



EVENT

1) *Training Programme for Oversea Drug Regulatory Authorities*



The National Pharmaceutical Control Bureau (NPCB) has successfully organised the Training Programme: Pharmaceutical Regulatory System on the 18 – 22 November 2013 at Eastin Hotel, Petaling Jaya. A total of 13 representatives from 9 countries attended this training programme.

The objective of this training was to introduce the Malaysian pharmaceutical regulatory system, which is on par with global regulatory systems, to the drug regulatory authorities of other countries. Besides, this programme would showcase NPCB's commitment to ensuring the quality, safety and efficacy of registered therapeutic products that are marketed in Malaysia.

The key focus of the programme was to provide assurance to these foreign countries on the quality, safety and efficacy of locally manufactured and registered pharmaceutical products. Subsequently, in line with the aspiration of EPP 3: Malaysian Pharmaceuticals under the National Key Economic Area (NKEA) Healthcare, NPCB is hopeful that pharmaceutical product export opportunities and growth will be attained in countries that have taken part in this training programme.

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NEW DIRECTIVE

1) **Directive 07/13 [Ref: (6) dlm. BPFK/PPP/07/25]: Extending the Scope of Halal Logo Usage on Non-Poison Pharmaceutical Products in Parenteral Dosage Forms**

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 Drug Control Authority (DCA) in its 268th Meeting on 26th September 2013.

The directive is issued to extend the scope of the use of halal logo on registered non-poison pharmaceutical products to include such products in parenteral dosage forms.

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

The use of halal logo is voluntary. 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.

This will take effect from 8 November 2013.

SUMMARY OF PRESS RELEASES

1) **TRADITIONAL PRODUCTS / HEALTH SUPPLEMENTS**

a) **Unregistered Traditional Products Containing Scheduled Poison**

The NPCB has obtained information from the Health Sciences Authority (HSA) Singapore regarding three traditional products that contain scheduled poisons.

No	Name of Products	Scheduled Poison Detected
1.	Li Long Mei Guo Mo Bang	Sildenafil
2.	Africa Black Ant	Sildenafil
3.	Ginseng Tu Chong Wan Lin Heong	Dexamethasone

All three products are not registered with the DCA. The product registration number MAL19991268TC and company details printed on the label for Ginseng Tu Chong Wan Lin Heong are found to be faked.

The use of scheduled poison in traditional products is strictly prohibited. Sildenafil is used to treat erectile dysfunction and should only be used when prescribed by a doctor. Its usage without proper medical advice can cause serious adverse reactions such as decreased or loss of vision and hearing, low blood pressure and other cardiovascular events such as stroke and heart attack. Dexamethasone is a potent corticosteroid and should only be used under medical supervision. Long term and unsupervised use of corticosteroids can cause serious adverse effects such as Cushing Syndrome, increased blood glucose level, high blood pressure, bone disorders such as osteoporosis and an increased risk of infections.



The public is advised not to buy or consume products that are not registered with the DCA as their quality and safety are not known.

*Source: Health Sciences Authority (HSA) Singapore

b) Product Registration Cancellation for Traditional Products: Cosa Grande Capsule 350mg Platinum and Vital + Essence Capsule

The public is advised to stop buying or using two traditional products namely Cosa Grande Platinum Capsule 350mg and Vital + Essence Capsule. Their registrations have been cancelled by the DCA following the detection of adulterants in these products.

No.	Product Name (Registration Number)	Scheduled Poison	Product Registration Holder	Manufacturer
1	Cosa Grande Platinum Capsule 350mg (MAL 10043765TC)	Avanafil	Natural Elixir (M) Sdn. Bhd., Klang, Selangor	Polens (M) Sdn. Bhd., Shah Alam Selangor
2	Vital + Essence Capsule (MAL 20040210T)	Nortadalafil	Polens (M) Sdn. Bhd., Shah Alam, Selangor	Polens (M) Sdn. Bhd., Shah Alam Selangor

Avanafil and tadalafil (nortadalafil is an analog of tadalafil) are used in the treatment of erectile dysfunction and should only be given with a doctor’s prescription. The use of avanafil or tadalafil without medical supervision can cause serious adverse events such as loss of vision and hearing, decreased blood pressure, stroke and heart attack.



COSA GRANDE PLATINUM CAPSULE 350 MG

VITAL + ESSENCE CAPSULE

Thus, those who are using these products are advised to stop using them immediately and seek medical advice from healthcare professionals should they experience any discomfort or adverse effects.

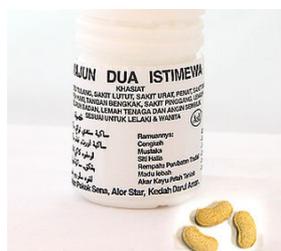
c) Unregistered Traditional Products

The public is advised to avoid buying and using the following traditional products that are not registered with the DCA and adulterated with scheduled poisons:

No	Name of Products	Scheduled Poison Detected
1.	Madu Adunan Herba	Dexamethasone
2.	Majun Dua Istimewa	Dexamethasone
3.	Majun Taufiq Dua Istimewa	Dexamethasone
4.	Figure Up	Sibutramine



Majun Taufiq Dua Istimewa



Majun Dua Istimewa



Madu Adunan Herba



Figure Up

d) Caution against Taking OxyElite Pro

The public is warned against taking OxyElite Pro which is not registered with the Drug Control Authority (DCA). This product has been marketed on the internet as food supplement and fat burner to lose weight.

Oxylite Pro contains Yohimbine which is classified as poison in the Poisons Act 1952. It is an alkaloid found in the Pausinystalia yohimbe plant. It can cause a drastic increase in blood pressure and/or a sudden drop in blood pressure if taken excessively. Other adverse effects associated with yohimbine are insomnia, anxiety, palpitations, seizures, chest pain and excessive sweating.



Therefore, anyone who is in possession of this unregistered product is advised to immediately stop selling, distributing or using it.

2. COSMETICS

a) Consumers Cautioned against Using Cosmetic Products Containing Scheduled Poison

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

No	Name of Products	Notification Number	Heavy Metal Detected	Notification Holder	Manufacturer
1.	Daily Protecting Cream – Joie et Beaute	NOT100778850K	Mercury	Rina Skincare (M) Sdn. Bhd.	ChiuMien Cosmetics Co., Ltd, Taiwan
2.	Yoko Whitening Cream Ginseng & Pearls	NOT100901081K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand
3.	Yoko Whitening Cream with SPF-15	NOT100901085K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand
4.	Yoko Yogurt Milk Whitening Cream	NOT100901088K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand
5.	Yoko Beauteen Sunflower Whitening Cream	NOT100901094K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand
6.	Yoko Freckle Cream	NOT100901098K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand
7.	Yoko Whitening Cream	NOT100901107K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand
8.	Yoko Whitening Cream Aloe Vera Extract	NOT100903039K	Mercury	PK-1 Wholesales Trading Sdn. Bhd.	Siam Yoko Co. Ltd, Thailand

The notifications of the cosmetics above have been cancelled following the detection of the heavy metal mercury.

Mercury is prohibited in cosmetic products due to its potential hazard on human health. Mercury 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 the brain, nervous system and kidneys. Using products containing mercury can also result in skin rashes, irritation, and other changes to the skin.

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

b) Caution against buying and using Sensual Meiji Skin Renewer Cream

Product Name	Notification Number	Scheduled Poison	Notification Holder	Manufacturer
Sensual Meiji Skin Renewer Cream	NOT120204451K	Azelaic Acid	De Cosmetics Malaysia Sdn Bhd	Hong Chuang International Beauty Co. Ltd, Taiwan

Sensual Meiji Skin Renewer Cream has been tested and found to contain scheduled poison azelaic acid which is not allowed in cosmetic products. Therefore, this product is no longer allowed to be sold in Malaysia.

Azelaic acid is found in pharmaceutical products for the indication of reducing inflammation in the treatment for acne vulgaris. Its usage without proper medical advice can cause undesirable adverse reactions such as the burning sensation on skin, itching, redness, flaking skin and skin pigmentation.



The notification holder has been ordered to stop the sale or supply immediately and withdraw all physical stocks from the market within 72 hours.

RESPONSE TO NEWSPAPER ARTICLES

1. Response to Newspaper Article 1

• **NANYANG SIANG PAU (24 AUGUST 2013)**
“IS NIU HUANG JIE DU PIAN POISONOUS? TONG REN TANG: THE STANDARD OF DRUG USAGE & POLICY FOR WESTERN MEDICATIONS IS DIFFERENT FROM CHINESE TRADITIONAL MEDICATIONS”

The Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom has issued a warning to the public against purchasing or using unlicensed traditional Chinese medicine (TCM) product that contains high levels of heavy metal.

Product Niu Huang Jie Du Pian (manufactured by Beijing Tong Ren Tang, China) has been reported to contain high level of arsenic. Arsenic poisoning can cause effects such as pigmentation and skin thickening (hyperkeratosis), vomiting, abdominal pain, diarrhea. Long term and excessive exposure to arsenic may also cause cancer.

Niu Huang Jie Du Pian is not registered with the DCA. The public is advised not to buy or use product that is not registered with the DCA since its quality and safety is not ensured.

2. *Response to Newspaper Article 2*

- **THE STAR (9 SEPTEMBER 2013)**
“UNLICENSED LIPSTICKS MAY CONTAIN LEAD”

The Food and Drug Administration (FDA) Philippines has warned the public against buying lipsticks from China that are marketed illegally. These products such as Baolishi, Miss Beauty, Shijing, Ling Mei and Heng Fang may contain high levels of heavy metals, particularly lead.

The lipsticks above are not notified with the MOH. Thus, they are not allowed in the market. However, some of these products are promoted through social media. NPCB is currently conducting further investigation regarding the sale of such products and necessary actions will be taken against those involved.

Lead is not allowed in cosmetic product formulation. It is a proven toxicant that accumulates in the body through constant exposure and absorption over a prolonged period. Health problems through chronic ingestion of high level of lead in lipsticks may manifest as neurologic, hematologic, gastrointestinal, cardiovascular, and renal problems. In adults, lead toxicant has been linked with high blood pressure, joint pain, poor memory, and concentration problems. Children are particularly at risk from neurotoxic effects of lead, which affect their brain development and cognition, memory and behavior.

NPCB will continuously monitor the safety of lipstick products through Surveillance Program.

3. *Response to Newspaper Article 3*

- **UTUSAN MALAYSIA (19 SEPTEMBER 2013)**
“PENGAWET BERI KESAN ALAHAN”

The local newspaper above has cited an article on the use of methylisothiazolinone in cosmetics. It has been reported in United Kingdom that more than 150 users experienced allergic reactions after using sun protection product known as Piz Buin which was marketed by Johnson & Johnson.

Piz Buin is not notified with MOH and it is not available in the local market. According to the Guidelines for Control of Cosmetic Products in Malaysia, the use of methylisothiazolinone (as a preservative) in cosmetic preparation is permitted with maximum concentration of up to 0.01%.

To date, NPCB has not received any complaint regarding the use of cosmetics containing methylisothiazolinone. Nevertheless, NPCB will review the safety level of methylisothiazolinone in cosmetics and take necessary action to ensure the safety and wellbeing of the public.

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	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, 5456, 5450
• Laboratory Services Section	5431
• Natural Product Testing Section	5471
• Reference Standard Section	5468
Centre for Administration	8458

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