



KEMENTERIAN KESIHATAN MALAYSIA

20  
22

*Laporan*  
**TAHUNAN**

**ANNUAL REPORT**

**Bahagian Regulatori Farmasi Negara**  
National Pharmaceutical Regulatory Agency (NPRA)



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# Visi, Misi, Objektif

## Vision, Mission, Objective

### 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*

### 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*

### Objektif Objective

Memastikan bahawa bahan-bahan terapeutik yang dibenarkan di pasaran tempatan adalah berkualiti, selamat dan berkesan 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 to ensure that notified cosmetics are safe and of quality*

## PERUTUSAN PENGARAH DIRECTOR'S FOREWORD

“

*The success of this programme is the result of NPRA's efforts in ensuring that Malaysians gain immediate access to the COVID-19 vaccine since the emergence of the virus in 2020. On behalf of the top management of the National Pharmaceutical Regulatory Agency (NPRA), I would like to express my sincerest gratitude to each and every staff from this Division who continue to deliver excellent service despite the challenging pandemic situation.*

”



Syukur Alhamdulillah pada tahun 2022 keadaan pandemik COVID-19 hampir beransur pulih dengan bilangan kes jangkitan yang semakin hari semakin berkurangan. Pada masa yang sama sebahagian besar rakyat Malaysia telah menerima vaksinasi lengkap dan dos penggalak melalui Program Imunisasi COVID-19 Kebangsaan (PICK).

Kejayaan program ini adalah hasil usaha warga NPRA sejak tahun 2020 lagi dalam memastikan akses segera rakyat Malaysia kepada produk vaksin COVID-19. Saya bagi pihak pengurusan tertinggi Bahagian Regulatori Farmasi Negara (NPRA) ingin merakamkan ucapan ribuan terima kasih kepada semua anggota dari Bahagian ini yang terus memberikan perkhidmatan yang cemerlang walaupun berhadapan situasi pandemik yang amat mencabar.

Seiring dengan Malaysia melangkah ke fasa endemik COVID-19 mulai 1 April 2022, pelbagai kelonggaran telah dilaksanakan oleh kerajaan sebagai langkah exit strategy bagi membolehkan kita semua kembali kepada kehidupan yang normal. Fasa pemulihan ini juga memberi peluang kepada NPRA untuk memberi penumpuan kepada aktiviti-aktiviti yang tergendala disebabkan pandemik seperti persediaan NPRA untuk melalui proses penilaian oleh *World Health Organization (WHO)* bagi menentukan tahap kematangan sistem regulatori melalui *WHO Global Benchmarking Tool*.

Di samping itu, terdapat keperluan untuk NPRA meningkatkan kepakaran dan memperluaskan kawalan skop regulatori sebagai persediaan untuk melaksanakan polisi-polisi baru yang dicadangkan oleh kerajaan. Antara aktiviti yang sedang diusahakan termasuk pembangunan rangka regulatori bagi kawalan produk kannabis untuk perubatan, pembangunan kapasiti makmal bagi menyokong Pelan Pembangunan Vaksin Negara (PPVN) dan pelaksanaan *e-labelling* ke atas produk farmaseutikal berdaftar secara berfasa, selari dengan kemajuan global dalam penyampaian perkhidmatan kesihatan digital.

Justeru, saya berharap semua warga NPRA sentiasa berusaha memberikan perkhidmatan terbaik dan kesungguhan yang jitu agar sistem regulatori produk farmaseutikal, semulajadi dan kosmetik di Malaysia sentiasa diperkuuh bagi menjamin keselamatan dan kesejahteraan rakyat.

*Alhamdulillah, in 2022 the COVID-19 pandemic situation has begun to subside as the number of cases continue to show a declining trend. At the same time, the majority of Malaysians have been fully vaccinated and have received booster doses through the National COVID-19 Immunisation Programme (PICK).*

*The success of this programme is the result of NPRA's efforts in ensuring that Malaysians gain immediate access to the COVID-19 vaccine since the emergence of the virus in 2020. On behalf of the top management of the National Pharmaceutical Regulatory Agency (NPRA), I would like to express my sincerest gratitude to each and every staff from this Division who continue to deliver excellent service despite the challenging pandemic situation.*

*In line with Malaysia stepping into the endemic phase of COVID-19 on 1 April 2022, various relaxations have been implemented by the government as an exit strategy to allow us to return to pre-pandemic normalcy. This recovery phase has also given NPRA the opportunity to focus on activities that have been disrupted due to the pandemic such as NPRA's preparations to undergo the benchmarking process by the World Health Organization (WHO) to ascertain its maturity level via the WHO Global Benchmarking Tool (GBT).*

*Furthermore, there is a need for NPRA to continuously expand expertise and the scope of regulatory control in preparation for implementing new policies proposed by the government. Among the activities that are currently in progress include the establishment of regulatory framework for regulation of cannabis products for medical use, the enhancement of NPRA's laboratory capacity to support the National Vaccine Development Roadmap (NVDR) as well as e-labelling of registered products in phases, which is in line with global advancement in digital healthcare.*

*Therefore, I sincerely hope NPRA will strive to provide the best service and be diligent to ensure the Malaysian regulatory system for pharmaceutical, natural products and cosmetics is continuously strengthened to guarantee the safety and well-being of the people.*

# PENGURUSAN TERTINGGI

## TOP MANAGEMENT



**YBrs Dr. Roshayati Binti Mohamad Sani**

Pengarah Gred Utama B  
Bahagian Regulatori Farmasi Negara

*Director National Pharmaceutical Regulatory Agency*



**YBrs. Puan Rosilawati  
Binti Ahmad**

Timbalan Pengarah,  
Gred Utama C  
Pusat Penilaian Produk  
& Kosmetik

*Deputy Director  
Centre of Product & Cosmetic  
Evaluation*



**YBrs. Puan Salwati  
Binti Abd. Kadir**

Timbalan Pengarah,  
Gred Utama C  
Pusat Koordinasi & Perancangan  
Strategik Regulatori

*Deputy Director  
Centre of Regulatory  
Coordination & Strategic  
Planning*



**YBrs. Dr. Noraida  
Binti Mohd Zainoor**

Timbalan Pengarah,  
Gred Utama C  
Pusat Komplians  
& Kawalan Kualiti

*Deputy Director  
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 Program Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia yang bertanggungjawab dalam memastikan kualiti, keselamatan dan keberkesanan produk farmaseutikal serta kualiti dan keselamatan produk semulajadi dan kosmetik yang dipasarkan di Malaysia.

NPRA yang dahulunya dikenali sebagai Makmal Kawalan Kimia Ubat Kebangsaan (MKKUK), telah ditubuhkan pada bulan Oktober 1978. Makmal ini telah ditubuhkan untuk melaksanakan kawalan kualiti ke atas ubat-ubatan di negara ini. Nama MKKUK kemudiannya ditukar kepada Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) pada tahun 1993 selaras dengan perkembangan fungsinya sebagai badan regulatori farmaseutikal dan sekretariat kepada Pihak Berkuasa Kawalan Dadah (PBKD). BPFK menjalankan fungsi regulatori seperti pendaftaran produk, analisis sampel, pemeriksaan dan pelesenan, aktiviti pasca pendaftaran dan pemantauan kesan sampingan ubat.

Pada 18 Julai 2016, nama BPFK secara rasminya ditukar kepada Bahagian Regulatori Farmasi Negara (NPRA). NPRA telah memperluaskan kawalan regulatori ke atas kualiti dan keselamatan produk generik (racun berjadual dan racun tidak berjadual), produk semula jadi, kosmetik, produk veterinar, Bahan Aktif Farmaseutikal (API) serta kawalan kualiti produk vaksin dan plasma melalui aktiviti Lot Release.

Sejajar dengan perkembangan serta keperluan semasa, NPRA telah melaksanakan perubahan struktur organisasi melalui proses penstrukturuan semula pada 2 Disember 2019. Dengan pelaksanaan pengstrukturuan semula ini, NPRA dapat menambah baik kualiti perkhidmatan yang diberikan bagi mencapai misi untuk menjamin kesihatan rakyat melalui kawalan regulatori ubat-ubatan dan kosmetik.

*National Pharmaceutical Regulatory Agency (NPRA) is a government agency under the Pharmaceutical Services Programme, Ministry of Health Malaysia which is responsible in ensuring the quality, safety and efficacy of pharmaceutical products as well as the quality and safety of natural products and cosmetics marketed in Malaysia.*

*NPRA, formerly known as the National Pharmaceutical Control Laboratory (MKKUK), was set up in October 1978. This institution was established to implement quality control on pharmaceutical products. MKKUK's name was later changed to National Pharmaceutical Control Bureau (NPCB) in 1993 in line with the expansion of its functions as a pharmaceutical regulatory agency and secretariat to the Drug Control Authority (DCA). NPCB carries out regulatory functions such as product registration, sample analysis, inspection and licensing, post-registration activities and adverse drug reaction monitoring.*

*On 18 July 2016, the name of NPCB was officially changed to National Pharmaceutical Regulatory Agency (NPRA). Over the years, NPRA has extended regulatory control of the quality and safety of generics (scheduled poison and non-scheduled poison), natural products, cosmetics, veterinary products, Active Pharmaceutical Ingredients (API) as well as the quality control of vaccine and plasma products through Lot Release activities.*

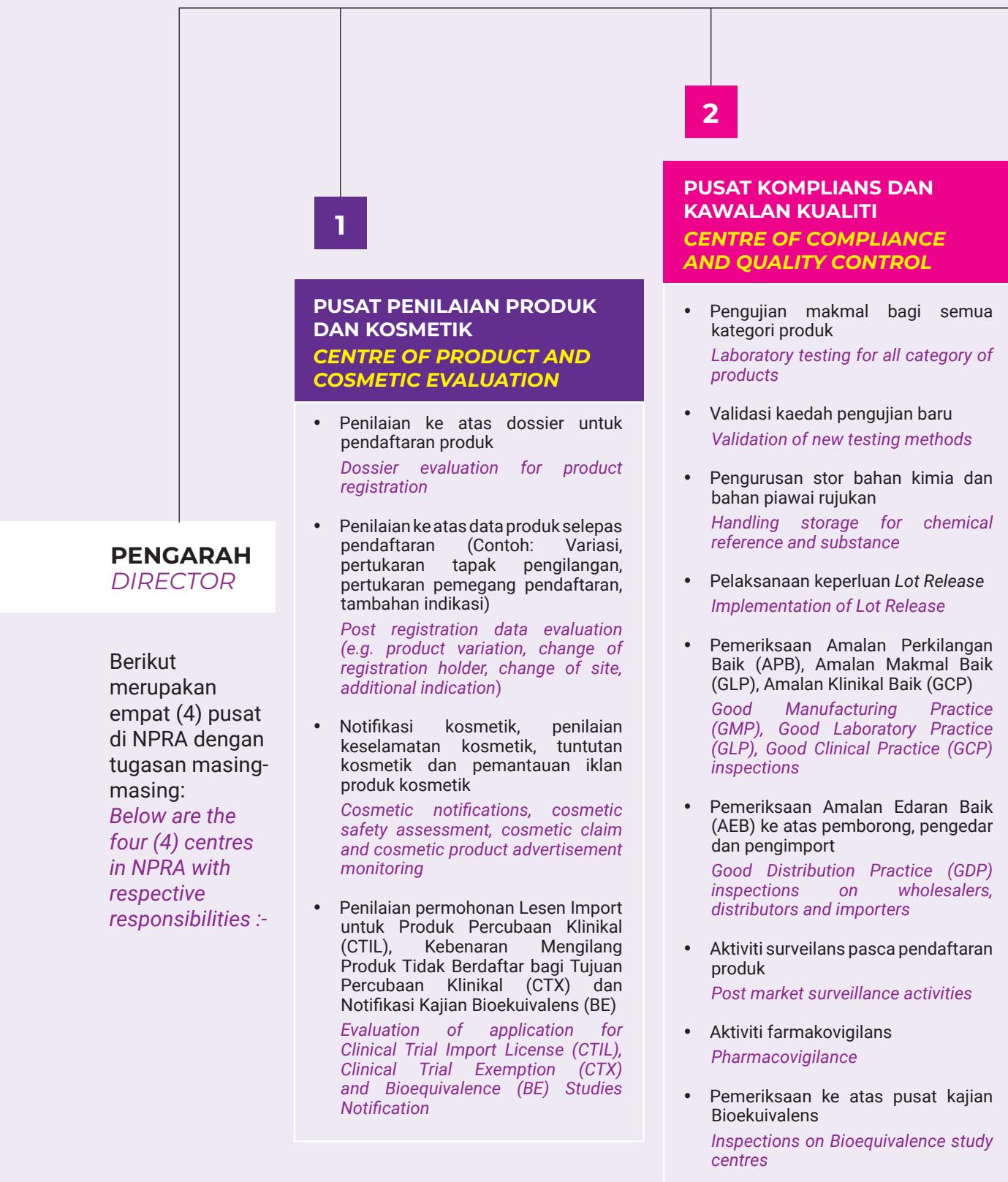
*In line with current developments, NPRA underwent a major restructuring process which came into effect on 2 December 2019. Through this restructuring exercise, NPRA will continuously strive to improve the services provided as we seek to achieve our mission to safeguard the nation's health through scientific excellence in the regulatory control of medicinal products and cosmetics.*

# CARTA ORGANISASI

*ORGANISATIONAL  
CHART*

# Carta Organisasi

## Organisational Chart



**3**

**PUSAT KOORDINASI & PERANCANGAN STRATEGIK REGULATORI**  
**CENTRE OF REGULATORY COORDINATION & STRATEGIC PLANNING**

- Perancangan halatuju, pelan strategik, koordinasi polisi baru dan penambahbaikan aktiviti serta prosedur kerja regulatori  
*Way forward and strategic planning, coordination of new policies and continuous improvement of activities and regulatory work procedures*
- Pengendalian dan pemantauan sistem pendaftaran produk dan notifikasi kosmetik dalam talian (*online*), laman web dan aplikasi *mobile* NPRA  
*Handling & monitoring of the online product registration and cosmetic notification system, NPRA website and mobile apps*
- Pengendalian latihan dalam dan luar negara, pengurusan sumber manusia, peruntukan dan perkembangan kerjaya  
*Handling of local & international trainings, human resource, allocations and career development*
- Menyelaraskan sistem pengurusan kualiti jabatan termasuk bagi pensijilan MS ISO 9001 dan Program Pengurusan Tenaga  
*Coordinates the quality management system including MS ISO 9001 and Energy Management Programme*
- Menyediakan perkhidmatan One-Stop Centre untuk komunikasi dan pembangunan industri  
*Providing One-Stop Centre services for industry communication and development*
- Penjanaan lesen dan sijil termasuk Lesen Pengilang, Lesen Pemborong, Lesen Mengimport, dan Sijil Amalan Perkilangan Baik (APB)  
*To generate licenses and certificates including manufacturer's license, wholesaler's license, import license and Good Manufacturing Practice (GMP) certificate*
- Pengelasan, pembatalan notifikasi, tarik balik pendaftaran produk, pemprosesan rayuan dan pengemaskinian status maklumat produk dan kosmetik  
*Classification, cancellation of notification, revocation of product registration, processing appeals and updating product and cosmetic information status*
- Sekretariat Mesyuarat Pihak Berkuastra Kawalan Dadah (PBKD)- Pengurusan aktiviti sebelum dan selepas mesyuarat  
*Secretariat to Drug Control Authority (DCA) Meetings –pre and post meetings activities*

**4**

**PUSAT PENTADBIRAN**  
**CENTRE OF ADMINISTRATION**

- Aktiviti pentadbiran dan kewangan  
*Administrative and financial activities*
- Aktiviti pengurusan stor alatulis  
*Stationery Store management activities*

# Piagam Pelanggan

## Client Charter

AKTIVITI ACTIVITIES	TEMPOH (hari bekerja) DURATION (Working days)
<b>PENILAIAN PRODUK &amp; KOSMETIK</b> <b>PRODUCT &amp; COSMETIC EVALUATION</b>	
<b>Penilaian Penuh</b> <i>Full Evaluation</i>	
<ul style="list-style-type: none"> <li>Menilai permohonan pendaftaran Produk: <i>To evaluate application for registration of:</i> <ul style="list-style-type: none"> <li>Ubat Generik Racun Berjadual <i>Generic Product (Scheduled Poison)</i></li> <li>Ubat Generik Bukan Racun Berjadual <i>Generic Product (Non-Scheduled Poison)</i></li> <li>Ubat Baru dan Produk Biologik <i>New Drug Product and Biological Product</i></li> </ul> </li> </ul>	210 * 210 * 245 *
<b>Penilaian Ringkas</b> <i>Abridged Evaluation</i>	
<ul style="list-style-type: none"> <li>Menilai permohonan pendaftaran Produk Ubat Generik Bukan Racun Berjadual#, Produk Suplemen Kesihatan dan Produk Semulajadi yang mengandungi: <i>To evaluate application for registration of Generic Product (Non-Scheduled Poison) #, Health Supplement and Natural Product containing:</i> <ul style="list-style-type: none"> <li>Bahan aktif tunggal <i>Single active ingredient</i></li> <li>Dua (2) atau lebih bahan aktif <i>Two (2) or more active ingredients</i></li> </ul> </li> <li>Pengeluaran notifikasi kosmetik <i>Issuance of cosmetic notification</i></li> <li>Keputusan permohonan pertukaran Pemegang Pendaftaran <i>Change of Registration Holder</i></li> <li>Keputusan permohonan pertukaran tapak pengilang <i>Change of manufacturing site application</i></li> </ul>	116 * 136 * 1 ^ 45 * 60 *

AKTIVITI ACTIVITIES	TEMPOH (hari bekerja) DURATION (Working days)
<b>PELESENAN LICENSING</b>	
<ul style="list-style-type: none"> <li>Kelulusan lesen pengilang, pemborong dan mengimport <i>Issuance of manufacturer's, wholesaler's and import license</i></li> <li>Penilaian Permohonan Lesen Import untuk Percubaan Klinikal (CTIL) dan Kebenaran Mengilang untuk Percubaan Klinikal (CTX): <i>Evaluation of application for Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX):</i> <ul style="list-style-type: none"> <li>Bagi produk yang melibatkan Kajian Fasa I, Produk Biologikal, Cell &amp; Gene Therapy Products (CGTPs) dan Produk Herba <i>For products involving Phase 1 Trial, Biological products, Cell &amp; Gene Therapy Products (CGTPs) and Herbal Products</i></li> <li>Bagi produk-produk selain daripada yang disebutkan di atas <i>For products other than stated above</i></li> </ul> </li> </ul>	4 *  45 *  30 *
<b>PENSIJILAN CERTIFICATION</b>	
<ul style="list-style-type: none"> <li>Pengeluaran Sijil Penjualan Bebas (CFS) bagi: <i>Issuance of Certificate of Free Sale (CFS) for:</i> <ul style="list-style-type: none"> <li>Kosmetik <i>Cosmetic</i></li> <li>Produk Veterinar <i>Veterinary products</i></li> </ul> </li> <li>Pengeluaran Sijil Produk Farmaseutikal (CPP) <i>Issuance of Certificate of Pharmaceutical Product</i></li> </ul>	15 *  15 *  15 *

\* Setelah permohonan lengkap diterima

*Upon receipt of complete application*

^ Bagi permohonan yang memenuhi keperluan yang ditetapkan

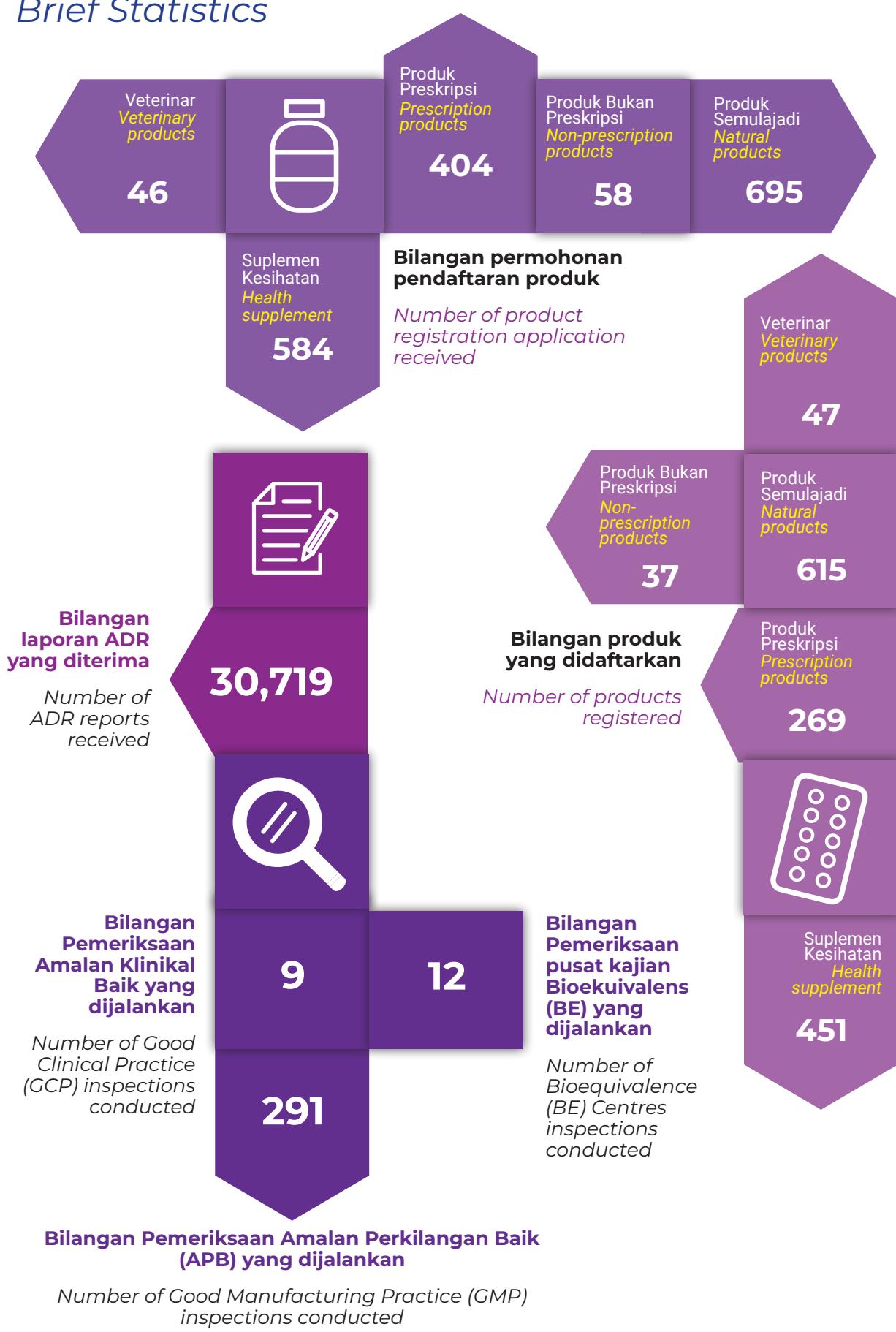
*For applications fulfilling the stipulated requirements*

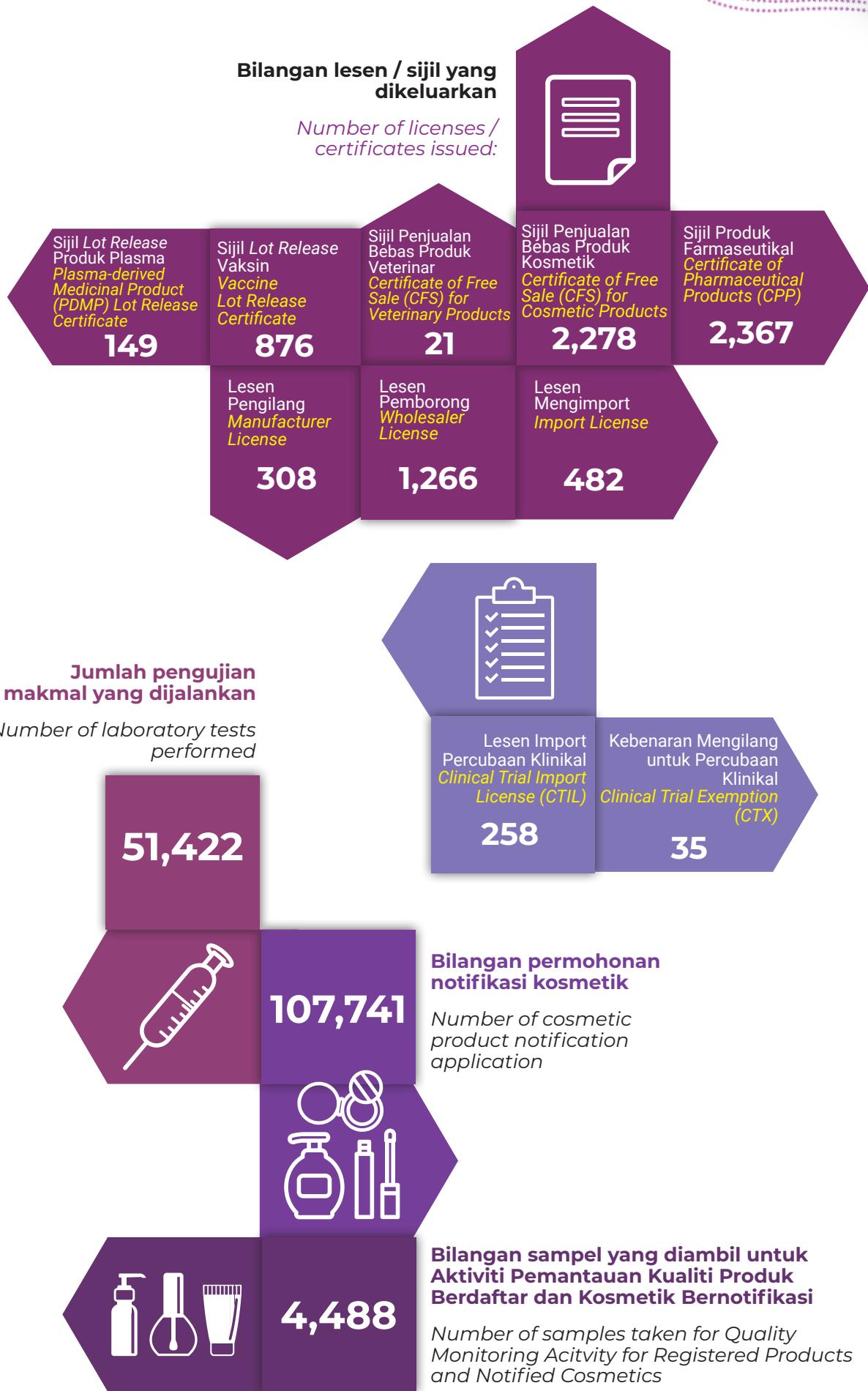
#Rujuk Drug Registration Guidance Document (DRGD) untuk senarai produk

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

# Statistik Ringkas

## Brief Statistics





# MAKLUMAT TERKINI REGULATORI

*REGULATORY  
UPDATES*



# Pelaksanaan Aktiviti Regulatori Baharu Sepanjang Tahun 2022

Implementation Of New Regulatory Activities Throughout 2022

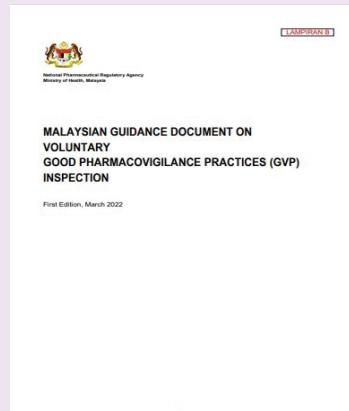
1

## Pelaksanaan Pemeriksaan Good Pharmacovigilance Practices (GVP) Secara Sukarela ke atas Pemegang Pendaftaran Produk Farmaseutikal

*Implementation of Voluntary Good Pharmacovigilance Practice (GVP) Inspection on Pharmaceutical Product Registration Holder*

Pada 2 September 2021, Bahagian Regulatori Farmasi Negara (NPRA) telah mengeluarkan dua (2) garis panduan yang baharu iaitu:

- (a) *Malaysian Guidelines on Good Pharmacovigilance Practice (GVP) for Product Registration Holders, First Edition 2021* (untuk rujukan Pemegang Pendaftaran Produk)
- (b) *Adverse Drug Reaction (ADR)/ Adverse Event Following Immunisation (AEFI) Reporting Manual for Healthcare Providers* (untuk rujukan anggota kesihatan)



Susulan itu, aktiviti pemeriksaan Good Pharmacovigilance Practice (GVP) akan dijalankan ke atas Pemegang Pendaftaran Produk (PRH) untuk menilai keupayaan dan pematuhan PRH dalam memenuhi keperluan farmakovigilans. Maklumat terperinci mengenai mekanisme pemeriksaan adalah seperti yang digariskan di dalam *Malaysian Guidance Document on Voluntary Good Pharmacovigilance Practices (GVP) Inspection*. Pemeriksaan ini dimulakan dengan fasa sukarela bagi memberi tempoh masa yang mencukupi untuk PRH mengukuhkan sistem farmakovigilans masing-masing sebelum pelaksanaan fasa seterusnya.

Melalui surat kepada PRH pada 28 Mac 2022, NPRA telah mempelawa PRH yang berminat untuk menyertai pemeriksaan GVP secara sukarela ini dengan mengemukakan permohonan bertulis dan dokumen *Pharmacovigilance System Summary Report (PVSS)*.

*On 2 September 2021, the National Pharmaceutical Regulatory Agency (NPRA) issued two (2) new guidelines which include the following:*

- (a) *Malaysian Guidelines on Good Pharmacovigilance Practice (GVP) for Product Registration Holders, First Edition 2021 [for reference of Product Registration Holders (PRH)]*

- (b) *Adverse Drug Reaction (ADR)/ Adverse Event Following Immunisation (AEFI) Reporting Manual for Healthcare Providers (for the reference of health personnel)*

*Following the issuance of these guidelines, the Good Pharmacovigilance Practice (GVP) inspection activities will be conducted on Product Registration Holders (PRH) to assess PRH's ability to comply to the GVP requirements. Detailed information on the mechanism of the inspection can be found in the Malaysian Guidance Document on Voluntary Good Pharmacovigilance Practices (GVP) Inspection. The inspection starts with a voluntary phase to allow sufficient time for PRH to strengthen their respective pharmacovigilance systems before moving on to the next phase of implementation.*

*Through a letter to PRH dated 28 March 2022, NPRA has invited PRH who are interested to participate in the voluntary GVP inspection to submit a written application together with the Pharmacovigilance System Summary Report (PVSS) document.*

## 2

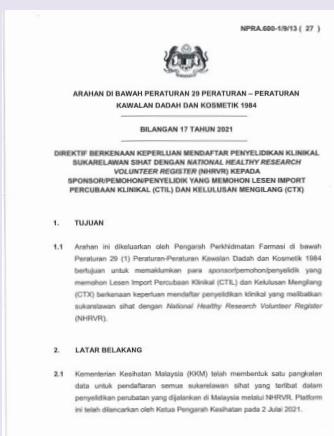
### **Direktif Berkeraan Keperluan Mendaftar Penyelidikan Klinikal Sukaralewan Sihat dengan National Healthy Research Volunteer Register (NHRVR) kepada Sponsor /Pemohon /Penyelidik yang Memohon Lesen Import Percubaan Klinikal (CTIL) dan Kelulusan Mengilang (CTX)**

### ***Directive on the Requirement to Register Healthy Research Volunteers with the National Healthy Research Volunteer Register (NHRVR) for Sponsor /Applicant /Researcher Applying Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX)***

Kementerian Kesihatan Malaysia (KKM) telah membentuk satu pangkalan data untuk pendaftaran semua sukarelawan sihat yang terlibat dalam penyelidikan klinikal yang dijalankan di Malaysia melalui NHRVR. Platform ini telah dilancarkan pada 2 Julai 2021.

Semua penyelidikan klinikal sukarelawan sihat yang melibatkan permohonan Lesen Import Percubaan Klinikal (CTIL) dan Kelulusan Mengilang (CTX) mesti didaftarkan dengan NHRVR. Kegagalan pemohon/sponsor/penyelidik mendaftarkan penyelidikan yang akan dijalankan dengan NHRVR boleh menyebabkan CTIL dan CTX ditarik balik dan data-data yang terhasil dari penyelidikan tersebut tidak dapat diterima/digantung untuk tujuan pendaftaran produk.

Semua unit Fasa I dan Pusat Kajian BE diwajibkan untuk menerapkan penggunaan NHRVR ke dalam kajian-kajian yang bakal dijalankan. Kegagalan berbuat demikian akan menyebabkan status penyenaraian dalam Program Akreditasi Unit Fasa I NPRA dan Program Komplians Pusat Kajian BE NPRA digantung atau permohonan akreditasi yang baharu tidak dapat disenaraikan dalam program berkaitan. Tarikh kuat kuasa direktif ialah 1 Jun 2022.



*The Ministry of Health Malaysia (MOH) has established a database for the registration of healthy volunteers involved in clinical research conducted in Malaysia through the NHRVR. The platform was launched on 2 July 2021.*

*Clinical research with healthy volunteers involving Clinical Trials Import License (CTIL) and Clinical Trial Exemption (CTX) applications must be registered with the NHRVR. Failure of the applicant/sponsor/researcher to register the research to be conducted with the NHRVR may cause the CTIL and CTX to be withdrawn and the data resulting from the research to be rejected/suspended for product registration.*

*All Phase I units and BE Study Centers are required to apply the use of NHRVR into the studies to be conducted. Failure to do so will result in the suspension of listing into the NPRA Phase I Unit Accreditation Program and NPRA BE Study Center Compliance Program or new accreditation applications not being listed in the relevant program. The effective date of the directive is 1 June 2022.*

# 3

## **Pekeliling Penamaan Semula Prosedur ‘Do & Tell’ kepada ‘Tell & Do’ dan Pengemaskinian Senarai Jenis Variasi Minor Variation (Prior Approval) dan Major Variation bagi Produk Farmaseutikal, Suplemen Kesihatan dan Produk Semulajadi**

### ***Circular on Renaming the ‘Do & Tell’ Procedure to ‘Tell & Do’ and updating of the Minor Variations (Prior Approval) and Major Variations Lists for Pharmaceutical Products, Health Supplements and Natural Products***

Sejak tahun 2020, beberapa jenis variasi Minor Variation Prior Approval (MiV-PA) dan Major Variation (MaV) telah dibenarkan untuk diproses sebagai Minor Variation Notification (MiV-N). Walau bagaimanapun, Bahagian Regulatori Farmasi Negara (NPRA) telah menamakan semula prosedur ini untuk menggambarkan proses kerja sebenar dengan lebih tepat. Prosedur yang baharu akan dikenali sebagai ‘Tell & Do’ di mana selepas permohonan variasi dikemukakan, pemegang pendaftaran boleh meneruskan perubahan pada produk sementara mendapat kelulusan daripada NPRA.

Pekeliling ini telah dikeluarkan pada 14 Julai 2022 dan pelaksanaan ini adalah terpakai untuk permohonan variasi yang diterima mulai 1 Ogos 2022.

*Since 2020, some types of Minor Variation Prior Approval (MiV-PA) and Major Variation (MaV) have been allowed to be processed as Minor Variation Notification (MiV-N). However, the National Pharmaceutical Regulatory Agency (NPRA) has renamed this procedure to reflect the actual work process more accurately. The new procedure will be known as ‘Tell & Do’ where after a variation application is submitted, the registration holder can proceed with changes to the product pending approval from NPRA.*

*This circular was issued on 14 July 2022 and is applicable to variation applications received from 1 August 2022 onwards.*



# 4

## Pekeliling Berkenaan Pengemaskinian Garis Panduan Malaysian Variation Guideline for Pharmaceutical Products

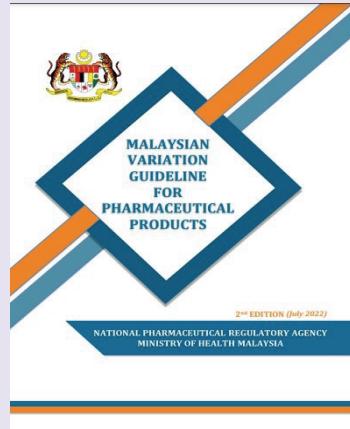
### Circular on the Updated Malaysian Variation Guideline for Pharmaceutical Products

Semakan semula telah dijalankan ke atas garis panduan *Malaysian Variation Guideline* (MVG) sedia ada untuk memastikan dokumen tersebut relevan dengan amalan semasa dan dikemaskini selaras dengan dokumen ASEAN Variation Guideline for Pharmaceutical Products (AVG) Revision 1 (2019) dan Revision 2 (2021).

Susulan pengemaskinian ini, penerbitan *Malaysian Variation Guideline for Pharmaceutical Products (2<sup>nd</sup> Edition)* akan menggantikan dokumen *Malaysian Variation Guideline (MVG) for Pharmaceutical Products, First Edition*. Pekeliling ini telah dikeluarkan pada 14 Julai 2022 dan tarikh kuat kuasa perkara ini adalah pada 1 Ogos 2022.

*A review on the existing Malaysian Variation Guideline (MVG) has been conducted to ensure that the document is relevant to current practice and updated in line with the ASEAN Variation Guideline for Pharmaceutical Products (AVG) Revision 1 (2019) and Revision 2 (2021) document.*

*Following this update, the publication of Malaysian Variation Guideline for Pharmaceutical Products (2nd Edition) will replace the document Malaysian Variation Guideline (MVG) for Pharmaceutical Products, First Edition. This circular was issued on 14 July 2022 and the effective date of this guideline is 1 August 2022.*



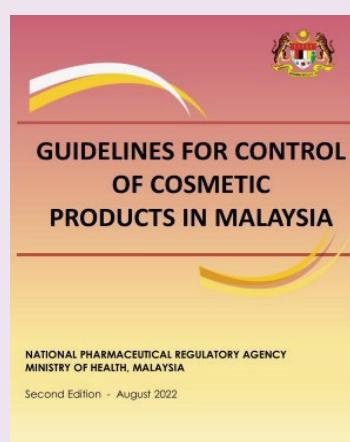
# 5

## Pekeliling Bil 2/2022 Makluman Penerbitan Edisi Terkini Garis Panduan Kosmetik- Guidelines for Control of Cosmetic Products in Malaysia- Second Edition, August 2022

### Circular No 2/2022 Publication of the Guidelines for Control of Cosmetic Products in Malaysia- Second Edition, August 2022

Garis Panduan Kawalan Produk Kosmetik di Malaysia merupakan rujukan untuk proses notifikasi kosmetik termasuk kawalan kualiti, pemeriksaan dan aktiviti pengawasan pasca pasaran produk kosmetik. Edisi kedua garis panduan ini, yang telah diterbitkan pada 1 Ogos 2022, menggantikan Garis Panduan Kawalan Produk Kosmetik di Malaysia Semakan Pertama 1 Februari 2017. Pekeliling pemakluman ini telah dikeluarkan pada 14 Julai 2022.

*The Guidelines for Control of Cosmetic Products in Malaysia serves as a reference for the notification process which include quality control, inspection and post-market surveillance activities for cosmetics. The second edition of this guideline, published on 1 August 2022, replaces the Guidelines for Control of Cosmetic Products in Malaysia First Revision 1<sup>st</sup> February 2017. The circular for this announcement was issued on 14 July 2022.*



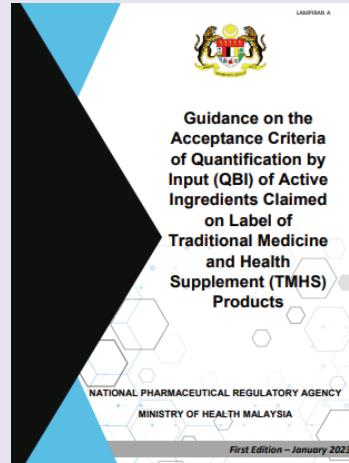
# 6

## Direktif Berkenaan Pelaksanaan Garis Panduan *Guidance on the Acceptance Criteria for Quantification by Input (QBI) of Active Ingredients Claimed on Label of Traditional Medicine and Health Supplements (TMHS Products)*

### *Directive on the Implementation of the Guidance on the Acceptance Criteria for Quantification by Input (QBI) of Active Ingredients Claimed on Label of Traditional Medicine and Health Supplements (TMHS Products)*

Berdasarkan *Drug Registration Guidance Document (DRGD)*, ujian assay bagi bahan aktif yang dituntut pada label produk semulajadi dan suplemen kesihatan merupakan salah satu keperluan dalam sijil analisis produk siap dan data stabiliti. Bahan aktif adalah merangkumi komponen (*component*)/ *compound* aktif yang dituntut pada label produk.

Pihak industri menghadapi kesukaran untuk melaksanakan pengujian bagi setiap komponen bahan aktif dalam produk terutamanya yang mengandungi formulasi produk siap yang kompleks (*multiple ingredients*). Oleh yang demikian, terdapat keperluan untuk mengkaji dan menetapkan kriteria penerimaan *Quantified by Input (QBI)* untuk produk semulajadi dan suplemen kesihatan.



*Quantified by Input (QBI)* adalah dibenarkan sekiranya memenuhi kriteria-kriteria yang diperincikan dalam *Guidance on the Acceptance Criteria for Quantification by Input (QBI) of Active Ingredients Claimed on Label of Traditional Medicine and Health Supplement (TMHS) Products*. Direktif ini telah dikeluarkan susulan Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) kali ke-378 pada 3 November 2022. Tarikh kuatkuasa direktif ini ialah mulai 1 Januari 2023.

*Based on the Drug Registration Guidance Document (DRGD), assay testing for active ingredients claimed on the label of natural products and health supplements is one of the requirements in the finished product certificate of analysis and stability data. Active ingredients include active components/compounds that are claimed on the product label.*

*The industry faces difficulties in conducting tests for each active ingredient component in products, especially those containing complex finished product formulations (multiple ingredients). Therefore, there is a need to study and establish Quantified by Input (QBI) acceptance criteria for natural products and health supplements.*

*QBI is allowed if it meets the criteria outlined in the Guidance on the Acceptance Criteria for Quantification by Input (QBI) of Active Ingredients Claimed on the Label of Traditional Medicine and Health Supplement (TMHS) Products. This directive was issued following the 378th Drug Control Authority (DCA) Meeting on 3 November 2022. The effective date of this directive is 1 January 2023.*

# 7

## Direktif untuk Menerima Permohonan Lesen Import Percubaan Klinikal (CTIL) dan Kebenaran Mengilang Produk Tidak Berdaftar untuk Tujuan Percubaan Klinikal (CTX) bagi Produk Biologik (kecuali Produk Cell and Gene Therapy) yang Melibatkan Kajian Klinikal First-in-Human (FIH)

### *Directive on the Acceptance of Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) for Biologics (except Cell and Gene Therapy Products) involving First-in-Human (FIH) Clinical Trials*

Mengikut kerangka regulatori semasa dan Direktif First-in-Human (FIH) sedia ada, permohonan CTIL/CTX yang melibatkan kajian FIH akan diterima oleh NPRA mengikut kategori produk secara berperingkat.

**Fasa pertama:** Hanya kajian FIH yang melibatkan produk entiti kimia baru dan produk herba dengan tuntutan tinggi akan diterima.

**Fasa kedua:** Kajian FIH produk vaksin COVID-19 keluaran pengilang tempatan yang menjalankan penyelidikan dan pembangunan (R&D) di Malaysia akan diterima

Penerimaan kajian FIH bagi produk biologik bukan sahaja kritikal untuk pembangunan vaksin buatan Malaysia, malah ia juga dipercayai dapat mendorong program pembangunan vaksin secara menyeluruh (dari Fasa I ke Fasa III) untuk dijalankan di Malaysia, selaras dengan hala tuju Pelan Pembangunan Vaksin Negara. Oleh itu, demi kepentingan negara dan berdasarkan pengalaman yang diperolehi ketika ini, pihak NPRA bersedia untuk menilai permohonan CTIL/CTX melibatkan kajian FIH untuk produk biologik (kecuali produk *Cell and Gene Therapy*).

Direktif ini telah dikeluarkan susulan Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) kali ke-379 pada 13 Disember 2022. Tarikh kuatkuasa direktif ini ialah mulai 1 Januari 2023.

*Based on the current regulatory framework and the existing First-in-Human (FIH) Directives, NPRA accepts applications for Clinical Trial Import License (CTIL) / Clinical Trial Exemption (CTX) for clinical trials involving FIH trials in stages, according to product category.*

**First phase:** Only FIH trials involving new chemical entity and herbal products with high claim will be accepted.

**Second phase:** FIH trials involving COVID-19 vaccines produced by local manufacturers conducting research and development (R&D) in Malaysia will be accepted.

*The acceptance of the FIH study for biological products is not only critical for the development of homegrown vaccines, but it is also anticipated to encourage the overall vaccine development program (from Phase I to Phase III) to be conducted in Malaysia, in line with the direction of the National Vaccine Development Roadmap. Therefore, in the interest of the country and based on the experience gained at this point of time, NPRA is ready to evaluate CTIL/CTX applications involving FIH trials for biologics (except for Cell and Gene Therapy products).*

*This directive was issued following the 379th Meeting of the Drug Control Authority (DCA) on 13 December 2022. The effective date of this directive is 1 January 2023.*



# 8

## Direktif Berkaitan Pengemaskinian Keperluan Standard Pematuhan Amalan Perkilangan Baik (APB) Produk Steril Veterinar

### Directive on the Updated Requirement for Good Manufacturing Practice (GMP) Standards for Sterile Veterinary Products

Pihak Berkuasa Kawalan Dada (PBKD) dalam mesyuarat kali ke-224, telah memutuskan untuk menguatkuaskan pelesenan terhadap pengilang tempatan yang mengilang produk veterinar di Malaysia berkuatkuasa 1 Januari 2012. Terdapat keperluan untuk menyeragamkan standard pematuhan APB yang perlu dipatuhi oleh semua pengilang tempatan dan luar negara bagi produk steril veterinar. Penyeragaman ini adalah untuk mewujudkan persaingan sihat di antara pengilang luar negara dan tempatan. Pengemaskinian keperluan standard pematuhan APB bagi produk steril veterinar adalah seperti berikut:

#### Bukti pematuhan APB yang diterima untuk produk steril veterinar:

Sijil APB atau Laporan Pemeriksaan APB yang dikeluarkan oleh:

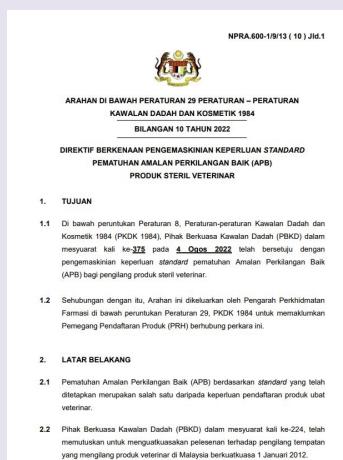
- Pihak berkuasa (PA) anggota *Pharmaceutical Inspection Co-operation Scheme* (PIC/S) dan Organisasi Rakan Kongsi Bersekutunya (Associated Partner Organisations) \* atau;
- PA bukan anggota PIC/S dari negara anggota PIC/S

Nota: Sijil APB dan Laporan Pemeriksaan APB yang dikeluarkan oleh PA bukan anggota PIC/S dari negara anggota PIC/S boleh diterima tertakluk kepada penilaian yang memuaskan ke atas:

- kesetaraan Sistem Kualiti Inspektoratnya berhubung dengan PA PIC/S atau;
- wujudnya sebarang kerjasama atau persefahaman rasmi antara kedua-dua pihak (PA bukan anggota PIC/S dan PA PIC/S)

Direktif ini telah dikeluarkan pada 11 Ogos 2022 dan terpakai kepada permohonan pendaftaran baru produk steril veterinar yang diterima bermula dari tarikh kuat kuasa, iaitu 1 Julai 2023.

*Compliance to Good Manufacturing Practice (GMP) is one of the requirements for the registration of veterinary products. The Drug Control Authority (DCA) at its 224th meeting, has agreed to enforce licensing on local manufacturers of veterinary products in Malaysia with effect from 1 January 2012. There is a need to standardise the GMP compliance standards which must be adhered by both local and foreign manufacturers of sterile veterinary products. This is to foster healthy competition between foreign and local manufacturers. The updated GMP compliance standard requirements for sterile veterinary products are shown below:*



**The GMP compliance evidence accepted for sterile veterinary product:**

GMP Certificate or GMP Inspection Report issued by:

- a) Pharmaceutical Inspection Co-operation Scheme (PIC/S) Participating Authorities (PA) and its Associated Partner Organisations\* or;
- b) Non-PIC/S PA of PIC/S member country

Note: GMP Certificate or GMP Inspection Report issued by Non-PIC/S PA of PIC/S member country may be accepted for review upon satisfactory evidence of:

- a) equivalency of its Inspectorate Quality System in relation to the PIC/S PA or;
- b) existence of any formal collaboration or understanding between both parties (Non-PIC/S PA and PIC/S PA)

This directive was issued on 11 August 2022 and is applicable to new registration applications for sterile veterinary products received from 1 July 2023 onwards.

# 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 internationally recognised as a "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals" in 1996. This recognition is an acknowledgement from World Health Organization (WHO) for NPRA's contributions in the field of pharmaceutical regulatory affairs.*



NPRA, Malaysia telah menjadi anggota *Pharmaceutical Inspection Co-operation Scheme (PIC/S)* sejak 1 Januari 2002. Sejak itu, NPRA terlibat secara aktif dalam aktiviti berkaitan program Amalan Perkilangan Baik (APB) dan *Quality Assurance Programme* di peringkat tempatan dan antarabangsa.

*NPRA, Malaysia, has been a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 1 January 2002. Since then, NPRA has been actively involved in activities related to Good Manufacturing Practice (GMP) and Quality Assurance Programme at the domestic and international level.*



NPRA, Malaysia telah diterima sebagai ahli penuh *Organisation for Economic Cooperation and Development Good Laboratory Practice (GLP) 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.

*NPRA, Malaysia has been accepted as a full adherent member to the Organisation for Economic Cooperation and Development Good Laboratory Practice (GLP) Mutual Acceptance of Data System (OECD MAD) since 29 March 2013. 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 telah diterima sebagai pemerhati kepada *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)* sejak bulan Jun 2018. Malaysia juga telah diterima sebagai ahli *The International Pharmaceutical Regulator's Programme (IPRP)* pada bulan November 2019.

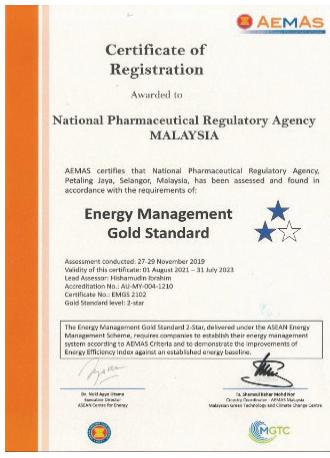
*Malaysia has been accepted as an observer to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) since June 2018. Malaysia has also been accepted as a member to The International Pharmaceutical Regulator's Programme (IPRP) since November 2019.*

NPRA telah berjaya mengekalkan pensijilan MS ISO 9001 dari pihak SIRIM QAS Sdn. Bhd. sejak tahun 2001. Pensijilan bermula dari versi MS ISO 9002:1994 dan terkini dengan versi MS ISO 9001:2015 dengan nombor sijil QMS 00894 yang sah sehingga 24 Mei 2025.

*NPRA has successfully maintained the MS ISO certification from SIRIM QAS Sdn. Bhd. since 2001. Starting with version MS ISO 9002: 1994 and most recently the certification of version MS ISO 9001:2015 with current certificate number QMS 00894 which is valid until 24 May 2025.*

Makmal NPRA telah memperoleh akreditasi MS ISO/IEC 17025:2005 dari Jabatan Standard Malaysia sejak 2010 dan telah berjaya naiktaraf ke MS ISO/IEC 17025:2017 pada bulan Oktober 2020 bagi pengujian produk tradisional dan kosmetik. Pada tahun 2022, makmal NPRA telah menambah skop akreditasi bagi penentuan kandungan aluminium dalam vaksin Hepatitis B. Sijil terkini dengan no. SAMM 450 adalah sah sehingga 14 Januari 2025.

*The NPRA laboratory has obtained MS ISO/IEC 17025:2005 accreditation from the Malaysian Standards Department in 2010 and MS ISO/IEC 17025:2017 in October 2020 for the testing of natural products and cosmetics. In the year 2022, the NPRA laboratory has increased the scope of accreditation to include the determination of aluminium content in Hepatitis B vaccine products. The current certificate no. SAMM 450 is valid until 14 January 2025.*



NPRA telah memperolehi pensijilan dari *Malaysian Green Technology and Climate Change Corporation* (MGTC) bermula dengan pensijilan 1-Star *Energy Management Gold Standard* (EMGS) ASEAN Energy Management Scheme (AEMAS) pada 1 Mei 2019 dan kini dengan pensijilan 2-Star EMGS AEMAS yang diperoleh pada 1 Ogos 2021.

*NPRA has obtained certification from the Malaysian Green Technology and Climate Change Corporation (MGTC), starting with the ASEAN Energy Management Scheme (AEMAS) 1-Star Energy Management Gold Standard (EMGS) certification on 1 May 2019 followed by the latest certification which is the 2-Star EMGS AEMAS certification obtained on 1 August 2021.*



NPRA telah diberi Anugerah Pengawal Selia Aktif / Unified Public Consultation (UPC) oleh *Malaysian Productivity Corporation* (MPC) di Persidangan Amalan Baik Peraturan 2021 bagi pencapaian sepanjang tahun 2020 dan 2021.

*NPRA was awarded the Active Regulator / Unified Public Consultation (UPC) Award by the Malaysian Productivity Corporation (MPC) at the 2021 Good Regulatory Practice Conference for its achievements throughout 2020 and 2021.*



NPRA telah berjaya mengekalkan pensijilan dari *Sustainable Energy Development Authority* (SEDA) sejak tahun 2021. Kini NPRA memperoleh pensijilan 2-diamond SEDA Malaysia Sustainable Energy Low Carbon Buildings pada 17 November 2022.

*NPRA has successfully maintained certification from the Sustainable Energy Development Authority (SEDA) since 2021. With that, NPRA has now obtained the 2-diamond SEDA Malaysia Sustainable Energy Low Carbon Buildings certification on 17 November 2022.*

# STATISTIK

*STATISTICS*

## A) KOORDINASI REGULATORI PRODUK DAN KOSMETIK

NPRA menerima dan memproses permohonan pengelasan produk mengikut tempoh masa yang ditetapkan. Permohonan dinilai berdasarkan formulasi bahan aktif dan indikasi produk. Ia merangkumi produk-produk seperti produk ubat baru, biologik, produk generik, suplemen kesihatan, produk semulajadi, veterinar, makanan, peranti perubatan, racun makhluk perosak dan produk pertanian.

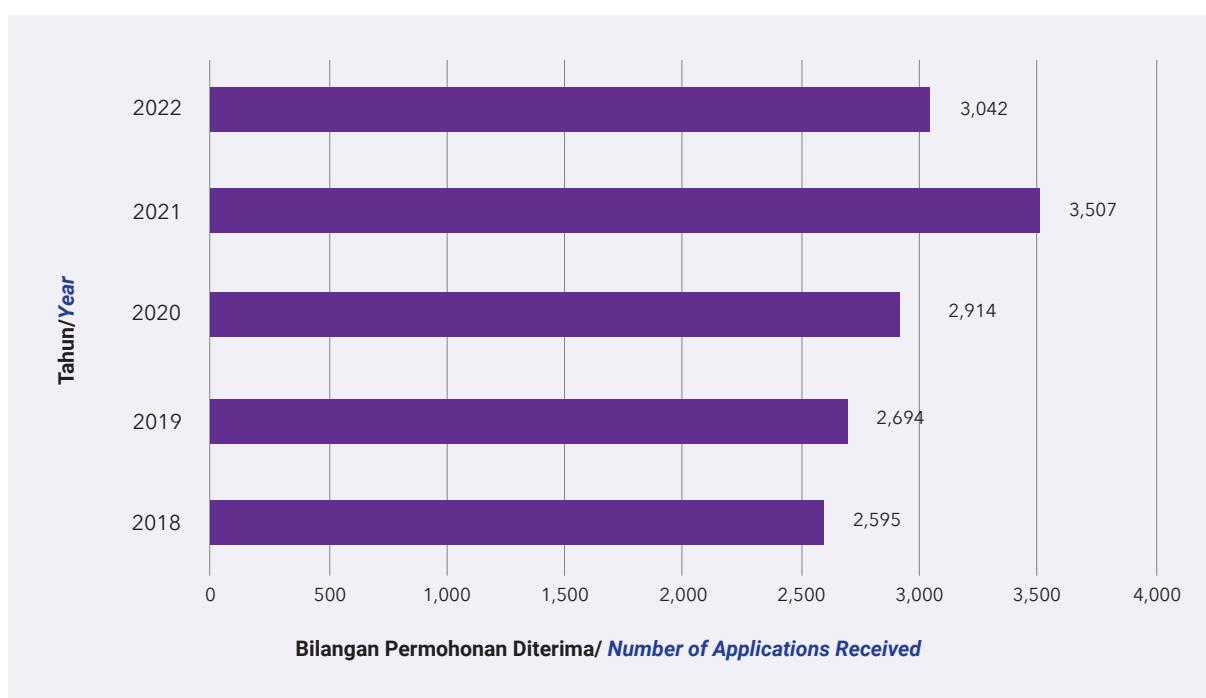
Bagi tahun 2022, sebanyak 3,042 permohonan pengelasan produk telah diterima berbanding dengan 3,507 permohonan yang telah diterima pada tahun tahun sebelumnya.

## A) PRODUCT AND COSMETIC REGULATORY COORDINATION

NPRA receives and processes product classification applications according to the stipulated timeline. The applications are evaluated based on the active ingredient, formulation and product indications. It includes products such as new drug products, biologics, generic products, health supplements, natural products, veterinary products, food, medical devices, pesticides, and agriculture products.

In year 2022, 3,042 product classification applications were received compared to 3,507 in the previous year.

**Rajah 1: Bilangan permohonan pengelasan produk yang diterima, 2018-2022**  
**Figure 1: Number of product classification application received, 2018-2022**



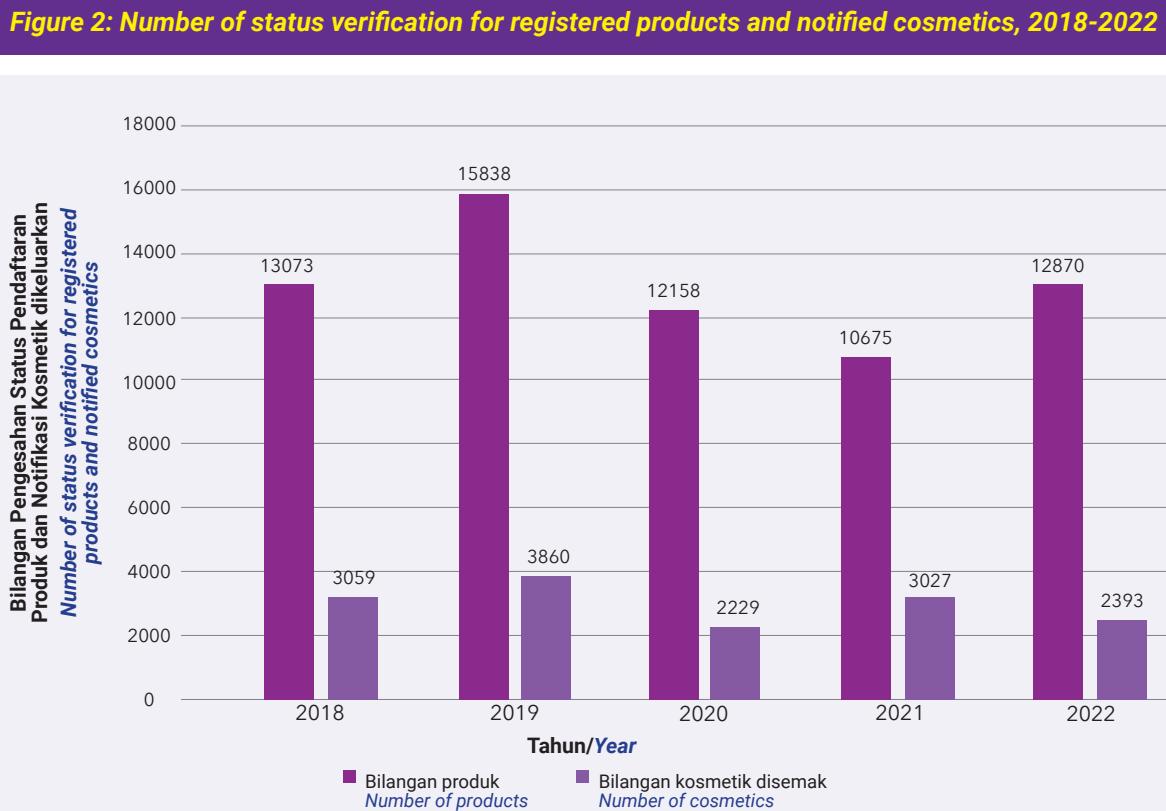
Aktiviti pemantauan dan rampasan produk-produk tidak berdaftar di pasaran tempatan dijalankan oleh Pegawai Penguatkuasaan Farmasi di seluruh negara. Dengan kerjasama NPRA, status pendaftaran produk farmaseutikal dan status notifikasi kosmetik yang disyaki tidak berdaftar/dinotifikasi di pasaran tempatan akan disemak dan ditentu sahkan.

Justeru, 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 dan status notifikasi kosmetik yang diterima untuk semakan pada tahun 2022 adalah masing-masing sebanyak 12,870 dan 2,393.

*Pharmacy Enforcement Officers throughout the country will monitor and seize unregistered products sold in the local market. 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 are checked and verified.*

*This 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 and cosmetic notification status applications received and processed in 2022 was 12,870 and 2,393 respectively.*

**Rajah 2: Bilangan pengesahan status pendaftaran produk dan status notifikasi kosmetik, 2018-2022**



## B) PELESENAN

Pada tahun 2022, sebanyak 308 Lesen Pengilang, 482 Lesen Mengimport dan 1,266 Lesen Pemborong telah dikeluarkan.

## B) LICENSING

In 2022, 308 Manufacturer Licenses, 482 Import Licenses and 1,266 Wholesaler Licenses were issued.

**Rajah 3: Bilangan lesen yang dikeluarkan, 2018-2022**  
*Figure 3: Number of licenses issued, 2018-2022*



## C) PENILAIAN DAN PENDAFTARAN PRODUK

NPRA bertanggungjawab untuk memproses permohonan pendaftaran untuk produk ubat baru, produk biologik, produk generik, suplemen kesihatan, produk semulajadi dan juga produk veterinar. Sepanjang tahun 2022, sebanyak 1,787 permohonan pendaftaran produk baru telah diterima dan 1,419 produk telah didaftarkan. Produk-produk yang telah didaftarkan ini terdiri daripada 63.9 peratus produk tempatan dan 36.1 peratus produk yang diimport. Kumulatif produk yang berdaftar sehingga Disember 2022 adalah 25,949 produk.

## C) PRODUCT EVALUATION AND REGISTRATION

NPRA is responsible for processing registration applications of new drug products, biologic products, generic products, health supplements, natural products as well as veterinary products. Throughout the year of 2022, a total of 1,787 new product registration applications were received and 1,419 products were registered. These newly registered products comprise of 63.9 percent local products and 36.1 percent imported products. The cumulative number of registered products until December 2022 is 25,949 products.

**Jadual 1: Bilangan produk yang didaftarkan, 2018-2022**  
**Table 1: Number of registered products, 2018-2022**

Kategori Produk <i>Product Category</i>	2018	2019	2020	2021	2022
<b>Produk Preskripsi <i>Prescription Products</i></b>	354	187	277	292	269
<b>Produk Bukan Preskripsi <i>Non-Prescription Products</i></b>	79	66	70	63	37
<b>Produk Semulajadi <i>Natural Products</i></b>	738	679	734	627	615
<b>Suplemen Kesihatan <i>Health Supplements</i></b>	322	315	424	438	451
<b>Produk Veterinar <i>Veterinary Products</i></b>	73	77	69	71	47
<b>Jumlah <i>Total</i></b>	<b>1,566</b>	<b>1,324</b>	<b>1,574</b>	<b>1,491</b>	<b>1,419</b>

### 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) pada 24 Februari 2021, Pihak Berkuasa Kawalan Dadah (PBKD) telah meluluskan pendaftaran bersyarat ke atas 17 produk vaksin COVID-19 berdasarkan penilaian oleh Bahagian Regulatori Farmasi Negara (NPRA).

### 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) on 24 February 2021, the Drug Control Authority (DCA) has granted approval for conditional registration for 17 COVID-19 vaccines listed in the following table, based on evaluation by the National Pharmaceutical Regulatory Agency (NPRA).*

**Jadual 2: Senarai Vaksin COVID-19 yang diberikan kelulusan pendaftaran bersyarat oleh PBKD (sehingga 31 Disember 2022)**

**Table 2: List of COVID-19 Vaccines granted conditional registration by the DCA (as of 31 December 2022)**

Bil No	Nama vaksin dan No MAL <i>Name of Vaccine and MAL no.</i>	Pemegang Pendaftaran Produk Product Registration Holder	Pengilang Manufacturer
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
3	COMIRNATY 10mcg Concentrate for Dispersion for Injection (MAL22016037AZ)	Pfizer (Malaysia) Sdn. Bhd	BioNTech Manufacturing GmbH, Germany
4	COMIRNATY (Tris/ Sucrose) 30 mcg Solution for Injection (MAL22016036AZ)	Pfizer (Malaysia) Sdn. Bhd	BioNTech Manufacturing GmbH, Germany
5	Comirnaty Original/ Omicron BA.4-5 (15/15 micrograms)/dose Dispersion for Injection (MAL22126012AZ)	Pfizer (Malaysia) Sdn. Bhd	BioNTech Manufacturing GmbH, Germany
6	Vaxzevria Solution for Injection (MAL21036009ACZ)	AstraZeneca Sdn. Bhd.	Astrazeneca Nijmegen B.V., Netherlands
7	Vaxzevria Solution for Injection (MAL21066001ACSZ)	AstraZeneca Sdn. Bhd	Siam Bioscience Co., Ltd., Thailand
8	COVID-19 Vaccine AstraZeneca Solution for Injection (The product approved by EMA is supplied under the commercial name: Vaxzevria) (MAL21046001AZ)	COVAX-KKM (COVAX Facility)	<ol style="list-style-type: none"> <li>1. SK Bioscience Co. Ltd, South Korea</li> <li>2. Catalent Anagni S.R.L, Italy</li> <li>3. CP Pharmaceuticals Ltd, United Kingdom</li> <li>4. IDT Biologika GmbH, Germany</li> <li>5. Seqirus Pty Ltd, Australia</li> <li>6. Daiichi Sankyo Biotech Co., LTD., Kitamoto Site, Japan</li> <li>7. KM Biologics Co. Ltd. Koshi Production Center, Japan</li> <li>8. ASTRAZENECA NIJMEGEN B.V., Netherlands</li> <li>9. Amylin Ohio LLC (AZ), United States</li> <li>10. Universal Farma, S.L. ("Chemo"), Spain</li> </ol> <p>For: Astrazeneca AB Sweden</p>

<b>Bil No</b>	<b>Nama vaksin dan No MAL <i>Name of Vaccine and MAL no.</i></b>	<b>Pemegang Pendaftaran Produk <i>Product Registration Holder</i></b>	<b>Pengilang Manufacturer</b>
<b>9</b>	CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated (MAL21036010ARZ)	Pharmaniaga LifeScience Sdn. Bhd.	Sinovac Life Sciences Co. Ltd., China
<b>10</b>	CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated (MAL21046125ACSZ)	Pharmaniaga LifeScience Sdn. Bhd.	Pharmaniaga LifeScience Sdn. Bhd., Malaysia
<b>11</b>	Convidecia™ Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection (MAL21066050AZ)	Solution Biologics Sdn. Bhd.	Cansino Biologics Inc, China
<b>12</b>	Convidecia™ Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection (MAL22126013ASZ)	Solution Biologics Sdn. Bhd.	Solution Biologics Sdn. Bhd., Malaysia
<b>13</b>	COVIGO Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated (MAL21076098AZ)	Duopharma (M) Sdn. Bhd	Beijing Institute of Biological Products Co., Ltd. (BIBP), China
<b>14</b>	Spikevax 0.20 mg/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) (MAL21086001ACZ)	Zuellig Pharma Sdn Bhd	Rovi Pharma Industrial Services, S.A. San Sebastian de los Reyes, Spain
<b>15</b>	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 Product Registration Holder	Pengilang Manufacturer
16	COVID-19 Vaccine Janssen Suspension for Injection (MAL21066049AZ)	COVAX-KKM (COVAX Facility)	<ul style="list-style-type: none"> <li>1. Janssen Biologics B.V. The Netherlands</li> <li>2. Janssen Pharmaceutica NV, Belgium</li> <li>3. Aspen SA Sterile Operations, South Africa</li> <li>4. Catalent Indiana LLC, USA</li> <li>5. Grand River Aseptic Manufacturing Inc, USA</li> <li>6. Catalent Anagni S.R.L., Italy</li> <li>7. Merck Sharp &amp; Dohme (MSD) Corp., United States</li> </ul> <p>For: Janssen-Cilag International NV, Belgium</p>
17	COVAXIN® (Whole Virion, Inactivated Coronavirus (SARS-CoV-2) Vaccine) Suspension for Intramuscular Injection (MAL22026024AZ)	Averroes Pharmaceuticals Sdn Bhd	Bharat Biotech International Limited, India

#### D) FARMAKOVIGILANS

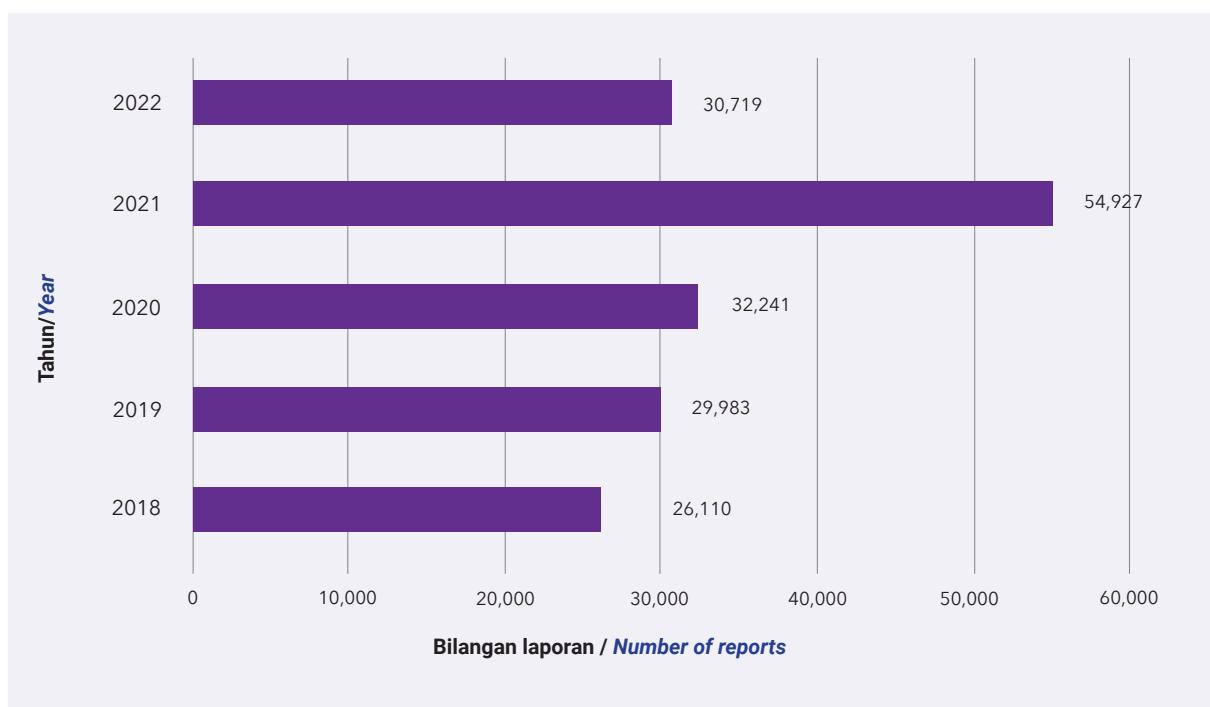
NPRA menjalankan pemantauan secara berterusan ke atas produk berdaftar di pasaran tempatan bagi memastikan produk tersebut menepati keperluan keselamatan, keberkesanan dan kualiti. Pada tahun 2022, Program Pemantauan Kesan Advers Ubat (ADR) Kebangsaan telah menerima sebanyak 30,719 laporan, pengurangan sebanyak 36.8 peratus berbanding tahun sebelumnya. Daripada 30,719 laporan, 3,890 merupakan laporan Kesan Advers Susulan Imunisasi (AEFI) yang melibatkan semua jenis vaksin berdaftar di Malaysia.

#### D) PHARMACOVIGILANCE

NPRA continuously monitors registered products in the local market to ensure the products adhere to safety, efficacy and quality requirements. In 2022, the National Adverse Drug Reactions (ADR) Monitoring Program received 30,719 reports, a reduction of 36.8 percent compared to the previous year. Out of 30,719 reports, 3,890 are Adverse Events Following Immunisation (AEFI) reports from all types of registered vaccines in Malaysia.

Rajah 4: Bilangan laporan ADR/AEFI yang diterima, 2018-2022

Figure 4: Number of ADR/AEFI reports received, 2018-2022



#### i) Pemantauan Status Keselamatan Vaksin COVID-19

Bahagian Regulatori Farmasi Negara (NPRA) terus memantau keselamatan semua vaksin berdaftar yang digunakan di Malaysia, termasuk vaksin COVID-19 yang digunakan di dalam Program Imunisasi COVID-19 Kebangsaan (PICK) melalui pemantauan pasif bagi semua Kesan Advers Susulan Imunisasi (AEFI) yang dilaporkan di Malaysia. Pada tahun 2022, pemonitoran laporan AEFI ini turut merangkumi Program Imunisasi COVID-19 Kebangsaan untuk kanak-kanak (PICKids) bagi memantau kesan advers yang dialami oleh kanak-kanak berumur lima (5) hingga 11 tahun yang mengambil vaksin Comirnaty 10mcg yang telah diluluskan pendaftaran secara bersyarat.

Laporan AEFI yang dikumpul adalah laporan spontan yang diterima melalui Sistem Pelaporan sedia ada di NPRA (PhIS-QUEST3+) daripada anggota kesihatan, syarikat farmaseutikal dan penerima vaksin. Selain itu, penerima vaksin juga boleh memberi respon kendiri kesan

#### i) COVID-19 Vaccine Safety Monitoring

The National Pharmaceutical Regulatory Agency (NPRA) continues to monitor the safety of all registered vaccines used in Malaysia including COVID-19 vaccines used in the National COVID-19 Immunisation Programme (PICK), mainly through passive surveillance of Adverse Effect Following Immunisation (AEFI) reported locally. In 2022, the monitoring of AEFI reports also included the National COVID-19 Immunisation Programme for children (PICKids) to monitor children aged five (5) to 11 years who were given the conditionally registered Comirnaty 10mcg Injection.

AEFI reports collected are 'spontaneous reports' received from healthcare professionals, pharmaceutical companies, and vaccine recipients via the existing Reporting System in NPRA (PhIS-QUEST3+). Additionally, vaccine recipients may also self-report or notify common and

advers ringan yang dialami melalui aplikasi MySejahtera masing-masing. Maklumat ini dapat membantu NPRA memantau ‘trend’ dan corak pelaporan kesan advers ini bagi mengesan sebarang isu keselamatan semasa pemberian vaksin.

Setakat ini, terdapat lima (5) vaksin COVID-19 yang digunakan untuk PICK, iaitu Comirnaty (Pfizer), CoronaVac (Sinovac), Vaxzevria (AstraZeneca), Convidecia (CanSino) dan Covilo (Sinopharm). Ringkasan laporan AEFI yang diterima sejak awal pelancaran PICK pada 24 Februari 2021 sehingga 31 Disember 2022 adalah seperti yang dinyatakan di dalam jadual di berikut:

*minor adverse events in the MySejahtera application, which enables NPRA to monitor the trends of documented adverse events among vaccine recipients.*

*There are five (5) COVID-19 vaccines currently used for PICK, which are Comirnaty (Pfizer), CoronaVac (Sinovac), Vaxzevria (AstraZeneca), Convidecia (CanSino) and Covilo (Sinopharm). The summary of AEFI reports received since the inception of PICK on 24 February 2021 up to 31 December 2022 is illustrated in the following table:*

**Jadual 3: Data AEFI PICK sehingga 31 Disember 2022**  
**Table 3: AEFI Data for PICK as of 31 December 2022**

		Comirnaty (Pfizer)	CoronaVac (Sinovac)	Vaxzevria (AstraZeneca)	Convidecia (CanSino)	Covilo (Sinopharm)	Kumulatif <i>Cumulative</i>
<b>Jumlah dos yang diberikan</b> <i>Total doses administered</i>	PICK (PICKids)	44,826,965 (3,309,111)	21,531,578 (3,775)	5,697,765	227,957	42,339	<b>72,326,604</b> (3,312,886)
<b>PELAPORAN MENERUSI SISTEM PELAPORAN NPRA SEDIA ADA</b> <i>REPORTING VIA EXISTING NPRA REPORTING SYSTEM</i>							
<b>Jumlah laporan yang diterima</b> <i>Total reports received</i>	PICK (PICKids)	20,153 (514)	5,099 (9)	1,374	48	2	<b>26,676</b> (523)
<b>Kadar pelaporan</b> (setiap sejuta dos)  <b>Reporting rate</b> (per million doses)	PICK (PICKids)	449.6 (155.3)	236.8 (2384.1)	241.1	210.6	47.2	<b>368.8</b> (157.9)
<b>Laporan AEFI tidak serius diterima</b>  <b>Non-serious AEFI reports received</b>	PICK (PICKids)	18,991 (480)	4,548 (9)	1,223	45	2	<b>24,809</b> (489)

		Comirnaty (Pfizer)	CoronaVac (Sinovac)	Vaxzevria (AstraZeneca)	Convidecia (CanSino)	Covilo (Sinopharm)	Kumulatif <b>Cumulative</b>
<b>Laporan AEFI serius diterima</b> <i>Serious AEFI reports received</i>	PICK (PICKids)	1,162 (34)	551 (0)	151	3	0	<b>1,867</b> (34)
<b>AEFI Serius/ Jumlah laporan AEFI (%)</b> <i>Serious AEFI/ Total AEFI reports (%)</i>	PICK (PICKids)	5.8 (6.6)	10.8 (0)	11.0	6.3	0	<b>7.0</b> (6.5)
<b>Kadar pelaporan AEFI serius (setiap sejuta dos)</b> <i>Serious AEFI reporting rate (per million doses)</i>	PICK (PICKids)	25.9 (10.3)	25.6 (0)	26.5	13.2	0.0	<b>25.8</b> (10.3)

Nota: Data yang dipaparkan adalah berdasarkan jumlah laporan kesan advers yang diterima di mana hubung kait kesan advers dengan vaksin yang diambil belum lagi dinilai dan disahkan. Ini bermaksud kesan advers yang dialami tidak semestinya disebabkan oleh vaksin yang diambil tersebut.

Note: The numbers presented here are the number of reports *received* by NPRA. The causal links of the event to the vaccination in these reports have not been ascertained meaning that the vaccines do not necessarily cause the adverse events.

## E) SURVEILANS

Aktiviti surveilans dan pengendalian aduan dilaksanakan untuk memantau dan memastikan standard kualiti dan keselamatan produk berdaftar dan kosmetik bernotifikasi di pasaran mematuhi ketetapan regulatori yang ditetapkan.

Sebanyak 4,488 produk telah disampel pada tahun 2022 di bawah Aktiviti Pemantauan Kualiti Produk Berdaftar dan Kosmetik Bernotifikasi. Sebanyak 1,041 aduan telah diterima pada tahun 2022. Aduan produk yang diterima telah dinilai, disiasat dan diambil tindakan berdasarkan hasil siasatan. 64 tindakan regulatori telah diambil melibatkan tiga (3) arahan pembatalan notifikasi, dua (2) arahan panggil balik, 57 amaran telah dikeluarkan serta dua (2) panggilbalik produk secara sukarela dari pasaran oleh pemegang pendaftaran produk.

## E) SURVEILLANCE

Surveillance and handling of product complaints are conducted to ensure the quality and safety standards of registered products and notified cosmetics in the market adhere to regulatory requirements.

A total of 4,488 products were sampled in 2022 under the Quality Monitoring Activity for Registered Products and Notified Cosmetics. 1,041 complaints were received in 2022. Product complaints received were evaluated, investigated and actions were taken based on the investigation findings. 64 regulatory actions were taken which include three (3) cancellation of notifications, two (2) recalls, 57 warnings issued as well as two (2) products recalled voluntarily from the market by product registration holders.

**Jadual 4: Jumlah dan kategori produk yang diambil untuk Aktiviti Pemantauan Kualiti Produk Berdaftar dan Kosmetik Bernotifikasi 2018-2022**  
**Table 4: Number and categories of products taken for Quality Monitoring Activity for Registered Products and Notified Cosmetics 2018-2022**

Kategori Produk <i>Product Category</i>	2018	2019	2020	2021	2022
Produk Preskripsi <i>Prescription Products</i>	657	843	767	688	723
Produk Bukan Preskripsi <i>Non-Prescription Products</i>	159	251	189	124	147
Suplemen Kesihatan <i>Health Supplements</i>	173	176	211	169	273
Produk Semulajadi <i>Natural Products</i>	699	817	973	951	918
Kosmetik <i>Cosmetic</i>	2,023	1,966	2,331	2,203	2,427
Jumlah <i>Total</i>	<b>3,711</b>	<b>4,053</b>	<b>4,471</b>	<b>4,135</b>	<b>4,488</b>

**Jadual 5: Bilangan aduan produk yang diterima 2018-2022**  
**Table 5: Number of product complaints received 2018-2022**

Kategori Produk <i>Product Category</i>	2018	2019	2020	2021	2022
Produk Preskripsi <i>Prescription Products</i>	844	879	736	2,993	720
Produk Bukan Preskripsi <i>Non-Prescription Products</i>	147	188	134	99	164
Suplemen Kesihatan <i>Health Supplements</i>	7	14	31	19	24
Produk Semulajadi <i>Natural Products</i>	15	17	18	9	13
Kosmetik <i>Cosmetic</i>	110	76	101	62	120
Jumlah <i>Total</i>	<b>1,123</b>	<b>1,174</b>	<b>1,020</b>	<b>3,182</b>	<b>1,041</b>

### i) Pemantauan Kualiti Vaksin COVID-19

Sejak Program Imunisasi COVID-19 Kebangsaan (PICK) dilancarkan pada 24 Februari 2021, NPRA telah menerima 2,497 laporan isu kualiti vaksin COVID-19 berdaftar. Defek kualiti boleh ditakrifkan sebagai atribut atau komponen yang boleh menjelaskan kualiti, keselamatan dan/atau keberkesanan produk yang tidak selaras dengan spesifikasi yang diluluskan atau keperluan regulatori.

Berdasarkan penyiasatan dan penilaian, 201 (8.05%) daripada kes yang dilaporkan disimpulkan sebagai defek kualiti 'minor' yang tidak memberi kesan kepada keselamatan dan keberkesanan vaksin. Walaupun tiada tindakan regulatori atau tindakan ke atas pasaran ('market action') yang diambil untuk produk yang mempunyai defek kualiti, pengilang dikehendaki mengambil tindakan yang sewajarnya untuk mengelakkan isu tersebut berulang.

Sebaliknya, 2,296 (91.95%) daripada laporan yang diterima dikaitkan dengan isu pengendalian dan tidak berasas.

### i) COVID-19 Vaccine Quality Monitoring

*Since the inception of the National COVID-19 Immunisation Programme (PICK) on 24 February 2021, NPRA has received 2,497 quality defect reports of registered COVID-19 vaccines. Quality defects may be defined as attributes of a product or component which may affect the quality, safety and/ or efficacy of the product which are not in line with the approved specifications or regulatory requirements.*

*Based on investigation and assessment, 201 (8.05%) of the cases reported were concluded as minor quality defect that has no impact on the safety and efficacy of the vaccines. Although no regulatory or market action were taken for the defective products, manufacturers are required to take appropriate actions to prevent recurrence of the defect.*

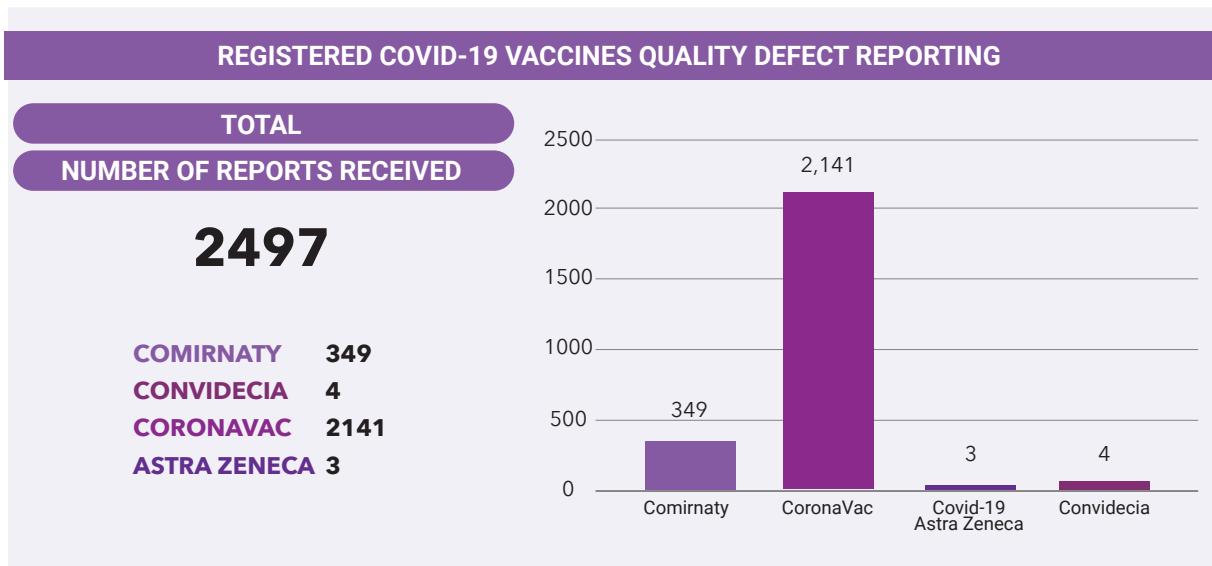
*On the other hand, 2,296 (91.95%) of the reports received were associated with handling and unsubstantiated issues.*

**Jadual 6: Data Defek Kualiti untuk PICK sehingga 31 Disember 2022**

**Table 6: Quality Defect Data for PICK as of 31 December 2022**

	Comirnaty (Pfizer)	CoronaVac (Sinovac)	AstraZeneca	Convidecia (CanSino)	Covilo (Sinopharm)	Kumulatif <i>Cumulative</i>
<b>Jumlah laporan yang diterima</b> <i>Total number of reports received</i>	349	2,141	3	4	0	2,497
<b>HASIL SIASATAN</b> <b>INVESTIGATION OUTCOMES</b>						
<b>Defek kualiti</b> <i>Quality defect</i>	21	180	0	0	0	<b>201</b>
<b>Defek bukan kualiti</b> <i>Non-quality defect</i>	328	1,961	3	4	0	<b>2,296</b>

**Rajah 5: Ringkasan Laporan Defek Kualiti untuk vaksin COVID-19 sehingga 31 Disember 2022**  
**Figure 5: Summary of Quality Defect Reports for COVID-19 vaccines as of 31 December 2022**



## 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. Sepanjang tahun 2022, sebanyak 291 pemeriksaan APB telah dijalankan dan 551 sijil APB telah dikeluarkan. Selain itu, bimbingan teknikal dan penyemakan pelan premis juga disediakan untuk pengilang sepanjang tahun.

Pemeriksaan Amalan Pengedaran Baik (AEB) dijalankan oleh NPRA dan juga dengan kerjasama Cawangan Penguatkuasa Farmasi Negeri untuk memastikan pematuhan oleh pengimport dan pemborong berlesen kepada prinsip dan keperluan garis panduan AEB semasa. Sebanyak 613 pemeriksaan AEB telah dijalankan sepanjang tahun 2022 yang melibatkan 149 premis pengimport dan 430 premis pemborong.

Selain itu, NPRA turut menjalankan pemeriksaan ke atas pusat kajian bioekuivalens (BE) dalam dan luar negara,

## F) INSPECTORATE ACTIVITIES

*Good Manufacturing Practice (GMP) inspections on manufacturers of registered products and notified cosmetics are conducted to ensure compliance to the current GMP requirements. In 2022, there were 291 GMP inspections conducted and 551 GMP certificates issued. Additional services such as technical guidance and manufacturer's layout plan evaluation were also provided to manufacturers throughout the year.*

*Good Distribution Practice (GDP) inspections are carried out by NPRA and also in collaboration with the States Pharmacy Enforcement Branch to ensure adherence of licenced importers and wholesalers to the principles and requirements of current GDP guideline. A total of 613 GDP inspections was performed throughout 2022, involving 149 importers and 430 wholesalers.*

*Besides GMP and GDP inspections, NPRA also conducts inspections on local and foreign Bioequivalence (BE) study centers,*

jawatankuasa etika serta fasiliti Amalan Makmal Baik (GLP). Sepanjang tahun 2022, lima (5) pemeriksaan dijalankan ke atas fasiliti GLP dan sebanyak tujuh (7) pemeriksaan Jawatankuasa Etika telah dilaksanakan.

Pada tahun 2022, 12 pemeriksaan pusat kajian BE telah dijalankan. NPRA juga telah memperkenalkan proses kerja Penilaian Keperluan Penentuan Pemeriksaan Kajian Bioekuivalens (BEDE) sejak bulan Oktober 2020.

Proses kerja ini bertujuan untuk menentukan keperluan pemeriksaan kajian-spesifik BE melalui penilaian secara desktop bagi kajian BE yang diperlukan untuk menyokong pendaftaran produk di Malaysia. Sepanjang tahun 2022 sebanyak 272 permohonan BEDE telah dinilai oleh NPRA.

*ethics committees and Good Laboratory Practice (GLP) facilities. Throughout of 2022, five (5) inspections were performed on GLP facilities while seven (7) inspections were conducted on Ethics Committee.*

*12 BE study center inspections were conducted in 2022. NPRA has also introduced the Desktop Evaluation on the Need for BE Study Inspection (BEDE) work process since October 2020.*

*This work process aims to determine the need for BE study-specific inspection through desktop evaluation for BE studies that are needed to support product registration in Malaysia. In 2022 a total of 272 BEDE applications were evaluated by NPRA.*

**Jadual 7: Bilangan pemeriksaan, semakan pelan premis serta bimbingan teknikal yang dijalankan, 2018-2022**

**Table 7: Number of inspections, premise plan review and technical guidance, 2018-2022**

Aktiviti <i>Activity</i>	2018	2019	2020	2021	2022
<b>Pemeriksaan Amalan Perkilangan Baik (APB) <i>GMP Inspections</i></b>	464	424	210	369	291
<b>Semakan Pelan Premis Pengilang <i>Manufacturers Layout Plan Evaluation</i></b>	127	99	138	110	125
<b>Bimbingan Teknikal <i>Technical Guidance</i></b>	51	39	603	968	685
<b>Pemeriksaan Amalan Edaran Baik <i>GDP Inspections</i></b>	171	162	130	190	613
<b>Pemeriksaan Amalan Klinikal Baik <i>GCP Inspections</i></b>	11	8	5	4	9
<b>Pemeriksaan Pusat Kajian Bioekuivalens (BE) <i>BE Study Centre Inspections</i></b>	18	34	4	1	12
<b>Pemeriksaan Jawatankuasa Etika <i>Ethics Committee Inspections</i></b>	5	7	0	1	7
<b>Pemeriksaan Amalan Makmal Baik <i>GLP Inspections</i></b>	5	4	2	4	5

GMP: Good Manufacturing Practice  
BE: Bioequivalence

GDP: Good Distribution Practice  
GLP: Good Laboratory Practice

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

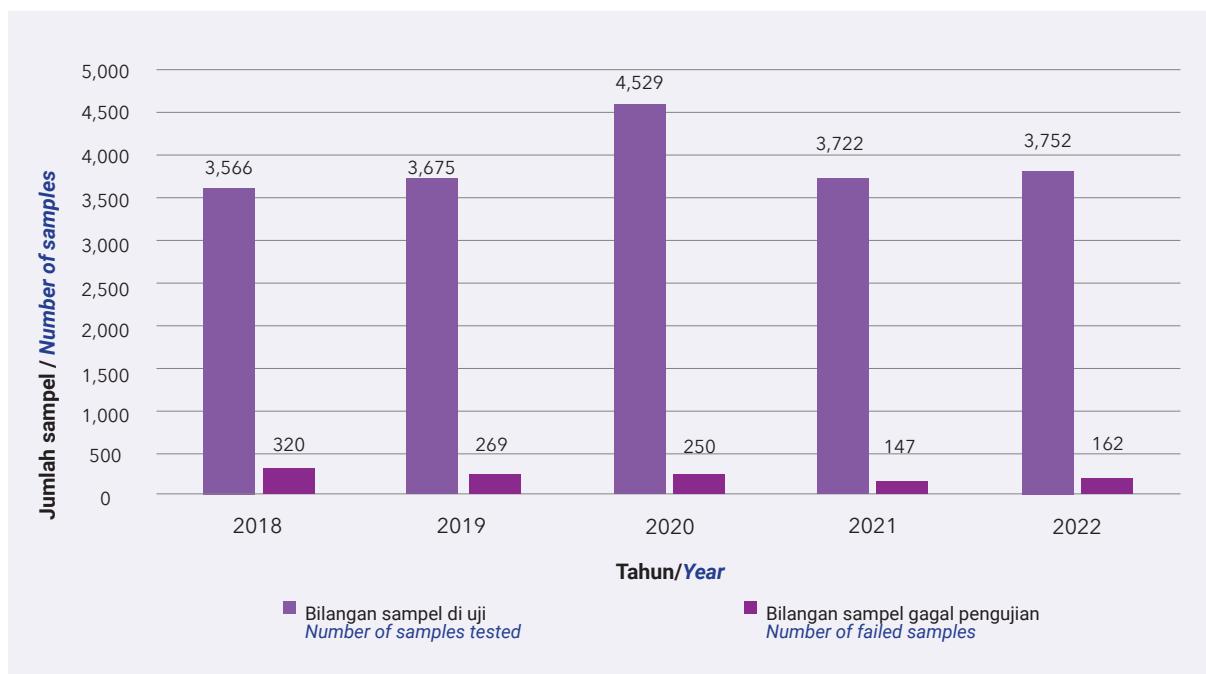
Pada tahun 2022, pengujian makmal telah dijalankan ke atas 3,752 sampel. Bilangan sampel yang gagal pengujian adalah sebanyak 162 sampel sahaja iaitu 4.3 peratus daripada jumlah sampel yang diuji. Pada tahun 2022, keseluruhan bilangan ujian makmal yang telah dijalankan adalah 51,422.

## G) LABORATORY TESTING

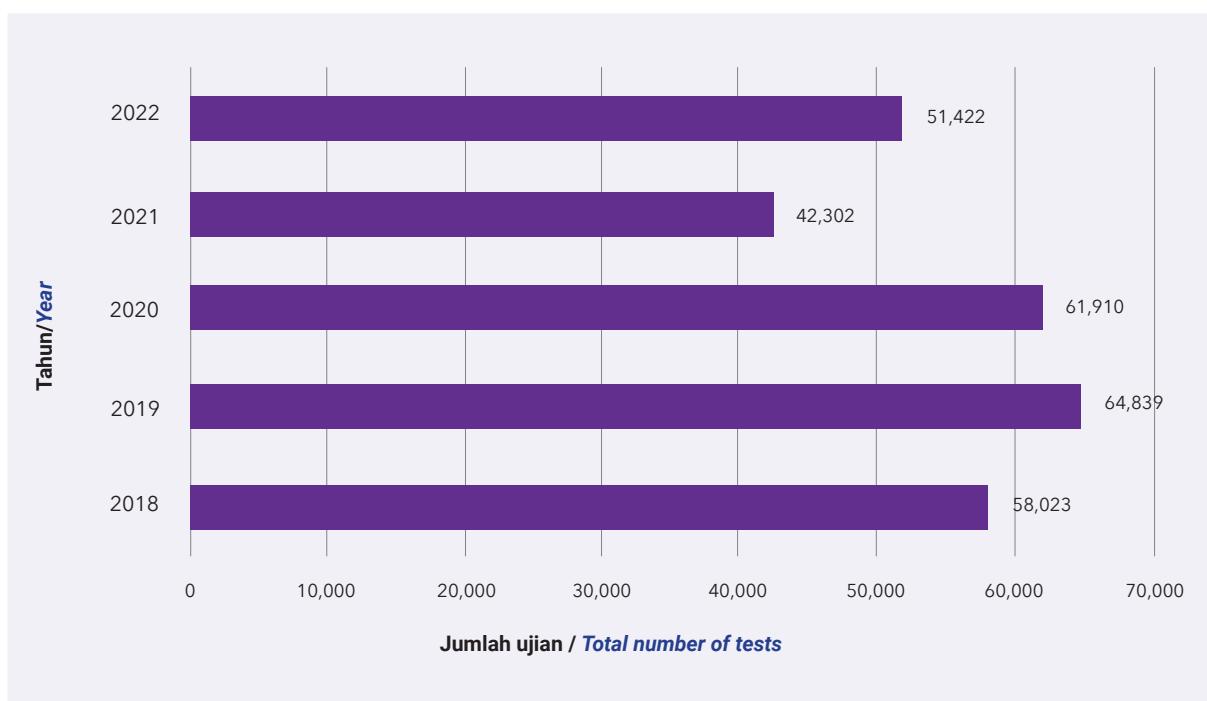
The NPRA laboratory has obtained MS ISO/IEC 17025: 2017 accreditation status for the scope of testing of natural products, cosmetics and pharmaceutical products (Hepatitis B vaccine). Sample testing is conducted on pharmaceutical products, natural products and cosmetics in accordance with global regulatory standard. These activities are conducted by trained and competent laboratory personnel.

In the year 2022, laboratory testing has been conducted on 3,752 samples. The number of samples that failed testing amounted to 162 samples only, which is equivalent to 4.3 percent of the total number of samples tested. In the year 2022, the total number of laboratory tests performed was 51,422.

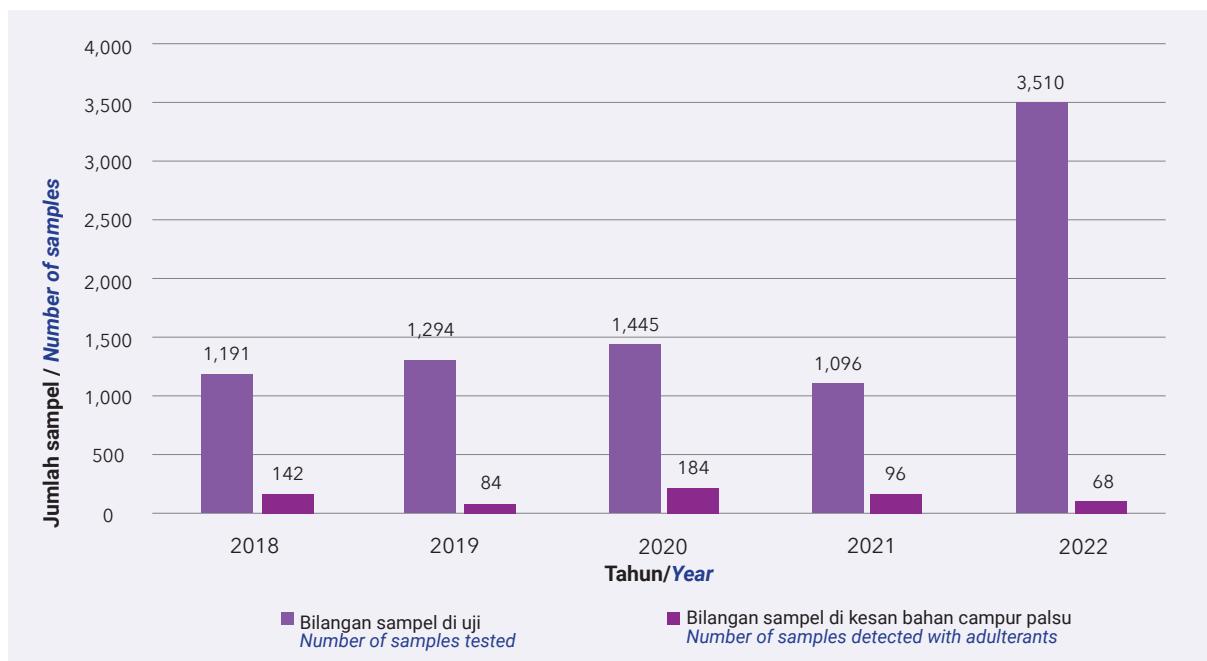
**Rajah 6: Bilangan sampel diuji dan bilangan sampel gagal pengujian, 2018-2022**  
**Figure 6: Number of samples tested & number of failed samples, 2018-2022**



**Rajah 7: Bilangan ujian yang dijalankan, 2018-2022**  
**Figure 7: Number of tests performed, 2018-2022**



**Rajah 8: Bilangan sampel produk semulajadi yang dikesan mengandungi bahan campur palsu, 2018-2022**  
**Figure 8: Number of natural products samples detected with adulterants, 2018-2022**



Melalui ujian-ujian analisis rutin yang dijalankan ke atas sampel bagi menilai kualiti produk, pengesahan bahan campur palsu dalam sampel merupakan antara sebab kegagalan ujian makmal. Pada tahun 2022, 68 daripada 3,510 sampel produk semulajadi telah dikesan mengandungi bahan campur palsu.

*Through the routine analytical tests conducted on samples to assess the products' quality, detection of adulterants is one of the reasons for failed samples. In the year 2022, 68 out of 3,510 samples of natural products tested have been found to be adulterated.*

## **H) AKTIVITI LOT RELEASE**

NPRA telah melaksanakan aktiviti *Lot Release* ke atas produk vaksin berdaftar di Malaysia sejak 1 Februari 2015 dan seterusnya ke atas produk plasma yang berdaftar di Malaysia bermula 1 Julai 2016. Pada tahun 2019, pelaksanaan ujian rupa bentuk fizikal turut dimasukkan sebagai keperluan *lot release* ke atas vaksin dan produk plasma yang diimport.

Lanjutan dari pandemik COVID-19 pada tahun 2021, terdapat inisiatif di kalangan pengilang tempatan untuk mengilang vaksin COVID-19 secara *Fill and Finish*. Susulan daripada itu, NPRA telah memulakan pelaksanaan *lot release* ke atas produk biologik yang dikilangkan di Malaysia.

Penilaian ke atas data kualiti serta data pengilangan ke atas setiap lot produk perlu dilaksanakan dengan teliti sebelum produk dilepaskan ke pasaran bagi memastikan kualiti, keselamatan dan keberkesanan setiap lot produk tersebut.

Bagi setiap lot produk vaksin dan produk plasma yang didapati memenuhi keperluan *lot release*, Sijil *Lot Release* akan dikeluarkan oleh NPRA. Manakala *Notification of Non-compliance* akan dikeluarkan ke atas lot yang didapati gagal memenuhi keperluan yang ditetapkan.

Pada tahun 2022, NPRA telah menerima sebanyak 253 permohonan *lot release*

## **H) LOT RELEASE ACTIVITY**

*NPRA has implemented Lot Release activities since 1 February 2015 for vaccines registered in Malaysia, followed by Plasma-derived Medicinal Products (PDMP) registered in Malaysia on 1 July 2016. In the year 2019, physical appearance testing was included as lot release requirement on imported vaccines and PDMPs.*

*Following the COVID-19 pandemic in 2021, there were efforts among local pharmaceutical manufacturers to produce COVID-19 vaccines through Fill and Finish. As a result, NPRA implemented lot release on locally manufactured biological products in Malaysia.*

*Review of manufacturing and quality control data on every lot of the product is required before they are released into the market to ensure the safety and effectiveness of every lot of these products.*

*Every lot of the vaccine product and PDMP which complies to Lot Release requirements will be issued a Lot Release Certificate by NPRA. Products which do not comply with the requirements will be issued with Notification of Non-Compliance.*

*In 2022, NPRA received 253 lot release applications for vaccines and 150 lot*

vaksin dan sebanyak 150 permohonan *lot release* produk plasma. Sebanyak 876 Sijil Lot Release vaksin dan 149 Sijil Lot Release produk plasma telah dikeluarkan. Daripada jumlah permohonan *lot release* yang dinilai, hanya dua (2) produk vaksin dan satu (1) produk plasma yang telah menerima *Notification of Non-compliance*.

*release applications for PDMP. A total of 876 Lot Release Certificates for vaccines and 149 Lot Release Certificates for PDMP were issued. Out of the total lot release applications evaluated, only two (2) vaccine products and one (1) PDMP received Notification of Non-compliance.*

**Jadual 8: Bilangan permohonan *Lot Release* yang diterima serta bilangan Sijil *Lot Release* dan *Notification of Non-compliance* yang dikeluarkan untuk produk vaksin dan produk plasma, 2018-2022**

**Table 8: Number of Lot Release applications received as well as Lot Release Certificates and Notification of Non-compliance issued for vaccines and PDMP, 2018-2022.**

Aktiviti <i>Activity</i>	2018	2019	2020	2021	2022
<b>Permohonan <i>Lot Release</i> <i>Lot Release Application</i></b>					
<b>Vaksin <i>Vaccine</i></b>	307	294	241	444	253
<b>Plasma <i>PDMP</i></b>	158	204	175	147	150
<b>Sijil <i>Lot Release</i> Yang Dikeluarkan <i>Issuance of Lot Release Certificate</i></b>					
<b>Vaksin <i>Vaccine</i></b>	303	289	255	2,495	876
<b>Plasma <i>PDMP</i></b>	159	205	170	143	149
<b><i>Notification of Non-Compliance</i> <i>Notification of Non-Compliance</i></b>					
<b>Vaksin <i>Vaccine</i></b>	3	2	1	9	2
<b>Plasma <i>PDMP</i></b>	2	2	1	0	1

## **AKTIVITI & SOROTAN**

*ACTIVITIES &  
HIGHLIGHTS*



**1) Latihan Sangkutan untuk anggota dari Pusat Darah Negara (PDN) di Bahagian Regulatori Farmasi Negara (NPRA)**

Pada 3, 21 dan 27 Januari 2022, NPRA telah menerima anggota dari Pusat Darah Negara (PDN) untuk mengikuti latihan berkenaan prinsip Amalan Perkilangan Baik (APB), Amalan Makmal Baik, Amalan Klinikal Baik serta prosedur audit untuk perkhidmatan perubatan transfusi. Latihan ini bertujuan untuk menyokong anggota PDN yang sedang mengikuti Program Latihan Subkepakaran dalam bidang *Blood Safety and Quality Regulation*.

Latihan ini dijalankan secara hibrid di mana seramai lapan (8) anggota dari PDN telah menyertai latihan ini secara fizikal di NPRA. Manakala 10 lagi peserta yang terdiri dari Pakar Perunding Patologi, Pakar Perubatan Transfusi Pegawai Perubatan, Pegawai Farmasi dan Pegawai Sains dari hospital dan insitusi Kementerian Kesihatan Malaysia (KKM) telah mengikuti latihan ini secara dalam talian. Sesi kedua pula telah berlangsung pada 10 sehingga 17 Februari 2022.

Latihan merangkumi ceramah dan pembentangan dari anggota NPRA yang melibatkan aspek kawalan kualiti Produk Darah, pengelasan, farmakovigilans dan pengendalian aduan kualiti Produk Darah, pemeriksaan Amalan Klinikal Baik dan Amalan Makmal Baik, prinsip APB untuk *Blood Establishment (BE)* serta Amalan Pengedaran Baik (AEB) yang melibatkan pengurusan rangkaian sejuk (*Cold Chain Management*).

**1) Training for officers from the National Blood Center (Pusat Darah Negara) at the National Pharmaceutical Regulatory Agency (NPRA)**

On 3, 21 and 27 January 2022, NPRA conducted a training on the principles of Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP) as well as audit procedures for transfusion medicine services for officers from the National Blood Centre (PDN). This training is in support of PDN officers who are currently pursuing the sub specialty training programme in the area of *Blood Safety and Quality Regulation*.

*This training was conducted in a hybrid method where a total of eight (8) officers from PDN participated in this training physically at NPRA, while another 10 participants comprising of Consultant Pathologists, Transfusion Physicians, Medical Officers, Pharmacy Officers and Science Officers from hospitals and Ministry of Health (MOH) institutions participated in the training online. The second session took place from 10 to 17 February 2022.*

*The training agenda includes presentations from NPRA officers involving aspects of Blood Product quality control, product classification, pharmacovigilance and handling of Blood Product quality complaints, GCP and GLP inspections, GMP principles for Blood Establishment (BE) and Good Distribution Practice (GDP) which includes cold chain management.*



Imej 1: Timbalan Pengarah Pusat Komplians dan Kawalan Kualiti (PKKK) dan pegawai dari Seksyen Amalan Perkilangan Baik (SAPB) bersama peserta latihan dari Pusat Darah Negara  
*Image 1: Deputy Director of Center of Compliance and Quality Control and officers from Good Manufacturing Practice (GMP) Section with the participants from the National Bood Center*



Image 2: Sesi latihan yang diadakan secara hibrid iaitu secara fizikal di Bilik Mesyuarat Bunga Raya, NPRA dan secara dalam talian  
*Image 2: Hybrid training conducted physically at Bunga Raya Meeting Room, NPRA and online*

## 2) Lawatan daripada Pelajar Universiti

## 2) Visits by University Students

Bahagian Regulatori Farmasi Negara (NPRA) telah menerima kunjungan daripada pelajar Sarjana Muda Farmasi dan Sarjana Muda Teknologi Farmaseutikal dari tiga (3) institusi pengajian tinggi sepanjang tahun 2022 seperti berikut:

*The National Pharmaceutical Regulatory Agency (NPRA) received study visits from Bachelor of Pharmacy and Bachelor of Pharmaceutical Technology university students from three (3) higher education institutions throughout the year 2022 as listed below:*

**Jadual 9: Senarai institusi yang telah membuat lawatan ke NPRA**

**Table 9: List of institutions involved in visits to NPRA**

Bil. No.	Institusi <i>Institution</i>	Program <i>Programme</i>	Bilangan peserta <i>Number of participants</i>	Tarikh <i>Date</i>
1	Universiti MAHSA <i>MAHSA University</i>	Sarjana Muda Farmasi <i>Bachelor of Pharmacy</i>	15	30 Jun 2022 <i>30 June 2022</i>
2	Universiti Kolej Antarabangsa MAIWP <i>University College MAIWP International</i>	Sarjana Muda Teknologi Farmaseutikal <i>Bachelor of Pharmaceutical Technology</i>	61	2 November 2022 <i>2 November 2022</i>
3	Universiti Kuala Lumpur <i>Royal College of Medicine</i> Perak (RMCP)  <i>Universiti Kuala Lumpur Royal College of Medicine Perak (RMCP)</i>	Sarjana Muda Teknologi Farmaseutikal <i>Bachelor of Pharmaceutical Technology</i>	45	7 Disember 2022 <i>7 December 2022</i>

Sesi lawatan sambil belajar tersebut bertujuan untuk memberi pendedahan dan maklumat kepada para pelajar universiti mengenai proses pendaftaran produk serta aspek kawalan regulatori produk farmaseutikal di Malaysia.

Agenda lawatan melibatkan pembentangan daripada anggota NPRA yang merangkumi topik seperti pengenalan kepada NPRA, pendaftaran produk dan notifikasi kosmetik di Malaysia, prinsip Amalan Perkilangan Baik (APB) serta aktiviti farmakovigilans.

*These study visits aim to provide information and exposure to the university students on the product registration process as well as aspects of regulatory control of pharmaceutical products in Malaysia.*

*The agenda of the visit includes presentations from NPRA covering topics such as introduction to NPRA, product registration and notification of cosmetics in Malaysia, Good Manufacturing Practice (GMP) principles and pharmacovigilance activities.*



**Imej 3: Pegawai NPRA bersama pelajar Universiti MAHSA**  
**Image 3: NPRA officers with MAHSA University students**



**Imej 4: Koleksi imej yang diambil semasa sesi lawatan  
dari pelajar Universiti MAHSA**  
**Image 4: A collection of images taken during the visit by  
MAHSA University**





Imej 5: Pegawai dari NPRA bersama pelajar Universiti Kuala Lumpur Royal College of Medicine Perak (RCMP) pada sesi penutup lawatan

*Image 5: NPRA officers with students from Universiti Kuala Lumpur Royal College of Medicine Perak (RCMP) at the closing session of the visit*



Imej 6: Pelajar dari Universiti Kolej Antarabangsa MAIWP pada sesi penutup lawatan

*Image 6: Students from MAIWP International College University at the closing session of the visit*



**Imej 7: Koleksi imej yang diambil semasa sesi lawatan dari Universiti Kolej Antarabangsa MAIWP**

*Image 7: A collection of images taken during the visit by MAIWP International College University*

**3) Lawatan Kerja Kongres Kesatuan Pekerja-pekerja di dalam Perkhidmatan Awam (CUEPACS) ke Bahagian Regulatori Farmasi Negara (NPRA)**

Pihak CUEPACS telah mengadakan lawatan kerja ke NPRA pada 27 Januari 2022 dengan tujuan untuk memahami dengan lebih mendalam fungsi NPRA sebagai badan regulatori serta peranannya dalam Program Imunisasi COVID-19 Kebangsaan (PICK). Pada masa yang sama, maklumat yang diperolehi mengenai vaksin COVID-19 dapat disampaikan kepada penjawat awam dan seterusnya menggalakkan mereka untuk menerima vaksin tersebut.

Delegasi dari CUEPACS telah diketuai oleh Encik Abdul Rahman bin Haji Mohd Noordin, selaku Setiausaha Agung CUEPACS. YBrs. Puan Salwati binti Abd. Kadir, Timbalan Pengarah Pusat Koordinasi dan Perancangan Strategik Regulatori telah menyampaikan kata-kata aluan bagi pihak Pengarah NPRA.

Agenda diteruskan dengan pembentangan dari anggota NPRA mengenai pengenalan kepada NPRA, pendaftaran vaksin COVID-19, aktiviti Lot Release vaksin serta pemantauan kesan advers susulan imunisasi (AEFI) dan farmakovigilans vaksin COVID-19. Sesi lawatan diakhiri dengan lawatan ke makmal analisis Pusat Komplians dan Kawalan Kualiti (PKKK).

**3) Working Visit from the Congress of Unions of Employees in the Public Service (CUEPACS) to the National Pharmaceutical Regulatory Agency (NPRA)**

CUEPACS initiated a working visit to NPRA on 27 January 2022 with the purpose of gaining an in depth understanding of NPRA's function as a regulatory body and its role in the National COVID-19 Immunisation Program (PICK). At the same time, the information obtained about the COVID-19 vaccine from this visit can be communicated to civil servants and further encourage them to get vaccinated.

The delegation from CUEPACS was led by the Secretary-General of CUEPACS, Mr. Abdul Rahman bin Haji Mohd Noordin. YBrs. Madam Salwati binti Abd. Kadir, Deputy Director of the Center for Regulatory Coordination and Strategic Planning delivered a welcome speech on behalf of the Director of NPRA.

The agenda continued with presentations from NPRA which included topics such as introduction to the NPRA, registration of the COVID-19 vaccine, vaccine Lot Release activities as well as Adverse Effect Following Immunisation (AEFI) monitoring and pharmacovigilance of the COVID-19 vaccine. The session ended with a visit to the analysis laboratory of the Center of Compliance and Quality Control.



Imej 8: Timbalan Pengarah Pusat Koordinasi dan Perancangan Strategik Regulatori bersama barisan delegasi CUEPACS

*Image 8: Deputy Director of Center of Regulatory Coordination and Strategic Planning with the CUEPACS delegates*

**4) Kunjungan Hormat dari wakil International Generic and Biosimilar Medicines Association (IGBA) dan Persatuan Industri Farmaseutikal Malaysia (MOPI) ke Bahagian Regulatori Farmasi Negara (NPRA)**

Susulan penganjuran Persidangan MOPI-IGBA ke-24 yang telah diadakan di Kuala Lumpur pada 7-9 September 2022, pihak MOPI dan IGBA telah mengambil kesempatan untuk mengadakan kunjungan hormat ke NPRA bagi memupuk kolaborasi regulatori antara kedua-dua pihak.

Delegasi dari IGBA diketuai oleh Encik Nicholas Cappuccino selaku Ketua Jawatankuasa Saintifik IGBA yang diiringi oleh wakil dari pihak MOPI iaitu Puan Grace Yap dan Puan Sharifah Fauziyah binti Syed Mohthar. Manakala delegasi dari NPRA yang diketuai oleh YBrs. Pengarah NPRA iaitu YBrs. Dr. Roshayati binti Mohamad Sani, terdiri dari Timbalan-timbalan Pengarah dan Ketua-ketua Seksyen yang berkaitan.

Semasa sesi perbincangan, pihak IGBA telah memberi penerangan mengenai struktur dan objektif IGBA dan Jawatankuasa Saintifik manakala NPRA telah melaporkan status pelaksanaan *Mutual Recognition Arrangement* (MRA) yang dibangunkan di peringkat ASEAN.

Selain itu ahli mesyuarat turut membuat perkongsian pendapat mengenai harmonisasi keperluan bioekuivalens, keutamaan kepada industri generik dan biosimilar serta kawalan nitrosamine.

**4) Courtesy Visit from representatives of International Generic and Biosimilar Medicines Association (IGBA) and Malaysian Organisation of Pharmaceutical Industries (MOPI) to the National Pharmaceutical Regulatory Agency (NPRA)**

*Following the successful organization of the 24th MOPI-IGBA Conference which was held in Kuala Lumpur on 7-9 September 2022, MOPI and IGBA have extended a courtesy visit to NPRA with the aim of fostering regulatory collaboration between the two parties.*

*The delegation from IGBA was led by the Head of the IGBA Scientific Committee, Mr. Nicholas Cappuccino. The IGBA delegation was accompanied by representatives from MOPI namely Madam Grace Yap and Madam Sharifah Fauziyah binti Syed Mohthar. The delegation from NPRA was led by YBrs. Dr. Roshayati binti Mohamad Sani, Director of NPRA and consisted of Deputy Directors and Heads of relevant Sections.*

*During the discussion, IGBA provided an overview of the structure and objectives of the IGBA and the Scientific Committee. On the other hand, NPRA provided updates on the implementation status of the Mutual Recognition Arrangement (MRA) developed at the ASEAN level.*

*Additionally, members of the meeting also shared opinions on the harmonisation of bioequivalence requirements, priorities for the generic and biosimilar industry and the regulation of nitrosamines.*



**Imej 9: Pengarah dan Pegawai NPRA bersama wakil MOPI dan IGBA**  
**Image 9: The Director of NPRA and NPRA officers with MOPI and IGBA representatives**



**Imej 10: Sesi perbincangan antara pihak IGBA dan NPRA di Bilik Mesyuarat Teratai, NPRA**  
**Image 10: Discussion session between IGBA and NPRA in Teratai Meeting Room, NPRA**



**Imej 11: YBrs. Pengarah NPRA menyampaikan cenderahati kepada wakil MOPI dan wakil IGBA**  
**Image 11: The Director of NPRA presenting a token of appreciation to representatives of MOPI and IGBA**

**5) Bengkel Pelaporan AEFI Vaksin COVID-19, Kes Siasatan dan Komunikasi Risiko Bahagian Regulatori Farmasi Negara (NPRA)**

Seksyen Farmakovigilans (SFV), NPRA telah berjaya menganjurkan dua (2) bengkel secara dalam talian yang berkaitan dengan kesan advers susulan imunisasi (AEFI) vaksin COVID-19 pada tahun 2022.

Pada 17 Februari 2022, seramai 90 Pegawai Perubatan dan Pegawai Farmasi dari pelbagai fasiliti kesihatan di negara ini telah menghadiri bengkel pertama dan menerima latihan komprehensif untuk menambahbaik pelaporan AEFI dan penyiasatan kes khusus bagi vaksin COVID-19. Kepentingan komunikasi risiko yang berkesan dan kesannya kepada kesihatan awam turut dibincangkan.

Bengkel kedua yang diadakan pada 21 April 2022, bertumpu kepada laporan kematian yang disyaki berkaitan dengan vaksin COVID-19. Bengkel tersebut melibatkan 284 Pakar Perubatan, Pegawai Farmasi, dan Pembantu Perubatan dari fasiliti Kementerian Kesihatan Malaysia di seluruh negara.

Dalam bengkel ini, salah tanggapan umum tentang penyiasatan AEFI dan penilaian hubung kait (*causality*) berkaitan kes kematian telah dijelaskan. Peranan ahli Patologi Forensik dalam penyiasatan kes kematian AEFI yang disyaki juga dijelaskan dan diberi penekanan. Pada sesi terakhir bengkel, para peserta terlibat secara aktif dalam perbincangan kes yang memerlukan penilaian forensik.

**5) NPRA's Training Workshops on COVID-19 Vaccine AEFI Reporting, Case Investigation and Risk Communication**

*The Pharmacovigilance Section (SFV) of NPRA had successfully organised two (2) virtual training workshops related to the adverse events following immunisation (AEFIs) of COVID-19 vaccines in 2022.*

*On 17 February 2022, a total of 90 medical doctors and pharmacists from various health facilities in the country attended the first training workshop to receive comprehensive training on how to improve COVID-19 vaccine-specific AEFI reporting and case investigation. The importance of effective risk communication and its impact to public health were also discussed.*

*The second training workshop, which was held on 21 April 2022, focused on death reports suspected to be COVID-19 vaccine-related. It was attended by a total of 284 physicians, pharmacists, and medical assistants from the Ministry of Health Malaysia facilities around the country.*

*In this workshop, common misconceptions about AEFI investigation and causality assessments pertaining to death cases were clarified. The roles of forensic pathologists in suspected AEFI death cases investigation was also explained and emphasised. In the last session of the workshop, the participants were actively engaging in the case discussions requiring forensic assessments.*



**Imej 12: Bengkel AEFI yang diadakan secara dalam talian pada 17 Februari 2022**  
**Image 12: Training Workshop on AEFI held online on 17 February 2022**



**Imej 13: Bengkel AEFI yang diadakan secara dalam talian pada 21 April 2022**  
**Image 13: Training Workshop on AEFI held online on 21 April 2022**

## **6) Program Latihan Amalan Perkilangan Baik (GMP) Kosmetik 2022**

Satu latihan Amalan Perkilangan Baik (APB) telah diadakan oleh Seksyen Amalan Perkilangan Baik (SAPB), Pusat Komplians dan Kawalan Kualiti (PKKK) pada 23 dan 24 Ogos 2022 untuk pengilang kosmetik tempatan. Program latihan ini telah dirasmikan oleh YBrs. Dr. Roshayati binti Mohamad Sani, Pengarah Bahagian Regulatori Farmasi Negara (NPRA). Seramai 318 orang peserta yang terdiri daripada 101 pengilang produk kosmetik tempatan dan anggota NPRA telah menghadiri sesi Latihan dalam talian.

Objektif utama latihan adalah untuk memberikan pendedahan berkaitan Amalan Perkilangan Baik (APB) kepada peserta dan memberikan maklumat terkini berkaitan penemuan semasa pemeriksaan APB. Para peserta telah diberi pendedahan kepada garispanduan APB yang merangkumi penerangan dari aspek Sistem Pengurusan Kualiti, Personel, Premis dan Peralatan, Dokumentasi, Pengeluaran, Kawalan Kualiti, Kontrak Analisa, Aduan dan Panggil Balik Produk dan Pemeriksaan Kendiri seperti yang perlu diamalkan oleh pengilang kosmetik bernotifikasi.

Selain itu, hasil analisa penemuan pemeriksaan APB pengilang kosmetik yang telah dijalankan pada tahun 2021 telah dibentangkan kepada para peserta untuk diamati dan menambahbaik amalan-amalan sedia ada di fasiliti masing-masing.

## **6) Cosmetic Good Manufacturing Practice (GMP) Training Programme 2022**

A Good Manufacturing Practice (GMP) training programme was organised by the GMP Section of the Center of Compliance and Quality Control on 23 and 24 August 2022 for local cosmetics manufacturers. This training program was inaugurated by YBrs. Dr. Roshayati binti Mohamad Sani, Director of the National Pharmacy Regulatory Agency (NPRA). A total of 318 participants which consists of 101 local cosmetic product manufacturers and NPRA staff attended this online training.

The main objectives of the training are to inform the participants of principles relating to GMP and to provide the latest information on the findings during a GMP inspection. The participants were given exposure to the GMP guidelines including explanations from aspects of the Quality Management System, Personnel, Premises and Equipment, Documentation, Production, Quality Control, Contract Analysis, Complaints and Product Recalls and Self-Inspection as required to be practiced by notified cosmetic manufacturers.

In addition, the results of the analysis of the findings of the GMP inspections of cosmetic manufacturers that were conducted in 2021 were presented to the participants to observed and improve the existing practices in their respective facilities.

# COSMETIC GMP TRAINING 2022

## 23 -24 AUGUST 2022



**Imej 14: Program Latihan Amalan Perkilangan Baik (GMP) Kosmetik yang diadakan secara dalam talian pada 23-24 Ogos 2022**

**Image 14: Cosmetic Good Manufacturing Practice (GMP) Training held online on 23-24 Ogos 2022**

# PENLIBATAN & KOLABORASI ANTARABANGSA

*INTERNATIONAL  
PARTICIPATION &  
COLLABORATION*



## A. PENGLIBATAN ANTARABANGSA INTERNATIONAL PARTICIPATION

### 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.

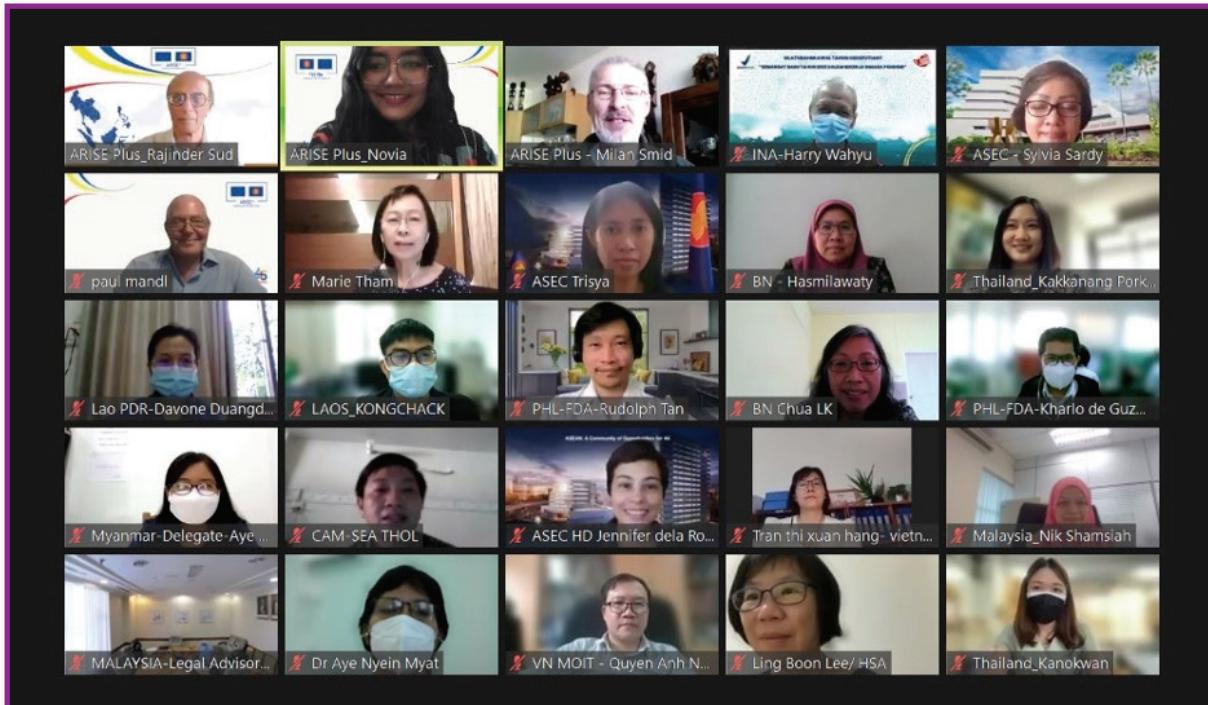
These working groups include the Pharmaceutical Product Working Group (PPWG), the Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) and the ASEAN Cosmetic Committee (ACC).

Jadual 10: Senarai mesyuarat di peringkat ASEAN yang telah dihadiri oleh pegawai NPRA sepanjang tahun 2022

Table 10: List of ASEAN meetings attended by NPRA officers in the year 2022

Bil. No.	Mesyuarat Meeting	Tarikh Date
1	1 <sup>st</sup> ASEAN Pharmaceutical Regulatory Framework (APRF) Agreement Workshop	21-22 March
2	1 <sup>st</sup> Task Force ASEAN Pharmaceutical Regulatory Framework (APRF) Meeting	23 March
3	35 <sup>th</sup> ASEAN Cosmetic Body (ACSB) Meeting	10-11 May
4	24 <sup>th</sup> Implementation Working Group Meeting	18 May 2022
5	33 <sup>rd</sup> Pharmaceutical Product Working Group Meeting	19-20 May
6	35 <sup>th</sup> ASEAN Cosmetic Committee (ACC) Meeting	25-27 May
7	Half Day Workshop on ASEAN Pharmaceutical Regulatory Framework	21 June
8	2 <sup>nd</sup> ASEAN Pharmaceutical Regulatory Framework Agreement Workshop	11-12 July

Bil. No.	Mesyuarat <i>Meeting</i>	Tarikh <i>Date</i>
9	2 <sup>nd</sup> Task Force ASEAN Pharmaceutical Regulatory Framework Meeting	13 July
10	3 <sup>rd</sup> ASEAN Pharmaceutical Regulatory Framework Agreement Workshop	18-20 October
11	4 <sup>th</sup> ASEAN Pharmaceutical Regulatory Framework Agreement Workshop	26 & 29-30 October
12	5 <sup>th</sup> Joint Sectoral Committee (JSC) Mutual Recognition Arrangement (MRA) on Bioequivalence (BE) Meeting	3-4 November
13	11 <sup>th</sup> Joint Sectoral Committee (JSC) Mutual Recognition Arrangement (MRA) on Good Manufacturing Practice (GMP) Meeting	7-8 November
14	3 <sup>rd</sup> ASEAN Pharmaceutical Testing Laboratory Committee (APLTC)	10-11 November
15	7 <sup>th</sup> Joint Assessment Coordinating Group (JACG) Meeting	14-15 November
16	34 <sup>th</sup> Pharmaceutical Product Working Group Meeting	17-18 November
17	36 <sup>th</sup> ASEAN Cosmetic Scientific Body (ACSB) Meeting	21-22 November
18	36 <sup>th</sup> ASEAN Cosmetic Committee (ACC) Meeting	30 November - 1 December



**Imej 15: Bengkel Pertama ASEAN Pharmaceutical Regulatory Framework (APRF) Agreement Workshop yang diadakan secara dalam talian pada 21-22 Mac 2022**

**Image 15: First ASEAN Pharmaceutical Regulatory Framework (APRF) Agreement Workshop held online on 21-22 March 2022**



Imej 16: Mesyuarat *Pharmaceutical Product Working Group* ke-33 yang diadakan secara dalam talian pada 19- 20 Mei 2022

Image 16: 33<sup>rd</sup> *Pharmaceutical Product Working Group* Meeting held online on 19-20 May 2022



Imej 17: Mesyuarat *Pharmaceutical Product Working Group* ke-34 yang diadakan secara dalam talian pada 17 -18 November 2022

Image 17: 34<sup>th</sup> *Pharmaceutical Product Working Group* Meeting held online on 17-18 November 2022

**2) PENGLIBATAN NPRA DI DALAM  
AKTIVITI INTERNATIONAL  
COUNCIL FOR HARMONISATION OF  
TECHNICAL REQUIREMENTS FOR  
MEDICINES FOR HUMAN USE (ICH)**

Malaysia diterima sebagai pemerhati kepada International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) sejak bulan Jun 2018. Malaysia juga telah diterima sebagai ahli The International Pharmaceutical Regulator's Programme (IPRP) pada bulan November 2019.

**2) NPRA'S PARTICIPATION IN  
INTERNATIONAL COUNCIL FOR  
HARMONISATION OF TECHNICAL  
REQUIREMENTS FOR MEDICINES  
FOR HUMAN USE (ICH)**

Malaysia was accepted as an observer to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) since June 2018. Malaysia has also been accepted as a member to The International Pharmaceutical Regulator's Programme (IPRP) from November 2019.

**Jadual 11: Senarai mesyuarat ICH dan IPRP yang telah dihadiri oleh pegawai NPRA sepanjang tahun 2022**

**Table 11: List of ICH and IPRP meetings attended by NPRA officers in the year 2022**

Bil. No.	Mesyuarat <i>Meeting</i>	Tarikh <i>Date</i>
1	<i>ICH Hybrid Meeting Athens</i>	24-25 May
2	<i>9<sup>th</sup> International Pharmaceutical Regulator's Programme Management Committee Teleconference</i>	25-26 May

**3) PENGLIBATAN NPRA DI DALAM AKTIVITI ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT-GOOD LABORATORY PRACTICE (OECD-GLP)**

Pada tahun 2022, NPRA telah terlibat dalam dua (2) aktiviti yang dianjurkan oleh OECD Working Party on Good Laboratory Practice (GLP) seperti di jadual berikut:

**3) NPRA'S PARTICIPATION IN ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT-GOOD LABORATORY PRACTICE (OECD-GLP) ACTIVITIES**

*In the year 2022, NPRA participated in two (2) activities organised by the OECD Working Party on Good Laboratory Practice (GLP) as listed in the following table:*

**Jadual 12: Senarai aktiviti OECD-GLP yang telah dihadiri oleh pegawai NPRA sepanjang tahun 2022**

**Table 12: List of OECD-GLP activities participated by NPRA officers in the year 2022**

Bil. No.	Mesyuarat Meeting	Tarikh Date
1	<i>OECD On-site Evaluation of India</i>	<i>24-29 July</i>
2	<i>15th OECD Training Course for GLP Inspectors</i>	<i>23-27 October</i>

Untuk kedua-dua acara OECD tersebut, Malaysia telah diwakili oleh Cik Fadhilah Hasbullah, Ketua Penolong Pengarah Kanan berdasarkan kepakaran beliau dalam pemeriksaan GLP.

NPRA telah dijemput untuk mengambil bahagian sebagai ahli pakar dalam pasukan penilai untuk penilaian lawatan tapak (OSE) India dari 25-27 Julai 2022. Objektif OSE ini adalah untuk memastikan pematuhan National Good Laboratory Practice Compliance Monitoring Authority of India (NGCMA India) kepada dokumen panduan OECD GLP dan untuk memastikan harmonisasi Program GLP di kalangan pihak berkuasa pemantauan di negara yang patuh kepada OECD Mutual Acceptance of Data System (OECD MAD). OSE dilaksanakan sekali setiap sepuluh tahun dan Malaysia dijangka akan dinilai pada bulan Mei 2023.

Peranan NPRA dalam 15<sup>th</sup> OECD Training Course for GLP inspectors pula adalah sebagai ahli Jawatankuasa Pemandu

*In both OECD events, Malaysia was represented by Ms. Fadhilah Hasbullah, Senior Principal Assistant Director based on her vast expertise in the area of GLP inspection.*

*NPRA was invited to participate as an expert member in the evaluation team for the on-site evaluation (OSE) visit to India from 25-27 July 2022. The objective of this OSE is to ascertain the adherence of the National Good Laboratory Practice Compliance Monitoring Authority of India (NGCMA India) to the OECD GLP guidance documents and to ensure harmonisation of GLP Programme across monitoring authorities in OECD Mutual Acceptance of Data System (OECD MAD) adherent countries. OSE takes place one in every ten years and Malaysia is expected to be evaluated in May 2023.*

*For the 15<sup>th</sup> OECD Training Course for GLP inspectors, NPRA was appointed as a member of the Steering Committee for*

bagi bengkel tersebut dan juga sebagai fasilitator. Standard Council of Canada (SCC) merupakan tuan rumah untuk bengkel yang telah diadakan di Montreal, Quebec pada 23-27 Oktober 2022.

Objektif bengkel adalah untuk memastikan pemeriksa GLP di kalangan negara OECD MAD mempelajari inovasi terkini dan amalan terbaik serta menggalakkan harmonisasi di kalangan pihak berkuasa pemantauan. Peserta bengkel terdiri daripada pemeriksa GLP dari negara anggota dan bukan anggota OECD seperti Kanada, Perancis, Belanda, Singapura dan Thailand. Penceramah dan fasilitator bengkel ini adalah ahli Jawatankuasa Pemandu yang terdiri daripada pakar GLP dari pelbagai negara anggota OECD.

*the workshop and also participated as a facilitator. The workshop, which was held in Montreal, Quebec on 23-27 October 2022 was hosted by the Standard Council of Canada (SCC).*

*The objectives of the workshop are to ensure GLP inspectors among OECD MAD adherent countries learn about the latest innovations and best practices and encourage harmonisation across monitoring authorities. Participants consisted of GLP inspectors from OECD and non-OECD member countries such as Canada, France, the Netherlands, Singapore and Thailand. Speakers and facilitators of this workshop are members of the steering committee which consists of GLP experts from various OECD member countries.*



**Imej 18: 15<sup>th</sup> OECD Training Course for GLP Inspectors yang diadakan di Montreal, Quebec pada 23-27 Oktober 2022**

**Image 18: 15<sup>th</sup> OECD Training Course for GLP Inspectors held in Montreal, Quebec on 23-27 October 2022**



Imej 19: Wakil NPRA sebagai Lead Auditor OSE India bersama dengan pasukan penilai dan pihak NGCMA India

*Image 19: NPRA representative as Lead Auditor for OSE India with the evaluation team and NGCMA India*

#### 4) MESYUARAT TEKNIKAL DUA HALA

##### **Mesyuarat Bilateral Bahagian Regulatori Farmasi Negara (NPRA) dengan Ministry of Health, Labour and Welfare (MHLW) dan Pharmaceutical and Medical Devices Agency (PMDA)**

Sepanjang tahun 2022, sebanyak dua (2) mesyuarat bilateral telah diadakan di antara NPRA dengan pihak MHLW dan PMDA pada 4 April dan 15 Julai.

Mesyuarat bilateral ini adalah inisiatif dari kedua-dua negara dalam memastikan kerjasama yang berterusan di dalam bidang regulatori farmaseutikal antara NPRA dan PMDA. Memandangkan situasi pandemik masih berlarutan, kedua-dua mesyuarat diadakan secara dalam talian.

Mesyuarat yang telah diadakan pada 4 April 2022 dipengerusikan bersama oleh YBrs. Dr. Roshayati binti Mohamad Sani, selaku Pengarah NPRA dan Pengarah Eksekutif PMDA, YBrs. Dr. Fujiwara Yasuhiro. Agenda mesyuarat tertumpu kepada persediaan penganjuran bersama Simposium Malaysia- Jepun Kedua serta peluang latihan dan aktiviti pembangunan kapasiti untuk aktiviti pemeriksaan Cell and Gene Therapy Products (CGTP).

Mesyuarat bilateral kedua yang diadakan pada 15 Julai 2022 diadakan susulan penganjuran Simposium Malaysia-Jepun Kedua dan Mesyuarat Asian Network Keempat yang telah dianjurkan pada minggu yang sama. NPRA dan PMDA telah bersetuju untuk menganjurkan simposium tersebut setiap dua (2) tahun dan dicadangkan simposium seterusnya untuk diadakan di Malaysia pada tahun 2025.

Selain itu mesyuarat turut membincangkan perancangan latihan anjuran PMDA berkaitan pemeriksaan CGTP dan First-in-Human untuk pegawai NPRA pada tahun 2022.

#### 4) BILATERAL TECHNICAL MEETINGS

##### **Bilateral Meeting Between National Pharmaceutical Regulatory Agency (NPRA) and the Ministry of Health, Labour and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA)**

*In 2022, two (2) bilateral meetings were held between NPRA and MHLW/PMDA on 4 April and 15 July.*

*These bilateral meetings are initiatives by both parties to ensure continued cooperation in the pharmaceutical regulatory field between NPRA and PMDA. As the pandemic situation was still ongoing, both meetings were conducted online.*

*The meeting held on 4 April 2022 was co-chaired by NPRA Director, YBrs. Dr. Roshayati binti Mohamad Sani and PMDA Executive Director, Dr. Fujiwara Yasuhiro. The main agenda was focused on the preparation of the joint organisation of the Second Malaysia-Japan Symposium as well as the planning for training opportunities and capacity building activities related to the on-site inspection for Cell and Gene Therapy Products (CGTP).*

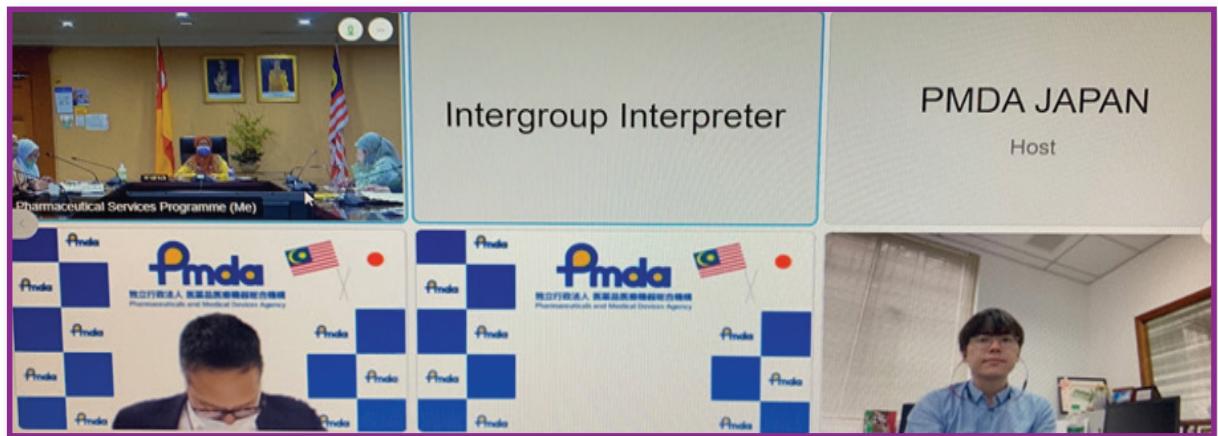
*The second bilateral meeting on 15 July 2022 was held in conjunction with the organisation of the Second Malaysia-Japan Symposium and the Fourth Asian Network Meeting which was held back-to-back within the same week. NPRA and PMDA have agreed to organise the symposium every two (2) years and the next symposium is suggested to be held in Malaysia in 2025.*

*In addition, the meeting also discussed the planning of PMDA-organised training related to CGTP and First-in-Human inspections to be held for NPRA officers in 2022.*



**Imej 20: Delegasi NPRA menyertai Mesyuarat Bilateral NPRA-PMDA yang diadakan secara dalam talian pada 4 April 2022**

**Image 20: The Malaysian delegation attending the NPRA-PMDA Bilateral Meeting held online on 4 April 2022**



**Imej 21: Mesyuarat Bilateral NPRA-PMDA yang diadakan secara dalam talian pada 15 Julai 2022**

**Image 21: NPRA-PMDA Bilateral Meeting held online on 15 July 2022**

## **5) MESUARAT ASIAN NETWORK KEEMPAT**

*Ministry of Health, Labour, and Welfare (MHLW) dan Pharmaceutical and Medical Devices Agency (PMDA) Jepun telah mengadakan Mesyuarat Asian Network Keempat pada 6 April 2022. Mesyuarat ini diadakan secara dalam talian dan peserta mesyuarat terdiri daripada wakil MHLW, PMDA dan wakil pengurusan tertinggi badan regulatori dari negara tuan rumah yang merangkumi China, India dan Singapura, serta negara Asia yang lain, seperti Indonesia, Korea, Malaysia, Filipina dan Thailand.*

*Malaysia melalui Bahagian Regulatori Farmasi Negara (NPRA) telah berkongsi pengalaman mengenai langkah-langkah yang diambil semasa pandemik COVID-19, termasuk memudahkan cara akses kepada vaksin COVID-19 melalui pendaftaran serta aktiviti *lot release* dan pemantauan farmakovigilans vaksin COVID-19.*

## **5) FOURTH ASIAN NETWORK MEETING**

*The Ministry of Health, Labour, and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA) Japan held the annual Asian Network Meeting on 6 April 2022. The fourth meeting was held virtually this year and the participants include representatives from the MHLW, PMDA and top-level representatives of regulatory agencies from host countries, including China, India, and Singapore, and other Asian member countries, such as Indonesia, Korea, Malaysia, the Philippines, and Thailand.*

*Malaysia through the National Pharmaceutical Regulatory Agency (NPRA), mainly shared her experience on regulatory measures taken during the COVID-19 pandemic, which include facilitating access to COVID-19 vaccines through registration, lot release and pharmacovigilance monitoring.*

**6) MESUARAT KEDUA BADAN REGULATORI UBAT KEBANGSAAN (NMRA) NEGARA ANGGOTA ORGANISATION OF ISLAMIC COOPERATION (OIC)**

Mesuarat yang telah diadakan di Istanbul, Republik Turki dari 5-7 September 2022 telah dianjurkan oleh Kementerian Kesihatan Republik Turki dan dihadiri oleh wakil badan regulatori dari negara anggota OIC. Mesuarat ini dianjurkan susulan Mesuarat Pertama yang telah diadakan pada tahun 2019 di Indonesia.

Objektif mesuarat ini adalah untuk membincangkan strategi negara anggota OIC dalam mengukuhkan badan regulatori dan peranan mereka dalam memerangi pandemik di samping berkongsi pengalaman dalam pembangunan dan pengilangan produk farmasutikal termasuk vaksin daripada perspektif perpaduan Islam. Tema keseluruhan program ini adalah *Access to Safe, Effective and Quality Medicines and Vaccines in OIC member states*.

Delegasi Malaysia yang diwakili oleh Bahagian Regulatori Farmasi Negara (NPRA) diketuai oleh YBrs. Puan Rosilawati binti Ahmad, Timbalan Pengarah Pusat Penilaian Produk dan Kosmetik. NPRA telah dijemput sebagai penceramah dalam sesi berkenaan Kawalan Regulatori ke atas Percubaan Klinikal di Negara Anggota OIC. Pada sesi ini pembentangan dari NPRA telah disampaikan oleh Puan Atiqah binti Kamal Rodin, Ketua Penolong Pengarah Kanan.

Mesuarat ditangguhkan selepas pertimbangan hasil dokumen pada akhir mesuarat yang termasuk Deklarasi Istanbul dan Pelan Tindakan 2022-2024 yang telah dikemaskini.

**6) THE SECOND MEETING OF THE ORGANISATION OF ISLAMIC COOPERATION (OIC) NATIONAL MEDICINES REGULATORY AUTHORITIES (NMRA)**

*The meeting hosted by the Ministry of Health, Republic of Turkiye was held in Istanbul from 5-7 September 2022 and was attended by representatives of NMRA from OIC member states. This meeting was a follow-up to the First Meeting of NMRA which was held in 2019 in Indonesia.*

*The objectives of this meeting are for OIC member states to discuss the strategies to strengthen their NMRA and the role of competent authorities in the fight against the pandemic while also sharing their experience on the development and manufacture of medicines including vaccines from the perspective of Islamic solidarity. The overarching theme of the programme revolves around Access to Safe, Effective and Quality Medicines and Vaccines in OIC member states.*

*The Malaysian delegation was represented by the National Pharmaceutical Regulatory Agency (NPRA) and was headed by YBrs. Madam Rosilawati binti Ahmad, Deputy Director of Centre of Product and Cosmetic Evaluation. NPRA was invited as a speaker in the session titled Clinical Trials Regulation in OIC Member States. In this session the presentation from NPRA was delivered by Madam Atiqah binti Kamal Rodin, Senior Principal Assistant Director.*

*The meeting was adjourned after the consideration of outcome documents at the end of the meeting which included the Istanbul Declaration and the updated Action Plan for 2022-2024.*



Imej 22: Barisan delegasi dari wakil negara anggota OIC  
Image 22: Assembly of delegates from OIC member states



Imej 23: Wakil NPRA dan wakil industri farmaseutikal Malaysia di Mesyuarat Kedua NMRA negara anggota OIC

Image 23: Representatives from NPRA and the Malaysian pharmaceutical industry at the Second OIC NMRA Meeting



**Imej 24: Wakil NPRA membuat pembentangan dalam salah satu sesi kerja yang dijadualkan**

**Image 24: NPRA representative presenting during one of the scheduled working sessions**



**Imej 25: Wakil NPRA bersama delegasi dari negara anggota OIC yang lain**

**Image 25: NPRA representatives with other delegates from OIC member states**

## **7) FORUM SERANTAU KEEMPAT WORLD HEALTH ORGANIZATION COLLABORATING CENTRES (WHO CC) DI RANTAU PASIFIK BARAT**

Bahagian Regulatori Farmasi Negara (NPRA) telah diiktiraf sebagai WHO Collaborating Centre (WHO CC) sejak tahun 1996. Pejabat WHO rantau Pasifik Barat telah menganjurkan Forum Keempat WHO CC di Siam Reap, Kemboja dari 28-29 November 2022.

*For the Future: Towards the Healthiest and Safest Region* menyatakan visi bersama WHO dengan negara anggota dan rakan kongsi untuk menjadikan Pasifik Barat sebagai rantau paling sihat dan selamat di dunia.

Berdasarkan rumusan daripada tiga (3) forum yang telah diadakan sebelum ini, objektif utama Forum Serantau Keempat adalah untuk:

- a) Mengimbas semula bagaimana WHO dan WHO CC telah bekerjasama sejak forum sebelumnya untuk memajukan wawasan serantau
- b) Untuk mengenal pasti peluang untuk memaksimumkan sumbangan usaha WHO CC
- c) Untuk meneroka mekanisme cara kerja yang lebih berkesan antara WHO dan WHO CC di rantau Pasifik Barat bagi mempercepatkan pelaksanaan visi *For the Future*

Sebagai WHO CC yang diktiraf, NPRA telah dijemput untuk menyertai forum tersebut dan diwakili oleh YBrs. Puan Salwati binti Abd. Kadir, selaku Timbalan Pengarah, Pusat Koordinasi dan Perancangan Strategik Regulatori. Agenda forum ini melibatkan sesi perbincangan berdasarkan *thematic priority* yang dikenal pasti seperti keselamatan kesihatan yang meliputi

## **7) FOURTH REGIONAL FORUM OF WORLD HEALTH ORGANIZATION COLLABORATING CENTRES (WHO CC) IN THE WESTERN PACIFIC REGION**

The National Pharmaceutical Regulatory Agency (NPRA) has been designated as a WHO Collaborating Centre (WHO CC) since 1996. The WHO Regional office for the Western Pacific organised the Fourth Regional Forum of WHO CCs in Siam Reap, Cambodia from 28 -29 November 2022.

*For the Future: Towards the Healthiest and Safest Region* articulates a shared vision for WHO's work with Member States and partners to make the Western Pacific the world's healthiest and safest region.

*Building on lessons identified and progress from the first three (3) forums, the Fourth Regional Forum main objectives are to:*

- a) Reflect on how WHO and WHO CC have worked together since the previous forums to advance the regional vision
- b) To identify opportunities to maximise the contribution of WHO CCs work
- c) To explore mechanisms for more effective ways of working between WHO and WHO CCs in the Region for accelerated implementation of *For the Future*

As a designated WHO CC, NPRA was invited to participate in the forum and was represented by YBrs. Madam Salwati binti Abd. Kadir, Deputy Director of Center of Regulatory Coordination and Strategic Planning. The agenda consisted of discussion sessions based on thematic priorities identified such as health security including antimicrobial resistance (AMR),

rintangan antimikrobial (AMR), penyakit tidak berjangkit (NCD) dan penuaan serta perubahan iklim dan alam sekitar.

Acara penutup forum diikuti dengan perundingan tidak rasmi mengenai pembangunan Asia Pacific Health Security Action Framework yang diadakan pada 30 November 2022 dan dianjurkan oleh WHO Western Pacific Region Health Emergencies Programme. Tujuan mesyuarat adalah untuk memberikan maklumbalas mengenai kertas teknikal yang dibentangkan dan membincangkan peranan WHO CC dalam kesiapsiagaan serantau, kesediaan dan tindak balas terhadap kecemasan kesihatan awam semasa dan masa depan.

non communicable diseases (NCD) and ageing, as well as climate change and environment.

*The closing of the forum was followed by an informal consultation on the development of new Asia Pacific Health Security Action Framework held on 30 November 2022, organised by the WHO Western Pacific Region Health Emergencies Programme. The purpose of the meeting was to provide feedback on presented technical papers and to discuss the role of WHO CCs in regional preparedness, readiness and response to current and future public health emergencies.*

**Imej 26: Wakil NPRA bersama dengan wakil WHO Collaborating Centre (WHO CC) yang lain di Forum tersebut**

**Image 26: NPRA representative with other WHO CC representatives at the Forum**



## B. KOLABORASI ANTARABANGSA DAN PENYERTAAN KURSUS LUAR NEGARA

### INTERNATIONAL COLLABORATION AND PARTICIPATION IN OVERSEAS COURSES

#### 1) Simposium Malaysia-Jepun Kedua

Simposium ini merupakan simposium kedua yang dianjurkan bersama oleh Bahagian Regulatori Farmasi Negara (NPRA) dan Pharmaceutical and Medical Devices Agency (PMDA) Jepun. Objektif simposium adalah untuk meningkatkan persefahaman antara Malaysia dan Jepun ke atas sistem regulatori masing-masing terutamanya semasa pandemik COVID-19 dan untuk menggalakkan pembangunan bidang regulatori farmaseutikal.

Simposium ini telah diadakan secara dalam talian pada 14 Julai 2022 dan telah disertai oleh 420 peserta yang terdiri daripada regulator dan wakil industri farmaseutikal dari negara Malaysia, Jepun, Singapura, Taiwan, Indonesia, Hong Kong dan Cuba.

Ketua delegasi Malaysia dan Jepun, YBrs. Puan Norhaliza binti A. Halim selaku Pengarah Kanan Perkhidmatan Farmasi dan YBrs. Dr. Fujiwara Yasuhiro, selaku Pengarah Eksekutif PMDA masing-masing telah menyampaikan kata-kata aluan bagi merasmikan pembukaan simposium tersebut.

Agenda program diteruskan dengan ucaptama yang disampaikan oleh YBrs. Dr. Roshayati Mohamad binti Sani, selaku Pengarah NPRA. Kedua-dua agensi telah berkongsi pengalaman negara masing-masing mengenai expedited review, cabaran e-labelling dan farmakovigilans vaksin COVID-19.

#### 1) Second Malaysia-Japan Symposium

*This is the second joint symposium hosted by the National Pharmaceutical Regulatory Agency (NPRA) Malaysia and Pharmaceutical and Medical Devices Agency (PMDA) Japan, with the aim to enhance Malaysia and Japan's mutual understanding of each other's regulatory system, particularly during the COVID-19 pandemic and to promote advancement of pharmaceutical regulations and development.*

*Held online on 14 July 2022, the symposium was attended by 420 participants consisting of both regulators and representatives from the pharmaceutical industries of Malaysia, Japan, Singapore, Taiwan, Indonesia, Hong Kong and Cuba.*

*As heads of delegations from Malaysia and Japan respectively, YBrs. Madam Norhaliza binti A. Halim, Senior Director of Pharmaceutical Services, Ministry of Health Malaysia and Dr. Fujiwara Yasuhiro, Chief Executive Officer of PMDA delivered opening remarks to officiate the start of the symposium.*

*The programme agenda continued with a keynote speech delivered by YBrs. Dr. Roshayati binti Mohamad Sani, Director of NPRA. Both agencies shared their respective country experiences on expedited review, challenges on e-labelling and pharmacovigilance of COVID-19 vaccines.*





Imej 27: Sesi pembukaan Simposium Malaysia-Jepun Kedua pada 14 Julai 2022

Image 27: Opening session of Second Malaysia-Japan Symposium on 14 July 2022

**2) Program Regulatory Strengthening oleh Therapeutic Goods Administration (TGA) Australia**

Bahagian Regulatori Farmasi Negara (NPRA) sentiasa mengambil langkah untuk terus memperkuuh dan memperhalusi proses kawalan regulatori melalui penglibatan dan perundingan dengan badan regulatori yang lain. Sejak tahun 2021, NPRA telah terlibat dengan *Regulatory Strengthening Programme* yang dikendalikan oleh Therapeutic Goods Administration (TGA), Australia.

Antara aktiviti yang dilaksanakan di bawah program ini termasuk bantuan teknikal dan kerjasama dalam bidang farmakovigilans, pengujian makmal ke atas produk serta kawalan ke atas produk seperti gas perubatan, kanabis dan Advanced Therapeutic Medical Products (ATMP) yang dikenali sebagai *Cell and Gene Therapy Products* (CGTP) di Malaysia.

Aktiviti-aktiviti yang dilaksanakan di bawah *Regulatory Strengthening Programme* anjuran pihak TGA merupakan tindakan susulan dari Mesyuarat Bilateral antara TGA dan NPRA yang telah berlangsung pada 29 Julai 2021 yang lalu di mana kedua-dua pihak bersetuju untuk meningkatkan kerjasama regulatori melalui pertukaran maklumat dan dokumentasi, serta perkongsian kepakaran melalui latihan dan pembangunan kapasiti. Semua sesi latihan dan perbincangan telah dilaksanakan secara dalam talian.

**2) Regulatory Strengthening Programme by the Australian Therapeutic Goods Administration (TGA)**

The National Pharmaceutical Regulatory Agency (NPRA) continuously takes steps to strengthen and refine regulatory control processes through engagements and consultations with other regulatory agencies. Since 2021, NPRA has participated in the Regulatory Strengthening Programme conducted by the Australian Therapeutic Goods Administration (TGA).

Among the activities conducted through this programme include technical assistance and collaboration in the areas of pharmacovigilance, laboratory product testing as well as regulatory control of products such as medicinal gas, cannabis and Advanced Therapeutic Medical Products (ATMP), otherwise referred to as Cell and Gene Therapy Products (CGTP) in Malaysia.

The events organised by TGA under the Regulatory Strengthening Programme were follow-up actions from the NPRA-TGA Bilateral Meeting that took place on 29 July 2021. In the meeting, both parties agreed to foster regulatory cooperation through exchange of information and documentation as well as sharing of expertise through training and capacity building activities. All training and discussions sessions were conducted online.

**Jadual 13: Senarai aktiviti anjuran Therapeutic Goods Administration (TGA) Australia yang telah disertai oleh anggota NPRA pada tahun 2022**

**Table 13: List of activities organised by the Therapeutic Goods Administration attended by NPRA officers in the year 2022**

Bil. No.	Acara Event	Tarikh Date
1	<i>Training on Fundamentals of Polymerase Chain Reactions (PCR)</i>	<i>2 February 2022</i>
2	<i>Training on Method Validation and Verification</i>	<i>11 February 2022</i>

Bil. No.	Acara Event	Tarikh Date
3	<i>Discussion on Effective Communication of Safety Risks</i>	<i>18 March 2022</i>
4	<i>Seminar on Safety Signal Management</i>	<i>30-31 March 2022</i>
5	<i>Training on Lot Release Testing of Vaccine</i>	<i>28 April 2022</i>
6	<i>Training on Medicinal Gas for NPRA officers</i>	<i>20 May 2022</i>
7	<i>Training on Regulation of Medicinal Cannabis</i>	<i>6 September 2022</i>
8	<i>Discussion on Signal Detection and Pharmacovigilance Inspection</i>	<i>12 September 2022</i>
9	<i>TGA Virtual Workshop on Good Manufacturing Practice (GMP) Advanced Therapeutic Medical Products (ATMP)</i>	<i>4-6 October 2022</i>



**Imej 28: Seminar Pengurusan Isyarat Keselamatan yang dikendalikan oleh TGA pada 30 dan 31 Mac 2022 secara dalam talian**

**Image 28: Seminar on Safety Signal conducted by TGA online on 30 & 31 March 2022**



**Imej 29: Sesi perbincangan NPRA-TGA mengenai pemeriksaan Farmakovigilans diadakan secara dalam talian pada 12 September 2022**

***Image 29: NPRA-TGA discussion on Pharmacovigilance inspections session held online on 12 September 2022***

### **3) Bengkel untuk Penilai Sistem Regulatori Menggunakan Global Benchmarking Tool (GBT)**

Pada tahun 2017, *World Health Organization* (WHO) telah memperkenalkan *Global Benchmarking Tool* (GBT) yang menggabungkan konsep ‘tahap kematangan’ atau ML (diadaptasi daripada ISO 9004), yang membolehkan WHO dan pihak berkuasa regulatori menilai ‘kematangan’ keseluruhan sistem regulatori.

Semasa pembangunan GBT, WHO telah mengambil maklum keperluan untuk meningkatkan kualiti dan konsistensi proses penilaian. Oleh itu, bengkel ini telah dibangunkan dengan tujuan mengharmonikan pendekatan yang digunakan oleh penilai dan meningkatkan kebolehpercayaan kepada hasil penilaian.

Pihak WHO telah menganjurkan dua (2) bengkel bersemuka pada tahun 2022 di Istanbul, Republik Turki untuk anggota terpilih dari Badan Regulatori Ubat-ubatan Kebangsaan di seluruh dunia. Dari Malaysia, pihak WHO telah menjemput Puan Norleen binti Mohamed Ali selaku Ketua Penolong Pengarah Kanan dari Bahagian Regulatori Farmasi Negara (NPRA) untuk mengambil bahagian dalam sesi bengkel yang diadakan pada 1 hingga 3 Jun 2022.

Bengkel ini telah dijalankan dengan jayanya kerana peserta diberi asas untuk melaksanakan penilaian yang berkesan. Sebagai penilai WHO GBT yang diktiraf, Puan Norleen telah mengambil bahagian sebagai ahli pasukan penilaian WHO GBT untuk *Saudi Food Drug Authority* yang telah diadakan pada 27 November sehingga 1 Disember 2022.

### **3) Workshop for Regulatory Systems Assessors Using the Global Benchmarking Tool (GBT)**

*The World Health Organization (WHO) introduced the Global Benchmarking Tool (GBT) in 2017 which incorporates the concept of ‘maturity level’ or ML (adapted from ISO 9004), allowing WHO and regulatory authorities to assess the overall ‘maturity’ of the regulatory system.*

*During the development of the GBT, the WHO received inputs on the need to enhance the quality and consistency of the benchmarking process. Hence, a training workshop was developed with the aim of enabling a harmonised approach by assessors and the reliability of benchmarking outcomes.*

*In 2022, the WHO organised two (2) face to face workshops in Istanbul, Turkiye for selected members from the National Drug Regulatory Authorities (NDRA) worldwide. The WHO extended its invitation to Madam Norleen binti Mohamed Ali, Senior Principal Assistant Director from the National Pharmaceutical Regulatory Agency (NPRA), Malaysia to take part in the workshop session held from 1 to 3 June 2022.*

*The workshop was successfully conducted as participants were given a foundation for the effective implementation of benchmarking skills. As a certified WHO GBT assessor, Madam Norleen participated as a team member to the WHO GBT assessment of the Saudi Food Drug Authority conducted from 27 November to 1 December 2022.*

## WHO Global Benchmarking Tool

Training course for assessors  
3<sup>rd</sup> workshop (01 – 03 Jun 2022)  
Turkey - Istanbul



Imej 30: Peserta dan pelatih WHO di Bengkel WHO GBT  
*Image 30: Participants and WHO trainers at the WHO GBT Workshop*



Imej 31: Pembentangan berkumpulan semasa bengkel berlangsung  
*Image 31: Group presentation during the workshop*



**Imej 32: Wakil NPRA menerima sijil penyertaan pada akhir bengkel**  
**Image 32: NPRA representative receives a certificate of completion of the course at the end of the workshop**

#### **4) Latihan Dalam Perkhidmatan di Luar Negara**

Berikut adalah senarai Pegawai dari NPRA yang telah menghadiri latihan dalam perkhidmatan luar negara. Tujuan Latihan adalah untuk mengukuhkan pengetahuan serta memastikan pegawai NPRA sedia maklum dengan amalan regulatori yang digunakan di peringkat antarabangsa.

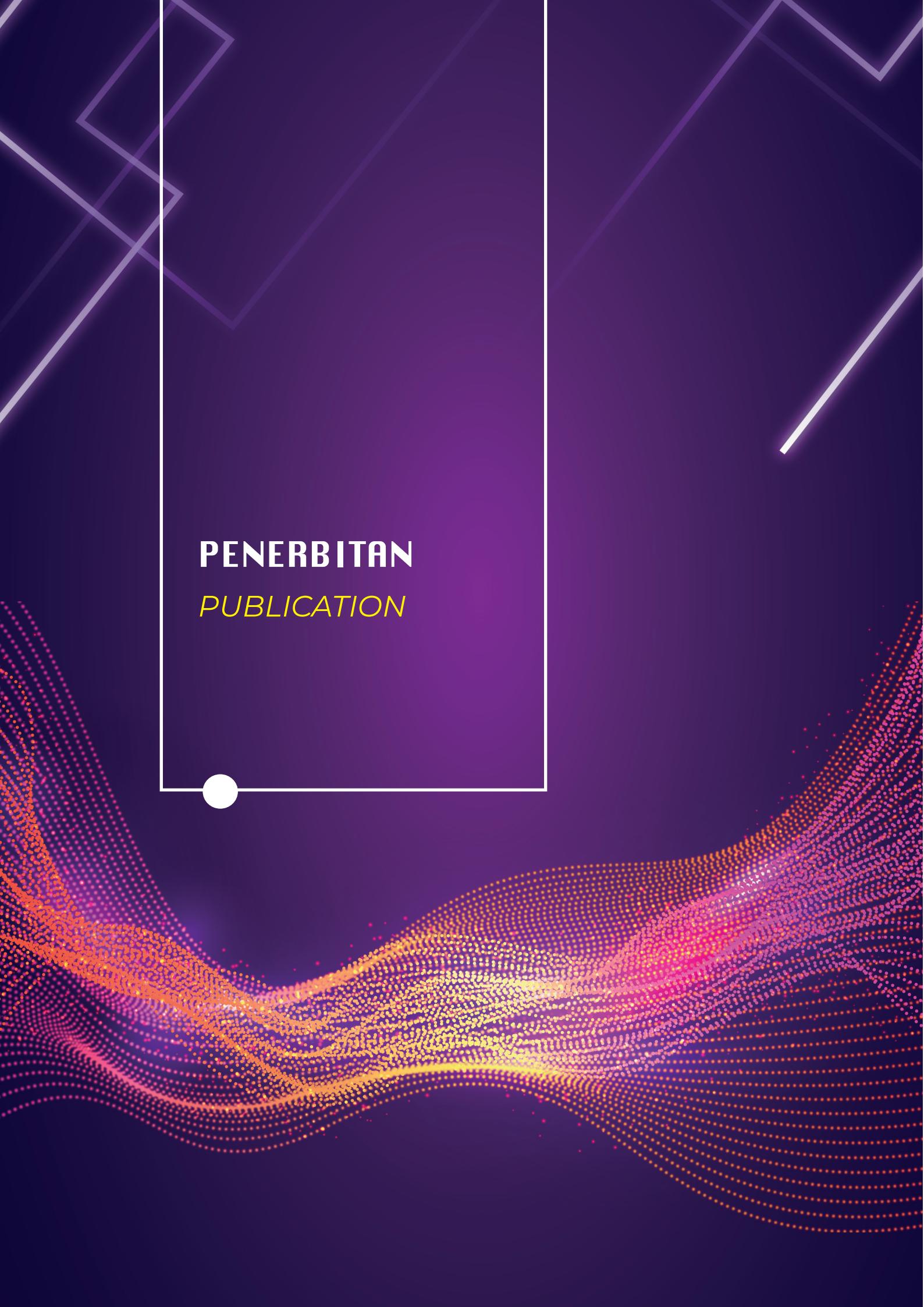
#### **4) In-Service Training for Overseas Courses**

Listed below are NPRA officers who attended in-service training overseas. The objectives of the trainings were to enhance and strengthen their knowledge and to ensure NPRA officers are equipped with the latest information on internationally adopted regulatory practices.

**Jadual 14: Senarai Pegawai NPRA yang mengikuti Latihan Dalam Perkhidmatan di Luar Negara**

**Table 14: List of NPRA officers who attended In-service Training overseas**

Bil. No.	Tajuk Latihan <i>Training Topic</i>	Tarikh Date	Penganjur Organiser	Lokasi Venue	Nama Pegawai Officer's name
1	<i>Regulations of Medicinal Cannabis at Therapeutic Goods Administration, Department of Health, Australia</i>	<i>5- 9 September 2022</i>	<i>Therapeutic Goods Administration (TGA)</i>	<i>Australia</i>	<i>Puan Fatin Diyana binti Fauzi</i>
2	<i>Training Programme for International Drug Regulatory Authorities on Evaluation of First-in-Human Clinical Trial</i>	<i>26-30 September 2022</i>	<i>Pharmaceutical and Medical Devices Agency (PMDA)</i>	<i>Tokyo, Japan</i>	<i>Dr. Zarin Harza bin Zakaria</i>



# PENERBITAN

*PUBLICATION*



# Buletin Jawatankuasa Penasihat Kesan Advers Malaysia (MADRAC) dan Laporan Ringkas Kesan Advers Susulan Imunisasi (AEFI) Vaksin COVID-19

## Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) Bulletin and Summary Report on Adverse Events Following Immunisation of COVID-19 Vaccines in Malaysia

Pada tahun 2022 NPRA telah menerbitkan tiga (3) edisi Buletin Jawatankuasa Penasihat Kesan Advers Malaysia (MADRAC) dan tiga (3) edisi Laporan Ringkas Kesan Advers Susulan Imunisasi (AEFI) Vaksin COVID-19 di Malaysia di mana kedua-dua penerbitan boleh dicapai menerusi laman web NPRA.

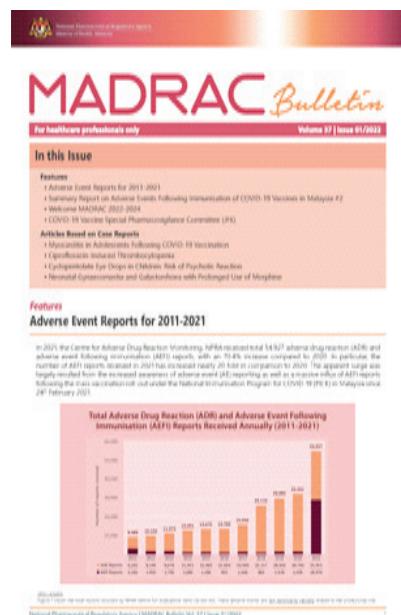
Buletin MADRAC memberi maklumat mengenai aktiviti Jawatankuasa Penasihat Kesan Advers Malaysia (MADRAC) yang bersidang setiap dua bulan dan memberi panduan kepada Pihak Berkuasa Kawalan Dadah (PBKD) mengenai isu keselamatan ubat-ubatan.

Laporan Ringkas Kesan Advers Susulan Imunisasi Vaksin COVID-19 di Malaysia pula merangkumi maklumat mengenai pengumpulan data oleh NPRA serta proses yang terlibat dalam pelaporan AEFI dan pemantauan keselamatan vaksin COVID-19.

Throughout 2022, NPRA has published three (3) editions of the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) Bulletin and three (3) issues of the Summary Report on Adverse Events Following Immunisation of COVID-19 Vaccines in Malaysia where both publications are readily available on NPRA's website.

The MADRAC Bulletin provides information on activities of the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC), which meets every two months and advises the Drug Control Authority (DCA) on drug safety issues.

Summary Report on Adverse Events Following Immunisation of COVID-19 Vaccines in Malaysia includes information on data collection by NPRA as well as the processes involved in AEFI reporting and COVID-19 vaccine safety monitoring.



Imej 33: Buletin MADRAC yang diterbitkan pada 2022  
Image 33: MADRAC Bulletins published in 2022



## Imej 34: Laporan Ringkas Kesan Adversus Susulan Imunisasi (AEFI) Vaksin COVID-19 yang diterbitkan pada tahun 2022

**Image 34: Summary Report on Adverse Events Following Immunisation of COVID-19 Vaccines in Malaysia issued in 2022**

# LAPORAN KEWANGAN

*FINANCIAL REPORT*

## BAJET MENGURUS 2022 OPERATING BUDGET 2022

Program <i>Program</i>	Kategori <i>Category</i>	Peruntukan <i>Allocation</i>	Perbelanjaan <i>Expenditure</i>		Baki <i>Balance</i>	
		(RM)	RM	%	RM	%
010100	Pengurusan Ibu Pejabat <i>Headquarters Management</i>	50,000.00	49,727.00	99.45%	273.00	0.55%
010500	Teknologi Maklumat Dan Komunikasi <i>Information Technology &amp; Communications</i>	200,000.00	174,616.32	87.31%	25,383.68	12.69%
050400	Farmasi Regulatori <i>Regulatory Pharmacy</i>	56,159,735.00	56,080,152.70	99.86%	79,582.30	0.14%
060200	Kejuruteraan <i>Engineering</i>	1,802,331.00	1,795,875.94	99.64%	6,455.06	0.36%
080800	Perolehan Aset <i>Asset Procurement</i>	91,778.00	91,778.00	100%	0.00	100%
<b>JUMLAH <i>TOTAL</i></b>		<b>58,273,844.00</b>	<b>58,162,149.96</b>	<b>99.81%</b>	<b>111,694.04</b>	<b>0.19%</b>

## BAJET PEMBANGUNAN 2022 DEVELOPMENT BUDGET 2022

Projek <i>Project</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>	32,689.00	32,299.00	98.81%	390.00	1.19%
01100	Peralatan Perubatan <i>Medical Equipment</i>	464,787.18	464,787.18	100%	0.00	100%
00300	Perkhidmatan Sokongan Hospital <i>Hospital Support Services</i>	3,601,413.00	3,595,308.98	99.83%	6,104.02	0.17%
006	Pembaikan Fasiliti Kesihatan <i>Health Facilities Repairs</i>	414,590.00	414,590.00	100%	0.00	100%
<b>JUMLAH <i>TOTAL</i></b>		<b>4,513,479.18</b>	<b>4,506,985.16</b>	<b>99.86%</b>	<b>6,494.02</b>	<b>0.14%</b>

## KUTIPAN HASIL TAHUN 2022

### REVENUE FOR 2022

Bil. No.	Perkara <i>Item</i>	Jumlah (RM) <i>Total (MYR)</i>
1	Akaun Amanah aktiviti pemeriksaan Amalan Perkilangan Baik (APB) <i>Good Manufacturing Practice (GMP) Trust Account</i>	1,183,323.89
2	Akaun Amanah aktiviti pemeriksaan Bioekuivalens (BE) <i>BE Trust Account</i>	705,107.64
3	Amalan Perkilangan Baik <i>Good Manufacturing Practice</i>	77,800.00
4	Invois Amalan Makmal Baik <i>Good Laboratory Practice Invoice</i>	24,000.00
5	Invois APB dalam negara <i>Local GMP Invoice</i>	384,500.00
6	Invois APB luar negara <i>Foreign GMP Invoice</i>	408,000.00
7	Invois BE <i>BE Invoice</i>	223,000.00
8	Penilaian Pelan Susun Atur Kilang <i>Factory Layout Plan</i>	121,000.00
9	<i>Lot Release Produk Plasma</i> <i>Plasma Product Lot Release</i>	78,200.00
10	<i>Lot Release Produk Vaksin</i> <i>Vaccine Lot Release</i>	111,500.00
11	Sijil APB <i>GMP Certificate</i>	43,850.00
12	Sijil APB Luar Negara <i>Foreign GMP Certificate</i>	3,250
13	Lesen Pemborong <i>Wholesaler's License</i>	608,000.00
14	Lesen Mengimport <i>Import License</i>	262,000.00
15	Lesen Pengilang <i>Manufacturer's License</i>	267,650.00
16	Pengelasan produk <i>Product Classification</i>	961,600.00
17	Perakuan Penjualan Bebas <i>Certificate of Free Sale</i>	239,750.00

Bil. No.	Perkara <i>Item</i>	Jumlah (RM) <i>Total (MYR)</i>
18	Sijil Indikasi <i>Certificate of Indication</i>	107,300.00
19	Sijil Deklarasi <i>Certificate of Declaration</i>	20,000
20	Fi Import Keluaran Tidak Berdaftar <i>Import Fee for Unregistered Item</i>	300.00
21	Notifikasi Kosmetik <i>Cosmetic Notification</i>	5,357,300.00
22	Pendaftaran Produk Baru <i>New Product Registration</i>	4,004,700.00
23	Pendaftaran Produk Veterinar <i>Veterinary Product Registration</i>	76,500.00
24	Pendaftaran Produk untuk Tujuan Eksport Sahaja <i>For Export Only (FEO) Registration</i>	75,000.00
25	Pendaftaran Semula Produk <i>Product Re-registration</i>	3,125,000.00
26	Pendaftaran Semula Produk Veterinar <i>Veterinary Product Re-registration</i>	111,100.00
27	Lesen Import Percubaan Klinikal <i>Clinical Trial Import License</i>	161,600.00
28	Tambahan Indikasi <i>Additional Indication</i>	54,000.00
29	Pertukaran Pemegang Pendaftaran <i>Change of Holder</i>	248,000.00
30	Pertukaran Tapak Pengilangan <i>Change of Manufacturer's site</i>	135,100.00
31	Variasi <i>Variation</i>	1,514,950.00
<b>Jumlah <i>Total</i></b>		<b>20,693,381.53</b>



**HALA TUJU**  
*WAY FORWARD*



Bahagian Regulatori Farmasi Negara (NPRA) sentiasa komited untuk merealisasikan aspirasi kerajaan demi mencapai tahap kesihatan yang lebih baik untuk rakyat. Perancangan hala tuju NPRA untuk tahun 2023 dan seterusnya adalah selaras dengan objektif dan insiatif jangka panjang yang telah diperincikan dalam Pelan Strategik Program Perkhidmatan Farmasi dan Dasar Ubat Nasional (DUNas).

Seiring dengan agenda nasional seperti Pelan Pembangunan Vaksin Negara (NVDR), NPRA meneruskan usaha untuk meningkatkan kawalan regulatori ke atas vaksin demi menyokong pembangunan vaksin oleh pengeluar tempatan. Antara perancangan untuk tahun 2023 termasuk mengukuhkan keupayaan makmal NPRA dalam melaksanakan ujian kawalan kualiti untuk produk vaksin berdaftar di Malaysia melalui pembangunan tatacara pengujian bagi pemantauan kualiti vaksin. Penumpuan diberi kepada pembangunan ujian potensi vaksin Meningococcal.

Penguatkuasaan pemeriksaan rutin Amalan Edaran Baik (AEB) ke atas pengimport dan pemborong yang mengendalikan produk sensitif masa dan suhu (*Time and Temperature Sensitive Products-TTSP*) turut diperkuuh dengan sasaran pemeriksaan ke atas 60 peratus daripada jumlah premis yang telah dikenalpasti. Objektif pelaksanaan adalah untuk memastikan pengimport dan pemborong yang dikenalpasti patuh kepada keperluan yang dinyatakan dalam Garis Panduan Amalan Pengedaran Baik (AEB).

Susulan pengeluaran direktif untuk penerimaan permohonan Lesen Import Percubaan Klinikal (CTIL) atau Kebenaran Mengilang untuk Percubaan Klinikal (CTX) bagi produk vaksin COVID-19 keluaran tempatan yang melibatkan kajian klinikal *First-in-Human* (FIH) pada tahun 2021, skop direktif akan diperluas kepada produk biologik pada tahun 2023. Perkara ini akan disusuli dengan usaha meningkatkan kepakaran dalam penilaian kajian klinikal

*The National Pharmaceutical Regulatory Agency (NPRA) is always committed in supporting the government's aspirations in achieving better health for the nation. NPRA's way forward for the year 2023 and beyond is in line with the long-term objectives and initiatives that have been outlined in the Pharmaceutical Services Programme Strategic Plan and the National Medicines Policy (DUNas).*

*In line with national agendas such as the National Vaccine Development Roadmap (NVDR), NPRA continues efforts to increase regulatory control of vaccines to support vaccine development by local manufacturers. Among the plans for the year 2023 include strengthening NPRA's laboratory capacity to conduct quality control testing of registered vaccine products in Malaysia through the development of testing methods for vaccine quality monitoring. Focus is given to the development of Meningococcal vaccine potency tests.*

*The enforcement of routine inspection of Good Distribution Practices (GDP) on importers and wholesalers handling time and temperature sensitive products (TTSP) is also strengthened with a target of inspection on 60 percent of the total number of premises identified. The objective of the implementation is to ensure that identified importers and wholesalers comply with the requirements set out in the Good Distribution Practice (GDP) Guidelines.*

*Following the issuance of the directive to accept applications for Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) for locally produced COVID-19 vaccine involving First-in-Human (FIH) clinical trials in 2021, the scope of the directive will be expanded to biological products in 2023. This will be followed by efforts to enhance expertise in the evaluation of FIH clinical trials for Cell and Gene Therapy products (CGTP) in preparation to expand the scope*

FIH bagi produk *Cell and Gene Therapy* (CGTP) sebagai persediaan untuk memperluas skop penilaian kepada produk CGTP sebagai sasaran jangka panjang.

Bagi menambahbaik proses kerja penilaian produk dan *Good Review Practice* (GrevP), strategi *reliance* akan digunakan dengan lebih luas lagi oleh NPRA bagi mengoptimumkan sumber dan kepakaran penilaian yang ada. Prinsip ini membolehkan NPRA memanfaatkan penilaian produk oleh Pihak Berkewajibkan rujukan. Dalam usaha ke arah menambahbaik proses pendaftaran produk, penumpuan turut diberi kepada penambahbaikan dalam prinsip *Good Submission Practice* (GSubP) oleh pihak industri melalui kajian rintis yang akan dimulakan dengan pihak industri generik.

Seiring dengan perkembangan era digital dan teknologi, NPRA sentiasa berusaha menambahbaik sistem pendaftaran dalam talian QUEST3+. Justeru, NPRA akan membangunkan sistem QUEST5, mengambil kira kejuruteraan semula proses kerja di NPRA dan keperluan integrasi dengan sistem lain di bawah Program Perkhidmatan Farmasi.

Pada tahun 2023 juga NPRA akan menempuh penilaian oleh *World Health Organization* (WHO) melalui WHO *Global Benchmarking Tool* (WHO GBT). WHO GBT digunakan oleh pihak WHO sebagai tools untuk menilai tahap kematangan sistem regulatori. Skop penilaian sistem regulatori ini termasuk produk farmaseutikal dan vaksin. Sasaran NPRA untuk penilaian ini adalah untuk mencapai tahap pematuhan tertinggi iaitu *Maturity Level 4*.

*of evaluation to CGTP products as a long-term target.*

*In order to improve the work processes of product evaluation and Good Review Practice (GrevP), the reliance strategy will be used more widely by NPRA to optimise current evaluation resources and expertise. This principle enables NPRA to make full use of the assessment already undertaken by reference authorities. In an effort towards improving the product registration process, focus will be towards enhancing the principles of Good Submission Practice (GSubP) by the industry through a pilot study that will be implemented with the generic industry as a start.*

*As we move alongside the advancements in the digital age and technology, NPRA is always working to improve the NPRA online registration system, QUEST3+. Thus, NPRA will develop the QUEST5 system, taking into account the re-engineering of work processes at NPRA and the need for integration with other systems under the Pharmacy Services Program.*

*In 2023, NPRA will undergo an assessment by the World Health Organization (WHO) through the WHO Global Benchmarking Tool (WHO GBT). WHO GBT is used by the WHO as a tool to evaluate the maturity level of regulatory systems. The scope of assessment includes pharmaceutical products and vaccines. NPRA's target for this assessment is to achieve the highest level of compliance which is Maturity Level 4.*



## CATATAN





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