WHO ANNUAL REPORT 2005

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
Fax: 03-79562924
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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
  (effective from 1st August 2005)

Deputy Heads

- Eisah bt. A. Rahman – B. Pharm, M. Sc., Dip. Medical Microbiology
  (until 31 July 2005)
- Yogeswary a/p Markandoo – B. Sc. Pharm (Hon), M.Sc (until 15 November 2005)
- Selvaraja Seerangam – B. Pharm (Hons), M. Phil. (effective from 16 November 2005)

Officers

1. Abida Haq bt Syed M. Haq - B.Pharm (Hons), Dip Med Microbiology, M. Clinical Pharmacy
2. Abdul Aziz b. Mansor – B. Pharm (Hons)
3. Abdullah Hisham Bin Ahmad Yaya – B. Pharm (Hons), M. Pharm (Clinical Pharmacy)
4. Ahmad Syamsury bin Sulaiman - 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
10. Asnida bt Mat Daud - B. Pharm (Hons)
11. Azraini bt Abdul Samat - B. Pharm (Hons)
12. Azrina bt Hassan - B. Pharm (Hons)
13. Azura bt Abdullah - B. Pharm (Hons)
14. Azlina bt. Ismail – B. Pharm (Hons)
15. Basmiah bt Md. Isa - B. Pharm (Hons)
16. Bariah bt. Abdul Rani – B.Pharm (Hons)
17. Belinna Binti Abu Bakar - B. Pharm (Hons)
18. Chiong Yuh Lian – B.Pharm (Hons)
19. Dayang Hanani bt. Umar – B. Pharm (Hons)
20. Faridah bt Hj. Abd. Malek - B. Pharm (Hons)
21. Fudziah bt Ariffin - B. Pharm, Dip. Med. Microbiology, M Sc
22. Fuziah bt. Abdul Rashid – B.Pharm (Hons)
23. Halimatussa'adiah bt. Mat Som – B. Pharm (Hons)
24. Hasenah bt. Ali - B. Pharm (Hons), M. Sc, Ph D
25. Hasniza bt. Zaidan – B. Pharm (Hons)
26. Hazlinda Nazli bt Naem - B. Pharm (Hons)
27. Ida Syazrina bt Ibrahim - B. Pharm (Hons)
28. Irdawaty bt. Mohd. Salleh – B.Pharm (Hons)
29. Kadariah bt. Mohd. Ali - B. Pharm (Hons), M. Sc
30. Kamaruzaman b. Saleh (Dr.) - B. Pharm (Hons), M. Sc, Ph D
31. Kamarudin bin Ahmad – B. Sc. (Pharm)
32. Khirul Falisa Binti Mustafa - B. Pharm (Hons)
33. Leong Yet Lee – B.Pharm (Hons)
34. Mazli bt. Muhamad - B. Pharm (Hons), M. Sc.
35. Mazuwin bt. Zainal Abidin - B. Pharm (Hons), M. Sc
36. Mohd. Nasrul b. Mohamad Noor – B. Pharm (Hons)
37. Muhammad Lukmani b. Ibrahim - B. Pharm (Hons)
38. Nik Juzaimah bt Nik Juhari – B. Pharm (Hons)
39. Nik Shamsiah bt Nik Salleh - B. Pharm (Hons)

40. Noor'ain bt. Shamsuddin – B. Pharm (Hons)
41. Noraisyah bt Mohd. Sani - B. Pharm (Hons)
42. Noorizam bt. Ibrahim – B. Pharm (Hons), M. Pharm
43. Nor Hafizah bt. Mohd. Potri – B. Pharm (Hons)
44. Noor Hidayah bt. Mohd. Nor – B. Pharm (Hons)
45. Norhayati bt. Musa – B. Pharm (Hons)
46. Nor Hayati Abdul Rahim – B. Pharm (Hons)
47. Norrehan bt. Abdullah – B. Pharm (Hons), M.Pharm (Clinical Pharmacy)
48. Norul Azmira bt. Abu Bakar – B. Pharm. (Hons)
49. Nurhayati bt. Omar – B. Pharm (Hons)
50. Nurhayati bt. Othman – B. Pharm (Hons)
51. Norleen bt. Mohamed Ali – B. Pharm (Hons)
52. Nurul Fajar bt Mohd. Jamid - B. Pharm (Hons)
53. Rohani bt Ismail – B. Pharm, M. Sc
54. Rosilawati bt Ahmad - B. Pharm (Hons), M. Sc.
55. Saleha bt Md. Ewan - B. Pharm (Hons)
56. Siti Hidayah bt. Kasbon – B. Pharm (Hons)
57. Siti Madziah bt. Mohamed - B. Pharm (Hons), M.Pharm
58. Somiyaton bt Dahalan @ Damuri - B. Pharm (Hons)
59. Sufian Hardi bin Mohamad Zuhair - B. Pharm (Hons)
60. Suhaili Binti Samad - B. Pharm (Hons)
61. Sulaikah bt V.K. Moideen (Dr.) - B. Pharm (Hons), M. Sc, Ph D
62. Sulaiman b Haji Ahmad - B. Pharm (Hons)
63. Suhailah bt Abu Bakar - B. Pharm (Hons)
64. Tajuddin Akasah (Dr.) - B. Pharm (Hons), M. Sc, Ph. D
65. Tan Ann Ling - B. Pharm (Hons)
66. Tan Chuan Ai – B. Pharm (Hons)
67. Tan Szi Szi – M. Pharm
68. Wan Nurul Aina bt. Mior Abdullah – B. Pharm (Hons)
69. Wan Othman Wan Ismail - B. Pharm (Hons)
70. Yvonne Khoo Siew Khoon – B. Pharm (Hons)
71. Yusni Rizal b. Khairul Anuar – B. Pharm (Hons)
72. Zahura bt. Mohamed @ Ismail - B. Pharm (Hons)
73. Zakiah bt Abd. Ghafar - B. Pharm (Hons)
74. Zaril Harza b. Zakaria – B. Pharm (Hons)
75. Zarina bt Rosli - B. Pharm (Hons)
76. Zuraida bt Abdullah - B. Pharm (Hons)

Provisionally Registered Pharmacist

1. Chua Hui Ming– B. Pharm (Hons)
2. Juanah Binti Garabus – B. Pharm (Hons)
3. Lian Lay Kim - B. Pharm (Hons)
4. Fazillahnor Binti Ab. Rahim - B. Pharm (Hons)
5. Low Joo Meing - B. Pharm (Hons)
6. Maslinda Binti Mahat - B. Pharm (Hons)
7. Tan Teck Koon - M. Pharm

TOTAL NUMBER OF PHARMACISTS – 85

Other Support Staff

- Pharmacy Assistants - 60
- Science Officers - 25
- Administrative and Support Staff – 51

TOTAL NUMBER OF STAFF: 221

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.

In 2005, the centre recorded a total of **55 international visitors** and WHO fellows from various countries namely Cambodia, India, Lao PDR, Singapore, EU, Indonesia, Tanzania, Namibia, USA, Spain, Sudan, Vietnam, Korea, and Iran.

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

5.2 Collaborative Studies for the Production of ASEAN Reference Standards

In 2005, 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 COMPLETION	TYPE	NAME	BATCH NO
3/29/05	ASEAN	Folic acid	M 197092
7/29/05	ASEAN	Atropine Sulphate	M 185015
7/29/05	ASEAN	Hyoscine Hydrobromide	M 100115
7/29/05	ASEAN	Betamethasone 17-Valerate	M 193079
8/30/05	ASEAN	Hyoscine Butylbromide	M 100115
8/30/05	ASEAN	Triamcinolone Acetonide	M 191077
9/30/05	ASEAN	Thiamine Nitrate	M 197097
9/30/05	ASEAN	Gemfibrozil	M 100114
11/28/05	ASEAN	Pyridoxine HCl	M 197096
11/28/05	ASEAN	Methyldopa	M 200056
11/28/05	ASEAN	Benzylpenicillin Potassium	M 191064
12/28/05	ASEAN	Indomethacin	M 200052
12/28/05	ASEAN	Atenolol	M 100108
12/28/05	ASEAN	Albendazole	M 100107

5.3 Network for Surveillance and Pharmacovigilance

As a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), the NPCB participated in the PIC/S Rapid Alert System which provided information pertaining to punitive actions taken by the Drug Control Authority (DCA) to other PIC/S member countries. Similar information was also disseminated to other regulatory authorities through the WHO network.

5.3 WHO Collaboration in the Field of GMP Inspection

The NPCB collaborated with the WHO and PIC/S in conducting GMP training and regional assessments under the EC-ASEAN Technical Cooperation Programme. A joint PIC/S GMP inspection was also conducted in Malaysia.

5.4 Capacity Building of other Regional National Regulatory Authorities

In accordance with the ASEAN harmonization initiatives**,** the NPCB provided technical assistance to Myanmar in the implementation of ASEAN Common Technical Dossier / Requirements. A Study Tour and Attachment Training in Atomic Absorption Spectroscopy was also conducted by NPCB for two NIDQC Vietnam officers from 14 November – 16 December 2005.

Under the EC-ASEAN Technical Cooperation Programme for pharmaceuticals, the NPCB also co-organised training in the assessment of data submitted for marketing authorisation: Bioavailability/Bioequivalence Studies. Several ASEAN member countries participated in the training course.

Through the above EC-ASEAN Program as well, NPCB participated in the Proficiency Testing Scheme for Pharmaceuticals and Cosmetics. To facilitate the setting-up of EC-ASEAN testing methods for cosmetics, NPCB contributed several testing protocols which have been adopted.

5.5 WHO Collaboration

In collaboration with the WHO, the NPCB was also involved in the evaluation of dossiers for HIV/AIDS, malaria and TB drugs for the purpose of pre-qualification. A workshop on the evaluation of analytical data validation and testing of Hepatitis B vaccine was organised by the NPCB with technical assistance from the WHO. Several ASEAN member countries also attended the one-week workshop.

NPCB also participated in collaboration with WHO in testing activities under the WHO Quality Assurance Program by carrying out tests on samples sent by WHO.

5.6 Staff Development

In 2005, a number of officers from the centre had undergone training courses in several areas to upgrade and improve their knowledge and skills.

5.6.1 Postgraduate studies

i) Seetha a/p Ramasamy - M Sc (2004 – 2005)
ii) Mokhtar bin Abdullah - M Sc (2005 – 2006)
iii) Muhammad Nasir b Hashim - M Sc (2005 – 2006)
iv) Noraida bt Mohamad Zainoor - PhD (2005 – 2008)

5.6.2 Participation of staff in local courses / seminars / meetings

i. EC-ASEAN Economic Cooperation on Standards, Quality & Conformity Assessment (Proficiency Tests), 17 - 18 January 2005, NPCB, Malaysia.
ii. International Good Manufacturing Practice Training Program - Module 1: International GMPs & Quality Assurance, 17 - 19 January 2005, Selangor, Malaysia.

iii. WHO Workshop on GMP/QA for Anti TB Products, 21 – 25 January 2005, Kuala Lumpur, Malaysia.
iv. Evidence - Based Medicine Workshop, 23 – 25 February 2005, NPCB, Malaysia.
v. International Good Manufacturing Practice Training Program - Module 2: GMP for Manufacturing Operations, 23 – 25 February 2005, Selangor, Malaysia.
vi. International Good Manufacturing Practice Training Program - Module 3: Good Quality Control Laboratory Practices, 23 – 25 March 2005, Selangor, Malaysia.
vii. 2nd Technical Meeting between NPCB and HSA, 4-5 April 2005, Singapore
viii. Training Course on ISO 9001:2000 - Internal Audit, 11 - 12 April 2005, Selangor, Malaysia.
ix. Seminar on `Strategic Management of Intellectual Property Assets', 25 April 2005, Putrajaya, Malaysia.
x. International Good Manufacturing Practice Training Program - Module 4: Validation Principles, 28 - 29 April 2005, Selangor, Malaysia.
xi. Cosmetic Seminar 2005, 25 – 26 May 2005, Selangor, Malaysia.
xii. Biregional Workshop On Promoting Ethical Practices In Medicines Registration And Procurement, 31 May – 2 June 2005, Universiti Sains Malaysia, Penang, Malaysia (Organised by WHO).
xiii. 4th ASEAN Cosmetic Committee Meeting, 7 - 8 June 2005, Kuala Lumpur, Malaysia.
xiv. Training in the assessment of data submitted for marketing authorization: Bioavailability / Bioequivalence studies, 13 – 15 June 2005, Selangor, Malaysia.
xv. Training on Good Aseptic Practices and Sterile Production, 22 – 24 June 2005, Selangor, Malaysia.
xvi. Workshop on Hospital Pharmacy Aseptic Practices, 27 – 29 June 2005, Terengganu, Malaysia.
xvii. National Regulatory Conference 2005, 6 - 7 September 2005, Selangor, Malaysia.
xviii. 1st National Oncology Pharmacy Conference, 6 - 7 September 2005, Penang, Malaysia.
xix. Workshop On Intellectual Property Protection For Biomedical Scientific Research, 15 September 2005, Kuala Lumpur, Malaysia.
xx. Development for Therapeutics: A Perspective for Pharmaceutical Products, 21 – 23 September 2005, Selangor, Malaysia.
xxi. International Good Manufacturing Practice Training Program - Module 9, 22 – 23 September 2005, Selangor, Malaysia.
xxii. Avaya Public Sector Conference 2005, 4 October 2005, Kuala Lumpur, Malaysia.
xxiii. GMP Workshop for Finalization of the GMP Modules (Cosmetics), 14 – 19 November 2005, Selangor, Malaysia.
xxiv. AHWP (ASEAN Harmonisation Working Group) Meeting on Medical Devices, 23 – 25 November 2005, Pahang, Malaysia.
xxv. Regional Seminar on the 13 Modules of GMP for Cosmetics, 30 November – 1 December 2005, Selangor, Malaysia.
xxvi. ASEAN GMP Cosmetic Training, 30 November – 2 December 2005, Selangor, Malaysia.
xxvii. Workshop on the Evaluation of Analytical Data Validation and testing of Hepatitis B vaccine, 5 - 9 December 2005, NPCB, Malaysia (Organised by WHO and NPCB).
xxviii. National Workshop On Promoting Ethical Practices in Medicines Registration, Selection and Procurement, 21 - 22 December 2005, Selangor, Malaysia.

5.6.3 *Participation of staff in International Events*

i) PIC/S Committee Meeting, 8 - 9 February 2005, Geneva, Switzerland.
ii) ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) Meeting, 21 - 24 February 2005, Makati City, Philippines.
iii) EC-ASEAN Training on the Production & Utilization of ASEAN Reference Substance, 21 - 25 February 2005, Jakarta, Indonesia.
iv) 3rd Conference on ASEAN Priority on e-ASEAN and Healthcare, 8 March 2005, Singapore
v) Training on the Understanding of EU and PIC/S GMP Requirements, 7 – 11 March 2005, Jakarta, Indonesia.
vi) EC-ASEAN Training for Auditors on International GMP Guidelines, 14 -18 March 2005, Jakarta, Indonesia.
vii) Meeting of PIC/S Expert Circle on Hospital Pharmacy, 4 – 5 April 2005, Riga, Republic of Latvia.
viii) Training on TPN and CDR Facilities and Practices, 28 April 2005, Singapore General Hospital, Singapore.
ix) EC-ASEAN Meeting of Experts on GMP in Pharmaceutical Sector, 2 – 4 May 2005, Jakarta, Indonesia.
x) Consultation on WHO GMP Guidelines, 2-5 May 2005, Geneva
xi) Hands on Training of GMP Inspectors and Local Industry Experts (Auditing on non-sterile facilities), 8 – 14 May 2005, Hanoi, Vietnam.
xii) Training in the Assessment of Data Submitted for Marketing Authorisation - Stability Data, 10 – 12 May 2005, Jakarta, Indonesia.
xiii) Hands on Training of GMP Inspectors and Local Industry Experts (Auditing on sterile facilities), 15 - 21 May 2005, Manila, Filipina.
xiv) Hands on Training of GMP Inspectors and Local Industry Experts: Auditing of Non Sterile Facilities, 16 – 20 May 2005, Hanoi, Vietnam.
xv) Third Conference on International Harmonisation of Veterinary Medicinal Products (VICH 3), 25 – 27 May 2005, Washington DC, USA.
xvi) WHO Consultation on Quality Control of Herbal Medicines, 13 – 15 June 2005, Abu Dhabi, United Arab Emirates.
xvii) Preparation of GMP Training Modules for Cosmetic Manufacturers in ASEAN, 13 – 16 June 2005, Jakarta, Indonesia.
xviii) ASEAN Australia Development Cooperation Program - ASEAN Good Regulatory Practice Workshops – Cosmetics, 15 - 16 June 2005, Bangkok, Thailand.
xix) EC-ASEAN Economic Cooperation - “Regional Expert Consultation on the Establishment of an ASEAN SPC” Meeting, 22 - 24 June 2005, Manila, Philippines.
xx) EC-ASEAN Training for Auditors on Quality System Documentation & Procedures, 4 – 8 July 2005, Bangkok, Thailand.
xxi) Consultative Meeting for the Priority Integration Sectors (COPS), 8-9 July 2005, Jakarta
xxii) Drug Regulatory Authority Mission, 16-23 July 2005, Islamabad, Pakistan
xxiii) The 3rd Meeting Of Traditional Medicines and Health supplements Product Working Group (TMHS-PWG), 6 – 8 July 2005, Bali, Indonesia.
xxiv) Training of GMP Inspectors and Local Experts “Quality System Documentation and Procedures”, 11 - 15 July 2005, Bangkok, Thailand.
xxv) Hands on Training of GMP Inspectors - Training of QA Managers, 8 -12 August 2005, Hanoi, Vietnam.
xxvi) 10th Meeting of ACCSQ PPWG, 23-26 August 2005, Singapore
xxvii) Pharmaceutical Inspection Cooperation Scheme (PIC/S) - Meeting of Officials, 12 - 13 September 2005, Bucharest, Romania.

xxviii) Seminar on Primary Packaging Material, Labelling and Prevention of Mix Up, 14 - 16 September 2005, Bucharest, Romania.

xxix) EC-ASEAN Meeting of Experts on GMP in Pharmaceutical Sector, 19 – 23 September 2005, Jakarta, Indonesia.

xxx) EC-ASEAN Meeting of Experts on GMP in Pharmaceutical Sector, 26 – 28 September 2005, Jakarta, Indonesia.

xxxi) EC-ASEAN Regional Workshop on Sampling Strategies and Procedures, 6 - 7 October 2005, Hanoi Vietnam.

xxxii) Meeting to launch for Field Testing of an Operational Guide to Ensure the Quality of Medicines in Low-income Countries, 11-13 October 2005, Siem Reap

xxxiii) Hands-on Training in the EU for GMP Inspectors, 10 – 21 October 2005, Lisbon-Porto-Coimbra, Portugal.

xxxiv) EC-ASEAN GMP Cosmetic Task Force Training, 22 – 30 October 2005, Paris, France.

xxxv) Hands-on Training in the EU for GMP Inspectors, 14 - 25 November 2005, Portugal.

xxxvi) Attachment Training on "Regulation of Non-Prescription / Complementary Medicines", 25 November – 9 December 2005, Therapeutic Goods Administration, Canberra, Australia.

xxxvii) WHO Working Group Meeting on the International Regulatory Cooperation of Herbal Medicines, 28 - 30 November 2005, Ottawa, Canada.

xxxviii) 5th ASEAN Cosmetic Committee Meeting, 6 - 8 December 2005, Brunei Darussalam.

xxxix) 3rd Senior Officials Meeting on Health Development and 2nd Meeting of ASEAN-India Working Group on Health and Pharmaceutical, 6-10 December 2005, Jakarta

xl) Conclusion Meeting on the Organisation of ASEAN Proficiency Test and Training in the Organisation of Proficiency Tests, 19 - 20 December 2005, Bangkok, Thailand.

5.7 Expert/Advisor/Consultancy Services

i) **Abida Haq Syed M. Haq** served as a moderator during the 28th WHO Annual Meeting of Representatives of the National Centres Participating in the WHO Program for International Drug Monitoring, 26 - 29 September 2005, Geneva, Switzerland.

ii) **Dr. Sulaikah Moideen** was appointed WHO Consultant on Quality Control of Herbal Medicines held in Abu Dhabi, UAE in June 2005.

iii) **Eisah A. Rahman** participated in the technical consultation on WHO GMP Guidelines organised by the WHO in May 2005 held in Geneva, Switzerland.

iv) **Eisah A. Rahman** was appointed as WHO Consultant to assist Pakistan in establishing a system of regulatory control for pharmaceuticals (DRA Mission) in July 2005 held in Islamabad.

v) **Eisah A. Rahman** was appointed as facilitator for the Meeting on Developing a Guide to Improve Quality Assurance in Low Income Countries in October 2005 held in Siem Reap, Cambodia.

vi) **Eisah A. Rahman** served as Co-Chair for the 2nd and 3rd Meeting of Traditional Medicine and Health Supplements Product Working Group held on 27 - 28 January 2005 in Kuala Lumpur and 6 - 8 July 2005 in Bali respectively.

vii) **Fudziah Ariffin** was appointed as the ASEAN Expert for the EC-ASEAN Training on BA/BE Studies in June 2005 held in Kuala Lumpur, Malaysia.

viii) **Fudziah Ariffin** was appointed as WHO Temporary Adviser for the Meeting on Consultation on Regulation Requirements for Bioequivalence and Interchangeability of Medicines in July 2005 held in Geneva, Switzerland.

ix) **Fudziah Ariffin** was appointed as WHO Temporary Adviser for the Meeting on WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2005 held in Geneva, Switzerland.

x) **Fudziah Ariffin** was appointed as the Chairman for the Meeting at the Biregional Consultation on the Production of ARVs and Other Essential Medicines in November 2005 held in Manila, Philippines.

xi) **Kadariah Mohd. Ali** served as the ASEAN Senior Expert in Pharmaceuticals for Indonesia 2005.

xii) **Kadariah Mohd. Ali** served as a consultant for setting up clean room facilities of public and private hospitals in Malaysia.

xiii) **Mohd Lukmani Ibrahim** participated in the ASEAN Senior Experts Debriefing and Presentation to the ASEAN Cosmetic Chair – The Cosmetic Work Programme for 2005 held on the 2nd of February 2005 in Bangkok, Thailand.

xiv) **Mohd Lukmani Ibrahim** served as Head of the ASEAN Senior Experts for The Cosmetic Work Program 2005. He also served as:

a. Chairperson for the Workshop on GMP Training Modules for Cosmetic, 13 - 16 June 2005, Jakarta, Indonesia.
b. Chairperson for the Workshop on Finalization of GMP Training Modules for Cosmetic, 14 - 16 November 2005, Kuala Lumpur, Malaysia.
c. Facilitator & Trainer for the On Site Auditing for Cosmetic "How To Conduct An Inspection" for ASEAN National Regulatory Authority, 17 - 19 November 2005, Kuala Lumpur, Malaysia.
d. Plenary Sessions Facilitator of the Regional Seminar on the GMP Training Modules, 30 November 2005 – 2 December 2005, Kuala Lumpur, Malaysia.

xv) **Noorizam Ibrahim** conducted training for the Food and Drug Administration, Ministry of Health, Myanmar from the 1st to the 4th of February 2005. The scope of training included the ASEAN Common Technical Dossier / Requirement in line with ASEAN Harmonization.

xvi) **Rosilawati Ahmad** served as facilitator for the Medicine Price Monitoring Workshop, 21 – 24 November 2005, Melaka, Malaysia.

5.8 Presentations

i) **Abida Haq Syed M. Haq -** *ADR Reporting & Product Complaints*. Paper presented at the Clinical Pharmacy Workshop, 1 April 2005, Penang, Malaysia.

ii) **Abida Haq Syed M. Haq -** *Adverse Drug Reactions, Complaints & Product Recall*. Paper presented at the Competency Level Assessment 4 ('Penilaian Tahap Kecekapan' 4) Course, 15 April 2005, Selangor, Malaysia.

iii) **Abida Haq Syed M. Haq -** *Adverse Dermatological Manifestations of Drugs*. Paper presented at the Melaka State Pharmacy Conference, 21 June 2005, Melaka, Malaysia.

iv) **Abida Haq Syed M. Haq -** *ADR Reporting: The Malaysian Experience (Plenary lecture)*. Paper presented at the Kelantan State Health Conference, 7 July 2005, Kelantan, Malaysia.

v) **Abida Haq Syed M. Haq -** *Complaints & Product Recall*. Paper presented at the Competency Training for Grade U48 Pharmacy Officers, 13 July 2005, Selangor, Malaysia.

vi) **Abida Haq Syed M. Haq -** *ADR Reporting*. Paper presented at the Competency Level Assessment 4 ('Penilaian Tahap Kecekapan' 4) Course, 26 July 2005, Negeri Sembilan, Malaysia.

vii) **Abida Haq Syed M. Haq -** *ADR Reporting*. Paper presented at the Kota Bharu Hospital CME Session, 4 August 2005, Kelantan, Malaysia.

viii) **Abida Haq Syed M. Haq -** *ADR Reporting*. Paper presented at the Competency Level Assessment 4 ('Penilaian Tahap Kecekapan' 4) Course, 16 September 2005, Selangor, Malaysia.

ix) **Anis Talib –** *Cosmetic Product Registration Updates*. Paper presented at the Updates on Health Supplements & Cosmetics Product Registration, 2 February 2005, Selangor, Malaysia.

x) **Anis Talib –** *Updates on Cosmetic Registration*. Paper presented at the Updates on Cosmetics Product Registration Session, 26 February 2005, Pahang, Malaysia.

xi) **Anis Talib –** *Opportunity for the Beauty Market in Malaysia*, 4 May 2005, Bangkok, Thailand.

xii) **Anis Talib –** Lecturer at the *Cosmetics and Health Supplements Consumer Awareness Workshop*, 29 May 2005, Kedah, Malaysia.

xiii) **Bariah Ab. Rani –** Briefing on the *Functions of the National Pharmaceutical Control Bureau* to Newly Appointed Pharmacist in the Public Sector 2004, 15 September 2005, Langkawi, Malaysia.

xiv) **Eisah A. Rahman –** *DCA Policy Updates*. Paper presented at the Seminar on Control of Quality and Safety of Traditional Medicines and Health Supplements, 26 January 2005, Kuala Lumpur, Malaysia.

xv) **Eisah A. Rahman** – *Regulatory Control in Malaysia and Registration of Pharmaceuticals, Traditional Medicines and Cosmetics*. Paper presented at the Competency Course for Senior Pharmacists, 14 April 2005, Selangor, Malaysia.

xvi) **Eisah A. Rahman** – *Role of the Drug Control Authority (DCA)*. Paper presented at the Annual Scientific Meeting of National Heart Association of Malaysia, 15 April 2005, Kuala Lumpur.

xvii) **Eisah A. Rahman** – *ASEAN Cosmetic Harmonisation.* Paper presented at the Cosmetic Seminar 2005, 25 May 2005, Selangor, Malaysia.

xviii) **Eisah A. Rahman** – *Updates on ASEAN Pharmaceutical Harmonisation and Strategies for Phasing Out Metered Dose Inhalers containing CFC*. Papers presented at the National Regulatory Conference 2005, 6 - 7 September 2005, Selangor, Malaysia.

xix) **Eisah A. Rahman** – *Regulatory Control of Pharmaceuticals*. Paper presented at the Meeting to Launch for Field Testing of an Operational Guide to ensure the Quality of Medicines in Low-income Countries, 11 - 13 October 2005, Siem Reap.

xx) **Fudziah Ariffin** – *ASEAN SPC.* Paper presented at the 9th ACCSQ-PPWG Meeting & Seminar 'Moving towards Harmonisation Implementation', 21 – 24 February 2005, Manila, Philippines.

xxi) **Fudziah Ariffin** – *ASEAN BA/BE Guidelines: Comparator Products*. Paper presented at the 9th ACCSQ-PPWG Meeting & Seminar 'Moving towards Harmonisation Implementation', 21 – 24 February 2005, Manila, Philippines.

xxii) **Fudziah Ariffin** – *ASEAN BA/BE Guidelines.* Paper presented at the EC-ASEAN Training on BA/BE Studies, 13 – 15 June 2005, Selangor, Malaysia.

xxiii) **Fudziah Ariffin** – *ASEAN List of Active Substances, Comparator Products & BE Centre Inspection.* Paper presented at the 10th ACCSQ-PPWG Meeting & Seminar 'Assuring the Quality of Medicines and Vaccines', 23 – 26 August 2005, Singapore.

xxiv) **Fudziah Ariffin** – *Phasing Out CFC MDIs by Year 2020*. Paper presented at the 5th MPS Pharmacy Scientific Conference 2005, 11 - 13 November 2005, Selangor, Malaysia.

xxv) **Fudziah Ariffin** – *Country Report on the production of Anti-retroviral (ARVs) and other Essential Medicines.* Paper presented at the Biregional Consultation on the Production of ARVs and Other Essential Medicines, 16 - 17 November 2005, Manila, Philippines.

xxvi) **Fudziah Ariffin** – *ASEAN Harmonization Regulatory Perspective*. Paper presented at the Sanofi Pasteur's Emerging Asian Countries Meeting, 1 December 2005, Selangor, Malaysia.

xxvii) **Kadariah Mohd. Ali -** *PIC/S Guidelines for current Good Manufacturing Practices of Biomanufacturing.* Paper presented at the Regional Seminar on Biomanufacturing – from Conceptual to Commercialization, 25 April 2005, Putrajaya, Malaysia.

xxviii) **Kadariah Mohd. Ali -** *GMP Audit.* Paper presented at the Seminar on Good Manufacturing Practices for Pharmacy Enforcement Officers, 9 – 10 June 2005, Kelantan, Malaysia.

xxix) **Kadariah Mohd. Ali -** *GMP Guidelines.* Paper presented at the Seminar on Good Manufacturing Practices for Pharmacy Enforcement Officers, 9 – 10 June 2005, Kelantan, Malaysia.

xxx) **Kadariah Mohd. Ali -** *Current Trends in GMP.* Paper presented at the Seminar on Good Manufacturing Practices for Pharmacy Enforcement Officers, 9 – 10 June 2005, Kelantan, Malaysia.

xxxi) **Kadariah Mohd. Ali -** *GMP Requirements for Aseptic Preparations – 2nd Speaker.* Paper presented at the Hospital Pharmacy Aseptic Workshop, 27 - 29 June 2005, Terengganu, Malaysia.

xxxii) **Kadariah Mohd. Ali -** *Development of Clean Rooms for Hospital Pharmacy – 2nd Speaker.* Paper presented at the Hospital Pharmacy Aseptic Workshop, 27 - 29 June 2005, Terengganu, Malaysia.

xxxiii) **Kadariah Mohd. Ali -** *Qualification & Maintenance of Clean Rooms.* Paper presented at the Hospital Pharmacy Aseptic Workshop, 27 - 29 June 2005, Terengganu, Malaysia.

xxxiv) **Kadariah Mohd. Ali -** *Product Complaints and Recall.* Paper presented at the Seminar on Good Storage Practice, 6 August 2005, Perlis, Malaysia.

xxxv) **Kadariah Mohd. Ali -** *Maintaining Products Quality Through Good Storage Practices.* Paper presented at the Seminar on Good Storage Practice, 6 August 2005, Perlis, Malaysia.

xxxvi) **Kadariah Mohd. Ali -** *Auditing an integrated pharmacy store.* Paper presented at the Workshop on Good Storage Practices – Auditing a Pharmacy Integrated Store, 7 August 2005, Perlis, Malaysia.

xxxvii) **Kadariah Mohd. Ali -** *PIC/S Good Production Practices in Hospital Pharmacy.* Paper presented at the National Oncology Pharmacy Seminar, 7 September 2005, Penang, Malaysia.

xxxviii) **Kadariah Mohd. Ali -** *PIC/S Training on Conducting GMP Audit of Aseptic Manufacturing Facilities.* 12 – 15 December 2005, Selangor, Malaysia.

xxxix) **Kamaruzaman b. Saleh (Dr.)** – Invited Lecturer of the Good Clinical Practise Meeting, 8 – 9 March 2005, Penang, Malaysia.

xl) **Kamaruzaman b. Saleh (Dr.)** – Lecturer at the Evidence Base Practise and Critical Appraisal Workshop, 28 – 29 April 2005, Penang, Malaysia.

xli) **Kamaruzaman b. Saleh (Dr.)** – Invited Lecturer of the NPCB Journal Club, 27 May 2005, Selangor, Malaysia.

xlii) **Kamaruzaman b. Saleh (Dr.)** – Lecturer at the Implementation of the Good Clinical Practise 2005 Meeting, 29 May 2005, Johor, Malaysia

xliii) **Kamaruzaman b. Saleh (Dr.)** – Invited Lecturer at the Good Clinical Practise Workshop, 31 May 2005 – 2 June 2005, Selangor, Malaysia.

xliv) **Kamaruzaman b. Saleh (Dr.)** – Lecturer at the Good Clinical Practise Meeting, 14 – 16 June 2005, Kuala Lumpur, Malaysia.

xlv) **Mazuwin Zainal Abidin** - *Regulating Pharmaceuticals in Malaysia*. Paper presented at the ASEAN-Australian Development Cooperation Program (AADCP) – "Good Regulatory Practice Workshop - Pharmaceutical", 13 - 14 June 2005, Bangkok, Thailand.

xlvi) **Nurhayati bt. Omar** – ASEAN - Post Market Surveillance. Paper presented at the Cosmetic Seminar 2005, 25 May 2005, Selangor, Malaysia.

xlvii) **Nurhayati bt. Omar** – Market Surveillance of Registered Products. Paper presented at the Pharmacy Officer Seminar - Northern Zone Level 2005, 1 September 2005, Penang, Malaysia.

xlviii) **Saleha Md**. **Ewan** – Lecturer at the Technical Program Seminar for Biotechnology Sector, organised by the Small and Medium Industries Development Corporation Malaysia (SMIDEC), 24 February 2005, Johor, Malaysia.

xlix) **Tajuddin Akasah (Dr.)** – Lecturer on *GMP for Investigational Medicinal Products* Training, 9 March 2005, Penang, Malaysia.

l) **Tajuddin Akasah (Dr.)** – Lecturer on *GMP for Investigational Medicinal Products* Training, 29 May 2005, Johor, Malaysia.

li) **Tajuddin Akasah (Dr.)** – Lecturer on *GMP for Investigational Medicinal Products* Training, 20 October 2005, Kuala Lumpur, Malaysia.

lii) **Tajuddin Akasah (Dr.)** – Lecturer on *Control of Drug and Cosmetic in Malaysia*, 7 December 2005, Kuala Lumpur, Malaysia.

5.9 Research

i) Hasenah Ali (Dr.) – Postgraduate (PhD) : Studies on Selected Malaysian Plants as Antidiabetic Agents, October 2001 - February 2005, King's College London, University of London, London, United Kingdom.

ii) Seetha Ramasamy – Quality Evaluation of Eurycoma Longifolia Jack Raw Material According to the Methods in the Malaysian Herbal Monograph & Development of a HPLC Profile for Tongkat Ali as Another Parameter of Quality Evaluation, 2004 – 2005, Faculty of Science, University of Malaya, Kuala Lumpur, Malaysia (part-fulfilment for Masters Program).

5.10 Journal Club

The National Pharmaceutical Control Bureau also formed the NPCB Journal Club in 2005 whereby the first session was held on the 27th of May 2005. The Journal Club Session is held once every month. A total of ***8 sessions*** were held throughout 2005. During each session, two NPCB officers will present on current relevant issues, recent articles from journals or a brief summary of a course that they recently attended.

6. REGULATORY STATUS

i. Up until December 2005, a cumulative total of **145,161** product applications for registration have been received, of which **115,886** have been approved.

The following are the breakdown for the type of applications received in 2005:

Scheduled poisons (prescription item)	- 703
Non-scheduled poisons (non – prescription item)	- 645
Traditional medicines	- 1807
Cosmetics	- 28,632
TOTAL	***- 31,787***

ii. Up until 2005, the cumulative total number of products registered is 115,886. Of these, 10,339 are prescription drugs, 7,732 are over-the-counter medicines, 14,385 are traditional medicines and health supplements and 83,430 are cosmetics.

iii. A total of 2,605 Certificates of Pharmaceutical Product (CPP) and 2,541 Certificates of Free Sale (CFS) were issued for the year 2005. The total number of Clinical Trial Import Licences (CTIL) issued was 210.

iv. A total of 296 manufacturing premises were licensed in 2005, of which 87 are for pharmaceutical, 148 for traditional and 61 for cosmetic. For importers, a total of 652 were licensed, of which 175 are for pharmaceutical, 137 traditional and 340 cosmetic. For wholesalers, a total of 943 were licensed, of which 422 are for

scheduled poisons while 521 are for non-scheduled poisons, traditional and cosmetics.

v. Under the post-market surveillance program, a total of 2,483 samples were taken from the market, 1,428 labels and package inserts examined, 74 products were recalled, 42 warnings were issued and 269 product complaints were handled.

vi. As for quality control testing, a total of 4,605 samples were tested of which 2,165 were registration samples, 1,985 were surveillance samples, 101 were from product complaints and 272 were enforcement samples. A total of 56,641 tests were conducted.

vii. A total of 556 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 484 vials were sold to the private sector (comprising of 395 NPCB reference standards and 89 ASEAN reference standards).

viii. Under the Adverse Drug Reactions Monitoring Program, a total of 2,363 ADR reports were received in 2005, of which 2,009 reports had been evaluated and sent to the Uppsala WHO Monitoring Centre for inclusion into the WHO database.

ix. A total of 3,006 queries pertaining to products and also general information from both the public and private sectors were dealt with.

7. HIGHLIGHTS OF ACHIEVEMENTS IN 2005

i. The on-line registration for pharmaceuticals and traditional medicines has successfully entered its third and second year of implementation respectively. The system has been further enhanced with additional new modules for application of product variation and appeals.

ii. Licensing of cosmetic manufacturers, importers and wholesalers have been put in place. Emphasis was given to technical guidance sessions to assist the cosmetic industry.

iii. Several new guidelines to facilitate product registration were revised and developed by the Technical Working Groups involving the NPCB and relevant industry. The adopted documents are made available in the NPCB website (www.bpfk.gov.my).

iv. The quality management system based on MS ISO 9001 version 2000 was successfully maintained and certified by SIRIM.

v. 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. The NPCB has also participated in other international consultations as well as Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries.

vi. The NPCB together with the pharmaceutical, traditional medicine and cosmetic industry organisations successfully organised the National Regulatory Conference 2005 in conjunction with the celebration of the 20th anniversary of the Drug Control Authority.

vii. The existing office areas were renovated and upgraded to provide a more conducive environment to its personnel and customers and to improve image.

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.

ii. Meeting of ASEAN Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP)

Malaysia will host the next Meeting of the ASEAN Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP) in Kuching, Sarawak. The NPCB has been tasked to take the lead in organising this meeting in May 2006.

In conjunction, a workshop on the implementation of Compulsory Licensing to improve access to ARV will also be conducted with technical assistance from the WHO.

An ASEAN Workshop for DRA to introduce Fast Track Registration System scheduled for August 2006 will also be hosted by Malaysia with technical support from the WHO.

iii. Reinforcing PIC/S GMP

To further strengthen and upgrade the level of GMP compliance of local pharmaceutical and traditional medicines manufacturers to gain global recognition and facilitate market penetration.

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

iv. Intensification of post-market surveillance

To intensify surveillance activities to combat problems associated with adulteration, counterfeits and product authentication and to promote public health protection through education and awareness.

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

v. ASEAN Harmonisation and Healthcare Integration

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

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

vi. Enhancement of Information and Communication Technology (ICT)

To implement the on-line registration for New Chemical Entities (NCE) and biotechnology products.

To integrate the different on-line modules involving product registration, licensing of premises, analytical testing, surveillance, ADR monitoring and dissemination of information to enable better networking.

Keeping abreast with rapid developments in ICT, the existing QUEST 2 computer system will be upgraded to QUEST 3 under the 9th Malaysia Plan (2006-2010).

vii. ISO 17025 Certification

To further upgrade the laboratory quality management system to achieve the ISO 17025 accreditation by 2007.

viii. Strengthening Clinical Research

To upgrade the existing unit to become a Centre for Clinical Research to coordinate activities related to GCP, GLP and BA/BE.

To strengthen capacity and capability in the inspection of clinical testing facilities.

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

9. CONCLUSION

International collaborations in relevant technical areas provide an excellent platform for NPCB in establishing mutual understanding amongst regulatory partners towards strengthening pharmaceutical quality assurance. As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals since 1996, the NPCB will strive and continue to play important roles to fulfil the commitments and expectations as laid down in the terms of reference. Capacity and capability building as well as upgrading infrastructure are important in our efforts to ensure continuous improvements and to keep abreast with current global regulatory developments.