Newsletter of the Drug Control Authority, Malaysia

BERITA UBAT-UBATAN

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EVENTS

1. *The Signing of Memorandum of Understanding (MoU) on Pharmaceutical Regulatory Matters*

Malaysia and Singapore signed their first health sector Memorandum of Understanding (MoU) related to pharmaceutical regulatory matters on 28th March 2012. The signing ceremony was held at Fullerton Hotel, Singapore.

The MoU was signed between the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman and Chief Executive Officer of the Health Sciences Authority (HSA) Singapore, Associate Prof. John Lim. It was also witnessed by Health Ministers of both countries namely Dato' Sri Liow Tiong Lai (Malaysia) and Mr. Gan Kim Yong (Singapore).

The MoU was a new milestone in cooperation as both Malaysia and Singapore faced similar challenges in the pharmaceutical field. The objective was to strengthen, promote and develop pharmaceutical regulatory affairs cooperation between Malaysia and Singapore on the basis of equality and mutual benefit.

IN THIS ISSUE

DCA EDITORIAL TEAM

The areas of pharmaceutical regulatory affairs cooperation, among others, include:

- Professional collaboration in the areas of pharmaceutical regulatory affairs;
- Information related to enforcement activities, post marketing surveillance and product investigations;
- Post marketing data and information that could have an impact on public health, such as pharmacovigilance data;
- Information on quality defects or product recalls of health products;
- Inspection reports or other forms of information that supports the compliance of facilities that manufacture or import pharmaceutical products, with relevant regulatory requirements;
- Product sample test results such as those describing conformity of health products;
- Information related to the classification of pharmaceutical products, health supplements and traditional products;
- Information about clinical trials in progress for pharmaceutical products, including information related to clinical trial site inspections directed at determining compliance with Good Clinical Practice (GCP)

2. *The 1st Technical Bilateral Meeting between National Pharmaceutical Control Bureau (NPCB) Malaysia and the Singapore Health Sciences Authority (HSA)*

The 1st Technical Bilateral Meeting between the NPCB, Malaysia and HSA, Singapore was held at the Gardens Hotel and Residences Kuala Lumpur on 9th April 2012 following the signing of MoU.

The Malaysian delegation was headed by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman while the Singaporean delegation was led by Assoc. Prof. John Lim, Chief Executive Officer of HSA Singapore. Both delegations carried out a joint group discussion to discuss the areas of mutual cooperation.

At the end of the meeting, both chairs expressed their gratitude to their counterparts for a successful and promising meeting that was held in a warm and cordial manner. They also appreciated the active participation and valuable contributions of delegates from both countries. It was agreed that both authorities will continue to work together to bring about greater cooperation and to enhance the existing close working relationship.

NEW DIRECTIVES

1. *Directive 01/2012: Good Manufacturing Practice (GMP) Requirements for the Registration of Pharmaceutical Products from Overseas*

A directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2006) has been issued by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman.

After reviewing the existing product registration requirements (regarding GMP), the Drug Control Authority (DCA) has agreed to impose GMP Requirements for the registration of pharmaceutical products from overseas.

GMP Requirements for the Purpose of Product Registration

Application for the registration of pharmaceutical product (from overseas) will only be considered if the manufacturer of the pharmaceutical product meets the following requirements:

a. Manufacturer from PIC / S or ICH Member Countries

The applicant will only need to submit the valid GMP certification document / certificate issued by the country's National Drug Regulatory Agency (NDRA).

b. Manufacturer that has been inspected by NDRA from PIC / S or ICH Member Countries

The applicant will need to submit the valid GMP certification document / certificate issued by the NDRA from the relevant country.

c. Manufacturer from ASEAN Countries

The applicant is required to submit the valid GMP certification document / certificate issued by the country's NDRA in line with the agreement between ASEAN countries through the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for GMP Inspection of Manufacturers of Medicinal Products.

These new requirements will be included in applications for new product registration (effective 1st July 2012) and re-registration of registered pharmaceutical products (effective 1st January 2014). The full Requirements are available on our website at http://www.bpfk.gov.my/

2. *Directive 03/2012: Updating Package Inserts of Products Containing Finasteride – Warning Related to the Risk of Breast Cancer Among Male Patients*

A directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2006) has been issued by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman following decision made by the DCA in its 250th Meeting on 29 March 2012.

Product registration holders are instructed to include warning statements on package inserts of products containing finasteride to warn of the risk of breast cancer among male patients. Upon implementation of this directive, it is compulsory to include the following warning statements in the package inserts of all finasteride products:

> ***WARNINGS & PRECAUTIONS:***
>
> ***Breast cancer has been reported in men taking finasteride [dose, mg] during the post-marketing period. Physicians should instruct their patients to promptly report any changes in their breast tissue such as lumps, pain, gynaecosmatia or nipple discharge.***
>
> ***ADVERSE EVENTS: POST MARKETING EXPERIENCE***
>
> ***Male breast cancer***

The directive came into force on 16 April 2012 and shall include all applications for the registration of new products and products that are being evaluated.

However, for registered products, the registration holders are allowed to use the old package inserts until stock finishes or if there are amendments in the package inserts (by Variation Section, Centre for Post Registration of Product, NPCB).

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

3. *Directive 02/2011: Supplementary Guidelines on Good Manufacturing Practice (GMP) for Veterinary Premixes, Supplements and Natural Herbal Preparations*

A directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2006) has been issued by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman.

Local veterinary product manufacturers are instructed to comply with the Good Manufacturing Practice (GMP) requirements as outlined in the Supplementary Guidelines on GMP for Veterinary Premixes, Supplements and Natural Herbal Preparations.

The directive came into force on 1st January 2012. All veterinary product manufacturers are instructed to comply with these requirements apart from requirements in the Guidelines on Good Distribution Practice (GDP) which was released in January 2011.

The full Guidelines are available on our website at http://www.bpfk.gov.my/

REMINDER

1. Requirements for the Registration of Foot Patch Products

As stated in the circular Bil.(3)dlm.BPFK/PPP/01/03Jld.1 (dated 30th September 2010), the Medical Device Drug Interface Committee, Ministry of Health Malaysia had decided that foot patch products containing herbs with medical / therapeutic claims should be classified as drug and controlled by the Drug Control Authority (DCA). Product holders are required to register such products with the DCA.

The registration requirements for foot patch products, among others, are as follows:

Product Indication
Traditionally used for
- general health
- promotes blood circulation
- relieving fatigue

If the product registration holder wishes to make a claim other than the ones listed above, clinical trial paper that supports the particular indication should be submitted.

Active ingredients / Excipients
The active ingredient and excipient in a foot patch product will determine the classification of product category. Hence, all foot patch products registered as traditional products should only contain ingredients that are registered under the traditional product category.

For pharmaceutical ingredients that may act as both active ingredient and excipient (such as Vitamin C), the limit of such ingredient in a registered traditional product must comply with the excipient limit (0.01 - 0.1%). If the excipient limit is exceeded, such product should be registered as a non-prescription (OTC) product and the registration requirement is subjected to the requirements for OTC products.

Certificate of Analysis (COA) for Finished Product
The Certificate of Analysis for finished product (at least 1 batch) mustbe submitted for registration.

Certificate of Free Sales (CFS)
The Certificate of Free Sales has to be issued by the governmental issuing body in the country of origin.

Certificate of Good Manufacturing Practice (GMP)

The Certificate of Good Manufacturing Practice has to be issued by the governmental issuing body who declares that the product manufacturer adheres to certain standards (such as GMP, ISO Standards and others) in the country of origin.

*Nevertheless, the DCA may amend any registration requirement for foot patch products from time to time to ensure the safety and quality of such registered products.

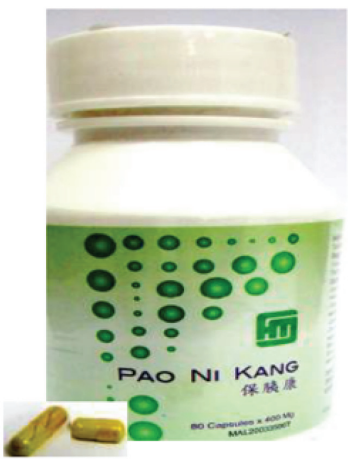
SUMMARY OF PRESS RELEASES

1. Cancellation of Registration for Traditional Product "Pao Ni Kang"

The DCA had cancelled the registration of traditional product Pao Ni Kang (MAL20033586T) following the detection of a scheduled poison namely repaglinide. Pao Ni Kang was registered for traditional use to invigorate vital energy and for sweating. The registration holder for this product is High Mean (M) Sdn. Bhd, Kuala Lumpur and the manufacturer is Shitek Micro Algae Sdn. Bhd, Selangor.

Repaglinide which is a controlled medicine for the treatment of diabetes can only be supplied by doctors or pharmacists. It is not allowed to be formulated in a product classified as traditional product.

The usage of repaglinide without proper diagnosis and monitoring can cause serious adverse events such as hypoglycemia. Symptoms of hypoglycaemia include dizziness, tremor, sweating, confusion and lethargy. Severe hypoglycaemia may lead to convulsion, unconsciousness or coma. In other words, Pao Ni Kang can cause detrimental effects to consumers especially diabetic patients.



Consumers are advised to stop taking Pao Ni Kang and seek medical advice from healthcare professionals if experiencing any unpleasant effects or adverse events. They may contact NPCB for further enquiry or information.

Anyone who is in possession of this product is advised to immediately cease selling, distributing or using it. The possession for sale of these products is an offence under the Control of Drugs and Cosmetics Regulations 1984.

2. *Response to Newspaper Article Regarding Cosmetic Products Containing Mercury*

- ***KWONG WAH YIT POH (17th MARCH 2012 - Page A20)***

"UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) FOUND THAT QUBAN SHUANG PRODUCTS FROM GUANG ZHOU CONTAIN HIGH LEVEL OF MERCURY"

The local newspaper article stated above was based on a statement issued by the United States Food and Drug Administration (FDA) regarding 35 cosmetic products found to contain high levels of mercury. Three of these cosmetics were quban shuang products from China namely Qian Mei, Lulanjina and Jiao Li.

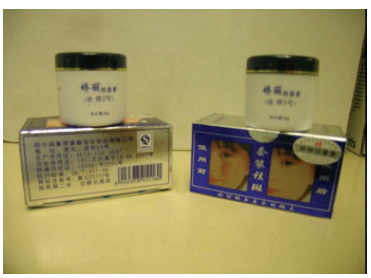
The three cosmetic products mentioned above were not notified with the National Pharmaceutical Control Bureau (NPCB). Therefore, these products should not be allowed in our market.

Mercury is not allowed in cosmetic product formulations because of the adverse effects it can cause. Mercury can be absorbed through the skin when applied topically. Continuous exposure to mercury can cause damage to the brain, nervous system as well as kidneys. In addition, the use of products containing mercury can cause various undesirable effects including rashes, irritation and other skin conditions.

The NPCB has been continuously monitoring cosmetic products (including products imported from China) through the Notified Cosmetic Products Quality Control Programme to ensure the safety and quality of cosmetic products in the market.

To date, the NPCB had detected a total of 10 cosmetic products containing mercury and notifications for these products had been cancelled. The complete list of such products is available on the NPCB website.

Qian Mei Cream



Jiao Li Cream

Lulanjina Cream

CONTACTS & MAP

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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	8408
• GCP Compliance Section	8401
• GLP Compliance Section	8404
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

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