Newsletter of the Drug Control Authority, Malaysia

BERITA UBAT-UBATAN

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EVENTS

MEMORANDUM OF UNDERSTANDING BETWEEN THE MINISTRY OF HEALTH MALAYSIA AND THE MALAYSIAN FORESTRY RESEARCH AND DEVELOPMENT BOARD

A Memorandum of Understanding (MoU) between the Ministry of Health Malaysia (MoH), as represented by the National Pharmaceutical Control Bureau (NPCB) and The Malaysian Forestry Research and Development Board (MFRDB) was signed on 16 February 2015.

The primary objective of this MoU is to set out the understanding and basic terms relating to the co-operation in the following areas:

- Encourage the collaboration of researchers and staff of both parties in projects and programmes to promote transfer of knowledge and expertise sharing with respect to the herbal field, particularly local herbs.
- Encourage the development of bilateral programmes which facilitates training between researchers and staff that will mutually benefit both Parties.
- Encourage the collaboration between both parties in organising Seminars/ Conference/Exhibitions for the purpose of information dissemination to the public and related industries.

IN THIS ISSUE

EVENTS

1ST MALAYSIA - JAPAN SYMPOSIUM 2015

The National Pharmaceutical Control Bureau (NPCB), Ministry of Health, Malaysia together with the Pharmaceutical and Medical Devices Agency (PMDA), Japan has successfully organised the 1st Malaysia - Japan Symposium 2015: Pharmaceutical Regulatory System at the Aloft Kuala Lumpur Sentral Hotel, Kuala Lumpur on 10 – 11 March 2015.

This joint conference is aimed to enhance Malaysia and Japan's mutual understanding of each other's regulatory system, and to promote advancement of pharmaceutical regulations and development. This symposium offered in-depth presentations and discussions in each area from the pharmaceutical regulatory perspective. It was attended by a total of 150 participants.

NEW DIRECTIVES

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

1. Directive 16/14 [Ruj: (23) dlm. BPFK/PPP/07/25]: Implementation of Vaccine Lot Release for all Registered Vaccines in Malaysia

Following the decision made by the Drug Control Authority (DCA) in its 281st Meeting on 24 November 2014, this directive was issued **to implement Vaccine Lot Release for all registered vaccines in Malaysia.**

For any registered vaccine which is **NON-COMPLIANT** to the **Vaccine Lot Release** in Malaysia:

a) The vaccine is **NOT** allowed to be distributed or marketed in Malaysia.
b) The vaccine **MUST** be disposed in Malaysia.
c) Evidence of collection for the purpose of disposal **MUST** be produced by the Registration Holder to NPCB within **30 days** from Notification of Non-Compliance release date.
d) Evidence of disposal **MUST** be produced by the Registration Holder to NPCB within 90 days from the date of collection for disposal.

This directive is effective from **1 February 2015.**

2. Directive 17/14 [Ruj: (24) dlm. BPFK/PPP/07/25]: Restriction on Indication and Dosage of all Metoclopramide Products Due to Neurological Adverse Effects

Following the decision made by the Drug Control Authority (DCA) in its 283rd Meeting on 23 December 2014, this directive was issued **to restrict the Indication and Dosage for all Metoclopramide products.**

Therefore, the following instructions must be adhered to **for all Metoclopramide products:**

The package insert update process must be done according to these dates:
New registration and products under evaluation : **15 January 2015**
Registered products : **1 July 2015**

The application for amendments of package inserts must be done through variation application.

This directive is effective from **15 January 2015.**

Indication
Adults Population
Injections
[BRAND NAME] (Metoclopramide) is indicated for use in adults for:

- Prevention of post-operative nausea and vomiting.
- Symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks.
- Prevention of radiotherapy-induced nausea and vomiting.

Oral – Tablet / Syrup
[BRAND NAME] (Metoclopramide) is indicated for use in adults for:

- Prevention of delayed chemotherapy induced nausea and vomiting (CINV).
- Prevention of radiotherapy-induced nausea and vomiting.
- Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting.

Rectal -Suppository
[BRAND NAME] (Metoclopramide) is indicated for use in adults for:

- Prevention of delayed chemotherapy-induced nausea and vomiting.
- Prevention of radiotherapy-induced nausea and vomiting (RIVN).

Paediatric Population (Children aged 1 – 18 years of age)
Injections
[BRAND NAME] (Metoclopramide) is indicated for use in children aged 1 - 18 years for:

- Prevention of delayed chemotherapy induced nausea and vomiting as a second-line option.
- Prevention of post-operative nausea and vomiting as a second line option.

Oral – Tablet / Syrup
[BRAND NAME] (Metoclopramide) is indicated in children aged 1 - 18 years for:

- Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second-line option.

Dose and Administration :
Adults Population
Injection

- The solution can be administered by the Intravenous or Intramuscular route.
- The Intravenous doses must be administered as a slow bolus (for at least 3 minutes).
- A single 10mg dose is recommended for the prevention of post-operative nausea and vomiting.

- The recommended dose for the symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks and for the prevention of radiotherapy-induced nausea and vomiting is 10mg per dose, 1 to 3 times daily. The maximum recommended daily dose is 30mg or 0.5mg/kg.
- Treatment duration when administering by injection should be as short as possible and a switch to administration via oral or rectal route should be instituted as quickly as possible

Oral – Tablet / Syrup

- The recommended single dose is 10mg, repeated up to three times daily.
- The maximum recommended daily dose is 30mg or 0.5mg/kg body weight.
- The maximum recommended treatment duration is 5 days.

Rectal - Suppository

- The recommended dosage is 10mg per dose, 1 to 3 times daily.
- The maximum recommended daily dose is 30mg or 0.5mg/kg.
- The maximum recommended treatment duration is 5 days.

Paediatric Population (Children aged 1 – 18 years of age)

Injection

- The solution can be administered by the Intravenous or Intramuscular route.
- The Intravenous doses must be administered as a slow bolus (for at least 3 minutes).
- The recommended dosage is 0.1 to 0.15mg/kg, 1 to 3 times daily, by Intravenous route.
- The maximum daily dose is 0.5mg/kg.
- Dosing table

Age	Body Weight	Dose	Dose Frequency
1-3 years	10-14kg	1mg	Up to 3 times daily
3-5 years	15-19kg	2mg	Up to 3 times daily
5-9 years	20-29kg	2.5mg	Up to 3 times daily
9-18 years	30-60kg	5mg	Up to 3 times daily
15-18 years	Over 60kg	10mg	Up to 3 times daily

- For the prevention of delayed chemotherapy-induced nausea and vomiting, the maximum treatment duration is 5 days.
- For the prevention of post-operative nausea and vomiting, the maximum treatment duration is 48 hours.

Oral – Tablet / Syrup

- The recommended dose is 0.1 to 0.15mg/kg body weight, 1 to 3 times daily, by oral route.
- The maximum dose in 24 hours is 0.5mg/kg body weight.
- The maximum recommended treatment duration is 5 days for prevention of delayed chemotherapy induced nausea and vomiting (CIVN).
- Tablets are not suitable for use in children weighing less than 30kg. Other pharmaceutical forms may be more appropriate for administration to this population.

Frequency of administration :
A minimum interval of 6 hours between two administrations is to be respected, even if vomiting or rejection of the dose occurs.

Special Population
Elderly

- In elderly patients, a dose reduction should be considered based on renal and hepatic function, and overall frailty.

Kidney Impairment

- In patients with end-stage kidney failure (Creatinine clearance ≤ 15 ml/min), the daily dose should be reduced by 75%.
- In patients with moderate to severe renal impairment (Creatinine clearance 15-60 ml/min), the dose should be reduced by 50%.

Hepatic Impairment

- In patients with severe hepatic impairment, the dose should be reduced by 50%.

3. Directive 01/15 [Ruj: (25) dlm. BPFK/PPP/07/25]: Compliance to the Requirements in the "Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes"

A directive was issued **to inform local manufacturers of veterinary products about compliance to Good Manufacturing Practice (GMP) particularly for Veterinary Premixes as stated in the "Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes"** alongside with other guidelines used in Malaysia.

This guideline serves to replace the "Supplementary Guidelines on Good Manufacturing Practice (GMP) for Veterinary Premixes, Supplements and Herbal / Natural Preparations" version January 2012.

Local manufacturers of veterinary products **MUST** be compliant to the requirements in the **"Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes"**

This directive is effective from **1 February 2015.**

4. Directive 02/15 [Ruj: (6) dlm. BPFK/30/05/1]: Requirement for Full Time Registered Pharmacist to lead the Manufacturing Section in Manufacturing Premises of Pharmaceutical, Radiopharmaceutical and Veterinary Products Registered with the Drug Control Authority (DCA): Extension of Implementation Date

A directive was issued **to inform about the extension of implementation of the requirement for Full Time Registered Pharmacist to lead the manufacturing section in manufacturing premises of Pharmaceutical, Radiopharmaceutical and Veterinary products registered with the Drug Control Authority (DCA).**

This directive does **NOT** exempt any Regulations or Acts related to the existing Registered Pharmacists.

This directive will take effect according to these dates;
Manufacturer of Pharmaceutical Products (including primary repackaging) and Radiopharmaceuticals registered with DCA : **1 January 2017**

Manufacturer of Veterinary Products (Scheduled Poison) registered with DCA : **1 January 2020**

5. Directive 03/15 [Ruj: (27) dlm. BPFK/PPP/07/27]: Enforcement of the Requirement for Bioequivalence (BE) Study for Generic Products in the Dosage Forms of Effervescent, Dispersible, Orodispersible, Sublingual, Buccal and Chewable Tablet / Capsule Containing Scheduled Poison as Active Ingredient

A directive was issued following the decision made by the Drug Control Authority (DCA) in its 284th meeting on 29 January 2015 ***to enforce the Requirement for Bioequivalence (BE) Study for Generic Products in the Dosage Forms of Effervescent, Dispersible, Orodispersible, Sublingual, Buccal and Chewable Tablet / Capsule Containing Scheduled Poison as Active Ingredient.***

The requirement for BE studies for Generic Products in the dosage forms of effervescent, dispersible, orodispersible, sublingual, buccal and chewable tablet / capsule containing Scheduled Poison as Active Ingredient will take effect from these dates :
New applications for registration : **1 July 2016**
Registration for products which registration period has expired : **1 July 2017**

This directive is effective from **1 March 2015.**

SUMMARY OF PRESS RELEASES

TRADITIONAL PRODUCTS / HEALTH SUPPLEMENTS

Caution on Using Unregistered Products Containing Scheduled Poison

Majun Tolak Angin
The National Centre for Adverse Drug Reactions Monitoring, NPCB would like to remind the public not to buy or use the unregistered product sold as a Malay traditional medicine labelled as 'Majun Tolak Angin'.

Sampling of the product through adverse reaction reports received by the National Centre for Adverse Drug Reactions Monitoring, NPCB has proven that the product contains **dexamethasone**, a corticosteroid which is scheduled under the Poisons Act 1952.

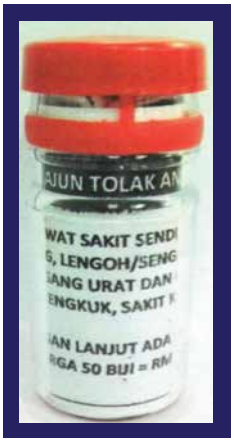
The product label claims that the product is to be used for joint pain, bone pain, nerve pain, back pain, aches, heel numbness, cramps, tense nerve and muscle, tiredness, neck fatigue and headache.

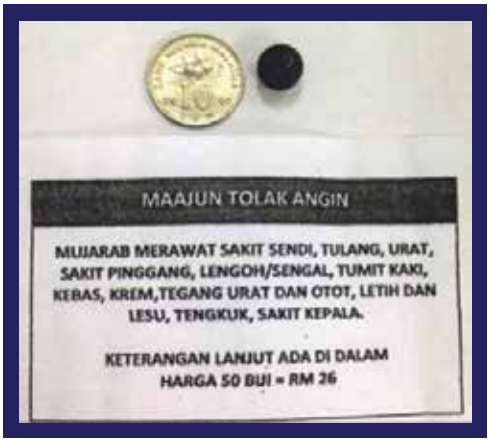
Three adverse reaction reports were received and reported to have caused headaches and more severely - Cushing's syndrome (round face and weight gain with central obesity).

Dexamethasone is a potent corticosteroid which should only be used under medical supervision and is not to be added in traditional products. Long term and unsupervised use of corticosteroids can cause serious adverse effects such as **Cushing Syndrome, increased blood glucose level, high blood pressure, cataracts and bone disorders such as osteoporosis.**

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. Patients with chronic diseases such as diabetes, poses higher risk and are advised not to use unregistered items as they may be adulterated with corticosteroids.

Corticosteroids can cause uncontrolled blood sugar levels and therefore cause serious complications.





COSMETICS

Caution on Using Cosmetic Products Containing Scheduled Poisons
The public is advised to avoid buying and using the following cosmetic products :

No.	Product Name	Notification Number	Scheduled Poison Detected	Name of Product Notification Holder	Name of Manufacturer
1.	Hans Beauty Treatment Toner	NOT130304284K	Hydroquinone	Hans Beauty & Health	Herca, Indonesia
2.	Hans Beauty Flawless Day Cream	NOT130304286K	Mercury	Hans Beauty & Health	Herca, Indonesia
3.	Hans Beauty Flawless Night Cream	NOT130304287K	Mercury	Hans Beauty & Health	Herca, Indonesia

The notifications of the above cosmetics have been cancelled following the detection of the scheduled poison, **hydroquinone** and heavy metal, **mercury** which are prohibited in cosmetic products. These products are no longer allowed to be sold in Malaysia.

Products containing hydroquinone are classified as pharmaceutical products that require registration with the Drug Control Authority (DCA) and can only be used under the advice of a healthcare professional. Hydroquinone is commonly used for hyperpigmentation of skin. Unsupervised use of preparations containing hydroquinone may cause unwanted side-effects.

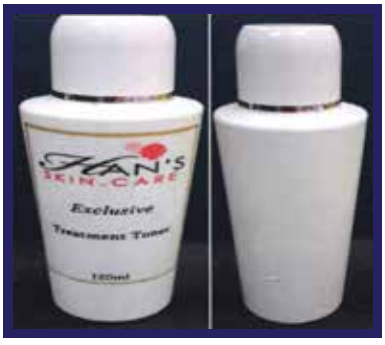
Cosmetic products adulterated with hydroquinone are typically marketed for skin lightening, as well as to treat blemishes and uneven skin tone. Hydroquinone can cause skin redness, discomfort, skin discoloration, hypersensitivity and a gradual blue-black darkening of the skin. Hydroquinone inhibits the pigmentation process (depigmentation) which reduces the skin's ability to be protected from harmful UV rays, thus, increasing the risk of skin cancer.

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. Usage of products containing mercury can also result in skin rashes, irritation and other changes to the skin.

The company responsible for placing the product in the market has been instructed to immediately halt the sale and supply of the product mentioned and remove all physical stocks from the market within 72 hours.

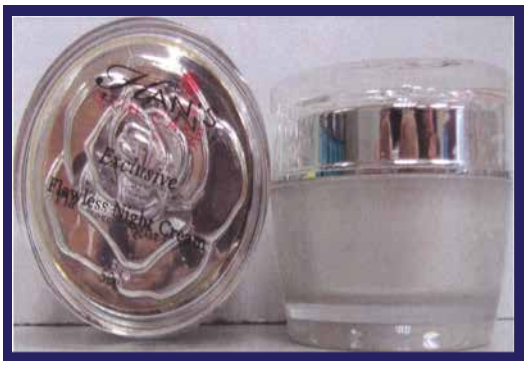
Any person who is in possession of this product is advised to immediately cease selling, distributing or using it. The possession of this product is an offence under the Control of Drugs and Cosmetics Regulations 1984.

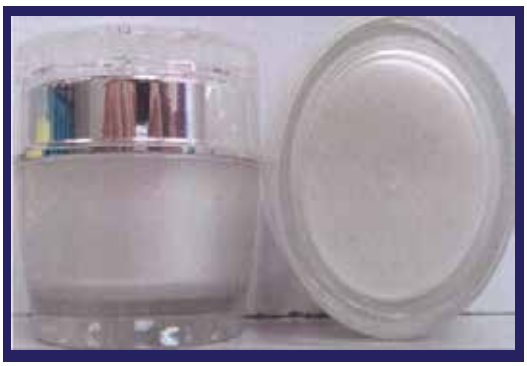
Hans Beauty Treatment Toner



Hans Beauty Flawless Day Cream

Hans Beauty Flawless Night Cream





CONTACTS & MAP

NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB) **+ 603 - 7883 5400**

CENTRES	EXTENSION NO.
Centre for Product Registration – Deputy Director	**5487**
• Active Pharmaceutical Ingredient Section	8424
• Biotechnology Section	8423
• Complementary Medicine Section	8415
• Generic Medicine Section	5490
• New Drug Section	5522
• Regulatory Coordination Section	5502
• Veterinary Medicine Section	5500
Centre for Post-Registration of Products – Deputy Director	**5538**
• Cosmetic Section	5532
• Pharmacovigilance Section	5543
• Surveillance and Product Complaints Section	5552
Centre for Investigational New Product – Deputy Director	**5581**
• BE Centre & Ethics Committee Compliance Section	8403
• GCP Compliance Section	8401
• GLP Compliance Section	8404
• Investigational Product Evaluation Section	8406
• Investigational Product Safety Monitoring Section	8405
Centre for Compliance and Licensing – Deputy Director	**5564**
• GDP Section	5568
• GMP 1 Section	5566
• GMP 2 Section	5567
• Licensing and Certification Section	5569
• Quality and Industry Development Section	8556
Centre for Organisational Development – Deputy Director	**5553**
• Helpdesk	5560, 5561, 5562
• Information and Communications Technology Section	5555
• Quality, Competency & Communication Coordination Section	8481
Centre for Quality Control – Deputy Director	**5429**
• Bio-Pharmaceutical Testing Section	8894
• Complementary Medicines Testing Section	8892
• Laboratory Services Section	5431
• Pharmaceutical Chemistry Testing Section	8490
• Reference Standard Section	5468
• Research Section	8446
Centre for Administration	**8458**

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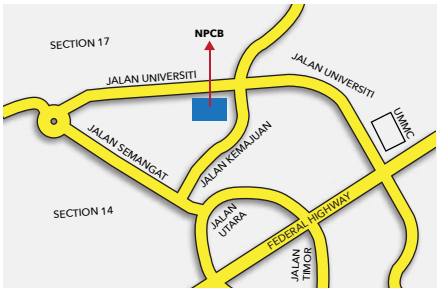

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