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BERITA Ubat-Ubatan

NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

IMMEDIATE RECALL AND SUSPENSION OF REGISTRATION OF PRODUCTS MANUFACTURED BY PAN PHARMACEUTICALS LIMITED, AUSTRALIA

Australia's national regulator for medicines and other therapeutic goods, namely the Therapeutic Goods Administration (TGA), has suspended the manufacturing license for Pan Pharmaceuticals Limited, Australia, for a period of six months with effect from 28 April 2003, as a result of a series of serious safety and quality breaches by the company. The TGA has issued notices to recall immediately all batches of 219 products manufactured by Pan Pharmaceuticals Limited since the 1st of May 2002.

Pan Pharmaceuticals Limited is Australia's largest contract manufacturer for complementary medicines which include herbals, vitamins, minerals and nutritional supplements. Products manufactured by the company are widely marketed in Australia as well as exported overseas including to Malaysia. These products are supplied either directly by the company itself, or supplied to other companies which market the products under their own brand names. There are approximately 1,650 "for export only" products manufactured by Pan Pharmaceuticals.

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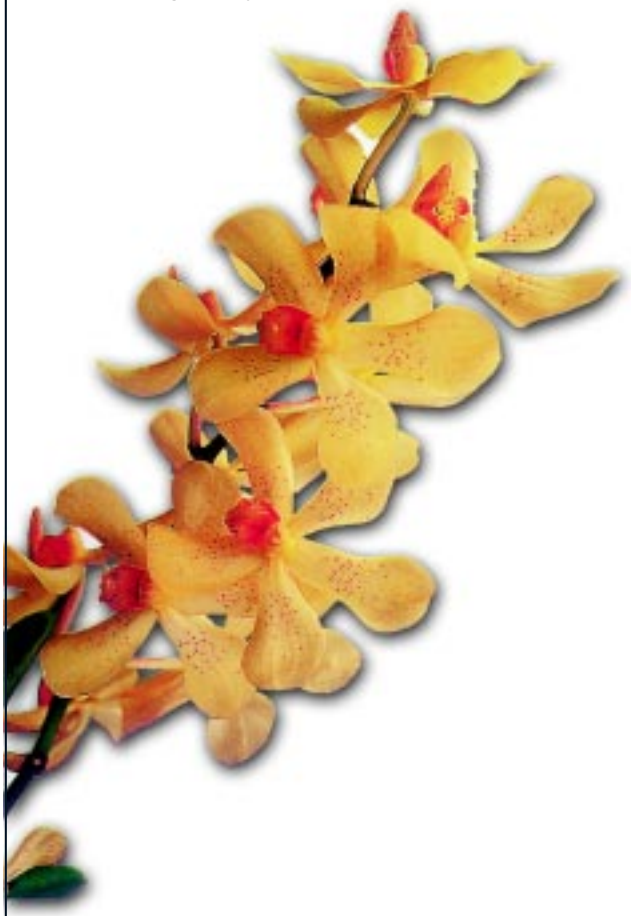
Following the action taken by the TGA and to ensure the safety of consumers in Malaysia, the Drug Control Authority (DCA) has decided to issue notices of immediate recall of all batches of products manufactured by Pan Pharmaceuticals Limited, Australia from the local market.

Taking into consideration the potential risks to consumers, the DCA will also suspend the registration of all products manufactured by Pan Pharmaceuticals Limited, Australia. Up to date, the DCA has registered 346 products manufactured by this manufacturer. Details of the product name, registration holder and number are listed and can be found at NPCB's website www.bpfk.gov.my.



Consequent to the decision made by the DCA, consumers are advised to stop taking all health products and nutritional supplements manufactured by Pan Pharmaceuticals Limited, Australia until the decision is withdrawn. Nevertheless, consumers are informed that no adverse drug reactions (ADR) associated with these products have been reported so far.

All registration holders, importers, wholesalers, distributors, retailers and direct selling companies are required to check their stocks and to stop selling these products immediately.

For new registration of products manufactured by Pan Pharmaceuticals, those that are still in Stage 1 are advised to withdraw their applications, whereas applications which are currently at Stage 2 and 3 will be rejected by the DCA.

All parties involved including consumers, importers, wholesalers, distributors, retailers and direct selling companies are urged to give their full support and cooperation to ensure that all products manufactured by Pan Pharmaceutical Limited, Australia are to be taken off the market immediately.

Information and press statements regarding the actions taken by the TGA are available on the TGA's website at www.health.gov.au/tga/recalls/pan.htm. The DCA will also make available the decision and relevant information via its website at www.bpfk.gov.my. Through regulatory networking with the TGA, the DCA will seek more relevant information to keep parties concerned updated from time to time.

INFORMATION REGARDING THE ON-LINE REGISTRATION SYSTEM

1. QUEST 2 ON-LINE REGISTRATION PLAN AND IMPLEMENTATION.

No.	Plan and implementation	Date/Period	Remarks
1	Proposal to upgrade computer infrastructure and system in NPCB Proposal to implement online registration.	2000/2001	NPCB
2	Tender for online registration project	Q2 2002	MOH
3	Project offered to Technology Innovation Resources Sdn. Bhd. (TIR)	Q3 2001	
4	Development of Quest 2 system Registration Module using ASEAN Common Technical Requirement (ACTR)/ASEAN Common Technical Dossier (ACTD) template.	Q3 2001- Q3 2002	TIR and NPCB.
5	Cosmetics Online Registration	Q1 2002	Jan 2003
6	Quest 2 Simulation study system test run.	Q4 2002	Selected pharmaceutical companies were invited to participate in the test run.
7	Online cosmetics registration training course	Q4 2002	TIR/NPCB
8	Establishment of Online Cosmetics Task Force.	Q4 2002	NPCB/CTFA/ FMMMCTIG
9	Module Test Run (Simulation) Internal Training Introduction of Online Quality System Management	Q1 2003	All officers/ evaluators involved
10	Integration and system validation	Q1 – Q2 2003	NPCB, BSF, BAU, GMP
11	Awareness seminar for pharmaceutical industry.	March – April 2003	NPCB/PhAMA MOPI
12	Contract with TIR expires Online Pharmaceutical Registration Training Course.	Q2 2003	May 2003 TIR
13	Establishment of online pharmaceutical Task Force.	Q2 2003	NPCB/MOPI/ PhAMA
14	Data migration from Quest1 to Quest 2	Q2 2003	May/June
15	Commencement of Online Registration	Q3-Q4 2003	Start-up (Jul-Dec)
16	Awareness seminar for Traditional Medicines Industry	Q3 2003	Umbrella Bodies TCM/NPCB
17	Launching of online registration	Q3 2003	YBMK
18	Implementation of Quest 2	Q1 2004	All involved

2. NEW REGISTRATION APPLICATION.

No.	Product Category	Implementation Date
1	Generic Medicines	1 July 2003
2	Abridged evaluation (over-the-counter)	1 July 2003
3	Traditional Medicines	1 January 2004
4	New Chemical Entities - Part I & II – Online - Part III & IV – CDROM	1 March 2004

3. UPDATING OF DATA FOR REGISTERED PRODUCTS

No.	Action by NPCB	Action by Registration Holder	Implementation Date
1	Data transfer from Quest 1 to Quest 2		May/June 2003
2	Data information entry for registered products.	All registration holders are required to submit applications for re-registration online.	1 July – 31 December 2003
3	Re-registration of products which will expire after 1 January 2004	All registration holders are required to submit applications for re-registration online.	Generic and abridged evaluation products- 1 July 2003 Traditional products- 1 January 2004
4	Up-dating of data for Quest 1 and product cancellation.	All registration holders are required to check their list of registered products. All registration holders are required to inform NPCB if they do not wish to market their registered products.	A circular has been released in October 2002.
5	Amendment to information/data: Change of holder Change of manufacturing site Amendment of product information/data.	To be submitted online	Pharmaceutical: July 2003 Traditional: Jan 2004

4. MEASURES TO OVERCOME BACKLOG

No.	Product Category	Proposed Measures	Implementation Date/Period
1	Generic & Abridged evaluation	Voluntary postponement for new applications. Voluntary withdrawal for Stage 1 and 2 applications. Evaluation will be continued for applications in Stage 3.	Until July 2003
2	Traditional Medicines	New applications temporarily stopped.	1 July – 31 December 2003

5. PAYMENT AND FEES

All fees for registration / laboratory analysis / licenses must be paid when application is submitted.

(1) Registration

No.	Product Category	Fees
1	Pharmaceuticals	RM 1000
2	Traditional Medicines	RM 500
3	Cosmetics - Variant	RM 100 RM 50

(2) Laboratory Analysis

No.	Product Category	Fees
1	Pharmaceuticals	Depends on type and number of tests carried out.
2	Traditional Medicines	RM 300

(3) Licenses

No.	License Category	Fees
1	Manufacturer	RM 1000
2	Others (importer, wholesaler, CTIL)	RM 500

6. *IMPACT OF ONLINE REGISTRATION.*

6.1 QUEST 2 is an integrated and computerised registration system, which will combine the current registration procedure from Stage 1 to Stage 3 including licensing and surveillance.

6.2 Productivity and efficiency of registration process is expected to increase PROVIDED that all applications submitted are COMPLETE, in PROPER ORDER and ACCURATE.

6.3 Time frame for online registration:

Generic Products	:	6 months (Full Evaluation)
Abridged Products	:	4 months (Abridged Evaluation)
NCE Products	:	12 months

7. *ENSURING SMOOTH RUNNING OF ONLINE SYSTEM.*

7.1 All relevant parties should take note of announcements made and follow up action should be taken accordingly.

7.2 All relevant parties should read the Registration Guidelines carefully and understand all requirements / conditions imposed.

7.3 All Applicants and Registration / License Holders are responsible for ensuring that the information / data submitted are COMPLETE and ACCURATE.

7.4 Support and cooperation from all parties is very important.

8. *QUERIES AND EXPLANATION.*

8.1 Enquiries or further clarification regarding the Online System can be referred to the Task Force officers or the respective Division / Unit Heads:

i.	Madam Tan Lie Sie	*Extension*	245
ii.	Madam Anis Talib		333
iii.	Madam Siti Aisah Bahari		252
iv.	Miss Nurulfajar Mohd Jamid		251
v.	Madam Mazuwin Zainal Abidin		267
vi.	Miss Basmiah Mohd Isa		325

NEW GUIDELINES AVAILABLE

The following guidelines have been compiled to provide assistance and guidance to the industry in the respective fields of interest. These guidelines can be found at NPCB's website at www.bpfk.gov.my.

(1) GUIDELINES ON REQUIREMENTS FOR CHANGE OF MANUFACTURING SITE FOR REGISTERED PRODUCTS.

(2) GUIDELINES FOR APPLICATION FOR REGISTRATION OF BIOLOGICAL / BIOTECHNOLOGY PRODUCTS.

(3) GUIDELINES FOR PROTOCOL OF ANALYSIS.

(4) GUIDELINES FOR THE CONDUCT OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES.

DCA UPDATES

REGISTRATION OF HERBAL TEAS IN THE FORM OF TEABAGS

The Drug Control Authority (DCA) at its 148th meeting held on 19th June 2003 agreed that ***only*** herbal teas in the form of ***teabags with medical claims*** will still be controlled by the DCA & thus require registration.

Applicants who wish to submit their applications are advised to refer to the Guidelines for Application of Registration of Traditional Medicines *(Garispanduan Permohonan Pendaftaran Keluaran Ubat Tradisional).*

PRODUCTS CONTAINING TRYPTOPHAN AS AN ACTIVE INGREDIENT

Based on Schedule 1 of the Poisons List under the Poisons Act 1952, all products containing the active ingredient **L-tryptophan for use in parenteral and enteral feeding** are classified as Group B Poisons as shown below.

POISON LIST (Section 2)						
Names	Part 1				Part II	Exempt
	Group A	Group B	Group C	Group D		
L-Tryptophan	Medicinal preparations, health and diet supplements containing synthetic L-Tryptophan in pharmaceutical dosage forms, unless in Group B or exempted.	Preparations for parenteral nutrition and enteral feed, Preparations for veterinary use.				Preparations containing L-Tryptophan from natural sources.

Please be informed that due to this reclassification, products containing L-tryptophan for use in parenteral and enteral feeding will still carry the same LOI number and registration number but will change from category 'X' to 'A'.

EXAMPLE

Existing product	*After reclassification*
LOI No. : 2003011234X	LOI No. : 2003011234A
Registration No. : MAL20031234X	Registration No. : MAL20031234A

A six (6) month grace period effective August 2003 will be given to product registration holders to comply with the new registration number labelling.

PRODUCTS CONTAINING DOPAMINERGIC ACTIVE INGREDIENTS: ADDITIONAL WARNINGS REGARDING 'SUDDEN SLEEP ONSET'

The DCA at its 149th meeting which was held on 24th July 2003 made the decision that a warning regarding 'Sudden Sleep Onset' be placed in the package inserts of all products containing dopaminergic active ingredients to reduce the risk of serious adverse effects to consumers.

Products containing dopaminergic active ingredients include:

a. Levodopa (including combination with carbidopa / benserazide / entacapone).
b. Apomorphine.
c. Bromocriptine.
d. Cabergoline.
e. Alpha-dihydroergocryptine.

f. Lisuride.
g. Pergolide.
h. Piribedil.
i. Pramipexole.
j. Quinagolide.
k. Ropinirole.

The warnings which are to be included in the package insert are as below:

i) Special Warnings & Special Precautions for Use:
.....has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported very rarely. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with …….. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore a reduction of dosage or termination of therapy may be considered.

ii) Effects on Ability to Drive and Use Machines:
Patients being treated with ……. and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved (see also section on special warnings and special precautions for use).

iii) Undesirable Effects:
…….. is associated with somnolence and has been associated very rarely with excessive daytime somnolence and sudden sleep onset episodes.

EXTENSION OF TIME TO CHANGE THE PRODUCT REGISTRATION NUMBER FROM "PBKD" TO "MAL"

The DCA had previously given a grace period until the 30th of June 2003 for all companies to update their product labels as stated above.

However, following appeals received from product registration holders for an extension, the DCA has agreed to extend this grace period until 31st December 2003.

COMING SOON

WORKSHOP ON THE SUBMISSION OF ANALYTICAL METHOD VALIDATION DATA

The Malaysian Organisation of Pharmaceutical Industries (MOPI) & the Pharmaceutical Association of Malaysia (PhAMA), in collaboration with the National Pharmaceutical Control Bureau, Ministry Of Health, Malaysia will be organizing a workshop on "Requirements for Submitting Analytical Method Validation Data" from 6th - 8th October 2003 (3 days: Monday to Wednesday, 8.30am – 4.30pm).

Regulatory officers from pharmaceutical companies, regulatory officers (with Laboratory experience) from ASEAN countries and officers from NPCB should attend this workshop. It will be conducted at Anggerik Hall, Block C2, National Pharmaceutical Control Bureau, 46730 Petaling Jaya, Selangor.

ON-LINE REGISTRATION SEMINAR FOR TRADITIONAL PRODUCTS

Jointly organized by:
National Pharmaceutical Control Bureau (NPCB), Persatuan Pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA) and Federation of Chinese Physicians and Medicines Dealers Associations of Malaysia (FCPMDAM).

As of 1st January 2004, registration of all traditional products with NPCB will be carried out on-line. This system will be convenient to all applicants to deal with NPCB whether it is from the office, home or anywhere else at any point of time.

NPCB with the cooperation of PURBATAMA and FPCMDAM will be organizing a seminar aimed at exposing applicants to the ON-LINE REGISTRATION PROCESS. All matters related to registration and license application will be done on-line through this new system which is also known as QUEST 2.

DON'T MISS THIS OPPORTUNITY; learn all you can from our lecturers. They will answer any questions or doubts you may have regarding this new procedure.

Seminar Fee: RM 200.00 per participant
(Fee includes lunch and documents)

Date	Town	Venue
28 September 2003	Kuala Lumpur	Sheraton Subang
2 October 2003	Alor Setar	Holiday Villa
12 October 2003	Johor Bahru	Eden Garden Hotel

TRADITIONAL COURSE – ON-LINE REGISTRATION OF TRADITIONAL PRODUCTS

Organized By: Technology Innovation Resources Sdn. Bhd.
Supported By: NPCB, MOH

Information on the course

This course is designed for traditional medicine companies that intend to obtain information and procedures on how to register traditional products on-line. This programme is a collaboration between the National Pharmaceutical Control Bureau of the Malaysian Ministry of Health and Technology Innovation Resources Sdn. Bhd. (TIR) and is conducted by EDU21, which is the corporate training department under TIR.

This course is suitable for and should be attended by all CEOs, Management Directors, Product Managers, Consultants and anyone that is involved in the registration of traditional products.

The course will be carried out through lectures and practical training sessions. Course notes will also be provided.

The course will be held at Bilik Dokumentasi, 1st floor, Block C1, National Pharmaceutical Control Bureau, Jalan Universiti, 46730 Petaling Jaya, Selangor.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

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

OFFICERS TO CONTACT

ISSUE/AREA	DIVISION/UNIT	NAME OF OFFICER	TEL-EXT
National Pharmaceutical Control Bureau	Director	Normal Sharif	301
Product Evaluation and Safety Division	Deputy Director	Eisah Abdul Rahman	270
– Certificate of free sale – General information regarding registration	Secretariat Unit	Ramli Zainal	242
Application for Registration of - Poisons - Non Poisons - Traditional Medicines - New Chemical Entities - Cosmetics / Nutritional Supplements	 – Poisons Unit – Non Poisons Unit – Traditional Medicines Unit – New Chemical Entity Unit – Cosmetics Unit	 Noorizam Ibrahim (Head) Tan Lie Sie (Head) Saleha Md. Ewan (Head) Fudziah Ariffin (Head) Anis Talib (Head)	 239 245 238 233 333
- Manufacturer's Licence - Import Licence - Wholesaler's Licence	GMP and Licensing Division	Dr. Tajuddin Akasah (Head)	201
- Clinical Trial Import Licence	New Chemical Entities Unit	Fudziah Ariffin (Head)	233
- Report of Adverse Drug Reaction - Market Surveillance Programme - Product Complaints / Product Recalls	Surveillance & Pharmacovigilance Division	Abida Haq (Head)	258
- Good Manufacturing Practice - Good Storage Practice	GMP and Licensing Division	Dr. Tajuddin Akasah (Head)	201
Drug Analysis Division	Deputy Director	Datin Hasiah Abdullah	204
- Request/Purchase of Reference Standards	Reference Standard Unit	Nasir Hashim (Head)	510
- Payment for Laboratory Tests	Laboratory Services Unit	Choy Khye Moon	512
- Submission of Samples for Stage 2 of Registration Application	Laboratory Officers on Duty	(according to schedule)	512
- Submission of Letters for Product Evaluation and Safety Division	Receiving Counter	Administrative Assistant	
- Collection of Application Forms - Purchase of NPCB Publications/Guidelines	Administrative Division	Rosnani Mhd. Yusoff (Head)	502
- Drug Information - Library - Classification of Products	Organisational Development & Information Technology Division	Abida Haq (Acting Head)	217
- General Inquiries and Technical Information - Classification of Products	Public Affairs Unit	Azlina Ismail	223