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NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

REVIEW OF THE 8TH MALAYSIA PLAN (2001-2005): QUALITY ASSURANCE OF PHARMACEUTICAL PRODUCTS

Introduction

The regulatory control of pharmaceuticals achieved through product registration and licensing schemes ensures quality, safety and efficacy of products prior to marketing approvals. It encompasses drug registration, compliance to Good Manufacturing Practice (GMP), quality control, post-marketing surveillance and adverse drug reactions monitoring. The National Pharmaceutical Control Bureau (NPCB) is entrusted to carry out these activities.

Strategies set under the 8th Malaysia Plan (8MP) were based on the relevant policies identified for the health sector. These include key elements such as Quality, Health Information System, Planning and Development of Human Resource, Intersectoral Collaboration, Research, Role of Ministry of Health, Traditional/Complementary Medicine and Pharmaceutical Industry.

Progress achieved against targets set were analyzed and some of the milestones during the first half of the 8MP (2001-2002) include NPCB's attainment of ISO 9000 certification by SIRIM, accession into the Pharmaceutical Inspection Cooperation Scheme (PIC/S), utilization of ICT in the implementation of

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cosmetic registration, feasibility study for the corporatization plan of NPCB, technical guidelines produced via collaboration and progress in harmonization efforts.

Prospects for the second half of 8MP

The challenges and limitations encountered during the first half of 8MP have been addressed, and the appropriate actions have been identified and measures taken in order to resolve pertinent issues. The prospects for the second half of the 8MP seem promising, and will continue to focus on the following key areas:-

- **Development of Domestic Pharmaceutical Industry**
  - Attract foreign investment and technology transfer and acquisition.
  - Promote merging of small and medium enterprises to increase viability and sustainability.
  - Promote bioavailability and bioequivalent studies for generic products to gain competitiveness for export markets.
  - Encourage setting up of plants to manufacture biotechnology products.
  - Promotion of R & D via joint-ventures and strategic alliances.
  - Improving time-lines for product registration.
  - Maintaining high standards of GMP.
  - Establish close collaboration with local agencies such as MOSTE, Domestic Trade & Consumer Affairs, MITI, MIDA, MATRADE and MiGHT, and international regulatory bodies.
  - Regular dialogues with industry organizations such as MOPI, PhAMA, CTFA, MCTIG, MLMA.
  - Regional and global harmonization of pharmaceutical regulatory control.

- **Development of the Traditional Medicine Industry**
  - Upgrade GMP of traditional manufacturers to meet current international standards.
  - Introduce requirements for in-house QC laboratory to ensure quality, safety and efficacy of raw materials as well as finished products.
  - Encourage mergers of small enterprises.
  - Compliance to Good Storage Practice (GSP) for importers and wholesalers.
  - To further expand the Herbal Monograph, incorporating more plant species commonly used in local traditional medicines.
  - To establish a database for local plant species.
  - Encourage product research and development via collaboration with local universities.

- **Expansion of Product Registration**
  - To implement registration of medical devices, veterinary medicines and active pharmaceutical ingredients.
  - To continue participation in global harmonization for pharmaceuticals, cosmetics and medical devices.
  - To improve the current work-processes.

- **GMP Benchmarking**
  - To strengthen efforts to upgrade the level of GMP compliance of local pharmaceutical and traditional medicines industries.
  - To participate in joint GMP audits with PIC/S member countries.
  - To develop a pool of local experts in GMP.
  - To export technical and professional services in GMP and licensing.

- **Post-marketing Surveillance**
  - To further intensify market surveillance of registered products via sampling, laboratory testing and monitoring of product labels and package inserts.
  - To focus more on safety monitoring of products.
  - To undertake stern punitive actions and publicize the sanctions applied.

- To combat problems associated with adulteration and counterfeiting of registered products.
- To promote public health protection via education and awareness.

- **Information and Communication Technology (ICT)**
  - To increase work efficiency through computerization.
  - To implement on-line registration of pharmaceuticals and traditional medicines.
  - To process new and renewals of license applications via on-line applications.
  - Electronic ADR reporting.
  - On-line drug information services.
  - Paperless administration and e-Government.
  - Establish information kiosks / on-line product registry and industry directory.
  - Networking with enforcement units via electronic palm-devices.

- **New ISO 9000 Certification**
  - To intensify efforts towards achieving ISO 9000 version 2000.
  - To achieve the ISO 17025 for the laboratory services.

- **Corporatization Plan of NPCB**
  - To recommend the best method to manage NPCB on a commercial basis.
  - To look at various well-established self-financing regulatory agency modalities.
  - To determine financial viability and capability.
  - To review the overall structure of the Pharmaceutical Services and other key components within the Ministry of Health Malaysia.
  - To recommend a new organizational structure.
  - To outline the impact of corporatization on career development of NPCB personnel.

Recommendations

- **Strengthen the existing regulatory system, focusing on safety and efficacy to protect public health**

  The regulatory review conducted by WHO in October 2002 highlighted certain weaknesses in the current system. The following remedial measures have been identified to improve the system:-

  Establish a Committee of Experts for the evaluation of product safety and efficacy for new chemical entities.

  Study new approaches of assessing traditional medicines.

  Conduct overseas GMP inspections.

  Replace the current practice of pre-market testing with post-market testing.

  Enhance pharmacovigilance activities.

  Exchange of technical information with other regulatory authorities such as product evaluation reports and GMP inspection reports to ascertain actual status.

  Publicize sanctions taken against defaulters.

  Emphasis on public education and public health promotion.

  Involvement of civil society.

- **To review existing legal provisions and current regulatory policies**

  Establish legal provisions for the conduct of clinical trials.

Review legal definitions of traditional medicines.

Study legal provisions for the existence of National Pharmaceutical Control Bureau.

Formulate new legislation for medical devices and active pharmaceutical ingredients.

Establish relevant guidelines through Technical Working Groups.

- **To improve quality, productivity and efficiency**

Establish quality benchmarking such as ISO 9000, ISO 17025 and PIC/S GMP.

Utilization of ICT in regulatory processes including registration, licensing, laboratory services, pharmacovigilance, surveillance and drug information.

Organizational restructuring.

Human resource development.

Infrastructure upgrading.

Meeting customers' needs.

- **To adapt to the global regulatory environment**

Intensification of efforts towards pharmaceutical harmonization.

Implementation of ASEAN cosmetic harmonization.

Adoption of harmonized guidelines for medical devices and veterinary medicines.

International networking and collaboration.

- **To pursue and embark on regulatory controls for veterinary products, medical devices and active pharmaceutical ingredients**

Enactment of relevant Act and Regulation.

Seek additional staff to cater for the expansion in the scope of activities.

Train relevant personnel in these fields.

Participate actively in relevant international meetings.

Exchange and share information with other regulatory agencies.

Collaboration with other local agencies involved in medical devices, veterinary products and active pharmaceutical ingredients.

Conclusion

Commitment towards public health protection remains the pillar of our regulatory business. Hence, assessment of quality, safety and efficacy of products available in the market through registration, licensing and surveillance will be further strengthened. Nevertheless, with the impact of globalization, efforts must be tailored towards adapting and adopting current international best regulatory practices. Emphasis on continuous quality initiatives, increasing efficiency and productivity is evident from the efforts undertaken and achievements recorded.

Based on the strategies, policies and targets specified for the 8MP, several milestones have been achieved within the first half of the 8MP. The second half of the 8MP will endeavour to look at the prospects, studying the various issues and implementation of recommendations as laid down.

REGISTRATION OF TRADITIONAL MEDICINES – TEN YEARS OF IMPLEMENTATION

The registration of traditional medicines dates back to 1992 and now, after ten years of implementation, the National Pharmaceutical Control Bureau (NPCB) has received about 23,048 applications (as of December 2002) for the registration of traditional products.

Out of the total of 23,048 applications, 10,758 products have been registered, 9,127 products have been rejected and another 3,163 have been either de-registered or suspended. Traditional products form the biggest group of medicines which have been registered (37.1%) as compared to prescription drugs (32.2%) and non-prescription (OTC) drugs (23.9%).

Over the years, NPCB has encountered various problems in the process of registration. These problems relate to increasing workload coupled with an inherent shortage of staff. Besides this, the majority of applications received are found to be incomplete, hence slowing down the registration process. There are also an increasing number of products which contain various combinations of herbs and nutritional supplements widely marketed in other countries and penetrating our Malaysian market. The fact that they contain so many ingredients has raised doubts as to whether they possess any therapeutic value or contribute to the well-being of the consumers. Then there was also the discovery of slimming products which were found to be adulterated. Imitation products and unregistered products also seem to find their way onto the shelves and as a result, enforcement has to be tightened and the penalty for selling unregistered products increased. Effective monitoring and testing is not possible with the limited resources that are available.

Various suggestions have been put forward in an effort to resolve these issues. This includes adopting a new approach in the registration of traditional medicines such as requiring clinical studies to determine the efficacy of the product before it can be registered. Another possible approach is based on the risk level of herbal ingredients which is being implemented by the TGA. GMP requirements must be enforced strictly in order to achieve a high standard of product quality. To do that a manufacturer must have proper facilities for in-process quality control and the qualification of all personnel involved must be reviewed. GMP facilities should be inspected from time to time. A time-frame to implement this must be well laid down so that adequate training is given to those involved.

In order to clear the backlogged files, the DCA has agreed that the registration of traditional medicines be temporarily put on hold for 6 months. This time period will enable the process of registration to be re-evaluated and also allows time to complete the processing of backlogged files. This 6 months freeze will also enable the NPCB to come out with a new guideline for registration based on the approach that will be adopted.

A workshop to re-evaluate the registration of traditional medicines will be held in May/June 2003. The resolutions from this workshop will form the basis for the formulation of new policies in the registration of traditional medicines.

After 10 years of regulatory control on traditional medicines, a review is deemed necessary to enhance the effectiveness of such a control so that products made available to the consumers are of the highest quality, safety and efficacy.

CONFIRMATION TEST BY AN INDEPENDENT LABORATORY

Starting from the year 2000, the Drug Analysis Division (DAD) of the National Pharmaceutical Control Bureau (NPCB) has implemented a procedure for test results to be confirmed by an external independent laboratory.

This procedure is intended for market surveillance samples which have failed tests conducted by the laboratories in the DAD. The manufacturers or the registration holder are given the choice as to whether they would like to have their test results confirmed by an independent laboratory. Should they agree, NPCB will then make the necessary arrangements with the relevant independent laboratory. All costs including those for handling, delivery and tests are to be borne by the manufacturer/registration holder.

The independent laboratory may either be a laboratory attached to an official regulatory agency or a laboratory which is ISO 17025 certified. Up to this date, the DAD has identified SIRIM QAS Sdn. Bhd. and Therapeutic Goods Administration (TGA) Laboratories Australia as independent laboratories. SIRIM QAS Sdn. Bhd, being an ISO 17025 certified laboratory, has been assigned by NPCB to conduct the limit test for heavy metals like Arsenic, Lead and Mercury and Microbial Limit Test for traditional products. On the other hand, TGA Laboratories, a laboratory attached to the Australian Regulatory Agency located in Canberra, has been assigned to conduct confirmation tests on physico-chemical characteristics and dosage performance for pharmaceutical products.

The test results from the independent laboratory are deemed to be conclusive.

Item	Number	Remarks
Manufacturers/registration holders who were given the choice for confirmation test on their products	57	–
Products sent to TGA Laboratories	10	The results of 9 products concurred with the results from DAD. 1 product which passed the test from TGA is a border line pass.
Manufacturers/registration holders who did not respond to letters from DAD within the specified time	33	Indirectly they agreed with results from DAD
Manufacturers/registration holders who did not agree to the independent lab. service and agreed to DAD's result	14	5 manufacturers retested their samples and the results concurred with DAD's results.

Table 1 above summarizes the response received by NPCB and the status of pharmaceutical products that have undergone the above-mentioned confirmation test procedures.

Table 2 below compares the test results from DAD and TGA:

No.	Content of Products	Tests and results (by DAD)	Tests and results (by TGA)
1.	Royal Jelly Tablet	Disintegration: >30 mins (Limit: NMT 30 mins)	TGA Report 0019/01740 >30 mins.
2.	Evening Primrose Oil Capsule	Disintegration: >45 mins (Limit: NMT 45 mins)	TGA Report 0019/01730 >45 mins.
3.	Chitosan Capsule	Disintegration: > 45 mins (Limit: NMT 45 mins)* DAD used apparatus A Uniformity of Weight: 3 out of 20 caps > ± 10% (Limit: NMT 2 caps > ± 10%)	TGA Report 0012/02076: Disintegration: 3 mins.* TGA used apparatus B Uniformity of Weight: 7 out of 20 caps > ± 10%
4.	Gel containing Piroctone Olamine	Assay of Piroctone Olamine: 0.651%w/w (Limit: 0.71% - 0.79%w/w)	TGA Report 0105/00949: 0.648%w/w
5.	Antiseptic powder containing menthol	Assay of Menthol: 0.56%w/w (Limit: 0.765% - 0.935%w/w)	TGA Report 0106/01120: 0.541%w/w
6.	Deep Heating Rub	pH: 4.82 (Limit: 5.0 – 6.0)	TGA Report 0106/01120: 4.4
7.	Tablet containing Piroxicam	Water content: 6.94% (Limit: NMT 6.0%)	TGA Report 0205/00792: 7.10%
8.	Tablet containing Ibuprofen	Dissolution: Min: 42.4% Max: 80.0% Average 12 tabs= 53.0% (Limit: NLT 75.0% dissolved in 60 mins, Average 12 tabs ≥ 70.0%)	TGA Report 0208/01211: Min: 55.0% Max: 80.0% Average 12 tabs =65.9%
9.	Tablet containing Metronidazole	Uniformity of Weight: 4 caps out of limit (Limit: NMT 2 caps out of range 508.0mg to 590.4 mg)	TGA Report 0208/01221: 2 caps out of range 508.0mg to 590.4mg * This is a border line pass
10.	Cream containing Hydroquinone	Assay Hydroquinone: 2.15% (Limit: 1.8% - 2.0%)	TGA Report 08012/01120: 2.3%

NMT: not more than
NLT: not less than

Results from DAD and TGA showed that the test results are comparable and hence the products did not comply with the quality control specifications. Inter-laboratory variations did not influence the results of the test conducted

GUIDELINES FOR THE REGISTRATION OF PHARMACEUTICAL PRODUCTS – THE NEED FOR A REVIEW

In line with plans for the ASEAN harmonization of pharmaceutical products by the year 2004, the NPCB is taking measures to adopt the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR) for the forthcoming on-line registration of pharmaceutical products.

A seminar was held in February 2003 to brief NPCB officers on general information pertaining to the ACTD and ACTR.

Based on the ACTD/ACTR (Part I-IV), the information and data that is required for registration will now be categorized as follows:-

i. Administrative Data (country specific and not part of ACTD).

ii. Part I – Common Administrative Data & Product Information.

iii. Part II – Quality (Overall Summary & Reports).

iv. Part III – Non-Clinical/Safety (Overview, Summary & Study Reports).

v. Part IV – Clinical (Summary, Assessment & Study Reports).

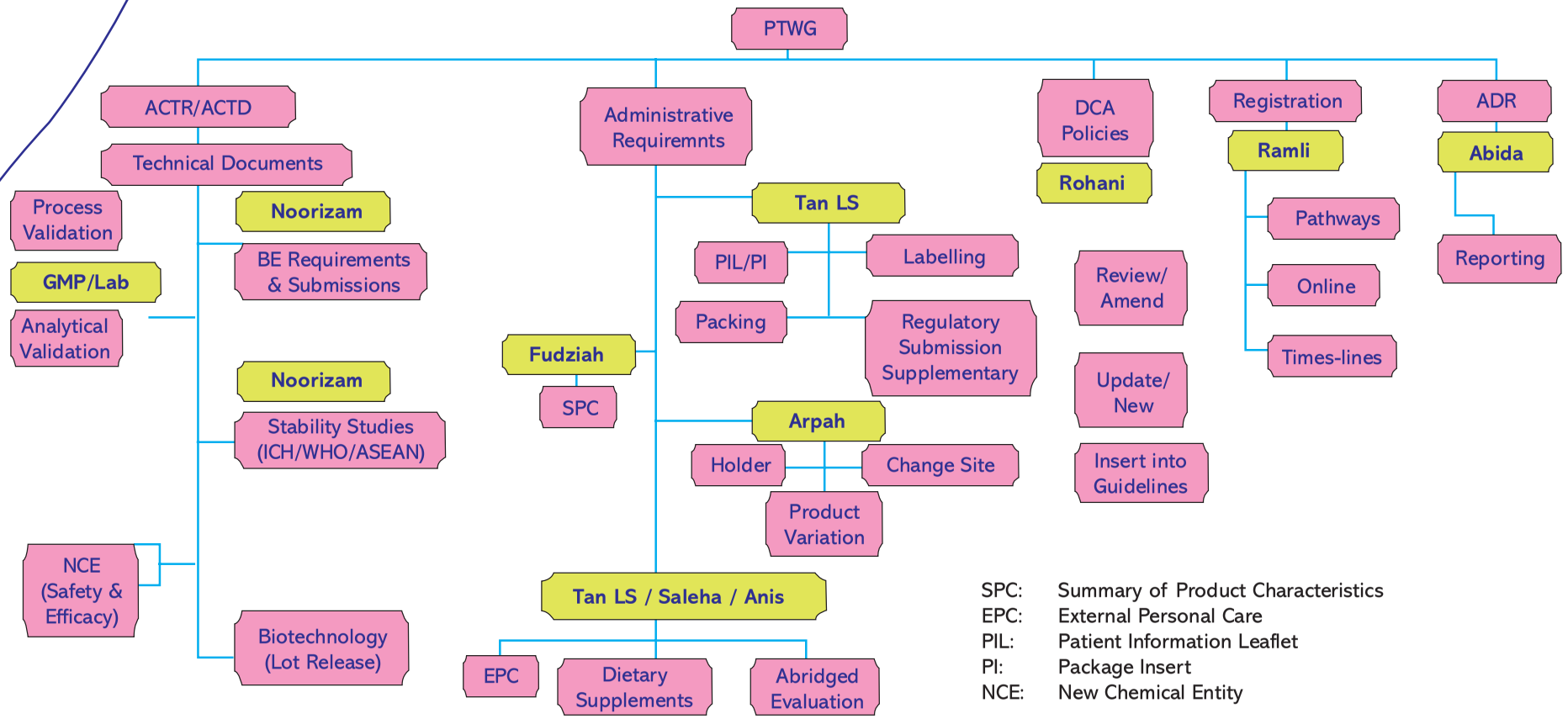
vi. Technical Documents – Bioequivalence Studies, Process & Analytical Validation, and Stability Studies.

Due to the above-mentioned developments in regulatory control, the guidelines for the registration of pharmaceutical products (1993 edition) which is currently being used will become irrelevant in due time, hence the need to review it.

The Pharmaceutical Technical Working Group (PTWG) is currently working to revise the guidelines. The PTWG has been established since 1997 and it is a technical collaborative effort consisting of NPCB officers and representatives from the industries, such as PhAMA and MOPI. The PTWG consists of several working groups, each designated with their own specific area of regulatory control which needs to be reviewed. The proposed expanded scope of the PTWG is shown in the diagram below together with the names of NPCB officers who are heading the respective groups.

The revised guidelines will be used when the on-line registration of pharmaceuticals is implemented later on. The revised guideline is expected to be ready by July 2003 and barring unforeseen circumstances, it will be launched at the Regulatory Seminar 2003 scheduled for September/October 2003.

PHARMACEUTICAL TECHNICAL WORKING GROUP (PTWG)



SPC: Summary of Product Characteristics
EPC: External Personal Care
PIL: Patient Information Leaflet
PI: Package Insert
NCE: New Chemical Entity

UPGRADING OF IT SYSTEM IN NPCB & IMPLEMENTATION OF ON-LINE REGISTRATION

NPCB is currently in the process of upgrading its IT system, a project costing RM7.8 million. A test-run was conducted in February this year whereby several pharmaceutical companies were invited to participate in testing the system. At the same time, the evaluating officers in NPCB were introduced to the online quality system and given in-house training on a simulated module. Besides this, NPCB also conducted seminars for the industries and registration holders in March and April to provide the latest information on our QUEST 2 system, the new registration guidelines and procedures for online registration of pharmaceuticals.

With this new and sophisticated IT system, NPCB plans to implement on-line registration for the various categories of products, as follows:-

For new applications for registration

Type of Product	Date of Implementation	Details
Generic	1 July 2003	Full evaluation
Abridged	1 July 2003	Abridged evaluation
Traditional	1 January 2004	Abridged evaluation
New Chemical Entity	1 March 2004	Part 1 & II – online Part III & IV – CDROM

Updating of Data for Registered Products

In order to enable NPCB to update its database, all registration holders have been requested to:-

i) submit information/additional data pertaining to their products between 1 July – 31 December 2003.

ii) check their lists of registered products and inform NPCB which products they have ceased to import/manufacture/ market.

iii) submit details of any changes made to their products, such as, change of holder, change of manufacturing site, change of product information etc.

Impact of On-line Registration

The implementation of on-line registration will undoubtedly improve the efficiency and productivity of NPCB, but this can only be achieved provided all applications received are complete and the information given is correct. The expected time-line for registration using this system is: –

- Generic products – 6 months (full evaluation).
- Abridged products – 4 months (abridged evaluation).
- New chemical entities – 12 months.

BIOEQUIVALENCE (B/E) STUDIES REQUIRED FOR GENERIC ANTI-RETROVIRAL DRUGS

The DCA has agreed to impose B/E requirements on generic anti-retroviral (ARV) drugs according to the WHO Guidelines. More information can be found on the following websites:-

http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotprocmain.shtml

http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotproc.shtml

http://www.who.int/medicines/library/qsm/manual-on-marketing/multisource-contents.html

COUGH PREPARATIONS CONTAINING CODEINE

The following list of products containing Codeine have been cancelled with effect from **1st January 2003.**

However, companies are given an extended six (6) months until **30th June 2003** to finish off the existing stocks in the market.

No.	Product Name	Registration No.
1.	Alphasedyl Cough Linctus	MAL19961006A
2.	Atlandryl CP Syrup	MAL19871748A
3.	Betafed Compound Linctus	MAL19961016A
4.	Benadryl CD	MAL20000833AC
5.	Benapress Linctus	MAL19871744A
6.	Benatussil & Codeine Syrup	MAL19871747AC
7.	Bencodyl Linctus CD	MAL19871745A
8.	Breacol Decongestant & Cough Suspension	MAL19973565A
9.	Chloromin Compound Linctus	MAL19961285A
10.	Clomit Cough Linctus Forte	MAL19960989A

No.	Product Name	Registration No.
11.	Codeine Phosphate Syrup 25mg/5ml	MAL19860118A
12.	Codeine Phosphate Syrup 25mg/5ml	MAL19861769A
13.	Codeine Syrup 25mg/5ml	MAL19861770A
14.	Cofnil CD Syrup	MAL19962874A
15.	Cophos Syrup 25mg/5ml	MAL19880210A
16.	Coredin CD Linctus	MAL19890566A
17.	Corifed Compound	MAL19961291AC
18.	Diphendryl CP	MAL19871750A
19.	Dycodeine Syrup 25mg/5ml	MAL19910826A
20.	Dynadryl CD Syrup	MAL19913382A
21.	HD-Hosolvon CD Elixir	MAL19961274A
22.	Hosedyl Cough Linctus	MAL19961273A
23.	L.T.R. (Forte) Syrup 15mg/5ml	MAL19861764A
24.	Macodrine Syrup	MAL19961232A
25.	PCE Syrup	MAL19960978A
26.	Phencodryl Linctus	MAL19960990A
27.	Phenexpect CD	MAL19910191A
28.	Phensedyl Linctus	MAL19900239A
29.	Phensedyl Linctus	MAL19962133AC
30.	Procodin Cough Linctus	MAL19961281A
31.	Procodrine Syrup	MAL19961018A
32.	Promedyl Linctus	MAL19961015A
33.	Promethazine Compound Linctus	MAL19960987A
34.	Prosedyl Cough Linctus	MAL19960972A
35.	Prosezine Linctus	MAL19961286A

No.	Product Name	Registration No.
36.	Russedyl Syrup	MAL20000217AC
37.	Sedilix Linctus	MAL19961021A
38.	Setlinctus	MAL20000845AC
39.	Sunsedyl Cough Linctus	MAL19961350A
40.	Triprodine Compound Syrup	MAL19961233A
41.	Tussedyl Cough Linctus	MAL19960992A
42.	Uphadyl CD Expectorant	MAL19871746A
43.	Wincodin Syrup 25mg/5ml	MAL19900152A
44.	Zainexpect CD	MAL20000834AC

CHANGE IN POISON CLASSIFICATION STATUS OF HYDROQUINONE

Hydroquinone, a scheduled poison, has been re-classified as follows:-

Group C Poison	:	All medicinal preparations unless in Part II or exempted.
Part II Poison	:	Preparations other than for medicinal purposes unless exempted.
Exempted	:	Strengths of 0.3% or less of hydroquinone as antioxidant in hair dyes.

This change was gazetted in *His Majesty's Government Gazette* P.U.(A) 3 dated 2nd January 2003.

The above information has been communicated to all registration holders of products containing Hydroquinone. Due to this re-classification, the LOI number and registration number of products formerly under the OTC category will be changed from "X" to "A" (for products containing poisons). However, there will be no changes to the digits.

The following is a list of registered products containing Hydroquinone

No.	Registration No.	Product Name	Registration Holder
1	MAL19984887XC	Basic I (Lotion)	Skin Fitness Centre S/B
2	MAL20020120XC	BML MB Lotion	Excellent Combination S/B
3	MAL19984888X	Clear I (Lotion)	Skin Fitness Centre S/B
4	MAL19971794X	Eldopaque 2% Cream	JDH Pharm S/B
5	MAL19971792A	Eldopaque Forte 4% cream	JDH Pharm S/B
6	MAL19971791A	Eldoquin Forte 4% Cream	Waleta (M) S/B
7	MAL19991330XC	Fade Out Cream	Apex Pharmacy Marketing
8	MAL19987388XC	Fade Out Extra Care	Apex Pharmacy Marketing
9	MAL19987400X	Krim Pemutih	Kosmetik Citra Ayu S/B
10	MAL20000084X	Light P Formulae	Clara International Beauty
11	MAL19989055XC	Neostrata Neoceuticals HQ Skin Lightening Gel	Zuellig Pharma S/B
12	MAL19992157XC	Neostrata Neoceuticals Skin Lightening Cream	Zuellig Pharma S/B
13	MAL19990118XC	Protec Fading Cream	CTL Fine Corp. S/B
14	MAL19971795X	Solaquin 2% Cream	JDH Pharm S/B
15	MAL19971790A	Solaquin Forte 4% Cream	Waleta (M) S/B
16	MAL19971793A	Solaquin Forte 4% Gel	Waleta (M) S/B
17	MAL19984889X	Sunfader I (Lotion)	Skin Fitness Centre S/B
18	MAL19990119XC	Triple Action Fading Cream	CTL Fine Corp. S/B

VALIDATION SEMINAR, 30TH JUNE 2003, IN CONJUNCTION WITH THE 7TH ACCSQ-PPWG MEETING.

Organized by the Pharmaceutical Association of Malaysia (PhAMA) and supported by the National Pharmaceutical Control Bureau.

Venue: Bay View Beach Resort, Penang.
Seminar fee per person: USD 100

Objectives:

- Gain a precise understanding of Process & Analytical Validation activities and how they are assessed in regulatory submissions.
- Let the industry experts share their experiences based on the practice of lead regulatory agencies in EU & US.

SEVENTH MEETING OF THE ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY – PHARMACEUTICAL PRODUCT WORKING GROUP (ACCSQ – PPWG), 1 – 3RD JULY, PENANG.

Training Course on Drug Evaluation, 28 July-1 August 2003, Kuala Lumpur

This course, jointly organized by WHO and NPCB, is specially designed for officers involved in the evaluation of safety (excluding non-clinical) and efficacy of drugs. The course will focus on three therapeutic groups – antihypertensives, anti-ulcer drugs and NSAIDs.

The purpose of this course is to offer elements for a standardized evaluation of new drugs which will take into account the specific national situation and therapeutic needs. Participants will learn how to complement information submitted by applicants. A standardized evaluation report is expected to be adopted for trial use.

Participants will comprise of staff from National Regulatory Authorities (NRAs) in Malaysia, Indonesia, Philippines, Singapore and Thailand as well as external experts involved by the NRAs in drug evaluation.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

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– 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 Entity 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
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