Newsletter of the Drug Control Authority, Malaysia

BERITA UBAT-UBATAN

VOLUME 53 • No. 31 • ISSN 0128-0627

September 2011

EVENTS

1) *The 15th ASEAN Consultative Committee Meeting for Standards and Quality on Traditional Medicines and Health Supplements Product Working Group*

NPCB was given the honour to host the 15th ASEAN Consultative Committee Meeting for Standards and Quality on Traditional Medicines and Health Supplements Product Working Group (ACCSQ TMHS PWG). It was held on 30th June – 1st July 2011 at the Grand Dorsett Subang Hotel, Selangor.

The meeting was chaired by Ms. Marie Tham (Advisor, International Collaboration, Health Products Regulation Group, Health Sciences Authority, Singapore) and co-chaired by Pn. Siti Aida Abdullah (Deputy Director, Centre for Product Registration, NPCB, MOH Malaysia).

Delegates from all 10 ASEAN member countries i.e. Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam were present at the meeting. Representatives from the ASEAN Secretariat, the WG 2 (ACCSQ Working Group

IN THIS ISSUE

DCA EDITORIAL TEAM

on Accreditation and Conformity Assessment), the ASEAN Alliance of Health Supplements Associations (AAHSA) and the ASEAN Alliance of Traditional Medicine Industry (AATMI) also attended the meeting.

The ASEAN Secretariat updated its members on the recent developments in the ASEAN economic integration agenda, the ASEAN Economic Ministers (AEM) Meeting as well as the Senior Economic Officials Meeting (SEOM) regarding trade facilitation, standards and conformance issues.

Ms Zubaidah, the Chair of ASEAN Technical and Scientific Committee (ATSC), presented the progress made on the harmonisation of technical requirements and the timelines for the completion of various tasks. These harmonised requirements will form an integral part of the ASEAN Regulatory Framework for TMHS in order to facilitate product placements in the ASEAN regions. Among the guidelines discussed were:

- Guidelines on Safety Data and Efficacy Data Requirements
- Guidelines for Stability Study and Shelf Life
- Guidelines on Product Dossier Submission
- Harmonisation on Labeling Requirements

2) The Good Manufacturing Practice (GMP) Seminar on Veterinary 2011

The GMP Seminar on Veterinary 2011 was organised by the NPCB in collaboration with the Malaysian Pharmaceutical Society (MPS) and the Malaysian Animal Health & Nutrition Industries Association (MAHNIA). It was held on 20th – 21st September 2011 at the Grand Dorsett Subang Hotel, Selangor.

The seminar was officiated by Dr. Tajuddin Akasah, Deputy Director of the Centre for Quality Control on behalf of the Director of Pharmacy Regulatory, NPCB. A total of 67 participants comprising of local pharmaceutical industry representatives, officers from the Pharmacy Services Division, MOH and regulatory officers from NPCB attended this seminar.

The 2-day seminar was accomplished with 15 presentation slots involving 14 speakers from NPCB as well as 4 sessions of Q & A.

Objectives of the seminar:

i. To disseminate current information on the requirements for veterinary products registration in Malaysia;
ii. To introduce basic requirements of GMP and GDP to the veterinary product manufacturers, importers and wholesalers towards the implementation of veterinary regulatory control in Malaysia;
iii. To assist the industry in understanding the requirements of Licensing.

NEW DIRECTIVES

A few directives under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2006) had been issued by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman following decisions made by the Drug Control Authority (DCA) in its recent meetings.

- ***241st DCA Meeting (23rd June 2011)***

a) Directive 07/2011: Implementation of the Change of Weight Uniformity Test Limits for Traditional Medicine and Health Supplements to the Current United States Pharmacopeia (USP) Limits

The DCA had decided to change the weight uniformity test limits for traditional medicine and health supplements from the NPCB Limits 1995 to the current USP Limits.

U.S. Pharmacopeia
The Standard of Quality℠

The directive was enforced on 27th July 2011 and would cover all the new registrations of traditional medicine and health supplement products.

All product registration holders are instructed to comply with the requirements.

Did You Know?

The first US Pharmacopeia was published in 1820 and only 217 drugs that met the criteria of "most fully established and best understood" were admitted.

- ***242nd DCA Meeting (28th July 2011)***

  - The following directives will be implemented from 22nd September 2011 onwards.
  - The full directives are available on our website at http://www.bpfk.gov.my/

a) Directive 08/2011: Strengthening of Warnings Related to the Risk of Serious Cardiac Adverse Reactions Including Death with the Use of Beta-agonists in Preterm Labour

The DCA had decided to strengthen the warning statements on the package inserts of beta-agonists (injectable and oral) used in preterm labour to warn of the risk of serious cardiac adverse effects including death.

b) Directive 09/2011: Warnings on Package Inserts for All 5-Alpha Reductase Inhibitor (5-ARI) Products - The Risk of High-Grade Prostate Cancer

All product registration holders are instructed to include warning statements on all 5-alpha reductase inhibitors (5-ARI) product package inserts to warn of the risk of high-grade prostate cancer.

c) Directive 10/2011: Strengthening of Warnings on Package Inserts for All Fluoroquinolones - Exacerbation of Myasthenia Gravis

The DCA had decided to strengthen the warning statements on the package inserts of all fluoroquinolones (antibiotics) products regarding the exacerbation of myasthenia gravis.

ANNOUNCEMENTS

1) The Issuance of Good Manufacturing Practices (GMP) Certificates (for Manufacturers of Notified Cosmetics) to ASEAN Countries

With the enforcement of notification of cosmetic products at ASEAN level, the Good Manufacturing Practices (GMP) Certificates will no longer be issued to the following countries starting from 1st January 2011:

Singapore, Indonesia, Brunei, Thailand, Myanmar, Philippines, Lao PDR, Vietnam and Cambodia.

Therefore, any application for the GMP Certificate to fellow ASEAN countries by the cosmetic notification holders or the manufacturers of notified cosmetics will not be processed.

2) *Quality Control of Finished Products (Certificate of Analysis) and Stability Studies of Pharmaceutical Products Manufactured in Malaysia for the Purpose of Product Registration*

From 1st January 2012 onwards, quality control of finished products and stability studies have to be conducted on the pilot batch of pharmaceutical products manufactured in Malaysia for the purpose of product registration. The Certificate of Analysis and stability data of the pilot batch must be submitted during the application for product registration. Therefore, Certificate of Analysis and stability data of the research and development (R&D) batch will not be accepted during the application for product registration.

All product registration applicants are requested to comply with these requirements.

REMINDERS

1) *Consumer Medicine Information Leaflet (RiMUP)*


PRODUCT X®
Generic Name / Active Ingredient
What is in this leaflet
How to take Product X
How much to take
When to take it
How long to take it
If you forget to take it
If you take too much (overdose)
While you are using Product X
Things you must do
Things you must not do
Things to be careful of
Side effects
After using product X
Storage
Disposal
Product description
what it looks like?
Ingredients
MAL NO:
Manufacturer
Marketing Authorisation Holder
What Product X is used for
How Product X works
Before you use Product X
When you must not take it
Before you start to take it
Taking other medicines
Date of revision

The requirement to provide Consumer Medicine Information Leaflet / *Risalah Maklumat Ubat Pengguna* (RiMUP) for products used in the treatment of chronic diseases such as diabetes and hypertension has been enforced in stages since April 2011.

The product registration holder is responsible for:

a) Preparing RiMUP and submitting it with other documents during product registration process.
b) The same RiMUP can be used for similar products with similar indications (despite different strengths).
c) Updating the information in RiMUP through Variation application.

The requirements (basic information, languages, and guidelines on the format) of RiMUP are available on our website at http://www.bpfk.gov.my/

All the RiMUPs will be uploaded onto our website and linked to the Pharmaceutical Services Division websites at http://www.pharmacy.gov.my and http://www.knowyourmedicine.gov.my

2) *Data Exclusivity (DE)*

Data exclusivity (DE) refers to the protection of undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort, submitted as required to the Director of Pharmaceutical Services for the purpose of scientific assessment in consideration of the:

i. Quality, safety and efficacy of any new drug product containing a New Chemical Entity (NCE)

ii. Safety and efficacy for a second indication of a registered drug product as a condition for:
   - Registration of any new drug product containing a NCE; or
   - Approval for a Second Indication of a registered drug product.

How to apply for DE

An application for DE can be made via a Letter of Intent (LOI). The application must comply with all terms and conditions of ***Directive 02/2011: DE in Malaysia.*** *The LOI should be addressed and submitted manually to the Director of NPCB.*

The LOI template and the Directive of DE are both available on our website at http://www.bpfk.gov.my/ (under 'News and Announcements').

3) *Use of Premix in Traditional Products*

The DCA at its 193rd Meeting (24th May 2007) had agreed not to allow the use of premix in traditional product formulations. Hence, all new traditional products consisting of premix as raw material will not be registered.

All traditional product manufacturers/registration holders are instructed to comply with the requirements.

UPCOMING EVENTS

Event	Date
Mutual Joint Visit (MJV) in an effort to turn Malaysia into a full member of the Organisation for Economic Co-operation and Development (OECD) - Mutual Acceptance Data (MAD) system	14th – 19th November 2011

DCA NEWS

Summary of the Drug Control Authority (DCA) policies/decisions for July – September 2011:

DCA Meetings	DCA Policies/ Decisions
244th Meeting 09/2011	***1) The registration for the two products below had been cancelled due to adulteration with scheduled poison:*** a) Product Name : HB' Lite Registration Number : MAL09032133TC Registration Holder : Metro Signature Sdn. Bhd., Selangor Original Manufacturer (as on label) : Solar Victory Sdn. Bhd. New Manufacturer : Reishilab Sdn. Bhd. Scheduled poison detected: Promethazine b) Product Name : Huo Li Bao Capsule 500mg Registration Number : MAL09062214TC Registration Holder : Wai Kang Enterprise, Johor Manufacturer : Shen Loon She Enterprise Sdn. Bhd., Pulau Pinang Scheduled poison detected: Frusemide and Chlorpheniramine ***2) Submission of notification by Bioequivalence (BE) Studies Centres to NPCB for all BE studies that do not require Clinical Trial Import License (CTIL) / Clinical Trial Exemption (CTX).*** Clinical trials have to be registered in many countries in order to overcome publication bias and hidden data. As a result, a number of regulations regarding the registration of clinical trials have been established to ensure: i. Transparency and to increase public confidence towards clinical trials. ii. Prevent the concealment of negative data or poor results. iii. Dissemination of information about the existence of clinical trials. The DCA has agreed on the requirement to submit notification to NPCB by BE Studies Centres for all BE studies that do not require CTIL / CTX (which will be conducted at either local or foreign BE studies centres) for registered products as well as products that will be registered in Malaysia. Implementation date: 1st January 2012

CONTACTS & MAP

National Pharmaceutical Control Bureau + 603 - 7883 5400

CENTRES	EXTENSION NO.
Centre for Product Registration – Deputy Director	5487
• New Drug Section	5522
• Generic Medicine Section	5490
• Biotechnology Section	8423
• Complementary Medicine Section	8415
• Active Pharmaceutical Ingredient Section	8424
• Veterinary Medicine Section	5500
• Regulatory Coordination Section	5502
Centre for Post-Registration of Products – Deputy Director	5538
• Surveillance and Product Complaints Section	5552
• Pharmacovigilance Section	5543
• Variation Section	5588
• Cosmetic Section	5532
Centre for Investigational New Product – Deputy Director	5581
• Investigational Product Evaluation Section	8406
• Investigational Product Safety Monitoring Section	8412
• GCP Compliance Section	8401
• GLP Compliance Section	8405
Centre for Compliance and Licensing – Deputy Diretor	5564
• GMP Section	5566
• Quality, Certification, Licensing and GDP Section	5569
Centre for Organisational Development – Deputy Director	5553
• Information, Communication & Technology Section	5555
• Quality System Section	5556
Centre for Quality Control – Deputy Director	5429
• Bio-Pharmaceutical Testing Section	8457
• Research and Development Section	8448
• Pharmaceutical Chemistry Testing Section	5462, 5456, 5450
• Laboratory Services Unit	5431
• Natural Product Testing Section	5471
• Reference Standard Unit	5468
Centre for Administration – Head	8458

National Pharmaceutical Control Bureau (NPCB),
Ministry Of Health Malaysia
Biro Pengawalan Farmaseutikal Kebangsaan (BPFK),
Kementerian Kesihatan Malaysia

Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor Darul Ehsan,
MALAYSIA

Tel: + 603 - 7883 5400
Fax: + 603 - 7956 2924

Website:

http://www.bpfk.gov.my