Berita
UBAT-UBATAN
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

VOLUME 31
NO. 9

ISSN 0128-0627
MARCH 2006

The Role of Proficiency Testing

Participating in proficiency testing schemes (PTS) provides a laboratory with an objective means of assessing and demonstrating the reliability of its data and also to assess the ability /competency of a laboratory in performing tests. Since 2002, the National Pharmaceutical Control Bureau (NPCB) has taken part in various PTS conducted by the World Health Organisation (WHO) and the EC-ASEAN Economic Cooperation Programme on Standards, Quality and Conformity Assessment. NPCB's participation in the PTS is also to gauge the readiness of its quality system to conform and meet the requirement of the MS ISO 17025:2005 certification. This is necessary as participation in proficiency testing is one of the key elements in this standard.

To date, NPCB has participated in 21 PTS which covers different techniques ranging from simple tests such as the measurement of pH to the highly technical and challenging tests such as the determination of impurities by *High Performance Liquid Chromatography*. Testing of various dosage forms such as tablets, creams, powders and parenteral products were included. Proficiency testing of cosmetics using the ASEAN harmonised cosmetic test methods also was started in 2005.

In This Issue

Berita Ubat-ubatan is published by the National Pharmaceutical Control Bureau, Ministry of Health Malaysia, Jalan Universiti, P.O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia. Tel: 60(3) 7957 3611 Fax: 60(3) 7956 2924 www.bpfk.gov.my

Table 1 below shows the breakdown in the number of PTS that NPCB has participated in from the year 2002 until March 2006. The figure clearly shows a trend that NPCB is participating in more PTS in recent years, which reflects NPCB's commitment towards greater accountability and quality in laboratory testing.

Table 1: Breakdown of PTS participated in per year

Year	Number of PTS participated in	
	Pharmaceutical	Cosmetic
2002	3	0
2003	0	0
2004	1	0
2005	7	5
2006 (up to March)	3	2
Total	**14**	**7**

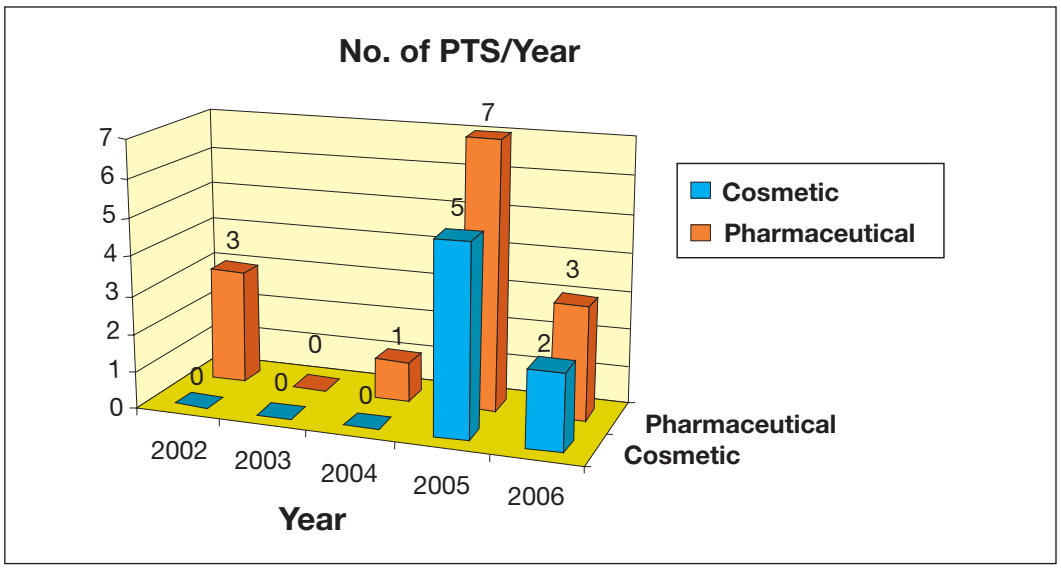


Table 2 shows the range of tests and techniques that was covered by the PTS which NPCB participated in. The most common tests and techniques carried out by NPCB were covered in the PTS and hence, this gives a complete picture on the performance of the different units in the Centre for Quality Control, NPCB.

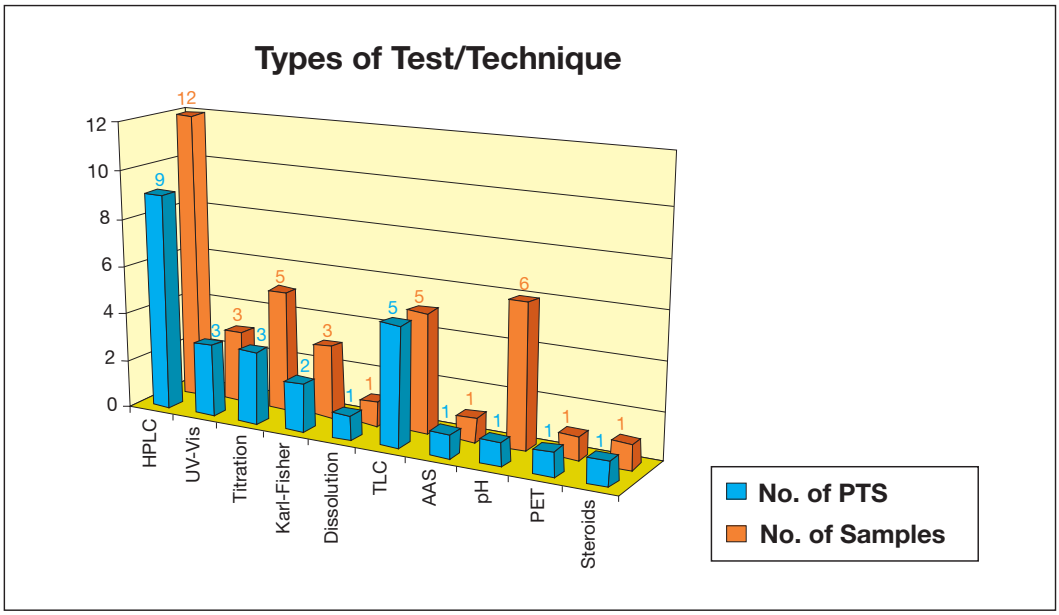
Table 2: Type of Test/Technique

Tests/Techniques	No. of PTS participated in	No. of Samples Tested
High Performance Liquid Chromatography (HPLC)	9	12
UV-Visible Spectrophotometry	3	3
Volumetric Titration	3	5
Water Determination by Karl-Fisher Method	2	3
Dissolution using UV-Visible Determination	1	1
Thin Layer Chromatography (TLC)	5	5
Atomic Absorption Spectrophotometry (AAS)	1	1
Measurement of pH	1	6
Preservative Efficacy Test (Microbiological)	1	1
Adulteration of Cosmetics by Steroids	1	1
Total	**27***	**38#**

Note:

* *Total is greater than 27 as 6 PTS involve more than 1 technique e.g. TLC & HPLC.*

\# *The number of samples tested is greater than 27 as most PTS involve more than 1 sample.*



An important mission of NPCB for the year 2006 is to obtain MS ISO 17025:2005 accreditation under the Laboratory Accreditation Scheme of Malaysia [SAMM]. Proficiency testing [PT] is a key area that will be given priority as it is both a requirement of the standard as well as a tool to be used in evaluating the competency of the laboratory staff and the laboratory quality system as a whole. Participating in PTS conducted by WHO and EC-ASEAN has proven to be very beneficial to the institution. It has fulfilled its purpose and NPCB is fully committed to participate in more PTS for continual improvement of its performance and hence, its service to the public.

Berita UBAT-UBATAN
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

NEWS UPDATE ON ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS HARMONISATION

Report of the Fourth Meeting of the ACCSQ Traditional Medicines and Health Supplements Product Working Group, 12-13 January 2006, Bangkok, Thailand

The 4th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) was held on 12-13 January 2006 in Bangkok, Thailand. Prior to the Meeting, the Regional Technical Seminar on ASEAN Traditional Medicines and Health Supplements Harmonisation Global Trend on Quality, Reliability and Opportunity was held on 11 January 2006 at the same venue. The meeting was officially opened by Prof. Dr. Pakdee Pothisiri, Secretary General of the Food and Drug Administration, Ministry of Public Health, Thailand.

The attendees included delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, The Philippines, Singapore and Thailand, and representatives of the ASEAN Secretariat. Representatives from the Traditional Medicines and Health Supplements Industry in ASEAN Member Countries also attended the meeting as observers.

The meeting was chaired by Ms. Mawarwati Djamaluddin, Diplm Pharm, Permanent Secretary, the National Agency of Drug and Food Control of the Republic of Indonesia. The Chair highlighted key issues for follow-up consideration in the 4th Meeting which included, amongst others, issues on harmonisation of definition and terminologies on traditional medicines and health supplements in ASEAN, the conduct of the comparative study on international and other regional technical requirements, the identification of specific areas for harmonisation of technical requirements for TMHS in ASEAN and the development of the ASEAN common technical requirement for TMHS.

On Definition of Traditional Medicine

Since nine Member Countries except Philippines have been using the same terminology and more or less the same definition and terminologies on traditional medicine and as supported by the Philippines, the meeting agreed to have an ASEAN Common Terminology and Definition on Traditional Medicine as follows:

"A Traditional Medicine means any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) used in the system of traditional practice. It should not include any sterile preparation, vaccines, any substances derived from human parts, any isolated and characterized chemical substances"

On Definition of Health Supplements

As different from the traditional medicines, Member Countries have been using different terminologies either health supplements, food supplements or dietary supplements and this terminology has been cited in the law/act in Member Countries. In this regard, the Meeting discussed and agreed that it is not necessary to harmonise the terminology on health supplements. However, there is a need to have an ASEAN common terminology to be used

as ASEAN working terminology. This enables regulators to have common understanding during the harmonisation process. The Meeting agreed to use Health Supplements as ASEAN Working Terminology to be in line with the name of the PWG and the roadmap for the healthcare integration.

It is also agreed that in order to avoid any confusion for stakeholders in terms of terminology used in the different Member Countries, the interpretative note should be provided, indicating that Health Supplements used in ASEAN context is equivalent to food supplements and dietary supplements in some ASEAN Member Countries. The Meeting also agreed that the following parameters will be taken into account when developing the ASEAN common definition on health supplements such as:

* Ingredients
* Purpose
* Dosage Forms
* Other Information

Compilation of Terminologies and Definitions on TMHS

To enable Indonesia to finalise the Profile on Terminologies and Definitions on TMHS in Member Countries for public reference, the meeting requested Member Countries to review the Draft Profile and provide Indonesia with comments or confirmation so that Indonesia can consolidate and present the final profile for adoption at the next meeting i.e. 26-28 July 2006.

Singapore presented the Draft Report on the Comparative Study on International and other Regional Technical Requirements and the identification of Specific Areas for Harmonisation of Technical Requirements to the Meeting.

The Meeting discussed and agreed to adopt the ASEAN Harmonisation Regulatory Scheme suggested by Singapore which consists of the following steps:

Step 1:
In-depth study based on risk management, legislative aspects, regulatory requirements and regulatory guidelines.

Step 2:
Identify regulatory and technical requirements.

Step 3:
Adapt useful features of ASEAN and benchmark countries

Step 4:
Developing the ASEAN Model

Step 5:
Adoption and Implementation

Development of ASEAN Common Technical Requirements for TMHS

GMP and Testing Methods

Malaysia reported to the Meeting that the questionnaire on GMP will be circulated to Member Countries by February 2006 while the questionnaire on Testing Methods will be circulated by April 2006. Member Countries are requested to submit their inputs to Malaysia as soon as possible so that Malaysia can finalise and report the outcome at the next meeting.

Requirements on Product Placement

Singapore presented to the Meeting the Draft Report on Survey on Product Placement Requirements as well as some initial observations for the discussion.

The Meeting noted from the Survey that Member Countries have different product placement systems to control traditional medicines and health supplements (e.g. some require product registration, some require product listing and some allow product notification).

This will be further discussed and analysed before providing inputs to the development of the ASEAN Harmonised Product Placement Requirements. In this context, the Meeting agreed with Singapore's proposal that risk assessment needs to be taken into account for the development of the ASEAN requirements in the near future.

The Meeting was also for the view that there is a need to have a common understanding within ASEAN on definitions on registration, listing and notification. In this regard, the Meeting requested Singapore to take into account this matter when finalising the survey.

Labelling and Advertising Requirements

The Chair raised an issue on whether it is necessary to harmonise advertisement requirements in ASEAN for traditional medicines and health supplements taking into account that there would be different organisations in Member Countries handling advertisement and the different requirements for advertisement in term of culture in Member Countries.

The Meeting decided that harmonisation of advertisement requirements be left out from the work programme of the TMHS. With regards to the labelling requirements, all Member Countries agreed that there is a need to harmonise labelling requirements in ASEAN. In this regard, the meeting proposed Thailand to further study the labelling issues based on the inputs submitted by Member Countries and to come up with the recommendation which include two aspects: (i) Minimum information to be labelled on TMHS products which is common for all ASEAN Member Countries and (ii) country specific. The recommendation will be submitted for consideration by the TMHS PWG at its next meeting.

Post Marketing Alert System

The Meeting considered the way to move forward the implementation of the Alert System in ASEAN without having common glossaries in ASEAN. In this regard, the Meeting agreed on the following:

a) Adopt the format prepared by Singapore as ASEAN Format for the Post-Marketing Alert System.

b) Glossaries are subjected to country specific. In this regard, the Meeting requested for Member Countries to provide all glossaries mentioned in Annex A when sending Alert to other Member Countries.

ANNEX A

GLOSSARY OF TERMS

1. **Adverse Drug Reaction (ADR)**

2. **Adverse Event (AE)**

3. **Complementary Medicines**

   * **Chinese Proprietary Medicine**
   * **Traditional Medicine**
   * **Health Supplement**

4. **Defect**

5. **Level of Confidentiality**

6. **Recall Classification**

7. **Recall Level**

8. **Withdrawal**

ANNUAL REPORT 2005

WHO Collaborating Centre for Regulatory Control of Pharmaceuticals

ACTIVITIES OF THE COLLABORATING CENTRE

(a) 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 programme 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.

(b) 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
29/3/05	ASEAN	Folic acid	M 197092
29/7/05	ASEAN	Atropine Sulphate	M 185015
29/7/05	ASEAN	Hyoscine Hydrobromide (Scopolamine)	M 100115
29/7/05	ASEAN	Betamethasone 17-Valerate	M 193079
30/8/05	ASEAN	Hyoscine Butylbromide	M 100115
30/8/05	ASEAN	Triamcinolone Acetonide	M 191077
30/9/05	ASEAN	Thiamine Nitrate	M 197097
30/9/05	ASEAN	Gemfibrozil	M 100114
28/11/05	ASEAN	Pyridoxine HCl	M 197096
28/11/05	ASEAN	Methyldopa	M 200056
28/11/05	ASEAN	Benzylpenicillin Potassium	M 191064
28/12/05	ASEAN	Indomethacin	M 200052
28/12/05	ASEAN	Atenolol	M 100108
28/12/05	ASEAN	Albendazole	M 100107

(c) 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.

(i) 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.

(ii) Capacity Building of other Regional National Regulatory Authorities

In accordance with the ASEAN harmonisation 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 Programme 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.

(iii) 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 Programme by carrying out tests on samples sent by WHO.

(d) 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.

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 programme, 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 Programme, 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 enqueries pertaining to products and also general information from both the public and private sectors were dealt with.

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 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 certified by SIRIM was successfully maintained.

v. 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. 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.

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 cosmetics 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 Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Bioavailability/ Bioequivalence (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.

continue to page **13**

WORKSHOP ON THE EVALUATION OF ANALYTICAL DATA VALIDATION AND TESTING OF HEPATITIS

The activity was initially approved by WHO (World Health Organisation) in 2004 with a title "Workshop on accessing quality of biotechnology derived products which will be used as drugs, biologics and diagnostics". Based on the Terms of Reference (TOR), WHO was not able to find a suitable consultant to cover such a wide topic on biotech. The activity was subsequently changed to the above title **"Workshop on the Evaluation of Analytical Data Validation and Testing of Hepatitis"** with a new TOR. The workshop was successfully carried out from 5th – 9th December 2005 at the National Pharmaceutical Control Bureau, Malaysia.

The consultants engaged by the WHO were from TGA Australia: Ms. Therese Marengo, Senior Virologist, Immunology Group and Mr. Christopher M. Bowell, Professional Officer, Immunology Group. The following topics were covered:

1. Development and production of Hep B vaccines (HbsAg) produced by recombinant DNA (rDNA) technology both in yeast and in the Chinese Hamster Ovary (CHO) cells.
2. Validation of HbsAg (rDNA) manufacturing process and QC testing.
3. Validation requirements for testing methods, including HbsAg potency testing, discussed within the framework of WHO and EP requirements and guidelines.
4. Lot release procedures for Hep B vaccines.
5. TGA testing of Hep B vaccines.
6. Laboratory set up for Hep B vaccines potency testing.

A total of twenty nine participants attended the workshop which included two participants from the National Agency for Drug and Food Indonesia, one from the Department of Drug and Food, Cambodia, one from the Health Sciences Authority Singapore and the rest were officers from the National Pharmaceutical Control Bureau, Malaysia.

The workshop was concluded with the following:

(i) The Lot Release concepts set out by WHO were recommended to initiate the process,

(ii) Further training to include appropriate theoretical courses to improve knowledge in the necessary aspects of immunology and molecular biology was recommended.

from page 12

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 of infrastructure are important in our efforts to ensure continuous improvement and to keep abreast with the current global regulatory development.

DCA NEWS

- ***Implementation of a New Application System for Variation Type I and Type II for Registered Product(s)***

A new guideline for application of variation for registered products is available online in the 'Drug Registration Guidance Document'. Variation application is categorised as Type I and Type II Variation. Applications can be made via online. Currently the application for Type I Variation still needs to be sent manually to the Variation Unit of the Centre for Post-Registration to allow sufficient time for processing. Application forms are available in the NPCB website **www.bpfk.gov.my.** The outcome for both types of application may be obtained via online.

Type I: Minor Variation with a 14 - day validation period

The marketing authorisation holder may proceed to implement the change(s) after a 14-day validation period, calculated based on the date of receipt of the documents by the Variation Unit.
Minor variations are subject to conditions specified.

FOR INTERIM PERIOD:
An applicant may submit application for Type I Variation manually, together with the required documents by using the form specified. The manual submission must be submitted together with variation online application. Approval will be notified via online.

Type II: Major Variation.

Type II Variation involves major change(s) and approval from the NPCB is required prior to implementation.

IMPORTANT DECISIONS BY THE DCA

(I) Registration Status of Registered Product Found to be Adulterated

The DCA made the following decisions in cases of registered products found to be adulterated:

To facilitate a prompt decision on the above, the DCA decided that:

a) Decisions whether to cancel the registration of a product and/or to revoke the product licence concerned will be made via ' procedure of circulation of such notice '.

b) Decisions of the DCA shall be considered valid based on the criteria, as follows:
   - Four members including the chairman, form a quorum.
   - Decisions reached will be based on simple majority.

c) Letter to cancel the registration of product/revoke licence concern shall be signed by the DCA Chairman.

d) In the event that decision from the majority cannot be reached, the DCA Secretary shall forward the matter to the DCA Chairman for a decision.

e) Decisions made shall be announced next up-coming DCA meeting.

f) Hologram label is tenable as proof in court proceedings.

(II) Review on Application Criteria and Evaluation Process for Health Supplements

The DCA agreed that the application criteria and process of evaluation of health supplements should be reviewed and the mechanism established to ascertain product quality in all registered products to be by way of post-marketing surveillance.

(III) Warning on Label and Package Insert for Products Containing Propolis(topical) and Royal Jelly(all forms)

The DCA agreed that:

a) the statement below must be included on labels and package inserts of all topical products containing propolis:
   - *Propolis may cause allergic skin reactions*

b) the statement below must be included on labels and package inserts of all products containing royal jelly:
   - *This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals.*
   - *Asthma and allergy sufferers may be at the greater risks.*

(IV) Additional Criteria for Manufacturing Licence

The DCA decided to impose an additional criterion pertaining to manufacturing licence. The onus is on the manufacturer/contract manufacturer to ascertain that products manufactured are not adulterated. In the event of any product adulteration, the DCA will exercise its power to revoke the manufacturing licence concerned immediately.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

Ministry of Health Malaysia
Jalan Universiti, P.O Box 319, 46730 Petaling Jaya
(Telephone : 603-79573611, Fax : 603-79562924)

Homepage http : //www.bpfk.gov.my

OFFICERS TO CONTACT

ORGANISATION	SECTIONS / UNITS	NAME OF OFFICER	TEL-EXT
National Pharmaceutical Control Bureau	Director	Eisah Abdul Rahman	300
Centre for Product Registration	Deputy Director	Selvaraja S. Seerangam	270
Application for Registration of: (i) Generic Medicines Section	-Prescription Unit -Non-Prescription Unit -Veterinary Unit	Rohani Ismail Abdullah Hisham Ahmat Yaya	255 233
(ii) Complementary Medicines & Cosmetic Section	-Natural Products Unit -Health Supplement Unit -Cosmetics Unit	Saleha Md. Ewan Mazuwin Zainal Abidin Anis Talib	238 278 333
(iii) Investigational & New Drug Section	-New Drug Unit -Clinical Trial Regulatory Unit -Biotechnology Unit	Noorizam Ibrahim Dr. Kamaruzaman Saleh Arpah Abas	239 371 241
(iv) Regulatory Coordination Unit	-Regulatory Coordination Unit	Rosilawati Ahmad	245
Centre for Post-Registration	-Pharmacovigilance Unit -Surveillance and Product Complaints Unit -Variations Unit	Abida Haq Syed M. Haq Norhayati Omar Fuziah Abdul Rashid	258 365 366
Centre for Organisational Development	-Human Resource Unit -Quality Management System Unit -Information & Communication Unit	Bariah Abd. Rani Norrehan Abdullah Kamarudin Ahmad	217 363 223
Centre for Good Manufacturing Practice	-Inspection I Unit -Inspection II Unit -Inspection III Unit -Licensing Section	Kadariah Mohd Ali Muhd. Lukmani Ibrahim Wan Othman Wan Ismail	818 838 808
Centre for Quality Control	Deputy Director	Dr. Sulaikah V.K. Moideen *(Acting)*	204
(i) Reference Standard Unit	Reference Standard Unit	Ahmad Zakhi Ramli	510
(ii) Laboratory Services Unit	Laboratory Services Unit	Tan Ann Ling	515
(iii) Pharmaceutical Chemistry Testing Section	-Chromatography Unit -Dosage Performance Unit -Spectroscopy/General Chemistry Unit -Chemistry Research Unit	Dr. Hasenah Ali Faridah Abdul Malek Ani Abdullah Dr. Hasenah Ali	521 613 604 521
(ii) Pharmaceutical Biology Testing Section	-Microbiology Unit -Pharmacology/Toxicology Unit	Siti Madziah Mohamed Ani Abdullah	608 346
(iii) Natural Product Testing Section	-Herbal Monograph Unit -Adulteration Screening Unit -Toxic Compound Detection Unit	Mazli Muhamad	250