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NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

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APPOINTMENT OF THE NEW SECRETARY OF THE DRUG CONTROL AUTHORITY (DCA)

Mr. Selvaraja S. Seerangam graduated with a B. Pharm (Hons) from Universiti Sains Malaysia in 1978 and holds an M.Phil Pharmacy from the University of Wales in the United Kingdom. He has served the government in many different places such as Hospital Besar Seremban, Hospital Daerah Tanjung Karang, Hospital Tengku Ampuan Rahimah Klang and Hospital Keningau Sabah. He previously worked at NPCB as an auditor in the Good Manufacturing Practice Department as well as in the Quality Control Department as the Head of the Chemistry and Pharmacology Laboratory. Subsequently he served as the Senior Principal Assistant Director in the Pharmaceutical Services Division in 2002. Mr. Selvaraja then returned to NPCB on the 16th of November 2005 to resume his duty as the Deputy Director of NPCB, Centre for Product Registration as well the new secretary of the DCA.

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BERITA Ubat-ubatan is published by the National Pharmaceutical Control Bureau(NPCB), Ministry of Health Malaysia, Jalan Universiti, P.O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia. Tel: 60(3) 79573611 Fax: 60(3) 79562924 www.bpfk.gov.my

THE REGIONAL WORKSHOP ON SAMPLING STRATEGIES AND PROCEDURES

06 - 07 October 2005, Hanoi, Vietnam

The Regional Workshop on Sampling Strategies and Procedures was held in Hanoi on 6 and 7 October 2005. It was organised in cooperation with the EC-ASEAN Economic Cooperation Program, the National Institute of Drug Quality Control (NIDQC) and the World Health Organisation (WHO).

The meeting was chaired by Dr. Nguyen Thi Phuong Thao of Vietnam. Ms. Zubaidah Mahmud, of Brunei Darusalam and Dr. V. Reggi acted as rapporteurs. Attendees of the meeting included, 1 WHO expert, 24 ASEAN participants supported by the EC-ASEAN programme and 9 additional participants from their respective drug regulatory agency (DRA). Malaysia was represented by Puan Noraisyah Mohd Sani and Puan Halimatussa'adiah Mat Som from National Pharmaceutical Control Bureau , Ministry of Health Malaysia.

The background to the meeting can be summarized as follows :

a) In several ASEAN countries, strategies for collection of samples to be tested in governmental quality control laboratories need improvement in order to concentrate the use of available resources on areas and products of greater risk.

b) In some ASEAN countries, there is a disproportion between the large amount of samples tested in the marketing authorisation process and the relatively small amount tested in conjunction with post-marketing quality control. In extreme cases, post marketing quality control is virtually non-existent. The samples tested prior to marketing authorisation are selected and submitted by the applicant company. The samples for post-marketing quality control, instead, are selected and collected by inspectors. It is therefore more likely that any quality problem be detected during the post-marketing quality control activities.

c) In addition to detecting substandard products, an intensification of post-marketing quality control will also contribute to the detection of counterfeit products. Post-marketing quality control needs more attention, especially in relation to the problem of illegal trade and counterfeited pharmaceutical products that affect all member states. A number of initiatives are ongoing at the international level in this area.

Against this background, the meeting was convened with the following objectives :

a) To expose ASEAN Officials to EU experience,

b) To permit exchange of information and experience among ASEAN regulatory officials engaged in sampling and testing,

c) To discuss strategies in post-marketing quality control towards strengthening post-marketing control in ASEAN and

d) To design recommendations for strategies and technical assistance programmes to be implemented in this area.

The meeting received and discussed country reports describing the current situation. A description of the system in place in the EU was also provided to all participants. The meeting then discussed possible practical approaches which aimed at strengthening ASEAN DRAs sampling strategies and therefore their capacity to detect substandard and counterfeit products.

A number of recommendations were identified and it was proposed that Vietnam should act as lead country in the development of an ASEAN document describing a number of common principles. This document will then be discussed and finalised with the other ASEAN member countries in view of improving mutual understanding and collaboration as well as gradually developing mutual recognition of laboratory testing results.

Having achieved its expected results, the meeting was successfully concluded on Friday, 7 October 2005. The outcomes of the meeting are summarised as follows :

- International meeting addressing this type of issues are not common, hence most participants met their colleagues from other ASEAN member countries for the first time,

- Participants learned how sampling and testing are performed in other ASEAN member countries and in the EU, thus improving their understanding of post-marketing control strategies,

- A number of recommendations were drawn for consideration by the national regulatory authorities of the participating countries and

- A concrete proposal was made for developing a set of common principles in view of gradually achieving mutual recognition of testing results among ASEAN laboratories.

THE WHO WORKING GROUP MEETING ON THE INTERNATIONAL REGULATORY COOPERATION ON HERBAL MEDICINES

28 - 30 November 2005, Ottawa, Canada

The 1st meeting for International Regulatory Cooperation on Herbal Medicines (IRCH) was held in Ottawa, Canada from 28 - 30 November 2005. About twenty countries participated in this meeting. Malaysia was represented by Puan Mazli Binti Muhamad from the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia.

The objectives of the meeting were :

- To resolve questions related to regulations of herbal medicines,

- To establish a network and partners for dialogue in the area of herbal medicines and

- To develop a WHO link with a contact/focal point in national regulatory authorities.

The focal point or contact person responsible for the regulatory information must be nominated by each member country which is interested to join IRCH. Duties of the focal point or contact person are to guarantee response, to coordinate with counterparts, to monitor and to collect regulatory information.

Terms of Reference (TOR) for the information focal point of IRCH are as follows :

- Each member of the 'Information Focal Point' is nominated from the respective national regulatory authorities,

- The role of the member is to act as a facilitator of communication between WHO and among the respective member states concerning the cooperation network and

- The scope of information exchange and requests will be limited to purely technical matters on quality, safety and regulatory aspects of herbal medicines.

Presentations on the experience of global/regional/sub regional regulatory cooperation of herbal medicines and other medicines were given by :

- FHH (Western Pacific Regional Forum For the Harmonisation of Herbal Medicine)
  - Dr. Weng Xinyu, China

- PANDRH (PaN American Network For Drug Regulatory Harmonisation)
  - Dr. Rosario D'Allesio, WHO/AMRO

- EU - Dr. Konstantin Keller, Germany

- ICH - Mr. Ward, Health Canada

- ASEAN - Dr. M. Hayatie Amal, Indonesia

- Latin America Parliament Commission - Senator Sonia M. Escudero, Brazil

The mechanism of IRCH will be in the form of a closed website with email linked to the WHO platform and open only to members. There will be a standard template / table given by WHO for information requested from members. This is to make it easier for the WHO to carry out surveys on the trend of information requested.

The subsequent meetings will begin with a small number of interested countries and representatives from regional governmental organisations. Subsequently, the membership will be extended to other countries. International cooperation will initially focus on information sharing and the setting up of a global database of national regulatory information, starting with herbal medicines. The initial focus will be related to safety and quality control of herbal medicines which will then be expanded to sharing of research and knowledge in this field.

The IRCH meeting will be hosted by interested member countries with their financial contribution. Each member country will bear the cost of participation at each IRCH meeting. The host country will cover meeting expenses, provide meeting support and also provide financial support to cover travel and accommodation for selected interested developing countries which are unable to cover the costs on their own.

The meeting is to be held annually. The next meeting is scheduled to be held in Beijing, China in October 2006. Offer letters to join IRCH will be sent in January 2006 to all countries that participated in the first meeting.

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' THE HANDS-ON TRAINING IN THE EU FOR GMP INSPECTORS ' UNDER THE EC-ASEAN ECONOMIC COOPERATION PROGRAMME ON STANDARDS, QUALITY AND CONFORMITY ASSESSMENT

10 - 21 October 2005 & 14 - 25 November 2005, Portugal

The 'Hands-on Training in the EU for GMP Inspectors' was held on 10 - 21 October 2005 (Session 1) and 14 - 25 November 2005 (Session 2) in Portugal. The training was attended by 18 Good Manufacturing Practice (GMP) inspectors from the National Regulatory Authority of ASEAN member countries including Brunei, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand and Vietnam (2 auditors per country for each session). Malaysia was represented by four inspectors from the Centre of GMP, National Pharmaceutical Control Bureau, Ministry of Health Malaysia.

The training was part of the activities under Component 2 of the framework for the 'Implementation of the Sectoral Action Plan for the Pharmaceutical Sector' **(Pharmacy-SAP)** which includes :

Component 1 : Intra-ASEAN mutual recognition agreements (completed in 2004)

Component 2 : Strengthening GMP implementation and enforcement

Component 3 : Strengthening quality control laboratories

Component 4 : Development of harmonised template for approved product information

Component 5 : Strengthening post-marketing monitoring of quality and capacity to combat illegal trade

Component 6 : Strengthening technical capacity of national authorities in the evaluation of the documentation required by ACTD/ACTR

The objective of the training was to enhance the understanding among the ASEAN Inspectors and Managers of ASEAN Pharmacy GMP Inspection Units on how the implementation of quality assurance and quality management systems of a national regulatory authority (NRA) can influence the standards and practices of companies (manufacturers and wholesalers).

It was expected that the NRAs within ASEAN could improve their GMP Inspectorate Quality Systems (QS) in order to have an effective enforcement in GMP and to gain international recognition. By having the established QS, all ASEAN member countries would ultimately be able to mutually recognise each others' GMP inspections and reports. Thus, this harmonisation would benefit every country in ASEAN in terms of cost savings as well as ensuring the quality aspects of medicines produced by ASEAN countries.

The training which took place in the three cities of Portugal namely Lisbon, Oporto and Coimbra was organised and coordinated by the Instituto de Soldadura Qualidade (ISQ) with the support of the institutions : INFARMED (National Medicine Authority of Portugal) as well as manufacturers and wholesalers namely, IBET, TECNIMEDE, HOVIONE, CIPAN, LUSOMEDICA MENTA, SOFARIMEX, BIAL, ALLIANCE UNICHEME, OCP, FRESENIUS LABESFAL, PHARMA LABOR, BLUE PHARMA, AIBILI, CODIFAR and LOGIFARMA.

The training included visits to premises of medicinal product manufacturers and wholesalers as well as visits to the Pharmacy Museum of the National Pharmacy Association (ANF), the Rectory of Coimbra University and the University Hospital of Coimbra.

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28th Annual Meeting of Representatives of the National Centres participating in the WHO Programme for International Drug Monitoring

26 - 29 September 2005, Geneva, Switzerland

The 28th annual meeting for member countries participating in the WHO Programme for International Drug Monitoring was held in the WHO Headquarters in Geneva, Switzerland from 26 - 29 September 2005. Over forty countries participated in this meeting with Malaysia being represented by Puan Abida Haq Syed M. Haq from the National Pharmaceutical Control Bureau, Ministry of Health Malaysia.

The focus for this year's meeting was on patient safety. Hence, the opening lecture entitled 'Patient Safety : A Global Challenge' delivered by Sir Liam Donaldson, Chief Medical Officer, United Kingdom and Chair of the World Alliance for Patient Safety, was significant in highlighting the common concern across professions in promoting patient care.

Presentations during the meeting covered topics such as adverse drug reactions (ADRs) to drugs of current interest, exploring means for promoting pharmacovigilance within several public health programmes such as HIV/AIDS, malaria, helminthes and the tuberculosis programme, as well as a demonstration of the new computer software produced by the Uppsala Monitoring Centre for pharmacovigilance centres to submit ADR reports to the WHO.

Malaysia was given the honour of chairing the plenary session on issues pertaining to high profile drug withdrawals. This session was followed by a working group session which came up with several pertinent recommendations for improving global-regulatory efficiency which include :

- improving information-sharing and multilateral collaborations,
- strengthening regulatory capacity by releasing, in a timely fashion, ADR reports, their evaluation and all risk-communication material even while still in development,

- promoting electronic exchange and discussion on safety issues of global concerns and

- undertaking literature review on high risk products and creating a data bank for such literature.

Working group sessions were held to discuss issues such as how monitoring of adverse events following immunisation could be improved, the implementation of a pharmacovigilance component in public health programme, the development of an international taxonomy for patient safety events and the relevance of the International Classification of Diseases (ICD) in pharmacovigilance.

A discussion was also held on how pharmacovigilance centres could play a role in monitoring medication errors so that such centres can expand their roles to not only look at drug safety but patients' safety as a whole. The WHO intends to conduct a pilot study and requested for approximately 15 countries representing different parts of the world to participate.

The annual meeting was fruitful and provided a useful forum for exchange of information, highlighted new areas in which pharmacovigilance should be included in and provided opportunities for valuable networking with other regulatory agencies.

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DCA NEWS

'Derived from Seafood' statement on product labels

The Drug Control Authority (DCA) at its 175th meeting on the 27 October 2005 decided to make it mandatory to include the statement : **'Derived from Seafood'** in all labels and product inserts (if present) for products containing active ingredients obtained from the sea in which the name of the products or active ingredients do not indicate clearly that the source is from the sea (eg. Chitosan and glucosamine).

The objective is to prevent consumption of these products by users who are allergic to seafood, thereby preventing potential adverse events from occurring. However, this statement is not mandatory for products containing fish oil, shark cartilage and other ingredients where it is clear the source is from the sea. The registration holders are to abide to this ruling within 6 months from the date of the DCA meeting.

Implementation of On-line Registration - Change of Marketing Authorisation Holder of Registered Products

In an effort to facilitate the industry in the on-line transaction in Quest 2 system, NPCB will be starting another on-line module beginning 1st January 2006 ie the application for 'Change of Marketing Authorisation Holder' of the registered products.

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
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