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BERITA Ubat-ubatan

NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

PRESS RELEASE

BY THE CHAIRMAN OF THE DRUG CONTROL AUTHORITY RELATING TO TRADITIONAL MEDICINES FOUND TO CONTAIN TADAFIL

The Drug Control Authority (DCA) would like to advise the public against buying and using the products **"Shitek Tongkat Ali 400mg"** and **"Longeria Capsule".** This is because these two products were tested and found to contain an ingredient which is not allowed to be used in traditional medicines and which could be deleterious to the user.

Through the post-market surveillance program, the DCA identified that these two products have been adulterated with tadalafil. Sampling of products from the market has been increased as a result of the slimming pill issue which occured in the past whereby several traditional medicines were found to be adulterated. As a result, the Ministry of Health has also strengthened the system for monitoring traditional medicines bearing claims for men's health to ensure that these products are free from adulterants. Apart from its own surveillance program, the DCA has also established a good networking system with regulatory agencies in other countries. Within this context, the ministry has

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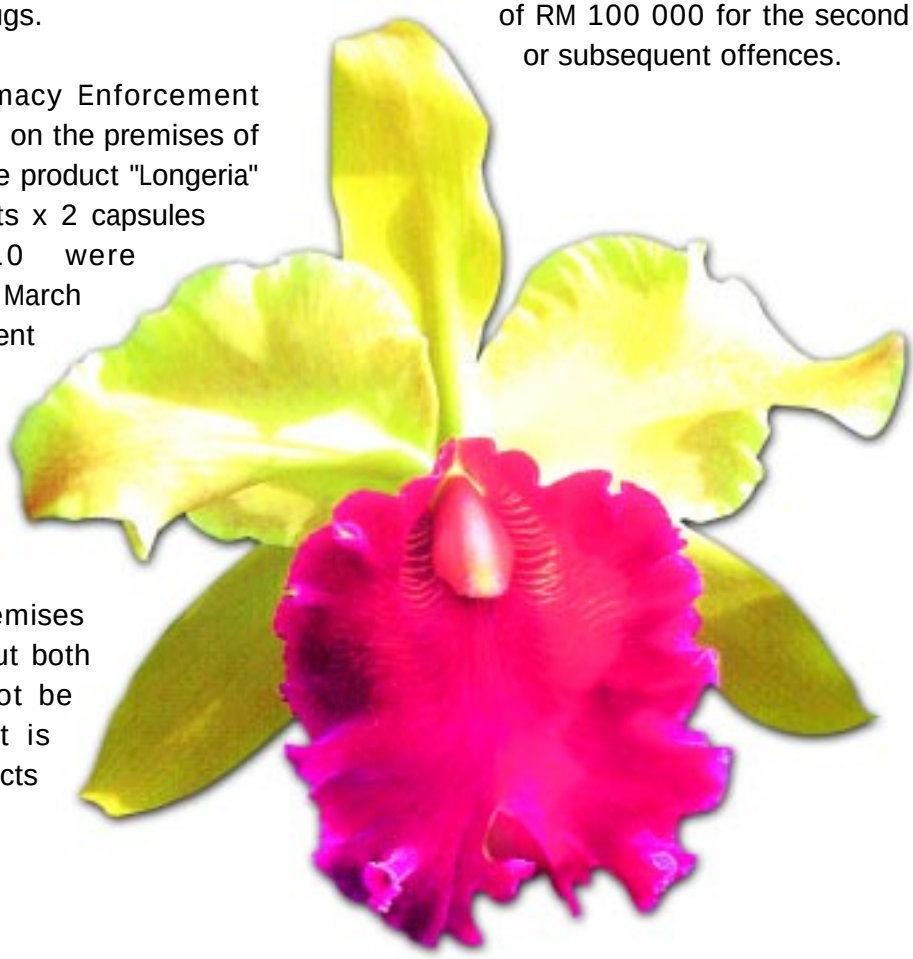
received information from regulatory agencies elsewhere that similar products which were imported from Malaysia were tested positive for sildenafil which is classified as a schedule poison.

Sildenafil and tadalafil are both medicines which can only be prescribed by doctors for men diagnosed with the condition "erectile dysfunction". The public should not use products containing sildenafil or tadalafil without first consulting a doctor as these drugs could cause deleterious effects to certain patients especially those with heart conditions or diabetes. These drugs could also interact with other medicines resulting in serious adverse effects such as the lowering of blood pressure if used together with some antihypertensive drugs.

Officers from the Pharmacy Enforcement Branches conducted a raid on the premises of the main distributor for the product "Longeria" and 539 x 10 x 5 sachets x 2 capsules worth RM1,072, 610 were confiscated. On 26-27th March 2004, pharmacy enforcement officers conducted inspections on 62 community pharmacies, 46 Chinese medicine shops, 37 Malay medicine outlets and 16 other premises throughout the country but both these products could not be found in the market. It is suspected that these products could be distributed through sales directly to customers.

Anyone in possession of either of these two products is advised to immediately cease selling/distributing/using these products. Sellers are reminded that possession for sale is an offence under the Drug and Cosmetics Regulation 1984. Any individual who commits an offence under these regulations can be fined up to a maximum of RM 25 000 or a jail sentence not exceeding 3 years or both for the first offence and a fine not exceeding RM 50 000 or a jail sentence not exceeding 5 years for the second or subsequent offences. A company found guilty can be fined up to RM 50 000 for the first offence and up to a maximum of RM 100 000 for the second or subsequent offences.



DECISION TREE FOR PRODUCT CLASSIFICATION

The Organizational Development & Information Technology Division (POTM), National Pharmaceutical Control Bureau (NPCB) has come up with a decision tree for the classification of products for registration.

This decision tree, which applies to all categories of products, will serve as a general guidance to the applicants (individuals/companies/market authorization holders) who intend to register or market their products in Malaysia. By using this decision tree, the applicants should be able to decide by themselves on products classification, category and whether or not need to be registered.

With the introduction of this decision tree, the advisory service by NPCB on classification (using BPFK 401) will cease to be offered. An official letter for product classification will not be issued. Instead, the applicants will be responsible for ensuring that their products comply with the laws and guidelines pertaining to registration.

The applicants are requested to use the decision tree and provide feedback on any problems encountered to NPCB. Suggestions for improvement are most welcome and please direct to POTM, NPCB or via e-mail to **fajar@bpfk.gov.my** or **azlina@bpfk.gov.my**

The decision tree for classification is available at NPCB's website at www.bpfk.gov.my.

THE 5TH LIST OF BIOEQUIVALENCE STUDIES FOR IMMEDIATE RELEASE GENERIC PRODUCTS

In an effort to improve the quality, efficacy and safety of generic products as compared to innovator products, Bioequivalence (BE) Studies Committee has decided to add sixteen (16) more immediate release products to the existing list. The needs to submit BE Studies Reports will be enforced periodically within two (2) years (2004-2005).

List of Test Products, Comparator Products and the effective date of submission of BE reports are as follows:

List of Test Products, Comparator products and Effective Submission Date for Bioequivalence (BE) Studies Report for 2004/2005

Bil.	TEST PRODUCTS (Pharma-ceutical Name	Comparator Products			Effective Date for Submission of BE Studies Report	Closing Date for Submission of BE Studies Report of Registered Products	
		Trade Mark/ Registration No.	Dosage Form/ Strength	Manu-facturer	New Application	Imported Products	Local Products
1.	Stavudine	i) Zerit 15mg Capsule MAL19972469A	Capsule/ 15mg	Bristol-Myers Squibb US, Pharm Group U. States	01/06/04	31/12/04	30/06/05
		ii) Zerit 20mg Capsule MAL 19961656A	Capsule/ 20mg	Bristol-Myers Squibb US, Pharm Group U. States			
		iii) Zerit 20mg Capsule MAL20014342AR	Capsule 20mg	Bristol-Myers Squibb Manu. Co., US			
2.	Nevirapine	i) Viramune Tablet 200mg MAL20002233A	Tablet/ 200mg	Boehringer Ingelheim Pharma KG, Germany	01/06/04	31/12/04	30/06/05

3.	Ritonavir	i) Norvir Capsule 100mg MAL 19970485A	Capsule/ 100mg	Abbott Labs, US	01/06/04	31/12/04	30/06/05
4.	Ciproflo xacin	i) Ciprobay Tablet 250mg MAL 19890115A ii) Ciprobay Tablet 500mg MAL 19890626A iii) Ciprobay Tablet 750mg	Tablet/ 250mg Tablet/ 500mg Tablet/ 750mg	Bayer AG, Germany Bayer AG, Germany Bayer AG, Germany	01/06/04	31/12/04	30/06/05
5.	Ofloxacin	MAL 19890627A i) Tarivid Tablet 100mg MAL 19890577A	Tablet/ 100mg	Daiichi Pharm Co. Ltd, Japan	01/06/04	31/12/04	30/06/05
6.	Clarith romycin	i) Klacid 250mg Tablet MAL 19940216A ii) Klacid 500mg Tablet MAL 19984348A	Tablet/ 250mg Tablet/ 500mg	Abbot S.P.A., Italy Abbot Labs Ltd, UK	01/06/04	31/12/04	30/06/05
7.	Metformin	i) Clucophage 500mg Tablet MAL 19930502A	Tablet/ 500mg	Lipha Pharm Ltd, United Kingdom	01/06/04	31/12/04	30/06/05

8.	Glibenc lamide	i) Daonil Tablet 5mg MAL19870392A	Tablet/ 5mg	Hoechst Aktienge sellch aft, German	01/06/04	31/12/04	30/06/05
9.	Diltiazem	i) Herbesser Tablet 30mg MAL19861581A ii) Herbesser Tablet 60mg MAL19890319A	Tablet/ 30mg Tablet/ 60mg	Tanabe Seiyaku Co. Ltd, Japan Tanabe Seiyaku Co. Ltd, Japan	01/06/04	31/12/04	30/06/05
10.	Salbutamol	i) Ventolin Tablet Tablet 4mg MAL19962831A ii) Ventolin Tablet Tablet 2mg MAL19961269A	Tablet/ 4mg Tablet/ 2mg	Glaxo Wellcome GMBH & Co, Germany Glaxo Wellcome GMBH & Co, Germany	01/06/04	31/12/04	30/06/05
11.	Rifampicin	i) Rimactane 300 Capsule MAL19860074A ii) Rimactane 150 Capsule MAL19860829A	Capsule/ 300mg Capsule/ 150mg	Novartis South Africa (Pty) Ltd, South Africa Novartis South Africa (Pty) Ltd, South Africa	01/12/04	30/06/05	31/12/05

12.	Sulpiride	i) Dogmatil 50mg Capsule MAL19930596A ii) Dogmatil 200mg Tablet MAL19913453A	Capsule/ 50mg Tablet 200mg	Sanofi Winthrop Industries, France Sanofi Winthrop Industries, France	01/12/04	30/06/05	31/12/05
13.	Dexamethasone	i) Decadron Tablet 0.5mg MAL19870645A	Tablet/ 0.5mg	Merck Sharp & Dohme Int., United States	01/12/04	30/06/05	31/12/05
14.	Verapamil	i) Isoptin Tablet 40mg MAL19880115A ii) Isoptin Tablet 80mg MAL19880155A	Tablet 40mg Tablet/ 80mg	Knoll AG Germany Knoll AG Germany	01/12/04	30/06/05	31/12/05
15.	Omeprazole	Will be determined later			01/12/04	30/06/05	31/12/05
16.	Prednisolone	Will be determined later			01/12/04	30/06/05	31/12/05

For further details kindly, refer to the “Malaysian Guidelines for the Conduct of Bioavailability and Bioequivalence Studies, Ministry of Health, Malaysia.”

DCA UPDATES

NEW LIMITS OF VITAMINS AND MINERALS ALLOWED IN DIETARY SUPPLEMENTS PER DAY FOR ADULT.

The Drug Control Authority (DCA) at its 154th meeting held on 23rd December 2003 has agreed to the new limits of three (3) vitamins and five (5) minerals allowed in dietary supplement per day for adult as shown below.

NO.	INGREDIENT	LIMIT (DAILY MAXIMUM DOSE FOR ADULT)
1.	Iodine	300mcg
2.	Iron	20mg; (***note:*** for pre and antenatal use, as part of multivitamin and mineral preparations, levels higher than 20mg limit established for adults may be permitted at the discretion of the DCA)
3.	Manganese	5mg
4.	Selenium	300mg
5.	Zinc	25mg
6.	Vitamin B5 (pantothenic acid)	200mg
7.	Vitamin B6(pyridoxine)	100mg
8.	Vitamin E	400 i.u (~270mg)

PRODUCTS CONTAINING CISAPRIDE AS AN ACTIVE INGREDIENT

The Drug Control Authority (DCA) at its 156th meeting held on 24th February 2004 decided to cancel the registration of five (5) products and to reject the application for registration of one (1) product containing the active ingredient CISAPRIDE as shown below due to **SAFETY** issue.

No.	Product Name	Ref. No. (Registration No.)	Product Holder	Product Manufacturer	Remarks
1.	PREPULSID SUSPENSION 1MG/ML	1989050019A (MAL19900360A)	JOHNSON & JOHNSON S/B	JANSSEN PHARM N.V.	CANCELLED
2.	PREPULSID TABLETS 10MG	1991080032A (MAL19921106A)	JOHNSON & JOHNSON S/B	JANSSEN PHARM N.V.	CANCELLED
3.	CISAPAN TABLET 5MG	2001086535A	DUOPHARMA (M) S/B	DUOPHARMA (M) S/B	REJECTED
4.	CISPRIDE TABLET 10MG	2000102988A (MAL200335510A)	YSP INDUSTRIES (M) S/B	YSP INDUSTRIES (M) S/B	CANCELLED
5.	CISPRIDE TABLET 5MG	2000102987A (MAL20033511A)	YSP INDUSTRIES (M) S/B	INDUSTRIES (M) S/B	CANCELLED
6.	CIZA TABLET 10MG	2000102931A (MAL20021145A)	KOMEDIC S/B	INTAS PHARM LTD	CANCELLED

However, all holders who have registered and marketed the products containing CISAPRIDE will be given an exemption to import such products based on prescriber's request on a named patient basis.

Holders of all registered products containing CISAPRIDE are given a grace period of six (6) months from the date of DCA 156th meeting to recall their products from the market.

RECALL OF PRODUCTS CONTAINING **Comfrey & *Senecio spp*** HERBS

The Drug Control Authority (DCA) at its 156th meeting held on 24th February 2004 made the decision to recall all products containing **Comfrey and *Senecio spp*** from the market as these ingredients contain **pyrrrolizidine alkaloid** and have been linked to **hepatic failure.**

The DCA has therefore decided not to register any product containing **Comfrey and *Senecio spp.*** Subsequently, all registration holders of products containing these ingredients are given a grace period of six (6) months from the date of DCA 156th meeting to recall their products from the market.

HALAL LOGO FOR REGISTERED PHARMACEUTICAL PRODUCTS, TRADITIONAL PRODUCTS AND COSMETIC PRODUCTS

The Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 decided on the following regarding "HALAL" logo for registered pharmaceutical, traditional and cosmetic products:

- To continue with the existing policy of **not allowing** the "HALAL" logo to be stated on the label of **pharmaceutical products,**
- To continue with the existing policy of **allowing** the "HALAL" logo to be stated on the label of local and 'for export only' **cosmetic products,**
- To consider the use of "HALAL" logo certified and issued by 'JAKIM' only on the label of local and 'for export only' **cosmetic products as well as dietary supplements,**
- To consider the use of "HALAL" logo for **traditional products, cosmetics and dietary supplements** based on request by the registration holders but non-mandatory.

NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

CONTROL ON PACKING SIZE OF ALL LIQUID COUGH PREPARATION FOR LOCAL AND "FOR EXPORT ONLY"

The Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 decided that no exemption on packing size of 'for export only' products. Packing size of 120ml +/- 10ml is applicable for local and 'for export only' of all liquid cough preparations.

REQUEST ON PACKING SIZE OF PARENTERAL PREPARATIONS, PERITONEAL DIALYSIS SOLUTIONS AND HAEMOFILTRATION SOLUTIONS

The Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 decided to consider the different packing sizes and packaging of parenteral preparations, peritoneal dialysis solutions and haemofiltration solutions (which are introduced into patients' bodies) as one single product for a particular product. However, comprehensive stability studies on the different types of packaging are required to determine suitable shelf lives and storage conditions for the products.

MALAYSIA – INDONESIA ISSUES ON PRODUCT REGISTRATION

For bilateral cooperation and teamwork by ASEAN, the Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 has agreed to allow both Malaysia and Indonesia to market their pharmaceutical products in their respective countries. Nevertheless, they must comply with the rules and regulations set by these countries as well as the standard and requirements stipulated by ASEAN.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

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OFFICERS TO CONTACT

ISSUE/AREA	DIVISION/UNIT	NAME OF OFFICER	TEL-EXT
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- Manufacturer's Licence - Import Licence - Wholesaler's Licence	GMP and Licensing Division	Dr. Tajuddin Akasah (Head)	201
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