Newsletter of the Drug Control Authority, Malaysia

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EVENT

Technical Bilateral Meeting between the National Pharmaceutical Control Bureau (NPCB), Malaysia and the National Agency of Drug and Food Control (NA-DFC), Republic of Indonesia

Technical Bilateral meeting between the NPCB, Malaysia and the NA-DFC, Republic of Indonesia was held at the Boulevard Hotel, Mid Valley, Kuala Lumpur on the 11th June 2012. The Malaysian delegation was headed by Dato' Eisah A. Rahman, Senior Director of Pharmaceutical Services, Ministry of Health Malaysia while the Indonesian delegation was led by Dra Lucky S. Slamet, the Head of NA-DFC, Republic of Indonesia.

Several issues relevant to the current regulatory system and the possible areas of collaboration were discussed during the meeting. It was agreed that both agencies will continue to work together to bring about greater cooperation and to enhance the close working relationship that exist. Both delegations also agreed to have further discussions on the joint work plan on the areas of cooperation in future.

IN THIS ISSUE

DCA EDITORIAL TEAM

NEW DIRECTIVES

1) *Burkholderia cepacia Contamination Test*

Did You Know?

Burkholderia cepacia was discovered by Walter Burkholder in 1949 as the cause of onion skin rot and was first described as a human pathogen in the 1950s. In the 1980s, it was first recognised in individuals with cystic fibrosis and outbreaks were associated with a 35% death rate.

In the 249th DCA Meeting, it was decided that the *Burkholderia cepacia* contamination test must be conducted on products as listed in Table 1 and Table 2. Therefore, relevant products manufactured from 1st January 2013 must comply with the stated requirements.

Table 1: Pharmaceutical and Traditional Products

Route of Administration	TAMC (CFU/g or CFU/ml)	TYMC (CFU/g or CFU/ml)	Specified micro-organisms
Non-aqueous preparations for oral use	10^3	10^2	Absence of *Escherichia coli* (1 g or 1 ml)
Aqueous preparations for oral use	10^2	10^1	Absence of *Escherichia coli* (1 g or 1 ml) Absence of *Burkholderia cepacia* (1 g or 1 ml)
Rectal use	10^3	10^2	
Oromucosal use Gingival use Cutaneous use Nasal use Auricular use	10^2	10^1	Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Pseudomonas aeruginosa* (1 g or 1 ml) Absence of *Burkholderia cepacia* (1 g or 1 ml)
Vaginal use	10^2	10^1	Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Pseudomonas aeruginosa* (1 g or 1 ml) Absence of *Candida albicans* (1 g or 1 ml) Absence of *Burkholderia cepacia* (1 g or 1 ml)
Transdermal patches (limits for one patch including adhesive layer and backing)	10^2	10^1	Absence of *Staphylococcus aureus* (1 patch) Absence of *Pseudomonas aeruginosa* (1 patch) Absence of *Burkholderia cepacia* (1 patch)
Inhalation use (special requirements apply to liquid preparations for nebulisation)	10^2	10^1	Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Pseudomonas aeruginosa* (1 g or 1 ml) Absence of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of *Burkholderia cepacia* (1 g or 1 ml)
Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU per gram or per millilitre	10^4	10^2	Not more than 10^2 CFU of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of *Salmonella* (10 g or 10 ml) Absence of *Escherichia coli* (1 g or 1 ml) Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Burkholderia cepacia* (1 g or 1 ml) – for aqueous preparation only
Special Ph. Eur provision for herbal medicinal products consisting solely of one or more herbal drugs (whole, reduced and powdered): - herbal medicinal products to which boiling water is added before use - herbal medicinal products to which boiling water is not added before use	10^7 10^5	10^5 10^4	Not more than 10^2 CFU of *Escherichia coli* (1 g or 1 ml) Not more than 10^3 CFU of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of *Escherichia coli* (1 g or 1 ml) Absence of Salmonella (10 g or 10 ml)

Table 2: Cosmetic Products

	Total Microbial Count (Bacteria, Yeast & Moulds)	Specified micro-organisms
Products for children under 3 years, eye area and mucous membranes	Not more than 500 CFU per gram or ml	Absence of *Staphylococcus aureus* (0.1 g or 0.1 ml) Absence of *Pseudomonas aeruginosa* (0.1 g or 0.1 ml) Absence of *Candida albicans* (0.1 g or 0.1 ml) Absence of *Burkholderia cepacia* (0.1 g or 0.1 ml) –for aqueous preparation only
Other products	Not more than 1000 CFU per gram or ml	Absence of *Staphylococcus aureus* (0.1 g or 0.1 ml) Absence of *Pseudomonas aeruginosa* (0.1 g or 0.1 ml) Absence of *Candida albicans* (0.1 g or 0.1 ml) Absence of *Burkholderia cepacia* (0.1 g or 0.1 ml) –for aqueous preparation only

TAMC: Total Aerobic Microbial Count
TYMC: Total Combined Yeasts / Moulds Count

2) Prohibition of the Manufacturing of Food Products / Drinks in Licensed Traditional Product Manufacturing Premises

A directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 was been issued by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman. Under this directive, the manufacturing of food products / drinks in licensed traditional product manufacturing premises is prohibited.

However, exemptions may be granted with the approval from the Senior Director of Pharmaceutical Services.

The directive shall come into force after six months from the date of its issuance (2 August 2012). Failure to comply with this directive is an offence.

REMINDER

Guidelines on Good Distribution Practice (GDP)

Manufacturers/importers/wholesalers of registered products and notified cosmetics are reminded to comply with the directive issued under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 regarding the requirements to comply with the Guidelines on Good Distribution Practice (GDP) which was released in January 2011. All relevant parties are reminded to comply with the requirements which came into force since January 2012.

ANNOUNCEMENTS

1) Changes in QUEST3 Membership Registration Procedure

In the effort to continuously improve its service and procedures, the NPCB has made some important changes to the QUEST3 membership registration procedure. The changes were effective from 1st August 2012. The registration application is pre-evaluated upon submission and will be approved if all criteria are met. Once approved, the NPCB will send an acknowledgment e-mail to the applicant within three (3) working days. Upon receipt of the acknowledgment e-mail, applicants must print the e-mail and proceed with payment to Digicert (M) Sdn. Bhd. to obtain the USB Token.

For the purpose of membership application, the company must be registered with *Suruhanjaya Syarikat Malaysia* (SSM) and the scope of business must be related to the pharmaceutical or cosmetic field. For 'Sdn. Bhd.' and 'Berhad' companies, the Memorandum Article of Association (MAA) and Form 9 (Company Registration Certificate) must be attached together with the application.

For further information, please refer to the latest Drug Registration Guidance Document (DRGD) which is available on the NPCB website.

2) *Upgrade of the National Pharmaceutical Control Bureau (NPCB) Website*

The NPCB website/portal had been given an extensive upgrade recently with its contents being reorganised to cater for effective and efficient access by members of the public, particularly **consumers, industry players and healthcare professionals.**

Some of the new features on the NPCB website:

i. The addition of full W3C (World Wide Web Consortium) compliance, including font size selection, contrast colours preferences, and multi-language capabilities (presently in English and Bahasa Malaysia)
ii. A breakthrough industry-strength search engine
iii. FAQs have been collated together into one section, but still logically segmentised to meet the multi-dimensional needs of a broad set of audience/stakeholders
iv. Documents and files have been re-organised for the convenience of locating relevant information easily, quickly and accurately

SUMMARY OF PRESS RELEASES

1) Cancellation of Registration for Two (2) Traditional Products – "Kapsul Benkwat Ginseng Plus 500mg" & "JT Cordyceps Mycelium"

The registration of two (2) registered traditional products namely ***Kapsul Benkwat Ginseng Plus 500 mg*** **(MAL07031076T)** and ***JT Cordyceps Mycelium*** **(MAL09080820T)** had been cancelled by the Drug Control Authority (DCA) at its 252nd meeting on 31st May 2012 following the detection of scheduled poison/adulterant which are not allowed to be formulated in a product classified as traditional product. *Kapsul Benkwat Ginseng Plus 500 mg* was detected to contain yohimbine while *JT Cordyceps Mycelium* was detected to contain thiodimethylsildenafil.

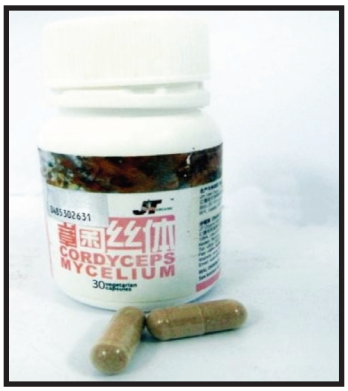
Yohimbine is an alkaloid found in a plant known as *Puasinystalia yohimbe*. It has been used to treat erectile dysfunction. The uncontrolled usage of yohimbine can cause serious adverse events such as high blood pressure, rapid heart rate, anxiety, insomnia, hallucination and manic reactions. Thus, *Kapsul Benkwat Ginseng Plus 500 mg* can cause detrimental effects to consumers particularly pregnant women and people with heart, kidney or liver disease.

Thiodimethylsildenafil is an analogue of sildenafil. The analogue has similar effect as sildenafil which is indicated for treating erectile dysfunction. Their usage without proper diagnosis and monitoring by a doctor can cause serious adverse events such as decreased or loss of vision/ hearing, may lower blood pressure to dangerous level and cause cardiovascular events such as stroke and myocardial infarction. Therefore, *JT Cordyceps Mycelium* can cause detrimental effects to consumers particularly angina patients receiving nitrates.

Consumers are advised to stop buying and taking these products and to seek medical advice from healthcare professionals should they experience any unpleasant effects or adverse events. Consumers may also contact NPCB for further enquiry or information.

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

***Kapsul Benkwat Ginseng Plus* 500 mg**



JT Cordyceps Mycelium

2) Response to Newspaper Article Regarding Bovine-sourced Gelatin in Capsules Not Suited for Vegetarians

- ***NEW STRAITS TIMES (29th MAY 2012, LETTERS TO THE EDITOR) "SUPPLEMENTS: BOVINE-SOURCED GELATIN IN CAPSULES NOT SUITED FOR VEGETARIANS"***

With reference to the article above published in a local newspaper:

The Ministry of Health (MOH) Malaysia is well aware of the importance of declaring and labeling all sources of ingredients derived from animal origin in supplements and medicines. Apart from religious reasons, the information on animal origin is very important especially for those with allergies such as allergic to bovine and seafood.

The NPCB MOH has enforced the requirements to declare source of active ingredients, excipients and/or capsule shell, including gelatin, derived from animal origin on immediate container and outer carton labelling of all registered products through the Drug Registration Guidance Document.

In addition, a directive was issued back in March 2009 to serve as a reminder to all product registration holders regarding the labeling requirements for registered products. The registration of a product may be suspended or cancelled by the Drug Control Authority if the registration holder does not comply with the relevant requirements.

The NPCB has been constantly monitoring products registered and marketed in this country through post marketing surveillance activities which include continuous inspection on the labels and package inserts of registered products.

Consumers are also advised to read the label of products to obtain accurate information before consuming.

3) Response to Newspaper Article on the Recall of Unregistered Medication in Hong Kong

- ***SIN CHEW DAILY (1st MAY 2012, Page 29)***

"HONG KONG RECALLED UNREGISTERED MEDICATION"

According to the local newspaper article stated above, the Department of Health Hong Kong had ordered the company Yuen Hui Trading Co. to recall their product, **Lorista Tablets 50mg** (Registration No. : HK-59349) due to the discovery of non-approved package insert supplied with this product. Subsequently, the product was classified as a non-registered product in Hong Kong. Lorista Tablet 50mg is a product registered with the DCA since March 2011. However, this product has not been marketed in Malaysia to date. Therefore, Malaysia is not involved with the recalling of such product as reported in Hong Kong.

DCA NEWS

Summary of the Drug Control Authority (DCA) policies/decisions for May – August 2012:

DCA Meeting	DCA Policies/ Decisions
252nd Meeting (05/2012)	***Proposal to Disallow the Use of Fluoride in Health Supplement Products*** Additional fluoride is not required orally as the fluoride content in water (in Malaysia) and cosmetic products such as fluoridated toothpaste is sufficient for the daily need of this mineral. Common side effects of excessive fluoride include dental fluorosis or the fragility of teeth. Fluoride toxicity may also lead to cardiac dysrhythmias and cardiovascular collapse as a result of calcium and magnesium chelation. In addition, it can also cause hyperkalemia. Hence, the DCA agreed with the proposal to disallow the use of fluoride in health supplement products.

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 Director	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	8458

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This newsletter is also available on our website