WHO ANNUAL REPORT 2007

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: 03-78835400
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.

3.10 To provide training on regulatory matters pertaining to pharmacy enforcement activities; and

3.11 To provide training on regulatory matters pertaining to the sale and advertisement of medicines**.**

4. STAFF LIST

Head of Centre

- Hasnah bt. Ismail -- B.Sc (Hons), M.SC (Pharm.Sci)

Deputy Heads

- Selvaraja Seerangam – B. Pharm (Hons), M. Phil.
- Dr. Sulaikah Bt. V.K. Moideen - B. Pharm (Hons), M.Sc, Ph.D
- Pn. Abida Haq bt Syed M. Haq – B. Pharm (Hons), Dip Med Microbiology, M. Clin Pharmacy

Officers

1. Abdullah Hisham Bin Ahmad Yaya – B. Pharm (Hons), M. Pharm (Clinical Pharmacy)
2. Ahmad Syamsury bin Sulaiman – B. Pharm (Hons)
3. Ahmad Zakhi bin Ramli – B. Pharm (Hons)
4. Aida Haryati bt. Abd. Rahim – B. Pharm (Hons)
5. Anis bt Talib - B. Pharm (Hons)
6. Arpah bt Abas - B. Pharm(Hons)
7. Asnida bt Mat Daud - B. Pharm (Hons)
8. Azraini bt Abdul Samat - B. Pharm (Hons)
9. Azrina bt Hassan - B. Pharm (Hons)
10. Azura bt Abdullah - B. Pharm (Hons)
11. Azlina bt. Ismail – B. Pharm (Hons)
12. Bariah bt. Abdul Rani – B.Pharm (Hons)
13. Belinna Binti Abu Bakar - B. Pharm (Hons)
14. Chin Fui Fui - B. Pharm (Hons)
15. Ching Shan Lii – B. Pharm (Hons)
16. Chiong Yuh Lian – B. Pharm (Hons)
17. Chua Hui Ming – B. Pharm (Hons)
18. Debbie Sim Sook En - B. Pharm (Hons)
19. Faridah bt Hj. Abd. Malek - B. Pharm (Hons)
20. Fazillahnor Binti Ab. Rahim - B. Pharm (Hons)
21. Fuziah bt. Abdul Rashid – B. Pharm (Hons)
22. Halimatussa'adiah bt. Mat Som – B. Pharm (Hons)
23. Han Mei Yin - B. Pharm (Hons)
24. Hasenah bt. Ali - B. Pharm (Hons), M. Sc, Ph D
25. Hasniza bt. Zaidan – B. Pharm (Hons)*
26. Hazlinda Nazli binti Naem – B. Pharm (Hons)
27. Hng Kim Mi - B. Pharm (Hons)
28. Ida Syazrina bt Ibrahim - B. Pharm (Hons)
29. Irdawaty bt. Mohd. Salleh – B. Pharm (Hons)
30. Juanah Binti Garabus – B. Pharm (Hons)
31. Kadariah bt. Mohd. Ali - B. Pharm (Hons), M. Sc
32. Kamaruzaman b. Saleh (Dr.) - B. Pharm (Hons), M. Sc, Ph D
33. Kamarudin bin Ahmad – B. Sc. (Pharm)
34. Khirul Falisa Binti Mustafa - B. Pharm (Hons)
35. Kok Chuan Fung - B. Pharm (Hons)

36. Lee Sher May – M. Pharm
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. Mazlifah Bt. Mohd Fahami - B. Pharm (Hons)
45. Mazuwin bt. Zainal Abidin - B. Pharm (Hons), M. Sc
46. Mohd. Nasrul b. Mohamad Noor – B. Pharm (Hons)
47. Mohamed Shahrizan Bin Shahrir - B. Pharm (Hons)
48. Mokhtar bin Abdullah - B. Pharm (Hons)
49. Muhammad Lukmani b. Ibrahim - B. Pharm (Hons)
50. Muhammad Nasir bin Hashim - B. Pharm (Hons)
51. Nahdiah Binti Ariffin - B. Pharm (Hons)
52. Narqes Bt. Mohd. Raimi - B. Pharm (Hons)
53. Nik Shamsiah bt Nik Salleh - B. Pharm (Hons)
54. Noor'ain bt. Shamsuddin – B. Pharm (Hons)
55. Noraida binti Mohamad Zainoor - B. Pharm (Hons)*
56. Noraisyah bt Mohd. Sani - B. Pharm (Hons)
57. Noorizam bt. Ibrahim – B. Pharm (Hons), M. Pharm
58. Noorul Akmar Bt. Mohd. Nur – B. Pharm (Hons)
59. Nor Hafizah bt. Mohd. Potri – B. Pharm (Hons)
60. Noor Hidayah bt. Mohd. Nor – B. Pharm (Hons)
61. Nor Hayati Bt. Hussein – B. Pharm (Hons)
62. Nor Hayati Bt. Musa – B. Pharm (Hons)
63. Nor Hayati Abdul Rahim – B. Pharm (Hons)
64. Norshida binti Kassim - B. Pharm (Hons)
65. Norul Azmira bt. Abu Bakar – B. Pharm. (Hons)
66. Nurhayati bt. Omar – B. Pharm (Hons)
67. Nurhayati bt. Othman – B. Pharm (Hons)
68. Norleen bt. Mohamed Ali – B. Pharm (Hons)
69. Nurul Fajar bt Mohd. Jamid - B. Pharm (Hons)*
70. Ong Yi Chin - B. Pharm (Hons)
71. Rosilawati bt Ahmad - B. Pharm (Hons), M. Sc.
72. Saleha bt. Md. Ewan - B. Pharm (Hons)
73. Sarawani binti Hassan - B. Pharm (Hons)
74. Seetha a/p Ramasamy - B. Pharm (Hons)
75. Siti Hidayah bt. Kasbon – B. Pharm (Hons)
76. Siti Madziah bt. Mohamed - B. Pharm (Hons), M. Pharm
77. Slavia Fifi Koh Yin Ying- B. Pharm (Hons)
78. Somiyaton bt Dahalan @ Damuri - B. Pharm (Hons)
79. Sufian Hardi bin Mohamad Zuhair - B. Pharm (Hons)
80. Suhaili Binti Samad - B. Pharm (Hons)
81. Suhailah bt Abu Bakar - B. Pharm (Hons)
82. Sulaiman Bin Hj. Ahmad – B. Pharm (Hons)
83. Suzana binti Mohd. Nor- B. Pharm (Hons)
84. Tan Ann Ling - B. Pharm (Hons)
85. Tan Lie Sie - B. Pharm (Hons)
86. Tan See Hooi - M. Pharm
87. Tan Shiau Yi - B. Pharm (Hons)
88. Tan Teck Koon - M. Pharm
89. Tg. Mira binti Tengku Fatimi - B. Pharm (Hons)
90. Vidhya a/p Hariraj - B. Pharm (Hons)
91. Wan Nurul Aina bt. Mior Abdullah – B. Pharm (Hons)

92. Wan Othman Wan Ismail - B. Pharm (Hons)
93. Yip Yi Hui – M. Pharm
94. Yvonne Khoo Siew Khoon – B. Pharm (Hons)
95. Yusni Rizal b. Khairul Anuar – B. Pharm (Hons)
96. Zahura bt. Mohamed @ Ismail - B. Pharm (Hons)
97. Zakiah bt Abd. Ghafar - B. Pharm (Hons)
98. Zaril Harza b. Zakaria – B. Pharm (Hons)
99. Zarina bt Rosli - B. Pharm (Hons)
100. Zuraida bt Abdullah - B. Pharm (Hons)*

Provisionally Registered Pharmacist

1. Tan Kar Yan
2. Jeannie Lee Jing Yi
3. Mesa Chieng Lee Li
4. Zeti Hulwani Bt. Baba
5. Chai Che Leong
6. James Ooi Joe Behn
7. Syahdatul Iman Mohamad
8. Woo Ai Ling
9. P'ng Ziyan
10. Teh Lih Yan
11. Atikah Bt. Shaharudin
12. Chow Guan Kuan
13. Shaik Muhammad Naquib Bin Shaik Mohamed
14. Erina Camilla Bt. Mohd. Ghazali
15. Fadhilah Bt. Hasbullah
16. Siti Nor Rahizah Bt. Abd. Razak
17. Lee Yee Chen
18. Nee Yuan Qi
19. Tan Chin Ling
20. Fauziah Binti Mohamed Kasim

TOTAL NUMBER OF PHARMACISTS – 121
(* _ posts borrowed from other government agencies)

Other Support Staff

- Pharmacy Assistants - 65
- Science Officers (temporary staff) - 22
- Administrative and Support Staff – 34
- Administrative and Support Staff (temporary staff) - 14

TOTAL NUMBER OF STAFF: 260

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 2007, the centre recorded a total of 65 international visitors and WHO fellows from various countries namely Bhutan, China, Mongolia, Ghana, Philippines, Singapore, Saudi Arabia, Macedonia, Nigeria and the United Kingdom.

The courses provided under this programme 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 2007, the National Pharmaceutical Control Bureau (NPCB) completed the standardisation of reference standards supplied to the ASEAN countries. The said reference standards are as listed below:

Date	Type	Reference standard	Batch No
09/01/2007	ASEAN	Diphenhydramine hydrochloride	M 206021
27/12/2006	ASEAN	Guaifenesin	M 206029
27/12/2006	ASEAN	Prednisolone	M 206011

5.3 Network for Surveillance and Pharmacovigilance

In 2007, the NPCB, as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) received a total of 118 Rapid Alerts sent out by PIC/S member countries pertaining to products with quality defects which had been recalled from the market.

Under the ASEAN Harmonisation Scheme, a total of 27 Post- Market Alerts were sent out while 9 Post Market Alerts were received.

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

In the year 2007 NPCB did not participate in any collaboration study in the area of quality assurance involving testing of samples with any other Regional National Regulatory Authorities. However, NPCB is always keen and available if invited by other Regional National Regulatory Authorities to participate in any collaborative work especially in the area of regulatory control of pharmaceuticals, natural products and cosmetics.

5.6 WHO Collaboration

NPCB continued to participate in various testing programmes organised by the WHO. In the year 2007, NPCB collaborated with the WHO for External Quality Assurance Assessment Scheme (Phase 4) on 2 pharmaceuticals using various analytical methods namely:-

i.	Oxytetracycline Dihydrate	:	Water content by Karl-Fischer Method
ii.	Isoniazid Tablet	:	Dissolution testing by UV Spectroscopy

The results of the first procedure was released in October 2007. NPCB performed extremely well with a z-score of -0.07 (any score between 2 to -2 is considered satisfactory). The results of the second procedure will be released in 2008.

5.7 Staff Development

In 2007, 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)	Azlina Ismail	- M Sc (2007- 2008)
iii)	Azrina bt Hassan	- M Sc (2007 - 2008)
iv)	Norhayati Abdul Rahim	- M Sc (2007 - 2008)
v)	Zarina bt Rosli	- M Sc (2007 - 2008)
vi)	Zuraida Abdullah	- M Sc (2007 - 2008)

5.7.2 Participation of staff in local courses / seminars / meetings

The following courses/ seminars/ meetings were held in 2007.

- *Biotech/NCE Preview*

No.	Activity	Date	Venue
1	NCE Preview - Prexige	26 January 2007	NPCB
2	Biotech Preview - Fabrazyme for Fabry Disease	9 March 2007	NPCB
3	NCE Preview - Januvia	23 March 2007	NPCB

4	NCE Preview - Sprycel	13 April 2007	NPCB
5	NCE Preview - Sebivo	20 April 2007	NPCB
6	Biotech Preview - TheraCIM	23 April 2007	NPCB
7	NCE Preview - Tykerb	4 May 2007	NPCB
8	NCE Preview - Acomplia	18 May 2007	NPCB
9	Biotech Preview - Cervarix	25 May 2007	NPCB
10	NCE Preview - Trends in Hypertension Management	29 June 2007	NPCB
11	NCE Preview - Rasilez	13 July 2007	NPCB
12	Biotech Preview - Myozyme	3 August 2007	NPCB
13	NCE Preview - Exforge	10 August 2007	NPCB
14	NCE Preview - Serdolect	17 August 2007	NPCB
15	NCE Preview - Invega	24 August 2007	NPCB
16	Biotech Preview – Biologicals Regulation in Australia Evolving Perspective	4 December 2007	NPCB

- *Conference and Symposium*

No.	Activity	Date	Venue
1	Conference on Manufacturing & Services Sectors 2006	13 Feb. 2007	MIDA
2	6th International Traditional and Complementary Medicine Conference and 3rd International Complementary and Traditional Medicine Materia Medica Conference	19 July 2007	Kuala Lumpur
3	ACCSQ PPWG Conference	23 - 27 July 2007	Sunway Resort Hotel & Spa
4	CPA - Malaysian Pharmaceutical Society Conference	2 - 5 August 2007	Park Royal, Kuala Lumpur
5	1st KL International Breast &Colorectal Cancer Congress	9-11 August 2007	KLCC, Kuala Lumpur
6	BioJohor 2007 International Biotech Conference	17-20 August 2007	Persada, Johor Bahru
7	Consumer Reporting Conference	1 September 2007	Subang Sheraton
8	National Conference on Clinical Research 2007: 'Assuring Medicine Quality'	24 – 26 October 2007	Berjaya Times Convention Centre,Klumpur

- *Courses*

No.	Activity	Date	Venue
1	In-house Induction Course NPCB 01/2006	27 February 2007	NPCB
2	5S Internal Audit Course	11-12 April 2007	Hotel Grand Blue Wave, Shah Alam
3	Evaluation Competency Level 3 Course (PTK 3)	8 May 2007	NPCB
4	In-house Induction Course NPCB 02/2007	18 June 2007	NPCB
5	Introduction course to ISO 9001:2000	19 June2007	NPCB

No.	Activity	Date	Venue
6	In-house Induction Course NPCB 03/2007	22 October 2007	NPCB
7	Text Writing and Public Speaking Course	29-31 October 2007	NPCB

- *Seminars*

No.	Activity	Date	Venue
1	Consumer Medicines Surveillance Seminar 2007– 'Pilot Project on Involving Consumers in Medicines Surveillance',	9 January 2007	Subang, Selangor
2	A short seminar on Concept and Practices in Spa Premises	27 June 2007	NPCB
3	Pharmacy Assistants Seminar	27-29 July 2007	NPCB
4	Seminar on Development of Fluid Therapy	4 September 07	NPCB
5	Critical Quality Attributes	11 September 2007	NPCB

- *Talks*

No.	Activity	Date	Venue
1	Biotech by Professor Dato' Dr. Mohamed Isa Abdul Majid (from Department of International Biotechology , Ministry of Science, Technology and Innovation, Malaysia)	19 January 2007	NPCB
2	Assets Planning (Will-writing and others)	31 January 2007	NPCB
3	Procter & Gamble Work Visit	7 May 2007	NPCB
4	Usage of Chemicals and Diluents	22 June 2007	NPCB
5	CUEPACS- Government Staff Welfare Programme	27 June 2007	NPCB
6	Payment of Obligatory Alms through Pay Deduction	19 July 2007	NPCB
7	Interior Designing	2 August 2007	NPCB
8	Veterinary Registration Presentation & Discussion	16 August 2007	NPCB
9	The role of pharmacotherapy in obesity management & safety of Sibutramine in high-risk cardiovascular patients	17 August 2007	NPCB
10	Retirement : Psychology and Financial Planning	25 October 2007	NPCB
11	Microbiology	1 November 2007	NPCB
12	Micromedex	12 November 2007	NPCB
13	Preparation for Forensic Exam	15 November 2007	NPCB
14	CME talk: Product Classification	17 December 2007	NPCB

- *Training*

No.	Activity	Date	Venue
1	International Good Manufacturing Practices and Quality Management Systems	12 - 14 February 2007	Eastin Hotel

No.	Activity	Date	Venue
2	Good Manufacturing Practice for Pharmaceutical Operations	19 - 21 March 2007	Eastin Hotel
3	Validation Principles	23 - 25 April 2007	Eastin Hotel
4	Contamination Control	21 - 23 May 2007	Eastin Hotel
5	Good Aseptic Practices and Sterile Products	18 - 20 June 2007	Eastin Hotel
2	Good Manufacturing Practice for Pharmaceutical Operations	19 - 21 March 2007	Eastin Hotel
3	Validation Principles	23 - 25 April 2007	Eastin Hotel
4	Contamination Control	21 - 23 May 2007	Eastin Hotel
5	Good Aseptic Practices and Sterile Products	18 - 20 June 2007	Eastin Hotel

- *Workshops*

No.	Activity	Date	Venue
1	Cosmetic Product Safety & Efficacy Evaluation and Post-Marketing Surveillance Workshop	23 - 24 January 2007	Subang, Selangor
2	Polymorphism: A Perspective (Workshop)	7 February 2007	Hilton KL
3	Evidence-Based Medicine Workshop	14 – 16 February 2007	NPCB
4	Evidence-Based Medicine Workshop	24-25 May 2007	NPCB
5	Validation Process Workshop	4-5 June 2007	NPCB
6	Training Workshop on 13 Module of ASEAN GMP for Malaysian Cosmetic and traditional Manufacturers	5-7 November 2007	NPCB

5.7.3 Participation of staff in International Events

Several staff had the opportunity to participate in the following international courses/ seminar/ meetings held in 2007.

No	Activity	Date	Venue
1	4th Malaysia-US Free Trade Agreement Discussion	8 - 12 January 2007	San Francisco, United States of America
2	Seminar on Pharmaceutical and Biotechnology Supply Chain	26 – 29 February 2007	Singapore
3	Expert Meeting on Trade and Health	6 – 7 March 2007	New Delhi, India
4	Study visit to cosmetics manufacturing premises	23 March 2007	Japan
5	Asia Generic Medicines Congress	26 – 28 March 2007	Singapore
6	GMP Inspection on Product Manufacturing Premise for products imported and marketed in Malaysia	26 – 31 March 2007	Hangzhou, China
7	The Complementary Healthcare Council Sponsors Obligations Conference	27 – 31 March 2007	Brisbane, Australia

No	Activity	Date	Venue
8	2nd Regional Meeting on Renal Anaemia Transplantation & SLE	6 – 9 April 2007	Yangon, Myanmar
9	6th Malaysia – US Free Trade Agreement Discussion	9 – 12 April 2007	Washington, United States of America
10	Workshop International Perspective On Dietary Supplement Regulation & IADSA Annual Meeting	15 – 19 April 2007	Yokohama, Japan
11	CDER Forum for International Drug Regulatory Authorities	16 – 20 April 2007	Maryland , United States of America
12	4th Meeting of the ASEAN MRA Task Force on GMP Inspection	16 – 21 April 2007	Ha Noi, Vietnam
13	Meeting On The Future Direction And Work Planning For Implementation Good Radiopharmacy Practices And GMP	22 – 28 April 2007	Shanghai, China
14	3rd Pharmaceutical Sciences World Congress (PSWC) & Post Satellite EAPB and EUFEPS : Workshop on Monoclonal Antibodies (MAWB)	22 – 27 April 2007	Amsterdam, The Netherlands
15	Pharmaceutical Inspection Co-operation (PIC/S) Joint Visit Inspection Group 62	23 – 27 April 2007	Oslo, Norway
16	Rimonabant – A Novel Approach to Cardiometabolic Risk Management	4 – 6 May 2007	Singapore
17	ASEAN Cosmetic Committee (ACC) Meeting	9 May 2007	Jakarta, Indonesia
18	Pharmacovigilance -The Study of Adverse Drug Reactions and Related Problems Training Course	14 – 26 May 2007	UPPSALA, Sweden
19	7th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 8th Meeting of ASEAN Cosmetic Committee (ACC)	5 – 9 June 2007	Lao, PDR
20	Semi Regional Training On PMS	10 – 11 June 2007	Laos
21	International Conference: “New Frontier In The Quality Of Medicine”	13 – 15 June 2007	Strasbourg, France
22	17th European Society of Hypertension Congress	14 – 19 June 2007	Milan, Italy
23	Bio-similars Conference	16 June 2007	Jakarta, Indonesia
24	Study Tour to EU For Head Of Delegation To Learn Experience From EU On Its Implementation Of The EU Cosmetic Directive	17 – 23 June 2007	Brussels & Paris
25	13th Meeting On Production of ASEAN Reference Subtances	25 – 27 June 2007	Nonthamburi, Thailand
26	WHO Consultation On Quality Of Homeopathic Medicine	25 – 27 June 2007	Milan, Italy
27	Technical visit	6 – 18 July 2007	United States of America
28	The 7th Meeting Of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) And Related Meetings	9 – 12 July 2007	Brunei Darussalam
29	World Halal Forum Industry Dialogue, Halal Food International Trade Exhibition, Commodity Fest and 2nd Islamic Industry Dialogue Conference	-	Ningxia, China
30	Head of Delegations’ Meeting on the ASEAN Cosmetic Committee (ACC)	2-5 September 2007	Jakarta , Indonesia

No	Activity	Date	Venue
31	Informal Inter-country Consultation On Public Health, Innovation and Intellectual Property	5-7 September 2007	Manila, Phillipines
32	Study Tour / Workshop on GMP Requirements for Veterinary Medicines, Biotech Products and Active Pharmaceutical Ingredients	5-15 September 2007	Strasbourg, France/ Warsaw, Poland
33	Meeting on the Streamlining Approval of Radiopharmaceuticals for Clinical Use	9-15 September 2007	Vienna, Austria
34	23rd Meeting of ASEAN Working Group on Technical Cooperation in Pharmaceutical (AWGTCP)	22-24 October 2007	Myanmar
35	The International Argoya 2007 Conference	25-29 October 2007	India
36	Regional Workshop – ASEAN Cosmetic Testing Laboratory Network	6-7 November 2007	Manila, Phillipines
37	Informal Inter - country Consultation And Inter-govermental Working Group On Public Health, Innovation And Intellectual Property (IGWG)	3-11 November 2007	Geneva, Switzerland
38	International Expert for GMP Cosmetic Meeting	11-17 November 2007	Manila, Phillipines
39	Regional Workshop – GMP Guidelines- Specific Guidance For Soap Industry in ASEAN	11-17 November 2007	Manila, Phillipines
40	First ASEAN-CHINA Conference on Combating Counterfeit Medical Products'	13-15 November 2007	Jakarta , Indonesia
41	Bi-regional Workshop On Improving Medicine Surveillance And Regulatory Functions'	19-21 November 2007	Manila, Phillipines
42	Workshop On Biopharmaceuticals And EMEA Bio-similar Guidelines	19 November 2007	Thailand
43	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S)	20-22 November 2007	Singapore
44	UNIDO Pharmaceutical Sector Stakeholder Workshop For LDCs'	22 November 2007	Phnom Penh, Cambodia
45	Symposium of APEC Network On Pharmaceuticals Regulatory Science	26-29 November 2007	Taipei, Taiwan
46	The 8th Meeting Of TMHS Product Working Group	26-29 November 2007	Manila, Phillipines
47	UNIDO Project: Strengthening The Local Production Of Essential Generic Drugs In Least Developed Countries(LDCs) Through The Promotion OG SMEs, Business Partnerships, Investment Promotion And South – South Cooperation'	28 November 2007	Vientien, Lao PDR
48	CMR International Institute For Regulatory Science Workshop On The Emerging Markets ' Models Of Best Practice For The Regulatory Review Of New Medicines'	5-6 December 2007	Geneva, Switzerland

No	Activity	Date	Venue
49	8th Meeting Of ASEAN Cosmetic Scientific Body (ACSB) & 9th Meeting Of ASEAN Cosmetic Committee (ACC)	12-13 December 2007	Ho Chi Minh, Vietnam

5.8 Expert/Advisor/Consultancy Services

The following officers served as experts / advisors / consultants in 2007.

No	Name	Activity	Date	Venue
1	Abida Haq bt. Syed M. Syed	Speaker in the Asia Generic Medicines Congress 2007	26 – 28 March 2007	Singapore
2	Abida Haq bt. Syed M. Syed	Session Chairman in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S)	20-22 November 2007	Singapore
3	Ahmad Syamsury Bin Sulaiman	Auditor in GMP Inspection on Product Manufacturing Premise for products imported and marketed in Malaysia	26 – 31 March 2007	Hangzhou, China
4	Anis binti Talib	Head Of Delegation for the ASEAN Cosmetic Committee (ACC)	9 May 2007	Jakarta, Indonesia
5	Anis binti Talib	Chairman for the 7th Meeting of ASEAN Cosmetic Scientific Body (ACSB)	5 – 9 June 2007	Lao, PDR
6	Anis binti Talib	Head Of Delegation for the study tour to EU for Head Of Delegation to learn experience from EU on Implementation of the EU Cosmetic Directive	17 – 23 June 2007	Brussels & Paris
7	Anis binti Talib	Head Of Delegation for The 7th Meeting Of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) And Related Meetings	9 – 12 July 2007	Brunei Darussalam
8	Anis binti Talib	Head Of Delegation in the Head Of Delegation Meeting of ASEAN Cosmetic Committee (ACC)	2-5 September 2007	Jakarta , Indonesia
9	Anis binti Talib	Head Of Delegation in the 8th ACCSQ Traditional Medicine & Health Supplements Product Working Group	26-29 November 2007	Manila, Philippines
10	Arpah binti Abas	Bio-similars Conference	16 June 2007	Jakarta, Indonesia
11	Dr. Sulaikah V.K Moideen	Auditor for Technical visit	6 – 18 July 2007	United States of America
12	Faridah binti Abdul Malek	Representative for Malaysia in the Regional Workshop – ASEAN Cosmetic Testing Laboratory Network	6-7 November 2007	Manila, Phillipines
13	Kadariah Mohd. Ali	Speaker, Meeting On The Future Direction And Work Planning For Implementation Good Radiopharmacy Practices And GMP	22 – 28 April 2007	Shanghai, China
14	Kadariah Mohd. Ali	Speaker , Meeting On 'Streamlining Approval of Radiopharmaceuticals for Clinical Use'	9-15 September 2007	Vienna, Austria

No	Name	Activity	Date	Venue
15	Mazuwin Zainal Abidin	Co-Chair in the Bi-regional Workshop On Improving Medicine Surveillance And Regulatory Functions	19-21 November 2007	Manila, Phillipines
16	Mohd. Nasrul bin Mohamad Noor	Auditor in GMP Inspection on Product Manufacturing Premise for products imported and marketed in Malaysia	26 – 31 March 2007	Hangzhou, China
17	Muhammad Lukmani Ibrahim	GMP expert in the 7th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & 8th Meeting of ASEAN Cosmetic Committee (ACC)	5 – 9 June 2007	Lao, PDR
18	Muhammad Lukmani Ibrahim	GMP expert, the International Expert for GMP Cosmetic Meeting	11-17 November 2007	Manila, Phillipines
19	Muhammad Lukmani Ibrahim	International expert for GMP cosmetics in the Regional Workshop – GMP Guidelines- Specific Guidance For Soap Industry in ASEAN	11-17 November 2007	Manila, Phillipines
20	Muhammad Lukmani Ibrahim	GMP expert in the 8th Meeting of ASEAN Cosmetic Scientific Body (ACSB) & the 9th Meeting of ASEAN Cosmetic Committee (ACC)	12-13 December	Ho Chi Minh, Vietnam
21	Noorizam binti Ibrahim	Speaker in the CMR International Institute For Regulatory Science Workshop On The Emerging Markets ' Models Of Best Practice For The Regulatory Review Of New Medicines	5-6 December 2007	Geneva, Switzerland
22	Seetha A/P Ramasamy	Negotiator in the WHO Consultation On Quality Of Homeophatic Medicine	25 – 27 June 2007	Milan, Italy
23	Seetha A/P Ramasamy	Negotiator in the The 7th Meeting Of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) And Related Meetings	9 – 12 July 2007	Brunei Darussalam
24	Selvaraja Seerangam	Negotiator in the 4th Malaysia-US Free Trade Agreement Discussion	8 - 12 January 2007	San Francisco, United States of America
25	Selvaraja Seerangam	Negotiator in the 4th Meeting of the ASEAN MRA Task Force on GMP Inspection	16 – 21 April 2007	Washington, United States of America
26	Selvaraja Seerangam	Co- Chair in the The 7th Meeting Of Traditional Medicine and Health Supplements Product Working Group (THMS-PWG) And Related Meetings	8 – 13 July 2007	Brunei Darussalam
27	Selvaraja Seerangam	Head of Delegation in the Informal Inter-country Consultation On Public Health, Innovation and Intellectual Property	5-7 September 2007	Manila, Phillipines
28	Tan Lie Sie	Temporary Consultant in the Bi-regional Workshop On Improving Medicine Surveillance And Regulatory Functions	19-21 November 2007	Manila, Phillipines
29	Tan Lie Sie	Facilitator in the UNIDO Pharmaceutical Sector Stakeholder Workshop for LDCs'	22 November 2007	Phnom Penh, Cambodia

5.9 Presentations

The staffs were also active in giving presentations during various training courses. The following presentations were delivered by staff members in 2007.

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

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Fuziah Abdul Rashid	Current Reporting System for Adverse Drug Reactions and Product Complaint	Consumer Medicines Surveillance Seminar 2007	9 January 2007	Subang Sheraton
2	Fuziah Abdul Rashid	Adverse Drug Reactions – The Responsibilities of Healthcare Professionals	Post Marketing Surveillance Workshop	23 January 2007	Subang Sheraton
3	Fuziah Abdul Rashid	Drug Safety Monitoring	Workshop on Regulatory Procedure for Traditional Medicine and New Chemical Entities	21 June 2007	Park Royal, Kuala Lumpur
4	Fuziah Abdul Rashid	Drug Safety Monitoring	National Conference on Clinical Research 2007	26 October 2007	Berjaya Times Square Convention Centre, Kuala Lumpur

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

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Dr. Hasenah Ali	GMP Auditing Technique in Chemical Laboratory	Auditing Technique Workshop	20 April 2007	NPCB
2	Kadariah Mohd. Ali	GMP of Investigational Medicines	Good Clinical Practice Workshop	11 March 2007	Penang Hospital, Malaysia
3	Kadariah Mohd. Ali	Application of GMP-Case Studies	Lecture to 3rd year Pharmacy students	12 March 2007	University of Science, Malaysia
4	Kadariah Mohd. Ali	Regulatory Controls of Radiopharmaceuticals in Malaysia - GMP Aspect	Meeting & Seminar on GMP & GRP	23 April 2007	Shanghai, China
5	Kadariah Mohd. Ali	GCP Workshop - GMP of Investigational Medicines	Good Clinical Practice Workshop	21 May 2007	Mandarin Oriental Hotel, Kuala Lumpur
6	Kadariah Mohd. Ali	Regulatory Requirements of Process Validations	Training on Process Validation for Drug Assessors, GMP	4 June 2007	NPCB

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
			Auditors & Drug Analysts		
7	Kadariah Mohd. Ali	Training on Preparation of Substantial GMP Audit Reports	Training for New GMP Auditors	15 June 2007	NPCB
8	Kadariah Mohd. Ali	Training for New Auditors - Pharmaceutical Water Systems	Training for New GMP Auditors	22 June 2007	NPCB
9	Kadariah Mohd. Ali	Training for Auditors - Pharmaceutical Premises Layout Plans	Training for New GMP Auditors	31 July 2007	NPCB
10	Kadariah Mohd. Ali	GMP of Investigational Medicines	Good Clinical Practice Workshop	9 August 2007	Hilton Hotel, Kuching, Sarawak, Malaysia
11	Kadariah Mohd. Ali	Training for New Auditors on Preparation for Investigational GMP Audit	Training for New GMP Auditors	30 August 2007	NPCB
12	Kadariah Mohd. Ali	GMP of Investigational Medicines	Good Clinical Practice Workshop	15 November 2007	Nikko Hotel, K.L. Malaysia

- *Quality Control/Laboratory*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Dr Hasenah Ali	Good Laboratory Practice for Safety Evaluation as OECD Guide and Malaysia Initiative	6th International conference on Traditional/Complementary Medicine Conference (INTRACOM) and 3rd International Congress on Traditional Medicine & Materia Medica (ICTMMM)	19 July 2007	Kuala Lumpur
2	Dr. Hasenah Ali	Introduction to Good Laboratory Practice as OECD Guide in Preclinical Studies	Good Clinical Practice Workshop	12 December 2007	Kuala Lumpur
3	Faridah Abdul Malek	Quality Control of Products – Analytical Aspect	Regulatory Controls of New Chemical Entities and Traditional Products Workshop	19 June 2007	Park Royal Hotel Kuala Lumpur

- *Product Registration*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Suhailah Abu Bakar	Overview of Regulatory Requirements of Generic Pharmaceutical Products, Natural Products & Cosmetic Products	Seminar 'The Role of Pharmacist in Medication Evaluation & Management of Poisoning'	10 July 2007	Awana Genting Golf & Country Resort, Pahang

- *Others*

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
1	Faridah Abdul Malek	Workplace Health And Safety Issues	Internal NPCB Induction Training 1/2007 2/2007 3/2007	27 Feb, 16 June and 22 October 2007	NPCB
2	Faridah Abdul Malek	Importance of Dosage Performance Tests and Methods in Pharmaceutical Products	Seminar for Pharmacy Assistants	29 July 2007	ESSET, Bangi
3	Faridah Abdul Malek	Product Quality and Safety	PTK 4 for Pharmacy Officers Grade U48	23 October 2007	NPCB
4	Kadariah Mohd. Ali	Medicines and Regulatory Challenges of Small & Medium Countries - MALAYSIAN Experience	Consultant Meeting on Streamlining Approvals of Radiopharmaceuticals for Clinical Use	10 September 2007	Vienna, Austria
5	Kadariah Mohd. Ali	The Activities of WHO Collaborating Centre for Medicines in Malaysia	Consultant Meeting on Streamlining Approvals of Radiopharmaceuticals for Clinical Use	12 September 2007	Vienna, Austria
6	Mazuwin Zainal Abidin	Malaysian Transition Strategy for the Phase-Out of CFC in Multi Dose Inhalers (MDI)	CFC Free MDIs Awareness Programme	21 June 2007	Hospital Duchess of Kent, Sandakan, Sabah
7	Mazuwin Zainal Abidin	Malaysian Transition Strategy for the Phase-Out of CFC in MDIs	CFC Free MDIs Awareness Programme	22 June 2007	Hospital Queen Elizabeth, Kota Kinabalu, Sabah
8	Mazuwin Zainal Abidin	Malaysian Transition Strategy for the Phase-Out of CFC in MDIs	CFC Free MDIs Awareness Programme	25 June 2007	Hotel Harbour View, Kuching, Sarawak
9	Mazuwin	Malaysian Transition	CFC Free MDIs	26 June	Hotel

No	Name	Presentation Topic	Forum/Seminar	Date	Venue
	Zainal Abidin	Strategy for the Phase-Out of CFC in MDIs	Awareness Programme	2007	Premier, Sibu, Sarawak
10	Mazuwin Zainal Abidin	Malaysian Transition Strategy for the Phase-Out of CFC in MDIs	CFC Free MDIs Awareness Programme	27 June 2007	Hotel Grand Palace, Miri, Sarawak
11	Mazuwin Zainal Abidin	Term of Reference (TOR) for the ASEAN BA/BE Task Force and Action Plan of the ASEAN BA/BE Task Force	3rd ASEAN BA/BE Taskforce Meeting	23 July 2007	Sunway Resort Hotel & Spa, Kuala Lumpur
12	Mazuwin Zainal Abidin	Current Procedures and Requirements for Generic Product	Commonwealth Pharmaceutical Associations-Malaysian Pharmaceutical Society Conference	4 August 2007	Park Royal Hotel, Kuala Lumpur
13	Mazuwin Zainal Abidin	Current Procedures and Requirements for Generic Product	Briefing Sessions for Delegates from LAO PDR	4 September 2007	NPCB
14	Mazuwin Zainal Abidin	Current Procedures and Requirements for Generic Product	Briefing Sessions for Delegates from Uruguay	15 November 2007	NPCB

5.10 Research

Research done in 2007:

i) No research was done in 2007 as the pharmacy research conference is conducted every 2 years. The last conference was conducted in 2006 and the following conference will be held in 2008.

5.11 Journal Club

The National Pharmaceutical Control Bureau held Journal Club Sessions. A total of ***11 sessions*** were held throughout the year 2007. The purpose of these sessions are 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	12 January 2007	Norhayati Othman	ASEAN Cosmetic Directive PIF AUDIT
2.			Ahmas Syamsury Sulaiman	9 Wonders of GMP

NO	SESSION	DATE	PRESENTER	TITLE OF PRESENTATION
3.			Nik Shamsiah Nik Salleh	Workshop on Product Safety Evaluation, Bohol, Phillipines (4-5 December 2006)
4.	Session 02	25 January 2007	Norhayati binti Musa	Evaluation of Natural Products
5.			Dr Kamaruzaman Saleh	Research Protocol
6.	Session 03	09 February 2007	Arpah bt. Abas	'Eye On' : Biotechnology Biopharmaceuticals
8.	Session 04	16 February 2007	Asnida Mat Daud	Food-Drug Interface & Classification of Health Supplement Products.
9.			Noor Hidayah Mohd. Noor	Additives Do Cause Temper Tantrums.
11.	Session 05	11 May 2007	Nik Juzaimah Juhari	Folic Acid Supplements and The Risk of Facial Cleft: National Population Case-Control Study.
12.			Zuraida Abdullah	Cosmetics and Your Health
13.	Session 06	29 June 2007	Nurulfajar Mohd Jamid	5S – A Way to Organizing and Managing the Workspace
14.			Chin Fui Fui	Colchicine in Gout
15.	Session 07	3 August 2007	Somiyaton Mohd Dahalan @ Damuri	Labelling Requirement for Non Prescription / OTC Products
16.			Chua Hui Ming	Observation Study of Drug Administration Errors in Two Paediatric Wards of a Teaching Hospital
17.	Session 08	30 August 2007	Belinna Abu Bakar & Sufian Hardi Mohamed Zuhair	National GMP Seminar: (Wonders of GMP
18.	Session 09	28 September 2007	Norleen Mohamed Ali	Getting The Message Across – Pharmacovigilance
19.			Suzana Mohd Nor	Randomized Controlled Trial: Prevention of Antigenically Drifted Influenza by Inactivated and Live Attenuated Vaccine.

NO	SESSION	DATE	PRESENTER	TITLE OF PRESENTATION
20.	Session 10	2 November 2007	Maslinda Mahat	Safety Issues on Mercury
21.			Ong Yi Chin	Wound Management
22.			Dr Kamaruzaman Saleh	Research Protocol
23.	Session 11	14 December 2007	Suhaili bt Samad	Use of Probiotics : Lactobacillus Preparation to prevent Diarrhoea - associated with Antibiotics
24.			Lian Lay Kim	Early Treatment with Prednisolone or Acyclovir in Bell's Palsy

6. REGULATORY STATUS

i. In 2007, a cumulative total of **200,314** product applications for registration were received of which 175,746 have been approved.

The breakdown for the type of applications received in 2007 is as follows:

Scheduled poisons (prescription items)	- 555
Non-scheduled poisons (non – prescription items	- 560
Traditional medicines	- 1325
Cosmetics	- 25,534
TOTAL	***- 27,974***

i. A total of 30607 product applications were approved in 2007, of which 449 were products containing scheduled poisons (prescription item), 413 non-scheduled poisons non – prescription items), 1342 traditional medicines and 28,403 cosmetics products.

ii. A total of **4637** Certificates of Pharmaceutical Product (CPP) and Certificates of Free Sale (CFS) were issued for the year 2007. The total number of Clinical Trial Import Licences (CTIL) issued was **231**.

iii. A total of **373** manufacturing premises were licensed in 2007. For importers, a total of **873** were licensed and for wholesalers, a total of **1028** were licensed.

iv. Under the post-market surveillance program, a total of **2538** samples were taken from the market, **2413** labels and package inserts examined, **144** batch recalls were instituted, **62** warning letters were issued and **361** product complaints were investigated.

v. As for quality control testing, a total of **5322** samples were tested of which 2128 were registration samples, 2761 were surveillance samples, 270 were enforcement samples, 155 were from product complaints and adverse drug reaction reports and 8 others. A total of **68,774** tests were conducted.

vi. A total of **248** 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 **508** vials were sold to the private sector (comprising of 370 NPCB reference standards and 138 ASEAN reference standards).

vii. Under the Adverse Drug Reactions (ADR) Monitoring Program, a total of **3056** ADR reports were received in 2007, of which **2808** reports were sent to Uppsala WHO Monitoring Centre for inclusion into the WHO database.

viii. A total of **1731** queries pertaining to products and also general information from both the public and private sectors were dealt with.

7. HIGHLIGHTS OF ACHIEVEMENTS IN 2007

i. The QUEST 2 system for on-line registration of pharmaceuticals and traditional medicines has successfully entered its fifth and fourth year of implementation respectively and the upgrading efforts of QUEST 2 to QUEST 3 is currently in progress.

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 such as the Registration Guidance Document for Veterinary Medicines Products to facilitate product registration were revised and developed. The adopted documents are made available in the NPCB website (www.bpfk.gov.my).

iv. The NPCB continues to play an active role in the harmonisation 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 is currently using the ASEAN Common Technical Dossier (ACTD), the ASEAN Guidelines for Bioavailability/Bioequivalence (BA/BE) as well as the ASEAN Guidelines for Stability Studies.

vi. Malaysia successfully hosted the 13th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) which was held on the 23rd-27th July 2007 in Kuala Lumpur, Malaysia. The ASEAN Regional Consultative Meeting on Fast Track Registration on Antiretrovirals (ARVs) and Diagnostic Reagents was also successfully held on 21st-23rd November 2007 in Penang, Malaysia.

vii. Malaysia has implemented the registration and licensing for veterinary medicines effective from 1st August 2007.The implementation of the registration and licensing of products includes all categories with the exception of cosmetics.

viii. The NPCB continues its efforts towards further upgrading the laboratory quality management system to achieve the ISO 17025 accreditation.

8. FUTURE PLANS

i. **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 especially for cosmetic products in Malaysia.

ii. **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.

iii. **Enhancement of Information and Communication Technology (ICT)**
NPCB continues to strive towards upgrading its ICT infrastructure. Under the 9th 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.

iv. **ISO 17025 Certification**
To continue the efforts towards further upgrading the laboratory quality management system to achieve the ISO 17025 accreditation by 2008.

v. **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 2008.

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

vi. **National Regulatory Conference 2008**
NPCB together with the pharmaceutical, traditional medicine and cosmetics industry will organise the National Regulatory Conference 2008.

vii. **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.

9. CONCLUSION

NPCB continues to ensure the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. International collaborations in relevant technical areas provide an excellent platform for NPCB in establishing mutual understanding amongst regulatory partners towards strengthening pharmaceutical quality assurance. The NPCB works closely and collaborates with the local industry, industry associations, health professionals, academia, consumers and other stakeholders to further ensure the quality, efficacy and safety of pharmaceutical products to improve the health of the people. 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.