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KATA-KATA ALUAN
FOREWORD

Setahun telah berlalu, menandakan lebih 20 tahun sejak Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) ditubuhkan dan 15 tahun skim pendaftaran ubat-ubatan dilaksanakan di Malaysia. BPFK telah banyak menyumbangkan demi kesihatan awam dengan memastikan kualiti, keselamatan dan efikasi ubat-ubatan yang berada di pasaran. Sehingga akhir tahun 1999, lebih kurang 24,000 produk telah didaftarkan dan 1,131 premis dilesenkan. Saya ingin mengambil kesempatan di sini untuk mengimbas kembali pencapaian-pencapaian BPFK dan meninjau kehadapan ke arah pembangunan kawalan regulatori yang mampan.

Sebagai sekretariat kepada Pihak Berkuasa Kawalan Dadah (PBKD), BPFK telah mengukir nama dalam arena regulatori di peringkat antarabangsa. Kejayaan BPFK merupakan hasil kepimpinan, kegigihan dan komitmen pelbagai pihak. Tunjukajar dan sokongan padu daripada pegawai-pegawai atasan, rakan-rakan setugas dan staf-staf lain sangat saya hargai dengan penuh keikhlasan.

Dalam usaha kita menjadi sebuah pusat kecemerlangan dalam bidang regulatori farmaseutikal, kita hendaklah mempraktikkan tahap piawaian yang tinggi dalam amalan regulatori. Dengan perubahan pesat yang berlaku dalam globalisasi pasaran produk farmaseutikal, kita perlu meningkatkan kecekapan dan keberkesanan. Kita mesti

Another year has just whizzed by, marking slightly over 20 years of the establishment of the National Pharmaceutical Control Bureau and 15 years of the drug registration era in Malaysia. Indeed, the Bureau has made significant contributions towards public health, by ensuring quality, safety and efficacy, and timely availability of medicinal products. By the end of 1999, approximately 24,000 products have been registered and 1,131 premises licensed. I would like to take this opportunity to reflect on the milestones achieved and to look forward to the new regulatory horizon.

Through the years, the Bureau which serves as the Secretariat to the Drug Control Authority (DCA) has earned worldwide reputation as an important player in the international regulatory arena. The Bureau's success is a tribute to the guidance, hard work and commitment of many. The wise advice and firm support from my superiors, my colleagues and all staff members are very much and sincerely appreciated.

As we strive to be a centre of excellence in pharmaceutical regulatory matters, we must pursue high standards of regulatory practices. With rapid changes taking place in the globalization of the market for pharmaceutical products, we need to increase effectiveness and improve efficiency. We must devote ourselves to continual improvements. Establishing a

berusaha secara berterusan untuk meningkatkan keterampilan. Kita perlu mewujudkan sistem kualiti bagi seluruh organisasi, meningkatkan sistem jaringan komputer sediada dan berusaha untuk mencapai pengiktirafan skim antarabangsa iaitu "Pharmaceutical Inspection Co-operation Scheme (PIC/S)".

Tahun lepas telah menyaksikan beberapa pendekatan baru yang positif, dan jalinan kerjasama yang erat di antara BPFK dan organisasi-organisasi industri. Beberapa kumpulan kerja teknikal yang terdiri daripada wakil-wakil industri berkenaan, Kementerian Kesihatan dan agensi kerajaan lain telah ditubuhkan dengan matlamat yang spesifik untuk membincangkan isu-isu teknikal mengenai pendaftaran dan Amalan Perkilangan Baik (APB) bagi keluaran farmaseutikal, ubat tradisional, produk tambahan khasiat makanan dan kosmetik. Kerjasama ini telah menghasilkan kejayaan dalam mencapai keputusan yang jitu dan penggubalan polisi-polisi yang pragmatik.

Di peringkat antarabangsa, tahun 1999 merupakan detik permulaan dalam usaha kita mengharmonisasikan keperluan dokumen-dokumen teknikal (farmaseutikal) di kalangan negara-negara ASEAN. Tujuan utama usaha ini ialah untuk mengatasi masalah sekatan regulatori demi membantu perdagangan keluaran-keluaran berkenaan. Dengan sokongan industri farmaseutikal, BPFK telah banyak memberi sumbangan teknikal dalam menjayakan penubuhan "ASEAN Consultative Committee for Standards and Quality (ACCSQ) Product Working Group on Pharmaceuticals" dan akan terus memainkan peranan yang aktif untuk mencapai matlamat yang ditetapkan.

Beberapa dasar baru telah diperkenalkan sepanjang tahun 1999. Antaranya termasuk pelesenan pengilang dan pengimport ubat-ubatan tradisional, pelaksanaan kajian bioequivalen untuk beberapa keluaran generik seperti Captopril, Nifedipine dan Cyclosporin, keperluan validasi proses dan analitikal untuk keluaran jenis suntikan, promosi Amalan Klinikal Baik (GCP) dalam kajian klinikal, pelaksanaan proses pendaftaran yang lebih mudah untuk menggalakkan eksport keluaran tempatan serta menembusi pasaran global, dan keperluan maklumat nilai jualan untuk keluaran-keluaran berdaftar. Namun demikian, terdapat isu-isu lain yang perlu dikaji dari perspektif perundangan seperti struktur yuran pendaftaran baru, pengimportan selari, perbezaan di antara makanan dan ubat-ubatan, dan pemeriksaan APB premis luar negara.

quality system for the entire organization, upgrading the existing computer network system and working towards achieving Pharmaceutical Inspection Co-operation Scheme (PIC/S) recognition are currently our main focus.

Glancing back the past year, we saw positive new approaches and enhanced co-operation between us, the regulators and the various industry organizations. Several Technical Working Groups (TWG), comprising of representatives from the relevant industry, Ministry of Health and other government agencies, have been set up with specific terms of reference, mainly to discuss technical issues related to registration and Good Manufacturing Practice of pharmaceuticals, traditional medicines, food supplements and cosmetics. The creation of such partnerships have led to tangible decisions and formulation of pragmatic policies.

On the international front, 1999 also marked the commencement of efforts towards harmonization of common technical documents (pharmaceuticals) among ASEAN countries, primarily aimed at elimination of technical regulatory barriers to facilitate trade. The Bureau with the support of the pharmaceutical industry, has made considerable technical contribution to the establishment of ASEAN Consultative Committee for Standards and Quality (ACCSQ) Product Working Group on Pharmaceuticals, and will continue to participate actively to achieve our ultimate goals.

Notable new policies have been made during 1999. These include licensing of traditional medicines manufacturers and importers, implementation of bio-equivalence studies for selected generics such as captopril, nifedipine and cyclosporin, process and analytical validation requirements for injectables, promoting Good Clinical Practice (GCP) in clinical studies, developing more streamlined registration processes to facilitate export and market access, and submission of sale values for registered products. However, there are other issues such as the new fee structure, parallel import, food and drug interface and foreign inspections that need to be further reviewed from the legislative perspective.

Memandang kehadapan secara positif, BPFK telah mengenalpasti arahtuju yang strategik selaras dengan perkembangan kawalan regulatori antarabangsa. Maka kita perlu memperluaskan peranan kawalan regulatori dalam berbagai-bagai bidang lain. Pendaftaran keatas keluaran kosmetik, keluaran veterinar, peralatan perubatan dan bahan aktif farmaseutikal telah dicadangkan untuk dilaksanakan di bawah Rancangan Malaysia Ke-8 (2001-2005). Meskipun kerja-kerja asas telah pun dimulakan, kita perlu berupaya dan bersedia berhadapan dengan cabaran-cabaran yang akan ditempohi kelak.

Akhir kata, sekali lagi saya ingin mengucapkan ribuan terima kasih kepada ketua-ketua saya yang telah banyak memberikan bimbingan dan galakan. Setinggi-tinggi penghargaan saya tujukan kepada semua anggota BPFK yang telah bekerja dengan penuh dedikasi. Semangat kerjasama dan sumbangan bakti anda sekalian amatlah penting demi kejayaan masa hadapan BPFK.

(CHE MOHD. ZIN BIN CHE AWANG)
Pengarah
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

Looking forward with optimism, we have identified our future goals and strategies towards charting new regulatory directions. Diversifying our role, registration of cosmetics, veterinary medicines, medical devices and active pharmaceutical ingredients have been targeted for implementation under the 8th Malaysia Plan (2001 - 2005). While the ground-breaking work has already started, we certainly have a challenging task ahead of us.

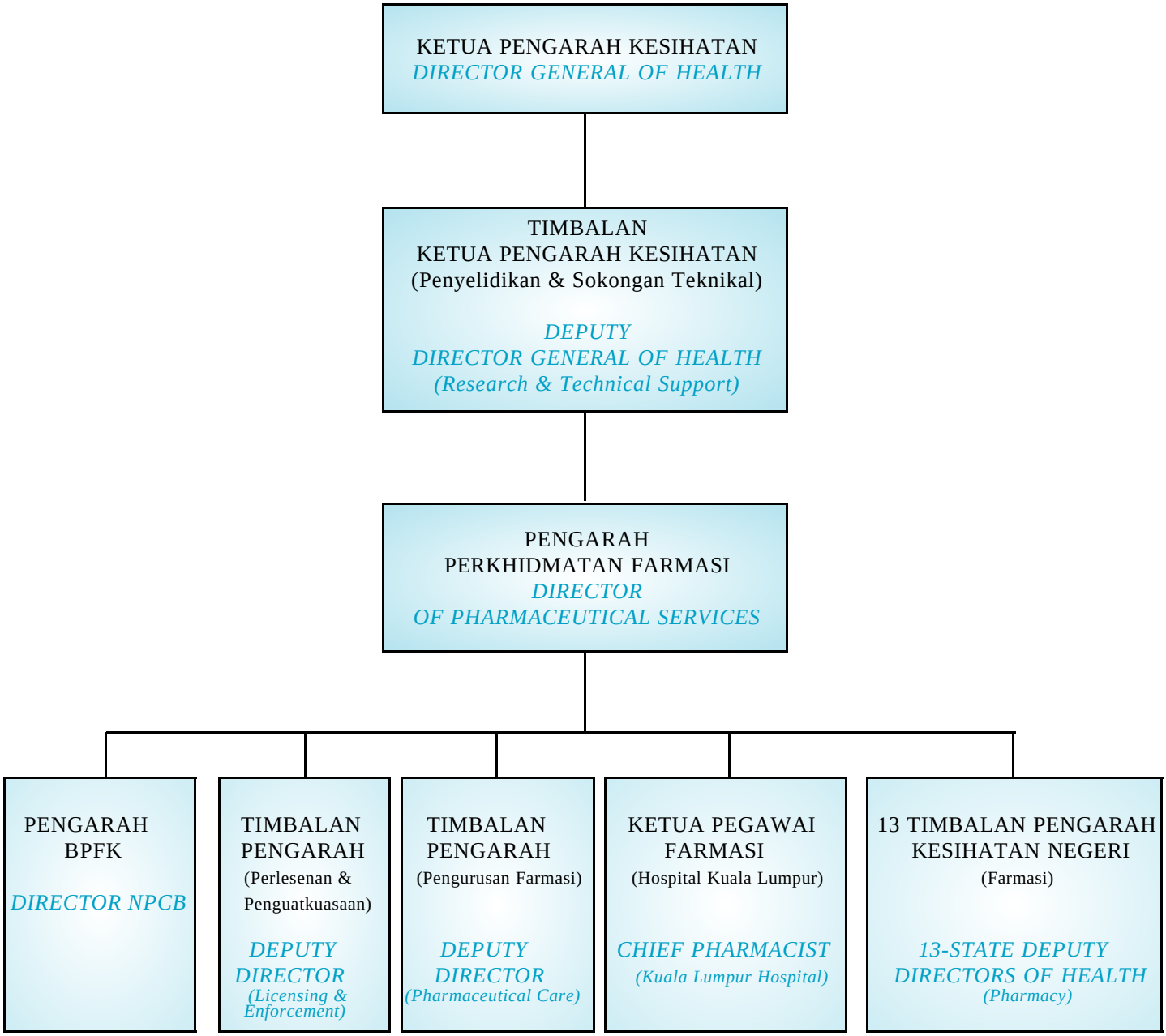
Once again, I would like to thank my superiors for their guidance and encouragement. To all my valued staff, the key to our achievements, reputation and our future success, are your dedication and the willingness to demonstrate commitment.

(CHE MOHD. ZIN BIN CHE AWANG)
Director
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

STRUKTUR ORGANISASI
ORGANIZATIONAL STRUCTURE OF

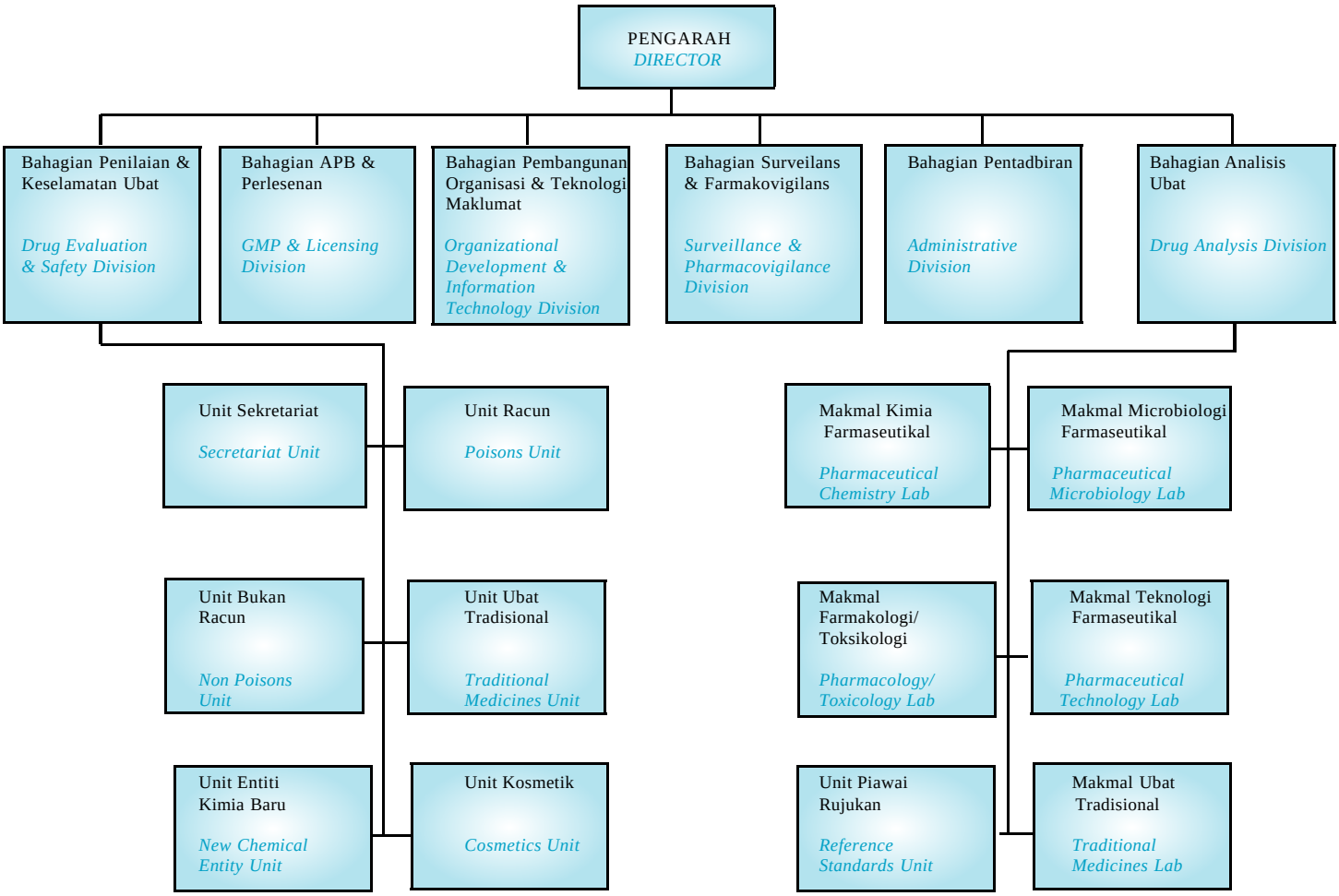
BAHAGIAN PERKHIDMATAN FARMASI
PHARMACEUTICAL DIVISION

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH



CARTA ORGANISASI
ORGANIZATIONAL CHART

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU



SENARAI JAWATAN PADA 31 DISEMBER 1999
LIST OF POSTS AS AT 31 DECEMBER 1999

Bil. *No.*	Nama Jawatan *Position*	Gred *Grade*	Jawatan *(Post)*		
			Bil. *No.*	Diisi *Filled*	Kosong *Vacant*
1.	Pengarah BPFK *Director of NPCB*	JUSA C	1	1	0
2.	Timbalan Pengarah *Deputy Director*	U1	2	2	0
3.	Ketua Penolong Pengarah *Principal Assistant Director*	U2	13	12	1
4.	Penolong Pengarah *Assistant Director*	U3	50	36	14
5.	Penolong Pegawai Perangkaan *Assistant Statistic Officer*	N6	1	1	0
6.	Pembantu Farmasi *Pharmacy Assistant*	U7	8	7	1
7.	Pembantu Farmasi *Pharmacy Assistant*	U8	65	63	2
8.	Pembantu Tadbir (Perkeranian/Operasi) *Administrative Assistant (Clerical/Operations)*	N7	1	1	0
9.	Pembantu Tadbir (Perkeranian/Operasi) *Administrative Assistant (Clerical/Operations)*	N9	11	9	2
10.	Pembantu Perpustakaan *Library Assistant*	S7	1	1	0
11.	Pembantu Tadbir (Penyelenggara Stor) *Administrative Assistant (Store)*	N9	1	1	0
12.	Pembantu Tadbir (Kesetiausahaan) *Administrative Assistant (Secretary)*	N7	1	0	1
13.	Pembantu Tadbir (Kesetiausahaan) *Administrative Assistant(Secretary)*	N9	2	1	1
14.	Pengawal Keselamatan *Security Guard*	KP10	3	1	2
15.	Pembantu Tadbir Rendah (Jurutaip) *Administrative Assistant (Typist)*	N11	4	2	2
16.	Pembantu Tadbir Rendah (Operator Telefon) *Administrative Assistant (Telephone Operator)*	N11	1	1	0
17.	Atendan Kesihatan *Health Attendant*	U16	10	7	3
18.	Pembantu Am Rendah *General Assistant*	N13	2	0	2
19.	Jaga *Security Guard*	R11	2	0	2
20.	Pemandu Kenderaan Bermotor *Driver*	R10	3	2	1
21.	Operator Mesin Prosesan Data *Data Processing Machine Operator*	F9	2	1	1
	Jumlah *(Total)*		**184**	**149**	**35**

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 terampil 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.

ORGANIZATIONAL 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 alliance 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 organizational efficiency and effectiveness through modernisation and automation of the office, laboratory and registration systems and regular review and improvement of service.

To strengthen enforcement activity of the related legislation.

To ensure continuous mutual understanding and cooperation between the regulatory body and the private sector through dialogue 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 purpose.

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.

MOTTO

UTAMAKAN KUALITI, EFIKASI DAN KESELAMATAN.
EMPHASIZE QUALITY, EFFICACY AND SAFETY

PIAGAM PELANGGAN

A. KEWAJIPAN BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN TEMA PIAGAM

Ditujukan khas kepada setiap pelanggan yang berurusan dengan BPFK.

1. AM

KEMUDAHAN UNTUK PELANGGAN

i) Setiap pelanggan Biro boleh mendapat perkhidmatan sewajarnya.

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

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.

MAKLUMAT PERKHIDMATAN

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

2. AKTIVITI -PENDAFTARAN

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

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

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

3. AKTIVITI - MAKMAL

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 :

Exclusive concern for clients who deal with NPCB.

1. GENERAL

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.

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.

INFORMATION SERVICE

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

2. ACTIVITY - REGISTRATION

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

All applications shall be evaluated with fairness and impartiality in accordance with the relevant regulations.

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

3. ACTIVITY - LABORATORY

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

4. AKVITIVI - PENGUATKUASAAN DAN KOMPLIANS

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.

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 dan Pengimport - tidak lebih dari 3 bulan.

iii) Lesen Baru Untuk Pemborong, Pengilang dan 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 - tdak 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

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

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.

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 daripada 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 rambang dan menjalankan ujian-ujian analisa.

4. Menguatkuasakan skim pelesenan pengilang, pengimport, 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 yang dianjurkan 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 masa 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 Programme and participate in the WHO International Adverse Drug Reaction Monitoring Programme.

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

8. To manage the drug information collecting and disseminating system in line with its 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 pharmacists, other professional and semi-professional officers who are placed in this institution from time to time through local training scheme or international cooperational scheme.

Laporan Bahagian
Divisional Reports

BAHAGIAN PENTADBIRAN

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

OBJEKTIF

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

KEWANGAN

Menguruskan pembayaran upahan dan gaji untuk 149 anggota :

Gaji bulanan : RM 3,155,200.00

KUTIPAN HASIL

Kutipan hasil diterima daripada pelanggan untuk bayaran pendaftaran ubat-ubatan, ujian makmal, lesen, perkhidmatan nasihat, jualan buku-buku panduan dan lain-lain. Jumlah kutipan mengikut disiplin adalah seperti di bawah:-

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 to ensure that each program and activity meets its objective.

FINANCE

Payment to 149 staff members.

Salary : RM 3,115,200.00

REVENUE

Revenue is collected from the public for drug registration, laboratory tests, licences, advisory services, sale of guideline books and others. The breakdown of total revenue is as follows:-

Jadual 1: Kutipan Hasil (RM)
Table 1: Revenue Until 31.12.1999

Tahun *Year*	Pendaftaran *Registration*	Lesen *Licences*	Makmal *Laboratory*	Pemeriksaan *Inspection*	Bahan Cetak *Printed Materials*	Lain-lain *Others*
1992	422,965	53,650	308,685	0	0	16,213
1993	759,284	91,951	686,690	4,920	4,920	7,621
1994	911,840	84601	516,805	25,805	9,720	38,610
1995	381,120	99,200	965,110	22,600	52,806	1,520,836
1996	728,253	97,101	963,570	17,700	28,316	14,050
1997	878,050	105,750	797,555	8,800	37,602	28,019
1998	793,825	129,350	750,360	8,400	18,296	12,100
1999	959,405	158,350	484,860	14,350	39,605	18,871
Jumlah ***Total***	**5,834,742**	**819,953**	**5,473,635**	**102,575**	**191,265**	**1,656,320**

Jadual 2: Tinjauan Belanjawan
Table 2: Budget Preview

Peruntukan dan Perbelanjaan Mengurus BPFK (1999) ***NPCB Operating Allocation and Expenditure***							
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*	3,528,744	3,861,420	4,067,384	105.33	(205,964)	5,33
20000	Perkhidmatan dan Bekalan *Services and Supply*	2,853,000	2,295,000	2,296,633	100.07	(1,633)	-
30000	Aset (Harta Modal) *Asset (Property Model)*	125,000	175,000	174,955	99.97	44.16	0.02
	Jumlah *Total*	6,506,744	6,331,420	6,538,972	305.37	(207,552)	5.35

BAHAGIAN PENILAIAN DAN KESELAMATAN UBAT

OBJEKTIF

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

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

PENCAPAIAN

Permohonan diterima

Sejumlah 43,299 permohonan diterima dari tahun 1985 sehingga 1999, dimana 13,545 (31.3 %) ubat racun, 9,519 (22.0 %) ubat bukan racun, 18,768 (43.3 %) ubat tradisional and 1,467 (3.4 %) kosmetik **(Jadual 3)**. Jumlah permohonan telah meningkat dengan ketara dari 6,448 pada 1986 kepada 20,257 pada 1992. Trend yang sama dapat diperhatikan pada 1992 hingga 1999, dimana jumlah permohonan meningkat sebanyak 53.2 %, kerana permohonan yang banyak untuk ubat tradisional dan kosmetik.

Keluaran didaftarkan

Sejumlah 23,935 keluaran telah didaftarkan sehingga 1999, dimana 8,792 (36.7 %) ialah ubat racun, 5,942 (24.8 %) ubat bukan racun, 7,966 (33.3 %) ubat tradisional dan 1,235 (5.2 %) kosmetik **(Jadual 4)**. Jumlah keluaran yang didaftarkan menunjukkan peningkatan bagi semua kategori.

Permohonan ditolak

Sehingga 1999, sejumlah 16,384 permohonan ditolak dan ini meliputi kira-kira 37.8% dari jumlah permohonan yang diterima. **(Jadual 5)**

DRUG 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 registration of products.

ACHIEVEMENTS

Applications Received

A total of 43,299 applications were received from 1985 to 1999, of which received 13,545 (31.3 %) were prescription drugs, 9,519 (22.0 %) OTC products, 18,768 (43.3 %) traditional medicines and 1,467 (3.4 %) cosmetics ***(Table 3).*** *The number of applications had increased very markedly, from 6,448 in 1986 to 20,257 in 1992. A similar increasing trend was observed from 1992 to 1999, where the number of applications had gone up by almost 53.2 %, mainly due to the enormous number of traditional medicines and cosmetics applications.*

Products Registered

A total of 23,935 products had been registered by 1999, of which 8,792 registered(36.7 %) are prescription drugs, 5,942 (24.8 %) OTCs, 7,966 (33.3 %) traditional medicines and 1,235 (5.2 %) cosmetics ***(Table 4)****. The number of products registered display increasing trends for all categories.*

Applications rejected

Up until 1999, a total of 16,384 applications had been rejected and this represents approximately 37.8 % of the total number of applications received. ***(Table 5)***

Jadual 3 : Permohonan Untuk Pendaftaran, 1985 - 1999
Table 3 : Applications Received For Registration, 1985 - 1999

Tahun *Year*	Ubat racun *Prescription drugs*	Ubat bukan racun *OTC products*	Ubat tradisional *Traditional medicines*	Kosmetik *Cosmetics*	Jumlah *Total*	Tahunan Kumulatif *Annual 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
Jumlah ***Total***	**13,545**	**9,519**	**18,768**	**1,467**	**43,299**	**43,299**

Jadual 4 : Bilangan Kumulatif Keluaran Yang Didaftarkan (1991 - 1999)
Table 4 :Cumulative Number Of Products Registered (1991 - 1999)

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
Jumlah ***Total***	**8,792**	**5,942**	**7,966**	**1,235**	**23,935**

Jadual 5 : Bilangan Kumulatif Permohonan Yang Ditolak, 1986 - 1999
Table 5 : Cumulative Number Of Applications Rejected By The DCA, 1986 - 1999

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	9,373
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
Jumlah ***Total***	**4,186**	**3,125**	**8,975**	**98**	**16,384**

Permohonan yang dibatalkan atau ditarik balik

Sehingga 1999, sejumlah 5,108 permohonan dibatalkan atau ditarik-balik, dan ini meliputi 1925 (37.7 %) ubat racun, 909 (17.8 %) ubat bukan racun, 2208 (43.2 %) ubat tradisional dan 66 (1.3 %) kosmetik **(Jadual 6)**. Jumlah keluaran yang dibatalkan atau ditarik-balik adalah 11.8 % daripada jumlah permohonan yang diterima.

Applications Cancelled or Withdrawn

Up until 1999, a total of 5,108 applications had been cancelled or withdrawn, which consisted of 1925 (37.7 %) prescription drugs, 909 (17.8 %) OTCs, 2208 (43.2 %) traditional medicines and 66 (1.3 %) cosmetics ***(Table 6).*** *The total number of products cancelled or withdrawn represents about 11.8 % of the total number of applications received.*

Jadual 6 : Permohonan Yang Dibatalkan /Ditarikbalik, 1989 - 1999
Table 6 : Applications Cancelled/Withdrawn, 1989 - 1999

Tahun *Year*	Ubat racun *Prescription drugs*	Ubat bukan racun *OTC products*	Ubat tradisional *Traditional medicines*	Kosmetik *Cosmetics*	Jumlah *Total*	Tahunan Kumulatif *Annual 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	-	618	1,453
1999	1,367	609	1,613	66	3,655	5,108
Jumlah *Total*	1,925	909	2,208	66	5,108	5,108

Rayuan

Jumlah rayuan yang diterima pada 1999 adalah 370 berbanding dengan 522 pada 1998 dan 388 pada 1997.

Entiti kimia baru

Dari 1985 hingga 1999, sejumlah 1,051 permohonan diterima untuk keluaran entiti kimia baru (Rajah 1). Daripada jumlah ini, 668 (63.5%) telah diluluskan, 275 (26.2%) ditolak dan 38 (3.6%) tertangguh.

Tempatan vs. Import

Sebanyak 42.0 % (10,128) daripada jumlah keluaran yang didaftarkan adalah dikilangkan di tempatan, sementara 58.0 % (13,807) adalah diimport. Keluaran tempatan dan import yang didaftarkan dari 1991 sehingga 1999, mengikut kategori berlainan diilustrasikan pada **Jadual 7**.

Appeals

The number of appeals received in 1999 was 370, as compared to 522 in 1998 and 388 in 1997.

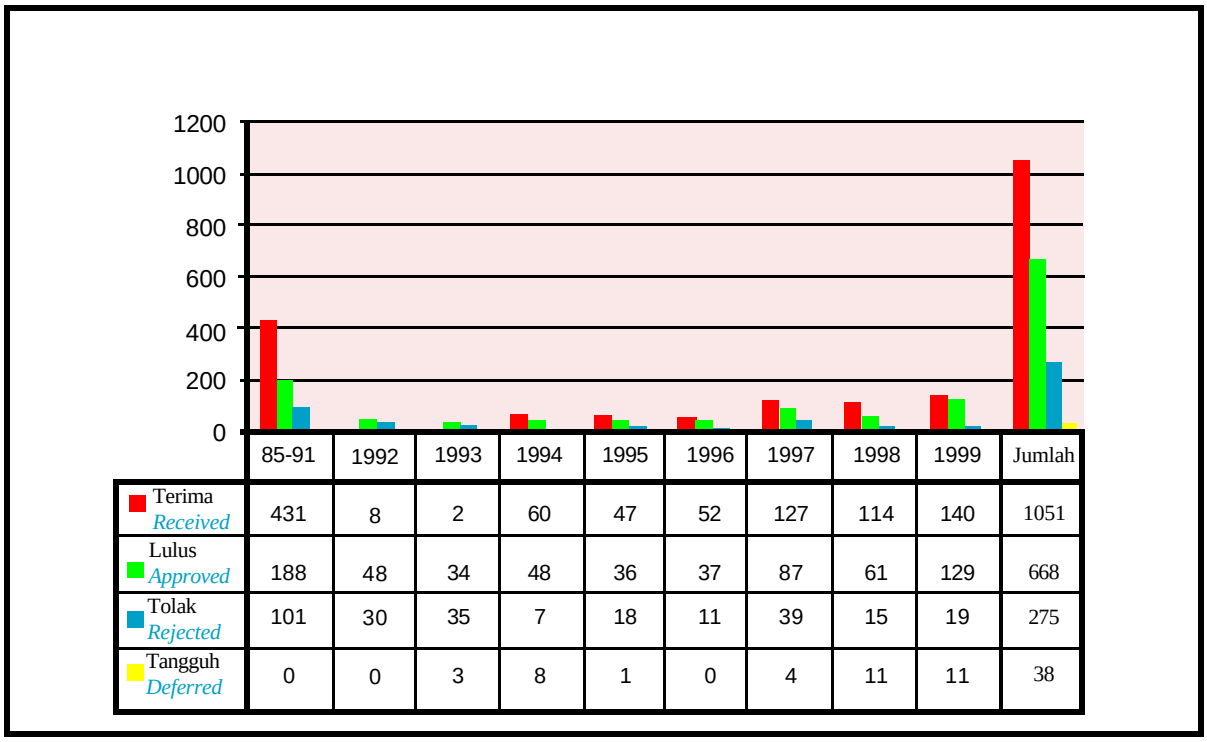
New chemical entities

From 1985 to 1999, a total of 1,051 applications were received for products classified as new chemical entities (Figure 1). Out of these, 668 (63.5 %) had been approved, 275 (26.2 %) rejected and 38 (3.6 %) deferred.

Local vs. Import

*About 42.0 % (10,128) of the total number of products registered are locally-manufactured, while 58.0 % (13,807) are imported. Locally manufactured and imported products registered for the period between 1991 to 1999, according to different categories, are cumulatively illustrated in **Table 7.***

Rajah 1: Status Pendaftaran Keluaran Entiti Kimia Baru 1985 - 1998
Figure 1: Registration Status Of New Chemical Entities, 1985 - 1998



	85-91	1992	1993	1994	1995	1996	1997	1998	1999	Jumlah
Terima *Received*	431	8	2	60	47	52	127	114	140	1051
Lulus *Approved*	188	48	34	48	36	37	87	61	129	668
Tolak *Rejected*	101	30	35	7	18	11	39	15	19	275
Tangguh *Deferred*	0	0	3	8	1	0	4	11	11	38

Jadual 7 : Jumlah Kumulatif Produk Tempatan Dan Import (1991 - 1999)
Table 7 : Cumulative Number Of Locally Manufactured And Imported Products Registered (1991 - 1999)

Tahun *Year*	Ubat racun *Prescription drugs*		Ubat bukan racun *OTC products*		Ubat tradisional *Traditional medicines*		Kosmetik *Cosmetics*		Jumlah *Total*	
	Local	*Import*	*Local*	*Import*	*Local*	*Import*	*Local*	*Import*	*Local*	*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	10,128	13,807
Jumlah ***Total***	**8,792**		**5,942**		**7,966**		**1,235**		**23,935**	

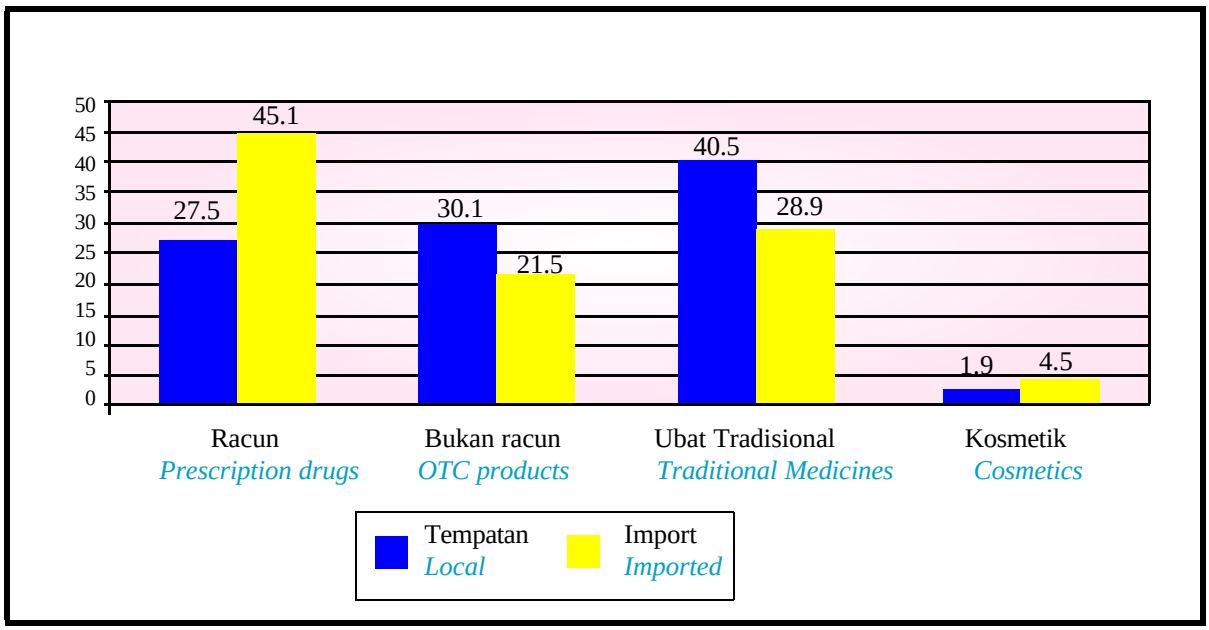
Semenjak 1999, peratusan nisbah antara produk tempatan dan produk import untuk ubat racun adalah 32:68 seperti data dalam Jadual 5. Bagi ubat bukan racun, peratusan keluaran tempatan adalah lebih tinggi seperti mana ditunjukkan dalam nisbah 51:49. Peratusan untuk ubat tradisional adalah 51:49, menunjukkan peratusan keluaran yang dikilang tempatan adalah lebih tinggi manakala peratusan nisbah kosmetik pula adalah 16:84.

Merujuk kepada jumlah produk tempatan yang didaftarkan (n = 10,128) seperti pada Jadual 5, 2,781 (27.5 %) adalah ubat racun, 3,052 (30.1 %) ubat bukan racun, 4,098 (40.5 %) ubat tradisional dan 197 (1.9%) kosmetik. Untuk produk import, berdasarkan kepada jumlah yang didaftarkan (n = 13,807), 6,011 (45.1 %) adalah ubat racun, 2,890 (21.5 %) ubat bukan racun, 3,868 (28.9 %) ubat tradisional dan 1,038 (4.5 %) kosmetik (Rajah 2).

As of 1999, the percentage ratio between locally manufactured and imported products for prescription drugs is in the order of 32:68 as shown by data in Table 5. For OTC products the percentage of locally manufactured products is slightly higher as indicated by a ratio of 51:49. The percentage ratio for traditional medicines is shown to be 51:49, indicating a higher proportion of locally manufactured products whereas the percentage ratio for cosmetics is 16:84.

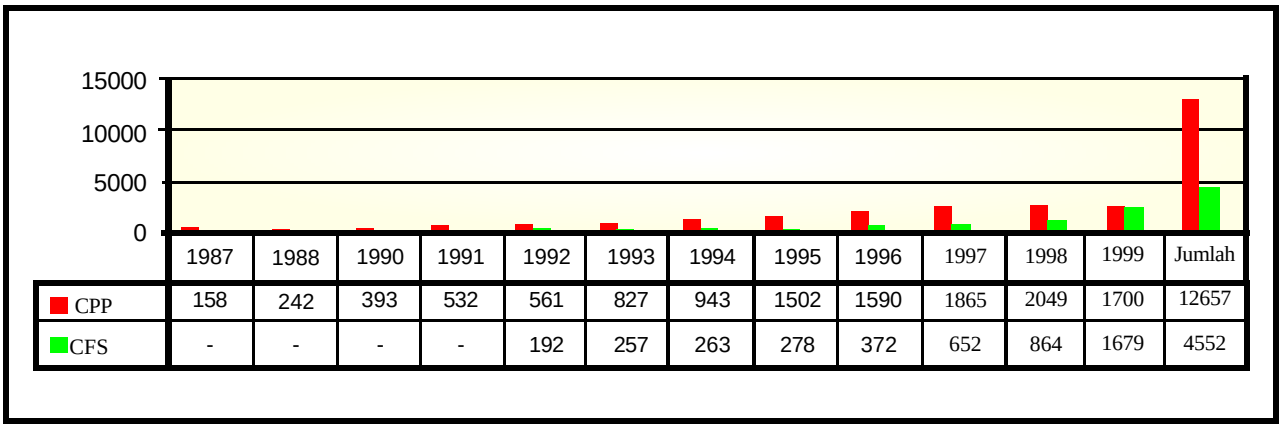
Based on the total number of locally-manufactured products registered (n = 10,128) as presented in Table 5, 2,781 (27.5 %) are prescription drugs, 3, 052 (30.1 %) OTC products, 4,098 (40.5 %) traditional medicines and 197 (1.9%) cosmetics. For imported products, based on the total number registered (n = 13,807), 6,011 (45.1 %) are prescription drugs, 2,890 (21.5 %) OTC products, 3,868 (28.9 %) traditional medicines and 1,038 (4.5 %) cosmetics (Figure 2).

Rajah 2: Produk berdaftar - Tempatan vs Import, 1999
Figure 2: Registered Products - Local vs. Imported, 1999



Rajah 3: Pengeluaran Sijil Perakuan Keluaran Farmaseutikal dan Sijil Perakuan Penjualan Bebas 1987 - 1999

Figure 3: Issuance of Certificate of Pharmaceutical Product and Certificate of Free Sale, 1987 - 1999



	1987	1988	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	Jumlah
CPP	158	242	393	532	561	827	943	1502	1590	1865	2049	1700	12657
CFS	-	-	-	-	192	257	263	278	372	652	864	1679	4552

Kebenaran Eksport

Pengeluaran sijil perakuan keluaran farmaseutikal [certificates of pharmaceutical products (CPP)] dan sijil perakuan penjualan bebas [certificates of free sale (CFS)] untuk alatan perubatan, untuk kebenaran mengeksport, telah bertambah sejak 1987 and 1992. Sejumlah 12,657 CPP dan 4,552 CFS telah dikeluarkan sejak 1999 **(Rajah 3)**.

Sumber Produk

Senarai untuk 50 negara pengeluar produk yang didaftarkan oleh PBKD menunjukkan Malaysia berada di tangga teratas (Jadual 6). 10 negara pengeluar utama ialah China, Amerika Syarikat, Australia, England, Germany, Indonesia, Switzerland, Thailand, India dan France. Negara-negara ini meliputi lebih kurang 73.0 % (10,074) daripada jumlah keluaran import (13,807). Produk yang diimport dari negara-negara ASEAN seperti Indonesia, Thailand, Singapore, dan Philippines meliputi hampir 12.2 % (1,678).

5 negara pengeluar utama bagi keluaran ubat racun, ubat bukan racun, ubat tradisional dan kosmetik ditunjukkan pada **Rajah 4.** Malaysia merupakan pengeluar utama keluaran ubat racun, ubat bukan racun dan ubat tradisional, sementara Germany ialah pengeluar utama keluaran kosmetik.

Export Authorisation

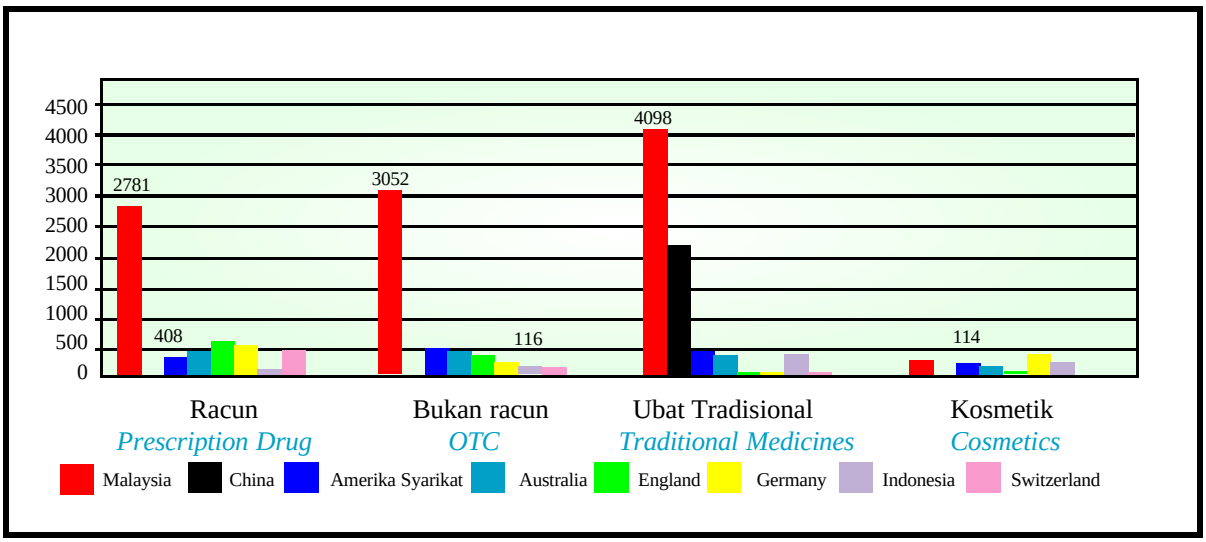
Issuance of certificates of pharmaceutical products (CPP) and certificates of free sale (CFS) for medical devices, for export authorisation, had increased steadily since 1987 and 1992 respectively. A total of 12,657 CPP and 4,552 CFS had been issued up to 1999 ***(Figure 3).***

Sources of Products

Listing of 50 different origins of products registered by the DCA products shows that Malaysia is ranked topmost (Table 6). The top 10 leading foreign sources include China, United States of America (USA), Australia, England, Germany, Indonesia, Switzerland, Thailand, India and France. Together they account for approximately 73.0 % (10,074) of our total imports (13,807). Products imported from neighbouring ASEAN countries, which include Indonesia, Thailand, Singapore, and Philippines constitute nearly 12.2 % (1,678).

The 5 leading sources for prescription drugs, OTC products, traditional medicines and cosmetics are illustrated in ***Figure 4.*** *Malaysia is the leading source for prescription drugs, OTCs and traditional medicines, while Germany is the leading source for cosmetics.*

Rajah 4: Pengeluar Utama Produk Berdaftar, 1999
Figure 4: Leading Sources For Registered Products, 1999



Jadual 8: Sumber Produk Yang Berdaftar Dengan PBKD, 1999
Table 8: Sources Of Products Registered By The DCA, 1999

Bil. *No.*	Sumber *Source*	Kategori Keluaran *Categories of Products*				Jumlah *Total*
		Ubat racun *Prescription Drugs*	Ubat bukan racun *OTC Products*	Ubat tradisional *Traditional Medicines*	Kosmetik *Cosmetics*	
1	MALAYSIA	2,781	3,052	4,098	197	10,128
2	CHINA	8	22	2231	-	2,261
3	U.S.A	408	502	477	144	1,531
4	AUSTRALIA	495	445	328	127	1,395
5	GERMANY	597	213	30	231	1,071
6	ENGLAND (U.K.)	658	311	16	28	1,013
7	INDONESIA	112	116	334	172	734
8	SWITZERLAND	486	111	9	-	606
9	THAILAND	259	259	3	53	574
10	INDIA	223	86	165	4	478
11	FRANCE	302	93	14	2	411
12	ITALY	194	60	4	86	344
13	CANADA	222	41	19	34	316
14	BELGIUM	204	28	6	56	294
15	TAIWAN	128	42	108	-	278
16	JAPAN	110	79	15	41	245
17	SINGAPORE	134	95	14	-	243

Bil. *No.*	Sumber *Source*	Kategori Keluaran *Categories of Products*				Jumlah *Total*
		Ubat racun *Prescription Drugs*	Ubat bukan racun *OTC Products*	Ubat tradisional *Traditional Medicines*	Kosmetik *Cosmetics*	
18	IRELAND	129	69	-	-	198
19	SWEDEN	118	47	23	-	188
20	CYPRUS	168	18	-	-	186
21	SOUTH KOREA	110	32	36	-	178
22	DENMARK	149	23	-	-	172
23	SPAIN	90	14	-	55	159
24	HOLLAND	94	27	2	5	128
25	PHILIPPINES	80	47	-	-	127
26	HUNGARY	100	19	-	-	119
27	FINLAND	74	13	2	-	89
28	AUSTRIA	62	8	2	-	72
29	NEW ZEALAND	41	1	20	-	62
30	SLOVENIA	38	9	-	-	47
31	YUGOSLAVIA	35	3	-	-	38
32	NORTH KOREA	32	-	1	-	33
33	POLAND	26	4	-	-	30
34	JORDAN	24	-	4	-	28
35	PORTUGAL	15	6	-	-	21
36	GREECE	20	-	-	-	20
37	NORWAY	7	12	-	-	19
38	S. AFRICA	13	5	1	-	19
39	REP. CZECH	16	-	-	-	16
40	EGYPT	-	12	3	-	15
41	TURKEY	9	3	-	-	12
42	SCOTLAND	8	3	-	-	11
43	CHILE	7	-	-	-	7
44	PAKISTAN	2	3	-	-	5
45	REP. SLOVAK	-	5	-	-	5
46	MEXICO	3	1	-	-	4
47	ICELAND	-	2	-	-	2
48	BANGLADESH	-	1	-	-	1
49	BULGARIA	-	-	1	-	1
50	PANAMA	1	-	-	-	1
Jumlah ***Total***		8,792	5,942	7,966	1,235	23,935

BAHAGIAN APB DAN PERLESENAN

OBJEKTIF

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

AKTIVITI-AKTIVITI

Bahagian ini menjalankan aktiviti-aktiviti seperti berikut :

- Memeriksa 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 premis pengilang keluaran berdaftar
- Memberi khidmat nasihat dan bimbingan kepada industri berkenaan dalam aspek APB, ASB dan perlesenan.
- Menganjur kursus latihan APB untuk industri farmaseutikal dan tradisional serta pelawat-pelawat luar negara
- Mengadakan perbincangan teknikal dengan industri farmaseutikal untuk meningkatkan tahap APB premis pengilang tempatan
- Mengumpul maklumat berkaitan industri farmaseutikal dan tradisional
- Mengeluarkan Perakuan APB dan mengesahkan salinan dokumen-dokmen berkaitan lesen

PENCAPAIAN

Pemeriksaan APB

Sebanyak 120 pemeriksaan APB telah dijalankan pada tahun 1999, berbanding dengan 111 pada tahun 1998. Pemeriksaan tersebut meliputi 23 premis pengilang keluaran racun, 24 keluaran bukan racun, 73 ubat tradisional , 1 kosmetik dan 1 keluaran veterinar. Pencapaian ini adalah 20 % melebihi sasaran yang ditetapkan dan menunjukkan peningkatan sebanyak 8.1 % daripada jumlah pemeriksaan tahun 1998. **Rajah 5** menunjukkan bilangan pemeriksaan APB yang dijalankan daripada 1995 hingga 1999.

GMP AND LICENSING DIVISION

OBJECTIVES

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

ACTIVITIES

This division carries out the following activities :

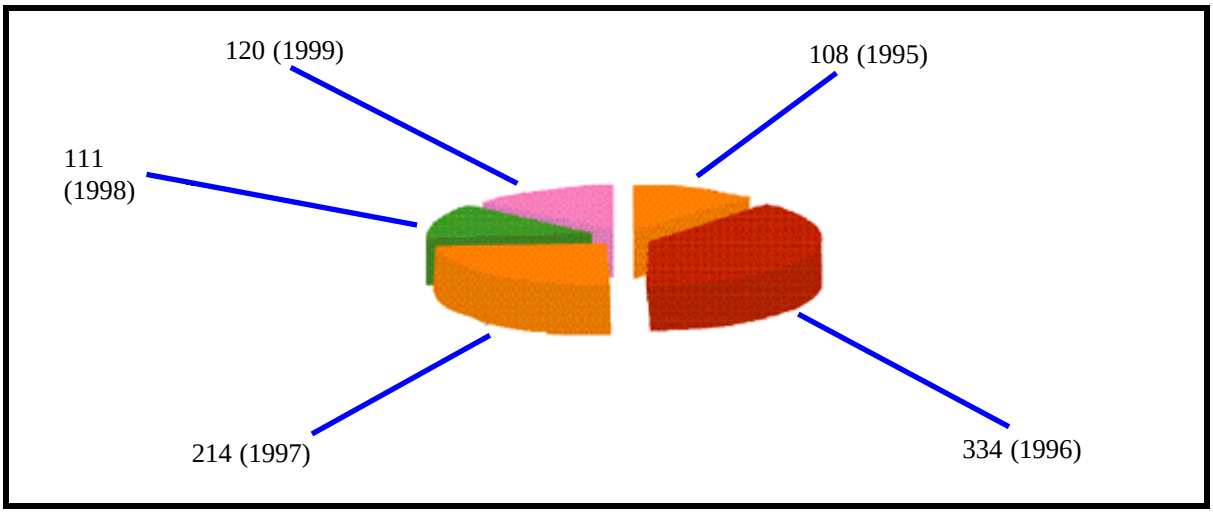
- *Inspection of premises for manufacturers, importers and wholesalers of registered products*
- *Processing of licence applications for manufacturers, importers and wholesalers of registered products*
- *Issuance of additional lists of registered products*
- *Evaluation of lay-out plans for manufacturing premises for registered products*
- *Advisory service to relevant industries on technical aspects regarding GMP, GSP and licensing*
- *Training courses for pharmaceutical and traditional medicines industries and also overseas visitors*
- *Technical discussions with pharmaceutical industries to upgrade the GMP standard of local manufacturing premises*
- *Collection of information related to pharmaceutical and traditional industries*
- *Issuance of GMP certificates and endorsement of licence related documents*

ACHIEVEMENTS

GMP Inspection

A total of 120 inspections were conducted in 1999 as compared with 111 in 1998. These inspections included 23 premises for scheduled poisons manufacturers, 24 non-scheduled poisons, 73 traditional medicines, 1 cosmetic and 1 veterinary medicine. This achievement is 20% more than the targeted output and it shows an increase of 8.1 % performance output, as compared to the output for 1998. ***Figure 5*** *shows the number of GMP inspections carried out since 1995 until 1999.*

Rajah 5: Pemeriksaan APB Premis Pengilang, 1995-1999
Figure 5: GMP Inspection Of Manufacturing Premises, 1995 - 1999



Penilaian Pelan Premis Pengilang

Sejumlah 62 pelan susun-atur premis pengilang baru dan sediada telah dinilai, termasuk 4 premis pengilang keluaran racun, 4 keluaran bukan racun, 47 ubat tradisional , 6 kosmetik dan 1 farmasi hospital. Pencapaian ini telah menurun 55.4 % berbanding dengan bilangan tahun 1998.

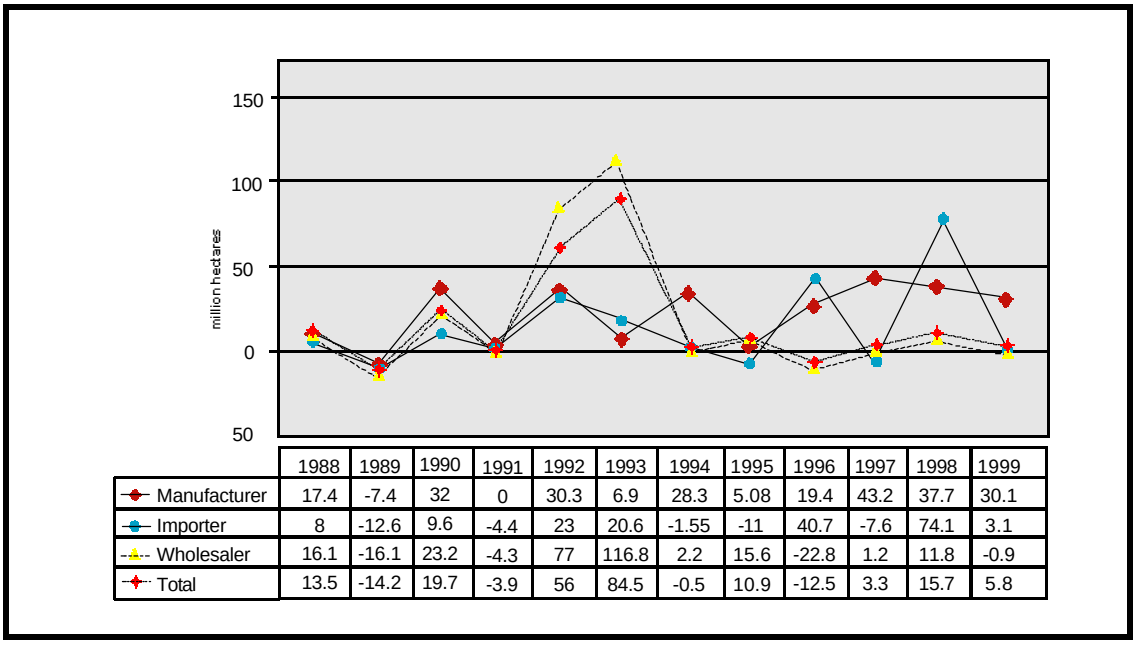
Dari segi kadar pertumbuhan premis berlesen, **Rajah 6** menunjukkan bahawa kadar pertumbuhan bagi jumlah premis adalah 5.8 % bagi tahun 1999 berbanding 15.7 % pada tahun 1998.

Evaluation of Manufacturing Premises Lay-out Plans

A total of 62 lay-out plans for new and existing manufacturing premises were evaluated, which included 4 premises of scheduled poisons manufacturers, 4 non-scheduled poisons, 47 traditional medicines, 6 cosmetics and 1 hospital pharmacy unit. This shows a 55.4% drop, as compared to 1998.

*With respect to growth rates of licensed premises, **Figure 6** shows the growth profile for 1988 until 1999, whereby the growth for 1999 is 5.8 %, as compared to 15.7 % for 1998.*

Rajah 6: Kadar Pertumbuhan Premis Berlesen, 1988-1999
Figure 6: Growth Rate of Licensed Premises, 1988 - 1999



	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Manufacturer	17.4	-7.4	32	0	30.3	6.9	28.3	5.08	19.4	43.2	37.7	30.1
Importer	8	-12.6	9.6	-4.4	23	20.6	-1.55	-11	40.7	-7.6	74.1	3.1
Wholesaler	16.1	-16.1	23.2	-4.3	77	116.8	2.2	15.6	-22.8	1.2	11.8	-0.9
Total	13.5	-14.2	19.7	-3.9	56	84.5	-0.5	10.9	-12.5	3.3	15.7	5.8

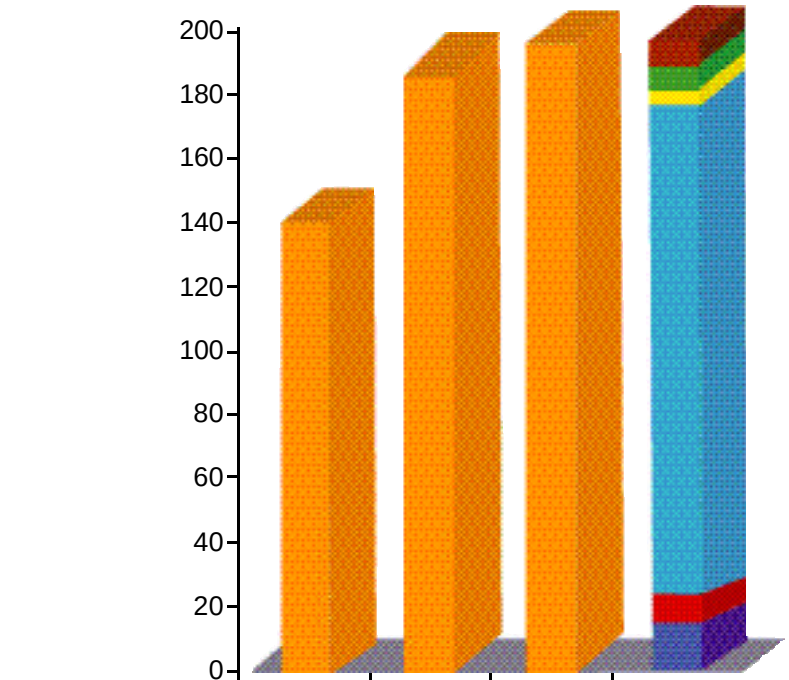
Khidmat Nasihat

Pada tahun 1999 sebanyak 196 khidmat nasihat dan bimbingan telah diberikan kepada pengilang atau pengusaha, berbanding dengan 185 pada tahun 1998 dan 140 pada tahun 1997. Daripada jumlah yang dicapai, 15 adalah berkaitan APB keluaran racun, 8 bukan racun, 153 ubat tradisional, 5 kosmetik, 1 peralatan perubatan, 7 keluaran veterinar dan 7 berkaitan ASB. **Rajah 7** menunjukkan bilangan khidmat nasihat yang diberikan daripada tahun 1997 hingga 1999.

Advisory Service

*In 1999, a total of 196 advisory services were given to the relevant industries, as compared to 185 in 1998 and 140 in 1997. For 1999, 15 of them were related to premises of scheduled poisons, 8 non-scheduled poisons, 153 traditional medicines, 5 cosmetics, 1 medical device, 7 veterinary medicines and 7 related to GSP. **Figure 7** shows the statistic from 1997 to 1999.*

Rajah 7: Khidmat Nasihat APB
Figure 7: GMP Advisory Service



	1990	1998	1999	1999
Total	140	185	196	
GSP				7
Veterinary				7
Medical Device				1
Cosmetic				5
Traditional				153
OTC				8
Scheduled Poison				15

Pemprosesan Lesen

- *Lesen Pengilang*

Sebanyak 237 permohonan lesen pengilang telah diproses pada tahun 1999, berbanding 148 pada tahun 1998 dan 100 pada tahun 1997. Daripada jumlah ini, 63 adalah permohonan baru manakala 174 lagi adalah pembaharuan. Pencapaian ini adalah sebanyak 2.37 kali ganda sasaran yang ditetapkan.

- Lesen Pengimport

Bagi lesen pengimport, sebanyak 305 permohonan telah diterima dan diproses. Daripada jumlah ini, 73 adalah permohonan baru dan 232 pembaharuan. Bilangan permohonan didapati telah meningkat berbanding 255 pada tahun 1998 dan 171 pada tahun 1997. Pencapaian ini juga adalah 22 % melebihi sasaran yang ditetapkan.

- Lesen Pemborong

Bilangan permohonan lesen pemborong yang diproses juga telah meningkat kepada 985, dimana 69 adalah permohonan baru dan 918 pembaharuan. Pencapaian ini adalah 40 % melebihi sasaran yang ditetapkan. Peningkatan ini begitu ketara sekali berbanding jumlah 705 pada tahun 1998 dan 642 pada tahun 1997.

Data mengenai jumlah lesen yang diproses daripada tahun 1995 hingga 1999 dipaparkan dalam **Rajah 8**. Pada keseluruhan, statistik ini menunjukkan bahawa jumlah lesen yang diproses telah meningkat tahun demi tahun.

Licence Processing

- *Manufacturers Licence*

A total of 237 applications for manufacturers licences were processed in 1999, compared to 148 in 1998 and 100 in 1997. From this total number, 63 applications are new applications whereas the remaining 174 are renewals. This performance achievement is 2.37 times more than the targeted output.

- *Importers Licence*

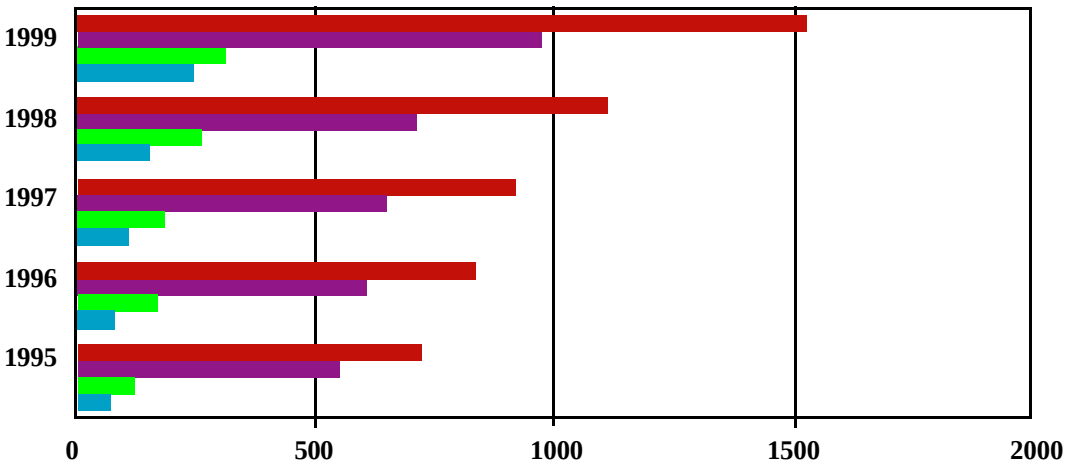
A total of 305 applications were received and processed for importers license. From this total, 73 applications are new applications, whereas the remaining 232 are renewals. The number of applications has increased significantly, compared to 255 in 1998 and 171 in 1997. The 1999 performance achievement is 22% more than the targeted output.

- *Wholesalers Licence*

The number of applications processed for wholesalers license has increased to 985, whereby 69 of them are new applications and 918 are renewals. This achievement shows 40% more than the targeted output specification. The increase is significant, as compared with 705 in 1998 and 642 in 1997.

*The overall statistic for processing of licenses from 1995 until 1999 is presented in **Figure 8**. On the whole, it shows that the number of licenses processed had increased year by year.*

Rajah 8: Pemprosesan Lesen, 1995-1999
Figure 8: Processing Of Licences, 1995 - 1999



	1995	1996	1997	1998	1999
Total	719	827	916	1108	1527
Wholesaler	544	596	642	705	985
Importer	113	159	171	255	305
Manufacturer	62	72	103	148	237

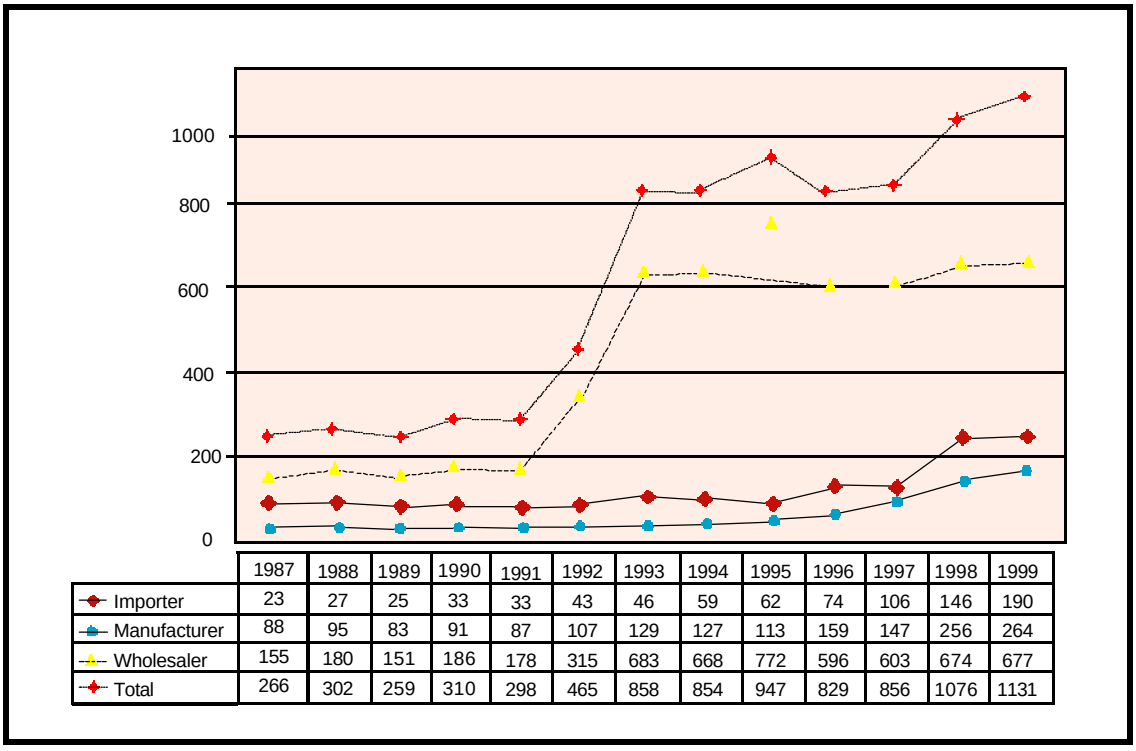
- Premis Berlesen

Rajah 9 menunjukkan jumlah premis berlesen daripada tahun 1987 sehingga 1999. Jumlah bilangan premis bagi tahun 1999 telah meningkat kepada 1,131 berbanding 1,076 pada tahun 1998.

- *Licensed Premises*

***Figure 9** shows the number of licensed premises from 1987 until 1999. For 1999, the number has increased to 1,131 as compared to 1,076 in 1998.*

Rajah 9: Bilangan Premis Berlesen, 1987-1999
Figure 9: Number Of Licensed Premises, 1987 - 1999



	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Importer	23	27	25	33	33	43	46	59	62	74	106	146	190
Manufacturer	88	95	83	91	87	107	129	127	113	159	147	256	264
Wholesaler	155	180	151	186	178	315	683	668	772	596	603	674	677
Total	266	302	259	310	298	465	858	854	947	829	856	1076	1131

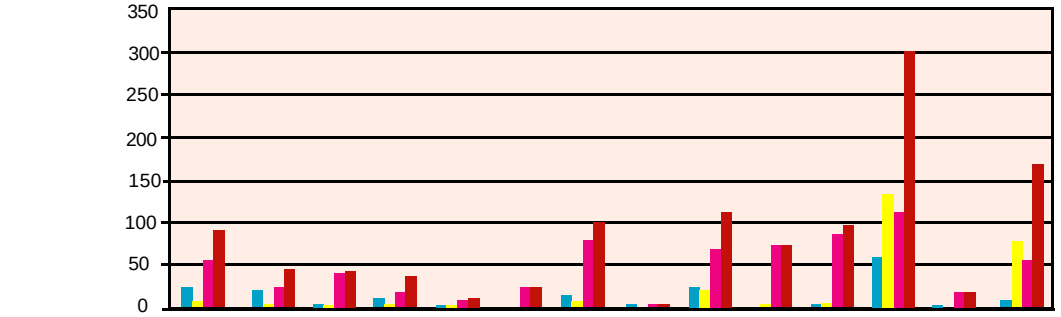
Rajah 10 menunjukkan taburan geografi mengikut negeri premis-premis berlesen bagi tahun 1999. Negeri Selangor mencatatkan jumlah yang tertinggi, diikuti oleh Wilayah Persekutuan dan Pulau Pinang.

***Figure 10** shows the geographical distribution of licensed premises according to states for 1999. Selangor recorded the highest number, followed by Wilayah Persekutuan and Pulau Pinang.*

Rajah 11 menunjukkan bilangan premis pengilang berlesen mengikut kategori bagi tahun 1999, dimana 55 adalah pengilang farmaseutikal, 131 pengilang tradisional dan 4 pula pengilang kosmetik, menjadikan jumlah keseluruhan sebanyak 190.

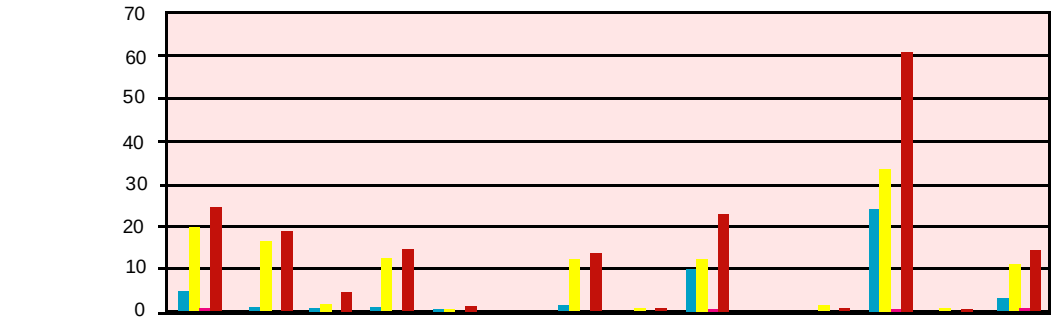
***Figure 11** shows the total number of 190 licensed manufacturers according to categories for 1999, whereby 55 are pharmaceutical, 131 traditional medicines and 4 cosmetics.*

Rajah 10: Taburan Geografi Premis Berlesen, 1999
Figure 10: Geographical Distribution Of Licensed Premises, 1999



	Joh	Ked	Kel	Mel	NS	Phg	Prk	Prs	PP	Sab	Swk	Sel	Trg	WP
Manufacturer	26	19	5	15	3	0	16	1	24	0	3	61	1	16
Importer	9	4	1	2	1	0	8	0	21	2	6	131	0	79
Wholesaler	56	23	38	19	10	29	76	1	67	72	88	110	23	56
Total	91	46	44	36	14	29	100	2	112	74	97	302	24	167

Rajah 11: Kategori Premis Pengilang Berlesen, 1999
Figure 11: Categories Of Licensed Manufacturing Premises, 1999



	Joh	Ked	Kel	Mel	NS	Phg	Prk	Prs	PP	Sab	Swk	Sel	Trg	WP
Pharmaceutical	5	3	1	2	1	0	3	0	10	0	0	26	0	4
Traditional	20	16	4	13	2	0	13	1	13	0	3	34	1	11
Cosmetic	1								1			1		1
Total	26	19	5	15	3	0	16	1	24	0	3	61	1	16

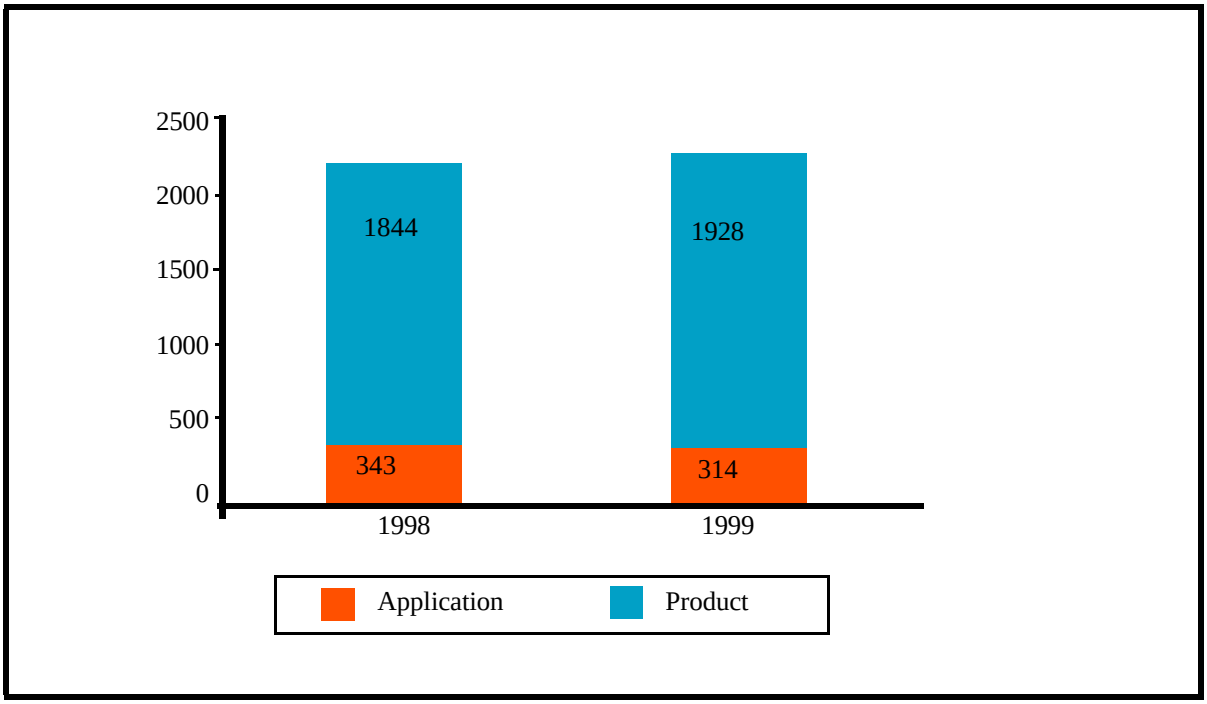
Senarai Tambahan Keluaran Berdaftar

Jumlah permohonan yang diproses pada tahun 1999 adalah sebanyak 314 dan melibatkan sebanyak 1,928 produk, berbanding 343 permohonan dan 1,844 produk pada tahun 1998. Walaupun bilangan permohonan didapati telah menurun tetapi bilangan produk telah meningkat. Statistik bagi tahun 1998 dan 1999 digambarkan dalam **Rajah 12.**

Additional Lists for Registered Products

The total number of applications that were processed in 1999 was 314 and they included a total of 1,928 registered products, as compared with 343 applications and 1,844 products in 1998. Although the number of applications shows decrease, the total number of products has actually increased. Statistics for 1998 and 1999 are shown in ***Figure 12.***

Rajah 12: Pengeluaran Senarai Tambahan Produk, 1998-1999
Figure 12: Issuance Of Additional Registered Product List 1998 - 1999



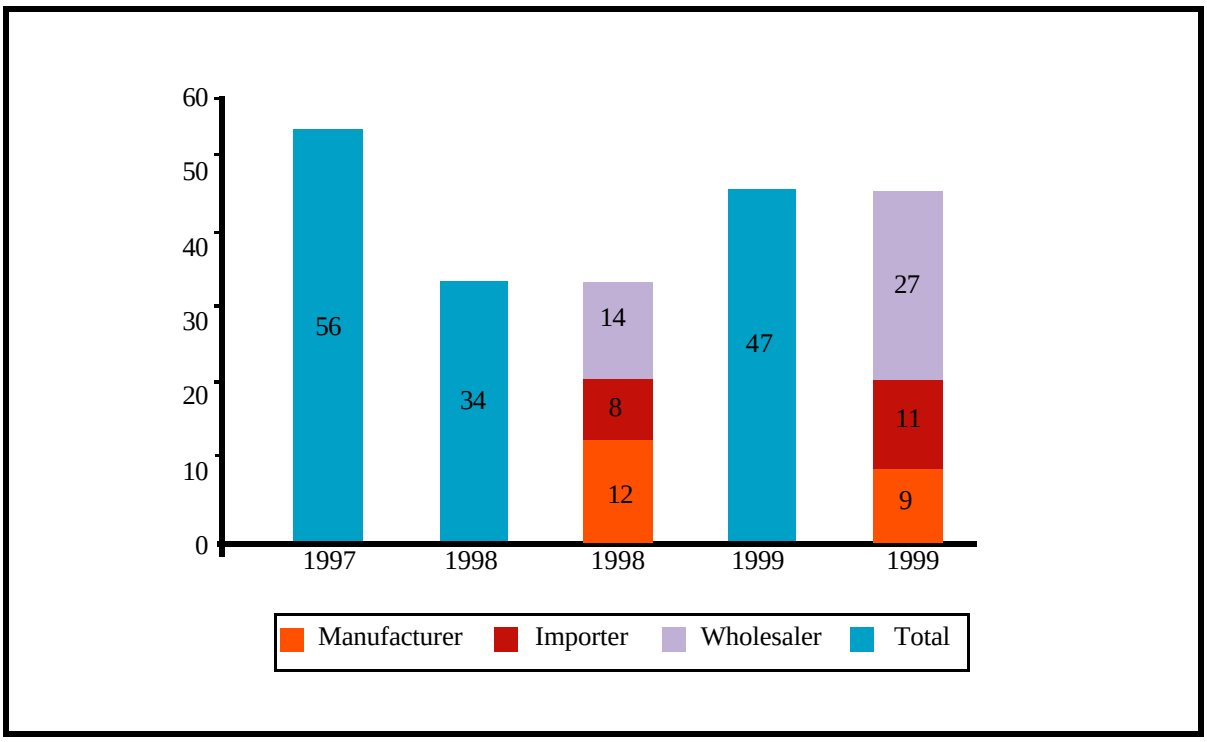
Pertukaran Pemegang Lesen

Sebanyak 47 permohonan pertukaran pemegang lesen telah diproses, di mana 9 adalah untuk pengilang, 11 pengimport dan 27 pemborong. Bilangan yang dicapai adalah 38.2 % lebih daripada tahun 1998. Statistik bagi tahun 1997 hingga 1999 dipaparkan dalam **Rajah 13.**

Change of Licence Holder

A total of 47 applications for change of licence holders were processed, whereby 9 were manufacturers, 11 importers and 27 wholesalers. The number of applications processed is 38.2% more than that for 1998. Statistics for 1997 to 1999 are presented in ***Figure 13.***

Rajah 13: Permohonan Pertukaran Pemegang, 1997 - 1999
Figure 13: Application For Change Of Holder, 1997 - 1999



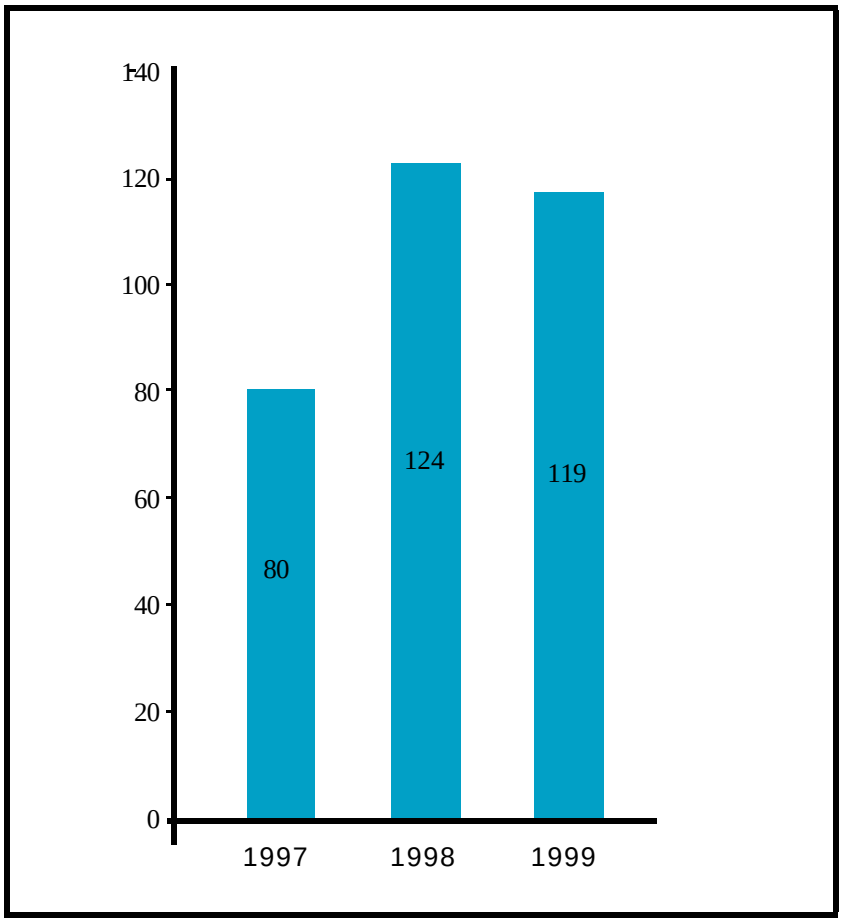
Perakuan APB Untuk Tujuan Eksport

Pada tahun 1999 jumlah perakuan APB yang dikeluarkan adalah sebanyak 119, berbanding 124 pada tahun 1998 dan 80 pada tahun 1997 **(Rajah 14)**. Sijil berkenaan adalah bagi negara-negara seperti Vietnam, Hong Kong, Filipina, Brazil, Cambodia, Bahrain, Qatar, United Arab Emirates, Namibia, Peru, Myanmar, Indonesia, Singapore, Australia, Iraq, Oman, Poland, Saudi Arabia, Barbados, Slovakia, Tanzania, Thailand, Taiwan, Bulgaria, Egypt, Pakistan, Sri Lanka, Maldives, Canada, Papua New Guinea, Dominican Republic, Yemen, Khazakhstan, China, Honduras, Lithuania, Malta, India, Brunei Darussalam, Romania dan Kenya.

GMP Certification

*In 1999, the total number of GMP certificates issued was 119, as compared with 124 in 1998 and 80 in 1997 **(Figure 14)**. These certificates are for countries such as Vietnam, Hong Kong, Philippines, Brazil, Cambodia, Bahrain, Qatar, United Arab Emirates, Namibia, Peru, Myanmar, Indonesia, Singapore, Australia, Iraq, Oman, Poland, Saudi Arabia, Barbados, Slovakia, Tanzania, Thailand, Taiwan, Bulgaria, Egypt, Pakistan, Sri Lanka, Maldives, Canada, Papua New Guinea, Dominican Republic, Yemen, Khazakhstan, China, Honduras, Lithuania, Malta, India, Brunei Darussalam, Romania and Kenya.*

Rajah 14: Permohonan Sijil APB, 1997-1999
Figure 14: Application Of GMP Certificates, 1997-1999



Tindakan Punitif

Pihak Berkuasa Kawalan Dadah (PBKD) telah menggantung sementara lesen pengilang bagi 5 premis farmaseutikal kerana gagal mematuhi keperluan APB. Pada tahun 1998, sebanyak 3 premis telah digantung lesen pengilangan dan 6 premis pula pada tahun 1997.

Dialog Dengan Industri

Bahagian ini telah menyelaraskan beberapa sessi dialog dengan persatuan-persatuan industri termasuk Persatuan Ubat Tradisional Melayu Malaysia (PURBATAMA), Malaysian Organisation of Pharmaceutical Indsutries (MOPI) dan Federation of Malaysian Manufacturers - Malaysian Cosmetic and Toiletries Industry Group (FMM MCTIG.).

Punitive Actions

In 1999, manufacturing licences for 5 pharmaceutical premises were temporarily suspended because of major non-compliances to GMP. In 1998, 3 manufacturing premises were temporarily suspended, compared to 6 suspensions in 1997.

Dialogues with Industries

This division coordinated dialogue sessions with industry associations such as the Persatuan Ubat Tradisional Melayu Malaysia (PURBATAMA), Malaysian Organization of Pharmaceutical Industries (MOPI) and the Federation of Malaysian Manufacturers-Malaysian Cosmetic and Toiletries Industry Group (FMM- MCTIG).

Satu kumpulan kerja teknikal yang dikenali sebagai Pharmaceutical GMP Technical Working Group (TWG) telah ditubuhkan untuk membincang isu-isu dan mengatasi masalah-masalah berkaitan APB farmaseutikal. Kumpulan ini telah mengenalpasti beberapa aspek seperti program latihan APB bercorak modul untuk jangka panjang termasuk aspek kawalan mutu, keperluan validasi, penggunaan garis panduan APB European Commission (Eudralex) dan lain-lain isu yang berkaitan.

Usahasama Dengan Unit Penguatkuasa Farmasi Negeri (UPFN)

Satu program usahasama dengan setiap UPFN telah dijalankan khususnya untuk membantu dalam menjalankan pemeriksaan APB bagi premis pengilang ubat tradisional. Sebuah Skim Inspektorat Kebangsaan yang melibatkan lebih kurang 30 orang pemeriksa serta pemeriksa kontrak APB telah ditubuhkan di bawah naungan Bahagian Perkhidmatan Farmasi. Seramai 14 orang pemeriksa kontrak, seorang dari setiap UPFN telah dilantik untuk menyertai inspektorat ini.

Pertubuhan Pusat Industri Farmaseutikal

Pembinaan pusat tersebut yang merangkumi kawasan kilang contoh, ruangan sumber maklumat dan ruangan untuk pameran telah dilaksanakan, walaupun terpaksa dibuat secara berperingkat. Cadangan untuk rangkaian sistem komputer, khusus untuk pusat tersebut telah dikemukakan untuk pertimbangan pihak berkenaan.

Permohonan Untuk Menjadi Ahli Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Dua orang pegawai dari bahagian ini telah menghadiri seminar PIC/S 1999 yang diadakan di Oxford, United Kingdom, sebagai langkah permulaan untuk menjalin hubungan dan memahami lebih mendalam syarat-syarat kemasukan PIC/S. Permohonan untuk menjadi ahli PIC/S telah mula-mula dikemukakan pada bulan Oktober 1999. Beberapa dokumen berkaitan termasuk Manual Kualiti telah disediakan. Malaysia juga telah menjemput wakil PIC/S untuk menyampaikan ceramah mengenai peranan dan aktiviti PIC/S pada Seminar Regulatori Farmaseutikal dan Kosmetik 1999 yang diadakan pada bulan Oktober 1999.

A Pharmaceutical GMP Technical Working Group (TWG) was established in 1999 to discuss pertinent issues and resolve problems related to pharmaceutical GMP. This TWG has already identified a few areas of interest such as quality control, validation requirements, adoption of European Commission (Eudralex) GMP Guidelines and other relevant technical issues.

Co-Operation With State Pharmacy Enforcement Units

The National Inspectorate Scheme comprising of about 30 GMP inspectors and sub-contract inspectors was established under the Pharmaceutical Services Division, Ministry of Health Malaysia. A total of 14 inspectors, one from each state was appointed as sub-contract GMP auditors. The aim of such co-operation was to work together in carrying out inspections of traditional medicine manufacturing premises throughout the country.

Establishment of Pharmaceutical Industry Centre

The proposed project includes a mock manufacturing facility, an information resource section and an exhibition area. Due to financial constraints, the physical construction of the centre was undertaken in stages. The funding for the proposed computerised networking system for the centre has already been submitted to the relevant department for consideration and approval.

Application To Be A Member of The Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Two officers from this division attended the PIC/S 1999 Seminar that was held in Oxford, United Kingdom in September 1999. This was an initial step towards establishing a close working relationship and also to understand further about the conditions for being a member of PIC/S. Malaysia's application to be a member of PIC/S was first submitted in October 1999. Several documents including the GMP Quality Manual were presented to PIC/S. Malaysia also invited a representative from PIC/S to present a paper on the role and activities of PIC/S at the Pharmaceutical and Cosmetic 1999 Regulatory Seminar that was held in October 1999.

Garis Panduan APB Kosmetik

Kumpulan Kerja Teknikal APB Kosmetik telah menyediakan draf garis panduan berkenaan dalam dua bahasa. Draf dokumen berkenaan juga telah dikemukakan kepada Asean Consulatative Committee for Standards and Quality (ACCSQ) Product Working Group for Cosmetic untuk dipertimbangkan dan diterima-pakai sebagai Garis Panduan APB Kosmetik ASEAN.

Kajian Semula Garis Panduan Fail Induk Pengilang

Bahagian ini telah mengkaji semula garis panduan berkenaan Edisi Pertama (Oktober 1994), agar selaras dengan keperluan PIC/S. Draf Edisi Kedua yang disediakan juga memuatkan terjemahan dalam Bahasa Malaysia, khususnya untuk diguna-pakai oleh pengilang ubat tradisional.

Persediaan Untuk ISO 9000

Selaras dengan usaha BPFK untuk mendapatkan pensijilan ISO 9000 yang diperakui oleh SIRIM, bahagian ini juga telah menyediakan prosedur-prosedur kualiti yang berkaitan dengan skop pemeriksaan dan pelesenan termasuk Manual Kualiti.

Kajiselidik Industri Farmaseutikal dan Tradisional

Satu kajiselidik yang bertujuan untuk mengkaji perkembangan industri farmaseutikal dan tradisional tempatan termasuk pengilang dan pengimport telah dijalankan. Aspek-aspek seperti hak milikan, nilai pelaburan, nilai jualan, nilai eksport, nilai import, pelaburan untuk R & D, pelaburan untuk peralatan, bilangan personel, perbelanjaan untuk latihan, aktiviti kontrak dan lain-lain telah dikaji.

Kursus-kursus yang dianjurkan

Bahagian ini telah bekerjasama dengan Jabatan Kesihatan Negeri Sabah dan Sarawak dan membantu dalam menganjurkan Seminar Ubat Tradisional yang diadakan di Sabah dan Sarawak pada bulan April 1999. Pada bulan Mei dan Jun, bahagian ini telah menyelaraskan beberapa program latihan termasuk 11 bengkel validasi anjuran bersama dengan MOPI di mana sejumlah 510 peserta industri dan BPFK telah menghadiri program ini.

Bahagian ini juga telah mengelolakan kursus APB selama 4 hari pada bulan Ogos, September dan Oktober untuk 12 Pegawai Penguatkuasa Farmasi Negeri. Pegawai-pegawai berkenaan telah dilantik sebagai pemeriksa kontrak APB khususnya untuk premis pengilang tradisional.

Cosmetic GMP Guidelines

The Cosmetic GMP Technical Working Group has completed the draft guidelines in two separate languages. The draft document has also been presented to the Asean Consultative Committee for Standards and Quality (ACCSQ) Product Working Group for Cosmetics for consideration and adoption as the ASEAN Cosmetic GMP Guidelines.

Revised Guidelines For Site Master File

The Guidelines for Site Master File, First Edition (October 1994) was reviewed to meet the requirements of PIC/S. The draft for the Second Edition was also translated into Bahasa Malaysia, in view of extending their applications to traditional medicine manufacturers.

Preparation for ISO 9000

In tandem with NPCB's efforts to obtain the ISO 9000 Certification by SIRIM, this division has prepared quality procedures relevant to the scope of inspection and licensing.

Survey of Pharmaceutical and Traditional Industries

A survey was conducted to study the development of the local pharmaceutical and traditional industries. Various aspects such as ownerships, investment values, sales values, export values, import values, investments in R & D, investments for equipment, number of personnel, expenditures for training, contract activities and others are included in the survey.

Courses Conducted

This division has worked together with the Sabah and Sarawak State Health Departments in organizing the Traditional Medicine Seminar, held in Sabah and Sarawak in April 1999. In May and June, a series of 11 validation workshops were jointly organized with MOPI, whereby a total of 510 participants from the industries and NPCB attended.

This division also conducts GMP courses, duration of 4 days in August, September and October for State Pharmacy Enforcement Officers. These officers were appointed as GMP sub-contract inspectors to assist mainly in inspection of traditional medicine manufacturing premises.

RANCANGAN UNTUK TAHUN 2000

Usahasama Pemeriksaan APB

Usahasama dengan UPFN dan BPKP, BAU dan BSF akan terus dipergiatkan untuk memantapkan Skim Inspektorat Kebangsaan dan meningkatkan pemantauan dan penguatkuasaan skim pelesenan, khususnya untuk premis pengilang ubat tradisional.

Pusat Industri Farmaseutikal

Langkah-langkah akan diambil untuk mengubahsuai dan melengkapkan infrastruktur dengan kemudahan-kemudahan asas termasuk perabot, peralatan pejabat dan lain-lain agar pusat berkenaan dapat berfungsi sebagai pusat bimbingan industri tempatan sepertimana yang dirancangkan. Jawatan-jawatan baru untuk membolehkan pusat berkenaan beroperasi dengan licin akan dipohon.

Permohonan Keahlian PIC/S

Permohonan menggunakan format baru serta dokumen-dokumen sokongan yang berkaitan akan dimajukan kepada Urusetia PIC/S. Kerjasama serta hubungan erat dengan PIC/S akan diperkukuhkan. Program latihan untuk pemeriksa dan pemeriksa kontrak APB akan dijalankan untuk meningkatkan kecekapan dalam bidang pemeriksaan selaras dengan piawaian antarabangsa.

Harmonisasi Kosmetik ASEAN

Bagi aspek APB, usaha-usaha gigih perlu diselaraskan dengan industri kosmetik tempatan serta pihak-pihak berkuasa negara-negara ASEAN lain untuk mewujudkan satu garis panduan APB kosmetik yang sesuai untuk diguna-pakai oleh semua negara ASEAN, dibawah program ACCSQ (Cosmetic).

Latihan APB Bercorak Modul

Program latihan APB untuk jangka panjang akan dirangka dan modul-modul yang sesuai akan dikenalpasti untuk meningkatkan kecekapan dan keterampilan personel-personel yang terlibat dalam bidang pengeluaran dan kawalan mutu disektor industri. Projek ini akan dikelolakan bersama dengan MOPI.

PLANS FOR YEAR 2000

GMP Inspection Co-Operation

Co-operation between various divisions within NPCB and State Pharmacy Enforcement Units will be enhanced to strengthen the National Inspectorate Scheme and to further strengthen enforcement of the licensing scheme, especially for traditional medicine manufacturing premises.

Pharmaceutical Industry Centre

Further steps will be taken to furnish the centre with basic facilities such as furniture, office equipment and other miscellaneous items to enable the centre to function as a guidance centre for the local industries. New posts for personnel will be put up to enable the centre to operate smoothly.

Application of PIC/S Membership

The new application format together with other supporting documents will be submitted to the PIC/S Secretariat. Co-operation and close working relationship with PIC/S will be strengthened. Training programmme for GMP inspectors and sub-contract inspectors will be conducted to improve their capability in the field of inspection, in accordance with international standards.

ASEAN Cosmetic Harmonization

With regards to GMP, the cosmetic industries and ASEAN regulatory authorities need to work hand in hand to establish and adopt the ASEAN Cosmetic GMP Guidelines that is suitable for all ASEAN countries, as proposed under the ACCSQ (Cosmetic) programme.

GMP Modular Training

A well-planned and long term GMP training programme, based on appropriate modules will be conducted to increase the skill and capabilities of personnel involved in production and quality control in the industry sector. This programme will be jointly organized with MOPI.

BAHAGIAN SURVEILANS DAN FARMAKOVIGILANS

OBJEKTIF

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

PENCAPAIAN

Sepanjang tahun 1999, program surveilans telah menyaksikan peningkatan sebanyak 128.9% dalam jumlah sampel keluaran untuk tujuan kajian kualiti berbanding pada tahun 1998. Julat dan bilangan sampel keluaran untuk tujuan surveilans telah meningkat dengan adanya kerjasama pegawai unit penguatkuasa farmasi negeri dimana dengan mereka membantu dalam pungutan sampel keluaran daripada premis pemegang lesen disemua negeri.

Manakala program pemonitoran kesan advers ubat telah berjaya mencapai satu peningkatan baru iaitu dengan penambahan sebanyak 45.1% dalam jumlah laporan yang diterima sepanjang tahun 1999 berbanding dengan tahun sebelumnya.

Kesedaran mengenai kepentingan kualiti keluaran oleh pihak pengguna juga telah menyebabkan peningkatan dalam bilangan aduan keluaran yang telah diterima.

SURVEILLANCE & PHARMACOVIGILANCE DIVISION

OBJECTIVE

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

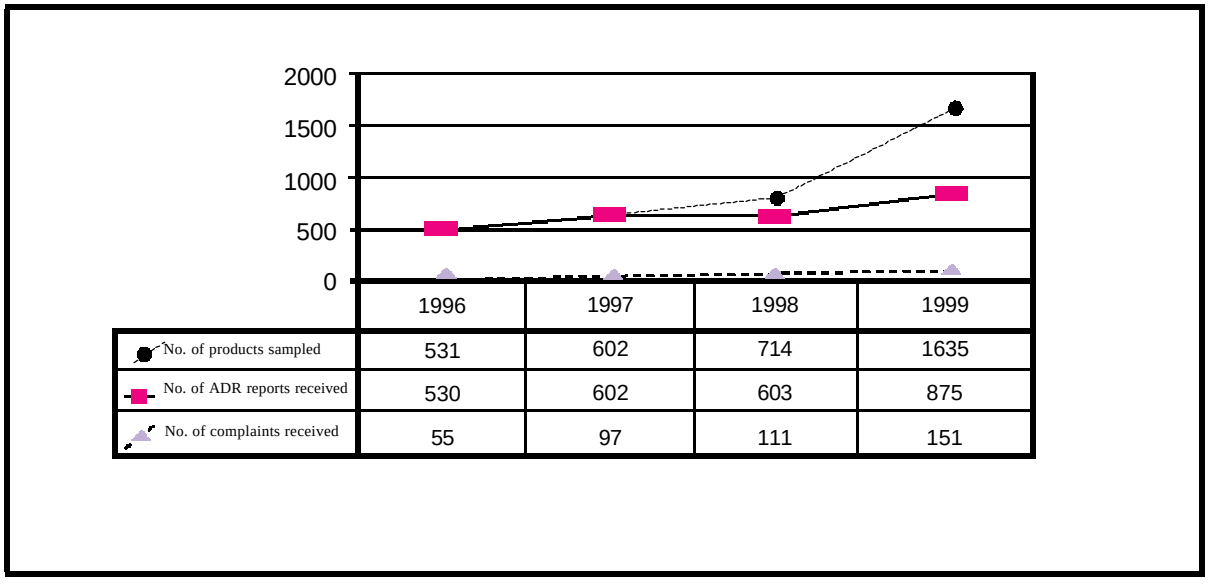
ACHIEVEMENTS

During the year 1999, the surveillance programme saw a 128.9% increase in the number of products sampled for quality testing as compared to 1998. The range and number of products sampled for surveillance was increased through the assistance of the state pharmacy enforcements officers who supplemented the activities of the surveillance officers by collecting samples of products from the premise of the registration holders throughout the country.

The adverse drug reactions monitoring programme also achieved new heights with an increase of 45.1% in the number of reports received in 1999 as compared to the previous year.

Awareness of this division also appears to have increased as demonstrated by the rising number of product complaints which were received.

Rajah 15: Aktiviti Surveilans
Figure 15: Surveillance Activities



	1996	1997	1998	1999
No. of products sampled	531	602	714	1635
No. of ADR reports received	530	602	603	875
No. of complaints received	55	97	111	151

Penyiasatan terhadap semua keluaran yang terdapat di premis 4 syarikat jualan langsung telah diadakan bersama dengan bantuan daripada pegawai Unit Penguatkuasa Farmasi Negeri Selangor.

Inspection of all products available at the premises of 4 direct selling companies were conducted together with the assistance of the Selangor state pharmacy enforcement officers.

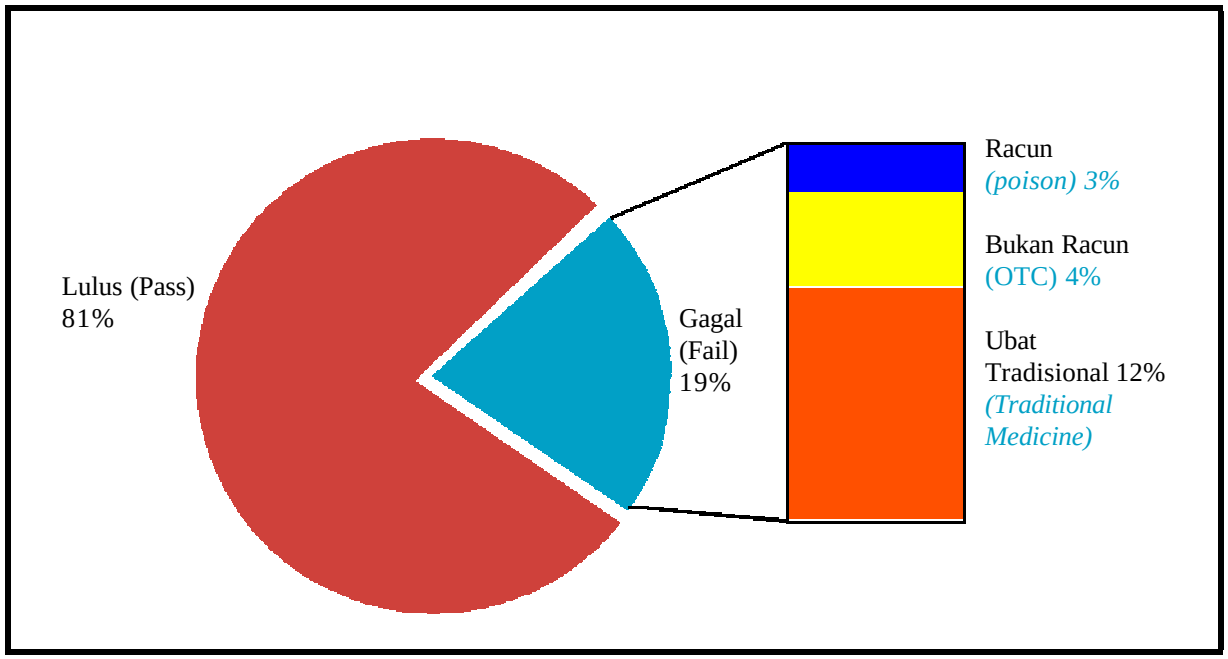
Surveilans

Sejumlah 1635 keluaran berdaftar yang digunakan di Malaysia telah dikaji sepanjang program ini dan 1584 keluaran tersebut telah dihantar ke makmal untuk diuji. Didapati daripada 1083 keluaran yang telah diuji sepanjang tahun ini, 204 sampel keluaran telah gagal memenuhi kriteria yang ditetapkan **(Rajah 16).**

Surveillance

A total of 1635 products registered for use in Malaysia were sampled through this programme of which a total of 1584 products were sent for laboratory testing. 204 samples out of 1083 products tested during the year failed to the meet the accepted standards ***(Figure 16).***

Rajah 16: Keputusan Ujian Sampel Surveilans
Figure 16: Test Results Of Surveillance Samples



Panggilbalik

Arahan telah dikeluarkan untuk membuat panggilbalik terhadap 113 kelompok keluaran dimana 14 daripadanya merupakan keluaran racun berjadual, 7 adalah persediaaan bukan racun dan 92 adalah keluaran tradisional. Manakala 35 keluaran lagi (21-racun, 13-OTC, 1-tradisional) telah dipanggilbalik secara sukarela oleh pemegang pendaftaran keluaran berdasarkan aduan yang diterima terhadap keluaran tersebut.

Recalls

Instructions were issued for the recall of 113 batches of products of which 14 were products containing scheduled poisons, 7 were over-the-counter preparations and 92 were traditional medicines. 35 other products (21-poisons; 13-OTC;1-traditional) were recalled voluntarily by the product registration holders mainly based on product complaints.

Jadual 9: Panggilbalik Keluaran
Table 9: Product Recalls (directive and voluntary)

Tahun (Year)	1995	1996	1997	1998	1999		
Jumlah (Total)	35	37	32	93	148		
Kategori (Category) (A/X/T)					35	20	93

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

Pemonitoran ADR

Dibawah program pemonitoran ADR, didapati peningkatan yang menggalakkan dalam bilangan laporan kesan advers ubat yang diterima sepanjang 1999 berbanding dengan tahun-tahun yang sebelumnya **(Rajah 17).**

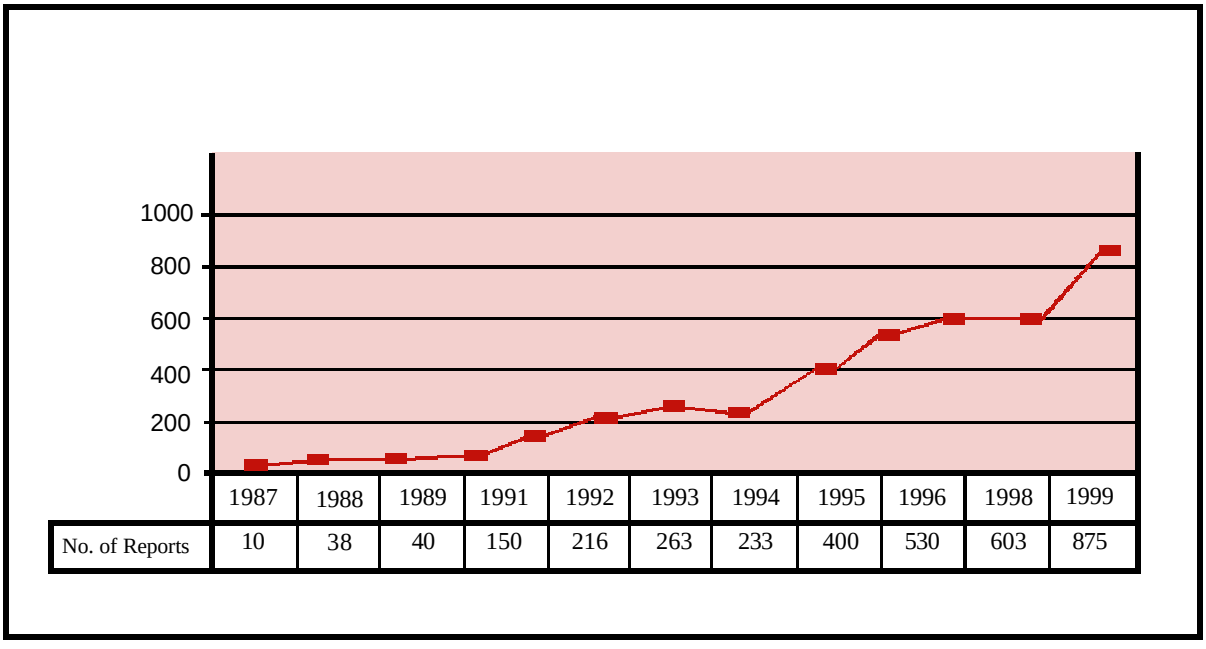
Sejumlah 15 ceramah/taklimat telah diadakan di beberapa tempat di seluruh negara sebagai satu usaha untuk memberi kesedaran mengenai kepentingan program pemonitoran ADR dan laman web MADRAC (www.madrac.gov.my/madrac) yang mana ia telah digunakan untuk menyebarkan maklumat berkaitan dengan isu keselamatan ubat. Laman web ini juga menyediakan satu perkhidmatan yang efektif untuk menerima laporan secara "on-line" dan penjelasan boleh dibuat secara terus kepada pelapor. Terdapat sejumlah 150 laporan telah dihantar menerusi laman web ini.

ADR Monitoring

Under the ADR monitoring programme, there was a marked increase in the number of adverse drug reaction reports received in 1999 as compared to previous years. ***(Figure 17)***

A total of 15 talks were conducted in several parts of the country in an effort to create awareness of the ADR monitoring program me and the MADRAC homepage (www.madrac.gov.my/madrac) which is being used to disseminate information pertaining to drug safety issues. The homepage has served as an effective means for receiving reports as correspondance and clarifications can be made almost immediately with the reporters. A total of 150 ADR reports were submitted through the homepage.

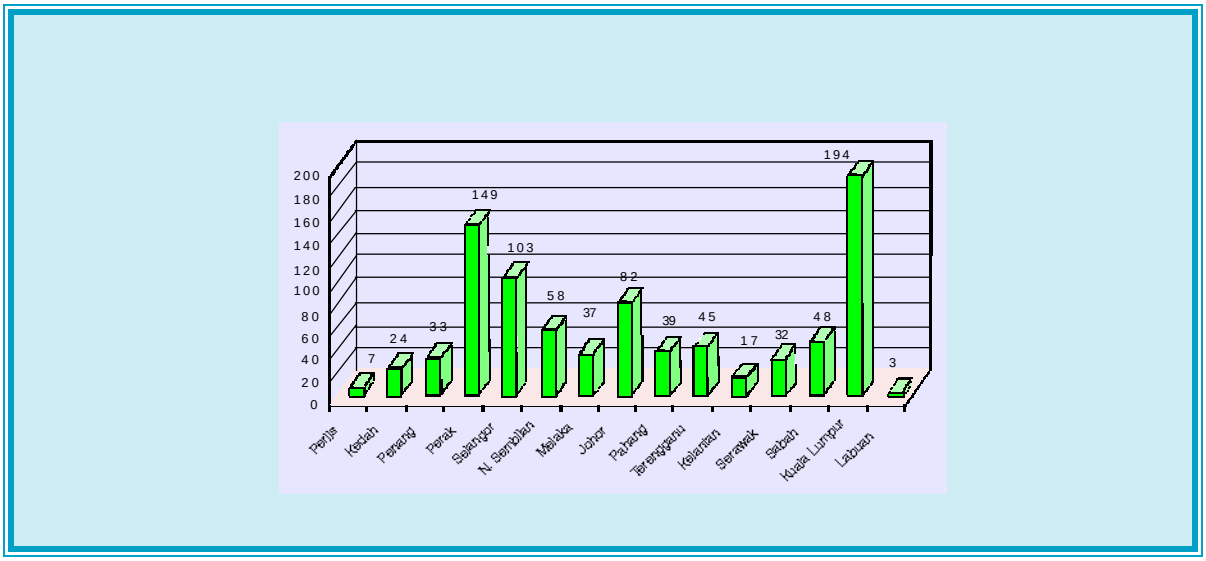
Rajah 17: Pemonitoran ADR: Kadar Laporan 1987-1999
Figure 17: ADR Monitoring: Reporting Rate 1987-1999



Rajah 18 meninjukkan bilangan laporan yang diterima daripada pelbagai negeri dan didapati bahawa sebahagian besar laporan yang diterima adalah daripada Hospital Besar Kuala Lumpur.

*The reporting rate from the various states is as shown in **Figure 18** with the highest number of reports being submitted from the Kuala Lumpur General Hospital.*

Rajah 18: Kadar Laporan Berdasarkan Negeri
Figure 18: Reporting Rate by State 1999



Usaha telah dijalankan untuk menggalakkan penglibatan daripada pelbagai bidang untuk mempertingkatkan kadar laporan ADR dimana sebelum ini kebanyakan laporan adalah daripada doktor dari sektor awam. Hasil daripada tindakan ini, satu peningkatan yang positif dalam bilangan laporan ADR telah diterima daripada ahli farmasi dan sektor swasta menerusi usaha daripada industri farmaseutikal **(Rajah 19).**

*Efforts were made to encourage a multidisciplinary approach to improve the reporting rate of ADRs which previously relied mainly on doctors in the public sector. As a result of this, an increase in ADR reporting by pharmacists and the private sector through the efforts of the pharmaceutical industry was seen **(Figure 19).***

Latihan

Satu lawatan sehari ke Unit Kosmetik, Kementerian Kesihatan Singapura telah di adakan untuk mengkaji sistem surveilans bagi pemonitoran kualiti dan keselamatan keluaran kosmetik.

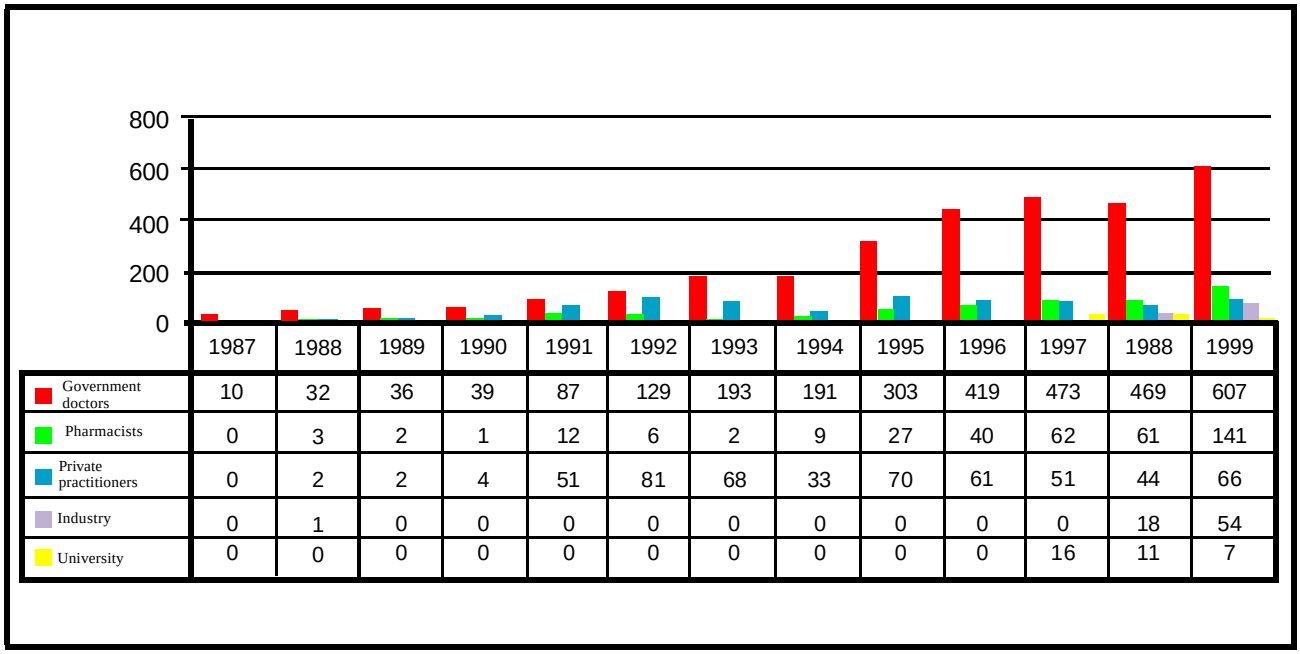
Kursus latihan pemonitoran ADR yang dikelolakan oleh Uppsala Monitoring Centre di Sweden telah diikuti oleh Abida Syed Haq.

Training

A one-day visit to the Cosmetic Unit, Ministry of Health Singapore was conducted to study the surveillance system for monitoring the quality and safety of cosmetic products.

The training course on ADR monitoring organised by the Uppsala Monitoring Centre in Sweden was attended by Abida Syed Haq.

Rajah 19: Sumber Laporan
Figure 19: Source Of Reports



	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1988	1999
Government doctors	10	32	36	39	87	129	193	191	303	419	473	469	607
Pharmacists	0	3	2	1	12	6	2	9	27	40	62	61	141
Private practitioners	0	2	2	4	51	81	68	33	70	61	51	44	66
Industry	0	1	0	0	0	0	0	0	0	0	0	18	54
University	0	0	0	0	0	0	0	0	0	0	16	11	7

RANCANGAN UNTUK MASA DEPAN

Bahagian ini bercadang untuk memperkembangkan lagi peranannnya dalam pengurusan surveilans untuk semua keluaran kosmetik dan veterinar selepas ia didaftarkan bermula pada tahun 2000.

Menjelang tahun 2000 ini juga, satu sistem yang lebih baik telah dirangka dengan kerjasama daripada pihak Pusat Kesihatan Umum untuk melaksanakan surveilans peristiwa advers yang berlaku selepas setiap immunisasi.

Selain daripada itu, satu edisi terbaru mengenai panduan kerja terhadap sistem pemonitoran ADR juga telah dirancang untuk diperkenalkan pada tahun tersebut.

FUTURE PLANS

The surveillance division will expand its role to conduct surveillance of cosmetics and veterinary products after registration of these products begins in the year 2000.

An improved system for surveillance of adverse events following immunisation in collaboration with the Public Health Division is being planned for the year 2000.

A new edition of the manual on ADR monitoring is also being planned to be produced in the year 2000.

BAHAGIAN ANALISIS UBAT

OBJEKTIF

Bahagian Analisis Ubat (BAU) meneruskan peranan yang efektif dalam kawalan kualiti produk yang merupakan satu komponen penting dalam penilaian produk farmaseutikal. Ujian yang dijalankan meliputi ujian-ujian kimia, fizikal, mikrobiologi, farmakologi dan toksikologi, yang merangkumi berbagai-bagai jenis ujian seperti ujian identifikasi, berjenis-jenis ujian had, penentuan kandungan bahan dalam produk dan juga penelitian kepada pelbagai parameter prestasi dosis. Kriteria untuk penerimaan keputusan ujian berasaskan kepada farmakopia, spesifikasi dalaman atau had/spesifikasi pengilang.

PENCAPAIAN

Pencapaian BAU bagi tahun 1999 diringkaskan seperti berikut.

Beban Kerja

Sepanjang tahun 1999, BAU telah menguji sebanyak 4583 sampel **(Rajah 20)** dan menjalankan 27235 ujian **(Rajah 23**). Berbanding dengan pencapaian di tahun 1998, bilangan sampel yang diuji telah menurun sebanyak 6.9% sementara bilangan ujian yang dilakukan telah meningkat sebanyak 14.9%. Kos penganalisaan yang diterima juga telah berkurangan sebanyak 34.3% dengan hanya RM 500,541 dipungut untuk tahun 1999.

DRUG ANALYSIS DIVISION

OBJECTIVE

Drug Analysis Division (DAD) continues to play an effective role in quality control assessment of products which constitute an important component of pharmaceutical product evaluation. The tests conducted include chemical, physical, microbiological, pharmacological and toxicological, covering various types such as identification tests, the various limit tests, quantitation of the content in the product and also assessing the various dosage performance parameters. Acceptance criteria are based on pharmacopoeial, in-house or manufacturers limits and specifications.

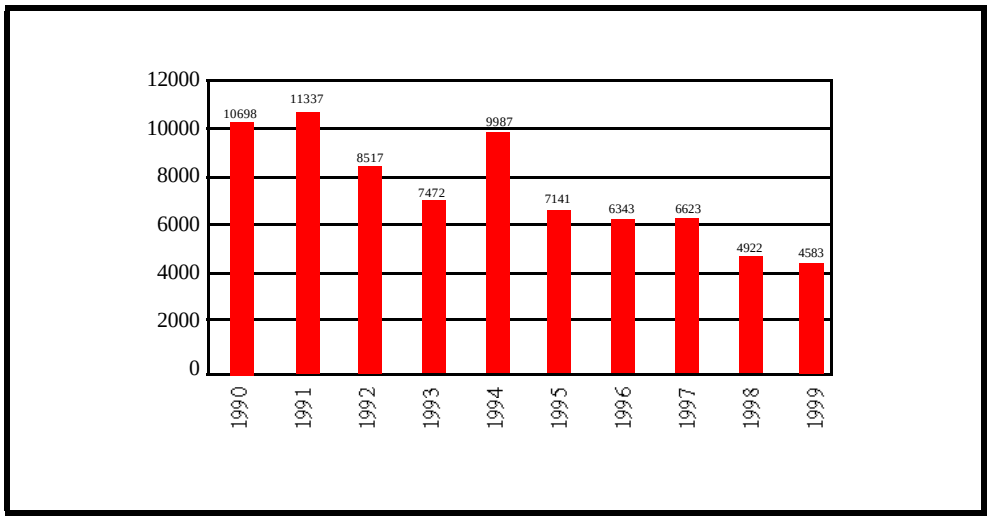
ACHIEVEMENTS

The achievements of DAD in 1999 are summarised as follows:-

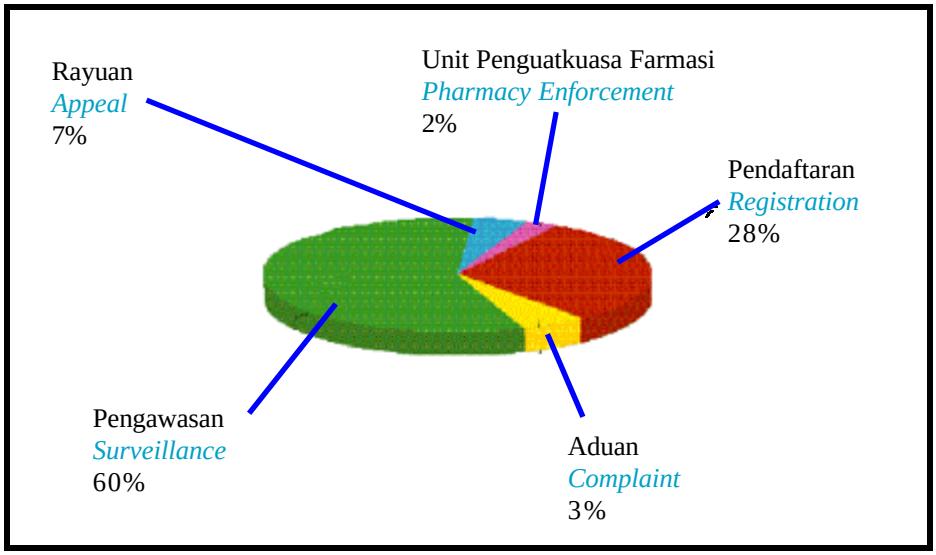
Workload

*Throughout the year 1999, DAD had analysed a total of 4583 samples **(Figure 20)** which generated a total of 27235 tests **(Figure 23).** In comparison to the achievement in 1998, the number of samples analysed were reduced by 6.9% while the number of tests done were increased by 14.9%. The collection of analytical fees had been reduced by 34.3% with only RM 500,541 collected for the year 1999.*

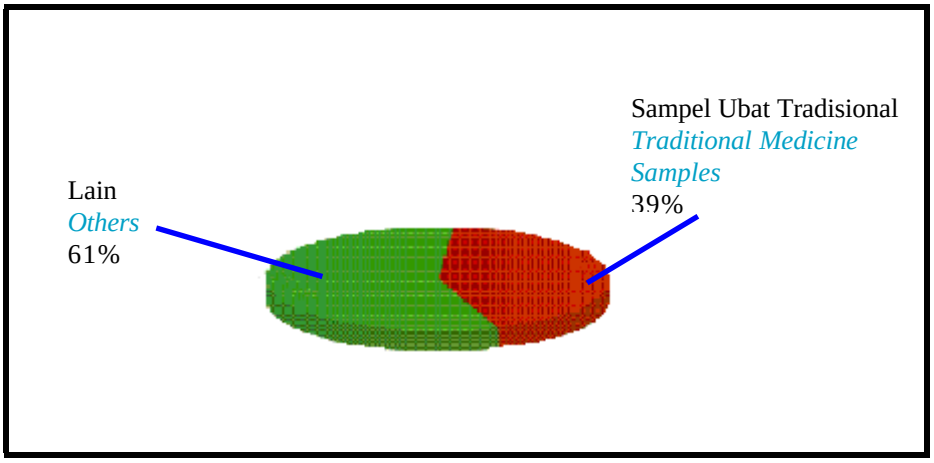
Rajah 20: Bilangan Sampel Diuji
Figure 20: Number Of Samples Tested



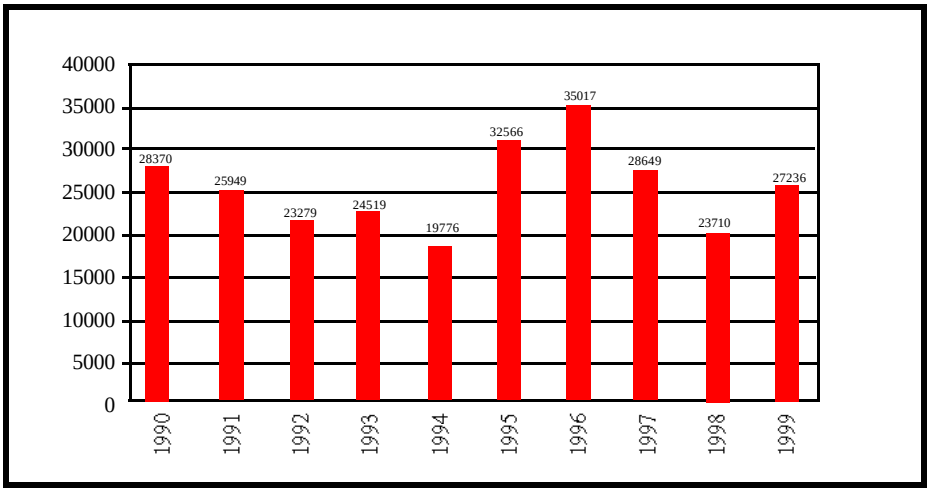
Rajah 21: Jenis Sampel Diterima
Figure 21: Types Of Samples Received



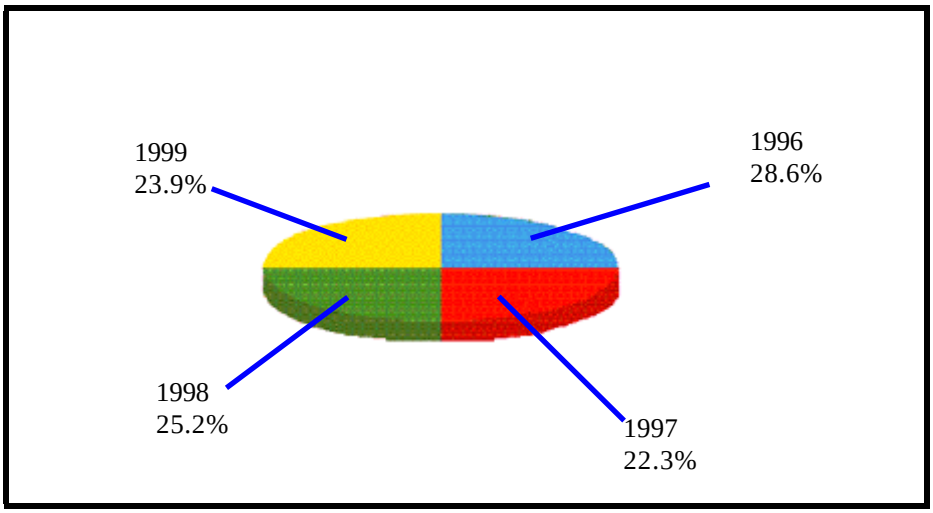
Rajah 22: Perbandingan Sampel Ubat Tradisional Dengan Sampel Lain
Figure 22: Traditional Medicine Versus Other Samples



Rajah 23: Bilangan Ujian Dijalankan
Figure 23: Number of Tests Done



Rajah 24: Protokol Penganalisaan Diterima
Figure 24: Analytical Protocols Received



Penilaian tatacara dan protokol ujian

Sebanyak 984 protokol penganalisaan telah diterima pada tahun 1999. Terdapat penurunan sebanyak 5.3% jika dibandingkan dengan jumlah terimaan pada tahun 1998 **(Rajah 24).**

Pemeriksaan premis untuk pematuhan APB

Empat belas pemeriksaan Amalan Perkilangan Baik (APB) telah dilakukan ke atas premis-premis pengilang farmaseutikal tempatan dan ini adalah lebih tinggi dari bilangan yang dilaporkan pada tahun 1998 (lapan premis).

Piawai Rujukan

Di tahun 1999 sejumlah 198 piawai rujukan (ASEAN/BPFK) telah dibekalkan kepada jabatan kerajaan dan ini merupakan penurunan kepada jumlah yang dilaporkan di tahun 1998 oleh kerana BPFK tidak perlu membuat pembekalan ke badan-badan kerajaan luar negera di tahun 1999. Walaupun begitu terda-pat peningkatan jualan tempatan piawai rujukan di tahun 1999 (329) berbanding dengan jualan yang dibuat dalam tahun 1998 (181).

GLP ASEAN

BAU telah berjaya mengendalikan kursus GLP peringkat ASEAN pada 23-24 November 1999 dengan penglibatan Dr. David Moore sebagai penasihat jangka pendek WHO.

The evaluation of testing methods and analytical protocols

984 analytical protocols were received in 1999 which showed a decrease of 5.3% from the number received in 1998 ***(Figure 24).***

Premise inspection for GMP compliance

Fourteen GLP inspections were done on the local pharmaceutical manufacturing premises and this was higher than the number reported in 1998 (eight premises)

Reference standards

In 1999 a total of 198 reference standards (ASEAN/NPCB) were supplied to government departments. The figure was lower than the 1998 report (884) since in 1999 NPCB was not required to send any standard to other government bodies overseas. However there was an increase in the standards sold locally in 1999 (329) compared to sales made in 1998 (181).

ASEAN GLP

DAD had successfully conducted an ASEAN GLP course from 23th till 24th November 1999 with the participation of Dr. David Moore as a WHO short-term consultant.

Pencapaian Profesional

Tahun 1999 melihat penglibatan profesional ahli BAU yang lebih aktif berbanding penglibatan di tahun 1998. Mr. Lai Lim Swee telah menghadiri Mesyuarat ke 17 ASEAN Working Group on Technical Cooperation in Pharmaceuticals di Bangkok, Thailand pada 24-26 Mac 1999. Dr. Sulaikah V.K. Moideen telah menjadi penasihat jangka pendek WHO dibidang kawalan mutu farmaseutikal (aspek mikrobiologi) di Vietnam dan menghadiri mesyuarat ke 105 Sesssion of the European Pharmacopoeia Commission yang masing-masing diadakan di Strasbourgh Negara Perancis pada 9-29 Mei and 23-25 November 1999.

Puan Yogeswary Markandoo, Dr. Sulaikah, En Jaafar Lassa, En. Tan Ann Ling and Puan Hasenah Ali menyampaikan syarahan di seminar mengenai "Kursus pengenalan jaminan kualiti ubat-ubat traditional" yang diadakan di Palace of Golden Horses Kuala Lumpur pada 15-16 Jun 1999. En Jaafar telah menyumbangkan satu kertas kerja "Kepastian mutu ubat-ubat tradisional" dalam satu seminar di FRIM Kuala Lumpur pada 22-23 Jun 1999.

Pematuhan ISO 9000

BAU memandang serius pematuhan ini dan terlibat dalam penyediaan dokumen yang berkaitan dengan prosedur pemprosesan kerja dan pengurusan makmal.

Lain-lain aktiviti

Satu ujian kualitatif ubat beta antagonis yang boleh ditambah sebagai campur palsu kepada makanan binatang telah berjaya dibangunkan.

Lima alat baru iaitu Karl Fischer Autotitrator, satu sistem ion kromatografi, satu Automated Dissolution Apparatus, satu Gradient HPLC dan satu Sistem Pemonitoran Pirogen telah ditauliahkan pada tahun 1999.

Professional achievements

In 1999 there was a more active professional involvement of DAD's personnel as compared to the involvement seen in 1998. Mr. Lai Lim Swee attended the 17th Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceuticals in Bangkok, Thailand on 24-26th March 1999. Dr. Sulaikah V.K. Moideen had served as a WHO short-term consultant for the microbiological quality control of pharmaceuticals in Vietnam and attended a meeting on the 105th Sesssion of the European Pharmacopoeial Commission held in Strasbourgh France on 9-29th May and 23-25th November 1999 respectively.

Puan Yogeswary Markandoo, Dr. Sulaikah, En Jaafar Lassa, En. Tan Ann Ling and Puan Hasenah Ali gave lectures in a seminar on "Kursus pengenalan jaminan kualiti ubat-ubat traditional" held at the Palace of Golden Horses Kuala Lumpur from 15-16th June 1999. En Jaafar presented a paper on "Kepastian mutu ubat-ubat tradisional" in a seminar at FRIM Kuala Lumpur on 22-23th June 1999.

Compliance to ISO 9000

DAD was seriously involved in preparing the documentation relating to work procedure and laboratory management.

Other activities

A test for detection of beta antagonist drugs which can be found as adulterants of the animal feeds was successfully developed.

Five new instruments namely a Karl Fischer Autotitrator, an ion chromatography system, an automated Dissolution Apparatus, a gradient HPLC and a pyrogen monitoring system were comissioned in 1999.

RANCANGAN UNTUK MASA DEPAN

BAU akan sentiasa bersedia untuk menghadapi cabaran baru bagi melengkapkan dan meningkatkan keupayaan agar dapat terlibat secara aktif dan efektif dalam melaksanakan fasa-fasa pendaftaran yang berikutnya. Sejajar dengan status BPFK sebagai pusat kolaboratif WHO dalam bidang regulatori dan pengawasan mutu, beberapa plan strategik telah dirangkakan untuk BAU yang diperjelaskan seperti berikut:

- Melengkapkan BAU secara total dengan aspek yang berkaitan dengan pematuhan ISO 9000 and Amalan Baik Makmal.
- Bekerjasama dengan Bahagian Farmakovigilans agar BAU dapat menjalankan ujian kawalan mutu yang dapat merangkumi aspek yang melibatkan perbandingan keluaran generik dengan keluaran asal.
- Mengendalikan kursus kawalan mutu untuk pengeluar ubat tradisional tempatan yang berhajat untuk mendapatkan pengetahuan “hands-on” dalam pengujian ubat tradisional.
- Mengendalikan kursus validasi analitikal untuk kakitangan BAU dan pengeluar tempatan.

FUTURE PLANS

DAD shall continue to provide professional services in the field of pharmaceutical analysis. DAD shall be in a position to accept new challenges and be able to play an active and effective role in the implementation of the future phases of registration exercise. In tandem with the status of NPCB as a WHO collaborating centre in regulatory control, several strategic plan of action are scheduled and they are as follows:

- *To complete the implementation of ISO 9000 and GLP to DAD.*
- *Involved in collaborative work with the Pharmacovigilance section to enable comparisons of generic preparations with their market leaders be made, in quality control testing aspects.*
- *To conduct quality control training course(s) for the local traditional manufacturer seeking hands-on experience in the testing of traditional products.*
- *To provide a training course on analytical validation to the evaluators of DAD and to the manufacturers.*

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

Untuk mencapai objektif-objektif tersebut, beberapa aktiviti telah dijalankan oleh bahagian ini seperti berikut :-

- perkhidmatan maklumat ubat dan maklumat am tentang pendaftaran ubat-ubatan
- perkhidmatan perpustakaan
- pengkelasan keluaran
- penerbitan

Perkhidmatan Maklumat Ubat dan Maklumat Am

Bahagian POTM telah menjawab 1027 pertanyaan sepanjang tahun 1999 dari sektor awam dan swasta **(Rajah 25)**. Kebanyakan daripada pertanyaan tersebut adalah berkenaan status pendaftaran keluaran-keluaran farmaseutikal, prosedur pendaftaran ubat-ubatan, indikasi keluaran, keberkesanan dan kesan advers ubat/keluaran **(Rajah 26)**.

Perkhidmatan Perpustakaan

Perpustakaan ini mempunyai hampir 950 buah buku, termasuk farmakopia-farmakopia utama dari pelbagai negara luar. Selain itu, perpustakaan ini juga melanggan 45 jenis jurnal/buletin ubat, Micromedex dan International Pharmaceutical Abstract. Perpustakaan ini dibuka kepada kakitangan BPFK sahaja. Ahli-ahli farmasi di bawah Kementerian Kesihatan boleh memohon untuk menggunakan kemudahan-kemudahan di perpustakaan ini.

ORGANIZATIONAL DEVELOPMENT AND INFORMATION TECHNOLOGY DIVISION (OD & IT)

OBJECTIVE

To provide an effective drug information service to officers who are involved in 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 organizations within the public and private sectors.

ACHIEVEMENTS

In order to achieve the above objectives, several activities undertaken by this division are as follows :-

- *drug information service and information on drug registration*
- *library service*
- *product classification*
- *publications*

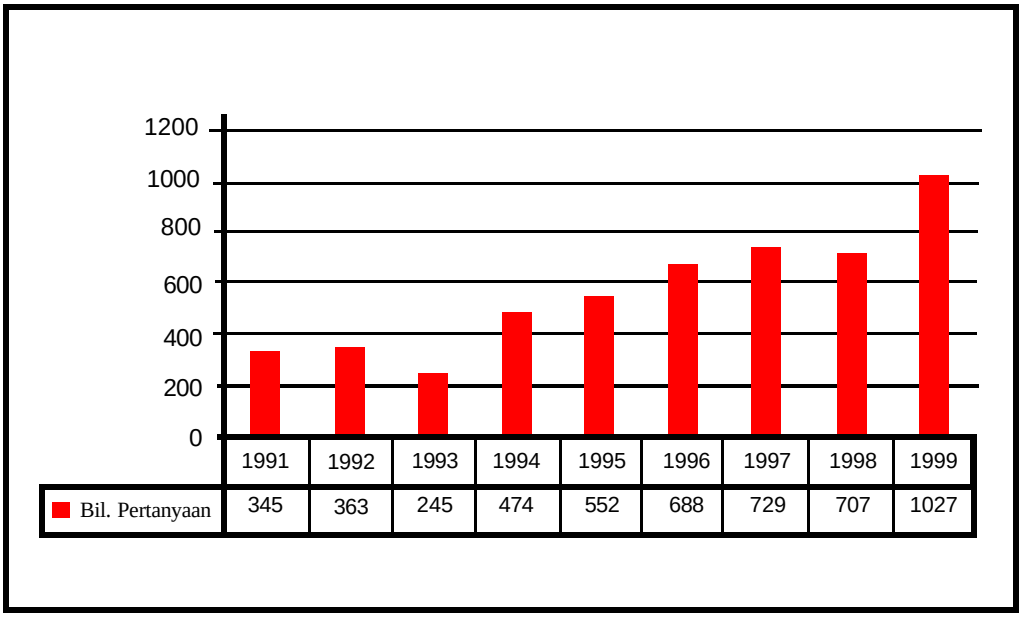
Drug Information Service and Information on Drug Registration

*The OD & IT division responded to 1027 inquiries in 1999 from both the public and private sectors **(Figure 25)**. The majority of the inquiries were on dosage, indications, efficacy, adverse drug reactions, registration status of pharmaceutical products and drug registration procedures **(Figure 26)**.*

Library Service

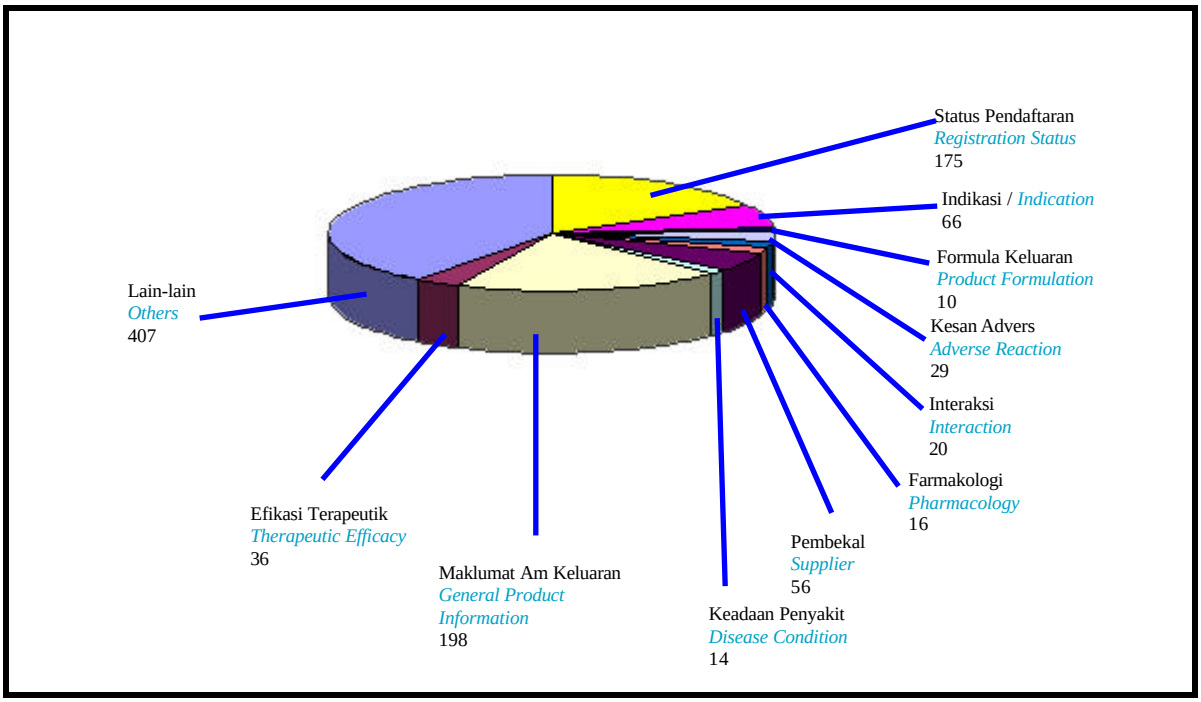
The library has about 950 books, including the major pharmacopoeias from various countries. Besides that, it subscribes to 45 journals/drug bulletins, Micromedex and International Pharmaceutical Abstracts. The library is open to the staff of the institution only. Pharmacists in the Ministry of Health may, by request, make use of the library facilities.

Rajah 25: Bilangan Pertanyaan Diterima Dari 1991 - 1999
Figure 25: Number Of Enquiries Received From 1991 - 1999



	1991	1992	1993	1994	1995	1996	1997	1998	1999
Bil. Pertanyaan	345	363	245	474	552	688	729	707	1027

Rajah 26: Jenis Pertanyaan Yang Diterima Pada Tahun 1999
Figure 26: Types Of Enquiries Received In 1999



Pengelasan Keluaran

Bahagian ini bertanggungjawab ke atas semua pertanyaan berkenaan dengan klasifikasi keluaran-keluaran "borderline", sama ada keluaran-keluaran itu perlu didaftar atau tidak. Antara 955 keluaran yang diterima untuk pengkelasan dalam tahun 1999, 600 keluaran merupakan butiran-butiran yang tidak perlu didaftar, seperti peralatan-peralatan perubatan, keluaran-keluaran penjagaan kulit, supplemen makanan (dalam bentuk jus/minuman), keluaran-keluaran "food-based" dan herba-herba mentah.

Baki 355 keluaran telah dikelaskan sebagai perlu didaftarkan.

Penerbitan

Penerbitan-penerbitan yang berikut telah dihasilkan dan diedarkan organisasi-organisasi dalam sektor awam dan swasta sepanjang tahun 1999.

(i) Berita Ubat-Ubatan (3 keluaran)

(ii) Pekeliling Maklumat Ubat (12 keluaran)

(iii) Monograf Ubat (17 keluaran)

(iv) Q Bulletin (1 keluaran)

(v) Laporan Tahunan (1 keluaran)

Product Classification

This division handles all queries pertaining to classification of "borderline products", as to whether they are registrable or not. Out of the 955 products received for classification in 1999, 600 products were non-registrable items such as medical devices, skin care products, food supplements in the form of juices/drinks, food-based products and raw herbs.

The remaining 355 products were classified as registrable.

Publications

The following publications were produced and distributed to organisations in the public and private sector in 1999.

(i) Drug Control Authority Newsletter (3 issues)

(ii) Drug Information Circular (12 issues)

(iii) Drug Monograph (17 issues)

(iv) Q Bulletin (1 issue)

(v) Annual Report (1 issue)

PELAWAT-PELAWAT ANTARABANGSA
INTERNATIONAL VISITORS

Tarikh *Date*	**Pelawat** *Visitors*	**Objektif** *Objective*
11.1.1999 until 3.3.1999	Two WHO Fellows from **Bangladesh:** *** Mr. Haque Mozammel** *** Mr. Das Ranjit Kumar**	Attachment Training on Quality Control of Essential Drugs
25.1.1999	WHO Fellow from Ministry Of Health & Welfare of **Japan:** *** Mr. Akira Hamada**	Temporary Advisor-South East Asian Regions & Western Pacific
8.2.1999 until 1.3.1999	WHO Fellow from Bangladesh: *** Mr. Md. Ruhul Amin**	Training on Quality Management in Pharmaceutical
23.3.1999 until 22.4.1999	WHO Fellow from MCA: * Dr. David Moore	As a Consultant Good Laboratory Practice (GLP)
3.5.1999 until 29.5.1999	Three WHO Fellows: *** Mr. Sun Lei (from China)** *** Ms. Prey Yean (from Ministry of Health of Cambodia)** *** Ms. Vongsavanh Insixiengmay (from Ministry of Health of Laos)**	Training on Drug Quality Control
10.5.1999 until 25.5.1999	WHO Fellow from Ministry of Health and Social Welfare of **Mongolia:** *** Ms. Zulzaga Zuzaan**	Training on Drug Registration
24.5.1999 until 27.5.1999	Three WHO Fellows from **Vietnam:** *** Mrs. Le Thi Nga** *** Ms. Chu Thi Tuyet** *** Mr. Luu Minh Triet**	Training on National Drug Policy Programme
1.6.1999 until 30.6.1999	Three WHO Fellows from **Mongolia:** *** Mrs. Gunjar Dolgormaa** *** Mr. Terbish Bayaraa** *** Dr/Mrs. Gendenjamts**	Training on Local Production & Methodology
7.6.1999 until 23.7.1999	Three WHO Fellows from **Vietnam:** *** Mr. Nguyen Duc Bon** *** Mr. Tran Cuc** *** Dr/Miss Hoang Thanh Mai**	Training on Methods to Organize and Run Drug Information Centres

Tarikh *Date*	**Pelawat** *Visitors*	**Objektif** *Objective*
19.7.1999 until 30.7.1999	Two Officers from Pharmacy Board, **Tanzania:** *** Mr. Henry Irunde** *** Mr. N. A Msuye**	In House Training on Adverse Drug Reactions Monitoring & Drug Information Services
2.8.1999 until 27.8.1999	WHO Fellows from **Vietnam:** *** Ms. Hoang Thai Phuong Cac** *** Ms. Budjav Tavanjin (from Mongolia)**	Study Tour on Drug Quality Control by Non-Pharmacopoeial Methods
5.10.1999 until 8.10.1999	Dra Rahmaniar Brahim from **Indonesia:** **(SEAMIC Travel Research Fellowship)**	Comparative Study on the Drug Information System
8.10.1999 until 12.10.1999	Miss Charunee Krisanaphan from **Thailand:** **(SEAMIC Travel Research Fellowship)**	Study Tour on Drug Control System

PUSPANITA BPFK

Puspanita BPFK 1999 yang diterajui oleh 19 orang ahli jawatankuasa telah berjaya menjalani beberapa aktiviti-aktiviti yang telah dapat dimanfaatkan oleh ahli-ahlinya yang berjumlah seramai 96 orang.

Aktiviti-aktiviti yang dijalankan keseluruhannya merangkumi aspek sukan, sosial, kebajikan dan pendidikan. "Hari Kesihatan dan Anda" yang telah diadakan pada bulan Jun 1999 telah berjaya memberi kesedaran dan keprihatinan ahli-ahli tentang permakanan seimbang dan gaya hidup yang sihat. Sukan "out-door" dan "in-door" seperti badminton, ping-pong, carrom, darts dan lain-lain sememangnya menjadi kegemaran ahli-ahli sepanjang tahun. Beberapa ceramah yang berbentuk pendidikan dan kebajikan juga telah didedahkan kepada ahli-ahli semua. Untuk menambahkan pengetahuan yang berkaitan dengan masak-memasak beberapa sessi demonstrasi masakan juga telah dijalankan.

Sepanjang tahun 1999, selain dari hasil yuran tahunan, pendapatan Puspanita BPFK adalah hasil dari diantaranya jualan tapak pasaria, keuntungan jualan kueh hari raya/makanan beku dan komisyen tempahan kasut.

Pada tahun 1999 juga, Puspanita telah diperuntukkan satu bilik oleh pihak pengurusan untuk penyimpanan harta-harta tetap Puspanita dan perkakas permainan "in-door" seperti carrom dan darts.

Puspanita BPFK masih dapat mempertahankan kesinambungan kegiatan dan aktiviti-aktivitinya disebabkan hasil dari kerjasama dan komitmen di kalangan ahli jawatankuasa dan sokongan padu yang berterusan dari ahli-ahli semua. Diharap pada tahun yang berikutnya, semua ahli akan terus bergiat demi memperjuangkan Puspanita BPFK khasnya.

" WANITA SEPAKAT NEGARA MENINGKAT "

PUSPANITA NPCB

In 1999 Puspanita BPFK consisted of 19 committee members and 96 ordinary members.

Several activities covering sports, social welfare and education were held. "Health and You" Day organized in June 1999 created the awareness of members towards the importance of a balanced diet and a healthy lifestyle. Educational and welfare talks were also held. Cooking demonstrations were conducted for those interested in enhancing their culinary skills

Throughout the year, out-door and in-door sports such as badminton, table tennis, carrom and darts were the favourite activities.

The revenue collection for Puspanita BPFK was derived from the yearly membership fee and earnings from 'pasaria' sites, sale of cakes/frozen food and commission from the sale of shoes.

In 1999, Puspanita was allocated a room by the management to store Puspanita's fixed assets and sports equipment.

Up to the end of the year, Puspanita BPFK was able to continue its activities for the benefit of its members due to the cooperation and strong commitment from its committee members and continued support from all its members.

Kursus / Seminar
Courses / Seminars

Kursus / Latihan Yang Dihadiri
Courses / Training for Staff

Nama Pegawai *Name*	Kursus *Course / Training*	Tarikh *Date*	Tempat *Place*	Anjuran *Sponsors*
Che Mohd Zin Che Awang	1. 2nd IFMA Asian Regulatory Conference	2-3 Mac 1999	Singapura	IFPMA & SAPI
	2. APEC workshop on the Food/	29 Nov-3 Dis 1999	Bangkok, Thailand	APEC
	3. 9th International Conference of Drug Regulatory Authorities	26 - 29 April 1999	Berlin, German	ICRDA
	4. Lawatan sambil belajar ke 'Cosmetic Control Unit' Singapura.	30 Jun-1 Julai 1999	Singapura	KKM
	5. First Meeting of ACCSQ-Product Working Group on Pharmaseutical	6-7 September 1999	Kuala Lumpur	KKM & Jabatan Standard Malaysia
	6. Second Meeting of ACCSQ-Product Working Group on Cosmetics	8-9 September 1999	Kuala Lumpur	KKM & Jabatan Standard Malaysia
	7. Seminar Regulatori 1999	19-20 Oktober 1999	Petaling Jaya	BPFK/MOPI/PhAMA/ FMM-MCTIG/CTFA
Hasnah Ismail	1. 2nd IFPMA Asian Regulatory Conference	2-3 Mac 1999	IFPMA & SAPI	Singapura
	2. Pharmaceutical GMP Training Analytical Validation	19-20 Mei 1999	BPFK, KKM & MOPI	BPFK
	3. Pharmaceutical GMP Training - Process Validation	24-25 Mei 1999	BPFK, KKM & MOPI	BPFK
	4. Lawatan sambil belajar ke 'Cosmetic Control Unit' Singapore	30 Jun-1 Julai 99	KKM	Singapura
	5. Persidangan Penguatkusaan Akta Ubat (Iklan dan Penjualan) 1956	27 Julai 1999	Bahagian Perkhidmatan Farmasi KKM	Langkawi, Kedah
	6. First Meeting of ACCSQ-Product Working Group on Cosmetics	6-7 September 99	KKM & Jabatan Standard M'sia	Kuala Lumpur
	7. Second Meeting of ACCSQ-Product Group on Cosmetics	6-7 Sept 1999	Kuala Lumpur	KKM & Jabatan Standarad Malaysia
	8. Mesyuarat Penyediaan Polisi Perubatan Tradisional/ Komplimentari Kebangsaan	15-17 Sept 1999	Port Dickson, N. Sembilan	KKM
	9. Seminar Regulatori 1999	19-20 Oktober 1999	Petaling Jaya	BPFK/MOPI/PhMA
	10. Commonwealth Working Group on Traditional Complementary Medicine	4 November 1999	Kuala Lumpur	KKM
	11. Kursus Komputer Microsoft Access 97 (beginner, Intermediate & Advance)	6-9 Disember 1999	Petaling Jaya	BPFK

Nama Pegawai *Name of Officer*	*Kursus* *Course*	*Tarikh* *Date*	Anjuran *Sponsor*	Tempat *Place*
Fudziah Ariffin	1. Bengkel "Improving The Availablity Of Pain Releif Drugs"	31 Mac - 2 April 1999	KKM	Awana, Genting Highlands
	2. Bengkel ISO 9000	10 - 14 Mei 1999	BPFK	A Farmosa Resort, Melaka
	3. Process Validation Workshop	19 - 20 Mei 1999	BPFK	BPFK, Petaling Jaya
	4. Analytical Method Validation	24 - 25 Mei 1999	BPFK	BPFK, Petaling Jaya
	5. Bengkel Odit Dalaman Untuk Perkhidmatan Farmasi	6 - 8 Julai 1999	Bahagian Farmasi Kem. Kesihatan Malaysia	Permai Park Inn, Kuala Terengganu
	6. Bengkel " Clinical Trials Methodology, Critical Appraisal and Meta-analysis"	18 - 19 Ogos 1999	Eli Lilly (M) Sdn Bhd	Sunway Resort, Sungai Way
	7. First Meeting of ACCSQ Product Working Group on Pharmaceutical	6 - 7 September 1999	KKM	Hotel Concorde, Kuala Lumpur
	8. Mesyuarat Penyediaan Polisi Perubatan Tradisional/Komplimentari Kebangsaan	15 - 17 September 1999	KKM	Avillion Village Resort, Port Dickson
	9. Seminar Pendidikan Berterusan -Drug Related Clinical Trials	27 - 28 September 1999	Universiti Sains Malaysia	USM, Pulau Pinang
	10. Pharmaceutical & Cosmetic Regulatory Seminar	19 - 20 October 1999	BPFK	Subang Sheraton,Subang
	11. The 11 th Meeting of the parties to the Montreal Protocol	29 Nov - 3 Disember 1999	Jabatan Alam Sekitar, Kem. Sains, Teknologi dan Alam Sekitar	Beijing, China
Arpah Abas	1. Bengkel MS ISO 9000	10 - 14 Mei 1999	BPFK	A Farmosa Resort, Melaka
	2. Process Validation Workshop	17 - 18 Mei 1999	BPFK	BPFK, Petaling Jaya
	3. Pharmaceutical & Cosmetic Regulatory Seminar	19 - 20 October 1999	BPFK	Subang Sheraton, Subang
	4. First Meeting of ACCSQ Product Working Group on Pharmaceutical	6 - 7 September	Kem. Kesihatan Malaysia	Hotel Concorde, Kuala Lumpur
	5. Microsoft Access 97	6 - 8 Disember 1999	BPFK	Bandar Sunway, Petaling Jaya
	6. WHO Training on Assessment of Application for Marketing Authorised (Generics)	29 Nov - 3 Disember 1999	WHO/BFAD Philippines	Manila, Philippines
Mazuwin Zainal Abidin	1. Bengkel Pelaksanaan MS ISO 9000	10 - 14 April 1999	BPFK	A Farmosa Resort, Melaka
	2. Process Validation Workshop	17 - 18 Mei, 1999	BPFK	BPFK, Petaling Jaya
	3. Pharmaceutical & Cosmetic Regulatory Seminar	19 - 20 October 1999	BPFK	Subang Sheraton, Subang
	4. Good Laboratory Practice Seminar	23 - 24 November 1999	BPFK	BBPFK

Nama Pegawai *Name of Officer*	*Kursus* *Courses*	*Tarikh* *Date*	Anjuran *Coordinator*	Tempat *Place*
Zainab Md. Yusuf	1. Bengkel Perlaksanaan MS ISO 9000 BPFK	10-14 Mei 1999	BPFK	Alor Gajah
	2. Latihan Komputer Kursus Excel 97 -Beginning	15 November 1999	BPFK	Bandar Sunway, PJ
	3. Persidangan QAP farmasi	16-19 Nov 1999	Bhg. Perkhidmatan Farmasi	Melaka
Mohd Tarmizi	1. Latihan Komputer Kursus Excel 97 - Beginning	15 November 1999	BPFK	Bandar Sunway, PJ
Napsah Mahmud	1. Bengkel Perlaksanaan MS ISO 9000	10-14.5.1999	INTAN	A'Famosa Resort Hotel, Melaka
	2. Pharmaceutical GMP Training Process Validation Workshop	26-27.5.1999	BPFK	BPFK
	3. First Meeting of ACCSQ Product Working on Pharmaceuticals	6-7.9.1999	KKM	Hotel Concorde, Kuala Lumpur
	4. Mesyuarat Penyediaan Polisi Perubatan Tradisional/Komplementari Kebangsaan	15.9.1999	KKM	Avillion Village Resort, Port Dickson
	5. Dialog Penasihat Antara Bangsa (International Advisory Panel) untuk Pembangunan Herba Industri Malaysia	1-2.11.1999	MARDI/KKM	Hotel Diamond Puteri, Kota Bharu
	6. Commonwealth Working Group on Traditional/Complementary Medicine	4.11.1999	KKM	Mandarin Oriental, Kuala Lumpur
Rosilawati Ahmad	1. Bengkel Perlaksanaan MS ISO 9000	10-14.5.1999	INTAN	A'Famosa Resort, Melaka
	2. Seminar Regulatori Farmaseutikal dan Kosmetik 1999	19-20.10.1999	BPFK, PhAMA, MOPI, CTFA, FMM-MGTIC	Hotel Subang Sheraton, Petaling Jaya Selangor
	3. Commonwealth Working Group on Traditional/Complementary Medicine	4.11.1999	KKM	Mandarin Oriental, Kuala Lumpur
	4. Seminar Good Laboratory Practice	23-24.11.1999	BAU (BPFK)& WHO	BPFK
	5. Kursus Komputer-Microsoft Access 97, Beginner, Intermediate, Advanced	6-9.12.1999	BPFK	New Horizons Computer Learning Centre
Ainul Salhani	1. Kursus Komputer-Microsoft Access 97 Beginner, Intermediate, Advanced	2-5.11.1999	BPFK	New Horizons Computer Learning Centre
	2. Kursus Komputer- Microsoft Excel 9, Beginner	15.11.1999	BPFK	New Horizons Computer Learning Centre
Asnida Mat Daud	1. Kursus Pengenalan Perkhidmatan Farmasi	10-11.1999	Bahagian Perkhidmatan	De Palma Inn, Shah Alam, Selamgor

Nama Pegawai *Name of Officer*	*Kursus* *Courses*	*Tarikh* *Date*	Anjuran *Coordinator*	Tempat *Place*
Zambin Rokiah Abdul Rashid	1. Computer (Microsoft Access)	1-4.11.99	BPFK	Horizon Computer Learning Centre
Zawiyah Abdul Wahab	1. Computer (Microsoft Access)	6-8.12.99	BPFK	Horizon Computer Learning Centre
Tan Lie Sie	1. National Seminar on Regulation and Registration of Cosmetics & Toiletries	1 April 1999	FMM-MCTIG	Shah Alam
	2. Bengkel Perlaksanaan MS ISO 9000 BPFK	10-14 Mei 1999	BPFK	Alor Gajah
	3. Pharmaceutical GMP Training Analytical Validation	19-20 Mei 1999	NPCB/MOH/MOPI	Petaling Jaya
	4. Pharmaceutical GMP Training Analytical Validation	24-25 Mei 1999	NPCB/MOH/MOPI	Petaling Jaya
	5. APEC Workshop on the Food/Drug	9-13 Ogos 1999	BPFK	Canberra,Australia
	6. ACCSQ Product Working Group on Pharmaceuticals	6-7 Sept 1999	Jabatan Standard	Kuala Lumpur
	7. Seminar Regulatori Farmaseutikal & Kosmetik 1999	19-20 Okt 1999	BPFK	Subang Jaya, PJ
	8. Latihan Komputer Kursus Excel 97 - Beginning	15 November 1999	BPFK	Bandar Sunway, PJ
	9. Latihan Komputer Kursus Excel 97 - Advanced	18 November 1999	BPFK	Bandar Sunway, PJ
	10. APEC Workshop on the Food/Drug Interface	27-3 Disember 1999	AusAID	Bangkok, Thailand
	11. Latihan Komputer Kursus Access 97- Beginning, Intermediate & Advanced	6-9 Disember 1999	BPFK	Bandar Sunway,PJ
Mazli Muhamad	1. Bengkel Perlaksanaan MS ISO 9000 BPFK	10-14 Mei 1999	BPFK	Alor Gajah
	2. Pharmaceutical GMP Training Analytical Validation	19-20 Mei 1999	NPCB/MOH/MOPI	Petaling Jaya
	3. Pharmaceutical GMP Training Validation	24-25 Mei 1999	NPCB/MOH/MOPI	Petaling Jaya
	4. Seminar Regulatori Farmaseutikal & Kosmetik 1999	19-20 Okt 1999	BPFK	Subang Jaya, PJ
	5. GLP Seminar	23-24 Nov 1999	BPFK	Petaling Jayas

Nama Pegawai *Name of Officer*	*Kursus* *Courses*	*Tarikh* *Date*	Anjuran *Coordinator*	Tempat *Place*
Shukri Mohd Arif	1. Computer (Microsoft Access - Beginner, Intermediate & Advance)	6-9.12.99	BPFK	Horizon Computer Learning
Soleha Che Ros	1. Latihan Amali Dispensing	Jan-Jun 1999	KKM	HKL
Talip Tawil	1. Bengkel Perlaksanaan ISO 2. Computer (Microsoft Access) 3. Seminar on GLP	10-14.5.99 Nov 1999 23-24.11.99	Intan/BPFK BPFK WHO	A Famosa Resort, Melaka Horizon Computer Learning Centre BPFK
Tan Ann Ling	1. Microbiology: from manual to automation 2. Analytical spectroscopy 3. Bengkel Perlaksanaan ISO 4. Analytical Validation 5. Process Validation 6. Seminar Regulatori Farmaseutikal & Kosmetik 7. Seminar GLP 8. Computer (Micorosoft Word, Excel & Advance)	29.4.99 4.5.99 10-14.5.99 17-18.5.99 19-20.5.99 19-20.10.99 23-24.11.99 Nov & Dis 1999	Fischer Scientific Bruker AXS Intan/BPFK BPFK/MOPI BPFK/MOPI BPFK/MOPI/CTFA/ Pharma/MCTIG WHO BPFK	PJ Hilton Holiday Villa, PJ A Famosa Resort, Melaka BPFK BPFK Sheraton Hotel, PJ BPFK Horizon Computer Learning Centre
Yogeswary Markandoo	1. Bengkel Perlaksanaan ISO 2. Analytical Spectroscopy 3. Analytical Validation 4. Process Validation 5. International Pharmacy Symposium 6. Seminar Regulatori Farmaseutikal & Kosmetik 7. Computer (Microsoft Words, Excel 7 Access) 8. Seminar on GLP	10-14.5.99 4.5.99 17-18.5.99 26-27.5.99 21-22.5.99 19-20.10.99 Nov & Dis 1999 23-24.11.9	Intan/BPFK Bruker AXS BPFK/MOPI BPFK/MOPI Persendirian BPFK/MOPI/CTFA/ Pharma/MCTIG BPFK WHO	A Famosa Resort, Melaka Holiday Villa, PJ BPFK BPFK Kota Kinabalu Sheraton Hotel, PJ Horizon Computer Learning Centre BPFK
Zaini Jamaluddin	1. Latihan Amali Dispensing 2. Pengurusan keselamatan dan kebakaran bangunan 3. Seminar on Sympatec's Particle Measurement 4. Computer (Microsoft Words)	Jan - Jun 1999 25.8.99 10.12.99 10.11.99	KKM Prime Consistence Sdn Bhd Interscience Sdn Bhd BPFK	HKL BPFK PJ Hilton Horizon Computer Learning Centre

Nama Pegawai *Name of Officer*	*Kursus* *Courses*	*Tarikh* *Date*	Anjuran *Coordinator*	Tempat *Place*
Noraida Mohd. Zainoor	11. Persidangan QAP Farmasi 12. Seminar on GLP 13. Meeting of ASSQC on cosmetics	16-19.12.99 23-14.11.99 8-9.9.99	Bahagian Farmasi WHO Jabatan Standard Malaysia	Makhota Century Hotel, Melaka BPFK Concord Hotel, KL
Mohd Nasir Hashim	1. Waters Vision 2000 2. Bengkel Perlaksanaan ISO 3. Analytical Validation 4. Process validation 5. Computer (Microsoft Words, Excel & Access)	6.5.99 10-14.5.99 17-18.5.99 24-25.5.99 Nov 1999	Research Instrument Intan/BPFK BPFK/MOPI BPFK/MOPI BPFK	Hyatt Saujana Hotel , PJ A Famosa Resort, Melaka BPFK BPFK Horizon Computer Learning Centre
Norzehan Yusoff	1. Latihan Amali Dispensing	Jan-Jun 1999	KKM	HKL
Nirmala Devi	1. Seminar on laser scattering particle size distribution 2. Computer (Microsoft Word)	31.3.99 11.11.99	Mecomb Malaysia BPFK	Petaling Jaya Horizon Computer Learning Centre
Oh Lay Eng	Computer (Microsoft Access)	6-9.12. 99	BPFK	Horizon Computer Learning Centre
Ong Chui Eng	Computer (Microsoft Excel)	18.11.99	BPFK	Horizon Computer Learning Centre
Pang Moy Yong	Ion Chromatography	19 & 22.3.99	Research Instrument	
Ropidah Yaacob	1. Seminar on lase scattering particle size distribution 2. Computer (Microsoft Words)	31.3.99 10.11.99	Mecomb Malaysia BPFK	Petaling Jaya Horizon Computer Learning Centre
Rosni Sharif	Computer (Microsoft Words)	10.11.99	BPFK	Horizon Computer Learning
Rusnah Rejab	Latihan Amali Dispensing	Julai-Dis 1999	KKM	HKL
Selvaraja Seerangam	1. Regulation of vaccines 2. Process validation 3. Analytical validation 4. Quality assurance of live attenuated polio and measles vaccine 5. Seminar on GLP 6. Computer (Microsoft - Word, Excel & Access)	5-12.5.99 17-18.5.99 26-27.5.99 26.9.99-27.10.9 23-24.11.9 3,5,12,16.11.99, 18.11.99	WHO BPFK/MOPI BPFK/MOPI WHO WHO BPFK	Canberra, Australia BPFK BPFK Bandung, Indonesia BPFK Horizon Computer Learning

Nama Pegawai *Name of Officer*	*Kursus* *Courses*	*Tarikh* *Date*	Anjuran *Coordinator*	Tempat *Place*
Kamsah Marjan	Computer (Microsoft Access)	6-7.12.99	BPFK	Horizon Computer Learning Centre
Latifah Mhd Tap	Computer (Microsoft Word)	10.11.99	BPFK	Horizon Computer Learning Centre
Lee Lian Chee	Water Visions 2000	6.5.99	Research Instrument	Hyatt Saujana, PJ
Lim Kah Hun	Ion Chromatography	19 & 22.3.99	Research Instrument	BPFK
Low Mooi Ling	Computer (Microsoft - Excel & Access)	Nov 1999	BPFK	Horizon Computer Learning Centre
Jaafar Lassa	1. Bengkel Perlaksanaan ISO 2. Analytical Validation 3. Process Validation 4. Bengkel Audit Dalaman (Perkhidmatan Farmasi)	10-15.5.99 19-20.5.99 26-27.5.99 6-8.7.99	Intan/BPFK BPFK/MOPI BPFK/MOPI Bahagian Farmasi	A Farmosa, Melaka BPFK BPFK Kuala Trengganu
Mior Zamri Mior Ahmad	1. Ion Chromatography	19 & 22.3.99	Research Instrument	BPFK
Mohd Harian Ahmad	1. Computer (Microsoft Word & Excel)	10 & 18.11.99	BPFK	Horizon Computer Learning Centre
Mohd Noor Nurudin	1. Latihan Amali Dispensing	Jun - Dis 1999	BPFK	HKL
Noraida Mohd Zainoor	1. Chemical assay on the production of regional reference substance 2. Ion chromatography 3. Bengkel Perlaksanaan ISO 4. Karl Fischer (GLP Approach) 5. Analytical Validation 6. Process Validation 7. Seminar regulatori farmaseutikal & kosmetik 8. National seminar on regulation of cosmetic 9. HPLC training 10.Computer (Microsoft Word & Access)	18-29.1.99 19 & 22.3.99 10-14.5.99 5.8.99 26-27.5.99 31.5.99-1.6.99 19-20.10.99 1.4.99 1-5.7.99 Nov 1999	WHO Research Instrument Intan/BPFK Mettler Toledo MOPI/BPFK MOPI/BPFK BPFK/MOPI/CTFA/ Pharma/MCTIG CTFA/BPFK Research Instrument BPFK	Bangkok, Thailand BPFK A Famosa Resort, Melaka Mettler Toledo, Petaling Jaya BPFK BPFK Sheraton Hotel, PJ Concord Hotel, Shah Alam Research Instrument Horizon Computer learning

Nama Pegawai *Name of Officer*	*Kursus* *Courses*	*Tarikh* *Date*	Anjuran *Coordinator*	Tempat *Place*
Dr. Sulaikah V.K. Moideen	1. Seminar on regulation of cosmetic and toiletries	1.4.99	CTFA/BPFK	Concorde Hotel, Shah Alam
	2. Microbiology: from manual to automation	29.4.99	Fischer Scientific	PJ Hilton
	3. Process Validation	31.5.99 & 1.6.99	BPFK/MOPI	BPFK
	4. Quality Assurance of Live Attenuated Polio and Measles Vaccine	26.9.99-27.10.99	WHO/JICA	Bandung Indonesia
	5. Computer (Microosoft Words, Excel & Access)	Nov & Dis 1999	BPFK	Horizon Computer Learning Centre
	6. Meeting of the ACCSQ on Pharmaceuticals	6-7 Sept 1999	Jabatan Standard Malaysia	Concord Hotel, KL
	7. Meeting of the ACCSQ on cosmetics	8-9 Sept 1999	Jabatan Standard Malaysia	Concord Hotel, KL
Faridah Malek	1. Waters Vision 2000 Seminar	6.5.99	Research Instrument	Hyatt Saujana Hotel, PJ
	2. Process Validation	17-18.5.99	BPFK/MOPI	BPFK
	3. Analytical Validation	26-27.5.99	BPFK/MOPI	BPFK
	4. First Meeting of ASSOC on Pharmaceuticals & Cosmetics	6-7.9.99	Jabatan Standard Malaysia	Concord Hotel KL
	5. Seminar Regulatori Farmaseutikal & Kosmetik	19-20.10.99	BPFK/MOPI/CTFA/ Pharma/MCTIG	Sheraton Hotel PJ
	6. Seminar on GLP	23-24.11.99	BPFK	BPFK
	7. Computer (Microsoft Words, Excel 7 Access)	Nov 1999	BPFK	Horizon Computer Learning Centre
Hasenah Ali	1. Standardisation of Traditional Medicine	15.3.99 - 14.4.99	WHO	Beijing, China
	2. Bengkel Perlaksanaan ISO	10 - 14.5.99	Intan/BPFK	A Famosa Resort, Melaka
	3. Process Validation	17-18.5.99	BPFK/MOPI	BPFK
	4. Analytical validation	19-20.5.99	BPFK/MOPI	BPFK
	5. Waters Vision 2000	6.5.99	Research Instrument	Hyatt Saujana Hotel, PJ
	6. Karl Fischer (GLP Approach)	5.8.99	Mettler Toledo	Mettler Toledo, PJ
	7. First Meeting of ASSQC on Pharmaceuticals	6-7.9.99	Jabatan Standard Malaysia	Concord Hotel, KL
	8. Mesyuarat Penyediaan Polisi Perubatan Traditional/komplementari	15-17.9.99	BPFK/IMR/BPPK	Avilion Hotel, Port Dickson
	9. Seminar Regulatori farmaseutikal & kosmetik	19-20.10.99	BPFK/MOPI/CTFA/ Pharma/MCTIG	Sheraton Hotel, PJ
	10.Seminar on GLP	23-24.11.99	WHO	BPFK
	11.Computer (Microsoft Excel & Access)	Nov 7 Dis 1999	BPFK	Horizon Computer Learning Centre

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Absah Awang	1. Kursus Keselamatan dan Kebakaran bangunan	25.8.99	Prime Consistense Sdn Bhd	BPFK
	2. Seminar on Sympatec's Particle Measurement	10.2.99	Interscience	PJ Hilton
	3. Karl Fischer (GLP Appraoch)	5.8.99	Mettler Toledo	Mettler Toledo
Ani Abdullah	1. Bengkel Perlaksanaan ISO	10-14.5.99	BPFK	A Famosa Resort, Melaka
	2. Anti-inflammatory: Invitro tests of herbal extracts	1-30.6.99	WHO	University of Uppsala, Sweden
	3. Seminar Regulatori farmaseutikal & kosmetik	19-20.10.99	BPFL/MOPI/CTFA/Pharma/MCTIG	Sheraton Hotel, PJ
	4. Persidangan QAP Farmasi	16-19.11.99	Bahagian Farmasi KKM	Mahkota Century Hotel, Melaka
	5. Seminar on GLP	23-24.11.99	WHO	BPFK
	6. Computer (Microsoft Word& Access)	Nov & Dis 1999	BPFK	Horizon Computer Learning Centre
Chan Sek Neo	1. Latihan Amali Dispensing	Jan-Jun 1999	KKM	HKL
	2. Karl Fischer (GLP Approach)	5.8.99	Mettler Toledo	Mettler Toledo, PJ
	3. Computer (Microsoft Excel)	Nov 1999	BPFK	Horizon Computer Learning Centre
	4. Seminar on Sympatec's Particle Measurement	10.12.99	Interscience Sdn Bhd	PJ Hilton
Chan Lai Peng	1. Training on ASEAN Reference Substances (Microbiological Assay)	4-15.10.99	WHO	Nonthanburi, Thailand
Chua Wone Tying	1. Seminar on Sympatec's Particle Measurement	10.12.99	Interscience Sdn Bhd	PJ Hilton
Sulaiman Ahmad	1. ISO 9000 Workshop	9 - 14 Mei 1999	BPFK	A'Famosa, Melaka
	2. Process Validation	24 - 25 Mei 1999	BPFK & MOPI	BPFK
	3. PIC/SSeminar - Non Technical Aspect	6 Sept - 10 Sept 1999	PIC/S, MCA, UK	Oxford University
	4. Towards Effective Standardisation	26 Okt 1999	SIRIM & DSM	Pan Pacific Glenmarie
	5. Regulatory Seminar 1999	19 - 20 Okt 1999	BPFK & industri	Subang Sheraton
	6. GLP Seminar	23 - 24 Nov 1999	BPFK & WHO	BPFK

Nama Pegawai *Name*	Kursus *Course / Training*	Tarikh *Date*	Tempat *Place*	Anjuran *Sponsors*
Kadariah Ali	1. ISO 9000 Workshop	9 - 14 Mei 1999	A'Famosa, Melaka	BPFK
	2. Analytical Validation	17 - 18 Mei 1999	BPFK	BPFK & MOPI
	3. Process Validation	19 - 20 Mei 1999	BPFK	BPFK & MOPI
	4. ACCSQ Pharmaceutical	6 - 7 Sept 1999	Concorde Hotel, KL	DSM
	5. Bengkel Polisi Perubatan Komplimentari dan Tradisional	15 - 17 Sept 1999	Avilion Resort, Port Dickson	KKM
	6. Seminar Regulatori 1999	19 - 20 Okt 1999	Subang Sheraton	BPFK & industri
	7. Seminar GLP Seminar	23 - 24 Nov 1999	BPFK	BPFK & industri
	8. Kursus komputer	6 - 10 Dis 1999	Bandar Sunway	BPFK
Wan Othman	1. ISO 9000 Workshop	9 - 14 Mei 1999	A'Famosa, Melaka	BPFK
	2. Analytical Validation	31 Mei - 1 Jun 1999	BPFK	BPFK & MOPI
	3. ACCSQ Cosmetic	8 - 9 Sept 1999	Concorde Hotel	DSM
	4. Regulatory Seminar 1999	19 - 20 Okt 1999	Subang Sheraton	BPFK & industry associations
	5. GMP Workshop	16 - 30 Nov 1999	Beijing, China	WHO
	6. Course in Computer	6 - 10 Dis 1999	Bandar Sunwa	BPFK

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Rosnani M. Ghazali	1. Bengkel ISO 900 2. Seminar Regulatori Farmasiutikal dan Kosmetik 1999 3. Kursus Komputer Microsoft Word 97 (Intermediate & Advanced)	10-14 Mei 1999 19-20 Okt 1999 11-12 Nov. 1999	Melaka Subang Jaya Subang Jaya	INTAN BPFK BPFK
Siti Aisah Bahari	1. Kursus Pengenalan Jaminan Kualiti Ubat-ubatan Tradisional 2. Seminar Regulatori, Farmaseutikal & Kosmetik 1999	15-16 July 1999 19-20 Okt 1999	Hotel Palace of The Golden Horses Subang Sheraton	BPFK BPFK/PHAMA/MOPI/ CTFA/FMM/MCTIG
Nurulfajar Mohd. Jamid	1. Seminar Regulatori, Farmaseutikal & Kosmetik 1999 2. Kursus Komputer Microsoft	1-3 1999 5 Nov 1999	Subang Jaya	BPFK
Eishah A. Rahman	1. Process Validation 2. Analytical Validation 3. Medicinal Plants - Quality Herbal Products For Healthy Living 4. Global Harmonisation Task Force 5. PIC/S - 1999 Seminar Non Technical Aspect 6. GMP Course in Vaccines 7. GLP Seminar	31 May - 1 Jun 1999 26 - 27 May 1999 22 - 23 June 1999 27 June - 2 Julai 1999 6 Sept - 10 Sept 1999 18 Oct - 5 Nov 1999 23 - 24 Nov 1999	BPFK BPFK FRIM Maryland, USA Oxford University MBL, Boston, USA BPFK	BPFK & MOPI BPFK & MOPI FRIM CDRH & US FDA PIC/S, MCA, UK WHO & USAID BPFK & WHO

Nama Pegawai *Name*	Kursus *Course / Training*	Tarikh *Date*	Tempat *Place*	Anjuran *Sponsors*
Ramli Zainal	1. 2nd Forum on Harmonized Regulatory Systems for Cosmetics	15-16 Mac 1999	Manila	ACCSQ
	2. National Seminar on Regulation and Registration of Cosmetics & Toiletries	1 April 1999	Shah Alam	FMM-MCTIG
	3. Bengkel ISO 9000	10-14 April 1999	Melaka	INTAN
	4. Pharmaceutical GMP Training on Process Validation	17-18 Mei 1999	BPFK	BPFK
	5. Bengkel Audit Dalaman Untuk Perkhidmatan Farmasi	6-8 Julai 1999	Kuala Terengganu	Bhg Farmasi
	6. 1st Meeting of ACCSQ of PWG on Pharmaceutical	6-7 Sept 1999	Kuala Lumpur	ACCSQ/DSM
	7. 2nd Meeting of ACCSQ of PWG on Cosmetic	8-9 Sept 1999	Kuala Lumpur	ACCSQ/DSM
	8. Mesyuarat penyediaan Polisi Perubatan Tradisional/ Komplementari Kebangsaan	15-17 Sept 1999	Port Dickson	KKM
	9. Seminar Regulatori 1999	19-20 Okt 1999	Subang Jaya	BPFK
Anis Talib	1. National Seminar on Regulation and Registration of Cosmetic & Toiletries	1 April 1999	Shah Alam	FMM-MCTIG
	2. Bengkel Perlaksanaan MS ISO 9000	10-14 Mei 1999	Melaka	BPFK
	3. Seminar Regulatori Farmaseutikal dan Kosmetik 1999	19-20 Oktober 1999	Subang Jaya	BPFK
	4. Good Laboratory Practice	23-24 Nov 1999	BPFK	BPFK
	5. Kursus Komputer MS Excell 97 (Beginner/Intermediate/advanced)	15-18 Nov 1999	Subang Jaya	BPFK
Zuraida Abdullah	1. Bengkel Perlaksanaan MS ISO 9000	10-14 Mei 1999	Melaka	BPFK
	2. 2nd Meeting of ACCSQ of PWG on Cosmetic	8-9 Sept 1999	Kuala Lumpur	ACCSQ/DSM
	3. Persidangan QAP Farmasi 1999	16-19 Nov 1999	Melaka	BPFK
	4. Kursus Komputer MS Acess 97	6-9 Dec 1999	Subang Jaya	BPFK

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Zawiah Zainal	1. ISO 9000 Workshop 2. Analytical Validation 3. Process Validation 4. Induction Course 5. Computer Access 6. Pharmacist Induction Course 7. Pharmacy QAP Conference 8. GLP Seminar	9 - 14 Mei 1999 19 - 20 Mei 1999 24 - 25 Mei 1999 17 - 31 Julai 1999 1,2,3,5 Nov 1999 10 - 12 Nov 1999 16 - 19 Nov 1999 23 - 24 Nov 1999	A'Famosa, Melaka BPFK BPFK Air Keroh D'Village, Melaka Bandar Sunway Shah Alam Melaka BPFK	BPFK BPFK & MOPI BPFK & MOPI KKM BPFK Bhg. Farmasi Bhg. Farmasi BPFK
Dalila Abd Wahid	Course in Computer	Nov 1999	Bandar Sunway	BPFK
Normah Ali	Course in Computer	Nov 1999	Bandar Sunway	BPFK
Tang Poh Yoong	Course in Computer Microsoft Words dan Excel	Nov 1999	Bandar Sunway	BPFK