Newsletter of the Drug Control Authority, Malaysia

BERITA UBAT-UBATAN

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EVENTS

1. *21ST ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY - PHARMACEUTICAL PRODUCT WORKING GROUP (ACCSQ-PPWG) MEETING*

IN THIS ISSUE

DCA EDITORIAL TEAM

The 21st ASEAN Consultative Committee for Standards and Quality - Product Working Group on Pharmaceutical (ACCSQ-PPWG) Meeting hosted by Malaysia was held at the Sunway Resort Hotel and Spa on 17 – 20 June 2014. This meeting is a harmonisation initiative for the regulation of pharmaceutical products in the ASEAN countries.

The objective of the ACCSQ-PPWG is to develop harmonisation schemes of pharmaceuticals' regulations of ASEAN member countries to complement and facilitate the objective of the ASEAN Free Trade Area (AFTA), particularly, the elimination of technical barriers to trade posed by the existing trade regulations, without compromising on drug quality, safety and efficacy.

The issues discussed included, among others, relevant matters related to Biologics as well as the Mutual Recognition Arrangement (MRA) for Bioequivalence Study Report (BE). In addition to this meeting, a seminar and related technical meetings were also held.

The National Pharmaceutical Control Bureau under the Ministry of Health Malaysia was given the responsibility of organizing the event that successfully received overwhelming participation from 8 ASEAN countries, comprising of 75 official delegates and 248 observers from government agencies and the industry. Official representatives of ASEAN countries consisted of officers from the respective National Drug Regulatory Authority (NDRA).

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 05/14 [Ref: (12) dlm. BPFK/PPP/07/25]: Enforcement of Licensing for Manufacturer, Importer and Wholesaler of Registered Veterinary Products

Following the decision made by the Drug Control Authority (DCA) in its 224th Meeting, this directive is to further extend the directive that was issued to enforce licensing for local manufacturers of veterinary products effective 1st January 2012, whereby it did not include importers and wholesalers of veterinary products. Therefore, this new directive is to enforce licensing for manufacturers, importers and wholesalers of registered veterinary products **effective 1st July 2014.**

Regulation 7(1) of the Control of Drugs and Cosmetics Regulations 1984 as shown below is applicable with the enforcement of licensing, thus failure to abide by this directive is an offence.

7. Prohibition against manufacture, sale, supply, importation, possession and administration.

(1) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import, possess or administer any product unless:

(a) the product is a registered product; and

(b) the person holds the appropriate licence required and issued under these Regulations.

2. ***Directive 06/14 [Ref: (13) dlm. BPFK/PPP/07/25]: Usage Limitation of Products Containing Lovastatin with Contraindication and New Dose Limit to Reduce Risk of Muscle Injury***

Following the decision made by the Drug Control Authority (DCA) in its 277th Meeting, this directive is to limit usage of products containing lovastatin with contraindication and new dose limit to reduce risk of muscle injury **effective 1st August 2014.**

Therefore, the following instructions must be adhered to:

The package insert updating process must be done according to these dates:

New registration and products under evaluation: **1st August 2014**

Registered products: **Six (6) months from 1st August 2014**

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

Contraindications:

- Concomitant administration of strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin and nefazodone).
- Concomitant administration of cyclosporine.

Dosage and Administration:

Concomitant Therapy
The combined use of lovastatin with gemfibrozil should be avoided.

In patients taking danazol, verapamil, diltiazem, fibrates (except gemfibrozil) or lipid-lowering dose of niacin (≥1 g/day) concomitantly with [Product Name], the dose of [Product Name] should not exceed 20 mg/day.

In patients taking amiodarone concomitantly with [Product Name], the dose of [Product Name] should not exceed 40 mg/day.

Warning and Precautions:

Colchicine: Cases of myopathy, including rhabdomyolysis, have been reported with lovastatin co-administered with colchicine, and caution should be exercised when prescribing lovastatin with colchicine.

Interactions:

Contraindicated Drugs

Strong inhibitors of CYP3A4: Concomitant use with strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin and nefazodone) is contraindicated.

Cyclosporine: The risk of myopathy/rhabdomyolysis is increased by concomitant administration of cyclosporine. Concomitant use of this drug with lovastatin is contraindicated.

Other drugs
- Gemfibrozil, other fibrates, niacin ≥ 1 g/day:

These drugs increase the risk of myopathy when given concomitantly with lovastatin, probably because they can produce myopathy when given alone. There is no evidence to suggest that these agents affect the pharmacokinetics of lovastatin. Myopathy, including rhabdomyolysis, has occurred in patients who were receiving co-administration of lovastatin with fibric acid derivatives or niacin.

- Danazol, verapamil, diltiazem: The risk of myopathy/rhabdomyolysis is increased by concomitant administration of danazol, verapamil, or diltiazem particularly with higher doses of lovastatin.

- Amiodarone: The risk of myopathy/rhabdomyolysis is increased when amiodarone is used concomitantly with higher doses of a closely related member of the HMG-CoA reductase inhibitor class.

- Colchicine: Cases of myopathy, including rhabdomyolysis, have been reported with lovastatin co-administered with colchicine, and caution should be exercised when prescribing lovastatin with colchicine.

SUMMARY OF PRESS RELEASES

TRADITIONAL PRODUCTS / HEALTH SUPPLEMENTS

a) Caution on Using Unregistered Products Containing Scheduled Poison

i. <u>Majun Burung Unta</u>

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 Burung Unta'.

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 Poison Act 1952.

The product label claims that the product is to be used for erectile dysfunction, muscle aches, joint aches, heart problems, asthma, blurred vision, headaches, post-natal care, dysmenorrhea and claims to promote youthful effect on women.

Four adverse reaction reports were received and reported to have caused weight gain, increase in blood sugar levels and Cushing's syndrome.

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 (round face), increased blood glucose level, high blood pressure, glaucoma 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.

ii. Skyline Al-Taqwa

The public is reminded not to use the unregistered products called 'Skyline Al-Taqwa Sakit Pinggang & Lutut' and 'Skyline Al-Taqwa Gaut Asam Urat'.

Sampling done by NPCB found that both products contain the scheduled poison, **dexamethasone.** The product label claims that the product is to be used for a variety of health problems such as muscle aches, joint aches, lethargy, swollen hands, numbness of soles and paralysis.

The NPCB has received four reports of adverse effects involving Skyline Al-Taqwa products. Among others, a patient experienced a change in behaviour and psychiatric experts diagnosed it as euphoric symptoms due to taking the products as they contained steroid.

Further investigation revealed that the registration numbers printed on both of the said products were fake and no products with the above names were registered with the Drug Control Authority (DCA). Consumers of these products are advised to immediately seek professional medical attention.

The public is reminded to beware of fake products that are sold on the internet. In addition, anyone who is in possession of this unregistered product is also advised to immediately stop selling, distributing or using it. The possession of this product is an offence under the Control of Drugs and Cosmetics Regulations 1984.

COSMETICS

a) Caution on Using Cosmetic Products Containing Scheduled Poisons

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

No.	*Name of Product*	*Notification Number*	*Scheduled Poison Detected*	*Notification Holder*	*Manufacturer*
1.	*Dermaceutic Spot Cream*	*NOT101104772K*	*Hydroquinone and Tretinoin*	*Parvus Sdn. Bhd.*	*Dermosciences, Ireland.*
2.	*Dermaceutic Spot Peel Cream*	*NOT101104771K*	*Hydroquinone and Tretinoin*	*Parvus Sdn. Bhd.*	*Dermosciences, Ireland*

The notifications of the above cosmetics have been cancelled following the detection of the scheduled poisons, **hydroquinone and tretinoin**. The usage of such poisons in cosmetic products is strictly prohibited. The said products are thus no longer allowed to be sold in Malaysia.

Products containing hydroquinone and/or tretinoin are pharmaceutical products that must be registered with the DCA and can only be used with medical supervision. Hydroquinone is used to treat skin with hyperpigmentation problems while tretinoin is used to reduce inflammation in the treatment of pimples (acne vulgaris). The usage of hydroquinone and/or tretinoin without medical supervision may cause unwanted effects.

Cosmetic products adulterated with hydroquinone are generally marketed for skin lightening, uneven skin and whiteheads. Hydroquinone can cause redness of the skin, discomfort, unwanted discolouring of the skin and also hypersensitivity. Usage of hydroquinone increases the risk of skin cancer due to depigmentation process whereby the skin is less protected from harmful ultraviolet rays.

On the other hand, cosmetic products adulterated with tretinoin are promoted with the purpose of treating pimples and reducing wrinkles. Usage of tretinoin without medical supervision can cause skin redness, discomfort, stinging sensation, skin peeling and hypersensitivity to sunlight.

The company responsible for placing these products in the market have been instructed to immediately cease the sale and supply of the mentioned products and remove all physical stock from the market within 72 hours.

CONTACTS & MAP

National Pharmaceutical Control Bureau (NPBC) + 603 - 7883 5400

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	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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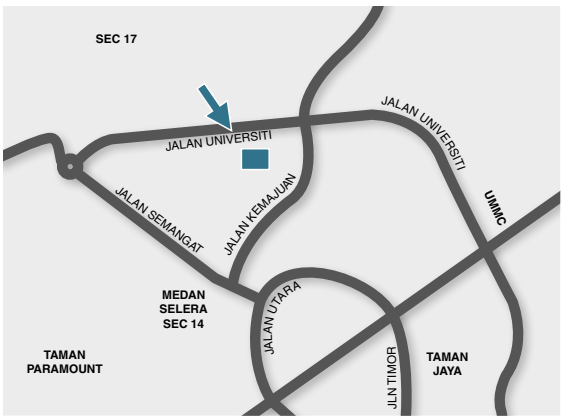

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