ANNUAL REPORT 2004
PHARMACEUTICAL SERVICES DIVISION

1. INTRODUCTION

1.1 Background

The Pharmaceutical Services Division (PSD) is a division under the Research and Technical Support Program (P&ST) of the Ministry of Health Malaysia (MOH). The main responsibility of the PSD is to ensure that pharmaceuticals and healthcare products available to the Malaysian public are safe, efficacious, and of good quality; to achieve definite outcomes and improve quality of life.

This division is headed by a director and assisted by two deputy directors responsible for the Pharmaceutical Enforcement Branch and Pharmaceutical Care Management, respectively and the director of the National Pharmaceutical Control Laboratory.

1.2 Vision and Mission of Pharmaceutical Services

The vision of the division is "to provide the best pharmacy service for the health and well being of the nation" and its mission is to "lead a dynamic pharmacy service emphasizing on the highest level of integrity, professionalism and excellence, that meets the aspiration and challenges of the nation.

1.3 OBJECTIVES

1.3.1 General Objective

To ensure that quality, safe, efficacious and affordable pharmaceutical and healthcare products are available and accessible to the public.

1.3.2 Specific Objectives

i) To ensure that pharmaceutical products permitted to be marketed locally are safe, of quality and effective as well as to ensure that cosmetic products are safe and of good quality.

ii) To enforce the related acts and regulations regarding pharmaceutical products.

iii) To formulate and determine policies on drugs and pharmaceuticals to align with and chart the National Health Policy.

iv) To optimise manpower utilisation for pharmaceutical service in the country.

v) To optimise drug therapy and provision of pharmaceutical care through effective pharmaceutical control and up-to-date clinical and professional pharmaceutical services.

vi) To ensure that drug expenditure is at the optimal economic level and quality medicines are available at the point of need.

vii) To generate consumer awareness on issues of informed and rational drug use and adverse events through constant consumer and patient education.

viii) To ensure that the pharmaceutical service provided is dynamic and progresses with current global development.

1.4 Organisation of Pharmaceutical Services

There are three main subdivisions within the Pharmaceutical Services Division, namely the National Pharmaceutical Control Bureau, Pharmaceutical Enforcement Branch and Pharmaceutical Care Management.

The general functions of PSD and specific functions of the 3 main subdivisions of the Pharmaceutical Services Division are as follows:

1.4.1 General Functions

i) As the Secretariat to the Poison's Board.

ii) As the Secretariat to the Pharmacy Board

iii) As the Secretariat to the Medicine's Advertisement Board

iv) As Secretariat to the Drug control Authority

v) To provide technical input to developing countries through international bodies and local agencies; and to provide training and expertise to health personnel of developing countries in regulatory, enforcement

and pharmaceutical care areas.

1.4.2 Specific Functions

i. The National Pharmaceutical Control Bureau

To contribute directly towards public health, through quality assurance by regulating the pharmaceutical industry. This is to ensure that products produced or imported conform to acceptable standards of quality, safety and efficacy before they are registered; and that all premises and practices employed to manufacture, store and distribute these products comply with the required standards until they are delivered to the end users.

ii. The Pharmaceutical Enforcement Branch

To ensure that the manufacture, importation, sale, supply, management and use of pharmaceuticals, cosmetics and healthcare products are conducted according to the following existing acts and regulations:

i) The Poisons Act 1952 (Revised 1989) and Regulations.
ii) The Sales of Drugs Act 1952 (Revised 1989) and Regulations.
ii) The Medicines (Advertisement and Sales) Act 1956 (Revised 1983) and Regulations.
iv) The Registration of Pharmacist Act 1951 (Revised 1989) and Regulations.
v) The Dangerous Drugs Act 1952 (Revised 1980) and Regulations.

iii. Pharmaceutical Care Management

i) As the Secretariat to the Ministry of Health Drug List Review Panel.
ii) To formulate policies for pharmacy practice in areas of services requirement, skills enhancement, human resource development, administrative functions and funds allocation.
iii) To provide advisory technical support in drugs and medical products procurement, supplies and distribution.

2. PROGRAMME STRATEGIES

The PSD has carried out its responsibilities through the following strategies:

i) Ensure the safety, efficacy and quality of medicines, including traditional medicines are maintained by: -

- Evaluation and registration of medicines prior to marketing.
- Licensing manufacturers, importers and wholesalers of medicines.
- Monitoring for adverse drug reaction arising from their use.
- Monitoring quality of medicines through post marketing surveillance programme.

ii) Improve the enforcement of existing acts and regulations by:

- Strengthening the enforcement units at Ministry and State levels.
- Formulating new legislations while reviewing and amending existing ones whenever necessary.
- Intensifying enforcement activities.

iii) Ensure continuous and adequate supply of pharmaceuticals by:

- Utilising information and communication technology to strengthen the inventory management system.
- Enhancing advisory technical input in the purchase of pharmaceutical products.

iv) Develop an efficient and effective pharmacy service in the Ministry of Health hospitals and health clinics by:

- Continuous improvement of existing facilities in pharmacy units and expansion of pharmacy services.
- Promoting efficient and quality use of medicine through clinical and pharmaceutical care activities.
- Expanding clinical pharmacy services by upgrading existing services and introducing new services.
- Creating Centre of Excellence for different clinical pharmacy service.
- Creating competitiveness and innovativeness through awards such as the best counter service.

- Ensure education to public on appropriate drug use is enhanced

v) Ensure adequate supply of qualified and trained personnel to manage and operate the expanding services by:

- Identifying levels and categories of personnel required.
- Intensifying post-graduate and in-service training to enhance competency and expertise of pharmacists.
- Enhancing content modules of workshops and seminars for continuous professional development and skills development.

3. PROGRAMME RESOURCES

3.1 Finance

The amount allocated for pharmacy activities and administration of the division for 2004 was RM1,053,600.00. The expenditure for the year was RM1,010,547.05 which is 96% of the allocation. **Table 1** shows the detail allocation and expenditure.

Table 1: Financial Allocation and Expenditure For 2004

ACTIVITY	ALLOCATION	ACTUAL ALLOCATION	EXPENDITURE
1. 040100 Headquarters - Technical, professional, management and support	**270,000.00**	**519,600.00**	**491,200.43**
2. 040200 Pharmacy	**460,000.00**	**534,000.00**	**519,346.62**
Total	**730,000.00**	**1,053,600.00**	**1,010,547.05**

3.2 Organisational and Human Resource Development

i. Organisational Restructuring

The PSD has created new portfolios for Grade U48 Pharmacists to strengthen planning activities, policy management and services implementation. There are currently 15 new and existing portfolios for Pharmaceutical Care Management and 10 for Pharmaceutical Enforcement Branch.

There were 41 professional personnel and 28 administrative and non-

professional staffs at the PSD.

Table 2: List of Portfolios at the Pharmaceutical Services Division

Pharmaceutical Care Management	Pharmaceutical Enforcement Branch
Human Resource and Career Development	Licensing
Pharmacy Board	Investigation
Training & CPD	Diversion Control
Compulsory Service	Surveillance
Clinical Pharmacy	Operational - Poison
Medicine Management & ICT	Operational – Counterfeit Medicine
Pharmacy Practice (Hospital)	Operational – Precursor and Cosmetics
Pharmacy Practice (Health)	Legislation
Research and Development	Prosecution
Complaint and Price Monitoring	Consumer Protection
Quality Management	
Interagency and International Relation	
National Medicine Policy	
Drug Information and Consumer Education	
MOH Drug Formulary	

Note: The shaded area shows the existing portfolios.

ii. Increase in Pharmacy Personnel

The shortage of Pharmacists and Pharmacy Assistants in 2004 had jeopardised the expansion, development and optimisation of the present pharmacy services at hospitals and health clinics, to the level of services available in developed countries.

The same drawback also affected the enforcement and regulatory activities, which were hard pressed to cope up with the rapid development in the pharmaceutical industry and trade. Several steps to overcome the shortage had been taken by the PSD, which include:

- Introduction of compulsory service in the public sector whereby the amendment to the regulation of the Registration of Pharmacists Act 1951 (Amendment 2003) for this purpose, was approved by the Minister of Health and was enforced on 02/09/2004.

- Request for an additional quota for reemployment of retired Pharmacy Assistants on contract basis.
- Recognition of the Diploma in Pharmacy Assistant / Pharmacy accorded to graduates from The Mara University of Technology and The Perak Medical College, to facilitate employment into public service.
- Proposal to recruit Indonesian pharmacists to work in Malaysia as Pharmacy Assistants on contractual basis.

iii. Promotion

A group of 107 pharmacists had been promoted to grade U48, and 19 Pharmacy Assistants had been promoted to grades U32 and 10 to grade U36. **Table 3 and 4** show the number of posts for grades U41 to VU6 for pharmacists and U29 to U40 for Pharmacy Assistants.

iv. Recruitment of new staff

One-hundred and forty (140) graduates who had completed their housemanship in 2004 were interviewed and were subsequently offered posts. One hundred and twenty two (122) accepted the posts. Some 42 pharmacy assistant diploma holders were appointed into public service, of whom 29 were diploma holders from UiTM and 13 were from the Pharmacy Assistant College of the MOH. The number of positions for each salary scale for Pharmacists and Pharmacy Assistants in all three areas of pharmaceutical services is shown in **Table 5 dan 6**.

Table 3: Total Number of Posts for Pharmacists

Grade	2001	2002	2003	2004
U41	569	849	972	980
U44				58
U48	68	97	113	180
U52				21
U54	13	13	13	13
VU 7	3	3	3	4
VU 6	1	1	1	1

Table 4: Total Number of Posts for Pharmacy Assistants

Grade	2001	2002	2003	2004
U29	2199	2319	2407	2447
U32	201	245	277	248
U36	33	41	47	51
U38			5	9
U40				1

Table 5: Status of Pharmacists' Post on 31/12/2004

Activity	Grade	No.	Filled	Vacant
Pharmaceutical Care Management	U41	785	382	403
	U44	52	0	52
	U48	112	118*	14
	U52	18	0	18
	U54	10	9	1
	JUSA C	1	1	0
	JUSA B	1	1	0
Enforcement and Licensing	U41	137	100	37
	U44	2	0	2
	U48	37	33	4
	U52	1	0	1
	U54	1	1	0
	JUSA C	1	1	0
Regulatory (National Pharmaceutical control Bureau)	U41	58	47	11
	U44	4	0	4
	U48	31	33	1
	U52	2	0	2
	U54	2	2	0
	JUSA C	1	0	1

Table 6: Status of Pharmacy Assistants Post on 31/12/2004

Activity	Grade of Post	No.	Filled	Vacant
Pharmaceutical Care Management	U29	2394	2041	303
	U32	298	245	53
	U36	48	32	16
	U38	5	4	1
Enforcement and Licensing	U29	2	0	2
	U32	4	3	1
	U36	3	2	1
	U38	0	0	0
Regulatory (National Pharmaceutical Control Bureau)	U29	65	57	8
	U32	8	5	3
	U36	2	1	1
	U38	1	0	1

4. ACTIVITIES AND ACHIEVEMENTS

4.1 REGULATORY CONTROL OF PHARMACEUTICAL

4.1.1 Pharmaceutical product quality assurance

This activity is responsible for ensuring safety, efficacy and quality of drugs; safety and quality of traditional medicines and cosmetics marketed locally. Samples for testing in National Pharmaceutical Control Bureau (NPCB) laboratories are either samples for registration, surveillance or enforcement activities. A total of 4,266 samples were tested in the year 2004. Statistics related to the tests is as shown in Figure **1 and 2.**

Until the end of the year 2004 a total of 77,939 products were registered. The statistics for product registration are as shown in **Table 7 and 8.** A total of 34,099 applications were received for the year 2004 which is an increase of 21% compared to the year before (28,177 in 2003). The bulk of the application was for cosmetics registration which was 89.8%, followed by traditional medicines 6.5%; OTC products 2.1% and prescription drugs 1.6%. All categories of products showed an increase in the number of applications compared to the year before. The total revenue collected by NPCB is as shown in **Table 9.**

NPCB publishes the Drug Control Authority (DCA) Newsletter, Drug Information Circular and Malaysian Adverse Drug Reaction Committee (MADRAC) Newsletter to disseminate drug information and drug regulatory matters to healthcare professionals and those in the industry. The Drug Monograph is no longer published since drug information can be accessed through the Internet and is always subjected to changes.

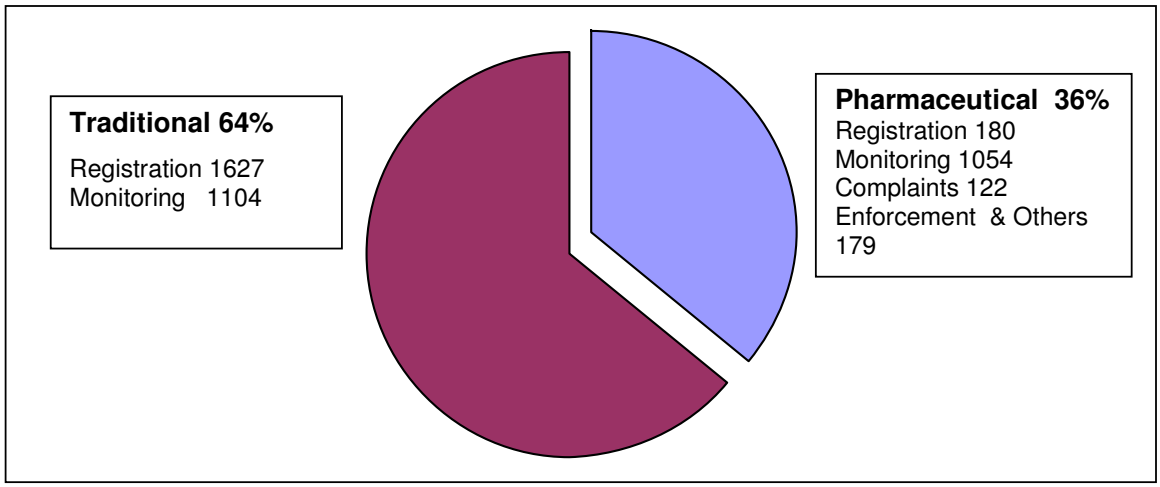

Figure 1: Type of samples received

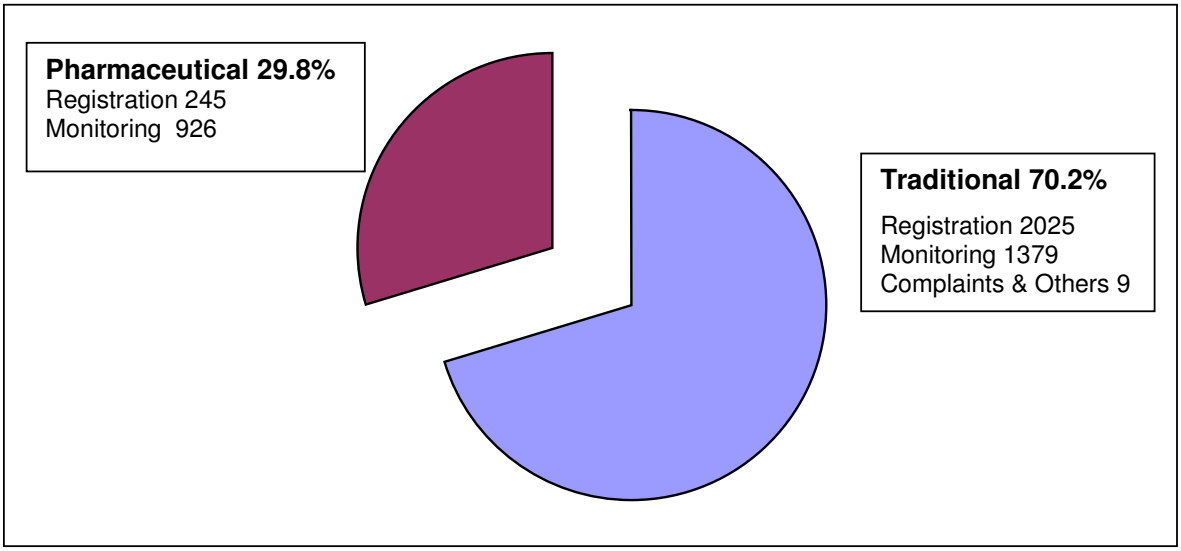

Figure 2: Type of samples tested

The Drug Information and Communication unit at the Centre for Organizational Development received 1,489 enquiries throughout the year through e-mail, telephone, facsimile and correspondence.

The quality of drugs in the market is monitored by NPCB through surveillance activities. A total of 2,793 samples of registered products had been taken for

this purpose and this represented 11.36% of the targeted number of registered products, that is 24,587 products. A total of 1792 labels and package inserts had been checked and 140 warning letters were issued.

Table 7: Application for Registration from 1985 to 2004

Year	Poison	Non-Poison	Traditional Medicine	Cosmetic	Total	
					Annually	Cummulative
1985	9	0			9	9
1986	6,439	-	-	-	6,439	6,448
1987	824	56	-	-	880	7,328
1988	702	2,532	-	-	3,234	10,562
1989	664	2,750	-		3,414	13,976
1990	528	597	-	-	1,125	15,101
1991	481	305	-	42	828	15,929
1992	150	60	3,973	145	4,328	20,257
1993	376	111	7,059	51	7,597	27,854
1994	400	168	4,080	31	4,679	32,533
1995	440	239	288	58	1,025	33,558
1996	617	671	415	130	1,833	35,391
1997	532	635	668	123	1,958	37,349
1998	587	606	938	277	2,408	39,757
1999	796	789	1,347	610	3,542	43,299
2000	427	444	1,523	262	2,656	45,955
2001	578	487	1,154	150	2,369	48,324
2002	509	448	1,603	214	2,774	51,098
2003	263	266	1,471	26,177	28,177	79,275
2004	529	720	2,220	30,630	34,099	113,374
Total	**15,851**	**11,884**	**26,739**	**58,900**	**113,374**	

Only 5 **degree 1** (within 24 hours) product recalls were issued, one for traditional medicine and 4 for OTC products. There was no **degree 2** (within 72 hours) product recall for the year 2004. A total of 145 product batches were ordered to be recalled within 30 days (**degree 3**), which comprised of 20 prescription drugs, 8 OTC products and 117 traditional medicines. Product registration holders **voluntarily recalled** 29 product batches which comprised of 15 prescription drugs, 12 OTC products and 2 traditional medicines.

Throughout the year 2004 BPFK received a total of 1665 **Adverse Drug Reaction reports** compared to 1063 reports received last year. Analysis of the reports based on the reporters is shown in **Figure 3.** The highest number

of reports came from Hospital Kuala Lumpur and the state of Selangor. Most of the reporters were doctors working in government hospitals.

Table 8: Cumulative products registered

Year	Poison	Non-Poison	Traditional Med.	Cosmetic	Total
1991	5,332	3,331	-	-	8,663
1992	5,862	3,743	-	14	9,619
1993	6,131	3,867	5	109	10,112
1994	6,444	3,954	57	149	10,604
1995	6,691	4,023	339	183	11,236
1996	7,027	4,237	1,852	292	13,408
1997	7,525	4,830	4,347	476	17,178
1998	8,187	5,415	7,819	664	22,085
1999	8,792	5,942	7,966	1,235	23,935
2000	8,813	6,072	8,550	1,467	24,902
2001	8,993	6,696	9,894	1,776	27,359
2002	9,335	6,931	10,758	1,935	28,959
2003	9,659	7,206	12,107	6,656	35,628
2004	10,012	7,432	13,077	47,418	77,939
					-
Total	**10,012**	**7,432**	**13,077**	**47,418**	**77,939**

Table 9: NPCB Revenues (RM) for 2004

ACTIVITIES	RM	ACTIVITIES	RM
Product registration	8,655,350	GMP inspection	81,295
Certificate of Pharmaceutical Products	181,900	Laboratory Services	342,882
Import Licence & Import Licence for Clinical Trials	360,500.5	Printed Materials Sales	16,055.50
Manufacturer's Licence	278,200	Other Sales	67,874.64
Wholesaler's Licence	423,500		
TOTAL			**10, 407,557.64**

A total of 1547 licenses were issued in year 2004. There were 227 licensed manufacturers, 456 licensed importers and 864 licensed wholesalers as shown in **Figure 4**.

The list and detail information on licensed premises can be browsed via

NPCB homepage at www.bpfk.gov.my. Information is updated monthly.

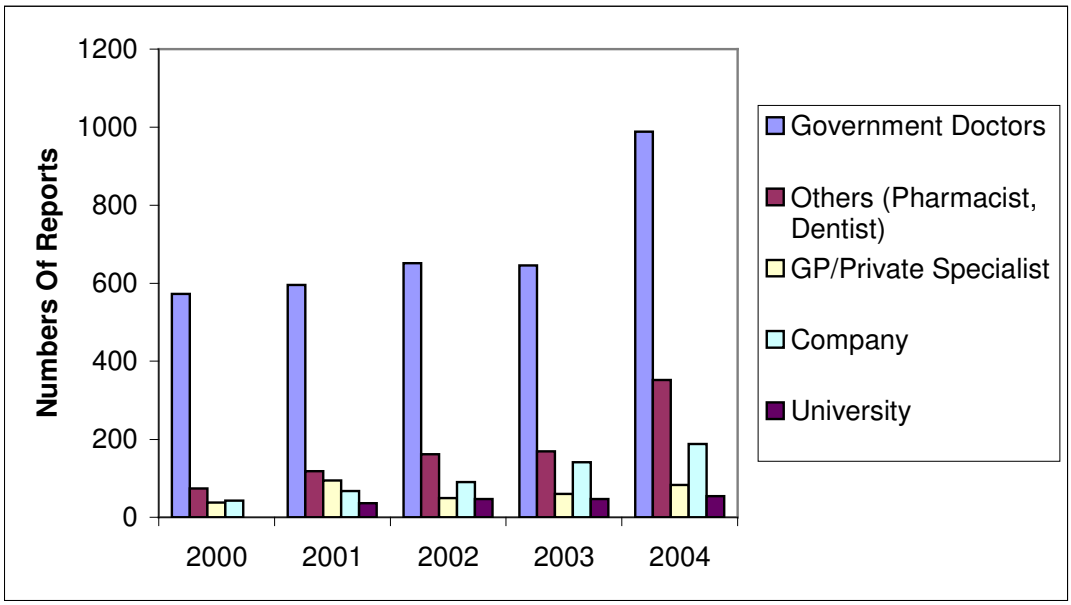

Figure 3: Analysis of ADR reports by Reporters

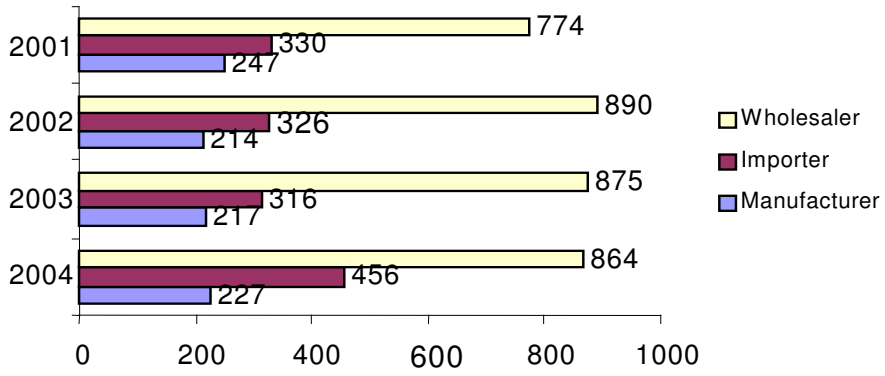

Figure 4: Total number of licence issued

4.1.2 Organisational Restructuring

In the middle of the year 2004, the organisation of NPCB was restructured to streamline the functions of registration, quality control, GMP, post registration and organisational developments. The physical infrastructure was also upgraded. New sections and units had been set up such as Clinical Trial Regulatory Unit, Health Supplements Unit, Variation Unit, Chromatography Unit, Tissue Culture Unit and others.

4.1.3 On-line Product Registration

All applications for registration of pharmaceutical products, traditional medicines and cosmetics are carried out on-line with the exception of new chemical entities and biotechnology products. An **on-line task force** was set up to identify problems and issues on on-line system implementation such as problems of principal smart card holder, supplementary card, payment, on-line product classification, data privacy and other related issues. Members of this task force are officers from NPCB, Technology Innovative Resources (TIR), Pharmaceutical Association of Malaysia (PhAMA) and Malaysian Organisation of Pharmaceutical Industries (MOPI). This task force had carried out 4 meetings throughout the year 2004.

4.1.4 Guidelines Review

A new guideline for registration of pharmaceutical products known as the Drug Registration Guidance Document was implemented in April 2004. With this effect, the existing guideline (1993 edition) and the guideline for the Registration of Traditional Medicines 1998 are no longer applicable. Other guidelines available are the Cosmetic registration guideline and guideline for the application of Clinical Trial Import Licence.

4.1.5 Hologram Security Device Implementation

The Drug Control Authority (DCA) in August 2004 has decided to enforce the use of the hologram security device for all registered products including over-the-counter products (OTC), natural products and health supplements with effect from 1st May 2005. Products exempted from this ruling are cosmetics, vaccines and biologicals. The purpose of this implementation is ensure the well being of the consumers by minimising the presence of counterfeit, false and unregistered products in the market, whether the product is manufactured locally or imported for sale in Malaysia.

4.1.6 International Involvement

The NPCB is actively involved in the harmonization efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ)

Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and Traditional Medicines and Health Supplements Product Working Group (PWGTMHS).

Other international involvements include facilitating the fast track ASEAN healthcare integration and EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments; Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries.

The NPCB collaborated with the WHO and PIC/S in conducting GMP training and regional assessments under the EC-ASEAN Technical Cooperation Programme. Joint PIC/S GMP inspections were also conducted in Greece and Netherlands.

4.1.7 International Visitors and Training

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, the NPCB continues to provide training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries.

The centre recorded a total of 28 international visitors and WHO fellows from various countries namely Brunei Darussalam, China, Cuba, Fiji, Hong Kong, Mongolia, Singapore, South Africa and Vietnam.

The courses provided under this program are designed specifically to cater for the needs of the individual fellows. Training is given either in Quality Control, drug registration, Good Manufacturing Practice and Licensing system, pharmacovigilance and post-marketing surveillance activities.

4.2 LICENSING AND ENFORCEMENT

The main activities of the Pharmacy Enforcement and Licensing Branch in the Pharmacy Division of Ministry Of Health Malaysia are carried out by 10 main units, which are the Advertisement Unit, Inspection Unit, Licensing Unit, Surveillance unit, Operation Unit (Unregistered Drugs), Operation Unit (Professional and Cosmetics), Investigation Unit, Prosecution Unit, Precursor

Control Unit, and Consumer Protection Unit.

4.2.1 Premise Inspection

The main activities of inspections are focused on pharmaceutical trade for the purpose of issuing licences to registered pharmacists. Type A licences were issued based on the inspection reports by the Pharmacy Enforcement Officers. In 2004 the premises inspected were 4,097 as compared to 2,515 premises in 2003. The inspections done in 2004 covered 1,643 pharmaceutical premises followed by 717 premises with type B licence, 9 type D licence, 6 type E licence, 761 Sodium Hydroxide permits, 328 PBKD Licences and 633 other premises without licence (**Figure 5**).

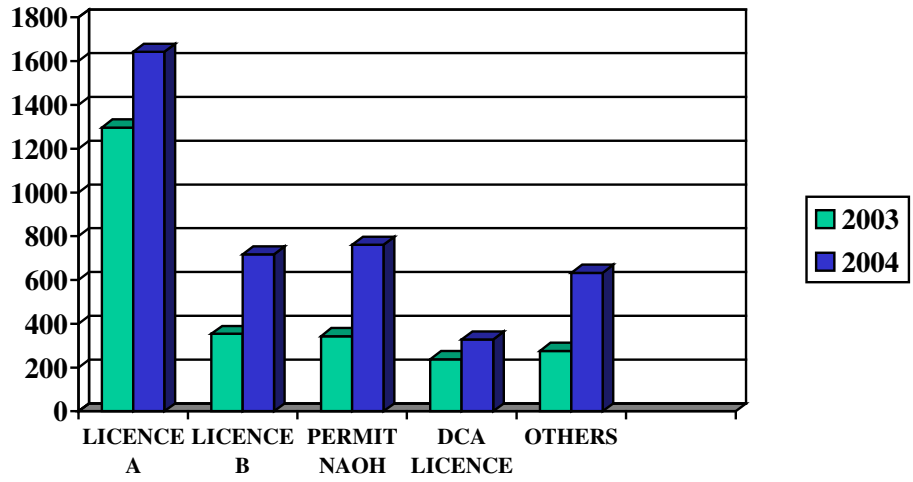

Figure 5: Premise Inspection for the year 2003 and 2004

The inspections of premises had increased in the year 2004 as compared to the year 2003 especially in Selangor where 771 premises were inspected in 2004 as compared to 396 premises in 2003, followed by Johor with 624 premises inspected in 2004 as compared to 354 in 2003 (**Figure 6 and 7**).

4.2.2 Registered Premises Inspection

There was a slight decrease in the inspections of registered premises where only 994 premises were inspected in 2004 as compared to 1088 in 2003.

Eight-hundred and seventy-give (875) medical clinics were inspected in 2004 followed by 99 dental clinic and 20 private hospitals **(Figure 8).**

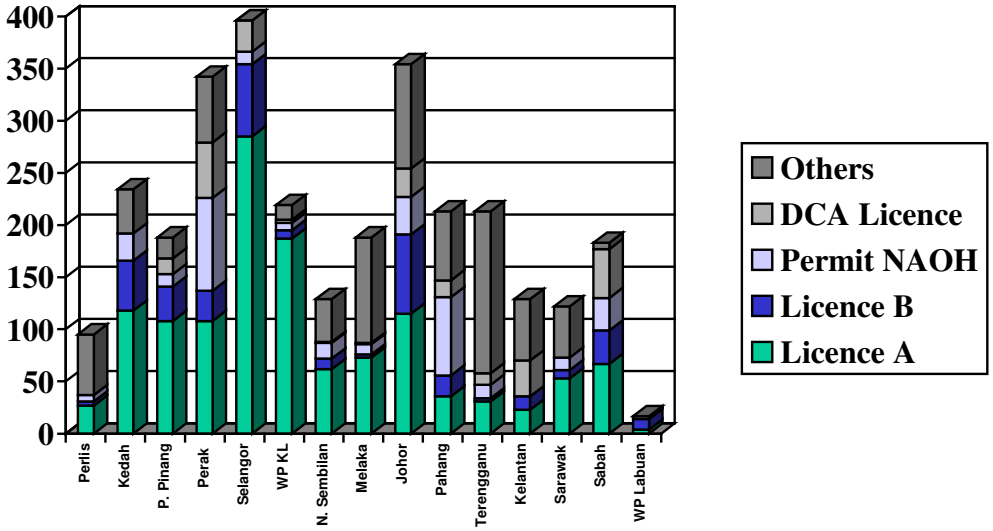

Figure 6: Premise Inspections by States in 2004

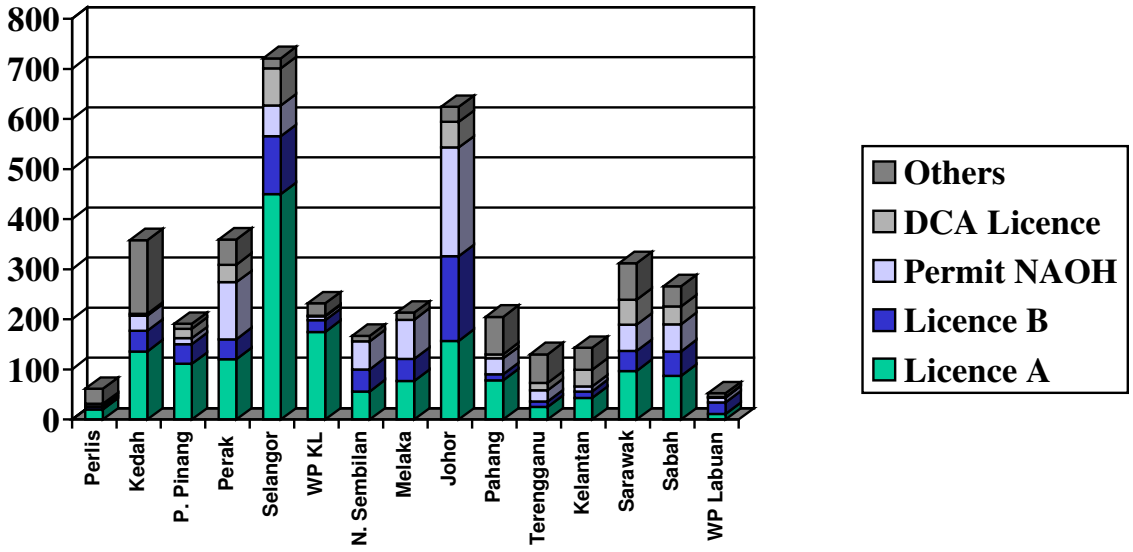

Figure 7: Premise Inspections by States in 2003

There was an increase in inspections in several states in 2004 as compared to the previous year. In Pulau Pinang 52 premises were inspected as compared to only 1; followed by Wilayah Persekutuan KL in 26 premises as

compared to 10, Terengganu 107 compared to 85 premises and in Wilayah Persekutuan Labuan 16 premises as compared to 10 premises **(Figure 9 and 10).**

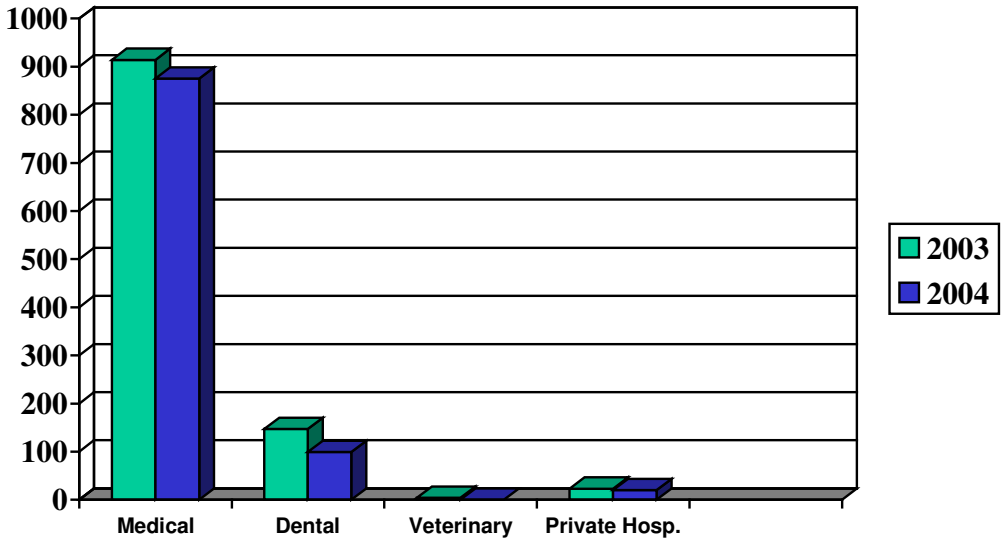

Figure 8: Clinics and Private Hospitals Inspections

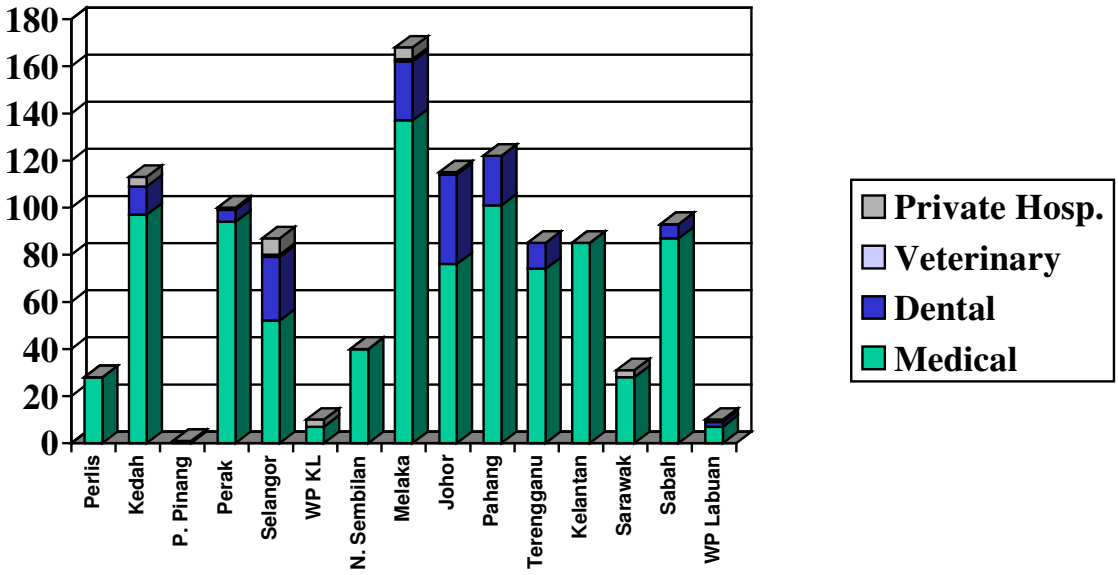

Figure 9: Private Clinics and Hospitals Inspections in 2003

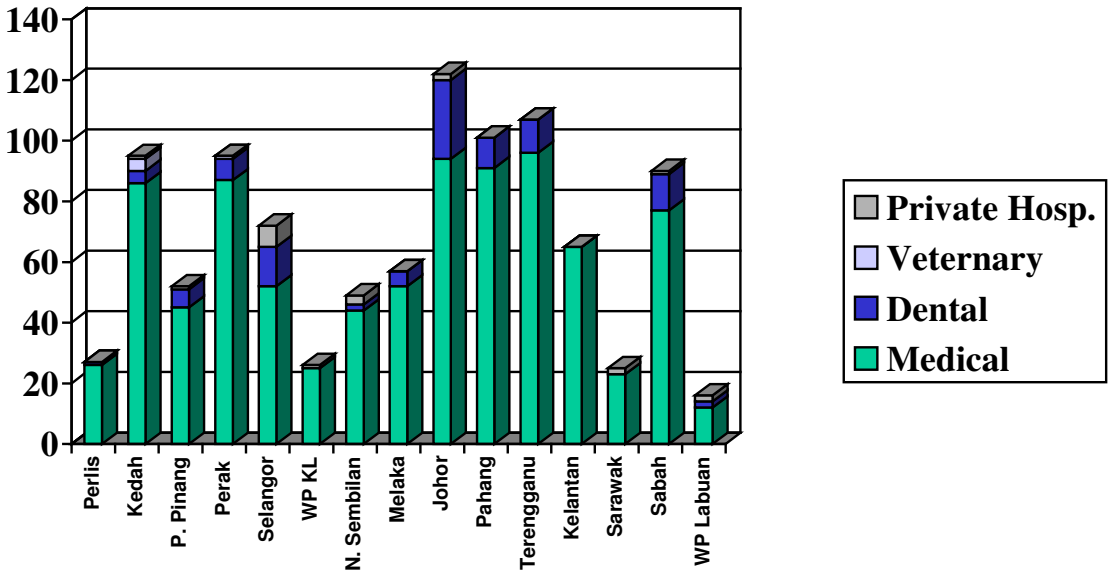

Figure 10: Private Clinics and Hospitals Inspections in 2004

4.2.3 Issuing Of Licences

i. Issuing Of Licences by the State Enforcement Branch

The number of licence issued has increased dramatically from 2887 poison licence type A in 2004 to 2705 in 2003. There was a slight increase in the type B licence and Sodium Hydroxide permit from 1281 and 1668 in 2003 to 1309 and 1679 in 2004, respectively **(Figure 11).**

The highest increase in the issuance of type A licences in 2004 was in Selangor, whereby 891 type A licences were issued compared to 836 in 2003; followed by WPKL where 447 licences A were issued in 2004 in comparison to 403 in the year 2003.

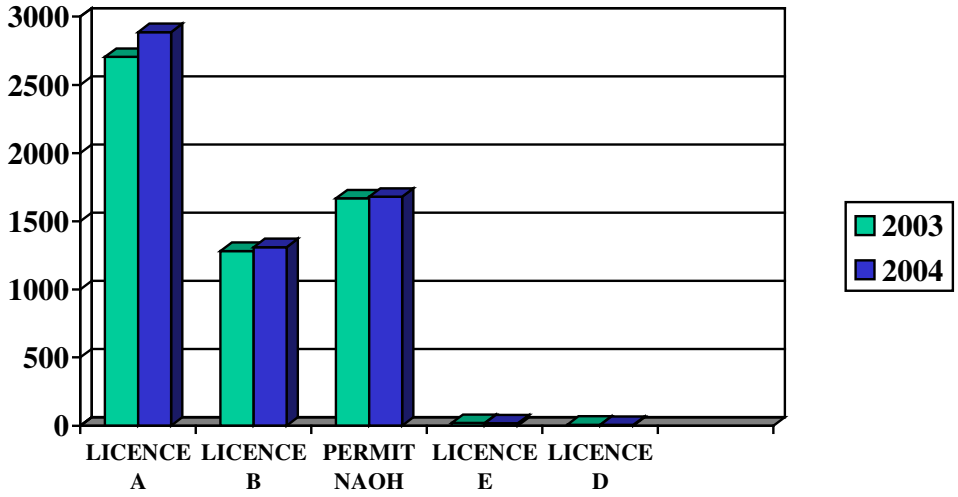

Figure 11: Issuing of Licence under Poison Act 1952 (Revised 1989)

For the issuance of type B licences, the increase in the licences issued was in Johor where 181 licences were issued compared to 170 licences in the year 2003 **(Figures 12 and 13).**

ii. Licences Issued by the Pharmaceutical Services Division MOH

The Pharmaceutical Services Division issued import/export authorisations for Dangerous Drug and Psychotropic Substances. The import authorisations issued for Dangerous Drugs in 2004 has increased from 147 in 2003 to 154. The number of export authorisation issued in 2004 was 31 compared to only 15 in 2003. The import authorisations for Psychotropic Substances has increased from 251 in the year 2003 to 278 in 2004, an increase of 11% **(Figure 14)**.

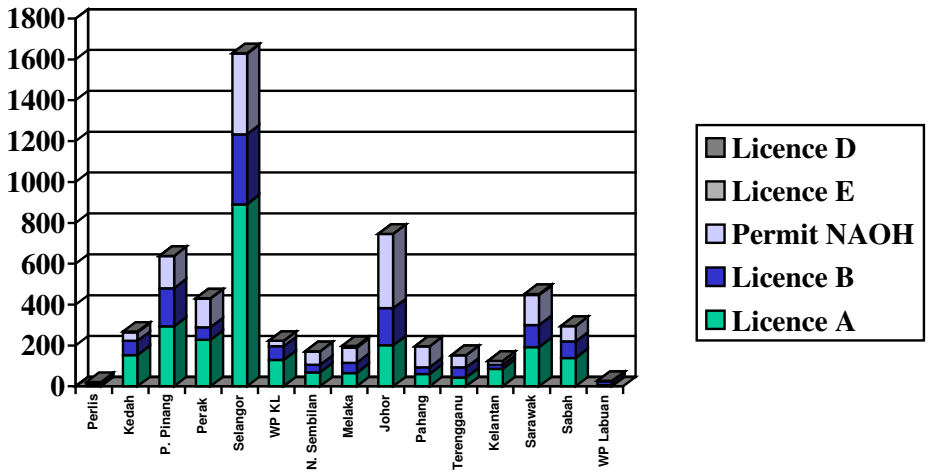

Figure 12: Licence Issued by State in 2004

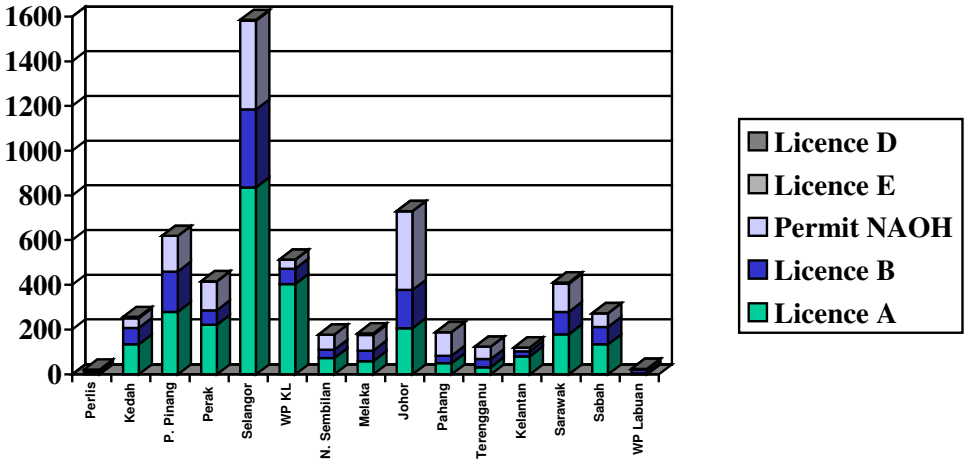

Figure 13: Licence Issued by State in 2003

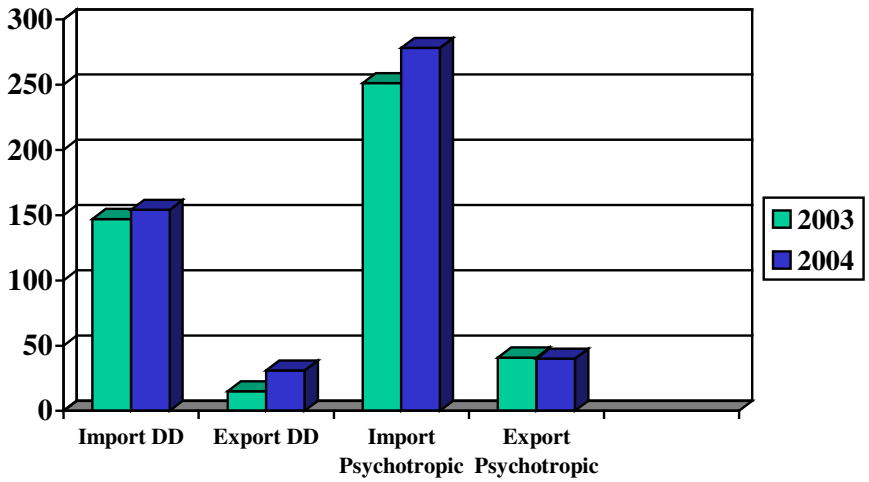

Figure 14: Import/Export Authorisation for Dangerous Drugs and Psychotropic Substances

4.2.4 Precursor Control

The export of precursor chemicals uses Pre-export Notification (PEN) mechanism to prevent diversion of precursor for illicit market. PEN is issued to inform the importing countries regarding export of precursor chemicals under the UN Convention against illicit traffic in Narcotic Drugs and Psychotropic Substances 1988. The numbers of PEN received in 2004 was 1676 as compared to 1516 in the year 2003. The numbers of PEN issued for export of precursor chemicals in 2004 was 656 compared to 595 in the year 2003.

Prohibition in import/export to control the precursor is by listing them under the Custom (Prohibition on Import/Export) Order. In 2004 prohibition of import approval for precursor was 208 compared to 203 in 2003. The approval for export was 656 in 2004 compared to 595 in 2003 **(Figure 15)**.

4.2.5 Surveillance

The number of surveillance conducted by all states before an operation in the year 2004 was 280 cases and this data was only collected starting from 2004 (**Figure 16**). Surveillance was actively done in Selangor with 46 cases followed by Kedah 38 cases and Kelantan 37 cases.

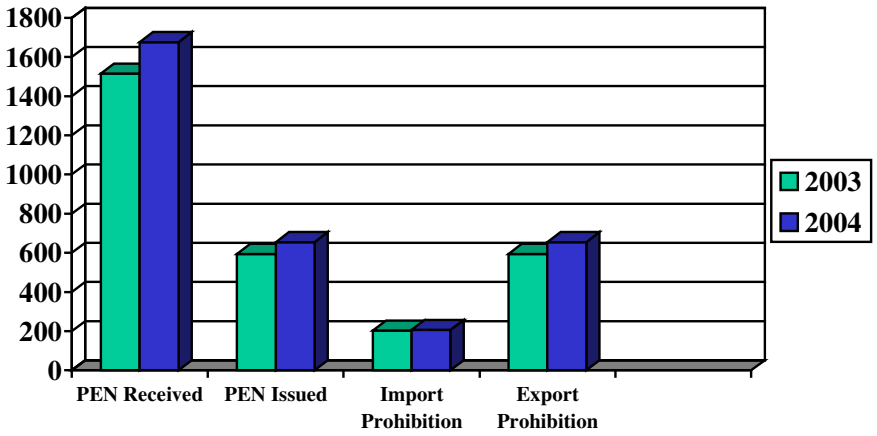

Figure 15: Control of Precursor Chemicals

4.2.6 Raids

The Pharmacy Enforcement Branch was active in carrying out raids in 2004 with 13,422 items seized as compared to 7,119 items in 2003, an increase of 88.54% **(Figure 17).** Success of raids has increased from 86.9% in the year 2003 to 91% in 2004. The value of seizure rose from RM 7.24 million in 2003 to RM 27.3 million in 2004 **(Figure 18).** The value of seizure was highest in Selangor with RM 14.93 million followed by WPKL and Sarawak at RM 3.12 million and RM 2.9 million respectively.

4.2.7. Seizures of Unregistered Products

The values of unregistered products seized rose tremendously in the year 2004 with the value of seizures at RM 20.62 million compared to RM 6.43 million in 2003 **(Figure 19).**

4.2.8 Prosecution

Four hundred and ninety-two (492) cases were mentioned in court for the year 2004 compared to 548 cases in 2003. The number of cases convicted was 226 in 2004 compared to 230 for 2003. However, the amount of penalty collected has increased from RM606.6 thousand in 2003 to RM856.7 thousand in 2004. The highest fine collected was RM253.2 thousand in Selangor followed by RM 250.8 thousand in Wilayah Persekutuan KL **(Figure 20).**

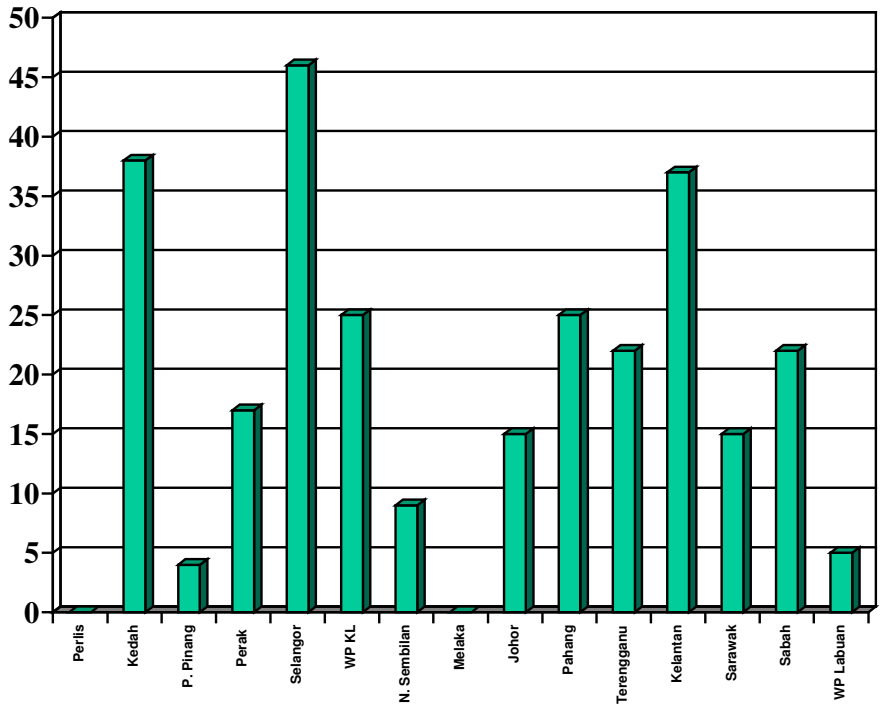

Figure 16: Number of Surveillance for Operations by State in 2004

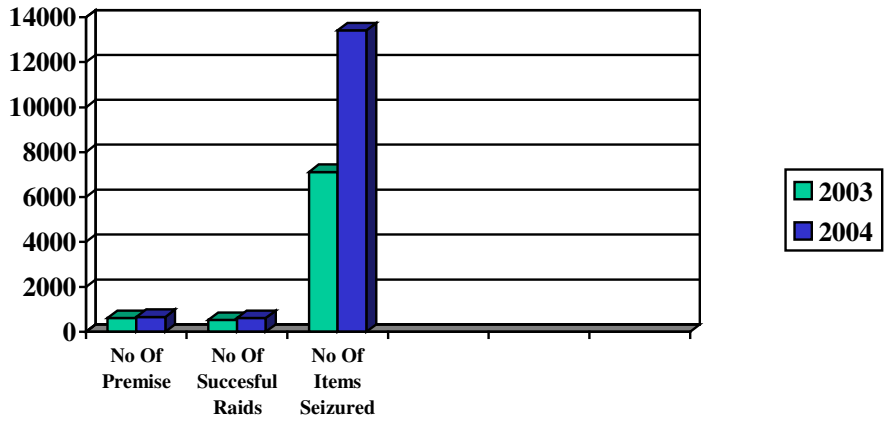

Figure 17: Number of premises raided and items confiscated

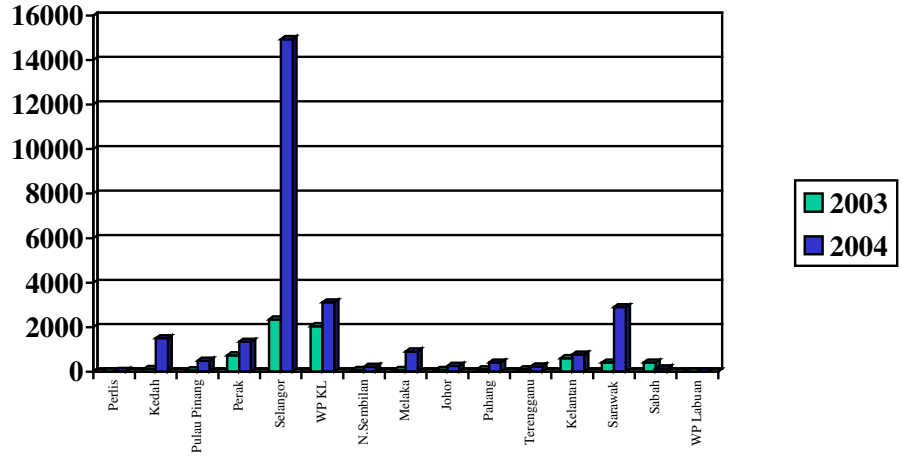

Figure 18: Value of seizure by State (RM Million)

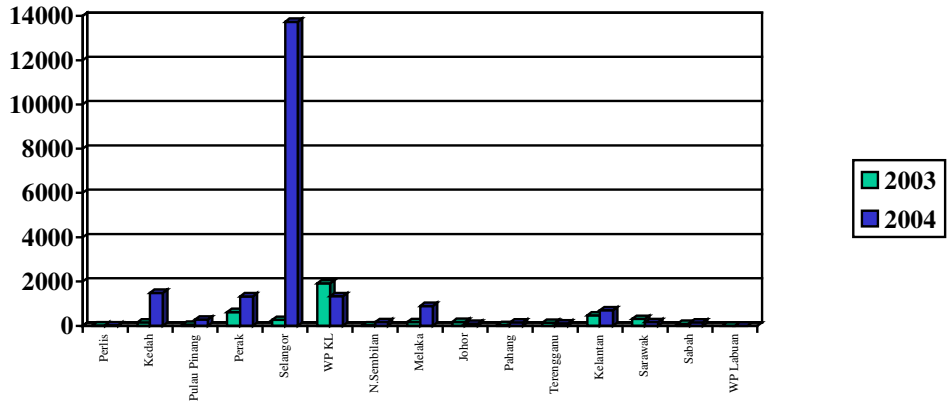

Figure 19: Seizure of Unregistered Products by State (RM Million)

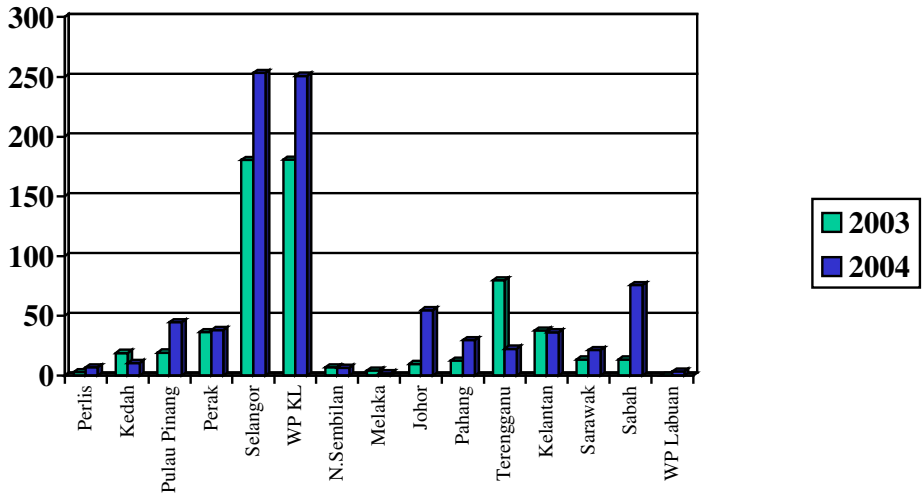

Figure 20: Amount of Fines Collected for Cases Prosecuted under The Poison Act 1952 and Sales of Drug Act 1952 (revised 1989) in RM thousand

4.2.9 Advertisements

The number of applications received in 2004 was 1236 consisting of 1129 applications for advertisement of medicines/remedies and 107 for advertisement of medical services. '*Fast Track'* approval was introduced in 2004 to fasten the approval for advertisement consisting of 677 for advertisement of medicine/remedies and 74 for advertisement of medical services. Normal applications were 302 for both types of advertisements. 54 applications were rejected and 5 applications did not require approval **(Figure 21).**

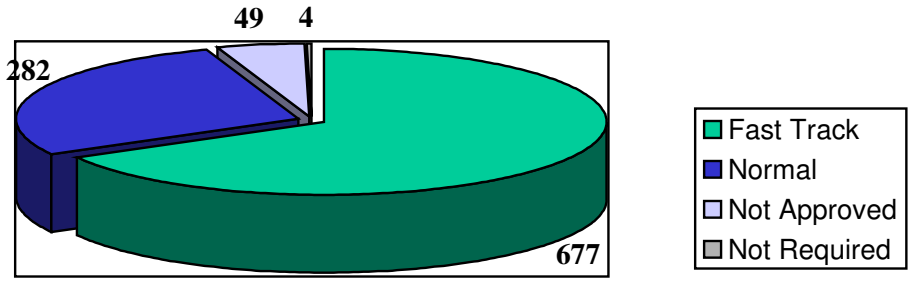

Figure 21: Advertisement Approval

4.3 PHARMACEUTICAL CARE MANAGEMENT

4.3.1 Procurement and Distribution

This Division handed the portfolio of Secretariat for the Price Negotiations Committee for the Approved Products Price List of Syarikat Pharmaniaga back to the Procurement and Privatisation Division.

This unit conducted 3 meetings to draw up the specifications of 60 drugs to be tendered and 5 meetings were held to evaluate tender offers for 53 drugs.

The total value of drug purchases from Syarikat Pharmaniaga Logistics Sdn Bhd for the year was RM 417 million for drugs and RM 77 million for medical equipment. For these purchases, the 5 highest value drugs are shown in **Table 10**.

Table 10: Comparison of 'highest value drugs' for 2003 and 2004

2003		2004	
DRUG CLASS	**PURCHASE VALUE (Million RM)**	**DRUG CLASS**	**PURCHASE VALUE (Million RM)**
Cardiovascular	**70.2**	**Cardiovascular**	**77.3**
Antibiotic	**60.7**	**Antibiotic**	**60.7**
Neuromuscular	**39.4**	**Neuromuscular**	**34.0**
Metabolism	**38.1**	**Metabolism**	**45.0**
Other Antimicrobial	**21.1**	**Other antimicrobial**	**35.3**

The value of all drug contracts handled in 2004 were RM 320.44 million as compared to RM 205.37 million in 2003 which is an increase of 56% (as shown in **Table 11**).

Table 11: Drug expenditure

Year	Expenditure (RM Million)
2000	346.3
2001	485.0
2002	526.5
2003	751.3
2004	808.0

4.3.2 Ministry of Health Drug Formulary

i. Drug Formulary

The Ministry of Health Drug Formulary contains a list of drugs approved for use in all hospitals/Institutions in the Ministry of Health. The Formulary is to promote rational and cost-effective use of drugs, whereby the introduction of newer and effective drugs are controlled so that funds to purchase drugs are optimally used.

The Ministry of Health Drug List Review Panel that is made up of Senior Consultants and pharmacists in the Ministry of Health will review and update the drug listed in the formulary from time to time. The Panel is assisted by 16 Working Committees from various specialised disciplines. This is to ensure that a comprehensive, evidence–based and dynamic list of drugs is available for prevention and treatment of patients in the Ministry of Health.

In 2004, 3 meetings were held to review the Ministry of Health Drug Formulary. Applications for proposal to delete or add a drug, to change indication, formulation or category of prescriber who can start prescribing were applied using a form known as proforma. These applications will first be discussed at the Hospital Drug & Therapeutic Committee and if approved will be reviewed again at the state level. It will then be sent to the secretariat at the PSD who will process the applications for review at the national level.

Table 12: Application, approved and deleted drugs in Ministry Of Health Drug List from 2000 to 2004

Year	Proforma Received	No. of Panel Meetings	No. of Circulars on Amendments	Drugs Approved		Drugs Deleted
				Proforma B	Proforma D	
2000	201	2	1	13	15	76
2001	206	2	3	26	63	3
2002	199	2	3	18	31	8
2003	270	2	3	20	23	40
2004	192	3	3	20	36	17

The Ministry of Health Drug Formulary 4th edition was printed at the end of 2004 and it contains 1389 preparations .The interactive CD-ROM version of the Drug Formulary was also produced for distribution to the users in the Ministry of Health.

ii) **Registered drugs out of The MOH Drug List**

In 2004, approval for using registered drugs out of the Ministry of Health Drug Formulary was given to 501 applications which consisted of about 120 types of drugs worth RM7,420,006 while 153 applications worth about RM 1,544,310.29 were rejected as they did not meet the criteria set by the Ministry of Health Drug List review Panel.

Table 13: Approval for use of registered drugs outside Ministry Of Health Drug List

Year	2000	2001	2002	2003	2004	
					Approved	Rejected
Value (RM)	3,195,815	5,775,582	8,036,549	8,088,467	7,429,006	1,544,310
Types of drugs	137	170	161	160	120	82
No. of requests	619	1024	929	642	501	153

4.3.3 Clinical Pharmacy Services

The Pharmaceutical Service of hospitals and health clinics under the Ministry of Health aims to provide comprehensive patient-centered pharmaceutical care. The activities have included the provision of clinical pharmacy services such as clinical pharmacokinetics (CPS), total parenteral nutrition (TPN), oncology pharmacy, ward pharmacy service, patient drug therapy monitoring and medication counselling.

i. Medication Counselling Service

Medication counselling through individual, discharge and group sessions is carried out by hospital pharmacists to help patients achieve intended health outcomes through better compliance as well as handling of adverse drug events that may arise from their drug use. A total of nearly 62,000 patients were counselled on their medication in 2004.

Pharmacists also actively participate in multidisciplinary group counselling sessions for asthma, diabetes mellitus, hypertension, renal, antenatal care as well as cardiac rehabilitation programmes.

A few major hospitals have been identified to establish pharmacists managed medication counselling/adherence clinics to provide pharmaceutical care to patients in critical areas of treatment such as asthma, renal transplant, HIV/AIDS, diabetes mellitus, coronary heart disease and others to ensure quality drug use.

ii. Ward Pharmacy Service

Almost all hospital pharmacies throughout the country have adopted individualized drug delivery system for in-patients by implementing the Unit-of-Use/Unit Dose System. This system of medication delivery has the advantage of providing personalised and continuous supply of medication to patients, with better compliance and reduced wastage as compared to the traditional system where the wards order drugs in large quantities, which have led to overstocking and wastage.

Clinical pharmacists are now based in medical wards as well as the intensive care units of hospitals. They contribute actively by participating in ward rounds with doctors and other health-care team members. They provide drug information and consultation on medication related issues as well as conducting medication therapy monitoring and thereby aid in optimising drug therapy and improving patient health outcomes

Specialisation in clinical pharmacy practice in the following pharmacotherapy disciplines and hospitals has been established in 2004 to improve the quality of pharmaceutical care to patients:

Respiratory pharmacy	-	Hospital Melaka
Critical Care pharmacy	-	Hospital Kuala Terengganu
	-	Hospital Selayang

	-	Hospital Kuala Lumpur
Cardiology pharmacy	-	Hospital Umum Kuching
Nephrology pharmacy	-	Hospital Selayang

iii. Clinical Pharmacokinetic Service

In 2004, a total of 57,402 patients had received individualized drug therapy through the pharmacy clinical pharmacokinetic service (CPS) provided by 67 hospitals throughout the country. Through the CPS, pharmacists provide consultation on appropriate dosing of 12 types of drugs namely:

- Gentamicin
- Amikacin
- Digoxin
- Carbamazepine
- Theophylline
- Lithium
- Netilmicin
- Vancomycin
- Phenytoin
- Valproic acid
- Ciclosporin
- Methotrexate

Apart from that, the pharmacy provides 24 hours call service for toxicology serum monitoring and consultation of paracetamol poisoning. A total of 712 calls were received by pharmacists in 2004. Through this service, the use of N-acetylcysteine in paracetamol poisoning had been optimised.

iv. Total Parenteral Nutrition and IV Admixture Service

By the end of 2004, there were 20 MOH hospitals providing total parenteral nutrition (TPN) service. A total of 8,051 and 19,691 TPN bags were prepared for paediatric and adult patients respectively. The TPN pharmacists provide consultation on individualized parenteral nutrition requirements as well as ensure safe ready-to-use preparations for the patients. An indicator whereby pharmacists need to conduct pharmaceutical review on patients that require TPN was introduced in 2004 to further improve quality of care in these patients.

Due to manpower constraints, only 10 (50%) of hospitals with clean room

facilities are able to provide IV Admixture service for 49,037 cases.

v. Oncology Pharmacy Service

A total of 31 hospital pharmacies in the country dispense cytotoxic drugs to cancer patients. By the end of 2004, only 12 hospitals have pharmacy cytotoxic drug reconstitution facilities. 21,953 cancer cases were supplied with reconstituted drugs by pharmacy and this number had almost tripled and doubled that of the year 2002 and 2003 respectively.

There is an urgent need to build new or upgrade current CDR facilities to meet GMP standards to ensure all reconstitution are carried out under controlled environment and not in open wards for personnel safety as well as ensuring prepared products are free from microbial contamination.

The Pharmaceutical Services Division has formed an Oncology Pharmacy Expert Group (OPEG) to discuss and address clinical as well as technical issues of oncology pharmacy practice. Members of the group include an oncology pharmacy consultant from University Sains Malaysia, oncology pharmacists from hospitals as well as Good Manufacturing Practice auditors from the National Pharmaceutical Control Bureau. The group has initially provided consultation on clean room facilities requirements to meet GMP standards as well as standardization of standard operating procedures (SOP) to ensure output of the highest quality and safety. The OPEG advisory group visited a total of 13 hospital pharmacies with CDR facilities and those planning to build new ones in 2004. It was found that all existing facilities (10) did not comply with GMP requirements. Funds will be requested under the 9th Malaysia Plan to upgrade all facilities to meet GMP requirements.

vi. Nuclear Pharmacy

Four hospitals have been identified to provide pharmacy nuclear services namely Hospital Pulau Pinang, Hospital Kuala Lumpur, Hospital Sultanah Aminah Johor Bahru and Hospital Umum Kuching. Till the end of 2004,

pharmacists from Hospital Pulau Pinang and Kuala Lumpur are involved in the Quality Control and preparation of radiopharmaceuticals for nuclear medicine use.

The progress of hospital pharmacy services is as shown in **Table 14.**

Table 14: Achievements in Hospital Pharmacy Service

SERVICES	2004
1. Clinical pharmacokinetic service	
i. No. of hospitals	*67*
ii. No. of cases	*57,402*
iii. No. of drugs	*14*
2. Parenteral nutrition service	
i. No. of hospitals	*20*
ii. No. of bags(adults)	*8,051*
iii. No. of bags(Children)	*19,691*
3. Intravenous admixture service	
i. No. of hospitals	*10*
ii. No. of cases	*49,037*
4. Cytotoxic drug reconstitution service	
i. No. of hospitals	*12*
ii. No. of cases	*21,953*
5. Patient medication counselling service	
i. No. of out-patients	*35,737*
ii No. of in-patients	*25,799*
iii Total	*61,536*
6. Drug dispensing service	
i. No. of prescriptions dispensed	*8,857,608*
ii No.(%) prescriptions screened	*7,528,967*

4.3.4 Drug Information and Consumer Education

A new unit to coordinate information provision and consumer education has been set up through the restructuring exercise of the PSD. This unit will be responsible in providing drugs and pharmaceutical information to health professionals and personnel, and the general public. At the same time this unit is also responsible in coordinating all programmes pertaining to consumer education within the pharmacy service and with other agencies. Presently this unit is in the process of getting knowledge databases and other references

and equipment for it to function effectively.

4.3.5 Primary Care Pharmacy

The Primary Care Pharmacy Unit was formed to improve the quality of primary care pharmacy services at the health clinics at both urban and rural areas. Pharmacists play an important role in enhancing the health of the public through provision of new scope of services in primary care pharmacy. Among the potential scope that pharmacists can explore is pharmaceutical care provision for chronic elderly patients and preventive programmes among babies and children through the immunisation and school programmes.

4.3.6 Integrated Drug Dispensing System

The Integrated Drugs Dispensing System (IDDS) was started in December 2001 whereby only a few states took part in the pilot project. Currently, only Sabah has not started the system.

The aim of introducing IDDS is to help the patients, particularly follow-up cases, to get drugs supplied at health facilities nearest to home, and this will especially benefit patients who stay in remote areas.

From the data collected, the following conclusions can be made:

1. The cost of category A drugs was higher compared to categories B&C, which was in the range of 71-78% from the total cost of IDDS drugs.
2. The cost of categories B&C drugs was about 22-29% only.
3. Cost of IDDS drugs at intrastate level was much higher compared to the interstate level.
4. Cost of IDDS drugs at intrastate level was about RM 1.16 million a year while for interstate level; the cost was about RM 0.46 million a year.
5. Regarding the number of prescription, about 34-36% of the intrastate prescription was IDDS referral cases; while for the interstate prescriptions the percentage is much higher, that is 50-60%.

4.3.7 Other Units

Several other units were formed as a breakaway from the existing units via the PSD restructuring and these units are the Pharmacy Practice (Hospital), Research and Development, Training and CPD and Quality Units. From this restructuring, the services provided under these units become more focussed. Other new units that were set up are the Price Monitoring Unit, National Medicine Policy Unit, Compulsory Service Unit and Interagency and International Relations Unit.

4.4 SECRETARIAT TO STATUTORY BOARDS

4.4.1 Pharmacy Board

The Pharmacy Board of Malaysia [PBM] is responsible for the registration of pharmacists, body corporate and pupil pharmacists in the whole country. At the end of 2004, the total number of pharmacists registered was 4613 (including the re-registered pharmacist).

Besides the registration of pharmacist, the Pharmacy Board is also actively involved in other activities such as the renewal of Annual retention for Pharmacist and Body Corporate, Accreditation Programme and conducting Forensic Examination.

On 2nd September 2004, the Compulsory Service for Pharmacist came into effect, whereby it is compulsory for new graduates to work for 4 years in a public hospital or institution. The new graduates will be given the title, provisional pharmacist for the first year before going for full registration. In the next three years, after finishing the provisional year they will work in a public hospital or institution as a fully registered pharmacist with the condition that they stay in the public service for the whole of the three years continuously. The statistics compiled by the board on the registration status of pharmacists in the country is shown in **Table 15.**

Table 15: Pharmacy Board – Registration Statistics

Bil	ACTIVITIES	2004
1.	No. of New Pharmacists Registered	444
2.	No. of Pupil Pharmacists Registered	333
3.	Number of Provisional Pharmacists	-
4.	No. of New Body Corporate Registered	92
5.	No. of Renewals of Annual Retention Certificate	3506
6.	No. of Renewals of Annual Certificate for Body Corporate	164
7.	Total Number of Pharmacist in the Register (including the re-registration)	4613
8.	Total Number of Active Pharmacist (Newly Registered and Renewed Annual Retention)	4394
9.	No. of New Premises Recognised for Pupillage Training	-
10.	No. of Evaluated Pharmacy Degree Qualifications	1

The PBM is known as the only Board, which actively monitors pharmacy programmes at universities during the early years, to see that they meet the needs of the public. The PBM evaluated the pharmacy programme at 2 public universities and 1 private university in 2004. They are the Bachelor of Pharmacy programmes at MARA University of Technology (UITM), Islamic International University (IIU) and University College International Sedaya (UCSI). UCSI now offers two different courses in Pharmacy. They are the UCSI-USM External and the UCSI-Curtin University of Technology. It is also in the process to start its own-UCSI Bachelor of Pharmacy programme. In the year 2004, the UCSI-USM External programme was recognised by PBM.

In the year 2004, the Pharmacy Board Training Committee was involved in reviewing the Training Module for Provisional Pharmacist. The aim of the review was to come out with a complete training module, which will cover various practices in pharmacy. The will enable the first batch of provisional pharmacists to be exposed to all the major areas of pharmacy practice before continuing into their 3-year compulsory service.

In the year 2004, many activities have been carried out to cater to the growing needs of pharmacists in public service. The PBM was actively involved in the accreditation of universities to cater for new students who are interested to do

pharmacy and also in drawing up policies to ensure the progress of the profession in the country.

4.4.2 Medicine Advertisements Board

The Medicine Advertisement Board is empowered by law to set policies and guidance on advertisements of medicines, appliances, remedies and skill and services that relate to medical and health claims. Accordingly, The Board has issued 2 guidelines to help advertisers in devising advertisement formats which are deemed acceptable and suitable for publication in the various media in the country. The objective of the guideline is to ensure responsible advertising in promoting the sale of medicines, appliances, remedies and skill and services that relate to medical and health claims. The board operates on the premise that advertisements to the general public should be guided by the following principles:

a. Advertisements should help people to make rational decisions on the use of medicines, appliances, remedies and skill and services that relate to medical and health claims.

b. Advertisements should take into account the people's legitimate desire for information regarding their health

c. Advertisements should not take undue advantage of people's concern for health.

The Board meets once a month to deliberate on advertisement applications that have been received for the month. The Board discusses each application and may decide on any of the following:

a. Approve an application without any changes
b. Approve an application with changes
c. Reject an application as being not suitable for publication.
d. Withhold decision subject to more information from the applicant or expert opinion from related agencies, associations or authorities.

Generally, the advertisers are advised to adhere strictly to principles laid down in the guidelines as the Board uses these guidelines as the basis for all its decisions. Apart from some specific examples, the guidelines are quite

general in nature. This is intended and is also inevitable because guidelines of this nature cannot be expected to deal in specific terms issues that may range from simple advertisements to promotional materials that contain complex technical information formulated in highly subjective terms. Advertisements may also differ in the way they are presented to the public. Some try to reach the consumer in simple terms yet some others may employ the use of words and statements that are highly exaggerated. So the guideline takes into consideration the aspirations of the advertisers without compromising on its responsibility to ensure only accurate and responsible information reaches the consumer.

Two committees have been formed to upgrade the advertisement guidelines. These committees are Advertisements Guideline Committee for Products and Advertisements Guideline Committee for Services. For the year 2004, the Board received a total of 1236 applications. **Table 16** shows the summary of applications processed by the Medicine Advertisement Board for year 2004 and **Table 17** shows the comparison of applications processed in the last 3 years.

Table 16: Summary of applications processed by MAB

ACTIVITIES	Products	Services	Total (%)
1. No. of applications	1129	107	1236
2. No. of approvals	959	94	1053 (85.2%)
3. No. of approvals through Fast Track System	677	74	751 (60.8%)
3. Fee collected	RM 112,900	RM 10,700	RM 123,600

Table 17: Comparison of applications processed

ACTIVITIES	2002	2003	2004
1. No. of applications	1029	881	1236
2. No. of approvals	900	803	1053
3. No. of FAST TRACK approvals	-	488 (55.4%)	751 (60.8%)
4. Fee collected	RM 102,900	RM 88,100	RM123,600

4.4.3 Poison Board

The Poison Board, as an advisory board has been empowered to assess the classification of medicine/chemical substance, and thereby to advice the minister in accordance to the provisions of the Poisons Act 1952. The Board met for its 59th meeting on 29th January 2004 and 60th meeting on 19th August 2004 and decided on the following:

i. Classification of poisons

The Board has agreed with the classification of thirty (30) chemicals as in **Table 18**.

Table 18: Classification of new chemical entities

No.	Name of Drug/ chemical entity	Therapeutic classification	Group
1.	Amilsulpride	Antipsychotic	B
2.	Ertapenem sodium	Antibiotic	B
3.	Tenecteplase	Fibrinolytics	B
4.	Ziprasidone Hydrochloride	Antipsychotic	B
5.	Bimatoprost	Antiglaucoma	B
6.	Arthemeter	Antimalarial	B
7.	Lumefantrine	Antimalarial	B
8.	Adefovir dipoxil	Acyclic nuclotide	B
9.	Etorcoxib	NSAID	B
10.	Natamycin	Antifungal	C
11.	Paraclacitol	Vitamin D analogue	C
12.	Ganirelix	Hormones	B
13.	Fondaparinux sodium	Antithrombotic	B
14.	Doxofylline	Bronchodilator	C
15.	Imidapril Hydrochloride	Ace Inhibitor	B
16.	Gefitinib	Anti cancer	B
17.	Rosuvastatin	Lipid lowering agent	B
18.	Deferiprone	Iron chelating agent	C
19.	Parecoxib sodium	NSAID	B
20	Mirtazapine	Antidepressant	B
21.	Aprepitant	Antiemetic	B
22.	Itopride Hydrochloride	Gastro-prokinetic	B
23.	Anagrelide	Platlet reducing agent	B
24.	Escitalopram	Antedepressant	B
25.	Doxazocin mesylate	Antihypertensive	B
26.	Voriconazole	Antifungal	B
27.	Ziprasidone mesylate	Neuroleptic	B
28.	Drospirenone	Contraceptive	C
29.	Ethinyl estradiol	Contraceptive	C
30.	Atosiban	Myometrial relaxant agent	B

ii. Amending the classification of a Poison

a. Deferiprone maintained as group C poison.

b. Desferrioxamine is classified as group C poison

c. All preparations containing ethyl ether is classified as group B poison in Part I. Exemption in part II for all preparations unless in group B

d. Thirteen precursors were added into the poison list as in **Table 19**.

Table 19: Precursors classified as Poisons

Name of precursor	Part I				Part II	Exempted
	Group A	Group B	Group C	Group D		
Lysergic acid and its salt					All preparations	
1-phenyl 2-propanone					All preparations	
N-acethylanthranilic acid					All preparations	
3-4 methylenedioxy phenyl-2 propanone					All preparations	
Safrole					All preparations	Preparations containing safrole as flavouring agents and perfumes
Isosafrole					All preparations	Preparations containing isosafrole as flavouring agents and perfumes
Piperonal					All preparations	Preparation containing piperonal as flavouring agents and perfumes
Anthranilic acid and it salts					All preparations	
Phenylacetic acid and its salt					All preparations	
Piperidine					All preparations	
Potassium permanganate					All preparations	Preparation containing 0.1% and less of potassium permanganate
Thionyl chloride					All preparations	
Caffeine					All preparations	Food and beverages containing caffeine

Ethyl ether	All prepara-tions for anesthetic use	All preparations unless in group B

e. Condoms containing local anaesthetic are classified as poison and the poison list was amended as in **Table 20**.

f. All preparations containing Ractopamine is classified as poison group A in Part I but when compounded with animal feeds it is classified in Part II

Table 20: Amendments involving local anaesthetics in Poison List

	Kumpulan A	Kumpulan B	Kumpulan C
Local anaesthetics ..... Benzocaine .....sehingga..... Ropivacaine	All condoms, appliances or preparations containing local anaesthetics unless group B or C	All preparations in pharmaceutical dosage forms unless group A or group C	All preparations in pharmaceutical dosage form for local anaesthetic, topical use in the nose, eyes and ears, suppository or external use. Lozenges and pastilles unless group A or group B

4.4.4 Drug Control Authority

The Drug Control Authority (DCA) is responsible for the registration of pharmaceutical, traditional and cosmetic products and issuing of manufacturer's, wholesaler's and import licences. The NPCB is the secretariat and the executive arm of the DCA. Throughout the year 2004 the DCA has held 11 meetings.

The DCA has made the decision to cancel the registration or not to allow products containing certain ingredients based on safety issues:

- To cancel registration of products containing Cisapride in view of the association of cardiotoxicity.
- To cancel the registration of all products containing Comfrey and Senecio

spp as both of these herbs contain unsaturated pyrrolizidine alkaloids (PA) which are considered to be hepatotoxicity and hepatocarcinogens.

- To cancel registration of products containing terfenadine in view of the association of cardiac adverse events arisisng from the use of terfenadine

4.5 TRAINING

The Pharmacy Services Division (PSD) has organised several short courses for the pharmacists and pharmacy assistants.

However, the number of scholarships provided for pharmacists to purse Masters and Ph.D. degrees was limited, and therefore postgraduate training opportunities is inadequate. Until the end of 2004, the number of pharmacists holding postgraduate degrees is as shown in **Table 21.**

Table 21: Existing Postgraduate degree holders and allocation

Post Basic Degree	Number of Pharmacists	Number of Pharmacists Pursuing	Number of Slots allocated in 2004
PhD	8	8	0
Master	73	7	3

The PSD has also formed a committee on Continuous Professional Development (CPD) Programme. The programme has been successful throughout the year 2004 in which 60% of pharmacists and pharmacy assistants has achieved the minimum credit points required. The achievement of CPD points by the pharmacy staffs is shown in **Table 22**.

Table 22: CPD points achieved by pharmacy personnel

No. of Pharmacists in MOH	No. Registered for CPD	No. Achieving Minimum Points of 30	% Achieving Minimum Points
728	599	338	56.5%
No. Of Pharmacy Assistants in MOH	No. Registered for CPD	No. Achieving Minimum Points of 10	% Achieving Minimum CPD Points
2390	1560	966	61.9%

The PSD has conducted 17 in-service courses whereby some 714 staffs of various categories have benefited. Of these 581 were pharmacists 133 were pharmacy assistants and administrative assistants (storekeepers). RM 156,872.80 was spent for the courses.

Four pharmacists have undergone short overseas training and a sum of RM79,348.00 was spent for these training. They include one pharmacist from Hospital Umum Kuching who went for a one-month attachment program in clinical cardiology pharmacy practice at Fremantle Hospital, Perth Australia, and 2 pharmacists from Hospital Kuala Lumpur and Hospital Tengku Ampuan Afzan, Kuantan were sent to Peter MacCallum Cancer Centre, Melbourne Australia to undergo a one-month training programme in clinical oncology pharmacy practice.

Hospital Melaka, Kuala Terengganu and Selayang have been identified as clinical pharmacy training centres for local and foreign pharmacists. Throughout the year 2004, 10 hospital pharmacists were trained in Hospital Melaka and Kuala Terengganu.

Hospital Pulau Pinang has been identified as a training centre for Nutrition Support Pharmacy Service and 6 hospital pharmacists have been provided training.

Two WHO fellows from Palestine underwent 3 weeks clinical pharmacy training in Hospital Melaka and Selayang and one week training in Hospital Pulau Pinang in the months of April and September 2004.

5. CONCLUSION

5.1 Impact of Pharmaceutical Services on Health Problems and the Pharmaceutical Sector

The successful implementation of the various pharmacy service activities has contributed towards the availability and accessibility of medicines and

pharmaceutical products that are of quality, safe and efficacious in the country. It has also contributed towards better provision of the service to patients and consumers.

The maintenance of quality medication in the market is further strengthened by the enforcement of the relevant pharmacy legislations and guidelines. The enforcement activities include licensing, surveillance, raids, prosecution and precursor control. Raids and inspections have been stepped up to stamp the illegal sale of poisons, unregistered products and adulterated traditional medicines that can cause harm to consumers. The value of unregistered products that were confiscated has increased tremendously (20.6 million in 2004 as compared to 6.43 million in 2003). This showed that there are many products that have no quality and hazardous to health in the market. Therefore, the increase in the sale and distribution of products that are unsafe and of no value to human lives has posed a great challenge and more efforts are needed to overcome this challenge.

Monitoring of advertisements has been enhanced towards ensuring public access to correct and reliable information on medicines and health services and efforts have been made to speed up the process.
Regional cooperation on pharmaceuticals has also taken place through the harmonization efforts by the various ASEAN and WHO committees and working groups. This is also one of the means to ensure that Malaysian products are of equal standing and accepted in the world.

The provision of pharmaceutical care has been enhanced through the improvement of the various clinical activities. The improvements carried out include the upgrading of infrastructure in various hospitals and strengthening of pharmacists' skills. More pharmacists were given training through workplace attachments either locally or overseas. The field of Clinical Pharmacy specialities has also been broaden and strengthened to enable pharmacists' to contribute more significantly towards the health of patients.

5.2 Expectations and Future Directions

The PSD will continue to intensify its various activities in the coming years given the improved manpower situation, to develop its services in tandem with the Ministry of Health's mission and vision.

The shortage of manpower, especially for pharmacists has jeopardised the provision of pharmacy services in the country, whereby expansion in the scope of service at the hospitals and health clinics could not take off well. Although the compulsory service was gazetted in September 2004, there was no intake of provisional pharmacists in that year. However, the intake of provisional pharmacists in 2005 will give a new light to the pharmacy service, which has been restrained due to the lack of human resource.

In the years ahead, the existing regulatory system focusing on safety and efficacy of pharmaceutical products to protect public health will be strengthened through enhancement of pharmacovigilance activities, exchange of technical information and collaboration with other regulatory authorities on product evaluations and Good Manufacturing Practice (GMP) inspections.

Improved in the awareness and knowledge on health among the pubic will augment the efforts taken in regulatory, enforcement and pharmaceutical care activities in ensuring the safety of medicines and pharmaceutical products that are available to them. Improved strategies in public education and health knowledge especially on medications and other pharmaceutical products will result in a more informed public and accord better consumer protection. Greater involvement of the media and increase utilisation of information and communication technology would be looked into as strategies in improving public education in pharmaceutical-related matters.

Geared towards improving and upgrading the quality of pharmacy practice, various strategies have been outlined, which include integrating pharmaceutical care service at all levels of healthcare, accreditation of pharmacy facilities, and application of the latest information technology

system in all pharmaceutical care service including the drug management system. The proficiency of the pharmacy personnel will be upgraded through credentialing system, continuous professional development programme and specialization of pharmacy service for various disciplines of pharmacy.

The PSD will also strengthen the rational utilisation of drugs and improve the inclusion process of drugs into the MOH Drug List through pharmacoeconomics evaluation and drug utilisation research. Greater efforts will be made to involve pharmacists at the practice level to carry out early evaluation of the drug literature through hands-on training of critical appraisal and evidence-based evaluation.

Proposals for more scholarships to be awarded to pharmacists for postgraduate training will be continuously pursued. Specialisation in appropriate fields of pharmacy will be identified so as to ensure pharmacists who have completed their postgraduate degrees are placed appropriately. Besides postgraduate courses, specialisation programmes will be continued with hands-on training in the country as well as overseas.