ANNUAL REPORT 2005
PHARMACEUTICAL SERVICES PROGRAMME

INTRODUCTION

The Pharmaceutical Services Division (PSD), Ministry of Health (MOH) as the key government agency in the pharmaceutical sector is responsible to ensure an equitable, adequate and affordable access by the people to safe, effective, good quality medicines and that they are used in a therapeutically sound and effective way to improve their health outcomes and quality of life.

This division that comprises of three main subdivisions, the National Pharmaceutical Control Bureau (NPCB), Pharmaceutical Enforcement Branch and Pharmaceutical Care Management and Development Branch plays three major roles:

i. Contributes directly to public health by establishing and implementing the national drug registration system besides regulating the pharmaceutical industry through the NPCB that assures the quality of medicines in the country;
ii. Protects consumers from hazardous drugs, misleading medicine advertisements and unscrupulous practices through the enforcement of related drug and pharmacy legislation that control the importation, sale and advertisement of drugs and the practices of pharmacy in the country and
iii. Optimises drug therapy and the provision of pharmaceutical care by ensuring efficient management of selection, procurement, distribution of pharmaceuticals and ensuring the rational and cost-effective use of medicines through effective up-to-date clinical and professional pharmaceutical services in tandem with current global development.

PROGRAMME RESOURCES

This division is headed by a director who is assisted by two deputy directors responsible for the Pharmaceutical Enforcement Branch and Pharmaceutical Care Management and Development Branch respectively, and the director of the NPCB. The manpower of the whole Pharmaceutical Services, MOH according to category and activity is shown in Table 1 and 2.

Table 1: Pharmacist Manpower of Pharmaceutical Services, 2005

Category/ Activity	Grade	No. of Posts	Filled	Vacant	% Filled
Director	**JUSB (A#)**	1	1	0	100
Pharmaceutical Care Management and Development	**U41**	729	873	-144*	+19
	U44	180	0	180*	0
	U48	125	122	13*	98
	U52	19	0	19*	0
	U54	10	9	1	90
	JUSA C	1	1	0	100
Licensing and Enforcement	**U41**	124	140	-16*	+13
	U44	33	0	33*	0
	U48	37	35	2*	95
	U52	1	0	1*	0
	U54	1	1	0	100
	JUSA C (B#)	1	1	0	100
Regulatory Control of Pharmaceuticals	**U41**	60	57	3	95
	U44	4	0	4	0
	U48	31	29	2	94
	U52	2	0	2	0
	U54	2	1	1	50
	JUSA C	1	1	0	100
Total		1,362	1,271	103	93

Source: PSD, MOH

\# Personal to holder

• Posts that have been traded-off, U41 for U44 and U48 for U52

Table 2: Pharmacy Assistant Manpower of Pharmaceutical Services, 2005

Category/ Activity	Grade	Number of Posts	Filled	Vacant	% Filled
Pharmaceutical Care Management and Development	U29	2,383	2,119	264	89
	U32	313	286	27	91
	U36	49	36	13	74
	U38	23	13	10	57
	U40	2	0	2	0
Licensing and Enforcement	U29	9	5	4	56
	U32	8	2	6	25
	U36	3	3	0	100
	U38	0	0	0	-
	U40	0	0	0	-
Regulatory Control of Pharmaceuticals	U29	67	53	14	79
	U32	8	5	3	63
	U36	2	2	0	100
	U38	0	0	0	-
	U40	0	0	0	-
Total		2,867	2,524	343	88

Source: PSD,MOH

ACTIVITIES AND ACHIEVEMENTS

ORGANISATIONAL AND HUMAN RESOURCE DEVELOPMENT

Organisational Restructuring

With the approval of several posts of U52 grade and U44 grade in 2005, PSD was reorganized based partly on the restructuring proposal to the MOH to strengthen planning activities, policy management and services implementation of the programme. This reorganisation saw the creation of a new sub-division, the Pharmacy Services and Profession Development sub-division. There are currently 9 portfolios for Pharmaceutical Care Management and Development, 10 for Pharmaceutical Enforcement Branch and 6 for the Pharmacy Services and Profession Development.

Improvement in Pharmacy Manpower

i. Increase in Number of Posts

The increase in the number of posts for Pharmacist and Pharmacy Assistant during the past 5 years has been very encouraging especially for the appointment posts of U41 and promotional posts of grade U44 up to U52 for the pharmacists and grade U32 up to U40 for the pharmacy assistants (please refer to Table 3).

Table 3: The Number of Posts for Pharmacy Personnel

Category/ Grade	2001	2002	2003	2004	2005
Pharmacist					
U41	569	849	972	980	*916
U44				58	*217
U48	68	97	113	180	184
U52				21	21
U54	13	13	13	13	13
Jusa C	3	3	3	4	4
Jusa B	1	1	1	1	1
Pharmacy Assistant					
U29	2199	2319	2407	2447	2459
U32	201	245	277	248	329
U36	33	41	47	51	54
U38			5	9	23
U40				1*	2

Source: PSD,MOH

* *In the year 2005, there is an increments of 94 new posts of U41, but in the same year 158 posts have to be traded-off for the higher grades of U44.*

ii. Recruitment of New Staff

In 2005, 416 Provisionally Registered Pharmacists (PRP) were recruited into the public service. This marked the beginning of the Compulsory Service for pharmacists in the government service and the enforcement of the Registration of Pharmacists Acts (Amendment 2003) and its Regulations. In addition, 110 pharmacists from the last group of graduates not affected by compulsory service who had undergone pre-registration pupilage training also joined the service.

As for the pharmacy assistants, 129 diploma holders were appointed in 2005. MOH had also succeeded in getting approval for an additional 80 places for re-employment of retired pharmacy assistants of which 26 were filled in 2005.

iii. Promotion

Apart from the 19 pharmacy assistants who were promoted to the grade of U38, 23 to U36 and 138 to U32, there was no other promotional exercise for the pharmacy personnel in 2005 following the changes of New Remuneration Scheme (SSB) to the Malaysian Remuneration Scheme (SSM), and also the introduction of Competency Evaluation (PTK) in the public service.

REGULATORY CONTROL OF PHARMACEUTICAL

Pharmaceutical Product Quality Assurance

The regulatory control of pharmaceuticals is responsible for ensuring the safety, efficacy and quality of pharmaceuticals as well as safety and quality of traditional medicines and cosmetics marketed locally. Until the end of 2005, a total of 115,886 products have been registered. A total of 31,787 applications were received for the year 2005, which was a decrease compared to the year before (34,099 in 2004). The bulk of the applications were for the registration of cosmetics (90.1%), followed by traditional products (5.7%), 'scheduled poison' drugs (2.2%) and non-poison drugs (2.0%). The total revenue collected by NPCB was RM8.9 million. The statistics relating to product registration is shown in Table 4, 5 and 6.

Table 4: Application for Registration

Year	'Scheduled Poison' drugs	Non poison drugs	Traditional products	Cosmetics	Total	
					Yearly	Cumulative
1985-1990	9,166	5,935	-	-	15,101	15,101
1991	481	305	-	42	828	15,929
1992	150	60	3973	145	4,328	20,257
1993	376	111	7059	51	7,597	27,854
1994	400	168	4080	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	1347	610	3,542	43,299
2000	427	444	1523	262	2,656	45,955
2001	578	487	1154	150	2,369	48,324
2002	509	448	1603	214	2,774	51,098
2003	263	266	1471	26,177	28,177	79,275
2004	529	720	2220	30,630	34,099	113,374
2005	703	645	1807	28632	31,787	145,161
Total	**16,554**	**12,529**	**28,546**	**87,532**	**145,161**	**145,161**

Source: PSD,MOH

Table 5: Cumulative Number of Registered Products

Year	'Scheduled Poison' drugs	Non poison drugs	Traditional products	Cosmetics	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
2005	10,339	7,732	14,385	83,430	115,886

Source: PSD,MOH

Table 6: NPCB Revenue Collection, 2005

Activity	RM
Product Registration	6,783,600.00
Pharmaceutical Product Authentication	251,500.00
Import License & Clinical Trial Import License	466,500.00
Manufacturer license	329,000.00
Wholesaler license	437000.00
GMP auditing	48,250.00
Laboratory services	304,762.00
Published goods sale	13335.00
Other sales	60,522.64
Total	**8,694,469.64**

After the products are registered, the quality of the products in the market is continuously monitored by NPCB through its surveillance activities. A total of 2,483 registered products were sampled for this purpose and this represented 8.13% of the targeted number of registered products. A total of 1,428 labels and package inserts had been checked. 42 products were issued warning letters and NPCB handled 269 complaints. 74 products were recalled from the market; 3 Degree One (within 24 hours) product recalls were issued, all of which were traditional medicines. There was no Degree Two (within 72 hours) product recall for the year 2005. A total of 71 product batches were recalled within 30 days (Degree Three) comprising 12 prescription drugs, 3 non-prescription drugs and 56 traditional medicines. Throughout the year 2005, NPCB received a total of 2,363 adverse drug reaction (ADR) reports, a 42% increase as compared to the previous year 2004 (please refer to Figure 1). Out of those reports, 2,009 reports were evaluated and subsequently submitted to become a part of the WHO ADR Monitoring Centre database in Uppsala, Sweden. The majority of the ADR reports were submitted by medical practitioners from government hospitals.

On the aspect of Quality Control, a total of 56,641 tests were done on 4,605 samples and of these samples, 2,165 were samples for application for registration, 1,985 samples from surveillance activities, 101 samples from complaints, 272 samples from enforcement activities and 82 samples were from other sources (please refer to Figure 2).

Figure 3 shows that in the year 2005, 296 manufacturing premise licenses were issued of which 87 were for pharmaceutical, 148 for traditional and 61 for cosmetic manufacturers. For importers, a total of 652 import licenses were issued comprising of 175 pharmaceutical, 137 traditional and 340 cosmetic import licenses. A total of 943 wholesaler licenses were issued of which 422 of these licenses were issued to wholesalers of 'scheduled poison' drugs and the remaining 521 licenses were issued to wholesaler of non-poison and traditional products as well as cosmetics. A monthly updated list containing information of the licensed premises is available on the NPCB website (www.bpfk.gov.my).

NPCB also publishes the Drug Control Authority '*Berita Ubat-ubatan'* and *Malaysian Adverse Drug Reactions* to disseminate drug and regulatory information to health professionals and the industry. In 2005, the Information and Communication Unit of the Centre for Organisational Development of NPSB received 3,739 enquiries through telephone, e-mail, facsimiles and letters from the government agencies, companies and the general public.

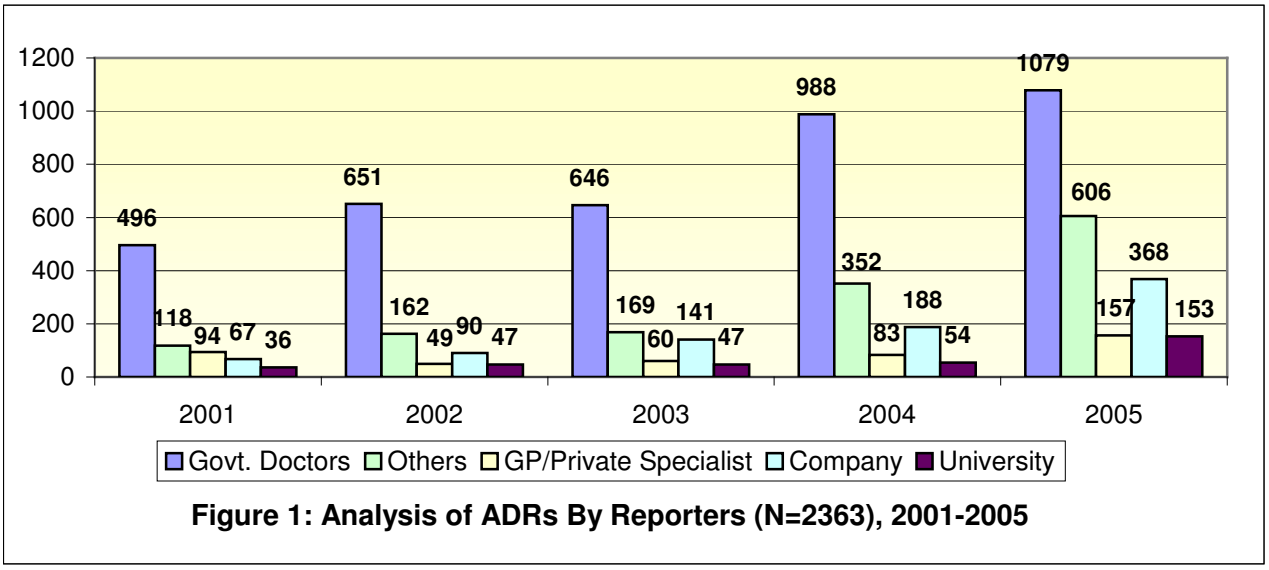


Figure 1: Analysis of ADRs By Reporters (N=2363), 2001-2005

Source: PSD,MOH

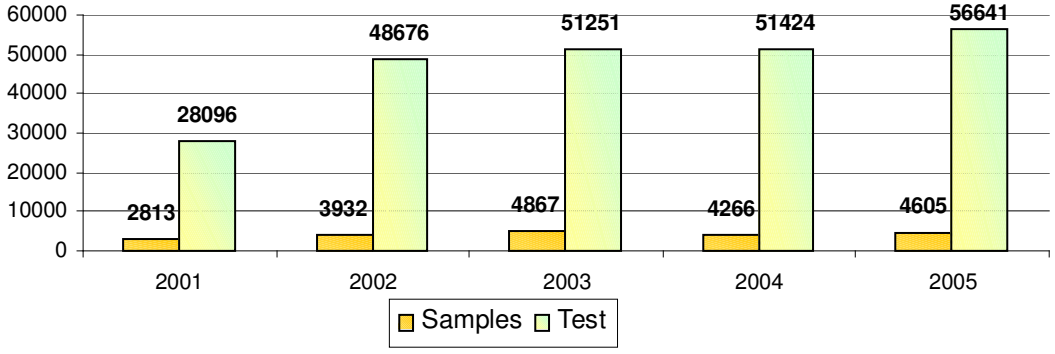


Figure 2: Samples Tested 2001 - 2005

Source: PSD,MOH

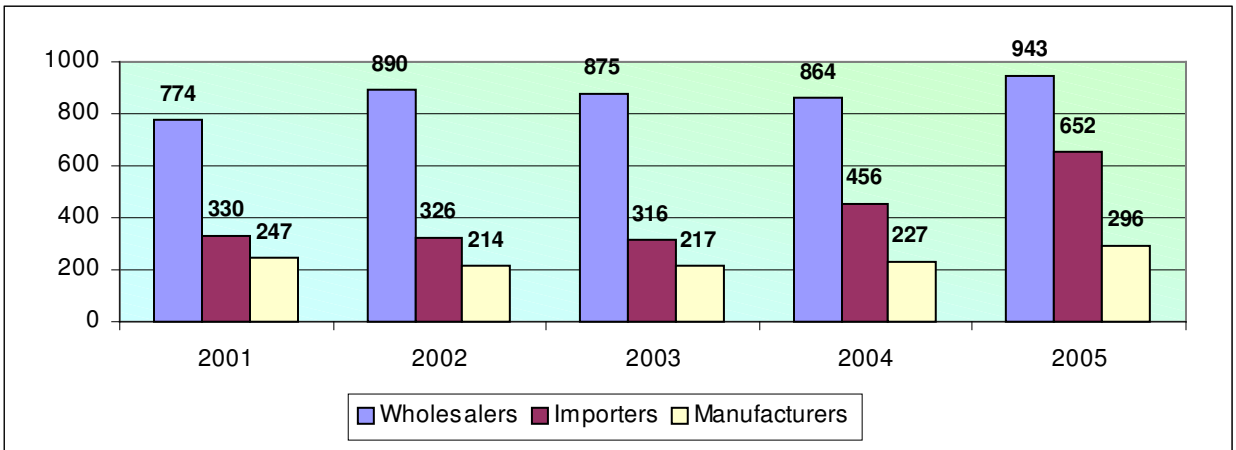


Figure 3: Total Licence Issued 2001-2005

Source: PSD,MOH

On-line Product Registration

All registration application for pharmaceutical, traditional, cosmetics were submitted via the system except for new chemical entity products and biotechnology products. In 2005, the on-line system was expanded to include new modules such as application for product variation and appeals.

The licensing of manufacturers, importers and wholesalers for cosmetics in the previous years was successful and in 2005, importance was given to technical guidance sessions conducted for the cosmetic industry. Some of the guidelines used to facilitate product registration were re-evaluated. The finished document was then made ready for download from the NPCB website (www.bpfk.gov.my).

International Involvement

NPCB continued to play an active role in its regulatory harmonisation efforts through ASEAN Consultative Committee for Standards and Quality (ASCSQ), Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and Traditional Medicines and Health Supplements Product Working Group (PWGTMHS). Other involvements include facilitating the fast track healthcare integration of ASEAN and Economic Co-operation EC-ASEAN towards quality, standards and conformity assessments. NPCB was also involved in technical meetings as well as initiate bilateral arrangements with other ASEAN countries. NPCB cooperated with the WHO and the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to handle training in the field of GMP and undertook auditing/checking of GMP regionally under the Technical Co-operation program EC-ASEAN. Auditing in co-operation with PIC/S was conducted with Danish auditors at the factory of Pharmaniaga Sdn. Bhd.

Visits and Training of Guests from Overseas

Through out the year 2005, NPCB received a total of 55 international visitors from various countries such as Cambodia, India, Laos, Singapore, EU, Indonesia, Tanzania, Namibia, USA, Spain, Sudan, Vietnam, France, Korea and Iran. Those who came on educational visits were given training according to their respective specific needs. Training given was in the aspect of Quality Control, Product Registration, Good Manufacturing Practices and Licensing or Pharmacovigilance and Surveillance.

ENFORCEMENT AND LICENSING

The main activities of the Pharmaceutical Enforcement Branch in PSD, MOH are carried out by 11 main units, which are the Advertisement Control Unit, Licensing Unit, Precursor Control Unit, Law Drafting Unit, Intelligence Unit, Special Task (Poisons, Unregistered Products and Counterfeit) Unit, Special Task (Cosmetic) Unit, Diversion Control Unit, Investigation Unit, Prosecution Unit and Consumer Protection Unit.

Advertisement Control

The Medicine (Advertisement and Sale) Act 1956 provides the basis for the control of advertisements of medicines, appliances, remedies, skill and services that relate to medical and health claims. The PSD, MOH as the custodian of this Act has put into place an enforcement mechanism that is committed to eradicating illegal advertisements. A total of 81 cases were investigated under Medicine (Advertisement and Sale) Act 1956 and 160 warning letters were issued in 2005 (please refer to Table 7 and 8).

Licensing

i. Licences issued by the State Enforcement Branch

The number of licence issued has increased from 2,887 poison licence type A in 2004 to 2,956 in 2005. There was a slight increase in the type B licence from 1,309 in 2004 to 1,340 in 2005. However the number of Sodium Hydroxide permit issued dropped from 1,679 in 2004 to 1,654 in 2005 (Figure 4). The highest increase in the issuance of type A licences in 2005 was in Sarawak, where 202 type A licences were issued compared to 163 in 2004; followed by Sabah where 171 licences A were issued in 2005 in comparison to 139 in the year 2004. For the issuance of type B licences, the biggest increase in the licences issued was in Penang where 202 licences were issued in 2005 compared to 186 licences in the year 2004 (Table 9).

ii. Licences Issued by the Pharmaceutical Services Division MOH

As shown in Figure 5, the import authorisations for Dangerous Drugs issued by PSD was almost similar in 2005 (150) and 2004 (154). The import authorisations for Psychotropic Substances was also almost constant at 272 in 2005 and 278 in the year 2004. However, the number of export authorisation issued in 2005 had decreased to only 20 as compared to 31 in 2004.

Table 7: Investigations And Legal Actions Against Unlawful Advertisements

Cases investigated and legal actions taken by	Number
Pharmaceutical Services Division, MOH	59
Pharmacy Enforcement Branches (from the various States of Malaysia)	22
Total	**81**

Source: PSD,MOH

Table 8: Warning Letters To The Media Editors And Advertisers

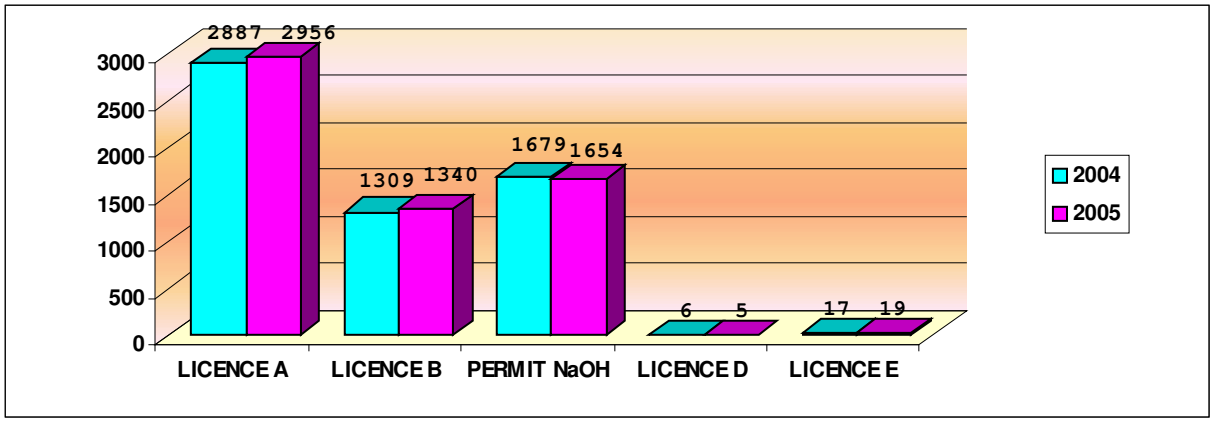
Warning letters sent to	Number
Editors	13
Advertisers	68
Editors & Advertisers	79
Total	**160**

Source: PSD,MOH

Table 9 Issuance of Licence Under Poison Act 1952 (Revised 1989) By States, 2005

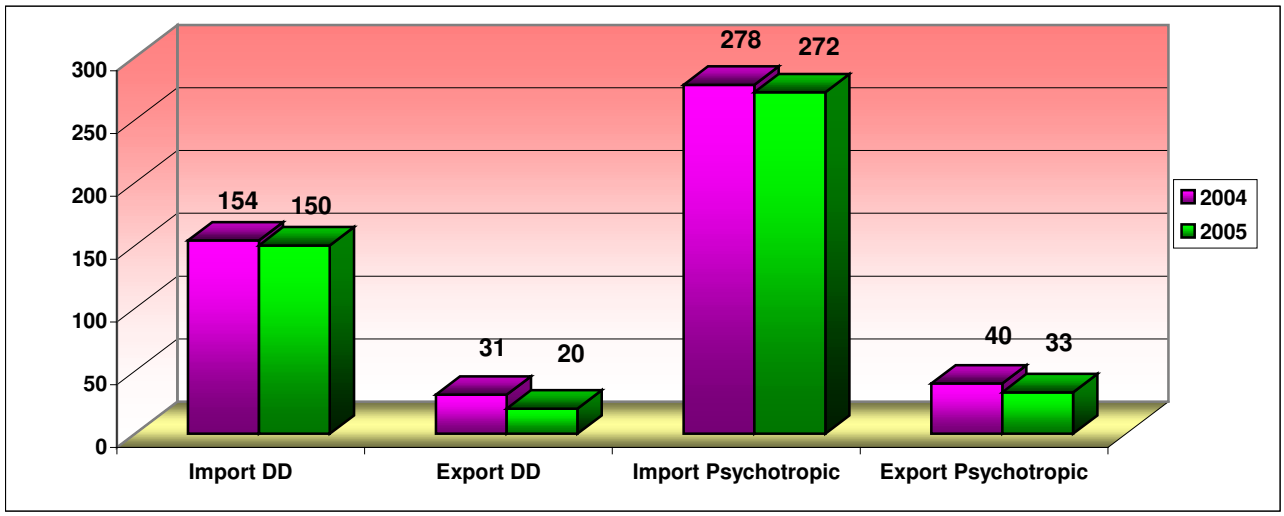
State	Licence A	Licence B	NaOH	Licence D	Licence E
Perlis	14	5	4	1	0
Kedah	124	61	34	4	0
P.Pinang	324	202	152	0	0
Perak	210	67	146	0	1
Selangor	920	344	404	0	2
W.P. K.Lumpur	440	69	25	0	1
N. Sembilan	80	42	73	0	0
Melaka	71	52	70	0	6
Johor	214	188	343	0	4
Pahang	59	43	108	0	0
Terengganu	34	39	58	0	0
Kelantan	89	18	18	0	0
Sabah	171	82	76	0	0
W.P. Labuan	4	17	4	0	0
Sarawak	202	111	139	0	5

Source: PSD,MOH



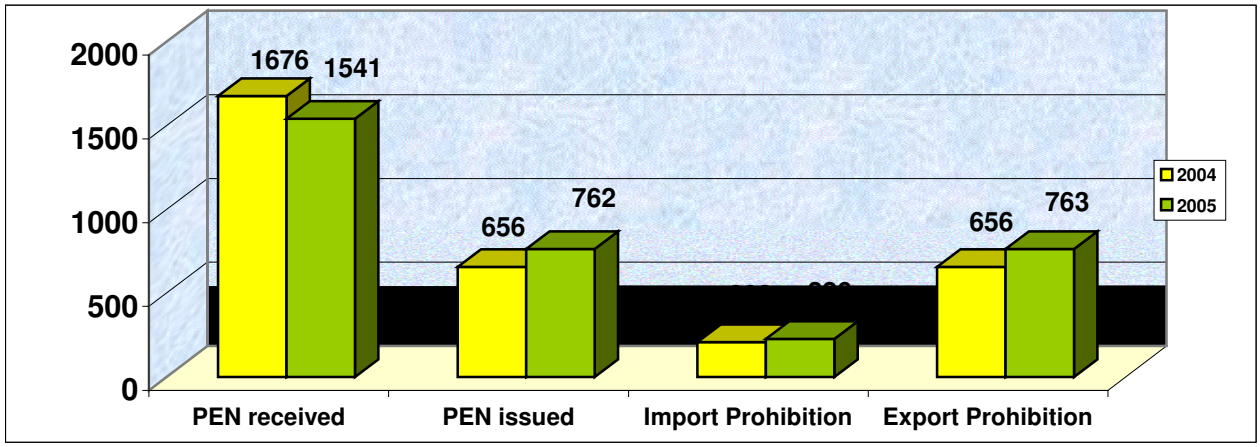
Source: PSD,MOH

Figure 4 : Issuance Of Licence Under Poison Act 1952 (Revised 1989), 2004 and 2005



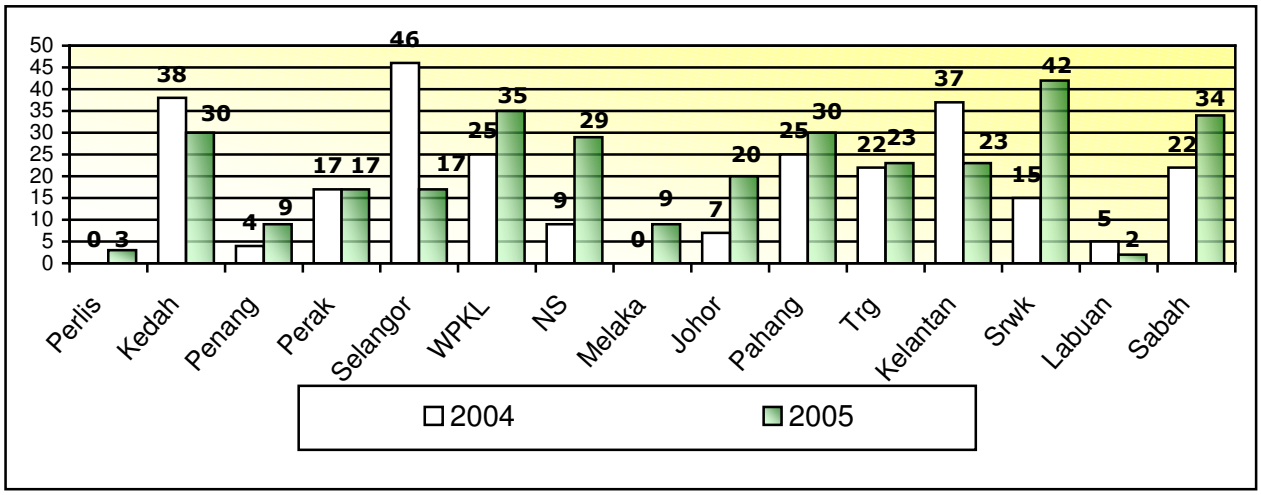
Source: PSD, MOH

Figure 5: Import/Export Authorisation for Dangerous Drugs & Psychotropic Subtances



Source: PSD, MOH

Figure 6: Control of Precursor Chemicals



Source: PSD, MOH

Figure 7: Pre-Operation Intelligence Activities by States

iii. Control of Precursor and Certain Chemicals

The control in the import/export of precursors and certain chemicals like beta-agonist and saccharin is under the Custom (Prohibition on Import/Export) Order. In 2005, prohibition of import approval for precursor was 226 compared to 208 in 2004. The approval for export was 763 in 2005 compared to 656 in 2004 (Figure 6).

The control of export of precursor chemicals uses Pre-export Notification (PEN) to prevent diversion of these precursors to 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 2005 was 1,541 as compared to 1,676 in the year 2004. The numbers of PEN issued for export of precursor chemicals in 2005 was 762 compared to 656 in the year 2004.

Drafting of Pharmacy Legislations

In 2005, the Pharmacy Legislations Drafting Unit of PSD updated the 4 Acts and Regulations below:

(a) Registration of Pharmacists (Amendment) Act 2003
(b) Registration of Pharmacists Regulations 2004
(c) Poisons Regulations (Amendment) 2003
(d) Dangerous Drugs Regulations (Amendment) 2004

Pre-Operation Intelligence

The number of pre-operation intelligence conducted by all states had increased from 272 in 2004 to 323 in 2005. Surveillance conducted prior to raid operation was highest in Sarawak with 42 cases followed by Wilayah Persekutuan Kuala Lumpur with 35 cases, Sabah 34 cases, and Pahang and Kedah respectively with 30 cases (Figure 7).

Special Task (Operation)

Based on information received from Special Task Operation unit together with that from Intelligence, Diversion Control and Special Task on Cosmetics unit and from other reliable sources of information coupled with specific Plan of Action for 2005, raids were carried out either by each state alone or with the help of other states and units, fighting against the

importation, manufacturing and distribution of unregistered drugs include products without registration numbers, products using false registration numbers or registration number of other registered products, products adulterated with poison and counterfeit products (Figure 8).

The value of seizure had decreased from RM 27.3 million in 2004 to RM 9.92 million in 2005 (Figure 9). The highest seizure was RM 2.86 million in Kuala Lumpur followed by RM 1.64 million in Selangor, RM 1.45 million in Penang and RM 1.16 million in Kelantan. Most of the products seized in 2005 were traditional medicines valued at more than RM 4.91 million followed by products classified as poisons at RM 1.87 million and over-the-counter products at RM 1.44 million (Table 10).

Pharmaceutical Diversion Control

Diversions of psychotropics substances especially buprenorphine, midazolam and precursors especially pseudoephedrine tablets were closely monitored and analysed for its trend of abuse. In 2005, 87 private medical clinics throughout Malaysia had been inspected with regards to the supply of buprenorphine tablets for the treatment of addicts, 36% of them were found to supply buprenorphine together with benzodiazepines which were not accordance to the treatment protocols. Meanwhile, 3 pharmacies and 2 private clinics had been investigated for the high volume purchase of pseudoephedrine tablets. In November 2005, a new approach using written attestation was introduced to control the diversion of psychotropics substances by using Regulation 12(2)(b) of the Poisons (Psychtropics Substances) Regulations 1989. Since then a wholesale pharmacy and a medical clinic had been investigated in the transactions of 14,000 tablets of Midazolam in a singe day without a written attestation.

Prosecution

The prosecution of 317 cases were completed in 2005 with a total collection of RM1,027,000 in fines. The breakdown of prosecutions completed within the year according to the Acts enforced and the respective states are tabled in Table 11. The amount collected in fines from offences under the Sales of Drugs Act 1952 were the highest with RM741,000 i.e. 46% collected followed by offences under Poisons Act 1952 with RM185,950 i.e. 38% collected. F.T. of Kuala Lumpur showed the highest collection in fines with a total amount of RM256,400 followed by Selangor (RM240,600) and Terengganu (RM102,700).

Consumer Protection

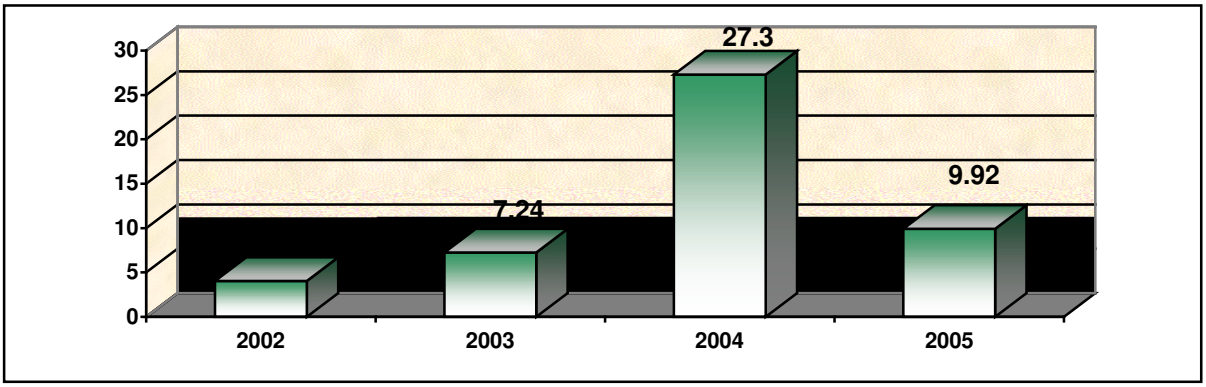
The main activities of the Consumer Protection Unit are focused on giving and disseminating information and knowledge on the usage and selling of medicine and cosmetics in the market to the public and target groups that include individual, family and the communities in urban and rural area. The information, knowledge and creation of awareness among the target groups were disseminated through the electronic and printed media. In 2005, 96 exhibitions, 16 dialogues and 51 talks were successfully delivered by the unit.

Achievement of information dissemination in 2005:

1. The distribution of posters and post cards “Know Your Medicine “ to the public through out the country via the State Pharmacy Enforcement Branch.
2. The distribution of Informative Calenders on medicine to the public through out the country via the state Pharmacy Enforcement Branch.
3. The dissemination of information through printed media in Sunday Star, *Mingguan Malaysia*, Sin Chew Jit Po newspaper and Mens Health magazine.
4. Special appearance through television programs such as *Malaysia Hari Ini (MHI)* in TV3 and *Selamat Pagi Malaysia (SPM)* in TV1.
5. Talks in radio
6. Exhibitions and talks in schools.
7. Exhibitions to the public and MOH Customers Day.
8. Road Show to provide training and awareness on how to identity Hologram labels for all the state Pharmacy Enforcement officers in the country.

Source: PSD,MOH

Figure 8 Raids and Special Inspection by The Pharmacy Enforcement Officers On Premises For Unregistered Medicines



Source: PSD,MOH

Figure 9: Value of items seized according to the year

Table 10: Types and Values of Products Seized

Type of products	Value (RM)
Poisons	1,872,474.00
Over-the-Counter	1,439,020.00
Traditional	4,911,386.00
Cosmetic	529,497.00
Psychotropic substances	489,536.00
Counterfeit	7,093.00
Sex stimulants	232,208.00
Non Steroidal Anti Inflammatory	4,795.00
Others	29,194.00

Source: PSD,MOH

Table 11: Prosecution *(Completed)* By Acts And States For Year 2005

No	State	Poisons Act 1952	Poisons Act 1952 *(Psychotropic Substances)*	Sales Of Drugs Act 1952	Medicines (Advertisement and Sales) Act 1956	Total No. of Cases	Total Fine Collected (RM)	(%)
1.	Perlis	**2**	**-**	**2**	**-**	**4**	**9,000**	**1**
2.	Kedah	**1**	**1**	**3**	**-**	**5**	**15,000**	**1.5**
3.	Pulau Pinang	**8**	**3**	**10**	**-**	**21**	**63,200**	**7**
4.	Perak	**9**	**-**	**10**	**-**	**19**	**49,000**	**6**
5.	Selangor	**13**	**4**	**24**	**-**	**41**	**240,600**	**13**
6.	W.P. KL	**16**	**4**	**35**	**-**	**55**	**256,400**	**17**
7.	N. Sembilan	**3**	**2**	**10**	**-**	**15**	**25,150**	**5**
8.	Melaka	**2**	**-**	**4**	**-**	**6**	**9,800**	**2**
9.	Johor	**14**	**2**	**19**	**1**	**36**	**74,750**	**11**
10.	Pahang	**4**	**-**	**4**	**-**	**8**	**21,500**	**3**
11.	Terenganu	**3**	**20**	**12**	**-**	**35**	**102,700**	**11**
12.	Kelantan	**12**	**-**	**6**	**1**	**19**	**27,400**	**6**
13.	Sarawak	**16**	**-**	**6**	**1**	**26**	**60,700**	**8**
14.	Sabah	**16**	**1**	**1**	**3**	**21**	**65,400**	**7**
15.	W.P. Labuan	**2**	**-**	**-**	**-**	**2**	**4,000**	**0.5**
16.	BPF, KKM	**-**	**-**	**-**	**4**	**4**	**2,400**	**1**
Total		**121**	**37**	**146**	**10**	**314**	**1,027,000**	**100**
Percentage(%)		**39**	**12**	**47**	**3**	**100**		
Total Fine Collected (RM)		**185,950**	**92,700**	**741,050**	**7,300**	**1,027,000**		

Source: PSD,MOH

PHARMACEUTICAL CARE MANAGEMENT

Procurement and Distribution

In 2005, this unit conducted 4 meetings to draw up the specifications of 109 drugs to be tendered and 5 meetings of the Drug Evaluation Technical Committee were held to evaluate tender offers for 96 drugs.

The value of all drug contracts handled in 2005 were RM 281.2 million as compared to RM 320.44 million in 2004 and RM 205.37 million in 2003.

The total of drug expenditures from the year 1995 to 2005 are shown in the Table 12 below. The total value of drug purchased from Syarikat Pharmaniaga Logistics Sdn. Bhd for 2005 was RM 428 million for drugs and RM 80 million for medical equipment. The 5 classes of drug with the highest purchased value are shown in Table 13.

Ministry of Health Drug Formulary

MOH Drug Formulary consists of drugs approved for use in all hospitals/institutions in MOH. The drugs in the formulary are listed according to generic names and coded with Malaysian Drug Code (MDC) for identification. By the end of 2005, the MOH Drug Formulary consisted of 1322 preparations. In 2005, 39 drugs were added to the Formulary while 106 drugs were deleted (please refer to Table 14).

Drugs Outside MOH Formulary

Approval for use of drugs outside the MOH Drug Formulary must be from the Director General of Health. As shown in Table 15, in 2005 approvals for use of registered drugs outside MOH Formulary were given to 152 types of drugs, amounting to nearly RM11, 936,387 while approvals for unregistered drugs from MOH Institutions alone was approximately RM11, 345,203, for 164 types of drugs.

Table 12: Annual Drug Expenditure

Year	Expenditure (RM Million)
1995	205.9
1996	224.7
1997	261.9
1998	303.8
1999	326.2
2000	346.3
2001	485.0
2002	526.5
2003	751.3
2004	808.0
2005	915.4

Source: PSD,MOH

Table 13: Drug Class with 'Highest Purchased Value', 2003 - 2005

2003		2004		2005	
Drug Class	Purchase Value (RM million)	Drug Class	Purchase Value (RM million)	Drug Class	Purchase Value (RM million)
Cardiovascular	70.2	Cardiovascular	77.3	Cardiovascular	76.0
Antibiotic	60.7	Antibiotic	60.7	Antibiotic	56.7
Neuromuscular	39.4	Metabolism	45.0	Metabolism	49.8
Metabolism	38.1	Other Antimicrobial	35.3	Neuromuscular	49.2
Other Antimicrobial	21.1	Neuromuscular	34.0	Respiratory	25.8

Source: PSD,MOH

Table 14: Statistics for MOH Drug Formulary, 2000 – 2005

Year	Proforma Received	No. Of Panel Meeting	No. Of Drug Circulars	Drugs Approved		Drug 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
2005	152	3	2	19	20	106

Source: PSD,MOH

Table 15: Request of Drugs Outside MOH Formulary by MOH hospitals/ Institution

Description		2004		2005	
		Approved	Not Approved	Approved	Not Approved
Registered Drugs	Approximate cost	7,429,006.00	1,544,310.29	11,936,387.00	3,551,758.38
	Types of Drugs	120	82	152	90
	No of request	501	153	452	166
Non-Registered Drugs	Approximate cost	5,924,699.22	1,131,656.36	11,345,203.00	1,191,774.53
	Types of Drugs	140	51	164	34
	No of request	323	67	512	52

Source: PSD,MOH

Malaysian Drug Code

In 2005, the first edition of Malaysian Drug Code (MDC) with 4,293 products was produced. This edition focuses only on the drugs in the MOH Formulary that are registered with Drug Control Authority (DCA) and is available on the Pharmaceutical Services Division's web www.pharmacy.gov.my. MDC is a code assigned to a particular drug for identification based on the Anatomical Therapeutic Chemical Classification (ATC) structure of WHO.

Clinical Pharmacy Services

The Pharmaceutical Service of hospitals and health clinics under MOH aims to provide comprehensive patient-centred pharmaceutical care. This is achieved through the provision of clinical pharmacy services such as medication counselling service, ward pharmacy service, drug information service, clinical pharmacokinetic service (CPS), total parenteral nutrition (TPN) and IV admixture service, oncology pharmacy service and nuclear pharmacy service. The achievements of these services are summarised in Table 16.

i. Medication Counselling Service

Medication counselling through individual, discharge and group sessions is carried out by 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 133,323 patients were counselled on their medications in 2005 as compared to 62,000 in 2004.

ii. Drug Information Service (DIS)

The primary goal of Drug Information Service (DIS) is to improve the quality of patient care by answering drug-related questions directly applicable to patient care. In 2005, a total of 19,648 enquiries were received by hospital pharmacies of which 1,342 enquiries related to Adverse Drug Reactions (ADR) were reported to the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC).

iii. 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. In 2005 specialised clinical pharmacy services in the areas of respiratory, critical care and nephrology was established in hospitals such as Melaka, Selayang and Kuala Lumpur.

iv. Clinical Pharmacokinetic Service

The Clinical Pharmacokinetic Service (CPS) is a major component of the Pharmaceutical Services in the country and is essential towards ensuring the safe and effective use of medications particularly those with narrow therapeutic windows and promoting positive outcomes in therapy. In 2005, a total of 61,907 patients had received individualized drug therapy through the pharmacy clinical pharmacokinetic service (CPS) provided by 73 hospitals throughout the country.

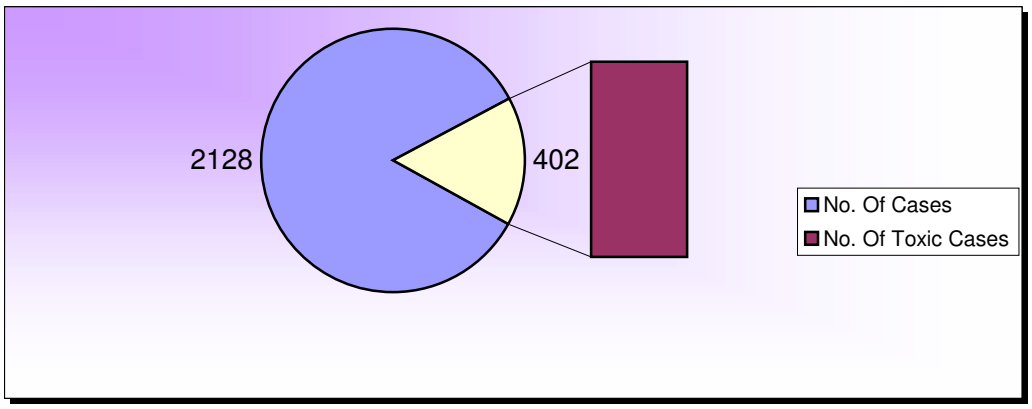
Through CPS, consultations were provided for the appropriate dosing of 14 types of drugs namely:

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

A total of 2,222 requests for toxicological monitoring were received in 2005 and 416 (18.72%) were in toxic range. 96 % of requests were for adults and 4% for paediatrics. Number of confirmed overdoses of paracetamol for adults and paediatrics are as shown in figure 10 and 11.

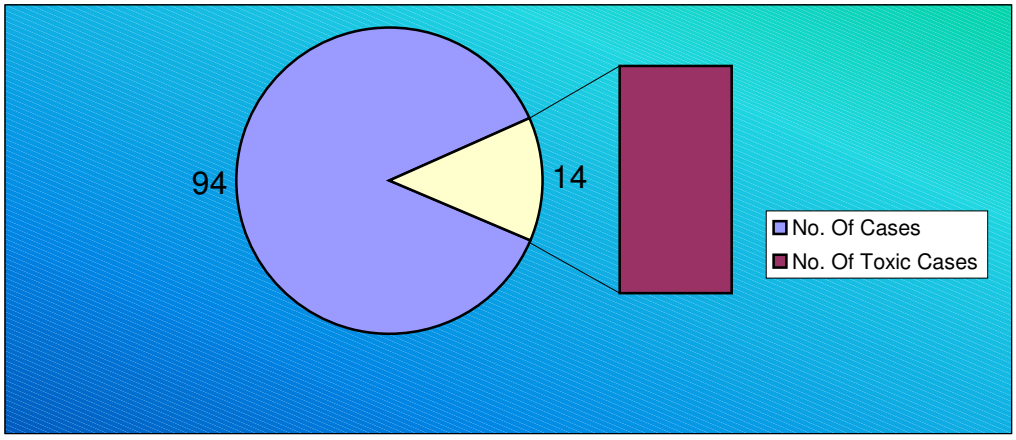
Through this service, the use of N-acetylcysteine as an antidote for paracetamol poisoning had been optimized because CPS can provides evidence for when antidote should or should not be given.

Figure 10 : Number Of Paracetamol Poisoning Cases In 2005 (Adult)



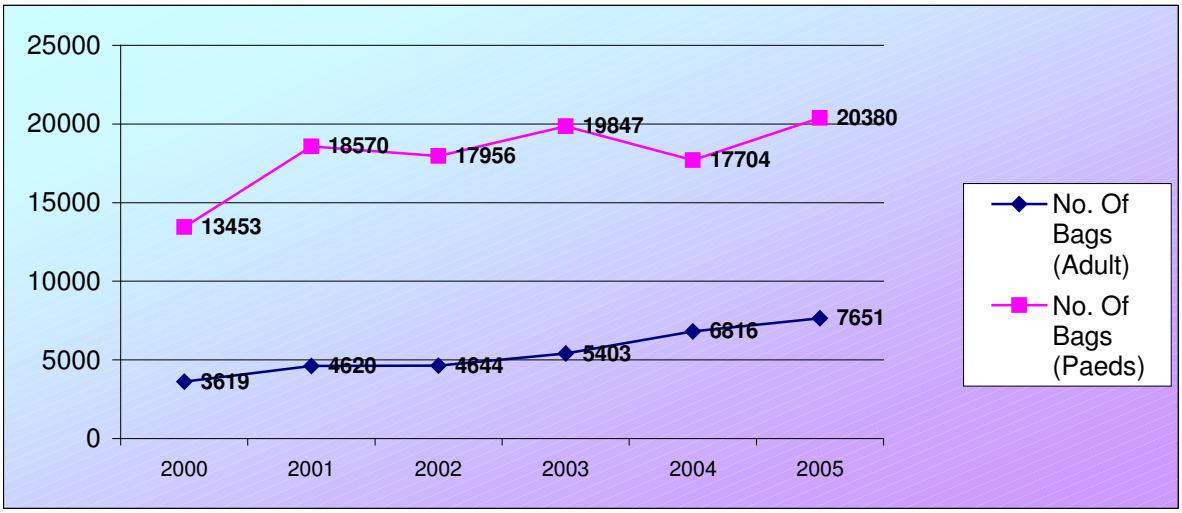
Source: PSD,MOH

Figure 11 :Number Of Paracetamol Poisoning Cases in 2005 (Paediatric)



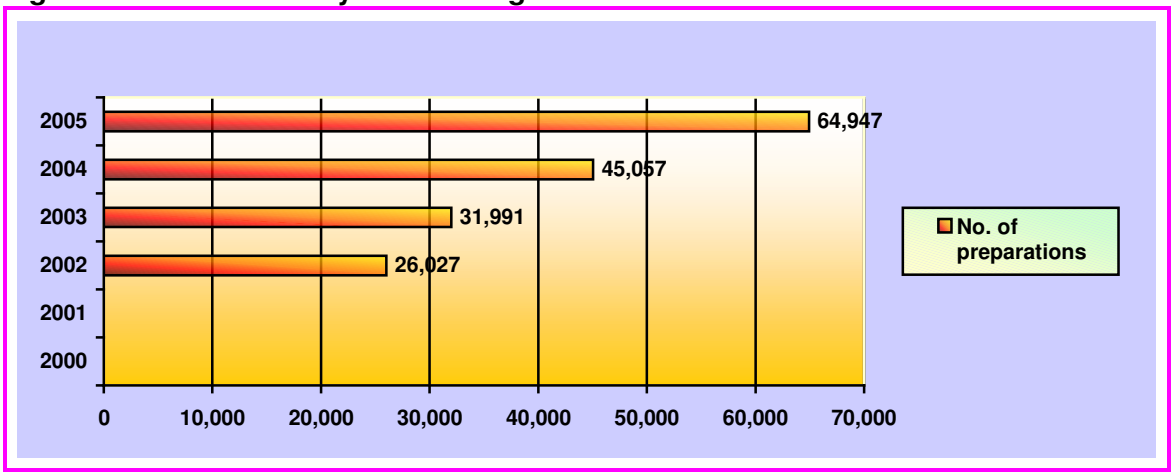
Source:PSD.MOH

Figure 12: Number of TPN Bags Prepared



Source:PSD.MOH

Figure 13 : Number of Cytotoxic Drugs Reconstituted



Source:PSD.MOH

Table 16: Achievements in Clinical Pharmacy Service

Services	2005
1. Medication Counselling Service	
i. No. of patients counselled:	63,760
• Out-patient	18,149
• In-patient	37,000
• Ward Discharged	14,414
• Health	
ii. Total no. of patients counselled	133,323
2. Drug Information Service	
i. No. of enquiries received	19,648
ii. No. of ADR reported	1,342
3. Clinical pharmacokinetic service	
i. No. of hospitals	73
ii. No. of cases	61,907
iii. No. of drugs	14
4. Parenteral nutrition service	
i. No. of hospitals	18
ii. No. of bags(adults)	7,651
iii. No. of bags(Children)	20,380
5. Intravenous admixture service	12
i. No. of hospitals	53,677
ii. No. of cases	108,307
iii. No. of preparations	
6. Cytotoxic drug reconstitution service	
i. No. of hospitals	16
ii. No. of preparations	64,947
7. Drug Dispensing Service	
A. Hospital	
i. No. of prescriptions received	11,280,531
ii. No. of prescriptions intervened	93,068
B. Health	
i. No. of prescriptions received	20,952,259
ii. No. of prescriptions intervened	647,816
C. Total no. of prescriptions received	32,232,790
D. Total no. of prescriptions intervened	740,884

Source: PSD,MOH

v. Total Parenteral Nutrition (TPN) and IV Admixture Services

By the end of 2005, there were 18 MOH hospitals providing total parenteral nutrition (TPN) service and consultation on individualized parenteral nutrition requirements as well as ensuring safe ready-to-use preparations for the patients. A total of 20,380 and 7,651 TPN bags were prepared in 2005 for paediatric and adult patients (table 16). The number of TPN bags prepared in 2005 was higher as compared to previous years (Figure 12).

12 hospitals with clean room facilities providing the IV Admixture service for 53,677 cases and 108,307 preparations are shown in Table 16.

vi. Oncology Pharmacy Service

Oncology pharmacists play a significant role in treatment of cancer patients by dispensing and reconstituting cytotoxic drugs. A total of 31 hospital pharmacies in the country dispense cytotoxic drugs to cancer patients but by the end of 2005, only 16 hospitals provided pharmacy cytotoxic drug reconstitution services. In 2005, 64,947 cytotoxic drugs were reconstituted by hospital pharmacies, an increase of almost 45% over the 45,057 drugs reconstituted in 2004 (Figure 13).

vii. Nuclear Pharmacy

In 2005, Hospital Pulau Pinang, Hospital Kuala Lumpur, Hospital Sultanah Aminah, Johor Bahru and Hospital Umum Kuching were identified to provide pharmacy nuclear services. Till the end of the year, pharmacists from Hospital Pulau Pinang and Kuala Lumpur were involved in the quality control and preparation of radiopharmaceuticals for nuclear medicine.

Primary Care Pharmacy Services

The pharmaceutical care services rendered at the health clinics aimed at improving the patients' quality of life through individual and group medication counseling, continuous medication education, home medication review and also community program. Specialized services are also being rendered to help patients in managing diabetes, hypertension, asthma and cigarette smoking cessation. In 2005, 10,836 patients were counselled individually and group counselling involving 2,901 patients were conducted. Lately, pharmacists at the clinics are also involved in the methadone therapy program.

Integrated Drug Dispensing System

The Integrated Drug Dispensing System (IDDS) was initially started as a pilot project from December 2001 to May 2002 in which 7 states took part. By 2005, all states in Malaysia have started the system. The aim of IDDS is to enable patients, particularly follow-up cases, obtain their drugs at health facilities nearest to their home, and this will especially benefit patients who stay in remote areas.

Table 19 shows that although the total number of prescriptions transacted in both years was quite constant, the total expenditure involved in the transactions have increased by 51% between 2004 and 2005. Intra-state referrals have increased by 16% and inter-state referrals increased by 44.27% between 2004 and 2005. The state that made the most intra-state referrals was Penang followed by Johor at increases of 103% and 15%, respectively. Meanwhile, Kedah (164%) and Perak (110%) had the highest increases in interstate referrals.

Research and Development (R&D)

Pharmacy research has a wide scope with high potentials. Generally researches done in 2005 were focussed on descriptive studies to obtain baseline data to initiate future studies. Even though research has not resulted in policy changes, efforts were made to study priority areas such as those pertaining to cost saving, patient safety, consumer's education, and clinical pharmacy. The pharmacy R&D activities in 2005 are shown in Table 18.

TRAINING

Apart from the various in-service courses conducted by the pharmacy departments in the states, a total of 43 courses on 35 topics were organized by PSD, MOH in 2005. In addition, 36 pharmacists were sent for attachments in the field of general pharmacotherapy at the Melaka General Hospital and in the field of nephrology pharmacy at Selayang Hospital.

In 2005, 16 pharmacists underwent short overseas training in countries such as Singapore, Thailand, Belgium, Germany, Japan, Philippines, Austria, Ethiopia, Indonesia, USA and China. 4 other hospital pharmacists were sent for attachment training in USA in the areas of diabetic and critical care.

Table 17: Transactions of Integrated Drug Dispensing System, 2004 and 2005

Transactions	2004			2005		
	Intra State	Inter State	Total	Intra State	Inter State	Total
Total No. of Prescriptions	24,772	7,953	32,725	28,705	11,474	40,179
Total No. of Cat. A Drugs	18,710	8,419	27,129	25,914	12,868	38,782
Total No. of Cat. B & C Drugs	43,133	16,189	59,322	50,845	23,561	74,406
Total Cost of Cat. A Drugs (RM)	857,486	350,903	1,208,389	1,278,718	556,931	1,835,649
Total Cost of Cat. B & C Drugs (RM)	310,011	117,170	427,181	427,909	203,443	631,352
Total Cost of Drugs (RM)	1,167,496	468,073	1,635,569	1,706,627	760,374	2,467,001

Source: PSD,MOH

Table 18: Activities of Pharmacy R & D in 2005

Activity	2005
Meeting of Research and Development Sub Committee	3
Number of Research Planned	12
Number of Research Conducted	5
Number of Training Conducted in 2005	4
Number of Research with collaboration with other agencies	2
Number of research presented at scientific conference, seminars	5

Source: PSD,MOH

Table 19: Activities of Pharmacy Board in 2005

Status	2005
No. of New Pharmacists Registered	379
No. of Pupil Pharmacists Registered (Compulsory service had started)	0
No. of Provisional Pharmacists	420
No. of New Body Corporate Registered	87
No. of Renewals of Annual Retention Certificate	3955
No. of Renewal of Annual Certificate for Body Corporate	218
Total No. of Pharmacists in the Register (including the re-registration)	4341
Total number of foreign pharmacist registered	7
Number of new premises recognized for provisional training	0
Number of pharmacy programme recognized/ monitored	4

Source: PSD,MOH

The Continuous Professional Development (CPD) Programme for the pharmacists and pharmacy assistants had also been successfully piloted in 2005 whereby 78% of pharmacists and 62% of pharmacy assistants had achieved the minimum credit points required.

SECRETARIAT TO STATUTORY BOARDS

Pharmacy Board

The Pharmacy Board of Malaysia (PBM) is responsible for the registration of pharmacists, body corporate and pupil pharmacists in Malaysia. In year 2005, the first batch of pharmacists for the four years compulsory service in the public sector were registered as Provisional Registered Pharmacists (PRP).

Besides the registration of pharmacists, PBM was also actively involved in other activities such as the renewal of Annual Certificate for Pharmacists, Annual Certificate for Body Corporate, accreditation and monitoring of pharmacy programme in universities and the conducting of Forensic Examination/ Jurisprudence Test in 2005. The PBM decided that PRP need to pass this Jurisprudence test during their provisional year. The statistics of the registration status of pharmacists in the country is shown in Table 19.

Medicine Advertisements Board

The Medicine (Advertisement and Sale) Act 1956 provides the basis for the control of advertisements of medicines, appliances, remedies and skill and services that relate to medical and health claims. The Act also provides for the formation of the Medicine Advertisement Board (MAB), which is responsible for the regulation of the relevant advertisements. The responsibility to enforce the Act rests with the PSD, MOH. In 2005, the board received a total of 1,613 applications. Table 20 listed the comparison of applications processed by MAB for the past 3 years.

Drug Control Authority

The Drug Control Authority (DCA) is the executive body responsible for the registration of pharmaceutical, traditional and cosmetic products and the issuance of manufacturer's, wholesaler's and import licences. The NPCB is the secretariat and executive arm of the DCA. DCA held 11 meetings throughout the year 2005. The DCA had discussed, agreed and

decided on policies as follows:

i. Not to register all products including cosmetic products containing Comfrey herb and Senecio *spp* due to safety reasons.
ii. Withdrawal of registration of products containing Thioridazine based on safety issue.
iii. Amendment of the mandatory statement on label and package insert for traditional products containing ginseng to "Safety on long term use has not been established".
iv. Requirement of warning statement on label and package insert for all products containing Propolis, Royal Jelly and Ginkgo Biloba/Gingko Extract.
v. Amendment of the word "Poison" which is the mandatory labelling requirement for all products containing scheduled poisons to "Controlled Medicines".

Poison Board

The Poison Board, as an advisory board, has been empowered to assess the classification of medicine/chemical substances, and thereby to advice the minister in accordance to the provisions of the Poisons Act 1952. The Board met for its 61st meeting on 1st September 2005 and decided on the following:-

i. Classification of poisons for 30 new chemical entities as listed in Table 21.
ii. Amending the classification of a Poison;
    Tacrolimus for external use is classified as group C poison
iii. Amending the Second Schedule
    The Board has agreed to list the following items in Second Schedule:
    a. Pipet
    b. Media Culture
    c. Microtitre Plate
    d. Test Strip

THE WAY FORWARD

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 year 2005 marked the beginning of Compulsory Service for pharmacists with the enforcement of the Registration of Pharmacists Acts (Amendment 2003) and its Regulations. Although the entry of the PRP poses a demanding task to the limited existing

Table 20: Comparison of Applications Processed by Medicine Advertisements Board (MAB), 2003, 2004 and 2005

Activities	2003	2004	2005
1. Total number of applications	881	1236	1613
2. Total number of approvals	803	1053	1338
3. Number of approvals through the Fast Track System	488 (61%)	751 (71%)	843 (63%)
4. Total amount of fees collected	RM 88, 100.00	RM 123, 600.00	RM 161, 300.00

Source: PSD,MOH

Table 21: Classification of New Chemical Entities

No.	Name of Drug/ chemical entity	Therapeutic classification	Group
1.	Pemetrexed	Folic acid analogues	B
2.	Duloxetine HCl	Antidepressant	B
3.	Teriparatide	Calcium homeostasis	B
4.	Atomoxetine	Centrally acting sympatomimetics	B
5.	Riluzole	Other nervous system drug	B
6.	Aripiprazole	Antipsychotic	B
7.	Adalimumab	Monoclonal antibody	B
8.	Melagatran Hcl	Thrombin inhibitors	B
9.	Ximelagatran	Thrombin inhibitors	B
10.	Rasburicase	Chemotherapeutic	B
11.	Diacerrein	Non steroid anti-inflammatory and antirheumatic agent	B
12.	Cilostazol	Anticoagulant	B
13.	Pioglitazone	Antidiabetic	B
14.	Ciclesonide	Glucocorticoids inhalants	B
15.	Levocetrizine dihydrochloride	Antihistamine	C

Source: PSD,MOH

pharmacists to supervise and provide the required training, it gives hope for a fast development of pharmaceutical services in the public sector.

In the years ahead, the existing regulatory system focusing on quality, 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. In 2005, NPCB continued with the preparation for the registration of veterinary products and pharmaceutical active ingredients. When implemented, it will be the fifth and sixth phase, respectively of the overall product registration package. In terms of quality control, the NPCB laboratory will continue the efforts towards obtaining ISO 17025 certification. From the perspective of ICT upgrading, on-line registration for New Chemical Entities and Biotechnology-derived products are currently being studied. Besides that, efforts are being taken to integrate different types of on-line modules such as product registration, premise licensing, analysing tests, surveillances, ADR monitoring and information dissemination to produce a more comprehensive regulatory system. The current computer system, QUEST 2 will also be upgraded to QUEST 3 under the 9th Malaysian Plan (2006-2010).

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

Geared towards improving and upgrading the quality of pharmacy practice, various strategies have been outlined, including integrating pharmaceutical care service at all levels of healthcare, accreditation of pharmacy facilities, application of the latest information technology system in all pharmaceutical care service and improving the economic management of the pharmaceutical supply system. Rational utilisation of drugs will also be enhanced by improving the selection process of drugs into the MOH Drug List through pharmacoeconomics evaluation and drug utilisation researches. Efforts to strengthen the quality of these researches should be intensified and to involve more pharmacists especially in multi-centred studies and encourage participations in scientific forums, conferences and publications.

Greater efforts will be made to involve pharmacists at all practice levels to carry out evaluation of drug literatures through hands-on training of critical appraisal and evidence-based evaluation.

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. Oncology pharmacy, radio pharmacy and clinical pharmacy are potential areas to be developed into specialized fields. In addition, specialities in pharmacokinetic laboratory techniques and analysis, pharmacoeconomics and regulatory activities could be expanded as these expertises are unique to pharmacists. Pharmacists in those identified areas need to make positive impacts to better patient care. Then only could the policy makers be convinced about the relevancy of these services towards health care of the people. These developments will be the momentum towards an established pharmacy specialization and the creation of pharmacy specialists.

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.

CONCLUSION

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 existing regulatory system continuously ensured the quality, safety and efficacy of pharmaceutical products to protect public health through enhancement of pharmacovigilance activities, exchange of technical information and collaboration with other regulatory authorities on product evaluations and Good Manufacturing Practice (GMP) inspections. Regional cooperation on pharmaceuticals continued 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 maintenance of quality drugs in the market is further strengthened by the enforcement of the relevant pharmacy legislations and guidelines. Enforcement activities that include licensing, surveillance, raids, prosecution and precursor control were also enhanced in 2005. 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. Efforts have also been intensified to improve the control of illicit trade of psychotropics substances and precursors through regional cooperation. Monitoring of advertisements has been enhanced to ensure public access to correct and reliable information on medicines and health services.

The MOH Drug Formulary has undergone a major restructuring process with the inclusion of the Malaysian Drug Code that is based on the WHO Anatomical Therapeutic Classification. This is to ensure that each chemical entity is unique in terms of substance, dosage, its salt and proprietary name. The code is important for future incorporation of the MOH Drug Formulary into any computerised system and also for drug utilisation analysis and studies.

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.