KANDUNGAN
CONTENTS

Struktur Organisasi
Organisational Structure 3

Carta Organisasi
Organisational Chart 4

Senarai Jawatan
List of Posts 5

Falsafah Organisasi
Organisational Philosophy 6

Piagam Pelanggan
Client's Charter 7

Ringkasan Aktiviti BPFK
Summary of NPCB Activities 10

Laporan Bahagian
Divisional Reports 11

Kata-Kata Aluan Daripada Pengarah

Message From The Director

Assalamualaikum dan salam sejahtera.

Masa yang diibaratkan umpama emas telah beredar dengan begitu pantas. Antara sedar atau tidak, setahun telah melangkah pergi dan kita bertemu kembali untuk ke lembaran baru.

Sebagai sebuah badan regulatori yang sememangnya bertanggungjawab terhadap produk-produk farmaseutikal, tradisional, serta kosmetik yang berada di pasaran, BPFK turut seiring dengan peredaran masa yang begitu pantas beredar. Pelbagai aktiviti telah dilakukan samada secara tempatan atau antarabangsa.

Sukacita ingin saya perkatakan beberapa aktiviti yang telah dijalankan sepanjang tahun 2002. Ini adalah berkat usaha kakitangan BPFK yang sememangnya komited dalam menjalankan tugas masing-masing. Walaupun sibuk dengan tugas harian, namun mereka masih dapat menjalankan pelbagai aktiviti. Terdapat juga aktiviti yang dijalankan secara usahasama dengan WHO serta dengan pihak industri.

Pada 1 Januari 2002, Malaysia secara rasminya telah menjadi ahli "Pharmaceutical Inspection Cooperation Scheme" (PIC/S). Skim ini menyediakan satu kerjasama yang aktif dan konstruktif dalam bidang Amalan Perkilangan Baik (APB). Penyertaan Malaysia ke dalam PIC/S membolehkan ia memperolehi pengiktirafan dan reputasi daripada arena antarabangsa dalam perlaksanaan APB dan perlesenan. Melalui pengiktirafan ini, Malaysia boleh mengambil bahagian dalam pemeriksaan secara bersama dengan PIC/S.

Selain daripada itu, Unit Piawaian dan Rujukan, Bahagian Analisis Ubat, telah dilawati oleh 3 pegawai dari Japanese Pharmaceutical Manufacturers Association (JPMA). Ini adalah untuk rancangan penyediaan ASEAN REFERENCE STANDARD.

Pada tahun 2002, beberapa siri Jerayawara mengenai pendaftaran kosmetik secara on-line telah diadakan. Kesinambungan itu, YB Menteri Kesihatan Malaysia telah mengumumkan bahawa pendaftaran produk kosmetik akan bermula pada 1 Februari 2002, dan penguatkuasaan akan dimulakan pada 1 Januari 2004. Jangka masa selama 2 tahun dirasakan mencukupi bagi pihak industri melakukan pendaftaran. Pendaftaran kosmetik ini dilakukan secara on-line. Sebagaimana Malaysia berbangga dengan koridor raya multimedianya, BPFK pula amat berbangga dengan sistem on-linenya.

Assalamualaikum and salam sejahtera,

How time flies. Without even realising it, a year has passed and we meet again to usher in the new year.

As a regulatory body entrusted with the responsibility of regulating the pharmaceutical, traditional and cosmetic products on the market, NPCB has indeed moved with the times. A host of activities have been organised whether on the local scale or internationally.

It is with great pleasure that I would like to state that the success of these activities were due to the commitment and hard work of the NPCB staff who, while still carrying out their daily responsibilities, went beyond the call of duty and found the time to help in the organisation and execution of these activities, some of which were organised jointly with the WHO as well as with industry members.

On the 1st of January 2002, Malaysia was formally accepted as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). This scheme creates an active and constructive cooperation within the area of Good Manufacturing Practise (GMP). The acceptance of Malaysia into the PIC/S paves the way for our country to build our reputation and to be recognised internationally in areas of GMP and licensing. With this recognition, Malaysia will be able to participate jointly with the PIC/S in conducting inspections.

On another matter, the Reference Standard Unit of the Drug Analytical Division was visited by 3 officers from the Japanese Pharmaceutical Manufacturers Association (JPMA) in regards to the preparation of the ASIAN REFERENCE STANDARD.

In 2002, several road-show series on the on-line registration of cosmetics were held. In culmination, the YB Minister of Health Malaysia has announced that the registration of cosmetic products will begin on the 1st of February 2002, and that the enforcement will be carried out beginning the 1st of January 2004. A grace period of two years was felt to be sufficient for the industry to conduct their registrations, which were to be done on-line. As Malaysia is proud with the Multimedia Super Corridor, we at NPCB are proud of our on-line system.

BPFK sememangnya bekerja rapat dengan WHO dalam melaksanakan pelbagai program, terutamanya berkaitan dengan peningkatan kepakaran dalam hal regulatori. Selain itu, latihan kepada "WHO Fellows" juga menjadi aktiviti utama. Ini adalah selaras dengan pengiktirafan yang diberikan kepada BPFK sebagai "Pusat Kolaboratif WHO". Sehubungan itu, Dr. Budiono Santoso, Penasihat Serantau dalam Farmaseutikal, Pejabat Serantau WHO dari Western Pacific, Manila telah melawat BPFK pada Julai 2002. Tujuannya adalah untuk mengintai peluang kerjasama yang dapat diadakan di antara BPFK dengan WHO.

Saya secara peribadi ingin berterima kasih kepada semua anggota BPFK yang begitu bertanggungjawab serta gigih dalam melaksanakan tugas masing-masing. Tanpa sokongan semua, pastinya pengurusan di BPFK akan menjadi sukar. Demi kepentingan BPFK juga maka satu kajian pengkorporatan telah diadakan. Tujuannya antara lain adalah untuk menyarankan kaedah yang terbaru bagi menguruskan BPFK secara komersial. Kajian dibuat dengan membandingkan modul-modul yang digunakan oleh agensi-agensi regulatori yang menguruskan sistem kewangan sendiri serta kukuh kedudukannya.

Jika disenaraikan segala aktiviti yang dijalankan sepanjang tahun 2002, pastinya kata-kata aluan saya tidak ubah seperti hikayat seribu satu malam. Saya pasti para pembaca budiman akan memperolehi pelbagai maklumat apabila membaca lembaran demi lembaran Laporan Tahunan 2002 ini. Oleh yang demikian, saya sekali lagi ingin mengucapkan ribuan terima kasih serta syabas kepada semua warga BPFK yang telah memartabatkan BPFK di mata dunia.

Sekian, terima kasih.

(HAJI NORMAL BIN SHARIF)
Pengarah
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

NPCB has been working closely with WHO in the organisation of several programs, the most important of which was in regards to increasing expertise concerning regulatory matters. Training tof "WHO Fellows" was another main activity. This is in line with the recognition given to NPCB as the WHO Collaborative Centre. In relation to that, Dr. Budiono Santoso, Regional Adviser for Pharmaceuticals, WHO Regional Office for Western Pacific, Manila visited NPCB in July 2002 with the intention of sourcing out opportunities for cooperation between NPCB and WHO.

I would personally like to thank all NPCB members who have carried out their duties responsibly and with determination. Without your support, I am sure that the management of NPCB would become next to impossible. With NPCB's welfare in mind, a corporatisation analysis was conducted with the intention of, among others, finding the most suitable way of running NPCB commercially. The analysis was conducted by comparing the modules used by regulatory agencies that have control over their own finances and are stable.

If we were to list every activity conducted throughout 2002, it is plain that this opening message would be no different than the thickest novel on your shelf. Thus I believe that the discerning reader would be best served by getting their information from each and every page of this Annual Report 2002. In closing, I would once again like to thank and congratulate each and every NPCB member who has helped put NPCB before the eyes of the world.

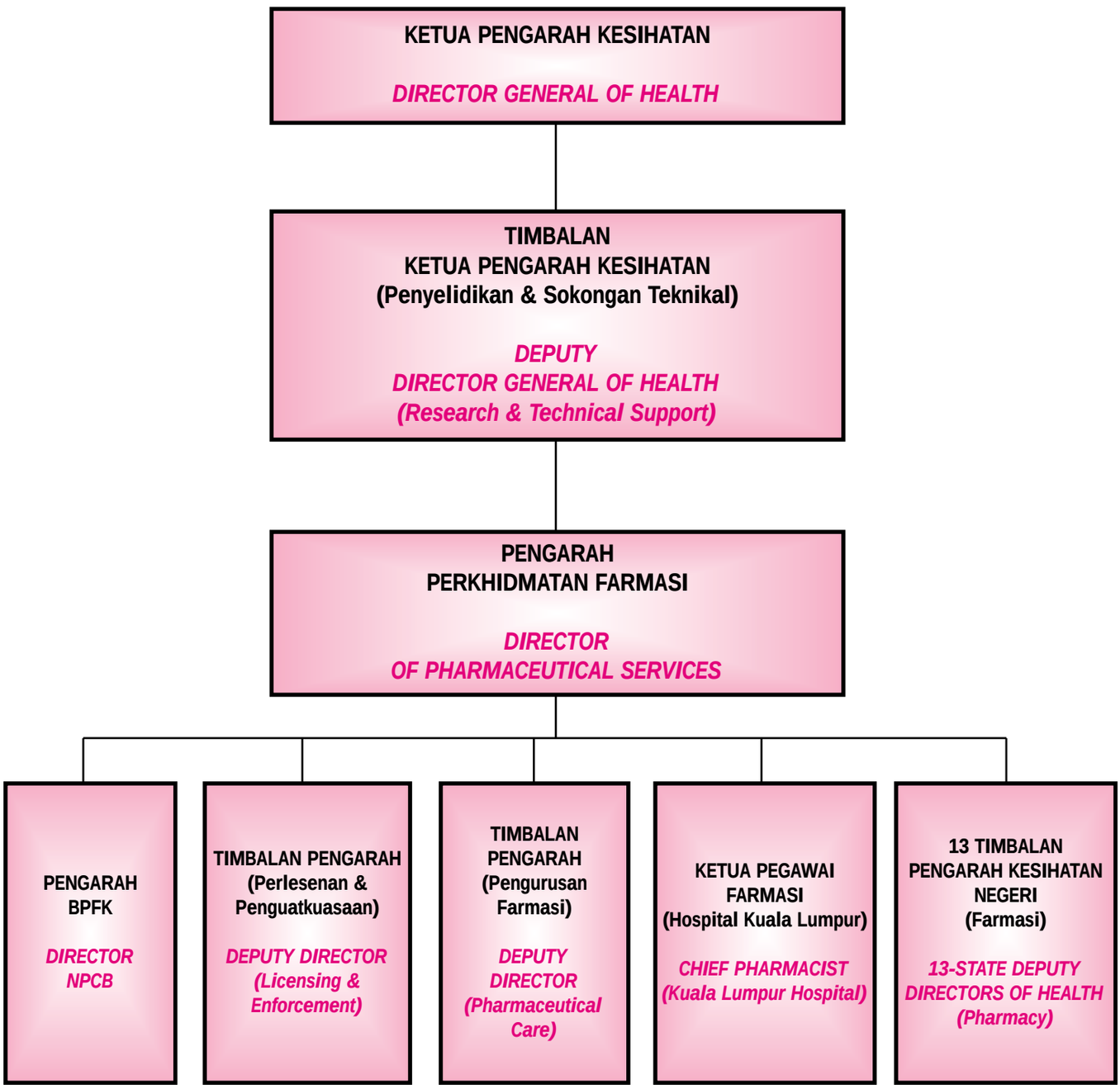
Thank you.

(HAJI NORMAL BIN SHARIF)
Director
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

STRUKTUR ORGANISASI
ORGANISATIONAL STRUCTURE OF

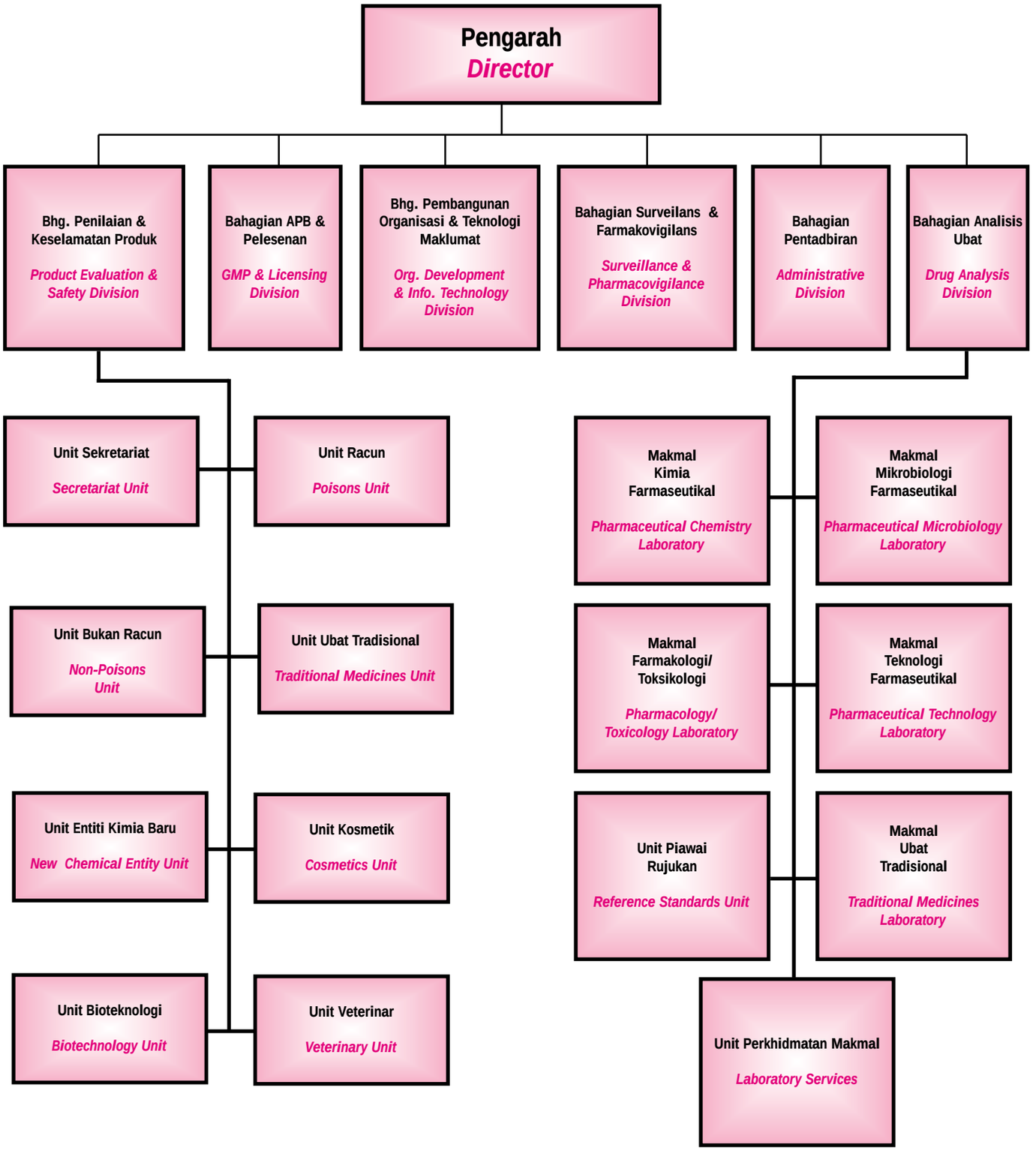
BAHAGIAN PERKHIDMATAN FARMASI
PHARMACEUTICAL SERVICES DIVISION

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH



CARTA ORGANISASI
ORGANISATIONAL CHART

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU



Senarai jawatan pada 31 Disember 2002
List of posts as at 31 December 2002

Bil. *No.*	Nama Jawatan *Position*	Gred *Grade*	Bil. *No.*	Jawatan *(Post)*	
				Diisi *Filled*	Kosong *Vacant*
1.	Pengarah BPFK *Director of NPCB*	C	1	1	0
2.	Pegawai Farmasi *Pharmacist*	U1	2	2	0
3.	Pegawai Farmasi *Pharmacist*	U2	26	17	9
4.	Pegawai Farmasi *Pharmacist*	U3	48	47	1
5.	Penolong Pegawai Perangkaan *Assistant Statistic Officer*	N6	1	1	0
6.	Pembantu Farmasi *Pharmacy Assistant*	U7	8	7	1
7.	Pembantu Farmasi *Pharmacy Assistant*	U8	65	60	5
8.	Pembantu Tadbir *Administrative Assistant*	N7	1	1	0
9.	Pembantu Tadbir (Kesetiausahaan) *Administrative Assistant (Secretary)*	N7	1	1	0
10.	Pembantu Perpustakaan *Library Assistant*	S7	1	1	0
11.	Pembantu Tadbir *Administrative Assistant*	N9	11	11	0
12.	Pembantu Tadbir (Kesetiausahaan) *Administrative Assistant (Secretary)*	N9	2	2	0
13.	Pembantu Tadbir (Setor) *Administrative Assistant (Store)*	N9	1	1	0
14.	Operator Mesin Prosesan Data *Data Processing Operator*	F9	2	2	0
15.	Pembantu Tadbir Rendah *Typist*	N11	4	1	3
16.	Pembantu Tadbir Rendah (Operator Telefon) *Administrative Assistant (Telephone Operator)*	N11	1	1	0
17.	Pembantu Am Rendah *General Assistant*	N13	2	2	0
18.	Atendan Kesihatan *Health Attendant*	U16	10	7	3
15.	Pengawal Keselamatan *Security Guard*	KP10	3	1	2
16.	Pemandu Kenderaan Bermotor *Driver*	R10	3	3	0
	JUMLAH *(Total)*		193	169	24

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 keluaran 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-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 sessi 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.

ORGANISATION 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 work force 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.

PIAGAM PELANGGAN

CLIENT'S CHARTER

A. KEWAJIPAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN TEMA PIAGAM

Ditujukan khas kepada setiap pelanggan yang berurusan dengan BPFK.

1. AM

1.1. KEMUDAHAN UNTUK PELANGGAN

(i) Setiap pelanggan biro boleh mendapat perkhidmatan yang sewajarnya.

(ii) Setiap pelanggan yang tergolong dalam keadaan yang memerlukan perhatian segera akan diberikan layanan dengan segera.

1.2. TARAF PERKHIDMATAN

(i) Setiap pelanggan akan dilayan dengan baik, mesra, bertimbang rasa, hormat dan ikhlas.

(ii) Setiap pelanggan akan diberi perkhidmatan yang terbaik secara profesional.

1.3. MAKLUMAT PERKHIDMATAN

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

2. AKTIVITI - PENDAFTARAN

2.1. Memastikan bahawa semua keluaran farmaseutikal yang berdaftar adalah selamat, berkesan dan berkualiti serta menentukan bahawa kosmetik-kosmetik yang berdaftar adalah selamat dan berkualiti.

2.2. Semua permohonan akan dinilai dengan adil dan saksama berlandaskan kepada peraturan-peraturan yang berkaitan.

2.3. Semua dokumen yang dikemukakan oleh pelanggan akan disimpan dalam keadaan selamat dan terkawal.

A. THE OBLIGATION OF THE NATIONAL PHARMACEUTICAL CONTROL BUREAU CHARTER THEME :

Exclusively targeted for clients who deal with NPCB.

1. GENERAL

1.1. FACILITIES FOR CLIENTS

(i) Every client of the bureau shall receive the appropriate service.

(ii) Every client who requires immediate attention shall be served immediately.

1.2. STANDARD OF SERVICE

(i) Every client shall be treated with courtesy, understanding, respect and sincerity.

(ii) Every client shall be given the best possible professional service.

1.3. INFORMATION SERVICE

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

2. ACTIVITY - REGISTRATION

2.1. To ensure the safety, efficacy and quality of all registered pharmaceutical products and the safety and quality of registered cosmetic products.

2.2. All applications shall be evaluated fairly and treated with impartiality in accordance with the relevant regulations.

2.3. All documents forwarded by clients shall be kept in a secure and organized manner.

3. AKTIVITI - MAKMAL

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

4. AKTIVITI - PENGUATKUASAAN DAN KOMPLIANS

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

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

5. SETIAP PERMOHONAN YANG LENGKAP AKAN DIPROSES MENGIKUT JANGKAMASA BERIKUT

(i) Lesen Untuk Percubaan Klinikal - tidak lebih dari 3 bulan.

(ii) Lesen Untuk Pemborong, Pengilang, Pengimport - tidak lebih dari 3 bulan.

(iii) Lesen Baru Untuk Pemborong, Pengilang, Pengimport - tidak lebih dari 6 bulan.

(iv) 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.

(v) Laporan Pemeriksaan APB.

Susulan - tidak lebih dari 2 bulan.

Baru/Rutin - tidak lebih dari 3 bulan.

3. ACTIVITY - LABORATORY

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

4. ACTIVITY - ENFORCEMENT AND COMPLIANCE

4.1. Every enforcement action on any offence under the law shall be carried out fairly and impartially without influence from whatsoever vested interest and prejudice.

4.2. Ever ready to co-operate with other enforcement agencies in matters related to drug enforcement.

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

(i) Licence For Clinical Trial - Not more than 3 months.

(ii) Licence For Wholesalers, Manufacturers and Importers - Not more than 3 months.

(iii) New Licence For Wholesalers, Manufacturers and Importers - Not more than 6 months.

(iv) 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.

(v) GMP Inspection Report

Follow-up - Not more than 2 months.

New/Routine - Not more than 3 months.

(vi) Perakuan Keluaran.

Alat Perubatan - tidak lebih dari 2 minggu.
Farmaseutikal - tidak lebih dari 1 bulan.

B. KEWAJIPAN PELANGGAN

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

(i) Mematuhi semua undang-undang dan peraturan-peraturan yang berkaitan.

(ii) Menggunakan kemudahan-kemudahan yang disediakan secara bertanggungjawab.

(vi) Product Certificate

Medical Devices - Not more than 2 weeks.

Pharmaceuticals - Not more than 1 month.

B. CLIENT'S OBLIGATION

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

(i) Comply with the requirements of the relevant legislation and regulations.

(ii) Use the facilities provided responsibly.

RINGKASAN AKTIVITI BPFK

Aktiviti-aktiviti Biro Pengawalan Farmaseutikal Kebangsaan pada amnya termasuk:-

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

2. Menjalankan ujian analisa, farmaseutik, mikrobiologi, farmakologi serta toksikologi ke atas ubat-ubatan dan kosmetik untuk menentukan mutu, keberkesanan dan keselamatan keluaran-keluaran tersebut.

3. Menguatkuasakan skim kawalan mutu ubat-ubatan di pasaran melalui penyampelan secara rambang dan menjalankan ujian-ujian analisa.

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

5. Mendorong dan membantu pengilang-pengilang ubat tempatan untuk meningkatkan mutu pengilangan setaraf dengan Amalan Perkilangan Baik (Good Manufacturing Practice) yang disarankan oleh Pertubuhan Kesihatan Sedunia.

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

7. Menguruskan skim panggilbalik ubat-ubat yang didapati atau dibuktikan merbahaya kepada pengguna.

8. Mengendalikan sistem pengumpulan dan penyebaran maklumat ubat-ubatan selaras dengan peranannya sebagai Pusat Maklumat Ubat Kebangsaan.

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

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

11. 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.

SUMMARY OF NPCB ACTIVITIES

The activities of NPCB are:-

1. *To implement the drug and cosmetic registration scheme through evaluation of technical data, laboratory analysis, research and information received from international agencies.*

2. *To carry out analytical, pharmaceutical, microbiological, pharmacological and toxicological tests on drugs and cosmetics to determine quality, efficacy and safety of such products.*

3. *To implement the regulatory scheme on quality of pharmaceutical products in the market through random sampling and carrying out analytical tests.*

4. *To implement the licensing scheme for pharmaceutical manufacturers, importers and wholesalers including a licensing scheme for clinical trials.*

5. *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 World Health Organisation (WHO).*

6. *To manage the Adverse Drug Reaction Monitoring Program and participate in the WHO International Adverse Drug Reaction Monitoring Program.*

7. *To manage the product recall scheme for pharmaceutical products which are found to be of substandard or dangerous to consumers.*

8. *To manage the drug information collection and dissemination system in line with the role as a national drug information centre.*

9. *To carry out research on methodology and basic research for the purpose of evaluating quality, efficacy and safety of drugs/cosmetics.*

10. *To establish a reference standard system for use in this country and also for neighbouring countries through a scheme of cooperation in the field of pharmaceuticals among ASEAN countries.*

11. *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.*

LAPORAN BAHAGIAN

DIVISIONAL REPORTS

BAHAGIAN PENTADBIRAN

Bahagian Pentadbiran adalah bertanggungjawab dalam menguruskan semua hal berhubung dengan kewangan, pentadbiran am, hasil dan tugas-tugas lain yang bukan bidang profesional.

OBJEKTIF

- Memastikan bahawa semua anggota menikmati upahan gaji bulanan dan tuntutan-tuntutan rasmi dibayar dalam tempoh yang ditetapkan.
- Segala keperluan yang asas dan penting diuruskan dengan segera.
- Urusan Perkhidmatan yang wajib dan perlu sentiasa dikemaskinikan.
- Mengawal peruntukan kewangan supaya sentiasa mencukupi bagi menjamin setiap aktiviti yang dirancang boleh mencapai objektif keseluruhannya.

KEWANGAN

Mengurus pembayaran upahan dan gaji untuk 169 anggota berjumlah RM 5,165,475.00

KUTIPAN HASIL

Kutipan hasil diterima daripada pelanggan untuk bayaran Pendaftaran Ubat-Ubatan, Ujian Makmal, Lesen, Perkhidmatan Nasihat, Jualan Buku-buku Garispaduan dan lain-lain. Jumlah kutipan hasil mengikut disiplin adalah seperti dibawah:-

ADMINISTRATIVE DIVISION

The Administrative Division is responsible for the management of all matters pertaining to finance, general administration and other non-professional tasks.

OBJECTIVES

- *To ensure all emoluments and claims are paid within the stipulated time.*
- *To take immediate action on basic and urgent matters.*
- *To constantly update compulsory records.*
- *To oversee that financial allocations are sufficient and ensure that each planned program and activity meets its objective.*

FINANCE

Payment to 169 staff members is RM 5,165,475.00

REVENUE

Revenue is collected from the public for Drug Registration, Laboratory Test, Licences, Advisory Services, Sale of Guideline Books and others. The breakdown of total revenue is as follows:-

KUTIPAN HASIL (RM) SEHINGGA AKHIR TAHUN 2002
REVENUE (RM) UNTIL END OF 2002

Tahun *Year*	Pendaftaran *Registration*	Lesen *License*	Makmal *Laboratory*	Pemeriksaan *Inspection*	Bahan Cetak *Printed Materials*	Lain-lain *Others*
1998	793,825	129,350	750,360	8,400	18,296	12,100
1999	959,405	158,350	484,860	14,350	39,605	18871
2000	1,111,440	152,100	502,620	6,500	28,340	27,193
2001	914,020	203,200	460,880	12,200	26,485	64,072
2002	2,002,370	454,800	745,839	24,700	28,875	55,669

TINJAUAN BELANJAWAN / *BUDGET PREVIEW*

Peruntukan dan Perbelanjaan Mengurus BPFK Bagi Tahun 2002
NPCB Operating Allocation and Expenditure 2002

Kod Objek *Object code*	Jenis Perbelanjaan Am *Expenditure*	Peruntukan (RM) *Allocation (RM)*		Perbelanjaan *Expenditure*		Baki *Balance*	
		Asal *Original*	Dipinda *Amended*	Perbelanjaan Bersih (RM) *Actual Expenditure (RM)*	%	(RM)	%
10000	Emolumen *Emolument*	4,000,000	5,165,475	5,470,129	106	304,654	5.90
20000	Perkhidmatan dan Bekalan *Services and Supply*	7,326,200	8,726,200	5,387,957	61.75	3,338,243	33
30000	Aset (Harta Modal) *Asset (Property)*	500,000	500,000	317,289	63.46	182,711	36.55
Jumlah *Total*		11,826,200	14,391,675	11,175,375	77.65	3,216,300	5.35

BAHAGIAN PENILAIAN DAN KESELAMATAN PRODUK

OBJEKTIF

Untuk memastikan semua keluaran berdaftar dinilai dari segi kualiti, keselamatan dan keberkesanan.

Untuk memberikan sokongan teknikal dan pentadbiran dalam semua bidang yang berhubung dengan pendaftaran keluaran.

PENCAPAIAN

Permohonan diterima

Sejumlah 51,098 permohonan diterima dari tahun 1985 sehingga 2002 dimana 15,059 (29.5%) adalah ubat racun, 10,898 (21.3%) ubat bukan racun, 23, 048 (45.1%) ubat tradisional dan 2,093 (4.1%) adalah kosmetik **(Jadual 1)**. Jumlah permohonan telah meningkat dengan ketara dari tahun 1986 hingga 1992. Begitu juga pada tahun 1992 hingga 1999, aliran yang sama telah berlaku di mana jumlah permohonan meningkat sebanyak 53.2% kerana permohonan bagi ubat tradisional dan kosmetik adalah tinggi. Pemohonan bagi ubat racun dan ubat bukan racun telah menurun bagi tahun 2002.

Keluaran didaftarkan

Sejumlah 28,959 keluaran telah didaftarkan sehingga tahun 2002, dimana 9,335 (32.2%) ialah ubat racun, 6,931 (24.0%) ubat bukan racun, 10,758 (37.1%) ubat tradisional dan 1,935 (6.7%) kosmetik **(Jadual 2)**. Jumlah keluaran yang didaftarkan menunjukkan peningkatan bagi semua kategori.

Permohonan Ditolak

Sehingga 2002, sejumlah 16,720 permohonan telah ditolak dan ini meliputi kira-kira 32.7% dari jumlah permohonan yang diterima.

PRODUCT EVALUATION AND SAFETY DIVISION

OBJECTIVES

To ensure that all registered products have been evaluated for quality, safety and efficacy.

To provide technical and administrative support in all matters pertaining to the registration of products.

ACHIEVEMENTS

Applications received

*A total of 51,098 applications were received from 1985 to 2002, of which 15,059 (29.5%) were prescription drugs, 10,898 (21.3%) were OTC products, 23,048 (45.1%) traditional medicines, and 2,093 (4.1%) cosmetics **(Table 1)**. The number of applications has increased significantly from 1992 to 1999, where the number of applications has gone up by almost 53.2%, mainly due to the enormous number of traditional medicines and cosmetics applications. However, the applications for prescription drugs, as well as OTC products have decreased for the year 2002.*

Products Registered

*A total of 28,959 products has been registered up until the year 2002, of which 9,335 (32.2%) are prescription drugs, 6,931 (24.0%) are OTC products, 10,758 (37.1%) traditional medicines, and 1,935 (6.7%) cosmetics **(Table 2)**. The number of products registered displays increasing trends for all categories.*

Applications Rejected

Up until 2002, a total of 16,720 applications have been rejected and those rejected represents approximately 32.7% of the total number of applications received.

Jadual 1 : Permohonan untuk pendaftaran (1985-2002)
Table 1 : Applications for registration (1985-2002)

Tahun *Year*	Ubat racun *Prescription drugs*	Ubat bukan racun *OTC products*	Ubat Tradisional *Traditional medicines*	Kosmetik *Cosmetics*	Jumlah *Total*	
					Tahunan *Annual*	Kumulatif *Cumulative*
1985	9	-	-	-	9	9
1986	6,439	-	-	-	6,439	6,448
1987	824	56	-	-	880	7,328
1988	702	2,532	-	-	3,234	10,562
1989	664	2,750	-	-	3,414	13,976
1990	528	597	-	-	1,125	15,101
1991	481	305	-	42	828	15,929
1992	150	60	3,973	145	4,328	20,257
1993	376	111	7,059	51	7,597	27,854
1994	400	168	4,080	31	4,679	32,533
1995	440	239	288	58	1,025	33,558
1996	617	671	415	130	1,833	35,391
1997	532	635	668	123	1,958	37,349
1998	587	606	938	277	2,408	39,757
1999	796	789	1,347	610	3,542	43,299
2000	427	444	1,523	262	2,656	45,955
2001	578	487	1,154	150	2,369	48,324
2002	509	448	1,603	214	2,774	51,098
Jumlah *Total*	**15,059**	**10,898**	**23,048**	**2,093**	**51,098**	**51,098**

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Jadual 2 : Kumulatif Keluaran yang didaftarkan (1991-2002)
Table 2 : Cumulative number of products registered (1991-2002)

Tahun *Year*	Ubat racun *Prescription drugs*	Ubat bukan racun *OTC products*	Ubat Tradisional *Traditional Medicines*	Kosmetik *Cosmetics*	Jumlah *Total*
1991	5,332	3,331	-	-	8,663
1992	5,862	3,743	-	14	9,619
1993	6,131	3,867	5	109	10,112
1994	6,444	3,954	57	149	10,604
1995	6,691	4,023	339	183	11,236
1996	7,027	4,237	1,852	292	13,408
1997	7,525	4,830	4,347	476	17,178
1998	8,187	5,415	7,819	664	22,085
1999	8,792	5,942	7,966	1,235	23,935
2000	8,813	6,072	8,550	1,467	24,902
2001	8,993	6,696	9,894	1,776	27,359
2002	9,335	6,931	10,758	1,935	28,959
Jumlah *Total*	**9,335**	**6,931**	**10,758**	**1,935**	**28,959**

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Jadual 3 : Kumulatif Permohonan yang ditolak (1986-2002)
Table 3 : Cumulative applications rejected by the DCA (1986-2002)

Tahun *Year*	Ubat racun *Prescription drugs*	Ubat bukan racun *OTC products*	Ubat Tradisional *Traditional Medicines*	Kosmetik *Cosmetics*	Jumlah *Total*
1986	955	-	-	-	955
1987	2,043	-	-	-	2,043
1988	2,389	329	-	-	2,718
1989	2,889	1,083	-	-	3,972
1990	3,206	1,318	-	-	4,524
1991	3,495	1,585	-	-	5,080
1992	3,693	2,127	-	14	5,834
1993	3,770	2,262	0	92	6,124
1994	3,860	2,362	410	98	6,730
1995	3,938	2,592	1,253	98	7,881
1996	4,020	2,783	2,570	98	9,471
1997	4,132	2,963	3,915	98	11,108
1998	4,164	3,065	7,190	98	14,517
1999	4,186	3,125	8,975	98	16,384
2000	4,206	3,165	9,021	98	16,490
2001	4,248	3,188	9,104	100	16,640
2002	4,255	3,213	9,127	125	16,720
Jumlah *Total*	**4,255**	**3,213**	**9,127**	**125**	**16,720**

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Permohonan yang dibatalkan atau ditarik-balik

Sehingga tahun 2002, sejumlah 7,248 permohonan yang dibatalkan atau ditarik-balik, dan ini meliputi 2,335 (32.2 %) ubat racun, 1,334 (18.4 %) ubat bukan racun, 3,513 (48.5 %) ubat tradisional dan 66 (0.9%) kosmetik **(Jadual 4)**. Jumlah keluaran yang dibatalkan atau ditarik-balik adalah 14.2 % daripada jumlah permohonan yang diterima.

Applications cancelled or withdrawn

*Until the year 2002, a total of 7,248 applications have been cancelled or withdrawn, which consists of 2,335 (32.2%) prescription drugs, 1,334 (18.4%) OTC products, 3,513 (48.5%) traditional medicines, and 66 (0.9%) cosmetics **(Table 4)**. The total number of products cancelled or withdrawn represents about 14.2% of the total number of applications received.*

Jadual 4 : Permohonan yang dibatalkan/ditarik-balik (1989-2002)
Table 4 : Applications cancelled/withdrawn (1989-2002)

Tahun *Year*	Ubat racun *Prescription drugs*	Ubat bukan racun *OTC products*	Ubat Tradisional *Traditional medicines*	Kosmetik *Cosmetics*	Jumlah *Total*	
					Tahunan *Annual*	Kumulatif *Cumulative*
1989	166	0	-	-	166	166
1990	114	0	-	-	114	280
1991	103	37	-	-	140	420
1992	0	15	-	-	15	435
1993	6	0	0	-	6	441
1994	9	28	0	-	37	478
1995	39	59	0	-	98	576
1996	59	62	0	-	121	697
1997	62	76	0	-	138	835
1998	0	23	595	66	684	1,519
1999	1,367	609	1,613	-	3,589	5,108
2000	306	120	499	-	925	6,033
2001	86	305	645	-	1,036	7,069
2002	18	0	161	-	179	7,248
Jumlah *Total*	**2,335**	**1,334**	**3,513**	**66**	**179**	**7,248**

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

RAYUAN

Jumlah rayuan yang diterima meningkat pada tahun 2002 iaitu sejumlah 76 berbanding hanya 16 sahaja pada tahun sebelumnya.

ENTITI KIMIA BARU

Dari tahun 1985 sehingga 2002, permohonan yang diterima untuk keluaran entiti kimia baru ialah 1,254 **(Rajah 1)**. Daripada jumlah ini, 842 (67.1%) telah diluluskan, 302 (24.1%) ditolak dan 64 (5.1%) tertangguh.

TAMBAHAN INDIKASI

Tambahan indikasi bagi produk-produk yang telah berdaftar juga dinilai dan diluluskan oleh PBKD. Sebanyak 34 permohonan diterima pada tahun 2002. Jumlah ini menurun jika dibandingkan pada tahun 2001 iaitu sejumlah 71 permohonan.

APPEAL

The number of appeals received has increased in the year 2002, i.e. 76 as compared to only 16 for the previous year.

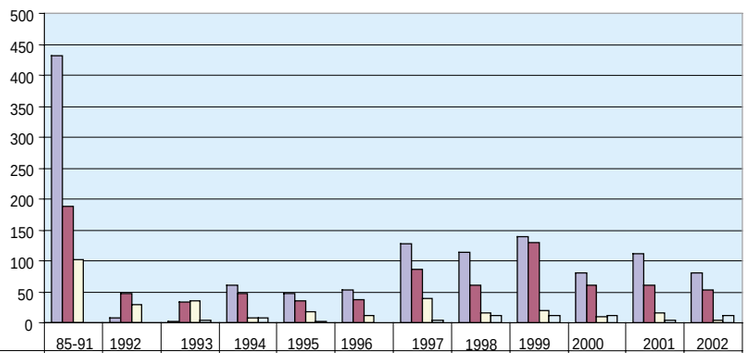
NEW CHEMICAL ENTITIES

From the year 1985 to 2002, the total number of applications received for products classified as new chemical entities was 1,254 ***(Figure 1)****. Out of these, 842 (67.1%) has been approved, 302 (24.1%) rejected, and 64 (5.1%) deferred.*

ADDITIONAL INDICATIONS

New indications for registered products were also assessed and approved by the DCA. A total of 34 applications were received in 2002. The total has decreased if compared to the year 2001, where a total of 71 applications were received.

Rajah 1: Status Pendaftaran Keluaran Entiti Kimia Baru 1985 - 2002
Figure 1: Registration Status of New Chemical Entities 1985 - 2002



	85-91	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Terima	431	8	2	60	47	52	127	114	140	81	111	81
Lulus	188	48	34	48	36	37	87	61	129	61	61	52
Tolak	101	30	35	7	18	11	39	15	19	9	15	3
Tangguh	0	0	3	8	1	0	4	11	11	11	4	11

Terima = *Received;* Lulus = *Approved;* Tolak = *Rejected;* Tangguh = *Deferred*

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

LESEN IMPORT PENYELIDIKAN KLINIKAL

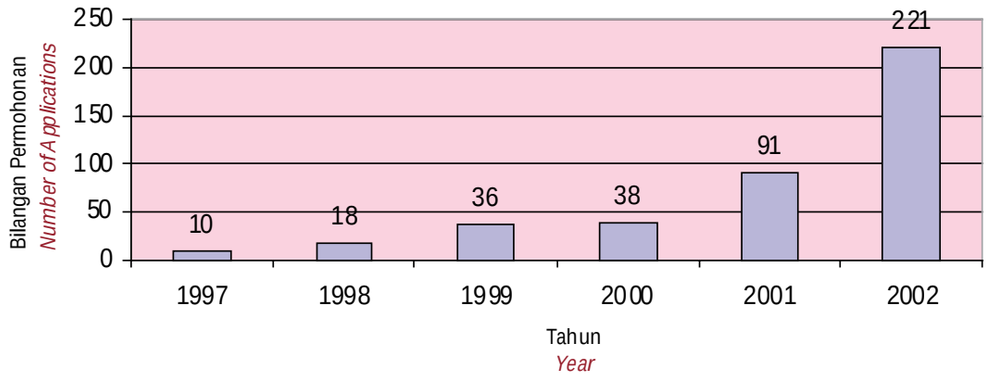
Jumlah permohonan LIPK yang diterima telah meningkat pada tahun 2002, mencatatkan jumlah tertinggi iaitu 221 permohonan berbanding pada tahun-tahun sebelumnya. Dari tahun 1997 – 2002, sejumlah 414 permohonan LIPK telah diterima.

CLINICAL TRIALS IMPORT LICENCE (CTIL)

The number of CTIL received has increased significantly in the year 2002, recording the highest total of 221 applications as compared to the previous years. From 1997 – 2002, 414 applications were received.

Rajah 2 : Lesen Impot Penyelidikan Klinikal 1997 - 2002

Figure 2 : Clinical Trial Import License 1997 - 2002



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

TEMPATAN VS. IMPOT

Sebanyak 43.9% (12,738) daripada jumlah keluaran yang didaftarkan adalah dikilangkan secara tempatan, sementara 56.1% (16,221) adalah diimpot. Keluaran tempatan dan impot yang didaftarkan dari tahun 1991 hingga 2002, mengikut kategori berlainan diilustrasikan pada **Jadual 5**.

LOCAL VS. IMPORT

*About 43.9% (12,738) of the total number of products registered are locally-manufactured, while 56.1% (16,221) are imported. Locally-manufactured and imported products registered for the period between the years 1991 to 2002, according to the different categories, are cumulatively illustrated in the **Table 5**.*

Jadual 5 : Jumlah Kumulatif Produk Tempatan dan Impot, (1991 – 2002)

Table 5 : Cumulative Number of Locally-Manufactured and Imported Products Registered, (1991 – 2002)

Tahun *Year*	Ubat racun *Prescription drugs*		Ubat bukan racun *OTC products*		Ubat tradisional *Traditional medicines*		Kosmetik *Cosmetics*		Jumlah *Total*	
	Tempatan *Local*	Impot *Import*	Tempatan *Local*	Impot *Import*	Tempatan *Local*	Impot *Import*	Tempatan *Local*	Impot *Import*	Tempatan *Local*	Impot *Import*
1991	1,602	3,730	1,750	1,581	-	-	-	-	3,352	5,311
1992	1,760	4,102	1,983	1,760	-	-	2	12	3,745	5,874
1993	1,867	4,264	2,032	1,835	1	4	22	87	3,922	6,190
1994	1,951	4,493	2,081	1,873	17	40	22	127	4,071	6,543
1995	2,041	4,650	2,083	1,940	145	194	22	161	4,291	6,945
1996	2,213	4,814	2,202	2,035	950	942	72	220	5,437	8,011
1997	2,347	5,178	2,475	2,355	2,300	2,047	72	404	7,194	9,984
1998	2,602	5,585	2,755	2,660	4,246	3,573	106	558	9,709	12,376
1999	2,781	6,011	3,052	2,890	4,098	3,868	197	1,038	10,038	13,807
2000	2,742	6,071	3,080	2,992	4,400	4,150	215	1,252	10,451	14,465
2001	2,770	6,223	3,454	3,242	5,560	4,334	319	1,457	12,103	15,256
2002	2,821	6,514	3,112	3,819	6,327	4,431	478	1,457	12,738	16,221
Jumlah *Total*	**9,335**		**6,931**		**10,758**		**1935**		**28,959**	

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Pada tahun 2002, peratusan nisbah antara produk tempatan dan produk impot untuk ubat racun adalah 30:70 seperti data dalam **Jadual 5**. Bagi ubat bukan racun, peratusan keluaran tempatan dan impot adalah hampir seimbang iaitu 45:55. Peratusan untuk ubat tradisional adalah 59:41, menunjukkan peratusan keluaran yang dikilangkan secara tempatan adalah lebih tinggi manakala peratusan nisbah kosmetik pula adalah 25:75.

Merujuk kepada jumlah produk tempatan yang didaftarkan (n = 12,738) seperti pada **Jadual 5**, 2,821 (22.1%) adalah ubat racun, 3,112 (24.4%) ubat bukan racun, 6,327 (49.7%) ubat tradisional dan 478 (3.8%) kosmetik. Untuk produk impot, berdasarkan kepada jumlah yang didaftarkan (n = 16,221), 6,514 (40.2%) adalah ubat racun, 3,819 (23.5%) ubat bukan racun, 4,431 (27.3%) ubat tradisional dan 1,457 (9.0%) kosmetik.

KEBENARAN EKSPOT

Pengeluaran sijil perakuan farmaseutikal [certificate of pharmaceutical products (CPP)] dan sijil perakuan bebas [certificate of free sale (CFS)] untuk alatan perubatan dan kosmetik telah bertambah sejak 1987 sehingga 2000. Sejumlah 2,033 CPP dan 1,717 CFS telah dikeluarkan pada tahun 2002 berbanding 2,131 CPP dan 1,551 CFS pada tahun 2001.

*In the year 2002, the percentage ratio between locally-manufactured and imported products for prescription drugs is in the order of 30:70, as shown by the data in **Table 5**. For OTC products, the percentage ratio of locally-manufactured and imported products are almost equivalent, i.e. 45:55. The percentage ratio for traditional medicines is shown to be 59:41, indicating a higher proportion of locally-manufactured products, whereas the percentage ratio for cosmetics is 25:75*

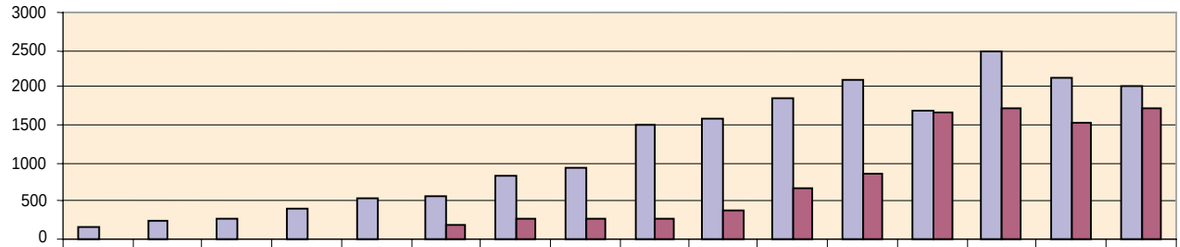
*Based on the total number of locally-manufactured products registered (n = 12,738) as presented in **Table 5**, 2,821 (22.1%) are prescription drugs, 3,112 (24.4%) are OTC products, 6,327 (49.7%) traditional medicines, and 478 (3.8%) cosmetics. For imported products, based on the total number of products registered (n = 16,221), 6,514 (40.2%) are prescription drugs, 3,819 (23.5%) are OTC products, 4,431 (27.3%) traditional medicines, and 1,457 (9.0%) cosmetics.*

EXPORT AUTHORISATION

Issuance of certificates of pharmaceutical products (CPP) and certificates of free sale (CFS) for medical devices and cosmetics for export authorization has increased steadily since 1987 and 2000 respectively. A total of 2,033 CPP and 1,717 CFS have been issued in the year 2002, as compared to 2,131 CPP and 1,551 CFS in the year 2001.

Rajah 4 : Pengeluaran Sijil Perakuan Farmaseutikal dan Sijil Perakuan Penjualan Bebas 1987 - 2002

Figure 4 : Issuance of Certificates of Pharmaceutical Products (CPP) and Certificates of Free Sale (CFS) 1987 - 2002



	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
CPP	158	242	250	393	532	561	827	943	1502	1590	1865	2094	1700	2478	2131	2,033
CFS	0	0	0	0	0	192	257	263	278	372	652	864	1679	1719	1551	1,717

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

SUMBER PRODUK

10 negara utama ialah China, Amerika Syarikat, Australia, Indonesia, Thailand, Jerman, India, England, Perancis dan Itali. Negara-negara ini meliputi lebih kurang 72% (11,754) daripada jumlah keluaran impot (n = 16,221). Produk yang diimpot dari negara-negara ASEAN seperti Indonesia, Thailand, Singapura dan Filipina meliputi hampir 12.8% (2,077).

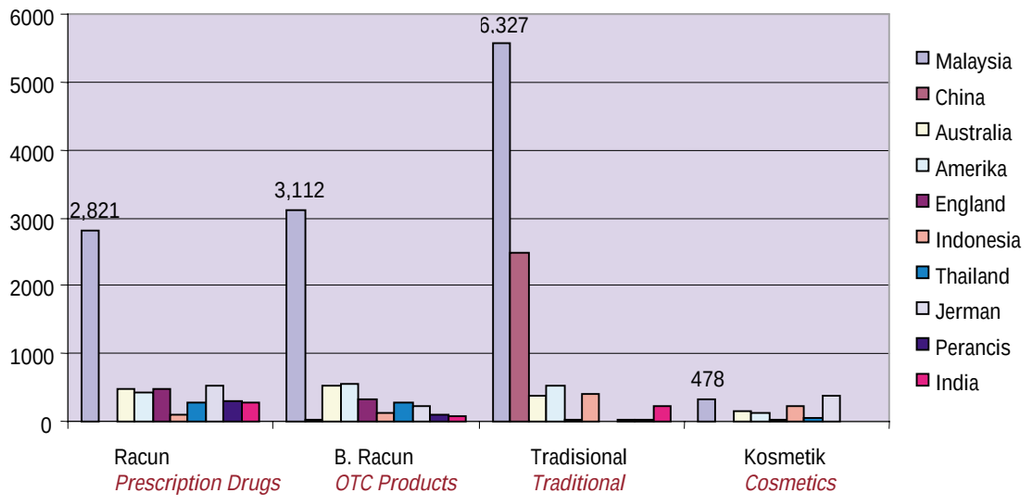
5 pengeluar utama bagi keluaran ubat racun, ubat bukan racun, ubat tradisional dan kosmetik ditunjukkan dalam ***Rajah 5***. Malaysia merupakan pengeluar utama keluaran ubat racun, ubat bukan racun, ubat tradisional dan kosmetik. Ini juga merupakan perkembangan yang baik dalam industri kosmetik negara kerana berjaya mengatasi Jerman yang merupakan pengeluar utama kosmetik pada tahun 2001.

SOURCES OF PRODUCTS

The top 10 leading foreign sources include China, United States of America (USA), Australia, Indonesia, Thailand, Germany, India, England, France and Italy. Together they account for approximately 72% (11,754) of our total imports (n = 16,221). Products imported from neighbouring ASEAN countries, which include Indonesia, Thailand, Singapore and Philippines constitute nearly 12.8% (2,077).

5 leading sources for prescription drugs, OTC products, traditional medicines, and cosmetics are illustrated in ***figure 5.*** *Malaysia is the major source for prescription drugs, OTC products, traditional medicines as well as cosmetics. This reflects a good growth for Malaysia's cosmetic industry as it was able to override Germany, which was the major cosmetic source in the year 2001.*

Rajah 5 : Pengeluar utama produk berdaftar, 2002
Figure 5: Major sources for registered products, 2002



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

BAHAGIAN APB DAN PELESENAN

GMP AND LICENSING DIVISION

OBJEKTIF

Objektif utama bahagian ini ialah untuk memastikan premis-premis pengilang keluaran farmaseutikal dan ubat-ubatan tradisional mematuhi keperluan Amalan Perkilangan Baik (APB). Bahagian ini juga bekerjasama dengan Unit Penguatkuasaan Farmasi Negeri (UPFN) dalam memastikan premis pengimpot dan pemborong mematuhi keperluan Amalan Penstoran Baik (ASB).

AKTIVITI

Bahagian ini menjalankan aktiviti-aktiviti seperti berikut:

- Memeriksa premis pengilang, pengimpot dan pemborong keluaran-keluaran berdaftar.
- Memproses permohonan dan mengeluarkan lesen pengilang, pengimpot dan pemborong keluaran-keluaran berdaftar.
- Mengeluarkan senarai tambahan keluaran-keluaran berdaftar.
- Menilai pelan susun-atur 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 pelawat-pelawat luar negara.
- 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.

PENCAPAIAN

Pemeriksaan APB

Tahun 2002 merupakan era baru bagi aktiviti pemeriksaan APB. Industri farmaseutikal di Malaysia kini perlu mematuhi Garispanduan APB PIC/S yang terkini untuk Produk Farmaseutikal dan aneks-aneksnya, terutama bagi utiliti farmaseutikal yang kritikal.

Sebanyak 117 pemeriksaan APB telah dijalankan pada tahun 2002. Pemeriksaan tersebut meliputi 27 premis pengilang keluaran racun, 26 keluaran bukan racun, 56 keluaran tradisional, 6 kosmetik dan 2 pemeriksaan luar negara bagi pengilang tradisional.

OBJECTIVES

The main objective of this division is to ensure that pharmaceutical and traditional medicine manufacturing premises adhere to the requirement of Good Manufacturing Practice (GMP). This division also co-operates with the State Pharmacy Enforcement Units to ensure that the premises of importers and wholesaler adhere to Good Storage Practice (GSP).

ACTIVITIES

This division carries out the following activities:

- *Inspection of premises for manufacturers, importers and wholesalers of registered products.*
- *Processing of license application for manufacturers, importers and wholesalers of registered products.*
- *Issuance of additional lists of registered products.*
- *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 also overseas visitors.*
- *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 documents relating to license.*

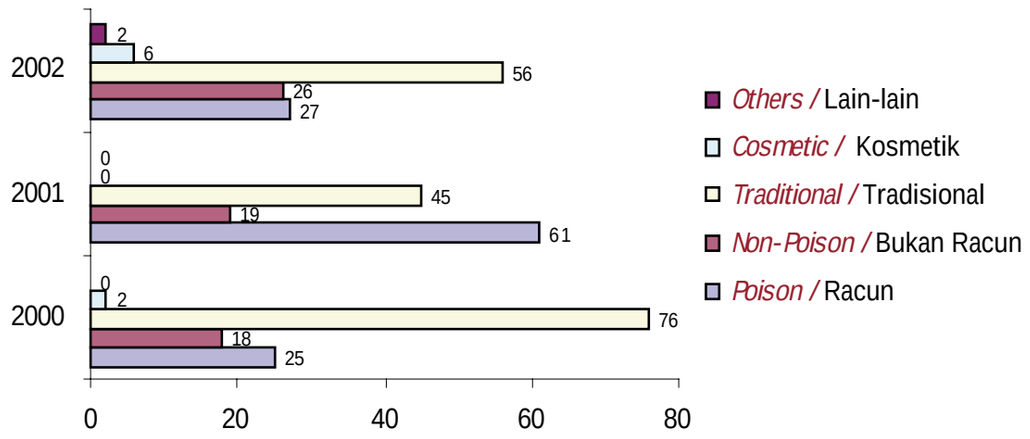
ACHIEVEMENTS

GMP Inspection

Year 2002 marked a new era in GMP inspections. Pharmaceutical industries in Malaysia will now have to comply with the current PIC/S Guide to GMP for Medicinal Products and its annexes, particularly on the critical pharmaceutical utilities.

A total of 117 inspections were conducted in 2002. These inspections included 27 premises for scheduled poison, 26 non-scheduled poison manufacturers, 56 traditional medicines manufacturers, 6 cosmetics manufacturers and 2 overseas inspections for traditional manufacturing facility. Figure 1 shows the number of GMP inspection carried out from 2000 to 2001.

Rajah 1: Pemeriksaan APB
Figure 1 : GMP Inspections



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

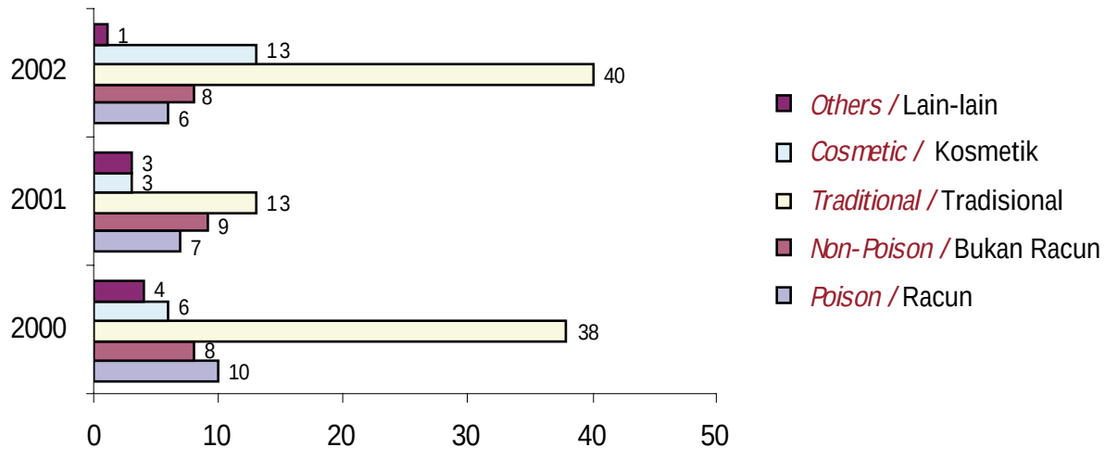
Penilaian Susun-Atur Pelan Premis Pengilang

Sejumlah 68 pelan susun-atur premis pengilang baru dan sediada telah dinilai, termasuk 27 premis pengilang keluaran racun, 26 keluaran bukan racun, 56 ubat tradisional, 6 kosmetik dan 2 premis luar negara agar mematuhi keperluan APB di Malaysia.

Evaluation of Manufacturing Premises Lay-out Plans

A total of 68 lay-out plans for new and remodeling of existing manufacturing premises were evaluated, which comprises of 27 premises of scheduled poisons manufacturers, 26 non-scheduled poison, 56 traditional medicines, 6 cosmetics and 2 overseas facilities to comply with our local requirements.

Rajah 2: Penilaian Plan Premis
Figure 2: Evaluation of Premise Lay-out Plans



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Status Perkembangan Premis Berlesen

Sebanyak 1425 lesen telah dikeluarkan pada tahun 2002. Pada tahun 2002, jumlah pengilang berlesen ialah 231, 313 pengimpot berlesen dan 881 pemborong berlesen.

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

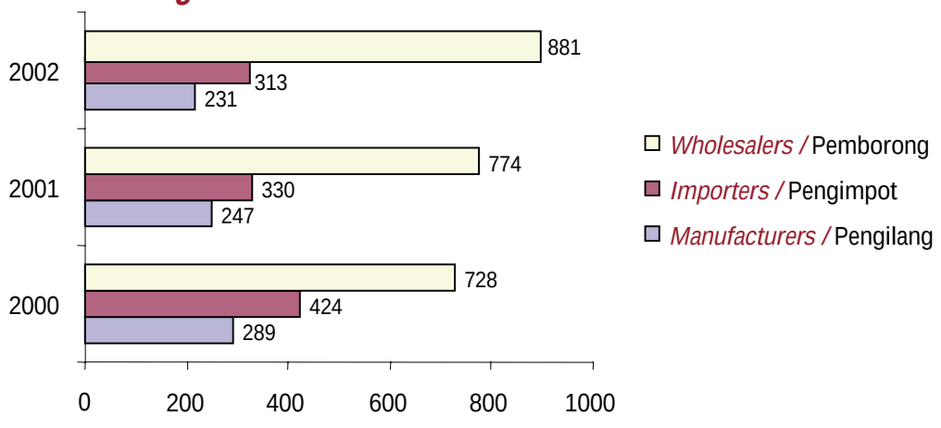
Growth Status of Licensed Premises

A total of 1425 licenses were issued in year 2002. There were 231 licensed manufacturers, 313 licensed importers and 881 licensed wholesalers.

A list and detailed information on licensed premises can be found via NPCB homepage at www.bpfk.gov.my. Information is updated monthly.

Rajah 3: Jumlah Lesen

Figure 3: Number of Licenses



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Taburan Geografi Premis Berlesen

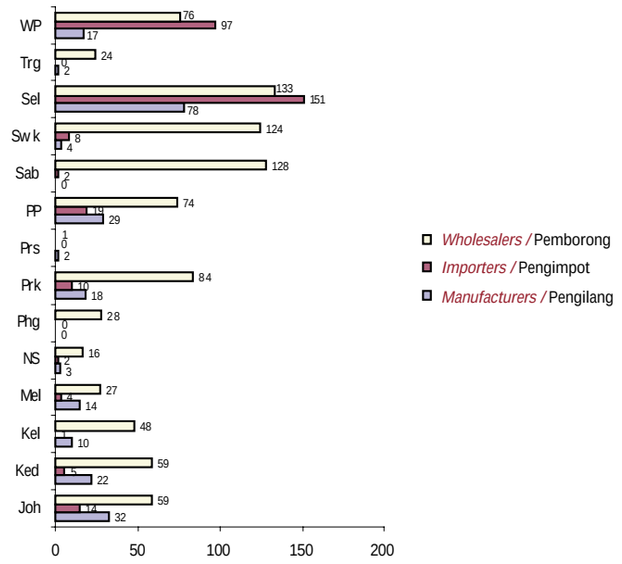
Taburan geografi premis-premis berlesen bagi tahun 2002 adalah seperti yang digambarkan dalam **Rajah 4.** Negeri Selangor mempunyai premis berlesen yang paling banyak, diikuti oleh Wilayah Persekutuan (Kuala Lumpur) dan Sarawak di tempat ketiga.

Geographical Distribution of Licensed Premises

*Geographical distribution of licensed premises for the year 2002 is illustrated in **Figure 5**. Selangor remained as having the highest number of licensed premises, followed by Wilayah Persekutuan (Kuala Lumpur) and Sarawak respectively.*

Rajah 4: Taburan Geografi Premis Berlesen

Figure 4: Geographical Distribution of Licensed Premises



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Kategori Premis Pengilang Berlesen

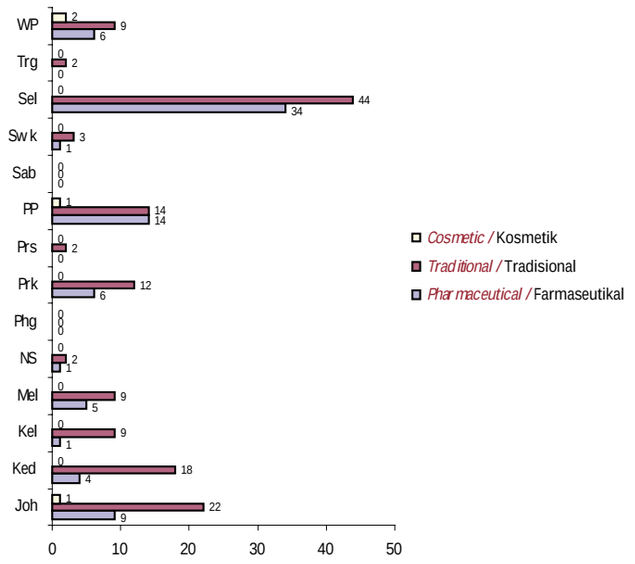
Kategori premis pengilang berlesen bagi tahun 2002 adalah seperti yang dipaparkan dalam **Rajah 5**. Negeri Selangor mempunyai bilangan premis pengilang berlesen yang tertinggi diikuti oleh Johor dan Pulau Pinang.

Categories of Licensed Manufacturing Premises

*Categories of licensed manufacturing premises for the year 2002 are illustrated in **Figure 6**. Selangor has the highest number of licensed manufacturing facilities, followed by Johor and Pulau Pinang.*

Rajah 5: Kategori Premis Lesen Pengilang

Figure 5: Categories of Licensed Manufacturing Premises



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Khidmat Nasihat

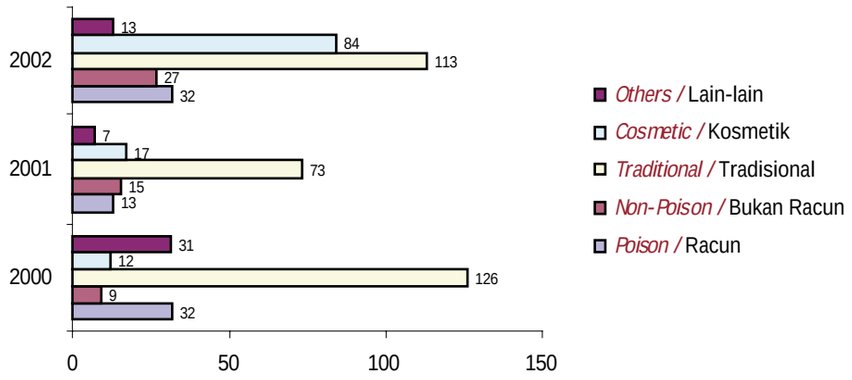
Pada tahun 2002, sebanyak 269 khidmat nasihat telah diberikan. Daripada jumlah yang dicapai, 32 daripadanya adalah berkaitan APB keluaran racun, 27 keluaran bukan racun, 113 ubat tradisional, 84 kosmetik dan 13 lain-lain. Statistik bagi tahun 2000 hingga 2002 diillustrasikan pada **Rajah 6**.

Advisory Service

*In 2002, a total of 269 advisory services were given. From this number of achievement, 32 of them were related to GMP scheduled poison, 27 non-scheduled poison, 113 traditional medicine, 84 cosmetic and 13 others. Statistic for the year 2000 until 2002 is illustrated in **Figure 6**.*

Rajah 6: Statistik bagi tahun 2000 hingga 2002 untuk Khidmat Nasihat

Figure 6: Statistics for Advisory Service for the year 2000 to 2002



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Lesen Pengilang, Lesen Pengimpot dan Lesen Pemborong

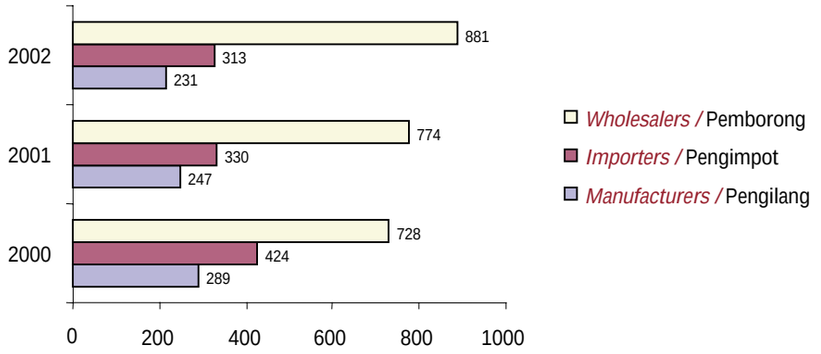
Sebanyak 1425 lesen telah dikeluarkan pada tahun 2002. Jumlah ini termasuk 231 lesen pengilang, 313 lesen pengimpot dan 881 lesen pemborong, seperti yang digambarkan pada **Rajah 7**.

Manufacturer's License, Import License and Wholesaler's License

*A total of 1425 licenses were issued in 2002. The total constitutes 231 manufacturer's license, 313 importer's license and 881 wholesaler's license. **Figure 7** illustrate the distribution of the said licenses.*

Rajah 7: Jumlah pemprosesan Lesen

Figure 7: Number of Licenses Processed



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Senarai Tambahan Keluaran Berdaftar

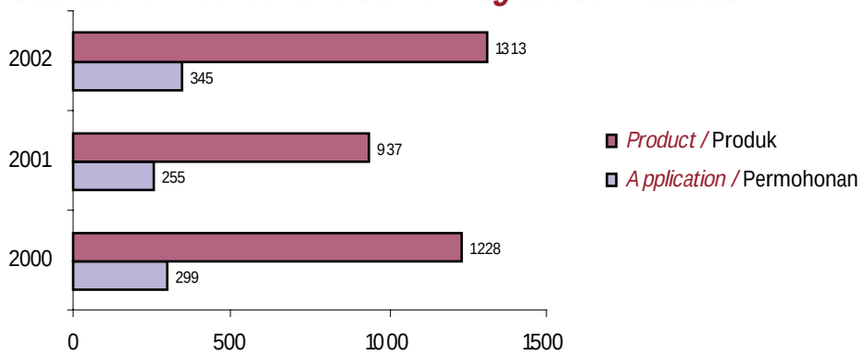
Jumlah permohonan yang diproses pada tahun 2002 adalah sebanyak 345 dan ini meliputi sebanyak 1313 produk.

Additional Lists for Registered Products

The total number of application processed in 2002 was 345 and these include 1313 products.

Rajah 8: Statistik bagi pengeluaran Senarai Tambahan Keluaran Berdaftar

Figure 8: Statistic for Additional Lists for Registered Products



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Pertukaran Pemegang Lesen

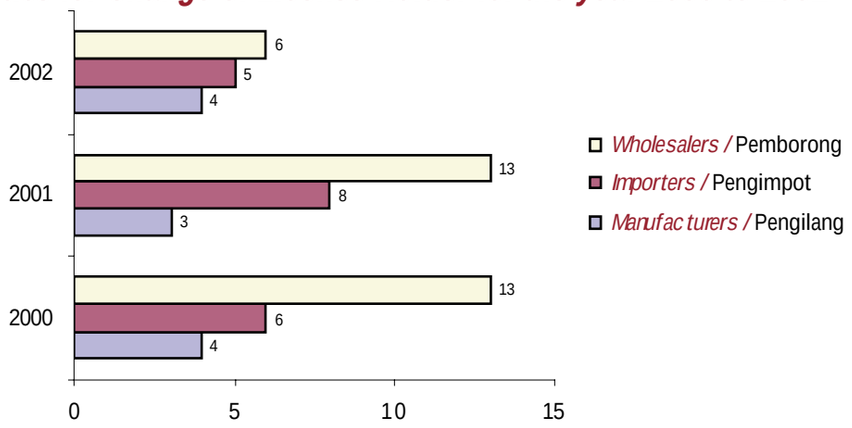
Bagi tahun 2002, sebanyak 30 permohonan pertukaran pemegang lesen telah diproses.

Change of License Holder.

A total of 30 applications for change of license holder were processed in the year 2002.

Rajah 9: Statistik Pertukaran Pemegang Lesen dari tahun 2000 hingga 2002

Figure 9: Statistics for Change of License Holder for the year 2000 to 2002



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Perakuan APB Untuk Tujuan Ekspot

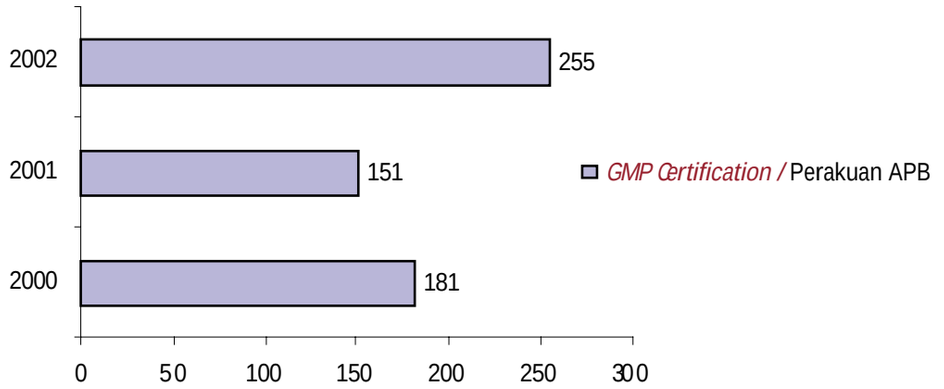
Pada tahun 2002, jumlah perakuan APB yang dikeluarkan adalah sebanyak 255. Perakuan ini adalah untuk negara-negara seperti Albania, Barbados, Botswana, Brazil, Brunei, Bulgaria, Kemboja, China, Costa Rica, Denmark, Mesir, Ethiopia, Honduras, Hong Kong, India, Iraq, Jordan, Kenya, Korea, Kuwait, Laos, Libya, Lithuania, Malawi, Maldives, Malta, Mauritius, Mexico, Morocco, Myanmar, New Zealand, Nigeria, Oman, Papua New Guinea, Filipina, Poland, Arab Saudi, Sierra Leone, Singapura, Slovakia, Sri Lanka, Afrika Selatan, Surinam, Taiwan, Tanzania, Thailand, Turki, Uganda, Venezuela, Vietnam, Yaman dan Zambia.

GMP Certification for Export Purposes

In 2002 the total number of GMP certificates issued was 255. These certification are for countries such as Albania, Australia, Barbados, Botswana, Brazil, Brunei, Bulgaria, Cambodia, China, Costa Rica, Denmark, Egypt, Ethiopia, Honduras, Hong Kong, India, Iraq, Jordan, Kenya, Korea, Kuwait, Laos, Libya, Lithuania, Macau, Malawi, Maldives, Malta, Mauritius, Mexico, Morocco, Myanmar, New Zealand, Nigeria, Oman, Papua New Guinea, Philippines, Poland, Saudi Arabia, Sierra Leone, Singapore, Slovakia, Sri Lanka, South Africa, Sudan, Suriname, Taiwan, Tanzania, Thailand, Turkey, Uganda, Venezuela, Vietnam, Yemen, and Zambia.

Rajah 10: Pengeluaran Perakuan APB untuk Tujuan Ekspot

Figure 10: Issuance of GMP Certification for Export Purposes



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Tindakan Punitif

Pihak Berkuasa Kawalan Dadah (PBKD) telah menggantung lesen pengilang atau sebahagian daripada pengeluaran premis pada tahun 2002. Lesen bagi empat pengilang tradisional telah ditarik balik kerana terlibat dengan pengeluaran produk yang tercemar.

TWG GMP

Kumpulan Kerja Teknikal (TWG) telah menganjurkan empat bengkel latihan APB bercorak modul untuk industri farmaseutikal. Bidang-bidang yang diliputi adalah seperti berikut:

Modul 1 - Quality Assurance and GMP Auditing

Modul 2 - GMP Documentation and Records

Modul 3 - Introduction to Good Laboratory Practices

Modul 4 - GMP for Utilities & Services

Seminar APB

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) sebagai pusat kolaborasi WHO untuk regulasi telah diberi kepercayaan untuk terlibat sebagai pelatih atau penasihat kepada penilaian implementasi Garispanduan APB ubat-ubatan bagi pegawai Biro Makanan Dan Ubatan, Jabatan Kesihatan, Filipina. Program ini telah dikelolakan dengan jayanya oleh pegawai dari Bahagian APB & Pelesenan bermula dari 13 Mei 2002 hingga 6 Jun 2002.

Pada Oktober 2002, seorang pegawai telah dijemput sebagai pensyarah ke seminar 2 hari tentang “cGMP support system” yang dikelolakan bersama oleh Biro Makanan Dan Ubatan Jabatan Kesihatan Filipina, Pertubuhan Industri Ubat Filipina, Chamber of the Filipino Drug Manufacturers and Distributors dan Pertubuhan Ubat Filipino yang berlangsung di Manila.

Pembentangan Panduan PIC/S mengenai produk perubatan dan radiofarmaseutikal telah dikendalikan untuk personel Pusat Penyelidikan Teknologi Nuklear Malaysia. Latihan ini adalah bertujuan untuk melengkapkan mereka dengan cGMP yang diperlukan untuk radiofarmaseutikal.

Permohonan Untuk Menjadi Ahli PIC/S

Pada 1 Januari 2002, Malaysia telah menjadi ahli ke 26 bagi “Pharmaceutical Inspection Cooperation Scheme (PIC/S).” “Pharmaceutical Inspection Convention (PIC)” dan PIC/S adalah satu persetujuan kerjasama yang informal dan fleksibel di antara pihak berkuasa pemeriksaan dimana mereka memberi kerjasama yang aktif serta membina dalam bidang APB. Di rantau Asia, hanya Australia dan Singapura yang merupakan ahli kepada PIC/S, manakala pihak-pihak lain adalah daripada negara-negara Eropah.

Punitive Actions

DCA has temporarily suspended manufacturer's licenses or part of manufacturing lines for premises in 2002. Four traditional manufacturing facilities had their license revoked; these facilities were involved with manufacturing of adulterated products.

TWG GMP

GMP Technical Working Group (TWG) has conducted four training workshop in GMP modular for local pharmaceutical industries (similar modules as in previous year). The modules carried out were:

Module 1 - Quality assurance and GMP auditing

Module 2 - GMP documentation and records

Module 3 - Introduction to Good Lab. Practices

Module 4 - GMP for Utilities & Services

GMP Seminar

NPCB as the WHO collaborating centre for regulatory has been entrusted to participate as trainer / consultant in the assessment of the implementation of current GMP guidelines for drugs with Drugs inspectors of the Bureau of Food and Drugs, Department of Health, Philippines. The program was successfully conducted by an officer from GMP & Licensing Division from 13 May 2002 to 6 June 2002.

In October 2002, an officer was invited as a lecturer at a two day seminar on cGMP support systems jointly organised by Bureau of Food and Drugs, Department of Health, Philippines, Association of Drug Industries of Philippines, Chamber of the Filipino Drug Manufacturers and Distributors and Filipino Drug Association, which was held in Manila.

Presentation on PIC/S Guide on medicinal products and radiopharmaceuticals was conducted for the personnel of Malaysian Institute for Nuclear Technology Research. The training is to update them on the cGMP that is required for a radiopharmaceutical facility.

Pharmaceutical Inspection Cooperation Scheme - PIC/S Membership

As of January 1st 2002, Malaysia became the 26th member of the Pharmaceutical Inspection Cooperation Scheme. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (jointly referred to as PIC/S) is an informal and flexible cooperative arrangement between pharmaceutical inspection authorities which provide an active and constructive co-operation in the field of GMP. Amongst the Asia region only Australia & Singapore are members of PIC/S and the other currently participating authorities in PIC/S (Convention and scheme taken together) are mostly from European countries. The accession procedures began in August 2000. The GMP & Licensing Division, NPCB was admitted following the standard PIC/S accession procedure, which was completed both rapidly and successfully.

Mesyuarat Luar Negara

Ketua Bahagian APB dan Pelesenan telah menghadiri Mesyuarat PIC/S ke 14 dan 15 di Geneva, Switzerland pada 23 dan 24 April 2002 dan di Montebello, Canada pada 8-11 Oktober 2002.

Penolong Pengarah APB dan Pelesenan telah menghadiri mesyuarat "ACCSQ Products Groups On Pharmaceutical" yang ke 5 pada bulan Februari 2002 di Yangoon, Myanmar dan mesyuarat "ACCSQ Cosmetics Product Group" yang ke 5 & 6 di Bangkok. Malaysia selaku negara yang mengetuai APB Kosmetik telah mengambil bahagian dengan aktifnya di dalam mesyuarat tersebut.

Juruaudit Kontrak

Latihan APB telah disediakan kepada Juruaudit Kontrak. Kerjasama dengan Unit Penguatkuasa Negeri telah dipertingkatkan melalui pemeriksaan bersama dalam pemeriksaan pra-pelesenan ke atas pengilang produk tradisional, farmaseutikal dan produk bukan racun. Semasa latihan tersebut, juruaudit kontrak didedahkan kepada prosedur semasa unit APB dan Pelesenan yang merujuk kepada pemeriksaan.

PERANCANGAN UNTUK TAHUN 2003

Latihan APB Farmaseutikal Bercorak Modul

Program latihan APB bercorak modul akan bermula pada Februari dan berakhir pada Jun 2003. Program ini dikelolakan bersama dengan MOPI.

Modul 5 - GMPs for Equipment, Cleaning and Computerized System

Modul 6 - Process Validation, Plan and Protocol

Modul 7 - Facility, Materials and Environment Control

Modul 8 - Process Control – Manufacturing and Packaging

Modul 9 - Staff Development and GMP Training

Pusat Industri Farmaseutikal

Menjalankan pengubahsuaian terakhir ke atas Pusat Industri Farmaseutikal dan melengkapkan infrastruktur pusat ini dengan perabot dan bahan-bahan pameran. Setelah lengkap, pusat ini akan menjadi pusat rujukan bagi semua pengilang-pengilang.

Meetings Abroad.

The head of GMP & Licensing attended the 14th & 15th PIC/S Meetings, which were held in Geneva, Switzerland from 23-24 April 2002 and Montebello, Canada from 8-11 October 2002.

Assistant Directors, of GMP & Licensing Division attended the 5th Meeting of the ACCSQ Products Groups on Pharmaceutical in February 2002 in Yangoon, Myanmar and the 5th & 6th Meetings of the ACCSQ Cosmetics Product Group, both held in Bangkok. Malaysia as the lead country for cosmetic GMP took part actively during the meetings.

Contract Auditor

GMP training was provided to Contract Auditors. The cooperation with the State Enforcement Unit was enhanced by joint inspections in the pre-licensing inspections of traditional medicines, pharmaceuticals and over the counter (OTC) manufacturers. During the training, the contract auditors were exposed to current procedures adhered by the GMP & Licensing Division with respect to inspections.

PLANS FOR YEAR 2003

GMP Modular training

The GMP modular training will start in February and end in June 2003. This program is jointly organised with MOPI.

Module 5 - GMPs for Equipment, Cleaning and Computerized System

Module 6 - Process Validation, Plan and Protocol

Module 7 - Facility, Materials and Environment control

Module 8 - Process Control - Manufacturing and Packaging

Module 9 - Staff Development and GMP training

Pharmaceutical Industry Centre

To carry out final renovation of the Pharmaceutical Industry Centre, to equip the centre with furniture and exhibits. When completed, the centre will be a reference centre for manufacturers.

Keahlian PIC/S

Oleh kerana Malaysia akan menjadi ahli PIC/S menjelang 1 Januari 2002, BPFK akan terlibat di dalam pelbagai aktiviti PIC/S seperti mesyuarat, seminar, bengkel latihan, pemeriksaan bersama dan sebagainya. Sebagai ahli baru, Malaysia digalakkan untuk menyertai seberapa banyak aktiviti yang dianjurkan bagi memastikan bahawa Malaysia memainkan peranan yang aktif sebagai ahli PIC/S.

Bengkel Dokumentasi APB untuk Pengilang Ubat Tradisional

Bengkel mengenai dokumentasi sangat berguna kepada pengilang-pengilang ubat tradisional. Pertubuhan atau badan-badan berkenaan akan diminta untuk bersama-sama mengelolakan bengkel-bengkel tersebut untuk ahli-ahli mereka dan lain-lain.

ASEAN Pharmaceutical Harmonisation

Sebagai ahli negara-negara ASEAN, Malaysia telah menyumbang dan memainkan peranan yang aktif di dalam 'harmonisation of ASEAN Pharmaceutical'. Sebagai ahli PIC/S pula, Malaysia akan memainkan peranannya dalam memastikan bahawa keperluan semasa APB selaras dengan garispanduan antarabangsa.

Meetings / Training Abroad

As Malaysia will be a member of PIC/S by 1 January 2002, we will be involved in a lot of PIC/S activities such as meetings, seminars, training, joint inspections and others. Malaysia as a new member is encouraged to join as many activities as possible to ensure that we play an active role as a member.

GMP Documentation Workshop for Traditional Medicine Manufacturers

The workshop on documentation will be very useful for traditional medicine manufacturers. The respective organisation or bodies will be asked to jointly organise the workshops for their members and others.

ASEAN Pharmaceutical Harmonisation

Malaysia as a member of ASEAN Nation has contributed and played an active part in the harmonisation of ASEAN Pharmaceutical. As a member of PIC/S, Malaysia will play its part to ensure that the current GMP requirements will harmonize with the international guidelines.

BAHAGIAN SURVEILANS DAN FARMAKOVIGILANS

OBJEKTIF

Objektif Bahagian Surveilans dan Farmakovigilans adalah untuk memastikan secara berterusan bahawa semua keluaran yang berdaftar dengan Pihak Berkuasa Kawalan Dadah adalah selamat, berefikasi dan memenuhi tahap kualiti yang diiktiraf.

PENCAPAIAN

Secara kesimpulan, pencapaian bahagian ini terbahagi kepada tiga aktiviti utama iaitu surveilans rutin, penyiasatan ke atas aduan mengenai produk dan pemonitoran profil keselamatan produk seperti yang ditunjukkan dalam **Gambarajah 1.**

SURVEILLANCE & PHARMACOVIGILANCE DIVISION

OBJECTIVE

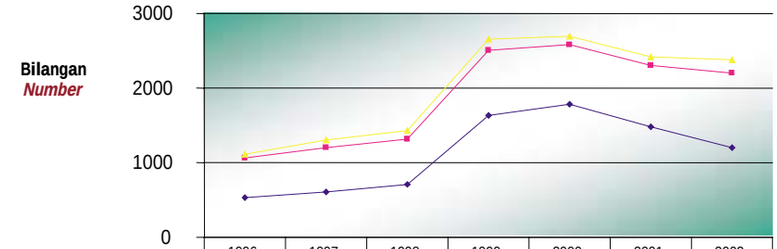
The objective of the Surveillance and Pharmacovigilance Division is to ensure that products registered by the Drug Control Authority (DCA) are safe, efficacious and comply with established standards of quality.

ACHIEVEMENTS

*The achievements of this division are summarised under the three main activities conducted i.e. routine surveillance, investigation of product complaints and the monitoring of the safety profile of products as shown in **Figure 1**.*

Gambarajah 1: Aktiviti surveilans, penyiasatan ke atas aduan mengenai produk dan pemonitoran kesan sampingan (ADR).

Figure 1: Workload under the activities of surveillance, investigation of product complaints and ADR monitoring.



	1996	1997	1998	1999	2000	2001	2002
No. of complaints recorded Bilangan aduan yang direkod	55	97	111	151	110	124	181
No. of ADR reports recorded Bilangan laporan ADR yang direkod	530	602	603	875	792	811	1000
No. of products sampled Bilangan produk yang disampel	531	602	714	1635	1789	1487	1201

Tahun ***Year***

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

SURVEILANS

Bagi tahun 2002, 1201 sampel keluaran berdaftar telah diambil untuk tujuan surveilans. Ini mewakili 4.14% jumlah keluaran yang berdaftar dibawah PBKD iaitu 28,959 keluaran. Akan tetapi, perlu diingatkan bahawa bukan semua keluaran yang berdaftar berada dalam pasaran. Walaupun jumlah keluaran berdaftar yang berada di pasaran tidak diketahui, peratusan keluaran yang disampel kemungkinan lebih tinggi berbanding dengan jumlah sebenar di pasaran.

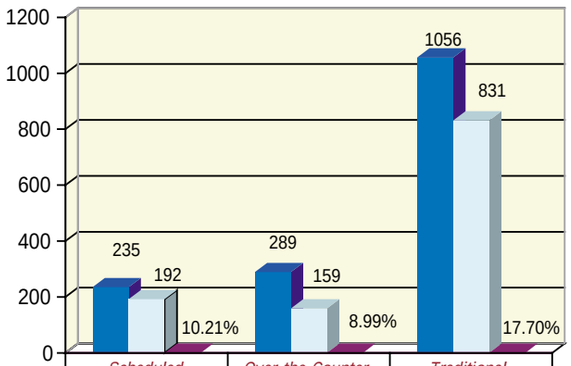
Kesemua sampel yang diambil di bawah program surveilans ini dihantar ke Bahagian Analisis Ubat untuk dianalisa. Ujian ke atas produk yang mengandungi racun berjadual (ubat preskripsi) dan persediaan bukan racun dijalankan mengikut protokol analisa terkini yang dikemukakan oleh pengilang. Ujian ke atas ubat-ubatan tradisional dijalankan berpandukan ujian yang ditetapkan, contohnya, ujian-ujian untuk pencemaran mikrob dan kulat, logam berat serta ujian-ujian farmaseutikal asas.

SURVEILLANCE

During the year 2002, a total of 1201 samples of registered products were collected for the purpose of surveillance. This represents 4.14% of the total number of products registered by the DCA, which is 28959. However, a fact to note is that not all the products which are registered are marketed. As the number of products actually being marketed is not available, the percentage of products sampled probably is higher in terms of actually marketed products.

All the samples picked up under the surveillance program were sent to the Drug Analysis Division for testing. Testing of products containing scheduled poisons (prescription drugs) and over-the-counter drugs were carried out in accordance to the latest protocols of analysis supplied by the manufacturers. Testing of traditional medicines was done in line with the established tests for this group of products, i.e. testing for microbial and fungal contamination, heavy metals and basic pharmaceutical tests.

Gambarajah 2: Keputusan ujian makmal untuk sampel surveilans.
Figure 2: Results of laboratory testing of surveillance samples



	Scheduled Poisons (Racun Berjadual)	*Over-the-Counter Products* (Produk OTC)	*Traditional Medicines* (Ubat Tradisional)
No. Tested (Bilangan Diuji)	235	289	1056
No. Passed (Bilangan Lulus)	192	159	831
% Failed (% Gagal)	10.21%	8.99%	17.70%

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Disebabkan lebihan dari tahun sebelumnya, keputusan daripada makmal adalah untuk 1495 keluaran. Analisis kadar kegagalan keluaran yang telah diuji berdasarkan kategori keluaran ditunjukkan pada **Gambarajah 2.**

Due to a spillover from the previous year, results were received from the laboratory for 1495 products. An analysis of the failure rate of products tested by category of products is shown in ***Figure 2.***

PANGGILBALIK

Bukan kesemua produk yang gagal ujian makmal memerlukan panggilbalik. Sekiranya kegagalan ujian tersebut tidak mempengaruhi kualiti produk secara ketara, surat amaran dikemukakan kepada pemegang pendaftaran.

Arahan telah dikeluarkan untuk membuat Panggilbalik Tahap 1 (dalam tempoh 24 jam) untuk 1 keluaran racun dan 2 keluaran tradisional. Terdapat 1 keluaran racun dikenakan arahan Panggilbalik Tahap 2 (dalam tempoh 72jam).

150 kelompok keluaran telah dikenakan arahan Panggilbalik Tahap 3 (dalam tempoh 30 hari) iaitu 18 keluaran racun, 20 keluaran bukan racun dan 112 keluaran tradisional. Kesemua panggilbalik dilakukan sehingga tahap peringkat penjualan/pembekalan kepada pelanggan. Tiada panggilbalik yang dilakukan memerlukan sehingga ke peringkat pelanggan. 44 kelompok keluaran telah secara sukarela dipanggilbalik oleh pemegang keluaran berdaftar iaitu 35 keluaran racun dan 9 keluaran bukan racun.

RECALLS

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 products, warning letters are issued to the registration holders.

Instructions were issued for three Degree I Recalls (within 24 hours) of which 1 product was a prescription drug and two were traditional medicines. There was one Degree 2 Recall (within 72 hours) for a prescription drug product.

150 directives were issued for Degree 3 Recalls (within 30 days) involving 18 prescription drugs, 20 over-the-counter products and 112 traditional medicines. All the recalls were up to the point of sale. There were no recalls which warranted recalling up to the consumer level. Forty-four product recalls were instituted voluntarily by the product registration holders for 35 prescription drugs and 9 OTC products.

Jadual 1: Panggilbalik Keluaran (atas arahan + sukarela)
Table 1: Product Recalls (directive + voluntary)

Tahun *Year*	1999			2000			2001			2002		
Jumlah *Total*	148			122			148			198		
Kategori *Category (A/X/T)*	35	20	93	22	13	87	32	17	99	55	29	114

A=Racun *(Poisons)*; X=OTC; T=Ubat Tradisional *(Traditional Medicine)*

ADUAN TERHADAP KELUARAN BERDAFTAR

Bilangan aduan terhadap keluaran berdaftar bertambah ke 181 aduan dalam tahun 2002 berbanding 124 aduan dalam tahun 2001. Tindakan susulan telah diambil untuk menyelesaikan aduan-aduan ini dalam tempoh 6 minggu untuk lebih daripada 95% kes.

PEMONITORAN ADR

Terdapat sedikit peningkatan dalam jumlah laporan kesan advers ubat yang diterima dalam tahun 2002, iaitu sebanyak 1000 laporan berbanding dengan 811 laporan pada tahun 2001 **(Gambarajah 3)**.

Bilangan laporan yang diterima daripada pelbagai negeri ditunjukkan pada **Gambarajah 4** dengan jumlah laporan tertinggi yang dihantar adalah dari Hospital Kuala Lumpur dan negeri Wilayah Persekutuan Kuala Lumpur.

PRODUCT COMPLAINTS

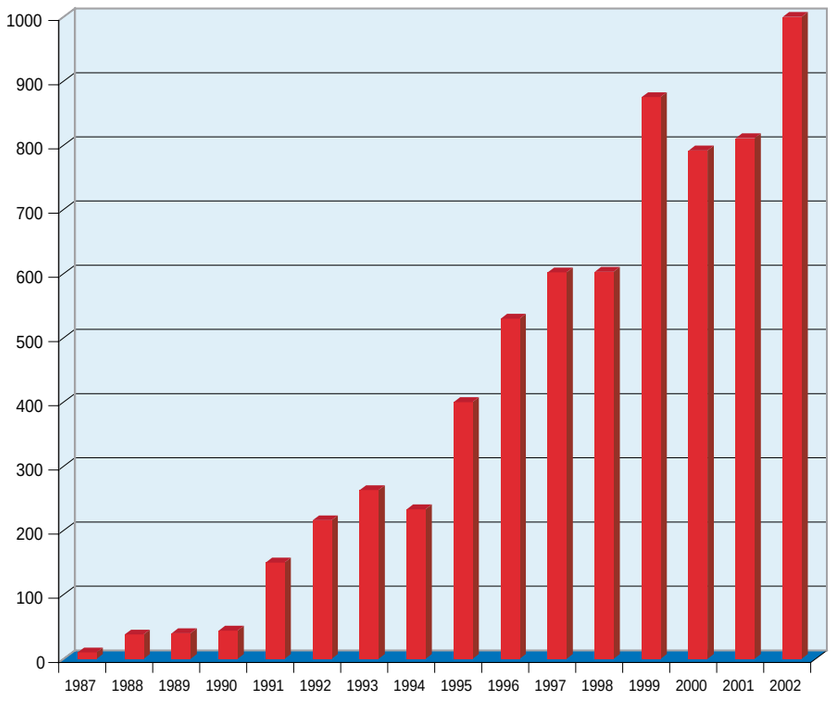
The number of product complaints for registered products increased in 2002 with a total of 181 complaints being received, as compared to 124 in the previous year. Action was taken to resolve these complaints within 6 weeks in more than 95% of the cases.

ADR MONITORING

The number of adverse drug reaction reports received increased in 2002 as a total of 1000 reports were received, as compared to 811 in 2001 ***(Figure 3)****.*

The reporting rate from the various states is as shown in ***Figure 4*** *with the highest number of reports being submitted from the Kuala Lumpur General Hospital and from the state of Wilayah Persekutuan Kuala Lumpur.*

Gambarajah 3: Bilangan Laporan ADR yang Diterima
Figure 3: Number of ADR Reports Received



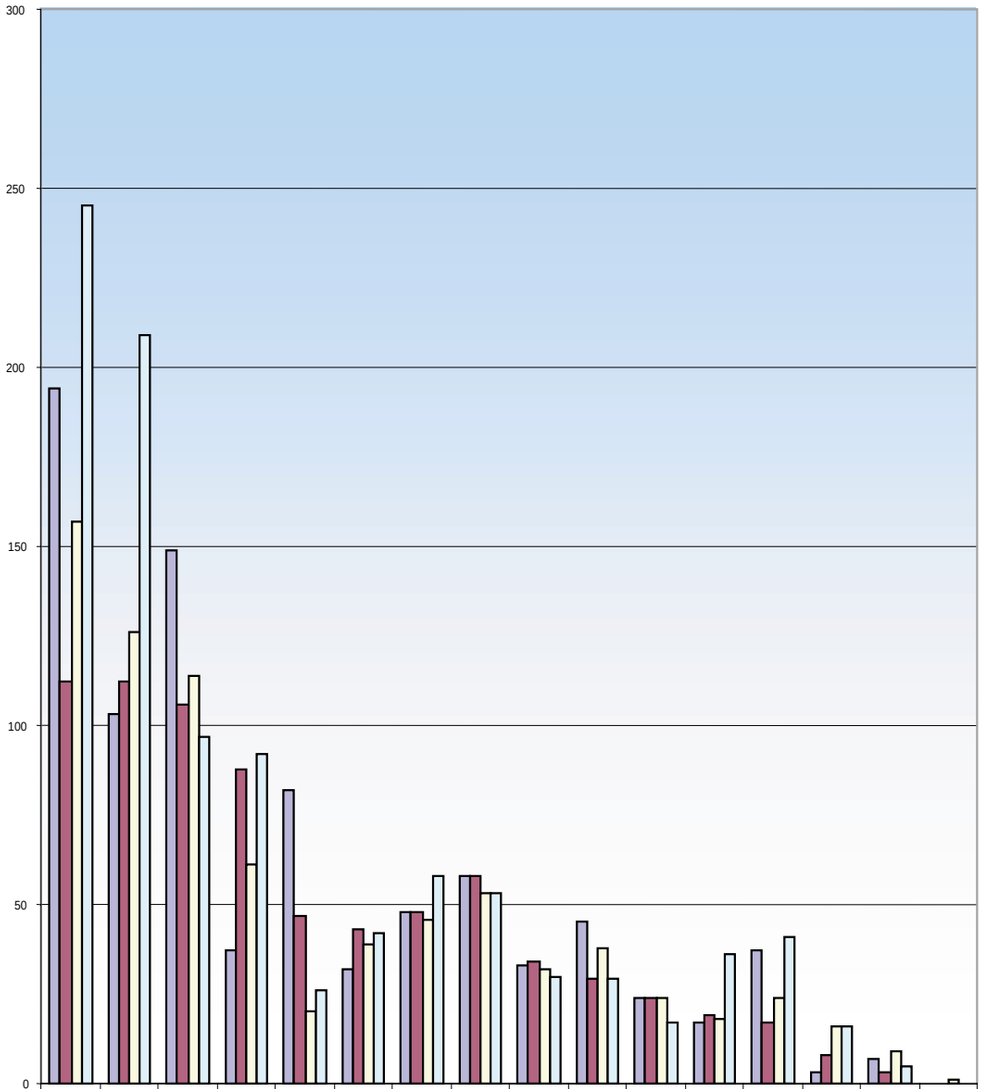
Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Seminar telah diadakan untuk pegawai farmasi di hospital untuk menggalakkan kaedah multidisiplin bagi memperbaiki kadar laporan ADR yang sebelum ini bergantung sepenuhnya pada doktor dan sektor publik. Berikutan dengan seminar ini, prosedur baru diadakan bagi pemonitoran ADR. Prosedur ini telah diedarkan ke hospital, badan-badan profesional dan industri. Prosedur ini juga terdapat di laman web BPFK.

A seminar was held for hospital pharmacists in an effort to encourage a multidisciplinary approach to improve the reporting rate of ADRs, which previously relied mainly on doctors in the public sector. In conjunction with this seminar, the new guidelines on ADR monitoring were launched. The ADR guideline was distributed to hospitals, professional associations and the industry. The guideline was also made available on the NPCB website.

Gambarajah 4 : Analisa Laporan ADR Berdasarkan Negeri Yang Melaporkan

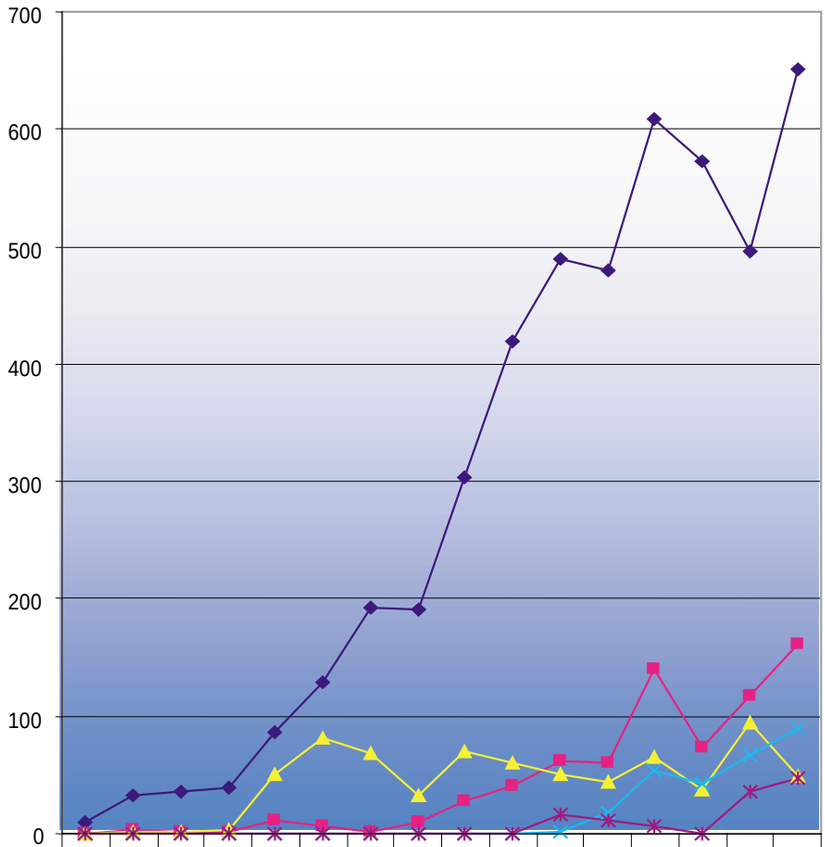
Figure 4 : Analysis of ADRs by Reporting States



	WPKL	SELANGOR	PERAK	JOHOR	PAHANG	SARAWAK	SABAH	N. SEMBILAN	P. PINANG	TERENGGANU	KEDAH	KELANTAN	MELAKA	WP. LABUAN	PERLIS	PUTRA JAYA
1999	194	103	149	37	82	32	48	58	33	45	24	17	37	3	7	0
2000	112	112	106	88	47	43	48	58	34	29	24	19	17	8	3	0
2001	157	126	114	61	20	39	46	53	32	38	24	18	24	16	9	1
2002	245	209	97	92	26	42	58	53	30	29	17	36	41	16	5	0

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Gambarajah 5: Analisa Laporan ADR Berdasarkan Kepada Pelapor
Figure 5: Analysis of ADR Reporters



	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Government Doctors Doktor Kerajaan	10	32	36	39	87	129	193	191	303	419	489	480	608	573	496	651
Pharmacists Pegawai Farmasi	0	3	2	1	12	6	2	9	27	40	62	61	141	74	118	162
Private Practitioners Doktor Swasta	0	1	2	4	51	81	68	33	70	61	51	44	66	38	94	49
Industry Industri	0	0	0	0	0	0	0	0	0	0	1	18	54	43	67	90
University Universiti	0	0	0	0	0	0	0	0	0	0	16	11	7	0	36	47

Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

PENJAWATAN

Terdapat beberapa perubahan ketara pada tahun 2002 dengan peningkatan jumlah jawatan untuk Pegawai Farmasi U3. Oleh itu, bahagian ini sekarang mempunyai jawatan bagi seorang Pegawai Farmasi U2 dan tiga orang Pegawai Farmasi U3, yang semuanya telah diisi pada tahun ini.

PRESENTASI

Selaras dengan polisi Biro Pengawalan Farmaseutikal Kebangsaan untuk memberi latihan kepada industri dan menyebarkan maklumat kepada pengguna terakhir, bahagian ini terlibat dalam penyampaian beberapa kertas pada pelbagai forum dalam topik berkaitan dengan surveilans dan pemonitoran keselamatan ubat.

PERANCANGAN

Berikutan kes yang melibatkan adulterasi ubat-ubatan tradisional, telah ditetapkan bahawa semua sampel untuk tujuan surveilans akan diambil oleh Pegawai Surveilans atau Pegawai Penguatkuasa Farmasi Negeri. Sampel yang dihantar oleh syarikat sendiri tidak akan diterima pada masa akan datang. Selain dari surveilans rutin, Bahagian Surveilans juga merancang untuk menjalankan surveilans berdasarkan isu-isu khusus, contohnya, pengskrinan ubat-ubatan tradisional untuk adulterasi.

Satu program latihan ADR khususnya untuk industri sedang dirancang demi mempertingkatkan pelaporan ADR, terutamanya bagi ubat-ubat yang baru diperkenalkan dalam pasaran Malaysia.

STAFFING

The year 2002 saw some changes in this division with an addition of a post for a U3 pharmacist. As such, the division now had one U2 and three U3 posts for pharmacists, all of which were filled during the course of the year.

PRESENTATIONS

In line with the National Pharmaceutical Control Bureau's policy to provide training for the industry and to disseminate information to end-users, this division was involved in presenting several papers at various forums on topics pertaining to surveillance and drug safety monitoring.

FUTURE PLANS

In view of the cases involving adulteration of traditional medicines, it was decided that all samples for surveillance would be collected by the surveillance staff or by state pharmacy enforcement officers in future. Samples submitted by the companies themselves would not be accepted in future. Besides the routine surveillance of registered products, the surveillance division plans to conduct surveillance based on specific issues such as screening of traditional medicines for adulteration.

An ADR training program especially for industries is being planned in a move to improve the reporting of ADRs, especially for new drugs introduced into the Malaysian market.

BAHAGIAN ANALISIS UBAT

DRUG ANALYTICAL DIVISION

PENGENALAN

Bahagian Analisis Ubat (BAU) merupakan salah satu daripada bahagian utama Biro Pengawalan Farmaseutikal Kebangsaan (BPFK). Sejajar dengan matlamat organisasi, BAU sekali lagi telah berjaya meneruskan peranan yang efektif dalam pengawalan kualiti produk yang merupakan satu elemen penting dalam penilaian produk-produk farmaseutikal, tradisional dan kosmetik. Produk-produk yang diterima merangkumi produk untuk permohonan pendaftaran, pengawasan ke atas produk berdaftar di pasaran, kes-kes aduan untuk produk berdaftar dan sampel penguatkuasaan. Ujian-ujian yang dijalankan meliputi ujian fisiko-kimia, farmaseutik, farmakologi, toksikologi, biokimia dan mikrobiologi, yang mana kriteria penerimaan keputusannya adalah berasaskan farmakopia, spesifikasi dalaman, atau had/spesifikasi pengilang yang diluluskan.

Selaku salah satu komponen pusat kolaborasi Pertubuhan Kesihatan Sedunia (WHO) di bidang kawalan regulatori farmaseutikal, BAU dilengkapi dengan peralatan dan teknik moden serta tenaga profesional yang berpengetahuan dan mahir. Justeru itu, BAU berupaya menyediakan latihan dalam aspek kawalan mutu produk untuk personel-personel tempatan dan luar negara.

PENCAPAIAN

Pencapaian BAU bagi tahun 2002 adalah seperti berikut:

BEBAN KERJA

Sepanjang tahun 2002, sebanyak 3,932 sampel untuk pengujian telah diterima oleh BAU. Ini terdiri daripada 63% sampel pendaftaran, 25% sampel pengawasan, 7% sampel aduan dan 5% sampel dari Unit Penguatkuasa Farmasi (UPF) dan lain-lain **(Rajah A)**.

INTRODUCTION

Drug Analytical Division (DAD) is one of the major divisions of National Pharmaceutical Control Bureau (NPCB). In line with the objective of the organisation, DAD continues to play an effective role in the quality control assessment of products, which is an important element in the evaluation of pharmaceutical, traditional and cosmetic products. The products received include products submitted for registration, post marketing surveillance of registered products, registered products with complaints and products from enforcement activities. The tests conducted include physico-chemical, pharmaceutical, pharmacological, toxicological, biochemical and microbiological tests, in which the acceptance criteria are based on pharmacopoeial, in-house or approved manufacturers' limits and specifications.

As a component of the collaboration centre for World Health Organisation in pharmaceutical regulatory control, DAD is well equipped with modern technical facilities and skilled human resources. Thus, DAD is able to conduct training in the pharmaceutical quality control aspect for personnel from local and abroad.

ACHIEVEMENT

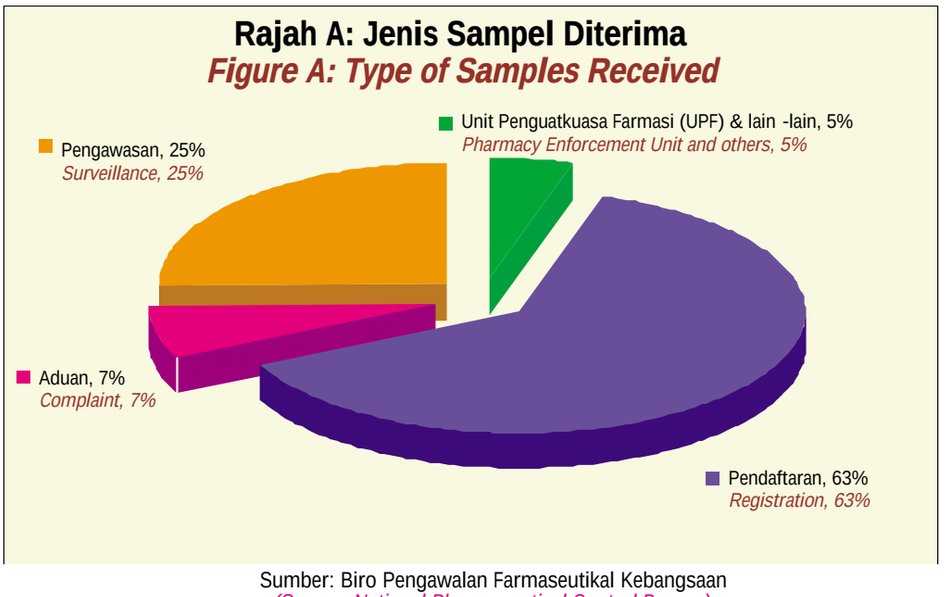
The achievements of DAD in 2002 are summarised as follows:

WORKLOAD

*Throughout the year 2002, DAD received a total of 3,932 samples for testing comprising of 63% registration samples, 25% post marketing surveillance samples, 7% complaint samples and 5% samples from the Pharmacy Enforcement Unit and others (**Figure A)**.*

Rajah A: Jenis Sampel Diterima

Figure A: Type of Samples Received

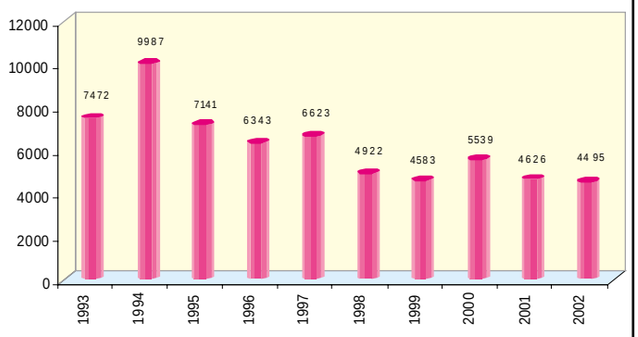


Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

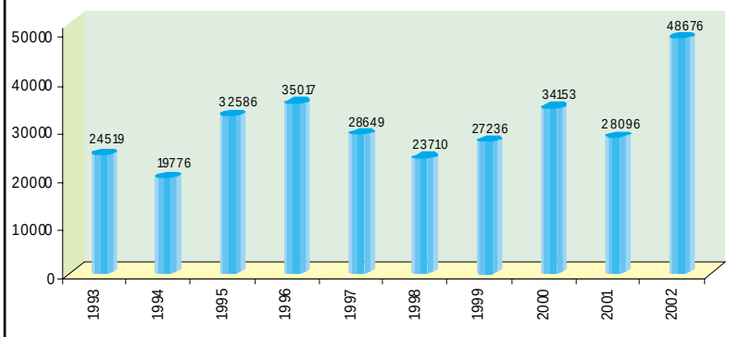
Sebanyak 4,495 sampel telah diuji **(Rajah B)** yang melibatkan sebanyak 48,676 ujian **(Rajah C)**. Berbanding dengan pencapaian tahun 2001, bilangan sampel yang diuji telah menurun sebanyak 2.8%, sebaliknya bilangan ujian yang dijalankan telah meningkat sebanyak 73.2%. Ujian had mikrobial adalah di antara ujian yang menyebabkan peningkatan yang ketara dalam bilangan ujian, iaitu daripada 14,048 ujian pada tahun 2001 kepada 27,116 ujian pada tahun 2002.

*A total of 4,495 samples were tested **(Figure B)**, which generated 48,676 tests **(Figure C)**. In comparison to the achievements in 2001, the number of samples analysed decreased by 2.8% while the number of tests done increased by 73.2%. Among the tests that contributed to this significant increase is microbial limit test, where the number of tests has risen from 14,048 in 2001 to 27,116 in 2002.*

Rajah B: Bilangan Sampel Diuji
Figure B: Number of Samples Analysed



Rajah C: Bilangan Ujian Dijalankan
Figure C: Number of Tests Done

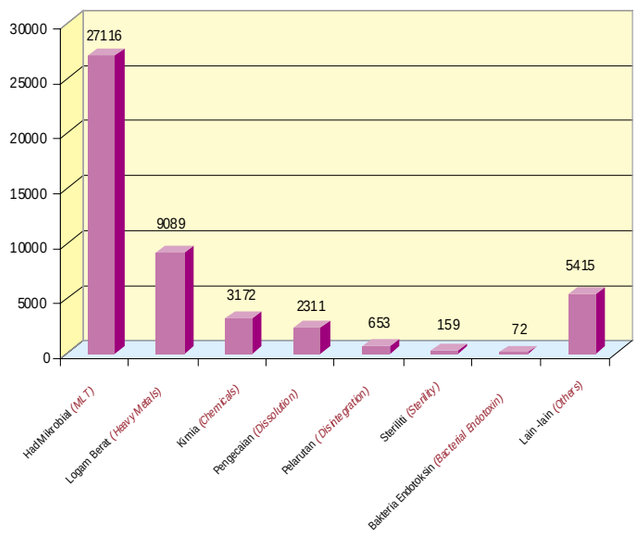


Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Jenis-jenis ujian yang dijalankan ialah ujian had mikrobial (MLT), kimia, logam berat (As, Hg, Pb, dan Cd), pengecaian, pelarutan, steriliti, bakteria endotoksin, dan lain-lain seperti toksisiti, biokimia, biologikal, bilangan partikel, serta esei antibiotik. Pecahan ujian tersebut adalah seperti dalam **Rajah D**.

*The types of tests done can be categorized as microbial limit test (MLT), chemical, heavy metals (As, Hg, Pb, and Cd), disintegration, dissolution, sterility, bacterial endotoxin and others such as toxicity, biochemical, biological, particle counts and antibiotic assay. The breakdown of the tests done is illustrated in **Figure D**.*

Rajah D: Jenis Ujian Yang Dijalankan
Figure D: Types Of Tests Done



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

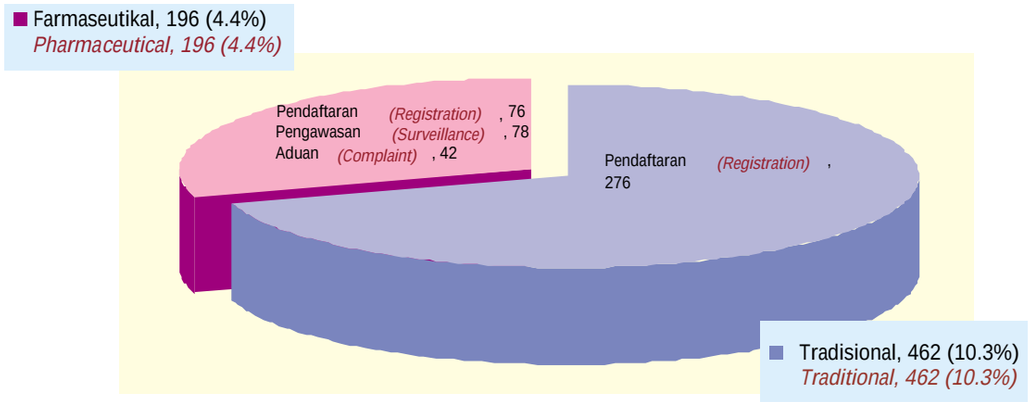
SAMPEL GAGAL UJIAN

Bilangan sampel yang gagal ujian pada tahun 2002 adalah sebanyak 658 iaitu 462 sampel produk tradisional dan 196 sampel produk farmaseutikal, yang pada keseluruhannya merangkumi sampel produk pendaftaran, pengawasan dan aduan **(Rajah E)**.

FAILED SAMPLES

*The number of failed samples in 2002 amounts to 658 samples, of which 462 are traditional samples and 196 are pharmaceuticals. These include samples from registration, surveillance and complaints **(Figure E)**.*

Rajah E : Perbandingan Sampel Gagal Ujian
Figure E : Comparison of Failed Samples



Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

BPFK telah melantik Therapeutic Goods Administration (TGA) Laboratories Australia dan SIRIM QAS Sdn. Bhd. sebagai makmal ketiga untuk menjalankan ujian ulangan ke atas sampel yang gagal ujian. Dengan persetujuan pemohon pendaftaran, 6 sampel produk farmaseutikal telah dihantar ke TGA manakala 26 sampel produk tradisional telah dihantar ke SIRIM QAS untuk ujian ulangan pada tahun 2002.

Pungutan Hasil Dari Pengujian Sampel

Pungutan hasil untuk tahun 2002 adalah sebanyak RM 744,639.00. Pertambahan dalam bilangan ujian yang dijalankan pada tahun 2002 telah menyebabkan peningkatan sebanyak 61.6% bagi yuran ujian berbanding dengan jumlah yang dipungut pada tahun 2001.

Penilaian Protokol Analisis dan Data Validasi

Sebanyak 2869 protokol analisis telah diterima pada tahun 2002. Terdapat peningkatan sebanyak 218.3% jika dibandingkan dengan bilangan protokol yang diterima pada tahun 2001 (iaitu hanya 900 protokol). Ini mencerminkan penambahan terhadap permohonan pendaftaran untuk keluaran di fasa 1 dan fasa 2. Penambahan ini telah menyebabkan sasaran piagam pelanggan BPFK (iaitu tidak kurang daripada 90%) menurun sedikit, di mana hanya 93.7% (2688) protokol dapat diselesaikan penilaiannya dalam masa satu bulan berbanding dengan tahun 2001 (97.6%).

DAD has appointed Therapeutic Goods Administration (TGA) Laboratories Australia and SIRIM QAS Sdn. Bhd. as the third laboratory to repeat tests on failed samples. With the company's agreement, 6 pharmaceutical products were sent to TGA and 26 traditional products were sent to SIRIM QAS for retesting in the year 2002.

Collection from the Analysis of Samples

The collection of analytical fees amounts to RM744,639.00. An increase in the number of tests done has resulted in an increase of 61.6% of analytical fees collected as compared to the collection made in 2001.

The Evaluation of Analytical Protocols and Data Validation

Two thousand eight hundred and sixty-nine (2869) analytical protocols were received in 2002. The figure showed an increase of 218.3% when compared to the number of protocols received in 2001 (only 900 protocols). This reflects an increase in the applications for registration of products in phase 1 and phase 2 of the registration exercise. In the year 2002, the protocol evaluations which were completed in less than one month was maintained at a high percentage, i.e. 93.7% (2688) as opposed to 97.6% in 2001, both of which complied with the NPCB QAP indicator (not less than 90%).

Piawai Rujukan

Di bawah Dasar Baru Unit Piawai Rujukan dengan matlamat pengeluaran piawai rujukan sekunder, Unit ini telah memperolehi peruntukan RM 1 juta untuk mendapatkan bahan-bahan permulaan termasuk bahan kaca, kimia dan reagen makmal, serta bahan pukal dan piawai rujukan primer. Sehingga 31 Disember 2002, 80 daripada lebih 1000 vial piawai rujukan primer yang dipesan telah diterima daripada British dan European 'Pharmacopoeial Commission'. Selain itu, sebanyak RM 500,000 telah diperuntukkan bagi pembelian 7 alat-alat analitikal bagi tujuan pengeluaran piawai rujukan sekunder ini. Alat-alat tersebut mula tiba di Unit ini dari pertengahan ke penghujung tahun 2002 dan terdiri daripada:

1. High Performance Liquid Chromatographer
2. Fourier Transform Infrared
3. Differential Scanning Calorimeter
4. Autotitrator
5. Hot Air Oven with Vacuum Pump
6. Karl Fisher Titrator
7. Ultra-Violet Spectrophotometer

Sebagai ahli dalam 'Pengeluaran dan Penggunaan Piawai Rujukan Asean' yang berpusat di Thailand, dan di bawah program Kerjasama Teknikal antara Negara-Negara Asean (Asean TCDC), Unit ini sebagai makmal utama telah menjalankan kajian kolaboratif terhadap 3 bahan iaitu:

1. Riboflavin (Vitamin B2)
2. Propylparaben
3. Methylparaben

Unit ini adalah juga sebagai salah satu rakan makmal yang bekerjasama dengan negara-negara Asean lain dalam kajian kolaboratif ke atas Dextromethorphan, Phenylpropanolamine, Dequalinium chloride dan Vancomycin hydrochloride (Singapura), serta Tetracycline hydrochloride (Thailand). Semua analisis dan kajian ke atas bahan-bahan tersebut telah berjaya diselesaikan menjelang September 2002.

Sejumlah 117 vial piawai rujukan ASEAN bernilai RM 17,550 dan 318 vial piawai rujukan BPFK bernilai RM 31,800 telah dijual kepada industri farmaseutikal tempatan dan luar negara oleh Unit ini.

Sebanyak 1068 vial piawai rujukan ASEAN/BPFK telah dibekalkan secara percuma kepada badan-badan kerajaan. Setiap vial piawai rujukan BPFK dikenakan bayaran sebanyak RM100 dan piawai rujukan ASEAN sebanyak RM150, tetapi badan-badan kerajaan menerima bekalan secara percuma.

Reference Standards

Under the Reference Standard Unit, with the one-off policy for the production of secondary reference standards, this Unit has obtained an allocation in the amount of RM 1 million for the procurement of starting materials including laboratory glassware, chemicals, reagents, bulk materials and primary reference standards. Up until 31 December 2002, 80 out of more than 1000 vials of the primary reference standards ordered have been received from the British and European Pharmacopoeial Commission. Another RM 500,000 has been allocated for the purchase of 7 analytical equipments meant for the production of the secondary reference standards. The equipments began arriving at this Unit from mid-year to the end of the year 2002. These equipments include:

1. *High Performance Liquid Chromatographer*
2. *Fourier Transform Infrared*
3. *Differential Scanning Calorimeter*
4. *Autotitrator*
5. *Hot Air Oven with Vacuum Pump*
6. *Karl Fisher Titrator*
7. *Ultra-Violet Spectrophotometer*

As a member of the 'Production and Utilization of Asean Reference Substances' with its centre in Thailand, and under the Asean Technical Cooperation among Developing Countries (TCDC) program, this Unit as the lead laboratory has undertaken the collaborative studies on 3 substances, namely;

1. *Riboflavin (Vitamin B2)*
2. *Propylparaben*
3. *Methylparaben*

This Unit is also one of the laboratory partners participating with other Asean countries in its collaborative studies on Dextromethorphan, Phenylpropanolamine, Dequalinium chloride and Vancomycin hydrochloride (Singapore) along with Tetracycline hydrochloride (Thailand). All the analysis and studies upon the said substances were successfully completed by September 2002.

One hundred and seventeen (117) vials of ASEAN reference standards worth RM 17,550 and 318 vials of NPCB reference standards worth RM 31,800 were sold to local pharmaceutical industries and abroad by this Unit.

One thousand and sixty-eight (1068) vials of ASEAN/NPCB reference standards were supplied free to the government departments. Each vial of NPCB reference standard was charged at RM100 and ASEAN reference standard at RM150 but no charges were made to the government departments.

Bahan Campur Palsu dalam Ubat Tradisional

Sepanjang tahun 2002, BAU telah memainkan peranan yang aktif dalam pengujian ke atas bahan campur palsu dalam produk tradisional berdaftar dan sampel-sampel penguatkuasaan. Sampel-sampel yang diuji diterima dari Bahagian Perkhidmatan Farmasi, Unit Penguatkuasa Farmasi Negeri dan Bahagian Surveilans BPFK.

Sejumlah 397 produk telah diuji, dan dari jumlah ini didapati 106 produk dikesan positif mengandungi bahan campur palsu seperti yang dinyatakan dalam **Jadual 1**.

Adulterants in Traditional Medicines

DAD has played an active role in testing adulterants in registered traditional medicines as a result of enforcement activities. The samples are obtained from the Pharmacy Service Division, State Pharmacy Enforcement Unit and Surveillance Division of NPCB.

*Three hundred and ninety seven (397) products were tested and 106 of those products were identified to contain adulterants as listed in **Table 1**.*

Penglibatan / Mesyuarat di Luar Negeri

Timbalan Pengarah BAU, Pn. Hasiah bte Abdullah telah menghadiri:

1. "The 5th Meeting of the Pharmaceutical Product Working Group" di Yangoon, Myanmar pada 25 hingga 27 Januari 2002.

2. "The 19th Meeting of ASEAN Working Group on Technical Cooperation in Pharmaceuticals" di Brunei Darussalam pada 26 hingga 28 Mac 2002.

3. "The Sixth Meeting of the ASEAN Consultative Committee for Standards and Quality – Product Working Group" di Siem Reap, Cambodia pada 3 hingga 6 September 2002.

Involvement / Meetings Abroad

Deputy Director of DAD, Pn. Hasiah bte Hj. Abdullah had attended:

1. *The 5th Meeting of the Pharmaceutical Product Working Group in Yangoon, Myanmar from 25 to 27 January 2002.*

2. *The 19th Meeting of ASEAN Working Group on Technical Cooperation in Pharmaceuticals in Brunei Darussalam from 26 to 28 March 2002.*

3. *The Sixth Meeting of the ASEAN Consultative Committee for Standards and Quality – Product Working Group in Siem Reap, Cambodia from 3 to 6 September 2002.*

Ketua Penolong Pengarah Makmal Mikrobiologi Farmaseutikal, Dr. Sulaikah Moideen, telah dilantik sebagai konsultan WHO ke Negara Arab Emiriyah Bersatu dari 21 hingga 29 Jun 2002 dalam bidang 'Evaluation of the Drug Control Laboratory in the United Arabic Emirates'.

Penolong Pengarah Makmal Teknologi Farmaseutikal, En. Tan Ann Ling, telah dilantik sebagai WHO Temporary Adviser ke Ho Chi Minh City, Vietnam, dari 22 hingga 27 Julai 2002 dalam bidang 'WHO Pilot Training Workshop Using Supplementary GMP Modules'.

Principal Assistant Director of the Pharmaceutical Microbiology Laboratory, Dr. Sulaikah V.K Moideen, was appointed as the WHO short-term consultant to United Arab Emirates from 21 to 29 June 2002 in Evaluation of the Drug Control Laboratory in United Arabic Emirates.

Assistant Director of the Pharmaceutical Technology Laboratory, Mr. Tan Ann Ling, was appointed as the WHO Temporary Adviser to Ho Chi Minh City, Vietnam, from 22 to 27 July 2002 in WHO Pilot Training Workshop Using Supplementary GMP Modules.

Pemeriksaan Premis untuk Pematuhan Amalan Makmal Baik

BAU masih aktif memberi khidmat sokongan dalam pemeriksaan Amalan Perkilangan Baik (APB) dalam aspek Amalan Makmal Baik. Pada tahun 2002, sebanyak 21 pemeriksaan telah dijalankan ke atas premis pengilang farmaseutikal tempatan dan bilangan ini agak menurun berbanding tahun 2001 (35 pemeriksaan).

Pada tahun 2002, pegawai farmasi di BAU telah menerokai bidang baru dengan melakukan pemeriksaan dan latihan di luar negara, iaitu sebagai konsultan jangka pendek WHO ke Negara Emiriyah Arab Bersatu dalam bidang Amalan Makmal Baik dan juga penasihat WHO ke Vietnam dalam bidang Amalan Perkilangan Baik.

Premise Inspection in Compliance to Good Laboratory Practice (GLP)

DAD continues to be active in Good Manufacturing Practice (GMP) inspections in GLP aspects. In 2002, 21 inspections were conducted on local pharmaceutical manufacturing premises and this was a decrease when compared to 2001 (35 inspections).

In the field of inspections for year 2002, the pharmacists in DAD embarked on a new field by conducting inspections and training abroad (as short term consultant to United Arab Emirates in GLP and as WHO temporary advisor in GMP).

Selain daripada itu, buat kali pertamanya BAU telah menjalankan pemeriksaan premis ke atas SIRIM QAS Sdn. Bhd. yang menjadi makmal ketiga untuk produk tradisional yang gagal ujian di makmal BPFK.

Lawatan dan Latihan

Pada 25 Februari 2002, BAU menerima kunjungan delegasi dari "Japan Pharmaceutical Manufacturers Association" (JPMA) yang telah mengadakan perbincangan dengan pihak Unit Piawai Rujukan (UPR) dan membuat lawatan ke makmal. Delegasi tersebut diwakili oleh:

1. Mr. Kazuyoshi Hirai – Director, Project Coordination Department
2. Mr. Takayoshi Matsumara – JPMA GMP Committee Member
3. Mr. Hiroyuki Arai – JPMA International Committee Member

Pada 23 Oktober 2002, 3 orang pelatih WHO dari Institute of Chinese Materia Medicine, China Academy of Traditional Chinese, Republik China, telah mengadakan lawatan sambil belajar ke BAU. Peserta tersebut adalah:

1. Mrs. Qian Wang – Professor
2. Mrs. Jinghua Fu – Assistant Professor Programme Officer
3. Dr. Ruixian Zhang – Professor

Latihan untuk Kakitangan

BAU selaku penyelaras BPFK dengan kerjasama Institut Kepimpinan Belia Negara (IKBN) telah menganjurkan Kursus Motivasi dan Pembinaan Pasukan untuk Pembantu Farmasi di Port Dickson. Kursus ini telah diadakan sebanyak 2 kali di mana kumpulan pertama telah mengikutinya pada 24 hingga 26 Mac 2002 dan kumpulan kedua pada 6 hingga 8 Oktober 2002.

BAU juga selaku penyelaras BPFK dengan kerjasama STC Professional Training telah menganjurkan Kursus Microsoft Word XP (Basics) di STC Professional Training, Kuala Lumpur. Kursus ini telah diadakan 2 kali di mana kumpulan pertama mengikutinya pada 20 hingga 21 Mei 2002 dan kumpulan kedua pada 5 hingga 6 Jun 2002.

Ahli Baru BAU

BAU mengalu-alukan kedatangan 7 orang pegawai farmasi baru iaitu Puan Siti Madziah Mohamed, Encik Chua Kong Seeng, Cik Azraini Abdul Samat, Cik Nor Hayati Abdul Rahim, Puan Zarina Rosli, Puan Mazli Muhamad dan Puan Noorul Akmar Mohd. Nur, serta 5 orang pembantu farmasi baru iaitu Cik Sheila Devi a/p Karupiah, Cik Sarimah Ismail, Cik Fatimah Said, Cik Norshahriza Ahmad dan Cik Siti Hajar Paiman.

Apart from that, DAD has for the first time inspected SIRIM QAS Sdn. Bhd., which is the third laboratory assigned to retest traditional products for NPCB.

Visits and Trainings

On the 25 February 2002, DAD welcomed the delegates from Japan Pharmaceutical Manufacturers Association (JPMA). During the visit, JPMA held discussions with the Reference Standard Unit besides visiting other laboratories. The delegates from JPMA were:

1. *Mr. Kazuyoshi Hirai – Director, Project Coordination Department.*
2. *Mr. Takayoshi Matsumara – JPMA GMP Committee member.*
3. *Mr. Hiroyuki Arai – JPMA International Committee member.*

On the 23 October 2002, three WHO Fellows from the Institute of Chinese Materia Medicine, China Academy of Traditional Chinese, Republic of China, underwent trainings in DAD. The participants were:

1. *Mrs. Qian Wang – Professor.*
2. *Mrs. Jinghua Fu – Assistant Professor Programme Officer.*
3. *Dr. Ruixian Zhang – Professor.*

Training for DAD Staff

DAD as the coordinator for NPCB, and with the cooperation of 'Institute Kepimpinan Belia Negara', had organised A Motivation and Team Building Course for the Pharmacy Assistants in Port Dickson. The course was held twice with the first group undergoing the training from 24 to 26 March 2002 and the second group from 6 to 8 October 2002.

Again, DAD as the coordinator for NPCB, and with the cooperation of STC Professional Training had organised Microsoft Word XP (Basics) Course in STC Professional Training, Kuala Lumpur. The course was held twice with the first group undergoing the training from 20 to 21 May 2002 and the second group from 5 to 6 June 2002.

New Members of DAD

DAD welcomed seven new pharmacists, namely Pn. Siti Madziah Mohamed, Mr. Chua Kong Seeng, Cik Azraini Abdul Samat, Cik Nor Hayati Abdul Rahim, Pn. Zarina Rosli, Pn. Mazli Muhamad, and Pn. Noorul Akmar Mohd. Nur, as well as five new pharmacy assistants, namely Cik Sheila Devi a/p Karupiah, Cik Sarimah Ismail, Cik Fatimah Said, Cik Norshahriza Ahmad and Cik Siti Hajar Paiman.

Penstrukturan Semula BAU

Penstrukturan semula BAU telah bermula pada 1 November 2002 dengan penubuhan Unit Perkhidmatan Makmal (UPM) yang berfungsi sebagai makmal utama, manakala makmal-makmal lain bertindak sebagai makmal setara. Peranan utama UPM adalah untuk menerima dan mengagihkan sampel-sampel kepada semua makmal setara kecuali sampel dari Unit Penguatkuasa Farmasi (UPF) yang diterima terus oleh Makmal Kimia Farmaseutikal.

Perbelanjaan

Sebanyak RM 500,000 telah diterima di bawah anggaran belanja mengurus dan RM1,398,100 di bawah peruntukan Dasar Baru 1 dan 2 untuk pembelian alat-alat makmal.

Satu lagi peruntukan khas sebanyak RM 1,700,000 telah diterima untuk pembelian peralatan makmal (Remedy Drug Profiling System, Liquid Chromatography Mass Spectrometry, dan Gas Chromatography Mass Spectrometry) bagi menangani masalah pencemaran racun berjadual dalam ubat tradisional.

Rancangan untuk Masa Depan

BAU akan bersedia untuk menghadapi cabaran baru bagi melengkapkan dan meningkatkan keupayaan agar dapat terlibat secara aktif dan efektif dalam melaksanakan fasa-fasa pendaftaran yang berikutnya. Rancangan yang dijadualkan untuk tahun 2003 adalah seperti berikut:

a) Meneruskan kajian mengenai tatacara dan teknik pengesanan racun berjadual dalam produk tradisional.

b) Meneruskan kajian pencirian bahan tumbuhan dalam produk tradisional.

c) Meneruskan kerjasama di antara negara ASEAN dengan mengambil bahagian dalam pengeluaran piawai rujukan ASEAN melalui ujian kolaboratif ke atas piawai rujukan yang dicadangkan.

d) Mendapatkan peruntukan khas di bawah Dasar Baru untuk pembelian alat-alat makmal tambahan.

e) Meneruskan usaha mengadakan latihan berterusan untuk pegawai farmasi baru dan pembantu farmasi di BAU berkaitan aspek yang melibatkan pengunaan komputer, keselamatan makmal dan latihan di bidang kromatografi, spektroskopi dan mikrobiologi.

f) Meneruskan proses penstrukturan semula BAU untuk menuju ke arah keberkesanan dan kelancaran proses kerja.

g) Meneruskan usaha mempertingkatkan sistem komputer baru (QUEST 2) untuk modul BAU.

Restructuring of DAD

Restructuring of DAD began on 1 November 2002 where the Laboratory Service Unit (LSU) was formed and functioned as the lead laboratory whilst the other laboratories become the supporting laboratories. The main role of LSU is to receive and distribute samples to all supporting laboratories except samples from the Pharmacy Enforcement Unit, which are received directly by the Pharmaceutical Chemical Laboratory.

Expenditure

A sum of RM 500,000 was received under operating allocation and expenditure and RM 1,398,100 under 'Dasar Baru 1 and 2' for the purchase of laboratory equipments.

Another sum of RM 1,700,000 was received under a special allocation for the purchase of laboratory equipments (Remedy Drug Profiling System, Liquid Chromatography Mass Spectrometry, and Gas Chromatography Mass Spectrometry) to detect contamination of scheduled poisons in traditional medicines.

Future Plans

DAD shall work towards preparing itself for new challenges and to be able to play an active and effective role in the implementation of future phases of registration exercise. Several strategic plans of action are scheduled for the year 2003 and they are as follows:

a) Embarking on the research of procedures and techniques in the detection of scheduled poisons in traditional medicines.

b) Embarking on the research in the characterization of herbal ingredients in traditional medicines.

c) Continuing with the collaboration amongst ASEAN countries in the production of ASEAN reference material through collaborative testing of the suggested reference materials.

d) Acquiring special funding for the purchase of additional laboratory equipment.

e) Continuing the effort to provide a continuous training to new pharmacists and laboratory assistants in DAD in aspects involving the use of computer, laboratory safety and training in the field of chromatography, spectroscopy and microbiology.

f) Continuing the restructuring process of DAD as a move towards a more effective and smooth work process.

g) Continuing the development of the computer system (QUEST 2) for DAD module.

h) Melakukan pemonitoran terhadap sampel pendaftaran dan pengawasan untuk mengesan bahan campur palsu ke atas 4 kategori produk tradisional yang mempunyai indikasi yang berikut:

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

i) Meneruskan latihan APB (aspek Amalan Makmal Baik) untuk pegawai farmasi baru BAU yang perlu menjalani sekurang-kurangnya 3 pemeriksaan lengkap di bawah seliaan seorang pemeriksa bertauliah sebelum layak dilantik sebagai pegawai pemeriksa APB.

j) Mengadakan kursus/seminar bersama industri (MOPI) dalam bidang validasi analitikal.

k) Mematuhi ketetapan ISO dengan mengemaskini dokumen dari versi ISO 9000:1994 ke ISO 9000:2000.

h) Monitoring of registration and surveillance samples for the detection of adulterants on 4 categories of traditional medicines with the indications as stated below:

- *for men's health*
- *for joints/muscle ache*
- *to reduce/control body weight*
- *for cough and cold*

i) Continuing with the GMP trainings for new pharmacists in DAD, with the ultimate aim of completing at least 3 complete audits under the supervision of Lead Auditors before being appointed as GMP Auditors.

j) Organising courses/seminars with the industries (MOPI) on Analytical Validation.

k) Continuing to comply with ISO requirements by updating documents from ISO 9000:1994 to ISO 9000:2000 versions.

Jadual 1: Bahan Campur Palsu dalam Ubat Tradisional
Table 1: Adulterants in Traditional Medicines

Bahan Campur Palsu *Adulterants*	**Bilangan Diuji** *No. of Tests Done*	**Bilangan Dikesan Positif** *Identified Positive*
Sildenafil *Sildenafil*	103	38
Agen Pelangsing *Slimming Agents (sibutramine, fenfluramine, phentermine)*	131	17
Antihistamine / Antitussive *Antihistamine / Antitussive (chlorpheniramine, promethazine, codeine, dextromethorphan, ephedrine, phenylpropanolamine)*	45	21
Agen Pemutih *Whitening Agents (hydroquinone, tretinoin)*	22	16
Steroid *Steroids (dexamethasone, betamethasone, hydrocortisone, cortisone, prednisolone)*	60	13
Hormon *Hormones*	3	0
NSAID *NSAIDs*	23	0
Quinine *Quinine*	1	0
Benzodiazepine *Benzodiazepine*	2	0
Terbutaline / Salbutamol *Terbutaline / Salbutamol*	1	0
Camphor *Camphor*	1	1
Antidiabetic *Antidiabetics*	2	0
Antiepileptic *Antiepileptics*	1	0
Laxative *Laxatives*	2	0

BAHAGIAN PEMBANGUNAN ORGANISASI DAN TEKNOLOGI MAKLUMAT (POTM)

OBJEKTIF

Memberi perkhidmatan maklumat ubat yang berkesan kepada personel-personel yang terlibat dalam penilaian keluaran-keluaran farmaseutikal/kosmetik dan pegawai-pegawai yang terlibat dalam rawatan pesakit bagi meningkatkan lagi mutu perkhidmatan kesihatan di negara ini.

Memberi perkhidmatan penerangan kepada orang awam berkenaan dengan pendaftaran keluaran-keluaran farmaseutikal dan kosmetik.

Menyebarkan maklumat-maklumat ubat kepada organisasi-organisasi dalam sektor awam dan swasta.

PENCAPAIAN

Perkhidmatan Maklumat Ubat dan Maklumat Am

Sepanjang tahun 2002, Bahagian POTM telah menjawab sejumlah 1267 pertanyaan dari sektor awam dan sector swasta. Kebanyakan daripada pertanyaan tersebut adalah berkenaan status pendaftaran keluaran-keluaran farmaseutikal, pendaftaran kosmetik, prosedur pendaftaran ubat-ubatan, maklumat am keluaran, identifikasi produk dan nama-nama pembekal keluaran yang telah didaftarkan.

Pengelasan Keluaran

Bahagian ini bertanggungjawab ke atas semua pertanyaan berkenaan dengan klasifikasi keluaran-keluaran "borderline", sama ada keluaran-keluaran itu perlu didaftar atau tidak. Antara 762 keluaran yang diterima untuk pengkelasan dalam tahun 2002, 265 keluaran dikelaskan sebagai butiran yang tidak perlu didaftar, seperti supplemen makanan (dalam bentuk jus/minuman), keluaran-keluaran "food-based", peralatan-peralatan perubatan, dan herba-herba mentah.

Baki 497 keluaran merupakan butiran yang perlu didaftarkan seperti supplemen makanan tambahan yang mengandungi bahan tradisional dan kosmetik/keluaran penjagaan kulit.

ORGANISATIONAL DEVELOPMENT AND INFORMATION TECHNOLOGY DIVISION

OBJECTIVES

To provide an effective drug information service to officers who are involved in the evaluation of drugs/cosmetics and also to officers who are involved in patient care, in order to improve the standard of health services in the country.

To provide an effective information service to the public with regards to the registration of pharmaceutical products and cosmetics.

To disseminate drug information to organisations within the public and private sectors.

ACHIEVEMENTS

Drug Information Service and General Information on Drug Registration

In the year 2002, the OD & IT division responded to 1267 enquiries from both the public and private sectors. The majority of the enquiries were on registration status of pharmaceutical products, registration of cosmetics, registration procedures, general product information, product identification and suppliers of registered products.

Product Classification

This division handles all queries pertaining to classification of "borderline products", as to whether they are registrable or not. Out of the 762 products received for classification in 2002, 265 products were classified as non-registrable items such as food supplements in the form of juices/drinks, food-based products, medical devices and raw materials.

The remaining 497 products were registrable products, comprising mainly of dietary supplements containing traditional ingredients and cosmetics/skin care products.

Penerbitan

Penerbitan-penerbitan yang berikut telah dihasilkan dan diedarkan ke organisasi-organisasi dalam sektor awam dan swasta sepanjang tahun 2002.

(i) Berita Ubat-Ubatan (3 isu)

(ii) Pekeliling Maklumat Ubat (12 isu)

(iii) Monograf Ubat (12 isu)

(iv) Laporan Tahunan

Terbitan-terbitan tersebut juga dipaparkan dalam laman web institusi ini iaitu di www.bpfk.gov.my.

Perkhidmatan Perpustakaan

Perpustakaan ini mempunyai hampir 1685 buah buku, termasuk farmakopia-farmakopia utama dari pelbagai negara luar. Selain itu, perpustakaan ini juga melanggan 33 jenis jurnal/buletin ubat, Micromedex dan International Pharmaceutical Abstract. Perpustakaan ini dibuka kepada kakitangan BPFK sahaja. Ahli-ahli farmasi di bawah Kementerian Kesihatan boleh memohon untuk menggunakan kemudahan-kemudahan di perpustakaan ini.

Perpustakaan ini juga dilengkapkan dengan dua buah komputer yang ada kemudahan internet.

Pelawat-pelawat Antarabangsa dan Delegasi ke BPFK

Berikut adalah pelawat-pelawat ke BPFK dalam tahun 2002:-

Publications

The following publications were produced and distributed to organisations in the public and private sector in 2002.

(i) Drug Control Authority Newsletter (3 issues)

(ii) Drug Information Circular (12 issues)

(iii) Drug Monograph (12 issues)

(iv) Annual Report

The above publications are also posted at NPCB's website www.bpfk.gov.my.

Library Service

The library has about 1685 books, including the major pharmacopoeias from various countries. Besides that, it subscribes to 33 journals/drug bulletins, Micromedex and International Pharmaceutical Abstracts. The library is open to staff of the institution only. Pharmacists in the Ministry of Health may, by request, make use of the library facilities.

The library has 2 computers with internet facilities.

International Visitors and Delegations to NPCB

The following people visited NPCB in the year 2002:-

International Visitors & Delegations to NPCB 2002

Name	Country	Date	Purpose of Visit
Mr. Micheal Tillmann Managing Director Artus Biotech GmBH	Germany	21 February	Discussion on control of medical devices
Dr. Finn Zedler Head of Technical Support Artus Biotech GmBH	Germany	21 February	Discussion on control of medical devices
Mr. Kazuyoshi Hirai Director, Project Coordination Department Japanese Pharmaceutical Manufacturers Association (JPMA)	Japan	25 February	Discussion on Reference Standards & Drug Registration
Mr. Takayoshi Matsumara JPMA GMP Committee Member	Japan	25 February	As above
Mr. Hiroyuki Arai JPMA International Committee Member	Japan	25 February	As above
Mr. Daas Bandaralage Dasin Gedara Hemasiri Pharmacist, Director General of Health Services	Sri Lanka	4-28 March	WHO Fellow - Programme on Management and Maintenance of GMP
Miss Mabula Marapperuma Arachchige Chinta Hema Abayawardana Senior Pharmacist, Director General of Health Services	Sri Lanka	4-28 March	As above
Mr. Arachchige Chulanaga Gnandera Sirinath Edirisinghe Pharmacist, Director General of Health Services	Sri Lanka	4-28 March	As above
Mr. Ranhaluge Leslie Asoka Warakagoda Pharmacist, Director General of Health Services	Sri Lanka	4-28 March	As above

Name	Country	Date	Purpose of Visit
Mr. Bimal Man Shresta Senior Pharmacist Drug Information Network of Nepal, Department of Drug Administration, Katmandu	Nepal	11-22 March	WHO Fellow - Programme on GMP
Mr. Balkrishna Khakurel Pharmacist (National Operations Officer), Department of Drug Administration, Katmandu	Nepal	11-22 March	As above
Dr. Luis Saturnino Herrera Martinez	Cuba	19 March	Discussion on System of Drug Registration in Malaysia
Ms. Wilhemina Clarisse, Technician, Ministry of Health	Republic of Seychelles	1 April – 29 June	Drug Quality Control Training
Dr. Bounlonh Ketsouvannasane Director of Administration Division, Ministry of Health, Food and Drug Department, Vientane	LAO P.D.R	10-14 June	Study visit to BPFK
Dr. Keonakhone Houamboun, Head of Health System Research Department, National Institute of Public Health, Ministry of Health	LAO P.D.R	10-14 June	Study visit to BPFK
Mr. Khamphet. S. Organisation and Personnel Department	LAO P.D.R	10-14 June	Study visit to BPFK
Mr. Thavy Atxayavong Deputy Chief of Food and Drug Inspection Division, Ministry of Health, Food and Drug Department, Vientane	LAO P.D.R	10-14 June	Study visit to BPFK
Dr. Amphayvanh Panyanouvong Hospital Administration Division, Ministry of Health, Curative Department	LAO P.D.R	10-14 June	Study visit to BPFK

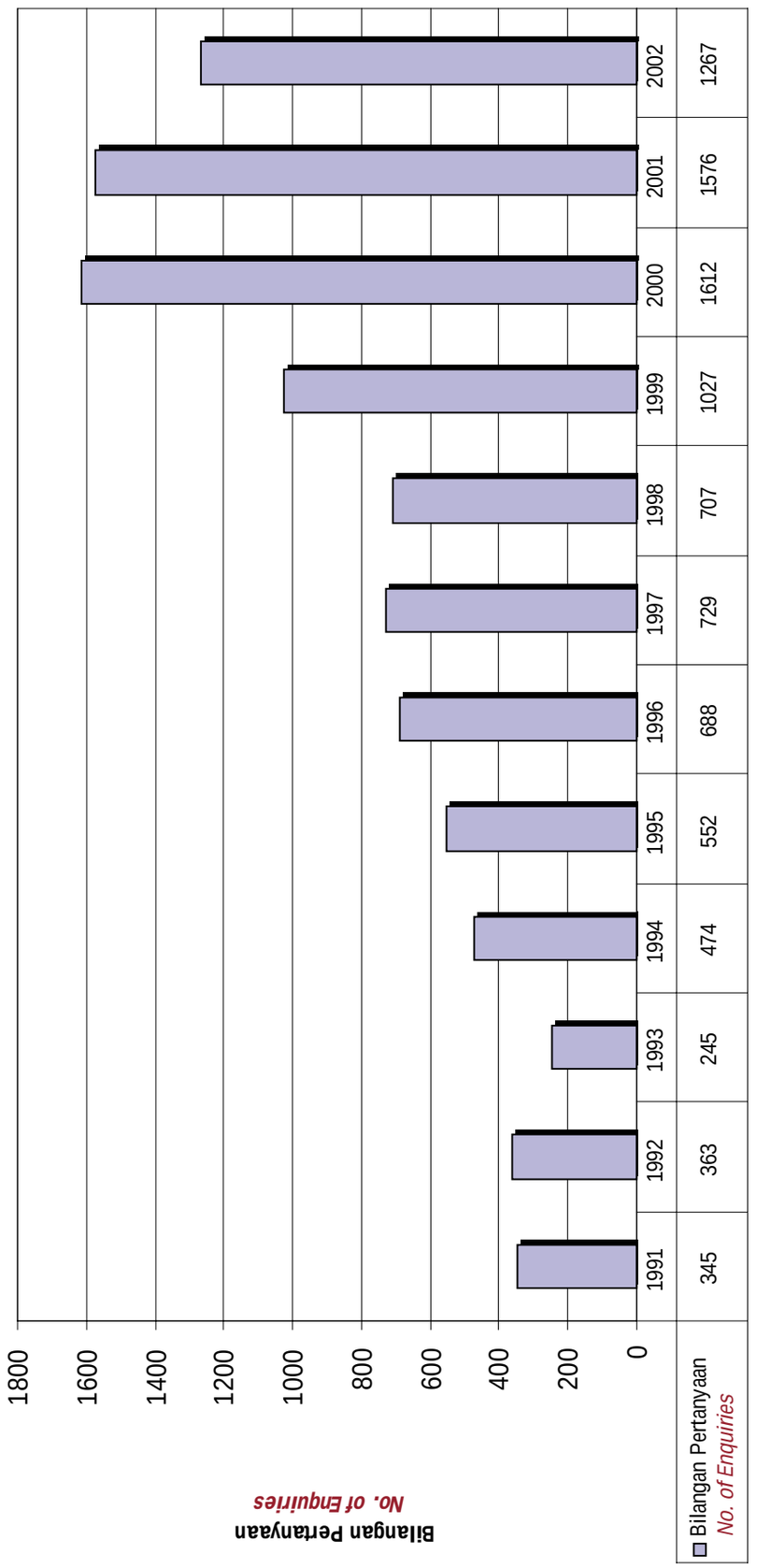
Name	Country	Date	Purpose of Visit
Dr. Somthavy Chagvisommid Deputy Director of FDD, Ministry of Health, Food and Drug Department, Vientane	LAO P.D.R	10-14 June	Study visit to BPFK
Mr. Kham Phme Planning and Budgeting Department, Ministry of Health, Food and Drug Department, Vientane	LAO P.D.R	10-14 June	Study visit to BPFK
Mr. S. Soukphathay Ministry of Health, Food and Drug Department, Vientane	LAO P.D.R	10-14 June	Study visit to BPFK
Dr. B. F. Samaranayake Director of Drug Regulatory Authority	Sri Lanka	18 – 20 June	Study visit
Dr. Budiono Santoso, Regional Adviser in Pharmaceuticals, WHO Regional Office for Western Pacific, Manila	Philippines	10 July	Official visit
Mr. T Gono Medicine Control Authority of Zimbabwe, Harare	Zimbabwe	18-19 July	Study visit
Dato Paduka Haji Zainal bin Haji Momin Permanent Secretary, Ministry of Health	Brunei	18 July	Official visit
Dr. Hj Affendy DSP Hj Abidin Director General of Medical Services, Ministry of Health	Brunei	18 July	Official visit
Dayang Aminah bte Hj Md Jaafar Director of Pharmaceutical Services, Ministry of Health	Brunei	18 July	Official visit
Abdul Mulok bin Hj Abdul Halim Acting Chief Executive Officer, Ministry of Health	Brunei	18 July	Official visit

Name	Country	Date	Purpose of Visit
Zhang Yanlin Vice Division Director, Senior Engineer Hubei Provincial Dept of Science & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Wang You Wei Deputy Director, Researcher, Wuhan Institute Of Botany, The Chinese Academy of Science	China	7 October	Study visit on Traditional Herbal Medicines
Cheng Peng Section Chief Hubai Academy of Science & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Wu Yongjie Hubei Provincial Dept of Science & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Chen Shuting Assistant Engineer Hubei Academy of Science & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Mrs Qian Wang Professor, Institute of China Materia Medicine, China Academy of Traditional Chinese Medicines, Beijing	China	22 – 24 October	WHO Fellow – Study tour on regulations & monitoring of the use of Traditional Herbal Medicines in Malaysia
Mrs. Jinghua Fu Assistant Professor Programme Officer, Institute of Chinese Materia Medicine, China Academy of Traditional Chinese Medicines, Beijing	China	22 – 24 October	WHO Fellow – Study tour on regulations & monitoring of the use of Traditional Herbal Medicines in Malaysia
Dr. Ruixian Zhang Professor, Institute of Chinese Materia Medicine, China Academy of Traditional Chinese Medicines, Beijing	China	22 – 24 October	WHO Fellow – Study tour on regulations & monitoring of the use of Traditional Herbal Medicines in Malaysia
Mr .Nguyen Xuan Tien Pharmacist, Drug and Cosmetic Registration Division, Drug Administration of Vietnam	Vietnam	21 – 25 October	Training programme on Drug Registration

Name	Country	Date	Purpose of Visit
Dr. Nguyen Van Loi Pharmacist, Drug and Cosmetic Quality Management Division, Drug Administration of Vietnam	Vietnam	21 – 25 October	Training programme on Drug Registration
Dr. Valerio Reggi Essential Drugs and Medicines Policy/Quality Assurance and Safety of Medicines (EDM/QSM), WHO Headquarters, Geneva	Switzerland	21 – 25 October	WHO Joint Assessment of National Regulatory Authority
Endang Woro Regulatory Officer, National Agency of Drug & Food Control	Indonesia	21 – 25 October	WHO Joint Assessment of National Regulatory Authority
Hui Foong Mei Regulatory Officer Health Sciences Authority	Singapore	21 – 25 October	WHO Joint Assessment of National Regulatory Authority
Lee Hui Keng Regulatory Officer Health Sciences Authority	Singapore	21 – 25 October	WHO Joint Assessment of National Regulatory Authority
Charunee Krisanaphan Regulatory Officer Food & Drug Administration, Ministry of Public Health	Thailand	21 – 25 October	WHO Joint Assessment of National Regulatory Authority
Pham Thi Biuh Minh Regulatory Officer Drug Administration of Vietnam	Vietnam	21 – 25 October	WHO Joint Assessment of National Regulatory Authority

Bilangan Pertanyaan Diterima Dari 1991-2002

Number of Enquiries Received From 1991 - 2002



JENIS PERTANYAAN YANG DITERIMA PADA TAHUN 2002
TYPES OF ENQUIRIES RECEIVED FOR THE YEAR 2002