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LAPORAN TAHUNAN BAHAGIAN REGULATORI FARMASI NEGARA **2020**



LAPORAN TAHUNAN ANNUAL REPORT

BAHAGIAN REGULATORI FARMASI NEGARA
NATIONAL PHARMACEUTICAL REGULATORY AGENCY



2020

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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

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

Misi Mission

Objektif Objective

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

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



PERUTUSAN PENGARAH DIRECTOR'S FOREWORD



Pengarah | *Director*
Dr. Hasenah Ali

Bahagian Regulatori Farmasi Negara |
National Pharmaceutical Regulatory Agency



Tidak dinafikan bahawa tahun 2020 merupakan tahun yang penuh cabaran dengan kemunculan coronavirus novel pada bulan Disember 2019 yang dikenali sebagai COVID-19. Susulan situasi yang tidak dijangka ini di mana seluruh dunia terkesan dengan situasi pandemik, badan regulatori di seluruh dunia termasuk Bahagian Regulatori Farmasi Negara (NPRA), terpaksa menyesuaikan diri kepada perubahan dalam kawalan regulatori.

Kesukaran yang dihadapi sewaktu menghadapi pandemik telah benar-benar mengubah cara kita beroperasi untuk memastikan penyampaian perkhidmatan yang berterusan kepada rakyat. Sepanjang tahun ini, norma baru seperti pematuhan Prosedur Operasi Standard (SOP) dan langkah-langkah penjarakan sosial seperti bekerja dari rumah telah diterapkan dalam budaya kerja. Penggunaan platform maya digalakkan untuk memastikan persekitaran kerja yang selamat dan produktif. Sehubungan dengan itu, saya ingin mengambil kesempatan ini untuk mengucapkan terima kasih dan tahniah kepada semua anggota NPRA yang sering memberikan komitmen dan dedikasi yang tinggi walaupun menghadapi cabaran untuk memberikan perkhidmatan yang berkualiti.

Fasa awal pandemik telah memberi impak yang besar kepada ekonomi negara. Dengan itu, NPRA mengambil langkah untuk mengutamakan dan memastikan bekalan produk farmaseutikal tidak terputus. Beberapa langkah pengemaskinian prosedur regulatori dilaksanakan untuk memastikan

There is no denying that 2020 was an unprecedented year following the emergence of the novel coronavirus in December 2019 known as COVID-19. Regulatory authorities around the world including the National Pharmaceutical Regulatory Agency (NPRA) were forced to adapt to changes in the regulatory landscape as the pandemic affected countries globally.

During these trying times, the pandemic has truly changed the way we operate to ensure continuous service delivery to the public. In this past year, we have embraced the new normal and adhered to Standard Operating Procedures (SOPs) and social distancing measures such as working from home. We have also utilised virtual platforms to ensure a safe and productive working environment. In this regard, I would like to take this opportunity to thank and congratulate all NPRA staff who have always given their utmost commitment and dedication despite such restrictions and challenges to deliver quality services.

In the early phase of the pandemic, the economy was impacted significantly. Thus, NPRA prioritized the need to ensure continuity of supply for pharmaceutical products. Several regulatory measures and procedures were updated to suit the current situation. These measures facilitate the supply



produk farmaseutikal yang digunakan untuk rawatan COVID-19 dan produk sanitasi dapat dibekalkan.

Salah satu pelan kesiapsiagaan utama NPRA dalam menghadapi pandemik ini termasuk persediaan pendaftaran vaksin COVID-19. Saya berbangga dengan usaha Kumpulan Vaksin NPRA, yang bertungkus-lumus menyediakan Garis Panduan Pendaftaran Bersyarat untuk Produk Farmaseutikal Semasa Bencana yang diluluskan di Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) ke-351. Penetapan mekanisme pendaftaran ini adalah langkah pertama dalam persediaan untuk menerima permohonan calon vaksin COVID-19 untuk penilaian, yang seterusnya akan mempercepatkan akses vaksin kepada rakyat ketika kita melangkah lebih jauh dalam pandemik ini.

Walaupun sentiasa berhadapan dengan cabaran situasi COVID-19, NPRA tetap memastikan dasar dan program kerajaan seperti Dasar Ubat Nasional (DUNas) (2017-2021) dan Pelan Strategik NPRA (2021-2025) berada di landasan yang tepat untuk dilaksanakan. Antara strategi utama yang ingin dilaksanakan dalam jangka waktu lima tahun termasuk memperkukuhkan kawalan gas perubatan di Malaysia, membangunkan rangka undang-undang untuk penyelidikan percubaan klinikal, memperkembangkan pelaksanaan Amalan Farmakovigilans Baik dan lain-lain. Sebilangan besar inisiatif ini adalah selari dengan persediaan NPRA untuk mencapai akreditasi *Maturity Level-4* sebagai *Listed Authority* Pertubuhan Kesihatan Sedunia (WHO) apabila dinilai oleh WHO kelak.

Walau bagaimanapun, perjalanan kita belum berakhir di sini kerana pelbagai inisiatif perlu diusahakan untuk menyokong Program Immunisasi COVID-19 Nasional bagi tahun 2021 dan seterusnya. Dengan kesungguhan yang ditunjukkan oleh NPRA setakat ini, saya yakin bahawa NPRA akan lebih maju ke hadapan dalam pengukuhan sistem kawalan regulatori serta menyumbang kepada usaha untuk menamatkan pandemik ini, insya Allah.

of pharmaceutical products for treatments related to COVID-19 as well as the urgent demand for sanitizing products.

One of NPRA's main preparedness plan during this pandemic include to register COVID-19 vaccines. I am proud of the teamwork exhibited by NPRA's Vaccine Team, who had been tirelessly contributing efforts to finalise the Guideline for Conditional Registration for Pharmaceutical Products During Disasters guideline which was approved at the 351st Meeting of the Drug Control Authority (DCA). This registration pathway is the first step in preparation towards receiving dossiers of many COVID-19 candidate vaccines for evaluation, and therefore facilitating expedited access of vaccines to the public as we navigate further in this pandemic.

Despite the challenges faced due to COVID-19, NPRA continues to ensure that government policies and programs such as Malaysian National Medicines Policy (DUNas) (2017-2021) and NPRA Strategic Plan (2021-2025) are on track for implementation. Among the strategic priorities aimed to be implemented within a five-year term include strengthening regulatory control of medicinal gases in Malaysia, developing a legal framework for clinical trial research, strengthening implementation of Good Pharmacovigilance Practice and many more. Many of these initiatives are aligned with NPRA's preparation towards becoming a World Health Organization (WHO) Listed Authority -Maturity Level 4, once benchmarking is conducted by WHO in the near future.

Nevertheless, our journey does not end here as there are still much work to be done towards supporting the National COVID-19 Immunisation Programme for 2021 and beyond. With the resilience shown by NPRA thus far, I am confident that NPRA will rise above expectations as we work towards continuously strengthening our regulatory system and also contribute towards initiatives to end the pandemic, insyaAllah.





PENGURUSAN TERTINGGI TOP MANAGEMENT



Dr. Hasenah Ali

Pengarah
Bahagian Regulatori Farmasi Negara
Director
National Pharmaceutical Regulatory Agency



Rosilawati Ahmad

Timbalan Pengarah
Pusat Penilaian Produk & Kosmetik
Deputy Director
Centre of Product & Cosmetic Evaluation



Dr. Roshayati Mohamad Sani

Timbalan Pengarah
Pusat Komplians & Kawalan Kualiti
Deputy Director
Centre of Compliance & Quality Control



Basariah Naina

Timbalan Pengarah
Pusat Koordinasi & Perancangan
Strategik Regulatori
Deputy Director
Centre of Regulatory Coordination & Strategic Planning



Azlin Ahmad

Ketua Pusat Pentadbiran
Head
Centre for Administration





Pengenalan INTRODUCTION

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

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

Bermula tahun 1985, NPRA dipertanggungjawab untuk memastikan kualiti, keberkesanan dan keselamatan produk farmaseutikal melalui penilaian data saintifik dan ujian makmal. Sistem pemantauan produk-produk di pasaran juga telah diwujudkan. Sejak itu, NPRA telah memperluaskan kawalan kualiti dan keselamatan ke atas produk-produk bukan preskripsi, tradisional, kosmetik, veterineri, bahan aktif farmaseutikal (API) dan seterusnya kawalan ke atas produk vaksin melalui aktiviti Vaccine Lot Release.

Sejajar dengan perkembangan semasa, NPRA telah melaksanakan perubahan struktur organisasi melalui proses pengstrukturkan semula yang telah berkuat kuasa mulai 2 Disember 2019. Proses ini melibatkan perubahan utama di mana tujuh pusat asal dalam NPRA telah disusun semula menjadi empat pusat sahaja bagi menyelaraskan semula semua aktiviti utama NPRA mengikut fungsi pusat. Dengan pelaksanaan pengstrukturkan semula ini, pihak NPRA akan terus berusaha untuk menambahbaik lagi kualiti perkhidmatan yang diberikan demi mencapai misi untuk menjamin kesihatan rakyat melalui kawalan regulatori ubat-ubatan dan kosmetik berlandaskan kecemerlangan saintifik.

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

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

Starting from 1985, NPRA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through evaluation of scientific data and laboratory tests. A system to monitor products in the market was also established. Over the years, NPRA has extended the regulatory control of the quality and safety for non-prescription medicines, traditional products, cosmetics, veterinary products, active pharmaceutical ingredients (API) including the quality control of vaccine through Vaccine Lot Release activities.

In line with current developments, NPRA underwent a major restructuring process which came into effect on the 2nd of December 2019, whereby the previous seven centres have been rearranged to four centres, and the main activities of NPRA have been streamlined according to the each centre's function. 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

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



PENGARAH | DIRECTOR



Pusat Komplians dan Kawalan Kualiti *Centre of Compliance and Quality Control*

- Pengujian makmal bagi semua kategori produk
Laboratory testing for all category of products
- Penilaian data validasi
Analytical validation data evaluation
- Validasi kaedah pengujian baru
Validation of new testing methods
- Pemeriksaan ke atas tapak pengilangan produk
Inspection on manufacturing sites
- Aktiviti surveilans pasca pendaftaran produk
Post registration surveillance activities
- Farmakovigilans
Pharmacovigilance
- Pemeriksaan ke atas tapak percubaan klinikal
Conduct inspections on clinical trial sites
- Pemeriksaan ke atas pusat kajian Bioequivalence
Conduct inspections on Bioequivalence centres



Pusat Penilaian Produk dan Kosmetik *Centre of Product and Cosmetic Evaluation*

- Penilaian ke atas dosier untuk pendaftaran produk
Dossier evaluation for product registration
- Notifikasi kosmetik
Cosmetic Notifications
- Penilaian permohonan serta penjaan lesen import untuk Produk Percubaan Klinikal (CTIL), Kebenaran Mengilang Produk Percubaan Klinikal (CTX) dan Notifikasi Kajian Bioekuivalens (BE)
Evaluation and issuance of licences for Clinical Trial Import License, Clinical Trial Exemption and BE studies notification



Pusat Koordinasi dan Perancangan Strategik Regulatori *Centre of Regulatory Coordination and Strategic Planning*

- Perancangan halatuju, penyelidikan, pelan strategik dan penambahbaikan aktiviti serta prosedur kerja regulatori
Way forward planning, research, strategic planning and improvement activities as well as regulatory work procedures
- Pengendalian dan pemantauan sistem pendaftaran produk dan notifikasi kosmetik atas talian (*online*), laman web dan mobile apps NPRA
Handling and monitoring of the online product registration and cosmetic notification system, website and NPRA mobile apps
- Pengendalian latihan dalam dan luar negara, pengurusan sumber manusia (Pegawai Farmasi), peruntukan dan perkembangan kerjaya
Handling local and international trainings, human resource (Pharmacist), allocations and career development
- Menyelaraskan sistem pengurusan kualiti jabatan termasuk bagi pensijilan MS ISO 9001
Coordinates the quality management system including MS ISO 9001



Pusat Pentadbiran *Centre of Administration*

- Aktiviti pentadbiran dan kewangan
Administrative and financial activities



PIAGAM PELANGGAN

CLIENT CHARTER

PENDAFTARAN PRODUK

MASA

Penilaian Penuh

- Menilai permohonan pendaftaran:
 - Ubat preskripsi 210 hari bekerja*
 - Ubat bukan preskripsi 210 hari bekerja*
 - Ubat baru dan biologiikal 245 hari bekerja*

Penilaian Ringkas

- Menilai permohonan pendaftaran ubat bukan preskripsi[#], produk suplemen kesihatan dan produk semulajadi yang mengandungi:
 - Bahan aktif tunggal 116 hari bekerja*
 - Dua (2) atau lebih bahan aktif 136 hari bekerja*
- Pengeluaran notifikasi kosmetik 1 hari bekerja^
- Sijil Penjualan Bebas Kosmetik 15 hari bekerja*
- Keputusan permohonan pertukaran Pemegang Pendaftaran 45 hari bekerja*
- Sijil Produk Farmaseutikal (CPP) / Sijil Penjualan Bebas (CFS) 15 hari bekerja*
- Keputusan permohonan pertukaran tapak pengilang 60 hari bekerja*

PELESENAN

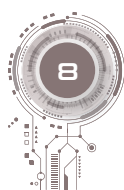
MASA

- Pengeluaran lesen pengilang, pemborong dan mengimport 4 hari bekerja*
- Penilaian Permohonan Lesen Import untuk Percubaan Klinik (CTIL) dan Kebenaran Mengilang untuk Percubaan Klinik (CTX):
 - Bagi produk yang melibatkan Kajian Fasa I, produk biologiikal, *Cell & Gene Therapy Products* (CGTPs) dan produk herba 45 hari bekerja*
 - Bagi produk-produk selain daripada yang disebutkan di atas 30 hari bekerja*

* Setelah permohonan lengkap diterima

^ Bagi permohonan yang memenuhi keperluan yang ditetapkan

#Bagi produk-produk yang disenaraikan pada Table V Drug Registration Guidance Document (DRGD)





PIAGAM PELANGGAN

CLIENT CHARTER



PRODUCT REGISTRATION

DURATION

Full Evaluation

- | | |
|--|-------------------|
| • To evaluate application for registration of: | |
| o Prescription drugs | 210 working days* |
| o Non-prescription drugs | 210 working days* |
| o New drugs and biological | 245 working days* |

Abridged Evaluation

- | | |
|--|-----------------------------|
| • To evaluate application for registration of non-prescription medicine [#] , health supplements and traditional products containing: | |
| o Single active ingredient | 116 working days* |
| o Two (2) or more active ingredients | 136 working days* |
| • Issuance of cosmetic notification | 1 working days [^] |
| • Certificate of Free Sale for Cosmetic Products | 15 working days* |
| • Change of registration holder | 45 working days* |
| • Certificate of Pharmaceutical Product (CPP) / Certificate of Free Sale (CFS) | 15 working days* |
| • Change of manufacturing site application | 60 working days* |

LICENSING

DURATION

- | | |
|---|------------------|
| • Issuance of manufacturer's, wholesaler's and importer's license | 4 working days* |
| • Evaluation of import license application for Clinical Trial License (CTIL) and Clinical Trial Exemption (CTX): | |
| o For products involving Phase 1 Trial, biological products, Cell & Gene Therapy Products (CGTPs) and herbal products | 45 working days* |
| o For products other than stated above | 30 working days* |

*Upon receipt of complete application

[^]For applications fulfilling the stipulated requirements

[#] For products that are listed in Table V of the Drug Registration Guidance Document (DRGD)



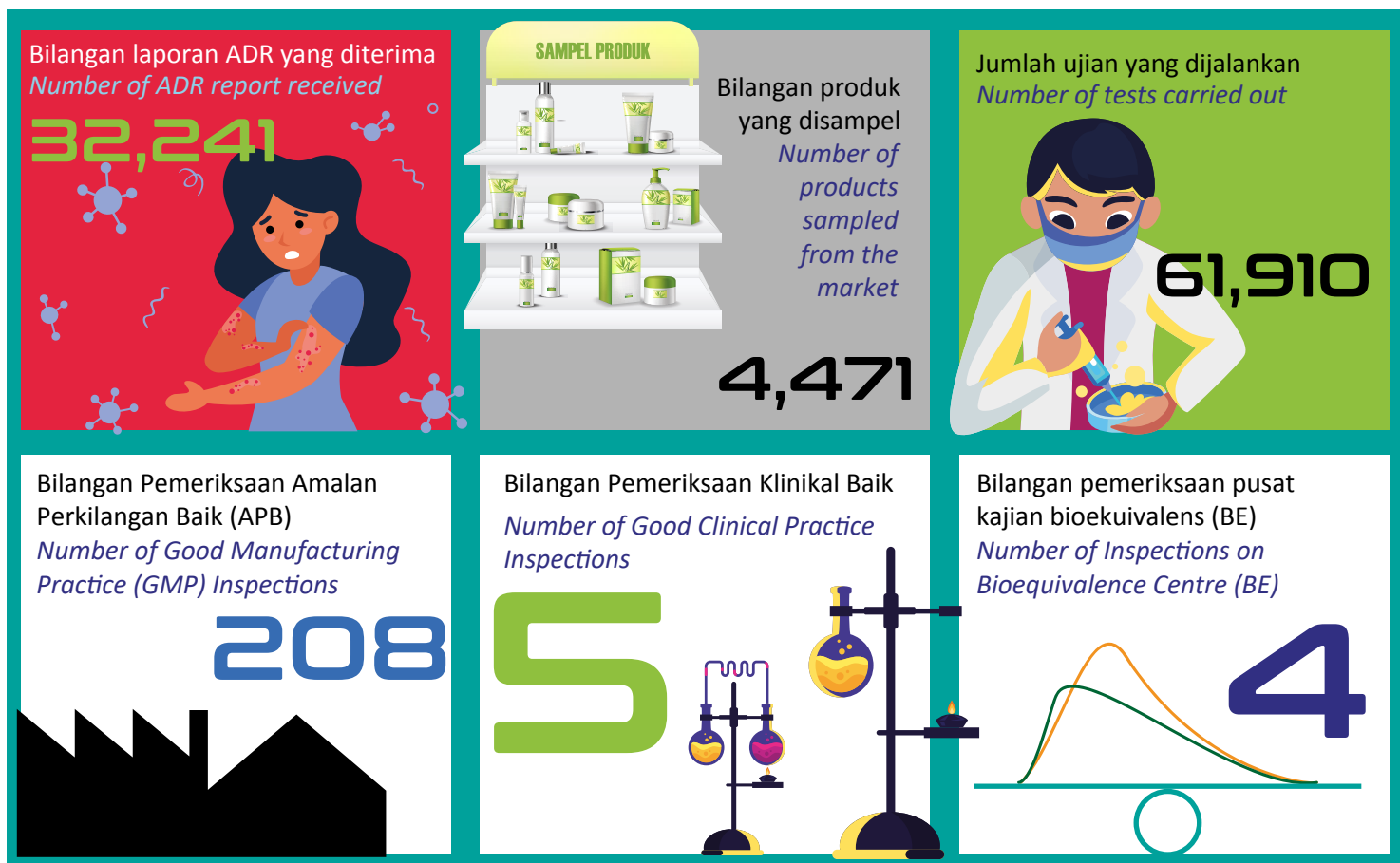
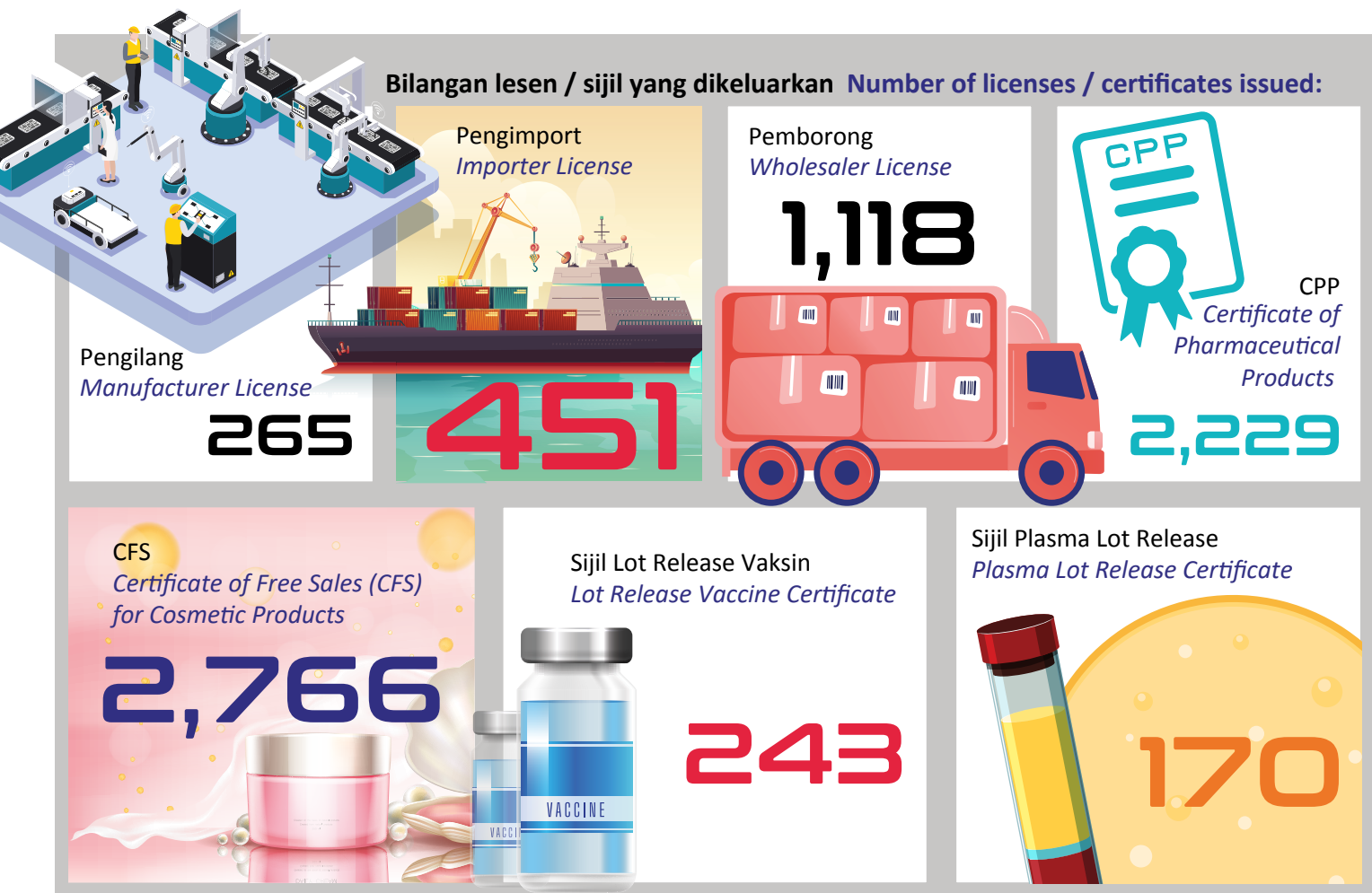
STATISTIK RINGKAS BRIEF STATISTICS

Bilangan Permohonan Pendaftaran Produk *Number of product registration applications received*



Bilangan Produk yang Didaftarkan *Number of products registered*





**KESIAPSIAGAAN DAN
TINDAKAN YANG DIAMBIL
OLEH BAHAGIAN
REGULATORI FARMASI
NEGARA SEMASA
PANDEMIK COVID-19**

**PREPAREDNESS AND ACTIONS TAKEN BY THE
NATIONAL PHARMACEUTICAL REGULATORY AGENCY
DURING COVID-19 PANDEMIC**

Seluruh dunia telah dikejutkan dengan kemunculan coronavirus baharu pada bulan Disember 2019 iaitu 2019-nCoV atau SARS-CoV-2, yang kemudiannya diberi nama COVID-19 oleh Pertubuhan Kesihatan Sedunia (WHO). Sehubungan dengan itu, negara-negara di seluruh dunia telah mengambil langkah proaktif untuk membendung penyebaran penyakit ini.

Dengan peningkatan kes positif di Malaysia, kerajaan telah melaksanakan Perintah Kawalan Pergerakan (PKP) bermula 18 Mac 2020. PKP bertujuan untuk membataskan pergerakan orang awam bagi mengurangkan penularan COVID-19. Hampir semua sektor ditutup kecuali perkhidmatan penting seperti sektor kesihatan.

Dalam situasi yang sukar sebegini, Bahagian Regulatori Farmasi Negara (NPRA) telah memastikan perkhidmatan kepada masyarakat diteruskan dan bekalan ubat-ubatan di negara ini tidak terjejas. Beberapa langkah yang diambil adalah seperti yang tersenarai di bawah:

- a. Pengeluaran Arahan oleh Pengarah Kanan Perkhidmatan Farmasi di bawah Peraturan-peraturan Kawalan Dadah dan Kosmetik (PKDK) 1984: Keperluan untuk Mengemaskini dan Mengemukakan Rekod Pembekalan Produk Berdaftar
 - Pemegang Pendaftaran Produk (PRH) perlu mengemukakan maklumat berkenaan status stok sedia ada dan melaporkan sekiranya terdapat kekurangan bekalan secara bulanan
- b. Pengeluaran Arahan Pengecualian di bawah Peraturan-peraturan Kawalan Dadah dan Kosmetik (PKDK) 1984
 - Untuk mengilang produk hydroxychloroquine dan *hand sanitiser*
- c. Memudahkan proses variasi melalui *Minor Variation (Notification) "Do and Tell"*
 - Pertukaran pengeluar bahan aktif farmaseutikal (API), *Intermediate API*, *excipients* dan *resizing of packaging packs* dimasukkan di bawah kategori

The whole world was shocked by the emergence of the novel coronavirus in December 2019 called 2019-nCoV or SARS-CoV-2, which was then renamed to COVID-19 by the World Health Organization (WHO). Hence, countries around the world took proactive measures to curb the spread of the disease.

Due to the surge of positive cases in Malaysia, the government implemented Movement Control Order (MCO) starting 18th of March 2020. The MCO is intended to limit the public's movement to reduce the rapid spread of COVID-19. Almost all sectors were closed except for the essential services which included the health sector.

In these trying times, the National Pharmaceutical Regulatory Agency (NPRA) continued to serve the public to ensure continuity of supply of pharmaceutical products in the country. Some of the regulatory measures taken are listed below:

- a. *Issuance of Directive by the Senior Director of Pharmaceutical Services under the Control of Drugs and Cosmetics Regulations (CDCR) 1984: Requirement to Update and Submit Records of Supply of Registered Products*
 - *Product Registration Holders (PRH) need to submit on monthly basis the current stock status information and report if there is a shortage of supply*
- b. *Issuance of exceptions under the Control of Drugs and Cosmetic Regulations (CDCR) 1984*
 - *For the manufacture of hydroxychloroquine and hand sanitiser products*
- c. *Facilitate the process of minor variation (Notification) through "Do and Tell"*
 - *The change of manufacturer of active pharmaceutical ingredient (API), Intermediate API, excipients and resizing of packaging packs is placed*

- “Do and Tell” memandangkan kesukaran untuk mendapatkan bekalan API dan *Intermediate* API semasa pandemik ini
- Bungkus kecil produk *hand sanitizer* juga diletakkan di bawah kategori “Do and Tell” kerana penggunaan yang tinggi semasa pandemik ini

d. Pengurusan pengujian klinikal

- Tempoh masa penilaian produk kajian bagi pengujian klinikal yang melibatkan COVID-19 telah dipendekkan untuk mempercepatkan penilaian produk tersebut. Walau bagaimanapun, keperluan regulatori yang perlu dipatuhi adalah tetap sama.

e. Pengurusan Pemeriksaan GxP (GMP / GCP / GLP)

- Semua pemeriksaan luar negara ditunda
- Untuk pemeriksaan domestik *on-site inspections* - tertakluk kepada kriteria, berdasarkan keutamaan dan penilaian risiko
- Untuk pemeriksaan domestik *off-site inspections* - *desktop inspection*, *desktop assessment* serta pemeriksaan jarak jauh (*online/web-based*) telah dijalankan

f. Memantau keselamatan ubat-ubatan yang digunakan untuk rawatan pesakit COVID-19

- Memantau laporan kesan advers (ADR) ubat kerana kebanyakan ubat yang digunakan untuk rawatan COVID-19 adalah produk yang digunakan selain daripada indikasi (*off-label use*) dan produk tidak berdaftar. Analisis ADR berdasarkan jumlah laporan, demografik pesakit dan kejadian yang dilaporkan disediakan setiap minggu untuk mengenal pasti sebarang isu keselamatan yang timbul daripada penggunaan ubat secara *off-label*

g. Pendaftaran produk-produk pembasmi kuman pada permukaan (*surface disinfectant*) secara sukarela

under the “Do and Tell” category to assist the industry in sourcing supply of API and intermediate API due to difficulties experienced during the pandemic

- *The pack size of hand sanitizer products is also placed under “Do and Tell” category due to high usage during the pandemic*

d. Management of clinical trials

- *Expedited pathway for COVID-19 related product by shortening evaluation timeline. However, other regulatory requirement remains the same.*

e. Management of GxP Inspections (GMP/ GCP/GLP)

- *All overseas inspections were postponed*
- *For domestic on-site inspections – subjected to criteria, based on priority and risk assessment*
- *For domestic off-site inspections – desktop inspections, assessment and remote inspections (online/web-based) were carried out*

f. Monitoring safety of medicines used for the treatment of COVID-19 patients

- *Monitor the adverse event reporting of drugs because majority of drugs used for COVID-19 treatment are off-label and are unregistered products. An analysis of ADR based on number of reports, patient demographic and reported events are prepared weekly in order to identify any safety signal arising from the off-label use of the drugs*

g. Voluntary Registration of surface disinfectants



- Oleh kerana permintaan yang tinggi daripada pengguna untuk produk *hand sanitizer* dan *disinfectant* sejak awal pandemik ini, terdapat keperluan untuk memastikan *surface disinfectant* yang terdapat di pasaran adalah selamat dan berkesan. Oleh itu, NPRA diberi mandat oleh Ketua Pengarah Kesihatan untuk memantau dan menguatkuasakan kawalan regulatori ke atas produk-produk ini
- Mulai 10 September 2020, NPRA menerima permohonan pendaftaran produk *surface disinfectant* secara sukarela
- Permohonan pendaftaran hendaklah dikemukakan secara manual dan produk tersebut mesti mematuhi syarat-syarat di dalam *Guidelines for Registration of Surface Disinfectants*
- *Due to the high demand from consumers for hand sanitizer and disinfectant products since the start of the pandemic, there is an urgent need to ensure the safety and efficacy of surface disinfectants in the market. Thus, NPRA is given the mandate by the Director General of Health to monitor and impose regulatory control on these products*
- *Beginning from the 10th of September 2020, NPRA started accepting applications for the voluntary registration of surface disinfectants*
- *The application shall be submitted manually and the product shall conform with the requirements in the Guidelines for Registration of Surface Disinfectants*



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MAKLUMAT REGULATORI TERKINI

REGULATORY UPDATES

Pendaftaran Vaksin Untuk COVID-19

Malaysia mempunyai beberapa mekanisme untuk mempercepatkan pendaftaran produk farmaseutikal untuk memastikan akses segera ubat-ubatan kepada orang awam.

New Vaccine registration for COVID-19

Malaysia has several accelerated pathways to expedite registration of pharmaceutical products to ensure timely access to public.

Jenis penilaian <i>Types of Pathway</i>	Masa penilaian maksimum <i>Maximum review time</i>	Nota <i>Notes</i>
1. Penilaian secara keutamaan <i>Priority review</i>	120 hari bekerja <i>120 working days</i>	Data dibenarkan dikemukakan secara berperingkat <i>Rolling submission is allowed</i>
2. Pendaftaran Bersyarat <i>Conditional Registration Pathway</i>	245 hari bekerja <i>245 working days</i>	Untuk produk dengan data klinikal yang terhad, kelulusan yang diberikan adalah untuk dua (2) tahun dan bukannya lima (5) tahun <i>For premature/ limited clinical data, approval given is for two (2) years instead of five (5) years</i>
3. Facilitated Registration Pathway <i>Facilitated Registration Pathway</i>		
a. Penilaian singkat <i>Abbreviated</i>	120 hari bekerja <i>120 working days</i>	Memerlukan kelulusan satu (1) agensi rujukan iaitu <i>European Medicines Agency (EMA)</i> atau <i>United States Food and Drug Administration (US FDA)</i> <i>Requires approval from one reference agency: European Medicines Agency (EMA) or United States Food and Drug Administration (US FDA)</i>
b. Verifikasi <i>Verification</i>	90 hari bekerja <i>90 working days</i>	Perlukan kelulusan kedua-dua agensi rujukan iaitu <i>European Medicines Agency (EMA)</i> dan <i>United States Food and Drug Administration (US FDA)</i> <i>Requires approval from both reference agencies: European Medicines Agency (EMA) or United States Food and Drug Administration (US FDA)</i>
4. Penilaian <i>Fast Track</i> Bersyarat untuk Produk Farmaseutikal Semasa Bencana (BAHARU) <i>Conditional Fast Track Registration for Pharmaceutical Products During Disasters (NEW)</i>	120 hari bekerja <i>120 working days</i>	Data dibenarkan dikemukakan secara berperingkat <i>Rolling submission is allowed</i>

Memandangkan keperluan mendesak untuk vaksin COVID-19 bagi kegunaan orang awam, Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) ke-351 pada 3 Disember 2020 telah bersetuju untuk melaksanakan pendaftaran *fast track* bersyarat untuk produk farmaseutikal semasa bencana seperti yang diperuntukkan di bawah Peraturan 8, Peraturan-peraturan Kawalan Dadah dan Kosmetik (PKDK) 1984.

Pelaksanaan mekanisme ini adalah sama seperti proses pendaftaran bersyarat sedia ada di NPRA seperti yang digariskan di dalam Garis Panduan Pendaftaran Bersyarat untuk Entiti Kimia Baru dan Produk Biologik di Malaysia, dengan tambahan pertimbangan beberapa syarat yang lain. Permohonan jenis ini akan diberikan status penilaian keutamaan (*priority review*). Tempoh masa yang diperuntukkan adalah 120 hari bekerja dari tarikh permohonan lengkap diterima.

Objektif pendaftaran bersyarat semasa bencana adalah untuk menyediakan akses segera kepada produk farmaseutikal (contohnya vaksin COVID-19) untuk rawatan atau pencegahan semasa bencana tanpa menjejaskan aspek kualiti, keselamatan dan keberkesanan produk kerana ia menggunakan pendekatan penilaian risiko. Produk yang diberi laluan ini perlu sekurang-kurangnya berada pada kajian klinikal Fasa III yang berterusan, di mana data awal berkenaan keselamatan dan keberkesanan produk dapat diperolehi. Produk ini juga mesti sekurang-kurangnya mendapat kelulusan (melalui kegunaan kecemasan atau mekanisme yang setaraf dengannya) daripada agensi regulatori negara asal atau mana-mana agensi rujukan PBKD atau Pertubuhan Kesihatan Sedunia (WHO).

Pendaftaran bersyarat ini sah untuk tempoh satu (1) tahun. Selepas itu, pendaftaran bersyarat boleh diperbaharui sebanyak dua (2) kali (dengan tempoh sah setahun bagi setiap pembaharuan).

In view of the urgent need for COVID-19 vaccines to be available for the public, the 351st Meeting of the Drug Control Authority (DCA) on the 3rd of December 2020 agreed to implement conditional fast track registration for pharmaceutical products during disasters as provided under Regulation 8, Control of Drugs and Cosmetics Regulations (CDCR) 1984.

The implementation of this conditional fast track registration mechanism is based on the existing conditional registration process in NPRA as stated in the Guideline on Conditional Registration for New Chemical Entities and Biologics in Malaysia with consideration of some other requirements and flexibilities. These applications will be given an automatic priority review. The timeline is 120 working days from the date whereby the complete application is received.

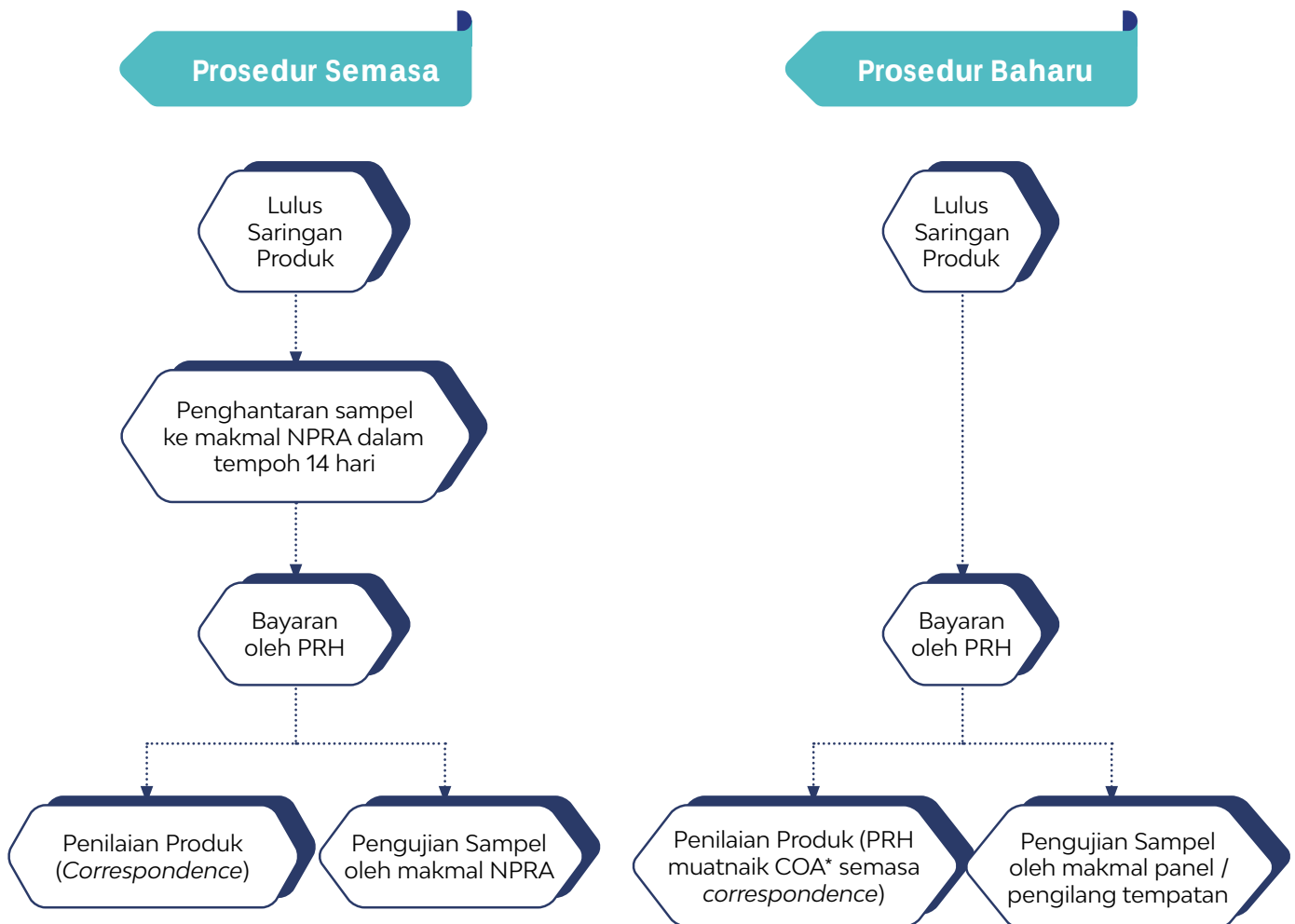
The objective of conditional registration during a disaster is to provide expedited access to pharmaceutical products (example COVID-19 vaccines) for treatment or prevention during disasters without compromising aspects of quality, safety and efficacy using a risk-based approach. The product given this pathway should at least be in an on-going Phase III clinical study that has preliminary data on safety and efficacy. The product must have at least been given /obtained authorization for use (via emergency use approval or any pathway equivalent to it) or have obtained marketing authorization from national regulatory authorities of country of origin OR any DCA reference agencies OR by World Health Organization (WHO).

A conditional registration is valid for one (1) year. Thereafter, the conditional registration may be renewed up to two (2) times (with a validity period of one (1) year for each renewal).



Penerimaan Keputusan Pengujian Pra-Pendaftaran Produk Semulajadi dari Makmal Swasta dan Makmal Kawalan Kualiti Pengilang Tempatan

Acceptance of Pre-Registration Testing of Natural Products from Private Laboratories and Quality Control Laboratories of Local Manufacturers



* Sijil analisa (COA) yang dikemukakan dari makmal panel / makmal pengilang tempatan semasa penilaian produk perlu menyatakan nombor rujukan (Reference Number) produk tersebut dari Sistem Quest 3+.

Pada 30 April 2020, Pihak Berkuasa Kawalan Dadah (PBKD) telah bersetuju untuk menerima keputusan pengujian pra-pendaftaran produk semulajadi dari makmal swasta yang telah diiktiraf oleh NPRA dan makmal kawalan kualiti pengilang tempatan. Sehubungan dengan itu, NPRA telah mula melaksanakan praktis ini sejak 1 Disember 2020.

On the 30th of April 2020, the Drug Control Authority (DCA) agreed to accept pre-registration test results of natural products from private laboratories that have been recognized by NPRA and quality control laboratories of local manufacturers. In this regard, the NPRA has started implementing this practice from 1st of December 2020.

► ► ► ►

Pelaksanaan praktis ini termasuklah keperluan Pemegang Pendaftaran Produk (PRH) untuk mengemukakan keputusan ujian dalam bentuk sijil analisa (*certificate of analysis*) dari makmal swasta yang telah diiktiraf oleh NPRA (makmal panel) atau makmal kawalan kualiti pengilang tempatan bagi tujuan penilaian permohonan pendaftaran produk semasa correspondence melalui sistem QUEST 3+. PRH tidak perlu menghantar sampel pra-pendaftaran ke makmal NPRA. Proses kerja dan kriteria penerimaan keputusan pengujian produk semulajadi pra-pendaftaran dari makmal NPRA atau makmal kawalan kualiti pengilang tempatan adalah seperti dalam gambar rajah di atas.

Antara ujian yang wajib dijalankan dan dinyatakan dalam sijil analisa produk siap oleh makmal panel atau makmal kawalan kualiti pengilang tempatan adalah seperti berikut:

- a) Organoleptik
- b) Pengecaian (bentuk dos tablet/ kapsul/ pil)
- c) Keseragaman berat (bentuk dos tablet/ kapsul)
- d) Ujian kontaminasi microbial (TAMC, TYMC, *Gram negative bile tolerant bacteria, specific pathogens*)
- e) Ujian logam berat (As, Hg, Pb, Cd)

Ujian lain seperti kandungan lovastatin, microcystin, bahan aktif (*assay*) dan lain-lain perlu dijalankan mengikut keperluan dalam *Drug Registration Guidance Document* (DRDG). Keputusan untuk ujian-ujian lain ini boleh diterima dari mana-mana makmal selain dari makmal panel atau makmal kawalan kualiti pengilang tempatan.

Senarai makmal panel dan Direktif Penerimaan Keputusan Pengujian Pra-Pendaftaran Produk Semulajadi dari Makmal Swasta boleh disemak melalui laman sesawang NPRA.

This implementation includes the requirement of Product Registration Holder (PRH) to submit test results in the form of certificate of analysis (COA) from private laboratories that have been recognized by NPRA (panel labs) or quality control laboratory of a local manufacturer to evaluate product registration applications through the QUEST 3+ system. PRH does not need to send pre-registration samples to the NPRA lab. The work process and criteria for accepting pre-registration natural product testing results from NPRA labs or quality control laboratory of a local manufacturer are as in the diagram above.

Among the tests that must be carried out and specified in the COA of the finished product by a panel laboratory or quality control laboratory of a local manufacturer are as follows:

- a) Organoleptic*
- b) Solution (tablet / capsule / pill dosage form)*
- c) Uniformity of weight (tablet/capsule dosage form)*
- d) Microbial contamination test (TAMC, TYMC, Gram-negative bile tolerant bacteria, specific pathogens)*
- e) Heavy metal test (As, Hg, Pb, Cd)*

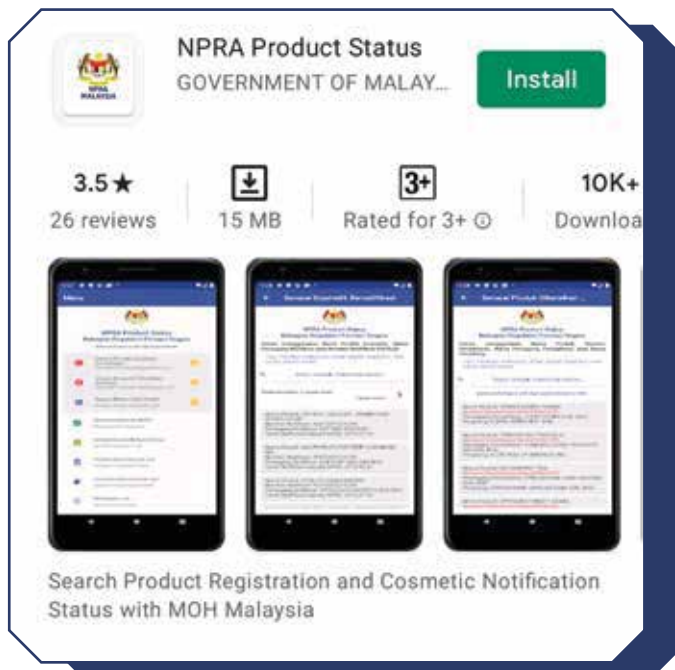
Other tests such as lovastatin, microcystin, active ingredient (assay), and others should be conducted as required in the Drug Registration Guidance Document (DRDG). These other tests can be received from any laboratory other than the panel laboratory or quality control laboratory of a local manufacturer.

List of panel laboratories and Directives for the Acceptance of Natural Product Pre-Registration Test Results from Private Laboratories can be viewed through the NPRA website.

Aplikasi NPRA Product Search

NPRA Product Status adalah aplikasi mudah alih yang dibangunkan secara *in-house* dan dilancarkan pada tahun 2019 untuk kegunaan umum di platform android. Pada 10 Februari 2020, aplikasi NPRA Product Status menyertai Galeri Aplikasi Mudah Alih Kerajaan Malaysia (GAMMA) dan sedia dimuat turun di platform iOS selain android.

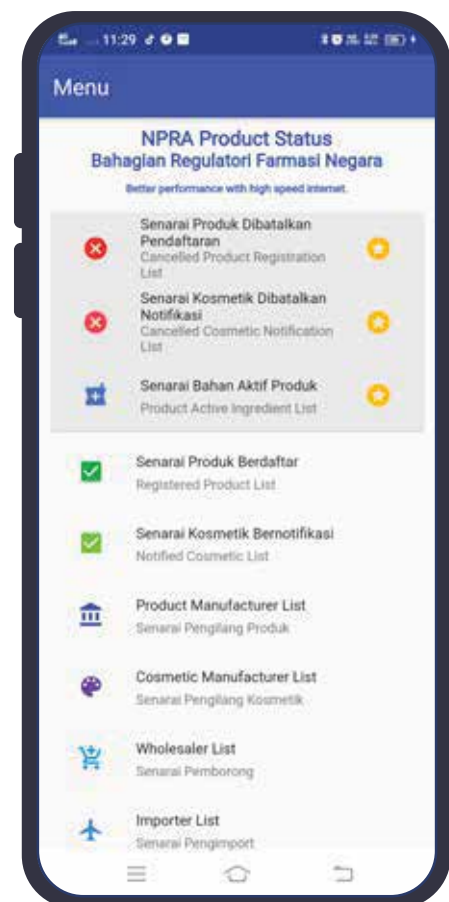
MAMPU telah melaksanakan projek GAMMA bermula pada tahun 2015. GAMMA merupakan inovasi perkhidmatan kerajaan berasaskan teknologi mudah alih di bawah pelaksanaan *Mobile Government* yang bertujuan mempelbagaikan perkhidmatan Kerajaan melalui peranti pintar yang akan menyumbang kepada sistem penyampaian perkhidmatan berpaksikan rakyat. Pada 18 Oktober 2020, NPRA Product Status telah dilancarkan di Huawei AppGallery supaya ia dapat diakses oleh pengguna peranti Huawei.



NPRA Product Search Application

NPRA Product Status is an in-house mobile application developed by NPRA and was launched in 2019 for public use on the android platform. On the 10th of February 2020, NPRA Product Status app joined GAMMA (Galeri Aplikasi Mudah Alih Kerajaan Malaysia) gallery and is made available on iOS platform in addition to android.

MAMPU had implemented GAMMA project since 2015. GAMMA is an innovation of government services based on mobile technology under the implementation of Mobile Government initiative. The aim of GAMMA is to increase and enhance delivery of Malaysian based government services via mobile platform. On the 18th of October 2020, NPRA Product Status was launched on the Huawei AppGallery to enable access to Huawei device users



QUEST 3+

Pada 21 Disember 2020, QUEST 3+ versi 2.0 telah dilancarkan bagi meningkatkan perlindungan dari serangan siber dan memastikan keselamatan data. QUEST 3+ versi 2.0 mempunyai fungsi yang sama seperti versi sebelum ini, dengan penambahbaikan pada ciri-ciri keselamatan. Kesukaran teknikal yang dihadapi adalah seperti naiktaraf bahasa pengaturcaraan daripada PHP 5.6 ke 7.4, pertukaran *plugins*, pengkodan semula dan pengujian fungsi serta operasi sistem sebelum dan selepas pelancaran QUEST 3+ versi 2.0.

Secara ringkas, projek naiktaraf tersebut mengambil tempoh masa tiga bulan bagi pembangunan dan ianya masih berterusan kerana terdapat kemungkinan berlaku ralat baru akibat perubahan teknikal yang besar. Projek naiktaraf ini merupakan pra syarat dan langkah penyediaan penyelesaian bagi isu *Adobe Flash Player* yang tamat tempoh hayat pada 31 December 2020 yang menyebabkan isu *incompatibilities* pelayan internet sebagai pemapar QUEST 3+.

QUEST 3+

On the 21st of December 2020, QUEST 3+ version 2.0 was launched to increase protection against cyberattacks and to enhance data security. Although QUEST 3+ version 2.0 has similar functionalities as the previous version, the security features were greatly enhanced and adjusted. Many technical difficulties were faced during the process of upgrading programming language from PHP 5.6 to 7.4, changing of plugins, re-writing of codes and testing of functionalities as well as operability of system before and after launching QUEST 3+ version 2.0.

In short, this security upgrade project took three months to develop and it is still ongoing as it is anticipated that new bugs will be reported from time to time due to the major revamp. This project is a prerequisite and is part of the solution to the Adobe Flash Player end-of-life (EOL) on the 31st of December 2020 issue which resulted in incompatibility issues of internet browser as a viewer tool of QUEST 3+.

QUEST 3+ Online System for Product Registration, Cosmetic Notification, Licensing & Market Sampling

Login | Register

Username
(alphanumeric, dot, dash and underscore only)

Password

[Forgot your password?](#)

[Register \(NEW USER\)](#)

Welcome to QUEST 3+:

QUEST 3+ Online Submission System enabled Product License Holder, Manufacturer, Importer, Re-packer, Reseller and other related users to conduct secured online transactions for product registration, variation, licensing, market sampling, renewal and other transactions.

- Helpdesk
- Market Sampling
For NON QUEST 3+ member only
- In House Evaluation
For NON QUEST 3+ member only
- Membership Application Status
- Announcement

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PENCAPAIAN ACHIEVEMENTS



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

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

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

Malaysia juga telah diterima sebagai pemerhati kepada *International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)* sejak Jun 2018. ICH merupakan platform bagi pihak regulatori dan industri farmaseutikal untuk membincangkan keperluan pendaftaran ubat-ubatan dari aspek saintifik dan teknikal. Misi ICH adalah untuk mencapai harmonisasi secara menyeluruh bagi memastikan ubat-ubatan yang selamat, berkesan, dan berkualiti tinggi dapat didaftarkan dengan efisien. Sebagai pemerhati, Malaysia akan dapat memastikan bahawa piawaian kawalan regulatori farmaseutikal yang digunapakai di negara ini adalah setara dengan piawaian antarabangsa.

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

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

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

Malaysia has also been accepted to become an observer to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) since June 2008. ICH brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner. As an observer, Malaysia will be able to ensure that the standard of pharmaceutical regulatory control practiced in this country is equivalent to international standards.



Bagi memastikan perkhidmatan yang berkesan dan berkualiti, NPRA telah memperolehi pensijilan MS ISO 9001 dari pihak SIRIM QAS Sdn. Bhd. NPRA telah berjaya mengekalkan pensijilan MS ISO selama 19 tahun berturut-turut (2001 - 2019) bermula dari versi MS ISO 9002:1994, diikuti dengan versi MS ISO 9001:2000, MS ISO 9001:2008 dan terkini dengan pensijilan versi MS ISO 9001:2015 pada tahun 2017 dengan nombor sijil adalah QMS 00894 dan sah sehingga 24 Mei 2022.

Selain pensijilan MS ISO 9001, makmal-makmal di NPRA telah memperoleh akreditasi dari Jabatan Standard Malaysia selaras dengan kompetensi untuk beroperasi berdasarkan MS ISO/IEC 17025. NPRA telah berjaya mengekalkan akreditasi MS ISO/IEC 17025:2005 selama 10 tahun berturut-turut (2010 hingga 2019) dan diikuti dengan pensijilan versi terkini MS ISO / IEC 17025: 2017 dalam skop pengujian kimia dan mikrobiologi. Sijil akreditasi dengan No. SAMM 450 adalah sah sehingga 14 Januari 2022.

In order to ensure high quality and efficient service, NPRA has obtained the MS ISO 9001 certification from SIRIM QAS Sdn. Bhd. NPRA has successfully maintained the MS ISO certification for 19 consecutive years (2001 - 2019) starting with version MS ISO 9002: 1994, followed by the MS ISO 9001: 2000, MS ISO 9001: 2008 and most recently with the certification of version MS ISO 9001:2015 in 2017 with certificate number QMS 00894 which is valid until the 24th of May 2022.

In addition to the MS ISO 9001 certification, NPRA laboratories are also accredited by the Department of Standards Malaysia for their competence and ability to operate in accordance with MS ISO / IEC 17025. NPRA has successfully maintained MS ISO / IEC 17025: 2005 accreditation for the past 10 years (2010 to 2019) and most recently followed by certification of version MS ISO / IEC 17025: 2017 in the scope of chemical and microbiological testing. This accreditation number of No. SAMM 450 is valid until the 14th of January 2022.





Pembangunan Monograf Herba Malaysia

Pembangunan Monograf Herba Malaysia (MHM) adalah projek progresif yang melibatkan pelbagai agensi dan kementerian dari Bahagian Industri Tanaman, Ternakan dan Perikanan Kementerian Pertanian dan Industri Asas Tani, Institut Penyelidikan Perubatan (IMR), Bahagian Regulatori Farmasi Negara (NPRA), Institut Penyelidikan Perhutanan Malaysia (FRIM), Institut Penyelidikan dan Kemajuan Pertanian Malaysia (MARDI), dan institusi pengajian tinggi tempatan seperti Universiti Putra Malaysia (UPM), Universiti Kebangsaan Malaysia (UKM) dan Universiti Sains Malaysia (USM).

Inisiatif pembangunan MHM adalah bertujuan untuk menyediakan rujukan maklumat yang menyeluruh dan komprehensif tentang identifikasi spesies herba, keperluan kawalan kualiti, kegunaan dari segi perubatan tradisional dan data keselamatan untuk herba tempatan yang bernilai tinggi. Oleh itu, MHM adalah wahana yang amat berguna khususnya untuk industri ubat tradisional, agensi regulatori, para penyelidik dan orang awam amnya.

Peranan NPRA dalam pembangunan Monograf Herba Malaysia adalah termasuk:

- a) Pengerusi bersama bagi Jawatankuasa Induk dan Jawatankuasa Teknikal MHM
- b) Menyokong aktiviti Sekretariat MHM yang diketuai oleh IMR (Menjalankan latihan untuk industri tradisional tempatan dan juga untuk jawatankuasa MHM).

Dari tahun 2011 hingga 2020, sebanyak 76 monograf telah diterbitkan dan dimuat naik di laman web *Global Information Hub on Integrated Medicine (GlobinMed)*.

Development of the Malaysian Herbal Monograph

The Malaysian Herbal Monograph (MHM) development is a progressive project carried out by various agencies and ministries which include Ministry of Agriculture and Agro-based Industry, Institute of Medical Research (IMR), National Pharmaceutical Regulatory Agency (NPRA), Forest Research Institute Malaysia (FRIM), Malaysian Agricultural Research and Development Institute (MARDI) and academia such as Universiti Putra Malaysia (UPM), Universiti Kebangsaan Malaysia (UKM) and Universiti Sains Malaysia (USM).

MHM serves as a crucial reference that provides invaluable, comprehensive information regarding identification of herbs, quality control requirements, medicinal usage and safety information for high value local herbal plants, which are extremely useful for the traditional medicines industry, regulatory agencies, researchers and the general public.

The roles of NPRA in the development of the Malaysian Herbal Monograph include:

- a) To Co-chair the MHM Main Committee and MHM Technical Committee*
- b) To support the MHM Secretariat activities led by IMR (Conduct training for the local traditional industry as well as for the MHM committee).*

From the year of 2011 to 2020, 76 monographs have been published and uploaded on Global Information Hub on Integrated Medicine (GlobinMed) website.



Imej 1: Sebahagian daripada Monograf Herba Malaysia
Image 1: A portion of the Malaysian Herbal Monograph



**Dukung Anak (aerial) -
 Phyllanthus urinaria
 (UKM)**



**Serai Wangi -
 Cymbopogon Nordus
 (USM)**



**Belimbing Buluh -
 Averrhoa Bilimbi
 (UPM)**



**Kulat Susu Rimau (Sclerotium) -
 Lignosus Rhinoceros
 (NPRA)**



**Kucing Galak (Aerial) -
 Acalypha Indica
 (USM)**



**Dukung Anak (Aerial) -
 Phyllanthus Amarus
 (UKM)**



**Kayu Manis (Daun) -
 Cinnamomum Verum
 (USM)**



**Urang-aring (Daun) -
 Eclipta Prostrata
 (MARDI)**



**Manggis (Kulit) -
 Garcinia Mongostana
 (UPM)**

The background of the entire image is a honeycomb pattern of hexagons. The pattern is composed of many hexagons, some of which are highlighted with a bright blue glow, while others are a darker blue. The overall effect is a modern, geometric, and technological aesthetic.

STATISTIK STATISTICS

A) Pengelasan Produk

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

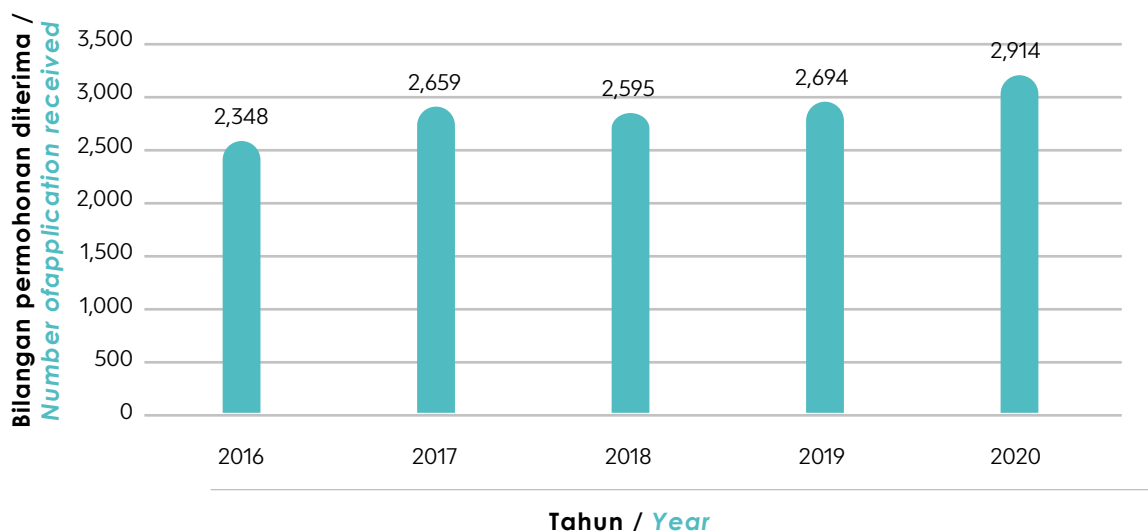
Bagi tahun 2020, sebanyak 2,914 permohonan pengelasan produk telah diterima berbanding dengan 2,694 permohonan yang telah diterima pada tahun 2019. Jumlah ini merupakan jumlah bilangan permohonan tertinggi yang tercatat sejak tahun 2016.

A) Product Classification

NPRA is responsible for the processing of product classification applications according to the stipulated time period. However, this service is voluntary and it is evaluated based on the active ingredient, formulation and product indications. This service covers products such as new chemical entities / new drug product, biologics, prescription, non-prescription, health supplements, traditional products, veterinary, food, medical devices, pesticides, and even agriculture products.

In year 2020, 2,914 product classification applications were received compared to 2,694 in the previous year. It was also recorded as the highest number of applications for product classification since 2016.

Rajah 1 : Bilangan Permohonan Pengelasan Produk Yang Diterima
Figure 1 : Number of Product Classification Application in 2016-2020



B) Pendaftaran Produk

NPRA bertanggungjawab untuk memproses permohonan pendaftaran untuk produk entiti baru kimia/ubat-ubatan baru, biologik, preskripsi, bukan preskripsi, suplemen

B) Product Registration

NPRA is responsible for processing registration applications for new chemical entities/new drugs, biologics, prescription, non-prescription, health supplements,

kesihatan, produk tradisional dan juga veterinar. Sepanjang tahun 2020, sebanyak 1,425 permohonan pendaftaran produk baru telah diterima dan 1,574 produk telah didaftarkan, termasuk permohonan yang diterima pada tahun sebelumnya (Jadual 1). Produk-produk ini terdiri daripada 53.84 peratus produk tempatan dan 46.16 peratus produk yang diimport. Kumulatif produk yang berdaftar sehingga Disember 2020 adalah 24,024 produk.

traditional as well as veterinary products. Throughout the year of 2020, a total of 1,425 new product registration applications were received and 1,574 products were registered, which include applications received in the previous year (Table 1). These newly registered products comprise of 53.84 percent local products and 46.16 percent imported products. The cumulative number of registered products up to December 2020 is 24,024 products.

Jadual 1: Bilangan Produk Baru Yang Didaftarkan, 2016-2020
Table 1: Number of New Products Registered, 2016-2020

Kategori Produk Product Category	2016	2017	2018	2019	2020
Produk Preskripsi Prescription Products	263	325	354	187	277
Produk Bukan Preskripsi Non-Prescription Products	40	61	79	66	70
Produk Tradisional Traditional Products	648	651	738	679	734
Suplemen Kesihatan Health Supplements	238	242	322	315	424
Produk Veterinar Veterinary Products	79	68	73	77	69
Jumlah Total	1,268	1,347	1,566	1,324	1,574

C) Aktiviti Pasca Pendaftaran Produk

NPRA menjalankan pemantauan berterusan ke atas produk berdaftar di pasaran tempatan bagi memastikan produk tersebut menepati keperluan keselamatan, keberkesanan dan kualiti. Pada tahun 2020, Program Pemantauan Kesan Advers Ubat (ADR) Kebangsaan telah menerima sebanyak 32,241 laporan, peningkatan 7.53 peratus berbanding tahun sebelumnya.

C) Product Post-Registration Activities

NPRA continuously monitors registered products in the local market to ensure that these products adhere to safety, efficacy and quality requirements. In 2020, the National Adverse Drug Reactions (ADR) Monitoring Program received a total of 32,241 reports, an increase of 7.53 percent compared to the previous year.

Rajah 2 : Bilangan Laporan ADR yang Diterima, 2016-2020
Figure 2: Number of ADR Reports Received, 2016-2020



Selain itu, sebanyak 914 laporan berkaitan kualiti produk telah diterima dari fasiliti kesihatan serta orang awam menerusi pelaporan kualiti produk berdaftar yang melibatkan 375 produk berdaftar. 24 daripada pelaporan tersebut telah diambil tindakan regulatori.

Besides that, a total of 914 reports related to product quality were received from health facilities and public involving 375 registered products. Out of these reports, 24 regulatory actions were taken.

Jadual 2: Bilangan Laporan Kualiti Produk Berdaftar yang Diterima, 2016-2020
Table 2 : Number of Quality Product Reporting Received, 2016-2020

Kategori Produk <i>Product Category</i>	2016	2017	2018	2019	2020
Produk Farmaseutikal <i>Pharmaceutical Products</i>	613	838	991	893	864
Produk Tradisional dan Suplemen Kesihatan (TMHS) <i>Traditional Medicines and Health Supplement (TMHS) Products</i>	6	3	22	236	50
Jumlah <i>Total</i>	619	841	1,013	1,129	914

D) Aktiviti Komplians dan Kawalan Kualiti

Pemeriksaan Amalan Perkilangan Baik (APB) ke atas pengilang produk berdaftar dan kosmetik bernotifikasi adalah bertujuan untuk memastikan pematuhan pengilang terhadap keperluan APB manakala Pemeriksaan Amalan Pengedaran Baik (AEB) adalah untuk memastikan pematuhan pengimport dan pemborong terhadap keperluan AEB semasa. Sepanjang tahun 2020, sebanyak 208 pemeriksaan APB dan 183 pemeriksaan AEB telah dijalankan. Khidmat nasihat dan penilaian pelan susun atur premis juga disediakan untuk pengilang sepanjang tahun 2020.

Selain pemeriksaan melibatkan pematuhan pengilang, pengimport dan pemborong di Malaysia, NPRA turut menjalankan pemeriksaan ke atas pusat kajian bioekuivalens (BE) dalam dan luar negara, jawatan kuasa etika serta fasiliti Amalan Makmal Baik (GLP). Sepanjang tahun 2020, sebanyak empat (4) pemeriksaan dijalankan ke atas pusat kajian BE, dan empat (4) lagi pemeriksaan dijalankan ke atas fasiliti GLP.

D) Compliance and Quality Control

Good Manufacturing Practice (GMP) inspections on the manufacturer of registered products and notified cosmetics are carried out to ensure their compliance with the current GMP requirements while Good Distribution Practice (GDP) inspections ensure adherence of importers and wholesalers to the current GDP requirements. There were 208 GMP inspections and 183 GDP inspections conducted in the year 2020. Additional services such as technical guidance and premise plan layout reviews were also provided to manufacturers.

Apart from conducting inspections on manufacturers, importers and wholesalers in Malaysia, NPRA also conduct inspections on local and foreign BE centers, ethics committees, and Good Laboratory Practice (GLP) facilities. Throughout the year of 2020, there were four (4) inspections conducted on BE centers, while another four (4) inspections were performed at GLP facilities.

Tahun 2020 merupakan tahun yang mencabar bagi NPRA di mana kebanyakan pemeriksaan yang dijalankan di lapangan terpaksa dijalankan secara maya bagi mengelakkan risiko jangkitan virus COVID-19. Susulan perubahan strategi pemeriksaan ini, jumlah pemeriksaan yang dijalankan ke atas fasiliti-fasiliti tersebut telah berkurang bagi tahun 2020 jika dibandingkan dengan tahun-tahun sebelumnya.

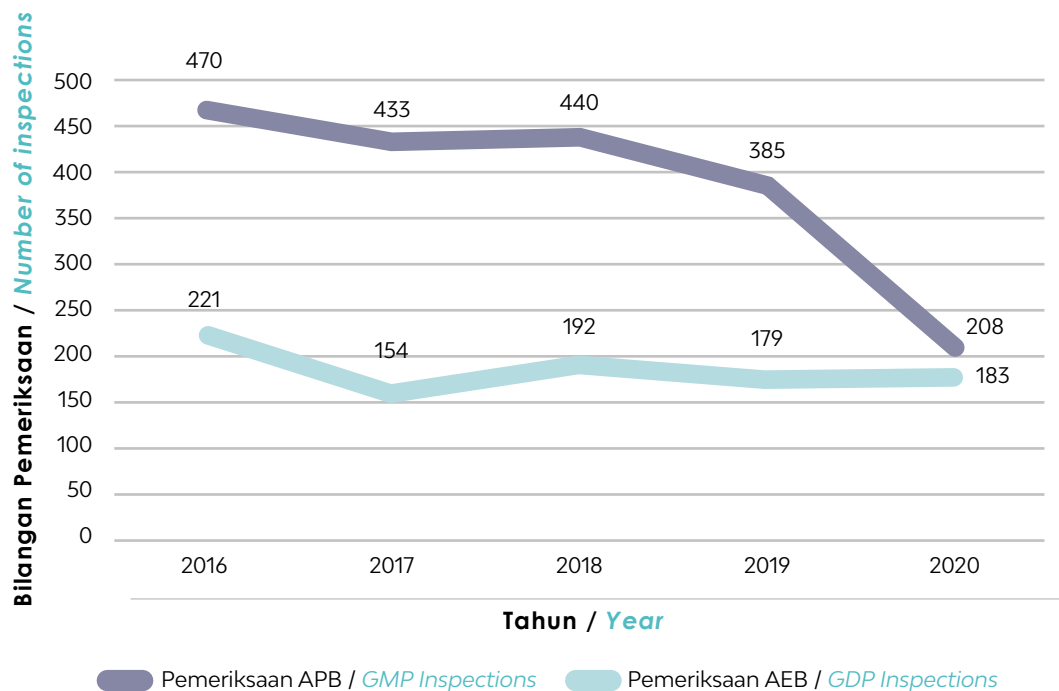
The year 2020 has been challenging to NPRA whereby most of the inspections that were usually conducted onsite had to be substituted with remote or online inspections to reduce the risk of COVID-19 infections. Following changes on the inspection strategy, the total number of inspections conducted throughout the year 2020 was reduced if compared to the previous years.

Jadual 3: Bilangan Pemeriksaan, Semakan Pelan Premis Pengilang serta Panduan Teknikal yang Dijalankan, 2016-2020
Table 3: Number of Inspections, Manufacturers Premise Layout Review and Technical Guidance, 2016-2020

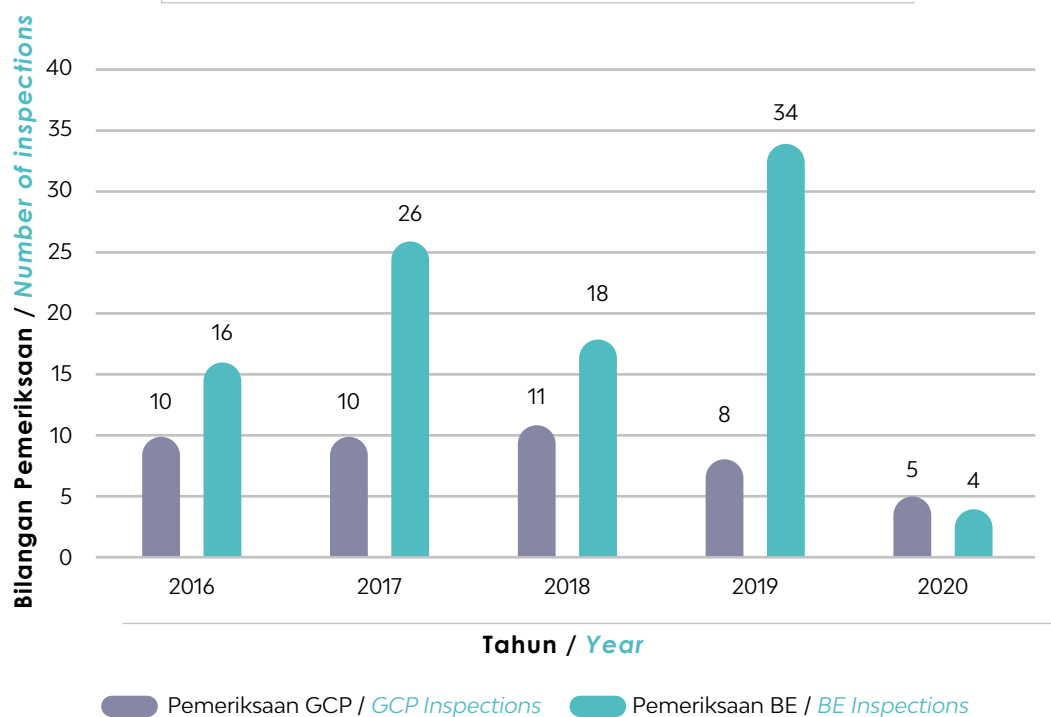
Aktiviti Activity	2016	2017	2018	2019	2020
Pemeriksaan APB GMP Inspections	470	433	440	385	208
Pemeriksaan AEB GDP Inspections	221	154	192	179	183
Pemeriksaan AKB GCP Inspections	10	10	11	8	5
Pemeriksaan BE BE Inspections	16	26	18	34	4
Pemeriksaan Jawatankuasa Etika Ethics Committee Inspections	6	0	5	7	0
Pemeriksaan AMB GLP Inspections	1	6	5	4	2
Semakan Pelan Premis Pengilang Manufacturers Layout Plan Evaluation	84	106	127	99	138
Panduan Teknikal Technical Guidance	86	113	51	39	603

APB: Amalan Perkilangan Baik *GMP: Good Manufacturing Practice*
AEB: Amalan Pengedaran Baik *GDP: Good Distribution Practice*
AKB: Amalan Klinikal Baik *GCP: Good Clinical Practice*
BE: Bioekuivalens *BE: Bioequivalence*
AMB: Amalan Makmal Baik *GLP: Good Laboratory Practice*

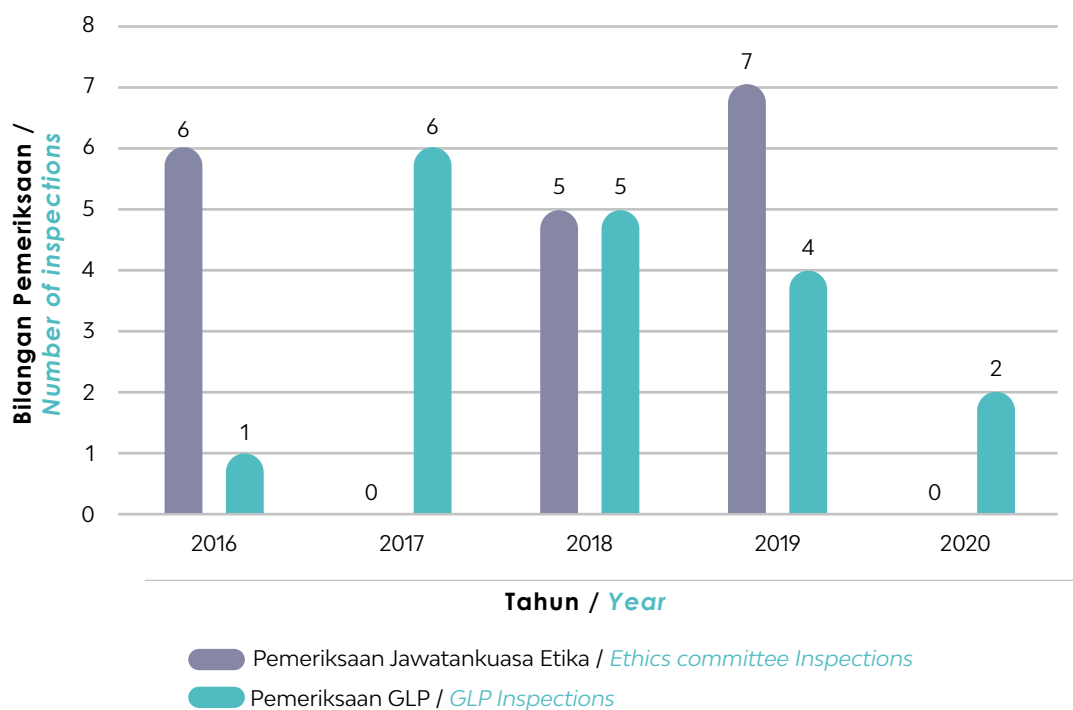
Rajah 3 : Bilangan Pemeriksaan APB dan AEB, 2016-2020
Figure 3 : Number of GMP and GDP Inspections, 2016-2020



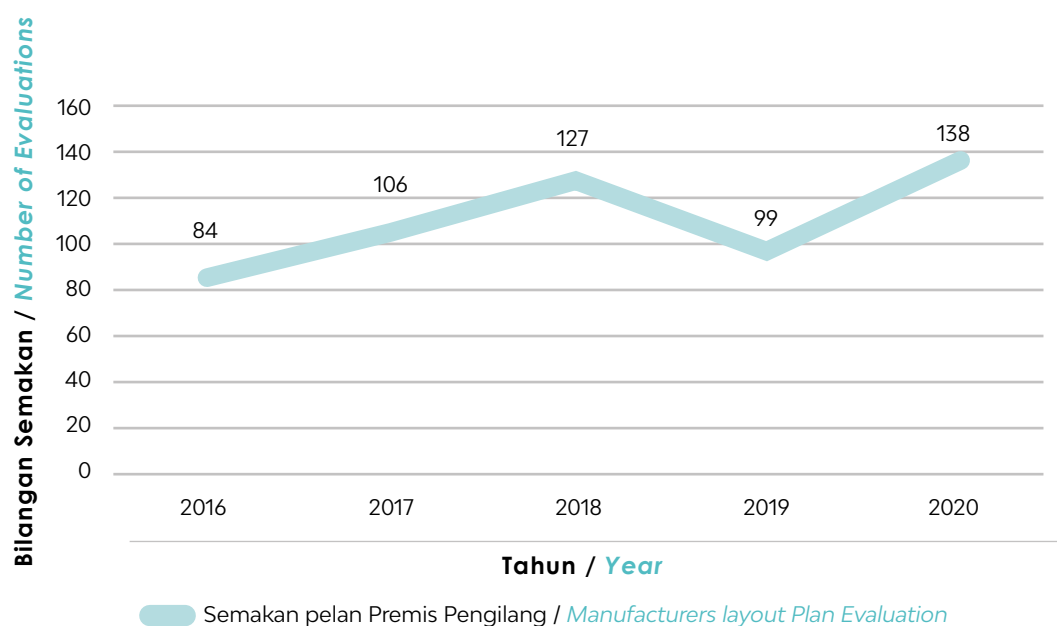
Rajah 4 : Bilangan Pemeriksaan GCP dan BE, 2016-2020
Figure 4 : Number of GCP and BE Inspections, 2016-2020



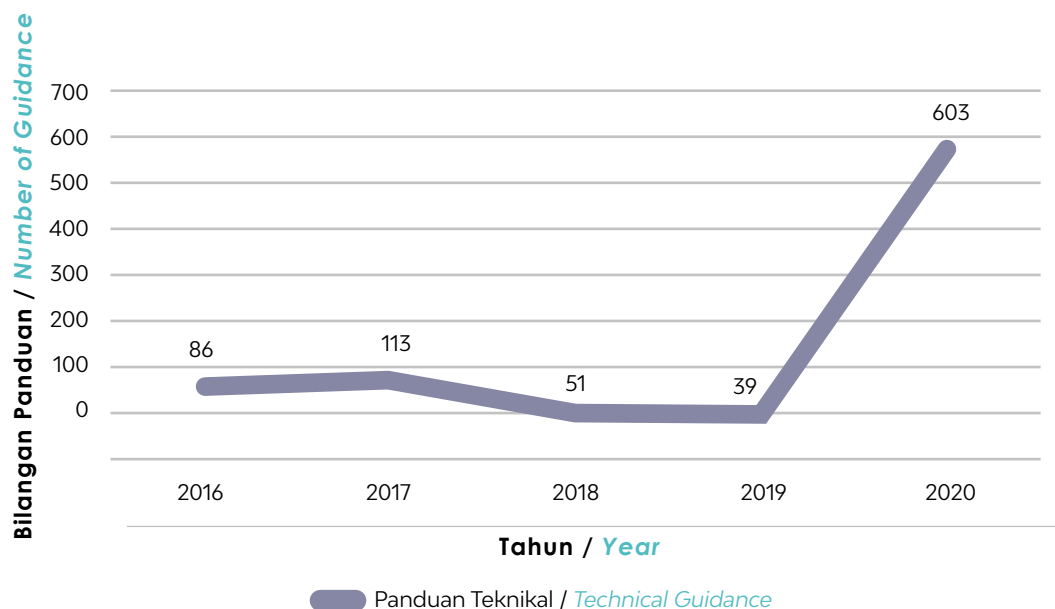
Rajah 5: Bilangan Pemeriksaan Jawatankuasa Etika dan GLP, 2016-2020
Figure 5 : Number of Ethics Committee and GLP Inspections, 2016-2020



Rajah 6: Bilangan Semakan Pelan Premis Pengilang, 2016-2020
Figure 6 : Number Manufacturers Layout Plan Evaluation, 2016-2020



Rajah 7: Bilangan Panduan Teknikal, 2016-2020
Figure 7 : Number of Technical Guidance, 2016-2020



E) Pengujian Makmal

Pengujian sampel ke atas produk farmaseutikal, produk semulajadi serta kosmetik dijalankan mengikut piawaian regulatori global. Tugas-tugas ini dijalankan oleh kakitangan makmal yang cekap dan terlatih.

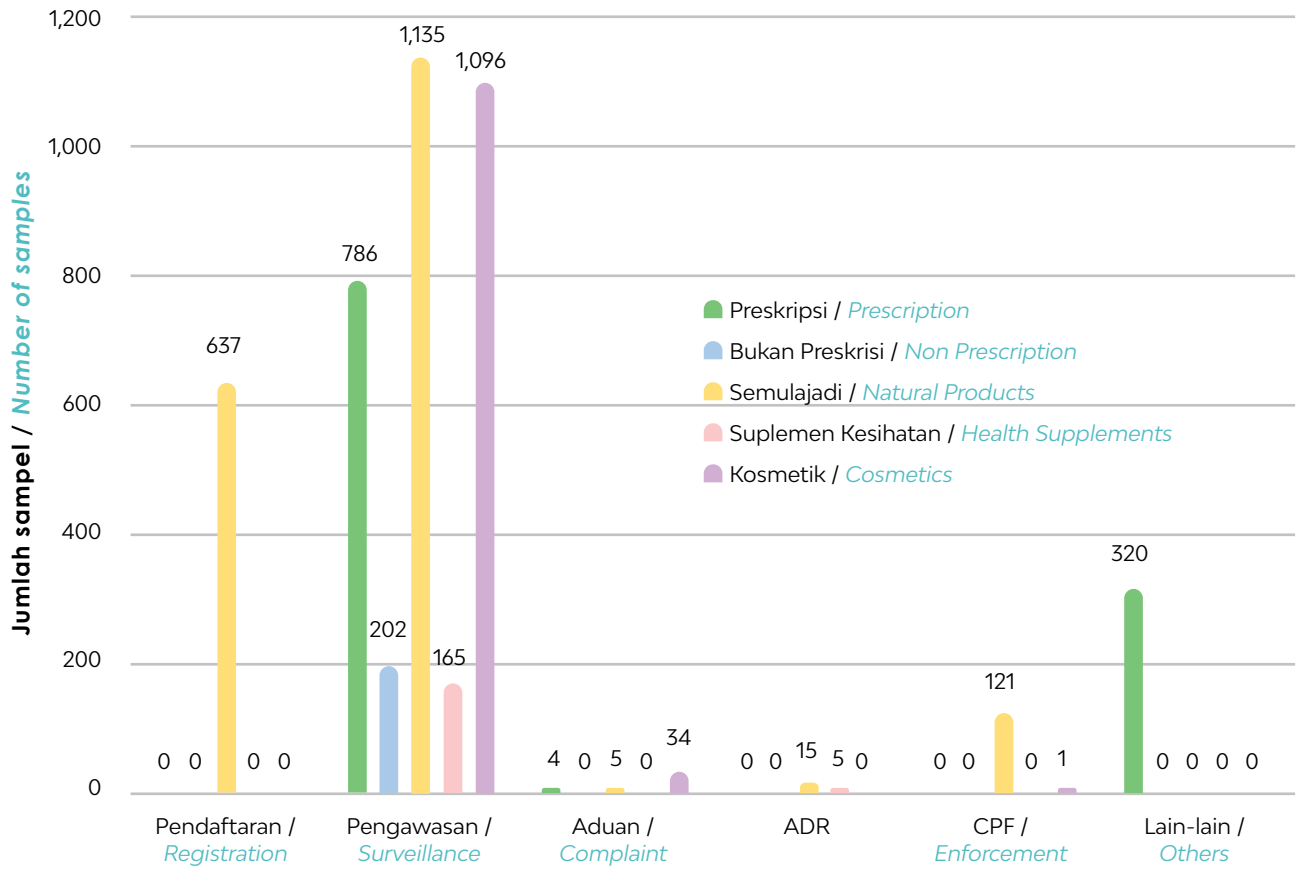
Pengujian produk dijalankan untuk tujuan pendaftaran ke atas produk semulajadi dan bagi tujuan pengawasan produk berdaftar dan kosmetik bernetifikasi. Pengujian turut dijalankan ke atas sampel yang menyebabkan kesan advers (ADR), sampel aduan dan sampel penguatkuasaan.

E) Laboratory Testing

Sampel testing is conducted on pharmaceutical products, traditional products and cosmetics in accordance with global regulatory standards. These duties are carried out by trained and competent laboratory personnel.

Product testing is carried out for the purpose of registration of traditional products and for surveillance of registered products and notified cosmetics. Testing is also performed on samples with adverse drug reactions (ADR) as well as on complaint and enforcement samples.

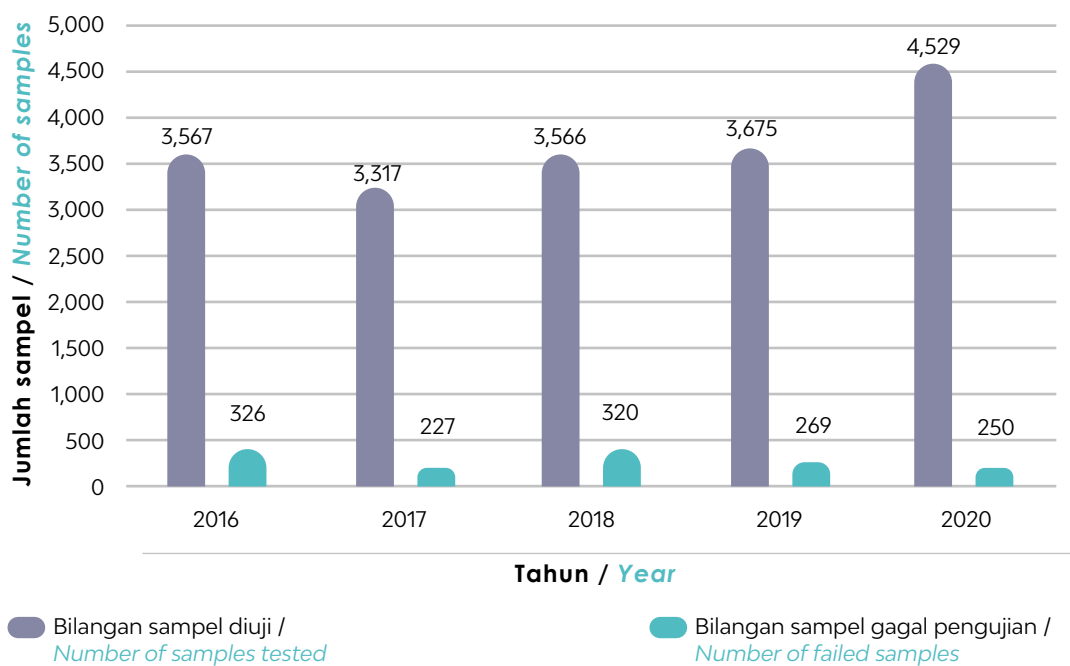
Rajah 8 : Sampel Yang Diuji Mengikut Kategori Untuk Tahun 2020
Figure 8 : Samples Tested Based on Category For Year 2020



Pada tahun 2020, pecahan sampel mengikut kategori produk adalah seperti pada Rajah 8. Sampel pengawasan mencatatkan bilangan sampel diuji tertinggi iaitu berjumlah 3,384 sampel dengan bilangan sampel tertinggi adalah dari kategori produk semulajadi iaitu sebanyak 1,135 sampel.

In the year 2020, the breakdown of samples tested according to categories are depicted in Figure 8. Surveillance samples recorded the highest number of samples at a total of 3,384 with the highest number of samples coming from the natural products category at 1,135 samples.

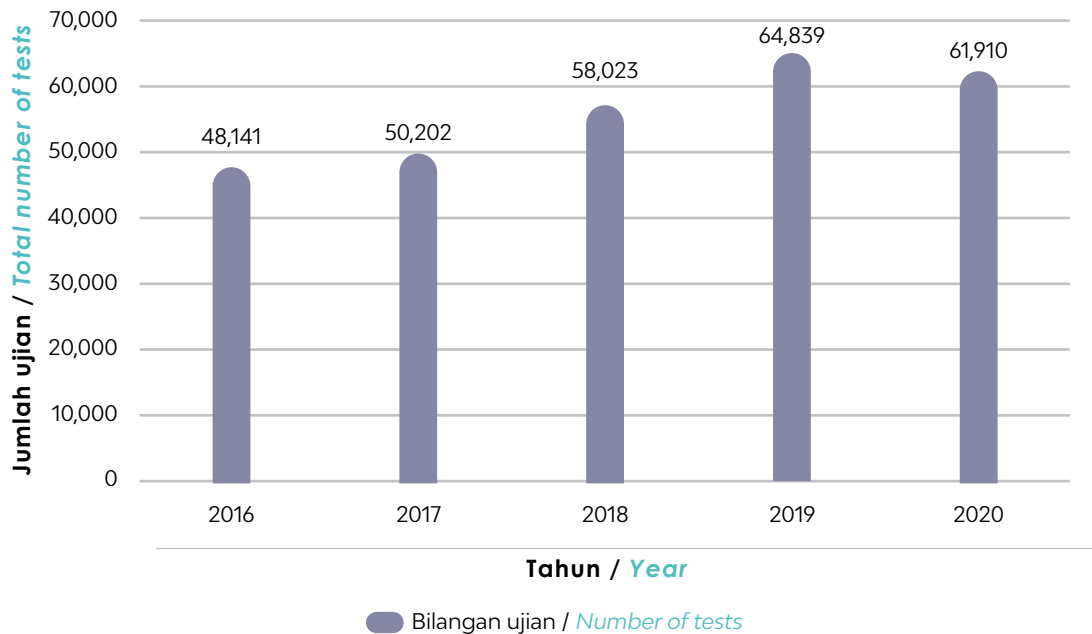
Rajah 9 : Bilangan Sampel Diuji dan Bilangan Sampel Gagal Pengujian, 2016-2020
Figure 9 : Number of Samples Tested & Number of Failed Samples, 2016-2020



Untuk tahun 2020, pengujian makmal telah dijalankan ke atas 4,529 sampel dan merupakan bilangan sampel tertinggi dicatatkan sejak tahun 2016 (Rajah 9).

For the year 2020, laboratory testing has been conducted on 4,529 samples which is the highest number recorded since 2016 (Figure 9).

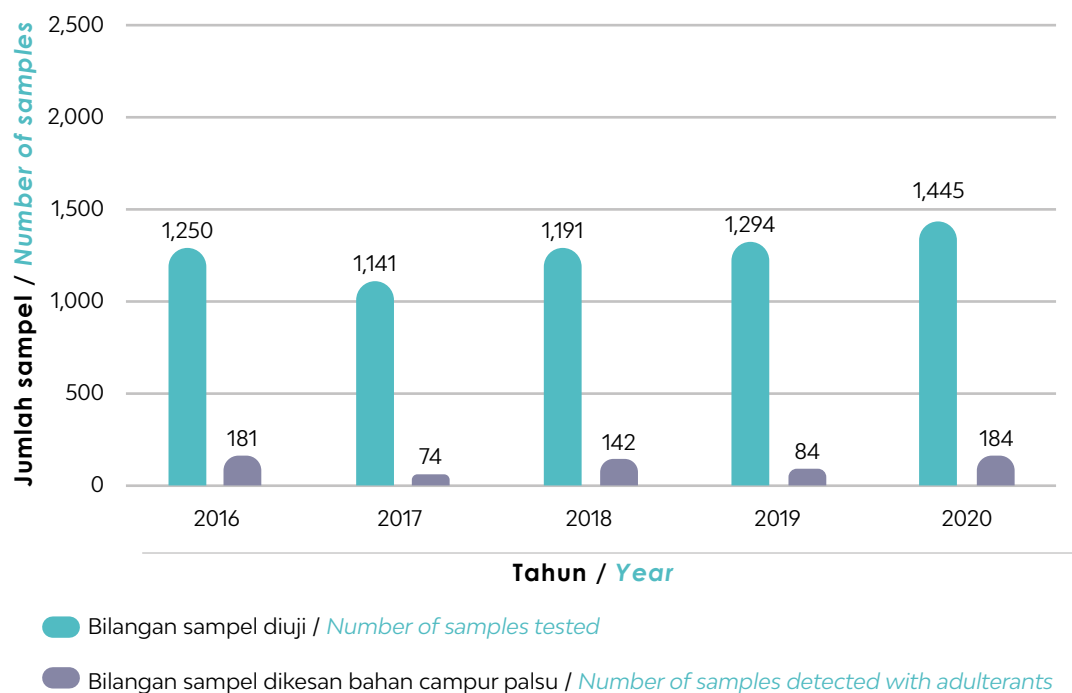
Rajah 10 : Bilangan Ujian yang Dijalankan, 2016-2020
Figure 10 : Number of Tests Performed, 2016-2020



Bilangan sampel yang gagal pengujian adalah sebanyak 250 sampel sahaja iaitu 5.5 peratus daripada jumlah sampel yang diuji. Pada tahun 2020, keseluruhan bilangan ujian yang telah dijalankan adalah 61,910 (Rajah 10).

The number of samples that failed testing amounted to 250 samples only, equivalent to 5.5 per cent of the total number of samples tested. In the year 2020, the number of overall tests performed was 61,910 (Figure 10).

Rajah 11 : Bilangan Produk Semulajadi yang Dikesan Mengandungi Bahan Campur Palsu
Figure 11 : Number of Natural Products Detected with Adulterants



Melalui ujian-ujian analisis rutin yang dijalankan ke atas sampel bagi menilai kualiti produk, pengesanan bahan campur palsu merupakan antara sebab kegagalan ujian makmal. Untuk tahun 2020, 184 daripada 1,445 sampel produk semulajadi telah dikesan mengandungi bahan campur palsu (Rajah 11).

Through the routine analytical tests conducted on samples to assess the products' quality, detection of adulterants is among the reason for testing failure. For the year 2020, 184 out of 1,445 samples of natural products tested have been found to be adulterated (Figure 11).

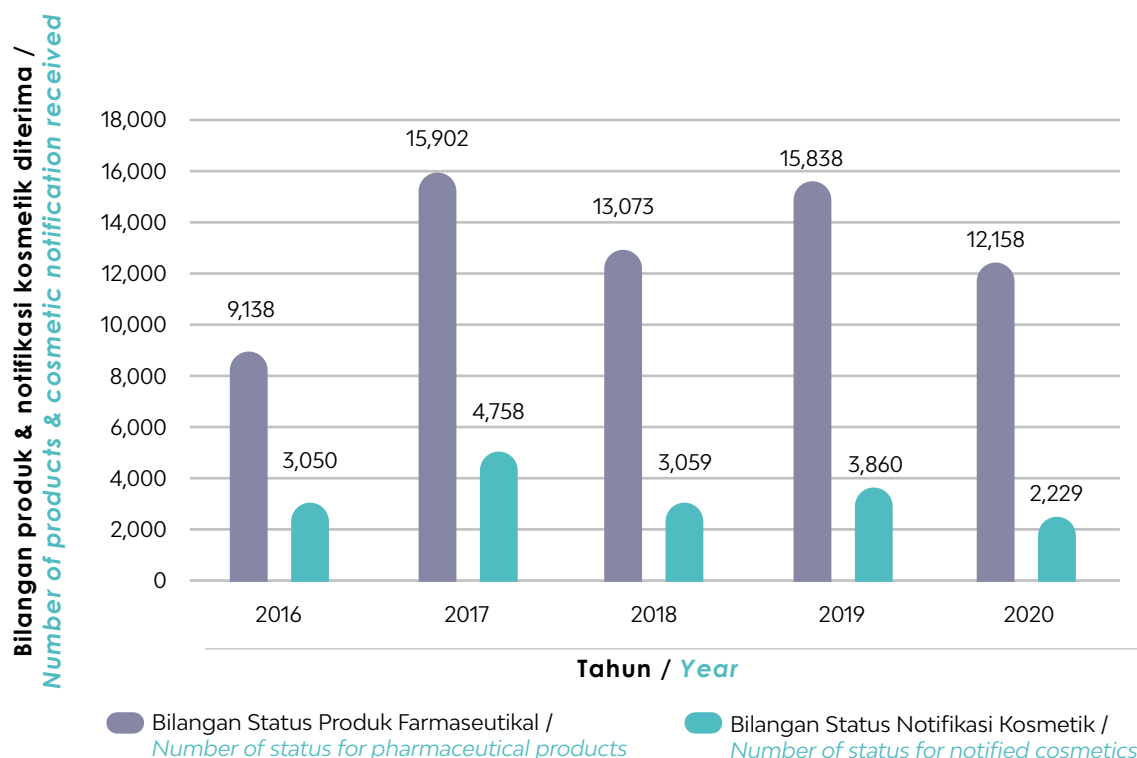
F) Semakan Status Pendaftaran untuk Cawangan Penguatkuasa Farmasi

Aktiviti pemantauan dan rampasan produk-produk tidak berdaftar di pasaran tempatan dijalankan oleh Pegawai Penguatkuasa Farmasi di seluruh negara. Dengan kerjasama NPRA, status pendaftaran dan notifikasi produk-produk farmaseutikal dan kosmetik yang disyaki tidak berdaftar/bernotifikasi di pasaran tempatan akan disemak dan ditentukan. Justeru itu, penjualan produk-produk yang tidak berdaftar dan kosmetik tidak bernotifikasi dapat dibendung dengan adanya tindakan penguatkuasaan farmasi dan aktiviti pendakwaan di Mahkamah. Jumlah bilangan permohonan status pendaftaran produk yang diterima untuk semakan adalah sebanyak 12,158 dan status notifikasi yang diterima untuk semakan adalah 2,229 (Rajah 12).

F) Product Registration Status Verification for Pharmacy Enforcement Division

Pharmacy Enforcement Officers from all states will monitor and seize unregistered products sold in the local market and premises. In cooperation with NPRA, the registration and notification status of these suspected unregistered pharmaceutical products and unnotified cosmetics products available in the local market can be verified. This in turn will facilitate pharmacy enforcement actions and prosecution in court which can curb the sale of unregistered products and unnotified cosmetics. The total number of products registration status applications received and processed was 12,158 and the cosmetics notification status received and processed was 2,229 (Figure 12).

Rajah 12 : Bilangan Produk dan Notifikasi Kosmetik Diterima untuk Pengesahan Status, 2016-2020
Figure 12 : Number of Products and Cosmetic Notifications Received for Verification Status, 2016-2020



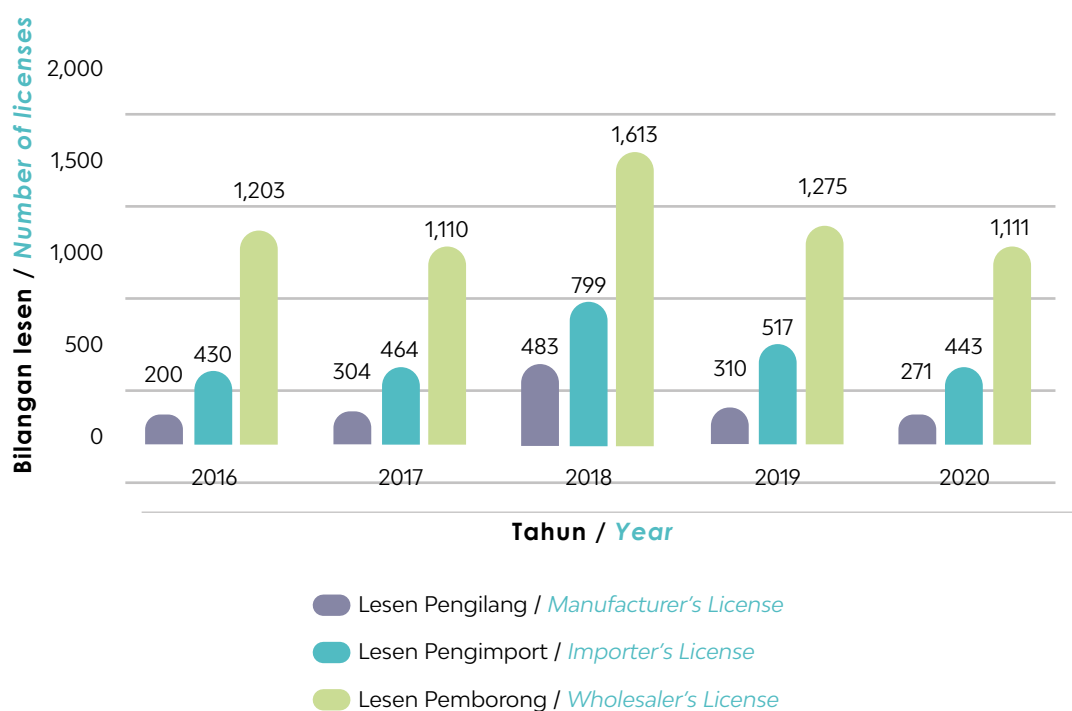
G) Pelesenan

Pada tahun 2020, sebanyak 271 Lesen Pengilang, 443 Lesen Pengimport dan 1,111 Lesen Pemborong telah dikeluarkan.

G) Licensing

In 2020, 271 Manufacturer Licenses, 443 Importer Licenses and 1,111 Wholesaler Licenses were issued.

Rajah 13 : Bilangan Lesen yang Dikeluarkan, 2016-2020
Figure 13 : Number of Licenses Issued, 2016-2020



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AKTIVITI & SOROTAN

HIGHLIGHTS & ACTIVITIES



Seksyen Baru di NPRA: Seksyen Pembangunan Industri & Komunikasi (OSC)

New Section in NPRA: One-Stop Centre (OSC)

Selain dari menjamin keselamatan masyarakat Malaysia melalui sistem kawalan regulatori farmaseutikal, NPRA sentiasa berusaha meningkatkan kualiti perkhidmatan bagi membantu pihak industri. Seksyen Pembangunan Industri & Komunikasi (*One-Stop Centre [OSC]*) telah diwujudkan di bawah Pusat Koordinasi & Perancangan Strategik Regulatori (PKPSR) bagi tujuan ini.

*Besides being the custodian of public safety for the Malaysian public through a pharmaceutical regulatory control system, NPRA is continuously advancing our services to assist the industry. The Industry Development & Communication Section (*One-Stop Centre [OSC]*) was established under Centre of Regulatory Coordination & Strategic Planning (PKPSR) for this particular reason.*

Fungsi seksyen baru ini adalah untuk menyediakan perkhidmatan komunikasi strategik kepada pihak industri dan orang awam seperti penyelarasan penyediaan kenyataan akhbar, perkhidmatan *Pre-Submission Meeting (PSM)*, perkhidmatan pusat kutipan permit, sijil dan lesen, perkhidmatan *Helpdesk* dan komunikasi umum dengan industri. Seksyen ini juga bertanggungjawab untuk menguruskan pertanyaan berkaitan NPRA melalui Sistem Pengurusan Aduan Awam (SisPAA).

*The functions of this new section are to provide strategic communication services for the industry and the public. This includes the coordination of the preparation of press releases, *Pre-Submission Meeting (PSM)* services, permit, certificate, and license collection centre, *Helpdesk* services and general communication with industry. This section is also responsible to manage inquiries relating to NPRA through the Public Complaints Management System (SisPAA).*

Pada tahun 2020, OSC telah menyelaraskan penyediaan lapan (8) kenyataan akhbar bagi terbitan KKM. Bagi *Pre-Submission Meeting* (PSM) pula, terdapat tujuh (7) permohonan PSM diterima dan diproses sepanjang tahun 2020. PSM adalah perkhidmatan di mana NPRA memberikan panduan regulatori kepada pemohon sebelum dosier dihantar bagi memastikan dokumen yang dikemukakan adalah lengkap dan mengikut garis panduan.

Perkhidmatan pusat kutipan permit, sijil dan lesen di OSC telah bermula pada 8 Jun 2020. Setakat ini, OSC telah memproses sebanyak 5,454 kutipan permit, sijil dan lesen yang diproses oleh Seksyen Pelesenan & Pensijilan dan Seksyen Amalan Perkilangan Baik (APB). Perkhidmatan pusat kutipan setempat ini mendapat sambutan yang baik dari pihak industri kerana lokasinya yang strategik dan mudah dikunjungi oleh orang ramai iaitu di Blok D, NPRA.

Seksyen OSC juga menyediakan perkhidmatan komunikasi secara meluas kepada pihak industri dan orang ramai, iaitu melalui perkhidmatan Helpdesk, emel, telefon, temujanji fizikal/maya dan sesi dialog bersama pihak industri. Sehingga Disember 2020, OSC telah menjawab sebanyak 12,730 pertanyaan dan 5,011 aduan secara kumulatif daripada pihak industri dan orang awam.

In 2020, OSC has coordinated the preparation of eight (8) press releases for MOH publications. As for the Pre-Submission Meeting (PSM), there were seven (7) PSM applications received and processed throughout the year 2020. PSM is a service whereby NPRA provides regulatory advice to applicants prior to the dossier submission to ensure the dossier submitted is complete and documents provided are according to the guideline.

The permit, certificate and license collection centre services at OSC started on 8th of June 2020. To date, OSC has processed the total of 5,454 collections of permits, certificates and licenses produced by the Licensing & Certification Section and Good Manufacturing Practice (GMP) Section. The service provided by this collection center has received good response from the industry because of its strategic location and easy access by the public at Block D, NPRA.

OSC section also provides extensive communication services to the industry and public via Helpdesk services, email, telephone, physical/virtual appointments and dialogue sessions with the industry. As of December 2020, OSC has addressed a total of 12,730 inquiries and 5,011 complaints cumulatively from the industry and public.



Bengkel Pemurnian Garis Panduan *Drug Registration Guidance Document (DRGD)*

Bengkel ini telah diadakan pada 24 dan 25 Februari 2020 di Dewan Anggerik, NPRA. Sejumlah 39 orang pegawai yang dilantik sebagai ahli Jawatankuasa telah menghadiri bengkel ini. Ahli Jawatankuasa yang dilantik mewakili seksyen-seksyen berkaitan di NPRA.

Tujuan utama bengkel ini adalah:

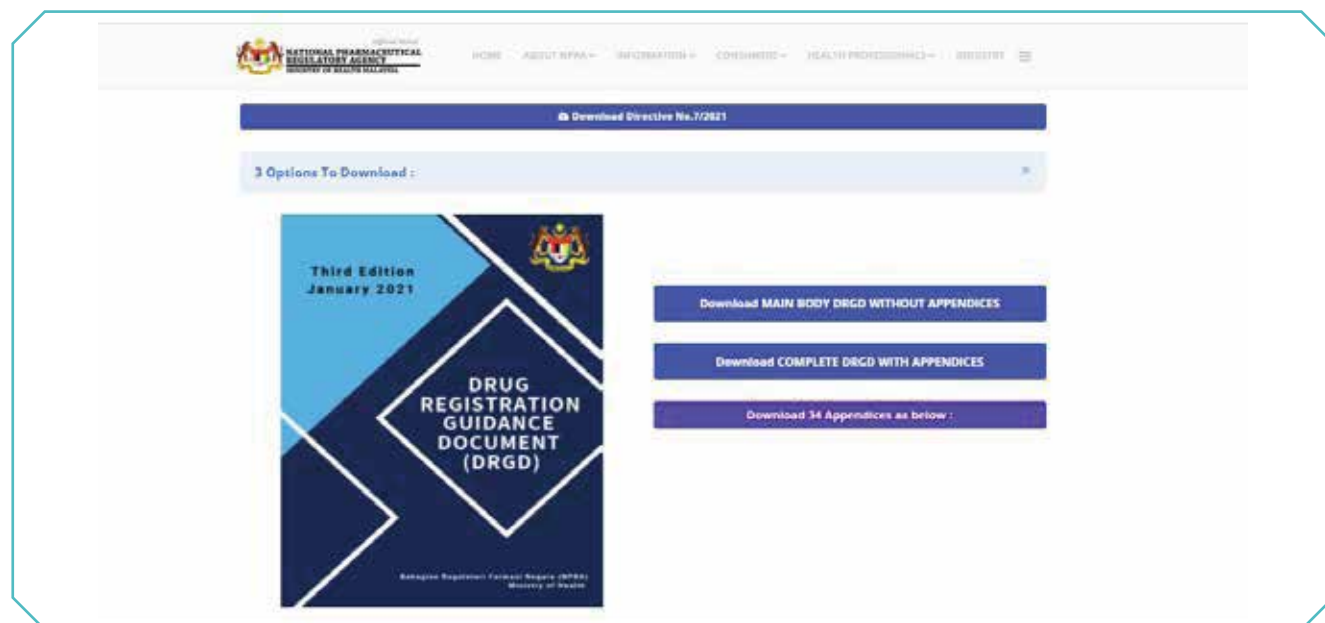
- mengemaskini dan menambah baik DRGD supaya lebih mesra pengguna dan mudah difahami
- menyusun semula kandungan DRGD supaya lebih teratur
- mengemaskini maklumat organisasi berikutan penstrukturan semula NPRA pada 2 Disember 2019

Drug Registration Guidance Document (DRGD) Workshop

This workshop was held on 24th and 25th of February 2020 at Dewan Anggerik, NPRA. A total of 39 officers were appointed as Committee members in this workshop. The appointed Committee members are the representative of each sections in NPRA.

The main purposes of this workshop are:

- *to update and improve DRGD to be more user friendly and easy to understand*
- *restructuring the content of DRGD to be more organized*
- *updating organization information in line with NPRA restructuring that occurred on 2nd of December 2019*



Hasil aktiviti bengkel ini telah mewujudkan DRGD edisi terbaru iaitu DRGD *Third Edition*, Januari 2021 dengan penambahbaikan di mana dokumen DRGD dapat dimuat turun di laman web NPRA dengan dua (2) cara iaitu:

- memuat turun *Main Body DRGD* dan 34 *Appendix* secara berasingan atau;
- memuat turun keseluruhan kandungan DRGD termasuk 34 *appendix*

From this workshop, the latest edition of DRGD which is the Third Edition DRGD, January 2021 was developed. The DRGD documents can be downloaded from the NPRA website in two (2) ways :

- *downloading the Main Body DRGD and 34 Appendixes separately or;*
- *downloading the entire DRGD content including 34 appendixes.*

Bengkel Implementing Risk-Based Thinking and Decision Rule as per MS ISO/ IEC 17025:2017 Requirement

Pusat Komplians dan Kawalan Kualiti (PKKK) telah dijadualkan untuk audit naik taraf susulan saranan Jabatan Standards Malaysia mengenai keperluan menaik taraf akreditasi dari MS ISO/IEC 17025:2005 kepada MS ISO/IEC 17025:2017 sebelum November 2020. *Risk-based Thinking dan Decision Rule* merupakan keperluan baru dalam versi MS ISO/IEC 17025:2017.

Bagi meningkatkan pemahaman di kalangan kakitangan PKKK, satu bengkel telah dianjurkan di Dewan Anggerik, NPRA pada 7 hingga 8 September 2020. En Yeoh Guan Huah dari GLP Consulting Singapura yang merupakan pakar jurulatih *Human Resources Development Fund* (HRDF) yang mahir di dalam bidang ini telah dijemput untuk memberikan latihan kepada para peserta yang terpilih selama dua (2) hari.

Objektif bengkel ini adalah untuk memberikan pendedahan kepada para peserta berkenaan dengan keperluan *risk-based thinking dan decision rule* terhadap pemeriksaan produk dan cara untuk mengaplikasikannya dalam kerja harian. Kakitangan makmal perlu merancang dan melaksanakan sebarang tindakan yang diperlukan ke atas sebarang kemungkinan risiko dan peluang yang berkaitan dengan aktiviti makmal. Ini termasuk mengeluarkan kenyataan berkaitan dengan keperluan untuk menepati ketepatan spesifikasi produk dan menepati had peraturan regulatori yang telah ditetapkan.

Implementing Risk-Based Thinking and Decision Rule as per MS ISO/ IEC 17025:2017 Requirement Workshop

The Centre of Compliance and Quality Control (PKKK) had been scheduled for an upgrade audit following the Malaysian Standards Department recommendation on the need to upgrade accreditation from MS ISO/IEC 17025: 2005 to MS ISO / IEC 17025: 2017 by November 2020. Risk-based Thinking and Decision Rule is part of the new requirement in MS ISO / IEC 17025: 2017 version. To increase understanding among PKKK staff, a workshop was organized at Dewan Anggerik, NPRA from 7th to 8th September 2020. Mr. Yeoh Guan Huah from GLP Consulting, Singapore who is an expert Human Resource Development Fund (HRDF) trainer skilled in this field was invited to conduct this workshop for two (2) days.



The objective of this workshop was to provide exposure to the participants regarding the need for risk-based thinking and decision rule on product inspection and on ways to apply it in their daily work. Laboratory staffs are required to plan and implement the necessary actions on any possible risks and opportunities associated with laboratory activities. This includes issuing statements related to the requirements to meet the accuracy of product specifications and to meet regulatory limits that have been set.



Kursus Keperluan Kawalan Kualiti Produk Tradisional dan Bahan Mentah Herba

Kursus Keperluan Kawalan Kualiti Produk Tradisional dan Bahan Mentah Herba merupakan sebahagian daripada perancangan latihan di bawah inisiatif *Safe and Secure*. Objektif kursus ini adalah untuk memperkukuhkan kawalan kualiti bagi Produk Semula Jadi. Kursus ini ditujukan kepada pegawai NPRA yang terlibat dalam pemeriksaan, penilaian dan analisis untuk menjana ilmu berkenaan dengan pengesanan bahan mentah dan produk siap.

Kursus ini telah dilaksanakan dalam dua sesi. Sesi pertama telah diadakan pada 20-21 Julai 2020. Profesor Madya Dr Jamia Azdina Jamal dari Universiti kebangsaan Malaysia telah dijemput pada hari pertama untuk memberikan taklimat kepada para peserta berkenaan dengan aspek kualiti dan keselamatan untuk produk mentah, penyediaan herba dan produk herba.

Pada hari kedua, Dr Lee Soon Leong, Pegawai Penyelidik dari Institut Penyelidikan Perhutanan Malaysia (FRIM) dijemput untuk berkongsi ilmu berkenaan dengan teknologi berkaitan dengan pengesanan dan identifikasi produk ubat herba melalui *DNA Barcoding*.

Sesi kedua telah dijalankan pada 27 Ogos 2020. Tujuan sesi kedua ini diadakan adalah supaya para peserta yang menyertai kursus sesi pertama ini dapat mengaplikasikan ilmu yang diperoleh secara *hands-on*. Kajian kes berdasarkan sampel sijil analisa (COA) yang telah dikumpulkan dari Pusat Penilaian Produk dan Kosmetik (PPPK) digunakan oleh para peserta untuk mengeluarkan senarai semak untuk ujian minimum bahan mentah herba oleh pihak pengeluar. Sesi ini telah difasilitasi oleh Profesor Madya Dr Jamia Azdina Jamal.

Quality Control Workshop Requirements for Traditional Products and Herbal Raw Materials

The Quality Control Workshop for Traditional Products and Herbal Raw Materials is part of the training planned under the Safe and Secure initiative. The objective of this course is to strengthen the quality control of natural products. This course is aimed at NPRA inspectors, evaluators and analysts to acquire knowledge with regards to the validation of raw materials and finished products.

This course was conducted in two sessions. The first session was held from the 20th to 21st July 2020 at Dewan Anggerik, NPRA. Associate Professor Dr Jamia Azdina Jamal from Universiti Kebangsaan Malaysia was invited on the first day to brief the participants on the quality and safety aspects for raw products, herbal preparation and herbal products.

On the second day, Dr Lee Soon Leong, Research Officer from the Forest Research Institute of Malaysia (FRIM) was invited to share knowledge on advanced technology related to the validation and identification of herbal medicine products through DNA Barcoding.

The second session was held on the 27th of August 2020. The purpose of this second session was to allow the participants from the first session to apply the knowledge received hands-on. Case studies based on Certificate of Analysis' (COA) collected by the Center for Product and Cosmetic Evaluation (PPPK) were used by the participants to issue a checklist for minimum testing of herbal raw materials that is required by the manufacturers. This session was facilitated by Associate Professor Dr Jamia Azdina Jamal.



Bengkel Pengurusan Krisis Emosi dan Penyelesaian - Cara Menangani Masalah Diri dan Kakitangan

Bengkel Pengurusan Krisis Emosi dan Penyelesaian telah diadakan pada 17 hingga 18 September 2020 di Dewan Serai Wangi, NPRA. Bagi membantu meningkatkan kemahiran pengurusan emosi di kalangan kakitangan NPRA, pihak NPRA telah menjemput Dr Rafidah Aga Mohd Jaladin, seorang ahli psikologi kaunseling yang berkhidmat sebagai pensyarah kanan di Jabatan Psikologi Pendidikan dan Kaunseling, Fakulti Pendidikan, Universiti Malaya.

Kursus ini bertujuan untuk meningkatkan pengetahuan dan kemahiran staf dalam pengurusan emosi, pengurusan stress, dan komunikasi berkesan di tempat kerja. Kepentingan dan pengaruh emosi dan stres dalam hubungan interpersonal dan prestasi kerja turut dibincangkan.

Fokus utama latihan ialah untuk membina strategi dan teknik pengurusan emosi dan stress yang sesuai dengan keperluan dan kemampuan peserta. Peserta juga dilatih untuk mengaplikasikan kemahiran asas kaunseling berpandukan teori Transaksional Analisis untuk berkomunikasi dengan lebih berkesan di tempat kerja.

Emotional Crisis Management and Solution Workshop - Ways to Deal with Personal and Staff Problems

An Emotional Crisis Management and Solution Workshop was held on 17th to 18th of September 2020 at Dewan Serai Wangi, NPRA. In an attempt to help improve emotion management skills among NPRA staff, NPRA invited Dr Rafidah Aga Mohd Jaladin, a counseling psychologist who serves as a senior lecturer in the Department of Educational and Counseling Psychology, Faculty of Education, University Malaya to provide training during this workshop.

This course aimed to enhance the knowledge and skills of staffs in emotion management, stress management, and effective communication within the working environment. The importance and influence of emotions and stress in interpersonal relationships and job performance were discussed as well.

The main focus of the training was to develop strategies and techniques for managing emotions and stress that are appropriate to the needs and abilities of the participants. Participants were also trained to apply basic counseling skills based on Transactional Analysis theory to communicate more effectively in the workplace.



Imej 2: Peserta Bengkel Pengurusan Krisis dan Penyelesaian: Cara Menangani Masalah Diri dan Kakitangan

Image 2: Participants of the Emotional Crisis Management and Solution Workshop- Ways to Deal with Personal and Staff Problems



Imej 3: Sesi Pengajaran Cara Menangani Stres
Image 3 : Teaching Sessions on Stress Management



Imej 4 : Sesi Pengajaran Pengurusan Emosi di Tempat Kerja
Image 4 : Emotional Management Teaching Sessions in the Workplace



Imej 5 : Sesi Pemberian Cendera Mata oleh Dr Rafidah kepada Pemenang Kuiz
Image 5 : Souvenir Giving Session by Dr Rafidah to quiz winner



Imej 6: Sesi Diskusi Secara Berkumpulan untuk Menangani Krisis Emosi di Tempat Kerja
Image 6 : Group Discussion Sessions to Deal with Emotional Crises in the Workplace



**PENGLIBATAN
& KOLABORASI
ANTARABANGSA**
INTERNATIONAL PARTICIPATION & COLLABORATIONS

Bengkel Pra-Penilaian WHO Global Benchmarking Tool (GBT)

Pada 2017 dan 2018, Pertubuhan Kesihatan Sedunia (WHO) telah memperkenalkan penggunaan *Global Benchmarking Tool (GBT)* yang menerapkan konsep *maturity level* atau ML (yang diadaptasi dari ISO 9004) untuk menilai *maturity* keseluruhan sistem regulatori dari skala satu (1) - kewujudan beberapa elemen sistem regulatori hingga skala empat (4) - beroperasi pada tahap prestasi yang maju dan adanya penambahbaikan yang berterusan.

NPRA komited untuk memperkukuhkan sistem regulatori bagi memastikan kualiti, keselamatan dan keberkesanan produk farmaseutikal di pasaran. Sehubungan dengan itu, NPRA telah menetapkan sasaran untuk mencapai akreditasi *Maturity Level-4* dalam penilaian WHO GBT untuk memastikan sistem regulatori yang dipraktikkan di Malaysia adalah komprehensif, telus dan selari dengan piawaian WHO.

Susulan lawatan WHO ke NPRA untuk memulakan proses penandaan aras pada 2014 dan 2017, satu bengkel pra-penilaian telah diadakan pada 12-13 Mac 2020 di NPRA. Sebagai persediaan kepada penilaian penuh, tiga (3) orang auditor dari WHO hadir ke

WHO Global Benchmarking Tool (GBT) Pre- Assessment Workshop

In 2017 and 2018, the World Health Organization (WHO) introduced the Global Benchmarking Tool (GBT) 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 on a scale of one (1) - existence of some elements of regulatory system) to four (4) - operating at advanced level of performance and continuous improvement.

NPRA is fully committed to strengthen regulatory control to ensure quality, safety & efficacy of pharmaceutical products in the market. Therefore, NPRA has set a target of achieving Maturity Level- 4 in the WHO GBT assessment to ensure that the regulatory system, which is practiced in Malaysia, is comprehensive, transparent and in-line with WHO standards.

As a follow up to WHO's previous visit to NPRA in 2014 and 2017 to initiate the process of benchmarking, a pre- assessment workshop was organized from the 12th to 13th of March 2020 in NPRA. As a preparation for the full assessment, three (3) assessors from



Imej 7: Peserta dan Auditor WHO Semasa Bengkel Pra Audit WHO GBT
Image 7: Participants and WHO Auditors During the WHO GBT Pre-Assessment Workshop

bengkel ini dan telah membincangkan dan menilai dokumen penilaian sendiri yang disediakan oleh NPRA yang merangkumi sembilan (9) modul GBT.

Auditor dari WHO yang telah mengambil bahagian termasuk:

- Dr. Jinho Shin (WHO Western Pacific Region, Fillipina)
- Dr. Alireza Khadem Broojerdi (WHO HQ, Switzerland)
- Dr. Teeranart Jivapaisarnpong (auditor jemputan dari Thailand)

Wakil dari setiap Pusat di NPRA yang mengambil bahagian dalam bengkel ini berpeluang berbincang dengan auditor mengenai keperluan pelaksanaan semua indikator yang ditetapkan dalam GBT. Para peserta juga diberi latihan mengenai cara menggunakan aplikasi GBT berkomputer (cGBT) untuk melaksanakan aktiviti penilaian sendiri. Aplikasi cGBT yang merekodkan laporan penilaian sendiri yang lengkap akan diserahkan kepada WHO sebelum lawatan mereka seterusnya bagi proses penilaian penuh dan penanda aras rasmi. Lawatan ini dijangka berlangsung antara tahun 2021 hingga 2022.

WHO had discussed and reviewed the self-assessment documents prepared by NPRA for all nine (9) modules of the GBT.

The participating assessors from WHO include:

- *Dr. Jinho Shin (WHO Western Pacific Region, Phillipines)*
- *Dr. Alireza Khadem Broojerdi (WHO HQ, Switzerland)*
- *Dr. Teeranart Jivapaisarnpong (invited auditor from Thailand)*

Representatives from each Centre of NPRA participated in the workshop and had a fruitful discussion with the assessors on the requirements and implementation of all GBT indicators. The participants were also given hands-on training on how to use the computerized GBT (cGBT) application to conduct the self-assessment exercise. The completed cGBT data capturing the self-assessment report is to be submitted to WHO before their next visit to conduct full assessment and official benchmarking. This visit is expected to take place from 2021 to 2022.



Imej 8: Peserta dan Auditor WHO Semasa Bengkel Pra Penilaian WHO GBT
Image 8: Participants and WHO Auditors During the WHO GBT Pre-Assessment Workshop

**Webinar Sistem Regulatori
Pertubuhan Kesihatan Sedunia
(WHO) 2020: Pengukuhan Sistem
Regulatori Bagi Jaminan Kualiti
ke atas Produk Perubahan Herba
(PPH) dan Perubatan Alternatif dan
Komplementari (PAK) Malaysia**

Malaysia telah menetapkan keperluan pendaftaran ke atas produk semulajadi sejak tahun 1992 dan keperluan pematuhan ke atas prinsip Amalan Perkilangan Baik (APB) pada tahun 1997. Proses pendaftaran yang terlibat termasuklah penilaian dokumen and pengujian produk yang disampel selepas produk semulajadi didaftarkan.

**World Health Organization (WHO)
Regulatory Systems Webinar 2020:
Strengthening The Regulatory
System for High Quality Assurance of
Herbal Medicinal Products (HMP) and
Complementary Alternative Medicines
(CAM) in Malaysia**

Malaysia has imposed the requirement for natural products to be registered since 1992 and followed by the requirement for natural products manufacturers to comply with Good Manufacturing Practice (GMP) in 1997. The registration processes include evaluation of documentary evidence and product testing, which is sampled during post-registration.



Imej 9: Koleksi gambar yang diambil sepanjang sesi latihan tersebut dijalankan
Image 9: Pictures taken during the training sessions

Walau bagaimanapun, sejak kebelakangan ini pihak regulatori menghadapi cabaran dari segi pengesahan kandungan, campuran bahan terlarang, bahan kontaminasi dan tuntutan perubatan yang tidak dibenarkan (tuntutan terapeutik). Ini disebabkan oleh perkembangan terbaru dalam produk perubatan herba (PPH) dan perubatan alternatif dan komplementari (PAK) di dalam

However, recently regulators are facing challenges in the form of authentication, adulteration, contaminants and misleading claims (therapeutic claim) due to current development of Herbal Medicinal Products (HMP) and Complementary Alternative Medicines (CAM) both locally and globally. Therefore, training on strengthening the regulatory system for high-quality assurance



dan juga luar negara. Sehubungan itu, satu sesi latihan berkenaan pengukuhan sistem regulatori bagi jaminan kualiti ke atas PPH dan PAK telah diadakan secara atas talian pada 7 hingga 9 Oktober 2020 bagi membincangkan isu-isu tersebut.

Objektif utama sesi latihan ini adalah untuk mengkaji keperluan regulatori semasa dengan mengenal pasti jurang dengan piawaian antarabangsa serta amalan baik badan-badan regulatori utama yang lain. Antara objektif khusus sesi latihan ini adalah untuk memahami amalan pendaftaran, cabaran dalam menjalankan aktiviti kawalan kualiti dan pengilangan, pengendalian aktiviti surveilans serta farmakovigilans. Pengetahuan dari latihan ini boleh menyumbang kepada penambahbaikan rangka kerja bagi memajukan pelan tindakan PPH dan PAK di Malaysia.

Sesi latihan tersebut ditaja oleh WHO dimana penceramah jemputan yang terlibat adalah daripada badan regulatori United Kingdom iaitu *Medicines and Healthcare Products Regulatory Agency (MHRA)* dan *Therapeutics Good Administration (TGA)*, Australia. Sebanyak 50 pegawai NPRA terlibat dalam sesi latihan ini dimana sesi ceramah, kajian kes serta sesi soal jawab telah diadakan sepanjang latihan tersebut. Penetapan cara latihan ini menyediakan platform untuk perkongsian pengalaman serta amalan baik yang boleh digunapakai oleh peserta serta badan regulatori lain.

of HMP and CAM in Malaysia was conducted virtually from 7th to 9th October 2020, to address these issues.

The main objective of this training was to review the current regulatory requirements by identifying gaps against international standards and best practices of other stringent regulatory agencies. The specific objectives were to have a better understanding of the registration practices, challenges in quality control and manufacturing, handling of post-market surveillance as well as pharmacovigilance activities. The outcome of this training will be the basis of a framework to further the plan of action on HMP and CAM for Malaysia.

The WHO-sponsored the training and the invited speakers were from Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom and Therapeutics Good Administration (TGA), Australia. A total of 50 officers from different expertises in NPRA participated in this training. The training was conducted in a mixture of modes, which include lectures, case studies, presentations as well as question and answer session. This setting served as a platform to share experiences and best practices among participants and other regulators.



Siri Webinar Persidangan Regulatori Asia ke-10

Persidangan Regulatori Asia ke-10 (ARC) yang dianjurkan bersama oleh *International Federation of Pharmaceutical Manufacturers and Associations* (IFPMA) dan Persatuan Farmaseutikal Malaysia (PhAMA) yang pada awalnya dijadualkan pada bulan Mac di Kuala Lumpur ditangguhkan kerana peningkatan kes COVID-19 yang juga merupakan permulaan gelombang pertama kepada pandemik tersebut. Sehubungan dengan itu, penganjur memutuskan untuk mengadakan persidangan sebagai siri webinar yang terdiri daripada webinar dua (2) jam dari 3-6 November, dengan tema yang berbeza setiap hari.

Tema utama persidangan adalah konsep *reliance*. Malaysia telah mengambil bahagian dalam dua sesi webinar.

Pengarah Kanan Program Perkhidmatan Farmasi, Datin Dr Faridah Aryani Md. Yusof telah dijemput untuk serta sebagai *Co-Chair* kepada sesi bertajuk *Regulatory Reliance* serta untuk mengambil bahagian sebagai ahli panel dalam sesi soal jawab kepada sesi ini.

Malaysia telah berpeluang berkongsi pengalaman mempraktikkan konsep *reliance* untuk aktiviti pendaftaran produk bagi mempercepatkan akses ubat-ubatan termasuk perspektif Malaysia dalam kolaborasi dengan persatuan pesakit dalam aplikasi *reliance*.

Dr Hasenah Ali, Pengarah NPRA telah dijemput untuk mengambil bahagian sebagai *Co-chair* dalam sesi *Regulatory Reliance in Asia* bersama Dr Fujiwara dari *Pharmaceutical and Medical Devices Agency* (PMDA), Jepun. Objektif sesi ini adalah untuk menambahkan pengetahuan mengenai perkembangan *regulatory reliance* di rantau Asia dari pakar dalam bidang ini.

Dr Hasenah Ali telah berkongsi pengalaman Malaysia dalam mengaplikasikan konsep *reliance*. Ini termasuk implementasi Garis

10th Asia Regulatory Conference Webinar Series

10th Asia Regulatory Conference which was jointly organized by International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Malaysian Pharmaceutical Association (PhAMA) was initially scheduled to be held in March in Kuala Lumpur but was indefinitely postponed due to the surge of cases of COVID-19 and eventually the emergence of first wave of the pandemic. Soon after the organizers decided to conduct the conference as webinar series which consists of a 2-hour webinar spanning from 3rd to 6th November each with a different theme.

The overarching theme of the conference is reliance. Malaysia participated in two of the webinar sessions.

Senior Director of Pharmaceutical Services Programme, Datin Dr Faridah Aryani Md. Yusof was invited to participate as a Co-chair of the session entitled Regulatory Reliance and to also contribute as a panelist in the final Q&A session.

Malaysia was able to share her experience in the use of reliance for product registration to facilitate access to medicines as well as Malaysia's perspectives in collaborating with patient groups to make use of reliance.

Dr Hasenah Ali, Director of NPRA was invited to participate as a Co-chair during the Regulatory Reliance in Asia session with Dr Fujiwara of Pharmaceutical and Medical Devices Agency (PMDA), Japan. The objectives for this session are to hear, first-hand about the progressive developments and views on regulatory reliance in Asia from global experts in the field.

Dr Hasenah took questions from the audience relating to Malaysia's experience with reliance. Dr Hasenah shared information

Panduan *Facilitated Registration Pathway (FRP)* NPRA serta penglibatan Malaysia dalam *Joint Assessment Coordinating Group (JACG)* di mana Malaysia berperanan sebagai Pengerusi. Inisiatif ini yang dibangunkan di bawah *ASEAN Consultative Committee for Standards and Quality (ACCSQ-PPWG)* bertujuan untuk mengalakkan penggunaan konsep *regulatory reliance* dalam penilaian regulatori di kalangan negara anggota ASEAN.

on NPRA's Facilitated Registration Pathway (FRP) and also shared the ASEAN experience with reliance through the implementation of the Joint Assessment Coordinating Group, which Malaysia leads as Chair. This initiative was established under ASEAN Consultative Committee for Standards and Quality (ACCSQ-PPWG), to promote the concept of reliance in regulatory reviews within ASEAN member states.



Imej 10: Persidangan Regulatori Asia ke-10 Diadakan Secara Maya
Image 10: 10th Asia Regulatory Conference Conducted Online

Bengkel Virtual APEC Mengenai Facilitated Regulatory Pathways (FRPs)

Bengkel ini dianjurkan oleh Jaringan Penyakit Jarang Jumpa (RDN) di bawah APEC Life Science and Innovation Forum (LSIF) yang diadakan secara maya dari Beijing, China pada 1 hingga 2 Disember 2020.

FRP adalah komponen penting dalam usaha-usaha APEC Life Sciences Innovation Forum (LSIF). Objektif FRP adalah untuk:

- 1) untuk menggalakkan *regulatory convergence* bagi prosedur pendaftaran produk ubat-ubatan melalui Jawatankuasa Pemandu Harmonisasi Regulatori (*Regulatory Harmonization Steering Committee-RHSC*) dengan sokongan dari APEC Harmonization Centre (AHC); dan
- 2) mengatasi faktor-faktor halangan kepada akses rawatan pesakit yang menghadapi penyakit jarang jumpa

Memandangkan Malaysia merupakan tuan rumah kepada Mesyuarat APEC 2020, NPRA telah dijemput untuk mengambil bahagian di dalam sesi bertajuk 'Peranan *Reliance* dalam Mempercepatkan Pendaftaran Produk Inovatif atau Produk Ubat Baru'.

Puan Rosilawati Ahmad, Timbalan Pengarah Pusat Penilaian Produk dan Kosmetik telah dijemput untuk berkongsi pengalaman ASEAN dalam aplikasi FRP dan implementasi kumpulan kerja *Joint Assessment Coordinating Group (JACG)* yang ditubuhkan bawah *ASEAN Consultative Committee for Standards and Quality (ACCSQ-PPWG)*. Memandangkan Malaysia berperanan sebagai Pengerusi atau *Chair* kepada JACG, Puan Rosilawati telah membentangkan prestasi usaha kumpulan kerja tersebut di samping cabaran yang dihadapi dalam menggalakkan penggunaan konsep *reliance* dalam kawalan regulatori farmaseutikal di rantau ASEAN. Malaysia juga telah membentangkan serba sedikit mengenai implementasi Garis Panduan FRP NPRA untuk pendaftaran ubat baru dan ubat biologi.

APEC Virtual Workshop on Facilitated Regulatory Pathways (FRPs)

The Rare Disease Network (RDN) of the APEC Life Science organized this workshop and Innovation Forum (LSIF) was held virtually from Beijing, China from 1st to 2nd of December 2020.

FRP is an important component of the efforts of the APEC LSIF. The objectives of FRP are:

- 1) to accelerate regulatory convergence for medical product approval procedures through its Regulatory Harmonization Steering Committee (RHSC) and with support from the APEC Harmonization Center (AHC); and*
- 2) to address barriers to treatment for people living with a rare disease*

As Malaysia was the host of APEC Meetings in 2020, NPRA was invited to participate in the session entitled: Role of Reliance in Expedited Approvals of Innovative Products.

Madam Rosilawati Ahmad, Deputy Director of Centre of Product and Cosmetic Evaluation was invited to share the ASEAN experience with FRP, as well as the implementation of the Joint Assessment Coordinating Group (JACG), an initiative established under the work of the ASEAN Consultative Committee for Standards and Quality (ACCSQ-PPWG). Malaysia is Chair to the JACG, therefore Madam Rosilawati was able to share the progress and implementation of JACG as well as the challenges faced by the region in broadening the concept of reliance within the ASEAN regulatory landscape. Malaysia also shared the experience of implementing NPRA's FRP Guideline for Innovative Drugs and Biologics.



Webinar PMDA-ATC Pharmaceuticals Review 2020 untuk NPRA, Malaysia

Pada 6 November, *Pharmaceutical and Medical Devices Agency* (PMDA) telah mengadakan seminar bertajuk *PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia*. Program ini pada mulanya dirancang sebagai latihan bersemuka anjuran bersama PMDA dan NPRA dan akan diadakan di pejabat NPRA pada Mei 2020. Namun, disebabkan oleh situasi pandemik, program ini terpaksa ditangguhkan.

Setelah kedua-dua pihak berbincang dengan lebih lanjut, PMDA dan NPRA bersetuju untuk menerapkan norma baru dan menganjurkan seminar tersebut secara maya /webinar. Sebanyak 19 pegawai dari NPRA yang terlibat dalam penilaian *First-In-Human (FIH) Clinical Trials* serta pemeriksaan Amalan Klinikal Baik (GCP) telah mengambil bahagian dalam webinar tersebut.

Objektif webinar ini adalah untuk memberi pengenalan mengenai proses penilaian kajian klinikal *FIH* serta proses pemeriksaan GCP secara umum. Webinar dimulakan dengan ucapan pembukaan oleh En Uzu Shinobu (Pengarah Pusat Latihan Asia untuk Hal-hal Regulatori Farmaseutikal dan Peranti Perubatan, PMDA) dan oleh Dr. Zaryl Harza Zakaria, Ketua Seksyen Penilaian & Keselamatan Produk Kajian, Pusat Penilaian Produk & Kosmetik NPRA. Program ini melibatkan pembentangan daripada regulator PMDA Jepun dan pensyarah dari Universiti Kitasato, Jepun. Untuk membandingkan amalan regulatori Malaysia dan Jepun mengenai *FIH*, pegawai dari NPRA juga dijemput untuk memberi pembentangan mengenai pengalaman Malaysia dalam pemeriksaan GCP dan rangkakerja regulatori bagi kajian klinikal *FIH* di Malaysia.

Di akhir majlis, Dr. Fujiwara Yasuhiro (Ketua Eksekutif PMDA) menyampaikan ucapan penutup melalui rakaman video. Dr Zaryl pula telah memberikan ucapan penutup yang menyatakan penghargaan Malaysia kepada

PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia

On November 6, Pharmaceutical and Medical Devices Agency (PMDA) held a seminar entitled "PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia". The program was initially intended to be a face to face training jointly organised by PMDA and NPRA and was to be held in NPRA offices in Malaysia on May 2020. However, due to the uncertainties caused by the pandemic, the program was postponed.

After further deliberations with both sides, PMDA and NPRA agree to embrace the new normal and pursue the training virtually as a webinar. A total of 19 regulators of National Pharmaceutical Regulatory Agency (NPRA), who are involved in review of First In Human Clinical Trials as well as Good Clinical Practice (GCP) inspections, participated in the webinar.

The objective of the webinar is to provide introduction on the review process for FIH trials as well as the process of conducting GCP inspections in general. The webinar opened with remarks by Mr. Uzu Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs of PMDA) and by Dr. Zaryl Harza Zakaria, Head of Evaluation & Safety of Investigational New Product Section, Centre of Product and Cosmetic Evaluation of NPRA. The programme consists of presentations from regulators from PMDA Japan and lecturers from Kitasato University, Japan. To compare the regulatory practice on FIH between both countries, NPRA officers were also invited to give presentations on the Malaysian experience of GCP Inspection as well as the regulatory framework for FIH trials in Malaysia.

At the end of the webinar, Dr. Fujiwara Yasuhiro (Chief Executive of PMDA) delivered his closing remarks virtually by recorded video, and Dr. Zaryl gave the closing remarks expressing Malaysia's appreciation to PMDA



PMDA atas kerjasama ini dan berharap PMDA dan NPRA akan terus menjalin hubungan dan kerjasama erat dalam bidang kawalan regulatori farmasi.

on this collaboration and hope that PMDA and NPRA will continue to foster close relations and further cooperation in the area of pharmaceutical regulatory control.



Imej 11: Peserta dan penceramah PMDA-ATC Pharmaceuticals Review Webinar for NPRA
Image 11: Participants and presenters from the PMDA-ATC Pharmaceuticals Review Webinar for NPRA

Penglibatan NPRA di dalam Kumpulan Kerja ASEAN

ASEAN Consultative Committee for Standards and Quality (ACCSQ) telah ditubuhkan pada tahun 1992 bagi memudahkan pencapaian objektif Perjanjian Perdagangan Bebas ASEAN. Pada tahun 2004, ACCSQ telah ditugaskan untuk menjalankan aktiviti-aktiviti yang berkaitan dengan penubuhan ASEAN Economic Community (AEC).

AEC dilancarkan pada 2015 dengan tujuan untuk mewujudkan pasaran tunggal di kalangan negara-negara ASEAN. Perkara ini akan membolehkan pergerakan bebas barangan, perkhidmatan, buruh mahir dan pelaburan di kalangan sepuluh (10) negara anggota ASEAN. Pengharmonian peraturan-peraturan teknikal dan *Mutual Recognition Agreements (MRA)* adalah antara strategi yang akan digunakan oleh AEC untuk mengurangkan kos perdagangan.

Malaysia, melalui NPRA giat mengambil bahagian dalam aktiviti tiga (3) kumpulan kerja yang ditubuhkan di bawah ACCSQ untuk membangunkan skim pengharmonian produk farmaseutikal, ubat-ubatan tradisional 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)*.

NPRA's Participation in ASEAN Working Groups

The ASEAN Consultative Committee for Standards and Quality (ACCSQ) was formed in 1992 to facilitate the accomplishment of the objectives of the ASEAN Free Trade Agreement. In 2004, the ACCSQ was tasked to undertake activities in relation to the establishment of an ASEAN Economic Community (AEC).

Launched in 2015, the AEC aims to eventually create a single market and production base within ASEAN countries. This will allow for the free movement of goods, services, skilled labour and investment among the ten (10) ASEAN member nations. Harmonisation of technical regulations and Mutual Recognition Agreements (MRA) are among the strategies that will be adopted by the AEC to reduce trade cost.

Through the NPRA, Malaysia actively participates in three (3) product-working groups established under the ACCSQ, which aim to develop harmonisation schemes of pharmaceuticals, traditional medicines and health supplements as well as cosmetics regulations in ASEAN countries. These working groups include the following- the Pharmaceutical Product Working Group (PPWG), the Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) and the ASEAN Cosmetic Committee (ACC).

Berikut merupakan mesyuarat peringkat ASEAN yang telah dihadiri oleh pegawai NPRA sepanjang tahun 2020:

Below are the ASEAN meetings attended by NPRA officers in the year 2020:

Bil. No.	Mesyuarat Meeting	Tarikh Date
1.	<i>The Intersessional Heads of Delegation Meeting Traditional Medicines and Health Supplements Product Working Group</i>	7-8 July 2020
2.	<i>22nd Implementation Working Group Meeting</i>	13 July 2020
3.	<i>29th Pharmaceutical Product Working Group</i>	16 July 2020
4.	<i>ASEAN Framework for Pharmaceutical Regulations Workshop</i>	2 September 2020
5.	<i>32nd Meeting of the ASEAN Cosmetic Committee</i>	23-24 September 2020
6.	<i>5th Joint Assessment Coordinating Group Meeting</i>	19 October
7.	<i>The First Meeting of the ASEAN Pharmaceutical Laboratory Network (APLN)</i>	22 October 2020
8.	<i>9th Joint Sectoral Committee for ASEAN Mutual Recognition Agreement for GMP Inspection of Manufacturers of Medicinal Products Meeting</i>	26 October 2020
9.	<i>3rd JSC BE MRA</i>	2 November 2020
10.	<i>30th Pharmaceutical Product Working Group</i>	5-6 November 2020
11.	<i>30th Task Force on ASEAN Regulatory Framework for Traditional Medicines & Health Supplements Meeting</i>	17-18 November 2020
12.	<i>2nd Workshop ASEAN Framework for Pharmaceutical Regulations</i>	8 December 2020

Imej 12: Mesyuarat Kumpulan Kerja Produk Farmaseutikal ke-29 Telah Diadakan Secara Maya Pada 16 Julai 2020

Image 12: 29th Pharmaceutical Product Working Group Meeting Being Held Virtually on 16 July 2020



Imej 13: Mesyuarat Kumpulan Kerja Produk Farmaseutikal ke-30 Telah Diadakan Secara Maya Pada 5-6 November 2020

Image 13: 30th Pharmaceutical Product Working Group Meeting Being Held Virtually on 5-6 November 2020



Mesyuarat Dua Hala di antara Bahagian Regulatori Farmasi Negara (NPRA) dan Pharmaceutical and Medical Devices Agency (PMDA), Jepun

Pharmaceutical and Medical Devices Agency (PMDA) Jepun telah menganjurkan Mesyuarat Dua Hala Malaysia-Jepun untuk tahun 2020. Mesyuarat dua hala ini kebiasaannya diadakan secara bersemuka sama ada di Jepun atau di Malaysia. Mesyuarat bilateral telah dirancang pada awal April 2020 di Tokyo tetapi mesyuarat tersebut terpaksa dibatalkan kerana situasi pandemik COVID-19. Oleh itu, mesyuarat bilateral diadakan secara virtual pada 17 November 2020.

Pegawai dari PMDA yang telah menghadiri mesyuarat tersebut termasuk Dr. Fujiwara Yasuhiro (Ketua Eksekutif), En. Uzu Shinobu (Pengarah Eksekutif Kanan), Dr. Nakashima Nobumasa (Pengarah Eksekutif Bersekutu untuk Program Antarabangsa) dan Dr. Sato Junko (Pengarah Program Antarabangsa). Wakil dari *Ministry of Health, Labour and Welfare (MHLW)*, Dr. Yasuda Naoyuki (Pengarah Pejabat Hal Regulatori Luar Negara) turut mengambil bahagian.

Pegawai dari Malaysia termasuk Datin Dr. Faridah Aryani Md Yusof (Pengarah Kanan Program Perkhidmatan Farmasi) dan Dr. Hasenah Ali (Pengarah NPRA), Timbalan-timbalan Pengarah - Puan Rosilawati Ahmad, Puan Basariah Naina dan Dr Roshayati Mohd Sani, termasuk Ketua-ketua Seksyen yang berkaitan. Dalam mesyuarat tersebut, Datin Dr. Faridah dan Dr. Fujiwara membuat ucapan pembukaan yang merumuskan kerjasama antara PMDA dan NPRA setakat ini. Walaupun dalam keadaan pandemik, kedua-dua pihak berbesar hati kerana dapat meneruskan perbincangan secara maya berkaitan bidang yang berkepentingan kepada kedua-dua pihak.

Agenda mesyuarat merangkumi pembentangan dari kedua-dua agensi berkenaan langkah-langkah regulatori yang diambil semasa pandemik COVID-19. Topik perbincangan lain termasuk peluang

Bilateral Meeting between the National Pharmaceutical Regulatory Agency (NPRA) and Pharmaceutical and Medical Devices Agency (PMDA), Japan

Pharmaceutical and Medical Devices Agency (PMDA) Japan hosted the Malaysia-Japan Bilateral Meeting for the year 2020. Bilateral meetings between the two parties are traditionally held face to face either in Japan or Malaysia. A bilateral meeting was planned in early April 2020 in Tokyo but the meeting was cancelled due to COVID-19 pandemic. Therefore, the bilateral meeting was held virtually on the 17th of November 2020.

Participants from PMDA included Dr. Fujiwara Yasuhiro (Chief Executive), Mr. Uzu Shinobu (Senior Executive Director), Dr. Nakashima Nobumasa (Associate Executive Director for International Programs) and Dr. Sato Junko (Director of Office of International Programs). Representative from Ministry of Health, Labour and Welfare (MHLW), Dr. Yasuda Naoyuki (Director of Office of International Regulatory Affairs) also participated in the meeting.

Participants from Malaysia included Datin Dr. Faridah Aryani Md Yusof (Senior Director of Pharmaceutical Services Programme) and Dr. Hasenah Ali (Director of NPRA), Deputy Directors - Mdm Rosilawati Ahmad, Mdm Basariah Naina and Dr Roshayati Mohd Sani, including relevant Heads of Sections. In the meeting, Datin Dr. Faridah and Dr. Fujiwara made opening remarks reflecting on the cooperation between PMDA and NPRA thus far. Both parties were glad that despite the pandemic, bilateral engagements were continued virtually in order to discuss further cooperation in areas of mutual interest.

Meeting agenda included presentations from both agencies on regulatory measures taken during the COVID-19 pandemic. Other topics of discussion include training and capacity building opportunities. PMDA also

latihan dan peningkatan kapasiti organisasi. Pihak PMDA juga turut membentangkan mekanisme regulatori yang digunakan oleh PMDA untuk mempercepatkan pendaftaran produk berkaitan COVID-19, termasuklah vaksin.

shared their available regulatory pathways to expedite the registration of COVID-19 related products, including vaccines.



Imej 14: Pengarah Kanan Perkhidmatan Farmasi Mengetuai Delegasi Malaysia ke Mesyuarat Bilateral NPRA-PMDA

Image 14: Senior Director of Pharmaceutical Services Heads the Malaysian Delegation for the NPRA-PMDA- Bilateral Meeting



Imej 15: Ketua Eksekutif PMDA, Dr Fujiwara Yasuhira Mengetuai Delegasi Jepun ke Mesyuarat Bilateral NPRA-PMDA

Image 15: Chief Executive of PMDA, Dr Fujiwara Yasuhiro Heads the Japanese Delegation for the NPRA-PMDA Bilateral Meeting

Mesyuarat COVID-19 oleh Taiwan Food and Drug Administration (TFDA)

Pada 16 Jun 2020, *Taiwan Food and Drug Administration (TFDA)* mengadakan mesyuarat maya dengan badan regulatori terpilih dari rantau Asia Pasifik untuk membincangkan dan berkongsi pengalaman menangani dan menghadapi pandemik COVID-19.

Badan regulatori yang mengambil bahagian termasuk *European Medicines Agency (EMA)*, *United States Food and Drug Administration (USFDA)*, *Thailand Food and Drug Administration (Thai FDA)*, *Pharmaceutical and Medical Devices Agency Japan (PMDA)* dan Bahagian Regulatori Farmasi Negara (NPRA). Peserta dari NPRA termasuk Pengarah NPRA - Dr Hasenah Ali beserta dua orang Timbalan Pengarah - Puan Rosilawati Ahmad dan Dr Roshayati Mohd Sani.

Dalam keadaan pandemik yang tidak dijangka ini, badan-badan regulatori harus membuat penambahbaikan kepada prosedur regulatori dengan mengambilkira kebarangkalian terjadinya gangguan kepada sektor ekonomi dan sosial ekoran peningkatan kes positif COVID-19.

Objektif utama mesyuarat ini adalah untuk menyediakan platform kepada badan-badan regulatori untuk berkongsi pengalaman dalam menangani isu-isu seperti kekurangan ubat atau gangguan bekalan ubat serta langkah yang diambil untuk memenuhi permintaan yang meningkat untuk produk *sanitizer* alkohol, produk pembasmi kuman dan *personal protective equipment (PPE)* semasa fasa awal COVID-19. Mesyuarat juga membincangkan potensi kolaborasi untuk membolehkan perkongsian maklumat regulatori terkini berkaitan dengan COVID-19.

Taiwan Food and Drug Administration (TFDA) COVID-19 Meeting

On 16th of June 2020, the *Taiwan Food and Drugs Administration (TFDA)* hosted a virtual meeting with selected regulatory authorities from Asia Pacific to discuss and share experiences relating to the COVID-19 pandemic.

Participating regulatory authorities include European Medicines Agency (EMA), United States Food and Drug Administration (USFDA), Thailand Food and Drug Administration (Thai FDA), Pharmaceutical and Medical Devices Agency Japan (PMDA) and the National Pharmaceutical Regulatory Agency Malaysia (NPRA). Participants from NPRA include the Director, Dr Hasenah Ali along with two Deputy Directors - Mdm Rosilawati Ahmad and Dr Roshayati Mohd Sani.

During this unprecedented time, many regulatory authorities must adapt and update regulatory procedures considering potential disruptions to the economic and social sector caused by rising cases of positive COVID-19.

Main objective of the meeting is to provide a platform for regulatory authorities to share the actions taken by their agencies to prevent potential drug shortages or supply disruptions and measures taken to fulfill increasing demand for alcohol sanitizer products, disinfectants and personal protective equipment (PPE) during the early phase of COVID-19 pandemic. The meeting also discussed potential collaborations to enable information sharing of regulatory updates with regards to COVID-19.



PENERBITAN PUBLICATION

Garis Panduan untuk Ubat-ubatan Orphan di Malaysia

Salah satu perkara yang diberi tumpuan dalam rangka kerja untuk pelan tindakan program *Asia Pacific Economic Cooperation* (APEC) bagi penyakit jarang jumpa (*rare disease*) adalah penyampaian dan akses ubat *orphan* serta rawatan baru untuk pesakit. Program ini menyarankan agar setiap ekonomi APEC menyediakan definisi rasmi bagi penyakit jarang jumpa yang boleh digunapakai secara bersama untuk membangunkan rangka kerja regulatori dan polisi – polisi yang relevan kepada agensi tempatan berkaitan.

Justeru itu, antara perkara yang perlu diberi perhatian melalui Dasar Ubat Nasional (DUNas) penggal ketiga adalah kebolehcapaian dan ketersediaan ubat – ubatan yang digunakan bagi merawat penyakit jarang jumpa (ubat *orphan*). Bagi mencapai hasrat ini, satu prosedur regulatori perlu dibangunkan bagi meningkatkan akses kepada produk – produk *orphan* yang diperlukan untuk pengurusan penyakit jarang jumpa di Malaysia.

Menyedari kepentingan situasi ini, Garis Panduan untuk Ubat-ubatan *Orphan* di Malaysia telah diterbitkan pada Disember 2020 oleh Program Perkhidmatan Farmasi dengan kerjasama daripada pelbagai pihak berkepentingan dengan tujuan menyediakan rangka kerja regulatori bagi designasi dan pendaftaran produk – produk ubat *orphan*.

Garis panduan ini yang akan dijadikan rujukan dan panduan bersama oleh industri farmaseutikal dan pakar – pakar perubatan di Malaysia yang terlibat dalam rawatan penyakit jarang jumpa, harus dirujuk bersama *Drug Registration Guidance Document* (DRGD) NPRA.

Garis panduan tersebut memberikan fleksibiliti di mana terdapat pengecualian kepada keperluan pendaftaran tertentu. Dengan syarat semua keperluan designasi dan pendaftaran dapat dipenuhi, sepertimana yang ditetapkan dalam garis panduan, pendaftaran ubat – ubat *orphan* yang dijamin

Malaysian Orphan Medicines Guideline

Through the Asia Pacific Economic Cooperation (APEC) program, among the focus area of the framework in the APEC action plan on rare disease is the delivery and accessibility of new orphan medicines and treatment to patients. Among the recommendations of this programme is for APEC member economies to establish an official definition for rare disease, which serves as the basis for regulatory frameworks and other relevant policies to local agencies and providers.

Hence, in the 3rd Edition Malaysian National Medicines Policy (MNMP), one of the main focus area is the accessibility and availability of orphan medicines and life-saving products. An appropriate regulatory procedure to enhance the availability of these products is seen as critical and crucial to enhance the accessibility of these orphan medicines required for the management of rare diseases in Malaysia.

Realising the importance of this situation, the Malaysian Orphan Medicines Guideline was published in December 2020 by Pharmaceutical Services Programme in collaboration with various stakeholders to provide the framework for the designation and registration of orphan medicines.

This guideline which serves as a guide for the pharmaceutical industry and healthcare professionals who are involved in the treatment of rare diseases, shall be read in conjunction with Drug Registration Guidance Document (DRGD) by NPRA.

The guideline provides certain flexibilities with certain registration requirements being waived. Provided that all the requirements of the designation and registration have been fulfilled as per guideline, the successful registration of quality, safe and efficacious orphan medicines will facilitate its accessibility

kualiti, keselamatan dan keberkesanannya akan meningkatkan capaian dan ketersediaan produk tersebut di pasaran tempatan. Ini bukan sahaja memberi manfaat kepada pesakit yang mengalami penyakit jarang jumpa tetapi turut membantu pakar perubatan dan industri farmaseutikal.

and availability in the local market. This will not only benefit patients with rare diseases, but also assist healthcare providers and the pharmaceutical industry.



Garis Panduan Produk Semulajadi Dengan Tuntutan Terapeutik

Keperluan pendaftaran produk semulajadi dengan tuntutan terapeutik telah dilaksanakan oleh NPRA bermula 1 Ogos 2020.

Produk semulajadi dengan tuntutan terapeutik perlu didaftarkan dengan Pihak Berkuasa Kawalan Dadah (PBKD) sebelum produk berkenaan boleh dipasarkan di Malaysia. Oleh itu, garis panduan ini bertujuan untuk menerangkan data yang diperlukan untuk menyokong kualiti, keselamatan dan keberkesan produk semulajadi dengan tuntutan terapeutik serta untuk melindungi pengguna daripada tuntutan yang mengelirukan.

Guideline On Natural Products with Therapeutic Claim

The requirement for registration of natural products with therapeutic claims was implemented beginning 1st August 2020.

Natural products with therapeutic claims are required to be registered with the Drug Control Authority (DCA) before they can be marketed in Malaysia. Therefore, this guideline aims to provide the requirements to support the quality, safety and efficacy of the natural product with therapeutic claims as well as to protect consumers from misleading claims.

Definisi tuntutan terapeutik adalah tuntutan yang tidak didokumentasikan di dalam farmakopia atau monograf, atau tuntutan yang bukan merupakan tuntutan tradisional bahan atau herba berkenaan. Ini merangkumi bukti dan pengesahan penggunaan produk semulajadi secara tradisional untuk menghilangkan gejala atau membantu merawat penyakit, dan tuntutan tersebut harus dibuktikan atau disokong dengan kajian saintifik.

Skop garis panduan ini merangkumi penerangan mengenai data yang perlu dikemukakan untuk menyokong tuntutan terapeutik bagi produk semulajadi untuk kegunaan manusia. Dokumen ini juga turut menyatakan keperluan data kualiti dan data keselamatan bagi produk semulajadi yang mengandungi herba / tumbuhan di dalam bentuk ekstrak yang dipiawaikan.

Maklumat terperinci mengenai keperluan pendaftaran produk semulajadi dengan tuntutan terapeutik ini boleh didapati melalui Garis Panduan Produk Semulajadi Dengan Tuntutan Terapeutik yang terdapat di *Drug Registration Guidance Document (DRGD)* di laman web NPRA.

Therapeutic claims are defined as a claim that is not documented in established pharmacopoeia or monographs, or a claim, which is not the traditional use of the ingredient or herb. It may include corroboration and verification of traditional use to relieve a symptom or help to treat a disease, disorder or medical condition, and it must be substantiated by scientific evidence.

The scope of this guideline encompasses the type of evidence to support the therapeutic claim for a Natural Product intended for human use. It also outlines what are the quality and safety data required and applicable to products containing herbal/plant-medicinal ingredients in the form of standardized extract.

In depth information on registration of natural products with therapeutic claims can be found in the Guideline on Natural Products with Therapeutic Claim which is available in the Drug Registration Guidance Document (DRGD) on the NPRA website.



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LAPORAN KEWANGAN

FINANCIAL REPORT

BAJET MENGURUS 2020 | OPERATING BUDGET 2020

Program <i>Program</i>	Kategori <i>Category</i>	Peruntukan <i>Allocation</i>	Perbelanjaan <i>Expenditure</i>		Baki <i>Balance</i>	
		(RM)	RM	%	RM	%
10300	Kewangan <i>Finance</i>	564,000.00	536,175.00	95.07%	27,825.00	4.93%
010500	Teknologi Maklumat Dan Komunikasi <i>Information Technology & Communications</i>	300,000.00	241,680.00	80.56%	58,320.00	19.44%
050400	Farmasi Regulatori <i>Regulatory Pharmacy</i>	50,209,100.00	51,355,233.26	102.28%	(1,146,133.26)	-2.28%
060200	Kejuruteraan <i>Engineering</i>	340,435.80	329,010.30	96.64%	11,425.50	3.36%
040101	Bayaran Balik Hasil <i>Refund</i>	58,600.00	58,600.00	100.00%	-	0.00%
080800	Harta Modal <i>Capital property</i>	81,648.00	81,648.00	100.00%	-	0.00%
JUMLAH <i>TOTAL</i>		51,553,783.80	52,602,346.56	102.03%	(1,048,562.76)	-2.03%

BAJET PEMBANGUNAN 2020 | DEVELOPMENT BUDGET 2020

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>	39,279.00	39,278.30	100.00%	0.70	0.00%
01100	Peralatan Perubatan <i>Medical Equipment</i>	1,626,187.00	1,604,544.15	0.00%	21,642.85	1.33%
00300	Perkhidmatan Sokongan Hospital <i>Hospital Support Services</i>	4,130,000.00	4,054,727.63	98.18%	75,272.37	1.82%
JUMLAH <i>TOTAL</i>		5,795,466.00	5,698,550.08	98.33%	96,915.92	1.67%

KUTIPAN HASIL TAHUN 2020 | *REVENUE FOR 2020*

Bil No	Perkara Item	Jumlah (RM) Total (MYR)
1	Akaun Amanah (APB) <i>GMP Trust Account</i>	55,869.80
2	Akaun Amanah (BE) <i>BE Trust Account</i>	178,065.12
3	Amalan Perkilangan Baik <i>Good Manufacturing Practice</i>	79,000.00
4	Invois Amalan Makmal Baik <i>Good Laboratory Practice Invoice</i>	15,000.00
5	Invois APB <i>GMP Invoice</i>	575,350.00
6	Invois APB Luar Negara <i>International GMP Invoice</i>	144,100.00
7	Invois BE <i>BE Invoice</i>	177,000.00
8	Pelan Susun Atur Kilang <i>Factory Layout Plan</i>	105,000.00
9	Plasma <i>Plasma</i>	80,300.00
10	Sijil APB <i>GMP Certificate</i>	29,000.00
11	Vaksin VLR <i>Vaccine Lot Release</i>	114,900.00
12	Lesen Borong <i>Wholesaler's License</i>	591,000.00
13	Lesen Impot <i>Import License</i>	234,500.00
14	Lesen Pengilang <i>Manufacturer License</i>	266,000.00
15	Pengelasan <i>Classification</i>	875,500.00
16	Perakuan Penjualan <i>Free Sale Certificate</i>	259,150.00
17	Sijil Indikasi <i>Certificate of indication</i>	94,850.00
18	Yuran Import Keluaran Tidak Berdaftar <i>Import Fee for Unregistered Item</i>	400.00
19	Daftar Produk Kosmetik <i>Registration of Cosmetic Product</i>	5,593,451.00
20	Daftar Ubat Baru <i>New Product Registration</i>	2,726,400.00
21	Daftar Ubat Eksport <i>Export Product Registration</i>	23,000.00
22	Daftar Ubat Semula <i>Product Re-registration</i>	2,410,000.00
23	Daftar Ubat Semula Veterinar <i>Veterinary Product Re-registration</i>	174,000.00
24	Daftar Ubat Veterinar <i>Veterinary Product Registration</i>	114,000.00
25	Lesen Impot Klinik <i>Clinical Import License</i>	139,500.00
26	Tambahan Indikasi <i>Additional Indication</i>	30,000.00
27	Tukar Pemegang <i>Change of Holder</i>	309,000.00
28	Tukar Tapak Kilang <i>Change of Manufacturer's site</i>	114,900.00
29	Variasi <i>Variation</i>	1,572,200.00
30	Hibah <i>Grant</i>	2.95
31	Jualan-Jualan Lain <i>Other Sales</i>	3,067.25
32	Sewa Bangunan Lain <i>Building Rental</i>	28,092.00
Jumlah <i>Total</i>		17,112,598.12

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HALATUJU

THE WAY FORWARD



NPRA sentiasa mengutamakan kesihatan dan kesejahteraan orang awam. Dengan adanya sistem farmakovigilans yang cekap, pemantauan keselamatan ubat-ubatan di pasaran dapat dijalankan secara berterusan dan seterusnya menjamin kualiti produk-produk tersebut. Perkara ini akan dilaksanakan melalui praktis Amalan Farmakovigilans Baik (GVP). Pemeriksaan GVP adalah bertujuan untuk memastikan pihak industri farmaseutikal mematuhi keperluan farmakovigilans serta keperluan pasca-pendaftaran lain yang telah ditetapkan oleh Pihak Berkuasa Kawalan Dadah (PBKD). Sasaran pelaksanaan GVP ini adalah pada tahun 2022.

PBKD telah mengeluarkan satu direktif dan garis panduan mengenai keperluan pendaftaran Produk Terapi Sel dan Gen (CGTPs) pada tahun 2016 yang menyatakan penguatkuasaan bagi CGTPs adalah mandatori bermula pada Januari 2021.

Memandangkan terdapat usaha daripada pihak industri untuk memenuhi keperluan regulatori CGTP dan mengambil kira bahawa industri CGTP adalah industri tempatan yang kecil, di bawah peraturan 8(1) Peraturan-peraturan Kawalan Dadah dan Kosmetik (PKDK) 1984, PBKD telah bersetuju untuk melaksanakan pendaftaran produk CGTP dan penguatkuasaan secara berperingkat bermula dengan produk yang telah berada di pasaran Malaysia sekurang-kurangnya selama satu tahun (bermula pada tarikh 1 Januari 2020 dan sebelumnya) tetapi belum dapat memenuhi keperluan regulatori dosier pendaftaran penuh. Walau bagaimanapun produk tersebut perlu berdaftar sepenuhnya dengan PBKD sebelum 1 Januari 2024.

Di peringkat antarabangsa, NPRA bersedia untuk melangkah maju ke hadapan bersama badan regulatori antarabangsa lain dalam bidang regulatori farmaseutikal dengan berusaha ke arah pengiktirafan sebagai *Listed Authority* Pertubuhan Kesihatan Sedunia (WHO). Oleh itu, NPRA telah mengambil bahagian dalam penilaian sendiri *WHO Global Benchmarking Tool (WHO GBT)*

NPRA places a high priority on the public's health and well-being. With the existence of an effective pharmacovigilance system, the safety profiles of registered products are continuously monitored to ensure the quality of these products. This will be done through the implementation of Good Pharmacovigilance Practice (GVP). GVP inspection is aimed to ensure compliance of the pharmaceutical industry towards pharmacovigilance requirements as well as other post-registration requirements imposed by the Drug Control Authority (DCA). The implementation of GVP is targeted to start in the year 2022.

DCA issued a directive and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia back in the year 2016 stating the enforcement of CGTPs is mandatory starting in January 2021.

Considering the small size of the CGTPs industry in Malaysia as well as their efforts to meet the regulatory requirements for CGTPs, DCA has agreed under regulation 8 (1) of CDCR 1984 to implement the CGTPs registration and enforcement in stages starting with the products that are in Malaysian market for at least one year (starting on 1st January 2020 and earlier) but have not yet been able to meet the regulatory requirements of full registration dossier. Hence, these CGTPs are allowed to be used on the market when they pass the screening stage. However, it must be fully registered with PBKD before 1st January 2024.

On the international front, NPRA is ready to move forward alongside other global counterparts in the area of medicine regulatory control by aiming to be recognized as a World Health Organization (WHO) Listed Authority. Therefore, NPRA has been participating in the self-assessment by WHO using the WHO Global Benchmarking Tool (WHO GBT) to ensure that our guidelines and



untuk memastikan garis panduan dan proses kerja yang dilaksanakan memenuhi piawaian WHO dengan memastikan pelaksanaan semua indikator yang ditetapkan di dalam WHO GBT. Sasaran NPRA untuk Penilaian WHO GBT yang akan datang adalah untuk mencapai pematuhan tertinggi WHO GBT iaitu akreditasi *Maturity Level 4*. NPRA menjangka akreditasi ini berlaku antara tahun 2021 hingga 2022.

work processes are up to the WHO standards and looking into the implementation of all the indicators under the WHO GBT. Our target for the upcoming WHO GBT Assessment is to reach the highest level of compliance to the tool – which is to be accredited with Maturity Level 4. NPRA foresees the accreditation taking place by the year 2021 to 2022.

