ANNUAL REPORT
LAPORAN TAHUNAN
2007

NPCB

National Pharmaceutical Control Bureau

Biro Pengawalan Farmaseutikal Kebangsaan

Director's Message Utusan Pengarah

Time certainly flies fast and now that we have come to the end of 2007, a new chapter opens with the coming of 2008. Alhamdulillah, the National Pharmaceutical Control Bureau (NPCB) has once again successfully played its role effectively as a regulatory body throughout the year of 2007. As the Director of the NPCB, I am entrusted to continue the efforts of the previous directors of NPCB in that the mission of the organisation is achieved.

NPCB is an institution with a workforce of almost 300 staff. Certainly for it to be successful, the spirit of helping one another and teamwork amongst the staff is essential. As the saying goes "together we stand, divided we fall". Without interaction and teamwork between departments as well as staff members, numerous problems may arise and this will definitely disrupt the flow of work processes. Thus, my advice here is that the good teamwork that exists between staff should be maintained and nurtured well.

NPCB is an organisation that is always striving towards excellence in the regulatory area by maintaining a high standard in the regulatory practice. In tandem with the rapid growth of the pharmaceutical industry, NPCB also needs to keep abreast, e.g. in terms of capacity and capability building so as to stay relevant.

In general, the year 2007 has been a very good year for NPCB in the regulatory field

Masa berlalu begitu pantas dan tanpa disedari tahun 2007 telah melabuhkan tirainya dan lembaran baru 2008 pula bermula. Syukur Alhamdulillah, Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah berjaya memainkan peranannya sebagai badan regulatori dengan baik sepanjang tahun 2007. Sebagai Pengarah BPFK, saya memikul tanggungjawab untuk meneruskan usaha pengarah-pengarah BPFK yang lalu bagi memastikan misi organisasi dapat dicapai dengan cemerlang.

BPFK mempunyai anggota seramai hampir 300 orang, dan semangat bantu-membantu serta bekerjasama antara anggota sangat penting bagi memastikan ianya sentiasa berjaya. Bak kata pepatah "bersatu kita teguh bercerai kita roboh". Tanpa interaksi serta kerjasama antara pusat-pusat dan anggota, pelbagai masalah mungkin timbul dan ini akan mengganggu kelancaran sesuatu proses kerja. Jadi saranan saya di sini ialah agar kerjasama yang baik terpupuk antara kakitangan selama ini dapat diteruskan lagi.

BPFK sentiasa menuju ke arah kecemerlangan dalam bidang regulatori dengan sentiasa mempraktikkan tahap piawaian yang tinggi dalam amalan regulatori. Dengan adanya industri farmaseutikal yang pesat membangun, BPFK juga perlu bergerak seiringan dengan perkembangan industri agar tidak ketinggalan dan sentiasa relevan.

because the QUEST2 on-line registration system for pharmaceutical, traditional and cosmetic products have been running smoothly. Efforts were taken to upgrade the ICT infrastructure from QUEST2 to QUEST3. Besides that, the registration of veterinary products was launched on the 1st of August 2007 for the existing products. At the same time, preparation was undertaken for the smooth implementation of the notification process for cosmetics which is due to take off on 1st January 2008.

The success of NPCB in maintaining the ISO 9001:2000 certification during the assessment audit by SIRIM on the 9th - 10th July 2007 has proven that quality management is highly emphasised by this organisation. On the same note, NPCB continues efforts to upgrade the laboratory quality management system to obtain the ISO 17025 accreditation with focus being given to traditional product testing. NPCB is also actively involved in harmonisation efforts. In 2007, NPCB was involved in several meetings on regional and international harmonisation which includes meeting of the ASEAN Consultative Committee for Standards & Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and ACCSQ Traditional Medicines and Health Supplements Product Working Group (PWGTMHS), EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments and Malaysia-US Free Trade Agreement (MUSFTA). NPCB was also given the honour to play host in a few important meetings that included the 13th ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) held on the 23rd-27th July 2007 in Kuala Lumpur and the ASEAN Regional Consultative Meeting on Fast Track Registration on Antiretrovirals (ARVs) and Diagnostic Reagents held in Penang on the 21st-23rd of November 2007.

As mentioned above, great teamwork and good relationship amongst the staffs was developed through various social and welfare activities that were conducted by Wives and Ladies of the Malaysian Civil Service (Puspanita) BPFK Society, and BPFK Club and Muslim Staff Welfare Body (BAKKI). The activities organised included the bazaar by Puspanita, talks, seminars, Khatam Quran ceremony, 'Aneka Perayaan' celebration and farewell ceremony to honor several retiring NPCB staffs.

To ensure a workplace that is conducive, some infrastructure upgrading was also undertaken. Renovation of office area were carried out in the various centres namely the Administration Centre, Centre for Post Product Registration, Centre for Product Registration, Centre for Compliance and

Secara amnya, tahun 2007 adalah tahun yang baik untuk BPFK dalam bidang regulatori kerana sistem pendaftaran atas-talian QUEST2 untuk produk farmaseutikal, tradisional dan kosmetik telah berjalan dengan lancar. Usaha untuk menaiktaraf sistem prasarana ICT daripada QUEST2 kepada QUEST3 telah giat dijalankan. Selain itu, pada 1 Ogos 2007, pendaftaran dan pelesenan produk veterinar telah pun dimulakan. Pada masa yang sama, persiapan rapi juga telah dijalankan sebagai persediaan bagi melaksanakan proses notifikasi produk kosmetik yang berkuatkuasa pada 1 Januari 2008.

Kejayaan BPFK mengekalkan pensijilan ISO 9001:2000 dalam audit SIRIM yang berlangsung pada 9-10 Julai 2007 telah menunjukkan betapa pengurusan berkualiti sangat dititikberatkan oleh organisasi ini. Disamping itu, BPFK juga sedang meneruskan usaha untuk menaiktaraf sistem pengurusan kualiti makmal bagi mencapai akreditasi ISO 17025 dengan memberi fokus kepada pengujian produk tradisional. BPFK juga telah terlibat dalam usaha harmonisasi dan terdapat anggotanya yang mewakili Malaysia ke beberapa mesyuarat kerjasama serantau dan antarabangsa. Di antara mesyuarat yang telah dihadiri ialah Mesyuarat ASEAN Consultative Committee for Standards & Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) dan ACCSQ Traditional Medicines and Health Supplements Product Working Group (PWGTMHS), EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assesments dan Rundingan Malaysia-US Free Trade Agreement (MUSFTA). Malaysia juga telah diberi penghormatan menjadi tuan rumah bagi Mesyuarat ACCSQ (PPWG) ke-13 yang diadakan pada 23-27 Julai 2007 di Kuala Lumpur dan Mesyuarat ASEAN Regional Consultative Meeting on Fast Track Registration on Antiretrovirals (ARVs) and Diagnostic Reagents yang telah diadakan di Pulau Pinang pada 21-23 November 2007.

Kerjasama dan keakraban sesama kakitangan BPFK telah dipupuk melalui pelbagai aktiviti sosial dan kebajikan yang dianjurkan oleh persatuan Puspanita BPFK, Kelab BPFK serta Badan Kebajikan Kakitangan Islam (BAKKI). Antara aktiviti-aktiviti yang telah dijalankan ialah pasaria Puspanita, ceramah, seminar, majlis khatam Quran, majlis beraneka perayaan serta majlis keraian sempena persaraan anggota BPFK.

Untuk memastikan keselesaan dan peningkatan mutu kerja anggota, pembangunan prasarana telah juga dititikberatkan. Pengubahsuaian ruang pejabat telah dilakukan di Pusat Pentadbiran, Pusat Pasca Pendaftaran Produk, Pusat Pendaftaran Produk, Pusat Komplians

Licensing, Centre for Quality Control and Centre for Organizational Development. A new Private Automatic Branch Exchange (PABX) telephone system was also introduced to replace the old system.

As a regulatory body, NPCB is responsible to disseminate information as well as to educate the public on regulatory decisions. The good relationship between the NPCB and the industry established through dialogues and meetings enabled problems that cropped up throughout the year to be ironed out. Throughout 2007, a total of 5 dialogues with the industry have been conducted.

Last but not least, I would like to express my deepest appreciation to all the staff of NPCB as well as those who are related to NPCB either directly or indirectly for all their contribution throughout the year. I would also like to extend my most sincere gratitude to the Director of Pharmaceutical Services for his support and suggestions on ways of improving the quality of services provided by this organisation. I also hope that the year 2008 will be a better and brighter year for the NPCB.

Thank you.

dan Pelesenan, Pusat Kawalan Kualiti dan Pusat Pembangunan Organisasi. Selain itu sistem telefon 'Private Automatic Branch Exchange' (PABX) baru juga telah diwujudkan untuk menggantikan sistem yang telah lama.

Sebagai badan regulatori di Malaysia, BPFK juga bertanggungjawab untuk menyebarkan maklumat serta memberi tunjuk ajar kepada orang awam dalam hal regulatori. Kerjasama yang erat antara BPFK dan pihak industri setakat ini memberi impak positif dalam usaha untuk meningkatkan prestasi dan kualiti keluaran-keluaran farmaseutikal tempatan. Melalui persefahaman yang jitu ini juga ditambah dengan dialog-dialog yang diadakan, sebarang masalah yang timbul dapat dibincang, dikaji dan diselesaikan dengan baik. Sepanjang tahun 2007, sebanyak 5 dialog telah diadakan dengan pihak industri.

Akhir kata, saya ingin mengucapkan setinggi-tinggi penghargaan kepada semua warga BPFK serta semua yang terlibat dengan BPFK secara langsung atau tidak langsung atas jasa dan sumbangan yang diberikan tanpa mengira waktu sepanjang tahun. Jutaan terima kasih juga saya ucapkan kepada Pengarah Bahagian Perkhidmatan Farmasi yang sentiasa memberi sokongan dan cadangan bagi memajukan lagi BPFK. Saya juga berharap agar tahun 2008 akan menjadi tahun yang lebih baik dan bersinar untuk BPFK.

Sekian, terima kasih.
Salam hormat.

Hasnah Ismail

DIRECTOR
National Pharmaceutical Control Bureau

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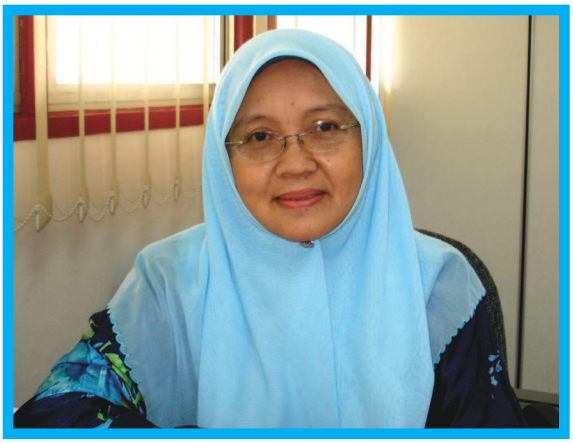

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The National Pharmaceutical Control Bureau

Biro Pengawalan Farmaseutikal Kebangsaan

The National Pharmaceutical Control Bureau

The National Pharmaceutical Control Bureau (NPCB), initially known as the National Pharmaceutical Control Laboratory (NPCL) was set up under the quality control activity of Pharmacy and Supply Programme. The institution was established to implement quality control testing of pharmaceutical products.

With the promulgation of the Control of Drugs and Cosmetics Regulations 1984 (CDCR) and the establishment of the Drug Control Authority (DCA) in 1985, the NPCB which acts as secretariat to the DCA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme.

In recognition of its role and functions in the international regulatory arena, since 1996 the NPCB was designated as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals. The NPCB has provided technical assistance and training of WHO fellows from ASEAN member countries and also other developing countries.

The NPCB gained accession as the 26th member of Pharmaceutical Inspection Co-operation Scheme (PIC/S) as from 1st January 2002. Since then, NPCB has been actively involved in international Good Manufacturing Practices (GMP) and Quality Assurance programmes organized by PIC/S and WHO.

In tandem with globalisation, the NPCB has also participated actively in the initiatives towards ASEAN harmonization for pharmaceuticals, cosmetics, traditional medicines and health supplements.

As an organization that continuously strives to provide efficient service to its clients, the NPCB has implemented the ISO 9001:2000 Quality Management System and acquired SIRIM certification for the regulatory control of pharmaceuticals, traditional medicines and cosmetics.

Biro Pengawalan Farmaseutikal Kebangsaan

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) yang dahulunya dikenali sebagai Makmal Kimia Ubat Kebangsaan ditubuhkan di bawah aktiviti kawalan kualiti Program Farmasi dan Bekalan. Institusi ini ditubuhkan untuk mengimplementasikan ujian kawalan kualiti produk farmaseutikal.

Apabila Peraturan Kawalan Dadah dan Kosmetik(Control of Drugs and Cosmetics Regulations) 1984 digubal dan Pihak Berkuasa Kawalan Dadah (PBKD)ditubuhkan pada tahun 1985, BPFK, yang dilantik sebagai sekretariat kepada PBKD telah diberikan tanggungjawab untuk memastikan kualiti, efikasi dan keselamatan produk farmaseutikal melalui program pendaftaran dan pelesenan produk.

Sebagai pengiktirafan untuk peranan dan fungsi yang dimainkan oleh BPFK dalam arena regulatori antarabangsa, BPFK telah dilantik sebagai Pusat Kolaborasi WHO bagi Kawalan Regulatori Farmaseutikal sejak tahun 1996. BPFK telah memberi bantuan teknikal dan latihan kepada ahli-ahli negara ASEAN serta negara-negara sedang membangun yang lain.

Pada 1 Januari 2002, BPFK telah menjadi ahli yang ke-26 dalam Pharmaceutical Inspection Co-operation Scheme (PIC/S). Sejak itu, BPFK telah terlibat secara aktif dalam program Amalan Pengilangan Baik Antarabangsa dan program Jaminan Kualiti yang dianjurkan oleh PIC/S dan WHO.

Selaras dengan globalisasi, BPFK telah melibatkan diri secara aktif dalam program harmonisasi ASEAN untuk produk farmaseutikal, kosmetik, ubat tradisional dan suplemen kesihatan.

Sebagai sebuah institusi yang sentiasa berazam untuk memberi perkhidmatan yang terbaik kepada pelanggannya, BPFK telah mengimplementasikan Sistem Pengurusan Kualiti ISO 9001:2000 dan telah mendapat pensijilan SIRIM dalam kawalan regulatori farmaseutikal, ubat tradisional dan kosmetik.

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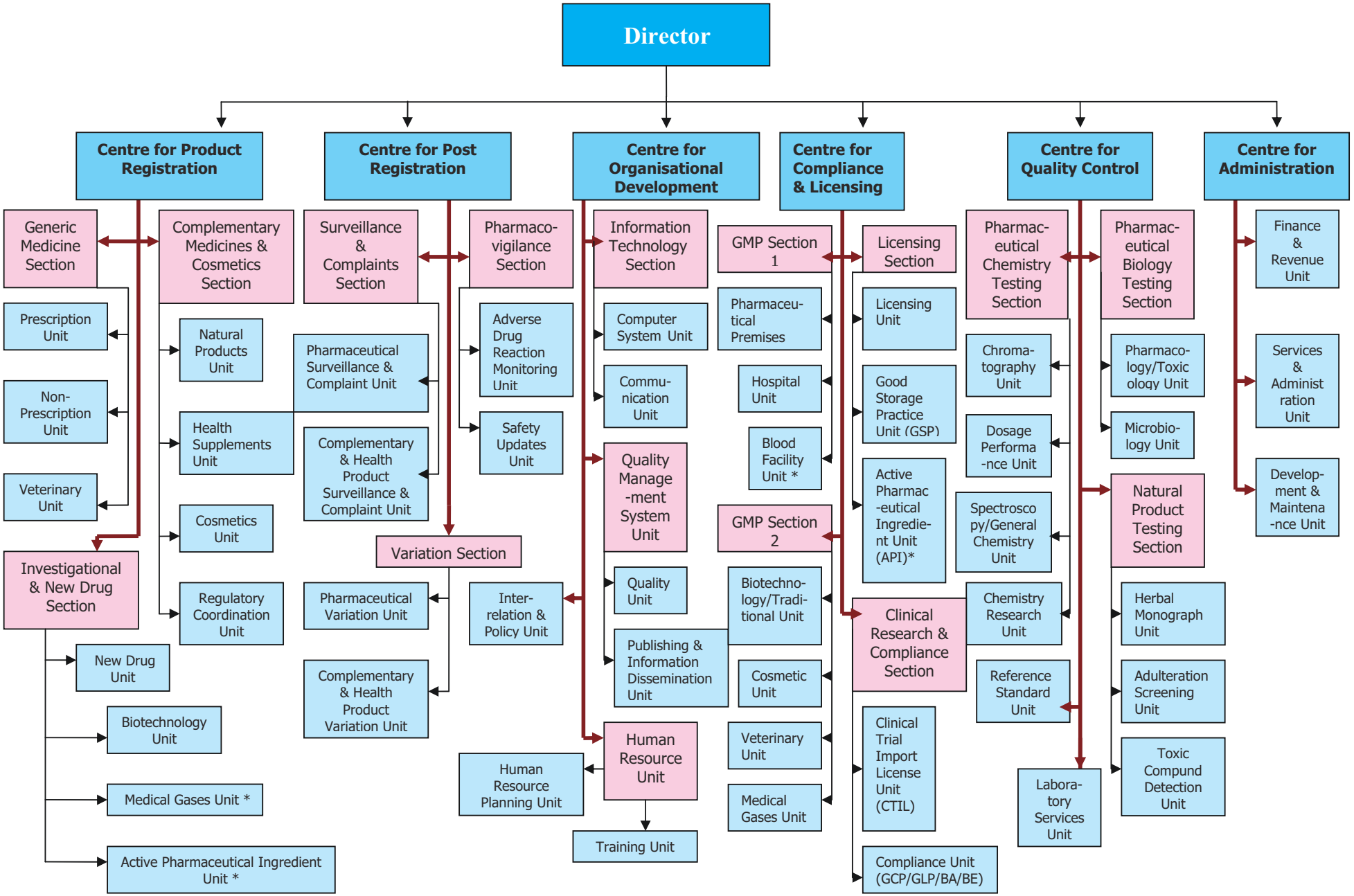
Organisation Chart of National Pharmaceutical Control Bureau

Carta Organisasi Biro Pengawalan Farmaseutikal Kebangsaan

Organisation Chart of National Pharmaceutical Control Bureau



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Highlights of Achievements in 2007

Kejayaan Dicapai Dalam Aktiviti Regulatori

Highlights of Achievements in 2007

i. The QUEST 2 system for on-line registration of pharmaceuticals and traditional medicines has successfully entered its fifth and fourth year of implementation respectively and the upgrading efforts of QUEST 2 to QUEST 3 is currently in progress.

ii. MS ISO 9001 version 2000 certification by SIRIM (an accreditation body for ISO) for the quality management system was successfully maintained.

iii. Malaysia has implemented the registration and licensing for veterinary medicines effective from 1st August 2007. Registration of product categories includes all categories of products with the exception of cosmetics. Several new/ updated guidelines such as the Registration Guidance Document for Veterinary Medicines Products to facilitate product registration were revised and developed. The adopted documents are available in the NPCB website (www.bpfk.gov.my).

iv. The NPCB continues to play an active role in the harmonisation efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and ACCSQ Traditional Medicines and Health Supplements Product Working Group (PWGTMHS). Other international involvements include facilitating the fast-track ASEAN healthcare integration and EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments, as well as other PIC/S activities. The NPCB has also participated in other international consultations such as Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries as well as participation in the Malaysia-US Free Trade Agreement (MUSFTA) negotiations.

v. Malaysia is currently using the ASEAN Common Technical Dossier (ACTD), the ASEAN Guidelines for Bioavailability/Bioequivalence (BA/BE) as well as the ASEAN Guidelines for Stability Studies.

Kejayaan Dicapai Dalam Aktiviti Regulatori

i. Sistem online, QUEST 2 untuk pendaftaran produk farmaseutikal, tradisional dan kosmetik berjalan dengan baik. Usaha menaiktaraf sistem QUEST 2 ke QUEST 3 sedang dijalankan.

ii. Pensijilan MS ISO 9001 versi 2000 oleh SIRIM (badan akreditasi ISO) untuk sistem pengurusan kualiti berjaya dikekalkan.

iii. Malaysia telah memulakan pendaftaran dan pelesenan ubat veterinar pada 1 Ogos 2007. Pendaftaran kategori produk termasuk semua kategori produk kecuali kosmetik. Beberapa panduan baru/terkini seperti Panduan Pendaftaran Produk Ubat Veterinar untuk memudahkan pendaftaran produk berkenaan telah dibangunkan. Dokumen-dokumen berkenaan boleh diperolehi daripada laman web BPFK (www.bpfk.gov.my).

iv. BPFK meneruskan usaha harmonisasi melalui penyertaannya dalam *ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and ACCSQ Traditional Medicines and Health Supplements Product Working Group (PWGTMHS)*. Penglibatan antarabangsa lain termasuk penyertaan dalam *fast-track ASEAN healthcare integration and EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments* dan juga aktiviti-aktiviti PIC/S. BPFK juga mengambil bahagian dalam perundingan antarabangsa lain seperti Mesyuarat Teknikal dan memulakan Bilateral Arrangements dengan negara ASEAN serta penglibatan dalam rundingan Malaysia-US Free Trade Agreement (MUSFTA).

v. Malaysia sedang menggunakan *ASEAN Common Technical Dossier (ACTD), ASEAN Guidelines for Bioavailability/Bioequivalence (BA/BE)* dan juga *ASEAN Guidelines for Stability Studies.*

vi. Malaysia telah menjadi tuan rumah Mesyuarat *ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG)* ke-13 yang berlangsung

vi. Malaysia successfully hosted the 13th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) which was held on the 23rd-27th July 2007 in Kuala Lumpur, Malaysia. The ASEAN Regional Consultative Meeting on Fast Track Registration on Antiretrovirals (ARVs) and Diagnostic Reagents was also successfully held on 21st-23rd November 2007 in Penang, Malaysia.

vii. The NPCB continues its efforts towards further upgrading the laboratory quality management system to achieve the ISO 17025 accreditation.

viii. Implementation of new fee structure for laboratory testing, effective from 1st January 2007.

ix. Implementation of validation data evaluation to replace sample testing (pre - registration) for galenical products (new product registration) starting from 1st July 2007.

pada 23-27 Julai 2007 di Kuala Lumpur. *ASEAN Regional Consultative Meeting on Fast Track Registration on Antiretrovirals (ARVs) and Diagnostic Reagents* juga diadakan pada 21-23 November 2007 di Pulau Pinang.

vii. BPFK meneruskan usaha untuk menaiktaraf sistem pengurusan kualiti makmal bagi mencapai akreditasi ISO 17025 dengan fokus kepada pengujian produk tradisional.

viii. Perlaksanaan skim pembayaran yuran pengujian makmal pada kadar baru, berkuatkuasa pada 1 Januari 2007.

ix. Perlaksanaan penilaian data validasi bagi menggantikan pengujian sampel (sebelum pendaftaran) bagi produk galenikal (permohonan pendaftaran produk baru) bermula 1 Julai 2007.

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Regulatory Status
Status Regulatori

Regulatory Status

i. In 2007, a cumulative total of **200,314** product applications for registration have been received, of which **175,746** have been approved.

The breakdown for the type of applications received in 2007 is as follows:

•Scheduled poisons	- **555**
•Non-scheduled poisons	- **560**
•Traditional medicines	- **1,325**
•Cosmetics	- **25,534**
TOTAL	- ***27,974***

A total of **30,607** product applications were approved in 2007, of which **449** are for scheduled poisons (prescription item), **413** for non-scheduled poisons (non - prescription items), **1,342** for traditional medicines and **28,403** for cosmetics.

ii. A total of **4,637** Certificates of Pharmaceutical Product (CPP) and Certificates of Free Sale (CFS) were issued for the year 2007. The total number of Clinical Trial Import Licences (CTIL) issued was **231**.

iii. A total of **301** manufacturing premises were licensed in 2007. For importers, a total of **576** were licensed and for wholesalers, a total of **1,063** were licensed.

iv. Under the post-market surveillance program, a total of **2,538** samples were taken from the market, **2,413** labels and package inserts examined, **144** batch recalls were instituted, **62** warning letters were issued and **361** product complaints were investigated.

v. As for quality control testing, a total of **5,322** samples were tested of which **2,128** were registration samples, **2,761** were surveillance samples, **270** were enforcement samples, **155** were from product complaints and adverse drug reaction reports and **8** others. A total of **68,774** tests were conducted.

Status Regulatori

i. Pada tahun 2007, jumlah kumulatif sebanyak **200,314** permohonan pendaftaran produk telah diterima, dimana **175,746** permohonan telah diluluskan.

Pecahan mengikut jenis permohonan diterima dalam tahun 2007 adalah seperti berikut:

Racun Berjadual	- **555**
Bukan Racun Berjadual	- **560**
Ubat Tradisional	- **1,325**
Kosmetik	- **25,534**
JUMLAH	- ***27,974***

Sebanyak **30,607** permohonan telah diluluskan pada tahun 2007, di mana **449** ialah produk preskripsi, **413** produk bukan preskripsi, **1,342** ialah ubat tradisional dan **28,403** untuk produk kosmetik.

ii. **4,637** Sijil Produk Farmaseutikal (*Certificate of Pharmaceutical Product (CPP)*) dan Sijil Jualan Bebas (*Certificates of Free Sale (CFS)*) telah dikeluarkan pada tahun 2007 manakala jumlah Lesen Import Ujian Klinikal (*Clinical Trial Import Licence (CTIL)*) yang dikeluarkan ialah **231**.

iii. Sebanyak **301** premis pengilang dilesenkan pada tahun 2007. Untuk premis pengimport, sebanyak **576** premis telah dilesenkan manakala **1,063** premis pemborong telah dilesenkan.

iv. Di bawah program surveilans pasca pasaran, sebanyak **2,538** sampel telah diambil dari pasaran, **2,413** label dan sisip bungkusan telah diperiksa, **144** kelompok telah ditarik balik dari pasaran, **62** surat amaran dikeluarkan dan **361** aduan tentang produk telah disiasat.

v. Di bawah ujian kawalan kualiti, sebanyak **5,322** sampel telah diuji di mana **2,128** merupakan sampel pendaftaran, **2,761** adalah sampel surveilans, **270** adalah sampel dari penguatkuasa, **155** adalah sampel aduan produk serta laporan kesan advers dan **8** sampel lain-lain. Sebanyak **68,774** ujian telah dijalankan.

vi. A total of **248** vials of ASEAN and NPCB reference standards were supplied to government departments (Chemistry Department, Government Medical Store Sarawak and State Enforcement Units) and a total of **508** vials were sold to the private sector (comprising of **370** NPCB reference standards and **138** ASEAN reference standards).

vii. Under the Adverse Drug Reactions Monitoring Program, a total of **3,056** ADR reports were received in 2007, of which **2,808** reports were sent to the Uppsala WHO Monitoring Centre for inclusion into the WHO database.

viii. A total of **2,935** queries pertaining to products and also general information from both the public and private sectors were dealt with.

vi. Sebanyak **248** vial piawai rujukan ASEAN dan BPFK telah dibekalkan ke jabatan-jabatan kerajaan (Jabatan Kimia, Stor Ubat Kerajaan Sarawak dan Unit-Unit Penguatkuasa Negeri) dan sejumlah **508** vial telah dijual kepada sektor swasta (melibatkan **370** piawai rujukan BPFK dan **138** piawai rujukan ASEAN).

vii. Di bawah Program Pemonitoran Kesan Advers Ubat, sebanyak **3,056** laporan kesan advers diterima pada tahun 2007, di mana **2,808** laporan telah dihantar ke WHO Monitoring Centre, Uppsala untuk dimasukkan ke dalam pangkalan data WHO.

viii. Sebanyak **2,935** pertanyaan mengenai produk dan maklumat am daripada sektor awam dan swasta telah dikendalikan.

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Staff List

Senarai Kakitangan

Staff List Senarai Kakitangan

Director | Pengarah

- Hasnah bt. Ismail - B.Sc (Hons), M.Sc (Pharm.SCi)

Deputy Director | Timbalan Pengarah

- Selvaraja Seerangam - B. Pharm (Hons), M. Phil.
- Sulaikah Bt. V.K. Moideen (Dr.) - B. Pharm (Hons), M.Sc, Ph.D
- Abida Haq bt Syed M. Haq - B. Pharm (Hons), Dip Med Microbiology, M. Clin Pharmacy

Officers | Pegawai

1. Abdullah Hisham Bin Ahmad Yaya - B. Pharm (Hons), M. Pharm(Clinical Pharmacy)
2. Ahmad Syamsury bin Sulaiman - B. Pharm (Hons)
3. Ahmad Zakhi bin Ramli - B. Pharm (Hons)
4. Aida Haryati bt. Abd. Rahim - B. Pharm (Hons)
5. Anis bt Talib - B. Pharm (Hons)
6. Arpah bt Abas - B. Pharm(Hons)
7. Asnida bt Mat Daud - B. Pharm (Hons)
8. Azraini bt Abdul Samat - B. Pharm (Hons)
9. Azrina bt Hassan - B. Pharm (Hons)
10. Azura bt Abdullah - B. Pharm (Hons)
11. Azlina bt. Ismail - B. Pharm (Hons)
12. Bariah bt. Abdul Rani - B.Pharm (Hons)
13. Belinna Binti Abu Bakar - B. Pharm (Hons)
14. Chin Fui Fui - B. Pharm (Hons)
15. Ching Shan Lii - B. Pharm (Hons)
16. Chiong Yuh Lian - B. Pharm (Hons)
17. Chua Hui Ming - B. Pharm (Hons)
18. Debbie Sim Sook En - B. Pharm (Hons)
19. Faridah bt Hj. Abd. Malek - B. Pharm (Hons)
20. Fazillahnor Binti Ab. Rahim - B. Pharm (Hons)
21. Fuziah bt. Abdul Rashid - B. Pharm (Hons)
22. Halimatussa'adiah bt. Mat Som - B. Pharm (Hons)
23. Han Mei Yin - B. Pharm (Hons)
24. Hasenah bt. Ali (Dr.) - B. Pharm (Hons), M.Sc, Ph.D
25. Hasniza bt. Zaidan - B. Pharm (Hons)
26. Hazlinda Nazli binti Naem - B. Pharm (Hons)
27. Hng Kim Mi - B. Pharm (Hons)
28. Ida Syazrina bt Ibrahim - B. Pharm (Hons)
29. Irdawaty bt. Mohd. Salleh - B. Pharm (Hons)
30. Juanah Binti Garabus - B. Pharm (Hons)
31. Kadariah bt. Mohd. Ali - B. Pharm (Hons), M.Sc
32. Kamaruzaman b. Saleh (Dr.) - B. Pharm (Hons), M.Sc, Ph.D
33. Kamarudin bin Ahmad - B. Sc. (Pharm)
34. Khirul Falisa Binti Mustafa - B. Pharm (Hons)
35. Kok Chuan Fung - B. Pharm (Hons)
36. Lee Sher May - M. Pharm
37. Leong Yet Lee - B. Pharm (Hons)
38. Lian Lay Kim - B. Pharm (Hons)
39. Low Joo Meing - B. Pharm (Hons)
40. Maria binti Ja'afar - B. Pharm (Hons)
41. Maslinda Binti Mahat - B. Pharm (Hons)
42. Masnor binti Mat Daud - B. Pharm (Hons)
43. Mazarisusanty Ibrahim - B. Pharm (Hons)
44. Mazli bt. Muhamad - B. Pharm (Hons), M.Sc.
45. Mazlifah Bt. Mohd Fahami - B. Pharm (Hons)
46. Mazuwin bt. Zainal Abidin - B. Pharm (Hons), M.Sc
47. Mohd. Nasrul b. Mohamad Noor - B. Pharm (Hons)
48. Mohamed Shahrizan Bin Shahrir - B. Pharm (Hons)
49. Mokhtar bin Abdullah - B. Pharm (Hons)
50. Muhammad Lukmani b. Ibrahim - B. Pharm (Hons)
51. Muhammad Nasir bin Hashim – M. Sc (Analytical Chemistry and Instrumental Analysis), B. Pharm (Hons)
52. Nahdiah Binti Ariffin - B. Pharm (Hons)
53. Narqes Bt. Mohd. Raimi - B. Pharm (Hons)
54. Nik Shamsiah bt Nik Salleh - B. Pharm (Hons)
55. Noor'ain bt. Shamsuddin - B. Pharm (Hons)
56. Noraida binti Mohamad Zainoor - B. Pharm (Hons)
57. Noraisyah bt Mohd. Sani - B. Pharm (Hons)
58. Noorizam bt. Ibrahim - B. Pharm (Hons), M. Pharm
59. Noorul Akmar Bt. Mohd. Nur – M. Pharmaceutical Technology, B. Pharm (Hons), Diploma in Medical Microbiology
60. Nor Hafizah bt. Mohd. Potri - B. Pharm (Hons)
61. Noor Hidayah bt. Mohd. Nor - B. Pharm (Hons)
62. Nor Hayati Bt. Hussein - B. Pharm (Hons)
63. Nor Hayati Bt. Musa - B. Pharm (Hons)
64. Nor Hayati Abdul Rahim - B. Pharm (Hons)
65. Norshida binti Kassim - B. Pharm (Hons)
66. Norul Azmira bt. Abu Bakar - B. Pharm. (Hons)
67. Nurhayati bt. Omar - B. Pharm (Hons)
68. Nurhayati bt. Othman - B. Pharm (Hons)
69. Nurleen bt. Mohamed Ali - B. Pharm (Hons)
70. Nurul Fajar bt Mohd. Jamid - B. Pharm (Hons)
71. Ong Yi Chin - B. Pharm (Hons)
72. Pua Ann Nee - B. Pharm (Hons)
73. Rosilawati bt Ahmad - B. Pharm (Hons), M.Sc.
74. Saleha bt. Md. Ewan - B. Pharm (Hons)
75. Sarawani binti Hassan - B. Pharm (Hons)
76. Seetha a/p Ramasamy - B. Pharm (Hons)
77. Siti Hidayah bt. Kasbon - B. Pharm (Hons)
78. Siti Madziah bt. Mohamed - B. Pharm (Hons), M. Pharm
79. Slavia Fifi Koh Yin Ying- B. Pharm (Hons)
80. Somiyaton bt Dahalan @ Damuri - B. Pharm (Hons)
81. Sufian Hardi bin Mohamad Zuhair - B. Pharm (Hons)
82. Suhaili Binti Samad - B. Pharm (Hons)
83. Suhailah bt Abu Bakar - B. Pharm (Hons)
84. Sulaiman Bin Hj. Ahmad - B. Pharm (Hons)

85. Suzana binti Mohd. Nor- B. Pharm (Hons)
86. Tan Ann Ling - B. Pharm (Hons)
87. Tan Lie Sie - B. Pharm (Hons)
88. Tan See Hooi - M. Pharm
89. Tan Shiau Yi - B. Pharm (Hons)
90. Tan Teck Koon - M. Pharm
91. Tg. Mira binti Tengku Fatimi - B. Pharm (Hons)
92. Vidhya a/p Hariraj - B. Pharm (Hons)
93. Wan Nurul Aina bt. Mior Abdullah - B. Pharm (Hons)
94. Wan Othman Wan Ismail - B. Pharm (Hons)
95. Yip Yi Hui - M. Pharm
96. Yvonne Khoo Siew Khoon - B. Pharm (Hons)
97. Yusni Rizal b. Khairul Anuar - B. Pharm (Hons)
98. Zahura bt. Mohamed @ Ismail - B. Pharm (Hons)
99. Zakiah bt Abd. Ghafar - B. Pharm (Hons)
100. Zaril Harza b. Zakaria - B. Pharm (Hons)
101. Zarina bt Rosli - B. Pharm (Hons)
102. Zuraida bt Abdullah - B. Pharm (Hons)

Provisionally Registered Pharmacist | Pegawai Farmasi Provisional

1. Tan Kar Yan
2. Jeannie Lee Jing Yi
3. Mesa Chieng Lee Li
4. Zeti Hulwani Bt. Baba
5. Chai Che Leong
6. James Ooi Joe Behn
7. Syahadatul Iman Mohamad
8. Woo Ai Ling
9. P'ng Ziyan
10. Teh Lih Yan
11. Atikah Bt. Shaharudin
12. Chow Guan Kuan
13. Shaik Muhammad Naquib Bin Shaik Mohamed
14. Erina Camilla Bt. Mohd. Ghazali
15. Fadhilah Bt. Hasbullah
16. Siti Nor Rahizah Bt. Abd. Razak
17. Lee Yee Chen
18. Nee Yuan Qi
19. Tan Chin Ling
20. Fauziah Binti Mohamed Kasim
21. Fathiyah Ahmad Faraid

Total Number of Pharmacists – 127
Jumlah Pegawai Farmasi – 127

Other Support Staff | Kakitangan Sokongan

- Pharmacy Assistants Pembantu Famasi - 67
- Science Officers (temporary staff) Pegawai Sains (Kakitangan Sementara) - 23
- Administrative and Support Staff Pentadbiran dan Kakitangan Sokongan- 34
- Administrative and Support Staff (temporary staff) Pentadbiran dan Kakitangan Sokongan (Kakitangan sementara)- 14

TOTAL NUMBER OF STAFF: 265 | JUMLAH KAKITANGAN: 265

National Pharmaceutical Control Bureau
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NPCB Clients' Charter

Piagam Pelanggan BPFK

NPCB Clients' Charter

1. PRODUCT REGISTRATION

a. Full Evaluation

Prescription and Non Prescription Drugs (on-line)	12 months
New Drug and Biologicals (manual-Stage 3)	12 months

b. Abridged Evaluation

Health Supplement Products	6 months
Natural Products	6 months
Non Prescription Drugs	6 months
Cosmetics	1 month

2. LICENSING

a. Wholesaler's, Manufacturer's, Importer's License

Not more than 3 months

b. Clinical Trial Import License

Not more than 2 months

3. LABORATORY TESTING

a. For registration purposes

Not more than 4 months

4. VARIATION APPLICATION PROCESSING

a. Variation application

Type 1 Change	2 weeks
Type 2 Change	2 months

b. Change of Manufacturing Site

Type I – Type V (manual)	2 months

5. CHANGE OF REGISTRATION HOLDER

2 months

6. PRODUCT CERTIFICATION

3 weeks

Piagam Pelanggan BPFK

1. PENDAFTARAN PRODUK

a. Penilaian Penuh / Full Evaluation

Ubat Preskripsi dan Bukan Preskripsi (on-line)	12 bulan
Ubat Baru dan Biologikal (manual-peringkat ke 3)	12 bulan

b. Penilaian Ringkas / Abridged Evaluation

Produk Suplemen Kesihatan	6 bulan
Produk Semula Jadi	6 bulan
Ubat Bukan Preskripsi	6 bulan
Produk Kosmetik	1 bulan

2. PELESENAN

a. Lesen Pemborong, Pengilang, Pengimport

Tidak lebih dari 3 bulan

b. Lesen Import untuk Percubaan Klinikal

Tidak lebih dari 2 bulan.

3. UJIAN MAKMAL

a. Bagi tujuan pendaftaran

Tidak lebih dari 4 bulan

4. PEMPROSESAN PERMOHONAN VARIASI

a. Permohonan Variasi

Pindaan – Jenis 1	2 minggu
Pindaan – Jenis 2	2 bulan

b. Pertukaran Tapak Pengilang

Jenis I – Jenis V (manual)	2 bulan

5. PERTUKARAN PEMEGANG PENDAFTARAN

2 bulan

6. PERAKUAN PRODUK

3 minggu

National Pharmaceutical Control Bureau
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Vision and Mission
Visi dan Misi

Vision and Mission

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.

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

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

STRATEGY
- To ensure organisational efficiency and effectiveness through modernisation and automation of the office, laboratory and registration systems, and regular review and improvement of services
- To strengthen enforcement activity of the related legislation
- To ensure continuous mutual understanding and co-operation between the regulatory body 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

Visi dan Misi

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

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

MATLAMAT
Memastikan bahawa bahan-bahan terapeutik yang dibenarkan di pasaran tempatan adalah selamat, berkesan dan bermutu, serta menentukan bahawa kosmetik yang dibenarkan di pasaran adalah selamat dan bermutu.

STRATEGI
- Memastikan kecekapan dan keberkesanan organisasi melalui pemodenan dan automasi sistem-sistem pejabat, makmal dan pendaftaran, peninjauan serta pembaikan perkhidmatan secara regular.
- Memperkukuhkan aktiviti penguatkuasaan undang-undang berkaitan.
- Memastikan suasana kefahaman dua hala dan kerjasama berterusan sentiasa wujud antara pihak pengawalan dengan sektor swasta melalui sesi dialog dan bimbingan.
- Meningkat potensi serta kepakaran kakitangan.
- 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 suatu suasana yang menggalakkan kakitangan bekerja secara berpasukan dengan sikap penyayang, serta melaksanakan tugas masing-masing secara profesional.

National Pharmaceutical Control Bureau
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Drug Control Authority

Pihak Berkuasa Kawalan Dadah

Drug Control Authority

The National Pharmaceutical Control Bureau (NPCB) has successfully played its role as the Secretariat to the Drug Control Authority (DCA), to ensure that therapeutic products approved for the local market are safe, efficacious and of quality, and also to ensure that traditional medicines and cosmetics approved are safe and of quality.

The DCA held 12 meetings throughout the year to make decisions on policy changes and on applications for product registration and licensing.

A total of 31,152 applications for product registration were tabled to the DCA in year 2007. After a thorough review on each submission, 30,607 products were registered by December 2007. Of these, 78 products approved are categorised as New Chemical Entities (NCEs) and 27 Biotechnology products.

NCEs approved in 2007 are as follows:

Pihak Berkuasa Kawalan Dadah

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah berjaya memainkan peranan sebagai Sekretariat kepada Pihak Berkuasa Kawalan Dadah (PBKD), untuk memastikan produk terapeutik yang diluluskan untuk pasaran adalah selamat, berkesan dan berkualiti, serta memastikan ubat semulajadi dan kosmetik yang diluluskan adalah selamat dan berkualiti.

Sebanyak 12 mesyuarat PBKD telah berlangsung sepanjang tahun untuk membincangkan perubahan polisi dan keputusan permohonan pendaftaran produk dan pelesenan.

Sebanyak 31,152 permohonan pendaftaran produk telah dibentangkan dalam mesyuarat PBKD pada tahun 2007. Setelah penilaian terperinci dibuat terhadap setiap permohonan sebanyak 30,607 produk berjaya didaftarkan sehingga Disember 2007. Daripada jumlah ini, 78 produk yang diluluskan adalah di bawah kategori Ubat Baru dan 27 produk Bioteknologi.

Ubat Baru yang diluluskan pada tahun 2007 adalah seperti berikut:

No.	Product Name Nama Produk
1	Ytracis Radioparmaceutical Precursor solution
2	Primovist 0.25 mmol/mol solutio n for Injection
3	Busulfex injection
4	Cerebrolysin Injection 10ml
5	Macugen 0.3mg Solution injection
6	Protaxos (Granules for Oral Suspension)
7	Tarceva Film coated Tablet 25mg Tarceva Film coated Tablet 100mg Tarceva Film coated Tablet 150mg
8	Gliadel Wafer Implant
9	Bonviva Film-coated Tablet 150mg
10	Ventavis Nebuliser Solution
11	Gynoflor Vaginal Tablets
12	Sutent 12.5mg Sutent 25mg Sutent 50mg
13	Navelbine 20mg soft capsule Navelbine 30mg soft capsule
14	Fluomizin Vaginal Tablet
15	Aclasta Solution for Infusion 5mg/100ml
16	Vantas™ Implant
17	Niaspan 375mg Prolonged-Release Tablets Niaspan 500mg Prolonged-Release Tablets Niaspan 750mg Prolonged-Release Tablets Niaspan 1000mg Prolonged-Release Tablets
18	Restasis 0.05% w/w (Cyclosporine Ophthalmic solution)

19	Gynofort 2% Vaginal Cream
20	Asmanex Twisthaler 200mcg/inhalation Dry Powder Inhaler Asmanex Twisthaler 400mcg/inhalation Dry Powder Inhaler
21	Januvia 25mg Januvia 50mg Januvia 100mg
22	Avandaryl 4mg/1mg Tablet Avandaryl 4mg/2mg Tablet Avandaryl 4mg/4mg Tablet
23	Nexavar Film-coated Tablet 200mg
24	Vfend Powder for Oral suspension 40mg/ml
25	Ebixa Oral Drops 10mg/g
26	Sebivo 600mg Tablets
27	Tykerb Film-coated Tablets 250mg
28	Certican 0.25mg tablet Certican 0.50mg tablet Certican 0.75mg tablet Certican 1.0mg tablet Certican 0.1mg dispersible tablet Certican 0.25mg dispersible tablet
29	Sprycel tablet 20mg Sprycel tablet 50mg Sprycel tablet 70mg
30	Bandronat Film-coated Tablet 50mg
31	Kivexa Tablets
32	Olmetec Plus 20/12.5mg Film Coated Tablet Olmetec Plus 40/12.5mg Film Coated Tablet Olmetec Plus 40/25mg Film Coated Tablet
33	Lotemax Sterile Ophthalmic Suspension
34	Alrex Sterile Ophthalmic Suspension
35	Byetta 5mcg Injection Byetta 10mcg Injection
36	Zemplar Capsules 1mcg Zemplar Capsules 2mcg Zemplar Capsules 4mcg
37	Mucosta 100mg Tablets
38	Asadin Injection 1.0mg/ml
39	Acomplia 20mg Film-coated Tablets
40	Revatio 20mg Film-coated Tablet
41	Faslodex Solution for Injection 250mg/5ml
42	Tobrex 2x, 3mg/ml Eye Drops Solution
43	Razilez 150mg Film-coated Tablet Razilez 300mg Film-coated Tablet
44	Nevanac Ophthalmic Suspension 0.1%
45	Exforge 5mg/80mg Film Coated Tablet Exforge 5mg/160mg Film Coated Tablet Exforge 10mg/160mg Film Coated Tablet
46	Serdolect Film-coated Tablets 4mg Serdolect Film-coated Tablets 12mg Serdolect Film-coated Tablets 16mg Serdolect Firm-coated Tablets 20mg
47	Spasmolyt Tablet 20mg

Biotechnology products approved in 2007 are as follows:

Produk Bioteknologi yang diluluskan pada tahun 2007 adalah seperti berikut:

No.	Product Name Nama Produk
1	Albuminativ 200g/l Solution for Infusion
2	KOGENATE FS 250 iu Formulated with Sucrose Injection KOGENATE FS 500 iu Formulated with Sucrose Injection KOGENATE FS 1000 iu Formulated with Sucrose Injection
3	LUCENTIS 10mg/ml Solution for Injection
4	Rota Teq (Rotavirus Vacine, live, oral Pentavalent) Solution for oral Administration
5	Neulastim Pre-filled Syringe 6mg/0.6ml solution for Injection
6	Peglasta Pre-filled Syringe 6mg/0.6ml solution for Injection
7	Cerezyme 200 Units Injection Cerezyme 400 Units Injection
8	Exubera 1mg Inhalation Powder Exubera 3mg Inhalation Powder
9	Flulaval Influenza vaccine (Split Virion, Inactivated)
10	Fabrazyme 5mg Injection Fabrazyme 35mg Injection
11	MYOZYME 50mg Powder for Solution for Injection
12	Flexbumin 20% Albumin (Human), USP, 20% solution Flexbumin 25% Albumin (Human), USP, 25% solution
13	Enbrel 25mg Powder & solvent for Solution for Injection Enbrel 25mg Solution for Injection In a prefilled Syringe Enbrel 50mg Solution for Injection In a prefilled Syringe
14	Adacel Suspension for Injection
15	Cervarix Suspension For Injection
16	Orencia Lyophilized Powder For IV Infusion
17	Thyrogen Powder For Injection
18	WinRho SDF Rho D Immune Globulin (Human) for Injection 5000iu (1000ug) WinRho SDF Rho D Immune Globulin (Human) for Injection 1500iu (300ug)

A total of 431 product applications which included 90 prescription drugs, 59 Over-The-Counter (OTC) products, 191 traditional medicines and 91 cosmetic products were rejected by the DCA for various reasons. The DCA cancelled the registration of 114 products, consisting of 48 cosmetic product registrations due to reasons such as cancellation of agreement for contract manufacturer, 64 traditional products for adulteration and 2 over-the-counter (OTC) products due to cancellation of agreement for contract manufacturing.

A total of 1,940 applications for various licenses were reviewed by the DCA and a total of 301 manufacturing licenses, 1,063 wholesale licenses and 576 import licenses were approved. However, 7 manufacturing licenses were revoked by the DCA following reports of poor compliance to Good Manufacturing Practice last year and 2 manufacturing licenses were revoked by the DCA due to adulteration issues.

Sejumlah 431 permohonan pendaftaran produk yang melibatkan 90 ubat preskripsi, 59 ubat bukan preskripsi, 191 ubat semulajadi dan 91 produk kosmetik ditolak oleh pihak PBKD atas sebab-sebab tertentu. Pihak PBKD telah membatalkan pendaftaran 114 produk yang melibatkan 48 produk kosmetik yang disebabkan pembatalan persetujuan pengilang kontrak, 64 produk semulajadi yang disebabkan isu campurpalsu, dan 2 produk bukan preskripsi yang disebabkan oleh pembatalan perjanjian persetujuan pengilang.

Sebanyak 1,940 permohonan pelesenan dibentangkan kepada pihak PBKD. Daripada jumlah ini, 301 lesen pengilang, 1063 lesen pemborong dan 576 lesen pengimport telah diluluskan. Sebaliknya, 7 lesen pengilang telah ditarikbalik kerana tidak memenuhi keperluan Amalan Perkilangan Baik pada tahun 2007 dan 2 lesen pengilang telah ditarikbalik kerana isu campurpalsu.

National Pharmaceutical Control Bureau
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Centre for Product Registration

Pusat Pendaftaran Produk

Centre for Product Registration

INTRODUCTION

The Centre for Product Registration deals with all matters pertaining to the registration of products including prescription, non-prescription, traditional and cosmetic products.

The Centre marked a milestone this year with the commencement of registration for veterinary products from the 1st of August 2007. The implementation of the guideline applies for all categories of veterinary products including traditional and health supplement as well as local and imported products. The registration fee would be according to the existing categories of products and includes the fee for post-registration analytical evaluation. The Registration Guidance Document for Veterinary Products may be obtained from the official NPCB website *www.bpfk.gov.my/veterinary*.

The registration process for all products is done via the online system to facilitate a convenient registration process with the exception of the biotechnology and biological products as well as new chemical entities, which are currently done manually as they require an extensive amount of information. The registration procedure is continuously revised to ensure an optimal system for the benefit of all parties involved. The registration procedure for all other products has been maintained as the previous year.

OBJECTIVES

The objectives of the Centre for Product Registration are to ensure that all pharmaceutical products registered by the Drug Control Authority are evaluated for safety, efficacy and quality aspects, whereas traditional products and cosmetics are evaluated for safety and quality aspects.

Pusat Pendaftaran Produk

PENGENALAN

Pusat Pendaftaran Produk berfungsi untuk melaksanakan semua hal yang berkaitan dengan pendaftaran produk, sama ada produk preskripsi, bukan preskripsi, tradisional atau kosmetik.

Mulai 1 Ogos 2007, pusat ini juga memulakan pendaftaran bagi produk veterinar bagi semua kategori produk termasuk suplemen kesihatan dan sediaan ubat tradisional. Keperluan pendaftaran ini meliputi produk tempatan serta produk yang diimport. Bayaran pemprosesan pendaftaran produk veterinar adalah sama dengan bayaran produk sedia ada dan merangkumi bayaran analisis produk/ penilaian analisis yang dijalankan selepas produk didaftarkan. Garis Panduan Permohonan Pendaftaran Produk Veterinar boleh dirujuk dari laman web BPFK di www.bpfk.gov.my/veterinary.

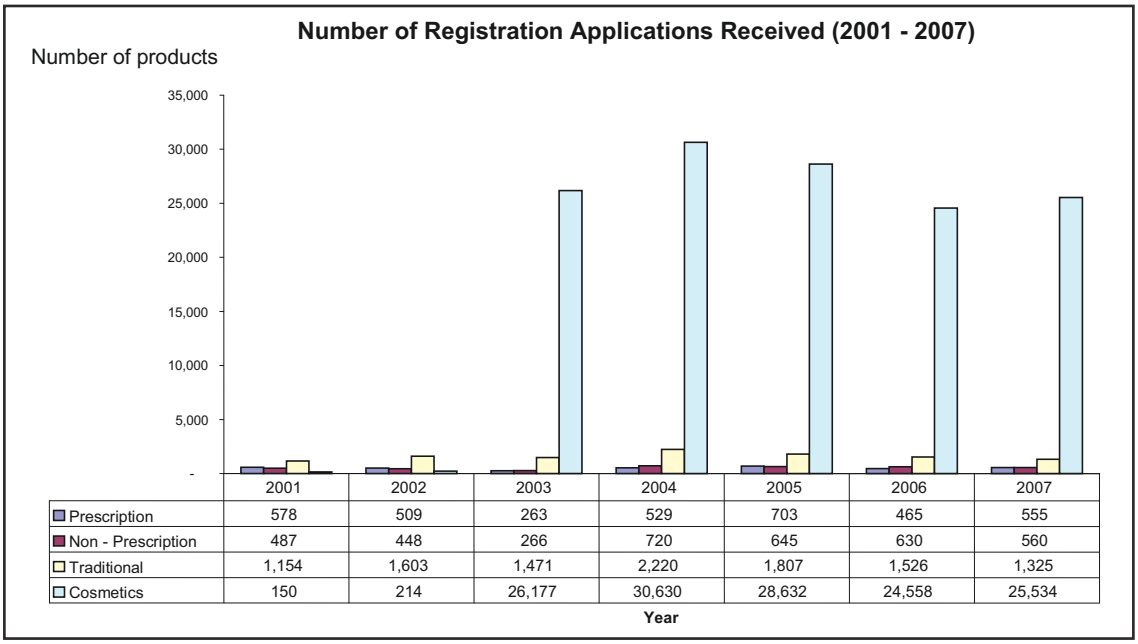
Pendaftaran produk dilakukan melalui sistem 'online' bagi memudahkan proses pendaftaran produk, kecuali bagi pendaftaran produk bioteknologi dan entiti kimia baru yang dijalankan secara manual disebabkan jumlah data yang besar. Proses pendaftaran sentiasa dikaji semula untuk memastikan penggunaan satu sistem optima untuk kebaikan semua pihak. Prosedur pendaftaran untuk semua produk lain dikekalkan seperti tahun 2006.

OBJEKTIF

Objektif pusat ini adalah untuk memastikan semua produk farmaseutikal yang didaftarkan oleh Pihak Berkuasa Kawalan Dadah dinilai dari aspek keselamatan, efikasi dan kualiti manakala ubat tradisional serta kosmetik dinilai dari aspek keselamatan dan kualiti.

CENTRE FOR PRODUCT REGISTRATION ACTIVITIES (YEAR 2007)

AKTIVITI PUSAT PENDAFTARAN PRODUK (TAHUN 2007)



	2001	2002	2003	2004	2005	2006	2007
Prescription	578	509	263	529	703	465	555
Non - Prescription	487	448	266	720	645	630	560
Traditional	1,154	1,603	1,471	2,220	1,807	1,526	1,325
Cosmetics	150	214	26,177	30,630	28,632	24,558	25,534

Chart 1 : Number of Registration Applications Received for Registration from Year 2001-2007

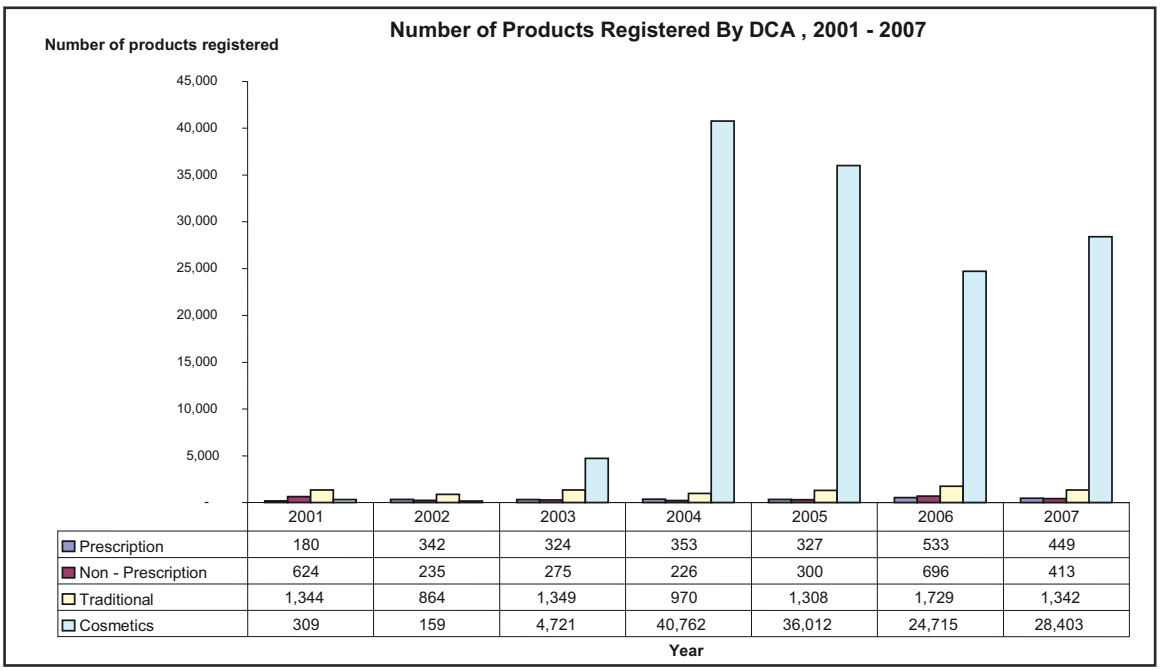
Carta 1 : Bilangan Permohonan yang Diterima untuk Pendaftaran dari Tahun 2001-2007

In the year 2007, a total of 27,974 product registration applications were received. (Chart 1)

Pada tahun 2007, sebanyak 27,974 permohonan telah diterima untuk pendaftaran. (Carta 1)

For prescription drugs, non-prescription drugs, traditional products and cosmetics, the cumulative number of registration applications starting from year 2001 to 2007 amounts to 3,602, 3,756, 11,106 and 135,895 applications respectively.

Bagi ubat preskripsi, bukan preskripsi, produk tradisional dan produk kosmetik, jumlah kumulatif permohonan pendaftaran dari tahun 2001 hingga 2007 masing-masing ialah 3,602, 3,756, 11,106 and 135,895 permohonan.



	2001	2002	2003	2004	2005	2006	2007
Prescription	180	342	324	353	327	533	449
Non - Prescription	624	235	275	226	300	696	413
Traditional	1,344	864	1,349	970	1,308	1,729	1,342
Cosmetics	309	159	4,721	40,762	36,012	24,715	28,403

Chart 2: *Number of Products Registered Yearly by the DCA from Year 2001-2007*

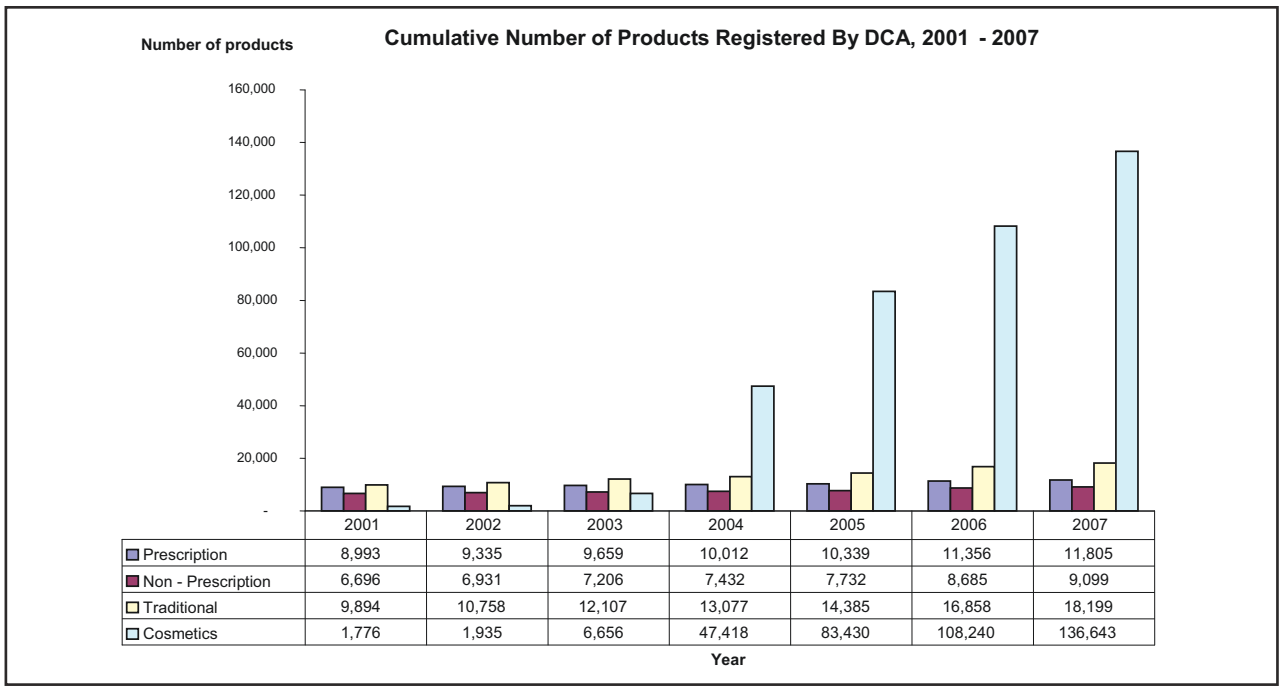
Carta 2: Bilangan Produk yang Didaftarkan oleh PBKD dari Tahun 2001 -2007

In the year 2007, the number of prescription drugs, non-prescription drugs, traditional products and

Bagi tahun 2007, bilangan produk preskripsi, bukan preskripsi, produk tradisional dan kosmetik

cosmetics registered by the DCA were 449, 413, 1,342 and 28,403 products respectively. (Chart 2)

yang didaftarkan oleh PBKD masing-masing berjumlah 449, 413, 1342 dan 28,403 produk. (Carta 2)



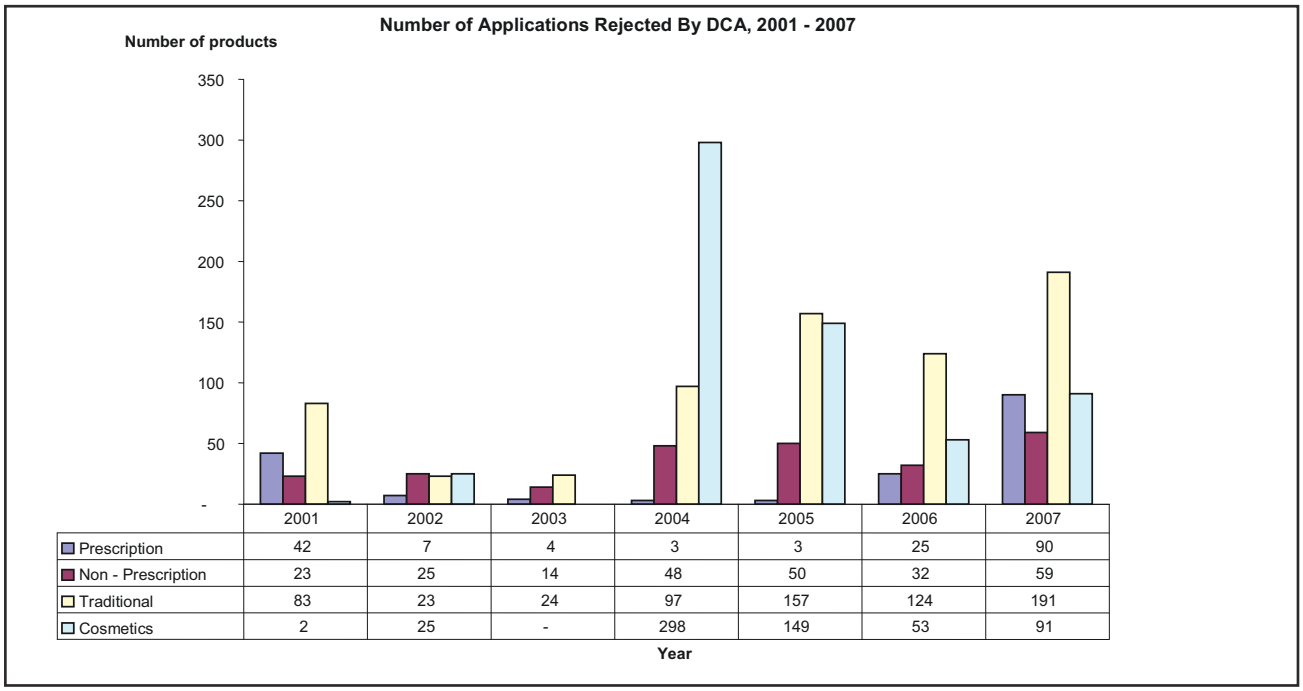
	2001	2002	2003	2004	2005	2006	2007
Prescription	8,993	9,335	9,659	10,012	10,339	11,356	11,805
Non - Prescription	6,696	6,931	7,206	7,432	7,732	8,685	9,099
Traditional	9,894	10,758	12,107	13,077	14,385	16,858	18,199
Cosmetics	1,776	1,935	6,656	47,418	83,430	108,240	136,643

Chart 3 : Cumulative Number of Products Registered by DCA from Year 2001-2007

Carta 3 : Jumlah Kumulatif Produk yang Didaftarkan oleh PBKD dari Tahun 2001 -2007

For prescription drugs, non-prescription drugs, traditional products and cosmetics, the cumulative number of products registered by DCA till the year 2007 was 11,805, 9,099, 18,199, and 136,643 products respectively. (Chart 3)

Bagi ubat preskripsi, bukan preskripsi, produk tradisional dan kosmetik, jumlah kumulatif yang didaftarkan oleh PBKD masing-masing berjumlah 11,805, 9,099, 18,199, dan 136,643 produk. (Carta 3)



	2001	2002	2003	2004	2005	2006	2007
Prescription	42	7	4	3	3	25	90
Non - Prescription	23	25	14	48	50	32	59
Traditional	83	23	24	97	157	124	191
Cosmetics	2	25	-	298	149	53	91

Chart *4: Number of Applications Rejected from Year 2001-2007*

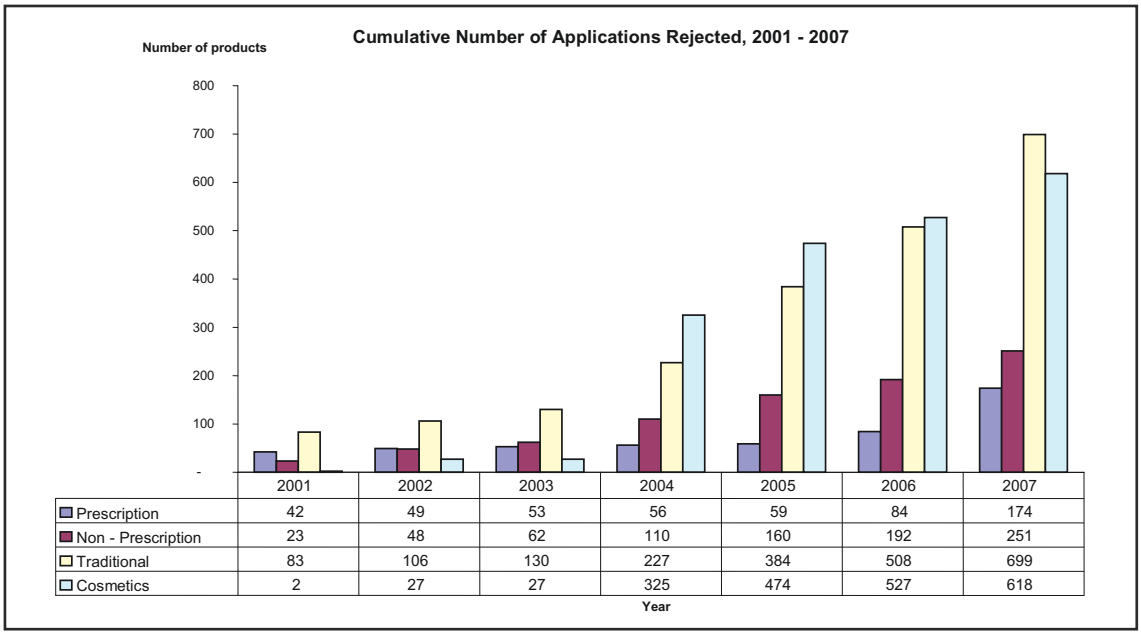
Carta 4: Bilangan Permohonan yang Ditolak dari Tahun 2001 -2007

In the year 2007, the number of applications rejected was 90 for prescription drugs, 59 for non-

Pada tahun 2007, jumlah permohonan yang ditolak adalah 90 bagi ubat preskripsi, 59 permohonan

prescription drugs, 191 for traditional products and 91 cosmetic applications. (Chart 4 & Chart 5)

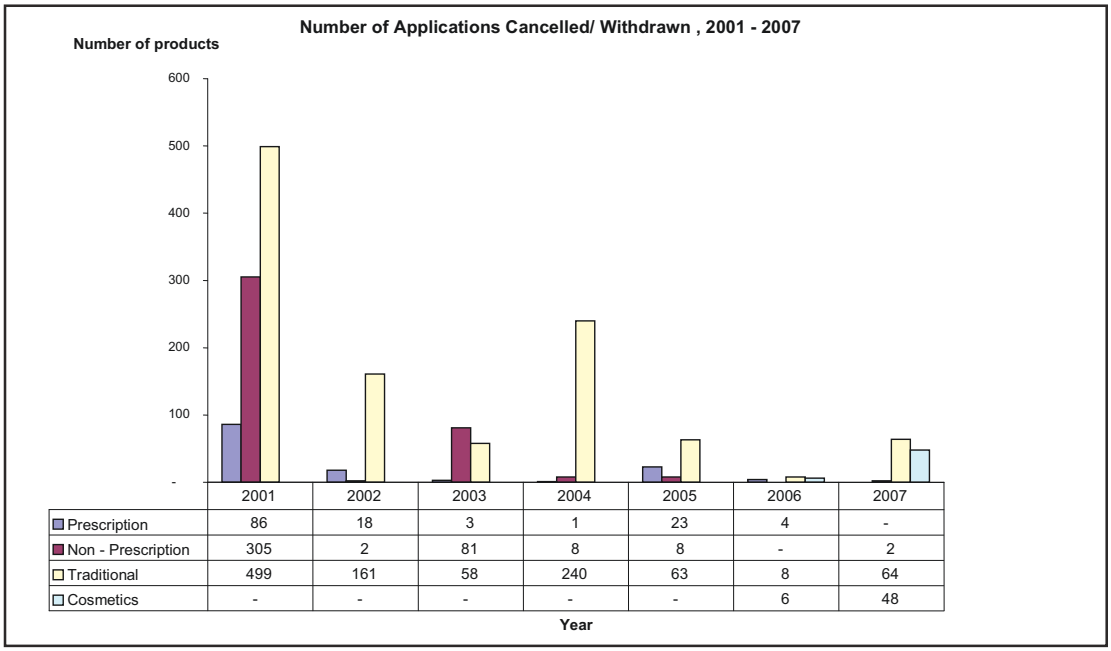
bukan preskripsi, 191 permohonan produk tradisional dan 91 permohonan kosmetik. (Carta 4 & Carta 5)



	2001	2002	2003	2004	2005	2006	2007
Prescription	42	49	53	56	59	84	174
Non - Prescription	23	48	62	110	160	192	251
Traditional	83	106	130	227	384	508	699
Cosmetics	2	27	27	325	474	527	618

Chart 5: Cumulative Number of Applications Rejected from Year 2001-2007

Carta 5: Jumlah Kumulatif Permohonan yang Ditolak Dari Tahun 2001 -2007



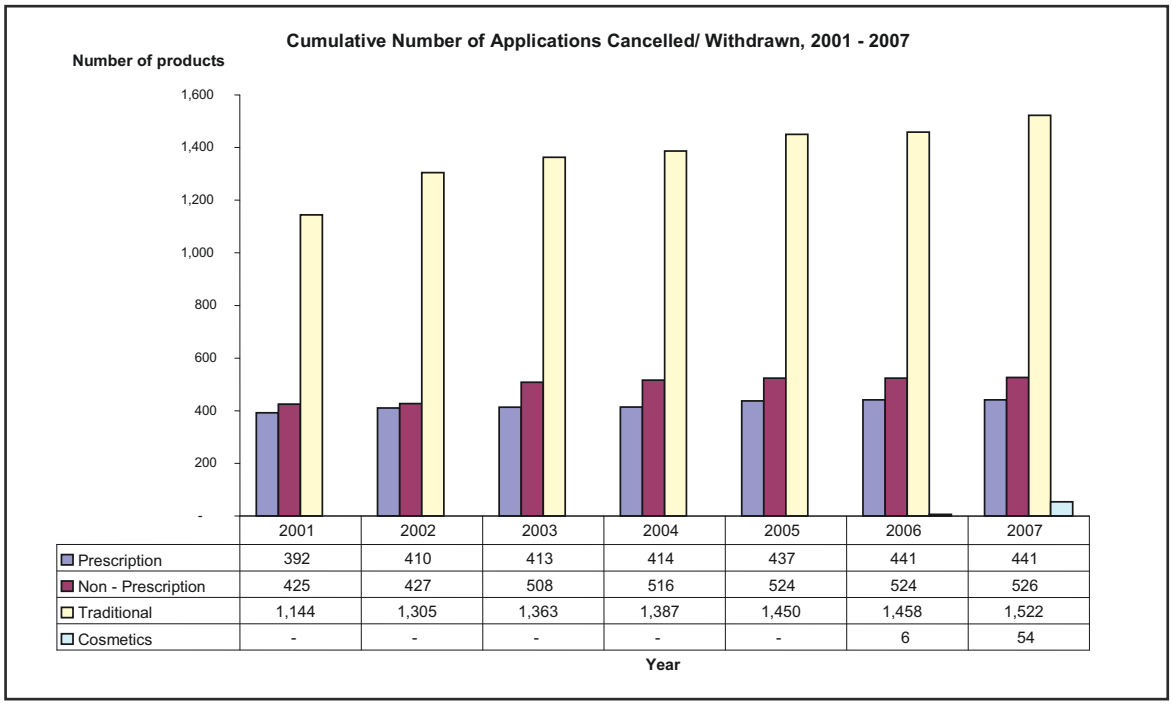
	2001	2002	2003	2004	2005	2006	2007
Prescription	86	18	3	1	23	4	-
Non - Prescription	305	2	81	8	8	-	2
Traditional	499	161	58	240	63	8	64
Cosmetics	-	-	-	-	-	6	48

Chart 6 : Number of Applications Cancelled/ Withdrawn for Year 2001-2007

Carta 6 : Bilangan Permohonan yang Dibatalkan/ Ditarik-Balik dari Tahun 2001 -2007

In the year 2007, no applications for prescription drug were cancelled/ withdrawn. However, 2 applications were cancelled/withdrawn for non-prescription drugs, apart from 64 for traditional products and 48 applications for cosmetic products. (Chart 6 & Chart 7)

Pada tahun 2007, tiada permohonan ubat preskripsi yang dibatalkan/ditarik-balik. Walaubagaimanapun, 2 permohonan ubat bukan preskripsi, 64 permohonan produk tradisional dan 48 permohonan produk kosmetik telah dibatalkan/ ditarik-balik. (Carta 6 & Carta 7)



	2001	2002	2003	2004	2005	2006	2007
Prescription	392	410	413	414	437	441	441
Non - Prescription	425	427	508	516	524	524	526
Traditional	1,144	1,305	1,363	1,387	1,450	1,458	1,522
Cosmetics	-	-	-	-	-	6	54

Chart 7: Cumulative Number of Applications Cancelled/Withdrawn for Year 2001-2007

Carta 7: Jumlah Kumulatif Permohonan yang Dibatalkan/Ditarik-Balik dari Tahun 2001 -2007

Chart 8: Countries of Main Sources of Importation for Traditional Products

From the graph above, the country with the most import sources for traditional products is China followed by the United States of America and India. (Chart 8)

Carta 8: Negara Import Utama Produk Semulajadi

Negara import utama bagi produk semulajadi ialah China diikuti dengan Amerika Syarikat dan India. (Carta 8)

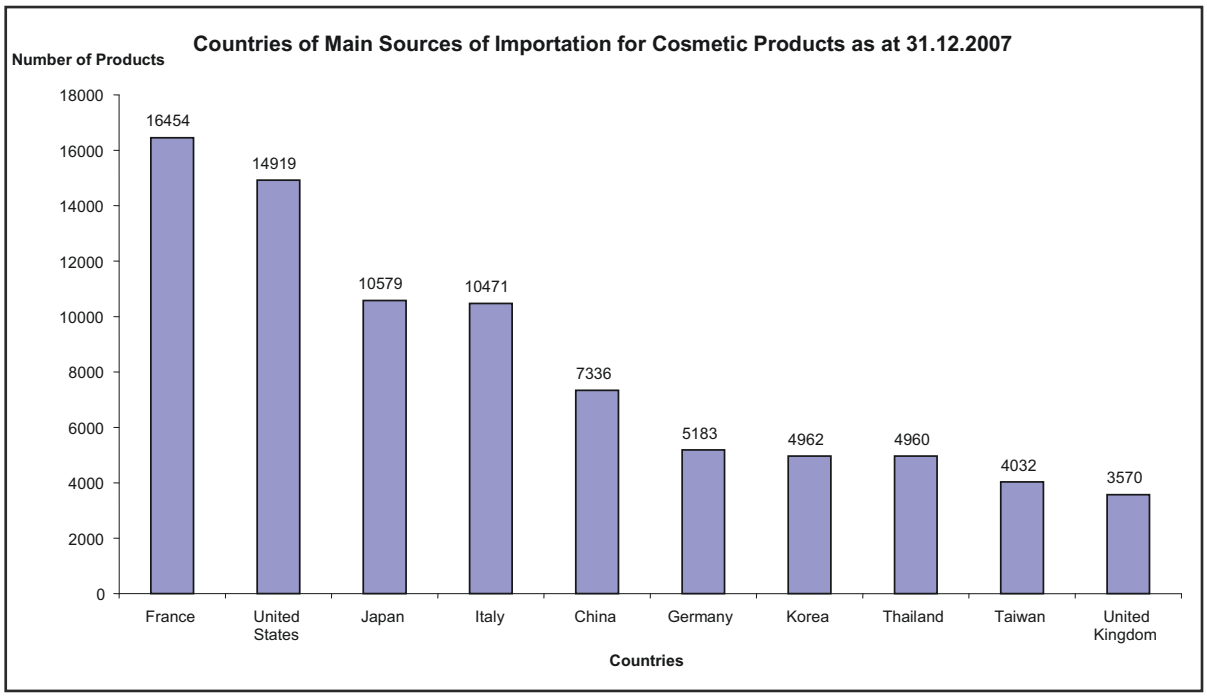


Chart 9 : Countries of Main Sources of Importation for Cosmetics

France is the main country of import for cosmetics followed by the United States of America and Japan. (Chart 9)

Carta 9: Sumber Import Utama Produk Kosmetik

Perancis merupakan pengeksport produk kosmetik utama diikuti dengan Amerika Syarikat dan Jepun. (Carta 9)

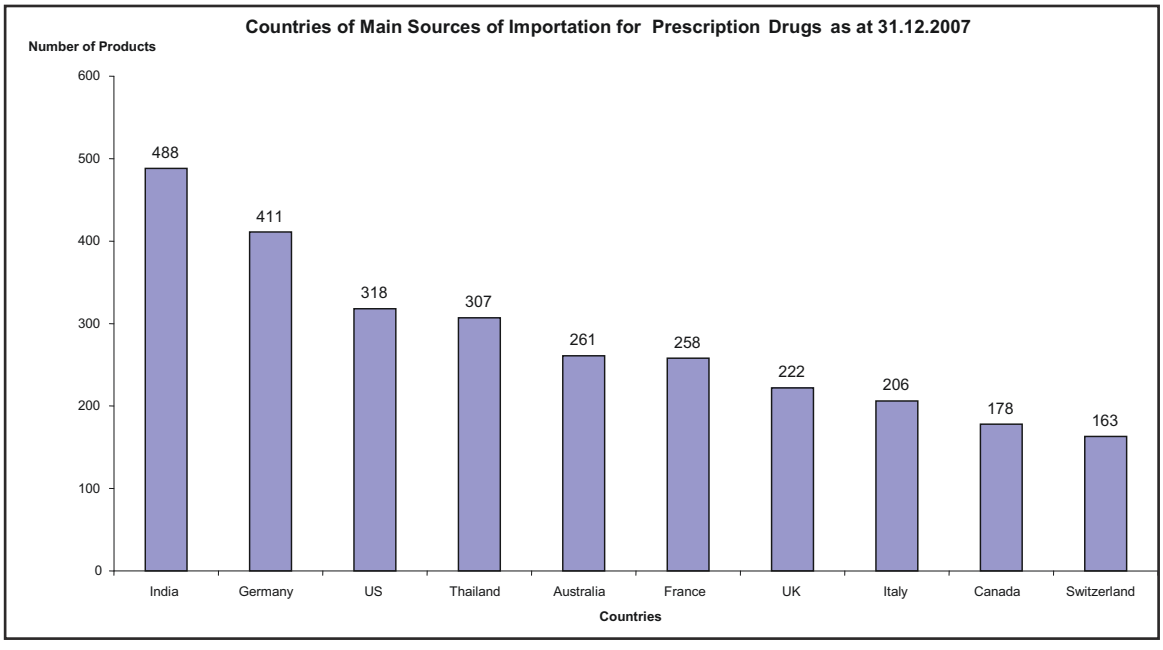


Chart 10 : Countries of Main Source of Importation of Pharmaceutical Products

The main import source for prescription drugs is India followed by Germany and the United States of America. (Chart 10)

Carta 10: Sumber Import Utama Produk Preskripsi

Bagi kategori ubat preskripsi, India adalah sumber import utama diikuti dengan Negara Jerman dan Amerika Syarikat. (Carta 10)

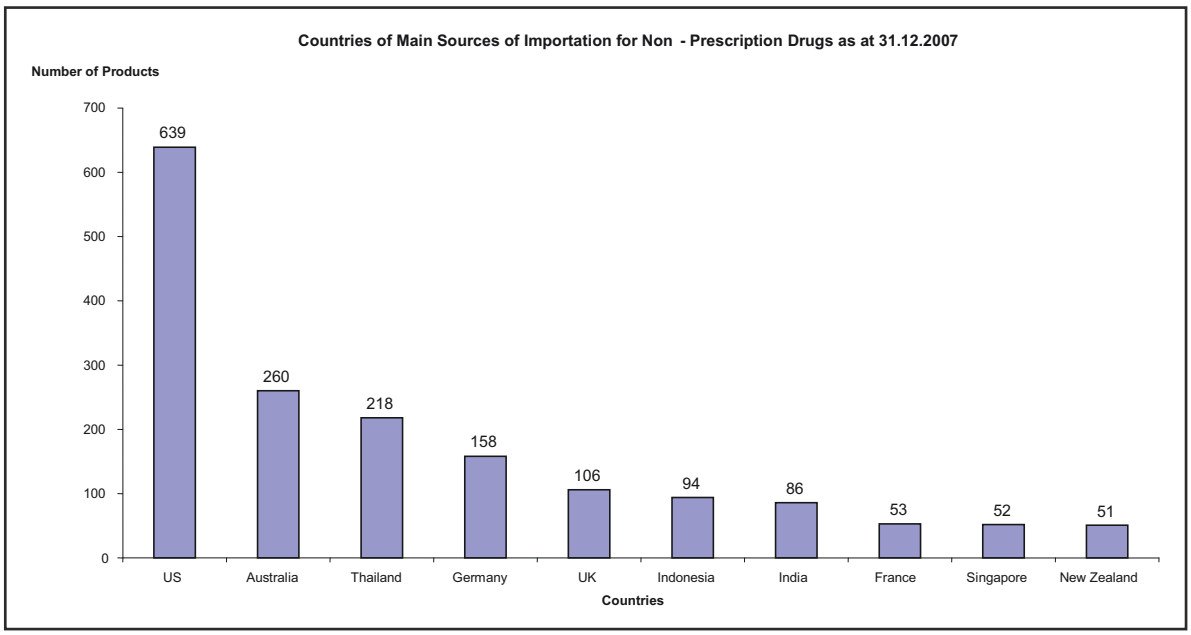


Chart 11 : Countries of Main Source of Importation for Non-Prescription Pharmaceutical Products

The graph above shows that the highest source of importation for non-prescription drugs is the United States of America followed by Australia and Thailand. (Chart 11)

FUTURE DIRECTION FOR 2008

1. **Active Pharmaceutical Ingredient (API) Registration**
NPCB is currently exploring the possibility of implementing the API registration by the 4th quarter of the year 2008 and on adopting the requirement of European Directorate for the Quality of Medicines and Healthcare (EDQM). NPCB is also keen to form a collaboration with Therapeutic Goods Administration (TGA), Australia in which Malaysia wishes to conduct a study on their API registration system. The NPCB is also planning to have structured training programme involving the EDQM officers to train NPCB evaluators in the related field.

2. **Implementation of Notification Scheme for Cosmetic Products**
Effective 1st January 2008, the online registration procedure for all cosmetics products will be replaced with the online notification procedure. Companies wanting to market new cosmetic products must notify NPCB before placing the products in the local market. Existing cosmetic products (products with valid registration / MAL no.) will require notification prior to the expiry of their registration period. Applicants may refer to the details of the notification

Carta 11: Sumber Import Utama Produk Farmaseutikal Bukan Preskripsi

Jumlah import ubat bukan preskripsi tertinggi adalah dari Amerika Syarikat diikuti dengan Australia dan Negara Thailand. (Carta 11)

HALATUJU TAHUN 2008

1. **Pendaftaran Bahan Aktif Farmaseutikal (Active Pharmaceutical Ingredient, API)**
BPFK sedang mempertimbangkan kemungkinan untuk melaksanakan pendaftaran bahan aktif farmaseutikal dalam suku keempat tahun 2008 dan penggunaan garis panduan mengikut European Directorate for the Quality of Medicines and Healthcare (EDQM). Selain itu, BPFK turut merancang untuk merangka kerjasama dengan Therapeutic Goods Administration (TGA), Australia bagi mempelajari sistem pendaftaran API di Australia. Perancangan juga dibuat untuk mengadakan program latihan bagi pegawai penilai BPFK yang bakal dikendalikan oleh pegawai daripada EDQM.

2. **Pelaksanaan Prosedur Notifikasi bagi Produk Kosmetik**
Bermula 1 Januari 2008, prosedur pendaftaran secara online bagi semua produk kosmetik akan digantikan dengan prosedur notifikasi. Sejajar dengan ACC Directive, syarikat yang ingin memasarkan produk kosmetik yang baru perlu mengemukakan notifikasi kepada BPFK sebelum memasarkannya di pasaran tempatan. Produk kosmetik yang telah berdaftar (produk dengan no. pendaftaran MAL yang sah) perlu membuat notifikasi sebelum tamat tempoh pendaftaran.

procedure through The Guidelines for Control of Cosmetic Products in Malaysia which is available at www.bpfk.gov.my/Quest2.

3. Moving Away from Pre-Registration Testing to Post Registration Testing

In line with the recommendation of WHO, the Drug Control Authority (DCA) has now adopted a policy in which the NPCB places more emphasis on post-registration testing and discontinuing the previous practice of pre-registration testing. The products involved include all types of dosage forms for prescription and non-prescription items with the exemption of traditional medicines. Thus from 1st January 2008, applicants for registration of the products concerned need to submit analytical method validation at the point of application for registration. The evaluation for registration will then be carried out the usual way. Such approach is considered more effective and practical than the current pre-registration testing in curbing substandard products from entering the market.

4. **Implementation of Veterinary Product Registration**

All existing veterinary products are scheduled to have been registered by 1st August 2008 and it is targeted that there will be no more existing unregistered veterinary products in the market by the cut-off date. Veterinary products which are imported, manufactured and marketed after 1st August 2008 will be considered as new products and require registration prior to their being manufactured, imported, marketed or possessed for administration. In view of the implementation of registration and licensing of the veterinary products, more awareness programmes for the local industries are scheduled to be conducted in 2008.

5. **Ensuring All Traditional Products Registered are Safe for Consumers**

To overcome the problem of adulteration of traditional products and to ensure that the products are safe for usage by the public, NPCB has taken a few measures, such as:

i) Banning of premixes in the formulation of all traditional products, a measure enforced since 1st December 2007.
ii) More stringent Post Market Surveillance.

Untuk maklumat lanjut tentang prosedur notifikasi, pemohon boleh merujuk kepada 'Guidelines for Control of Cosmetic Products in Malaysia' yang dipaparkan di laman web www.bpfk.gov.my/Quest2.

3. **Penggantian Pengujian Pra-pendaftaran dengan Pengujian Pasca-Pendaftaran.**

Sejajar dengan saranan oleh Pertubuhan Kesihatan Sedunia (WHO), Pihak Berkuasa Kawalan Dadah (PBKD) telah menjadikannya polisi dalam mana BPFK memberi tumpuan kepada pengujian produk selepas didaftarkan (Post Marketing Testing). Oleh itu, mulai 1 Januari 2008, pemegang pendaftaran bagi semua kategori produk kecuali produk tradisional (semua bentuk dos bagi produk preskripsi dan bukan preskripsi sahaja) perlu mengemukakan data validasi tatacara analitikal dan validasi proses bagi setiap permohonan pendaftaran. Prosedur ini adalah lebih efektif berbanding pengujian pra-pendaftaran.

4. **Pelaksanaan Pendaftaran Produk Veterinar**

BPFK sedang dalam proses menggembeleng tenaga untuk memastikan terdapat kapasiti dan kebolehan untuk menjayakan pelaksanaan pendaftaran bagi produk veterinar. Semua produk veterinar sediada dalam pasaran (existing) diwajibkan berdaftar sebelum 1 Ogos 2008 dan selepas tarikh tersebut, dijangka tiada lagi produk sedemikian yang belum berdaftar. Produk veterinar yang diimport, dikilang atau dipasarkan selepas 1 Ogos 2008 adalah dianggap sebagai produk baru dan perlu didaftarkan sebelum ianya boleh diimport, dikilang, dibekalkan atau dimiliki. Sebagai persediaan pelaksanaan pendaftaran dan pelesenan produk veterinar. BPFK juga merancang untuk mengadakan lebih banyak program kesedaran untuk meningkatkan pengetahuan di kalangan industri tempatan.

5. **Memastikan Semua Produk Semulajadi yang Didaftarkan adalah Selamat untuk Pengguna**

Bagi mengatasi masalah campurpalsu dalam produk semulajadi dan untuk memastikan produk adalah selamat untuk kegunaan orang awam, BPFK telah mengambil beberapa langkah seperti:

i) Larangan penggunaaan bahan 'premix' dalam formulasi produk semulajadi (tradisional), arahan yang berkuatkuasa semenjak 1 Disember 2007.
ii) Program 'Post Market Surveillance' yang lebih ketat.

6. Pendaftaran Secara 'Fast Track' bagi Produk Antiretroviral

Berdasarkan 'ASEAN Regional Consultative Meeting on Fast Track Registration of

6. **Fast Track Registration of Antiretrovirals (ARVs)**

Based on the ASEAN Regional Consultative Meeting on Fast Track Registration of Antiretrovirals (ARVs) and Diagnostic Reagents which was held on 21st-23rd November 2007 in Penang, it was decided that each Drug Regulatory Authority needs to establish a fast track mechanism for the registration of Antiretroviral products. In line with the decision reached, NPCB is planning to establish a fast track mechanism which includes:

- Identifying priorities
- Ensuring that fast track mechanisms are acceptable within existing legislation and pursuing amendment of legislation if necessary
- Adoption of timelines for decisions on evaluation of good quality applications to register innovator and generic medicines, such as not more than 3 months for generics and not more than 6 months for innovator products
- Preparing a description of the fast track procedure including fees and to make it readily available, for the public.

CHALLENGES AND ROOM FOR IMPROVEMENT

1. With the implementation of the 3-year compulsory service for fresh graduates in the pharmacy service of the government sector, there is a marked increase in the number of new officers attached with the NPCB. Although this has overcome the problem of staff shortage to a certain extent, lack of facilities such as computers and proper workstations poses a crucial problem. In response to this, the management has taken steps to carry out the expansion of the building capacity with enhancement of the facilities in all centres including the Centre for Product Registration.

2. Since the full implementation of the online registration system in 2003 until now, the centre is still receiving poor documentation submission from applicants and this subsequently delays the registration of products concerned. Therefore, there is a need to create awareness especially for the new stakeholders on NPCB requirements and guideline in registration. For example, to conduct more seminars and to work with the industry more closely so that they can acquire complete understanding on the registration procedure and smoothen the process with minimal request for

Antiretrovirals (ARVs) and Diagnostic Reagents' yang telah diadakan pada 21-23 November 2007 di Pulau Pinang, telah dipersetujui bahawa setiap Pihak Berkuasa Kawalan Dadah perlu membangunkan mekanisma 'fast track' bagi pendaftaran ubat antiretroviral. Selaras dengan itu, BPFK sedang dalam proses perancangan untuk membangunkan mekanisma 'fast track' yang merangkumi perkara berikut :

- mengenalpasti keutamaan (Priorities)
- memastikan mekanisma 'fast track' diterima pakai dalam undang-undang sedia ada atau melakukan pindaan pada undang-undang jika perlu
- menggunapakai jangka waktu penilaian bagi permohonan yang berkualiti iaitu untuk mendaftarkan produk 'innovator' tidak lebih daripada 6 bulan dan tidak lebih daripada 3 bulan untuk produk generik
- Menyediakan deskripsi prosedur 'fast track' termasuk yuran dikenakan yang boleh dirujuk oleh orang ramai.

CABARAN DAN LANGKAH PENAMBAHBAIKAN

1. Dengan pelaksanaan perkhidmatan wajib 3 tahun bagi semua graduan Farmasi dalam sektor kerajaan, terdapat penambahan yang ketara dari segi bilangan pegawai baru yang ditempatkan di BPFK. Walaupun perkara ini secara tidak langsung dapat mengatasi masalah kekurangan pegawai di BPFK, kekurangan kemudahan asas seperti komputer dan ruang kerja yang sesuai menjadi masalah dengan penambahan bilangan kakitangan secara mendadak. Bagi mengatasi masalah ini, pihak pengurusan sedang merancang mengoptimakan penggunaan ruang bangunan serta penambahan kemudahan bagi semua pusat termasuk Pusat Pendaftaran Produk. Untuk itu, kerja-kerja pengubahsuaian sedang dilakukan dengan penambahan ruang kerja dan kemudahan berkaitan.

2. Sejak pelaksanaan sistem pendaftaran produk secara online secara penuh pada tahun 2003, pihak Pusat Pendaftaran Produk masih menerima data-data yang agak lemah daripada pemohon yang seterusnya melambatkan proses pendaftaran produk berkenaan. Bagi mengatasi masalah ini, program kesedaran terutama kepada pemegang pendaftaran yang baru adalah perlu bagi menerangkan tentang keperluan dan prosedur pendaftaran produk. Sebagai contoh, mengadakan lebih seminar serta kerjasama erat dengan pihak industri supaya mereka mendapat pemahaman yang lebih

re-submission.

3. On the ASEAN harmonisation effort, it has been a challenge to harmonise certain requirements within the ASEAN region since every country has developed their own specific requirement. To harmonise certain requirements e.g. stability, Bioequivalence, Good Manufacturing Practice (GMP), process and analytical validation as well as cosmetics registration procedure, NPCB is playing an active role to host and coordinate meetings in Malaysia and promote further discussion on the harmonisation of registration procedure.

4. Issues on Data Exclusivity and Patent have been brought up by the Innovator companies and it will have a big impact on the accessibility and availability of pharmaceutical products (generics) in the market. The biggest challenge for NPCB on the related issues are as follows:

   i) To comprehend and interpret legal documents and to ensure registered generics do not infringe patent rights
   ii) To get updated information on patent status in view of the possibility of additional patent grants to innovator
   iii) Cancellation of registration of generic products upon confirmation of updated patent status
   - In view of this, NPCB is unsure whether it is legally correct to act based on patent holder's updates/ complaints and whether to recall the registered products.
   iv) Accuracy of Patent Search since it is always accompanied by Disclaimer Statement

   Therefore, more discussion with the Legal Advisor is needed to develop the right procedure to overcome these problems since the current practice is to allow registration of a product that is still under patent as generic products.

jelas tentang prosedur pendaftaran bagi melicinkan proses pendaftaran produk dan mengelakkan data dikemukakan berulang kali.

3. Usaha mengharmonisasikan keperluan pendaftaran di kalangan negara-negara ASEAN adalah merupakan satu cabaran memandangkan setiap negara telah membangunkan keperluan spesifik mereka yang tersendiri. Bagi mengharmonisasikan keperluan dalam stabiliti, bioequivalens, amalan pengilangan baik, validasi proses dan analitikal serta prosedur pendaftaran produk kosmetik, BPFK memainkan peranan secara aktif dengan menjadi tuan rumah bagi beberapa mesyuarat bagi membincangkan proses mengharmonisasikan keperluan pendaftaran di negara-negara ASEAN.

4. Isu Data Eksklusiviti dan paten telah dibangkitkan oleh syarikat-syarikat 'Innovator' dan hal ini akan memberi kesan terhadap kebolehcapaian dan kewujudan produk farmaseutikal (generik) di pasaran. Cabaran paling besar bagi BPFK dalam isu ini adalah :

   i) Bagi memahami dan mengintepretasikan dokumen-dokumen berkaitan undang-undang dan untuk memastikan produk generik yang berdaftar tidak melanggar hak paten
   ii) Untuk mendapatkan maklumat mengenai status paten yang terkini kerana terdapat kemungkinan syarikat 'Innovator' melanjutkan tempoh paten
   iii) Membatalkan pendaftaran produk generik setelah mendapat status paten yang terkini
   -BPFK tidak pasti samada pembatalan tersebut adalah tepat dari segi undang-undang kerana pembatalan tersebut hanya berdasarkan maklumat terkini daripada pemegang pendaftaran/aduan. BPFK juga kurang jelas samada semua produk yang telah dibatalkan pendaftarannya perlu dipanggil balik
   iv) Ketepatan 'Patent Search' kerana kebiasaannya semua maklumat berkaitan paten disertakan dengan 'Disclaimer Statement'

   Oleh itu, perbincangan lanjut dengan Penasihat Undang-undang adalah perlu untuk membangunkan prosedur yang tepat bagi mengatasi masalah ini memandangkan buat masa sekarang BPFK membenarkan pendaftaran produk yang masih di bawah paten.

National Pharmaceutical Control Bureau
2007 Annual Report

Centre for Quality Control

Pusat Kawalan Kualiti

Centre for Quality Control

INTRODUCTION

The Centre for Quality Control is responsible for ensuring that the quality of all registered products marketed in Malaysia are compliant to the specifications claimed by the manufacturer, and to ensure that products are of quality, safe and effective.

The quality control process managed by this centre in the pharmaceutical, traditional and cosmetic products registration process are based on important procedures of protocol evaluation and data validation and analytical testing. This allows pre-registration, post registration, quality testing for complaint cases and adulterated samples from enforcement sources to be carried out. The tests conducted follow in-house or manufacturers' approved protocol and specification as well as the international pharmacopoeias as reference.

OBJECTIVES

The Centre for Quality Control aims to ensure that all therapeutic and cosmetic products allowed to be marketed are being regulated in the aspects of quality and safety.

The procedures adopted include the following:

- Chemical and biological tests in compliance with international standard procedures
- Establishment and expanding of test and research methodologies
- Establishment of chemical and biological reference standards for local institution and pharmaceutical industry use
- Active involvement in collaborative research and proficiency testing scheme organised by ASEAN, WHO and EDQM to ensure continual competency in testing
- Continuous education in quality control analysis aspects for analyst in this institution and the local pharmaceutical industry
- Support and technical assistance to the Centre for Compliance and Licensing in audits on therapeutic and cosmetic products.

CENTRE FOR QUALITY CONTROL ACTIVITIES (YEAR 2007)

The Centre for Quality Control is responsible for ensuring that the quality of all registered products marketed in Malaysia comply to specifications as stipulated by the manufacturers and to ensure that pharmaceutical products are of quality, safe, and effective and traditional

Pusat Kawalan Kualiti

PENGENALAN

Pusat Kawalan Kualiti bertanggungjawab dalam memastikan kualiti produk berdaftar di pasaran tempatan mematuhi spesifikasi yang ditetapkan oleh pengeluar serta memastikan produk selamat, berkesan dan bermutu selaras dengan matlamat organisasi BPFK.

Proses pengawalan kualiti yang dijalankan oleh pusat ini dalam pendaftaran produk farmaseutikal, tradisional dan kosmetik adalah berdasarkan prosedur penting iaitu penilaian protokol dan data validasi keluaran serta pengujian analitikal. Ini membolehkan ujian dilakukan bagi sampel-sampel pra-pendaftaran, pasca pendaftaran, pengujian kualiti bagi kes-kes aduan kualiti produk berdaftar dan sampel dari penguatkuasa farmasi yang disyaki mengandungi bahan campurpalsu. Pengujian dijalankan berpandukan spesifikasi dan protokol analisa pengilang yang telah diluluskan serta farmakopia-farmakopia antarabangsa sebagai rujukan.

OBJEKTIF

Objektif Pusat Kawalan Kualiti adalah untuk memastikan produk-produk terapeutik dan kosmetik yang dibenarkan di pasaran tempatan dipantau dari aspek kualiti dan keselamatan dengan :

- Menjalankan ujian-ujian kimia dan biologikal berlandaskan prosedur dan tatacara yang mematuhi piawaian antarabangsa
- Membangun dan memperkembangkan metodologi pengujian dan penyelidikan
- Menubuhkan piawai rujukan kimia dan biologikal untuk kegunaan institusi dan industri farmaseutikal tempatan
- Mengambil bahagian dalam kajian kolaboratif dan skim ujian profisiensi di bawah anjuran ASEAN, WHO dan EDQM untuk memastikan kompetensi berterusan dalam bidang penganalisaan
- Memberi latihan berterusan dalam analisis kawalan mutu kepada penganalisa di institusi ini dan juga industri farmaseutikal tempatan
- Memberi sokongan dan input teknikal kepada Pusat Komplians dan Pelesenan dalam pengauditan pengilang produk-produk terapeutik dan kosmetik.

AKTIVITI PUSAT KAWALAN KUALITI (TAHUN 2007)

Pusat Kawalan Kualiti bertanggungjawab dalam memastikan semua produk berdaftar yang berada di pasaran mematuhi spesifikasi yang ditetapkan,

products are safe and of quality.
The activities held in the year 2007 are listed as follows:

serta memastikan produk farmaseutikal adalah berkualiti, berkesan dan selamat untuk digunakan, manakala produk tradisional adalah berkualiti dan selamat untuk digunakan.

Berikut adalah ringkasan aktiviti setiap unit di bawah pusat tersebut:

Table 1 : Summary of Activities for the Centre for Quality Control (Year 2007)

Jadual 1 : Ringkasan Aktiviti Pusat Kawalan Kualiti (Tahun 2007)

Section/Unit Seksyen/Unit	Unit Unit	Activities Aktiviti
Pharmaceutical Chemistry Testing Section Seksyen Pengujian Kimia Farmaseutikal	Chromatography Unit Unit Kromatografi	Pharmaceutical chemistry testing such as identification, related substances and content/assay using chromatographic separation method. Menjalankan ujian kimia farmaseutikal seperti identifikasi, bahan-bahan berkaitan dan kandungan/esei melalui kaedah pemisahan kromatografik.
	Chemistry Research Unit Unit Penyelidikan Kimia	Method development and screening for adulterants in cosmetic products. Menjalankan penyaringan bahan campurpalsu bagi produk kosmetik dan pembangunan kaedah baru.
	Dosage Performance Unit Unit Prestasi Dosej	Bioavailability test such as dissolution, disintegration and dosage performance in terms of friability, viscosity and particulate matter. Menjalankan ujian kebioperolehan seperti pelarutan, pengecaian, dan prestasi dosej seperti perapuhan, kelikatan dan saiz partikel.
	General Chemistry and Spectroscopy Unit Unit Kimia Am dan Spektroskopi	General chemistry testing, assay and identification e.g. colour/ precipitation/Infra Red/Ultra Violet, titration, refractive index, uniformity of weight, loss on drying/water content and atomic absorption spectroscopy. Menjalankan ujian kimia am, esei dan identifikasi seperti warna/ mendakan/Infra Merah/Ultra Lembayung, pentitratan , pH, indeks bias, keseragaman berat tablet, susut pengeringan/ kandungan air dan spektroskopi penyerapan atomik.
Bio-Pharmaceutical Testing Section Seksyen Pengujian Bio-Farmaseutikal	Microbiology Unit Unit Mikrobiologi	Microbial limit test, microbiology assay, sterility and preservative efficacy test. Menjalankan ujian had mikrobial, esei mikrobiologi, steriliti dan ujian efikasi pengawet.
	Pharmacology Toxicology Unit Unit Farmakologi Toksikologi	Bacterial Endotoxin test. Menjalankan ujian Bakteria Endotoksin.
Natural Product Testing Section Seksyen Pengujian Produk Semulajadi	Toxic Compound Detection Unit Unit Pengesanan Bahan Toksik	Detection of heavy metal testing (lead, mercury, arsenic and cadmium). Menjalankan ujian pengesanan logam berat (plumbum, raksa, arsenik dan kadmium).
	Adulteration Screening Unit Unit Penyaringan Campurpalsu	Screening of adulteration in traditional product. Penyaringan bahan campurpalsu dalam produk tradisional.
	Herbal Monograph Unit Unit Monograf Herba	Development of the local herbal monograph. Membangunkan monograf herba tempatan.
Laboratory Services Unit Unit Perkhidmatan Makmal		Handling, receiving and distribution of samples and documentation (protocol analysis, validation data, worksheets and correspondences). Menguruskan penerimaan & pengagihan sampel dan pengendalian dokumen (protokol analisis, data validasi, kertas kerja, surat-menyurat).

Reference Standard Unit Unit Piawai Rujukan	Handling and production of reference standards. Menguruskan dan produksi piawai rujukan.

ANALYTICAL LABORATORY TESTING

Sample Receiving

Throughout the year 2007, a total of 4,793 samples were received for testing; an 8.2% reduction compared to the year 2006 (5,222 samples). Registration samples received for pharmaceutical, traditional and other category products also recorded a reduction in the number of samples. Although this centre received more market surveillance samples as compared to samples for registration, complaint, samples from the enforcement and others, the major reduction is contributed by pharmaceutical market surveillance samples at 33% (974 samples) compared to year 2006 (1,457 samples). However the number of enforcement (CPF) samples received for testing had increased by 39.6% (268 samples) as compared to the previous year (192 samples). (Chart 12)

PENGUJIAN ANALISIS MAKMAL

Penerimaan Sampel Bagi Pengujian

Pada tahun 2007, Pusat Kawalan Kualiti menerima jumlah sampel sebanyak 4,793 bagi pengujian analisis; iaitu penurunan sebanyak 8.2% berbanding tahun 2006 (5,222 sampel). Penerimaan sampel bagi kategori sampel pendaftaran (farmaseutikal dan tradisional) dan kategori lain-lain juga menunjukkan sedikit penurunan. Walaupun pusat ini paling banyak menerima sampel pengawasan, tetapi penurunan paling ketara adalah disumbangkan oleh kategori pengawasan untuk produk farmaseutikal iaitu sebanyak 33% (974 sampel) berbanding 1,457 sampel bagi tahun 2006. Manakala sampel dari Cawangan Penguatkuasa Farmasi menunjukkan peningkatan sebanyak 39.6% (268 sampel) berbanding 192 sampel pada tahun sebelumnya. (Carta 12)

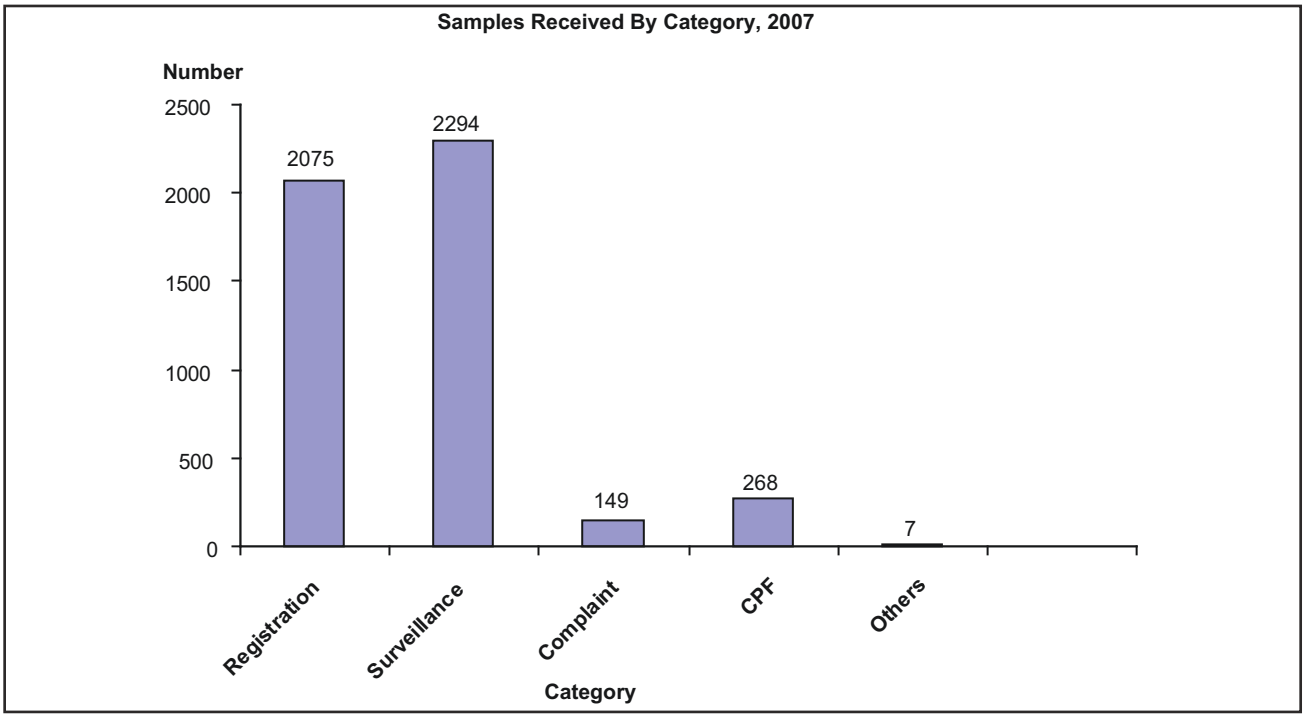


Chart 12 : Number of Samples Received By Category (Year 2007)

Carta 12 : Bilangan Sampel Diterima Mengikut Kategori (Tahun 2007)

Sample Testing

From the total of 5,322 samples tested in the year 2007, 34.54% (1,838 samples) were pharmaceutical products and 57.33% (3,051 samples) traditional products , 2.90% (155 samples) complaint samples, 5.07% (270 samples) enforcement samples and 0.15% (8) samples from other categories. The number of samples received for testing continued to show an increase compared to previous years. (Chart 13 & Chart 14)

Pengujian Sampel

Dari jumlah 5,322 sampel yang diuji dalam tahun 2007, sebanyak 34.54% (1,838 sampel) adalah dari kategori farmaseutikal, 57.33% (3,051 sampel) di bawah kategori tradisional , 2.90% (155 sampel) sampel aduan, 5.07% (270 sampel) Cawangan Penguatkuasa Farmasi dan 0.15% (8 sampel) dari kategori lain-lain. Selain itu, bilangan sampel yang diuji terus menunjukkan peningkatan berbanding tahun-tahun sebelumnya. (Carta 13 & Carta 14)

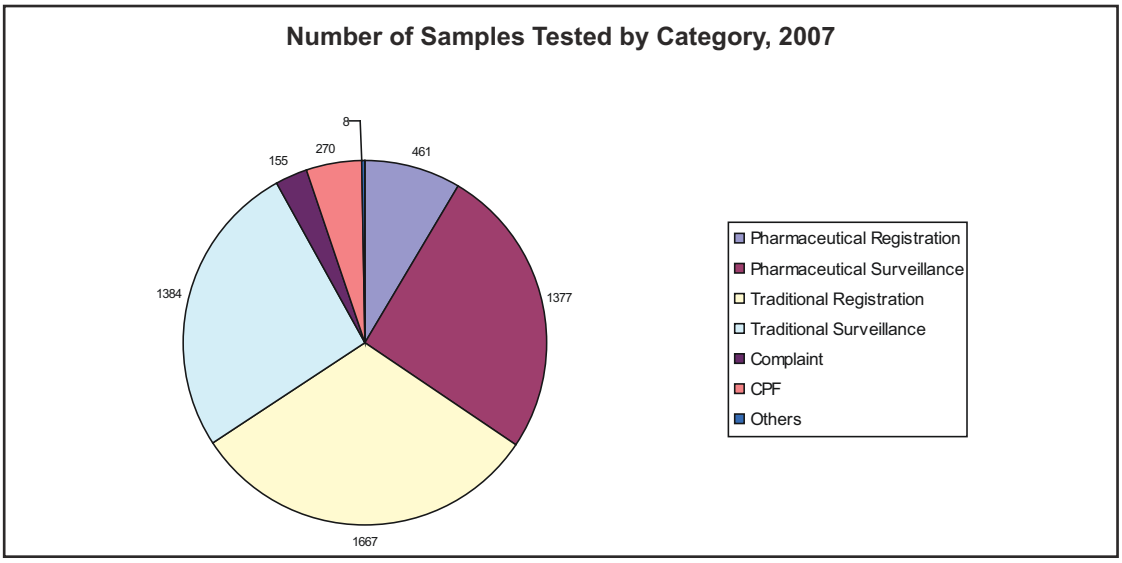


Chart 13 : Number of Samples Tested (Year 2007)

Carta 13 : Bilangan Sampel Diuji Mengikut Kategori (Tahun 2007)

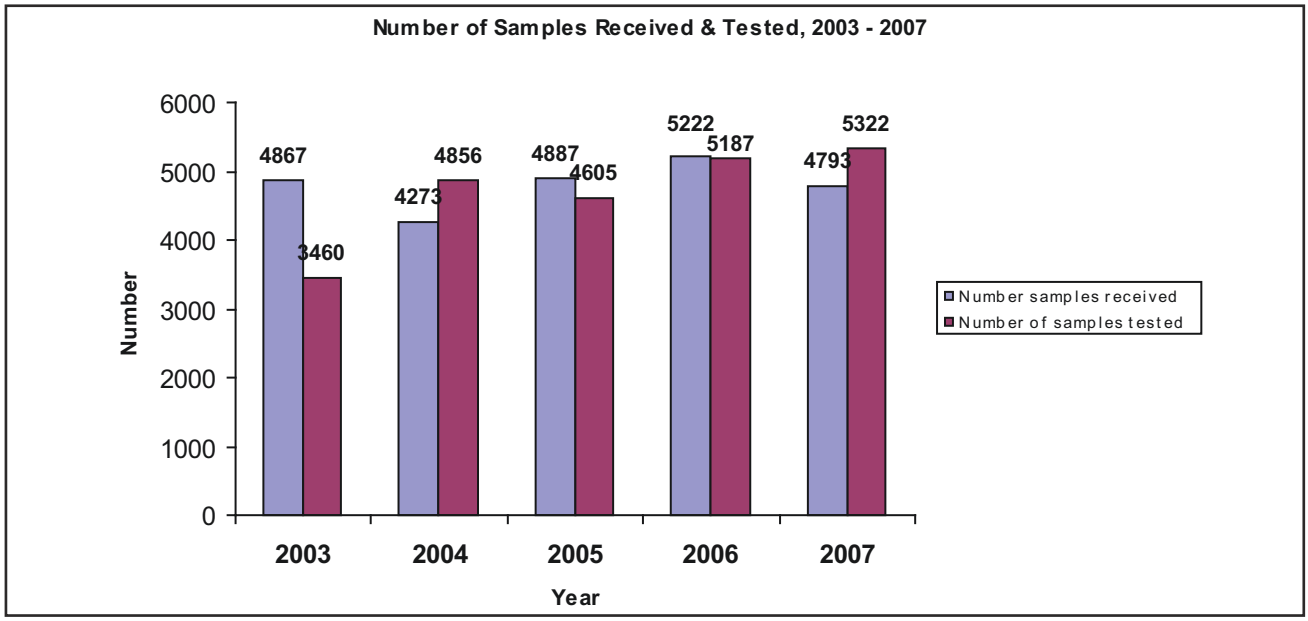


Chart 14 : Number of Samples Received and Tested (Year 2003 -2007)

Carta 14 : Penerimaan dan Pengujian Sampel (Tahun 2003 -2007)

Types of Tests Performed

The number of tests performed has increased consistently since 2003. In the year 2007, the total number of tests done was 68,774, an increase of 9.19% compared to the year 2006 (62,989). Majority of the tests were microbial limit test (MLT) at 52.69% (36,239) followed by heavy metal test 13.74% (9,450) and chemical test 11.4% (7,857). The percentage of screening tests has decreased to 17.2% (4,154) compared to last year (5,018) and this showed that the tests requested by the pharmacy enforcement unit were more focused and specific to substances suspected as adulterants in traditional products. (Chart 15)

Jenis Ujian yang Dijalankan

Statistik tahunan bagi jumlah ujian yang dijalankan menunjukkan peningkatan secara konsisten sejak tahun 2003. Pada tahun 2007, jumlah ujian yang dijalankan adalah 68,774 iaitu meningkat sebanyak 9.19% berbanding tahun 2006 (62,989). Majoriti ujian adalah ujian had Mikrobial (MLT) yang menyumbangkan 52.69% (36,239 ujian), diikuti ujian logam berat 13.74% (9,450 ujian) dan ujian kimia 11.4% (7,857 ujian). Penurunan peratus ujian penskrinan sebanyak 17.2% (4,154 ujian) berbanding tahun 2006 (5,018 ujian) menunjukkan jenis ujian yang diminta oleh pihak penguatkuasa lebih memfokus kepada penyaringan bahan campurpalsu spesifik yang disyaki. (Carta 15)

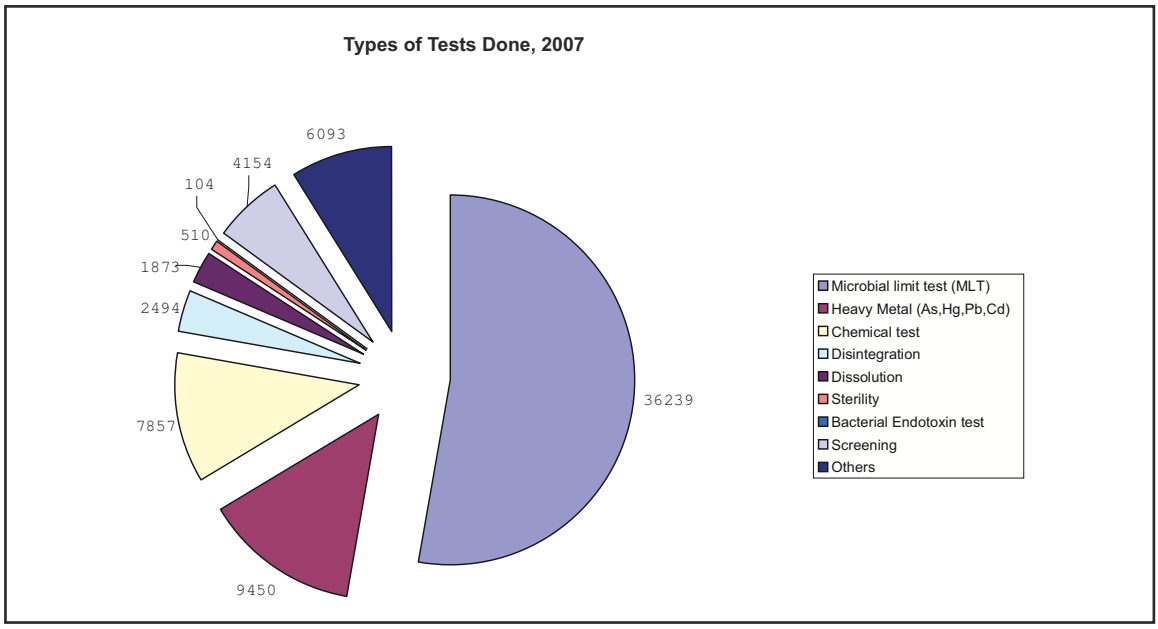


Chart 15: Types of Tests Done (Year 2007)

Carta 15: Jenis Ujian yang Dijalankan (Tahun 2007)

Failed Samples

In the year 2007, the number of samples tested and found not compliant to their specifications had increased by 29% (601) as compared to the previous year (465). This contributed to 11.29% from the total number of samples tested. The highest percentage of failed samples was for surveillance samples 43.3% (260), followed by registration samples 39.3% (236), 5.16% (31) complaint samples and 12.3% (74) from enforcement samples. (Chart 16)

Sampel yang Tidak Mematuhi Spesifikasi Sampel (Gagal)

Sepanjang tahun 2007, statistik bagi jumlah sampel yang diuji dan didapati gagal mematuhi spesifikasi yang ditetapkan meningkat sebanyak 29% (601 sampel) berbanding tahun sebelumnya (465 sampel). Jumlah ini merupakan 11.29% dari jumlah sampel yang diuji bagi tahun 2007. Peratus kegagalan sampel disumbangkan oleh sampel pengawasan sebanyak 43.3% (260 sampel) , sampel pendaftaran 39.3% (236 sampel) , 5.16% (31) sampel aduan dan 12.3% (74 sampel) dari Cawangan Penguatkuasa Farmasi (CPF). (Carta 16)

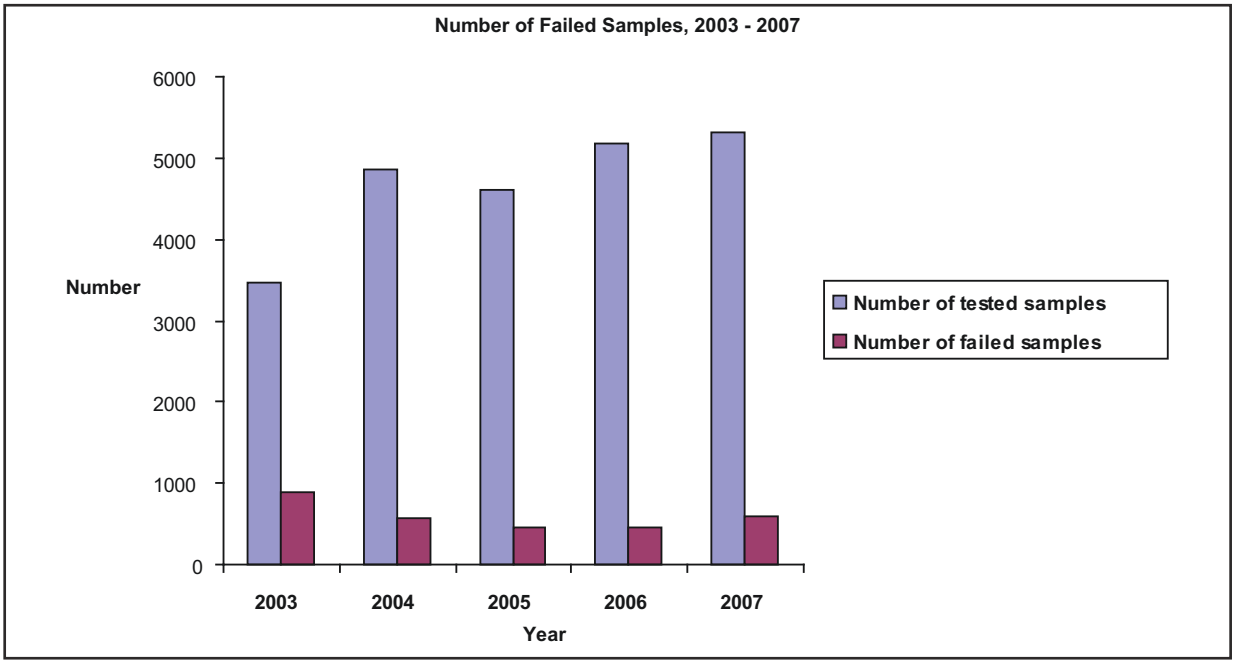


Chart 16 : Number of Failed Samples (Year 2003 -2007)

Carta 16 : Bilangan Sampel Gagal Ujian (Tahun 2003 -2007)

Screening of Adulterants in Traditional Medicines

In 2007, the number of samples screened for adulteration was 90 from pre-registered traditional products, 369 from surveillance and complaint samples as well as 269 samples from the enforcement unit. These products were screened for adulterants as they were claimed for the following four indications:

* for men's health
* for joint and muscle pain
* for reduction/control of body weight
* for cough and cold

Throughout 2007, the number of samples received requiring screening for adulterants increased drastically by 165% (986 samples) as compared to the year 2006 (372 samples). In addition, the total number of samples found positive for adulterants had increased by almost 50% (126 samples). Most of the products were positive for Sildenafil and its analogue at 21.4% (27 samples) compared to other adulterant types, of which 23 were enforcements samples, 1 surveillance sample and 2 registration samples for traditional products. (Chart 17)

Pengujian Bahan Campurpalsu dalam Keluaran Tradisional

Bagi tahun 2007, sebanyak 90 sampel pendaftaran tradisional, 369 sampel pengawasan & aduan serta 269 sampel penguatkuasaan telah diuji bagi tujuan penyaringan. Empat kategori produk tradisional yang mempunyai indikasi seperti di bawah diberi keutamaan untuk disaring:

* produk kesihatan lelaki
* produk bagi sakit-sakit sendi dan otot
* produk bagi mengurangkan/mengawal berat badan
* produk bagi batuk dan selsema

Terdapat peningkatan mendadak dari segi bilangan sampel yang diterima untuk penyaringan bahan campurpalsu pada tahun 2007 iaitu sebanyak 165% (986 sampel) berbanding 372 sampel pada tahun 2006. Pada masa yang sama, jumlah sampel yang didapati positif juga didapati meningkat hampir 50% (126 sampel) berbanding 85 sampel pada tahun 2006. Seperti tahun-tahun sebelumnya, sampel yang didapati positif dengan Sildenafil dan analognya mendahului sebanyak 21.4% (27 sampel) berbanding bahan campurpalsu lain di mana 23 sampel adalah dari penguatkuasa, 1 sampel pengawasan dan 2 sampel pendaftaran tradisional. (Carta 17)

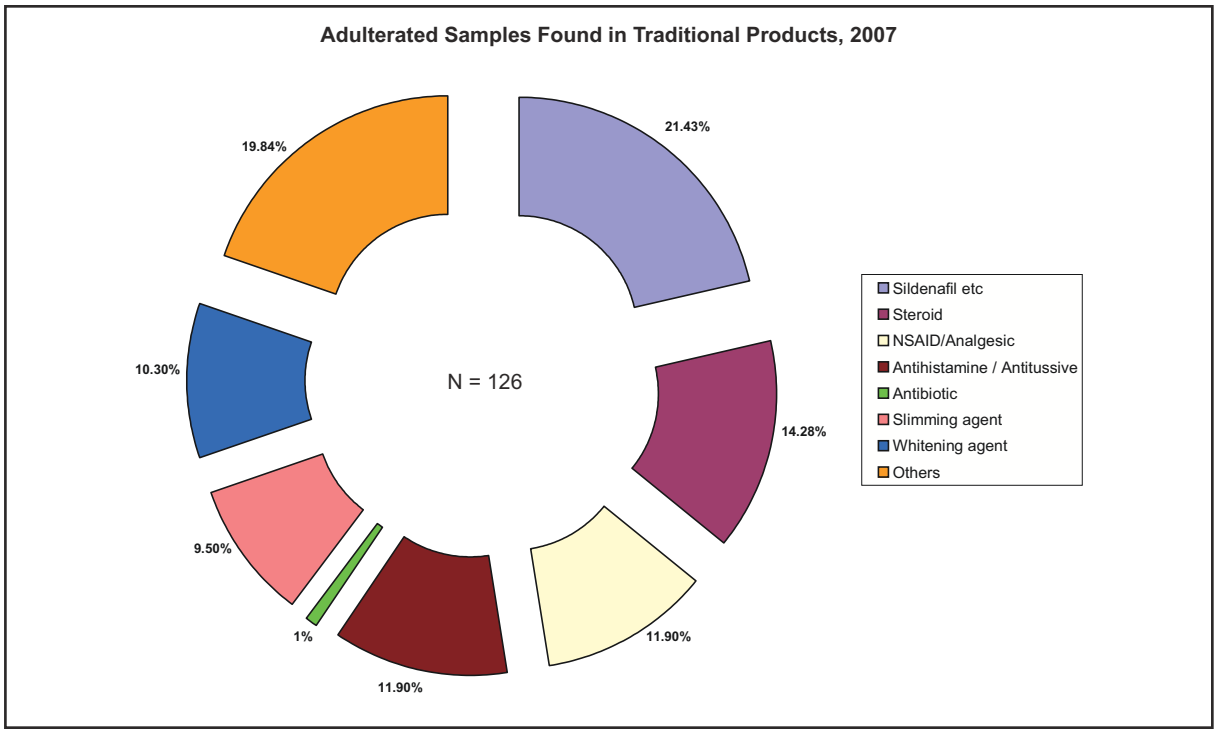


Chart 17 : Percentage of Adulterated Samples in Traditional Products (Year 2007)

Carta 17 : Peratus Sampel Keluaran Tradisional yang Dicampurpalsu (Tahun 2007)

F. Testing of Cosmetic Products

The Centre for Quality Control is actively involved in the testing of cosmetic products. Currently, the screening process for cosmetic products are conducted by the Chemistry Research Unit, focusing on the tests for the presence of Hydroquinone, Tretinoin and Diethylene Glycol (DEG). The samples were submitted by the Surveillance Unit and the Pharmacy Enforcement Unit. (Table 2)

F. Pengujian Keluaran Kosmetik

Penglibatan aktif Pusat Kawalan Kualiti dalam pengujian produk kosmetik secara tidak langsung dapat menunjukkan prestasi keluaran tersebut di pasaran. Proses penyaringan keluaran kosmetik kini dijalankan dengan lebih sistematik di mana tugas ini diambilalih oleh Unit Penyelidikan Kimia dan Unit Penyaringan Campurpalsu. Sampel-sampel diperolehi dari Unit Surveillance dan Cawangan Penguatkuasa Farmasi. Fokus pengujian adalah terhadap bahan-bahan Hydroquinone, Tretinoin dan Diethylene Glycol (DEG). (Jadual 2)

	Chemistry Research Unit Unit Penyelidikan Kimia	Adulteration Screening Unit Unit Penyaringan Campurpalsu
Number of samples tested Bilangan sampel diuji	315	80
Number of positive samples Bilangan sampel positif	18	13
Detected compound(s) Bahan dikesan	- Hydroquinone (12 samples) - Tretinoin (1 sample) - Hydroquinone & Tretinoin (4 samples) - Diethylene Glycol (6 samples)	- Hydroquinone (10 samples) - Tretinoin (1 sample) - Hydroquinone & Tretinoin (2 samples)

Table 2 : Number of Cosmetic Samples Tested Positive for Adulterants (Year 2007)

Jadual 2 : Bilangan Keluaran Kosmetik Diuji Positif mengandungi Bahan Campurpalsu (Tahun 2007)

ANTACID PRODUCT TESTING

The Centre for Quality Control in cooperation with the Centre for Post Registration of Products sampled 14 different antacid formulations from the market in a study to investigate the preservatives content chemically (methyl and propylparabens) and the preservative activity of the product by microbiological method. The study was aimed to examine the compliance of the products to the standard and specifications set by the manufacturers.

The results obtained showed that all the samples tested failed the chemical assay for preservatives, 25.0% of the samples failed microbial limit test and 78.6% of the samples failed the preservative efficacy test conducted. Subsequently the manufacturers were advised to study the stability of the products, improve their formulations and also the testing specifications.

PENGUJIAN KELUARAN ANTASID

Pusat Kawalan Kualiti bersama Pusat Pasca Pendaftaran Produk telah mengambil 14 sampel antasid dengan formulasi berlainan untuk menjalankan kajian kandungan pengawet secara kimia (kandungan methyl dan propylparaben) dan pengujian mikrobiologi yang meneliti efikasi pengawet. Kajian ini bertujuan menilai kepatuhan produk tersebut kepada piawaian dan spesifikasi pengilang yang telah ditetapkan.

Keputusan yang diperolehi menunjukkan semua sampel didapati gagal ujian kimia untuk kandungan pengawet, 25.0% sampel gagal ujian had mikrobial dan 78.6% sampel gagal ujian efikasi pengawet. Seterusnya pengilang telah dinasihatkan untuk mengkaji kestabilan produk mereka serta memperbaiki formulasi keluaran dan juga spesifikasi ujian.

PROTOCOL ANALYSIS EVALUATION AND VALIDATION DATA

The Laboratory Services Unit received a total of 1243 protocols and validation data evaluation requests for the purpose of registration, where in entirety this showed a decline of 6.89% as opposed to last year's (1335). Procedural review upon pharmaceutical

PENILAIAN PROTOKOL ANALISA DAN DATA VALIDASI

Unit Perkhidmatan Makmal telah menerima sebanyak 1243 protokol dan data validasi untuk dinilai bagi tujuan pendaftaran di mana jumlah ini menunjukkan penurunan sebanyak 6.89% berbanding tahun sebelumnya (1335). Ini disebabkan oleh kajian semula prosedur pengujian sampel produk farmaseutikal dari pra pendaftaran

product testing from pre to post registration by way of analytical method data substantiation evaluation was the main reason for the drop. Contributing to the reduction too, was the fact that companies needed time in the preparation of their documents. Furthermore, the Centre for Quality Control has extended the assessment time on data validation to 2 months, in contrast to 1 month for protocol evaluation. Especially visible in phase two in the year 2007, was an increase in the quantity of data validation received. (Chart 18)

kepada pasca pendaftaran melalui pendekatan penilaian data validasi tatacara analitikal. Penurunan ini adalah lanjutan dari syarikat yang memerlukan masa untuk penyediaan dokumen. Tambahan pula, PKK diberi masa 2 bulan bagi penilaian data validasi berbanding dengan hanya 1 bulan untuk penilaian protokol. Jelas dilihat pada fasa kedua tahun 2007, terdapat peningkatan jumlah validasi data yang diterima. (Carta 18)

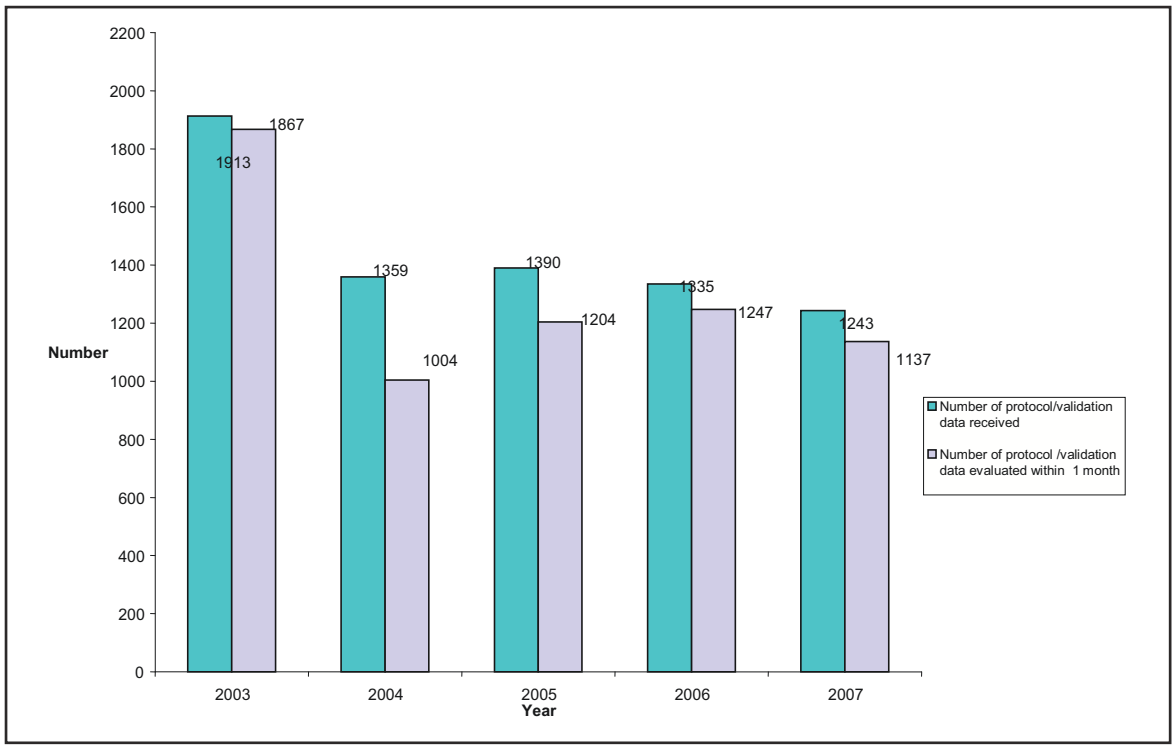


Chart 18 : Evaluation of Protocol and Validation Data (Year 2003 – 2007)

Carta 18 : Penilaian Protokol dan Data Validasi (Tahun 2003 – 2007)

GOOD MANUFACTURING PRACTICE INSPECTION

The Centre for Quality Control has constantly given support and technical input to the Centre for Compliance and Licensing in auditing cosmetic and therapeutic product manufacturers.

This centre also works as a team with Clinical Regulatory Research Unit, Centre for Compliance and Licensing, where it plays an active role in the National Good Laboratory Practice Committee, Ministry of Health Malaysia. It augurs well with Malaysia's endeavor to be a non-OECD (Organisation for Economics Cooperation and Development) member "adhering to Mutual Acceptance of Data".

Expanding its role further, the Centre for Quality Control was involved in the clinical trial facility inspection in Malaysia. The three facilities that were inspected included Sarawak General Hospital, Queen Elizabeth Hospital, Sabah and Sultanah

PEMERIKSAAN AMALAN PERKILANGAN BAIK

Pusat Kawalan Kualiti (PKK) sentiasa memberi sokongan dan input teknikal kepada Pusat Komplians dan Pelesenan (PKP) dalam pengauditan pengilang produk-produk terapeutik dan kosmetik.

Pusat ini telah melangkah setapak lagi di mana dengan kerjasama Unit Penyelidikan Klinikal Regulatori, Pusat Komplians dan Pelesenan, ia memainkan peranan aktif dalam Jawatankuasa Amalan Makmal Baik Kebangsaan, Kementerian Kesihatan Malaysia. Ini adalah lanjutan usaha Malaysia untuk menjadi negara bukan-OECD (Organisation for Economic Coorperation and Development) yang saling menerimapakai data.

PKK juga telah terlibat dalam pemeriksaan fasiliti percubaan klinikal di Malaysia. Sebanyak 3 fasiliti telah diperiksa dalam tahun 2007 (selain 6 fasiliti pada tahun 2006) iaitu Hospital Umum Sarawak, Hospital Queen Elizabeth, Sabah dan Hospital Sultanah Aminah, Johor. Pemeriksaan

Aminah Hospital, Johor. Inspections carried out were to appraise the facilities in the aspect of capacity in running clinical trials in Malaysia.

REFERENCE STANDARD UNIT

The Reference Standard Unit recorded a sale of 508 vials of both ASEAN and NPCB reference standards to the private sector. The cost of one vial of ASEAN reference standard is RM150 while the NPCB reference standard costs RM100 each. In the same period, the Reference Standard Unit supplied free of charge 248 vials to various government agencies for their usage. (Chart 19 & Chart 20)

Apart from producing and providing good storage to safeguard the integrity of the reference standards, this unit is also involved in investigative analysis when the quality of a particular standard is in suspicion. Whenever results obtained were outside product specification, the reference standards were disposed off.

dijalankan untuk menilai keupayaan fasiliti-fasiliti ini menjalankan percubaan klinikal.

UNIT PIAWAI RUJUKAN

Unit Piawai Rujukan (UPR) telah merekodkan penjualan sebanyak 508 vial piawai rujukan ASEAN dan BPFK ke pihak swasta. Kos satu vial piawai rujukan ASEAN adalah RM150 manakala piawai rujukan BPFK adalah RM100. Unit berkenaan juga membekal secara percuma 248 vial piawai rujukan pelbagai jenis kepada badan-badan kerajaan lain yang memerlukan. (Carta 19 & Carta 20)

Selain pengeluaran dan memastikan penyimpanan yang baik bagi menjaga integriti piawai rujukan, unit ini juga akan melakukan analisis penyiasatan jika disyaki mutu sesuatu piawai rujukan itu telah menurun. Sekiranya didapati kualiti piawai rujukan terjejas teruk atau berada di luar spesifikasi pengeluaran, piawai rujukan berkenaan akan dilupuskan.

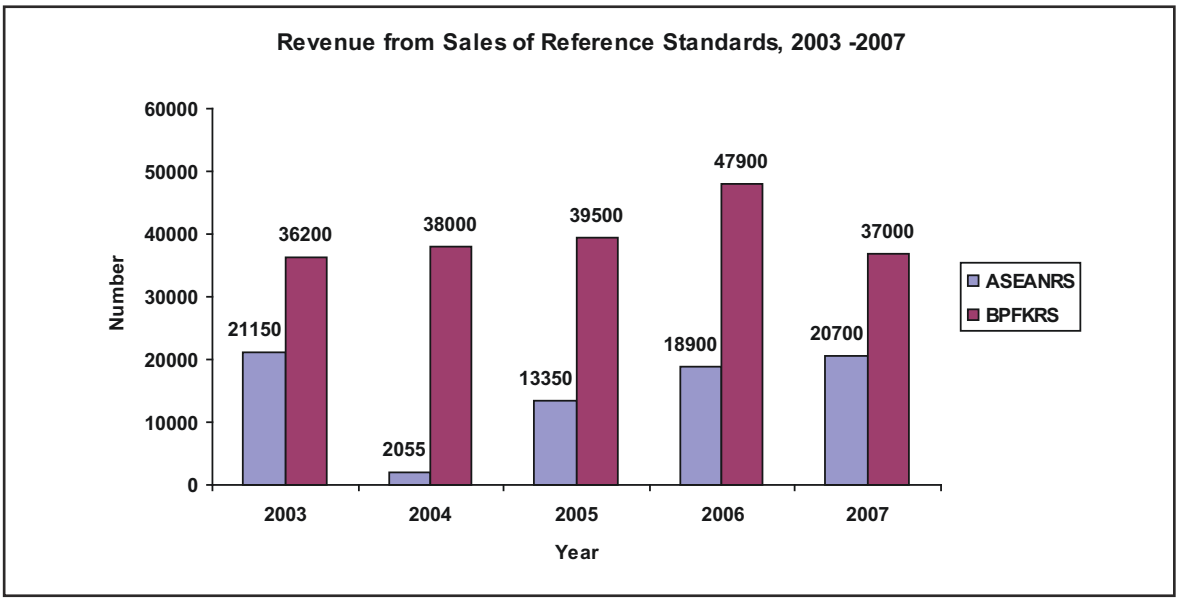


Chart 19: Revenue from Sales of Reference Standards (Year 2003 - 2007)

Carta 19: Hasil Jualan Piawai Rujukan (Tahun 2003 -2007)

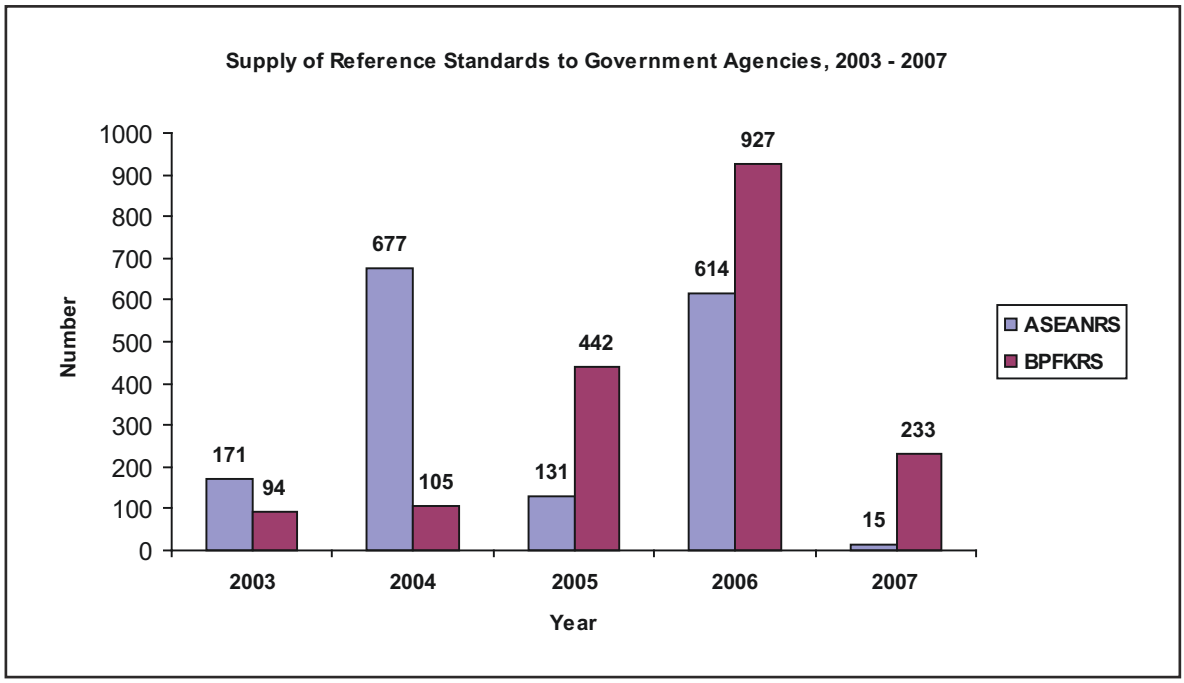


Chart 20 : Supply of Reference Standards to Government Agencies (Year 2003-2007)

Carta 20: Bekalan Piawai Rujukan kepada Badan Kerajaan (Tahun 2003 -2007)

FUTURE DIRECTIONS FOR 2008

1. To continue preparations towards accreditation for ISO 17025: 2005.
2. To actively engage in Proficiency Testing Scheme (PTS) conducted by WHO and EC-ASEAN Program as an attempt for continuous laboratory performance monitoring.
3. To continue cooperation between ASEAN countries by participation in the ASEAN reference standard production through collaborative studies.
4. Training new officers in protocol analysis and analytical data validation evaluation.
5. To conduct courses alongside local cosmetic industry in supervising microbial limit (MLT) and preservative efficacy tests (PET).
6. To continue cooperation among ASEAN member countries in harmonising traditional product testing parameters (Traditional Medicines and Health Supplement).
7. To continue preparations for organising a Pharmacy Research Conference.

CHALLENGES AND ROOM FOR IMPROVEMENT

1. To explore the possibility of a revamp in the testing procedure of products from pre to post registration whereby pre-registration evaluation involves entirely documentation assessment (protocol analysis and validation data).

HALATUJU TAHUN 2008

1. Meneruskan persediaan ke arah akreditasi ISO 17025 : 2005.
2. Penglibatan aktif dalam 'Proficiency Testing Scheme' yang dikendalikan oleh WHO dan Program EC-ASEAN sebagai satu usaha pemantauan berterusan prestasi makmal.
3. Meneruskan kerjasama antara Negara-negara ASEAN dengan mengambil bahagian dalam pengeluaran piawai rujukan ASEAN melalui kajian kolaboratif.
4. Melatih pegawai-pegawai baru dalam penilaian protokol analisis dan data validasi analitikal.
5. Menganjurkan kursus bersama industri kosmetik tempatan bagi pengujian had mikrobial (MLT) dan Ujian Keberkesanan Pengawet (PET).
6. Meneruskan kerjasama antara negara - negara ASEAN dalam usaha menyeragamkan parameter dalam pengujian keluaran tradisional (Traditional Medicine & Health Supplement).
7. Meneruskan usaha dalam persediaan mengadakan Persidangan Penyelidikan Farmasi.

CABARAN DAN LANGKAH PENAMBAHBAIKAN

1. Mempertimbangkan untuk melaksanakan prosedur pengujian produk farmaseutikal dari pra pendaftaran kepada pasca pendaftaran di mana penilaian pra-

2. Strengthening the capacity for Post-Registration Testing.
3. Enhancement of staffs' ability in tandem with meeting the requirement of ISO 17025 through suitable trainings and courses.
4. Training in method development using Liquid Chromatograph – Mass Spectrometer (LC-MS) for the Natural Product Testing Section to cater to the needs in adulteration screening.

pendaftaran oleh makmal dibuat berdasarkan penilaian dokumentasi sahaja (protokol analisis dan data validasi).

2. Meningkatkan kapasiti untuk Pengujian Pasca Pendaftaran.
3. Meneruskan usaha meningkatkan keupayaan anggota bagi memenuhi keperluan akreditasi ISO 17025 melalui latihan-latihan serta kursus yang bersesuaian.
4. Memberi latihan dalam membangunkan tatacara ujian menggunakan alat Liquid Chromatograph – Mass Spectrometer (LC-MS) untuk Seksyen Pengujian Produk Semulajadi bagi menampung keperluan penyaringan bahan campurpalsu.

National Pharmaceutical Control Bureau
2007 Annual Report

Centre for Post Registration of Products

Pusat Pasca Pendaftaran Produk

Centre for Post Registration of Products

INTRODUCTION

The centre for Post Registration of Products is responsible in ensuring that all registered products conform to established standards and requirements of the Drug Control Authority. The main activities of this centre include Post Market Surveillance (PMS) programme, investigation of product complaints and reports of adverse drug reactions received. Appropriate actions such as issuance of warning letters, instructions for product recalls and the institution of regulatory action such as label changes are undertaken in an effort to ensure the safety and well being of end users.

OBJECTIVES

This centre aims to ensure that all marketed registered products in Malaysia are compliant to the standard and registration conditions on quality, efficacy and aspects stipulated.

Safety aspects include potential or actual adverse effects as a result of product usage. Quality aspects include manufacture of products and efficacy aspects include desirable and undesirable effects from the usage of a product.

CENTRE FOR POST REGISTRATION ACTIVITIES (YEAR 2007)

SURVEILLANCE AND PRODUCT COMPLAINTS

Under the Post Market Surveillance (PMS) programme, samples of registered products are obtained and sent to the laboratory for testing. In 2007, a total of 2,559 registered products comprising of 386 pharmaceutical, 438 non-pharmaceutical, 1,376 traditional products and 359 cosmetic products were obtained from the market and analysed in the Centre for Quality Control.

It was found that 232 samples out of 2,795 products tested failed the laboratory tests which comprised of 27 prescription medicines 47 non-prescription medicines, 133 traditional medicines and 25 cosmetic products. Of the products which failed, 144 had to be recalled from the market. Six products were recalled under Degree 2 in which the affected batches were required to be recalled within 72 hours. 138 products were recalled under Degree 3 Recall. 62 warning letters were issued to the product registration holders as their product failed the laboratory tests but were not serious enough to warrant recalls. (Chart 21)

Pusat Pasca Pendaftaran Produk

PENGENALAN

Pusat Pasca Pendaftaran Produk (PPPP) bertanggungjawab dalam memastikan semua produk berdaftar mematuhi garispanduan dan memenuhi keperluan Pihak Berkuasa Kawalan Dadah (PBKD). Aktiviti utama yang dijalankan oleh Pusat Pasca Pendaftaran Produk adalah surveilans terhadap produk yang didaftarkan oleh PBKD, penyiasatan aduan mengenai produk, pemonitoran profil keselamatan produk, penilaian permohonan variasi dan pemprosesan permohonan tapak pengilang.

OBJEKTIF

Objektif pusat ini ialah untuk memastikan bahawa semua produk berdaftar yang dipasarkan di Malaysia mematuhi kepiawaian, keperluan dan syarat-syarat pendaftaran yang ditetapkan dari segi kualiti, keberkesanan dan keselamatan.

Aspek keselamatan adalah merangkumi potensi atau kesan berbahaya sebenar akibat penggunaan produk tersebut. Aspek kualiti adalah berkaitan dengan pengilangan produk dan aspek keberkesanan merangkumi kesan yang diingini atau tidak diingini daripada penggunaan produk tersebut.

AKTIVITI PUSAT PASCA PENDAFTARAN PRODUK (TAHUN 2007)

SURVEILANS DAN ADUAN PRODUK

Di bawah program 'Post Market Surveillance (PMS)', sampel-sampel produk berdaftar di pasaran akan diambil dan dihantar ke makmal untuk diuji. Pada tahun 2007, sejumlah 2,559 produk berdaftar yang terdiri daripada 386 produk farmaseutikal, 438 produk bukan farmaseutikal, 1,376 produk tradisional dan 359 produk kosmetik telah disampel dari pasaran dan diuji di Pusat Kawalan Kualiti (PKK).

Daripada 2,795 produk yang diuji, sebanyak 232 sampel gagal ujian yang dijalankan di makmal. Sampel-sampel ini terdiri daripada 133 produk tradisional, 27 produk preskripsi, 47 bukan preskripsi dan 25 produk kosmetik. Sebanyak 144 daripada jumlah produk yang gagal telah dipanggilbalik dimana 6 produk dipanggilbalik di bawah kelas 2 dan 138 produk telah dipanggilbalik di bawah kelas 3. Selain itu, sebanyak 62 surat amaran telah dikeluarkan kepada pemegang pendaftaran produk atas alasan produk mereka gagal ujian makmal. (Carta 21)

A total of 2,413 product labels and package inserts were screened to verify compliance with the approved label and inserts. Subsequently, a total of 157 warning letters were issued to the product registration holders where non-conformance was detected.

332 product complaints involving 8 cosmetics, 45 traditional medicines, 58 non-prescription medicines, 150 prescription medicines and 71 unregistered products were received. Actions were taken to resolve the complaints within 6 weeks in 85% of these cases. Complaints on unregistered products were forwarded to the Pharmacy Enforcement Branch for further action. (Chart 22)

Bagi memastikan produk di pasaran mematuhi keperluan pelabelan, sejumlah 2,413 label dan sisip bungkusan telah disemak. Sebanyak 157 surat amaran telah dikeluarkan kepada pemegang pendaftaran produk yang tidak mematuhi keperluan pelabelan oleh PBKD.

Sebanyak 332 aduan diterima yang melibatkan 150 produk preskripsi, 58 bukan preskripsi, 45 produk tradisional, 8 produk kosmetik dan 71 produk tidak berdaftar. Tindakan susulan dalam tempoh 6 minggu telah dijalankan bagi 85% kes yang diterima. Aduan berkenaan produk tidak berdaftar dikemukakan kepada Cawangan Penguatkuasa Farmasi (CPF) untuk tindakan susulan. (Carta 22)

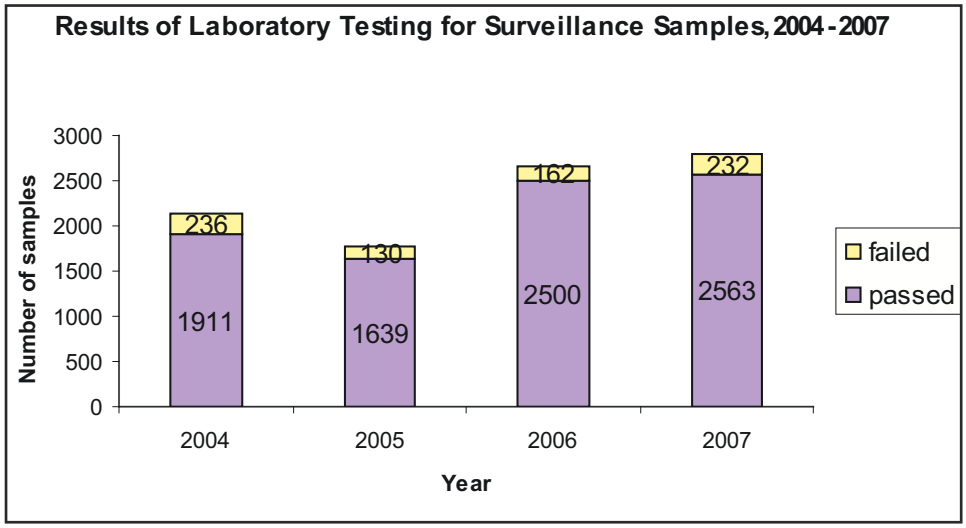


Chart 21: Results of Laboratory Testing for Surveillance Samples, (Year 2004 - 2007)

Carta 21: Keputusan Pengujian Makmal untuk Sampel Surveillans, (Tahun 2004 - 2007)

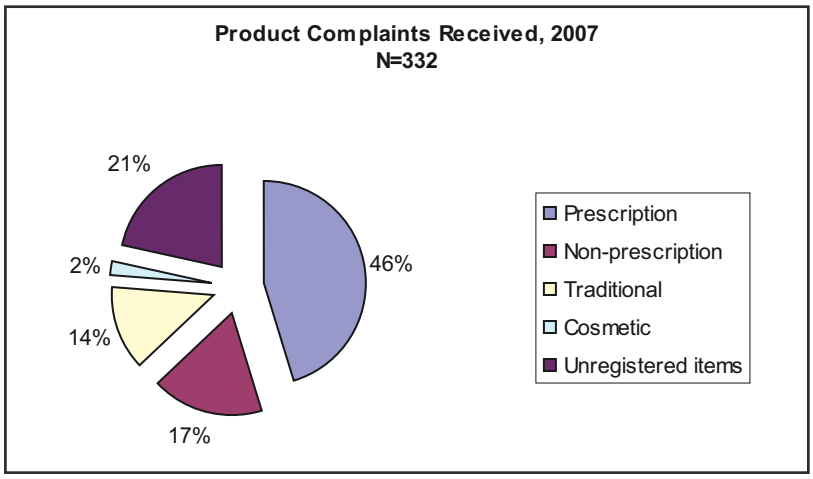


Chart 22: Product Complaints Received (Year 2007)

Carta 22: Aduan Produk Diterima (Tahun 2007)

In the year 2007, registration of 23 products that were sampled from the market was cancelled by the DCA as these products were tested and found to be adulterated with scheduled poisons. (Table 3)

Pada tahun 2007, 23 produk telah dibatalkan pendaftaran oleh PBKD kerana dicampurpalsu dengan racun berjadual (Jadual 3).

No	Product Name Nama Produk	Adulterant (s) Bahan Campurpalsu
1.	RIHANNA BEAUTY CREAM	Tretinoin
2.	EDOLY CAPSULE	Piroxicam, niacinamide and was suspected to contain frusemide
3.	CLEAR II CREAM	hydroquinone
4.	FACE LOTION 1	hydroquinone
5.	FACE LOTION 2	hydroquinone
6.	DEEP SKIN WHITE PLUS	hydroquinone
7.	GOLDEN DEER WHITE COMPLEX CREAM	hydroquinone
8.	HERBARITES SKIN WHITENING (SENSITIVE SKIN)	hydroquinone
9.	SUB INSTANT WHITE CREAM	hydroquinone
10.	SUB WHITENING REVITALIZING CREAM	hydroquinone
11.	ATIKA BEAUTY SKIN LIGHTENING CREAM	hydroquinone
12.	CRYSTAL WHITE NIGHT CREAM	hydroquinone
13.	CRYSTAL WHITE EXTRA NIGHT CREAM	hydroquinone
14.	SLENDERINE CAPSULE	Fluoxetin, Fenfluramine,
15.	SKIN WHITENING ESSENCE 1	hydroquinone
16.	SKIN WHITENING PLUS II	hydroquinone
17.	CHATLIN BRAND HAO ZHOU SAN	ephedrine
18.	COOL & LIGHTENING SOAP	hydroquinone
19.	N-HANZ	homosildenafil (sildenafil analogue).
20.	SAN QI LUOHAN CHUANBEI PLUS CAPSULE	Pseudoephedrine, chlorpheniramine
21.	BLACK KNIGHT LIQUID 30ML	sildenafil
22.	CHING DU WAN 300MG	chloramphenicol, chlorpheniramine, caffein
23.	MAXONHERBS	Aminotadalafil (analogue of tadalafil) Hydroxyhomosildenafil (analogue of sildenafil)

PRODUCT SAFETY PROFILE MONITORING

In 2007, a total of 3,068 Adverse Drug Reaction (ADR) reports involving 3,524 products were received and presented to the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) (Chart 23). Out of this, 3,276 products were prescription medicines, 148 non-prescription medicines, 24 traditional medicines, 9 cosmetics, 49 unregistered products and 18 products categorised as food.

As in the previous years, most reports were received mainly from government health professionals. From the total of ADR reports received, 35% were from doctors in the government sector, 2.3% from private practitioners, 41.8% from pharmacists, 7.8% from university hospitals and 13.1% from product owners themselves. Selangor submitted the highest number of reports followed by Wilayah Persekutuan Kuala Lumpur and Sabah. (Chart 24)

An analysis of the reports by organ system class showed that ADRs involving skin and appendages disorders contributed to the highest number of reports.

Several talks and seminars were conducted in various hospitals throughout the country to promote awareness and encourage ADR reporting in relation to this.

PEMONITORAN PROFIL KESELAMATAN PRODUK

Di bawah program farmakovigilans, sebanyak 3,068 laporan kesan advers ubat (ADR) yang melibatkan 3,524 produk telah diterima (Carta 23). Daripada jumlah tersebut, 3,276 adalah produk preskripsi, 148 produk bukan preskripsi, 24 produk tradisional, 9 produk kosmetik, 49 produk tidak berdaftar dan 18 produk makanan.

Seperti tahun–tahun sebelum ini, kebanyakan laporan ADR yang diterima adalah dari kalangan ahli profesional perubatan dalam sektor kerajaan. Bagi tahun 2007, 35% dari jumlah laporan yang diterima adalah daripada doktor yang berkhidmat di hospital kerajaan, 2.3% dari sektor swasta, 41.8% ahli farmasi yang berkhidmat di sektor awam, 7.8% dari hospital universiti dan 13.1% dari pemegang pendaftaran produk. Selangor merupakan negeri paling banyak menghantar laporan ADR diikuti dengan Wilayah Persekutuan Kuala Lumpur dan Sabah. (Carta 24)

Analisa laporan ADR yang diterima mengikut "sistem pengkelasan organ" menunjukkan ADR yang paling banyak berlaku dilaporkan melibatkan kesan pada kulit.

Pada awal tahun 2007, satu "pilot study" telah diadakan selama 3 bulan bagi menggalakkan penglibatan pengguna dalam program pemantauan ubat – ubatan di pasaran. Projek ini

A 3-month pilot study on consumer involvement in reporting ADRs, complaints on quality, safety and efficacy of products as well as unregistered products in the Klang Valley was launched in 2007. Most of the reports received involve non-prescription items.

merangkumi laporan pengguna mengenai ADR, produk yang kurang berkesan, produk yang tidak berkualiti dan produk tidak berdaftar.

Beberapa ceramah dan seminar berkaitan dengan Pemonitoran Kesan Advers Ubat telah diadakan di beberapa buah hospital di seluruh Malaysia. Sesi-sesi ini bertujuan meningkatkan kesedaran mengenai kepentingan melaporkan ADR serta pemonitoran kesan advers ubat di kalangan ahli perubatan profesional.

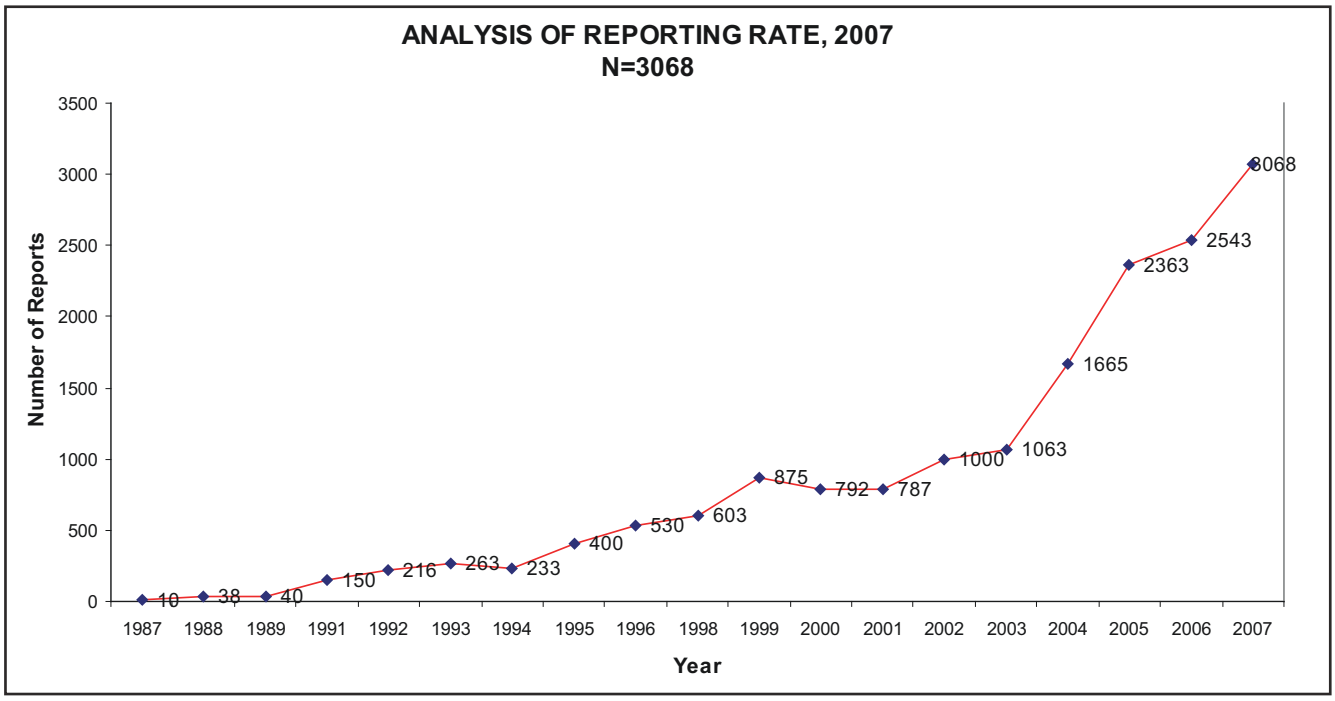


Chart 23: Analysis of Reporting Rate (Year 2007)

Carta 23: Analisa Kadar Pelaporan (Tahun 2007)

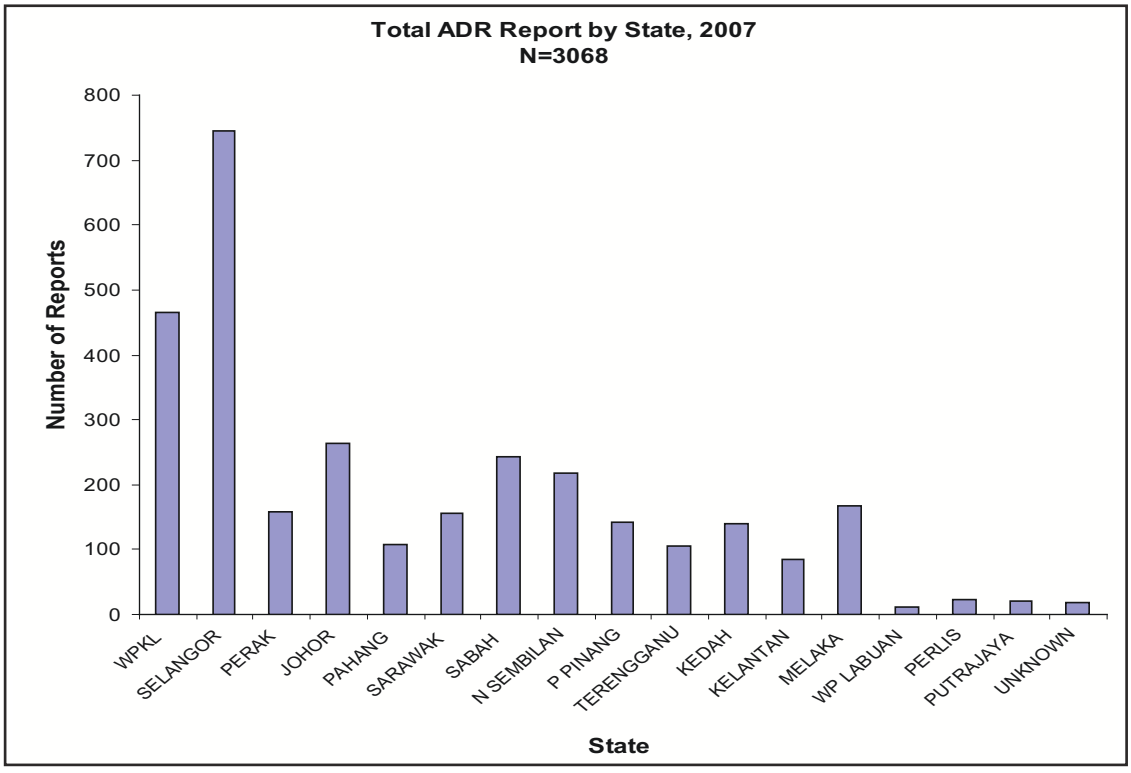


Chart 24: ADR Report by State (Year 2007)

Carta 24: Laporan ADR Mengikut Negeri (Tahun 2007)

PRODUCT VARIATION

Variation Unit is responsible to process applications submitted by Product Registration Holders for any changes made to the registered products as well as applications for change of manufacturing site.

In the year 2007, a total of 39,456 applications for variations were received - a 34% increase compared to the year 2006. Of these, 35,379 applications were evaluated. As a result, 23,583 applications were approved and 11,796 rejected. Reasons for rejection include:

a) Changes not in accordance to regulatory requirements
b) Incomplete documents
c) Incorrect documents submitted.

A total of 263 applications for change of manufacturing site were received and reviewed. Of these, 205 applications were approved, six applications were rejected, one had to be forwarded to the relevant department (cosmetic product) and 51 applications were still under review.

FUTURE DIRECTIONS FOR 2008

1. Under the post-market surveillance programme, to further increase surveillance activities on registered products suspected of containing adulterated substance, products manufactured by manufacturers that are not complying with GMP requirements and products that are difficult to formulate.

2. Steps are also undertaken to increase monitoring of high risk cosmetic products that are under category 1 and the whitening cream.

3. To intensify screening for antihypertensives, diabetics and products containing active ingredients such as Tongkat Ali and Red Yeast Rice in order to ensure that Post Market Surveillance activities are carried out objectively.

4. To extend the consumer reporting programme by having 'roadshows' in other states as well as to create awareness and encourage consumers to report ADRs, complaints or any matters pertaining to the quality, safety and efficacy of registered products. The awareness programme will be focused on non-prescription items such as traditional products and dietary supplements.

5. Currently, applications for change of manufacturing site are processed manually. It is our aim to upgrade our service by providing online application for change of manufacturing site application in the near future.

VARIASI PRODUK

Unit Variasi bertanggungjawab dalam memproses permohonan pertukaran maklumat pada produk berdaftar dan juga permohonan pertukaran tapak pengilang.

Pada tahun 2007, sebanyak 39,456 permohonan diterima untuk variasi, di mana jumlah permohonan meningkat 34.4% berbanding tahun 2006 . Jumlah permohonan yang telah diproses adalah 35,379 . Daripada jumlah ini, sebanyak 23,583 permohohan telah dilulus dan 11,796 ditolak. Antara faktor yang menyebabkan permohonan ditolak termasuk:

a) Pertukaran yang dibuat tidak mematuhi keperluan regulatori
b) Dokumen yang dikemukakan tidak lengkap
c) Dokumen yang dilampirkan tidak berkaitan dengan maklumat yang dikehendaki.

Sejumlah 263 permohonan pertukaran tapak pengilang diterima dan telah dinilai. Daripada jumlah ini, sebanyak 205 permohonan diluluskan, 6 permohonan ditolak, 1 permohonan dimajukan ke unit lain (kosmetik) dan 51 permohonan sedang disemak.

HALATUJU TAHUN 2008

1. Memperkasakan aktiviti surveilans ke atas produk-produk yang berdaftar dan juga produk-produk yang disyaki mengandungi bahan campurpalsu, produk-produk dari pengilang yang tidak memantuhi standard APB serta produk-produk yang sukar dikilangkan.

2. Mempertingkatkan pemantauan ke atas produk kosmetik berisiko tinggi iaitu produk kategori 1 dan krim pemutih .

3. Menjalankan penyaringan ke atas produk-produk penyakit darah tinggi, kencing manis, serta produk yang mengandungi bahan aktif Tongkat Ali dan red yeast rice bagi memastikan aktiviti PMS adalah lebih objektif.

4. Program pelaporan dari pengguna akan diteruskan lagi pada tahun 2008 dan akan diperluaskan dengan mengadakan 'roadshow' ke seluruh negeri di Malaysia. Program ini akan lebih menumpukan kepada produk – produk bukan preskripsi seperti produk tradisional dan suplemen kesihatan. Ini adalah kerana produk – produk seperti ini mudah diperolehi di pasaran dan pengguna menggunakan produk berkenaan tanpa nasihat dari ahli perubatan profesional.

5. Buat masa ini, permohonan pertukaran tapak pengilang diproses secara manual. Unit Variasi sedang dalam usaha untuk menaiktaraf perkhidmatan dengan menyediakan sistem permohonan secara online.

National Pharmaceutical Control Bureau
2007 Annual Report

Centre for Compliance and Licensing

Pusat Komplians dan Pelesenan

Centre for Compliance and Licensing

INTRODUCTION

The Centre for Compliance & Licensing is responsible for the inspection and licensing of manufacturers of pharmaceuticals, traditional medicines and cosmetics to ensure compliance with Good Manufacturing Practices. The centre is also involved in matters pertaining to the licensing of importers' and wholesalers' premises with the assistance of the State Pharmacy Enforcement Branch to ensure compliance with Good Storage Practices (GSP) among the importers and wholesalers. The Section for Clinical Research & Compliance, which is now part of the Centre for Compliance & Licensing, is responsible for the issuance of Clinical Trial Import Licenses and Clinical Trial Exemptions (CTX) for unregistered products, monitoring of Serious Adverse Events (SAE) and inspections of clinical research centres to ensure that the studies carried out are in accordance to the Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines.

OBJECTIVES

The Centre for Compliance & Licensing strives to ensure that all pharmaceuticals, traditional medicines and cosmetic products approved for the local market are safe, efficacious and of quality through inspections conducted by this centre. Besides that, the Centre for Compliance & Licensing also strives to ensure that clinical research conducted complies to the Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines, in order for clinical research conducted in Malaysia to be internationally accepted and recognised.

CENTRE FOR COMPLIANCE AND LICENSING ACTIVITIES (YEAR 2007)

GMP INSPECTIONS

321 GMP inspections were conducted in 2007, compared to 291 inspections and 226 inspections conducted in 2006 and 2005 respectively. The inspections undertaken covered a total of 33 prescription manufacturer premises, 18 non-prescription manufacturer premises, 144 traditional medicine manufacturer premises, 121 cosmetic products manufacturer premises and 5 other premises (Chart 25). The inspections conducted in 2007, according to their types, were 224 routine inspections, 53 pre-licensing inspections, 14 verification inspections, 10 pre-approval inspections, 3 pre-certification inspections and 1

Pusat Komplians dan Pelesenan

PENGENALAN

Pusat Komplians dan Pelesenan (PKP) adalah pusat yang bertanggungjawab mengendalikan pemeriksaan dan pelesenan ke atas pengilang-pengilang produk farmaseutikal, ubat-ubatan tradisional dan kosmetik bagi memastikan bahawa produk-produk tersebut dikilangkan menurut keperluan Amalan Perkilangan Baik (APB). Pusat ini juga terlibat dalam mengendalikan urusan pelesenan premis-premis pengimport dan pemborong dengan kerjasama daripada Cawangan Penguatkuasa Farmasi Negeri (CPFN) dalam usaha memastikan bahawa pengimport dan pemborong produk-produk berdaftar mematuhi keperluan Amalan Penstoran Baik (ASB). Seksyen Penyelidikan Klinikal dan Komplians yang sekarang merupakan sebahagian daripada Pusat Komplians dan Pelesenan pula bertanggungjawab dalam pengeluaran Lesen Mengimport untuk Penyelidikan Klinikal (CTIL) dan Kebenaran Mengilang untuk Penyelidikan Klinikal (CTX) bagi produk-produk tidak berdaftar, pemantauan 'Serious Adverse Events (SAE)' serta menjalankan pemeriksaan di pusat-pusat penyelidikan klinikal untuk memastikan penyelidikan klinikal yang dijalankan mematuhi garis panduan 'Good Clinical Practice (GCP)' dan 'Good Laboratory Practice (GLP)'.

OBJEKTIF

Pusat Komplians dan Pelesenan sentiasa berusaha dalam memastikan produk-produk farmaseutikal, ubat-ubatan tradisional dan kosmetik yang dibenarkan berada di pasaran tempatan adalah selamat, berkesan dan berkualiti serta memastikan penyelidikan klinikal yang dijalankan menepati garispanduan 'Good Clinical Practice (GCP)' dan 'Good Laboratory Practice (GLP)' agar penyelidikan-penyelidikan klinikal di Malaysia diterima dan diiktiraf di peringkat antarabangsa.

AKTIVITI PUSAT KOMPLIANS DAN PELESENAN (TAHUN 2007)

PEMERIKSAAN APB

Sebanyak 321 pemeriksaan Amalan Pengilangan Baik (APB) telah dijalankan pada tahun 2007 berbanding dengan 291 pemeriksaan pada tahun 2006 dan 226 pemeriksaan pada tahun 2005. Pemeriksaan tersebut merangkumi 33 premis pengilang produk preskripsi, 18 premis pengilang produk bukan preskripsi, 144 premis pengilang produk tradisional, 121 premis pengilang kosmetik dan 5 premis pengilang bagi produk selain daripada yang telah dinyatakan (Carta 25). Pemeriksaan-

investigative inspection. Although the auditors went to the premises, 16 inspections were unable to be conducted due to various reasons, including closed premises. The compliance rating for the inspections which were conducted was as follows:

- Routine inspections : 6 good, 201 marginal / satisfactory, 41 poor
- Other inspections : 26 satisfactory, 14 unsatisfactory

** Note: Some inspections may have been carried out more than once on the same premise

pemeriksaan yang dijalankan pada tahun 2007 berdasarkan jenis-jenis pemeriksaan adalah seperti berikut, iaitu 224 pemeriksaan rutin, 53 pemeriksaan pra-pelesenan, 14 pemeriksaan verifikasi, 10 pemeriksaan pra-kelulusan, 3 pemeriksaan pra-pensijilan dan 1 pemeriksaan penyiasatan. Terdapat sebanyak 16 pemeriksaan yang tidak dapat dijalankan atas sebab premis kilang ditutup. Taraf komplians bagi pemeriksaan yang telah dijalankan adalah seperti berikut:

- Pemeriksaan rutin : 6 baik, 201 sederhana, 41 lemah.
- Lain-lain pemeriksaan : 26 memuaskan, 14 tidak memuaskan

**Nota: Terdapat sesetengah pemeriksaan telah dijalankan lebih daripada sekali di premis yang sama

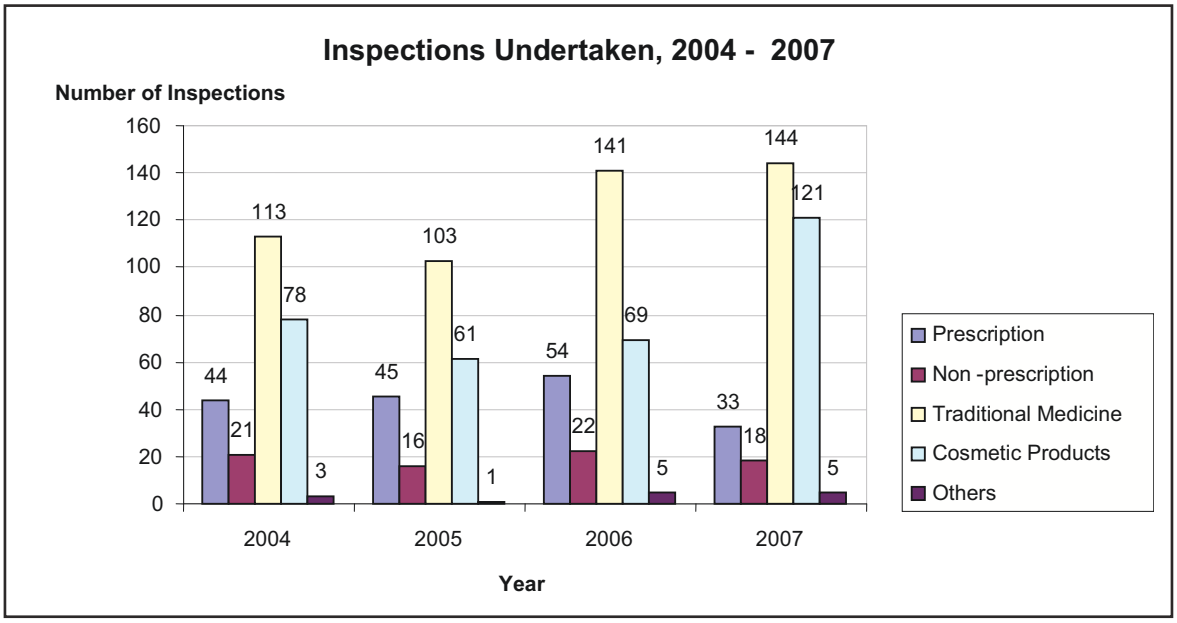


Chart 25: Number of Inspections Undertaken (Year 2004 - 2007)

Carta 25: Bilangan Pemeriksaan Dijalankan (Tahun 2004 - 2007)

INSPECTIONS OF CLINICAL RESEARCH CENTRES

The Clinical Trial Section functions as the secretariat for two national committees, namely the National Committee for Clinical Research and the National Committee for Good Laboratory Practice (GLP). In 2007, a total of 3 clinical trial facilities were inspected to evaluate the ability to conduct clinical research.

INSPECTIONS OF GOOD STORAGE PRACTICE (GSP)

Inspections of Good Storage Practice (GSP) have been carried out by the Centre for Compliance & Licensing since mid 2006. Its purpose is to ensure good level of GMP compliance on Good Storage Practice (GSP) which is vital in ensuring good distribution control and storage of registered products. Within the period of August 2006 – December 2007, 21 premises within the Klang Valley have been inspected for compliance to GSP.

PEMERIKSAAN PUSAT-PUSAT PENYELIDIKAN KLINIKAL

Seksyen Penyelidikan Klinikal dan Komplians berfungsi sebagai sekretariat kepada 2 jawatankuasa kebangsaan, iaitu Jawatankuasa Penyelidikan Klinikal Kebangsaan dan Jawatankuasa 'Good Laboratory Practice (GLP)' Kebangsaan. Pada tahun 2007, 3 fasiliti penyelidikan klinikal telah diperiksa untuk menilai keupayaan dalam menjalankan penyelidikan klinikal.

PEMERIKSAAN AMALAN PENSTORAN BAIK (ASB)

Pemeriksaan Amalan Penstoran Baik (ASB) telah dilaksanakan oleh Pusat Komplians dan Pelesenan sejak pertengahan tahun 2006. Tujuannya adalah untuk memastikan tahap komplians APB yang baik dalam Amalan Penstoran Baik (ASB), di mana ia adalah sangat penting dalam memastikan

Premises were selected based on their product category; namely Non-prescription and Traditional medicines. Inspections of Good Storage Practice (GSP) on Poisons are conducted by the Pharmacy Enforcement Branch.

INSPECTIONS OF FACILITIES FOR PREPARATION OF PHARMACEUTICAL, RADIOPHARMACEUTICAL AND BIOLOGICAL PRODUCTS

In order to ensure that all products prepared in the production facilities by hospitals and research institutions are safe for patient use, workers are safe from production hazard and environment is protected from drug contamination, the preparation facilities must be inspected. The inspection of these facilities, which include the government and private hospitals, is carried out by the Centre for Compliance and Licensing of NPCB. In 2007, the Centre inspected 17 clean room facilities of pharmaceutical, radiopharmaceutical and biological preparations. Since the inspection activity of these facilities was newly introduced, most of the inspections were done to qualify new preparation facilities. Inspections performed in 2007 include 13 pharmaceutical preparation facilities (i.e. Cytotoxic Drug Reconstitutions [CDR] and Total Parenteral Nutrition [TPN]), 3 radiopharmaceutical premises and 1 biological preparation facility. The facilities covered were an industrial scale radiopharmaceutical producer, hospitals' pharmaceutical and radiopharmaceutical clean rooms and also a biotechnology laboratory in a university setting.

EVALUATION OF MANUFACTURER'S LAYOUT PLAN

39 manufacturer premises layout plans were evaluated for GMP compliance in the year 2007, which consist of 7 prescription manufacturer premises, 7 non-prescription manufacturer premises, 13 traditional manufacturer premises, 10 cosmetic manufacturer premises and 2 veterinary medicine manufacturer premises. (Chart 26)

kawalan pengagihan dan penyimpanan yang baik bagi produk-produk berdaftar. Sepanjang Ogos 2006 hingga Disember 2007, sebanyak 21 premis di Lembah Klang telah diperiksa dari segi komplians terhadap Amalan Penstoran Baik (ASB). Premis-premis tersebut dipilih berdasarkan kategori produk iaitu produk bukan preskripsi dan produk tradisional. Pemeriksaan Amalan Penstoran Baik (ASB) bagi produk preskripsi dijalankan oleh Cawangan Penguatkuasa Farmasi Negeri.

PEMERIKSAAN FASILITI-FASILITI UNTUK PENYEDIAAN PRODUK-PRODUK FARMASEUTIKAL, RADIOFARMASEUTIKAL DAN BIOLOGIKAL

Dalam memastikan semua produk yang disediakan oleh hospital-hospital dan institusi-institusi penyelidikan adalah selamat untuk kegunaan pesakit, kakitangan selamat daripada bahaya pengeluaran dan persekitaran dilindungi daripada kontaminasi ubat, fasiliti-fasiliti berkenaan mestilah diperiksa. Pemeriksaan fasiliti-fasiliti ini, termasuklah di hospital-hospital kerajaan dan swasta, telah dijalankan oleh Pusat Komplians dan Pelesenan, BPFK. Pada tahun 2007, sebanyak 17 bilik bersih fasiliti-fasiliti penyediaan farmaseutikal, radiofarmaseutikal dan biologikal telah diperiksa. Memandangkan aktiviti pemeriksaan fasiliti-fasiliti ini baru diperkenalkan, kebanyakan pemeriksaan yang dijalankan adalah untuk kualifikasi fasiliti-fasiliti penyediaan yang baru. Pemeriksaan-pemeriksaan yang telah dijalankan pada tahun 2007 adalah seperti berikut, iaitu sebanyak 13 fasiliti farmaseutikal (Rekonstitusi Ubat Sitotoksik, dan Total Parenteral Nutrition [TPN]), 3 premis radiofarmaseutikal dan 1 fasiliti penyediaan produk biologikal. Fasiliti-fasiliti tersebut merangkumi industri pengeluar radiofarmaseutikal, bilik bersih farmaseutikal dan radiofarmaseutikal di hospital serta makmal bioteknologi di universiti.

PENILAIAN PELAN SUSUN ATUR PREMIS PENGILANG

Pada tahun 2007, sebanyak 39 pelan susun atur premis pengilang telah dinilai untuk kepatuhan APB. Premis-premis tersebut termasuk 7 premis pengilang produk preskripsi, 7 produk bukan preskripsi, 13 premis pengilang produk ubat tradisional, 10 premis pengilang kosmetik dan 2 premis pengilang produk veterinar. (Carta 26)

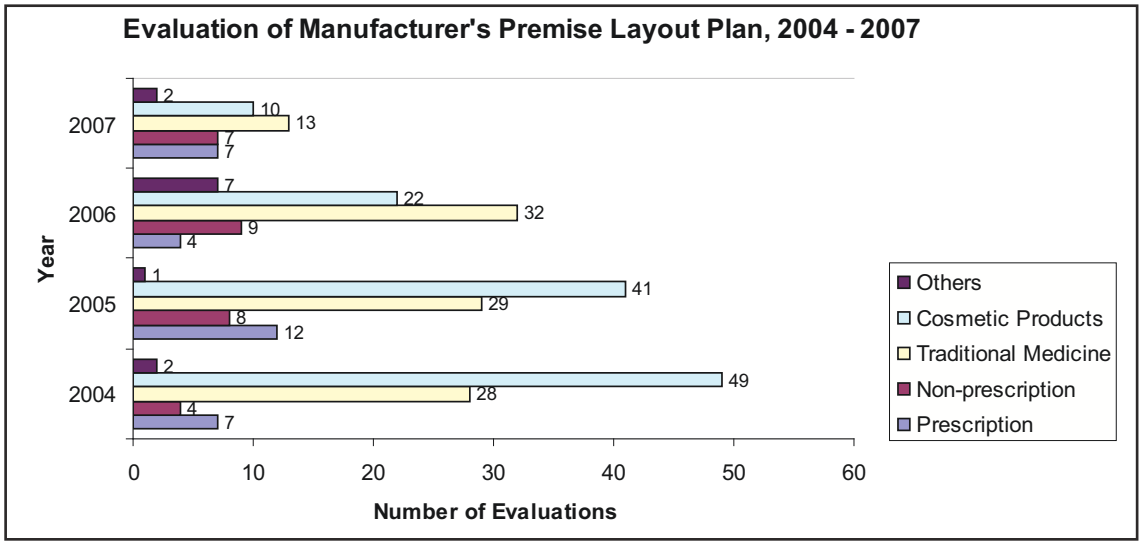


Chart 26: Evaluation of Manufacturer's Premise Layout Plan (Year 2004 - 2007)

Carta 26: Penilaian Pelan Susun Atur Premis Pengilang (Tahun 2004 - 2007)

ISSUANCE OF LICENSES

Under the provision of sub-section 12(1) of the Control of Drugs and Cosmetic Regulations 1984, the Drug Control Authority (DCA) is authorised to issue Manufacturer's License, Importer's License and Wholesaler's License, which are under the purview of this centre. In the year 2007, a total of 301 Manufacturer's License, 576 Importer's License and 1063 Wholesaler's License were issued. (Chart 27)

PENGELUARAN LESEN

Di bawah peruntukan sub-peraturan 12 (1) Peraturan-Peraturan Kawalan Dadah Dan Kosmetik 1984, Pihak Berkuasa Kawalan Dadah (PBKD) diberi kuasa untuk mengeluarkan lesen pengilang, lesen pengimport dan lesen pemborong. Pemprosesan lesen adalah tanggungjawab pusat ini. Pada tahun 2007, sebanyak 301 lesen pengilang, 576 lesen pengimport dan 1,063 lesen pemborong telah dikeluarkan. (Carta 27)

Chart 27: Number of Manufacturer, Importer & Wholesaler Licenses Issued (Year 2001 - 2007)

Carta 27: Bilangan Lesen Pengilang, Pengimport & Pemborong yang Dikeluarkan (Tahun 2001 - 2007)

A total of 190 Clinical Trial Import Licenses and 2 Clinical Trial Exemptions (CTX) for unregistered products were issued in the year 2007. On a different note, a total of 279 variation applications, which include the addition of quantities of imported products, research site changes and the usage of new protocols were processed. (Chart 28 & Chart 29)

Selain itu, sebanyak 190 Lesen Mengimport untuk Penyelidikan Klinikal (CTIL) dan 2 Kebenaran Mengilang untuk Penyelidikan Klinikal (CTX) bagi produk-produk tidak berdaftar telah dikeluarkan pada tahun 2007, manakala permohonan variasi yang melibatkan permohonan untuk menambah kuantiti produk diimport, pertukaran tapak (pusat) penyelidikan, penggunaan protokol yang baru dan

sebagainya yang telah diproses sepanjang tahun 2007 adalah sebanyak 279. (Carta 28 & Carta 29)

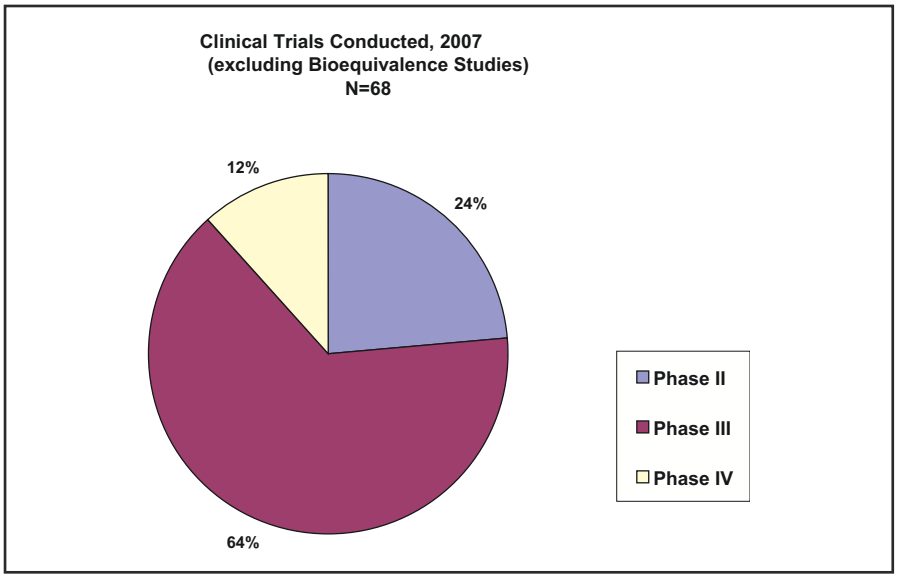


Chart 28: Clinical Trials Conducted (Year 2007)

Carta 28: Penyelidikan Klinikal yang Dijalankan (Tahun 2007)

Note: These statistics are based on the number of applications received by the National Pharmaceutical Control Bureau for the Clinical Trial Import License for unregistered products.
Drug-related clinical trials for registered products which do not require clinical trial import license is not controlled by the Drug Control Authority.

Nota: Statistik ini adalah berdasarkan kepada bilangan permohonan Lesen Mengimport untuk Penyelidikan Klinikal (CTIL) bagi produk-produk tidak berdaftar yang diterima oleh Biro Pengawalan Farmaseutikal Kebangsaan.
Penyelidikan klinikal berkaitan produk-produk berdaftar yang tidak memerlukan CTIL adalah bukan di bawah kawalan Pihak Berkuasa Kawalan Dadah.

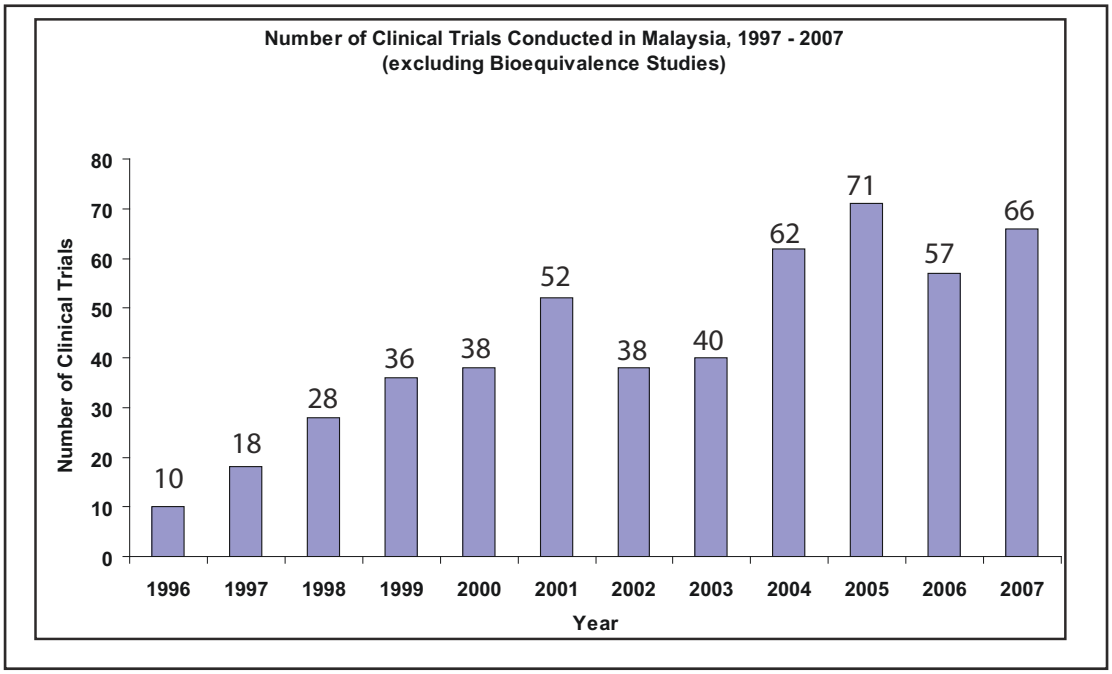


Chart 29: Number of Clinical Trials Conducted (Year 1997 - 2007)

Carta 29: Bilangan Penyelidikan Klinikal yang Dijalankan (Tahun 1997 - 2007)

In the year 2007, license processing for manufacturers, importers and wholesalers have been reduced from 3 months to 1 month for complete applications; while license processing for Clinical Trial Import Licenses (CTIL) and Clinical Trial Exemptions (CTX) have been reduced from 3 months to 2 months for complete applications.

REGISTERED PRODUCT ADDITIONAL LIST

A total of 2572 applications were processed in the year 2007, covering a total of 20590 products. The list is processed according to applications submitted during the registration of new products and this list shall be attached to the Manufacturer's or Importer's License. (Chart 30)

Pada tahun 2007, tempoh masa pemprosesan lesen untuk pengilang, pengimport dan pemborong telah dikurangkan dari 3 bulan ke 1 bulan, sementara bagi Lesen Mengimport untuk Penyelidikan Klinikal (CTIL) dan Kebenaran Mengilang untuk Penyelidikan Klinikal (CTX) bagi produk-produk tidak berdaftar pula telah dikurangkan dari 3 bulan kepada 2 bulan bagi setiap permohonan yang telah lengkap.

SENARAI TAMBAHAN PRODUK BERDAFTAR

Jumlah permohonan yang diproses pada tahun 2007 adalah sebanyak 2572 dan ini meliputi sebanyak 20590 produk. Senarai ini diproses berdasarkan permohonan yang dikemukakan apabila terdapat produk yang baru didaftarkan dan senarai perlu dikepilkan bersama Lesen Pengilang atau Lesen Pengimport. (Carta 30)

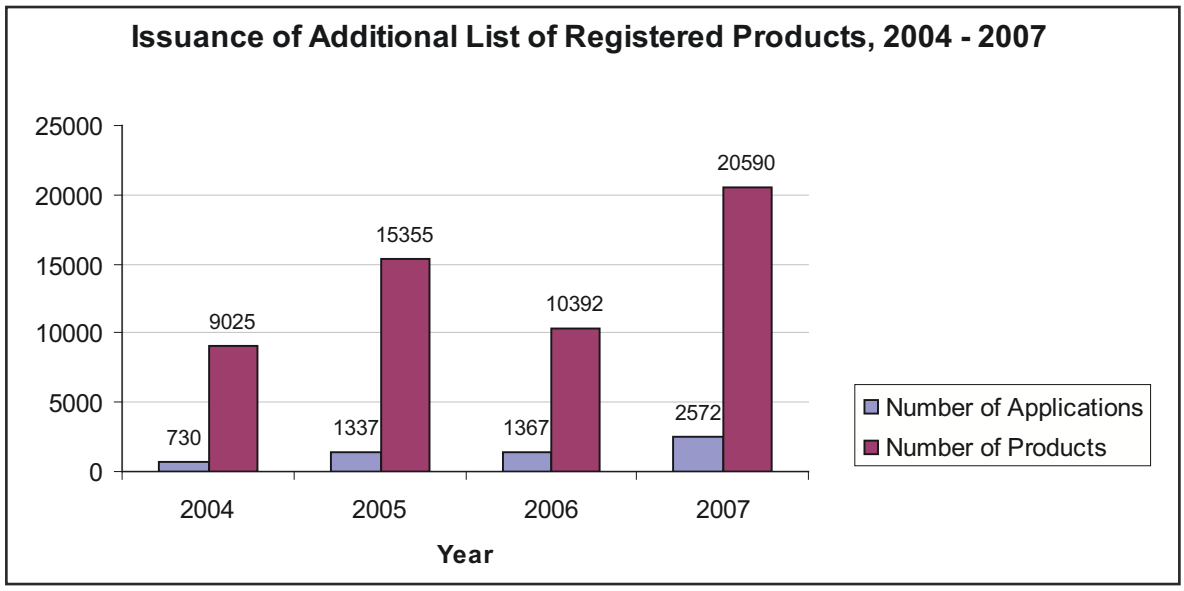


Chart 30: Issuance of Additional List of Registered Products (Year 2004 - 2007)

Carta 30: Senarai Tambahan Produk Berdaftar (Tahun 2004 - 2007)

MANUFACTURING LICENSE REVOCATION

In 2007, a total of 9 Manufacturing Licenses have been revoked by the Drug Control Authority (DCA), whereby 7 Manufacturing Licenses have been revoked due to non-compliance to current Good Manufacturing Practices (GMP), while 2 Manufacturing Licenses were revoked due to adulteration issues.

PEMBATALAN LESEN PENGILANG

Pada tahun 2007, sebanyak 9 Lesen Pengilang telah dibatalkan oleh Pihak Berkuasa Kawalan Dadah (PBKD) iaitu 7 darinya dibatalkan kerana tidak mematuhi Amalan Perkilangan Baik (APB) yang terkini, sementara 2 lagi dibatalkan atas sebab produk campurpalsu.

NATIONAL GMP SEMINAR ON COSMETICS

The Centre for Compliance & Licensing took the initiative to conduct the National GMP Seminar on Cosmetics, which was themed "Towards ASEAN Harmonised Cosmetic Regulatory Scheme" on 5th – 7th November 2007. The objective of this seminar was to strengthen the capability of the Malaysian cosmetics industry on the implementation of Good Manufacturing Practice (GMP) control towards the ASEAN Harmonised Regulatory Scheme. The seminar introduced the New Licensing Scheme for the year 2008, provided training based on the modules of Good Manufacturing Practices for Cosmetics, as

SEMINAR KEBANGSAAN APB KOSMETIK (NATIONAL GMP SEMINAR ON COSMETICS)

Pusat Komplians dan Pelesenan telah mengambil inisiatif menganjurkan 'National GMP Seminar on Cosmetics 2007' bertema "Towards ASEAN Harmonised Cosmetic Regulatory Scheme" pada 5 – 7 November 2007. Objektif seminar ini adalah untuk memperkukuhkan keupayaan industri kosmetik di Malaysia dalam mengimplementasikan Amalan Perkilangan Baik (APB) ke arah 'ASEAN Harmonised Regulatory Scheme'. Seminar ini memperkenalkan 'New Licensing Scheme for Year 2008', menyediakan latihan berdasarkan modul Amalan Perkilangan Baik Untuk Kosmetik serta

well as introduced the Notification Procedure for Cosmetic Products.

REGIONAL WORKSHOP ON TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS (TMHS) – GOOD MANUFACTURING PRACTICE (GMP)

The Regional Workshop on Traditional Medicines and Health Supplements (TMHS) – Good Manufacturing Practice (GMP) was conducted by the Centre for Compliance & Licensing on 22nd – 24th May 2007. Delegates from several ASEAN regulatory bodies convened to review the first draft of the Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements, which was prepared by the Centre for Compliance & Licensing, National Pharmaceutical Control Bureau.

FUTURE DIRECTIONS FOR 2008

1. **Control of Active Pharmaceutical Ingredients (API) and Veterinary Products**
   To date, Active Pharmaceutical Ingredients (API) have not been regulated by the Drug Control Authority (DCA). However, pre-certification inspections are conducted by the Centre for Compliance & Licensing for the purpose of the issuance of the GMP Certificate, which is used as a pre-requisite for export-only products. In the future, a database for API shall be established as a reference for product complaints. Besides that, training sessions will be offered to officers to ensure better exposure in manufacturing APIs and to promote the importance of GMP in the manufacturing aspects of APIs.

2. **Good Storage Practice (GSP) Inspection for Importers and Wholesalers**
   Good Storage Practice inspections on importers and wholesalers of registered products are planned to be executed in stages, according to state and product category. As an introduction to GSP aspects, theoretical and practical trainings were conducted and similar trainings are planned for the Pharmacy Enforcement Branch.

3. **Hospital Pharmacy**
   Guide to Good Preparation Practice for Medicinal Product will be established for inspections on sterile facilities. Trainings for hospital pharmacists are planned to be executed in the year 2008.

4. **Traditional Medicines and Health Supplements (TMHS)**
   The Centre for Compliance & Licensing aims to further develop the draft guidelines for Traditional Medicines and Health Supplements (TMHS) in order to produce an accepted Guideline for Traditional Medicine

memperkenalkan Prosedur Notifikasi untuk Produk-produk Kosmetik.

REGIONAL WORKSHOP ON TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS (TMHS) – GOOD MANUFACTURING PRACTICE (GMP)

'Regional Workshop on Traditional Medicines and Health Supplements (TMHS) – Good Manufacturing Practice (GMP)' telah dianjurkan oleh Pusat Komplians dan Pelesenan pada 22 – 24 Mei 2007. Delegasi dari beberapa badan regulatori ASEAN bersama-sama meneliti deraf pertama Garispanduan Amalan Perkilangan Baik bagi Produk Tradisional dan Suplemen Kesihatan yang telah disediakan oleh Pusat Komplians dan Pelesenan, Biro Pengawalan Farmaseutikal Kebangsaan.

HALATUJU TAHUN 2008

1. **Pengawalan Produk Kategori Bahan Aktif Farmaseutikal (API)**
   Setakat ini, produk-produk bahan aktif farmaseutikal (API) tidak dikawal oleh PBKD. Walaubagaimanapun, pemeriksaan pra-pensijilan dilakukan oleh Pusat Komplians dan Pelesenan bagi tujuan pengeluaran sijil APB yang digunakan sebagai salah satu dokumen pendaftaran untuk produk yang ingin dieksport ke luar negara. Satu pangkalan data berhubung produk-produk API akan diwujudkan untuk dijadikan bahan rujukan dan pemantauan dalam penerimaan aduan bagi produk-produk berkenaan. Selain itu, pegawai-pegawai akan didedahkan kepada sesi latihan supaya kepentingan Amalan Perkilangan Baik dapat dipraktikkan dalam pengilangan produk API.

2. **Pemeriksaan Amalan Penstoran Baik (ASB) terhadap Pengimport dan Pemborong**
   Pemeriksaan Amalan Penstoran Baik terhadap premis pengimport dan pemborong produk-produk berdaftar akan dilaksanakan secara berperingkat, berdasarkan keadaan dan kategori produk. Sebagai pengenalan kepada aspek-aspek ASB, latihan teori dan praktikal akan diadakan dan latihan yang sama ini juga dirancang untuk diadakan di peringkat Cawangan Penguatkuasa Farmasi.

3. **Hospital Farmasi**
   Garispanduan untuk pemeriksaan fasiliti-fasiliti steril telah disediakan, manakala latihan untuk pegawai-pegawai farmasi di hospital telah dirancang untuk diadakan pada tahun 2008.

and Health Supplements.

5. **Cosmetic Notification Procedure**
In conjunction with the Cosmetic Notification Procedure that will take effect from 1st January 2008, changes in the system are planned in order to control this post-notification system.

6. **Mutual Recognition Agreement (MRA) for Good Manufacturing Practice (GMP)**
A proposal for a Mutual Recognition Agreement (MRA) for Good Manufacturing Practice (GMP) has been submitted to the ACCSQ-PPWG Meeting. It is aimed that this proposal be accepted at ASEAN level.

7. **Serious Adverse Events (SAE) Monitoring Program**
A monitoring program for Serious Adverse Events (SAE) resulting from clinical trials that have been conducted will be implemented.

8. **Inspections for Good Laboratory Practice (GLP)**
Inspections for Good Laboratory Practice (GLP) on laboratories conducting pre-clinical studies and Bioavailability/Bioequivalence (BA/BE) studies in Malaysia will be conducted to ensure that the laboratories involved comply to Good Laboratory Practices (GLP) that are based on the Principles of OECD GLP, in accordance to the Organisation for Economic Co-operation and Development (OECD) System. This is in line with efforts of Malaysia as a member for the 'Mutual Acceptance of Data in the Assessment of Chemicals' for non-OECD countries.

CHALLENGES & ROOM FOR IMPROVEMENT

The Centre for Compliance & Licensing are faced with several tasks which include the following:

I. To further improve the standards of local manufacturers, in terms of Good Manufacturing Practice (GMP).
II. To further shorten the license processing time.
III. To strive towards 100% online license applications.
IV. To evaluate the qualification system for blood production facilities.
V. To implement effective inspectorate programs in clinical research centres to ensure Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) principles are adhered to.

4. **Produk Tradisional dan Suplemen Kesihatan (TMHS)**
Pusat Komplians dan Pelesenan akan meneruskan usaha untuk menghasilkan deraf garispanduan untuk Produk Tradisional dan Suplemen Kesihatan (TMHS) dan seterusnya menghasilkan Garispanduan yang lengkap untuk Produk Tradisional dan Suplemen Kesihatan.

5. **Prosedur Notifikasi Kosmetik**
Selaras dengan perlaksanaan Prosedur Notifikasi Kosmetik yang akan dimulakan pada 1 Januari 2008, perubahan dalam sistem sedang dirancang untuk mengawal sistem pasca notifikasi.

6. **'Mutual Recognition Agreement (MRA)' untuk Amalan Perkilangan Baik (APB)**
Kertas kerja berkenaan 'Mutual Recognition Agreement (MRA)' untuk Amalan Perkilangan Baik (APB) telah dikemukakan ke Mesyuarat ACCSQ-PPWG, dengan matlamat agar kertas kerja ini diterima di peringkat ASEAN.

7. **Program Pemonitoran 'Serious Adverse Events (SAE)'**
Program pemonitoran terhadap 'Serious Adverse Events (SAE)' yang berpunca daripada penyelidikan-penyelidikan klinikal yang dijalankan akan dilaksanakan.

8. **Pemeriksaan 'Good Laboratory Practice (GLP)'**
Pemeriksaan 'Good Laboratory Practice (GLP)' ke atas makmal-makmal yang menjalankan penyelidikan pra-klinikal dan kajian 'Bioavailability/Bioequivalence (BA/BE)' di Malaysia akan dijalankan. Langkah ini diambil untuk memastikan makmal-makmal terlibat mengamalkan 'Good Laboratory Practice (GLP)' yang berdasarkan 'Principles of OECD GLP'. Ini adalah sejajar dengan usaha Malaysia menerima pakai 'Good Laboratory Practice (GLP)' dalam mematuhi sistem 'Organisation for Economic Co-operation and Development (OECD)' berkaitan 'Mutual Acceptance of Data in the Assessment of Chemicals' bagi negara-negara bukan ahli OECD.

CABARAN & CADANGAN PENAMBAHBAIKAN

Pusat Komplians dan Pelesenan menghadapi beberapa cabaran dalam usaha pusat:

I. Untuk meningkatkan taraf pengilang-pengilang tempatan dalam aspek APB.
II. Mengurangkan tempoh masa pemprosesan lesen.

III. Meneruskan usaha ke arah 100% permohonan lesen secara online.
IV. Menilai sistem kelayakan bagi fasiliti-fasiliti 'blood production'.
V. Mengimplementasikan program pemeriksaan yang berkesan ke atas pusat-pusat penyelidikan klinikal bagi memastikan keakuran kepada prinsip-prinsip 'Good Clinical Practice (GCP)' dan 'Good Laboratory Practice (GLP)' .

National Pharmaceutical Control Bureau
2007 Annual Report

Centre for Organisational Development

Pusat Pembangunan Organisasi

Centre for Organisational Development

Noting the importance of internal as well as external communications, the National Pharmaceutical Control Bureau (NPCB) continues to work closely and collaborate with the local industry, industry associations, health professionals, academia, consumers as well as other stakeholders. This is mainly with the aim to further enhance the overall effectiveness of the regulatory system in Malaysia.

OBJECTIVES

- Responsible in providing product/drug information to officers involved in product evaluation and also to those who are involved in patient care to provide the best service to the public.
- Ensure only updated information is found on the NPCB website
- Monitor NPCB's computer system and to ensure that the online registration system (Quest 2) functions smoothly
- Responsible in providing information on product registration procedures and matters relevant to this, such as registration status (for pharmaceutical, traditional and cosmetic products) and other information which is required by the public
- Responsible in publications pertaining to DCA policies (Berita Ubat-Ubatan) and the NPCB Annual Report
- Coordinate training and placements for the Provisionally Registered Pharmacists (PRPs) in NPCB
- Coordinate placements for professional and semi professional officers who are attached to the NPCB for training

CENTRE FOR ORGANISATIONAL DEVELOPMENT ACTIVITIES (YEAR 2007)

MANAGEMENT OF THE INFORMATION TECHNOLOGY (I.T.) SYSTEM

The ICT Section of the centre has put in continuous effort to ensure the smooth running of the QUEST 2 System. This includes the establishment of a dedicated IT Unit within NPCB which oversees the computer system, a "Help-Desk" maintained within NPCB and not at the vendor's premise (to ensure better monitoring of problems encountered by customers), outsourcing of maintenance and trouble shooting to an IT company and an in-house "Help Desk" manned by two pharmacists dedicated for attending to customer complaints and problems. The QUEST

Pusat Pembangunan Organisasi

Menyedari kepentingan komunikasi dalaman dan luaran, Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) meneruskan usaha dan kerjasama yang erat dengan industri tempatan, persatuan industri, pakar perubatan, anggota akademik, pengguna serta beberapa pihak lain yang berkaitan untuk memantapkan lagi keberkesanan sistem regulatori di Malaysia.

OBJEKTIF

- Sebagai sumber maklumat ubat-ubatan/ produk kepada pegawai yang terlibat dalam penilaian ubat-ubatan/produk dan juga kepada anggota yang terlibat dalam penjagaan kesihatan pesakit untuk penambahbaikan mutu perkhidmatan kesihatan dalam negara
- Memastikan maklumat yang dipaparkan di laman web BPFK adalah terkini
- Memantau sistem rangkaian komputer BPFK dan memastikan sistem pendaftaran secara online (Quest 2) berjalan dengan lancar
- Memberi penerangan mengenai kaedah pendaftaran produk dan lain-lain yang berkaitan dengannya seperti status pendaftaran (untuk produk farmaseutikal, tradisional dan kosmetik) serta lain-lain maklumat sepertimana dikehendaki oleh pelanggan
- Menyelenggarakan penerbitan makalah mengenai polisi PBKD (Berita Ubat-Ubatan) dan Laporan Tahunan BPFK
- Menyelaraskan latihan dan penempatan Pegawai Farmasi Provisional (PRP)
- Mengendalikan penempatan latihan pegawai profesional atau separa profesional yang menjalani latihan di jabatan ini dari masa ke semasa samada anjuran oleh badan dalam negeri atau luar negara

AKTIVITI PUSAT PEMBANGUNAN ORGANISASI (TAHUN 2007)

PENGURUSAN SISTEM TEKNOLOGI MAKLUMAT

Seksyen Teknologi Maklumat telah berusaha secara berterusan untuk memastikan kelancaran Sistem QUEST 2. Langkah-langkah yang diambil untuk mencapai kelancaran tersebut termasuk meletakkan Unit IT di BPFK yang berfungsi untuk memantau sistem komputer serta `Help-Desk' yang diselia oleh BPFK sendiri dan bukannya di tempat vendor. Ini membolehkan penyelesaian masalah dibuat dengan lebih sempurna dari segi penyampaian masalah yang dihadapi pengguna dan penyelenggaraan sistem oleh pihak vendor.

2 system for on-line registration of pharmaceutical and traditional medicines has successfully entered its fifth and fourth year of implementation respectively. In addition, the on-line registration and licensing for veterinary medicines has been introduced effective from 1st August 2007.

MAINTENANCE OF THE NPCB WEBPAGE

Several new/updated guidelines such as the Registration Guidance Document for Veterinary Medicines Products to facilitate product registration were revised and developed. The adopted documents are made available on the NPCB website (www.bpfk.gov.my).

HANDLING OF ENQUERIES

The centre plays an important role to consumers and industries in supplying general information to consumers and the industry. In addition, the centre has also been actively attending to enquiries from clients of QUEST 2 on the implementation of the control of cosmetics by notification procedure effective from 1st January 2008. A total of 2935 enqueries have been received by the centre in the year 2007. A fall of 19.9% (Chart 31) is seen compared to the previous year which could be attributed to enquiries pertaining to classification of products that were no longer channelled to the centre. This is due to the streamlining of activities in NPCB whereby the task of classification of products is now under the purview of the Regulatory Coordination Section, Centre for Product Registration.

Sistem `Help-Desk' dalaman diwujudkan dan dikendalikan oleh dua orang pegawai farmasi yang dikhususkan untuk menangani masalah serta aduan pengguna. Pada masa ini, pendaftaran `on-line' (QUEST 2) untuk produk farmaseutikal dan tradisional sudah memasuki tahun ke-5 dan ke-4, dan telah dilaksanakan dengan jayanya. Tambahan pula, pendaftaran `on-line' untuk produk perubatan veterinar telah diperkenalkan dan berkuatkuasa pada 1 Ogos 2007.

PENGURUSAN LAMAN WEB BPFK

Sebarang pembaharuan dan maklumat terkini untuk memudahkan pendaftaran produk seperti Panduan Pendaftaran Produk untuk Produk Veterinar sentiasa disemak semula. Dokumen ini dipaparkan dan sedia dimuat turun di laman web BPFK (www.bpfk.gov.my).

PENGURUSAN PERTANYAAN

Pusat Pembangunan Organisasi (PPO) memainkan peranan yang penting dalam memberi maklumat am kepada pengguna dan industri. Dalam pada itu, PPO juga menerima banyak pertanyaan daripada pelanggan mengenai implimentasi sistem QUEST 2 berkaitan prosedur notifikasi produk kosmetik yang dikuatkuasakan pada 1 Januari 2008. Sebanyak 2935 pertanyaan telah diterima oleh PPO pada tahun 2007 dimana terdapat penurunan sebanyak 19.9% berbanding tahun sebelumnya (Carta 31). Penurunan ini disebabkan pertanyaan jenis pengkelasan produk telah dimansuhkan dari aktiviti PPO dan diambil alih oleh Seksyen Kordinasi Regulatori, Pusat Pendaftaran Produk (PPP).

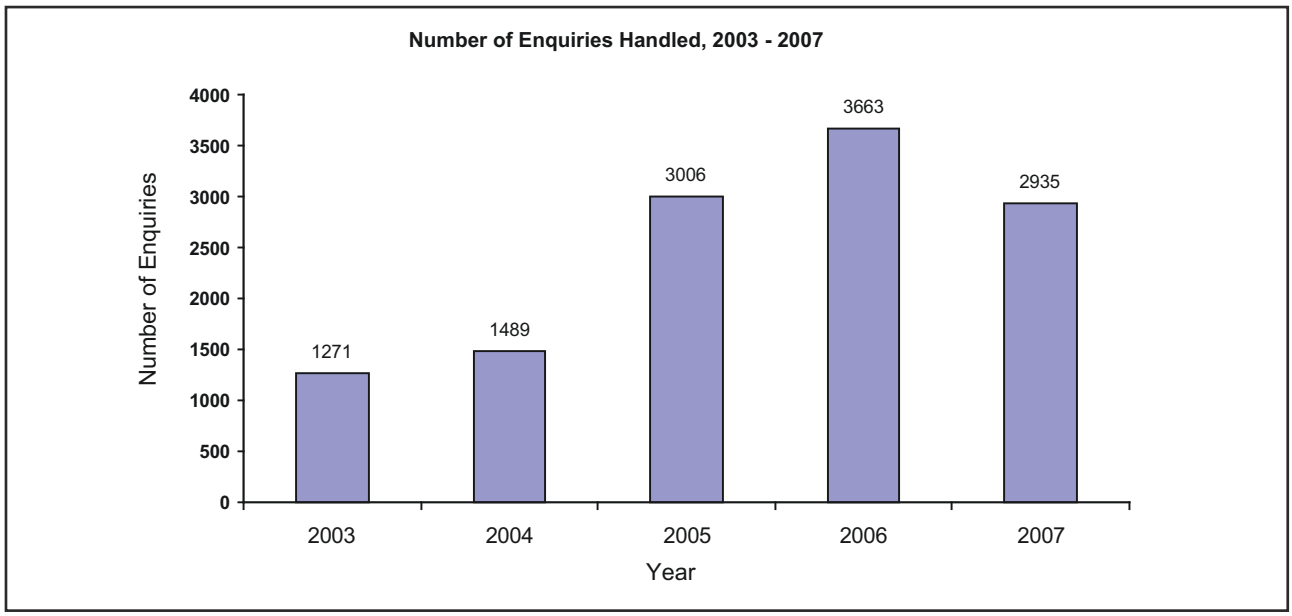


Chart 31: Enquiries (Year 2003 - 2007)

Carta 31: Pertanyaan (Tahun 2003 - 2007)

PUBLICATIONS

In the year 2007, four editions of the Drug Control Authority (DCA) bulletin i.e Berita Ubat-Ubatan (containing news and updated policies of the DCA) and the NPCB 2006 Annual Report were published.

PENERBITAN

Pada tahun 2007, empat edisi Berita Ubat-Ubatan yang mengandungi berita dan polisi terkini PBKD dan 1 naskah Laporan Tahunan BPFK telah diterbitkan untuk edaran.

COORDINATING DIALOGUES WITH THE RELEVANT INDUSTRY ASSOCIATIONS

The NPCB works closely and collaborates with the local industry, industry associations, health professionals, academia, consumers and other stakeholders to further enhance the effectiveness of the comprehensive regulatory system currently in place. In line with this, NPCB frequently plans and organises meetings, technical working groups (TWG) and dialogues with the relevant industries as and when necessary.

A total of five dialogue sessions were held in the year 2007 as follows:

PENGURUSAN SESI DIALOG DENGAN PIHAK INDUSTRI

BPFK bekerjasama erat dengan pihak industri tempatan, persatuan industri, pakar perubatan, golongan akademik, pengguna dan pihak-pihak yang berkaitan bagi memastikan keberkesanan sistem regulatori yang digunapakai. Sehubungan dengan itu, pihak BPFK kerap menganjurkan mesyuarat kumpulan kerja teknikal *(technical working group,TWG)* dan dialog dengan pihak industri yang berkaitan dari masa ke semasa mengikut keperluan.

Sebanyak 5 sesi dialog telah berjaya dianjurkan sepanjang tahun 2007 seperti berikut:

Association/Industry Persatuan/Industri		Date Tarikh
Malaysian Organisation of Pharmaceutical Industries (MOPI)	MOPI	14 May 2007
Pharmaceutical Association of Malaysia (PhAMA)	PhAMA	2 August 2007
Traditional Industry : Chinese Medicine Manufacturers Association of Malaysia (PPUCM)	PPUCM/ PURBATAMA / FCPMDAM	11 May 2007
Traditional Malay Medicine Manufacturers Association (PURBATAMA)	PURBATAMA	2 May 2007
Cosmetic Industry : Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFA) and Federation of Malaysian Manufacturers Malaysian Cosmetics and Toiletries Industry Group (FMM MCTIG)	CTFA, FMM MCTIG	17 May 2007
Direct Selling/ Direct Distribution Industry : Malaysian Direct Distribution Association (MDDA) and Direct Selling Association of Malaysia (DSAM)	MDDA,DSAM	8 June 2007

TRAINING

The Continuous Professional Development (CPD) Programme for pharmacists and assistant pharmacists is a part of the training programme under the purview of this centre. In the year 2007, NPCB organised a total of 57 CPD sessions which encompassed educational talks, workshops, Journal Club Sessions as well as seminars. Many NPCB staffs were also sent for relevant training sessions organised by other parties/organisations/agencies.

VISITS BY LOCAL AND INTERNATIONAL VISITORS

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia continues to provide training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries.

Throughout the year 2007, the centre recorded a total of 65 international visitors and WHO fellows from various countries namely Bhutan, China, Mongolia, Ghana, Philippines, Singapore, Saudi Arabia, Macedonia, Nigeria and the United Kingdom.

The courses provided are designed specifically to gratify the needs of the individual fellows. For example, training in pharmaceutical analysis which includes dosage performance testing, testing of traditional medicines, chemical, microbiological, pharmacological and toxicological test methods

KURSUS DAN LATIHAN

Pusat Pembangunan Organisasi (PPO) sering menganjurkan pelbagai ceramah, bengkel dan seminar untuk anggota BPFK. Program *Continuous Professional Development (CPD)* dianjurkan bagi pegawai farmasi dan pembantu farmasi sebagai sebahagian daripada program latihan yang dikelolakan oleh PPO.

Pada tahun 2007, BPFK telah menganjurkan sebanyak 57 sesi CPD yang terdiri daripada ceramah, bengkel, kelab jurnal dan seminar. BPFK juga turut menghantar anggotanya menghadiri kursus yang berkaitan di bawah anjuran pihak kementerian serta pihak luar.

PENGURUSAN LAWATAN PELAWAT TEMPATAN DAN ANTARABANGSA

Sebagai satu-satunya badan regulatori di Malaysia yang juga merupakan *WHO Collaborating Centre for Regulatory Control of Pharmaceuticals,* pihak BPFK, Kementerian Kesihatan Malaysia sering menyediakan latihan berkaitan kawalan kualiti farmaseutikal dan sistem regulatori kepada pelawat luar negara semasa latihan sangkutan mereka di BPFK.

Sepanjang tahun 2007, pihak BPFK telah menerima kunjungan 228 pelawat tempatan dan 65 kunjungan dari luar negara, antaranya dari Bhutan, Mongolia, Saudi Arabia, Nigeria, Vietnam, United Kingdom,

as well as preparation and handling of reference standards are provided to personnel with laboratory background. Other areas of training include aspects pertaining to drug registration, pharmacovigilance, post-marketing surveillance activities, good manufacturing practice (GMP) requirements and licensing system.

FUTURE DIRECTIONS FOR 2008

NPCB continues to strive towards upgrading its ICT infrastructure. Under the 9th Malaysia Plan (2006-2010), NPCB has been granted a certain allocation that will be used for upgrading the present on-line system i.e. QUEST 2 to QUEST 3.

This enhancement will further facilitate efforts towards implementation of the on-line registration for New Chemical Entities (NCE) and biotechnology products as well as facilitate the integration of the different on-line modules (involving product registration, licensing of premises, analytical testing, surveillance, ADR monitoring and dissemination of information). As a whole, these efforts will enable better networking and an increase in efficiency of the regulatory agency.

CHALLENGES AND ROOM FOR IMPROVEMENT

Due to the implementation of Compulsory Service for pharmacists, the entry of Provisionally Registered Pharmacists (PRP) poses a demanding task to the limited existing pharmacists to supervise and provide the required training. To accommodate the increase in staff, the NPCB also requires more work space and computers, the latter being under the charge of the ICT Section of the centre.

The upgrading of the centre's ICT infrastructure which involves the upgrade of QUEST 2 to QUEST 3 and the inclusion of on-line registration for New Chemical Entities (NCE) and biotechnology products in QUEST 3, to name a few, would prove to be a challenge to the centre as the number of enqueries from the public would be expected to increase significantly. To ensure that the staffs of PPO are better equipped to handle these foreseen challenges, more training and workshops should be provided.

Ghana, China, Filipina, Singapura, Sri Lanka, Lao PDR, Uganda, Uruguay dan Macedonia.
Kursus-kursus yang disediakan diatur secara spesifik untuk memenuhi keperluan pelawat luar negara dan bidang yang ingin dipelajari pelawat berkenaan.Latihan-latihan lain yang dijalankan termasuk pendaftaran produk generik, farmakovigilan, surveilans untuk pasca pendaftaran, amalan perkilangan baik dan perlesenan .

HALATUJU TAHUN 2008

BPFK sedang berusaha menaiktaraf infrastruktur sistem teknologi maklumat. Di bawah Rancangan Malaysia Ke-9 (2006-2010), BPFK telah diberi peruntukan untuk menaiktaraf sistem pendaftaran on-line yang sedia ada dari QUEST 2 kepada QUEST 3.

Penaiktarafan ini bukan sahaja membolehkan pendaftaran secara `on-line` untuk produk entiti kimia baru (NCE) dan biotek; ianya juga membolehkan integrasi pelbagai modul `on-line` yang merangkumi pendaftaran produk, lesen premis, ujian analisa, surveilans, pemantauan kesan advers ubat (ADR) dan penyebaran maklumat. Secara keseluruhan, usaha ini membolehkan jaringan yang baik dan berkesan di antara agensi regulatori berkaitan.

CABARAN DAN CADANGAN PENAMBAHBAIKAN

Selaras dengan khidmat wajib yang dikenakan ke atas Pegawai Farmasi baru, kemasukan Provisionally Registered Pharmacists (PRP) membebankan kerja pegawai farmasi yang sedia ada dalam menyelia latihan yang diperlukan oleh PRP yang meningkat bilangannya. Dengan peningkatan ini, BPFK memerlukan lebih banyak ruang kerja dan komputer. Masalah kekurangan komputer menjadi dan tanggungjawab Seksyen Teknologi Maklumat di Pusat ini.

Penaiktarafan infrastruktur ICT yang melibatkan penaiktarafan sistem QUEST2 kepada QUEST3 serta kemasukan pendaftaran `on-line` produk NCE dan biotek ke dalam QUEST3 merupakan satu lagi cabaran kepada pusat ini di mana bilangan pertanyaan daripada orang awam dijangka bertambah. Untuk menyiapsediakan anggota PPO bagi menangani cabaran yang mendatang, latihan tambahan dan bengkel berkaitan adalah diperlukan.

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Administration Centre

Pusat Pentadbiran

Administration Centre

All matters pertaining to the management of finance is handled by the Administration Centre which is also responsible for general administration and other non-technical matters. The Administration Centre ensures that emolument and claims are paid within the stipulated time and oversees that financial allocations are sufficient to ensure each planned activity meets its objective.

FINANCIAL STATEMENTS

PAYMENT
The emolument paid out to the 200 permanent and 45 temporary staff for the year 2007 was RM7,806,907.83.

REVENUE
In 2007, the total revenue collected for drug and cosmetic registrations, laboratory tests, licenses, advisory services, sales of guidelines and others was RM12, 248,997.28.

Pusat Pentadbiran

Semua hal berhubung dengan pengurusan kewangan dikendalikan oleh Pusat Pentadbiran yang juga bertanggungjawab dalam pentadbiran am dan tugas-tugas lain yang bukan bidang teknikal. Pusat Pentadbiran memastikan bahawa semua anggota menikmati bayaran gaji bulanan dan pembayaran bagi tuntutan-tuntutan rasmi dibayar dalam tempoh yang ditetapkan. Selain daripada itu, Pusat Pentadbiran juga berfungsi mengawal peruntukan kewangan agar sentiasa mencukupi bagi menjamin setiap aktiviti yang dirancang boleh mencapai objektif keseluruhannya.

TINJAUAN BELANJAWAN

PEMBAYARAN
Pada tahun 2007, pembayaran upahan dan gaji untuk 200 anggota tetap dan 45 anggota sambilan berjumlah RM7,806,907.83.

KUTIPAN HASIL
Jumlah kutipan hasil dari aktiviti pendaftaran ubat-ubatan serta kosmetik, ujian makmal, lesen, khidmat nasihat, jualan buku-buku garis panduan dan lain-lain bagi tahun 2007 ialah RM12,248,997.28.

REVENUE (RM) (JANUARY – DECEMBER 2007)

KUTIPAN HASIL (RM) (BULAN JANUARI – DISEMBER 2007)

Month	Product Registration	Licenses	Laboratory Services	GMP Inspection	Published Goods Sales	Other Sales	TOTAL
Jan	950,300.00	165,500.00	48,060.00	1,350.00	875.00	7,717.09	1,173,802.09
Feb	729,700.00	48,500.00	39,170.00	2,200.00	400.00	20,917.04	840,887.04
March	752,400.00	27,500.00	44,390.00	600.00	1,375.00	6,703.23	832,968.23
Apr	595,550.00	154,000.00	78,470.00	1,250.00	840.00	8,405.21	838,515.21
May	1,215,250.00	147,000.00	36,810.00	1,200.00	800.00	7,005.79	1,408,065.79
June	589,050.00	142,000.00	70,300.00	8,800.00	500.00	8,177.72	818,827.72
July	1,088,550.00	66,500.00	4,200.00	48,025.00	490.00	14,847.37	1,222,612.37
Aug	912,950.00	37,000.00	7,600.00	18,295.00	500.00	8,333.79	984,678.79
Sept	875,900.00	112,000.00	111,510.00	6,800.00	430.00	9,402.03	1,116,042.03
Oct	794,700.00	169,500.00	41,255.00	8,200.00	525.00	7,275.69	1,021,455.69
Nov	1,135,300.00	121,000.00	39,175.00	8,200.00	690.00	14,297.32	1,318,662.32
Dec	593,400.00	47,500.00	26,710.00	2,500.00	200.00	2,170.00	672,480.00
	10,233,050.00	1,238,000.00	547,650.00	107,420.00	7,625.00	115,252.28	12,248,997.28

NPCB OPERATING ALLOCATION AND EXPENDITURE (YEAR 2007)

PERUNTUKAN DAN PERBELANJAAN MENGURUS BPFK (TAHUN 2007)

Object Code	Expenditure	Allocation (RM)		Expenditure (RM)		Balance	
		Original	Amended	Nett Expenditure	%	(RM)	%
10000	Emolument	8,128,380.00	9,203,280.00	9,154,111.23	99.47	49,168.77	0.53
20000	Services & Supply	8,517,00.00	10,289,765.00	9,474,995.14	92.08	712,881.58	6.93
30000	Asset (Property)	99,670.00	-	70,890.20	71.12	10,989.80	11.03
	TOTAL	16,745,050.00	19,493,045.00	18,699,996.57	95.93	773,040.15	4.13

REMEMBERING YOUR SERVICES 2007

In the year 2007, a total of 26 staff left the NPCB due to retirement and work transfer to new places. The details are as follows:

JASAMU DIKENANG TAHUN 2007

Pada tahun 2007, sejumlah 26 orang anggota telah bersara atau bertukar ke tempat kerja baru. Mereka yang terlibat adalah seperti berikut:

NO	NAME	POST	DATE (NEW WORK PLACE)
1.	Lim Siang Kwang	Pharmacist Jusa 'C"	16.6.2007 (Compulsory retirement)
2.	Rohani bt Ismail	Pharmacist U52	16.3.2007 (Hosp. Serdang)
3.	Aryani bt Ahmad	Pharmacist U41	1.4.2007 (Pahang)
4.	Ani bt Abdullah	Pharmacist U44	16.8.2007 (Kelantan)
5.	Hazlinda Nazli Naem	Pharmacist U41	1.9.2007 (KKM)
6.	Norhayati Musa	Pharmacist U41	1.9.2007 (KKM)
7.	Masnor bt Daud	Pharmacist U41	1.11.2007 (Kelantan)
8.	Yaacob bin Kidin	Health Attendant	18.1.2007 (Hosp. Ampang)
9.	Thanaletchumi A/P Varatharaju	Pharmacy Assistant	15.2.2007 (JKWP)
10.	Rohani bt Ramli	Pharmacy Assistant	15.2.2007 (JKWP)
11.	Nur Zuramini bt Che Masnor	Pharmacy Assistant	15.2.2007 (Terengganu)
12.	Kamala Bai A/P Muthalia	Pharmacy Assistant	15.2.2007 (JKWP)
13.	Sukmawani bt Razali	Health Attendant	15.3.2007 (N.Sembilan)
14.	Ong Chui Eng	Pharmacy Assistant	16.4.2007 (JKWP)
15.	Sharifah Hafiza bt Tuan Wook	Pharmacy Assistant	16.4.2007 (Terengganu)
16.	Farahnaam Teoh Arman Ishak Teoh	Pharmacy Assistant	16.4.2007 (Pulau Pinang)
17.	Ahmidar Asna bt Ahmad	Pharmacy Assistant	16.4.2007 (Kedah)
18.	Nor Izzati bt A.Malek @ Abdul Malek	Administrative Assistant	17.9.2007 (KKM)
19.	Marini bt Omar	Administrative Assistant	17.9.2007 (Sarawak)
20.	Chin Jenny	Pharmacy Assistant	10.10.2007 (Sabah)
21.	Ruzaini bt Makhtar@Johari	Pharmacy Assistant	10.10.2007 (Selangor)
22.	Azni bin Abu Bakar	Executive Officer	6.11.2007 (Sarawak)
23.	Maimunah bt Ahmad	Administrative Assistant	30.7.2007 (Compulsory retirement)
24.	Muniyandy A/L Vellayan	Health Attendant	15.8.2007 (Compulsory retirement)
25.	Sukardi bin Salamon	Driver	2.11.2007 (Optional retirement)
26.	Yunus bin Sulaiman	Health Attendant	5.11.2007 (Compulsory retirement)

To all staff of NPCB who have transferred to a new work place or retired, the NPCB wishes to convey our best wishes and to record our gratitude to them for their contribution, commitment and hard work during their tenure of service at the NPCB.

Kepada semua anggota yang telah meninggalkan BPFK kerana bertukar ke tempat baru, kami ucapkan selamat maju jaya dalam bidang tugas baru; kepada yang bersara, diucapkan selamat berbahagia.

Segala khidmat dan jasa bakti yang telah dicurahkan oleh semua kepada BPFK selama ini amatlah dihargai dan akan dikenang untuk selamanya.

FUTURE DIRECTIONS FOR 2008

The centre for administration always seeks to explore the possibility of improving the quality of service rendered to the staff of NPCB as well as to abide by the ruling of the government in the services provided.

To aid a fast attainment of business license for the company/individual, ICU JPM is seeking for approval from the Accountant General's Department to execute the e-payment BLESS (Business Licensing Electronic Support System) module system, whereby it acts as an online service center for companies/ individuals which/who intend to apply for business license and permit via the online system. BLESS also provides e-payment services. This system is expected to be launched by early February 2008 and it will take place in the Klang Valley region. In line with the Treasury Circular 6 Year 2007, Bank Islam Malaysia Bhd (BIMB) is elected as the Payment Gateway Provider to aid in revenue and non-revenue collection via online for a period of one (1) year starting from the date of agreement between the Government Agency and BIMB . Online collection include transactions done through Direct Debit (Financial Process Exchange – FPX) and credit card (Master Card and Visa) payment.

HALATUJU TAHUN 2008

Pusat Pentadbiran sentiasa berusaha ke arah meningkatkan kualiti perkhidmatan yang diberikan kepada anggota BPFK serta mematuhi arahan kerajaan berkaitan perkhidmatan yang diberikan oleh pusat ini.

Bagi membantu syarikat atau individu mendapatkan lesen perniagaan dengan lebih cepat dan teratur, ICU JPM sedang dalam proses mendapatkan kelulusan pelaksanaan modul *e-payment BLESS (Business Licensing Electronic Support System)* dari Jabatan Akauntan Negara. Ia berfungsi sebagai *online services center* untuk syarikat atau individu yang ingin memohon lesen dan permit secara *online* bagi memulakan perniagaan di Malaysia. *BLESS* juga menyediakan kemudahan pembayaran secara *online (e-payment)*. Sistem ini dijangka akan mula dilaksanakan di sekitar Lembah Klang pada awal Februari 2008. Selaras dengan Pekeliling Perbendaharaan Bil 6 Tahun 2007, Bank Islam Malaysia Bhd (BIMB) telah dilantik sebagai *Payment Gateway Provider* untuk mengendalikan urusan pungutan hasil dan terimaan bukan hasil secara *online* bagi tempoh satu (1) tahun bermula dari tarikh perjanjian ditandatangani di antara Agensi Kerajaan dan BIMB. Pungutan secara *online* ini merangkumi transaksi secara *Direct Debit (Financial Process Exchange – FPX)* dan kad kredit (Master Card dan Visa).

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Social Events
Kegiatan Sosial

Social Events

ASSOCIATION OF WIVES AND LADIES OF THE MALAYSIAN CIVIL SERVICE (PUSPANITA)

In the year 2007, NPCB PUSPANITA was successfully headed by Madam Hasnah bt Ismail as advisor and Dr. Sulaikah bt V.K. Moideen as the president of PUSPANITA. The association had participation from 130 members. Numerous activities were successfully organised by this association. The activities are as follows:

- NPCB PUSPANITA 19th Annual General Meeting
- Choir activities
- Study of Tafsir Al-Quran
- Talk on *Zakat By Pay Deduction*
- Talk on Interior Design
- PUSPANITA Sale
- Ceremony of Tadarus & Khatam Al-Quran
- Cheerleeding Competition for MOH PUSPANITA
- Talk on *Fadhilat Ibadah Qurban & Aqiqah*

NPCB PUSPANITA was also actively involved in the following activities held outside NPCB:

- 25th National PUSPANITA Delegation General Meeting
- Health talk – Obesity and its Effects on Health
- Fitball Robic for Healthy Life Style Workshop
- Women Health Day
- Master of Ceremony Course
- Seminar on *Penampilan Diri Lebih Positif Dengan Senamrobik & Aura Seri Dalaman*
- *Mesra Bersama Penaung* PUSPANITA Ceremony
- Hari Raya Card Sale
- MOH PUSPANITA Family Day
- Visit to *Darul Falah Orphanage Home*
- 'Jasamu Dikenang' Ceremony by MOH PUSPANITA

Kegiatan Sosial

PERSATUAN SURI DAN ANGGOTA WANITA PERKHIDMATAN AWAM MALAYSIA (PUSPANITA)

Pada tahun 2007, PUSPANITA Cawangan Kecil BPFK telah diterajui dengan jayanya oleh anggota BPFK di bawah naungan Pn. Hasnah bt Ismail, Pengarah BPFK sebagai penasihat dan Dr. Sulaikah bt V.K. Moideen sebagai pengerusinya. Keahlian adalah seramai lebih kurang 130 orang. Pelbagai aktiviti telah dijalankan sepanjang tahun 2007 iaitu:

- Mesyuarat Agung Tahunan PUSPANITA Cawangan Kecil BPFK Kali Ke-19
- Aktiviti Koir
- Pembelajaran Tafsir Al-Quran
- Taklimat Pembayaran Zakat Melalui Potongan Gaji
- Seminar Hiasan Dalaman
- Pasaria PUSPANITA Cawangan Kecil BPFK
- Tadarus & Majlis Khatam Al-Quran
- Pertandingan Pasukan Sorak bagi PUSPANITA Cawangan KKM
- Ceramah Fadhilat Ibadah Qurban dan Aqiqah

Ahli-ahli PUSPANITA Cawangan Kecil BPFK juga aktif menyertai aktiviti-aktiviti yang dianjurkan oleh PUSPANITA Cawangan Kementerian Kesihatan Malaysia (KKM) yang lain seperti:

- Mesyuarat Agung perwakilan PUSPANITA Kebangsaan ke-25
- Seminar Kesihatan: Masalah 3G (Gebu, Gempal & Gemuk) dan Kesannya Kepada Kesihatan
- Bengkel Fitball Robik Untuk Gaya Hidup Sihat
- Hari Kesihatan Wanita
- Kursus Pengacara Majlis
- Seminar Penampilan Diri Lebih Positif dengan Senamrobik dan Aura Seri Dalaman
- Majlis Mesra Bersama Penaung PUSPANITA
- Aktiviti Jualan Kad Hari Raya
- Hari Keluarga PUSPANITA KKM
- Lawatan Ke Rumah Anak-anak Yatim Darul Falah
- Majlis Jasamu Dikenang PUSPANITA KKM

NPCB CLUB

Until December 2007, the BPFK Club, headed by the Director of the National Pharmaceutical Control Bureau comprised of 186 members.

The activities for 2007 started off with the 14th Annual General Meeting (AGM) that was held on 4th May 2007. New committee members were elected during this meeting and several future activities were carefully planned. Pharmacy Family Day was planned to be held in 2007; however, due to time constraint, it had to be postponed to the year 2008.

Among the activities planned for the year 2008 are the annual sports tournament and the Pharmacy Family Day that will be jointly organised with the Pharmaceutical Services Division, Ministry of Health, Malaysia. These activities are aimed to strengthen the bond between the National Pharmaceutical Control Bureau and the Pharmaceutical Services Division, Ministry of Health, Malaysia.

NPCB MUSLIMS STAFF WELFARE ASSOCIATION (BAKKI)

BAKKI is the association that organises various activities related to welfare, education and religion for its members such as managing the welfare fund for people in need. Besides educating members through the activities, this association also encourages members to work as a team to strengthen and improve the relationship among muslim staff.
In the year 2007, BAKKI held activities such as:

1) Internal activities:
   - Souvenir contribution for:
     - Farewell Ceremony for Madam Eishah bt Abd Rahman, Director of NPCB (held on the 12th of January 2007) on the occasion of her transfer to the Pharmaceutical Services Division
     - Farewell Ceremony for Mr Ya'acob b Kidin, Health Attendant (held on the 31st of January 2007) on his promotion and transfer to Hospital Ampang
     - Farewell Ceremony for Tn Hj Yunus b Sulaiman, Health Attendant (held on the 12th of November 2007) on his retirement from the government service
   - Ceremony for the Recitation of Surah Yassin, Tahlil Arwah & Doa Selamat
   - Working together in preparing and providing *bubur lambuk* for NPCB muslim

KELAB BPFK

Kelab BPFK yang diterajui oleh Pengarah Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) mempunyai keahlian seramai 186 orang sehingga Disember 2007.

Aktiviti Kelab bagi tahun 2007 telah dimulakan dengan Mesyuarat Agong Kelab BPFK Ke-14 yang telah diadakan pada 4 Mei 2007. Ahli-ahli jawatankuasa yang baru telah dilantik pada mesyuarat tersebut dan aktiviti-aktiviti 2008 telah dirancang dengan teliti. Hari Keluarga Farmasi telah dirancang untuk tahun 2007 tetapi disebabkan oleh kesuntukan masa, aktiviti ini telah ditunda ke tahun 2008.

Antara aktiviti yang telah dirancang adalah pertandingan sukan serta Program Hari Keluarga Farmasi yang akan dianjurkan bersama Bahagian Perkhidmatan Farmasi, KKM. Kedua-dua aktiviti tersebut bertujuan untuk merapatkan lagi perhubungan silaturrahim warga-warga BPFK dan Bahagian Perkhidmatan Farmasi.

BADAN KEBAJIKAN KAKITANGAN ISLAM BPFK (BAKKI)

Badan Kebajikan Kakitangan Islam Biro Pengawalan Farmaseutikal Kebangsaan, dengan nama singkatnya BAKKI, merupakan satu badan atau pertubuhan yang dibentuk bagi tujuan menjalankan aktiviti kebajikan, pendidikan dan keagamaan untuk anggota beragama Islam di organisasi ini. Badan ini juga menguruskan tabung kebajikan untuk memberi bantuan segera kepada ahli yang terlibat dalam bencana, kemalangan, kematian dan juga untuk tujuan kebajikan lain.

Badan atau pertubuhan ini memainkan peranan utamanya bagi kepentingan kebajikan dan memberi pendidikan/ilmu pengetahuan agama di samping dapat mengeratkan lagi pergaulan dan hubungan mesra di antara anggota beragama Islam di dalam atau di luar organisasi ini.

Aktiviti-aktiviti BAKKI yang dijalankan sepanjang tahun 2007 termasuk:
1) Aktiviti Dalaman:
   - BAKKI telah membiayai sumbangan atau cenderahati untuk:
     – Pn.Eishah Bt. Abd. Rahman, Pengarah BPFK (pada 12 Januari 2007) sempena pertukaran beliau ke Bahagian Perkhidmatan Farmasi.
     – En Yaakob Bin Kidin, Pembantu Perawatan Kesihatan (pada 31Januari 2007) atas kenaikan pangkat dan pertukaran beliau ke Hospital Ampang.
     – Tuan Hj. Yunus Bin Sulaiman,

staff during Ramadhan fasting month.
- NPCB Breaking of Fast (Iftar) Ceremony and Solat Tarawih
- Collection of donation from NPCB staff for flood victims chanelled via *Pusat Pemungutan Bantuan Banjir* at Sekolah Tunas Bakti Sungai Besi, Kuala Lumpur, held on 22nd January 2007.

2) External activities:
- Feredal Territory, MOH Tilawah Al-Quran Ceremony in Hospital Kuala Lumpur Auditorium held on 24th July 2007. NPCB was represented by Mr. Tarmizi bin Dollah as a Qari.
- Forum Perdana National MOH Tilawah Al-Quran Ceremony held at Sultan Abdul Halim Mu'adzam Shah Hall, Alor Star, Kedah held on 2nd-4th September 2007. NPCB was represented by :

1. Pn. Che Zawiyah binti Abdul Wahab
2. Tuan Haji Kamarudin bin Ahmad
3. Cik Adifa binti Adilah
4. Cik Haslina binti Selamat
5. Cik Norhafizah binti Jazmi

Pembantu Perawatan Kesihatan (pada 12 November 2007) atas persaraan beliau dari perkhidmatan kerajaan.

- Majlis bacaan Surah Yassin, Tahlil Arwah dan Doa Selamat.

- Gotong-royong menyediakan bubur lambuk pada bulan Ramadhan untuk diagihkan kepada anggota beragama Islam BPFK.

- Majlis Berbuka Puasa & Solat Tarawih peringkat BPFK.

- Program Kebajikan:

  Mengumpul barangan dari anggota BPFK untuk sumbangan kepada mangsa banjir. Semua hasil kutipan di hantar ke Pusat Pemungutan Bantuan Banjir di Sekolah Tunas Bakti, Sungai Besi, Kuala Lumpur pada 22 Januari 2007.

2) Aktiviti Luar BPFK:

- Majlis Tilawah Al-Quran Kementerian Kesihatan Peringkat Wilayah Persekutuan di Auditorium HKL pada 24 Julai 2007. BPFK di wakili oleh Encik Tarmizi bin Dollah sebagai Qari.

- Forum Perdana sempena Majlis Tilawah Al-Quran Kementerian Kesihatan Peringkat Kebangsaan yang berlangsung di Dewan Sultan Abdul Halim Mu'adzam Shah, Alor Star, Kedah pada 2-4 September 2007. BPFK diwakili oleh :

1. Pn. Che Zawiyah binti Abdul Wahab
2. Tuan Haji Kamarudin bin Ahmad
3. Cik Adifa binti Adilah
4. Cik Haslina binti Selamat
5. Cik Norhafizah binti Jazmi

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Expert/Advisor/ Consultancy Services

Perkhidmatan Kepakaran/ Penasihat/ Perundingan

Expert/Advisor/ Consultancy Services

Perkhidmatan Kepakaran/ Penasihat/ Perundingan

The following officers served as experts / advisors / consultants in 2007:

Pegawai-pegawai berikutnya bertugas sebagai pakar/penasihat/perunding dalam tahun 2007:

No	Name	Activity	Date	Venue
1	Abida Haq bt. Syed M. Haq	Speaker in the Asia Generic Medicines Congress 2007 Penceramah Kongres *Asia Generic Medicines 2007*	26 – 28 March 2007	Singapore
2	Abida Haq bt. Syed M. Haq	Session Chairman in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) Pengerusi Sesi untuk Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S)	20-22 November 2007	Singapore
3	Ahmad Syamsury Bin Sulaiman	Auditor in GMP Inspection on Product Manufacturing Premise for products imported and marketed in Malaysia Auditor untuk pemeriksaan GMP dalam Premis Pengilang Produk untuk produk import dan dipasarkan di Malaysia	26 – 31 March 2007	Hangzhou, China
4	Anis binti Talib	Head Of Delegation for the ASEAN Cosmetic Committee (ACC) Meeting Ketua delegasi untuk Mesyuarat ASEAN Cosmetic Committee (ACC)	9 May 2007	Jakarta, Indonesia
5	Anis binti Talib	Chairman for the 7th Meeting of ASEAN Cosmetic Scientific Body (ACSB) Pengerusi untuk 7th Meeting of ASEAN Cosmetic Scientific Body (ACSB)	5 – 9 June 2007	Lao, PDR
6	Anis binti Talib	Head Of Delegation for the study tour to EU for Head Of Delegation to learn experience from EU on its implementation of the EU Cosmetic Directive Ketua delegasi untuk lawatan sambil belajar ke EU untuk mempelajari implementasi EU Cosmetic Directive	17 – 23 June 2007	Brussels & Paris
7	Anis binti Talib	Head Of Delegation for the 7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings Ketua delegasi untuk *7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings*	9 – 12 July 2007	Brunei Darussalam
8	Anis binti Talib	Head of Delegation in the Head of Delegation Meeting of the ASEAN Cosmetic Committee (ACC) Ketua delegasi untuk *Head of Delegation Meeting of the ASEAN Cosmetic Committee (ACC)*	2-5 September 2007	Jakarta , Indonesia
9	Anis binti Talib	Head of Delegation in the 8th ACCSQ Traditional Medicine & Health Supplements Product Working Group Meeting Ketua delegasi untuk Mesyuarat ke-8 *ACCSQ Traditional Medicine & Health Supplements Product Working Group*	26-29 November 2007	Manila, Philippines
10	Arpah binti Abas	Biosimilars Conference Persidangan Biosimilars	16 June 2007	Jakarta, Indonesia
11	Dr. Sulaikah V.K Moideen	Auditor for Technical visit Auditor untuk lawatan teknikal	6 – 18 July 2007	United States of America
12	Faridah binti Abdul. Malek	Representative for Malaysia in the Regional Workshop – ASEAN Cosmetic Testing Laboratory Network Wakil Malaysia dalam *Regional Workshop – ASEAN Cosmetic Testing Laboratory Network*	6-7 November 2007	Manila, Phillipines
13	Kadariah Mohd. Ali	Speaker in the Meeting on the Future Direction and Work Planning for the Implementation of Good Radiopharmacy Practices and GMP Penceramah untuk *Meeting on the Future Direction and Work Planning for the Implementation of Good Radiopharmacy Practices and GMP*	22 – 28 April 2007	Shanghai, China
14	Kadariah Mohd. Ali	Speaker in the Meeting on 'Streamlining Approval of Radiopharmaceuticals for Clinical Use' Penceramah untuk Mesyuarat *'Streamlining Approval of Radiopharmaceuticals for Clinical Use'*	9-15 September 2007	Vienna, Austria

15	Mazuwin Zainal Abidin	Co-Chair in the Biregional Workshop on Improving Medicine Surveillance and Regulatory Functions' Pengerusi bersama untuk *Biregional Workshop on Improving Medicine Surveillance and Regulatory Functions*	19-21 November 2007	Manila, Phillipines
16	Mohd. Nasrul bin Mohamad Noor	Auditor in GMP Inspection on Product Manufacturing Premise for products imported and marketed in Malaysia Auditor dalam pemeriksaan GMP untuk Premis Pengilangan Produk untuk produk diimport dan dipasarkan di Malaysia	26 – 31 March 2007	Hangzhou, China
17	Muhammad Lukmani Ibrahim	GMP expert in the 7th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 8th Meeting of ASEAN Cosmetic Committee (ACC) Pakar GMP dalam *7th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 8th Meeting of ASEAN Cosmetic Committee (ACC)*	5 – 9 June 2007	Lao, PDR
18	Muhammad Lukmani Ibrahim	GMP expert in the International Expert for GMP Cosmetic Pakar GMP dalam *International Expert for GMP Cosmetic*	11-17 November 2007	Manila, Phillipines
19	Muhammad Lukmani Ibrahim	International expert for GMP cosmetics in the Regional Workshop – GMP Guidelines- Specific Guidance for Soap Industry in ASEAN Pakar GMP dalam Cosmetics in the Regional Workshop – GMP Guidelines- Specific Guidance for Soap Industry in ASEAN	11-17 November 2007	Manila, Phillipines
20	Muhammad Lukmani Ibrahim	GMP expert in the 8th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 9th Meeting of ASEAN Cosmetic Committee (ACC) Pakar GMP dalam *8th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 9th Meeting of ASEAN Cosmetic Committee (ACC)*	12-13 December	Ho Chi Minh, City Vietnam
21	Noorizam binti Ibrahim	Speaker in the CMR International Institute for Regulatory Science Workshop on the Emerging Markets ' Models of Best Practice for the Regulatory Review of New Medicines' Penceramah untuk *CMR International Institute for Regulatory Science Workshop on the Emerging Markets ' Models of Best Practice for the Regulatory Review of New Medicines'*	5-6 December 2007	Geneva, Switzerland
22	Seetha A/P Ramasamy	Negotiator in the WHO Consultation on Quality of Homeophatic Medicine Perunding dalam *WHO Consultation on Quality of Homeophatic Medicine*	25 – 27 June 2007	Milan, Italy
23	Seetha A/P Ramasamy	Negotiator in the 7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings Perunding dalam *7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings*	9 – 12 July 2007	Brunei Darussalam
24	Selvaraja Seerangam	Negotiator in the 4th Malaysia-US Free Trade Agreement discussion Perunding dalam *4th Malaysia-US Free Trade Agreement discussion*	8 - 12 January 2007	San Francisco, United States of America
25	Selvaraja Seerangam	Negotiator in the 4th Meeting of the ASEAN MRA Task Force on GMP Inspection Perunding dalam *4th Meeting of the ASEAN MRA Task Force on GMP Inspection*	16 – 21 April 2007	Washington, United States of America
26	Selvaraja Seerangam	Co- Chair in the 7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings Pengerusi bersama dalam *7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings*	8 – 13 July 2007	Brunei Darussalam
27	Selvaraja Seerangam	Head of Delegation in the Informal Intercountry Consultation on Public Health, Innovation and Intellectual Property Ketua Delegasi dalam *Informal Intercountry Consultation on Public Health, Innovation and Intellectual Property*	5-7 September 2007	Manila, Phillipines
28	Tan Lie Sie	Temporary Consultant in the Biregional Workshop on Improving Medicine Surveillance and Regulatory Functions' Perunding sementara dalam *Biregional Workshop on Improving Medicine Surveillance and Regulatory Functions*	19-21 November 2007	Manila, Phillipines
29	Tan Lie Sie	Facilitator in the Unido Pharmaceutical Sector Stakeholder Workshop for Least Developed Countries (LDCs) Fasilitator untuk Unido Pharmaceutical Sector Stakeholder Workshop for Least Developed Countries (LDCs)	22 November 2007	Phnom Penh, Cambodia

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Participation in International Events

Penyertaan dalam Aktiviti Antarabangsa

Participation in International Events

Several staff had the opportunity to participate in the following international courses/ seminar/ meetings which were held in 2007:

Penyertaan dalam Aktiviti Antarabangsa

Beberapa orang kakitangan telah mendapat peluang untuk menyertai kursus/seminar/mesyuarat di bawah yang telah diadakan pada tahun 2007:

No	Activity	Date	Venue
1	4th Malaysia-US Free Trade Agreement discussion Perbincangan *Malaysia-US Free Trade Agreement* ke-4	8 - 12 January 2007	San Francisco, USA
2	Seminar on Pharmaceutical and Biotechnology Supply Chain Seminar *Pharmaceutical and Biotechnology Supply Chain*	26 - 29 February 2007	Singapore
3	Expert Meeting on Trade and Health Mesyuarat Pakar tentang *Trade and Health*	6 - 7 March 2007	New Delhi, India
4	Study visit to cosmetics manufacturing premises Lawatan sambil belajar ke premis pengilang kosmetik	23 March 2007	Japan
5	Asia Generic Medicines Congress Kongres *Asia Generic Medicines*	26 - 28 March 2007	Singapore
6	GMP Inspection on Product Manufacturing Premise for products imported and marketed in Malaysia Pemeriksaan GMP ke atas premis pengilang produk untuk produk yang diimport dan dipasarkan di Malaysia	26 - 31 March 2007	Hangzhou, China
7	The Complementary Healthcare Council Sponsors Obligations Conference Persidangan *The Complementary Healthcare Council Sponsors Obligations*	27 - 31 March 2007	Brisbane, Australia
8	2nd Regional Renal Anemia Transplantation & SLE meeting Mesyuarat *Regional Renal Anemia Transplantation & SLE* ke-2	6 – 9 April 2007	Yangon, Myanmar
9	6th Malaysia – US Free Trade Agreement Discussion Perbincangan *Malaysia – US Free Trade Agreement* ke-6	9 – 12 April 2007	Washington, USA
10	Workshop International Perspective on Dietary Supplement Regulation & IADSA Annual Meeting Bengkel *International Perspective on Dietary Supplement Regulation* & Mesyuarat Tahunan IADSA	15 – 19 April 2007	Yokohama, Japan
11	CDER Forum for International Drug Regulatory Authorities CDER Forum for International Drug Regulatory Authorities	16 – 20 April 2007	Maryland , USA
12	4th Meeting of the ASEAN MRA Task Force on GMP Inspection Mesyuarat ke-4 *ASEAN MRA Task Force on GMP Inspection*	16 – 21 April 2007	Ha Noi, Vietnam
13	Meeting on The Future Direction and Work Planning for Implementation of Good Radiopharmacy Practices and GMP Mesyuarat tentang *The Future Direction and Work Planning for Implementation of Good Radiopharmacy Practices and GMP*	22 – 28 April 2007	Shanghai, China
14	3rd Pharmaceutical Sciences World Congress (PSWC) & Post Satellite EAPB and EUFEPS : Workshop on Monoclonal Antibodies (MAWB) *Pharmaceutical Sciences World Congress (PSWC)* ke-3 & *Post Satellite EAPB and EUFEPS : Workshop on Monoclonal Antibodies (MAWB)*	22 – 27 April 2007	Amsterdam, The Netherlands
15	Pharmaceutical Inspection Co-operation (PIC/S) Joint Visit Inspection Group 62 *Pharmaceutical Inspection Co-operation (PIC/S) Joint Visit Inspection* Kumpulan 62	23 – 27 April 2007	Oslo, Norway
16	Rimonabant – A Novel Approach to Cardiometabolic Risk Management *Rimonabant – A Novel Approach to Cardiometabolic Risk Management*	4 – 6 May 2007	Singapore
17	ASEAN Cosmetic Committee (ACC) Meeting Mesyuarat *ASEAN Cosmetic Committee (ACC)*	9 May 2007	Jakarta, Indonesia
18	Pharmacovigilance -The Study of Adverse Drug Reactions and Related Problems Training Course *Pharmacovigilance -The Study of Adverse Drug Reactions and Related Problems Training Course*	14 – 26 May 2007	Uppsala, Sweden
19	7th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 8th Meeting of ASEAN Cosmetic Committee (ACC) Mesyuarat *ASEAN Cosmetic Scientific Body (ACSB)* ke-7 & Mesyuarat *ASEAN Cosmetic Committee (ACC)* ke-8	5 – 9 June 2007	Lao, PDR
20	Semi Regional Training on PMS *Semi Regional Training on PMS*	10 – 11 June 2007	Lao, PDR
21	International Conference: "New Frontier in the Quality of Medicine" Persidangan Antarabangsa : *"New Frontier in the Quality of Medicine"*	13 – 15 June 2007	Strasbourg, France

22	17th European Society of Hypertension Congress Kongres *European Society of Hypertension* ke-17	14 – 19 June 2007	Milan, Italy
23	Biosimilars Conference Persidangan *Biosimilars*	16 June 2007	Jakarta, Indonesia
24	Study Tour to EU for the Head of Delegation to Gain Experience from EU on its Implementation of the EU Cosmetic Directive *Study Tour to EU for the Head of Delegation to Gain Experience from EU on its Implementation of the EU Cosmetic Directive*	17 – 23 June 2007	Brussels & Paris
25	13th Meeting on Production of Asean Reference Subtances Mesyuarat *Production of Asean Reference Subtances* ke-13	25 – 27 June 2007	Nonthaburi, Thailand
26	WHO Consultation on Quality of Homeopathic Medicine *WHO Consultation on Quality of Homeopathic Medicine*	25 – 27 June 2007	Milan, Italy
27	Technical visit Lawatan Teknikal	6 – 18 July 2007	USA
28	The 7th Meeting of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) and Related Meetings Mesyuarat *Traditional Medicine and Health Supplements Product Working Group (THMS-PWG)* ke-7 dan Mesyuarat Berkait	9 – 12 July 2007	Brunei Darussalam
29	World Halal Forum Industry Dialogue, Halal Food International Trade Exhibition, Comodity Fest and 2nd Islamic Industry Dialogue Conference Dialog *World Halal Forum Industry*, Pameran *Halal Food International Trade, Comodity Fest* dan Persidangan *Dialog Islamic Industry* ke-2	-	Ningxia, China
30	Head of Delegations' meeting on the ASEAN Cosmetic Committee (ACC) Mesyuarat Ketua-Ketua Delegasi tentang *ASEAN Cosmetic Committee (ACC)*	2-5 September 2007	Jakarta , Indonesia
31	Informal Intercountry Consultation on Public Health, Innovation and Intellectual Property *Informal Intercountry Consultation on Public Health, Innovation and Intellectual Property*	5-7 September 2007	Manila, Phillipines
32	Study Tour/ Workshop on GMP Requirements for Veterinary Medicines, Biotech Products and Active Pharmaceutical Ingredients Lawatan Sambil Belajar/Bengkel *GMP Requirements for Veterinary Medicines, Biotech Products and Active Pharmaceutical Ingredients*	5-15 September 2007	Strasbourg, France & Warsaw, Poland
33	Meeting on the Streamlining Approval of Radiopharmaceuticals for Clinical Use Mesyuarat tentang the *Streamlining Approval of Radiopharmaceuticals for Clinical Use*	9-15 September 2007	Vienna, Austria
34	23rd Meeting of ASEAN Working Group on Technical Cooperation in Pharmaceutical (AWGTCP) Mesyuarat *ASEAN Working Group on Technical Cooperation in Pharmaceutical (AWGTCP)* ke-23	22-24 October 2007	Myanmar
35	The International Argoya 2007 Conference Persidangan *The International Argoya 2007*	25-29 October 2007	India
36	Regional Workshop – ASEAN Cosmetic Testing Laboratory Network Bengkel Serantau – *ASEAN Cosmetic Testing Laboratory Network*	6-7 November 2007	Manila, Phillipines
37	Informal Intercountry Consultation and Intergovermental Working Group on Public Health, Innovation and Intellectual Property (IGWG) *Informal Intercountry Consultation and Intergovermental Working Group on Public Health, Innovation and Intellectual Property (IGWG)*	3-11 November 2007	Geneva, Switzerland
38	International Expert for GMP Cosmetic *International Expert for GMP Cosmetic*	11-17 November 2007	Manila, Phillipines
39	Regional Workshop – GMP Guidelines- Specific Guidance for Soap Industry in ASEAN *Regional Workshop – GMP Guidelines- Specific Guidance for Soap Industry in ASEAN*	11-17 November 2007	Manila, Phillipines
40	First ASEAN-CHINA Conference on Combating Counterfeit Medical Products Persidangan Pertama ASEAN-CHINA tentang '*Combating Counterfeit Medical Products*'	13-15 November 2007	Jakarta , Indonesia
41	Biregional Workshop on Improving Medicine Surveillance and Regulatory Functions *Biregional Workshop on Improving Medicine Surveillance and Regulatory Functions*	19-21 November 2007	Manila, Phillipines
42	Workshop on Biopharmaceuticals and EMEA Biosimiliar Guidelines Bengkel tentang *Biopharmaceuticals and EMEA Biosimiliar Guidelines*	19 November 2007	Thailand
43	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) *Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S)*	20-22 November 2007	Singapore
44	UNIDO Pharmaceutical Sector Stakeholder Workshop for Least Developed Countries (LCDs) Bengkel *UNIDO Pharmaceutical Sector Stakeholder for Least Developed Countries (LDCs)*	22 November 2007	Phnom Penh, Cambodia
45	SYMPOSIUM of APEC Network on Pharmaceuticals Regulatory Science Simposium *APEC Network on Pharmaceuticals Regulatory Science*	26-29 November 2007	Taipei, Taiwan
46	The 8th Meeting of TMHS Product Working Group Mesyuarat ke-8 *TMHS Product Working Group*	26-29 November 2007	Manila, Phillipines

47	UNIDO Project: Strengthening the Local Production of Essential Generic Drugs in Least Developed Countries(LDCs) through the Promotion OG SMEs, Business Partnerships, Investment Promotion and South – South Cooperation Projek UNIDO: *Strengthening the Local Production of Essential Generic Drugs in Least Developed Countries(LDCs) through the Promotion OG SMEs, Business Partnerships, Investment Promotion and South – South Cooperation*	28 November 2007	Vientien, Lao PDR
48	CMR International Institute for Regulatory Science Workshop on the Emerging Markets ' Models of Best Practice for the Regulatory Review of New Medicines' *CMR International Institute for Regulatory Science Workshop on the Emerging Markets ' Models of Best Practice for the Regulatory Review of New Medicines'*	5-6 December 2007	Geneva, Switzerland
49	8th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 9th Meeting of ASEAN Cosmetic Committee (ACC) Mesyuarat ke-8 *ASEAN Cosmetic Scientific Body (ACSB)* & Mesyuarat ke-9 *ASEAN Cosmetic Committee (ACC)*	12-13 December 2007	Ho Chi Minh City Vietnam

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Participation in Local Events

Penyertaan dalam Aktiviti Tempatan

Participation in Local Events

The following courses/seminars/meetings were held in 2007:

- *Biotech/NCE Preview*

No.	Activity	Date	Venue
1	NCE Preview - Prexige	26 January 2007	NPCB
2	Biotech Preview - Fabrazyme for Fabry Disease	9 March 2007	NPCB
3	NCE Preview - Januvia	23 March 2007	NPCB
4	NCE Preview - Sprycel	13 April 2007	NPCB
5	NCE Preview - Sebivo	20 April 2007	NPCB
6	Biotech Preview - TheraCIM	23 April 2007	NPCB
7	NCE Preview - Tykerb	4 May 2007	NPCB
8	NCE Preview - Acomplia	18 May 2007	NPCB
9	Biotech Preview - Cervarix	25 May 2007	NPCB
10	NCE Preview - Trends in Hypertension Management	29 June 2007	NPCB
11	NCE Preview - Rasilez	13 July 2007	NPCB
12	Biotech Preview - Myozyme	3 August 2007	NPCB
13	NCE Preview - Exforge	10 August 2007	NPCB
14	NCE Preview - Serdolect	17 August 2007	NPCB
15	NCE Preview - Invega	24 August 2007	NPCB
16	Biotech Preview – Biologicals Regulation in Australia Evolving Perspective	4 December 2007	NPCB

- *Conference and Symposium*

No.	Activity	Date	Venue
1	Conference on Manufacturing & Services Sectors 2007 Persidangan Pengilangan & Sektor Servis 2007	13 February 2007	MIDA
2	6th International Traditional and Complementary Medicines Conference Persidangan Antarabangsa Komplimentari dan Ubat Tradisional ke-6	19 July 2007	Kuala Lumpur
3	ACCSQ PPWG Conference Persidangan ACCSQ PPWG	23 - 27 July 2007	Sunway Resort Hotel & Spa
4	Commonwealth Pharmaceutical Association- Malaysian Pharmaceutical Society Conference Persidangan Commonwealth Pharmaceutical Association- Malaysian Pharmaceutical Society	2 - 5 August 2007	Park Royal, Kuala Lumpur
5	1st KL International Breast & Colorectal Cancer Congress Kongres pertama KL International Breast & Colorectal Cancer	9-11 August 2007	KLCC, Kuala Lumpur
6	BioJohor 2007 International Biotech Conference Persidangan Biotech Antarabangsa BioJohor 2007	17-20 August 2007	Persada, Johor Bahru
7	Consumer Reporting Conference Persidangan Pelaporan Pengguna	1 September 2007	Subang Sheraton
8	National Conference on Clinical Research 2007: Speaker on 'Assuring Medicine Quality' Persidangan Kebangsaan Kajian Klinikal 2007: Penceramah untuk 'Assuring Medicine Quality'	24 - 26 October 2007	Berjaya Times Convention Centre,Kuala Lumpur

- *Course*

No.	Activity	Date	Venue
1	In-house Induction Course NPCB 01/2006 Kursus Induksi Dalaman BPFK 01/2007	27 February 2007	NPCB
2	5S Internal Audit Course Kursus Audit Dalaman 5S	11-12 April 2007	Hotel Grand Blue Wave, Shah Alam
3	Level 3 Competency Evaluation Course (PTK 3) Kursus Penilaian Tahap Kecekapan Aras 3 (PTK 3)	8 May 2007	NPCB
4	In-house Induction Course NPCB 02/2007 Kursus Induksi Dalaman BPFK 02/2007	18 June 2007	NPCB

Penyertaan dalam Aktiviti Tempatan

Kursus/seminar/mesyuarat berikut telah diadakan pada tahun 2007:

- *Biotech/NCE Preview*

- *Persidangan dan Simposium*

- *Kursus*

5	Introduction Course to ISO 9001:2000 Kursus Pengenalan ISO 9001:2000	19 June 2007	NPCB
6	In-house Induction Course NPCB 03/2007 Kursus Induksi Dalaman BPFK 03/2007	22 October 2007	NPCB
7	Text Writing and Public Speaking Course Kursus Penulisan Teks dan Ucapan Umum	29-31 October 2007	NPCB

- *Seminars*
- *Seminar*

No.	Activity	Date	Venue
1	Consumer Medicines Surveillance Seminar 2007– 'Pilot Project on Involving Consumers in Medicines Surveillance' Seminar *Consumer Medicines Surveillance 2007– 'Pilot Project on Involving Consumers in Medicines Surveillance'*	9 January 2007	Subang, Selangor
2	A short seminar on Concept and Practices in Spa Premises Seminar pendek dalam Konsep dan Amalan dalam Premis Spa	27 June 2007	NPCB
3	Pharmacy Assistants Seminar Seminar Pembantu Farmasi	27-29 July 2007	NPCB
4	Seminar Development of Fluid therapy Seminar Kemajuan Terapi Cecair	4 September 07	NPCB
5	Critical Quality Attributes Ciri-ciri Kualiti Kritikal	11 September 2007	NPCB

- *Talks*
- *Ceramah*

No.	Activity	Date	Venue
1	Biotech by Professor Dato' Dr. Mohamed Isa Abdul Majid (from the Department of International Biotechology, Ministry of Science, Technology and Innovation, Malaysia) Ceramah Biotech oleh Professor Dato' Dr. Mohamed Isa Abdul Majid (dari Jabatan Bioteknologi Antarabangsa, Kementerian Sains, Teknologi dan Inovasi, Malaysia)	19 January 2007	NPCB
2	Assets Planning (will and others) Perancangan Aset (wasiat dan lain-lain)	31 January 2007	NPCB
3	Procter & Gamble Work Visit Lawatan sambil belajar dari Procter & Gamble	7 May 2007	NPCB
4	Usage of Chemicals and Diluents Kegunaan Bahan Kimia dan Diluents	22 June 2007	NPCB
5	CUEPACS- Government Staff Welfare Programme CUEPACS- Program Kebajikan Pegawai Kerajaan	27 June 2007	NPCB
6	Payment of Obligatory Alms Through Pay Deduction Pembayaran Zakat Melalui Potongan Gaji	19 July 2007	NPCB
7	Interior Designing Hiasan Dalaman	2 August 2007	NPCB
8	Veterinary Registration Presentation & Discussion Perbincangan dan Taklimat Pendaftaran Veterinar	16 August 2007	NPCB
9	The role of pharmacotherapy in obesity management & safety of Sibutramine in high-risk cardiovascular patients Peranan farmakoterapi Sibutramine dalam kawalan obesiti & keselamatan pesakit kardiovaskular berisiko tinggi	17 August 2007	NPCB
10	Retirement Psychology and Financial Planning Perancangan Kewangan dan Psikologi Persaraan	25 October 2007	NPCB
11	Microbiology Microbiologi	1 November 2007	NPCB
12	Micromedex Micromedex	12 November 2007	NPCB
13	Preparation for Forensic Exam Persediaan untuk Peperiksaan Forensik	15 November 2007	NPCB
14	CME talk: Product Classification Sesi CME : Klasifikasi Produk	17 December 2007	NPCB

- *Training* • *Latihan*

No.	Activity	Date	Venue
1	International Good Manufacturing Practices and Quality Management Systems Amalan Pengilangan Baik Antarabangsa dan Sistem Pengurusan Kualiti	12 - 14 February 2007	Eastin Hotel
2	Good Manufacturing Practice for Pharmaceutical Operations Amalan Pengilangan Baik Untuk Operasi Farmaseutikal	19 - 21 March 2007	Eastin Hotel
3	Validation Principles Prinsip Validasi	23 - 25 April 2007	Eastin Hotel
4	Contamination Control Kawalan Kontaminasi	21 - 23 May 2007	Eastin Hotel
5	Good Aseptic Practices and Sterile Products Amalan Aseptik Baik dan Produk Steril	18 - 20 June 2007	Eastin Hotel

- *Workshops* • *Bengkel*

No.	Activity	Date	Venue
1	Cosmetic Product Safety & Efficacy Evaluation and Post-Marketing Surveillance Workshop Bengkel Penilaian Efikasi dan Keselamatan Produk Kosmetik dan Surveilans Pasca Pemasaran	23 - 24 January 2007	Subang, Selangor
2	Polymorphism: A Perspective (Workshop) *Polymorphism: A Perspective*	7 February 2007	Hilton KL
3	Evidence-Based Medicine Workshop Bengkel *Evidence-Based Medicine*	14 - 16 February 2007	NPCB
4	Evidence-Based Medicine Workshop Bengkel *Evidence-Based Medicine*	24 - 25 May 2007	NPCB
5	Validation Process Workshop Bengkel Proses Validasi	4 - 5 June 2007	NPCB
6	Training Workshop on 13 Modules of ASEAN GMP for Malaysian Cosmetic and Traditional Manufacturers Bengkel Latihan 13 Modul *ASEAN GMP for Malaysian Cosmetic and Traditional Manufacturers*	5 - 7 November 2007	NPCB

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International Visitors (Year 2007)

Pelawat Antarabangsa (Tahun 2007)

International Visitors (Year 2007)

Pelawat Antarabangsa (Tahun 2007)

Country Negara	Number of Visitors Bil. Pelawat
Bhutan	2
China	3
Ghana	6
Lao PDR	8
Macedonia	8
Mongolia	3
Nigeria	14
Philippines	1
Saudi Arabia	4
Singapore	2
Sri Lanka	3
Uganda	6
United Kingdom	2
Vietnam	3
TOTAL Jumlah	**65**

LIST OF VISITORS (INTERNATIONAL) IN NPCB FOR THE YEAR 2007

SENARAI NAMA PELAWAT (LUAR NEGARA) BPFK TAHUN 2007

No	Visitor's name	Number of Visitors	Country	Date / Duration	Purpose	Position
1.	Mr. Tandin Tshering	1	Bhutan	10 – 22 January 2007	Training Attachment-Pharmacovigilance Penempatan Latihan-"Pharmacovigilance"	Jigme Dorji Wangchuck National Referral Hospital (JDWNRH), Bhutan Hospital Rujukan Kebangsaan Jigme Dorji Wangchuck (JDWNRH), Bhutan
2.	Mr. Krishna Gurung	1	Bhutan	10 – 22 January 2007	Training Attachment-Pharmacovigilance Penempatan Latihan-"Pharmacovigilance"	Jigme Dorji Wangchuck National Referral Hospital (JDWNRH), Bhutan Hospital Rujukan Kebangsaan Jigme Dorji Wangchuck (JDWNRH), Bhutan
3.	Dr. Amarjargal Choijoo	1	Mongolia	23 January 2007	Official Visit Lawatan Rasmi	WHO Fellowship Mongolia Pharmacy Department, MOH, Mongolia (melalui BPF,KKM) WHO Fellowship Mongolia Jabatan Farmasi, Kementerian Kesihatan, Mongolia (melalui BPF,KKM)
4.	Dr. Regsuren Baigal	1	Mongolia	23 January 2007	Official Visit Lawatan Rasmi	WHO Fellowship Mongolia Pharmacist, Second General Hospital, Mongolia (melalui BPF,KKM) WHO Fellowship Mongolia Jabatan Farmasi, Kementerian Kesihatan, Mongolia (melalui BPF,KKM)
5.	Mrs. Bayarmaaa Nansal	1	Mongolia	23 January 2007	Official Visit Lawatan Rasmi	WHO Fellowship Mongolia Pharmacist, Second General Hospital, Mongolia (melalui BPF,KKM) WHO Fellowship Mongolia Jabatan Farmasi, Kementerian Kesihatan, Mongolia (melalui BPF,KKM)
6.	Mrs. Omokira O. Akanji + delegates	12	Nigeria	08 February 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Technical Committee on Import Supervision Scheme (CISS), Nigeria Jawatankuasa Teknikal Skim Penyeliaan Import (CISS), Nigeria
7.	Ms. Yap Leng Leng	1	Singapore	08 February 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Service Provider for Nigeria & delegate sponsor for the visit of the Technical Committee on Import Supervision Scheme (CISS), Nigeria Jawatankuasa Teknikal Skim Penyeliaan Import (CISS), Nigeria

No	Visitor's name	Number of Visitors	Country	Date / Duration	Purpose	Position
8.	Mr. Romy Frago	1	Phillpines (Manila)	08 February 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Service Provider for Nigeria & delegate sponsor for the visit of the Technical Committee on Import Supervision Scheme (CISS), Nigeria Pembekal Perkhidmatan untuk Nigeria & delegasi yang ditaja untuk lawatan bagi Jawatankuasa Teknikal Skim Penyeliaan Import (CISS), Nigeria
9.	Mr. Emmanuel Nkrumah	1	Ghana	20 – 30 March 2007	Training Attachment Penempatan untuk Latihan	Food and Drugs Board, Ghana Lembaga Dadah dan Makanan, Ghana
10.	Mr. Francis Kennedy Amoni	1	Ghana	20 – 30 March 2007	Training Attachment Penempatan untuk Latihan	Food and Drugs Board, Ghana Lembaga Dadah dan Makanan, Ghana
11.	Mr. Francis Anhugar	1	Ghana	20 – 30 March 2007	Training Attachment Penempatan untuk Latihan	Food and Drugs Board, Ghana Lembaga Dadah dan Makanan, Ghana
12.	Mr. Sebastian Mawuli Hotor	1	Ghana	20 – 30 March 2007	Training Attachment Penempatan untuk Latihan	Food and Drugs Board, Ghana Lembaga Dadah dan Makanan, Ghana
13.	Mr. Anthony K. Ghartey	1	Ghana	20 – 30 March 2007	Training Attachment Penempatan untuk Latihan	Food and Drugs Board, Ghana Lembaga Dadah dan Makanan, Ghana
14.	Ms. Nana Afrakumah Ashia	1	Ghana	20 – 30 March 2007	Training Attachment Penempatan untuk Latihan	Food and Drugs Board, Ghana Lembaga Dadah dan Makanan, Ghana
15.	Prof. Saleh Abdullah Bawazir	1	Saudi Arabia	2 – 4 April 2007	Training Attachment Penempatan untuk Latihan	VP, Drug Section, Saudi Food and Drug Authority (SFDA) VP, Bahagian Dadah, Pihak Berkuasa Dadah dan Makanan Saudi (SFDA)
16.	Dr. Saad AlKasabi	1	Saudi Arabia	2 – 4 April 2007	Training Attachment Penempatan untuk Latihan	DG IT Section, Saudi Food and Drug Authority (SFDA) Bahagian DG IT, Pihak Berkuasa Dadah dan Makanan Saudi (SFDA)
17.	Mr. Hajed M. Hashan	1	Saudi Arabia	2 – 4 April 2007	Training Attachment Penempatan untuk Latihan	Director of Registration, Saudi Food and Drug Authority (SFDA) Pengarah Pendaftaran, Pihak Berkuasa Dadah dan Makanan Saudi (SFDA)
18.	Mr. Khalid AlRasheed	1	Saudi Arabia	2 – 4 April 2007	Training Attachment Penempatan untuk Latihan	Application & DB Manager, Saudi Food and Drug Authority (SFDA) Pengurus bagi Application & DB, Pihak Berkuasa Dadah dan Makanan Saudi (SFDA)
19.	Henry Uzum	1	Nigeria	18-21 June 2007	Training Attachment Penempatan untuk Latihan	NAFDAC Nigeria NAFDAC Nigeria
20.	Adewumi Gboyega	1	Nigeria	18-21 June 2007	Training Attachment Penempatan untuk Latihan	NAFDAC Nigeria NAFDAC Nigeria
21.	Vo Thi Nhi Ha	1	Vietnam	19 July 2007	Training Attachment Penempatan untuk Latihan	Ministry of Health, Vietnam Kementerian Kesihatan, Vietnam
22.	Rham Van Trong	1	Vietnam	19 July 2007	Training Attachment Penempatan untuk Latihan	Thai Binh Medical College Vietnam Kolej Perubatan Thai Binh Vietnam
23.	Tran Van Ve	1	Vietnam	19 July 2007	Training Attachment Penempatan untuk Latihan	Ministry of Health, Vietnam Kementerian Kesihatan, Vietnam
24.	Stella Ee Guat Ling	1	Singapore	16 July 2007	Official Visit Lawatan Rasmi	Senior Regulatory Technical Officer, Medical Advertisement Unit, Centre for Drug Administration, Health Products, Regulation Group, HSA, Singapore Pegawai Teknikal Regulatori Kanan, Unit Iklan Perubatan, Pusat Pengurusan Dadah, Produk Kesihatan, Kumpulan Regulasi, HSA, Singapore
25.	Dr Michael Jepson	1	United Kingdom	3 August 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Aston University, Birmingham UK Universiti Aston, Birmingham UK

No	Visitor's name	Number of Visitors	Country	Date / Duration	Purpose	Position
26.	Mrs. Jean Jepson	1	United Kingdom	3 August 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Vet Pharmacists' Group RPSGB UK Kumpulan Ahli Farmasi Vet RPSGB UK
27.	Prof. Tuley De Silva	1	Sri Lanka	3 August 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Pharmaceutical Society of Sri Lanka Persatuan Farmaseutikal, Sri Lanka
28.	Chinta Abayuwardana	1	Sri Lanka	3 August 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	WHO Office Pejabat WHO
29.	M.A.M Fatha	1	Sri Lanka	3 August 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Pan Pharm Pt. Ltd. Pan Pharm Pt. Ltd.
30.	Soaklatsamy Vongsack	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
31.	Bounxou Keohanvong	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
32.	Boun Leuane Douane Deuane	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
33.	Soulyvanh Keoklmmaly	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
34.	Phouthavanh Inlorkham	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
35.	Souksomkhovane Chanthanat	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
36.	Sommaly Phomtavone	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Department of Pharmacy, Faculty of Medical Sceince, National University of Science Lao Jabatan Farmasi, Fakulti Sains Perubatan , Universiti Kebangsaan Sains Lao
38.	Vongviensa Sitthedeth	1	Lao PDR	3 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Food & Drug Quality Control Department (FDQCC) Jabatan Kawalan Kualiti Makanan dan Ubat-Ubatan (FDQCC)
37.	Jean Rubakuba	1	Uganda	6 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Uganda Research Industrial Institute Institut Penyelidikan Industri Uganda
42.	Jane Mayambala	1	Uganda	6 September 2007	Official Visit/ Study Lawatan Rasmi/ Sambil Belajar	Uganda Research Industrial Institute Institut Penyelidikan Industri Uganda
43.	Gao Wenkuan	1	China	13 September 2007	Dialogue Dialog	Embassy of People's Republic of China in Malaysia Kedutaan Republik China Di Malaysia
44.	Xu Yan Guang	1	China	13 September 2007	Dialogue Dialog	Embassy of People's Republic of China in Malaysia Kedutaan Republik China Di Malaysia
45.	Hu Wen Xing	1	China	13 September 2007	Dialogue Dialog	Embassy of People's Republic of China in Malaysia Kedutaan Republik China Di Malaysia
46.	Kementerian Kesihatan Republik Macedonia	8	Macedonia	13 September 2007	Official Visit Lawatan Rasmi	Republic of Macedonia Republik Macedonia
47.	Delegates from Uganda	4	Uganda	15 November 2007	Dialogue Dialog	Uganda Pharmaceutical Company Syarikat Farmaseutikal Uganda

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Local Visitors (Year 2007)

Pelawat Tempatan (Tahun 2007)

Local Visitors (Year 2007)

Pelawat Tempatan (Tahun 2007)

LIST OF VISITORS IN NPCB FOR THE YEAR 2007

SENARAI NAMA PELAWAT BPFK TAHUN 2007

No.	Visitor(s)	Total	Date/Duration	Objective	Position
1.	Y.B. Datuk Seri Dr. Chua Soi Lek	1	15 February 2007	Official Visit Lawatan Rasmi	Official Visit of the Health Minister of Malaysia to Headquarters of Pharmacy Services Programme. Lawatan Rasmi Menteri Kesihatan Malaysia ke Ibu Pejabat Program Perkhidmatan Farmasi.
2.	Students of Sedaya College	4	February 2007	Study Visit Lawatan Sambil Belajar	Pharmacy Students Pelajar Farmasi
3.	Students of KUTPM	32	22 February 2007	Study Visit Lawatan Sambil Belajar	Students of 1st & 2nd Year in Biomedics Pelajar Tahun 1 & 2, Bioperubatan
4.	Students of UM + Lecturer	27	27 February 2007	Study Visit Lawatan Sambil Belajar	Students of 3rd Year in Pharmacy Pelajar Tahun 3, Farmasi
5.	Students of MASTERSKILL (38 person) and lecturers (10 person)	48	27 April 2007	Study Visit Lawatan Sambil Belajar	Students of 1st Year in Diploma of Pharmacy Pelajar Tahun 1, Diploma Farmasi
6.	Rosliza Che Hassan	1	4 July 2007	BTMK	Dialogue/ Meeting Dialog / Mesyuarat
7.	Rohana A. Rahman	1	4 July 2007	BTMK	Dialogue/ Meeting Dialog / Mesyuarat
8.	Students of MASTERSKILL (23 person) and lecturers (3 person)	26	30 August 2007	Study Visit Lawatan Sambil Belajar	Students of Final Semester in Diploma of Pharmacy Pelajar Semester Akhir, Diploma Farmasi
9.	Dato' Dr. Hj. Mohd. Nasir Bin Mohd. Ashraf	1	20 August 2007	Official Visit Lawatan Rasmi	Official Visit of the Secretary General, Ministry of Health to Headquarters of Pharmacy Services Programme. Lawatan Rasmi Ketua Setiausaha Kementerian Kesihatan Malaysia ke Ibu Pejabat Program Perkhidmatan Farmasi.
10.	Zulaikha Paidi	1	6 September 2007	Study Visit Lawatan Sambil Belajar	Sirim Berhad Sirim Berhad
11.	Norhana Hashim	1	6 September 2007	Study Visit Lawatan Sambil Belajar	Sirim Berhad Sirim Berhad
12.	Students of Universiti Sains Malaysia	40	26 November 2007	Study Visit Lawatan Sambil Belajar	Students of Year 1-4 in Pharmacy Pelajar Farmasi Tahun 1-4
13.	Students of IMU + Lecturers	47	10 December 2007	Study Visit Lawatan Sambil Belajar	Students of 2nd Year in Medicine Pelajar Perubatan Tahun 2

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Future Plans

Rancangan Masa Depan

Future Plans

1. **INTENSIFICATION OF POST-MARKET SURVEILLANCE**
To intensify surveillance activities with the aim of combating problems associated with adulteration, counterfeits and product authentication as well as to promote public health protection through education and awareness.

To further enhance post-marketing surveillance and reduce emphasis on pre-market assessment especially for cosmetic products in Malaysia.

2. **ASEAN HARMONISATION AND HEALTHCARE INTEGRATION**
A system of notification for cosmetics will be introduced by 2008 in tandem with the ASEAN cosmetic harmonisation.

The ASEAN Common Technical Dossier (ACTD) for pharmaceuticals will be fully implemented by January 2009 to facilitate registration.

3. **ENHANCEMENT OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT)**
NPCB continues to strive towards upgrading its ICT infrastructure. Under the 9th Malaysia Plan (2006-2010), NPCB has been granted a certain allocation that will be used for upgrading the present on-line system i.e. QUEST 2 to QUEST 3.

This enhancement will further facilitate efforts towards implementation of the on-line registration for New Chemical Entities (NCE) and biotechnology products, as well as facilitate the integration of the different on-line modules (involving product registration, licensing of premises, analytical testing, surveillance, ADR monitoring and dissemination of information). As a whole, these efforts will enable better networking.

4. **ISO 17025 CERTIFICATION**
To continue the efforts towards further upgrading the laboratory quality management system to achieve the ISO 17025 accreditation by 2008.

5. **REINFORCING PIC/S GMP**
To continue efforts towards strengthening and upgrading the level of GMP compliance of local pharmaceutical and traditional medicines manufacturers in order to gain global recognition and facilitate market penetration. A GMP Seminar for Traditional

Rancangan Masa Depan

1. **MEMPERGIATKAN AKTIVITI SURVEILANS**
Mempergiatkan aktiviti surveilans dengan tujuan mengatasi masalah produk campurpalsu, pemalsuan dan ketulenan produk serta mempromosi penjagaan kesihatan umum melalui pendidikan dan kesedaran umum.

Menambah aktiviti surveilans pasca pendaftaran ekoran dari pengurangan aktiviti penilaian sebelum pendaftaran, khasnya bagi produk kosmetik di Malaysia.

2. **HARMONISASI ASEAN DAN INTEGRASI KESIHATAN**
Selaras dengan usaha harmonisasi kosmetik ASEAN, sistem notifikasi untuk kosmetik akan dikuatkuasakan pada tahun 2008.

Untuk memudahkan pendaftaran produk, *ASEAN Common Technical Dossier (ACTD)* untuk produk farmaseutikal akan dilaksanakan secara menyeluruh pada tahun 2009.

3. **NAIKTARAF TEKNOLOGI MAKLUMAT DAN KOMUNIKASI (ICT)**
BPFK meneruskan usaha untuk menaiktaraf infrastruktur ICT. Di bawah Rancangan Malaysia Ke-9 (2006-2010), BPFK diberi peruntukan untuk menaiktaraf sistem atas talian QUEST 2 kepada QUEST 3.

Proses naiktaraf ini akan memudahkan perlaksanaan pendaftaran atas-talian untuk produk Ubat Baru dan produk bioteknologi serta membolehkan integrasi modul atas-talian yang berlainan (melibatkan pendaftaran produk, pelesenan premis, kajian analitikal, surveilans, pemonitoran ADR dan penyebaran maklumat). Secara amnya, usaha ini akan memudahkan rangkaian kerja (networking) yang lebih efisien.

4. **PENSIJILAN ISO 17025**
BPFK sedang meneruskan usaha untuk menaiktaraf sistem pengurusan kualiti makmal untuk mendapat pensijilan ISO 17025 sebelum/pada tahun 2008.

5. **MENGGIATKAN AKTIVITI AMALAN PENGILANGAN BAIK (APB) PIC/S**
Meneruskan usaha ke arah pematuhan APB oleh pengilang farmaseutikal dan tradisional tempatan agar mereka

Medicines will be planned for the year 2008.

To pursue the plans for conducting GMP inspections of foreign manufacturers particularly the non-PIC/S countries to ensure they fully comply with the current guidelines.

6. NATIONAL REGULATORY CONFERENCE 2008

NPCB together with the pharmaceutical, traditional medicine and cosmetics industry will organise the National Regulatory Conference 2008.

7. STRENGTHENING CLINICAL RESEARCH

To strengthen capacity and capability in the inspection of clinical testing facilities as well as to upgrade the existing resources with the aim of facilitating the coordination of activities related to GCP, GLP and BA/BE.

To implement a system of inspection for clinical testing facilities in accordance to the adopted GCP, GLP and BA / BE requirements.

mendapat pengiktirafan secara global dan memudahkan penembusan ke pasaran antarabangsa. Satu seminar APB untuk pengusaha Ubat Tradisional dirancang diadakan pada tahun 2008.

Meneruskan usaha untuk mengadakan pemeriksaan APB ke atas pengilang luar negara khasnya ke atas pengilang di negara bukan-PIC/S untuk memastikan pematuhan terhadap garispanduan terkini.

6. NATIONAL REGULATORY CONFERENCE 2008

BPFK dengan kerjasama industri farmaseutikal, tradisional dan kosmetik sedang merancang untuk menganjurkan 'National Regulatory Conference 2008'.

7. MEMPERKASAKAN USAHA KAJIAN KLINIKAL

Usaha sedang dijalankan untuk meningkatkan kapasiti dan keupayaan dalam pemeriksaan premis kajian klinikal serta menaiktaraf sumber yang sedia ada bagi tujuan memudahkan koordinasi aktiviti berkaitan Good Clinical Practice (GCP), Good Laboratory Practice (GLP) dan ujian Bioavailability/Bioequivalence (BA/BE).

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Conclusion
Kesimpulan

Conclusion

NPCB continues to ensure the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. International collaborations in relevant technical areas provide an excellent platform for NPCB in establishing mutual understanding amongst regulatory partners towards strengthening pharmaceutical quality assurance. The NPCB works closely and collaborates with the local industry, industry associations, health professionals, academia, consumers and other stakeholders to further ensure the quality, efficacy and safety of pharmaceutical products to improve the health of the people. As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals since 1996, the NPCB will strive and continue to play an important role to fulfil the commitments and expectations as laid down in the terms of reference.

Kesimpulan

BPFK terus memastikan kualiti, keberkesanan dan keselamatan produk-produk farmaseutikal melalui proses pendaftaran dan pelesenan. Kolaborasi di peringkat antarabangsa dalam bidang teknikal yang berkaitan menjadi asas yang kukuh bagi BPFK untuk mengukuhkan lagi persefahaman yang jitu sesama badan regulatori demi meningkatkan lagi mutu farmaseutikal. BPFK bekerja dengan rapat dan menjalin kerjasama kolaborasi dengan industri tempatan, persatuan-persatuan industri, profesional bidang kesihatan, pihak ilmuan, pengguna dan lain-lain untuk menjamin kualiti, keberkesanan dan keselamatan produk farmaseutikal untuk meningkatkan taraf kesihatan penduduk. Sebagai sebuah pusat kolaborasi WHO dalam bidang regulatori produk farmaseutikal sejak 1996, BPFK akan terus berusaha untuk memainkan peranan penting bagi memenuhi komitmen dan sasaran sepertimana yang terkandung dalam terma rujukan.