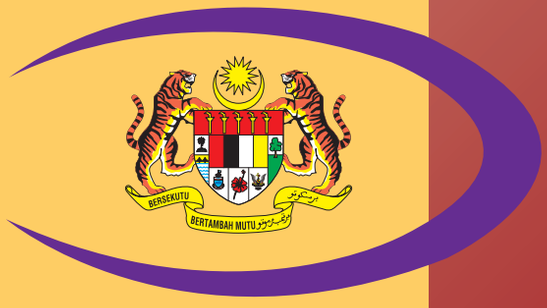
Laporan Tahunan 2006

Annual Report 2006

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
Kementerian Kesihatan Malaysia

NATIONAL PHARMACEUTICAL CONTROL BUREAU
Ministry of Health Malaysia



Laporan Tahunan Biro Pengawalan Farmaseutikal Kebangsaan • 2006 • National Pharmaceutical Control Bureau Annual Report

KANDUNGAN

2006

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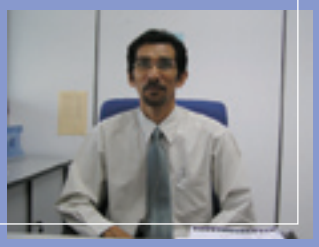

En. Ahmad Zakhi Bin Ramli

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Cik. Nor Hafizah Bt Mohd Potri

Pn. Halimatussa'adiah Bt Mat Som

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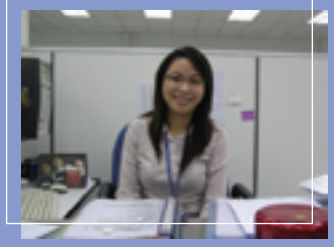

Cik. Debbie Sim

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PENGARAH BPFK 2006

Pengarah
Pn. Eisah Abdul Rahman

KETUA PUSAT BPFK 2006

Timbalan Pengarah Pusat Pendaftaran Produk
En. Selvaraja Seerangam

Timbalan Pengarah Pusat Kawalan Kualiti
Dr Sulaikah V.K. Moideen

Ketua Penolong Pengarah Pusat Pasca Pendaftaran Produk
Pn. Tan Lie Sie

Ketua Penolong Pengarah Pusat Pembangunan Organisasi
Pn. Abida Syed M. Haq

Ketua Penolong Pengarah Pusat Amalan Perkilangan Baik
En. Sulaiman Hj Ahmad

Ketua Unit Pentadbiran
Cik. Zuraidah Zainuddin

PERUTUSAN PENGARAH

Assalamualaikum dan Salam Sejahtera,

Satu tahun lagi telah berlalu. Tahun 2006 terus diliputi dengan pelbagai aktiviti yang membanggakan Biro Pengawalan Farmaseutikal Kebangsaaan(BPFK). Seperti yang dipaparkan, BPFK telah terlibat dalam berbagai aktiviti di peringkat Kebangsaan dan antarabangsa termasuk mesyuarat rundingan, forum, dialog, persidangan, bengkel dan sebagainya. Perubahan-perubahan yang memberangsangkan telah berlaku pada tahun lepas. Beberapa seksyen telah dinaiktaraf dan diubah-suai dari segi infrastruktur fizikal. Sistem atas -talian sediada (QUEST 2) telah dipertingkatkan. Program-program Pembelajaran Profesional Secara Berterusan (CPD) telah dianjurkan untuk memperkukuh dan meningkatkan keterampilan tenaga kerja. Inisiatif kualiti yang baru telah dilaksanakan untuk memperbaiki perkhidmatan. Disamping itu juga, dasar-dasar serta proses-proses yang berkenaan telah dikaji semula bagi memperkasakan sistem regulatori secara keseluruhan.

Selaku Sekretariat kepada Pihak Berkuasa Kawalan Dadah(PBKD), Kementerian Kesihatan Malaysia(KKM), BPFK terus memainkan peranan yang penting dalam memastikan kualiti, keselamatan dan efikasi produk-produk farmaseutikal, ubat-ubatan tradisional,suplemen kesihatan dan kosmetik yang terdapat di pasaran Malaysia. Laporan tahunan ini memberikan gambaran mengenai perkembangan,pencapaian prestasi dan perancangan masa hadapan yang dibentangkan mengikut komponen-komponen utama. Dalam usaha menggalakkan interaksi, mengeratkan persahabatan dan memupuk semangat berkumpulan, program-program menarik seperti acara social, sukan dan pembelajaran anjuran Puspanita BPFK, Kelab BPFK dan BAKKI juga diberi liputan.

Sebagai sebuah Pusat Kolaborasi WHO Dalam Bidang Regulatori Farmaseutikal dan ahli Pharmaceutical Inspection Cooperation Scheme(PIC/S),BPFK telah memainkan peranan yang membanggakan dalam aspek regulatori di peringkat antarabangsa. BPFK terlibat dalam kerjasama teknikal dalam pelbagai program latihan khususnya untuk negara-negara membangun dan juga pemeriksaan GMP bersama PIC/S. Kolaborasi teknikal dengan WHO terus diperkukuhkan dalam aspek-aspek seperti pemeriksaan GMP jaringan-kerja dalam surveilans dan farmakovigilans, penilaian dokumen untuk program pra-perakuan,kawalan kualiti ke atas ubat-ubatan herba, validasi analitikal dan ujian profisiensi.

Di bawah program ASEAN *Consultative Committee for Standards and Quality (ACCSQ)* dan *EC-ASEAN Economic Cooperation Programme ON Standards, Quality and Confirmity Assessment*, BPFK aktif terlibat dalam usaha meningkatkan keupayaan dalam memudah-carakan harmonisasi produk-produk farmaseutikal, ubat-ubatan tradisional, suplemen kesihatan dan juga kosmetik ke arah merealisasikan pelan integrasi pemeliharaan kesihatan ASEAN. Penglibatan antarabangsa lain termasuk melaksanakan "fast track" bagi ASEAN healthcare integration, *ASEAN Cosmetic Committee (ACC) dan Tradisional Medicine and Health Supplements Product Working Group (TMHSPWG)*.

Dengan tambahan sumber manusia yang diperolehi melalui Skim Perkhidmatan Wajib Pegawai Farmasi, BPFK terus berusaha untuk memenuhi kepuasan pelanggan terutama sekali memperbaiki masa pemprosesan untuk pendaftaran produk. Berlandaskan cirri-ciri Amalan Regulatori Baik(Good Regulatory Governance), BPFK semakin gigih untuk menjadi sebuah pusat kecemerlangan unggul dalam bidang regulatori farmaseutikal demi menjaminkan kesihatan dan kesejahteraan insan sejagat.

Tahun 2006 juga melibatkan Malaysia menjadi tuan rumah untuk *Meeting of Asean Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP)*. Bengkel implementasi Perlesenan Wajib (Compulsory Licensing) untuk memudahkan perolehan ubat retroviral juga telah dijalankan dengan bantuan teknikal daripada World Health Organisation (WHO). Satu bengkel ASEAN DRA untuk memperkenalkan Fast Track Registration System berlangsung pada bulan Ogos 2006 dan dipimpini oleh Malaysia dengan bantuan teknikal daripada WHO.

Di bawah Rancangan Malaysia Kesembilan(2006-2010), tumpuan akan diberikan ke arah meningkatkan prasarana ICT(system QUEST 3), melaksanakan fasa-fasa seterusnya pendaftaran produk (keluaran veterinar dan bahan aktif farmaseutikal), memperkasakan penyelidikan klinikal khususnya permatuhan GCP(Good Clinical Practice) dan GLP (Good Labotory Practice) serta memperolehi akreditasi ISO 17025. Usaha-usaha sewajarnya sedang ditumpukan terhadap isu-isu berkaitan halangan teknikal perdagangan yang timbul akibat globalisasi dan liberalisasi, khususnya implikasi regulatori.

Sumbangan BPFK terhadap pembangunan Negara sepertimana yang diimbaskan oleh pencapaian tahunan 2006 telah memberikan impak yang positif kepada industri farmaseutikal, ubat-ubatan tradisional dan kosmetik tempatan serta membawa perubahan kepada senario regulatori semasa. Ekoran perkembangan tersebut, banyak ubat-ubatan baru telah diluluskan untuk memenuhi keperluan klinikal semasa dan semakin bertambah premis-premis pengilang GMP telah dilesenkan untuk mengeluarkan produk-produk berkenaan.

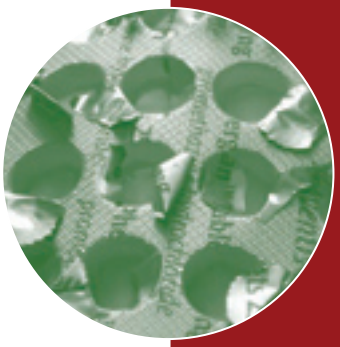
Akhir kata saya ingin merakamkan setinggi-tinggi penghargaan terutama sekali kepada anggota-anggota PBKD, MADRAC dan kumpulan-kumpulan Kerja Teknikal yang berkaitan diatas sumbangan dan jasa bakti yang telah dicurahkan. Terima kasih juga diucapkan kepada semua rakan-dialog dan pihak- pihak yang terlibat di atas kerjasama erat yang berterusan. Saya juga ingin mengucapkan terima kasih kepada pegawai-pegawai atasan Kementerian Kesihatan Malaysia khususnya Pengarah Perkhidmatan Farmasi yang telah memberi bimbingan dan dorongan. Kepada semua warga BPFK yang telah bertungkus lumus melaksanakan tugas dan tanggungjawab masing-masing dengan baik, terima kasih yang tidak terhingga diatas sokongan dan pengorbanan anda sekalian. Semoga tahun 2007 akan membawa kejayaan yang lebih memberangsangkan.

Sekian terima kasih,
Salam Hormat .

EISAH BINTI A RAHMAN
Pengarah,
Biro Pengawalan Farmaseutikal Kebangsaan.

BAB 1

FALSAFAH ORGANISASI



FALSAFAH ORGANISASI

WAWASAN

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 perlaksanaan undang-undang oleh tenaga kerja yang berketerampilan dan usahasama strategik ke arah peningkatan status kesihatan rakyat.

MATLAMAT

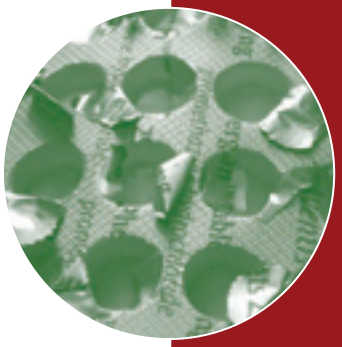
Memastikan bahawa bahan-bahan terapeutik yang dibenarkan di pasaran tempatan adalah selamat, berkesan dan bermutu, serta menentukan bahawa kosmetik yang dibenarkan di pasaran adalah selamat dan bermutu.

STRATEGI

- Memastikan kecekapan dan keberkesanan organisasi melalui permodenan 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 personel
- 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.

BAB 2

PIAGAM PELANGGAN



PIAGAM PELANGGAN

KEWAJIPAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN

Ditujukan khas kepada setiap pelanggan yang berurusan dengan BPFK.

1 Kemudahan Untuk Pelanggan

- Setiap pelanggan bol
  eh mendapat perkhidmatan yang sewajarnya.
- Setiap pelanggan yang tergolong dalam keadaan yang memerlukan perhatian segera akan diberikan layanan dengan segera.

2 Taraf Perkhidmatan

- Setiap pelanggan akan dilayan dengan baik, mesra, bertimbang rasa, hormat dan ikhlas.
- Setiap pelanggan akan diberi perkhidmatan yang terbaik secara profesional.

3 Maklumat Perkhidmatan

- Setiap pelanggan boleh mendapat penjelasan dan nasihat mengenai perkhidmatan yang diberikan kepadanya.

4 Pendaftaran Produk

- Memastikan bahawa semua produk farmaseutikal yang berdaftar adalah selamat, berkesan dan berkualiti serta menentukan bahawa kosmetik yang berdaftar adalah selamat dan berkualiti.
- Semua permohonan akan dinilai dengan adil dan saksama berlandaskan peraturan-peraturan yang berkaitan.
- Semua dokumen yang dikemukakan oleh pelanggan akan disimpan dalam keadaan selamat dan terkawal.

5 Kawalan Kualiti

- Semua ujian makmal akan dijalankan dengan adil dan saksama mengikut peraturan-peraturan dan prosedur-prosedur berkaitan.

6 Penguatkuasaan Dan Komplikasi

- Setiap tindakan dan penguatkuasaan atas mana-mana pelanggaran undang-undang yang dikuatkuasakan akan dilakukan dengan adil dan saksama tanpa dipengaruhi oleh apa-apa kepentingan dan prasangka.

- Bersedia bekerjasama dengan agensi penguatkuasaan lain dalam perkara yang berkaitan dengan penguatkuasaan ubat-ubatan.

SETIAP PERMOHONAN YANG LENGKAP AKAN DIPROSES MENGIKUT JANGKAMASA BERIKUT

1. PENDAFTARAN PRODUK

a. Penilaian Penuh / Full Evaluation

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

b. Penilaian Ringkas / Abridged Evaluation

Produk Suplemen Kesihatan	6 bulan
Produk Semulajadi	6 bulan
Ubat Bukan Preskripsi	6 bulan
Produk Kosmetik	1 bulan

2. PERLESENAN

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 bulan

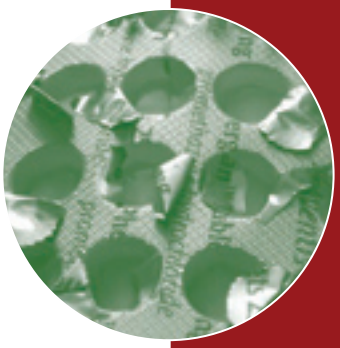
KEWAJIPAN PELANGGAN

Bagi membolehkan piagam ini dilaksanakan dengan berkesan, pelanggan adalah berkewajipan untuk:

- Mematuhi semua undang-undang dan peraturan-peraturan yang berkaitan
- Menggunakan kemudahan-kemudahan yang disediakan secara bertanggungjawab

BAB 3

PENCAPAIAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK) 2006



PENCAPAIAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK) 2006

i. Pendaftaran produk secara online dalam sistem QUEST 2 untuk ubat farmaseutikal selama sudah 4 tahun dan 3 tahun traditional telah berjaya dilaksanakan . Sistem QUEST 2 telah melalui proses peningkatan dengan penambahan modul baru yang merangkumi permohonan variasi produk dan rayuan.

ii. Pelesenan pengilang, pengimport dan pemborong kosmetik telah dikemaskini. Penekanan diberi kepada sesi panduan teknikal untuk memberi bimbingan kepada industri kosmetik.

iii. Pensijilan oleh SIRIM untuk sistem pengurusan kualiti berdasarkan MS ISO versi 2000 berjaya dikekalkan.

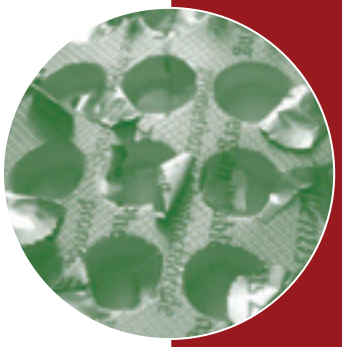
iv. Beberapa panduan baru untuk memudahkan pendaftaran produk telah dikemaskini dan dibangunkan oleh Kumpulan Kerja Teknikal (*Technical Working Groups)* yang melibatkan BPFK dan pihak industri. Dokumen yang digunapakai boleh dirujuk melalui halaman web BPFK (www.bpfk.gov.my).

v. BPFK masih memainkan peranan yang aktif dalam usaha harmonisasi melalui *ASEAN Consultative Commitee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and Traditional Medicines and Health Supplements Product Working Group (PWG TMHS)*. Penglibatan antarabangsa lain termasuk memudahcarakan "fast track" bagi *ASEAN healthcare integration dan EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments*. BPFK juga telah mengambil bahagian dalam perundingan antarabangsa dan mesyuarat teknikal dan bilateral dengan Negara ASEAN.

iv. Malaysia telah menjadi tuan rumah untuk *Meeting of ASEAN Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP)* di Kuching, Sarawak yang mana BPFK mengetuai dalam penganjuran mesyuarat yang berlangsung pada Mei 2006. Bengkel implementasi Pelesenan Wajib (*Compulsory Licensing)* untuk memudahkan perolehan ubat retroviral telah dijalankan dengan bantuan teknikal daripada World Health Organization (WHO). Satu bengkel ASEAN DRA untuk memperkenalkan *Fast Track Registration System* berlangsung pada bulan Ogos 2006 dan ia diketuai oleh Malaysia dengan bantuan teknikal daripada WHO.

BAB 4

AKTIVITI BPFK 2006



AKTIVITI BPFK 2006

Aktiviti-aktiviti Biro Pengawalan Farmaseutikal Kebangsaan secara amnya termasuklah:

- Menguatkuasakan skim pendaftaran ubat dan kosmetik melalui penilaian data teknikal, ujian makmal, penyelidikan dan maklumat yang diterima daripada badan-badan antarabangsa.

- Menjalankan ujian analitikal, farmaseutikal, mikrobiologi, farmaseutikal serta toksikologi atas ubat-ubatan untuk menentukan mutu, keberkesanan dan keselamatan produk-produk tersebut dan menentukan mutu serta keselamatan produk kosmetik.

- Menguatkuasakan skim kawalan mutu ubat-ubatan dalam pasaran melalui penyempelan secara rambang dan menjalankan ujian-ujian analitikal.

- Menguatkuasakan skim perlesenan pengilang, pengimport dan pemborong ubat-ubatan, termasuk skim pelesenan import produk untuk percubaan klinikal.

- Mendorong dan membantu pengilang-pengilang ubat tempatan untuk meningkatkan mutu setaraf dengan Amalan Perkilangan Baik (Good Manufacturing Practice) yang disarankan oleh 'Pharmaceutical Inspection Cooperation Scheme (PIC/S)' dan Pertubuhan Kesihatan Sedunia (WHO).

- Menguruskan program pemonitoran kesan advers ubat dan menganggotai Program Pemonitoran Ubat Antarabangsa WHO.

- Menguruskan skim panggilbalik produk berdaftar yang didapati 'substandard' atau dibuktikan tidak selamat bagi pengguna.

- Mengendalikan sistem pengumpulan dan penyebaran maklumat ubat.

- Menjalankan penyelidikan metodologi dan penyelidikan asas untuk tujuan penilaian mutu, keberkesanan dan keselamatan ubat-ubatan / kosmetik.

- Menubuhkan sistem piawai rujukan untuk kegunaan negara ini dan negara jiran melalui skim kerjasama dalam bidang farmaseutikal antara negara-negara ASEAN.

- Menjalankan latihan bagi pegawai-pegawai farmasi, pegawai-pegawai profesional lain dan juga pegawai-pegawai separuh profesional yang ditempatkan di institusi ini dari semasa ke semasa melalui skim latihan tempatan atau skim kerjasama antarabangsa.

Aktiviti-aktiviti khusus yang dilaksanakan oleh setiap Pusat di BPFK adalah seperti berikut :

Pusat Pendaftaran Produk

- Menerima dan menilai permohonan pendaftaran produk farmaseutikal, ubat tradisional dan kosmetik.
- Menjadi urusetia kepada mesyuarat Pihak Berkuasa Kawalan Dadah, memproses pengeluaran keputusan mesyuarat dan mengeluarkan Sijil Perakuan Pendaftaran.
- Memproses permohonan lesen import untuk tujuan Percubaan Klinikal.
- Memproses permohonan pertukaran pemegang pendaftaran.
- Menilai permohonan tambahan indikasi.
- Memproses rayuan terhadap permohonan produk yang ditolak oleh PBKD.
- Mengeluarkan Perakuan Produk Farmaseutikal, kosmetik dan Peralatan Perubatan untuk tujuan eksport.
- Menilai dan memproses permohonan pindaan maklumat produk berdaftar (sebelum penstrukturan semula organisasi).
- Memproses permohonan pendaftaran semula produk (sebelum penstrukturan semula organisasi).
- Memproses permohonan pertukaran tapak perkilangan (sebelum penstrukturan semula organisasi).

Pusat Kawalan Kualiti (PKK)

- Menjalankan ujian kawalan kualiti untuk menentukan kualiti, keberkesanan dan keselamatan produk berdaftar sebelum dan selepas dipasarkan.
- Menjalankan penyelidikan dan perkembangan metodologi serta protokol analisis produk.
- Menubuhkan sistem piawai rujukan kimia serta biologikal untuk kegunaan institusi, industri farmaseutikal tempatan dan negara ASEAN.
- Menjalankan pemeriksaan Amalan Perkilangan Baik terhadap makmal kawalan kualiti di premis farmaseutikal tempatan.
- Mengkaji dan menilai protokol analisis dan data validasi.

Pusat Amalan Perkilangan Baik (PAPB)

- Menjalankan pemeriksaan APB atas premis pengilang, pengimport dan pemborong produk berdaftar.

- Menjalankan pemeriksaan penyiasatan APB berkaitan kualiti produk atas premis pengilang sekiranya perlu.
- Memproses permohonan dan mengeluarkan lesen pengilang, pengimport dan pemborong produk berdaftar.
- Mengeluarkan senarai tambahan produk berdaftar.
- Menilai pelan susun-atur APB premis pengilang keluaran berdaftar.
- Memberi khidmat nasihat dan bimbingan dari segi teknikal kepada industri berkenaan dalam aspek APB, Amalan Penstoran Baik (ASB) dan pelesenan.
- Menganjur kursus latihan APB untuk industri farmaseutikal dan tradisional serta 'WHO fellows'.
- Mengadakan perbincangan teknikal dengan farmaseutikal untuk meningkatkan tahap APB premis pengilang tempatan.
- Mengumpul maklumat berkaitan industri farmaseutikal dan tradisional.
- Mengeluarkan perakuan APB dan mengesahkan salinan dokumen-dokumen berkaitan lesen.

Pusat Pasca Pendaftaran Produk (PPPP)

I Pemonitoran Kesan Advers Ubat

- Menguruskan pengesanan dan pemonitoran kesan advers ubat.
- Mengenalpasti langkah-langkah untuk mengurangkan kejadian kesan advers ubat.
- Menggalakkan pelaporan kesan advers ubat.
- Menganggotai Program Pemonitoran Ubat Antarabangsa WHO.

II Surveilans dan Aduan Produk

- Mengambil sampel dalam pasaran dan dihantar untuk ujian.
- Membuat pemonitoran terhadap label dan sisip bungkusan.
- Menjalankan penyiasatan terhadap produk.
- Mengambil tindakan punitif seperti mengeluarkan surat amaran atau arahan panggil balik atas produk apabila perlu.
- Melaksanakan pemonitoran terhadap arahan PBKD.

III Aktiviti berikut mula dilaksanakan oleh PPPP selepas penstrukturan semula BPFK:

- Menilai dan memproses permohonan pindaan maklumat produk berdaftar.
- Memproses permohonan pendaftaran semula produk.
- Memproses permohonan pertukaran tapak perkilangan.

Pusat Pembangunan Organisasi (PPO)

I Maklumat dan Komunikasi

- Memberi penerangan serta maklumat kepada orang awam berkenaan dengan proses pendaftaran, produk berdaftar dan pengkelasan produk.
- Mengendali sistem komputer dan mengemaskini laman web BPFK.
- Mengendali sistem pengumpulan dan penyebaran maklumat ubat-ubat melalui penerbitan Berita Ubat-ubatan.
- Menyediakan perkhidmatan perpustakaan serta membekalkan buku-buku rujukan kepada pegawai-pegawai BPFK.

II Pengurusan Latihan

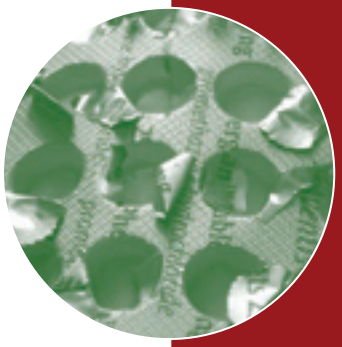
- Mengendalikan program latihan bagi Pegawai Farmasi Provisional (PRP- Provisionally Registered Pharmacist) dan pelawat dari luar negara yang berkursus di BPFK.
- Mengendalikan program lawatan / taklimat bagi pelawat-pelawat ke BPFK.
- Mengendalikan program pembelajaran berterusan untuk pegawai / kakitangan BPFK.

III Pengurusan Sistem Kualiti

- Menguruskan sistem kualiti BPFK – memastikan semua dokumen berkaitan BPFK terkawal, selamat dan mematuhi garis panduan / keperluan ISO.

BAB 5

PIHAK BERKUASA KAWALAN DADAH



Pihak Berkuasa Kawalan Dadah

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah berjaya memainkan peranan sebagai sekrefariat 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.

12 mesyuarat PBKD telah berlangsung sepanjang tahun 2006 untuk membincang polisi dan permohonan pendaftaran produk serta pelesenan.

Sebanyak 30,189 permohonan pendaftaran produk dibentangkan dalam mesyuarat PBKD pada tahun 2006. Sehingga Disember 2006, sebanyak 29,832 produk berjaya didaftarkan. Daripada jumlah ini, 41 produk yang diluluskan adalah di bawah kategori Ubat Baru dan 19 produk Bioteknologi.

Produk Bioteknologi yang diluluskan pada tahun 2006 adalah seperti berikut:

	Nama Produk
1	Immunine 600 iu injection
2	Avaxim 80 u Pedriatric suspension for injection
3	Tritanrix HB+ HIB vaccine
4	Apidra 100u/ml, solution for inj in vial Apidra 100u/ml, 3 ml Cartridges for Optipen- solution for injection in cartridge. Apidra 100u/ml Optiset - solution for injection in pre filled pen.
5	Recormon Prefilled Syringes 30,000iu/ 0.6ml
6	Amevive 15 mg powder for injection
7	Rotarix Rotavirus vaccine
8	Mabcampath 30 mg/ml, Concentrate for solution for Infusion
9	Immunate 50 iu / ml powder for injection Immunate 100 iu / ml powder for injection
10	Levemir Penfill 100 u/ml, 3 ml Levemir Flexpen 100 u/ml, 3 ml
11	INFLUVAC 2004/2005 Suspension for Injection
12	Xolair 150 mg powder & solvent for Injection
13	Gardasil Suspension for Injection
14	PROQUAD (Measles, Mumps,Rubella and Varicella (Oka/Merck) Virus Vaccine Live, MSD) LYOPHILIZED VACCINE
15	Raptiva Powder and Solvent for solution for injection

Ubat Baru yang diluluskan pada tahun 2006 adalah seperti berikut:

	Nama Produk
1	Bifril 30
2	Ebixa film coated tablet 10 mg
3	Relenza Rotadisk 5 mg
4	Tamiflu oral suspension 12 mg /ml
5	Bonviva 2.5 mg film coated Tablet
6	Bondronat vial 6 mg/6 ml
7	Pletaal 50 mg Pletaal 100 mg tablet
8	Baraclude Tablet 0.5 mg Baraclude Tablet 1 mg Baraclude oral solution 0.05 mg / ml
9	Tri-Luma Cream
10	Caduet film-coated tablet 5 mg/10 mg Caduet film-coated tablet 5 mg/20 mg Caduet film-coated tablet 5 mg/40 mg Caduet film-coated tablet 5 mg/80 mg Caduet film-coated tablet 10 mg/10 mg Caduet film-coated tablet 10 mg/20 mg Caduet film-coated tablet 10 mg/40 mg Caduet film-coated tablet 10 mg/80 mg
11	Zymar 0.3% Eye Drop
12	Chirocaine 2.5 mg / ml Injection Chirocaine 5.0 mg / ml Injection Chirocaine 7.5 mg / ml Injection
13	Nebido 1000 mg for Injection
14	Reyataz Capsule 100 mg Reyataz Capsule 150 mg Reyataz Capsule 200 mg
15	Suboxone 2 mg sublingual tablet Suboxone 8 mg sublingual tablet
16	Fosamax Plus Tablet
17	Mictonorm Tablet
18	Zaditen Eye Drop
19	Angelic Tablets
20	Ketesse 25 mg Film-coated Tablet
21	Exjade 125 mg Dispersible Tablet Exjade 250 mg Dispersible Tablet Exjade 500 mg Dispersible Tablet
22	Tygacil (Tigecycline) 50mg Lyophilized Powder for Intravenous Infusion
23	Ixel 25 mg Hard Capsule Ixel 50 mg Hard Capsule

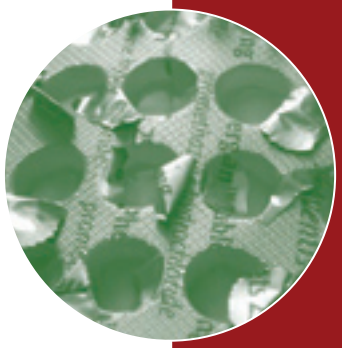
Sejumlah 234 permohonan pendaftaran produk yang melibatkan 25 ubat preskripsi, 32 ubat bukan preskripsi, 124 ubat semulajadi dan 53 produk kosmetik ditolak oleh pihak PBKD atas sebab-sebab tertentu. Pihak PBKD telah membatalkan pendaftaran 18 produk yang melibatkan 4 ubat preskripsi dalam bentuk dos yang dilarang, 5 produk kosmetik yang dicampurpalsu dan 9 produk semulajadi yang disebabkan isu campurpalsu, lesen pemegang ditarikbalik dan persetujuan pengilang kontrak yang dibatalkan.

Sebanyak 2363 permohonan pelesenan dibentangkan kepada pihak PBKD. Daripada jumlah ini, 446 lesen pengilang, 1016 lesen pemborong dan 901 lesen pengimport telah diluluskan. Sebaliknya, 8 lesen pengilang telah ditarikbalik kerana tidak memenuhi keperluan Amalan Perkilangan Baik pada tahun 2006.

PBKD juga telah meluluskan 277 Lesen Import Percubaan Klinikal untuk tujuan percubaan fasa 4 di Malaysia.

BAB 6

PUSAT PENDAFTARAN PRODUK



PUSAT PENDAFTARAN PRODUK

Pengenalan:

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

Pendaftaran produk dilakukan melalui sistem 'online' bagi memudahkan proses pendaftaran produk. Namun demikian, pendaftaran produk bioteknologi and ubat baru masih menggunakan proses manual disebabkan data yang perlu dikemukakan terlalu banyak dan kaedah manual lebih sesuai dan praktikal pada masa kini.

Proses pendaftaran sentiasa dikaji semula untuk memastikan penggunaan satu sistem optima untuk kebaikan semua pihak. Sehubungan dengan itu, sistem penilaian ringkas diwujudkan bagi pendaftaran produk suplemen kesihatan. Prosedur pendaftaran untuk semua produk lain dikekalkan sepertimana pada tahun 2005.

Objektif:

Objektif Pusat Pendaftaran Produk adalah untuk memastikan semua produk farmaseutikal yang didaftarkan oleh Pihak Berkuasa Kawalan Dadah (PBKD) dinilai dari segi keselamatan, efikasi dan kualiti, manakala ubat tradisional serta produk kosmetik dinilai dari segi keselamatan dan kualiti. Pusat ini juga bertanggungjawab dalam memberi bantuan administratif dan teknikal yang terlibat dalam proses pendaftaran.

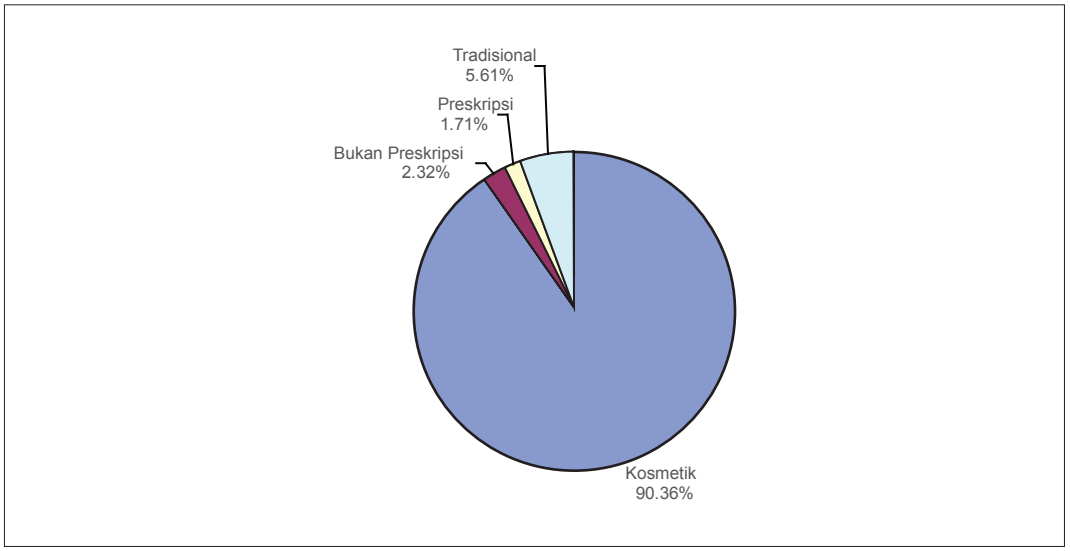
Aktiviti 2006:

Pendaftaran Produk

Sejak tahun 2001, bilangan permohonan pendaftaran yang diterima oleh pusat ini telah bertambah. Pada tahun 2006, sebanyak 27,179 permohonan telah diterima, yang mana 90.4% daripadanya adalah permohonan bagi produk kosmetik (Carta 1).

Permohonan Pendaftaran Yang Diterima (Tahun 2006)
N = 27179

Carta 1

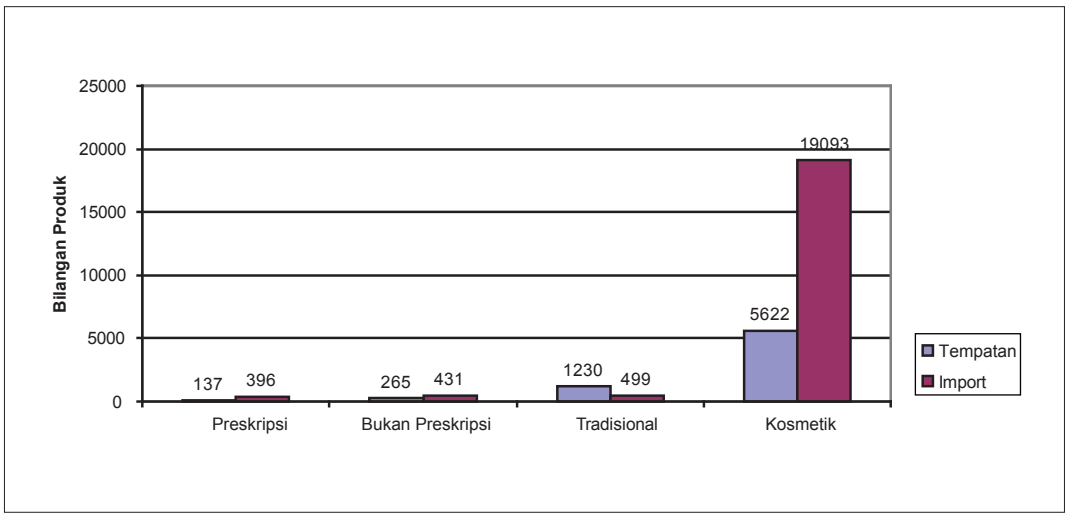


27,907 permohonan baru telah dinilai dan dimajukan kepada Pihak Berkuasa Kawalan Dadah (PBKD) untuk kelulusan. Keputusannya, 27,673 permohonan telah diluluskan (carta 2) dan 234 ditolak atas sebab-sebab tertentu seperti sampel gagal ujian makmal, formulasi mengandungi bahan terlarang, maklumat tidak lengkap semasa pendaftaran, gagal Amalan Perkilangan Baik (APB) dan penarikan balik Lesen Pengilang. Didapati bahawa lebih kurang 53% permohonan pendaftaran yang ditolak melibatkan ubat tradisional atas sebab ketidakakuran dari segi piawai kualiti.

Bilangan pendaftaran produk yang dibatalkan oleh PBKD telah berkurang sejak tahun 2001. Pada tahun 2006, hanya 18 pendaftaran produk telah dibatal dibandingkan dengan 890 pendaftaran produk pada tahun 2001 (Carta 3). Dengan pengecualian bagi tahun 2003, perbandingan data 6 tahun menunjukkan bahawa pembatalan pendaftaran produk tradisional menyumbangkan kepada bilangan pembatalan pendaftaran produk yang tertinggi sejak tahun 2001. 4 ubat preskripsi dibatal atas sebab bentuk dos yang dilarang, 5 produk kosmetik atas sebab campurpalsu dan 9 produk semulajadi atas sebab isu campurpalsu, lesen pemegang ditarikbalik dan persetujuan pengilang kontrak yang dibatalkan.

Produk Yang Didaftar (Tahun 2006)

Carta 2



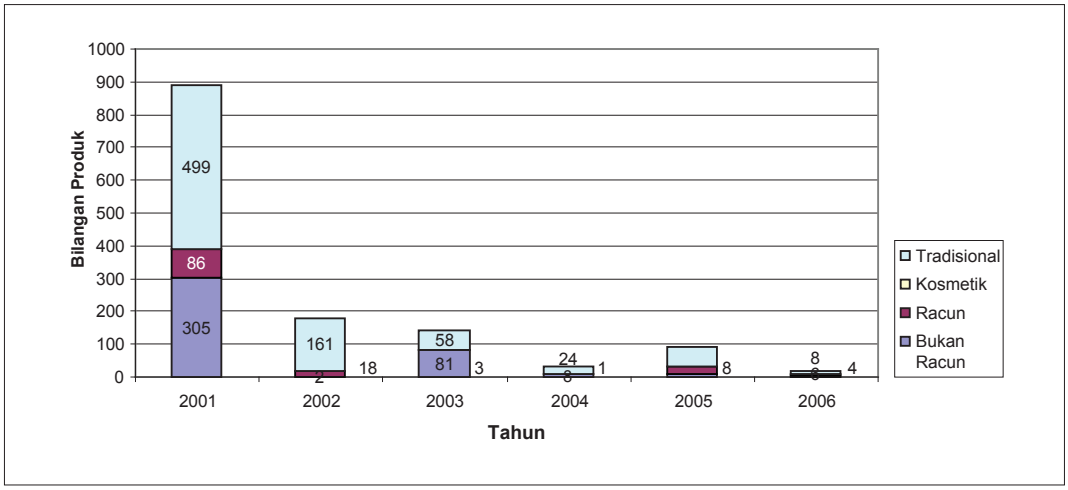
Pendaftaran Produk Yang Dibatal pada Tahun 2006

Bil	Nama Produk	Nombor Pendaftaran
1	Trebest Plus Capsule	MAL20034665TC
2	Shang Shi Zhi Tong Gao	MAL20034419T
3	Mas Ayu Sendi Tulang Capsule	MAL05041874TC
4	Bio Gents	MAL05041928TC
5	Watermelon Frost 3gm	MAL19971244T
6	Dr's Seagar Skin Recon	MAL04120601K
7	Sri Mutiara Krim Kecantikan Malam	MAL05071157K
8	Qmax Kapsul 350gm	MAL05101709TC
9	Natural Lightening Cream	MAL05011917K
10	GP Lotion	MAL05020114K
11	Dewajah Night Cream	MAL05071145K
12	Methadot 10 Tablet	MAL05092205AC
13	Methadot 5 Tablet	MAL05092204AC
14	Methadot 40 Tablet	MAL05092206AC
15	Aseptone Dispersible Tablet 40mg	MAL20031737A
16	Fructus Sophorae Compound Pills	MAL06071200T
17	Danggui Yangxue Gao	MAL06071199T
18	Houtou Jun Tablets 250mg	MAL06081286T

Daripada 27,673 pendaftaran produk yang diluluskan pada tahun 2006, sebanyak 73.8% pendaftaran adalah untuk produk import yang melibatkan semua kategori produk kecuali ubat tradisional di mana 71.1% ubat traditional dikilangkan di Malaysia. Sehingga Disember 2006, Negara China, diikuti oleh Amerika Syarikat dan India merupakan 3 negara yang paling banyak membekalkan sumber import untuk ubat tradstional yang didaftarkan di Malaysia. Sumber import yang paling tinggi untuk produk kosmetik ialah negara Perancis diikuti oleh Amerika Syarikat dan Itali, manakala Amerika Syarikat adalah negara utama untuk sumber import produk farmaseutikal yang diikuti oleh negara German dan Thailand.

Pendaftaran Produk (Tahun 2001-2006)

Carta 3



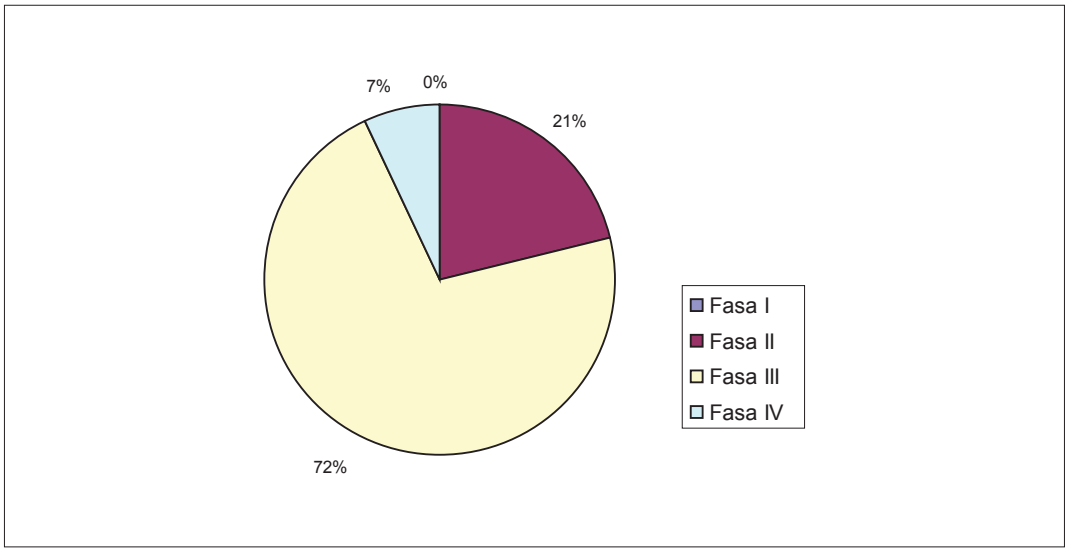
Lesen Percubaan Klinikal

Sebanyak 177 Lesen Import Percubaan Klinikal (LIPK) dan 4 Lesen Mengilang Bagi Ubat Tidak Berdaftar telah dikeluarkan pada tahun 2006. Di samping itu, sebanyak 180 permohonan variasi yang melibatkan permohonan untuk menambah kuantiti produk diimport, pertukaran tapak (pusat) penyelidikan, penggunaan protokol penyelidikan yang baru dan sebagainya telah diproses sepanjang tahun 2006. 57 percubaan klinikal yang melibatkan beberapa kelas ubat seperti ubat antikanser, ubat berkaitan dengan sistem kardiovaskular, antidiabetik, antipsikotik, antidepresan dan lain-lain telah dijalankan pada tahun 2006 (Carta 4 dan 5).

Unit Penyelidikan Klinikal Regulatori berfungsi sebagai sekretariat kepada 2 jawatankuasa kebangsaan, iaitu jawatankuasa Penyelidikan Klinikal Kebangsaan dan Jawatankuasa 'Good Laboratory Practice (GLP)'. Pada tahun 2006, 8 fasiliti percubaan klinikal telah diperiksa untuk menilai keupayaan dalam menjalankan percubaan klinikal.

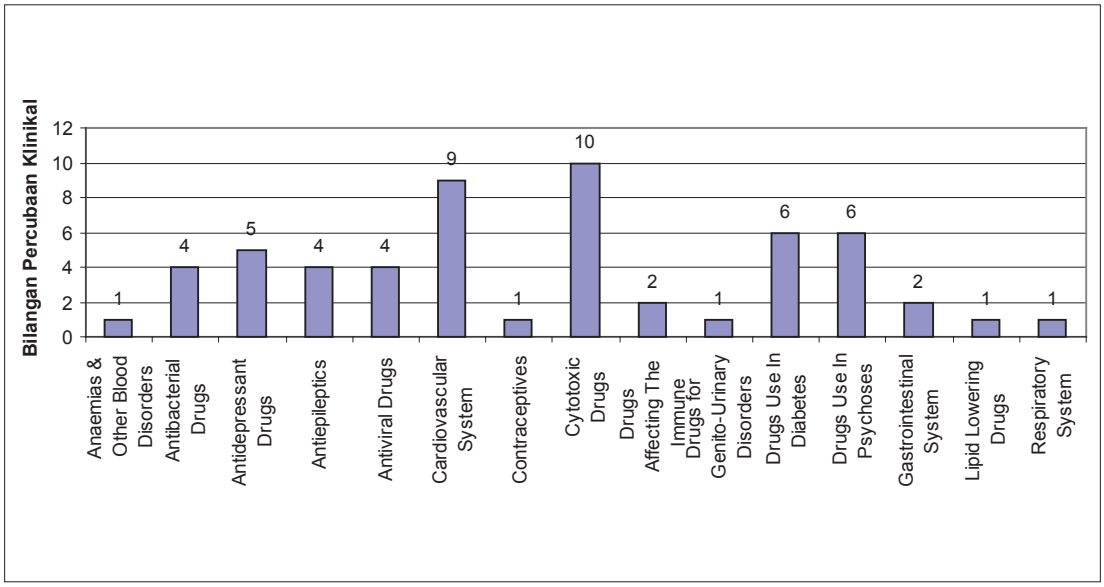
Percubaan Klinikal Yang Dilaksanakan (Tahun 2006)
N = 57

Carta 4



Aplikasi Melalui Kelas Terapeutik (Tahun 2006)

Carta 5



Kajian Semula Proses Pendaftaran

Kajian semula kriteria yang digunapakai dalam proses penilaian permohonan pendaftaran produk suplemen kesihatan telah dilakukan berdasarkan sistem 'listing' yang diamalkan oleh Therapeutic Goods Administration (TGA), Australia. Menurut kriteria penilaian baru ini, sebahagian maklumat seperti 'Finished Product Quality Control/Specification', 'Protocol Analysis/Testing Methods', 'Certificate of Analysis of Finished Product' dan 'Stability Data' bagi produk tersebut boleh dikemukakan selepas produk didaftarkan. Walau bagaimanapun, adalah menjadi tanggungjawab pihak pemohon untuk membekalkan maklumat-maklumat yang diperlukan kepada BPFK semasa aktiviti surveilans pasca-pendaftaran. Kajian semula ini telah berjaya mempercepatkan proses penilaian dan pendaftaran produk suplemen kesihatan. Tempoh masa untuk pendaftaran produk suplemen kesihatan telah dipendekkan dari 12 bulan ke 6 bulan.

Halatuju 2007

- **Kos Baru Penilaian Analisis Sampel**

Mesyuarat PBKD ke-173 yang diadakan pada 1hb September 2005 telah menetapkan bahawa kos baru penilaian analisis sampel akan berkuatkuasa Januari 2007. Kos baru ini akan menyelaraskan kos penilaian analisis bagi pendaftaran produk farmaseutikal dan tradisional.

- **Pendaftaran Produk Veterinar**

Pendaftaran produk veterinar dijangka akan bermula pada tahun 2007. BPFK akan menggemblengkan tenaga untuk memastikan terdapat kapasiti dan kebolehan untuk menjayakan perlaksanaan sistem pendaftaran serta pelesenan bagi produk veterinar. BPFK juga akan menganjurkan program-program kesedaran bagi industri tempatan berkenaan proses pendaftaran produk veterinar.

- **Pengkelasan Semula Produk External Personal Care (EPC) Kepada Kosmetik**

Mesyuarat PBKD ke-185 telah menetapkan untuk mengubah klasifikasi produk dandanan diri (seperti produk anti jerawat, anti bakteria, kesihatan oral, anti kelumumur dan pelindung kulit) kepada kosmetik. Ini adalah supaya klasifikasi produk dandanan diri di Malaysia dapat diselaraskan dengan klasifikasi produk dandanan diri di negara-negara ASEAN yang lain, negara Eropah dan USA sejajar dengan perlaksanaan ASEAN Free Trade Area Agreement (AFTA). Klasifikasi ini akan berkuatkuasa pada 1 Januari 2007.

- **Penstrukturan Semula Pusat Pendaftaran Produk**

Ekoran daripada penstrukturan semula organisasi BPFK, Unit Penyelidikan Klinikal yang pada masa ini di bawah Pusat Pendaftaran Produk akan menjadi sebuah seksyen dalam Pusat Komplians dan Pelesenan mulai tahun 2007.

Ubat-ubat Unik Yang Diluluskan Pendaftaran Pada Tahun 2006

1. **Relenza Rotadisk (Zanamivir)** ialah 'neuraminidase inhibitor' dalam bentuk serbuk yang disedut daripada alat plastik. Inhaler ini digunakan untuk mengubati serta mencegah Influenza A dan B untuk golongan dewasa and pediatrik berumur 5 tahun ke atas. Walaupun vaksinasi merupakan cara utama mengawal dan mencegah influenza, Relenza boleh digunakan semasa pandemik untuk 'strain' yang tidak termasuk dalam program vaksin atau apabila vaksin tidak diperolehi.

2. **Tamiflu oral suspension (Oseltamivir)** ialah 'neuraminidase inhibitor' yang juga boleh digunakan untuk mengubati influenza di kalangan dewasa dan pediatrik yang berumur satu tahun ke atas. Kapsul Tamiflu pernah didaftarkan untuk mengubati influenza di kalangan dewasa. Suspension ini boleh juga digunakan untuk pencegahan selepas terdedah kepada virus influenza oleh dewasa dan remaja

berumur 13 tahun ke atas yang telah berhubung dengan pesakit yang secara klinikal disahkan mempunyai influenza.

3. **Baraclude Tablet (Entecavir)** ialah sejenis antiviral yang digunakan untuk mengubati penyakit kronik Hepatitis B virus (HBV) di kalangan dewasa. Baraclude digunakan untuk pesakit 'nucleoside-treatment-naïve' yang telah menerima rawatan selama satu tahun dan pesakit yang rintang terhadap lamivudine yang mempunyai HBeAg-positif atau HbeAg-negatif dengan penyakit hati dan dalam pesakit dewasa HIV/HBV yang pernah menerima lamivudine

4. **Suboxone Sublingual Tablets (Buprenorphine and Nalaxone)** ialah kombinasi yang digunakan oleh penagih opioid sebagai terapi ganti. Buprenorphine ialah agonis opioid separa manakala naloxone ialah antagonis opioid. Naloxone mengelakkan orang daripada melarutkan tablet dan menyuntiknya. Apabila Suboxone diletakkan di bawah lidah, hanya sedikit nalaxone akan diserap ke dalam peredaran darah menyebabkan hanya sedikit kesan buprenorphine dapat dirasai.

5. **Angeliq (Estradiol and Drosperinone)** ialah tablet kombinasi yang digunakan sebagai terapi penggantian hormon. Tablet ini digunakan untuk mengubati sindrom perempuan yang putus haid serta untuk mencegah osteoporosis putus haid. Kebanyakan terapi penggantian hormone mengandungi estrogen dan progestin. Dalam tablet ini, progestin (drosperinone) menyerupai dan bertindak seperti hormon progesteron yang dihasilkan dalam badan manusia.

6. **Exjade (Deferasirox)** ialah tablet boleh larut yang digunakan untuk mengubati pesakit dewasa dan pediatrik berumur 2 tahun ke atas yang mempunyai elemen besi berlebihan disebabkan oleh pemindahan darah (tranfusional haemosiderosis). Ubat ini bertindak sebagai agen pengkelatan yang perlu diambil secara oral sekali dalam sehari. Agen pengkelatan desferoxamine hanya boleh digunakan dalam bentuk suntikan.

7. **Ixel (Milnacipran)** ialah kapsul antidepresan untuk mengubati penyakit depresi di kalangan dewasa. Milnacipran merupakan agen pertama dalam kelas baru yang dinamakan 'norepinephrine serotonin reuptake inhibitors' (NSRI) yang bertindak meningkatkan paras norepinephrine lebih daripada paras serotonin.

8. **Gardasil** ialah vaksin yang digunakan untuk mencegah penyakit seperti barah serviks, 'genital warts' dan 'precancerous' atau 'dysplastic lesions' yang disebabkan virus jenis 6, 11, 16 dan 18 Human Papillomavirus (HPV).

9. **Rotarix vaccine (Live attenuated human rotavirus)** ialah vaksin oral yang digunakan untuk mencegah gastro-enteritis (cirit birit dan muntah) yang disebabkan rotavirus di kalangan kanak-kanak. Rotarix diberi dalam dua dos. Ubat ini diberikan secara terus ke dalam mulut bayi menggunakan jarum suntikan oral. Rotarix boleh diberi bersama-sama vaksin lain.

10. **Xolair (omalizumab)** ialah antibodi terapeutik 'humanised' pertama yang digunakan untuk mengubati dewasa dan kanak-kanak berumur 12 tahun ke atas yang mempunyai penyakit kronik lelah alergi di mana simptomnya tidak dapat dikawal dengan sempurna oleh kortikosteroid yang disedut. Xolair dalam bentuk suntikan bertindak untuk menghalang immunoglobulin E (IgE) yang merupakan faktor terjadinya penyakit lelah alergi.

11. **ProQuad lyophilized vaccine** ialah vaksin kombinasi yang berupaya memberi perlindungan terhadap semua penyakit 'measles', 'mumps', 'rubella' dan 'varicella' dalam individu yang berumur di antara 12 bulan ke 12 tahun. ProQuad diberi sebagai suntikan di bawah kulit. Bahan aktif terdiri daripada virus yang menyebabkan sakit measles', 'mumps', 'rubella' dan 'varicella' yang telah dilemahkan.

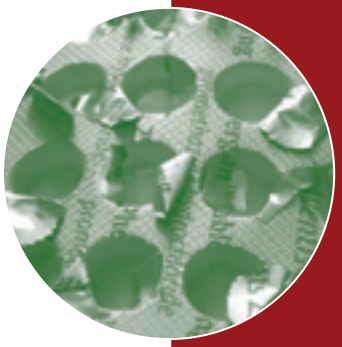
12. **Amevive (Alefacept)** ialah ubat suntikan yang digunakan untuk mengubati 'plaque psoriasis' kronik yang sederhana hingga kes yang serius di kalangan dewasa yang sesuai untuk terapi sistemik atau terapi foto. Ubat ini adalah produk biologikal pertama yang didaftarkan untuk indikasi psoriasis. Amevive bertindak dengan menghalang di samping mengurangkan komponen sel sistem imun yang dipercayai memainkan peranan penting dalam proses penyakit psoriasis.

13. **Avaxim 80U** ialah formulasi pediatrik yang digunakan sebagai imunisasi aktif terhadap jangkitan virus hepatitis A di kalangan kanak-kanak yang berumur 12 bulan ke 15 tahun dan ke atas yang mempunyai risiko menjangkiti ,menyebarkan penyakit atau mempunyai risiko maut jika terjangkit.

14. **Mabcampath (Alemtuzumab)** secara infusi, digunakan untuk mengubati Leukimia Limfositik Kronik dalam pesakit yang pernah menggunakan agen pengalkilan tetapi gagal atau separa sembuh atau hanya mencapai remisi untuk tempoh yang pendek setelah diberi terapi fludarabine fosfat. Mabcampath adalah DNA-derived humanized'antibodi monoclonal rekombinan 'yang bertindak terhadap CD-52, sejenis protein yang hadir di dalam limfosit matang.

BAB 7

PUSAT KAWALAN KUALITI



PUSAT KAWALAN KUALITI

Pengenalan

Proses kawalan kualiti yang dikendalikan oleh Pusat Kawalan Kualiti (PKK) berasaskan spesifikasi farmakopia dan kaedah dalaman, disamping protokol analisis yang diluluskan. Dalam kes tertentu, spesifikasi yang disediakan oleh pengilang boleh juga digunapakai. Standard yang sama digunakan untuk pematuhan sampel bagi sampel farmaseutikal, tradisional dan kosmetik yang berdaftar di pasaran. Dengan itu produk berkenaan perlulah mematuhi kualiti yang merangkumi penilaian dokumen serta pengujian sampel sebelum dan selepas dipasarkan.

Produk-produk yang diuji adalah untuk tujuan pendaftaran, pengawasan produk berdaftar dalam pasaran, kes-kes aduan bagi produk berdaftar dan sampel produk dari Cawangan Penguatkuasa Farmasi (CPF). Pendaftaran produk farmaseutikal dimulakan dengan penilaian protokol analisis produk diikuti dengan ujian ke atas sampel produk. Bagi produk parenteral, pemohon hanya perlu mengemukakan protokol analisis serta data validasi sahaja, manakala produk tradisional dimulakan dengan pengujian sampel.

Objektif

Memastikan produk-produk terapeutik dan kosmetik yang dibenarkan di pasaran tempatan dipantau dari aspek kualiti dan keselamatan dengan:

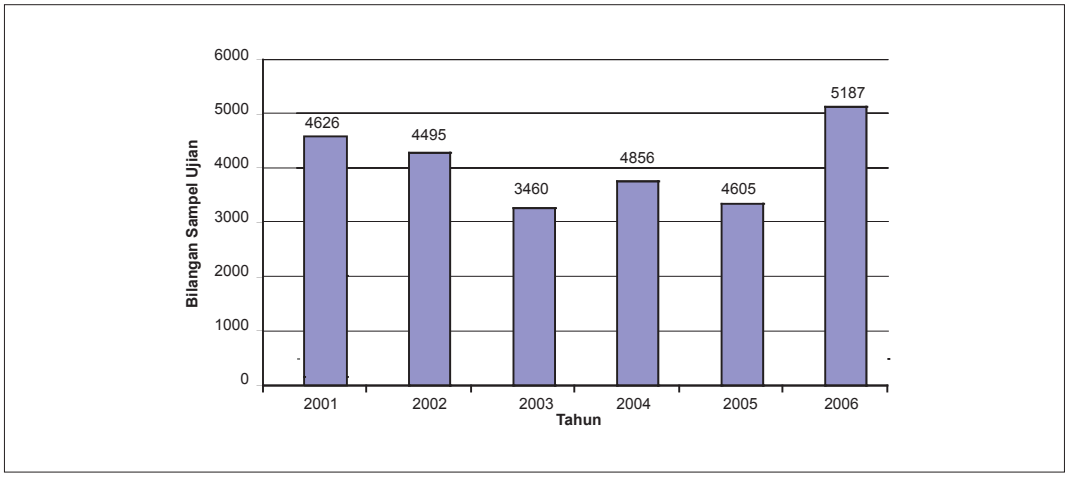
- Menjalankan ujian-ujian kimia dan biologikal berlandaskan prosedur dan tatacara yang mematuhi piawaian antarabangsa
- Membangunkan dan memperkembangkan metodologi pengujian dan penyelidikan
- Menubuhkan piawai rujukan kimia dan biologikal untuk kegunaan institusi dan industri farmaseutikal tempatan
- 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 institusi dan industri farmaseutikal tempatan
- Memberi sokongan dan input teknikal kepada Pusat Amalan Perkilangan Baik dalam pengauditan pengilang produk-produk terapeutik dan kosmetik

Aktiviti 2006;

Bagi tahun 2006 Pusat Kawalan Kualiti menerima sebanyak 5222 sampel untuk pelbagai jenis ujian. Dari 5187 sampel yang diuji pada tahun 2006,terdapat sebanyak 2196 sampel pendaftaran dan 2690 sampel pengawasan yang diuji. Bilangan sampel ujian ini telah meningkat dari 4605 pada tahun 2005 kepada 5187 sampel pada tahun 2006. (Carta 6)

Bilangan Sampel Diuji (Tahun 2001-2006)

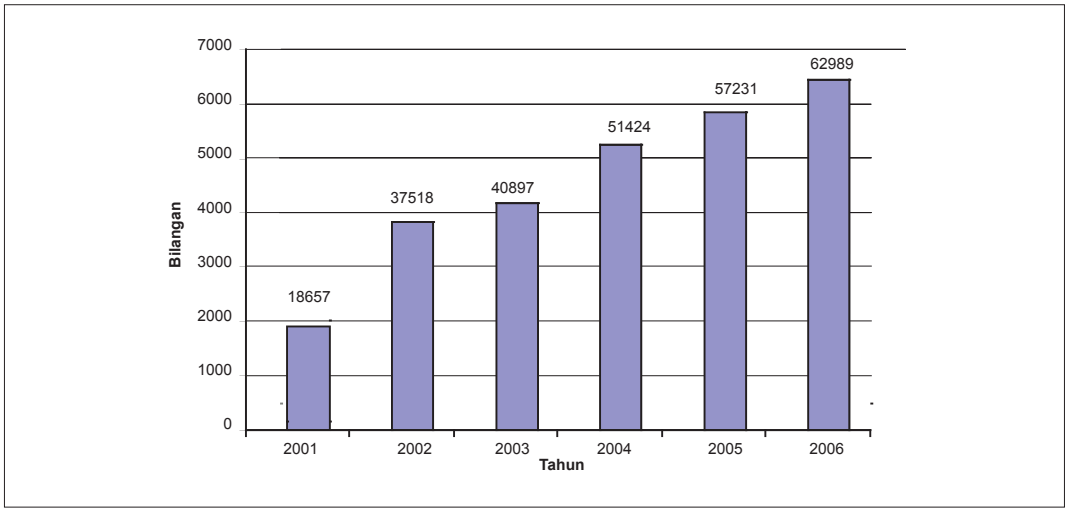
Carta 2



Daripada bilangan ujian pula, didapati jumlah meningkat dari tahun ke tahun. Pada tahun 2006 terdapat peningkatan sebanyak 1.3 % (57,971) dari 57,231 ujian pada tahun 2005 kepada 57,971 ujian pada tahun 2006- suatu jumlah yang tertinggi sebelum ini.(Carta 7)

Bilangan Ujian Dijalankan (Tahun 2001-2006)

Carta 3

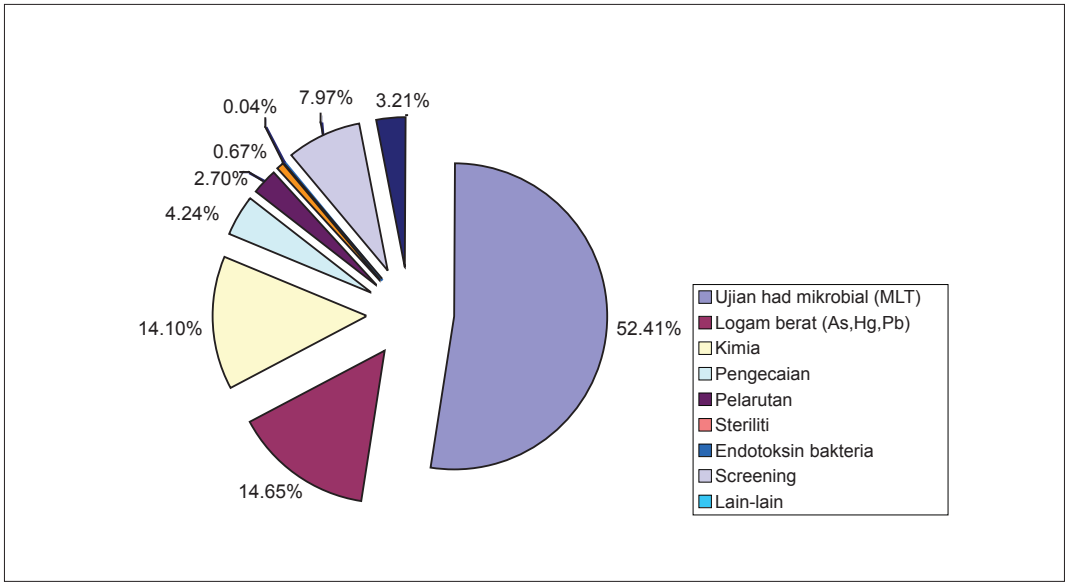


Sebahagian besar ujian melibatkan ujian had mikrob (52.4%) diikuti dengan ujian logam berat (As, Hg, Pb, Cd) (14.6%) dan ujian kimia (14.1%). Selain daripada itu, terdapat ujian pengecaian, pelarutan, steriliti, endotoksin bakteria, toksisiti, biokimia, biologikal, bilangan partikel serta esei antibiotik. (Carta 8)

Terdapat beberapa kes di mana ujian berkenaan didapati tidak mengikut spesifikasi yang dinyatakan. Bagi tahun 2006 sebanyak 465 sampel gagal mematuhi spesifikasi atau syarat yang diperlukan. Ini merupakan sebanyak 8.96% dari jumlah sampel yang diuji. Didapati kebanyakan sampel yang gagal ujian adalah sampel tradisional iaitu sebanyak 280 (62.4%) sampel dari keseluruhan sampel yang gagal. 16.5% sampel farmaseutikal pula didapati gagal ujian. Bilangan kegagalan ujian didapati meningkat berbanding dengan tahun 2005 iaitu sebanyak 3.6%.

Ujian Yang Dijalankan (Tahun 2006)
N = 62989

Carta 8



Pada tahun 2006 terdapat peningkatan bilangan ujian sebanyak 1.3% (57,971) berbanding dengan 57,231 pada tahun 2005.

Bahan Campurpalsu Dalam Ubat Tradisional

Bagi tempoh tahun 2006, sebanyak 339 sampel ubat tradisional iaitu 154 dari CPF, 109 sampel surveilans (termasuk laporan kesan advers) dan 76 sampel pendaftaran diuji bagi tujuan penyaringan bahan campurpalsu. 936 ujian telah dijalankan ke atas 4 kategori produk tradisional sebagai langkah pengawasan terhadap sampel pendaftaran & surveilans bagi menguji kehadiran bahan campur palsu. Kategori produk-produk tersebut mempunyai indikasi berikut :

- produk kesihatan lelaki
- produk bagi sakit-sakit sendi dan otot (NSAID)
- produk dan bahan steroids
- produk bagi mengurang atau mengawal berat badan

Kebanyakan ujian tersebut adalah untuk indikasi kesihatan lelaki di mana ianya merupakan kes campurpalsu yang tertinggi dalam ubat tradisional. Ujian tersebut dijalankan untuk menguji kehadiran Sildenafil, Tadalafil, Vardenafil serta analog bagi Sildenafil (Acetyldenafil), Dari sampel yang diuji, bahan-bahan berkenaan telah dicampurpalsukan dalam produk tradisional. Sebaliknya, antihypertensive, antidiuretics, antifungal, antidiabetik, beta-agonist, amphetamine dan hormon tidak dikesan dalam ketiga-tiga jenis sampel CPF, Surveilans dan Pendaftaran.

Kebanyakan sampel CPF dan surveilans mengandungi bahan-bahan seperti steroids, NSAID's dan analgesik, anthistamine, kafein, sildenafil, tadalafil, acetildenafil dan hydroxyhomosildenafil. Bagi sampel pendaftaran, bahan-bahan seperti di atas tidak ditemui kecuali kafein dalam peratusan yang agak tinggi (Carta 9).

Piawai Rujukan

Pada tahun 2006 sebanyak 126 vial piawai rujukan ASEAN bernilai RM 18,900.00 dan 479 vial piawai rujukan BPFK bernilai RM 47,900.00 telah dijual kepada industri farmaseutikal tempatan dan luar negara.

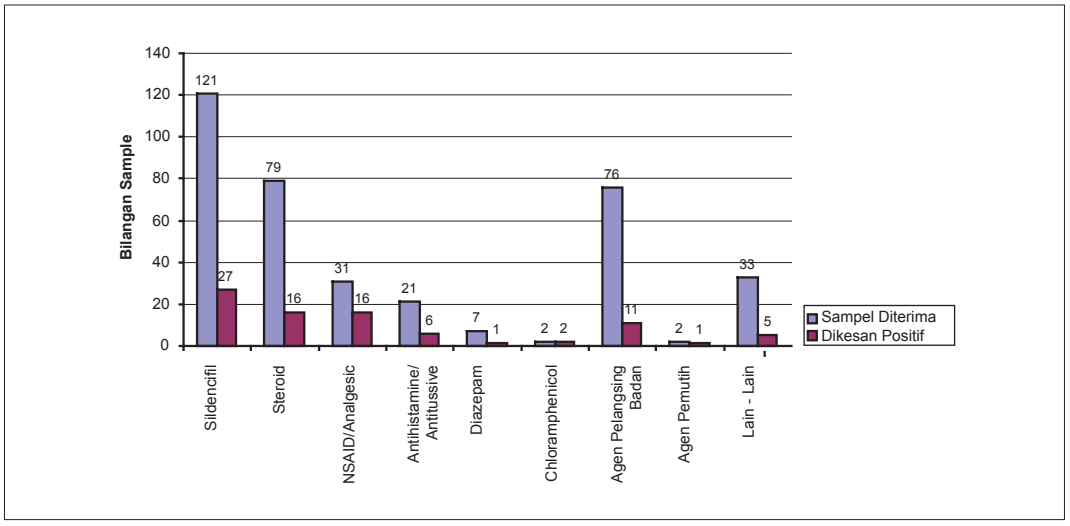
Jumlah keseluruhannya sebanyak RM 66,800.00, suatu peningkatan sebanyak RM13,750.00 dari tahun 2005, merupakan kutipan hasil jualan tertinggi dalam tempoh enam tahun. (Carta 10)

Pembekalan piawai rujukan adalah percuma bagi kegunaan badan-badan kerajaan, seperti Jabatan Kimia, Makmal Ubat dan Stor Sarawak, CPF Negeri serta badan regulatori negara-negara ASEAN. Dalam tahun 2006 sahaja sebanyak 1441 vial piawai rujukan telah dibekalkan secara percuma kepada badan-badan di atas; di mana 614 vial adalah dari jenis ASEAN manakala bakinya dari jenis BPFK. (Carta 11)

Pusat Kawalan Kualiti juga terlibat secara langsung dalam projek kolaborasi bagi negara ASEAN iaitu di bawah kerjasama dan naungan WHO. Ini melibatkan pengeluaran dan penggunaan piawai rujukan ASEAN (ARS) serta ujian ARS. Ujian-ujian untuk kajian kolaborasi juga dijalankan ke atas bahan mentah yang diterima dari negara ASEAN.

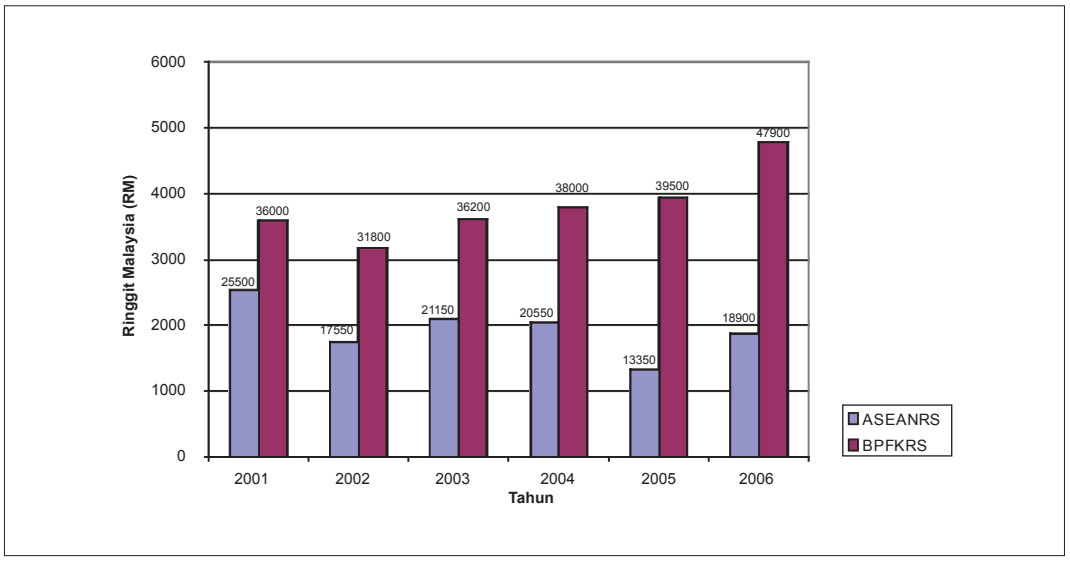
Bilangan Sampel Yang Diuji Dan Dikesan Positif Kehadiran Bahan Campur Palsu Mengikut Kategori (Tahun 2006)

Carta 9



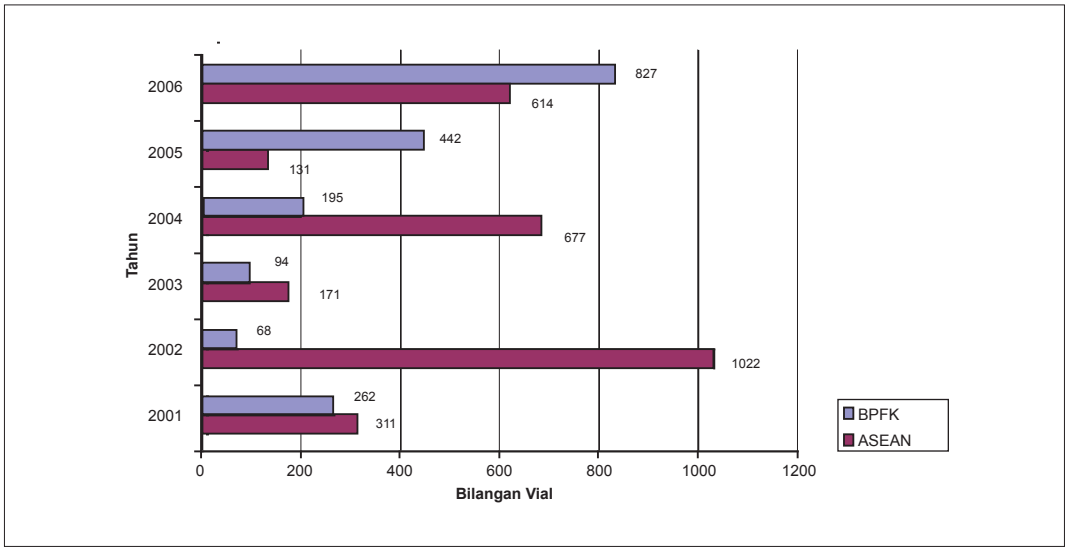
Hasil Jualan Tahunan Piawai Rujukan (Tahun 2001-2006)

Carta 10



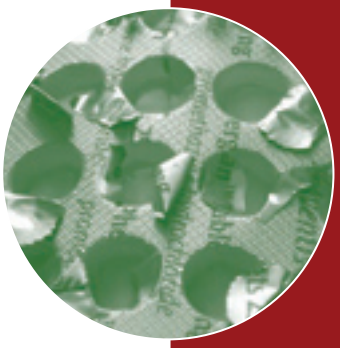
Bekalan Piawai Rujukan Kepada Agensi Kerajaan (Tahun 2001-2006)

Carta 11



BAB 8

PUSAT PASCA PENDAFTARAN PRODUK



PUSAT PASCA PENDAFTARAN PRODUK

Pengenalan:

Adalah menjadi tanggungjawab Pusat Pasca Pendaftaran Produk (PPPP) dalam memastikan semua produk-produk berdaftar mematuhi garispanduan dan memenuhi keperluan Pihak Berkuasa Kawalan Dadah (PBKD). Di bawah program 'Post Marketing Surveillance (PMS)', sampel-sampel produk berdaftar di pasaran akan diambil dan di hantar ke makmal untuk diuji. Pusat ini juga menjalankan penyiasatan untuk aduan produk dan laporan kesan advers ubat (ADRs) yang diterima. Tindakan susulan seperti mengeluarkan surat amaran, panggil balik keluaran dan mengenakan tindakan regulatori seperti pertukaran label akan dilakukan jika perlu untuk memastikan keselamatan pengguna sekaligus rakyat Malaysia.

Objektif:

Objektif pusat ini ialah untuk memastikan bahawa semua produk yang didaftarkan oleh Pihak Berkuasa Kawalan Dadah 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 yang sebenarnya akibat penggunaan produk tersebut. Aspek kualiti adalah berkaitan dengan pembuatan produk dan aspek keberkesanan merangkumi samada keluaran tersebut memberi kesan yang diingini atau tidak daripada penggunaan produk tersebut.

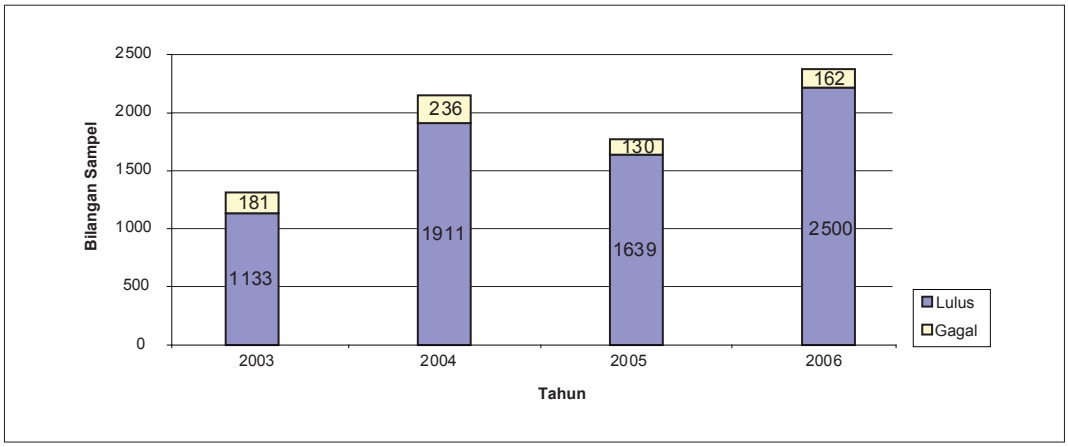
Aktiviti 2006:

Surveilans dan Aduan Produk

Di bawah program Post Marketing Surveillance (PMS), pada tahun 2006 sahaja, sejumlah 2549 produk berdaftar yang terdiri daripada 713 produk farmaseutikal, 561 produk bukan farmaseutikal dan 1320 produk tradisional telah disampel dari pasaran dan diuji di Pusat Kawalan Kualiti (PKK), BPFK.(Carta 12 dan 13)

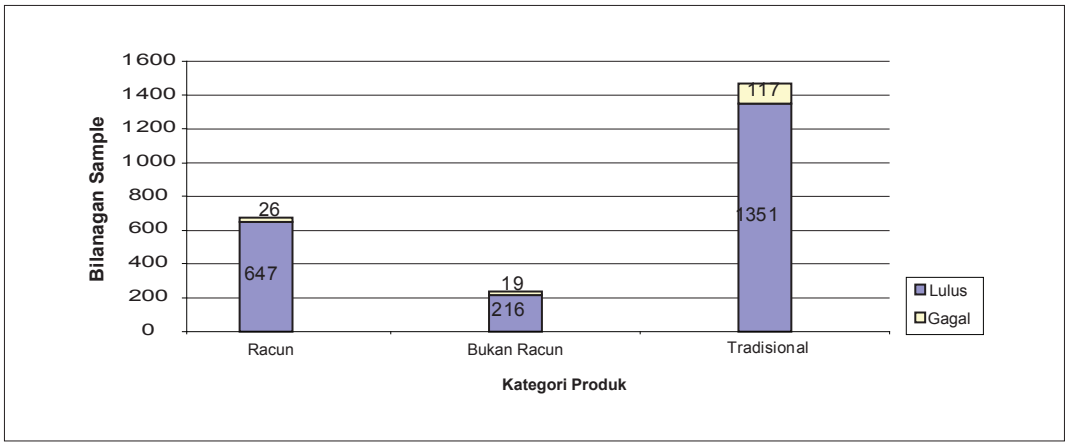
Keputusan Ujian Makmal Bagi Sampel Surveilans (Tahun 2003-2006)

Carta 12



Keputusan Ujian Makmal Bagi Sampel Surveilans Mengikut Kategori Produk (Tahun 2006)

Carta 13



Daripada 2376 produk yang diuji, sebanyak 162 sampel gagal ujian yang dijalankan di makmal. 108 daripada jumlah produk yang gagal telah dipanggil balik di mana 85 adalah produk tradisional, 19 produk preskripsi, 3 produk bukan preskripsi dan 1 produk kosmetik. Bagaimanapun, ia hanya melibatkan panggil balik kelas 3 yang berkenaan dengan isu kualiti. Kelompok yang terlibat perlu dipanggil balik dalam tempoh 30 hari daripada tarikh surat jawatan. Selain itu, sebanyak 41 surat amaran telah dikeluarkan kepada pemegang bagi produk yang gagal ujian makmal. Untuk 13 produk dalam Jadual 1, tiada tindakan susulan dijalankan kerana pihak pemegang telah mengemukakan alasan yang munasabah.

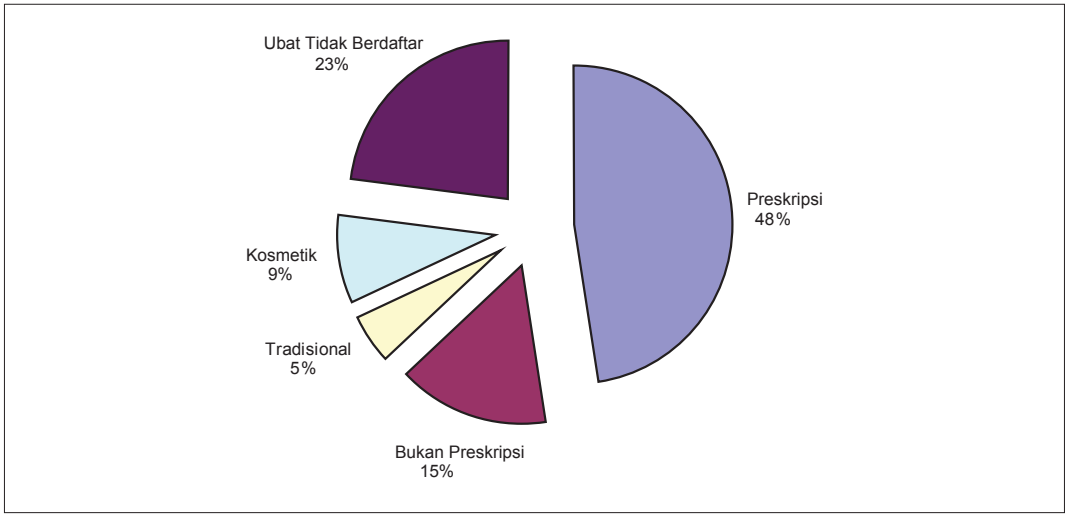
Di bawah program surveilans, sejumlah 2631 label dan sisip bungkusan produk telah disemak untuk memastikan ia memenuhi keperluan. Dalam aspek ini, sebanyak 68 surat amaran telah dikeluarkan kepada pemegang produk yang tidak mematuhi keperluan PBKD.

Bilangan aduan yang diterima telah meningkat sebanyak 15% pada tahun 2006 jika dibandingkan dengan tahun sebelumnya. Sebanyak 317 aduan diterima melibatkan 28 produk kosmetik, 16 produk tradisional, 49 produk bukan preskripsi, 151 produk preskripsi dan 73 produk tidak berdaftar (Carta 14) Tindakan susulan telah dijalankan dalam tempoh 6 minggu bagi 85% kes yang diterima. Aduan berkenaan produk tidak berdaftar dikemukakan kepada Cawangan Penguatkuasa Farmasi (CPF) untuk tindakan susulan.

Aduan Produk Diterima (Tahun 2006)

N = 317

Carta 14



13 produk yang telah dibatalkan pendaftaran oleh PBKD kerana dicampurpalsu dengan racun berjadual:

	Nama Produk	Bahan Campur Palsu
1	Herbs-U	Sibutramine
2	Ching Du Yan Capsule	Chlorphenaramine, Chloramphenicol, Ibuprofen, Kafein
3	Han Palace	Acetildenafil
4	Trebest Plus Capsule	Acetildenafil
5	Mas Ayu Sendi Tulang Capsule 250mg	Acetaminophen
6	Bio Gents	Acetildenafil
7	Dr. Seagar SkinRecon	Hydroquinone, Tretinoin
8	Kintop Capsule	Sibutramine
9	Natural Lightening Cream	Hydroquinone
10	GP Lotion	Tretinoin
11	Sri Mutiara Krim Kecantikan Malam	Tretinoin
12	Dewajah Night Cream	Tretinoin
13	Qmax Kapsul 350mg	Acetildenafil

Pemonitoran Profil Keselamatan Produk

Di bawah program farmakovigilans, sebanyak 2543 laporan kesan advers ubat (ADR) yang melibatkan 2938 produk telah diterima. Daripada jumlah produk tersebut, 2799 adalah produk preskripsi, 52 produk bukan preskripsi, 14 produk tradisional, 5 produk kosmetik dan 68 produk tidak berdaftar. Sebanyak 50% daripada laporan ADR yang diterima adalah daripada kakitangan kesihatan profesional dalam sektor kerajaan (Carta 15)

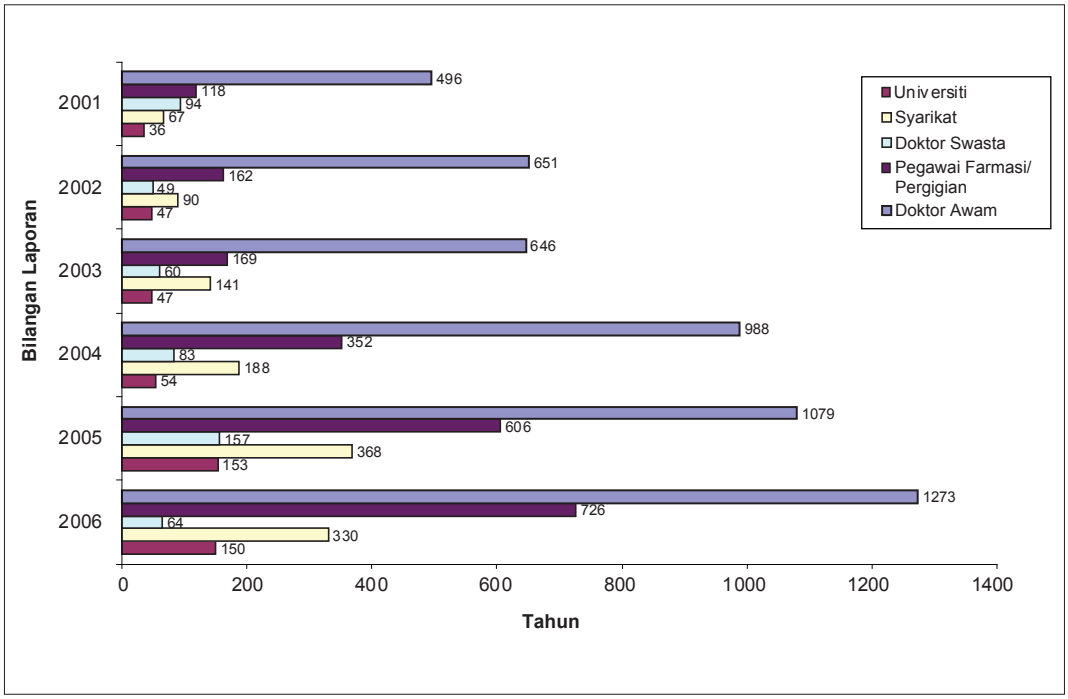
Semua laporan ADR yang diterima disiasat dan dikemukakan kepada Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) di mana ahli jawatankuasa tersebut bermesyuarat 6 kali dalam setahun. Berikutan dengan ini, sebanyak 2491 laporan yang dinilai telah dihantar ke Uppsala Monitoring Centre, Sweden untuk dimasukkan ke dalam Pangkalan Data Pertubuhan Kesihatan Sedunia (WHO).

Analisa laporan ADR melalui sistem pengelasan organ menunjukkan bahawa laporan ADR yang melibatkan sistem kulit dan dermatologi adalah laporan yang paling banyak diterima (Carta 16). Berdasarkan carta di bawah, ubat traditional dan diclofenac dalam produk farmaseutikal dilapor menyumbangkan kes ADR yang tertinggi di kalangan pesakit atau pengguna.

Sebanyak 11 ceramah telah diadakan di beberapa negeri untuk mempromosikan kesedaran mengenai pelaporan ADR dan sistem pemonitoran ADR terutama di kalangan anggota kesihatan profesional.

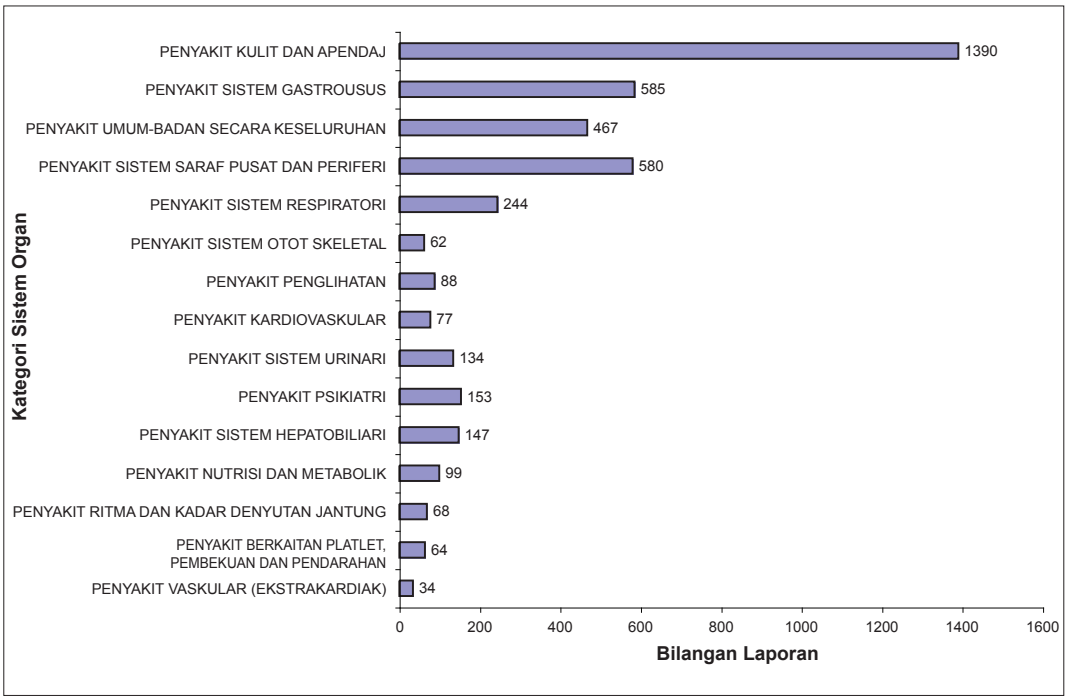
Analisa Laporan ADR Mengikut Kategori Pengadu

Carta 15



Analisa Laporan ADR Bagi 15 Kelas/Sistem Organ

Carta 16



Variasi

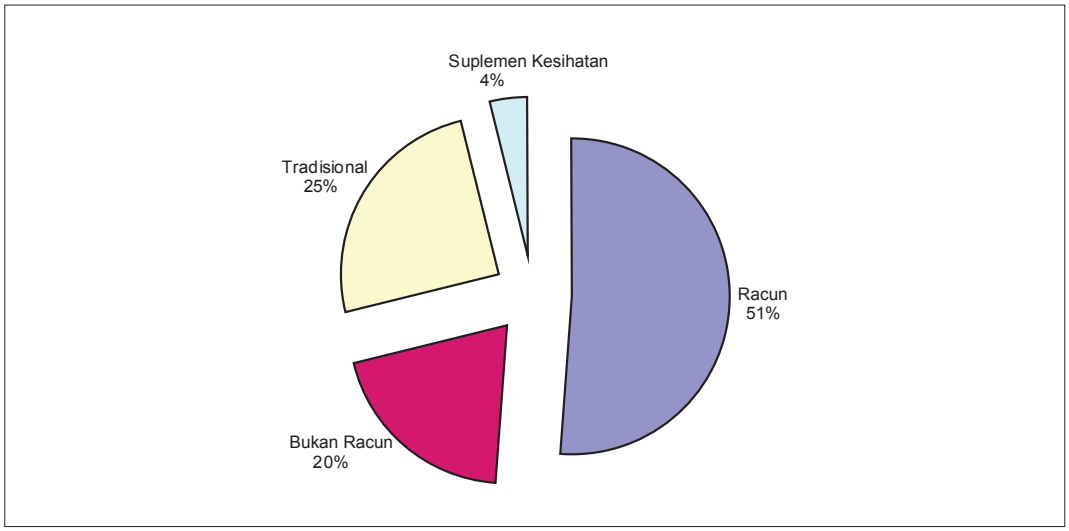
Unit variasi bertanggungjawab dalam memproses permohonan untuk tujuan pertukaran yang melibatkan pertukaran major atau minor pada produk berdaftar dan juga permohonan untuk pertukaran tapak pengilang.

Pada tahun 2006 sahaja, sebanyak 29532 permohonan diterima untuk variasi (Carta 17). Daripada jumlah ini, sebanyak 19473 permohonan telah dilulus dan sebanyak 8625 ditolak (Carta 18). Antara sebab-sebab yang menyebabkan permohonan ditolak termasuklah:

a. Dokumen yang dilampirkan tidak berkaitan dengan maklumat yang dikehendaki. Permohonan ditolak agar pemohon boleh menghantar semula lampiran yang berkenaan.
b. Pertukaran yang dibuat tidak mematuhi keperluan regulatori.
   Sejumlah 324 permohonan untuk pertukaran tapak pengilang diterima dan telah dinilai. Daripada jumlah ini, sebanyak 282 permohonan diluluskan, 32 permohonan berada dalam status 'Under Review' dan 10 permohonan ditolak.

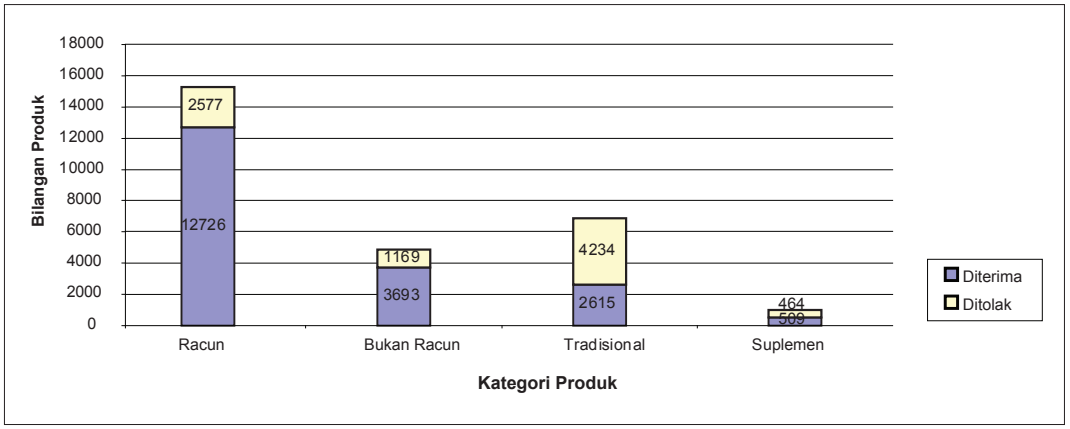
Permohonan Variasi Mengikut Kategori Produk untuk Tahun 2006
N = 29532

Carta 17



Permohonan Variasi Mengikut Kategori Produk (Tahun 2006)

Carta 18



Perancangan untuk 2007:

AKTIVITI SURVEILANS

- Berikutan pengenalan sistem 'abridged evaluation' untuk produk suplemen kesihatan pada pertengahan 2006, program pemonitoran aktif untuk produk kesihatan suplemen telah dirancang.
- Meningkatkan lagi surveilans untuk produk kosmetik.

Laporan Pengguna

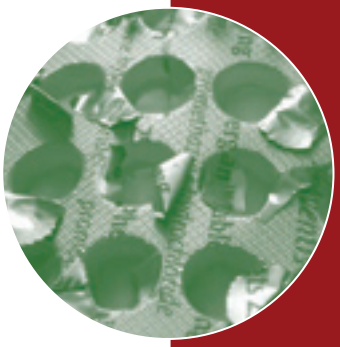
Projek perintis akan dilancarkan di sekitar Lembah Klang iaitu kajian akan dilakukan berkenaan penglibatan pengguna dalam program surveilans ubat. Jika program ini berjaya, ia akan diteruskan untuk memberi peluang kepada pengguna untuk menyalurkan laporan kepada pihak yang berkenaan. Aduan mengenai kualiti dan keselamatan produk juga dapat disalurkan dengan tepat, lebih-lebih lagi untuk produk yang dijual tanpa preskripsi.

Pemonitoran ADR untuk produk-produk veterinar

Program pemonitoran ADR untuk produk veterinar akan dijalankan serentak dengan pelaksanaan sistem pendaftaran produk veterinar. Sistem pemonitoran akan melibatkan juga kesan advers ubat yang berlaku pada manusia yang berpunca daripada penggunaan ubat veterinar sama ada secara sengaja atau tidak sengaja. Satu garispanduan akan dirangka untuk membantu kakitangan kesihatan profesional, kakitangan industri dan juga pengguna dalam membuat laporan kesan advers berkaitan dengan produk veterinar.

BAB 9

PUSAT AMALAN PERKILANGAN BAIK



PUSAT AMALAN PERKILANGAN BAIK

PENGENALAN:

Pusat Amalan Perkilangan Baik (Pusat APB) 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 (Pusat APB). Selain itu, Pusat ini juga terlibat dalam mengendallikan 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).

OBJEKTIF:

Pusat Amalan Perkilangan Baik (Pusat APB) akan sentiasa berusaha dalam memastikan produk-produk farmaseutikal, ubat-ubatan tradisional dan kosmetik yang dibenarkan berada di pasaran tempatan adalah selamat, berkesan dan berkualiti melalui aktiviti-aktiviti pemeriksaan yang dijalankan.

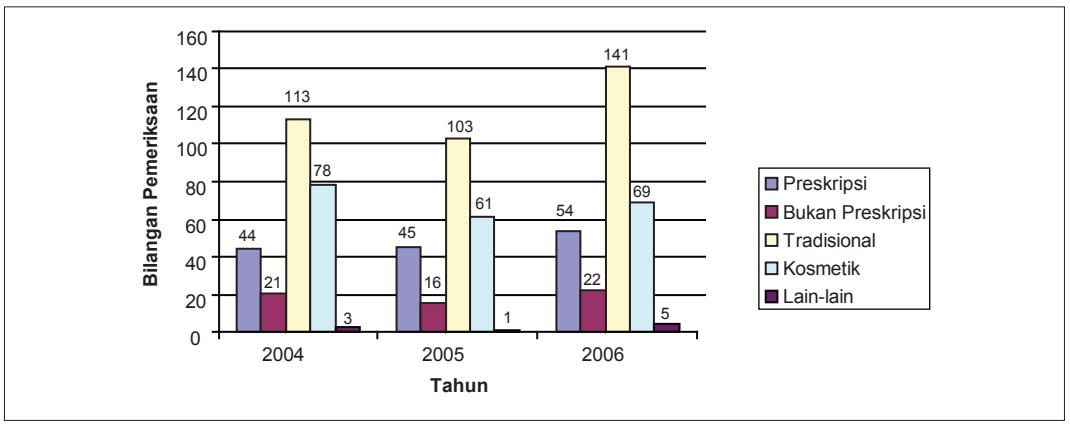
Aktiviti 2006:

Pemeriksaan APB

Sebanyak 291 pemeriksaan APB telah dijalankan pada tahun 2006 berbanding dengan 226 pemeriksaan pada tahun 2005. Pemeriksaan tersebut meliputi 54 premis pengilang produk preskripsi, 22 produk bukan preskripsi, 141 produk tradisional, 69 kosmetik dan 5 premis pengilang produk selain daripada kategori yang tersebut di atas (Carta 19).

Pemeriksaan APB Yang Dijalankan (Tahun 2004-2006)

Carta 19

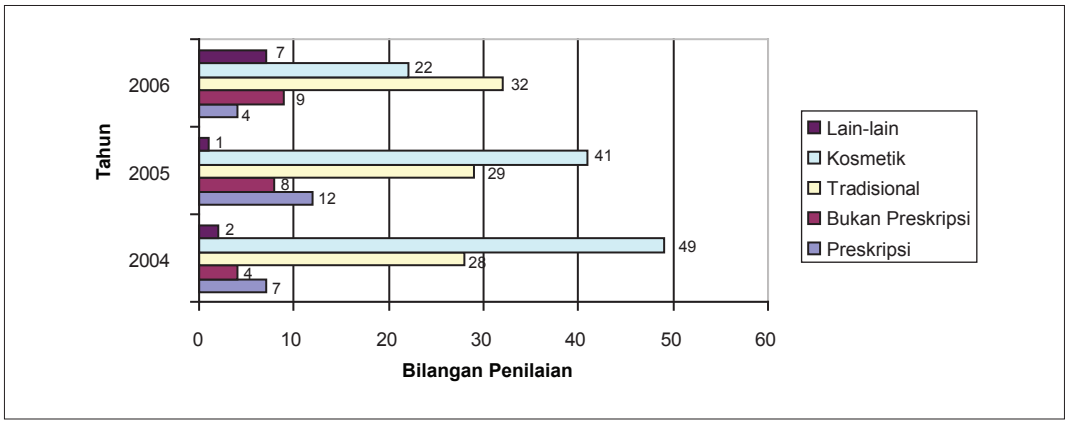


Penilaian Pelan Susun Atur Premis Pengilang

Sejumlah 74 pelan susun atur premis pengilang baru dan sediada telah dinilai untuk kepatuhan APB pada tahun 2006 . Premis-premis tersebut termasuk 4 premis pengilang produk preskripsi, 9 produk bukan preskripsi, 32 produk ubat tradisional, 22 kosmetik dan 7 lain-lain premis untuk bahan aktif farmaseutikal (API) serta produk veterinar (Carta 20).

Penilaian Pelan Susun Atur Premis Pengilang (Tahun 2004-2006)

Carta 20



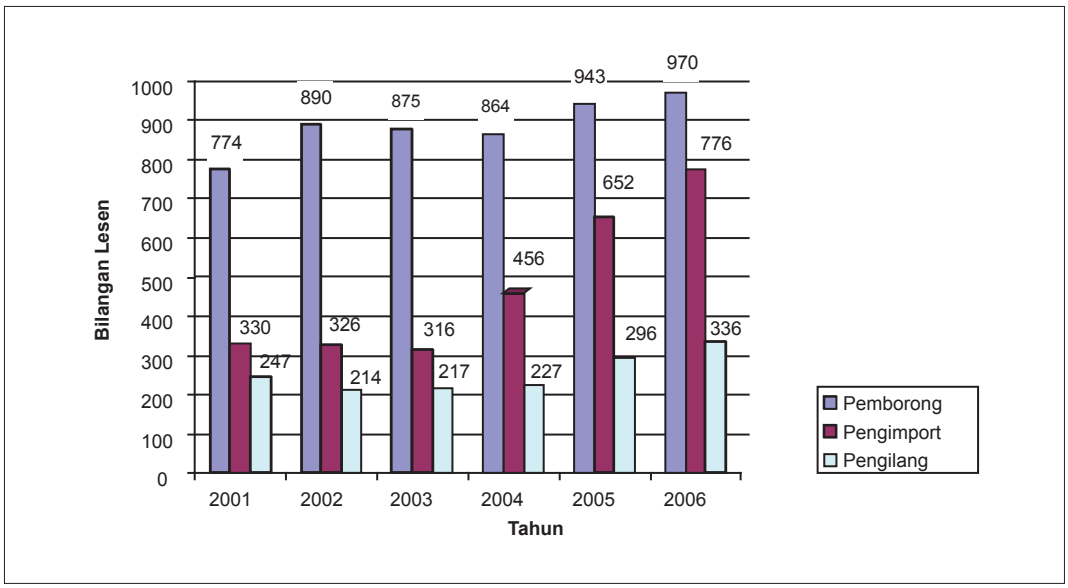
Pengeluaran Lesen

Di bawah peruntukan sub-peraturan 12 (1) Peraturan-Peraturan Kawalan Dadah Dan Kosmetik 1984, PBKD diberi kuasa untuk mengeluarkan 4 jenis lesen di mana 3 daripadanya adalah di bawah tanggungjawab pusat ini. Jenis-jenis lesen adalah seperti lesen pengilang, lesen pengimport dan lesen pemborong.

Pada tahun 2006, sebanyak 336 premis pengilangan, 776 premis pengimport dan 970 premis pemborong telah dilesenkan (Carta 21) di mana pecahan jumlah lesen yang dikeluarkan mengikut kategori produk adalah seperti di Jadual 1. Senarai serta maklumat mengenai premis-premis berlesen boleh didapati dengan melayari laman web BPFK (www.bpfk.gov.my) di mana maklumat dan data dikemaskini setiap bulan.

Jumlah Lesen Yang Dikeluarkan (Tahun 2001-2006)

Carta 21



Premis Yang Dilesenkan (Tahun 2006)

Jadual 1

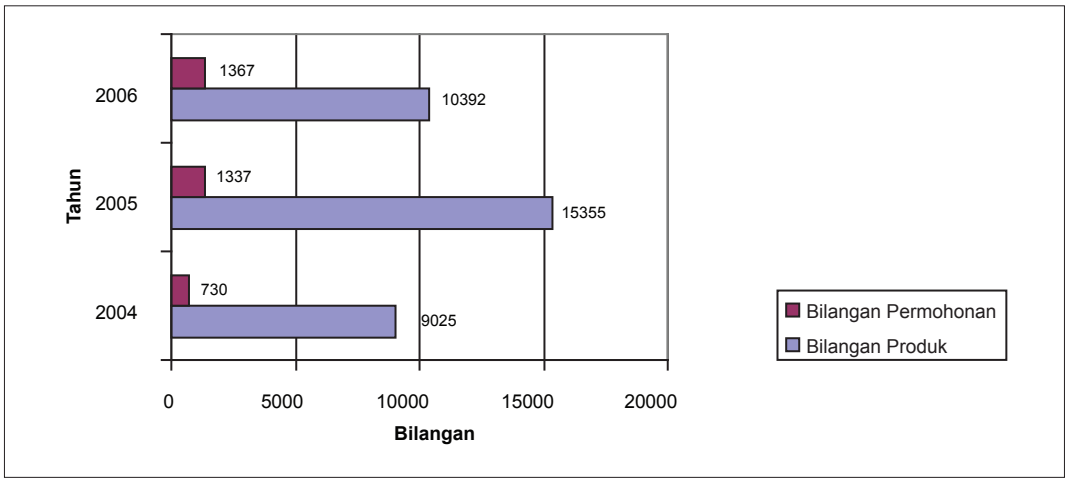
Kategori Produk	Pengilang	Pengimport		Kategori Produk	Pemborong
Farmaseutikal	85	180		Preskripsi	426
Tradisional	161	149		Bukan Preskripsi / Tradisional / Kosmetik	544
Kosmetik	90	447			
Jumlah	**336**	**776**		**Jumlah**	**970**

Pengeluaran Senarai Tambahan Keluaran Berdaftar

Jumlah permohonan yang diproses pada tahun 2006 adalah sebanyak 1367 dan ini meliputi sebanyak 10392 produk (Carta 22). Senarai ini diproses berdasarkan permohonan yang dikemukakan apabila terdapat produk yang baru didaftarkan dan senarai perlu dikepilkan bersama Lesen Pengilang atau Lesen Import.

Pengeluaran Senarai Tambahan Keluaran Berdaftar (Tahun 2004 - 2006)

Carta 22



Pemeriksaan Fasiliti Penyediaan Produk-Produk Steril Farmaseutikal Dan Radiofarmaseutikal Di Hospital-Hospital Kerajaan Dan Swasta

Pusat APB turut terlibat dalam pemeriksaan ke atas fasiliti-fasiliti bilik bersih yang digunakan untuk penyediaan produk-produk steril di hospital-hospital kerajaan dan swasta. Pada tahun 2006, sebanyak 19 pemeriksaan telah dijalankan ke atas fasiliti-fasiliti penyediaan produk sediada dan baru di seluruh negara. Pemeriksaan yang dijalankan adalah sebagai salah satu usaha untuk memastikan bahawa produk-produk yang disediakan di fasiliti-fasiliti tersebut adalah selamat bagi kegunaan pesakit di samping menjamin keselamatan petugas dan alam sekitar. Sehingga kini, terdapat 7 buah hospital kerajaan dan sebuah hospital swasta yang telah berjaya dikualifikasikan kerana fasiliti penyediaan produk titisan mata, 'Cytotoxic Drug Reconstitutions' (CDR) dan 'Total Parenteral Nutritions' (TPN) mereka didapati mencapai standard yang telah ditetapkan dari aspek premis dan peralatan. Selain itu, sebuah hospital kerajaan dan sebuah hospital swasta telah berjaya dikualifikasikan bagi penyediaan produk radiofarmaseutikal (siklotron).

Pemeriksaan Amalan Penstoran Baik (ASB) Ke Atas Premis-Premis Pengimport dan Pemborong Untuk Produk Bukan Preskripsi dan Tradisional

Pusat APB telah memulakan aktiviti pemeriksaan Amalan Penstoran Baik (ASB) ke atas premis-premis pengimport dan pemborong sekitar Lembah Klang bermula pertengahan tahun 2006. Aktiviti pemeriksaan ini dijalankan bagi melihat tahap pematuhan premis-premis berkenaan terhadap aspek ASB yang penting bagi memastikan produk-produk berdaftar disimpan dan diedarkan dalam keadaan yang terkawal.

National GMP Seminar 2006

Bagi menyumbang ke arah peningkatan pencapaian industri ubatan tradisional di Malaysia, Pusat APB, BPFK telah menganjurkan "NATIONAL GMP SEMINAR 2006" bertema "Meeting Current GMP Challenges" pada 19-21 Disember 2006. Objektif seminar ini adalah untuk mempertingkatkan kesedaran di kalangan industri yang terlibat dalam aktiviti pengilangan, penstoran dan pengedaran produk-produk berdaftar tentang kepentingan pengawasan kualiti sebelum dan selepas diterima oleh pengguna. Seiring dengan seminar tersebut, satu sesi khas telah diadakan untuk ketua-ketua pegawai eksekutif (CEOs) syarikat pengilang tempatan untuk membincangkan isu-isu berkaitan regulatori termasuk aspek pendaftaran produk, kawalan kualiti, aktiviti surveilans terhadap produk yang telah didaftarkan oleh PBKD serta aspek Amalan Perkilangan Baik.

Penglibatan Pusat APB Di Peringkat Antarabangsa

Penerimaan dan pengiktirafan oleh *Pharmaceutical Inspection Cooperation Scheme (PIC/S)* semakin ketara apabila Pusat ini terus diundang bersama untuk menjayakan program-program pemeriksaan ke atas negara-negara anggota dan negara-negara yang ingin menganggotai pertubuhan tersebut, contohnya: Medicine & Health product Regulatory Agency (MHRA)-United Kingdom dan Istituto Nacional des Medicamentos (INAME) –Argentina. Selain itu, Pusat ini juga telah dilantik menjadi co-rapportuer dalam penilaian permohonan negara Thailand yang berhasrat untuk menganggotai PIC/S.

HALATUJU 2007

Pengawalan Produk Kategori Bahan Aktif Farmaseutikal (API) dan Veterinar

Setakat ini, produk-produk bahan aktif farmasutikal (API) dan veterinar tidak dikawal oleh PBKD. Akan tetapi, pemeriksaan pra-pensijilan bagi tujuan pengeluaran sijil APB yang digunakan sebagai salah satu dokumen pendaftaran untuk produk yang ingin dieksport ke luar negara dilakukan oleh Pusat APB. Satu pangkalan data berhubung produk-produk API dan veterinar 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.

Kerjasama di Peringkat ASEAN dalam Bidang APB bagi Produk Farmaseutikal

Pada Mesyuarat Ke-9 ACCSQ-PPWG Februari 2005 di Filipina, 3 bidang pengawalan farmaseutikal telah dikenalpasti untuk pembangunan Sectoral Mutual Recognition Arrangements (MRAs) – iaitu 'Medicinal Product GMP Inspection, QC Testing Method and Results, dan Bioequivalence'. Sebuah badan iaitu MRA Taskforce bagi Pemeriksaan APB yang diketuai oleh Singapura dan Malaysia telah ditubuhkan untuk memantau pembangunan Sectoral MRA dalam bidang pemeriksaan APB. Beberapa mesyuarat telah diadakan bagi membincangkan tema rujukan dan menderaf garispanduan am bagi 'ASEAN MRA on GMP Inspection'yang akan ditandatangani oleh kesemua 10 negara anggota pada akhir tahun 2007.

Perlaksanaan APB Untuk Produk Tradisional dan Suplemen Kesihatan di Peringkat ASEAN

Lanjutan daripada Mesyuarat Asean Consultative Committee on Standards and Quality (ACCSQ) Traditional Medicines And Health Supplements Product Working Group (TMHS PWG) yang ke-6, Malaysia telah dilantik untuk mengetuai pengendalian perkara-perkara yang berkaitan dengan APB. Salah satu tanggungjawab APB adalah penyediaan senarai semak untuk kegunaan pihak industri dari negara-negara ASEAN dalam penilaian isu komplians APB. Malaysia juga dipertanggungjawabkan untuk mengendali dan mengkoordinasi Bengkel Teknikal, bagi mengenalpasti pendekatan yang sesuai bagi ASEAN untuk menghasilkan keperluan APB produk tradisional dan suplemen kesihatan. Bengkel Teknikal ini dijangka akan diadakan awal bulan Mei 2007 di Kuala Lumpur. Perkara yang akan dibincangkan adalah kompilasi hasil senarai semak dari negara ASEAN untuk digunakan oleh pihak industri bagi menilai potensi tahap pematuhan APB negara masing-masing serta merancang halatuju implementasi APB terhadap produk tradisional dan suplemen kesihatan. Kesimpulan perbincangan di Bengkel Teknikal akan dibentangkan pada Mesyuarat ACCSQ TMHS PWG yang ke-7 yang akan diadakan pada Julai 2007 di Brunei.

Pemeriksaan Amalan Penstoran Baik (ASB) bagi pengimport dan pemborong

Pemeriksaan Amalan Penstoran Baik ke atas pengimport dan pemborong bagi keluaran berdaftar akan dilaksanakan secara berperingkat mengikut negeri dan kategori produk. Latihan berbentuk teori dan praktikal telah dijalankan sebagai pengenalan terhadap aspek ASB oleh Cawangan Penguatkuasa Farmasi.

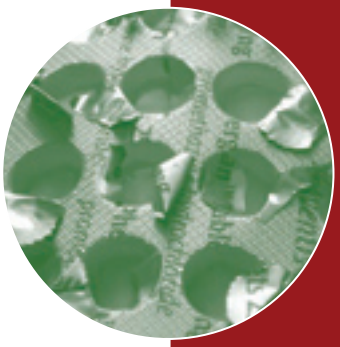
Latihan APB Farmaseutikal Bercorak Modul

Program latihan APB bercorak modul akan bermula pada Januari dan berakhir pada November 2007. Program ini dikelolakan bersama dengan MOPI.

Module 1 - International GMPs and Quality Assurance
Module 2 - GMP for Manufacturing Operations
Module 3 - Validation Principles
Module 4 - Contamination Control and Clean rooms
Module 5 - Validation Practices
Module 6 - Good Aseptic Practices and Sterile Products
Module 7 - Pharmaceutical Engineering – Facility, Equipment and Process Design
Module 8 - Solid Dose Manufacture Principles and Practices
Module 9 - Liquid and Cream Manufacture Principles and Practices

BAB 10

PUSAT PEMBANGUNAN ORGANISASI



PUSAT PEMBANGUNAN ORGANISASI

PENGENALAN:

Menyedari kepentingan komunikasi dalaman dan luaran, pihak 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 online (Quest 2) berjalan secara lancar
- Memberikan penerangan mengenai kaedah pendaftaran produk dan lain-lain berkaitan dengannya seperti status pendaftaran (samada produk farmaseutikal, tradisional dan kosmetik) serta lain-lain maklumat sepertimana dikehendaki 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 semasa ke semasa samada anjuran badan dalam negeri atau luar negara

Aktiviti 2006:

PENGURUSAN SISTEM TEKNOLOGI MAKLUMAT

Pengenalan sistem pendaftaran produk dan perlesenan secara 'on-line' oleh BPFK merupakan satu langkah ke arah kemajuan dalam bidang pengawalan farmaseutikal di Malaysia. Sejajar dengan pelaksanaan e-kerajaan, pendaftaran dan pelesenan secara 'on-line' dilihat sebagai satu usaha untuk meningkatkan kualiti perkhidmatan BPFK. Sistem pendaftaran produk secara 'on-line' ini dikenali sebagai sistem Quest2 telah berjaya dilancarkan secara rasminya pada tahun 2002 bagi memudahcara proses pendaftaran. Pada peringkat awalnya, sistem pendaftaran secara 'on-line' hanya diimplementasikan bagi pendaftaran produk kosmetik. kejayaan sistem ini kemudiannya diguna pakai bagi pendaftaran produk mengandungi racun berjadual dan produk OTC pada Julai 2003 diikuti

dengan produk tradisional pada Januari 2004. Walaubagaimanapun, sistem pendaftaran secara 'on-line' bagi produk Entiti Kimia Baru dan Bioteknologi sedang dalam perancangan untuk dilaksanakan menerusi Sistem Quest3 yang merupakan Sistem Quest2 (yang dinaik-taraf) pada masa akan datang. Pusat Pembangunan Organisasi memainkan peranan yang penting dalam memantau dan menguruskan Sistem Quest2. Segala permasalahan yang dihadapi berkenaan sistem ini sama ada oleh pemohon mahupun kakitangan BPFK disiasat dan tindakan pencegahan diambil bagi mengelakkan permasalahan yang sama daripada berulang. Sistem ini sedang dinaik taraf ke sistem Quest3 yang merupakan salah satu projek di bawah Rancangan Malaysia ke-9 (2006-2010).

PENGURUSAN LAMAN WEB BPFK

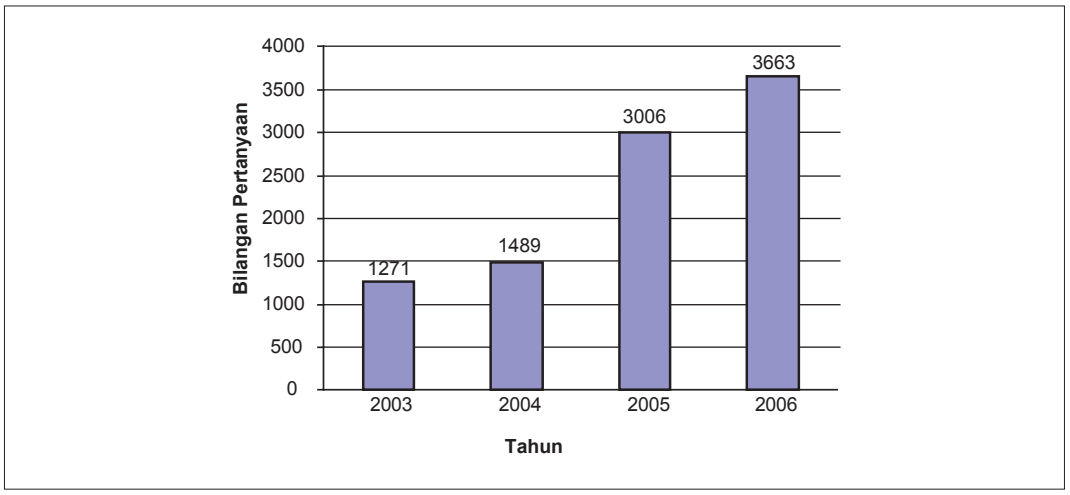
Laman web BPFK memainkan peranan yang penting dalam memastikan mutu perkhidmatan yang diberikan kerana segala urusan berkaitan permohonan pendaftaran, pelesenan dan laporan kesan advers ubat-ubatan dilakukan menerusi sistem 'on-line'.

Selain itu, berita dan maklumat terkini berkaitan dengan polisi Pihak Berkuasa Kawalan Dadah (PBKD), senarai pendaftaran produk berdaftar, keputusan PBKD dan kursus-kursus yang disediakan turut dipaparkan di laman web BPFK di www.bpfk.gov.my.

PENGURUSKAN PERTANYAAN

Pusat Pembangunan Organisasi (PPO) memainkan peranan yang penting kepada para penguna dan industri dalam memberi maklumat am. Sebanyak 3663 pertanyaan telah diterima oleh PPO pada tahun 2006 yang mana peningkatan sebanyak 21.9% telah dilihat berbanding tahun sebelumnya (Carta 23). Jenis pertanyaan termasuk pengkelasan produk, status pendaftaran produk, indikasi produk serta pertanyaan am.

Carta 23



PENERBITAN

Pada tahun 2006, 4 edisi Berita Ubat-Ubatan yang mengandungi pelbagai berita dan polisi terkini PBKD dan 1 naskah laporan tahunan BPFK telah diterbitkan untuk edaran.

PENGURUSAN SESI DIALOG DENGAN PIHAK INDUSTRI YANG BERKAITAN

BPFK bekerjasama erat dengan pihak industri tempatan, persatuan industri, pakar perubatan, ahli akademik, pengguna dan pihak-pihak yang berkaitan bagi memastikan keberkesanan sistem regulatori yang diguna pakai. Sehubungan dengan itu, pihak BPFK kerap menganjurkan mesyuarat kumpulan kerja teknikal (technical working group,TWG) dan dialog dengan pihak industri yang berkaitan berdasarkan keperluan semasa.

Sebanyak 5 sesi dialog yang telah berjaya dianjurkan sepanjang tahun 2006:

PERSATUAN/ INDUSTRI	TARIKH DIALOG
Persatuan Industri Farmaseutikal Malaysia (MOPI)	30 Mac 2006
Persatuan Farmaseutikal Malaysia (PhAMA)	13 Julai 2006
Industri Produk Tradisional :Persatuan Pengeluar Ubat Cina Malaysia (PPUCM) dan Persatuan Pengeluar-Pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA)	30 Ogos 2006
Industri Kosmetik: Persatuan Kosmetik, Dandanan Diri dan Haruman Malaysia (CFTA) dan Persatuan Pengilang Malaysia – Kumpulan Industri Kosmetik dan Dandanan Diri Malaysia (FMM MCTIG)	7 Julai 2006
Persatuan Edaran Terus Malaysia (MDDA)/ Persatuan Jualan Lansong Malaysia (DSAM)	8 Jun 2006

KURSUS DAN LATIHAN

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

Pada tahun 2006, BPFK telah menganjurkan sebanyak 51 sesi CPD yang terdiri daripada ceramah, bengkel, kelab jurnal dan seminar. Pihak 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 Colaborating Centre for Regulatory Control of Pharmaceuticals,* pihak BPFK sering menerima lawatan dari dalam dan luar negara. Pelawat dalam negara antaranya termasuklah dari pelajar universiti serta wakil-wakil agensi tempatan, manakala lawatan dari luar negara pula kerap diadakan dengan tujuan untuk menjalani latihan di institusi ini serta untuk memahami sistem regulatori yang diguna pakai di Malaysia. Urusan bagi merancang program lawatan dan sambutan pelawat-pelawat ini diuruskan oleh Pusat Pembangunan Organisasi.

Sepanjang tahun 2006, pihak BPFK telah menerima 195 kunjungan pelawat tempatan dan 68 kunjungan dari luar negara antaranya dari Bhutan, Brunei Darussalam, China, Mesir, India, Filipina, Singapura, Sri Lanka, Taiwan dan Tanzania.

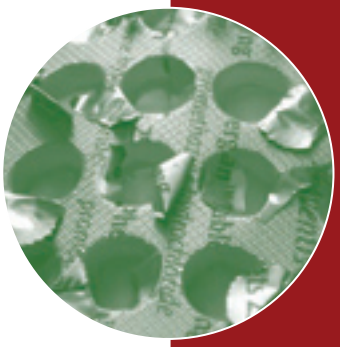
HALATUJU 2007:

Pusat Pembangunan Organisasi (PPO) sedang berusaha dalam mengimplementasikan rancangan BPFK untuk menaik taraf sistem teknologi maklumat dalam Rancangan Malaysia Ke-9 (2006-2010). Selain itu, pusat ini juga merancang untuk menambah bilangan bahan rujukan bentuk elektronik untuk kegunaan anggota BPFK. Pusat ini juga bercadang untuk menjalankan pengstrukturan semula unit-unit dalam pusat ini dengan tujuan untuk membangun serta meluaskan skop perkhidmatan sedia ada.

BAB

11

UNIT PENTADBIRAN



UNIT PENTADBIRAN

Semua hal berhubung dengan pengurusan kewangan dikendalikan oleh Unit Pentadbiran yang juga bertanggungjawab dalam pentadbiran am dan tugas-tugas lain yang bukan bidang profesional. Unit Pentadbiran memastikan bahawa semua anggota menikmati upahan gaji bulanan, tuntutan-tuntutan rasmi dibayar dalam tempoh yang ditetapkan, dan mengawal peruntukan kewangan supaya sentiasa mencukupi bagi menjamin setiap aktiviti yang dirancang boleh mencapai objektif keseluruhannya.

TINJAUAN BELANJAWAN

PEMBAYARAN

Pada tahun 2006, pembayaran upahan dan gaji untuk 200 anggota tetap dan 45 anggota sambilan berjumlah RM7,806,907.83.

KUTIPAN HASIL

Jumlah kutipan hasil untuk bayaran pendaftaran ubat-ubatan serta kosmetik, ujian makmal, lesen, perkhidmatan nasihat, jualan buku-buku garis panduan dan lain-lain bagi tahun 2006 ialah RM8,707,403.83.

KUTIPAN HASIL (RM) (TAHUN 2002 – 2006)

Tahun	Pendaftaran	Lesen	Makmal	Pemeriksaan	Bahan Cetak	Lain-Lain	JUMLAH
2002	2,002,370	454,800	745,839	24,700	28,875	55,669	3,312,253
2003	5,540,795	942,650	1,126,027	62,700	18,420	64,230	7,754,822
2004	8,837,250	1,062,200	342,882	81,295	16,055	67,874	10,407,556
2005	7,239,500	1,232,500	304,762	48,250	13,335	60,522	8,898,869
2006	6,811,250	1,351,750	386,595	79,285	7,635.50	70,888	8,707,403

PERUNTUKAN DAN PERBELANJAAN MENGURUS BPFK (TAHUN 2006)

Kod Objek	Jenis Perbelanjaan Am	Peruntukan (RM)		Perbelanjaan (RM)		Baki	
		Asal	Dipinda	Perbelanjaan Bersih	%	(RM)	%
10000	Emolumen	7,700,000	7,200,000	7,806,907.83	108.43		8.43
20000	Perkhidmatan dan Bekalan	8,688,600	9,868,600	9,601,829.63	97.29	266,770.37	2.71
30000	Aset (Harta Modal)	1,223,000	1,291,833	1,277,397.06	98.88	14,435.94	1.12
	JUMLAH	17,611,600	18,360,433	18,686,134.52	101.77	(325,701.52)	1.77

SENARAI KEDUDUKAN PERJAWATAN SEHINGGA 31 DISEMBER 2006

BIL .	NAMA JAWATAN	GRED	BIL	JAWATAN	
				DIISI	KOSONG
1.	PENGARAH	VU7	1	1	0
2.	PEGAWAI FARMASI	U54	2	1	1
3.	PEGAWAI FARMASI	U52	6	2	4
4.	PEGAWAI FARMASI	U48	33	23	10
5.	PEGAWAI FARMASI	U44	4	4	0
6.	PEGAWAI FARMASI	U41	85	75	10
7.	PEMBANTU FARMASI	U36, U32, U29	77	65	12
8.	PEGAWAI PENYELIDIKAN	Q41	25	25	0
9.	PEGAWAI SAINS	C41	1	1	0
10.	ANGGOTA SOKONGAN		62	48	14
	JUMLAH		296	245	51

JASAMU DIKENANG TAHUN 2006

Pada tahun 2006, sejumlah 21 orang anggota telah bertukar ke tempat kerja baru. Mereka yang terlibat adalah seperti berikut:

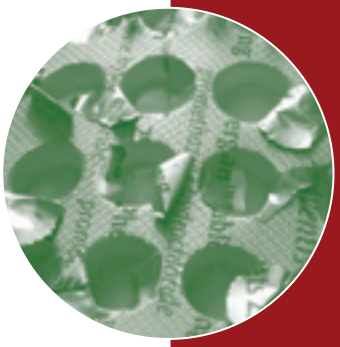
BIL	NAMA	JAWATAN	TARIKH (TEMPAT BARU)
1.	Dayang Hanani bt. Umar	Pegawai Farmasi	1.1.2006 (Terengganu)
2.	Fudziah binti Ariffin	Pegawai Farmasi	16.1.2006 (Sabah)
3.	Dr. Tajuddin bin Akasah	Pegawai Farmasi	16.1.2006 (KKM)
5.	Sulaiman bin Hj. Ahmad	Pegawai Farmasi	16.1.2006 (KKM)
4.	Abdul Aziz bin Mansor	Pegawai Farmasi	16.1.2006 (Institut Keb. Produk Asli)
6.	Norinawati binti Zainudin	Pembantu Tadbir	16.1.2006 (Hospital Sg. Petani)
7.	Norhaslina binti Hashim	Pembantu Tadbir	16.1.2006 (Kedah)
8.	Tan Chuan Ai	Pegawai Farmasi	16.2.2006 (Perlis)
9.	Rosnani bt. Mhd. Yusoff	Pembantu Tadbir	3.4.2006 (IKU)
10.	Roshayati bt. Hashim	Pembantu Tadbir	3.4.2006 (IMR)
11.	Nor Hasliza binti Ahmad	Pembantu Farmasi	19.5.2006 (Perlis)
12.	Syariza binti Saidin	Pembantu Farmasi	19.5.2006 (Perak)
13.	Zainul bin Mues	Pembandu Bermotor	19.6.2006 (JKWP)
14.	Norrehan binti Abdullah	Pegawai Farmasi	1.8.2006 (HKL)
15.	Manida a/p Pin	Pembantu Farmasi	18.9.2006 (Kedah)
16.	Rohaniah binti Che Seman	Pembantu Farmasi	18.9.2006 (N.Sembilan)
17.	Suzila binti Hamid	Pembantu Farmasi	18.9.2006 (Kelantan)
18.	Rosnah binti Dardak	Pembantu Tadbir (Kew)	15.9.2006 (KKM)
19.	Azrul Azam bin Rafie	Pembantu Tadbir (Kew)	15.9.2006 (Kelantan)
20.	Mohd. Mukhrish b. Abu Hasan	Pembantu Farmasi	2.10.2006 (Kedah)
21.	Eisah bt. A. Rahman	Pengarah, BPFK	16.12.2006 (KKM)

Kepada semua anggota yang telah meninggalkan BPFK kerana bertukar ke tempat baru kami ucapkan selamat maju jaya dalam bidang tugas baru.

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

BAB 12

PERSATUAN SURI DAN ANGGOTA WANITA PERKHIDMATAN AWAM MALAYSIA (PUSPANITA)



PERSATUAN SURI DAN ANGGOTA WANITA PERKHIDMATAN AWAM MALAYSIA (PUSPANITA)

Pada tahun 2006, biro-biro kecil PUSPANITA BPFK telah menjalankan pelbagai aktiviti sosial dan kebudayaan, kebajikan, pendidikan dan sukan. Aktiviti-aktiviti tersebut adalah:

- Majlis Jasamu Dikenang 2005
- Taklimat Breast Health Awareness Campaign & Breast Cancer Screening
- Mesyuarat Agung Tahunan Puspanita BPFK Kali Ke-18
- Ceramah Amalan Semasa Mengandung & Selepas Bersalin
- Pertandingan *Indoor Games* (congkak dan batu seremban)
- Jualan Buku Kanak-kanak & Majalah
- Jualan menjelang Pasaria
- Tadarus Al-Quran
- Majlis Jasamu Dikenang 2006
- Persembahan Koir PUSPANITA BPFK

Selain menganjurkan aktiviti-aktiviti di atas, ahli-ahli Puspanita BPFK juga telah menyertai aktiviti-aktiviti yang dianjurkan oleh cawangan kecil PUSPANITA Kementerian Kesihatan Malaysia yang lain seperti ceramah-ceramah kesihatan, seminar keterampilan diri dan pembentukan imej, hiasan dalaman, landskap halaman rumah serta pertandingan sukan seperti bola jaring, badminton, bola tampar dan bowling. Ahli PUSPANITA BPFK juga telah terpilih untuk mewakili PUSPANITA KKM ke Pertandingan Bowling Anjuran PUSPANITA Kebangsaan.

Gambar-gambar sekitar aktiviti Puspanita Cawangan BPFK

Mesyuarat Agung PUSPANITA BPFK ke -18

Pasaria Puspanita

Pertandingan *Indoor Games*

Ceramah Kesihatan & Free Skin Analysis


Majlis Khatam Quran

KELAB BPFK

Kelab BPFK yang diterajui oleh Pengarah Biro Pengawalan Farmaseutikal Kebangsaan BPFK mempunyai keahlian seramai 170 orang sehingga Disember 2006. Aktiviti Kelab BPFK sepanjang tahun 2006 lebih tertumpu kepada acara sukan.

Dua aktiviti utama yang telah dijalankan ialah pertandingan sukan dan acara sukaneka. Pertandingan sukan telah diadakan secara berperingkat pada bulan Januari, Mac, April, Mei dan Julai. Sebanyak 7 acara telah dipertandingkan iaitu dart, karom, badminton, bola tampar, ping pong, sepak takraw dan bola jaring.

Kemuncak aktiviti kelab pada tahun 2006 ialah Hari Sukaneka yang telah diadakan pada 29 Ogos 2006. Acara-acara yang telah dijalankan ialah acara berpasukan (Le tour de BPFK, Chinese Cuisine, Acid river, Genie in the bottle, Raja bersiram dan Merebut takhta), Mini Jogathon, Pertandingan Rumah Berhias dan Pertandingan Bayi Comel.








Pasukan Merah, Biru, Kuning & Hijau

Pertandingan Bayi Comel

Mini Jogathon

Pertandingan Rumah Berhias

BADAN KEBAJIKAN KAKITANGAN ISLAM BPFK (BAKKI)

Aktiviti-aktiviti yang dijalankan oleh BAKKI adalah tertumpu kepada aktiviti kebajikan dan keagamaan yang bertujuan untuk mengeratkan pergaulan dan hubungan mesra di antara kakitangan Islam. Di samping itu, BAKKI juga menguruskan tabung kebajikan melalui pungutan derma kilat untuk memberi bantuan segera kepada ahli yang terlibat dalam kemalangan, kematian dan juga untuk tujuan kebajikan yang lain.

Beberapa aktiviti yang telah dijalankan oleh BAKKI sepanjang tahun 2006 adalah:

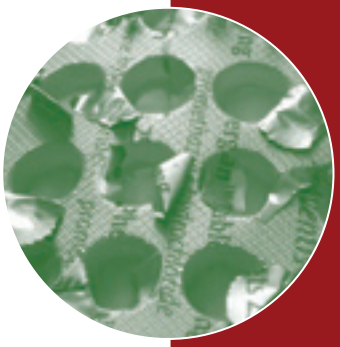
- Majlis Bacaan Surah Yassin, Tahlil Arwah & Doa Selamat
- Gotong-Royong menyediakan Bubur Lambuk pada bulan Ramadhan untuk diagihkan kepada kakitangan Islam BPFK
- Majlis Berbuka Puasa & Solat Tarawih peringkat jabatan

Aktiviti-aktiviti lain anjuran KKM yang telah disertai oleh ahli-ahli BAKKI pula ialah:

- Majlis Tilawah Al-Quran Kementerian Kesihatan Malaysia Peringkat Wilayah Persekutuan
- Forum Perdana sempena Majlis Tilawah Al-Quran Kementerian Kesihatan Malaysia Peringkat Kebangsaan yang berlangsung di Universiti Sains Malaysia, Kubang Kerian, Kelantan

BAB 13

RINGKASAN POLISI PBKD 2006



RINGKASAN POLISI PBKD 2006

MESYUARAT PBKD	POLISI
PBKD 177 (26/01/2006)	**CADANGAN KAJIAN SEMULA STATUS PENDAFTARAN PRODUK SEKIRANYA SAMPEL PRODUK YANG DIPEROLEH DARI PASARAN DIDAPATI DICAMPUR PALSU** Mesyuarat telah mengambil keputusan : i) Bersetuju dengan cadangan di mana status pendaftaran produk dibatalkan jika terdapat produk dicampurpalsu dari sampel produk yang diperolehi dari pasaran oleh cawangan penguatkuasa Farmasi, laporan dari pihak berkuasa di negara lain , laporan kesan advers ataupun aduan berkaitan dengan produk yang telah didaftarkan oleh PBKD. ii) Mesyuarat juga bersetuju dengan pendekatan menggunakan label hologram untuk mengenalpasti pengilang yang bertanggungjawab mengilang produk yang dicampurpalsu. Label hologram boleh dijadikan sebagai bukti mahkamah. **RAYUAN UNTUK MENGEKALKAN PENGGUNAAN LABEL `RACUN' DI SAMPING PENGGUNAAN 'CONTROLLED MEDICINE' PADA LABEL PRODUK** Mesyuarat tidak bersetuju terhadap rayuan yang telah dikemukakan oleh pihak industri terutamanya dari 'Multi national company' bagi rayuan untuk mengekalkan penggunaan label 'Racun' di samping penggunaan 'Controlled Medicine' pada label produk dengan alasan ianya boleh mengelirukan pesakit serta tidak menepati tujuan sebenar pindaan kepada Akta Racun 1952, Peraturan-peraturan Racun (pindaan) 2003 ini dilakukan.
PBKD 178 (23/02/2006)	**CADANGAN UNTUK MEMUATKAN AMARAN PADA LABEL DAN SISIP BUNGKUSAN PRODUK YANG MENGANDUNGI PROPOLIS (TOPIKAL) DAN ROYAL JELLY (SEMUA BENTUK)** Mesyuarat PBKD yang ke-170 telah bersetuju bahawa :- (i) Kenyataan berikut perlu dimuatkan pada label dan sisip bungkusan semua produk sediaan topikal yang mengandungi propolis: ***- Propolis may cause allergic skin reactions*** (ii) Kenyataan berikut perlu dimuatkan pada label dan sisip bungkusan semua produk yang mengandungi royal jelly:

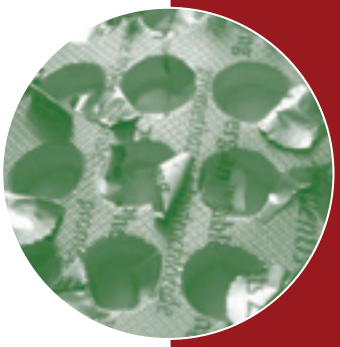
MESYUARAT PBKD	POLISI
	- ***This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals*** - ***Asthma and allergy sufferers may be at greater risks***
PBKD 179 (23/03/2006)	**SYARAT TAMBAHAN LESEN PENGILANG** Mesyuarat bersetuju supaya syarat tambahan dikenakan kepada pemohon Lesen Pengilang bagi memastikan produk yang ingin dikilang tidak dicampurpalsu. Syarat baru ini akan dimasukkan sebagai tambahan kepada syarat-syarat yang sedia ada pada Lesen Pengilang. Syarat tambahan tersebut adalah seperti berikut:- "Pengilang adalah bertanggungjawab memastikan bahawa semua produk yang dikilangkan adalah bebas dari sebarang campurpalsu (adulteration) dengan bahan-bahan yang tidak dibenarkan. Sekiranya berlaku sebarang campurpalsu, PBKD akan menarikbalik Lesen Pengilang dengan sertamerta".
PBKD 181 (29/05/2006)	**CADANGAN UNTUK MEMUATKAN AMARAN PADA LABEL DAN SISIP BUNGKUSAN PRODUK YANG MENGANDUNGI PROMETHAZINE HYDROCHLORIDE BERKAITAN DENGAN "THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION OF PROMETHAZINE HYDROCHLORIDE IN PEDIATRIC PATIENTS LESS THAN 2 YEARS".** Mesyuarat mengambil maklum dengan cadangan tersebut dan bersetuju: i) Amaran berkaitan kesan advers ini diwajibkan untuk dimuatkan pada sisip bungkusan semua keluaran (sirap, tablet, injeksi, larutan, dan linktus) yang mengandungi promethazine HCl. ii) Amaran yang perlu dimuatkan di bawah bahagian 'Warning' adalah seperti berikut: ***"This product contains promethazine hydrochloride. It should not be used in paediatric patient less than 2 years of age because of the potential for fatal respiratory depression".***
PBKD 183 (27/07/2006)	**CADANGAN UNTUK MEMUATKAN AMARAN PADA LABEL DAN SISIP BUNGKUSAN PRODUK TRADISIONAL/ SEMULAJADI YANG MENGANDUNGI BLACK COHOSH(CIMICIFUGAE RACEMOSAE) BERKAITAN DENGAN "SERIOUS HEPATIC REACTIONS"** Mesyuarat mengambil maklum mengenai cadangan tersebut dan bersetuju: a) supaya amaran berkaitan 'serious hepatic reactions' ini diwajibkan untuk dimuatkan pada label dan sisip bungkusan produk tradisional/semulajadi yang mengandungi Black Cohosh (Cimicifugae racemosae).

MESYUARAT PBKD	POLISI
	b) Amaran yang perlu dimuatkan pada label ataupun sisip bungkusan di bawah bahagian "Warning" adalah seperti berikut: ***i- Stop taking this product if signs and symptoms suggestive of liver injury develop such as tiredness, loss of appetite, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine and consult your doctor immediately.*** ***ii- Patients using herbal medicinal products should inform their doctor about it.***
PBKD 185 (29/09/2006)	**CADANGAN UNTUK MEMUATKAN AMARAN PADA LABEL DAN SISIP BUNGKUSAN PRODUK SUPLEMEN KESIHATAN ORAL YANG MENGANDUNGI ARGININE BERKAITAN DENGAN "ARGININE IS NOT RECOMMENDED FOR PATIENTS FOLLOWING A HEART ATTACK".** **Keputusan:** Mesyuarat mengambil maklum mengenai cadangan tersebut dan bersetuju supaya amaran berkaitan isu keselamatan ini diwajibkan untuk dimuatkan pada label dan sisip bungkusan produk supplemen kesihatan oral yang mengandungi Arginine. ***"Arginine is not recommended for patients following a heart attack"***
PBKD 185 (29/09/2006)	**KAJIAN SEMULA PENGKELASAN PRODUK 'EXTERNAL PERSONAL CARE (EPC)' DARI PRODUK BUKAN RACUN (OTC) KEPADA KOSMETIK.** Mesyuarat PBKD kali ke-185 telah bersetuju dengan cadangan mengkaji semula pengkelasan produk 'External Personal Care' (EPC) dari Produk Bukan Racun (OTC) kepada Kosmetik. Perubahan ini dijangka dilaksanakan mulai 1 Januari 2007.
PBKD 186 (19/10/2006)	**CADANGAN UNTUK MEMUATKAN AMARAN PADA SISIP BUNGKUSAN SEMUA PRODUK 'ACE-INHIBITORS' TERMASUK KOMBINASI** **Keputusan:** Mesyuarat mengambil maklum dan bersetuju mengenai cadangan tersebut: a) amaran berkaitan kesan advers kepada wanita hamil akibat penggunaan ACE Inhibitors dimuatkan pada sisip bungkusan semua produk yang mengandungi ACE Inhibitors sebagai bahan tunggal ataupun kombinasi dengan bahan lain. b) amaran yang perlu dimuatkan pada sisip bungkusan di bawah bahagian "Warning" dan "Use in Pregnancy" adalah seperti berikut: ***"Increased risk of birth defects, fetal and neonatal morbidity and death when used throughout pregnancy"***

MESYUARAT PBKD	POLISI
PBKD 187 (23/11/2006)	**PERLAKSANAAN KAWALAN KE ATAS PRODUK KOSMETIK DARIPADA PROSEDUR PENDAFTARAN KEPADA PROSEDUR NOTIFIKASI** **Keputusan:** Mesyuarat mengambil maklum mengenai cadangan tersebut dan bersetuju: a) Perubahan prosedur pendaftaran produk kosmetik sedia ada iaitu dari prosedur pendaftaran kepada prosedur pemberitahuan atau notifikasi (Notification). b) Melaksanakan perubahan kepada prosedur notifikasi ini mulai **1 Januari 2008.**

BAB 14

PELAWAT ANTARABANGSA DI BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK)



PELAWAT ANTARABANGSA DI BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK)

Sepanjang tahun 2006, BPFK telah menerima sebanyak 68 lawatan dari luar negara termasuk Singapura, Egypt, India, China, Taiwan, Brunei, Bhutan dan Tanzania. Delegasi yang berkunjung bagi tujuan lawatan diberi penerangan secara am tentang BPFK manakala delegasi yang melawat bagi tujuan latihan diberi kursus yang sewajarnya.

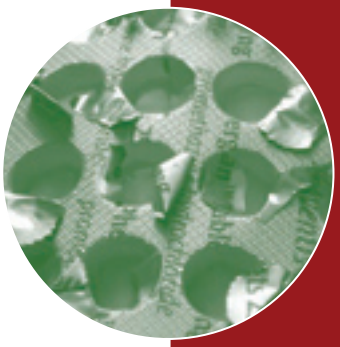
Pelawat	*Organisasi*	*Negara*	*Tarikh*	*Tujuan*
Chan Ek Huar	Diketuai oleh Pengarah + delegasi dari Pharmaceutical Purchasing for Singapore Health Services.	Singapura	27 Februari 2006	Lawatan Sambil Belajar
Choong Wei Sim				
Mabel Phng				
Hassan El Bamna	Egyptian Embassy KL	Egypt	24 April 2006	Lawatan Sambil Belajar/ Lawatan Rasmi
Ali Ibrahim Ammar	Egyptian Int. Pharm Industries Company (EIPICO)			
Adhem Shacker Helmi	Pharmco. Corp.			
Sham K. Mudgia	High Commission of India	India	28 April 2006	Lawatan Sambil Belajar/ Lawatan Rasmi
M. Roja Rani	Pharmetcil, India			
Joseph Vincent	Khandelwal Laboratories (Pvt) Ltd.			
T. Ravichandiran	Pharm Products (P) Ltd.			
J.S. Murthy	Sven Genetech Ltd., Hyderabad, India			
Asma A'tiyah PDIDPSS Ustaz Hj. Abd. Hamid	Drug & Poison Information Section, Department of Pharmaceutical Service, Ministry of Health, Brunei Darussalam.	Brunei	8 – 15 Mei 2006	Lawatan Sambil Belajar (ADR)
Dorji Thinlay (Head of DRA)	Drug Regulatory Authority, MOH, Kingdom of Bhutan	Bhutan	27 Jun – 14 Julai 2006	Lawatan Sambil Belajar
Ms. Ngawang Dema (Pharmacist)				
Mr. Sang Po				

Pelawat	*Organisasi*	*Negara*	*Tarikh*	*Tujuan*
Mr. Kyaruzi, J.J.	Tanzania FDA	Tanzania	24 – 28 Julai 2006	Lawatan Sambil Belajar (ICT)
Mr. Mtumwa Simba				
Mr. Emmanuel Mremi				
Xia Jin Wang	Beijing Drug Administration, MOH China via Malaysian Chamber of Commerce and Industry in China (MAYCHAM)	China	16 Ogos 2006	Lawatan Sambil Belajar/ Lawatan Rasmi
Li Jia Xing				
Hu Jun Ping				
Chen Jiang				
Shen Bao Zen				
Dong Ya Xin				
Zhao Qing Yuan				
Lee Yao Jiang				
David Ong				
Dr. John Lim	Health Sciences Authority, Singapore	Singapura	28-29 Ogos 2006	3rd Technical Meeting of NPCB & HSA
Mr Yee Shen Kuan				
Mrs Marie Tham				
Ms Chan Cheng Leng				
Mr Sia Chong Hock				
Ms Jessica Teo				
Ms Lim Peck Seah				

Pelawat	*Organisasi*	*Negara*	*Tarikh*	*Tujuan*
Ms. Zubaidah Hj. Mahmud	Pharmaceutical Services, Ministry of Health, Brunei Darussalam	Brunei	4 – 12 September 2006	Sangkutan
Ms. Rosni Jair				
Dr. Choi Seung Hoon	Wakil Unit Perubatan Komplementari / Alternatif, Pertubuhan Kesihatan Sedunia (WPRO, WHO) [melalui Bahagian T/CM, KKM)	Filipina	6 September 2006	Lawatan Rasmi
Lain-Tze Lee	BEL of ITRI-Pharmaceutical Technology Division	Taiwan	20 September 2006	Taiwan Bioindustrial Visiting Delegation to Malaysia
Huey-Min Lai				
Yuh-Chyun Wey				
Su-Jing Chen				
Ping-Chuan Chen	BEL of ITRI -Business Development Division			
J. Jeffrey Yang	Maywufa Biopharmaceutical Enterprise Group			
Simon Lee	Phytohealth Corporation			
David C.P. Chen	Asia Hepato Gene Co.			
Min-Wen Hsieh	Haichao Enterprise Corporation			
Jody D.C. Chen	Yeastern Biotech. Co., Ltd.			
Patti Tang Pei Li	Willy Event Consultants Co., LTD. PCO.			
Mindin Lin	Vita Genomics, Inc			
Sherine Helmy, Dr.	Egyptian Pharmaceuticals Export Council	Egypt	3 November 2006	Lawatan Sambil Belajar/ Lawatan Rasmi

BAB 15

RANCANGAN MASA HADAPAN



RANCANGAN MASA HADAPAN

Dalam usaha penambahbaikan, Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah merancang untuk melaksanakan beberapa perkara seperti berikut:

Pendaftaran Produk Veterinar Dan Bahan Aktif Farmaseutikal (API)

Pada tahun 2006, BPFK telah meneruskan usaha dalam persediaan untuk pendaftaran produk veterinar dan bahan aktif farmaseutikal. Apabila dilaksanakan kelak ianya masing-masing merupakan fasa kelima dan keenam keseluruhan fasa pendaftaran produk oleh BPFK.

Kajian Pendaftaran Produk Entiti Kimia Baru dan Bioteknologi

Dalam aspek pendaftaran on-line, produk jenis entiti kimia baru dan bioteknologi sedang dalam peringkat kajian pelaksanaannya. Selain itu,usaha juga dijalankan dalam mengintegrasi modul pendaftaran produk, pelesenan premis, ujian analisa, surveilans, pemantauan kesan advers dan penyebaran maklumat untuk penambahbaikan 'networking'. Quest 2 sedang dinaiktaraf kepada Quest 3 di bawah Pelan Malaysia ke-9 (2006-2010)

Kualiti, Keselamatan dan Efikasi

Sistem regulatori yang sekarang ini berfokus pada kualiti, keselamatan dan efikasi produk farmaseutikal akan diperkasakan lagi melalui:

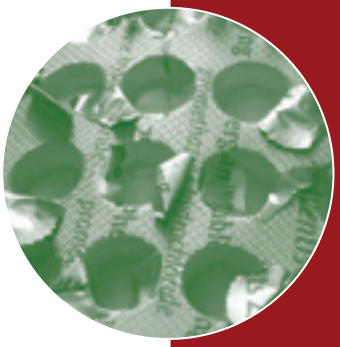
- Pemantapan kawalan kualiti di kalangan pengilang produk semula jadi (tradisional)
- Peningkatan kepakaran dalam bidang-bidang khusus seperti bioteknologi
- Pemeriksaan premis kajian klinikal
- Pelesenan premis pengeluaran produk plasma dan darah

Pensijilan ISO 17025

Dalam aspek kualiti pula, BPFK yang telah mendapat pensijilan MS ISO 9001:2000 sedang meneruskan usaha untuk mendapatkan pensijilan ISO 17025 bagi Pusat Kawalan Kualiti. Buat permulaan ini, bidang yang difokus ialah dalam pengujian ubat –ubatan tradisional. Setakat ini, Pusat Kawalan Kualiti telah menganjurkan sesi Latihan Audit Dalaman Makmal ISO 17025 yang melibatkan semua pegawai di Pusat Kawalan Kualiti pada 2-3 November 2006.

CHAPTER 1

VISION, MISSION, OBJECTIVE, STRATEGY



VISION, MISSION, OBJECTIVE, STRATEGY

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

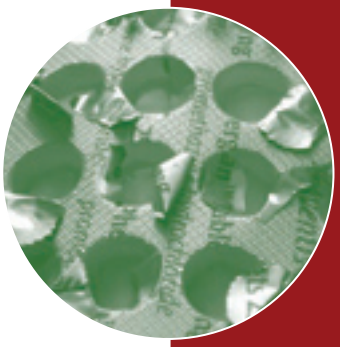
To ensure that therapeutic substances approved for the local market are safe, effective and of quality and also to ensure that cosmetic products approved are safe and of quality.

Strategy

- To ensure organizational 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 a working environment conducive for the personnel to work as a team with a caring attitude whilst discharging their duties in a professional manner

CHAPTER 2

CLIENTS' CHARTER



CLIENTS' CHARTER

THE OBLIGATION OF THE NATIONAL PHARMACEUTICAL CONTROL BUREAU

Exclusively targeted for clients who deal with NPCB.

1 Facilities for Clients

- Every client shall receive the appropriate service.
- Every client who requires immediate attention shall be served immediately.

2 Standard of Service

- Every client shall be treated with courtesy, understanding, respect and sincerity.
- Every client shall be given the best possible professional service.

3 Information Service

- Every client shall be given explanation and advice on the services provided.

4 Product Registration

- To ensure the safety, efficacy and quality of all registered pharmaceutical products and the safety and quality of registered cosmetic products.
- All applications shall be evaluated fairly and treated with impartiality in accordance with relevant regulations.
- All documents forwarded by clients shall be kept in a secure and organised manner.

5 Quality Control

- All laboratory tests shall be carried out fairly and impartially in accordance with the reference regulations and procedures.

6 Enforcement and Compliance

- Every enforcement action on any offence under the law shall be carried out fairly and impartially without influence from whatsoever vested interest and prejudice.
- Ever ready to co-operate with other enforcement agencies in matters related to drug enforcement.

EVERY COMPLETE APPLICATION SHALL BE PROCESSED IN ACCORDANCE TO THE FOLLOWING TIME-FRAME

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 Presciption Drugs	6 months
Cosmetics	1 months

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

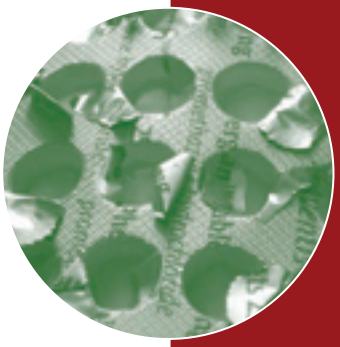
CLIENT'S OBLIGATION

To enable this charter to be implemented effectively, clients are obliged to fulfil the following:

- Comply with the requirements or the relevant legislation and regulations.
- Use the facilities provided responsibly.

CHAPTER 3

HIGHLIGHTS OF ACHIEVEMENTS IN 2006



HIGHLIGHTS OF ACHIEVEMENTS IN 2006

i. QUEST 2 system for on-line registration of pharmaceutical and traditional medicines has successfully entered its fourth and third year of implementation respectively. QUEST 2 system has been further enhanced with additional new modules for application of product variation and appeals.

ii. Licensing of cosmetic manufacturers, importers and wholesalers have been put in place. Emphasis was given to technical guidance sessions to assist the cosmetic industry.

iii. Certification by SIRIM for the quality management system based on MS ISO 9001 version 2000 was successfully maintained.

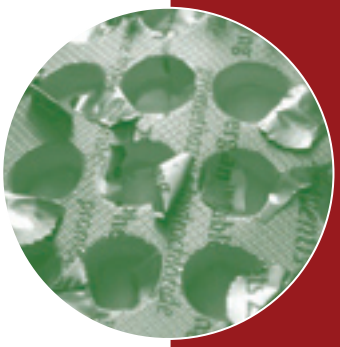
iv. Several new guidelines to facilitate product registration were revised and developed by the Technical Working Groups involving the NPCB and relevant industry. The adopted documents are made available in the NPCB website (www.bpfk.gov.my).

v. The NPCB continues to play an active role in the harmonization efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and Traditional Medicines and Health Supplements Products 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. The NPCB has also participated in other international consultation as well as Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries.

iv. Malaysia became the host for the Meeting of ASEAN Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP) in Kuching, Sarawak. The NPCB was the leader in organizing this meeting which was held on May 2006. A workshop on the implementation of Compulsory Licensing to improve access to Anti Retrovirals (ARVs) had been conducted with technical assistance from the World Health Organization (WHO). An ASEAN Workshop for DRA to introduce Fast Track registration System scheduled for August 2006 will also be hosted by Malaysia with technical support from the WHO.

CHAPTER 4

NPCB ACTIVITIES 2006



NPCB ACTIVITIES 2006

The Activities of NPCB are as follows:-

- To implement the drug and cosmetic registration scheme through evaluation of technical data, laboratory analysis, research and information received from international agencies.
- To carry out analytical, pharmaceutical, microbiological, pharmacological and toxicological tests to determine quality, efficacy and safety of such products and to determine quality and safety of cosmetic.
- To implement the regulatory scheme on quality of pharmaceutical products in the market through random sampling and carrying out analytical tests.
- To implement the licensing scheme for pharmaceutical manufacturers, importers and wholesalers including a licensing scheme to regulate the import of products for clinical trials.
- To encourage and assist local pharmaceutical manufacturers to upgrade manufacturing standards to levels equivalent to the requirements of Good Manufacturing Practice as recommended by the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the World Health Organisation (WHO).
- To manage the Adverse Drug Reaction Monitoring Program and participate in the WHO International Adverse Drug Reaction Monitoring Program.
- To manage product recalls for registered product which are found to be substandard or unsafe for consumers.
- To manage the collection and disseminations of drug information
- To carry out research on methodology and basic research for the purpose of evaluating quality, efficacy and safety of drugs/cosmetics.
- To establish a reference standards system for use in this country and also for neighbouring countries through a scheme of cooperation in the field of pharmaceutical among ASEAN countries.
- To carry out training for pharmaceutical officers, other professional officers and other semi-professional officers who are placed in this institution through local training scheme or international co-operation schemes.

Each centre carries out specific activities as follows:

Centre for Product Registration

- Receives and evaluates applications for registration of pharmaceutical, traditional medicines & cosmetic products
- Serves as a secretariat to the DCA Meeting, processing of the decisions and assuring Product Registration Certificates
- Processing applications for the Clinical Trial Import License (CTIL)
- Processing applications for Change of Registration Holders
- Evaluation of applications for Additional Indications
- Processing applications for Appeals for products which have been rejected by the DCA
- Certification of pharmaceuticals, medical devices and cosmetic products for export purpose
- Processing of application for change in particulars of registered products (before organisational restructuring)
- Processing of application for renewal of product registration (before organisation restructuring)
- Processing of application for change of manufacturing site (before organisation restructuring)

Centre for Quality Control

- Conducting quality control tests to determine quality, efficacy and safety of registered products in both the pre-and post market phases
- Research and development of methodology and analytical protocols
- Establishment of chemical and biological reference standards for use in the institution, local pharmaceutical industries and ASEAN countries
- Good Laboratory Practice Inspection of quality control laboratories in local pharmaceutical premises
- Review and evaluation of analytical protocols and validation data

Centre for Good Manufacturing Practice

- GMP inspection of premises for manufacturers, importers and wholesalers of registered products
- To conduct GMP Investigation Inspection that is relevant with quality defect on manufacturing premises if necessary

- Issuance of additional lists of registered products
- GMP Evaluation of lay-out plans for manufacturing premises for registered products
- Advisory service to relevant industries on technical aspects regarding GMP, Good Storage Practice (GSP) and licensing
- Provide training course for pharmaceutical and traditional medicines industries and WHO fellows
- Technical discussion with pharmaceutical industries to upgrade the GMP standard of local manufacturing premises
- Collection of information related to pharmaceutical and traditional industries
- Issuance of GMP certificates and endorsement of licence related documents

Centre for Post-Registration

I Adverse Drug Reaction Monitoring

- Detection and monitoring of ADR
- Identifying measures to reduce incidents of adverse reactions
- Promoting reporting of ADR
- Participation in WHO's International ADR Monitoring Programme

II Post Market Surveillance and Product Complaints

- Sample collection and testing
- Monitoring of labels and package inserts
- Punitive action – product recall, Warning
- Monitoring of the DCA Directives

III The Actives Carried Out After Organisation Restructuring:

- Processing of applications for change in particulars of registration products
- Processing of applications for renewal of product registration
- Processing of applications for change of manufacturing site

Centre for Organisational Development

I Information and Communication

- Disseminate information or give explanation to the public regarding process of registration, information on registered products and classification of products
- Maintain and update the website of NPCB
- Manage the drug information collection and dissemination system – publication of newsletters 'Berita Ubat-ubatan'
- Provide library service and reference books for the use of the officers of NPCB

II Human Resource

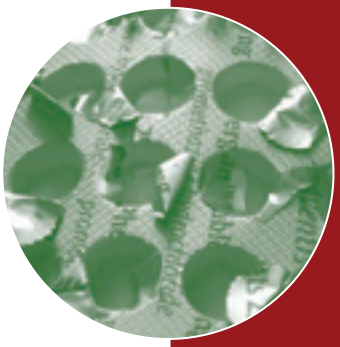
- Manage the programme for attachment training of Provisionally Registered Pharmacist (PRP) and visitors from overseas
- Handling of programme and briefing for visitors to NPCB
- Handling of Continuous Professional Development programmes for staffs of NPCB

III Quality System Management

- Manage the quality system of NPCB – to ensure all documents pertaining to NPCB are safe and conform to ISO guidelines/requirement

CHAPTER 5

DRUG CONTROL AUTHORITY



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, effective 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 30,189 applications for product registration were tabled to the DCA in the year 2006. After a thorough review on each submission, 29,832 products were registered by December 2006. Of these, 41 products approved are categorised as New Chemical Entities (NCEs) and 19 Biotechnology products.

Biotechnology products approved in the year 2006 are as follows:

	Product Name
1	Immunine 600 iu injection
2	Avaxim 80 u Pedriatric suspension for injection
3	Tritanrix HB+ HIB vaccine
4	Apidra 100u/ml, solution for inj in vial Apidra 100u/ml, 3 ml Cartridges for Optipen- solution for injection in cartridge. Apidra 100u/ml Optiset - solution for injection in pre filled pen.
5	Recormon Prefilled Syringes 30,000iu/ 0.6ml
6	Amevive 15 mg powder for injection
7	Rotarix Rotavirus vaccine
8	Mabcampath 30 mg/ml, Concentrate for solution for Infusion
9	Immunate 50 iu / ml powder for injection Immunate 100 iu / ml powder for injection
10	Levemir Penfill 100 u/ml, 3 ml Levemir Flexpen 100 u/ml, 3 ml
11	INFLUVAC 2004/2005 Suspension for Injection
12	Xolair 150 mg powder & solvent for Injection
13	Gardasil Suspension for Injection
14	PROQUAD (Measles, Mumps,Rubella and Varicella (Oka/Merck) Virus Vaccine Live, MSD) LYOPHILIZED VACCINE
15	Raptiva Powder and Solvent for solution for injection

NCEs approved in the year 2006 are as follows :

	Product Name
1	Bifril 30
2	Ebixa film coated tablet 10 mg
3	Relenza Rotadisk 5 mg
4	Tamiflu oral suspension 12 mg /ml
5	Bonviva 2.5 mg film coated Tablet
6	Bondronat vial 6 mg/6 ml
7	Pletaal 50 mg Pletaal 100 mg tablet
8	Baraclude Tablet 0.5 mg Baraclude Tablet 1 mg Baraclude oral solution 0.05 mg / ml
9	Tri-Luma Cream
10	Caduet film-coated tablet 5 mg/10 mg Caduet film-coated tablet 5 mg/20 mg Caduet film-coated tablet 5 mg/40 mg Caduet film-coated tablet 5 mg/80 mg Caduet film-coated tablet 10 mg/10 mg Caduet film-coated tablet 10 mg/20 mg Caduet film-coated tablet 10 mg/40 mg Caduet film-coated tablet 10 mg/80 mg
11	Zymar 0.3% Eye Drop
12	Chirocaine 2.5 mg / ml Injection Chirocaine 5.0 mg / ml Injection Chirocaine 7.5 mg / ml Injection
13	Nebido 1000 mg for Injection
14	Reyataz Capsule 100 mg Reyataz Capsule 150 mg Reyataz Capsule 200 mg
15	Suboxone 2 mg sublingual tablet Suboxone 8 mg sublingual tablet
16	Fosamax Plus Tablet
17	Mictonorm Tablet
18	Zaditen Eye Drop
19	Angelic Tablets
20	Ketesse 25 mg Film-coated Tablet
21	Exjade 125 mg Dispersible Tablet Exjade 250 mg Dispersible Tablet Exjade 500 mg Dispersible Tablet
22	Tygacil (Tigecycline) 50mg Lyophilized Powder for Intravenous Infusion
23	Ixel 25 mg Hard Capsule Ixel 50 mg Hard Capsule

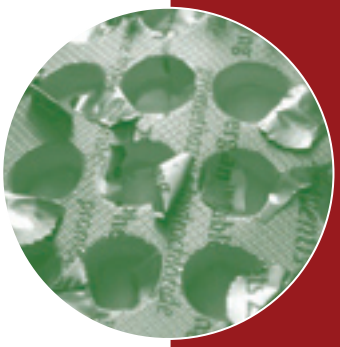
A total of 234 product applications which included 25 prescription drugs, 32 Over-The-Counter (OTC) products, 124 traditional medicines and 53 cosmetic products were rejected by the DCA for various reasons. The DCA cancelled the registration of 18 products, consisting of 4 prescription drugs due to banned dosage form, 5 cosmetic product registrations due to reasons of adulteration and 9 traditional products for adulteration, revocation of registration holder's license and cancellation of agreement for contract manufacturing.

A total of 2363 applications for various licenses were reviewed by the DCA and a total of 446 manufacturer's License, 1016 wholesaler's License and 901 importer's License were approved. However, 8 manufacturing licenses were revoked by the DCA following reports of poor compliance to Good Manufacturing Practice last year.

The DCA also approved 277 Clinical Trial Import Licenses (CTIL) for the purpose of the conduct of Phase 4 trials in Malaysia.

CHAPTER 6

CENTRE FOR PRODUCT REGISTRATION



CENTRE FOR PRODUCT REGISTRATION

Introduction:

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

The application for registration for all product categories with the exception of New Chemical Entities (NCEs) and Biotechnology products are done via the online system to facilitate a more convenient registration process. The data needed to be submitted for NCEs and biotechnology products is huge and thus, a manual approach would be more appropriate and practical at current time.

The registration procedure is continuously revised to ensure an optimal system for the benefit of all parties involved. This resulted in the adoption of an abridged system for the evaluation of health supplements. However, the registration procedures for all other products were maintained as it was in the previous year, 2005.

Objectives:

The objectives of the Centre for Product Registration is to ensure that all pharmaceutical products registered by the Drug Control Authority (DCA) are evaluated for quality, safety and efficacy; and all traditional medicines and cosmetic products have been evaluated for safety and quality. This centre is also responsible in providing technical and administrative support in all fields with regard to the registration process.

Activities of 2006:

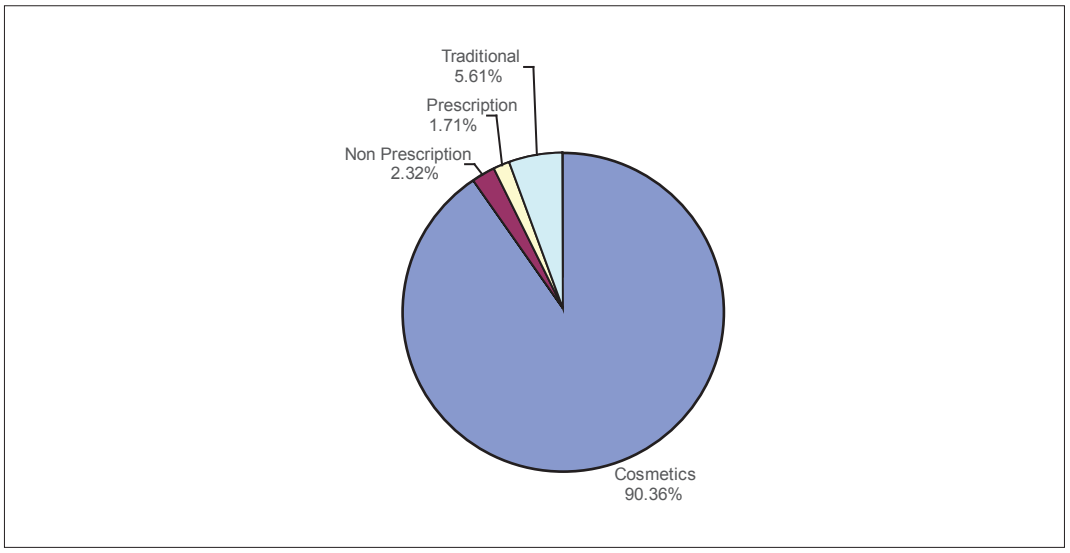
Product Registration

Since year 2001, the number of registration applications received by this centre has increased steadily. In the year 2006, a total of 27,179 applications were received, of which 90.4% were for the registration of cosmetic products. (Chart 1)

Registration Applications Received (Year 2006)

N = 27179

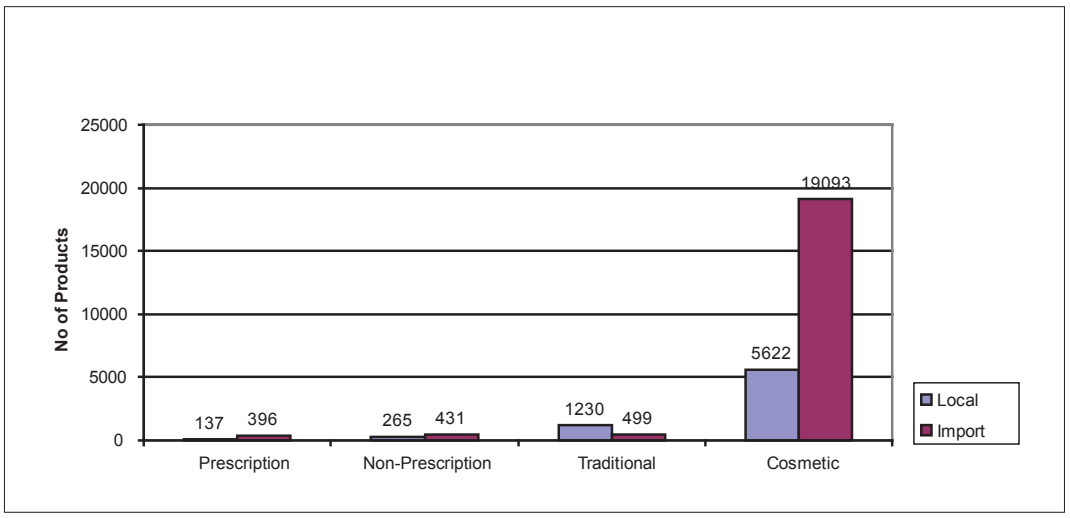
Chart 1



27,907 new registration applications were evaluated and tabled to the Drug Control Authority (DCA) for approval. As a result, 27,673 applications were approved (Chart 2) and 234 rejected due to various reasons such as failure in laboratory testing, formulation contained banned substances, incomplete information during registration, failure in Good Manufacturing Practice (GMP) and revocation of Manufacturer's License amongst others. It was noted that almost 53% of the rejected product registration applications involved traditional medicines as they did not comply to the quality standards.

Products Approved (Year 2006)

Chart 2



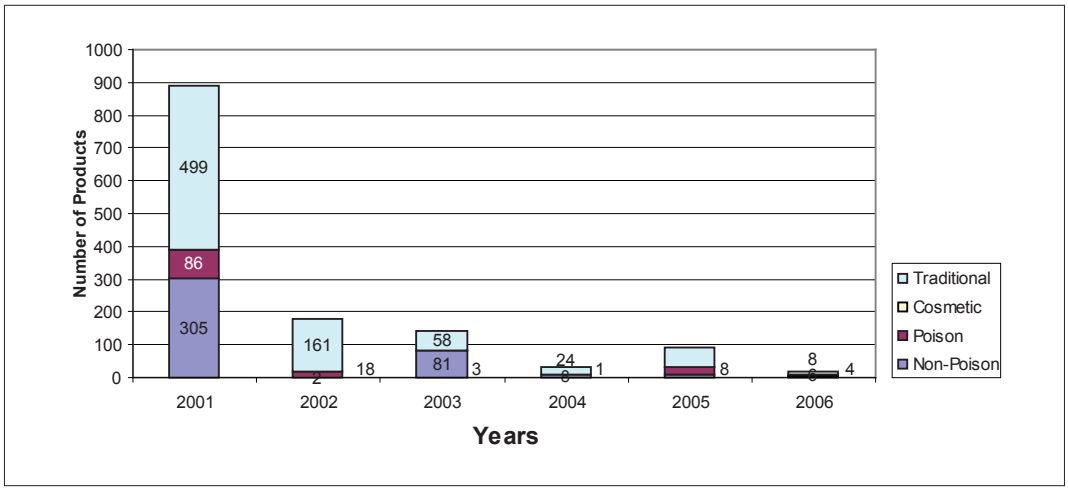
Product registrations cancelled in the year 2006 are as follows:

Number	Product Name	Registration Number
1	Trebest Plus Capsule	MAL20034665TC
2	Shang Shi Zhi Tong Gao	MAL20034419T
3	Mas Ayu Sendi Tulang Capsule	MAL05041874TC
4	Bio Gents	MAL05041928TC
5	Watermelon Frost 3gm	MAL19971244T
6	Dr's Seagar Skin Recon	MAL04120601K
7	Sri Mutiara Krim Kecantikan Malam	MAL05071157K
8	Qmax Kapsul 350gm	MAL05101709TC
9	Natural Lightening Cream	MAL05011917K
10	GP Lotion	MAL05020114K
11	Dewajah Night Cream	MAL05071145K
12	Methadot 10 Tablet	MAL05092205AC
13	Methadot 5 Tablet	MAL05092204AC
14	Methadot 40 Tablet	MAL05092206AC
15	Aseptone Dispersible Tablet 40mg	MAL20031737A
16	Fructus Sophorae Compound Pills	MAL06071200T
17	Danggui Yangxue Gao	MAL06071199T
18	Houtou Jun Tablets 250mg	MAL06081286T

The number of product registrations cancelled by the DCA has decreased steadily since year 2001. In the year 2006, only 18 product registrations were cancelled compared to a total of 890 product registrations in the year 2001(Chart 3). Except for year 2003, a comparison of a 6-year data shows that traditional product registration cancellation contributes to the highest number of product registration cancellation since 2001. For the year 2006, 4 prescription drug registrations were cancelled due to banned dosage form, 5 cosmetic product registrations due to reasons of adulteration and 9 traditional products for adulteration, revocation of registration holder's license and cancellation of agreement for contract manufacturing.

Product Registrations Cancelled (Year 2001-2006)

Chart 3



Of 27,673 product registrations approved for year 2006, almost 73.8% of the registrations were for imported products involving all product categories with the exception for traditional products where 71.1% of the traditional products were locally manufactured. Until December 2006, China, followed by the United States of America and India are the top 3 countries of import source for traditional products registered in Malaysia. The highest source of importation for cosmetic products is France followed by the United States of America and Italy, whereas the United States of America is the main country of import sources for pharmaceutical products followed by Germany and Thailand.

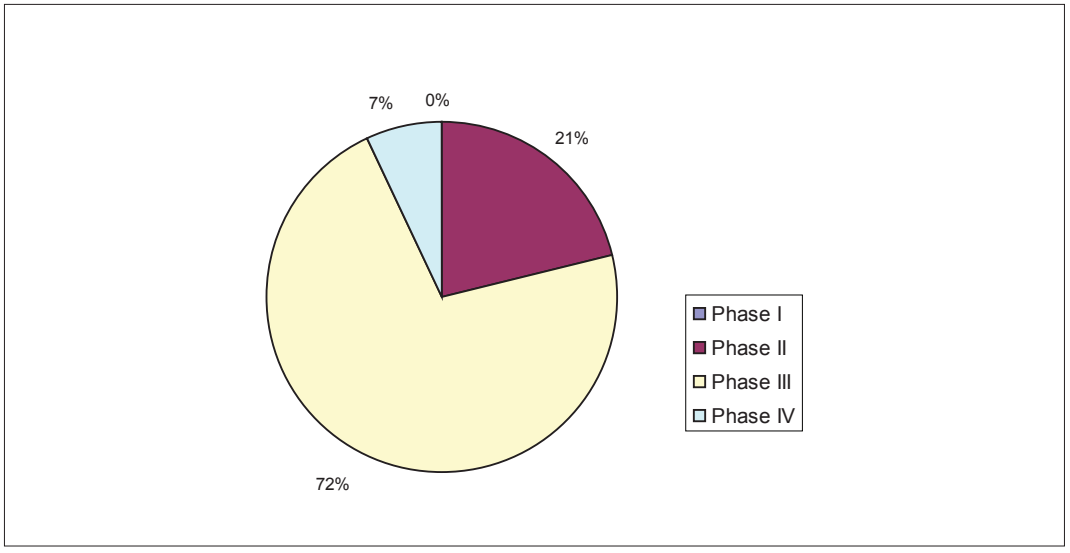
Clinical Trial Licenses

A total of 177 Clinical Trial Import Licenses (CTIL) and 4 Clinical Trial Exemptions were issued in the year 2006. Besides application for licences, 180 variation applications pertaining to additional quantity of import products, change of research sites and adoption of new trial protocols were also processed throughout the year 2006. 57 clinical trials involving various classes of drugs such as anticancer, drugs for cardiovascular events, antidiabetics, antipsychotics and antidepressants amongst others were conducted in 2006 (Chart 4 and 5).

The Clinical Trial Regulatory unit serves as a secretariat to 2 national committees namely the National Committee for Clinical Research and National Committee for Good Laboratory Practice (GLP). In 2006, 8 clinical trial facilities in Malaysia were subjected to inspection to ensure its capability to conduct clinical trials.

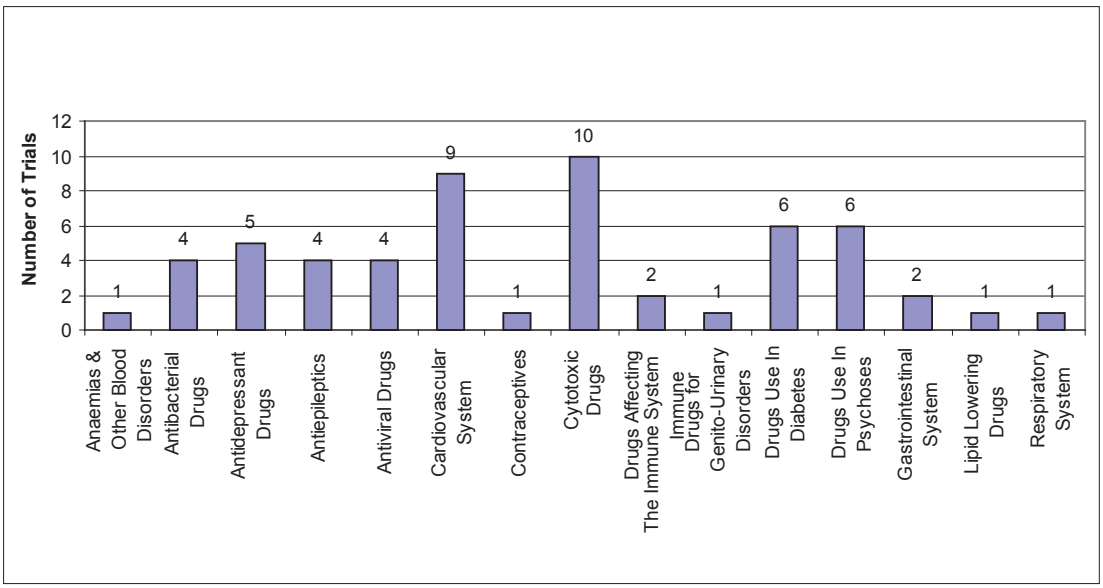
Clinical Trials Conducted (Year 2006)
N = 57

Chart 4



Application by Therapeutic Class (Year 2006)

Chart 5



Registration Process Review

The review of criteria used in the evaluation process of health supplement products was done based on a listing system that is adopted by the Therapeutic Goods Administration (TGA), Australia. According to the new evaluation criteria, part of the product information such as information on Finished Product Quality Control/Specification, Protocol Analysis/Testing Methods, Certificate of Analysis of Finished Product and Stability Data can be submitted after a product is successfully registered. However, the onus is on the registration holder to furnish the National Pharmaceutical Control Bureau (NPCB) with information of their product during post-marketing surveillance. This change has helped to expedite the evaluation and registration process of health supplement products. The timeline for registering these products has thus been shortened from 12 months to 6 months.

Future Plans for 2007:

- **Revised Cost Schedule for Laboratory Testing**

A revised cost schedule for new products analysis was decided in the 173th DCA meeting held on 1st September 2005 which was to be implemented in the year 2007. The new analytical evaluation cost for pharmaceutical and traditional products were revised.

- **Veterinary Products Registration**

The registration of veterinary medicines is scheduled to start in year 2007. NPCB is focusing on capacity and capability building for the implementation of registration and licensing system for veterinary medicines and intends to conduct awareness programmes for the local industry on registration of veterinary medicines.

- **Reclassification of External Personal Care (EPC) Products As Cosmetics**

The DCA at its 185th meeting, has agreed to reclassify the external personal care (EPC) products (anti acne, anti bacterial, oral care, anti dandruff and skin protectants) as cosmetics to be in line with the categorisation of these products in other ASEAN countries, the EU and the USA as well as in line with the implementation of ASEAN Free Trade Area Agreement (AFTA). The reclassification will be effective from 1st January 2007.

- **Restructuring of Centre for Product Registration**

Due to restructuring activities in NPCB, the Clinical Trial Regulatory Unit which was initially under the Investigational & New Drug Section in the Centre for Product Registration would be placed under the Centre for Compliance and Licensing starting year 2007.

Notable 2006 New approvals

1. **Relenza Rotadisk (Zanamivir)** is a neuraminidase inhibitor in the form of a powder that is inhaled from a breath-activated plastic device. It is used to treat and prevent influenza A and B in adults and children aged 5 years and above. Although vaccination is the primary method of preventing and controlling influenza, Relenza can be used in a pandemic with a strain that is not included in the annual vaccine or when vaccine is unavailable.

2. **Tamiflu oral suspension (Oseltamivir)** is a neuraminidase inhibitor which can be used to treat influenza in adults and children from the ages 1 year and above. The capsule was previously approved to treat and prevent influenza in adults. The suspension is also used for post exposure prevention in adults and adolescents 13 years of age or older following contact with a clinically diagnosed influenza case.

3. **Baraclude Tablet (Entecavir)** is an antiviral used to treat chronic Hepatitis B virus (HBV) infection in adults. Baraclude is used after one year of treatment in nucleoside-treatment-naïve and lamivudine-resistant adult patients with HBeAg-positve or HbeAg-negative chronic HBV infection with compensated liver disease and in adult patients with HIV/HBV co-infection who have received prior lamivudine therapy.

4. **Suboxone Sublingual Tablets (Buprenorphine and Naloxone)** is a combination therapy for use in opioid drug dependent people as a substitution treatment. Buprenorphine is a partial opioid agonist while naloxone is an opioid antagonist. Naloxone deters people from dissolving the tablet and injecting it. When Suboxone is placed under the tongue, very little naloxone is absorbed into the blood stream so the patient only feels the effects of buprenorphine

5. **Angeliq (Estradiol and Drosperinone)** is a combination tablet used as a hormone replacement therapy (HRT) to treat the climacteric syndrome in postmenopausal women as well as to prevent postmenopausal osteoporosis. Most HRTs consist of estrogen and progestin. In this preparation, the progestin (drosperinone) closely resembles and acts like the hormone progesterone produced in the human body.

6. **Exjade (Deferasirox)** is a dispersible tablet used to treat chronic iron overload due to blood transfusions (tranfusional haemosiderosis) in adults and paediatrics aged 2 years and above. It is an iron-chelating agent which is dosed orally once daily. Previous iron chelating agents such as deferoxamine were administered parenteral.

7. **Ixel (Milnacipran)** is an antidepressant capsule used to treat depressive episodes in adults. Milnacipran is the first of a new class of agents called norepinephrine serotonin reuptake inhibitors (NSRI) which increases the level of norepinephrine more than serotonin.

8. **Gardasil** is a vaccine used to prevent diseases such as cervical cancer, genital warts and precancerous or dysplastic lesions caused by Human Papillomavirus (HPV) types 6, 11, 16 and 18.

9. **Rotarix vaccine (Live attenuated human rotavirus)** is an oral vaccine used to prevent gastro-enteritis (diarrhoea and vomiting) in infants caused by the rotavirus. Rotarix is given as two doses. The suspension is given directly to the mouth of the baby using an oral syringe provided. Rotarix can be given at the same time as other vaccinations.

10. **Xolair (omalizumab)** is the first humanised therapeutic antibody used for the treatment of adults and adolesecents aged 12 years who have moderate to severe persistent allergic asthma in which symptoms are inadequately controlled with inhaled corticosteroids. Xolair is an injectable that blocks the immunoglobulin E (IgE) which is an underlying cause of allergic asthma.

11. **ProQuad lyophilized vaccine** is a combination vaccine to provide simultaneous vaccination against measles, mumps, rubella and varicella in individuals 12 months to 12 years of age. ProQuad is a suspension given by subcutaneous injection. The active substances are the attenuated viruses for the measles, mumps, rubella and varicella.

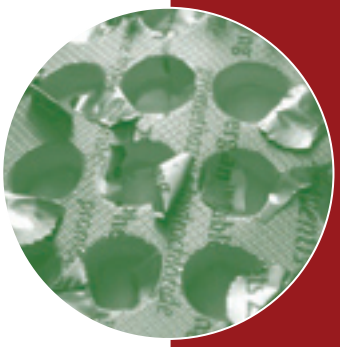
12. **Amevive (Alefacept)** is an injectable used to treat moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. It is the first biologic approved for treatment of psoriasis. It works by simultaneously blocking and reducing the cellular component of the immune system which is thought to play a role in the disease process.

13. **Avaxim 80U** is the paediatric formulation for active immunisation against infection caused by hepatitis A virus in children aged from 12 months to 15 years inclusive who are at risk either contaminating or spreading infection or of a life-threatening disease if infected.

14. **Mabcampath (Alemtuzumab)** is administered through infusion to treat Chronic Lymphocytic Leukaemia in patients who have been treated with alkylating agents and who have failed to achieve a complete or partial response or achieved on a short remission following fludarabine phosphate therapy. It is a recombinant DNA-derived humanized monoclonal antibody which targets CD-52, a protein present on mature lymphocytes.

CHAPTER 7

CENTRE FOR QUALITY CONTROL



CENTRE FOR QUALITY CONTROL

Introduction:

The quality control process is managed by the Centre for Quality Control based on the pharmacopoeia specifications, internal procedures and using approved protocol analysis. In certain situations, specifications prepared by the manufacturer may be used. Similar standards are used for marketed registered sample adherence for pharmaceutical, traditional and cosmetic samples. Thus, products must abide to good quality measures which include document evaluation and sample testing prior to registration and thereafter marketed.

Products tested are for the purpose of registration, surveillance of registered products in the market, registered product complaints and sample products from the Pharmacy Enforcement Branch. Pharmaceutical product registration starts with protocol of analysis evaluation, which is followed by laboratory testing on product samples. For parenteral products, applicants are required to submit protocol of analysis and validation data only, whereas for traditional products, only laboratory testing is required.

Objectives:

This centre aims to ensure that quality and safety aspects of all therapeutic and cosmetic products found in the local market are monitored through:

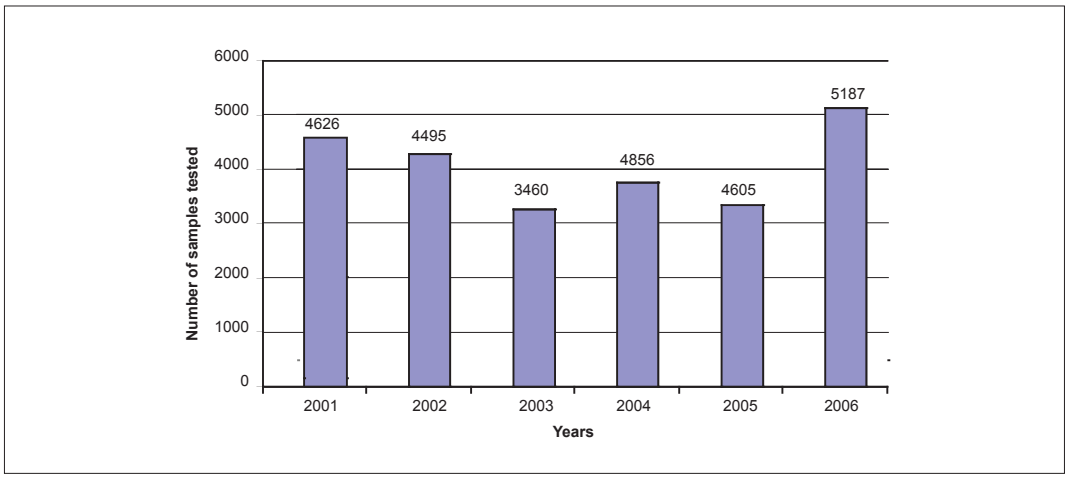
- Chemical and biological tests in compliance with international standard procedures
- Establishment and expanding of test and research methodologies
- Establishment of chemical and biological reference standards for institution and local pharmaceutical industry use
- Active involvement in collaboration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

Activities of 2006:

Throughout the year 2006, a total of 5222 samples were received for testing. From the total of 5187 samples tested in the year 2006, 2196 were registration samples and 2690 surveillance samples. There was an increase from 4605 samples in year 2005 to 5187 samples in year 2006 (Chart 6)

Total Samples Tested (Year 2001-2006)

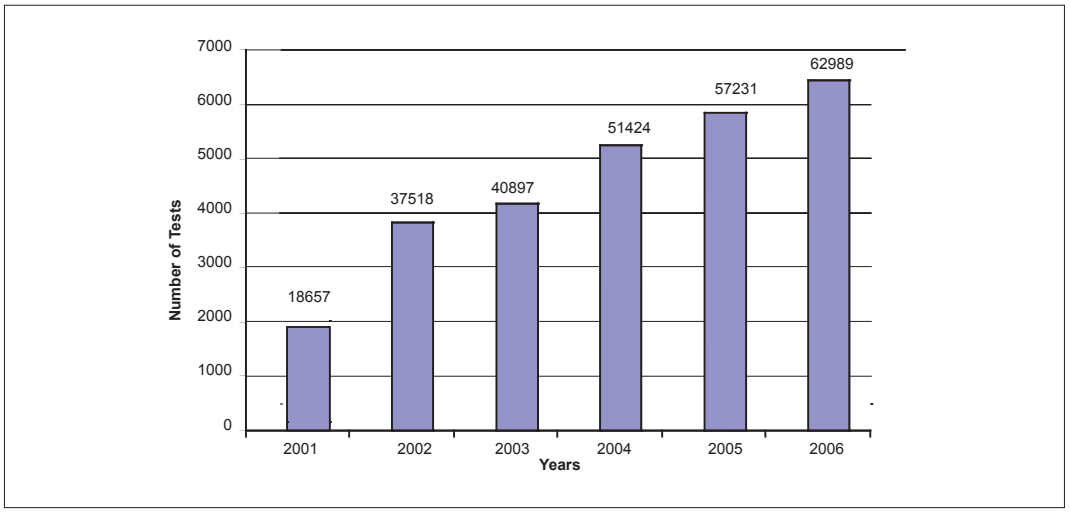
Chart 6



There was a 1.3% increase from 57,231 tests done in 2005 to 57,971 tests done in the year 2006; a record high figure for number of tests done in a year (Chart 7)

Number of Tests Done (Year 2001-2006)

Chart 7

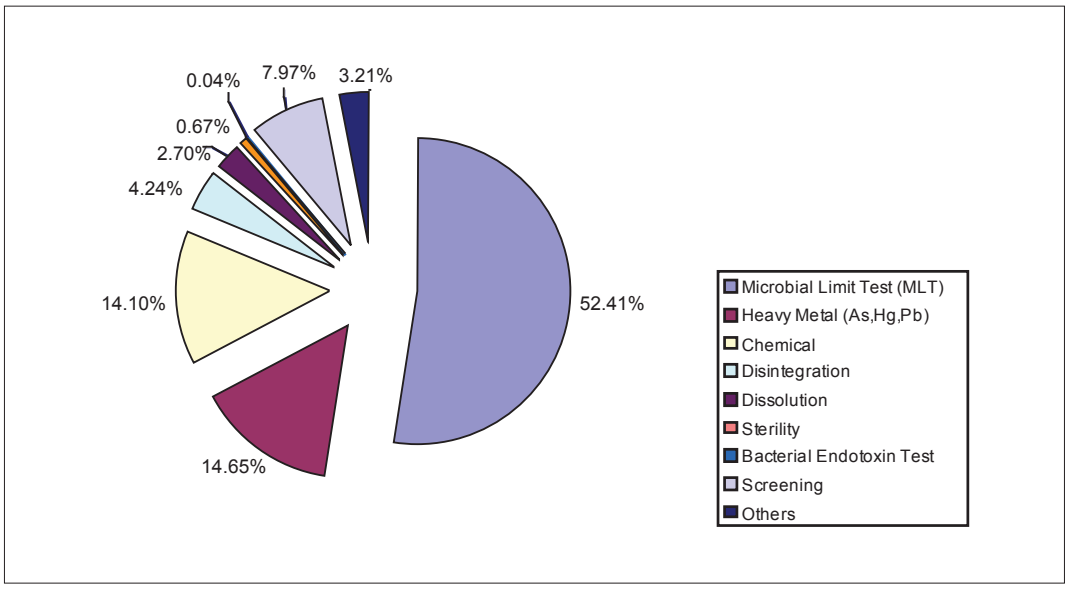


Most of the tests done are microbial limit test (MLT) (52.4%), followed by heavy metals test (As, Hg, Pb, Cd) (14.6%) and chemical tests (14.1%). Other tests carried out include disintegration, dissolution, sterility, bacterial endotoxin, toxicity, biochemical, biological, particulate matter and antibiotic assay (Chart 8)

There are cases where the tests done did not comply with specifications, thus were reported as failed samples. The number of failed samples in 2006 amounted to 465 samples, which was 8.96% of the total number of samples tested. Most of the failed samples were traditional samples that totaled to 280 samples (62.4%) out of the total failed samples, whereas 16.5% were pharmaceutical products. However, the total number of failed samples only showed a slight increase of 3.6% as compared to the previous year.

Tests Done (Year 2006)
N = 62989

Chart 8



Adulterants in Traditional Medicine

For the year 2006, 339 traditional samples that were tested for the purpose of adulteration screening comprised of 154 enforcement samples, 109 surveillance samples (including ADR reports) and 76 registration samples. 936 tests were done in effort to monitor registration and surveillance samples for the presence of adulterants in traditional medicines for 4 categories of products with the following indications:

- for men's health
- for joint and muscular pains
- for the reduction / control of body weight
- for cough and cold

A high percentage of the tests done were for the indication of men's health which amounted to the highest adulteration cases in traditional medicine. This test screens for the presence of sildenafil, tadalafil, vardenafil and/or the analog for sildenafil (acetyldenafil). On the contrary, antihypertensives, antidiuretics, antifungal, antidiabetic, beta-agonist, amphetamine and hormones were rarely used as adulterants.

Most of the enforcement and surveillance samples tested were found to contain steroids, NSAIDS and analgesic, antihistamine, caffeine as well as sildenafil, tadalafil, acetildenafil and hydroxyhomosildenafil. For registration samples, no such substances were found except for caffeine (chart 9).

Reference Standards

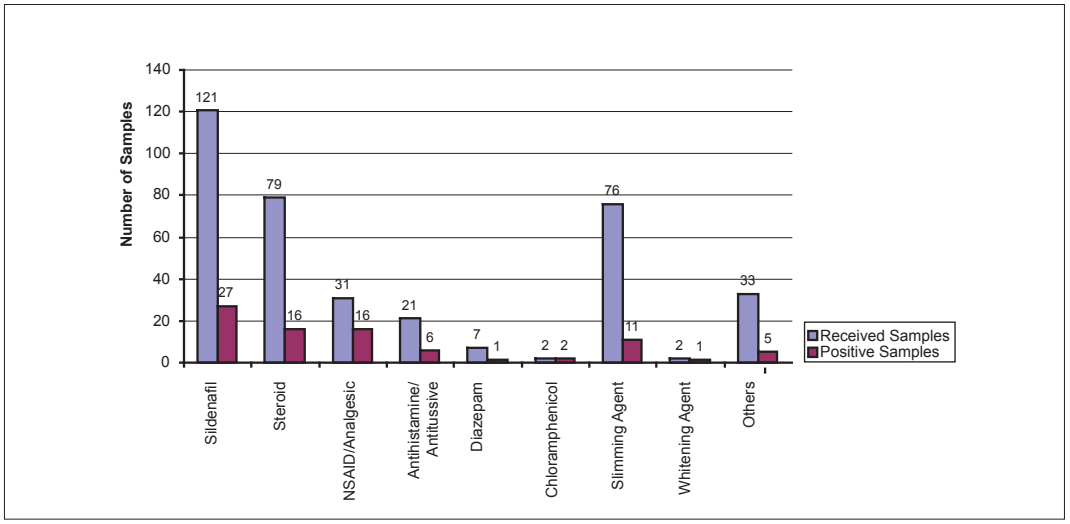
In year 2006, a total of 126 vials of ASEAN reference standards worth RM 18,900.00 and 479 vials of NPCB reference standards worth RM 47,900.00 were sold to the local pharmaceutical industries and abroad. The grand total amounted to RM 66,800.00 with an increase of RM13,750.00 from the year 2005; a record high total of collection in a period of six years (Chart 10).

This centre provides reference standards to various government departments such as the Chemistry Department, Sarawak Medicine Laboratory and Store, state Pharmacy Enforcement branches and other ASEAN regulatory bodies for free. In 2006, 1441 vials were supplied to the above mentioned departments; of which 614 vials are ASEAN reference standards while the balance are NPCB reference standards (Chart 11)

Centre for Quality Control is also actively involved in the collaborative project among ASEAN countries under the auspices of the World Health Organisation (WHO) which include production and utilization of ASEAN reference standards (ARS) along with laboratory testing of ARS. Tests for collaborative study are also conducted on raw materials received from ASEAN countries.

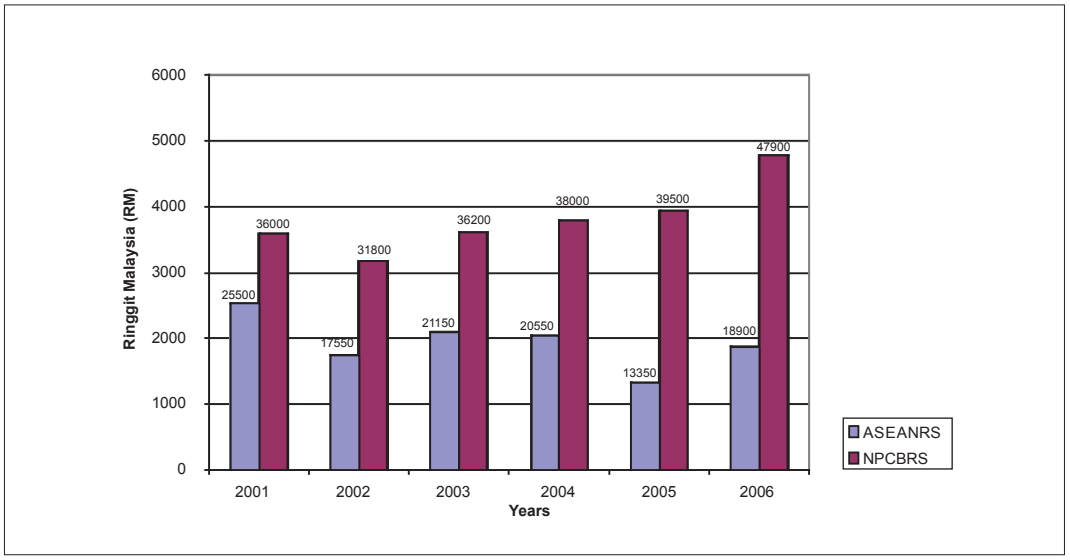
Number of Samples Screened and Detected Positive For Adulterants (Year 2006)

Chart 9



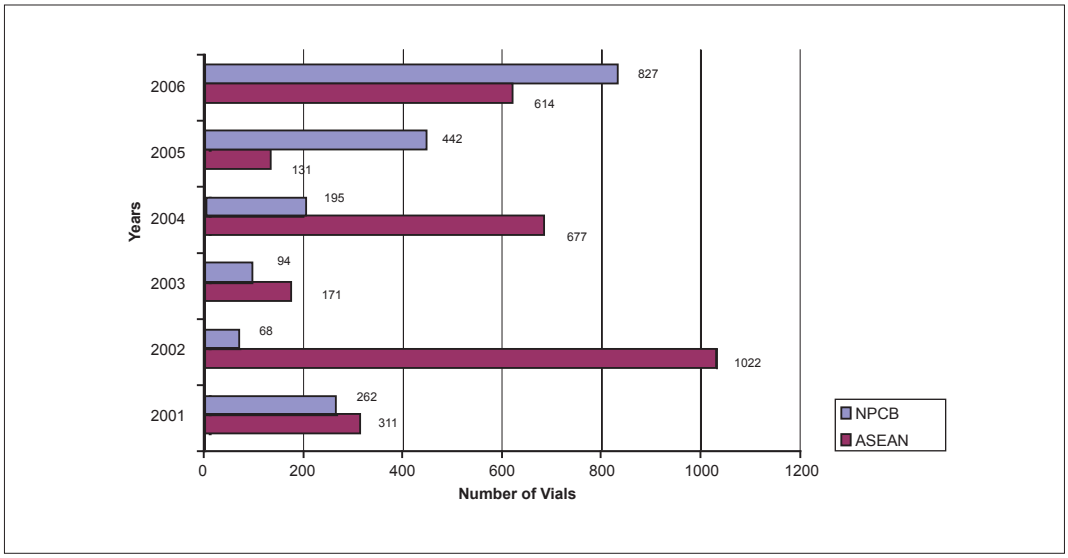
Revenue From Sales of Reference Standards (Year 2001-2006)

Chart 10



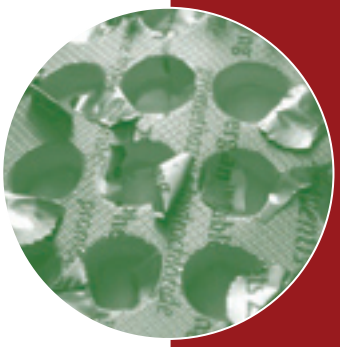
Supply of Reference Standards to Government Agencies (Year 2001-2006)

Chart 11



CHAPTER 8

CENTRE FOR POST REGISTRATION OF PRODUCTS



CENTRE FOR POST REGISTRATION OF PRODUCTS

Introduction:

Ensuring that all registered products conform to established standards and the Drug Control Authority's requirements is under the purview of the Centre for Post Registration of Products. Samples of registered products are obtained under the Post Marketing Surveillance (PMS) program and sent to laboratory for testing. This centre also investigates all 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 safety aspects stipulated.

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

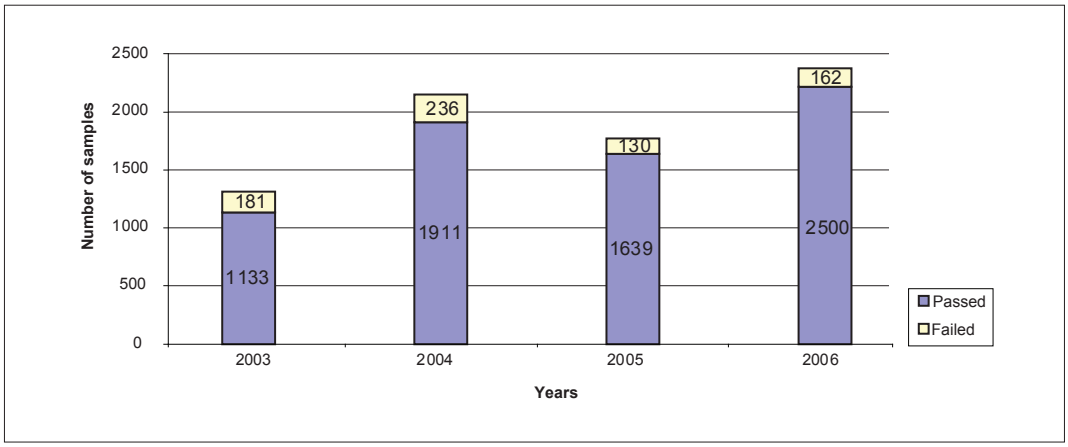
Activities of 2006:

Surveillance and Product Complaints

Under the Post Marketing Surveillance (PMS) program, in 2006, a total of 2594 registered products comprising of 713 pharmaceutical, 561 non-pharmaceutical and 1320 traditional products were obtained from the market and some analysed in the NPCB laboratory (Chart 12 & 13).

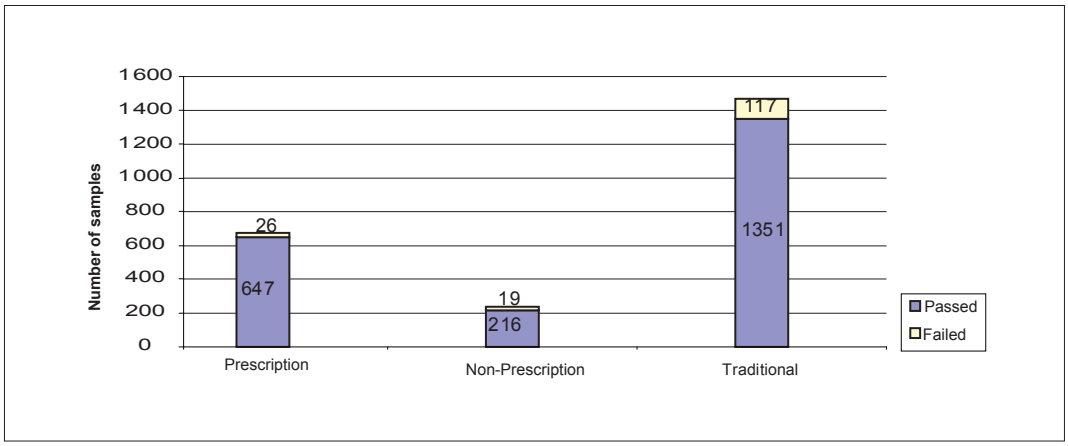
Results of Lab Testing of Surveillance Samples (Year 2003-2006)

Chart 12



Lab Testing of Surveillance Samples (Year 2006)

Chart 13



It was found that 162 samples out of 2376 products tested failed the laboratory tests. Of the products which failed, 108 were recalled from the market which involved 85 traditional medicines, 19 prescription and 3 non-prescription medicines and 1 cosmetic product. All these involved Degree 3 recalls i.e. quality issues whereby the affected batches were required to be recalled within 30 days of order. 41 warning letters were issued to the registration holders for products which failed the laboratory tests but were not serious enough to warrant a recall. Another 13 products did not warrant further action upon further assessment of the reason for non-conformity.

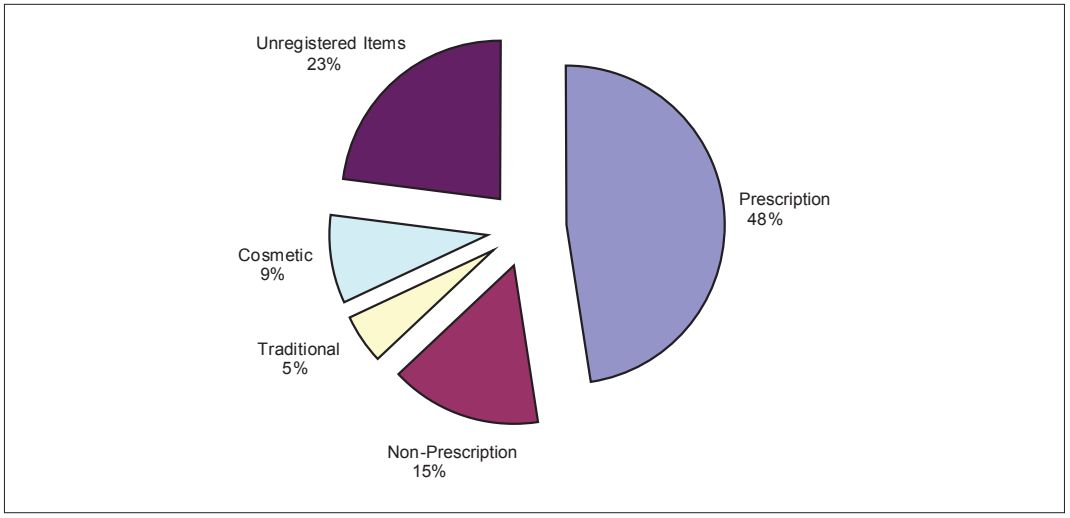
Under the surveillance program, a total of 2631 product labels and inserts were screened to verify for compliance . As a result of this, a total of 68 warning letters were issued to the registration holders of products where non-conformance was detected.

The number of complaints received increased by 15% in the year 2006 as compared to 2005. 317 products complaints involving 28 cosmetics, 16 traditional medicines, 49 non-prescription drugs, 151 prescription medicines and 73 unregistered products were received (Chart 14). Actions were taken to resolve the complaints within 6 weeks in 85% of these cases and all complaints on unregistered products were forwarded to the Pharmacy Enforcement Branch for further action.

Product Complaints Received (Year 2006)

N = 317

Chart 14



The cancellation of registration for 13 products due to adulteration in the year 2006 are as follows:

	Product Name	Adulterant(s)
1	Herbs-U	Sibutramine
2	Ching Du Yan Capsule	Chlorphenarimine, Chloramphenicol, Ibuprofen, Kafein
3	Han Palace	Acetildenafil
4	Trebest Plus Capsule	Acetildenafil
5	Mas Ayu Sendi Tulang Capsule 250mg	Acetaminophen
6	Bio Gents	Acetildenafil
7	Dr. Seagar SkinRecon	Hydroquinone, Tretinoin
8	Kintop Capsule	Sibutramine
9	Natural Lightening Cream	Hydroquinone
10	GP Lotion	Tretinoin
11	Sri Mutiara Krim Kecantikan Malam	Tretinoin
12	Dewajah Night Cream	Tretinoin
13	Qmax Kapsul 350mg	Acetildenafil

Product Safety Profile Monitoring

Under the Pharmacovigilance Program, 2543 Adverse Drug Reaction (ADR) reports involving 2938 products were received. Of these, 2799 products were prescription medicines, 52 non prescription drugs, 14 traditional medicines, 5 cosmetics and 68 unregistered products. 50% of the total ADR reports received were submitted by health professionals from the government sector (Chart 15).

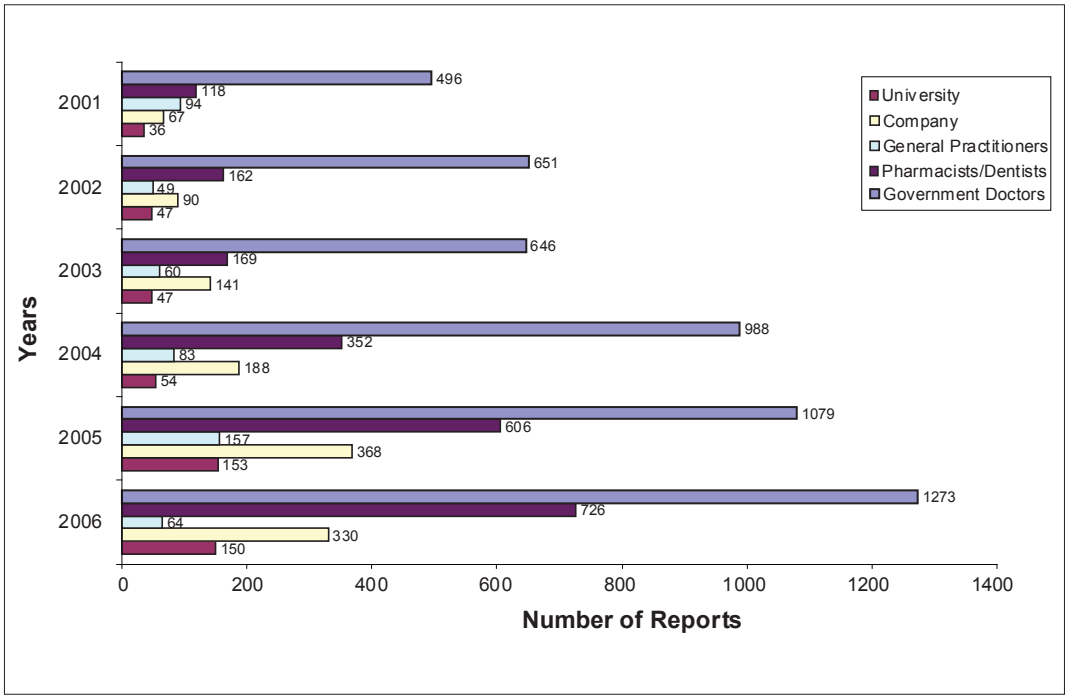
All ADR reports received by this centre were investigated and tabled to the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) Meeting which met 6 times in the year. Subsequently, 2491 reports evaluated were submitted to the Uppsala Monitoring Centre, Sweden for inclusion in the WHO database of ADR reports.

An analysis of the reports by organ system class showed that ADRs involving disorders of the skin and appendages contributed to the highest number of reports received (Chart 16). Traditional medicines and diclofenac in pharmaceutical products were reported to cause the highest incidence of ADR among patients/users.

11 talks were conducted in various parts of the country to promote awareness mainly to the health professionals on ADR reporting and the monitoring system.

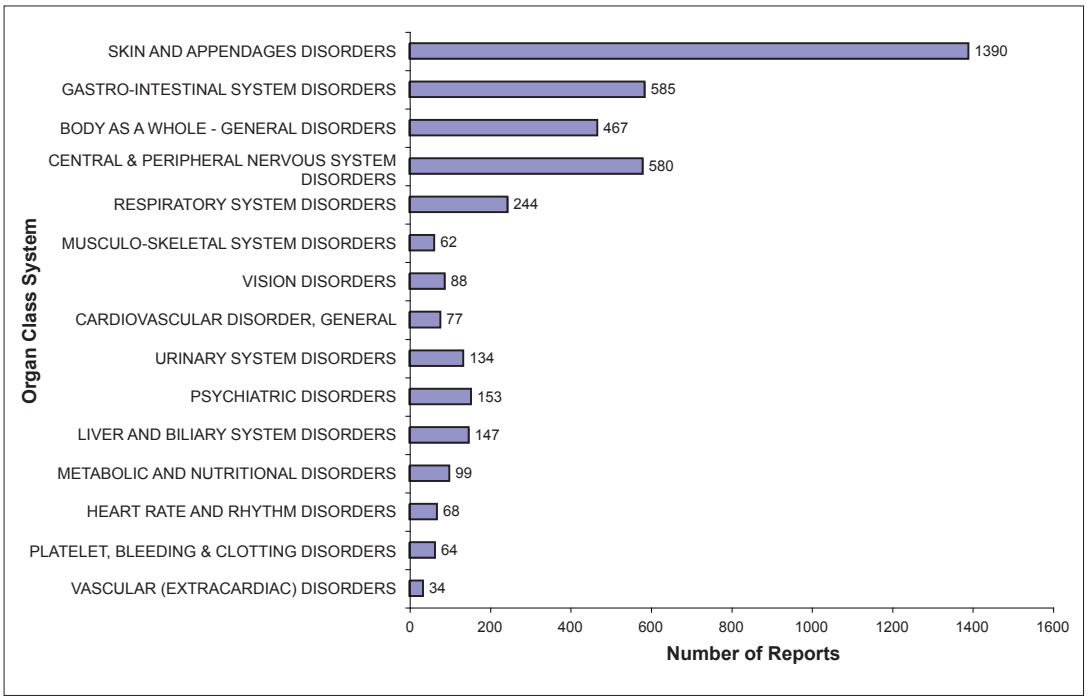
ADR Reports by Complainant Categories (Year 2001-2006)

Chart 15



ADR Reports by Top 15 Organ Class System(Year 2006)

Chart 16



Variations

The Variations Unit is responsible for processing applications submitted by product registration holders for major and minor changes made to registered products as well as applications for change of manufacturing site.

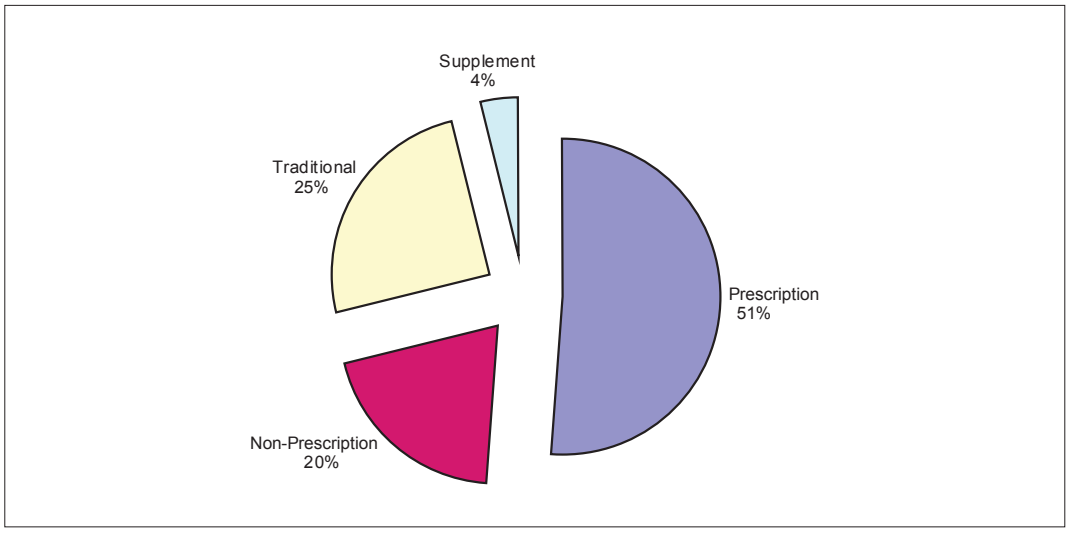
A total of 29532 applications for variations were received in the year 2006 (Chart 17). Of these, 19473 applications were approved and 8625 rejected (Chart 18). Reasons for rejection include:

a) Documents attached at the respective field may not be relevant for the intended application.
b) Changes are not in accordance to regulatory requirements

A total of 324 applications for change of manufacturing site were received and reviewed. Of this, 282 applications were approved, 32 applications are still under review status and 10 applications were rejected.

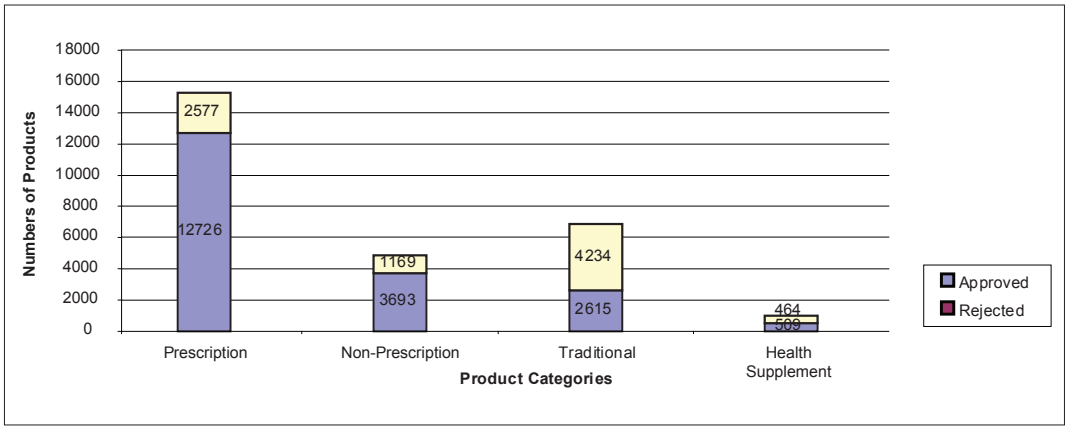
Variation Application by Product Categories (Year 2006)
N = 29532

Chart 17



Outcome of Variation Application by Product Categories (Year 2006)

Chart 18



Future Plans for 2007:

Heightened Surveillance Activities

- In view of introduction of abridged evaluation for Health Supplement products in mid 2006, an active monitoring program for Health Supplement products has been planned.

- Increase surveillance activities of cosmetic products.

Consumer reporting

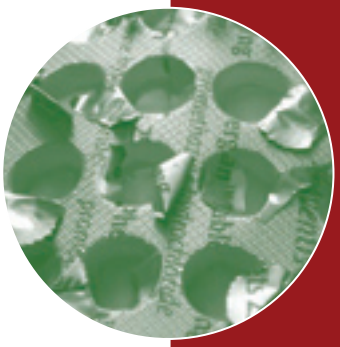
A pilot project will be executed in the Klang Valley to research on consumer involvement in the surveillance of medication program. If the program succeeds, it will be launched as an on-going program to deliver opportunities for consumers to channel reports and complaints on the quality, efficacy and also safety of products, especially for products that can be purchased without a prescription.

ADR monitoring for veterinary products

A monitoring program for adverse events associated with the use of veterinay products will be started along side with the registration of veterinary products. The monitoring program will cover adverse events in humans as a result of use or when administering an animal drug or in other situations involving accidental human exposure. A guideline or Frequently Asked Questions (FAQs) will be drafted to assist the healthcare professionals, industries as well as consumers in reporting adverse events related to veterinary products.

CHAPTER 9

CENTRE FOR GOOD MANUFACTURING PRACTICE



CENTRE FOR GOOD MANUFACTURING PRACTICE

Introduction:

The Centre for Good Manufacturing Practice (GMP) is responsible for inspection and licensing activities for pharmaceutical, traditional and cosmetics manufacturers to ensure Good Manufacturing Practice compliance among the manufacturers. This centre is also involved in matters pertaining to licensing of importer and wholesaler's premises with the assistance of the State Pharmacy Enforcement Branch in effort to ensure Good Storage Practice (GSP) compliance among the importers and wholesalers.

Objectives:

The Centre for Good Manufacturing Practice (GMP) always strives to ensure all pharmaceutical, traditional and cosmetic products approved for the local market are safe, effective and of quality through inspections conducted by thes centre.

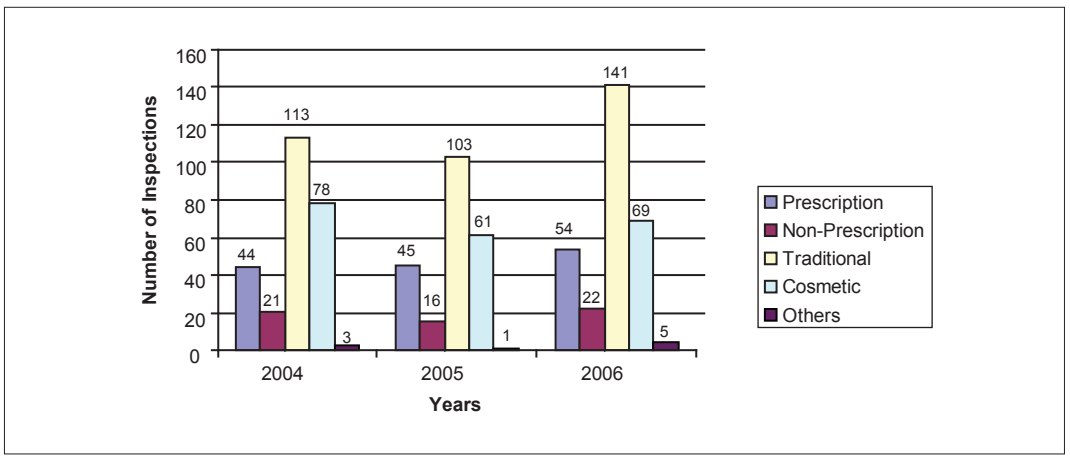
Activities of 2006:

GMP Inspection

291 GMP inspections were done in 2006 compared to 226 inspections in 2005. The inspections covered 54 prescription manufacturer premises, 22 non-prescription manufacturer premises, 141 traditional manufacturer premises, 69 cosmetic manufacturer premises and 5 other premises (Chart 19).

Inspections Done (Year 2004-2006)

Chart 19

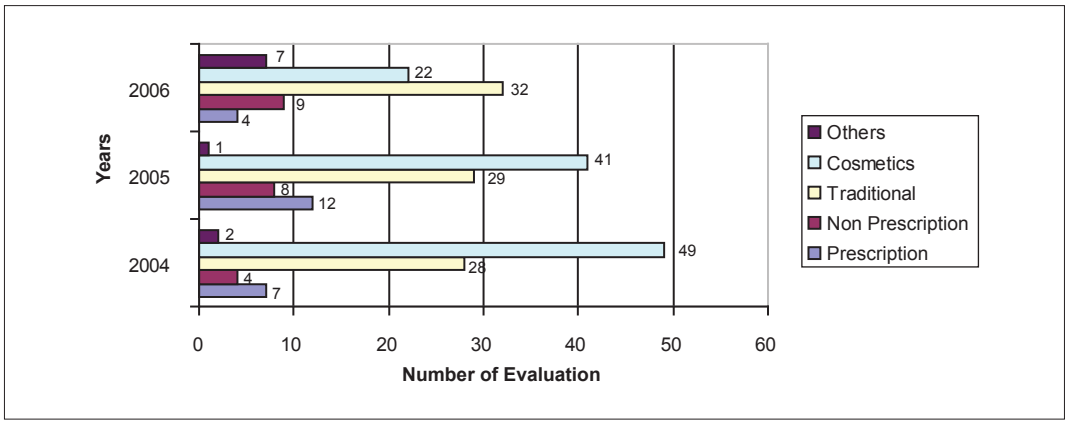


Evaluation of Manufacturer's Layout Plan

74 new manufacturer premises layout plans for GMP compliance were evaluated in the year 2006, of which 4 prescription manufacturer premises, 9 non-prescription manufacturer premises, 32 traditional manufacturer premises, 22 cosmetic manufacturer premises and 7 other premises for Active Pharmaceutical Ingredient (API) and veterinary product were evaluated (Chart 20).

Evaluation of Manufacturer's Premise Layout Plan (Year 2004-2006)

Chart 20



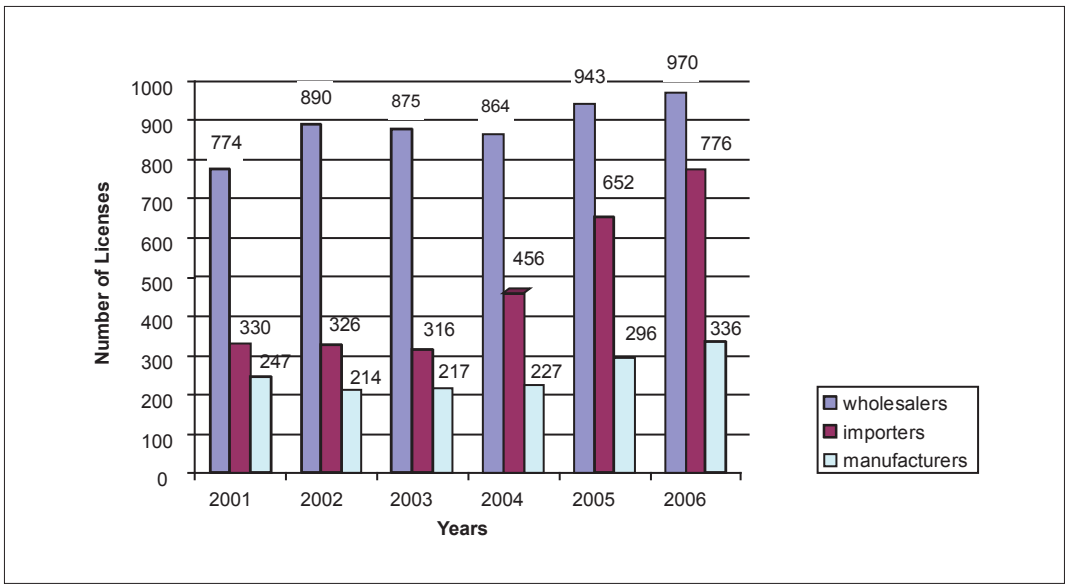
Issuance of Licenses

Under the provision of sub-section 12(1) Control of Drugs and Cosmetic Regulation 1984, the Drug Control Authority (DCA) is authorised to issue 4 types of licenses, of which issuance of 3 types of licenses (ie. Manufacturer's License, Importer's License and Wholesaler's License) are under the care of this centre.

In the year 2006, 336 Manufacturer's License, 776 Importer's License and 970 Wholesaler's License were issued (Chart 21). License issued according to product category is as in Schedule 1. The list and details of the licensed premises can be found in the NPCB website (www.bpfk.gov.my). The website also contains monthly updated information on license issuance.

Total License Issued (Year 2001-2006)

Chart 21



License Issued (Year 2006)

Schedule 1

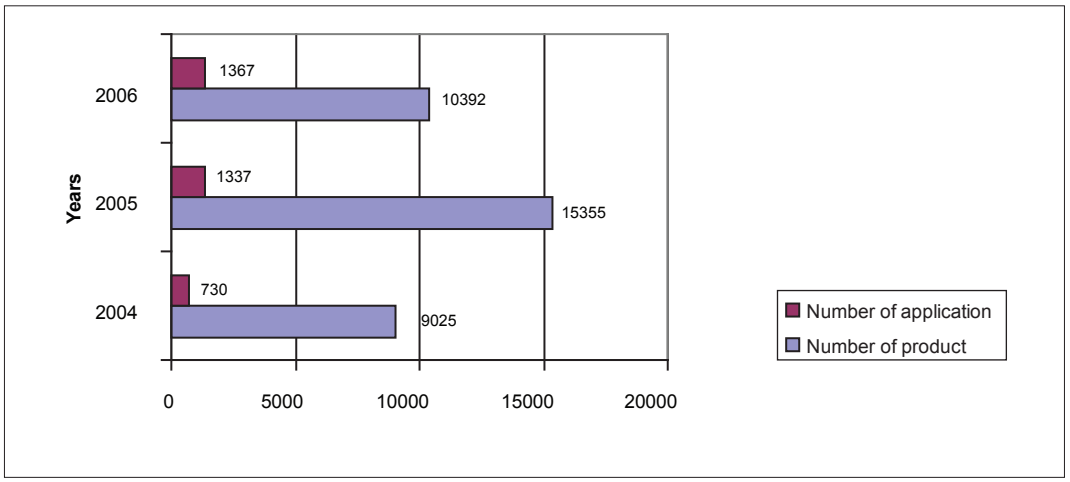
Product Category	Manufacturer	Importers		Product Category	Wholesalers
Pharmaceutical	85	180		Prescription	426
Traditional	161	149		Non Prescription/Traditional / Cosmetic	544
Cosmetic	90	447			
Total	**336**	**776**		**Total**	**970**

Registered Product Additional List

A total of 1367 applications were processed in the year 2006, involving 10392 products (Chart 22).The list was 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.

Issuance of Additional List of Registered Products
(Year 2004 - 2006)

Chart 22



Inspections on Preparation of Pharmaceutical Sterile Products and Radiopharmaceuticals Facilities in Government and Private Hospitals

Centre for GMP is involved in the inspection of clean room facilities that are used for the preparation of sterile products in the private and government hospitals. In the year 2006, 19 inspections were conducted on new and existing product preparation facilities in Malaysia. The inspections were done to ensure all products provided by the facilities are safe for patient use, and to ensure worker and environment safety. Until end of 2006, a total of 7 government hospitals and 1 private hospitals have their facilities qualified for eye drop preparation, Cytotoxic Drug Reconstitutions (CDR) and Total Parenteral Nutrition (TPN) preparations having achieved the required standard stipulated for premise and device aspects. 1government hospital and 1 private hospital are also qualified for radiopharmaceutical product preparation (siklotron) facility.

Inspection of Good Storage Practice (GSP) On Importer's and Wholesaler's Premises for Non Prescription and Traditional Products

Since mid 2006, the Centre for GMP started its inspection activities for Good Storage Practice on importer's and wholesaler's premises in the Klang Valley . Its purpose is to ensure a good level of GMP compliance on Good Storage Practice (GSP) which is vital in ensuring good distribution control and storage of registered products.

National GMP Seminar 2006

In tandem with achieving improvements in the traditional industry in Malaysia, the Centre for GMP had taken initiative to organise "**NATIONAL GMP SEMINAR 2006**" which was held on the 19th-21st December 2006. The objective of the seminar which was themed "**Meeting Current GMP Challenges**" is to improve awareness on the importance of quality control among members of the industry who are involved in manufacturing, storing and distribution of registered products. An exclusive session was conducted for all CEOs from local manufacturing companies to discuss regulatory issues relating to product registration, quality control, surveillance activities on registered products and Good Manufacturing Practice.

Involvement of the Centre for GMP at International Level

Due to acceptance and acknowledgement by the Pharmaceutical Inspection Cooperation Scheme (PIC/S), this centre was invited to join inspection programs for member countries and countries which intended to join PIC/S, such as Medicine & Health product Regulatory Agency (MHRA)-United Kingdom and Istituto Nacional des Medicamentos (INAME) –Argentina. The Centre for GMP was also appointed to be a co-rapporteur in evaluation of applications from Thailand prior to becoming a member of PIC/S.

FUTURE PLANS FOR 2007

Control of Active Pharmaceutical Ingredient (API) and Veterinary Products

To date, Active Pharmaceutical Ingredients (API) and veterinary products are not regulated by the Drug Control Authority (DCA). However, pre-certification inspections are conducted by the Centre for GMP for the purpose of issuance of GMP Certificate which is used as a pre-requisite for export-only products. In future, a database for API and veterinary products 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 GMP importance in the manufacturing aspects of APIs.

Collaboration on GMP course for Pharmaceutical Products at ASEAN Level

During the 9th ACCSQ-PPWG Meeting held on February 2005 in the Phillipines, 3 areas of pharmaceutical control were detected for the improvements on the Sectoral Mutual Recognition Arrangements (MRAs)- they are Medicinal Product GMP Inspection, QC Testing Method and Results, and Bioequivalence. Therefore, a taskforce named the MRA Taskforce for GMP Inspection led by Singapore and Malaysia was formed to track the development of Sectoral MRA in GMP inspections. Several meetings were held to discuss on reference terms and drafting a general outline for 'ASEAN MRA on GMP Inspection'. The final MRA draft which is currently being checked by the Ministry of Health Regulatory Advisory shall be discussed again during the Taskforce Meeting in Viet Nam on April 2007 prior to its presentation during the ACCSQ-PPWG Meeting for approval on August 2007 in Kuala Lumpur, Malaysia. According to plan, 'ASEAN MRA on GMP Inspection' shall be enforced by all 10 member countries by the end of year 2007.

GMP Implementation for Traditional and Health Supplement Products at ASEAN level

Continuation from the 6th Asean Consultative Committee on Standards and Quality (ACCSQ) Traditional Medicines And Health Supplements Product Working Group (TMHS PWG) Meeting held in Ha Noi, Malaysia has been appointed to lead all matters on GMP. One of the role that needs to be undertaken is the preparation of a check list for the use of industries from the ASEAN countries for the evaluation of GMP compliance. Malaysia is also responsible for conducting and coordinating Technical Workshop to identify suitable measures for ASEAN to provide GMP requirements for traditional and health supplement products. This Technical Workshop is expected to be held early May 2007 in Kuala Lumpur and it shall hold a discussion on the check list compilation results from the ASEAN countries and draw up a plan in GMP implementation on traditional and health supplement products. In line with the above, the conclusion from the Technical Workshop shall be presented during the 7th ACCSQ TMHS PWG meeting, which will be held in Brunei on July 2007.

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 by state and product category. As an introduction to GSP aspects, theoretical and practical trainings were conducted and this similar trainings are planned for the Pharmacy Enforcement Branch and it shall be executed in stages in time to come.

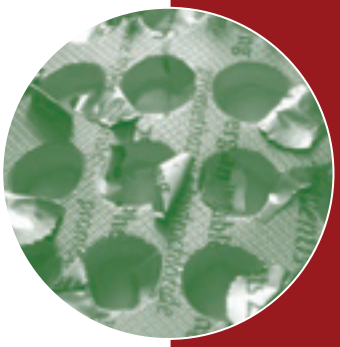
Pharmaceutical GMP Training in Module Design

Module designed GMP training programs shall begin in January and end in November 2007. These programs are jointly organised with MOPI.

Module 1 - International GMPs and Quality Assurance
Module 2 - GMP for Manufacturing Operations
Module 3 - Validation Principles
Module 4 - Contamination Control and Clean rooms
Module 5 - Validation Practices
Module 6 - Good Aseptic Practices and Sterile Products
Module 7 - Pharmaceutical Engineering – Facility, Equipment and Process Design
Module 8 - Solid Dose Manufacture Principles and Practices
Module 9 - Liquid and Cream Manufacture Principles and Practices

CHAPTER 10

CENTRE FOR ORGANISATIONAL DEVELOPMENT



CENTRE FOR ORGANISATIONAL DEVELOPMENT

Introduction:

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 and drug information to officers involved in product evaluation and 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

Activities of 2006:

Management of the Information Technology (I.T.) System

The introduction of the online system for product registration and licensing by the National Pharmaceutical Control Bureau (NPCB) marked a new chapter in the history of pharmaceutical regulatory development in Malaysia. In line with the directive for the implementation of e-government as well as in an effort to enhance the quality of service rendered by NPCB, the on-line registration system known as QUEST2 was successfully launched in 2002 with the intention of simplifying and expediting the registration process. The web-based on-line registration system was initially used for the registration of cosmetic products. After it was shown to be successful, it was then extended in stages for the registration of products containing scheduled poisons (controlled items) and non-poison products (over-the-counter products) in July 2003 and traditional medicines in January 2004. The implementation of on-line registration for New Chemical Entity (NCE) and Biotechnology products are however proposed to be implemented under the QUEST 3 system (enhanced QUEST 2 system) at a later date.

The Centre for Organisational Development plays an important role in monitoring and managing the QUEST 2 system. Any problems regarding the system which may be encountered either by applicants or NPCB's staff themselves are thoroughly investigated and measures are then taken not only to solve the current problem but also to avoid recurrence of similar problems in the future. A project has been approved for the upgrading and further enhancement of the current system under the 9th Malaysia Plan (2006-2010) and has been dubbed as the **QUEST 3 System**.

Maintenance of the NPCB Website

The NPCB website plays an important role as it is through this that the clients of NPCB submit their application for registration via on-line, submit adverse drug reaction reports and apply for the various licences.

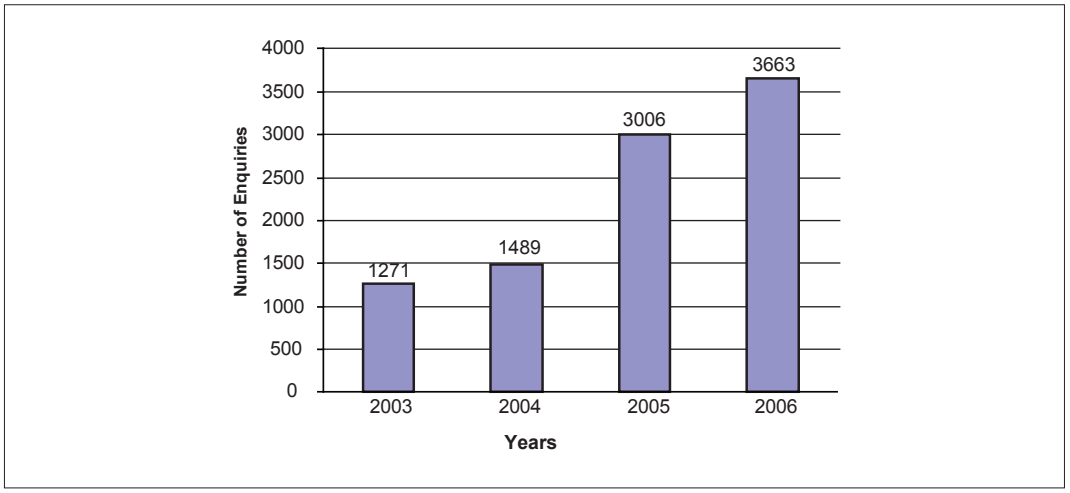
Besides this, the latest news, updates and information especially with regard to the Drug Control Authority (DCA) policies, list of registered products, decisions of the DCA as well as upcoming trainings can be accessed via the NPCB website at www.bpfk.gov.my.

Handling of Enquiries

The Centre for Organisational Development plays a very important role to the public and industry as it is the front liner for general enquiries. In the year 2006, a total of 3663 enquiries were received by the centre, an increase of 21.9% compared to the previous year (Chart 23). The enquiries received by the centre were of various nature, and included enquiries pertaining to product classification, status of product registration, product indication as well as general product information.

Enquiries Received (Year 2003-2006)

Chart 23



Publications

In the year 2006, 4 editions of Berita Ubat-Ubatan, a bulletin of the Drug Control Authority (DCA) containing news and updated policies of the DCA and 1 edition of NPCB Annual Report was published for circulation.

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 2006:

Association / Industry	Date of Dialogue
Malaysian Organisation of Pharmaceutical Industries (MOPI)	30 March 2006
Pharmaceutical Association of Malaysia (PhAMA)	13 July 2006
Traditional Industry: Chinese Medicine Manufacturers Association of Malaysia (PPUCM) and Traditional Malay Medicine Manufacturers Association (PURBATAMA)	30 August 2006
Cosmetic Industry: Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFA) and Federation of Malaysian Manufacturers Malaysian Cosmetics and Toiletries Industry Group (FMM MCTIG)	7 July 2006
Direct Selling / Direct Distribution Industry: Malaysian Direct Distribution Association (MDDA) and Direct Selling Association of Malaysia (DSAM)	8 June 2006

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 2006, NPCB organised a total of 51 CPD sessions which encompassed educational talks, workshops, Journal Club Sessions as well as seminars. Many NPCB staff were also sent for relevant training sessions organized by other parties/organisations/ agencies

Coordinating Visits of External Delegates / Visitors

As the sole regulatory body in Malaysia and in line with NPCB's role as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, NPCB receives many local and foreign visitors every year. Local visitors include students from universities/academic institutions as well as delegates from other local agencies, whereas international delegates usually visit with the aim of undergoing training attachment at this institution or as an official visit to increase their understanding on the regulatory system in Malaysia. The planning, arrangement and reception of these visitors are coordinated by the Centre for Organisational Development.

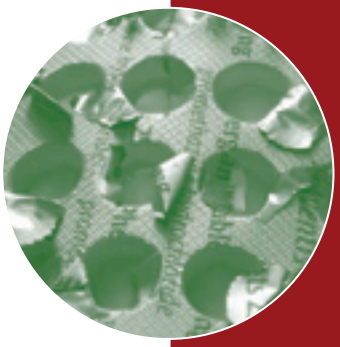
Throughout the year 2006, NPCB recorded a total of 195 visitors from within the country and 68 international visitors/delegates from various countries namely Bhutan, Brunei Darussalam, China, Egypt, India, Philippines, Singapore, Sri Lanka, Taiwan and Tanzania.

Future Plans for 2007

The Centre for Organisational Development will pursue NPCB's plans to upgrade the existing ICT infrastructure as planned under the 9th Malaysia Plan (2006 – 2010). The Centre will also look into increasing the number of reference books and electronic media available at NPCB to facilitate easy access and availability of references for the staff of NPCB. The centre may further explore the possibility of expanding and undergoing minor restructuring so as to widen the scope of services rendered by this centre.

CHAPTER 11

ADMINISTRATION UNIT



ADMINISTRATION UNIT

All matters pertaining to the management of finance is handled by the Administration Unit which is also responsible for general administration and other non-professional tasks. The Administration Unit ensures that all emoluments and claims are paid within the stipulated time, and oversee that financial allocations are sufficient to ensure that each planned activity meets its objective.

FINANCIAL STATEMENTS

PAYMENT

The emoluments for 200 staff members and 45 temporary staff for the year 2006 is RM7,806,907.83

REVENUE:

In 2006, the total revenue collected for drug and cosmetics registrations, laboratory tests, licences, advisory services, sales of guidelines and others is RM8,707,403.83.

REVENUE (RM) (YEAR 2002 – 2006)

Year	Registration	Licence	Laboratory	Inspection	Printed Materials	Others	TOTAL
2002	2,002,370	454,800	745,839	24,700	28,875	55,669	3,312,253
2003	5,540,795	942,650	1,126,027	62,700	18,420	64,230	7,754,822
2004	8,837,250	1,062,200	342,882	81,295	16,055	67,874	10,407,556
2005	7,239,500	1,232,500	304,762	48,250	13,335	60,522	8,898,869
2006	6,811,250	1,351,750	386,595	79,285	7,635.50	70,888	8,707,403

NPCB OPERATING ALLOCATION AND EXPENDITURE (YEAR 2006)

Object Code	Expenditure	Allocation (RM)		Expenditure (RM)		Balance	
		Original	Amended	Nett Expenditure	%	(RM)	%
10000	Emolumen	7,700,000	7,200,000	7,806,907.83	108.43		8.43
20000	Perkhidmatan dan Bekalan	8,688,600	9,868,600	9,601,829.63	97.29	266,770.37	2.71
30000	Aset (Harta Modal)	1,223,000	1,291,833	1,277,397.06	98.88	14,435.94	1.12
	JUMLAH	17,611,600	18,360,433	18,686,134.52	101.77	(325,701.52)	1.77

LIST OF POST AS ON 31 DECEMBER 2006

NO.	POST	GRADE	NO	POST	
				FILLED	VACANT
1.	DIRECTOR	VU7	1	1	0
2.	PHARMACIST	U54	2	1	1
3.	PHARMACIST	U52	6	2	4
4.	PHARMACIST	U48	33	23	10
5.	PHARMACIST	U44	4	4	0
6.	PHARMACIST	U41	85	75	10
7.	PHARMACY ASSISTANT	U36, U32, U29	77	65	12
8.	RESEARCH OFFICER	Q41	25	25	0
9.	SCIENCE OFFICER	C41	1	1	0
10.	SUPPORTING STAFF		62	48	14
	TOTAL		296	245	51

REMEMBERING YOUR SERVICES 2006

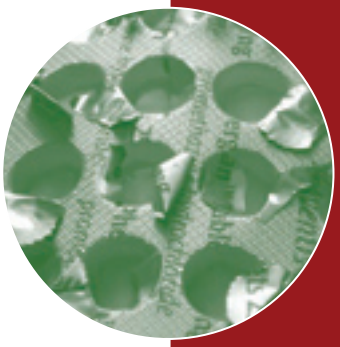
In the year 2006, a total of 21 staff left the NPCB due to work transfer to new places. The details are as follows:

NO	NAME	POST	DATE (NEW WORK PLACE)
1.	Dayang Hanani bt. Umar	Pharmacist	1.1.2006 (Terengganu)
2.	Fudziah binti Ariffin	Pharmacist	16.1.2006 (Sabah)
3.	Dr. Tajuddin bin Akasah	Pharmacist	16.1.2006 (KKM)
4.	Sulaiman bin Hj. Ahmad	Pharmacist	16.1.2006 (KKM)
5.	Abdul Aziz bin Mansor	Pharmacist	16.1.2006 (Institut Keb. Produk Asli)
6.	Norinawati binti Zainudin	Administrative Assistant	16.1.2006 (Hospital Sg. Petani)
7.	Norhaslina binti Hashim	Administrative Assistant	16.1.2006 (Kedah)
8.	Tan Chuan Ai	Pharmacist	16.2.2006 (Perlis)
9.	Rosnani bt. Mhd. Yusoff	Administrative Assistant	3.4.2006 (IKU)
10.	Roshayati bt. Hashim	Administrative Assistant	3.4.2006 (IMR)
11.	Nor Hasliza binti Ahmad	Pharmacy Assistant	19.5.2006 (Perlis)
12.	Syariza binti Saidin	Pharmacy Assistant	19.5.2006 (Perak)
13.	Zainul bin Mues	Driver	19.6.2006 (JKWP)
14.	Norrehan binti Abdullah	Pharmacist	1.8.2006 (HKL)
15.	Manida a/p Pin	Pharmacy Assistant	18.9.2006 (Kedah)
16.	Rohaniah binti Che Seman	Pharmacy Assistant	18.9.2006 (N.Sembilan)
17.	Suzila binti Hamid	Pharmacy Assistant	18.9.2006 (Kelantan)
18.	Rosnah binti Dardak	Administrative Assistant(Finance)	15.9.2006 (KKM)
19.	Azrul Azam bin Rafie	Administrative Assistant(Finance)	15.9.2006 (Kelantan)
20.	Mohd. Mukhrish b. Abu Hasan	Pharmacy Assistant	2.10.2006 (Kedah)
21.	Eisah bt. A. Rahman	Director, NPCB	16.12.2006 (KKM)

To all the staff of NPCB who had transferred to a new work place, the NPCB wish 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.

CHAPTER 12

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



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

In the year 2006, PUSPANITA in NPCB held various social, cultural, welfare, educational and sports activities such as:

- Majlis Jasamu Dikenang 2005
- Talk on Breast Health Awareness Campaign & Breast Cancer Screening
- 18th Annual Meeting of PUSPANITA, NPCB
- Talk on Amalan Semasa Mengandung Dan Selepas Bersalin
- Indoor Games Tournament (congkak and batu seremban)
- Children's Books and Magazines Sale
- Ramadhan Sale
- Tadarus Al-Quran
- Majlis Jasamu Dikenang 2006
- Choir Group Performance

A few members from PUSPANITA NPCB participated in other activities such as health-related talks, seminars on self-image development, internal designing, landscaping and also sports tournaments such as netball, badminton, volley ball and bowling organized by other PUSPANITA branches under the Ministry of Health (MOH). A NPCB member had been selected to represent PUSPANITA MOH in the Bowling Tournament organized by the National PUSPANITA.

BPFK CLUB

Until December 2006, the BPFK Club, headed by the National Pharmaceutical Control Bureau director had participation from 170 staff. All activities carried out in the year 2006 were sports activities.

The two main activities held were sports tournament and Sukaneka with the sports tournament held in January, Mac, April, May and July which involved seven events such as dart, carom, badminton, volley ball, ping pong, sepak takraw and netball.

The highlight of the event was Hari Sukaneka held on the 29th of August 2006. The events held included team events (Le tour de BPFK, Chinese Cuisine, Acid river, Genie in the bottle, Raja bersiram and Merebut takhta), jogathon, Rumah Berhias and Bayi Comel Contest.

NPCB MUSLIM STAFF WELFARE ASSOCIATION (BAKKI)

Activities organised by BAKKI were mainly welfare and religious activities. The purpose of the activities was to strengthen and improve relationship among Muslim staff. BAKKI also managed the welfare fund through collection of instant donation for immediate financial help to staff and their family members who were involved in an accident or death. The financial help was also used for other welfare purposes.

Activities organised by BAKKI in the year 2006 were as follows:

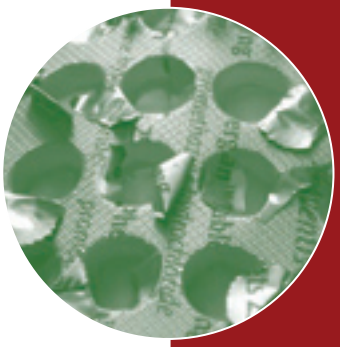
- Majlis Bacaan Surah Yassin, Tahlil Arwah & Doa Selamat
- Bubur lambuk preparation during the fasting month which was distributed to all Muslim staff
- Majlis Berbuka Puasa & Solat Tarawih

BAKKI members also participated in the following activities organised by the Ministry of Health:

- Ministry of Health Majlis Tilawah Al-Quran at Federal Teritory level
- A forum during the Majlis Tilawah Al-Quran of the Ministry of Health (at national level) which was held at Universiti Sains Malaysia, Kubang Kerian, Kelantan

CHAPTER 13

DCA POLICIES SUMMARY 2006



DCA POLICIES SUMMARY 2006

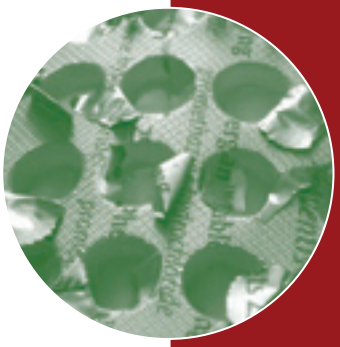
DCA MEETING	POLICY
DCA 177 (26/01/2006)	**PROPOSAL TO REVIEW PRODUCT REGISTRATION STATUS IF PRODUCT MARKETED WAS SAMPLED AND FOUND ADULTERATED** The DCA: i) Agreed to revoke the product registration license if the product marketed was sampled and found adulterated by the local Drug Enforcement Officer, or reported by the drug authorities from other countries, reported adverse effects or other reports made related to the product registered by DCA. ii) Agreed with the approach of using hologram in order to identify the manufacturer which is responsible for the manufacturing of the adulterated product. The legal advisor also agrees with the use of hologram label as legal evidence. **APPEAL TO CONTINUE THE USE OF 'POISON' LABEL AND 'CONTROLLED MEDICINE' LABEL FOR PRODUCT LABELLING** The DCA refuses the appeal from the industry to continue the use of 'Poison' and 'Controlled Medicine' label for product labeling especially use of labels from multi national companies as it may lead to confusion to the patients and is not coherent with the objective of the Poison Act 1952, Poison Regulations (Revised) 2003.
DCA 178 (23/02/2006)	**PROPOSAL TO INCLUDE WARNING ON THE LABEL AND LEAFLET FOR PRODUCT CONTAINING PROPOLIS (TOPICAL) AND ROYAL JELLY (ALL DOSAGE FORMS)** The DCA decided that: i) The statement below must be included on labels and leaflets of all topical products containing propolis: ***"Propolis may cause allergic skin reactions"*** ii) The statement below must be included on labels and leaflets of all products containing royal jelly: ***"This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals"*** ***"Asthma and allergy sufferers may be at the greater risks"***

DCA MEETING	POLICY
DCA 179 (23/03/2006)	**ADDITIONAL CONDITION FOR MANUFACTURING LICENSE** The DCA decided to impose additional condition for manufacturing license holders whereby it is the onus of the manufacturer or the contract manufacturer to ensure that their product(s) is/are free from adulteration. The additional condition imposed is as below: ***"Pengilang adalah bertanggungjawab memastikan bahawa semua produk yang dikilangkan adalah bebas dari sebarang campurpalsu (adulteration) dengan bahan-bahan yang tidak dibenarkan. Sekiranya berlaku sebarang campurpalsu, PBKD akan menarikbalik Lesen Pengilang dengan serta merta"***
DCA 181 (29/05/2006)	**WARNING STATEMENT ON THE LABEL AND LEAFLET OF PRODUCTS CONTAINING PROMETHAZINE HYDROCHLORIDE DUE TO "THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION OF PROMETHAZINE HYDROCHLORIDE IN PAEDIATRIC PATIENTS LESS THAN 2 YEARS"** The DCA decided to include the warning statement on the leaflet of all products (syrup, tablet, injection, solution and linctus) containing promethazine hydrochloride. The warning statement is as follows: ***"This product contains promethazine hydrochloride and should not be used in paediatric patienst less than 2 years of age due to the potential for fatal respiratory depression"***
DCA 183 (27/07/2006)	**WARNING ON THE LABEL AND LEAFLET OF TRADITIONAL PRODUCTs CONTAINING BLACK COHOSH (CIMIFUGAE RACEMOSAE) DUE TO 'SERIOUS HEPATIC REACTIONS'** The DCA decided to include the following warning statement shall be included on the label and leaflet of traditional products containing Black Cohosh (Cimicifugae racemosae) ***"Stop taking this product if signs and symptoms suggestive of liver injury develop such as tiredness, loss of appetite, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine and consult your doctor immediately"*** ***"Patients using herbal medicinal products should tell their doctor about it"***

DCA MEETING	POLICY
DCA 185 (29/09/2006)	**WARNING STATEMENT ON THE LABEL AND LEAFLET FOR ORAL HEALTH SUPPLEMENT PRODUCTS CONTAINING ARGININE** The DCA decided to include the following warning statement on the labels and leaflets of all health supplement products containing Arginine: ***"Arginine is not recommended for patients following a heart attack"***
DCA 185 (29/09/2006)	**REVIEW ON THE CLASSIFICATION OF 'EXTERNAL PERSONAL CARE' (EPC) PRODUCTS FROM NON-POISON PRODUCT TO COSMETIC** The DCA decided to reclassify 'External Personal Care' (EPC) products from Non-Poison products to cosmetic products starting 1 January 2007.
DCA 186 (19/10/2006)	**WARNING STATEMENT ON THE LEAFLET OF ALL PRODUCTS CONTAINING 'ACE-INHIBITORS' AS A SINGLE AGENT OR IN CONBINATION** The DCA decided to include the following warning statement on the leaflet of all products containing ACE-Inhibitors either as a single agent or in combination with other substances. The statement for 'Warning' and 'Use in Pregnancy' shall be as follows: ***"Increased risk of birth defect, fetal and neonatal morbidity and death when used throughout pregnancy"***
DCA 187 (23/11/2006)	**ESTABLISHMENT ON THE CONTROL OF COSMETIC PRODUCTS FROM REGISTRATION PROCEDURE TO NOTIFICATION PROCEDURE** The DCA decided to replace the registration of cosmetic products from registration procedure to notification procedure. The establishment of the notification procedure shall begin on 1st January 2008.

CHAPTER 14

INTERNATIONAL VISITORS AT NPCB



INTERNATIONAL VISITORS AT NPCB

Throughout the year 2006, NPCB received a total of 68 international visitors from various countries such as Singapore, Egypt, India, China, Taiwan, Brunei, Bhutan and Tanzania. Delegates who came for a study/courtesy visit were given a brief overview of NPCB during their visit and those who came for educational visits/training attachments were given training according to their respective specific needs.

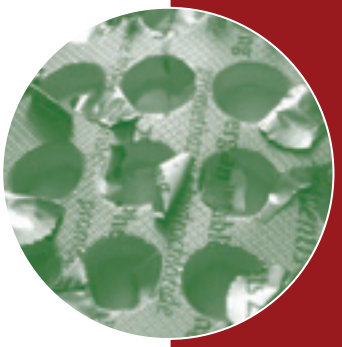
Visitor	*Organisation*	*Country of Origin*	*Date*	*Purpose*
Chan Ek Huar	Pharmaceutical Purchasing for Singapore Health Services.	Singapore	27 February 2006	Study Visit
Choong Wei Sim				
Mabel Phng				
Hassan El Bamna	Egyptian Embassy KL	Egypt	24 April 2006	Study / Official Visit
Ali Ibrahim Ammar	Egyptian Int. Pharm Industries Company (EIPICO)			
Adhem Shacker Helmi	Pharmco. Corp.			
Sham K. Mudgia	High Commission of India	India	28 April 2006	Study / Official Visit
M. Roja Rani	Pharmetcil, India			
Joseph Vincent	Khandelwal Laboratories (Pvt) Ltd.			
T. Ravichandiran	Pharm Products (P) Ltd.			
J.S. Murthy	Sven Genetech Ltd., Hyderabad, India			
Asma A'tiyah PDIDPSS Ustaz Hj. Abd. Hamid	Drug & Poison Information Section, Department of Pharmaceutical Service, ministry of Health, Brunei Darussalam.	Brunei	8 – 15 Mei 2006	Study Tour (ADR)
Dorji Thinlay (Head of DRA)	Drug Regulatory Authority, MOH, Kingdom of Bhutan	Bhutan	27 Jun – 14 July 2006	Study Tour
Ms. Ngawang Dema (Pharrmacist)				
Mr. Sang po				

Visitor	*Organisation*	*Country of Origin*	*Date*	*Purpose*
Mr. Kyaruzi, J.J.	Tanzania FDA	Tanzania	24 – 28 July 2006	Study Tour (ICT)
Mr. Mtumwa Simba				
Mr. Emmanuel Mremi				
Xia Jin Wang	Beijing Drug Administration, MOH China via Malaysian Chamber of Commerce and Industry in China (MAYCHAM)	China	16 August 2006	Study / Official Visit
Li Jia Xing				
Hu Jun Ping				
Chen Jiang				
Shen Bao Zen				
Dong Ya Xin				
Zhao Qing Yuan				
Lee Yao Jiang				
David Ong				
Dr. John Lim	Health Sciences Authority, Singapore	Singapore	28-29 August 2006	3rd Technical Meeting of NPCB & HSA
Mr Yee Shen Kuan				
Mrs Marie Tham				
Ms Chan Cheng Leng				
Mr Sia Chong Hock				
Ms Jessica Teo				
Ms Lim Peck Seah				
Mr Sham Leong				

Visitor	*Organisation*	*Country of Origin*	*Date*	*Purpose*
Ms. Zubaidah HJ. Mahmud	Pharmaceutical Services, Ministry of Health, Brunei Darussalam	Brunei	4 – 12 September 2006	Training Attachment
Ms. Rosni Jair				
Dr. Choi Seung Hoon	Wakil Unit Perubatan Komplementari / Alternatif, Pertubuhan Kesihatan Sedunia (WPRO, WHO) [melalui Bahagian T/CM, KKM)	Phillipine	6 September 2006	Official Visit
Lain-Tze Lee	BEL of ITRI -Pharmaceutical Technology Division	Taiwan	20 September 2006	Taiwan Bioindustrial Visiting Delegation to Malaysia
Huey-Min Lai				
Yuh-Chyun Wey				
Su-Jing Chen				
Ping-Chuan Chen	BEL of ITRI -Business Development Division			
J. Jeffrey Yang	Maywufa Biopharmaceutical Enterprise Group			
Simon Lee	Phytohealth Corporation			
David C.P. Chen	Asia Hepato Gene Co.			
Min-Wen Hsieh	Haichao Enterprise Corporation			
Jody D.C. Chen	Yeastern Biotech. Co., Ltd.			
Patti Tang Pei Li	Willy Event Consultants Co., LTD. PCO.			
Mindin Lin	Vita Genomics, Inc			
Sherine Helmy, Dr.	Egyptian Pharmaceuticals Export Council	Egypt	3 November 2006	Study / Official Visit

CHAPTER 15

FUTURE DIRECTION



FUTURE DIRECTION

To further improve the services rendered by NPCB, following are the plans to be undertaken in the future:

Registration of Veterinary Products and Active Pharmaceutical Ingredients (API)

In 2006, NPCB continued with the preparation for the registration of veterinary products and active pharmaceutical ingredients. When implemented, it will be the fifth and sixth phase, respectively of the overall product registration package.

Studies on the Registration of New Chemical Entities and Biotechnology Products

From the perspective of ICT upgrading, on-line registration for New Chemical Entities and Biotechnology-derived products are currently studied. Efforts are being taken to integrate different types of on-line modules such as product registration, premise licensing, analysing tests, surveillances, Adverse Drug Registration (ADR) monitoring and information dissemination to produce a more comprehensive regulatory system. The current computer system, QUEST 2 will also be upgraded to QUEST 3 under the 9th Malaysian Plan (2006-2010).

Quality, Safety and Efficacy

In the years ahead, the existing regulatory system focusing on quality, safety and efficacy of pharmaceutical products to protect public health will be strengthened through a multi-tiered strategy which includes the following:

- Enhancement of quality control aspects among the manufacturers of traditional products
- Capacity building in specific fields such as biotechnology section
- Inspection of clinical trial centres
- Licensing of manufacturing facilities of plasma and blood products

ISO 17025 Certification

In terms of quality control, NPCB, which has been successful in attaining the MS ISO 9001:2000 certification, will continue its efforts towards obtaining ISO 17025 certification for the Centre for Quality Control. As a start, the focus will be on the testing of traditional products. On 2-3 November 2006, the centre has conducted the ISO 17025 Internal Laboratory Audit Training for all officers from the centre.

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