LAPORAN TAHUNAN 2015

ANNUAL REPORT

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU

PENGIKHTIRAFAN DAN PENSIJILAN

ACCREDITATIONS AND CERTIFICATIONS

1996
WHO Collaborating Centre for Regulatory Control of Pharmaceuticals

2002
Member of Pharmaceutical Inspection Cooperation Scheme (PIC/S)

2009
MS ISO 9001 : 2008

2010
MS ISO/IEC 17025 : 2005

2012
5S Certification

2013
Non - Organisation for Economic Cooperation and Development (OECD) member adhering to Mutual Acceptance of Data (MAD) on Good Laboratory Practice (GLP)

2014
EKSA Certification

Isi Kandungan
Contents

Visi, Misi & Matlamat

Vision, Mission & Objective

VISI

Biro Pengawalan Farmaseutikal Kebangsaan sebagai pusat kecemerlangan unggul dalam bidang regulatori farmaseutikal demi menjamin kesihatan dan kesejahteraan insan sejagat.

VISION

The National Pharmaceutical Control Bureau will be a centre of excellence on pharmaceutical regulatory matters to ensure the health and well-being of mankind.

MISI

Biro Pengawalan Farmaseutikal Kebangsaan akan memastikan kualiti, keberkesanan dan keselamatan produk farmaseutikal melalui pelaksanaan undang-undang oleh tenaga kerja yang kompeten dan usahasama strategik ke arah peningkatan status kesihatan rakyat.

MISSION

The National Pharmaceutical Control Bureau shall ensure the quality, efficacy and safety of pharmaceutical products through the implementation of relevant legislation by a competent workforce working together in strategic alliance towards improving the health of the people.

MATLAMAT

Memastikan bahawa bahan-bahan terapeutik yang dibenarkan di pasaran tempatan adalah selamat, berkesan dan berkualiti, serta menentukan bahawa produk semulajadi dan kosmetik yang dibenarkan di pasaran adalah selamat dan berkualiti.

OBJECTIVE

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.

Strategi
Strategies

STRATEGI

- Memastikan kecekapan dan keberkesanan organisasi melalui pemodenan dan automasi sistem-sistem pejabat, makmal dan pendaftaran, peninjauan serta penambahbaikan perkhidmatan secara berterusan
- Memperkukuh aktiviti penguatkuasaan undang-undang berkaitan
- Memastikan suasana kefahaman dua hala dan kerjasama berterusan sentiasa wujud antara pihak regulatori dengan sektor swasta melalui sesi dialog dan bimbingan
- Meningkatkan potensi serta kepakaran warga kerja
- Mewujudkan satu kumpulan tenaga kerja yang berdedikasi dan penuh komitmen melalui motivasi, penghargaan serta ganjaran yang berpatutan
- Mempergiatkan aktiviti penyelidikan serta meningkatkan kemudahan-kemudahan bagi tujuan tersebut
- Mewujudkan satu suasana yang menggalakkan kerja secara berpasukan dengan sikap penyayang, serta melaksanakan tugas-tugas secara professional

STRATEGIES

- *To ensure organisational efficiency and effectiveness through modernisation and automation of the office, laboratory and registration systems, with regular review and improvement of services*
- *To strengthen enforcement activity of the related legislations*
- *To ensure continuous mutual understanding and co-operation between the regulatory bodies and the private sector through dialogues and guidance*
- *To upgrade personnel potential and expertise*
- *To attain a dedicated and fully committed workforce through motivation, appreciation, and appropriate remuneration*
- *To strengthen research activities and upgrade facilities for such purposes*
- *To create working environment conducive for the personnel to work as a team with a caring attitude whilst discharging their duties in a professional manner*

Perutusan Pengarah

Director's Foreword

Tan Ann Ling

Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan

Director of Regulatory Pharmacy
National Pharmaceutical Control Bureau

Visi Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) untuk menjadi sebuah pusat kecemerlangan dalam bidang regulatori farmaseutikal diteruskan pada tahun 2015 dengan bergerak maju ke hadapan seiring dengan agensi antarabangsa lain, di mana jalinan kerjasama baru diwujudkan serta hubungan kerja sedia ada dengan mereka terus diperkukuhkan.

The National Pharmaceutical Control Bureau's (NPCB) vision of becoming a centre of excellence on pharmaceutical regulatory matters continued to gain ground in 2015 as we continue to move forward alongside our international counterparts by establishing new cooperation and strengthening current work relationships with them.

Tahun ini, buat pertama kalinya, BPFK telah bekerjasama dengan Pharmaceutical and Medical Devices Agency (PMDA), Jepun untuk menganjurkan Simposium Malaysia-Jepun yang pertama. Persidangan selama dua hari ini telah diadakan di Hotel Aloft Kuala Lumpur Sentral dan dihadiri oleh 150 orang peserta termasuk ahli-ahli industri farmaseutikal kedua-dua negara. Ini diikuti dengan mesyuarat di antara agensi regulatori kedua-dua negara untuk membincangkan secara mendalam berkaitan projek masa hadapan yang dapat memberi faedah serta meningkatkan lagi kerjasama di antara kedua-dua agensi tersebut.

This year, for the first time, NPCB jointly organised the 1st Malaysia-Japan Symposium together with the Pharmaceutical and Medical Devices Agency (PMDA), Japan. This two day conference was held in Aloft Kuala Lumpur Sentral Hotel and attended by 150 participants including members of the pharmaceutical industry of both countries. This was followed by a fruitful meeting between the regulators of both countries to discuss in-depth future projects that are of mutual benefit and to further enhance the partnership between the two agencies.

BPFK juga telah menganjurkan persidangan yang amat dinanti-nantikan iaitu Persidangan Regulatori Kebangsaan kelima dengan tema "Transformation towards a New Regulatory Paradigm". Persidangan ini mempunyai objektif untuk menyebarkan maklumat mengenai perkembangan terkini serta cabaran dalam arena regulatori yang sentiasa berubah, menggalak dan mengukuhkan kerjasama di kalangan pihak berkepentingan serta meningkatkan kesediaan dalam suasana perniagaan penjagaan kesihatan yang

NPCB has also organised the long awaited 5th National Regulatory Conference (NRC) with the theme "Transformation towards a New Regulatory Paradigm". The conference had the objective of disseminating information on the latest development and challenges in the evolving regulatory landscape, promoting and strengthening smart partnership amongst stakeholders as well as enhancing readiness in the competitive healthcare business environment. With over 500 participants, the event was deemed to have achieved

kompetitif. Dengan bilangan peserta yang melebihi 500 orang, ulasan serta maklum balas baik yang diterima daripada para peserta dan juga penceramah jelas membuktikan bahawa matlamat persidangan tersebut telah tercapai. BPFK akan meneruskan penganjuran persidangan ini secara berkala.

its objectives, as could be seen from the favourable feedback and reviews from both participants as well as the speakers. NPCB will continue to organise this conference on a regular basis.

Pencapaian utama lain pada tahun 2015 termasuk penerbitan Monograf Herba Malaysia 2015 yang mempamerkan 15 Monograf Herba baru yang telah dibangunkan, penerbitan Guidelines for the Registration of Cell and Gene Therapy Products (CGTPs) serta pelaksanaan Lot Release dan Pemeriksaan Rangkaian Sejuk bagi semua vaksin yang diimport ke Malaysia. Pencapaian ini adalah hasil kerjasama erat di antara BPFK dan semua pihak berkepentingan termasuk agensi-agensi lain dalam Kementerian Kesihatan, agensi-agensi daripada kementerian lain, pihak akademia dan juga sektor swasta yang diwakili oleh pelbagai persatuan industri. Saya ingin merakamkan penghargaan dan terima kasih kepada semua pihak ini atas sumbangan mereka.

Other notable achievements in 2015 include the publication of the Malaysian Herbal Monograph 2015, which showcased the 15 new Herbal Monographs that has been developed, the finalisation of the Guidelines for the Registration of Cell and Gene Therapy Products (CGTPs) as well as the implementation of the Lot Release and Cold Chain Inspection for all vaccines imported into Malaysia. These achievements are the result of the close cooperation that have been developed between NPCB with all relevant stakeholders including other agencies from the Ministry of Health, agencies from other ministries, the academia and also the private sector represented by the various industry associations. I would like to acknowledge and thank them for their substantial contributions.

Akhir kata, saya ingin merakamkan ucapan terima kasih kepada semua anggota BPFK yang sentiasa fokus dan komited dalam menjalankan tugas harian mereka serta sentiasa berusaha untuk memberi perkhidmatan yang terbaik kepada orang awam. Saya menyeru mereka untuk meneruskan kecemerlangan kerja ini bagi tahun-tahun seterusnya serta sentiasa bekerjasama bagi mencapai misi kita. Berseorangan pencapaian kita sangat terhad, bersama-sama tiada apa yang mustahil.

In conclusion, I would like to express my sincere thanks to each and every one of the NPCB staff for staying focused and committed while carrying out their daily tasks as well as striving to give the best service to the public. I urge all of them to keep up the outstanding work for the years to come as we work together in our journey to achieve our mission. Alone we can do so little, together nothing is impossible.

Dengan sukacitanya saya mempersembahkan Laporan Tahunan BPFK bagi tahun 2015.

It is with great pleasure I present to you the Annual Report of NPCB for the year 2015.

Pengurusan Tertinggi
Top Management

Tan Ann Ling
Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan
Director of Regulatory Pharmacy
National Pharmaceutical Control Bureau

Dr. Tajuddin Akasah
Timbalan Pengarah
Pusat Kawalan Kualiti
Deputy Director of Centre for Quality Control

Siti Aida Abdullah
Timbalan Pengarah
Pusat Pembangunan Organisasi
Deputy Director of Centre for Organisational Development

Sameerah Shaikh Abd. Rahman
Timbalan Pengarah
Pusat Pasca Pendaftaran Produk
Deputy Director of Centre for Post Registration of Products

Muhammad Lukmani Ibrahim
Timbalan Pengarah
Pusat Komplians dan Perlesenan
Deputy Director of Centre for Compliance and Licensing

Dr. Kamaruzaman Saleh
Timbalan Pengarah
Pusat Kajian Produk Baru
Deputy Director of Centre for Investigational New Product

Anis Talib
Timbalan Pengarah
Pusat Pendaftaran Produk
Deputy Director of Centre for Product Registration

Othman Ahmad
Ketua Pusat Pentadbiran
Head of Centre for Administration

Sidang Pengarang
Editorial Board

Kiri ke Kanan | *Left to right*

Barisan belakang | *Back row :*
Nor Hazwan Ali, Yogamalar a/p Dorairajoo, Balqis Abd Ghani, Wendy Ng Siaw Wee, Oh Chen Wei

Barisan tengah | *Middle row :*
Nordalila Sabuan, Carol Ling Hui Ming, Meera Kumari a/p Ram Navas, Sharon Ling Yu Leng

Barisan hadapan | *Front row :*
Lee Wei Xin, Rema Panickar, Wayne Wong Guan Wei

Tiada dalam gambar | *Not in the picture :*
Angeline Phua Wee Ling, Su Siew Ching, Syuhadah Mohamed Hassan

Terima kasih kepada semua di atas kerjasama dan sumbangan anda dalam penerbitan Laporan Tahunan BPFK 2015
"Kerjasama adalah teras kejayaan"

A heartfelt thank you to all for the contribution and cooperation in the publication of NPCB Annual Report 2015
"Teamwork is the key to success"

Pengenalan kepada BPFK

Introduction to NPCB

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK), yang sebelum ini 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.

The National Pharmaceutical Control Bureau (NPCB), 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.

Bermula tahun 1985, BPFK bertanggungjawab untuk memastikan kualiti, keberkesanan dan keselamatan produk farmaseutikal melalui penilaian data saintifik dan ujian makmal. Sistem untuk memantau produk-produk di pasaran juga telah ditubuhkan. Sejak itu, BPFK telah memperluaskan kawalan kualiti dan kesemalatan ke atas produk-produk bukan preskripsi, tradisional, kosmetik, veterinari, bahan aktif farmaseutikal (API) dan seterusnya kawalan ke atas produk vaksin melalui aktiviti Vaccine Lot Release bermula tahun ini.

Starting from 1985, NPCB 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, NPCB has extended the control of the quality and safety of non-prescription medicines, traditional products, cosmetics, veterinary products, active pharmaceutical ingredients (API) including the quality control of vaccine through Vaccine Lot Release activities which started this year.

Dengan kepakaran dan kemampuan yang dimiliki, BPFK telah diberi pengiktirafan antarabangsa sebagai "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals" pada tahun 1996. Pengiktirafan ini diberikan oleh World Health Organization (WHO) untuk sumbangan BPFK dalam bidang regulatori. Pengikhtirafan ini telah menarik minat agensi regulatori luar untuk menjalani latihan di BPFK. Selain itu, pengiktirafan ini telah meletakkan BPFK di platform antarabangsa dan meningkatkan kerjasama di antara BPFK dan agensi regulatori luar negara.

In view of its technical expertise and training capabilities, NPCB was 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 NPCB's contribution in the field of regulatory affairs. This recognition has attracted foreign regulatory agencies to undergo training in NPCB. Apart from that, this recognition has placed NPCB on an international platform and enhanced cooperation between NPCB and other international regulatory agencies.

Di samping itu, BPFK telah diterima sebagai ahli ke-26 dalam Pharmaceutical Inspection Co-operation Scheme (PIC/S) pada 1 Januari 2002. Sejak itu, BPFK telah terlibat secara aktif dalam program Amalan Perkilangan Baik (APB) dan program Jaminan Kualiti Antarabangsa. BPFK sentiasa berusaha dalam menaiktarafkan Sistem Pengurusan Kualiti. BPFK telah menerima pensijilan MS ISO 9001:2008 daripada SIRIM dan berjaya mengekalkannya sehingga kini. Selain itu, Pusat Kawalan Kualiti, BPFK telah memperolehi akreditasi

In addition to that, NPCB has successfully gained accession as the 26th member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on 1st January 2002. Since then, NPCB has been actively involved in international Good Manufacturing Practice (GMP) and Quality Assurance programmes.
NPCB is constantly striving towards upgrading its Quality Management System. NPCB has successfully obtained and retained the MS ISO 9001:2008 certification from SIRIM. Apart from that, NPCB has obtained MS ISO 17025:2005 accreditations for Centre

MS ISO 17025:2005 di bawah Skim Akreditasi Makmal Malaysia (SAMM) pada tahun 2010.

BPFK telah bertanggungjawab menjaga keselamatan awam selama 36 tahun. Sejak penubuhannya, BPFK telah melalui pelbagai transformasi bagi memajukan institusi ini supaya menjadi institusi regulatori yang setanding dengan agensi regulatori antarabangsa. Dengan komitmen dan dedikasi semua kakitangan BPFK, BPFK bersedia untuk mengatasi cabaran pada masa hadapan dan akan terus memastikan bahawa ubat-ubatan di pasaran adalah selamat, berkualiti dan berkesan untuk kegunaan awam.

for Quality Control under the Malaysian Laboratory Accreditation Scheme (SAMM) in 2010.

NPCB has been the custodian of public safety for 36 years. From the moment it was established, NPCB has gone through a series of transformation to advance itself as a regulator and to be on par with international counterparts. With the commitment and dedication of all NPCB staff, NPCB is well equipped to overcome future challenges and will continue to ensure that the medicines in the market are safe, of good quality and efficacious for public consumptions.

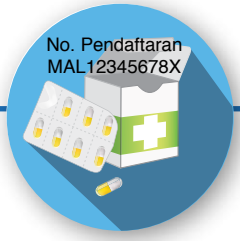
Carta Organisasi

Organisation Chart

PENGARAH REGULATORI FARMASI
DIRECTOR OF REGULATORY PHARMACY

Pusat Kawalan Kualiti I *Centre for Quality Control*

- Menjalankan ujian kimia dan mikrobiologi bagi menjamin kualiti dan keselamatan ubat-ubatan, kosmetik dan suplemen kesihatan di pasaran
- *Conducts chemical and microbiological testing to ensure the quality and safety of medicines, cosmetics and health supplements in the market*



Pusat Pendaftaran Produk I *Centre for Product Registration*

- Menerima permohonan pendaftaran produk dan menjalankan penilaian ke atas dossier pelbagai jenis ubat-ubatan dan suplemen kesihatan
- *Receives application and conducts evaluation on the dossier for registration of pharmaceuticals, traditional / natural products and health supplements*

Pusat Pasca Pendaftaran Produk I *Centre for Post Registration of Products*

- Mengawasi kualiti dan keselamatan ubat-ubatan serta produk supplemen kesihatan yang berada di pasaran
- Mengambil tindakan punitif ke atas pengilang produk yang gagal mematuhi keperluan serta standard yang ditetapkan seperti mengeluarkan arahan panggilbalik ke atas produk terlibat
- Menerima laporan kesan advers ubat daripada pengamal perubatan dan orang awam serta menjalankan siasatan ke atas laporan berkenaan bagi mengetahui punca kesan advers tersebut
- Notifikasi dan kawalan kosmetik
- *Monitor the quality and safety of medicines, cosmetics and health supplements in the market*
- *Take punitive actions (such as issuing recalls on products involved) towards companies which fail to comply to the requirements of the stipulated standard*
- *Receive reports of adverse drug reactions from medical practitioners as well as the general public and investigate the cause of the adverse events*
- *Notification and control of cosmetic products*

Pusat Komplians dan Pelesenan I *Centre for Compliance and Licensing*

- Menjalankan pemeriksaan ke atas tapak pengilangan produk-produk serta mengeluarkan lesen bagi pengilang, pengimpot dan pemborong
- *Conducts inspection on manufacturing sites and issuance of licenses for manufacturers, importers and wholesalers*

Pusat Kajian Produk Baru I *Centre for Investigational New Product*

- Menjalankan penilaian ke atas permohonan dan mengeluarkan lesen import bagi ubat yang diimport serta kebenaran mengilang produk (CTX) untuk tujuan percubaan klinikal
- Menjalankan pemeriksaan ke atas tapak percubaan klinikal
- Menjalankan pemeriksaan ke atas pusat kajian Bioequivalance (BE centres) dalam dan luar negara
- *Conducts evaluation for the application and issuance of import license to import drugs for clinical trials as well as exemptions for manufacture of products for this purpose*
- *Conduct inspections on clinical trial sites*
- *Conduct inspections on Bioequivalence centres (BE centres) locally and overseas*

Pusat Pembangunan Organisasi I *Centre for Organisational Development*

- Mengendalikan sistem pendaftaran atas talian (QUEST system) dan laman web rasmi BPFK
- Menyelaraskan aktiviti latihan kepada industri tempatan dan juga pelawat antarabangsa
- Mengendalikan pertanyaan daripada orang awam melalui perkhidmatan Helpdesk BPFK sama ada menerusi telefon, emel mahupun pertanyaan di kaunter
- *Manages the on-line registration system (QUEST system) and NPCB's official website*
- *Coordinate training activities for the local industry and international visitors*
- *Handles inquiries received by the NPCB Helpdesk from the public via phone, email or walk – in inquiries*

Pusat Pentadbiran I *Centre for Administration*

- Menjalankan tugas-tugas pentadbiran dan kewangan termasuk urusan hal ehwal pegawai, perolehan aset & stor, pengurusan akaun & hasil, pembangunan dan sebagainya.
- *Responsible for administrative and financial tasks including management of aspects related to staff, asset procurement and store management, account management and revenue, development and so forth.*

Piagam Pelanggan

Client's Charter

PENDAFTARAN PRODUK	MASA
Penilaian Penuh	
• Menilai permohonan pendaftaran:	
◊ Ubat preskripsi	210 hari bekerja*
◊ Ubat bukan preskripsi	210 hari bekerja*
◊ Ubat baru dan biologikal	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*
◊ 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 Klinikal (CTIL) dan Kebenaran Mengilang untuk Percubaan Klinikal (CTX):	
◊ Bagi produk yang melibatkan Kajian Fasa 1, produk biologikal, 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 Bagi permohonan yang memenuhi keperluan yang

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

PRODUCT REGISTRATION	DURATION
Full Evaluation	
• To evaluate application for registration ofUbat preskripsi	
◊ Prescription drugs	210 working days*
◊ Non-prescription drugs	210 working days*
◊ New drugs and biological	245 working days*
Abridged Evaluation	
• To evalute application for registration of non-prescription medicine#, health supplements and traditional products containing	
◊ Single active ingredient	116 working days*
◊ 2 or more active ingredients	136 working days*
• Issuance of cosmetic notification	1 working day^
• 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):	
◊ For products involving Phase 1 Trial, biological products, Cell & Gene Therapy Products (CGTPs) and herbal products	45 working days*
◊ 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)

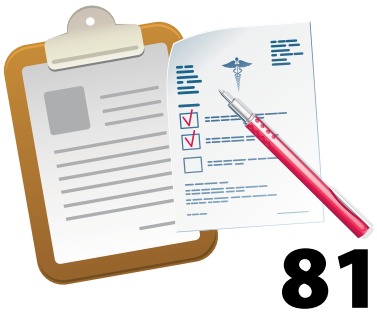
Statistik Ringkas

Brief Statistics

Bilangan produk yang disampel (sampel pasca pendaftaran)
Total number of products sampled (post-market sampling)

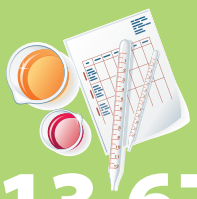
2,290

Bilangan aduan produk yang diterima
Total product complaints received



811

Bilangan ADR yang diterima
Total number of ADR reports received



13,675

Bilangan tindakan regulatori yang diambil berdasarkan isu keselamatan ubat
Number of drug safety issues with regulatory action

12

Bilangan produk kosmetik yang dinotifikasi
Number of New Cosmetic Products Notified

85,018

Bilangan produk yang didaftarakan
Number of product registered

Preskripsi / *Prescription* : **280**

Bukan preskripsi / *Non-prescription* : **41**

Semulajadi / *Natural* : **569**

Supplemen kesihatan / *Health supplement* : **236**

Veterinari / *Veterinary* : **94**

Jumlah penolakan notifikasi produk kosmetik semasa proses penyaringan
Total Cosmetics Notifications Rejected During Screening

621

Sampel yang diuji mengikut kategori
Samples tested according to categories

Pendaftaran / *Registration* : **649**

Pengawasan / *Surveillance* : **2222**

Aduan / *Complaint* : **96**

ADR / *Adverse Drug Reaction* : **142**

Penguatkuasa Farmasi / *Pharmacy Enforcement* : **98**

Lain-lain / *Others* : **9**

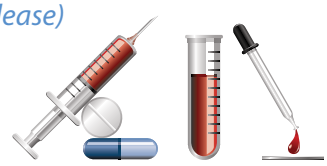
Aktiviti Vaccine Lot Release (VLR) (Julai – Disember 2014)
Vaccine Lot Release (VLR) activity (July – December 2014)
(*Nota : Aktiviti VLR projek perintis bermula pada Julai 2014 / **Note : VLR pilot study started in July 2014)*

a) Bilangan permohonan VLR yang diterima / *Number of VLR application received* : **265**

b) Bilangan konsainan vaksin yang diluluskan / *Number of vaccine consignments released* : **265**

c) Bilangan konsainan vaksin yang ditolak / *Number of vaccine consignments rejected* : **1**

(Nota: Untuk keputusan (b), 1 konsainan merupakan pelepasan separa / *Note: For result (b), 1 consignment indicates partial release)*



Penilaian Data Validasi
Validation Data Evaluation

1117

Bilangan sampel yang gagal ujian
Number of failed sample testing

263

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

350

Bilangan lesen dikeluarkan / *Number of licenses issued*

a) Premis pengilang / *Manufacturer* : **266**

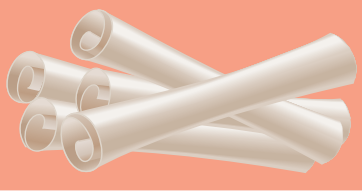
b) Pengimport / *Importer* : **455**

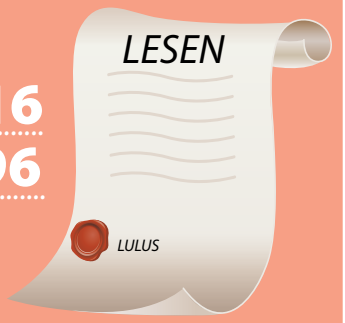
c) Pemborong / *Wholesaler* : **1,164**

d) Lesen Import Percubaan Klinikal / *Clinical Trial Import Licence (CTIL)* : **209**

e) Kebenaran Mengilang / *Clinical Trial Exemption (CTX)* : **16**

f) Variasi / *Variation* : **296**





Bilangan Pemeriksaan Amalan Edaran Baik (AEB)
Number of Good Distribution Practice (GDP) Inspections

124

Bilangan Pemeriksaan Amalan Makmal Baik
Number of Good Laboratory Practice (GLP) Inspections

2

Bilangan Pemeriksaan Pusat Kajian Bioekuivalens (BE)
Number of Inspections on Bioequivalence Centre (BE)

11

Bilangan Pemeriksaan tapak Kajian Klinikal
Number of Clinical Trial Site Inspections

8

Bilangan Laporan Suspected Unexpected Serious Adverse Reaction (SUSAR)
Number of Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports received

4,824

Bilangan dialog yang dijalankan dengan pihak industry tempatan
Number of dialogues carried out with the local industry

8

Bilangan pelawat yang diterima
Number of visitors

a) Tempatan / *Local* : **259**

b) Antarabangsa / *International* : **74**

Bilangan pertanyaan yang diterima
Number of queries received

a) Telefon / *Telephone* : **5,564**

b) Emel & Modul Pertanyaan / *Email & online module* : **503**

c) Pertanyaan di kaunter / *Walk-in* : **683**

Pencapaian BPFK

NPCB's achievements

PENCAPAIAN

1. MS ISO/IEC 17025:2005

Pada 30 Januari 2015, BPFK telah mengemaskini spesifikasi untuk Ujian Kontaminasi Mikrobial bagi produk tradisional berdasarkan British Pharmacopoeia 2014.

Berdasarkan audit pensijilan semula yang dijalankan pada 27 Julai 2015, BPFK telah berjaya mengekalkan skop akreditasi berikut:

a. Penentuan arsenik, plumbum dan kadmium dalam produk tradisional dengan Graphite Furnace Atomic Absorption Spectrometry
b. Penentuan had merkuri dalam produk tradisional dengan Cold Vapour Atomic Absorption Spectrometry
c. Kontaminasi mikrobial dalam produk tradisional berdasarkan British Pharmacopoeia 2014 dan produk kosmetik berdasarkan metodologi in-house
d. Pengecaian kapsul dan tablet bagi produk-produk tradisional
e. Keseragaman berat untuk kapsul dan tablet bagi produk-produk tradisional

2. Pembangunan Monograf Herba Malaysia

Pada tahun 2015, sebanyak 15 Monograf Herba telah dibangunkan di bawah projek NKEA, iaitu:

a. Ketum (Mitragyna speciosa) leaves
b. Kayu manis (Cinnamomum verum) stem bark
c. Cengkih (Szygium aromaticum) flower buds
d. Cekur (Kaempferia galanga) rhizome
e. Karas (Aquilaria malaccensis) leaves
f. Lada hitam (Piper nigrum) fruits
g. Kari (Murraya koenigii) leaves
h. Kunyit (Curcuma longa) rhizome
i. Peria katak (Momordica charantia) fruits
j. Kantan (Etlingera elatior) flower
k. Kenanga (Cananga odorata) flower

ACHIEVEMENTS

1. MS ISO/IEC 17025:2005

On 30th January 2015, NPCB has updated the specification for Microbial Contamination Test in traditional products based on British Pharmacopoeia 2014.

Based on the re-assessment audit conducted on 27th July 2015, NPCB is able to maintain the following accreditation scopes:

a. Determination of arsenic, lead and cadmium in traditional products using Graphite Furnace Atomic Absorption Spectrometry
b. Determination of mercury limit in traditional products using Cold Vapour Atomic Absorption Spectrometry
c. Microbial Contamination Test in traditional and cosmetic products based on British Pharmacopoeia 2014 and in-house method respectively
d. Disintegration test for capsules and tablets in traditional products
e. Uniformity of weight for capsules and tablets in traditional products

2. Development of Malaysian Herbal Monograph

In 2015, 15 Herbal Monographs were developed under the NKEA project as listed below:

a. Ketum (Mitragyna speciosa) leaves
b. Kayu manis (Cinnamomum verum) stem bark
c. Cengkih (Szygium aromaticum) flower buds
d. Cekur (Kaempferia galanga) rhizome
e. Karas (Aquilaria malaccensis) leaves
f. Lada hitam (Piper nigrum) fruits
g. Kari (Murraya koenigii) leaves
h. Kunyit (Curcuma longa) rhizome
i. Peria katak (Momordica charantia) fruits
j. Kantan (Etlingera elatior) flower
k. Kenanga (Cananga odorata) flower

l. Pecah beling (Strobilanthes crispus) leaves

m. Serai makan (Cymbopogon citratus) leaf sheath and stem

n. Tutup bumi (Elephantopus scaber) whole plant

o. Buah pala (Myristica fragrans) seeds and arillus

Monograph herba tersebut boleh diakses secara percuma melalui laman sesawang: http://www.globinmed.com/

l. Pecah beling (Strobilanthes crispus) leaves

m. Serai makan (Cymbopogon citratus) leaf sheath and stem

n. utup bumi (Elephantopus scaber) whole plant

o. Buah pala (Myristica fragrans) seeds and arillus

The herbal monograph can be assessed for free via: http://www.globinmed.com/

3. Penerbitan Hardcopy Malaysian Herbal Monograf 2015

Malaysian Herbal Monograph 2015 dalam bentuk hardcopy dijangka akan berada di pasaran mulai Februari 2016.

3. Publication of Malaysian Herbal Monograph 2015 in hardcopy form

The Malaysian Herbal Monograph 2015 is expected to be available in the market from February 2016 onwards.

4. Proficiency Testing (PT)

BPFK telah menyertai beberapa program Proficiency Testing sepanjang tahun 2015 iaitu:

a. Ujian Kontaminasi Mikrobial untuk sampel losyen (kosmetik) dan tablet (tradisional) anjuran IFM Quality Services Australia.

b. Identifikasi dan penentuan Hydroquinone dalam produk kosmetik anjuran Biro Kosmetik dan Bahan Merbahaya, Jabatan Sains Perubatan, Kementerian Kesihatan Awam Thailand.

c. Cosmetics and Toiletries PT Scheme-Mercury in Toothpaste anjuran LGC Standards Proficiency Testing, United Kingdom.

d. Kandungan logam dalam air (Kadmium, Plumbum, Arsenik dan Merkuri) anjuran Jabatan Kimia Malaysia, Kementerian Sains, Teknologi & Inovasi

e. Ujian pelarutan untuk sampel farmaseutikal anjuran Bureau of Drug and Narcotic, Department of Medical Sciences, Thailand

f. Ujian penentuan pH sampel larutan bufer anjuran Bureau of Drug and Narcotic, Department of Medical Sciences, Thailand

4. Proficiency Testing (PT)

In 2015, NPCB has participated in several Proficiency Testing as follows:

a. Microbial Contamination Test for lotion (cosmetic) and tablet (traditional) organized by IFM Quality Services Australia.

b. Identification and determination of Hydroquinone in cosmetic product organized by Bureau of Cosmetics and Hazardous Substances, Department of Medical Sciences, Ministry of Public Health, Thailand.

c. Cosmetics and Toiletries PT Scheme (Round 20) - Mercury in Toothpaste organized by LGC Standards Proficiency Testing, United Kingdom.

d. Trace metal in water (Cadmium, Lead, Arsenic and Mercury) organized by Department of Chemistry Malaysia, Ministry of Science, Technology and Innovation

e. Dissolution test for pharmaceutical sample organized by Bureau of Drug and Narcotic, Department of Medical Sciences, Thailand

f. pH determination test for sample buffer solution organized by Bureau of Drug and Narcotic, Department of Medical Sciences, Thailand

5. Penglibatan dalam aktiviti pemiawaian piawai rujukan ASEAN

Seksyen Piawaian Rujukan (SPR) mengambil bahagian dalam aktiviti pemiawaian piawai rujukan ASEAN pada setiap tahun. Hasil daripada kerjasama antara negara-negara ASEAN seperti Thailand, Singapura, Indonesia, Vietnam, Filipina & Myanmar telah membolehkan beberapa jenis piawai rujukan digunakan di dalam makmal BPFK. Selain itu, piawai rujukan ini juga dijual kepada pengilang-pengilang farmaseutikal di Malaysia

5. Participation in standardization of ASEAN Reference Substances

Reference Standard Section takes part in standardizing ASEAN reference substances every year. This collaboration with ASEAN countries namely Thailand, Singapore, Indonesia, Vietnam, Philippines and Myanmar enables these reference substances to be available for use in NPCB laboratories. These reference substances are also available for sale to pharmaceutical manufacturers in Malaysia by request at

atas permintaan dengan harga yang berpatutan. Contoh piawai rujukan ASEAN yang telah dipiawai dan diedarkan untuk kegunaan pada tahun 2015 termasuk Ibuprofen dan Chloramphenicol.

a reasonable price. ASEAN reference substances that were standardized and distributed in year 2015 include Ibuprofen and Chloramphenicol.

6. 'Guidance Document and Guidelines for Plasma Products Lot Release in Malaysia' telah diterbitkan pada Disember 2015 dan akan digunapakai mulai 1 Januari 2016.

6. *Guidance Document and Guidelines for Plasma Products Lot Release in Malaysia' was published on December 2015 and will be enforced effective 1st January 2016.*

7. Bilangan laporan ADR yang diterima pada tahun 2014 terus menunjukkan peningkatan, dan melebihi norma WHO (200 laporan untuk setiap juta penduduk) sebanyak 135%.

7. *The number of ADR reports received in 2015 continued to show an increase, exceeding the WHO norm of 200 reports per million population by about 135%.*

8. Dalam 29th Meeting of Working Group on GLP yang berlangsung pada April 2015 di Paris, Malaysia telah dipilih sebagai salah satu negara penilai untuk On Site Evaluation (OSE) keatas Estonia bersama-sama dengan Amerika Syarikat dan Norway. OSE ini akan dijalankan pada bulan Februari 2016 nanti. Pemilihan ini merupakan satu penghargaan OECD kepada Malaysia. Penyertaan seorang inspektor BPFK mewakili Malaysia dalam OSE ini nanti merupakan satu pengiktirafan OECD kepada BPFK khasnya dan Malaysia amnya terhadap sistem dan kompetensi inspektor GLP Malaysia.

8. *In the 29th Meeting of Working Group on GLP, Paris, April 2015, Malaysia has been nominated as one of the OECD team members together with inspectors from the United States of America and Norway for the On Site Evaluation (OSE) to Estonia. The OSE will be held in February 2016. Participation of NPCB inspector in the OSE is recognition by the OECD to NPCB and Malaysia. This participation also indicates that OECD recognised our system and our competencies are of the same standards with other OECD members.*

BPFK sebagai Pusat Kolaborasi WHO bagi Kawalan Regulatori untuk Produk Farmaseutikal

NPCB as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals

BPFK telah diberi pengiktirafan antarabangsa sebagai "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals" pada tahun 1996. Pengiktirafan ini diberikan oleh World Health Organization (WHO) untuk sumbangan BPFK dalam bidang regulatori. Pengiktirafan ini telah menarik minat agensi regulatori luar untuk menjalani latihan di BPFK. Sepanjang 2015, BPFK telah menerima kunjungan lawatan daripada 74 orang pelawat antarabangsa daripada 13 negara.

The NPCB 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 NPCB's contribution in the field of regulatory affairs. . This recognition has attracted foreign regulatory agencies to undergo training in NPCB. Throughout 2015, NPCB received 74 international visitors from 13 countries around the world.

Pada bulan September 2015, BPFK berbesar hati menerima kunjungan daripada Ketua Pengarah Kesihatan Cambodia. H.E. Dr. Or Vandine bersama tujuh pegawai beliau (dengan pelbagai kepakaran) telah menjalani sesi latihan selama 5 hari pada 14-18 September 2015.

In September 2015, NPCB is pleased to receive a visit from the Director General of Health Cambodia. H.E. Dr. Or Vandine along with seven of her officers (of different expertise) underwent a 5-day training session from 14 to 18 September 2015.

Objektif sesi latihan termasuk bertukar pengalaman mengenai pendaftaran dan peraturan ubat-ubatan, untuk mengkaji pengalaman BPFK dalam pengenalan dan pelaksanaan sistem pendaftaran atas talian untuk ubat-ubatan serta meneroka mekanisme kerjasama yang dapat dilaksanakan di antara kedua-dua agensi untuk mengukuhkan sistem pendaftaran ubat-ubatan dan keupayaan kawalan regulatori.

The objective of the training session include exchange experiences on registration and regulation of medicines, to study NPCB's experiences on introduction and implementation of online registration system for medicines as well as to explore feasible collaborative mechanisms between the NRAs to strengthen medicines registration system and regulatory capacity.

Sesi latihan berjalan dengan lancar dan pasukan Cambodia berpuas hati dengan maklumat yang diperolehi serta layanan yang diterima selama mereka berada di sini.

The training session went well and the Cambodian team was satisfied with the information obtained as well as the hospitality provided during their stay.

Mr. Tan Ann Ling selaku Pengarah Biro Pengawalan Farmaseutikal Kebangsaan menyampaikan sijil kehadiran kepada Ketua Pengarah Kesihatan Cambodia, H.E. Dr. Or Vandine.
The Director of the National Pharmaceutical Control Bureau, Mr. Tan Ann Ling presenting the certificate of attendance to the Director General of Health Cambodia, H.E. Dr. Or Vandine.

Selain daripada menerima pelawat untuk latihan di BPFK, kakitangan BPFK juga telah dijemput oleh agensi luar negara sebagai penceramah di forum serta simposium antarabangsa.

Ketua Unit Ubat Racun, Seksyen Ubat Generik, Pn Somiyaton Mohd Dahalan @ Damuri dijemput sebagai penceramah dalam "The 3rd China-ASEAN Drug Cooperation And Development Summit Forum" di Nanning, China pada 18 September 2015. Ceramah beliau bertajuk Overview of Pharmaceutical Product Registration in Malaysia.

Ketua Seksyen Ubat Generik, Pn Mazuwin Zainal Abidin dijemput sebagai penceramah untuk "2015 APEC Harmonization Center Generic Drugs Workshop" yang berlangsung di Seoul, Korea pada 6hb November 2015. Ceramah beliau bertajuk "Approval Process and Regulatory Updates on Generic Drugs in Malaysia".

Ketua Seksyen Biologik, Dr Azizah Ab Ghani telah dijemput untuk menyampaikan topik "Regulation on Biologics: Experiences sharing on the process of product registration in Malaysia" di "2nd Joint International Symposium on Animal Cell Technology for Asian Network - Biologics and Food: Trend in Technology, Regulation and Safety" yang berlangsung di Bangkok pada 18hb November 2015.

Apart from receiving visitors for training in NPCB, the staffs of the institution have also been invited by foreign agencies as a speaker at international forums and symposiums.

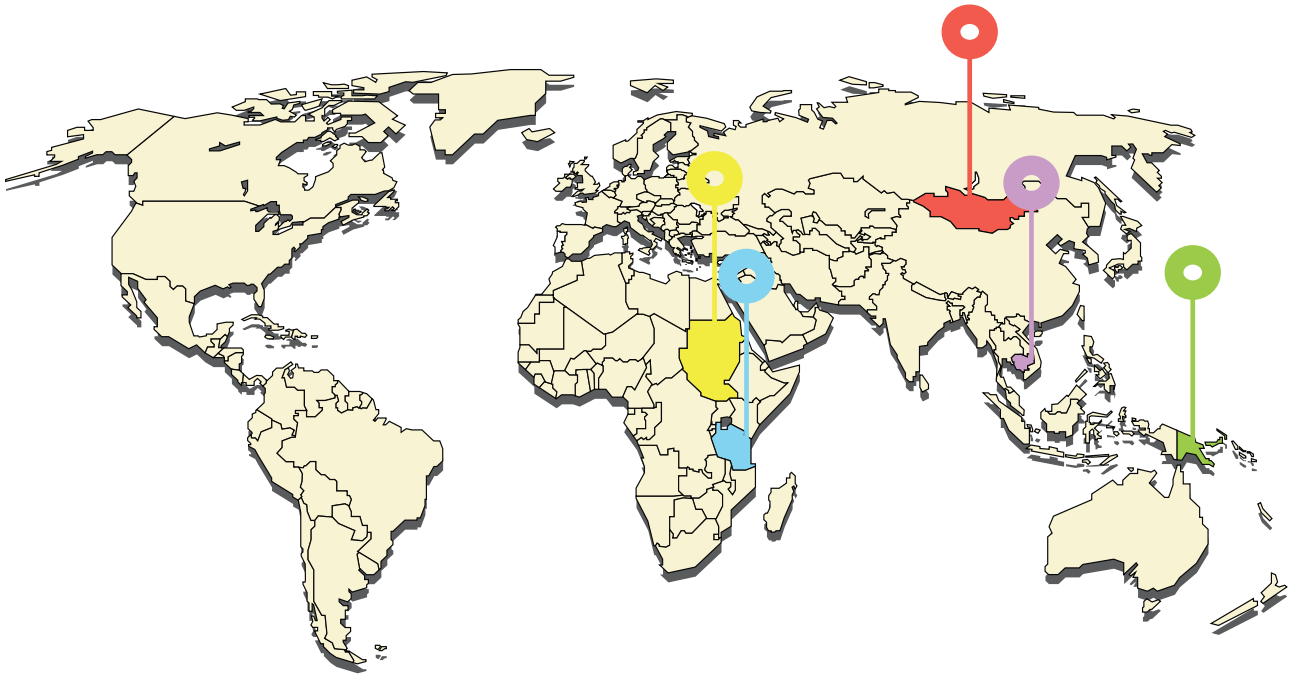
Head of Poison Unit, Generic Section, Mdm Somiyaton Mohd Dahalan @ Damuri was invited as a guest speaker for "The 3rd China-ASEAN Drug Cooperation And Development Summit Forum" in Nanning, China on 18 September 2015. She spoke on the Overview of Pharmaceutical Product Registration in Malaysia.

Head of Generic Section, Mdm Mazuwin Zainal Abidin was invited as a speaker for "The 2015 APEC Harmonization Center Generic Drugs Workshop" held at Seoul, Korea on the 6th November 2015. She spoke on "Approval Process and Regulatory Updates on Generic Drugs in Malaysia".

Head of Biologic Section, Dr Azizah Ab Ghani was invited as a guest speaker to deliver a presentation on "Regulation on Biologics: Experiences sharing on the process of product registration in Malaysia" at the "2nd Joint International Symposium on Animal Cell Technology for Asian Network - Biologics and Foods: Trend in Technology, Regulation and Safety" held at Bangkok on the 18th November 2015.

Pelawat Antarabangsa

International Visitors



Mongolia	**"Thank you!"** – *Dr. Oyun Bayar* *Director of Health Policy Implementation Coordination Department, Ministry of Health & Sports, Mongolia*
Papua New Guinea	**"We truly appreciate your assistance and we look forward to fully utilize what we have learn back in Papua New Guinea"** – *Ms. Marlene Be'eu Lohia* *Senior Medicine Assessor, National Department of Health, Ministry of Health Papua New Guinea*
Cambodia	**"Many thanks for your kindness in presenting your activities"** – *H.E. Dr. Or Vandine* *Director General for Health, Ministry of Health Cambodia* **"Thank you so much for your kind hospitality during my stay"** – *Dr. Srun Sok* *Director of Department of Hospital Services, Ministry of Health Cambodia*
Sudan	**"Thank you for this chance. Very useful and great presentation. I like the system of NPCB"** – *Ms. Eslam Mohammed Basheir* *Medical Anthropologist, Herbal Medicine Department, Khartoum State – Ministry of Health, Sudan*
Tanzania	**"Thank you for accepting us. We have learnt the good things you are doing"** – *Ms. Grace Shimwela* *Manager, Department of Cosmetics and Complementary Products , Tanzania Food and Drug Authority* **"Excellent training and hospitality for all 2 weeks. Terima kasih!"** – *Mr. Gerald Sambu Kulwa* *Laboratory Technician, Tanzania Food and Drug Authority*

Kolaborasi Antarabangsa

International Collaboration

MESYUARAT DUA HALA MALAYSIA - JEPUN

Sebagai langkah kerjasama berterusan, Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) dan Pharmaceutical and Medical Devices Agency (PMDA) Jepun mengambil peluang untuk mengadakan mesyuarat dua hala selepas 1st Malaysia-Japan Symposium 2015 yang diadakan di Kuala Lumpur pada 10-11 Mac 2015. Mesyuarat dua hala tersebut diadakan pada petang 11 Mac 2015 dan dipengerusikan oleh ketua delegasi Malaysia, Pn. Siti Aida Abdullah bersama ketua delegasi Jepun, Dr. Taisuke Hojo.

Kedua-dua agensi telah membincang dengan mendalam mengenai bidang kerjasama pada masa hadapan termasuk aktiviti Surveilens Pasca Pemasaran (PMS) dan menjalankan pemeriksaan bersama untuk Amalan Pengilangan Baik (APB).

MALAYSIA - JAPAN BILATERAL MEETING

As part of the continuing collaboration, both National Pharmaceutical Control Bureau (NPCB) and Medical Devices Agency (PMDA) Japan took the opportunity to have a bilateral meeting right after the 1st Malaysia—Japan Symposium 2015 held in Kuala Lumpur on 10-11 March 2015. The bilateral meeting which was carried out on the afternoon of 11 March 2015 was chaired by Malaysia's head of delegation, Mdm. Siti Aida Abdullah and co-chaired by the head of the Japanese delegation, Dr. Taisuke Hojo.

Both agencies discussed in-depth on areas of the future partnership including Post-Market Surveillance (PMS) activities and Good Manufacturing Practice (GMP) joint inspections.

MESYUARAT TEKNIKAL DUA HALA BPFK-HSA

Malaysia dan Singapura telah berjaya menandatangani Memorandum of Understanding (MoU) berkaitan regulatori farmasi pada 28 Mac 2012.

Susulan daripada MoU, Mesyuarat Teknikal Dua Hala Keempat telah diadakan di antara BPFK dan pihak Health Sciences Authority (HSA) Singapura pada 28 Julai 2015 di pejabat Health Sciences Authority (HSA) di Singapura.

Delegasi dari kedua-dua buah negara telah mengadakan perbincangan secara terperinci yang meliputi aspek pendaftaran produk, penguatkuasaan farmasi, amalan perkilangan baik serta dan pemantauan dan keselamatan produk.

Adalah dipersetujui bahawa kedua-dua agensi akan terus meningkatkan hubungan kerja sedia serta mengukuhkan kerjasama antara Malaysia dan Singapura dalam aspek regulatori farmasi untuk faedah bersama.

NPCB – HSA TECHNICAL BILATERAL MEETING

On 28th March 2012, Malaysia and Singapore signed their first Memorandum of Understanding (MoU) related to pharmaceutical regulatory matters.

Following the signing of MoU, the 4th Technical Bilateral Meeting between NPCB and Health Sciences Authority (HSA) Singapore was held in Health Sciences Authority, Singapore on 28th July 2015.

Delegations from the both countries discussed in detail of aspects of product registration, pharmacy enforcement, good manufacturing practices as well as product safety and monitoring activities.

It was agreed that both agencies will continue to improve the existing working relationship and strengthen cooperation between Malaysia and Singapore in the matters pertaining to pharmacy regulatory for mutual benefit.

Pendaftaran Produk

Product Registration

Pusat Pendaftaran Produk, BPFK bertanggungjawab untuk mengendalikan permohonan pendaftaran produk-produk entity kimia baru/ ubat baru, biologik, preskripsi, bukan preskripsi, suplemen kesihatan, semulajadi serta veterinar.

Permohonan pendaftaran bagi produk farmaseutikal perlu dikemukakan menerusi sistem atas talian (online) QUEST 3, manakala produk semulajadi perlu dikemukakan menerusi sistem QUEST 2.

Permohonan pendaftaran bagi semua produk farmaseutikal dinilai dari aspek keselamatan, keberkesanan dan kualiti, manakala produk semulajadi dinilai dari aspek keselamatan dan kualiti. Produk yang telah selesai dinilai akan dibentangkan dalam Mesyuarat PBKD untuk keputusan status pendaftaran produk tersebut.

Selain itu, kawalan regulatori terhadap bahan aktif farmaseutikal (API) dijalankan bagi memastikan penggunaan API dalam formulasi produk adalah berkualiti. Kawalan ini dilaksanakan dengan penguatkuasaan keperluan teknikal tambahan berhubung API sebagai sebahagian daripada keperluan

The Centre for Product Registration , NPCB is responsible for processing registration application for new chemical entities (NCE)/ new drugs, biologics, prescription, non prescription, health supplements, natural as well as veterinary products.

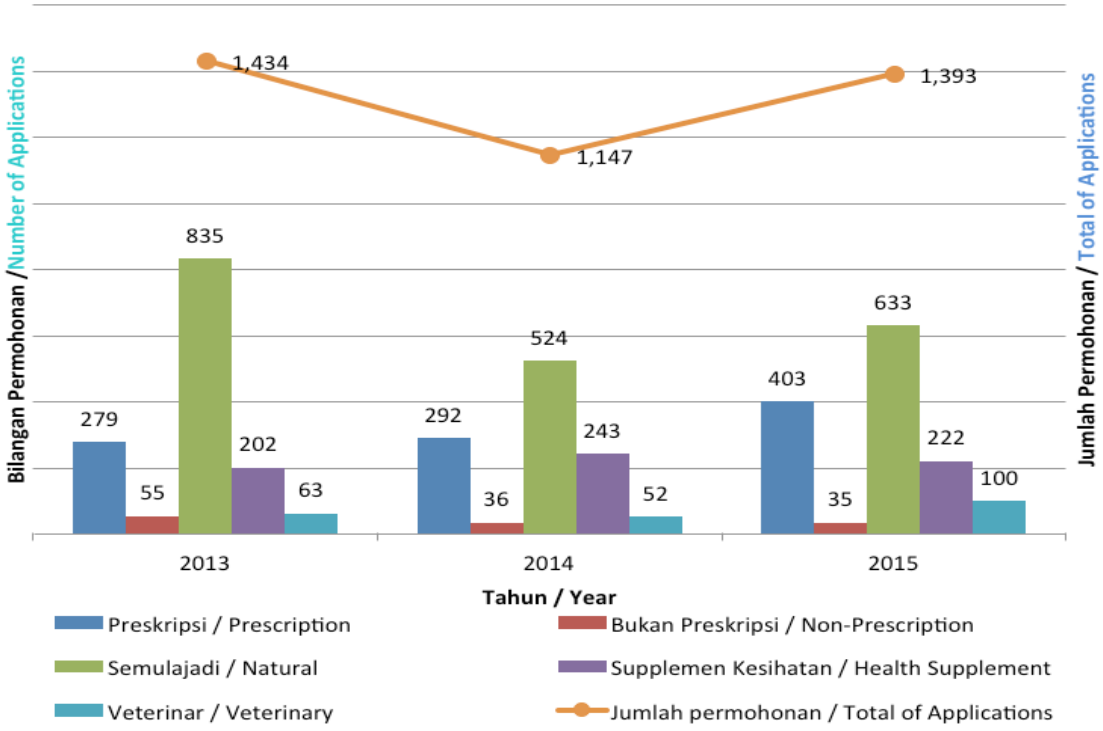
Registration applications for pharmaceutical products have to be submitted via the online system QUEST 3, whereas natural products to be submitted via QUEST 2 system.

Registration applications for pharmaceutical products are evaluated for safety, efficacy and quality whereas for traditional products, safety and quality are evaluated. Products which have been evaluated will be tabled in the DCA meetings for decision on the product registration status.

In addition, regulatory control of active pharmaceutical ingredients (API) is carried out to ensure the good quality of API used in product formulation. This has been implemented through the enforcement of additional technical requirements related to API as part of the requirements for product registration. This

Rajah 1: Taburan dan Jumlah Permohonan Pendaftaran yang Diterima (2013-2015)

Figure 1: Distribution and Total Registration Applications Received (2013-2015)



untuk pendaftaran produk. Pelaksanaan ini telah dijalankan secara prospektif dan berperingkat, bermula secara sukarela untuk pendaftaran produk kimia baru/ ubat baru mulai 1 April 2011, diikuti dengan pelaksanaan secara mandatori mulai 1 Janauari 2012. Seterusnya, pelaksanaan ini dipanjangkan kepada produk preskripsi dalam bentuk injeksi mulai 1 Julai 2014.

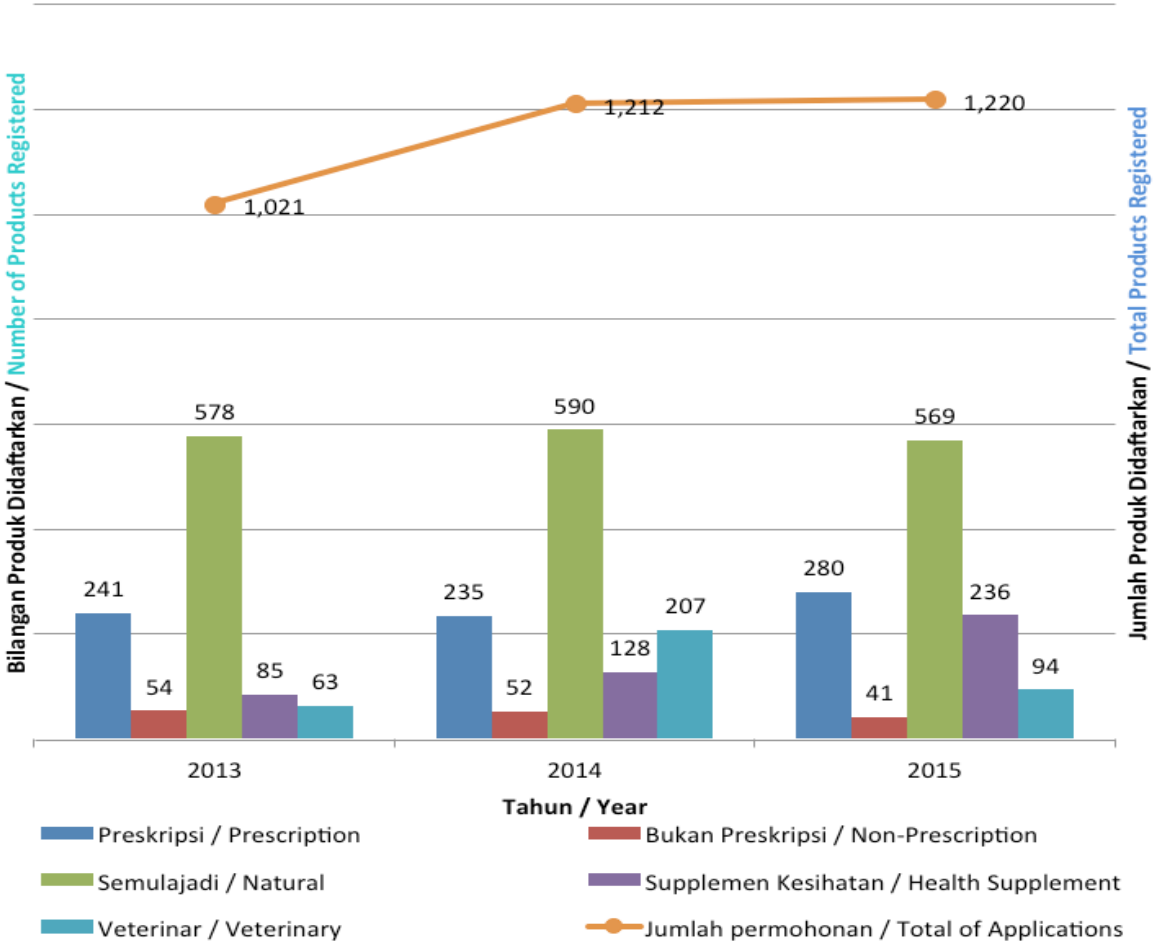
Sebanyak 12 mesyuarat PBKD telah diadakan pada tahun 2015 dengan sejumlah 1,220 produk telah diluluskan untuk pendaftaran. Buat masa kini, sejumlah 49, 545 produk telah didaftarkan oleh PBKD.

implementation was carried out prospectively and in stages, first voluntarily for entities (NCE)/ new drug product registration starting 1 April 2011, followed by mandatory implementation from 1 January 2012 onwards. This implementation is entended to registration of prescription products in parenteral dosage form starting from 1 July 2014 onwards.

12 DCA meetings were conducted in year 2015 with a total of 1,220 products approved for registration. As of now, a total of 49,545 products have been registered by DCA.

Rajah 2: Taburan dan Jumlah Produk Didaftar (2013-2015)

Figure 2: Distribution and Total Products Registered (2013-2015)



a. Penerimaan Permohonan Pendaftaran Produk dan Jumlah Produk yang Didaftar

Tahun 2015 menunjukkan peningkatan sebanyak 21.45% dalam jumlah permohonan pendaftaran yang diterima berbanding dengan tahun 2014 (Rajah 1). Ini adalah berikutan proses pendaftaran produk semulajadi yang telah dilakukan semula melalui Sistem Quest 2 mulai 1 April 2014, di mana 45.44% produk berdaftar pada tahun 2015 merupakan produk semulajadi (Rajah 2). Produk semulajadi juga mendominasi kategori produk yang didaftarkan pada ketiga-tiga tahun tersebut, dengan mencatatkan bilangan permohonan perdaftaran tertinggi setiap tahun.

a. Registration Applications Received and Total Products Registered

Year 2015 showed 21.45% increment in total of registration application received as compared to year 2014 (Figure 1). This is due to the re-implementation of natural products registration process via Quest 2 system starting 1st April 2014, of which 45.44% of registered products were natural products (Figure 2). Natural products also dominated the category of products registered in year 2013, 2014 and 2015, as applications received for this product category were the highest for the 3 years.

b. Jumlah Pendaftaran Mengikut Status (2013-2015)

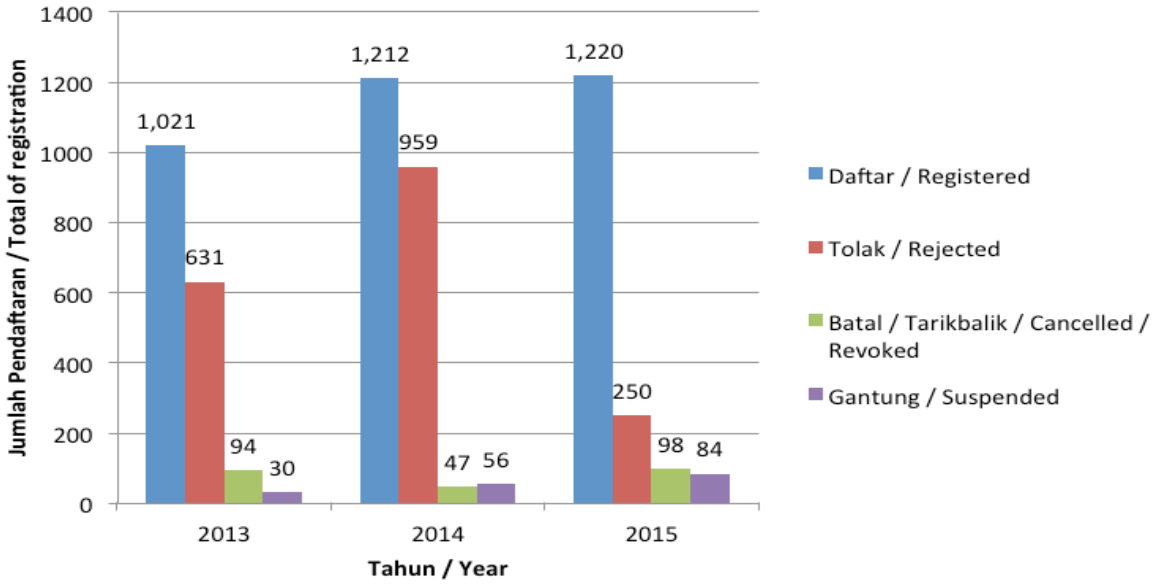
Permohonan produk yang ditolak didapati menurun pada tahun 2015 iaitu mencatatkan penurunan sebanyak 73.93% berbanding dengan tahun 2014 (Rajah 3). Ini adalah berikutan pematuhan pemohon kepada polisi PBKD untuk memberikan maklumbalas yang lengkap dalam tempoh enam (6) bulan selepas penyerahan dokumen dosier.

b. Total Registration Based on Status (2013-2015)

Number of product application rejected in year 2015 was found to be reduced as much as 73.93% compared to year 2014 (Figure 3). This was due to improved compliance of the applicant to DCA policy to provide the required documentations within six (6) months after product dossier submission.

Rajah 3: Jumlah Pendaftaran Mengikut Status (2013–2015)

Total Registration Based on Status (2013–2015)



c. Produk Tempatan dan Import Bagi Produk Didaftar Mengikut Kategori pada tahun 2015

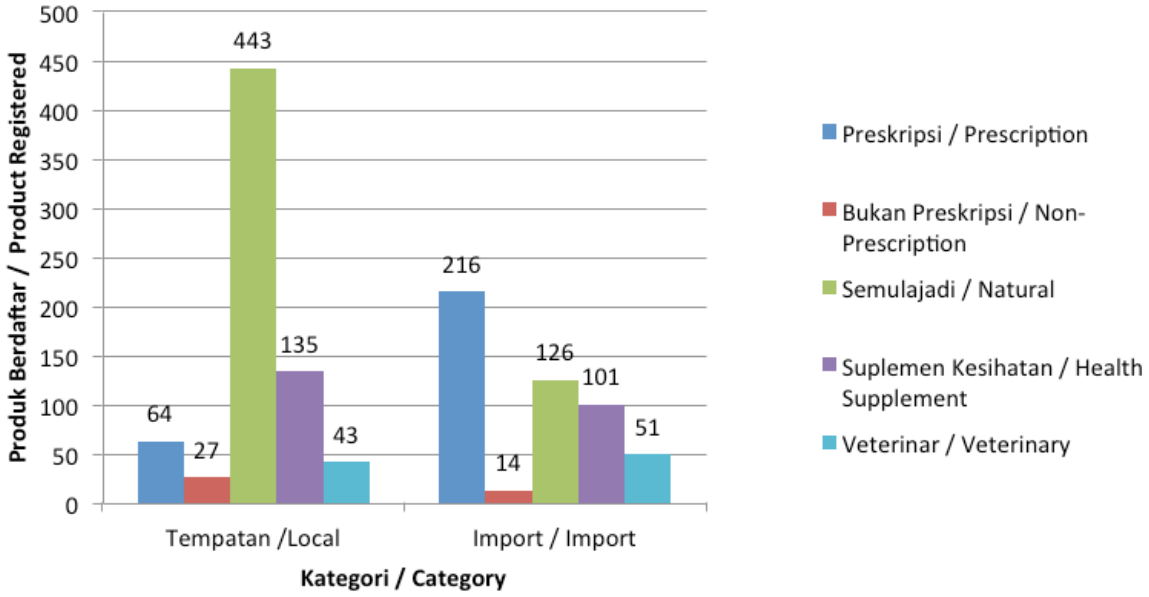
Pada tahun 2015, sebanyak 53.8% produk tempatan didaftarkan berbanding dengan produk import iaitu sebanyak 46.2%. Produk semulajadi merupakan produk tempatan yang paling banyak didaftarkan (Rajah 4).

c. Local and Import Products Registered Based on Category in year 2015

In 2015, there are a total of 53.8% local products being registered compared to imported products which accounted for 46.2%. The highest number of local products registered is natural products (Figure 4).

Rajah 4: Produk Tempatan dan Import Bagi Produk Didaftar Mengikut Kategori pada tahun 2015

Figure 4: Local and Import Products Registered Based on Category in year 2015



d. Sumber Utama Produk Berdaftar (Rajah 5, 6, 7)

Secara keseluruhan, produk tempatan merupakan sumber utama bagi produk berdaftar pada tahun 2015. Rajah 5 menunjukkan negara India merupakan sumber utama bagi produk preskripsi yang diimport manakala untuk produk bukan preskripsi, sumber utama adalah dari Amerika Syarikat diikuti dengan Australia (Rajah 6).

Negara China kekal sebagai sumber utama bagi produk semulajadi yang diimport pada tahun 2015 (Rujuk Rajah 7).

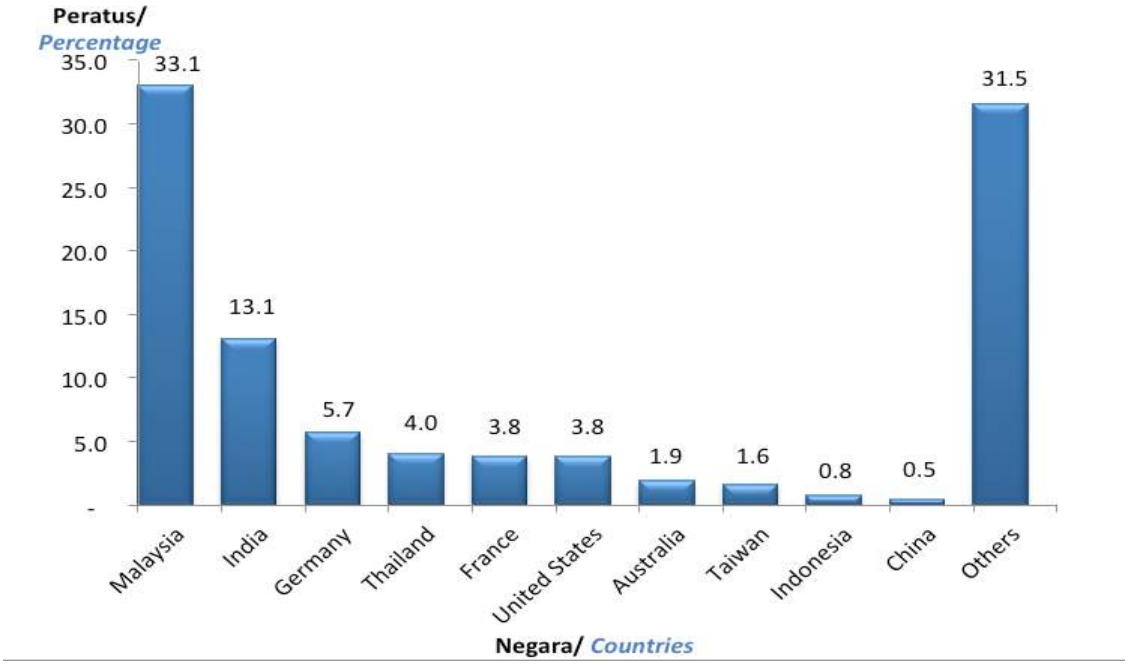
d. Main Source of Registered Products (Figure 5, 6,7)

Overall, local products were the main sources of products registered in year 2015. Figure 5 shows that India topped the list for imported prescription products whereas for non-prescription products, the largest source is from United States of America followed by Australia. (Figure 6).

China remained as the main source of imported natural products in year 2015. (Refer Figure 7).

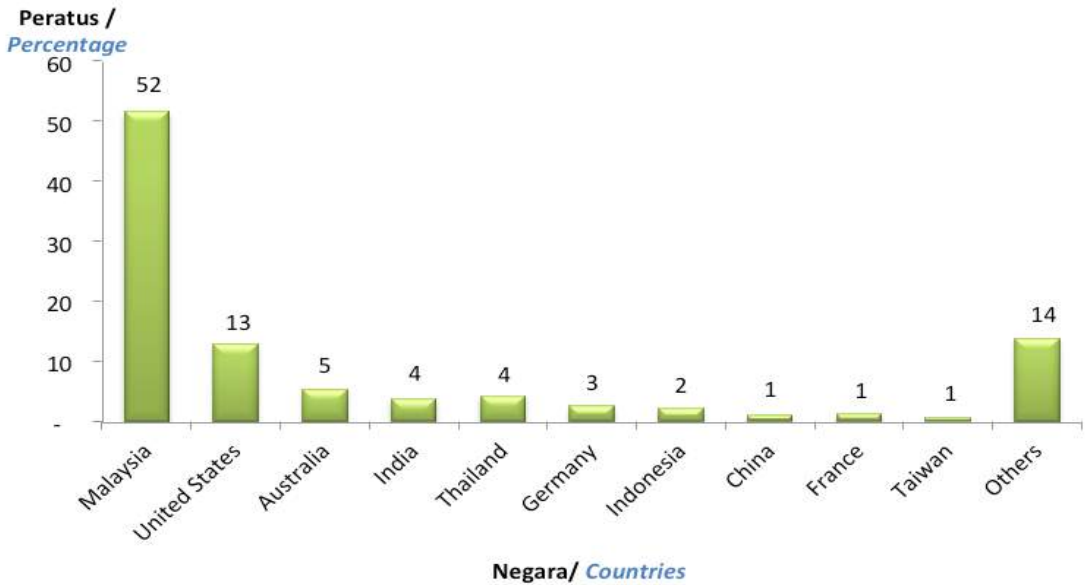
Rajah 5: Peratusan Produk Preskripsi Berdaftar Mengikut Sumber Negara Setakat 31.12.2015

Figure 5: Percentage of Registered Prescription Products Based on Source as of 31.12.2015



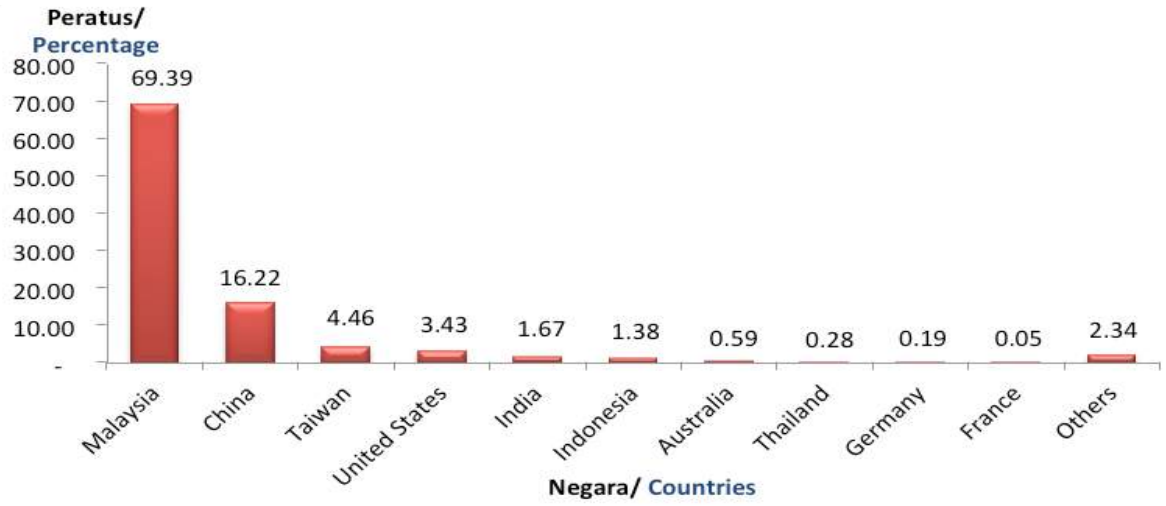
Rajah 6: Peratusan Produk Bukan Preskripsi Berdaftar Mengikut Sumber Negara Setakat 31.12.2015

Figure 6: Percentage of Registered Non Prescription Products Based on Source as of 31.12.2015



Rajah 7: Peratusan Produk Semula Jadi Berdaftar Mengikut Sumber Negara Setakat 31.12.2015

Figure 7: Percentage of Registered Natural Products Based on Source as of 31.12.2015



e. Aktiviti-aktiviti Lain yang berkaitan dengan Pendaftaran Produk

i. Pengeluaran Sijil Produk Farmaseutikal (Rajah 8, 9)

Rajah 8 menunjukkan jumlah pengeluaran Sijil Produk Farmaseutikal sejak tahun 2013. Daripada jumlah 2398 Sijil Produk Farmaseutikal yang telah dikeluarkan pada tahun 2015, 14.6% adalah untuk pengeksportan ke Brunei diikuti dengan Macau (7.7%). Rajah 9 menunjukkan bahawa kebanyakan produk juga dieksport ke negara-negara ASEAN lain.

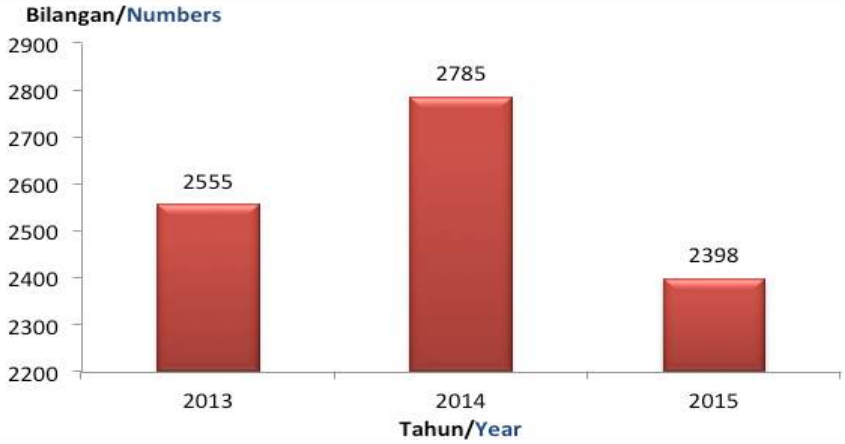
e. Other Activities Related to Product Registration

i. Issuance of Certificate of Pharmaceutical Product (CPP) (Figure 8, 9)

Figure 8 shows the number of Certificate of Pharmaceutical Products issued since year 2013. From the 2398 certificates issued in 2015, 14.6% were for products exported to Brunei followed by Macau (7.7%). Figure 9 shows the majority of products were also exported to other ASEAN member states.

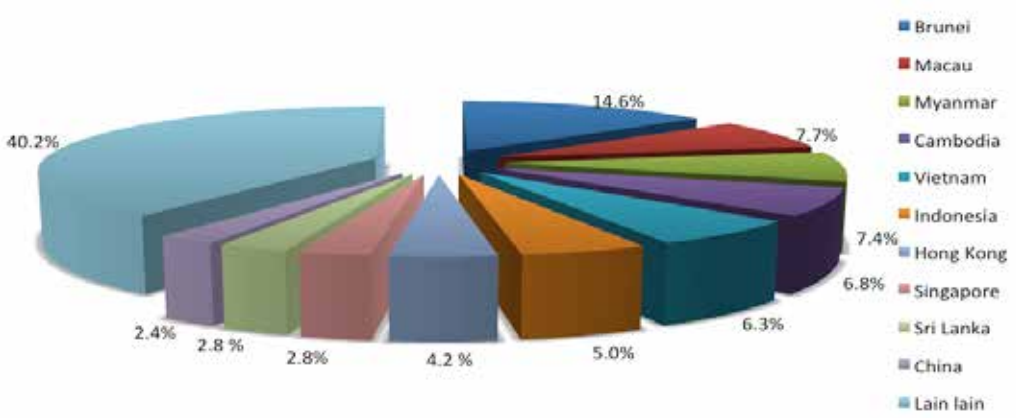
Rajah 8: Bilangan Sijil Produk Farmaseutikal yang Dikeluarkan (2013-2015)

Figure 8: Number of Certificate of Pharmaceutical Product Issued (2013-2015)



Rajah 9: Pengeluaran Sijil Produk Farmaseutikal ke Negara-negara Utama pada tahun 2015

Figure 9: Issuance of Certificate of Pharmaceutical Product to other countries in the year 2015



ii. Pembaharuan Pendaftaran Produk (Rajah 10, 11)

Bagi setiap produk berdaftar di Malaysia, permohonan pembaharuan pendaftaran produk perlu dilakukan setiap lima (5) tahun. Permohonan pembaharuan pendaftaran produk perlu dikemukakan oleh pemohon sekurang-kurangnya enam (6) bulan sebelum tarikh luput pendaftaran. Rajah 10 menunjukkan bahawa bilangan pembaharuan pendaftaran produk pada tahun 2015 telah menurun berbanding dengan tahun-tahun sebelumnya.

Rajah 11 menunjukkan pecahan kategori produk yang telah diperbaharui pendaftaran bagi tahun 2015. 49.37% daripada jumlah keseluruhan pembaharuan untuk produk terdiri daripada kategori produk semulajadi diikuti dengan produk Preskripsi (27.29%).

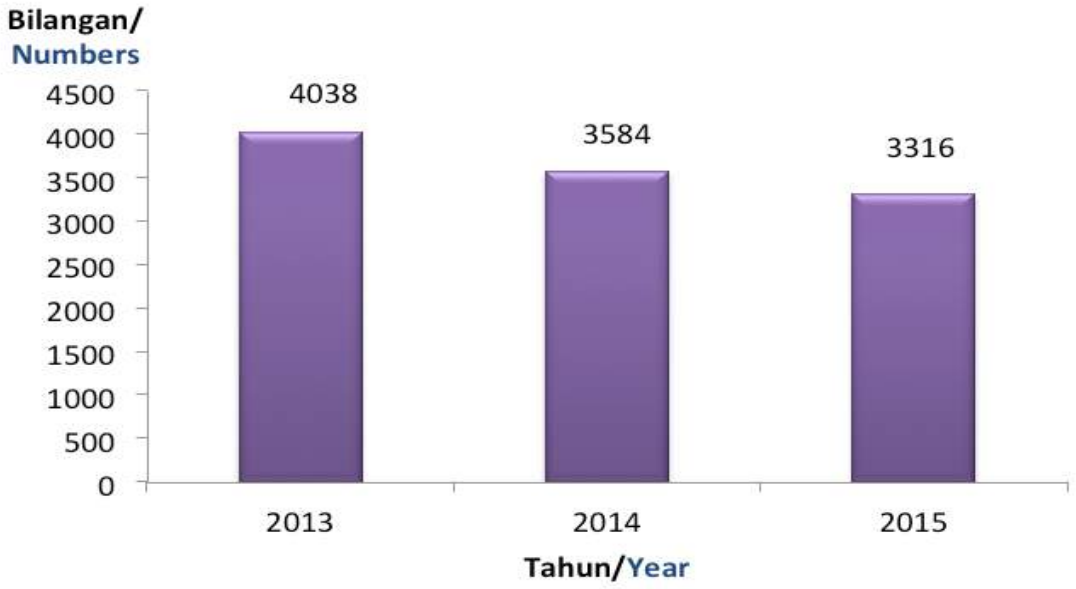
ii. Renewal of Product Registration (Figure 10, 11)

The application for renewal of registered product in Malaysia has to be done every five (5) years. The application should be submitted at least six (6) months prior to the expiry of the product registration. Figure 10 shows that the number of product registration renewal in year 2015 was in reducing trend compared to previous years.

Figure 11 provides a summary on the breakdown of registration renewal by product categories in 2015. 49.37% of total products renewals were from natural products, followed by Prescription products (27.29%).

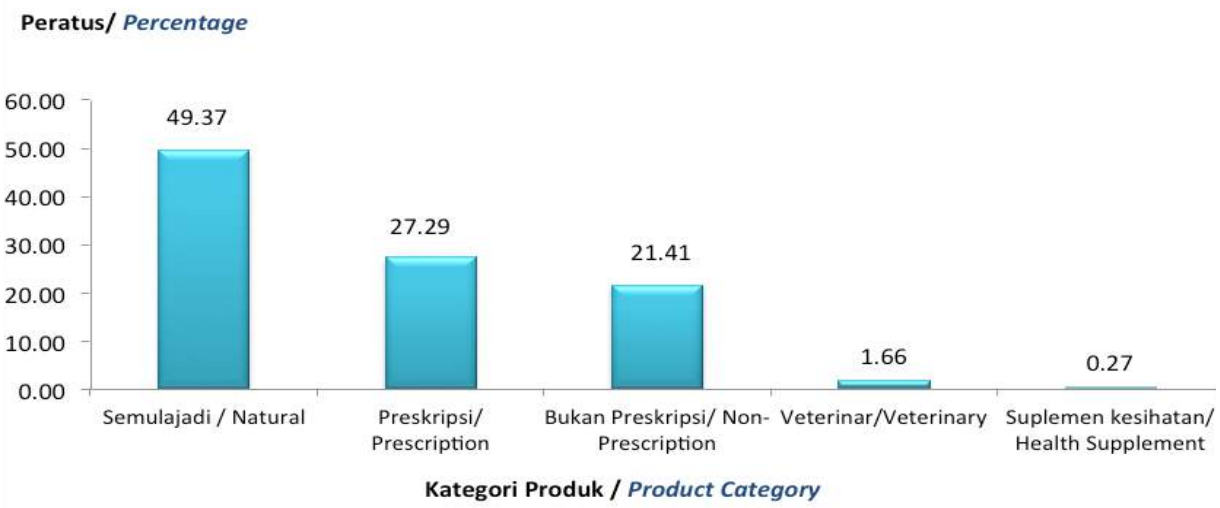
Rajah 10: Permohonan Pembaharuan Pendaftaran Produk yang diluluskan (2013-2015)

Figure 10: Number of Applications Approved for Renewal of Product Registration (2013-2015)



Rajah 11: Kategori Produk bagi Pembaharuan Pendaftaran pada tahun 2015

Figure 11: Registration Renewal Based on Product Category in the year 2015



iii. Pertukaran Pemegang Pendaftaran Produk (Rajah 12)

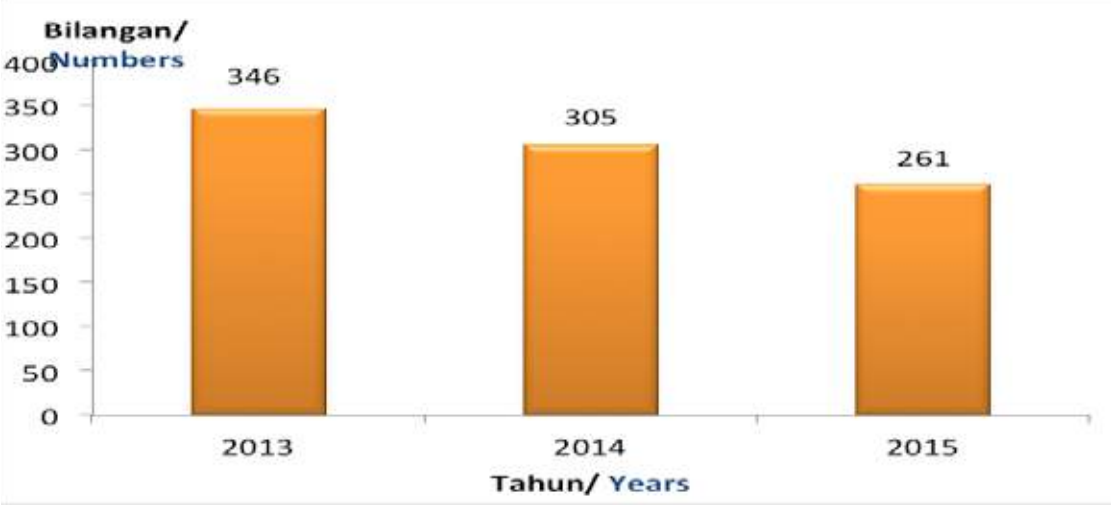
Rajah 12 menunjukkan bilangan permohonan pertukaran pemegang pendaftaran yang diluluskan pada tahun 2015 telah menurun berbanding dengan tahun-tahun sebelumnya.

iii. Change of Product Registration Holder (Figure 12)

Figure 12 shows the number of application approved for Change of Product Registration Holder in year 2015 has decreased as compared to previous years.

Rajah 12: Bilangan Permohonan Pertukaran Pemegang Pendaftaran Produk yang diluluskan (2013-2015)

Figure 12: Number of Applications Approved for Change of Product Registration Holder (2013-2015)



iv. Verifikasi Status Pendaftaran Produk bagi Aktiviti Penguatkuasaan (Rajah 13)

Antara aktiviti Bahagian Penguatkuasa Farmasi adalah penguatkuasaan terhadap peraturan-peraturan di bawah Peraturan Kawalan Dadah dan Kosmetik 1984. Produk-produk yang dirampas perlu disahkan status pendaftaran oleh pihak BPFK sebelum tindakan undang-undang dapat diambil.

Rajah 13 menunjukkan jumlah pertanyaan yang diterima untuk pengesahan status pendaftaran produk bagi tempoh 2013-2015.

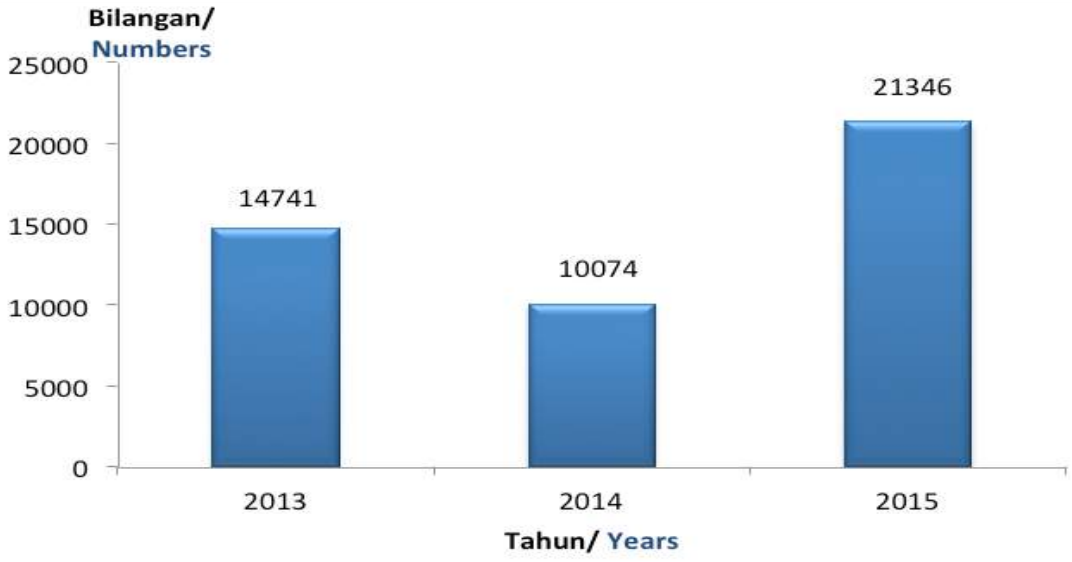
iv. Product Registration Status Verification for Enforcement Activities (Figure 13)

The registration status of a product seized by the Pharmacy Enforcement Division under the Control of Drugs and Cosmetics Regulations 1984 would require verification by NPCB before any legal action could be taken.

Figure 13 shows the number of requests received for the verification of registration status of products for year 2013-2015.

Rajah 13: Verifikasi Status Pendaftaran Produk Bagi Tujuan Penguatkuasaan Farmasi(2013-2015)

Figure 13: Product Registration Status Verification For Enforcement Activities (2013-2015)



v. Permohonan Tambahan indikasi bagi produk berdaftar (produk entity kimia baru dan biologic sahaja)

Pada tahun 2015, terdapat 30 permohonan untuk produk entiti kimia baru dan 29 permohonan untuk produk biologik yang dibentangkan untuk kelulusan oleh PBKD bagi tambahan indikasi.

v. Additional Indication Application for Registered Products (for NCE and Biologics only)

In year 2015, there were a total of 30 and 29 additional indication applications for NCE and biologic products respectively tabled in the DCA meeting for approval.

f. Permohonan Variasi

Tugas utama Unit Variasi untuk setiap seksyen, adalah menjalankan penilaian terhadap permohonan untuk melakukan sebarang perubahan maklumat produk termasuk mengemaskinikan maklumat produk berdaftar (kecuali produk kosmetik) bagi memastikan keselamatan, keberkesanan dan kualiti produk selepas proses pendaftaran. Perubahan-perubahan maklumat produk berkenaan termasuk penambahan maklumat di dalam sisip bungkusan dan label, perubahan pada formulasi produk dan pertukaran tapak pengilangan dan lain-lain.

Pada tahun 2015, sebanyak 108,528 permohonan variasi telah diterima. Berdasarkan kepada Rajah 14, bilangan permohonan variasi bagi produk preskripsi adalah paling tinggi iaitu 47,657 (43.9%), diikuti dengan produk tradisional sebanyak 34,987 (32.2%), produk suplemen kesihatan sebanyak 16,953 (15.6%), bukan preskripsi sebanyak 8,730 (8.1%) dan produk veterinar sebanyak 201 (0.2%)

Unit Variasi telah memproses sebanyak 93,872 permohonan iaitu 86.5% daripada jumlah permohonan diterima pada tahun 2015 (Rajah 15). Sebanyak 44,065 permohonan telah diluluskan sepanjang tahun 2015.

v. Variation Application

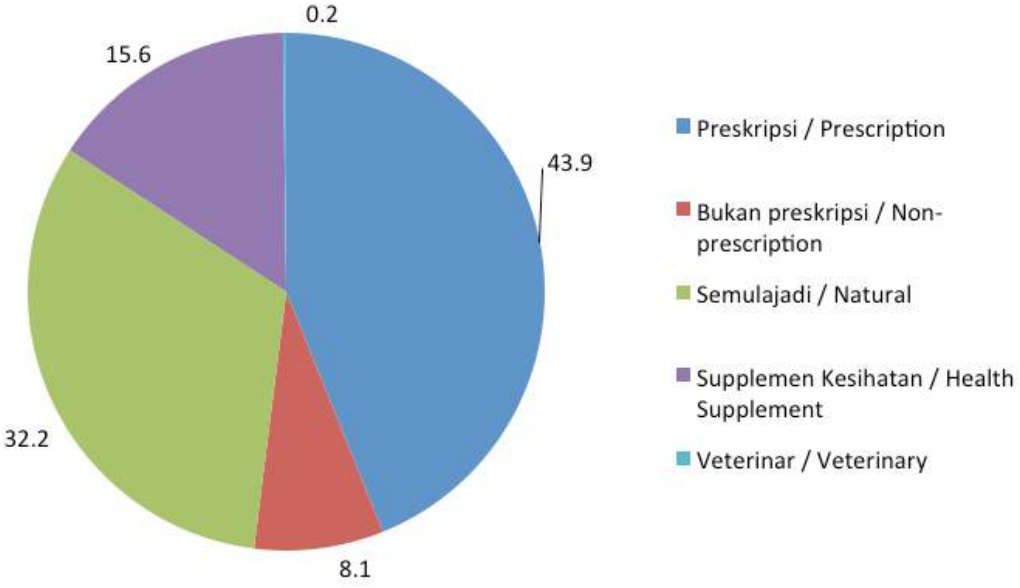
The Variation Unit for each section is responsible for evaluating applications pertaining to information updates or change of registered product information (excluding cosmetic products) with the aim of ensuring that the safety, efficacy and quality of products are maintained after registration. Changes to the information of registered products include addition of information in the package insert and label, changes to the product formulation as well as the manufacturing site and others.

In the year 2015, a total of 108,528 variation applications were received. As shown in Figure 14, the number of applications for prescription products is the highest with 47,657 applications (43.9%), followed by traditional products with 34,987 applications (32.2%), health supplement products with 16,953 applications (15.6%), non-prescription products with 8,730 applications (8.1%) and veterinary products with 201 applications (0.2%).

Figure 15 shows that the Variation Units had processed a total of 93,872 applications which is 86.5% of the total number of applications received in the year 2015. In year 2015, a total of 44,065 applications were approved.

Rajah 14: Permohonan Variasi Yang Diterima pada Tahun 2015

Figure 14: Variation Applications Received in year 2015

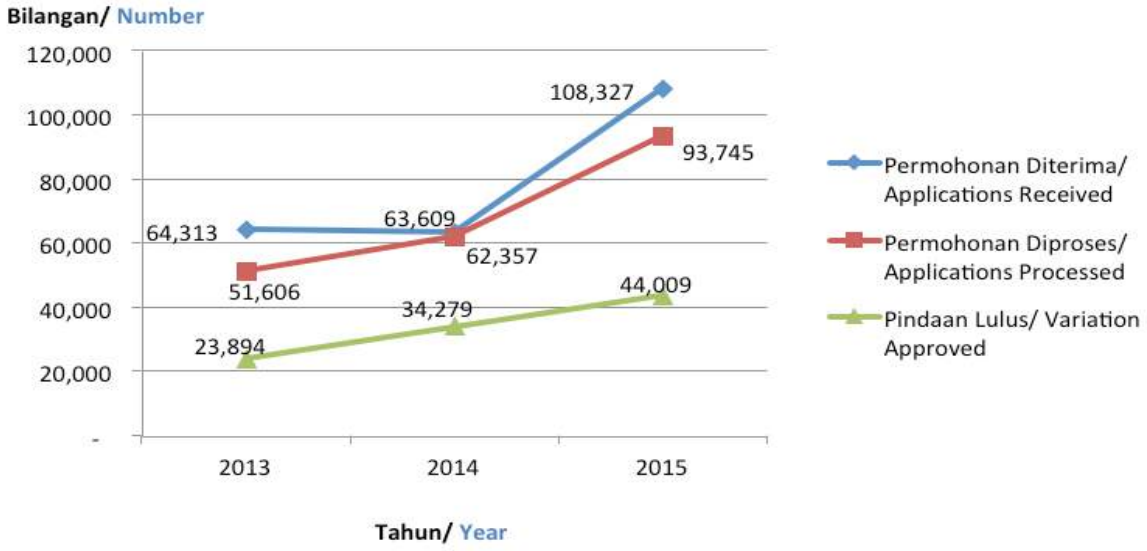


Bilangan permohonan variasi yang diterima semakin meningkat dari tahun 2013 hingga 2015. Pada tahun 2015, terdapat peningkatan sebanyak 70.6% dalam bilangan permohonan variasi yang diterima dan 50.5% peningkatan dalam bilangan permohonan variasi yang diproses berbanding dengan tahun 2014 (Rajah 15).

From year 2013 to 2015, the number of variation applications received has been on the rise. In year 2015, there was an increase of 70.6% in the number of variation applications received and an increase of 50.5% for the number of variation applications processed as compared to year 2014 (Figure 15).

Rajah 15: Permohonan Variasi Diterima Berbanding Bilangan Diproses Serta Lulus (2013-2015)

Figure 15: Comparison of Variation Applications Received, Processed and Approved (2013 – 2015)



Senarai Produk Entiti Kimia Baru yang diluluskan pendaftaran oleh PKPB bagi tahun 2015

New Chemical Entity Products Approved by the DCA in 2015

NO *No*	NAMA PRODUK *Product Name*
1	Betmiga prolonged-release tablets 25mg Betmiga prolonged-release tablets 50mg
2	Ultibro Breezhaler 110/50mcg Inhalation Powder Hard Capsule
3	Esmya 5mg Tablets
4	AUBAGIO 14mg Film-Coated Tablets
5	Lyxumia 10mcg Solution for Injection Lyxumia 20mcg Solution for Injection
6	Nucynta ER Tablets 50mg Nucynta ER Tablets 100mg Nucynta ER Tablets 150mg Nucynta ER Tablets 200mg Nucynta ER Tablets 250mg
7	Brintellix 5mg Film-coated Tablets Brintellix 10mg Film-coated Tablets Brintellix 15mg Film-coated Tablets Brintellix 20mg Film-coated Tablets
8	Ribomustin 25mg/Vial Powder for Concentrate for Solution for Infusion Ribomustin 100mg/Vial Powder for Concentrate for Solution for Infusion
9	Taflotan Ophthalmic Solution 0.0015%
10	Zymaxid (Gatifloxacin Ophthalmic Solution) 0.5%
11	Cetraxal 2mg/ml Ear Drops Solution
12	Striverdi Respimat 2.5mcg Solution for Inhalation
13	Viekirax 12.5mg/75mg/50mg Film Coated Tablets

NO *No*	NAMA PRODUK *Product Name*
14	Exviera 250mg Film Coated Tablets
15	Edarbi 40mg Tablets Edarbi 80mg Tablets
16	Edarbyclor 40mg/12.5mg Film-Coated Tablet Edarbyclor 40mg/25mg Film-Coated Tablet
17	Cetraxal Plus Ear Drops Solution
18	Tecfidera 120 mg gastro-resistant hard capsules Tecfidera 240mg gastro-resistant hard capsules
19	PLIAGLIS 70 mg/g + 70 mg/g CREAM
20	Anoro Ellipta 62.5/25 Micrograms Inhalation Powder, Pre-Dispensed
21	Sovaldi 400mg Film-Coated Tablets
22	Maxigesic 500mg/150mg Film-Coated Tablets
23	Jardiance 10mg Film-Coated Tablets Jardiance 25mg Film-Coated Tablets
24	Natrixam 1.5mg/5mg, Modified Release Tablets Natrixam 1.5mg/10mg, Modified Release Tablets
25	Triplixam 2.5mg/0.625mg/5mg Film-Coated Tablets Triplixam 5mg/1.25mg/5mg Film-Coated Tablets Triplixam 5mg/1.25mg/10mg Film-Coated Tablets Triplixam 10mg/2.5mg/5mg Film-Coated Tablets Triplixam 10mg/2.5mg/10mg Film-Coated Tablets
26	Entresto 50mg Film-Coated Tablets Entresto 100mg Film-Coated Tablets Entresto 200mg Film-Coated Tablets
27	Afinitor 2mg Dispersible Tablet Afinitor 3mg Dispersible Tablet Afinitor 5mg Dispersible Tablet

Senarai Produk Biologik yang diluluskan pendaftaran oleh PKPB bagi tahun 2015

Biologic Products Approved by the DCA in 2015

Jadual 2 : Produk Biologik yang Diluluskan oleh PBKD pada 2015

Table 2 : Biologic Products Approved by the DCA in 2015

NO *No*	NAMA PRODUK *Product Name*
1	Alburx 5, Human Albumin 5% Solution Alburx 20, Human Albumin 20% Solution Alburx 25, Human Albumin 25% Solution
2	Remsima Powder For Concentrate For Solution For Injection
3	Adcetris 50mg, Powder for Concentrate for Solution for Infusion
4	Tisseel, (Fibrin Sealant) Frozen Solution
5	Recormon Prefilled Syringe 4000iu/0.3ml
6	Varivax Refrigerated Varicella Virus Vaccine, Live (Oka/Merck)
7	Artiss Solutions for Sealant, Deep Frozen
8	Fluarix Tetra Influenza Vaccine
9	Rabipur Lyophilized Powder For Injection
10	Vimizim 1mg/ml Concentrate For Solution For Infusion
11	Herceptin Vial 440 mg Powder For Concentrate
12	EPO Stada 2000 IU/0.6 ml Solution for Injection In a Pre-filled Syringe EPO Stada 10000 IU/1.0 ml Solution for Injection In a Pre-filled Syringe EPO Stada 40000 IU/0.4 ml Solution for Injection In a Pre-filled Syringe
13	Gazyva 1000mg/40ml Concentrate for Solution for Infusion

NO *No*	NAMA PRODUK *Product Name*
14	Lucentis 10mg/ml Solution for Injection In Pre-Filled Syringe
15	Lemtrada Concentrate for Solution for Infusion 12mg
16	Herceptin 600mg/5ml Solution for Injection
17	Xeomin Powder for Solution for Injection 50 LD50 Units Xeomin Powder for Solution for Injection 100 LD50 Units
18	INSUGEN-R (Regular) Insulin Injection, Soluble 100iu/ml INSUGEN-N (NPH) Insulin Injection, Isophane 100iu/ml INSUGEN-30/70 (Biphasic) Insulin Injection, Biphasic Isophane 100iu/ml

Aktiviti Pasca Pendaftaran Produk

Product Post-Registration Activities

SURVEILANS & ADUAN PRODUK

Aktiviti surveilans dan pengendalian aduan produk dijalankan untuk memantau produk berdaftar dan kosmetik bernotifikasi di Malaysia bagi memastikan semua produk memenuhi piawaian kualiti dan keselamatan yang ditetapkan oleh Pihak Berkuasa Kawalan Dadah.

SURVEILLANCE & PRODUCT COMPLAINTS

Market surveillance and handling of product complaints are in place to monitor registered medicinal products and notified cosmetics in Malaysia, ensuring that they comply with the quality and safety standards set by the Drug Control Authority.

Program Pengawasan Mutu Produk Berdaftar

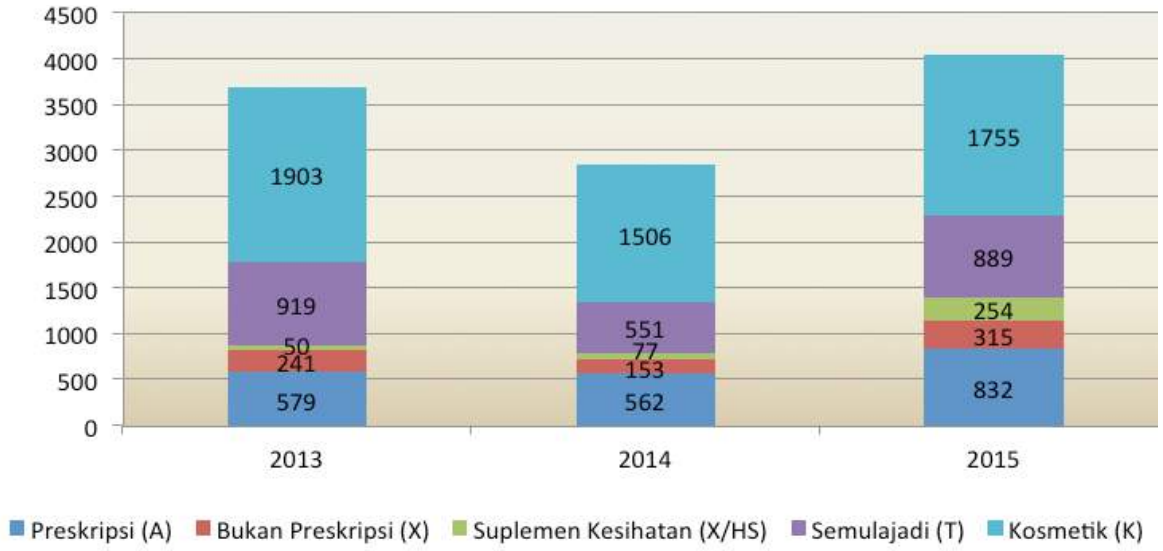
Daripada 6,422 produk yang disasar di bawah Program Pengawasan Mutu Produk Berdaftar pada tahun 2015, sejumlah 4,045 (63%) produk telah berjaya disampel manakala 2,377 (37%) produk gagal disampel (Rajah 1). Produk farmaseutikal disampel berdasarkan kriteria tertentu termasuk laporan kesan advers, isu amalan pengilangan baik (APB), aduan produk, dan surveilans lepas.

Market Surveillance for Registered Products

From 6,422 products that were targeted for sampling under the Market Surveillance for Registered Products, 4,045 (63%) products were successfully sampled and 2,377 (37%) products failed to be sampled in 2015. Pharmaceutical products are targeted based on criteria including adverse drug reaction reports, good manufacturing practice (GMP) issues, complaints, and surveillance history.

Rajah 1: Bilangan Produk yang Disampel Mengikut Kategori (2013-2015)

Figure 1: Number of Products Sampled by Category (2013-2015)



Sejumlah 3,162 pemeriksaan label telah dijalankan ke atas produk-produk berdaftar dan kosmetik bernotifikasi untuk memastikan label/ sisip bungkusan mematuhi keperluan yang ditetapkan oleh PBKD dan garis panduan kosmetik (Jadual 1). Selain itu, pemeriksaan dan pengesahan ke atas label yang dikemukakan oleh penguatkuasa farmasi turut dijalankan. Tindakan regulatori diambil sekiranya label produk tidak mematuhi keperluan tersebut.

A total of 3,162 labelling checks were performed on registered products and notified cosmetics to ensure the labels / package inserts comply with the latest requirements specified by the DCA and cosmetic guidelines (Table 1). Besides that, label checking and verification are also performed in response to queries from enforcement pharmacy division. Regulatory action is taken if the product labels do not comply.

Produk-produk yang disampel dihantar ke Pusat Kawalan Kualiti BPFK untuk pengujian makmal. Keputusan ujian untuk 1,695 produk telah diterima pada tahun 2015, di mana sebanyak 1,579 (93%) telah lulus manakala baki 116 gagal ujian makmal. Majoriti produk yang gagal ujian makmal terdiri daripada produk semulajadi (46.5%).

Products sampled are sent to the NPCB Centre for Quality Control for laboratory testing. A total of 1,695 laboratory test results were received in 2015, of which 1,579 (93%) passed and 116 failed. The majority of the products that failed laboratory testing were natural products (46.5%).

Jadual 1: Pemantauan Kepatuhan Pelabelan

Table 1: Monitoring of Labelling Compliance

Kategori produk / *Product Category*	Lulus / *Pass*	Amaran / *Warning*	Panggilbalik / *Recall*	Jumlah / *Total*
Preskripsi / *Prescription (A)*	475	71	0	546
Bukan Preskripsi / *Non-prescription (X)*	128	20	2	150
Supplemen Kesihatan / *Health Supplement (X/T)*	151	41	37	229
Semulajadi / *Natural (T)*	137	365	88	590
Kosmetik / *Cosmetic (K)*	86	1561	-	1647
Jumlah / ***Total***	977	2058	127	3162

Tindakan Regulatori

Sekiranya sesuatu produk gagal ujian makmal, tindakan regulatori akan diambil berdasarkan tahap kegagalan dan risiko yang terlibat. Tindakan yang diambil termasuk pengeluaran surat amaran, arahan panggil balik produk, penggantungan atau pembatalan pendaftaran produk / notifikasi kosmetik.

Sejumlah 59 arahan panggil balik telah dikeluarkan pada tahun 2015 disebabkan isu-isu kualiti (Rajah 2). Lebih kurang 76% produk yang dipanggil balik merupakan produk semulajadi, dengan punca seperti kegagalan ujian had mikrob, ujian logam berat, dan produk dicampur palsu.

Pada tahun 2015, BPFK telah mengeluarkan dua (2) amaran berkaitan kualiti produk, dan 56 amaran berkaitan dokumentasi. Sejumlah lima (5) produk semulajadi dan lima (5) kosmetik telah didapati dicampur palsu, dan dicadangkan untuk pembatalan pendaftaran atau notifikasi kosmetik, seperti tersenarai di Jadual 2(a) dan 2(b). Senarai ini juga dipaparkan pada laman sesawang BPFK.

Regulatory Action

If a product fails laboratory testing, regulatory action is taken based on the level of failure and risk associated. Action taken may include issuance of warning letters, product recall, suspension or cancellation of product registration / cosmetic notification.

A total of 59 recall directives were issued in 2015 due to quality issues (Figure 2). More than half the recalls (76%) involved natural products, for reasons such as failing laboratory tests on microbial limit, heavy metals, and adulteration.

In 2015, NPCB issued two (2) warnings related to product quality and 56 warnings related to documentation. A total of five (5) natural products and five (5) cosmetics were found to be adulterated and were tabled for cancellation of product registration, as shown in Table 2(a) and 2(b). This list is also published on the NPCB website.

Jadual 2(a): Senarai Produk Berdaftar yang Dibatalkan pada Tahun 2015 kerana Dicampur Palsu

Table 2(a): List of Registered Products Cancelled Due to Adulteration in 2015

Bil. *No.*	Nama Produk *Product Name*	No. Pendaftaran Produk *Product Registration No.*	Bahan Campur Palsu yang *Dikesan Adulterant Detected*
1.	Yunnan Ken Ku Oil	MAL05051199T	Methyl Salicylate
2.	Minyak Qian Li Zhui Fen Yew	MAL05051197T	Methyl Salicylate
3.	Bam Gamat Gemilang Plus	MAL10012478TC	Methyl Salicylate
4.	El Biozing	MAL10070646TC	Dexamethasone
5.	Li Chung Pill	MAL05061546T	Aconite

Jadual 2(b): Senarai Produk Kosmetik yang Dibatalkan pada Tahun 2015 kerana Dicampur Palsu

Table 2(b): List of Cosmetic Products Cancelled Due to Adulteration in 2015

Bil. *No.*	Nama Produk *Product Name*	No. Notifikasi *Notification No.*	Bahan Campur Palsu yang *Dikesan Adulterant Detected*
1.	Hans Beauty Flawless Day Cream	NOT130304286K	Mercury
2.	Hans Beauty Flawless Night Cream	NOT130304287K	Mercury
3.	Hans Beauty Treatment Toner	NOT130304284K	Hydroquinone
4.	Royal Expert White Cream	NOT141006150K	Mercury
5.	Anti Sensitiveness Essence	NOT130804064K	Mometasone

Pensampelan secara *risk-based*

Bagi memantapkan aktiviti surveilans ke atas produk di pasaran, satu unit baru telah diwujudkan pada penghujung tahun 2014 bagi memfokuskan aktiviti pensampelan secara *risk-based*. Ini termasuklah mendapatkan sampel produk di pasaran secara *test buy* bagi produk-produk terpilih, dan membuat pensampelan produk susulan kes-kes aduan produk / laporan kesan advers / sejarah ketidak patuhan kualiti. Unit ini juga menjalankan penyaringan media dari semasa ke semasa bagi mengenal pasti produk-produk berisiko untuk disampel.

Pada tahun 2015, sejumlah 54 produk telah disampel dari pasaran secara test buy. Daripada jumlah ini, 34 produk tidak memenuhi piawai pelabelan dan satu (1) produk telah positif dengan bahan campur palsu racun berjadual. Tindakan regulatori telah diambil ke atas produk-produk tersebut.

Aduan Produk

Dalam tempoh masa sepuluh tahun yang lepas, bilangan aduan produk yang diterima telah meningkat sebanyak 73%, namun menurun sebanyak 19% dari tahun 2014 ke 2015 (Rajah 3). Trend peningkatan yang ketara dapat diperhatikan pada tahun 2010 disebabkan peningkatan kesedaran di kalangan ahli profesional kesihatan dan orang awam berkaitan kualiti dan efikasi produk berdaftar yang terdapat di pasaran.

Risk-based Sampling

A new unit has been established since late 2014 focusing on risk-based sampling which aims to strengthen surveillance activities on products available in the market. Its functions include sampling of selected products through test-buy from the market, and sampling of products following product complaint/ adverse drug reaction report/ history of quality non-compliance. This unit also identifies products that are high-risk for sampling by screening media from time to time.

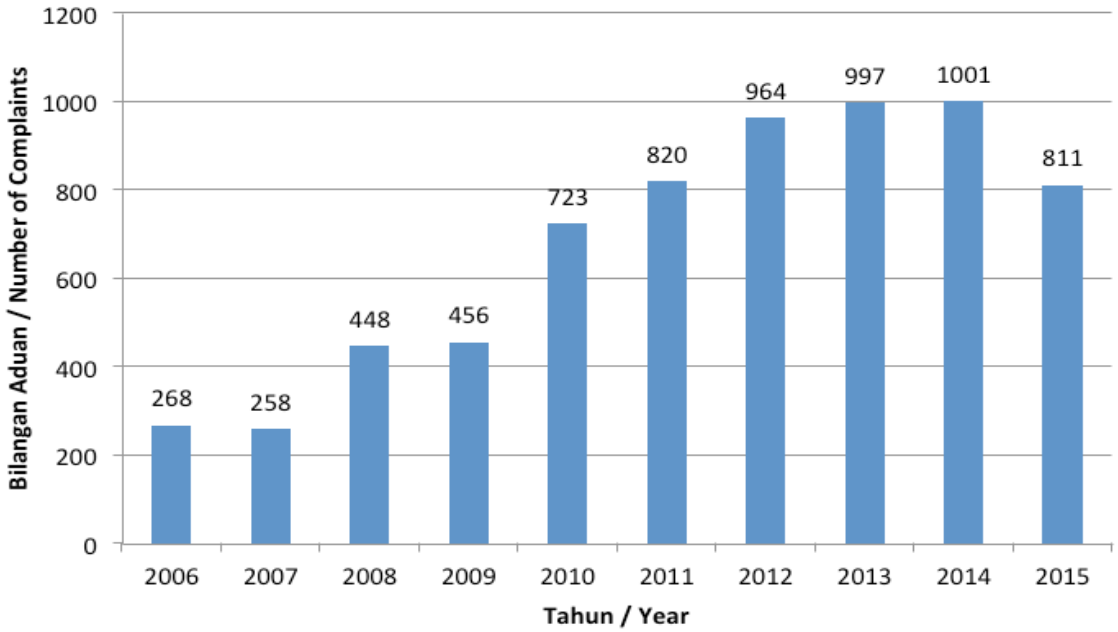
In year 2015, a total of 54 samples were purchased from the market through test-buy of which 34 samples were found to be not compliant on labelling requirements and one (1) product was detected to contain undeclared scheduled poisons. Regulatory action had been taken upon these products.

Product Complaints

Over the last ten years, the number of product complaints received has steadily increased by 73%, but has decreased by 19% from 2014 to 2015 (Figure 3). A significant upward trend was noted in 2010 due to increasing awareness among both healthcare professionals and the public on quality and efficacy of registered products available in the market.

Rajah 3: Jumlah Aduan Produk Berdaftar yang Diterima (2006-2015)

Figure 3: Total Product Complaints Received (2006-2015)



Pada tahun 2015, sejumlah 811 aduan telah diterima yang melibatkan 401 produk berdaftar, iaitu 592 aduan (73%) melibatkan produk preskripsi, 201 aduan (25%) untuk produk bukan preskripsi, 12 aduan (1.5%) untuk suplemen kesihatan, dan 6 aduan (0.7%) untuk produk semulajadi. Bilangan aduan yang diterima mengikut kategori ditunjukkan di dalam Rajah 4.

Aduan produk yang diterima telah dinilai, disiasat, dan tindakan berkenaan telah diambil berdasarkan hasil siasatan. Di antara tindakan yang diambil, satu (0.1%) arahan panggil balik telah dikeluarkan disebabkan label produk tidak mematuhi spesifikasi. Sejumlah lima produk/ kelompok (0.7%) telah dipanggil balik secara sukarela dari pasaran oleh pemegang pendaftaran produk.

Merujuk kepada produk kosmetik, BPFK telah menerima sebanyak 44 aduan pada tahun 2015, kebanyakannya melibatkan isu kualiti dan kesan sampingan, seperti pembungkusan produk dan kesan advers yang dialami selepas penggunaan produk. Di antara aduan yang diterima, 37 (84%) melibatkan produk kosmetik bernotifikasi sementara baki tujuh (7) atau 16% adalah untuk produk tidak bernotifikasi. Aduan yang melibatkan produk tidak bernotifikasi telah dimajukan kepada Bahagian Penguatkuasaan Farmasi untuk tindakan undang-undang.

Selain tindakan punitif, BPFK juga terlibat di dalam perbincangan bersama pemegang pendaftaran produk dan pengilang dalam usaha menangani isu-isu berkaitan kualiti, keselamatan, dan efikasi produk berdaftar di Malaysia. Ini adalah selaras dengan misi BPFK untuk sentiasa melindungi kesihatan rakyat.

In 2015, a total of 811 complaints involving 401 registered products were received. These comprised of 592 complaints (73%) for prescription products, 201 (25%) for non-prescription products, 12 (1.5%) for health supplements and 6 (0.7%) for natural products. The number of complaints received according to category is shown in Figure 4.

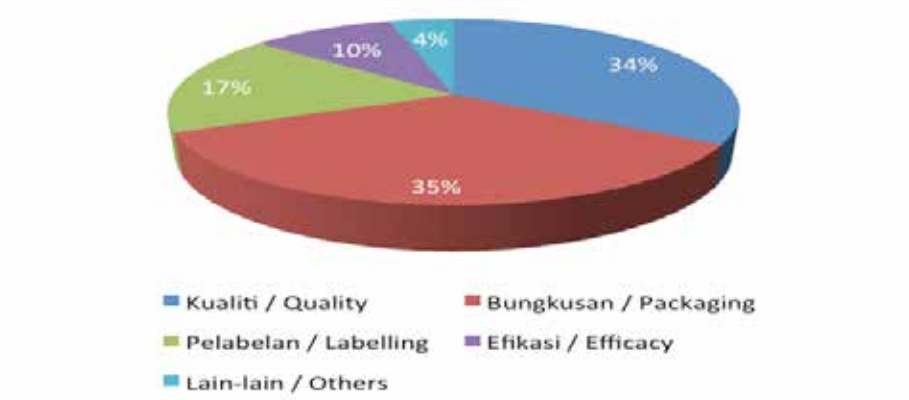
Products complaints received were evaluated, investigated, and necessary actions were taken based on the findings. Out of the total outcomes, one (0.1%) recall directive was issued due to label incompliance. A total of five (0.7%) products/ batches were voluntarily recalled from the market by product registration holders.

With regards to cosmetic products, NPCB received a total of 44 complaints in 2015 which were mainly due to quality and side effect issues, such as packaging and adverse reactions following use. Among the complaints received, 37 (84%) involved notified cosmetics, while seven (7) or 16% were for unnotified products. The complaints involving unnotified cosmetics were forwarded to the Pharmacy Enforcement Division for further action.

Apart from punitive action, the NPCB was also involved in discussions with product registration holders and manufacturers as part of the effort to resolve numerous issues pertaining to the quality and safety of products in Malaysia. This is in tandem with our mission to continually safeguard the nation's health.

Rajah 4: Aduan Produk yang Diterima Mengikut Kategori (2015)

Figure 4: Product Complaints Received Based on Categories (2015)



Kerjasama Antarabangsa Berkaitan Kualiti dan Keselamatan

Malaysia terlibat dalam perkongsian maklumat kualiti dan keselamatan produk ubat-ubatan, termasuk kosmetik, melalui ASEAN Post Marketing Alert System (PMAS) dan Pharmaceutical Inspection Cooperation Scheme (PIC/S) – Rapid Alert Notification System (RAS) bagi negara bukan ASEAN. BPFK merupakan penyelaras bagi PMAS.

Pada tahun 2015, sejumlah 384 makluman telah diterima melalui rangkaian PMAS yang melibatkan 385 produk, dengan 244 makluman (63.5%) disumbang oleh Malaysia. Melalui RAS, 84 makluman telah diterima yang melibatkan 305 produk, dan hasilnya empat (4) produk telah dipanggil balik secara sukarela oleh pemegang pendaftaran produk.

International Collaboration on Quality and Safety

Malaysia is involved in sharing the information on quality and safety of medicinal products, including cosmetics, through the ASEAN Post Marketing Alert System (PMAS) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S) – Rapid Alert Notification System (RAS) for non-ASEAN countries. NPCB is the coordinator for PMAS.

In 2015, there were a total of 384 alerts received via the PMAS network involving 385 products, with 244 alerts (63.5%) contributed by Malaysia. Through RAS, 84 alerts involving 305 products were received, resulting in the voluntary recall of four (4) products by respective registration holders.

Cabaran

1. Bagi kategori produk semulajadi dan supplemen kesihatan, kesedaran syarikat terhadap keperluan yang telah ditetapkan oleh BPFK masih rendah. Kebanyakan label atau dokumentasi tidak dikemaskini semenjak produk didaftarkan. Disamping itu, susulan tidak dibuat oleh syarikat terhadap komitmen yang telah diberikan semasa proses pendaftaran. Perubahan dibuat terhadap produk tanpa memaklumkan kepada BPFK atau dikemaskini melalui permohonan variasi. Ini menyebabkan majoriti produk yang diperiksa berbeza daripada yang diluluskan.
2. Selain itu, kefahaman pengadu mengenai prosedur menyalurkan aduan produk berdaftar dan kualiti pelaporan yang diterima setakat ini masih perlu meningkat. Hanya segelintir laporan aduan yang diterima memberikan impak yang signifikan dalam memastikan kualiti produk-produk berdaftar yang berada di pasaran. Sebagai contoh, laporan produk yang tidak stabil disebabkan oleh formulasi telah membawa kepada perubahan formulasi produk.

Challenges

1. *The regulation of natural products and health supplements in Malaysia remains a challenge. The level of awareness on the NPCB current requirements and guidelines among some product registration holders is still low. There are many instances of labels or documents not being updated since the products were registered. Apart from that, there are companies which fail to commit on their products post-registration. Product labels and packaging are changed without informing NPCB or submitting a variation application. These result in discrepancies between the products checked and the products approved.*
2. *Besides that, understanding of complainants on the complaint procedure for registered products and the quality of complaint reporting needs to be improved further. Only a few of the complaint reports received produced a significant impact in ensuring the quality of registered products in the market, such as reports of unstable product due to formulation that led to the changing of product formulation.*

FARMAKOVIGILANS / *PHARMACOVIGILANCE*

PELAPORAN KESAN ADVERS UBAT

BPFK berusaha menjamin keselamatan ubat-ubatan yang berdaftar di Malaysia, melalui pemantauan laporan kesan advers ubat (ADR), mengenal pasti dan menilai isu-isu keselamatan ubat di peringkat tempatan dan antarabangsa, serta melalui latihan dan komunikasi risiko.

Pada tahun 2015, BPFK telah menerima sejumlah 13,675 laporan ADR (Rajah 1). Setelah dibentangkan dan disahkan semasa mesyuarat MADRAC, semua laporan ADR tersebut dihantar untuk dimasukkan ke dalam pangkalan data laporan kesan advers antarabangsa World Health Organisation (WHO). Pada bulan November 2015, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden (WHO-UMC) telah melaporkan Malaysia menduduki tangga pertama di kalangan negara-negara berpendapatan rendah-sederhana dari segi bilangan laporan ADR yang diterima dalam setahun mengikut populasi negara.

Maklumat lanjut boleh diperoleh dengan merujuk kepada laporan tahunan Pusat Pemonitoran Kesan Advers Ubat Kebangsaan (bpfk.moh.gov.my).

MONITORING OF ADR REPORTS

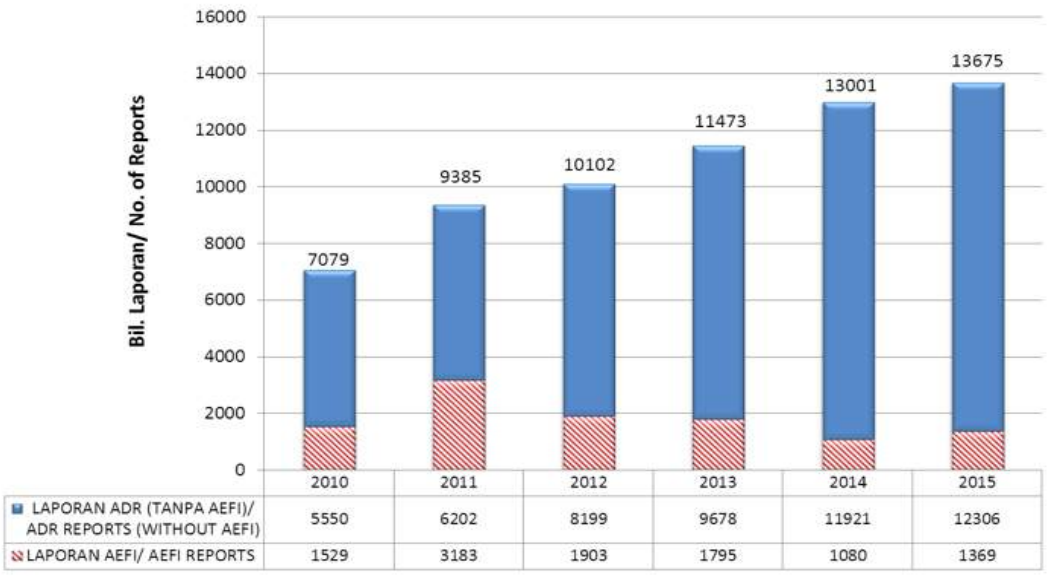
The NPCB strives to ensure the safety of medicinal products registered in Malaysia, through monitoring of adverse drug reaction (ADR) reports, identification and review of local and international drug safety issues, training and risk communication.

In 2015, the NPCB received a total of 13,675 ADR reports (Figure 1). After being presented and approved at MADRAC meetings, the reports were submitted to be included in the WHO International Database of ADR reports. In November 2015, the World Health Organisation Collaborating Centre for International Drug Monitoring, Uppsala, Sweden (WHO-UMC), reported that Malaysia was top among low-middle income countries in terms of number of ADR reports submitted per year and population.

For full details please refer to the annual report of the National Centre for Adverse Drug Reactions Monitoring (bpfk.moh.gov.my).

Rajah 1: Jumlah Laporan Kesan Advers Ubat yang Diterima di Malaysia (2000-2015)

Figure 1: Total Number of ADR Reports Received in Malaysia (2000-2015)



	2010	2011	2012	2013	2014	2015
LAPORAN ADR (TANPA AEFI)/ ADR REPORTS (WITHOUT AEFI)	5550	6202	8199	9678	11921	12306
LAPORAN AEFI/ AEFI REPORTS	1529	3183	1903	1795	1080	1369

MEMPERKUKUHKAN ANALISIS DATA DAN PENGESANAN ISYARAT KESELAMATAN

Sistem farmakovigilans (FV) BPFK yang baru mula digunakan oleh staf FV pada bulan Disember 2015. Sistem ini dijangka sedia untuk digunakan oleh pemegang pendaftaran produk, ahli profesional kesihatan, dan pengguna pada hujung tahun 2016. Elemen baru bagi sistem ini adalah:

STRENGTHENING DATA ANALYSIS AND SIGNAL DETECTION

The new NPCB pharmacovigilance (PV) system started being used by PV staff in December 2015. The system is targeted to be available for use by product registration holders, healthcare professionals and consumers by the end of 2016. The highlights of the new system include:

- Mengikut format ICH-E2B, yang membolehkan pemindahan data antara pangkalan data. Ini memudahkan penghantaran laporan kesan advers ke WHO dan penerimaan laporan kesan advers dari pemegang pendaftaran yang menggunakan format pangkalan data yang sama;
- Sistem penjanaan signal keselamatan secara automatik menggunakan algorithm yang telah diimplementasikan di dalam sistem;
- Sistem pengekstrakan data yang lebih mesra pengguna dan membenarkan pencarian mengikut keperluan;
- Akan diintegrasikan bersama Pharmacy Information System (PhIS) dan Clinic Pharmacy System (CPS) pada tahun 2016. Adalah dijangkakan dengan kemudahan penghantaran laporan secara elektronik ini meningkatkan lagi bilangan laporan kesan advers dari institusi kesihatan awam.

- *ICH-E2B compatible format allowing ease of data transfer between databases, such as NPCB data submission to WHO, and receipt of ADR reports from product registrations holders;*
- *Automated safety signal generation using an in-built algorithm;*
- *User-friendly data extraction system which allows customised queries;*
- *To be integrated with the Pharmacy Information System (PhIS) and Clinic Pharmacy System (CPS) in 2016. This will further enhance electronic submission of ADR reports nationwide, with an expected increase in the number of reports received from public healthcare facilities.*

MEMPERKUKUHKAN FARMAKOVIGILANS VAKSIN

BPFK telah menerima 1,369 laporan kesan advers berikutan pelalian (AEFI) pada tahun 2015, 1,094 (79.9%) daripadanya melibatkan vaksin Human Papilloma Virus (HPV). Pemantauan secara aktif dijalankan untuk vaksin ini sejak diperkenalkan ke dalam Program Imunisasi Kebangsaan pada tahun 2010. Didapati majoriti kesan advers yang dilaporkan melalui program pemantauan secara aktif ini adalah kesan advers ringan, dan pelalian HPV di Malaysia terus merupakan program pencegahan kanser serviks yang selamat.

Jawatankuasa Farmakovigilans Vaksin dan Jawatankuasa Pakar Keselamatan Vaksin

Selaras dengan peranan BPFK dalam pemonitoran keselamatan vaksin terutamanya dalam pengendalian dan pemantauan AEFI, pihak BPFK telah mengambil alih Jawatankuasa Kecil Farmakovigilans Keselamatan Vaksin (JKFKV) ini dari Bahagian Perkhidmatan Farmasi mulai **Februari 2015.** Nama telah dipinda kepada **Jawatankuasa Farmakovigilans Vaksin (JFV)** dan pengemaskinian ahli mesyuarat dibuat dengan perlantikan baru.

Selain itu, proses penubuhan **Jawatankuasa Pakar Keselamatan Vaksin (JPKV)** juga telah dimulakan pada tahun 2015. Jawatankuasa ini berfungsi untuk membuat keputusan akhir mengenai hubungkait vaksin dengan kes-kes AEFI serius yang memerlukan perbincangan lanjut.

STRENGTHENING THE PHARMACOVIGILANCE OF VACCINES

The NPCB received 1,369 Adverse Events Following Immunisation (AEFI) reports in 2015, 1,094 (79.9%) involving the Human Papilloma Virus (HPV) vaccine. Active surveillance is conducted for this vaccine since it was introduced into the National Immunisation Programme in 2010. The majority of the adverse events reported via this active surveillance programme have been non-serious, and HPV vaccination in Malaysia continues to be a safe programme for prevention of cervical cancer.

Vaccine Pharmacovigilance Committee and Safety Expert Group

*In line with the role of NPCB in monitoring the safety of vaccines, especially in handling and monitoring AEFI, NPCB has taken over the "Jawatankuasa Kecil Farmakovigilans Keselamatan Vaksin (JKFKV)" from the Pharmaceutical Services Division since **February 2015.** The committee was renamed as the **'Vaccine Pharmacovigilance Committee (JFV)'** and new members have been appointed, continuing the close collaboration with the Public Health division.*

*NPCB also began the process of establishing a **Vaccine Safety Expert Group (JPKV)** in 2015. The role of this group is to make the final decision regarding the causal relationship between a vaccine and serious AEFI cases which require further discussion.*

Garispanduan Berkaitan Vaksin

Edisi kedua Garispanduan Farmakovigilans Vaksin di Malaysia telah dikemas kini dengan pindaan kepada carta alir pengendalian kejadian AEFI serius yang melibatkan fasiliti KKM serta fasiliti kesihatan swasta. Prosedur yang dikaji semula termasuk: kuarantin dan siasatan kualiti vaksin, siasatan terhadap pesakit, dan pemeriksaan ke atas stor penyimpanan vaksin di fasiliti yang memberi pelalian.

KESAN ADVERS BERKAITAN PRODUK YANG DISYAKI CAMPUR PALSU

BPFK juga menerima laporan ADR yang beserta sampel produk, biasanya untuk produk-produk tradisional, makanan dan kosmetik, yang dihantar oleh pengguna atau pengamal perubatan yang mengesyaki produk dicampur palsu. BPFK menjalankan ujian makmal ke atas sampel-sampel ini bagi mengenal pasti bahan terlarang yang dicampur palsu, termasuk steroid, antihistamin, ubat antiradang bukan steroid (NSAID), atau agen pelangsing. Sila rujuk kepada bahagian "Pengujian Sampel" laporan tahunan ini untuk maklumat lanjut.

Satu (1) draf kenyataan akhbar telah disediakan berkaitan produk traditional tidak berdaftar yang dilaporkan menyebabkan ADR berulang kali. Komunikasi berkaitan keselamatan ubat turut dilaksanakan melalui surat amaran atau pekeliling, dan maklum balas kepada pelapor ADR.

KUALITI LAPORAN ADR

Usaha juga diambil untuk meningkatkan kualiti laporan ADR yang diterima di Malaysia. WHO-UMC menilai kualiti laporan dengan menggunakan sistem 'Documentation Grading - Completeness Score'. Malaysia telah memperoleh skor purata sebanyak 0.45 dari tahun 2010-2013, dan telah berjaya meningkatkan skor kepada 0.72 pada tahun 2015.

Dengan adanya sistem farmakovigilans dan pangkalan data yang baru, serta latihan berterusan untuk pelapor, diharapkan agar laporan yang lebih lengkap akan diterima.

JAWATANKUASA PENASIHAT KESAN ADVERS UBAT KEBANGSAAN (MADRAC)

MADRAC telah ditubuhkan pada tahun 1987 di bawah PBKD untuk memainkan peranan memantau profil keselamatan ubat-ubatan yang berdaftar di Malaysia. Ahli-ahli MADRAC untuk sesi 2013-2015 terdiri daripada pakar-pakar perunding Kementerian Kesihatan Malaysia (KKM) dari pelbagai bidang kepakaran, ahli farmasi, ahli

Guidelines Related To Vaccines

The second edition of the Malaysian Guidelines on Pharmacovigilance of Vaccines has been updated with revision to the investigation procedures for serious AEFI cases involving MOH and private healthcare facilities. The revised procedures include: vaccine quarantining, vaccine handling, vaccine quality investigation, patient investigation, and investigation of vaccine storage at the immunisation facility.

ADVERSE EVENTS DUE TO SUSPECTED ADULTERATED PRODUCTS

The NPCB receives ADR reports with samples of products, mainly for traditional medicines, food and cosmetics, sent in by consumers or healthcare professionals who suspect adulteration. The NPCB conducts tests on these samples to identify suspected adulterants including steroids, antihistamines, Nonsteroidal anti-inflammatory drugs (NSAIDs), or slimming agents. Please refer to the "Sample Testing" section of this report for further details.

One (1) press release was prepared regarding unregistered traditional products associated with recurrent ADR reports. Drug safety communication was also carried out through product alerts or circulars, and feedback to ADR reporters.

QUALITY OF ADR REPORTS

Further measures are being taken to increase the quality of ADR reports in Malaysia. The WHO-UMC measures report quality using the 'Documentation Grading - Completeness Score' system. Malaysia obtained an average score of 0.45 from 2010 to 2013, and has successfully increased this to 0.72 in 2015.

With the new Pharmacovigilance system and database, as well as continuous training for reporters, it is hoped that more complete reports will be received.

MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC)

MADRAC was established in 1987 under the DCA to perform the function of monitoring safety profiles of drugs registered for use in Malaysia. MADRAC members for the 2013-2015 session comprise of Ministry of Health consultants from various specialties,

akademi dari universiti tempatan, dan wakil daripada beberapa pertubuhan profesional.

Semasa mesyuarat MADRAC yang diadakan dua bulan sekali, verifikasi causality dilakukan untuk semua laporan ADR tempatan, dan sebarang isu keselamatan ubat yang berkaitan akan dibincangkan supaya PBKD dapat dibekalkan dengan maklumat dan cadangan pengurangan risiko, jika perlu.

pharmacists, academicians from local universities, and representatives from professional bodies.

During MADRAC meetings held once in two months, causality verification is done for all local ADR reports, and all pertinent drug safety issues are discussed to provide DCA with information and recommendations if required.

PEMANTAUAN ISU KESELAMATAN UBAT-UBATAN

Pada tahun 2015, sejumlah 82 makluman isu keselamatan ubat telah dikenal pasti melalui aktiviti penyaringan laman sesawang agensi regulatori rujukan BPFK, yang dijalankan setiap hari bekerja. Setelah dikaji, 16 isu telah dibentangkan semasa mesyuarat MADRAC untuk memutuskan tindakan pengurangan risiko yang perlu diambil. Kebanyakan daripada isu tersebut melibatkan tindakan pengemaskinian maklumat sisip bungkusan produk, contohnya mengetatkan indikasi atau menambah kontraindikasi. Tindakan regulatori bagi lima (5) isu telah dicadangkan kepada PBKD. Hasilnya, direktif PBKD telah dikeluarkan untuk memastikan sisip bungkusan semua produk generik yang mengandungi bahan aktif terbabit dikemas kini dengan maklumat keselamatan berkenaan.

MONITORING DRUG SAFETY ISSUES

In 2015, a total of 82 drug safety issue alerts were identified through screening of reference regulatory agency alerts which is carried out daily. Following review, 16 issues were presented at MADRAC meetings to determine the appropriate risk minimisation measures. The majority of these issues resulted in updates to the package insert safety information, such as tightening of indications or additional contraindications. Regulatory actions for five (5) of these issues were proposed to the DCA, resulting in DCA directives issued to ensure package inserts of all generic products containing the affected active ingredients are updated with the required safety information.

Selain itu, BPFK teleh menilai dan meluluskan permohonan pengemaskinian maklumat keselamatan sisip bungkusan untuk 246 produk (95%) daripada sejumlah 259 permohonan yang diterima.

Besides that, review and approval of safety-related updates to product package inserts were carried out for 246 products (95%) out of 259 applications received.

PEMANTAUAN KESELAMATAN PRODUK YANG BARU BERDAFTAR

Produk-produk yang baru berdaftar, iaitu Entiti Kimia Baru (NCE) dan produk biologik, diwajibkan mengemukakan Periodic Benefit-Risk Evaluation Reports/ Periodic Safety Update Reports (PBRERs/ PSURs) selama lima (5) tahun selepas pendaftaran. PBRER/ PSUR mengandungi maklumat tentang profil keselamatan produk di negara-negara di mana ia didaftarkan, dan sebarang perubahan atau penemuan baru berkaitan keselamatan produk. Pada tahun 2015, sebanyak 264 PBRER/PSUR yang melibatkan 162 produk telah dinilai, seterusnya melibatkan kemas kini sisip bungkusan 18 produk (11.1%) untuk memastikan ia mengandungi maklumat keselamatan terkini.

SAFETY MONITORING OF NEWLY REGISTERED PRODUCTS

Newly registered products, namely New Chemical Entities (NCEs) and biologic products are required to submit Periodic Benefit-Risk Evaluation Reports/ Periodic Safety Update Reports (PBRERs/ PSURs) for the first five years post-registration. PBRERs/ PSURs contain information on the product safety profile in countries where it is registered, and any changes or new findings related to product safety. In 2015, a total of 264 PBRERs/ PSURs involving 162 products were assessed, resulting in implementation of package insert changes for 18 products (11.1%) to ensure that they contain the latest safety information.

Pelan pengendalian risiko (RMP) juga dikemukakan oleh pemegang pendaftaran produk kepada BPFK sekiranya timbul sebarang risiko yang menjejaskan keseimbangan faedah-risiko sesuatu produk. Pada tahun 2015, 28 RMP yang melibatkan 26 produk berdaftar telah dinilai. Pengemaskinian maklumat keselamatan sisip bungkusan telah dilaksanakan untuk satu produk

Risk management plans (RMPs) are also submitted by product registration holders to NPCB when there is any concern about a risk affecting the benefit-risk balance of a product. In 2015, 28 RMPs involving 26 registered products were reviewed. Package insert safety updates were initiated for one product based on the information in the RMP to maintain product safety. Besides that, the

berdasarkan maklumat daripada RMP dalam usaha mengekalkan keselamatan produk. Selain itu, BPFK telah menjalankan penilaian RMP pra-pendaftaran, serta memberikan panduan dan nasihat kepada pemegang pendaftaran produk bagi beberapa produk biologik sebelum RMP dilaksanakan.

NPCB conducted pre-registration RMP evaluation, as well as provided consultation and advice to the product registration holders prior to implementation of RMPs for some biologic products.

RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP)

Sejak bulan April 2011, pengemukaan Risalah Maklumat Ubat untuk Pengguna (RiMUP) telah diwajibkan untuk produk yang boleh diadministrasi sendiri oleh pengguna. RiMUP untuk lebih daripada 1,100 produk berdaftar telah dimuat naik pada laman web BPFK untuk dibaca dan dicetak oleh pengguna atau ahli professional kesihatan.

Pada tahun 2015, sejumlah 3,426 RiMUP telah dinilai untuk produk berdaftar. Daripada jumlah ini, 451 (13.2%) telah diluluskan dan dimuat naik pada laman sesawang BPFK untuk kegunaan pengguna atau ahli profesional kesihatan. Baki RIMUP yang dikemukakan masih di bawah penilaian. Langkah-langkah sewajarnya akan diambil untuk memastikan lebih banyak RiMUP dipaparkan sebagai rujukan dan kegunaan pihak tersebut di atas.

CONSUMER MEDICATION INFORMATION LEAFLETS (RiMUPs)

Since April 2011, the submission of Consumer Medication Information Leaflets (or Risalah Maklumat Ubat untuk Pengguna- RiMUP) is compulsory for products which are self-administered by consumers. RiMUPs for more than 1,100 registered products are currently available on the NPCB website for consumers and healthcare professionals to view and print out.

In the year 2015, a total of 3,426 RiMUPs of registered products were reviewed, with 451 (13.2%) approved and uploaded on the NPCB website for use by consumers or healthcare professionals. The remaining RiMUPs are still under evaluation. The necessary steps will be taken to ensure more RiMUPs are available for use by all parties mentioned above.

MEMPERKUKUHKAN PERANAN PELAPOR ADR

Sepanjang empat tahun yang lepas, BPFK telah menjalankan sesi latihan analisis Laporan ADR dan causality assessment di seluruh Malaysia. Pada tahun 2015, latihan ini diadakan di kawasan zon utara (meliputi Pulai Pinang, Kedah dan Perlis) serta Sabah, yang melibatkan lebih daripada 100 orang pegawai farmasi. Latihan ini diadakan selaras dengan rancangan supaya penilaian causality dilaksanakan pada peringkat fasiliti pelapor sendiri pada masa hadapan, dan diverifikasi oleh BPFK.

Selain latihan causality assessment, 15 sesi latihan atau ceramah telah disampaikan, termasuk di fasiliti kesihatan swasta seperti Pusat Perubatan Subang Jaya (SJMC) dan Institut Jantung Negara (IJN). Matlamat sesi tersebut adalah untuk meningkatkan kesedaran berkaitan kepentingan melapor ADR, meningkatkan kualiti pelaporan ADR, dan melatih pelapor untuk menjalankan causality assessment.

STRENGTHENING THE ROLE OF ADR REPORTERS

Over the past four years, NPCB has conducted training sessions all across Malaysia on ADR report analysis and causality assessment. In 2015, training was held in the northern region (covering Penang, Kedah and Perlis) and Sabah, involving more than 100 pharmacists. Such training is in-line with the future plan for causality assessment to be done at reporter institution level, for verification by the NPCB.

Besides causality assessment training, there were 15 training programmes conducted or presentations delivered, including at private healthcare facilities such as Subang Jaya Medical Centre (SJMC) and the National Heart Institute (IJN). These aimed to increase awareness on the importance of reporting, improve the quality of ADR reporting, and train reporters to perform causality assessment.

MEMPERKUKUHKAN AKTIVITI FARMAKOVIGILANS OLEH INDUSTRI FARMASEUTIKAL

Industri farmaseutikal juga memainkan peranan penting dalam menjamin keselamatan produk ubat-ubatan di Malaysia. Pada 3 Ogos 2015, BPFK telah menjalankan sesi latihan bertajuk “Preparing for Pharmacovigilance (PV) Inspection” untuk peserta daripada industri

STRENGTHENING PHARMACOVIGILANCE BY THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry also plays a big role in ensuring the safety of medicinal products in Malaysia. On 3 August 2015, the NPCB conducted a training session entitled “Preparing for Pharmacovigilance (PV) Inspection” for participants from the industry.

farmaseutikal. Topik-topik yang diliputi termasuk pengemaskinian Garispanduan Farmakovigilans Malaysia, langkah penubuhan Unit Farmakovigilans (FV) dan peranan pegawai FV di industri, serta pengenalan kepada praktis audit dan pemeriksaan FV, yang akan dilaksanakan di Malaysia secara berperingkat.

BPFK akan bekerjasama dengan pihak industri, termasuk syarikat tempatan/ generik, dengan matlamat untuk memastikan setiap syarikat mewujudkan unit FV yang berdedikasi dan efektif.

Topics covered included updates on the Malaysian Pharmacovigilance Guidelines, establishing a PV Unit and the role of a PV Officer in the industry, as well as an introduction to the practice of PV audit and inspection, which will be implemented in phases.

The NPCB will work together with the industry, including local/ generic companies, with the aim of ensuring every company establishes a dedicated and effective PV unit.

KERJASAMA DALAM BIDANG PENYELIDIKAN

Institusi pengajian tinggi tempatan sering bekerjasama dengan BPFK untuk projek penyelidikan, termasuk untuk pelajar peringkat Sarjana dan PhD.

RESEARCH COLLABORATION

Local universities often collaborate with the NPCB for research projects, including for Masters and PhD students.

PENCAPAIAN

Bilangan laporan ADR yang diterima pada tahun 2014 terus menunjukkan peningkatan, dan melebihi norma WHO (200 laporan untuk setiap juta penduduk) sebanyak 135%.

ACHIEVEMENTS

The number of ADR reports received in 2015 continued to show an increase, exceeding the WHO norm of 200 reports per million population by about 135%.

CABARAN

1. Sebilangan besar laporan ADR yang kurang berkualiti masih diterima, terutamanya daripada pemegang pendaftaran produk. Laporan tersebut tidak mengandungi maklumat penting, justeru itu menyukarkan proses penilaian causality dan pengesanan isyarat keselamatan.
2. Kekurangan pelaporan ADR oleh sektor swasta menghalang BPFK daripada mendapat gambaran penuh situasi keselamatan ubat tempatan, dan mungkin melambatkan proses pengesanan isyarat keselamatan.
3. Jurang maklumat juga wujud disebabkan bilangan laporan ADR yang dikemukakan oleh golongan pengguna masih rendah.

CHALLENGES

1. *A large percentage of poor quality ADR reports are still received, especially from product registration holders, with important details missing which hamper causality assessment as well as signal detection.*
2. *Under-reporting of ADRs by the private healthcare sector prevents NPCB from obtaining a full picture of the local drug safety situation and may delay detection of drug safety signals.*
3. *There is also an information gap due to the small number of ADR reports submitted by consumers.*

KOSMETIK / *COSMETICS*

Semua produk kosmetik perlu bernotifikasi dengan BPFK sebelum pengilangan, pengimportan dan pemasaran di Malaysia. Pemegang notifikasi bertanggungjawab sepenuhnya untuk memastikan keselamatan, kualiti dan tuntutan produk mematuhi semua keperluan yang ditetapkan di dalam Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 dan juga Guidelines for Control of Cosmetic Products in Malaysia.

Program Pengawasan Mutu Produk Kosmetik Bernotifikasi dijalankan secara aktif dan sistematik untuk memastikan produk kosmetik di pasaran mematuhi keperluan yang ditetapkan. Tindakan punitif seperti pembatalan notifikasi akan diambil ke atas produk kosmetik yang gagal mematuhi peraturan dan keperluan tersebut.

All cosmetic products require notification with the NPCB prior to manufacture, import, sale or marketing in Malaysia. The notification holder is fully responsible to ensure that the safety, quality and claimed benefits of the product complies with all requirements stipulated by the Control of Drugs and Cosmetics Regulation 1984 as well as the Guidelines for Control of Cosmetic Products in Malaysia.

The Market Surveillance for Notified Cosmetics Programme is carried out actively and systematically to ensure that cosmetic products in Malaysia fulfill all the requirements. Punitive action such as cancellation of notification will be taken on products that fail to comply with the said regulations and requirements.

NOTIFIKASI KOSMETIK

Syarikat perlu mengemukakan notifikasi kosmetik kepada BPFK secara atas talian melalui sistem Quest. Sistem Quest tersebut telah dibangunkan dengan sistem yang berupaya untuk menyaring dan menyekat produk-produk kosmetik yang tidak mematuhi keperluan regulatori dari dinotifikasikan. Sistem ini dapat menyekat atau menghalang produk-produk kosmetik yang mengandungi bahan terlarang atau melebihi had dan syarat yang dibenarkan daripada memasuki pasaran Malaysia. Notifikasi yang disekat memerlukan semakan lanjut ke atas maklumat notifikasi oleh pegawai BPFK.

Pada tahun 2015, sebanyak 85,018 notifikasi kosmetik telah dikemukakan kepada BPFK, iaitu peningkatan sebanyak 7.7% berbanding tahun sebelumnya (Rajah 1).

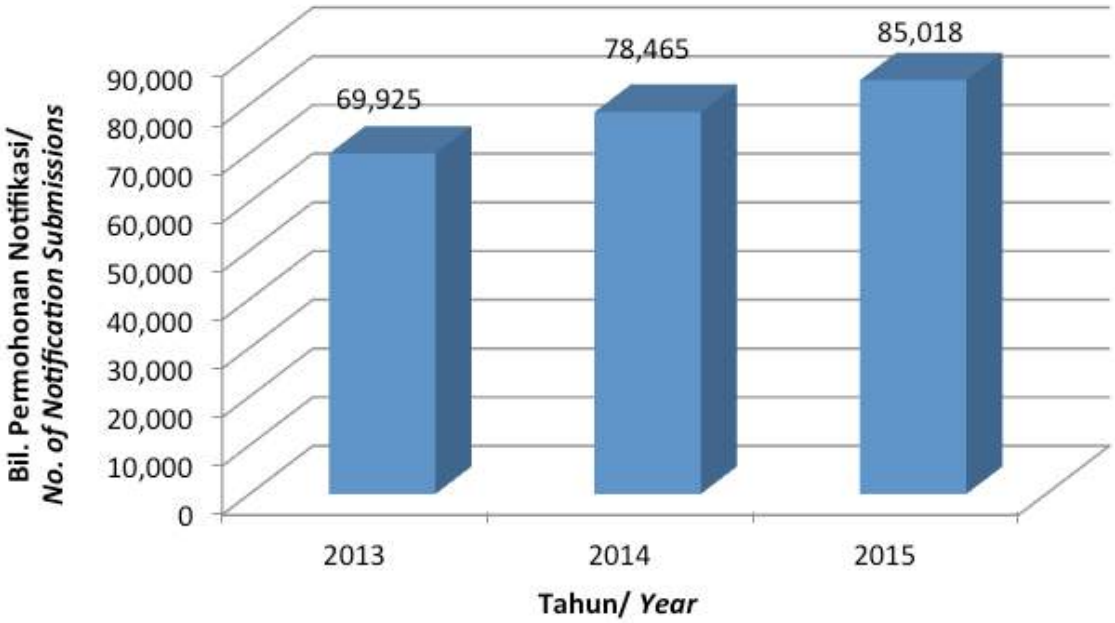
COSMETIC NOTIFICATION

A company needs to submit cosmetic notification to NPCB via the Quest online system. The Quest system was developed with the ability to screen and block cosmetic products that do not meet the regulatory requirement from being notified. This system can prevent cosmetic products with formulations that contain banned substances or substances exceeding the allowable limit or permitted conditions of use from entering the Malaysian market. Blocked notifications will undergo further evaluation.

In year 2015, a total of 85,018 cosmetic notifications were submitted to NPCB, representing an increase of 7.7% compared to 2014 (Figure 1). As of 31 December

Rajah 1: Bilangan Notifikasi Kosmetik yang Dikemukakan (2013-2015)

Figure 1: Number of Cosmetic Notification Submissions (2013-2015)



Sehingga 31 Disember 2015, terdapat sejumlah 146,283 kosmetik bernotifikasi di Malaysia.

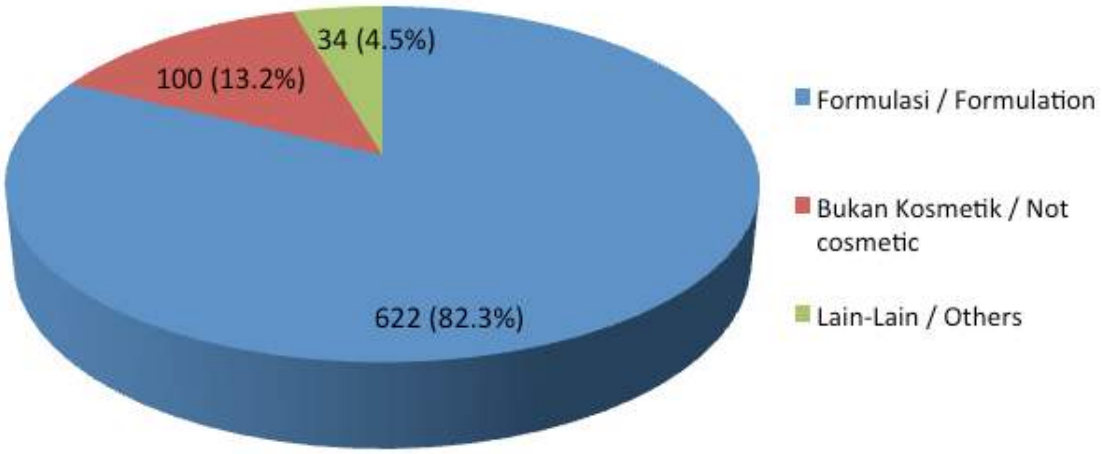
Sejumlah 756 notifikasi kosmetik yang dikemukakan telah ditolak pada tahun 2015, di mana 622 (82.3%) ditolak kerana formulasi tidak menepati garispanduan, 100 (13.2%) kerana produk tersebut tidak dikelaskan sebagai kosmetik dan 34 (4.5%) atas sebab-sebab lain (Rajah 2). Bilangan penolakan telah meningkat sebanyak 35.5% berbanding dengan tahun 2014.

2015, there were a total of 146,283 notified cosmetics in Malaysia.

A total of 756 cosmetic notifications submissions were rejected in year 2015, of which 622 (82.3%) were due to non-compliance of product formulation to the guideline, 100 (13.2%) were because the products were not classified as cosmetic products and 34 (4.5%) due to other reasons (Figure 2). The number of cosmetics rejected increased 35.5% compared to 2014.

Rajah 2: Penolakan Notifikasi Kosmetik (2015)

Figure 2: Cosmetic Notification Rejection (2015)



AKTIVITI SURVEILANS KOSMETIK DI PASARAN

Aktiviti surveilans seperti penyaringan maklumat produk, ujian makmal ke atas sampel produk, pemantauan label, audit Product Information File (PIF), pemantauan iklan produk kosmetik, pengendalian aduan produk, dan penilaian tuntutan produk dijalankan ke atas produk kosmetik yang dipasarkan di Malaysia untuk memastikan produk tersebut mematuhi peraturan dan garis panduan yang ditetapkan.

Produk kosmetik yang disasarkan untuk surveilans termasuk produk berisiko tinggi seperti produk untuk kegunaan bayi, produk untuk digunakan di sekitar mata atau membran mukus, serta produk pemutih kulit yang berpotensi dicampur palsu dengan bahan racun berjadual seperti hydroquinone dan merkuri. Manakala, produk kosmetik yang disasarkan untuk pemantauan label adalah produk dengan nama atau kegunaan yang mengelirukan atau 'ganjil', produk pengkonturan badan, produk untuk urutan, produk untuk payudara, dan produk berpotensi membuat tuntutan berlebihan seperti produk anti-jerawat dan anti-kedut.

Untuk maklumat lanjut berkaitan dengan persampelan dan pengujian makmal ke atas produk kosmetik serta semakan label, sila rujuk kepada bahagian "Surveilans" laporan tahunan ini.

MARKET SURVEILLANCE OF COSMETICS

Surveillance activities such as product information screening, laboratory testing on cosmetic samples, label monitoring, Product Information Files audit, cosmetic advertisement monitoring, cosmetic complaint investigation and product claim evaluation are carried out to ensure that notified cosmetics comply with the regulation and guidelines.

Cosmetic products that are targeted for surveillance include high risk products for use on babies, products to be used around the eye area and mucous membrane, and whitening products have the potential to be adulterated with scheduled poisons such as hydroquinone and mercury. In contrast, cosmetic products that are targeted for label check comprise of products with name and function that are confusing or "unusual", body contouring, massage and bust area products, as well as products with potential for over-claim such as anti-acne and anti-wrinkle products.

For further information regarding cosmetic product sampling, lab testing and label monitoring, please refer to the Surveillance section of this report.

AUDIT FAIL MAKLUMAT PRODUK (PIF)

BPFK menjalankan audit Fail Maklumat Produk (PIF) untuk memastikan pemegang notifikasi mematuhi keperluan notifikasi dengan menyimpan maklumat terperinci berkaitan produk kosmetik, termasuk dokumen berkaitan data kualiti bahan mentah dan produk siap, serta data keselamatan dan dokumen sokongan untuk tuntutan.

Sebanyak 702 PIF telah diaudit pada tahun 2015, iaitu peningkatan hampir 30% berbanding tahun 2014 (Rajah 3).

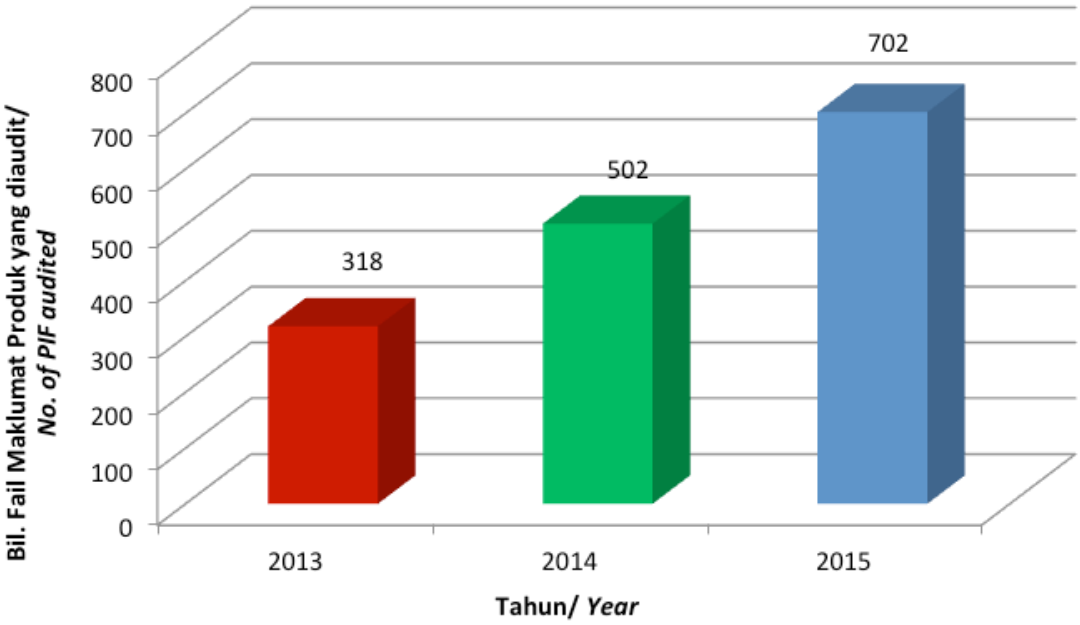
PRODUCT INFORMATION FILE (PIF) AUDIT

The NPCB carries out PIF audits to ensure that notification holders fulfill the notification requirement by keeping detailed information regarding their cosmetic products. These include quality data for raw materials and finished products, as well as safety data and supporting documents for product claims.

A total of 702 PIFs were audited in year 2015, which is almost a 30% increase compared to 2014 (Figure 3).

Rajah 3: Bilangan Fail Maklumat Produk Yang Diaudit (2013-2015)

Figure 3: Number of Product Information Files (PIF) Audited (2013-2015)



PEMANTAUAN IKLAN KOSMETIK

Bermula tahun 2012, BPFK telah meningkatkan pemantauan ke atas iklan produk kosmetik. Tindakan regulatori telah diambil ke atas iklan yang tidak mematuhi Kod Pengiklanan Kosmetik. Pada tahun 2015, sejumlah 1,340 iklan dari media cetak dan elektronik telah dipantau, dan tindakan punitif diambil ke atas 388 (29%) iklan yang terlibat kerana iklan-iklan tersebut didapati melampaui skop takrifan kosmetik (74.2%) dan diiklankan dengan tuntutan yang tidak berasas (25.8%).

Selain itu, BPFK turut menerima 85 aduan berkaitan iklan kosmetik daripada syarikat dan Bahagian Penguatkuasaan Farmasi. Tindakan telah diambil ke atas semua produk terlibat, di mana 79 (93%) produk telah diberikan surat amaran untuk mengeluarkan tuntutan-tuntutan yang melampaui skop takrifan kosmetik, 4 (3.5%) produk diarahkan untuk membuat pengkelasan semula kerana produk-produk tersebut bukan merupakan kosmetik, sementara baki dua produk (2.4%) diminta untuk mengemukakan dokumen sokongan bagi menyokong tuntutan yang dibuat.

MONITORING OF COSMETIC ADVERTISEMENTS

Starting from year 2012, NPCB increased monitoring activities on cosmetic advertisements. Regulatory action has been taken on advertisers who fail to comply with the Cosmetic Advertising Code. In year 2015, a total of 1,340 printed and electronic media advertisements were monitored. Punitive action was taken against 388 (29%) advertisements whereby 74.2% were beyond the cosmetic scope and 25.8% contained unsubstantiated claims.

Besides that, NPCB also received 85 advertisement-related complaints from companies and the Pharmacy Enforcement Division. Action was taken towards all affected products where 79 (93%) were issued warning letters to remove the non-permissible claim, 4 (4.7%) products were instructed to be reclassified while the remaining two (2.3%) were required to provide supporting documents for the claims made.

PEMBATALAN NOTIFIKASI

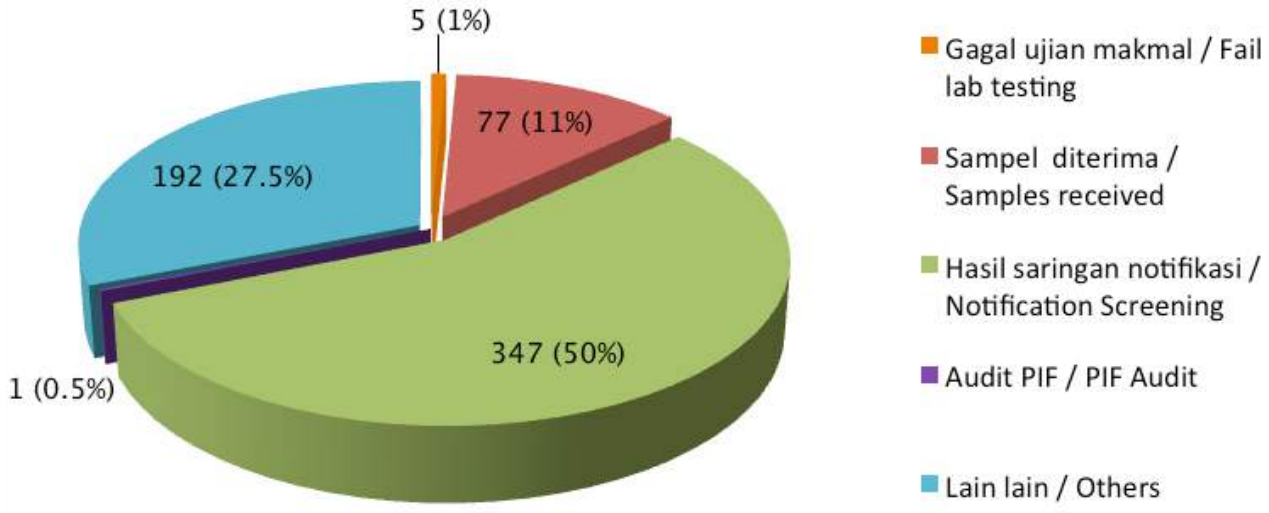
Pembatalan notifikasi telah dijalankan ke atas 698 produk kosmetik pada tahun 2015 atas sebab-sebab seperti dalam Rajah 4.

NOTIFICATION CANCELLATION

Notification cancellation was carried out on 698 cosmetic products in year 2015 due to reasons stated in Figure 4.

Rajah 4: Sebab-sebab Pembatalan Notifikasi Kosmetik (2015)

Figure 4: Reasons for Notification Cancellations (2015)



KERJASAMA DENGAN BAHAGIAN PENGUATKUASAAN FARMASI

BPFK sentiasa bekerjasama dengan Bahagian Penguatkuasaan Farmasi dalam usaha membanteras produk kosmetik yang tidak mematuhi keperluan notifikasi kosmetik dan produk kosmetik tidak bernotifikasi di pasaran. BPFK telah menerima sebanyak 2,588 produk untuk pengesahan status notifikasi pada tahun 2015, iaitu peningkatan sebanyak 12.3% berbanding tahun 2014. Daripada 1,905 status notifikasi produk yang telah disahkan, 1,506 (79%) produk didapati tidak bernotifikasi dan akan diambil tindakan undang-undang selanjutnya oleh Bahagian Perkhidmatan Farmasi. Sejumlah 207 (10.9%) adalah bukan produk kosmetik dan senarai ini telah dimajukan kepada Pusat Pendaftaran Produk, BPFK untuk pengesahan lanjut, sementara baki 192 produk (10.1%) merupakan kosmetik yang bernotifikasi.

COLLABORATION WITH THE PHARMACY ENFORCEMENT DIVISION

The NPCB also collaborates with the Pharmacy Enforcement Division in an effort to eliminate non-compliant as well as unnotified cosmetic products. NPCB has received notification verification for a total of 2,588 products in 2015 which showed an increase of 12.3% compared to year 2014. From the number of notification verifications received, 1,905 notification statuses were verified, of which 1,506 (79%) were un-notified products and were subjected to further legal action by the Pharmacy Enforcement Division. A total of 207 (10.9%) were not cosmetic products and this list was forwarded to the Centre for Product Registration, NPCB, for further verification while the remaining 192 products (10.1%) were notified cosmetics.

AKTIVITI DAN PENGLIBATAN LAIN

BPFK turut terlibat dalam aktiviti-aktiviti lain berkaitan kawalan produk kosmetik, seperti ditunjukkan pada Jadual 1.

OTHER ACTIVITIES AND INVOLVEMENT

NPCB is also involved in other activities related to cosmetics regulation, as shown in Table 1.

Jadual 1: Aktiviti dan Penglibatan Lain Berkaitan Pengawalan Kosmetik (2015)

Table 1: Other Activities and Involvement Related to Control of Cosmetics (2015)

Bil./*No*	Aktiviti / Penglibatan	*Activities / Involvement*
1.	Penglibatan dalam mesyuarat di peringkat ASEAN iaitu mesyuarat ASEAN Cosmetic Committee dan mesyuarat ASEAN Cosmetic Scientific Body. Mengusulkan kepada mesyuarat untuk mengkaji semula kegunaan beberapa bahan dalam produk kosmetik iaitu : • Thioglycolic Acid • Kemasukkan 9 bahan-bahan baru dalam produk pewarna rambut • 3-Benzylidene Camphor Terlibat dalam Jawatankuasa Kerja untuk menyemak semula bahan-bahan di dalam Annex III ASEAN Cosmetic Directive.	*Involvement in meetings at ASEAN level, namely the ASEAN Cosmetic Committee meeting and ASEAN Cosmetic Scientific Body meeting.* *Proposed to review the use of a few substances in cosmetic products as follows :* • *Thioglycolic Acid* • *The entry of 9 new substances in hair dye products* • *3-Benzylidene Camphor* *Involved in the Task Force to recheck substances listed in Annex III of ASEAN Cosmetic Directive.*
2.	Sesi taklimat telah diberikan kepada wakil syarikat dari negara Perancis dan Kedutaan Russia serta latihan sangkutan kepada pegawai dari negara Tanzania dan Papua New Guinea	*Talks were given to French companies and representatives from the Russian Embassy, and attachment training was given to officers from Tanzania and Papua New Guinea.*
3.	Kerjasama dengan Bahagian Penguatkuasaan Farmasi bagi memantau status produk yang diimport masuk ke Malaysia di pintu masuk negara. Selain itu, beberapa sesi ceramah telah diberikan kepada pegawai-pegawai Cawangan Penguatkuasa Farmasi Negeri bagi tujuan perkongsian maklumat	*Collaborations with the Pharmacy Enforcement Division in monitoring the status of products imported to Malaysia at entry points. In addition to that, talks were given to State Pharmacy Enforcement officers as a mean for information sharing.*
4.	Beberapa sesi taklimat kepada syarikat telah dianjurkan melalui Program Transformasi Luar Bandar (RTC) bagi meningkatkan kemampuan perusahaan kecil dan sederhana (SME)	*Several briefing session for companies were organised through the Rural Transformation Programme (RTC) to enhance the industrial capabilities of Small Medium Enterprises (SMEs*
5.	Kerjasama berterusan dengan Persatuan Kosmetik Malaysia : (i) Jawatankuasa Kerja Teknikal Kosmetik (BPFK, CTFAM & FMM-MCTIG) (ii) Jawatankuasa Pakar Keselamatan Kosmetik (CoSEC)	*On-going collaborations with the Malaysian Cosmetic Associations :* *(i) Cosmetic Technical Working Group (NPCB, CTFAM & FMM-MCTIG)* *(ii) Cosmetic Safety Expert Committee (CoSEC)*
6.	Menganjurkan seminar dan pameran untuk Program Pencegahan dan Kesedaran Pengguna.	*Organising seminars and exhibitions for Consumer Awareness & Prevention Programmes.*

CABARAN

1. Kurangnya kesedaran dan tanggungjawab syarikat dan individu yang mengiklankan kosmetik. Iklan kosmetik tersebut mengandungi maklumat yang tidak tepat, mengelirukan, tidak berasas, atau melampaui skop takrifan kosmetik terutamanya melalui internet seperti blogspot® dan media sosial Facebook®.
2. Terdapat pihak syarikat yang masih kurang memahami keperluan pelabelan kosmetik di mana tahap pematuhan kepada keperluan pelabelan masih lemah.
3. Pemegang notifikasi dan pengilang juga didapati masih kurang kemahiran teknikal untuk menyediakan dokumen-dokumen yang diperlukan bagi Fail Maklumat Produk (PIF) serta menjalankan peniliaian keselamatan terhadap bahan dan produk kosmetik.

CHALLENGES

1. *There is a lack of awareness and sense of responsibility among companies and individuals involved in producing cosmetics advertisements. Some advertisements were inaccurate, confusing, and baseless, containing claims beyond the cosmetic scope, for example on blogspot® webpages and the social media networking site, Facebook®.*
2. *Some companies lack understanding of the cosmetic labeling requirements, whereby the compliance towards these requirements is low.*
3. *Notification holders and manufacturers were found to have poor technical knowledge in preparing Product Information Files and in conducting safety assessments for cosmetic products.*

Pengujian Sampel dan Penilaian Protokol & Data Validasi

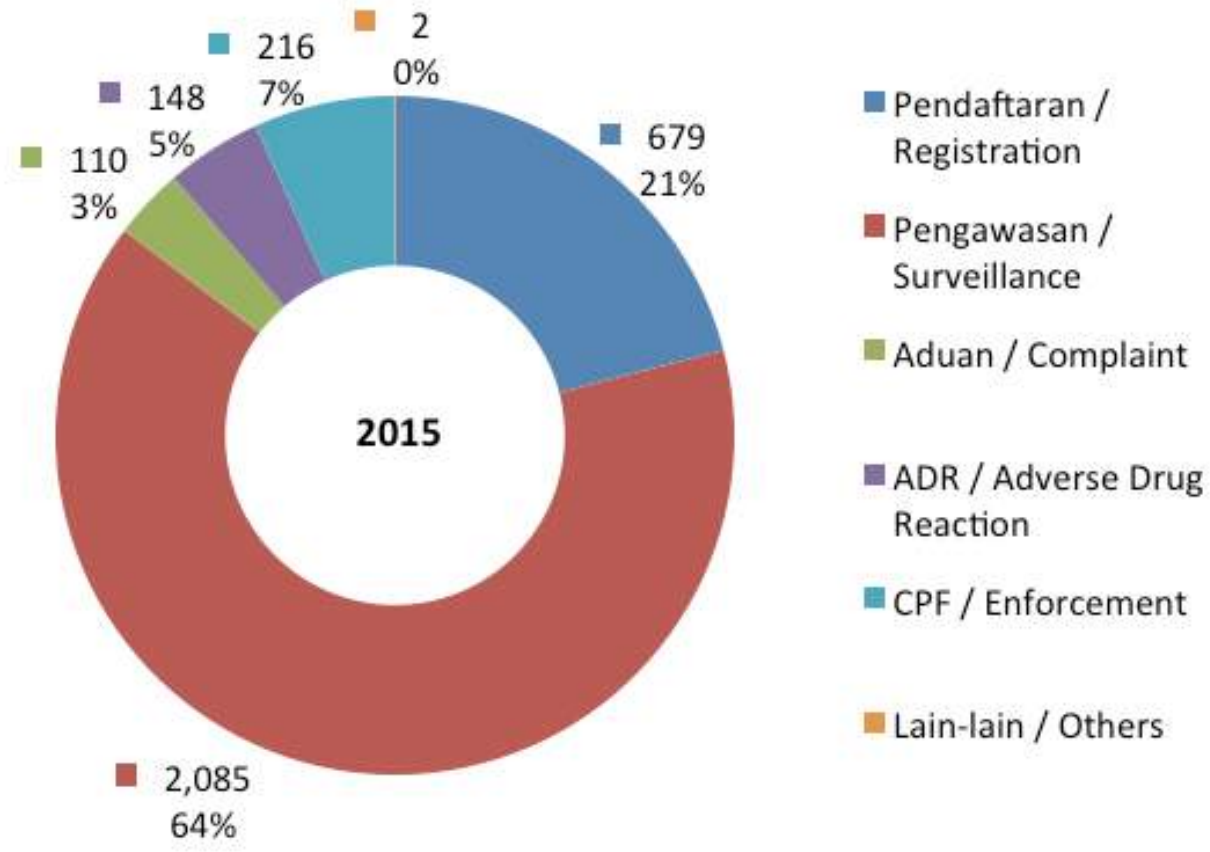
Sample Testing and Evaluation of Protocol & Validation Data

Pusat Kawalan Kualiti (PKK) bertanggungjawab menjalankan pengujian sampel dan penilaian dokumentasi data validasi berdasarkan standard regulatori global dan dilaksanakan oleh personel yang terlatih dan kompeten. Produk yang diuji adalah untuk tujuan pendaftaran bagi produk tradisional, pengawasan produk berdaftar dan juga produk komestik yang dinotifikasi dalam pasaran, kes-kes adverse drug reaction (ADR) & aduan serta sampel daripada penguatkuasa.

The Centre for Quality Control (CQC) is responsible for product testing and evaluation of analytical method validation in accordance with global regulatory standard and these duties are carried out by trained and competent personnel. Product testing is carried out for the purposes of registration for traditional products, product surveillance for registered products and notified cosmetic products, adverse drug reaction (ADR) reporting & complaint and samples from enforcement.

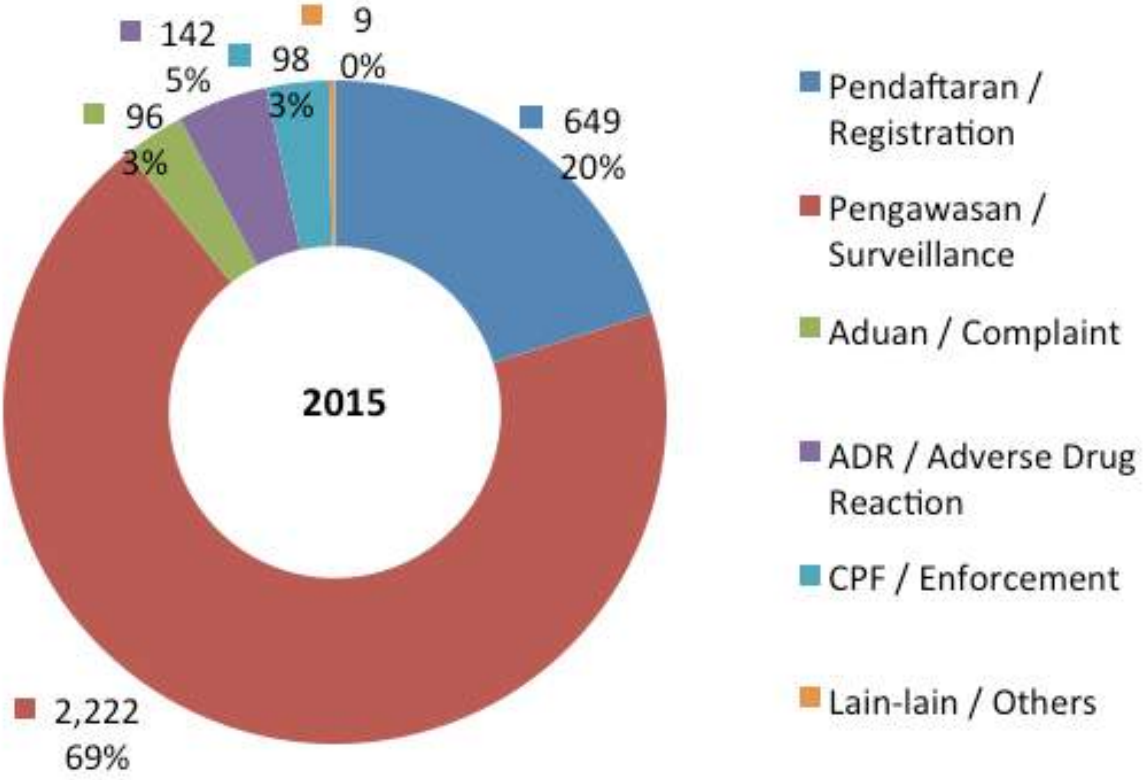
STATISTIK / *STATISTICS*

Rajah 1 : Sampel yang Diterima mengikut Kategori
Figure 1 : Sample Received according to Categories



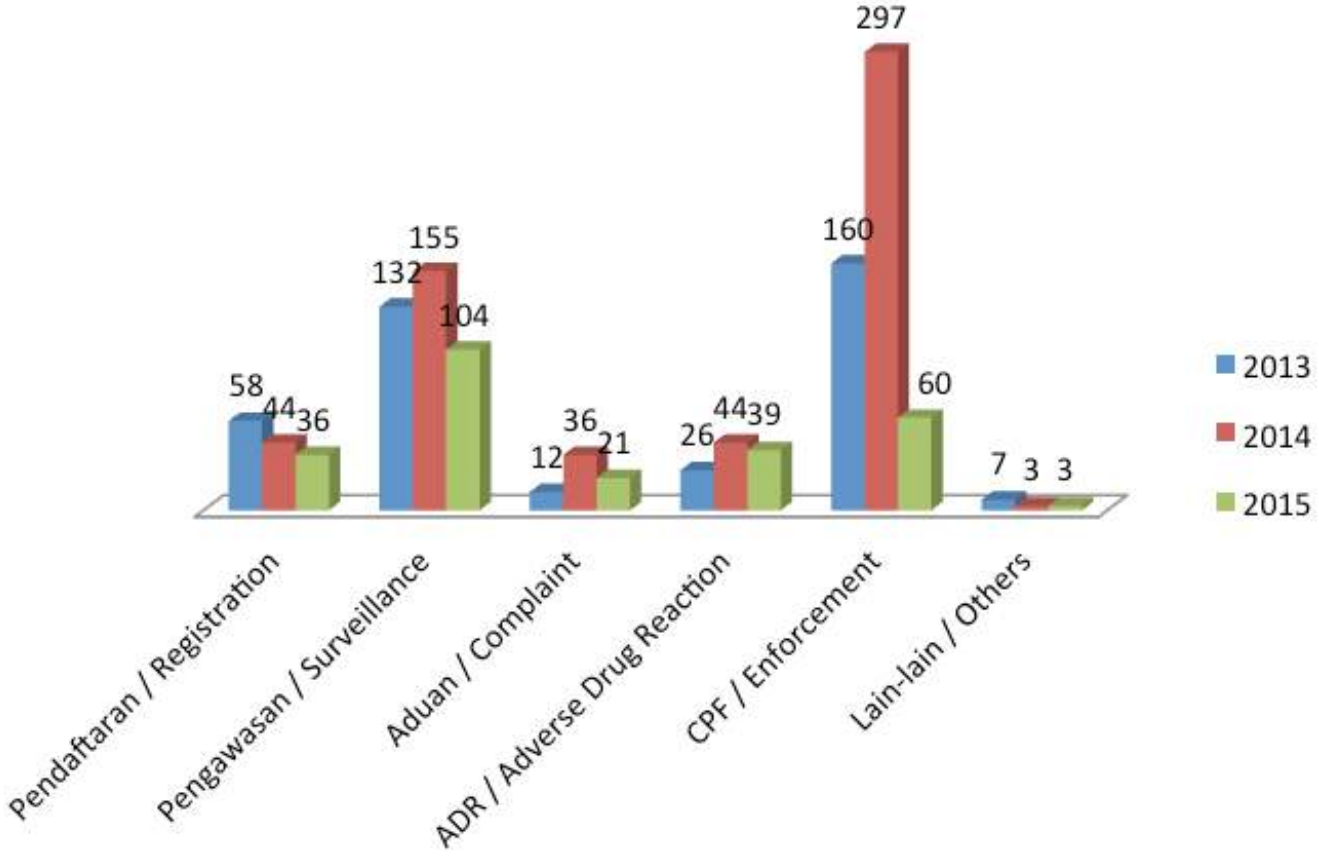
Rajah 2 : Sampel yand Diuji mengikut Kategori

Figure 2 : Sample Tested according to Categories



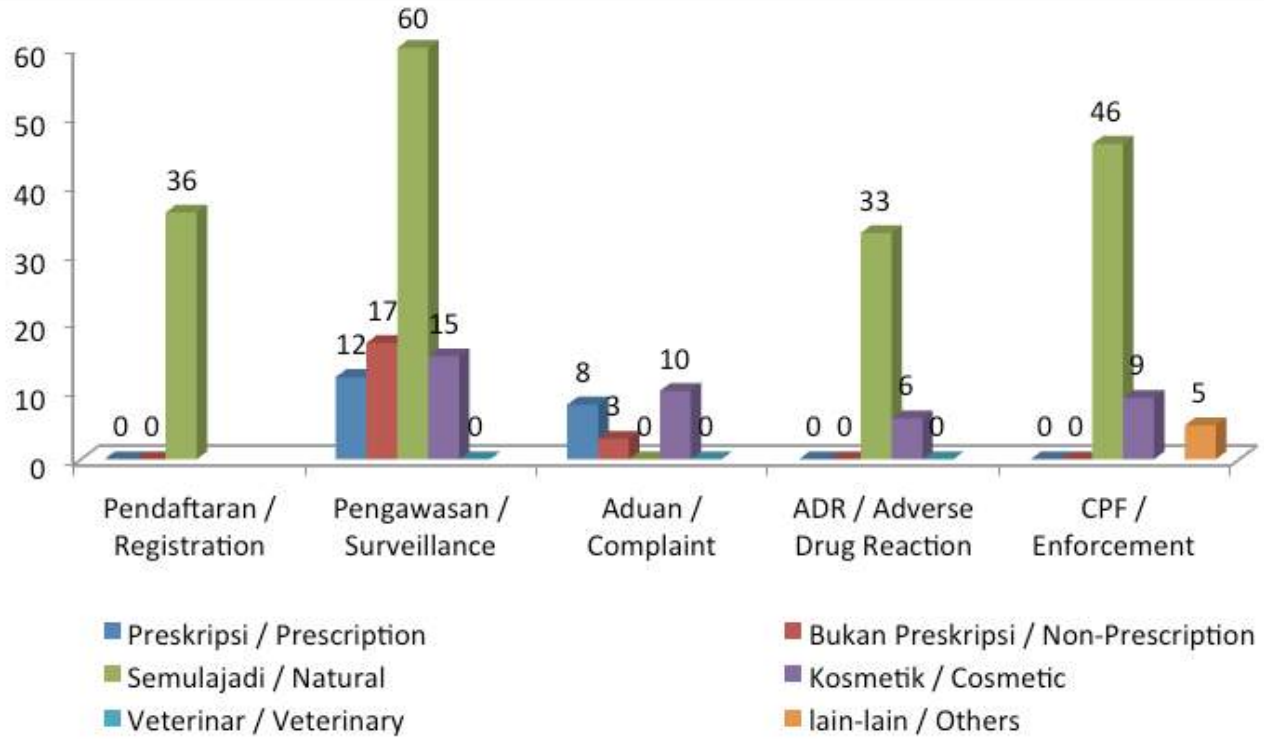
Rajah 3 : Bilangan Sampel yang Gagal Ujian untuk Tahun 2013-2015

Figure 3 : Number of Failed Samples for 2013-2015



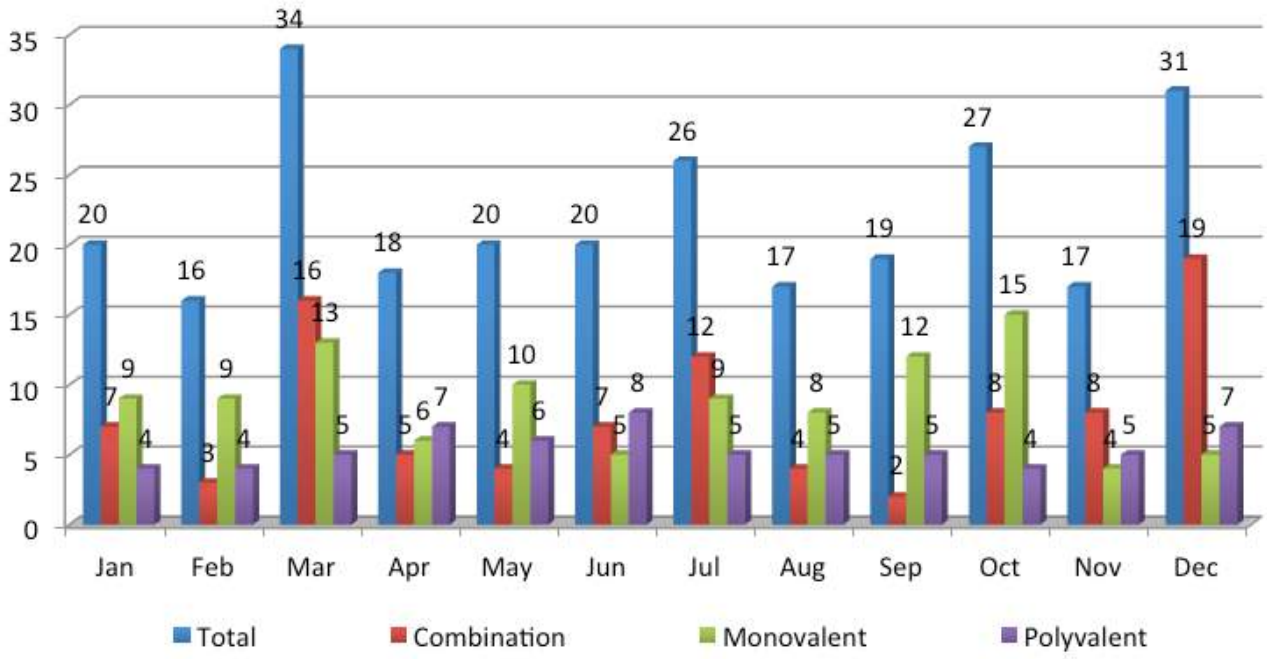
Rajah 4 : Bilangan Sampel yang Gagal Ujian Mengikut Kategori untuk Tahun 2015

Figure 4 : Number of Failed Samples by Category for 2015



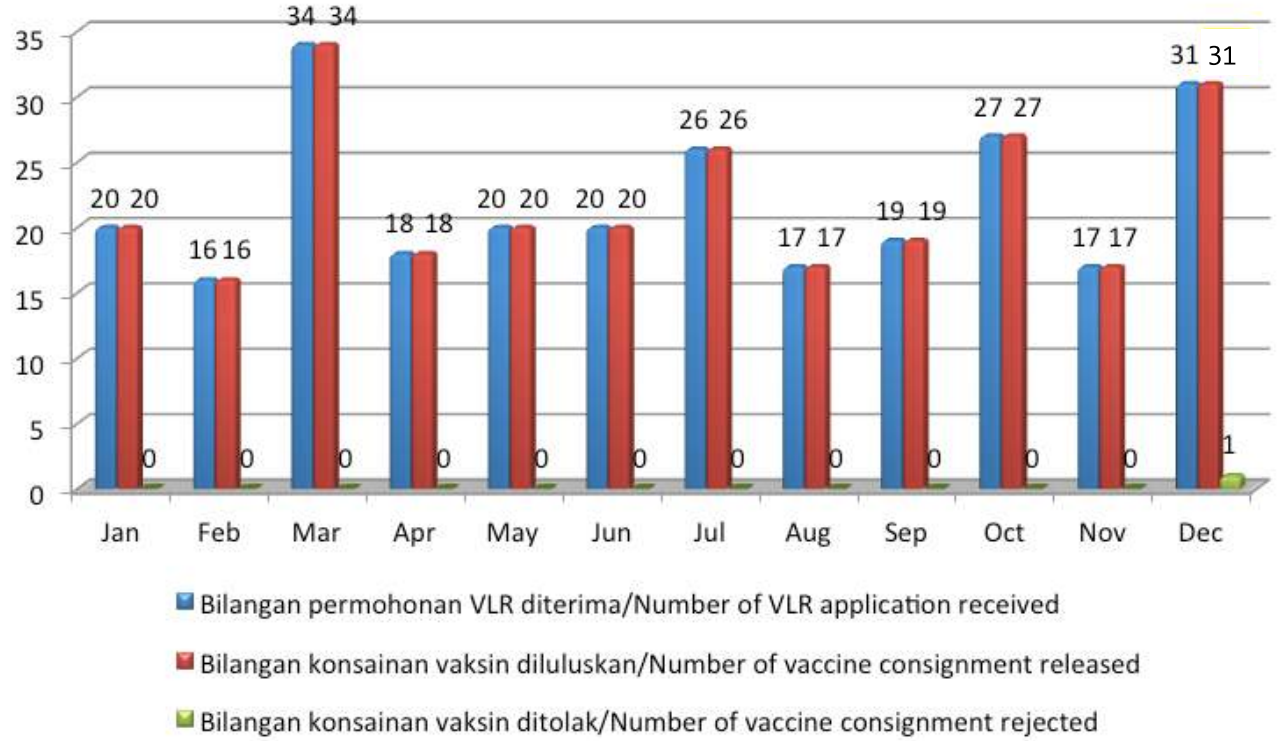
Rajah 5: Bilangan permohonan Vaccine Lot Release (VLR) diterima (Januari - Disember 2015).

Figure 5: No. of Vaccine Lot Release (VLR) application received (January - December 2015).



Rajah 6: Aktiviti Vaccine Lot Release (VLR) (Januari - Disember 2015). Keputusan yang dilabelkan kuning bermaksud pelepasan separa.

Figure 6: Vaccine Lot Release (VLR) activity (January - December 2015). Result highlighted in yellow indicates partial release.



Aktiviti Pemeriksaan

Inspection Activities

Pusat Komplians dan Pelesenan (PKP) bertanggungjawab untuk menjalankan pemeriksaan Amalan Perkilangan Baik (APB) ke atas premis pengilang keluaran berdaftar dan kosmetik bernotifikasi serta memastikan pematuhan pengilang terhadap garis panduan APB semasa. PKP juga bekerjasama dengan Cawangan Penguatkuasa Farmasi (CPF) Negeri bagi memastikan pengimport dan pemborong keluaran berdaftar mematuhi garis panduan semasa.

Pemeriksaan melibatkan jenis rutin (berjadual dari awal tahun) dan jenis bukan rutin (mengikut permohonan syarikat melalui Borang BPFK 504). Kategori premis yang diperiksa termasuk farmaseutikal (racun dan bukan racun), tradisional, kosmetik dan lain-lain (termasuk veterinar, suplemen kesihatan dan bahan aktif farmaseutikal).

Sebanyak 350 pemeriksaan APB telah dijalankan pada tahun 2015. Daripada jumlah ini, bilangan pemeriksaan ke atas premis farmaseutikal, tradisional, kosmetik dan lain-lain adalah 68, 117, 120 dan 45 masing-masing. Antara 68 pemeriksaan premis farmaseutikal yang telah dijalankan, sebanyak 17 premis melibatkan pemeriksaan luar negara.

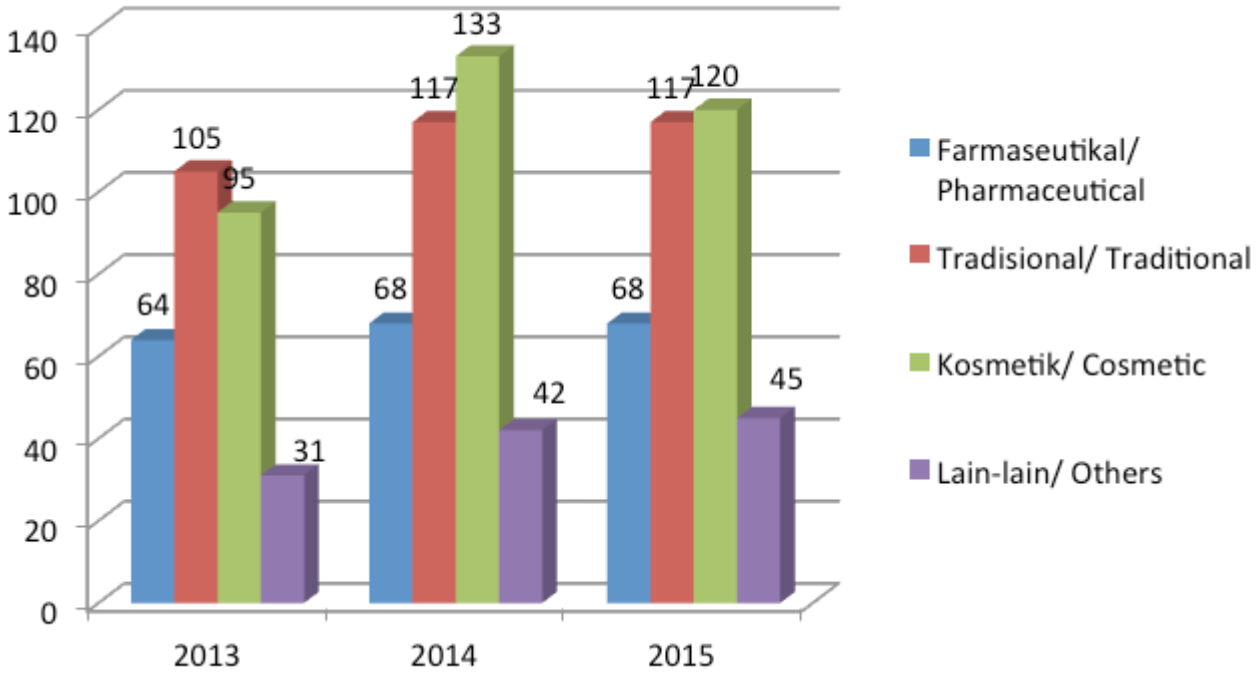
The Centre of Compliance and Licensing (CCL) is responsible for the Good Manufacturing Practice (GMP) inspections on manufacturer of registered products and notified cosmetics to ensure their compliance towards the current GMP requirements. CCL, with assistance of the State Pharmacy Enforcement Division, is also responsible to ensure the adherence of importers and wholesalers to the current Good Distribution Practice (GDP) requirements.

The inspections are of two 2 types, i.e. routine (scheduled at the beginning of the year) and non-routine (as per company's application through BPFK Form 504). The category of premises covered varies from pharmaceutical (poison and over-the-counter), traditional, cosmetic and others (includes veterinary, health supplement and active pharmaceutical ingredient).

There were 350 GMP inspections conducted in year 2015. Of these, the number of inspections on pharmaceutical, traditional, cosmetic and other premises was 68, 117, 120 and 45 respectively. There were 17 overseas inspections conducted out of the 68 pharmaceutical premises inspected.

Rajah 1: Bilangan Pemeriksaan APB yang telah dijalankan dari tahun 2013 – 2015.

Figure 1: Number of GMP Inspections carried out from year 2013 – 2015.



Sepanjang tahun 2015, pemeriksaan Amalan Pengedaran Baik (AEB) telah dijalankan ke atas 124 premis pengimport dan/ atau pemborong di sekitar Kuala Lumpur dan Selangor.

Throughout year 2015, Good Distribution Practice (GDP) inspections were conducted on 124 importer and/ or wholesaler premises within Kuala Lumpur and Selangor.

Pusat Kajian Produk Baru (PKPB) merupakan salah satu pusat dalam Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) yang bertanggungjawab:

- Menjalankan pemeriksaan ke atas Jawatankuasa Etika serta pusat kajian bioekuivalens (BE) tempatan dan luar negara
- Menjalankan pemeriksaan ke atas tapak percubaan klinikal, Sponsor dan Contract Research Organisations (CRO)
- Menjalankan pemeriksaan ke atas fasiliti-fasiliti yang menjalankan kajian bukan klinikal

The Centre for Investigational New Product (CINP) is an integral part of the National Pharmaceutical Control Bureau (NPCB). It is responsible to:

- *Conduct of inspections on ethic committee (EC), local and oversea bioequivalence (BE) center*
- *Conduct of inspections on clinical trial sites, sponsor and contract research organizations (CRO)*
- *Conduct of inspections on facilities which perform non-clinical studies*

PKPB juga bertanggungjawab memastikan semua produk kajian yang digunakan ke atas subjek-subjek dalam percubaan klinikal dipantau keselamatannya.

CINP is responsible in ensuring the investigational products administered to subjects in clinical trial are monitored in terms of safety.

1. PEMERIKSAAN GOOD LABORATORY PRACTICE (GLP)

Pada tahun 2015, Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah menjalankan sebanyak dua pemeriksaan surveilans GLP seperti berikut:

1. GOOD LABORATORY PRACTICE (GLP) INSPECTION

In 2015, the National Pharmaceutical Control Bureau (NPCB) had conducted two surveillance GLP inspections as detailed below :

Bil. *No*	Jenis Pemeriksaan *Type of Inspection*	Fasiliti Kajian *Test Facility*	Tarikh *Date of Inspection*
1.	Pemeriksaan Surveilans *Surveillance Inspection*	Environmental Technology Research Centre (ETRC), SIRIM Berhad	29 June - 1 July 2015
2.	Pemeriksaan Surveilans *Surveillance Inspection*	Herbal Medicine Research Centre (HMRC), Institute of Medical Research (IMR)	26 -30 October 2015

2. PEMERIKSAAN PUSAT KAJIAN BIOEKUIVALENS (BE)

BPFK bertanggungjawab untuk menjalankan pemeriksaan Pusat Kajian BE Tempatan dan Luar Negara untuk memastikan kajian BE yang dijalankan adalah mengikut keperluan regulatori di Malaysia dan garispanduan antarabangsa sebelum sesuatu produk generik didaftarkan di Malaysia. Ini adalah berdasarkan direktif yang dikeluarkan di bawah Peraturan 29, Peraturan Kawalan Dadah dan Kosmetik 1984, Bilangan 1 Tahun 2011. Pemeriksaan Pusat Kajian BE meliputi pemeriksaan fasiliti dan audit kajian bagi bahagian klinikal, bioanalitikal serta analisis farmakokinetik dan statistik bagi sesuatu kajian BE. Ini adalah untuk memastikan bahawa kajian BE yang dijalankan adalah mengikut keperluan regulatori, GCP dan prinsip-prinsip GLP yang berkaitan.

2. INSPECTION ON BIOEQUIVALENCE (BE) CENTRE

The NPCB is responsible for conducting inspections at Local and Foreign BE Centres to ensure that the BE studies are conducted according to the Malaysian regulatory requirements and international guidelines before the generic product is registered in Malaysia. This is in accordance with the directive issued under Regulation 29 of The Control of Drugs and Cosmetics Regulations (CDCR) 1984, Number 1 Year 2011. BE Centre inspection covers the facilities inspection and study audit for the clinical part, bioanalytical part as well as pharmacokinetic and statistical analyses of a BE study. This is to ensure that the BE studies are conducted in accordance with applicable regulatory requirements, GCP and applicable principles of GLP

a. PEMERIKSAAN PUSAT KAJIAN BE TEMPATAN

Pada tahun 2015, sebanyak lima (5) pemeriksaan telah dijalankan di pusat kajian BE tempatan yang tersenarai di bawah. Semua pemeriksaan tersebut adalah pemeriksaan penuh.

a. LOCAL BE CENTRE INSPECTION

In 2015, a total of five (5) inspections were conducted at local BE centre as listed below. All the inspections conducted were full inspectiosn.

1. Info Kinetics Sdn Bhd
2. Pusat Pengajian Sains Farmasi, Universiti Sains Malaysia (USM)
   [Institut Perubatan dan Pergigian Termaju (IPPT)- tapak kinikal dan Pusat Pengajian Sains Farmasi (PPSF)-tapak bioanalitikal]
3. University of Malaya Bioequivalence and Testing Centre (UBAT)
   [Clinical Examination Ward 2-tapak klinikal dan UBAT-tapak bioanalitikal]
4. Borneo Kinetic Sdn Bhd
   [Borneo Kinetic Sdn Bhd- tapak klinikal dan Info Kinetics Sdn Bhd- tapak bioanalitikal]
5. Questra Clinical Research Sdn Bhd

b. PEMERIKSAAN PUSAT KAJIAN BE LUAR NEGARA

Pada tahun 2015, sebanyak enam (6) Pemeriksaan Pusat Kajian BE Luar Negara telah dijalankan yang melibatkan pemeriksaan penuh seperti berikut :

b. FOREIGN BE CENTRE INSPECTION

The NPCB had conducted six (6) foreign BE centre inspections in 2015, as listed below. All the inspections conducted were full inspections.

1. Pharmacy Service Center, Chiang Mai University, Thailand
2. Quest /life Sciences Pvt. Ltd., India
3. Genuine Research Centre, Egypt
4. Vimta Labs Limited, India
5. Lotus Labs Pvt. Ltd., India
6. SC Kynetyx HT SRL, Romania

c. PEMERIKSAAN JAWATANKUASA ETIKA

Pada tahun 2015, sebanyak tujuh (7) pemeriksaan surveilans telah dijalankan ke atas Jawatankuasa Etika yang berdaftar dengan PBKD seperti berikut :

c. ETHICS COMMITTEE INSPECTION

In 2015, NPCB had conducted seven (7) surveillance inspections on Ethics Committee that are registered with DCA, as listed below :

1. Medical Research & Ethics Committee, Ministry of Health Malaysia (MREC)
2. Joint Penang Independent Ethics Committee (JPEC)
3. Medical Ethics Committee, University Malaya Medical Centre (MEC UMMC)
4. Independent Ethics Committee, Ramsay Sime Darby Health Care (IEC RSDHC)
5. Sunway Medical Centre Independent Research Ethics Committee (SREC
6. International Medical University Ethics Committee (IMUJC)
7. International Islamic University Malaysia Research Ethics Committee (IREC)

d. PEMERIKSAAN TAPAK PENYELIDIKAN KLINIKAL

Pada tahun 2015, sebanyak lapan (8) pemeriksaan Tapak Kajian Klinikal dan tiga (3) pemeriksaan Tapak Sponsor/CRO telah dijalankan seperti berikut :

d. CLINICAL TRIAL SITE INSPECTION

In 2015, a total of eight (8) inspections at clinical trial sites and three (3) inspections at Sponsor/CRO site were conducted, as listed below :

Tapak Kajian Klinikal / *Clinical Trial Site*

1. Pusat Perubatan Universiti Malaya (Protocol No: CYD 32)
2. Putrajaya Health Centre (Protocol No: CYD 14)
3. Hospital Kuala Lumpur (Protocol No: CYD 14)
4. Hospital Raja Permaisuri Bainun (Protocol No: CYD 32)
5. Hospital Pulau Pinang (Protocol No: CYD 14)
6. Hospital Umum Sarawak (Protocol No: CYD 32)
7. ISEC Sdn. Bhd. (Protocol No: C-10-041)
8. Pusat Perubatan Universiti Malaya (Protocol No: C-10-041)

Tapak Sponsor / *Sponsor Site (CRO)*

1. Dynapharm (M) Sdn. Bhd. [Protocol No.: IK0370-(04)-Meloxicam IK0350-(01)-Gabapentin]
2. Sanofi-Aventis (M) Sdn. Bhd. [Protocol No.: CYD14]
3. Pharmaniaga Manufacturing Berhad [Protocol No.: IK1690-(01) & IK1680-(01) (Gliclazide MR), IK1610-(02) Valsartan]

Aktiviti Pelesenan

Licensing Activities

BPFK bertanggungjawab untuk pengeluaran lesen bagi premis pengilang, pengimport dan pemborong. Pada tahun 2015, Pusat Komplians dan Pelesenan telah mengeluarkan sebanyak 1,885 lesen iaitu 266 Lesen Pengilang, 455 Lesen Mengimport dan 1,165 Lesen Pemborong (rujuk Rajah 1).

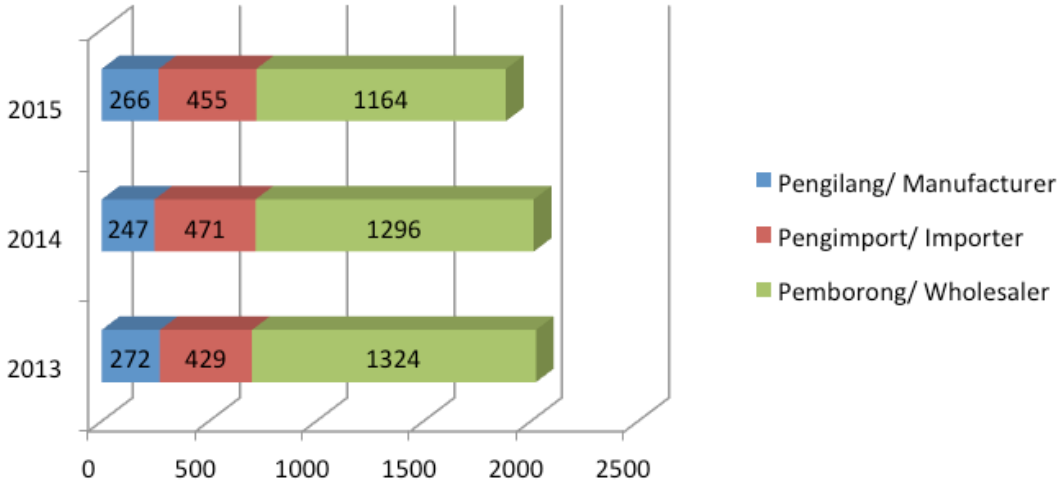
Sebanyak 739 senarai keluaran (tambahan) lesen keluaran berdaftar dan 470 sijil APB telah dikeluarkan pada tahun 2015 (rujuk Rajah 2).

The NPCB plays a role in the issuance of licenses to premises of manufacturer, importer and wholesalers. In the year 2015, the Centre for Compliance and Licensing has issued a total of 1,885 licenses which comprised of 266 Manufacturer's License, 455 Import License and 1,165 Wholesaler's License (refer to Figure 1).

There were 739 additional product list for registered products along with 470 GMP certificates issued in year 2015 (refer to Figure 2).

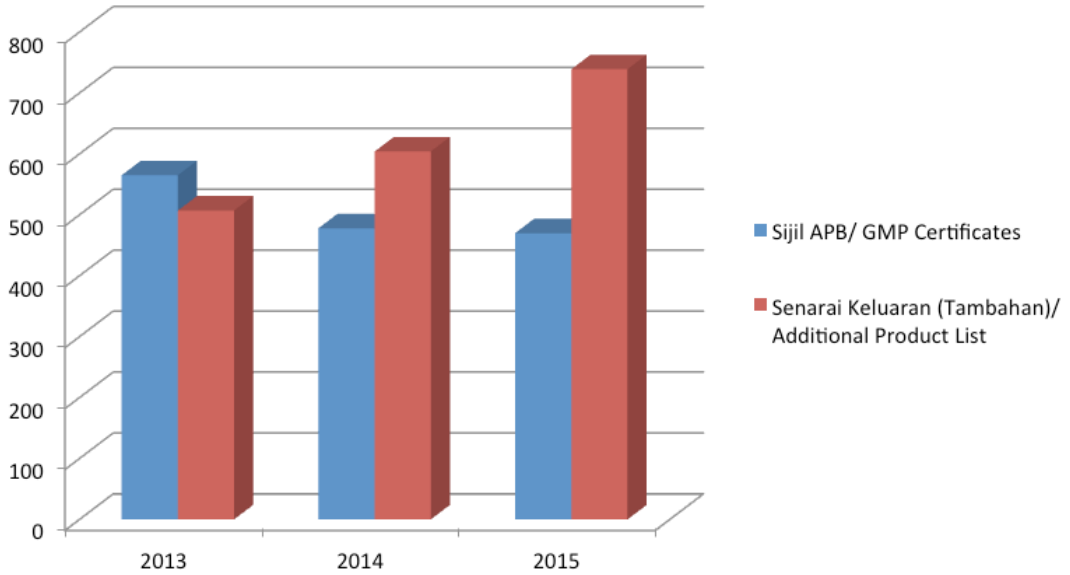
Rajah 1: Bilangan lesen dikeluarkan berdasarkan premis pengilang, pengimport dan pemborong, 2013 - 2015

Figure 1: Number of licenses issued according to premises of manufacturer, importer and wholesaler, 2013 – 2015



Rajah 2 : Bilangan Sijil APB dan Senarai Keluaran (Tambahan) , 2013 - 2015

Figure 2: Number of GMP Certificates and Additional Product List for Registered Products, 2013 – 2015



Pada tahun 2015, Pusat Kajian Produk Baru (PKPB) telah menilai sebanyak 68 permohonan baru yang melibatkan produk farmaseutikal, biologik, supplemen kesihatan dan lain-lain.

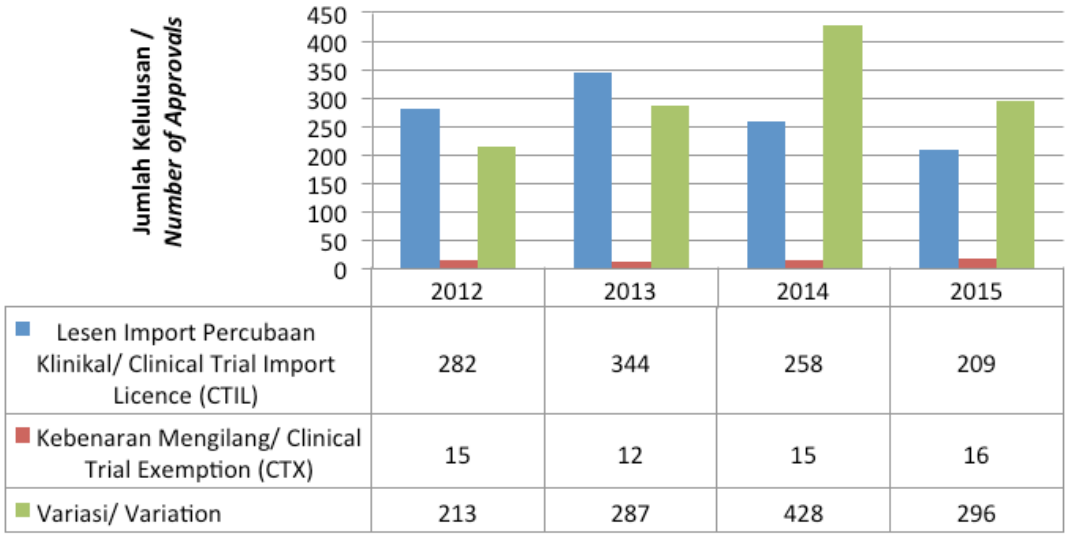
Hasil daripada penilaian permohonan di atas, sebanyak 209 lesen import percubaan klinikal (CTIL), 16 kebenaran mengilang (CTX) dan 296 kelulusan permohonan variasi telah dikeluarkan seperti yang ditunjukkan di dalam Rajah 3.

NPCB In 2015, the Centre for Investigational New Product (CINP) had evaluated 68 new applications of pharmaceutical products, biologicals, health supplements and others in Malaysia.

From the total of these completed evaluations, 209 clinical trial import licenses (CTIL) and 16 clinical trial exemptions (CTX) had been issued, and 296 variations had been approved as shown in Figure 3 below.

Rajah 3 : Kelulusan Lesen CTIL, CTX dan Variasi (2012-2015)

Figure 3: Approval of CTIL, CTX and Variation (2012-2015)



	2012	2013	2014	2015
Lesen Import Percubaan Klinikal/ Clinical Trial Import Licence (CTIL)	282	344	258	209
Kebenaran Mengilang/ Clinical Trial Exemption (CTX)	15	12	15	16
Variasi/ Variation	213	287	428	296

Penyebaran Maklumat dan Aktiviti Latihan

Information Dissemination and Training Activities

Sesi Dialog dengan Pihak Industri

BPFK sentiasa berkerjasama erat dengan pihak industri tempatan dan persatuan industri bagi memastikan keberkesanan sistem regulatori sedia ada. Sesi dialog bersama industri ini juga digunakan sebagai landasan penyebaran maklumat regulatori terkini. Sepanjang tahun 2015, BPFK telah menganjurkan 8 sesi dialog bersama pesatuan-persatuan.

Pameran sempena Fiesta Kenali Ubat Anda yang diadakan pada 19 September 2015

Exhibition in conjunction with Know Your Medicine Fiesta held on 19 September 2015

Dialogues between NPCB and association

NPCB works closely and collaborates with the local industry and the industry associations to further enhance the effectiveness of the current practices in the regulatory system. These dialogue sessions are used as a platform to ensure the industry is constantly updated with the current regulatory affairs. A total of 8 dialogue sessions with associations were conducted in 2015.

Jadual 1: Dialog di antara BPFK dengan Persatuan-persatuan pada tahun 2015

Table 1: Dialogues between NPCB and Associations in 2015

Bil. *No*	Persatuan / Industri *Associations / Industry*	Tarikh *Date*
1.	*Malaysia Dietary Supplement Association (MADSA)*	*21 May 2015*
2.	*Malaysian Organisation of Pharmaceutical Industries (MOPI)*	*24 June 2015*
3.	*Pharmaceutical Association of Malaysia (PhAMA)*	*30 June 2015*
4.	*Malaysian Association of Pharmaceutical Suppliers (MAPS)*	*14 July 2015*
5.	• *Chinese Medicine Manufacturers Association of Malaysia (PPUCM)* • *Federation of Chinese Physicians and Medicine Dealers Association of Malaysia (FCPMDAM)*	*25 August 2015*
6.	• *Direct Selling Association of Malaysia (DSAM)* • *Malaysian Direct Distribution Association (MDDA)*	*8 September 2015*
7.	• *Gabungan Pertubuhan Pengamal Perubatan Melayu Malaysia (GAPERA)* • *Persatuan Pengeluar-pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA*	*11 November 2015*
8.	*Malaysian Animal Health and Nutrition Industries Association (MAHNIA)*	*18 November 2015*

Penglibatan BPFK dalam aktiviti pameran sepanjang 2015

Selain berkerjasama dengan pihak industri, BPFK sentiasa berusaha untuk mendidik pengamal kesihatan serta orang awam mengenai sistem regulatori ubat-ubatan dan isu-isu lain yang berkaitan di Malaysia. Ini adalah penting untuk memastikan orang ramai memahami peranan dan usaha BPFK untuk melindungi orang awam dengan memastikan kualiti dan keselamatan ubat-ubat berdaftar di pasaran. Sepanjang 2015, BPFK telah mengambil bahagian dalam 10 pameran.

NPCB's Participation in Exhibition Events in 2015

Apart from being in touch with the industry, NPCB strives to continuously educate health professionals and the public on the regulatory control system and other relevant issues in the country. This is to ensure the public understands NPCB's role and effort to safeguard public's safety by ensuring the quality and safety of registered products in the market. Throughout 2015, NPCB has participated in 10 exhibitions.

Jadual 2: Penglibatan BPFK dalam Pameran sepanjang 2015

Table 2: NPCB's Participation in Exhibitions Events in 2015

Bil. *No.*	Pameran *Exhibition*	Penganjur *Organizer*	Lokasi *Location*	*Tarikh Date*
1.	*Exhibition in conjunction with ISPE Malaysia GMP Conference 2015*	*International Society for Pharmaceutical Engineering (ISPE) Malaysia*	*Puri Pujangga Hotel, Bangi*	*10 – 11 February 2014*
2.	*Annual Scientific Congress 2015 of PMPASKL*	*Private Medical Practitioners Association of Selangor and Kuala Lumpur (PMPASKL)*	*Puri Pujangga Hotel, Bangi*	*18 – 19 April 2015*
3.	*Exportation in Herbal Industry Seminar 2015*	*Ministry of Agriculture*	*Puri Pujangga Hotel, Bangi*	*17-19 August 2015*
4.	*Know Your Medicine Fiesta*	*Pharmaceutical Services Division, Ministry of Health*	*Puri Pujangga Hotel, Bangi*	*19 September 2015*
5.	*Herbal Industry Conference 2015*	*Ministry of Agriculture*	*Wisma Tani, Ministry of Agriculture, Putrajaya*	*3 – 5 November 2015*
6.	*Malaysia External Trade Development Corporation (MATRADE) Exhibition*	*Malaysia External Trade Development Corporation (MATRADE)*	*MATRADE Convention Centre, Kuala Lumpur*	*12 November 2015*
7..	*Advertising Content Compliance Workshop 2015*	*The Malaysian Communications and Multimedia Commission*	*Putrajaya Marriott Hotel, IOI Resort City, Sepang Utara*	*9 December 2015*

Pelawat tempatan dan antarabangsa ke BPFK

BPFK sentiasa mengalu-alukan pelawat tempatan mahupun antarabangsa dari universiti dan agensi kerajaan yang lain untuk memahami dengan lebih mendalam proses kerja BPFK. Ini secara tidak langsung dapat membantu proses pertukaran maklumat serta mengukuhkan kerjasama antara agensi.

Local and International Visitors to NPCB

NPCB welcomes local and international visitors from universities and other government agencies to learn and better understand our work processes. This may indirectly help the process of information exchange and strengthen cooperation between the agencies

(a) Pelawat Tempatan ke BPFK sepanjang 2015 / *Local Visitors to NPCB in 2015*

Bil. *No.*	Pelawat *Vistior*	Objektif Lawatan *Purpose of Visit*	Tarikh
1.	Pharmacist from National Pharmacy Call Centre (NPCC)	Training Attachment	6-7 April 2015
2.	Master Students from Universiti Putra Malaysia (UPM)	Academic Visit	20 April 2015
3.	Bachelor of Nutrition Students from Management & Science University (MSU)	Academic Visit	24 August 2015
4.	Students from the Perdana Fellowship Program	Academic Visit	3 September 2015
5.	Bachelor of Pharmacy Students from Universiti Sains Malaysia (USM)	Academic Visit	12 November 2015
6.	Masters of Public Health Students from University of Malaya (UM)	Academic Visit	24 November 2015
7.	Year One Pharmacy Students from University of Malaya(UM)	Academic Visit	26 November 2015
8.	Year One Pharmacy Students from University of Malaya(UM)	Academic Visit	1 December 2015
9.	Bachelor of Pharmacy and Master of Pharmacy Students from Universiti Kebangsaan Malaysia (UKM)	Academic Visit	18 December 2015

Lawatan Akademik oleh Pelajar Pasca Siswazah daripada Jabatan Pemakanan & Dietetik, Universiti Putra Malaysia (UPM) pada 20 April 2015

Academic Visit by the Master Students from the Department of Nutrition & Dietetics, Universiti Putra Malaysia (UPM) on 20 April 2015

Taklimat sistem QUEST kepada Pegawai Farmasi daripada Pusat Panggilan Farmasi Kebangsaan pada 6-7 April 2015

Briefing on the QUEST system to Pharmacists from National Pharmacy Call Centre (NPCC) on 6-7 April 2015

(b) Pelawat Antarabangsa ke BPFK sepanjang 2015 / *International Visitors to NPCB in 2015*

Bil. No	Institusi Institution	Objektif Lawatan / Skop lawatan Purpose of Visit / Scope of study	Tarikh Date
1.	*The Federation of Pharmaceutical Manufacturers' Associations, Japan*	*Courtesy Visit*	*6 February 2015*
2.	*General Directorate of Pharmacy, Khartoum State, Ministry of Health, Republic of Sudan*	*Courtesy Visit*	*10 February 2015*
3.	*Faculty of Pharmacy, Mahidol University, Bangkok, Thailand*	*Study visit focusing on pharmacovigilance system and management system*	*24 March 2015*
4.	*Maldives Food and Drug Authority, Maldives*	*Attachment Training in the field of Good Manufacturing Practice (GMP)*	*13 – 24 April 2015*
5.	*Tanzania Food and Drug Authority, Tanzania*	*Attachment Training in the field of notification, surveillance, quality control and GMP of cosmetic products*	*13 – 24 April 2015*
6.	*Sri Lanka Pharmaceutical Society, Sri Lanka*	*Study Visit*	*3 June 2015*
7.	*Myanmar Food and Drug Authority, Myanmar*	*Study visit focusing on registration, surveillance, quality control and ADR monitoring of pharmaceuticals*	*17 August 2015*
8.	*Myanmar Food and Drug Authority, Myanmar*	*Attachment Training in the field of Pharmacovigilance*	*24-28 August 2015*
9.	*National Drug Quality Control Laboratory, Republic of Sudan*	*Attachment training in the field of Quality Control testing of pharmaceuticals and cosmetic products*	*1-11 September 2015*
10.	*Ministry of Health & Sports, Mongolia*	*Study visit focusing on registration & the regulatory control of medicines in Malaysia*	*3 September 2015*
11.	*Ministry of Health Cambodia*	*Attachment Training on the regulatory control of medicines in Malaysia including the online registration system*	*14 – 18 September 2015*
12.	*National Department of Health, Ministry of Health Papua New Guinea*	*Training attachment focusing on registration, surveillance, quality control and enforcement activities of medicines in Malaysia*	*28 September – 2 October 2015*
13.	*ASEAN Core Team*	*Country Visit for Implementation of ASEAN-WHO Project on 'Support for Implementation of ASEAN Harmonized Requirements for Drug Registration'*	*29 September 2015*
14.	*National Drug Quality Assurance Laboratory, Sri Lanka*	*Attachment training in the field of Quality Control testing of pharmaceuticals including maintaining & calibrating laboratory equipment*	*9-13 November 2015*

Kunjungan hormat oleh pegawai daripada The Federation of Pharmaceutical Manufacturers' Associations, Japan ke BPFK pada 6 Februari 2015

Courtesy Visit to NPCB by officers from The Federation of Pharmaceutical Manufacturers' Associations, Japan on 6 February 2015

Pegawai daripada Tanzania Food and Drug Authority (Latihan Sangkutan : 13-24 April 2015)

Officers from Tanzania Food and Drug Authority (Attachment Training : 13 – 24 April 2015)

Pegawai daripada ASEAN CORE Team (Lawatan : 29 September 2015)

Officers from ASEAN CORE Team (Visit : 29 September 2015)

Latihan Dalaman BPFK

Latihan berterusan amat penting bagi pegawai farmasi dan penolong pegawai farmasi bagi memastikan kakitangan BPFK sentiasa memperolehi maklumat yang terkini dalam bidang farmaseutikal dan bidang-bidang lain yang berkaitan. BPFK berpendapat bahawa keupayaan dan kepakaran warga kerja adalah elemen utama dalam merealisasikan matlamat institusi bagi memberikan perkhidmatan yang lebih baik kepada orang awam.

Pusat Pembangunan Organisasi bertanggungjawab untuk menyelaraskan latihan, seminar dan kursus di bawah program Continuous Professional Development (CPD). Pada tahun 2015, sebanyak 279 sesi CPD telah dianjurkan. Ini termasuk ceramah, seminar, bengkel dan Kelab Jurnal yang telah diadakan di BPFK mahupun di lokasi luar.

NPCB's Internal Training

Continuous training for pharmacist and assistant pharmacists is important in order to keep them updated on the latest information in regards to pharmaceuticals and other related fields. NPCB believes that member staff's expertise and capabilities is the key elements to achieve our goal to better serve the public.

The Centre for Organisational Development is responsible for coordinating these trainings, seminars and courses for the staff as part of the Continuous Professional Development (CPD) Program. In the year 2015, a total of 279 CPD sessions were conducted. The sessions included educational talks, seminars, workshops and Journal Club sessions conducted both externally and in-house.

Sesi CPD yang dijalankan di Dewan Anggerik, BPFK
CPD session held in Anggerik Hall, NPCB

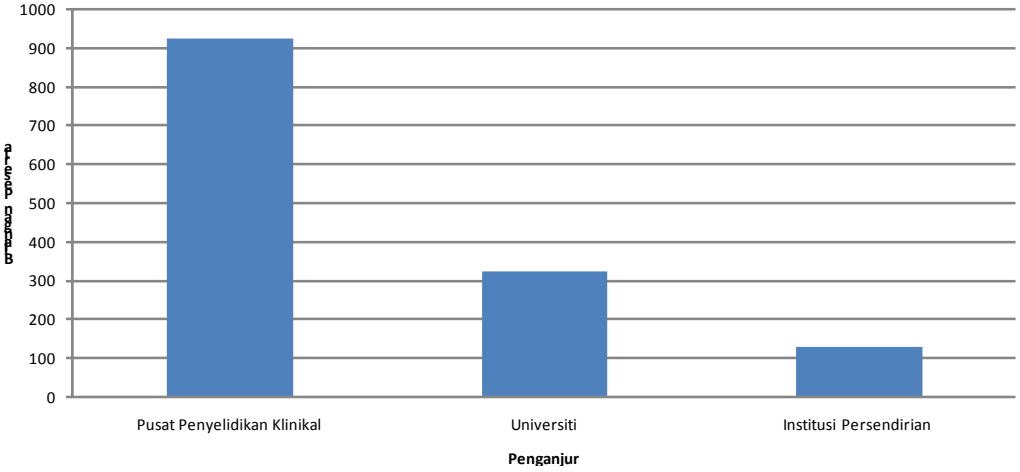
Kursus Amalan Klinikal Baik (GCP)

Lima puluh satu kursus GCP yang melibatkan sebanyak 2450 orang peserta telah dianjurkan oleh Pusat Penyelidikan Klinikal, Kementerian Kesihatan Malaysia, institusi swasta dan universiti pada tahun 2015. Pusat Kajian Produk Baru, BPFK memainkan peranan penting dalam memberi ceramah dan menyelaraskan peperiksaan GCP. Bermula pada tahun 2012, sijil untuk semua peserta yang lulus dalam peperiksaan GCP telah dikeluarkan oleh BPFK yang bertindak sebagai secretariat kepada Jawatankuasa Penyelidikan Klinikal Kebangsaan (JPKK). Dengan ini, BPFK telah mengeluarkan sebanyak 1383 sijil GCP termasuk peserta yang lulus dalam peperiksaan berulang dalam tahun 2015.

Good Clinical Practice Course

Fifty one GCP courses which involved 2450 participants had been organised by Clinical Research Centre, MOH, private institutions and universities in year 2015. Centre for Investigational New Product (CINP), NPCB played an important role in giving lectures and coordinating the GCP examinations. Starting from year 2012, the certificates for all participants who passed the GCP examination were issued by NPCB who acted as a secretariat to the National Committee for Clinical Research (NCCR). NPCB had issued a total of 1383 certificates which included re-sit participants in the year 2015.

Bilangan Peserta Yang Lulus Kursus Amalan Klinikal Baik (GCP)
Tahun 2015



Pengurusan Pertanyaan

Unit Helpdesk di Pusat Pembangunan Organisasi memainkan peranan yang penting dalam mengendalikan pertanyaan oleh pengamal kesihatan, pihak industri dan orang awam. Pertanyaan diterima melalui pelbagai saluran seperti telefon, e-mel, faks/surat, serta pelanggan di kaunter. Pada tahun 2015, sebanyak 6750 pertanyaan telah diterima melalui pelbagai saluran seperti yang ditunjukkan dalam carta di bawah.

Handling of Inquiries

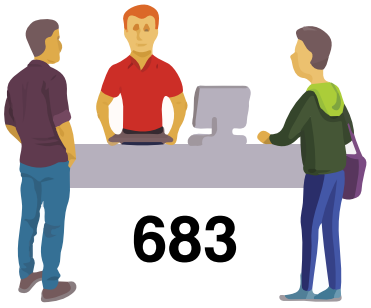
The Helpdesk Unit in the Centre for Organisational Development plays a substantial role in handling enquiries made by healthcare professionals, industry players and the general public. These enquiries are received via different channels such as phone, e-mail, fax/letter, and walk-in customers. In 2015, a total of 6750 enquiries had been received through the various channels as shown in the chart below.

5564

Telefon
Telephone

503

Emel
Email



683

Pertanyaaan kaunter
Walk-ins

Penerbitan Newsletter

BPFK menerbitkan newsletter yang bertajuk Berita Ubat-ubatan (BUU) secara berkala sebagai media untuk penyebaran maklumat. Penerbitan ini mengandungi maklumat berkaitan acara dan mesyuarat regulatori, direktif regulatori yang baru serta ringkasan keratan akhbar berkaitan produk traidisional dan kosmetik untuk maklumat pengamal kesihatan dan orang awam. Penerbitan ini dimuat naik ke laman web rasmi BPFK dan boleh diakses oleh orang awam. Terdapat 2 BUU yang diterbitkan dalam tahun 2015.

BPFK telah mengeluarkan tiga (3) edisi Buletin MADRAC pada tahun 2015, dan lima (5) edisi Reaksi Drug Safety News. Artikel di dalam terbitan-terbitan ini menekankan isu-isu keselamatan ubat yang telah dibincangkan oleh MADRAC dengan memuatkan nasihat kepada ahli profesional kesihatan. Selain itu, laporan kes ADR yang menarik dan isu-isu terkini yang melibatkan keselamatan ubat turut diterbitkan.

Publication of Newsletter

As means of information dissemination, NPCB periodically publishes a Newsletter called Berita Ubat-ubatan (BUU). This publication contains news on regulatory events and meetings, updates of regulatory directives and summary of press releases regarding traditional dan cosmetic products for the information of health professionals as well as the public. These publications are uploaded onto NPCB's official website and can be accessed by the public. There are 2 BUU published in 2015.

The NPCB released three (3) issues of the MADRAC Bulletin in 2015, as well as five (5) issues of Reaksi Drug Safety News. Articles in these publications highlight drug safety issues discussed by MADRAC along with advice to healthcare professionals, as well as present case reports and other latest issues.


BERITA UBAT-UBATAN

EVENTS

MEMORANDUM OF UNDERSTANDING BETWEEN THE MINISTRY OF HEALTH MALAYSIA AND THE MALAYSIAN FORESTRY RESEARCH AND DEVELOPMENT BOARD

IN THIS ISSUE

DCA EDITORIAL TEAM


BERITA UBAT-UBATAN

EVENTS

23rd ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY (ACCSQ) TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS PRODUCT WORKING GROUP (TMHS PWG) MEETING

FULL REPORT ON PAGE 2

IN THIS ISSUE

KOMUNIKASI KESELAMATAN UBAT

Komunikasi yang berkesan adalah sangat penting di dalam bidang farmakovigilans, bagi memastikan maklumat keselamatan ubat disebarkan secara cepat dan jelas. BPFK telah mengeluarkan tiga (3) edisi Buletin MADRAC pada tahun 2015, dan lima (5) edisi Reaksi Drug Safety News.

BPFK turut mengekalkan senarai mel elektronik untuk semua ahli profesional kesihatan, dalam usaha memastikan maklumat keselamatan ubat disebarkan dengan lebih cepat dan meluas. Senarai mel ini kini terdiri daripada lebih 1,800 ahli. Maklumat lanjut boleh diperoleh daripada laman web BPFK, ataupun emel pertanyaan kepada fv@bpfk.gov.my.

Selain daripada terbitan tersebut di atas, sebanyak lima (5) Direct Healthcare Professional Communications (DHPCs) telah diluluskan oleh BPFK untuk diedarkan pada tahun 2015. DHPC dikeluarkan oleh pemegang pendaftaran produk untuk menekankan perubahan yang penting pada maklumat sisip bungkusan, profil keselamatan, ataupun penggunaan sesuatu produk.

Tiga (3) Makluman Terkini Isu Keselamatan telah diedarkan oleh BPFK pada tahun 2015 kepada semua fasiliti KKM serta pertubuhan ahli profesional kesihatan seperti Persatuan Perubatan Malaysia (MMA) dan Persatuan Farmasi Malaysia (MPS). Ini melibatkan produk intravenous succinylated gelatin infusion, metoclopramide dan domperidone.

Garispanduan Farmakovigilans Malaysia telah dikemas kini untuk memberi pihak-pihak terlibat panduan yang lebih jelas berkaitan semua aspek farmakovigilans di Malaysia. Draf garispanduan ini telah diedarkan dan dibincangkan bersama industri farmaseutikal serta stakeholders lain, dengan versi akhir dijadualkan untuk dikeluarkan pada tahun 2016.

DRUG SAFETY COMMUNICATION

Effective communication is essential in pharmacovigilance, to ensure the timely and transparent sharing of medicine safety information. The NPCB released three (3) issues of the MADRAC Bulletin in 2015, as well as five (5) issues of Reaksi Drug Safety News.

An electronic mailing list of healthcare professionals will be maintained in the continuous effort to ensure wider and prompt dissemination of safety information. This mailing list currently consists of more than 1,800 contacts. Further information may be obtained from the NPCB website, or by emailing queries to fv@bpfk.gov.my.

Besides the publications, a total of five (5) Direct Healthcare Professional Communications (DHPCs) were approved by the NPCB for distribution in 2015. These were issued by the product registration holders to highlight important changes in the prescribing information, safety profile or use of a product.

Three (3) early safety issue communications were distributed by NPCB in 2015 to all Ministry of Health facilities as well as universities and healthcare professional associations such as the Malaysian Medical Association and the Malaysian Pharmaceutical Society. These involved intravenous succinylated gelatin infusion products, metoclopramide and domperidone.

The Malaysian Pharmacovigilance Guidelines have been updated to provide all stakeholders with a clearer guide on all aspects of pharmacovigilance in Malaysia. The draft guidelines were circulated and discussed with the pharmaceutical industry as well as other stakeholders, with the finalised version scheduled to be released in 2016.

BARU
NEW

Pada Ogos 2015, BPFK telah menaiktaraf laman web rasmi yang dilengkapi dengan susun atur baru yang menarik dan kemas. Ianya juga telah direka supaya lebih mesra pengguna. Ia kini menyediakan akses terus untuk pengguna melakukan pencarian produk di Quest2 dan Quest3 yang terletak di laman utama website tersebut.

In August 2015, NPCB upgraded the official website which features a neat and attractive layout. It has been designed to be more user-friendly. It now provides direct access for users to search products in QUEST2 and Quest3 which is located on the main page of the website

Sorotan Penting & Aktiviti Sepanjang 2015

Highlights & Activities Throughout 2015

Pembangunan, pengeluaran, perdagangan, dan pemasaran ubat-ubatan telah berkembang secara global dan kerjasama dalam aktiviti kawal selia dalam kalangan agensi regulatori farmaseutikal telah menjadi satu keperluan utama. Kini, negara-negara Asia telah menjadi negara penting dalam pembangunan klinikal dan pengeluaran ubat-ubatan di seluruh dunia. Oleh itu, kerjasama di antara agensi regulatori negara-negara Asia adalah sangat penting.

Dengan ini, Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah bekerjasama dengan Pharmaceutical and Medical Devices Agency (PMDA) Jepun untuk mengadakan persidangan bersama dengan tujuan untuk meningkatkan kefahaman mengenai sistem kawal selia kedua-dua negara dan menggalakkan kemajuan dalam aspek pengawalan farmaseutikal.

Persidangan 2-hari tersebut telah diadakan pada 10 & 11 Mac 2015 di Aloft Kuala Lumpur Sentral yang terletak di tengah-tengah Kuala Lumpur. Simposium tresebut mencatatkan kehadiran seramai 150 orang peserta yang terdiri daripada pegawai BPFK dan PMDA serta ahli-ahli industri farmaseutikal dari kedua-dua buah negara. Dato' Eisah A. Rahman, Pengarah Kanan Perkhidmatan

Globalization of development, manufacturing, trade, and marketing of drugs has been progressing, and cooperation of regulatory activities among pharmaceutical regulatory agencies has become a necessity. Nowadays, Asian countries have become crucial in the clinical development and manufacturing of drugs globally. Therefore, collaborative relationships among the Asian regulatory agencies are highly important.

With this in mind, the National Pharmaceutical Control Bureau (NPCB) worked together with the Pharmaceutical and Medical Devices Agency (PMDA) Japan to hold a joint conference with the aim to enhance Malaysia and Japan's mutual understanding of each other's regulatory system and to promote the advancement of pharmaceutical regulations and development.

The 2-day conference was held on 10 & 11 March 2015 at the Aloft Kuala Lumpur Central located in the heart of Kuala Lumpur. The symposium recorded a total attendance of 150 participants which consists of officers from both NPCB and PMDA along with members of the pharmaceutical industry of both countries. Dato' Eisah A. Rahman, the Senior Director of Pharmaceutical

Farmasi, Kementerian Kesihatan Malaysia (KKM) telah menyampaikan ucapan alu-aluannya serta merasmikan simposium tersebut manakala penutupan simposium telah dilakukan oleh Dr. Taisuke Hojo, Pengarah Eksekutif Kanan PMDA Jepun.

Services, Ministry of Health Malaysia delivered her welcoming remarks and officiated the symposium whereas the closing of the symposium was done by Dr. Taisuke Hojo, Senior Executive Director of PMDA Japan.

Simposium ini merangkumi penyampaian taklimat daripada kedua-dua agensi serta perbincangan dalam semua topik berkaitan dengan kawalan regulatori ubat-ubatan. Topik lain termasuk pengenalan kepada MS 2424: Garis Panduan Malaysia bagi Farmaseutikal Halal, Monograf Herba Malaysia dan Pharmacopeia Jepun. Simposium pertama Malaysia-Jepun ini telah dijalankan dengan jayanya dan merupakan platform untuk membina hubungan kerjasama yang rapat di antara kedua-dua negara.

This symposium included presentations from both agencies as well as discussions in each area of regulatory control of medicines. Other topics included were introduction to MS2424: Malaysia's Guideline for Halal Pharmaceuticals, Malaysian Herbal Monograph and Japanese Pharmacopeia. The 1st Malaysian-Japan symposium was a success as a platform to build a close working relationship between the two countries.

Sebagai langkah kerjasama berterusan, BPFK dan PMDA mengambil peluang untuk mengadakan mesyuarat dua hala selepas simposium tersebut. Kedua-dua agensi telah berbincang dengan mendalam mengenai bidang kerjasama pada masa hadapan termasuk aktiviti Surveilens Pasca Pemasaran (PMS) dan menjalankan pemeriksaan bersama untuk Amalan Pengilangan Baik (APB).

As part of the continuing collaboration, both NPCB and PMDA took the opportunity to have a bilateral meeting right after the symposium. Both agencies discussed in-depth on areas of the future partnership including Post-Market Surveillance (PMS) activities and Good Manufacturing Practice (GMP) joint inspections.

Malaysia – Japan Bilateral Meeting

ASEAN Training on Testing Methods for the Detection of Pharmaceutical Adulterants in Traditional Medicinal Products 6-10 April 2015

Antara objektif latihan ini adalah untuk melindungi kesihatan awam dengan memastikan produk ubatan tradisional adalah selamat dan berkualiti melalui pengujian serta mengukuhkan dan meningkatkan kemahiran dan kompetensi kakitangan makmal melalui perkongsian pengetahuan dan pengalaman teknikal apabila berdepan dengan isu campur palsu dalam produk ubatan tradisional.

Program latihan ini terdiri daripada pembentangan laporan dari negara asal, sesi praktikal menggunakan peralatan analisis High Performance Liquid Chromatography (HPLC) dan demonstrasi kaedah ujian menggunakan Thin Layer Chromatography (TLC), Gas Chromatography coupled with Mass Spectrometry (GCMS) dan Liquid Chromatography-Mass Spectrometry (LC-MS).

Latihan ini telah dihadiri oleh para peserta dari Filipina, Singapura dan Thailand. Maklum balas positif telah diterima daripada para peserta terutamanya dari segi sesi praktikal dan perkongsian serta pertukaran pengalaman dan kemahiran teknikal.

The objective of this training programme are to protect public health by ensuring traditional medicinal products are safe and of quality through laboratory testing and to improve and strengthen laboratory skill and competency of regulatory laboratory personnel by technical knowledge and experience sharing in dealing with issues of pharmaceutical adulterants in traditional medicinal products.

The training programme comprised of presentation of country report, practical (hands-on) session using analytical instrument - High Performance Liquid Chromatography (HPLC) and demonstration of several testing methods using Thin Layer Chromatography (TLC), Gas Chromatography coupled with Mass Spectrometry (GCMS) and Liquid Chromatography-Mass Spectrometry (LC-MS).

The training was attended by participants from Philippines, Singapore and Thailand. Positive feedbacks were received from participants especially for the hands-on sessions as well as sharing and exchanging of experiences and technical knowledge.

Sesi penerangan dan latihan teknikal oleh pegawai BPFK kepada para peserta di dalam makmal BPFK
Briefing and hands-on training session by NPCB's officer in NPCB's laboratory

National Regulatory Conference 2015 : Transformation Towards A New Regulatory Paradigm 4 - 6 August 2015

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) mula menganjurkan Persidangan Regulatori Kebangsaan (NRC) sebagai landasan untuk menyebarkan maklumat terkini dalam bidang sistem kawal selia farmaseutikal. Dengan kejayaan persidangan pertama pada tahun 2001 yang bertemakan "Malaysia's QUEST Towards Product Excellence", BPFK telah meneruskan penggunaan landasan ini sebagai cara untuk menyampaikan maklumat terkini kepada pihak industri.

Pada tahun 2015, BPFK telah menganjurkan Persidangan Regulatori Kebangsaan yang kelima dengan tema "Transformation Towards A New Regulatory Paradigm" yang telah diadakan di One World Hotel, Petaling Jaya pada 4-6 Ogos 2015. Persidangan selama 3 hari ini telah dirasmikan oleh Yg. Bhg. Datuk Seri Dr S. Subramaniam, Menteri Kesihatan Malaysia. Persidangan ini menerima banyak penyertaan daripada peserta tempatan dan luar negara. Seramai 534 orang peserta dan penceramah dari dalam dan luar negara termasuk dari Amerika Syarikat, Brunei Darussalam, Hong Kong, Indonesia, Korea, Singapura dan Thailand telah menghadiri persidangan ini.

NRC 2015 mempunyai objektif untuk menyebarkan maklumat mengenai perkembangan terkini dan cabaran dalam bidang regulatori yang sentiasa berubah, menggalakkan dan mengukuhkan kerjasama di antara

The National Pharmaceutical Control Bureau (NPCB) started organizing the National Regulatory Conference (NRC) as a platform to disseminate the latest information in the area of the pharmaceutical regulatory system. With the success of the very first conference in 2001, with the theme "Malaysia's QUEST Towards Product Excellence", NPCB has continued using this platform over the years as a means to convey updates to the industry.

In 2015, NPCB organized the Fifth National Regulatory Conference with the theme "Transformation Towards A New Regulatory Paradigm" which was held at One World Hotel, Petaling Jaya from 4-6 August 2015. The 3-day conference was officiated by the Minister of Health Malaysia, Yg. Bhg. Datuk Seri Dr. S. Subramaniam. The event received overwhelming participation from local and foreign participants. A total of 534 participants and speakers from Malaysia as well as from Brunei Darussalam, Hong Kong, Indonesia, Korea, Singapore, Thailand, and the United States of America attended the conference.

The NRC 2015 had the objective of disseminating information on the latest development and challenges in the evolving regulatory landscape, promoting and strengthening smart partnership amongst stakeholders

pihak-pihak berkepentingan serta meningkatkan kesediaan dalam sektor penjagaan kesihatan yang kompetitif. Selepas 3 hari dan 10 sesi plenary, BPFK yakin objektif persidangan ini telah dipenuhi.

BPFK akan terus menganjurkan persidangan ini dari masa ke semasa untuk meningkatkan kesedaran dan kefahaman mengenai keperluan peraturan terkini serta untuk berkongsi visi masa hadapan untuk sistem kawal selia ubat-ubatan di Malaysia. Ini akan membantu merapatkan jurang antara pihak berkuasa dan pihak industri dengan tujuan untuk memastikan kualiti, keselamatan dan keberkesanan ubat-ubatan di pasaran Malaysia.

as well as enhancing readiness in the competitive healthcare business environment. After 3 days and 10 plenary sessions, NPCB is confident that the objectives of the conference have been met.

NPCB will continue to organize this conference from time to time to increase the awareness and understanding of the latest regulatory requirements as well as to share the way forward for the Malaysian drug regulatory system. This will help to close the gap between the authority and the industry with the aim to ensure the quality, safety and efficacy of the medicines in the Malaysian market.

Enhancement of Capacity Building for Malaysian Herbal Monograph Team in Chemical Testing Aspects
12 May 2015

Tarikh : 12 Mei 2015
Tempat : Pusat Kawalan Kualiti, BPFK

Aktiviti-aktiviti :

1. Sesi pembentangan & perbincangan
   - MHM SOP Review : Identification Test By High Performance Liquid Chromatography (HPLC) review- Do's & Don'ts
   - Knowledge & experience sharing: HPLC herbal method development- Tips & Tricks
   - HPLC maintenance- fix & care

2. Sesi perkongsian:
   - Extractive Value- Hot Method
   - Extractive Value- Cold Method
   - Total Ash & Acid- Insoluble Ash
   - Loss on Drying

Date: 12 May 2015
Venue: Centre for Quality Control, NPCB

Activities:

1. *Presentation & discussion session:*
   - *MHM SOP Review : Identification Test By High Performance Liquid Chromatography (HPLC) review- Do's & Don'ts*
   - *Knowledge & experience sharing: HPLC herbal method development- Tips & Tricks*
   - *HPLC maintenance- fix & care*

2. *Sharing session:*
   - *Extractive Value- Hot Method*
   - *Extractive Value- Cold Method*
   - *Total Ash & Acid- Insoluble Ash*
   - *Loss on Drying*

Analytical Method Validation for Biological Products Workshop
10 – 13 August 2015

Tarikh : 10 - 13 August 2015

Tempat: Grand Seasons Hotel, Kuala Lumpur

Penceramah Jemputan & fasilitator :
Teeranart Jivapaisarnpong, Director of Institute of Biological Products, Ministry of Public Health Thailand

Peserta : Pegawai BPFK

Antara objektif latihan ini adalah:

- Untuk memahami dengan lebih mendalam prosedur analisis untuk produk biologikal
- Untuk menambah pengetahuan dalam penilaian data validasi untuk produk biologikal dari segi keperluan setiap ciri validasi bagi tujuan meningkatkan kemahiran dan kecekapan setiap penilai produk biologikal
- Untuk mendapatkan pengetahuan dan informasi terkini tentang situasi semasa, masalah dan cabaran dalam penilaian data validasi yang dihadapi oleh negara-negara lain

Date: 10 - 13 August 2015

Venue: Grand Seasons Hotel, Kuala Lumpur

Invited speaker & facilitator: Teeranart Jivapaisarnpong, Director of Institute of Biological Products, Ministry of Public Health Thailand

Participants : Officers from NPCB

The objectives of this training are as follows:

- *To have a better understanding on analytical procedures for biological products*
- *To gain knowledge in evaluating validation data for biological products in terms of the requirement of each validation characteristic for the purpose of improving the skill and competency of evaluators of biological products*
- *To update the knowledge and information on current situation, problems and challenges faced by other countries in evaluating validation data*

Visit by the Secretary General, Ministry of Health Malaysia
19 August 2015

Tarikh 19 Ogos 2015 merupakan satu tarikh penting bagi Bahagian Perkhidmatan Farmasi (BPF) dan Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) di mana YBhg. Datuk Dr Chen Chaw Min, Ketua Setiausaha, Kementerian Kesihatan Malaysia, telah membuat lawatan pertama beliau ke kedua-dua institusi ini untuk mendapatkan maklumat berkaitan Program Farmasi.

Ketua Setiausaha disambut mesra oleh Pengarah Kanan Perkhidmatan Farmasi, YBhg. Dato 'Eisah A. Rahman, yang kemudiannya menyampaikan taklimat pengenalan, fungsi, aktiviti dan pencapaian organisasi serta hala tuju Program Farmasi. Beliau juga berkongsi maklumat serta cabaran yang dihadapi oleh Program Farmasi. Ketua Setiausaha kemudian menyampaikan ucapannya dan menjawab sebahagian daripada isu-isu yang dibangkitkan semasa sesi taklimat itu.

Lawatan ini diakhiri dengan lawatan ke makmal-makmal di Pusat Kawalan Kualiti, BPFK serta Makmal Forensik Penguatkuasa Farmasi.

19 August 2015 marks a memorable date for the Pharmaceutical Services Division (PSD) and the National Pharmaceutical Control Bureau (NPCB) as YBhg. Datuk Dr. Chen Chaw Min, the Secretary General, Ministry of Health Malaysia, made his first visit to this two institutions to gain first-hand information related to the Pharmacy Programme.

The Secretary General was welcomed by the Senior Director of Pharmaceutical Services, YBhg. Dato' Eisah A. Rahman, whom whom later delivered a briefing which included an introduction to the organization, functions, activities, achievements and future direction of the Pharmacy Programme. She also shared information related to challenges faced by the Pharmacy Programme. The Secretary General then delivered his speech and addressed some of the issues raised during the briefing.

The visit ended with a tour to the laboratories in Centre for Quality Control, NPCB as well as the Pharmacy Enforcement Forensic Laboratory.

Pegawai BPFK sedang menerangkan kepada YBhg. Datuk Dr. Chen Chaw Min mengenai ujian yang dijalankan di makmal BPFK

NPCB officer explaining to YBhg. Datuk Dr. Chen Chaw Min details on the test performed in the NPCB laboratory

Scientific Workshop on Biopharmaceutical Products -Biosimilars
9 September 2015

Sesi pembentangan dan soal jawab semasa bengkel
Presentation and Q&A session during the workshop

Penganjur : Seksyen Biologik, Pusat Pendaftaran Produk, BPFK
Tempat: Dewan Anggerik, BPFK

Penceramah :
Dr. Thomas Schreitmueller,
Head Regulatory Policy, Biologics (Roche)
Dr. Sannie Chong,
Pharma Tech Regulatory APAC Policy (Roche)

Objektif :

- Untuk mengukuhkan kemahiran dan kepakaran di kalangan penilai dalam penilaian dan kelulusan produk biosimilar di Malaysia
- Untuk mengenal pasti perkara penting dalam penilaian dossier permohonan biosimilar melalui kajian kes

Organizer : Biologics Section, Centre of Product Registration, NPCB
Location : Anggerik Hall, NPCB

Speakers:
Dr. Thomas Schreitmueller,
Head Regulatory Policy, Biologics (Roche)
Dr. Sannie Chong,
Pharma Tech Regulatory APAC Policy (Roche)

Objectives :

- *To strengthen the skills and expertise among evaluators in evaluation and approval of biosimilar products in Malaysia*
- *To identify the key points in evaluating biosimilar application dossier through case studies*

Quality Management in Vaccine Manufacturing
17 November 2015

Penganjur : Seksyen Biologik, Pusat Pendaftaran Produk, BPFK
Tempat : Dewan Anggerik, BPFK

Penceramah : Dr. Chris Yan, Ms Luo Wei (Sanofi Pasteur)

Objektif :

- Untuk mengukuhkan kemahiran dan kepakaran di kalangan penilai dalam penilaian dan kelulusan vaksin di Malaysia
- Untuk mendedahkan kepentingan pengurusan berkualiti dalam sektor pembuatan vaksin
- Untuk memberikan contoh pemindahan teknolog dan proses yang terlibat
- Untuk memberi penekanan kepada proses pengesahan dan pemantauan secara khususnya dalam reka bentuk dan kualifikasi
- Untuk memahami pengurusan deviasi, CAPAs dan CCRs

Organizer : Biologics Section, Centre of Product Registration, NPCB
Location : Anggerik Hall, NPCB

Speakers : Dr. Chris Yan, Ms Luo Wei (Sanofi Pasteur)

Objectives:

- *To strengthen the skills and expertise among evaluators in evaluation and approval of vaccines in Malaysia*
- *To exposure of importance of quality management in vaccine manufacturing*
- *To give examples of technology transfer and processes involved*
- *To emphasis on process validation and monitoring in specific it's design and qualification*
- *To understand the management of deviations, CAPAs and CCRs.*

Transformation of Monograph to Pharmacopoeia 2015
1-2 December 2015

Sejumlah 64 peserta daripada pelbagai agensi telah menghadiri bengkel ini. Kebanyakan daripada mereka terdiri daripada penyelidik dan pakar daripada pelbagai bidang yang menyokong pembangunan data monograph herba yang berkualiti dan boleh digunakan sebagai rujukan.

A total of 64 participants from various agencies attended this workshop in which majority of them are researchers and experts from various fields whom supports the development effort to ensure herbal monographs data are accurate and of quality and can be used as reference.

Sesi pembentangan dan soal jawab semasa bengkel
Presentation and Q&A session during the workshop

Tujuan bengkel ini adalah untuk memberikan panduan bagi pembangunan herbal pharmacopoeia yang merangkumi pembangunan kandungan monograph dan format penulisan yang berasaskan rujukan yang bersesuaian.

The objective of this workshop is to provide guidance for the development of herbal pharmacopoeia which includes enrichment of the content of monograph and best writing format with appropriate references.

Rural Transformation Centre (RTC) programme

Biro Pengawalan Farmaseutikal Kebangsaan melalui Pusat Komplians dan Pelesenan, terlibat dalam menganjurkan latihan kepada industri melalui program Pusat Transformasi Luar Bandar (RTC). Tujuan program ini adalah untuk memberi pendedahan berkaitan kawalan ubat tradisional dan kosmetik di Malaysia. Ia juga bertujuan untuk memberi kefahaman asas mengenai keperluan Amalan Perkilangan Baik (APB) dan Amalan Pengedaran Baik (AEB). Sepanjang tahun 2015, sebanyak tiga seminar telah dijalankan iaitu:

i. Zon Timur: 11-12 Ogos 2015.
   Lokasi: Grand Riverview Hotel, Kota Bharu, Kelantan
ii. Zon Sarawak: 22-23 September 2015.
   Lokasi: Majestic Hotel, Kuching
iii. Zon Sabah: 17-18 November 2015. Lokasi: Hotel Grandis, Suria Sabah Shopping Mall, Kota Kinabalu.

The National Pharmaceutical Control Bureau through its Centre of Compliance and Licensing is involved in organizing training under the Rural Transformation Centre (RTC) programme for the industry. The purpose of this programme is to provide exposure related to the control of traditional and cosmetic products in Malaysia. It also aims to provide general understanding regarding Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) requirements. In 2015, three seminars were conducted:

i. East Zone: 11-12 August 2015. Location: Grand Riverview Hotel, Kota Bharu, Kelantan
ii. Sarawak Zone: 22-23 September 2015. Location: Majestic Hotel, Kuching
iii. Sabah Zone: 17-18 November 2015. Location: Hotel Grandis, Suria Sabah Shopping Mall, Kota Kinabalu.

Sesi Latihan di RTC Zon Timur
Training session at the East Zone RTC

Laporan Kewangan

Financial Report

Pengurusan kewangan dikendalikan oleh Pusat Pentadbiran yang juga bertanggungjawab dalam hal-hal pentadbiran am termasuk tugas-tugas lain yang bukan teknikal. Pusat Pentadbiran memastikan bahawa gaji bulanan serta tuntutan-tuntutan rasmi dibayar dalam tempoh yang ditetapkan serta mengawal peruntukan kewangan supaya sentiasa mencukupi bagi manjamin setiap aktiviti yang dirancang boleh dijalankan dengan jayanya.

The financial management is handled by the Administrative Centre which is also responsible for other general administrative duties including non-technical tasks. The Centre for Administration ensures that all emoluments and claims are paid within the specified timeframe and ensures that the allocations of funds are sufficient for all planned activities to be carried out successfully.

Pada tahun 2015, BPFK telah menerima peruntukkan sebanyak RM40,360,834.00 bagi bajet Mengurus dan sebanyak RM2,853,099.93 bagi bajet Pembangunan.

In 2015, NPCB received an allocation of RM40,360,834.00 for Operating Budget and RM2,853,099.93 for Development Budget.

BAJET MENGURUS 2015 I *OPERATING BUDGET 2015*

Objek Am *Objek Code*	Kategori *Category*	Peruntkan *Allocation* (RM)	Perbelanjaan *Expenditure*		Baki *Balance*	
			RM	%	RM	%
10000	Emolumen Emolument	27,109,100.00	31,213,337.73	115.14	(4,104,237.73)	-15.14
20000	Perkhidmatan & Bekalan Service & Supply	13,176,900.00	11,919,451.76	90.46	1,257,448.24	9.54
30000	Aset Asset	71,834.00	71,745.00	99.88	89.00	0.12
40000	Pemberian & KenaanTetap Giftand Fixed Payment	3,000.00	0.00	0.00	3,000.00	100
JUMLAH / TOTAL		40,360,834.00	43,204,534.49	107.05	(2,843,700.49)	-7.05

BAJET PEMBANGUNAN 2015 I *DEVELOPMENT BUDGET 2015*

Objek Am *Objek Code*	Kategori *Category*	Peruntukan *Allocation* (RM)	Perbelanjaan Expenditure		Baki Balance	
			RM	%	RM	%
00105	Latihan Dalam Perkhidmatan *Inservice Training*	120,000.00	110,020.00	91.68	9,980.00	8.32
94000	Pembangunan Monograph Herbal Malaysia *Malaysian Herbal Monograph Development*	524,000.00	515,348.69	98.35	8,651.31	1.65
01100	Peralatan Makmal *Laboratory Equipment*	1,794,350.00	1,794,325.00	99.99	25.00	0.01
00800	Kemudahan Teknologi ICT (Quest 3+) *ICT Technolgy Infrastructure (Quest 3+)*	298,000.00	298,00.00	100.00	0.00	0.00
010100	Projek National Blue Ocean Strategy (RTC) *National Blue Ocean Strategy Project*	116,749.93	59,765.04	51.19	56,984.89	48.81
JUMLAH / *TOTAL*		**2,853,099.93**	**2,777,458.73**	**97.35**	**75,641.20**	**2.65**

Kutipan Hasil Tahun 2015 | *Revenue for 2015*

Kod / *Code*	Perkara / *Item*	Jumlah / *Total* (RM)
72199	Daftar Produk Kosmetik | *Registration of Cosmetic Product*	4,189,050.00
	Daftar Ubat Baru | *New Product Registration*	2,715,593.37
	Daftar Ubat Semula | *Product Re-registration*	2,610,550.00
	Daftar Ubat Veteriner | *Veteriner Product Registration*	162,000.00
	Daftar Ubat Semula Veteriner | *Product Re-registration Veteriner*	33,000.00
	Perakuan Penjualan | *Free Sale Certificate*	265,550.00
	Tukar Pemegang | *Change of Holder*	201,500.00
	Tukar Pemegang Veteriner | *Change of Holder (Veteriner)*	16,000.00
	Pertukaran Tapak Kilang | *Change of Site*	143,000.00
	Pertukaran Tapak Kilang Veteriner | *Change of Site (Veteriner)*	4,000.00
	Daftar Ubat Ekspot | *Export Product Registration*	122,700.00
73301	Jualan Aset | *Selling of Asset*	720.00
71999	Bayaran-bayaran Lain | *Other Payments*	136.30
71499	Lesen Impot Klinikal | *Clinical Import License*	118,000.00
72499	Lesen Pengilang | *Manufacturer License*	278,000.00
	Lesen Impot| *Import License*	220,000.00
	Lesen Borong | *Manufacturer's License*	434,700.00
	Invois BE | *BE Invoice*	104,234.50
	Invois APB | *GMP Invoice*	720,611.50
	Amalan Perkilangan Baik | *Good Manufacturing Practice*	49,000.00
	Sijil APB | *GMP License*	23,150.00
73999	Perkhidmatan Makmal | *Laboratory Testing*	17,500.00
	Jualan Lain | *Other Sales*	4,360.00
Jumlah | *Total*		**12,433,355.67**

Halatuju BPFK

The Way Forward

Kajian rintis Plasma Produk Lot Release akan dijalankan dari 1 Januari 2016 hingga 30 Jun 2016 dan akan melibatkan tiga jenis produk plasma, iaitu Faktor VIII, Albumin Manusia dan Faktor VIII: Von Willebrand Factor (VWF) complex. Ini akan disusuli dengan pelaksanaan penuh ke atas semua produk plasma yang didaftarkan di Malaysia bermula 1 Julai 2016.

The pilot study for Plasma Products Lot Release will be conducted from 1st January 2016 to 30th June 2016 and involves three types of plasma products, namely Factor VIII, Human Albumin and Factor VIII: Von Willebrand Factor (VWF) complex. This will be followed by full implementation for all plasma products registered in Malaysia from 1st July 2016 onwards.

Selaras dengan rancangan Malaysia untuk menceburi bidang penghasilan vaksin, kami sedang membuat persiapan bagi menjalankan ujian ke atas produk - produk biologikal yang telah dibangunkan dengan pesat sejak kebelakangan ini. BPFK kini dalam proses persediaan untuk membangunkan makmal pengujian bagi produk-produk ini.

As Malaysia plans to venture into vaccine production, we are preparing ourselves to conduct testing on biological products which have developed tremendously in recent years. The NPCB is in the midst of preparatory works to set up a testing laboratory for these products.

Pada masa yang sama, senarai makmal swasta yang mematuhi keperluan BPFK akan disediakan dan dipaparkan di laman sesawang BPFK. Pada masa akan datang, pengeluar tempatan akan diberi pilihan untuk menghantar produk mereka ke BPFK atau pun ke makmal swasta yang tersenarai bagi tujuan ujian pra-pendaftaran. Tanggungjawab bersama dalam menjalankan ujian rutin seperti Ujian Had Logam Berat serta Ujian Had Mikrobial akan membolehkan BPFK menumpukan lebih perhatian kepada ujian yang lebih kompleks.

At the same time, a list of private laboratories which comply with NPCB's requirements will be established and made available on the NPCB's website. In the future, local manufacturers will be given the choice to send their products either to NPCB or to the listed private laboratories for the purpose of pre-registration testing. The shared responsibility to perform routine testing such as Heavy Metal Limit Test as well as Microbial Limit Test, will allow NPCB to focus on more complex testing.

BPFK sangat mengutamakan kesihatan dan kesejahteraan orang awam. Dengan pelaksanaan Cukai Barangan dan Perkhidmatan (GST) di negara ini, BPFK memastikan akses kepada ubat-ubatan penting bagi orang awam tidak terjejas. Untuk membantu orang awam dalam mengenal pasti ubat-ubatan penting yang tidak dikenakan cukai di bawah GST, BPFK akan memperkenalkan huruf akhiran baru iaitu 'Z' pada nombor pendaftaran bagi semua ubat di bawah Senarai Ubat Penting Kebangsaan. Bagi membantu para pengilang dan mempercepatkan perubahan ini, BPFK membenarkan label dicetak semula dengan nombor pendaftaran baru tanpa melalui proses variasi.

The NPCB places a high priority on the public's health and well-being. In view of the Goods and Services Tax (GST) implementation in the country, the NPCB ensures that access to essential medicines for the public remains unaffected. To assist the public in identifying the essential medicines which are not taxable under GST, NPCB will be introducing a new suffix 'Z' in the registration number for all medicines under the National Essential Medicine List. To assist the manufacturers and to speed up this change, NPCB is allowing the label to be reprinted with the new registration number without going through the variation process.

BPFK akan menaik taraf sistem pendaftaran atas talian bagi menampung jumlah produk baru yang semakin meningkat. Sistem baru ini yang dikenali sebagai QUEST3+ mempunyai ciri-ciri baru seperti pembayaran atas talian dan token keselamatan yang baru. Sistem ini direkacipta supaya lebih kukuh bagi menampung peningkatan jumlah pengguna dan produk untuk didaftarkan.

To cater to the escalating number of new products, the NPCB will be upgrading the online registration system. This upgraded system called QUEST3+ will include new features such as online payment and a new security token. The new system will be more robust to cater for the continuously increasing number of users and products to be registered.

Di samping itu, BPFK akan terus mengekalkan keahlian antarabangsa seperti Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (dirujuk bersama sebagai PIC/S) dan juga Non-Organisation for Economic Cooperation and Development (OECD) member adhering to Mutual Acceptance Data (MAD) system in the Assessment of Chemicals on Good Laboratory Practice (GLP). Pada masa yang sama, BPFK akan sentiasa bekerja ke arah mewujudkan lebih banyak kerjasama dengan agensi antarabangsa dan mengambil bahagian dalam kumpulan kerja antarabangsa untuk memastikan BPFK bergerak ke hadapan bersama agensi lain di peringkat global dalam bidang kawalan ubat-ubatan.

On top of all that, NPCB will continue to maintain its international memberships such as the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (jointly referred to as PIC/S) as well as the Non-Organisation for Economic Cooperation and Development (OECD) member adhering to Mutual Acceptance Data (MAD) system in the Assessment of Chemicals on Good Laboratory Practice (GLP). In addition, the NPCB will continue to work towards having more cooperation with international agencies and participate in international working groups to ensure NPCB moves forward alongside our counterparts globally in the area of medicine control.

Setelah Malaysia memberi komitmen terhadap Perjanjian Perkongsian Trans Pasifik (TPPA), BPFK akan meneruskan kecekapan dalam kerja-kerja rutin bagi memastikan tanggungjawab di bawah TPPA dipenuhi. Objektifnya adalah untuk memastikan keseimbangan di antara memberi peluang bagi penemuan ubat-ubatan baru dan pada masa yang sama, mengekalkan akses kepada ubat-ubatan penting. Ini akan memberi manfaat kepada ekonomi Malaysia dan meningkatkan perdagangan antarabangsa negara ini, serta pada masa yang sama memastikan kebajikan dan kepentingan rakyat Malaysia terjaga.

Upon Malaysia's commitment to the Trans Pacific Partnership Agreement (TPPA), NPCB will continue our efficiency in the routine work processes in order to make sure the obligations under the TPPA are met. The objective is to find the right balance between providing opportunity for the discovery of new medicines and at the same time maintaining access to essential medicines. This will be beneficial for Malaysia's economy and increase our country's international trade, and at the same time ensures that the welfare and interest of the people of Malaysia is well taken care of.

Nota I *Notes:*

Nota I *Notes:*

National Pharmaceutical Control Bureau (NPCB)
Biro Pengawalan Farmaseutikal Kebangsaan
Lot 36, Jalan Universiti
46200 Petaling Jaya
+603-7883 5400
+603-7956 2924
www.bpfk.gov.my