Newsletter of the Drug Control Authority, Malaysia

BERITA UBAT-UBATAN

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NEW DIRECTIVES

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

1. *Directive 04/2012: The Use of Meditag™ III Hologram Label with Upgraded Safety Features*

The above directive was issued to inform product registration holders about the use of the new Meditag™ III hologram label.

Mediharta Sdn. Bhd. as the supplier for Meditag™ hologram label is responsible for reviewing the safety aspects of the hologram label. As a result, they have replaced the exsiting hologram label with Meditag™ III hologram label that comes with more dynamic safety features.

The new safety features of Meditag™ III hologram label includes:

- Showcase of a new image in an effort to curb counterfeit hologram labels. It also provides extra features to the existing hologram label that could assist the enforcement division, industry players and consumers in authentication of products in the market.
- New serial number on the hologram label. The 'Roll' form begins with the letter D + 9 digits while the 'Sheet' form starts with 1 + 9 digits (1xxxxxxxxx).
- Similar label size (8mm x 16mm) as the first version of Meditag™ hologram label.

The Meditag™ III hologram label retains some of its existing features and specifications such as same pricing and same method in checking the authenticity of the hologram (by using the existing decoder that was provided to community pharmacies and other premises).

The use of Meditag™ III hologram label was implemented prospectively since 1 November 2012. Nevertheless, existing hologram labels can still be used while stock lasts.

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DCA EDITORIAL TEAM

2. *Directive 05/2012: The Updated Upper Daily Limits for Vitamins and Minerals (for Adults) in Health Supplements*

The above directive was issued to update the upper daily limits for vitamins and minerals allowed for adults in health supplements.

For health supplements with formulation that exceeds the new upper daily limit:

- Flexibility will be given to product registration holders to clear up existing stock within 6 months after the circular has been issued.
- Product registration holders will be advised to withdraw such products within that period, failing which the product registration will be canceled in the following Drug Control Authority (DCA) Meeting.

For health supplements with formulation that does not exceed the new upper daily limit (but with recommended dosage that exceeds the limit):

- Product registration holders will be notified to change the recommended dosage according to the limit.
- Product registration holders will also be given 6 months to do variation, failing which the renewal of registration will not be approved.

The directive came into force on **2 November 2012** and shall cover all applications for the registration of new products and products that are being evaluated. All product registration holders are required to comply with these requirements.

The Updated Upper Daily Limits for Vitamins and Minerals

NO.	VITAMINS & MINERALS	UPPER DAILY LIMIT
1	Vitamin A	5000 IU
2	Vitamin D	1000 IU
3	Vitamin E	800 IU
4	Vitamin B1 (Thiamine)	100 mg
5	Vitamin B2 (Riboflavine)	40 mg
6	Vitamin B5 (Panthothenic Acid)	200 mg
7	Vitamin B6 (Pyridoxine)	100 mg
8	Vitamin B12 (Cynocobalamin)	0.6 mg
9	Vitamin C (Ascorbic Acid)	1000 mg
10	Folic Acid	0.9 mg
11	Nicotinic Acid	15 mg
12	Niacinamide (Nicotinamide)	450 mg
13	Biotin	0.9 mg
14	Boron	6.4 mg

NO.	VITAMINS & MINERALS	UPPER DAILY LIMIT
15	Calcium	1200 mg
16	Chromium	0.5 mg
17	Copper	2 mg
18	Iodine	0.3 mg
19	Iron	20 mg*
20	Magnesium	350 mg
21	Manganese	3.5 mg
22	Molybdenum	0.36 mg
23	Phosphorus	800 mg
24	Selenium	0.2 mg
25	Zinc	15 mg

*Note: * For pre and antenatal use, as part of a multivitamin and mineral preparation, levels higher than the 20 mg limit established for adults may be permitted at the discretion of DCA*

3. *Directive 06/2012: Drug Registration Guidance Document (DRGD) First Edition, January 2013*

The above directive was issued to notify applicants and product registration holders regarding the use of the Drug Registration Guidance Document (DRGD) First Edition, January 2013 which covers regulatory requirements related to the registration of pharmaceutical products (including health supplements and natural products) in Malaysia.

The DRGD was reviewed and updated in an effort to make it more comprehensive for the ease of reference.

All product registration holders are instructed to adhere to the guidelines.

NEWS & ANNOUNCEMENTS

1. *The Use of Halal Logo on Over-the-Counter (OTC) Products*

The Drug Control Authority (DCA), in its 258th Meeting on 29 November 2012, agreed with the use of halal logo on registered non-poison pharmaceutical products (OTC products) excluding OTC in parenteral dosage forms and veterinary products. This will take effect from **1 January 2013**.

However, only certified halal logos issued by Jabatan Kemajuan Islam (JAKIM) or by any Islamic body recognised by JAKIM are accepted.

The use of halal logo on OTC products is voluntary whereby the consideration of its use is based on application. The product registration holder would need to submit Type II variation application to NPCB to update the halal logo information on the product label after obtaining halal certification. A valid halal certificate must be submitted during the variation application.

2. Food-Drug Interphase Product Classification

The Food-Drug Interphase Committee Meeting on 14 December 2012 has agreed that all food-drug interphase products for example products containing olive oil, colostrum and soya bean as their active ingredients are required to undergo product classification by the National Pharmaceutical Control Bureau (NPCB).

It is the responsibility of companies that are involved in the manufacturing, importing or marketing of food-drug interphase products to verify the product classification status with NPCB. If a product is classified as a drug and is required to be registered with the Drug Control Authority (DCA), the company must submit the product registration application through NPCB's online registration system.

The requirement above will be enforced from **1st January 2013**.

3. Withdrawing the Requirement to Submit Supporting Documents for the Verification of Radioactive Contamination Level for Products Imported from Japan

The NPCB has **withdrawn** the requirement to submit supporting documents for the verification of radioactive contamination level for every batch of products/cosmetics imported from Japan.

Nevertheless, product registration holders should monitor their products and report to NPCB if there is any concern/issue related to the quality and safety of the products involved.

4. Burkholderia cepacia Contamination Test

A directive [(62)dlm.BPFK/PPP/01/03Jld.1] which was previously issued stated that the *Burkholderia cepacia* contamination test must be conducted on products listed in the directive.

However, based on the feedback received, the NPCB has decided that the *Burkholderia cepacia* contamination test is not mandatory for both local and overseas manufacturers. Nevertheless, manufacturers must ensure that the products manufactured are free from contamination by this microorganism.

The NPCB will also continue to monitor the presence of *Burkholderia cepacia* in relevant products to ensure that the products are safe and of high quality. Appropriate regulatory action will be taken if the microorganism is detected in the said products.

SUMMARY OF PRESS RELEASES

1. *Cosmetic Products Containing Scheduled Poison*

The public is advised to avoid buying and using the following cosmetic products:

No.	Product Name	Notification Number	Scheduled Poison Detected	Name of Product Holder	Name of Manufacturer	Notification Status
1.	La Bliss Skin Brightening Cream	NOT100764560K	Tretinoin	Bliss Skin Care Marketing	Cyclin Cosmetic Sdn Bhd	Expired on 5 February 2012
2.	Sans Dynamic Intensive Light Cream	NOT100769625K	Mercury	Noble Aspect Sdn Bhd	Noble Aspect Sdn Bhd	Expired on 5 April 2012
3.	Putih Gebu Sunblock Collagen Lotion	NOT100771321K	Mercury	Ramaju Sdn Bhd	Ramaju Sdn Bhd	Expired on 28 April 2012
4.	MS Wellmood Enhancing Cream	NOT100777776K	Tretinoin	Noble Aspect Sdn Bhd	Noble Aspect Sdn Bhd	Expired on 23 June 2012
5.	Renewing Cream	NOT100761728K	Tretinoin	Noble Aspect Sdn Bhd	Noble Aspect Sdn Bhd	Expired on 14 January 2012
6.	Bio-Clear Intensive Renewal Complex	NOT120503338K	Tretinoin	Noble Aspect Sdn Bhd	Noble Aspect Sdn Bhd	Cancelled on 8 October 2012
7.	E Beaute Total Revitalizer Night Cream	NOT100777765K	Mercury	Noble Aspect Sdn Bhd	Noble Aspect Sdn Bhd	Expired on 17 June 2012
8.	MS Wellmood Lightening Complex	NOT100777789K	Mercury	Noble Aspect Sdn Bhd	Noble Aspect Sdn Bhd	Expired on 17 June 2012

The cosmetic products mentioned above have been tested and were found to contain scheduled poisons namely tretinoin and mercury. All eight products are no longer allowed to be sold in Malaysia. Companies responsible for marketing these products have been instructed to immediately halt the sales and supply of the product and remove all physical stock from the market within 72 hours.

The usage of tretinoin and mercury in cosmetic products are strictly prohibited. Preparations containing tretinoin should only be used under the supervision of healthcare professionals. The unsupervised usage of tretinoin can cause redness to the skin, peeling, discomfort and skin turns sensitive to sunlight.

Any person who is in possession of these products 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. Consumers are also advised to contact the National Pharmaceutical Control Bureau if they experience any allergic reactions or adverse events from the use of cosmetic products.

2. *Cancellation of Registration for Two (2) Traditional Products:*

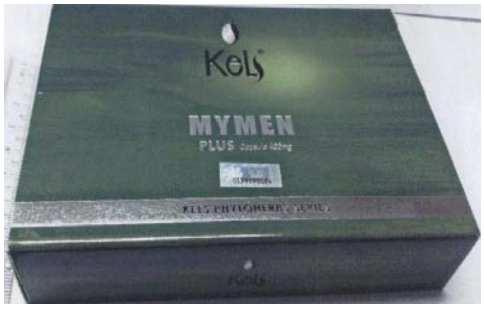
a) Jin Fei Cao San Extract Powder "Sheng Chang"

The public is advised to avoid buying and using traditional product Jin Fei Cao San Extract Powder "Sheng Chang" (MAL09111756T). The registration of this product had been cancelled by the Drug Control Authority (DCA) at its 236th meeting on 27 September 2012 following the detection of scheduled poisons namely ephedrine and pseudoephedrine. This product was registered for traditional use to relief common cold, cough, phlegm and headache.

Ephedrine and/or pseudoephedrine are controlled medicines often found as decongestants in cold medicines. Their usage at therapeutic doses prescribed by healthcare professionals provide benefit to patients, but if used indiscriminately without proper diagnosis and supervision, it can cause serious adverse events such as hypertension, psychiatric-related symptoms such as hallucination, schizophrenia, delusion and even risk of getting stroke if taken on prolonged use. Ephedrine and/or pseudoephedrine are not allowed in traditional products and if taken, can be harmful to consumers who are at high risk of getting these adverse events as well as patients with underlying heart disease, hypertension and hyperthyroidism.

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

b) MYMEN PLUS Capsule 400mg



The public is advised to avoid buying and using traditional product MYMEN PLUS Capsule 400mg (MAL09082840TC) following cancellation of its registration by the DCA due to the detection of a scheduled poison, tadalafil. It was registered for traditional use to promote blood circulation, reduce fatigue and tiredness, relief muscle and joints pain, relief waist ache and backache, and improve digestive and wind.

Tadalafil is used to treat erectile dysfunction (ED) or impotence and can only be supplied by doctors or available at pharmacies upon a prescription. Usage of tadalafil without proper diagnosis and monitoring by the doctor can cause serious adverse events such as decreased or loss of vision

and hearing, may lower blood pressure to dangerous levels and cardiovascular events such as stroke and myocardial infarction. Tadalafil or its analogues are not allowed to be formulated in a traditional product. Hence, this product can cause detrimental effects to consumers who are at high risk of getting these adverse events, particularly angina patients receiving nitrates.

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

EVENT

Hari Bersama Pelanggan (Clients Day)

Hari Bersama Pelanggan (Clients Day) was organised by the NPCB on 22 November 2012 at Serai Wangi Hall. The purpose of this event was to provide a platform for NPCB's clients to make any enquiries pertaining to regulatory affairs as well as the functions and roles of NPCB. A total of 49 clients representing 32 companies were present at the morning session while the afternoon session was attended by 20 clients or representatives from 20 companies.

UPCOMING EVENT

The NPCB will be organising the National Regulatory Conference (NRC) 2013 on 7 – 9 May 2013 at Istana Hotel, Kuala Lumpur. The conference will involve participation from international and local speakers, the Malaysian Pharmaceutical Society (MPS) as well as other associations.

THEME: Regulatory Innovation towards Transformations

OBJECTIVES:

- To update on developments and challenges in the evolving regulatory landscape.
- To strengthen collaboration and understanding among stakeholders.
- To enhance competitiveness through regulatory transformation.

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	8577
• Helpdesk	5561
Centre for Quality Control – Deputy Director	5429
• Bio-Pharmaceutical Testing Section	8457
• Research and Development Section	8448
• Pharmaceutical Chemistry Testing Section	5462
• Laboratory Services Section	5431
• Natural Product Testing Section	5471
• Reference Standard Section	5468
Centre for Administration	8458

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