Newsletter of the Drug Control Authority, Malaysia

# BERITA UBAT-UBATAN

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## NEW DIRECTIVES

### PHARMACEUTICALS

***1. Directive 06/2011: Warning on Package Inserts for All Antipsychotic Products - The Risk of Extrapyramidal and/or Withdrawal Symptoms for Neonates Exposed to Antipsychotic Products During Third Trimester of Pregnancy***

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 decisions made by the Drug Control Authority (DCA) in its 240th meeting on 26th May 2011.

Product registration holders are instructed to include warning statements on all antipsychotic product package inserts to warn of the risk of extrapyramidal and/or withdrawal symptoms for neonates exposed to antipsychotic products during third trimester of pregnancy.

Upon the implementation of this directive, it is compulsory to include the warning statements below in the package inserts for all antipsychotic products:

***Pregnancy and Lactation***

***Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, tremor, somnolence, respiratory distress, and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalisation.***

***[BRAND NAME] should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.***

## IN THIS ISSUE





## DCA EDITORIAL TEAM

The directive comes into force on 16th June 2011 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 old package inserts until stock finishes or if there are amendments in the package inserts (by the Variation Section, Centre for Post Registration of Products, NPCB).

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

## COSMETICS

### 1. *Directive 01/2011: Products With Names, Claims and Usage for Slimming Purposes Are Not Classified as Cosmetic Products*

A directive for cosmetics under the Control of Drugs and Cosmetics Regulations 1984 (Regulation 29) has been issued on 31st March 2011 by the Senior Director of Pharmaceutical Services, Ministry of Health Malaysia.

The directive states that products with the names, claims and usage for slimming purposes (whether clearly stated or having similar meanings and intents) are not classified as cosmetic products.

**Background**

Under the Notified Cosmetic Products Quality Control Programme (Program Pengawasan Mutu Produk Kosmetik Bernotifikasi), NPCB found that many products marketed with the names, claims and usage for slimming purposes are notified as cosmetic products. Such products are beyond the scope of cosmetic product and are clearly contrary to the ASEAN Cosmetic Directives and the Guidelines of Control of Cosmetic Products in Malaysia. This is due to the fact that slimming could not be achieved through external application of cosmetic products.

**Implementation**

The following instructions have been issued:

- Products with names, claims and are intended for slimming **are not classified as a cosmetic product.**
- Products with related names, claims (eg: modified meanings, pronunciations, spellings) that are intended for slimming **are also not classified as cosmetic products**.
- The display of "before and after" (referring to slimming process) graphics on notified cosmetic products is not allowed.

- Cosmetic notification holders who had previously notified such products as cosmetic products are requested to **withdraw the product notifications** immediately. The failure to comply will result in the **cancellation of product notifications** since the use of these products are misleading and beyond the scope of cosmetic product definition.

- Cosmetic notification holders are reminded that the Senior Director of Pharmaceutical Services has the right to reject any notification applications for the products mentioned above without prior notice.

- Cosmetic notification holders are instructed to comply with all the directives and legislations under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984, ASEAN Cosmetic Directives and Guidelines of Control of Cosmetic Products in Malaysia.

# ANNOUNCEMENTS

## 1. *Submission of Supporting Documents for the Verification of Radioactive Contamination Level for Products Imported from Japan*


All product registration/cosmetic notification holders are required to submit supporting documents for verification of the level of radioactive contamination for every batch of imported registered products/notified cosmetics from the five prefectures in Japan namely **Ibaraki**, **Gunma**, **Tochigi**, **Fukushima** and **Chiba**.

These documents need to be submitted by the authorized importers at every entry point for inspection by the Pharmacy Enforcement Division, Ministry of Health.

Failing to comply with this requirement, samples will be taken and tested by the authority. These products are not allowed to be marketed until the test results are satisfactory. However, the products will be immediately returned to the country of origin if they do not conform to the standard.

All product registration/cosmetic notification holders are responsible to follow the requirement in order to ensure public safety.

## 2. *The Use of Dentists in Dental Product Advertisements*

The use of dental practitioners/dentists to promote dental products (including toothpaste) in advertisements is prohibited by the Malaysian Dental Council (MDC), Oral Health Division, Ministry of Health. This prohibition includes the use of foreign dental practitioners.

The use of the title 'doctor' and individual wearing white coat that resembles a dental practitioner in dental product advertisements are also prohibited. Such dental product advertisement might confuse the public as it seems to have been certified by a qualified dentist under the Dental Act 1971.

According to the Cosmetic Advertising Code, testimonies made by professionals in advertisements must comply with the ethics of their profession and must not conflict with regulations set by the authorities or institutions that regulate such profession.

As a result, all dental product companies are instructed to comply with these requirements and remove all advertisements that use dentists or individuals wearing white coats for promotional purpose immediately.

***Did you know?***

- First attempts at tooth cleaning included using abrasives such as crushed bone, crushed egg and oyster shells, which were used to clean debris from teeth.
- Tooth powders were the first noticeable advance in tooth cleaning and were made up of elements like powdered charcoal, powdered bark and some flavouring agents. This was applied to teeth by using a simple stick.
- Modern toothpastes were developed in the 1800s. It was first mass-produced in 1873. Toothpaste in collapsible tube was then introduced in 1892.
- It is only within the last thirty years that toothpastes contain calcium and fluoride.

# SUMMARY OF PRESS RELEASES

## 1. *Consumers Cautioned Against Using Cosmetic Product (Sensual Whitening Cream) Containing Mercury*

The public is advised to avoid purchasing and using the following cosmetic (skin care product):

| Product Name | Notification Number | Scheduled Poison Detected | Name of Product Holder | Name of Manufacturer |
|---|---|---|---|---|
| Sensual Whitening Cream | NOT100751321K | Mercury | Sensere Marketing Sdn. Bhd. | Liberta Co. Ltd, JAPAN |

The notification of the above cosmetic product has been cancelled by the Director of Pharmaceutical Services following the detection of a scheduled poison heavy metal - mercury.


Mercury is prohibited in cosmetic products due to its toxicity and potential hazard to human health. Its compounds are readily absorbed through the skin on topical application and tend to accumulate in the body. Direct and prolonged exposure to mercury can cause damage to brain, nervous system as well as kidneys. Using products containing mercury can also result in skin rashes and irritation. Pregnant women who use products containing mercury may not experience symptoms of mercury poisoning. However, the foetuses could become severely poisoned, resulting in brain damage and other malformations.

Sensere Marketing Sdn. Bhd., the company responsible for placing this product in the market has been instructed to immediately stop the sale and supply of this product and remove all physical stocks from the market within 72 hours.

Anyone who is in possession of this product is advised to immediately cease selling/distributing/using it. Sellers are reminded that possession of this product is an offence under the Control Of Drugs and Cosmetics Regulations 1984. Any individual who commits an offence under these Regulations can be heftily fined or imprisoned.

# DCA NEWS

**Summary of the Drug Control Authority (DCA) policies/decisions from April till June 2011:**

| DCA Meetings | DCA Policies/ Decisions |
|---|---|
| **240th Meeting 05/2011** | **The registration for the three traditional products below has been cancelled due to adulteration with scheduled poison:**<br>1. Product Name : Herbaios-Zuekertec Capsule<br>Registration Number : MAL08091522T<br>Registration Holder : Sinar Aman Pharmaceutical (M) Sdn. Bhd., Selangor<br>Manufacturer : Sinar Aman Pharmaceutical (M) Sdn. Bhd., Selangor<br>Substance Detected : Glibenclamide and metformin<br><br>2. Product Name : Chi Kat Pills<br>Registration Number : MAL07090990T<br>Registration Holder : Nature Pack Enterprise, Kuala Lumpur<br>Manufacturer : Nature Pack Enterprise, Kuala Lumpur<br>Substance Detected : Ephedrine<br><br>3. Product Name : Mistura Zhike<br>Registration Number : MAL08042248T<br>Registration Holder : Metro Signature Sdn. Bhd., Selangor<br>Manufacturer : Guangzhou Pangaoshou Pharmaceutical Co. Ltd., China<br>Substance Detected : Ephedrine and pseudoephedrine |
| **241st Meeting 06/2011** | **1. Weight Uniformity Test Method for Traditional Products and Health Supplements**<br>The DCA has decided to adopt the United States Pharmacopeia (USP) - *Weight Variation of Dietary Supplements* <2091> as the reference method for the weight uniformity test of traditional products as well as health supplements.<br><br>**2. Updates on Safety Issues:**<br><br>a) **Products Containing Pioglitazone**<br>On 9th June 2011, *The Healthcare Product Health Safety Control Authority of France* (AFSSAPS) has decided to suspend the use of medications containing pioglitazone, Actos® and Competact® (combination of pioglitazone hydrochloride/metformin hydrochloride) following the results from a study conducted by the CNAMTS which confirm that there is a slight increase in the risk of bladder cancer in patients treated with pioglitazone.<br><br>b) **Products Containing Ketoconazole**<br>The AFSSAPS has also released a statement regarding the suspension of the use of ketoconazole tablets (starting on 11th July 2011). This decision was made following the evaluation of the product's safety profile that reveals a higher risk of hepatotoxicity compared to other anti-fungals of the same group. Ketoconazole (used systemically) is the only anti-fungal that is related to the risk of chronic liver disease or cirrhosis.<br><br>**The DCA will continuously monitor the safety issues of these products and further regulatory actions will be considered if necessary.** |

# EVENTS

***International Conference on Harmonisation - Global Cooperation Group (ICH-GCG) ASEAN Training Workshop on ICH Q5C: Stability Testing for Biotechnological/ Biological Products***

The ICH-GCG ASEAN Training Workshop on ICH Q5C was held on 30th–31st May 2011 at the One World Hotel, Kuala Lumpur. It was organized by National Pharmaceutical Control Bureau (NPCB) under the ICH-GCG ASEAN Collaboration Scheme.

The response to the workshop was overwhelming with a total of 117 participants comprising of regulators and pharmaceutical industry representatives from the ASEAN Member Countries. The speakers were members of the CHMP Biologics Working Party, European Medicines Agency (BWP/EMA): Dr. Alberto Ganan Jimenez, from EMA and Dr. Brigitte Brake from the Federal Institute for Drugs and Medical Devices (BfArM), Germany.

The objective of the workshop was to provide better understanding of the scientific basis of stability testings/requirements as outlined in the ICH Q5C, as well as the relevant elements of ICH Q5E (comparability) and ICH Q6B (specifications). The workshop also highlighted data and studies required to establish stability profile, product storage conditions and shelf life, including several practical case studies on stability of drug substances and drug products.

An added feature to the workshop was general discussion and updates on other ICH and EU regulatory guidelines. Since EU continues to lead in Biosimilars and has a specific regulatory framework on Advanced Therapy Medicinal Products (ATMPs), presentations on updates and sharing of experiences as well as challenges on Biosimilars and ATMPs were also provided.

*(Prepared by: Arpah Abas, Organizing Committee)*

| No. | Upcoming Events | Date |
|---|---|---|
| 1 | Awareness Seminar on the Regulatory Control of Active Pharmaceutical Ingredients (API) | 1st October 2011 |
| 2 | WHO Consultative Meeting on Building Global Capacity for Surveillance and Monitoring of Counterfeit Medicines | 3rd-5th October 2011 |

# 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 and Safety Monitoring Section | 8405 |
| • Research Compliance Section | 8401 |
| 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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