LAPORAN TAHUNAN
ANNUAL REPORT
2003

BPFK NPCB

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU

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Kata-Kata Aluan Daripada Pengarah

Message From The Director

Assalamualaikum dan salam sejahtera,

Setahun baru berlalu menandakan hampir dua puluh tahun pelaksanaan skim pendaftaran ubat-ubatan dibawah Peraturan Kawalan Dadah dan Kosmetik 1984 di Malaysia.

Mengimbau kembali tahun-tahun yang telah berlalu itu, sesungguhnya kita telah memulakan satu perjalanan yang berbaloi dengan halatuju dan strategi yang jelas iaitu untuk memastikan rakyat Malaysia mendapat bekalan produk yang berkualiti, selamat dan berkesan hasil daripada aktiviti regulatori kita.

Sehingga 31 Disember 2003, sebanyak 35628 produk telah didaftarkan oleh Pihak Berkuasa Kawalan Dadah. .Jumlah keluaran yang didaftarkan itu menunjukkan peningkatan bagi semua kategori produk yang ada dalam pasaran.

Manakala Bahagian Analisa Ubat telah menerima 4867 sampel dan telah menjalankan 51,251 ujian, peningkatan sebanyak 5.3% dari tahun 2002.

Dalam program Pemonitoran Kesan Advers pula, 1063 kes telah dilaporkan dalam tahun 2003 iaitu mencatatkan sedikit pertambahan berbanding dengan tahun 2002 di mana sebanyak 1000 kes sahaja dilaporkan.
Dari segi perjawatan terdapat pertambahan dengan pengambilan 32 orang pegawai sains secara kontrak

Assalamualaikum and salam sejahtera,

Another year has passed by marking almost twenty years of the implementation of the Control of Drugs and Cosmetics Regulations 1984 in Malaysia.

Looking back over those years gone by we have indeed embarked on a worthy journey with objective goals and strategies in ensuring that the Malaysian public has access to quality, safe and efficacious product that we have been regulating.

As of 31 December 2003, a total of 35628 products have been registered by the Drug Control Authority. From the overall figure, it can be deduced that there has been an increase in number of registered products in all categories.

The Drug Analysis Division received a total of 4867 samples and has conducted 51251 tests, an increase of 5.3% over the figure for the year 2002.

The Adverse Drug Reaction Monitoring Programme meanwhile received a total of 1063 reports of ADR in 2003; a slight increase over the 2002 figure where 1000 cases were reported .

There has been an increase in personnel with the intake of 32 scientific officers on contract basis

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bermula dari Ogos 2003.Kontrak perlu diperbaharuisetiap tahun. Pegawai-pegawai ini ditempatkan di unit-unit yang berlainan untuk mengurangkan kerja-kerja yang tertunggak dari kaedah pendaftaran cara lama. Pendaftaran secara on-line keatas semua produk (farmasiutikal,tradisional dan kosmetik) kecuali produk jenis entiti kimia baru dan bioteknologi akan dilaksanakan pada awal tahun 2004.

Dialog yang berterusan sentiasa diadakan bersama persatuan-persatuan yang mewakili industri dalam mengatasi masalah yang timbul dan demi untuk menjayakan sistem pendaftaran on-line ini.

Biro juga telah maju setapak lagi kehadapan dengan mendapat persijilan kualiti yang dianugerahkan oleh SIRIM (Institut Pemiawaian dan Penyelidikan Perindustrian Malaysia) iaitu MS ISO 9001 versi 2000,satu peningkatan dari persijilan terdahulu iaitu MS ISO 9002 versi 1994.

Kejayaan Biro adalah hasil dari kerjasama semua lapisan warganya. Saya mengambil kesempatan ini untuk mengucapkan syabas kepada semua anggota BPFK diatas usaha yang berterusan, iltizam, kesungguhan dalam menjalankan tugas yang diamanahkan.

Sekian, terima kasih.

(HJ. NORMAL BIN SHARIF)
Pengarah,
Biro Pengawalan Farmaseutikal Kebangsaan,
Kementerian Kesihatan Malaysia.

starting from Ogos 2003.Their contract is on a year to year basis.These officers were assigned to the various units mainly to reduce the backlog of work from the manual registration system. The on-line products registration system will be implemented for all products (Pharmaceutical, traditional and cosmetics) except for new chemical biotechnology products by early 2004.

Dialogues are ongoingly held between NPCB and associations representing the industry to resolve problems encountered and to ensure success of the new on-line registration system.

In the year 2003, NPCB successfully obtained quality certification awarded by SIRIM (Standards and Industrial Research Institute of Malaysia), this being MS ISO 9001 version 2000, an upgrading from MS ISO 9002 version 1994 awarded earlier.

NPCB owes the success to the job well done by all staff.I take this opportunity to congratulate everyone for the continous support, commitment and dedication in performing the duties entrusted to them.

Thank You.

(HJ. NORMAL BIN SHARIF)
Director,
National Pharmaceutical Control Bureau,
Ministry of Health Malaysia.

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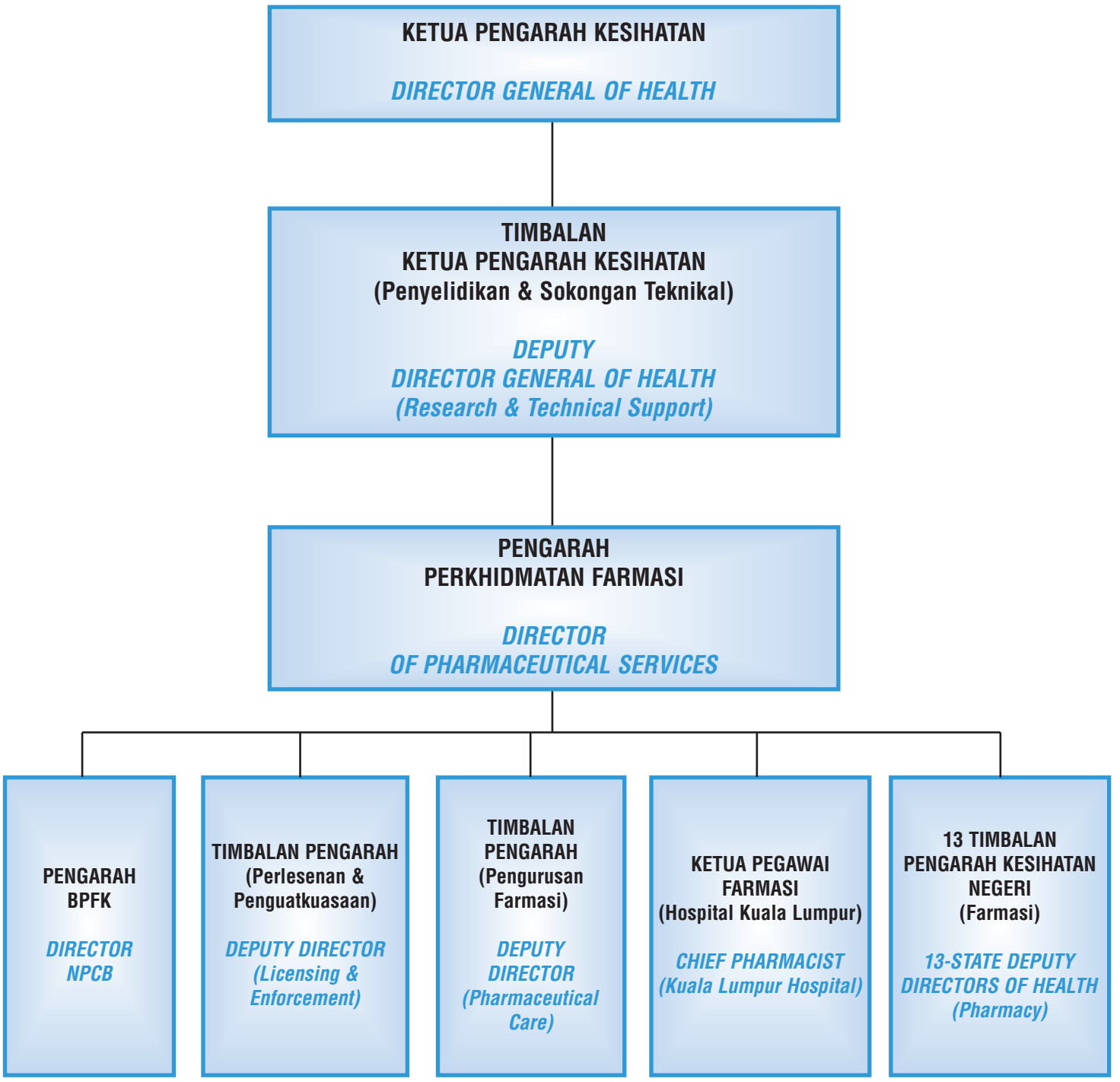
STRUKTUR ORGANISASI
ORGANISATIONAL STRUCTURE OF

BAHAGIAN PERKHIDMATAN FARMASI
PHARMACEUTICAL SERVICES DIVISION

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH



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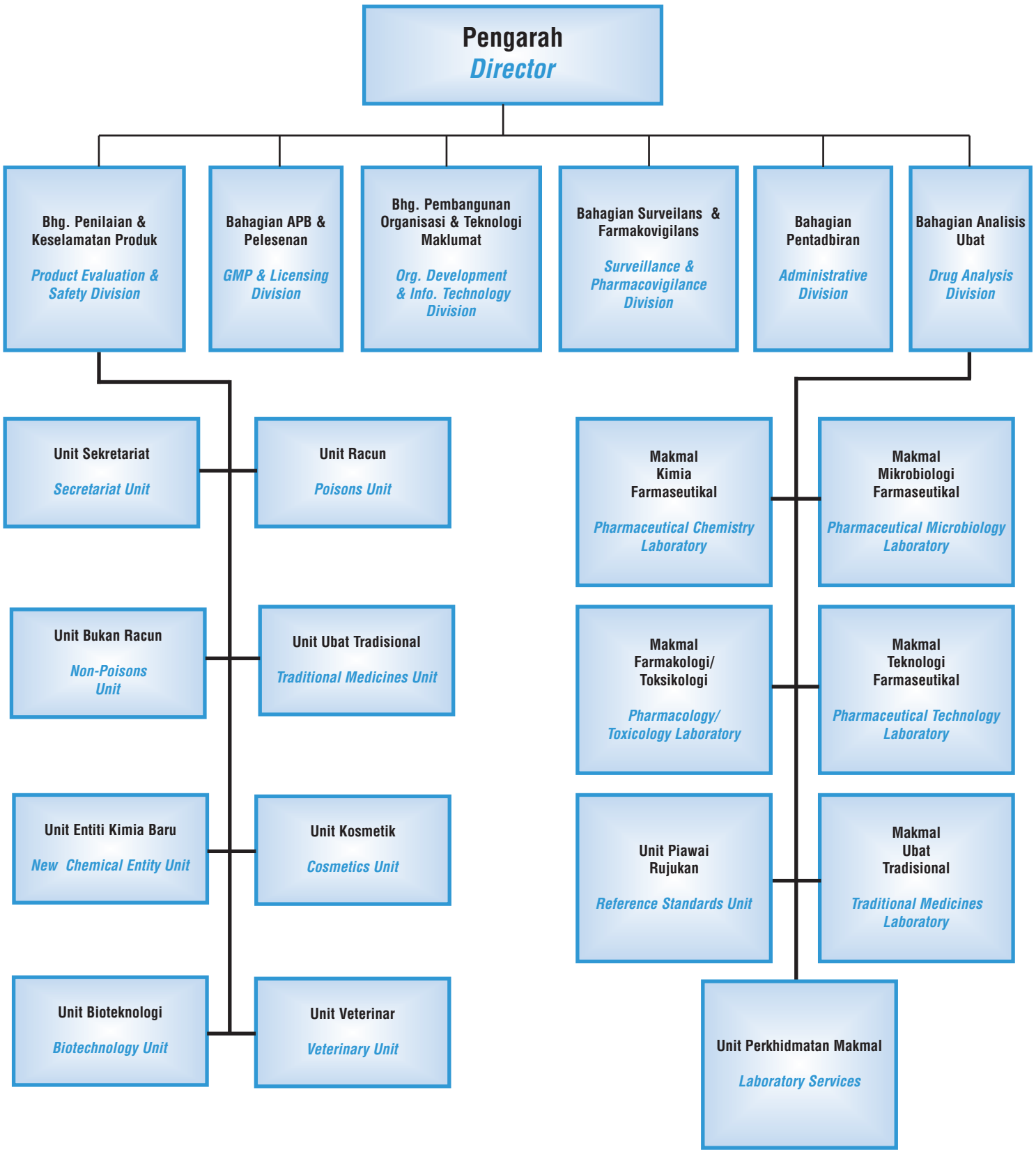
CARTA ORGANISASI
ORGANISATIONAL CHART

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU



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SENARAI KEDUDUKAN PERJAWATAN SEHINGGA 31 DISEMBER 2003
LIST OF POSTS AS AT 31 DECEMBER 2003

Bil. *No.*	Nama Jawatan *Position*	Gred *Grade*	Bil. *No.*	Jawatan *(Post)*	
				Disi *(Filled)*	Kosong *(Vacant)*
1	Pengarah BPFK *Director of NPCB*	VU7	1	1	0
2	Pegawai Farmasi *Pharmacist*	U54	2	2	0
3	Pegawai Farmasi *Pharmacist.*	U48	19	16	3
4	Pegawai Farmasi *Pharmacist*	U41	62	54	8
5	Pembantu Farmasi *Pharmacy Assistant*	U38	1	0	1
6	Pembantu Farmasi *Pharmacy Assistant*	U36	1	1	0
7	Penolong Pegawai Perangkaan *Assistant Statistic Officer*	N27	1	1	0
8	Pembantu Farmasi *Pharmacy Assistant*	U32	8	5	3
9	Pembantu Farmasi *Pharmacy Assistant*	U29	65	57	8
10	Pembantu Tadbir (Perkeranian/Operasi) *Administrative Assistant (management))*	N22	1	1	8
11	Pembantu Tadbir (Perkeranian/Operasi) *Administrative Assistant (management)*	N17 W17	6 5	5 5	1 0
12	Pembantu Perpustakaan. *(Library Assistant)*	S17	1	1	0
13	Pembantu Tadbir (Penyelenggara Stor) *Administrative Assistant (stor)*	N17	1	0	1
14	Pembantu Tadbir (Kesetiausahaan) *Administrative Assistant (Secretary).*	N22	1	1	0
15	Pembantu Tadbir. (Kesetiausahaan). *Administrative Assistant(secretary).*	N17	2	1	1
16	Pengawal Keselamatan. *Security guard.*	KP11	3	1	2
17	Pembantu Tadbir Rendah. *Typist.*	N11	4	1	3
18	Pembantu Tadbir Rendah (Operator Telefon). *Administrative Assistant(Telephone operator).*	N11	1	1	0
19	Pembantu Am Rendah. *General Assistant.*	N1	2	2	0
20	Atendan Kesihatan. *Health Attendant.*	U3	10	7	3
21	Pemandu Kenderaan Bermotor. *Driver.*	R3	3	3	0
22	Operator Mesin Prosesan Data. *Data Processing Operator.*	F11	2	2	0
JUMLAH *TOTAL*			**202**	**168**	**34**

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PENGARAH DAN KETUA-KETUA BAHAGIAN
DIRECTOR AND HEAD OF DIVISIONS

Tuan Hj Normal bin Sharif
Pengarah BPFK / *Director of NPCB.*
Sehingga 25.12.2003 / *Until 25.12.2003*

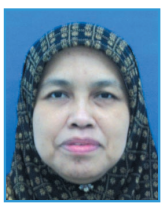
BAHAGIAN PENILAIAN & KESELAMATAN PRODUK
PRODUCT EVALUATION & SAFETY DIVISION

Pn. Eisah bt. Abd Rahman
Timbalan Pengarah / *Deputy Director*

Pn. Noorizam Ibrahim
Ketua Unit Racun
Head of Poison Unit

Pn. Tan Lie Sie
Ketua Unit Bukan Racun
Head of Non-Poison Unit

En. Ramli Zainal
Ketua Unit Sekretariat
Head of SecretariatUnit



Cik Fudziah Ariffin
Ketua Unit Entiti Kimia Baru
Head of New Chemical Entity

Pn Saleha Md Ewan
Ketua Unit Ubat Tradisional
Head of Traditional Medicine Unit

Pn Anis Talib
Ketua Unit Kosmetik
Head of Cosmetics Unit

Pn. Arpah Abas
Ketua Unit Bioteknologi
Head of Biotechnology Unit

Pn. Rohani Ismail
Ketua Unit Veterinar
Head of Veterinary Unit

BAHAGIAN ANALISIS UBAT
DRUG ANALYSIS DIVISION

Datin Hjh Hasiah Hj Abdullah
Timbalan Pengarah / *Deputy Director*

Pn. Siti Madziah Mohamed
Ketua Unit Mikrobiologi Farmaseutikal
Head of Pharmaceutical Microbiology Unit

En. Chua Kong Seeng
Ketua Unit Farmakologi/Toksikologi
Head of Pharmacology/Toxicology Unit

Dr. Sulaikah Moideen
Ketua Unit Kimia Farmaseutikal
Head of Pharmaceutical Checmistry

En. Tan Ann Ling
Ketua Unit Perkhidmatan Makmal
Head of Laboratory Services

En. Mohd Nasir Hashim
Ketua Unit Piawai Rujukan
Head of Reference Standard Unit

En. Jaafar Lassa
Ketua Unit Makmal Ubat Tradisional
Head of Traditional Medicine Laborator

Puan Faridah bt Abd Malek
Ketua Unit Makmal Teknologi Farmaseutikal
Head of Pharmaceutical Technology Laboratory

BAHAGIAN PEMBANGUNAN ORGANISASI DAN TEKNOLOGI MAKLUMAT
ORGANISATIONAL DEVELOPMENT & INFORMATION TECHNOLOGY DIVISION

Pn. Chuah Siew Khim
Ketua Bahagian Pembangunan Organisasi dan Teknologi Malklumat
Head of Organisation Development and Information Technology
Sehingga Jun 2003 *Until June 2003*

Pn Abida Haq (memangku ketua bahagian) ***(acting Head)***
Dari Julai 2003 *From July 2003*

BAHAGIAN SURVEILANS DAN FARMAKOVIGILANS
SURVEILLANCE & PHARMACOVIGILANCE DIVISION

Pn. Abida Haq
Ketua Bahagian Farmakovigilans
Head of Pharmacovigilance Division

BAHAGIAN AMALAN PERKILANGAN BAIK & PELESENAN
GOOD MANUFACTURING PRACTICE & LICENSING DIVISION

Dr. Tajuddin Akasah
Ketua Bahagian Amalan Perkilangan Baik & Pelesenan
Head of Good Manufacturing Practice & Licensing Division

BAHAGIAN PENTADBIRAN
ADMINISTRATIVE DIVISION

Pn. Rosnani Mohd Yusoff
Ketua Bahagian
Head of Division

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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.

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PIAGAM PELANGGAN

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.

3. AKTIVITI - MAKMAL

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

CLIENT'S CHARTER

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. ACTIVITY - LABORATORY

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

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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.

(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.

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) 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.

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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.*

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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 171 anggota berjumlah RM 5,383,062.00

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 bagi 2003 ialah RM7,754,822.

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 171 staff members is RM 5,383,062.00

REVENUE

Revenue is collected from the public for Drug Registration, Laboratory Test, Licences, Advisory Services, Sale of Guideline Books and others. The total revenue is RM7,754,822.

Kutipan Hasil (RM) Sehingga Akhir Tahun 2003
Revenue (RM) Until End Of 2003

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
2003	5,540,795	942,650	1,126,027	62,700	18,420	64,230

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Peruntukan dan Perbelanjaan Mengurus BPFK Bagi Tahun 2003
NPCB Operating Allocation and Expenditure 2003

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*	5,166,000	5,383,062	5,424,714	100.77	(41,652)	0.77
20000	Perkhidmatan dan Bekalan *Services and Supply*	7,926,000	8,257,499	6,838,869	82.82	1,418,630	20.74
30000	Aset (Harta Modal) *Asset (Property)*	300,000	300,050	146,603	48.87	153,447	51.15
Jumlah *Total*		13,392,000	13,940,611	12,410,186	89.02	1,530,425	10.98

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BAHAGIAN PENILAIAN DAN KESELAMATAN PRODUK

OBJEKTIF

Memastikan semua keluaran yang didaftar dinilai dari segi kualiti, keselamatan dan efikasi.

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

Pencapaian

Permohonan Pendaftaran

Sejumlah 28,177 permohonan diterima sepanjang tahun 2003 dan jumlah yang meningkat ini berbanding tahun 2002 adalah kerana permohonan pendaftaran kosmetik secara on-line yang meliputi 92.84%. Bagi produk racun, bukan racun dan tradisional, secara keseluruhannya, permohonan yang diterima telah menurun berbanding tahun 2002 **(Jadual 1)**.

Status Keluaran Berdaftar

Sejumlah 35,628 keluaran telah didaftarkan sehingga 2003, yang mana 9,659 (27.1%) ialah ubat racun, 7,206 (20.2%) ubat bukan racun, 12,107 (34.0%) ubat tradisional dan 6,656 (18.7%) kosmetik **(Jadual 2)**. Sebanyak 6669 keluaran telah dibentangkan untuk didaftarkan pada tahun 2003 dan peningkatan yang signifikan berbanding tahun sebelumnya adalah kerana pendaftaran kosmetik secara on-line yang mana waktu pemprosesan/penilaian lebih singkat dan lebih banyak keluaran didaftarkan.

Status Permohonan Yang Ditolak

Sehingga 2003, sejumlah 16,762 permohonan telah ditolak **(Jadual 3)** yang mana jumlah pada tahun 2003 (42) didapati menurun berbanding tahun-tahun sebelumnya. Kesan positif ini menunjukkan peningkatan permohonan keluaran yang mematuhi keperluan pendaftaran.

Status Permohonan Yang Dibatalkan atau Tarik-balik

Sehingga 2003, sejumlah 7,300 permohonan telah dibatalkan atau ditarik-balik, dan ini meliputi 2,338 (31.6%) ubat racun, 1,415 (19.1 %) ubat bukan racun, 3,571 (48.3 %) ubat tradisional dan 66 (0.9 %) kosmetik **(Jadual 4)**. Pembatalan pendaftaran keluaran kebanyakannya atas alasan keselamatan dan ada juga kerana keluaran tidak lagi mematuhi keperluan pendaftaran.

Rayuan

Jumlah rayuan yang diterima pada tahun 2003 ialah sebanyak 29 permohonan berbanding 76 pada tahun sebelumnya. Penurunan jumlah rayuan selaras dengan penurunan jumlah keluaran yang ditolak.

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 28,177 applications were received in 2003 and this significant increase as compared to the year 2002, was mainly due to the on-line registration of cosmetics which represents 92.84%. The number of applications received for prescription drugs, OTC products and traditional medicines have decreased as compared to the applications received in 2002 ***(Table 1)****.*

Products Registered

A total of 35,628 products has been registered up until the year 2003, of which 9,659 (27.1%) were prescription drugs, 7,206 (20.2%) were OTC products, 12,107 (34.0%) traditional medicines and 6,656 (18.7%) cosmetics ***(Table 2)****. A total of 6,669 products has been tabled for registration in 2003 and this significant increase compared to the year before was contributed by the short processing and evaluating time of the on-line cosmetics registration that resulted in more products being registered.*

Applications Rejected

Up until 2003, a total of 16,762 applications have been rejected ***(Table 3)*** *and the number for 2003 (42) has decreased as compared to the previous years. This positive trend indicates the number of applications that complied with the requirements for registration has increased.*

Registration cancelled or withdrawn

Up until 2003, a total of 7,300 registration of products has been cancelled or withdrawn, which consists of 2,388 (31.6%) prescription drugs, 1,415 (19.1%) OTC products, 3,571 (48.3%) traditional medicines and 66 (0.9%) cosmetics ***(Table 4).*** *The reason for the cancellation of registration is mainly on safety issues and also products do not comply with the registration requirements.*

Appeal

The number of appeals received in the year 2003 was 29, as compared to 76 in the previous year. This decrease is in line with the decreased number of applications being rejected.

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Jadual 1 : Permohonan untuk pendaftaran (1985-2003)
Table 1 : Applications for registration (1985-2003)

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
2003	263	266	1,471	26,177	28,177	79,275
Jumlah *Total*	**15,322**	**11,164**	**24,519**	**28,270**	**79,275**	**79,275**

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

Jadual 2 : Kumulatif Keluaran yang didaftarkan (1991-2003)
Table 2 : Cumulative number of products registered (1991-2003)

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
2003	9,659	7,206	12,107	6,656	35,628
Jumlah *Total*	**9,659**	**7,206**	**12,107**	**6,656**	**35,628**

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

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Jadual 3 : Kumulatif Permohonan yang ditolak (1986-2003)
Table 3 : Cumulative applications rejected by the DCA (1986-2003)

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
2003	4,259	3,227	9,151	125	16,762
Jumlah *Total*	**4,259**	**3,227**	**9,151**	**125**	**16,762**

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

Jadual 4 : Permohonan yang dibatalkan/ditarik-balik (1989-2003)
Table 4 : Applications cancelled/withdrawn (1989-2003)

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
2003	3	81	58	-	142	7,390
Jumlah *Total*	**2,338**	**1,415**	**3,571**	**66**	**7,390**	**7,390**

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

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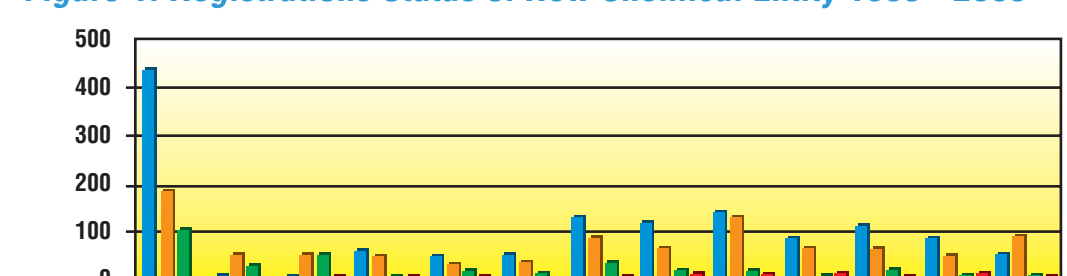
Entiti Kimia Baru

Dari tahun 1985 sehingga 2003, permohonan yang diterima untuk keluaran entiti kimia baru adalah 1,307 **(Rajah 1)**. Daripada jumlah ini, 931 (71.2%) telah diluluskan, 306 (23.4%) ditolak dan 65 (5.0%) keluaran keputusannya ditangguhkan untuk maklumat tambahan. Bagi tahun 2003, 94 permohonan telah dinilai dan jumlah ini meningkat berbanding tahun-tahun sebelumnya kerana bertambahnya pegawai penilai.

New Chemical Entities

*From the year 1985 to 2003, the total number of applications received for products classified as new chemical entities was 1,307 **(Figure 1)**. Out of these, 931 (71.2%) has been approved, 306 (23.4%) rejected and 65 (5.0%) deferred for additional information. A total of 94 applications has been evaluated in 2003 and this increase is due to the increased number of evaluators.*

Rajah 1: Status Pendaftaran Entiti Kimia Baru 1985 - 2003
Figure 1: Registrations Status of New Chemical Entity 1985 - 2003



	85-91	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Terima *Accept*	431	8	2	60	47	52	127	114	140	81	111	81	53
Lulus *Approve*	188	48	34	48	36	37	87	61	129	61	61	52	89
Tolak *Reject*	101	30	35	7	18	11	39	15	19	9	15	3	4
Tangguh *Post Pone*	0	0	3	8	1	0	4	11	11	11	4	11	1

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

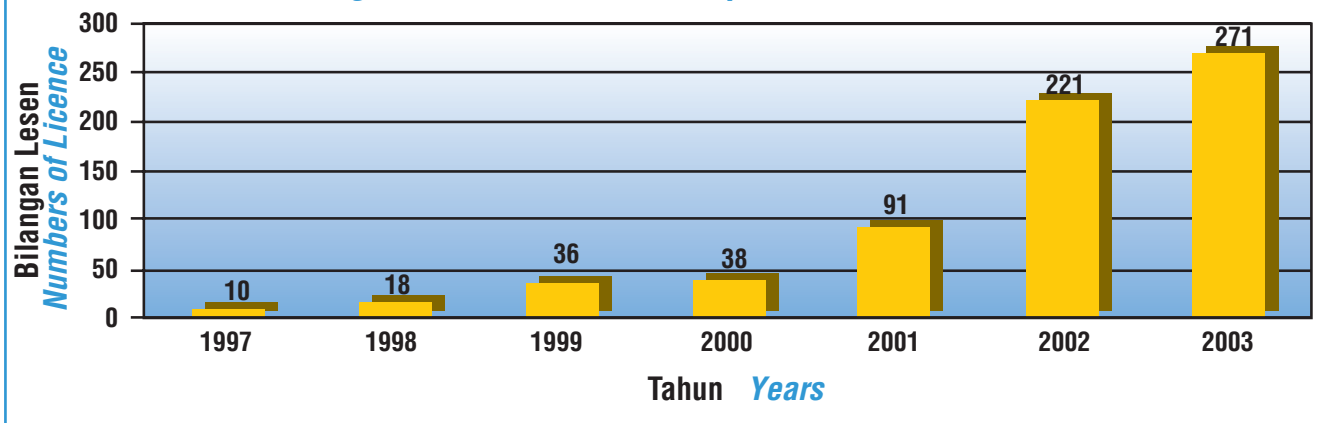
Lesen Import Penyelidikan Klinikal

Jumlah Lesen Import Penyelidikan Klinikal yang dikeluarkan telah meningkat pada tahun 2003 iaitu sebanyak 271 lesen berbanding tahun sebelumnya. Dari tahun 1997 sehingga 2003 sejumlah 685 lesen telah dikeluarkan **(Rajah 2)**.

Clinical Trials Import Licence (CTIL)

*The number of CTIL issued has increased significantly in the year 2003, that is 271 licences as compared to the previous years. From the year 1997 to 2003, 685 licences were issued **(Figure 2)**.*

Rajah 2 : Lesen Import Penyelidikan Klinikal 1997 - 2003
Figure 2 : Clinical Trial Import License 1997 - 2003



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

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Tambahan Indikasi

Tambahan indikasi bagi keluaran berdaftar juga diluluskan oleh PBKD. Pada tahun 2003, sebanyak 56 permohonan diterima dan tambahan indikasi bagi 63 keluaran berdaftar telah diluluskan.

Keluaran Tempatan dan Import

Keluaran tempatan dan import yang didaftarkan dari tahun 1991 hingga 2003, mengikut kategori keluaran diilustrasikan pada **Jadual 5**. Jumlah keluaran tempatan adalah sebanyak 41.4% (14,752), dan jumlah keluaran yang diimport adalah 58.6% (20,879).

Additional Indications

New indications for registered products were also approved by the DCA. In the year 2003, a total of 56 applications were received and new indication for 63 registered products were approved.

Local vs. Import

*Locally-manufactured and imported products registered from the year 1991 to 2003, according to the different categories, are illustrated in the **Table 5**. About 41.4% (14,752) of the total number of products registered are locally-manufactured, while 58.6% (20,879) are imported.*

Jadual 5 : Jumlah Kumulatif Produk Tempatan dan Impot, (1991 – 2003)

Table 5 : Cumulative Number of Locally-Manufactured and Imported Products Registered, (1991 – 2003)

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
2003	2,915	6,744	3,203	4,003	7,289	4,818	1,345	5,311	14,752	20,879
Jumlah *Total*	**9,659**		**7,206**		**12,107**		**6,656**		**35,628**	

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

Pada tahun 2003, berdasarkan data dalam **Jadual 5**, peratusan nisbah antara keluaran tempatan dan keluaran import untuk ubat racun adalah 30:70; ubat bukan racun adalah 44:56; ubat tradisional adalah 60:40; dan kosmetik pula adalah 20:80.

Merujuk kepada jumlah keluaran tempatan yang didaftarkan (n = 14,752), 19.8% adalah ubat racun, 21.7% ubat bukan racun, 49.4% ubat tradisional dan 9.1% kosmetik. Untuk keluaran import (n = 20,879), 32.3% adalah ubat racun, 19.2% ubat bukan racun, 23.1% ubat tradisional dan 25.4% kosmetik.

Perakuan Keluaran Untuk Tujuan Eksport

Jumlah pengeluaran Perakuan Keluaran Farmaseutikal [Certificates of Pharmaceutical Products (CPP)] dan Perakuan Penjualan Bebas [Certificate of Free Sale (CFS)] untuk alat perubatan dan kosmetik bagi tujuan eksport sejak tahun 1987 sehingga 2003 dapat dilihat pada **Rajah 3** dan pada tahun 2003 sebanyak 2,410 CPP dan 1,309 CFS telah dikeluarkan.

*In the year 2003, the percentage ratio between locally-manufactured and imported products is in the order of 30:70 for prescription drugs **(Table 5)**, 45:56 for OTC products, 60:40 for traditional medicines and 20:80 for cosmetics.*

Based on the total number of locally-manufactured products registered (n = 14,752), 19.8% are prescription drugs, 21.7% are OTC products, 49.4% traditional medicines, and 9.1% cosmetics. For imported products, based on the total number of products registered (n = 20,879), 32.3% are prescription drugs, 19.2% are OTC products, 23.1% traditional medicines and 25.4% cosmetics.

Export Authorisation

*Issuance of certificates of pharmaceutical products (CPP) and certificates of free sale (CFS) for medical devices and cosmetics for export authorization from the year 1987 to 2003 is illustrated in **Figure 3**. A total of 2,489 CPP and 1,778 CFS had been issued in 2003.*

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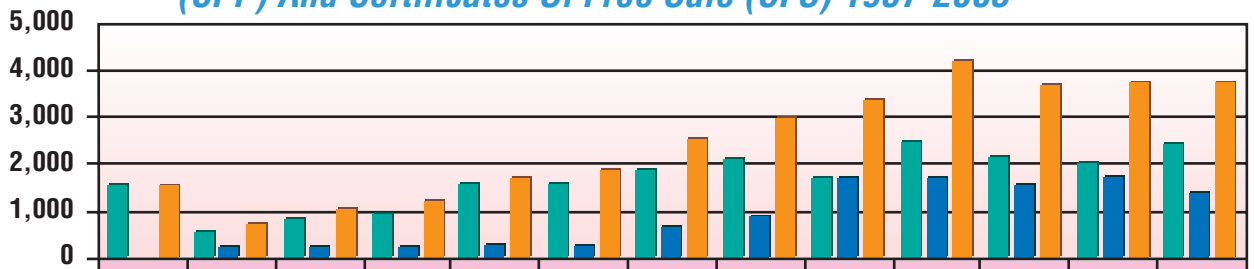
Rajah 3 : Pengeluaran Sijil Perakuan Farmaseutikal dan Sijil Perakuan Penjualan Bebas 1987 - 2003

Figure 3 : Issuance Of Certificates Of Pharmaceutical Products (CPP) And Certificates Of Free Sale (CFS) 1987-2003



	87-91	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
CPP	1,575	561	827	943	1,502	1,590	1,865	2,094	1,700	2,478	2,131	2,033	2,489
CFS	0	192	257	263	278	278	652	864	1,679	1,719	1,551	1,717	1,778
Jumlah *Total*	**1,575**	**753**	**1,084**	**1,206**	**1,708**	**1,868**	**2,517**	**2,958**	**3,379**	**4,197**	**3,682**	**3,750**	**4,267**

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

Sumber keluaran

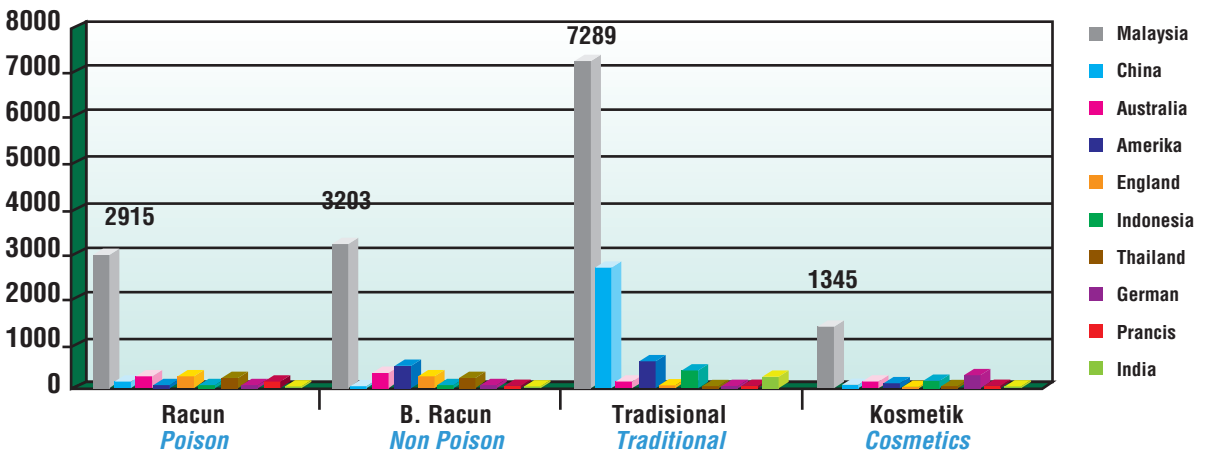
10 negara utama yang menjadi sumber keluaran import ialah China, Amerika Syarikat, Australia, Indonesia, Thailand, Jerman, India, England, Perancis dan Itali. Keluaran dari negara-negara ini meliputi lebih kurang 47.7% (9,949) daripada jumlah keluaran import (n = 20,879). Keluaran yang diimport dari Negara ASEAN seperti Indonesia, Thailand, Singapura dan Filipina meliputi hampir 8.9% (1,849) **(Rajah 4)**.

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 47.7% (9,949) of our total imports (n = 20,879). Products imported from neighbouring ASEAN countries, which include Indonesia, Thailand, Singapore and Philippines constitute nearly 8.9% (1,849) **(Figure 4)**.*

Rajah 4 : Pengeluar Utama Produk Berdaftar 2003

Figure 4 : Major Sources For Registered Products 2003



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

Permohonan Pindaan Maklumat Pendaftaran

Jumlah permohonan pindaan maklumat bagi keluaran berdaftar meningkat dari tahun ke tahun dan pada tahun 2003, sebanyak 6680 pindaan **(Rajah 5)** telah dinilai bagi 4749 permohonan yang diterima.

Change In Particulars Of Registered Products

*The number of applications for change in particulars of registered products shows an increasing trend. In the year 2003, a total of 6,680 amendments **(Figure 5)** has been evaluated from the 4749 applications received.*

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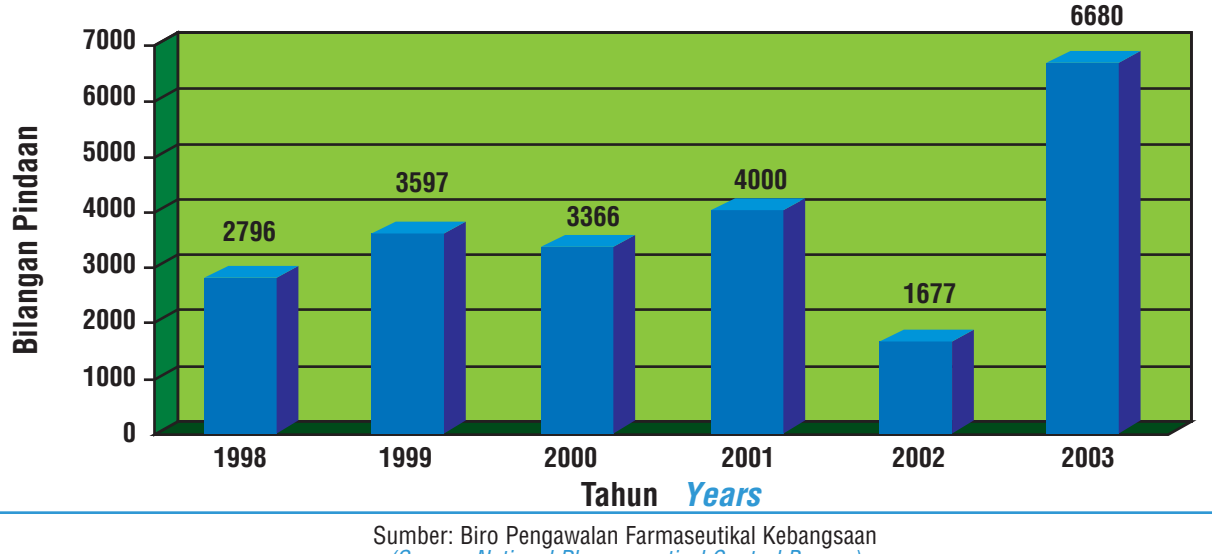
Rajah 5 : Bilangan Pindaan Data Produk (1998 – 2003)
Figure 5 : Number Of Product Data Changes (1998-2003)



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

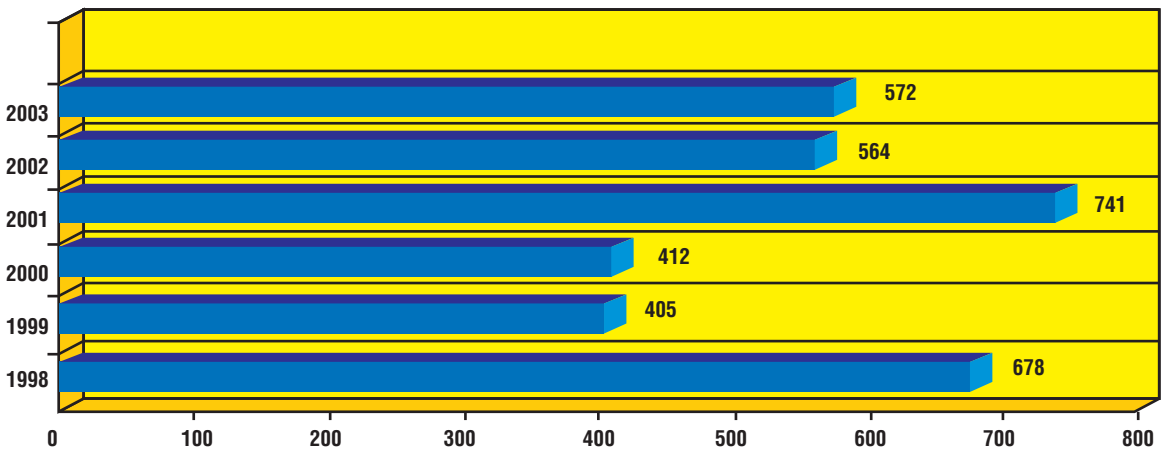
Permohonan Pertukaran Pemegang Pendaftaran

Jumlah permohonan pertukaran pemegang pendaftaran yang diterima dari tahun 1998 dapat dilihat pada **Rajah 6** dan permohonan yang diterima pada tahun 2003 adalah sebanyak 572 permohonan.

Change Of Registration Holder

*The number of applications received from the year 1998 to 2003 is illustrated in **Figure 6**. A total of 572 applications were received in 2003.*

Rajah 6 : Bilangan Permohonan Pertukaran Pemegang (1998 - 2003)
Figure 6 : Number Of Application For Change Of Registration Holder (1998 - 2003)



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

Pertukaran Tapak Perkilangan

Permohonan pertukaran tapak perkilangan meliputi pertukaran yang disebabkan oleh naiktaraf kelengkapan/kemudahan kilang, penambahan aktiviti perkilangan atau pertukaran ke premis yang baru dibina dan pertukaran ini adalah bagi syarikat yang sama. Pertukaran boleh juga disebabkan oleh pergabungan syarikat atau "rationalization of manufacturing site". Jumlah permohonan sejak tahun 2001 dapat dilihat pada **Rajah 7** yang mana pada tahun 2003, 351 permohonan diterima.

Change Of Manufacturing Site

*Application for change in manufacturing site may be due to upgrading of facilities, expansion of manufacturing activities or moving to a newly constructed plant of the same company. It may also be due to a merger or rationalization of manufacturing sites. The number of appication received since the year 2001 is shown in **Figure 7** and 351 applications were received in 2003.*

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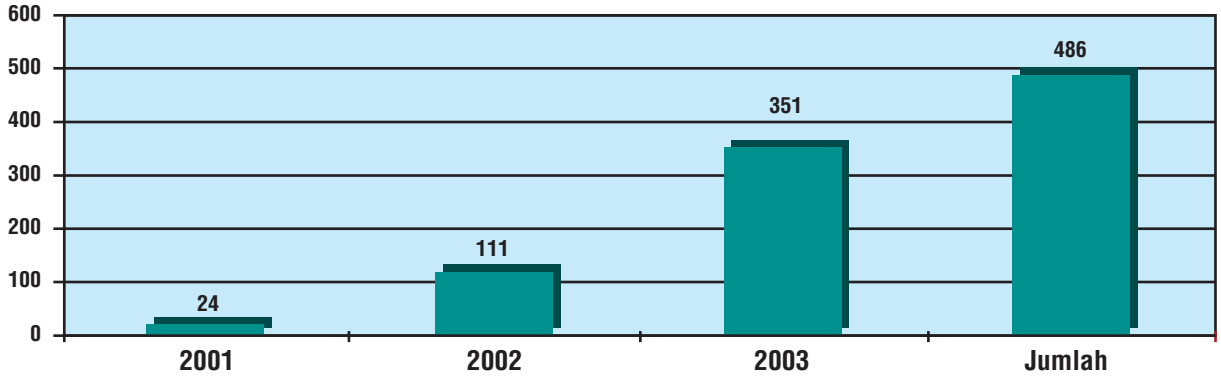
Rajah 7 : Pertukaran Tapak Pengilang (2001 - 2003)
Figure 7 : Change Of Manufacturing Site (2001-2003)



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

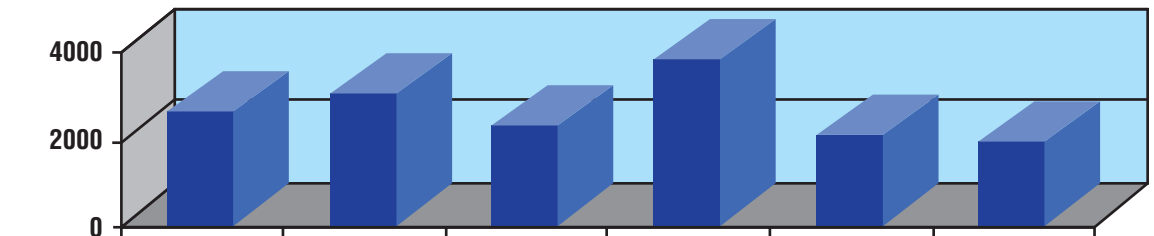
Permohonan Pendaftaran Semula

Pendaftaran keluaran lazimnya bagi tempoh lima tahun atau bagi tempoh yang dinyatakan dalam perakuan pendaftaran. Permohonan pendaftaran semula perlu dikemukakan sebelum tamat tempoh pendaftaran sesuatu keluaran dan permohonan yang diterima bagi tahun 2003 adalah 1950 **(Rajah 8)**.

Renewal Of Product Registration

The registration of a product shall be valid for 5 years or such period as spesified in the registration certificate. Application for renewal of product registration has to be submitted before the expiry of the validity period and a total of 1950 applications were received in 2003 ***(Figure 8)***.

Rajah 8 : Permohonan Pendaftaran Semula Yang Diterima 1998 - 2003
Figure 8 : Application For Registration Received 1998 - 2003



	1998	1999	2000	2001	2002	2003
Bilangan	2583	3004	2322	3855	2042	1950

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

Permohonan Pengesahan Status Pendaftaran

Permohonan pengesahan status pendaftaran keluaran biasanya dikemukakan oleh penguatkuasa farmasi negeri bagi keluaran yang disita dalam serbuan-serbuan yang dijalankan. Pengesahan ini diperlukan untuk kes-kes pendakwaan di mahkamah dan sepanjang tahun 2003 sebanyak 3664 keluaran disahkan status pendaftarannya **(Rajah 9)**.

Confirmation Of Registration Status

Confirmation of registration status is normally requested by the State Pharmacy Enforcement Unit for products that are confiscated during raids and enforcement activities. This confirmation is required for prosecution cases in courts and throughout the year 2003, registration status of 3,664 products have been confirmed.

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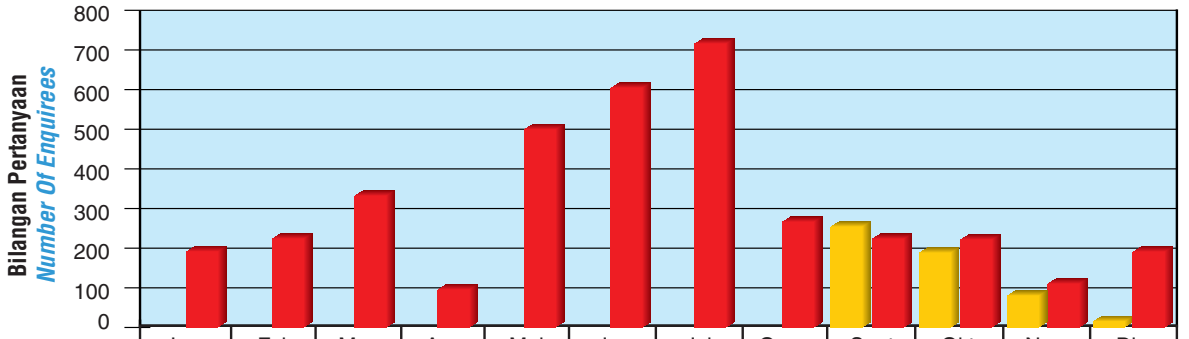
Rajah 9 : Pertanyaan Status Pendaftaran Oleh UPF 2002 & 2003

Figure 9 : Enquiries On Registration Status By Enforcement Unit (EU) 2002 & 2003



	Jan	Feb	Mac	Apr	Mei	Jun	Jul	Ogos	Sept	Okt	Nov	Dis
2002	-	-	-	-	-	-	-	-	253	167	79	15
2003	191	223	331	95	499	603	715	265	222	221	109	190

*** Data bagi Jan-Ogos 2002 tidak diperolehi**

Jan-August 2002 data not available

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

Perkembangan-perkembangan Lain

Pendaftaran Kosmetik Secara On-line

Pendaftaran keluaran kosmetik secara on-line telah dimulakan sejak 1hb. Februari 2002 dan untuk membantu pengusaha-pengusaha kosmetik mengemukakan permohonan pendaftaran, pihak BPFK telah mengadakan program penerangan di seluruh negara termasuk Sabah dan Sarawak untuk menjelaskan kepada pemohon berhubung dengan keperluan-keperluan pendaftaran kosmetik. Pihak BPFK dengan kerjasama Technology Innovative Resources (TIR) Sdn. Bhd. telah menganjurkan beberapa siri latihan untuk membantu pihak industri terutamanya pengguna sistem Quest 2 memahami dengan lebih terperinci pendaftaran secara 'on-line' keluaran-keluaran kosmetik.

Sepanjang tahun 2003, sebanyak 35996 permohonan pendaftaran telah diterima yang terdiri dari 7578 keluaran tempatan dan 28,418 keluaran yang di import dari luar negara. Jumlah permohonan didapati meningkat menjelang akhir tahun.

Untuk memastikan perlaksanaan pengawalan kosmetik dari segi keperluan-keperluan teknikal, satu Jawatankuasa Kerja Teknikal Kosmetik telah ditubuhkan dan dianggotai oleh wakil-wakil dari Biro Pengawalan Farmaseutikal Kebangsaan, Cosmetic, Toiletry and Fragrance Association Malaysia (CTFA), FMM Malaysian Cosmetic and Toiletries Industry Group (FMM-MCTIG). Pihak BPFK juga telah mengadakan 13 sesi perbincangan dengan pihak industri melalui mesyuarat Cosmetic Task Force dan 6 kali mesyuarat Jawatankuasa Kerja Teknikal berkenaan sepanjang tahun 2003.

Pendaftaran Keluaran Farmaseutikal

Pendaftaran keluaran mengandungi racun dan keluaran bukan racun secara on-line dimulakan pada 1 Julai 2003. Sebanyak 3 sesi penerangan telah diadakan untuk peserta-peserta industri farmaseutikal untuk menjelaskan kepada pemohon berhubung dengan sistem pendaftaran secara 'on-line' serta dokumen/maklumat yang perlu dikemukakan dan sambutan adalah

OTHER DEVELOPMENTS

On-line Cosmetic Registration

Cosmetic product registration via on-line was implemented since the 1st of February 2002. To assist cosmetic manufacturers to submit application for registration, the NPCB has conducted series of nation-wide road-shows which includes Sabah and Sarawak, to provide information and clarification to applicants regarding cosmetic registration requirements. The NPCB with technical cooperation from Technology Innovative Resources (TIR) Sdn Bhd has organized series of training courses to assist the industry especially to ensure users of the QUEST 2 system understand the details of the "on-line" registration process for cosmetic products.

A total of 35,996 applications were received in 2003 which consist of 7,578 locally manufactured and 28,418 imported products. The number of application continued to increase towards the end of the year.

To ensure the effective implementation of cosmetic control with respect to technical requirements, a Cosmetic Technical Working Group was formed which consisted of representatives from NPCB, Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFA), FMM Malaysian Cosmetic and Toiletries Industry Group (FMM-MCTIG). The NPCB has held 13 dialogue sessions with the industry through the Cosmetic Task Force and 6 Technical Working Group meetings throughout the year 2003.

Registration of Pharmaceutical Products

The on-line registration for prescription drugs and OTC products was implemented since the 1st of July 2003. Three series of road-shows were held for participants from the pharmaceutical industy to provide information regarding the registration on-line system and the documents that need to be submitted. Several hands-on training courses were also organized by TIR. The number of applications received via on-line until 31st December 2003 were 260 for prescription drugs and 270 for OTC products.

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menggalakkan. Beberapa siri kursus hands-on juga telah dianjurkan oleh TIR. Jumlah permohonan yang diterima secara on-line sehingga 31 Disember 2003 adalah 260 keluaran Racun dan 270 keluaran bukan racun.

Gerak Kerja On-line

Satu gerak kerja on-line diwujudkan untuk memastikan implementasi permohonan pendaftaran secara on-line berjalan lancar. Gerak kerja ini yang terdiri daripada pegawai BPFK dan juga pihak industri telah bermesyuarat sebanyak 8 kali pada tahun 2003 untuk membantu mengatasi apa-apa masalah yang dihadapi oleh pihak industri dan juga pihak BPFK.

Kajian Semula Garispanduan Pendaftaran

Selaras dengan perancangan untuk melaksanakan skim harmonisasi ASEAN atas keluaran farmaseutikal, pihak BPFK telah dan sedang mengambil beberapa langkah untuk mengguna-pakai ASEAN Common Technical Dossier (ACTD) dan ASEAN Common Technical Requirements (ACTR) bagi tujuan permohonan pendaftaran produk farmaseutikal secara on-line.
Sejajar dengan perkembangan keperluan regulatori semasa, Garis Panduan Pendaftaran sedia ada (Edisi 1993) dikajisemula dan dikemaskini. 2 sessi bengkel dalaman telah diadakan bagi tujuan tersebut.

Draf garis panduan yang dikajisemula diedarkan untuk ulasan pihak industri dan pihak BPFK telah membincangkan mengenai ulasan tersebut dan mengambil tindakan yang perlu. Satu konsensus dengan pihak industri akan diadakan pada awal tahun 2004 untuk persetujuan garis panduan baru yang akan diguna-pakai untuk pendaftaran secara on-line.

Kumpulan Kerja Teknikal

Kumpulan Kerja Teknikal (TWG) merupakan satu kumpulan kerjasama teknikal yang melibatkan pegawai-pegawai BPFK serta wakil-wakil pihak industri yang pakar dalam bidang regulatori dan teknikal. TWG yang merangkumi beberapa skop dibahagikan kepada beberapa kumpulan kecil yang mempunyai peranan spesifik berdasarkan bidang keutamaan yang memerlukan kajian terperinci dan mengkaji dengan mendalam aspek-aspek berkaitan keperluan pendaftaran.
Garis panduan 'Change of Manufacturing Site' yang telah digunapakai merupakan hasil kumpulan kerja teknikal pada tahun 2003. Garis Panduan Permohonan Pindaan Keluaran Berdaftar sedang dalam peringkat akhir dan akan dapat digunakan pada suku pertama tahun 2004.

PENGLIBATAN DI PERINGKAT ANTARABANGSA

Harmonisasi Farmaseutikal ASEAN

Malaysia menjadi tuan rumah kepada Mesyuarat ASEAN Consultative Committee on Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) ke-7 yang diadakan pada 1 hingga 3 Julai 2003 di Pulau Pinang. Mesyuarat tersebut diwakili oleh delegasi dari Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand dan Viet Nam. Agenda utama mesyuarat adalah membincangkan isu harmonisasi keperluan regulatori serta dokumentasi pendaftaran bagi rantau ASEAN. Seminar Validasi dianjurkan sehari sebelum mesyuarat dan disertai oleh peserta negara ASEAN.

On-line Task Force

An on-line task force was formed in order to ensure the smooth running of the implementation of the on-line registration process. This task force which consisted of representatives from the NPCB and the industry has held 8 meetings in 2003 to discuss and overcome any problems faced by the industry and the NPCB regarding the on-line registration.

Registration Guideline Review

In line with the implementation of the ASEAN Harmonization Scheme, the NPCB has taken action to adopt the ASEAN Common Technical Dossier (ACTD) and the ASEAN Common Technical Requirement (ACTR) for the application for registration of pharmaceutical products via on-line.

In line with the current regulatory requirements, 2 series of internal workshops were held to review the existing Registration Guideline (1993 ed.). The draft reviewed guideline was distributed to the industry for their comments. NPCB had compiled and discussed the feedbacks obtained from the industry. A consensus was reached between both parties to implement and use the new guideline for the on-line registration of products.

Technical Working Group

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

The guideline for the 'Change of Manufacturing Site' that is currently being used is the outcome of the task of the TWG in 2003. The guideline for the 'Application for Variation to Registered Information' has been reviewed and will be finalised by the first quarter of 2004.

INTERNATIONAL PARTICIPATION

ASEAN Pharmaceutical Harmonization

Malaysia hosted the 7th ASEAN Consultative Committee on Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) meeting from 1st till 3rd July 2003. The meeting was represented by delegates and observers from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand and Vietnam. A one-day Validation Seminar attended by ASEAN participants was held prior to the meeting.

ASEAN Cosmetic Harmonization

Under the ASEAN Consultative Committee on Standards and Quality (ACCSQ) Cosmetic Product Working Group (CPWG) program, Malaysia has already signed the agreement on ASEAN Harmonized Cosmetic Regulatory Scheme. The implementation of this scheme is in accordance to the requirements of AFTA (ASEAN Free Trade Area) and is expected to provide competitive edge to the domestic cosmetic industry to penetrate the ASEAN market.

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Harmonisasi Kosmetik ASEAN

Di bawah program ASEAN Consultative Committee on Standards and Quality (ACCSQ) Cosmetic Product Working Group (CPWG), Malaysia telah menandatangani perjanjian ASEAN Harmonized Cosmetic Regulatory Scheme. Perlaksanaan skim tersebut adalah selaras dengan keperluan AFTA (ASEAN Free Trade Area) dan dijangka akan memberi daya saing kepada industri kosmetik tempatan untuk menembusi pasaran ASEAN. Skim ini merangkumi Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme; ASEAN Mutual Recognition Arrangement of Product Registration Approvals For Cosmetic ; dan ASEAN Cosmetic Directives.

Kerjasama dalam Kursus Antarabangsa Penilaian Regulatori Ubat anjuran WHO

Malaysia menjadi tuan rumah kepada An International Course on Regulatory Drug Evaluation dari 28 Julai hingga 1 Ogos 2003. Dua puluh (20) peserta dari Indonesia, Malaysia, Philippines, Singapore dan Thailand menyertai bengkel/kursus tersebut yang dianjurkan oleh WHO dan diadakan di BPFK. Kursus memberi pendedahan terhadap proses penilaian standard produk baru dengan mengambilkira situasi spesifik dan keperluan terapeutik negara terbabit.

Kerjasama dalam Kajian Semula Bagi Kelulusan Pemasaran Keatas Produk Generik anjuran WHO

Serentak dengan Kursus Antarabangsa Penilaian Regulatori Ubat di atas, satu mesyuarat Kajian Semula Bagi Kelulusan Pemasaran Keatas Produk Generik yang juga dianjurkan oleh WHO diadakan di BPFK pada 30 dan 31 Julai 2003. Mesyuarat ini melibatkan seorang peserta dari 5 negara ASEAN iaitu Indonesia, Malaysia, Philippines, Singapore dan Thailand. Objektif mesyuarat adalah untuk mengkaji semula manual sedia ada 'The WHO manual on "Marketing Authorisation of Pharmaceutical Product with Special Reference to Multisource (Generic Product)' dan membincangkan pindaan yang dicadangkan. Beberapa syor yang berkaitan telah diajukan untuk dipertimbangkan.

Penilaian sistem regulatori negara-negara ASEAN

Pegawai Farmasi BPFK turut terlibat dalam penilaian sistem regulatori negara ASEAN dalam projek usahama WHO-ASEAN untuk harmonisasi keperluan regulatori serantau. Seorang Pegawai BPFK telah turut serta dalam delegasi yang diterajui WHO ke Bureau of Drug and Cosmetic, Ministry of Health, Cambodia untuk menilai sistem regulatori semasa pada bulan November 2003.

KESIMPULAN

Secara keseluruhannya, permohonan pendaftaran untuk produk telah meningkat sehingga 35.6% berbanding tahun sebelumnya manakala permohonan yang telah didaftarkan meningkat sebanyak 18.7%. Bahagian Penilaian dan Keselamatan Produk juga telah memperkenalkan sistem pendaftaran secara on-line pada Julai 2003 untuk memastikan proses pendaftaran produk dapat dijalankan dengan lebih cepat dan lancar.

The harmonization scheme comprises of Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme; ASEAN Mutual Recognition Arrangement of Product Registration Approvals For Cosmetic ; and ASEAN Cosmetic Directives.

Collaboration in an International Course on Regulatory Drug Evaluation organized by WHO

Malaysia hosted an International Course on Regulatory Drug Evaluation from 28th July till 1st August 2003. Twenty participants from Indonesia, Malaysia, Philippines, Singapore and Thailand attended the workshop. The course which was funded and facilitated by the WHO offered elements for a standardized evaluation of new drugs that takes into account the specific national situation and therapeutic needs.

Collaboration in the Review of Marketing Authorization on Generic Products organized by WHO

Concurrent with the above-mentioned International Course on Regulatory Drug Evaluation, another meeting involving one participant each from the same 5 ASEAN member countries namely Indonesia, Malaysia, Philippines, Singapore and Thailand was held on 30th till 31st July 2003. The aim of the meeting was to review the existing Manual for a Drug Regulatory Authority, The WHO manual on "Marketing Authorization of Pharmaceutical Product with Special Reference to Multi Source (Generic Product)" and proposed changes were discussed. Several pertinent recommendations were put forward by the group for consideration. The two-day meeting was also funded and facilitated by WHO.

Review of the regulatory systems of ASEAN countries

Officers from the NPCB are also involved in the review visits to other ASEAN regulatory authorities in conjunction with the WHO-ASEAN project on harmonization of regulatory requirements. An officer from NPCB has joined a WHO-led delegation to visit the Bureau of Drug and Cosmetic, Ministry of Health, Cambodia, to review its present regulatory system in November 2003.

CONCLUSION

In general, applications for product registration had increased to 35.6% compared to the previous year and applications being approved increased to 18.7%. The Product Evaluation and Safety Division had introduced the on-line registration system in July 2003 to ensure a faster and more efficient registration process.

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BAHAGIAN APB DAN PELESENAN

OBJEKTIF

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

AKTIVITI

Bahagian ini menjalankan aktiviti-aktiviti seperti berikut:

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

PENCAPAIAN

Pemeriksaan APB

Tahun 2003 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 176 pemeriksaan APB telah dijalankan pada tahun 2003. Pemeriksaan tersebut meliputi 40 premis pengilang keluaran racun, 21 keluaran bukan racun, 98 keluaran tradisional, 15 kosmetik dan 2 pemeriksaan veterinari.

GMP AND LICENSING DIVISION

OBJECTIVES

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

ACTIVITIES

The following activities are carried out:

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

ACHIEVEMENTS

GMP Inspection

Year 2003 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 176 inspections were conducted in 2003. These inspections included 40 premises for scheduled poison, 21 non-scheduled poison manufacturers, 98 traditional medicines, 15 cosmetics and 2 veterinary. ***Figure 1*** *shows the number of GMP inspection carried out from 2000 to 2003.*

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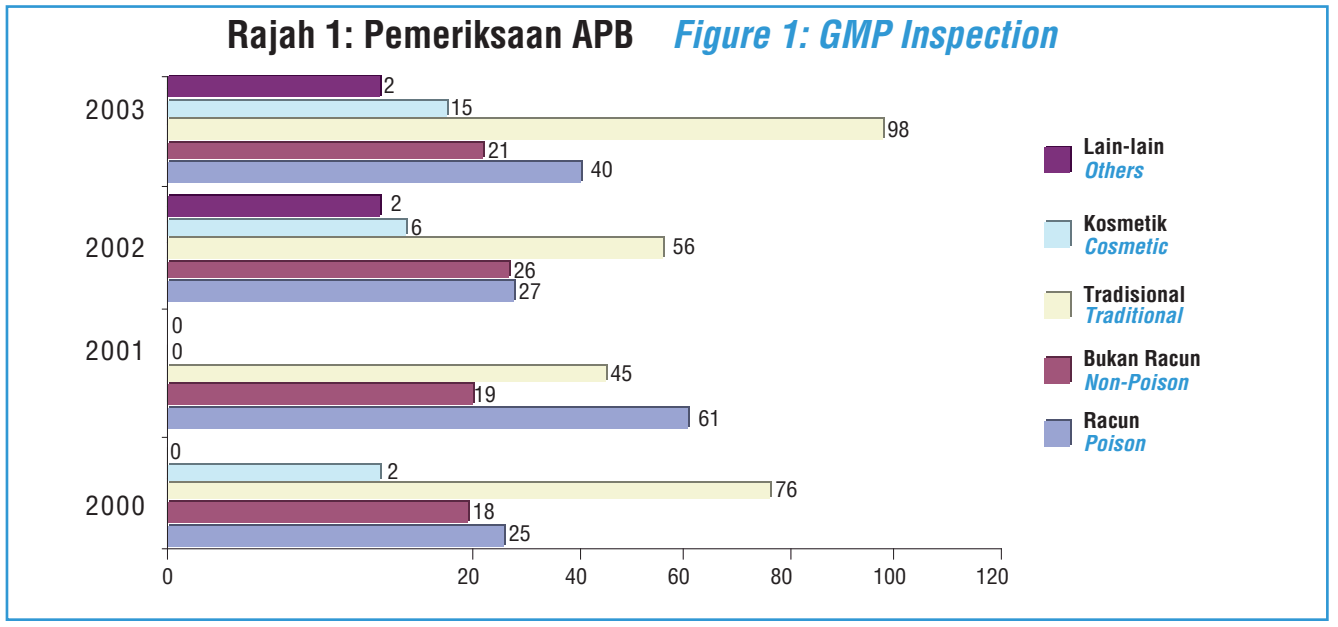


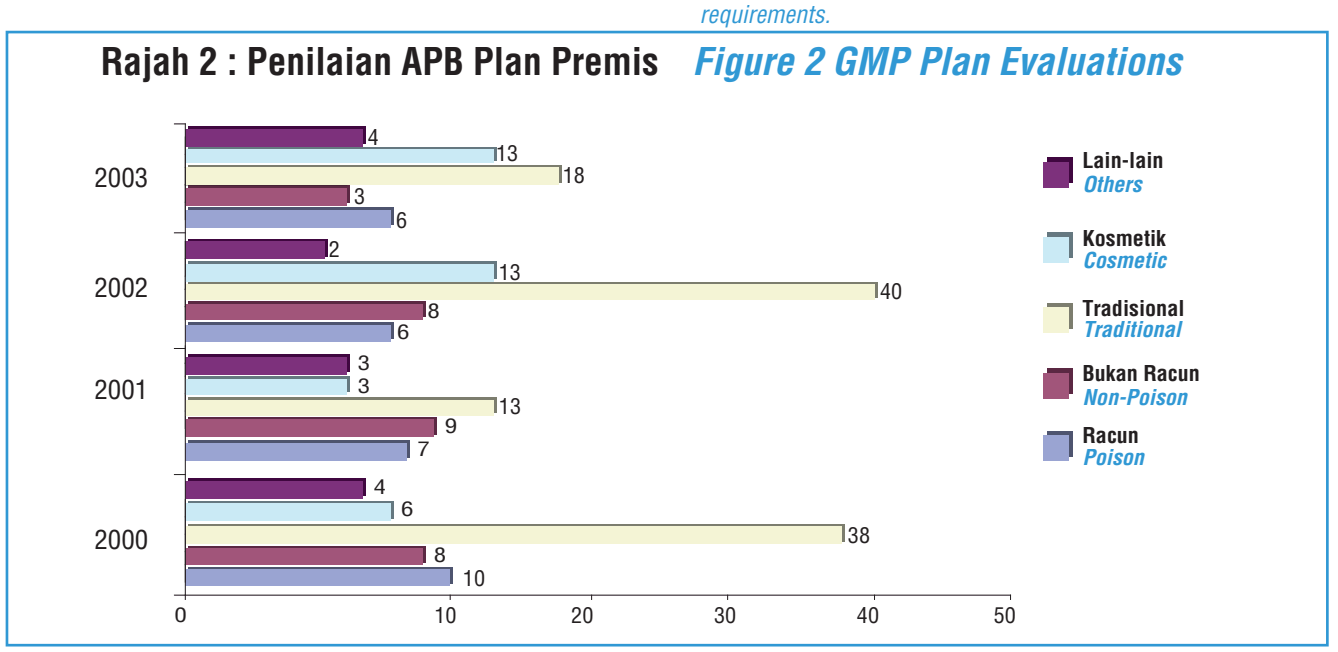
Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
(Source: National Pharmaceutical Control Bureau)

Penilaian Susun-Atur APB Pelan Premis Pengilang

Sejumlah 44 pelan susun-atur premis pengilang baru dan sediada telah dinilai, termasuk 6 premis pengilang keluaran racun, 3 keluaran bukan racun, 18 ubat tradisional, 13 kosmetik dan 4 lain-lain premis hospital dan veterinari agar mematuhi keperluan APB di Malaysia.

GMP Evaluation of Manufacturing Premises Lay-out Plans

A total of 44 lay-out plans for new and remodeling of existing manufacturing premises were evaluated, which comprises of 6 premises of scheduled poisons manufacturers, 3 non-scheduled poison, 18 traditional medicines, 13 cosmetics and 4 others hospital and veterinary facilities to comply with our local requirements.



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

Status Perkembangan Premis Berlesen

Sebanyak 1408 lesen telah dikeluarkan pada tahun 2003. Pada tahun 2003, jumlah pengilang berlesen ialah 217, 316 pengimpot berlesen dan 875 pemborong berlesen.

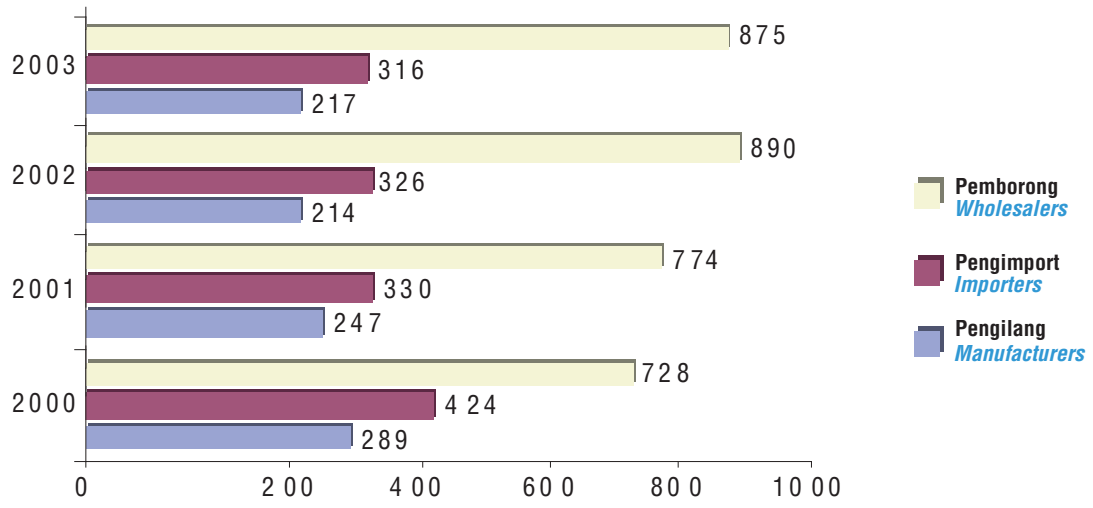
Senarai serta maklumat lengkap mengenai premis-premis berlesen boleh dilayari menerusi laman web BPFK (www.bpfk.gov.my). Segala maklumat dikemaskini setiap bulan.

Growth Status of Licensed Premises

A total of 1408 licenses were issued in year 2003. There were 217 licensed manufacturers, 316 licensed importers and 875 licensed wholesalers.

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

Rajah 3 Jumlah Lesen *Figure 3: Number of Licences*



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

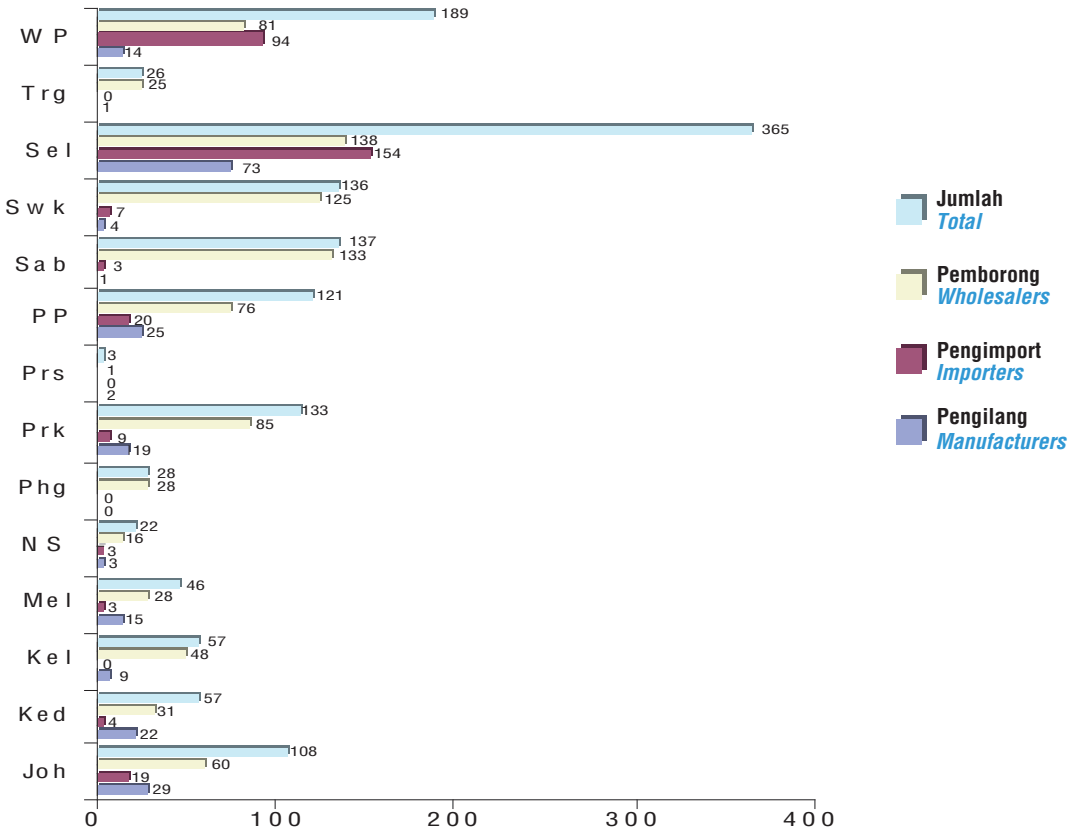
Taburan Geografi Premis Berlesen

Taburan geografi premis-premis berlesen bagi tahun 2003 adalah seperti yang digambarkan dalam **Rajah 4**. Negeri Selangor mempunyai premis berlesen yang paling banyak, diikuti oleh Wilayah Persekutuan (Kuala Lumpur) dan Sabah di tempat ketiga.

Geographical Distribution of Licensed Premises

*Geographical distribution of licensed premises for the year 2003 is illustrated in **Figure 4**. Selangor remained the highest number of licensed premises, followed by Wilayah Persekutuan (Kuala Lumpur) and Sabah respectively.*

Rajah 4 : Taburan Geografi Premis Berlesen
Figure 4: Geographical Distribution of Licensed Premises



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

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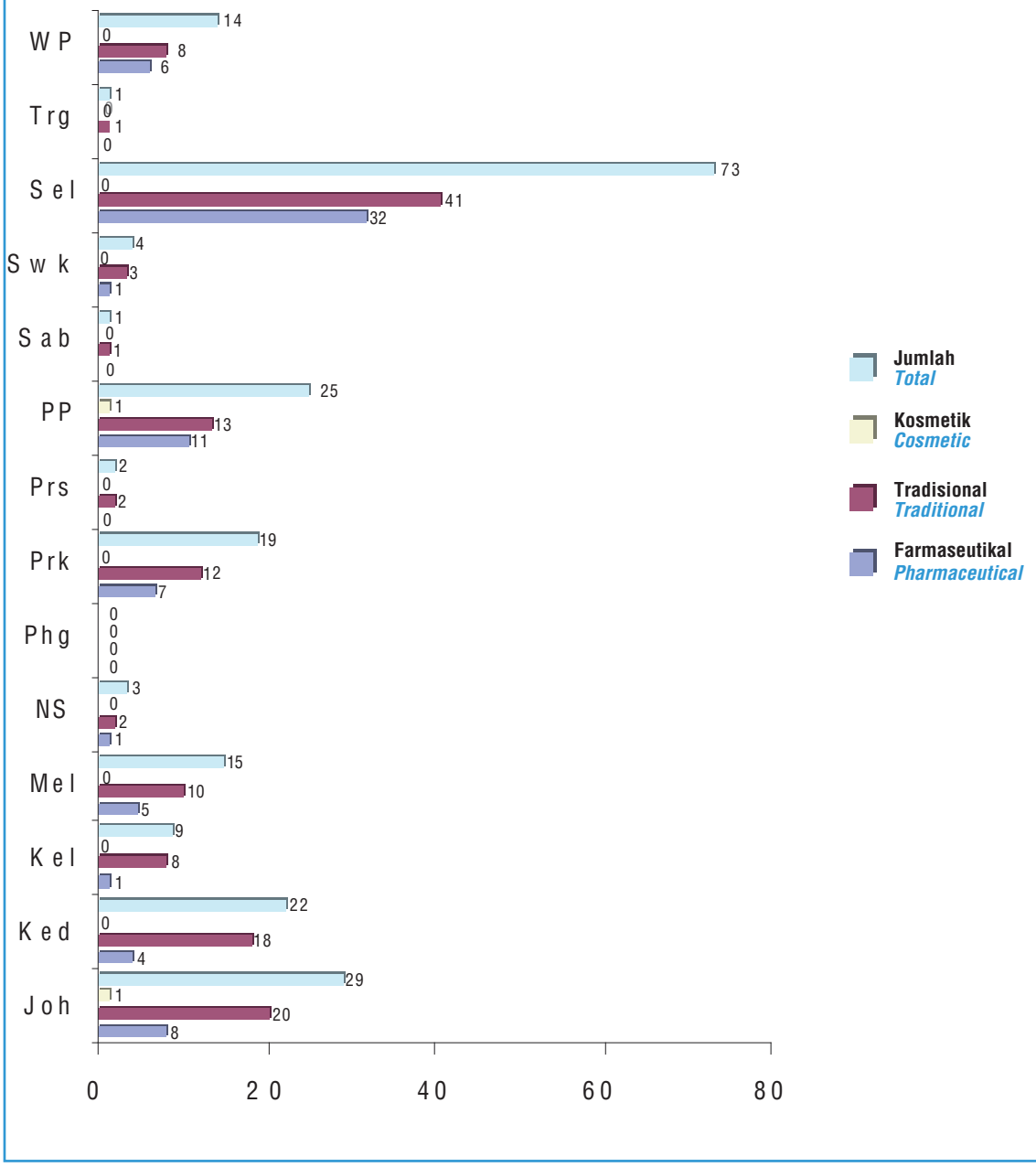
Rajah 5 Kategori Premis Lesen Pengilang

Figure 5: Categories of Licensed Manufacturers



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

Kategori Premis Pengilang Berlesen

Kategori premis pengilang berlesen bagi tahun 2003 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 2003 as illustrated in **Figure 5**. Selangor has highest number of licensed manufacturing facilities, followed by Johor and Pulau Pinang.*

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Khidmat Nasihat

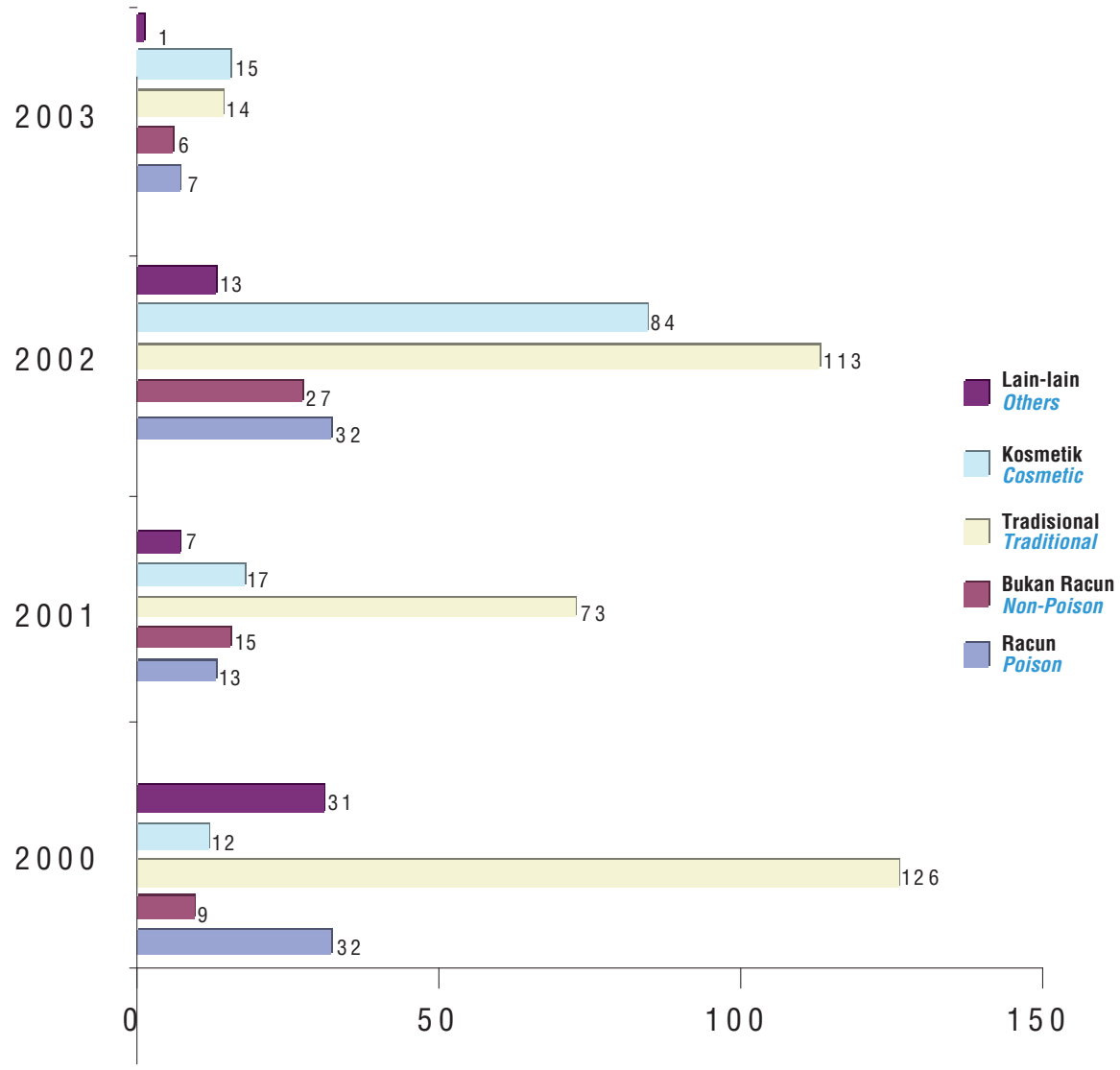
Pada tahun 2003, sebanyak 43 khidmat nasihat telah diberikan, daripada jumlah yang dicapai, 15 adalah berkenaan dengan keluaran racun, 6 keluaran bukan racun, 14 ubat tradisional, 15 kosmetik dan 1 lain-lain.

Advisory Service

In 2003, a total of 43 advisory services were given. From this number of achievement, 15 of them were related to GMP scheduled poison, 6 non-scheduled poison, 14 traditional medicine, 15 cosmetic and 1 others. Statistic for the year 2000 until 2003 as illustrated in ***Figure 6****.*

Rajah 6 : Statistik bagi tahun 2000 hingga 2003 untuk Khidmat Nasihat

Figure 6: GMP Advisory Service



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

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Senarai Tambahan Keluaran Berdaftar

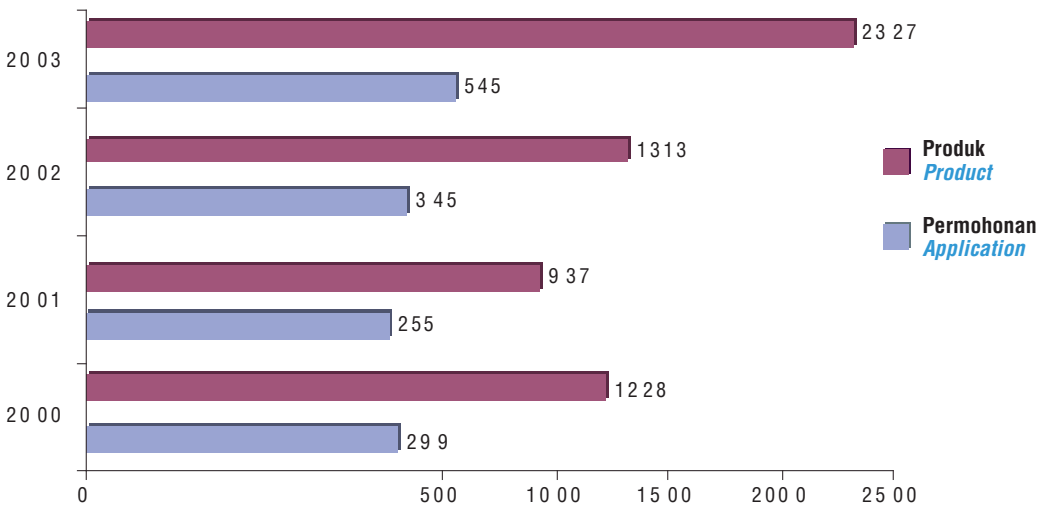
Jumlah permohonan yang diproses pada tahun 2003 adalah sebanyak 545 dan ini meliputi sebanyak 2327 produk.

Additional Lists for Registered Products

The total number of application processed in 2003 was 545 and these include 2327 products.

Rajah 7: Statistik bagi pengeluaran Senarai Tambahan Keluaran Berdaftar dari tahun 2000 sehingga 2003

Figure 7: Statistic for issuance of Additional Registered Product List for the year 2000 until 2003



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

Perakuan APB Untuk Tujuan Eksport

Pada tahun 2003, jumlah perakuan APB yang dikeluarkan adalah sebanyak 297. Perakuan ini adalah untuk negara-negara seperti Albania, Armenia, Azerbajian, Georgia, Australia, Bostwana, Belgium, Kemboja, China, Jamaica, Romania, Iraq, Nepal, Jepun, Fiji, Ethiopia, Honduras, Hong Kong, Indonesia, Kenya, Korea, Laos, Libya, Lithuania, Maldova, Kazakhstan, Kyrgystan, Maldives, Mauritius, Netherlands, Macau, Madagascar, Myanmar, New Zealand, Nigeria, Papua New Guinea, Filipina, Pakistan, Ghana, Sudan, Arab Saudi, Syria, Singapura, Sri Lanka, Afrika Selatan, Russia, Bangladesh, Taiwan, Tanzania, Thailand, Trinidad & Tobago, Turki, Ukraine, U.A.E, U.S.A, Vietnam, Yaman dan Zimbabwe.

GMP Certification for Export Purposes

In 2003 the total number of GMP certificates issued was 297. These certification are for countries such as Albania, Armenia, Azerbajian, Georgia, Australia, Bostwana, Belgium, Kemboja, China, Jamaica, Romania, Iraq, Nepal, Jepun, Fiji, Ethiopia, Honduras, Hong Kong, Indonesia, Kenya, Korea, Laos, Libya, Lithuania, Maldova, Kazakhstan, Kyrgystan, Maldives, Mauritius, Netherlands, Macau, Madagascar, Myanmar, New Zealand, Nigeria, Papua New Guinea, Filipina, Pakistan, Ghana, Sudan, Arab Saudi, Syria, Singapura, Sri Lanka, Afrika Selatan, Russia, Bangladesh, Taiwan, Tanzania, Thailand, Trinidad & Tobago, Turki, Ukraine, U.A.E, U.S.A, Vietnam, Yaman dan Zimbabwe.

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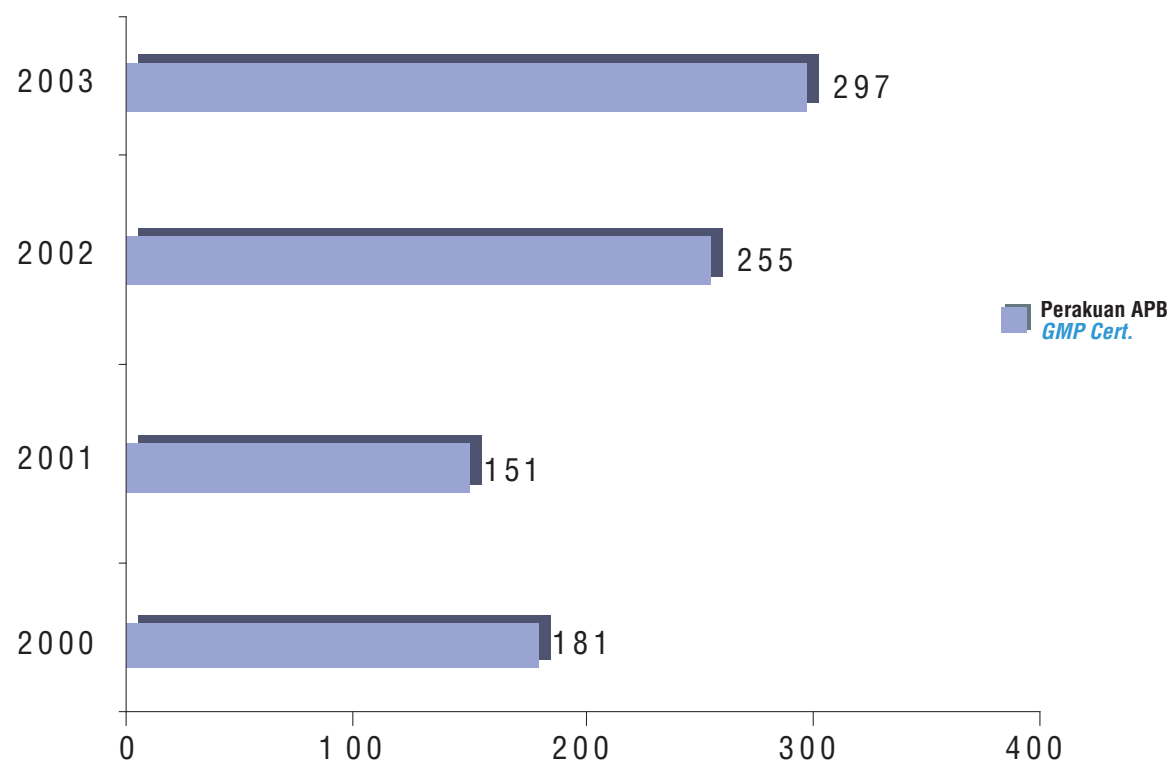
Rajah 8 : Pengeluaran Perakuan APB untuk tujuan eksport

Figure 8 : GMP Certificates Issued from 2000 to 2003



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

Tindakan Punitif

Pihak Berkuasa Kawalan Dadah (PBKD) telah menggantung 7 lesen pengilang pada tahun 2003. Lesen bagi lima pengilang tradisional dan dua pengilang farmaseutikal telah ditarik balik kerana terlibat dengan pengeluaran produk yang tercemar dan mempunyai tahap APB yang amat lemah.

Mesyuarat Luar Negara

BPFK selaku pusat kerjasama regulatori untuk WHO telah diberi kepercayaan untuk mengendalikan latihan; SEARO dari WHO telah melantik seorang pegawai dari bahagian APB & Pelesenan untuk menjadi jururunding jangka pendek/pengajar untuk mengendalikan kuliah dan latihan setempat berkenaan dengan pematuhan terhadap komplians APB yang dianjurkan oleh Drug Adminisration, Kementerian Kesihatan Nepal didalam kerjasama teknikal dengan WHO.

Seorang Ketua Penolong Pengarah, APB dan Pelesenan telah menghadiri mesyuarat ACCSQ Cosmetics Products Group yang ke 7 di Manila, Flippina dalam bulan Jun, 2003. Dalam mesyuarat pertama komiti kosmetik ASEAN yang diadakan di Vietnam pada bulan Disember 2003, Malaysia sekali lagi telah diberi kepercayaan untuk mengetuai projek implementasi/intepretasi kosmetik APB di kalangan Negara ASEAN.

Punitive Actions

DCA has revoke seven manufacturer's licenses in 2003. Five traditional manufacturing facilities and two pharmaceutical manufacturing facilities had their license revoked. These facilities were involved with manufacturing of adulterated of products and very poor compliance of GMP respectively.

Meetings Abroad.

NPCB as the WHO collaborating centre for regulatory has been trusted to conduct training; SEARO of WHO has engaged an officer from the GMP & Licensing Division as a short term consultant/trainer to conduct lectures and on site training on compliance audit for GMP organized by the Department of Drug Administration, Ministry of Health Nepal in technical cooperation with WHO.

One of Head Assistant Director of the Division attended the 7th meeting of the ACCSQ Cosmetic Working Group in Jun 2003 in Manila, Philippines. At the 1st ASEAN Cosmetic Committee meeting in Vietnam in December 2003, Malaysia again has been trusted to lead the project in implementation/interpretation of GMP for cosmetic among the ASEAN member countries.

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Perancangan Untuk Tahun 2004

Latihan APB Farmaseutikal Bercorak Modul

Program latihan APB bercorak modul akan bermula pada Mei dan berakhir pada November 2004. Program ini dikelolakan bersama dengan MOPI.

Modul 1 – Quality Assurance and Quality Management

Modul 2 – Good (Analytical) Laboratory Practices

Modul 3 – Validation Management

Modul 4 – Practical Exercise in Preparing Validation Protocol

Modul 5 – Production Management and GMPs

Modul 6 – Facility, Services and Water System

Modul 7 – Computer System Validation

Modul 8 – Sterile Manufacturing Program

Modul 9 – Microbiology Quality Control

Modul 10 – Practical Internal Auditing Programs

Modul 11 – Biotechnology Products and GMPs

Modul 12 – Risk Management and Utilising Risk Assessment in Pharmaceutical GMPs

Modul 13 – Pharmaceutical Leadership and Staff Development Program

Plans for Year 2004

GMP Modular training

The GMP modular training will start in May and ends in November 2004. This program is jointly organized with MOPI.

Module 1 – Quality Assurance and Quality Management

Module 2 – Good (Analytical) Laboratory Practices

Module 3 – Validation Management

Module 4 – Practical Exercise in Preparing Validation Protocol

Module 5 – Production Management and GMPs

Module 6 – Facility, Services and Water System

Module 7 – Computer System Validation

Module 8 – Sterile Manufacturing Program

Module 9 – Microbiology Quality Control

Module 10 – Practical Internal Auditing Programs

Module 11 – Biotechnology Products and GMPs

Module 12 – Risk Management and Utilising Risk Assessment in Pharmaceutical GMPs

Module 13 – Pharmaceutical Leadership and Staff Development Program

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.

ASEAN Pharmaceutical Harmonisation

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

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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

OBJECTIVES

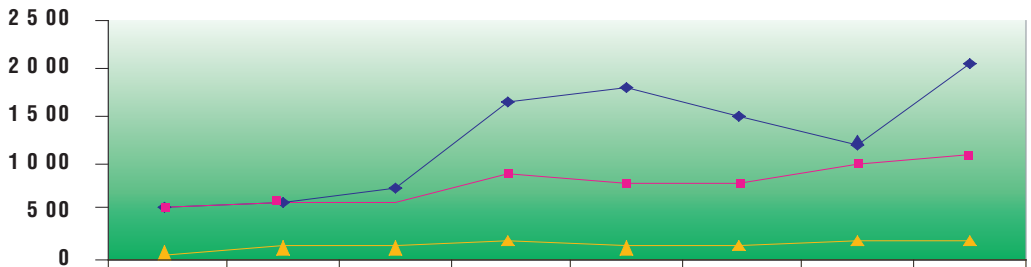
The objectives of the Surveillance and Pharmacovigilance Division are to ensure that products registered by the Drug Control Authority (DCA) are safe, efficacious and meet the established standards of quality.

ACHIEVEMENTS

*The achievements of this division are summarized 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 **Fig.1**.*

Rajah 1 : Bebankerja dibawah aktiviti pemantauan & penyiasataan produk dan pemantauan kesan ADR

Fig. 1. Workload under the activities of surveillance, investigation of products complaints and ADR monitoring.



	1996	1997	1998	1999	2000	2001	2002	2003
No. of products sampled	531	602	714	1635	1789	1487	1201	2037
No. of ADR	530	602	603	875	792	811	1000	1063
No. of complaints reports	55	97	111	151	110	124	181	180

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

SURVEILANS

Bagi tahun 2003, terdapat 28959 keluaran yang bedaftar dibawah PBKD dan sebanyak 2037 sampel telah diambil untuk tujuan surveilans. Ini mewakili 7.03% jumlah keluaran yang berdaftar dibawah PBKD. Akan tetapi, perlu diingatkan bahawa bukan semua keluaran yang berdaftar berada dalam pasaran dan peratusan keluaran yang disampel kemungkinan lebih tinggi berbanding dengan jumlah sebenar dipasaran.

Kesemua sampel yang diambil dibawah program surveilans 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 2003, a total of 2037 samples from a total of 28 959 registered products were sampled for quality testing. This represents 7.03% of the total number of products registered by the DCA. However, it must be noted that not all registered products may actually be marketed and so the number of products sampled may actually represent a higher percentage in terms of marketed products.

All the products sampled 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 current protocols of analysis supplied by the manufacturers themselves. Testing of traditional medicines was done in line with the established tests i.e. testing for microbial and fungal contamination, heavy metals and basic pharmaceutical tests.

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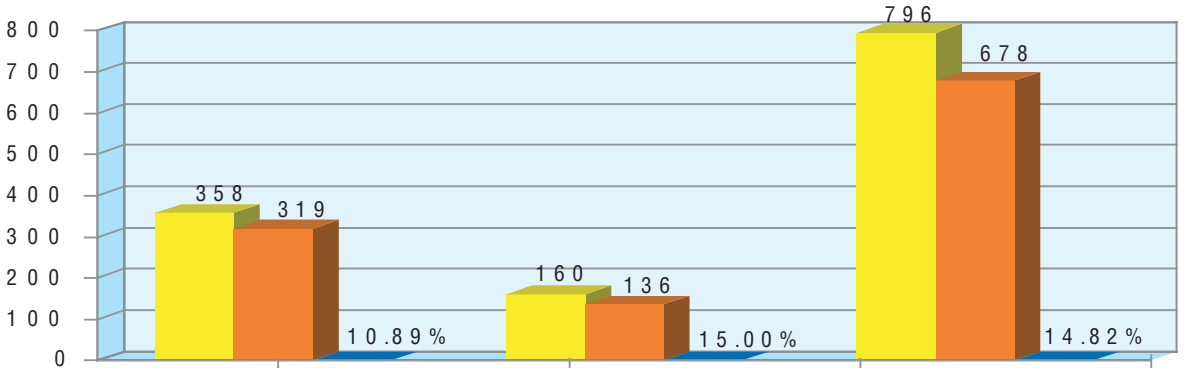
Rajah 2 : Keputusan ujian makmal untuk sampel surveilans
Fig. 2: Results of laboratory testing of surveillance samples



	Racun Berjadual *Scheduled Poisons*	Produk OTC *Over-the-Counter Products*	Ubat Tradisional *Traditional Medicines*
Bilangan diuji *No. Tested*	358	160	796
Bilangan Lulus *No. Passed*	319	136	678
% Gagal *% Failed*	10.89%	15.00%	14.82%

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

Disebabkan lebihan dari tahun sebelumnya, keputusan daripada makmal adalah untuk 1314 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 1314 products. An analysis of the failure rate of products tested by category of products is shown in **Fig. 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.

Sebanyak 346 Panggilbalik Tahap 1 (dalam tempoh 24 jam) telah dikeluarkan dimana 204 adalah keluaran tradisional dan 142 adalah keluaran bukan racun disebabkan isu panggilbalik produk PAN Pharmaceutical dari Australia.

115 kelompok keluaran telah dikenakan arahan Panggilbalik Tahap 3 (dalam tempoh 30 hari) iaitu 27 keluaran racun, 16 keluaran bukan racun dan 72 keluaran traditional. Kesemua panggilbalik dilakukan sehingga tahap peringkat penjualan/pembekalan kepada pelanggan. Tiada panggilbalik yang dilakukan memerlukan sehingga ke peringkat pelanggan.

35 kelompok keluaran telah secara sukarela dipanggilbalik oleh pemegang keluaran berdaftar iaitu 25 keluaran racun, 8 keluaran bukan racun dan 2 keluaran tradisional.

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.

A total of 346 Degree I Recalls (within 24 hours) were instituted of which 204 were traditional medicines and 142 were Over- the-Counter products as a result of the Pan Pharmaceuticals recall issue from Australia. There were two Degree 2 Recalls (within 72 hours) for traditional medicines.

115 directives were issued for Degree 3 Recalls (within 30 days) for a batch recall of 27 prescription drugs, 16 Over-the-Counter products and 72 traditional medicines. All the recalls were up to point of sale. There were no recalls which warranted recalling up to the consumer level.

There were 35 recalls conducted voluntarily by the product registration holders involving 25 prescription drugs, 8 OTC products and 2 traditional medicines.

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

Tahun *Year*	1999			2000			2001			2002			2003		
Jumlah *Total*	148			148			122			198			464		
Kategori *Category (A/X/T)*	35	20	93	22	13	87	32	17	99	55	29	114	52	166	280

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

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ADUAN TERHADAP KELUARAN BERDAFTAR 2003

Bilangan aduan terhadap keluaran berdaftar bagi tahun 2003 tidak banyak berbeza jika dibandingkan dengan tahun 2002 dimana bilangan aduan terhadap keluaran berdaftar bagi tahun 2003 adalah 180 berbanding 181 bagi tahun 2002. Tindakan susulan telah diambil untuk menyelesaikan aduan-aduan ini dalam tempoh 6 minggu dalam lebih dari 95% kes.

PEMONITORAN ADR

Terdapat sedikit peningkatan dalam jumlah laporan kesan advers ubat yang diterima dalam tahun 2003, iaitu sebanyak 1063 laporan berbanding dengan 1000 laporan dalam tahun 2002 **(Gambarajah 3)**.

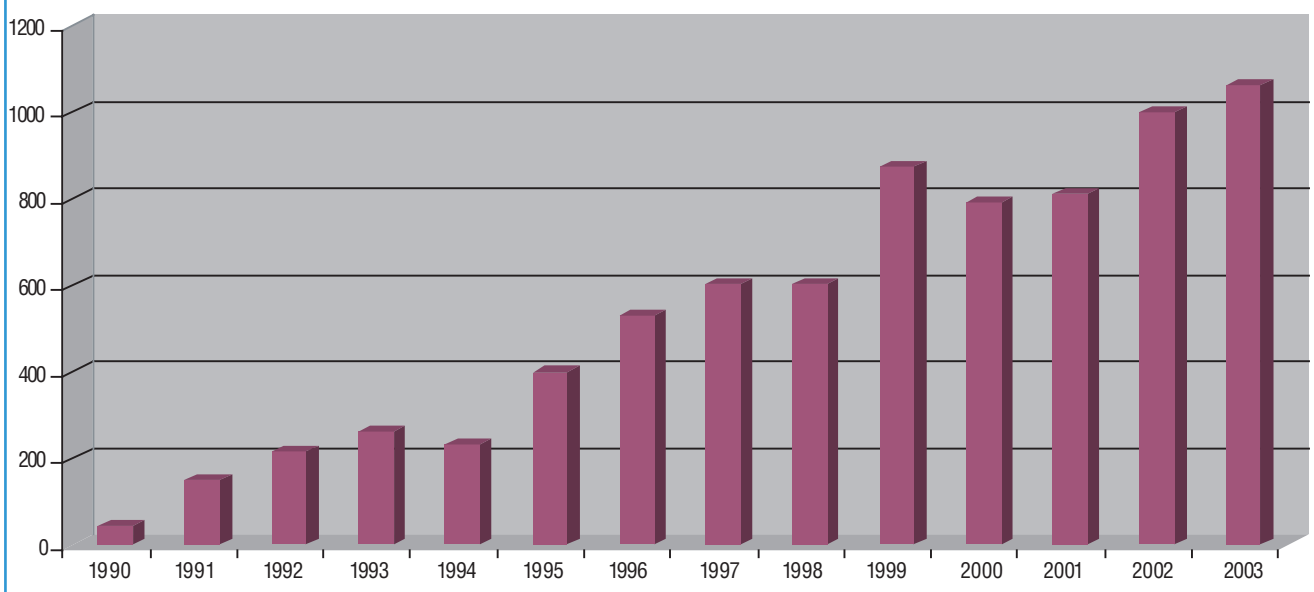
PRODUCT COMPLAINTS

The number of product complaints received in 2003 for registered products was almost the same as that in 2002 with a total of 180 complaints being received as compared to 181 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 reactions reports received increased in 2003 as a total of 1063 reports were received as compared to 1000 In 2002 ***(Fig. 3)****.*

Rajah 3: Bilangan Laporan Diterima
Fig. 3: No. Of ADR Reports Received



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

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

Dari analisa laporan ADR berdasarkan pelapor, kebanyakan laporan kesan advers ubat diterima dari Pegawai Perubatan yang bertugas di hospital- hospital kerajaan.Laporan kesan advers ubat juga meningkat sebanyak 36% bagi tahun 2003 bagi pemegang pendaftaran.

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.

The breakdown of ADR reports submitted from the various states is shown in ***Fig. 4****.*

From the analysis of the health professionals who submitted ADR reports it can be seen that doctors based in government hospitals submitted the most reports. Reporting by product registration holders also increased in 2003 by 36% as compared to 2002. ***(Fig 5)***

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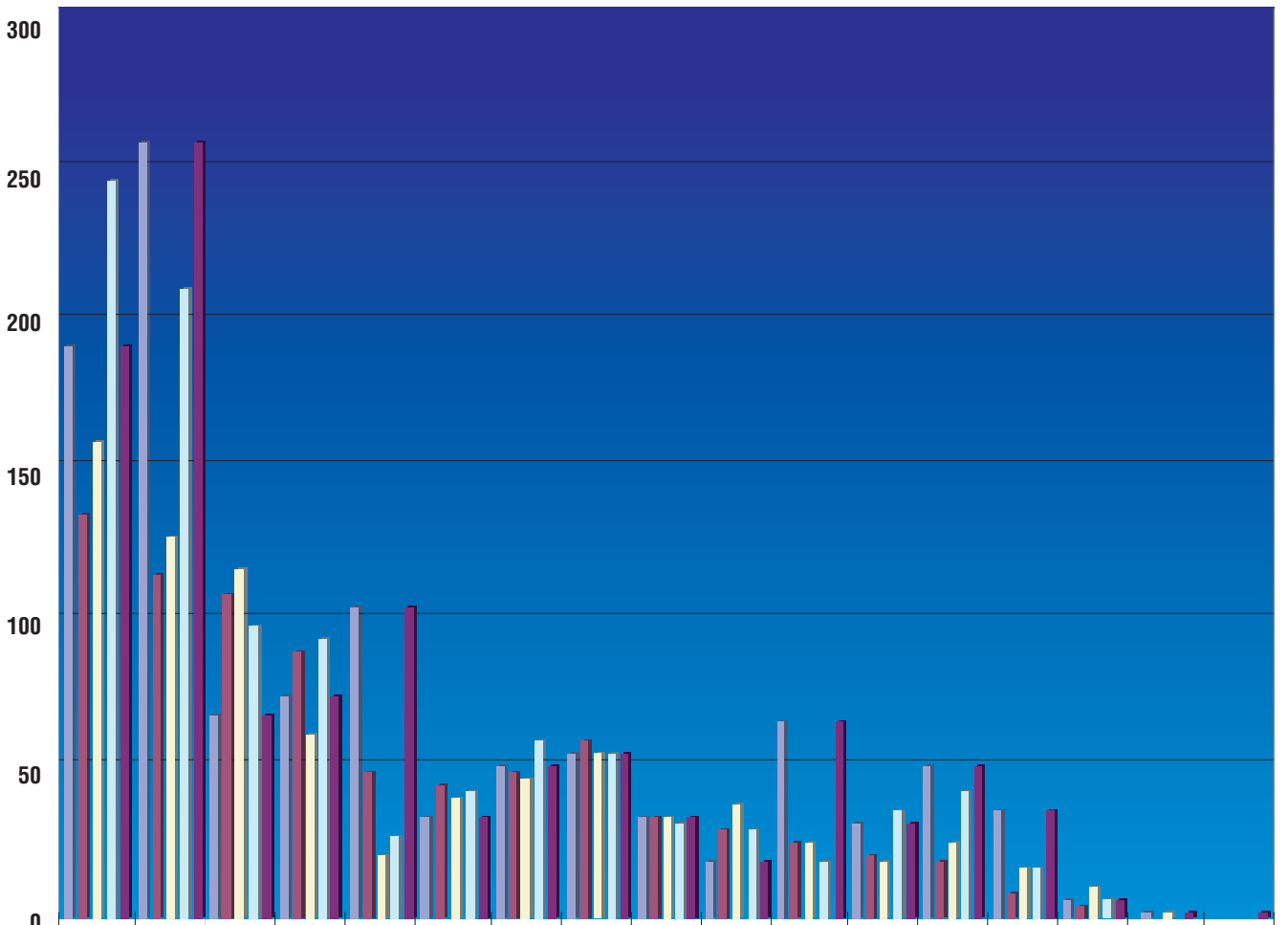
GAMBARAJAH 4 : ANALISA LAPORAN 'ADR' BERDASARKAN NEGERI YANG MELAPORKAN

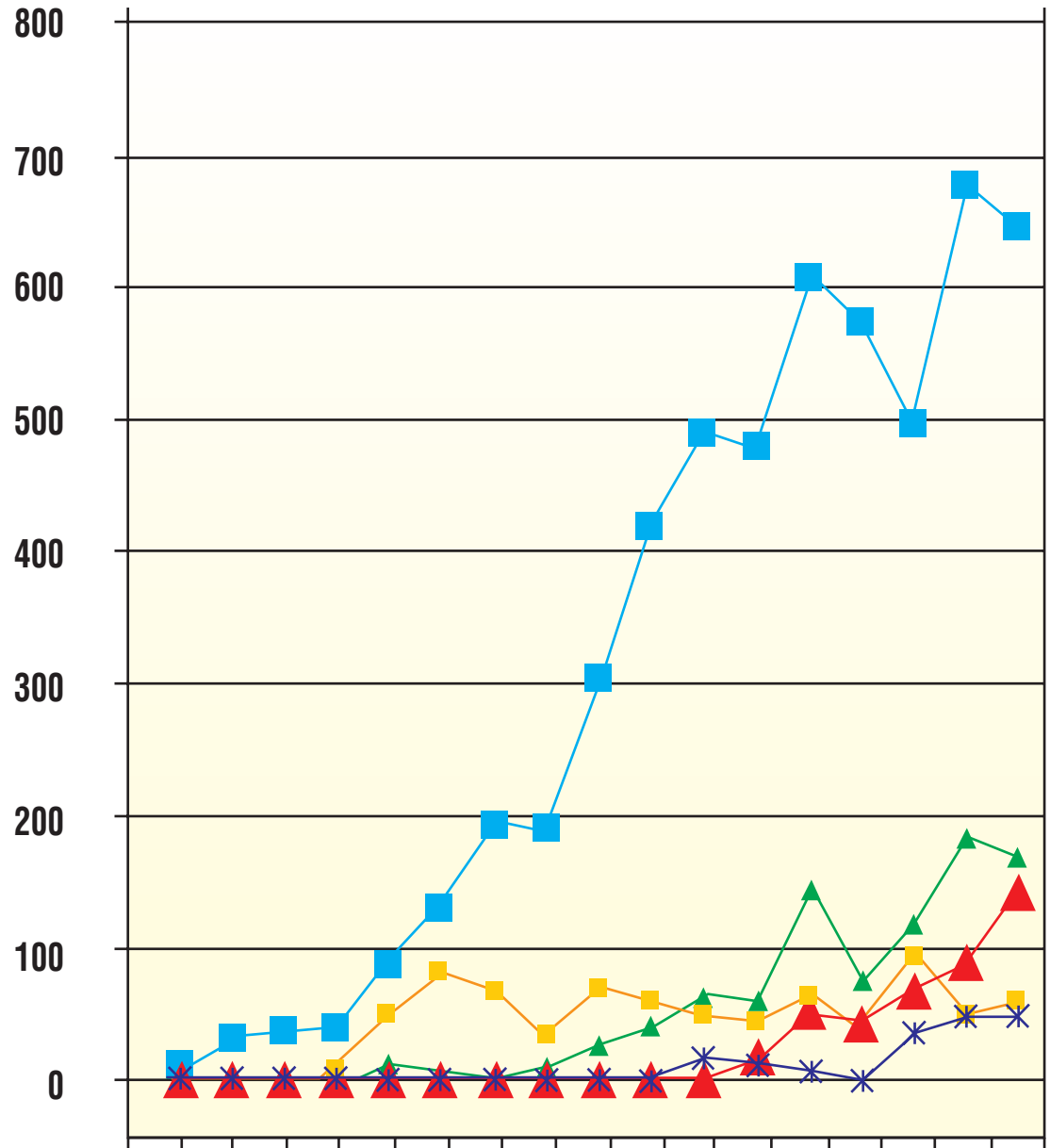
FIGURE 4 : ANALYSIS OF ADRs BY REPORTING STATES



	WPKL	SEL	PRK	JHOR	PHG	SWAK	SBAH	N. SEM	P. PNG	TRGNU	KDH	KEL	MEL	WP LABUAN	PRLIS	PUTRA JAYA	UN KNOWN
1999	188	257	66	74	102	34	50	54	33	17	65	30	50	36	5	1	0
2000	112	112	106	88	47	43	48	58	34	29	24	19	17	8	3	0	0
2001	157	126	114	61	20	39	46	53	32	38	24	18	24	16	9	1	0
2002	245	209	97	92	26	42	58	53	30	29	17	36	41	16	5	0	0
2003	188	257	66	74	102	34	50	54	33	17	65	30	50	36	5	1	1

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

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



	87	88	89	90	91	92	93	94	95	96	97	98	99	'00	'01	'02	'03
Govt Drs	10	32	36	39	87	129	193	191	303	419	489	480	608	573	496	678	646
Private Drs	0	1	2	4	51	81	68	33	70	61	51	44	66	38	94	49	61
Pharmacists	0	3	2	1	12	6	2	9	27	40	62	61	141	74	118	182	169
Industry	0	0	0	0	0	0	0	0	0	0	1	18	54	43	67	90	141
University	0	0	0	0	0	0	0	0	0	0	16	11	7	0	36	47	47

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

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PENJAWATAN

Terdapat beberapa perubahan ketara pada tahun 2003 dengan pertambahan satu jawatan Pegawai Farmasi U3 yang ditempatkan di bahagian surveilans untuk keluaran tradisional.

LATIHAN

Pn. Abida telah membuat latihan sangkutan dengan TGA Australia selama dua minggu untuk "hands on training" di dalam pemonitoran kesan advers ubat dan aktiviti surveilans.

PRESENTASI

B ahagian ini terlibat di dalam penyampaian beberapa kertas pada pelbagai forum dalam topik berkaitan dengan surveilans dan pemonitoran keselamatan ubat.

PERANCANGAN

Bahagian ini akan meneruskan surveilans rutin ke atas produk-produk yang berdaftar dan juga akan menjalankan surveilans ke atas produk-produk yang disyaki mengandungi adulteran, produk-produk dari pengilang-pengilang bermasalah yang dikenalpasti serta produk-produk yang sukar dikilangkan.

Bahagian ini juga di dalam perncangan untuk menjalankan kajian di kalangan pengamal-pengamal perubatan dan industri-industri farmaseutikal bagi mengenalpasti kaedah sistem melapor yang lebih baik..

STAFFING

The year 2003 saw some changes in this division with an additional U3 pharmacist being posted to handle surveillance of traditional medicines.

TRAINING

Pn Abida Haq was attached with the TGA Australia for two weeks for "hands-on training" in ADR monitoring and surveillance activities

PRESENTATIONS

This division was involved in presenting several papers at various forums on topics both locally and internationally pertaining to surveillance and drug safety monitoring.

FUTURE PLANS

The division will continue to conduct routine surveillance of registered products and to do targeted surveillance of products suspected to contain adulterants, products from problematic manufacturers identified and difficult to manufacture products.

Plans are underway to conduct surveys amongst health professionals and the pharmaceutical industry to identify means by which the reporting system can be further improved.

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BAHAGIAN ANALISIS UBAT

PENGENALAN

Selaras dengan matlamat organisasi, Bahagian Analisis Ubat (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 diuji termasuk produk untuk permohonan pendaftaran, pengawasan ke atas produk berdaftar di pasaran, kes-kes aduan untuk produk berdaftar dan sampel penguatkuasaan. Ujian-ujian yang dijalankan adalah berasaskan penentuan 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 teknikal yang moden serta tenaga profesional yang berpengetahuan dan mahir. Justeru itu BAU berupaya menyediakan latihan dalam aspek kawalan kualiti produk untuk personel-personel tempatan dan luar negeri.

PENCAPAIAN

Pencapaian BAU bagi tahun 2003 adalah seperti berikut :

Beban Kerja

Sepanjang tahun 2003 sebanyak 4,867 sampel telah diterima untuk ujian yang terdiri dari 1,654 (34%) sampel produk farmaseutikal dan 3,213 (66%) sampel produk tradisional **(Rajah A)**. Keseluruhannya merangkumi 2,483 (51%) sampel pendaftaran, 1,891 (38.9%) sampel pengawasan, 88 (1.8%) sampel aduan dan 405 (8.3%) sampel dari Unit Penguatkuasa Farmasi (UPF) dan lain-lain.

Dari angka-angka di atas, sebanyak 4,180 sampel telah diuji yang terdiri dari 1,388 (33.2%) sampel produk farmaseutikal dan 2,792 (66.8%) sampel produk tradisional **(Rajah B)**. Keseluruhannya merangkumi 2,420 (57.9%) sampel pendaftaran, 1,337 (32%) sampel pengawasan, 114 (2.8%) sampel aduan dan 305 (7.3%) sampel UPF dan lain-lain.

DRUG ANALYSIS DIVISION

INTRODUCTION

In line with the objective of the organisation, Drug Analytical Division (DAD) continues to play an effective role in 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, complaint upon registered products and products from enforcement activities. The tests conducted are based on pharmacopoeial, in-house or approved manufacturers' limits and specifications.

As a component of 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 pharmaceutical quality control aspect for personnel from local establishments and abroad.

ACHIEVEMENT

The achievements of DAD in 2003 are as follows:

Workload

*Throughout the year 2003, DAD has received a total of 4,867 samples for testing comprising of 1,654 (34%) pharmaceutical products and 3,213 (66%) traditional products **(Figure A)**. The types of sample included 2,483 (51%) registration samples, 1,891 (38.9%) surveillance samples, 88 (1.8%) complaint samples and 405 (8.3%) samples from Pharmacy Enforcement Unit (PEU) and others.*

*From the above figures, a total of 4,180 samples were tested in the year 2003 comprising of 1,388 (33.2%) samples of pharmaceutical products and 2,792 (66.8%) samples of traditional products **(Figure B)**. The sample types included 2,420 (57.9%) registration samples, 1,337 (32%) surveillance samples, 114 (2.8%) complaint samples and 305 (7.3%) enforcement and other samples.*

Rajah A : Jenis Sampel Diterima
Figure A : Type Of Samples Received

TRADISIONAL 66%
TRADITIONAL

- **Pendaftaran 2027**
  Registration
- **Pengawasan 1186**
  Surveillance

FARMASEUTIKAL 34%
PHARMASEUTICAL

- **Pendaftaran 456**
  Registration
- **Pengawasan 705**
  Surveillance
- **Aduan 88**
  Complaint
- **UPF & Lain-Lain 405**
  FEU & Others

Rajah : B Jenis Sampel Diuji
Figure B : Types Of Samples Tested

TRADISIONAL 66.8%
TRADITIONAL

- **Pendaftaran 2011**
  Registration
- **Pengawasan 777**
  Surveillance
- **Aduan & Lain-Lain 4**
  Complaint & Others

FARMASEUTIKAL 33.2%
PHARMASEUTICAL

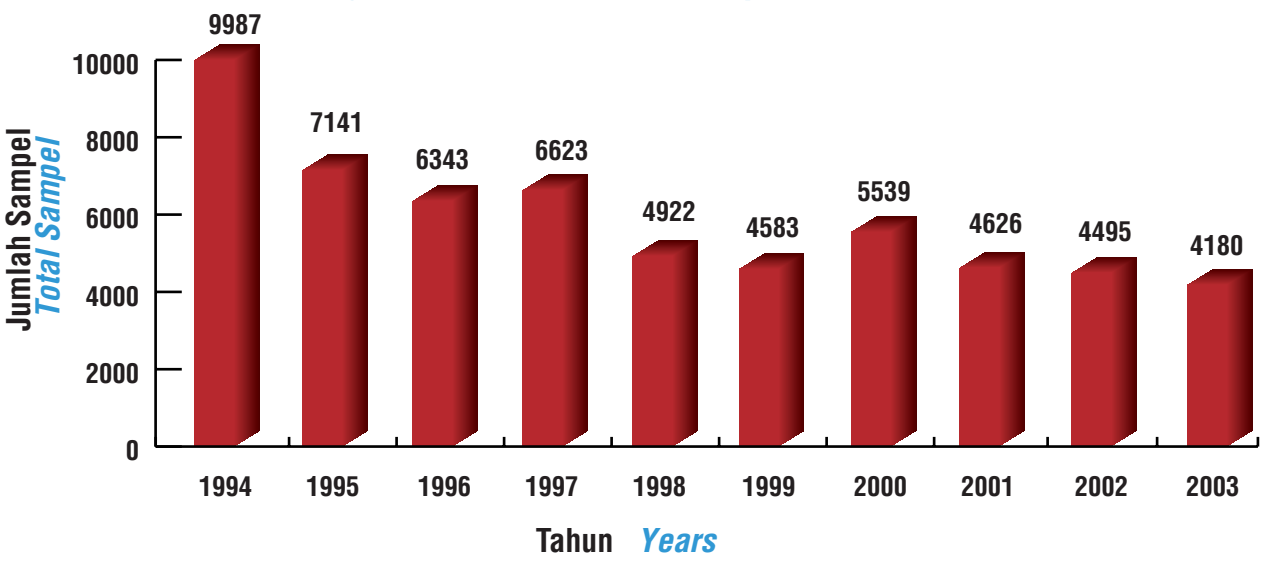
- **Pendaftaran 409**
  Registration
- **Pengawasan 560**
  Surveillance
- **Aduan 114**
  Complaint
- **UPF & Lain-Lain 305**
  FEU & Others

Berbanding dengan pencapaian tahun 2002, bilangan sampel yang diuji pada tahun 2003 menurun sebanyak 7% **(Rajah C)**. Walaubagaimanapun bilangan ujian telah meningkat sebanyak 5.3%, iaitu dari 48,676 (tahun 2002) kepada 51,251 untuk tahun 2003 **(Rajah D)**. Ujian had mikrobial adalah di antara ujian yang menyebabkan peningkatan ketara iaitu dari 27,116 (tahun 2002) kepada 30,409 ujian pada tahun 2003, peningkatan keseluruhan sebanyak 10.8%.

The number of samples tested in 2003 has decreased by 7% as compared to the performance in 2002 ***(Figure C)****. However the number of tests carried out has increased by 5.3%, from 48,676 (in 2002) to 51,251 for the year 2003* ***(Figure D)****. Among the tests that contributed to this significant increase is the microbial limit test where the number of test has risen from 27,116 (in 2002) to 30,409 for the year 2003, with an overall increment of 10.8%.*

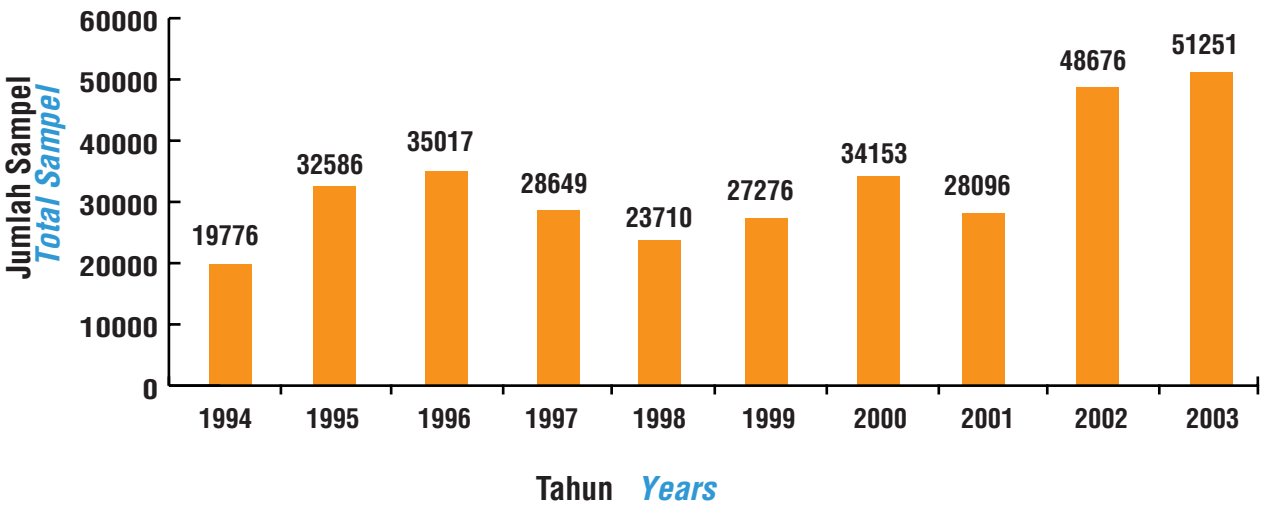
Rajah C : Bilangan Sampel Diuji

Figure C : Numbers Of Samples Tested



Rajah D : Bilangan Ujian Dijalankan

Figure D : Number Of Tests Done



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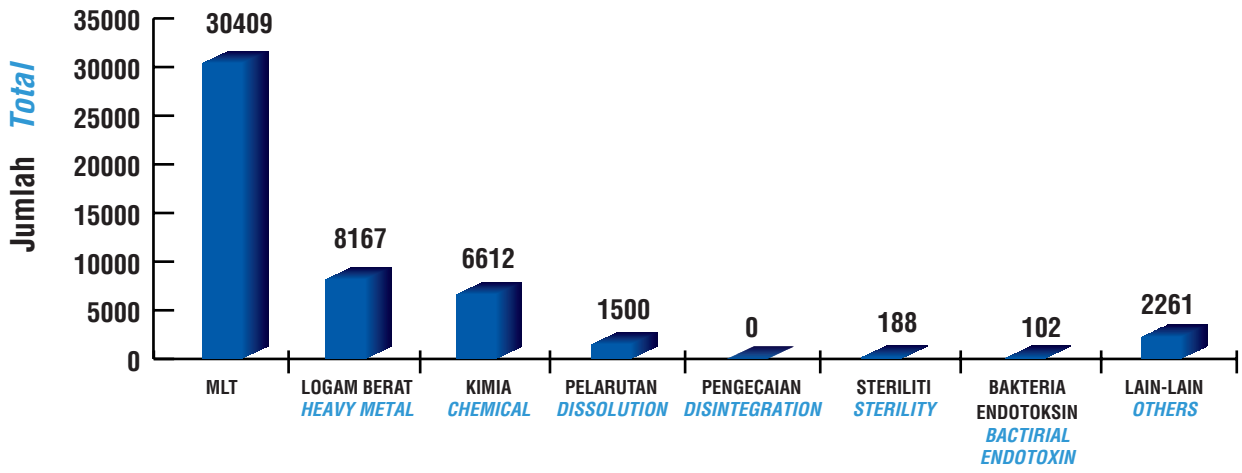
Jenis-jenis ujian yang dijalankan terdiri dari ujian had mikrobial (MLT), kimia, logam berat (As, Hg, Pb, Cd), pengecaian, pelarutan, steriliti, bakteria endotoksin, dan lain-lain seperti toksisiti, biokimia, biologikal, bilangan partikel, esei antibiotik. Statistik ujian adalah seperti dalam **Rajah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

*The types of tests done were 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. Statistic of the tests is as in **Figure E**.*

Rajah E : Jenis Ujian Yang Dijalankan

Figure E : Types Of Tests Done



Sampel Gagal Ujian

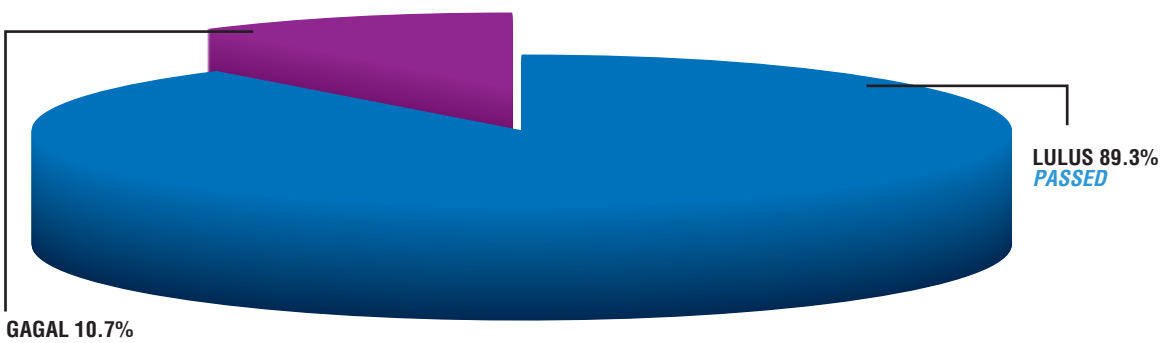
Bilangan sampel yang gagal ujian pada tahun 2003 adalah sebanyak 448 iaitu 10.7% dari jumlah sampel yang diuji (Rajah F), merangkumi 261 (6.2%) sampel pendaftaran, 171 (4.1%) sampel pengawasan dan 16 (0.4%) sampel aduan. Keseluruhannya terdiri dari 339 (8.1%) sampel produk tradisional dan 109 (2.6%) sampel produk farmaseutikal **(Rajah G)**.

Failed Samples

*The number of failed samples in 2003 amounts to 448 which was 10.7% from the total samples tested (Figure F), comprising of 261 (6.2%) registration samples, 171 (4.1%) surveillance samples and 16 (0.4%) complaint samples. Overall consisting of 339 (8.1%) samples of traditional products and 109 (2.6%) samples of pharmaceutical products **(Figure G)**.*

Rajah F : Perbandingan Sampel Lulus & Gagal Ujian

Figure F : Comparison Of Sampels Passed And Failed Tests



- **Tradisional 339**
  Traditional
- **Farmaseutikal 109**
  Pharmaseutical

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BAU telah melantik 'Therapeutic Goods Administration (TGA) Laboratories' Australia sebagai makmal ketiga untuk menjalankan ujian ulangan ke atas sampel yang gagal ujian BPFK. Di tahun 2003 prosedur ini telah diubahsuai di mana sampel yang gagal ujian tidak lagi dihantar ke TGA secara rutin. Pengubahsuaian ini dilaksanakan setelah BPFK mendapati bahawa keputusan TGA sebenarnya tidak berbeza dengan keputusan BPFK. Ekoran dari itu dialog dengan pemegang pendaftaran diadakan dan ujian ulangan hanya akan dijalankan oleh TGA atas permintaan pemegang pendaftaran.

Pungutan Hasil

Pungutan hasil untuk tahun 2003 adalah sebanyak RM 1,190,058.00. Pertambahan dalam bilangan ujian yang dijalankan serta penjualan piawai rujukan dan kultur mikroorganisma pada tahun 2003 telah menyebabkan peningkatan pungutan hasil sebanyak 59.8% berbanding dengan jumlah yang diterima pada tahun 2002 (RM 744,639.00).

Penilaian Protokol Analisis Dan Data Validasi

Sebanyak 2548 penilaian protokol analisis telah dibuat pada tahun 2003. Terdapat penurunan sebanyak 11.2% berbanding penilaian pada tahun 2002 (2869). Penurunan ini ekoran dari penangguhan penghantaran protokol oleh pelanggan BPFK akibat dari perlaksanaan sistem pendaftaran on-line untuk keluaran generik mulai Julai 2003.

Dalam tahun 2003, jumlah protokol penganalisaan yang dinilai dalam masa satu bulan telah meningkat dari 93.7% (di tahun 2002) kepada 95.3% dan pencapaian ini masih mematuhi sasaran piagam pelanggan BPFK (tidak kurang dari 90%).

Piawai Rujukan

Sejumlah 141 vial piawai rujukan ASEAN bernilai RM21,150 dan 362 vial piawai rujukan BPFK bernilai RM36,200 telah dijual kepada industri farmaseutikal tempatan dan luar negeri. Hasil jualan (RM 57,350) didapati meningkat dari hasil jualan (RM 49,350) dalam tahun 2002.

Sebanyak 273 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.

BPFK masih bergiat aktif menyokong projek kolaborasi di antara negara ASEAN di bawah naungan Pertubuhan Kesihatan Sedunia (WHO) untuk "ASEAN Reference Substances Production & Utilisation". Dalam mesyuarat di Thailand pada Februari 2003, Malaysia mencadangkan 8 bahan (prednisolone, cyanocobalamine, diphenhydramine hydrochloride, nystatin, erythromycin, norfloxacin, lidocaine dan guaifenesin) sebagai `Proposed ASEAN Reference Substances'.

Bahan mentah untuk prednisolone dan nystatin telah dibekalkan oleh Japan Pharmaceutical Manufacturers Association (JPMA), penyumbang dana terbesar untuk projek kolaborasi ini. Ujian-ujian terbabit telah dimulakan sebelum sebahagian dari bahan-bahan tersebut dihantar ke dua negara ASEAN lain untuk kajian kolaborasi

DAD has appointed Therapeutic Goods Administration (TGA) Laboratories Australia to carry out testing on samples that failed tests conducted by NPCB. However, in 2003, the procedure of testing by the third laboratory was modified, whereby failed samples would not be sent for repeat test routinely. Instead dialogs with the registration holders were held. Repeat testing is only carried out on samples upon request by the registration holders if the issues could not be resolved in the dialog. This modified procedure was a result of an earlier findings where there was no significant difference between the NPCB's conducted test results and the result obtained by the third laboratory.

Revenue Collected

Revenue collected in 2003 amounts to RM1,190,058.00. An increase in the number of tests done and the sale of reference standards and microorganism culture in 2003 has resulted in this increase of 59.8% revenue collected as compared to the collection made in 2002 (RM 744,639.00).

The Evaluation Of Analytical Protocols And Data Validation

Two thousand five hundred and forty-eight (2548) evaluation of analytical protocols were done in 2003. The figure showed a decrease of 11.2% when compared to the number of evaluation done in 2002 (2869). This is due to the delay in the applications for the registration of generic pharmaceutical products as a result of the implementation of on-line registration system in July 2003.

The number of analytical protocols evaluated within the targeted NPCB's client charter of not less than 90% within a month has increased from 93.7% (year 2002) to 95.3% in the year 2003.

Reference Standards

One hundred and forty-one (141) vials of ASEAN reference standards worth RM21,150 and 362 vials of NPCB reference standards worth RM 36,200 were sold to the local pharmaceutical industries and abroad. The total collection (RM57,350) showed an increase from the collection made in 2002 (RM49,350)

Two hundred and seventy-three (273) vials of ASEAN/NPCB reference standards were supplied free to various 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.

NPCB is actively supporting the collaborative project among ASEAN countries under the auspices of the World Health Organisation (WHO), in the `Production and Utilisation of ASEAN Reference Substances'. In the last meeting of February 2003 held in Thailand, Malaysia listed 8 substances (Prednisolone, Cyanocobalamine, Diphenhydramine Hydrochloride, Nystatin, Erythromycin, Norfloxacin, Lidocaine and Guaiphenesin) as the `Proposed ASEAN Reference Substances'.

The raw bulk materials for prednisolone and nystatin have been supplied by Japan Pharmaceutical Manufacturers' Association (JPMA), the biggest fund contributor to this collaborative project. The tests involved have begun, before portions of the materials are sent to two other ASEAN member countries for the collaborative studies. Using the same above fund, Thailand will send the raw

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seterusnya. Thailand akan menghantar bahan mentah norfloxacin dan guaifenesin, menggunakan dana yang sama, sementara Malaysia dikehendaki mendapatkan sendiri bahan-bahan selebihnya bersama piawai rujukan primer terlibat.

Ekoran dari sambungan Dasar Baru Unit Piawai Rujukan (UPR) 2002, BPFK menerima peruntukkan RM 1 juta bagi perolehan piawai rujukan primer, bahan-bahan mentah piawai rujukan serta lain-lain keperluan makmal bagi projek pengeluaran piawai rujukan sekunder. Dengan aktiviti sedia ada dan ditambah dengan aktiviti ujian, skop kerja telah meluas sehingga UPR berkembang menjadi makmal serba lengkap di BAU.

Bahan Campur Palsu Dalam Ubat Tradisional

Sepanjang tahun 2003 BAU memainkan peranan aktif mengesan bahan campur palsu dalam produk tradisional untuk sampel-sampel dari aktiviti penguatkuasaan Bahagian Perkhidmatan Farmasi, UPF Negeri dan Bahagian Surveilans BPFK. Selain dari itu atas arahan Pihak Berkuasa Kawalan Dadah, mulai tahun 2003 BAU terlibat dalam pemonitoran sampel pendaftaran dan pengawasan produk tradisional dengan mengesan bahan campur palsu ke atas 4 kategori produk yang mempunyai indikasi yang berikut :

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

Keseluruhannya sebanyak 407 sampel telah diuji dengan jumlah ujian sebanyak 727. Ekoran dari penglibatan tersebut BAU telah berupaya membangunkan tatacara dan teknik penganalisaan baru yang bersesuaian dengan sampel yang diterima menggunakan sistem yang dapat mengesahkan keputusan ujian yang diperolehi. Dari usaha tersebut terdapat 68 sampel (16.7%) daripada 70 kes yang dikesan positif mengandungi bahan campur palsu seperti yang dinyatakan dalam **Jadual 1**.

Penglibatan / Mesyuarat Di Luar Negeri

Pada tahun 2003, ahli BAU telah menglibatkan diri dalam beberapa aktiviti di luar negeri seperti dinyatakan dalam **Jadual 2.**

Penglibatan Dalam Negeri

Pada tahun 2003, beberapa anggota BAU terlibat dalam memberikan ceramah seperti disenaraikan dalam **Jadual 3**.

Pemeriksaan Premis Untuk Pematuhan Amalan Makmal Baik

BAU masih aktif memberi khidmat sokongan dalam pemeriksaan Amalan Perkilangan Baik (APB) untuk aspek Amalan Makmal Baik. Pada tahun 2003 sebanyak 18 pemeriksaan telah dijalankan ke atas premis pengilang farmaseutikal tempatan dan bilangan ini menurun berbanding pencapaian tahun 2002 (21 pemeriksaan). Namun begitu mulai tahun 2003 juru odit BAU terlibat dengan aktiviti baru mengadakan latihan pemeriksaan premis untuk Pegawai Farmasi Baru.

materials of norfloxacin and guaiphenesin, while Malaysia is expected to procure the rest of the items along with the primary standards required.

Upon continuation of the Reference Standard Unit 2002 One-Off policy, NPCB received a RM 1 million allocation for the procurement of primary reference standards, reference standard's raw materials and other laboratory requirement for the production of secondary reference standards. With the on-going activities coupled with the testing tasks, the scope of work in the Reference Standard Unit has broadened, with the incooperation of a laboratory in this unit.

Adulterants In Traditional Medicines

Throughout the year 2003 DAD has played an active role in screening for the presence of adulterants in traditional medicines for samples received from the enforcement activity of the Pharmacy Service Division, the State PEU and the Surveillance Division of NPCB. In addition, following the directive of the Drug Control Authority starting from the year 2003 DAD was involved in the monitoring of registration and surveillance samples, in the detection of adulterants for 4 categories of products with the following indications:

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

A total of 407 samples were tested with 727 number of tests conducted. As a result of that DAD has managed to develop new analytical methods and techniques suitable for the samples received using detection systems that give confirmatory results. The effort has resulted in the detection of 68 samples (16.7%) out of the 70 cases which were confirmed containing the adulterants as listed in Table 1.

Involvement / Meetings Abroad

*In the year 2003 members of DAD were involved in several actitivies abroad as indicated in **Table 2**.*

Involvement in Malaysia

*In the year 2003 several members of DAD were actively involved in giving presentations as listed in **Table 3.***

Premise Inspection For Compliance To Good Laboratory Practice (GLP)

DAD continue to be actively involved in the inspection of Good Manufacturing Practice (GMP) in GLP aspects. Eighteen (18) inspections were conducted on local pharmaceutical manufacturing premises in 2003. The figure showed a decrease in the number of inspection conducted as compared to the inspections done in year 2002 (21 inspections). Nevertheless, starting from 2003 DAD auditors were involved in a new activity in providing inspection trainings for new auditors.

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Lawatan Dan Latihan

BAU bagi pihak BPFK dengan kerjasama `Malaysian Organisation of Pharmaceutical Industries (MOPI)' dan `Pharmaceutical Association of Malaysia (PhAMA)' telah menganjurkan bengkel `Requirements for Submitting Analytical Method Validation Data' dari 6 Oktober 2003 hingga 8 Oktober 2003 di mana fasilitaturnya ialah En. Paul Sidhu dari Therapeutic Goods Administration(TGA) dan Dr. Sulaikah Moideen. Para peserta terdiri daripada 5 orang Pegawai Farmasi dari BAU dan 25 orang dari industri farmaseutikal, tradisional dan kosmetik tempatan.

BAU juga telah memberi latihan dalam aspek kawalan kualiti kepada 3 kumpulan pelatih dari luar negeri dan 2 kumpulan dari dalam negara. Mereka telah menjalani latihan sangkutan di makmal-makmal BAU mengikut jadual yang telah disediakan. Pelatih – pelatih tersebut adalah seperti berikut:

1. Ms. Gar Elnabi Noon, WHO Fellow dari Sudan (27 Januari 2003 – 18 Mac 2003)
2. Mr. Sherab Tensin, WHO Fellow dari Pharmaceutical and Research Unit, Ministry of Health and Education, Bhutan (3 Mac 2003 – 16 Mei 2003).
3. Ms. Balqess Abdel Rasit, WHO Fellow dari Ministry of Health, Sudan (28 Mei 2003 – 10 Julai 2003)
4. Pegawai Farmasi dan Pembantu Farmasi dari Makmal Farmasi negeri Sabah (29 September 2003 – 31 Disember 2003)
5. Kumpulan pelajar farmasi (Intermediate Level 1), Universiti Kebangsaan Malaysia (7 April 2003 – 18 April 2003)

Latihan Untuk Kakitangan

BAU dengan kerjasama NIOSH telah menganjurkan kursus `Keselamatan dan Kesihatan Pekerjaan' untuk kakitangan BAU pada 20 hingga 21 Februari 2003 di Dewan Anggerik, BPFK. Kursus ini telah dihadiri oleh 26 orang peserta yang terdiri dari Pegawai Farmasi dan Pembantu Farmasi.

Sebanyak 10 latihan seperti berikut untuk kakitangan BAU telah dianjurkan oleh Radicare (M) Sdn. Bhd. sepanjang tahun 2003:

1. Latihan kebakaran sebanyak 2 kali untuk semua kakitangan BAU
2. Latihan alat Maxi Dry (25 peserta)
3. Latihan komputer (25 peserta)
4. Latihan untuk alatan autoklaf (20 peserta)
5. Teori mengenai Gas Chromatography (30 peserta)
6. `Hands-on' mengenai Gas Chromatography (10 peserta)
7. Taklimat mengenai pembuangan sisa kimia (30 peserta)
8. Latihan alat penghawa dingin (20 peserta)
9. Latihan mengenai GCMS (43 peserta)

Visits And Trainings

DAD on behalf of NPCB has organised a workshop on 'Requirements for Submitting Analytical Method Validation Data', co-jointly with the Malaysian Organisation of Pharmaceutical Industries (MOPI) and Pharmaceutical Association of Malaysia (PhAMA) from 6th till 8th October 2003 whereby Mr. Paul Sidhu from TGA and Dr. Sulaikah Moideen were the facilitators. The participants consisted of 5 pharmacists from DAD and 25 from the local pharmaceutical, traditional and cosmetic industries.

DAD also has provided training in the aspect of quality control to 3 groups of trainees from abroad and 2 groups from within the country. They have undergone attachment training in various laboratories of DAD according to the prepared schedule. The trainees are as follows:

1. *Ms. Gar Elnabi Noon, WHO Fellow from Sudan (27th January till 18th March 2003)*
2. *Mr. Sherab Tensin, WHO Fellow from Pharmaceutical and Research Unit, Ministry of Health and Education, Bhutan (3rd March till 16th May 2003)*
3. *Ms. Balqess Abdel Rasit, WHO Fellow from Ministry of Health, Sudan (28th May till 10th July 2003)*
4. *Pharmacist and Pharmacist Assistant from Pharmacy Laboratory, Sabah (29th September till 31st December 2003)*
5. *A group of pharmacy students (Intermediate Level 1) from Universiti Kebangsaan Malaysia (7th till 18th April 2003)*

Training For DAD Staff

DAD with the cooperation of NIOSH has organised a course on ' Occupational Safety and Health' for the staff on 20th till 21st February 2003 at the Anggerik Hall, NPCB. The course was attended by 26 participants comprising of Pharmacists and Pharmacy Assistants.

Ten (10) trainings for instrument users in DAD were conducted by Radicare (M) Sdn. Bhd throughout the year 2003 as follows :

1. *Twice on fire drill attended by all staff of DAD*
2. *Training on Maxi Dry (25 participants)*
3. *Computer training (20 participants)*
4. *Training on autoclave (20 participants)*
5. *Theory on Gas Chromatography (30 participants)*
6. *Hands-on training on Gas Chromatography (10 participants)*
7. *Briefing on disposal of chemical waste (30 participants)*
8. *Training on air - conditioner (20 participants)*
9. *Training on GCMS (43 participants)*

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Ahli Baru BAU

BAU mengalu-alukan kedatangan 3 orang Pegawai Farmasi baru iaitu Cik Juliana Abdullah, Cik Wan Nurul Aina Mior Abdullah dan Cik Aida Haryati Abdul Rahim serta 3 orang Pembantu Farmasi baru iaitu Puan Manida a/p Pin, Puan Sharifah Haji Abdul Rahman dan Puan Rohaniah Seman.

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 aktiviti-aktiviti yang berikutnya. Rancangan yang dijadualkan untuk tahun 2004 adalah seperti berikut :

a) Meneruskan kajian untuk memperkembangkan tatacara dan teknik penganalisaan dalam pengesanan bahan campur palsu dalam keluaran tradisional terutama yang melibatkan penggunaan alat LCMS-MS.

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

c) Meneruskan usaha mengadakan latihan berterusan untuk Pegawai Farmasi baru dan Pembantu Farmasi di BAU berkaitan aspek yang melibatkan pengunaan komputer, keselamatan makmal dan latihan pengunaan alat-alat makmal dan teknik penganalisaan.

d) Menjalankan proses penstrukturan semula BAU secara menyeluruh untuk keberkesanan dan kelancaran proses kerja.

e) Mempergiatkan usaha mempertingkatkan sistem komputer baru (QUEST 2) untuk modul BAU.

f) 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.

g) Menganjurkan kursus/seminar bersama industri (MOPI) dalam bidang validasi analitikal (aspek kimia).

h) Menganjurkan "Workshop on assessing quality of biotechnology-derived products which will be used as drugs, biologics and diagnostics" untuk Pegawai Farmasi BAU.

i) Meneruskan persediaan ke arah pensijilan ISO 17025 dengan menguruskan latihan untuk kakitangan dan mengenalpasti skop pensijilan.

New Members Of DAD

DAD welcomes 3 new Pharmacists namely, Cik Juliana Abdullah, Cik Wan Nurul Aina Mior Abdullah and Cik Aida Haryati Abdul Rahim and 3 new Pharmacy Assistants namely Pn. Manida a/p Pin, Pn. Sharifah Haji Abdul Rahman and Puan Rohaniah Seman.

Future Plans

DAD shall work towards preparing itself for new challenges to be able to play an active and effective role in the implementation of future activities. Several strategic plan of actions are scheduled for the year 2004 and they are as follows:

a) Embarking on research in procedures and techniques for the detection of adulterants in traditional medicines particularly involving the usage of LCMS-MS.

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

c) Continuing the effort to provide a continuous training to new Pharmacists and Pharmacy Assistants of DAD in aspects involving the use of computer, laboratory safety and training in the field of laboratory and analysis techniques.

d) Going ahead with restructuring of DAD as a move towards more effective and smooth work process.

e) Continuing the development of the on-line registration system (QUEST 2) for DAD module.

f) Continuing with the GMP (GLP aspect) trainings for new Pharmacists of DAD, who need to undergo at least 3 complete inspections under the supervision of Lead Auditors before being accepted as qualified GMP Auditors.

g) Organising courses/seminars co-jointly with the industries (MOPI) on aspects pertaining to `Analytical Validation' (chemical)

h) Organising "Workshop on assessing quality of biotechnologically-derived products which will be used as drugs, biologics and diagnostics", for new Pharmacists of DAD.

i) Embarking on the continual preparation towards ISO 17025 with emphasis on training for staff and to identify the scope for certification.

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

Sasaran *Target*	Sampel UPF *PEU Samples*			Sampel Pendaftaran dan Pengawasan *Registration and Surveillance samples*		
	Bilangan Diuji *Number tested*	Bilangan Positif *Number confirmed positive*	% Positif *% confirmed positive*	Bilangan Diuji *Number tested*	Bilangan Positif *Number confirmed positive*	% Positif *% confirmed positive*
Sildenafil dan Tadalafil	170	27	15.88%	28	--	--
Steroid	228	6	2.63%	48	3	6.25%
NSAID & Phenylbutazone	72	2	5.56%	12	2	16.67%
Antihistamine/ Antitussive	37	21	43.20%	--	--	--
"Cardiovascular drugs"	5	--	--	--	--	--
Antibiotik	13	--	--	--	--	--
Antidepressant/ Tranquilizers	6	--	--	--	--	--
H2 Antagonist	5	--	--	--	--	--
Agen Pelangsing	13	1	9.09%	14	0	--
Agen Pemutih	27	6	22.22%	--	--	--
Analgesik	7	2	28.57%	--	--	--
Hormon	24	--	--	--	--	--
Lain-lain (Antihyperlipidaemic, Andiabetics, Antifungal dan Antiasthmatic)	18	--	--	--	--	--

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Jadual 2: Mesyuarat/Penglibatan Luar Negeri
Table 2: Meetings/Involvement Abroad

Tajuk *Title*	Nama *Name*	Tempat/ Tarikh *Place/date*	Penglibatan *Involvement*
• Expert Committee Meeting on Specification for Pharmaceutical Preparation	Dr. Sulaikah V.K. Moideen	Geneva, Switzerland 10/3/03-14/3/03	WHO Temporary Advisor
• Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceuticals		Denpasar, Indonesia 9/9/03-11/9/03	Pemerhati
• WHO Consultation on Good Agriculture and Field Collection Practices for Medicinal Plants	Encik Jaafar Lassa	WHO Headquarters, Geneva, Switzerland 7/7/03-9/7/03	WHO Consultant
• WHO Working Group Meeting on Safety Assessment of Herbal Medicines		WHO Headquarters, Geneva, Switzerland 10/7/03-11/7/03	WHO Committee
• Assessment of Nepal's Regulatory System on GLP Requirement		Nepal 1/12/03-19/12/03	WHO Short-term Consultant
• PIC/S Annual Seminar on Inspection of QC Lab	Puan Faridah Abdul Malek	Bratislava, Slovak 4/6/03- 6/6/03	Peserta
• Meeting on the Production and Utilization of ASEAN Reference Substances	Encik Muhammad Nasir Hashim	Thailand 11/2/03-13/2/03	Wakil Malaysia

Jadual 3: Penglibatan Dalam Negeri
Table 3: Involvement in Malaysia

Tajuk *Title*	Nama *Name*	Tempat/ Tarikh *Place/date*	Penglibatan *Involvement*
• Regulatory issues in herbal medicine	Dr. Sulaikah V.K. Moideen19/2/03	UITM Shah Alam	Penceramah jemputan
• Keperluan Kawalan Kualiti (Aspek Kimia) dan Kajian Stabiliti	Encik Jaafar Lassa	Alor Setar 2/4/03	Penceramah
• Ubat-ubat Tradisional,		Kuah, Langkawi Kedah 3/5/03	Penceramah
• The Determination of Cd, As, Pb and Hg in Traditional Medicine by AAS		Kuala Lumpur 25/6/03	Penceramah
• The Role of Pharmacist in the Practice of T/CM		Kota Bahru Kelantan 28/9/03	Penceramah
• On-Line registration		Langkawi 21/10/03	Penceramah
• Pengujian Ubat Tradisional Dalam Menentukan Mutu dan Keselamatan Ubat	Puan Mazli Muhamad	Pusat Sains Negara Bukit Kiara 3/5/03	Penceramah
• Kawalan Mutu Ubat Tradisional dalam `On-line Registration		Hotel Sheraton Subang Jaya 28/9/03	Penceramah
• Determination of Paracetamol or Aspirin Adulterant in Selected Traditional Medicines by TLC Validated by HPLC.		Holiday Villa Langkawi 16/10/03- 19/10/03	Pembentang kertas kerja
• Kajian Kestabilan Ubat Tradisional Untuk Produk Baru dan Pendaftaran Semula		Crown Princess Kuala Lumpur 24/12/03	Penceramah
• Validation of Gas Chromatography-Mass Spectrometry for the Determination of DDT in selected registered Traditional Remedies	Puan Noraida Mohamad Zainoor	Holiday Villa Langkawi 16/10/2003-19/10/2003	Pembentang Kertas Kerja
• Kawalan Mutu Ubat Tradisional dalam `On-line Registration	Cik Azrina Hassan	Hotel Eden Garden Johor Bahru 12/10/03	Penceramah
• Pengesanan Logam Kadmium dalam Ubat Tradisional		Holiday Villa Langkawi 16/10/03-19/10/03	Pembentang Kertas Kerja

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BAHAGIAN PEMBANGUNAN ORGANISASI DAN TEKNOLOGI MAKLUMAT (POTM)

OBJEKTIF

Memberi perkhidmatan maklumat ubat yang berkesan kepada personnel-personnel 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 Drug dan Maklumat Am

Sepanjang tahun 2003, Bahagian POTM telah menjawab sejumlah 1271 pertanyaan dari sektor awam dan sektor 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.

Pengkelasan Keluaran

Bahagian ini bertanggungjawab ke atas semua pertanyaan berkenaan dengan klasifikasi keluaran-keluaran "borderline", samada keluaran-keluaran itu perlu didaftar atau tidak. Antara 1490 keluaran yang diterima untuk pengkelasan dalam tahun 2003, 748 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 742 keluaran merupakan butiran yang perlu didaftarkan seperti supplemen makanan tambahan yang mengandungi bahan tadisional dan kosmetik / keluaran penjagaan kulit.

Penerbitan

Penerbitan-penerbitan yang berikut telah dihasilkan dan diedarkan ke organisasi-organisasi dalam sekor awam dan swasta sepanjang tahun 2003

(i) Berita Ubat-Ubatan (1 isu)

(ii) Pekeliling Maklumat Ubat (8 isu)

(iii) Monograf Ubat (8 isu)

(iv) Laporan Tahunan

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 organization within the public and private sectors.

ACHIEVEMENTS

Drug Information Service and General Information on Drug Registration

In the year 2003, the OD & IT division responded to 1271 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

The division handles all queries pertaining to classification of "borderline products", as to whether they are registrable or not. Out of the 1490 products received for classification in 2003, 748 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 742 products were registrable products, comprising mainly of dietary supplements containing traditional ingredients and cosmetics/skin care products.

Publications

The following publications were produced and distributed to organizations in the public and private sector in 2003.

(i) Drug Control Authority Newsletter (1 issue)

(ii) Drug Information Circular (8 issues)

(iii) Drug Monograph (8 issues)

(iv) Annual Report

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

Perkhidmatan Perpustakaan

Perpustakaan ini mempunyai hampir 1792 buah buku, termasuk farmakopia-farmakopia utama dari pelbagai negara luar. Selain itu, perpustakaan ini juga melanggan 31 jenis jurnal / bulletin ubat, Micromedex, dan International Pharmaceutical Abstracts. 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 2003:-

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

Library Service

The library has about 1762 books, including the major pharmacopoeias from various countries. Besides that, it subscribes to 31 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 2003:-

Training provided	Name of Participants	Country	Date
Traning Programme on the Quality Assurance System	Ms Noon GarEl Ghabar	Sudan	27 January – 26 March
Training Programme on the Quality Assurance System	Ms Iqbal Sid Ahmad Abd. El Rahim	Sudan	27 January – 26 March
Study visit to BPFK	Ms Catherina Kafo	Tongga	2 February
Study visit to BPFK	Mr Sherab Tenzin	Bhutan	3 March -23 May
Study visit to BPFK	Ms Saffa Dawie	Sudan	7 April
Study Tour Programme on Good Manufacturing Practices	Mr Md Mizra Md, Adwarul WHO fellow	Bangladesh	21 April-2 May
Study Tour Programme on Good Manufacturing Practices	Mr Md Wahidur Rahman WHO fellow	Bangladesh	21 April-2 May
Management of Rational Drug Use	Dr. Nguyen Tab Hai WHO fellow	Vietnam	28 April
Management of Rational Drug Use	Dr Tran Thi Minh Huong WHO fellow	Vietnam	28 April
Management of Rational Drug Use	Dr Luong Ngoe Khue WHO fellow	Vietnam	28 April
Management of Rational Drug Use	Miss Ha Manh Tuan WHO fellow	Vietnam	28 April
Management of Rational Drug Use	Miss Le Thi Kim Thanh WHO fellow	Vietnam	28 April
Quality Assurance System	Ms Balgess Abdel Basit	Sudan	28 May-28 July

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Training provided	Name of Participants	Country	Date
Study visit to BPFK	Mr Hamad Al Naemi Director of the Department of Economy, United Arab Emirates	UAE	15 August
Study Tour Programme on Good Manufacturing Practices	Mr Md Nazrul Islam Khan WHO fellow	Bangladesh	2-26 September
Offical visit to BPFK	Mr Apollo Regulatory Agency of Uganda	Uganda	29 September
Offical visit to BPFK	Ms Florence Regulatory Agency of Uganda	Uganda	29 September
Offical visit to BPFK	Mr Said Heydary	Islamic Republic Of Iran	20 October
Offical visit to BPFK	Mr Mahdian	Islamic Republic Of Iran	20 October
Offical visit to BPFK	Mr Melchior Minister of Health Papua New Guinea	Papua New Guinea	30 October
Registration Process of Cosmetic	Mr Chong Chee Kiong Ministry of Health Brunei Darussalam	Brunei	3-15 November
Registration Process of Cosmetic	Dr DK Nurul Aini bte Pg Haji Md. Kifli Ministry Health Brunei Darussalam	Brunei	3-15 November
Study Tour Programme on Good Manufacturing Process	Mr.Md Nazrul Islam Khan WHO fellow	Bangladesh	2-26 September
Official visit to BPFK	Mr Apollo, Regulatory Agency of Uganda	Uganda	29 September
Official visit to BPFK	Ms Florence, Regulatory Agency of Uganda	Uganda	29 September
Official visit to BPFK	Mr Said Heydary	Islamic Republic Of Iran	20 October
Official visit to BPFK	Mr Mahdian	Islamic Republic Of Iran	20 October
Official visit to BPFK	Mr Melchior Minister of Health, Papua New Guinea	Papua New Guinea	30 October
Registration process of Cosmetic	Mr Chong Chee Kiong Ministry of Health Brunei Darussalam	Brunei	3 – 15 November
Registration process of Cosmetic	Dr DK Nurul Aini binte Pg Haji Md Kifli Ministry of Health Brunei Darussalam	Brunei	3 – 15 November

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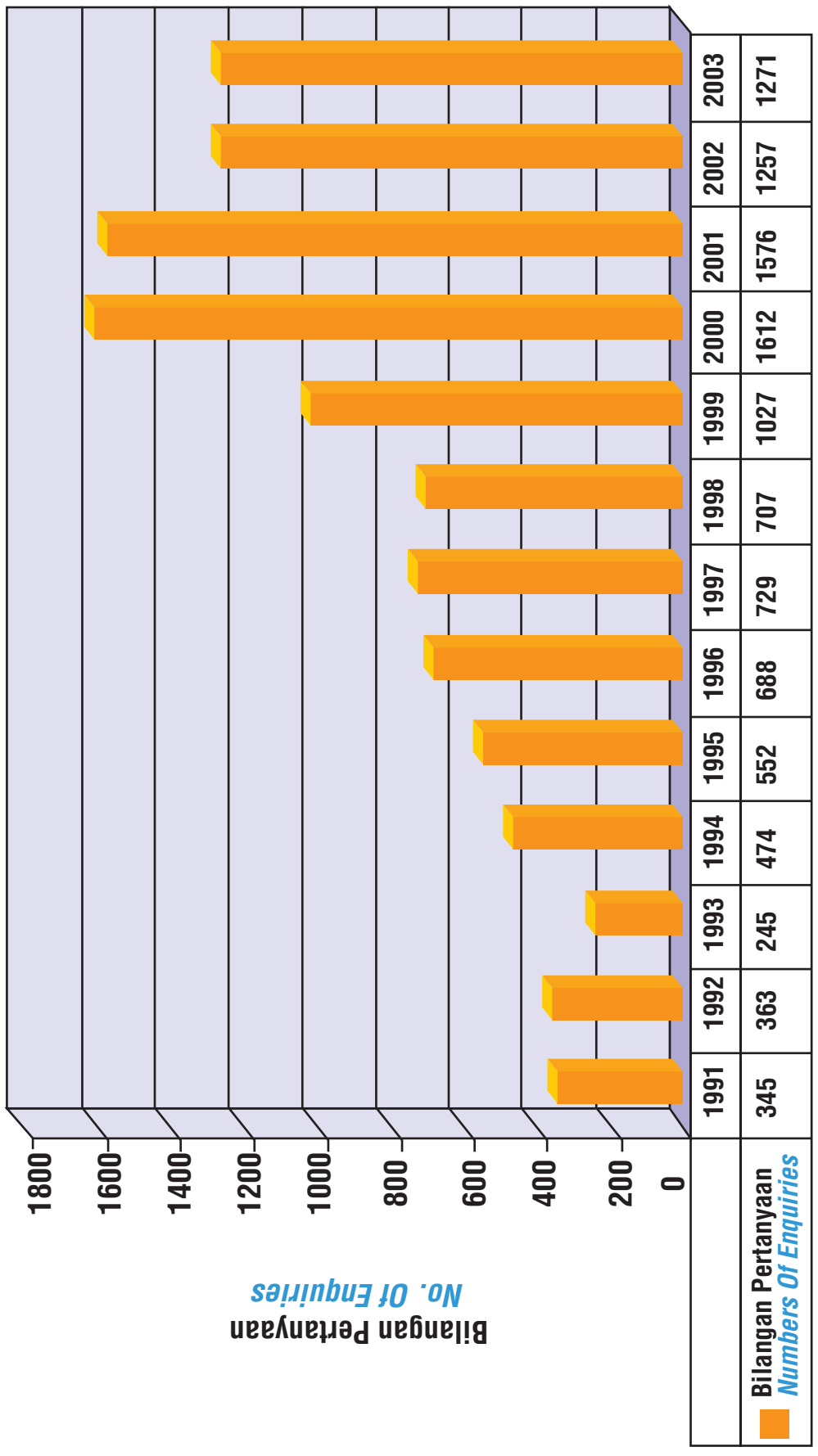
Bilangan Pertanyaan Diterima Dari 1991 - 2003
Number Of Enquiries Received From 1991 - 2003



	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Bilangan Pertanyaan *Numbers Of Enquiries*	345	363	245	474	552	688	729	707	1027	1612	1576	1257	1271

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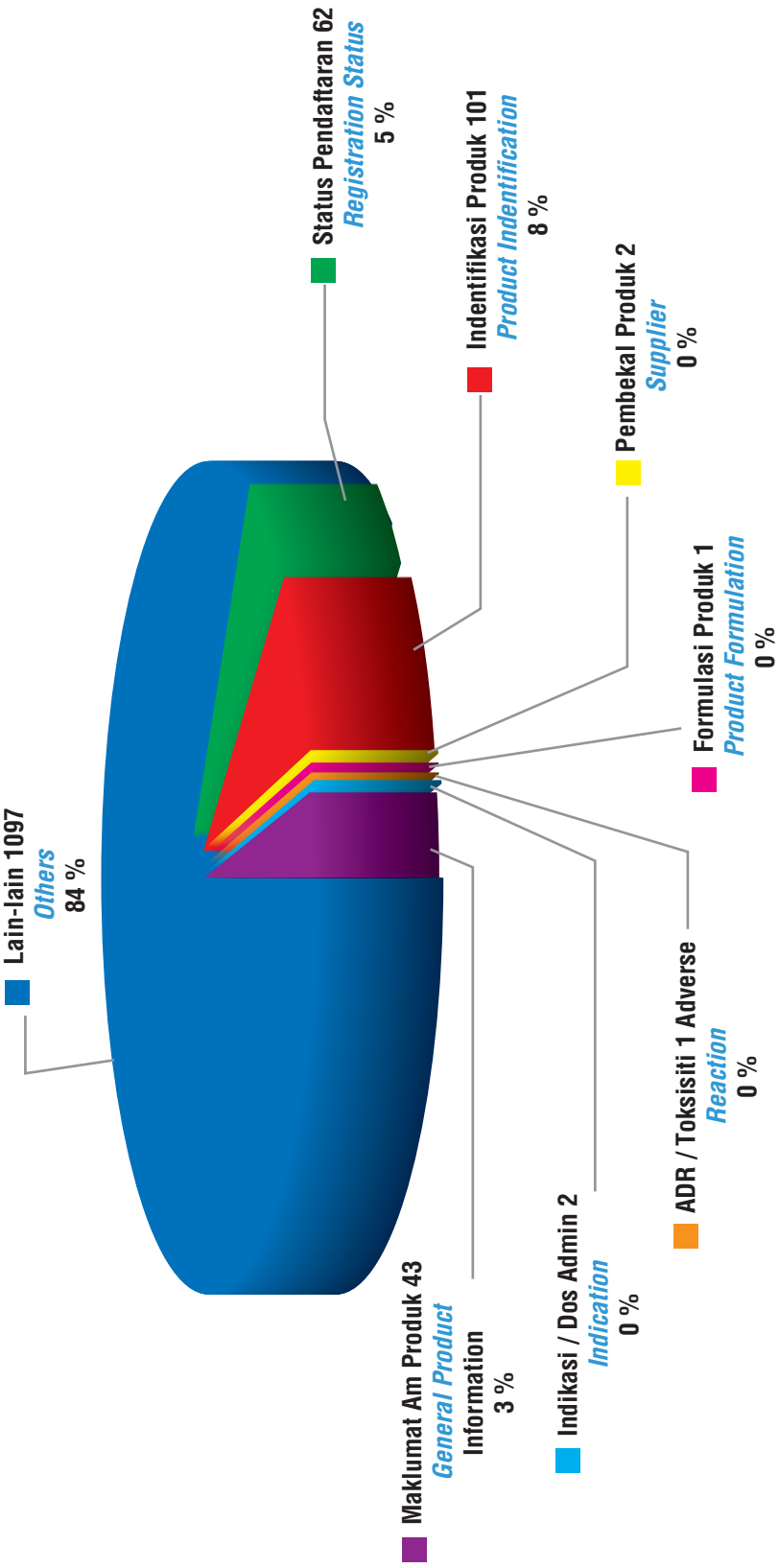
Jenis Pertanyaan Yang Diterima Pada Tahun 2003
Types Of Enquiries Received For The Year 2003



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