Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

LAPORAN TAHUNAN
2004

kandungan

Perutusan Pengarah

Assalamualaikum dan Salam Sejahtera

Alhamdulillah, dengan sokongan padu semua kakitangan yang bekerja bersama saya dengan penuh dedikasi, gigih serta berkeyakinan tinggi, kejayaan yang dicapai dalam tahun 2004 boleh dibanggakan.

Pengstrukturan semula organisasi secara menyeluruh yang dilakukan pada bulan Jun 2004 telah menjadikan tugas lebih fokus dan berkesan, meningkatkan perkhidmatan ke tahap yang lebih cemerlang dan gemilang. Penubuhan beberapa seksyen serta unit baru juga mencerminkan tugas yang lebih spesifik dan proses kawalan regulatori yang lebih teratur demi mengekalkan prestasi unggul.

Dalam menyahut hasrat kerajaan ke arah 'e-government' selari dengan perkembangan ICT semasa, sistem pendaftaran produk secara online yang diperkenalkan pada tahun 2002 bagi pendaftaran produk kosmetik, diperluaskan kepada pendaftaran Ubat Tradisional mulai Januari 2004. Sikap keterbukaan pihak BPFK dicerminkan oleh sikap sedia mendengar dan prihatin terhadap masalah yang dihadapi oleh pihak industri dan penyelesaian masalah dicapai menerusi dialog serta kumpulan kerja yang bergiat aktif sepanjang tahun 2004. Ucapan ribuan terima kasih kepada pihak industri yang telah bekerjasama dalam merealisasikan sistem pendaftaran secara online ini.

Salah satu kejayaan yang amat saya hargai adalah pengekalan pensijilan MS ISO 9001 versi 2000 yang diperoleh pada 13 Ogos 2003. Audit Penilaian Semula yang dijalankan oleh pihak SIRIM dalam bulan Ogos 2004 menunjukkan BPFK sememangnya serius dalam pelaksanaan sistem kualitinya, sayugia mengekalkan pengiktirafan tersebut tanpa sebarang laporan ketakakuran kepada keperluan yang ditetapkan. Pihak pengurusan amat berterima kasih kepada semua kakitangan BPFK yang melaksanakan tanggungjawab dengan amanah serta penuh dedikasi.

Dalam arena regulatori serantau dan antarabangsa, BPFK masih dan akan terus memainkan peranan aktif dalam semua aktiviti regulatori yang dianjurkan sama ada oleh WHO atau badan lain. Dalam usaha sama harmonisasi keperluan regulatori di rantau ASEAN, BPFK menerajui beberapa aktiviti utama bagi produk farmaseutikal, ubat tradisional & suplemen kesihatan dan kosmetik.

Sebagai ahli 'Pharmaceutical Inspection Cooperation Scheme', BPFK merasa bangga apabila wakil dari BPFK dijemput lagi menjadi peserta bagi program 'Joint Inspection' dalam tahun 2004 yang menunjukkan pengiktirafan sistem pemeriksaan Amalan Perkilangan Baik yang diamalkan.

Sebagai sebuah pusat kolaboratif WHO bagi kawalan regulatori produk farmaseutikal, sepanjang tahun 2004 BPFK telah terlibat dalam banyak aktiviti yang dianjurkan WHO termasuk memberi latihan kepada 'WHO fellows' dari berbagai negara.

Kejayaan demi kejayaan telah dicapai, namun BPFK terus bersikap positif untuk menjangkau lebih banyak kejayaan pada masa mendatang. Syabas diucapkan kepada semua kakitangan yang selalu bersikap ingin maju dan penghargaan kepada semua yang bertungkus lumus mengekalkan prestasi kecemerlangan BPFK.

Akhir kata, ucapan terima kasih saya tujukan kepada pihak pengurusan atasan Kementerian Kesihatan Malaysia khususnya Pengarah Perkhidmatan Farmasi atas bimbingan dan sokongan yang telah diberikan kepada BPFK sepanjang tahun 2004.

Datin Hjh. Hasiah Hj. Abdullah
PENGARAH
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

struktur organisasi

BAHAGIAN PERKHIDMATAN FARMASI

Kementerian Kesihatan Malaysia

carta organisasi

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN

(Sebelum Jun 2004)

carta organisasi

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
(Selepas Jun 2004)

PENGARAH
Y Bhg Datin Hasiah Abdullah

Unit Penyenggaraan

Unit Pentadbiran

Pusat Pendaftaran Produk
Eishah Abd. Rahman

- Seksyen Produk Generik
  Noorizam Ibrahim
- Unit Preskripsi
  Noorizam Ibrahim
- Unit Bukan Preskripsi
  Mazuwin Zainal Abidin
- Unit Veterinar
  Rohani Ismail
- Seksyen Ubat Komplementari & Kosmetik
  Saleha Md. Ewan
- Unit Produk Semulajadi
  Saleha Md Ewan
- Unit Suplemen Kesihatan
  Abdullah Hisham Ahmat Yaya
- Unit Kosmetik
  Anis Talib
- Seksyen Penyiasatan & Ubat Baru
  Fudziah Ariffin
- Unit Ubat Baru
  Fudziah Ariffin
- Unit Bioteknologi
  Arpah Abas
- Unit Penyelidikan Klinikal Regulatori
  Dr. Kamaruzaman Saleh
- Unit Koordinasi Regulatori
  Tan Lie Sie

Pusat Pasca-Pendaftaran Produk
Abida Haq Sy Md Haq

- Unit Farmakovigilans
  Abida Haq
- Unit Surveilans & Aduan Produk
  Nurhayati Omar
- Unit Variasi Farmaseutikal
  Mokhtar Abdullah
- Unit Variasi Bukan Farmaseutikal
  Kosong

Pusat Pembangunan Organisasi
Bariah Ab Rani

- Unit Sumber Manusia
  Bariah Ab Rani
- Unit Pengurusan Sistem Kualiti
  Norrehan Abdullah
- Unit Maklumat & Komunikasi
  Fuziah Abd Rashid

Pusat Amalan Perkilangan Baik
Dr. Tajuddin Akasah

- Unit Inspektorat I
  Dr. Tajuddin Akasah
- Unit Inspektorat II
  Sulaiman Ahmad
- Unit Khid. Nasihat APB
  Kadariah Mohd Ali
- Unit Siasatan APB
  Mohd Lukmani Ibrahim
- Unit Pelesenan & Pensijilan
  Wan Othman Wan Ismail

Pusat Kawalan Kualiti
Yogeswary Markandoo

- Seksyen Pengujian Kimia Farmaseutikal
  Dr.Sulaikah Moideen
- Unit Kromatografi
  Dr. Sulaikah Moideen
- Unit Prestasi Dosej
  Muhd. Nasir Hashim
- Unit Spektro/ Kimia Am
  Tan Chuan Ai
- Unit Penyelidikan Kimia
  Kosong
- Unit Piawai Rujukan
  Abdul Aziz Mansor
- Unit Perkhidmatan Makmal
  Tan Ann Ling
- Seksyen Pengujian Bio-Farmaseutikal
  Faridah Abd. Malek
- Unit Toksi/ Farmakologi
  Faridah Abd. Malek
- Unit Mikrobiologi
  Siti Madziah Mohamed
- Unit Kultur Tisu & Penyelidikan Biologi
  Kosong
- Seksyen Pengujian Produk Semulajadi
  Jaafar Lassa
- Unit Monograf Herba
  Jaafar Lassa
- Unit Penyaringan Campur-palsu
  Mazli Muhamad
- Unit Pengesanan Bahan Toksik
  Kosong

SENARAI KEDUDUKAN PERJAWATAN

Sehingga 31 Disember, 2004

JAWATAN TETAP

BIL	NAMA JAWATAN	GRED	BIL	JAWATAN	
				DIISI	KOSONG
1.	PENGARAH	VU7	1	1	0
2.	PEGAWAI FARMASI	U54	2	2	0
3.	PEGAWAI FARMASI	U52	2	0	2
4.	PEGAWAI FARMASI	U48	31	30	1
5.	PEGAWAI FARMASI	U44	4	0	4
6.	PEGAWAI FARMASI	U41	58	47	11
7.	PEMBANTU FARMASI	U38	1	0	1
8.	PEMBANTU FARMASI	U36	1	1	0
9.	PEMBANTU FARMASI	U32	8	5	3
10.	PEMBANTU FARMASI	U29	65	56	9
11.	PENOLONG PEGAWAI PERANGKAAN	N27	1	1	0
12	PEMBANTU TADBIR (P/O)	N22	1	1	0
13	PEMBANTU TADBIR (KESETIAUSAHAAN)	N22	1	1	0
14.	PEMBANTU TADBIR (KESETIAUSAHAAN)	N17	2	1	1
15.	PEMBANTU TADBIR (P/O)	N17	6	6	0
16.	PEMBANTU TADBIR (STOR)	N17	1	1	0
17.	PEMBANTU TADBIR (KEW)	W17	5	5	0
18.	PEMBANTU PERPUSTAKAAN	S17	1	1	0
19.	PEMBANTU TADBIR RENDAH (JURUTAIP)	N11	4	0	4
20.	PEMBANTU TADBIR RENDAH (OPERATOR)	N11	1	1	0
21.	OPERATOR MESIN PEMPROSESAN DATA	F11	2	2	0
22.	PENGAWALAN KESELAMATAN	KP11	3	1	2
23.	ATENDAN KESIHATAN	U3	10	9	1
24.	PEMANDU KENDERAAN BERMOTOR	R3	3	3	0
25.	PEMBANTU AM RENDAH	N1	2	2	0
	JUMLAH		**216**	**177**	**39**

JAWATAN SAMBILAN

BIL	NAMA JAWATAN	GRED	BIL	JAWATAN	
				DIISI	KOSONG
1.	PEGAWAI SAINS	C41	25	23	2
2.	PEMBANTU TADBIR	N17	6	6	0
3.	PEMBANTU AM RENDAH	N1	3	3	0
4.	PEGAWAI FARMASI PELATIH	-	16	16	-
	JUMLAH		**50**	**48**	**2**

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.

::
Meningkatkan 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.

piagam pelanggan

KEWAJIPAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN

Ditujukan khas kepada setiap pelanggan yang berurusan dengan BPFK.

1. **Kemudahan Untuk Pelanggan**
   - Setiap pelanggan boleh 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 yang berkaitan.

6. **Penguatkuasaan Dan Komplians**
   - 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

:: **Lesen**
- Lesen Import Untuk Percubaan Klinikal - tidak lebih dari 3 bulan
- Lesen Untuk Pemborong, Pengilang, Pengimport - tidak lebih dari 3 bulan
- Lesen Baru Untuk Pemborong, Pengilang, Pengimport - tidak lebih dari 6 bulan

:: **Pendaftaran**
- Peringkat 1 - tidak lebih dari 6 minggu
- Peringkat 2 - tidak lebih dari 4 bulan
- Peringkat 3 - Generik - tidak lebih dari 6 bulan
- NCE - tidak lebih dari 12 bulan
- Tambahan Indikasi - tidak lebih dari 6 bulan

:: **Laporan Pemeriksaan APB**
- Susulan - tidak lebih dari 2 bulan
- Baru/Rutin - tidak lebih dari 3 bulan

:: **Perakuan Produk**
- Alat Perubatan - tidak lebih dari 2 minggu
- Farmaseutikal - tidak lebih dari 1 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

Aktiviti & Pencapaian

Ringkasan Aktiviti BPFK

Pada pertengahan tahun 2004, BPFK telah membuat penstrukturan semula organisasinya. Pembahagian kerja yang lebih sistematik dan tersusun bagi perjalanan pentadbiran dan penyelarasan aktiviti-aktiviti khusus telah menjadikan tugas lebih fokus dan berkesan, meningkatkan perkhidmatan ke tahap yang cemerlang, gemilang dan terbilang.

Penstrukturan semula organisasi mewujudkan bahagian-bahagian dan unit-unit yang khusus untuk menjalankan aktiviti-aktiviti yang lebih spesifik dan terperinci. Ekoran dari penstrukturan semula, nama bahagian serta unit telah ditukar dan beberapa unit baru telah diwujudkan seperti dalam Jadual 1 dan Carta Organisasi.

Jadual 1 : Pertukaran Nama Bahagian, Makmal & Unit- Unit
Biro Pengawalan Farmaseutikal Kebangsaan

NAMA LAMA (SEBELUM PENSTRUKTURAN SEMULA)	NAMA BARU (JUN 2004)
1. **Bahagian Penilaian & Keselamatan Produk (BPKP)** - Unit Racun - Unit Bukan Racun - Unit Veterinar	1. **Pusat Pendaftaran Produk (PPP)** a) Seksyen Produk Generik - Unit Preskripsi - Unit Bukan Preskripsi - Unit Veterinar
- Unit Entiti Kimia Baru - Unit Bioteknologi -	b) Seksyen Penyiasatan & Ubat Baru - Unit Ubat Baru - Unit Bioteknologi - Unit Penyelidikan Klinikal Regulatori
- Unit Ubat Tradisional - - Unit Kosmetik	c) Seksyen Ubat Komplementari & Kosmetik - Unit Produk Semulajadi - Unit Suplemen Kesihatan - Unit Kosmetik
- Unit Sekretariat	d) Unit Koordinasi Regulatori
2. **Bahagian Analisis Ubat** a) Makmal Kimia Farmaseutikal & b) Makmal Teknologi Farmaseutikal - - - -	2. **Pusat Kawalan Kualiti (PKK)** a) Seksyen Pengujian Kimia Farmaseutikal - Unit Kromatografi - Unit Prestasi Dosej - Unit Spektro/Kimia Am - Unit Penyelidikan Kimia

Aktiviti

NAMA LAMA	NAMA BARU
c) Makmal Mikrobiologi & d) Makmal Farmakologi/Toksikologi - - -	b) Seksyen Pengujian Bio-Farmaseutikal - Unit Mikrobiologi - Unit Farmakologi/Toksikologi - Unit Kultur Tisu & Penyelidikan Biologi
e) Makmal Ubat Tradisional - - -	c) Seksyen Pengujian Produk Semulajadi - Unit Monograf Herba - Unit Penyaringan Campur-palsu - Unit Pengesanan Bahan Toksik
f) Unit Piawai Rujukan	d) Unit Piawai Rujukan
g) Unit Perkhidmatan Makmal	e) Unit Perkhidmatan Makmal
3. **Bahagian APB & Pelesenan** - - - - -	3. **Pusat Amalan Perkilangan Baik (APB)** - Unit Inspektorat I - Unit Inspektorat II - Unit Khidmat Nasihat APB - Unit Siasatan APB - Unit Pelesenan & Persijilan
4. **Bahagian Surveilans & Farmakovigilans** - - - -	4. **Pusat Pasca Pendaftaran Produk (PPPP)** - Unit Farmakovigilans - Unit Surveilans & Aduan Produk - Unit Variasi Farmaseutikal - Unit Variasi Bukan Farmaseutikal
5. **Bahagian Pembangunan Organisasi & Teknologi Maklumat** - - -	5. **Pusat Pembangunan Organisasi** - Unit Sumber Manusia - Unit Pengurusan Sistem Kualiti - Unit Maklumat & Komunikasi
6. **Bahagian Pentadbiran**	6. **Unit Pentadbiran**
7. **-**	7. **Unit Penyenggaraan**

Aktiviti

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, farmakologi 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 penyampelan secara rambang dan menjalankan ujian-ujian analitikal

- Menguatkuasakan skim pelesenan 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 (PPP)

- 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)

Aktiviti

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 Makmal 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, ASB dan pelesenan.
- Menganjur kursus latihan APB untuk industri farmaseutikal dan tradisional serta 'WHO fellows'.
- Mengadakan perbincangan teknikal dengan industri 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 aduan 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 dan Pekeliling Maklumat Ubat
- Menyediakan perkhidmatan perpustakaan serta membekalkan buku-buku rujukan kepada pegawai-pegawai BPFK

Aktiviti

II Pengurusan Latihan
- Mengendalikan program latihan bagi Pegawai Farmasi Pelatih 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

pendaftaran produk

Pendaftaran Produk

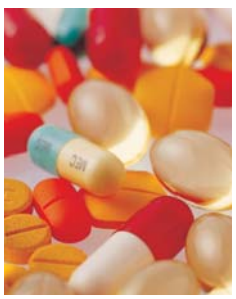
Pemprosesan permohonan pendaftaran produk dikendalikan oleh Pusat Pendaftaran Produk (PPP) yang memastikan semua produk farmaseutikal yang didaftarkan dinilai dari segi kualiti, keselamatan dan efikasi, manakala ubat tradisional serta kosmetik dinilai dari segi keselamatan dan kualiti. Pemprosesan permohonan rayuan terhadap penolakan pendaftaran dan permohonan tambahan indikasi juga dikendalikan oleh PPP.

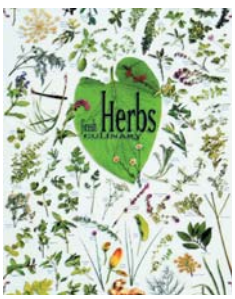
• Permohonan Pendaftaran

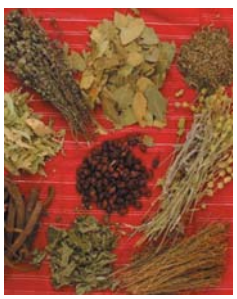
Sejumlah 34,099 permohonan diterima sepanjang tahun 2004 dan jumlah ini meningkat sebanyak 21% berbanding tahun 2003 (28,177). Daripada jumlah permohonan, 1.6% adalah bagi produk racun, 2.1% bagi produk bukan racun, 6.5% adalah produk ubat tradisional dan baki 89.8% bagi produk kosmetik. Secara keseluruhan, permohonan yang diterima bagi semua kategori produk untuk tahun 2004 telah meningkat berbanding dengan tahun 2003. Tahun 2004 merupakan tahun yang kedua yang mana bilangan permohonan telah meningkat secara mendadak berbanding dengan tahun-tahun sebelumnya. Data bilangan permohonan yang diterima dari tahun 2000 hingga tahun 2004 adalah seperti dalam Jadual 2.

Jadual 2 : Permohonan Untuk Pendaftaran (Tahun 2000-2004)

Tahun	Produk Racun	Produk Bukan Racun	Produk Ubat Tradisional	Kosmetik	Jumlah Tahunan
2000	427	444	1,523	262	2,656
2001	578	487	1,154	150	2,369
2002	509	448	1,603	214	2,774
2003	263	266	1,471	26,177	28,177
2004	529	720	2,220	30,630	34,099








Pendaftaran Produk

- **Status Produk Berdaftar**

Sejumlah 79,519 produk telah didaftarkan sehingga tahun 2004, yang mana 10,496 (13.2%), [2003: (27.3%)] ialah produk racun; 7,689 (9.7%), [2003: (20.1%)] ialah produk bukan racun; 13,821 (17.4%), [2003: (34.5%)] produk ubat tradisional, dan 47,513 (60.8%), [2003 (18.1%)] kosmetik. Ini menunjukkan pendaftaran bagi kosmetik telah meningkat secara mendadak berbanding tahun 2003. Sebanyak 47,513 produk kosmetik telah didaftarkan oleh Pihak Berkuasa Kawalan Dadah (PBKD) sehingga tahun 2004, manakala hanya 6,751 sahaja sehingga tahun 2003.

Sebanyak 42,311 produk telah didaftarkan pada tahun 2004 berbanding dengan tahun sebelumnya (2003) iaitu sebanyak 6,669. Peningkatan yang signifikan ini adalah disebabkan oleh pertambahan permohonan pendaftaran kosmetik yang diterima secara mendadak pada akhir tahun 2003 dan proses penilaian yang lebih singkat. Pecahan mengikut kategori produk yang didaftarkan pada tahun 2000 hingga 2004 adalah seperti dalam Jadual 3.

Jadual 3 : Jumlah Produk Yang Didaftarkan (Tahun 2000-2004)

Tahun	Produk Racun	Produk Bukan Racun	Produk Ubat Tradisional	Kosmetik	Jumlah Tahunan
2000	505	387	1,328	327	2,547
2001	180	624	1,344	309	2,457
2002	342	235	864	159	1,600
2003	324	275	1,349	4,721	6,669
2004	353	226	970	40,762	42,311

- **Status Permohonan Yang Ditolak**

Sepanjang 5 tahun terakhir, iaitu dari tahun 2000 sehingga 2004, sejumlah 824 permohonan telah ditolak yang mana jumlah pada tahun 2004 (446) didapati meningkat berbanding tahun sebelumnya. Peningkatan ini adalah ekoran daripada meningkatnya jumlah permohonan pendaftaran produk kosmetik (298) yang ditolak atas alasan tidak mematuhi keperluan pendaftaran. Data terperinci adalah seperti dalam Jadual 4.

Jadual 4 : Jumlah Permohonan Yang Ditolak (Tahun 2000-2004)

Tahun	Produk Racun	Produk Bukan Racun	Produk Ubat Tradisional	Kosmetik	Jumlah Tahunan
2000	20	40	46	0	106
2001	42	23	83	2	150
2002	7	25	23	23	80
2003	4	14	24	0	42
2004	3	48	97	298	446

Pendaftaran Produk

- **Status Pendaftaran Yang Dibatalkan atau Tarik-balik**

Sepanjang 5 tahun terakhir, pendaftaran 2,317 produk telah dibatalkan atau ditarik-balik. Ini meliputi 414 (17.8%) produk racun; 516 (22.3%) produk bukan racun dan 1387 (59.9%) produk ubat tradisional (Jadual 5). Pembatalan pendaftaran produk kebanyakannya adalah berdasarkan isu keselamatan dan kegagalan untuk mematuhi keperluan pendaftaran.

Jadual 5 : Jumlah Pendaftaran Produk yang dibatalkan/ditarik-balik (Tahun 2000-2004)

Tahun	Produk Racun	Produk Bukan Racun	Produk Ubat Tradisional	Kosmetik	Jumlah Tahunan
2000	306	120	499	-	925
2001	86	305	645	-	1,036
2002	18	2	161	-	181
2003	3	81	58	-	142
2004	1	8	24	-	33

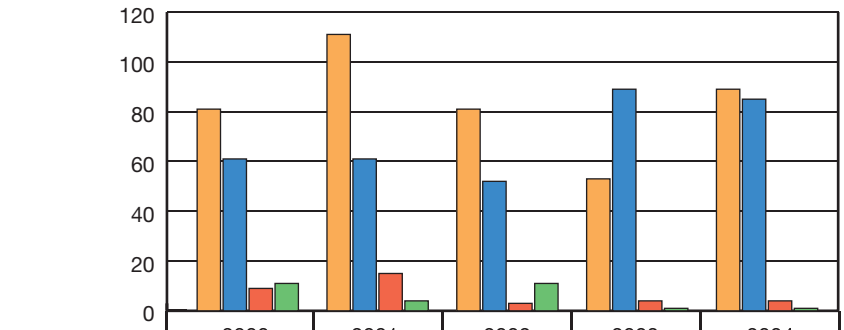
- **Rayuan**

Jumlah rayuan yang diterima pada tahun 2004 ialah sebanyak 69 permohonan berbanding 29 pada tahun sebelumnya. Peningkatan jumlah rayuan selaras dengan peningkatan jumlah permohonan yang ditolak.

- **Produk Baru (dahulu dikenali sebagai Entiti Kimia Baru)**

Dari tahun 2000 sehingga 2004, permohonan yang diterima untuk produk baru (dahulu dikenali sebagai entiti kimia baru) adalah 415 (Rajah 1). Daripada jumlah ini, 348 (83.9%) telah diluluskan, 35 (8.4%) ditolak dan 28 (6.7%) produk keputusannya ditangguhkan untuk maklumat tambahan.

Rajah 1 : Status Pendaftaran Produk Baru (Tahun 2000-2004)



	2000	2001	2002	2003	2004
Terima	81	111	81	53	89
Lulus	61	61	52	89	85
Tolak	9	15	3	4	4
Tangguh	11	4	11	1	1

Pendaftaran Produk

- **Pendaftaran Produk Bioteknologi**

Unit Bioteknologi yang diwujudkan pada tahun 2002 bertanggungjawab untuk menilai permohonan pendaftaran produk-produk biologikal yang sebelum ini dilakukan oleh Unit Preskripsi. Contoh produk biologikal ialah vaksin, serum yang digunakan untuk tujuan terapeutik, antitoksin, komponen darah dan terbitannya serta produk-produk yang dihasilkan melalui kaedah bioteknologi seperti interferon dan erithropoietin.

Sepanjang tahun 2004, 35 permohonan diterima manakala 27 produk telah didaftarkan.

- **Tambahan Indikasi**

Sebanyak 76 permohonan tambahan indikasi telah diterima sepanjang tahun 2004. Daripada jumlah tersebut, sebanyak 70 permohonan telah diluluskan manakala baki permohonan masih dalam penilaian.

- **Produk Tempatan dan Import**

Produk tempatan dan import yang didaftarkan pada tahun 2004 mengikut kategori produk diilustrasikan dalam Jadual 6. Jumlah produk tempatan adalah sebanyak 21.9% (9,285) dan jumlah produk yang diimport adalah 78.1% (33,026).

Pada tahun 2004, berdasarkan data dalam Jadual 6, peratusan nisbah antara produk tempatan dan produk import untuk produk racun adalah 35:65; produk bukan racun adalah 36:64; produk ubat tradisional adalah 59:41; dan kosmetik pula adalah 21:79.

Merujuk kepada jumlah produk tempatan yang didaftarkan sepanjang tahun 2004 (n = 9285), 1.3% adalah produk racun, 0.9% produk bukan racun, 6.2% produk tradisional dan 91.6% kosmetik. Untuk produk import (n = 33,026), 0.7% adalah produk racun, 0.4% produk bukan racun, 1.2% produk tradisional dan 97.7% kosmetik.

Jadual 6 : Bilangan Produk Tempatan dan Produk Import Yang Didaftarkan (Tahun 2004)

Bulan	Produk Racun		Produk Bukan Racun		Ubat Tradisional		Kosmetik		Jumlah	
	Temp	Import	Temp	Import	Temp	Import	Temp	Import	Temp	Import
Jan	13	20	10	12	91	53	112	942	226	1027
Feb	19	26	6	14	36	30	150	782	211	852
Mac	12	17	5	19	87	53	251	1133	355	1222
Apr	19	34	3	13	41	20	159	1240	222	1307
Mei	11	7	11	8	41	13	167	1055	230	1083
Jun*	-	-	-	-	-	-	-	-	-	-
Julai	2	18	1	9	23	8	684	3726	710	3761
Ogos	9	23	10	7	33	55	1331	5689	1383	5774
Sept	6	17	6	12	42	23	905	3215	959	3267
Okt	9	31	18	17	55	81	1896	5370	1978	5499
Nov	4	12	5	6	29	14	1001	3126	1039	3158
Dis	19	25	6	28	96	46	1851	5977	1972	6076
Jumlah	**123**	**230**	**81**	**145**	**574**	**396**	**8507**	**32255**	**9285**	**33026**

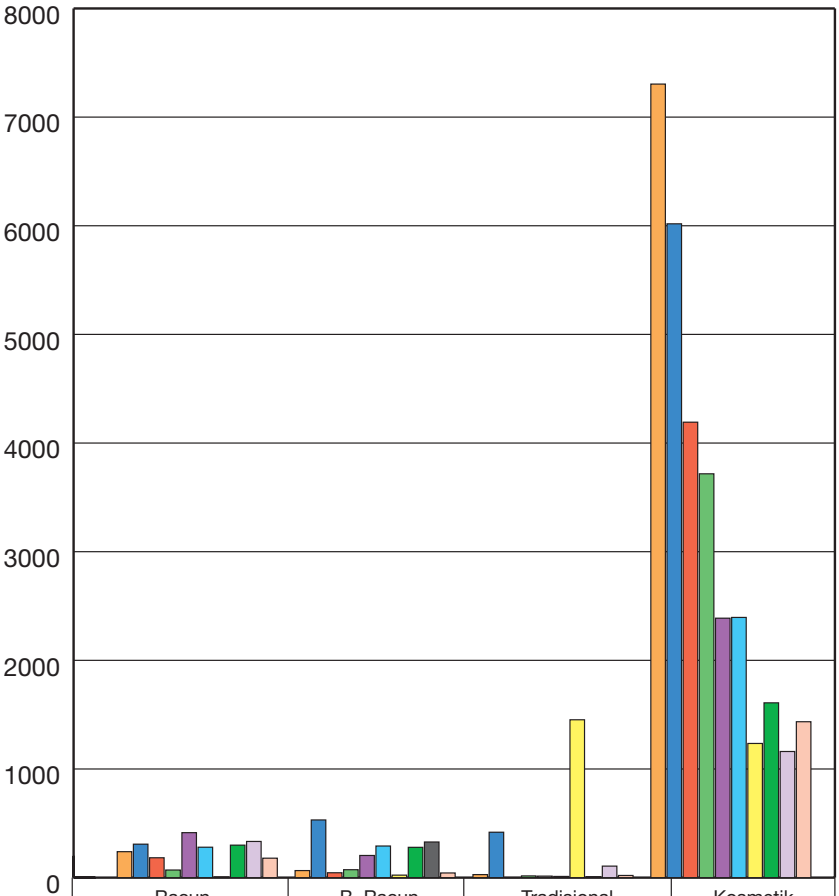
*Tiada mesyuarat PBKD pada bulan Jun 2004

Pendaftaran Produk

- **Sumber produk**

Antara 10 negara utama yang menjadi sumber produk import ialah Perancis, Amerika Syarikat, Itali, Jepun, Jerman, Thailand, China, U.K, Australia, dan Kanada. Produk dari negara-negara ini meliputi lebih kurang 68.9% (37,724) daripada jumlah produk import (n = 54,729). Produk yang diimport dari Negara ASEAN seperti Indonesia, Thailand, Singapura dan Filipina meliputi hampir 10.2% (5,555) (Rajah 2).

Rajah 2 : Negara-negara Sumber Keluaran Import



	Racun	B. Racun	Tradisional	Kosmetik
Perancis	239	65	28	7304
US	308	531	418	6018
Itali	183	45	1	4192
Japun	70	73	16	3717
Jerman	414	204	14	2388
Thailand	280	291	11	2395
China	7	23	1453	1235
UK	299	279	9	1609
Australia	333	328	106	1161
Kanada	179	43	20	1435

Rancangan masa hadapan

Skop pendaftaran produk akan diperluaskan dengan melaksanakan pendaftaran serta pelesenan produk veterinar dan bahan aktif farmaseutikal.

kawalan kualiti

Kawalan Kualiti

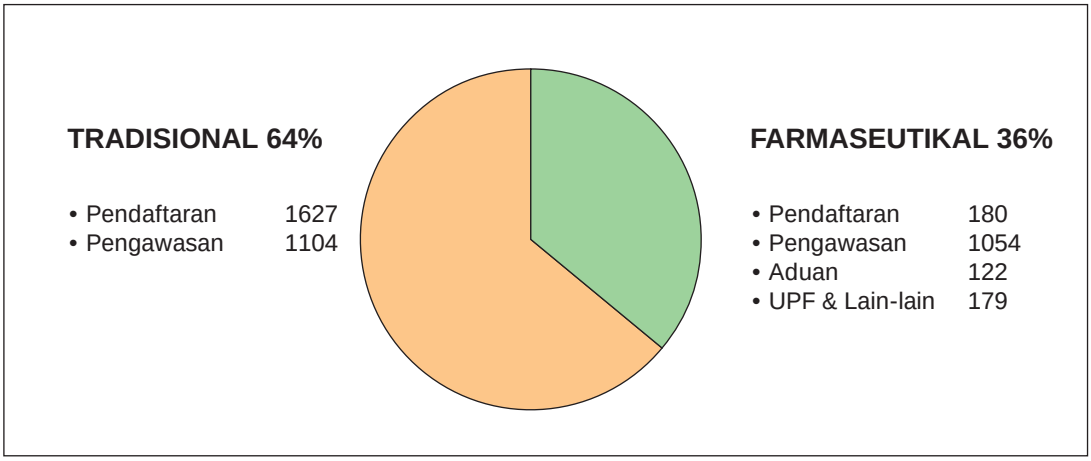
Aktiviti pengawalan kualiti produk yang dikendalikan oleh Pusat Kawalan Kualiti (PKK) merupakan satu elemen penting dalam penilaian produk-produk farmaseutikal, tradisional dan kosmetik. Produk-produk yang diuji termasuk produk untuk permohonan pendaftaran, pengawasan produk berdaftar dalam pasaran, kes-kes aduan untuk produk berdaftar dan sampel penguatkuasaan. Ujian-ujian yang dijalankan adalah berasaskan penentuan farmakopia, spesifikasi dalaman atau protokol analisis yang diluluskan dan spesifikasi pengilang.

Pemohon pendaftaran produk farmaseutikal perlu mengemukakan protokol analisis produk untuk dinilai sebelum ujian dijalankan dan bagi produk parenteral, pemohon perlu mengemukakan protokol analisis serta data validasi memandangkan ujian tidak dijalankan secara rutin bagi produk berkenaan sebelum pendaftaran.

- **Beban Kerja**

Sepanjang tahun 2004 sebanyak 4266 sampel telah diterima untuk pengujian yang terdiri dari 1535 (36%) sampel produk farmaseutikal dan 2731 (64%) sampel ubat tradisional (Rajah 3). Keseluruhannya merangkumi 1807 (42.4%) sampel pendaftaran, 2158 (50.6%) sampel pengawasan, 122 (2.8%) sampel aduan dan 179 (4.2%) sampel dari Cawangan Penguatkuasa Farmasi (CPF) dan lain-lain.

Rajah 3 : Jenis Sampel Diterima

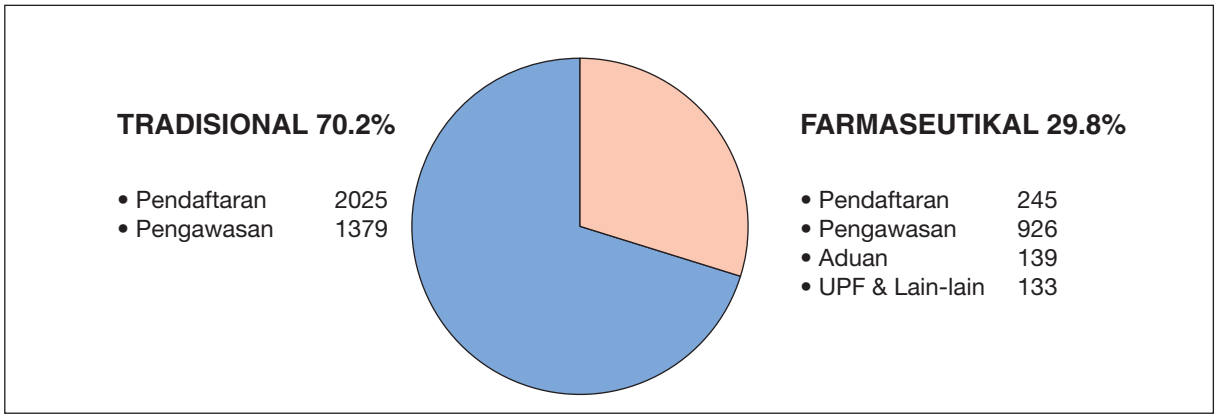






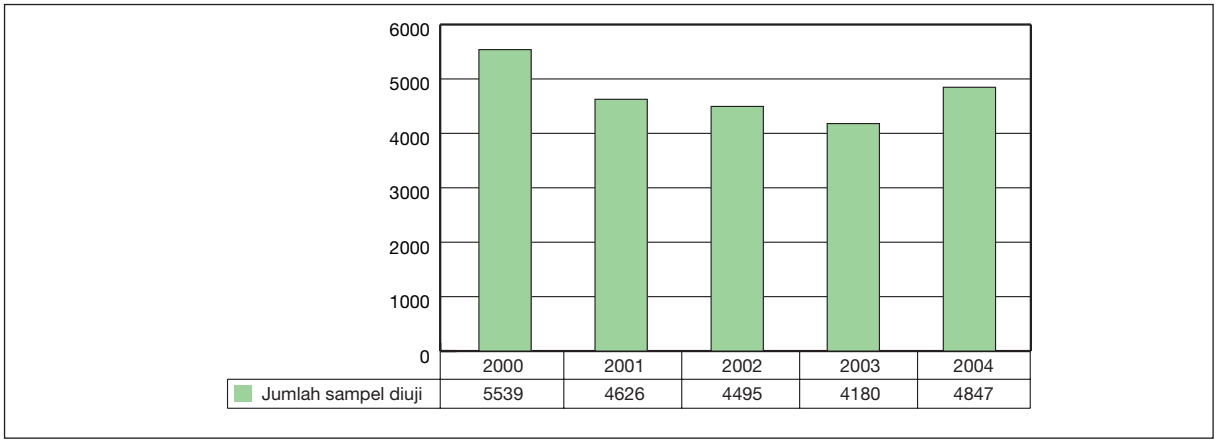

Daripada 4847 sampel yang telah diuji, 1443 (29.8%) terdiri dari sampel produk farmaseutikal dan 3404 (70.2%) sampel ubat tradisional (Rajah 4). Keseluruhannya merangkumi 2270 (46.8%) sampel pendaftaran, 2305 (47.5%) sampel pengawasan, 139 (2.9%) sampel aduan dan 133 (2.7%) sampel CPF dan lain-lain.

Rajah 4 : Jenis Sampel Diuji

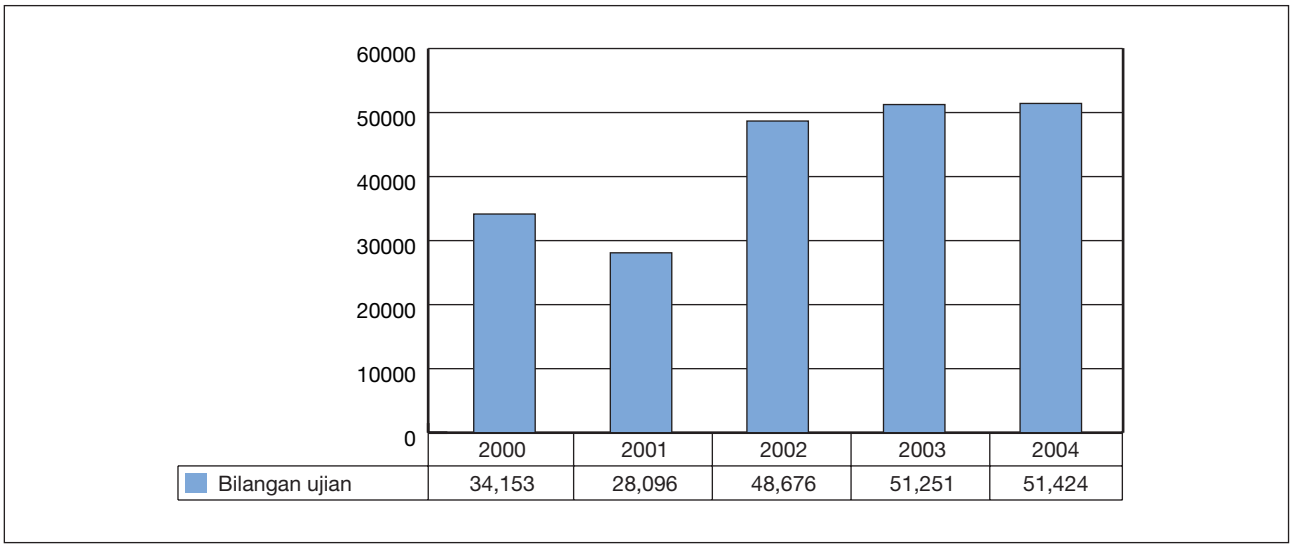


Berbanding dengan pencapaian tahun 2003, bilangan sampel yang diuji pada tahun 2004 meningkat sebanyak 16% (Rajah 5). Bilangan ujian pula meningkat sebanyak 0.3%, iaitu dari 51251 (tahun 2003) kepada 51424 untuk tahun 2004 (Rajah 6).

Rajah 5 : Bilangan Sampel Diuji (Tahun 2000-2004)

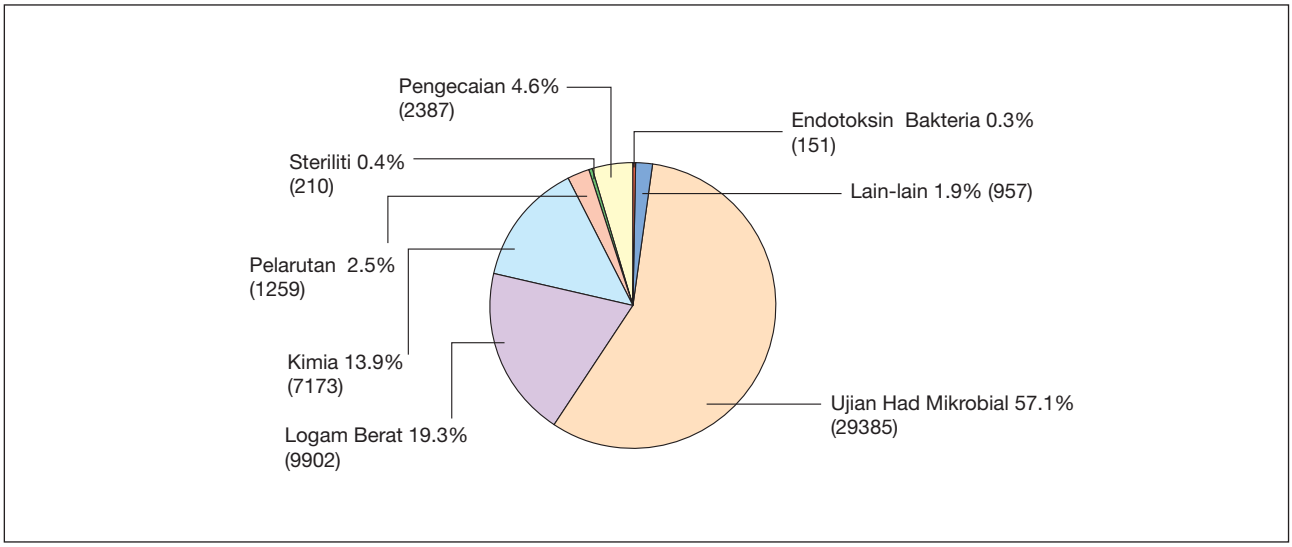


Rajah 6 : Bilangan Ujian Dijalankan (Tahun 2000-2004)



Jenis-jenis ujian yang dijalankan terdiri dari ujian had mikrobial (MLT), kimia, logam berat (As, Hg, Pb), pengecaian, pelarutan, steriliti, bakteria endotoksin, dan lain-lain seperti toksisiti, biokimia, biologikal, bilangan partikel, esei antibiotik. Statistik ujian adalah seperti pada Rajah 7.

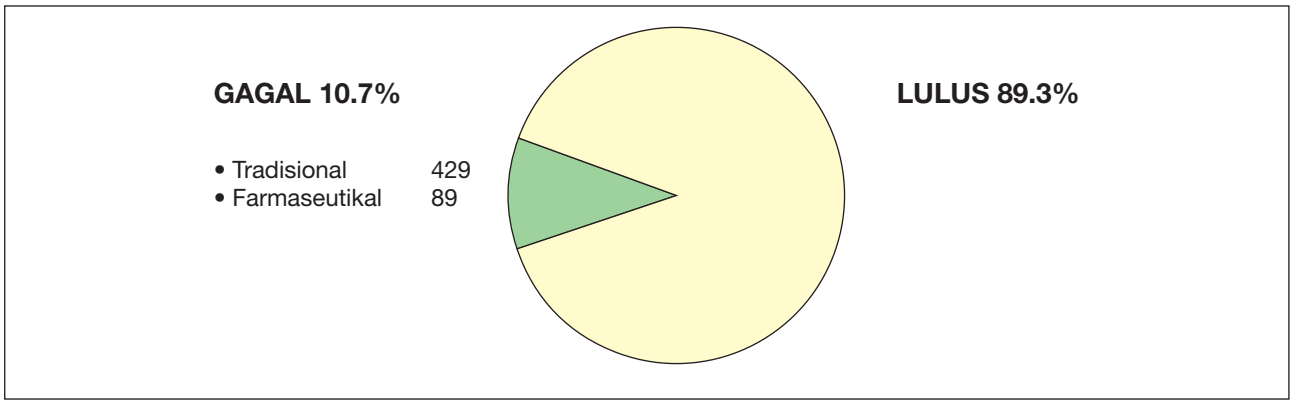
Rajah 7 : Jenis Ujian Dijalankan



- **Sampel Gagal Ujian**

Bilangan sampel yang gagal ujian pada tahun 2004 adalah sebanyak 518 iaitu 10.7% dari jumlah sampel yang diuji (Rajah 8), merangkumi 266 (5.5%) sampel pendaftaran, 228 (4.7%) sampel pengawasan dan 24 (0.5%) sampel aduan; keseluruhannya terdiri dari 429 (8.9%) sampel produk tradisional dan 89 (1.8%) sampel produk farmaseutikal.

Rajah 8 : Perbandingan Sampel Lulus & Gagal Ujian



- **Penilaian Protokol Analisis Dan Data Validasi**

Sebanyak 1359 protokol analisis telah dinilai pada tahun 2004 manakala jumlah yang dilaporkan untuk tahun 2003 ialah 2548. Dalam tahun 2003, bilangan penilaian protokol analisis dilaporkan oleh setiap makmal. Ini bermakna satu protokol boleh dilaporkan lebih dari satu kali. Cara melaporkan penilaian protokol analisis telah berubah pada tahun 2004 yang mana Unit Perkhidmatan Makmal telah ditugaskan untuk menyelaraskan bilangan protokol analisis yang dinilai oleh PKK. Dengan cara ini, pengiraan bilangan protokol yang dinilai tidak lagi bertindih sepertimana yang berlaku untuk tahun 2003.

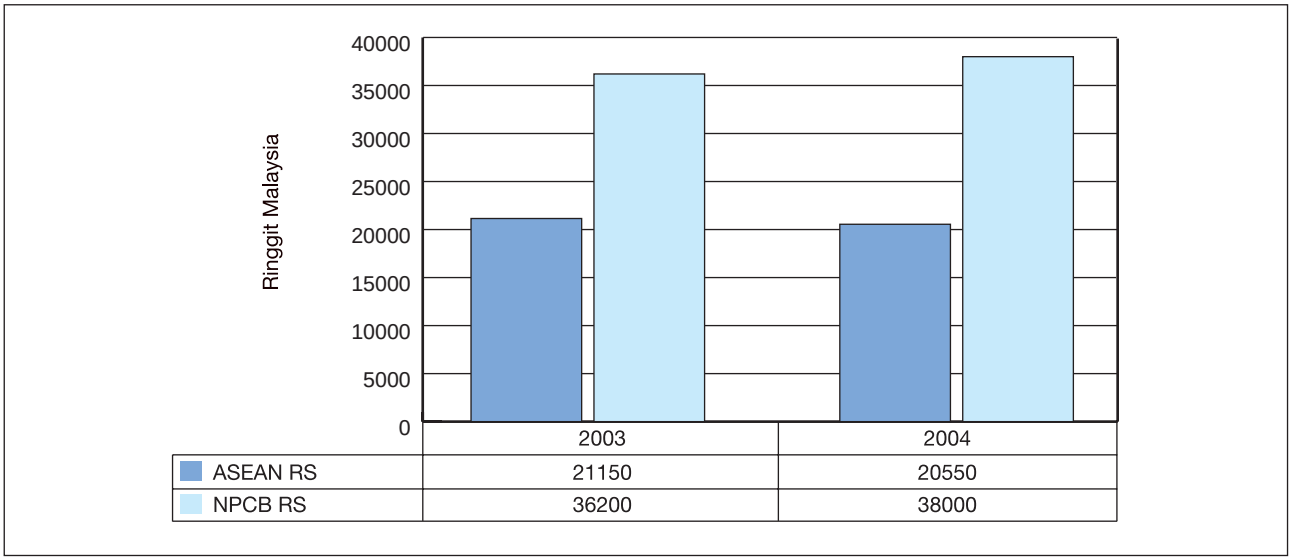
Jumlah protokol analisis yang dinilai dalam masa satu bulan telah menurun dari 95.3% (2003) kepada 73.9% (2004) dan pencapaian ini tidak memenuhi sasaran indikator QAP/Quality Assurance Program BPFK (tidak kurang dari 90% dinilai dalam masa 30 hari bekerja). Faktor utama yang menyebabkan kemerosotan pencapaian indikasi ini adalah kerana semua penilaian protokol analisis perlu dibuat secara online mulai tahun 2004 yang mana telah menimbulkan beberapa masalah seperti berikut:

a) Penilai perlu menyesuaikan diri dengan membaca dokumen-dokumen dalam skrin komputer dan ini memanjangkan masa penilaian.
b) Penilaian hanya boleh dilakukan pada waktu pejabat sahaja
c) Penilaian tidak dapat dijalankan apabila sistem QUEST2 tidak berfungsi akibat masalah yang dialami pada peringkat awal sistem baru digunakan.

- **Piawai Rujukan**

Sejumlah 137 vial piawai rujukan ASEAN bernilai RM20,550 dan 380 vial piawai rujukan BPFK bernilai RM38,000 telah dijual kepada industri farmaseutikal tempatan dan luar negara. Setiap vial piawai rujukan BPFK dikenakan bayaran sebanyak RM100 dan piawai rujukan ASEAN sebanyak RM150. Hasil jualan pada tahun 2004 (RM 58,550) didapati meningkat berbanding dengan hasil jualan (RM 57,350) pada tahun 2003 (Rajah 9).

Rajah 9 : Hasil daripada Piawai Rujukan (Tahun 2003-2004)



Sebanyak 876 vial piawai rujukan ASEAN/BPFK telah dibekalkan secara percuma kepada badan-badan kerajaan seperti Jabatan Kimia, Makmal Ubat dan Stor Sarawak, Cawangan-cawangan Penguatkuasa Farmasi Negeri dan badan-badan regulatori negara-negara ASEAN yang terlibat dalam projek kolaborasi.

Dalam menyokong projek kolaborasi antara negara ASEAN di bawah naungan Pertubuhan Kesihatan Sedunia (WHO) untuk "ASEAN Reference Substances (RS) Production & Utilization", Unit Piawai Rujukan (UPR) telah menjalankan ujian atas 5 dari 8 bahan yang telah dicadangkan dalam mesyuarat ke 12 di Thailand pada Februari 2003. Ujian-ujian tersebut dijalankan terlebih dahulu sebelum bahan mentah, piawai rujukan primer dan kaedah analisis dihantar kepada 2 negara ASEAN lain untuk kajian kolaborasi. UPR juga telah membungkus 300 vial bahan mentah nystatin (projek kolaborasi) sebelum ujian esei mikrobiologi dijalankan.

Bahan mentah untuk prednisolone dan nystatin telah dibekalkan oleh Japan Pharmaceutical Manufacturers Association (JPMA) sementara badan regulatori Thailand membekal bahan mentah norfloxacin dan guaifenesin serta piawai rujukan primer prednisolone, nystatin, norfloxacin dan guaifenesin. BPFK telah membekalkan bahan mentah dan piawai rujukan primer diphenhydramine hydrochloride.

Di samping ini, ujian-ujian untuk kajian kolaborasi juga dijalankan atas bahan mentah yang diterima dari negara-negara ASEAN. Sejumlah 7 bahan telah diterima dari negara ASEAN; 4 bahan dari Thailand, 1 dari Indonesia dan 2 dari Vietnam dalam tahun 2004.

Dalam mesyuarat ke-12 yang telah berlangsung di Thailand, beberapa bahan telah diterima untuk digunakan sebagai ASEAN RS. BPFK sebagai badan penyelaras untuk methylparaben, propylparaben dan riboflavin telah membungkus dan melabel 300 vial methylparaben, 300

vial propylparaben dan 300 vial riboflavin. ASEAN RS ini telah diagihkan ke semua negara ASEAN; 120 vial ke Indonesia, 90 vial ke Filipina, 90 vial ke Singapura, 120 vial ke Thailand, 90 vial ke Vietnam, 45 vial ke Myanmar, 45 vial ke Cambodia dan 45 vial ke Laos. Malaysia juga telah menerima sejumlah 265 vial ASEAN RS dari negara-negara ASEAN; 110 vial dari Indonesia, 90 vial dari Thailand, 60 vial dari Singapura dan 5 vial dari Filipina.

- **Bahan Campur Palsu Dalam Ubat Tradisional**

Sepanjang tahun 2004, aktiviti pengesanan bahan campur palsu dalam produk ubat tradisional untuk sampel-sampel dari aktiviti penguatkuasaan dan surveilans giat dilaksanakan.

Selain daripada itu, atas arahan Pihak Berkuasa Kawalan Dadah, pemonitoran sampel pendaftaran dan pengawasan produk ubat tradisional dilaksanakan dengan mengesan bahan campur palsu atas 4 kategori produk yang mempunyai indikasi berikut:

- 'untuk kesihatan lelaki'
- 'untuk sakit-sakit sendi/otot'
- 'untuk mengurangkan/mengawal berat badan'
- 'untuk batuk dan selsema'

Sebanyak 462 sampel telah diuji yang melibatkan 645 ujian. Terdapat 66 sampel (14.3%) yang dikesan positif mengandungi bahan campur palsu seperti dinyatakan dalam Jadual 7.

Jadual 7 : Bahan Campur Palsu Dalam Ubat Tradisional

Sasaran	Sampel CPF			Sampel Pendaftaran dan Pengawasan		
	Bilangan Diuji	Bilangan Positif	% Positif	Bilangan Diuji	Bilangan Positif	% Positif
Sildenafil dan Tadalafil	90	25	27.78%	35	4	11.43%
Steroid	203	7	3.45%	56	--	--
NSAID & Phenylbutazone	31	1	3.22%	33	5	15.15%
Antihistamine/Antitussive	20	4	20.00%	11	3	27.27%
“Cardiovascular drugs”	3	-	-	-	-	-
Antibiotik	4	1	25.00%	4	-	-
Antidepressant/Tranquilizers	--	-	-	1	-	-
H2 Antagonist	1	-	-	-	-	-
Agen Pelangsing	25	--	--	29	1	3.45%
Agen Pemutih	30	5	16.67%	-	-	-
Analgesik	--	--	--	4	-	-
Hormon	25	-	-	-	-	-
Opiate	3	--	--	2	2	100%
Lain-lain (Antihyperlipidaemic, Antidiabetic, Antifungal dan Antiasthmatic)	12	3	25.00%	23	7	30.43%

Kawalan Kualiti

Dalam tahun 2004, tatacara dan teknik penganalisaan baru yang bersesuaian telah dibangunkan yang mana penganalisaan telah dijalankan atas 4 sampel persediaan dan air daun ketom. Hasil ujian didapati 2 sampel air ketom mengandungi mitragynine.

Perancangan Untuk Tahun 2005

Aktiviti yang dijadualkan untuk tahun 2005 adalah seperti berikut:

a) Meneruskan persediaan ke arah akreditasi ISO 17025 untuk makmal dengan mengadakan latihan untuk kakitangan dan juga mengenalpasti skop akreditasi.
b) Meneruskan kerjasama antara negara ASEAN dengan mengambil bahagian dalam pengeluaran piawai rujukan ASEAN melalui ujian kolaboratif atas piawai rujukan yang dicadangkan.
c) Mengambil bahagian secara aktif dalam 'Proficiency Testing Schemes' yang dikendalikan oleh WHO dan Program EC-ASEAN sebagai satu usaha pemonitoran berterusan atas prestasi makmal.
d) Menganjurkan 'Workshop on Assessing Quality of Vaccines' khususnya vaksin Hepatitis B.
e) Melatih pegawai menerusi latihan sangkutan dengan institusi yang bertauliah dalam bidang 'tissue culture' untuk ujian keselamatan produk vaksin.
f) Menganjurkan kursus bersama industri tempatan (MOPI) dalam bidang penyaringan bahan campur palsu seperti racun berjadual.
g) Meneruskan usaha untuk memperkembangkan tatacara dan teknik penganalisaan dalam pengesanan racun berjadual dalam ubat tradisional terutama yang melibatkan penggunaan alat LCMS-MS.

amalan perkilangan baik








Amalan Perkilangan Baik

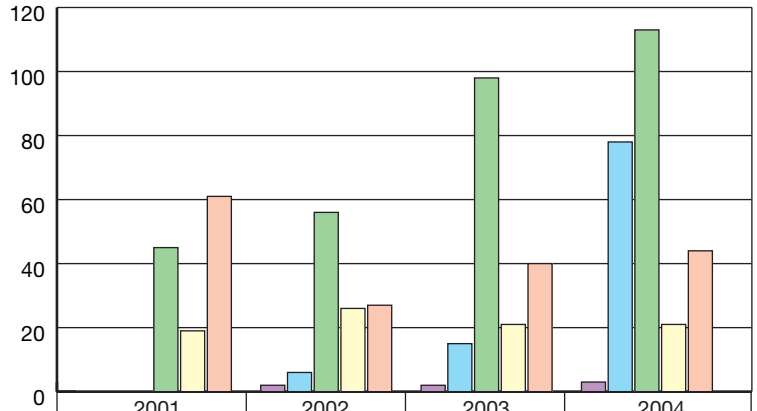


Aktiviti ini dikendalikan oleh Pusat Amalan Perkilangan Baik yang memastikan pengilang produk farmaseutikal, ubat-ubatan tradisional dan kosmetik yang berlesen mematuhi keperluan Amalan Perkilangan Baik (APB). Pusat APB bekerjasama dengan Cawangan Penguatkuasa Farmasi Negeri (CPFN) dalam memastikan premis pengimport dan pemborong berlesen mematuhi keperluan Amalan Penstoran Baik (ASB). Pusat Kawalan Kualiti memberi khidmat sokongan dalam pemeriksaan Amalan Perkilangan Baik bagi aspek Amalan Makmal Baik.

- **Pemeriksaan APB**

Sebanyak 259 pemeriksaan APB telah dijalankan pada tahun 2004. Pemeriksaan tersebut meliputi 44 premis pengilang produk racun, 21 produk bukan racun, 113 produk ubat tradisional, 78 kosmetik dan 3 produk veterinar (Rajah 10).

Rajah 10 : Jumlah Pemeriksaan Premis Oleh APB (Tahun 2001-2004)

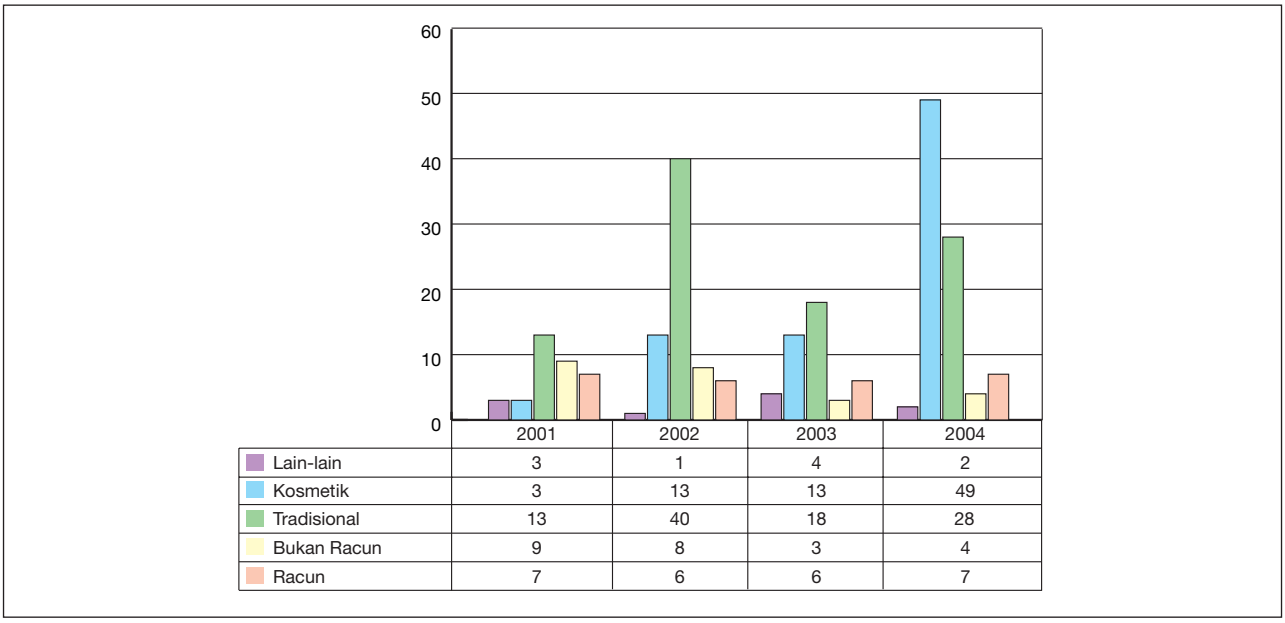


	2001	2002	2003	2004
Lain-lain	0	2	2	3
Kosmetik	0	6	15	78
Tradisional	45	56	98	113
Bukan Racun	19	26	21	21
Racun	61	27	40	44

- **Penilaian Susun-Atur APB Pelan Premis Pengilang**

Sejumlah 90 pelan susun-atur premis pengilang baru dan sedia ada telah dinilai pada tahun 2004 agar mematuhi keperluan APB, ini termasuk 7 premis pengilang produk racun, 4 produk bukan racun, 28 produk ubat tradisional, 49 kosmetik dan 2 lain-lain seperti bahan aktif farmaseutikal (API) serta veterinar (Rajah 11).

Rajah 11 : Jumlah Pelan Premis Dinilai (Tahun 2001-2004)

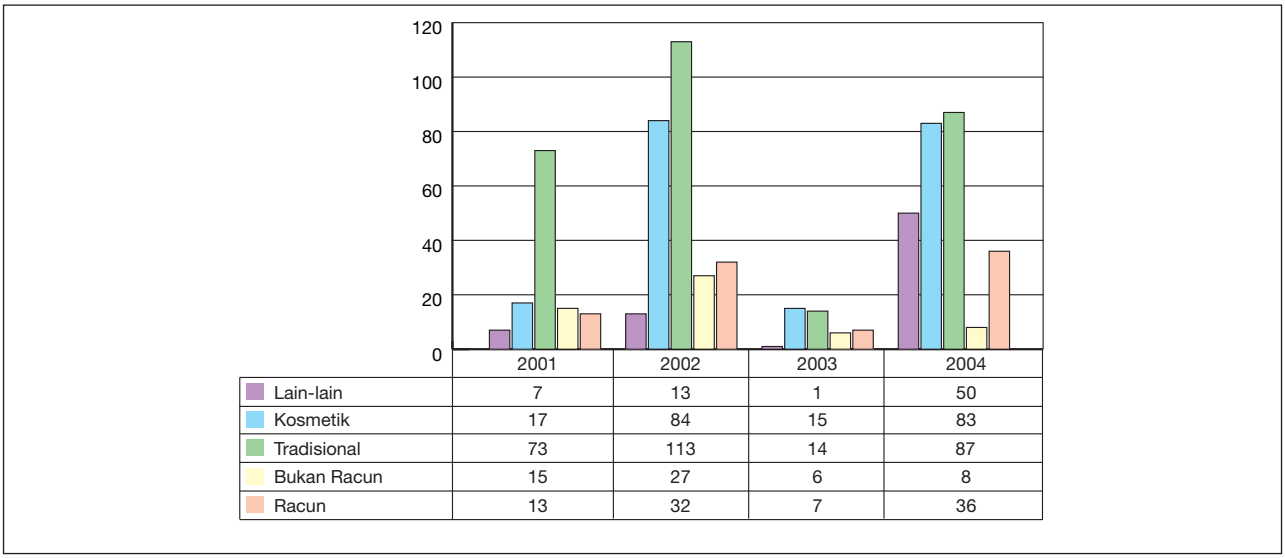


	2001	2002	2003	2004
Lain-lain	3	1	4	2
Kosmetik	3	13	13	49
Tradisional	13	40	18	28
Bukan Racun	9	8	3	4
Racun	7	6	6	7

- **Khidmat Nasihat**

Pada tahun 2004, sebanyak 264 khidmat nasihat telah diberikan, 36 daripada jumlah tersebut adalah berkenaan dengan APB produk racun, 8 produk bukan racun, 87 ubat tradisional, 83 kosmetik dan 50 lain-lain (Rajah 12).

Rajah 12 : Khidmat Nasihat Yang Diberikan Oleh APB (Tahun 2001-2004)



	2001	2002	2003	2004
Lain-lain	7	13	1	50
Kosmetik	17	84	15	83
Tradisional	73	113	14	87
Bukan Racun	15	27	6	8
Racun	13	32	7	36

- **Pemeriksaan Premis Untuk Pematuhan Amalan Makmal Baik**

  Khidmat sokongan diperoleh daripada Pusat Kawalan Kualiti dalam pemeriksaan Amalan Perkilangan Baik (APB) bagi aspek Amalan Makmal Baik. Pada tahun 2004 sebanyak 25 pemeriksaan telah dijalankan atas premis pengilang farmaseutikal tempatan dan bilangan ini meningkat berbanding pencapaian tahun 2003 (18 pemeriksaan).

Perancangan Untuk Tahun 2005

- Latihan APB Farmaseutikal Bercorak Modul

  Program latihan APB bercorak modul akan bermula pada Januari dan berakhir pada September 2005. Program ini dikelolakan bersama dengan MOPI.

  Modul 1 - International GMPs and Quality Assurance
  Modul 2 - GMP for Manufacturing Operations
  Modul 3 - Good Quality Control Laboratory
  Modul 4 - Validation Principles
  Modul 5 - Contamination Control and Cleanrooms
  Modul 6 - Good Aseptic Practices and Sterile Products
  Modul 7 - Computer System Validation
  Modul 8 - Process Development for Therapeutics-A Perspective for Pharmaceutical Products I
  Modul 9 - Process Development for Therapeutics-A Perspective for Pharmaceutical Products II

- Seminar APB untuk Pengilang-pengilang Ubat Tradisional

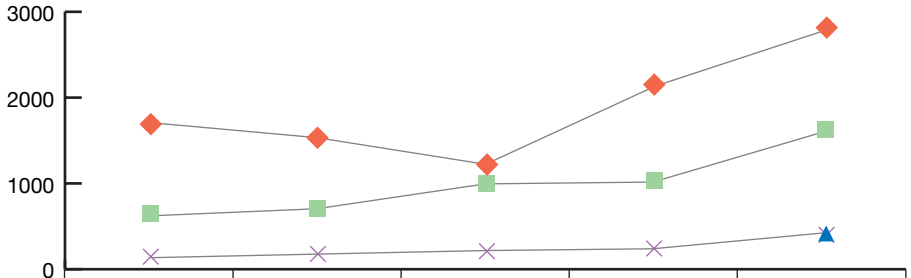
  Satu seminar akan dirancang pada pertengahan tahun 2005 khususnya untuk pengilang ubat tradisional dalam usaha untuk meningkatkan tahap pematuhan terhadap aspek Amalan Perkilangan Baik (APB) dan diharapkan tahap pematuhan APB akan dapat ditingkatkan dari semasa ke semasa.

pasca pendaftaran produk

Pasca Pendaftaran Produk

Aktiviti surveilans rutin, penyiasatan atas aduan mengenai produk dan pemonitoran kesan advers (farmakovigilans) serta meluluskan permohonan variasi dan juga pendaftaran semula produk seperti yang ditunjukkan pada Rajah 13 adalah aktiviti utama Pusat Pasca Pendaftaran Produk. Aktiviti pemprosesan permohonan Pertukaran Pemegang Pendaftaran dikendalikan oleh Unit Koordinasi Regulatori, Pusat Pendaftaran Produk.

Rajah 13 : Tugasan aktiviti surveilans, aktiviti penyiasatan aduan produk, farmakovigilans dan variasi (Tahun 2000-2004)



	2000	2001	2002	2003	2004
Bil. Sampel Produk	1789	1487	1201	2037	2793
Bil. ADR	792	811	1000	1067	1665
Bil. Laporan Aduan	110	124	181	180	297
Bil. Variasi*					338

*Aktiviti penilaian permohonan variasi dipindah dari Pusat Pendaftaran Produk ke PPPP hanya mulai Julai 2004 secara berperingkat

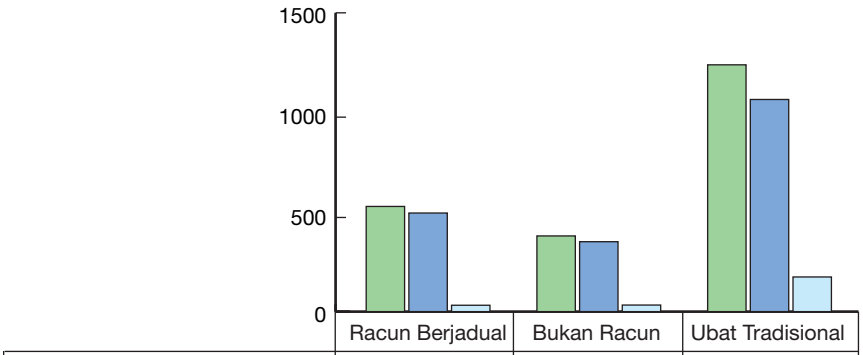
- **Surveilans**

Bagi aktiviti surveilans pada tahun 2004, sebanyak 2793 sampel daripada 24,587 produk yang berdaftar telah diambil untuk tujuan surveilans, dan ini mewakili 11.36%. Akan tetapi, perlu diingatkan bahawa bukan semua produk berdaftar berada dalam pasaran dan peratusan produk yang disampel ada kemungkinan lebih tinggi berbanding dengan jumlah sebenar dalam pasaran.

Kesemua sampel yang diambil di bawah program surveilans dihantar ke Pusat Kawalan Kualiti untuk dianalisis. Ujian atas produk yang mengandungi racun berjadual dan produk bukan racun dijalankan mengikut protokol analisis terkini yang dikemukakan oleh pengilang.

Ujian atas ubat-ubatan tradisional dijalankan berpandukan ujian yang ditetapkan, contohnya, ujian-ujian untuk pencemaran mikrob dan kulat, logam berat serta ujian-ujian farmaseutikal asas. Analisis kadar kegagalan produk yang telah diuji berdasarkan kategori produk ditunjukkan pada Rajah 14.

Rajah 14 : Keputusan ujian makmal terhadap sampel surveilans (Tahun 2004)



	Racun Berjadual	Bukan Racun	Ubat Tradisional
Bil. Yang Diuji	528	380	1239
Bil. Yang Diluluskan	495	351	1065
Bil. Gagal	32	33	174

Keputusan ujian makmal untuk 2295 sampel produk telah diterima bagi kategori Racun, Bukan Racun dan ubat Traditional, yang mana 2055 sampel telah lulus ujian makmal dan 239 telah gagal ujian makmal. Bukan kesemua produk yang gagal ujian makmal perlu dipanggil balik. Sekiranya kegagalan ujian tersebut tidak mempengaruhi kualiti produk secara ketara, surat amaran dikeluarkan kepada pemegang pendaftaran. Bagi produk yang gagal ujian makmal bagi 2 kelompok yang berlainan dan dikenakan panggilbalik sebanyak 2 kali, pendaftaran produk tersebut akan dibatalkan.

Sebanyak 5 arahan Panggilbalik Tahap 1 (dalam tempoh 24 jam) telah dikeluarkan yang mana satu adalah bagi ubat tradisional dan 4 bagi produk bukan racun. Tiada panggilbalik Tahap 2 (dalam tempoh 72 jam) pada tahun 2004.

145 kelompok produk telah dikenakan arahan Panggilbalik Tahap 3 (dalam tempoh 30 hari) iaitu 20 produk racun, 8 produk bukan racun dan 117 ubat traditional. Kesemua panggilbalik dilakukan sehingga tahap peringkat penjualan/pembekalan kepada pelanggan. Tiada panggilbalik yang perlu dilakukan sehingga ke peringkat pengguna.

29 kelompok produk telah dipanggilbalik secara sukarela oleh pemegang produk berdaftar iaitu 15 produk racun, 12 produk bukan racun dan 2 ubat tradisional.

Pasca Pendaftaran Produk

Jadual 8 : Produk Panggilbalik (arahan + sukarela)

Tahun	2000			2001			2002			2003			2004		
Jumlah Panggilbalik	148			122			198			498			179		
Kategori (A/X/T)	32	17	99	22	13	87	55	29	114	52	166	280	35	24	120

A=Racun; X=Bukan Racun; T=Tradisional

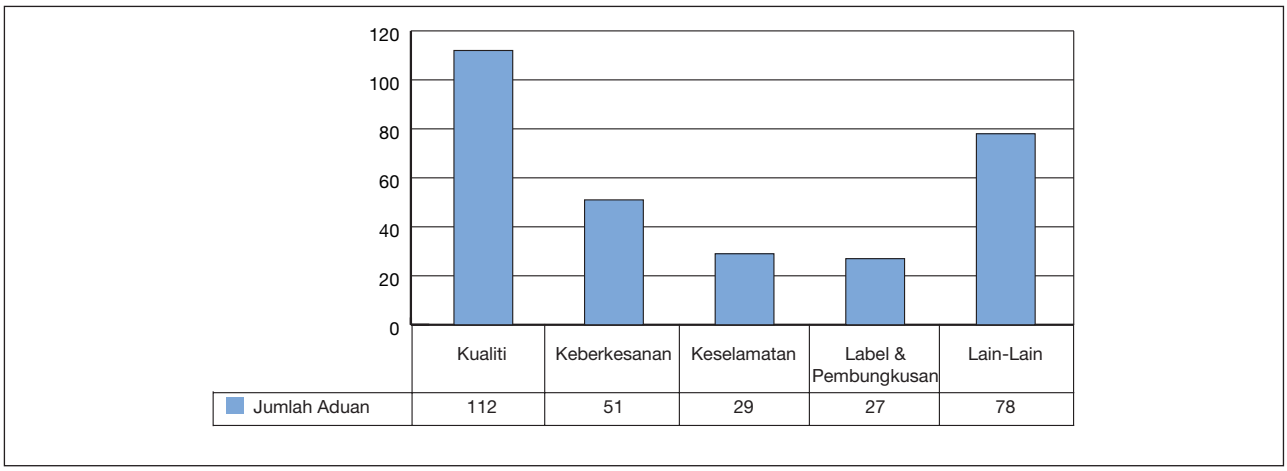
Pemonitoran label dan sisip bungkusan juga dilakukan terhadap sampel produk untuk memastikan label dalam pasaran memenuhi keperluan pelabelan yang diluluskan. Jika label yang disemak tidak memenuhi keperluan yang diluluskan, amaran label akan dikeluarkan. Pada tahun 2004, sebanyak 1792 label telah disemak dan 140 amaran label telah dikeluarkan.

- **Aduan Produk**

Bilangan aduan terhadap produk berdaftar bagi tahun 2004 didapati meningkat dengan banyaknya berbanding dengan tahun 2003, yang mana bilangan aduan bagi tahun 2004 adalah 297 berbanding 180 bagi tahun 2003, iaitu peningkatan sebanyak 65%. Tindakan susulan telah diambil untuk menyelesaikan aduan-aduan ini dalam tempoh 6 minggu bagi lebih daripada 95% kes.

Jenis-jenis aduan yang diterima oleh Unit Surveilans dan Aduan Produk, Pusat Pasca Pendaftaran Produk, terbahagi kepada kualiti, keberkesanan, keselamatan, label dan lain-lain seperti yang ditunjukkan pada Rajah 15. Tindakan yang akan diambil terhadap aduan adalah berasaskan jenis aduan yang diterima. Sebanyak 67 aduan terhadap produk tidak berdaftar telah dimajukan ke Bahagian Perkhidmatan Farmasi, Cawangan Penguatkuasa untuk tindakan lanjut. Manakala aduan mengenai kualiti produk yang dikilangkan oleh pengilang tempatan akan dimajukan ke Pusat Amalan Perkilangan Baik untuk tindakan semasa kilang diaudit. Jika terdapat aduan mengenai produk campur palsu (adulteration) dan melibatkan isu keselamatan pengguna, pendaftaran produk tersebut akan dibatalkan dan terdapat 1 produk telah dibatalkan pendaftarannya.

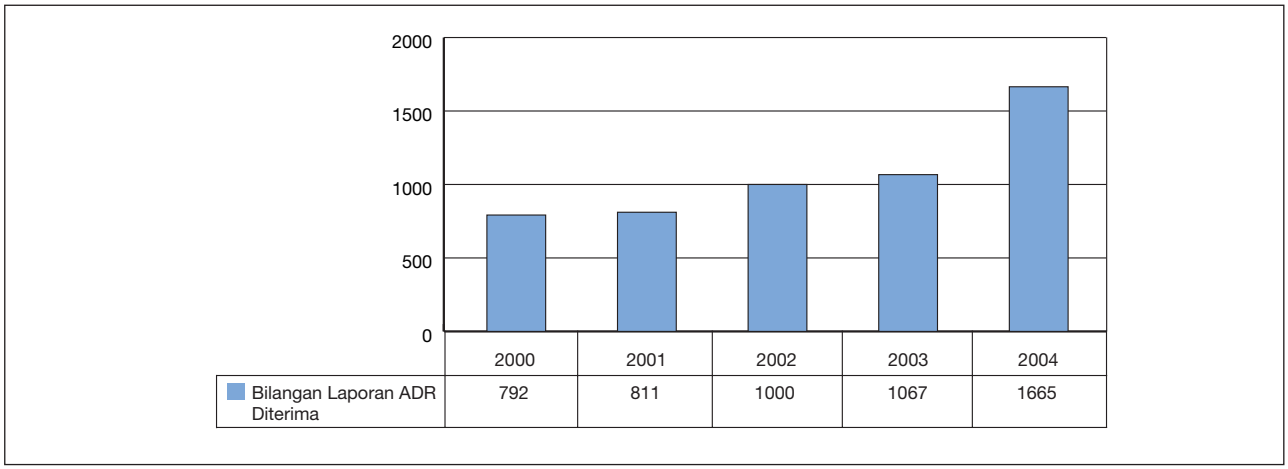
Rajah 15 : Jenis-Jenis Aduan (Tahun 2004)



- **Pemonitoran Kesan Advers Ubat**

Bagi aktiviti pemonitoran kesan advers ubat (ADR), terdapat peningkatan sebanyak 56% dalam jumlah laporan kesan advers ubat yang diterima dalam tahun 2004, iaitu sebanyak 1665 laporan berbanding dengan 1067 laporan dalam tahun 2003 (Rajah 16). Sebanyak 1591 laporan untuk kategori produk racun (A), 31 laporan untuk produk bukan racun (X) dan 43 laporan untuk ubat tradisional (T).

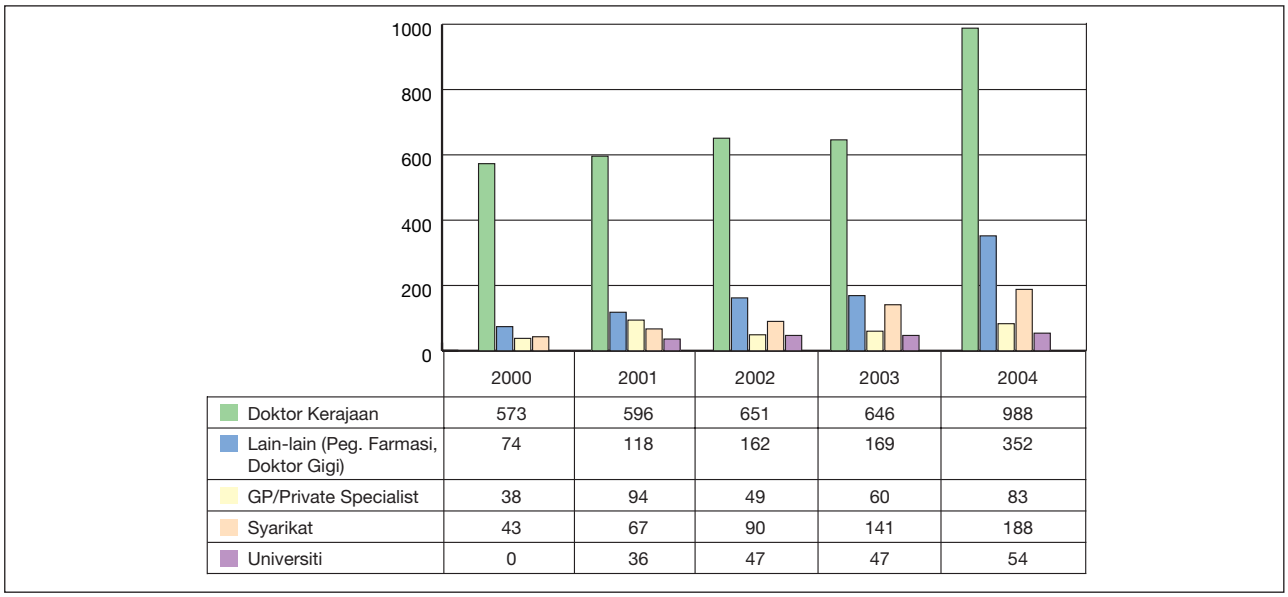
Rajah 16 : Bilangan Laporan ADR Diterima (Tahun 2000-2004)



	2000	2001	2002	2003	2004
Bilangan Laporan ADR Diterima	792	811	1000	1067	1665

Bilangan laporan yang diterima daripada pelbagai negeri dapat dilihat pada Rajah 18 yang mana jumlah laporan tertinggi telah dikemukakan oleh Hospital Kuala Lumpur dan negeri Selangor. Dari analisis laporan ADR berdasarkan pelapor, kebanyakan laporan kesan advers ubat diterima daripada Pegawai Perubatan yang bertugas di hospital-hospital kerajaan. Laporan kesan advers ubat daripada pemegang pendaftaran juga meningkat sebanyak 36% bagi tahun 2004 (Rajah 17).

Rajah 17 : Analisis Laporan ADR Berdasarkan Pelapor (Tahun 2000-2004)

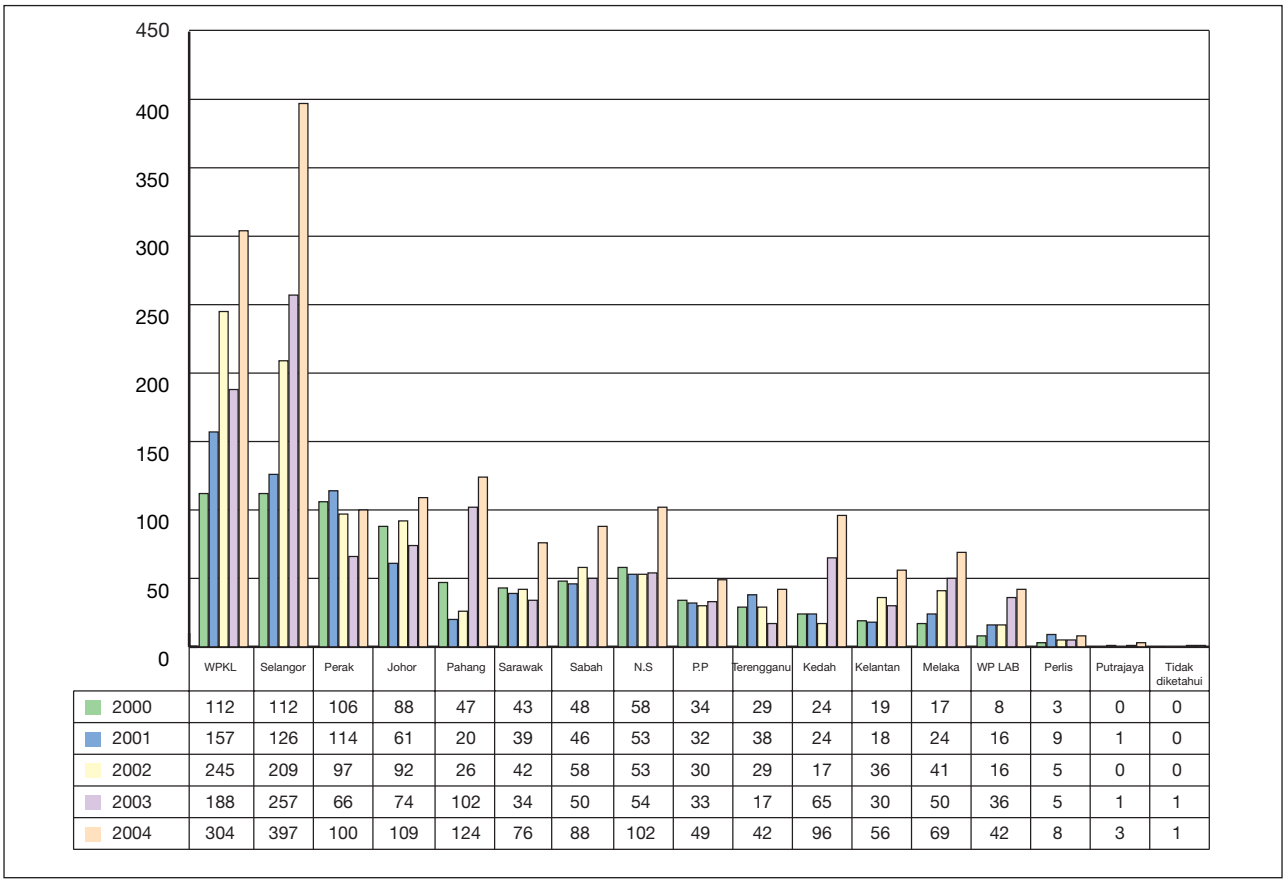


	2000	2001	2002	2003	2004
Doktor Kerajaan	573	596	651	646	988
Lain-lain (Peg. Farmasi, Doktor Gigi)	74	118	162	169	352
GP/Private Specialist	38	94	49	60	83
Syarikat	43	67	90	141	188
Universiti	0	36	47	47	54

Merujuk kepada Rajah 17 dan laporan ADR yang diterima, kesedaran pemantauan kesan advers produk racun (A) di peringkat hospital amat tinggi bagi menjamin keselamatan pesakit berbanding dengan ubat tradisional yang tiada pemantauan yang khusus terhadap profil keselamatan dilaksanakan.

Berdasarkan laporan ADR yang diterima, data-data tersebut dibincangkan semasa mesyuarat MADRAC dan tindakan lanjutan akan diambil sepertimana dibincangkan. Laporan ADR juga disediakan untuk WHO (World Health Organisation) yang mana laporan ini dihantar ke The Uppsala Monitoring Centre supaya segala data ini dapat dikumpulkan.

Rajah 18 : Analisis Laporan ADR Berdasarkan Negeri (n=1665) (Tahun 2000-2004)



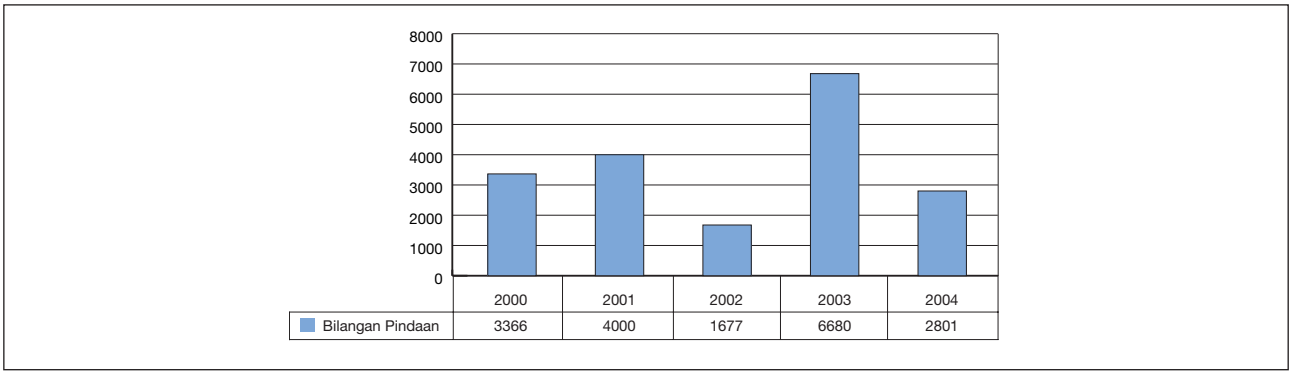
	WPKL	Selangor	Perak	Johor	Pahang	Sarawak	Sabah	N.S	P.P	Terengganu	Kedah	Kelantan	Melaka	WP LAB	Perlis	Putrajaya	Tidak diketahui
2000	112	112	106	88	47	43	48	58	34	29	24	19	17	8	3	0	0
2001	157	126	114	61	20	39	46	53	32	38	24	18	24	16	9	1	0
2002	245	209	97	92	26	42	58	53	30	29	17	36	41	16	5	0	0
2003	188	257	66	74	102	34	50	54	33	17	65	30	50	36	5	1	1
2004	304	397	100	109	124	76	88	102	49	42	96	56	69	42	8	3	1

- **Permohonan Variasi Produk**

Bermula dari Julai 2004, Pusat Pasca Pendaftaran Produk mengambil alih aktiviti permohonan variasi bagi produk-produk berdaftar yang dahulunya di bawah tanggungjawab setiap unit di Pusat Pendaftaran Produk. Permohonan variasi merangkumi permohonan pindaan data dan permohonan pertukaran tapak perkilangan. Pusat ini juga memproses permohonan pendaftaran semula.

Berdasarkan Rajah 19, jumlah permohonan pindaan data bagi produk berdaftar pada tahun 2004 didapati menurun berbanding tahun 2003 iaitu 2801 permohonan berbanding 6680.

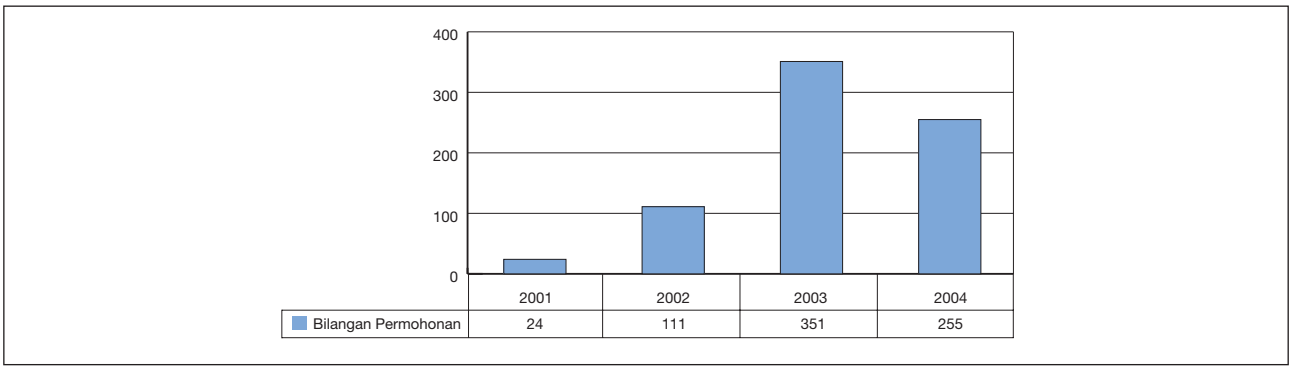
Rajah 19 : Bilangan Pindaan Data (Tahun 2000-2004)



- **Pertukaran Tapak Perkilangan**

Permohonan pertukaran tapak perkilangan meliputi pertukaran yang disebabkan oleh pergabungan syarikat, menaiktaraf kelengkapan/kemudahan kilang, 'rationalization of manufacturing site', kes krisis dan sebagainya. Jumlah permohonan sejak tahun 2001 dapat dilihat pada Rajah 20 yang mana pada tahun 2004, 255 permohonan diterima.

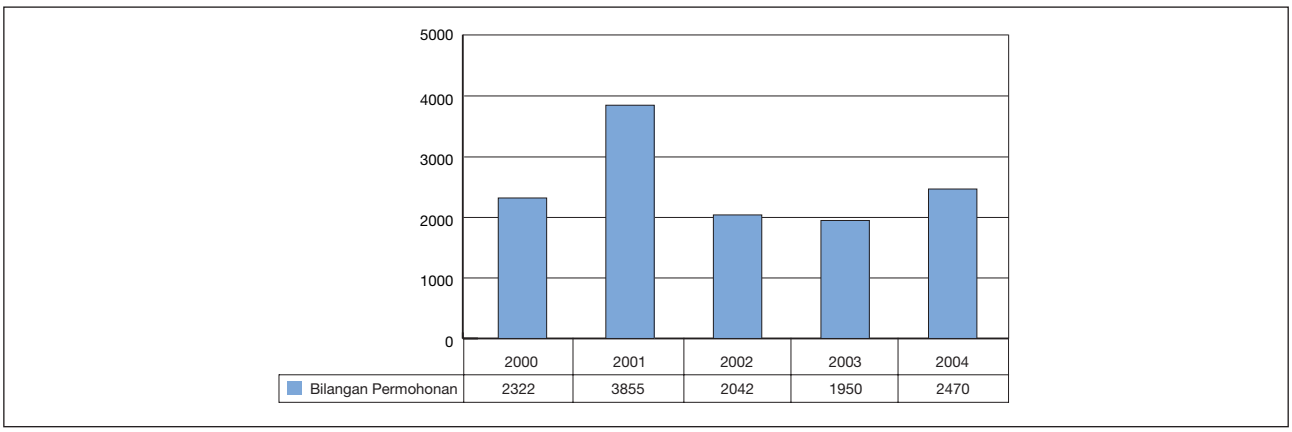
Rajah 20 : Pertukaran Tapak Pengilang (Tahun 2001-2004)



- **Permohonan Pendaftaran Semula**

Pendaftaran produk lazimnya bagi tempoh lima tahun dan permohonan pendaftaran semula perlu dikemukakan sebelum tamat tempoh pendaftaran sesuatu produk. Permohonan yang diterima bagi tahun 2004 adalah 2,470 (Rajah 21).

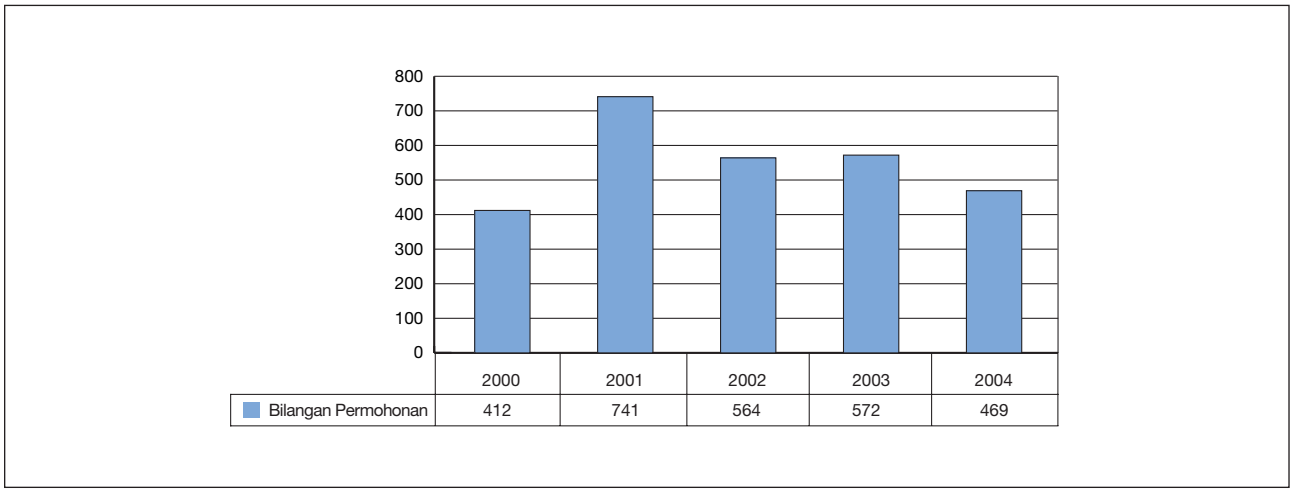
Rajah 21 : Permohonan Pendaftaran Semula Yang Diterima (Tahun 2000-2004)



- **Permohonan Pertukaran Pemegang Pendaftaran**

Jumlah permohonan pertukaran pemegang pendaftaran yang diterima dari tahun 2000 dapat dilihat pada Rajah 22 dan permohonan yang diterima pada tahun 2004 adalah sebanyak 469 permohonan.

Rajah 22 : Bilangan Permohonan Pertukaran Pemegang (Tahun 2000-2004)



- **Halatuju 2005**

Aktiviti surveilans rutin akan diteruskan atas produk-produk yang berdaftar dan aktiviti surveilans akan dipergiatkan lagi atas produk-produk yang disyaki mengandungi adulteran, produk-produk dari pengilang-pengilang bermasalah yang dikenalpasti serta produk-produk yang sukar dikilangkan.

Memandangkan produk kosmetik telah mula didaftarkan pada 2003, aktiviti surveilans, aduan dan pemonitoran kesan advers terhadap produk kosmetik akan dimulakan pada tahun 2005.

Satu kaji selidik akan dilaksanakan di kalangan pengamal-pengamal perubatan dan industri-industri farmaseutikal bagi mengenalpasti kaedah sistem melapor ADR yang lebih baik.

pelesenan

Pelesenan

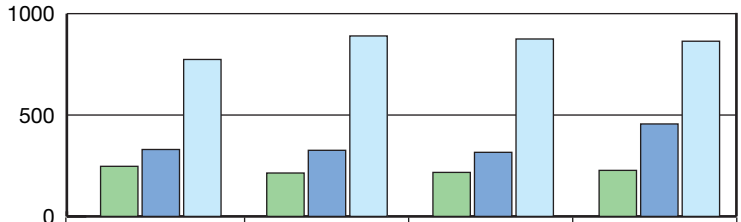
Pihak Berkuasa Kawalan Dadah mengeluarkan 4 jenis lesen di bawah peruntukan sub-Peraturan 12 (1) Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984. Pengeluaran Lesen Pengilang, Lesen Import dan Lesen Pemborong dikendalikan oleh Unit Pelesenan dan Pensijilan, Pusat APB, manakala Lesen Import Percubaan Klinikal dikendalikan oleh Unit Penyelidikan Klinikal Regulatori, Pusat Pendaftaran Produk.

- **Status Perkembangan Premis Berlesen**

Sebanyak 1547 lesen telah dikeluarkan pada tahun 2004 yang mana jumlah pengilang berlesen ialah 227, 456 pengimport berlesen dan 864 pemborong berlesen (Rajah 23).

Senarai serta maklumat lengkap mengenai premis-premis berlesen boleh dilayari menerusi laman web BPFK (www.bpfk.gov.my). Segala maklumat dikemaskini setiap bulan.

Rajah 23 : Status Perkembangan Premis Berlesen (Tahun 2001-2004)

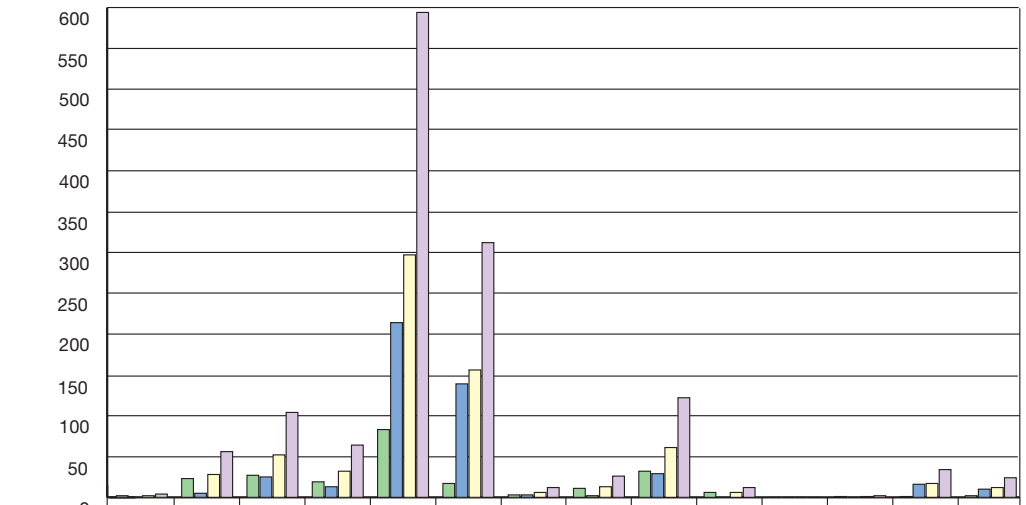


	2001	2002	2003	2004
Pengilang	247	214	217	227
Pengimport	330	326	316	456
Pemborong	774	890	875	864

- **Taburan Geografi Premis Berlesen**

Taburan geografi premis-premis berlesen bagi tahun 2004 adalah seperti yang digambarkan pada Rajah 24. Negeri Selangor mempunyai premis berlesen yang paling banyak, diikuti oleh Wilayah Persekutuan (Kuala Lumpur) dan Johor.

Rajah 24 : Taburan Geografi Premis Berlesen (Tahun 2004)

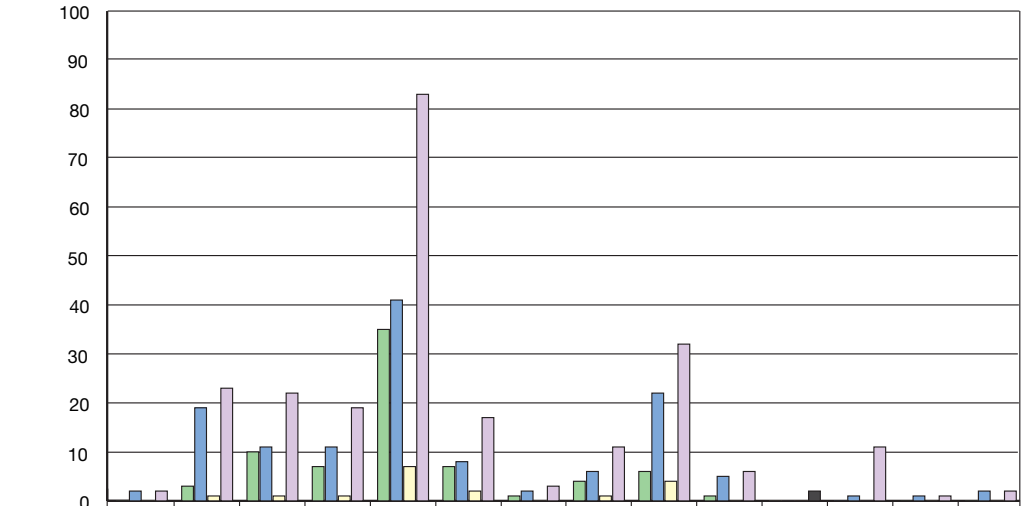


	PERLIS	KED	PP	PRK	SGR	WPKL	N.S	MEL	JOH	KEL	TGN	PAH	SAB/ LAB	SWK
Pengilang	2	23	27	19	83	17	3	11	32	6	0	1	1	2
Pengimport	0	5	25	13	214	139	3	2	29	0	0	0	16	10
Pemborong	2	28	52	32	297	156	6	13	61	6	0	1	17	12
Jumlah	4	56	104	64	594	312	12	26	122	12	0	2	34	24

- **Kategori Premis Pengilang Berlesen**

Kategori premis pengilang berlesen bagi tahun 2004 adalah seperti yang dipaparkan pada Rajah 25. Negeri Selangor mempunyai bilangan premis pengilang berlesen yang tertinggi diikuti oleh Johor, Kedah dan Pulau Pinang.

Rajah 25 : Kategori Premis Lesen Pengilang (Tahun 2004)

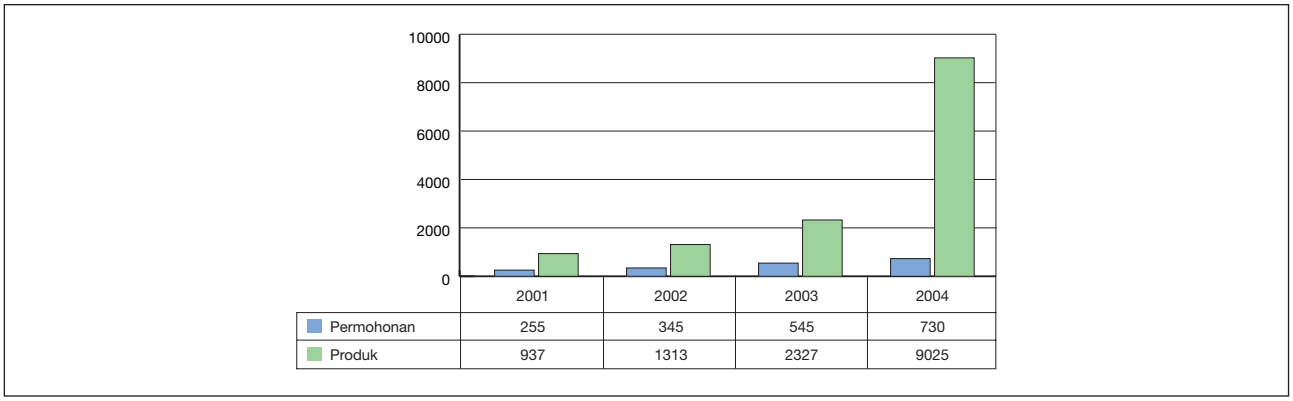


	PERLIS	KED	PP	PRK	SGR	WPKL	N.S	MEL	JOH	KEL	TGN	PAH	SAB/ LAB	SWK
Farmaseutikal	0	3	10	7	35	7	1	4	6	1	0	0	0	0
Tradisional	2	19	11	11	41	8	2	6	22	5	0	1	1	2
Kosmetik	0	1	1	1	7	2	0	1	4	0	0	0	0	0
Jumlah	2	23	22	19	83	17	3	11	32	6	2	1	1	2

- **Senarai Tambahan Keluaran Berdaftar**

Jumlah permohonan yang diproses pada tahun 2004 adalah sebanyak 730 dan ini meliputi sebanyak 9,025 produk (Rajah 26). Senarai ini diproses berdasarkan permohonan yang dikemukakan apabila terdapat produk yang baru didaftarkan dan senarai perlu dikepilkan bersama Lesen Pengilang atau Lesen Import.

Rajah 26 : Statistik Bagi Pengeluaran Senarai Tambahan Keluaran Berdaftar (Tahun 2001-2004)



	2001	2002	2003	2004
Permohonan	255	345	545	730
Produk	937	1313	2327	9025

- **Tindakan Punitif**

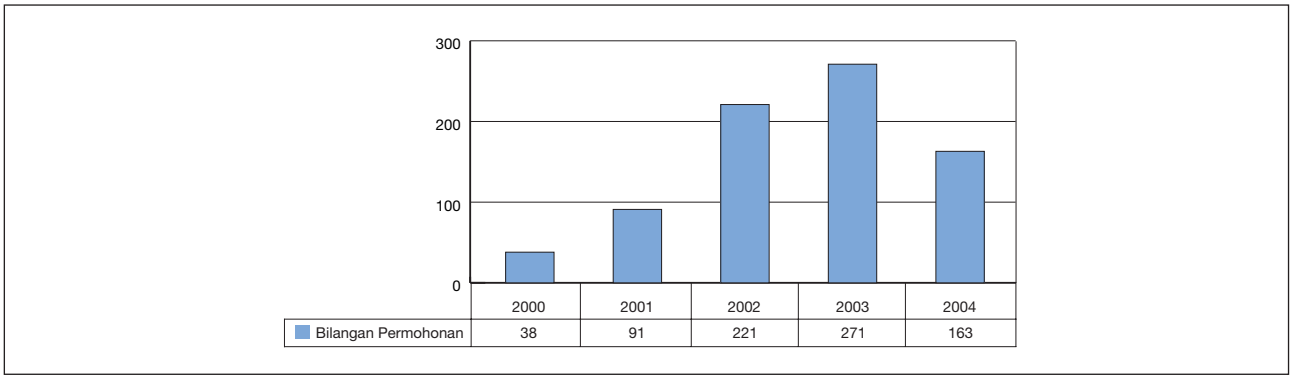
Pihak Berkuasa Kawalan Dadah (PBKD) telah menarik balik enam lesen pengilang pada tahun 2004. Lesen bagi tiga pengilang ubat tradisional ditarik balik kerana terlibat dengan pengeluaran produk yang tercemar/dicampurpalsu dan lesen tiga pengilang farmaseutikal ditarik balik kerana mempunyai tahap APB yang amat lemah.

- **Lesen Import Percubaan Klinikal (LIPK)**

Jumlah LIPK yang dikeluarkan pada tahun 2004 ialah sebanyak 163 lesen (Rajah 27). Dari tahun 1997 sehingga 2004 sejumlah 848 lesen telah dikeluarkan. Di samping itu, sebanyak 180 permohonan tambahan yang melibatkan permohonan untuk menambah kuantiti produk diimport, pertukaran tapak (pusat) penyelidikan, penggunaan protokol penyelidikan yang baru dan sebagainya telah diproses sepanjang tahun 2004.

Satu sistem pemeriksaan fasiliti percubaan klinikal akan dilaksanakan pada masa hadapan untuk memastikan pematuhan kepada keperluan 'Good Clinical Practice' dan 'Good Laboratory Practice'.

Rajah 27 : Lesen Import Percubaan Klinikal (Tahun 2001-2004)



	2000	2001	2002	2003	2004
Bilangan Permohonan	38	91	221	271	163

pensijilan & pengesahan status produk

Pensijilan & Pengesahan Status Produk

Aktiviti pengeluaran Perakuan Pendaftaran, Perakuan Produk untuk tujuan eksport serta pengesahan status pendaftaran produk dikendalikan oleh Unit Koordinasi Regulatori, Pusat Pendaftaran Produk, manakala pengeluaran Perakuan Amalan Perkilangan Baik (APB) untuk tujuan eksport dikendalikan oleh Unit Pelesenan & Pensijilan, Pusat APB.

• Perakuan Pendaftaran (PP)

Jumlah pengeluaran Perakuan Pendaftaran untuk produk berdaftar sepanjang lima tahun terakhir, iaitu sejak tahun 2000 sehingga 2004 adalah seperti yang ditunjukkan dalam Jadual 9. Pada tahun 2004 sebanyak 42,311 sijil dikeluarkan. Peningkatan pengeluaran sijil adalah selaras dengan peningkatan produk yang didaftarkan terutamanya pendaftaran produk kosmetik.

Jadual 9 : Jumlah PP Yang Dikeluarkan (Tahun 2000-2004)

Tahun	Produk Racun	Produk Bukan Racun	Produk Tradisional	Kosmetik	Jumlah
2000	505	387	1,328	327	2,547
2001	180	624	1,344	309	2,457
2002	342	235	864	159	1,600
2003	324	275	1,349	4,721	6,669
2004	353	226	970	40,762	42,311

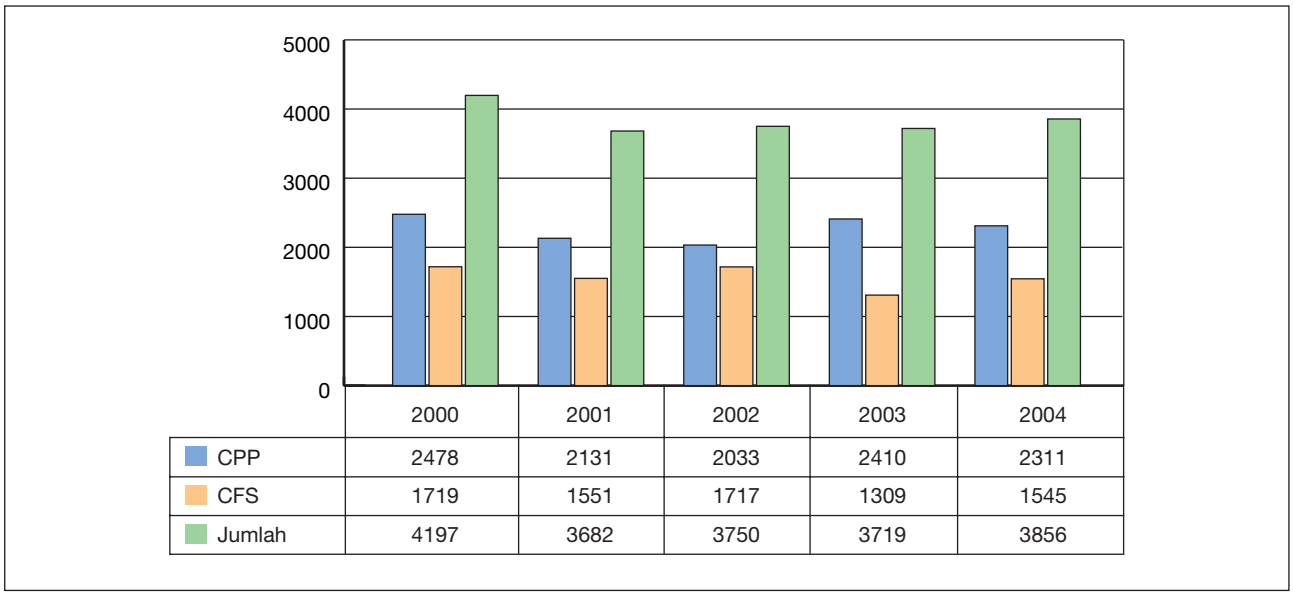
• Perakuan Produk Untuk Tujuan Eksport

Jumlah pengeluaran Perakuan Produk Farmaseutikal [Certificates of Pharmaceutical Products (CPP)] dan Perakuan Penjualan Bebas [Certificate of Free Sale (CFS)] untuk alat perubatan dan kosmetik bagi tujuan eksport sejak tahun 2000 sehingga 2004 adalah seperti yang ditunjukkan pada Rajah 28. Pada tahun 2004 sebanyak 2,311 CPP dan 1,545 CFS telah dikeluarkan.

CPP yang dikeluarkan adalah untuk eksport ke negara seperti Afghanistan, Australia, Austria, Bangladesh, Botswana, Brunei, Kemboja, China, Ethiopia, Jerman, Ghana, Hong Kong, India, Indonesia, Iraq, Itali, Jepun, Jordan, Kenya, Kuwait, Arab Saudi, Macau, Maldives, Mauritius, Myanmar, New Zealand, Nigeria, Pakistan, Panama, Papua New Guinea, Filipina, Singapura, Sri Lanka, Sudan, Taiwan, Thailand, Emiriyah Arab Bersatu (UAE), Vietnam, Afrika Selatan, Zimbabwe, Yaman dan Zambia.

CFS pula adalah untuk eksport kosmetik atau peralatan perubatan ke negara seperti Argentina, Bangladesh, Bolivia, Brazil, Brunei, Bulgaria, China, Chile, Colombia, Ecuador, Mesir, Ethiopia, Guatemala, Hong Kong, India, Indonesia, Iran, Khazastan, Korea, Kuwait, Arab Saudi, Mauritius, Mexico, Nigeria, Pakistan, Panama, Peru, Filipina, Russia, Sri Langka, Taiwan, Thailand, Turki, Vietnam, Afrika Selatan dan Yaman.

Rajah 28 : Pengeluaran Perakuan Produk Farmaseutikal dan Perakuan Penjualan Bebas (Tahun 2000-2004)

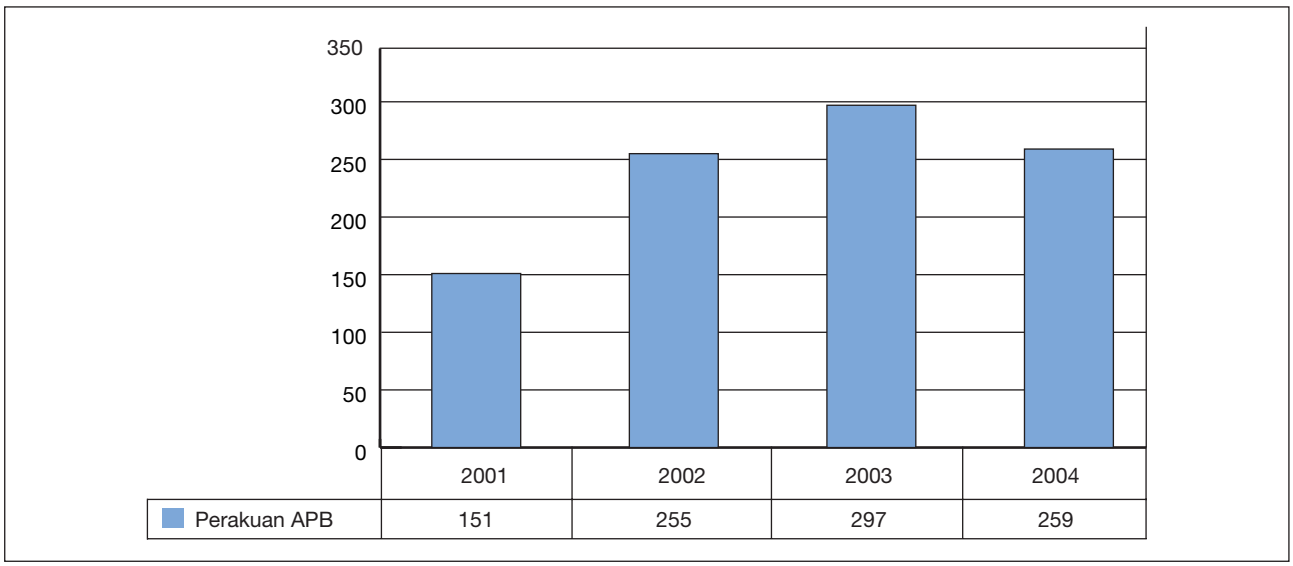


	2000	2001	2002	2003	2004
CPP	2478	2131	2033	2410	2311
CFS	1719	1551	1717	1309	1545
Jumlah	4197	3682	3750	3719	3856

- **Perakuan APB Untuk Tujuan Eksport**

Pada tahun 2004, jumlah perakuan APB yang dikeluarkan adalah sebanyak 259 (Rajah 29). Perakuan ini adalah untuk negara-negara seperti Afghanistan, Australia, Botswana, Brunei, Kemboja, Kanada, China, Mesir, Ethiopia, Amerika Syarikat, Fiji, Ghana, Hong Kong, India, Indonesia, Iran, Iraq, Jepun, Jordan, Khazastan, Arab Saudi, Kuwait, Republik Korea, Laos, Macau, Maldives, Mexico, Mozambique, Myanmar, Nigeria, Pakistan, Papua New Guinea, Thailand, Turki, Uganda, Emiriyah Arab Bersatu (UAE), Vietnam, Afrika Selatan, Oman, Sri Lanka, Taiwan, Zimbabwe, Yaman, Sudan, Romania, Singapura dan Zambia.

Rajah 29 : Perakuan APB Untuk Tujuan Eksport (Tahun 2001-2004)

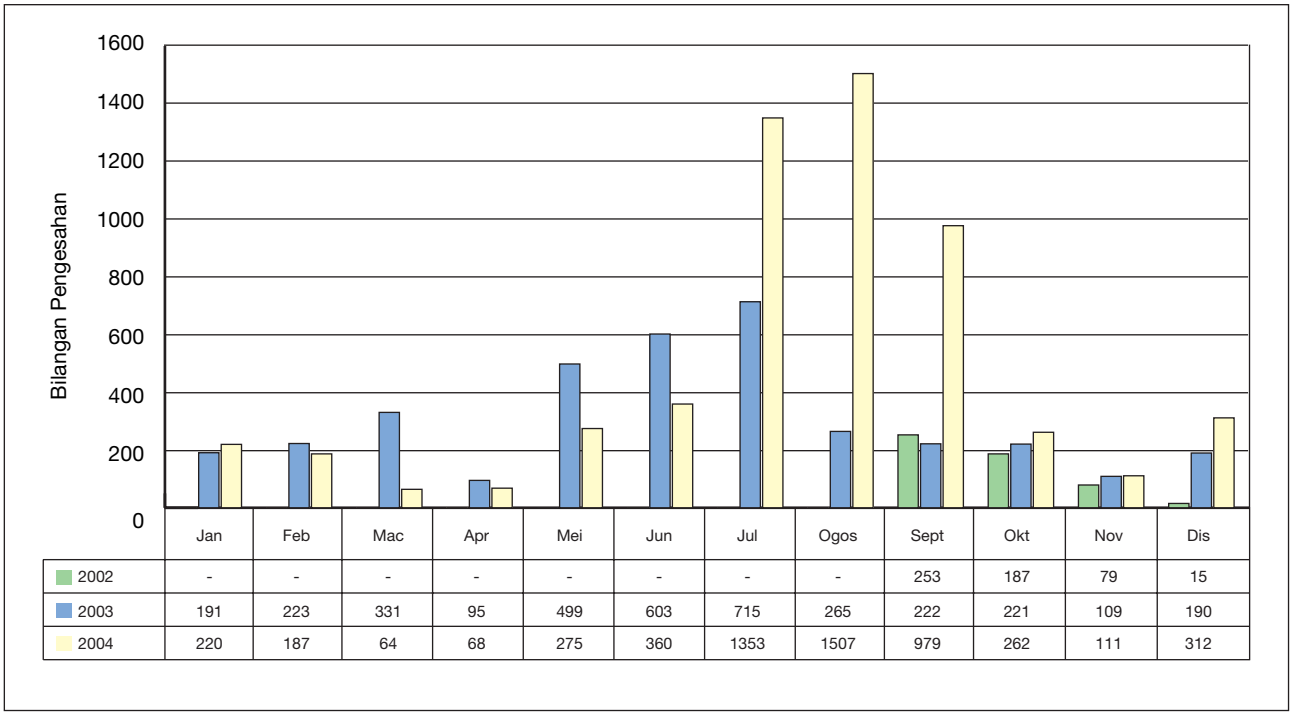


	2001	2002	2003	2004
Perakuan APB	151	255	297	259

- **Permohonan Pengesahan Status Pendaftaran**

Permohonan pengesahan status pendaftaran produk biasanya dikemukakan oleh Cawangan Penguatkuasa Farmasi (CPF), Kementerian Kesihatan Malaysia bagi produk yang disita dalam serbuan-serbuan yang dijalankan. Pengesahan ini diperlukan untuk tujuan pendakwaan di mahkamah dan sepanjang tahun 2004 sebanyak 5,698 produk telah disahkan status pendaftarannya (Rajah 30).

Rajah 30 : Pengesahan Status Pendaftaran Produk Oleh CPF (Tahun 2002-2004)



	Jan	Feb	Mac	Apr	Mei	Jun	Jul	Ogos	Sept	Okt	Nov	Dis
2002	-	-	-	-	-	-	-	-	253	187	79	15
2003	191	223	331	95	499	603	715	265	222	221	109	190
2004	220	187	64	68	275	360	1353	1507	979	262	111	312

Data bagi Januari - Ogos 2002 tidak diperolehi

komunikasi

Komunikasi

Komunikasi memainkan peranan yang penting dalam menghubungkan BPFK dengan pihak industri, orang ramai dan juga agensi kerajaan yang lain. Mulai pertengahan tahun 2004 dengan penstrukturan semula organisasi, dua orang pegawai (seorang Ketua Penolong Pengarah dan seorang Penolong Pengarah) telah ditempatkan di Unit Informasi & Komunikasi bagi memastikan komunikasi beroperasi dengan lancar. Antara aktiviti-aktiviti yang telah dijalankan oleh Unit Informasi dan Komunikasi adalah seperti berikut:

- **Laman Web**

Laman web BPFK adalah merupakan sumber komunikasi yang amat penting untuk berhubung dengan pihak pelanggan terutama pihak industri dan orang awam. Maklumat-maklumat terkini terutamanya polisi Pihak Berkuasa Kawalan Dadah (PBKD), senarai ubat berdaftar, keputusan mesyuarat PBKD boleh didapati dengan mudah dan cepat melalui laman web ini.

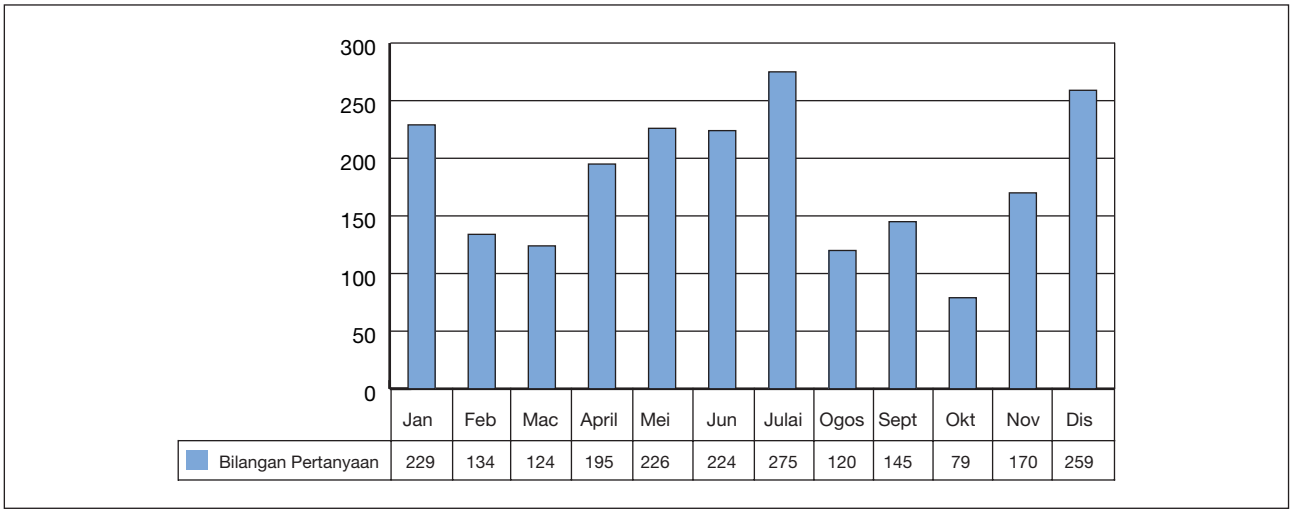
Untuk memperbaiki lagi laman web BPFK, cadangan dan komen daripada pelanggan amat dialu-alukan.

- **Pertanyaan**

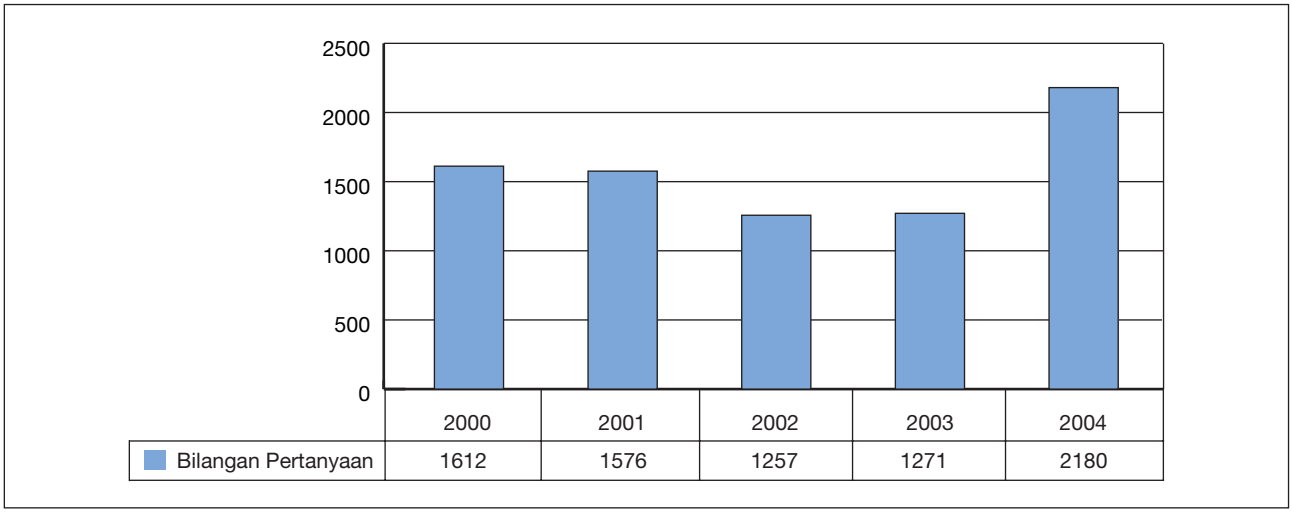
Pada tahun 2004 sebanyak 2180 pertanyaan telah diterima oleh Unit Informasi dan Komunikasi dan pecahan pertanyaan mengikut bulan adalah seperti dalam Rajah 31. Perbandingan tahunan pertanyaan yang diterima adalah seperti dalam Rajah 32. Unit Informasi dan Komunikasi menerima pelbagai jenis pertanyaan daripada pelanggan dan pecahan jenis pertanyaan boleh dilihat pada Jadual 10. Pada tahun 2004 jumlah pertanyaan telah didapati meningkat terutama pertanyaan berkaitan pengkelasan produk (28.4%). Keadaan ini berkemungkinan disebabkan oleh semakin banyaknya syarikat yang ingin mendaftar produk tetapi tidak pasti pengkelasannya. Pertanyaan yang diterima adalah melalui telefon, faks, surat, e-mel dan juga secara 'walk-in'.

Komunikasi

Rajah 31 : Bilangan Pertanyaan Diterima (Tahun 2004)



Rajah 32 : Bilangan Pertanyaan Diterima (Tahun 2000-2004)



Jadual 10 : Jenis Pertanyaan Yang Diterima (Tahun 2004)

Jenis Pertanyaan		Jumlah	Peratus
Maklumat Am Produk		93	4.3
Indikasi Produk		28	1.3
Status Pendaftaran		144	6.6
Pembekal Produk		2	0.1
Klasifikasi Produk		619	28.4
Kemaskini Produk		55	2.5
On-line Quest		310	14.2
Isu Regulatori		204	9.4
Alat Perubatan		19	0.9
Lain-lain		40	1.8
Pendaftaran online	Farmaseutikal	175	8.0
	Tradisional	275	12.6
	Kosmetik	197	9.0
	Lain-lain	19	0.9

Komunikasi

• Penerbitan

BPFK juga menghasilkan beberapa penerbitan yang berkaitan dengan kawalan regulatori ubat-ubatan. Antara penerbitan yang telah diterbitkan sepanjang tahun 2004 adalah:

- Berita Ubat-Ubatan
- Pekeliling Maklumat Ubat
- Laporan Tahunan BPFK

• Perkhidmatan Perpustakaan

Perpustakaan BPFK mempunyai sebanyak 1817 buah buku, termasuk farmakopia-farmakopia utama dari pelbagai negara luar. Selain itu, perpustakaan ini juga melanggan 30 jenis jurnal dan buletin ubat, 'On-line Micromedex' dan 'International Pharmaceutical Abstracts'. Pada masa ini perpustakaan dibuka kepada kakitangan BPFK sahaja. Kakitangan di bawah Kementerian Kesihatan boleh memohon untuk menggunakan kemudahan-kemudahan di perpustakaan ini.

Perpustakaan ini juga dilengkapi dengan komputer yang ada kemudahan internet.

• Rancangan masa hadapan

Infrastruktur IT sedia ada akan terus dipertingkatkan dan koleksi bahan-bahan rujukan dalam bentuk elektronik akan ditambahkan lagi bagi memudahkan kakitangan BPFK membuat rujukan.

kualiti

Sistem Pengurusan Kualiti

Biro Pengawalan Farmaseutikal Kebangsaan telah memperoleh pengiktirafan MS ISO 9002:1994 pada 17 Julai 2001. Manakala pensijilan kepada versi 9001:2000 telah berjaya diperoleh pada 13 Ogos 2003. Pada Audit Penilaian Semula yang telah dijalankan oleh pihak SIRIM pada 23 dan 24 Ogos 2004, BPFK telah berjaya mengekalkan pengiktirafan MS ISO 9001:2000 tanpa sebarang laporan ketakakuran kepada keperluan yang ditetapkan.

Skop pensijilan adalah **Pengawalan regulatori produk-produk farmaseutikal, ubat tradisional dan kosmetik melalui aktiviti pendaftaran, pelesenan dan surveilans.**

Aktiviti-aktiviti berkaitan sistem pengurusan kualiti yang telah dijalankan pada tahun 2004 adalah seperti berikut:

1. Kursus Pengenalan ISO 9001:2000
   - 12 April 2004
2. Sistem Pengurusan Kualiti: Kursus Juruaudit Dalaman
   - 14-15 April 2004
3. Audit Dalaman BPFK
   - Jun 2004
4. Mesyuarat Jawatankuasa Kualiti (JKQ)
   - 2 kali
5. Mesyuarat Kajian Semula Pengurusan
   - 2 kali

Anugerah Khidmat Cemerlang

Pihak pengurusan BPFK sentiasa berusaha untuk memupuk semangat bekerja ke arah kecemerlangan di kalangan kakitangannya. Salah satu cara ke arah ini adalah dengan pemberian anugerah khidmat cemerlang kepada sekumpulan kakitangan yang telah menunjukkan prestasi kerja yang cemerlang setiap tahun. Pada tahun 2004, Majlis anugerah khidmat cemerlang telah diadakan pada 10hb September 2004 di Dewan Anggerik BPFK. Sijil penghargaan dan cek bernilai RM1000.00 bagi setiap penerima telah disampaikan oleh Pengarah BPFK, Datin Hjh.Hasiah bt Hj. Abdullah. Senarai nama pegawai yang berjaya menerima anugerah cemerlang bagi perkhidmatan tahun 2003 adalah seperti berikut:

1. Pn. Abida Haq bt. Syed M. Haq.
2. Cik Fudziah bt. Ariffin.
3. Cik Gnanasakthi a/p Kanagasabai.
4. Pn. Haslina bt. Ithnin.
5. En. Jaafar b. Lassa.
6. Pn. Masfiza bt. Abdul Hamid.
7. En. Mohammad Harian b. Ahmad.
8. Pn. Normah bt. Ali.
9. Pn. Ong Chui Eng.
10. En. Ramly b. Ahmad.
11. Pn. Ropidah bt. Hj. Yaakob.
12. Pn. Siti Madziah bt. Mohamed.
13. Pn. Yap Soo Huat.
14. En. Yunus b. Sulaiman.
15. En. Zulkifli b. Abd. Malek.
16. Cik Zuraida bt. Abdullah.



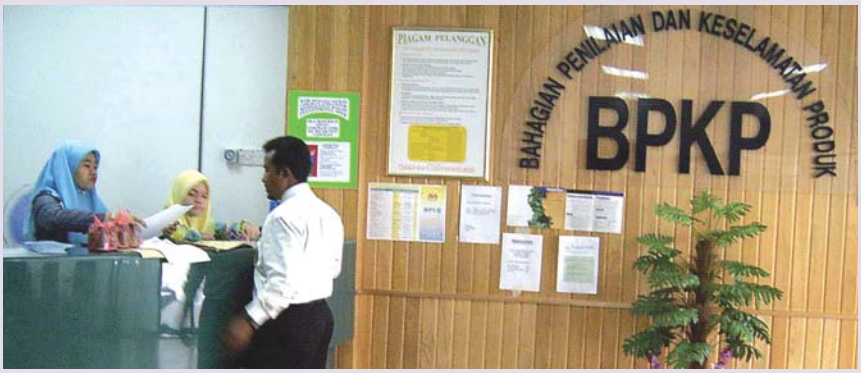






Sehari Bersama Pelanggan

Program sehari bersama pelanggan BPFK diadakan pada setiap hari Sabtu kedua setiap bulan. Pelanggan-pelanggan boleh datang pada hari ini untuk mendapat bantuan atau penjelasan daripada mana-mana pegawai mengenai masalah atau kemusykilan yang berkaitan. Pelanggan boleh berjumpa dengan pegawai atasan atau Pengarah jika pegawai yang ingin ditemui tidak ada atas sebab-sebab yang tidak dapat dielakkan.



Perhimpunan Pagi Bulanan

Perhimpunan pagi bulanan BPFK telah dimulakan pada bulan Jun 2004. Biasanya perhimpunan akan diadakan pada hari Khamis pertama setiap bulan kecuali atas sebab-sebab yang tidak dapat dielakkan. Atur cara untuk perhimpunan ini ialah bacaan doa, amanat dan nasihat daripada Pengarah BPFK, taklimat mengenai isu-isu semasa oleh pegawai kanan BPFK, nyanyian lagu kebangsaan serta lagu-lagu patriotik, bacaan ikrar perkhidmatan awam dan perkenalan pegawai-pegawai baru jika ada. Sepanjang tahun 2004, perhimpunan bulanan telah diadakan sebanyak 7 kali.

latihan & pembangunan sumber manusia

Program Latihan & Pembangunan Sumber Manusia

Dalam proses untuk memantapkan keupayaan sumber manusia supaya lebih kompeten, berpengetahuan, memiliki nilai peribadi yang positif, mempertingkatkan kecekapan dan keberkesanan sistem penyampaian dalam perkhidmatan awam serta memenuhi kehendak pelanggan, satu program latihan yang mantap perlu disediakan oleh pihak pengurusan BPFK.

BPFK dalam program latihan ini telah menganjurkan kursus, seminar, ceramah saintifik secara bersendirian atau bekerjasama dengan pihak industri. BPFK juga menggalakkan anggotanya menghadiri kursus serta seminar berkaitan yang dianjurkan oleh pihak lain dalam negeri mahupun di luar negara.

Satu program "Continuous Professional Development (CPD)" telah diperkenalkan dalam tahun 2004 sebagai satu program untuk pembelajaran berterusan seperti yang dituntut sebagai penjawat awam bagi Pegawai Farmasi dan Pembantu Farmasi. Sepanjang tahun 2004, sebanyak 22 sesi CPD telah dianjurkan oleh BPFK dengan kerjasama pihak industri atau agensi lain dan sebanyak 8 sesi 'NCE Preview' telah diadakan.

Kursus, latihan, seminar, persidangan serta bengkel yang telah dihadiri oleh anggota BPFK sepanjang tahun 2004 adalah seperti dalam Jadual 11 dan 12.

Beberapa anggota BPFK dilantik sebagai 'WHO Consultant' atau 'Temporary Advisor/Expert'/ Fasilitator dalam bidang spesifik bagi mesyuarat atau bengkel yang dikendalikan oleh WHO atau dalam program kerjasama ASEAN dan ada juga yang terlibat dalam program yang memerlukan kepakaran dalam bidang tertentu (Jadual 13).

Beberapa anggota BPFK telah dijemput untuk memberi ceramah mengenai topik yang relevan di dalam negeri dan juga di luar negara (Jadual 14).

Selain daripada program latihan untuk kakitangannya, BPFK juga menganjurkan kursus untuk pihak industri terutama dalam bidang kawalan kualiti ubat tradisional.

Jadual 11 : Latihan/Kursus Yang Disertai

BIL.	LATIHAN	TEMPAT	TARIKH	BIL. PESERTA
1.	Latihan Pemeriksaan GMP	BPFK	6-7/1/2004	1
2.	Latihan Pengguna untuk alat pelarutan PWT 300	BPFK	6-9/1/2004 & 13-15/1/2004	11
3.	Latihan Teknik Mengaudit Makmal Mikrobiologi-Ujian MLT	BPFK	10/1/2004	9
4.	Latihan 'Amino Acid Analysis Using Pre-Column Derivatization' menggunakan kaedah ACCQ	BPFK	12/1/2004	20
5.	Kursus Komunikasi Berkesan Bahasa Inggeris Bil 1/04	Kampus Wilayah Tengah	12-16/1/2004	1
6.	Kursus Pengenalan PC	BPFK	19/1/2004	3
7.	Pemeriksaan APB Aspek Amalan Makmal Baik	AIN MEDICARE SDN BHD	19-21/1/2004	1
8.	Latihan Pengguna TLC	BPFK	19/1/2004	4
9.	Kursus 'Thin Layer Chromatography'	BPFK	29/1/2004	48
10.	Latihan Pengguna 'Clinical Waste'	BPFK	19/2/2004	7
11.	Kursus 'Desktop Productivity Spreadsheet' (Bil 1/2004)	INTAN	15-17/3/2004	1
12.	Kursus Induksi Awam & Khusus	J.K Selangor & Concord In KLIA, Sepang	7-24/4/2004	6
13.	Pengenalan kepada ISO 9001:2000	BPFK	12/4/2004	11
14.	Latihan untuk 'CGMP Compliance for Biopharmaceutical API Manufacturing'	Hotel Equitorial, Bangi	12-16/4/2004	1
15.	Kursus 'Internal QMS Auditor'	BPFK	14-15/4/2004	9
16.	Latihan Sangkutan di 'Drug Control Division, Veterinary Group, Thai FDA'	Bangkok	19-21/4/2004	1
17.	Kursus Penilaian Kecekapan 4	Palm Garden IOI Hotel, Putrajaya	19-30/4/2004	2
18.	Kursus Pengurusan Islam	INTAN, Bukit Kiara	20-22/4/2004	3
19.	Program Latihan Tentang Aktiviti Standardisasi Kebangsaan & A/B	SIRIM Berhad, Shah Alam	21/4/2004	1
20.	Latihan 'Fundamental of UV/Vis Spectroscopy'	BPFK	21/4/2004	43
21.	Solid Phase Extraction	UM	19/5/2004	2
22.	Latihan Pengguna untuk 'Particle Size & Colony Counters'	BPFK	3/6/2004	9
23.	Kursus Kesedaran Keselamatan & Kesihatan	BPFK	16/6/2004	10
24.	Pemeriksaan APB aspek Amalan Makmal Baik	Safire Pharmaceutical	6-7/7/2004	1
25.	Taklimat Penilaian Protokol	BPFK	7/7/2004	5
26.	Kursus Induksi Dalaman	BPFK	21/7/2004	24
27.	Latihan Pengguna Untuk 'Cleansing Maintenance'	BPFK	22/7/2004	1
28.	Kursus Keselamatan Perlindungan Modul Pengurusan	Putrajaya	3-5/8/2004	3
29.	Latihan untuk 'Aseptic Process'	Puri Pujangga, UKM	10-11/8/2004	1
30.	Kursus Komunikasi Korporat Bil 2/04	INTAN, Bukit Kiara	16-18/8/2004	1
31.	Latihan Pengguna untuk alat 'Maxi Dry'	BPFK	25/8/2004	15
32.	Latihan 'TLC for the analysis of Botanicals'	BPFK	26/8/2004	3
33.	Analisis Herba dengan Kaedah 'HPLC'	BPFK	26/8/2004	1
34.	Kursus 'HPLC'	BPFK	6/9/2004	46
35.	Latihan Auditor GMP	BPFK	10/9/2004	13
36.	Kursus Kepimpinan & Pengurusan Utama (JUSA)	INTAN, Bukit Kiara	16/9-8/10/2004	1
37.	Latihan 'Kwik Stik-Use Instruction'	BPFK	17/9/2004	10
38.	Latihan untuk 'Technique on Quadrapole LC/MS'	Wood-Dale, Illinois, USA	27-30/9/2004	2
39.	Kursus Amali Pengawalan Mutu Ubat Tradisional	BPFK	4/10/2004	32
40.	Latihan tentang Hologram untuk Penguatkuasa Farmasi	Johor Bahru	4-5/10/2004	1
41.	Latihan Auditor GMP	BPFK	6-7/10/2004	10
42.	Audit Penyiasatan	BPFK	9/10/2004	1
43.	Kursus 'AA Spectrophotometer'	BPFK	13/10/2004	46
44.	Kesan Toksik Bahan Kimia & Cara Pengendalian Bahan Kimia	BPFK	15/10/2004	3
45.	'Regional Laboratory Training on Harmonisation of ASEAN Cosmetics' test methods (tretinoin & colorants)	HSA, Singapore	11-15/10/2004	2
46.	'Regional Laboratory Training on Harmonisation of ASEAN Cosmetics test methods'	Badan POM Jakarta	22-26/11/2004	1
47.	'Regional Laboratory Training on Harmonisation of ASEAN Cosmetics test methods'	Bangkok, Thailand	29/11-3/12/2004	3
48.	'Regional Laboratory Training Harmonisation of ASEAN Cosmetics test methods'	BPFK	6-10/12/2004	4
49.	Kursus Pengenalan Perkhidmatan Farmasi bagi Pegawai Farmasi baru 2003	Crystal Crown Hotel, Port Klang	5-7/12/2004	2
50.	Program Ph. D	USM	2004	4
51.	Program 'Masters Degree'	UM	2004	2

Jadual 12 : Seminar/Persidangan/Bengkel yang dihadiri

BIL.	SEMINAR/PERSIDANGAN/BENGKEL	TEMPAT	TARIKH	BIL. PESERTA
1.	Seminar 'Limulus Amebocyte Lysate (LAL) 2004'	Hyatt Regency Saujana Hotel, Subang	14/1/2004	5
2.	Seminar 'Regulation & Safety of Dietary Supplement'	Hotel Holiday Villa, Subang	15/1/2004	10
3.	Persidangan 'Integration on Healthcare Industry In ASEAN'	Singapore	16/1/2004	1
4.	Seminar 'Regulatory Updates on Vaccines'	BPFK	19/1/2004	11
5.	Seminar 'Supelco Discovery HPLC Column & Equity GC Column'	BPFK	24/1/2004	3
6.	Seminar 'Workshop On Advertising vs Information In Medical Profession'	HKL	9-10/2/2004	1
7.	Seminar 'Vaccinology'	Sheraton Hotel	9-10/2/2004	2
8.	'International Conference of Drug Regulatory Authorities (ICDRA)' yang ke-11	Madrid, Spain	16-17/2/2004	2
9.	Bengkel 'IDB COMSTECH INTROM IMR on Herbal Medicine'	IMR-KL	16-20/2/2004	2
10.	'Laboratory Accreditation to ISO/IEC 17025'	Hotel Blue Wave, Shah Alam	19/2/2004	1
11.	'Management Of Environmental Hazardous Substances'	Renaissance Palm Garden Hotel, Putrajaya	26/2/2004	1
12.	Seminar 'Launching & Working' untuk Sub-program Kosmetik	Manila, Philippines	1-3/3/2004	1
13.	Taklimat untuk 'Privatise HSS'	BPFK	2-3/3/2004	1
14.	'Microbiology QA For Biopharmaceutical Industry'	Hotel Equatorial, Bangi	24/3/2004	4
15.	'Safety & Benefits of Food Supplements (Public Talk)'	Eastin Hotel, PJ	29/3/2004	1
16.	Persidangan untuk 'Fixed Dose Combination'	Gaborone Sun Hotel, Botswana	29-30/3/2004	1
17.	'International Conference on Improving Use Of Medicines (ICIUM)' yang ke-2	Chiangmai, Thailand	30/3-2/4/2004	1
18.	Program Sehari Bersama BPFK oleh CPF Wilayah	BPFK	4/4/2004	3
19.	Persidangan 'IFPMA ASEAN Regulatory' yang ke-4	Kerry Hotel, Beijing China	4-8/4/2004	1
20.	Seminar 'Generic Pharmaceuticals'	Hotel Equatorial Bangi	7/4/2004	3
21.	Seminar 'Risk Assessment -Use Of Antibiotic In Food'	Bangkok	7/4/2004	1
22.	Persidangan untuk 'Healthy Ageing'	Berjaya Times Square, KL	9-11/4/2004	1
23.	Seminar PRISMA	Putrajaya	10/4/2004	1
24.	Simposium Kebangsaan 'Adolescent Health' ke-2	Hotel Evergreen	10/4/2004	1
25.	'Regional Seminar on Healthcare Financing Traditional Medicines'	-	15-17/4/2004	1
26.	Simposium Saintifik 'Erythropoietin' yang ke-3	Nexuskarambrunei, Sabah	16-18/4/2004	1
27.	Seminar Kebangsaan untuk 'Regulatory Procedure on Traditional Products & NCE'	Marriot Hotel, Putrajaya	19-20/4/2004	5
28.	Seminar dan Bengkel - 'Update of Cosmetic Registration'	Hyatt Saujana Subang	24/4/2004	1
29.	Forum Industri tentang Pendaftaran ubat tradisional	JW Marriot, Putrajaya	24/4/2004	2
30.	Seminar 'Preservation of Progency Islamic Perspective'	UITM, Shah Alam	27-28/4/2004	1
31.	Seminar 'GMP for Packaging Materials Suppliers'	Holiday Villa, Subang Jaya	28/4/2004	1

Jadual 12 : Seminar/Persidangan/Bengkel yang dihadiri (sambungan)

BIL.	SEMINAR/PERSIDANGAN/BENGKEL	TEMPAT	TARIKH	BIL. PESERTA
32.	Persidangan Pengurusan KKM (Bil 1/2004)	Hotel Concorde Shah Alam	28-30/4/2004	1
33.	Seminar 'Environmental & Chemical Analysis'	BPFK	6/5/2004	4
34.	Seminar Kesedaran & konsensus Mengenai MDI CFC	Subang Sheraton	9/5/2004	7
35.	Seminar 'Rethinking Malaysia-Meeting the challenges of a new era'	Hotel Nikko, KL	10/5/2004	1
36.	Persidangan PF N. Selangor	Hotel Residence, UTM Bangi	14-16/5/2004	2
37.	Simposium 'Endocrine Disrupting 'Chemicals (EDC)'	Fakulti Pergigian, UM	17-18/5/2004	2
38.	Persidangan R & D Farmasi	Hotel Pan Pacific, KLIA	17-20/5/2004	1
39.	Seminar Ubat-Ubatan Antiretroviral	Hotel Cititel, KL	22/5/2004	3
40.	Seminar Pendaftaran Kosmetik	Hotel Grand Riverview, Kelantan	23/5/2004	2
41.	Seminar 'CNS Illness'	Hotel Singgahsana, PJ	27/5/2004	1
42.	Persidangan 'DIS'	City Bayview, Langkawi	9-10/6/2004	1
43.	Seminar untuk 'APIs PIC/S'	Barcelona, Spain	16-18/6/2004	1
44.	Seminar untuk 'Practical Approach to Gynaecology'	Armada Hotel, PJ	20/6/2004	2
45.	Majlis Orientasi Pegawai Farmasi U48	BPFK	21/6/2004	23
46.	Persidangan Perkhidmatan Awam Ke-9	INTAN Bukit Kiara	24-26/6/2004	1
47.	Seminar Kesedaran Kepenggunaan barangan kosmetik dan makanan supplemen	Hotel Palm Garden IOI	26/6/2004	1
48.	'Developing Psychiatric Services for 2020 : Challenges Ahead'	JW Marriot, KL	26/6/2004	1
49.	Forum 'Asia Pharmaceutical 2004'	Sentosa Hotel, Singapura	13-15/7/2004	1
50.	Seminar Tumbuhan & Ubatan Beraroma	FRIM, Kepong	20-21/7/2004	1
51.	Seminar 'Thailand International On ASEAN Harmonization' Ke-3	Amari Watergate Bangkok, Thailand	21/7/2004	1
52.	'Regional Workshop on Quality Control Of Medicinal Plant Product In SEA'	Hotel Vistana, KL	23-24/7/2004	1
53.	Bengkel 'Good Clinical Practice'	Crown Princess Hotel, KL	24-26/7/2004	1
54.	Seminar 'Evidence Based Medicine'	Imperial Sheraton	26/7/2004	1
55.	Persidangan 'National Health Outcomes' yang Pertama	Sheraton Imperial Hotel, KL	27-28/7/2004	3
56.	Persidangan Penguatkuasa Farmasi (risikan & siasatan)	Swiss Garden Golf & Spa, Kuantan	29/7-1/8/2004	1
57.	Persidangan Saintifik UiTM-MPS	Berjaya Times Square, KL	6-8/8/2004	3
58.	Seminar 'Global Trend in Vaccinology'	Bandung, Indonesia	6-9/8/2004	2
59.	Seminar 'Recent Advances In Tools For Protein ID & Biomarker Discovery'	Hotel Equatorial Bangi	10/8/2004	3
60.	Seminar 'Ion Chromatography'	Hyatt Regency Saujana, Subang	12/8/2004	1
61.	Seminar 'Atherothrombosis'	The Amari Watergate Hotel, Bangkok Thailand	13-15/8/2004	5
62.	Majlis Taklimat Pelaksanaan Modul Sebutharga Projek ePerolehan PTJ KKM	Institut Pengurusan Kesihatan, KL	18/8/2004	1
63.	Persidangan 'ASEAN Congress of Pediatric Infectious Diseases' ke-2	Sutera Harbour Kota Kinabalu	2-4/9/2004	1
64.	Persidangan 'KL Mental Health Conference 2004' ke-4	Prince Hotel & Residence KUALA LUMPUR	6-8/9/2004	1
65.	Persidangan R&D Farmasi	Pan Pacific KLIA	6-8/9/2004	5

Jadual 12 : Seminar/Persidangan/Bengkel yang dihadiri (sambungan)

BIL.	SEMINAR/PERSIDANGAN/BENGKEL	TEMPAT	TARIKH	BIL. PESERTA
66.	Taklimat 'Total Pure Water Solution from LAB to Building'	Cyberjaya Lodge, Cyberjaya	7/9/2004	1
67.	Forum 'Malaysian Standard for Certification'	SIRIM	9/9/2004	1
68.	Bengkel untuk 'Harmonisation of ASEAN Testing Methods For Cosmetics'	Hotel Sheraton, Subang	13-17/9/2004	3
69.	Seminar Antarabangsa untuk 'Challenges & Prospects in Global Market'	Marriott Hotel, Putrajaya	28-30/9/2004	1
70.	Bengkel 'EC-ASEAN' untuk 'Centralised System of Marketing Authorisation and Mutual Recognition Agreements for Pharmaceuticals'	Hotel Ambahara, Jakarta	29-30/9/2004	1
71.	Seminar- 'Pharmaceutical Non-Viable Particular Monitoring & Parenteral'	Sunway Lagoon Resort Hotel	30/9/2004	1
72.	Bengkel EC-ASEAN 'Regional Training on ACTD/ACTR'	Hotel Crown Princess, KL	11-15/10/ 2004	3
73.	Ceramah 'Principal Of Skin Toxicity Test & Abnormal Toxicity Test'	BPFK	1/10/2004	6
74.	Bengkel untuk 'GMP and QA of Antimalarial Medicines with Emphasis on Prequalification of ACT's'	Bangkok, Thailand	18-22/10/ 2004	1
75.	Bengkel 'EC-ASEAN Regional Workshop untuk 'Access to Reference Substances'	Asia Hotel, Bangkok,Thailand	21-22/10/ 2004	3
76.	'Australian Natural Health Products Showcase & Forum'	Hotel Le Meridien, KL Sentral	22/11/2004	1
77.	Bengkel 'Evidence-based' untuk Medicine Clinical Epidemiology	Insitute Of Health, Bangsar	22-24/11/ 2004	1
78.	Ceramah Persediaan untuk Peperiksaan PTK 1 & PTK 2	BPFK	24/11/2004	39
79.	Seminar 'MPS Entrepreneurship & Management in Pharmacy'	Hotel JW Marriot, KL	27-28/11/ 2004	2
80.	Seminar :'The New Frontier in Quantitative & Qualitative GC'	Mines Resort City	30/11/2004	1
81.	Persidangan Pegawai Farmasi Gred U48 (Kumpulan 2004)	Hotel Vistana, Kuantan	8-9/12/2004	1

Jadual 13 : Anggota BPFK sebagai Konsultan/Temporary Adviser/Expert/Fasilitator

BIL.	NAMA ANGGOTA	PERKHIDMATAN SEBAGAI KONSULTAN/PENASIHAT/EXPERT
1.	Arpah Abas	Sebagai Ahli Panel Penilaian Projek IRPA Kategori Strategic Research, 16-20/05/2004 dan 29/09/2004, UPM Selangor
2.	Dr. Sulaikah Moideen	Sebagai konsultan WHO pada mesyuarat 'Assessing Safety and Quality of Herbal Medicines with Reference to Contaminants and Residues', 12 -14 Julai 2004, Milan, Italy
3.	Eisah A. Rahman	Sebagai 'Co-writer for USP Drug Quality Control Guide for Low Income Countries', Mac 2004, Chiangmai
		Sebagai Fasilitator pada bengkel 'Asian Workshop on Drugs for Neglected Diseases Initiative DNDI)', Februari 2004, Kuala Lumpur
		Sebagai Pengerusi 'EC-ASEAN Conference on Centralised Marketing Authorisations and Mutual Recognition System for Pharmaceuticals', September 2004, Jakarta
		Sebagai 'Co-Chair of Product Working Group Traditional Medicines and Health Supplements under ACCSQ', Ogos 2004, Jakarta
		Sebagai Fasilitator bagi Sesi Kumpulan Regulator pada 'The 2nd Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses', November 2004, Kuala Lumpur
		Sebagai Konsultan pada 'Expert Consultation on ACTD and ACTR under ASEAN Harmonization Program', 19-20 Julai 2004, Bangkok, Thailand
4.	Faridah Abd. Malek	Sebagai ASEAN Senior Expert pada 'Regional Laboratory Training on Harmonisation of Asean Cosmetic Test Methods', 6-10 Disember 2004, BPFK, Petaling Jaya
5.	Fudziah Ariffin	Memberi latihan kepada 'the Drug Administration of Vietnam' yang merangkumi implementasi ASEAN Common Technical Dossier/ Requirement in line with ASEAN Harmonisation', 30 Mei-6 Jun 2004, Vietnam
		Sebagai 'WHO Temporary Adviser' pada mesyuarat '8th ACCSQ-PPWG Meeting & 3rd Thailand International Seminar on ASEAN Harmonisation', 21-23 Julai 2004, Bangkok, Thailand
		Sebagai 'WHO Temporary Adviser' pada mesyuarat 'WHO Consultation on Stability Studies in a Global Environment', 13-14 Disember 2004, Geneva
		Sebagai Konsultan pada 'Expert Consultation on ACTD and ACTR under ASEAN Harmonisation Program', 19-20 Julai 2004, Bangkok Thailand
6.	Kadariah Mohd. Ali	Terlibat dalam penyediaan 'Guidelines on Requirements for the Development of Pharmacy Department' Kementerian Kesihatan
		Sebagai Konsultan Teknikal untuk pembinaan 'Clean rooms for CDR activities, TPN, Eye-drop and IV Admixtures production' di hospital Kementerian Kesihatan dan Kementerian Pertahanan
		Sebagai Ahli 'Evaluation Expert Committee' bagi 'Clean room Suppliers' untuk hospital kerajaan
		Sebagai Expert dalam 'Construction of New Facilities for the Manufacture of Sterile Products and Ventilation and Purification Systems'
		Sebagai ASEAN Expert untuk program 'GMP Inspection and Premises Licensing System' di bawah Program EC-ASEAN, Indonesia
		Sebagai auditor dalam 'Joint Inspection (PIC/S)', November 2004, Switzerland
7.	Mohammad Lukmani Ibrahim	Sebagai auditor dalam 'Biotechnology Joint Inspection (PIC/S)', 1-4 Jun 2004, Hague & Groningen, Netherlands
		Sebagai ASEAN Senior Expert bagi GMP dalam 'Preparation Workshop and ASEAN Cosmetic Committee and in Regional Assessment GMP for Cosmetic' di bawah Program EC-ASEAN, 18-20 Ogos 2004, Singapore
		Sebagai ASEAN Senior Expert bagi 'Regional Assessment GMP for cosmetics' di bawah Program EC-ASEAN, 1-4 September 2004, Jakarta Indonesia; 7-9 September 2004, Ho Chi Minh City, Vietnam
8.	Noorizam Ibrahim	Menyertai kumpulan WHO-ASEAN dalam 'the review visit to the regulatory authority of Thailand in conjunction with WHO-ASEAN project on harmonisation of regulatory requirements', 26-30 April 2004, Bangkok
		Memberi latihan kepada 'the Drug Administration of Vietnam' yang merangkumi implementasi 'ASEAN Common Technical Dossier/ Requirement in line with ASEAN Harmonisation', 30 Mei-6 Jun 2004, Vietnam
9.	Siti Madziah Mohamed	Sebagai ASEAN Expert pada 'EC-ASEAN Regional Workshop on Access to Reference Substances', 21-22 Oktober, Bangkok, Thailand
10.	Yogeswary Markandoo	Sebagai 'Vice-Chairperson of 21st Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceutical', 22-24 September 2004, Vientiane, Lao PDR

Jadual 14 : Anggota BPFK sebagai penceramah

BIL.	NAMA ANGGOTA	TAJUK	TARIKH/TEMPAT
1.	Abida Haq	'Factors for Success in Pharmacovigilance' yang dibentangkan pada Persidangan ke-11 'International Conference for Drug Regulatory Authorities (ICDRA)'	19 Februari 2004, Madrid
		'Pharmacovigilance Planning: Impact on Non-ICH Countries' yang dibentangkan pada persidangan tahunan 'International Society for Pharmacovigilance'	7 Oktober 2004, Dublin, Ireland
		'Monitoring Safety of Dietary Supplements' yang dibentangkan pada seminar yang dianjurkan oleh 'the Direct Selling Association of Malaysia'	29 Mac 2004, Petaling Jaya
		'Food Supplements - Do we really need them?' yang dibentangkan pada Forum yang dianjurkan oleh Bahagian Kesihatan Keluarga, Kementerian Kesihatan	13 Julai 2004, Kuala Lumpur
		'Studies on Adverse Drug Reactions to Traditional Medicines' yang dibentangkan pada Seminar 'Research and Development in Pharmacy'	7 September 2004, Sepang
2.	Anis Talib	'Regulations and The Control of Food Supplements & Cosmetics in Malaysia' yang dibentangkan pada Seminar Kesedaran Pengguna anjuran Kementerian Perdagangan Antarabangsa dan Industri di beberapa negeri	Januari 2004, Langkawi; 28 Februari 2004 & Oktober 2004, Perlis; 5-7 Mac 2004, Sarawak (Sarikei, Kapit & Sibu) 17 April 2004, K. Lumpur 17 Mei 2004, Sandakan, Sabah
		'Overview of Cosmetic Regulations' yang dibentangkan pada Seminar Pendaftaran Kosmetik anjuran BPFK dan CTFA	23-24 Mac 2004, Subang Jaya
		'Current Issues on the Control and Registration Of Cosmetics' yang dibentangkan pada Seminar Pendaftaran Kosmetik anjuran Jabatan Farmasi negeri Kelantan	23 Mei 2004, Kelantan
		'Current Issues on the Control and Registration Of Cosmetics' yang dibentangkan pada seminar anjuran Jabatan Farmasi negeri Selangor	11 Ogos 2004, Klang; 28 Ogos 2004, Shah Alam
		'The Control of Health Supplement and Cosmetics' yang dibentangkan pada Seminar Kosmetik anjuran Jabatan Farmasi Melaka dan HEP Melaka	4 Disember 2004, Melaka
		'Progress on ASEAN Harmonised Cosmetic Regulatory Scheme in Malaysia' yang dibentangkan pada 'The 2nd ASEAN Cosmetic Committee (ACC) Meeting & 1st ASEAN Cosmetic Scientific Body (ACSB) for Cosmetics'	7-9 Jun 2004, Bangkok, Thailand
		'Progress on ASEAN Harmonised Cosmetic Regulatory Scheme in Malaysia' yang dibentangkan pada 'The 3rd ACC Meeting & 2nd ACSB Meeting'	7-9 Disember 2004, Yogyakarta, Indonesia.
3.	Arpah Abas	'Regulation of Blood Product in Malaysia' yang dibentangkan pada Mesyuarat 'Development of Harmonisation of QA System in Blood Product FDA/WHO'	30 Oktober 2004, Thailand
		'Overview: Regulations of Biotechnology Products in Malaysia' yang dibentangkan pada 'The National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity' anjuran Direktorat Bioteknologi, Kementerian Sains, Teknologi dan Alam Sekitar	20 April 2004. Putrajaya,
		'Overview: Product Registration' yang dibentangkan pada Mesyuarat Tentang Isu-isu Halal, Jabatan Kemajuan Islam Malaysia (JAKIM)	30 April 2004, Putrajaya
4.	Bariah Abdul Rani	'Product Classification' yang dibentangkan pada 'The National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity' anjuran Direktorat Bioteknologi, Kementerian Sains, Teknologi dan Alam Sekitar	19 April 2004, Putrajaya
5.	Dr. Sulaikah Moideen	Teknik Mengaudit Makmal Mikrobiologi (Ujian MLT)	10 Januari 2004, BPFK, Petaling Jaya
		Kursus PTK 4 Pembantu Farmasi	25 Februari 2004, Nilai
		Kawalan Kualiti Produk (Aspek Pengujian) yang dibentangkan pada 'The National Seminar on Regulatory Procedures for Traditional Medicine Products and New Chemical Entities' anjuran Direktorat Bioteknologi, Kementerian Sains, Teknologi dan Alam Sekitar	20 April 2004, Putrajaya

Jadual 14 : Anggota BPFK sebagai penceramah (sambungan)

BIL.	NAMA ANGGOTA	TAJUK	TARIKH/TEMPAT
6.	Dr.Tajuddin Akasah	'Good Manufacturing Practice (GMP) for Investigational Medicinal Product (IMP)' yang dibentangkan di 'Clinical Research Centre', Kementerian Kesihatan Malaysia	26 Julai 2004; 5 Disember 2004, CRC, Kuala Lumpur
		'GMP and Safety Requirement of Total Parenteral Nutrition (TPN) and Cytotoxic Drug Reconstitution (CDR) Facilities' yang dibentangkan pada Persidangan Pegawai Farmasi U48 anjuran Bahagian Perkhidmatan Farmaseutikal, Kementerian Kesihatan Malaysia	9 Disember 2004, Kuantan
		'GMP in Herbal/Biotech Manufacturing' yang dibentangkan pada 'The National Seminar on Regulatory Procedures for Traditional Medicinal Products and New Chemical Entities' anjuran Kementerian Sains, Teknologi dan Alam Sekitar Malaysia	April 2004, Putrajaya
		'GMP for Traditional Medicines' yang dibentangkan pada Seminar yang dianjurkan oleh Institut Penyelidikan Perhutanan Malaysia (FRIM)	21 Julai, 2004, Kuala Lumpur
		'GMP and GSP for Cosmetics' yang dibentangkan pada Seminar Pendaftaran Kosmetik anjuran Jabatan Farmasi Negeri Kelantan	23 Mei 2004
		Halatuju BPFK dalam GMP dalam Jangkamasa Panjang dibentangkan dalam seminar yang dianjurkan oleh PURBATAMA	19 April 2004, Langkawi
		'GMP - an update' yang dibentangkan dalam Persidangan Farmasi Sabah	6 Oktober 2004, Kudat, Sabah
		'ASEAN Guidelines for Cosmetic GMP' yang dibentangkan pada Seminar Pendaftaran Kosmetik anjuran BPFK dan CTFA	Mac 2004, Subang Jaya
7.	Dr. Kamaruzaman Saleh	'Regulatory Aspects of Clinical Trial in Malaysia' yang dibentangkan pada bengkel GCP, Universiti Sains Malaysia	17 Ogos 2004, Kubang Krian
		'Regulatory Aspects of Clinical Trial in Malaysia' yang dibentangkan pada Mesyuarat Pelaksanaan GCP	3 September 2004, Mersing
8.	Eisah A. Rahman	'Promoting Good Regulatory Practice, Malaysian Experience' yang dibentangkan pada Persidangan ke-11 'International Conference for Drug Regulatory Authorities (ICDRA)'	Februari 2004, Madrid
		'Current Review of Traditional Medicines Registration' yang dibentangkan pada Forum Industri mengenai Pendaftaran Ubat Tradisional	April 2004, Putrajaya
		'Malaysian Transition Strategy for the Phase out of CFC Use in MDI', yang dibentangkan pada Seminar Kesedaran 'CFC free MDIS'.	Mei 2004, Subang Jaya
		'Introduction to Cosmetic Control' yang dibentangkan pada Seminar Pendaftaran Kosmetik	Mei 2004, Kota Bharu
		'Regulatory Updates' yang dibentangkan pada Majlis Orientasi Pegawai Farmasi U48	Jun 2004, NPCB
		'Drug Policy in Malaysia: Improving Accessibility and Availability' yang dibentangkan pada Seminar Pertama 'National Health Outcome'.	Julai 2004, Kuala Lumpur
		'Regulating Pharmaceuticals in Malaysia - Challenges Faced by the National Pharmaceutical Control Bureau' yang dibentangkan pada Seminar MPS 'Entrepreneurship and Management in Pharmacy'	November 2004, Kuala Lumpur
		'Current Regulatory Development, Local, Regional and Global Challenges' yang dibentangkan pada Persidangan Pegawai Farmasi U48 Baru (2004)	Disember 2004, Kuantan
		'New Registration Procedure' yang dibentangkan pada Kursus PTK4 untuk Pegawai Farmasi U48	Mei dan Ogos 2004
		'GMP and Licensing' yang dibentangkan pada Kursus PTK4 untuk Pegawai Farmasi U48	Mei dan Ogos 2004
		'Policy, Issues and Recommendations (Group A- Fiji, Indonesia, Malaysia, Papua New Guinea, Philippines and Thailand)' yang dibentangkan pada 'Asian Regional Workshop on WTO/TRIPS Agreement and Access to Medicines'	November 2004, Kuala Lumpur

Jadual 14 : Anggota BPFK sebagai penceramah (sambungan)

BIL.	NAMA ANGGOTA	TAJUK	TARIKH/TEMPAT
9.	Fudziah Ariffin	'Regulatory Aspects of Clinical Trials in Malaysia', Bengkel GCP, Malaysia (5 kali)	
		'An Overview of NCE Registration in Malaysia'	April 2004, Putrajaya
		'Pharmacovigilance Initiatives in Malaysia' yang dibentangkan pada Persidangan 'IFPMA 4th Asian Regulatory'	April 2004, Beijing
		'Selection of BE Comparator Products' dibentangkan pada mesyuarat BA/BE 'in conjuction with 8th ACCSQ-PPWG Meeting & 3rd Thailand International Seminar on ASEAN Harmonisation'	20 Julai 2004, Bangkok, Thailand
		'ACTD Part 1: Administrative Data' yang dibentangkan pada Bengkel 'EC-ASEAN Regional Training Workshop on ACTD/ACTR'	Oktober 2004, Kuala Lumpur
10.	Jaafar Lassa	'Quality Assurance of Herbal Products in Malaysia' yang dibentangkan pada 'IDB-COMSTECT-INTROM IMR Workshop on Herbal Medicine,	16 Februari 2004, Kuala Lumpur.
		'New Regulation and Quality Control of Herbal Products' yang dibentangkan pada Dialog dengan Industri Herba Malaysia	Februari 2004
11.	Kadariah Mohd. Ali	'Pharmaceutical HVAC System'.	Februari 2004
		'GMP Requirements and Implementation'	April 2004, Seremban
		Keperluan APB untuk Industri Ubat Tradisional	April 2004, Putrajaya
		'GMP: Regulatory Requirements and Achievements of NPCB in PIC/S'	Jun 2004, Fraser Hill
		Pengenalan kepada ISO 9001-2000	Julai 2004, NPCB
		Penyediaan Laporan Pemeriksaan APB	September 2004, NPCB
		Audit Siasatan APB	September 2004, NPCB
		Amalan Penstoran Baik	September 2004, Hospital Kangar, Perlis
12.	Mazuwin Zainal Abidin	'Online Registration' yang dibentangkan pada 'National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity' anjuran Direktorat Bioteknologi Kementerian Sains, Teknologi dan Alam Sekitar	20 April 2004, Putrajaya
		'Control of Nutraceuticals and Cosmeceuticals in Malaysia' yang dibentangkan pada 'Seminar on Nutraceuticals, Complementary Medicine and Cosmeceuticals Asia - Middle East'	29 Jun 2004, Bangkok, Thailand
		'Procedure for Registration of Pharmaceutical Product' yang dibentangkan pada sesi CPD Bahagian Farmasi, Jabatan Kesihatan Selangor	28 Ogos 2004, Shah Alam
		'Pharmacy Regulatory' yang dibentangkan pada Persidangan Pembantu Farmasi Selangor 2004	16 Mei 2004, Bangi
13.	Muhammad Nasir Hashim	Amalan Makmal Baik yang dibentangkan kepada Pembantu Farmasi BPFK	24 November 2004, NPCB
14.	Saleha Mohd. Ewan	'Market Entry and Product Registration of Herbal and Natural Products in Malaysia' yang dibentangkan pada seminar anjuran 'Malaysian Herbal Corporation'	14 Oktober 2004, Jakarta
		'Registration of Traditional Medicine in Malaysia' yang dibentangkan pada 'National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity' anjuran Direktorat Bioteknologi, Kementerian Sains, Teknologi dan Alam Sekitar	19 April 2004, Putrajaya
15.	Yogeswary Markandoo	'Progress Report by Malaysia on Implementation of Activities' yang dibentangkan pada '21st Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceutical'	22 - 24 September 2004, Vientiane, Lao PDR

penglibatan serantau & antarabangsa

Penglibatan Serantau Dan Antarabangsa

BPFK sebagai sebuah Pusat Kolaboratif WHO semenjak tahun 1996 bagi Kawalan Regulatori Farmaseutikal terus memainkan peranan aktif dalam hal ehwal regulatori di peringkat global mahupun di rantau ASEAN. Usaha kerjasama dalam harmonisasi keperluan regulatori di rantau ASEAN dipelopori dengan pembentukan 'Pharmaceutical Product Working Group (PPWG)' di bawah program *ASEAN Consultative Committee on Standards and Quality (ACCSQ)* dan BPFK memberi sokongan padu serta sumbangan teknikal secara berterusan kepada semua aktiviti untuk mencapai matlamat yang ditetapkan. Hasil positif daripada kerjasama tersebut telah menjadi perintis untuk kerjasama regulatori bagi kategori produk lain dan ini disusuli dengan penubuhan 'Cosmetic Products Working Group (CPWG)' dan 'Traditional Medicines & Health Supplements Working Group (TMHSWG)'. BPFK juga terlibat dalam program kerjasama ekonomi EC-ASEAN dan 'Pharmaceutical Inspection Cooperation Scheme (PIC/S)'. Aktiviti-aktiviti yang melibatkan anggota BPFK dalam arena serantau mahupun antarabangsa adalah seperti berikut :

- **Harmonisasi Farmaseutikal ASEAN**

Mesyuarat ke-8 *ASEAN Consultative Committee on Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG)* diadakan pada 21 hingga 23 Julai 2004 di Bangkok, Thailand. Agenda utama mesyuarat adalah membincangkan skim harmonisasi keperluan regulatori farmaseutikal di rantau ASEAN supaya dapat menyempurnakan objektif *ASEAN Free Trade Area (AFTA)*, khusus bagi menghapuskan segala "technical barriers" ekoran tindakan regulatori dengan tidak memkompromi dalam kualiti, keselamatan atau efikasi ubat-ubatan. Ekoran pelancaran roadmap dalam integrasi sektor kesihatan di ASEAN, dua Kumpulan Kerja Produk (PWG) diwujudkan di bawah ACCSQ , iaitu satu bagi mengendalikan peralatan dan kelengkapan perubatan (medical device) manakala satu lagi bagi mengendalikan ubat tradisional dan supplemen kesihatan. Skim *Mutual Recognition Arrangement (MRA) for Pharmaceutical Sector* di ASEAN akan tercapai sekiranya *ASEAN Common Technical Dossier (ACTD) on Quality* berjaya diimplementasikan. Dalam usaha merapatkan kerjasama antara ASEAN dengan agensi antarabangsa, PPWG telah bekerja rapat dengan WHO dalam usaha mewujudkan *ASEAN Summary on Product Characteristics* (SPC). Berhubung *EC-ASEAN Regional Economic Cooperation Programme on Standards, Quality and Conformity Assessment,* Malaysia telah memberi sokongan yang padu dalam segala aktiviti.

- **Harmonisasi Kosmetik ASEAN**

Mesyuarat kedua *ASEAN Consultative Committee on Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC)* diadakan pada 7-8 Jun 2004 di Bangkok. Peranan ACC adalah meninjau implementasi perjanjian *ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRS)* yang diusahakan di bawah 'Terms of Reference of the ASEAN Cosmetics Committee'. Malaysia telah mengambil bahagian dalam *Agreement on ASEAN Mutual Recognition Arrangement (MRA).* Perlaksanaan berikut telah dipersetujui untuk dilaksanakan: (i) menubuhkan '*Guidelines for the Implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme*' *(ii)* '*Requirements for Notification under Schedule B-ASEAN*

Cosmetic Directives' (iii) penubuhan '*ASEAN Cosmetics GMP*' (iv) penubuhan '*ASEAN Cosmetic Scientific Body*'.
Mesyuarat mempertimbangkan cadangan untuk mempercepatkan implementasi AHCRS iaitu sebelum akhir tahun 2005.

- **'ACCSQ Product Working Group On Traditional Medicines And Health Supplements (ACCSQ TMHS PWG)'**

Mesyuarat pertama yang melibatkan Negara-negara ASEAN diadakan pada 25-26 Ogos 2004 di Jakarta, Indonesia. Tujuan *Product Working Group (PWG)* ini adalah untuk memberi sokongan dalam pelaksanaan roadmap bagi mengintegrasikan bidang kesihatan di negara-negara ASEAN. Ke arah ini, persetujuan telah dicapai bahawa segala sekatan teknikal perlu dihapuskan melalui harmonisasi teknikal dan persetujuan *mutual recognition.* Beberapa langkah dan strategi dilaksanakan seperti berkongsi maklumat dan piawaian analisis (analysis standards) yang sedia ada; menyeragamkan peraturan dan prosedur regulatori; serta keperluan teknikal di setiap negara ASEAN dikaji dan diatasi.

Susulan ini, satu mesyuarat bagi membincangkan langkah-langkah ke arah mengharmonisasikan keperluan-keperluan teknikal bagi ubat-ubatan tradisional dan suplemen kesihatan di Negara ASEAN dicadangkan pada tahun 2005. Sempena ini juga satu seminar berkaitan dengan ubat tradisional dan suplemen kesihatan juga dicadangkan.

- **'ASEAN Working Group on Technical Cooperation in Pharmaseuticals (AWGTCP)'**

Mesyuarat ke-21 AWGTCP diadakan pada 22-24 September 2004 di Vientiane, Lao PDR yang dihadiri oleh delegasi dari Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapura dan Thailand.

Mesyuarat AWGTCP adalah acara penting dalam Sektor Farmaseutikal negara ASEAN yang diadakan setiap tahun. Objektif AWGTCP adalah untuk memperkukuh sektor farmaseutikal di semua negara ASEAN bagi memastikan bekalan ubat-ubatan penting yang berkesan, selamat dan berkualiti adalah mencukupi; bagi mencapai ketidakbergantungan pada orang lain dalam pembangunan sumber manusia dalam bidang tertentu dan untuk memudahkan pembangunan industri farmaseutikal berdaya maju di rantau ASEAN; dengan mengambilkira faktor kekuatan dan kepelbagaian setiap negara ASEAN. Salah satu misi AWGTCP adalah untuk memperhebat pembangunan sumber manusia dan peningkatan keupayaan dalam bidang yang perlu diberi keutamaan yang telah dikenalpasti; dan memperkukuh kolaborasi peringkat nasional, rantau ASEAN dan antarabangsa.

Pelan tindakan untuk tahun 2004 hingga 2008 telah dikaji semula dalam mesyuarat ini dengan mengambilkira kekangan kewangan dan teknikal. AWGTCP mengharapkan WHO akan terus bekerjasama untuk menghadapai cabaran-cabaran baru.

- **'Cosmetic Sub-Program PMS/PSE (1)'**

Dalam tahun 2004, BPFK telah terlibat secara aktif dalam aktiviti *Cosmetic Sub-Program* di bawah program kerjasama ekonomi EC-ASEAN bagi 'Standards, Quality and Conformity Assessment'. Aktiviti yang terlibat secara langsung ialah *Post Marketing Surveillance/Product Safety Evaluation - Laboratory Capacity Building [PMS/PSE (1)].*

Objektif aktiviti PMS/PSE (1) ini adalah untuk membuat penilaian atas makmal-makmal badan regulatori di rantau ASEAN; mengenalpasti tatacara ujian atas produk kosmetik untuk diselaraskan; mengenalpasti makmal regulatori di rantau ASEAN yang boleh menjalankan latihan atas tatacara ujian yang telah dikenalpasti; menjalankan 'Proficiency Testing Scheme' atas tatacara ujian yang

telah diselaraskan antara makmal regulatori di rantau ASEAN; dan menggunapakai tatacara ujian yang telah diselaraskan apabila "ASEAN Cosmetic Directive" dikuatkuasakan.

Tatacara ujian atas produk kosmetik yang telah dikenalpasti untuk diselaraskan adalah:-

1. Identifikasi tretinoin dalam produk kosmetik
2. Identifikasi pewarna yang tidak dibenarkan dalam produk kosmetik
3. Identifikasi dan penentuan hydroquinone dalam produk kosmetik
4. Identifikasi dan penentuan 2-phenoxy-ethanol, 1-phenoxypropan-2-ol, methyl, ethyl, propyl, butyl dan benzyl-4hydroxybenzoate dalam produk kosmetik
5. Identifikasi hydrocortisone acetate, dexamethasone, betamethaone and triamcinolone acetonide
6. Penentuan Logam Berat (mercury, lead. arsenic and cadmium)
7. 'Microbial Limit Test'
8. 'Preservative Efficacy Testing (PET)'

Singapura, Indonesia, Thailand dan Malaysia telah dikenalpasti untuk menjalankan latihan atas tatacara ujian yang akan diselaraskan. Latihan telah dijalankan dalam bulan November dan Disember 2004 dan dihadiri oleh peserta-peserta dari semua negara ASEAN. BPFK telah mengkoordinasikan latihan untuk ujian identifikasi steroid (hydrocortisone acetate, dexamethasone, betamethasone dan triamcinolone acetonide) dan 'Preservative Efficacy Testing' dalam bulan Disember 2004.

- **'Pharmaceutical Inspection Cooperation/Scheme'**

Sebagai ahli PIC/S, wakil-wakil dari BPFK telah menjadi peserta bagi program 'Biotechnology Joint Inspection' di Belanda pada bulan Jun 2004 dan 'Joint Inspection' di Switzerland pada bulan November 2004. BPFK juga memastikan keperluan APB semasa mematuhi keperluan APB PIC/S dan antarabangsa.

- **Lawatan dan Latihan Pengunjung dari Luar Negara**

Sebagai sebuah pusat kolaboratif WHO bagi kawalan regulatori produk farmaseutikal, BPFK meneruskan penyediaan latihan bagi WHO Fellows dalam pemastian kualiti farmaseutikal dan hal-ehwal regulatori. Sepanjang tahun 2004 BPFK telah menerima seramai 28 orang pelawat antarabangsa dan WHO fellows dari berbagai negara iaitu Brunei Darussalam, China, Cuba, Fiji, Hong Kong, Mongolia, Singapura, Afrika Selatan dan Vietnam. Latihan yang diberikan dalam program ini dirancang mengikut keperluan spesifik setiap peserta dan boleh diberi dalam aspek aktiviti Kawalan Kualiti, Pendaftaran Produk, Amalan Perkilangan Baik serta Pelesenan, dan aktiviti Farmakovigilans serta Surveillans.

- **Kerjasama Dua Hala**

Penglibatan serantau lain termasuklah mesyuarat teknikal serta kerjasama dua hala dengan negara ASEAN seperti Brunei, Singapura dan Indonesia dalam aspek kesihatan dan regulatori.

tinjauan belanjawan

Tinjauan Belanjawan

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 dan 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.

- **Kewangan**

Pada tahun 2004, pembayaran upahan dan gaji untuk 177 anggota tetap dan 48 anggota sambilan berjumlah RM5,997,333.00

- **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 2004 ialah RM10,407,556 seperti dalam Jadual 15.

Jadual 15 : Kutipan Hasil (RM) (Tahun 1999-2004)

Tahun	Pendaftaran	Lesen	Makmal	Pemeriksaan	Bahan Cetak	Lain-lain	JUMLAH
1999	959,405	158,350	484,860	14,350	39,605	18,871	1,675,441
2000	1,111,440	152,100	502,620	6,500	28,340	27,193	1,828,193
2001	914,020	203,200	460,880	12,200	26,485	64,072	1,680,857
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

Jadual 16 : Peruntukan dan Perbelanjaan Mengurus BPFK (Tahun 2004)

Kod Objek	Jenis Perbelanjaan Am	Peruntukan (RM)		Perbelanjaan (RM)		Baki	
		Asal	Dipinda	Perbelanjaan Bersih	%	(RM)	%
						Tanggungan	
10000	Emolumen	5,744,00	5,744,000	5,997,333	104.41	-253,333	-4.41
20000	Perkhidmatan dan Bekalan	7,950,000	7,959,000	7,563,326	95.03	362,068	4.55
30000	Aset (Harta Modal)	108,430	108,430	97,862	90.25	10,568	9.75
	JUMLAH	13,802,430	13,811,430	13,658,521	96.56	119,303	9.89

pihak berkuasa kawalan dadah

Ringkasan Polisi Pihak Berkuasa Kawalan Dadah (PBKD)

Sepanjang tahun 2004, Pihak Berkuasa Kawalan Dadah (PBKD) telah bermesyuarat sebanyak sebelas (11) kali. Melalui mesyuarat PBKD ini, beberapa polisi terkini telah dibincangkan dan dipersetujui oleh anggota PBKD. Ringkasan polisi yang berkenaan adalah seperti dalam Jadual 17 di bawah:

Jadual 17 : Keputusan Penting PBKD Tahun 2004

MESYUARAT PBKD	POLISI
PBKD 155 27.1.2004	**"Product Authentication: Directive on security Device - Guidance For Labelling"** Mesyuarat bersetuju dengan cadangan: a) 'The implementation and use of the security device as a means to authenticate and verify drug product registration'. b) The inclusion of the proposed section headed "product authentication" as another condition for product registration, together with the product identification chart as a labelling guide to the affixing of the security device.
PBKD 156 24.2.2004	**Cadangan Pembatalan Pendaftaran Semua Keluaran Yang Mengandungi Cisapride** Mesyuarat bersetuju untuk tidak mendaftarkan keluaran yang mengandungi cisapride atas isu keselamatan. i) Syarikat-syarikat yang pernah mendaftarkan cisapride dibenarkan membawa masuk keluaran ini atas permintaan preskriber bagi penggunaan pesakit tertentu *(allow exemption on a named patient basis*) ii) Bagi produk yang sudah berdaftar dan sedang dipasarkan, pemegang pendaftaran akan diberi tempoh masa enam bulan dari tarikh keputusan PBKD diambil, untuk menarik balik produk dari pasaran di Malaysia.
	Cadangan Pembatalan Pendaftaran Semua Keluaran Yang mengandungi Herba *Comfrey & Senecio spp* Mesyuarat bersetuju untuk tidak mendaftarkan produk yang mengandungi Herba Comfrey *(symphytum officinale) & Senecio spp* atas isu keselamatan. Kedua-dua herba ini mengandungi pyrrolizidine alkaloid yang telah dikaitkan dengan kesan advers hepar. Bagi produk yang sudah berdaftar dan sedang dipasarkan, pemegang pendaftaran akan diberi tempoh masa enam bulan dari tarikh keputusan PBKD diambil, untuk menarik balik produk dari pasaran Malaysia.
	Kawalan Semua Ubat Batuk Farmaseutikal kepada saiz maksimum 120ml - kaji semula Mesyuarat telah bersetuju untuk membenarkan sedikit kelonggaran kepada had maksimum 120+/- *(plus-minus)*. Tarikh perlaksanaan masih kekal pada 1 hb April 2004.
PBKD 157 23.3.2004	**Isu Pendaftaran Semula Produk Dari Indonesia** Demi kepentingan dua-hala dan semangat kerjasama ASEAN, Malaysia dan Indonesia telah bersetuju untuk membenarkan produk-produk farmaseutikal dipasarkan di negara masing-masing mengikut peraturan-peraturan negara berkenaan, serta piawaian dan keperluan ASEAN.
	Kawalan Semula Ubat Batuk Farmaseutikal kepada saiz maksimum 120ml - kaji semula PBKD telah menerima rayuan dari pengilang tempatan untuk kebenaran mengilang pek 3.8L bagi tujuan eksport sahaja. Mesyuarat mengambil keputusan tidak membenarkan sebarang kelonggaran untuk tujuan eksport sahaja.

Jadual 17 : Keputusan Penting PBKD Tahun 2004 (sambungan)

MESYUARAT PBKD	POLISI
PBKD 157 23.3.2004	**Pertimbangan Penggunaan Tanda Halal Bagi Keluaran-keluaran Berdaftar Farmaseutikal, Tradisional dan Kosmetik** Mesyuarat bersetuju dengan cadangan untuk: (i) Mengekalkan polisi sedia ada iaitu tidak membenarkan logo HALAL digunakan untuk keluaran-keluaran farmaseutikal; (ii) Mengekalkan polisi sedia ada membenarkan logo HALAL digunakan untuk keluaran-keluaran kosmetik bagi pasaran tempatan dan eksport; (iii) Mempertimbangkan penggunaan logo HALAL yang diperakui dan dikeluarkan oleh JAKIM sahaja untuk ubat-ubat tradisional dan produk-produk tambahan khasiat makanan bagi pasaran tempatan dan eksport; & (iv) Mempertimbangkan penggunaan logo HALAL tersebut untuk produk-produk berkenaan berdasarkan permohonan dan bukan sebagai keperluan mandatori.
	Senarai Kajian Bioequivalens (BE) Bagi Produk Generik " Immediate Release" Mesyuarat mengambil maklum senarai tambahan baru produk generik yang perlu dijalankan kajian BE bagi tahun 2004/2005. **"Test Product (Pharmaceutical name)":** Stavudine, Nevirapine, Ritonavir, Ciprofloxacin, Ofloxacin, Clarithromycin, Metformin, Glibenclamide, Diltiazem, Salbutamol, Rifampicin, Sulpiride, Dexamethasone, Verapamil, Omeprazole & Prednisolone.
	"Proposal to request that the DCA consider parenteral preparations, peritoneal dialysis solutions and haemofiltration solutions (which are introduced into patients' bodies), which are packaged in different materials and pack sizes, as one product." Mesyuarat bersetuju mempertimbangkan produk jenis intravena, peritoneal dialysis dan haemofiltration yang dibungkus dalam bahan pembungkusan berlainan dan/atau saiz pek berbeza sebagai satu produk. Penilaian terperinci terhadap data kestabilan perlu dijalankan untuk memastikan jangkahayat simpan yang bersesuaian untuk setiap jenis bahan pembungkusan yang digunakan. Oleh itu, semua jenis pek bagi sesuatu keluaran dapat dikesan dalam satu fail.
PBKD 158 27.4.2004	**Cadangan Pembatalan Pendaftaran Semua Keluaran Yang mengandungi Terfenadine** Mesyuarat bersetuju dengan cadangan a) membatalkan pendaftaran semua produk yang mengandungi terfenadine. Tempoh masa enam bulan diberi dari tarikh keputusan PBKD dikeluarkan untuk memastikan keluaran tiada lagi di pasaran; & b) mengeluarkan semua produk yang dibatalkan pendaftaran dari lesen pengilang/lesen pengimport syarikat-syarikat berkenaan.
PBKD 159 27.5.2004	**Cadangan Melanjutkan Tempoh Pemasaran Keluaran-keluaran Kosmetik "Sedia Ada"** Mesyuarat mengambil maklum cadangan melanjutkan tempoh pemasaran keluaran-keluaran kosmetik "sedia ada" yang telah mengemukakan permohonan pendaftaran sebelum 31 Januari 2004, daripada 30 Jun 2004 kepada **31 Disember 2004**. Menjelang 1 Januari 2005 semua keluaran kosmetik yang berada dalam pasaran perlu mematuhi keperluan pelabelan seperti yang telah ditetapkan dalam Garis Panduan Pendaftaran Kosmetik.
	Cadangan menarik balik penggantungan pendaftaran produk mengandungi nimesulide, menghadkan posologi dan dos serta menghadkan indikasi. Mesyuarat bersetuju dengan cadangan: (i) Menarik balik penggantungan pendaftaran produk yang mengandungi nimesulide di Malaysia. (ii) Bagi produk yang mengandungi nimesulide dalam bentuk tablet untuk penggunaan oral, posologi dihadkan kepada 100mg dan dos maksima yang dibenarkan adalah 100mg dua kali sehari. (iii) Indikasi bagi produk yang mengandungi nimesulide bagi penggunaan oral dihadkan seperti berikut: a. Treatment of acute pain b. Symptomatic treatment of painful osteoarthritis c. Primary dysmenorrhoea (iv) Maklumat pada sisip bungkusan bagi produk yang dipasarkan di Malaysia diubahsuai supaya selaras dengan maklumat yang terkandung dalam SPC Eropah. (v) Pemegang pendaftaran produk yang mengandungi nimesulide dipertanggungjawabkan untuk memaklumkan kepada pihak profesional tentang indikasi yang dibenarkan oleh PBKD, dos maksima baru dan kontraindikasi berkaitan penggunaan nimesulide supaya risiko kepada pengguna diminimakan.

Jadual 17 : Keputusan Penting PBKD Tahun 2004 (sambungan)

MESYUARAT PBKD	POLISI
PBKD 160 1.7.2004	**Tambahan amaran berkaitan dengan hyperglycaemia bagi keluaran "Atypical Antipsychotic Agents"** Mesyuarat membuat keputusan berikut: (i) Amaran berkaitan dengan kesan advers "hyperglycemia" wajib untuk dimuatkan pada sisip bungkusan bagi semua keluaran yang merupakan agen "atypical antipsychotic". (ii) Keluaran yang terlibat adalah produk yang mengandungi bahan aktif berikut: Clozapine, olanzepine, risperidone, quetiapine, ziprasidone & aripiprazole. (iii) Amaran yang perlu dimuatkan di bawah bahagian "Warning" adalah seperti berikut: **WARNINGS:** **Hyperglycemia and Diabetes Mellitus** Hyperglycemia in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given this confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factor for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with atypical antipsyhotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
PBKD 161 5.8.2004	**"Use of Thiomersal in Vaccines - An Update"** Mesyuarat telah membuat keputusan berikut: i) Penggunaan thiomersal sebagai bahan pengawet dalam persediaan vaksin *(multidose)* boleh dipertimbangkan. ii) Permohonan pendaftaran vaksin yang mengandungi thiomersal akan dinilai secara "case by case" dengan mengambil kira khususnya efikasi produk dan keperluan kesihatan umum. iii) Kandungan thiomersal (serta bahan pengawet yang lain) perlu ternyata pada label produk dan amaran berkaitan dengan "risk of sensitization in relation to thiomersal and other preservatives" perlu ditambahkan dalam sisip bungkusan produk. iv) Selaras dengan sasaran global untuk menurunkan pendedahan kepada merkuri, persediaan vaksin tanpa thiomersal ataupun yang mengandungi kuantiti thiomersal yang paling rendah sekali adalah digalakkan.
	"Product Authentication" : Penggunaan "security label" oleh Syarikat Mediharta Sdn Bhd. Mesyuarat bersetuju bahawa: (i) Tarikh implementasi mandatori bagi penggunaan label Meditag adalah **1hb. Januari 2005** untuk produk bukan jenis suntikan *(non-parenterals)*. Semua produk berkaitan yang dikilang atau diimport mulai 1 hb. Januari 2005, untuk pasaran tempatan, harus mempamerkan label Meditag tersebut (tarikh implementasi ditunda kepada **1hb. Mei 2005** seperti yang diputuskan dalam mesyuarat PBKD ke-164 yang diadakan pada 4 November 2004). (ii) Penggunaan label Meditag bagi produk suntikan akan bermula enam (6) bulan kemudian, iaitu pada **1 hb. Julai 2005.** (iii) Produk-produk yang sensitif terhadap pertukaran suhu *(temperature sensitive)* dan perlu pengekalan "cold-chain", seperti vaksin dan keluaran biologikal, adalah **dikecualikan** daripada keperluan pelabelan hologram Meditag. (iv) Penggunaan label Meditag secara sukarela *(voluntary)* boleh dimulakan bila-bila masa. (v) Mediharta adalah bertanggungjawab untuk menjalankan program kesedaran *(awareness programme)* untuk pegawai-pegawai Kementerian Kesihatan Malaysia, pihak industri serta pengguna terhadap penggunaan label Meditag. (vi) Pengumuman media *(media announcement)* akan diadakan mengenai usaha yang sedang dijalankan oleh Kementerian Kesihatan untuk mengatasi masalah produk tidak berdaftar yang makin berleluasa dan peranan label hologram Meditag sebagai salah satu langkah untuk menangani situasi berkenaan.

Jadual 17 : Keputusan Penting PBKD Tahun 2004 (sambungan)

MESYUARAT PBKD	POLISI
PBKD 161 5.8.2004	**Penambahan Ujian Kadmium (Cd) dalam Pengujian Logam Toksik untuk produk Tradisional** Mesyuarat bersetuju dengan cadangan supaya: (i) Memasukkan ujian **kadmium** dalam pengujian produk tradisional dimana had bagi ujian tersebut adalah **0.3mg/kg**. Penambahan ujian cadmium ini akan berkuatkuasa mulai **1hb. Januari 2005.** (ii) Menerima had kawalan kualiti produk tradisional (Quality Control Test specifications for Traditional Medicine Products) seperti dalam Lampiran 1 sebagai spesifikasi yang terkini.
PBKD 165 23.12.2004	**Cadangan untuk mengeluarkan bahan aktif `Hexylresorcinol' dari senarai 'ingredients (active) not allowed to be registered by the Drug Control Authority'.** Mesyuarat mengambil keputusan mengeluarkan bahan aktif 'Hexylresorcinol' dari senarai 'ingredients (active) not allowed to be registered by the Drug Control Authority' seperti mana yang terdapat dalam 'Drug Registration Guidance Document' dan penggunaannya boleh dibenarkan dalam semua sediaan farmaseutikal termasuk sediaan oral berdasarkan alasan seperti berikut: i. Rujukan asas yang digunakan ketika membuat keputusan menghalang penggunaan bahan ini seperti yang dibentangkan dalam Mesyuarat PBKD 28 iaitu Martindale, tidak lagi menyatakan bahawa bahan ini boleh menyebabkan kesan kerengsaan (irritation) pada kulit dan mukosa oral kecuali dalam kepekatan yang tinggi. ii. Sediaan Hexylresorsinol Lozenges merupakan sediaan yang dinyatakan dalam monograf rasmi United States Pharmacopoea edisi terkini. iii. Sediaan Hexylresorcinol Lozenges telah didaftarkan dan dipasarkan di banyak negara di dunia termasuk Australia,Kanada, United Kingdom dan United States of America. iv. Sediaan Lozenges yang mengandungi bahan aktif dari kumpulan yang sama iaitu 'phenolic antiseptics' seperti Amylmetacresol telah didaftarkan dan dipasarkan di Malaysia. **Tambahan Amaran Berkaitan dengan "Suicidality in Children and Adolescents Treated with Antidepressants".** Mesyuarat bersetuju bahawa: (i) Amaran yang perlu dimuatkan di bawah bahagian "Warning" adalah seperti berikut diwajibkan dimuatkan pada sisip bungkusan semua keluaran yang merupakan "antidepressant': **Suicidality in Children and Adolescents** • Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. • Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need. • Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. • Famillies and caregivers should be advised to closely observe the patient and to communicate with the prescriber. • A statement regarding whether the particular drug is approved for any pediatric indication(s) and, if so, which one(s). (ii) Pemegang pendaftaran produk perlu mengkaji kesesuaian penggunaan "Medication Guides" (MedGuides) sepertimana diamalkan di Amerika Syarikat. Tujuan MedGuides ini ialah untuk menyampaikan maklumat kepada pesakit dan penjaga berkaitan dengan kesan advers "suicidality" ini dan perlu diberi semasa ubat dibekalkan. MedGuides yang diubahsuaikan untuk penggunaan di Malaysia perlu dikemukakan kepada PBKD untuk penyemakan sebelum diedarkan.

Jadual 17 : Keputusan Penting PBKD Tahun 2004 (sambungan)

MESYUARAT PBKD	POLISI
PBKD 165 23.12.2004	**"New information regarding cardiovascular safety of Celebrex (Celecoxib), Bextra (Valdecoxib) and Naproxen"** Mesyuarat telah membincangkan perkara di atas dan bersetuju: **(i) CELEBREX:** Selaras dengan tindakan yang telah diambil oleh USFDA, PBKD bersetuju bahawa surat "Dear Health Professional" dikeluarkan oleh pemegang pendaftaran untuk maklumkan perkara ini kepada profesional kesihatan. Amaran berikut seperti mana dikeluarkan oleh USFDA juga perlu dipaparkan pada laman web BPFK: Based on emerging information, including preliminary reports from one of several long term National Institutes of Health (NIH) prevention studies, the risk of cardiovascular events (composite endpoint including MI, CVA and death) may be increased in patients receiving Celebrex. Subsequently, the DCA will be analyzing all available information from these studies to determine whether additional regulatory action is needed. **(ii) NAPROXEN:** Selaras dengan tindakan yang telah diambil oleh USFDA, PBKD bersetuju agar maklumat berikut dipaparkan melalui laman web BPFK untuk maklumat profesional kesihatan dan juga orang awam: Patients who are currently taking naproxen products should be advised to carefully follow the instructions on the label and not to exceed the recommended doses for naproxen (220 milligrams twice daily). Naproxen should not be taken for longer than ten days unless a physician directs otherwise. **(iii) BEXTRA:** Selaras dengan tindakan yang diambil oleh USFDA, amaran berkaitan kesan sampingan "Steven-Johnson Syndrome and Toxic Epidermal Necrolysis" dan risiko cardiovascular perlu dimuatkan pada sisip bungkusan produk di Malaysia juga.
	"Iressa : New finding from ISEL study" PBKD dalam mesyuaratnya kali ke 150 telah meluluskan permohonan pendaftaran produk Irresa. Walaubagaimanapun maklumat terbaru mengenai produk Iressa dari "ISEL clinical study" menunjukkan bahawa keberkesanan produk diragui. Mesyuarat mengambil keputusan berikut: a. Mendapatkan hasil kajian percubaan klinikal yang dijalankan. b. Mendapatkan maklumat dan data tambahan berkaitan memandangkan kelulusan pendaftaran tidak berdasarkan maklumat dan data untuk pesakit Caucasian atau Oriental. c. Selaras dengan tindakan yang telah diambil oleh USFDA, meminta syarikat memberhentikan promosi produk.

aktiviti sosial

PERSATUAN SURI DAN ANGGOTA WANITA PERKHIDMATAN AWAM (PUSPANITA)

Sejumlah kakitangan wanita BPFK menganggotai Persatuan Suri Dan Anggota Wanita Perkhidmatan Awam atau ringkasnya PUSPANITA Cawangan Kementerian Kesihatan Malaysia dan dipertanggungjawabkan untuk menerajui Biro Pendidikan.

Puan Eishah Abdul Rahman, Timbalan Pengarah BPFK telah dilantik sebagai Pengerusi PUSPANITA BPFK. Beberapa aktiviti seperti dalam Jadual 18 telah dijalankan sepanjang tahun 2004:

Jadual 18 : Aktiviti PUSPANITA BPFK

TARIKH	AKTIVITI
Januari	Jamuan Perpisahan Pn. Jamilah (Pengerusi PUSPANITA)
April	Kursus Jenazah & Pesta Tupperware
Jun	Pameran & Jualan Barangan Jenama “Natasha”
Julai	Pasaria & Demonstrasi Periuk Elektrik oleh “Graes Appliances”
September	Pemilihan Pelajar-pelajar Cemerlang
November	Tadarus Al-Quran & Pertandingan Bowling

Kelab BPFK

BPFK juga telah menubuhkan Kelab BPFK dengan ahli berdaftar berjumlah 181 orang sehingga September 2004. Biro sukan telah mengadakan Hari Sukaneka untuk para ahlinya di BPFK (gelanggang bola tampar-Blok B1 & B2) pada 9 Oktober 2004 (Sabtu). Sementara itu, Biro Pendidikan telah mengadakan majlis penganugerahan sijil dan hadiah kepada anak-anak ahli Kelab BPFK yang cemerlang dalam peperiksaan UPSR, PMR dan SPM bagi tahun 2003. Biro Sosial pula telah membuat perancangan bagi pakej pelancongan ke Pulau Redang dan Padang/Bukit Tinggi, Indonesia tetapi telah dibatalkan atas sebab-sebab yang tidak dapat dielakkan.

Jasamu Dikenang

Pada tahun 2004, sejumlah 20 orang kakitangan telah meninggalkan BPFK sama ada kerana bersara, bertukar atau meletak jawatan. Tuan Hj. Normal Shariff dan Datin Hjh. Hasiah Hj. Abdullah telah bersara sebagai Pengarah BPFK masing-masing pada 1 Februari 2004 dan 31 Disember 2004. Sementara itu, Puan Tang Poh Yoong, seorang Pembantu Tadbir dari Pusat Amalan Perkilangan Baik juga turut bersara pada 30 Julai 2004.

Terdapat 16 orang pegawai BPFK yang telah bertukar tempat bertugas seperti berikut:

BIL.	NAMA	JAWATAN	TARIKH (TEMPAT BARU)
1.	En. Hj. Abdul Rahman Kassim	Penyelenggara Stor	12.1.2004 (Hospital Serdang)
2.	Pn. Haslina Ithnin	Pembantu Tadbir	16.1.2004 (KKM)
3.	En. Chua Kong Seng	Pegawai Farmasi	1.3.2004 (Kedah)
4.	Pn. Noraizan Che Mel	Pembantu Tadbir	8.3.2004 (Kelantan)
5.	Pn. Kamarolaini Sapiei	Pembantu Tadbir	26.4.2004 (Pusat Darah Negara)
6.	Cik Siti Hajar Paiman	Operator Mesin Pemprosesan Data	1.5.2004 (Putrajaya)
7.	Cik Wahida Ramli	Penolong Pegawai Perangkaan	17.5.2004 (Putrajaya)
8.	Pn. Siti Aisah Bahari	Pegawai Farmasi	1.7.2004 (Hospital Ampang)
9.	Pn. Mahani Mahmud	Pegawai Farmasi	2.8.2004 (Bahagian Perkhidmatan Farmasi)
10.	Pn. Asmawiza Ghazali	Pembantu Farmasi	2.8.2004 (Hospital Serdang)
11.	Pn. Sarijah Awang	Pembantu Farmasi	2.8.2004 (Kolej Pembantu Farmasi, Sg. Buloh)
12.	Pn. Tan Lie Sie	Pegawai Farmasi	1.11.2004 (Johor)
13.	Pn. Sharifah Hj. Abdul Rahman	Pembantu Farmasi	22.11.2004 (Terengganu)
14.	En. Ramli Zainal	Pegawai Farmasi	1.3.2004 (KKM - Cuti Belajar)
15.	Cik Roshayati Mohd. Sani	Pegawai Farmasi	1.3.2004 (KKM - Cuti Belajar)
16.	Pn. Noorul Akmar Mohd. Nor	Pegawai Farmasi	1.3.2004 (KKM - Cuti Belajar)

Puan Suriani Ibrahim dari Pusat Pasca Pendaftaran Produk telah mengambil keputusan meletak jawatan sebagai Pegawai Farmasi pada 15.04.2004 dan beliau memilih untuk bekerja sendiri.

Kepada semua pegawai yang telah meninggalkan BPFK, diucapkan selamat maju jaya dan berbahagia dalam menjalani kehidupan ini. Segala khidmat dan jasa bakti yang telah dicurahkan oleh semua kepada BFPK selama ini amatlah dihargai dan akan dikenang untuk selamanya











Ucapan Datin








aktiviti lain

Aktiviti Lain

Dalam tahun 2004, selain daripada aktiviti utama yang dijalankan oleh BPFK, terdapat aktiviti-aktiviti lain yang dijalankan untuk melicin serta melancarkan pelaksanaan dan mengatasi masalah-masalah yang mungkin timbul apabila sesuatu prosedur atau polisi baru diperkenalkan. Beberapa aktiviti yang telah dijalankan adalah seperti berikut:

GERAK KERJA ONLINE

- **Pharmaceutical TWG-Joint Online Task Force** telah bermesyuarat sebanyak empat kali sepanjang tahun 2004. Kumpulan gerak kerja ini diwakili oleh pegawai dari BPFK, Technology Innovation Resources (TIR), Pharmaceuticals Association Malaysia (PhAMA) serta Malaysian Organisation of Pharmaceutical Industries (MOPI). Objektif kumpulan kerja ini adalah untuk mengenalpasti dan membantu mengatasi beberapa masalah dan isu yang dikemukakan oleh pihak industri dalam pelaksanaan sistem o-line seperti masalah kad pintar pemegang utama, kad suplementari, bayaran, klasifikasi produk online, kerahsiaan data dan lain-lain.

- Sepanjang tahun 2004, **Traditional TWG-Joint Online Task Force** pula telah bermesyuarat sebanyak dua kali. Kumpulan gerak kerja ini terdiri daripada pegawai dari BPFK, TIR, Persatuan Pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA), Majlis Perubatan Homeopathy Malaysia (MPHM), Persekutuan Perubatan Tradisional Melayu Malaysia (PUTRAMAS), Pertubuhan Perubatan Tradisional India Malaysia (PEPTIM), "Federation of Chinese Physicians & Medicines Dealers Association Malaysia (FCPMDAM)", Persatuan Pengeluar Ubat China Malaysia (PPUCM) dan MOPI. Melalui mesyuarat yang dijalankan, isu-isu berkaitan dengan pendaftaran secara online seperti masalah 'server Quest 2', 'product updating', 'variation' (pindaan) dan sebagainya telah dikenalpasti dan dibincangkan supaya masalah yang dihadapi dapat diatasi.

- Mesyuarat **'Task Force'** Kosmetik telah diadakan sebanyak dua kali sepanjang 2004 dan ahli terdiri daripada wakil BPFK dan Persatuan Kosmetik, Dandanan Diri & Haruman Malaysia (CTFA). Mesyuarat ini pula membincangkan dengan terperinci tentang isu-isu pendaftaran secara online serta masalah yang dihadapi dengan sistem Quest 2. Pihak TIR akan dipanggil untuk turut serta jika melibatkan masalah dengan 'front-end' sistem Quest 2.

KAJIAN SEMULA GARIS PANDUAN PENDAFTARAN

Garis Panduan Pendaftaran produk farmaseutikal baru telah mula diimplementasikan pada April 2004 dan ia dikenali sebagai **Dokumen Garis Panduan Pendaftaran Farmaseutikal**. Dengan penguatkuasaan ini, Garis Panduan Permohonan Pendaftaran Produk Farmaseutikal sedia ada (Edisi 1993) dan garis panduan Permohonan Pendaftaran

Keluaran Ubat Tradisional, 1998 adalah terbatal. Sebelum dimuktamadkan, draf garis panduan yang dikajisemula diedarkan untuk ulasan dan satu konsensus dengan pihak industri diadakan pada awal tahun 2004 bagi mendapatkan persetujuan berkenaan garis panduan untuk pendaftaran secara online.

Selaras dengan perancangan untuk melaksanakan skim harmonisasi ASEAN atas keluaran farmaseutikal, pihak BPFK telah mengambil langkah untuk mengguna-pakai ASEAN Common Technical Dossier (ACTD) dan ASEAN Common Technical Requirements (ACTR) bagi tujuan permohonan pendaftaran produk farmaseutikal. Penyediaan garis panduan baru juga telah mengambil kira perkembangan terbaru dalam arena regulatori di peringkat global. Garis panduan terbaru ini telah mengambilkira keperluan undang-undang seperti ternyata dalam **Sale of Drugs Act 1952** dan **Control of Drugs and Cosmetics Regulations 1984,** namun adalah menjadi tanggungjawab pemohon untuk memastikan keperluan undang-undang seperti **Dangerous Drugs Act 1952, Poisons Act 1952, Medicine (Advertisement & Sale) Act 1956, Patent Act 1983** serta lain-lain yang berkaitan dipatuhi.

KUMPULAN KERJA TEKNIKAL

Kumpulan Kerja Teknikal (TWG) merupakan satu kumpulan kerjasama teknikal yang melibatkan pegawai-pegawai BPFK serta wakil-wakil pihak industri yang pakar dalam bidang regulatori dan teknikal. TWG yang merangkumi beberapa skop dibahagikan kepada beberapa kumpulan kecil yang mempunyai peranan spesifik berdasarkan bidang keutamaan yang memerlukan kajian terperinci dan mengkaji dengan mendalam aspek-aspek berkaitan keperluan pendaftaran.

- Garis Panduan Permohonan Pindaan Keluaran Berdaftar dan Garis Panduan Permohonan Lesen Import Percubaan Klinikal adalah hasil TWG Farmaseutikal bagi tahun 2004.

- Sepanjang tahun 2004, mesyuarat **Jawatankuasa Kerja Teknikal Kosmetik (Cosmetic-TWG)** telah diadakan sebanyak tiga kali. Ahli terdiri daripada wakil dari BPFK, Persatuan Kosmetik, Dandanan Diri & Haruman Malaysia (CTFA) dan Kumpulan Industri Kosmetik dan Dandanan Diri Malaysia (FMM-MCTIG). Mesyuarat ini membincangkan isu-isu berkaitan dengan pendaftaran produk kosmetik, dari segi keperluan pendaftaran, badan yang mengeluarkan GMP dan CFS dan isu-isu spesifik serta isu-isu semasa mengenai produk kosmetik.

Anugerah & Penghargaan
Awards & Recognition

Anugerah Inovasi Perkhidmatan Awam 1995

Public Service Innovation Award 1995

Sijil Penghargaan daripada Kementerian Kesihatan Malaysia atas kejayaan menerima Anugerah Inovasi Perkhidmatan Awam 1995

Certificate of Recognition from Ministry of Health Malaysia for being awarded The Public Service Innovation 1995

SIJIL PENDAFTARAN SISTEM KUALITI
Quality System Registration Certificate

SIRIM QAS International Sdn. Bhd. dengan ini mengesahkan bahawa
SIRIM QAS International Sdn. Bhd. hereby certifies that
BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
KEMENTERIAN KESIHATAN MALAYSIA
JALAN UNIVERSITI
46730 PETALING JAYA SELANGOR DARUL EHSAN
MALAYSIA

telah melaksanakan Sistem Kualiti yang menepati
has implemented a Quality System complying with

MS ISO 9002 : 2000 Quality Management Systems - Requirements

Skop Pendaftaran
Scope of Registration

PENGAWALAN PRODUK FARMASEUTIKAL, UBAT TRADISIONAL DAN KOSMETIK MELALUI AKTIVITI PENDAFTARAN, PERLESENAN DAN SURVEILANS.

Hj. Ab. Rasak bin Salim
Pengarah Eksekutif
Executive Director
SIRIM QAS International Sdn. Bhd.

Dato' Dr. Mohd. Ariffin bin Hj. Alon
Pengerusi
Chairman
SIRIM QAS International Sdn. Bhd.

Tarikh Pensijilan : 25 May 2001
Certification Date :

Sah Sehingga : 24 May 2007
Expiry Date :

No. Siri : 1110
Serial No. :

Sijil Pendaftaran Sistem Kualiti MS ISO 9002: 1994 (2001); MS ISO 9001:2000 (2003)

Quality System Registration Certificate MS ISO 9002:1994 (2001); MS ISO 9001:2000 (2003)

SIJIL PENDAFTARAN SISTEM KUALITI
Quality System Registration Certificate

SIRIM QAS Sdn. Bhd. dengan ini mengesahkan bahawa
SIRIM QAS Sdn. Bhd. hereby certifies that
BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
KEMENTERIAN KESIHATAN MALAYSIA
JALAN UNIVERSITI
46730 PETALING JAYA SELANGOR DARUL EHSAN
MALAYSIA

telah melaksanakan Sistem Kualiti yang menepati
has implemented a quality system complying with

MS ISO 9002 : 1994 Quality Systems - Model for Quality Assurance in Production, Installation and Servicing.

Skop Pendaftaran
Scope of Registration

PENGAWALAN PRODUK FARMASEUTIKAL DAN UBAT TRADISIONAL MELALUI AKTIVITI PENDAFTARAN, PERLESENAN DAN SURVEILANS.

Dr. Mohd. Yusoff Zakaria
Pengerusi
Chairman
Jawatankuasa Penasihat Pensijilan
Certification Advisory Committee

Dato' Dr. Mohd. Ariffin bin Hj. Alon
Pengerusi
Chairman
SIRIM QAS Sdn. Bhd.

Tarikh Pensijilan : 25 May 2001
Certification Date

Sah Sehingga : 15 December 2003
Expiry Date

No. Siri : 6716
Serial No. :

Sijil Penghargaan

Dengan sukacitanya
Kementerian Kesihatan Malaysia
menganugerahkan sijil penghargaan ini
kepada

BAHAGIAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN

Kerana telah menerima

ANUGERAH PERSIJILAN MS ISO 9001: 2000
KATEGORI AGENSI

Pada tahun

2004

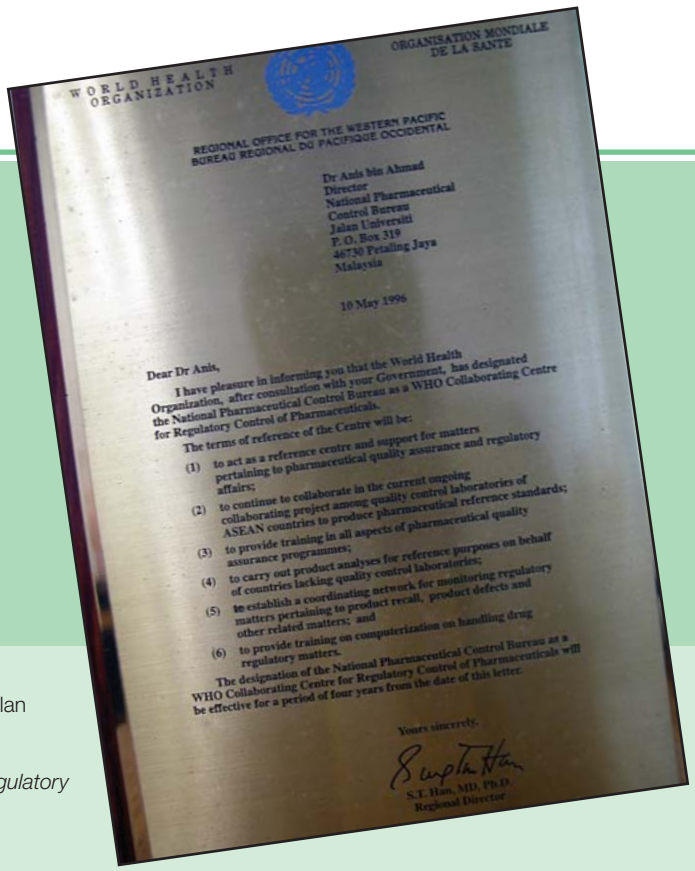
DATO' DR. CHUA SOI LEK DPN3, PIS, PPN
MENTERI KESIHATAN MALAYSIA

Sijil Penghargaan daripada Kementerian Kesihatan Malaysia atas kejayaan menerima Pensijilan MS ISO 9001:2000 pada tahun 2004

Certificate of Recognition from Ministry of Health Malaysia for being certified for MS ISO 9001:2000 in 2004

Naib Johan Kedua bagi Anugerah Kualiti Laman Web pada tahun 2001

Second Runner Up for The Web Site Quality Award in 2001



WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

Dr Anis bin Ahmad
Director
National Pharmaceutical
Control Bureau
Jalan Universiti
P. O. Box 319
46730 Petaling Jaya
Malaysia

10 May 1996

Dear Dr Anis,

I have pleasure in informing you that the World Health Organization, after consultation with your Government, has designated the National Pharmaceutical Control Bureau as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals.

The terms of reference of the Centre will be:

(1) to act as a reference centre and support for matters pertaining to pharmaceutical quality assurance and regulatory affairs;

(2) to continue to collaborate in the current ongoing collaborating project among quality control laboratories of ASEAN countries to produce pharmaceutical reference standards;

(3) to provide training in all aspects of pharmaceutical quality assurance programmes;

(4) to carry out product analyses for reference purposes on behalf of countries lacking quality control laboratories;

(5) to establish a coordinating network for monitoring regulatory matters pertaining to product recall, product defects and other related matters; and

(6) to provide training on computerization on handling drug regulatory matters.

The designation of the National Pharmaceutical Control Bureau as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals will be effective for a period of four years from the date of this letter.

Yours sincerely,

S.T. Han, MD, Ph.D.
Regional Director

Dilantik sebagai Pusat Kolaboratif WHO bagi Kawalan Regulatori Farmaseutikal pada tahun 1996

Designated as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals in 1996

PIC/S

Pharmaceuticals Inspection Cooperation Scheme

Ahli PIC/S ke-26 mulai Januari 2002

26th Member of PIC/S since January 2002

National Pharmaceutical Control Bureau
Ministry of Health Malaysia

ANNUAL REPORT 2004

contents

Message From The Director

Alhamdulillah, with the support, commitment, cooperation and dedication of everyone in the National Pharmaceutical Control Bureau (NPCB), many projects were implemented successfully in the year 2004.

Restructuring of the organisation of NPCB was carried out in June 2004 with the objective of strengthening and streamlining the management system to ensure that the work process is more focussed and efficient, thus leading towards excellent delivery of services to our clients. New sections and units were established to reflect the specific duties and processes of regulatory system practised in NPCB.

In line with the directive for implementation of e-government, NPCB launched an online registration system (Quest 2) in the year 2002 for registration of cosmetics and this was extended for registration of traditional medicines in January 2004. NPCB practised an open door policy during the implementation of the online registration system whereby dialogues were held with the relevant industries and a taskforce committee was established together with the various sectors of the industry to obtain valuable feedback in which to improve the Quest 2 system. I would like to express my heartfelt appreciation to the industry representatives for their cooperation and assistance in making the Quest 2 online registration system a reality.

One of the achievements of NPCB that I treasure most is the successful certification of MS ISO 9001 version 2000 Quality Management since 13th August 2003. In the reassessment audit conducted by SIRIM QAS Sdn. Bhd. in August 2004, no non-conformance reports (NCRs) were issued by the auditors. This success reflects the total commitment by the top management and staff towards implementing the philosophy and requirements of the MS ISO 9001 version 2000 in their management system.

NPCB will continue to play an active role both regionally and globally in all fields of regulatory control, including those organised by WHO and other bodies such as the EC-ASEAN Economic Cooperation.

NPCB has played a leading role in activities involving harmonisation requirements of regulatory control amongst ASEAN countries for pharmaceuticals, traditional medicines & health supplements and cosmetics.

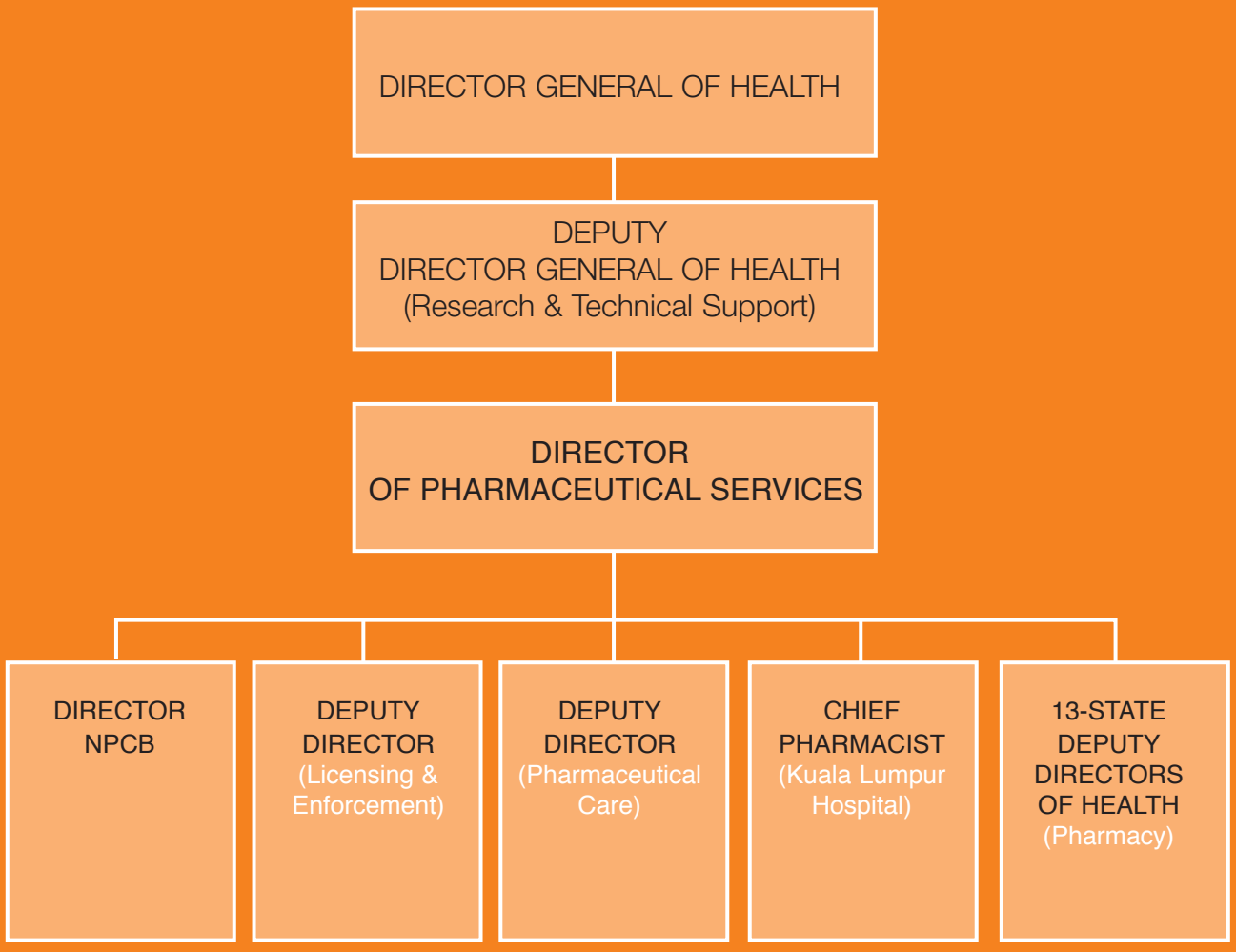
As a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), NPCB was honoured to be invited to participate in Good Manufacturing Practice joint inspections as this also indicates the recognition of the GMP inspection system practised in Malaysia. Furthermore, as a WHO Collaborating Centre for pharmaceutical regulatory control, NPCB participated in several programmes organised by the WHO and also conducted training for WHO fellows in 2004 from various countries.

Although we have had many successful achievements in the past, NPCB will not rest on its laurels but will continue to strive towards further improvements in the future. I would like to express my heartfelt appreciation and gratitude to all the staff of NPCB for their dedication and hard work in 2004. I am positive that they will continue in their quest for greater heights in excellence in the years ahead and to propel NPCB in achieving its goals of excellent service to both the nation and mankind. Last but not least I wish to thank the top management of the Ministry of Health Malaysia especially the Director of Pharmaceutical Services for their guidance and support given to NPCB throughout 2004.

Datin Hjh. Hasiah Hj. Abdullah
DIRECTOR
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

organisational structure of

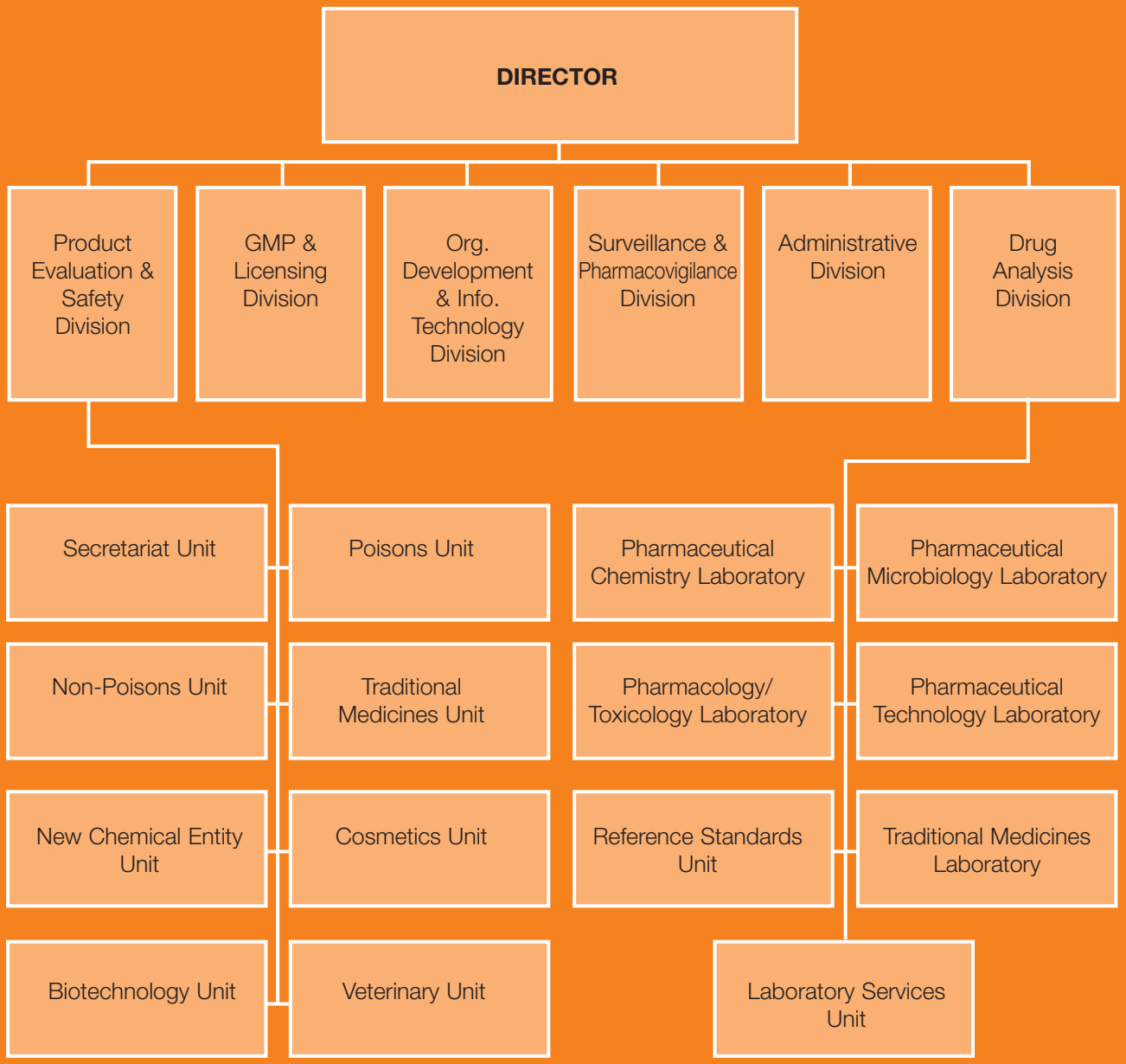
PHARMACEUTICAL DIVISION
Ministry of Health



organisation chart

NATIONAL PHARMACEUTICAL CONTROL BUREAU

(Before June 2004)



organisation chart

NATIONAL PHARMACEUTICAL CONTROL BUREAU
(After June 2004)

DIRECTOR
Y Bhg Datin Hasiah Abdullah

Maintenance Unit

Administration Unit

Centre for Product Registration
Eishah Abd. Rahman

- Generic Medicine Section
  Noorizam Ibrahim
- Prescription Unit
  Noorizam Ibrahim
- Non Prescription Unit
  Mazuwin Zainal Abidin
- Veterinary Unit
  Rohani Ismail
- Complementary Medicine & Cosmetic Section
  Saleha Md. Ewan
- Natural Products Unit
  Saleha Md Ewan
- Health Supplement Unit
  Abdullah Hisham Ahmat Yaya
- Cosmetic Unit
  Anis Talib
- Investigational & New Drug Section
  Fudziah Ariffin
- New Drug Unit
  Fudziah Ariffin
- Biotechnology Unit
  Arpah Abas
- Clinical Trial Regulatory Unit
  Dr. Kamaruzaman Saleh
- Regulatory Coordination Unit
  Tan Lie Sie

Centre for Post-Registration
Abida Haq Sy Md Haq

- Pharmacovigilance Unit
  Abida Haq
- Surveillance & Product Complaints Unit
  Nurhayati Omar
- Pharmaceutical Variations Unit
  Mokhtar Abdullah
- Non-Pharmaceutical Variations Unit
  Vacant

Centre for Organisational Development
Bariah Ab Rani

- Human Resource Unit
  Bariah Ab Rani
- Quality System Management Unit
  Norrehan Abdullah
- Information & Communication Unit
  Fuziah Abd Rashid

Centre for Good Manufacturing Practice
Dr. Tajuddin Akasah

- Inspectorate 1 Unit
  Dr. Tajuddin Akasah
- Inspectorate II Unit
  Sulaiman Ahmad
- GMP Guidance Unit
  Kadariah Mohd Ali
- GMP Investigation Unit
  Mohd Lukmani Ibrahim
- Licensing & Certification Unit
  Wan Othman Wan Ismail

Centre for Quality Control
Yogeswary Markandoo

- Pharmaceutical Chemistry Testing Section
  Dr.Sulaikah Moideen
- Chromatography Unit
  Dr. Sulaikah Moideen
- Dosage Performance Unit
  Muhd Nasir Hashim
- Spectroscopy/General Chemistry Unit
  Tan Chuan Ai
- Chemistry Research Unit
  Vacant
- Reference Standards Unit
  Abdul Aziz Mansor
- Laboratory Services Unit
  Tan Ann Ling
- Pharmaceutical Biology Testing Section
  Faridah Abd. Malek
- Pharmacology/Toxicology Unit
  Faridah Abd. Malek
- Microbiology Unit
  Siti Madziah Mohamed
- Tissue Culture & Biological Research Unit
  Vacant
- Natural Products Testing Section
  Jaafar Lassa
- Herbal Monograph Unit
  Jaafar Lassa
- Adulteration Screening Unit
  Mazli Muhamad
- Toxic Compound Detection Unit
  Vacant

LIST OF POSTS

As on 31 December 2004

PERMANENT POST

NO.	NAME OF POST	GRADE	NO.	POST	
				FILLED	VACANT
1.	DIRECTOR	VU7	1	1	0
2.	PHARMACIST	U54	2	2	0
3.	PHARMACIST	U52	2	0	2
4.	PHARMACIST	U48	31	30	1
5.	PHARMACIST	U44	4	0	4
6.	PHARMACIST	U41	58	47	11
7.	PHARMACY ASSISTANT	U38	1	0	1
8.	PHARMACY ASSISTANT	U36	1	1	0
9.	PHARMACY ASSISTANT	U32	8	5	3
10.	PHARMACY ASSISTANT	U29	65	56	9
11.	ASSISTANT STATISTIC OFFICER	N27	1	1	0
12.	ADMINISTRATIVE ASSISTANT (MANAGEMENT)	N22	1	1	0
13.	ADMINISTRATIVE ASSISTANT (SECRETARY)	N22	1	1	0
14.	ADMINISTRATIVE ASSISTANT (SECRETARY)	N17	2	1	1
15.	ADMINISTRATIVE ASSISTANT (MANAGEMENT)	N17	6	6	0
16.	ADMINISTRATIVE ASSISTANT (STORE)	N17	1	1	0
17.	ADMINISTRATIVE ASSISTANT (FINANCE)	W17	5	5	0
18.	LIBRARY ASSISTANT	S17	1	1	0
19.	TYPIST	N11	4	0	4
20.	TELEPHONE OPERATOR	N11	1	1	0
21.	DATA PROCESSING OPERATOR	F11	2	2	0
22.	SECURITY GUARD	KP11	3	1	2
23.	HEALTH ATTENDANT	U3	10	9	1
24.	DRIVER	R3	3	3	0
25.	GENERAL ASSISTANT	N1	2	2	0
	TOTAL		**216**	**177**	**39**

TEMPORARY POST

NO.	NAME OF POST	GRADE	NO.	POST	
				FILLED	VACANT
1.	SCIENCE OFFICER	C41	25	23	2
2.	ADMINISTRATIVE ASSISTANT	N17	6	6	0
3.	GENERAL ASSISTANT	N1	3	3	0
4.	HOUSEMANSHIP PHARMACIST	-	16	16	-
	TOTAL		**50**	**48**	**2**

organisation's philosophy

VISION

The National Pharmaceutical Control Bureau will be a centre of excellence in 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.

OBJECTIVE

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

STRATEGY

:: To ensure organisational efficiency and effectiveness through modernisation and automation of the office, laboratory and registration systems and regular review and improvement of services.

:: To strengthen enforcement activity of the related legislations.

:: 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.

client's 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 the 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

:: **Licences**
- Licence to Import for Clinical Trial - Not more than 3 months.
- Licence for Wholesalers, Manufacturers and Importers - Not more than 3 months.
- New Licence for Wholesalers, Manufacturers and Importers - Not more than 6 months.

:: **Registration**
- Stage 1 - Not more than 6 weeks.
- Stage 2 - Not more than 4 months.
- Stage 3 - Generic - Not more than 6 months.
- NCE - Not more than 12 months.
- Additional Indications - Not more than 6 months indications.

:: **GMP Inspection Report**
- Follow-up - Not more than 2 months.
- New/Routine - Not more than 3 months.

:: **Product Certification**
- Medical Devices - Not more than 2 weeks.
- Pharmaceuticals - Not more than 1 month.

CLIENT'S OBLIGATION

To enable this charter to be implemented effectively, clients are obliged to fulfil the following:
- Comply with the requirements of the relevant legislation and regulations.
- Use the facilities provided responsibly.

Activity & Performance

Summary Of NPCB Activities

The NPCB underwent a major restructuring exercise in June 2004. Through systematic assignment of functions, NPCB has managed to create sections with specific activities that has led to a more focussed and effective work process, and thus enhanced service delivery.

Organisational restructuring has created redefined sections and units to carry out specific activities and have been renamed as in Table 1.

Table 1 : Change Of Name of Divisions, Laboratories & Units

BEFORE RESTRUCTURING	EFFECTIVE JUNE 2004
1. **Drug Evaluation and Safety Division** - Poisons Unit - Non-Poisons Unit - Veterinary Unit	1. **Centre for Product Registration** a) Generic Medicine Section - Prescription Unit - Non Prescription Unit - Veterinary Unit
- New Chemical Entity Unit - Biotechnology Unit -	b) Investigational & New Drug Section - New Drug Unit - Biotechnology Unit - Clinical Trial Regulatory Unit
- Traditional Medicines Unit - - Cosmetics Unit	c) Complementary Medicine & Cosmetic Section - Natural Products Unit - Health Supplement Unit - Cosmetic Unit
- Secretariat Unit	d) Regulatory Coordination Unit
2. **Drug Analysis Division** a) Pharmaceutical Chemistry Laboratory & b) Pharmaceutical Technology Laboratory - - - -	2. **Centre for Quality Control** a) Pharmaceutical Chemistry Testing Section - Chromatography Unit - Dosage Performance Unit - Spectroscopy/General Chemistry Unit - Chemistry Research Unit

Activities

BEFORE RESTRUCTURING	EFFECTIVE JUNE 2004
c) Pharmaceutical Microbiology Laboratory & d) Pharmacology/Toxicology Unit - - -	b) Pharmaceutical Biology Testing Section - Microbiology Unit - Toxicology/Pharmacology Unit - Tissue Culture & Biological Research Unit
e) Traditional Drug Laboratory - - -	c) Natural Product Testing Section - Herbal Monograph Unit - Adulteration Screening Unit - Toxic Compound Detection Unit
f) Reference Standards Unit	d) Reference Standards Unit
g) Laboratory Services Unit	e) Laboratory Services Unit
3. **GMP and Licensing Division** - - - - -	3. **Centre for Good Manufacturing Practice** - Inspectorate I Unit - Inspectorate II Unit - GMP Guidance Unit - GMP Investigation Unit - Licensing & Certification Unit
4. **Surveillance & Pharmacovigilance Division** - - - -	4. **Centre for Post-Registration** - Pharmacovigilance Unit - Surveillance & Product Complaints Unit - Pharmaceutical Variations Unit - Non-Pharmaceutical Variations Unit
5. **Organisational Development & Information Technology Division** - - -	5. **Centre for Organisational Development** - Human Resource Unit - Quality System Management Unit - Information & Communication Unit
6. **Administration Unit**	6. **Administration Unit**
7. **-**	7. **Maintenance Unit**

Activities

The activities of NPCB are:-

- 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 on drugs to determine quality, efficacy and safety of such products and to determine quality and safety of cosmetics.

- 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 products 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 pharmaceuticals among ASEAN countries.

- To carry out training for pharmaceutical officers, other professional officers and other semi-professional officers who are placed in this institution from time to time through local training schemes or international co-operational schemes.

Each Centre carries out Specific Activities as follows :

Centre for Product Registration

- Receives & evaluates applications for registration of pharmaceutical, traditional medicines & cosmetic products
- Serves as a secretariat to the DCA Meetings, processing of the decisions and issuing Product Registration Certificates
- Processing applications for the Clinical Trial Import Licence
- Processing applications for Change of Registration Holders
- Evaluation of application 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 purposes
- Processing of application for change in particulars of registered products (before organisational restructuring)
- Processing of application for renewal of product registration (before organisational restructuring)
- Processing of application for change of manufacturing site (before organisational restructuring)

Activities

Centre for Quality Control

- Conducting quality control tests to determine quality, efficacy & safety of registered products in both the pre- and post market phases
- Research & development of methodology & analytical protocols
- Establishment of chemical & 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 & evaluation of analytical protocols & 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
- Processing of licence application for manufacturers, importers and wholesalers of registered products
- 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, 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 & 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 & Product Complaints
- Sample collection & testing
- Monitoring of labels & package inserts
- Investigation of product complaints
- Punitive action - Product recall, Warning
- Monitoring of the DCA Directives

III The activities carried out after organisational restructuring :
- Processing of applications for change in particulars of registered products
- Processing of application for renewal of product registration
- Processing of application for change of manufacturing site

Centre for Organisational Development

I Information and Communication
- Disseminate information/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 and Pekeliling Maklumat Ubat'
- Provide library service and reference books for the use of the officers of NPCB

Activities

II Human Resource
- Manage the programme for attachment training of housepharmacists and visitors from overseas
- Handling of programmes 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

product registration

Product Registration

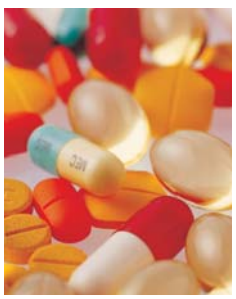
Processing the application for product registration is under the purview of the Centre for Product Registration which ensures that all registered pharmaceutical products have been evaluated for quality, safety and efficacy and all traditional medicines and cosmetic products have been evaluated for safety and quality. The activity also includes the processing of the application for appeals for products which have been rejected by the DCA and applications for additional indications.

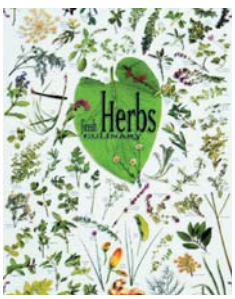
- **Applications for Registration**

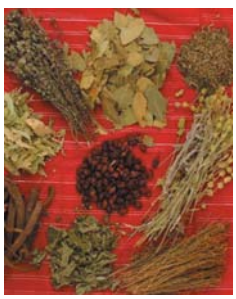
A total of 34,099 applications were received in 2004, an increase of 21% compared to 2003 (28,177). From this total, 1.6% were prescription drugs, 2.1% were OTC products, 6.5% were traditional medicines and the balance of 89.8% were cosmetics. In 2004, applications for all categories of products had increased when compared to 2003 and was the second consecutive year in which the number of applications showed a marked increase compared to the previous years. The number of applications received from 2000 to 2004 are as in Table 2.

Table 2 : Applications Received (Year 2000-2004)

Year	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics	Yearly Total
2000	427	444	1,523	262	2,656
2001	578	487	1,154	150	2,369
2002	509	448	1,603	214	2,774
2003	263	266	1,471	26,177	28,177
2004	529	720	2,220	30,630	34,099








- **Status of Products Registered**

A total of 79,519 products had been registered by 2004 of which 10,496 (13.2%), [2003: (27.3%)] are prescription drugs; 7,689 (9.7%), [2003: (20.1%)] are OTC products; 13,821 (17.4%), [2003: (34.5%)] are traditional medicines, and 47,513 (60.8%), [2003 (18.1%)] are cosmetics. This indicates that registration for cosmetics increased tremendously in 2004 compared to 2003. 47,513 cosmetic products had been registered by the Drug Control Authority by 2004, whereas only 6,751 were registered by 2003. In 2004, a total of 42,311 products had been registered compared to the previous year (2003), which was a total of 6,669 products. This significant increase is due to the increase in applications received for registration of cosmetics at the end of 2003, and the shorter evaluation process. Breakdown of products registered between 2000 and 2004 is shown in Table 3.

Table 3 : Total Number of Products Registered (Year 2000-2004)

Year	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics	Yearly Total
2000	505	387	1,328	327	2,547
2001	180	624	1,344	309	2,457
2002	342	235	864	159	1,600
2003	324	275	1,349	4,721	6,669
2004	353	226	970	40,762	42,311

- **Status of Applications Rejected**

In the last 5 years, from 2000 to 2004 a total of 824 applications were rejected, with an increase in the number for 2004 (446) compared to the previous year. This increase is due to the increase in the number of applications for cosmetics (298) that had been rejected because of non compliance to the registration requirements. The details are shown in Table 4.

Table 4 : Total Number of Rejected Applications (Year 2000-2004)

Year	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics	Yearly Total
2000	20	40	46	0	106
2001	42	23	83	2	150
2002	7	25	23	23	80
2003	4	14	24	0	42
2004	3	48	97	298	446

- **Status of Registration Cancelled or Withdrawn**

In the last 5 years, registration of 2,317 products were cancelled or withdrawn. This consist of 414 (17.8%) prescription drugs; 516 (22.3%) OTC products and 1387 (59.9%) traditional medicines (Table 5). The cancellation of product registration is mainly due to safety issues and non compliance to the registration requirements.

Table 5 : Total Number of Registration Cancelled/Withdrawn (Year 2000-2004)

Year	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics	Yearly Total
2000	306	120	499	-	925
2001	86	305	645	-	1,036
2002	18	2	161	-	181
2003	3	81	58	-	142
2004	1	8	24	-	33

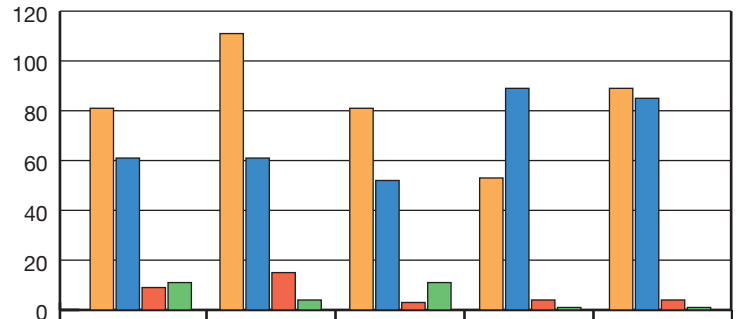
- **Appeal**

The number of appeals received in 2004 was 69 compared to 29 in the previous year. This increase is in line with the increased number of applications being rejected.

- **New Drugs (previously known as New Chemical Entity)**

From the year 2000 to 2004, the total number of applications received for new drugs (previously known as new chemical entity) was 415 (Figure 1) of which 348 (83.9%) were approved, 35 (8.4%) rejected and 28 (6.7%) deferred as additional information was required.

Figure 1 : Registrations Status of New Drugs (Year 2000-2004)



	2000	2001	2002	2003	2004
Received	81	111	81	53	89
Approved	61	61	52	89	85
Rejected	9	15	3	4	4
Deferred	11	4	11	1	1

- **Registration of Biotechnology Products**

The Biotechnology Unit which was established in 2002 is responsible for evaluating applications for the registration of biological products which previously was carried out by the Prescription Unit. Examples of biological products are vaccines, serum for therapeutic use, antitoxin, blood components and its derivatives as well as other products derived by biotechnology methods such as interferon and erythropoietin.

In 2004, 27 products were registered out of 35 applications received.

- **Additional Indications**

Throughout 2004, a total of 76 applications for additional indications were received. Out of this total, 70 applications had been approved whereas the balance of the applications are still under evaluation.

- **Local and Imported Products**

Local and imported products registered in 2004 according to the different categories are illustrated in Table 6. The number of locally manufactured products constitutes 21.9% (9,285) of the total number of registered products whereas imported products is 78.1% (33,026).

In 2004, based on the data in Table 6, the ratio between locally-manufactured and imported products for prescription drugs is in the order of 35:65; 36:64 for OTC products; 59:41 for traditional medicines; and 21:79 for cosmetics.

Based on the total number of locally-manufactured products registered in 2004 (n = 9285), 1.3% are prescription drugs, 0.9% OTC products, 6.2% traditional medicines and 91.6% cosmetics. For imported products (n = 33,026), 0.7% are prescription drugs, 0.4% OTC products, 1.2% traditional medicines and 97.7% cosmetics.

Table 6 : Number of Local and Imported Products Registered (Year 2004)

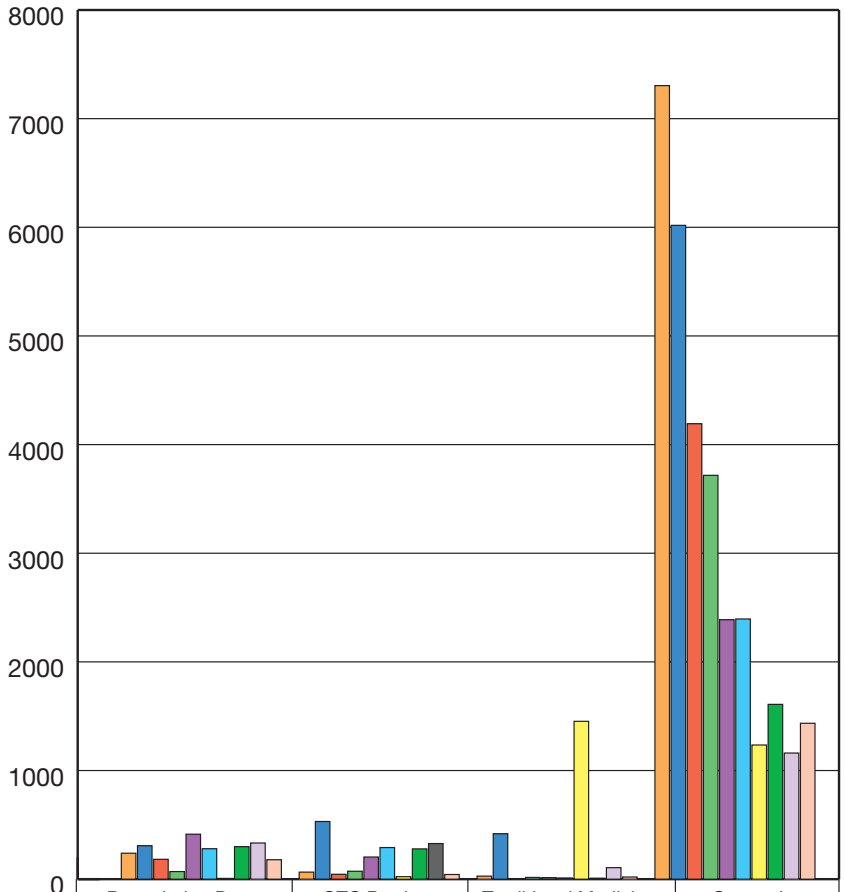
Month	Prescription Drugs		OTC Products		Traditional Medicines		Cosmetics		Total	
	Local	Import	Local	Import	Local	Import	Local	Import	Local	Import
Jan	13	20	10	12	91	53	112	942	226	1027
Feb	19	26	6	14	36	30	150	782	211	852
March	12	17	5	19	87	53	251	1133	355	1222
Apr	19	34	3	13	41	20	159	1240	222	1307
May	11	7	11	8	41	13	167	1055	230	1083
*June	-	-	-	-	-	-	-	-	-	-
July	2	18	1	9	23	8	684	3726	710	3761
Aug	9	23	10	7	33	55	1331	5689	1383	5774
Sept	6	17	6	12	42	23	905	3215	959	3267
Oct	9	31	18	17	55	81	1896	5370	1978	5499
Nov	4	12	5	6	29	14	1001	3126	1039	3158
Dec	19	25	6	28	96	46	1851	5977	1972	6076
Total	**123**	**230**	**81**	**145**	**574**	**396**	**8507**	**32255**	**9285**	**33026**

*No DCA meeting in June 2004

- **Sources of products**

The top 10 leading foreign sources includes France, United States of America, Italy, Japan, Germany, Thailand , China, U.K, Australia, and Canada. Together they account for approximately 68.9% (37,724) of our total imports (n = 54,729). Products imported from ASEAN countries such as Indonesia, Thailand, Singapore and Philippines constitute nearly 10.2% (5,555) (Figure 2).

Figure 2 : Major Sources of Imported Products



	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics
France	239	65	28	7304
US	308	531	418	6018
Italy	183	45	1	4192
Japan	70	73	16	3717
Germany	414	204	14	2388
Thailand	280	291	11	2395
China	7	23	1453	1235
UK	299	279	9	1609
Australia	333	328	106	1161
Canada	179	43	20	1435

Future Plans

Implementation of the registration and licensing of veterinary medicinal products and active pharmaceutical ingredients (API) is planned for the near future.

quality control

Quality Control

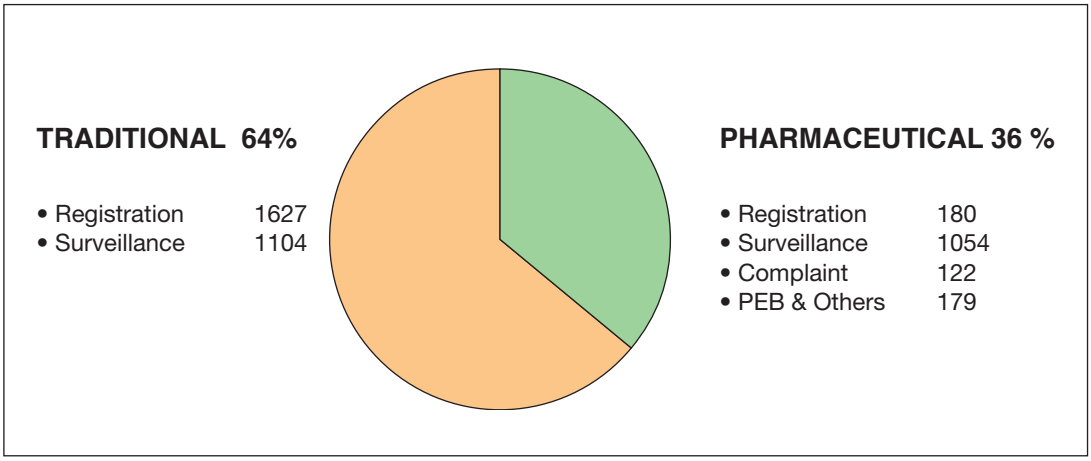
Quality control activity which is handled by the Centre for Quality Control (CQC) is an important element in the evaluation of pharmaceutical, traditional and cosmetic products. The products tested include products for registration, post marketing surveillance of registered products, complaints on registered products and products from enforcement activities. The tests conducted are based on pharmacopoeias, in-house or manufacturers' approved protocols of analysis and specifications.

The applicants for product registration of pharmaceuticals have to submit the product's protocol of analysis for evaluation before submission of samples for testing. As for parenteral preparations, applicants have to only submit the protocol of analysis as well as analytical method validation documents as such products are not routinely tested during the pre-registration phase.

- **Workload**

Throughout the year 2004, a total of 4266 samples comprising of 1535 (36%) pharmaceutical products and 2731 (64%) traditional medicines were received for testing (Figure 3). There were 1807 (42.4%) registration samples, 2158 (50.6%) surveillance samples, 122 (2.8%) complaint samples and 179 (4.2%) samples from the Pharmacy Enforcement Branch (PEB) and others.

Figure 3 : Types of Sample Received

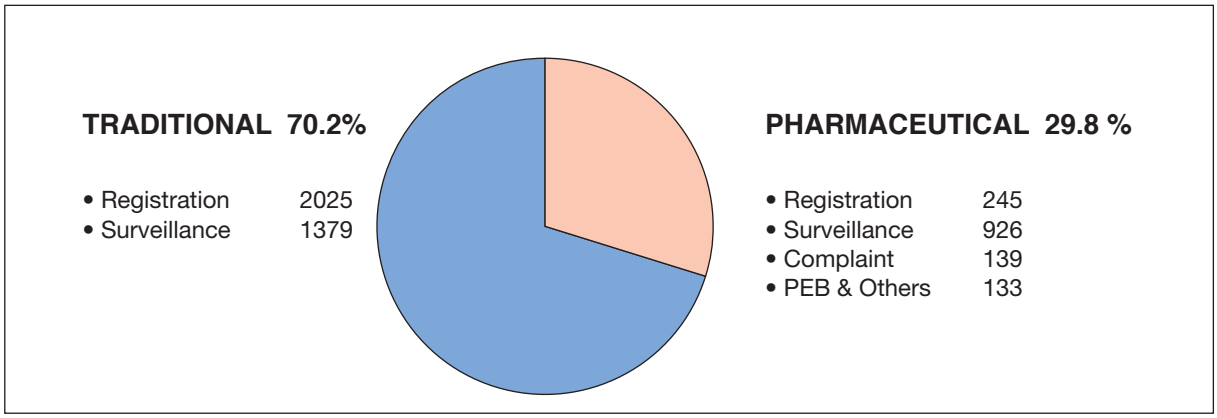







From the total of 4847 samples tested in the year 2004, 1443 (29.8%) were pharmaceutical products and 3404 (70.2%) traditional medicines (Figure 4). The sample types included 2270 (46.8%) registration samples, 2305 (47.5%) surveillance samples, 139 (2.9%) complaint samples and 133 (2.7%) enforcement and other samples.

Figure 4 : Types of Sample Tested



The number of samples tested in 2004 had increased by 16% as compared to the performance in 2003 (Figure 5). The number of tests carried out had increased by 0.3%, that is from 51251 (2003) to 51424 for the year 2004 (Figure 6).

Figure 5 : Number of Samples Tested (Year 2000-2004)

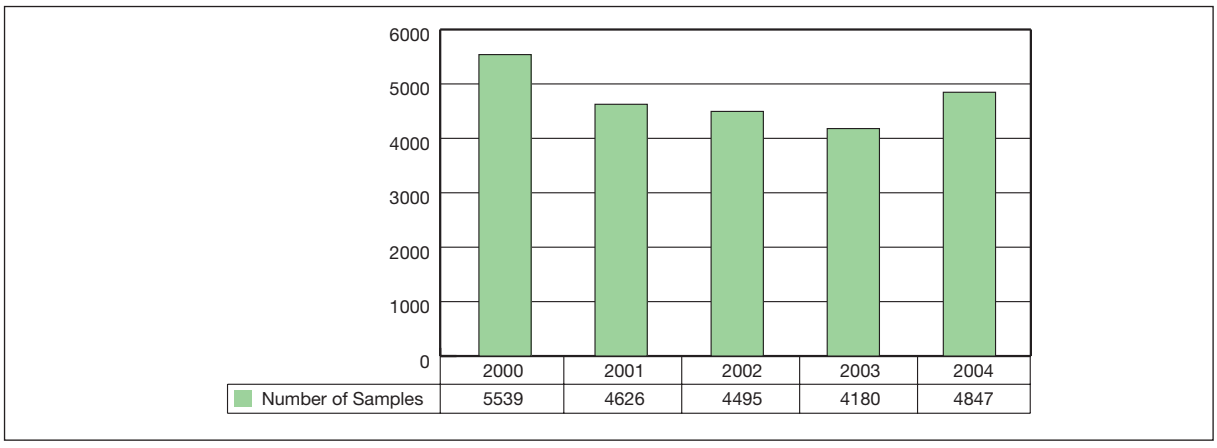
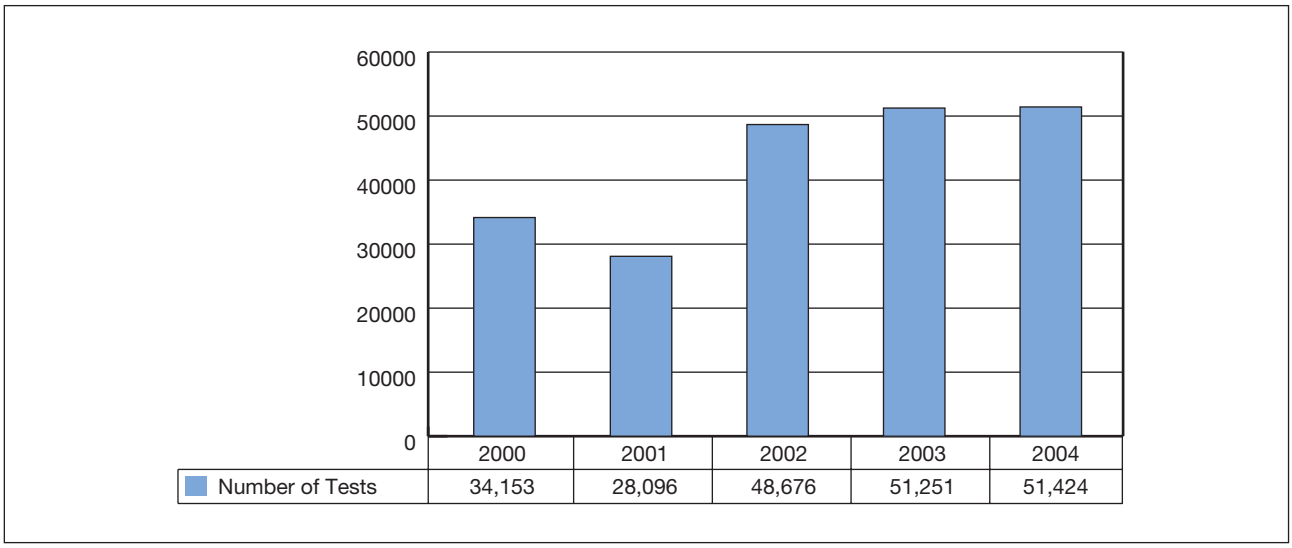
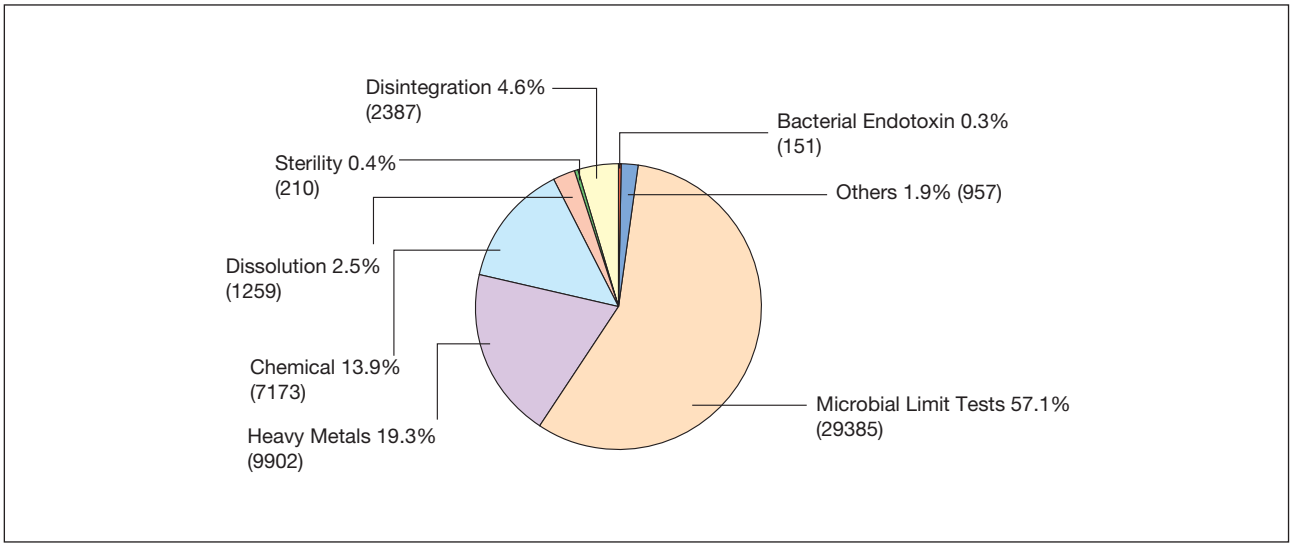


Figure 6 : Number of Tests Done (Year 2000-2004)



The types of test done were microbial limit test (MLT), chemical, heavy metals (As, Hg, Pb), disintegration, dissolution, sterility, bacterial endotoxin and others such as toxicity, biochemical, biological, particle counts and antibiotic assay. Statistic of the tests is as in Figure 7.

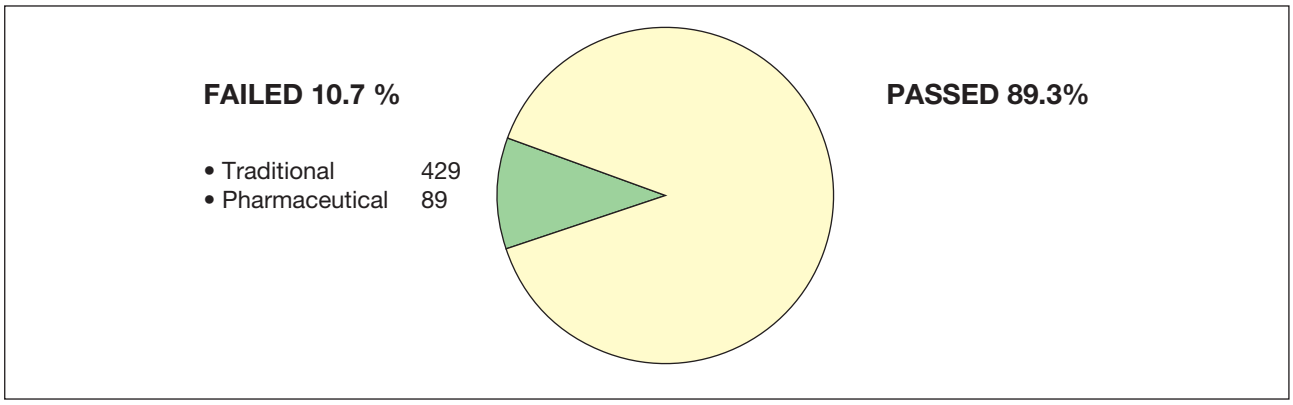
Figure 7 : Types of Tests Done



- **Failed Samples**

The number of failed samples in 2004 amounted to 518 which was 10.7% of the total number of samples tested (Figure 8), comprising of 266 (5.5%) registration samples, 228 (4.7%) surveillance samples, and 24 (0.5%) complaint samples; overall 429 (8.9%) samples were traditional medicines and 89 (1.8%) samples were pharmaceutical products.

Figure 8 : Comparison of Samples Passed and Failed Tests



- **Evaluation Of Analytical Protocols And Data Validation**

A total of 1359 analytical protocol evaluation was done in 2004 whereas the figure reported for the year 2003 was 2548. The vast difference in the number reported in the year 2003 when compared with 2004 was due to the fact that each laboratory reported the number of analytical protocols they evaluated which was then totalled. This practice gave artificially inflated figures as there was duplication, one protocol might be counted more than once. This method of reporting was corrected in 2004 when the laboratory services unit was given the task of coordinating the evaluation of protocol analysis in CQC. Thus, there is no duplication in the number of evaluations reported as happened in the year 2003.

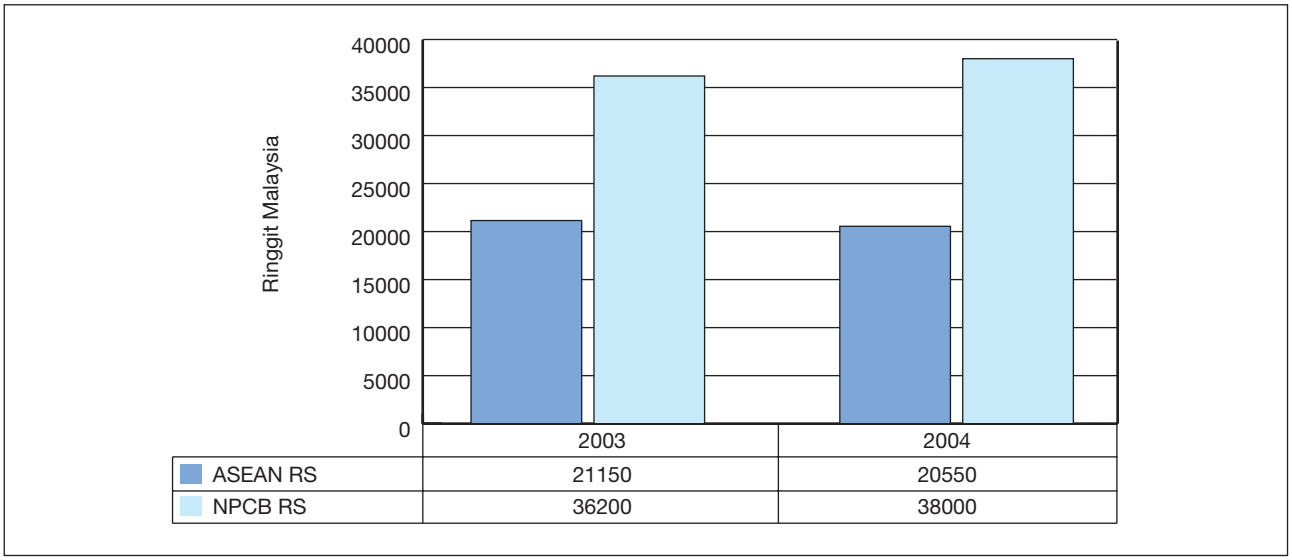
The number of analytical protocols evaluated within the targeted NPCB's Quality Assurance Program (QAP) indicator (of not less than 90% within a month) decreased from 95.3% (2003) to 73.9% in the year 2004. The main factor contributing to the decline in the performance of this indicator is the implementation of the online registration system (Quest 2) in 2004. With this system, all evaluations of analytical protocols have to be done via the online system which gave rise to a few problems such as:-

a. The evaluator has to adapt to reading documents on the computer screen and this prolonged time needed to do the evaluation.
b. Evaluation can only be done during office hours
c. Breakdown in the QUEST 2 system which was quite common in 2004 due to teething problems with the new system.

- **Reference Standards**

One hundred and thirty-seven (137) vials of ASEAN reference standards worth RM20,550 and 380 vials of NPCB reference standards worth RM 38,000 were sold to local pharmaceutical industries and abroad. Each vial of NPCB reference standard was charged at RM100 and ASEAN reference standard at RM 150. The total collection in 2004 (RM59,550) showed an increase from the collection (RM 57,350) made in 2003 (Figure 9).

Figure 9 : Revenue from Reference Standards (Year 2003-2004)



Eight hundred and seventy-six (876) vials of ASEAN/NPCB reference standards were supplied free to various government departments such as the chemistry department, Sarawak laboratory and medical store, state pharmacy enforcement branches and ASEAN countries involved in collaborative projects .

NPCB is actively supporting the collaborative project among ASEAN countries under the auspices of the World Health Organisation (WHO), in the `Production and Utilisation of ASEAN Reference Substances'. The Reference Standards Unit (RSU) has carried out testing on 5 of the 8 substances proposed in the 12th meeting in Thailand held in February 2003. Tests are conducted at RSU before the raw materials, primary reference standards and method of analysis are sent to 2 other ASEAN countries for collaboration. RSU has also packaged 300 vials of nystatin raw material (collaboration project) before microbiological assays are carried out.

The raw bulk materials for prednisolone and nystatin were supplied by Japan Pharmaceutical Manufacturers' Association (JPMA) whereas the Thai regulatory body supplied norfloxacin and guaifenesin raw materials, as well as primary reference standards of prednisolone, nystatin, norfloxacin and guaifenesin. NPCB supplied the raw material and primary standard for diphenhydramine hydrochloride.

Collaborative study tests are also being conducted on raw materials from ASEAN countries. Seven (7) substances were received from ASEAN countries in the year 2004; 4 from Thailand, 1 from Indonesia and 2 from Vietnam.

At the 12th meeting held in Thailand, several substances have been adopted as ASEAN RS. NPCB as the coordinating body for methylparaben, propylparaben and riboflavin has packaged and labelled 300 vials methylparaben, 300 vials propylparaben and 300 vials riboflavin. These ASEAN RS has

been distributed to all ASEAN countries; 120 vials to Indonesia, 90 vials to the Philippines, 90 vials to Singapore, 120 vials to Thailand, 90 vials to Vietnam, 45 vials to Myanmar, 45 vials to Cambodia and 45 vials to Laos. Malaysia has received 265 vials of ASEAN RS; 110 vials from Indonesia, 90 vials from Thailand, 60 vials from Singapore and 5 vials from the Philippines.

- **Adulterants In Traditional Medicines**

Throughout the year 2004, CQC played an active role in screening for the presence of adulterants in traditional medicines received from the enforcement and surveillance activities. In addition, following the directive of the Drug Control Authority, registration and surveillance samples were monitored for adulterants 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 total of 462 samples were tested with 645 number of tests conducted. A total of 66 samples (14.3%) which were confirmed to contain the adulterants as listed in Table 7.

Table 7 : Adulterants in Traditional Medicines

Target	PEU Samples			Registration and Surveillance Samples		
	Number tested	Number confirmed Positive	% Confirmed Positive	Number tested	Number confirmed Positive	% Confirmed Positive
Sildenafil and Tadalafil	90	25	27.78%	35	4	11.43%
Steroids	203	7	3.45%	56	--	--
NSAIDs & Phenylbutazone	31	1	3.22%	33	5	15.15%
Antihistamine/Antitussive	20	4	20.00%	11	3	27.27%
“Cardiovascular drugs”	3	-	-	-	-	-
Antibiotics	4	1	25.00%	4	-	-
Antidepressants/Tranquilizers	--	-	-	1	-	-
H2 Antagonists	1	-	-	-	-	-
Slimming agents	25	--	--	29	1	3.45%
Whitening agents	30	5	16.67%	-	-	-
Analgesics	--	--	--	4	-	-
Hormones	25	-	-	-	-	-
Opiates	3	--	--	2	2	100%
Others (Antihyperlipidaemics, Antidiabetics, Antifungals and Antiasthmatics)	12	3	25.00%	23	7	30.43%

Quality Control

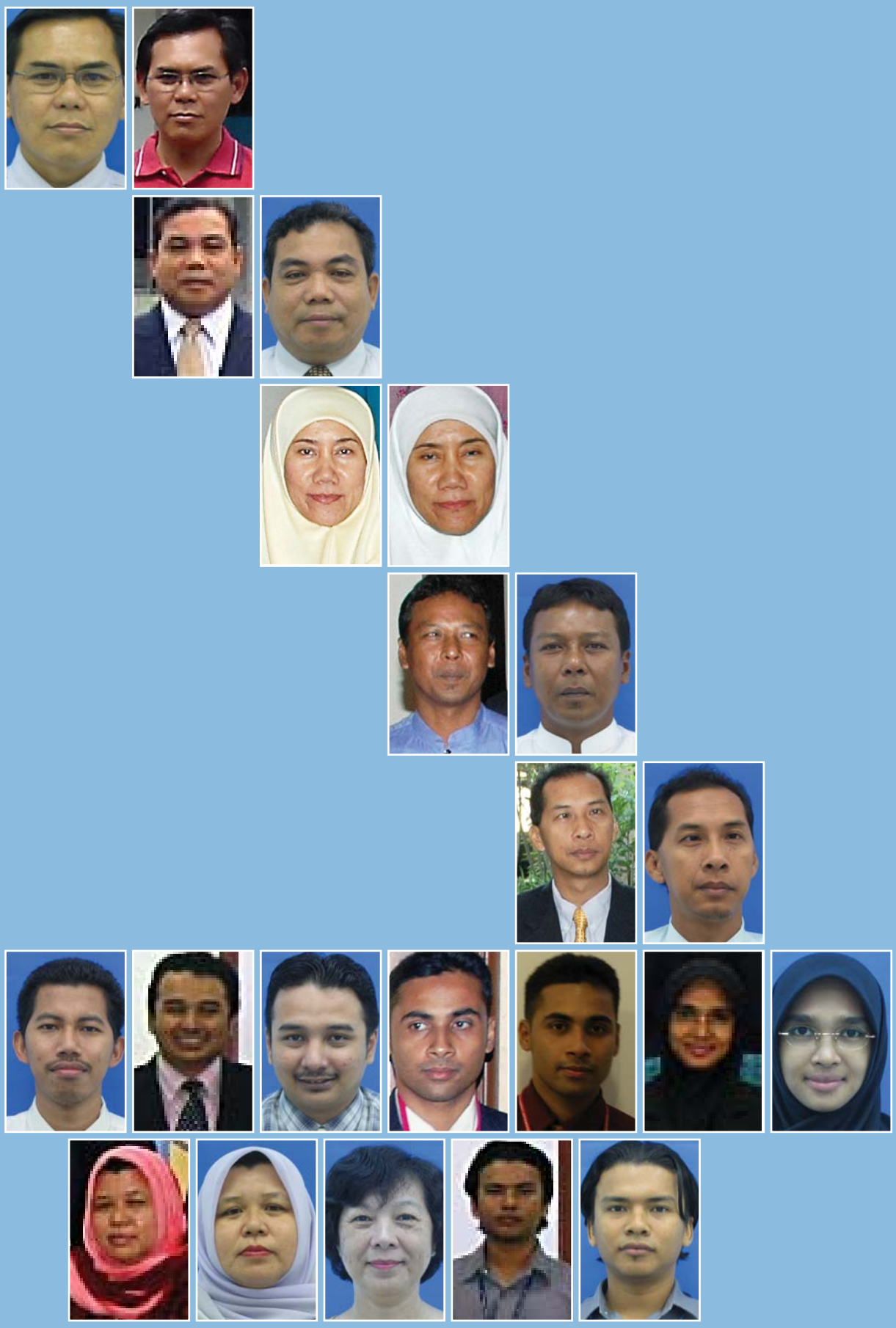
In 2004, new and suitable analytical methods and techniques were developed whereby analysis was done on 4 samples of “daun ketom” preparations and drinks. Two samples of “daun ketom” drinks were tested positive for mitragynine.

Plans for Year 2005

Several activities are scheduled for the year 2005:

a) Continuing preparations towards ISO 17025 accreditation for the laboratories with emphasis on training for staff and to identify the scope for accreditation.
b) Continuing the collaboration amongst ASEAN countries in the production of ASEAN reference materials through collaborative testing of the suggested reference materials.
c) To monitor the laboratories' performance, CQC will continue to participate actively in Proficiency Testing Schemes conducted by WHO and the EC-ASEAN Programme.
d) Organising workshops on assessing the quality of vaccines specifically hepatitis B vaccines.
e) Organising training for relevant laboratory staff in tissue cultures for testing of the safety of vaccines through attachments at recognised institutions.
f) Organising courses in collaboration with the local industries (MOPI) on aspects pertaining to the screening of adulterants such as scheduled poisons.
g) Continuing efforts on analytical method development in techniques for the detection of adulterants in traditional medicines particularly those which involve the use of LCMS-MS.

good manufacturing practice




Good Manufacturing Practice

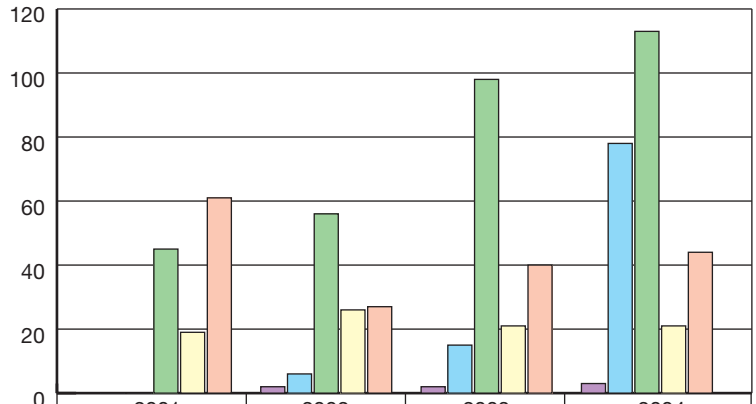


Good Manufacturing Practice (GMP) activity is the main activity of the Centre for GMP which ensures that manufacturing premises of pharmaceutical products, traditional medicines and cosmetics licensed manufacturers adhere to the requirement of GMP. This centre also cooperates with the State Pharmacy Enforcement Branches to ensure that the licensed importers and wholesalers adhere to Good Storage Practice (GSP). The GMP inspections include Good Laboratory Practice (GLP) aspects which are carried out by the Centre for Quality Control (CQC).

- **GMP Inspection**

A total of 259 inspections were conducted in 2004. These inspections included 44 premises for prescription drugs, 21 OTC products manufacturers, 113 traditional medicines, 78 cosmetics and 3 veterinary. Figure 10 shows the number of GMP inspection carried out from 2001 to 2004.

Figure 10 : GMP Inspection (Year 2001-2004)

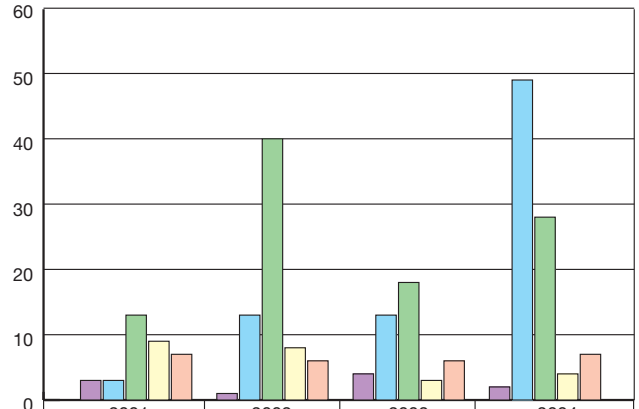


	2001	2002	2003	2004
Others	0	2	2	3
Cosmetics	0	6	15	78
Traditional Medicines	45	56	98	113
OTC Products	19	26	21	21
Prescription Drugs	61	27	40	44

- **GMP Evaluation of Manufacturing Premises Lay-out Plans**

A total of 90 lay-out plans for new and remodelling of existing manufacturing premises were evaluated in 2004 to ensure compliance with GMP requirements, which comprised of 7 premises of prescription drugs manufacturers, 4 OTC products, 28 traditional medicines, 49 cosmetics and 2 others (Active Pharmaceutical Ingredients and Veterinary facilities) (Figure 11).

Figure 11 : GMP Plan Evaluation (Year 2001-2004)

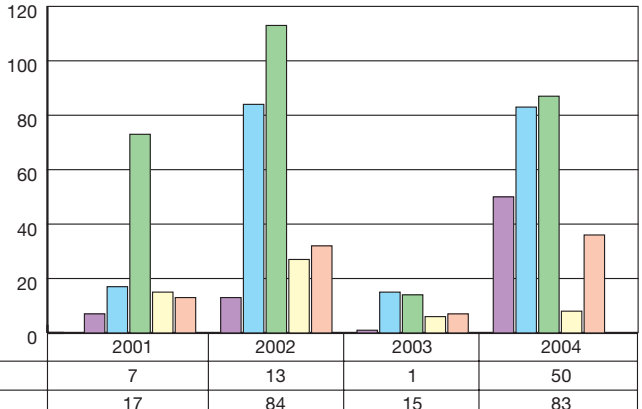


	2001	2002	2003	2004
Others	3	1	4	2
Cosmetics	3	13	13	49
Traditional Medicines	13	40	18	28
OTC Products	9	8	3	4
Prescription Drugs	7	6	6	7

- **Advisory Service**

A total of 264 advisory services were given in 2004, 36 of them were related to GMP of prescription drugs, 8 of OTC products, 87 of traditional medicines, 83 of cosmetics and 50 others (Figure 12).

Figure 12 : GMP Advisory Service (Year 2001-2004)



	2001	2002	2003	2004
Others	7	13	1	50
Cosmetics	17	84	15	83
Traditional Medicines	73	113	14	87
OTC Products	15	27	6	8
Prescription Drugs	13	32	7	36

- **Premise Inspection for Compliance to Good Laboratory Practice (GLP)**

  Centre for Quality Control continues to be actively involved in Good Manufacturing Practice (GMP) inspections, especially in GLP aspects. In 2004, a total of 25 inspections were conducted on local pharmaceutical manufacturing premises as compared to 18 in 2003.

Plans for Year 2005

- GMP Modular training

  The GMP modular training will start in January and ends in September 2005. This program is jointly organized with MOPI.

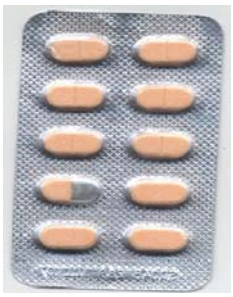
Module 1 - International GMPs and Quality Assurance
Module 2 - GMP for Manufacturing Operations
Module 3 - Good Quality Control Laboratory
Module 4 - Validation Principles
Module 5 - Contamination Control and Clean rooms
Module 6 - Good Aseptic Practices and Sterile Products
Module 7 - Computer System Validation
Module 8 - Process Development for Therapeutics-A Perspective for Pharmaceutical Products I
Module 9 - Process Development for Therapeutics-A Perspective for Pharmaceutical Products II

- GMP Seminar for Traditional Medicines Manufacturers

  In an effort to enhance compliance status to Good Manufacturing Practice (GMP), a seminar is scheduled to be organised in the middle of 2005 specifically for traditional medicines manufacturers, with the hope that compliance to GMP would increase from time to time.

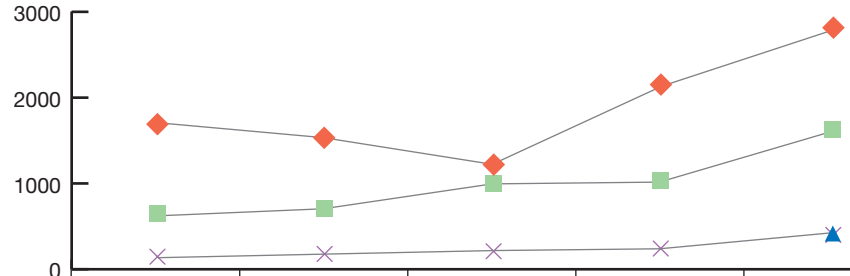
post registration

Post-Registration



Routine surveillance, investigation of products complaints, monitoring of adverse reactions (pharmacovigilance), product variation evaluation as well as renewal of product registration are the main activities of the Centre for Post-Registration (Figure 13). The applications for change of registration holders are processed by the Regulatory Coordination Unit, Centre for Product Registration.

Figure 13 : Workload Under the Activities of Surveillance, Investigation of Products Complaints, Pharmacovigilance and Variation (Year 2000-2004)



	2000	2001	2002	2003	2004
No. of Products Sampled	1789	1487	1201	2037	2793
No. of ADR	792	811	1000	1067	1665
No. of Complaints Report	110	124	181	180	297
No. of Variations*					338

* The activity of evaluation of variation applications was transferred in stages from the Centre for Product Registration to the Centre for Post-Registration since July 2004.

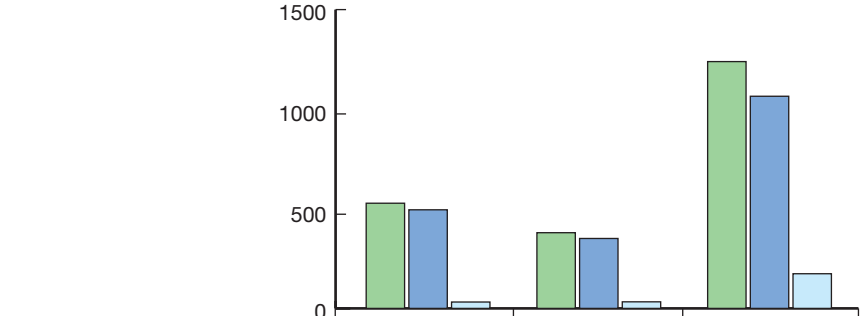
- **Surveillance**

In 2004, a total of 2793 samples from a total of 24,587 registered products were sampled for quality testing which represents 11.36%. However, it must be noted that not all registered products are actually marketed so the number of products sampled may actually represent a higher percentage in terms of marketed products.

All the samples picked up under the surveillance program were sent to the Centre for Quality Control for testing. Testing of products containing scheduled poisons (prescription drugs) and over the counter products were carried out in accordance to the current protocols of analysis supplied by the manufacturers. Testing of traditional medicines was done in line with the established tests for example, tests for microbial and

fungal contamination, heavy metals as well as basic pharmaceutical tests. An analysis of the failure rate of samples tested by category of products is shown in Figure 14.

Figure 14 : Results of Laboratory Testing of Surveillance Samples



	Scheduled Poisons	Over-the-Counter Products	Traditional Medicines
No. Tested	528	380	1239
No. Passed	495	351	1065
No. Failed	32	33	174

Results were received from the laboratory for 2295 products which included prescription drugs, OTC products and traditional medicines, of which 2055 samples passed and 239 failed the laboratory tests.

Not all products which fail the laboratory tests are required to be recalled. Where the tests failed are deemed not to significantly affect the quality of the products, warning letters are issued to the registration holder. For those products that fail laboratory testing for 2 different batches and need to be recalled twice, the product registration will be cancelled

A total of five (5) Degree 1 recalls (within 24 hours) were instituted of which one was a traditional medicine and four were OTC products. There were no Degree 2 recalls (within 72 hour) in 2004.

145 directives were issued for Degree 3 recalls (within 30 days) involving 20 prescription drugs, 8 OTC products and 117 traditional medicines. All the recalls were up to the point of sale/distribution. There was no recall which warranted recalling up to the consumer level.

There were 29 batches of products recalled voluntarily by the product registration holder involving 15 prescription drugs, 12 over-the-counter products and 2 traditional medicines.

Table 8 : Product Recall (directive + voluntary)

Year	2000			2001			2002			2003			2004		
Total Recall	148			122			198			498			179		
Category (A/X/T)	32	17	99	22	13	87	55	29	114	52	166	280	35	24	120

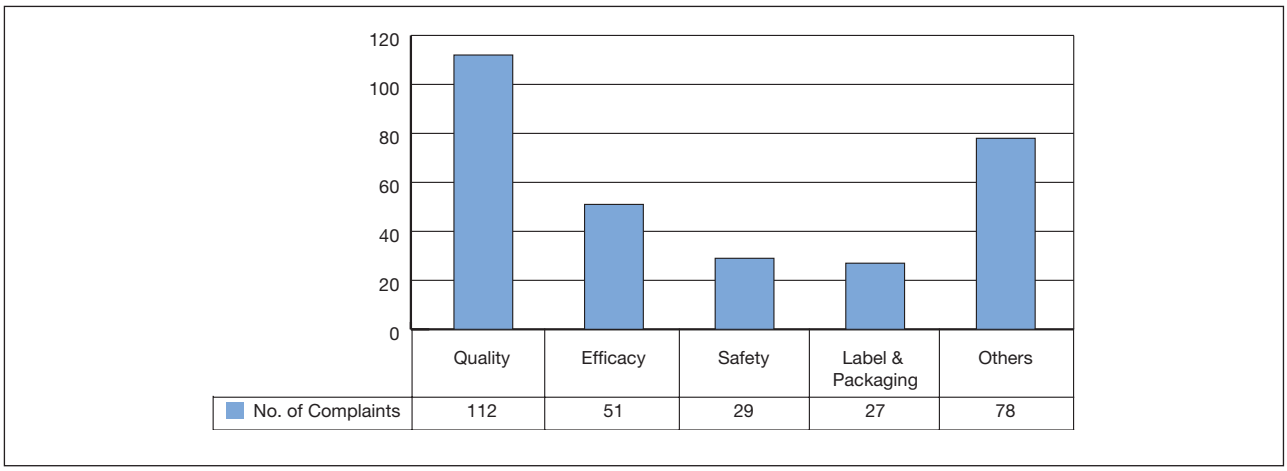
A=Poison; X=Over-the-Counter; T=Traditional

Monitoring of labels and package inserts is also carried out on the products to make sure that the labels on products in the market comply with the labelling requirements. If the label does not comply with the requirements, a label warning is issued. In 2004, a total of 1792 labels were checked and 140 label warnings were issued.

- **Product Complaints**

The number of complaints for registered products increased tremendously in 2004 compared to 2003 where the number of complaints received was 297 compared to 180 in 2003, that is an increase of 65%. Action was taken to resolve these complaints within 6 weeks in more than 95% of the cases. The types of complaints received by the Surveillance and Complaints Unit of the Centre for Post-Registration are divided into quality, efficacy, safety, label and others as shown in Figure 15. Action taken will depend on the type of complaint. A total of 67 complaints against unregistered products were forwarded to the Pharmaceutical Services Division, Enforcement Branch for further action. Complaints about the quality of products which are locally manufactured are forwarded to the Centre for Good Manufacturing Practice for further action during inspection of the premise. For products which are found to be adulterated and products with safety issues, the registration of the product will be cancelled and there was one product which had been cancelled due to this reason in 2004.

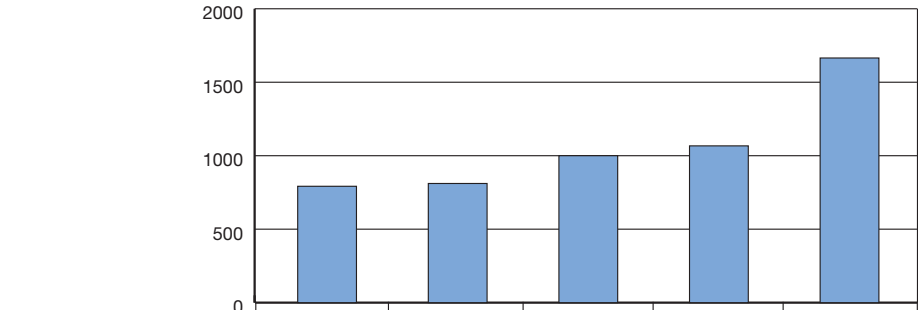
Figure 15 : Types of Complaints



- **Adverse Drug Reactions Monitoring**

In 2004, there was a sharp increase in the number of adverse drug reactions reports received. A total of 1665 reports were received compared to 1067 in 2003, that is an increase of 56% (Figure 16). Out of this total, 1591 reports were for the prescription drugs (A), 31 reports for OTC products (X) and 43 reports for traditional medicines(T).

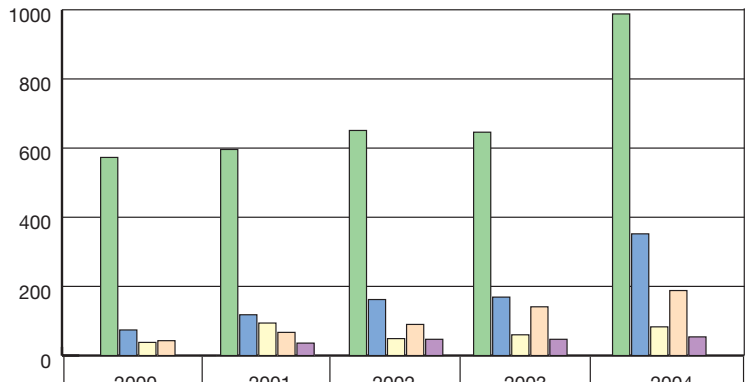
Figure 16 : Number of ADR Reports Received (Year 2000-2004)



	2000	2001	2002	2003	2004
Number of ADR Reports Received	792	811	1000	1067	1665

The reporting rate from the various states is shown in Figure 18 with the highest number of reports being submitted by Kuala Lumpur Hospital and the state of Selangor. From the analysis of the health professionals who submitted ADR reports, it can be seen that doctors based in Government Hospitals submitted the most reports. Reporting by product registration holders also increased in 2004 by 36% (Figure 17).

Figure 17 : Analysis of ADR Reporters (Year 2000-2004)

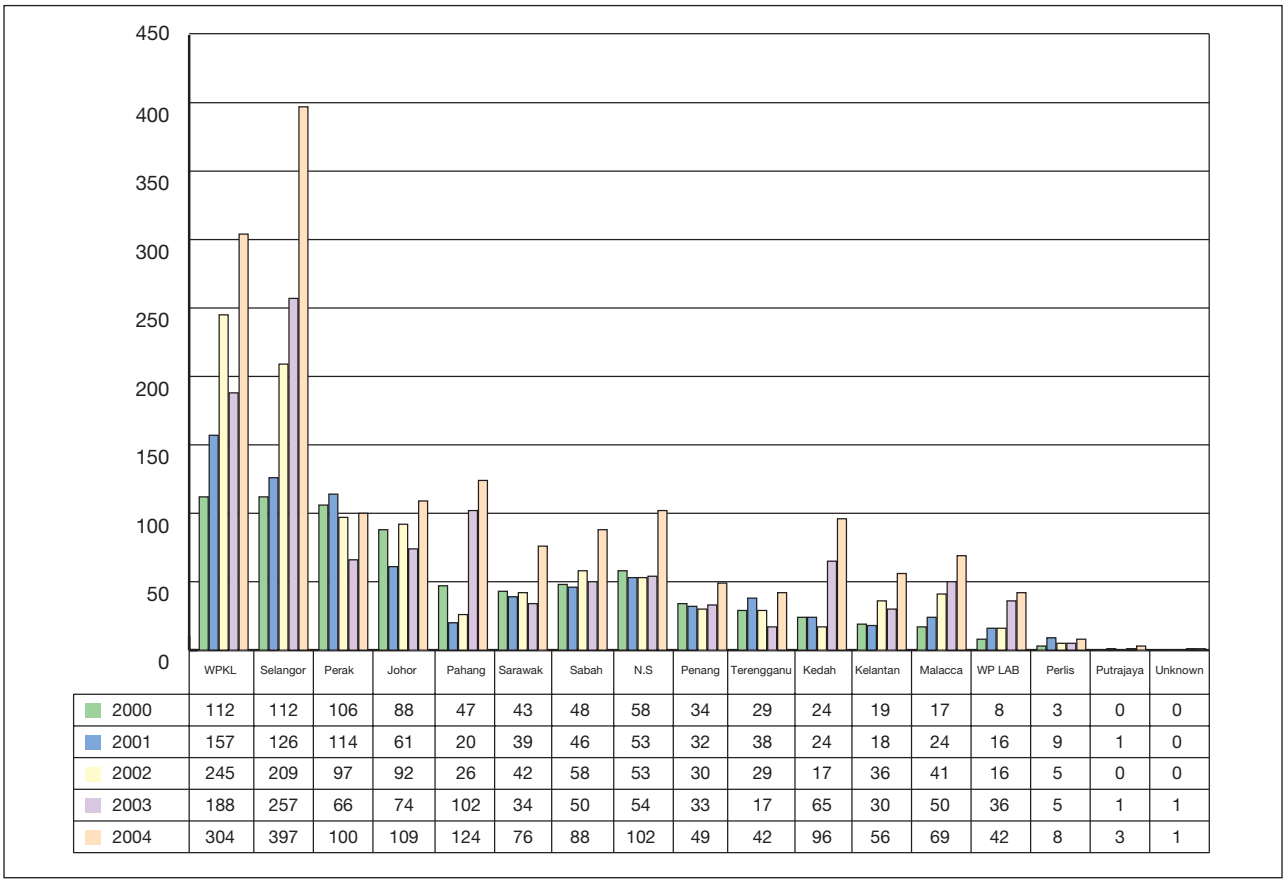


	2000	2001	2002	2003	2004
Government Doctors	573	596	651	646	988
Others (Pharmacist, Dentists)	74	118	162	169	352
GP/Private Specialist	38	94	49	60	83
Company	43	67	90	141	188
University	0	36	47	47	54

Based on Figure 17 and ADR reports received, awareness of the adverse reactions monitoring of prescription drugs in hospital setting is high as compared to traditional medicines which has no specific safety profile monitoring.

Based on ADR reports received, the data were discussed during MADRAC meetings and the reports were sent to WHO Monitoring Centre in Uppsala, Sweden.

Figure 18 : Analysis of ADR's Reporting States (n=1665) (Year 2000-2004)



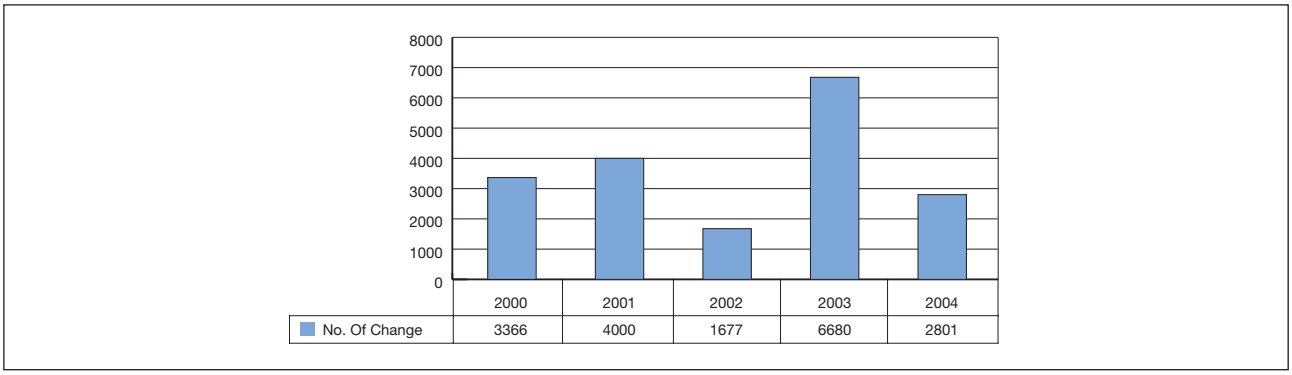
	WPKL	Selangor	Perak	Johor	Pahang	Sarawak	Sabah	N.S	Penang	Terengganu	Kedah	Kelantan	Malacca	WP LAB	Perlis	Putrajaya	Unknown
2000	112	112	106	88	47	43	48	58	34	29	24	19	17	8	3	0	0
2001	157	126	114	61	20	39	46	53	32	38	24	18	24	16	9	1	0
2002	245	209	97	92	26	42	58	53	30	29	17	36	41	16	5	0	0
2003	188	257	66	74	102	34	50	54	33	17	65	30	50	36	5	1	1
2004	304	397	100	109	124	76	88	102	49	42	96	56	69	42	8	3	1

- **Application For Product Variation**

Since July 2004, the Centre For Post-Registration took over the activity of processing applications for product variation of registered products which previously was under the responsibility of each individual unit in the Centre for Product Registration. Applications for product variations include application for change in particulars of registered products and change of manufacturing site. The centre is also responsible for renewal of product registration.

Based on Figure 19, the total number of changes in particulars of registered products went down to 2801 as compared to 6680 in 2003.

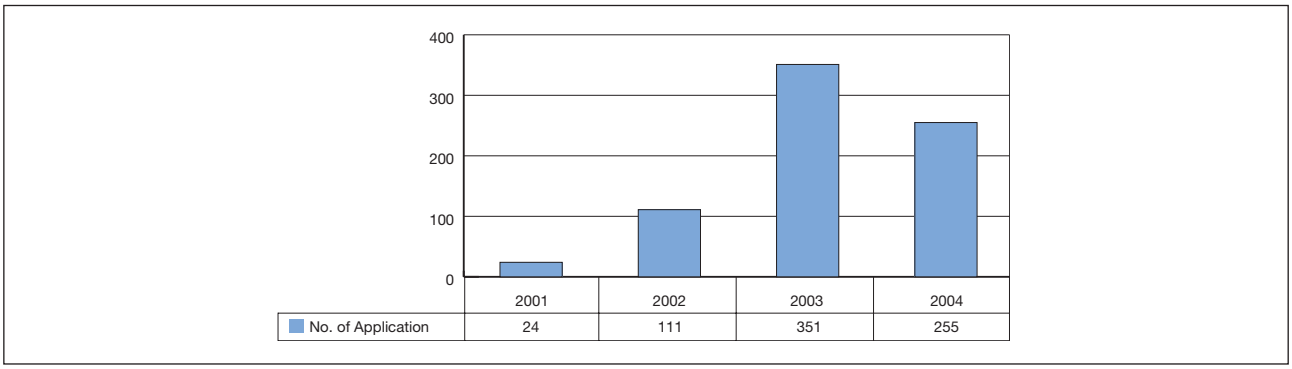
Figure 19 : No. Of Change in Particulars Of Registered Products (Year 2000-2004)



- **Change in Manufacturing Site**

Application for change in manufacturing site may be due to mergers, upgrading of facilities, "rationalisation of manufacturing site", crisis and others. The number of applications received since 2001 is shown in Figure 20 where 255 applications were received in 2004.

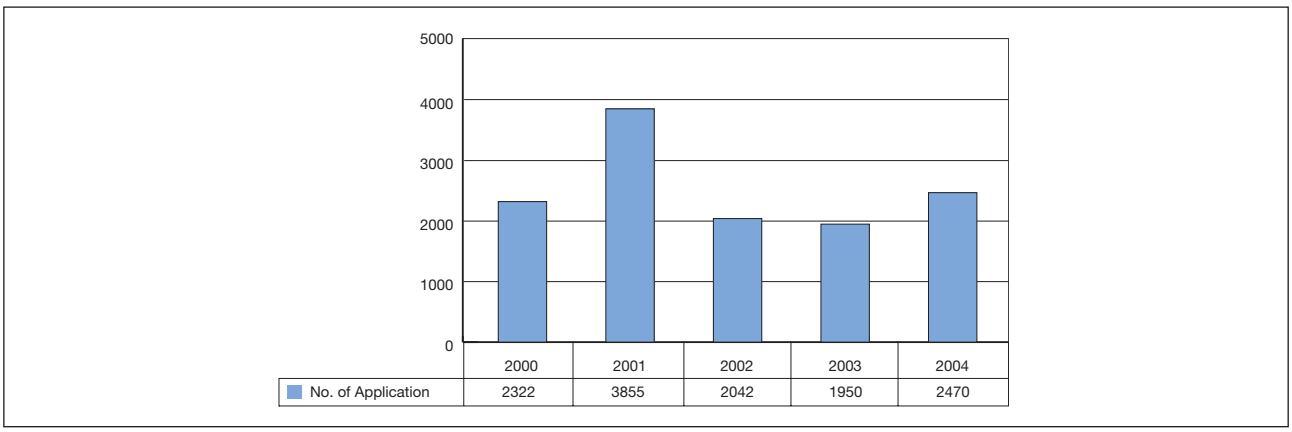
Figure 20 : Change in Manufacturing Site (Year 2001-2004)



- **Renewal Of Product Registration**

The registration of a product is valid for 5 years and applications for the renewal has to be submitted before the expiry of the validity period. The number of applications received in 2004 was 2,470 (Figure 21).

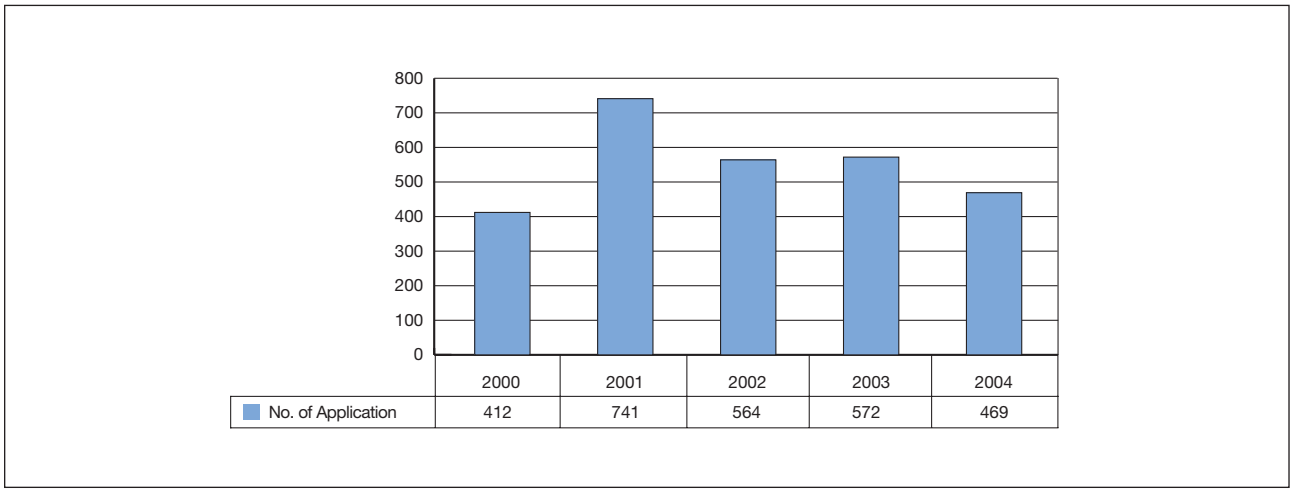
Figure 21 : Renewal Of Product Registration (Year 2000-2004)



- **Application For Change Of Registration Holder**

The total number of applications for change of registration holder received from 2000 is shown in Figure 22 and a total of 469 applications were received in 2004.

Figure 22 : No. Of Application For Change Of Registration Holder (Year 2000-2004)



- **Future Plans for 2005**

Routine surveillance will be continued on registered products and surveillance activities will be intensified on products suspected to contain adulterants, products from problematic manufacturers that had been identified and products that are difficult to manufacture.

As the registration of cosmetic products was implemented in the beginning of 2003, the activity of surveillance, complaints and adverse reactions monitoring will be implemented in 2005.

A survey among medical practitioners and pharmaceutical industries will be conducted to identify a better ADR reporting system.

licensing

Licensing

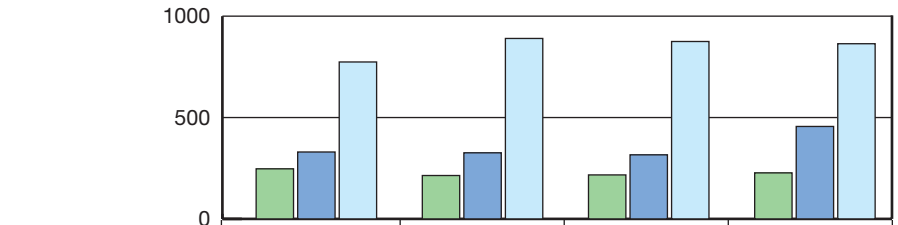
The Drug Control Authority (DCA) issues 4 types of licences under the provisions of subregulation 12 (1) of the Control of Drugs and Cosmetics Regulations 1984. The unit responsible for the issuance of Manufacturer's Licence, Import Licence and Wholesaler's Licence is the Licensing & Certification Unit of the Centre for GMP whereas Clinical Trial Import Licence (CTIL) is handled by Clinical Trial Regulatory Unit of the Centre for Product Registration.

- **Growth Status of Licensed Premises**

A total of 1547 licences were issued in year 2004. There were 227 licensed manufacturers, 456 licensed importers and 864 licensed wholesalers (Figure 23).

List and detail information on licensed premises can be browsed via NPCB homepage at www.bpfk.gov.my. The information is updated monthly.

Figure 23 : Number of Licences (Year 2001-2004)

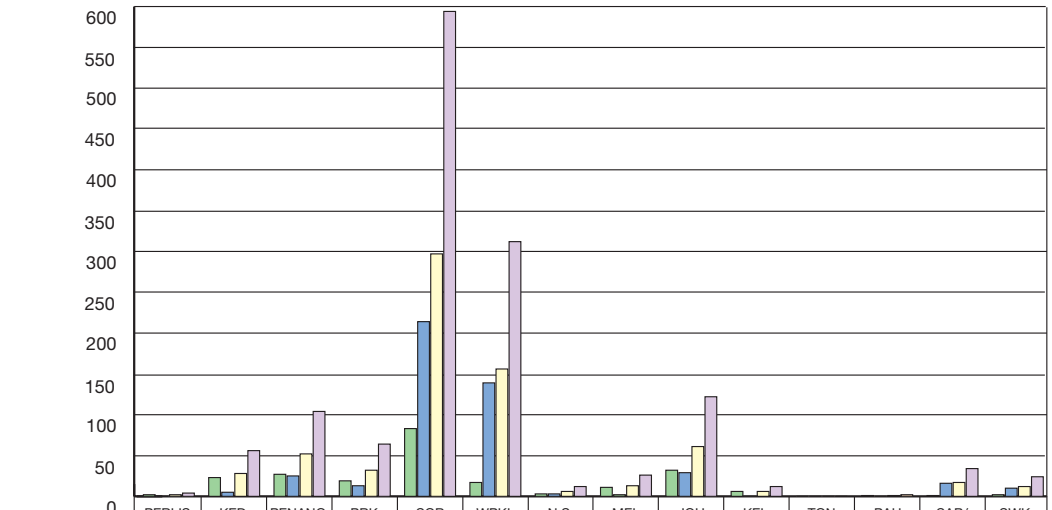


	2001	2002	2003	2004
Manufacturers	247	214	217	227
Importers	330	326	316	456
Wholesalers	774	890	875	864

- **Geographical Distribution of Licensed Premises**

Geographical distribution of licensed premises for the year 2004 is illustrated in Figure 24. Selangor remained as the state with the highest number of licensed premises, followed by Wilayah Persekutuan (Kuala Lumpur) and Johor.

Figure 24 : Geographical Distribution of Licensed Premises (Year 2004)

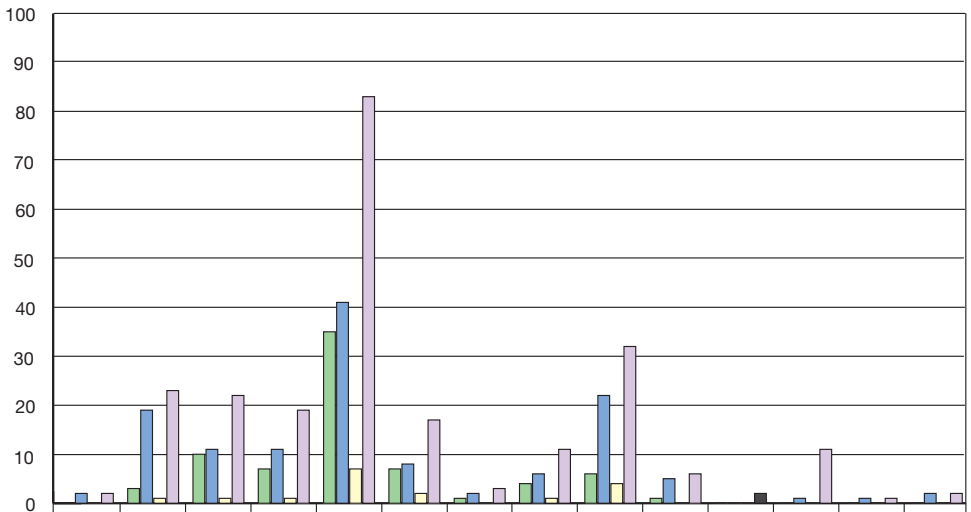


	PERLIS	KED	PENANG	PRK	SGR	WPKL	N.S	MEL	JOH	KEL	TGN	PAH	SAB/ LAB	SWK
Manufacturers	2	23	27	19	83	17	3	11	32	6	0	1	1	2
Importers	0	5	25	13	214	139	3	2	29	0	0	0	16	10
Wholesalers	2	28	52	32	297	156	6	13	61	6	0	1	17	12
Total	4	56	104	64	594	312	12	26	122	12	0	2	34	24

- **Categories of Licensed Manufacturing Premises**

Categories of licensed manufacturing premises for the year 2004 are as illustrated in Figure 25. Selangor has the highest number of licensed manufacturing facilities, followed by Johor, Kedah and Pulau Pinang.

Figure 25 : Categories of Licensed Manufacturers (Year 2004)

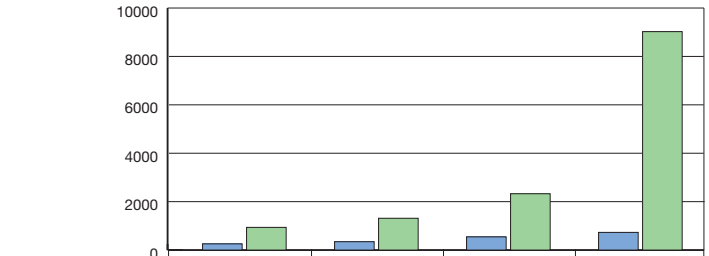


	PERLIS	KED	PP	PRK	SGR	WPKL	N.S	MEL	JOH	KEL	TGN	PAH	SAB/ LAB	SWK
Pharmaceutical	0	3	10	7	35	7	1	4	6	1	0	0	0	0
Traditional	2	19	11	11	41	8	2	6	22	5	0	1	1	2
Cosmetic	0	1	1	1	7	2	0	1	4	0	0	0	0	0
Total	2	23	22	19	83	17	3	11	32	6	2	1	1	2

- **Additional Lists of Registered Products**

The total number of applications processed in 2004 was 730 and these include 9025 products (Figure 26). Additional list is processed based on applications to include a newly registered product into the list attached to the manufacturer's or import licences.

Figure 26 : Statistic For Issuance Of Additional Registered Product List (Year 2001 - 2004)



	2001	2002	2003	2004
Application	255	345	545	730
Product	937	1313	2327	9025

- **Punitive Actions**

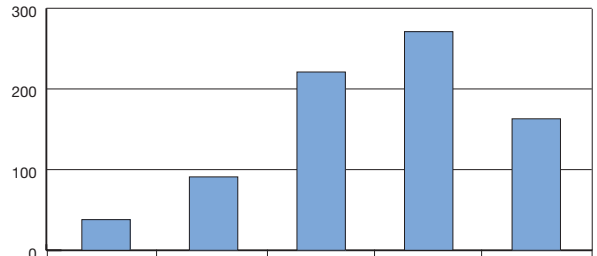
DCA had revoked six manufacturer's licences in 2004. Licences of three traditional medicines manufacturing facilities had been revoked because their facilities were involved with manufacturing of adulterated products and another three pharmaceutical manufacturing facilities had their licences revoked due to very poor compliance to the GMP requirements.

- **Clinical Trials Import Licence (CTIL)**

A total number of 163 Clinical Trial Import licences were issued in the year 2004 (Figure 27). From the year 1997 till 2004, a total number of 848 licences had been issued. Besides application for licences, 180 additional applications pertaining to additional quantity of trial products, change of research site, usage of new protocol and others were also processed throughout the year 2004.

A system for inspection of clinical testing facilities will be implemented soon to ensure that Good Clinical Practice and Good Laboratory Practice are adhered to.

Figure 27 : Clinical Trials Import Licence (Year 2000-2004)



	2000	2001	2002	2003	2004
No. Of Licence	38	91	221	271	163

certification & product status confirmation

Certification And Confirmation Of Registration Status

Issuance of registration certificates, product certification for export purposes as well as confirmation of products registration status is the responsibility of the Regulatory Coordination Unit of the Centre for Product Registration and the issuance of Good Manufacturing Practice (GMP) certification is handled by the Licensing and Certification Unit of the Centre for GMP.

- **Registration Certificates**

Issuance of Registration Certificates for registered products throughout the last 5 years that is from 2000 to 2004 is shown in Table 9. In 2004, a total of 42,311 certificates were issued. This increase is in line with the increase in the number of registered products particularly cosmetics.

Table 9 : Total Number of CPP Issued (Year 2000-2004)

Year	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics	Total
2000	505	387	1,328	327	2,547
2001	180	624	1,344	309	2,457
2002	342	235	864	159	1,600
2003	324	275	1,349	4,721	6,669
2004	353	226	970	40,762	42,311

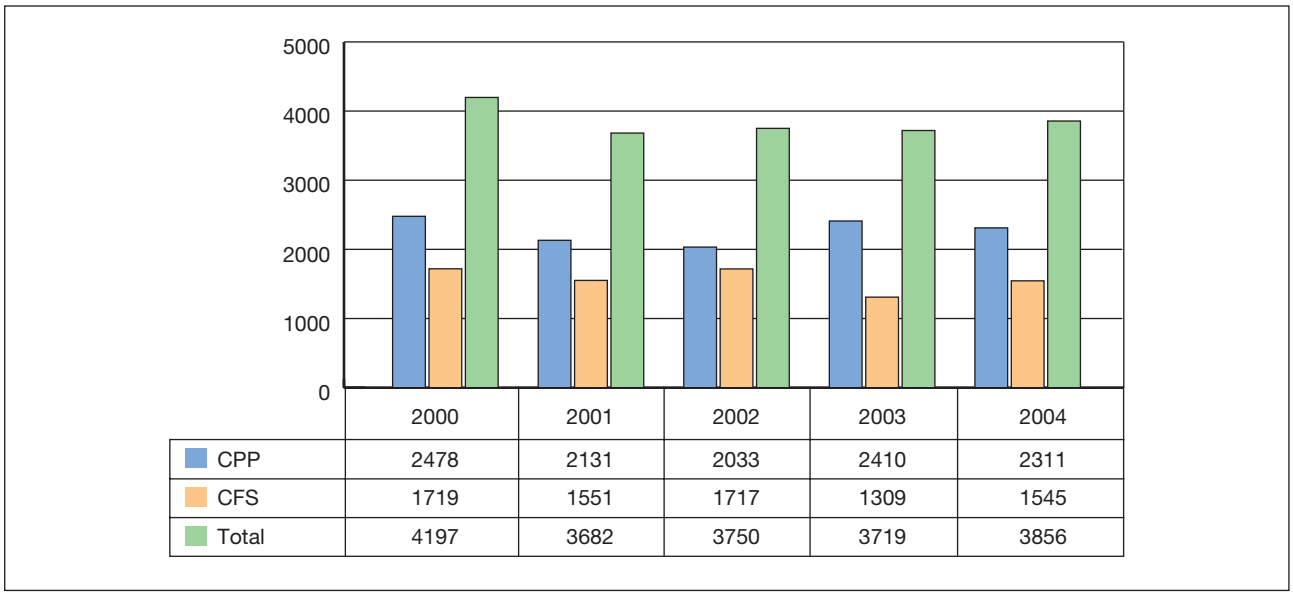
- **Export Authorisation**

Issuance of certificates of pharmaceutical products (CPP) and certificates of free sale (CFS) for medical devices and cosmetics for export authorization from the year 2000 to 2004 is illustrated in Figure 28. A total of 2,311 CPP and 1,545 CFS were issued in 2004.

CPP issued were for export purposes to countries such as Afghanistan, Australia, Austria, Bangladesh, Botswana, Brunei, Cambodia, China, Ethiopia, Germany, Ghana, Hong Kong, India, Indonesia, Iraq, Italy, Japan, Jordan, Kenya, Kuwait, Saudi Arabia, Macau, Maldives, Mauritius, Myanmar, New Zealand, Nigeria, Pakistan, Panama, Papua New Guinea, Philippines, Singapore, Sri Lanka, Sudan, Taiwan, Thailand, United Arab Emirates, Vietnam, South Africa, Zimbabwe, Yemen and Zambia.

CFS issued were for export purposes of cosmetics and medical devices to countries such as Argentina, Bangladesh, Bolivia, Brazil, Brunei, Bulgaria, China, Chile, Colombia, Ecuador, Egypt, Ethiopia, Guatemala, Hong Kong, India, Indonesia, Iran, Khazastan, Korea, Kuwait, Saudi Arabia, Mauritius, Mexico, Nigeria, Pakistan, Panama, Peru, Philippines, Russia, Sri Lanka, Taiwan, Thailand, Turkey, Vietnam, South Africa and Yemen.

Figure 28 : Issuance Of Certificates Of Pharmaceutical Products (CPP) And Certificates Of Free Sale (CFS) (Year 2000-2004)

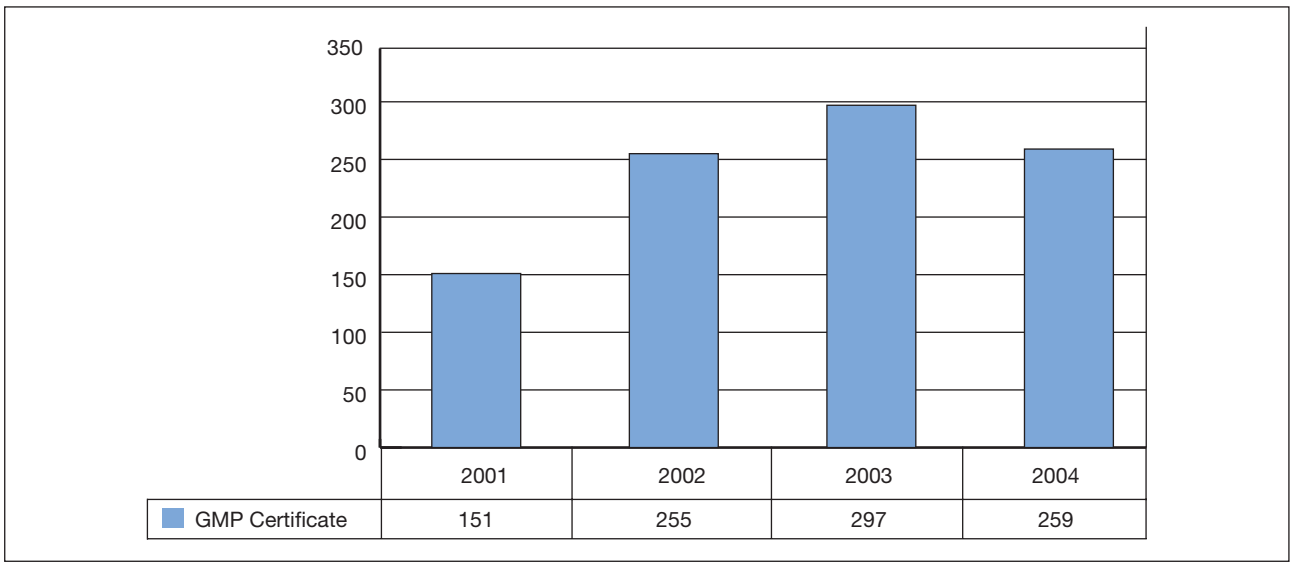


	2000	2001	2002	2003	2004
CPP	2478	2131	2033	2410	2311
CFS	1719	1551	1717	1309	1545
Total	4197	3682	3750	3719	3856

- **GMP Certification for Export Purposes**

In 2004 the total number of GMP certificates issued was 259 (Figure 29). These certifications are for countries such as Afghanistan, Australia, Botswana, Brunei, Cambodia, Canada, China, Egypt, Ethiopia, USA, Fiji, Ghana, Hong Kong, India, Indonesia, Iran, Iraq, Japan, Jordan, Khazastan, Saudi Arabia, Kuwait, Korea, Laos, Macau, Maldives, Mexico, Mozambique, Myanmar, Nigeria, Pakistan, Papua New Guinea, Thailand, Turkey, Uganda, United Arab Emirates (UAE), Vietnam, South Africa, Oman, Sri Lanka, Taiwan, Zimbabwe, Yemen, Sudan, Romania, Singapore and Zambia.

Figure 29 : GMP Certification For Export Purposes (Year 2001-2004)



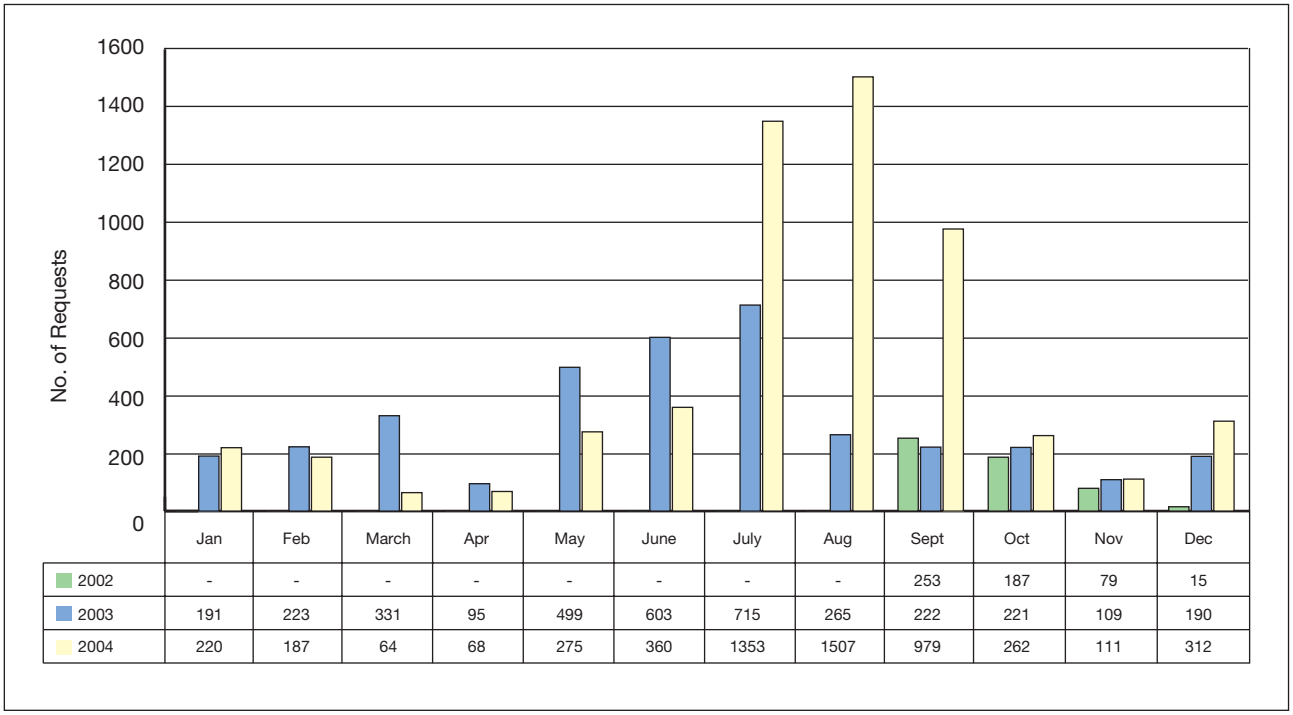
	2001	2002	2003	2004
GMP Certificate	151	255	297	259

Certification And Confirmation Of Registration Status

- **Confirmation Of Registration Status**

Confirmation of registration status is normally requested by the State Pharmacy Enforcement Branch of Ministry of Health Malaysia for products that are confiscated during raids and enforcement activities. The confirmation is required for purposes of prosecution in courts and a total of 5,698 product registration status confirmation were done in 2004 (Figure 30).

Figure 30 : Request On Product Registration Status By Pharmacy Enforcement Branch (Year 2002-2004))



	Jan	Feb	March	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
2002	-	-	-	-	-	-	-	-	253	187	79	15
2003	191	223	331	95	499	603	715	265	222	221	109	190
2004	220	187	64	68	275	360	1353	1507	979	262	111	312

*Jan-August 2002 data not available

communication

Communication

Communication plays an important role in providing a link between NPCB and the industry, public and other government agencies. After the restructuring of NPCB in the middle of 2004, two officers (a Principal Assistant Director and an Assistant Director) have been stationed fulltime at the Information and Communication Unit, Centre for Organisation Development to oversee the area of communication. Some of the activities undertaken by the Information and Communication Unit are as follows:

- **Website**

The NPCB website is a very vital communication tool with our clients, be it industry or the public. The latest news and information especially the Drug Control Authority (DCA) policies, list of registered products, decisions of DCA; can be immediately accessed through the website.

In order to improve our website further, we also welcome feedbacks from our direct and indirect clients.

- **Enquiries**

A total of 2180 enquiries were received in 2004 and the monthly details are shown in Figure 31. The number of yearly enquiries are shown in Figure 32. The types of enquiries received by the Information and Communication unit is shown in Table 10.

For the year 2004, the number of enquiries had increased and a large number of enquiries were regarding product classification (28.4%). The reason for this could be various but the one main reason is that many applicants are still unsure of classification of their products.

Enquiries are received through the telephone, faxes, letters, emails, and also “walk-in”.

Figure 31: Number of Enquiries Received (Year 2004)

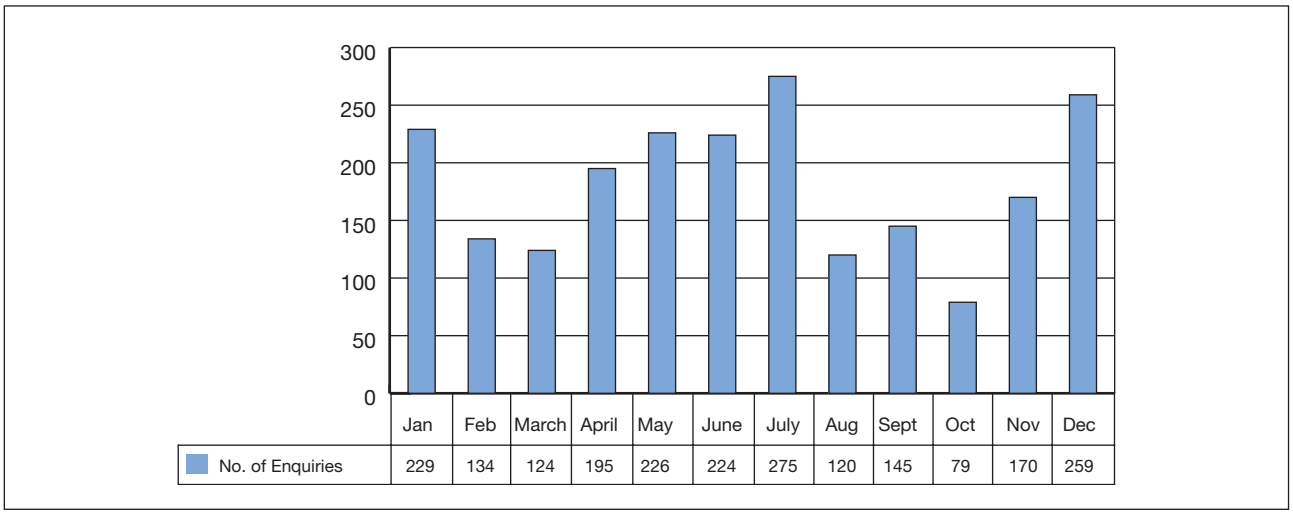


Figure 32: Number of Enquiries Received (Year 2000-2004)

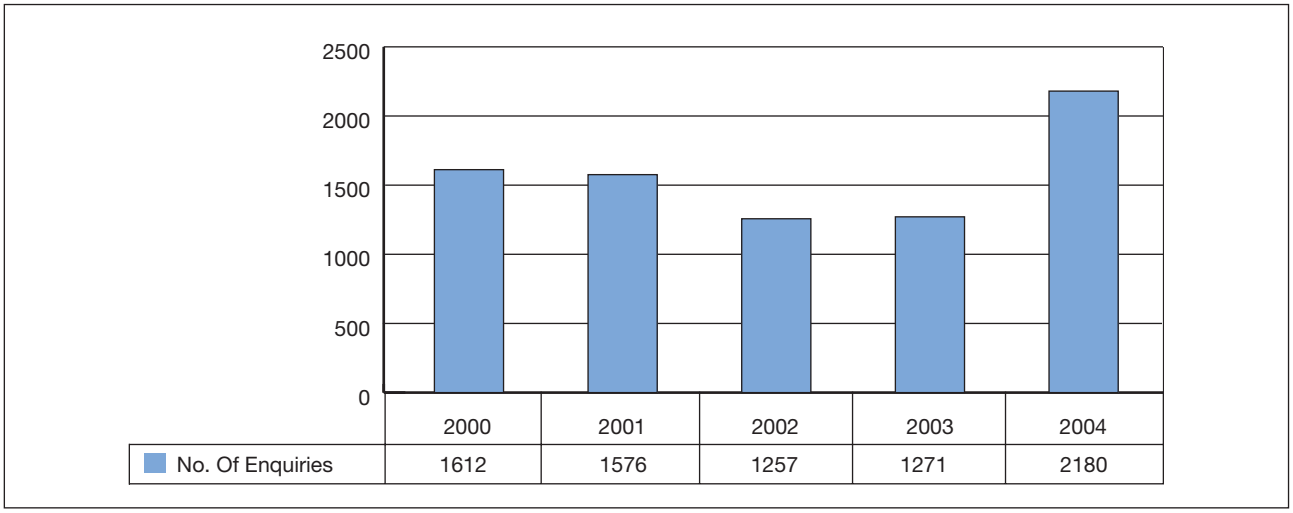


Table 10 : Types of Enquiries Received (Year 2004)

Type of Enquiries		Number	Percentage
General Product Information		93	4.3
Product Indication		28	1.3
Status of Registered Product		144	6.6
Product Supplier		2	0.1
Product Classification		619	28.4
Product Review		55	2.5
On-line Quest		310	14.2
Regulatory Issues		204	9.4
Medical Devices		19	0.9
Others		40	1.8
On-line Registration	Pharmaceutical	175	8.0
	Traditional	275	12.6
	Cosmetics	197	9.0
	Others	19	0.9

Communication

- **Publications**

NPCB prepares a few publications pertaining to drug regulatory control.

In 2004, the following publications were produced:

- Drug Control Authority Newsletter *(Berita Ubat-Ubatan)*
- Drug Information Circular
- Annual Report of NPCB

- **Library Service**

The NPCB library has a total of 1817 books including major pharmacopoeias. The library also subscribes to about 30 journals and drug bulletins, Online Micromedex and International Pharmaceutical Abstracts. Currently the library only services the staff of NPCB. Personnel from Ministry of Health Malaysia can also request for the use of the library facilities. Other facilities available in the library are computers and access to the internet.

- **Future plan**

The ICT infrastructure and the number of reference books especially the electronic media has to be further enhanced and increased for easy access and availability for references by the staff of NPCB.

quality

Quality Management System

National Pharmaceutical Control Bureau acquired MS ISO 9002:1994 certification on 17th July 2001. Upgrading of the quality management system to MS ISO 9001:2000 version was achieved on 13 August 2003. In the reassessment audit carried out by SIRIM on the 23rd and 24th August 2004, NPCB was found to be fully compliant to the requirements of the MS ISO 9001:2000 standard with no non-conformity reports, thus maintaining the MS ISO 9001:2000 certification. The scope of certification is **Regulatory control of pharmaceuticals, traditional products and cosmetics through registration, licensing and surveillance activities.**

The following activities related to quality management system carried out in 2004:

1. ISO 9001:2000 Introductory Course
   - 12 April 2004
2. Quality Management System: Internal Auditors Course
   - 14-15 April 2004
3. Internal Audit on NPCB Quality System
   - June 2004
4. Quality Committee Meeting
   - Twice
5. Management Review Meeting
   - Twice

Excellent Service Awards

The top management of NPCB is continually and tirelessly promoting and instilling service of excellence amongst her staff. Towards this end, yearly excellent service awards are given to those who excel in their work. In 2004, the excellent service award function was held on 10th September 2004 at Dewan Anggerik, NPCB and this function was officiated and graced by the Director of NPCB, Datin Hjh. Hasiah Hj. Abdullah. The recipients are given a certificate of appreciation and a cheque for the amount of RM 1000.00

The names of officers who received the 2003 year excellent service awards are as follows:

1. Mdm. Abida Haq bt. Syed M. Haq.
2. Ms. Fudziah bt. Ariffin.
3. Ms. Gnanasakthi a/p Kanagasabai.
4. Mdm Haslina bt. Ithnin.
5. Mr. Jaafar b. Lassa.
6. Mdm. Masfiza bt. Abdul Hamid.
7. Mr. Mohammad Harian b. Ahmad.
8. Mdm. Normah bt. Ali.
9. Mdm. Ong Chui Eng.
10. Mr. Ramly b. Ahmad.
11. Mdm. Ropidah bt. Hj. Yaakob.
12. Mdm. Siti Madziah bt. Mohamed.
13. Mdm. Yap Soo Huat.
14. Mr. Yunus b. Sulaiman.
15. Mr. Zulkifli b. Abd. Malek.
16. Ms. Zuraida bt. Abdullah.



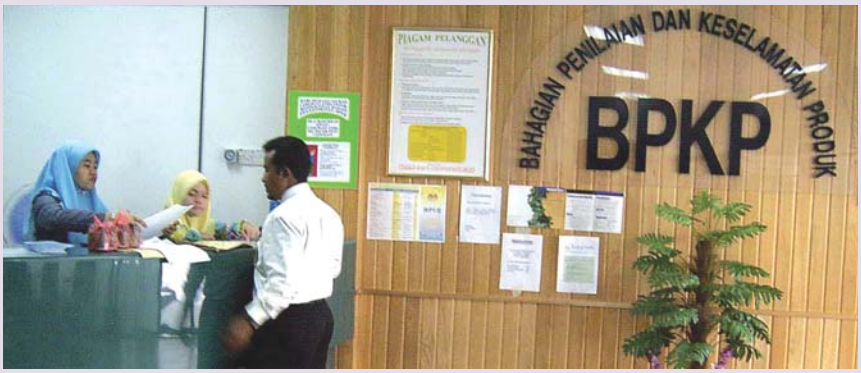






Open Day For Clients

NPCB has designated every second Saturday of the month to be an open day for her clients. On this day, clients can walk in and seek help from any of the NPCB officers on any problems related to registration applications as well as obtain explanations for any queries related to registration. They can also seek the assistance of the Director of NPCB directly if a particular officer concerned is unavailable on that day.



Monthly Morning Assembly

The monthly morning assembly of staff in NPCB was started in June 2004. The morning assembly is held on the first Thursday of every month. The programme for the assembly includes prayer; briefings, advice and guidance by the Director of NPCB; talks by senior NPCB officers on current issues; singing of the national anthem and patriotic songs; taking of the civil service oath; and introduction of new appointees and staff. Seven assemblies were held in 2004.

training & human resource development

Training Programme & Human Resource Development

Just like any other responsible management of an organisation, NPCB also had planned and provided a comprehensive training programme to all her staff to strengthen their competency and knowledge in order to improve the delivery of service and also meet the high expectations of her clients.

In this respect, NPCB had organised various courses, seminars and scientific talks on its own budget and also some jointly with the related industry associations. Several personnel from NPCB also had attended courses and seminars held locally and overseas which were solely organised by other institutions and agencies.

Continuous Professional Development (CPD) program was introduced in 2004 for all pharmacists and pharmacy assistants. In 2004, 22 short CPD sessions and 8 new chemical entities (NCE) previews were held in NPCB organised jointly with the related industry and associations.

The list of courses, workshops, seminars and conferences attended by NPCB personnel are shown in Table 11 and 12.

A few officers from NPCB were appointed as WHO Consultant/TemporaryAdviser/Expert /Facilitator in specific fields at workshops and meetings organised by WHO or in ASEAN cooperation programmes (Table 13).

NPCB officers had also been invited to deliver presentations/talks both locally and overseas on regulatory matters (Table 14).

In addition NPCB also had organised courses for our local industry especially in the field of quality control of traditional medicines.

Table 11 : Training/Courses - 2004

NO.	TRAINING/COURSE	PLACE	DATE	NO. OF PARTICIPANTS
1.	Training on GMP Inspection	NPCB	6-7/1/2004	1
2.	User Training Dissolution Pharmatest PWT 300	NPCB	6-9/1/2004 & 13-15/1/2004	11
3.	Seminar on Technique In Auditing Microbiology Laboratory-MLT	NPCB	10/1/2004	9
4.	Amino Acid Analysis Using Pre-Column Derivatization With ACCQ Method	NPCB	12/1/2004	20
5.	Course on Effective Communication No. 1/04	Central Regional Campus	12-16/1/2004	1
6.	PC Introductory Course	NPCB	19/1/2004	3
7.	GMP Inspection on Good Laboratory Practice	AIN MEDICARE SDN BHD	19-21/1/2004	1
8.	User Training on TLC	NPCB	19/1/2004	4
9.	User Training on TLC	NPCB	29/1/2004	48
10.	User Training on Clinical Waste	NPCB	19/2/2004	7
11.	Desktop Productivity Spreadsheet (No. 1/2004) Course	INTAN	15-17/3/2004	1
12.	General and Specific Induction Course	J.K Selangor & Concord In KLIA, Sepang	7-24/4/2004	6
13.	Introduction to ISO 9001:2000	NPCB	12/4/2004	11
14.	Training on CGMP Compliance for Biopharmaceutical API Manufacturing	Hotel Equitorial, Bangi	12-16/4/2004	1
15.	Internal QMS Auditor Training Course	NPCB	14-15/4/2004	9
16.	Attachment Training At Drug Control Division, Veterinary Group, Thai FDA	Bangkok	19-21/4/2004	1
17.	Competency Course 4	Palm Garden IOI Hotel, Putrajaya	19-30/4/2004	2
18.	Islamic Management Course	INTAN, Bukit Kiara	20-22/4/2004	3
19.	Training Program on National and International Standardisation Activities	SIRIM Berhad, Shah Alam	21/4/2004	1
20.	Fundamental of UV/Vis Spectroscopy	NPCB	21/4/2004	43
21.	Solid Phase Extraction	UM	19/5/2004	2
22.	User Training In Particle Size & Colony Counters	NPCB	3/6/2004	9
23.	Awareness Course on Safety and Health of Workers	NPCB	16/6/2004	10
24.	GMP Inspection on Good Laboratory Practice	Safire Pharmaceutical	6-7/7/2004	1
25.	Briefing on Evaluation of Protocol	NPCB	7/7/2004	5
26.	Internal Induction Course	NPCB	21/7/2004	24
27.	User Training for Cleansing Maintenance	NPCB	22/7/2004	1
28.	Course on Protective Security - Management Module	Putrajaya	3-5/8/2004	3
29.	Training on Aseptic Process	Puri Pujangga, UKM	10-11/8/2004	1
30.	Corporate Communication Course (No. 2/04)	INTAN, Bukit Kiara	16-18/8/2004	1
31.	User Training-Maxi Dry	NPCB	25/8/2004	15
32.	TLC for the analysis of Botanicals	NPCB	26/8/2004	3
33.	Analysis of herbal Preparations with HPLC	NPCB	26/8/2004	1
34.	HPLC Course	NPCB	6/9/2004	46
35.	GMP Auditor Training	NPCB	10/9/2004	13
36.	Advanced Leadership Course (JUSA)	INTAN, Bukit Kiara	16/9-8/10/2004	1
37.	Training on 'Kwik Stik-Use Instruction"	NPCB	17/9/2004	10
38.	Technique on Quadrapole LC/MS	Wood-Dale, Illinois, USA	27-30/9/2004	2
39.	Practical Course on Quality Control of Traditional Medicines	NPCB	4/10/2004	32
40.	Training on Hologram Security Labelling for Enforcement Officers	Johor Bahru	4-5/10/2004	1
41.	GMP Auditor Training	NPCB	6-7/10/2004	10
42.	Investigative Auditing	NPCB	9/10/2004	1
43.	AA Spectrophotometer Course	NPCB	13/10/2004	46
44.	Toxic Effect and Handling of Chemicals	NPCB	15/10/2004	3
45.	Regional Laboratory Training on Harmonisation of ASEAN Cosmetics test methods (tretinoin & colorants)	HSA, Singapore	11-15/10/2004	2
46.	Regional Laboratory Training on Harmonisation of ASEAN Cosmetics test methods	Badan POM Jakarta	22-26/11/2004	1
47.	Regional Laboratory Training on Harmonisation of ASEAN Cosmetics test methods	Bangkok, Thailand	29/11-3/12/2004	3
48.	Regional Laboratory Training Harmonisation of ASEAN Cosmetics test methods	NPCB	6-10/12/2004	4
49.	An Introduction Course on Pharmacy Service for New Pharmacist (2003)	Crystal Crown Hotel, Port Klang	5-7/12/2004	2
50.	Ph D Program (A-9)	USM	2004	4
51.	Masters Degree Program	UM	2004	2

Table 12 : Seminar/Conference/Workshop - 2004

NO.	SEMINAR/CONFERENCE/WORKSHOP	PLACE	DATE	NO. OF PARTICIPANTS
1.	Limulus Amebocyte Lysate (LAL) Seminar 2004	Hyatt Regency Saujana Hotel, Subang	14/1/2004	5
2.	Seminar on Regulation & Safety of Dietary Supplement	Hotel Holiday Villa, Subang	15/1/2004	10
3.	Conference: Integration on Healthcare Industry In ASEAN	Singapore	16/1/2004	1
4.	Regulatory Updates on Vaccines Seminar	NPCB	19/1/2004	11
5.	Seminar On Supelco Discovery HPLC Column & Equity GC Column	NPCB	24/1/2004	3
6.	Seminar Workshop On Advertising vs Information In Medical Profession	HKL	9-10/2/2004	1
7.	Seminar On Vaccinology	Sheraton Hotel	9-10/2/2004	2
8.	11th International Conference of Drug Regulatory Authorities (ICDRA)	Madrid, Spain	16-17/2/2004	2
9.	IDB COMSTECH INTROM IMR Workshop on Herbal Medicine	IMR-KL	16-20/2/2004	2
10.	Laboratory Accreditation to ISO/IEC 17025	Hotel Blue Wave, Shah Alam	19/2/2004	1
11.	Management Of Environmental Hazardous Substances	Renaissance Palm Garden Hotel, Putrajaya	26/2/2004	1
12.	Launching & Working Seminar of the Cosmetic sub programme	Manila, Philippines	1-3/3/2004	1
13.	Briefing On Privatise HSS	NPCB	2-3/3/2004	1
14.	Microbiology QA For Biopharmaceutical Industry	Hotel Equatorial, Bangi	24/3/2004	4
15.	Safety & Benefits of Food Supplements (Public Talk)	Eastin Hotel, PJ	29/3/2004	1
16.	Conference on Fixed Dose Combination	Gaborone Sun Hotel, Botswana	29-30/3/2004	1
17.	2nd International Conference on Improving Use Of Medicines (ICIUM)	Chiangmai, Thailand	30/3-2/4/2004	1
18.	'Program Sehari Bersama NPCB oleh CPF Wilayah'	NPCB	4/4/2004	3
19.	IFPMA 4th ASEAN Regulatory Conference	Kerry Hotel, Beijing China	4-8/4/2004	1
20.	Generic Pharmaceutical Seminar	Hotel Equatorial Bangi	7/4/2004	3
21.	Risk Assessment Seminar-Use Of Antibiotic In Food	Bangkok	7/4/2004	1
22.	Conference on Healthy Ageing	Berjaya Times Square, KL	9-11/4/2004	1
23.	PRISMA Seminar	Putrajaya	10/4/2004	1
24.	2nd National Symposium On Adolescent Health	Hotel Evergreen	10/4/2004	1
25.	Regional Seminar on Healthcare Financing Traditional Medicines	-	15-17/4/2004	1
26.	3rd Scientific Symposium on Erythropoietin	Nexuskarambrunei, Sabah	16-18/4/2004	1
27.	National Seminar on Regulatory Procedure on Traditional Products & NCE	Marriot Hotel, Putrajaya	19-20/4/2004	5
28.	Seminar & Workshop - Update of Cosmetic Registration	Hyatt Saujana Subang	24/4/2004	1
29.	Industry Forum on Registration of Traditional Medicines	JW Marriot, Putrajaya	24/4/2004	2
30.	Seminar on Preservation of Progency Islamic Perspective	UITM, Shah Alam	27-28/4/2004	1
31.	Seminar on GMP for Packaging Materials Suppliers	Holiday Villa, Subang Jaya	28/4/2004	1

Table 12 : Seminar/Conference/Workshop - 2004 (continued)

NO.	SEMINAR/CONFERENCE/WORKSHOP	PLACE	DATE	NO. OF PARTICIPANTS
32.	MOH Management Conference (No. 1/2004)	Hotel Concorde Shah Alam	28-30/4/2004	1
33.	Seminar on Environmental & Chemical Analysis	NPCB	6/5/2004	4
34.	Awareness and Consensus Seminar on Implementation of CFC-free MDIs	Subang Sheraton	9/5/2004	7
35.	Seminar on Rethinking Malaysia-Meeting The Challenges of a New Era	Hotel Nikko, KL	10/5/2004	1
36.	Selangor State Pharmacist Conference	Hotel Residence, UTM Bangi	14-16/5/2004	2
37.	Endocrine Disrupting Chemicals (EDC) Symposium	Fakulti Pergigian, UM	17-18/5/2004	2
38.	R&D Pharmacy Conference	Hotel Pan Pacific, KLIA	17-20/5/2004	1
39.	Seminar on Antiretroviral Medicines	Hotel Cititel, KL	22/5/2004	3
40.	Seminar on Cosmetic Registration	Hotel Grand Riverview, Kelantan	23/5/2004	2
41.	Seminar on CNS Illness	Hotel Singgahsana, PJ	27/5/2004	1
42.	DIS Conference	City Bayview, Langkawi	9-10/6/2004	1
43.	Seminar on APIs PIC/S	Barcelona, Spain	16-18/6/2004	1
44.	Seminar on Practical Approach to Gynaecology	Armada Hotel, PJ	20/6/2004	2
45.	Orientation for Pharmacist U48	NPCB	21/6/2004	23
46.	9th Public Service Conference	INTAN Bukit Kiara	24-26/6/2004	1
47.	Consumer Awareness Seminar on Cosmetic and Food Supplement	Hotel Palm Garden IOI	26/6/2004	1
48.	Developing Psychiatric Services for 2020 : Challenges Ahead	JW Marriot, KL	26/6/2004	1
49.	Asia Pharmaceutical Forum 2004	Sentosa Hotel, Singapura	13-15/7/2004	1
50.	Seminar on Aromatic Plants & Medicines	FRIM, Kepong	20-21/7/2004	1
51.	3rd Thailand International Seminar On ASEAN Harmonisation	Amari watergate Bangkok, Thailand	21/7/2004	1
52.	Regional Workshop On Quality Control Of Medicinal Plant Product In SEA	Hotel Vistana, KL	23-24/7/2004	1
53.	Good Clinical Practice Workshop	Crown Princess Hotel, KL	24-26/7/2004	1
54.	Evidence Based Medicine Seminar	Imperial Sheraton	26/7/2004	1
55.	1st National Health Outcomes Conference	Sheraton Imperial Hotel, KL	27-28/7/2004	3
56.	Pharmacy Enforcement Conference (Intelligent & Investigation)	Swiss Garden Golf & Spa, Kuantan	29/7-1/8/2004	1
57.	4th UiTM-MPS Scientific Conference	Berjaya Times Square, KL	6-8/8/2004	3
58.	Seminar on Global Trend in Vaccinology	Bandung, Indonesia	6-9/8/2004	2
59.	Seminar on Recent Advances In Tools For Protein ID & Biomarker Discovery	Hotel Equatorial Bangi	10/8/2004	3
60.	Ion Chromatography Seminar	Hyatt Regency Saujana, Subang	12/8/2004	1
61.	Seminar on Atherothrombosis	The Amari Watergate Hotel, Bangkok Thailand	13-15/8/2004	5
62.	Briefing on Implementation of Quotation Module for 'ePerolehan PTJ KKM' Project	Institut Pengurusan Kesihatan, KL	18/8/2004	1
63.	2nd ASEAN Congress on Paediatric Infectious Diseases	Sutera Harbour Kota Kinabalu	2-4/9/2004	1
64.	4th KL Mental Health Conference 2004	Prince Hotel & Residence KUALA LUMPUR	6-8/9/2004	1
65.	Conference for R&D Pharmacy	Pan Pacific KLIA	6-8/9/2004	5

Table 12 : Seminar/Conference/Workshop - 2004 (continued)

NO.	SEMINAR/CONFERENCE/WORKSHOP	PLACE	DATE	NO. OF PARTICIPANTS
66.	Total Pure Water Solution from LAB to Building	Cyberjaya Lodge, Cyberjaya	7/9/2004	1
67.	Forum Malaysian Standard for Certification	SIRIM	9/9/2004	1
68.	Workshop On Harmonisation of ASEAN Testing Methods For Cosmetics	Hotel Sheraton, Subang	13-17/9/2004	3
69.	"Challenges & Prospects in Global Market" International Seminar	Marriott Hotel, Putrajaya	28-30/9/2004	1
70.	EC-ASEAN Workshop on Centralised System of Marketing Authorisation and Mutual Recognition Agreements for Pharmaceuticals	Hotel Ambahara, Jakarta	29-30/9/2004	1
71.	Seminar on Pharmaceutical Non-Viable Particular Monitoring & Parenteral	Sunway Lagoon Resort Hotel	30/9/2004	1
72.	EC-ASEAN Regional Training Workshop On ACTD/ACTR	Hotel Crown Princess, KL	11-15/10/ 2004	3
73.	Seminar on Principal Of Skin Toxicity Test & Abnormal Toxicity Test	NPCB	1/10/2004	6
74.	Workshop on GMP and QA of Antimalarial Medicines with Emphasis on Prequalification of ACT's	Bangkok, Thailand	18-22/10/ 2004	1
75.	EC-ASEAN Regional Workshop on Access to Reference Substances	Asia Hotel,Bangkok,Thailand	21-22/10/ 2004	3
76.	Australian Natural Health Products Showcase & Forum	Hotel Le Meridien, KL Sentral	22/11/2004	1
77.	Evidence-based Medicine Workshop, Clinical Epidemiology	Institute Of Health, Bangsar	22-24/11/ 2004	1
78.	Preparations for PTK 1 & PTK 2 Examination Briefing	NPCB	24/11/2004	39
79.	Seminar on MPS Entrepreneurship & Management in Pharmacy	Hotel JW Marriot, KL	27-28/11/ 2004	2
80.	Seminar :The New Frontier in Quantitative & Qualitative GC	Mines Resort City	30/11/2004	1
81.	Conference for U48 Pharmacists (2004)	Hotel Vistana, Kuantan	8-9/12/2004	12

Table 13 : Expert/Temporary Adviser/Consultancy Services

NO.	NAME	EXPERT/TEMPORARY ADVISER/CONSULTANCY SERVICES
1.	Arpah Abas	As a panellist in the evaluation of IRPA Projects, Strategic Research Category, 16-20th May 2004 and 29th September 2004, UPM Selangor
2.	Dr. Sulaikah Moideen	Appointed as a WHO Consultant on Assessing Safety and Quality of Herbal Medicines with Reference to Contaminants and Residues, 12 -14th July 2004, Milan, Italy
3.	Eisah A. Rahman	Served as Co-writer for USP Drug Quality Control Guide for Low Income Countries, March 2004, Chiangmai
		Served as facilitator for Asian Workshop on Drugs for Neglected Diseases Initiative (DNDI), February 2004, Kuala Lumpur
		Served as Chair of EC-ASEAN Conference on Centralised Marketing Authorisations and Mutual Recognition System for Pharmaceuticals, September 2004, Jakarta
		Served as Co-Chair of Product Working Group Traditional Medicines and Health Supplements under ACCSQ, August 2004, Jakarta
		Served as Facilitator for the Regulators Group Session at The 2nd Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses, November 2004, Kuala Lumpur
		Served as Consultant on Expert Consultation on ACTD and ACTR under ASEAN Harmonisation Program, 19-20th July 2004, Bangkok, Thailand
4.	Faridah Abd. Malek	Served as ASEAN Senior Expert at the Regional Laboratory Training on Harmonisation of ASEAN Cosmetic Test Methods, 6-10th December 2004, NPCB, Petaling Jaya
5.	Fudziah Ariffin	Conducted training for the Drug Administration of Vietnam which includes the implementation of ASEAN Common Technical Dossier/Requirement in line with ASEAN Harmonisation, 30th May-6th June 2004, Vietnam
		Served as WHO Temporary Adviser at the 8th ACCSQ-PPWG Meeting & 3rd Thailand International Seminar on ASEAN Harmonisation, 21st-23rd July 2004, Bangkok, Thailand
		Served as WHO Temporary Adviser at the WHO Consultation on Stability Studies in a Global Environment, 13-14th December 2004, Geneva
		Served as Consultant on Expert Consultation on ACTD and ACTR under ASEAN Harmonisation Program, 19-20th July 2004, Bangkok Thailand
6.	Kadariah Mohd. Ali	Preparation of Guidelines on Requirements for the Development of Pharmacy Department, Ministry Of Health
		Technical Consultant for the Construction of Clean rooms for CDR activities, TPN, Eye-drop and IV Admixtures production in public hospitals under Ministry of Health and Ministry of Defence
		Evaluation Expert Committee for Clean room Suppliers for Government Hospitals
		Expert in the Construction of New Facilities for the Manufacture of Sterile Products and Ventilation and Purification Systems
		ASEAN Expert for GMP Inspection and Premises Licensing System in Indonesia under EC-ASEAN Programme
		Served as an auditor in Joint Inspection (PIC/S), November 2004, Switzerland
7.	Mohammad Lukmani Ibrahim	Served as an auditor in Biotechnology Joint Inspection (PIC/S), 1-4/6/2004 Hague & Groningen, Netherlands
		Served as ASEAN Senior Expert for GMP in Preparation Workshop and ASEAN Cosmetic Committee and in Regional Assessment GMP for Cosmetic under EC-ASEAN Programme, 18-20th August 2004, Singapore
		Served as ASEAN Senior Expert for Regional Assessment GMP for cosmetics under EC-ASEAN Programme, 1-4th September 2004, Jakarta Indonesia; 7-9th September 2004, Ho Chi Minh City, Vietnam
8.	Noorizam Ibrahim	As a participant in the review visit to the regulatory authority of Thailand in conjunction with WHO-ASEAN project on harmonisation of regulatory requirements, 26-30th April 2004, Bangkok
		Conducted training for the Drug Administration of Vietnam including the implementation of ASEAN Common Technical Dossier/Requirement in line with ASEAN Harmonisation, 30th May-6th June 2004, Vietnam
9.	Siti Madziah Mohamed	Served as ASEAN Expert at the EC-ASEAN Regional Workshop on Access to Reference Substances, 21st-22nd October, Bangkok, Thailand
10.	Yogeswary Markandoo	Served as Vice-Chairperson of 21st Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceutical, 22-24th September 2004, Vientiane, Lao PDR

Table 14 : Presentation of Papers

NO.	NAME	TITLES OF PRESENTATION PAPER	DATE/PLACE
1.	Abida Haq	Factors for Success in Pharmacovigilance. Paper presented at 11th 'International Conference for Drug Regulatory Authorities (ICDRA)'	19th February 2004, Madrid
		Pharmacovigilance Planning: Impact on Non-ICH Countries. Paper presented to 'International Society for Pharmacovigilance'	7th October 2004, Dublin, Ireland
		Monitoring Safety of Dietary Supplements. Paper presented at the Seminar organised by the Direct Selling Association of Malaysia'	29 March 2004, Petaling Jaya
		'Food Supplements - Do we really need them?. Paper presented at Forum organised by Family Health Division Ministry of Health	13th July 2004, Kuala Lumpur
		'Studies on Adverse Drug Reactions to Traditional Medicines' Paper presented at Seminar for 'Research and Development in Pharmacy'	7th September 2004, Sepang
2.	Anis Talib	Regulations and The Control of Food Supplements & Cosmetics in Malaysia. Paper presented at Seminar for Consumers Awareness organised by Ministry of International Trade and Industry Malaysia in various states	Langkawi (January 2004), Perlis (28th February 2004, October 2004), Sarawak-Sarikei, Kapit & Sibu (5th - 7th March 2004), K. Lumpur (17th April 2004), Sabah-Sandakan (17th May 2004)
		Overview of Cosmetic Regulations. Paper presented at Seminar on Cosmetic Registration organised by National Pharmaceutical Control Bureau and Cosmetic, Toiletry & Fragrance Association	23rd - 24th March 2004, Subang Jaya
		Current Issues on the Control and Registration Of Cosmetics. Paper presented at the Seminar on Cosmetics Registration organised by the Kelantan State Pharmacy Department	23rd May 2004, Kelantan
		Current Issues on the Control and Registration Of Cosmetics organised by the Selangor State Pharmacy Department	11th August 2004, Klang; 28th August 2004, Shah Alam
		The Control of Health Supplement and Cosmetics. Paper presented at Cosmetic Seminar Organised by Malacca State Pharmacy Department and HEP Malacca	4th December 2004, Melaka
		Progress on ASEAN Harmonised Cosmetic Regulatory Scheme in Malaysia. Paper presented at the 2nd ASEAN Cosmetic Committee (ACC) Meeting & 1st ASEAN Cosmetic Scientific Body (ACSB) for Cosmetics	7th - 9th June 2004 Bangkok, Thailand
		Progress on ASEAN Harmonised Cosmetic Regulatory Scheme in Malaysia. Paper presented at the 3rd ACC Meeting & 2nd ACSB Meeting	7th - 9th December 2004, Yogyakarta, Indonesia.
3.	Arpah Abas	Regulation of Blood Product in Malaysia. Paper presented at Meeting of Development of Harmonisation of QA System in Blood Product FDA/WHO	30th October 2004, Thailand
		Overview: Regulations of Biotechnology Products in Malaysia. Paper presented at the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organised by Biotechnology Directorate, Ministry of Science, Technology and Environment.	20th April 2004, Putrajaya
		Overview: Product Registration at Meeting Regarding Halal issues Islamic Development Department of Malaysia (JAKIM)	30th April 2004, Putrajaya
4.	Bariah Abdul Rani	Product Classification. Paper presented at the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organised by Biotechnology Directorate, Ministry of Science, Technology and Environment.	19th April 2004, Putrajaya
5.	Dr. Sulaikah Moideen	Technique In Auditing Microbiology Laboratory-MLT	10th January 2004, NPCB, Petaling Jaya
		PTK 4 Course for Pharmacy Assistant	25th February 2004, Nilai
		Quality Control of Products (Analytical aspect). Paper presented at the National Seminar on Regulatory Procedures for Traditional Medicine Products and New Chemical Entities organised by Biotechnology Directorate, Ministry of Science, Technology and Environment.	20th April 2004, Putrajaya

Table 14 : Presentation of Papers (continued)

NO.	NAME	TITLES OF PRESENTATION PAPER	DATE/PLACE
6.	Dr.Tajuddin Akasah	Good Manufacturing Practice (GMP) for Investigational Medicinal Product (IMP)' presented at the Clinical Research Centre, Ministry of Health	26th July 2004; 5th December 2004, CRC, Kuala Lumpur
		GMP and Safety Requirement of Total Parenteral Nutrition (TPN) and Cytotoxic Drug Reconstitution (CDR) Facilities. Paper presented at the Senior Pharmacist U48 Conference organised by the Pharmaceutical Services Division, Ministry of Health	9th December 2004, Kuantan
		GMP in Herbal/Biotech Manufacturing. Paper presented at the National Seminar on Regulatory Procedures for Traditional Medicinal Products and New Chemical Entities organised by the Ministry of Science and Technology and Environment, Malaysia	April 2004, Putrajaya
		GMP for Traditional Medicines. Paper presented at the Seminar organised by Forest Research Institute (FRIM)	21st July, 2004 Kuala Lumpur
		GMP and GSP for Cosmetics. Paper presented at the Seminar on Cosmetics Registration organised by the Kelantan State Pharmacy Department	23rd May 2004
		'Halatuju NPCB dalam GMP dalam Jangkamasa Panjang' presented at a seminar organised by PURBATAMA	19th April 2004, Langkawi
		GMP - an update. Paper presented in Sabah State Pharmacy Conference	6th October 2004, Kudat, Sabah
		ASEAN Guidelines for Cosmetic GMP. Paper presented at a seminar on Cosmetic Registration organised by NPCB and Cosmetic, Toiletry & Fragrance Association	March 2004, Subang Jaya
7.	Dr. Kamaruzaman Saleh	Regulatory Aspects of Clinical Trial in Malaysia. Paper presented at Good Clinical Practice Workshop at Universiti Sains Malaysia	17th August 2004, Kubang Krian
		Regulatory Aspects of Clinical Trial in Malaysia. Paper presented at Implementation of Good Clinical Practice Meeting	3rd September 2004, Mersing
8.	Eisah A. Rahman	Promoting Good Regulatory Practice, Malaysian Experience, 11th ICDRA.	February 2004, Madrid.
		Current Review of Traditional Medicines Registration, Industry Forum on Registration of Traditional Medicines.	April 2004, Putrajaya
		Malaysian Transition Strategy for the Phase out of CFC Use in MDI, Awareness Seminar on CFC free MDIS.	May 2004, Subang Jaya
		Introduction to Cosmetic Control, Seminar on Cosmetic Registration.	May 2004, Kota Bharu
		Regulatory Updates, Briefing for New Pharmacists U48	June 2004, NPCB
		Drug Policy in Malaysia: Improving Accessibility and Availability, 1st National Health Outcome Seminar.	July 2004, Kuala Lumpur
		Regulating Pharmaceuticals in Malaysia - Challenges Faced by the National Pharmaceutical Control Bureau, MPS Seminar on Entrepreneurship and Management in Pharmacy.	November 2004, Kuala Lumpur
		Current Regulatory Development, Local, Regional and Global Challenges, Conference for Pharmacists U48 (2004).	December 2004, Kuantan
		Lecture on New Registration Procedure, Competency Course (PTK4) for Pharmacists U48.	May and August 2004
		Lecture on GMP and Licensing, Competency Course (PTK4) for Pharmacists U48.	May and August 2004
		Policy Issues and Recommendations (Group A- Fiji, Indonesia, Malaysia, Papua New Guinea, Philippines and Thailand), Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines.	November 2004, Kuala Lumpur

Table 14 : Presentation of Papers (continued)

NO.	NAME	TITLES OF PRESENTATION PAPERS	DATE/PLACE
9.	Fudziah Ariffin	Regulatory Aspects of Clinical Trials in Malaysia, GCP Workshops, Malaysia (5 times)	
		An Overview of NCE Registration in Malaysia	April 2004, Putrajaya
		Pharmacovigilance Initiatives in Malaysia. Paper presented at the IFPMA 4th Asian Regulatory Conference	April 2004, Beijing
		Selection of BE Comparator Products. Paper presented to BA/BE meeting in conjunction with 8th ACCSQ-PPWG Meeting & 3rd Thailand International Seminar on ASEAN Harmonisation'	20th July 2004, Bangkok, Thailand
		ACTD Part 1: Administrative Data. Paper presented to 'EC-ASEAN Regional Training Workshop on ACTD/ACTR'	October 2004, Kuala Lumpur
10.	Jaafar Lassa	Quality Assurance of Herbal Products in Malaysia. Paper presented at IDB-COMSTECT-INTROM IMR Workshop on Herbal Medicine	16th February 2004 Kuala Lumpur.
		New Regulation and Quality Control of Herbal Products. Paper presented in Dialogue with Herbal Industry of Malaysia.	February 2004
11.	Kadariah Mohd. Ali	Pharmaceutical HVAC System.	February 2004
		GMP Requirements and Implementation	April 2004, Seremban
		GMP Requirements for Traditional Industry	April 2004, Putrajaya
		GMP: Regulatory Requirements and Achievements of NPCB in PIC/S	June 2004, Fraser Hill
		Introduction to ISO 9001-2000	July 2004, NPCB
		Preparing a GMP Audit Report	September 2004, NPCB
		GMP Investigative Auditing	September 2004, NPCB
		Good Storage Practice	September 2004, Kangar Hospital, Perlis
12.	Mazuwin Zainal Abidin	Online Registration. Paper presented at the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organised by Biotechnology Directorate Ministry of Science and Technology and Environment.	20th April 2004, Putrajaya
		Control of Nutraceuticals and Cosmeceuticals in Malaysia. Paper presented at the Seminar on Nutraceuticals, Complementary Medicine and Cosmeceuticals Asia - Middle East	29th June 2004, Bangkok, Thailand
		Procedure for Registration of Pharmaceutical Product. Paper presented at Continuous Professional Development Program (CPD) session. Pharmacy Services Division State Health Department Selangor, Malaysia	28th August 2004, Shah Alam
		Pharmacy Regulatory. Paper presented at Pharmacy Assistant Conference for the State of Selangor 2004	16th May 2004, Bangi.
13.	Muhammad Nasir Hashim	Good Laboratory Practice. Paper presented to Pharmacy Assistants of NPCB.	24th November 2004, NPCB
14.	Saleha Mohd. Ewan	Market Entry and Product Registration of Herbal and Natural Products in Malaysia. Paper presented at the seminar organised by Malaysian Herbal Corporation.	14th October 2004, Jakarta
		Registration of Traditional Medicine in Malaysia. Paper presented at the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organised by Biotechnology Directorate, Ministry of Science, Technology and Environment.	19 April 2004, Putrajaya
15.	Yogeswary Markandoo	Progress Report by Malaysia on Implementation of Activities. Paper presented at the 21st Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceutical.	22nd - 24th September 2004 Vientiane, Lao PDR

regional and international involvement

Regional And International Involvement

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals since 1996, NPCB had continued to play an active role both globally as well as regionally on regulatory matters. The arrangement to harmonise the regulatory requirement in the ASEAN region was initiated with the formation of the Pharmaceutical Product Working Group (PPWG) under the ASEAN Consultative Committee on Standards and Quality (ACCSQ) programme and NPCB had given full technical support for all activities to achieve the objective. The positive outcome from this arrangement had become the pioneer for regulatory cooperation for other categories of products and this was followed by the formation of Cosmetic Products Working Group (CPWG) and the Traditional Medicines & Health Supplements Working Group (TMHSWG). NPCB was also involved in the EC-ASEAN Economic Cooperation programmes as well as Pharmaceutical Inspection Cooperation Scheme (PIC/S). NPCB personnel were involved in the following regional and international activities :

- **ASEAN Pharmaceutical Harmonisation**

The 8th ASEAN Consultative Committee on Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) meeting was held in Bangkok, Thailand on 21st to 23rd July 2004. The main agenda of the meeting was to discuss harmonisation schemes of pharmaceutical regulatory requirements in the ASEAN member countries to complement and facilitate the objective of the ASEAN Free Trade Area (AFTA), particularly the elimination of technical barriers to trade posed by these requirements without compromising on drug quality, safety and efficacy.

Two Product Working Groups (PWG) were established under ACCSQ as an outcome of the launching of the roadmap for integration of the healthcare sector in ASEAN, one working group will handle medical devices and the other traditional medicines and health supplements. **Mutual Recognition Arrangement (MRA) for Pharmaceutical Sector** Scheme in ASEAN could only be worked out if all member countries have successfully implemented the **ASEAN Common Technical Dossier (ACTD) on Quality.**

With regards to cooperation with the relevant international organisation, the PPWG has worked closely with WHO on the proposed **ASEAN Summary on Product Characteristics** (SPC). Pertaining to the **EC-ASEAN Regional Economic Cooperation Programme on Standards, Quality and Conformity Assessment,** Malaysia had given her full support in all of its activities.

- **ASEAN Cosmetic Harmonisation**

The 2nd Meeting of the ASEAN Consultative Committee on Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held in Bangkok on 7th-8th June 2004. The role of ACC is to oversee the implementation of the Agreement on ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRS) under the **Terms of Reference of the ASEAN Cosmetics Committee.** Malaysia had taken part in the Agreement on ASEAN Mutual Recognition Arrangement (MRA).

The following had been agreed for implementation: (i) To establish Guidelines for the Implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme (ii) Requirements for Notification under Schedule

B-ASEAN Cosmetic Directives (iii) To establish ASEAN Cosmetics GMP and (iv) To establish ASEAN Cosmetic Scientific Body.

The meeting had also considered the recommendation on acceleration of the implementation of AHCRS before the end of 2005.

- **ACCSQ Product Working Group On Traditional Medicines And Health Supplements (ACCSQ TMHS PWG)**

The 1st meeting involving ASEAN member countries was held in Jakarta, Indonesia on 25th -26th August 2004. The aim of the Product Working Group (PWG) is to provide support for the implementation of the roadmap for integration of the healthcare sector in ASEAN countries. It had been agreed that all technical barriers to trade have to be eliminated through technical harmonisation and mutual recognition. A number of steps and strategies had to be implemented such as sharing of available information and analysis standards; to harmonise the regulations and regulatory procedures; as well as to study and overcome technical requirements in every ASEAN member country.

A meeting to discuss the measures need to be taken to harmonise technical requirements for traditional medicines and health supplement in ASEAN member countries was proposed to be held in 2005. A seminar on traditional medicines and health supplements was also proposed to be held in conjunction with the meeting.

- **ASEAN Working Group on Technical Cooperation in Pharmaceuticals (AWGTCP)**

The 21st AWGTCP was held form 22nd-24th September 2004 in Vientiane, Lao PDR. This working group meeting was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore and Thailand.

The meeting of the AWGTCP is an important event of the ASEAN in Pharmaceutical Sector that is held annually. The objectives of the AWGTCP are to strengthen the pharmaceutical sectors in all ASEAN member countries to ensure sufficient and regular supplies of effective and safe essential drugs of acceptable quality, to achieve self-reliance in development of human resources within the region in certain fields, and to facilitate the development of a viable pharmaceutical industry in the ASEAN region, taking into consideration the strength and diversity among ASEAN member countries. It is also part of the mission of AWGTCP to intensify human resources development and capacity building in identified priority areas and strengthening national, regional and international collaboration.

The work plan for the year 2004 to 2008 was reviewed at this meeting taking into consideration the financial and technical constraints. It was also hoped that WHO would continue to work together with AWGTCP to address all the new challenges.

- **Cosmetic Sub-Programme PMS/PSE (1)**

In 2004, NPCB had actively participated in the Cosmetic Sub-Program under the EC-ASEAN Economic Cooperation Programme on Standards, Quality and Conformity Assessment. NPCB is directly involved in the activities of its second component, Post Marketing Surveillance/Product Safety Evaluation - Laboratory Capacity Building [PMS/PSE (1)].

The objectives of PMS/PSE (1) activities are to conduct evaluation on regulatory laboratories in the ASEAN countries; to identify test methods for cosmetic products for harmonisation among ASEAN countries; to identify regulatory laboratories in the ASEAN countries capable to conduct training of the identified test methods; to conduct 'Proficiency Test Scheme' on harmonised test methods among

Regional And International Involvement

regulatory laboratories in the ASEAN countries; and to carry out all the harmonised test methods for cosmetic products when "the ASEAN Cosmetic Directive" is enforced.

Test methods for cosmetic products that were identified for harmonisation are :-

1. Identification of tretinoin in cosmetic products
2. Identification of prohibited colorants in cosmetic products
3. Identification and determination of hydroquinone in cosmetic products
4. Identification and determination of 2-phenoxy-ethanol, 1-phenoxypropan-2-ol, methyl, ethyl, propyl, butyl and benzyl-4hydroxybenzoate in cosmetic products
5. Determination of heavy metals (mercury, lead. arsenic and cadmium)
6. Microbial Limit Test
7. Identification of hydrocortisone acetate, dexamethasone, betamethasone and triamcinolone acetonide
8. Preservative Efficacy Testing (PET)

Singapore, Indonesia, Thailand and Malaysia had been identified to conduct the training on test methods for harmonisation. The training was conducted in November and December 2004 and was attended by representatives from all the ASEAN member countries. NPCB had conducted the training on the test methods for identification of steroids (hydrocortisone acetate, dexamethasone, betamethasone and triamcinolone acetonide) and Preservative Efficacy Testing in December 2004.

- **Pharmaceutical Inspection Cooperation/Scheme**

As a member of PIC/S, representatives from NPCB participated in the Biotechnology Joint Inspection Program in Holland in June 2004 and the Joint Inspection in Switzerland in November 2004. NPCB always ensures that the current GMP requirements comply with the PIC/S and international requirements.

- **International Visitors and Training**

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, NPCB had continued to provide training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries. The centre recorded a total of 28 international visitors and WHO fellows from various countries namely Brunei Darussalam, China, Cuba, Fiji, Hong Kong, Mongolia, Singapore, South Africa and Vietnam. The courses provided under this programme are designed specifically to cater for the needs of the individual fellow. Training is given either in Quality Control, Drug Registration, Good Manufacturing Practice and Licensing System, Pharmacovigilance and Post-Marketing Surveillance activities.

- **Bilateral Arrangements**

Other international involvements include Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries such as Brunei, Singapore and Indonesia in health and regulatory aspects.

financial statement

Financial Statements

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 to oversee that financial allocations are sufficient to ensure that each planned activity meets its objective.

• Finance

In the year 2004, the emoluments for 177 staff members and 48 temporary staff is RM5,997,333.00

• Revenue

In 2004, the total revenue collected for drug and cosmetics registration, laboratory tests, licences, advisory services, sale of guidelines and others is RM10,407,556 as shown in Table 15.

Table 15 : Revenue (RM) (Year 1999-2004)

Year	Registration	Licence	Laboratory	Inspection	Printed Materials	Others	TOTAL
1999	959,405	158,350	484,860	14,350	39,605	18,871	1,675,441
2000	1,111,440	152,100	502,620	6,500	28,340	27,193	1,828,193
2001	914,020	203,200	460,880	12,200	26,485	64,072	1,680,857
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

Table 16 : NPCB Operating Allocation and Expenditure 2004

Object Code	Expenditure	Allocation (RM)		Expenditure (RM)		Balance	
		Original	Amended	Actual Expenditure	%	(RM)	%
10000	Emolument	5,744,00	5,744,000	5,997,333	104.41	Liabilities -253,333	-4.41
20000	Services and Supply	7,950,000	7,959,000	7,563,326	95.03	362,068	4.55
30000	Asset (Property)	108,430	108,430	97,862	90.25	10,568	9.75
	TOTAL	13,802,430	13,811,430	13,658,521	96.56	119,303	9.89


drug control
authorithy

Summary of Policies of the Drug Control Authority (DCA)

The DCA held 11 meetings throughout the year 2004. The DCA had discussed, agreed and decided on the policies as stated in Table 17 below:

Table 17 : Important decisions of the DCA in 2004

DCA MEETING	POLICY
DCA 155 27.1.2004	**Product Authentication: Directive on security Device - Guidance For Labelling.** The DCA agreed to the following proposal: a) 'The implementation and use of the security device as a means to authenticate and verify drug product registration'. b) The inclusion of the proposed section headed "product authentication" as another condition for product registration, together with the product identification chart as a labelling guide to the affixing of the security device.
DCA 156 24.2.2004	**Cancellation of Registration of Products containing Cisapride** The DCA decided not to register any product containing Cisapride due to safety issue : i) Previously registered products will be given exemption to be imported based on prescriber's request on a named patient basis. ii) Holders of registered products are given a grace period of six (6) months from the date of the meeting to recall their products from the market.
	Cancellation of Registration of Products containing Comfrey & Senecio spp Herbs The DCA decided not to register any product containing Comfrey *(symphytum officinale)* & *Senecio spp* herbs due to safety issue. These herbs contain unsaturated pyrrolizidine alkaloids (PA) which are considered to be hepatotoxicity and hepatocarcinogens. Holders of registered products are given a grace period of six (6) months from the date of the meeting to recall their products from the market
	Control on Packing Size of All Liquid Cough Preparations The DCA decided to allow the maximum limit of cough preparations to 120+/-10ml(plus-minus). The implementation date is still **1 April 2004.**
DCA 157 23.3.2004	**Issues on Product Registration, Malaysia-Indonesia** For bilateral cooperation and teamwork by ASEAN, the DCA agreed to allow both Malaysia and Indonesia to market their pharmaceutical products in their respective countries. Nevertheless, they must comply with the rules and regulations set by these countries as well as the standard and requirements stipulated by ASEAN.
	Control on Packing Size of All Liquid Cough Preparations The DCA decided that no exemption on packing size of 'for export only' products. Packing size of 120 ml+/-10 ml is applicable for local and 'for export only' of all liquid cough preparations.

Table 17 : Important decisions of the DCA in 2004 (continued)

DCA MEETING	POLICY
DCA 157 23.3.2004	**Halal Logo for Registered Pharmaceutical Products, Traditional medicines and Cosmetics** The DCA decided on the following regarding "HALAL" logo for registered pharmaceutical, traditional and cosmetic products: (i) To continue with the existing policy of not allowing the "HALAL" logo to be stated on the label of pharmaceutical products; (ii) To continue with the existing policy of allowing the "HALAL" logo to be stated on the label of local and for export only' cosmetic products; (iii) To consider the use of "HALAL" logo certified and issued by 'JAKIM' only on the label of local and 'for export only' cosmetic products as well as dietary supplements; (iv) To consider the use of "HALAL" logo for traditional products, cosmetics and dietary supplements based on request by the registration holders but non-mandatory.
	The List of Bioequivalence Studies for " Immediate Release" Generic Products In an effort to improve the quality, efficacy and safety of generic products as compared to innovator products, Bioequivalence (BE) Studies Committee has decided to add sixteen more immediate release products to the existing list. The needs to submit BE Studies Reports will be enforced periodically within two years (2004-2005) **Test Product (Pharmaceutical name):** Stavudine, Nevirapine, Ritonavir, Ciprofloxacin, Ofloxacin, Clarithromycin, Metformin, Glibenclamide, Diltiazem, Salbutamol, Rifampicin, Sulpiride, Dexamethasone, Verapamil, Omeprazole & Prednisolone.
	Proposal to request that the DCA consider parenteral preparations, peritoneal dialysis solutions and haemofiltration solutions (which are introduced into patients' bodies), which are packaged in different materials and pack sizes, as one product. The DCA decided to consider the different packing sizes and packaging of parenteral preparations, peritoneal dialysis solutions and haemofiltration solutions (which are introduced into patients' bodies) as one single product for a particular product. However, comprehensive stability studies on the different types of packaging are required to determine suitable shelf lives and storage conditions for the products.
DCA 158 27.4.2004	**Cancellation of Products containing Terfenadine** The DCA decided to a) Cancel the registration of all products containing terfenadine in view of the association of cardiac adverse events arising from the use of terfenadine. Grant a 6-month grace period for the product registration holders to withdraw all the products that have already been registered from the Malaysian market; b) The affected products will also be deleted from the manufacturers' or the import licences of the companies concerned.
DCA 159 27.5.2004	**Extension on the marketing duration of Cosmetic Products in the Market** The DCA took into consideration the suggestion to extend the marketing duration of cosmetic products which had been submitted for registration before 31st January 2004. The deadline has been extended from 30th June 2004 to 31st December 2004. As of 1st January 2005, all cosmetic products in the market are required to comply with the labeling requirements as stated in the Guidelines For Cosmetic Registration.
	Suggestion to disregard the Suspension of Products containing Nimesulide, to limit the dosage and posology as well as the indication In view of the findings of the review of nimesulide by the European Medicines Evaluation Agency, it was recommended that i) The earlier suspension on the registration of products containing nimesulide be withdrawn with the condition that dosage is limited to a maximum of 100mg twice a day. ii) The indication for oral products be restricted for: • Treatment of acute pain • Symptomatic treatment of painful osteoarthritis. • Primary dysmenorrhoea. iii) The information in the package insert for products marketed in Malaysia should be aligned with the information contained in the European SPC iv) All product registration holders are responsible to inform health care professionals on the restriction on indications, the newly permitted maximum dosage and contraindications in order to minimize the risk of hepatotoxicity.

Table 17 : Important decisions of the DCA in 2004 (continued)

DCA MEETING	POLICY
DCA 160 1.7.2004	**Additional Warning related to hyperglycaemia for all "Atypical Antipsychotic Agents"** To add a warning pertaining to the potential hyperglycemic effect associated with the use of Atypical Antipsychotic Agents: (a) Clozapine (b) Olanzepine (c) Risperidone (d) Quetiapine (e) Ziprasidone (f) Aripiprazole The warning that the DCA agreed to put in the package insert is as follows: **WARNINGS:** **Hyperglycemia and Diabetes Mellitus** Hyperglycemia in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given this confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factor for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with atypical antipsyhotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
DCA 161 5.8.2004	**"Use of Thiomersal in Vaccines - An Update"** The DCA has taken into account that the latest epidemiological research showed no relation of thiomersal-containing-vaccine causing specific neurodevelopmental disorders. Therefore, the DCA has decided the following: (i) Thiomersal can be considered in being used as a preservative in vaccines. (ii) Vaccines registration application, which has thiomersal content, will be evaluated case by case while taking into account product efficacy and general health needs. (iii) Products with thiomersal content have to be accompanied with a label and warning stating 'risk of sensitization in relation to thiomersal and other preservatives'. (iv) In accordance with the global aim of reducing exposure to mercury, vaccine preparations without thiomersal or minimum thiomersal content is encouraged.
	Product Authentication : the use of "security label (Meditag)" - Syarikat Mediharta Sdn Bhd. The DCA acknowledged the decision of Our Honorary Health Minister to approve the proposal to use hologram labels on registered products. This is due to the concern of the Government in respect of counterfeit, imitation and unregistered products being manufactured or imported and sold, and in an effort to streamline the manufacture, import and sale of genuine products. The requirement for the affixation of this security device (called the MeditagTM) to product labels, is only applicable to pharmaceuticals, including OTC external personal care products, traditional products and health supplements. Cosmetics are currently excluded from the excercise. Implementation on the use of the hologram label will be carried out in 2 phases. 1. Phase 1 beginning 1st January 2005 for products which are non-parenterals (postponed to 1st May 2005 as decided in 164th meeting which was held on 4th November 2004) 2. Phase 2 from 1st July 2005 for parenterals/injectables However, products like vaccines and biologicals which are temperature sensitive and require cold chain maintenance are exempted from the requirement. Mediharta is responsible to conduct awareness programme on the hologram label for the Ministry of Health personnel, the industries concerned and the consumers.

Table 17 : Important decisions of the DCA in 2004 (continued)

DCA MEETING	POLICY
DCA 161 5.8.2004	**Cadmium (Cd) in the Toxic Metal Tests for Traditional Products** The DCA agreed on the following: (i) Cadmium test is included in the testing of traditional products whereby the limit for the test is 0.3mg/kg. This rule will come into effect from 1st January 2005. (ii) To accept the limit stated in Appendix 1 as the latest specification for Quality Control of Traditional Medicine Products.
DCA 165 23.12.2004	**Proposal to take out `Hexylresorcinol' from the list of ingredients (active) not allowed to be registered by the Drug Control Authority'.** The DCA decided that hexylresorcinol will be taken out from the List of Active ingredients Not Alllowed to be registered with the Drug Control Authority as stated in the Drug Registration Guidance Document. It was decided that the use of hexylresorcinol is permitted in all pharmaceutical preparations based on the following reasons: (i) The documented reference (Martindale) no longer states that the substance causes irritation on the skin or oral mucosa EXCEPT at high concentrations. (ii) Hexylresorcinol Lozenges is a preparation that is included in the official monograph of the latest edition of the United States Pharmacopoeia (USP). (iii) Preparation containing hexylresorcinol had been registered and marketed in a number of countries such as Australia, Canada, United Kingdom and United States of America. (iv) Lozenges containing active substances from the same chemical group (PHENOLIC ANTISEPTICS) such as Amylmetacresol have already been registered in Malaysia.
	Additional Warnings : "Suicidality in Children and Adolescents Treated with Antidepressants". The DCA decided that i) Warning regarding **"Suicidality in Children and Adolescents Treated with Antidepressants"** should be included in the package inserts of all antidepressants products. The warnings are: **Suicidality in Children and Adolescents** • Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. • Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need. • Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. • Famillies and caregivers should be advised to closely observe the patient and to communicate with the prescriber. • A statement regarding whether the particular drug is approved for any pediatric indication(s) and, if so, which one(s). ii) The registration holder needs to study the suitability of the medicines guides (MedGuides) as practised by the United States. The purpose of MedGuides is to provide information to the patient and caregivers on the suicidality adverse effects and this information should be given during treatment. MedGuides must be amended to suit its uses in Malaysia and should be revised by the DCA before being distributed.

Table 17 : Important decisions of the DCA in 2004 (continued)

DCA MEETING	POLICY
DCA 165 23.12.2004	**New information regarding cardiovascular safety of Celebrex (Celecoxib), Bextra (Valdecoxib) and Naproxen** The DCA decided on the following information for the above mentioned products; **(i) CELEBREX:** Based on emerging information, including preliminary reports from one of several long term National Institutes of Health (NIH) prevention studies, the risk of cardiovascular events (composite endpoint including MI, CVA and death) may be increased in patients receiving Celebrex. Subsequently, the DCA will be analysing all available information from these studies to determine whether additional regulatory action is needed. **(ii) NAPROXEN:** Patients who are currently taking naproxen products should be advised to carefully follow the instructions on the label and not to exceed the recommended doses for naproxen (220 milligrams twice daily). Naproxen should not be taken for longer than ten days unless a physician directs otherwise. **(iii) BEXTRA:** Based on action taken by US FDA, the DCA has instructed the product registration holder to include a 'boxed warning' in the package insert about the risk of life-threatening skin reactions 'Steven-Johnson Syndrome and Toxic Epidermal Necrolysis' & Cardiovascular Risks.
	Iressa: New finding from ISEL study The registration application of IRESSA was approved in the 150th DCA meeting but the findings of the ISEL Clinical Study showed that the efficacy could be doubted. Based on that study, it has been decided in the DCA meeting, these actions must be taken: a. To obtain the complete results of the clinical studies regarding the product. b. To obtain the relevant information and additional data due to the absence of the data regarding Caucasian or Oriental Patients. c. The company will be instructed to stop all product promotion activities in accordance with the actions taken by the USFDA.

social activities

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

A number of female staff of NPCB had joined the Ministry of Health PUSPANITA Branch. They were entrusted with the task to spearhead the Education Bureau of the PUSPANITA Branch.

Mdm. Eishah Abdul Rahman, the Deputy Director of NPCB was appointed as the Chairman of PUSPANITA NPCB . Various activities were held in 2004 and they are as stated in Table 18 below:

Table 18 : Activities of PUSPANITA NPCB

DATE	ACTIVITY
January	Farewell gathering for Mdm. Jamilah (PUSPANITA Chairman)
April	"Kursus Jenazah" & Tupperware Party
June	Exhibition & Sales "Natasha" items
July	Fun Fair & Electric Pot Demonstration by "Graes Appliances"
September	Ceremony for the recognition for Outstanding Students
November	"Tadarus Al-Quran" & Bowling Competition

BPFK Club

The BPFK Club had a total of 181 registered members until September 2004. The Sports section of the Club had organised a Sports Day for its members in NPCB (volleyball court between Block B1 & B2) held on 9th October 2004 (Saturday). Meanwhile the Education section of the Club also had presented certificates and tokens of appreciation to the children of the members who had outstanding achievements in the government UPSR, PMR and SPM examinations held in 2003. The Social section had arranged tour packages to Redang Island and Padang/Bukit Tinggi, Indonesia but these tours had to be cancelled due to unforseen circumstances.

Remembering Your Services

In 2004, a total of 20 officers left NPCB either due to retirement, transfer or resignation. Mr. Hj. Normal Shariff and Datin Hjh. Hasiah Hj. Abdullah retired on 1st February 2004 and 31st December 2004 respectively as Director of NPCB. Meanwhile Mdm. Tang Poh Yoong, a long serving clerical staff from the Centre for Good Manufacturing Practice retired on 30th July 2004.

16 NPCB officers were transferred to other posts in Ministry of Health Malaysia and the details are as follows:

NO.	NAME	POST	DATE (NEW WORK PLACE)
1.	Mr. Hj. Abdul Rahman Kassim	Store Keeper	12.1.2004 (Serdang Hospital)
2.	Mdm. Haslina Ithnin	Administrative Assistant	16.1.2004 (KKM)
3.	Mr. Chua Kong Seng	Pharmacist	1.3.2004 (Kedah)
4.	Mdm. Noraizan Che Mel	Administrative Assistant	8.3.2004 (Kelantan)
5.	Mdm. Kamarolaini Sapiei	Administrative Assistant	26.4.2004 (National Blood Bank)
6.	Ms. Siti Hajar Paiman	Data Processing Operator	1.5.2004 (Putrajaya)
7.	Ms. Wahida Ramli	Assistant Statistician	17.5.2004 (Putrajaya)
8.	Mdm. Siti Aisah Bahari	Pharmacist	1.7.2004 (Hospital Ampang)
9.	Mdm. Mahani Mahmud	Pharmacist	2.8.2004 (Pharmacy Services Division)
10.	Mdm. Asmawiza Ghazali	Pharmacy Assistant	2.8.2004 (Serdang Hospital)
11.	Mdm. Sarijah Awang	Pharmacy Assistant	2.8.2004 (College Pharmacy Assistant, Sg. Buloh)
12.	Mdm. Tan Lie Sie	Pharmacist	1.11.2004 (Johore)
13.	Mdm. Sharifah Hj. Abdul Rahman	Pharmacy Assistant	22.11.2004 (Terengganu)
14.	Mr. Ramli Zainal	Pharmacist	1.3.2004 ((KKM - Study Leave)
15.	Ms Roshayati Mohd. Sani	Pharmacist	1.3.2004 ((KKM - Study Leave)
16.	Mdm. Noorul Akmar Mohd. Nor	Pharmacist	1.3.2004 ((KKM - Study Leave)

Mdm. Suriani Ibrahim from the Centre for Post-Registration resigned as a Pharmacist on 15th April 2004 to be self employed.

To all the staff of NPCB who had either retired, transferred or resigned, we would like to convey our best wishes and happiness. NPCB also wishes to record our heartfelt gratitude for their contributions, commitment and hard work during their tenor of service with us.


Ucapan Datin

other activities

Other Activities

In 2004, many other activities were carried out to ensure the smooth implementation as well as to overcome any problems that may arise from the introduction of any new procedure or policy. Among these activities are:

ONLINE TASK FORCE

- There were four **Pharmaceutical TWG-Joint Online Task Force** meetings in 2004. This task force was represented by officers from NPCB, Technology Innovation Resources Sdn. Bhd. (TIR), Pharmaceuticals Association Malaysia (PhAMA) as well as Malaysian Organisation of Pharmaceutical Industries (MOPI). The objective of this task force is to identify and to assist in overcoming a number of issues brought up by the industry during the implementation of the online system such as the problem of the principal smart card holder, supplementary card, payment, online classification of products, data secrecy and others.

- There were two meetings by the **Traditional TWG-Joint Online Task Force** in 2004. This task force which consisted of representatives from NPCB, TIR, "Persatuan Pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA)", "Majlis Perubatan Homepathy Malaysia (MPHM)", "Persekutuan Perubatan Tradisional Melayu Malaysia (PUTRAMAS)", "Pertubuhan Perubatan Tradisional India Malaysia (PEPTIM)", Federation of Chinese Physicians & Medicines Dealers Association Malaysia (FCPMDAM), "Persatuan Pengeluar Ubat China Malaysia (PPUCM)" dan MOPI. In these meetings, issues regarding online registration system such as problems regarding Quest 2 server, product updating, variation and others were identified and discussed so as to overcome these problems.

- In 2004, there were two meetings by the **Cosmetics Task Force** consisting of representatives from NPCB and Cosmetics, Toiletry & Fragrance Association of Malaysia (CTFA). These meetings discussed in detail the issues regarding the online registration and problems encountered in Quest 2 system. TIR was called to the meeting when problems regarding front-end system was raised by the industry.

REVIEW ON REGISTRATION GUIDELINES

The new guidelines for registration of pharmaceutical products was implemented in April 2004 and it is known as **Drug Registration Guidance Document,** which replaced the existing Guidelines for Application for Registration of Pharmaceutical Products (1993 Edition) and guidelines for Application for Registration of Traditional Medicines 1998. The draft guidelines was distributed to the industry for their comments and a consensus was reached at the beginning of 2004 to use the guidelines for the online registration system.

In line with the implementation of the ASEAN harmonisation scheme for pharmaceutical products, NPCB has taken action to adopt the ASEAN Common Technical Dossier (ACTD) and

ASEAN Common Technical Requirements (ACTR) for the application for registration of pharmaceutical products. The preparation of the new guidelines took into account the latest development in the global regulatory environment. Every effort has been made to include the legal requirements of the **Sale of Drugs Act 1952** and **Control of Drugs and Cosmetics Regulations 1984,** and it is the responsibility of the applicant to ensure that legal requirements of other related legislation such as the **Dangerous Drugs Act 1952, Poisons Act 1952, Medicine(Advertisement & Sale) Act 1956, Patent Act 1983** and others are complied.

TECHNICAL WORKING GROUP

Technical Working Group (TWG) is a joint technical group consisting of officers from NPCB as well as the representatives from the industry who are experts in the relevant regulatory and technical fields. TWG were divided into smaller groups that were assigned to look into specific registration requirements that need to be reviewed.

- The Guidelines for Application for Change in particulars of Registered Products and Guidelines for Application for Clinical Trial Import Licence, are the outcome of the works of TWG Pharmaceutical for the year 2004.

- In 2004, there were three meetings by **Cosmetic Technical Working Group (Cosmetic-TWG)**. The members consists of representatives from NPCB, Cosmetics, Toiletry & Fragrance Association of Malaysia (CTFA) and Federation of Malaysian Manufacturers-Malaysian Cosmetics and Toiletries Industry Group (FMM-MCTIG). The meeting discussed issues regarding registration of cosmetics, from the aspect of registration requirement, the body issuing certification of GMP and CFS, and also specific and current issues pertaining to cosmetic products.