National Pharmaceutical Control Bureau (NPCB)
Ministry of Health
MALAYSIA

Berita Ubat-ubatan
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

Berita Ubat - Ubatan December 2002

BIOTECHNOLOGY UNIT
NATIONAL PHARMACEUTICAL CONTROL BUREAU

The Biotechnology Unit, which is a unit under the Product Evaluation and Safety Division of the National Pharmaceutical Control Bureau (NPCB), was formed in May 2002. This unit is responsible for the evaluation and registration of biological products, which was previously undertaken by the Poisons Unit of the Division. (For a complete organizational structure of NPCB, please refer to page 3).

Biological products include, but are not limited to, bacterial and viral vaccines, therapeutic serums, antitoxins, human blood components and their derivatives, and certain products produced by means of biotechnology, such as interferons and erythropoietins.

The contemporary meaning of 'Biotechnology' includes the use of the new genetic tools of recombinant DNA to make new genetically modified organisms or genetic engineering, bioinformatics, transformation, diagnostics and vaccine technology.

Because of their unique origin (Biotechnology products are inherently variable in the composition of the products themselves, as well as the raw materials used in their production and the biological assays), each product must be evaluated on its own merits and as such they require special quality control and regulatory approaches.

As most of the mature biotechnology products have recently approached the end of their patent terms, many 'biogenerics' / multisource products have emerged. Experience has shown that even small differences in a product can result in significant safety or efficacy alteration. Therefore, in the current state of scientific knowledge and technique, a clinical trial remains the principal means by which the safety and effectiveness of a biotechnology product can be evaluated. Approval of 'follow-on' biotechnology products must be based on the same rigorous standards applied for the approval of pioneer/original products.

New vaccines that are being developed at a rapid pace (such as conjugate vaccines, vaccines of a fundamentally new design structure, eg. DNA vaccines and vaccine delivery system) and various combination vaccines are being evaluated.

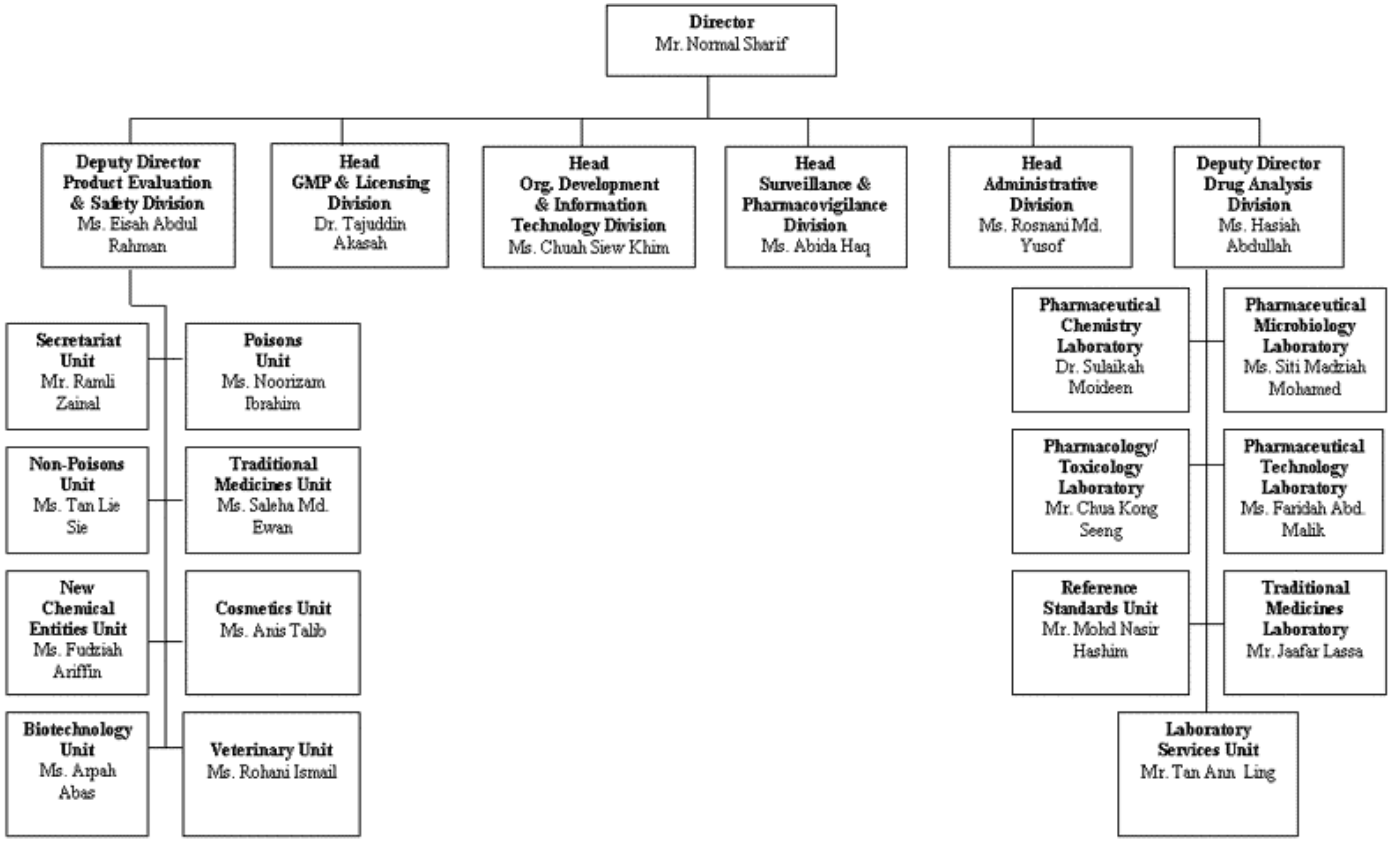
The new discoveries and scientific developments in biotechnology and in the field of vaccines represent a highly complex and demanding challenge for regulatory authorities as well as manufacturers.

In view of the fact that biotechnology is one of the key drivers of Malaysia's transformation towards a technology-driven economy, it receives large-scale support from the Government. Biotechnology is earmarked as one of the areas of advancement under the 8th Malaysia Plan (2001-2005) and it received a further boost with the announcement of the Biovalley initiative.

This implies a need for expanding the activity of NPCB and enhancing the efforts of promoting biotechnology, hence the formation of the Biotechnology unit with the following roles:

1-To establish a comprehensive framework on the regulation of biotechnology products.
2-To facilitate the registration of quality, safe and efficacious biotechnology products.
3-To assist and advise on requirements and procedures applicable to biotechnology to companies engaged in biotechnology.
4-To participate and exchange information pertaining to the development and research of biotechnology products.
5-To promote the development of local content of industries and ensure a supportive regulatory regime.
6-To review and modify standards and control of biotechnology products to reflect the state of the art, science and technology and to reflect an improved understanding of quality and safety issues.
7-To complement the Government's keen interest in facilitating the cost-effective and timely market access of biotechnology products.

ORGANISATIONAL STRUCTURE NATIONAL PHARMACEUTICAL CONTROL BUREAU



GUIDELINES FOR APPLICATION FOR REGISTRATION OF BIOLOGICALS / BIOTECHNOLOGY PRODUCTS

Follow the requirements for Registration of Pharmaceutical Product - as laid down in the Guidelines For Application For Registration of Pharmaceutical Products (Containing Scheduled Poisons and Non-Scheduled Products) BPFK/P/GP/01

Where appropriate the relevant EC guidelines should be consulted for products produced by recombinant DNA technology, and for monoclonal antibodies intended for therapeutic use.

The additional requirements for registration of Biotechnology Products, Vaccines and Blood Products

1. Comply with WHO requirements for the product as found in the WHO Technical Report Series
Including:
- Control of starting materials, including baseline data both on the host cell and on the source, nature and sequence of the gene used in the production. A well-characterized, clean starting material.
- Control of the manufacturing process.
- Control of the final product.
- Stabilisation and storage.
- Viral Safety Evaluation.

2. Product formulation containing ingredients from human origin/plasma (eg. Albumin) also require supporting documents regarding the quality of the ingredient and confirmation that it is obtained from a safe source of plasma. (eg. Statement on accreditation/GMP status of the plasma collection centres by the relevant authority and viral safety).

3. Product formulation containing materials from bovine, ovine or caprine, used in pharmaceuticals as raw materials, active principles, reagents or excipients, a certificate of suitability concerning transmissible spongiform encephalopathy (TSE) risk should be produced.

4. Summary Lot Protocol as WHO model (for vaccines only)

5. Certification of the product: Certificate of approval of a biological product and Certificate for release of a lot or lots of biological product/ Batch Release Certificate issued by the relevant authority in the country of manufacture

6. Plasma Master Files of the collection establishments/centres.

7. Certificate of Fitness for Purpose/Compliance Certificate confirming that the blood or plasma used in the production of the lot is tested and found to be negative for HIV antibody and HBsAg, and that high-risk donors are excluded

8. Summary of scientific and medical basis of claims for safety and efficacy.

9. Published Clinical Trials Studies/Data.

10. Periodic Safety Update Reports (PSUR)

11. Analytical Validation, Process Validation and Viral Validation Studies Documents

12. Worldwide product registration status

Review of the Drug Regulatory System in Malaysia

A joint assessment of Malaysia's National Drug Regulatory System was carried out on 21st-25th October 2002 at the National Pharmaceutical Control Bureau. It was conducted by a delegation comprising of Dr. Valerio Reggi from Essential Drugs and Medicines Policy/Quality Assurance and Safety of Medicines (EDM/QSM), WHO Headquarters, and regulatory officials from Indonesia (Ms. Endang Woro), Singapore (Ms. Hui Foong Mei and Ms. Lee Hui Keng), Thailand (Ms. Charunee Krisanophon) and Vietnam (Dr. Pham Thi Binh Minh).

On 21st October the delegation was received on arrival at NPCB by the Director and senior officers of NPCB. In his opening address, the Director of NPCB, Mr. Normal Sharif, welcomed Dr. V. Reggi and his team to NPCB. He noted that this was the first time NPCB was being reviewed by WHO since being designated as the WHO Collaborating Centre for the Regulatory Control of Pharmaceuticals in May 1996. Also present during the opening meeting was the WHO Representative in Malaysia, Mr. Stephen Tamplin. The delegation was also briefed on the various activities of the NPCB and the role of the Drug Control Authority within the regulatory framework in Malaysia by Ms. Eisah Abd. Rahman, Deputy Director of Drug Evaluation & Safety Division.

The objectives of the review were as follows:-

1. to identify areas of weakness where possible support should be focused
2. to develop an institutional development plan which would also cover human resource training needs
3. to improve collaboration and mutual understanding among national regulatory authorities of ASEAN countries
4. to form a group of ASEAN regulatory officials who will be able to conduct future reviews using the same data collection tool

The review focused on NPCB's regulatory functions in its capacity as a national regulatory authority (NRA), with emphasis on the following aspects:-

i. Licensing - Marketing authorizations, companies
ii. Post-marketing activities - pharmacovigilance, monitoring of quality, control of promotion and advertising
iii. Laboratory testing
iv. Inspection - GMP and distribution channels
v. Clinical Trials

At the end of the week-long review, an exit meeting was held on 25th October 2002. During this meeting, Dr. Reggi presented the team's findings to the Director of NPCB, heads of divisions and all unit heads of NPCB. Several members of the DCA and the WHO Representative in Malaysia were also present.

REPORT OF THE ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY PHARMACEUTICAL PRODUCT WORKING GROUP

Background

Efforts toward harmonization of ASEAN pharmaceutical regulations were initiated in 1992 through the ASEAN Consultative Committee for Standards and Quality (ACCSQ). At the 13th Meeting of the ACCSQ held in March 1999 in Manila, agreed that a Product Working Group on Pharmaceutical (PPWG) be set up, with Malaysia as the lead country. Hence the formation of ACCSQ-PPWG in September, 1999 in Kuala Lumpur, Malaysia.

Objective

The objective of the ACCSQ-PPWG is to develop harmonization schemes of pharmaceuticals' regulations of the ASEAN member countries to complement and facilitate the objective of ASEAN Free Trade Area (AFTA), particularly, the elimination of technical barriers to trade posed by these regulations, without compromising on drug quality, safety and efficacy.

Summary of Achievements and Meeting Updates

The Meetings were attended by delegates and observers from all the ASEAN member countries, comprising of both regulatory and industry representatives. A staff of the ASEAN Secretariat and a representative from the World Health Organisation (WHO) were also in attendance.

First Meeting 6-7 September, 1999 in Kuala Lumpur , Malaysia

1Terms of reference formulated
2Workplan drawn : goals, strategies, activities, expected output and status.
3Update on Common Effective Preferential Tariff (CEPT) Scheme for AFTA
4Sharing of experience through presentation of country reports
5Review of efforts towards international harmonization of regulatory requirements.

Second Meeting 5-6 March, 2000 in Bangkok, Thailand

1 Review of reports of core activities
2 Update on Trend of Pharmaceutical Harmonisation
3 Formation of Ad-Hoc Committees on Quality, Safety (Pre-Clinical), Efficacy (Clinical Data) and Admistrative Data and Product Information with the respective lead countries Indonesia, Philippines, Thailand and Malaysia.
4 Designation of coordinating countries
5 Selection of specific areas for harmonization based on Safety, Quality, and Efficacy

Third Meeting 6-7 February, 2001 in Ho Chi Minh City, Vietnam

1 Plenary sessions of Ad-Hoc Committees
2 Drafting of ASEAN Common Technical Requirements (ACTR)
3 Scientific and technical aspects deliberated : Pharmaceutics-Quality, Pharmacological/Toxicological Data-Safety, Clinical data-Efficacy and Administrative data and product information

Fourth Meeting 28-29 September, 2001 in Bali, Indonesia

1 Consideration of the ACTR and ASEAN Common Technical Dossier (ACTD) on Administrative data and product information - Malaysia.
2 Consideration of the ACTR and ACTD on Quality - Indonesia
3 Consideration of the ACTR and ACTD on Safety - Philippines
4 Consideration of the ACTR and ACTD on Efficacy - Thailand
5 Consideration of ASEAN glossary - Malaysia
6 Revision of the work programme of ACCSQ-PPWG

Fifth Meeting 25-27 February, 2002 in Yangon, Myanmar

1 Consideration and confirmation of guidelines on ACTR- Quality, Safety (non-clinical study), Efficacy (clinical data) and Administrative data and product information.
2 Consideration of the first draft of overall ACTD's organization -Thailand
3 § Adoption of ACTR and first draft of ACTD together with the proposed ASEAN guidelines.
4 Adoption of draft ASEAN glossary
5 Consideration of implementation issues of ACTD
6 Cooperation with international organizations and dialogue partners
7 Revision of the work programme of ACCSQ-PPWG

Sixth Meeting 4-6 Sptember, 2002 in Siem Reap, Cambodia

1 The meeting was preceeded by the Technical Meeting of PPWG on product information and stability
2 Adoption of final draft of ASEAN glossary
3 Adoption of the final drafts of ACTD on safety, efficacy and administrative data and product information.
4 Consideration of ACTD's organization and proposal to compare it with ICH CTD.
5 Agreement of first draft of working guidelines namely :
-Draft Guidelines on Stability Studies-Indonesia
-Draft Guidelines on Analytical Validation-Thailand
-Draft Guidelines on Process Validation-Singapore
-Draft Guidelines on Bioavailability and Bioequivalence (BA/BE) Studies-Malaysia
6 Formation of Implementation Working group (IWG) - Singapore as Chair and Indonesia as Co-chair, in view of the implementation of the ACTD in 2003
7 Cooperation with international organizations and dialogue partners
8 ACCSQ-US Coorperation - 3 three PPWG project proposals.
9 Revision of the work programme of ACCSQ-PPWG

Conclusion

Overall, the ACCSQ-PPWG has made considerable progress, despite limitations in the existing capability and capacity of the Regulatory Authorities of ASEAN member countries. Due to varying readiness expressed by some member countries to conform to the harmonized requirements a transition period of two years is provided. The coordinating and monitoring activities as well as other assistance will be under the purview of the IWG.

The Seventh Meeting of the ACCSQ-PPWG will be held in June 2003 in Malaysia.

Conditions for Registration of Products Containing Isotretinoin and Etretinate/Acitretin

At its 139th meeting held on 20th August 2002, the DCA agreed to change the conditions for the registration of products containing Isotretinoin and Etretinate/Acitretin..

The following conditions for registration now apply:-

Isotretinoin

1. The product shall only be sold or supplied to:

(a) Dermatologists (Skin Specialists) who are gazetted with the Ministry of Health, Malaysia, or registered with the Academy of Medicine, Malaysia, Specialist Registry and approved by the Drug Control Authority.

(b) A hospital or institution maintained by the government, having the services of a skin specialist or a registered medical practitioner with experience in dermatology and approved by the Drug Control Authority.

2. The container of the product shall be labeled in a conspicuous and distinct manner, with the following statements:

"Isotretinoin is teratogenic.
Pregnancy must be avoided during treatment and for at least four weeks after completing treatment."

3. A proper record of product supplied stating the product name, product registration number, name, address and contact number of purchaser (prescriber) shall be kept and submitted to Drug Control Authority on a monthly basis.

Etretinate/Acitretin

1. The product shall only be sold or supplied to:

(a) Dermatologists (Skin Specialists) who are gazetted with the Ministry of Health, Malaysia, or registered with the Academy of Medicine, Malaysia, Specialist Registry and approved by the Drug Control Authority.

(b) A hospital or institution maintained by the government, having the services of a skin specialist or a registered medical practitioner with experience in dermatology and approved by the Drug Control Authority.

2. The container of the product shall be labeled in a conspicuous and distinct manner, with the following statements:

"Etretinate/Acitretin is teratogenic.
Pregnancy must be avoided during treatment and for at least three years after completing treatment."

3. A proper record of product supplied stating the product name, product registration number, name, address and contact number of purchaser (prescriber) shall be kept and submitted to Drug Control Authority on a monthly basis.

MADRAC NEWS

ADR MONITORING: A CO-OPERATIVE PROGRAMME FOR ENHANCING THE SAFER USE OF MEDICINES

The Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) seeks your cooperation in monitoring and reporting any adverse reactions to the following products which have been classified as New Chemical Entities:

DRUG	ACTIVE INGREDIENT
AVANDIA TABLET	Rosiglitazone Maleate
TELFAST CAPSULE	Fexofenadine HCl
MAXALT TABLET	Rizatriptan Benzoate
SYSCOR CC TABLET	Nisoldipine
ACCOLATE TABLET	Zafirlukast
ZOMIG TABLET	Zolmitriptan
SEROQUEL TABLET	Quetiapine Fumarate
MIZOLLEN TABLET 10 mg	Mizolastine 10 mg
ATACAND TABLET	Candesartan Cilexetil
ARAVA TABLET	Leflunomide
INTEGRILIN	Eptifibatide
EDRONAX TABLET	Reboxetine Methane sulphonate
NICORETTE INHALER	Nicotine 10 mg (cartridge)
ZOMETA powder for infusion	Zoledronic acid anhydrous
MALARONE TABLETS	Atovaquone 250.0 mg Proguanil Hydrochloride 100.0 mg
PERDIX TABLET	Moexipril Hydrochloride
VEXOL 1% sterile ophthalmic solution	Rimexolone
DIHYDERGOT nasal spray	Dihydroergotamine Mesylate
HERCEPTIN 440 mg/vial	Trastuzumab 440 mg
STARLIX TABLET	Nateglinide
SINGULAIR TABLET	Montelukast Sodium
NEXIUM TABLET	Esomeprazole Magnesium Trihydrate 22.3 mg
VENOFER® INJECTION	Iron(III) Hydroxide sucrose complex 2%w/v
ANZEMET IV	Dolasetron Mesilate
CETROTIDE INJ	Cetrorelix

YOU NEED NOT BE CERTAIN ABOUT AN ADR - JUST SUSPICIOUS

The reporting of seemingly insignificant or suspicious adverse reactions may highlight a widespread prescribing problem.
The Drug Control Authority requests for reports on:

1Reactions to ALL NEW DRUGS
2Drug interactions
3ALL serious reactions which may have resulted in

- Death
- Increased morbidity
- Disability
- Hospitalization
- Prolongation of hospitalization

· Increased investigational or treatment costs
· Birth defects

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CURRENT ISSUES

HRT:THE FINDINGS OF THE WOMEN'S HEALTH INITIATIVE TRIAL

The US Women's Health Intiative has released important information about the long-term safety of oestrogen plus progestin combination hormone replacement therapy. In a trial enrolling more than 16,000 women, they report an increase in the incidence of heart attacks, stroke, clotting events and breast cancer. The trial was designed only to investigate the efficacy and safety of long-term hormone replacement therapy in preventing diseases, such as coronary heart disease and hip fracture, in post menopausal women. One treatment arm of this trial included > 16,000 post-menopausal women who were receiving a combined HRT regimen comprising conjugated equine estrogens 0.625mg/day and medroxyprogesterone 2.5mg/day. This trial was stopped early after 5 years as the number of breast cancer cases had reached a predefined safety limit. For 10,000 women taking HRT, compared with women not taking HRT, there would be another 8 cases of invasive breast cancer, 7 heart attacks, 8 strokes and 8 pulmonary embolisms each year. However, they pointed out that these findings only apply to the HRT regimen described above.

Ref: Reactions 27 Jul 2002 No 912

ESTROGEN-ONLY HRT INCREASES RISK OF OVARIAN CANCER

Long-term use of estrogen-only hormone replacement therapy (HRT) is associated with a significantly increased risk of ovarian cancer among post-menopausal women, says researchers from the US. They conducted a large prospective cohort study between 1979 and 1998 to determine whether the use of HRT using estrogen alone, combined estrogen/progesterone, or estrogen followed by estrogen/progesterone, increased the risk of ovarian cancer. The study involved 44,241 postmenopausal women where the researchers have identified 329 women who developed ovarian cancer during follow-up.

The researchers concluded that in their study 'women who used ERT[estrogen replacment therapy], particularly for 10 or more years, were at significantly increased risk of ovarian cancer', and that women who used short-term estrogen/progesterone HRT alone were not at increased risk. However, the researchers noted that the risk associated with short- and long-term use of estrogen/progesterone HRT warrants further investigation.

Ref: Reactions 27 Jul 2002 No 912

NO EVIDENCE TO LINK MMR VACCINE WITH AUTISM OR BOWEL DISEASE

In a report published in Clinical Evidence* by Drs Anna Donald and Vivek Muthu, no evidence was found in any scientific literature on MMR or single measles vaccines which are related with autism or inflammatory bowel disease (IBD). However, studies have shown that these vaccines eradicate the risk of measles and its complications, and also provide protection against mumps and rubella. In another finding, they found evidence of a rosk of fever within within 3 weeks of vaccination. A study conducted by Wakefield and colleagues** which linked MMR vaccination, developmental regression and IBD was reviewed and several weak points were pointed out, such as retrospective study, small sample size, lacked a control group and sample selection bias. Hence, the study does not establish MMR as a cause of autism, developmental regression or IBD.

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HRT:THE FINDINGS OF THE WOMEN'S HEALTH INITIATIVE TRIAL

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Ref: Reactions 6 Jul 2002 No. 909

LATEST NEWS FROM THE DCA ON COUGH PREPARATIONS CONTAINING CODEINE

At its 141st meeting held on 18th November 2002, the DCA agreed to allow an extended six months grace period until 30th June 2003 for relevant parties to clear off existing stocks of cough preparations containing codeine that are available in the market. The decision to cancel the registration of all liquid codeine cough preparations is ultimate. Quota for the importation of codeine raw material will also be significantly reduced as from next year.

INTERNATIONAL VISITORS & DELEGATIONS TO NPCB

Name	Country	Date	Purpose of visit
Zhang Yanlin Vice Division Director, Senior EngineerHubei Provincial Dept of Science & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Wang You Wei Deputy Director, Researcher,Wuhan Institute Of Botany, The Chinese Academy of Science	China	7 October	Study visit on Traditional Herbal Medicines
Cheng Peng Section Chief , Hubai Academy of Science & Technology,	China	7 October	Study visit on Traditional Herbal Medicines
Wu Yongjie Hubei Provincial Dept of Sience & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Chen Shuting Assistant Engineer Hubei Academy of Science & Technology	China	7 October	Study visit on Traditional Herbal Medicines
Mrs Qian Wang Professor, Institute of China Materia	China	22 - 24 October	WHO Fellow -Study tour on regulations & monitoring of the use of Traditional Herbal

Medicine, China Academy of Traditional Chinese Medicines, Beijing			Medicines in Malaysia
Mrs Jinghua Fu Assistant Professor Programme Officer, Institute of Chinese Materia Medicine,China Academy of Traditional Chinese Medicines, Beijing	China	22 - 24 October	WHO Fellow -Study tour on regulations & monitoring of the use of Traditional Herbal Medicines in Malaysia
Dr. Ruixian Zhang Professor, Institute of Chinese Materia Medicine,China Academy of Traditional Chinese Medicines, Beijing	China	22 - 24 October	WHO Fellow -Study tour on regulations & monitoring of the use of Traditional Herbal Medicines in Malaysia
Mr .Nguyen Xuan Tien Pharmacist, Drug and Cosmetic Registration Division, Drug Administration of Vietnam	Vietnam	21 - 25 October	Training programme on Drug Registration
Dr. Nguyen Van Loi Pharmacist, Drug and Cosmetic Quality Management Division, Drug Administration of Vietnam	Vietnam	21 - 25 October	Training programme on Drug Registration
Dr. Valerio Reggi Essential Drugs and Medicines Policy/Quality Assurance and Safety of Medicines (EDM/QSM), WHO Headquarters, Geneva	Switzerland	21 - 25 October	WHO Joint Assessment of National Regulatory Authority
Endang Woro Regulatory Officer,National Agency of Drug & Food Control	Indonesia	21 - 25 October	WHO Joint Assessment of National Regulatory Authority
Hui Foong Mei Regulatory OfficerHealth Sciences Authority	Singapore	21 - 25 October	WHO Joint Assessment of National Regulatory Authority
Lee Hui Keng Regulatory OfficerHealth	Singapore	21 - 25 October	WHO Joint Assessment of National Regulatory Authority

Sciences Authority			
Charunee Krisanaphan Regulatory OfficerFood & Drug Administration, Ministry of Public Health	Thailand	21 - 25 October	WHO Joint Assessment of National Regulatory Authority
Pham Thi Biuh MinhRegulatory OfficerDrug Administration of Vietnam	Vietnam	21 - 25 October	WHO Joint Assessment of National Regulatory Authority