

# WHO ANNUAL REPORT 2006

## 1. NAME OF COLLABORATING CENTRE

**WHO Collaborating Centre for Regulatory Control of Pharmaceuticals**

## 2. ADDRESS

National Pharmaceutical Control Bureau  
Ministry of Health Malaysia  
Jalan Universiti  
P.O. Box 319  
46730 Petaling Jaya  
Selangor Darul Ehsan  
MALAYSIA.

Tel: 03-79573611

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## 3. TERMS OF REFERENCE

- 3.1 To act as a reference centre and support for matters pertaining to pharmaceutical quality assurance and regulatory affairs.
- 3.2 To continue to collaborate in the current on-going collaborating project among quality control laboratories of ASEAN countries to produce pharmaceutical reference standards.
- 3.3 To provide training in all aspects of pharmaceutical quality assurance programme.
- 3.4 To carry out product analysis for reference purposes or on behalf of countries lacking quality control laboratories.
- 3.5 To establish a co-coordinating network for monitoring regulatory matters pertaining to product recall, product defects and other related matters.
- 3.6 To provide training on computerization on handling drug regulatory matters.
- 3.7 Closer collaboration with WHO in drug regulatory matters, especially in the field of inspection.
- 3.8 Providing support for training and capacity building of other regional national Drug Regulatory Authorities.
- 3.9 Collaboration in the evaluation of dossiers received from manufacturers expressing interest in the supply of drugs for the treatment of HIV/AIDS, malaria and tuberculosis.

#### 4. **STAFF LIST**

##### **Head of Centre**

- Eisah bt. A. Rahman – B. Pharm, M. Sc., Dip. Medical Microbiology

##### **Deputy Heads**

- Selvaraja Seerangam – B. Pharm (Hons), M. Phil.

##### **Officers**

1. Abida Haq bt Syed M. Haq – B. Pharm (Hons), Dip Med Microbiology, M. Clin Pharmacy
2. Abdullah Hisham Bin Ahmad Yaya – B. Pharm ( Hons ), M. Pharm (Clinical Pharmacy)
3. Ahmad Syamsury bin Sulaiman – B. Pharm (Hons)
4. Ahmad Zakhi bin Ramli – B. Pharm (Hons)
5. Aida Haryati bt. Abd. Rahim – B. Pharm (Hons)
6. Ani bt Abdullah - B. Pharm (Hons)
7. Anis bt Talib - B. Pharm (Hons)
8. Aryani bt Ahmad - B. Pharm (Hons)
9. Arpah bt Abas - B. Pharm(Hons)
10. Asnida bt Mat Daud - B. Pharm (Hons)
11. Aswani Yanti binti Baharuddin - B. Pharm (Hons)
12. Azraini bt Abdul Samat - B. Pharm (Hons)
13. Azrina bt Hassan - B. Pharm (Hons)
14. Azura bt Abdullah - B. Pharm (Hons)
15. Azlina bt. Ismail – B. Pharm (Hons)
16. Basmiah bt Md. Isa - B. Pharm (Hons)\*
17. Bariah bt. Abdul Rani – B.Pharm (Hons)
18. Belinna Binti Abu Bakar - B. Pharm (Hons)
19. Chin Fui Fui - B. Pharm (Hons)
20. Chiong Yuh Lian – B. Pharm (Hons)
21. Chua Hui Ming – B. Pharm (Hons)
22. Debbie Sim Sook En - B. Pharm (Hons)
23. Faridah bt Hj. Abd. Malek - B. Pharm (Hons)
24. Fazillahnor Binti Ab. Rahim - B. Pharm (Hons)
25. Fuziah bt. Abdul Rashid – B. Pharm ( Hons )
26. Halimatussa'adiyah bt. Mat Som – B. Pharm (Hons)
27. Hasenah bt. Ali - B. Pharm (Hons), M. Sc, Ph D
28. Hasniza bt. Zaidan – B. Pharm (Hons)\*
29. Hazlinda Nazli bt Naem - B. Pharm (Hons)
30. Ida Syazrina bt Ibrahim - B. Pharm (Hons)
31. Irdawaty bt. Mohd. Salleh – B. Pharm (Hons)
32. Juanah Binti Garabus – B. Pharm (Hons)
33. Kadariah bt. Mohd. Ali - B. Pharm (Hons), M. Sc
34. Kamaruzaman b. Saleh ( Dr. ) - B. Pharm (Hons), M. Sc, Ph D
35. Kamarudin bin Ahmad – B. Sc. (Pharm)
36. Khirul Falisa Binti Mustafa - B. Pharm (Hons)
37. Leong Yet Lee – B. Pharm (Hons)
38. Lian Lay Kim - B. Pharm (Hons)
39. Low Joo Meing - B. Pharm (Hons)
40. Maria binti Ja'afar - B. Pharm (Hons)
41. Maslinda Binti Mahat - B. Pharm (Hons)
42. Masnor binti Mat Daud - B. Pharm (Hons)
43. Mazli bt. Muhamad - B. Pharm (Hons), M. Sc.
44. Mazuwin bt. Zainal Abidin - B. Pharm (Hons), M. Sc

45. Mohd. Nasrul b. Mohamad Noor – B. Pharm (Hons)
46. Mokhtar bin Abdullah - B. Pharm (Hons)
47. Muhammad Lukmani b. Ibrahim - B. Pharm (Hons)
48. Muhammad Nasir bin Hashim - B. Pharm (Hons)
49. Nik Juzaimah bt Nik Juhari – B. Pharm (Hons)
50. Nik Shamsiah bt Nik Salleh - B. Pharm (Hons)
51. Noor'ain bt. Shamsuddin – B. Pharm (Hons)
52. Noraida binti Mohamad Zainoor - B. Pharm (Hons)\*
53. Noraisyah bt Mohd. Sani - B. Pharm (Hons)
54. Noorizam bt. Ibrahim – B. Pharm (Hons), M. Pharm
55. Nor Hafizah bt. Mohd. Potri – B. Pharm (Hons)
56. Noor Hidayah bt. Mohd. Nor – B. Pharm (Hons)
57. Norhayati bt. Musa – B. Pharm (Hons)
58. Nor Hayati Abdul Rahim – B. Pharm (Hons)
59. Norshida binti Kassim - B. Pharm (Hons)
60. Norul Azmira bt. Abu Bakar – B. Pharm. (Hons)
61. Nurhayati bt. Omar – B. Pharm (Hons)
62. Nurhayati bt. Othman – B. Pharm (Hons)
63. Norleen bt. Mohamed Ali – B. Pharm (Hons)
64. Nurul Fajar bt Mohd. Jamid - B. Pharm (Hons)\*
65. Ong Yi Chin - B. Pharm (Hons)
66. Rohani bt Ismail – B. Pharm, M. Sc
67. Rosilawati bt Ahmad - B. Pharm (Hons), M. Sc.
68. Saleha bt. Md. Ewan - B. Pharm (Hons)
69. Sarawani binti Hassan - B. Pharm (Hons)
70. Seetha a/p Ramasamy - B. Pharm (Hons)
71. Siti Hidayah bt. Kasbon – B. Pharm (Hons)
72. Siti Madziah bt. Mohamed - B. Pharm (Hons), M. Pharm
73. Somiyaton bt Dahalan @ Damuri - B. Pharm (Hons)
74. Sufian Hardi bin Mohamad Zuhair - B. Pharm (Hons)
75. Suhaili Binti Samad - B. Pharm (Hons)
76. Sulaikah bt V.K. Moideen ( Dr. ) - B. Pharm (Hons), M. Sc, Ph D
77. Suhailah bt Abu Bakar - B. Pharm (Hons)
78. Suzana binti Mohd. Nor- B. Pharm (Hons)
79. Tan Ann Ling - B. Pharm (Hons)
80. Tan Lie Sie - B. Pharm (Hons)
81. Tan Szi Szi – M. Pharm
82. Tan Teck Koon - M. Pharm
83. Teo Yen Teng - B. Pharm (Hons)
84. Tg. Mira binti Tengku Fatimi - B. Pharm (Hons)
85. Wan Nurul Aina bt. Mior Abdullah – B. Pharm (Hons)
86. Wan Othman Wan Ismail - B. Pharm (Hons)
87. Yvonne Khoo Siew Khoo – B. Pharm (Hons)
88. Yusni Rizal b. Khairul Anuar – B. Pharm (Hons)
89. Zahura bt. Mohamed @ Ismail - B. Pharm (Hons)
90. Zakiah bt Abd. Ghafar - B. Pharm (Hons)
91. Zaryl Harza b. Zakaria – B. Pharm (Hons)
92. Zarina bt Rosli - B. Pharm (Hons)
93. Zuraida bt Abdullah - B. Pharm (Hons)\*

#### Provisionally Registered Pharmacist

1. Cheong Wing Loong - B. Pharm (Hons)
2. Ching Shan Lii - B. Pharm (Hons)
3. Hana Radhiah binti Mohd. Din - B. Pharm (Hons)
4. Kok Chuan Fung - B. Pharm (Hons)

5. Mazlifah binti Mohd. Fahimi - B. Pharm (Hons)
6. Mohamed Shahrizan b. Shahrir - B. Pharm (Hons)
7. Muhd. Fakrurazi bin Ahmad Fadzil - B. Pharm (Hons)
8. Narqes binti Mohd. Raimi - B. Pharm (Hons)
9. Nik Zurianiarina binti Mohd. Zaki - B. Pharm (Hons)
10. Norul Aishah binti Mohd. Yunus - B. Pharm (Hons)
11. Raffik Najmuddin bin Jamaludin - B. Pharm (Hons)
12. Tan Shiau Yi - B. Pharm (Hons)

**TOTAL NUMBER OF PHARMACISTS – 107**

(\* 5 posts borrowed from other government agencies)

**Other Support Staff**

- Pharmacy Assistants - 65
- Science Officers (temporary staff) - 26
- Administrative and Support Staff – 34
- Administrative and Support Staff (temporary staff) - 14

**TOTAL NUMBER OF STAFF: 246**

**5. ACTIVITIES OF THE COLLABORATING CENTRE**

**5.1 Training for WHO Fellows**

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia continues to provide training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries.

Throughout the year 2006, the centre recorded a total of **68** international visitors and WHO fellows from various countries namely Bhutan, Brunei Darussalam, China, Egypt, India, Philippines, Singapore, Sri Lanka, Taiwan and Tanzania.

The courses provided under this program are designed specifically to gratify the needs of the individual fellows. For example, training in pharmaceutical analysis which includes dosage performance testing, testing of traditional medicines, chemical, microbiological, pharmacological and toxicological test methods as well as preparation and handling of reference standards are provided to personnel with laboratory background. Other areas of training include aspects pertaining to drug registration, pharmacovigilance, post-marketing surveillance activities, GMP requirements and licensing system.

**5.2 Collaborative Studies for the Production of ASEAN Reference Standards**

In 2006, the National Pharmaceutical Control Bureau (NPCB) completed the re-standardisation of reference standards supplied to the ASEAN countries. The said reference standards are as listed below:

Date	Type	Reference standard	Batch No
10/26/2006	ASEAN	Riboflavin	M 203012
10/26/2006	ASEAN	Propyl Paraben	M 103127
10/27/2006	ASEAN	Methyl Paraben	M 103126

### **5.3 Network for Surveillance and Pharmacovigilance**

In 2006, the NPCB, as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) received a total of 94 Rapid Alerts sent out by PIC/S member countries pertaining to products with quality defects which were being recalled from the market. Malaysia in turn sent out 2 Rapid Alerts.

Under the ASEAN Harmonisation Scheme, a total of 4 Post- Market Alerts were received mainly from Singapore while 7 Post Market Alerts were sent out.

Malaysia also participated actively in the Vigimed system which is a forum mainly for exchange of information pertaining to pharmacovigilance coordinated by the Uppsala Monitoring Centre.

### **5.4 WHO Collaboration in the Field of GMP Inspection**

The NPCB collaborated with the WHO in conducting GMP inspections of pharmaceutical manufacturing factories in Malaysia and also participated in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) reassessments of MHRA of United Kingdom and ENAME of Argentina.

### **5.5 Collaboration with other Regional National Regulatory Authorities**

Through the year 2006, NPCB participated in two Proficiency Testing Schemes for pharmaceuticals organised by EDQM under the EC-ASEAN programmes. In the same year, NPCB has undertaken a new collaboration work with EDQM involving an antibiotic assay. With the encouraging results obtained on nystatin assay, NPCB hopes to continue the projects on other antibiotics.

### **5.6 WHO Collaboration**

NPCB continued to participate in various testing programmes organised by WHO. In the year 2006, NPCB collaborated with WHO for External Quality Assurance Assessment Scheme (Phase 3) on 5 pharmaceuticals involving various chemical analytical techniques.

### **5.7 Staff Development**

In 2006, a number of officers from the centre participated in training courses in several areas to upgrade and improve their knowledge and skills.

#### **5.7.1 Postgraduate studies**

- |      |                            |                      |
|------|----------------------------|----------------------|
| i)   | Noraida bt Mohamad Zainoor | - PhD (2005 – 2008)  |
| ii)  | Mokhtar bin Abdullah       | - M Sc (2005 – 2006) |
| iii) | Muhammad Nasir b Hashim    | - M Sc (2005 – 2006) |

#### **5.7.2 Participation of staff in local courses / seminars / meetings**

The following courses/ seminars/ meetings were held in 2006.

- Biotech/NCE Preview

No	Activity	Date	Venue
1	NCE Preview - Bonviva/Bondronat	13 Jan 06	NPCB
2	NCE Preview - Entecavir In The Treatment Of Chronic Hepatitis B	17 Feb 06	NPCB
3	NCE Preview -Macugen	18 Apr 06	NPCB
4	NCE Preview - Caduet	21 Apr 06	NPCB
5	NCE Preview - Reyataz in the Treatment of HIV-1 infection	20 Jul 06	NPCB
6	Biotech Preview - Rotateq (Rotavirus vaccine) & Gardasil (HPV Vaccine)	21 Jul 06	NPCB
7	NCE Preview - Exjade (Deferasirox)	28 Jul 06	NPCB
8	NCE Preview - Erbitux, Niaspan & New Development in EU Regulations	29 Aug 06	NPCB
9	NCE Preview - Sutent	15 Sep 06	NPCB
10	Biotech Preview - Lucentis	1 Dec 06	NPCB
11	NCE Preview - Sorafenib	8 Dec 06	NPCB
12	NCE Preview - Tykerb	15 Dec 06	NPCB

- Conference and Symposium

No	Activity	Date	Venue
1	The 10 <sup>th</sup> International Symposium on Oncology Pharmacy Practice ISOPP X-2006	3-6 Apr 06	Kuala Lumpur
2	The Pharmacist Symposium On Osteoporosis	26-28 May 06	Langkawi
3	National Summit Symposium on Breast Cancer Education	1 Jul 06	Selangor
4	National Conference on Research Priorities for RM9	27-28 Jul 06	Selangor
5	Women's Health and ASIAN Traditional Medicine (WHAT Medicine) Conference 2006	28-30 Jul 06	Kuala Lumpur
6	The 6 <sup>th</sup> Pharmacy Scientific Conference 2006	8-10 Sep 06	Kuala Lumpur
7	The 4 <sup>th</sup> Research & Development Pharmacy Conference 2006	26-30 Nov 06	Malacca
8	A Global Perspective Conference on Counterfeit Pharmaceuticals	5 Dec 06	Selangor

- Course

No	Activity	Date	Venue
1	In-house Induction Course NPCB 01/2006	15 Feb 06	NPCB
2	Evaluation Competency Level 4 Course Session 01/2006 <Kursus Penilaian Tahap Kecekapan 4 (PTK 4) Bil 01/2006>	26-31 Mar 06	Selangor
3	Performance and Management Course for Officers in the Public Sector - Session 02/2006	5-7 Apr 06	Langkawi
4	Career Motivation for Pharmacy Assistants 2006	29 Apr 06 – 01 May 06	Langkawi
5	Basics and Principles of GCMS in Pharmaceutical Analysis	16-17 May 06	Kuala Lumpur
6	Legislation and Regulatory Control	24 May 06	Pahang
7	Motivation Course for Pharmacists ('PERASA')	24-27 May 06	Selangor
8	In-house Induction Course NPCB Session 02/2006	21 Jun 06	NPCB
9	Public and Private Induction Course for Professional Management and Support Group	26 Jun 06 – 09 Jul 06	Perak

No	Activity	Date	Venue
10	Intelligence and Raids	10-13 Jul 06	Perak
11	Motivation Course for Pharmacists ('PERASA')	19-22 Jul 06	Perak
12	Evaluation Competency Level 1 Course (PTK 1)	10-14 Aug 06	Kuala Lumpur
13	Evaluation Competency Level 4 Course Session 04/2006 (PTK 4)	13-20 Sep 06	Selangor
14	Quality Control of Traditional Products - MLT	18-22 Sep 06	NPCB
15	In-house Induction Course NPCB Session 03/2006	18 Sep 06	NPCB
16	Items H1122	2 Oct 06	NPCB
17	Introduction Course to ISO 9001:2000	6 Oct 06	Kuala Lumpur
18	Cardio Pulmonary Resuscitation	1-2 Nov 06	NPCB
19	Evaluation Competency Level Course for Pharmacy and Medical Officers	8-10 Nov 06	Kuala Lumpur
20	Evaluation Competency Level 4 Course (PTK4)	21-22 Nov 06	NPCB
21	Internal Audit Course ISO 9001:2000	21-23 Nov 06	Selangor
22	Evaluation Competency Level 4 Course (PTK4)	22-29 Nov 06	Selangor

- Seminars

No	Activity	Date	Venue
1	GC/MS, LC/MS Spectrometry	1 Mar 06	Kuala Lumpur
2	Health & Beauty	3 Mar 06	Selangor
3	Pharmaceutical Quality Control Involving Equipment Qualification, Weighing Criteria/Requirement & Measurement of Uncertainty	30 Mar 06	NPCB
4	Current Trends in HPLC Methodology	6 Apr 06	Selangor
5	Pharmacist Care in the Management of Diabetes Mellitus	15-16 Apr 06	Selangor
6	Eye Care: Modern Refractive Surgery	17 Apr 06	NPCB
7	Complementary and Traditional Medicine (Middle Zone)	24-25 Apr 06	Selangor
8	New Trend Sanitizer	28 Apr 06	Kuala Lumpur
9	Agilent Regulatory Compliance	2 May 06	Selangor
10	Differences between European Union (EU) & US Drug Master File (DMF)	16 May 06	NPCB
11	Regulatory and Quality Control of Medicines	17 May 06	Selangor
12	Particle Measurement Technology	6 Jun 06	Kuala Lumpur
13	Scientific Programme on Vaccines 2006	24-25 Jun 06	Putrajaya
14	Personnel ICT in Public Sector	3-4 Jul 06	Selangor
15	Cyclotron and PET in Medicine Workshop (FNCA)	14-15 Aug 06	Kuala Lumpur
16	Complementary and Traditional Medicine	22-23 Aug 06	Pahang
17	Elemental Techniques Solutions	6 Sep 06	Selangor
18	Manual and Automated Dissolution Testing	12 Sep 06	Putrajaya
19	Medicinal and Aromatic Plants 2006 (FRIM)	12-13 Sep 06	Selangor
20	Solid Phase Extraction Solutions	19 Sep 06	Selangor
21	Microbial Monitoring for Pharmaceutical Industry (MILLIPORE)	18 Oct 06	Selangor
22	Information update for Pharmacy Assistant 2006	9-10 Nov 06	NPCB
23	FUME Cupboard Safety Alarms System	14 Nov 06	NPCB

No	Activity	Date	Venue
24	Health Supplement Seminar 2006	22 Nov 06	Kuala Lumpur
25	Products Safety for Consumers	27-28 Nov 06	Kuala Lumpur
26	National GMP Seminar 2006	19-21 Dec 06	Selangor

- Talks

No	Activity	Date	Venue
1	MycoAlert RM: A Rapid Bioluminescent Method for Detecting of Mycoplasma and Other Molecules	21 Mar 06	NPCB
2	Advance Digital Imaging for Early Breast Cancer Detection	23 Mar 06	NPCB
3	Menopause & Hormone Replacement Therapy	14 Apr 06	NPCB
4	Filling System	20 Apr 06	NPCB
5	HPV & Cervical Cancer	5 May 06	NPCB
6	Basic and Principles of HPLC in Pharmaceutical Analysis	8-9 May 06	Kuala Lumpur
7	Hepatitis B	22 May 06	NPCB
8	Hepatitis B & Their Treatment Advancements	20 Jun 06	NPCB
9	General Order for Government Servant	21 Jun 06	NPCB
10	a) Fakes, Counterfeits - what's in it? b) Forteo, Teriparatide rhPTH (1-34)	19 Jul 06	NPCB
11	Introducing Cardinal Health Australia's Animal Free Soft Capsules	19 Jul 06	NPCB
12	Validation of Analytical Procedures for Testing of Heavy Metal	24 Jul 06	NPCB
13	Current Management of Vulvovaginal Candidiasis	6 Aug 06	Kuala Lumpur
14	Dehydrated Culture Media	6 Sep 06	NPCB
15	Auditing Technique: Test for Microbial Contamination	13 Sep 06	NPCB
16	Polymorphism & Zone IV Stability Study	4 Oct 06	NPCB
17	Bioequivalence & Therapeutic Equivalence	5 Oct 06	NPCB
18	Varian Atomic Absorption Spectrophotometry	27 Nov 06	NPCB
19	Health Risks Associated with Abdominal Obesity	1 Dec 06	NPCB
20	Drug Free Working Environment	13 Dec 06	NPCB
21	Environmental Health Forum	19 Dec 06	Kuala Lumpur
22	Fire Safety and Evacuation	20 Dec 06	NPCB

- Training

No	Activity	Date	Venue
1	MOPI Training (Module 1: International GMP's and Quality Assurance)	22-24 Feb 06	Selangor
2	The Silent Stalking Disease: Multiple Sclerosis	24 Feb 06	NPCB
3	Water Purification System	1 Mar 06	NPCB
4	Documentation & Implementation of ISO/IEC 17025:2005	15-16 Mar 06	Selangor
5	MOPI Training (Module 2: GMP or Manufacturing Operations)	20-22 Mar 06	Selangor
6	Dissolution Testing with Online UV-Vis Dissolution Software	4-5 Apr 06	NPCB
7	Slow Release & Multicomponent	4-5 Apr 06	NPCB
8	Preservative Efficacy Test	18 Apr 06	NPCB



No	Activity	Date	Venue
9	MOPI Training (Module 3: Validation Principles)	24-26 Apr 06	Selangor
10	Understanding on ISO 9001:2000	2 May 06	NPCB
11	Advanced / Refresher QMS Auditor	3-4 May 06	NPCB
12	MOPI Training (Module 4: Contamination Control and Clean rooms)	22-24 May 06	Selangor
13	Solid Phase Extraction	22 May 06	NPCB
14	Automation in Density & Refractive Index Measurement	24 May 06	Selangor
15	Varian Atomic Absorption Spectrometer	1 Jun 06	NPCB
16	Quality Management Representative Skills	6-7 Jun 06	Kuala Lumpur
17	MOPI Training (Module 5: Good Aseptic Practices and Sterile Products)	19-21 Jun 06	Selangor
18	Titration	28 Jun 06	NPCB
19	MOPI Training (Module 6: Workshop on Preparation of Guidelines for Hospital Pharmacy Development)	24-26 Jul 06	Selangor
20	Clinical Waste & Cleaning	27 Jul 06	NPCB
21	Fourier Transform Infrared Spectroscopy (FTIR)	7 Aug 06	NPCB
22	Good Storage Practice	7 Sep 06	NPCB
23	High Performance Liquid Chromatography (HPLC)	7 Sep 06	NPCB
24	Preparing Substantial Audit Reports	10 Sep 06	NPCB
25	Training on Six Sigma and Key Performance Index (KPI)	14 Sep 06	NPCB
26	MOPI Training (Module 8: Process Development for Therapeutics - A Perspective for Pharmaceutical Products)	20-22 Sep 06	Selangor
27	Pharmaceutical Gases & Steam	28 Sep 06	NPCB
28	HVAC and Environment Monitoring	29 Sep 06	NPCB
29	Gas Chromatography-Mass Spectrometry (GCMS)	5 Oct 06	NPCB
30	Good Storage Practice (theory)	19 Oct 06	NPCB
31	Laboratory Internal Audit for MS ISO/IEC 17025:2005	2-3 Nov 06	NPCB
32	Measurement of Uncertainty for MS ISO/IEC 17025	13-15 Nov 06	NPCB
33	Clean Room Protocols & Product Applications in Regulatory Requirements	15 Nov 06	Kuala Lumpur
34	Autoclave	17 Nov 06	NPCB
35	MOPI Training (Module 9: Process Development for Therapeutics - A Perspective for Pharmaceutical Products)	20-22 Nov 06	Selangor
36	Understanding an ISO 9001:2000 Quality Management System	23 Nov 06	NPCB

- Workshops

No	Activity	Date	Venue
1	Waters ACQUITY HPLC	24 Feb 06	Selangor
2	Globally Harmonised System for Classification and Labelling of Hazardous Chemicals for Government Agencies	9-10 Mar 06	Kuala Lumpur
3	Metrohm pH Measurement	12 Mar 06	Selangor
4	Evidence Based Medicine (EBM & Critical Appraisal of Cohort & Case Control Studies)	6-7 Apr 06	NPCB
5	Pharmacy Transplant & Renal Anaemia	21-23 Apr 06	Perak
6	Compulsory Licensing to Increase Access to Antiretrovirals (ARVs) and Diagnostic Reagents (ASEAN)	23-24 May 06	Kuala Lumpur

No	Activity	Date	Venue
7	Identification of Cosmetics Containing Illegal Adulterated Substances and Identifications of Sub-Standard Cosmetics Imported Into ASEAN	10-12 Jul 06	Selangor
8	Pre-congress Workshop - Molecules to Medicine	10 Aug 06	Putrajaya
9	ISO/IEC 17020:2005 - Requirements for Inspection Bodies	4-5 Sep 06	Selangor
10	Drug Price Monitoring Study and Evaluation	4-6 Sep 06	Selangor
11	Pharmacy Course Review Workshop	23 Sep 06	Putrajaya
12	Writing up of Quality Manual MS ISO/IEC 17025:2005	7-8 Nov 06	NPCB
13	Awareness Workshop on the National Strategy and Action Plan of the Ozone Destroying Substance (ODS) (NCFCP 2002-2010)	8-9 Nov 06	Selangor
14	Good Clinical Practice	22-24 Nov 06	Sarawak
15	Good Laboratory Practice	11-13 Dec 06	Kuala Lumpur

### 5.7.3 Participation of staff in International Events

Several staff had the opportunity to participate in the following international courses/ seminar/ meetings which were held in 2006.

No	Activity	Date	Venue
1	International Conference on Thalassemia & Haemoglobinopathies	7-9 Jan 06	Dubai
2	The 4 <sup>th</sup> Meeting of Traditional Medicines and Health Supplements Products Working Group (TMHS - PWG)	11-14 Jan 06	Bangkok, Thailand
3	CMR International Institute Workshop on the Emerging Markets: Regulatory Issues and the Impact on Patients' Access to Medicines	2-3 Mar 06	Geneva, Switzerland
4	The 11 <sup>th</sup> Meeting of the ASEAN Consultative for Standards & Quality (ACCSQ): Pharmaceuticals Product Working Group (PPWG)	6-11 Mar 06	Hanoi, Vietnam
5	Cosmetic Good Regulatory Practice Workshop	13-15 Mar 06	Jakarta
6	Notification Workshop	16-17 Mar 06	Jakarta
7	Regional Workshop on Certain Topical Issue in Regard to Intellectual Property for Asian Countries.	28-30 Mar 06	Macao, China
8	The 12 <sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA) - Improving World Health through Regulation of Biological Medicines	1-6 Apr 06	Seoul, Korea
9	Investigation of Regulatory Control of Cosmetic in Switzerland and United Kingdom	24-29 Apr 06	Switzerland and United Kingdom
10	Pharmaceutical Inspection Co-Operation Scheme (PIC/s) Joint Visit Inspection Group 61	1-5 May 06	Copenhagen, Denmark
11	Advance Workshop on Post Marketing Surveillance (PMS) on Cosmetics	8-11 May 06	Manila, Philippines
12	Clinical Trial Method & Model of Asia	18 May 06	Singapore
13	Saudi Food & Drug Authority (SFDA) International Conference	20-22 May 06	Riyadh, Arab Saudi
14	Pharmaceutical Inspection Co-operation Scheme Meeting of Official and Seminar on Risk Management and Related ICH Topics	29 May 06 – 03 Apr 06	Düsseldorf, Germany

No	Activity	Date	Venue
15	Good Regulatory Practice Toolkit Workshop - Pharmaceuticals Sector	30-31 May 06	Manila, Philippines
16	Pharmaceutical Inspection Co-Operation Scheme (PIC/s) Seminar On Risk Management and Related ICH Topics	30 May 06 – 03 Apr 06	Düsseldorf, German
17	Workshop on Safety Evaluation Guidelines on Cosmetics	12-13 Jun 06	Siem Reap, Cambodia
18	The 5 <sup>th</sup> Meeting of Asian Cosmetic Scientific Body (ACSB) & 6 <sup>th</sup> Meeting of the Asian Cosmetic Committee (ACC)	14-16 Jun 06	Siem Reap, Cambodia
19	The 42 <sup>nd</sup> Drug Information Association (DIA) Annual Meeting	18-22 Jun 06	Philadelphia, USA
20	Workshop on Pharmacovigilance: Future Perspectives	28 Jun 06 – 2 Jul 06	Sicily, Italy
21	Educational Visit to Manufacturer in Italy: Occupational Exposure to Potent Active Pharmaceutical Ingredients (Risperidone)	3-7 Jul 06	Italy
22	The 1 <sup>st</sup> Malaysia – US Free Trade Agreement (FTA) Meeting	17-21 Jul 06	Washington, USA
23	The 5 <sup>th</sup> Meeting of the Traditional Medicines & Health Supplements Product Working Group (TMHS PWG) ASEAN Consultative Committee for Standards and Quality (ACCSQ)	26-28 Jul 06	Singapore
24	Good Clinical Practice (GCP) Course: Pharmacovigilance	28-29 Jul 06	Singapore
25	Annual ASIAN-PACIFIC Conference Perspectives in Lung Cancer	4-5 Aug 06	Shanghai, China
26	Semi Regional Training on Post-marketing Surveillance (PMS) on Cosmetics	8-10 Aug 06	Jakarta, Indonesia
27	Review of Clinical Drug Development Course	16-18 Aug 06	Bangkok, Thailand
28	Asian Regional Conference on Intellectual Property Rights, Innovation and Health (IFPMA)	23-24 Aug 06	Singapore
29	Seminar on the Regulation of Medicines and Health Supplements - The Challenges	28 Aug 06	Singapore
30	The 14 <sup>th</sup> International Conference on Pharmaceutical Medicine	3-6 Sep 06	Seoul, Korea
31	CDER Forum for International Drug Regulatory Authorities	25-28 Sep 06	Maryland, United States
32	The Study Program on Manufacturing Control of Essential Drugs	1 Oct 06 – 31 Oct 06	Tokyo, Japan
33	The 3 <sup>rd</sup> Annual C.E.R.A. Anaemia Academy Meeting	6-8 Oct 06	Budapest, Hungary
34	International Conference on Thalassemia & Haemoglobinopathies	7-10 Oct 06	Dubai
33	The 12 <sup>th</sup> Meeting of the ASEAN Consultative Committee for Standards & Quality (ACCSQ): Pharmaceuticals Product Working Group (PPWG)	30 Oct 06 – 4 Nov 06	Jakarta, Indonesia
36	ASEAN Senior GMP Expert for Cosmetic in ASEAN Countries, Upgrading Selected ASEAN Member Countries Capability To Implement The ASEAN Harmonized Cosmetic Regulatory Scheme	31 Oct 06 – 2 Dec 06	Ho Chin Minh City, Vietnam
37	GMP Inspection in Traditional Factory in Hong Kong	20-24 Nov 06	Hong Kong
38	PMS Training for Cosmetic on Safety Evaluation	20-22 Nov 06	Jakarta
39	Meeting of the Pharmaceutical Inspection Co-operation Scheme (PICS)	21-22 Nov 06	Geneva, Switzerland

No	Activity	Date	Venue
40	Semi Regional Training in PMS	21-22 Nov 06	Jakarta, Indonesia
41	The 3 <sup>rd</sup> Dimensional Health Meeting between Malaysia and Brunei Darussalam	21-23 Nov 06	Bandar Seri Begawan, Brunei Darussalam
42	GMP Audit Of Biopharma SA di Argentina	22 Nov 06 – 06 Dec 06	Argentina
43	Training Course on Regulatory Control of Active Pharmaceutical Ingredients (API)	27 Nov 06 – 8 Dec 06	SwissMedic, Switzerland
44	Asia Pharmaceutical Summit 2006	27-29 Nov 06	Singapore
45	WHO Consultation on Technical Regulatory Package and Model for Making Regulatory Decision for Marketing Authorization	27-29 Nov 06	Geneva, Switzerland
46	Regional Scientific Meeting on Osteoporosis & SLE	1-3 Dec 06	Ho Chi Minh City, Vietnam
47	The 19 <sup>th</sup> World Diabetes Congress	3-7 Dec 06	Cape Town, South Africa
48	The 2 <sup>nd</sup> Regional Workshop On Safety Evaluation Guidelines	4-5 Dec 06	Bohol, Filipina
49	Session on Intergovernmental Working Group on Public Health, Innovation and Intellectual Property	4-8 Dec 06	Geneva, Switzerland
50	6 <sup>th</sup> Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 7 <sup>th</sup> Meeting of the ASEAN Cosmetic Committee (ACC)	5-9 Dec 06	Bohol, Filipina
51	Symposium on Cosmetic Regulations	10-13 Dec 06	Taipei, Taiwan
52	6 <sup>th</sup> Meeting of Traditional Medicines and Health Supplements Product Working Group (TMHS-PWG)	19-21 Dec 06	Hanoi, Vietnam

## 5.8 Expert/Advisor/Consultancy Services

The following officers served as experts / advisors / consultants in 2006.

No.	Name	Activity	Date	Venue
1	Abida Haq Syed M. Haq	Short term Consultancy in WIPRO Manila for the Project Involving Consumers in Medicines Surveillance	14-18 Aug 06	Manila, Philippines
2	Anis Binti Talib	Co-chair in the 6 <sup>th</sup> ACC and 5 <sup>th</sup> ACSB Meeting	13-16 Jun 06	Cambodia
3	Dr. Hasenah Ali	Facilitator/ coordinator in the Workshop on Requirement for Testing of Traditional Medicines (held prior to the 6 <sup>th</sup> ACCSQ TM-HS Product Working Group)	19 Dec 06	Hanoi, Vietnam
4	Dr. Sulaikah V.K. Moideen	Auditor in the Area of Pharmacy under the National Accreditation Board	2006 - current	Malaysia

No.	Name	Activity	Date	Venue
5	Mazli bt. Muhamad	Facilitator / coordinator in the Workshop on Requirement for Testing of Traditional Medicines (held prior to the 6 <sup>th</sup> ACCSQ TM-HS Product Working Group)	19 Dec 06	Hanoi, Vietnam
6	Muhammad Lukmani Ibrahim	ASEAN Senior Expert in the Advanced Regional Training on Good Manufacturing Practice (GMP) in the Cosmetic Sector	31 Jul 06 – 3 Aug 06	Kuala Lumpur, Malaysia
7	Muhammad Lukmani Ibrahim	ASEAN Senior Expert in Upgrading Selected ASEAN Member Countries' Capacity to Implement the ASEAN Harmonized Cosmetic Regulatory Scheme National GMP Follow Up	30 Oct 06 – 2 Nov 06	Ho Chih Minh, Vietnam
8	Muhammad Lukmani Ibrahim	ASEAN Senior Expert in Upgrading Selected ASEAN Member Countries' Capacity to Implement the ASEAN Harmonized Cosmetic Regulatory Scheme National GMP Follow Up	7-8 Nov 06	Manila, Philippines
9	Muhammad Lukmani Ibrahim	ASEAN Senior Expert in Upgrading Selected ASEAN Member Countries' Capacity to Implement the ASEAN Harmonized Cosmetic Regulatory Scheme National GMP Follow Up	14-15 Nov 06	Bangkok Thailand

## 5.9 Presentations

The centre's staffs were also active in giving presentations during various training courses. The following presentations were delivered by staff members in 2006.

- *Pharmacovigilance (Adverse Drug Reaction) and Post Marketing Surveillance*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Abida Haq Syed M. Haq	ADR Monitoring	PTK 6 Course for Pharmacy Officers U52	9 Jun 06	Kuala Lumpur, Malaysia
2	Abida Haq Syed M. Haq	Pharmacovigilance in Emerging Nations	Future Perspectives on Pharmacovigilance	30 Jun 06	Italy
3	Abida Haq Syed M. Haq	Importance of Pharmacy Assistants in ADR Monitoring	Course for Pharmacy Assistants	3 Sept 06	Perak, Malaysia
4	Abida Haq Syed M. Haq	Case Study on Product Recalls	Seminar KPND	28 Nov 06	Kuala Lumpur, Malaysia
5	Fuziah bt Abdul Rashid	ADR	CPD talk to Pharmacy Officers	3 Mar 06	Kuala Lumpur, Malaysia
6	Fuziah bt Abdul Rashid	ADR	CPD talk to Pharmacy Officers	7 Apr 06	Sarawak, Malaysia
7	Halimatussa'adiyah Binti Mat Som	Surveillance and Products Complaint	Information update Seminar for Pharmacy Assistants 2006	9-Nov-06	NPCB, Malaysia
8	Nurhayati Othman	Regulating Health Supplements: Post-Market Strategies	Health Supplement Seminar 2006	22 Nov 06	Kuala Lumpur, Malaysia

• *Clinical Trials*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Kamaruzaman Salleh	Regulatory Aspects of Clinical Trial in Malaysia	Good Clinical Practice Workshop	26 Mar 06	Penang, Malaysia
2	Kamaruzaman Salleh	Regulatory Aspects of Clinical Trial in Malaysia	Good Clinical Practice Workshop	22 Apr 06	Sabah, Malaysia
3	Kamaruzaman Salleh	Cross-cutting Issues for Pharmaceutical & Medical Device Research Program	Good Clinical Practice Workshop	29 Jun 06	Kuala Lumpur, Malaysia
4	Kamaruzaman Salleh	Regulatory Aspects of Clinical Trial in Malaysia	Good Clinical Practice Workshop	26 Aug 06	Pahang, Malaysia
5	Kamaruzaman Salleh	Regulatory Aspects of Clinical Trial in Malaysia	Good Clinical Practice Workshop	24 Nov 06	Sarawak, Malaysia
6	Muhammad Lukmani Ibrahim	Good Clinical Practice	Good Clinical Practice Workshop	22 Apr 06	Sabah, Malaysia
7	Muhammad Lukmani Ibrahim	Good Clinical Practice	Good Clinical Practice Workshop	6 Oct 06	Kuala Lumpur, Malaysia
8	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	18 Jan 06	Pahang, Malaysia
9	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	13 Jun 06	Kelantan, Malaysia
10	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	14 Aug 06	Kelantan, Malaysia
11	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	17 Sep 06	Selangor, Malaysia
12	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	4 Oct 06	Kuala Lumpur, Malaysia
13	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	5 Oct 06	Kuala Lumpur, Malaysia
14	Zaril Harza Bin Zakaria	Regulatory Aspects of Clinical Trial	Good Clinical Practice Workshop	12 Dec 06	Malacca, Malaysia

• *Cosmetics*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Abida Haq Syed M. Haq	Quality & Safety of Cosmetics	International Symposium on Food & Drug Regulations	22 May 06	Riyadh, Saudi Arabia
2	Anis Binti Talib	Good Regulatory Practice in Cosmetics	Cosmetic Good Regulatory Workshop	13-15 Mar 06	Jakarta
3	Anis Binti Talib	Good Regulatory Practice in Cosmetics	The Need of Products Registration in Malaysia	11 May 06	Alor Star, Kedah
4	Anis Binti Talib	Regulatory Control of Cosmetics	Asia Business Forum	15-16 May 06	Kuala Lumpur, Malaysia
5	Anis Binti Talib	ASEAN Cosmetic Directive	PMS1 Workshop	17-18 May 06	Selangor, Malaysia
6	Nik Shamsiah binti Nik Salleh	Safety Assessment of Cosmetic Products	Cosmetic Product Safety & Efficacy Evaluation & PMS workshop	17 May 06	Selangor, Malaysia
7	Nik Shamsiah binti Nik Salleh	Safety Assessment of Cosmetic Products	Cosmetic Product Safety & Efficacy Evaluation & PMS Workshop	21 Sep 06	Selangor, Malaysia
8	Nurhayati Omar	Efficacy and Evaluation of Finished Products	Seminar Cosmetic Products Safety & Efficacy Evaluation	17 May 06	Selangor, Malaysia

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
9	Nurhayati Omar	Efficacy and Evaluation of Finished Products	Seminar Cosmetic Products Safety & Efficacy Evaluation	21 Sep 06	Selangor, Malaysia

• *Good Manufacturing Practice (GMP)/ Good Storage Practice (GSP)*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Ahmad Syamsury Sulaiman	9 Wonders of GMP	National GMP Seminar 2006	19 Dec 06	Selangor, Malaysia
2	Ahmad Syamsury Sulaiman	GMP	A Talk to Pharmacy Students	19 Oct 06	Pahang, Malaysia
3	Ahmad Syamsury Sulaiman	GSP and GMP	GSP and Control of Medicine Course	18 Apr 06	Kedah, Malaysia
4	Kadariah Mohd. Ali	Talk on Pharmaceutical Water Systems	GMP Training for GMP Auditors	3 Jan 06	NPCB, Malaysia
5	Kadariah Mohd. Ali	GMP for Investigatory Medicinal Products	Good Clinical Practice Workshop	26 Mac 06	Penang, Malaysia
6	Kadariah Mohd. Ali	Licensing & Legal Control of Herbal Products - GMP & GSP Aspects	Herbal Medicine Conference	25 May 06	Sabah, Malaysia
7	Kadariah Mohd. Ali	GMP for Investigatory Medicinal Products	Good Clinical Practice Workshop	10 Nov 06	Johor Bahru, Malaysia
8	Kadariah Mohd. Ali	Lecture on GMP Audit Findings	National GMP Seminar 2006	19 Dec 06	Selangor, Malaysia
9	Kadariah Mohd. Ali	Lecture on Managing GMP Regulatory Audit	National GMP Seminar 2006	20 Dec 06	Selangor, Malaysia
10	Kadariah Mohd. Ali	Talk on Licensing of Premises	PTK 4 Course	21 Nov 06	NPCB, Malaysia
11	Kadariah Mohd. Ali	Lecture on Risk of Contamination in the Manufacture of Medicines	National GMP Seminar 2006	21 Dec 06	Selangor, Malaysia
12	Mohd Nasrul Mohamad Noor	9 Wonders of GMP: Personnel, Premises and Equipment	National GMP Seminar 2006	19-21Dec 06	Selangor, Malaysia
13	Muhammad Lukmani Ibrahim	(a) Improving Your Internal Audit Skill (b) Packaging and Related Issues (c) Risk Assessment and ICH Related Topics	National GMP Seminar 2006	19-21Dec 06	Selangor, Malaysia
14	Nor Hafizah binti Mohd Potri	GSP	Pharmacy Conference 2006	19 Aug 06	Pahang, Malaysia
15	Nor Hafizah binti Mohd Potri	GMP	Good Clinical Practice Workshop	26 Aug 06	Pahang, Malaysia
16	Nor Hafizah binti Mohd Potri	9 Wonders of GMP - Complaint & Product Recall & Self-Inspection	National GMP Seminar 2006	20 Aug 06	Selangor, Malaysia
17	Norhayati binti Musa	Seminar GSP and Quality Control of Medicine	Control of Drugs and Cosmetics	28 Apr 06	Kedah, Malaysia
18	Norleen Mohamed Ali	GSP and Regulatory Control of Pharmaceuticals	Introduction Course to GSP	27-28 Apr 06	Kedah, Malaysia
19	Nurhayati Omar	Methods Dealing with Adulterated and Recall of Product	National GMP Seminar 2006	19 Dec 06	Selangor, Malaysia

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
20	Wan Othman Wan Ismail	The need of GMP, GSP and Licensing of Registered Product	Regulatory Pharmacy Conference	24-25 May 06	Pahang, Malaysia
21	Wan Othman Wan Ismail	ASEAN GMP for Cosmetic: Storage Requirements	Regional Seminar on EC-ASEAN for Cosmetic GMP	31 Aug 06 – 3 Sep 06	Selangor, Malaysia
22	Wan Othman Wan Ismail	The need of GSP and Licensing of Registered Product	The Necessity of Wholesaler Licence and GSP Seminar	18 Nov 06	Johor Bahru, Malaysia
23	Wan Othman Wan Ismail	GMP Requirements for Investigational Products	GCP Workshop	1-2 Dec 06	Penang, Malaysia
24	Wan Othman Wan Ismail	The need of GSP and Licensing of Registered Product	National GMP Seminar 2006	19-21 Dec 06	Selangor, Malaysia

- *Quality Control/Laboratory*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Ahmad Zakhi bin Ramli	The Management of Reference Standard in UPR	Information update Seminar for Pharmacy Assistants 2006	10 Nov 06	NPCB, Malaysia
2	Halimatussa'adiah Mat Som	The Supervision of the Quality of Registered Products	Legislation and Regulatory Control	24-May-06	Pahang, Malaysia
3	Halimatussa'adiah Mat Som	The Supervision of the Quality of Registered Products	Respiratory Seminar	12-Jul-06	Pahang, Malaysia
4	Mazli Binti Muhamad	Quality Control on Herbal Medicines	A Talk to Pharmacy Students	24 Jan 06	Kuala Lumpur, Malaysia
5	Mazli binti Muhamad	Outcome of the Survey on Quality Control Testing for Traditional Medicine & Health Supplement	5th Meeting ACCSQ TMHS PWG	27 Jul 06	Singapore
6	Mazli binti Muhamad	Quality Control Testing for Traditional Medicine and Health Supplement Workshop	6th Meeting ACCSQ TMHS PWG	19 Dec 06	Vietnam
7	Seetha a/p Ramasamy	Quality And Safety Control And Claims of T/CM Products	Complementary and Traditional Medicine Seminar (Zone Sabah)	19-20 Jul 06	Sabah, Malaysia
8	Nor Hayati Abdul Rahim	Test for Microbial Contamination (Theory)	Quality Control of Traditional Product Course	18-22 Sep 06	NPCB, Malaysia
9	Siti Madziah Mohamed	Test for Microbial Contamination (Theory and Practical)	Quality Control of Traditional Product Course	18-22 Oct 06	NPCB, Malaysia
10	Siti Madziah Mohamed	Microbiology Aspects and Its Related Tests	Information update Seminar for Pharmacy Assistants 2006	9-10 Nov 06	NPCB, Malaysia
11	Tan Ann Ling	Workflow in Quality Control Department	Information update Seminar for Pharmacy Assistants 2006	9-10 Nov 06	NPCB, Malaysia
12	Tan Ann Ling	Quality Aspects in the Dietary Supplement	Health Supplement Seminar 2006	22 Nov 06	Kuala Lumpur, Malaysia



No	Name	Presentation Topic	Forum/Seminar	Date	Venue
13	Zakiah binti Abd. Ghafar	Quality And Safety Control And Claims of T/CM Products	Complementary and Traditional Medicine Seminar (South Zone)	23 May 06	Johor, Malaysia
14	Zarina Rosli	Audit Findings in Quality Control Aspect	National GMP Seminar	19-21 Dec 06	Selangor, Malaysia

• *Product Registration*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Eisah bt. A. Rahman	The Malaysian Regulatory System	WHO Consultation on Technical Regulatory Package and Model for Making Regulatory Decision for Marketing Authorization	27-29 Nov 06	Geneva, Switzerland
2	Mazuwin Zainal Abidin	Review of Evaluation Process and Criteria for Registration of Health Supplements	Dialog of NPCB with MDDA and DSAM	8 Jun 06	NPCB, Malaysia
3	Mazuwin Zainal Abidin	Procedure for Product Registration	Entrepreneur Clinic	27 Jun 06	Selangor, Malaysia
4	Mazuwin Zainal Abidin	Procedures for Registration of Traditional, Health Supplements and Cosmetics	Antioxidant Seminar	7 Nov 06	Malacca, Malaysia
5	Mazuwin Zainal Abidin	Registration Requirements - Section A-F of the Online Format	Health Supplements Seminar	22 Nov 06	Kuala Lumpur, Malaysia
6	Mazuwin Zainal Abidin	Registration Requirements	Entrepreneur Clinic	13 Dec 06	Terengganu, Malaysia
7	Rosilawati Ahmad	Procedure of Products Registration	Legislation and Regulatory Control Course	24 May 06	Pahang, Malaysia
8	Siti Madziah Mohamed	Procedure of Products Registration	Seminar Groom Big	10 Nov 06	Kedah, Malaysia
9	Somiyaton Mohd Dahalan @ Damuri	Procedure of Products Registration	CPF Conference 2006	14 Jun 06	Malacca, Malaysia
10	Zakiah binti Abd. Ghafar	The Control and Registration of Traditional Products in Malaysia	The Recognition and Use of Herbs Course	20 Jun 06	Selangor, Malaysia
11	Zuraida bt Abdullah	Registration of Cosmetic Products and its Relationship with Consumers' Right	Consumers Protection Conference	14-Jun-06	Malacca, Malaysia

• *Others*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Abida Haq Syed M. Haq	Role of Clinical Pharmacists in Pharmacovigilance	Masters Program for Clinical Pharmacists	21 Jul 06	Kuala Lumpur, Malaysia
2	Abida Haq Syed M. Haq	R&D in Pharmacy Practice- Smart partnerships with Industry	National Pharmacy R&D Conference	30 Nov 06	Malacca, Malaysia
3	Aryani binti Ahmad	Labelling Requirements	Health Supplement Seminar 2006	22 Nov 06	Kuala Lumpur, Malaysia

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
4	Asnida Mat Daud	Food Drug Interphase	Investigation Course for Regulatory Pharmacy	15 Nov 06	Pahang, Malaysia
5	Azlina Ismail	Overview of NPCB (History, Organisation Structure and Function)	Internal Induction Course NPCB Session 02/2006	21 Jun 06	NPCB, Malaysia
6	Azlina Ismail	Overview of NPCB (History, Organisation Structure and Function)	Internal Induction Course NPCB Session 03/2006	18 Sep 06	NPCB, Malaysia
7	Dr Sulaikah V.K. Moideen	Progress Report for Malaysia	AWGTCP Meeting	25-27 May 06	Kuala Lumpur, Malaysia
8	Dr Sulaikah V.K. Moideen	Quality Control	Support Class	7 Sep 06	Selangor, Malaysia
9	Dr Sulaikah V.K. Moideen	Quality Control	PTK 4 Course	28 Nov 06	Negeri Sembilan, Malaysia
10	Eisah bt. A. Rahman	The Malaysian Perspective	CMR International Institute Workshop on the Emerging Markets: Regulatory Issues and the Impact on Patients' Access to Medicines	2-3 Mar 06	Geneva, Switzerland
11	Eisah bt. A. Rahman	Impact of IPR on Access to Medicines: Malaysia's Viewpoint	The 12 <sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA) - Improving World Health through Regulation of Biological Medicines	1-6 Apr 06	Seoul, Korea
12	Eisah bt. A. Rahman	Current Status of the Work Plan for Pharmaceuticals and Cosmetic Control	The 3 <sup>rd</sup> Dimensional Health Meeting between Malaysia and Brunei Darussalam	21-23 Nov 06	Brunei Darussalam
13	Kadariah Mohd. Ali	Overview of NPCB (History, Organisation Structure and Function)	Internal Induction NPCB	14 Mar 06	NPCB, Malaysia
14	Kadariah Mohd. Ali	Herbal Potential & Dilemma – Industry Prospective	Forum PURBATAMA	6 Jun 06	Johor Bahru, Malaysia
15	Kamarudin Ahmad	Overview of NPCB (History, Organisation Structure and Function)	Internal Induction NPCB Session 01/2006	15 Feb 06	NPCB, Malaysia
16	Muhammad Lukmani Ibrahim	Clinical Applications of Positron Emission Tomography in Cancer Management and Cardiovascular Diseases	National Training Course	21 Mar 06	Penang, Malaysia
17	Muhammad Lukmani Ibrahim	Clinical Applications of Positron Emission Tomography in Cancer Management and Cardiovascular Diseases	National Training Course	21 Mar 06	Kuala Lumpur, Malaysia
18	Rosilawati Ahmad	DCA and The Industry	10 <sup>th</sup> NHAM Annual Scientific Meeting 2006	31 Mar 06	Kuala Lumpur, Malaysia
19	Rosilawati Ahmad	Procedure for Product Registration	Seminar One District One Industry	8 Apr 06	Malacca, Malaysia

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
20	Seetha a/p Ramasamy	Regulatory Control of Herbal Products in Malaysia	Industry Skill Upgrading Program for Graduate (INSEP-NBD)	11 Oct 06	Selangor, Malaysia

### 5.10 Research

#### Research done in 2006:

- i) Fuziah binti Abdul Rashid, Mazli binti Muhamad, Wan Nurul Aina bt Mior Abdullah – A Retrospective Study on Adulteration by Therapeutics Substances of Traditional Medicines in Malaysia, April 2006 – November 2006, National Pharmaceutical Control Bureau, Selangor, Malaysia.

#### Future Research:

- i) Norleen bt. Mohamed Ali – Pilot Project On Involving Consumers In Medicines Surveillance, January 2007 – January 2009, National Pharmaceutical Control Bureau, Selangor, Malaysia.
- ii) Abida Haq Syed M. Haq - Medication Errors, January 2007-2008 (under the Institute for Health Systems Research, Ministry of Health, Malaysia)

### 5.11 Journal Club

The National Pharmaceutical Control Bureau held Journal Club Sessions. A total of **8 sessions** were held throughout the year 2006. The purpose of these sessions is for NPCB officers to do a presentation on current relevant issues, recent articles from journals or a brief summary of a course that they recently attended.

NO	SESSION	DATE	PRESENTER	TITLE OF PRESENTATION
1.	Session 01	27 January 2006	Noraisyah Md. Sani	Being Big or Growing Fast: Systematic Review of Size and Growth in Infancy and Later Obesity
2.			Azrina Hassan	Malaysia Herbal Monograph
3.			Mazuwin Zainal Abidin <i>(Additional presentation)</i>	Attachment Training on Regulations on Complimentary Medicines (28 November - 9 Disember 2005, TGA, Australia)
4.	Session 02	31 March 2006	Yusni Rizal b. Khairul Anuar	Introduction to Good Manufacturing Practice
5.			Aryani Ahmad	Alternative Therapies for Weight Loss
6.	Session 03	16 June 2006	Leong Yet Lee	Risk and Benefits of Omega 3 Fats for Mortality, Cardiovascular Disease, and Cancer: Systemic Review
7.			Khurul Falisa Mustafa	Pharmacist Symposium on Osteoporosis

NO	SESSION	DATE	PRESENTER	TITLE OF PRESENTATION
8.	Session 04	30 June 2006	Norhayati Abdul Rahim	GMP Aspects of Equipment Qualification in QC Laboratory (EQ).
9.			Wan Nurul Aina Mior Abdullah	A Retrospective Study on Adulteration by Therapeutic Substances of Traditional Medicines in Malaysia)
10.			Dr. Kamaruzaman Salleh (Additional presentation)	Preparing a Research Protocol
11.	Session 05	14 July 2006	Mohd. Nasrul Mohamad Noor	Good Storage Practice
12.			Kadariah Mohd. Ali (Additional presentation)	GMP Audit for Non-GMP Auditors
12	Session 06	25 August 2006	Irdawaty Mohd. Salleh	ASEAN Harmonisation On Test Methods For Cosmetic Products
13			Zarina Rosli	Post Market Surveillance For Cosmetic Product
14	Session 07	13 October 2006	Chiong Yuh Lian	Chromatography
15			Seetha a/p Ramasamy	Quality Evaluation of Eurycoma Longifolia Jack (Tongkat Ali) Raw Material According to the Methods in the Malaysian Herbal Monograph
16	Session 08	16 November 2006	Zakiah bt Abd Ghafar	Micronutrients and Premenstrual Syndrome
17			Siti Hidayah binti Kasbon	Leave

## 6. REGULATORY STATUS

- i. Until December 2006, a cumulative total of **172,319** product applications for registration have been received, of which **145,139** have been approved.

The breakdown for the type of applications received in 2006 is as follows:

Scheduled poisons (prescription item)	- 465
Non-scheduled poisons (non – prescription item)	- 609
Traditional medicines	- 1826
Cosmetics	- 24,558
<b><u>TOTAL</u></b>	<b>- 27,458</b>

A total of **27,673** product applications were approved in 2006, of which 533 are for scheduled poisons (prescription item), 694 for non-scheduled poisons (non – prescription items), 1729 for traditional medicines and 24,715 for cosmetics.

- ii. A total of **5,116** Certificates of Pharmaceutical Product (CPP) and Certificates of Free Sale (CFS) were issued for the year 2006. The total number of Clinical Trial Import Licences (CTIL) issued was **277**.
- iii. A total of **336** manufacturing premises were licensed in 2006, of which 85 are for pharmaceutical, 161 for traditional and 90 for cosmetic. For importers, a total of **776** were licensed, of which 180 are for pharmaceutical, 149 traditional and 447 cosmetic. For wholesalers, a total of **970** were licensed, of which 426 are for scheduled poisons while 544 are for non-scheduled poisons, traditional and cosmetics.
- iv. Under the post-market surveillance program, a total of **2,748** samples were taken from the market, **2,631** labels and package inserts examined, **108** batch recalls were instituted, **41** warning letters were issued and **317** product complaints were investigated.
- v. As for quality control testing, a total of **5,185** samples were tested of which 2,196 were registration samples, 2,690 were surveillance samples, 154 were enforcement samples, 110 were from product complaints and adverse drug reaction reports and 35 others. A total of **63,410** tests were conducted.
- vi. A total of **840** vials of ASEAN and NPCB reference standards were supplied to government departments (Chemistry Department, Government Medical Store Sarawak and State Enforcement Units) and a total of **605** vials were sold to the private sector (comprising of 479 NPCB reference standards and 126 ASEAN reference standards).
- vii. Under the Adverse Drug Reactions Monitoring Program, a total of **2,543** ADR reports were received in 2006, of which **2,491** reports were sent to the Uppsala WHO Monitoring Centre for inclusion into the WHO database.
- viii. A total of **3,663** queries pertaining to products and also general information from both the public and private sectors were dealt with.

## **7. HIGHLIGHTS OF ACHIEVEMENTS IN 2006**

- i. The QUEST 2 system for on-line registration of pharmaceuticals and traditional medicines has successfully entered its fourth and third year of implementation respectively.
- ii. MS ISO 9001 version 2000 certification by SIRIM (an accreditation body for ISO) for the quality management system was successfully maintained.
- iii. Several new/updated guidelines to facilitate product registration were revised and developed. The adopted documents are made available in the NPCB website ([www.bpfk.gov.my](http://www.bpfk.gov.my)).
- iv. The NPCB continues to play an active role in the harmonization efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and Traditional Medicines and Health Supplements Product Working Group (PWGTMHS). Other international involvements include facilitating the fast-track ASEAN healthcare integration and EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments, as well as other PIC/S

activities. The NPCB has also participated in other international consultations such as Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries as well as participation in the Malaysia-US Free Trade Agreement (MUSFTA) negotiations.

- v. Malaysia has implemented the ASEAN Common Technical Dossier (ACTD) and is also currently using the ASEAN Guidelines for Bioavailability/Bioequivalence (BA/BE) as well as the ASEAN Guidelines for Stability Studies.
- vi. Malaysia successfully hosted the 22<sup>nd</sup> Meeting of the ASEAN Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP) which was held on the 25<sup>th</sup> – 27<sup>th</sup> of May 2006 in Kuala Lumpur, Malaysia. The Workshop on Compulsory Licensing to Increase Access to Antiretrovirals (ARVs) and Diagnostic Reagents (ASEAN) was also successfully held prior to the above meeting i.e. on the 23<sup>rd</sup> – 24<sup>th</sup> of May 2006 at the same venue.

## 8. FUTURE PLANS

### i. **Registration of Veterinary Medicines and Active Pharmaceutical Ingredients**

To focus on capacity and capability building for the implementation of registration and licensing system for veterinary medicines and active pharmaceutical ingredients (API).

To conduct awareness programmes for the local industry on registration of veterinary medicines and API.

Voluntary registration of veterinary medicines is planned to begin within the year of 2007.

### ii. **Intensification of post-market surveillance**

To intensify surveillance activities with the aim of combating problems associated with adulteration, counterfeits and product authentication as well as to promote public health protection through education and awareness.

To further enhance post-marketing surveillance and reduce emphasis on pre-market assessment.

### iii. **ASEAN Harmonisation and Healthcare Integration**

A system of notification for cosmetic will be introduced by 2008 in tandem with the ASEAN cosmetic harmonisation.

The ASEAN Common Technical Dossier (ACTD) for pharmaceuticals will be fully implemented by January 2009 to facilitate registration.

Malaysia will host the 13<sup>th</sup> Meeting of the ASEAN Consultative Committee for Standards & Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) in 2007.

### iv. **Enhancement of Information and Communication Technology (ICT)**

NPCB continues to strive towards upgrading its ICT infrastructure. Under the 9<sup>th</sup> Malaysia Plan (2006-2010), NPCB has been granted a certain allocation that will be used for upgrading the present on-line system i.e. QUEST 2 to QUEST 3.

This enhancement will further facilitate efforts towards implementation of the on-line registration for New Chemical Entities (NCE) and biotechnology products, as well as facilitate the integration of the different on-line modules (involving product registration, licensing of premises, analytical testing, surveillance, ADR monitoring and dissemination of information). As a whole, these efforts will enable better networking.

**v. ISO 17025 Certification**

To continue the efforts towards further upgrading the laboratory quality management system to achieve the ISO 17025 accreditation by early 2007.

**vi. Reinforcing PIC/S GMP**

To continue efforts towards strengthening and upgrading the level of GMP compliance of local pharmaceutical and traditional medicines manufacturers in order to gain global recognition and facilitate market penetration. A GMP Seminar for Traditional Medicines will be planned for the year 2007.

To pursue the plans for conducting GMP inspections of foreign manufacturers particularly the non-PIC/S countries to ensure they fully comply with current guidelines.

**vii. National Regulatory Conference 2007**

NPCB together with the pharmaceutical, traditional medicine and cosmetics industry will organise the National Regulatory Conference 2007.

**viii. Strengthening Clinical Research**

To strengthen capacity and capability in the inspection of clinical testing facilities as well as to upgrade the existing resources with the aim of facilitating the coordination of activities related to GCP, GLP and BA/BE.

To implement a system of inspection for clinical testing facilities in accordance to the adopted GCP, GLP and BA / BE requirements.

**vii. Renovation of the office areas**

To further extend efforts in upgrading and renovating the existing office areas with the aim of providing a more comfortable and conducive environment to its personnel and customers.

## **9. CONCLUSION**

Malaysia has a comprehensive regulatory system in place. The NPCB works closely and collaborates with the local industry, industry associations, health professionals, academia, consumers and other stakeholders to further enhance the effectiveness of this system. International collaborations in relevant technical areas provide an excellent platform for NPCB in establishing mutual understanding amongst regulatory partners towards strengthening pharmaceutical quality assurance. Capacity and capability building as well as further upgrading of infrastructure are important in our efforts to ensure continuous improvements and to keep abreast with current global regulatory developments. As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals since 1996, the NPCB will strive and continue to play an important role to fulfil the commitments and expectations as laid down in the terms of reference.