Berita
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NATIONAL PHARMACEUTICAL CONTROL BUREAU WELCOMES ITS NEW DIRECTOR, *MADAM EISAH BT. A. RAHMAN*

The Editorial Board extends its congratulations to Madam Eisah bt. A. Rahman, for being appointed as the new Director of National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia on 1st August 2005.

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Madam Eisah graduated with a Degree in Pharmacy in 1977 from Curtin University of Technology, Australia. She then embarked on her career as a pharmacist in the Microbiological Laboratory, NPCB in 1979. Seven years later, she received her Masters in Science from University of Manchester, United Kingdom. She also possesses a post-graduate Diploma in Medical Microbiology, awarded by the Institute for Medical Research, Malaysia.

In 1992, Madam Eisah was promoted as the Head of the Microbiological Laboratory, NPCB. From 1997 to 2001, she helmed the Good Manufacturing Practice and Licensing Department, NPCB. There was a brief change in environment when she was appointed as Deputy State Health Director (Pharmacy), Kelantan State Health Department, a position which she held from 2001 to 2002. Thereafter, it was back to her familiar territory, NPCB where she was appointed as the Secretary to the Drug Control Authority besides her hectic duties as Deputy Director for the Centre for Product Registration. Madam Eisah then climbed the ranks as Deputy Director to the Director of NPCB today.

Having been with NPCB since the early days of its existence, Madam Eisah is very knowledgeable on matters pertaining to drug and cosmetics regulations. She has participated and served as an expert in various seminars, meetings, forums, etc related to regulatory matters. She has also presented many major papers pertaining to regulatory control both locally and internationally.

Those who have met her will know that she has a warm and pleasant personality that endears her to the staff of all levels as well as outsiders whom she has dealings with. A lady with a thousand smiles always makes her staff feel very comfortable to work with. Looking at her, one can hardly see any signs of stress in spite of the mountainous pile of work which she clears everyday.

Looking back on her past achievements and with her vast experience and knowledge, Madam Eisah definitely will show her true capability in providing the best to all. For your dedication and efforts, Madam Eisah, we wish you all the best in your new position! Once again,

CONGRATULATIONS!!

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THE ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY (ACCSQ) PRODUCT WORKING GROUP ON TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS

7 – 8 JULY 2005, BALI, INDONESIA

The 3rd Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Product Working Group on Traditional Medicines and Health Supplements (TMHS PWG) was held on 7 – 8 July 2005 in Bali, Indonesia. Prior to the Meeting, a Seminar on Traditional Medicines and Health Supplements Industries Challenge towards Harmonisation 2010 in ASEAN Countries was held on 6 July 2005 at the same venue.

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 and co-chaired by Ms. Eishah Abd Rahman, Deputy Director, Centre for Product Registration, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia.

The Meeting was attended by delegates from Brunei Darussalam, Indonesia, Lao PDR, Malaysia, Singapore, Thailand, Viet Nam and representatives of the ASEAN Secretariat. Representatives from Traditional Medicines and Health Supplements Industry in ASEAN Member Countries also attended the Meeting as observers.

The Meeting noted the proposed measures to be included in the Roadmap for Traditional Medicines (TM) and Health Supplements (HS) are as follows:

(i) Harmonize the labeling requirements of TM and HS

(ii) Formulate a common definition and a common product category for Health Supplements in their local and subsequently ASEAN context

(iii) Establish a common positive list of allowable ingredients, maximum dosage and suggested claims for Health Supplements and provide a common list of prohibited/banned ingredients

(iv) Establish a harmonized list of Recommended Daily Intake (RDI) values for Vitamin and Mineral Supplements (VMS) and non VMS (where applicable)

(v) Establish a framework for allowable claims that defines the types of claims allowed, the level of scientific evidence demanded, local infrastructures to assist industry, if need be, to conduct additional product quality (identifications/quantifications of active ingredients/biomarkers), toxicology and clinical testing

(vi) Provide a list of ASEAN allowable and prohibited claims

The Meeting considered the following as the potential areas for harmonization exercise:

(i) Definitions and terminologies

(ii) Market authorization which include product placement requirements and licensing

(iii) Safety requirements/Quality requirements

(iv) Post-Marketing Surveillance

(v) Monitoring of adverse product reaction, incl. adverse product incidence reporting

(vi) Advertisements

(vii) Efficacy or claims requirements

The 4th meeting of the TMHSPWG is scheduled to be held in mid-January 2006 in Thailand, subject to confirmation by Thailand. The Meeting also agreed that the 5th Meeting of the PWG will be held in Singapore in 2006.

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

24-26 August 2005, Singapore

The Tenth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held on 24-26 August 2005 in Singapore.

The Meeting was chaired by Y. Bhg. Dato' Che Mohd Zin Che Awang, Director of Pharmaceutical Services, Ministry of Health, Malaysia and co-chaired by Dr. Yuppadee Javroongrit, Senior Pharmacist, Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand.

The Meeting was attended by regulatory representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. Staff Members of the ASEAN Secretariat and WHO were also in attendance. Representatives from pharmaceutical associations and industry in ASEAN attended the Meeting as observers.

The Meeting noted recommendations on ASEAN BA/BE (Bioavailability/Bioequivalence) Studies. The following areas need to be looked at for the purpose of harmonisation:

(i) Definition of a comparator product/ ASEAN Comparator Product;

(ii) Decision Tree in Determining Comparator Products at ASEAN and National Level; and

(iii) List of ASEAN Comparator Products.

The Meeting discussed the proposal not to have an ASEAN priority list at the present time as each member country has its own needs and some may not have the infrastructure to pursue local BE studies. Member Countries have been encouraged to look into the acceptance of the BE Studies conducted by recognized BE Centres in order to reduce unnecessary repetition of BE Studies and transaction cost for industry.

The Meeting also endorsed the following recommendations of the technical discussion group:

i. Establishment of an Advisory Group of Expert Committee to look into all technical issues related to quality, while policy issues should be discussed at the PPWG meetings;

ii. Member countries are encouraged to be more active in giving inputs or comments on the adopted ACTD and ASEAN Guidelines specifically related to its implementation.

iii. All inputs and questions will be circulated to member countries for comments before finalising the Q&A Documents

The Meeting noted that in addition to harmonized labelling requirements, there are still a number of country specific requirements. In this regard, the Meeting agreed that the harmonization of labelling requirements willl need to review the current legislation in order to minimize it as much as possible.

The Meeting also agreed the ACTD implementation by 31 December 2008 only refers to the full acceptance of the dossier format taking into account the ACTR and its relevant guidelines. Besides that, Training Needs and Training Syllabus for ASEAN Regulators in ACTD also has been discussed.

The Meeting agreed that the Taskforce conducts the GMP implementation survey in Member Countries, except Malaysia and Singapore in order to identify the current GMP situation of these countries as well as to work out the roadmap for improvement of GMP infrastructure if necessary to enable them to participate in the forthcoming MRA.

The Meeting discussed and agreed to adopt in principle the establishment of a pilot Post Marketing Alert (PMA) System in the region, subject to modification and revision of the format and all Member Countries need to submit their inputs.

The Meeting agreed that there is a need to establish a strong cooperation amongst National Regulatory Authorities in ASEAN Member Countries on the regulation of vaccines.

The 11th PPWG will be held tentatively in second week of February 2006 in Ha Noi, Viet Nam.

Papers presented included subjects such as the Global Review on Medicines Regulation, ASEAN & China Regulatory Updates, Intellectual Property (IP) & Data Exclusivity, Pharmaceutical Products from Biotechnology, Hazards and Risk Management. Advances and developments in the field of pharmaceuticals, vaccines, traditional medicines, cosmetics and dietary supplements and updates on the CFC-Phase Out Plan were also discussed. There was also a presentation on "Incentives for Exporting Malaysian Products" as well as Branding Malaysian Products.

Aside from the actual conference per se, there were also exhibition booths set up and a total of nine companies, associations and agencies took part in the exhibition, namely the Drug Control Authority (DCA) of the Ministry of Health, Ain Medicare Sdn. Bhd., Swiss Bio Pharma, CCM Pharma Sdn. Bhd., Hovid Bhd., Hoe Pharmaceutical Sdn. Bhd., Traditional Malay Medicine Manufacturers Association (PURBATAMA), GlaxoSmithKline Consumer Healthcare Sdn Bhd & Global Manufacturing & Supply as well as the Federation Of Malaysian Manufacturers - Malaysian Cosmetics and Toiletries Industry Group (FMM MCTIG) / Unza (Malaysia) Sdn. Bhd. / PRICEABUSE.COM. The exhibition was also declared open by the Honourable Minister of Health.

The Honourable Minister of Health viewing the displayed items and posters at the Drug Control Authority (DCA) exhibition booth.

An official dinner was held in conjunction with the conference to commemorate the 20th anniversary of the Drug Control Authority and was attended by many officials from the Ministry of Health, past and present members of the DCA, MADRAC as well as the participants of the conference and representatives from their respective companies and agencies.

The memorable evening began with the rendering of the Malaysian national anthem "Negaraku" followed by the welcoming remarks by Yg. Bhg. Dato' Che' Mohd. Zin Che Awang, Director of Pharmaceutical Services, Ministry of Health, Malaysia. A highlight of the evening was the cake cutting ceremony to celebrate DCA's 20th anniversary by Yg. Bhg. Dato' Che' Mohd. Zin Che Awang who was joined on stage for this event by members of the Organising Committee as well as the speakers participating in the conference.

With the completion of the cake cutting event, the evening continued with an excellent Chinese dinner. Whilst the guests were enjoying their meal, they were entertained with a multimedia presentation about the National Pharmaceutical Control Bureau (NPCB) and a cultural show. The evening ended pleasantly with the guests from various different agencies, bodies and companies enjoying themselves and a feeling of camaraderie.

The National Regulatory Conference 2005 was deemed a success as the conference preceded smoothly without any major incidents and managed to achieve the objectives of the conference, as may be concluded by the positive responses obtained from the participants.

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Centre for Product Registration	Deputy Director	Selvaraja S. Seerangam	270
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