Berita
UBAT-UBATAN
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

VOLUME 34
NO. 12

ISSN 0128-0627
DECEMBER 2006

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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) 7957 3611 Fax: 60(3) 7956 2924 www.bpfk.gov.my

NEWS UPDATE ON ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY (ACCSQ) PHARMACEUTICAL PRODUCT WORKING GROUP (PPWG)

The Twelfth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held on 1st – 3rd November 2006 in Jakarta, Indonesia.

The Meeting was preceded by a series of TaskForce Meetings as follows:

- The 2nd Bioavailability/ Bioequivalence (BA/BE) Taskforce Meeting (30th October 2006)
- Technical Discussion on Quality and Stability Q&A (30th October 2006)
- The 3rd Meeting of the ASEAN Taskforce on MRA for GMP Inspections (31st October 2006)
- Implementation Working Group Dialogue with the Pharmaceutical Industry and the 7th IWG Meeting (31st October 2006)
- The WHO- ASEAN Vaccine Chapter Meeting (1st November 2006.)

The PPWG Meeting was chaired by Mdm. Eisah Abd. Rahman, Director, National Pharmaceutical Control Bureau, Ministry of Health Malaysia and co-chaired by Dr. Yuppadee Javroongrit, Assistant Director, Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand.

The attendees included representatives from the Drug Regulatory Authorities of all the ASEAN countries with the exception of Myanmar. The ASEAN Secretariat and the WHO representative were also in attendance. Representatives from pharmaceutical associations and industries in ASEAN attended the Meeting as observers.

The Meeting was officiated by Dr. Husniah Rubiana Thamrin Akib, Head of National Agency of Drug and Food Control, Indonesia. In her opening remarks, she highlighted the importance of the role of the PPWG in facilitating the harmonisation of technical regulations amongst ASEAN Member Countries in order to facilitate the movement of pharmaceutical products for faster access of medicines for public health in the region.

The ASEAN Secretariat briefed the Meeting on the latest developments of the regional economic integration as well as the main outcome of the 28th ACCSQ Meeting. The Meeting noted, among others, the following:

Acceleration of establishment of ASEAN Economic Community (AEC) in which the 38th Meeting of ASEAN Economic Ministers (AEM) agreed to recommend to the ASEAN Leaders to shorten the timeframe for regional economic integration from 2020 to 2015, with some flexibility for the new Member Countries.

Second Phase – Priority Sector Integration Roadmap – recommendation by the Special Senior Officials Meeting (SEOM) to change the timeline for Measure No. 54 i.e. *"Explore the feasibility of adopting a harmonized placement system for pharmaceutical/medicinal products into the ASEAN market",* to 'beginning 01 January 2007'.

Regarding the above decision, the Meeting agreed to recommend to SEOM to keep the deadline proposed by the PPWG for Measure No. 54 as "after 31st December 2009" as Member Countries have committed to implement the ACTD by 31st December 2008.

The Meeting had discussions on the progress on the implementation issues of ASEAN Harmonised Products in the following aspects:

1. **ASEAN Bioavailability/Bioequivalent(BA/BE) Studies**
   The Meeting revised the Terms of Reference (TOR) and the Action Plan of the BA/BE Taskforce and agreed to the proposal of the Taskforce to change the BA/BE Study Evaluation Report to BA/BE Study Report, which is the report submitted by the BA/BE Centre. The Meeting also agreed to endorse the Report of the Taskforce, the revised TOR and Action Plan of the BA/BE Taskforce. The Meeting encouraged the Taskforce to start the implementation of the endorsed Action Plan as soon as possible.

2. **Q & A for ASEAN Stability Guidelines and ACTD Quality**
   The Draft Booklets on ACTD Quality Q&A and ASEAN Guideline on Stability Q&A was discussed. The Meeting agreed on the recommendation of the Technical Meeting that a mechanism be developed involving national and regional experts from Member Countries in providing scientific opinions/justifications in a more objective manner.The meeting further agreed on the

recommendation of the Technical Meeting that Q&A Version 1 and Stability Q&A Version 1 be adopted and Indonesia to continue updating the Booklets when necessary.

4. Guideline on Process Validation Q&A

The Meeting agreed to defer discussion on this issue to the next meeting as more input from Member Countries was required.

5. Report of the 7th Implementation Working Group (IWG) Meeting

Defining Flexibility on Categories of Product for Accepting ICH CTD format

The Meeting discussed the recommendations of the IWG and agreed on the following:

i. Member Countries are committed to the ACTD format for submission of product registration

ii. Member Countries are allowed to exercise flexibility in accepting the ICH CTD format for NCEs and biologics as well as in consideration of national policies and specific needs of individual Member Countries whereby public health interests and new medicine accessibility should be considered a priority.

IWG Industry Dialogue – Discussion on Issues and Follow-up Actions

IWG was not able to consider the recommendations submitted by the ASEAN Pharmaceutical Industry Club (APC) and ASEAN Pharmaceutical Research Industry Association (APRIA) due to the need for more clarifications on certain issues.

It was suggested that the IWG hold Industry dialogues with PPWG in the future since recommendations from the Industry are mostly beyond the jurisdiction of the IWG.

Update on ACTD Implementation Status and Assistance needed

The implementation date for the ACTD by Member Countries is 31 December 2007.

ASEAN Training Accreditation Scheme

The Meeting noted the importance of establishing an ASEAN Regulatory Sciences Training and Accreditation scheme for Member Countries and it was proposed that Singapore be the contact point for the Scheme.

6. Other Activities Related to the ASEAN Healthcare Integration Roadmap

Requirements for compilation and accessibility

The Meeting agreed that the list of country specific labelling requirements be posted on the ASEAN Website as well as websites of individual Drug Regulatory Authorities (DRAs) for easy reference by the stakeholders.

Report of the 3rd Meeting of the ASEAN MRA Taskforce on GMP Inspection

The Sectoral MRA on GMP Inspection was expected to be ready for signing tentatively by the end of 2007. The 4th Meeting of the Taskforce would be held in March/April 2007 tentatively in Viet Nam to finalize the Draft Sectoral MRA before submission to the PPWG meeting. The Meeting also agreed that Member Countries send their legal advisers to attend the Taskforce Meeting if necessary.

Post Marketing Alert (PMA) System

The Meeting agreed that the PMA System could be considered as a formal system in the future to ensure the interactions and cooperation between Regulatory Authorities in ASEAN towards unsafe and defective pharmaceutical products.

7. Cooperation with the Relevant International Organization and Dialogue Partners

Vaccine Chapter

Thailand and Indonesia will coordinate with the WHO to ensure that the capacity building programme be implemented in a timely and effective manner and that all Member Countries participate in the designed programme.

Cooperation with WHO on Counterfeit Drugs

The WHO representative presented to the Meeting the WHOs' initiative to combat counterfeit drugs. Member Countries were encouraged to actively participate in the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) network created recently by the WHO.

The Meeting concluded on 3rd December and it was agreed that the 13th PPWG and its related Meetings be held in Malaysia in August 2007. The Meeting also agreed to hold a Special PPWG Meeting in March 2007 for the Heads of Delegations in Lao PDR or Thailand to enable regulators to discuss, among others, issues related to the ACTD implementation and other proposals received from the industry.

MEMBERS OF THE DRUG CONTROL AUTHORITY

The Editorial Board would like to express its gratitude and heartfelt appreciation to
Dr. Ahmad Asmadi Yusof
Lecturer and Head
Department of Pharmacology
Universiti Kebangsaan Malaysia
for his commitment, dedication and commendable contributions during his tenure as a distinguished member of the DCA from the year 2005-2006:

Members of the Drug Control Authority (DCA) effective from 14th November, 2006 are as follows:

Ex-officio members:

Tan Sri Datuk Dr. Haji Mohd. Ismail Merican *(Chairman)*
Director General of Health Malaysia

Dato' Che Mohd Zin bin Che Awang *(Alternate Chairman)*
Director of Pharmaceutical Services
Ministry of Health Malaysia

Selvaraja S. Seerangam
Drug Control Authority (Secretary)
Ministry Health of Malaysia

Appointed Members	Appointed Alternate Members
Datin Dr. Hajah Aziah Ahmad Mahayiddin Institut Perubatan Respiratori Kuala Lumpur	Dr. Chandran Krishnan@ Aris Abdullah Hospital Ipoh, Perak
Dr. Mohamed Mansor Manan Hospital Sultan Ismail, Johor	En. Abdol Malek Abd Aziz Hospital Melaka Melaka
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Dr. A. Rajamohan Annamalai Registered Medical Practitioner Kuala Lumpur	Dr. M. Ponnusamy a/l Muthaya Registered Medical Practitioner Kuala Lumpur
Mdm. Eisah A. Rahman Director National Pharmaceutical Control Bureau Ministry of Health Malaysia	

DCA NEWS

REVISED COST FOR PRODUCT ANALYSIS

The Drug Control Authority (DCA) at its 173rd meeting held on 1st September, 2005 agreed to the proposed increase in fees for product analysis by the NPCB laboratory. The increase in cost will be effective from 1st January, 2007.

No.	Type/Product Category		Cost (RM) of Analysis per Product
1.	Pharmaceutical	One active ingredient	1,200.00
		Two or more active ingredients	2,000.00
2.	New Chemical Entity	One active ingredient	3,000.00
		Two or more active ingredients	4,000.00
3.	Traditional Products		700.00

Procedure for Payment for Product Analysis

Online registration (QUEST 2):

Payment is to be made during the application for registration together with the registration processing fee.

Manual application (New Chemical Entity and Biotech products):

Payment is to be made upon submission of the registration forms to the Centre for Product Registration, National Pharmaceutical Control Bureau (NPCB)

REVISED WARNING STATEMENT FOR PRODUCTS CONTAINING ACE-INHIBITORS

The DCA at its 186th meeting held on 19th October 2006 reviewed the current warning on the use of ACE Inhibitors in pregnancy and a decision was made that the product inserts for this category of products carry the following statement under the section of ***"Warning"*** and ***"Use in Pregnancy":***

"Increased risk of birth defects, fetal and neonatal morbidity and death when used in pregnancy"

CANCELLATION OF THE REGISTRATION OF PRODUCTS CONTAINING INGREDIENTS PROHIBITED IN COSMETICS/TRADITIONAL FORMULATION

The DCA at its 185th meeting held on 29th September 2006 made the decision to cancel the registration of the following products based on the fact that samples of the products tested were found to contain some adulterants:

Product Name	Registration No.	Adulterant
Natural Lightening Cream	MAL05011917K	hydroquinone
GP Lotion	MAL05020114K	tretinoin
Dewajah Night Cream	MAL05071145K	tretinoin
Sri Mutiara Krim Kecantikan Malam	MAL05071157K	tretinoin
Qmax Capsule 350mg	MAL05101709TC	acetildenafil *(analog of sildenafil)*

POLICY ON THE REGISTRATION OF PRODUCTS CONTAINING GLUCOSAMINE AND CHONDROITIN

At its 185th Meeting, the DCA meeting agreed on the following additional policies concerning the registration of products containing glucosamine and chondroitin. However, previous policies related to the ingredient(s) are still applicable. The additional policies are as follows:

i. Products containing glucosamine as single active ingredient are registrable as non-prescription (OTC) products via the **full evaluation procedure** and with the indication: **'As adjuvant therapy for osteoarthritis'.**

ii. Products containing glucosamine in combination with chondroitin are registrable as non-prescription (OTC) products via the **full evaluation procedure** and with the same indication as in (i). Such combination will not to be considered as a New Chemical Entity since this combination has been well documented in the United States Pharmacopoiea and the National Formulary.

iii. Products containing glucosamine either as single ingredient or in combination with other ingredients normally used in health supplements are **not allowed** to be registered as dietary supplements. This is based on the fact that glucosamine has a therapeutic effect and is well documented in the references.

iv. Products containing chondroitin either as a single ingredient or in combination with other supplement ingredients, are considered as dietary supplements and no therapeutic claims are to be made. Applications for registration of such products are to be submitted as pharmaceutical dietary supplements and the evaluation process will be by the 'abridged procedure'.

All applicants for registration of the products are to abide by the ruling. Any application for registration wrongly submitted may result in the application being rejected and the processing fee forfeited.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

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OFFICER TO CONTACT

ORGANISATION	SECTION / UNIT	NAME OF OFFICER	TEL-EXT
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Centre for Product Registration	Deputy Director	Selvaraja S. Seerangam	270
Application for Registration of:			
(i) Generic Medicines Section	-Prescription Unit	Rohani Ismail	255
	-Non-Prescription Unit	Abdullah Hisham Ahmat Yaya	233
	-Veterinary Unit		
(ii) Complementary Medicines & Cosmetic Section	-Natural Products Unit	Saleha Md. Ewan	238
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(iii) Investigational & New Drug Section	-New Drug Unit	Noorizam Ibrahim	239
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	-Licensing Section	Wan Othman Wan Ismail	808
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(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	Dr. Hasenah Ali	521
	-Dosage Performance Unit	Faridah Abdul Malek	613
	-Spectroscopy/General Chemistry Unit	Ani Abdullah	604
	-Chemistry Research Unit	Dr. Hasenah Ali	521
(ii) Pharmaceutical Biology Testing Section	-Microbiology Unit	Siti Madziah Mohamed	608
	-Pharmacology/Toxicology Unit	Ani Abdullah	346
(iii) Natural Product Testing Section	-Herbal Monograph Unit	Mazli Muhamad	250
	-Adulteration Screening Unit		
	-Toxic Compound Detection Unit		