# National Pharmaceutical Control Bureau


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# ANNUAL REPORT 2009

# National Pharmaceutical Control Bureau


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# Vision

The National Pharmaceutical Control Bureau will be a centre of excellence on pharmaceutical regulatory matters to ensure the health and well-being of mankind

# Mision

The National Pharmaceutical Control Bureau shall ensure the quality, efficacy and safety of pharmaceutical products through the implementation of relevant legislation by a competent workforce working together in strategic alliance towards improving the health of the people

# Objectives

To ensure that therapeutic substances approved for the local market are safe, effective and of quality and also to ensure that natural (traditional) products and cosmetics approved are safe and of quality

# Strategy

- To ensure organisational efficiency and effectiveness through modernisation and automation of the office, laboratory and registration systems, with regular review and improvement of services
- To strengthen enforcement activity of the related legislations
- To ensure continuous mutual understanding and co-operation between the regulatory bodies and the private sector through dialogues and guidance
- To upgrade personnel potential and expertise
- To attain a dedicated and fully committed workforce through motivation, appreciation, and appropriate remuneration
- To strengthen research activities and upgrade facilities for such purposes
- To create working environment conducive for the personnel to work as a team with a caring attitude whilst discharging their duties in a professional manner

The National Pharmaceutical Control Bureau (NPCB) endeavours to uphold the highest level of professionalism and integrity in carrying out its mission of protecting and improving the health of the people. In this regard, the NPCB has made excellent progress over the years in striving to ensure the quality, efficacy and safety of approved therapeutic products as well as the safety and quality of natural (traditional) and cosmetic products by employing sound scientific principles.

Recognising the need to keep abreast with the latest initiatives and technologies in regulatory management and to move along further in this journey, the NPCB has embarked on various strategies to upgrade its capabilities and skills. It has been working towards obtaining the MS ISO/IEC 17025 accreditation for its Centre for Quality Control in the past few years and successfully underwent a series of audits and assessments by Department of Standards Malaysia throughout the year 2009. It is expected that NPCB will be fully accredited for MS ISO/IEC 17025 under the Malaysian Laboratory Scheme (SAMM) in January 2010 in the fields of chemical and microbiological testing. The NPCB has also successfully upgraded its quality management system from MS ISO 9001:2000 to MS ISO 9001:2008 following the compliance audit by SIRIM in July 2009.

We are confident that these measures attest to our constant search for excellence and our commitment to fulfill the expectations, trust and confidence placed upon us by our stakeholders and the public at large.

The NPCB has been successful in formulating a well developed evaluation process and regulatory framework in the control of pharmaceuticals. This process enables us to approve safe and effective drugs efficiently while maintaining high standards in the evaluation of product dossiers. This fact is recognised by other national drug regulatory agencies as manifested by the increasing number of requests that NPCB receives each year for attachment training in various aspects of regulatory control of pharmaceuticals. As a World Health Organization (WHO) Collaborating Centre for regulatory control of pharmaceuticals since 1996, NPCB is thankful for this recognition. While continuing to share our expertise with other regulatory agencies, NPCB will also strive to enhance its own capabilities through appropriate capacity building and greater co-operation and collaboration with more established regulatory agencies.

Realising the importance of international collaboration with strategic partners in achieving its mission, NPCB continues to engage with other regulatory agencies of the world in matters pertaining to registration of pharmaceuticals. Regionally, it also continues to play an active role in the harmonisation efforts of the ASEAN through its involvement in the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) as well as the ASEAN Cosmetic Committee (ACC).

To conclude, I would like to thank the NPCB staff for their tireless efforts and teamwork through which we have once again delivered quality service throughout the year. From the day of its inception, NPCB has nurtured a dream to become a centre of excellence in pharmaceutical regulatory matters to ensure the health and well-being of mankind. As we pass the year 2009, we

confidently take another step forward in our journey to attain our cherished dreams and goals. As this annual report represents another chapter in the journey of NPCB, it is my sincere hope that you will enjoy reading this report and at the same time find the contents informative and useful too.

It is with great pleasure that I present to you the Annual Report of NPCB for the year 2009.

# NPCB

**Left to Right :**

**Head of Centre for Administration**
Mdm. Zuraidah Zainuddin

**Head of Centre for Post-Registration of Products**
Mdm. Tan Lie Sie

**Deputy Director of Centre for Quality Control**
Dr. Sulaikah V.K. Moideen

**Director of Pharmacy Regulatory**
Mr. Selvaraja Seerangam

**Deputy Director of Centre for Compliance and Licensing**
Dr. Tajuddin Akasah

**Deputy Director of Centre for Product Registration**
Mdm. Abida Haq Syed M. Haq

**Head of Centre for Organisational Development**
Mdm. Anis Talib

**Left to Right :**

**Front**

Mr. Ravin Chin a/l Thillainathan
Mdm. Lee Sher May
Ms. Haslinda binti Rustam Afandi
Ms. Nik Juzaimah binti Juhari
Mr. Mior Zamri bin Mior Ahmad
Mr. Ng Sheng Xyng

**Centre**

Mdm. Azlina binti Ismail
Mdm. Hasniza binti Zaidan
Mdm. Siti Hidayah binti Kasbon
Mdm. Nor Azian binti Megat Osman

**Back**

Mdm. Shantini a/p Thevendran
Mdm. Norhayati binti Abdul Rahim
Mdm. Zarina binti Rosli

**Absent**

Mdm. Normi binti Abdullah
Dr. Hasenah binti Ali
Mr. Yusni Rizal bin Khairul Anuar
Mdm. Saniah binti Daud
Mdm. Nahdia binti Ariffin

The National Pharmaceutical Control Bureau (NPCB) is a government agency in Malaysia that regulates pharmaceutical, natural (traditional) and cosmetic products. The NPCB is responsible for ensuring the quality, efficacy and safety of pharmaceutical products, as well as the quality and safety of natural (traditional) products and cosmetics marketed in the country.

With the promulgation of the Control of Drugs and Cosmetics Regulations 1984 (CDCR), the Drug Control Authority (DCA) was established in 1985. The NPCB which acts as the secretariat to the DCA achieves its objectives through its registration and licensing scheme. Apart from that, the NPCB also monitors registered products through surveillance and pharmacovigilance activities.

In view of its technical expertise and training capabilities, the NPCB was recognised by the World Health Organization (WHO) as a Collaborating Centre in the Regulatory Control of Pharmaceuticals on the 10th of May 1996. As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, the NPCB has provided training in the fields of pharmaceutical quality assurance and regulatory affairs to fellows from other National Regulatory Agencies.

NPCB, as the National Drug Safety Monitoring Centre was accepted as the 30th member of the World Health Organization (WHO) Drug Safety Monitoring Programme in 1990. Through this program, adverse drug reaction (ADR) reports which have been received and screened by NPCB will be included in the WHO database.

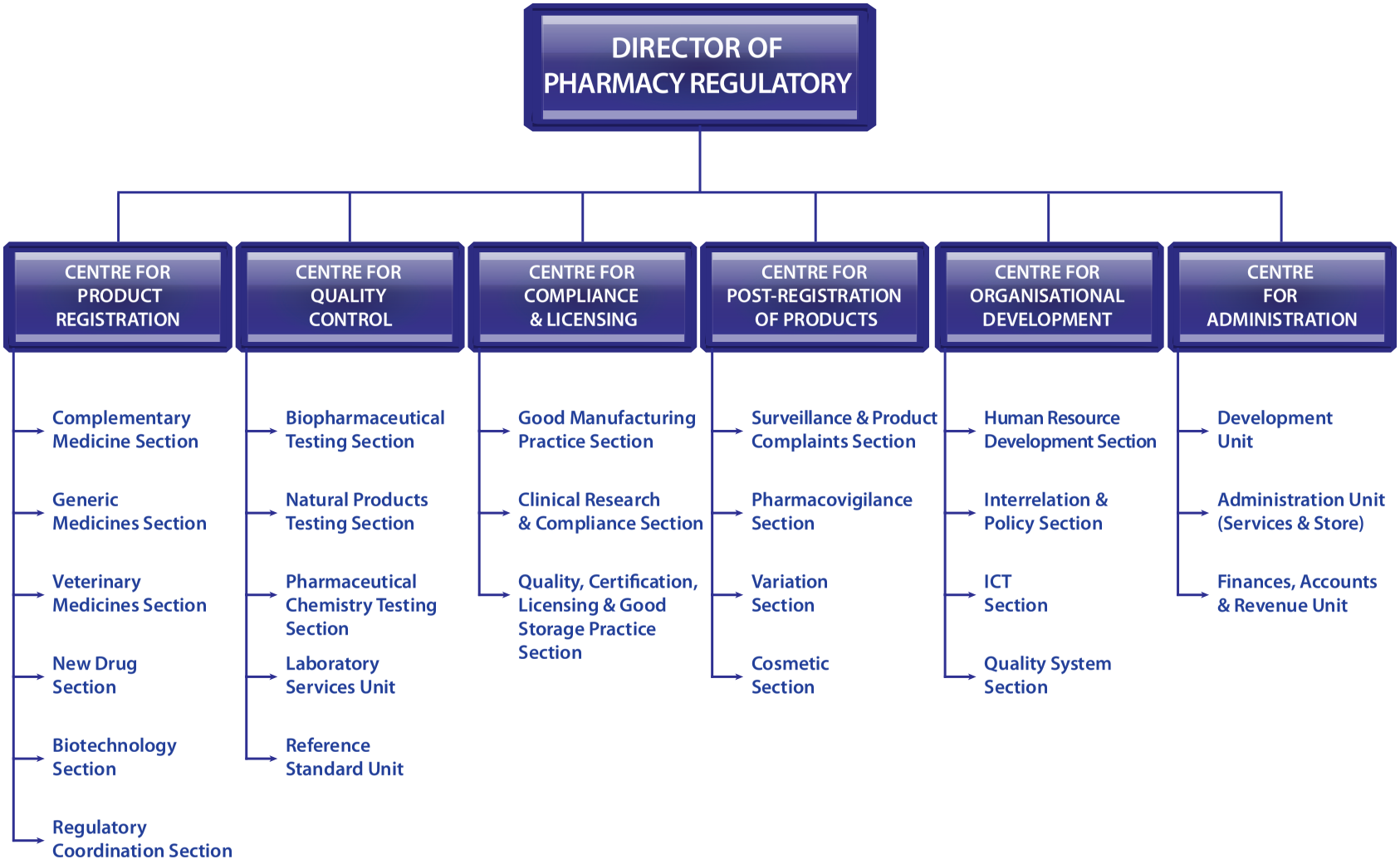
In recognition of the high level of its inspection system, the NPCB successfully gained accession as the 26th member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on 1st January 2002. Since then, NPCB has been actively involved in international Good Manufacturing Practice (GMP) and Quality Assurance programmes organised by PIC/S as well as WHO.

To further improve the quality of the services provided to its clients, the NPCB continues to strive towards upgrading its Quality Management System. As a result, the NPCB has successfully upgraded its MS ISO certification from version MS ISO 9001:2000 to the latest version MS ISO 9001:2008.

WHO Collaborating Centre
for Regulatory Control
of Pharmaceuticals

PIC/S
26th Member
Pharmaceutical Inspection
Co-operation Scheme

QUALITY SYSTEM
SIRIM
Certified to ISO 9001:2008
Cert. No: AR 2293


DIRECTOR OF PHARMACY REGULATORY
CENTRE FOR PRODUCT REGISTRATION
Complementary Medicine Section
Generic Medicines Section
Veterinary Medicines Section
New Drug Section
Biotechnology Section
Regulatory Coordination Section
CENTRE FOR QUALITY CONTROL
Biopharmaceutical Testing Section
Natural Products Testing Section
Pharmaceutical Chemistry Testing Section
Laboratory Services Unit
Reference Standard Unit
CENTRE FOR COMPLIANCE & LICENSING
Good Manufacturing Practice Section
Clinical Research & Compliance Section
Quality, Certification, Licensing & Good Storage Practice Section
CENTRE FOR POST-REGISTRATION OF PRODUCTS
Surveillance & Product Complaints Section
Pharmacovigilance Section
Variation Section
Cosmetic Section
CENTRE FOR ORGANISATIONAL DEVELOPMENT
Human Resource Development Section
Interrelation & Policy Section
ICT Section
Quality System Section
CENTRE FOR ADMINISTRATION
Development Unit
Administration Unit (Services & Store)
Finances, Accounts & Revenue Unit

| PRODUCT REGISTRATION | TIME FRAME |
|---|---|
| FULL EVALUATION | |
| Prescription And Non-prescription | 12 months |
| New Drug And Biologicals (Manual-stage 3) | 12 months |
| ABRIDGED EVALUATION | |
| Health Supplements | 6 months |
| Natural Products | 6 months |
| Non-prescription | 6 months |
| PRODUCT NOTIFICATION | |
| Cosmetic Products | 3 days |
| **LICENSING** | |
| Wholesaler, Manufacturer, Import License | Not More Than 1 month |
| Clinical Trial Import License | Not More Than 2 months |
| **LABORATORY TESTING** | |
| For Purpose of Registration | Not More Than 3 months |
| **PROCESSING OF VARIATION APPLICATIONS** | |
| Application for Variation | |
| Variation – Type 1 | 2 weeks |
| Variation – Type 2 | 2 months |
| CHANGE OF MANUFACTURING SITE | |
| Type 1-Type V (Manual) | 2 months |
| **CHANGE OF MARKETING AUTHORISATION HOLDER** | |
| - | 2 months |
| **PRODUCT CERTIFICATION** | |
| - | 3 weeks |

| POST | GRADE | NO. OF POST | FILLED | VACANT |
|---|---|---|---|---|
| Director of Regulatory Pharmacy (JUSA C) | VU7 | 1 | 1 | 0 |
| Pharmacist | U54 | 5 | 4 | 1 |
| Pharmacist | U52 | 16 | 13 | 3 |
| Pharmacist | U48 | 37 | 9 | 28 |
| Pharmacist | U44 | 23 | 21 | 2 |
| Pharmacist | U41 | 153 | 137 | 16 |
| Information Technology Officer | F41 | 1 | 1 | 0 |
| Science Officer (Temporary) | C41 | 18 | 11 | 7 |
| Pharmacist Assistant | U36 | 2 | 2 | 0 |
| Pharmacist Assistant | U32 | 8 | 8 | 0 |
| Information Technology Officer Assistant | F32 | 1 | 0 | 1 |
| Pharmacist Assistant | U29 | 70 | 59 | 11 |
| Information Technology Officer Assistant (Temporary) | F29 | 1 | 1 | 0 |
| Statistic Officer Assistant | E27 | 1 | 1 | 0 |
| Administrative Assistant | N27 | 2 | 2 | 0 |
| Administrative Assistant | N22 | 2 | 2 | 0 |
| Administrative Assistant | W22 | 2 | 2 | 0 |
| Administrative Assistant | N17 | 21 | 20 | 1 |
| Administrative Assistant | W17 | 9 | 9 | 0 |
| Administrative Assistant (Temporary) | N17 | 9 | 7 | 2 |
| Library Assistant | S17 | 1 | 1 | 0 |
| Data Processing Machine Operator | F11 | 2 | 2 | 0 |
| Security Officer | KP11 | 3 | 0 | 3 |
| Administrative Assistant | N11 | 4 | 1 | 3 |
| Office General Assistant | N4 | 1 | 1 | 0 |
| Office General Assistant | N1 | 4 | 2 | 2 |
| Office General Assistant (Temporary) | N1 | 2 | 2 | 0 |
| Healthcare Assistant | U3 | 10 | 10 | 0 |
| Driver | R3 | 5 | 3 | 2 |
| Driver (Temporary) | R3 | 1 | 1 | 0 |
| **TOTAL** | | **415** | **333** | **82** |

To each of the following NPCB staff who has been transferred to a new work place or retired, the NPCB wishes them all the best and extends our gratitude for their contribution, commitment and hard work during their tenure of service at the NPCB.

| NAME | POSITION/GRADE | PLACE TRANSFERRED |
|---|---|---|
| Abida Haq binti Syed M. Haq | Pharmacist U54 | Pharmaceutical Services Division |
| Tan Lie Sie | Pharmacist U54 | Pharmaceutical Services Division |
| Anis binti Talib | Pharmacist U54 | Pharmaceutical Services Division |
| Saleha binti Md. Ewan | Pharmacist U54 | Kuala Lumpur Hospital |
| Ahmad Zakhi bin Ramli | Pharmacist U52 | Tengku Ampuan Afzan Hospital, Pahang |
| Kamarudin bin Ahmad | Pharmacist U52 | Pharmaceutical Services Division |
| Abdullah Hisham bin Ahmat Yaya | Pharmacist U48 | Kuala Lumpur Hospital |
| Mokhtar bin Abdullah | Pharmacist U48 | Pharmacy Enforcement, Kedah |
| Fuziah binti Abdul Rashid | Pharmacist U48 | Pharmaceutical Services Division |
| Halimatussa'adiah binti Mat Som | Pharmacist U41 | Pharmacy Enforcement, Perak |
| Syahadatul Iman binti Mohamad | Pharmacist U41 | Kuala Ketil Health Clinic, Kedah |
| Nur Arina binti Sariffudin | Pharmacist U41 | Sungai Buloh Hospital |
| Nurul Maya binti Ahmad Sa'ad | Pharmacist U41 | State Health Department, Selangor |
| Phang Chee Kiat | Pharmacist U41 | State Health Department, Kelantan |
| Lim Ming Teng | Pharmacist U41 | State Health Department, Sabah |
| Moo Kai Shing | Pharmacist U41 | State Health Department, Pahang |
| Tang Woan Torng | Pharmacist U41 | State Health Department, Pahang |
| Loh Siao Ching | Pharmacist U41 | State Health Department, Sabah |
| Norhilmiah Hayati binti Mohd Yaacob | Pharmacist U41 | State Health Department, Pahang |
| Ali Reza Riazi bin Mehdi Riazi | Pharmacist U41 | State Health Department, Kelantan |
| Cheok Xin Yin | Pharmacist U41 | State Health Department, Kelantan |
| Dennis Ko Khang Chiem | Pharmacist U41 | State Health Department, Sarawak |
| Robin Tan Tiow Heng | Pharmacist U41 | State Health Department, Sarawak |
| Hasryn Azzuar bin Mohd Khairy | Pharmacist U41 | Kuala Lumpur Hospital |
| Liew Fei Hoong | Pharmacist U41 | State Health Department, Sabah |
| Mohd Bokhari bin Mohamed Nor | Pharmacist U41 | Pharmaceutical Services Division |
| Othman bin Alias | Pharmacist Assistant U36 | Kuala Lumpur Hospital |
| Zuraik bin Mustaffa | Pharmacist Assistant U32 | Pharmaceutical Services Division |
| Norhasidah binti Tahir | Pharmacist Assistant U29 | Jempol District Health Centre, N. Sembilan |
| Nur Hafizah binti Jazmi | Pharmacist Assistant U29 | Alor Gajah District Health Centre, Melaka |
| Rossamayati binti Awang | Pharmacist Assistant U29 | Setiu District Health Centre, Terengganu |
| Chan Lai Peng | Pharmacist Assistant U29 | Retired |
| Irnawati binti Mohamad | Pharmacist Assistant U29 | Kemaman District Health Centre, Terengganu |
| Azita binti Ismail | Pharmacist Assistant U29 | Tengku Ampuan Rahimah Hospital, Selangor |
| Robiah binti Mohd Hassan | Administrative Assistant W22 | Ministry of Local Government and Housing |
| Norbaizura binti Mat | Administrative Assistant (Temporary) N17 | Kuala Langat District Health Centre, Selangor |
| Hj. Sahar bin Samad | Healthcare Assistant U3 | Serdang Hospital, Selangor |
| Azizah binti Razali | Healthcare Assistant U3 | Melaka Hospital |

## ALL THE BEST...

To the following staff of NPCB who has resigned in 2009, the NPCB wishes them all the best in their future undertakings.

| NAME | POSITION/GRADE |
|---|---|
| Ong Yi Chin | Pharmacist U41 |
| Sufian Hardi bin Mohamed Zuhair | Pharmacist U41 |
| Mohd Alfazari bin Mohd Ghazali | Pharmacist U41 |
| Ng Sue Phay | Pharmacist U41 |
| Tan Teck Koon | Pharmacist U41 |
| Han Mei Yin | Pharmacist U41 |
| Debbie Sim Sook En | Pharmacist U41 |

## IN MEMORY...

The NPCB wishes to extend our deepest heartfelt condolence to the family members of the late Madam Mahani binti Mahmud (Pharmacist, Grade U48) who passed away on 26th May 2009 as well as Tuan Haji Muhammad Nasir bin Hashim (Pharmacist, Grade U52) who passed away on 29th August 2009. Their demise is a great loss to the NPCB and they will be greatly missed.

| NAME | POST |
|---|---|
| Dr. Kamaruzaman bin Saleh | Pharmacist U52 |
| Nurulfajar binti Mohd. Jamid | Pharmacist U48 |
| Azlina binti Ismail | Pharmacist U44 |
| Azrina binti Hassan | Pharmacist U44 |
| Chiong Yuh Lian | Pharmacist U41 |
| Mazarisusanty binti Ibrahim | Pharmacist U41 |
| Nor Hayati binti Hussien | Pharmacist U41 |
| Sarawani binti Hassan | Pharmacist U41 |
| Lian Lay Kim | Pharmacist U41 |
| Syuhadah binti Mohamad Hassan | Pharmacist U41 |
| Belinna binti Abu Bakar | Pharmacist U41 |
| Tg. Mira Darami binti Tg. Fatimi | Pharmacist U41 |
| Siti Hidayah binti Kasbon | Pharmacist U41 |
| Mior Zamri bin Mior Ahmad | Pharmacist Assistant U32 |
| Che Zawiyah binti Haji Abd. Wahab | Pharmacist Assistant U32 |
| Shukri bin Mohd. Ariff | Pharmacist Assistant U32 |
| Faridah binti Yacob | Pharmacist Assistant U32 |
| Lahung Mering | Pharmacist Assistant U29 |
| Rohaniah binti Che Seman | Pharmacist Assistant U29 |
| Maznin binti Hj. Abd. Majed | Administrative Assistant N22 |
| Hasli Hisham bin Haslan Mohd. Nasir | Administrative Assistant W17 |
| Noor Aliyah binti Musa | Administrative Assistant N17 |
| Raman a/l Palaniappan | Driver R3 (KUP R6) |

1. The National Pharmaceutical Control Bureau (NPCB) has gone through a series of audits and assessment throughout the year to fulfill the requirements for MS ISO/IEC 17025:2005 Accreditation. The proposed scope of accreditation is:
   - Test for Microbial Contamination (Total Viable Aerobic Count and Specified Microorganisms) for natural (traditional) medicinal products
   - Test for Limits of Arsenic (As), Lead (Pb) and Cadmium (Cd) in natural (traditional) medicinal products
   - Disintegration test for natural (traditional) medicinal products (Tablets & Capsules)
   - Uniformity of Weight Test for natural (traditional) medicinal products (Tablets & Capsules)

   The NPCB aims to achieve the above accreditation under the Malaysian Laboratories Accreditation Scheme (SAMM) by January 2010

2. The NPCB was subjected to an audit by SIRIM on the 1st - 2nd July 2009 whereby the NPCB showed compliance to the requirements of the MS ISO 9001:2008 standard. Subsequently, the NPCB's certification was successfully upgraded from version MS ISO 9001:2000 to MS ISO 9001:2008.

3. The QUEST2 system introduced in 2002 has successfully served as a tool for online registration of pharmaceutical and natural (traditional) products as well as notification for cosmetic products. This system is currently being upgraded to QUEST3 which is scheduled to be implemented in 2010.

4. The NPCB has been appointed as the National Compliance Monitoring Authority (CMA) for the compliance towards the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) for Test Facilities which conducts non-clinical studies involving pharmaceutical products, cosmetics, veterinary products and food additives. The Directive appointing NPCB as the CMA was issued by the Senior Director of Pharmaceutical Services and was effective on 1st June 2009.

5. The National Good Laboratory Practice (GLP) Programme organised by the NPCB was launched by the Director General of Health, Tan Sri Dato' Seri Dr. Hj. Mohd Ismail bin Merican on 9th July 2009 at the National Conference for Clinical Research (NCCR) 2009 in Penang. With the launch, the NPCB is now ready to conduct inspections on Test Facilities for GLP compliance.

6. The Guidelines for the Application for Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) 5th edition was successfully launched and uploaded onto the NPCB official website in June 2009. The main purpose of revamping this guideline was to streamline the existing guidelines in accordance with the current regulatory requirements and international standards.

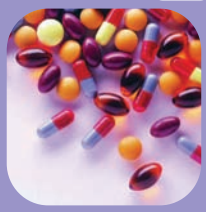
7. A Directive on the Requirement for Registration of Clinical Trials with the National Medical Research Registry for Sponsor/Applicant/Investigator who applies for CTIL and CTX was released in November 2009 to ensure transparency as well as to increase public trust and confidence in the conduct of medical research in Malaysia. This registration scheme enables the Ministry of Health management to document the level of research activity in Malaysia and also to keep track of the progress of researches approved and/or to provide support such as funding.

8. Several workshops on Adverse Drug Reaction & Adverse Events Following Immunisation were carried out in 2009 in collaboration with the Pharmaceutical Services Division. In addition, two workshops on this topic were organised by the NPCB which focused on the role of pharmacists in health clinics as well as in the private sector. Subsequent to invitations received, the NPCB also conducted talks regarding ADR reporting to some external agencies such as universities and government hospitals. These workshops and talks were aimed at increasing awareness of the importance of reporting adverse events of drugs and vaccines as well as improving the quality of ADR reports submitted.

9. As an institution that always strives to improve services rendered to its customers, the NPCB reviews the relevant policies regularly, one of which involves the time taken to start the evaluation of an application which has now been set as within one month from the time of receipt of the application.

10. The NPCB continues to play an active role in the harmonisation efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Products Working Group (PPWG), ASEAN Cosmetic Committee (ACC) as well as the Traditional Medicines and Health Supplements Product Working Group (TMHS PWG). Other international involvements include Pharmaceutical Inspection Co-operation Scheme (PIC/S) activities, participation in various WHO initiatives such as the WHO Consultation on Regulatory Considerations in Evaluating Similar Biotherapeutic Products, held in Canada in July 2009 and the WHO Workshop on Implementation of Lot Release of Vaccines, held in China in December 2009.

11. The NPCB was involved in establishing the ASEAN Mutual Recognition Agreement (MRA) for GMP Inspection of Manufacturers of Medicinal Products which calls for the mutual recognition of GMP certifications and/or inspection reports issued by inspection bodies that are parties to this MRA. In addition, the MRA also serves as a forum for the respective regulatory agencies to exchange experiences and work towards better regulatory practices.



# PRODUCT REGISTRATION

As the secretariat to the Drug Control Authority (DCA), the NPCB plays an important role in the registration of new chemical entity (NCE), biotechnology products, prescription products, non-prescription products, veterinary products, health supplements as well as natural (traditional) medicinal products. All applications will be evaluated by the Centre for Product Registration. The application will then be tabled to the DCA meeting for decision following the completion of the evaluation process.

DCA's main objective is to ensure that all pharmaceutical products registered are assessed from the aspects of safety, efficacy and quality, whereas natural (traditional) medicinal products are accessed for safety and quality.

For the year 2009, twelve DCA meetings were conducted. A total of 2,107 applications for product registration were presented in these meetings whereby 1,765 products were granted registration approval.

The registration of products is done via an online system (QUEST2) to facilitate the registration process. However, registration for NCE and biotechnology products are still being done manually as registration of these products require substantial amount of data. However, with the implementation of the QUEST3 system in 2010, registration of all products including NCE and biotechnology products will be done online.

The NCE products approved by the DCA in 2009 are as follows:

| NO. | PRODUCT NAME |
|---|---|
| 1. | Spiriva Respimat 2.5mcg Solution for Inhalation |
| 2. | Revlimid Capsules 5mg<br>Revlimid Capsules 10mg<br>Revlimid Capsules 15mg<br>Revlimid Capsules 25mg |
| 3. | Galvus Met 50/850mg Film Coated Tablet<br>Galvus Met 50/1000mg Film Coated Tablet |
| 4. | Amaryl M 1/250mg Tablet<br>Amaryl M 2/500mg Tablet |
| 5. | Pradaxa 75mg Hard Capsule<br>Pradaxa 110mg Hard Capsule |
| 6. | Emend® IV Powder for Injection |
| 7. | Elmiron (Pentosan Polysulfate Sodium) 100mg Capsule |
| 8. | Yaz™ Tablet |
| 9. | Fuzeon 90mg/ml Powder for Solution for Injection |
| 10. | Yondelis™ 1mg for Injection |
| 11. | Xarelto Film-coated Tablets 10mg |
| 12. | Zonegran Tablets 100mg |
| 13. | Aridol Mannitol Powder for Inhalation |

| NO. | PRODUCT NAME |
|---|---|
| 14. | Coveram 5mg/5mg Tablet<br>Coveram 5mg/10mg Tablet<br>Coveram 10mg/5mg Tablet<br>Coveram 10mg/10mg Tablet |
| 15. | Harnal Ocas 400mcg Film-Coated Tablet |
| 16. | Reminyl Prolonged Release Capsule 8mg<br>Reminyl Prolonged Release Capsule 16mg<br>Reminyl Prolonged Release Capsule 24mg |
| 17. | Pristiq™ 50mg Extended Release Tablet<br>Pristiq™ 100mg Extended Release Tablet |
| 18. | Torisel™ Concentrate for Injection 25mg/ml |
| 19. | Inomax (Nitric Oxide for Inhalation) 800ppm |
| 20. | Noxafil Oral Suspension |
| 21. | Tenvir Film-Coated Tablet |
| 22. | Afinitor 5mg Tablet<br>Afinitor 10mg Tablet |
| 23. | Intelence™ 100mg Tablet |
| 24. | Azarga 10mg/ml + 5mg/ml Eye Drops Suspension |
| 25. | Relistor 12mg/0.6ml solution for Injection |
| 26. | Coversyl plus 10mg Film-Coated Tablets |
| 27. | Rasilez HCT 150/12.5mg Film Coated Tablet<br>Rasilez HCT 150/25mg Film Coated Tablet<br>Rasilez HCT 300/12.5mg Film Coated Tablet<br>Rasilez HCT 300/25mg Film Coated Tablet |
| 28. | Hycamtin 0.25mg Hard Capsule<br>Hycamtin 1mg Hard Capsule |
| 29. | Tenvir EM Film-Coated Tablet |
| 30. | Vesicare 5mg film-coated Tablet<br>Vesicare 10mg film-coated Tablet |
| 31. | Valdoxan 25mg film-coated Tablet |
| 32. | Neupro 2mg/24h Transdermal Patch<br>Neupro 4mg/24h Transdermal Patch<br>Neupro 6mg/24h Transdermal Patch<br>Neupro 8mg/24h Transdermal Patch |
| 33. | Zydena 100mg Tablet<br>Zydena 200mg Tablet |

Biotechnology products approved by the DCA in 2009 are as follows:

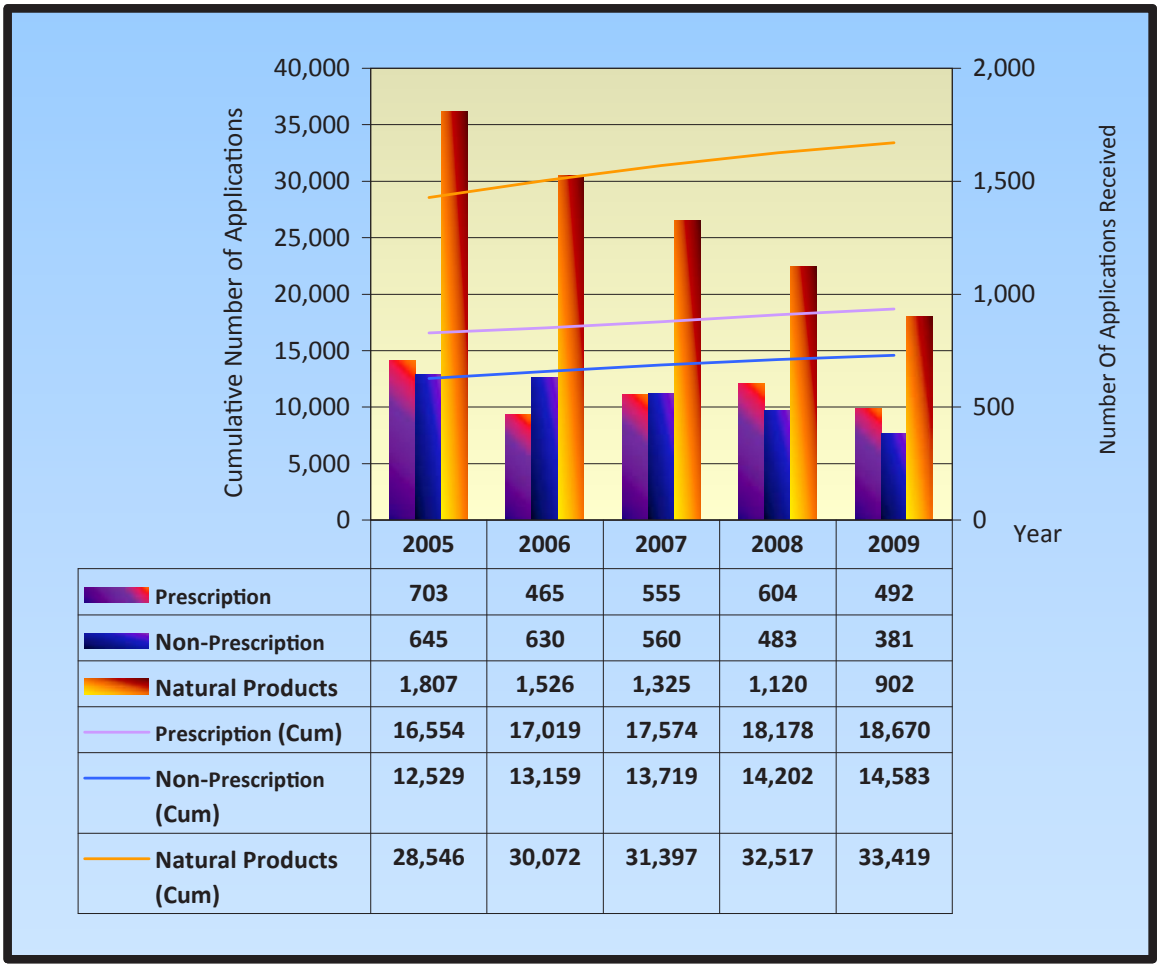
| NO. | PRODUCT NAME |
|---|---|
| 1. | Vaxigrip® Suspension for Injection Multidose Vial |
| 2. | Hepatitis-B Vaccine (rDNA) (Paediatric) Suspension for Injection |
| 3. | Hepatitis-B Vaccine (rDNA) (Adult) Suspension for Injection |
| 4. | Xolair® 150mg Powder and Solvent for Solution for Injection |
| 5. | Rotarix™ Oral Vaccine |
| 6. | Mircera® Solution for Injection in Pre Filled Syringe, 30µg/0.3ml<br>Mircera® Solution for Injection in Pre Filled Syringe, 120µg/0.3ml<br>Mircera® Solution for Injection in Pre Filled Syringe, 360µg/0.6ml |
| 7. | Rhesonativ® 625 IU/Ml Solution for Injection |
| 8. | Aldurazyme® Concentrate Solution for Intravenous Infusion |
| 9. | Benefix™ Powder and Solvent for Solution for Injection 250 IU/Vial<br>Benefix™ Powder and Solvent for Solution for Injection 500 IU/Vial<br>Benefix™ Powder and Solvent for Solution for Injection 1000 IU/Vial<br>Benefix™ Powder and Solvent for Solution for Injection 2000 IU/Vial |
| 10. | Adacel™ Polio Suspension for Injection |
| 11. | Synflorix™ Suspension for Injection |
| 12. | Elaprase™ Solution for Intravenous Infusion |
| 13. | Intrapure™ Normal Immunoglobulin (Human) 6%(6g/100ml)<br>Solution for Intravenous Infusion |
| 14. | Arepanrix™ Suspension and Emulsion for Emulsion For Injection |
| 15. | Myozyme™ Powder for Solution for Injection |
| 16. | Actemra™ 20mg/Ml Concentrate for Solution for Infusion |
| 17. | Xyntha® 250 IU/Vial Powder and Solvent for Solution for Intravenous Injection<br>Xyntha® 500 IU/Vial Powder and Solvent for Solution for Intravenous Injection<br>Xyntha® 1000 IU/Vial Powder and Solvent for Solution for Intravenous Injection<br>Xyntha® 2000 IU/Vial Powder and Solvent for Solution for Intravenous Injection |
| 18. | Pandemrix™ Suspension and Emulsion for Emulsion for Injection |

## STATISTICS OF ACTIVITIES

### (a) Number of Applications Received for Product Registration

The figure below shows that there is generally a downward trend in the total number of applications received from 2005 to 2009. The total cumulative number of applications received until the end of 2009 is 66,672 applications.

The registration scheme for veterinary products has been implemented since 1st August 2007 for existing products in the market. The total number of registration applications received in 2009 was 1,924.

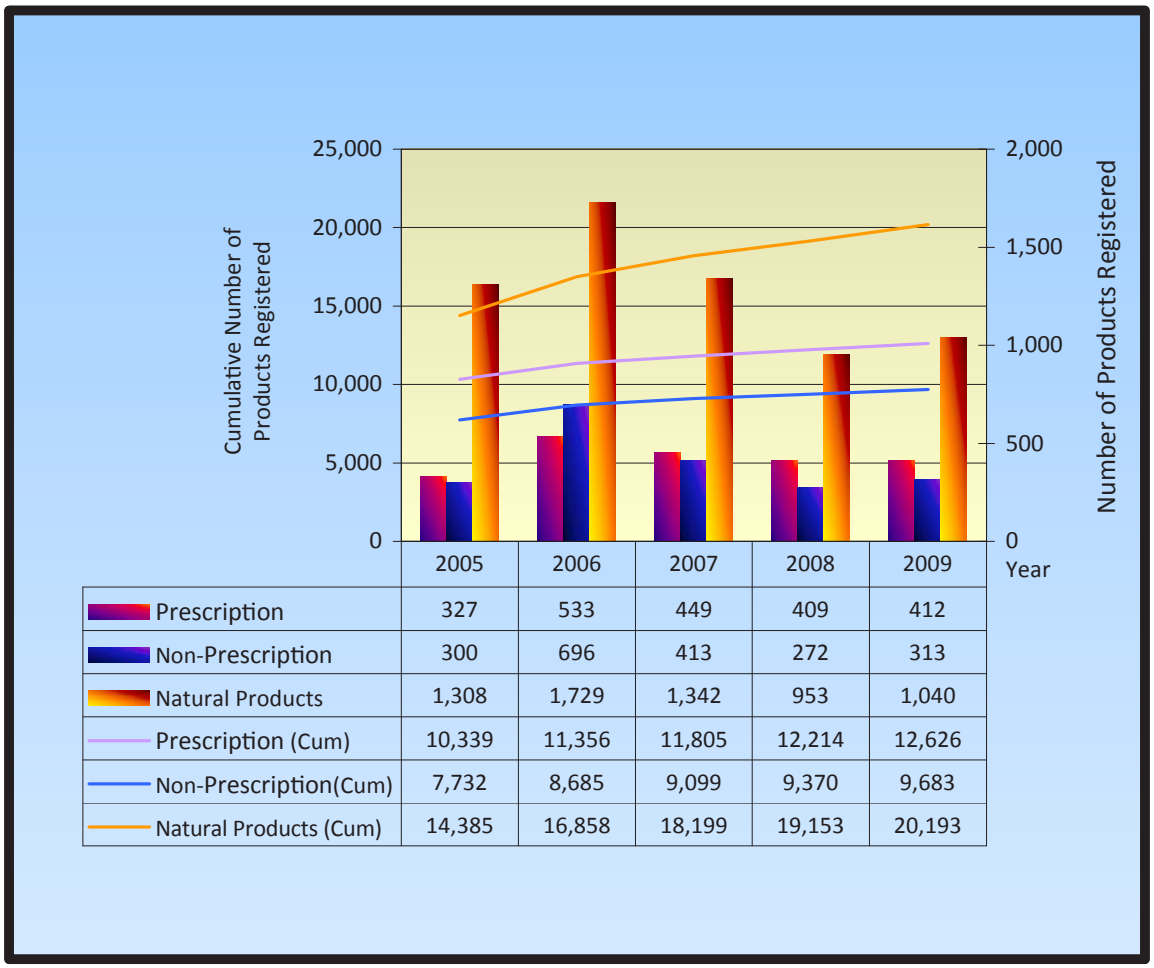



| | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|
| Prescription | 703 | 465 | 555 | 604 | 492 |
| Non-Prescription | 645 | 630 | 560 | 483 | 381 |
| Natural Products | 1,807 | 1,526 | 1,325 | 1,120 | 902 |
| Prescription (Cum) | 16,554 | 17,019 | 17,574 | 18,178 | 18,670 |
| Non-Prescription (Cum) | 12,529 | 13,159 | 13,719 | 14,202 | 14,583 |
| Natural Products (Cum) | 28,546 | 30,072 | 31,397 | 32,517 | 33,419 |

**Figure 1: Cumulative Number of Applications Received and Number of Applications Received, 2005 – 2009**

## (b) Number of Products Approved for Registration

The total number of products approved for registration in 2009 is higher compared to 2008. The total cumulative number of products approved for registration until the end of 2009 is 42,502 applications (Figure 2).

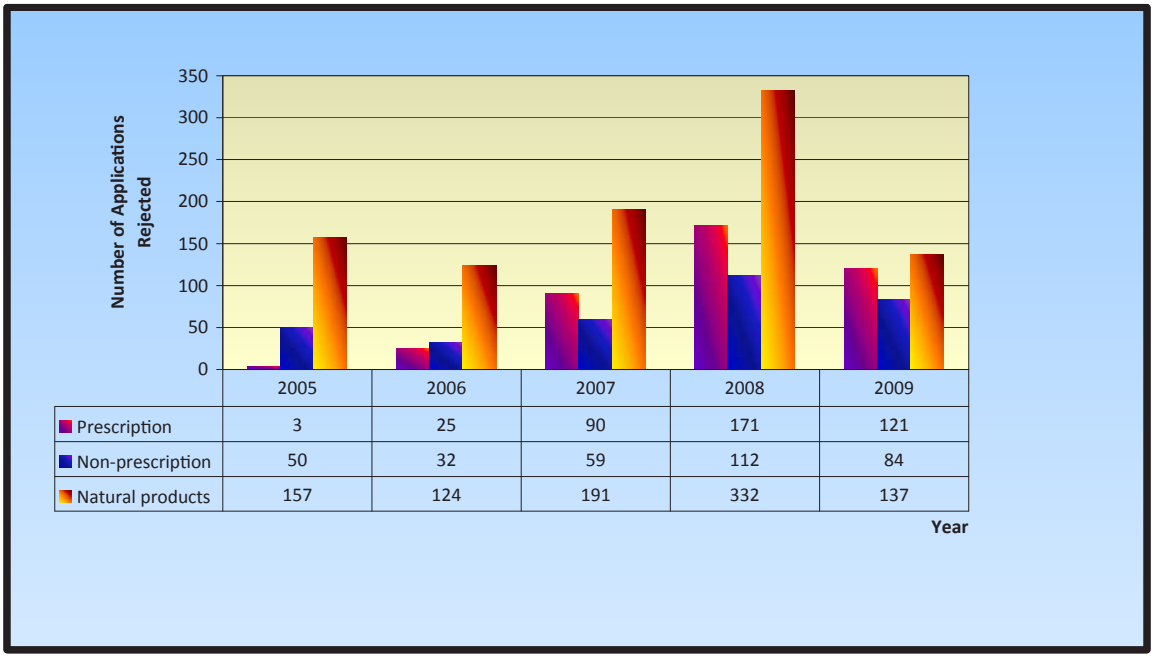



| | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|
| Prescription | 327 | 533 | 449 | 409 | 412 |
| Non-Prescription | 300 | 696 | 413 | 272 | 313 |
| Natural Products | 1,308 | 1,729 | 1,342 | 953 | 1,040 |
| Prescription (Cum) | 10,339 | 11,356 | 11,805 | 12,214 | 12,626 |
| Non-Prescription(Cum) | 7,732 | 8,685 | 9,099 | 9,370 | 9,683 |
| Natural Products (Cum) | 14,385 | 16,858 | 18,199 | 19,153 | 20,193 |

**Figure 2: Cumulative Number of Products Registered and Number of Products Registered, 2005 - 2009**

## (c) Number of Applications Rejected

The number of applications rejected for all product categories declined in 2009 as compared to the year 2008. This is due to the DCA policy introduced in the year 2008 whereby products which the applicants have not responded to correspondence within 6 months will be tabled to the DCA for rejection (Figure 3).




| | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|
| Prescription | 3 | 25 | 90 | 171 | 121 |
| Non-prescription | 50 | 32 | 59 | 112 | 84 |
| Natural products | 157 | 124 | 191 | 332 | 137 |

**Figure 3: Number of Applications Rejected, 2005 - 2009**

## (d) Number of Products Cancelled/Withdrawn

In 2009, there was a marked decrease in the number of products cancelled/ withdrawn for all categories of products in comparison to the previous years. This may be due to several activities in 2008, such as pharmacovigilance activities pertaining to the requirements for bioequivalence (BE) study reports for prescription products (investigations on 974 registered products with 69 active ingredients that require BE study), increase in the detection of adulterated products, products containing ingredients not permitted for registration and cancellation of product registration holders.

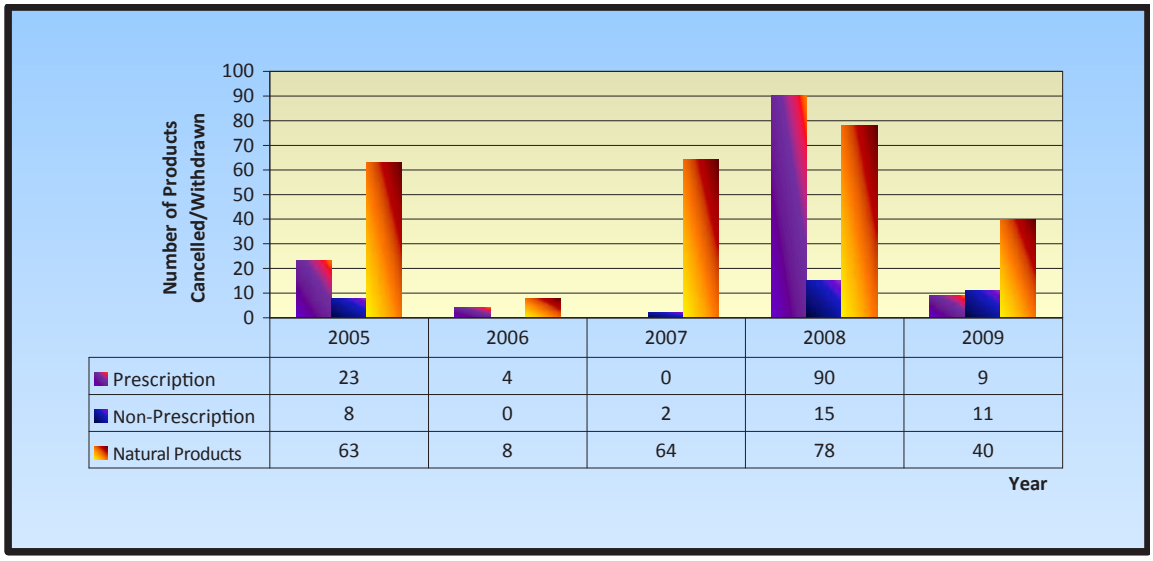



**Figure 4: Number of Products Cancelled/Withdrawn, 2005 – 2009**

## (e) Sources of Importation

India is still the primary source for importation of prescription products in 2009, reflecting the trend seen in the previous year (Figure 5).

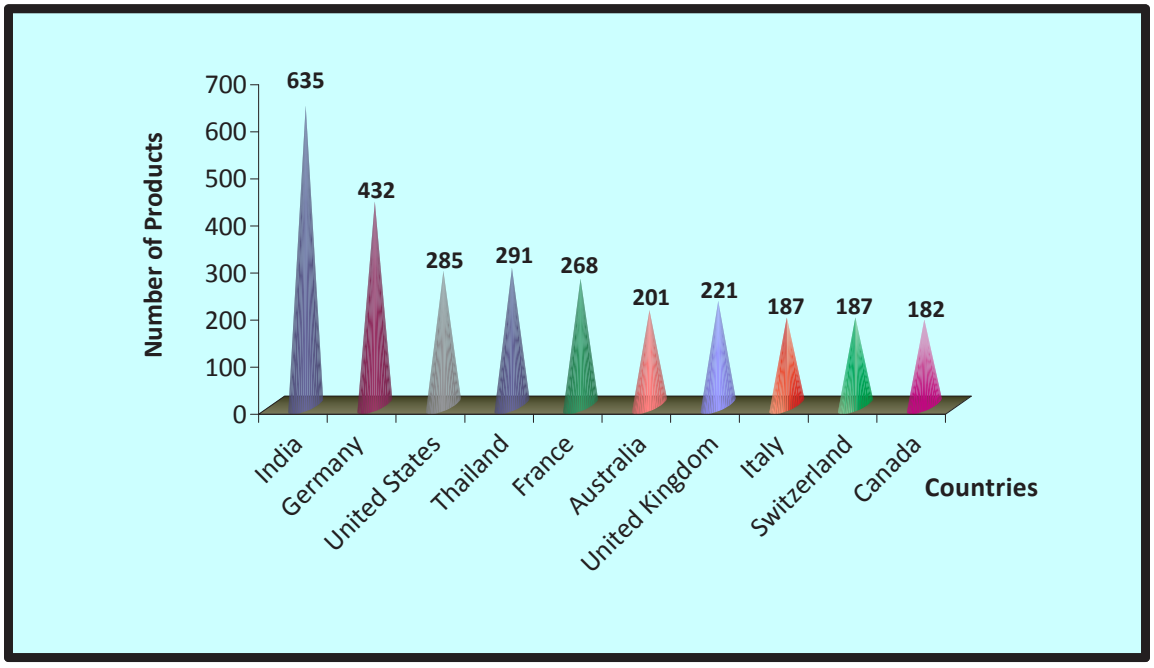



**Figure 5: Countries of Main Sources for Importation of Prescription Products, 2009**

United States is the leading source for the importation of non-prescription products (Figure 6).

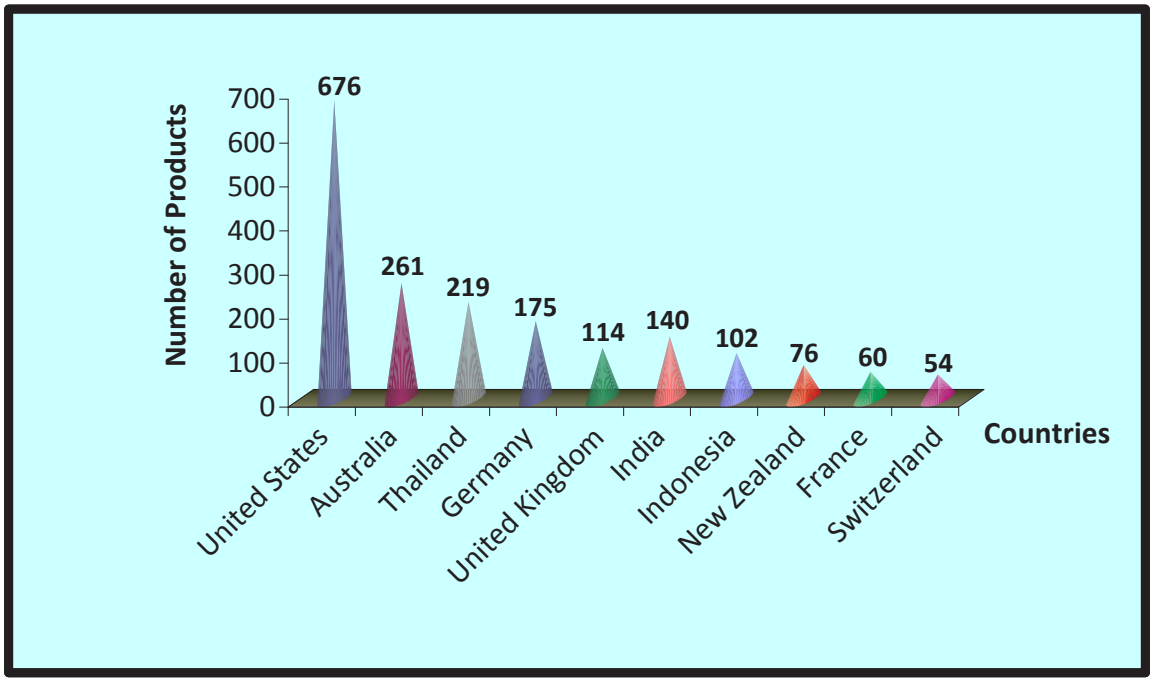



**Figure 6: Countries of Main Sources for Importation of Non-Prescription Products, 2009**

China, as in previous years, continues to be the primary source for the importation of natural products (Figure 7).

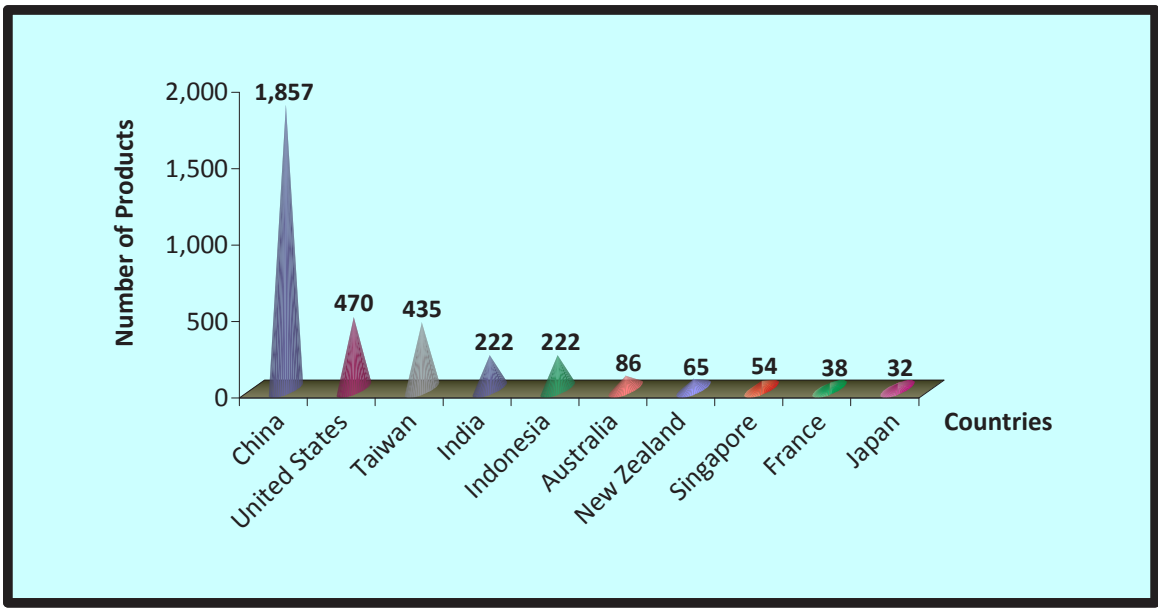



**Figure 7: Countries of Main Sources for Importation of Natural Products, 2009**

## (f) Other Activities

### i) Certificate of Pharmaceutical Product (CPP)

Figure 8 shows the issuance of Certificate of Pharmaceutical Product (CPP) to countries for the year 2009. CPP, in the format recommended by WHO, is issued to applicants of the exporting country.

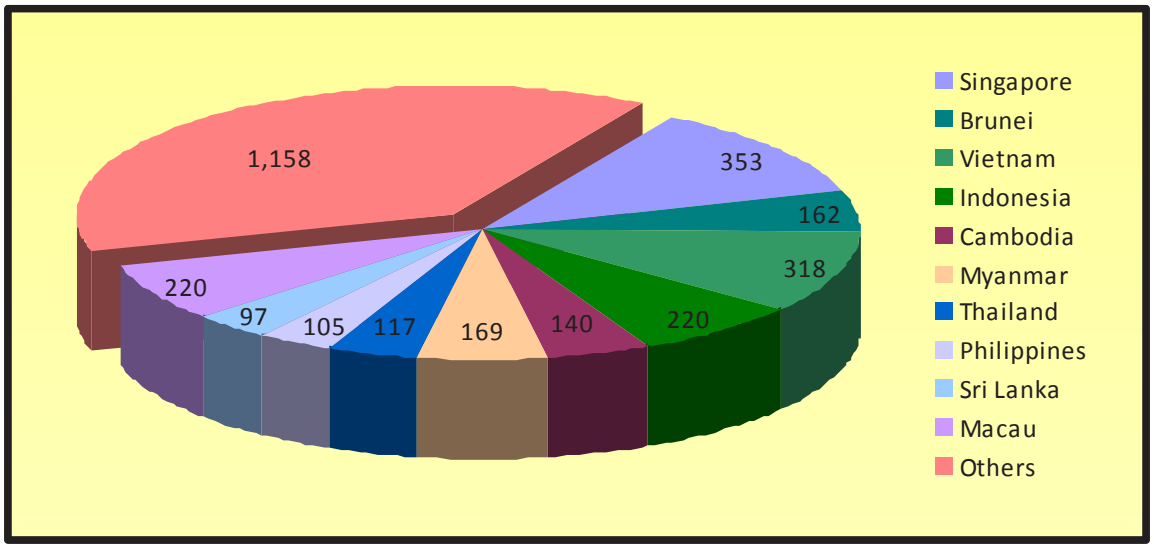
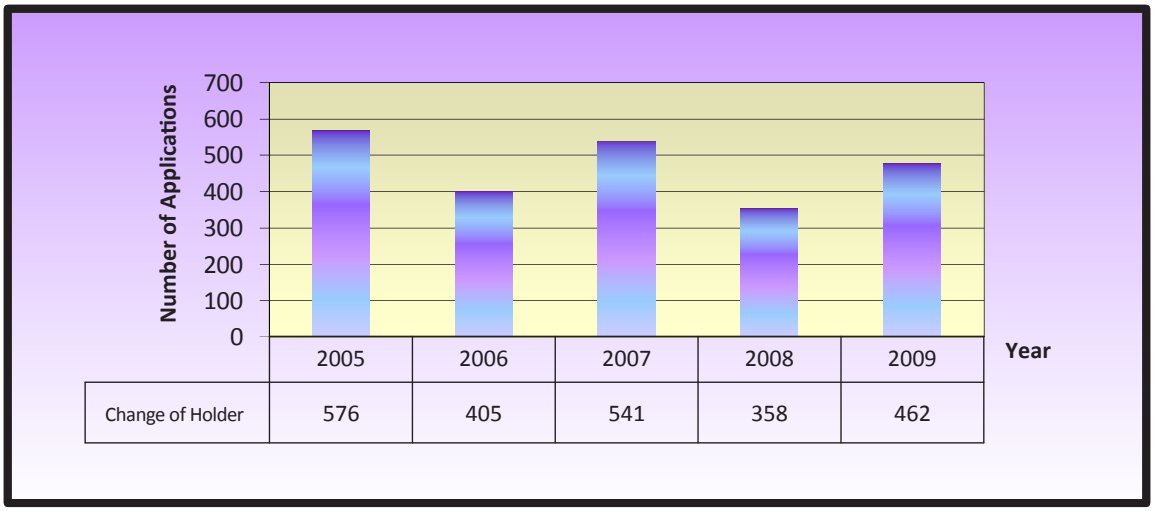



**Figure 8: Issuance of Certificate of Pharmaceutical Product (CPP), 2009**

### ii) Change of Product Holder

Figure 9 shows the number of changes of holder applications approved from 2005 to 2009 to be fairly consistent.




| | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|
| Change of Holder | 576 | 405 | 541 | 358 | 462 |

**Figure 9: Number of Change of Holder Applications Approved, 2005 – 2009**

### iii) Product Registration Renewals

The registration of a product is valid for a period of 5 years or such a period as specified in the registration certificate (unless suspended or cancelled by the DCA). The number of product registrations renewed in 2009 was slightly reduced compared to the previous year (Figure 10).

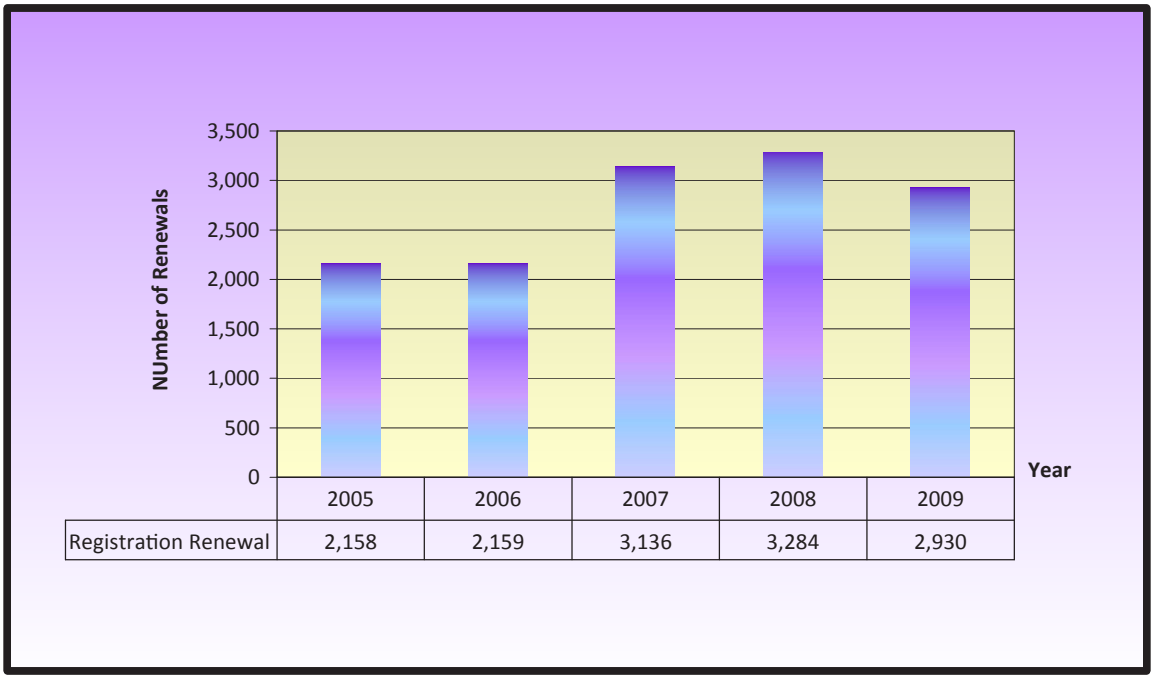



**Figure 10: Number of Product Registration Renewal, 2005 – 2009**

### iv) Pharmacy Enforcement Division (CPF) Activities

The NPCB has been collaborating with the Pharmacy Enforcement Divisions (CPF) in verifying the registration status of products suspected of breaching registration requirements. In 2009, the number of requests received for verification of product registration status for enforcement purposes increased in comparison to the previous years. This is a reflection of the increase in enforcement activities (Figure 11).

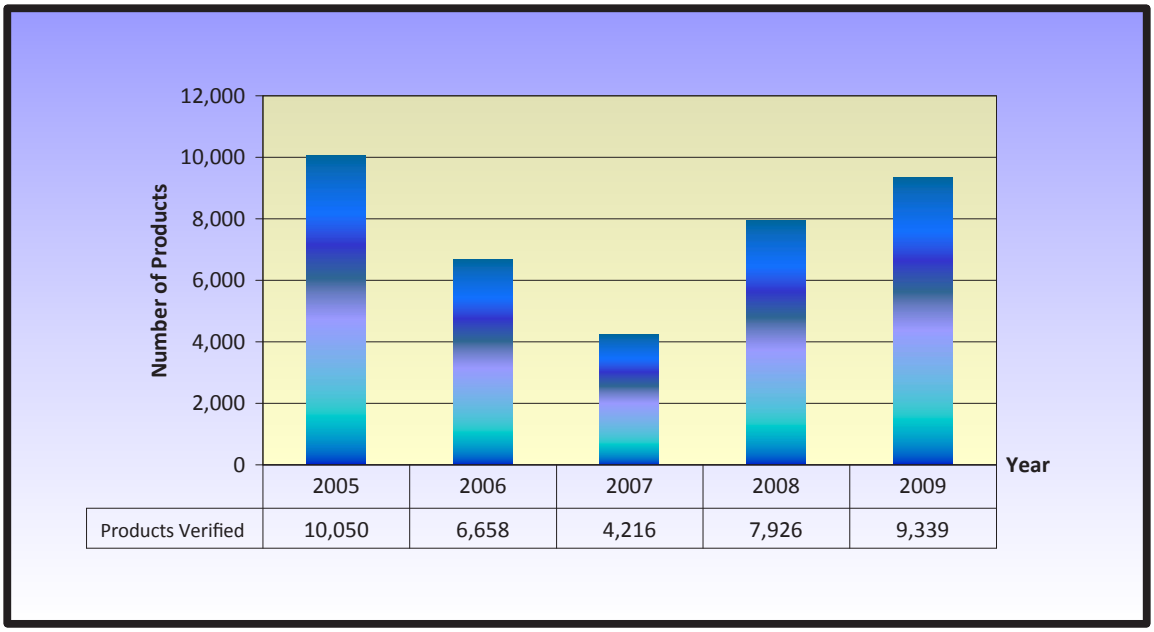



**Figure 11: Verification of Product Registration Status for Enforcement Purposes, 2005 – 2009**

Figure 12 shows that the Johor CPF continues to submit the highest number of products for verification of registration status followed by the Sarawak CPF.

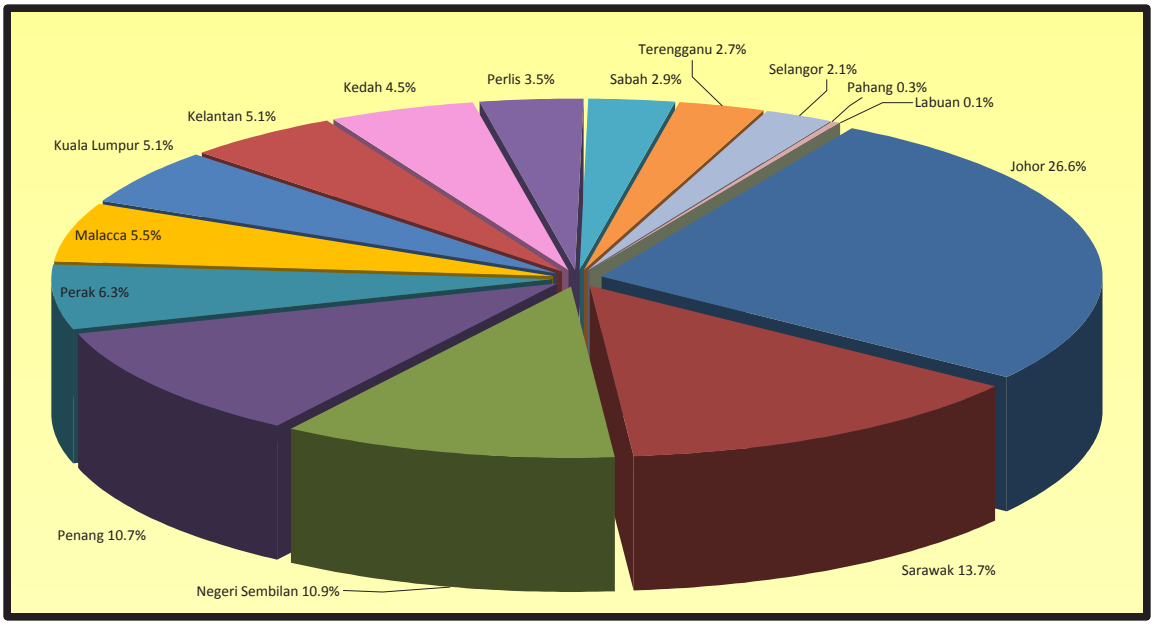
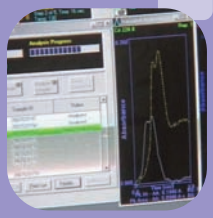



**Figure 12: Number of Product Registration Status Verified by the Pharmacy Enforcement Division (by State), 2009**



# EVALUATION OF PROTOCOL OF ANALYSIS AND ANALYTICAL METHOD VALIDATION DATA

The NPCB has implemented a new policy for the registration process of pharmaceutical products as of 1st January 2008, whereby the pre-registration sample testing was replaced with the evaluation of analytical method validation data.

Figure 13 shows the marked increase in the number of evaluations of analytical method validation data done in 2008 and 2009 as compared to the evaluation of protocol of analysis. Previously, evaluation of protocol of analysis was carried out prior to testing to ensure that the methods of analysis in the protocols are satisfactory so as to minimise problems encountered during sample testing. Sample testing is currently still being carried out on applications that were submitted prior to 2008.

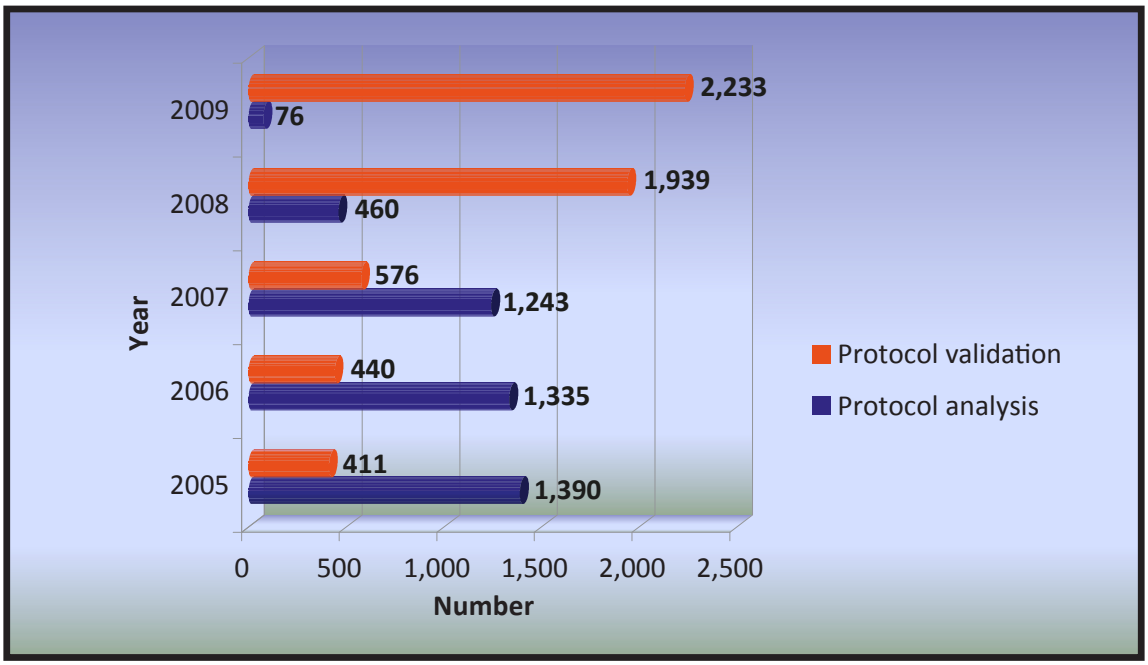
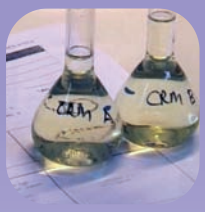



**Figure 13: Evaluation of protocol analysis and analytical method validation data, 2005 - 2009**

# SAMPLE TESTING



## SAMPLES RECEIVED

In the year 2009, the NPCB received a total of 4,554 samples of various categories. This was an increase of 4% compared to the previous year (4,376 samples). Figure 14 below shows the breakdown of the samples according to category.

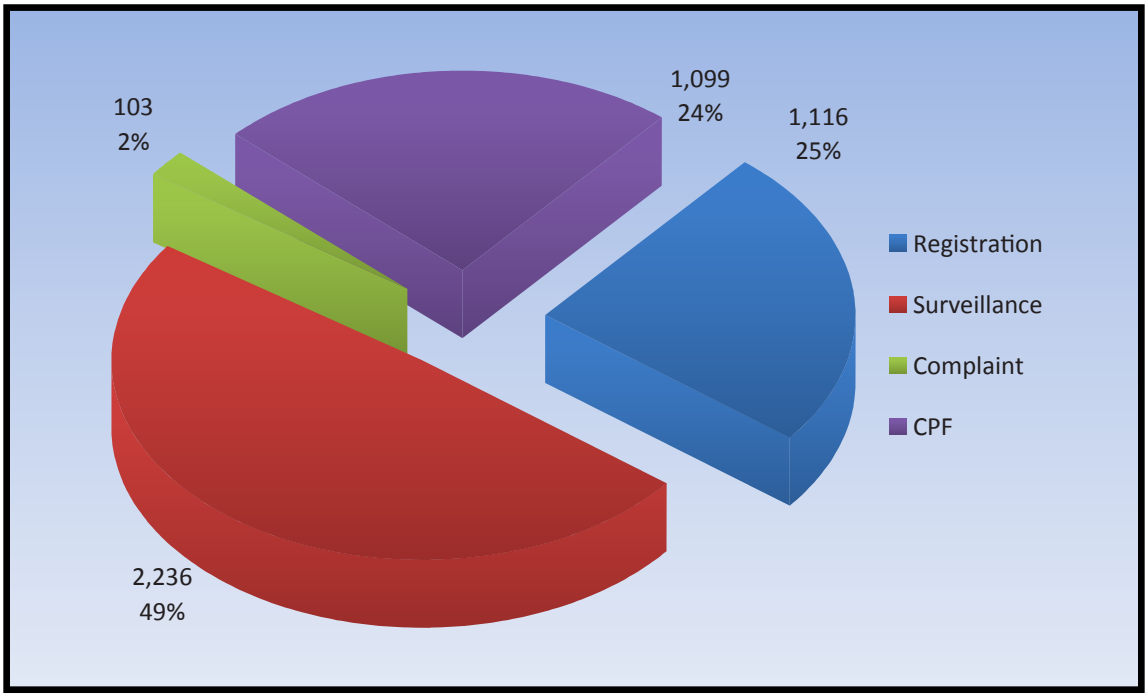



**Figure 14: Number of samples received by category, 2009**

Samples received from the Pharmacy Enforcement Division (CPF) which increased by 260% in 2009 as compared to 2008, contributed to the increase in the number of samples received for that year (Table 1).

| SAMPLE CATEGORY | 2008 | 2009 |
|---|---|---|
| Registration | 1,487 | 1,116 |
| Surveillance | 2,296 | 2,236 |
| Complaint | 132 | 103 |
| CPF | 408 | 1,099 |
| Others | 53 | 0 |

**Table 1: Number of samples received by category, 2008 - 2009**

Figure 15 shows the different categories of samples received for testing in 2009. The sample types are based on the classification of these samples during registration with the exception of CPF samples which may not be registered with the Drug Control Authority (DCA).

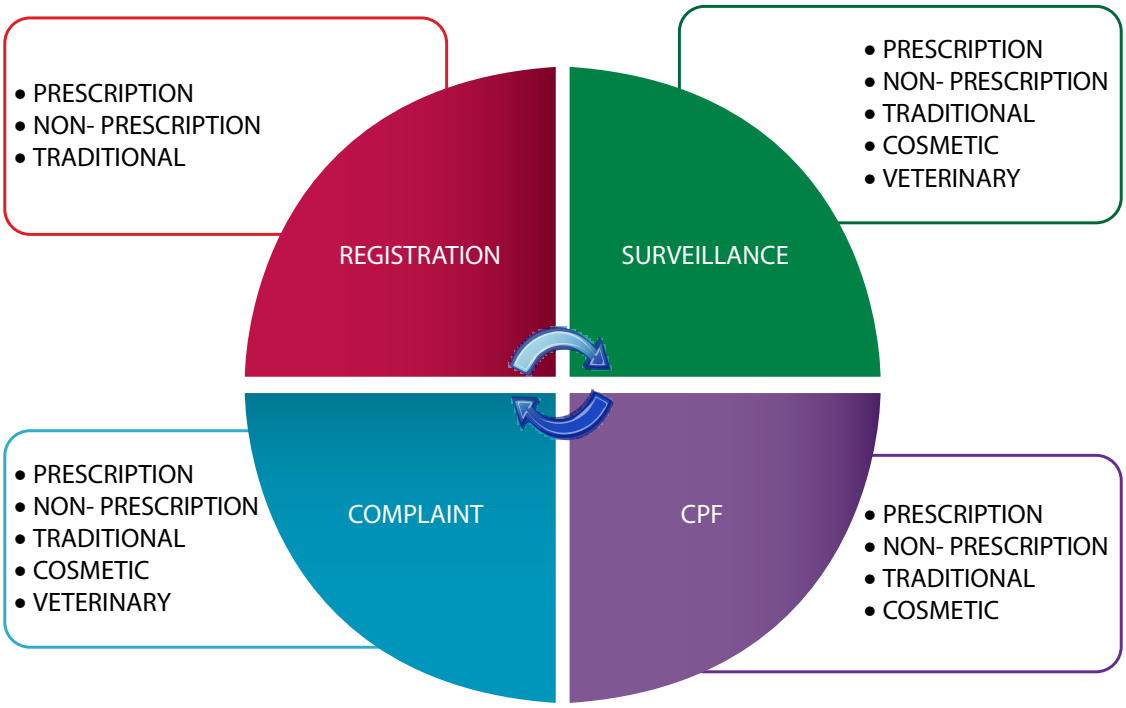



**Figure 15: Types of samples by categories, 2009**

## SAMPLE TESTING

Sample testing is one of the core activities of the Centre for Quality Control (CQC). Looking at the trend of samples tested in the past 5 years (Figure 16), the marked changes are:

(i) From the year 2007, the number of registration samples tested showed a marked decline. This decline was due to a change in policy whereby pre-registration testing for pharmaceuticals was replaced by the evaluation of analytical method validation data and post-registration testing. This policy change was implemented in stages starting from July 2007 whereby all products in dosage forms other than tablets/capsules were required to submit validation data for evaluation as part of the registration requirements. In January 2008, this requirement was extended to all dosage forms. However, pre-registration testing for traditional products was continued due to the significant failure rate of traditional product samples.

(ii) The number of CPF samples tested also showed a marked increase in 2009 as compared to previous years which is probably due to the increase in investigations and raiding activities on products suspected to be adulterated with scheduled poisons (Figure 16).

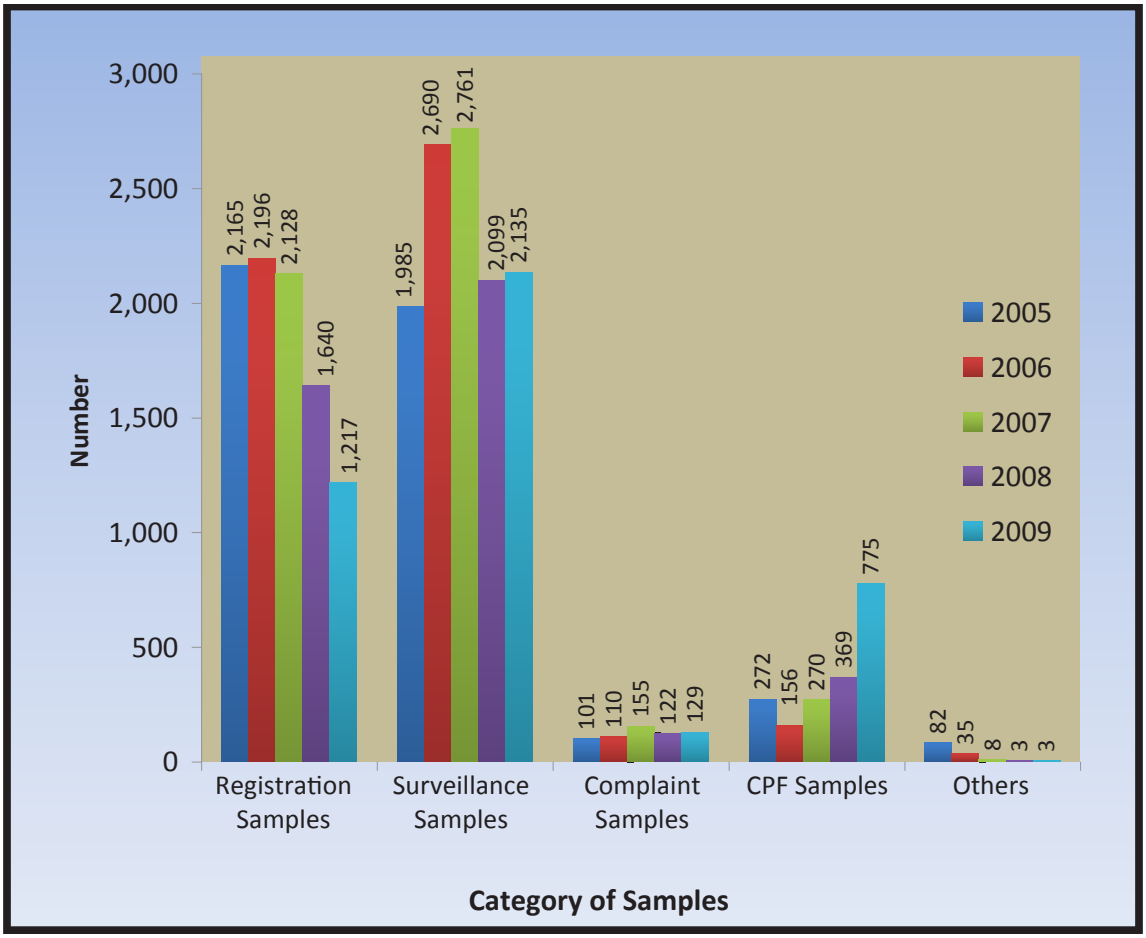



**Figure 16: Number of samples tested by category, 2005 - 2009**

From the total number of samples tested in the year 2009, 12.87% were found to be out of specification. The highest contribution to this was samples received from CPF as well as the Centre for Post-Registration under the pharmacovigilance activity (Table 2).

Out of 438 cosmetic samples tested, 59 were found to be non-compliant to the requirements of which more than 70% were positive for either hydroquinone or tretinoin or both. Other tests carried out on cosmetic samples include limit test for mercury and lead as well as microbial contamination test.

| | | FAILED SAMPLES | SAMPLES TESTED | % FAILED |
|---|---|---|---|---|
| Registration Sample | Prescription | 6 | 49 | 12.24 |
| | Non-Prescription | 5 | 13 | 38.46 |
| | Traditional | 114 | 1,155 | 9.87 |
| **Total** | | **125** | **1,217** | **10.27** |
| Surveillance Sample | Prescription | 17 | 392 | 4.34 |
| | Non-Prescription | 21 | 211 | 9.95 |
| | Traditional | 102 | 1,183 | 8.62 |
| | Cosmetic | 35 | 349 | 10.03 |
| | Veterinary | NA | NA | NA |
| **Total** | | **175** | **2,135** | **8.20** |
| Complaint Sample | Prescription | 2 | 34 | 5.88 |
| | Non-Prescription | 7 | 19 | 36.84 |
| | Traditional | 15 | 42 | 35.71 |
| | Cosmetic | 8 | 34 | 23.53 |
| | Veterinary | NA | NA | NA |
| **Total** | | **32** | **129** | **24.81** |
| CPF | Traditional | 183 | 649 | 28.20 |
| | Cosmetic | 16 | 55 | 29.09 |
| | Veterinary | 0 | 29 | 0 |
| | Others | 10 | 42 | 23.81 |
| **TOTAL** | | **209** | **775** | **26.97** |
| OTHERS | | 7 | 3 | 0 |
| **TOTAL** | | **548** | **4,259** | **12.87** |

**Table 2: Number of samples with out of specification results, 2009**

**NA = Not Applicable*

Traditional products registered in Malaysia are regulated in the aspect of quality and safety of the product. A total of 1,203 traditional samples were screened for adulterants of which 15.3% were found to be adulterated (Figure 17). The majority of adulterated samples were those received from the CPF (Figure 18).

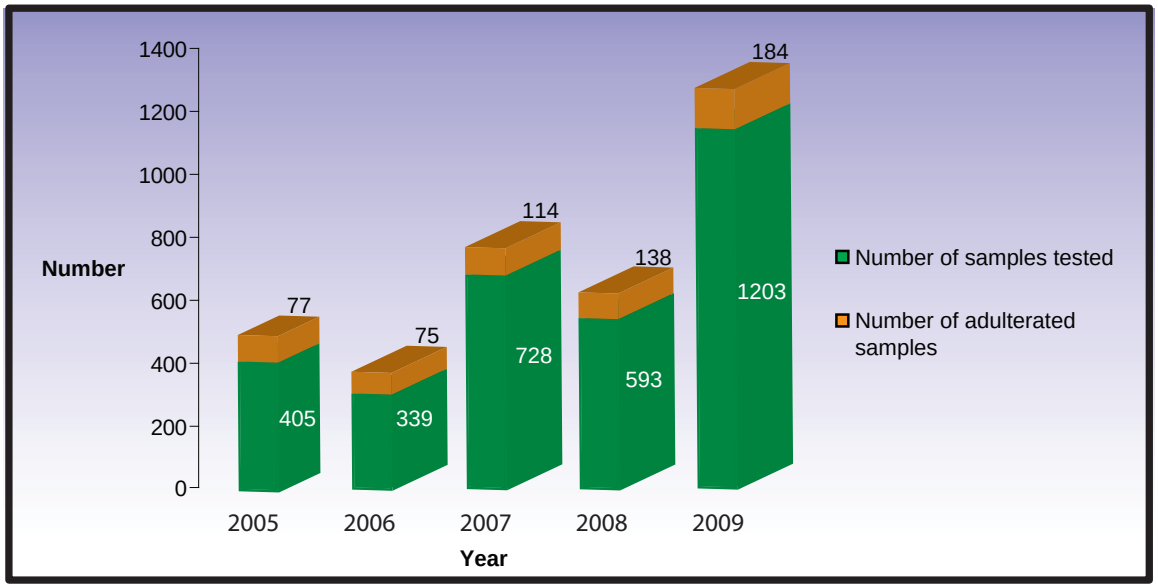



**Figure 17: Number of samples tested and adulterated, 2005 - 2009**

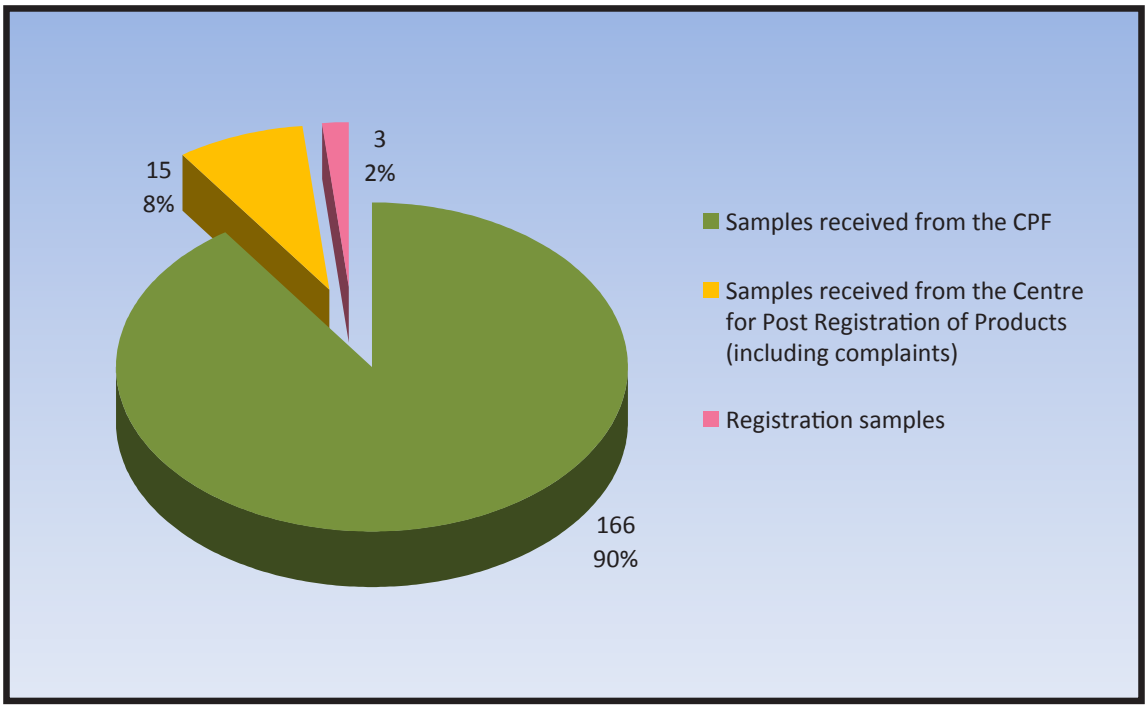



**Figure 18: Number of adulterated samples (by category), 2009**

The adulterants detected in traditional samples in the year 2009 are as listed in Table 3 below:

| ADULTERANTS | CPF SAMPLE | SURVEILLANCE SAMPLE | REGISTRATION SAMPLE |
|---|---|---|---|
| ED Drugs* | 53.73% | 14.70% | 8.52% |
| Steroids | 12.44% | 4.76% | - |
| NSAIDs | 12.41% | 1.52% | - |
| Antihistamines | 29.76% | 5.00% | - |
| Antidiabetics | 5.56% | 8.33% | - |
| Slimming agents | 10.79% | 5.08% | - |
| Xanthine Stimulants: Caffeine | 70.69% | 100.00% | 100.00% |
| Others (statins, niacinamide,phenolphtalein, psilocaine, cimetidine) | 7.25% | 20.00% | 35.71% |

**Erectile dysfunction drug: sildenafil, tadalafil, analogues of sildenafil (acetildenafil, hydroxyhomosildenafil, homosildenafil), analogue of acetildenafil (nor-acetildenafil) and analogue of tadalafil (aminotadalafil).*

**Table 3: List of adulterants detected in traditional samples**

## REFERENCE STANDARD

Reference standards are a critical part of sample testing as most quality control tests require the use of reference standards. Thus, the NPCB formed the Reference Standard Unit in October 1994 to be responsible for all activities pertaining to the procurement, production, storage, distribution and handling of reference materials and standards. The main purpose of this unit is to ensure adequate supply as well as control the quality of reference standards required to fulfil the needs of the Centre for Quality Control. In addition, the NPCB also supplies reference standards to other government agencies and also to the pharmaceutical industry in Malaysia (Figure 19).

Reference standards are produced by standardisation of the certified reference materials against primary standards. These standards are labelled as NPCB Working/ Secondary Standards. Apart from this, the NPCB also collaborates with other ASEAN countries to produce ASEAN Reference Standards (Figure 20).

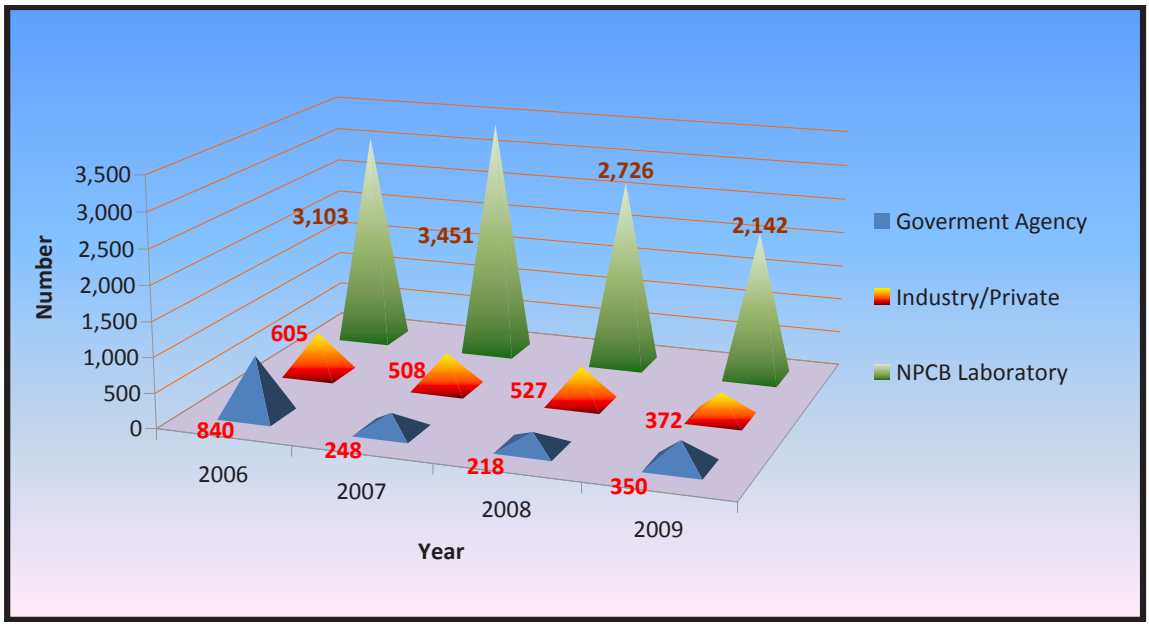



**Figure 19: Supply of Reference Standards, 2006 - 2009**

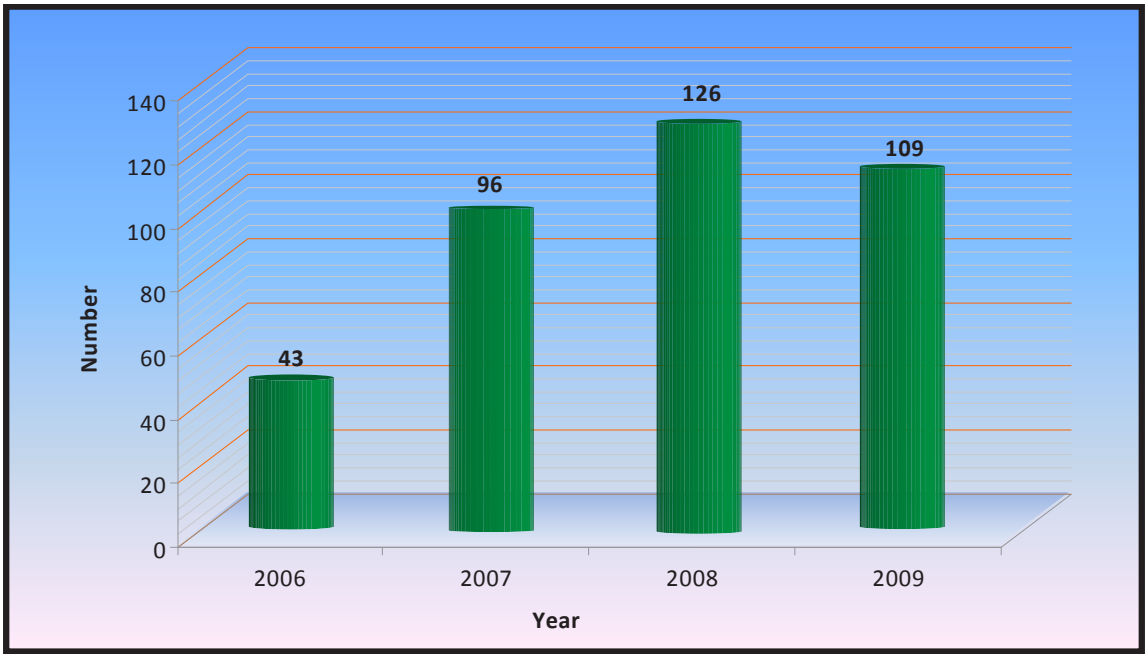



**Figure 20: Reference Standards produced (ASEAN & NPCB), 2006 - 2009**

# INSPECTION OF PREMISES

## GOOD MANUFACTURING PRACTICE (GMP) INSPECTIONS

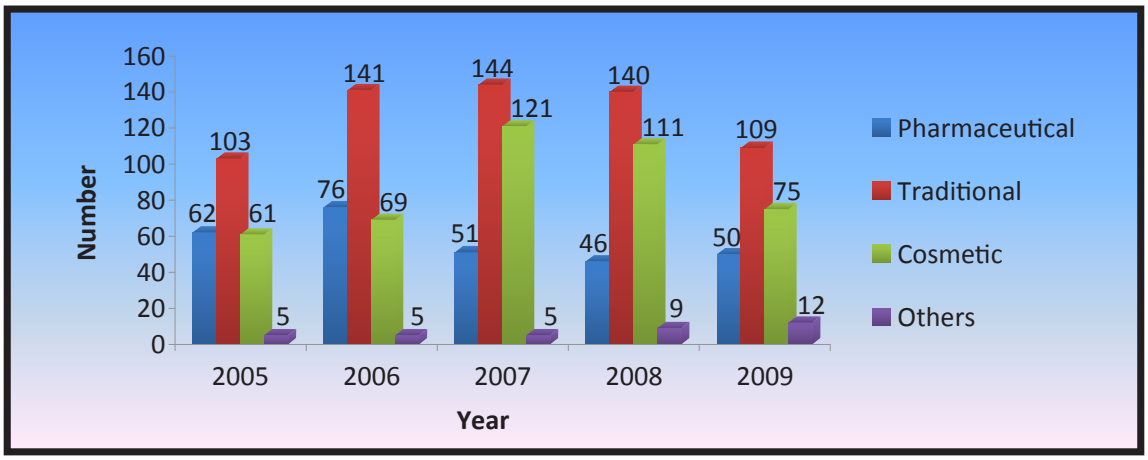



**Figure 21: Number of GMP inspections carried out, 2005 – 2009**

A total of 246 GMP inspections were carried out in 2009 compared to 306 inspections in 2008. The number of inspections carried out over the past five years is as shown in Figure 21. The reduction in the number of inspections is due to the decrease in the number of ad-hoc or unscheduled inspections.

## OVERSEAS GMP INSPECTIONS

Aside from carrying out local inspections, the NPCB also conducts inspections on manufacturing premises overseas. The overseas inspections are carried out as part of the NPCB's effort to ensure that products intended to be registered and marketed in Malaysia are manufactured by companies that are compliant with the current GMP requirements. Only products that are manufactured by GMP compliant premises are allowed to be registered and marketed in Malaysia. Throughout the year 2009, a total of 38 applications for overseas inspections were received by the NPCB of which eight overseas inspections were carried out.

## EVALUATION OF MANUFACTURER'S SUGGESTED LAYOUT PLAN

A total of 31 suggested layout plans were received and evaluated throughout the year 2009 compared to 79 in the previous year, as shown in Figure 22.

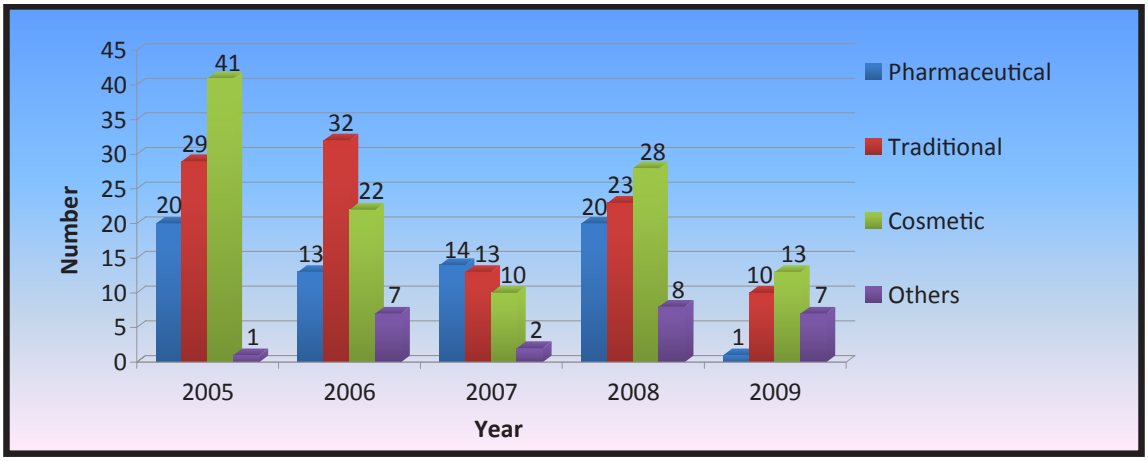



**Figure 22: Number of layout plans evaluated, 2005 - 2009**

## INSPECTION ON ACTIVE PHARMACEUTICAL INGREDIENT (API), BIOTECHNOLOGY AND BIOLOGICAL MANUFACTURERS

In the year 2009, six invitations were received for GMP inspection on Active Pharmaceutical Ingredient (API), Biotechnology and Biological Manufacturing premises. Out of the six inspections carried out, three were on API premises while the remaining three were on biotechnology manufacturing facilities (stem cell).

## EARLY VISIT TO VETERINARY PRODUCT MANUFACTURERS

The registration of veterinary products was enforced on 1st August 2007 whereby all categories of veterinary products including health supplements and drug preparations need to be registered with the Drug Control Authority (DCA) through the online system, QUEST2. However, the requirements for compliance to GMP and licensing activities for veterinary product manufacturers have not been enforced. Initial inspection programmes were carried out on veterinary product manufacturers to ensure that the current quality system practised by these manufacturers comply with GMP requirements for manufacturing veterinary products.

## GOOD STORAGE PRACTICE (GSP) INSPECTIONS

The NPCB is also involved in conducting GSP inspections on wholesalers and importers licensed by the DCA. The main objectives of GSP inspections are to ensure that the storage and handling of registered therapeutic substances and traditional products as well as notified cosmetics by licensed wholesalers and importers are carried out in accordance to established guidelines so as to ensure that these products remain safe and of good quality when it reaches the consumers. A total of 60 premises around the Klang Valley were

inspected for GSP in the year 2009 compared to 18 inspections in 2008. The increase in the number of inspections was due to the availability of more trained auditors to carry out such inspections.

## INFRASTRUCTURE EVALUATION AND GAP ANALYSIS VISIT TO POTENTIAL TEST FACILITIES TOWARDS GOOD LABORATORY PRACTICE (GLP) COMPLIANCE

In tandem with the government's aspiration of promoting Malaysia as a hub for non-clinical studies, the NPCB has conducted a Gap Analysis Visit to potential non-clinical Test Facilities. The first visit was conducted on the Environmental Bioprocess and Technology Centre (EBTC), SIRIM Berhad on 29th December 2009. The objectives of the visit were to identify the strengths of the existing infrastructure in the Test Facility, to evaluate the readiness of the Test Facility towards GLP Compliance and their current achievements in non-clinical studies as well as to identify the area of expertise for this Test Facility.

## PREPARATIONS AS THE NATIONAL COMPLIANCE MONITORING AUTHORITY FOR GLP INSPECTION

Efforts have been made to ensure the National GLP programme is successful. These include the development of the National GLP Programme Manual, standard operating procedures as well as related forms. Ten procedures and 16 forms have been prepared and are ready for use. The related documents are also available on the NPCB website.

In addition to this, the Workshop on Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) Documents for Test Facilities was held on the 3rd – 5th of August 2009 in Kuala Lumpur. The objective of the workshop was to expose the non-clinical Test Facilities to the requirements of the OECD GLP.

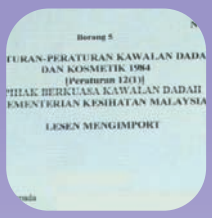
## NATIONAL COMMITTEE ON CLINICAL RESEARCH

The Clinical Research and Compliance Section, Centre for Compliance and Licensing, NPCB functions as the secretariat to the National Committee on Clinical Research. The committee is chaired by the Director General of Health, Ministry of Health Malaysia, Y.Bhg. Tan Sri Dato' Seri Dr. Hj. Mohd. Ismail bin Merican. Two meetings were conducted in 2009, i.e. on the 16th of April 2009 and 27th of October 2009.

## GOOD CLINICAL PRACTICE (GCP) COURSE

In 2009, a total of 21 GCP courses jointly organised by the Clinical Research Centre, Ministry of Health Malaysia and various Universities were held throughout the country. The Clinical Research and Compliance Section played an important role in these courses by giving lectures as well as invigilating the GCP examination. These courses were organised to provide exposure and training on all aspects of GCP to researchers and staff who are involved in clinical trials so that the clinical trials conducted in Malaysia complies with international standards and subsequently would be accepted and recognised internationally.

# LICENSING


Borang 5

TURAN-PERATURAN KAWALAN DADA
DAN KOSMETIK 1984
[Peraturan 12(1)]
PIHAK BERKUASA KAWALAN DADAH
EMENTERIAN KESIHATAN MALAYSIA

LESEN MENGIMPORT


PERATURAN-PERATURAN KAWA
DADAH DAN KOSMETIK 1984

[ Peraturan 12(1) ]

PIHAK BERKUASA KAWALAN DADAH
KEMENTERIAN KESIHATAN MALAYSIA

LESEN IMPORT PERCUBAAN KLINIKAL

## ISSUANCE OF MANUFACTURING, IMPORT AND WHOLESALER LICENSE

Under the provisions of sub-regulation 12(1), Control of Drugs and Cosmetics Regulations 1984, the Senior Director of Pharmaceutical Services has been given the authorisation to issue manufacturing license as well as wholesaler and import license. In 2009, a total of 255 Manufacturing Licenses, 358 Import Licenses and 955 Wholesaler Licenses were issued (Figure 23). Following the implementation of the cosmetic notification system in 2008, it is no longer a requirement for the manufacturers or importers of cosmetic products to have licenses. The impact of this change can still be seen in 2009 whereby the issuance of licenses recorded a decreasing trend from 1,743 licenses in the year 2008 to 1,568 licenses in 2009.

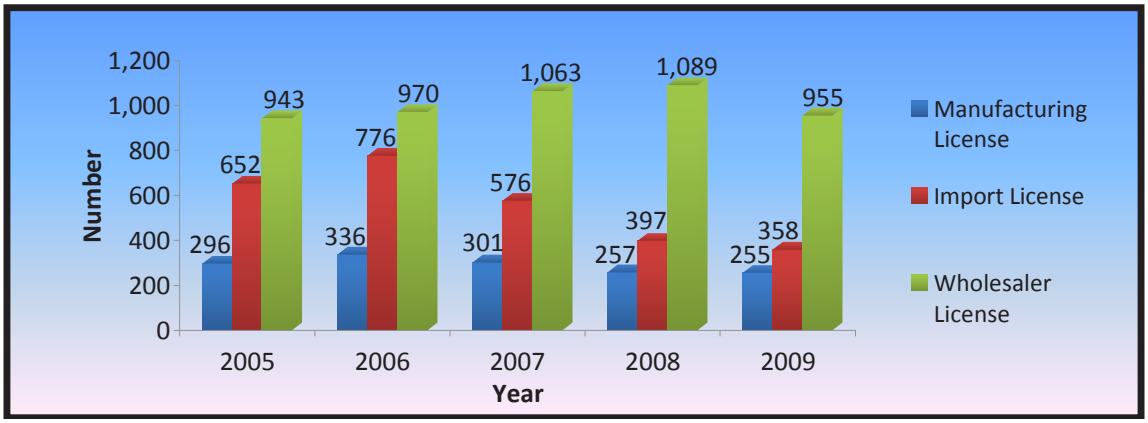



**Figure 23: Number of Licenses Processed and Issued, 2005 – 2009**

## ISSUANCE OF CLINICAL TRIAL IMPORT LICENSE (CTIL), PERMIT TO MANUFACTURE/ CLINICAL TRIAL EXEMPTION (CTX) AND VARIATION

In 2009, a total of 62 new protocols for clinical trials in Malaysia which included pharmaceutical, biotechnology, traditional medicines, health supplements and others were evaluated. In addition, bioequivalence studies of two locally manufactured unregistered products were also evaluated.

There were a total of 119 variation applications processed in 2009. These variations included changes in the quantity of products, additional or change of trial sites, additional or change of importing ports, manufacturers, principal investigators and so forth.

In the year 2009, a total of two Permits to Manufacture/Clinical Trial Exemption (CTX), 212 Clinical Trial Import Licenses (CTIL) and 373 variations were issued as shown in Figure 24.

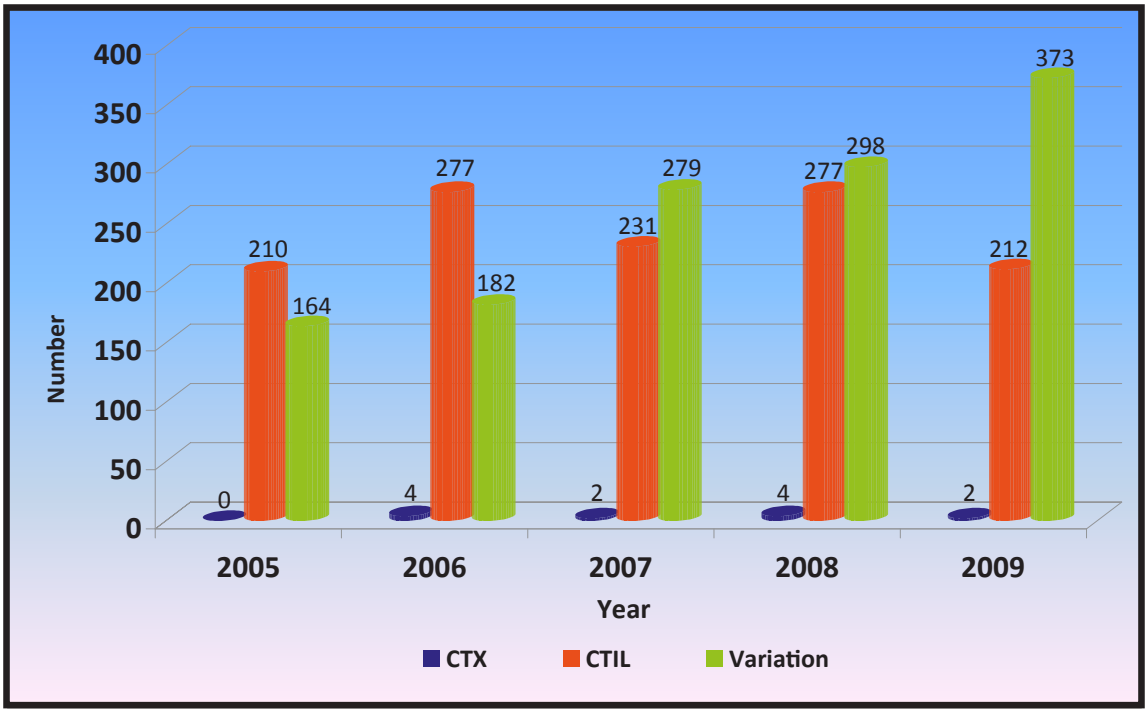



**Figure 24: Number of Clinical Trial Exemptions (CTX), Clinical Trial Import Licenses (CTIL) and Variations, 2005 - 2009**

## ISSUANCE OF REGISTERED PRODUCT ADDITIONAL LIST

A total of 445 applications for 2,551 registered product additional lists were processed in the year 2009 (Figure 25). The registered product additional lists were processed based on applications for new products registered by the registration holder. The vast decrease in the number of registered product additional list applications in the year 2008 and 2009 as compared to 2007 was due to implementation of the cosmetic notification system in 2008 in which cosmetic products are no longer required to be registered.

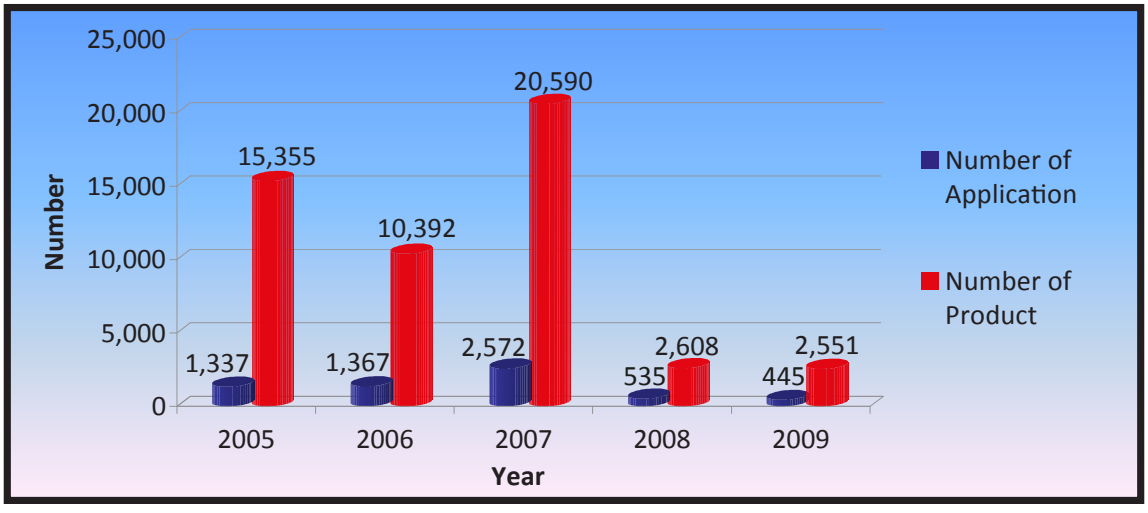



**Figure 25: Number of applications for Registered Product Additional List, 2005 - 2009**

## ISSUANCE OF GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

GMP Certification is issued for the purpose of exporting products manufactured by local manufacturers as an endorsement that the company has complied with current GMP requirements. There were a total of 536 GMP Certificates issued in 2009. The total number of GMP Certificates issued from the year 2006 to 2009 is shown in Figure 26 below.

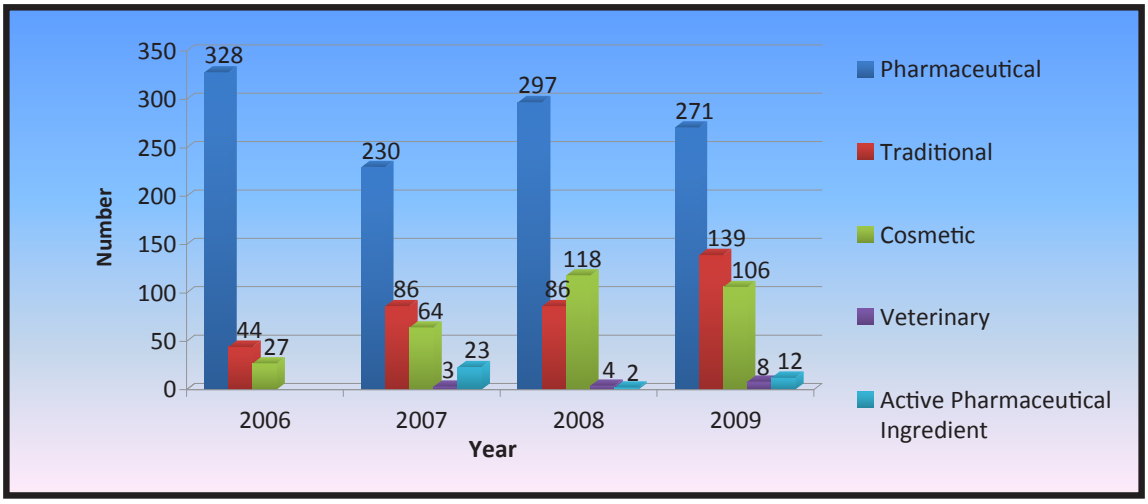



**Figure 26: Number of GMP Certificate Issued, 2006 - 2009**

## REVOCATION OF MANUFACTURING LICENSE

In 2009, a total of six manufacturing licenses were revoked, of which all were for manufacturers of traditional medicines (Figure 27). The revocations were due to non-compliance to GMP as well as adulteration issues on products manufactured by these companies.

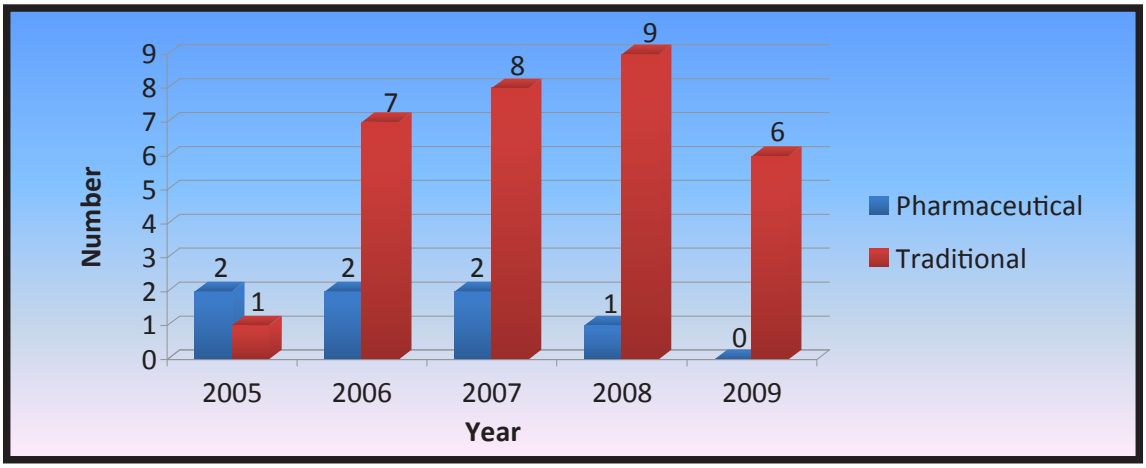



**Figure 27: Number of Licenses Revoked, 2005 - 2009**

# SURVEILLANCE

The objective of the Post Market Surveillance Programme (PMS) is to ensure that all marketed registered medicinal products and notified cosmetics are compliant to the standards and registration/notification conditions stipulated by the Drug Control Authority (DCA) for quality, safety and efficacy.

## PRODUCT SAMPLING

In the year 2009, a total of 2,656 products were sampled in this programme, of which 893 (33.6 %) were pharmaceuticals, 903 (34.0%) traditional medicines and 860 (32.4%) cosmetics (Figure 28). Products sampled under this programme undergo one or both of the following processes; sample testing for compliance with the required specifications and screening of labels as well as product inserts to ensure compliance to labelling requirements. A total of 2,108 certificates of analysis were received from the Centre for Quality Control of which 6.6% (140) did not comply with the required specifications and standards.

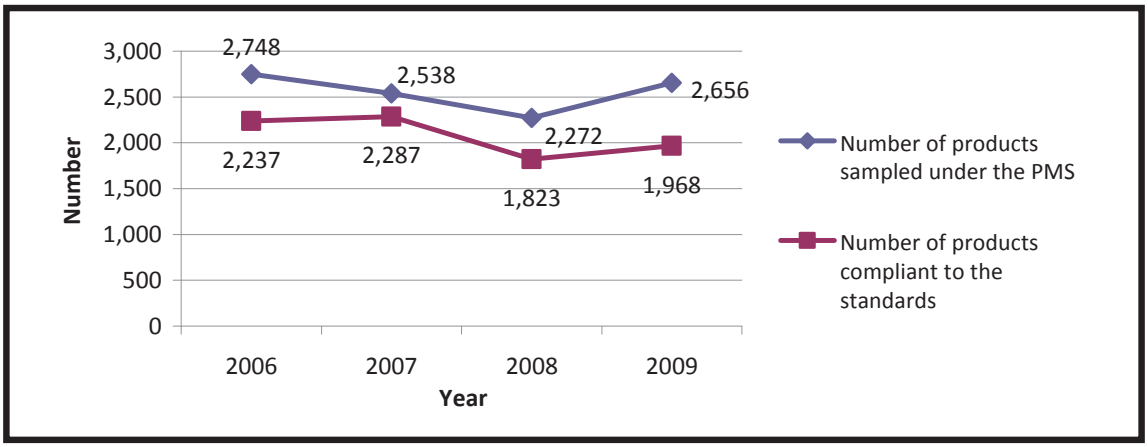



**Figure 28: Number of products involved in PMS and number of products complied with the standards, 2006 – 2009**

To ensure compliance of products in the market to labelling requirements, 2,073 labels and product inserts were screened and 660 warning letters were issued to registration holders of products found to be non-compliant to labelling requirements.

## PRODUCT RECALLS

A total of 110 directive for recalls were issued in the year 2009, of which two (1.8%) were degree I recall, one (0.9%) degree II recall and 107 (97.3%) degree III recall. Twenty warning letters were issued to the registration holders of products found to be non-compliant to the requirements. The percentage of products directed for degree III recall according to the product category as well as failed laboratory tests are shown in Figure 29 and 30 respectively.

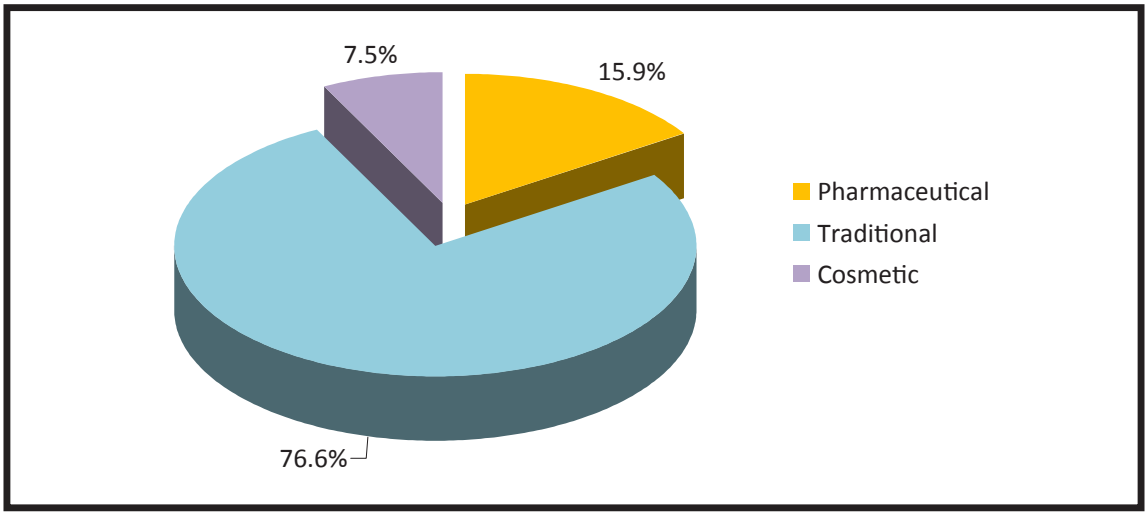



**Figure 29: Category of products directed for Degree III recall, 2009**

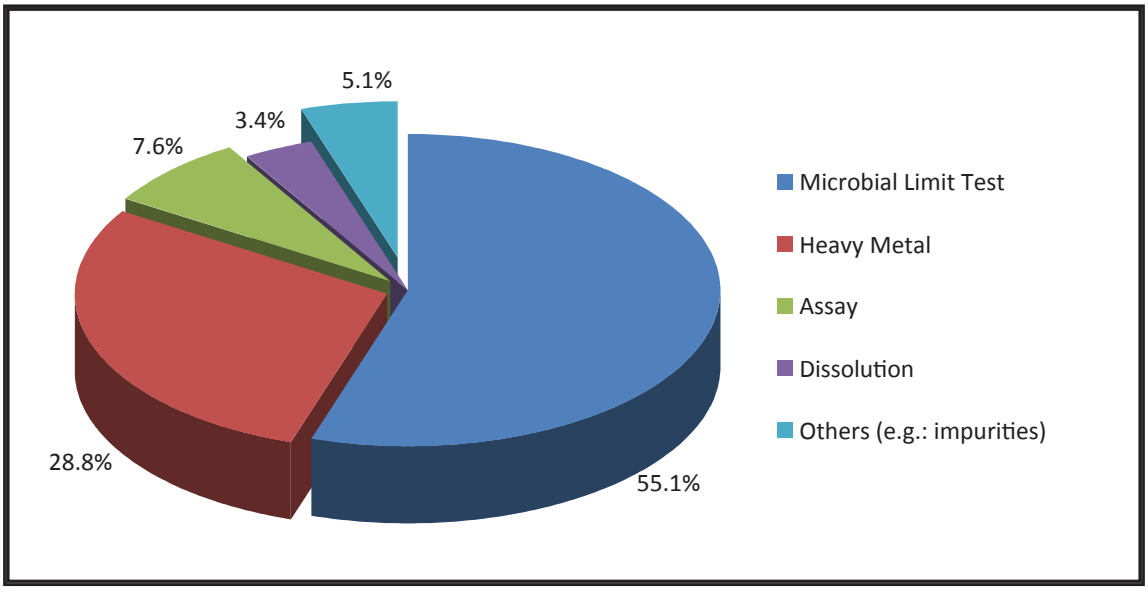



**Figure 30: Failed laboratory tests resulting in product Degree III recall, 2009**

For the year 2009, a total of 8 traditional and 12 cosmetic products were cancelled by the DCA due to adulteration which included samples from the Pharmacy Enforcement Division (CPF).

The products for which registration has been cancelled due to adulteration in the year 2009 are as listed in the table below:-

| NO. | PRODUCT NAME | REGISTRATION NUMBER | SUBSTANCE DETECTED |
|---|---|---|---|
| 1. | Phyto-Hape | MAL05101774T | Sibutramine |
| 2. | Phyto Shape | MAL20051399TE | Sibutramine |
| 3. | Etumax Eurycoma Active Plus | MAL05101707T | Sildenafil Analogue |
| 4. | Eng Leong Cordyceps, Chuanbei Plus Cough Pill 3.5gm | MAL19992654TC | Diphenhydramine |
| 5. | Loong Choo Brand Reh Bih Ho Herbal Teh | MAL20001175T | Paracetamol |
| 6. | Bodybeaus | MAL06030982TCS | Sibutramine |
| 7. | Jinglida | MAL07031203T | Aminotadalafil |
| 8. | Senna Plus Capsule 400mg | MAL06100615TC | Sibutramine |

## PRODUCT COMPLAINTS

The quality and efficacy of products can also be determined via complaints received. For the year 2009, the number of complaints received on registered products as well as notified cosmetics increased from 468 in the previous year to 523 complaints. The complaint samples received comprise of 316 (60.4%) prescription products, 119 (22.7%) non-prescription products, 73 (14.0%) cosmetic products and 15 (2.9%) traditional products. The number of complaints received according to category is shown in Figure 31.

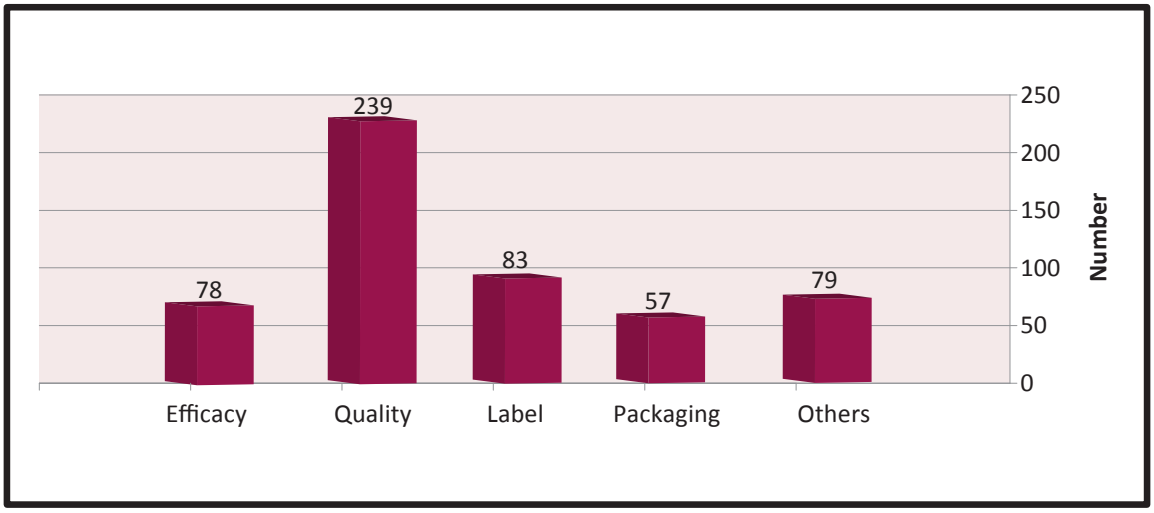
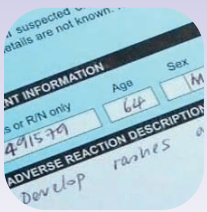



**Figure 31: Categories of product complaints, 2009**

All complaints received are investigated and necessary actions are taken based on the findings. A total of 9 recall directives were issued and 26 products were recalled voluntarily from the market by the companies involved. The NPCB also held discussion sessions with holders/manufacturers to resolve issues and to ensure that corrective actions such as reformulation, revised packaging material/type of packaging and ensuring accurate information on labels/product inserts were carried out by the registration holders.


# PHARMACOVIGILANCE

## MONITORING PRODUCT SAFETY PROFILE

In 2009, a total of 5,850 adverse drug reaction (ADR) reports were received whereby this is an increase of 21% as compared to 2008. Figure 32 shows a rising trend in the number of ADR reports received from 2000 to 2009. The biggest increase can be seen in 2008, which recorded an encouraging rise of 36.4% as compared to the year 2007.

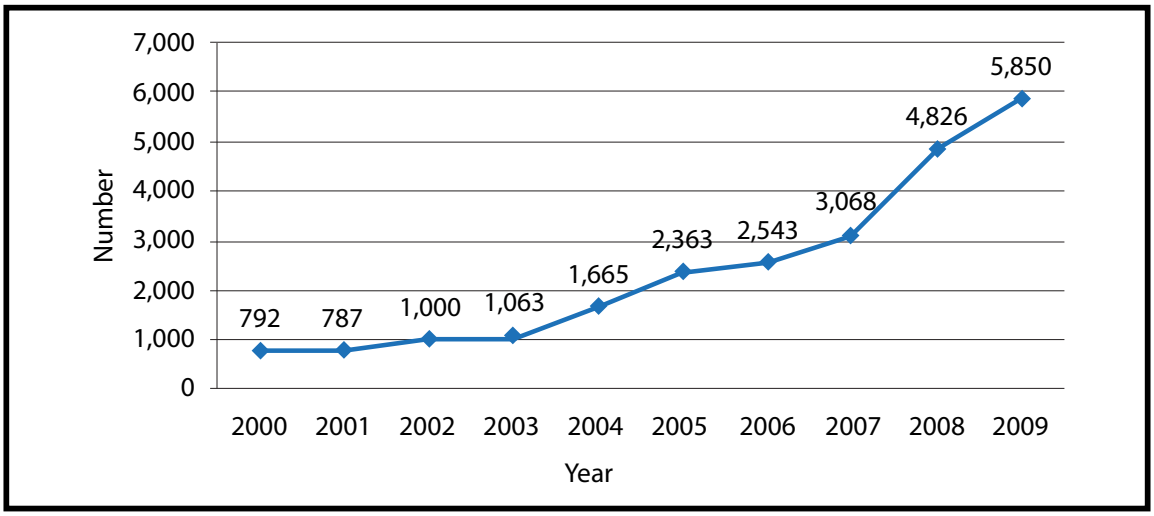



**Figure 32: Number of Adverse Drug Reaction (ADR) reports received, 2000 - 2009**

The reports involved 6,444 suspected products, of which 6,038 (93.7%) were prescription products while 286 (4.4%) were non-prescription products. There were also 97 (1.5%) ADR reports related to consumption of traditional products, and nearly 80% of these products were unregistered. The remaining 0.4% was reports related to cosmetics, food and unregistered products. This trend is consistent with the findings from previous years (Figure 33).

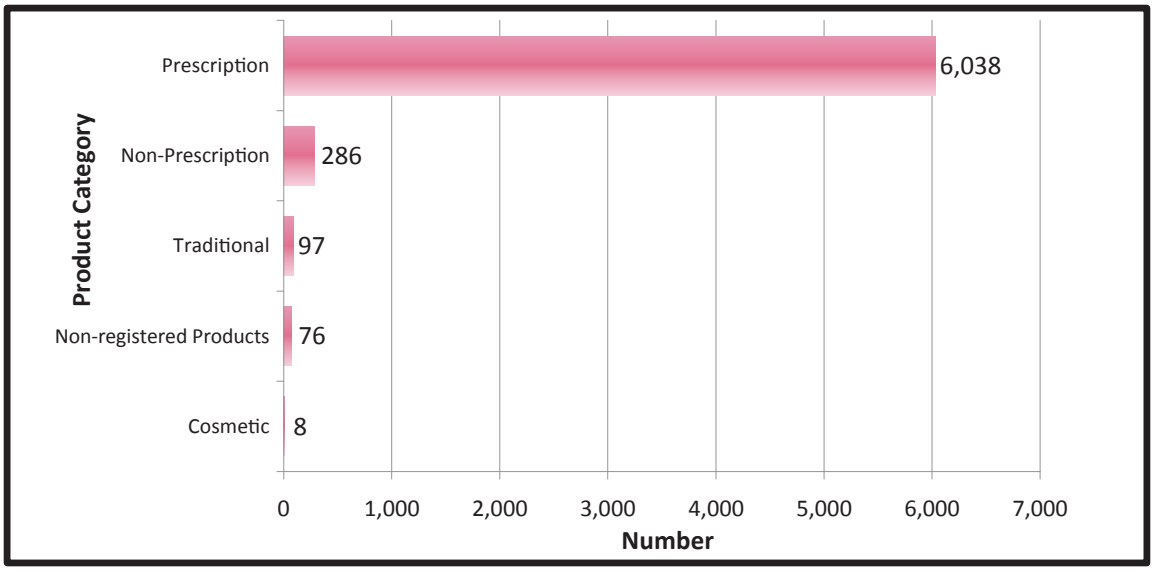



**Figure 33: Number of Adverse Drug Reaction (ADR) reports by product category, 2009**

From the 6,444 products involved, ADR reports for the pharmacological group "Cardiovascular" were the highest, with a total of 1,651 (25.6%) reports. This was followed by 954 (14.8%) reports for "Anti-infectives" and 566 (8.8%) for "Analgesics" (Figure 34). This trend mirrored that of the year 2008

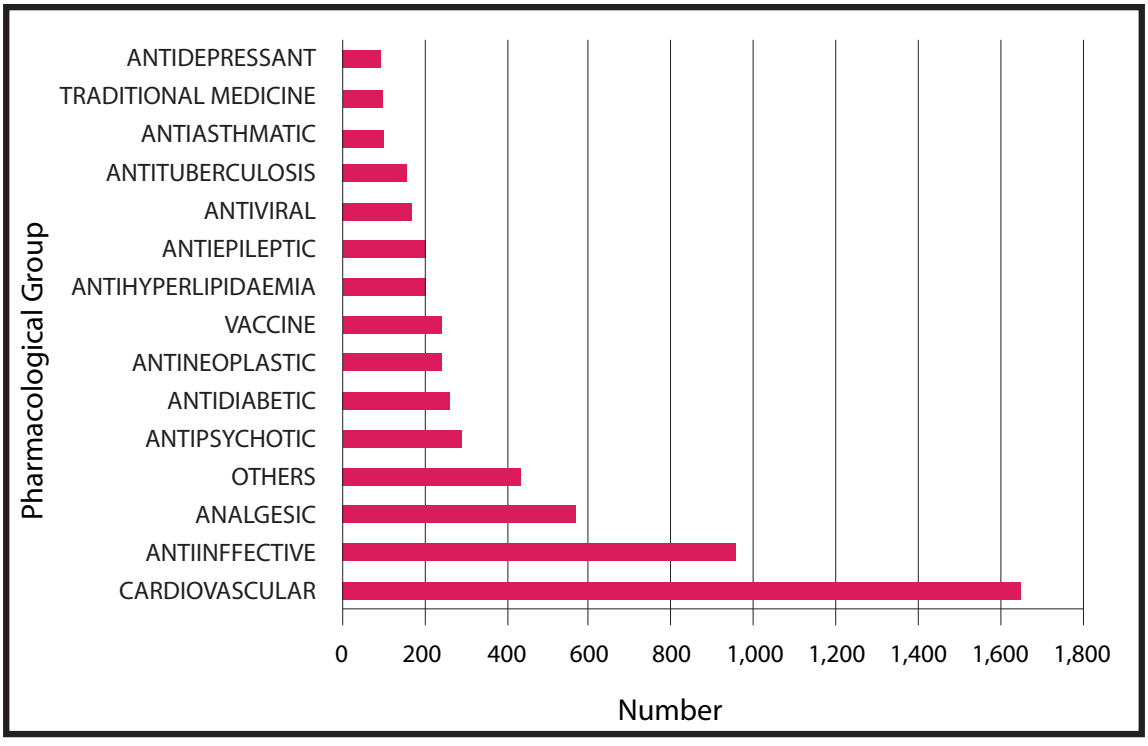


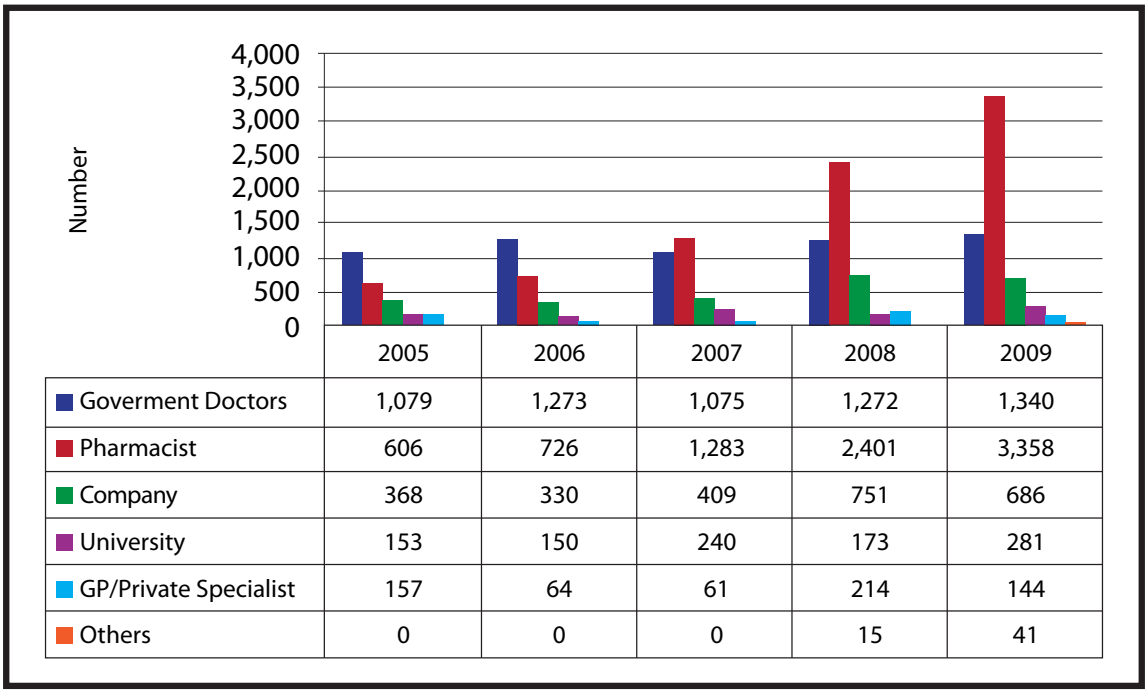

**Figure 34: Adverse Drug Reaction (ADR) reports by pharmacological group, 2009**

## ADR REPORTS BY SYSTEM ORGAN CLASS (SOC)

Analysis of the ADR reports using System Organ Class indicated that the most reported adverse events were related to the Skin and appendages disorders with 2,337 reports. This is followed by adverse events involving the Central & peripheral nervous system and Gastro-intestinal System, with 1,548 and 1,342 cases respectively.

## ADR REPORTERS

As with previous years, most of the reports were submitted by healthcare professionals in the government sector. In 2009, a vast majority of the reports were submitted by pharmacists with a total of 3,358 reports, an increase of 28.5% as compared to the previous year. Doctors in the government sector made 1,340 reports, showing a rise of 5.1% from the year 2008. On the other hand, there was a decline in the number of reports from Marketing Authorisation Holders (MAH) as well as healthcare professionals from the private sector. The MAHs put forward 686 reports while the latter contributed 214 reports, with a 8.6% and 32.7% drop from the previous year respectively. Reports from other categories such as nurses, assistant medical officers and consumers constituted 5.5% of the reports (Figure 35).




| | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|
| Goverment Doctors | 1,079 | 1,273 | 1,075 | 1,272 | 1,340 |
| Pharmacist | 606 | 726 | 1,283 | 2,401 | 3,358 |
| Company | 368 | 330 | 409 | 751 | 686 |
| University | 153 | 150 | 240 | 173 | 281 |
| GP/Private Specialist | 157 | 64 | 61 | 214 | 144 |
| Others | 0 | 0 | 0 | 15 | 41 |

**Figure 35: Adverse Drug Reaction (ADR) reports by reporters, 2009**

Selangor emerged as the state with the highest number of ADR reports sent, which was 1,352 (23.1%). This was followed by Wilayah Persekutuan Kuala Lumpur with 827 (14.1%) reports and Sabah which sent in 606 (10.4%) reports. Other states such as Perak, Negeri Sembilan, Pahang, Pulau Pinang and Kelantan exhibited an encouraging increase in the reporting of adverse events.

## PHARMACOVIGILANCE ACTIVITIES: PROMOTING ADR REPORTING

Six Adverse Drug Reaction (ADR) & Adverse Events Following Immunisation (AEFI) workshops were held in collaboration with the Pharmaceutical Services Division as listed below:

- March 2009 – East Malaysia Zone, Kota Kinabalu, Sabah
- June 2009 – National Level, National Pharmaceutical Control Bureau, Selangor
- July 2009 – Northern Zone, Alor Setar, Kedah
- July 2009 – National Level, National Pharmaceutical Control Bureau, Selangor
- October 2009 – East Coast Zone, Kuala Terengganu, Terengganu
- November 2009 – Central & Southern Zone, Negeri Sembilan

In addition, talks were also conducted following invitations by some institutions and universities, as listed below. These workshops and talks were aimed at increasing awareness of the importance of reporting adverse events of drugs and vaccines, as well as improving the quality of ADR reports submitted.

| NO. | WORKSHOP | DATE | ORGANISER |
|---|---|---|---|
| 1 | Pharmacovigilance in Malaysia | February 2009 & November 2009 | Cyberjaya University College of Medical Sciences |
| 2 | Pharmacovigilance: Safety of Vaccines | May 2009 | *Jabatan Hal Ehwal Orang Asli* Hospital |
| 3 | Adverse Drug Reaction Reporting & Monitoring | July 2009 | Port Dickson Hospital |
| 4 | Adverse Drug Reaction & Adverse Event Following Immunisation Workshop | October 2009 | *Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur*/ Putrajaya |

## DCA REGULATORY ACTION

a) Suspension of the following registered products was lifted as the investigation that was carried out showed that these products were safe to be used. Nevertheless, close monitoring on these products will continue.
   - Cardiamed Injection® 1mg/1ml, 4ml ampoule (MAL20051326A)
   - Hydroxycut® (MAL06061641TC)

b) Major amendments were made to package inserts following the DCA's directive as follows:

| NO. | MADRAC Meeting | Product Name | Changes | DCA Meeting |
|---|---|---|---|---|
| 1 | 108 (12/03/09) | **Cough & cold products** | **Additional Warnings for Use in Children**<br>• Not to be used in children less than 2 years of age.<br>• To be used with caution and doctor's advice in children 2 to 6 years of age. | 216 (28/05/09) |
| 2 | 110 (23/07/09) | **Propylthiouracil** | **Additional Warnings on Potential Risk of Hepatotoxicity**<br>• Potential risk of serious hepatotoxicity or liver injury including liver failure and death.<br>• Not to be used in pediatric patients unless the patient is allergic to or intolerant of the alternatives available. | 218 (30/07/09) |
| 3 | 110 (23/07/09) | **Clopidogrel** | **Additional Warnings on Possible Interaction with Proton Pump Inhibitors**<br>• Concomitant use of drugs that inhibit CYP2C19 (e.g. proton pump inhibitors) should be discouraged | 218 (30/07/09) |
| 4 | 110 (23/07/09) | **Antiepileptics** | **Additional Warnings on Potential Risk of Suicidal Thoughts or Behaviour**<br>• Potential for an increase in risk of suicidal thoughts or behaviours. | 218 (30/07/09) |
| 5 | 111 (10/09/09) | **Colchicine** | **Additional Warnings on Severe Drug Interaction with P-glycoprotein or Strong CYP3A4 Inhibitors**<br>• Potential risk of severe drug interactions, including death, in certain patients treated with colchicine and concomitant P-glycoprotein or strong CYP3A4 inhibitors.<br>• P-glycoprotein or strong CYP3A4 inhibitors are not to be used in patients with renal or hepatic impairment who are taking colchicines.<br>• A dose reduction or interruption of colchicines treatment should be considered in patients with normal renal and hepatic function if treatment with a P-glycoprotein or a strong CYP3A4 inhibitor is required.<br>• Avoid consuming grapefruit and grapefruit juice while using colchicines. | 220 (01/10/09) |
| 6 | 111 (10/09/09) | **Immunosuppressant** | **Additional Warnings on Increased Risk for Opportunistic Infections**<br>• Immunosuppressed patients are at increased risk for opportunistic infections, including activation of latent viral infections. These include BK virus associated nephropathy, which may lead to serious, including fatal, outcomes. | 220 (01/10/09) |
| 7 | 112 (10/12/09) | **Ceftriaxone** | **Update to the Previous Warning on Potential Interaction with Calcium-containing Intravenous Solutions**<br>• Ceftriaxone is contraindicated in neonates (≤ 28 days of age) if they require treatment with calcium-containing intravenous solutions because of the risk of ceftriaxone-calcium precipitation.<br>• In patients other than neonates, ceftriaxone and calcium-containing solutions may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid. | 223 (24/12/09) |

# COSMETIC

## NOTIFICATION OF COSMETIC PRODUCTS

Malaysia has implemented the notification procedure through the ASEAN Cosmetic Directive (ACD) since 1st January 2008. This is in line with the cosmetic harmonisation scheme which has been agreed on by all member states in the ASEAN Region. The implementation of the ACD has benefited both the regulators as well as the industry. A network among regulators has been created to facilitate the sharing of information and knowledge through the Post Market Surveillance Programme and the ASEAN Alert System to ensure that cosmetic products in the market are safe and of high quality, thus ensuring the consumers' best interest is protected.

In 2009, a total of 37,466 cosmetic products have been notified with the NPCB, Ministry of Health Malaysia which is an increment of 23% compared to the year 2008 (Figure 36).

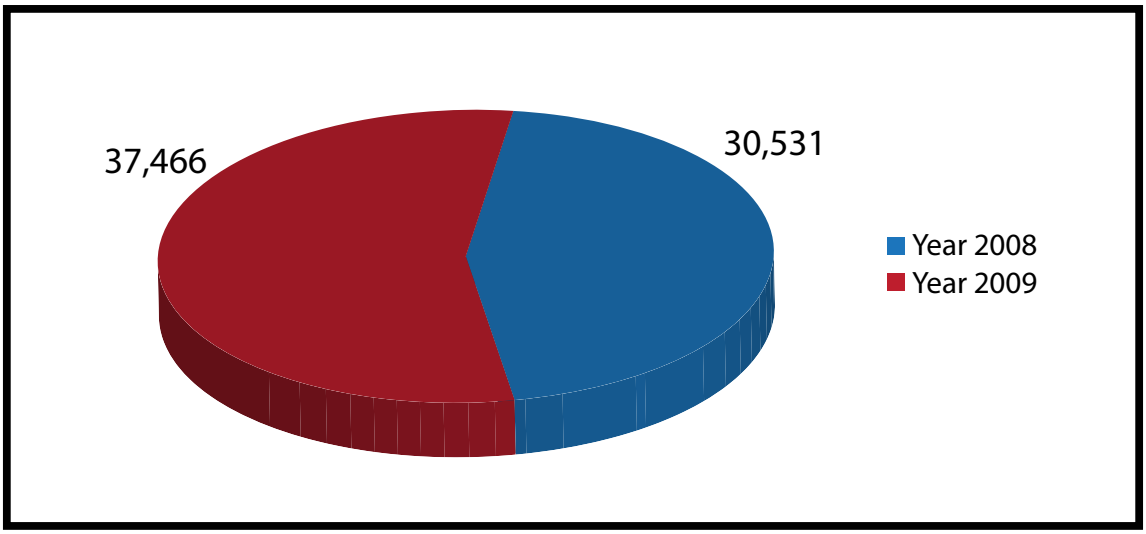



**Figure 36: Number of Cosmetic Products Notified, 2008 – 2009**

A total of 293 product notifications were cancelled in the year 2009 due to non-compliance to the ASEAN Cosmetic Directive (ACD) requirements. From this, 12 (4.10%) products were found to contain banned ingredients or ingredients listed in the Poison Schedule, 244 (82.99%) products contained ingredients used beyond the permitted limit and conditions laid down in the ACD, 24 (8.16%) products were revoked due to failure of the manufacturer to comply with Good Manufacturing Practice (GMP) or not having proper manufacturing premises, and 13 (4.42%) products did not fall under the scope of cosmetic (Figure 37).

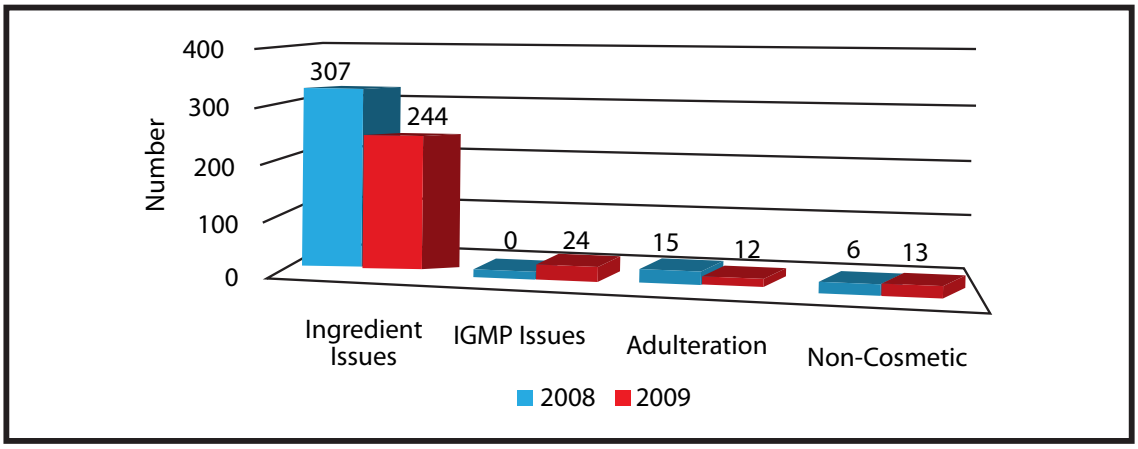



**Figure 37: Number of Cosmetic Notifications Cancelled, 2008 - 2009**

The number of product notification cancellations declined in 2009 compared to the previous years. This may reflect an increase in awareness and knowledge among cosmetic companies and manufacturers towards the requirements of the ASEAN Cosmetic Directive (ACD).

In 2009, the notification of 12 cosmetic products were cancelled due to adulteration. The said cosmetic products are as listed below:

| NO. | PRODUCT NAME | NOTIFICATION NUMBER | SUBSTANCE DETECTED |
|---|---|---|---|
| 1. | Felisa Gentle Peeling Solution | NOT07080210KE | TRETINOIN |
| 2. | Krim Malam Rahsia Rimba | NOT08080111 2K | HYDROQUINONE |
| 3. | Biocosmet Whitening Essence Cream | NOT07122920KE | HYDROQUINONE |
| 4. | ~H2O+ Waterwhite Brightening Night Cream | NOT04102838KE | HYDROQUINONE |
| 5. | Magixpress Lightening Plus | NOT07121009KE | HYDROQUINONE |
| 6. | A.Vant Cream | NOT05022860KE | TRETINOIN |
| 7. | Eriesya Spa Beauty Cream | NOT07122412KE | HYDROQUINONE |
| 8. | Natasya Krim Herba | NOT07090337KE | HYDROQUINONE & TRETINOIN |
| 9. | Temulawak Whitening Pearl Cream Papaya | NOT03090150KE | TRETINOIN |
| 10. | Ratna Sari Whitening Night Cream | NOT080700826K | TRETINOIN |
| 11. | ATIKA BEAUTY Renewal Night Cream | NOT04082451KE | HYDROQUINONE |
| 12. | Chantique - Whitening Night Cream | NOT04121404KE | TRETINOIN |

## MARKET SAMPLING PERMIT AND IN-HOUSE EVALUATION PERMIT FOR COSMETIC PRODUCTS

In 2009, a total of 6,024 market sampling permits and in-house evaluation permits were issued to cosmetic companies, showing an increment of 4.9% compared to the previous year (Figure 38). This is an indication that the implementation of the ACD has helped the cosmetic industry and assisted the local cosmetic industry in doing business and gaining market access for its products in ASEAN as well as international markets.

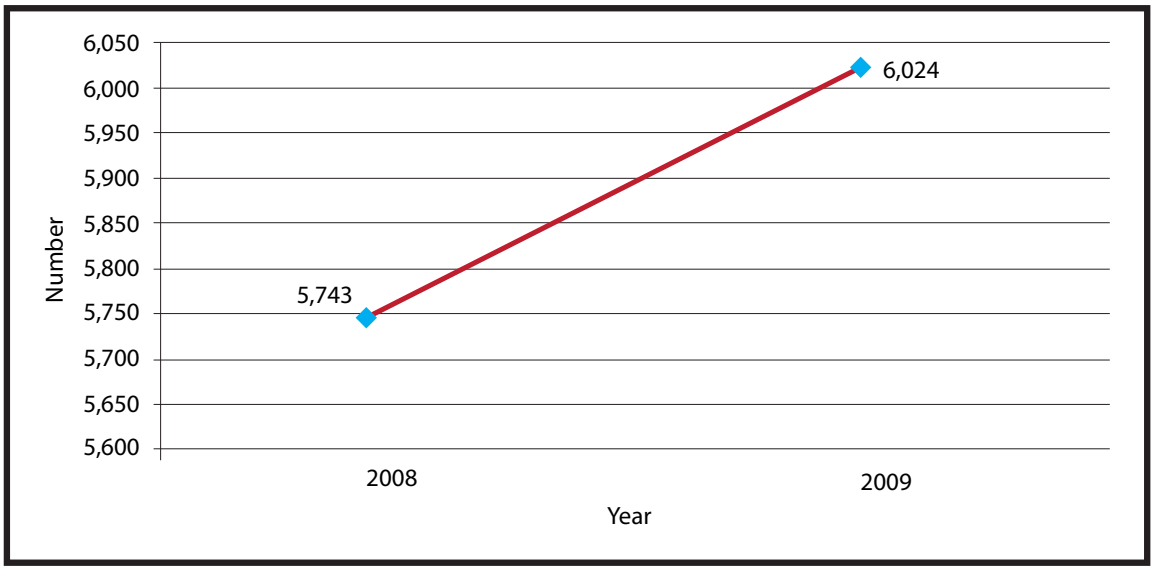



**Figure 38: Number of Market Sampling Permits & In-House Evaluation Permits Issued, 2008 - 2009**

As shown in Figure 39, the number of applications for Certificate of Free Sales (CFS) decreased by 8.5% in 2009 compared to the previous year, where a total of 1,597 applications were received. This is a positive indication that Malaysia is in line with one of the objectives of the ASEAN Harmonisation of Cosmetic Products which is to eliminate technical impediment in order to advance towards the realisation of the ASEAN Free Trade Zone.

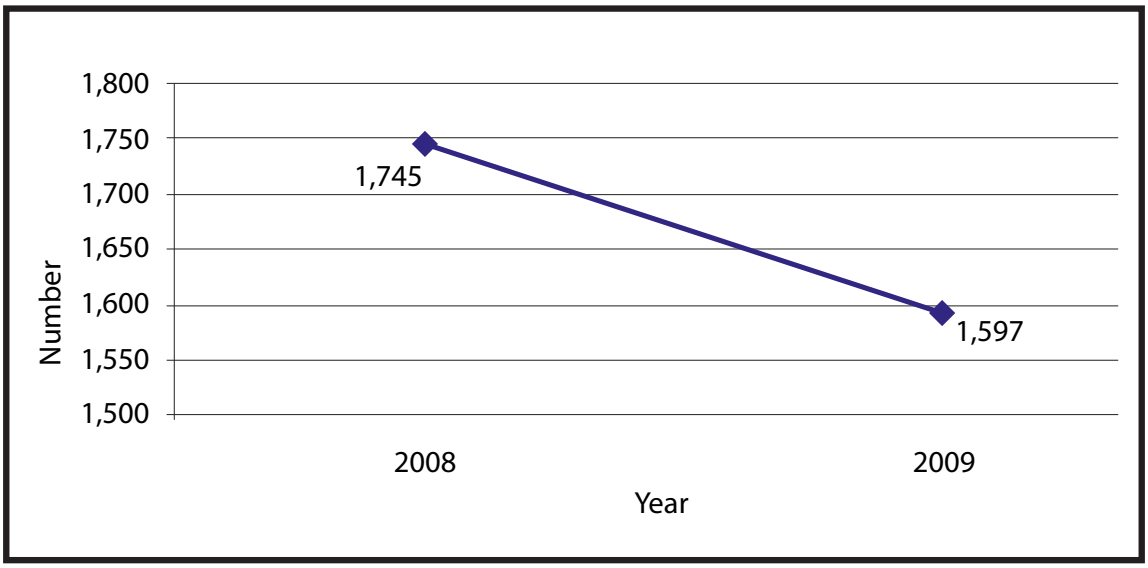



**Figure 39: Number of Applications for Certificate of Free Sales (CFS), 2008 - 2009**

## PRODUCT INFORMATION FILE (PIF) AUDIT

Audits on Product Information File (PIF) for notified cosmetics began in 2009. A total of 285 PIF were audited (Figure 40) which include whitening products, high risk products such as eye and baby products, manufacturers or companies with history of product recalls, product complaints, products that failed laboratory tests and weak GMP status as well as based on inputs gathered during the initial product screening.

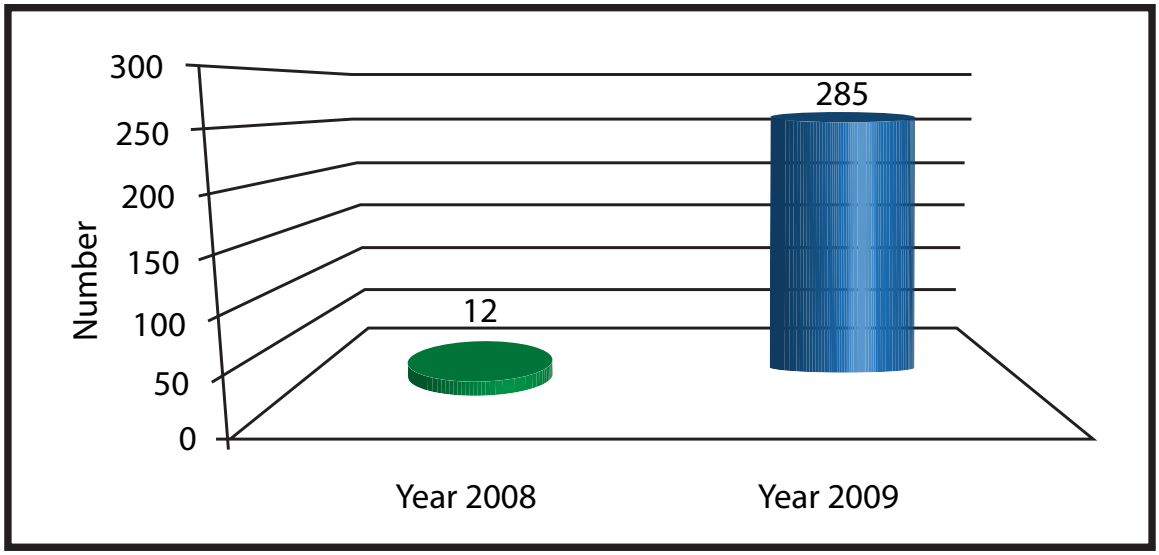
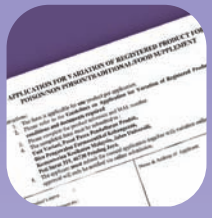



**Figure 40: Number of Product Information File (PIF) Audited, 2008 – 2009**

The audit findings showed that most notification holders understand the need of PIF and its requirements as stated in the ACD. However, small and medium enterprises (SMEs) are still having difficulties to complete PART II to Part IV of the PIF requirements as there is a lack of co-operation from the manufacturers. These companies have been identified by the NPCB for regular training which is aimed to increase their understanding on the requirements as well as to improve adherence to the ACD.

# VARIATION APPLICATION



The Variation Section, Centre for Post-Registration of Products is responsible for evaluating applications pertaining to information updates or change of registered product information (excluding cosmetic and veterinary products) with the aim of ensuring that the safety, efficacy and quality of products are maintained after it has been registered. Changes to the information of registered products include addition of information in the package insert, changes to the product formulation as well as change of manufacturing site.

In the year 2009, a total of 50,522 variation applications were received, which is a 2.2% increase compared to the year 2008. As shown in Figure 41, the number of applications for prescription products is the highest with 29,755 (59%) applications, followed by traditional products with 9,659 (19%) applications, non-prescription products with 8,662 (17%) applications and health supplement products with 2,281 (5%) applications.

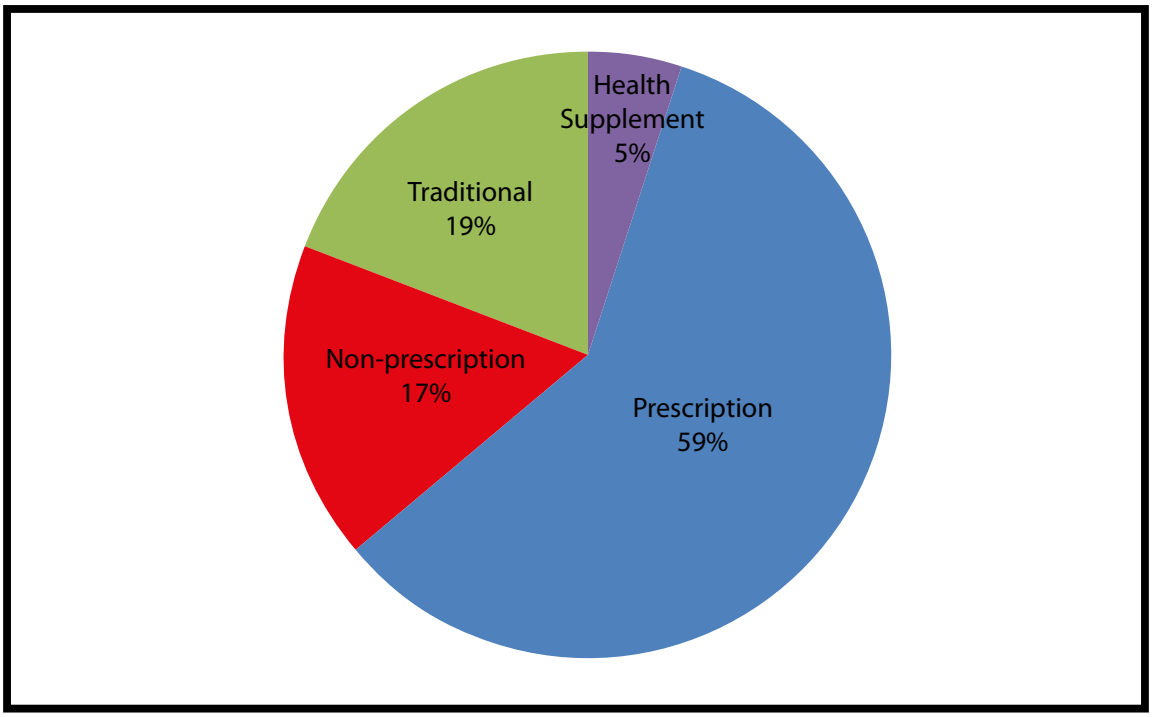



**Figure 41: Variation applications received, 2009**

Figure 42 shows that the Variation Section had processed a total of 46,604 applications which is 92.2% of the total number of applications received in the year 2009. Of this, a total of 30,368 applications were approved while 16,236 applications were rejected.

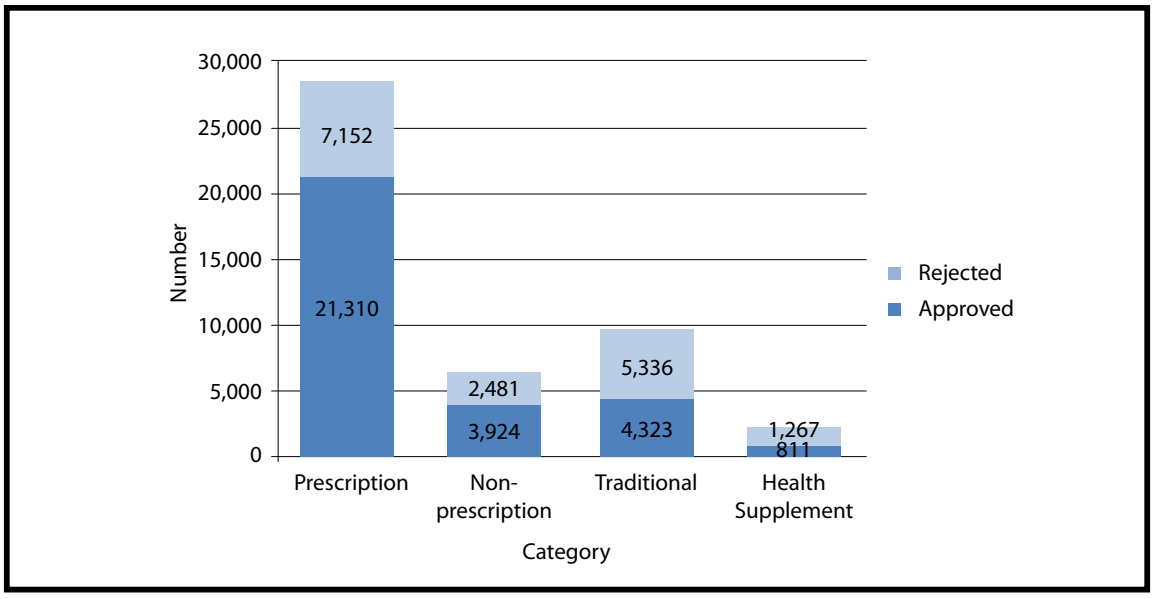
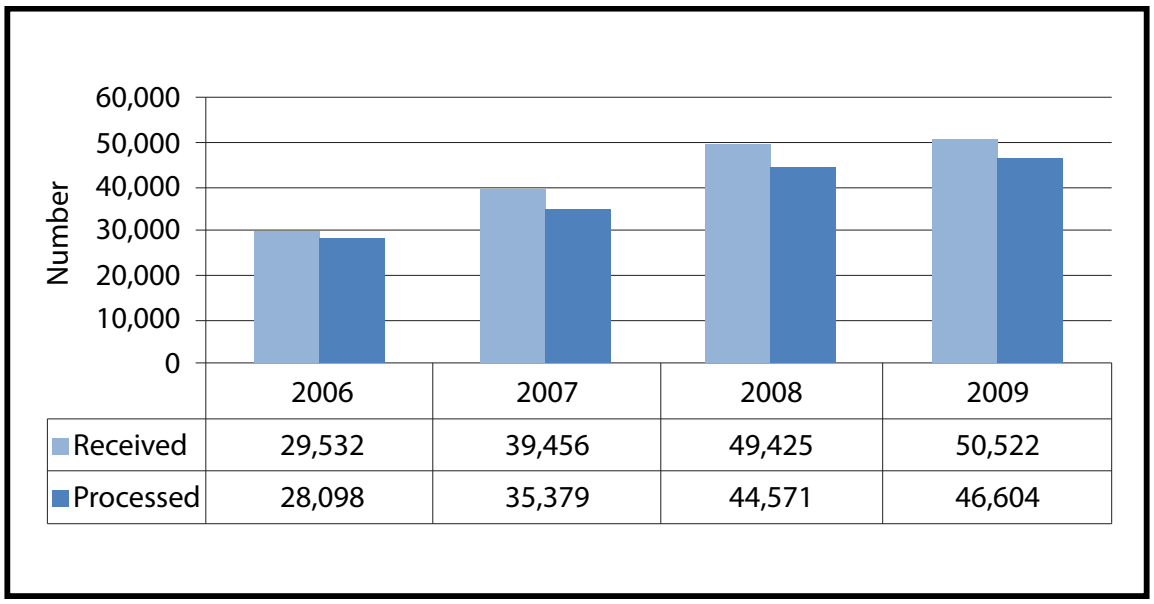



**Figure 42: Variation applications processed according to category of product, 2009**

Factors that led to the applications being rejected include:

a) Changes made were not in accordance to regulatory requirements
b) Documents submitted were incomplete
c) Documents attached were not related to the required information

From 2006 to 2009, the number of variation applications received has been on the rise. In 2009, there was an increase of 2.2% in the number of variation applications received and an increase of 4% for the number of variation applications processed as compared to 2008 (Figure 43).




| | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|
| Received | 29,532 | 39,456 | 49,425 | 50,522 |
| Processed | 28,098 | 35,379 | 44,571 | 46,604 |

**Figure 43: Variation applications received and processed, 2006 -2009**

Factors that led to the increase of variation applications include:

- Follow-up action taken by the Marketing Authorisation Holder to update the information of registered products after receiving instructions from Pharmacovigilance Section to include safety information
- Instructions from the Surveillance and Product Complaint Section to update information which had been changed without prior approval from the Variation Section
- Circulars from the Drug Control Authority (DCA) that requires Marketing Authorisation Holders to update information of registered products. The circulars from the DCA that resulted in a significant increase in the number of variation applications include 'Implementation of Patient Pack Size Concept' dated 20th February 2008 and 'Compliance to the Labelling Requirements for Registered Products – Declaration of Source of Gelatine for Capsule' dated 24th March 2009.

As reflected in Figure 44, the year 2009 showed an increase of 112.8% in the change in manufacturing site applications as compared to 2008 (Figure 44). Among factors that contributed to this increase include:

- Merger of pharmaceutical companies
- Changes in the manufacturing location
- Appointment of new manufacturer for traditional products due to the suspension of the manufacturing license of the previous manufacturer by the DCA

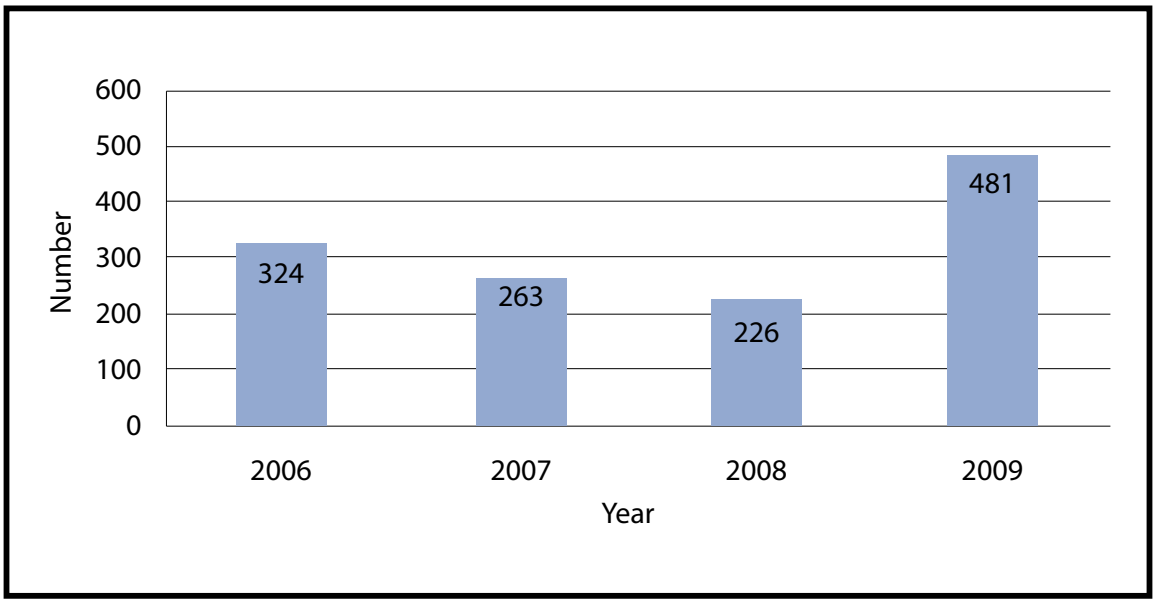



**Figure 44: Change of manufacturing site applications, 2006 -2009**

# INFORMATION DISSEMINATION



## NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB) WEBSITE

The NPCB website www.bpfk.gov.my functions as a medium for information dissemination to the public, industries, other government agencies as well as international regulatory bodies. The information that is available in the website includes constantly revised guidelines, decisions of the Drug Control Authority (DCA) as well as upcoming trainings and seminars. The website also enables the public to check on the registration status of a product through the product search system as well as important announcements regarding medicines and cosmetics.

## HANDLING OF ENQUIRIES

In the year 2009, the NPCB actively attended to a total of 2,607 enquiries (Figure 45) of various natures such as enquiries pertaining to the product registration process, product indications, documents needed for product application, status of product registration, product classification, information about wholesalers/importers/manufacturers as well as the QUEST2 system. There was an increase of 57% in the total number of enquiries received in 2009 as compared to 2008. This may be due to the increase in the number of importers of cosmetic products resulting from the simplified notification procedure implemented in 2008 in place of the registration procedure.

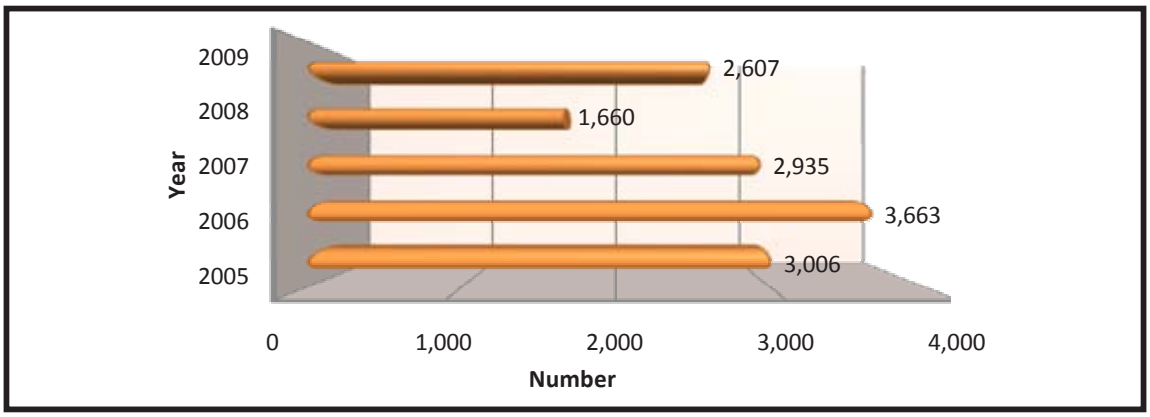



**Figure 45: Number of Enquiries Handled, 2005 – 2009**

## PUBLICATIONS

As the secretariat to the DCA, the NPCB is also responsible for the dissemination of drug related information as well as the DCA's policies. One of the means of doing so is through the publication of the Newsletter of the Drug Control Authority (*Berita Ubat-ubatan)* every three months. In addition, information regarding activities and performance of every centre in the NPCB is conveyed through the publication of the NPCB Annual Report.

# FINANCIAL REPORT

The Finance and Revenue Unit under the Centre for Administration is responsible for managing all matters related to finance and accounts in accordance to the rules and regulations set by the government. It ensures that all financial allocations are effectively and efficiently used as well as sufficient so that each planned activity meets its objective.

## ALLOCATION AND EXPENDITURE

Summary of the allocation and expenditure for the year 2009 is as follows:

| TYPE OF ALLOCATION | CODE | TYPE | ALLOCATION (RM) | EXPENDITURE (RM) | BALANCE (RM) |
|---|---|---|---|---|---|
| OPERATING | 10000 | Emolument | 14,844,704.00 | 15,239,397.55 | - 394,693.55 |
| | 20000 | Supply and Services | 9,669,109.00 | 9,629,835.71 | 39,273.29 |
| | 30000 | Asset (Property) | 573,601.00 | 567,759.00 | 5,842.00 |
| DEVELOPMENT | | | 12,997,417.00 | 12,478,437.74 | 518,979.26 |
| **TOTAL** | | | **38,084,831.00** | **37,915,430.00** | **169,401.00** |

## REVENUE

In 2009, a total revenue of RM12,702,780.04 was collected, showing an increase of 10% compared to the previous year. The collection is from product registrations and cosmetic notifications, laboratory tests, licenses, Good Manufacturing Practice (GMP) audits, sales of guidelines and others (Figure 46).

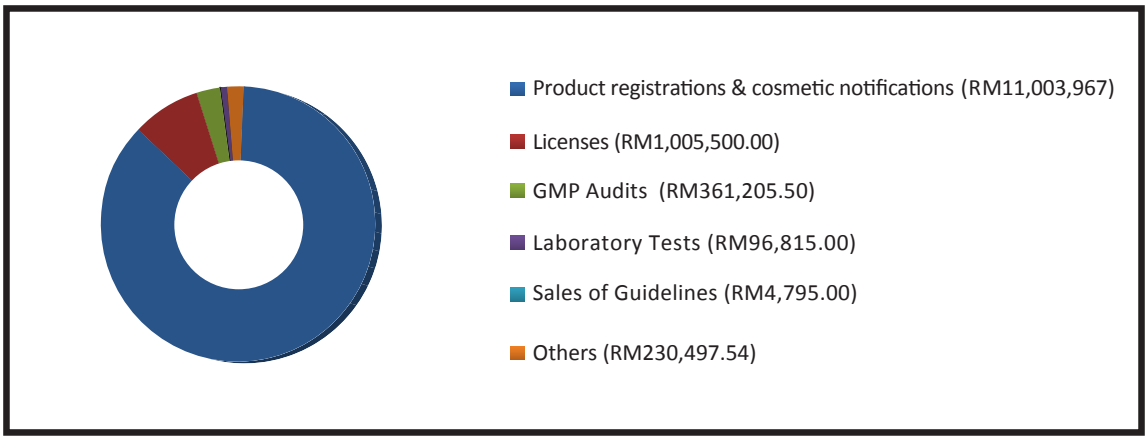



**Figure 46: NPCB's revenue, 2009**

# CHALLENGES

1. Malaysia is now entering the compliance phase of the Montreal Protocol to reduce the use of chlorofluorocarbon (CFC) and to freeze its production at a global level. The NPCB role as the working body has set a target date to completely phase-out the importation of products containing CFC by 1st January 2010.

2. Since 1999, NPCB requires the submission of Bioequivalence (BE) study reports for generic products via the listing method. To date, 95 active ingredients under the first to the seventh schedule are required to submit BE study reports as supporting documents during the registration process. Thus, the number of BE study reports to be evaluated is rising. The ASEAN Reporting Format has also been agreed on during the 15th ASEAN Consultative Committee for Standards and Quality (ACCSQ) – Pharmaceutical Product Working Group (PPWG) and was implemented on 1st September 2009. Consequently, a more detailed assessment of BE study reports received will be required. There are many applications which fail to meet this requirement. This has caused difficulties for NPCB in evaluating most reports as they do not follow the latest format.

3. Challenges with regards to the registration of veterinary products:
   - **Products for Aquaculture Use**
     Many companies involved in the aquaculture industry do not realise that products for aquaculture use with medicinal purposes must be registered with the DCA.
   - **Product Registration Requirements for Products used in Certain Animal Species in Small Quantities**
     Exemptions from registration have been given for products that are imported only in small quantities for specific use in certain species (specific purposes, minor species and minor use in animals), such as products used for wild animals or domestic animals in labs for research purposes. This matter must be fine tuned so that a clearer and more transparent mechanism can be established to overcome this problem.

4. The timeline for registration of products must be reduced as patients will benefit if products enter the market sooner. NPCB will review all steps involved in the product registration procedure in order to accelerate the product registration process in the future.

5. Efforts to harmonise the requirements for product registration among ASEAN countries is a challenge as each country has its own country specific requirements for product registration. The safety and quality of products must also be greatly emphasized for consumer safety without hindering the development of the local industry.

6. There is lack of understanding of some stakeholders especially Small and Medium Enterprises (SMEs) in complying with the PIF requirements such as safety assessment, labelling requirements, claims benefit and advertisement as well as

the technical knowledge on cosmetic ingredients. Therefore, training sessions and intensive workshops will be conducted to educate and achieve common understanding pertaining to the implementation of the ASEAN Cosmetic Directive (ACD).

7. Seminars to inform the industry about the latest updates on the ACD implementation and various important aspects of the ACD need to be conducted regularly to help improve the competency levels of both the regulator and the industry as well as to ensure common interpretations of the ACD for a smooth implementation of the cosmetic notification procedure.

8. Due to the free movement of cosmetics in the ASEAN Region, there exist possibilities of consumers having access to substandard products that make unsubstantiated claims. Thus, Consumer Awareness Programmes and seminars need to be conducted regularly to better educate and improve consumer satisfaction.

9. There is a need for the authority to develop competency and capability to conduct the Post Market Surveillance Programme (PMS) such as upgrading of laboratory capability and capacity to cope with the increasing number of product samples.

10. With the increasing detection of various analogues of Phosphodiesterase-5 (PDE5) inhibitors reported as adulterants in traditional products, it is a challenge for the NPCB to identify these analogues in the absence of reference standards.

11. Projects to expand the scope of accreditation under MS ISO/IEC 17025 which require strategic planning and efforts will include:
    - Validation of analytical methods used in the detection of :
        - Hydroquinone/tretinoin and steroids in cosmetics
        - Steroids and sildenafil analogues in traditional products
    - Validation of analytical methods for limit of Mercury (Hg) in traditional and cosmetic products
    - Measurement of Uncertainty (MU) on analytical methods for limit of Mercury (Hg) in traditional and cosmetic products

12. The upgrading of the QUEST2 to the QUEST3 system with the inclusion of online registration of New Chemical Entity (NCE) as well as biotechnology products in QUEST3 are expected to cause a significant increase in the number of enquiries from the public. To ensure staffs of NPCB are better equipped to handle this upcoming challenge, more training and workshops should be devised and provided.

13. With the technology advancement in the pharmaceutical industry, there has been growing interest from Contract Research Organisations (CRO) and investigators in conducting clinical research especially for the following areas in Malaysia:
    - First-in-Man trial or commonly known as the Phase I clinical trial
    - Stem cell
    - Advance Therapy Medicinal Product (ATMP)
    - Medical Device-Drug

    Subsequently, evaluating Clinical Trial Import License (CTIL) applications in these complex fields to ensure the quality, safety and efficacy of the innovative products require staff to undergo specialized training.

14. To ensure all Good Clinical Practice (GCP) principles in clinical research centres are being adhered to, an effective GCP inspection programme needs to be implemented.

15. With the national aspiration for Malaysia to get full adherence to the Mutual Acceptance of Data (MAD) System of the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) system, the NPCB is facing a challenge in getting Test Facilities which conducts non-clinical studies, complying with the OECD GLP and getting the GLP Certification.

16. To create a database to assist in the monitoring of existing or new cosmetic manufacturers.

17. To enhance the understanding of Good Manufacturing Practice (GMP) among local cosmetic and veterinary manufacturers. For example, by conducting seminars or dialogues between the local cosmetic manufacturers, veterinary manufacturers and the NPCB.

18. To organise seminars that provide training opportunity relating to GMP and Good Distribution Practice (GDP) for the local industries.

19. To carry out GDP inspections on licensed wholesalers and importers as well as the notified cosmetic importers.


# THE WAY FORWARD

1. It is known that Malaysia has set a target date to completely phase-out importation of products containing CFC as of 1st January 2010. The National Pharmaceutical Control Bureau (NPCB) plans to increase awareness regarding the use of MDI without CFC among patients and the public. There will be announcements in the mass media such as newspapers, radio and the television. The implementation is expected to start before June 2010.

2. The NPCB is in the process of implementing the registration of active pharmaceutical ingredients (API) which will be carried out during the registration of new products. This will be implemented prospectively for new product applications according to a timeline which consists of three phases such as:
   - Phase 1 : Prescription : September 2010
   - Phase 2 : Non-Prescription : 2011
   - Phase 3 : New Chemical Entity : 2012

   The work plan involves establishment of an API core team, continuous training, establishment of a technical working group (TWG) to draft the guidance document for the control of API, preparation of an online module system for registration, awareness programmes as well as public notification. This work plan will start from the year 2010 to 2014.

3. Initiatives will be carried out to strengthen the Post Market Surveillance (PMS) programme for notified cosmetics. This includes:
   a. The new Quest3 system is designed to enable the regulators to better control, handle and manage the Post Market Surveillance activities. Likewise, the new system will also benefit the industry as the system is more user-friendly and the notification process will be further simplified.
   b. Training of competent personnel to conduct systematic and educational PIF auditing
   c. Recognition of other criteria for targeted product sampling apart from the existing criteria i.e. hair dyes tested for heavy metal content
   d. Encourage industry (competitors) to provide information to the regulator as an initial input for PMS (e.g. label/claims)

4. Mutual partnership between the NPCB and the State Pharmacy Enforcement to monitor notified cosmetics in the local market via:
   a. Sampling of cosmetics from the retailers/distributer
   b. Verifying the availability of the adulterated/cancelled product at the retailers based on the list provided by the NPCB
   c. Monitoring of cosmetics advertisement
   d. Initial collaboration between the Pharmacy Enforcement and Customs to monitor product clearance at the entry point
   e. Systematic and smart system to verify the product status with the establishment of the new Quest3 system

5. Regular trainings and workshops will be held by the NPCB with the assistance of the industrial associations to create awareness and understanding of the PIF requirements as well as to increase the technical knowledge among the Small and Medium Enterprises (SMEs). In addition, the industrial associations which include the Cosmetic, Toiletries and Fragrance Association (CTFA) as well as the Federation of Malaysia Manufacturer (FMM) will also encourage the initiation of training among their members for better understanding of the ASEAN Cosmetic Directives (ACD) requirements.

6. The NPCB will further strengthen the registration activities of vaccines and biotechnology products through the establishment of related policies and guidelines, protocol reviews, GMP inspections, laboratory testing and collaboration with relevant stakeholders. In addition, the NPCB will continue to carry out research activities on method development and method validation for testing of traditional and cosmetic products as well as to intensify its research work on isolating analogues of PDE5 inhibitors from adulterated samples to be used as working standards.

7. The NPCB also plans to extend the scope of its accreditation under MS ISO/IEC 17025 to include the following tests:
   a. Test for the limit of mercury in traditional herbal products
   b. Test for the limit of mercury and lead in cosmetics
   c. Test for the detection of lovastatin in traditional herbal products

8. The NPCB aims to achieve full adherence to the Mutual Acceptance of Data (MAD) System of the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP). By adhering to the MAD, all non-clinical data produced in Malaysia will be accepted in other member countries. This will give a boost to Malaysia as one of the non-clinical studies hub in Southeast Asia.

9. To further improve the system for pharmacovigilance and pharmaceutical safety monitoring in clinical research, the NPCB will collaborate with the International Conference on Harmonization (ICH) - Global Cooperation Group (GCG) – ASEAN Collaboration to hold an ASEAN workshop pertaining to the Medical Dictionary for Regulatory Activities (MedDRA) and its application in safety drug monitoring. Benefits gained from the workshop will help the NPCB to prepare and implement a programme for pharmacovigilance and safety monitoring in clinical research.

10. Efforts are being taken to emphasize Information Technology (IT) culture within the organisation by increasing exposure of staff to IT as well as improving the current online registration system (by upgrading the QUEST2 system to the QUEST3 system). The NPCB is striving to upgrade the existing IT infrastructure in order to facilitate the implementation of online registration for New Chemical Entity (NCE) and Biotechnology products. In addition, the QUEST3 system will facilitate the integration of different online modules involving product registration, licensing of

premises, analytical testing, surveillance, Adverse Drug Reaction (ADR) monitoring as well as dissemination of information.

11. To create a database for cosmetic manufacturers as well as carrying out Good Distribution Practice (GDP) inspection on these premises.

12. To introduce and carry out inspection based on Good Distribution Practice (GDP) on all licensed wholesalers and importers.

13. To strengthen the local veterinary product manufacturers in terms of adherence to GMP requirements and to enforce licensing requirements as practiced overseas.

14. To increase participation of the NPCB at international level as a pioneer of traditional medicines manufacturing within the ASEAN region, such as by organising the PIC/S Seminar.

# SOCIAL ACTIVITIES

## ASSOCIATION OF WIVES AND LADIES OF MALAYSIAN CIVIL SERVICE (PUSPANITA)

In 2009, the NPCB PUSPANITA was led by Mr. Selvaraja Seerangam as its advisor. Thanks to the support from the advisor as well as the dedicated contribution from the president of the NPCB PUSPANITA, Dr. Sulaikah binti V.K. Moideen, this association successfully carried out various activities for its members as well as the staff of NPCB.

In collaboration with the NPCB Muslim Staff Welfare Association (BAKKI) and the NPCB Sports Club, all activities planned in 2009 were carried out smoothly and with great success. The response to these activities was overwhelming and this was a contributing factor to the increase in membership to a total of 167 members.

## COMMITTEE OF THE NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB) PUSPANITA

| | | |
|---|---|---|
| **PRESIDENT** | : | Dr. Sulaikah binti V. K. Moideen |
| **DEPUTY PRESIDENT** | : | Mdm. Noorul Akmar binti Mohd Nur |
| **SECRETARY** | : | Mdm. Maria binti Ja'afar |
| **ASSISTANT SECRETARY** | : | Mdm. Nahdia binti Ariffin |
| **TREASURER** | : | Mdm. Junainah binti Omar |
| **ASSISTANT TREASURER** | : | Mdm. Maslinda binti Mahat |
| **COMMITTEE MEMBERS** | : | Mdm. Narqes binti Mohd Raimi |
| | | Miss Khirul Falisa binti Mustafa |
| | | Mdm. Hasniza binti Zaidan |
| | | Miss Siti Norehan binti Jaafar |
| | | Miss Fadhilah binti Hasbullah |
| | | Mdm. Zuraidah binti Zainuddin |
| | | Mdm. Atikah binti Shaharudin |
| | | Mdm. Lahung Mering |
| | | Miss Noni Suliatikah binti Che Yusoff |
| | | Miss Jeannie Lee Jing Yi |
| | | Mdm. Normah binti Ali |
| | | Mdm. Aminah binti Jaafar |
| | | Mdm. Maznin binti Abdul Majid |

| NO. | ACTIVITIES IN 2009 |
|---|---|
| 1. | *Kitab Mihajul 'Abidin* Learning Class was held every week on Thursday |
| 2. | Involvement of Biro Seranta PUSPANITA NPCB in the production of *Buletin Sri Teratai* for PUSPANITA MOH |
| 3. | Participation in *Ceramah Anti Ragut dan Penderaan* organised by PUSPANITA MOH |
| 4. | Participation in Seminar *Kesihatan dan Kecergasan* organised by PUSPANITA MOH |
| 5. | 21st Annual General Meeting of PUSPANITA NPCB |
| 6. | Participation in *Majlis Sambutan Maulidur Rasul* organised by PUSPANITA IMR at Auditorium Ungku Omar, IMR |
| 7. | *Majlis Sambutan Maulidur Rasul* and religious talk entitled *Keunggulan Rasulullah* in conjunction with *Maulidur Rasul* |
| 8. | 26th General Meeting of *Perwakilan PUSPANITA Cawangan Kementerian Kesihatan Malaysia* in Auditorium Mutiara, IPK |
| 9. | Participation in Seminar *Kepimpinan Berkesan Dalam Kerjaya, NGO dan Keluarga melalui Neuro-Linguistic Programming (NLP)* |
| 10. | Participation in *Ceramah Hak-hak Wanita dari Aspek Undang-undang Syariah dan Sivil* organised by PUSPANITA IKU/IPK/IPSK/IPTK |
| 11. | Netball Tournament in collaboration with NPCB Sports Club |
| 12. | *Seminar Mahligai Kasih – Semakin Hari Semakin Sayang* |
| 13. | *Majlis Jasamu Dikenang* organised by PUSPANITA MOH |
| 14. | Volleyball Tournament in collaboration with NPCB Sports Club |
| 15. | Health Seminar: *Penglihatan & Kesihatan Mata – Risiko dan Pencegahannya* organised by PUSPANITA Kebangsaan |
| 16. | Carom Games in collaboration with NPCB Sports Club |
| 17. | Congkak Games in collaboration with NPCB Sports Club |
| 18. | Participated in *Majlis Ramah Mesra Bersama Penaung PUSPANITA, Datin Seri Paduka Rosmah Mansor* |
| 19. | Seminar & Health Screening for all NPCB staff |
| 20. | *Tadarus Al-Quran* during the month of Ramadhan |
| 21. | *Majlis Khatam Al-Quran* and religious talk entitled *Wanita dan Al-Quran* |
| 22. | Participated in Motivation Talk: *Keberkatan Rezeki Dalam Perkhidmatan* organised by PUSPANITA MOH |
| 23. | Hari Raya Aidilfitri and Deepavali Celebration MOH 2009 |
| 24. | Seminar *Personaliti Unggul – Serlahkan Keanggunan Anda Secara Sihat!* |

## NPCB MUSLIM STAFF WELFARE ASSOCIATION (BAKKI)

Established in the year 1979, BAKKI has carried out welfare related activities for 31 years. As BAKKI works very closely with PUSPANITA, many activities were jointly organised such as lecture events, prayers for the deceased and so forth. In 2009, six sessions of prayers for the deceased were held, of which two were for NPCB officers who had passed away and the others were for relatives of members who had passed away.

# PARTICIPATION IN INTERNATIONAL AND LOCAL EVENTS

## PARTICIPATION OF NPCB IN INTERNATIONAL EVENTS, 2009

| NO. | ACTIVITY | DATE | VENUE |
|---|---|---|---|
| 1. | GMP Inspection on Premises where Manufactured Products are Imported and Marketed in Malaysia | 5-9 January | Mumbai, India |
| 2. | Study Visit by Minister of Health Malaysia | 18-23 January | People's Republic of China |
| 3. | ASEAN Cosmetic Committee (ACC) Head of Delegation Workshop | 2-5 February | Brunei Darussalam |
| 4. | Advanced Workshop: Review of Drug Development Clinical Trial | 2-6 February | Bangkok, Thailand |
| 5. | 2nd Drug Safety Conference | 17-18 February | Singapore |
| 6. | 3rd Annual Meeting of International Regulatory Cooperation for Herbal Medicines (IRCH) | 24-27 February | Montreal, Canada |
| 7. | 21st Drug Information Association (DIA) Annual Euromeeting | 23-25 March | Berlin, Germany |
| 8. | Good Manufacturing Practice (GMP) Inspection on Premises where Sterile Manufactured Products are Imported and Marketed in Malaysia | 30 Mac – 2 April | Bangkok, Thailand |
| 9. | 21st Meeting of the Working Group of National Coordinators of the Test Guidelines Programme | 31 Mac – 2 April | Paris, France |
| 10. | World Health Organization Pre-Qualification Programme: Priority Essential Medicines Good Manufacturing Practices (GMP) | 31 Mac – 5 April | Geneva, Switzerland |
| 11. | GMP Inspection on Premises where Manufactured Products are Imported and Marketed in Malaysia | 14-16 April | Indonesia |
| 12. | Centre for Drug Evaluation and Research (CDER) Forum for International Drug Regulatory Authorities | 20-24 April | Maryland, USA |
| 13. | 7th EGA Annual Symposium on Biosimilar Medicines | 23-24 April | London, United Kingdom |
| 14. | Pharmaceutical Inspection Co-operation Scheme – Working Group on the Training of Inspectors & Meeting of Committee Officials | 3-8 May | Geneva, Switzerland |
| 15. | Training in Good Laboratory Practice (GLP) Compliance Monitoring Programme, GLP Inspections and Non-clinical Study Audits | 4-8 May | Kjeller, Norway |
| 16. | 23rd Meeting of the Working Group on Good Laboratory Practice | 12-14 May | Paris, France |
| 17. | 16th ASEAN Consultative Committee on Standards & Quality Pharmaceutical Products Working Group (ACCSQ-PPWG) Meeting | 25-29 May | Manila, Philippines |
| 18. | World Vaccine Congress Asia 2009 | 8-11 June | Singapore |
| 19. | Multi-Regional Clinical Trials Seoul Workshop Inaugural Workshop of the APEC Harmonization Center | 15-18 June | Seoul, Korea |
| 20. | 12th ASEAN Cosmetic Committee (ACC) and the 11th ASEAN Cosmetic Scientific Body (ACSB) Meetings | 23-25 June | Kuala Lumpur, Malaysia |
| 21. | 14th Meeting on the Production of ASEAN Reference Substance | 23-25 June | Thailand |
| 22. | Regional Workshop on the Implementation of the ASEAN Guidelines on Good Manufacturing Practice (GMP) | 28 June-3 July | Jakarta, Indonesia |

| NO. | ACTIVITY | DATE | VENUE |
|---|---|---|---|
| 23. | SDFA Meeting following the study visit by Minister of Health Malaysia | 1-4 July | People's Republic of China |
| 24. | 2009 Asian Healthcare Forum | 8-9 July | Singapore |
| 25. | International Association of Biologicals (IABS) Workshop | 13-14 July | Ottawa, Canada |
| 26. | WHO Consultation on Regulatory Considerations in Evaluating Similar Biotherapeutic Products | 15-16 July | Ottawa, Canada |
| 27. | WHO Global Training Network - Clinical Trial Evaluation Training Course | 27-31 July | Jakarta, Indonesia |
| 28. | 11th Meeting of the ASEAN Consultative Committee for Standard and Quality (ACCSQ)-Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) | 27-31 July | Bali, Indonesia |
| 29. | Meeting Consultation on WHO Guidelines for Medicines Quality Assurance, Quality Control Laboratories and Technology Transfer | 27-31 July | Geneva, Switzerland |
| 30. | Invitation to the APEC Harmonization Center Biosimilar Workshop | 16-18 September | Seoul, Korea |
| 31. | Regulatory Pathways for Dengue Vaccines Workshop | 1-2 October | Bangkok, Thailand |
| 32. | 9th Organisation for Economic Co-operation and Development (OECD) Training Course for GLP Inspectors | 4-9 October | Basel, Switzerland |
| 33. | Regional Workshop for ASEAN Cosmetic Testing Laboratory Network (ACTLN) | 19-23 October | Bangkok, Thailand |
| 34. | Lecture on 2009 Forum of Cosmetic Regulation and GMP Updates | 19-24 October | Taipei, Taiwan |
| 35. | 1st ASEAN Regional ASEAN Common Technical Documents (ACTD) and ASEAN Common Technical Requirements (ACTR) Training the Trainers on Part I: Administrative Data and Part II: Quality | 26-30 October | Manila, Philippines |
| 36. | Meeting of PIC/S Committee of Officials and PIC/S Seminar on Aseptic and Sterile Manufacturing from API to Finished Dosage Forms Mesyuarat ASEAN Working Group on Pharmaceuticals Development | 2-6 November | Uppsala, Sweden |
| 37. | 25th Meeting of the ASEAN Working Group on Pharmaceuticals Development (AWGPD) | 3-5 November | Singapore |
| 38. | PIC/S Seminar on Aseptic and Sterile Manufacturing from Active Pharmaceutical Ingredient (API) to Finished Dosage Forms / Attachment with Swedish Medical Product Agency | 4-13 November | Uppsala, Sweden |
| 39. | WHO Global Training Network - GCP Inspection Training Course | 9-13 November | Jakarta, Indonesia |
| 40. | L'Oreal Safety Seminar | 20 November | Singapore |
| 41. | Meeting and Workshop of Regulatory Authorities | 22-24 November | Geneva, Switzerland |
| 42. | 12th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ)-Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) | 23-26 November | Siam Reap, Cambodia |
| 43. | 13th ASEAN Cosmetic Committee (ACC) and 12th ASEAN Cosmetic Scientific Body (ACSB) Meetings | 1-3 December | Chiang Mai, Thailand |

| NO. | ACTIVITY | DATE | VENUE |
|---|---|---|---|
| 44. | Consultation Meeting for National Pharmacopoeia / Authorities of Observer States to the European Pharmacopoeia Commission | 3-4 December | Strasbourg, France |
| 45. | ASEAN-EU Programme for Regional Integration Support – Phase II (APRIS II), Regional Workshop on ASEAN Common Technical Requirements (ACTR) | 3-4 December | Vientiane, Lao PDR |
| 46. | Traditional Medicine Expo 2009 | 4-6 December | Singapore |
| 47. | WHO Workshop on Implementation of Lot Release of Vaccines | 8-10 December | Beijing, China |
| 48. | ASEAN-EU Programme for Regional Support (APRIS II) Technical Assistance – Regional Training on Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice Requirements | 10-11 December | Singapore |

## PARTICIPATION OF NPCB IN LOCAL EVENTS, 2009

| NO. | ACTIVITY | DATE | VENUE |
|---|---|---|---|
| 1. | Visit to Olipro Biotechnology Sdn. Bhd. | 18 February | Olipro Biotechnology Sdn. Bhd., Selangor |
| 2. | Quality Report Writing and Proposal Paper Course | 17-20 March | INTAN, Kuala Lumpur |
| 3. | Induction Course: General & Specific Modules | 15-29 March | Golden Straits Villa, Port Dickson |
| 4. | Professional *Halal* Workshop Pharmaceutical Industry | 13-14 April | HDC & CCM Pharma |
| 5. | 7th International Traditional & Complementary Medicine Conference (INTRACOM) and 2nd International Conference on Biotechnology for The Wellness Industry (ICBWI) | 23-26 July | Putra World Trade Centre, Kuala Lumpur |
| 6. | Seminar on Dietary Fibre – Current Science and Regulatory Update | 28 September | Crowne Plaza Mutiara Hotel, Kuala Lumpur |
| 7. | Malaysian Organisation of Pharmaceutical Industries (MOPI): Bioanalytical Seminar | 29 September | MOPI, Petaling Jaya |
| 8. | Pharmacy Quality Convention 2009 | 23-25 November | Summit Hotel, Subang Jaya |
| 9. | Effective Secretarial Skill Workshop | 9-10 December | Dorsett Regency Hotel, Kuala Lumpur |

## COLLABORATION WITH LOCAL INDUSTRIES

The NPCB is actively involved in organising meetings, Technical Working Groups (TWG) and dialogues with the local industry, industry associations, health professionals, academia, consumers as well as other stakeholders to ensure all concerned are kept abreast of relevant developments in the NPCB as well as the regulatory arena. A total of seven dialogue sessions were conducted in 2009, as listed below:

| ASSOCIATION/INDUSTRY | DATE |
|---|---|
| *Persatuan Pengeluar Ubat Cina Malaysia* (PPUCM) | 16 March |
| Cosmetic, Toiletry and Fragrance Association (CTFA) | 7 August |
| Federation of Malaysian Manufacturers Malaysian Cosmetics and Toiletries Industry Group (FMM MCTIG) | 7 August |
| Pharmaceutical Association of Malaysia (PhAMA) | 19 August |
| Malaysian Direct Distribution Association (MDDA) | 25 August |
| Malaysian Organisation of Pharmaceutical Industries (MOPI) | 20 April<br>30 November |

# INTERNATIONAL AND LOCAL VISITORS


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

The NPCB provides courses which are specifically designed to suit their needs which include peer GMP Inspection, module pertaining to drug registration, pharmacovigilance as well as post-marketing and surveillance activities. Other areas include training in pharmaceutical analysis which includes testing of traditional medicines, chemical, microbiology, pharmacology and toxicology test methods, dosage performance as well as preparation and handling of reference standards.

Apart from international visitors in the year 2009, there were also requests from local universities/academic institutions and local companies to visit the NPCB. The details of the international and local visitors are as shown below:

## INTERNATIONAL VISITORS

| DATE | ORGANISATION | COUNTRY | NO. OF VISITORS |
|---|---|---|---|
| 10-20 March | National Drug Quality Assurance Laboratory, MOH | Sri Lanka | 2 |
| 31 March | Ministry of Chemicals and Fertilizers, Govt. of India & Representative from Industry | India | 27 |
| 25 May | Pharmacists | Sudan | 11 |
| 20 July | Department of Ayush, Ministry of Health and Family Welfare & Representative from the Indian Traditional Medicine Industry | India | 19 |
| 6 August | Food & Drug Authority (KFDA) | Korea | 5 |
| 5-9 October | National Institute of Drug Quality Control & Drugs, Cosmetics and Food Quality Control Centre | Vietnam | 4 |
| 19 October | Regulators from Drug Administration | Vietnam | 7 |
| 5 November | Representative from ASEAN Countries | ASEAN | 20 |
| 5 November | Ministry of Health, Hanoi | Vietnam | 4 |
| 9-10 November | National Agency of Drug and Food Control (NADFC) & Bandung Institute of Technology | Indonesia | 4 |
| 23 November | State Administration of Traditional Chinese Medicine (SATCM) | China | 7 |
| 30 November-10 December | Directorate of Drug Administration, Ministry of Health and Family Welfare | Bangladesh | 1 |
| 14-24 December | Officers from Pharmacy Services Department, Ministry of Health | Brunei Darussalam | 3 |

## LOCAL VISITORS

| DATE | INSTITUTION | DELEGATES | NO. OF VISITORS |
|---|---|---|---|
| 20 January | Asian Institute of Medicine, Science & Technology (AIMST) University, Kedah | 72 Students and 5 Lecturers | 77 |
| 24 February | Pharmacy Enforcement Johor Branch | Officers | 18 |
| 8 May | Food Safety & Quality Division (BKKM) | Director and 10 delegates | 11 |
| 8 July | Pharmaceutical Services Division | New officers from the Pharmaceutical Services Division | 22 |
| 21 October | Malaysian Administrative Modernisation & Management Planning Unit (MAMPU) | Officers | 4 |
| 5 November | Department of Veterinary Services (DVS) | Officers | 11 |
| 9-10 November | Universiti Malaya & the Clinical Research Centre, Hospital Kuala Lumpur | Officers | 2 |
| 16 November | Cyberjaya University College of Medical Sciences (CUCMS), Selangor | Year 4 Students and 2 Lecturers | 25 |