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BERITA Ubat-Ubatan

NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

CONGRATULATIONS TO Y. BHG. DATIN HJH. HASIAH HJ. ABDULLAH

National Pharmaceutical Control Bureau (NPCB) congratulates Y. Bhg. Datin Hjh. Hasiah Hj. Abdullah for having been appointed as the new Director effective from 26th December, 2003.

Datin Hjh. Hasiah graduated with her Bachelor of Science (Pharmacy) from Baghdad University, Iraq in 1972. She started her career as a hospital pharmacist in Hospital Taiping in 1974. She has been working in many areas and places before joining NPCB as a Deputy Director of Drug Analysis Division in 2001. She has served in many major hospitals such as Hospital Selayang, Hospital Ipoh, Hospital Kota Bharu and Hospital Pulau Pinang. Datin Hjh. Hasiah also worked in Kelantan State Health Department as a Principal Assistant Director in 1997.

For her dedication and excellent service, she has also been nominated as recipient for several awards such as 'Ahli Mangku Negara' by DYMM Seri Paduka Baginda Yang Di Pertuan Agong and 'Anugerah Pingat Cemerlang' by Hospital Kuala Lumpur and Kelantan State Director.

With her vast experience and dedication, NPCB is very grateful to work together under her wings and hope our organization will have "flying colours".

CONGRATULATIONS AND BEST WISHES TO YOU Y. BHG. DATIN!

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Artwork, Design and Printing by
CETAKRAPI SDN. BHD.

"DRUG REGISTRATION GUIDANCE DOCUMENT"

The National Pharmaceutical Control Bureau has come up with new guidelines for drug registration namely **"DRUG REGISTRATION GUIDANCE DOCUMENT"**

This **"DRUG REGISTRATION GUIDANCE DOCUMENT"** will serve as the reference guide for both pharmaceutical products for human use and traditional products. It replaces the **"Guidelines For Application For Registration of Pharmaceutical Products"** Third Edition of October 1993, and **"Garispanduan Permohonan Pendaftaran Keluaran Ubat Tradisional"** Second Edition, December 1998.

The contents of this version include:

- Updated information relating to administrative requirements and procedures.
- Information on Drug Control Authority (DCA) policies currently applicable.
- Guidelines on the on-line application process and requirements which will incorporate the ASEAN technical requirements and standards for pharmaceuticals (where applicable).

An on-going review of policy matters will continue, taking into account the global regulatory environment, to allow for timely and pertinent changes.

Information relating to DCA policy decisions is current, up to its 158th meeting on 27 April 2004.

The guidelines outlined in this document are primarily drawn up in accordance to the legal requirements of the **Sale of Drugs Act 1952** and the **Control of Drugs and Cosmetics Regulations 1984.** While every effort has been made to include the legal requirements of other related legislation, wherever possible, applicants are reminded that it is still their responsibility to ensure that their products comply with the requirements of these legislation, namely:-

(i) **Dangerous Drugs Act 1952;**
(ii) **Poisons Act 1952;**
(iii) **Medicine (Advertisement & Sale) Act 1956;**
(iv) **Patent Act 1983;** and also
(v) Any **other relevant Acts.**

A SEPARATE GUIDELINE IS AVAILABLE FOR THE APPLICATION FOR REGISTRATION OF COSMETIC PRODUCTS.

A SEPARATE GUIDELINE FOR APPLICATION FOR THE REGISTRATION OF VETERINARY PRODUCTS WILL BE AVAILABLE.

A SEPARATE GUIDELINE FOR APPLICATION FOR CLINICAL TRIAL IMPORT LICENCE IS AVAILABLE.

"DRUG REGISTRATION GUIDANCE DOCUMENT" is now available at http://www.bpfk.gov.my.

Please visit the National Pharmaceutical Control Bureau (NPCB) website for updates in regulatory information.

Restructuring of the National Pharmaceutical Control Bureau

The National Pharmaceutical Control Bureau has undergone a major restructuring, which involves expansion of Product Evaluation and Safety Division, Surveillance & Pharmacovigilance Division, GMP and Licensing Division and Organisational Development & Information Technology Division as well as Drug Analysis Division. This restructuring was the result of a long period of review and discussion commencing in 1999 and extending through to the end of 2003.

Now, with effect from 1st June, 2004 the National Pharmaceutical Control Bureau headed by the Director, Datin Hjh. Hasiah Abdullah comprises of five main centres namely Centre for Product Registration, Centre for Post-Registration, Centre for Organization Development, Centre for Good Manufacturing Practice and Centre for Quality Control. The sections and units have been created and renamed as follows:

BEFORE RESTRUCTURING	EFFECTIVE 1ST JUNE 2004
Drug Evaluation and Safety Division	**Centre for Product Registration** (Pusat Pendaftaran Produk) ***Eishah Abd. Rahman***
	Generic Medicine Section (Seksyen Produk Generik) ***Noorizam Ibrahim***
Poisons Unit	Prescription Unit (Unit Preskripsi) ***Noorizam Ibrahim***
Non-Poisons Unit	Non Prescription Unit (Unit Bukan Preskripsi) ***Mazuwin Zainal Abidin***
Veterinary Unit	Veterinary Unit (Unit Veterinar) ***Rohani Ismail***
	Complementary Medicine & Cosmetic Section **Cosmetics Unit** (Seksyen Ubat Komplementari & Kosmetik) ***Saleha Md Ewan***
Traditional Medicines Unit	Natural Products Unit (Unit Produk Semulajadi) ***Saleha Md Ewan***

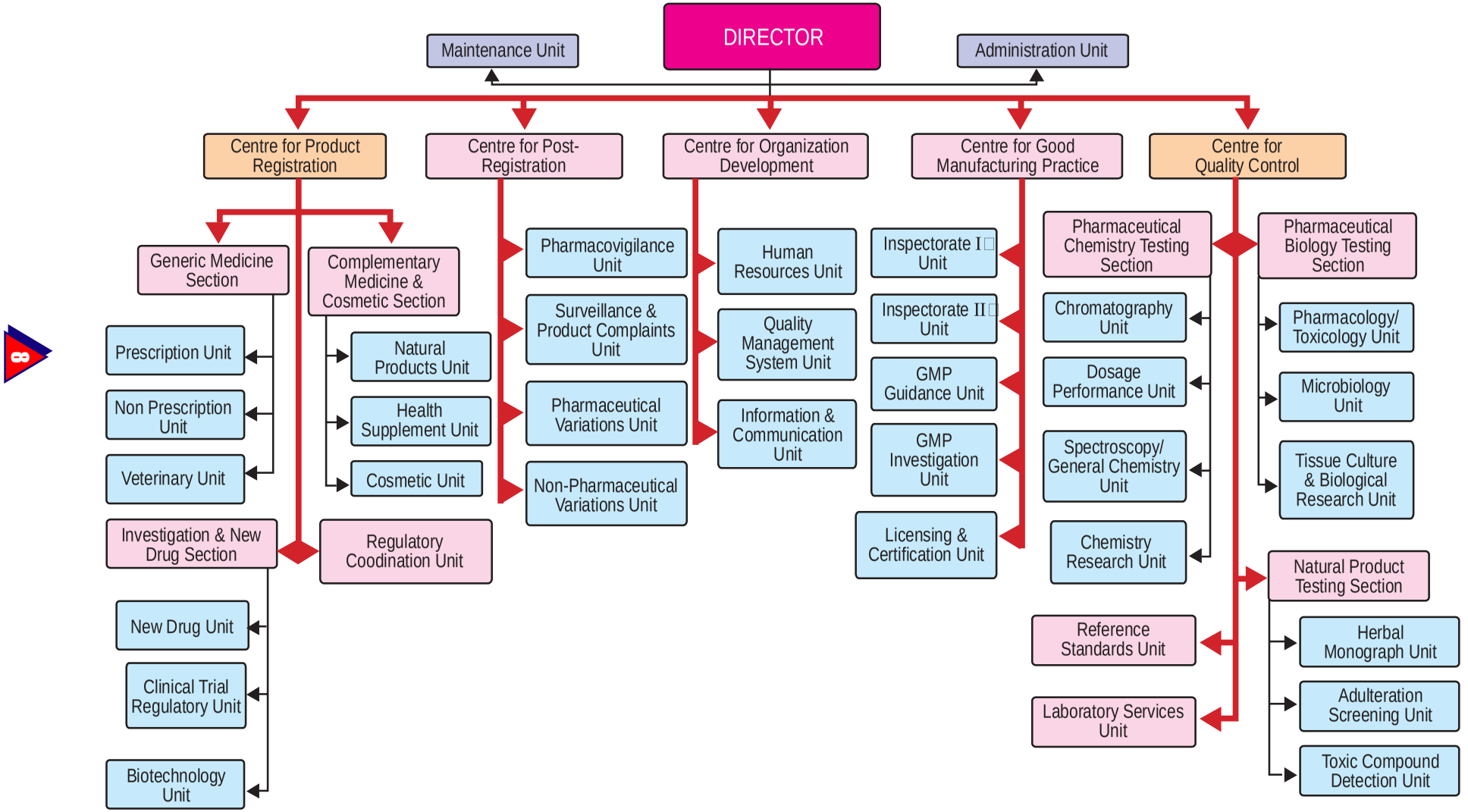
BEFORE RESTRUCTURING	EFFECTIVE 1ST JUNE 2004
	Health Supplement Unit (Unit Supplemen Kesihatan) ***Abdullah Hisham Ahmat Yaya***
Cosmetics Unit	Cosmetic Unit (Unit Kosmetik) ***Anis Talib***
	Investigation & New Drug Section (Seksyen Penyiasatan & Ubat Baru) ***Fudziah Ariffin***
New Chemical Entity Unit	New Drug Unit (Unit Ubat Baru) ***Fudziah Ariffin***
	Clinical Trial Regulatory Unit (Unit Penyelidikan Klinikal Regulatori) ***Dr. Kamaruzaman Saleh***
Biotechnology Unit	Biotechnology Unit (Unit Bioteknologi) ***Arpah Abas***
Secretariat Unit	**Regulatory Coodination Unit** (Unit Koordinasi Regulatori) ***Tan Lie Sie***
Organizational Development & Information Technology Division	**Centre for Organization Development** (Pusat Pembangunan Organisasi) ***Bariah Abd. Rani***
	Human Resources Unit (Unit Sumber Manusia) ***Bariah Abd. Rani***
	Quality Management System Unit (Unit Pengurusan Sistem Kualiti) ***Norrehan Abdullah***
	Information & Communication Unit (Unit Maklumat & Komunikasi) ***Fuziah Abdul Rashid***

BEFORE RESTRUCTURING	EFFECTIVE 1ST JUNE 2004
Surveillance & Pharmacovigilance Division	**Centre for Post- Registration** (Pusat Pasca-Pendaftaran Produk) ***Abida Haq Syed Haq*** Pharmacovigilance Unit (Unit Farmakovigilans) ***Abida Haq Syed Haq*** Surveillance & Product Complaints Unit (Unit Surveilans & Aduan Produk) ***Norhayati Omar*** Pharmaceutical Variations Unit (Unit Variasi Farmaseutikal) ***Mokhtar Abdullah*** Non-Pharmaceutical Variations Unit (Unit Variasi Bukan Farmaseutikal) ***Vacant***
GMP and Licensing Division	**Centre for Good Manufacturing Practice** (Pusat Amalan Perkilangan Baik) ***Dr. Tajuddin Akasah*** Inspectorate I Unit (Unit Inspektorat I) ***Dr. Tajuddin Akasah*** Inspectorate II Unit (Unit Inspektorat II) ***Sulaiman Ahmad*** GMP Guidance Unit (Unit Khidmat Nasihat APB) ***Kadariah Mohd Ali*** GMP Investigation Unit (Unit Penyiasatan) ***Muhd Lukmani Ibrahim*** Licensing & Certification Unit (Unit Pelesenan & Pensijilan) ***Wan Othman Wan Ismail***

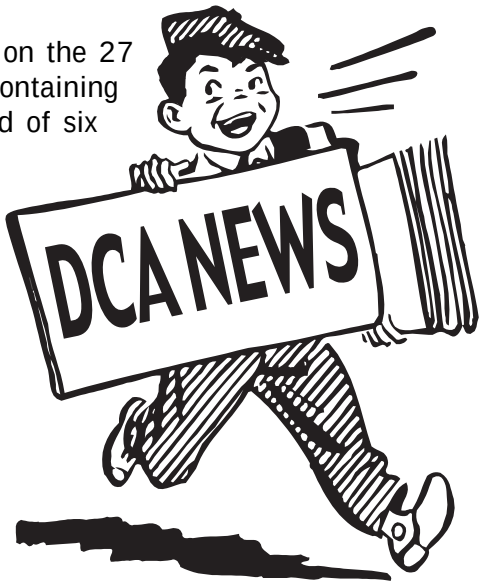
BEFORE RESTRUCTURING	EFFECTIVE 1ST JUNE 2004
Drug Analysis Division	**Centre for Quality Control** (Pusat Kawalan Kualiti) ***Yogeswary Markandoo***
Laboratory Services Unit	**Laboratory Services Unit** (Unit Perkhidmatan Makmal) ***Tan Ann Ling***
Reference Standards Unit	**Reference Standards Unit** (Unit Piawai Rujukan) ***Abdul Aziz Mansor***
Pharmaceutical Chemistry Laboratory Pharmaceutical Technology Laboratory	**Pharmaceutical Chemistry Testing Section** (Seksyen Pengujian Kimia Farmaseutikal) ***Dr. Sulaikah Moideen*** Chromatography Unit (Unit Kromatografi) ***Dr. Sulaikah Moideen*** Dosage Performance Unit (Unit Prestasi Dosej) ***Muhd Nasir Hashim*** Spectroscopy/ General Chemistry Unit (Unit Spektro/ Kimia Am) ***Tan Chuan Ai*** Chemistry Research Unit (Unit Penyelidikan Kimia)
Pharmaceutical Microbiology Laboratory Toxicology/Pharmacology Unit	**Pharmaceutical Biology Testing Section** (Seksyen Pengujian Bio-Farmaseutikal) ***Faridah Ab. Malek*** Pharmacology/ Toxicology Unit (Unit Farmakologi/Toksikologi) ***Faridah Ab. Malek*** Microbiology Unit (Unit Mikrobiologi) ***Siti Madziah Mohamed*** Tissue Culture & Biological Research Unit (Unit Kultur Tisu & Penyelidikan Biologi) ***Vacant***

BEFORE RESTRUCTURING	EFFECTIVE 1ST JUNE 2004
Traditional Drug Laboratory	**Natural Product Testing Section** (Seksyen Pengujian Produk Semulajadi ***Jaafar Lassa*** Herbal Monograph Unit (Unit Monograf Herba) ***Jaafar Lassa*** Adulteration Screening Unit (Unit Penyaringan Campur-palsu) ***Mazli Muhamad*** Toxic Compound Detection Unit (Unit Pengesanan Bahan Toksik) ***Vacant***

ORGANIZATION CHART OF NATIONAL PHARMACEUTICAL CONTROL BUREAU
(Effective Date 1st June 2004)



Cancellation of Product Containing Terfenadine



The Drug Control Authority (DCA) at its 158th meeting held on the 27 April 2004 decided to cancel the registration of all products containing **Terfenadine**. All registration holders are given a grace period of six months starting from the date of DCA 158th meeting to ensure that all products containing **Terfenadine** are no longer in the market.

The affected products will also be deleted from the manufacturers' or the importers' license of the companies concerned.

Suggestion To Disregard The Suspension Of Products Containing Nimesulide, To Limit The Dosage And Posology As Well As The Indication

At its 159th meeting held on the 27 May 2004, the DCA decided to disregard the suspension of registration of products containing Nimesulide, in Malaysia. For products in tablet form intended for oral usage, the posology is limited to 100mg and the permitted maximum dose is 100mg twice daily. Whereas, the indications of this oral drug are limited to the following:

1) Treatment of acute pain.
2) Symptomatic treatment of painful osteoarthritis.
3) Primary dysmenorrhea.

The information on the package insert of Nimesulide products marketed in Malaysia should be aligned, in-line with the information contained in the European SPC. The registration holders are responsible to inform the professionals regarding the approved indications by the DCA, the newly permitted maximum dosage and the contraindications of Nimesulide, in order to minimize unwanted risks to consumers.

Cancellation Of Registered Products - Yi Shou Fang and Long Dan Cao

At its 159th meeting held on the 27 May 2004, the Drug Control Authority (DCA) had agreed and decided to cancel the registration of two products, registered under Versinix Pharm Sdn. Bhd. The products are as follows:

Name of Product	Registration No.	Registration Holder/Manufacturer	Reason For Cancellation
1) Yi Shou Fang	MAL 20032105TC	Versinix Pharm Sdn.Bhd. (Vitarite Pharm Sdn. Bhd.)	Adulteration issues (Sample of product had been tested and found positive for **Dexamathasone** and **Chlorpheniramine).**
2) Long Dan Cao	MAL 20032106TC	Versinix Pharm Sdn. Bhd. (Vitarite Pharm Sdn. Bhd.)	The registration number was used to manufacture and market unregistered product under the name 'Supertox'.

Extension on the Marketing Duration of Cosmetic Products in the Market

At its 159th meeting on the 27 May 2004, DCA took into consideration the suggestion to extend the marketing duration of cosmetic products which had been submitted for registration before **31 January 2004.** The dateline has been extended from **30 June 2004** to **31 December 2004.**
As of **1 January 2005,** all cosmetic products in the market are required to comply with the labeling requirements as stated in the Guidelines For Cosmetic Registration.

Additional Warning Related to 'Hyperglycaemia' for all Atypical Antipsychotic Agents.

The Drug Control Authority (DCA) at its 160th meeting held on the 1 July, 2004 made the decision that the following warning on 'hyperglycemia' adverse event **must** be included in package insert of all 'atypical antipsychotic' agents listed below:

- **clozapine**
- **olanzepine**
- **risperidone**
- **quetiapine**
- **ziprasidone**
- **aripiprazole.**

WARNINGS:

Hyperglycemia and Diabetes Mellitus.

Hyperglycemia in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalties is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given this confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during teatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydypsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however some patients require continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

Ministry of Health Malaysia
Jalan Universiti, P. O. Box 319, 46730 Petaling Jaya.
(Telephone: 603-79573611, Fax: 603-79562924)

Homepage http://www.bpfk.gov.my

OFFICERS TO CONTACT

ISSUE/AREA	DIVISION/UNIT	NAME OF OFFICER	TEL-EXT
National Pharmaceutical Control Bureau	Director	Datin Hasiah Abdullah	204
Centre for Product Classification	Deputy Director	Eishah Abdul Rahman	270
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(i) Generic Medicine Section	-Prescription Unit	Noorizam Ibrahim	239
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	-Spectroscopy/General Chemistry Unit	Tan Chuan Ai	614
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(iv) Pharmaceutical Biology Testing Section	-Pharmacology/Toxicology Unit	Faridah Ab. Malek	605
	-Microbiology Unit	Siti Madziah Mohamed	608
	-Tissue Culture & Biological Research Unit		605
(v) Natural Product Testing Section	-Herbal Monograph Unit	Jaafar Lassa	250
	-Adulteration Screening Unit	Mazli Muhamad	249
	-Toxic Compound Detection Unit		250