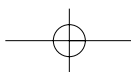
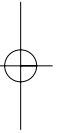
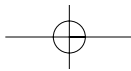
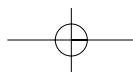


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KATA-KATA ALUAN DARIPADA PENGARAH *MESSAGE FROM THE DIRECTOR*



BPFK adalah badan eksekutif yang bertindak selaku sekretariat kepada PBKD. Sudah melebihi 20 tahun institusi ini ditubuhkan. Peranannya adalah untuk memastikan semua keluaran yang berada di pasaran adalah berkualiti, selamat dan berkesan. Jika diteliti tanggungjawab ini amatlah besar untuk dipikul. Walaubagaimanapun, dengan dianggotai oleh 60 pegawai farmasi, 68 pembantu farmasi, 18 orang pembantu tadbir, BPFK telah berjaya melaksanakan amanah yang diberi. Hal ini adalah berkat kegigihan kakitangan BPFK yang telah bertungkus lumus melaksanakan tugas masing-masing. Syabas diucapkan.

Kerjasama antara BPFK dengan pihak industri juga telah menghasilkan sinergi yang optimum. BPFK sentiasa bersikap terbuka dengan sebarang teguran. Permasalahan pihak industri sentiasa diberi perhatian. Komunikasi dua hala sering dipraktikkan. Lebih-lebih lagi melalui sesi dialog di antara industri dan BPFK. Sesi dialog ini diadakan dua kali setahun. Pihak industri akan mengemukakan sebarang masalah yang timbul dan BPFK akan memberi maklumbalas secara terus. Selain daripada itu jawatankuasa teknikal [TWG] juga diwujudkan untuk menyelesaikan sesuatu isu yang khas. Apabila isu tersebut selesai, jawatankuasa ini akan dibubarkan.

Selaras dengan pembangunan negara Malaysia yang maju dan berteknologi tinggi ke arah negara IT, BPFK turut seiring dengan arus perubahan tersebut. BPFK telah mewujudkan

The National Pharmaceutical Control Bureau (NPCB) is an executive body which acts as the secretariat to the Drug Control Authority (DCA). This institution has been established for over 20 years. Our core function is to ensure that all products in the market are of quality, efficacious and safe. And of course with power comes huge responsibility. Nevertheless, with a group of dedicated workforce comprising of 60 pharmacists, 68 assistant pharmacists and 18 administrative staff, NPCB has succeeded in accomplishing the task bestowed upon her. This outstanding success can only be achieved due to the hard work, perseverance, sheer dedication and commitment of our beloved staff. Congratulations to all!

The co-operation between NPCB and the industrial sector has been overwhelming, resulting in an optimal synergy. While vigorously pursuing our goal, we have never neglected the problems faced by the industry. A two-way communication is always practiced. In order to achieve this, dialogue sessions are always held between the industrial sector and NPCB. These sessions are held twice a year. If necessary, a technical working group (TWG) will be set up to oversee impending issues.

We have seen Malaysia moving into the information revolution with big high-tech ambitions. In conjunction with this, NPCB has developed an 'On-Line Registration' for the purpose of registering cosmetics. This is to

satu sistem 'On-Line Registration' untuk pendaftaran produk kosmetik. Ini adalah bertujuan untuk memudahkan dan memendekkan proses pendaftaran. Beberapa siri taklimat telah diadakan di seluruh Malaysia bagi memberi pendedahan kepada pihak industri tentang sistem tersebut di samping mewar-warkan tentang keperluan pendaftaran produk kosmetik di Malaysia.

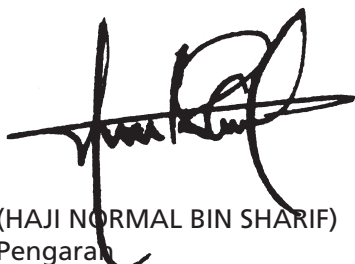
Sekali lagi saya ingin mengucapkan syabas kepada semua kakitangan BPFK yang bertungkus-lumus untuk memastikan Audit Compliance ISO MS 9002 berjaya.

Pada Julai 2001 BPFK telah berjaya memperolehi status MS ISO 9002 di mana ini membawa maksud semua prosedur yang dijalankan oleh BPFK didokumenkan dan mematuhi syarat-syarat ISO.

Setelah mencapai status ISO adalah menjadi tanggungjawab warga BPFK untuk mematuhi dan mengikuti setiap prosedur yang ada iaitu 'Buat apa yang didokumenkan dan dokumenkan apa yang dibuat'.

Selaras dengan saranan kerajaan agar institusi kerajaan membantu pihak swasta, maka BPFK telah mengambil inisiatif menjadi ahli PIC/S. Juruaudit BPFK telah diaudit sebanyak dua kali oleh wakil PIC/S. Dan akhirnya mereka berpuas hati dengan prestasi juruaudit BPFK. Pada mesyuarat PIC/S dalam bulan November 2001 di Geneva, Malaysia telah diterima sebagai negara PIC/S yang ke-26 mulai 1 Januari 2002. Dengan diiktiraf sebagai ahli PIC/S sijil GMP dari Malaysia diiktiraf bertaraf antarabangsa. Maka halangan teknikal dari segi regulatori dapat diatasi.

Adalah diharapkan dengan kerjasama yang jitu di antara kakitangan BPFK serta usaha yang gigih maka prestasi kecemerlangan dapat dikekalkan seterusnya dapat ditingkatkan pada masa-masa mendatang. Ibarat kata, "Bulat air kerana pemetung, bulat kata kerana muafakah".



(HAJI NORMAL BIN SHARIF)
Pengeran
Biro Pengawasan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

simplify and shorten the registration process. A series of briefing have been done throughout the nation to give an exposure to the industry and the public regarding this on-line registration system.

Once again, I would like to express my deepest gratitude to all NPCB staff who have worked very hard towards the success of the MS ISO 9002 Compliance Audit.

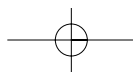
On July 2001, NPCB succeeded in obtaining the MS ISO 9002 certification from SIRIM. Hence, all procedures involved will be documented and it is also our duty to ensure all our activities comply with MS ISO standards. As the saying goes, 'Do what you document, and document what you do'.

It has always been the government's policy to work alongside and guide the private sector. In the case of NPCB, we have become a member of the Pharmaceutical Inspection Co-operation Scheme (PICIS) and we have adopted its guideline into our existing GMP guidelines. Auditors from NPCB have been audited twice by two delegations from the PICIS and we are proud to say that the results have been more than satisfactory. Malaysia was officially appointed as the 26th member of PICIS as from 1st January 2002 in the November 2001 PICIS meeting held in Geneva and through this; our GMP standards have obtained international recognition. As such, previous trading barriers from the regulatory aspect have been overcome.

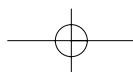
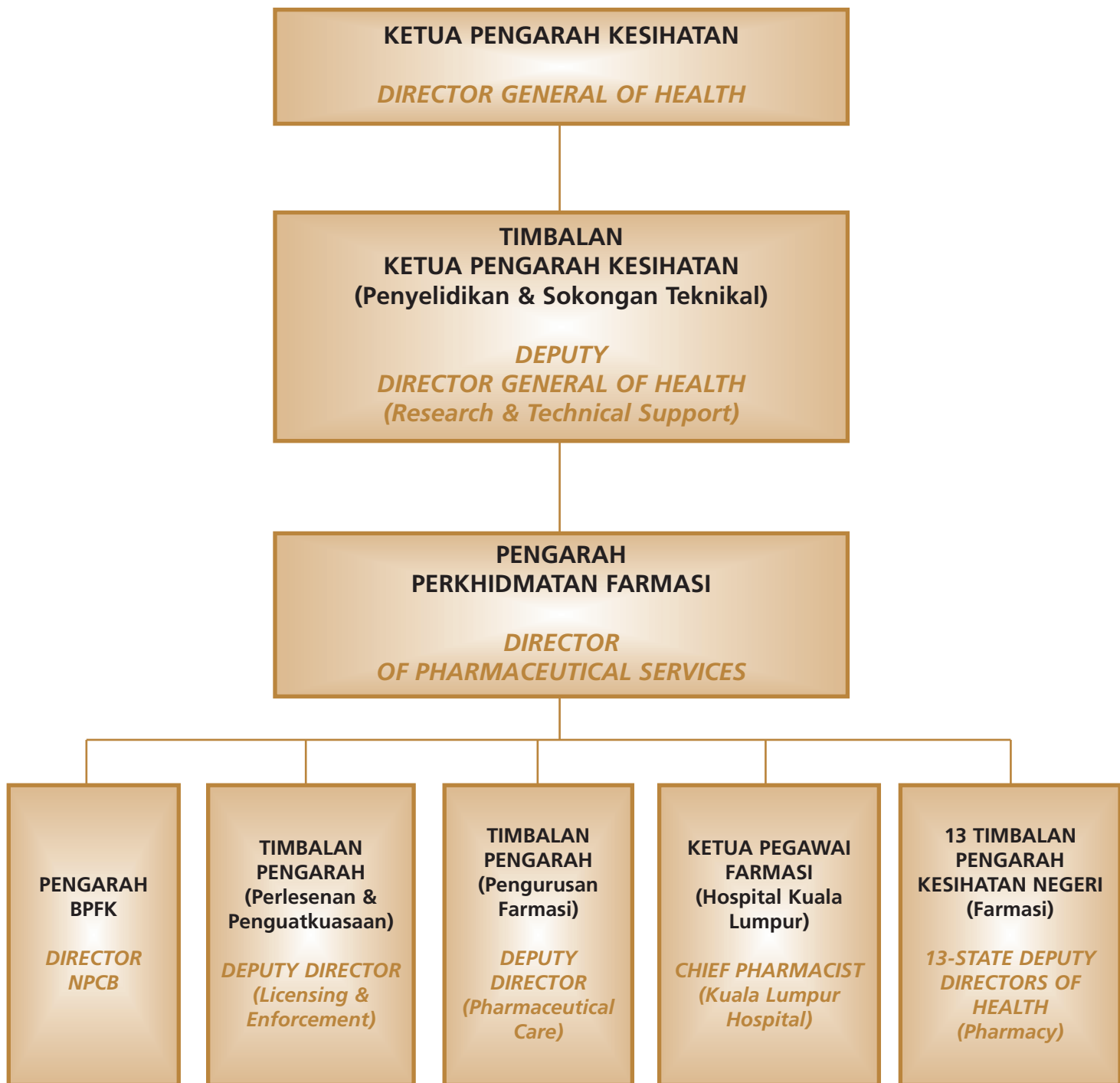
I hope with the full cooperation of the NPCB staff, our excellent performance will be maintained and we shall excel further in times to come. "Ability is what you're capable of doing, motivation determines what you do, attitude determines how well you do it".

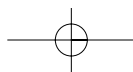


(HAJI NORMAL BIN SHARIF)
Director
National Pharmaceutical Control Bureau
Ministry of Health Malaysia



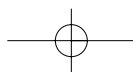
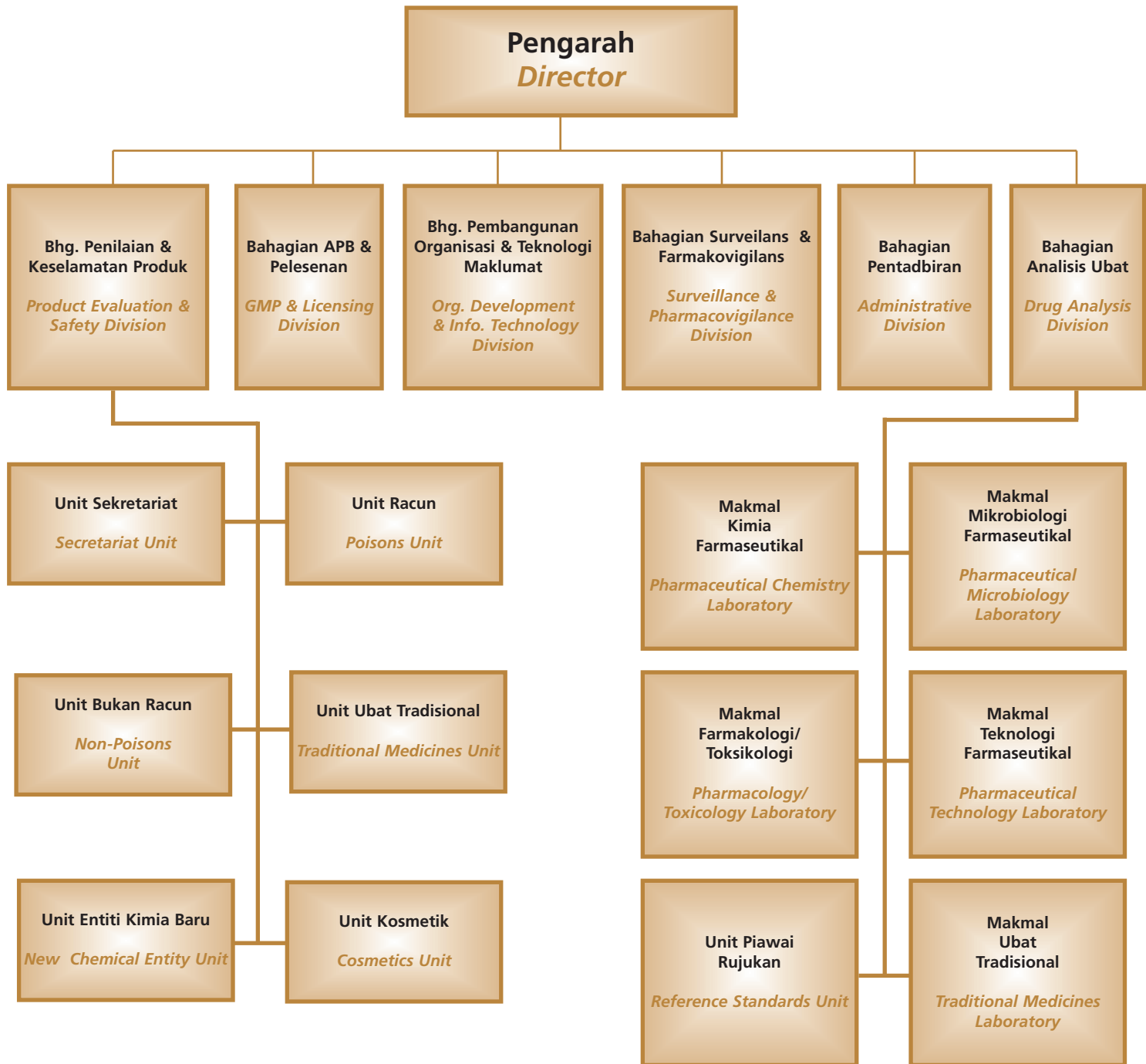
STRUKTUR ORGANISASI
ORGANIZATIONAL STRUCTURE OF
BAHAGIAN PERKHIDMATAN FARMASI
PHARMACEUTICAL DIVISION
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH





CARTA ORGANISASI ORGANIZATIONAL CHART

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN NATIONAL PHARMACEUTICAL CONTROL BUREAU



Senarai jawatan pada 31 Disember 2001
List of posts as at 31 December 2001

| Bil. No. | Nama Jawatan Position | Gred Grade | Bil. No. | Jawatan (Post) | |
|-----------------------|--|---------------|-------------|-----------------|------------------|
| | | | | Diisi Filled | Kosong Vacant |
| 1. | Pengarah BPFK Director of NPCB | C | 1 | 1 | 0 |
| 2. | Pegawai Farmasi Pharmacist | U1 | 2 | 1 | 1 |
| 3. | Pegawai Farmasi Pharmacist | U2 | 19 | 19 | 0 |
| 4. | Pegawai Farmasi Pharmacist | U3 | 44 | 39 | 5 |
| 5. | Penolong Pegawai Perangkaan Assistant Statistic Officer | N6 | 1 | 0 | 1 |
| 6. | Pembantu Farmasi Pharmacy Assistant | U7 | 8 | 7 | 1 |
| 7. | Pembantu Farmasi Pharmacy Assistant | U8 | 65 | 61 | 4 |
| 8. | Pembantu Tadbir Administrative Assistant | N7 | 1 | 1 | 0 |
| 9. | Pembantu Tadbir (Kesetiausahaan) Administrative Assistant (Secretary) | N7 | 1 | 1 | 0 |
| 10. | Pembantu Perpustakaan Library Assistant | S7 | 1 | 1 | 0 |
| 11. | Pembantu Tadbir Administrative Assistant | N9 | 11 | 10 | 1 |
| 12. | Pembantu Tadbir (Kesetiausahaan) Administrative Assistant (Secretary) | N9 | 2 | 2 | 0 |
| 13. | Pembantu Tadbir (Setor) Administrative Assistant (Store) | N9 | 1 | 1 | 0 |
| 14. | Operator Mesin Prosesan Data Data Processing Operator | F9 | 2 | 1 | 1 |
| 15. | Pembantu Tadbir Rendah Typist | N11 | 4 | 2 | 2 |
| 16. | Pembantu Tadbir Rendah (Operator Telefon) Administrative Assistant (Telephone Operator) | N11 | 1 | 1 | 0 |
| 17. | Pembantu Am Rendah General Assistant | N13 | 2 | 0 | 2 |
| 18. | Atendan Kesihatan Health Attendant | U16 | 10 | 7 | 3 |
| 19. | Pengawal Keselamatan Security Guard | KP10 | 3 | 1 | 2 |
| 20. | Pemandu Kenderaan Bermotor Driver | R10 | 3 | 2 | 1 |
| JUMLAH (Total) | | | 182 | 158 | 24 |

FALSAFAH ORGANISASI

WAWASAN

Biro Pengawasan Farmaseutikal Kebangsaan sebagai pusat kecemerlangan unggul dalam bidang regulatori farmaseutikal demi menjamin kesihatan dan kesejahteraan insan sejagat.

MISI

Biro Pengawasan Farmaseutikal Kebangsaan akan memastikan kualiti, keberkesanan dan keselamatan keluaran farmaseutikal melalui pelaksanaan undang-undang oleh tenaga kerja yang berketerampilan dan usahasama strategik ke arah peningkatan status kesihatan rakyat.

MATLAMAT

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

STRATEGI

Memastikan kecekapan dan keberkesanan organisasi melalui permodenan dan automasi sistem-sistem pejabat, makmal dan pendaftaran, peninjauan serta pembaikan perkhidmatan secara regular.

Memperkukuhkan aktiviti penguatkuasaan undang-undang berkaitan.

Memastikan suasana kefahaman dua hala dan kerjasama berterusan sentiasa wujud antara pihak pengawalan dengan sektor swasta melalui sesi dialog dan bimbingan.

Meningkatkan potensi serta kepakaran personel.

Mewujudkan satu kumpulan tenaga kerja yang berdedikasi dan penuh komitmen melalui motivasi, penghargaan serta ganjaran yang berpatutan.

Mempergiatkan aktiviti penyelidikan serta meningkatkan kemudahan-kemudahan bagi tujuan tersebut.

Mewujudkan suatu suasana yang menggalakkan kakitangan bekerja secara berpasukan dengan sikap penyayang, serta melaksanakan tugas masing-masing secara profesional.

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 alliances towards improving the health of the people.

OBJECTIVE

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

STRATEGY

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

To strengthen enforcement activities of the related legislation.

To ensure continuous mutual understanding and co-operation between the regulatory body and the private sector through dialogues and guidances.

To upgrade personnel potential and expertise.

To attain a dedicated and fully committed work force through motivation, appreciation and appropriate remuneration.

To strengthen research activities and upgrade facilities for such purposes.

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

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

1.1. 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.

1.2. TARAF PERKHIDMATAN

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

1.3. MAKLUMAT PERKHIDMATAN

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

2. AKTIVITI - PENDAFTARAN

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

CLIENT'S CHARTER

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

Exclusive concern for clients who deal with NPCB.

1. GENERAL

1.1. FACILITIES FOR CLIENTS

- (i) Every client of the bureau shall receive the appropriate service.*
- (ii) Every client who requires immediate attention shall be served immediately.*

1.2. STANDARD OF SERVICE

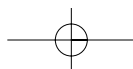
- (i) Every client shall be treated with courtesy, understanding, respect and sincerity.*
- (ii) Every client shall be given the best possible professional service.*

1.3. INFORMATION SERVICE

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

2. ACTIVITY - REGISTRATION

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



3. AKTIVITI - MAKMAL

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

4. AKTIVITI - PENGUATKUASAAN DAN KOMPLIANS

- 4.1. Setiap tindakan penguatkuasaan ke atas mana-mana pelanggaran undang-undang yang dikuatkuasakan akan dilakukan dengan adil dan saksama tanpa dipengaruhi oleh apa-apa kepentingan dan prasangka.
- 4.2. Bersedia bekerjasama dengan agensi penguatkuasaan lain dalam perkara yang berkaitan dengan penguatkuasaan ubat-ubatan.

5. SETIAP PERMOHONAN YANG LENGKAP AKAN DIPROSES MENGIKUT JANGKAMASA BERIKUT

- (i) Lesen Untuk Percubaan Klinikal - tidak lebih dari 3 bulan.
- (ii) Lesen Untuk Pemborong, Pengilang, Pengimport - tidak lebih dari 3 bulan.
- (iii) Lesen Baru Untuk Pemborong, Pengilang, Pengimport - tidak lebih dari 6 bulan.
- (iv) Pendaftaran.
- | | | |
|-------------------|---|-------------------------------------|
| Peringkat 1 | - | tidak lebih dari 6 minggu. |
| Peringkat 2 | - | tidak lebih dari 4 bulan. |
| Peringkat 3 | - | Generik - tidak lebih dari 6 bulan. |
| NCE | - | tidak lebih dari 12 bulan. |
| Tambahan Indikasi | - | tidak lebih dari 6 bulan. |

3. ACTIVITY - LABORATORY

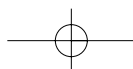
- 3.1. All laboratory tests shall be carried out fairly and impartially in accordance with the relevant regulations and procedures.

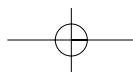
4. ACTIVITY - ENFORCEMENT & COMPLIANCE

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

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

- (i) Licence For Clinical Trial - Not more than 3 months.
- (ii) Licence For Wholesalers, Manufacturers and Importers - Not more than 3 months.
- (iii) New Licence For Wholesalers, Manufacturers and Importers - Not more than 6 months.
- (iv) Registration
- | | | |
|------------------------|---|-----------------------------------|
| Stage 1 | - | Not more than 6 weeks. |
| Stage 2 | - | Not more than 4 months. |
| Stage 3 | - | Generic - Not more than 6 months. |
| NCE | - | Not more than 12 months. |
| Additional Indications | - | Not more than 6 months. |





(v) 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.

(v) *GMP Inspection Report*

- Follow-up* - *Not more than 2 months.*
- New/Routine* - *Not more than 3 months.*

(vi) *Product Certificate*

- Medical Device* - *Not more than 2 weeks.*
- Pharmaceuticals* - *Not more than 1 month.*

B. KEWAJIPAN PELANGGAN

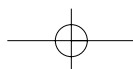
Bagi membolehkan piagam ini dilaksanakan dengan berkesan, pelanggan adalah berkewajipan untuk :

- (i) Mematuhi semua undang-undang dan peraturan-peraturan yang berkaitan.
- (ii) Menggunakan kemudahan-kemudahan yang disediakan secara bertanggungjawab.

B. CLIENT'S OBLIGATION

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

- (i) Comply with the requirements of the relevant legislation and regulations.*
- (ii) Use the facilities provided responsibly.*



RINGKASAN AKTIVITI BPFK

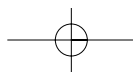
Aktiviti-aktiviti Biro Pengawasan Farmaseutikal Kebangsaan pada amnya termasuk :-

1. Menguatkuasakan skim pendaftaran ubat dan kosmetik melalui penilaian data teknikal, ujian makmal, penyelidikan dan maklumat yang diterima dari badan-badan antarabangsa.
2. Menjalankan ujian analisa, farmaseutik, mikrobiologi, farmakologi serta toksikologi ke atas ubat-ubatan dan kosmetik untuk menentukan mutu, keberkesanan dan keselamatan keluaran-keluaran tersebut.
3. Menguatkuasakan skim kawalan mutu ubat-ubatan di pasaran melalui penyampelan 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 (Good Manufacturing Practice) yang disarankan oleh Pertubuhan Kesihatan Sedunia.
6. Menguruskan program pemantauan kesan advers ubat dan menganggotai Program Pemantauan Ubat Antarabangsa WHO.
7. Menguruskan skim panggilbalik ubat-ubat yang didapati atau dibuktikan merbahaya kepada pengguna.

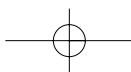
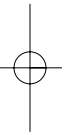
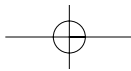
SUMMARY OF NPCB ACTIVITIES

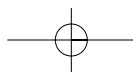
The activities of NPCB are :-

1. To implement the drug and cosmetic registration scheme through evaluation of technical data, laboratory analysis, research and information received from international agencies.
2. To carry out analytical, pharmaceutical, microbiological, pharmacological and toxicological tests on drugs and cosmetics to determine quality, efficacy and safety of such products.
3. To implement the regulatory scheme on quality of pharmaceutical products in the market through random sampling and carrying out analytical tests.
4. To implement the licensing scheme for pharmaceutical manufacturers, importers and wholesalers including a licensing scheme for clinical trials.
5. To encourage and assist local pharmaceutical manufacturers to upgrade manufacturing standards to levels equivalent to the requirements of Good Manufacturing Practice as recommended by the World Health Organisation (WHO).
6. To manage the Adverse Drug Reaction Monitoring Program and participate in the WHO International Adverse Drug Reaction Monitoring Program.
7. To manage the product recall scheme for pharmaceutical products which are found to be substandard or dangerous to consumers.

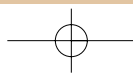


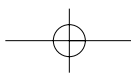
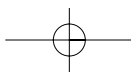
8. Mengendalikan sistem pengumpulan dan penyebaran maklumat ubat-ubatan selaras dengan peranannya sebagai Pusat Maklumat Ubat Kebangsaan.
 9. Menjalankan penyelidikan metodologi dan penyelidikan asas untuk tujuan menilai mutu, keberkesanan dan keselamatan ubat-ubatan/kosmetik.
 10. Menubuhkan sistem 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.
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 pharmaceutical officers, other professional and semi-professional officers who are placed in this institution from time to time through local training or international cooperational schemes.*





**LAPORAN
BAHAGIAN**
***DIVISIONAL
REPORTS***





BAHAGIAN PENTADBIRAN

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

OBJEKTIF

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

KEWANGAN

Mengurus pembayaran upahan dan gaji untuk 151 anggota berjumlah RM 4,646,591.00

KUTIPAN HASIL

Kutipan hasil diterima daripada pelanggan untuk bayaran Pendaftaran Ubat-Ubatan, Ujian Makmal, Lesen, Perkhidmatan Nasihat, Jualan Buku-buku Garispaduan dan lain-lain. Jumlah kutipan hasil mengikut disiplin adalah seperti 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 ensure that each planned program and activity meets its objective*

FINANCE

Payment to 151 staff members is RM 4,646,591.00

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 :-

KUTIPAN HASIL (RM) SEHINGGA AKHIR TAHUN 2001 REVENUE UNTIL END OF 2001

| Tahun Year | Pendaftaran Registration | Lesen Licence | Makmal Laboratory | Pemeriksaan Inspection | Bahan Cetak Printed Materials | Lain-lain Other |
|---------------|-----------------------------|------------------|----------------------|---------------------------|----------------------------------|--------------------|
| 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 |
| 2000 | 1,111,440 | 152,100 | 502,620 | 6,500 | 28,340 | 27,193 |
| 2001 | 914,020 | 203,200 | 460,880 | 12,200 | 26,485 | 64,072 |

TINJAUAN BELANJAWAN / *BUDGET REVIEW*

Peruntukan dan Perbelanjaan Mengurus BPFK Bagi Tahun 2001 *2001 NPCB Operating Allocation and Expenditure*

| Kod Objek <i>Object code</i> | Jenis Perbelanjaan <i>Am Expenditure</i> | Peruntukan (RM) <i>Allocation (RM)</i> | | Perbelanjaan <i>Expenditure</i> | | Baki <i>Balance</i> | |
|---------------------------------|---|---|---------------------------|--|-------|------------------------|-------|
| | | Asal <i>Original</i> | Dipinda <i>Amended</i> | Perbelanjaan Bersih (RM) <i>Actual Expenditure (RM)</i> | % | (RM) | % |
| 10000 | Emolumen Emolument | 4,134,000 | 4,847,800 | 4,646,591 | 95.85 | 201,208 | 4.15 |
| 20000 | Perkhidmatan dan Bekalan Services and Supply | 5,032,700 | 7,199,700 | 6,743,260 | 93.66 | 456,440 | 6.34 |
| 30000 | Aset (Harta Modal) Asset (Property) | 300,000 | 300,000 | 297,265 | 99.08 | 2,734 | 0.911 |
| Jumlah Total | | 9,466,700 | 12,347,500 | 11,687,116 | 94.65 | 660,383 | 5.35 |

Bahagian Penilaian dan Keselamatan Produk

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

Pemohonan yang diterima

diterima Sejumlah 48,324 permohonan diterima dari tahun 1985 sehingga 2001, dimana 14,550 (30.4%) ubat racun, 10,450 (21.7%) ubat bukan racun, 21,445 (44.2%) ubat tradisional dan 1,879 (3.8%) kosmetik (Jadual 1). Jumlah permohonan telah meningkat dengan ketara dari 6,448 pada 1986 kepada 20,257 pada 1992. Aliran yang sama dapat diperhatikan pada 1992 hingga 1999, dimana jumlah permohonan meningkat sebanyak 53.2%, kerana permohonan yang banyak untuk ubat tradisional dan kosmetik. Walau bagaimanapun, pada tahun 2001 jumlah permohonan telah menurun sedikit bagi ubat tradisional serta kosmetik dan meningkat sedikit bagi ubat racun dan ubat bukan racun.

Produk berdaftar

didaftarkan Sejumlah 27,359 keluaran telah didaftarkan sehingga 2001, dimana 8,893 (33.6%) ialah ubat racun, 6,996 (26.1%) ubat bukan racun, 9,894 (36.9%) ubat tradisional dan 1,776 (6.6%) kosmetik (Jadual 2). Jumlah keluaran yang didaftarkan menunjukkan peningkatan bagi semua kategori.

Pemohonan Ditolak

ditolak Sehingga 2001, sejumlah 16,640 permohonan telah ditolak dan ini meliputi kira-kira 34.4% dari jumlah permohonan yang diterima.

Jadual 1 : Permohonan untuk pendaftaran, 1985 – 2001
Table 1 : Applications received for registration, 1985 – 2001

| 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 |
| 2000 | 427 | 444 | 1,523 | 262 | 2,656 | 45,955 |
| 2001 | 578 | 487 | 1,154 | 150 | 2,369 | 48,324 |
| Jumlah Total | 14,550 | 10,450 | 21,445 | 1,879 | 48,324 | 48,324 |

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

Laporan Tahunan 2001

Annual Report 2001

Product Evaluation and Safety Division

OBJECTIVES

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

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

ACHIEVEMENTS

Application received

Applications A total of 48,324 applications were received from 1985 to 2001, of which received 14,550 (30.4%) were prescription drugs, 10,450 (21.7%) OTC products, 21,445 (44.2%) traditional medicines and 1,879 (3.8%) cosmetics (Table 1). The number of applications had increased significantly, 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. However, the total application for registration of prescription drugs and OTC products has increased slightly in year 2001.

Products Registered

A total of 27,359 products had been registered by 2001, of which 8,893 registered (33.6%) are prescription drugs, 6,996 (26.1%) OTCs, 9,894 (36.9%) traditional medicines and 1,776 (6.6%) cosmetics (Table 2). The number of products registered display increasing trends for all categories.

Applications Rejected

Up until 2001, a total of 16,640 applications had been rejected and this rejected represents approximately 34.4% of the total number of applications received.

Jadual 2 :Kumulatif keluaran yang didaftarkan (1991 – 2001)
Table 2 :Cumulative number of products registered (1991 – 2001)

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

Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Jadual 3 : Kumulatif permohonan yang ditolak (1986 – 2001)
Table 3 : Cumulative applications rejected by the DCA, 1986 – 2001

| 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 |
| 2000 | 4,206 | 3,165 | 9,021 | 98 | 16,392 |
| 2001 | 4,248 | 3,188 | 9,104 | 100 | 16,640 |
| Jumlah Total | 4,248 | 3,188 | 9,104 | 100 | 16,640 |

Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Permohonan yang dibatalkan atau ditarik-balik

Sehingga 2001, sejumlah 7,069 permohonan telah dibatalkan atau ditarik-balik, dan ini meliputi 2,317 (32.8%) ubat racun, 1,334 (18.9%) ubat bukan racun, 3,352 (32.3%) ubat tradisional dan 66 (0.9%) kosmetik (**Jadual 4**). Jumlah keluaran yang dibatalkan atau ditarik-balik adalah 14.6% daripada jumlah permohonan yang diterima.

Applications cancelled or withdrawn

Up until 2001, a total of 7,069 applications had been cancelled or withdrawn, which consists of 2,317 (32.8%) prescription drugs, 1,334 (18.9%) OTCs, 3,352 (32.3%) traditional medicines and cosmetics 66 (0.9%) (**Table 4**). The total number of products cancelled or withdrawn represents about 14.6% of the total number of applications received.

Jadual 4 : Permohonan yang dibatalkan /ditarik-balik (1989 – 2001)
Table 4 : Applications cancelled/withdrawn, 1989 – 2001

| 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 |
| 2000 | 306 | 120 | 499 | - | 925 | 6,033 |
| 2001 | 86 | 305 | 645 | - | 1,036 | 7,069 |
| Jumlah Total | 2,317 | 1,334 | 3,352 | 66 | 1,036 | 7,069 |

Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

RAYUAN

Jumlah rayuan yang diterima telah menurun kepada 16 pada tahun 2001 berbanding dengan 32 pada 2000 dan 370 pada 1999.

ENTITI KIMIA BARU

Dari 1985 hingga 2001, sejumlah 1,173 permohonan diterima untuk keluaran entiti kimia baru (Rajah 1). Daripada jumlah ini, 790 (67.2%) telah diluluskan, 299 (25.5%) ditolak dan 53 (4.5%) tertangguh.

TAMBAHAN INDIKASI

Tambahan indikasi bagi produk-produk yang telah berdaftar juga dinilai dan diluluskan oleh PBKD. Sebanyak 27 permohonan telah diterima bagi tahun 2000 dan 71 pada tahun 2001. Jumlah permohonan meningkat lebih dua kali ganda pada tahun 2001 berbanding tahun 2000.

LESEN IMPORT PENYELIDIKAN KLINIKAL (LIPK)

Jumlah permohonan LIPK yang diterima telah meningkat pada tahun 2000 dan 2001 berbanding dengan tahun 1998 dan 1999 (Rajah 2). Dari tahun 1997 hingga 2001, sejumlah 243 permohonan LIPK diterima.

APPEALS

The number of appeals received has decreased significantly to 16 for the year 2001, as compared to 32 in 2000 and 370 in 1999.

NEW CHEMICAL ENTITIES

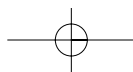
From 1985 to 2001, a total of 1,173 applications were received for products classified as new chemical entities (Figure 1). Out of these, 790 (67.2%) had been approved, 299 (25.5%) rejected and 53 (4.5%) deferred.

ADDITIONAL INDICATIONS

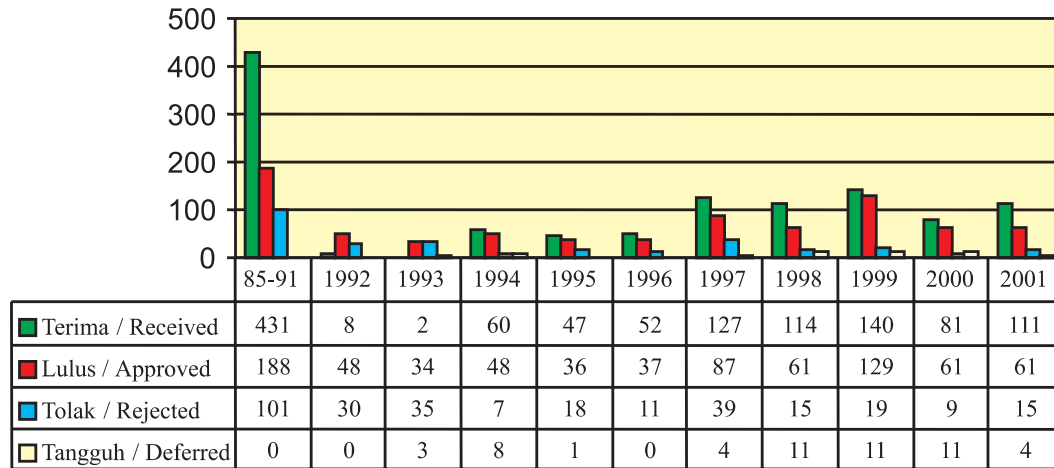
New indications for registered products were also assessed and approved by the DCA. A total of 27 applications were received in 2000 and 71 in the year 2001. The number of application for additional indication has increased double in year 2001 compared to year 2000.

CLINICAL TRIALS IMPORT LICENCE (CTIL)

The number of CTIL received has increased significantly in 2000 and 2001 as compared to 1998 and 1999 (Figure 2). From 1997 to 2001, a total of 243 applications of CTIL were received.

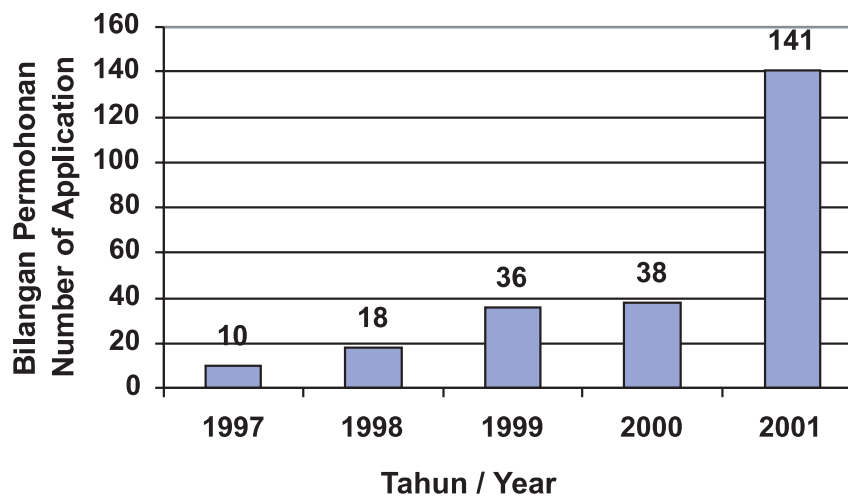


Rajah 1 : Status pendaftaran keluaran entiti kimia baru
Figure 1 : Registration status of new chemical entities
1985 - 2001



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

Rajah 2 : Lesen Import Penyelidikan Klinik
Figure 2 : Clinical Trial Import Licence
1997 - 2001



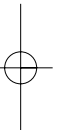
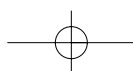
Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

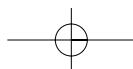
TEMPATAN VS. IMPORT

Sebanyak 44.2% (12,103) daripada jumlah keluaran yang didaftarkan adalah dikilangkan secara tempatan, sementara 55.8% (15,256) adalah diimport. Keluaran tempatan dan keluaran import yang didaftarkan dari 1991 sehingga 2001, mengikut kategori berlainan diilustrasikan pada **Jadual 5**.

LOCAL VS. IMPORT

About 44.2% (12,103) of the total number of products registered are locally-manufactured, while 55.8% (15,256) are imported. Locally-manufactured and imported products registered for period between 1991 to 2001, according to different categories, are cumulatively illustrated in **Table 5**.





Jadual 5 : Jumlah kumulatif produk tempatan dan produk import
Table 5 : Cumulative number of locally-manufactured and imported products registered
(1991 – 2001)

| Tahun Year | Ubat racun Prescription drugs | | Ubat bukan racun OTC products | | Ubat tradisional Traditional medicines | | Kosmetik Cosmetics | | Jumlah Total | |
|-------------------------|----------------------------------|------------------|----------------------------------|------------------|---|------------------|-----------------------|------------------|-----------------|------------------|
| | Temp Local | Import Import | Temp Local | Import Import | Temp Local | Import Import | Temp Local | Import Import | Temp Local | Import 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 |
| 2000 | 2,742 | 6,071 | 3,080 | 2,992 | 4,400 | 4,150 | 215 | 1,252 | 10,451 | 14,465 |
| 2001 | 2,770 | 6,223 | 3,454 | 3,242 | 5,560 | 4,334 | 319 | 1,457 | 12,103 | 15,256 |
| Jumlah Total | 8,993 | | 6,696 | | 9,894 | | 1,776 | | 27,359 | |

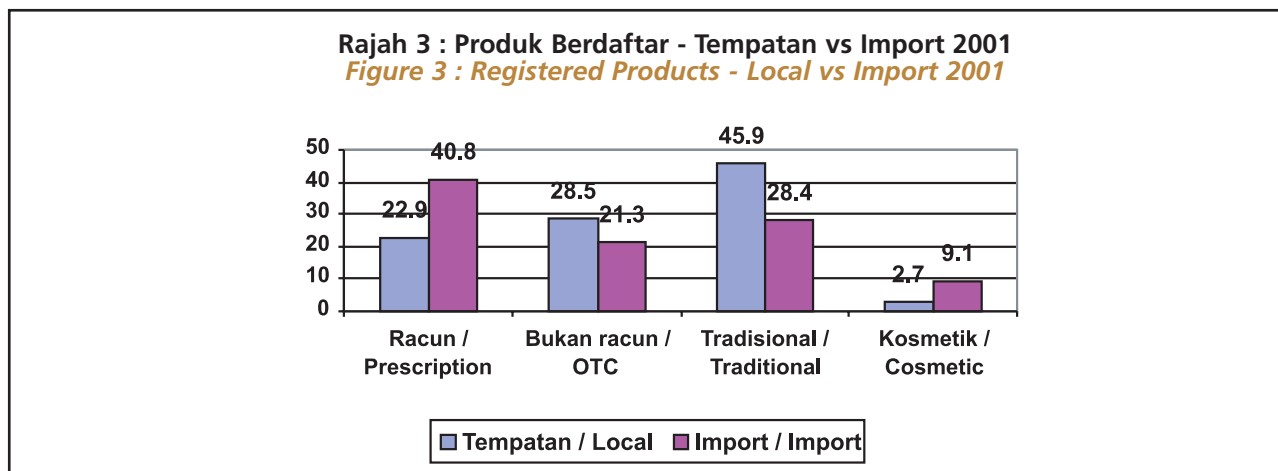
Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

Semenjak 2001, peratusan nisbah antara produk tempatan dan produk import untuk ubat racun adalah 31:69 seperti data dalam Jadual 5. Bagi ubat bukan racun, peratusan keluaran tempatan adalah lebih tinggi seperti mana ditunjukkan dalam nisbah 52:48. Peratusan untuk ubat tradisional adalah 56:44, menunjukkan peratusan keluaran yang dikilang secara tempatan adalah lebih tinggi manakala peratusan nisbah kosmetik pula adalah 18:82.

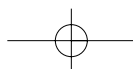
As of 2001, the percentage ratio between locally-manufactured and imported products for prescription drugs is in the order of 31:69 as shown by data in Table 5. For OTC products the percentage of locally-manufactured products is slightly higher as indicated by a ratio of 52:48. The percentage ratio for traditional medicines is shown to be 56:44, indicating a higher proportion of locally manufactured products whereas the percentage ratio for cosmetics is 18:82.

Merujuk kepada jumlah produk tempatan yang didaftarkan (n = 12,103) seperti pada Jadual 5, 2,770 (22.9%) adalah ubat racun, 3,454 (28.5%) ubat bukan racun, 5,560 (45.9%) ubat tradisional dan 319 (2.7%) kosmetik. Untuk produk import, berdasarkan kepada jumlah yang didaftarkan (n = 15,256), 6,223 (40.8%) adalah ubat racun, 3,242 (21.3%) ubat bukan racun, 4,334 (28.4%) ubat tradisional dan 1,457 (9.1%) kosmetik (Rajah 3).

Based on the total number of locally-manufactured products registered (n = 12,103) as presented in Table 5, 2,770 (22.9%) are prescription drugs, 3,454 (28.5%) OTC products, 5,560 (45.9%) traditional medicines and 319 (2.7%) cosmetics. For imported products, based on the total number registered (n = 15,256), 6,223 (40.8%) are prescription drugs, 3,242 (21.3%) OTC products, 4,334 (28.4%) traditional medicines and 1,457 (9.1%) cosmetics (Figure 3).



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

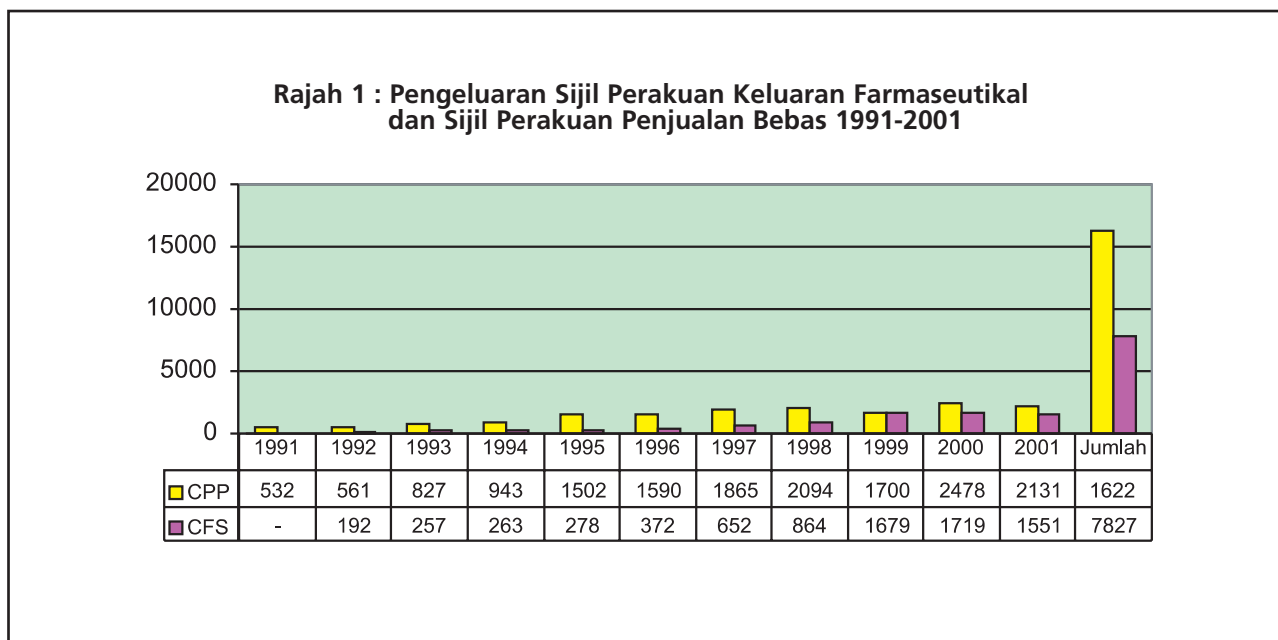


KEBENARAN EKSPORT

Pengeluaran sijil perakuan keluaran farmaseutikal [Certificates of Pharmaceutical Products (CPP)] dan sijil perakuan penjualan bebas [Certificates of Free Sale (CFS)] untuk alatan perubatan dan kosmetik telah bertambah sejak 1987 sehingga 2001. Sejumlah 2,131 CPP dan 1,551 CFS telah dikeluarkan pada tahun 2001 berbanding 2,478 CPP dan 1,719 CFS pada tahun 2000 (**Rajah 4**).

EXPORT AUTHORISATION

*Issuance of certificates of pharmaceutical products (CPP) and certificates of free sale (CFS) for medical devices and cosmetics for export authorisation had increased steadily since 1987 and 2001 respectively. A total of 2,131 CPP and 1,551 CFS had been issued in year 2001 compared to 2,478 CPP and 1,719 CFS in year 2000 (**Figure 4**).*



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

SUMBER PRODUK

10 negara pengeluar utama ialah China, Amerika Syarikat, Australia, Indonesia, Thailand, Jerman, India, Switzerland, Perancis dan Itali. Negara-negara ini meliputi lebih kurang 75% (9,433) daripada jumlah keluaran import. Produk yang diimport dari negara-negara ASEAN seperti Indonesia, Thailand, Singapura, dan Filipina meliputi hampir 14.6 % (1,841).

SOURCES OF PRODUCTS

The top 10 leading foreign sources include China, United States of America (USA), Australia, Indonesia, Thailand, Germany, India, Switzerland, France and Italy. Together they account for approximately 75% (9,443) of our total imports. Products imported from neighbouring ASEAN countries, which include Indonesia, Thailand, Singapore and Philippines constitute nearly 14.6% (1,841).

BAHAGIAN APB DAN PELESENAN

OBJEKTIF

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

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

PENCAPAIAN

Pemeriksaan APB

Sebanyak 126 pemeriksaan APB telah dijalankan pada tahun 2001 berbanding 126 pada tahun 2000 dan 120 pada tahun 1999. Pemeriksaan tersebut meliputi 61 premis pengilang keluaran racun, 19 keluaran bukan racun, 45 ubat tradisional dan 1 kosmetik. **Rajah 1** menunjukkan statistik pemeriksaan APB bagi tahun 1995 hingga 2001.

GMP AND LICENSING DIVISION

OBJECTIVES

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

ACTIVITIES

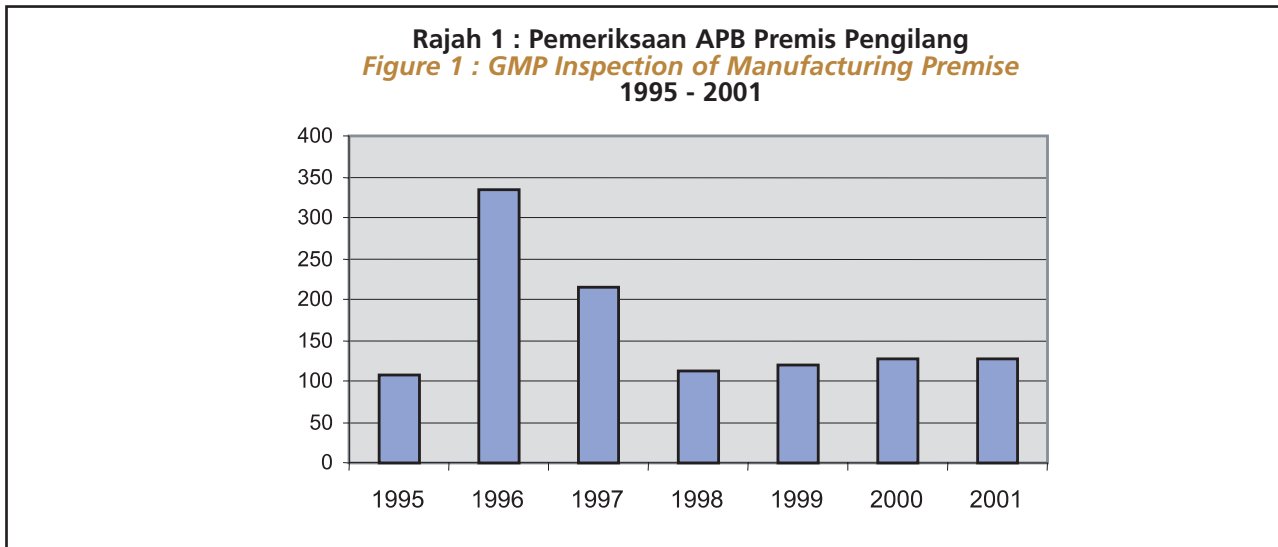
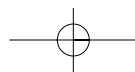
This division carries out the following activities:

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

ACHIEVEMENTS

GMP Inspection

A total of 126 inspections were conducted in 2001 as compared with 126 in 2000 and 120 in 1999. These inspections included 61 premises for scheduled poison manufacturers, 19 non-scheduled poison manufacturers, 45 traditional medicines and 1 cosmetic. **Figure 1** shows the number of GMP inspections carried out since 1995 until 2001.



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Penilaian Pelan Premis Pengilang

Sejumlah 35 pelan susun-atur premis pengilang baru dan sediaada telah dinilai, termasuk 7 premis pengilang keluaran racun, 9 keluaran bukan racun, 13 ubat tradisional, 3 kosmetik dan 3 lain-lain.

Evaluation of Manufacturing Premises Lay-out Plans

A total of 35 lay-out plans for new and existing manufacturing premises were evaluated, which included 7 premises of scheduled poisons manufacturers, 9 non-scheduled poison, 13 traditional medicines, 3 cosmetics and 3 others.

Status Perkembangan Premis Berlesen

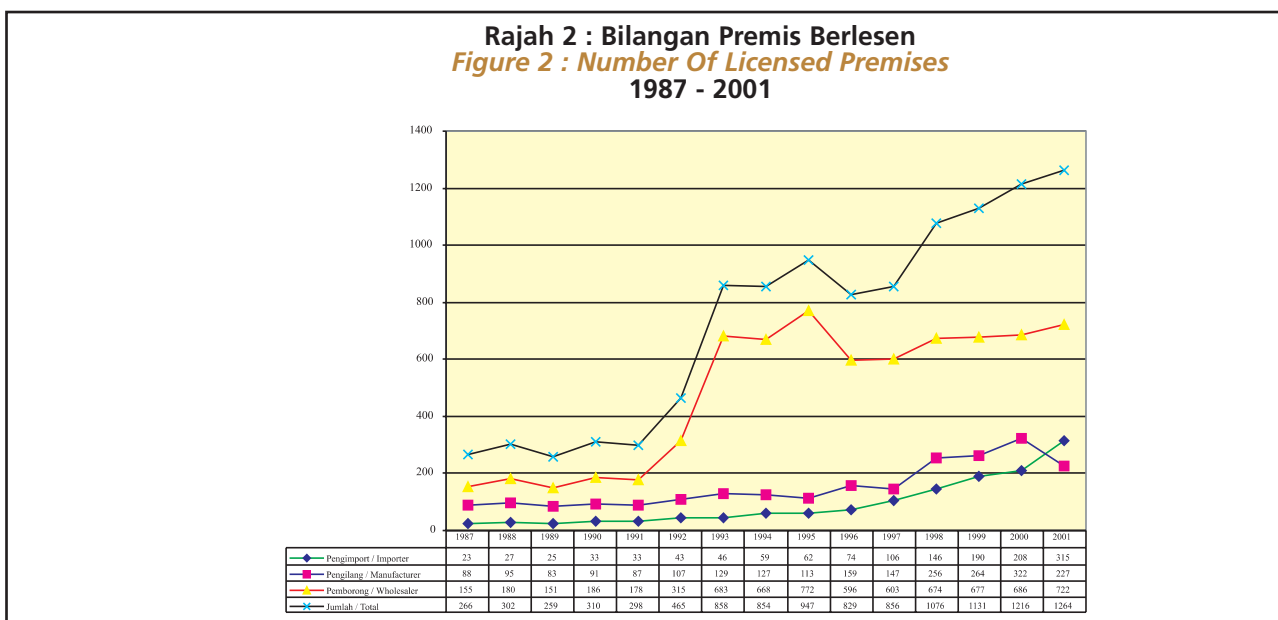
Status perkembangan premis-premis pengilang, pengimport dan pemborong berlesen bagi tahun 1987 hingga 2001 adalah seperti yang dipaparkan dalam **Rajah 2**. Pada tahun 2001, jumlah pengilang berlesen ialah 227, pengimport 315 dan pemborong 722, menjadikan jumlah besar adalah 1,264.

Growth Status of Licensed Premises.

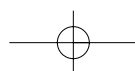
Growth status of licensed premises for manufacturers, importers and wholesalers for the year 1987 until 2001 are shown in **Figure 2**. In 2001, there were 227 licensed manufacturers, 315 licensed importers and 722 licensed wholesalers contribute to 1264 in total.

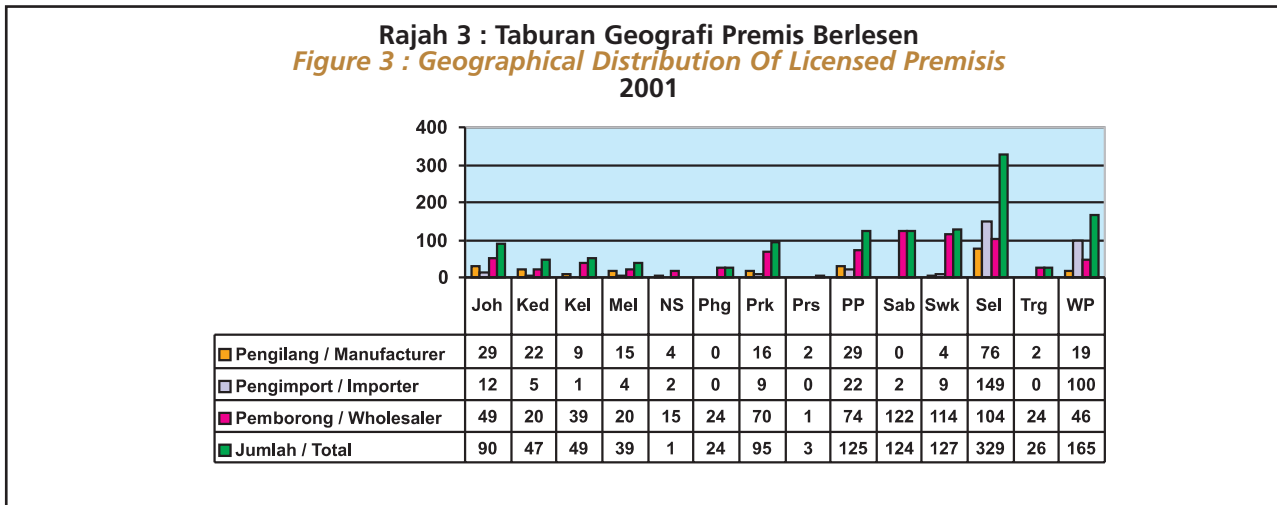
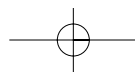
Senarai serta maklumat lengkap mengenai premis-premis berlesen boleh dilayari menerusi laman web BPFK (www.bpfk.gov.my).

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



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau





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

Taburan Geografi Premis Berlesen

Taburan geografi premis-premis berlesen bagi tahun 2001 adalah seperti yang digambarkan dalam **Rajah 3**. Negeri Selangor mempunyai premis berlesen yang paling banyak, diikuti oleh Wilayah Persekutuan (Kuala Lumpur) dan Pulau Pinang di tempat ketiga.

Geographical Distribution of Licensed Premises.

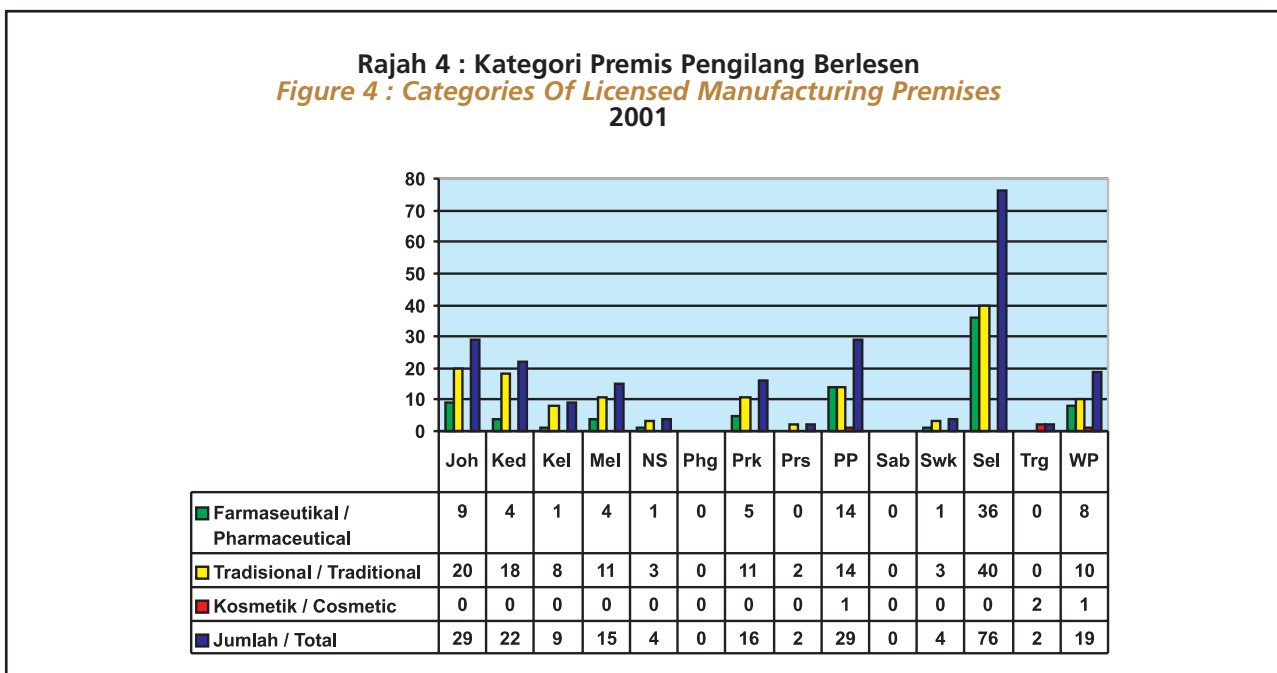
Geographical distribution of licensed premises for the year 2001 is illustrated in **Figure 3**. Selangor scored the highest number of licensed premises, followed by Wilayah Persekutuan (Kuala Lumpur) and Pulau Pinang at the third place.

Kategori Pengilang Berlesen

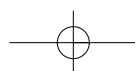
Kategori premis pengilang berlesen bagi tahun 2001 adalah seperti yang dipaparkan dalam **Rajah 4**. Negeri selangor mempunyai bilangan premis pengilang yang tertinggi diikuti oleh Johor dan Pulau Pinang.

Categories of Licensed Manufacturing Premises

Categories of licensed manufacturing premises for the year 2001 are illustrated in **Figure 4**. Selangor scored the highest number of licensed manufacturing premises, followed by Johor and Pulau Pinang.



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

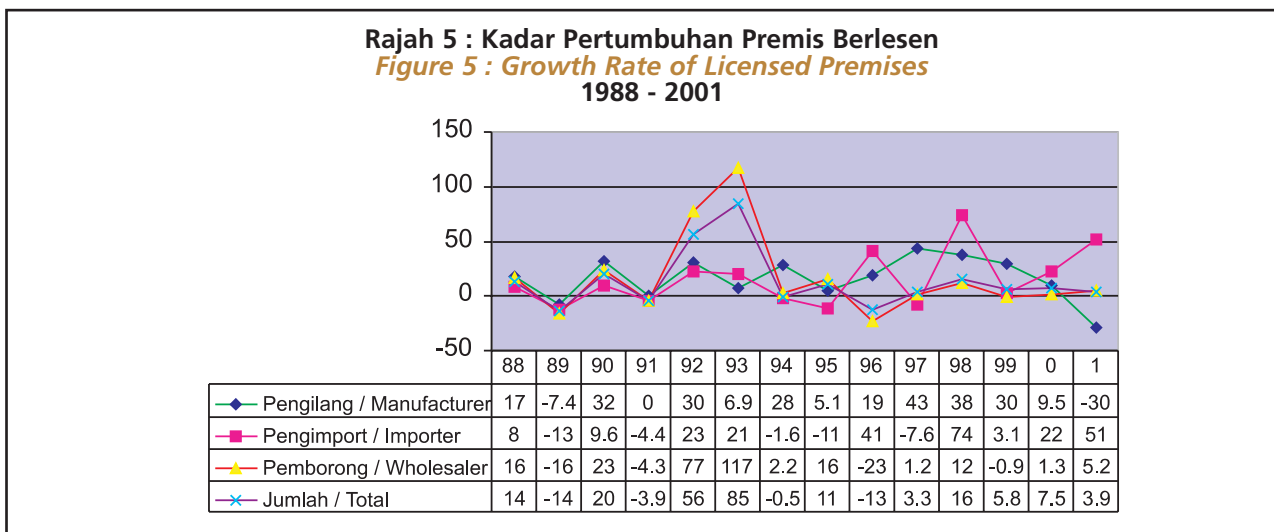


Kadar Pertumbuhan Premis Berlesen

Kadar pertumbuhan premis berlesen adalah seperti yang digambarkan dalam **Rajah 5**. Bagi tahun 2001, pengimport menunjukkan kadar pertumbuhan yang paling tinggi berbanding pengilang dan pemborong. Pada keseluruhannya, kadar pertumbuhan yang dicatatkan ialah 3.9% berbanding 7.5% pada tahun 2000.

Growth Rate of Licensed Premises

Growth rate of licensed premises are illustrated in **Figure 5**. In 2001, importer shows the highest growth rate as compared to manufacturer and wholesaler. As a whole, recorded growth rate was 3.9% compared to 7.5% in year 2000.



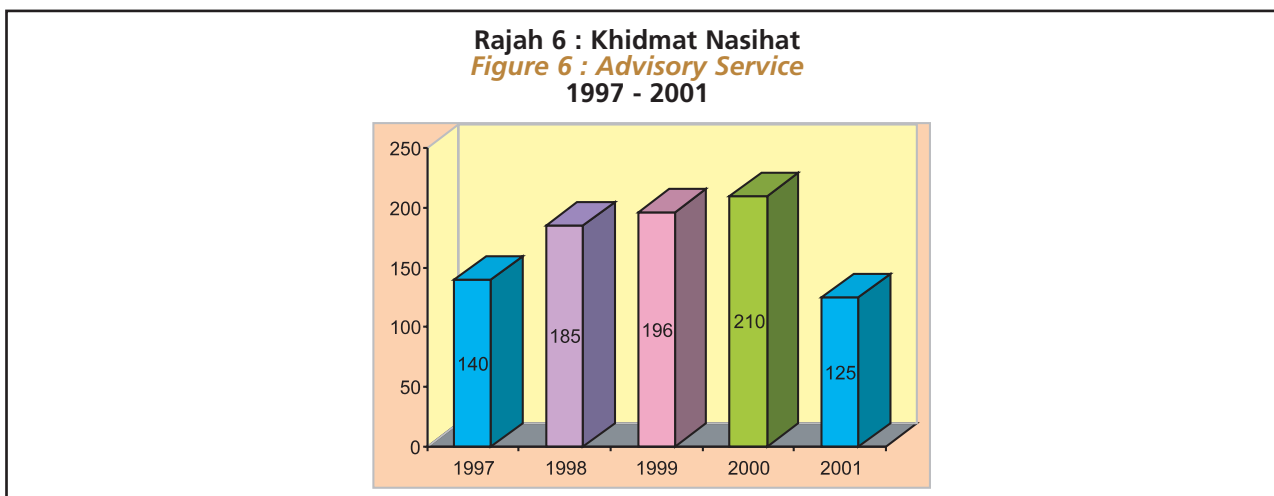
Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

Khidmat Nasihat

Bagi tahun 2001, sebanyak 125 khidmat nasihat telah diberikan berbanding 210 pada tahun 2000, 196 pada tahun 1999, 185 pada tahun 1998 dan 140 pada tahun 1997. Daripada jumlah yang dicapai, 13 daripadanya adalah berkaitan APB keluaran racun, 15 keluaran bukan racun, 73 ubat tradisional, 17 kosmetik dan 7 lain-lain. Statistik bagi tahun 1997 hingga 2001 adalah seperti yang ditunjukkan dalam **Rajah 6**.

Advisory Service

In 2001, a total of 125 advisory services were given compared to 210 in 2000, 196 in 1999, 185 in 1998 and 140 in 1997. From these numbers of achievements, 13 of them were related to GMP scheduled poison, 15 non-scheduled poison, 73 traditional medicine, 17 cosmetic and 7 others. Statistics for the year 1997 until 2001 is illustrated in **Figure 6**.



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

PEMROSESAN LESEN

Lesen Pengilang

Sebanyak 247 lesen pengilang telah diproses pada tahun 2001 berbanding 289 pada tahun 2000, 237 pada tahun 1999, 148 pada tahun 1998 dan 100 pada tahun 1997. Daripada jumlah ini, 26 adalah permohonan baru manakala 221 lagi adalah pembaharuan.

lesen Pengimport

Bagi lesen pengimport, sebanyak 330 permohonan telah diterima dan diproses. Daripada jumlah ini, 41 daripadanya adalah permohonan baru dan 289 adalah pembaharuan. Bilangan permohonan didapati telah menurun berbanding 424 pada tahun 2000, 305 pada tahun 1999, 255 pada tahun 1998 dan 171 pada tahun 1997. Bilangan permohonan yang diterima telah menurun sebanyak 22.2% daripada tahun sebelumnya.

Lesen Pemborong

Bilangan permohonan lesen pemborong yang diproses adalah sebanyak 774, di mana 73 daripadanya adalah permohonan baru dan 701 adalah pembaharuan. Bilangan permohonan yang diproses telah meningkat 6.3% berbanding tahun 2000.

LICENCE PROCESSING

Manufacturer's Licence

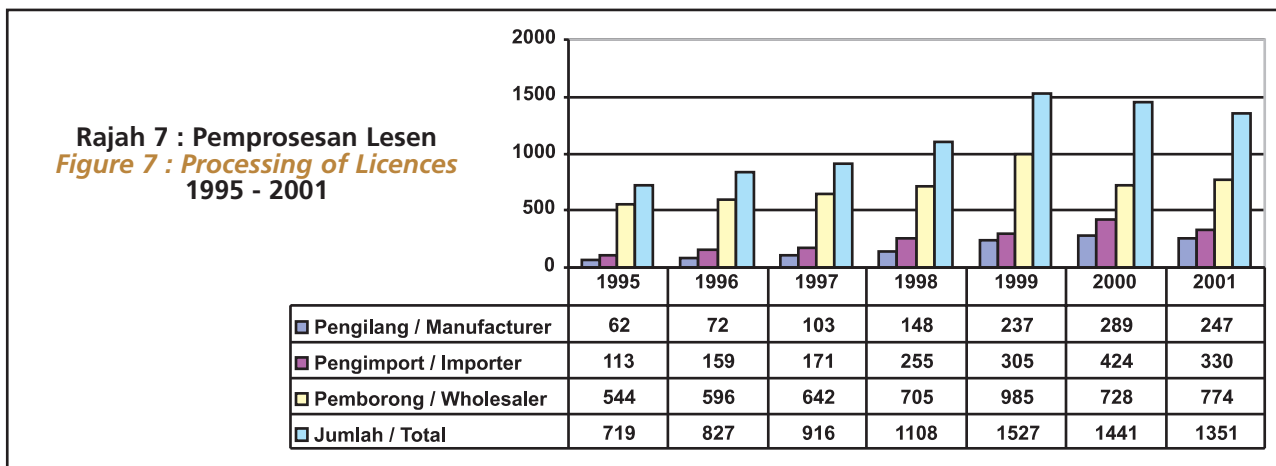
A total of 247 manufacturer's licences were processed in 2001 compared to 289 in 2000, 237 in 1999, 148 in 1998 and 100 in 1997. From this total number, 26 are new applications whereas the remaining 221 are renewals.

Importer's Licence

A total of 330 applications were received and processed for import licence. From this total, 41 applications are new applications and 289 are renewal. The number of applications has decreased significantly, compared to 424 in 2000, 305 in 1999, 255 in 1998 and 171 in 1997. The number of application has decreased by 22.2 % from the previous year.

Wholesaler's Licence

The number of application processed for wholesaler's licence was 774, whereby 73 were new applications and 701 renewals. The number of applications processed increased by 6.3% as compared in 2000.



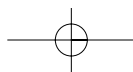
Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Senarai Tambahan Keluaran Berdaftar

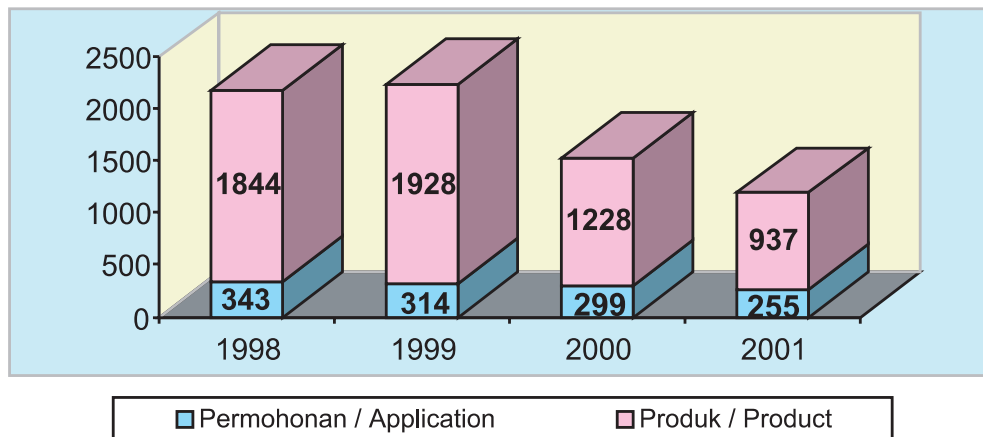
Jumlah permohonan yang diproses pada tahun 2001 adalah sebanyak 255 dan ini meliputi sebanyak 937 produk. Pada tahun 2000, jumlah permohonan adalah sebanyak 299 dan melibatkan 1,228 produk berbanding 314 permohonan yang melibatkan 1,928 produk pada tahun 1999 dan 343 permohonan melibatkan 1,844 produk pada tahun 1998. **Rajah 8** menunjukkan statistik bagi pengeluaran senarai tambahan produk untuk tahun 1998 hingga 2001.

Additional Lists for Registered Products

The total number of applications processed in 2001 was 255 and these include 937 products. In 2000, the number of applications was 299 and these include 1,228 products compared with 314 applications and 1,928 products in 1999, 343 applications and 1,844 products in 1998. **Figure 8** shows statistic for issuance of additional registered product list for the year 1998 until 2001.



Rajah 8 : Senarai Tambahan Keluaran Berdaftar
Figure 8 : Issuance Of Additional Registered Product List
 1998 - 2001



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

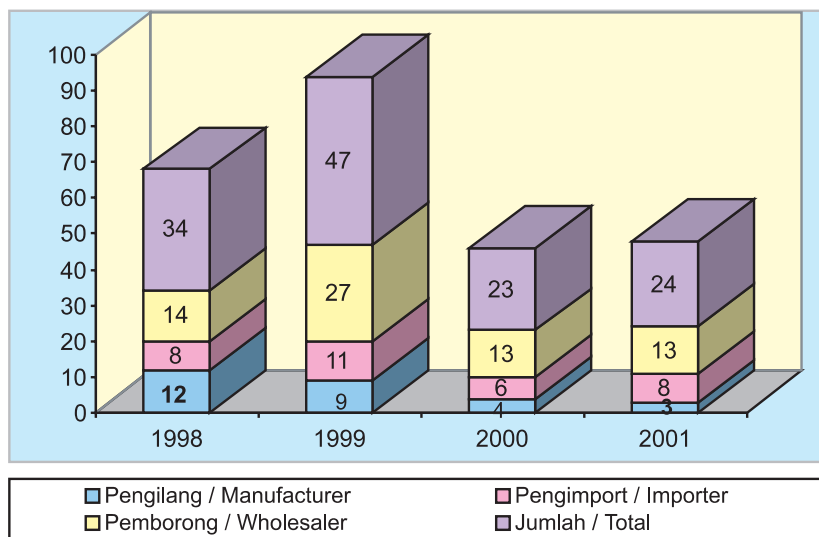
Pertukaran Pemegang Lesen

Bagi tahun 2001, sebanyak 24 permohonan pertukaran pemegang lesen telah diproses di mana 3 adalah untuk pengilang, 8 pengimport dan 13 pemborong. Bilangan yang dicapai telah meningkat 4.3% berbanding tahun 2000. Statistik bagi permohonan pertukaran pemegang lesen bagi tahun 1998 hingga 2001 adalah seperti yang ditunjukkan dalam **Rajah 9**.

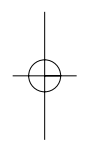
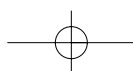
Change of Licence Holder.

*In 2001, a total of 24 applications for change of licence holder were processed, whereby 3 were manufacturers, 8 importers and 13 wholesalers. The number of achievements was increased to 4.3% as compared in 2000. Statistics for change of holder for the year 1998 until 2001 is illustrated in **Figure 9**.*

Rajah 9 : Permohonan Pertukaran Pemegang Lesen
Figure 9 : Application for Change of Holder
 1998 - 2001



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau



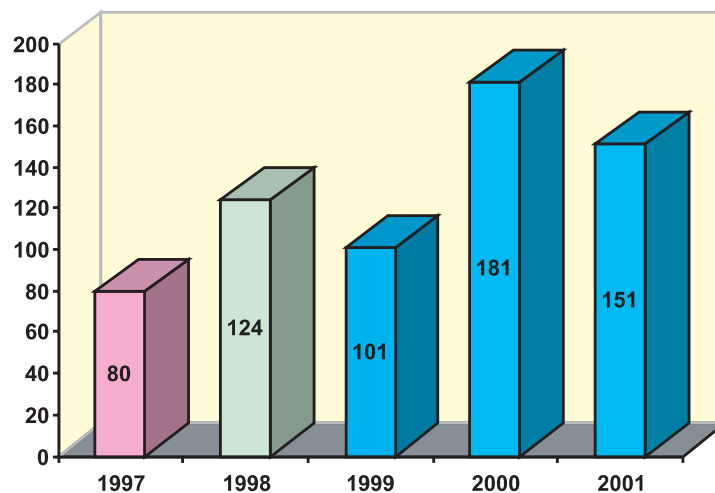
Perakuan APB Untuk Tujuan Eksport

Pada tahun 2001, jumlah perakuan APB yang dikeluarkan adalah sebanyak 151 berbanding 181 pada tahun 2000, 101 pada tahun 1999, 124 pada tahun 1998 dan 80 pada tahun 1997. Perakuan ini adalah untuk negara-negara seperti Albania, Barbados, Botswana, Brazil, Brunei, Bulgaria, Kemboja, China, Costa Rica, Denmark, Mesir, Ethiopia, Honduras, Hong Kong, India, Iraq, Jordan, Kenya, Korea, Kuwait, Laos, Libya, Lithuania, Malawi, Maldives, Malta, Mauritius, Mexico, Morocco, Myanmar, New Zealand, Nigeria, Oman, Papua New Guinea, Filipina, Poland, Arab Saudi, Sierra Leone, Singapura, Slovakia, Sri Lanka, Afrika Selatan, Surinam, Taiwan, Tanzania, Thailand, Turki, Uganda, Venezuela, Vietnam, Yaman dan Zambia.

GMP Certification

In 2001, the total number of GMP certificates issued was 151, as compared with 181 in 2000, 101 in 1999, 124 in 1998 and 80 in 1997. These certifications are for countries such as Albania, Australia, Barbados, Botswana, Brazil, Brunei, Bulgaria, Cambodia, China, Costa Rica, Denmark, Egypt, Ethiopia, Honduras, Hong Kong, India, Iraq, Jordan, Kenya, Korea, Kuwait, Laos, Libya, Lithuania, Macau, Malawi, Maldives, Malta, Mauritius, Mexico, Morocco, Myanmar, New Zealand, Nigeria, Oman, Papua New Guinea, Philippines, Poland, Saudi Arabia, Sierra Leone, Singapore, Slovakia, Sri Lanka, South Africa, Sudan, Suriname, Taiwan, Tanzania, Thailand, Turkey, Uganda, Venezuela, Vietnam, Yemen, and Zambia.

Rajah 10 : Permohonan Perakuan Amalan Perkilangan Baik (APB)
Figure 10 : Application of Good Manufacturing Practice (GMP) Certificates
1997 - 2001



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Tindakan Punitif

Pihak Berkuasa Kawalan Dadah (PBKD) telah menggantung sementara lesen pengilang bagi 2 premis pada tahun 2001 berbanding 4 pada tahun 2000, 5 pada tahun 1999, 3 pada tahun 1998 dan 6 pada tahun 1997.

Punitive Actions

DCA has temporarily suspended manufacturer's licences or part of manufacturing lines for two premises in 2001 compared with 4 in 2000, 5 in 1999, 3 in 1998 and 6 in 1997.

TWG GMP

Kumpulan kerja teknikal (TWG) GMP telah menganjurkan 4 bengkel latihan APB bercorak modul untuk industri farmaseutikal. Bidang-bidang yang diliputi adalah seperti berikut :

TWG GMP

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

Module 1 – Quality Assurance and GMP Auditing

Module 2 – GMP Documentation and Records

Module 3 – Introduction to Good Laboratory Practices

Module 4 – GMP for Utilities & Services

Seminar APB

Latihan dokumentasi untuk pengilang ubat tradisional telah diadakan di Langkawi, Kedah pada 25 – 26 April 2001 dengan dibantu oleh PURBATAMA Northern Branch. Satu seminar mengenai 'Current Good Manufacturing Practices for Pharmaceuticals' juga telah diadakan. Seminar ini dikendalikan oleh Mr. Alan Duff, juruaudit dari TGA Australia dengan kerjasama MOPI (Malaysian Organisation of Pharmaceutical Industries).

Permohonan Untuk Menjadi Ahli PIC/S

Pada 12 – 16 Mac 2001, satu delegasi seramai enam juruaudit dari PIC/S, yang diketuai oleh pengerusinya, Mr. Bob Tribe, Mr. Daniel Brunner dan delegasi dari United Kingdom, Switzerland, Republik Slovak dan Singapura telah datang untuk menilai Sistem Kualiti APB dan prosedur pemeriksaan. Delegasi tersebut juga telah membuat pemerhatian ke atas juruaudit APB (BPFK) semasa pengauditan empat premis kilang. Secara keseluruhannya, para juruaudit berpuas hati dengan sistem kualiti dan mutu pengauditan yang dilakukan. Walaubagaimanapun, masih terdapat sedikit kelemahan yang perlu diperbaiki dan diambil tindakan sebelum diterima menjadi ahli PIC/S.

Dalam 'Mesyuarat Rasmi Jawatankuasa PIC/S' di Prague, Republik Czech pada 21 – 25 Mei 2001, mereka mengambil keputusan untuk menerima Malaysia sebagai ahli PIC/S mulai 1 Januari 2002, dengan syarat Malaysia haruslah mengambil beberapa langkah untuk memperbaiki semua kelemahan yang dikenalpasti melalui audit terdahulu.

Audit susulan telah dijalankan oleh dua juruaudit yang diketuai oleh Mr. Bob Tribe, pengerusi PIC/S dan Mr. Sia dari Singapura

Module 1 – Quality Assurance and GMP Auditing

Module 2 – GMP Documentation and Records

Module 3 – Introduction to Good Laboratory Practices

Module 4 – GMP for Utilities & Services

GMP Seminar

Documentation training for traditional medicine manufacturers was conducted in Langkawi, Kedah on 25 – 26 April 2001 with the assistance of PURBATAMA Northern Branch, for traditional manufacturers. A seminar on Current Good Manufacturing Practices for pharmaceuticals was also conducted by Mr. Alan Duff, Senior Auditor of TGA Australia with the co-operation of Malaysia Organization of Pharmaceutical Industries (MOPI).

Application of Pharmaceutical Inspection Cooperation Scheme - PIC/S Membership

On 12 – 16 March 2001, a delegate of six auditors from PIC/S, lead by its chairman Mr. Bob Tribe, PIC/S Secretary, Mr. Daniel Brunner and delegates from United Kingdom, Switzerland, Slovak Republic and Singapore evaluated our GMP Quality System and inspection procedures. The delegates observed our GMP auditors during the auditing of four manufacturing premises. Overall they were quite satisfied with our quality system and the standard of auditing but there were still some weaknesses that we had to improve and take action before we become a member.

During the PIC/S Committee of Official Meeting in Prague, Czech Republic on 21 - 25 May 2001, the committee decided to admit Malaysia as a member of PIC/S from 1 January 2002, provided that Malaysia take the necessary action on all the weaknesses from previous audit.

Follow-up audit by a delegate of two auditors lead by Mr. Bob Tribe, chairman of PIC/S and Mr. Sia from Singapore. Our auditors conducted the

semasa juruaudit BPFK mengendalikan pemeriksaan ke atas dua premis. Mereka amat berpuas hati dengan langkah-langkah yang diambil untuk memperbaiki kelemahan serta peningkatan dalam tahap/mutu pengauditan tersebut.

Dalam 'Mesyuarat Rasmi Jawatankuasa PIC/S Ke-13' di Geneva pada 27 dan 28 November 2001, pengerusi PIC/S dengan rasminya telah mengumumkan bahawa Malaysia telah diterima sebagai ahli PIC/S yang ke-26 mulai 1 Januari 2002.

Garis panduan APB Kosmetik

Draf akhir 'Garis panduan APB Kosmetik' telah dibincangkan ketika 'ASEAN Consultative Committee for Standard and Quality (ACCSQ) Cosmetic Product Working Group' di Ho Chi Minh, Vietnam. Anggota ASEAN telah bersetuju untuk menggunakannya sebagai 'Garis panduan Kosmetik ASEAN'.

Seminar Mengenai Pendaftaran Kosmetik

Bahagian ini juga terlibat dalam seminar yang dianjurkan bersama dengan Unit Kosmetik untuk memupuk kesedaran mengenai keperluan pendaftaran, Amalan Perkilangan Baik (APB) untuk kosmetik dan dokumentasi lain. Ia meliputi Sabah dan Sarawak.

Juruaudit Kontrak

Latihan APB telah disediakan kepada Pegawai Penguatkuasa, Unit Penguatkuasa Negeri yang seterusnya akan dilantik sebagai juruaudit kontrak. Kerjasama dengan Unit Penguatkuasa Negeri telah dipertingkatkan melalui pemeriksaan bersama yang dijalankan ke atas pengilang ubat tradisional, farmaseutikal dan OTC.

PERANCANGAN UNTUK TAHUN 2002

Latihan APB Farmaseutikal Bercorak Modul

Program latihan APB bercorak modul akan bermula pada Februari dan berakhir pada Jun 2002. Program ini dikelola bersama dengan MOPI.

audit on two premises. They were very impressed and satisfied with the actions taken on the weaknesses and improvements on the standard of the audit.

On the 13th PIC/S Committee Official Meeting in Geneva on 27 and 28 November 2001, the Chairman officially announced that Malaysia is accepted as 26th member of PIC/S starting from 1 January 2002.

Cosmetic GMP Guidelines

The final draft of Cosmetic GMP Guidelines was discussed during ASEAN Consultative Committee for Standard and Quality (ACCSQ) Cosmetic Product Working Group in Ho Chi Minh City, Vietnam. Principly ASEAN members agreed to adopt it as ASEAN Cosmetic Guidelines.

Cosmetic Registration Awareness Road Show

This division was also involved in the road show together with Cosmetic Unit to create the awareness on the requirement of registration, requirement of GMP for cosmetic and other documentation. It covered central, northern, southern region, Sarawak and Sabah.

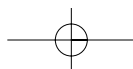
Contract Auditor

GMP training was provided to chosen Enforcement Officers of the State Enforcement Unit who were later appointed as Contract Auditors. The co-operation with the State Enforcement Unit was enhanced by joint inspection in the pre-licensing inspection of traditional medicine manufacturers, pharmaceutical and over-the-counter (OTC) manufacturers.

PLANS FOR YEAR 2002.

GMP Modular Training

The GMP modular training will start in February and ends in June 2002. This program is jointly organized with MOPI.



Module 5 – GMPs for Equipment, Cleaning and Computerized System

Module 6 – Process Validation, Plan and Protocol

Module 7 - Facility, Materials and Environment Control

Module 8 - Process Control- Manufacturing and Packaging

Module 9 - Staff Development and GMP Training

Pusat Industri Farmaseutikal

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

Keahlian PIC/S

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

Bengkel Dokumentasi APB untuk Pengilang Ubat Tradisional

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

ASEAN Pharmaceutical Harmonization

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

Module 5 – GMPs for Equipment, Cleaning and Computerized System

Module 6 – Process Validation, Plan and Protocol

Module 7 - Facility, Materials and Environment Control

Module 8 - Process Control- Manufacturing and Packaging

Module 9 - Staff Development and GMP Training

Pharmaceutical Industry Centre

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

PIC/S Members

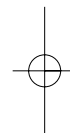
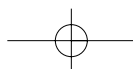
As Malaysia will be a member of PICIS by 1 January 2002, we will be involved in a lot of PICIS activity such as meetings, seminars, training, joint inspections and others. Malaysia as a new member is encouraged to join as many activities as possible to ensure that we play an active role as a member.

GMP Documentation Workshop for Traditional Medicines Manufacturers

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

ASEAN Pharmaceutical Harmonization

Malaysia as a member of ASEAN Nation had contributed and plays an active part in the harmonization of ASEAN Pharmaceutical. As a member of PICIS, Malaysia will play its part in ensuring that the current GMP requirement will harmonize with the international guidelines.



BAHAGIAN SURVEILANS DAN FARMAKOVIGILANS

OBJEKTIF

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

PENCAPAIAN

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

SURVEILLANCE & PHARMACOVIGILANCE DIVISION

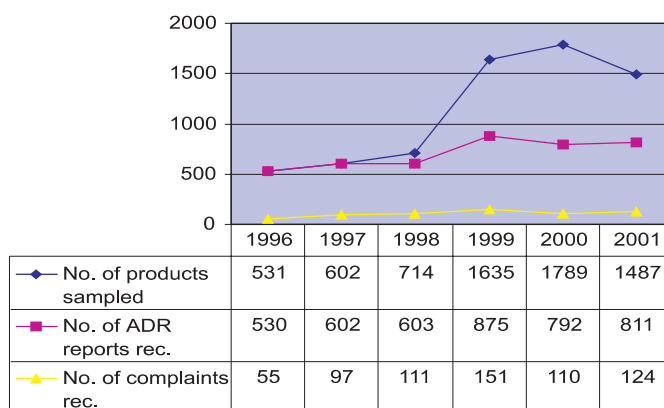
OBJECTIVES

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

ACHIEVEMENTS

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

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



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

SURVEILANS

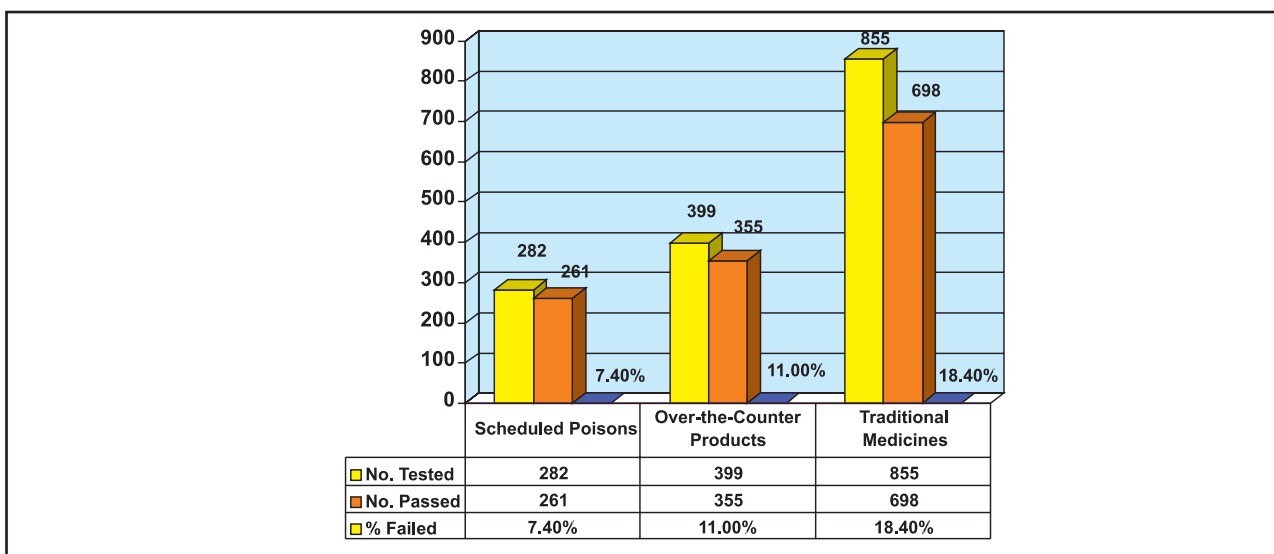
Untuk tahun 2001, 1487 sampel keluaran berdaftar di Malaysia telah diambil untuk surveilans. Walaupun ini hanya mewakili 5.5% jumlah produk yang berdaftar dibawah PBKD, ia memberi satu petanda ukur yang memuaskan terhadap kualiti produk yang terdapat di dalam pasaran tempatan.

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

SURVEILLANCE

During the year 2001, a total of 1487 registered products were sampled for quality testing. Although this represents only approximately 5.5% of the total number of products registered by the DCA, it gives a fairly good reflection of the quality of products available on the local market.

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



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau

Disebabkan lebih dari tahun sebelumnya, keputusan daripada makmal adalah untuk 1536 keluaran. Analisis kadar kegagalan keluaran yang telah diuji berdasarkan kategori keluaran ditunjukkan pada **Gambarajah 2**.

*Due to a spillover from the previous year, results were received from the laboratory for 1536 products. An analysis of the failure rate of products tested by category of products is shown in **Fig.2**.*

PANGGILBALIK

RECALLS

Bukan kesemua produk yang gagal ujian makmal memerlukan panggilanbalik. Sekiranya kegagalan ujian tersebut tidak mempengaruhi kualiti produk secara ketara, surat amaran dikemukakan kepada pemegang pendaftaran. Arahan telah dikeluarkan untuk membuat panggilanbalik terhadap 100 kelompok keluaran dimana 9 adalah keluaran racun berjadual, 6 persediaan bukan racun dan 85 keluaran tradisional. 22 keluaran lagi (13 – racun; 7 – bukan racun; 2 – tradisional) telah dipanggilbalik secara sukarela oleh pemegang pendaftaran keluaran berdasarkan aduan yang diterima terhadap keluaran tersebut.

*Not all products which fail the laboratory tests are required to be recalled. Where the tests failed are deemed not to significantly affect the quality of products, warning letters are issued to the registration holders. Instructions were issued for the recall of 100 batches of products of which 9 were products containing scheduled poisons, 6 were over-the-counter preparations and 85 were traditional medicines. 22 other products (13 - poisons; 7 - OTC; 2 - traditional) were recalled voluntarily by the product registration holders mainly based on product complaints (**Table 1**).*

Tiada panggilanbalik yang begitu serius yang menghendaki panggilanbalik Paras I atau II. Semua panggilanbalik adalah panggilanbalik Paras III, Tahap B iaitu dilakukan dalam tempoh 30 hari dan sehingga tahap peringkat penjualan/pembekalan kepada pelanggan.

There were no recalls which were serious enough to warrant a Degree I or Degree II recall. All recalls were Degree III recalls i.e. carried out over period of 30 days and were done up to Level B which is up to the point of distribution.

Table 1: Product Recalls (directive + voluntary)

| Year | 1996 | 1997 | 1998 | 1999 | | | 2000 | | | 2001 | | |
|----------------------|------|------|------|------|----|----|------|----|----|------|----|----|
| Total No. of Recalls | 37 | 32 | 93 | 148 | | | 148 | | | 122 | | |
| Category (A/X/T) | NA | NA | NA | 35 | 20 | 93 | 32 | 17 | 99 | 22 | 13 | 87 |

A=Poisons; X=OTC; T=Traditional

ADUAN TERHADAP KELUARAN BERDAFTAR

Bilangan aduan terhadap keluaran berdaftar bertambah ke 124 Keluaran aduan dalam tahun 2001 berbanding 110 aduan dalam tahun 2000.

Tindakan susulan telah diambil untuk menyelesaikan aduan-aduan ini dalam tempoh 6 minggu dalam lebih dari 90% kes.

PEMONITORAN ADR

Terdapat sedikit peningkatan dalam jumlah laporan kesan advers ubat yang diterima dalam tahun 2001, iaitu sebanyak 811 laporan berbanding dengan 794 laporan dalam tahun 2000 (**Gambarajah 3**).

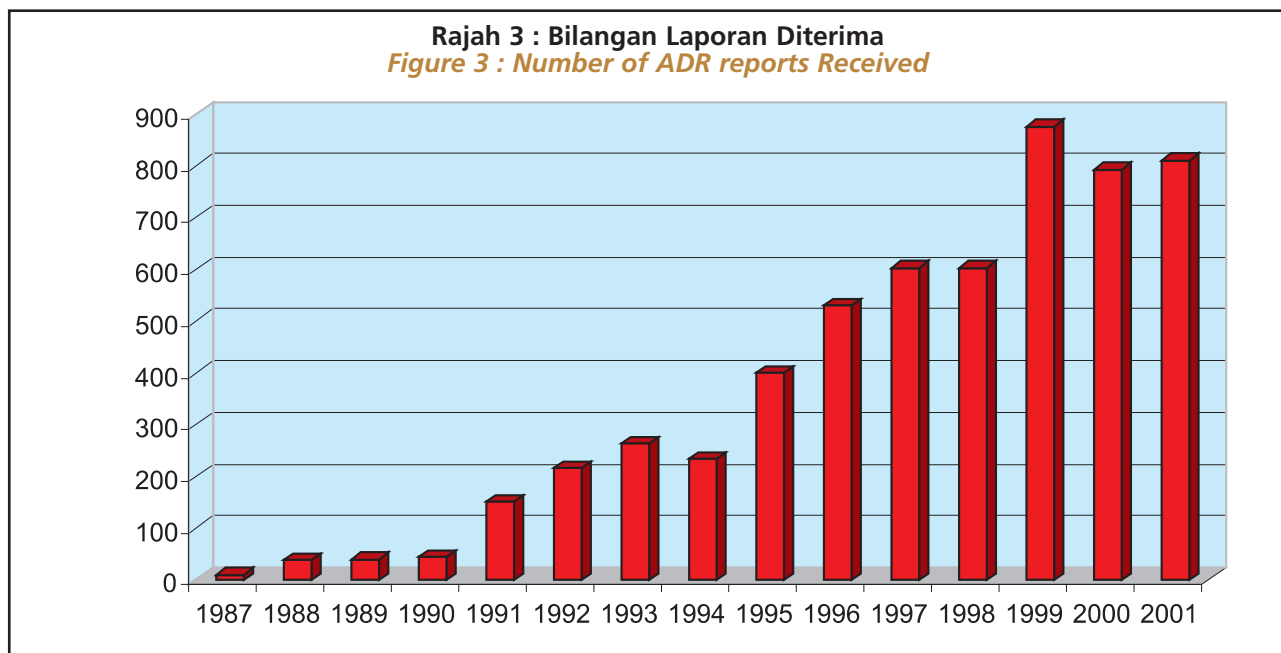
PRODUCT COMPLAINTS

The number of product complaints for registered products increased in 2001 with a total of 124 complaints being received as compared to 110 in the previous year.

Action was taken to resolve these complaints within 6 weeks in more than 90% of the cases.

ADR MONITORING

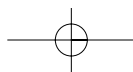
The number of adverse drug reactions reports received increased slightly in 2001 as a total of 811 reports were received as to 794 in 2000 (**Fig. 3**).



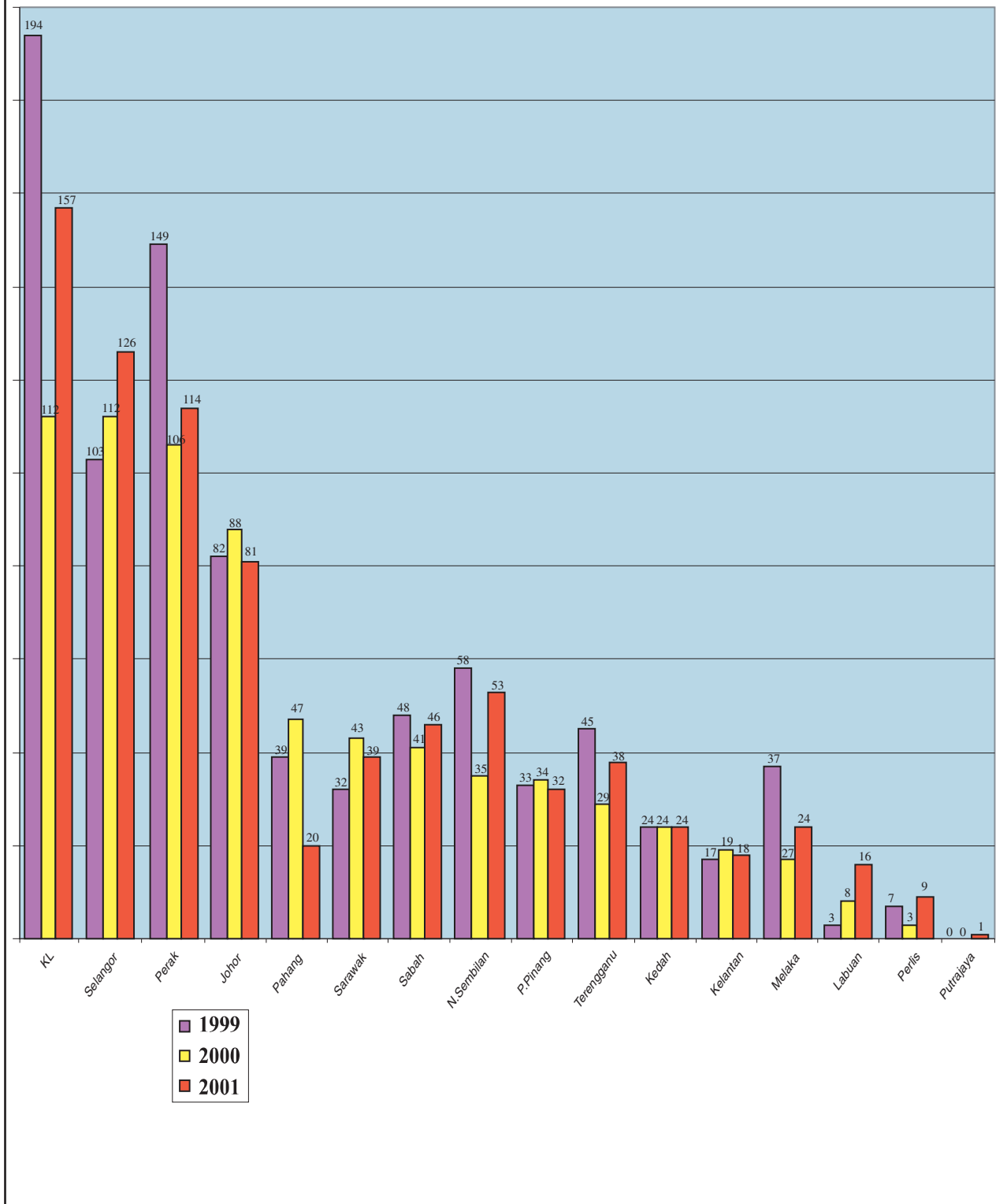
Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

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

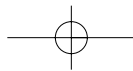
The reporting rate of the various states is as shown in **Figure 4** with the highest number of reports being submitted from the Kuala Lumpur General Hospital and from the state of Selangor.



ANALYSIS OF ADRs BY REPORTING STATES



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau



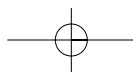
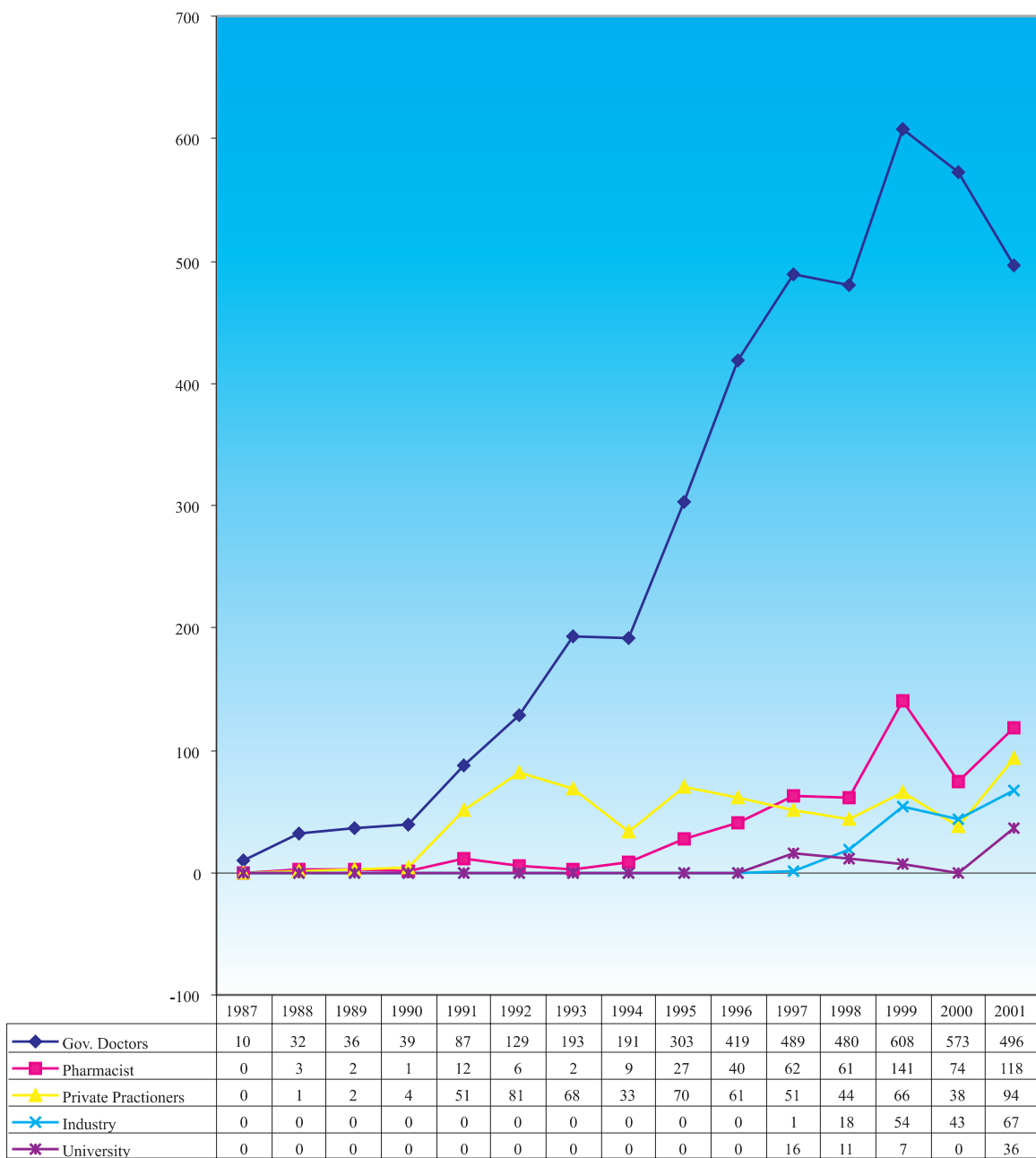
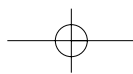
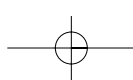


Fig. 5: Analisa Laporan ADR Berdasar Kepada Pelapor (Analysis of ADR Reporters)



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau





Usaha telah dijalankan untuk menggalakkan penglibatan daripada pelbagai bidang untuk mempertingkatkan kadar laporan ADR di mana sebelum ini banyak bergantung kepada doktor dari sektor awam.

PERJAWATAN

Terdapat beberapa perubahan ketara dalam perjawatan di bahagian ini. Oleh kerana kenaikan pangkat, Pn. Nik Noriah Nik Hussein telah meninggalkan bahagian ini manakala En. Kamaruzaman melanjutkan pendidikan dengan mengikuti program Ijazah Kedoktoran.

Pn. Mazlin Mastar, Pn. Sathikala dan Pn. Suriani Ibrahim menyertai bahagian ini untuk menggantikan pegawai-pegawai tersebut serta untuk mengisi satu jawatan yang baru dibentuk akibat bebanan kerja yang kian meningkat.

LATIHAN

Selaras dengan hasrat Biro Pengawasan Farmaseutikal Kebangsaan untuk melaksanakan sistem kualiti sejajar dengan standard ISO 9001, pegawai-pegawai farmasi bahagian ini telah diberikan latihan dalam ISO 9001.

Sejajar dengan pelaksanaan pendaftaran untuk barangan kosmetik, pegawai-pegawai farmasi bahagian ini turut menyertai Bengkel Pendaftaran Kosmetik yang dikendalikan bersama oleh BPFK dan industri kosmetik.

Pn. Abida Haq telah menyertai "DIA-TGA Fellowship Program on Post-Market Vigilance of Therapeutic Goods" di Australia selama 10 hari.

PRESENTAS

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

Pn. Abida Haq juga telah memberi satu presentasi bertajuk "Monitoring Traditional Medicines: The Malaysian Experience" pada mesyuarat "24th Annual Meeting of National Centres Participating in the WHO Program for Drug Safety Monitoring" di New Zealand.

PERANCANGAN

Selain dari surveilans rutin, bahagian surveilans juga merancang untuk menjalankan surveilans berdasarkan isu-isu khusus contohnya 'pengskrinan' ubat-ubatan tradisional untuk adulterasi.

Program latihan ADR khususnya untuk hospital sedang dirancang demi mempertingkatkan pelaporan ADR daripada hospital dan meningkatkan penglibatan farmasi hospital dalam program ini.

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. In 2001, there was a slight increase in the number of ADRs reported by doctors from the private sector. Unfortunately, the number of ADRs reported by doctors from government hospitals decreased slightly but there was a slight increase in the number of reports submitted by pharmacists. There was no significant difference in the monitoring of ADRs by pharmaceutical industry in 2001 as compared to 2000 (Fig.5).

STAFFING

The year 2001 saw some changes in this division with several significant changes to staffing. Pn. Nik Noriah Nik Husein left the division as a result of a promotion and Mr. Karamuzaman left to do a PhD.

Pn. Mazlin Mastar, Pn. Sathikala and Pn. Suriani Ibrahim joined this division to replace the officers who left and to fill a new post which was created in view of the increasing workload.

TRAINING

As the National Pharmaceutical Control Bureau was to implement a quality system in compliance to ISO 9001 standards, the pharmacists under this division were given training on ISO 9001.

In view of the implementation of the registration for cosmetics, the pharmacists also attended the Cosmetic Registration road shows which were conducted jointly by NPCB and the cosmetics industry.

Pn. Abida Haq attended the DIA-TGA Fellowship Program on Post-Market Vigilance of Therapeutic Goods in Australia.

PRESENTATIONS

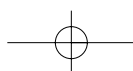
In line with the National Pharmaceutical Control Bureau's policy to provide training for the industry and to disseminate information to end-users, this division was involved in presenting several papers at various forums on topics pertaining to surveillance and drug safety monitoring.

Pn. Abida Haq also gave a presentation entitled "Monitoring Traditional Medicines: the Malaysian Experience" during the 24th Annual Meeting of National Centres Participating in the WHO Program for Drug safety Monitoring in New Zealand.

FUTURE PLANS

Besides the routine surveillance of registered products, the surveillance division plans to conduct surveillance based on specific issues such as screening of selected traditional medicines for adulteration.

An ADR training program especially for hospitals is being planned in a move to improve the reporting of ADRs from hospitals and also to increase the involvement of hospital pharmacists in this program.



BAHAGIAN ANALISIS UBAT

PENGAWALAN MUTU UBAT

Bahagian Analisis Ubat (BAU) meneruskan peranan yang efektif dalam kawalan kualiti produk yang merupakan satu komponen penting dalam penilaian produk farmaseutikal. Produk yang diterima merangkumi produk untuk permohonan pendaftaran, pengawalan mutu ubat di pasaran ke atas keluaran berdaftar, kes-kes aduan untuk keluaran berdaftar dan sampel dari penguatkuasaan. Ujian yang dijalankan meliputi ujian-ujian kimia, fizikal, mikrobiologi, farmakologi dan toksikologi, yang merangkumi berbagai-bagai jenis ujian seperti ujian identifikasi, berbagai 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 yang diluluskan.

PENCAPAIAN

Pencapaian BAU bagi tahun 2001 adalah seperti berikut:

BEBAN KERJA

Pengujian sampel

Sepanjang tahun 2001, BAU telah menguji sebanyak 4,626 sampel (**Rajah A**) dan menjalankan 28,096 ujian (**Rajah B**). Berbanding dengan pencapaian di tahun 2000, bilangan sampel yang diuji telah menurun sebanyak 16.5% sementara bilangan ujian yang dilakukan juga menurun sebanyak 17.7%.

DRUG ANALYTICAL DIVISION

QUALITY CONTROL

Drug Analytical Division (DAD) continues to play an effective role in quality control assessment of products which constitute an important component of pharmaceutical product evaluation. The products received include samples submitted for registration, registered products submitted for post marketing surveillance, complaint samples and enforcement samples. 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 pharmacopoeia, in-house or approved manufacturers' limits and specifications.

ACHIEVEMENT

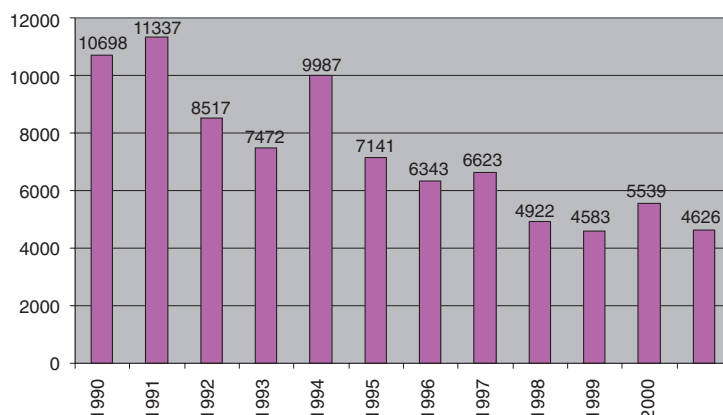
The achievements of DAD in 2001 are summarised as follows :

WORKLOAD

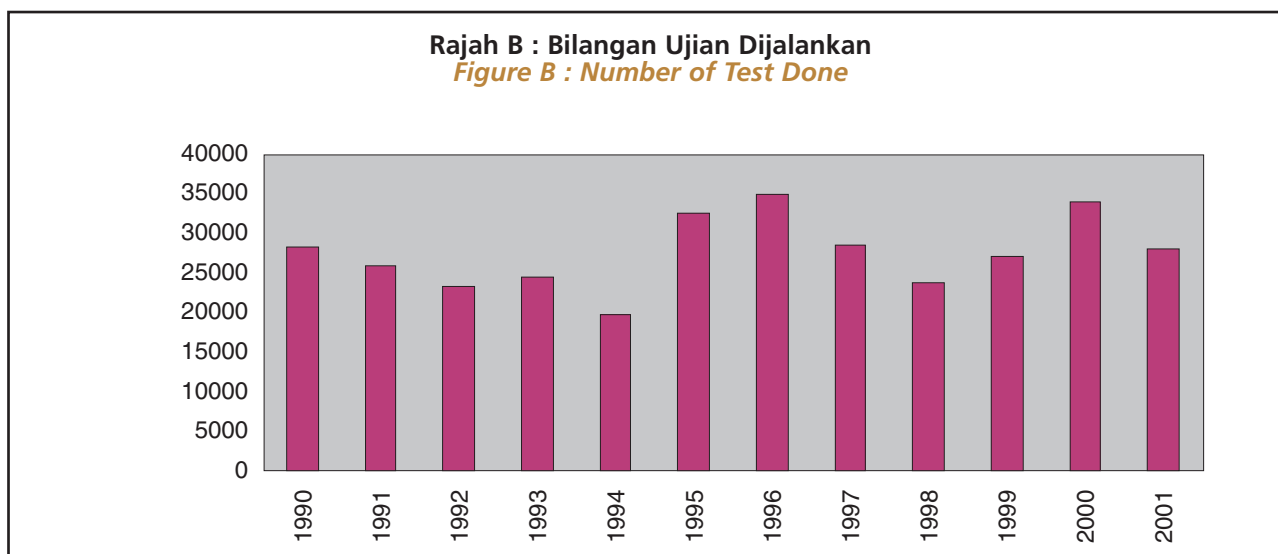
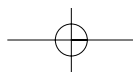
Analysis of samples

Throughout the year 2001, DAD had analysed a total of 4626 samples (Figure A) which generated a total of 28,096 tests (Figure B). In comparison to the achievement in 2000, the number of samples analysed has decreased by 16.5% while the number of tests done were also decreased by 17.7%.

Rajah A : Bilangan Sampel Diuji
Figure A : Number of Samples Tested



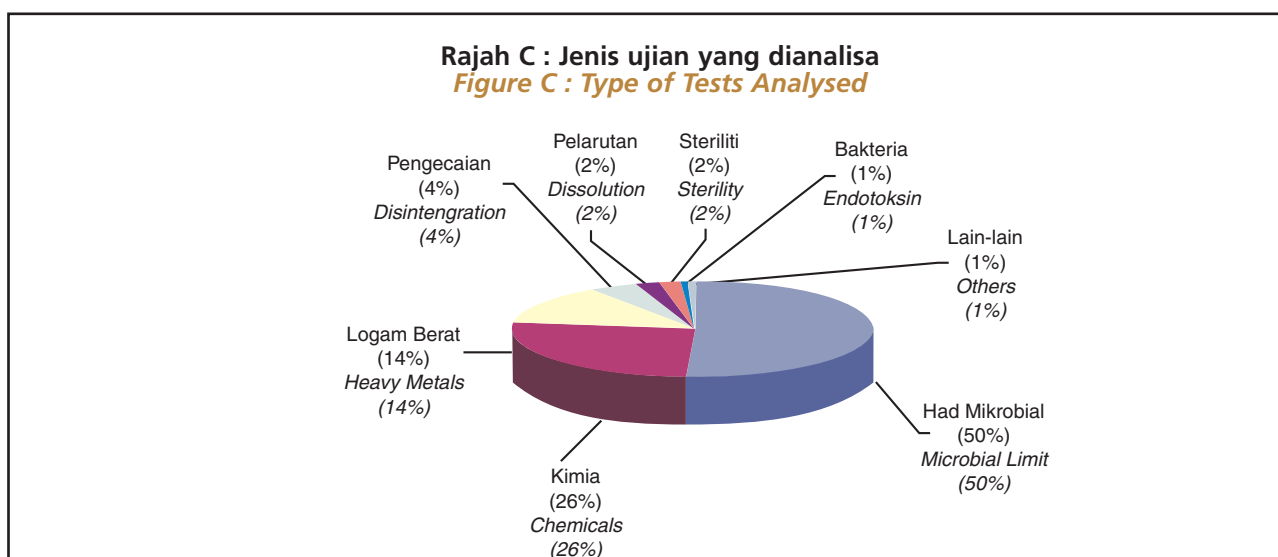
Sumber: Biro Pengawalan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Jenis-jenis ujian yang dilakukan boleh dikategorikan sebagai ujian had mikrobial (MLT), kimia, logam berat (As,Hg,Pb,Cd), pengecaian, pelarutan, steriliti, endotoksin bakteria, dan lain-lain seperti toksisiti, biokimia, biologikal, bilangan partikel, esei antibiotik. Pecahan ujian-ujian tersebut diilustrasikan dalam Rajah C.

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



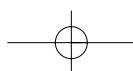
Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

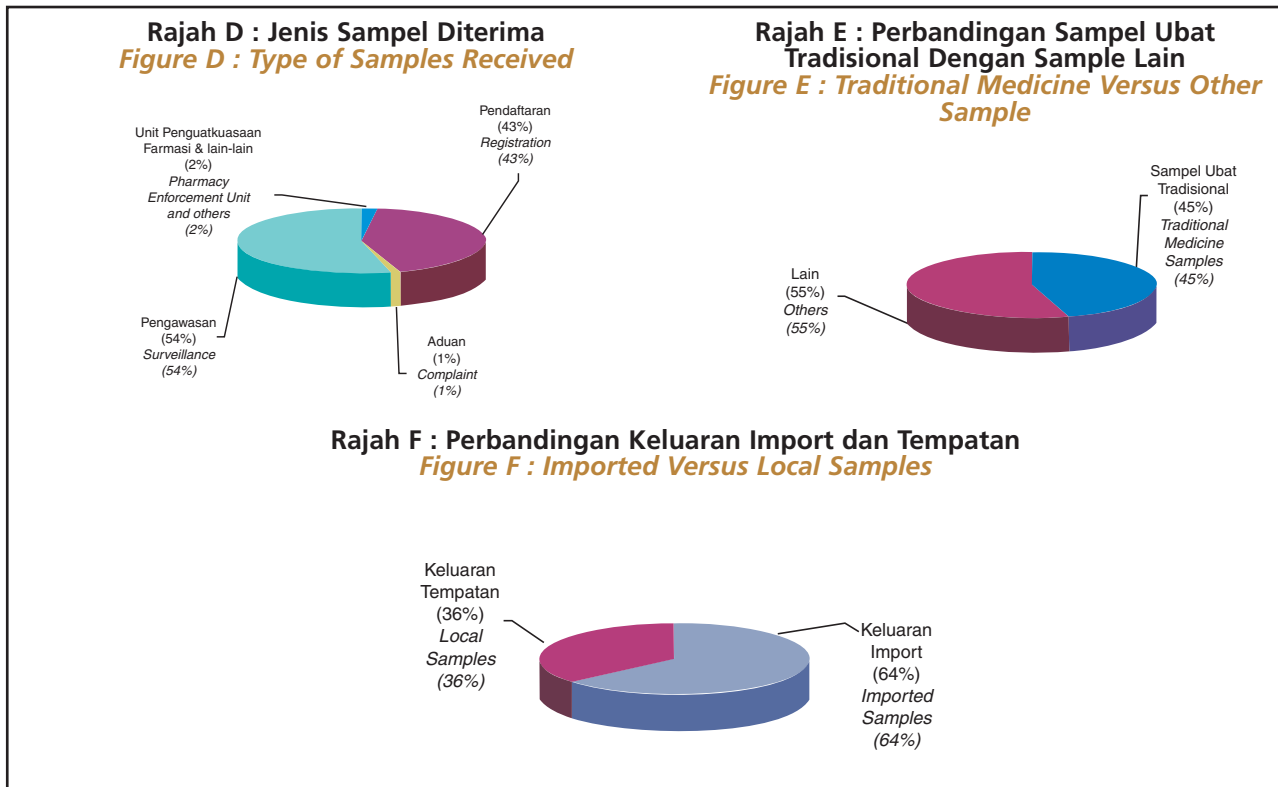
Jenis sampel yang di terima

Jenis sampel yang diterima diperjelaskan dalam Rajah D. Untuk sampel pendaftaran yang diterima, perbandingan keluaran tradisional dan bukan tradisional diilustrasikan dalam Rajah E dan perbandingan keluaran import dan tempatan digambarkan dalam Rajah F.

Types of sample received

The types of samples received are illustrated in Figure D. With respect to registration samples received, a comparison between traditional and non-traditional samples is indicated in Figure E and comparison between imported and locally-manufactured samples is illustrated in Figure F.





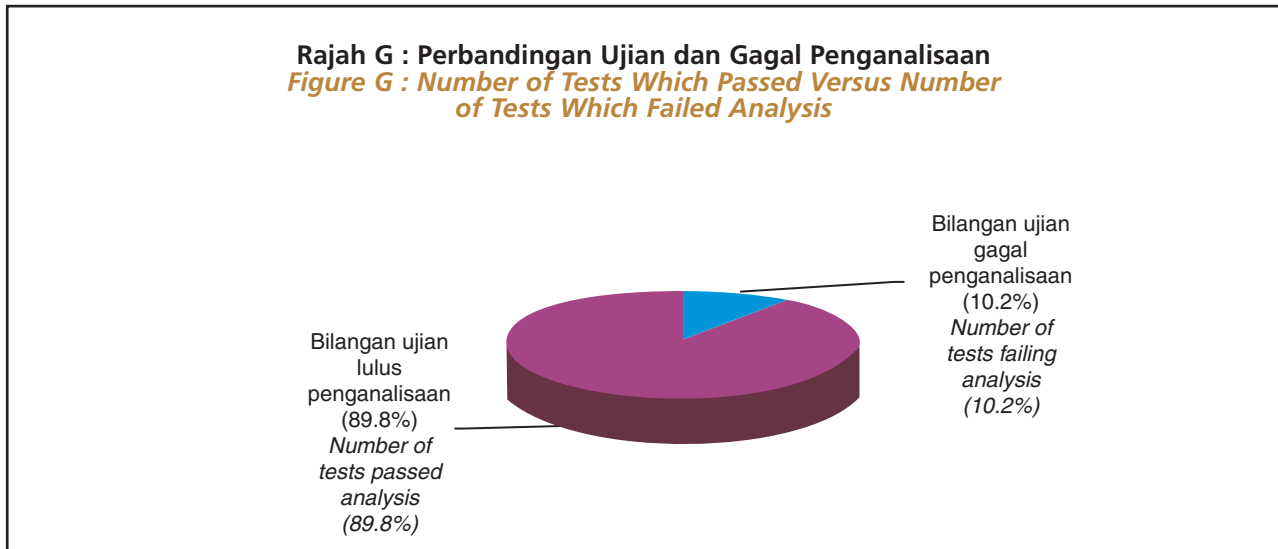
Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

Sampel gagal ujian

Penganalisan terhadap keputusan ujian menunjukkan bahawa 10.2% daripada jumlah ujian telah gagal (Rajah G) dan ini menunjukkan peningkatan sebanyak 1.7% dari tahun 2000.

Failed samples

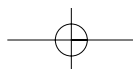
Additionally analysis of the test results has shown that 10.2% of the tests done had failed laboratory tests (Figure G). This showed an increased of 1.7% from year 2000 figure.



Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

BAU telah melantik Therapeutic Goods Administration (TGA) Laboratories Australia dan Sirim QAS Sdn. Bhd. sebagai makmal ketiga untuk menjalankan ujian yang gagal untuk sampel-sampel pengawasan mutu ubat di

DAD had appointed Therapeutic Goods Administration (TGA) Laboratories Australia and Sirim QAS Sdn. Bhd. as third laboratory to repeat the test on the failed market surveillance samples. Four failed samples had been sent to



pasaran. Empat sample yang gagal telah di hantar ke TGA atas persetujuan syarikat berkenaan untuk ujian ulangan dan keputusan yang di perolehi dari TGA juga gagal.

Pungutan hasil dari pengujian sampel

Oleh kerana bilangan ujian yang dijalankan menurun, maka kos pengujian yang diperolehi juga telah menurun iaitu sebanyak 12.8% dari tahun 2000 dengan pungutan sebanyak RM 460,880.00 untuk tahun 2001.

Penilaian tatacara pengujian dan data validasi

Sebanyak 900 protokol penganalisaan telah diterima pada tahun 2001. Terdapat peningkatan sebanyak 23.3% jika dibandingkan dengan bilangan protokol pada tahun 2000. Ini mencerminkan penambahan terhadap permohonan pendaftaran untuk keluaran di fasa 1 dan 2. Penilaian protokol pada tahun 2001 yang dapat diselesaikan kurang dari satu bulan dikekalkan ditahap peratusan yang tinggi iaitu 97.7%, juga mematuhi petunjuk QAP.

Menjalankan Pemeriksaan Amalan Perkilangan Baik

BAU masih aktif memberi khidmat sokongan dalam pemeriksaan Amalan Perkilangan Baik (APB) dalam aspek Amalan Makmal Baik. Dalam tahun 2001, sebanyak 35 pemeriksaan (APB) untuk aspek mengenai Amalan Makmal Baik telah dilakukan ke atas premis pengilang farmaseutikal tempatan dan ini adalah lebih tinggi dari bilangan yang dilaporkan pada tahun 2000 (11 pemeriksaan).

Pada bulan Mac 2001, empat orang pemeriksa dari BAU telah terlibat dalam menjalankan pemeriksaan Amalan Perkilangan Baik dalam aspek Amalan Makmal Baik untuk tujuan mendapatkan pengiktirafan PIC/S. Berikutnya pada bulan Oktober 2001, dua orang pemeriksa dari BAU juga telah terlibat dalam pemeriksaan yang serupa.

Piawai Rujukan

Pada tahun 2001, sejumlah 349 vial piawai rujukan (ASEAN/BPFK) telah dibekalkan kepada jabatan kerajaan dan ini merupakan peningkatan kepada jumlah pada tahun 2000 (237 vial). Selain daripada itu, terdapat peningkatan untuk jumlah piawai yang dijual kepada industri tempatan (470 vial pada tahun 2001 berbanding dengan 446 vial pada tahun 2000). Dalam tahun 2001 juga, sebanyak 215 vial telah dijual ke luar negara seperti Cambodia, Bangladesh, Nepal dan Indonesia. Pungutan yang diperolehi daripada jualan piawai rujukan adalah sebanyak RM 59,822.50.50.

TGA with the company's agreement and the results from TGA are in accordance with DAD's results.

Collection from the analysis of samples

Since the number of tests done was decreased hence the collection of analytical fees had also been decreased by 12.8% with RM 460,880.00 collected for the year 2001.

The evaluation of analytical protocols

900 analytical protocols were received in 2001. The figure showed an increase of 23.3% when compared to the number received in 2000. This reflects an increase in the applications for registration of products in phase 1 and phase 2 of the registration exercise. However in the year 2001, the protocol evaluation which was completed in less than one month has been maintained at high percentage that is 97.7%, which also complied with the NPCB QAP indicator.

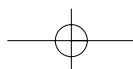
Good Manufacturing Practice (GMP) Inspection

DAD continues to be active in GMP inspections for Good Laboratory Practice (GLP) aspect. In 2001, 35 GMP inspections were conducted on local pharmaceutical manufacturing premises. The figure showed an increased as compared to year 2000 (11 inspections).

In March 2001, four auditors from DAD were involved in GLP inspection for the purpose of PIC/S certification. In October 2001, two auditors were involved for the same purpose but the inspections were done on different pharmaceutical manufacturing premises.

Reference Standards

In year 2001, a total of 349 reference standards (ASEAN/NPCB) were supplied to government departments and this figure reflects an increase to the number reported in 2000 (237 vial). There was also an increase in the standards sold locally (470 vial compared to 446 vial in 2000). In year 2001, a total of 215 vials were sold to foreign countries namely Cambodia (189), Bangladesh (4), Nepal (4) and Indonesia (18). Total collection for year 2001 was of RM 59, 822.50.



Latihan Yang Dikendalikan Oleh BAU

BAU telah menganjurkan bengkel 'Evaluation of Analytical Method Validation Data' dari 11 Ogos 2001 hingga 18 Ogos 2001 di mana fasilitatornya adalah Mr. Paul Sidhu dari Therapeutic Goods Administration (TGA) Australia. Para peserta terdiri daripada semua Pegawai Farmasi dari BAU manakala beberapa pegawai dari bahagian lain di BPFK hanya menghadiri sesi hari pertama sahaja. Tiga orang peserta dari luar negara juga turut mengikuti bengkel tersebut. Mereka adalah Dini Prapti Karyani dan Mirawati dari National Agency of Drug and Food Control, Indonesia dan Mdm. Nam Nivanna dari National Laboratory for Drug Quality Control, Cambodia.

Dalam tahun 2001, BAU telah memberi latihan dalam aspek kawalan mutu kepada empat kumpulan pelatih dari luar negara dan satu kumpulan pelajar Farmasi dari UKM. Mereka telah menjalani latihan sangkutan di makmal-makmal di BAU mengikut jadual yang telah disediakan. Mereka adalah :

1. Mr. Farruque Ahmad, WHO Fellow dari Ministry of Health and Family Welfare, Government of Bangladesh (29 Januari 2001-10 Februari 2001)
2. Mrs. Dorj Ulziidulam, WHO Fellow dari Mongolia (7 Mei 2001 – 1 Jun 2001)
3. Awg. Hj. Zulkiflee bin Hj. Mohammad dan Awg. Hj. Saifulbahri bin Hj. Mohsin, dari Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan, Negara Brunei Darussalam (3 September 2001 – 5 Oktober 2001)
4. Mrs. Mery Meiya Mahajan dari Nepal dan Miss Rahima Khaitun dari Bangladesh (17 September 2001 – 29 September 2001)
5. Kumpulan pelajar Farmasi Tahun 3, Universiti Kebangsaan Malaysia (19 Mac 2001 – 6 April 2001)

Satu kumpulan pelajar Farmasi Tahun Akhir, Universiti Malaya telah melawat BAU pada 28 Ogos 2001 sebagai salah satu daripada program lawatan sambil belajar mereka.

Latihan Untuk Kakitangan

BAU dengan kerjasama Fisher Scientific (M) S/B telah menganjurkan seminar bertajuk 'Fundamental of Gas Chromatography' pada 12 Jun 2001 bertempat di Dewan Anggerik BPFK untuk semua Pembantu Farmasi yang bertugas di BAU.

Trainings conducted by DAD and co-operation with the industry

DAD had conducted a workshop on Evaluation of Analytical Method Validation Data from 11th till 18th August 2001 with Mr. Paul Sidhu from TGA Australia as a facilitator. Participants consist of officers from DAD, while a few officers from other divisions of NPCB attended the first session on the first day. There were three participants from the neighbouring ASEAN countries. They were Ms. Dini, Mrs. Prapti Karyani and Mirawati from National Agency of Drug and Food Control, Indonesia and Mdm. Nam Nivanna from National Laboratory for Drug Quality Control, Cambodia.

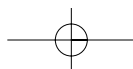
In year 2001, DAD has given training in quality control aspects to three groups of trainees from oversea and one group of Pharmacy students from UKM. They were attached to various laboratories in DAD according to the schedule which had been prepared for them. They were:

1. Mr. Farruque Ahmad, WHO Fellow from Ministry of Health and Family Welfare, Government of Bangladesh (29th January till 10th February 2001)
2. Mrs. Dorj ULziidulam, WHO Fellow from Mongolia (7th Mei till 1st Jun 2001)
3. Awg. Hj. Zulkiflee bin Hj. Mohammad and Awang Hj. Saifulbahri bin Hj. Mohsin from Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan, Negara Brunei Darussalam
4. Mrs. Mery Meiya Mahajan from Nepal and Miss Rahima Khaitun from Bangladesh (17 September 2001 – 29 September 2001)
5. Third year Pharmacy Students, University Kebangsaan Malaysia (19th Mac till 6th April 2001)

A group of final year Pharmacy students from University Malaya visited DAD on 29 August 2001 as part of their study tour program.

Training for DAD staff

DAD and Fisher Scientific (M) Sdn. Bhd. had jointly organized a one day seminar on Fundamental of Gas Chromatography on 12th Jun 2001 held at Dewan Anggerik NPCB. For the second time, DAD and NIOSH organized a course on Safety Use of Chemicals for DAD staff



Untuk kali kedua, BPFK dengan kerjasama NIOSH telah menganjurkan kursus Keselamatan Dalam Penggunaan Bahan Kimia untuk kakitangan BAU pada 19 – 20 Jun 2001 di Dewan Anggerik BPFK. Satu kumpulan, 20 orang Pembantu Farmasi telah menghadiri seminar dua hari pada 27 hingga 28 Ogos 2001 yang dikendalikan oleh SUCXes Laboratory, University Malaya bertajuk 'Basic and Principles of HPLC in Pharmaceuticals Analysis' di Dewan Anggerik BPFK.

Pematuhan ISO 9002

BAU seperti bahagian-bahagian lain di BPFK, telah diaudit oleh Sirim QAS Sdn. Bhd. untuk tujuan pensijilan MS ISO 9002 pada 18 April 2001 hingga 20 April 2001. Sebelum itu sebagai persediaan, BAU telah diaudit oleh sekumpulan audit dalaman sebanyak dua kali.

Ahli baru BAU

BAU mengalu-alukan kedatangan 3 orang Pegawai Farmasi dan 2 orang Pembantu Farmasi baru iaitu Cik Ida Syazrina Ibrahim, Cik Azrina Hassan, En. Othman Ahmad dan Puan Zuriati Naw, Cik Rohaiza bt Zaitun masing-masing.

Mesyuarat Di luar Negeri

Timbalan Pengarah BAU, Pn. Hasiah bte Abdullah telah menghadiri 'The 4th Meeting of ACCSQ Products Group on Pharmaceuticals' di Bali, Indonesia pada 27 hingga 28 September 2001. Beliau adalah ketua delegasi bagi Malaysia untuk mesyuarat ini dan telah membentangkan laporan aktiviti yang dikoordinasikan oleh Malaysia mengenai 'Administrative Data for Registration Submission'.

Ketua Penolong Pengarah Makmal Farmakologi / Toksikologi, En. Selvaraja, telah menghadiri 'Conference on Advancing Science and Elimination of the Use of Laboratory Animals' di Holland, Amsterdam pada 12 – 14 November 2001. En. Selvaraja juga telah menghadiri 'The 4th Meeting of ACCSQ Products Group on Pharmaceuticals' di Bali, Indonesia pada 27 – 28 September 2001. Beliau bertindak sebagai pemerhati dalam mesyuarat tersebut.

which was held from 19th till 20th Jun 2001 at Dewan Anggerik NPCB. A group of Pharmacy Assistant from DAD attended a two day seminar on the 27th till 28th August 2001 on Basic and Principles of HPLC in Pharmaceutical Analysis conducted by SUCXes Laboratory of University Malaya.

Compliance to ISO 9002

DAD had been audited by Sirim QAS Sdn. Bhd. for compliance audit in view of MS ISO 9002 certification from the 18th till 20th April 2001. Prior to the compliance audit, DAD had been audited twice by the internal audit group.

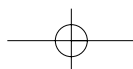
New members of DAD

DAD welcomes three new Pharmacists and two new Pharmacy Assistants namely Cik Ida Syazrina Ibrahim, Cik Azrina Hassan, En. Othman Ahmad and Puan Zuriati Naw, Cik Rohaiza bt Zaitun respectively.

Meetings abroad

Deputy Director DAD, Pn. Hasiah bte Hj. Abdullah, attended 'The 4th Meeting of the ACCSQ Products Group on Pharmaceuticals' on 27th September till 28th September 2001 in Bali, Indonesia. She was the Chief delegate for this meeting and had delivered an activity report coordinated by Malaysia on 'Administrative Data for Registration Submission'.

Principle Assistant Director, Pharmacology / Toxicology Laboratory, En. Selvaraja Seerangam, had attended a 'Conference on Advancing Science and Elimination of the Use of Laboratory Animals' in Amsterdam, Holland on 12 – 14 November 2001. He was an observer at "The 4th Meeting of the ACCSQ Products Group on Pharmaceuticals' on 27th till 28th September 2001 in Bali, Indonesia.



Rancangan Untuk Masa Depan

BAU akan bersedia untuk menghadapi cabaran baru bagi melengkapkan dan meningkatkan keupayaan agar dapat terlibat secara aktif dan efektif dalam melaksanakan fasa-fasa pendaftaran yang berikutnya. Rancangan yang dijadualkan untuk tahun 2002 adalah seperti berikut:

- a) Memulakan kajian mengenai pengesanan racun berjadual dalam ubat tradisional
- b) Memulakan kajian pencirian bahan tumbuhan dalam ubat tradisional
- c) Terlibat dalam penyediaan "Malaysian Herbal Monograph - Volume 2" yang akan dicetak pada akhir tahun
- d) Meneruskan kerjasama diantara negara ASEAN dengan mengambil bahagian dalam pengeluaran piawai rujukan ASEAN melalui ujian kolaboratif ke atas piawai rujukan yang dicadangkan
- e) Menghadiri kursus "ASEAN Group Training of GMP for Biologicals" di Indonesia
- f) Penswastaaan ujian untuk keluaran di peringkat kedua permohonan pendaftaran
- g) Mendapatkan peruntukan khas di bawah dasar baru untuk pembelian alat-alat makmal tambahan dan untuk unit piawai rujukan
- h) Meneruskan usaha mengadakan latihan berterusan untuk Pegawai Farmasi baru dan Pembantu Farmasi di BAU untuk aspek yang melibatkan penggunaan komputer, keselamatan makmal dan latihan dalam bidang kromatografi, spektroskopi dan mikrobiologi
- i) Memulakan proses penstrukturan semula BAU ke arah keberkesanan dan kelicinan proses kerja
- j) Ke arah pematuhan farmakopia untuk pengendalian dan pelabelan mikroorganisma dengan mengambil kira "passage number" untuk mikroorganisma yang digunakan dalam ujian validasi dan menggantikan *Ps. aeruginosa* dan *E. coli* kepada strain yang terkini
- k) Terlibat dalam pembangunan sistem komputer baru (QUEST 2) untuk modul BAU

Future plans

DAD shall work towards preparing it for new challenges and be able to play an active and effective role in the implementation of future phases of registration exercise. Several strategic plans of actions are scheduled for the year 2002 and they are as follows :

- a) *Embarking on research in the detection of schedule poisons in traditional medicines.*
- b) *Embarking on research in the characterization of herbal ingredients in traditional medicines.*
- c) *Involving itself in the preparation of "Malaysian Herbal Monograph – Volume 2" which is scheduled to be printed at the end of the year.*
- d) *Continuing with the collaboration amongst ASEAN countries in the production of ASEAN reference material through collaborative testing of the suggested reference materials.*
- e) *Attending a course on "ASEAN Group Training of GMP for Biologicals" in Indonesia.*
- f) *Privatization of laboratory testing of products at the second stage of registration.*
- g) *Acquiring special funding under the "one off project" for purchase of additional laboratory equipment and for reference standard unit.*
- h) *Continuing the effort to provide a continuous training to new Pharmacists and Laboratory Assistants in DAD in aspects involving the use of computer, laboratory safety and training in the field of chromatography, spectroscopy and microbiology.*
- i) *Starting the restructuring process for DAD as a move towards more effective and smooth work process.*
- j) *Working towards compliance to pharmacopoeial requirement for the management and labeling of microorganisms by considering "passage number" for the microorganisms that are used in validation tests and the replacement of *Ps. aeruginosa* and *E. coli* with the current strain.*
- k) *Involving itself in the development of computer system (QUEST 2) for DAD module.*

BAHAGIAN PEMBANGUNAN ORGANISASI DAN TEKNOLOGI MAKLUMAT (POTM)

OBJEKTIF

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

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

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

PENCAPAIAN

Perkhidmatan Maklumat Ubat dan Maklumat Am

Sepanjang tahun 2001, Bahagian POTM telah menjawab 1576 pertanyaan dari sektor awam dan swasta. Kebanyakan daripada pertanyaan tersebut adalah berkenaan status pendaftaran keluaran-keluaran farmaseutikal, pendaftaran kosmetik, prosedur pendaftaran ubat-ubatan dan pembekal keluaran-keluaran yang telah didaftarkan.

Pengelasan Keluaran

Bahagian ini bertanggungjawab ke atas semua pertanyaan berkenaan dengan klasifikasi keluaran-keluaran "borderline", sama ada keluaran-keluaran itu perlu didaftar atau tidak. Antara 681 keluaran yang diterima untuk pengelasan dalam tahun 2001, 344 keluaran merupakan butiran-butiran yang tidak perlu didaftar, seperti peralatan-peralatan perubatan, keluaran-keluaran penjagaan kulit, suplemen makanan (dalam bentuk jus/minuman), keluaran-keluaran "food-based" dan herba-herba mentah.

Baki 337 keluaran telah dikelaskan sebagai perlu didaftarkan.

Penerbitan

Penerbitan-penerbitan yang berikut telah dihasilkan dan diedarkan kepada organisasi-organisasi dalam sektor awam dan swasta sepanjang tahun 2001.

ORGANISATIONAL DEVELOPMENT AND INFORMATION TECHNOLOGY DIVISION

OBJECTIVES

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 organisations within the public and private sectors.

ACHIEVEMENTS

Drug Information Service and General Information on Drug Registration

In the year 2001, the OD & IT division responded to 1576 enquiries from both the public and private sectors. The majority of the inquiries were on registration, status of pharmaceutical products, registration of cosmetics, registration procedures and suppliers of registered products.

Product Classification

This division handles all queries pertaining to classification of "borderline products", as to whether they are registrable or not. Out of the 681 products received for classification in 2001, 344 products were non-registrable items such as medical devices, contact lens care solution, skin care products, food supplements in the form of juices/drinks, food-based products and raw herbs.

The remaining 337 products were classified as registrable products, and were mainly dietary supplements containing traditional ingredients.

Publications

The following publications were produced and distributed to organisations in the public and private sector in 2001.

- (i) Berita Ubat-Ubatan (3 keluaran)
- (ii) Pekeliling Maklumat Ubat (12 keluaran)
- (iii) Monograf Ubat (12 keluaran)
- (iv) Laporan Tahunan (1 keluaran)

Penerbitan-penerbitan di atas juga boleh didapati di laman web BPFK iaitu di www.bpfk.gov.my.

Perkhidmatan Perpustakaan

Perpustakaan ini mempunyai hampir 1547 buah buku, termasuk farmakopia-farmakopia utama dari pelbagai negara. Selain itu, perpustakaan ini juga melanggan 32 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.

Dalam tahun 2001, perpustakaan ini diperuntukkan sebanyak RM 5,000 di bawah program SEAMIC (South East Asian Medical Information Centre) untuk membeli buku-buku perubatan.

Pelawat-pelawat antarabangsa dan delegasi ke BPFK pada tahun 2001 adalah seperti berikut:-

- (i) *Drug Control Authority Newsletter (3 issues)*
- (ii) *Drug Information Circular (12 issues)*
- (iii) *Drug Monograph (12 issues)*
- (iv) *Annual Report (1 issue)*

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

Library Service

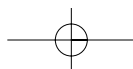
The library has about 1547 books, including the major pharmacopoeias from various countries. Besides that, it subscribes to 32 journals/drug bulletins, Micromedex and International Pharmaceutical Abstracts. The library is open to the staff of the institution only. Pharmacists in the Ministry of Health may, by request, make use of the library facilities.

In the year 2001, the library was allocated RM 5,000 under the SEAMIC (South East Asian Medical Information Centre) program to purchase medical books.

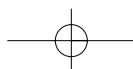
International Visitors and Delegations to NPCB

The following people visited NPCB in year 2001:-

| Nama | Negara | Tarikh | Tujuan Lawatan |
|--|-----------------|-----------------------------|---|
| Mr. Farruque Ahmad Director, Ministry of Health and Family Welfare | Bangladesh | 29 January – 10 February | WHO Fellow - Laboratory Quality System Analysis in Relation to Drug Testing |
| Mr. Robert Tribe PIC/S Chairman TGA Australia | Australia | 12-16 March | PIC/S Assessment Visit to Malaysia |
| Mr. Sia Chong Hock PIC/S Member | Singapore | 12-16 March | PIC/S Assessment Visit to Malaysia |
| Dr. Ludevít Martinec PIC/S Member | Slovak Republic | 12-16 March | PIC/S Assessment Visit to Malaysia |
| Mr. Daniel Brunner PIC/S Secretary, Geneva | Geneva | 12-16 March | PIC/S Assessment Visit to Malaysia |



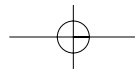
| Nama | Negara | Tarikh | Tujuan Lawatan |
|--|------------------|----------------|---|
| Dr. Gordon Munro PIC/S member from Medicines Control Agency, London | United Kingdom | 12-16 March | PIC/S Assessment Visit to Malaysia |
| Dr. Matteo Schaffhauser PIC/S Member | Switzerland | 12-16 March | PIC/S Assessment Visit to Malaysia |
| Mrs. Dorj Ulziidulam | Mongolia. | 7 May – 1 June | WHO Fellow - Training Program in Quality Control of Pharmaceuticals |
| The Honourable Baraniko Mooa Minister of Health Kiribati | Kiribati. | 10 May | Official Visit |
| Pham Dinh Hien Ngugen Nhu Chinh Ngo Pham Kien Pham Thi Trinh Thuen Ngugen Thi Hiep Ministry of Health | Vietnam | 14 – 17 May | Drug Management Course |
| Dr. Nguyen Xuan Chinh Mrs. Nguyen Thi Bieh Hai Mr. Mai Thi Hien Mr. Le Truc Phuong Mrs. Trinh Thi Le Tram Ministry of Health | Vietnam | 8 August | Program on Health Legislation Development |
| Dr. Torres Director, Bureau of Food and Drug Administration, Manila | Philippines | 10 August | Discussion on Cosmetic Registration |
| He Di Ung Phu Run Secretary of State Ministry of Health | Cambodia | 24 August | Official Visit |
| Dr. Nuth Sokhom | As aboveAs above | As above | |
| Dr. Chieng Phana Department of Drug and Food, Ministry of Health | As above | | |
| Dr. Cheng Doran | As above | | |
| Ph. Heng Huot As above Chief of Drug Regulation Bureau | As above | | |



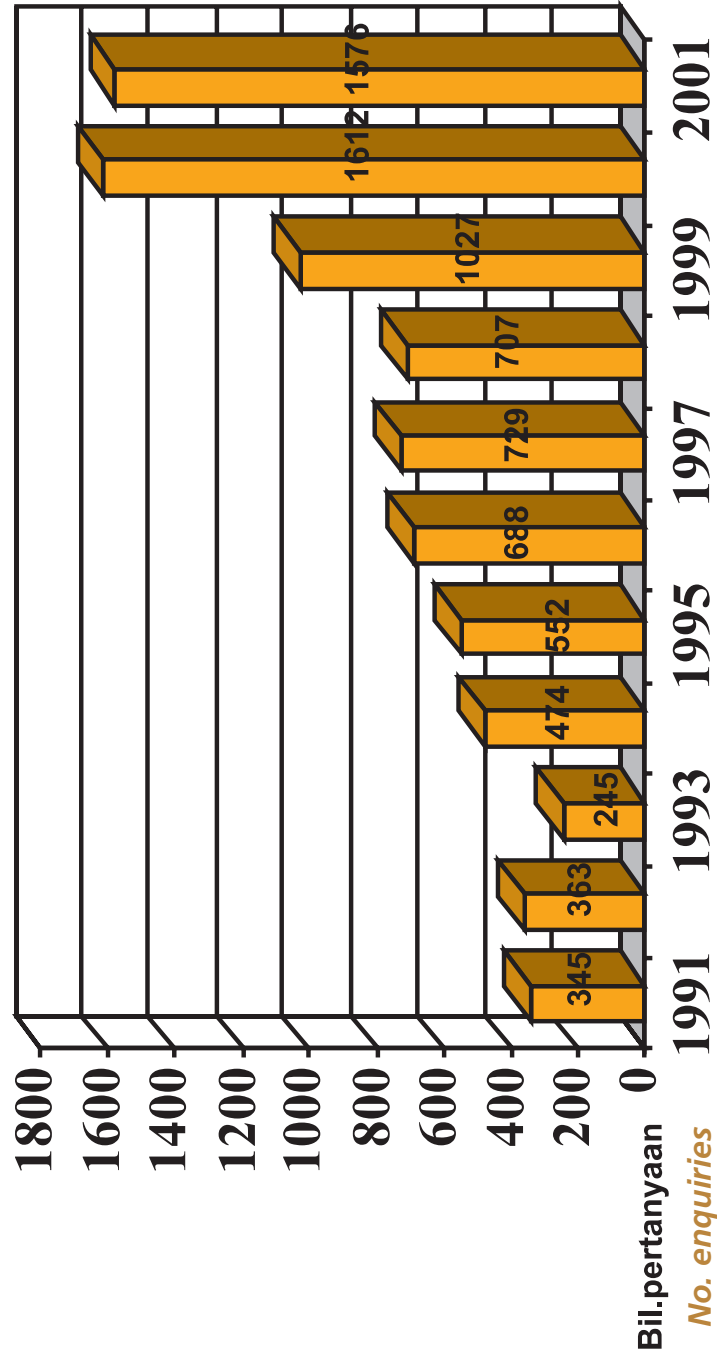
| Nama | Negara | Tarikh | Tujuan Lawatan |
|---|------------|---------------------|---|
| Ms. Rahima Khatun Bacteriologist, Drug Testing Laboratory Institute of Public Health | Bangladesh | 3 – 29 September | WHO Fellow – Program in Pharmacy |
| Mrs. Mery Maiya Maharjan Assistant Quality Controller, Royal Drug Research Laboratory | Nepal | 3 – 29 September | WHO Fellow – Program on Development of Secondary Reference Standards and Quality Assurance of Biological Products |
| Dr. Sabah N. Salim Technical Affairs Division Ministry of Health Baghdad | Iraq | 3 September | Official Visit |
| Dr. Raed A. Sultan Pharmacist, KIMADIA Ministry of Health | Iraq | 3 September | Official Visit |
| Dr. Boonchii Somboonsuk Deputy Secretary General, Food and Drug Administration, Ministry of Public Health | Thailand | 8 September | Discussion on Implementation of MS ISO 9002 |
| Mr. Wattana Akraethalin Director, Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health | As above | As above | As above |
| Ms. Siriphan Eamrunroj Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health | As above | As above | As above |
| Mrs. Wimonwan Witayapiboon Medical Device Control Division, Food and Drug Administration, Ministry of Public Health | As above | As above | As above |
| Mrs. Suchada Trisarnsri Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health | As above | As above | As above |

| Nama | Negara | Tarikh | Tujuan Lawatan |
|---|-------------------|------------------|--|
| The Honourable Mr. Allan Paul , Minister of Health | Solomon Island | 18 September | Official Visit |
| Dr. George Malefoasi Secretary, Health Care Division, Ministry of Health | Solomon Island | 18 September | As above |
| Hjh. Siti Mariam Jaafar Principal Pharmaceutical Chemist, Pharmaceutical Services Department, Ministry of Health | Brunei Darussalam | 26 September | Discussion on Training of Pharmacists |
| Mr. Rosni Jair Senior Pharmaceutical Chemist | Brunei Darussalam | 26 September | As above |
| Mr. Chong Chee Kiong Scientific Officer, Drug Quality Control Section, Pharmaceutical Services Department, Ministry of Health | Brunei Darussalam | 8 - 19 October | Training in Drug Registration |
| Ms. Jamilah H. Metussin Pharmaceutical Chemist, Pharmaceutical Services Department, Ministry of Health | Brunei Darussalam | As above | Training in Drug Registration |
| Ms. Zanatul Aini Haji Zainin Pharmaceutical Chemist, Drug Quality Control Section, Pharmaceutical Services Department, Ministry of Health | Brunei Darussalam | As above | WHO Fellow – Training in Drug Registration |
| Mr. Robert Tribe PIC/S Chairman | Australia | 29 – 31 October | 2nd PIC/S Assessment Visit |
| Mr. Sia Chong Hock PIC/S Member | Singapore | 20 – 31 October | 2nd PIC/S Assessment Visit |
| Mr. M. N. Dauramanzi Director General, Medicines Control Authority | Zimbabwe | 12 - 16 November | Attachment to NPCB |
| Ms. G. N. Mahlangu Director of Medicines Control, Medicines Control Authority | Zimbabwe | As above | As above |

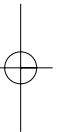
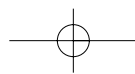
| Nama | Negara | Tarikh | Tujuan Lawatan |
|--|-----------|---------------------|--|
| Mr. P. S. Mutsigwa Director of Finance, Medicines Control Authority | Zimbabwe | As above | As above |
| Mr. Derek Rochford Chairman, International Affairs, European Commission for Medical Devices | Belgium | 26 November | Discussion & Update on Proposed Regulations for Medical Devices in Malaysia |
| Ms. Jolynn Lim Boston Scientific Asia Pacific | Singapore | 26 November | As above |
| Mr. Lam Thanh Nghi Pharmacist, Drug Administration of Vietnam | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mrs. Tran Tuyet Quy Pharmacist, The Pharmaceutical Journal | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mrs. Nguyen Thi Phuong Cham, Pharmacist, Expert of Department of Therapy | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mr. Nguyen Duy Than Pharmacist, Vice Director of Yen Bai Health Bureau | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mrs. Nguyen Thi Dai Phong Pharmacist, Bach Mai Hospital | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Ms. Tran Thi Le Ha Pharmacist, Hanoi Health Bureau | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mr. Nguyen Manh Pha Pharmacist, DIC Hanoi Pharmaceutical College | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mrs. Pham Thi Minh Chau ADPC Office, The Drug Administration of Vietnam | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mrs. Cao Thi Mai Phuong Pharmacist, Pharmacopoeia Committee | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |
| Mr. Cao Xuan Son Pharmacist, Uong Bi General Hospital | Vietnam | 10 – 11 December | Attachment – Drug Information & ADR Monitoring |



BILANGAN PERTANYAAN DITERIMA DARI 1991-2001 NUMBER OF ENQUIRIES RECEIVED FROM 1991-2001

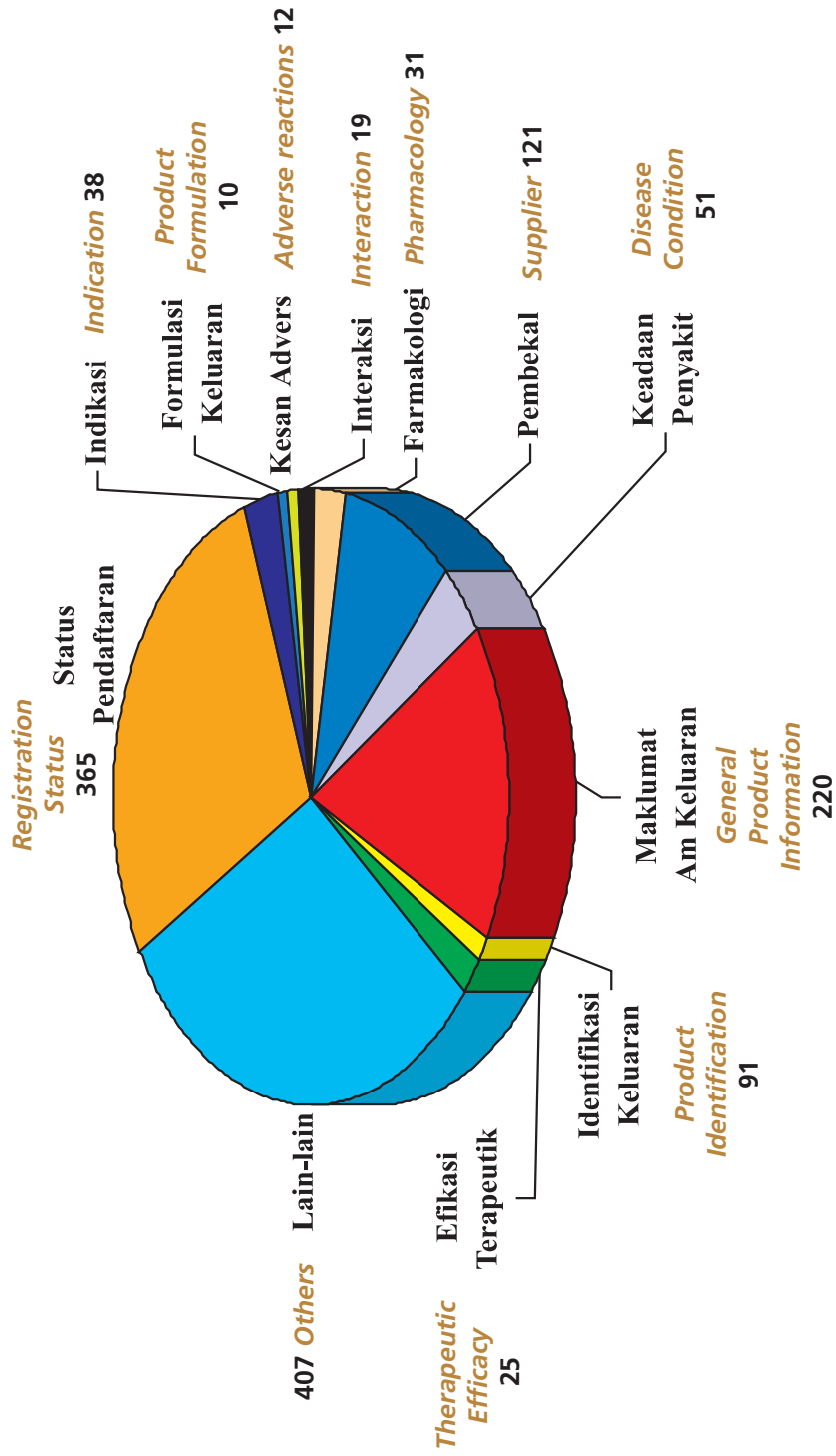


Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
Source : National Pharmaceutical Control Bureau

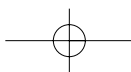
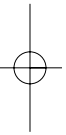
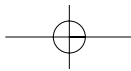


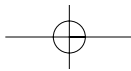
JENIS PERTANYAAN YANG DITERIMA PADA TAHUN 2001

TYPES OF ENQUIRIES RECEIVED FOR 2001

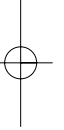
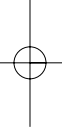


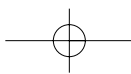
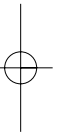
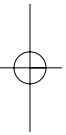
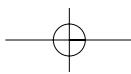
Sumber: Biro Pengawasan Farmaseutikal Kebangsaan
 Source : National Pharmaceutical Control Bureau





**KURSUS /
SEMINAR**
**COURSES /
SEMINARS**





KURSUS / LATIHAN YANG DIHADAPI COURSES / TRAINING FOR STAFF

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|--|---|--|
| Pembantu Farmasi BAU | Fundamentals of Gas Chromatography | 12.6.2001 | Fisher Scientific (M) Sdn Bhd | BPFK |
| Pembantu Farmasi BAU | Seminar on Safety in the Use of Chemicals | 19 – 20.6.2001 | BPFK/NIOSH | BPFK |
| Abdul Ghani b. Yusof | Kursus Amalan Makmal Yang Baik (GLP) Kursus Audit Kualiti Dalam | 6.4.2001 7 - 8.11.2001 | BPFK BPFK | BPFK BPFK |
| Absah Awang | Latest Development on GC, GCMS Technology Seminar Karl-Fisher & Potentiometric Titration Theory & Practical Training for AX and MX Balance Latihan Pengguna – Cara Pembuangan Sisa Klinikal LAL Seminar 2001 | 16.4.2001 22.8.2001 4.9.2001 27.9.2001 15.10.2001 | Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA Metrohm BPFK Radicare Choice-Care Sdn. Bhd | Hotel Palace of Golden Horses, Seri Kembangan Hotel Hyatt Regency Saujana, Subang BPFK BPFK Hotel Hyatt Regency Saujana, Subang BPFK BPFK |
| Ani Abdullah | Seminar on Vaccine Seminar on Regulatory Procedures For Veterinary Products in some Major Countries Seminar on Current Good Manufacturing Practices (CGMP) Workshop on Evaluation of Analytical Method Validation Data Cosmetic Seminar 2001 International GMP Training Program: Principle of GLP, Analytical Method Validation & Microbiological GLP | 5.2.2001 7.4.2001 23.7.2001 13 – 17.8.2001 10.10.2001 19 – 20.11.2001 | BPFK BPFK BPFK BPFK BPFK BPFK /MOPI | BPFK BPFK BPFK BPFK Hotel Sheraton, Subang Jaya Hotel Pan Pacific, Shah Alam |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---|--|---|
| Asmawiza Ghazali | Latest Development on GC, GCMS Technology Kursus Basics and Principles of HPLC in Pharmaceuticals Analysis Latihan Penggunaan "Personnel Protective Equipment" | 16.4.2001 27 - 28.8.2001 28.12.2001 | Alpha Analytical (M) Sdn. Bhd. /Thermo Finnigan Austin USA SUCXes Laboratory, UM BPFK | Hotel Palace of Golden Horses, Seri Kembangan BPFK BPFK |
| Azrina bt Hassan | Kesedaran ISO 9000 Latihan Pengguna untuk GC | 6.11.2001 15.11.2001 | BPFK Radicare | BPFK BPFK |
| Chan Lai Peng | Understanding Filter Validation Based on PDA Technical Report No. 26 Latihan Penggunaan "Personnel Protective Equipment" | 30.10.2001 28.12.2001 | Sartorius BPFK | Hotel Sunway Lagoon, P.J BPFK |
| Chan Sek Neo | Gas Chromatography Seminar | 9.5.2001 | BPFK | Hotel Eastin, P.J |
| Che Amah Hassan | Basic and Principles of HPLC in Pharmaceutical Analysis Latihan Pengguna - Cara Pembuangan Sisa Klinikal | 27 - 28.8.2001 27.9.2001 | SUCXes Laboratory, UM BPFK | BPFK BPFK |

| NAMA PEGAWAI <i>NAME OF OFFICER</i> | KURSUS <i>COURSES</i> | TARIKH <i>DATE</i> | ANJURAN <i>SPONSOR</i> | TEMPAT <i>PLACE</i> |
|---|--|------------------------------|--|--|
| Che Zawiyah Hj Abd Wahab | Latest Development on GC, GCMS Technology | 16.4.2001 | Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA | Hotel Palace of Golden Horses, Seri Kembangan |
| Chua WoneTying | Latihan Pengguna untuk GC | 15.11.2001 | BPFK | BPFK |
| Faridah Abd. Malek | Karl Fisher & Moisture Technique Workshop 2001 | 20.2.2001 | Mettler Toledo (M) S/B | Mettler Toledo Office |
| | Basic and Principles of HPLC in Pharmaceuticals Analysis | 27 - 28.8.2001 | SUCXes Laboratory, UM | BPFK |
| | Kursus Leadership & Team Building | 9 - 11.4.2001 | Jabatan Kesihatan, Kedah | Harvard Suasana Resort Sg. Petani |
| | Seminar on Water Activity Measurement on Pharmaceutical & Food | 23.5.2001 | Team Medical Scientific Sdn Bhd | MARDI, Serdang |
| | Seminar on Safety in the Use of Chemicals | 19 - 20.6.2001 | BPFK/NIOSH | BPFK |
| | National Regulatory Seminar 2001. | 17 - 18.7.2001 | BPFK/PhAMA/MOPI | Hotel Sheraton, Subang Jaya |
| | Workshop on Evaluation of Analytical Method Validation Data | 13 - 17.8.2001 | BPFK | BPFK |
| | The 33rd Executive Development Program for Malaysian Senior Government Officers | 11 - 27.9.2001 | JPA | Seoul, Republic of Korea |
| | Kursus Audit Kualiti Dalam | 7 - 8.11.2001 | BPFK/ Neville Clerk | BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------------|--|---|---|---|
| Faridah Yaacob | Theory & Practical Training for AX & MX Balance Latihan Pengguna – Cara Pembuangan Sisa Klinikal Rapid ID System for Bacteria Latihan Penggunaan "Personnel Protective Equipment" | 4.9.2001 27.9.2001 12.11.2001 28.12.2001 | BPFK Radicare FC-Bios Sdn Bhd BPFK | BPFK BPFK HUKM, KL BPFK |
| Ghanasakti Kanagasabai Hasenah Ali | Cara Pembuangan Bahan Sisa Klinikal Latihan HPLC LC-10VP Seminar on Latest Development on GC, GCMS Technology Seminar on Regulatory Procedures For Veterinary Products in some major countries Safety in the Use of Chemicals National Regulatory Seminar 2001 Seminar on Current Good Manufacturing Practices (CGMP) Seminar on ISO 17025 and GLP/GMP for Analytical Laboratories Workshop on Evaluation of Analytical Method Validation Data | 27.9.2001 20 – 21.2.2001 16.4.2001 17.4.2001 19 – 20.6.2001 17 – 18.7.2001 23.7.2001 25.7.2001 13 – 17.8.2001 | BPFK BPFK Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA BPFK BPFK BPFK/PhAMA/MOPI BPFK Agilent Technologies/ KKM BPFK | BPFK BPFK Hotel Palace of the Golden Horses, Seri Kembangan BPFK BPFK Hotel Sheraton, Subang Jaya BPFK Hotel Sheraton, Subang Jaya BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---|--|--|
| Hasiah Hj. Abdullah | <p>Bengkel Pengurusan Kewangan & Bekalan</p> <p>Bengkel "Value-based Leadership" Untuk Pegawai-Pegawai Farmasi, KKM</p> <p>National Regulatory Seminar 2001</p> <p>Workshop On Evaluation of Analytical Method Validation Data</p> <p>Persidangan Pengurusan Sumber Manusia, KKM</p> <p>National Medicines Policy Workshop</p> <p>Understanding & Documenting an ISO 9001: 2000</p> <p>Kursus Internal Quality Audit</p> | <p>1 – 4.5.2001</p> <p>9 – 11.5.2001</p> <p>17 – 18.7.2001</p> <p>13 – 17.8.2001</p> <p>3 – 6.10.2001</p> <p>9 – 11.10.2001</p> <p>5 – 6.11.2001</p> <p>7 – 8.11.2001</p> | <p>Bhg. Perkhidmatan Farmasi/ KKM</p> <p>KKM</p> <p>BPFK/PhAMA/MOPI</p> <p>BPFK</p> <p>Bhg. Sumber Manusia, KKM</p> <p>KKM/WHO</p> <p>Neville Clarke</p> <p>Neville Clarke</p> | <p>Hotel City Bayview, Langkawi</p> <p>Hotel Awana Porto Malai, Langkawi</p> <p>Hotel Sheraton, Subang Jaya</p> <p>BPFK</p> <p>Hotel Bayview Beach Resort, Pulau Pinang</p> <p>Hotel Eastin, Petaling Jaya</p> <p>Hotel Parkroyal, K. Lumpur</p> <p>BPFK</p> |
| Isma Zairika bt Zainol | <p>Kursus Basis and Principles of HPLC in Pharmaceuticals Analysis</p> <p>LAL Seminar 2001</p> <p>Kursus Kesedaran ISO 9000</p> <p>Latihan Penggunaan "Personnel Protective Equipment"</p> | <p>27 – 28.8.2001</p> <p>15.10.2001</p> <p>6.11.2001</p> <p>28.12.2001</p> | <p>SUCXes Laboratory, UM</p> <p>Choice-Care Sdn. Bhd</p> <p>BPFK</p> <p>BPFK</p> | <p>BPFK</p> <p>Hotel Hyatt Regency Saujana, Subang</p> <p>BPFK</p> <p>BPFK</p> |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|--|---|--|
| Jaafar Lassa | Persidangan Tele-Health bagi Pegawai-pegawai Pengurusan KKM Standardization of Traditional Medicines Fundamentals of Gas Chromatography National Regulatory Seminar 2001 Bengkel Pengurusan IT Farmasi Workshop On Evaluation of Analytical Method Validation Data Seminar "EU Legislation on Herbal Medicinal Products" Kursus Keutuhan Pengurusan Farmasi (Penguatkuasa) Seminar Penghayatan Nilai-nilai Islam Dalam Perkhidmatan Awam National Ethics Seminar 2001 Briefing on Strategic Transformation of Public Enterprises | 7 – 10.2.2001 1 – 28.4.2001 12.6.2001 17 – 18.7.2001 24 – 27.7.2001 13 – 17.8.2001 10.9.2001 24 – 27.9.2001 28 – 29.9.2001 4.11.2001 5.11.2001 | KKM WHO BPFK BPFK/PhAMA/MOPI Bahagian Farmasi BPFK MATRADE Bahagian Farmasi KKM Malaysian Medical Council Arthur Andersen & Co. | Pulau Pinang China BPFK Hotel Sheraton, Subang Jaya Pahang BPFK Kuala Lumpur Kota Bharu, Kelantan Kota Kinabalu, Sabah Kuala Lumpur Kuala Lumpur |
| Kamala Bai | Gas Chromatography Seminar Latihan Pengguna - Cara Pembuangan Sisa Klinikal | 9.5.2001 27.9.2001 | BPFK Radicare | Hotel Eastin, P.J BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|----------------|---|---|
| Kwan Wai Lin | Understanding Filter Validation Based on PDA Technical Report No. 26 | 30.10.2001 | Sartorius | Hotel Sunway lagoon, P.J |
| | Latihan Penggunaan "Personnel Protective Equipment" | 28.12.2001 | BPFK | BPFK |
| Latifah Mhd. Tap | Theory & Practical Training for AX and MX Balance | 4.9.2001 | BPFK | BPFK |
| | Latihan Penggunaan "Personnel Protective Equipment" | 28.12.2001 | BPFK | BPFK |
| Lim Kah Hun | Operation of Instrument and Class-VP Software Training | 20 – 21.2.2001 | BPFK | BPFK |
| | Latest Development on GC, GCMS Technology | 16.4.2001 | Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA | Hotel Palace of the Golden Horses, Seri Kembangan |
| Mior Zamri b. Mior Ahmad | Training on Class-VP Software | 20 – 21.2.2001 | BPFK | BPFK |
| | Latest Development on GC, GCMS Technology | 16.4.2001 | Alpha Analytical (M) Sdn Bhd / Thermo Finnigan Austin USA | Hotel Palace of the Golden Horses, Seri Kembangan |
| Mohamad Harian b. Ahmad | Seminar on Biological Indicator | 11.1.2001 | Biotech Inc. USA | Hotel PJ Hilton |
| | Latihan Penggunaan untuk GC | 15.11.2001 | Radicare | BPFK |
| | Latihan Penggunaan "Personnel Protective Equipment" | 28.12.2001 | BPFK | BPFK |

| NAMA PEGAWAI <i>NAME OF OFFICER</i> | KURSUS <i>COURSES</i> | TARIKH <i>DATE</i> | ANJURAN <i>SPONSOR</i> | TEMPAT <i>PLACE</i> |
|---|--|---|--|---|
| Mohd. Noor b. Nurudin | Seminar on Biological Indicator Latest Development on GC, GCMS Technology LAL Seminar 2001 | 11.1.2001 16.4.2001 15.10.2001 | Biotech Inc. USA Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA Choice-Care Sdn. Bhd. | Hotel PJ Hilton Hotel Palace of the Golden Horses, Seri Kembangan Hotel Hyatt Regency Saujana, Subang |
| Mohd. Sani b. Nawi | Basic and Principles of HPLC in Pharmaceutical Analysis | 27 – 28.8.2001 | SUCXes Laboratory, UM | BPFK |
| Mohd. Tarmizi b. Dollah | Basic and Principles of HPLC in Pharmaceutical Analysis | 27 – 28.8.2001 | SUCXes Laboratory, UM | BPFK |
| Muhammad Nasir b. Hashim | Seminar Kosmetik Fundamentals of Gas Chromatography The 3rd. International Congress of the Asia Pacific Association of Medical Toxicology Internal Quality Audit National Regulatory Seminar 2001 | 1.11.2001 12.6.2001 12 – 15.11.2001 7 – 8.11.2001 7 – 8.11.2001 17 – 18.7.2001 | BPFK Fisher Scientific (M) Sdn. Bhd. USM/APAMT/WHO/ Nat. Poison Centre/ KKM BPFK /Neville Clarke BPFK/PhAMA/MOPI WHO | BPFK BPFK Bayview Beach Resort, Penang BPFK Hotel Sheraton, Subang Jaya National Quality Control Laboratory of Drug and Food, Jakarta, Indonesia |
| Nazeha bt Jusoh | Operation of Instrument Class VP Software Training Latest Development on GC, GCMS Technology | 20 – 21.2.2001 16.4.2001 | BPFK Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA | BPFK Hotel Palace of the Golden Horses, Seri Kembangan |

| NAMA PEGAWAI <i>NAME OF OFFICER</i> | KURSUS <i>COURSES</i> | TARIKH <i>DATE</i> | ANJURAN <i>SPONSOR</i> | TEMPAT <i>PLACE</i> |
|---|--|------------------------------|----------------------------------|--|
| Nazura bt Mohd. Rashid | Understanding Filter Validation Based on PDA Technical Report No. 26 | 30.10.2001 | Sartorius | Hotel Sunway Lagoon, P.J |
| Nik Ismail b. Jaafar | Latihan Penggunaan "Personnel Protective Equipment" | 28.12.2001 | BPFK | BPFK |
| Nirmala Devi | Latihan HPLC LC-10 VP – Shimadzu Chromatography | 20 – 21.2.2001 | BPFK | BPFK |
| Noraida bt Mohammad Zainoor | Kursus Pengenalan ISO 9001:2000 | 6.11.2001 | BPFK | BPFK |
| Norhana bt Ahmad | HPLC Gradient | 20 – 21.2.2001 | BPFK | BPFK |
| | Seminar on Modern Approach to Asthma Management | 9.3.2001 | KKM | Hotel Pan Pacific, KL |
| | Seminar on Regulatory Procedures for Veterinary Products in Some Major Countries | 17.4.2001 | BPFK | BPFK |
| | Basic and Principles of HPLC in Pharmaceutical Analysis | 27 – 28.8.2001 | SUCXes Laboratory, UM | BPFK |
| Oh Lay Eng | Gas Chromatography Seminar | 9.5.2001 | BPFK | Hotel Eastin, P. Jaya |
| | Latihan Pengguna untuk " Air Conditioner" | 13.7.2001 | Radicare | BPFK |
| | Seminar mengenai kerja-kerja Konsessi oleh SIHAT | 19.7.2001 | Radicare | BPFK |
| | LAL Seminar 2001 | 15.10.2001 | Choice-Care Sdn. Bhd. | Hotel Hyatt Regency Saujana, Subang |
| | Kursus Kesedaran ISO 9000 Theory & Practical Training for AX and MX Balance | 6.11.2001 4.9.2001 | BPFK BPFK | BPFK BPFK |
| | Latihan Penggunaan " Personnel Protective Equipment" | 28.12.2001 | BPFK | BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|--|---|--|
| Osman b. Ahamad | Latihan Pengguna – Cara Pembuangan Sisa Klinikal Seminar Kosmetik 2001 Kursus Kesedaran ISO 9000 Audit Kualiti Dalam Rapid ID System for Bacteria Latihan Pengguna untuk GC Latihan Penggunaan "Personnel Protective Equipment" | 10.10.2001 10.10.2001 6.11.2001 7 – 8.11.2001 12.11.2001 15.11.2001 28.12.2001 | Radicare BPFK BPFK/Neville Clarke BPFK/Neville Clarke FC-BIOS Sdn. Bhd. Radicare BPFK | BPFK Hotel Sheraton, Subang Jaya BPFK BPFK HUKM, Kuala Lumpur BPFK BPFK |
| Othman b. Alias | Latihan Pengguna untuk "Air Conditioner" Seminar mengenai kerja-kerja Konsessi oleh SIHAT Theory & Practical Training for AX and MX Balance Latihan Pengguna – Cara Pembuangan Sisa Klinikal Kursus Kesedaran ISO 9000 Kursus Audit Kualiti Dalam Latihan Penggunaan "Personnel Protective Equipment" | 13.7.2001 19.7.2001 4.9.2001 27.9.2001 6.11.2001 7 – 8.11.2001 28.12.2001 | Radicare Radicare BPFK Radicare BPFK BPFK BPFK | BPFK BPFK BPFK BPFK BPFK BPFK BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|--|---|--|
| Rahmah bt. Abas | Theory & Practical Training for AX and MX Balance Understanding Filter Validation Based on PDA Technical Report No. 26 Latihan Pengguna untuk GC Latihan Penggunaan "Personnel Protective Equipment" | 4.9.2001 30.10.2001 15.11.2001 28.12.2001 | BPFK Sartorius Radicare BPFK | BPFK Hotel Sunway Lagoon, P.J BPFK BPFK |
| Rohaiza bt. Zainun | Theory & Practical Training for AX and MX Balance Latihan Pengguna untuk GC Latihan Menggunakan "Personnel Protective Equipment" | 4.9.2001 15.11.2001 28.12.2001 | BPFK Radicare BPFK | BPFK BPFK BPFK |
| Rohani bt. Ramli | Operation of Instruments of Class VP Software Training Latest Development on GC, GCMS Technology | 20 – 21.2.2001 16.4.2001 | BPFK Alpha Analytical (M) Sdn Bhd / Thermo Finnigan Austin USA | BPFK Palace of The Golden Horses, Sri Kembangan |
| Rusnah bt. Rejab | Kursus Basics and Principles of HPLC in Pharmaceuticals Analysis Theory & Practical Training for AX and MX Balance | 27 – 28.8.2001 13.7.2001 | SUCXes Laboratory, UM BPFK | BPFK BPFK |
| Salmah bt. Mohd. Zahid | Seminar Biological Indicator Theory & Practical Training for AX and MX Balance | 11.1.2001 4.9.2001 | BPFK BPFK | BPFK BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---|--|---|
| Hj. Sahar b. Samad | Latihan menggunakan "Personnel Protective Equipment" | 28.12.2001 | BPFK | BPFK |
| Selvaraja Seerangam | Mesyuarat/Taklimat mengenai permohonan Malaysia ke PIC/s 1st. National Conference on Transfusion Medium Seminar on OHSAS, 1800:1999 Workshop on Evaluation of Analytical Method Validation Data Mesy. & Seminar 4th Meeting of ASEAN Consultation Committees for Standard & Quality Product Working Group Conference on Advancing Science and Elimination of the Use of Laboratory Animal | 10.1.2001 27 – 31.3.2001 11.4.2001 13 – 17.8.2001 25 – 29.9.2001 12 – 14.11.2001 | BPFK Pusat Darah Negara SIRIM BPFK WHO WHO | BPFK Hotel Hilton, K. Lumpur Shah Alam BPFK Bali, Indonesia Amsterdam, Holland |
| Sethiaram a/l Seripal | Bengkel Ke-empat Kawalan Doping Sukan Sea ke 21, KI 2001 | 22.8.2001 | KKM | IMR |
| Shukri Mohd. Ariff | Latest Development on GC, GCMS Technology | 16.4.2001 | Alpha Analytical (M) Sdn. Bhd. / Thermo Finnigan Austin USA | Hotel Palace of Golden Horses, Seri Kembangan |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|-----------------------------------|---|--|---|---|
| Dr. Sulaikah bt. V. K. Moideen | Seminar Biological Indicator International GMP Course (Module 7) Good Clinical Practice Workshop Seminar on Safety in the Use of Chemicals National Regulatory Seminar 2001 ISO 17025 & GLP/GMP for Analytical Laboratories Workshop on Evaluation of Analytical Method Validation Data Asia Pacific Clinical Trials Conference Seminar Kosmetik 2001 | 11.1.2001 21 – 23.3.2001 9 – 11.4.2001 19 – 20.6.2001 17 – 18.7.2001 25.7.2001 13 – 17.8.2001 24 – 26.9.2001 1.11.2001 | BPFK BPFK/MOPI BPFK/Eli Lilly BPFK/NIOSH BPFK/PhAMA/MOPI Agilent Technologies/KKM BPFK KKM BPFK | BPFK BPFK Hotel Sheraton, Subang Jaya BPFK Hotel Sheraton, Subang Jaya Hotel Sheraton, Subang Jaya BPFK Sunway Lagoon Resort Hotel BPFK |
| Hj. Supaiman b. Mat Som | Latihan Pengguna – Cara Pembuangan Sisa Klinikal Latihan Penggunaan 'Personnel Protective Equipment (PPE)' | 27.9.2001 28.12.2001 | Radicare BPFK | BPFK BPFK |
| Suzila Abd. Hamid | Pharmalyzir Workshop | 26.4.2001 | Mecomb Technologies | Hotel Sheraton Subang Jaya |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---|--|--|
| Talip Tawil | Pengurusan Pelupusan dan Verifikasi Stok 'Training for the Trainers' Basic and Principles of HPLC Audit Kualiti Dalam Latihan Pengguna untuk GC Latihan Penggunaan "Personnel Protective Equipment" | 5 - 9.8.2001 27 - 28.8.2001 7 - 8.11.2001 15.11.2001 28.12.2001 | KKM BPFK Radicare Radicare BPFK | Hotel Crystal Crown, Johor Bahru BPFK BPFK BPFK BPFK |
| Tan Ann Ling | Fundamental of Gas Chromatography Workshop on Evaluation of Analytical Method Validation Data Filter Validation:PDA Technical Report No. 26 Principle of GLP & Analytical Method Validation, Microbiological GLP | 12.6.2001 13 - 17.8.2001 30.10.2001 19 - 20.11.2001 | Fisher Scientific (M) Sdn. Bhd. BPFK Schmidt Scientific Sdn. Bhd. BPFK / MOPI | BPFK BPFK Hotel Sunway Lagoon, PJ Hotel Pan Pacific Glenmarie |
| Yam Chau Yit | HPLC Class VP Software Training & Operation of Instrument Bengkel Pertama Kawalan Doping Sukan Sea ke 21, KI 2001 Bengkel Ke-empat Kawalan Doping Sukan Sea ke 21, KI 2001 Bengkel Ke-empat Kawalan Doping Sukan Sea ke 21, KI 2001 | 19 - 20.2.2001 16.5.2001 11.7.2001 22.8.2001 | BPFK KKM KKM KKM | BPFK IMR IMR IMR |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|---|---|---|
| Yogeswary Markandoo | EU Legislation for the Pharmaceutical Industry Seminar on Regulatory Procedures for Veterinary Products in some major countries Seminar on Vaccines IT in Pharmacy Practice and Project 2001 Update and Follow-Up ICP-MS- oleh Perkin Elmer Fundamentals of Gas Chromatography Value Based Leadership Seminar on safety in the use of chemicals National Regulatory Seminar 2001 Workshop on Evaluation of Analytical Method Validation Data | 23.1.2001 17.4.2001 5.2.2001 28.4.2001 9.5.2001 12.6.2001 9 – 11.7.2001 19 – 20.6.2001 17 – 18.7.2001 13 – 17.8.2001 | MATRADE/European Business Information/BPFK BPFK BPFK MPS Perkin Elmer Fisher Scientific (M) Sdn. Bhd. KKM BPFK/NIOSH BPFK BPFK | Hotel Hilton, P. Jaya BPFK BPFK Hotel Sunway Lagoon Hotel Sheraton, Subang Jaya BPFK Hotel Awana, Langkawi BPFK Hotel Sheraton, Subang Jaya BPFK |
| Zaini bt. Jamaludin | Theory & Practical Training for AX and MX Balance Latihan Pengguna untuk GC Latihan Penggunaan " Personnel Protective Equipment " | 4.9.2001 15.11.2001 28.12.2001 | BPFK BPFK BPFK | BPFK BPFK BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---|---|--|
| Zambin Rokiah Abd. Rashid | Gas Chromatography Seminar | 9.5.2001 | Fischer Scientific (M) Sdn. Bhd. | Eastin Hotel, P. Jaya |
| Zuraik b. Mustaffa | Latihan Pengguna untuk GC Latihan Penggunaan "Personnel Protective Equipment" | 15.11.2001 28.12.2001 | Radicare BPFK | BPFK BPFK |
| Hasnah bt. Ismail | 3rd Meeting of the ACCSQ P-PWG on Pharmaceuticals National Regulatory Seminar 2001 4th Meeting of the ACCSQ-P-PWG on Pharmaceuticals and related event National Drug Policy Workshop International Course on Drug Policies Issues in Developing Countries | 5 – 7 Februari 2001 17 & 18 Julai 2001 25 - 29 September 2001 9 – 12 Oktober 2001 29 Okt – 9 Nov 2001 | ASEAN Sekretariat BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG ASEAN Sekretariat MOH, WHO WHO | Ho Chi Minh City, Vietnam Sheraton Subang, P. Jaya Bali, Indonesia Eastin Hotel Jogjakarta, Indonesia |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|------------------------|---|---------------------------|
| Rohani bt. Ismail | Seminar "EU Legislation for the Pharmaceutical Industry" | 23 Mac 2001 | Matrade & EBIC Malaysia | Petaling Jaya |
| | Seminar on Regulatory Procedures for Veterinary Products in Some Major Countries | 17 April 2001 | BPFK | BPFK, P. Jaya |
| | National Regulatory Seminar 2001 | 17 - 18 Julai 2001 | BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG | Sheraton Subang, P. Jaya |
| | Workshop on Introduction to the Analytical Method Validation | 13 Ogos 2001 | BPFK | BPFK |
| | 2nd International Congress/13th VAM Congress CVA-Australia/Oceania Region Symposium | 27 - 30 Ogos 2001 | VAM, SAMPAM, MEVA, UPM VET, ALUMNI, CVA | The Mines, Kuala Lumpur |
| | Asia Pacific Clinical Trials Conference | 24 - 26 September 2001 | KKM & Academy of Medicines, Malaysia | Bandar Sunway, P. Jaya |
| | Seminar Kosmetik | 1 November 2001 | BPFK | BPFK |
| | Kursus Audit Kualiti Dalamana | 7 - 8 November 2001 | BPFK | BPFK |
| | National Regulatory Seminar 2001 | 17 - 18 Julai 2001 | BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG | Sheraton Subang, P. Jaya |
| | Health Technology Assessment Training Course | 27 - 30 Ogos 2001 | KKM | Micasa Hotel, Johor Bahru |
| | Asia Pacific Clinical Trials Conference | 24 - 26 September 2001 | KKM & College of Physicians | Sunway Hotel, P. Jaya |
| | Seminar Kosmetik | 10 Oktober 2001 | BPFK | Sheraton Subang, P. Jaya |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---|--|---|
| Siti Aisah bt. Bahari | National Regulatory Seminar 2001 Workshop on Introduction to the Analytical Method Validation 2nd International Congress/13th VAM Congress CVA-Australia/Oceania Region Symposium Kursus Audit Kualiti Dalamann Seminar Kosmetik 2001 | 7 & 18 Julai 2001 13 Ogos 2001 27 – 30 Ogos 2001 7 – 8 November 2001 1 November 2001 | BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG BPFK VAM, SAMPAM, MEVA, UPM VET, ALUMNI, CVA BPFK BPFK | Sheraton Subang, P. Jaya BPFK The Mines, K. Lumpur BPFK BPFK |
| Nurulfajar bt. Mohd. Jamid | Seminar on Vaccines Seminar on Regulatory Procedures for Veterinary Products in Some Major Countries Kursus Biro Tatanegara (Induksi) National Regulatory Seminar 2001 Workshop on Introduction to the Analytical Method Validation Pharmacy Scientific Conference 2001 Seminar Kosmetik 2001 Kursus Audit Kualiti Dalamann | 5 Februari 2001 1 April 2001 10 – 12 Mei 2001 17 – 18 Julai 2001 13 Ogos 2001 22 – 23 Oktober 2001 1 November 2001 7 – 8 November 2001 | BPFK BPFK Biro Tatanegara, Jabatan Perdana Menteri BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG BPFK & Therapeutic Good Administration Australia Persatuan Farmasi Malaysia, Universiti Malaya BPFK BPFK | BPFK BPFK Kolej Latihan Telekom Kuching, Sarawak Sheraton Subang, P. Jaya BPFK Summit Hotel, P. Jaya BPFK BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|--|--|--|
| Fudziah bt. Ariffin | 3rd Meeting of the ACCSQ P-PWG on Pharmaceuticals Persidangan Farmasi 2001 – Modern Approach to Management of Asthma Seminar "EU Legislation for the Pharmaceutical Industry 1st National Transfusion Medicine Conference 2001 Quality Management in Malaysian Blood Services Mesyuarat " Council for TRIPs – Access to Essential Medicine" National Regulatory Seminar 2001 Bengkel "Value-Based Leadership" untuk pegawai-pegawai Farmasi, KKM Workshop on Introduction to the Analytical Method of Validation 4th Meeting of the ACCSQ-P-PWG on Pharmaceuticals and Related Event National Drug Policy Workshop Pharmacy Scientific Conference 2001 Seminar Kosmetik Bengkel " Implications of Globalisation and Multilateral Trade Agreements on Health Care Services | 5 – 7 Februari 2001 9 Mac 2001 23 Mac 2001 27 – 31 Mac 2001 2 – 4 Mei 2001 19 – 21 Jun 2001 17 & 18 Julai 2001 9 – 11 Julai 2001 13 Ogos 2001 25–29 September 2001 9 – 11 Oktober 2001 20 – 23 Oktober 2001 1 November 2001 12–13 November 2001 | ASEAN Sekretariat KKM, MPS Matrade & EBIC KKM, Pusat Darah Negara, Malaysian Blood Transfusion Society KKM, Malaysian Transfusion Blood Society WTO BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG PPF, KKM BPFK ASEAN Sekretariat KKM, WHO MPS, UM BPFK KKM | Ho Chi Minh City, Vietnam Pan Pacific Hotel, K. Lumpur Hilton Hotel, P. Jaya Hilton Hotel, P. Jaya Pusat Darah Negara Geneva, Switzerland Sheraton Subang, P. Jaya Awana Porto Malai, Langkawi BPFK Bali, Indonesia Eastin Hotel, P. Jaya Summit Hotel, P. Jaya BPFK Grand Seasons, K. Lumpur |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|---|--|---|
| Arpah bt. Abas | 3rd Meeting of the ACCSQ P-PWG on Pharmaceuticals 1st National Transfusion Medicine Conference 2001 National Regulatory Seminar 2001 1st AHWP Technical Committee & Workshop 4th Meeting of the ACCSQ P-PWG on Pharmaceuticals and Related Event Pharmacy Scientific Conference 2001 Seminar Kosmetik | 5 – 7 Februari 2001 27 –31 Mac 2001 17 & 18 Julai 2001 6 – 7 September 2001 25 – 29 Oktober 2001 22 – 23 Oktober 2001 1 November 2001 | ASEAN Sekretariat Pusat Darah Negara BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG Health Sciences Authority, Singapore ASEAN Sekretariat MPS, UM BPFK | Ho Chi Minh City, Vietnam Hotel Hilton K. Lumpur Sheraton Subang, P. Jaya Sheraton Subang, P. Jaya Bali, Indonesia Summit Hotel, P. Jaya BPFK |
| Mazuwin Bt. Zainal Abidin | Good Clinical Practice Workshop National Regulatory Seminar 2001 Workshop on Introduction to the Analytical Method Validation Asia Pacific Clinical Trials Conference | 9 – 11 Apr 2001 17 & 18 Julai 2001 13 Ogos 2001 24-26 September 2001 | BPFK & Eli Lilly (M) Sdn. Bhd. BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG BPFK KKM & Academy of Medicines, Malaysia | Sheraton Subang, P. Jaya Sheraton Subang, P. Jaya BPFK Sunway Hotel, P. Jaya |
| Suhailah bt. Abu Bakar | Seminar Kosmetik In-House Training - Kefahaman ISO 9000:2000 | 1 November 2001 6 November 2001 | BPFK BPFK | BPFK BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|--|--|---|
| Tan Lie Sie | Seminar on Vaccines Persidangan Farmasi 2001 – Modern Approach to Management of Asthma Seminar "EU Legislation for the Pharmaceutical Industry" Bengkel "Value-Based Leadership" untuk pegawai-pegawai Farmasi, KKM Seminar Regulatori Kebangsaan 2001 Asia Pacific Clinical Trials Conference Seminar Kosmetik Asean Direct Selling Conference - ADSC | 5 Februari 2001 9 Mac 2001 23 Mac 2001 9 – 11 Julai 2001 17 – 18 Julai 2001 24–26 September 2001 1 November 2001 15 November 2001 | BPFK KKM, MPS Matrade, EBIC PPF, KKM BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG KKM & College of Physician, Academy of Medicine of Malaysia BPFK Salihin Ramli Management Sdn. Bhd. | BPFK Pan Pacific K. Lumpur Hilton, P. Jaya Awana Porto Malai, Langkawi Sheraton, Subang, P. Jaya Sunway Hotel, P. Jaya BPFK Palace of Golden Horses, K. L. |
| Basmiah bt. Md. Isa | Seminar on Vaccines Persidangan Farmasi 2001- Modern Approach to Management of Asthma Seminar On Regulatory Procedures for Veterinary Products in Some Major Countries Kursus Biro Tatanegara (Induksi) Seminar Regulatori Kebangsaan 2001 Seminar on "Drug Abuse Prevention Activities" Asia Pacific Clinical Trials Conference Seminar Kosmetik 2001 Pharmacy Scientific Conference 2001 In-House Training on Internal Quality Auditing Asean Direct Selling Conference - ADSC | 5 Februari 2001 9 Mac 2001 1 April 2001 10 – 12 Mei 2001 17 – 18 Julai 2001 12 September 2001 24–26 September 2001 10 Oktober 2001 22 – 23 Oktober 2001 7 – 8 November 2001 15 November 2001 | BPFK KKM dan Persatuan Farmasi Malaysia BPFK Biro Tatanegara, Jabatan Perdana Menteri BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG Agensi Dadah Kebangsaan KM & College of Physician, Academy of Medicine of Malaysia BPFK UM, MPS & Bhg.Farmasi Selangor BPFK Salihin Ramli Management Sdn. Bhd. | BPFK Hotel Pan Pacific, K. Lumpur BPFK Kolej Latihan Telekom, Kuching, Sarawak Sheraton, Subang, P. Jaya Hotel Pan Pacific, K. Lumpur Sunway Hotel, P. Jaya Sheraton Subang, P. Jaya Hotel Summit, Subang Jaya BPFK Palace of Golden Horses |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|-----------------------------------|--|---|--|---|
| Somiyaton bt. Dahalan @ Damuri | Seminar Kosmetik Kursus Kesedaran ISO 9000 | 1 November 2001 6 November 2001 | BPFK BPFK | BPFK BPFK |
| Ramli bin Zainal | Taklimat Halal 4th Meeting ACCSQ-Cosmetic Product Working Group Taklimat Penggunaan Kod ATC Bengkel Pengurusan Kewangan dan Bekalan National Regulatory Seminar (Scientific Committee) Bengkel Pengurusan IT Farmasi Kursus Keutuhan Pengurusan Farmasi Strategic Transformation of Public Enterprise | 11 Januari 2001 8 – 9 Februari 2001 14 Februari 2001 1 – 4 Mei 2001 17 – 18 Julai 2001 24 – 27 Julai 2001 25 – 27 September 2001 5 November 2001 | CTFA ACCSQ BPFK Bahagian Perkhidmatan Farmasi BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG Bahagian Perkhidmatan Farmasi Bahagian Perkhidmatan Farmasi Arthur Andersen | P. Jaya Ho Chi-Minh City, Vietnam BPFK Langkawi Sheraton Subang, P. Jaya Cherating, Pahang Kota Bharu Kuala Lumpur |
| Anis bt. Talib | 3rd Meeting of the ACCSQ-PPWG on Pharmaceuticals 4rd Meeting of the ACCSQ-PPWG on Cosmetics Conference on Functional Food – latest development | 5 – 7 Februari 2001 8 – 9 Februari 2001 10 – 11 April 2001 | ACCSQ ACCSQ Universiti Putra Malaysia | Ho Chi Minh City, Vietnam Ho Chi Minh City, Vietnam Renaissance Palm Garden, Putra Jaya |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|--|--|--|
| Zuraida bt. Abdullah | Conference on Functional Food – latest development Seminar on Regulatory Procedures for Veterinary Products Seminar Regulatori Kebangsaan 2001 Workshop on Introduction to the Analytical Method Validation | 10 – 11 April 2001 17 April 2001 17 – 18 Julai 2001 13 Ogos 2001 | Universiti Putra Malaysia BPFK BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG BPFK | Renaissance Palm Garden, Putra Jaya BPFK Sheraton Subang, P. Jaya BPFK |
| Saleha bt. Mohd. Ewan | Workshop on Evaluation of Efficacy of Anti-Malarial Drugs Kursus menerajui perubahan Clinical Trial Conference 3rd International Congress Assessment of Application for Marketing Authorization of Multisource Drugs | 27 – 31 Mac 2001 22 – 25 Mei 2001 24 – 27 September 2001 12 – 15 November 2001 3 – 7 Disember 2001 | WHO INTAN MOH College of Physician APAMT WHO | Bangkok, Thailand INTAN, Bukit Kiara Sunway Resort, P. Jaya Pulau Pinang Manila, Philippines |
| Rosilawati bt. Ahmad | Post Conference Workshop – Clinical Trial in Herbal Medicine Research National Regulatory Seminar Seminar Tumbuhan-tumbuhan Ubatan dan Beraroma 2001 Seminar Complementary Healthcare | 27 September 2001 17 – 18 Julai 2001 24 – 25 Julai 2001 6 – 7 September 2001 | KKM & College of Physicians, Academy of Medicine of Malaysia BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG FRIM (Institut Perhutanan Malaysia) KKM, UIM dan Trans Evert | IMR, K. Lumpur Sheraton Subang, P. Jaya FRIM PWTC, K. Lumpur |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|--|---|--|
| Syaliza Omar | Seminar on "Regulatory Procedures for Veterinary Products in Some Major Countries" Seminar Regulatori Kebangsaan Seminar Tumbuhan-tumbuhan Ubatan dan Beraroma 2001 Workshop on Introduction to the Analytical Method Validation Kursus Pengenalan ISO 9001-2000 Kursus Audit Dalaman | 17 April 2001 17 – 18 Julai 2001 24 – 25 Julai 2001 13 Ogos 2001 6 November 2001 7 – 8 November 2001 | BPFK BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG FRIM (Institut Perhutanan Malaysia) BPFK BPFK BPFK | BPFK Sheraton Subang, P. Jaya FRIM BPFK BPFK BPFK |
| Asnida bt. Mat Daud | Seminar on Vaccines On-line Education: What to Expect (Continuous Medical Education) Kursus Biro Tatanegara Kursus Induksi khusus bagi Kumpulan Pengurusan dan Profesional Seminar Regulatori Kebangsaan Seminar EU Legislation on Herbal Medicinal Products Asia-Pacific Clinical Trials Conference Clinical Trial in Herbal Medicine Research Pharmacy Scientific Conference 2001 Seminar Kosmetik Kursus Audit Kualiti Dalaman | 5 Februari 2001 16 Mac 2001 10 – 12 Mei 2001 13 – 26 Mei 2001 17 – 18 Julai 2001 11 September 2001 24 – 26 September 2001 27 September 2001 22 – 23 Oktober 2001 1 November 2001 7 – 8 November 2001 | BPFK Intramedicine USA Biro Tatanegara, Jabatan Perdana Menteri KKM BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG MATRADE, European Business Information Centre (EBIC) KKM & College of Physician, Academy of Medicine of Malaysia KKM & College of Physician, Academy of Medicine of Malaysia MPS, UM & Bhg.Farmasi Selangor BPFK BPFK | BPFK IMR Kolej Latihan Telekom Kuching, Sarawak Hotel Grand Continental Kuching, Sarawak Sheraton Subang, P. Jaya PWTC K. Lumpur Sunway Hotel, P. Jaya IMR K. Lumpur Summit Hotel, P. Jaya BPFK BPFK |

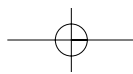
| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|------------------------|--------------------------------------|--------------------------------|
| Dr. Ramli bt. Abd. Ghani | Third IFPMA Asian Regulatory Seminar | 20 – 22 Mac 2001 | IFPMA/WHO | Bangkok, Thailand |
| | GCP Workshop (organizer) | 9 – 11 April 2001 | BPFK, Eli Lilly | Sheraton Hotel, Subang Jaya |
| | Conference on R & D Coalition for TB Drug Dev. in Asia | 2 – 4 Mei 2001 | CDR, USM/Global Alliance for TB Drug | Pulau Pinang |
| | Bridging Study Conference | 24 – 26 Mei 2001 | APEC/DOH Taiwan | Taipei, ROC |
| | Evidence-Based Vaccinology | 22 – 23 Jun 2001 | MOH/MLF | Mandarin Hotel, K. Lumpur |
| | National Regulatory Seminar (Scientific Committee) | 17 – 18 Julai 2001 | BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG | Hotel Sheraton Subang, P. Jaya |
| | GLP Seminar (organizer) | 25 Julai 2001 | BPFK/UIMMC/Agilent Tech | Hotel Sheraton Subang, P. Jaya |
| | Training on Int. Practice for Drug Registration on NCE | 3 – 21 September 2001 | WHO/TDR Program | Canberra/Sydney |
| | Asia-Pacific Clinical Trials Conference Workshop (organizer) | 24 September 2001 | MOH/CP, AMM | Sunway Hotel, P. Jaya |
| | AP Clinical Trials Conference (scientific committee) | 25 – 26 September 2001 | MOH/CP, AMM | Sunway Hotel, P. Jaya |
| | Third Int. Congress of AP of Medical Toxicology (speaker/AJK) | 12 – 15 November 2001 | USM/MOH/WHO | Pulau Pinang |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|---|---|---|--|
| Norizam bt. Ibrahim | Seminar on Vaccines 1st National Transfusion Medicine Conference 2001 Seminar on "Regulatory Procedures for Veterinary Products in Some Major Countries" Seminar on Blood Products Evidence-Based Vaccinology Symposium National Regulatory Seminar 2001 Pre-Conference Workshop: New Drug Application in Malaysia: Asia Pacific Clinical Trial Conference 2001 4th Meeting of the ACCSQ P-PWG on Pharmaceuticals and Related Event Pharmacy Scientific Conference 2001 Seminar Kosmetik In-House Training on Internal Quality Auditing | 5 Februari 2001 27 – 31 Mac 2001 17 April 2001 8 Mei 2001 22 – 23 Jun 2001 17 – 18 Julai 2001 24 September 2001 25 – 29 September 2001 22 – 23 Oktober 2001 1 November 2001 7 – 8 November 2001 | BPFK Pusat Darah Negara BPFK Pusat Darah Negara KKM BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG KKM ASEAN Sekretariat MPS, UM BPFK BPFK | BPFK Hotel Hilton, K. Lumpur BPFK Pusat Darah Negara Mandarin Oriental Hotel, K. Lumpur Hotel Sheraton Subang, P. Jaya Sunway Lagoon Resort, P. Jaya Bali, Indonesia Summit Hotel, P. Jaya BPFK BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|------------------------|--------------------------------------|--------------------------------|
| Norhayati bt. Hanafiah | Seminar on Vaccines | 5 Februari 2001 | BPFK | BPFK |
| | Persidangan Farmasi 2001 (Respiratori) | 9 Mac 2001 | Bahagian Perkhidmatan Farmasi & MPS | Hotel Pan Pacific, K. Lumpur |
| | Seminar on "Regulatory Procedures for Veterinary Products in Some Major Countries" | 17 April 2001 | BPFK | BPFK |
| | Seminar on "Blood Products" | 8 Mei 2001 | Pusat Darah Negara | Pusat Darah Negara |
| | Workshop on "Evaluation of Analytical Method Validation Data" | 13 Ogos 2001 | BPFK | BPFK |
| | Seminar on "Drug Abuse Prevention Activities" | 12 September 2001 | Agensi Dadah Kebangsaan | Hotel Pan Pacific, K. Lumpur |
| | Asia Pacific Clinical Trials Conference | 24 – 26 September 2001 | KKM & Academy of Medicines, Malaysia | Sunway Resort Hotel, P. Jaya |
| | Seminar Kosmetik 2001 | 10 Oktober 2001 | BPFK, CTFA & FMM-MCTIG | Sheraton Hotel, P. Jaya |
| | Sambutan Hari Q 2001 | 1 November 2001 | KKM | Hotel Cititel, Mid Valley, K.L |
| | Kursus "Kesedaran ISO 9000" | 6 November 2001 | BPFK | BPFK |
| | Kursus "Audit Kualiti Dalamam" | 7 – 8 November 2001 | BPFK | BPFK |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|----------------------|---|--|
| Chuah Siew Khim | Seminar Status Terkini Perkembangan Peraturan Makanan dan Dadah | 12 Mac 2002 | JICA /KKM | Renaissance Palm Garden Hotel, Putrajaya |
| | Persidangan Akta dan Peraturan Ahli Farmasi | 19 - 21 Mac 2002 | Bhg. Farmasi KKM | Hotel Awana Porto Malai, Langkawi |
| | Workshop on Communication Skills in Pharmaceutical Care | 2 - 5 April 2002 | Jabatan Kesihatan Negeri Kedah | |
| | Clinical Pharmacy Conference "Lipid and Pain Management" | 14 - 17 April 2002 | Bhg. Farmasi KKM/MPS/ Pfizer | A' Famosa Resort, Melaka |
| | Kursus "Pharmacy Updates" untuk Pegawai Farmasi | 15 - 16 Mei 2002 | Jabatan Kesihatan Negeri Pahang | Hotel Grand Continental, Kuantan |
| | 1st National Conference on Life Sciences on "Genomics and Health Implications for Malaysia | 21 - 22 Mei 2002 | KKM/College of Physicians, Academy of Medicine of Malaysia | Malaysia International Exhibition & Convention Centre K. Lumpur. |
| | Clinical Pharmacy Seminar on CNS-Related Illnesses | 4 Julai 2002 | Selangor State Health Dept/ MPS/Janssen Cilag Hotel Grand Seasons, KL | Hotel Armada |
| | Bengkel "Value-Based Leadership" untuk pegawai-pegawai Farmasi, KKM | 9-11 Julai 2001 | Bhg. Farmasi KKM | Awana Porto Malai, Langkawi |
| | National Regulatory Seminar 2001 | 17-18 Julai 2001 | BPFK | Hotel Subang Sheraton |
| | 33rd Executive Development Program for Malaysian Senior Government Officials | 11-27 September 2001 | Jab. Perkhidmatan Awam | Republik Korea |
| | ASEAN Direct Selling Conference 2001 | 15 December 2001 | | Palace of the Golden Horses, K. Lumpur |

| NAMA PEGAWAI NAME OF OFFICER | KURSUS COURSES | TARIKH DATE | ANJURAN SPONSOR | TEMPAT PLACE |
|---------------------------------|--|---------------------|-------------------------------------|--------------------------|
| Masfiza bt. Abdul Hamid | Seminar On Regulatory Procedures for Veterinary Products in Some Major Countries | 17 April 2001 | BPFK | BPFK, P. Jaya |
| | National Regulatory Seminar 2001 | 17 & 18 Julai 2001 | BPFK, PhAMA, MOPI, CTFA & FMM-MCTIG | Sheraton Subang, P. Jaya |
| | Seminar Kosmetik | 10 Oktober 2001 | BPFK | Sheraton Subang, P. Jaya |
| | Kursus Audit Kualiti Dalamman | 7 – 8 November 2001 | BPFK | BPFK |



AKTIVITI-AKTIVITI BPFK SEPANJANG TAHUN 2001 *ACTIVITIES OF NPCB THROUGHOUT THE YEAR 2001*



Ahli Pihak Berkuasa Kawalan Dadah



Mesyuarat Pihak Berkuasa Kawalan Dadah

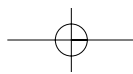


National Regulatory Seminar 2001



PI C/S accessment





Demonstasi masakan oleh Pn. Zaidah - Puspanita



Majlis Penganugerahan Perkhidmatan Cemerlang



Pelawat dari Zimbabwe



Pasaria Puspanita

