WHO ANNUAL REPORT 2004

1. NAME OF COLLABORATING CENTRE

WHO Collaborating Centre for Regulatory Control of Pharmaceuticals

2. ADDRESS

National Pharmaceutical Control Bureau
Ministry of Health
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 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

- Datin Hasiah bt. Hj. Abdullah – B.Sc (Pharmacy)

Deputy Heads

- Eisah bt. A. Rahman – B. Pharm, M. Sc.,Dip. Medical Microbiology
- Yogeswary a/p Markandoo – B. Sc. Pharm (Hon), M.Sc

Officers

1. Abida Haq bt Syed M. Haq - B.Pharm (Hons), Dip Med Microbiology, M. Sc
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. Ainul Salhani bt Abdul Rahman – B. Pharm (Hons)
6. Aida Haryati bt. Abd. Rahim – B. Pharm (Hons)
7. Ani bt Abdullah - B. Pharm (Hons)
8. Anis bt Talib - B. Pharm (Hons)
9. Aryani bt Ahmad - B. Pharm (Hons)
10. Arpah bt Abas - B. Pharm
11. Asnida bt Mat Daud - 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. Dayang Hanani bt. Umar – B. Pharm (Hons)
19. Faridah bt Hj. Abd. Malek - B. Pharm (Hons)
20. Fudziah bt Ariffin - B. Pharm, Dip. Med. Microbiology, M Sc
21. Fuziah bt. Abdul Rashid – B.Pharm (Hons)
22. Halimatussa'adiah bt. Mat Som – B. Pharm (Hons)
23. Hasniza bt. Zaidan – B. Pharm (Hons)
24. Hazlinda Nazli bt Naem - B. Pharm (Hons)
25. Ida Syazrina bt Ibrahim - B. Pharm (Hons)
26. Jaafar b Lassa - B. Pharm (Hons), M. Sc
27. Juliana bt. Abdullah – B. Pharm (Hons)
28. Kadariah Mohd. Ali - B. Pharm (Hons), M. Sc
29. Kamaruzaman b Saleh (Dr.) - B. Pharm (Hons), M. Sc, Ph D
30. Mazli bt Muhamad - B. Pharm (Hons), M. Sc.
31. Mazuwin bt Zainal Abidin - B. Pharm (Hons), M. Sc
32. Mohd. Nasrul b. Mohamad Noor – B. Pharm (Hons)
33. Mokhtar bin Abdullah – B. Pharm (Hons)
34. Muhammad Lukmani b Ibrahim - B. Pharm (Hons)
35. Muhammad Nasir b Hashim - B. Pharm (Hons)
36. Nik Juzaimah bt Nik Juhari – B. Pharm (Hons)
37. Nik Shamsiah bt Nik Salleh - B. Pharm (Hons)
38. Noraida bt Mohamad Zainoor - B. Sc Pharm (Hons), M. Sc.
39. Noor' Ain bt Shamsuddin – B. Pharm (Hons)
40. Noraisyah bt Mohd. Sani - B. Pharm (Hons)
41. Noorizam bt. Ibrahim – B. Pharm (Hons), M. Sc
42. Norhafizah bt. Mohd. Potri – B. Pharm (Hons)
43. Noor Hidayah bt. Mohd. Nor – B. Pharm (Hons)

44. Norhayati bt. Musa – B. Pharm (Hons)
45. Norhayati bt. Omar – B. Pharm (Hons)
46. Norrehan bt. Abdullah – B. Pharm (Hons), M.Pharm (Clinical Pharmacy)
47. Norul Azmira bt. Abu Bakar – B. Pharm. (Hons)
48. Nurhayati bt. Othman – B. Pharm (Hons)
49. Nurleen Mohamed Ali – B. Pharm (Hons)
50. Nurul Fajar bt Mohd. Jamid - B. Pharm (Hons)
51. Rohani bt Ismail – B. Pharm, M. Sc
52. Rosilawati bt Ahmad - B. Pharm (Hons), M. Sc.
53. Saleha bt Md. Ewan - B. Pharm (Hons)
54. Siti Azzyatty bt Ismail - B. Pharm (Hons)
55. Siti Hidayah bt. Kasbon – B. Pharm (Hons)
56. Siti Madziah bt. Mohamed - B. Pharm (Hons)
57. Somiyaton bt Dahalan @ Damuri - B. Pharm (Hons)
58. Sulaikah bt V.K. Moideen (Dr.) - B. Pharm (Hons), M. Sc, Ph D
59. Zuraida bt Abdullah - B. Pharm (Hons)
60. Sulaiman b Haji Ahmad - B. Pharm (Hons)
61. Suhailah bt Abu Bakar - B. Pharm (Hons)
62. Tajuddin Akasah (Dr.) - B. Pharm (Hons), M. Sc, Ph. D
63. Tan Ann Ling - B. Pharm (Hons)
64. Tan Chuan Ai – B. Pharm (Hons)
65. Wan Nurul Aina bt. Mior Abdullah – B. Pharm (Hons)
66. Wan Othman Ismail - B. Pharm (Hons)
67. Yvonne Khoo Siew Khoon – B. Pharm (Hons)
68. Yusni Rizal b. Khairul Anuar – B. Pharm (Hons)
69. Zahura bt Ismail - B. Pharm (Hons)
70. Zakiah bt Abd. Ghafar - B. Pharm (Hons)
71. Zaril Harza b. Zakaria – B. Pharm (Hons)
72. Zarina bt Rosli - B. Pharm (Hons)

Total Number of Pharmacists – 75

Other Support Staff

- Pharmacy Assistants - 62
- Science Officers - 24
- Administrative and Support Staff – 35

TOTAL NUMBER OF STAFF: 196

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.

The centre recorded a total of 28 international visitors and WHO fellows from various countries namely Brunei Darussalam, China, Cuba, Fiji, Hong Kong, Mongolia, Singapore, South Africa and Vietnam.

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 2004, Malaysia sent 3 proposed ASEAN reference standards namely prednisolone, nystatin and diphenhydramine to Singapore and Philippines. Malaysia also participated and had submitted collaborative study reports for other proposed ASEAN reference standards which include betamethasone dipropionate, rifampicin and cefradoxil.

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.

5.4 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. Joint PIC/S GMP inspections were also conducted in Greece and Netherlands.

5.5 Capacity Building of other Regional National Regulatory Authorities

In accordance with the ASEAN harmonization initiatives**,** the NPCB had provided technical assistance to Vietnam in the implementation of ASEAN Common Technical Dossier/Requirement. Review of regulatory systems in Cambodia and Thailand were also conducted in collaboration with the WHO.

5.6 WHO Collaboration in the Evaluation of Dossiers

In collaboration with the WHO, the NPCB had also been involved in the evaluation of dossiers for HIV/AIDS, malaria and TB drugs for the purpose of pre-qualification.

5.7 Staff Development

In 2004, officers from the centre had undergone training courses in several areas to upgrade and improve their knowledge and skills.

5.7.1 Postgraduate studies

i)	Hasenah bt. Ali	- PhD (2002 – 2005)
ii)	Noorul Akmal bt. Mohd Nor	- PhD (2003 – 2006)
iii)	Ramli bin Zainal	- PhD (2003 – 2006)
iv)	Rosehayati bt. Sani	- PhD (2003 – 2006)
v)	Roselawati bt. Ahmad	- M Sc (2003 – 2004)
vi)	Seetha a/p Ramasamy	- M Sc (2004 – 2005)

5.7.2 Participation of staff in local courses/ seminars/ meetings

i. Training on Amino Acid analysis using pre-column derivatising with ACCQ Tag method.
ii. Theory on Dissolution Testing Lecture and Hands-on Practical Training.
iii. Theoretical aspects and techniques of TLC.
iv. Techniques in auditing a microbiology laboratory.
v. Seminar on Regulation and Safety of Dietary Supplements in Safeguarding Public Health, January 2004, Petaling Jaya.
vi. Vaccine Expert Meeting, January 2004, NPCB
vii. Awareness and Consensus Seminar on Implementation of CFC – free MDIs, May 2004, Petaling Jaya
viii. ASEAN Cosmetic Harmonization Seminar, March 2004, Petaling Jaya
ix. Asian Workshop on Drugs for Neglected Diseases Initiative, February 2004, IMR, Kuala Lumpur
x. Industry Forum on Regulatory Requirements for Traditional Medicines, April 2004, Putrajaya
xi. Seminar "Rethinking Malaysia – Meeting the Challenges of a New Era", May 2004, Kuala Lumpur
xii. Seminar on Cosmetic Registration, May 2004, Kota Bharu
xiii. Seminar for new Pharmacists Grade U48 attached to NPCB and Pharmaceutical Services Division, June 2004, NPCB
xiv. Seminar on Time Management, July 2004, NPCB
xv. 1st National Health Outcome Seminar, July 2004, Kuala Lumpur
xvi. 24th Meeting of ASEAN Consultative Committee for Standards and Quality (ACCSQ), August 2004, Kuala Lumpur
xvii. APEC Chemical Dialogue Seminar on Globally Harmonized System, September 2004, Kuala Lumpur
xviii. Regional Training Workshop ASEAN Common Technical Dossier/ Requirement (ACTD/R) under EC–ASEAN Program, October 2004, Kuala Lumpur.
xix. Training on Hologram Security Labelling for Enforcement, October 2004, Johor Bahru
xx. Australian Natural Product Showcase and Forum between AUSTRDE and NPCB, November 2004, Kuala Lumpur
xxi. 2nd Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses, November 2004, Kuala Lumpur
xxii. Conference for U48 Pharmacists (2004), December 2004, Kuantan
xxiii. Seminar on GMP Auditing,
xxiv. Seminar on MS ISO 9000 Implementation/Certification
xxv. Seminar on Water System for Use in the QC Laboratories and Production Areas, September 2004, Cyberjaya
xxvi. Seminar on Particle Counting Technology, September 2004, Petaling Jaya

5.7.3 ***Participation of staff in International Events***

i) Biotechnology Joint PIC/S Inspection, Netherlands
ii) PIC/S Joint Visit Programme – Training for GMP Inspectors, Switzerland and Malaysia
iii) Training Course on ACTD/ACTR, Vietnam
iv) WHO Consultation on Contaminants and Residues in Herbal Medicines, Milan, Italy
v) 8th ACCSQ Pharmaceutical Product Working Group Meeting, Bangkok
vi) EC-ASEAN Consultation on Implementation of ACTD/ACTR, Bangkok
vii) 11th International Conference for Drug Regulatory Authorities, Madrid
viii) USP Meeting on Quality Control of Drugs, Chiengmai

ix) 1st Meeting PWG Traditional Medicines and Health Supplements, Jakarta
x) EC-ASEAN Workshop on Mutual Recognition System, Jakarta
xi) WHO Meeting on Stability Studies, Geneva
xii) ASEAN Cosmetic Committee Meeting, Jog Jakarta
xiii) 21st Meeting ASEAN Working Group in Technical Cooperation of Pharmaceuticals, Vientiane
xiv) Meeting of the International Society for Pharmacovigilance, Dublin, Ireland.
xv) Seminar in Nutraceutical, Complimentary Medicine & Cosmoceutical Asia – Middle East, Bangkok, Thailand
xvi) EC-ASEAN Economic Cooperation Programmer CCSQ Manila, Philippines
xvii) Regional Assessment GMP for Cosmetic under EC-ASEAN Programme Singapore
xviii) 1st Technical Meeting between NPCB, Malaysia and National Agency for Drugs and Food Control (NADFC), Indonesia, March 2004, NPCB
xix) 1st Technical Meeting between NPCB, Malaysia and Health Sciences Authority (HSA), Singapore, May 2004, NPCB
xx) 1st Bilateral Meeting between Malaysia and China PDR on Health Issues, April 2004, Kuala Lumpur
xxi) EC-ASEAN Workshop on Centralised System of Marketing Authorisation and Mutual Recognition Agreements for Pharmaceuticals, September 2004, Jakarta.
xxii) ISPE Fundamental Training Course on Containment, March 2004, Basel, Switzerland
xxiii) ISPE Job Focus Training Course on Pharmaceutical Manufacturing Facility Design and Development, April 2004, Basel, Switzerland
xxiv) Training Course on Pharmaceutical Water System – Design, Qualification and Maintenance, October 2004, St. Denis, France
xxv) WHO workshop on GMP of Antimalarial Drugs, October 2004, Bangkok
xxvi) PIC/S Executive Bureau Meeting – Joint Reassessment Visit Programme, Geneva, Switzerland
xxvii) EU-ASEAN Economic Cooperation Programme on Standards, Quality and Conformity Assessment Expert Meeting, December 2004, Hanoi

5.8 Expert/Advisor/Consultancy Services

i) **Noorizam Ibrahim** and **Fudziah Ariffin** conducted training for the Drug Administration of Vietnam from 30th May to 6th June 2004. The scope of training includes the implementation of ASEAN Common Technical Dossier / Requirement in line with ASEAN Harmonization.

ii) **Mohd Lukmani Ibrahim** served as ASEAN Senior Expert for GMP in Preparation Workshop and ASEAN Cosmetic Committee and in Regional Assessment GMP for Cosmetic under EC-ASEAN program 18 – 20th August 2004, Singapore.

iii) **Mohd Lukmani Ibrahim** served as ASEAN Senior Expert for Regional Assessment GMP for cosmetics under EC-ASEAN program, Badan Pengawasan Ubat dan Makanan Jakarta Indonesia 1st – 4th September 2004, Drug & Cosmetic Quality Management Division, Drug Administration of Vietnam, 7 – 9th September 2004 Ho Chi Minh City, Vietnam.

iv) **Eisah A. Rahman, Fudziah Ariffin and Mazuwin Zainal Abidin** participated in the Expert Consultation on ACTD and ACTR under ASEAN Harmonization Program, 19 – 20th July, 2004, Bangkok Thailand .

v) **Fudziah Ariffin** served as WHO Temporary Adviser in 8th CCSQ-PPWG Meeting & 3rd Thailand International Seminar on ASEAN Harmonization-ICH Experienced on CTD Implementation. 21 – 23rd July 2004, Bangkok Thailand; in the WHO Meeting on Consultation on Stability Studies in a Global Environment, 13th -14th December 2004, Geneva

vi) **Eisah A. Rahman** served as co-writer for USP Drug Quality Control Guide for Low Income Countries, March 2004, Chiangmai

vii) **Dr Sulaikah Moideen** appointed as a WHO Consultant on Contaminants and Residues in Herbal Medicines, Milan, Italy

viii) **Eisah A. Rahman** served as facilitator for Asian Workshop on Drugs for Neglected Diseases Initiative (DNDi), February 2004, Kuala Lumpur

ix) **Eisah A. Rahman** served as Chair of EC-ASEAN Conference on Centralised Marketing Authorisations and Mutual Recognition System for Pharmaceuticals, September 2004, Jakarta.

x) **Eisah A. Rahman** served as Co-Chair of Product Working Group Traditional Medicines and Health Supplements under ACCSQ, August 2004, Jakarta

xi) **Eisah A. Rahman** served as Facilitator for the Regulators Group Session at the 2nd Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses, November 2004, Kuala Lumpur

xii) **Kadariah Mohd Ali –** Preparation of Guidelines on Requirements for the Development of Pharmacy Department within Ministry of Health.

xiii) **Kadariah Mohd Ali –** Technical Consultant for the Construction of Clean rooms for CDR activities, TPN, Eye-drop and IV Admixtures production in public hospitals under Ministry of Health and Ministry of Defence.

xiv) **Kadariah Mohd Ali** – Evaluation Expert Committee for Clean room Suppliers for Government Hospitals

xv) **Kadariah Mohd Ali** – Expert in the Construction of New Facilities for the Manufacture of Sterile Products and Ventilation and Purification Systems.

xvi) **Kadariah Mohd Ali** – ASEAN Expert for GMP Inspection and Premises Licensing System in Indonesia under EC-ASEAN Programme.

5.9 Presentations

i) **Abida Haq -** Factors for Success in Pharmacovigilance . Paper presented at 11th International Conference for Drug Regulatory Authorities (ICDRA), 19th February 2004, Madrid.

ii) **Abida Haq -** Pharmacovigilance Planning: Impact on Non-ICH Countries. Paper presented to International Society for Pharmacovigilance,. 7th October 2004, Dublin, Ireland

iii) **Abida Haq -** Food Supplements – Do we really need them? Paper presented at Forum organized by Family Health Division Ministry of Health, 13th July 2004,Kuala Lumpur

iv) **Abida Haq -** Studies on Adverse Drug Reactions to Traditional Medicines. Paper presented at Seminar for Research and Development in Pharmacy 13th July 2004, Kuala Lumpur

v) **Anis Talib –** Regulations and The Control of Food Supplements & Cosmetics in Malaysia. Paper presented at Seminar for Consumers Awareness organized by Ministry of International Trade and Industry Malaysia in various states ie Langkawi (January 2004), Perlis (28th February 2004), Sarawak (Sarikei, Kapit & Sibu 5th -7th March 2004), K. Lumpur (17th April 2004), Sandakan Sabah (17th May 2004), Perlis (October 2004).

vi) **Anis Talib -** Overview of Cosmetic Regulations . Paper presented at Seminar on Cosmetic Registration organized by National Pharmaceutical Control Bureau and Cosmetic ,Toiletry & Fragrance Association 23rd -24th March 2004, Hyatt Subang Hotel, Malaysia

vii) **Anis Talib -** Current Issues on the Control and Registration Of Cosmetics . Paper presented at the Seminar on Cosmetics Registration organized by the Kelantan State Pharmacy Department 23rd May 2004.

viii) **Anis Talib -** Current Issues on the Control and Registration Of Cosmetics organized by the Selangor State Pharmacy Department in Klang 11th August 2004 and in Shah Alam 28th August 2004.

ix) **Anis Talib -** The Control of Health Supplement and Cosmetics. Paper presented at Cosmetic Seminar Organized by Malacca State Pharmacy Department and HEP Malacca 4th December 2004

x) **Anis Talib -** Progress on ASEAN Harmonized Cosmetic Regulatory Scheme in Malaysia. Paper presented at the 2nd ASEAN Cosmetic Committee (ACC) Meeting & 1st ASEAN Cosmetic Scientific Body (ACSB) for Cosmetics on 7th - 9th June 2004 Bangkok and 3rd ACC Meeting & 2nd ACSB Meeting on 7th - 9th December 2004 Yogyakarta, Indonesia.

xi) **Arpah Abas** – Regulation of Blood Product in Malaysia. Paper presented at Meeting of Development of Harmonization of QA System in Blood Product FDA/WHO Thailand 30th October 2004

xii) **Arpah Abas** - Registration of Traditional Medicine in Malaysia. Paper presented in the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organized by Biotechnology Directorate, Ministry of Science, Technology and Environment. Putrajaya, 20th April 2004.

xiii) **Arpah Abas** – Overview : Product Registration at Meeting Regarding Halal issues Islamic Development Department of Malaysia (JAKIM) 30th April 2004

xiv) **Bariah Abdul Rani –** Product Classification. Paper presented the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organized by Biotechnology Directorate, Ministry of Science, Technology and Environment. 19th April 2004, Putrajaya.

xv) Dr. Sulaikah Moideen - Sample Management (Regulatory aspect), Good Laboratory Practice (Regulatory aspect). Papers presented to Pharmacy Assistants NPCB 25th February 2004.

xvi) **Dr. Tajuddin Akasah -** Good Manufacturing Practice (GMP) for Investigational Medicinal Product (IMP). Paper presented at Clinical Research Centre, Ministry of Health, Malaysia on 26th July 2004 and 5th December 2004.

xvii) **Dr. Tajuddin Akasah** - GMP and Safety Requirement of Total Parenteral Nutrition (TPN) and Cytotoxic Drug Reconstitution (CDR) Facilities. Paper presented at the Senior Pharmacist U48 Conference organized by the Pharmaceutical Services Division, Ministry of Health, 9th December 2004.

xviii) **Dr. Tajuddin Akasah** - GMP in Herbal / Biotech Manufacturing. Paper presented at the National Seminar on Regulatory Procedures for Traditional Medicinal Products and New Chemical Entities organized by the Ministry of Science and Technology and Environment, Malaysia 11th September 2004, Putrajaya.

xix) **Dr. Tajuddin Akasah** - GMP for Traditional Medicines. Paper presented at the Seminar organization by Forest Research Substitute (FRIM) 21st July, 2004, Kuala Lumpur.

xx) **Dr. Tajuddin Akasah** - GMP and GSP for Cosmetics. Paper presented at the Seminar on Cosmetics Registration organized by the Kelantan State Pharmacy Department.

xxi) **Dr. Tajuddin Akasah -** ASEAN Guidelines for Cosmetic GMP. Paper presented at the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organized by Biotechnology Directorate, Ministry of Science Technology and Environment. 19 –20 April 2004, Putrajaya.

xxii) **Dr Kamaruzzaman Salleh -** Regulatory Aspects of Clinical Trial in Malaysia .Paper presented at Good Clinical Practice Workshop at Universiti Sains Malaysia Kubang Krian Malaysia 17th August 2004

xxiii) **Dr Kamaruzzaman Salleh –** Regulatory Aspects of Clinical Trial in Malaysia .Paper presented at Implementation of Good Clinical Practice Meeting Pulau Sibu Resort Mersing Johore , Malaysia 3rd September 2004

xxiv) **Eisah A. Rahman** – Promoting Good Regulatory Practice, Malaysian Experience, 11th ICDRA. February 2004, Madrid.

xxv) **Eisah A. Rahman** – Current Review of Traditional Medicines Registration, Industry Forum on Registration of Traditional Medicines. April 2004, Putrajaya.

xxvi) **Eisah A. Rahman** – Malaysian Transition Strategy for the Phase out of CFC Use in MDI, Awareness Seminar on CFC free MDIS.May 2004, Subang Jaya.

xxvii) **Eisah A. Rahman** – Introduction to Cosmetic Control, Seminar on Cosmetic Registration. May 2004, Kota Bharu.

xxviii) **Eisah A. Rahman** – Regulatory Updates, Briefing for New Pharmacists U48, NPCB, June 2004

xxix) **Eisah A. Rahman –** Drug Policy in Malaysia: Improving Accessibility and Availability, 1st National Health Outcome Seminar. July 2004, Kuala Lumpur.

xxx) **Eisah A. Rahman** – Regulating Pharmaceuticals in Malaysia – Challenges Faced by the National Pharmaceutical Control Bureau, MPS Seminar on Entrepreneurship and Management in Pharmacy, November 2004, Kuala Lumpur

xxxi) **Eisah A. Rahman** – Current Regulatory Development, Local, Regional and Global Challenges, Conference for Pharmacists U48 (2004). December 2004, Kuantan.

xxxii) **Eisah A**. **Rahman** – Lecture on New Registration Procedure, Competency Course (PTK4) for Pharmacists U48, May and August 2004

xxxiii) **Eisah A**. **Rahman** – Lecture on GMP and Licensing, Competency Course (PTK4) for Pharmacists U48, May and August 2004

xxxiv) **Eisah A**. **Rahman** – Policy Issues and Recommendations (Group A- Fiji, Indonesia, Malaysia, Papua New Guinea, Philippines and Thailand), Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines, November 2004, Kuala Lumpur

xxxv) **Fudziah Ariffin** – Regulatory Aspects of Clinical Trials in Malaysia, GCP Workshops, Malaysia (5 times)

xxxvi) **Fudziah Ariffin** – An Overview of NCE Registration in Malaysia, April 2004, Putrajaya

xxxvii) **Fudziah Ariffin** – Pharmacovigilance Initiatives in Malaysia, April 2004, Beijing

xxxviii) **Fudziah Ariffin -** Selection of BE Comparator Products, July 2004, Bangkok

xxxix) **Fudziah Ariffin –** ACTD Part 1 : Administrative Data, October 2004, Kuala Lumpur

xl) **Jaafar Lassa** - Quality Assurance of Herbal Products in Malaysia. Paper presented at IDB-COMSTECT-INTROM IMR Workshop on Herbal Medicine 16th February 2004, Kuala Lumpur.

xli) **Jaafar Lassa -** New Regulation and Quality Control of Herbal Products. Paper presented in Dialogue with Herbal Industry of Malaysia. 6th April 2004, Kuala Lumpur.

xlii) **Kadariah Mohd Ali –** Pharmaceutical HVAC System. February 2004, NPCB.

xliii) **Kadariah Mohd Ali** – GMP Requirements and Implementation, April 2004, Seremban

xliv) **Kadariah Mohd Ali** – GMP Requirements for Traditional Industry, April 2004, Putrajaya

xlv) **Kadariah Mohd Ali** – GMP: Regulatory Requirements and Achievements of NPCB in PIC/S, June 2004, Fraser Hill

xlvi) **Kadariah Mohd Ali -** Introduction to ISO 9001-2000, July 2004, NPCB

xlvii) **Kadariah Mohd Ali** – Preparing a GMP Audit Report, September 2004, NPCB

xlviii) **Kadariah Mohd Ali** – GMP Investigative Auditing, September 2004, NPCB

xlix) **Kadariah Mohd Ali** – Good Storage Practice, September 2004, Kangar Hospital, Perlis

l) **Mazuwin Zainal Abidin -** Online Registration. Paper presented at the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New

Chemical Entity organized by Biotechnology Directorate Ministry of Science and Technology and Environment. 20th April 2004, Putrajaya.

li) **Mazuwin Zainal Abidin** - Control of Nutraceuticals and Cosmeceuticals in Malaysia. Paper presented at the Seminar on Nutraceuticals, Complimentary Medicine and Cosmoceuticals Asia – Middle East 2004, 29th June, 2004 Bangkok Thailand.

lii) **Mazuwin Zainal Abidin** – Procedure for Registration of Pharmaceutical Product. Paper presented at Continuous Professional Development Program (CPD) session . Pharmacy Services Division State Health Department Selangor, Malaysia 28th August 2004.

liii) **Muhammad Nasir Hashim** - Good Laboratory Practice. Paper presented to Laboratory Assistants of NPCB. 24th November 2004.

liv) **Saleha Mohd Ewan** – Market Entry and Product Registration of Herbal and Natural Products in Malaysia .Paper presented in seminar organized by Malaysian Herbal Corporation , 14th October,2004,Jakarta

lv) **Saleha Mohd Ewan** – Registration of Traditional Medicine in Malaysia. Paper presented in the National Seminar on Regulatory Procedure for Traditional Medicinal Product and New Chemical Entity organized by Biotechnology Directorate, Ministry of Science, Technology and Environment. 19th April 2004 Putrajaya.

lvi) **Yogeswary Markandoo –** Progress Report by Malaysia on Implementation of Activities. Paper presented at 21st Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceutical. 22nd – 24th September 2004 Vientiane, Lao PDR.

6. REGULATORY STATUS

i. Up to December 2004, a cumulative total of 113,347 product applications for registration have been received, of which 77,939 have been approved.

The following are the breakdown for the type of applications received in 2004:

Scheduled poisons (prescription item)	- 529
Non-scheduled poisons (non – prescription item)	- 720
Cosmetics	- 30,630
Traditional medicines	- 2,220

ii. Up until 2004, the cumulative total number of products registered is 77,939. Of these, 10,012 are prescription drugs, 7432 are over-the-counter medicines, 13,077 are traditional medicines and health supplements and 47,418 are cosmetics.

iii. A total of 1886 Certificates of Pharmaceutical Product (CPP) and 1305 Certificates of Free Sale (CFS) were issued for the year 2004. The total number of Clinical Trial Import Licences (CTIL) issued was 277.

iv. A total of 227 manufacturing premises were licensed in 2004, of which 74 are for pharmaceutical, 131 for traditional and 22 for cosmetic. For importers, a total of 456 were licensed, of which 180 are for pharmaceutical, 131 traditional and 145

cosmetic. For wholesalers, a total of 867 were licensed, of which 407 are for scheduled poisons while 460 are for non-scheduled poisons.

v. Under the post-market surveillance program, a total of 3094 samples were taken from the market, 1792 labels and package inserts examined, 179 products were recalled, 81 warnings were issued and 297 product complaints were handled.

vi. As for quality control testing, a total of 4847 samples were tested of which 2270 were registration samples, 2305 were surveillance samples, 139 were from complaints and 124 were enforcement samples. A total of 51,424 tests were conducted.

vii. A total of 885 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 507 vials were sold to the private sector.

viii. Under the Adverse Drug Reactions Monitoring Program, a total of 1665 ADR reports were received in 2004, of which 1454 reports had been evaluated and sent to the Uppsala WHO Monitoring Centre for inclusion into the WHO database.

ix. A total of 1489 queries pertaining to products and also general information from both the public and private sectors were dealt with.

7. HIGHLIGHTS OF ACHIEVEMENTS IN 2004

i. The organization of NPCB was restructured in June 2004 to streamline the registration, quality control, GMP, post registration and organizational developments functions. The physical infrastructure was also upgraded.

ii. The on-line registration for traditional medicines and health supplements was implemented in January 2004. Additional funds were acquired for upgrading the QUEST 2 computer infrastructure and maintenance, both in terms of hardware and software. Additional new on-line modules were developed to increase work efficiency and productivity.

iii. Several new guidelines pertaining to product registration were adopted and made available in the NPCB website (www.bpfk.gov.my).

iv. Licensing for cosmetic manufacturers, importers and wholesalers was enforced in January 2004.

v. The quality management system based on MS ISO 9001 version 2000 was maintained and certified by SIRIM. The scope of accreditation was expanded to include cosmetics registration and QUEST 2 on-line procedure.

vi. The ASEAN Common Technical Dossier/Requirements for the purpose of harmonization was incorporated into the QUEST 2 on-line system and implemented as requirement for registration.

vii. The NPCB was actively involved 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.

viii. Other international involvements include Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries.

8. FUTURE PLANS

i. Expansion of Scope for Product Registration

To implement a system for registration and licensing of veterinary medicines and active pharmaceutical ingredients (API).

ii. 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 global market penetration.

iii. 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.

iv. Detection method for adulterants in traditional medicines

To organize laboratory training on analytical techniques for the detection of adulterants particularly in traditional preparations and health supplements.

v. 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.

To further enhance the existing IT infrastructure.

vi. ISO 17025 Certification

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

vii. Inspection of Clinical Testing Facilities

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

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