against COVID-19:

- Vaccination Centres (PPV)
- Crisis and Preparedness Response Centre (CPRC)
- Pharmaceutical Services Programme COVID-19 Operational Room ('war room')
- Hospital Angkatan Tentera Tuanku Mizan

Imej 4: Mobilisasi anggota NPRA ke beberapa fasiliti semasa kemuncak COVID-19
Image 4: Deployment of NPRA staff to various facilities during the COVID-19 pandemic



g. Penyebaran maklumat mengenai vaksin COVID-19

Pada ketika penularan COVID-19 membimbangkan orang ramai, NPRA memainkan peranan dalam menyampaikan maklumat sahih mengenai vaksin COVID-19 untuk memberi jaminan kepada orang ramai tentang keselamatan, kualiti dan keberkesanannya. Sebahagian besar pegawai NPRA telah mengambil bahagian dalam penyampaian maklumat melalui media massa untuk menangani infodemik.

g. Dissemination of information on COVID-19 vaccines

In the age of misleading information in digital and physical environments during a disease outbreak, NPRA played a significant role in highlighting the facts on COVID-19 vaccines to provide assurance to the public on its safety, quality and efficacy. Many NPRA officers participated in public engagement with various media outlets to address infodemics.

Imej 5: Penyampaian maklumat mengenai vaksin COVID-19 oleh anggota NPRA melalui media massa untuk menangani infodemik

Image 5: Dissemination of information related to COVID-19 by NPRA officers through various media outlets to address infodemics



Sumber: Pelbagai media
Source: Various media outlets

Disember 2021



Pencapaian Pendaftaran Vaksin COVID-19 oleh NPRA

PBKD	: Pihak Berkuasa Kawalan Dادا
CTIL	: Lesen Import Percubaan Klinikal
APB	: Amalan Perkilangan Baik
PSV	: Pusat Simpanan Vaksin

- Lot Release Vaksin
- Pemantauan farmakovigilans & pemantauan surveillans dan aduan vaksin

Disember 2020

- 14.12.20 Direktif 18/2020 Pendaftaran Fast Track Bersyarat Produk Farmaseutikal Semasa Bencana

Januari

- 7.01.21 CTIL diluluskan untuk vaksin COVID-19 IMBCAMS
- 8.01.21 Kelulusan PBKD pendaftaran bersyarat
 - ◊ Comirnaty (Belgium)
- 29-30.01.21 Aktiviti Dry Run Lot Release: Penghantaran vaksin COVID-19 ke KK Belaga dan Hospital Bintulu

Februari

- 19.02.21 Pengecualian PBKD ke atas keperluan ujian fizikal untuk aktiviti Lot Release bagi vaksin COVID -19
- 21.02.21 Penghantaran pertama Comirnaty ke Malaysia
- 22.02.21 Pemeriksaan rangkaian sejuk ke atas Vaksin Comirnaty di 53 PSV secara serentak
- 24.02.21 Program Imunisasi COVID-19 Kebangsaan (PICK) dilancarkan

Jun

- 4.06.21 Kelulusan PBKD pendaftaran bersyarat
 - ◊ AstraZeneca (Siam BiosciencesCo., Ltd)
- 16.06.21 Kelulusan PBKD tambahan indikasi Comirnaty untuk individu 12-17 tahun
- 16.06.21 Kelulusan PBKD pendaftaran bersyarat
 - ◊ Covidecia (CanSino)
 - ◊ Janssen, dari COVAX Facility (7 tapak pengilang tambahan)

Mac

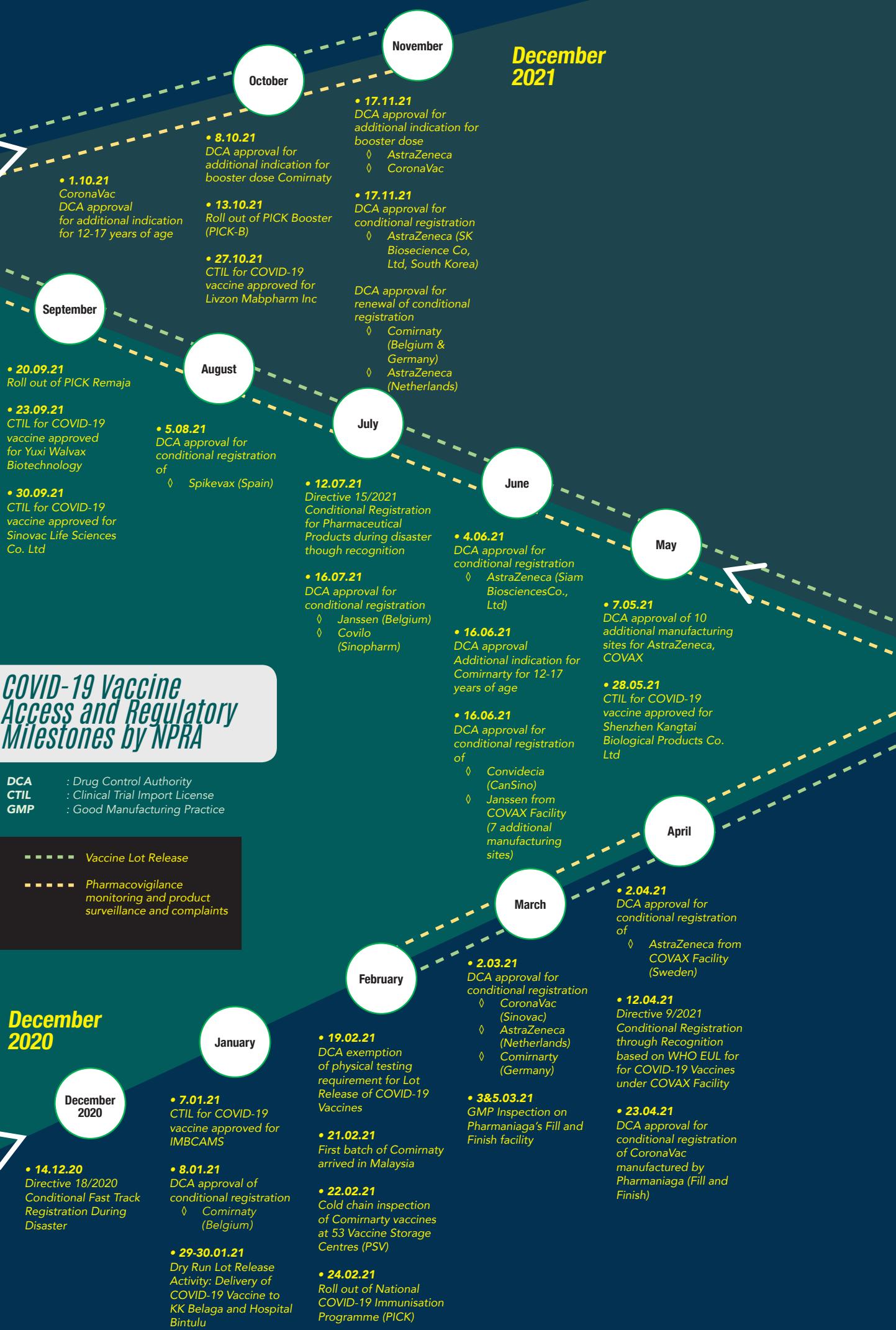
- 2.03.21 Kelulusan PBKD pendaftaran bersyarat
 - ◊ CoronaVac (Sinovac, China)
 - ◊ AstraZeneca (Netherlands)
 - ◊ Comirnaty (Germany)
- 3&5.03.21 Pemeriksaan APB ke atas fasiliti Fill and Finish Pharmaniaga dijalankan

Mei

- 7.05.21 Kelulusan PBKD untuk 10 tapak pengilang tambahan AstraZeneca, COVAX
- 28.05.21 CTIL diluluskan untuk vaksin COVID-19 Shenzhen Kangtai Biological Products Co. Ltd

April

- 2.04.21 Kelulusan PBKD pendaftaran bersyarat
 - ◊ AstraZeneca dari COVAX Facility (Sweden)
- 12.04.21 Direktif 9/2021 Pendaftaran Bersyarat secara Recognition berdasarkan WHO EUL bagi Vaksin COVID-19 yang diperolehi dari COVAX Facility
- 23.04.21 Kelulusan PBKD pendaftaran bersyarat CoronaVac yang dikilangkan Pharmaniaga Malaysia (Fill and Finish)





Maklumat Regulatori Terkini

Regulatory Updates

Pelaksanaan Aktiviti Regulatori Baru Sepanjang Tahun 2021

Bil	Maklumat Regulatori Terkini	Perincian
1.	Pelaksanaan Aktiviti <i>Lot Release</i> ke atas Produk Vaksin dan Produk Plasma yang dikilangkan di Malaysia	<p>Lanjutan dari situasi pandemik dan keperluan akses segera kepada vaksin COVID-19, terdapat insiatif di kalangan pengilang tempatan untuk menghasilkan vaksin COVID-19 di Malaysia secara "Fill and Finish".</p> <p>Bagi memastikan setiap kelompok vaksin yang dihasilkan mematuhi semua proses pengilangan dan spesifikasi produk seperti mana yang ditetapkan semasa proses pendaftaran produk, aktiviti <i>Lot Release</i> dikenakan ke atas setiap kelompok produk vaksin dan produk plasma yang dikilangkan di Malaysia. Aktiviti ini dilaksanakan secara berfasa mengikut prosedur dan keperluan yang telah diperincikan dalam <i>Guidance Document for Lot Release of Biological Products Manufactured in Malaysia</i>. Fasa pelaksanaan ditetapkan berdasarkan ketersediaan fasiliti dan kepakaran makmal NPRA.</p> <p>Tarikh kuatkuasa pelaksanaan aktiviti ini adalah pada 28 April 2021.</p>
2.	Pemeriksaan Amalan Perkilangan Baik (APB) Dalam dan Luar Negara oleh Bahagian Regulatori Farmasi Negara Semasa Pandemik COVID-19	<p>Pemeriksaan Amalan Perkilangan Baik dalam dan luar negara tidak dapat dijalankan sejak awal tahun 2020 disebabkan oleh larangan perjalanan merentas negeri dan sekatan di sempadan pintu masuk negara yang diumumkan oleh pihak Majlis Keselamatan Negara. Sehubungan itu, suatu pelan mitigasi telah dibangunkan dengan mewujudkan mekanisme <i>Good Manufacturing Practice (GMP) Distant Assessment (DiA)</i> bagi memastikan aktiviti pendaftaran produk tidak terjejas semasa situasi pandemik. Pelaksanaan DiA telah dijalankan seperti berikut:</p> <ul style="list-style-type: none">• Fasiliti dalam negara- Pemeriksaan APB dijalankan secara <i>Remote Inspection (RI)</i> atau <i>Hybrid Inspection (HI)</i>• Fasiliti luar negara- Pemeriksaan APB dijalankan secara <i>Remote Inspection</i> <p>Pemeriksaan APB dengan kaedah DiA mula dijalankan pada 1 September 2021.</p>

Bil	Maklumat Regulatori Terkini	Perincian
3.	Pengukuhan Pelaksanaan Kawalan Regulatori ke atas Produk-produk Gas Perubatan	<p>Bagi memastikan semua produk gas perubatan yang digunakan adalah berkualiti, selamat dan berkesan, kawalan regulatori ke atas produk gas perubatan telah diperkuuhkan dengan menjalankan aktiviti seperti berikut:</p> <ul style="list-style-type: none"> • Pemeriksaan APB ke atas fasiliti pengilangan gas perubatan dalam silinder • Pelesenan dan pendaftaran produk <p>Gas perubatan yang dikelaskan sebagai ubat dan dikawal Pihak Berkusa Kawalan Dadah (PBKD) adalah gas atau campuran gas dengan mekanisma tindakan utama berdasarkan kesan farmakologi, immunologi atau metabolismik ke atas badan.</p> <p>Pelaksanaan aktiviti regulatori ke atas produk gas perubatan adalah seperti berikut:</p> <ul style="list-style-type: none"> • Pemeriksaan APB ke atas fasiliti pengilang gas perubatan dalam silinder bermula pada 1 Jun 2021 • Pelesenan dan pendaftaran produk secara sukarela (<i>voluntary</i>) bermula pada 1 Januari 2022 • Pelesenan dan pendaftaran produk secara mandatori (<i>mandatory</i>) akan bermula 1 Januari 2023 <p>Keperluan pendaftaran yang khusus untuk gas perubatan diperincikan dalam <i>Guideline on Registration of Medicinal Gases</i>.</p>
4.	Penerimaan Permohonan Kebenaran Mengilang Produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal (CTX) bagi Produk Vaksin COVID-19 Keluaran Pengilang Tempatan yang Menjalankan Penyelidikan dan Pembangunan R&D di Malaysia yang Melibatkan Kajian First-In-Human (FIH)	<p>Malaysia kini sedang dalam proses membangunkan vaksin COVID-19 melalui kerjasama dengan Institut Kajian Perubatan (IMR) dan Universiti Putra Malaysia (UPM). Bagi tujuan ini, beberapa fasa kajian klinikal perlu dijalankan untuk memastikan keselamatan, keberkesaan dan kualiti produk sebelum produk vaksin tersebut diluluskan oleh PBKD selaras dengan keperluan antarabangsa. Kajian klinikal ini termasuklah kajian <i>First in Human</i> (FIH).</p> <p>Mengikut kerangka regulatori semasa, NPRA menerima permohonan Lesen Import Percubaan Klinikal (CTIL)/ Kebenaran Mengilang Produk Kajian Tidak Berdaftar (CTX) bagi tujuan percubaan klinikal yang melibatkan kajian <i>First-In Human</i> (FIH) mengikut kategori produk secara berperingkat.</p> <p>Fasa pertama hanya melibatkan produk entiti kimia baru dan produk herba dengan tuntutan tinggi sahaja. Produk biologik masih belum diterima pada ketika ini memandangkan sifat molekulnya yang kompleks serta memerlukan pengalaman dan kepakaran yang tinggi untuk dinilai dari segi keselamatannya.</p> <p>Penerimaan kajian FIH bagi produk vaksin COVID-19 keluaran pengilang tempatan yang menjalankan R&D di Malaysia bukan sahaja kritikal untuk pembangunan vaksin buatan Malaysia tetapi dipercayai dapat mendorong program pembangunan vaksin dari fasa I ke fasa III dijalankan di Malaysia.</p> <p>Sehubungan dengan itu, demi kepentingan negara, permohonan CTX melibatkan kajian FIH untuk produk vaksin COVID-19 keluaran pengilang tempatan yang menjalankan R&D di Malaysia akan diterima oleh NPRA berkuatkuasa 1 Januari 2022.</p>

Implementation of New Regulatory Activities Throughout 2021

No	Regulatory Updates	Details
1.	Implementation of Lot Release Activity on Vaccine and Plasma Products Manufactured in Malaysia	<p>Following the pandemic situation and the urgent need for timely access to COVID-19 vaccines, several local manufacturers have begun undertaking the fill and finish process for COVID-19 vaccines.</p> <p>To ensure that each batch of vaccines produced complies with all manufacturing processes and product specifications as specified during the product registration process, Lot Release activities are imposed on each batch of vaccine and plasma products manufactured in Malaysia. This activity is implemented in phases according to the requirements and procedures outlined in the Guidance Document for Lot Release of Biological Products Manufactured in Malaysia. Phases of implementation is determined based on readiness of NPRA's facilities and laboratory expertise.</p> <p>Lot Release activity on vaccine and plasma products manufactured in Malaysia has been implemented starting 28 April 2021.</p>
2.	Good Manufacturing Practice (GMP) Inspection during the COVID-19 Pandemic	<p>Local and foreign Good Manufacturing Practice (GMP) inspections were not conducted since early 2020 due to cross-state travel prohibition and national entry restrictions at the country's borders as announced by the National Security Council. Accordingly, a mitigation plan has been developed by establishing a GMP Distant Assessment (DiA) mechanism to ensure that product registration activities are not affected during pandemic situations. The DiA has been implemented as follows:</p> <ul style="list-style-type: none">• Local manufacturing facility – GMP inspection is conducted via Remote Inspection (RI) or Hybrid Inspection (HI)• Foreign manufacturing facility– GMP inspection is conducted via RI only <p>GMP inspections via DiA has been conducted starting 1 September 2021.</p>

No	Regulatory Updates	Details
3.	Strengthening Regulatory Control of Medicinal Gases	<p>To ensure that all medicinal gas products used are of quality, safe and effective, regulatory control on medicinal gas products has been strengthened through the following activities:</p> <ul style="list-style-type: none"> • GMP inspections on manufacturing facilities of medicinal gas in cylinders • Product licensing and registration <p>Medicinal gases that are classified as drugs and are controlled by the Drug Control Authority (DCA) include any gas or mixture of gases where the main mechanism of action is based on pharmacological, immunological or metabolic effects on the body.</p> <p>The implementation of regulatory activities on medicinal gas products is as follows:</p> <ul style="list-style-type: none"> • GMP inspection on manufacturing facilities of medicinal gases effective from 1 June 2021 • Voluntary licensing and registration effective from 1 January 2022 • Mandatory licensing and registration will be effective from 1 January 2023 <p>The specific requirements for registration are detailed in the Guideline on Registration of Medicinal Gases.</p>
4.	Acceptance of Clinical Trial Exemption (CTX) Applications for COVID-19 Vaccine Products Manufactured by Local Manufacturer that Conducts Research and Development (R&D) in Malaysia involving First in Human (FIH) trials	<p>Malaysia is currently in the process of developing COVID-19 vaccine in collaboration with the Institute of Medical Research (IMR) and Universiti Putra Malaysia (UPM). In line with international requirements, several phases of clinical trials need to be conducted to ensure the safety, efficacy and quality of the vaccine before it is approved by the Drug Control Authority (DCA). These clinical trials include First in Human (FIH) trials.</p> <p>Based on the current regulatory framework, NPRA accepts applications for Clinical Trial Import License (CTIL) / Clinical Trial Exemption (CTX) for clinical trials involving FIH trials, according to product category in stages.</p> <p>In the first phase, only FIH trials involving new chemical entity and herbal products with high claim is accepted. Biological products are still not accepted at this time given their complex molecular nature and require a high level of experience and expertise to evaluate its safety.</p> <p>The acceptance of FIH trials for COVID-19 vaccine products manufactured by local manufacturer that conducts R&D in Malaysia is not only critical for the development of home-grown vaccines but is also anticipated to drive vaccine development programs from Phase I to Phase III in Malaysia.</p> <p>In the interest of the country, CTX applications involving FIH trials for COVID-19 vaccines manufactured by local manufacturer that conducts R&D in Malaysia will be accepted by NPRA effective from 1 January 2022.</p>

Pencapaian

Achievements



NPRA telah mendapat pengiktirafan antarabangsa sebagai WHO *Collaborating Centre for Regulatory Control of Pharmaceuticals* pada tahun 1996. Pengiktirafan ini telah diberi oleh World Health Organization (WHO) atas sumbangan NPRA dalam bidang regulatori farmasi.

NPRA has been given an international recognition as "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals" in the year 1996. This recognition is an acknowledgement from World Health Organization (WHO) for NPRA's contribution in the field of pharmaceutical regulatory affairs.



Malaysia telah menjadi negara anggota *Pharmaceutical Inspection Co-operation Scheme (PIC/S)* melalui NPRA sejak Januari 2002. Sejak daripada itu, NPRA terlibat secara aktif dalam program Amalan Perkilangan Baik (APB) dan *Quality Assurance Programme*. Tujuan PIC/S ini adalah untuk membantu jaringan kerjasama di antara badan regulatori negara-negara anggota di dalam pertukaran maklumat dan pengalaman di dalam bidang APB serta latihan pemeriksa APB.

Malaysia, via NPRA, is also a Member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 1 January 2002. Since then, NPRA has been actively involved in international Good Manufacturing Practice (GMP) and Quality Assurance Programme. The purpose of PIC/S is to facilitate the networking between participating authorities in the exchange of information and experience in the field of GMP and related areas as well as training of GMP inspectors.



Melalui NPRA, Malaysia telah diterima sebagai ahli penuh *Organisation for Economic Cooperation and Development Good Laboratory Practice Mutual Acceptance of Data System (OECD MAD)* sejak 29 Mac 2013. Data dari kajian bukan klinikal yang dijalankan di bawah fasiliti yang tersenarai di bawah Program Pemantauan Komplians GLP NPRA akan diterima untuk penilaian selanjutnya oleh semua negara OECD dan negara bukan OECD yang mematuhi sistem MAD.

Through NPRA, Malaysia has been accepted as a full adherent member to Organisation for Economic Cooperation and Development Good Laboratory Practice Mutual Acceptance of Data System (OECD MAD) for Good Laboratory Practice (GLP) since 29 March 2013. The data from the non-clinical studies conducted by facilities listed under the NPRA Compliance Monitoring Programme shall be accepted for further evaluation by all OECD countries and non-OECD countries that adhere to the MAD System.



Malaysia juga telah diterima sebagai pemerhati kepada *International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)* sejak Jun 2018. ICH merupakan platform bagi pihak regulatori dan industri farmaseutikal untuk membincangkan keperluan pendaftaran ubat-ubatan dari aspek saintifik dan teknikal. Malaysia juga telah diterima sebagai ahli *The International Pharmaceutical Regulator's Programme (IPRP)* pada November 2019.

Malaysia has also been accepted to become an observer to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) since June 2008. ICH brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Malaysia has also been accepted as a member to The International Pharmaceutical Regulator's Programme (IPRP) from November 2019.



Certified to MS ISO 9001:2015
Cert No.: QMS 00894

Bagi memastikan perkhidmatan yang berkesan dan berkualiti, NPRA telah memperolehi pensijilan MS ISO 9001 dari pihak SIRIM QAS Sdn. Bhd. NPRA telah berjaya mengekalkan pensijilan MS ISO selama 19 tahun berturut-turut (2001 - 2019) bermula dari versi MS ISO 9002:1994, diikuti dengan versi MS ISO 9001:2000, MS ISO 9001:2008 dan terkini dengan pensijilan versi MS ISO 9001:2015 pada tahun 2017 dengan nombor sijil terkini adalah QMS 00894 dan sah sehingga 24 Mei 2025.

In order to ensure high quality and efficient service, NPRA has obtained the MS ISO 9001 certification from SIRIM QAS Sdn. Bhd. NPRA has successfully maintained the MS ISO certification for 19 consecutive years (2001 - 2019) starting with version MS ISO 9002: 1994, followed by the MS ISO 9001: 2000, MS ISO 9001: 2008 and most recently with the certification of version MS ISO 9001:2015 in 2017 with current certificate number QMS 00894 which is valid until 24 May 2025.



MS ISO/IEC 17025:2017
Accredited

Selain pensijilan MS ISO 9001, makmal-makmal di NPRA telah memperoleh akreditasi dari Jabatan Standard Malaysia selaras dengan kompetensi untuk beroperasi berdasarkan MS ISO/IEC 17025. NPRA telah berjaya mengekalkan akreditasi MS ISO/IEC 17025:2005 selama 10 tahun berturut-turut (2010 hingga 2019) dan diikuti dengan pensijilan versi terkini MS ISO / IEC 17025: 2017 dalam skop pengujian kimia dan mikrobiologi. Sijil akreditasi dengan No. SAMM 450 adalah sah sehingga 14 Januari 2025.

In addition to the MS ISO 9001 certification, NPRA laboratories are also accredited by the Department of Standards Malaysia for their competence and ability to operate in accordance with MS ISO / IEC 17025. NPRA has successfully maintained MS ISO / IEC 17025: 2005 accreditation for the past 10 years (2010 to 2019) and most recently followed by certification of version MS ISO / IEC 17025: 2017 in the scope of chemical and microbiological testing. This accreditation certificate with No. SAMM 450 is valid until 14 January 2025.



Statistik
Statistics

A) KOORDINASI REGULATORI PRODUK DAN KOSMETIK

NPRA bertanggungjawab untuk memproses permohonan pengkelasaran produk mengikut tempoh masa yang ditetapkan. Walau bagaimanapun, perkhidmatan ini merupakan perkhidmatan secara volontari dan dinilai berdasarkan formulasi bahan aktif dan indikasi produk. Ia merangkumi produk-produk seperti entiti kimia baru / ubat-ubatan baru, biologik, generik (racun berjadual dan bukan racun berjadual), suplemen kesihatan, produk semulajadi, veterinar, makanan, peranti perubatan, racun makhluk perosak dan produk pertanian.

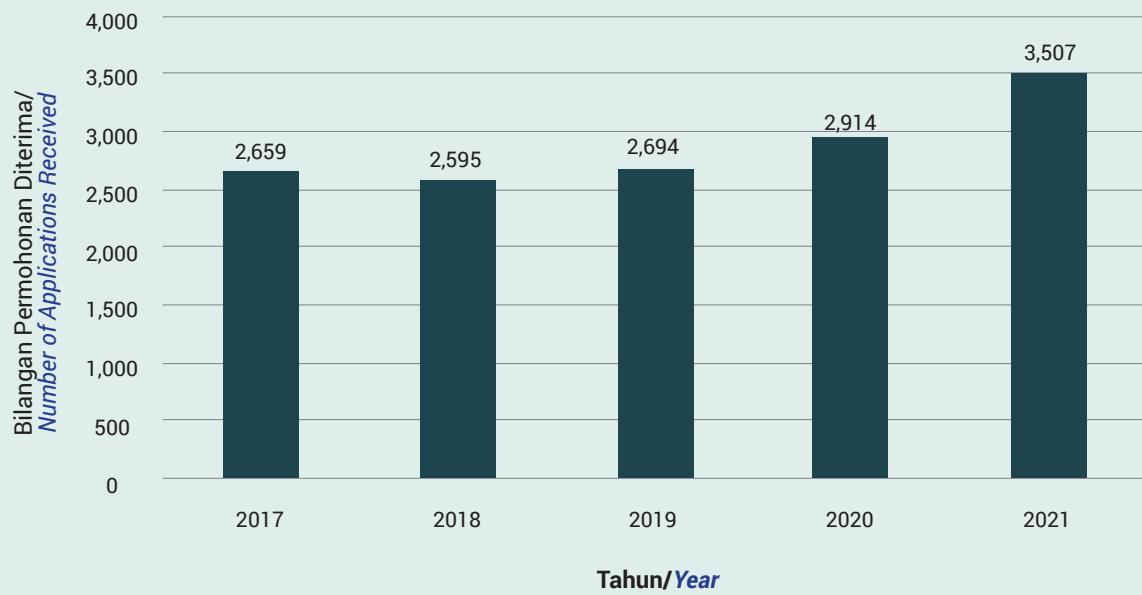
Bagi tahun 2021, sebanyak 3,507 permohonan pengkelasaran produk telah diterima berbanding dengan 2,914 permohonan yang telah diterima pada tahun 2020. Jumlah ini merupakan jumlah bilangan permohonan tertinggi yang tercatat sejak tahun 2017.

A) PRODUCT AND COSMETIC REGULATORY COORDINATION

NPRA is responsible for the processing of product classification applications according to the stipulated timeline. However, this service is voluntary and it is evaluated based on the active ingredient, formulation and product indications. This service includes products such as new chemical entities / new drug product, biologics, generics (scheduled poison and non-scheduled poison), health supplements, natural products, veterinary, food, medical devices, pesticides, and agriculture products.

In year 2021, 3,507 product classification applications were received compared to 2,914 in the previous year. It was also recorded as the highest number of applications for product classification since 2017.

Rajah 3: Bilangan permohonan pengkelasaran produk yang diterima, 2017-2021
Figure 3: Number of product classification applications received, 2017-2021



Aktiviti pemantauan dan rampasan produk-produk tidak berdaftar di pasaran tempatan dijalankan oleh Pegawai Penguatkuasaan Farmasi di seluruh negara. Dengan kerjasama NPRA, status pendaftaran produk farmaseutikal dan status notifikasi kosmetik yang disyaki tidak berdaftar/dinotifikasi di pasaran tempatan akan disemak dan ditentu sahkan. Justeru itu, penjualan produk-produk yang tidak berdaftar dan kosmetik tidak bernotifikasi dapat dibendung dengan adanya tindakan penguatkuasaan farmasi dan aktiviti pendakwaan di Mahkamah. Jumlah bilangan permohonan pengesahan status pendaftaran produk yang diterima untuk semakan adalah sebanyak 10,675 dan status notifikasi yang diterima untuk semakan adalah 3,027.

Pharmacy Enforcement Officers throughout the country will monitor and seize unregistered products sold in the local market and premises. In cooperation with NPRA, the registration/ notification status of pharmaceutical products as well as cosmetics which are suspected to be unregistered /unnotified in the local market can be verified. This in turn will facilitate pharmacy enforcement actions and prosecution in court which can curb the sale of unregistered products and unnotified cosmetics. The total number of product registration status applications received and processed was 10,675 and the cosmetics notification status received and processed was 3,027.

Rajah 4: Bilangan pengesahan status pendaftaran produk dan status notifikasi kosmetik,2017-2021
Figure 4: Number of status verifications for registered products and notified cosmetics,2017-2021



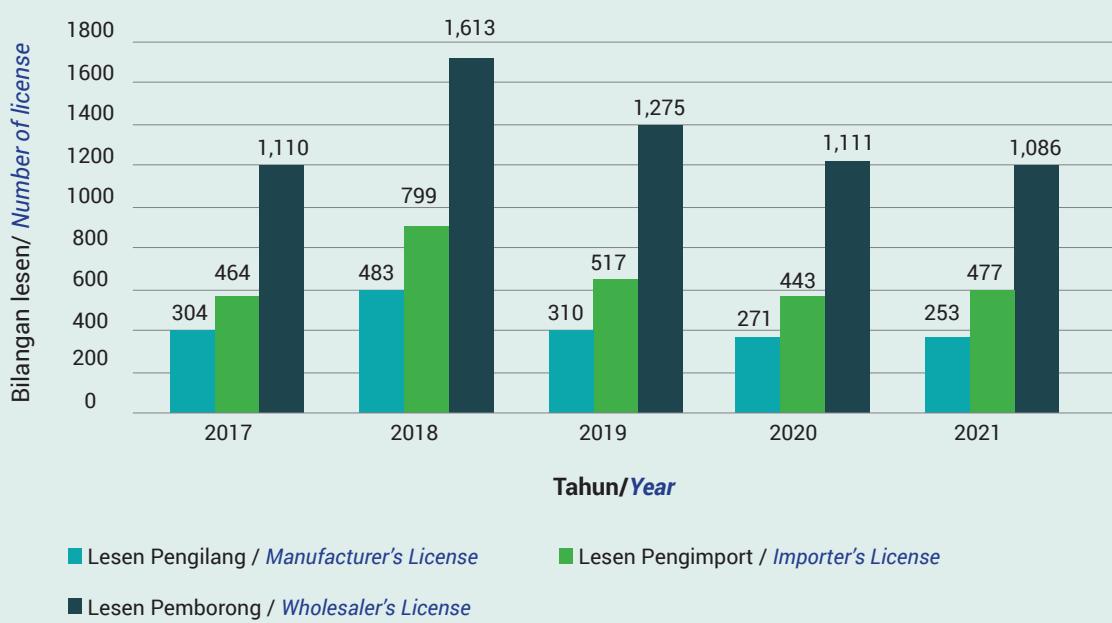
B) PELESENAN

Pada tahun 2021, sebanyak 253 Lesen Pengilang, 477 Lesen Pengimport dan 1,086 Lesen Pemborong telah dikeluarkan.

B) LICENSING

In 2021, 253 Manufacturer Licenses ,477 Importer Licenses and 1,086 Wholesaler Licenses were issued.

Rajah 5: Bilangan lesen yang dikeluarkan, 2017-2021
Figure 5: Number of licenses issued, 2017-2021



C) PENILAIAN DAN PENDAFTARAN PRODUK

NPRA bertanggungjawab untuk memproses permohonan pendaftaran untuk produk ubat baru, produk biologik, produk ubat generik (racun berjadual dan bukan racun berjadual), suplemen kesihatan, produk semulajadi dan juga produk veterinar. Sepanjang tahun 2021, sebanyak 1,732 permohonan pendaftaran produk baru telah diterima dan 1,491 produk telah didaftarkan. Produk-produk ini terdiri daripada 60.33 peratus produk tempatan dan 39.67 peratus produk yang diimport. Kumulatif produk yang berdaftar sehingga Disember 2021 adalah 24,399 produk.

C) PRODUCT EVALUATION AND REGISTRATION

NPRA is responsible for processing registration applications for new drug products, biologic products, generic products (scheduled poison and non-scheduled poison), health supplements, natural products as well as veterinary products. Throughout the year of 2021, a total of 1,732 new product registration applications were received and 1,491 products were registered. These newly registered products comprise of 60.33 percent local products and 39.67 percent imported products. The cumulative number of registered products until December 2021 is 24,399 products.

Jadual 1: Bilangan produk yang didaftarkan, 2017-2021
Table 1: Number of registered products, 2017-2021

Kategori Produk <i>Product Category</i>	2017	2018	2019	2020	2021
Produk Preskripsi <i>Prescription Products</i>	325	354	187	277	292
Produk Bukan Preskripsi <i>Non-Prescription Products</i>	61	79	66	70	63
Produk Semulajadi <i>Natural Products</i>	651	738	679	734	627
Suplemen Kesihatan <i>Health Supplements</i>	242	322	315	424	438
Produk Veterinar <i>Veterinary Products</i>	68	73	77	69	71
Jumlah <i>Total</i>	1,347	1,566	1,324	1,574	1,491

i) Pendaftaran Vaksin COVID-19

Sebagai usaha menyokong aspirasi negara untuk memastikan populasi di Malaysia menerima vaksin secepat mungkin dan selaras dengan pelancaran Program Imunisasi COVID-19 Kebangsaan (PICK), Pihak Berkuasa Kawalan Dadah (PBKD) telah meluluskan pendaftaran bersyarat ke atas 13 produk vaksin COVID-19 berdasarkan penilaian oleh Bahagian Regulatori Farmasi Negara (NPRA) sepanjang tahun 2021.

i) *Registration of COVID-19 Vaccine*

In support of the government's aim to vaccinate as many of Malaysia's population as soon as possible, and in line with the launch of the National COVID-19 Immunisation Programme (PICK), the Drug Control Authority (DCA) has granted approval for conditional registration based on evaluation by National Pharmaceutical Regulatory Agency (NPRA) for 13 COVID-19 vaccines as listed below.

Jadual 2: Senarai Vaksin COVID-19 yang diluluskan PBKD untuk pendaftaran bersyarat pada 2021
Table 2: List of COVID-19 Vaccines approved by DCA for conditional registration in 2021

Bil <i>No</i>	Nama vaksin dan No MAL <i>Name of Vaccine and MAL No.</i>	Pemegang Pendaftaran Produk <i>Product Registration Holder</i>	Pengilang <i>Manufacturer</i>
1.	COMIRNATY Concentrate for Dispersion for Injection (MAL21016022AZ)	Pfizer (Malaysia) Sdn. Bhd.	Pfizer Manufacturing Belgium NV, Belgium
2.	COMIRNATY Concentrate for Dispersion for Injection (MAL21036039ASZ)	Pfizer (Malaysia) Sdn. Bhd.	BioNTech Manufacturing GmbH, Germany

Bil No	Nama vaksin dan No MAL <i>Name of Vaccine and MAL No.</i>	Pemegang Pendaftaran Produk <i>Product Registration Holder</i>	Pengilang Manufacturer <i>Manufacturer</i>
3.	COVID-19 Vaccine AstraZeneca Solution for Injection (MAL21036009ACZ)	AstraZeneca Sdn. Bhd.	Astrazeneca Nijmegen B.V., Netherlands
4.	COVID-19 Vaccine AstraZeneca Solution for Injection (MAL21066001ACSZ)	AstraZeneca Sdn. Bhd.	Siam Bioscience Co., Ltd., Thailand
5.	COVID-19 Vaccine AstraZeneca Solution for Injection (The product approved by EMA is supplied under the commercial name: Vaxzevria) (MAL21046001AZ)	COVAX-MOH (COVAX Facility)	<ol style="list-style-type: none"> 1. SK Bioscience Co. Ltd, South Korea 2. Catalent Anagni S.R.L, Italy 3. CP Pharmaceuticals Ltd, United Kingdom 4. IDT Biologika GmbH, Germany 5. Seqirus Pty Ltd, Australia 6. Daiichi Sankyo Biotech Co., LTD., Kitamoto Site, Japan 7. KM Biologics Co. Ltd. Koshi Production Center, Japan 8. Astrazeneca NijmegenB.V., Neherlands 9. Amylin Ohio LLC (AZ), United States 10. Universal Farma, S.L. ("Chemo"), Spain For: Astrazeneca AB Sweden
6.	COVID-19 Vaccine AstraZeneca Solution for Injection (MAL21116002ASZ)	AstraZeneca Sdn. Bhd.	SK Bioscience Co. Ltd, South Korea
7.	CoronaVac Suspension for Injection SARS-CoV-2 Vaccine (Vero Cell), Inactivated (MAL21036010ARZ)	Pharmaniaga LifeScience Sdn. Bhd.	Sinovac Life Sciences Co. Ltd., China
8.	CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated (MAL21046125ACSZ)	Pharmaniaga LifeScience Sdn. Bhd.	Pharmaniaga LifeScience Sdn. Bhd., Malaysia
9.	Convidecia™ Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (MAL21066050AZ)	Solution Biologics Sdn. Bhd.	Cansino Biologics Inc, China
10.	Janssen Covid-19 Vaccine Suspension for Injection (MAL21076097ACZ)	Johnson & Johnson Sdn. Bhd.	Janssen Pharmaceutica N.V., Belgium

Bil No	Nama vaksin dan No MAL <i>Name of Vaccine and MAL No.</i>	Pemegang Pendaftaran Produk <i>Product Registration Holder</i>	Pengilang <i>Manufacturer</i>
11.	COVILO Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated (MAL21076098AZ)	Duopharma (M) Sdn. Bhd.	Beijing Institute of Biological Products Co., Ltd. (BIBP), China
12.	Spikevax 0.20 mg/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) (MAL21086001ACZ)	Zuelig Pharma Sdn. Bhd.	Rovi Pharma Industrial Services, S.A. San Sebastian de los Reyes, Spain
13.	COVID-19 Vaccine Janssen Suspension for Injection (MAL21066049AZ)	COVAX-MOH (COVAX Facility)	<ul style="list-style-type: none"> 1. Janssen Biologics B.V. Netherlands 2. Janssen Pharmaceutica NV Belgium 3. Aspen SA Sterile Operations, South Africa 4. Catalent Indiana LLC, USA 5. Grand River Aseptic Manufacturing Inc, USA 6. Catalent Anagni S.R.L., Italy 7. Merck Sharp & Dohme (MSD) Corp., United States <p>For: Janssen-Cilag International NV, Belgium</p>

D) FARMAKOVIGILANS

NPRA menjalankan pemantauan secara berterusan ke atas produk berdaftar di pasaran tempatan bagi memastikan produk tersebut menepati keperluan keselamatan, keberkesaan dan kualiti. Pada tahun 2021, Program Pemantauan Kesan Advers Ubat (ADR) Kebangsaan telah menerima sebanyak 54,927 laporan, peningkatan sebanyak 41.3 peratus berbanding tahun sebelumnya (**Rajah 6**). Peningkatan laporan ini melibatkan pelaporan Kesan Advers Susulan Imunisasi (AEFI) untuk vaksin COVID-19, selaras dengan pelancaran Program Imunisasi COVID-19 Kebangsaan (PICK) yang dilancarkan pada 24 Februari 2021. Dari jumlah ini, 24,042 laporan adalah laporan AEFI melibatkan produk vaksin COVID-19.

D) PHARMACOVIGILANCE

NPRA continuously monitors registered products in the local market to ensure the products adhere to safety, efficacy and quality requirements. In 2021, the National Adverse Drug Reactions (ADR) Monitoring Program received 54,927 reports, an increase of 41.3 percent compared to the previous year (**Figure 6**). The increase in reporting is due to adverse event following immunisation (AEFI) reporting for COVID-19 vaccines, in line with the launch of the National COVID-19 Immunisation Programme (PICK) on 24 February 2021. From the final total, 24,042 reports consist of AEFI reports of COVID-19 vaccines.

Rajah 6: Bilangan laporan ADR/AEFI yang diterima, 2017-2021
Figure 6: Number of ADR/AEFI reports received, 2017-2021



i) **Pemantauan Status Kualiti dan Keselamatan Vaksin COVID-19**

NPRA memantau risiko keselamatan semua vaksin berdaftar yang digunakan di Malaysia termasuk vaksin COVID-19 melalui pemantauan laporan Kesan Advers Susulan Imunisasi (AEFI).

Laporan/respon yang diterima adalah laporan 'spontaneous' melalui pemantauan pasif. Laporan/respon AEFI diterima secara langsung oleh NPRA melalui sistem pelaporan Adverse Drug Reaction (ADR)/AEFI sedia ada (PhIS, QUEST3+) dan aplikasi MySejahtera (respon kendiri).

Pada masa ini terdapat lima (5) vaksin COVID-19 yang sedang digunakan untuk Program Imunisasi COVID-19 Kebangsaan (PICK) iaitu: Comirnaty (Pfizer), CoronaVac (Sinovac), AstraZeneca, Convidecia (CanSino) dan Covilo (Sinopharm). Pelaporan AEFI merangkumi kelima-lima (5) vaksin tersebut.

i) ***COVID-19 Vaccine Safety and Quality Monitoring***

The National Pharmaceutical Regulatory Agency (NPRA) monitors the safety risks of all registered vaccines used in Malaysia including COVID-19 vaccines through the monitoring of Adverse Effect Following Immunisation (AEFI) reports.

Reports/responses received are 'spontaneous' reports through passive monitoring. AEFI reports/responses are received directly by NPRA through the existing Adverse Drug Reaction (ADR)/AEFI reporting system (PhIS, QUEST3+) and MySejahtera application (self-reporting).

There are five (5) COVID-19 vaccines currently used for the National COVID-19 Immunisation Programme (PICK) which are Comirnaty (Pfizer), CoronaVac (Sinovac), AstraZeneca, Convidecia (CanSino) and Covilo (Sinopharm). AEFI reporting covers all five (5) vaccines.

Jadual 3: Data AEFI PICK sehingga 31 Disember 2021

Table 3: AEFI Data for PICK as of 31 December 2021

	Comirnaty (Pfizer)	CoronaVac (Sinovac)	AstraZeneca	Convidecia (CanSino)	Covilo (Sinopharm)	Kumulatif Cumulative
Jumlah dos yang telah diberikan <i>Total doses administered</i>	32,120,991	20,608,643	4,157,338	199,676	33,129	57,119,777
RESPONS MELALUI APLIKASI MySEJAHTERA: RESPONSES VIA MySEJAHTERA APPLICATION:						
Jumlah respons <i>Total responses</i>	400,752	186,961	386,342	13	66	974,134
Jumlah kesan advers <i>Total adverse reactions</i> (31/12/2021)	1,134,066	472,042	1,871,387	37	243	3,477,775
Kadar respon per 1,000 dos <i>Response rate per 1,000 doses</i>	12.5	9.1	92.9	0.1	2.0	17.1
PELAPORAN MELALUI SISTEM SEDIA ADA: REPORTING VIA EXISTING SYSTEM:						
Jumlah Laporan <i>Total responses</i>	17,954	4,887	1,155	45	1	24,042
Kadar pelaporan per 1,000 dos <i>Reporting rate per 1,000 doses</i>	0.56	0.24	0.28	0.23	0.03	0.42
Laporan AEFI non-serious <i>Non-serious AEFI reports</i>	16,979	4,347	1,021	42	1	22,390
Laporan AEFI serious <i>Serious AEFI reports</i>	975	540	134	3	0	1,652
AEFI Serius/Jumlah laporan AEFI (%) <i>Serious AEFI /Total AEFI reports (%)</i>	5.4	11.0	11.6	6.7	0	6.9
Kadar pelaporan serius per 1,000 dos <i>Serious report rate per 1,000 dos</i>	0.03	0.03	0.03	0.02	0.00	0.03

E) SURVEILANS

Pengawasan pasaran dan pengendalian aduan produk dilaksanakan untuk memantau produk berdaftar dan kosmetik bernotifikasi di Malaysia, dan memastikan standard kualiti dan keselamatan produk mematuhi ketetapan regulatori.

E) SURVEILLANCE

Market surveillance and handling of product complaints procedures are in place to monitor registered medicinal products and notified cosmetics in Malaysia, ensuring the quality and safety standards of the products adhere to regulatory requirements.

Sebanyak 4,135 produk telah disampel pada tahun 2021 di bawah Program Pengawasan Pasca Pendaftaran Produk Berdaftar dan Kosmetik Bernotifikasi. Sebanyak 3,182 aduan telah diterima pada tahun 2021. Aduan produk yang diterima telah dinilai, disiasat, dan tindakan berkenaan telah diambil berdasarkan hasil siasatan. 26 tindakan regulatori telah diambil melibatkan dua (2) pembatalan pendaftaran / notifikasi, dua (2) arahan panggil balik, 20 amaran telah dikeluarkan serta dua (2) produk telah dipanggil balik secara sukarela dari pasaran oleh pemegang pendaftaran produk.

A total of 4,135 products were sampled in 2021 under the Market Surveillance Programme for Registered Products and Notified Cosmetics. 3,182 complaints were received in 2021. Products complaints received were evaluated, investigated, and necessary actions were taken based on the investigation findings. 26 regulatory actions were taken which include two (2) cancellation of registration / notification, two (2) recalls, 20 warnings issued as well as two (2) products voluntarily recalled from the market by product registration holders.

Jadual 4: Jumlah dan kategori produk yang diambil untuk Program Post Market Surveillance 2017-2021

Table 4: Number and categories of products taken for Post Market Surveillance (PMS) 2017-2021

Kategori Produk <i>Product Category</i>	2017	2018	2019	2020	2021
Produk Preskripsi <i>Prescription Products</i>	652	657	843	767	688
Produk Bukan Preskripsi <i>Non-Prescription Products</i>	160	159	251	189	124
Suplemen Kesihatan <i>Health Supplements</i>	99	173	176	211	169
Semulajadi <i>Natural Products</i>	1,220	699	817	973	951
Kosmetik <i>Cosmetic</i>	1,799	2,023	1,966	2,331	2,203
Jumlah <i>Total</i>	3,930	3,711	4,053	4,471	4,135

Jadual 5: Bilangan aduan produk yang diterima 2017-2021

Table 5: Number of product complaints received 2017-2021

Kategori Produk <i>Product Category</i>	2017	2018	2019	2020	2021
Produk Preskripsi <i>Prescription Products</i>	667	844	879	736	2993
Produk Bukan Preskripsi <i>Non-Prescription Products</i>	171	147	188	134	99
Suplemen Kesihatan <i>Health Supplements</i>	3	7	14	31	19
Semulajadi <i>Natural Products</i>	0	15	17	18	9
Kosmetik <i>Cosmetic</i>	41	110	76	101	62
Jumlah <i>Total</i>	882	1,123	1,174	1,020	3,182

F) AKTIVITI INSPEKTORAT

Pemeriksaan Amalan Perkilangan Baik (APB) ke atas pengilang produk berdaftar dan kosmetik bernotifikasi adalah bertujuan untuk memastikan pematuhan pengilang terhadap keperluan APB. Manakala Pemeriksaan Amalan Pengedaran Baik (AEB) dijalankan untuk memastikan pematuhan pengimport dan pemborong terhadap keperluan AEB semasa. Sepanjang tahun 2021, sebanyak 369 pemeriksaan APB dan 190 pemeriksaan AEB telah dijalankan. Selain itu, khidmat nasihat dan penilaian pelan susun atur premis juga disediakan untuk pengilang sepanjang tahun 2021.

Jumlah pemeriksaan yang dijalankan ke atas fasiliti-fasiliti tersebut telah berkurang bagi tahun 2020 jika dibandingkan dengan tahun-tahun sebelumnya disebabkan kekangan dari situasi pandemik COVID-19. Namun begitu NPRA telah memperkenalkan mekanisme pemeriksaan di luar lapangan secara jarak jauh atau *remote inspection* yang telah meningkatkan bilangan pemeriksaan yang dilaksanakan pada tahun 2021.

Selain pemeriksaan melibatkan pematuhan pengilang, pengimport dan pemborong di Malaysia, NPRA turut menjalankan pemeriksaan ke atas pusat kajian bioekuivalens (BE) dalam dan luar negara, jawatankuasa etika serta fasiliti Amalan Makmal Baik (GLP). Sepanjang tahun 2021, empat (4) pemeriksaan dijalankan ke atas fasiliti GLP dan sebanyak satu (1) pemeriksaan Jawatankuasa Etika telah dilaksanakan.

Untuk pemeriksaan pusat kajian BE hanya satu (1) pemeriksaan telah dijalankan pada tahun 2021. Namun begitu NPRA telah memperkenalkan proses kerja Penilaian Keperluan Penentuan Pemeriksaan Kajian Bioekuivalens (BEDE) sejak bulan Oktober 2020. Proses kerja ini bertujuan untuk menentukan keperluan pemeriksaan

F) INSPECTORATE ACTIVITIES

Good Manufacturing Practice (GMP) inspections on the manufacturer of registered products and notified cosmetics are conducted to ensure compliance to the current GMP requirements while Good Distribution Practice (GDP) inspections ensure adherence of importers and wholesalers to the current GDP requirements. There were 369 GMP inspections and 190 GDP inspections conducted in the year 2021. Additional services such as technical guidance and premise plan layout reviews were also provided to manufacturers.

The number of inspections conducted on these facilities decreased for 2020 compared to previous years due to restrictions arising from the COVID-19 pandemic situation. However, NPRA has introduced an off-site remote inspection mechanism which has contributed to the increase in the number of inspections conducted for the year 2021.

Apart from conducting inspections to assess the compliance of manufacturers, importers and wholesalers in Malaysia, NPRA also conducts inspections on local and foreign BE centers, ethics committees, and Good Laboratory Practice (GLP) facilities. Throughout the year of 2021, four (4) inspections were performed on GLP facilities while one (1) inspection was conducted on Ethics Committee.

For BE study center inspections only one (1) inspection was conducted in 2021. However, NPRA has introduced the Bioequivalence Study Inspection Requirement Evaluation (BEDE) work process since October 2020. This work process aims to determine the requirement for BE study-specific inspection through desktop evaluation. Applications for

kajian-spesifik BE melalui penilaian secara *desktop*. Permohonan untuk BEDE dijalankan untuk kajian BE yang dijalankan di pusat kajian BE yang tidak disenaraikan atau bukan dalam tempoh sah Program Komplians Pusat Kajian BE NPRA dan bertujuan untuk menyokong pendaftaran produk di Malaysia. Sepanjang 2021 sebanyak 130 permohonan BEDE telah dinilai oleh NPRA. Secara tidak langsung, proses kerja ini dapat mengoptimumkan keperluan pemeriksaan kajian-spesifik BE luar negara secara 'on-site' oleh NPRA.

BEDE applies to BE studies conducted at BE study centers that are not listed or not within the validity period of the NPRA BE Study Center Compliance Programme and aims to support product registration in Malaysia. In 2021 a total of 130 BEDE applications were evaluated by NPRA. Indirectly, this work process can optimize the need for overseas BE study-specific on-site inspections by NPRA.

Jadual 6: Bilangan pemeriksaan premis, semakan pelan premis serta bimbingan teknikal yang dijalankan, 2017-2021

Table 6: Number of inspections, premise plan review and technical guidance, 2017-2021

Aktiviti <i>Activity</i>	2017	2018	2019	2020	2021
Pemeriksaan Amalan Perkilangan Baik (APB) <i>GMP Inspections</i>	461	464	424	210	369
Pemeriksaan Amalan Edaran Baik <i>GDP Inspections</i>	133	171	162	130	190
Pemeriksaan Amalan Klinikal Baik <i>GCP Inspections</i>	10	11	8	5	4
Pemeriksaan Pusat Kajian Bioekuivalens (BE) <i>BE Study Centre Inspections</i>	26	18	34	4	1
Pemeriksaan Jawatankuasa Etika <i>Ethics Committee Inspections</i>	0	5	7	0	1
Pemeriksaan Amalan Makmal Baik <i>GLP Inspections</i>	6	5	4	2	4
Semakan Pelan Premis Pengilang <i>Manufacturers Layout Plan Evaluation</i>	106	127	99	138	110
Bimbingan Teknikal <i>Technical Guidance</i>	113	51	39	603	968

GMP: Good Manufacturing Practice
GDP: Good Distribution Practice

GCP: Good Clinical Practice
BE: Bioequivalence

GLP: Good Laboratory Practice

G) PENGUJIAN MAKMAL

Makmal NPRA telah mendapat status akreditasi MS ISO/IEC 17025:2017 bagi skop pengujian produk tradisional, kosmetik dan farmaseutikal (vaksin Hepatitis B). Pengujian sampel ke atas

G) LABORATORY TESTING

The NPRA laboratory has obtained MS ISO/IEC 17025: 2017 accreditation status for the scope of testing of traditional, cosmetic and pharmaceutical products (Hepatitis B vaccine). Sample testing is conducted on

produk farmaseutikal, produk semulajadi serta kosmetik dijalankan mengikut standard regulatori antarabangsa. Tugas-tugas ini dijalankan oleh kakitangan makmal yang kompeten dan terlatih.

Pengujian produk dijalankan ke atas sampel pendaftaran untuk produk semulajadi dan bagi tujuan pengawasan produk berdaftar dan kosmetik bernotifikasi. Pengujian turut dijalankan ke atas sampel produk yang menyebabkan kesan advers (ADR), sampel aduan produk dan sampel produk dari aktiviti penguatkuasaan.

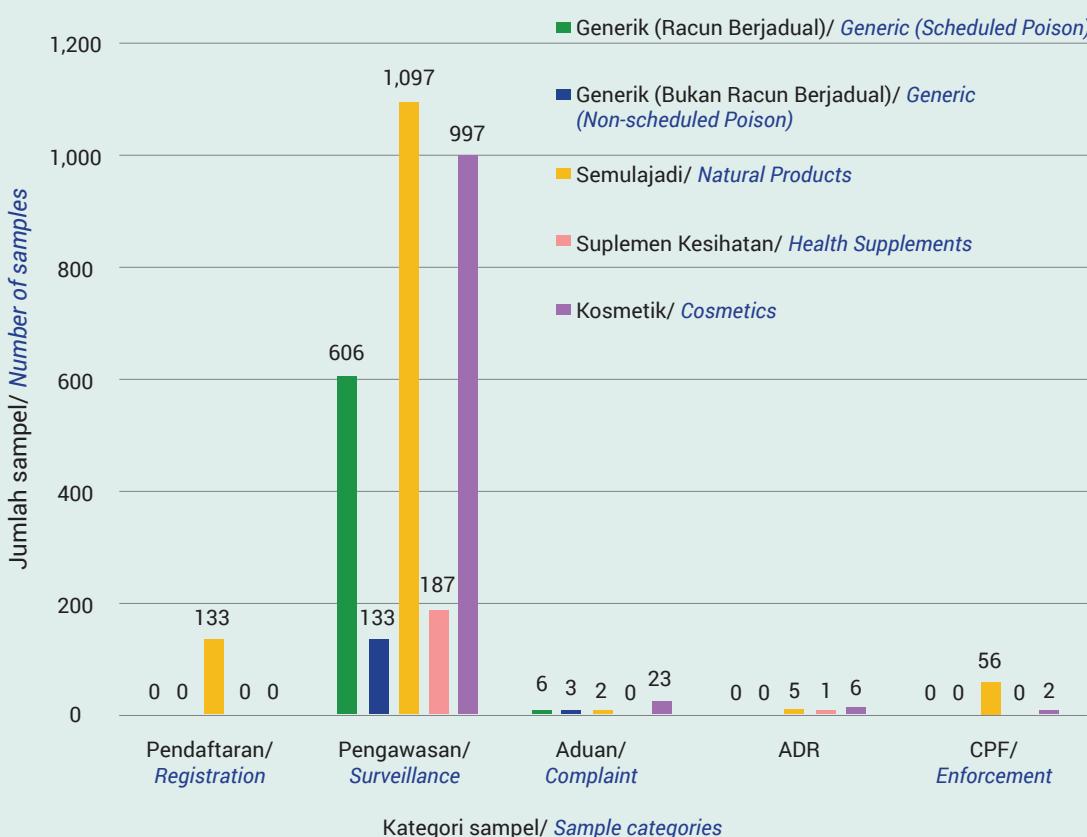
Pada tahun 2021, sampel pengawasan mencatatkan bilangan sampel diuji tertinggi iaitu sebanyak 3,020 sampel. Kategori yang mempunyai bilangan sampel diuji tertinggi ialah kategori produk semulajadi iaitu sebanyak 1,097 sampel.

pharmaceutical products, natural products and cosmetics in accordance with global regulatory standard. These activities are conducted by trained and competent laboratory personnel.

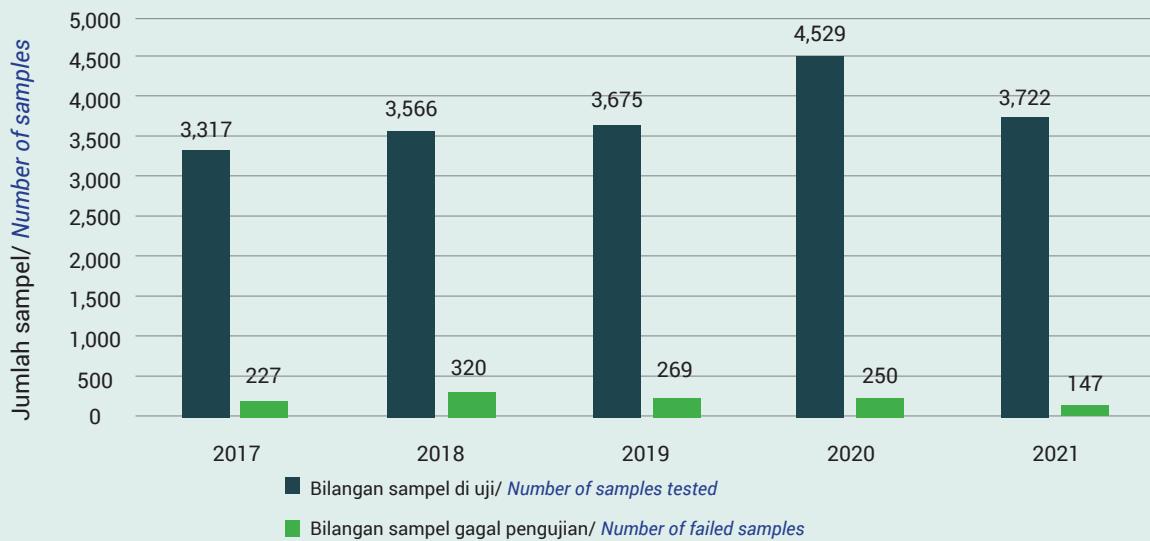
Product testing is conducted for the purpose of registration of natural products and for surveillance of registered products and notified cosmetics. Testing is also performed on samples of products with reported adverse drug reactions (ADR) as well as on samples from product complaints and enforcement activities.

In the year 2021, surveillance samples recorded the highest number of samples tested with a total of 3,020 samples. The product category with highest number of samples tested is natural products with 1,097 samples tested.

Rajah 7: Sampel yang diuji mengikut kategori untuk tahun 2021
Figure 7: Samples tested based on category for year 2021



Rajah 8: Bilangan sampel diuji dan bilangan sampel gagal pengujian, 2017-2021
Figure 8: Number of samples tested & number of failed samples, 2017-2021



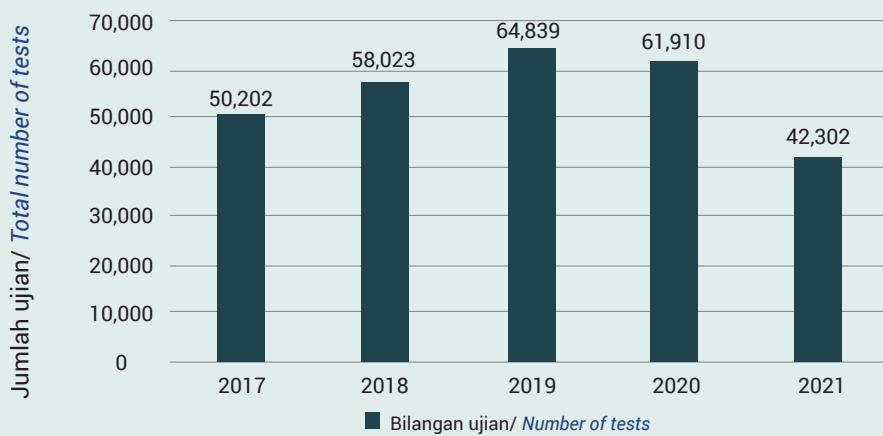
Untuk tahun 2021, pengujian makmal telah dijalankan ke atas 3,722 sampel. Bilangan sampel yang gagal pengujian adalah sebanyak 147 sampel sahaja iaitu 3.9 peratus daripada jumlah sampel yang diuji. Pada tahun 2021, keseluruhan bilangan ujian makmal yang telah dijalankan adalah 42,302.

Melalui ujian-ujian analisis rutin yang dijalankan ke atas sampel bagi menilai kualiti produk, pengesanan bahan campur palsu dalam sampel merupakan antara sebab kegagalan ujian makmal. Untuk tahun 2021, 96 daripada 1,096 sampel produk semulajadi telah dikesan mengandungi bahan campur palsu.

For the year 2021, laboratory testing has been conducted on 3,722 samples. The number of samples that failed testing amounted to 147 samples only, which is equivalent to 3.9 percent of the total number of samples tested. In the year 2021, the overall number of laboratory tests performed was 42,302.

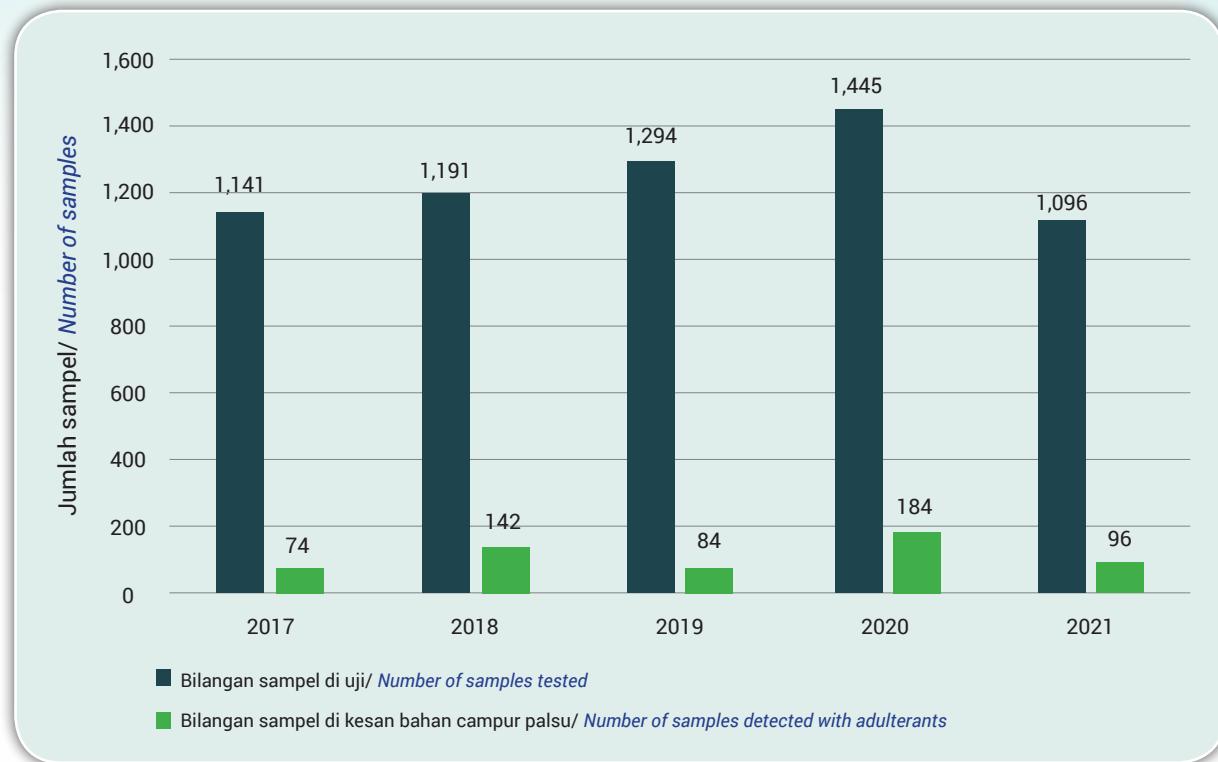
Through the routine analytical tests conducted on samples to assess the products' quality, detection of adulterants is one of the reasons for failed samples. For the year 2021, 96 out of 1,096 samples of natural products tested have been found to be adulterated.

Rajah 9: Bilangan ujian yang dijalankan, 2017-2021
Figure 9: Number of tests performed, 2017-2021



Rajah 10: Bilangan sampel produk semulajadi yang dikesan mengandungi bahan campur palsu, 2017-2021

Figure 10: Number of natural products samples detected with adulterants, 2017-2021





Aktiviti & Sorotan

Highlights & Activities

Anugerah Amalan Baik Peraturan dari Perbadanan Produktiviti Malaysia MPC

Sempena penganjuran Persidangan Kebangsaan Amalan Baik Peraturan 2021, Perbadanan Produktiviti Malaysia (MPC) telah menyampaikan Anugerah *Regulatory Champions* sebagai pengiktirafan dan penghargaan kepada kementerian, agensi, kerajaan negeri, pihak berkuasa tempatan dan individu terpilih yang terlibat secara aktif dan memberikan sumbangan dalam menjayakan inisiatif Amalan Baik Peraturan (GRP).

Kementerian Kesihatan Malaysia (KKM) telah menerima tiga anugerah dalam persidangan tersebut dari MPC iaitu Kementerian Aktif Melaksanakan GRP, Anugerah Pengawal Selia Aktif / *Unified Public Consultation* (UPC) dan Tokoh Amalan Baik Peraturan Peringkat Kementerian.

Anugerah Pengawal Selia Aktif / *Unified Public Consultation* (UPC) dimenangi oleh Bahagian Regulatori Farmasi Negara (NPRA). YBrs. Dr Roshayati binti Mohamad Sani, Pengarah NPRA menerima anugerah ini bagi pihak NPRA.

Penganugerahan ini diberikan atas komitmen dan penglibatan aktif NPRA dalam melaksanakan inisiatif GRP melalui penggunaan UPC sebagai medium seranta awam. Sejak pelancaran UPC pada tahun 2020, sebanyak 13 seranta awam dalam talian bagi garis panduan dan polisi baru NPRA dilaksanakan melalui platform tersebut. Pelaksanaan seranta awam ini adalah penting untuk memastikan pandangan pemegang taruh diambil kira dan menggalakkan akauntabiliti, ketelusan dan keterangkuman.

Good Regulatory Practice Award from Malaysian Productivity Corporation (MPC)

In conjunction with the 2021 National Conference on Good Regulatory Practices, the Malaysian Productivity Corporation (MPC) presented the Regulatory Champions Award in recognition and appreciation to ministries, agencies, state governments, local authorities and selected individuals who are actively involved and contribute to the success of Good Regulatory Practices (GRP) initiatives.

The Ministry of Health Malaysia (MOH) was honoured with three awards from MPC in the conference namely the Ministry Actively Implementing GRP, the Active Regulator Award/Unified Public Consultation (UPC) and the Good Regulatory Practice Figure Ministry –Level.

The Active Regulator Award / Unified Public Consultation (UPC) category was won by the National Pharmaceutical Regulatory Division (NPRA). Dr Roshayati binti Mohamad Sani, Director of NPRA received this award on behalf of NPRA.

This award is given in recognition of the commitment and active involvement of NPRA in implementing GRP initiatives via UPC as a medium for stakeholder engagements. Since its launch in 2020, 13 online public consultations were conducted for new guidelines and policies introduced by NPRA via the UPC platform. The implementation of UPC is vital to allow stakeholder views to be heard and promotes accountability, transparency and inclusiveness.

Imej 6: NPRA diberi Anugerah Pengawal Selia Aktif / *Unified Public Consultation (UPC)* di Persidangan Amalan Baik Peraturan 2021

Image 6: NPRA awarded the Active Regulator Award / Unified Public Consultation (UPC) at the 2021 National Conference on Good Regulatory Practices



Sumber: Facebook, KKM
Source: Facebook, KKM

Seminar Regulatori Persatuan Industri Farmaseutikal Malaysia (MOPI) Kedua, 2021

Seminar ini yang dianjurkan oleh Persatuan Industri Farmaseutikal Malaysia (MOPI) secara kolaborasi dengan NPRA telah diadakan dengan jayanya pada 23 sehingga 24 November 2021 secara dalam talian.

Objektif utama seminar ini adalah untuk memberikan penjelasan dan kefahaman yang lebih mendalam kepada pihak industri berkaitan keperluan-keperluan pendaftaran produk dan punca permohonan pendaftaran ditolak selepas proses penyaringan permohonan dijalankan oleh pihak NPRA. Di samping itu, seminar ini diharap dapat memberi manfaat kepada peserta dan seterusnya membantu pihak industri dalam penghantaran dokumen yang berkualiti seperti mana yang digariskan di dalam *Good Registration Management* (GRM) yang merangkumi *Good Review Practice* (GRevP) dan *Good Submission Practice* (GSubP).

Seminar tersebut telah dihadiri oleh 180 orang peserta yang merupakan ahli MOPI serta 20 pegawai dari NPRA. Agenda seminar melibatkan pembentangan dari pihak NPRA dan juga pihak industri. Salah satu topik atau perkongsian utama adalah mengenai impuriti nitrosamine. Topik berkaitan impuriti ini sangat relevan dengan keperluan semasa dan diharapkan agar ianya dapat sedikit sebanyak membantu kedua-dua pihak regulatori dan industri untuk menetapkan kawalan yang bersesuaian serta menjalankan *risk-assessment* yang sewajarnya bagi menjamin keselamatan dan kualiti produk-produk farmaseutikal yang dipasarkan di Malaysia.

The Second Malaysian Organisation of Pharmaceutical Industries (MOPI) Regulatory Seminar 2021

This seminar was organized by Malaysian Organisation of Pharmaceutical Industries (MOPI) in collaboration with NPRA and was held virtually on 23 and 24 November 2021.

The objective of this seminar is to promote an in depth understanding to the industry on the requirements for product registration as well as highlighting the reasons why some application dossiers were rejected by NPRA upon undergoing the screening process. In addition to that, the seminar hopes to benefit the industry and guide applicants in developing quality dossiers for submission as outlined and promoted by Good Registration Management (GRM) which consists of Good Review Practice (GRevP) and Good Submission Practice (GSubP).

The seminar was attended by 180 participants who are MOPI members and 20 officers from NPRA. The programme of the seminar includes presentations from NPRA as well as from the industry. One of the main topic of interest is on nitrosamine impurity which is relevant with current needs. This knowledge sharing session will enable both regulators and industry players to determine the best practices in regulatory control and implement the appropriate risk-assessment procedures which will guarantee the safety and quality of pharmaceutical products marketed in Malaysia.

Imej 7: Anggota NPRA yang terlibat sebagai pembentang dalam Seminar MOPI
Image 7: NPRA officers participating as speakers during the MOPI Seminar



Bengkel Kesedaran dan Latihan Kawalan Kualiti Bahan Mentah Herba untuk Produk Semulajadi

Seperti yang dinyatakan dalam Pelan Strategik Bahagian Regulatori Farmasi Negara (NPRA), pengukuhan kawalan kualiti untuk pengujian produk semulajadi merupakan strategi jangka panjang bagi tempoh 2021 sehingga 2025. Di bawah seliaan Jawatankuasa Pengukuhan Kawalan Kualiti Pengujian Produk Semulajadi NPRA, beberapa aktiviti telah dirancang dalam pelan tindakan bagi mencapai matlamat ini. Jawatankuasa ini terdiri daripada anggota-anggota NPRA yang terlibat dalam kawal selia produk herba dan semulajadi dan jawatankuasa ini dipengerusikan oleh YBrs. Dr. Noraida Mohd Zainoor, Timbalan Pengarah Pusat Komplians dan Kawalan Kualiti.

Antara pelan tindakan jawatankuasa ini termasuk penganjuran latihan bagi meningkatkan kesedaran mengenai pengujian kawalan kualiti bahan mentah herba. Pada tahun 2021, sebanyak dua sesi bengkel diadakan untuk dua kumpulan sasaran yang berbeza. Sesi pertama yang diadakan pada 17 sehingga 18 Ogos melibatkan pengilang produk semulajadi dan persatuan yang terlibat dengan produk semulajadi berdaftar. Objektif latihan adalah untuk meningkatkan kesedaran dan pemahaman pihak pengilang mengenai keperluan kawalan kualiti bahan mentah herba bagi tujuan pendaftaran dan pengilangan produk semulajadi.

Susulan latihan tersebut, satu sesi latihan diadakan pada 5 sehingga 6 Oktober untuk makmal panel yang menjalankan pengujian ke atas produk semulajadi. Sesi ini mempunyai objektif tambahan yang spesifik kepada makmal panel iaitu mempromosikan program pengiktirafan ke atas makmal panel yang melaksanakan pengujian kawalan kualiti ke atas bahan mentah herba.

Awareness and Training on Quality Control of Herbal Raw Materials for Natural Products Workshop

Strengthening quality control on natural product testing is one of the long term strategies listed under NPRA's Strategic Plan for the term 2021 to 2025. Several activities have been planned under NPRA's Strengthening Quality Control Testing for Natural Products Committee to achieve this objective. The committee members consist of NPRA officers involved in different areas of herbal and natural product regulatory control. The committee is chaired by Dr. Noraida Mohd Zainoor, Deputy Director of Centre of Compliance and Quality Control.

The action plan developed by this committee include awareness training on quality control testing for herbal raw material. In 2021, two sessions of the awareness and training workshop were held for two different target groups. The first session was held on 17 and 18 August for natural product manufacturers and members of associations related to registered natural products. The objective of the training was to provide awareness and understanding to manufacturers on the quality control requirements of herbal raw materials for the purpose of registration and manufacturing of natural products.

The second session held on 5 and 6 October was held for private laboratories conducting natural product testing. This session has an additional objective specific to panel labs which is to promote NPRA's recognition programme for private labs conducting quality control testing on herbal raw materials.

Kedua-dua sesi tersebut melibatkan pembentangan dari pihak NPRA mengenai kepentingan kawalan kualiti ke atas bahan mentah herba untuk pengilangan produk semulajadi, serta keperluan Amalan Perkilangan Baik. NPRA turut berkongsi maklumat mengenai program pengiktirafan makmal panel yang menjalankan pengujian produk semulajadi di mana program ini telah dimulakan sejak tahun 2016 oleh NPRA.

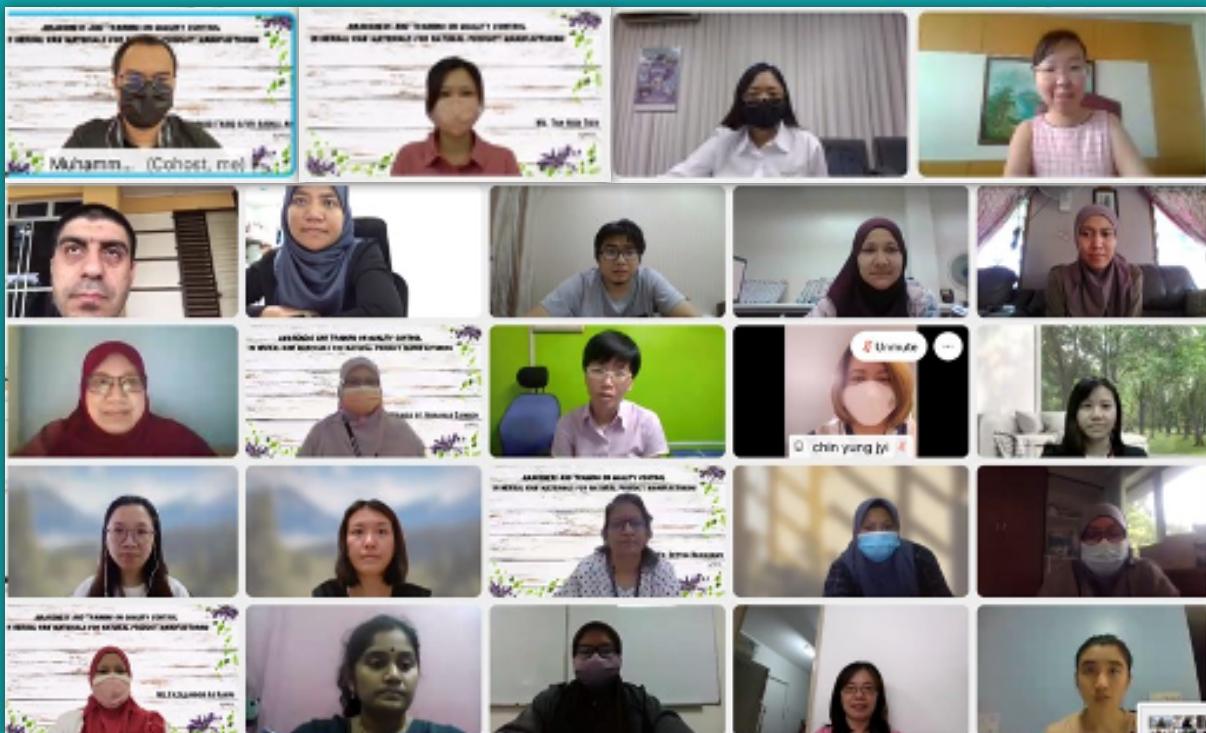
NPRA juga turut menjemput penceramah dari Universiti Kebangsaan Malaysia (UKM) iaitu YBrs. Prof. Dr. Jamia Azdina Jamal dan YBrs. Dr. Lee Soon Leong dari *Forest Research Institute Malaysia* (FRIM) untuk berkongsi pengetahuan mengenai kaedah pengujian kawalan kualiti ke atas bahan mentah produk semulajadi termasuk ujian identifikasi dan analisis DNA untuk bahan herba.

Both sessions include presentations from NPRA officers on the importance of quality control of herbal raw materials for natural product manufacturing and the requirements for Good Manufacturing Practice. NPRA also shared information on the recognition programme for private laboratories conducting quality control testing for natural products, which was first introduced by NPRA in 2016.

Apart from in-house speakers, NPRA also invited external speakers such as Professor Dr Jamia Azdina Jamal from Universiti Kebangsaan Malaysia (UKM) and Dr Lee Soon Leong from Forest Research Institute Malaysia (FRIM) to share their expert knowledge on quality test methods for raw material of natural products which include identification tests as well as DNA analysis for herbal material.

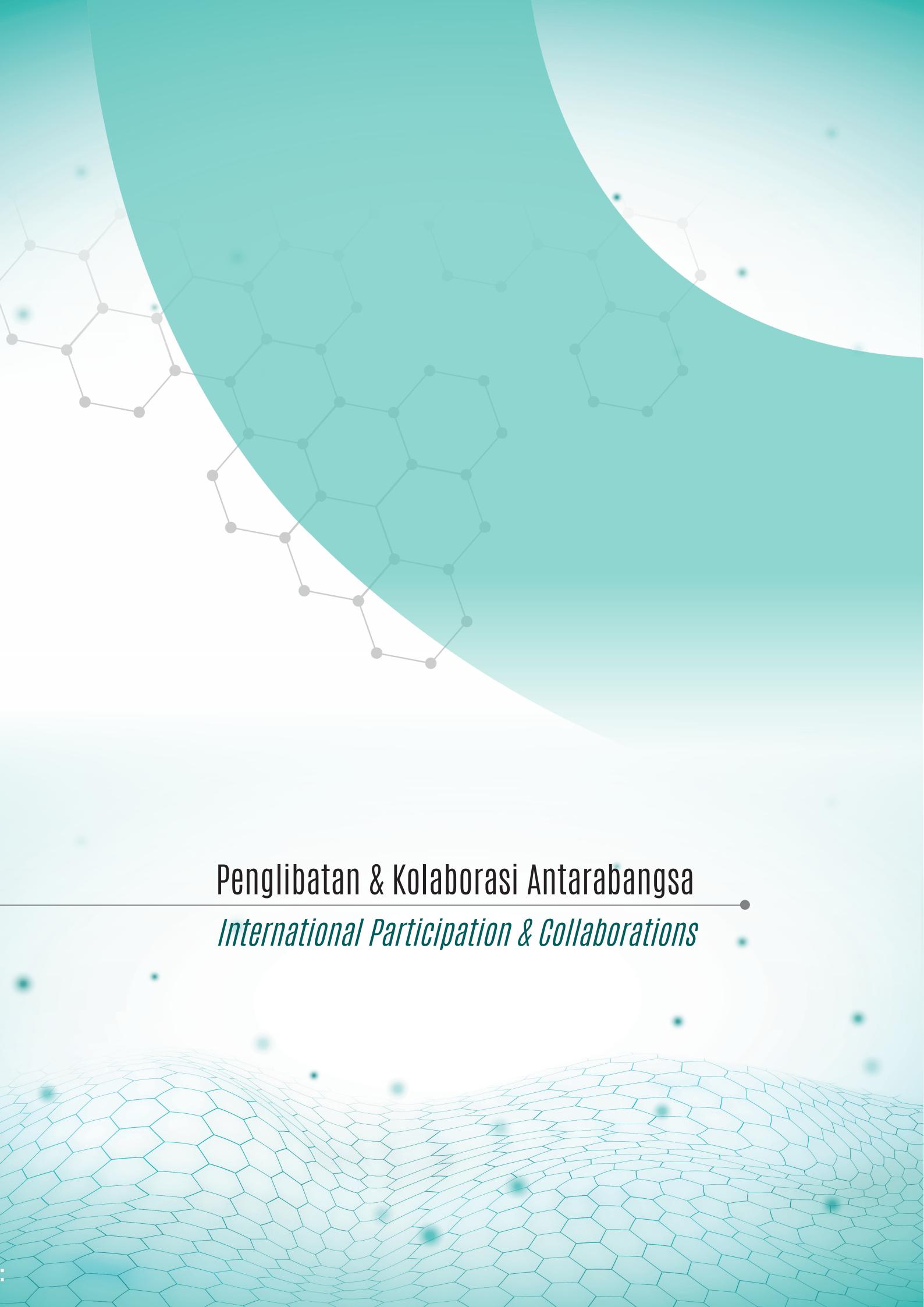
Imej 8: Sesi bengkel pertama yang diadakan secara maya pada 17 dan 18 Ogos 2021

Image 8: First workshop held virtually on 17 and 18 August 2021



Imej 9: Sesi bengkel kedua yang diadakan secara maya pada 5 dan 6 Oktober 2021
Image 9: Second workshop held virtually on 5 and 6 October 2021





Penglibatan & Kolaborasi Antarabangsa

International Participation & Collaborations

1) PENGLIBATAN NPRA DI DALAM KUMPULAN KERJA ASEAN

Malaysia, melalui NPRA giat mengambil bahagian dalam aktiviti tiga (3) kumpulan kerja yang ditubuhkan di bawah ASEAN Consultative Committee for Standards and Quality (ACCSQ) untuk membangunkan skim pengharmonian produk farmaseutikal, produk semulajadi dan suplemen kesihatan serta peraturan-peraturan kosmetik di negara-negara ASEAN.

Kumpulan kerja tersebut termasuk *Pharmaceutical Product Working Group (PPWG)*, *Traditional Medicines and Health Supplements Product Working Group (TMHS PWG)* dan *ASEAN Cosmetic Committee (ACC)*.

1) NPRA'S PARTICIPATION IN ASEAN WORKING GROUPS

Through the NPRA, Malaysia actively participates in three (3) product-working groups established under the ASEAN Consultative Committee for Standards and Quality (ACCSQ) which aim to develop harmonisation schemes of pharmaceuticals, natural products and health supplements as well as cosmetics regulations in ASEAN countries.

These working groups include the Pharmaceutical Product Working Group (PPWG), the Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) and the ASEAN Cosmetic Committee (ACC).

Jadual 7: Senarai mesyuarat di peringkat ASEAN yang telah dihadiri oleh pegawai NPRA sepanjang tahun 2021

Table 7: List of ASEAN meetings attended by NPRA officers in the year 2021

Bil No	Mesyuarat Meeting	Tarikh Date
1.	<i>Intersessional PPWG Meeting</i>	<i>25 January</i>
2.	<i>IWG Discussion on ASEAN Variation Guideline (AVG) For Pharmaceutical Products, Revision 2</i>	<i>9 -10 March</i>
3.	<i>Special PPWG Meeting: Viet Nam Briefing Session on Circular 29</i>	<i>7 April</i>
4.	<i>3rd Workshop on ASEAN Pharmaceutical Regulatory Policy / ASEAN Pharmaceutical Regulatory Framework (APRP/APRF)</i>	<i>21-22 April & 4-5 August</i>
5.	<i>1st Intersessional JSC MRA on GMP Meeting</i>	<i>29-30 April</i>
6.	<i>23rd Implementation Working Group Meeting</i>	<i>9 June</i>
7.	<i>31st Pharmaceutical Product Working Group Meeting</i>	<i>10-11 June</i>
8.	<i>55th ASEAN Consultative Committee on Standards and Quality (ACCSQ)</i>	<i>15-17 June</i>
9.	<i>Special PPWG Meeting: Discussion on the 2nd Draft Protocol to amend the ASEAN MRA on GMP Inspection for Manufacturers of Medicinal Products (MRA on GMP)</i>	<i>23 August</i>

Bil No	Mesyuarat Meeting	Tarikh Date
10.	<i>Special ASEAN Consultative Committee on Standards and Quality (ACCSQ) Meeting (to discuss on CPP)</i>	2 August
11.	<i>34th ASEAN Cosmetic Scientific Body (ACSB) Meeting</i>	5-6 October
12.	<i>2nd Meeting of ASEAN Pharmaceutical Testing Laboratory Committee (APLTC)</i>	7-8 October
13.	<i>34th Meeting of the Heads of Delegations of The ASEAN Cosmetic Committee</i>	13-14 October
14.	<i>10th Meeting of Joint Sectoral Committee on MRA on Good Manufacturing Practice (JSC MRA GMP)</i>	21-22 October
15.	<i>6th Meeting of Joint Assessment Coordinating Group (JACG)</i>	28-29 October
16.	<i>4th Meeting of Joint Sectoral Committee on MRA on Bioequivalence Study Report (JSC MRA BE)</i>	8-9 November
17.	<i>32nd Meeting of ACCSQ – Pharmaceutical Product Working Group (PPWG)</i>	11-12 November
18.	<i>34th ASEAN Cosmetic Committee (ACC) Meeting</i>	15-16 November
19.	<i>56th ASEAN Consultative Committee on Standards and Quality (ACCSQ)</i>	23-24 November

Imej 10: Mesyuarat Intersessional Pharmaceutical Product Working Group (PPWG) yang diadakan secara dalam talian pada 25 Januari 2021

Image 10: Intersessional Pharmaceutical Product Working Group (PPWG) meeting held online on 25 January 2021



Imej 11: Mesyuarat *First Intersessional Joint Sectoral Committee (JSC) MRA GMP* diadakan secara dalam talian pada 29 dan 30 April 2021

Image 11: The First Intersessional JSC MRA GMP Meeting held online on 29 and 30 April 2021



Imej 12: Mesyuarat *Pharmaceutical Product Working Group* ke-32 telah diadakan secara maya pada 11 dan 12 November 2021

Image 12: The Thirty Second Pharmaceutical Product Working Group Meeting being held virtually on 11 and 12 November 2021



2) PENGLIBATAN NPRA DALAM AKTIVITI ASIA-PACIFIC ECONOMIC COOPERATION (APEC)

Life-Sciences Innovation Forum (LSIF) telah ditubuhkan oleh pemimpin Kerjasama Ekonomi Asia-Pasifik (APEC) untuk menerajui inisiatif inovasi sains kesihatan. Forum ini melibatkan wakil daripada peringkat tertinggi kerajaan, industri dan akademia untuk mewujudkan persekitaran dasar untuk inovasi sains hayat.

Regulatory Harmonisation Steering Committee (RHSC) telah ditubuhkan pada Jun 2009 di bawah naungan APEC LSIF untuk menggalakkan pendekatan strategik kepada penyelesaian regulatori dengan melaksanakan aktiviti untuk badan regulatori dan industri terkawal dengan visi untuk mencapai regulatory convergence dalam ekonomi APEC.

2) NPRA'S PARTICIPATION IN ASIA-PACIFIC ECONOMIC COOPERATION (APEC) ACTIVITIES

The Life Sciences Innovation Forum (LSIF) was established by the leaders of Asia-Pacific Economic Cooperation (APEC) to lead APEC initiatives on health sciences innovation. It is a forum that engages representatives from the highest levels of government, industry and academia to create the right policy environment for life sciences innovation.

The Regulatory Harmonization Steering Committee (RHSC) was formed in June 2009 under the auspices of the APEC LSIF to promote a strategic approach to regulatory harmonization by undertaking activities of greatest value to regulatory authorities and regulated industries with the vision of achieving greater regulatory convergence within the APEC economies.

Jadual 8: Senarai mesyuarat anjuran APEC yang telah dihadiri oleh pegawai NPRA sepanjang tahun 2021

Table 8: List of APEC meetings attended by NPRA officers in the year 2021

Bil No	Mesyuarat Meeting	Tarikh Date
1.	APEC Life Science Innovation Forum (LSIF) Virtual Policy Dialogue titled Enabling a Resilient Vaccination Ecosystem	28-29 January
2.	APEC Life Science Innovation Forum (LSIF) Meeting, Senior Officials Meeting 1 (SOM 1)	24-25 February
3.	11th High Level Meeting On Health & The Economy (HLM11) APEC Senior Officials Meeting 3 (SOM 3) 2021	24 August
4.	Regulatory Harmonisation Steering Committee (RHSC) Virtual Meeting	26 October
5.	APEC Life Sciences Innovation Forum (LSIF) and Asia-Pacific Financial Forum (APFF) Health Financing Policy Dialogue	9 December

3) MESUARAT TEKNIKAL DUA HALA

- a) Mesyuarat Bilateral di antara NPRA dan *Pharmaceutical and Medical Devices Agency (PMDA)*, Jepun

Pharmaceutical and Medical Devices Agency (PMDA), Jepun telah menganjurkan Mesyuarat Bilateral NPRA-PMDA yang diadakan secara maya pada 15 April 2021. Mesyuarat ini dianjurkan bersekali dengan *Asian Network Meeting* Ketiga yang diadakan pada 14 April 2021.

Delegasi dari PMDA yang diketuai oleh YBrs. Dr. Fujiwara Yasuhiro (Ketua Eksekutif) PMDA. YBrs. Dr. Hasenah Ali, selaku Pengarah NPRA pada ketika itu mengetuai delegasi Malaysia yang terdiri dari anggota NPRA.

Dalam mesyuarat tersebut, YBrs. Dr. Hasenah dan YBrs. Dr. Fujiwara memberi ucapan pembukaan yang merumuskan kerjasama antara PMDA dan NPRA setakat ini. Walaupun dalam keadaan pandemik, kedua-dua pihak berbesar hati kerana dapat meneruskan perbincangan secara maya berkaitan bidang yang berkepentingan kepada kedua-dua pihak.

Agenda mesyuarat merangkumi peluang latihan dan peningkatan kapasiti organisasi di mana PMDA berbesar hati menawarkan latihan berkaitan farmakovigilans dan kawalan produk disinfektan kepada anggota NPRA. Pihak NPRA juga turut berkongsi maklumat mengenai *facilitated registration pathway* yang dilaksanakan di NPRA. Perbincangan lain termasuk cadangan penganjuran *Second Joint Symposium* Malaysia-Jepun pada tahun 2022 dan perkongsian mengenai *Asian Clinical Trial Networks*.

3) BILATERAL TECHNICAL MEETINGS

- a) *Bilateral Meeting between NPRA and the Pharmaceutical and Medical Devices Agency (PMDA), Japan*

Pharmaceutical and Medical Devices Agency (PMDA), Japan hosted the NPRA-PMDA Bilateral meeting which was held virtually on 15 April 2021 on the sidelines of the Third Asian Network Meeting held on 14 April 2021.

The delegation from PMDA was led by Dr. Fujiwara Yasuhiro (Chief Executive of PMDA). Whereas Dr Hasenah Ali, Director of NPRA at the time led the delegation from NPRA, just in time before her retirement from public service.

In the meeting, Dr Hasenah and Dr. Fujiwara made opening remarks reflecting on the cooperation between PMDA and NPRA thus far. Both parties were pleased that bilateral engagements were continued virtually despite the pandemic to enable discussions on further cooperation in areas of mutual interest.

Meeting agenda included discussions on training and capacity building opportunities. PMDA offered to provide trainings in the field of pharmacovigilance and regulation of disinfectant products. NPRA also shared their experience on the implementation of the facilitated registration pathway. Other topics of interest include the proposal to organize the Second Malaysia-Japan Joint Symposium in 2022 as well as information sharing on the Asian Clinical Trial Networks.

Imej 13: Mesyuarat Bilateral NPRA-PMDA yang diadakan secara maya pada 15 April 2021

Image 13: NPRA-PMDA Bilateral Meeting held virtually on 15 April 2021



b) Mesyuarat Bilateral di antara NPRA dengan *Therapeutic Goods Administration (TGA)*, Australia

Mesyuarat dengan pihak TGA dianjurkan secara dalam talian pada 29 Julai 2021 di mana ianya dipengerusikan secara bersama oleh Pengarah NPRA, YBrs. Dr Roshayati Mohamad Sani dan Ms Kristy Thomas, Pengarah *Regulatory Strengthening Section*, TGA.

Objektif mesyuarat ini adalah untuk memupuk kerjasama regulatori antara kedua-dua agensi di samping mengenalpasti isu-isu regulatori yang boleh diatasi. Antara bidang kerjasama yang dibincangkan termasuk:

- GMP clearance framework and GMP reliance mechanism di bawah *Manufacturing Quality Branch (MQB)*, TGA
- sokongan teknikal untuk pengujian vaksin COVID-19
- perkongsian laporan penilaian vaksin COVID-19 termasuk dossier vaksin COVID-19 yang belum diluluskan oleh *Stringent Regulatory Authorities (SRA)*

b) *Virtual Meeting between NPRA and the Therapeutic Goods Administration (TGA), Australia*

The meeting with TGA was held online on 29 July 2021 where it was jointly chaired by Director of NPRA, Dr Roshayati Mohamad Sani and Ms Kristy Thomas, Director of Regulatory Strengthening Section, TGA.

The objective of the meeting is to foster close regulatory cooperation between the two agencies while also addressing any regulatory issues experienced by either parties. Some of the areas of cooperation discussed include:

- GMP clearance framework and GMP reliance mechanism by TGA's *Manufacturing Quality Branch (MQB)*
- technical assistance on testing of COVID-19 vaccines
- sharing evaluation reports for COVID-19 vaccines and assistance in evaluating quality dossiers for COVID-19 vaccines that have not been approved by Stringent Regulatory Authorities (SRA)

- peluang kolaborasi dan *networking* dengan badan regulatori negara lain untuk perkongsian maklumat dan pengalaman berhubung COVID-19 dan penggunaan vaksin COVID-19 di negara masing-masing.

Susulan mesyuarat 29 Julai, tiga (3) sesi perbincangan diadakan secara virtual untuk membincangkan isu-isu seperti berikut:

- 22 September 2021: Perbincangan mengenai *reliance pathway* dan isu regulatori berkaitan pendaftaran vaksin
- 28 September 2021: Perbincangan untuk mengenalpasti keperluan latihan berkaitan pengujian vaksin COVID-19
- 11 Oktober 2021: Perbincangan mengenai latihan farmakovigilans yang dicadangkan untuk tahun 2022

- collaboration opportunities via networking with other national regulatory authorities to exchange information and experiences related to COVID-19 vaccines used in their respective countries.

Following the meeting on 29 July 2021, three (3) separate discussion sessions were held to discuss the proposed issues as below:

- 22 September 2021: Discussion on *reliance pathway and other regulatory issues on marketing authorization*
- 28 September 2021: Discussion to identify specific trainings on testing of COVID-19 vaccines
- 11 October 2021: Discussion on pharmacovigilance training that is planned for March 2022

Imej 14: Mesyuarat Bilateral NPRA-TGA diadakan secara maya pada 29 Julai 2021

Image 14: NPRA-TGA Bilateral Meeting held virtually on 29 July 2021



Bahagian Regulatori Farmasi Negara (Me)



4) MESYUARAT THIRD ASIAN NETWORK

Mesyuarat *Third Asian Network* (ANM) telah diadakan secara dalam talian dan dianjurkan oleh badan regulatori dari kerajaan China, India, Singapura dan Jepun. Mesyuarat ini disertai oleh 45 peserta dari

4) THIRD ASIAN NETWORK MEETING

The Third Asian Network Meeting was held with 45 participants from 10 countries and co-hosted by the regulatory authorities of China, India, Singapore and Japan. The overarching principle of the meeting was to

10 negara. Prinsip utama mesyuarat ini adalah penumpuan kepada isu/aktiviti regulatori yang berkepentingan kepada semua pihak di samping mengalakkkan kolaborasi antara badan regulatori di rantau Asia.

Malaysia melalui NPRA telah dijemput untuk mengambil bahagian dalam mesyuarat ini untuk membincangkan tindakan yang telah diambil untuk pandemik COVID-19, persekitaran regulatori di Asia serta akses kepada ubat inovatif.

Malaysia telah berkongsi pengalaman mengenai kesiapsiagaan vaksin yang merangkumi mekanisme untuk menyegerakan pendaftaran vaksin serta cabaran yang dihadapi oleh NPRA dalam memastikan akses vaksin tanpa menjelaskan kualiti, keselamatan dan keberkesanan vaksin. Malaysia juga membentangkan insiatif yang dilaksanakan NPRA dalam meningkatkan akses ubat inovatif melalui ASEAN Joint Coordinating Group (JACG) di mana Malaysia berperanan sebagai Pengurus, serta membentangkan serba sedikit mengenai implementasi *Facilitated Registration Pathway* untuk pendaftaran produk di peringkat NPRA.

Ahli mesyuarat juga mengambil maklum, khususnya dalam usaha membendung COVID-19, perkongsian maklumat mengenai status pendaftaran produk seperti vaksin, maklumat pasca pendaftaran serta amalan baik bagi pengecualian regulatori adalah amat penting dan harus diteruskan.

focus on the regulatory issues/activities of mutual interest to all parties and to promote regulatory collaboration between regulatory authorities in the Asian region.

Malaysia through NPRA, was invited to participate in this meeting to discuss the measures taken in combatting the COVID-19 pandemic, the regulatory environment in Asia as well as access to innovative medicines.

Malaysia shared her experience specifically on vaccine preparedness which include the expedited pathway for vaccine registration and the challenges faced by regulators in ensuring timely access without compromising on quality, safety and efficacy of the vaccines. Malaysia also presented initiatives by NPRA on promoting access to innovative medicines, via the ASEAN Joint Coordinating Group (JACG) where Malaysia is Chair to the committee. Malaysia also presented and shared some information on the implementation of the Facilitated Registration Pathway in NPRA.

The Members also acknowledged, particularly in the context of the fight against COVID-19, the significance to share and exchange information on approval/authorization status of COVID-19 related products such as vaccines, post-marketing safety information of such products, as well as best practices for regulatory flexibilities/agilities.

5) **MESYUARAT THE WESTERN PACIFIC REGIONAL ALLIANCE OF NATIONAL REGULATORY AUTHORITIES FOR MEDICAL PRODUCTS: PENUMPuan KEPADA KESIAPSIAGAAN REGULATORI SEMASA KECEMASAN KESIHATAN AWAM**

Sebagai badan regulatori di rantau Pasifik Barat dan ahli yang aktif dalam inisiatif di bawah *Regional Alliance of National Regulatory Authorities*, Malaysia melalui NPRA telah mengambil bahagian dalam mesyuarat tersebut yang diadakan secara dalam talian antara 24 sehingga 26 Ogos 2021.

Mesyuarat tersebut dipengerusikan oleh YBrs Dr. Takeshi Kasai, *Regional Director WHO Western Pacific Regional Office (WPRO)* dan peserta melibatkan delegasi dari setiap badan regulatori di rantau pasifik barat. Delegasi Malaysia yang merangkumi pegawai NPRA diketuai oleh Pengarah NPRA, YBrs Dr. Roshayati Mohamad Sani.

Tema utama mesyuarat ini adalah penumpuan kepada cabaran regulatori semasa kecemasan kesihatan awam untuk memastikan keselamatan, kualiti dan keberkesaan vaksin, ubat-ubatan dan diagnostik in-vitro. Pembentangan negara termasuk perkongsian pengalaman oleh badan regulatori seperti *Therapeutic Goods Administration (TGA)* Australia, *Ministry of Food and Drug Safety (MFDS)* Korea, *Pharmaceutical and Medical Devices Agency (PMDA)*, Jepun dan lain-lain.

Pembentangan negara diikuti dengan bengkel di mana peserta mengambil bahagian dalam perbincangan panel mengenai bagaimana pandemik telah mengubah landskap regulatori serta kerjasama antara ahli negara untuk meningkatkan kolaborasi bagi mengukuhkan rangkaian sistem regulatori di rantau ini.

5) **MEETING OF THE WESTERN PACIFIC REGIONAL ALLIANCE OF NATIONAL REGULATORY AUTHORITIES FOR MEDICAL PRODUCTS: FOCUS ON REGULATORY PREPAREDNESS DURING PUBLIC HEALTH EMERGENCIES**

As a regulatory authority in the Western Pacific and an active member to the initiatives established under the Regional Alliance of National Regulatory Authorities (NRA), Malaysia through NPRA, participated in the above meeting held from 24 to 26 August 2021 virtually.

This meeting was chaired by Dr. Takeshi Kasai, Regional Director of WHO Western Pacific Regional Office (WPRO) and participants include delegations from all NRAs within the western pacific region. Delegation from Malaysia consists of NPRA officers led by Dr. Roshayati Mohamad Sani, Director of NPRA.

The overarching theme of this meeting is the focus on regulatory challenges during public health emergencies and ensuring quality, safety and efficacy of vaccines, medicines and in vitro diagnostics in a pandemic situation. Country presentations include sharing of experiences by other regulatory authorities such as Therapeutic Goods Administration (TGA) Australia, Ministry of Food and Drug Safety, South Korea, Pharmaceuticals and Medical Devices Agency (PMDA), Japan among others.

The country presentations sessions were followed by two workshops in which participants took part in panel discussions on how the pandemic has affected the regulatory landscape and also on the cooperation between member states to promote collaboration and strengthen the regulatory network within the region.

6) PENYERTAAN KURSUS LUAR NEGARA

a) Bengkel Latihan Siasatan Kes AEFI dan Penilaian Kausaliti

Bengkel ini telah diadakan pada 28 September dan 6 Oktober 2021 secara maya dan dihadiri 118 peserta yang terdiri dari Pegawai Perubatan dan Pegawai Farmasi yang mewakili setiap negeri dan juga ahli kepada Jawatankuasa Farmakovigilans Khas Vaksin COVID-19 (JFK).

YBrs. Dr. Roshayati Mohamad Sani, Pengarah NPRA dan YBrs. Dr. Lo Ying-Ru Jacqueline, wakil Malaysia, Brunei Darussalam dan Singapura kepada World Health Organization (WHO) telah merasmikan bengkel tersebut.

Bengkel ini diadakan bagi melatih peserta untuk menjalankan penyiasatan dan penilaian kausaliti kes-kes kesan advers susulan imunisasi (AEFI) yang berkaitan terutamanya bagi vaksin COVID-19. Agenda pada 28 September meliputi pembentangan daripada perunding WHO berkenaan keselamatan vaksin COVID-19 dan siasatan keselamatan susulan vaksinasi COVID-19. Sesi ceramah diikuti dengan kerja berkumpulan bagi Pasukan Penyiasat yang melibatkan pembentangan penilaian kes dan seterusnya perbincangan plenari untuk penambahbaikan kepada siasatan AEFI.

Sesikeduapada6Okttober2021melibatkan penilaian kes oleh wakil Jawatankuasa Farmakovigilans Khas Kebangsaan (JFK), sesi perkongsian oleh pihak WHO mengenai kaedah penilaian kausaliti Adverse Events of Special Interest (AESI) dan pembentangan mengenai penemuan penilaian kausaliti yang dilaksanakan di Malaysia.

6) PARTICIPATION IN OVERSEAS COURSES

a) Training Workshop on AEFI Cases Investigation and Causality Assessment

The workshop was held virtually on 28 September and 6 October 2021. The workshop was attended by 118 participants comprising of Medical Officers and Pharmacy Officers representing each state as well as members of the COVID-19 Vaccine Pharmacovigilance Expert Committee (JFK).

Dr. Roshayati Mohamad Sani, Director of NPRA and Dr. Lo Ying-Ru Jacqueline, World Health Organization (WHO) Representative to Malaysia, Brunei Darussalam and Singapore, were present during the opening to grace the workshop.

The objective of this workshop was to train participants on how to conduct investigation and causality assessment of adverse effects following immunisation (AEFI) cases especially those cases involving COVID-19 vaccines. The workshop agenda on 28 September consists of presentations from WHO consultants on COVID-19 vaccine safety and investigation of safety events following COVID-19 vaccinations. This was followed by a group work session including presentations by Investigation Team on case reviews as well as a plenary discussion on improving AEFI investigations.

The second session on 6 October include case reviews by the COVID-19 Vaccine Pharmacovigilance Expert Committee (JFK) and a knowledge sharing session by WHO on the method of assessing the causality of COVID-19 related Adverse Events of Special Interest (AESI). The JFK committee also shared their findings on the causality assessment conducted in Malaysia.

Imej 15: Sesi pembukaan Bengkel AEFI pada 28 September 2021
Image 15: Opening session of the Training Workshop on AEFI on 28 September 2021



Imej 16: Peserta dan fasilitator menghadiri Bengkel AEFI secara maya pada 6 Oktober 2021
Image 16: Participants and facilitators of the Training Workshop on AEFI attended the event virtually on 6 October 2021



b) **Webinar Pharmaceutical and Medical Devices Agency – Asian Training Centre (PMDA-ATC)**

Sebelum dunia dilanda pandemik, pihak PMDA-ATC sering menganjurkan sesi latihan untuk badan regulatori ASEAN termasuk NPRA. Memandangkan situasi

b) **Pharmaceutical and Medical Devices Agency- Asian Training Centre (PMDA-ATC) Webinars**

Before the pandemic, NPRA and many ASEAN National Regulatory Authorities (NRA) participated in face to face trainings organized by the PMDA -ATC. As the

pandemik masih belum reda pada 2021, latihan tersebut tetap diteruskan secara dalam talian.

Sepanjang tahun 2021 pihak PMDA telah menganjurkan webinar khas untuk anggota NPRA seperti berikut:

- PMDA-ATC *Regenerative Medicines Review Webinar 2021* untuk NPRA,
- PMDA-ATC *Pharmacovigilance Webinar* untuk NPRA

Penganjuran seminar tersebut merupakan hasil kerjasama teknikal antara PMDA dan NPRA menerusi hubungan bilateral pada tahun 2019 dan 2020. Latihan yang dianjurkan adalah berdasarkan bidang yang dicadangkan oleh NPRA.

Objektif webinar *Regenerative Medicines* adalah untuk memberi pengenalan mengenai rangka kerja regulatori bagi *regenerative medicines* di Jepun termasuk proses penilaian produk atau rawatan menggunakan *regenerative medicines*. NPRA juga telah berkongsi maklumat mengenai rangka kerja kawalan *Cell and Gene Therapy Products (CGTPs)* di Malaysia. Manakala semasa webinar Farmakovigilans, pihak PMDA telah berkongsi pengalaman mengenai farmakovigilans dan pengurusan risiko di Jepun.

pandemic situation still has not subsided in 2021, PMDA has offered to conduct the trainings online.

Throughout 2021, PMDA had organized the following seminars for NPRA:

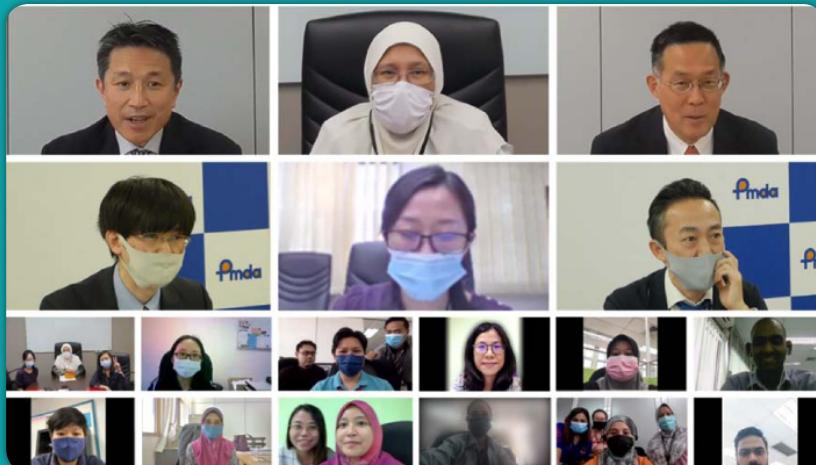
- *PMDA-ATC Regenerative Medicines Review Seminar 2021 for NPRA*
- *PMDA-ATC Pharmacovigilance Webinar for NPRA*

These seminars are the result from the technical cooperation between PMDA and NPRA through bilateral discussions in 2019 and 2020. The trainings organized were based on topics proposed by NPRA.

The objective of the Regenerative Medicines webinar is to provide introduction to the regulatory framework of regenerative medicines in Japan as well as the review process of products or treatments using regenerative medicines. NPRA also shared information on the current framework for regulation of Cell and Gene Therapy Products (CGTPs) in Malaysia. As for the Pharmacovigilance Webinar, the training aimed to share knowledge on the pharmacovigilance and risk management practiced in Japan.

Imej 17: PMDA-ATC *Regenerative Medicines Review Webinar 2021* untuk NPRA diadakan secara maya

Image 17: PMDA-ATC *Regenerative Medicines Review Seminar 2021 for NPRA* held virtually



Sumber: PMDA, Jepun
Source: PMDA, Japan

c) Kursus Regulatori oleh *Therapeutic Goods Administration* (TGA), Australia

Kursus tersebut di atas telah diadakan pada 24 Mei 2021 secara virtual di mana 25 pegawai dari Seksyen Ubat Komplementari dan Alternatif, NPRA telah mengambil bahagian sebagai peserta.

Tujuan latihan ini dianjurkan adalah untuk memperkasakan pengetahuan penilai terhadap ubat komplementari serta bahan aktif ubat komplementari yang digunakan di Australia. NPRA telah memohon *Therapeutic Goods Administration* (TGA), Australia untuk memberikan latihan ini memandangkan TGA merupakan salah satu negara rujukan Pihak Berkuasa Kawalan Dadah (PBKD). Kolaborasi ini merupakan satu usaha ke arah memperkuuhkan *networking* serta hubungan kerja dengan pihak TGA.

Kursus ini melibatkan pembentangan daripada anggota TGA mengenai kawalan regulatori produk ubat komplementari di Australia yang terbahagi kepada beberapa kategori, indikasi yang dibenarkan untuk ubat komplementari, penilaian keberkesanan pasca pendaftaran, penilaian kualiti ke atas produk herba dan sebagainya.

Imej 18: Kursus regulatori yang dijalankan oleh pihak TGA secara maya pada 24 Mei 2021
Image 18: Regulatory course conducted by TGA virtually on 24 May 2021

c) *Regulatory Course on Complementary Medicines by the Therapeutic Goods Administration (TGA), Australia*

The training course was held virtually on 24 May 2021 where 25 officers from the Complementary and Alternative Medicines Section of NPRA was in attendance as participants.

The objective of this course is to strengthen evaluator's knowledge on the regulation of complementary medicines and the evaluation of active ingredients in complementary medicines in Australia. NPRA had requested TGA to provide this training as TGA is one of the Drug Control Authority's (DCA) reference authority. Another main purpose is to establish a working relationship and network between NPRA and TGA.

The one-day course consists of presentations from TGA officers on regulation of complementary medicines; which are divided into several categories, permitted indications, post-market efficacy evaluations and quality evaluation of herbal substances and herbal medicinal product, among others.



NPRA Malaysia (Me)



d) **10th Asia Partnership Conference of Pharmaceutical Associations (APAC)**

Persidangan ini yang dianjurkan secara tahunan oleh persatuan industri farmaseutikal Asia telah diadakan secara dalam talian pada 13 April 2021. Setiap tahun acara ini merangkumi pembentangan serta perbincangan panel yang melibatkan wakil-wakil dari badan regulatori dari seluruh Asia.

Sejajar dengan situasi semasa, tema persidangan pada tahun 2021 adalah '*Overcoming COVID-19 and taking on new innovative challenges for the next decade in Asia*'.

Malaysia turut juga dijemput untuk mengambil bahagian dalam perbincangan panel untuk sesi *Regulations and Approvals* (RA). YBrs. Puan Rosilawati Ahmad, selaku Timbalan Pengarah Pusat Penilaian Produk dan Kosmetik telah berkongsi pengalaman Malaysia dalam pelaksanaan laluan Pendaftaran *Fast Track* Bersyarat Produk Farmaseutikal Semasa Bencana yang digunakan untuk menyegerakan pendaftaran vaksin COVID-19 di Malaysia. Selaku peranan Malaysia sebagai Pengerusi ASEAN *Joint Assessment Coordinating Group* (JACG) yang ditubuhkan di bawah ASEAN *Consultative Committee for Standards and Quality* (ACCSQ)- *Pharmaceutical Product Working Group* (PPWG), Malaysia juga turut membentangkan status terkini prosedur *joint assessment* (JA) yang dilaksanakan di peringkat ASEAN serta cabaran yang dihadapi dalam kolaborasi penilaian bersama tersebut.

d) **10th Asia Partnership Conference of Pharmaceutical Associations (APAC)**

The conference which is organized annually by the Asian pharmaceutical industry association was held online on 13 April 2021. Each year the event includes presentations as well as panel discussions involving representatives from regulatory bodies across Asia.

In line with the current situation, the theme of the conference in 2021 is 'Overcoming COVID-19 and taking on new innovative challenges for the next decade in Asia'.

*Malaysia was also invited to participate in panel discussions for the *Regulations and Approvals* (RA) session. Madam Rosilawati Ahmad, Deputy Director of the Center of Product and Cosmetics Evaluation shared Malaysia's experience in implementing the *Conditional Fast-Track Registration of Pharmaceutical Products During Disaster pathway* which is used to expedite the registration of COVID-19 vaccines in Malaysia. As Malaysia is currently the Chair to the ASEAN Joint Assessment Coordinating Group (JACG) established under the ASEAN Consultative Committee for Standards and Quality-*Pharmaceutical Product Working Group* (ACCSQ-PPWG), Malaysia also presented the latest updates of the joint assessment (JA) procedure implemented at the ASEAN level as well as the challenges faced in the joint assessment collaboration.*

Imej 19: Wakil NPRA mengambil bahagian dalam perbincangan panel untuk sesi *Regulations and Approvals*

Image 19: NPRA representative participated in the panel discussion for the Regulations and Approvals session





Penerbitan

Publications

1) Garis Panduan Amalan Farmakovigilans Baik (GVP) untuk Pemegang Pendaftaran Produk, Edisi Pertama Ogos 2021

Salah satu keperluan farmakovigilans untuk syarikat farmaseutikal ialah pembangunan sistem farmakovigilans dalam organisasi. Syarikat harus pastikan sistem farmakovigilans adalah setara dengan keperluan semasa kerana sebarang kekurangan boleh memberi impak besar kepada keselamatan pesakit.

Mengambil kira keperluan ini, garis panduan ini telah dibangunkan untuk membantu dan memberi panduan kepada syarikat untuk menyediakan sistem farmakovigilans yang baik di dalam organisasi. Garis panduan baharu ini yang menggantikan garis panduan farmakovigilans sedia ada iaitu Malaysian Pharmacovigilance Guidelines 2nd Edition 2016, menggariskan keperluan dan prosedur untuk aktiviti Amalan Farmakovigilans Baik (GVP) yang merangkumi pelaporan kesan advers (ADR) /kesan advers susulan imunisasi (AEFI), Risk Management Plan (RMP) and Periodic Benefit-Risk Evaluation Report (PBRER).

Objektif garis panduan ini adalah untuk memudahkan cara Pemegang Pendaftaran Produk (PRH) untuk menjalankan tanggungjawab mereka di samping memperkasakan usaha jaminan keselamatan produk di Malaysia. Bagi tujuan ini, satu (1) bahagian baru berhubung System Master File farmakovigilans telah dimasukkan dalam garis panduan.

1) *The Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders, First Edition August 2021*

One of the pharmacovigilance requirements for pharmaceutical companies is the establishment of a pharmacovigilance system within their organisations. Pharmaceutical companies need to ensure their pharmacovigilance systems are up to standards as any deficiencies may impact patient safety.

In view of this necessity, this guideline has been developed to assist and provide guidance to pharmaceutical companies to establish good pharmacovigilance systems within their organisations. This new guideline which replaces the previous pharmacovigilance guideline which is the Malaysian Pharmacovigilance Guidelines 2nd Edition, 2016, outlines requirements and procedures for Good Pharmacovigilance Practice (GVP) which include activities such as Adverse Drug Reaction (ADR)/Adverse Effects Following Immunisation (AEFI) Reports Management, Risk Management Plan (RMP) and Periodic Benefit-Risk Evaluation Report (PBRER).

The goal of this guideline is to facilitate the Product Registration Holder (PRH) in carrying out their pharmacovigilance responsibilities and to ultimately enhance the efforts to ensure product safety in Malaysia. For this purpose, one (1) new part related to Pharmacovigilance System Master File has been included in this guideline.

2) Manual Pelaporan Adverse Drug Reaction (ADR)/ Adverse Event Following Immunisation (AEFI) Reporting untuk Anggota Kesihatan

Manual ini menggariskan keperluan dan prosedur untuk pelaporan kesan advers ubat (ADR) dan kesan advers susulan imunisasi (AEFI) oleh anggota penjagaan kesihatan kepada Pihak Berkuasa Kawalan Dadah (PBKD), termasuk pelaporan dan penyiasatan AEFI. Manual ini turut merangkumi komponen berkenaan penilaian *causality* baru untuk AEFI. Keperluan yang digariskan dalam manual ini akan menambahbaik kualiti dan standard pelaporan ADR/AEFI di Malaysia.

2) Adverse Drug Reaction (ADR)/ Adverse Event Following Immunisation (AEFI) Reporting Manual for Healthcare Providers

This manual has been developed to outline the requirements and procedures for submission of adverse drug reaction (ADR) and adverse event following immunisation (AEFI) reports by healthcare providers to the Drug Control Authority (DCA) as well as reporting and investigation of AEFI. It has also included a component on new causality assessment for AEFI. The requirements outlined in this manual will help improve the quality and standard of ADR/AEFI reporting in Malaysia.

Imej 20: Garispanduan Farmakovigilans yang diterbitkan pada 2021
Image 20: Pharmacovigilance Guidelines published in 2021



3) Laporan Ringkasan Kesan Advers Susulan Imunisasi Vaksin COVID-19 di Malaysia

Susulan pelancaran Program Imunisasi COVID-19 Kebangsaan (PICK), NPRA sentiasa melaksanakan pemantauan berterusan ke atas risiko keselamatan semua vaksin berdaftar yang digunakan

3) Summary Report on Adverse Events Following Immunisation of COVID-19 Vaccines in Malaysia

Following the launch of the National COVID-19 Immunisation Program, NPRA continuously monitors the safety risks of all registered vaccines used in PICK through the monitoring of the Adverse Effect Following

dalam PICK melalui pemantauan laporan Kesan Advers Susulan Imunisasi (AEFI).

Satu laporan ringkas AEFI telah dimuatnaik di laman sesawang NPRA di mana kandungan merangkumi maklumat mengenai pengumpulan data oleh NPRA serta proses yang terlibat dalam pelaporan AEFI dan pemantauan keselamatan vaksin COVID-19. Tujuan laporan ringkas diterbitkan adalah untuk pemakluman kepada orang awam mengenai data AEFI vaksin COVID-19 terkini serta usaha yang dilaksanakan oleh NPRA dalam pemantauan keselamatan vaksin.

Immunisation (AEFI) reports.

A summary report of AEFI has been published on the NPRA website which includes information on data collection by NPRA as well as the processes involved in AEFI reporting and COVID-19 vaccine safety monitoring. The purpose of publishing the summary report is to inform the public on the latest COVID-19 vaccine AEFI safety data as well as the efforts undertaken by NPRA in vaccine safety monitoring.

Imej 21: Laporan ringkas AEFI dimuatnaik di laman sesawang NPRA
Image 21: Summary report on AEFI uploaded at NPRA website





Laporan Kewangan

Financial Report

BAJET MENGURUS 2021 | OPERATING BUDGET 2021

Program <i>Program</i>	Kategori <i>Category</i>	Peruntukan <i>Allocation</i>	Perbelanjaan <i>Expenditure</i>		Baki <i>Balance</i>	
		(RM)	RM	%	RM	%
10300	Kewangan <i>Finance</i>	65,000.00	64,561.50	99.33%	438.50	0.67%
010500	Teknologi Maklumat Dan Komunikasi <i>Information Technology & Communications</i>	200,000.00	182,276.42	91.14%	17,723.58	8.86%
050400	Farmasi Regulatori <i>Regulatory Pharmacy</i>	51,681,900.00	52,395,315.01	101.38%	(713,415.01)	-1.38%
060200	Kejuruteraan <i>Engineering</i>	238,878.90	226,739.70	94.92%	12,139.20	5.08%
080900	Harta Modal <i>Capital property</i>	60,000.00	51,758.20	86.26%	8,241.80	13.74%
JUMLAH <i>TOTAL</i>		52,245,778.90	52,920,650.83	101.29%	(674,871.93)	-1.29%

BAJET PEMBANGUNAN 2021 | DEVELOPMENT BUDGET 2021

Program <i>Program</i>	Kategori <i>Category</i>	Peruntukan <i>Allocation</i>	Perbelanjaan <i>Expenditure</i>		Baki <i>Balance</i>	
		(RM)	RM	%	RM	%
00105	Latihan Dalam Perkhidmatan <i>In-service training</i>	50,057.00	49,897.00	99.68%	160.00	0.32%
01100	Peralatan Perubatan <i>Medical Equipment</i>	280,500.00	279,800.00	99.75%	700.00	0.25%
00300	Perkhidmatan Sokongan Hospital <i>Hospital Support Services</i>	4,485,500.00	4,446,058.46	99.12%	39,441.54	0.88%
JUMLAH <i>TOTAL</i>		4,816,057.00	4,775,755.46	99.16%	40,301.54	0.84%

Kutipan Hasil Tahun 2021 | Revenue for 2021

Bil No	Perkara Item	Jumlah (RM) Total (MYR)
1.	Akaun Amanah aktiviti pemeriksaan Amalan Perkilangan Baik (APB) <i>GMP Trust Account</i>	-
2.	Akaun Amanah aktiviti pemeriksaan Bioekuivalens (BE) <i>BE Trust Account</i>	572.36
3.	Amalan Perkilangan Baik <i>Good Manufacturing Practice</i>	86,700.00
4.	Invois Amalan Makmal Baik <i>Good Laboratory Practice Invoice</i>	13,000.00
5.	Invois APB dalam negara <i>Local GMP Invoice</i>	446,200.00
6.	Invois APB luar negara <i>International GMP Invoice</i>	60,000.00
7.	Invois BE <i>BE Invoice</i>	500.00
8.	Penilaian Pelan Susun Atur Kilang <i>Factory Layout Plan</i>	101,850.00
9.	Lot Release Produk Plasma <i>Plasma Product Lot Release</i>	79,800.00
10.	Lot Release Produk Vaksin <i>Vaccine Lot Release</i>	113,700.00
11.	Sijil APB <i>GMP Certificate</i>	32,925.00
12.	Lesen Pemborong <i>Wholesaler's License</i>	571,500.00
13.	Lesen Pengimport <i>Import License</i>	245,000.00
14.	Lesen Pengilang <i>Manufacturer's License</i>	268,500.00
15.	Pengelasan Produk <i>Product Classification</i>	1,056,150.00
16.	Perakuan Penjualan Bebas <i>Certificate of Free Sale</i>	248,550.00
17.	Sijil Indikasi <i>Certificate of Indication</i>	92,100.00
18.	Fi Import Keluaran Tidak Berdaftar <i>Import Fee for Unregistered Item</i>	1,000.00
19.	Notifikasi Kosmetik <i>Cosmetic Notification</i>	5,472,252.00
20.	Pendaftaran Produk Baru <i>New Product Registration</i>	3,601,000.00
21.	Pendaftaran Produk Veterinar <i>Veterinary Product Registration</i>	103,500.00
22.	Pendaftaran Produk Untuk Tujuan Eksport Sahaja <i>For Export Only (FEO) Registration</i>	46,900.00
23.	Pendaftaran Semula Produk <i>Product Re-registration</i>	2,791,500.00
24.	Pendaftaran Semua Produk Veterinar <i>Veterinary Product Re-registration</i>	85,000.00
25.	Lesen Import Percubaan Klinikal <i>Clinical Trial Import License</i>	154,000.00
26.	Tambahan Indikasi <i>Additional Indication</i>	76,000.00
27.	Pertukaran Pemegang Pendaftaran <i>Change of Holder</i>	235,000.00
28.	Pertukaran Tapak Pengilangan <i>Change of Manufacturer's site</i>	94,400.00
29.	Variasi <i>Variation</i>	1,661,900.00
Jumlah Total		17,739,499.36



A large, semi-transparent teal hexagonal shape is positioned in the upper half of the image, containing several smaller hexagonal patterns and glowing teal dots. The bottom half features three large, semi-transparent white hexagonal shapes with a fine grid pattern, set against a light blue background.

Halatuju

The Way Forward

Selaras dengan matlamat negara untuk melangkah ke fasa endemik COVID-19, adalah penting bagi sektor farmaseutikal negara mengurangkan kebergantungan kepada vaksin COVID-19 yang diimport. Pelancaran Pelan Halatuju Pembangunan Vaksin Negara (NVDR) pada tahun ini telah menyarankan beberapa strategi bagi menyokong usaha ke arah *vaccine self-sufficiency* dan *security*, seperti proses pengilangan vaksin secara *fill and finish* oleh pengilang tempatan dan pembangunan vaksin hasil penyelidikan dan pembangunan tempatan.

Sehubungan dengan itu, pelbagai usaha telah dirancang oleh NPRA dalam usaha meningkatkan kawalan regulatori ke atas vaksin COVID-19 untuk menyokong pembangunan vaksin oleh pengeluar tempatan. Antara aktiviti yang telah dirancang ialah:

- a) penerimaan permohonan Kebenaran Mengilang Produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal (CTX) bagi produk vaksin COVID-19 keluaran pengilang tempatan yang menjalankan penyelidikan dan pembangunan (R&D) di Malaysia yang melibatkan kajian *First-in-Human* (FIH).
- b) pengukuhan kawalan kualiti ke atas produk vaksin COVID-19 merangkumi pembangunan fasiliti dan kepakaran NPRA untuk menjalankan pengujian ke atas vaksin COVID-19 yang dikilangkan di Malaysia bagi tujuan *Lot Release*. Strategi pengukuhan kapasiti makmal juga turut bertumpu kepada kawalan kualiti vaksin lain seperti pembangunan tatacara pengujian potensi vaksin Meningococcal dan vaksin Pneumococcal serta menjalankan ujian potensi ke atas vaksin Hepatitis B bagi tujuan surveilans dan pemantauan kualiti produk di pasaran.

Selain dari aktiviti regulatori yang melibatkan fasa endemik COVID-19, NPRA juga turut meletakkan keutamaan ke atas aktiviti-aktiviti regulatori yang lain.

As we move forward into the endemic phase of COVID-19, it is imperative that the local pharmaceutical sector reduces its dependency on imports of COVID-19 vaccines. The National Vaccine Development Roadmap recently launched this year has recommended several strategies to support the government's aspirations towards vaccine self-reliance and security starting with local vaccine manufacturing through the fill and finish process and moving towards developing vaccines from local research and development.

In this regard, various efforts by NPRA are in place to strengthen regulatory control of COVID-19 vaccines and to support vaccine development by local manufacturers. Among the activities planned include:

- a) *acceptance of applications for Clinical Trial Exemption (CTX) for COVID-19 vaccine products manufactured by local manufacturer that conducts research and development (R&D) in Malaysia involving First-in-Human (FIH) trials*
- b) *enhancing NPRA's facilities and laboratory expertise to conduct testing on COVID-19 vaccines manufactured in Malaysia for Lot Release purposes. Laboratory capacity building strategies also focuses on the quality control of other vaccines which include the development of potency testing procedures for Meningococcal and Pneumococcal vaccines as well as conducting potency testing on Hepatitis B vaccines to enhance surveillance and quality monitoring of products in the market.*

Apart from regulatory activities focusing on the COVID-19 endemic phase, NPRA also prioritises other regulatory activities.

Perkongsian maklumat dan kerjasama antara pihak berkuasa di peringkat antarabangsa adalah penting agar kelulusan penggunaan produk boleh diperoleh tepat pada masanya berdasarkan pergantungan (*reliance*) dan pengiktirafan (*recognition*) laporan penilaian yang dilakukan oleh pihak berkuasa kompeten negara lain. Dengan itu, bagi menambahbaik proses kerja penilaian produk dan meningkatkan akses ubat-ubatan, konsep *reliance* akan digunakan dengan lebih luas lagi oleh NPRA bagi produk yang telah diluluskan oleh *Stringent Regulatory Authorities* (SRA) serta menggunakan mekanisme yang disediakan oleh *World Health Organization* (WHO) iaitu WHO CRP (*Collaborative Registration Procedure*).

Dari segi perkembangan pengujian produk tradisional pula, beberapa strategi dirancang seperti latihan kepada pihak regulatori dan industri, pengiktirafan makmal panel yang menjalankan ujian keaslian dan identifikasi bagi bahan mentah herba serta penyediaan kertas polisi ke arah menguatkuasa keperluan penyerahan Sijil Analisa bahan mentah herba semasa pendaftaran produk.

Dari sudut pemantauan farmakovigilans, NPRA juga telah melaksanakan persediaan untuk menjalankan pemeriksaan *Good Pharmacovigilance Practice* (GVP) secara sukarela dengan mengemaskini garis panduan dengan kaedah pemeriksaan secara *remote* dan *hybrid*. Garis panduan yang dikemaskini akan diterbitkan pada suku pertama 2022.

Di peringkat ASEAN, NPRA sentiasa aktif menerajui aktiviti-aktiviti *Pharmaceutical Product Working Group* (PPWG) yang ditubuhkan di bawah *ASEAN Consultative Committee on Standards and Quality* (ACCSQ). NPRA berhasrat untuk membina kepakaran baru dalam skop pemeriksaan Bioekuivalens (BE) selaras dengan objektif untuk menjadi pakar rujukan

Information sharing and collaboration between authorities at the international level is important especially during the pandemic where authorization of products used for COVID-19 can be obtained in a timely manner based on reliance and recognition of evaluation performed by another competent authority. Thus, to improve product evaluation work process and promote timely access to medicines, NPRA will utilize the concept of reliance for products that have been approved by the Stringent Regulatory Authorities (SRA) as well as making use of mechanisms provided by the World Health Organization (WHO), namely the WHO CRP (Collaborative Registration Procedure).

In terms of development in natural product testing, several strategies have been planned which include trainings for regulators and industries, recognition of private laboratories conducting identification and authentication tests for herbal raw material as well as preparations towards introducing a policy to enforce the submission of Certificate of Analysis (COA) of raw material with specified tests during product registration.

From the pharmacovigilance monitoring perspective, NPRA has also initiated plans to conduct Good Pharmacovigilance Practice (GVP) voluntary inspections by updating the guidelines with remote and hybrid inspection methods. The updated guidelines will be published in the first quarter of 2022.

At the ASEAN level, NPRA has always actively spearheaded the activities of the Pharmaceutical Product Working Group (PPWG) established under the ASEAN Consultative Committee on Standards and Quality (ACCSQ). NPRA aims to build new expertise in the scope of Bioequivalence (BE) inspections with the objective of becoming a reference expert in the field

dalam bidang tersebut di peringkat dalaman dan juga di peringkat ASEAN melalui *Joint Sectoral Committee (JSC) on ASEAN Mutual Recognition Arrangement for Bioequivalence (MRA BE)*. Di bawah ASEAN Cosmetic Committee (ACC) pula Malaysia dipertanggungjawabkan untuk mengetuai tiga (3) projek utama iaitu kajian mengenai *personalized cosmetics*, kajian kosmetik dalam bentuk vial/ampul dan kajian kosmetik untuk keperluan kosmetik isian semula.

Perancangan inisiatif pengukuhan kapasiti dari pelbagai aspek kawalan regulatori menyumbang kepada persediaan NPRA ke arah pengiktirafan WHO *Listed Authority*. Penilaian oleh WHO bertujuan untuk menilai pelaksanaan indikator berdasarkan WHO *Global Benchmarking Tool* (WHO GBT). Penilaian oleh pihak WHO yang dirancang pada akhir tahun 2020 telah tertangguh disebabkan oleh situasi pandemik. Namun begitu proses akreditasi ini dijangka akan dilaksanakan pada tahun 2022. Sasaran NPRA untuk akreditasi ini adalah untuk mencapai tahap pematuhan tertinggi iaitu *Maturity Level 4*.

internally as well as for ASEAN via the Joint Sectoral Committee (JSC) on ASEAN Mutual Recognition Arrangement for Bioequivalence (MRA BE). Under the ASEAN Cosmetic Committee (ACC), Malaysia will be responsible for leading three (3) main projects, namely the study of personalised cosmetics, the study of cosmetics in the form of vials/ampoules and the study of cosmetics requirements for refill cosmetics.

These capacity building initiatives from various aspects of regulatory control are contributing towards NPRA's preparation to become a WHO Listed Authority. The assessment by WHO aims to review the implementation of indicators based on the WHO Global Benchmarking Tool (WHO GBT). The benchmarking exercise by WHO which was planned for end of 2020 was postponed due to the pandemic situation. However, this process is expected to be take place in 2022. NPRA's target for this accreditation is to achieve the highest level of compliance, which is Maturity Level 4.



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