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ACHIEVEMENTS OF THE DRUG CONTROL AUTHORITY (DCA)

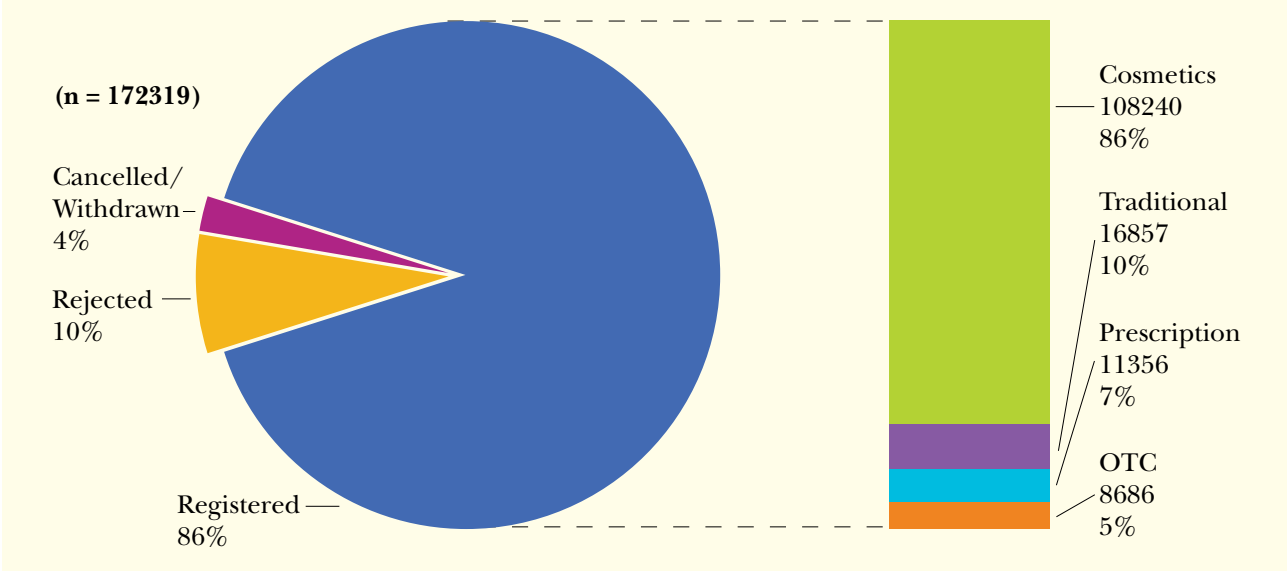
The introduction of the online system for product registration and licensing by the National Pharmaceutical Control Bureau (NPCB) marks a new chapter in the history of pharmaceutical regulatory development in Malaysia. In line with the directive for the implementation of e-government, the on-line registration system known as QUEST2 was successfully launched in 2002 with the intention of simplifying and expediting the registration process. The web-based on-line registration system was initially used for the registration of cosmetic products. After it was shown to be successful, it was then extended in stages for the registration of products containing scheduled poisons (controlled items) and non-poison products (over-the-counter products) in July 2003 followed by traditional medicines in January 2004.

Although the system had several teething problems especially in the initial stages, it has proven to be beneficial to NPCB as well as to the local pharmaceutical industry as it has streamlined the registration process and reduced bureaucracy. The implementation of on-line registration for New Chemical Entity (NCE) and Biotechnology products are proposed to be implemented under the QUEST 3 system (enhanced QUEST 2 system) at a later date.

DRUG REGISTRATION

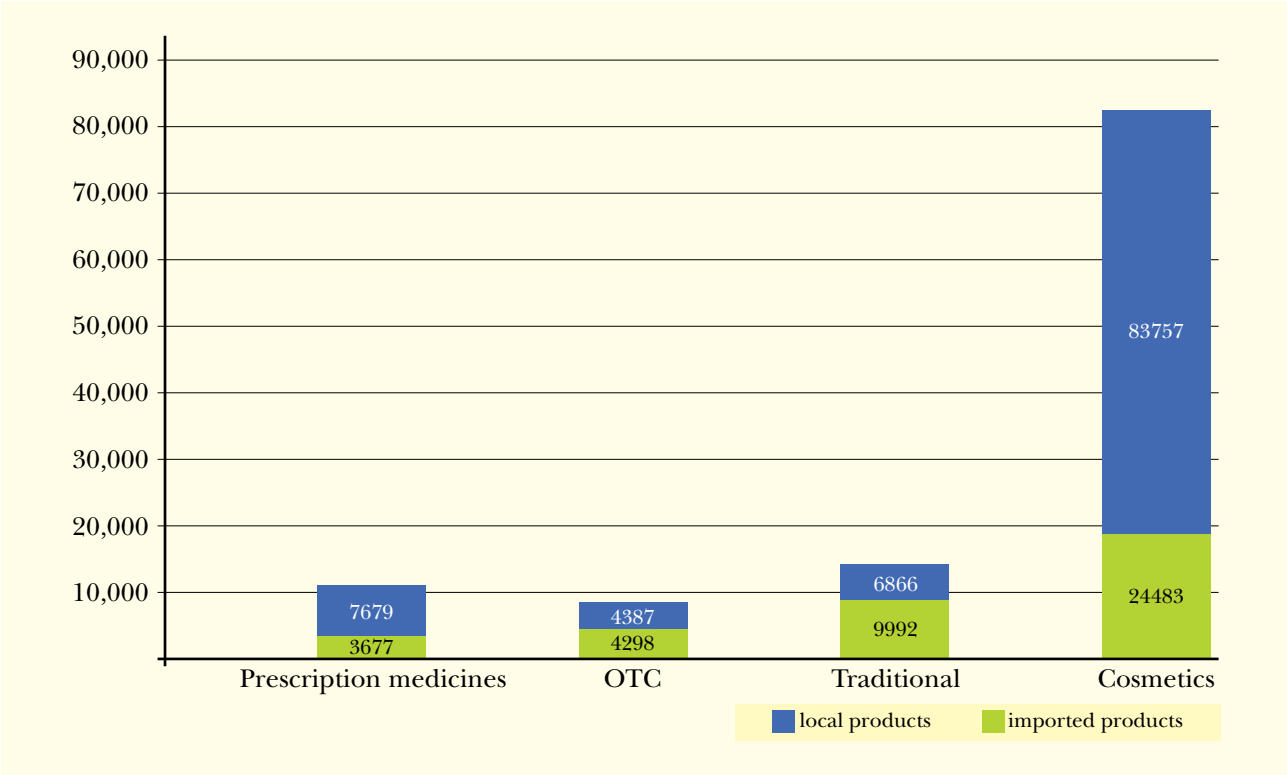
Since drug registration started in 1985, a total of **172,319** applications for product registration have been received. Of this, a total of 145,139 products were registered, 17,801 applications were rejected and the registration of 7,544 products have subsequently been either cancelled or withdrawn by the companies themselves or by the Drug Control Authority for various reasons (Figure 1).

Figure 1: Statistics on Product Registration 1985 - 2006



Of the total number of registered products, 42,450 (29.2%) are locally manufactured while 102,689 (70.8%) are imported (Chart 1).

Chart 1: Cumulative Number of Products Registered as at 31.12.2006



In the year 2006, 27,158 applications for registration were received. The majority of applications received were for the registration of cosmetics (90.4%), followed by traditional medicines (5.6%), prescription medicines (2.3%) and over-the-counter products (OTC) (1.7%). A total of 29,253 products were registered in 2006, some of which were applications received in the previous year.

POST-MARKET SURVEILLANCE

As part of the regulatory process, in order to ensure continued compliance to safety, efficacy and quality, all registered products are subject to testing under the post market surveillance programme. For this purpose, a total of 2,748 registered products were sampled. Based on the outcome of laboratory testing, 108 product batches were subjected to Degree 3 product recalls (i.e. within 30 days) due to quality defects. The recalls involved 19 prescription medicines, 3 non-prescription (over–the-counter) drugs, 85 traditional medicines and 1 cosmetic product. The registration of 13 products were cancelled as the samples tested were found to contain adulterants - 2 products contained sibutramine, 4 analogues of sildenafil, 3 tretinoin, 1 hydroquinone, 1 hydroquinone + tretinoin, 1 phenylpropanolamine and 1 chlorpheniramine + chloramphenicol + ibuprofen + caffeine.

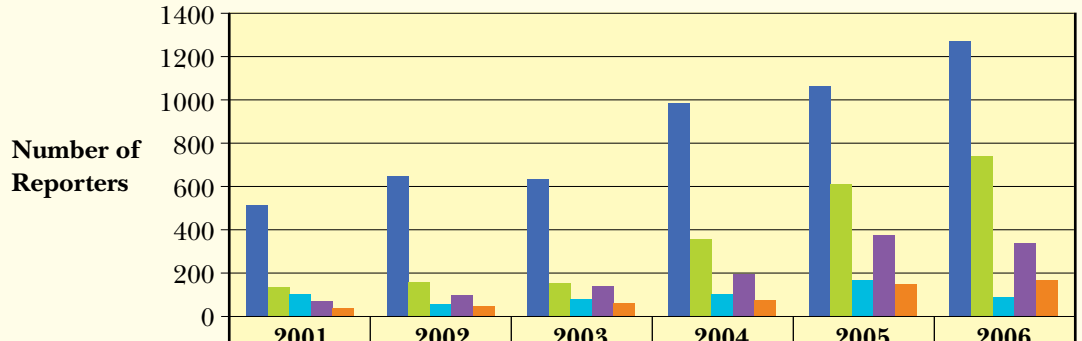
2,631 labels and package inserts were also checked under the surveillance program. Warning letters were issued for 41 products which were found to be non-compliant with the labelling requirements.

The NPCB also investigated 317 product complaints submitted by health professionals and the general public which subsequently led to punitive actions such as recalls being conducted for some of these products from the market.

ADVERSE REACTION MONITORING

In 2006, a total of 2,543 adverse drug reaction (ADR) reports were received, a 7.62% increase as compared to the previous year. Of this, 2491 reports were evaluated and subsequently submitted to the WHO ADR Monitoring Centre in Uppsala, Sweden. Analysis of the ADR reports submitted showed that slightly more than 50% were from medical doctors attached to the government hospitals (Chart 2).

Chart 2: Analysis of ADR by Reporters 2001-2006

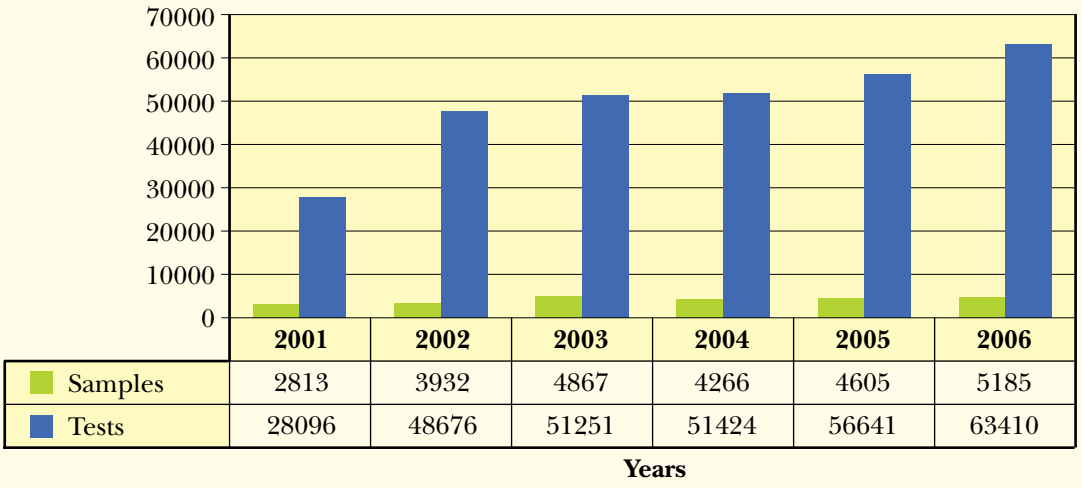


	2001	2002	2003	2004	2005	2006
Govt. Doctor	496	651	646	988	1079	1273
Others	118	162	169	352	606	726
GP/Private Specialist	237 4	49	60	83	157	64
Company	67	90	141	188	368	330
University	36	47	47	54	153	150

QUALITY CONTROL

On the aspect of Quality Control, a total of 63,410 tests were done on 5,185 samples. 2,196 samples were for applications for registration, 2,690 samples from surveillance activities, 110 samples arose from product complaints, 154 samples were as a result of enforcement activities and 35 samples were from other sources (Chart 3).

Chart 3: Statistics on Tests of Samples 2001-2006

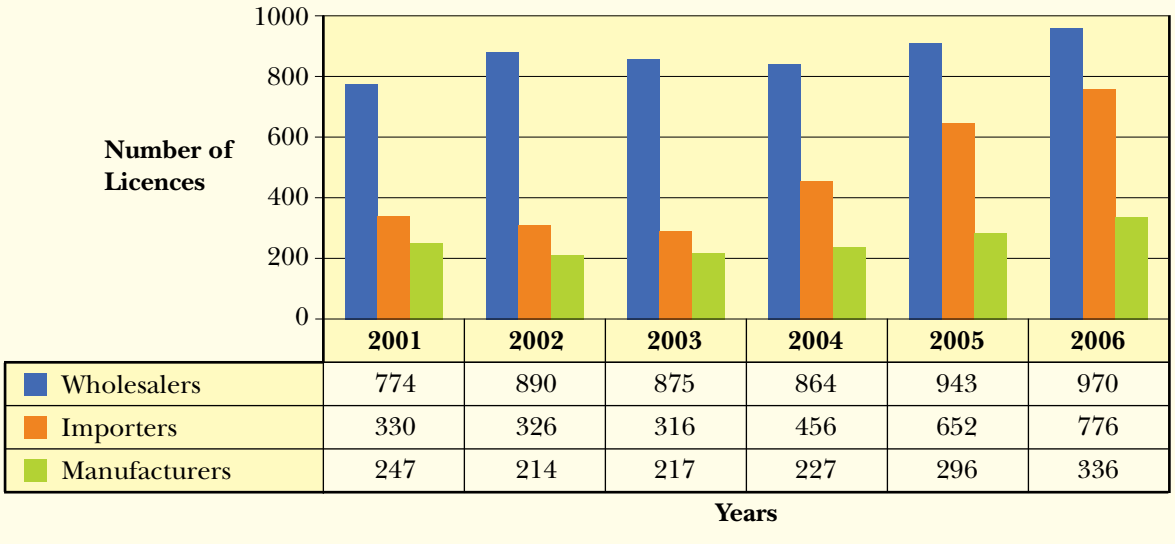


	2001	2002	2003	2004	2005	2006
Samples	2813	3932	4867	4266	4605	5185
Tests	28096	48676	51251	51424	56641	63410

INSPECTIONS & LICENSING

Chart 4 shows that in the year 2006, 336 manufacturing premise licenses were issued of which 85 were for pharmaceutical, 161 for traditional medicines and 90 for cosmetic manufacturers. 776 import licenses were issued comprising of 180 pharmaceutical, 149 traditional and 447 cosmetic import licenses. As for wholesalers' licenses, 970 were issued of which 426 of these licenses were issued to wholesalers of products containing 'scheduled poison' drugs and the remaining 544 licenses were issued to wholesalers dealing with non-poisons, traditional medicines and cosmetics. Information on the licensed manufacturing premises, importers and wholesalers is regularly updated and is available in the NPCB website (*www.bpfk.gov.my*).

Chart 4: No. of Licenses Issued 2001-2006

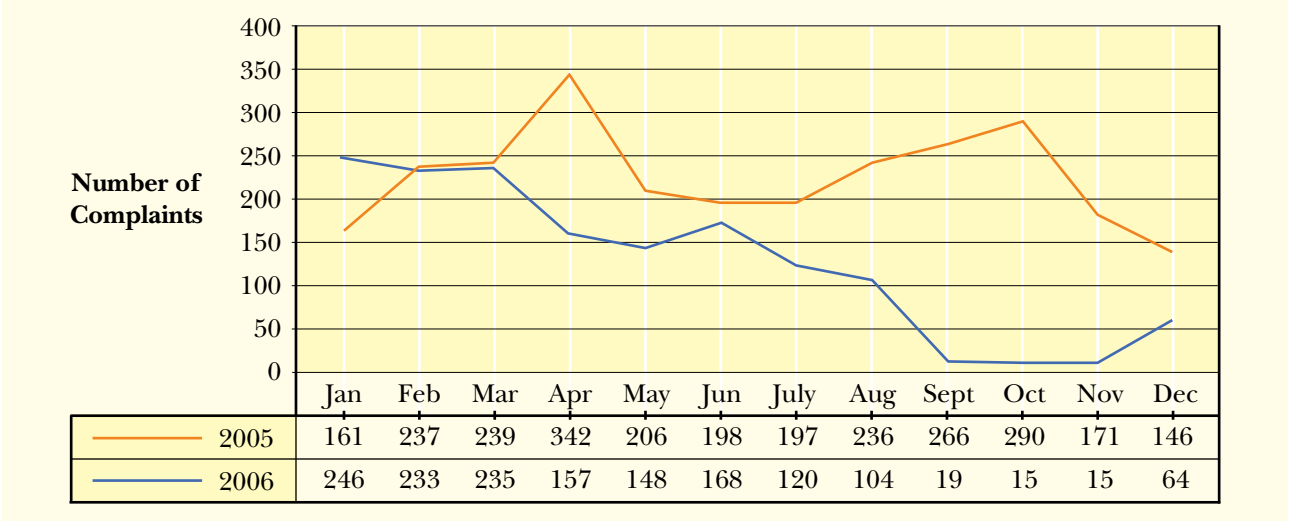


	2001	2002	2003	2004	2005	2006
Wholesalers	774	890	875	864	943	970
Importers	330	326	316	456	652	776
Manufacturers	247	214	217	227	296	336

QUEST2 SYSTEM

NPCB has worked together with the industry to improve the QUEST2 on-line registration system. Figure 2 shows the trend for complaints received pertaining to the QUEST2 system.

Figure 2: Number of Complaints on QUEST2 System



The number of complaints decreased substantially in 2006 due partly to the introduction of an in-house "Help Desk" dedicated to attending to customers' complaints & problems. The average time for rectifying the complaints ranged from 1 day to 72 days depending on the severity of the case at hand (Table 1).

Table 1: Average Time Taken To Rectify Complaints Received (September – December 2006)

Nature of Problem	No. of Complaints Received			Average No. of Days Taken to Rectify Problems (days)
	Pharmaceutical	Traditional	Cosmetic	
Uploading of file	4	1	1	2
Correspondence	1	0	1	8
Withdrawal	0	2	0	8
Product Updating	3	0	1	6
Add Change Info	4	0	6	4
Licensing	1	0	1	10
Adding Manufacturer's Name	11	12	10	1
Membership	2	14	3	8
Registration	2	6	9	3
Smart Card	3	14	3	14
Payment Voucher	1	3	1	72

NEWS UPDATE ON THE ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS HARMONISATION

The Sixth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG)

The Sixth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) was held on 20-21st December 2006 in Ha Noi, Viet Nam. The Meeting was preceded by a Regional Seminar on "Herbal Issues in Health Supplements and Traditional Medicines" and a Technical Discussion on Testing Methods on 19 December 2006 at the same venue.

The Meeting was chaired by Mrs. Mawarwati Djamaluddin, Former Permanent Secretary and Special Advisor to the National Agency of Drug and Food Control of the Republic of Indonesia and co-chaired by Mdm. Eisah A. Rahman from the Pharmaceutical Services Division, Ministry of Health, Malaysia. The Meeting was attended by the ASEAN Secretariat as well as delegates from the Drug Regulatory Authorities of all the ASEAN countries with the exception of Myanmar together with representatives from the relevant industries who attended the Meeting as observers.

The Meeting was officially opened by H.E Dr. Tran Chi Liem, Vice Minister of Health, Viet Nam. In his opening speech, he highlighted the tremendous potential in ASEAN as well as in Viet Nam on traditional medicines and health supplements. He also highlighted the challenges ahead for the TMHS PWG and for Viet Nam on harmonisation due to the complexity of products. H.E expressed his confidence that with the strong commitment among Regulatory Authorities and with a strong collaboration of private sector, the TMHS PWG will continue to progress towards meeting the set objectives and timelines of its Work Programme.

The Meeting noted, among others, the following:

Acceleration of establishment of ASEAN Economic Community (AEC) in which the 38th Meeting of ASEAN Economic Ministers (AEM) agreed to recommend to the ASEAN Leaders to shorten the timeframe for regional economic integration from 2020 to 2015, with some flexibility for the new Member Countries.

Second Phase – Priority Sector Integration Roadmap - to ensure the integration of 11 Priority Sectors by 2010, the 2nd Phase of Roadmaps for Priority Sectors Integration has been finalized by Senior Economic Officials and signed by the ASEAN Economic Ministers at their Meeting held in December 2006 in Philippines which included slight amendments to the roadmap for the Traditional Medicines and Health Supplements.

The following issues with respect to the TMHS Work Programme were discussed at the meeting:-

Harmonisation on Specific Areas of Technical Requirements - Harmonisation of definition and terminologies on TMHS in ASEAN

The Meeting considered and agreed to adopt the final Profile on Terminologies, Definitions and Technical Requirements as put up by Indonesia and requested the ASEAN Secretariat to post the Profile in the ASEAN Secretariat's website for public reference.

Comparative Study on International and Other Regional Technical Requirements

The Meeting agreed that the Comparative Study on International and Other Regional Technical Requirements would be used as a reference document in developing an ASEAN Model on Traditional Medicines and Health Supplements.

Requirements of Specific Areas for Harmonisation of Technical Requirements for TMHS in ASEAN

The Meeting agreed on the responsibilities of the ASEAN Scientific Committee on Traditional Medicines and Health Supplements (ATSC) which includes the identification of relevant experts and working committees/groups. The Meeting further agreed that Member Countries would submit their nomination of experts to the ASEAN Secretariat by **28 March 2007** and that the 1st Meeting of the ATSC would take place prior to the next TMHS PWG Meeting.

Development of ASEAN Common Technical Requirements for TMHS

On the issue of Good Manufacturing Practice standards, the Meeting was informed that the

checklist for developing ASEAN GMP Requirements with reference to the WHO GMP and PIC/S GMP Guidelines was being developed and would be circulated for consideration by Member Countries by **28th February 2007**.

With regard to laboratory test methods, the Meeting noted recommendations of the Workshop held on 19th December 2006 that while the following three testing parameters would be harmonized in ASEAN Member Countries, other testing parameters such as impurity and pesticide residue should also be considered if necessary and upon recommendation by the ATSC :

a) Tests for microbial contamination

b) Heavy Metals; and

c) Screening of adulterants.

Malaysia was requested by the Meeting to be the lead country to coordinate with the ATSC on matters related to testing methods and specifications and to report the progress to the next TMHS PWG Meeting.

Requirements on Product Placement

The Meeting agreed that a Technical Discussion would be held in conjunction with the next TMHS PWG Meeting in order to deliberate on the draft of ASEAN Common Technical Requirements for Product Placement.

Labeling Requirements

The Meeting agreed that Thailand would revise the draft and submit for consideration and discussion at the next TMHS PWG Meeting.

Post Marketing Alert System

The Meeting agreed to further consider and discuss the level of information to be exchanged among Member Countries under the Alert System after the Pharmaceutical PWG has completed one year trial period of the PMS Alert System.

Mapping of Existing and Potential Capacity of Member Countries

The Meeting agreed on the urgent need to conduct the following activities in 2007 and the ASEAN Secretariat to explore the possible funding to assist the TMHS PWG in conducting the activities:

a) GMP Workshop on TMHS to be held in Malaysia prior to the next TMHS PWG Meeting;

b) Workshop on Technical Requirements for Product Placement.

c) The Meeting of the ATSC.

The Meeting agreed that tentatively, the 7th TMHS PWG Meeting will be held in Brunei Darussalam in July 2007.

INVOLVING CONSUMERS IN MEDICINES SURVEILLANCE – A PILOT PROJECT

The post-marketing surveillance programme for medicines has long been established in Malaysia. The aim has always been to ensure the safety, quality and efficacy of products registered by the Drug Control Authority (DCA), as well as to identify possible risks, if any, due to the use of the products by patients in particular and consumers at large. Currently, reports are received mainly from health professionals on a voluntary basis and thus they are confined only to a limited number of products which are used in hospitals, clinics and pharmacies. The majority of complaints and adverse drug reaction (ADR) reports received from health professional and industry are those of prescription products. The number of reports for traditional medicines and health supplements, products which are available in abundance in the market is still relatively low as compared to the number of products registered by the Drug Control Authority (DCA). There is therefore a growing need for the involvement of consumers to participate in medicines surveillance especially with the ever-increasing number of products available in the market.

Direct consumer reporting in the form of product complaints has been received by the National Pharmaceutical Control Bureau (NPCB). The information has proven to be very reliable and some reports have even led to the detection of counterfeit and unsafe marketed drugs. In some instances, it is unlikely that such reports can be made by or obtained from the health professionals. Consumer awareness is increasing and direct involvement of consumers in medicines surveillance can be very useful. Thus, the existing system needs to be extended to encourage consumer reporting, especially since there is an increasing trend towards self-medication.

To give a jumpstart to consumer reporting, a pilot project on **involving consumers in medicines surveillance** is being conducted in Selangor and Wilayah Persekutuan in 2007 whereby consumers are encouraged to report any quality defects, ADR experienced, fraudulent/misleading claims, inappropriate product labelling and suspected counterfeit / unregistered products. To facilitate the reporting by consumers, forms that need to be filled by consumers are made available at public places such as pharmacies, clinics and hospitals as well as the NPCB website at *http://www.bpfk.gov.my*. Information received directly from consumers through other channels such as letters, phone calls, e-mails or complaints made personally will also be attended to. In addition, the NPCB also welcomes information channelled through product owners, market authorisation

holders, consumer associations or other trade and industry organisations. The outcome of the pilot project will be assessed in view of the feasibility of expanding the project to other areas / states and subsequently making it an integral part of the post-market surveillance programme.

As an introduction to the pilot project, which is sponsored by the WHO, a one-day awareness seminar was held on the 9th of January 2007. The seminar was attended by approximately 100 participants from government and private hospitals, consumer associations, retail pharmacies, members of the academia and other trade and industry organisations.

DCA NEWS

RECLASSIFICATION OF EXTERNAL PERSONAL CARE (EPC) PRODUCTS

The DCA at its 185th Meeting approved the proposal to reclassify the EPC products (anti acne, anti bacterial, oral care, antidandruff and skin protectants) as cosmetics to be in line with the categorisation of these products in other ASEAN countries, the EU and the USA as well as in line with the implementation of ASEAN Free Trade Area Agreement (AFTA). The reclassification will be effective from 1st January 2007.

The stand taken by the DCA is also in preparation for the implementation of the ASEAN Cosmetic Directive in January 2008 whereby the regulation of cosmetic products will be through a Notification Process instead of the current registration process.

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