NATIONAL REGULATORY CONFERENCE 2013

7 – 9 MAY 2013

ISTANA HOTEL
KUALA LUMPUR

Pharmacy Legislative Transformation

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9 MAY 2013
@ 11.00am -11.45am

ISTANA HOTEL
KUALA LUMPUR

Scope of Presentation

- **Pharmacy Legislative: Existing Laws**

1. Poisons Act 1952 *[Act366]*
2. Sale of Drugs Act 1952 *[Act368]*
3. Medicines (Advertisement and Sale) Act 1956 *[Act 290]*
4. Registration of Pharmacists Act 1951 *[Act 371]*

- **Constraints in the present Legislations**

1. None deterrent penalties
2. Do not accommodate current needs
3. Bureaucratic
4. Limitations on Enforcement Activities
5. Limited access to accommodate International Obligations

- **Proposals in the new "Pharmacy Act 201_?"**

1. Merging all 4 existing Acts through Consolidation, Harmonisation, and Liberalisation in the Pharmacy Legislations
2. Address lacunae and loopholes in present legislations
3. Deterrent penalties on serious offences
4. May accommodate current needs through directives
5. Reduce bureaucracy (through directives)
6. Wider scope of coverage in Enforcement Activities
7. At all time may accommodate to current International Requirements

➢Pharmacy Legislative: Existing Laws

1. **Poisons Act 1952 *[Act366]***
   - ✓ ***Regulating the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons.***

2. **Sale of Drugs Act 1952 *[Act368]***
   - ✓ ***Regulating the sale of drugs.***

3. **Medicines (Advertisement and Sale) Act 1956 *[Act 290]***
   - ✓ ***Control on advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine.***

4. **Registration of Pharmacists Act 1951 *[Act 371*]**
   - ✓ ***Establishment of a Pharmacy Board and the registration of pharmacists.***

➢ Constraints in the present Legislations

1. **None deterrent penalties**
   - ✓ *Highest penalty of fine RM25,000 or 3 years imprisonment or both do not deter offenders either to commit or to repeat.*
   - ✓ *Some offences may harm the public and may also cause death eg. Diversion of psychotropic substances and precursor chemicals & adulteration of poisons in traditional medicines and food & beverages.*
2. **Do not accommodate current needs**
   - ✓ *Changes in current technologies cannot be applied.*
   - ✓ *The need to put certain changes or requirements in the Act may take a long time as it has to go through Parliament*
3. **Bureaucratic**
   - ✓ *Most amendments has to go through Parliament or through the Minister.*
   - ✓ *Some decisions has to be made by Boards or Authority that meet less frequent.*
   - ✓ *Certain implementations cannot be done immediately.*
4. **Limitations on Enforcement Activities**
   - ✓ *Restricted enforcement powers that may easily be challenged in Court like power to audit, detain, seal or closure of premises.*
   - ✓ *No provision on accessibility to computer data*
   - ✓ *Most directives are not legally binding*
5. **Limited access to accommodate International Obligations**
   - ✓ *Most International requirements are done administratively and do not have legal standing.*

➢Proposals in the new "Pharmacy Act 201_?"

1. Merging all 4 existing Acts through Consolidation, Harmonisation, and Liberalisation in the Pharmacy Legislations.

2. Addresses lacunae and loopholes in present legislations.

3. Deterrent penalties on serious offences.

4. May accommodate current needs through directives.

5. Reduce bureaucracy (through directives).

6. Wider scope of coverage in Enforcement Activities.

7. At all time may accommodate to current International Requirements.

Powers of Minister of Health

- Appointment of Members of Pharmacy Council
- Make Regulations
- Make Schedules
  - ✓ Classification of Medicines/Medicinal Substances
  - ✓ Prohibited Substances
  - ✓ Fees for Registrations and licenses
  - ✓ Controlled Substances/Products
- Consider Appeals
- Giving Exemptions

(* with advise of Competent Authority)

Establishment of Pharmacy Council

- Senior Director of Pharmaceutical Services as the Chairman of the Pharmacy Council.

- Consisting 16 members (8 pharmacists in Public Sector, 3 academicians, 2 industrial pharmacists, 3 private pharmacists *[1 Semanjung, 1 Sabah and 1 Sarawak]*).
  - **Retention of pharmacists registration and disciplinary action.**
  - **Start registering pharmacy assistant s**
    - ✓ Involving more than 6,000 pharmacy assistants
    - ✓ More than 50% serving MOH
    - ✓ Maintain the quality of diploma graduates from 29 private institutions

Powers of Competent Authority *(CA)*

[Senior Director of Pharmaceutical Services as The Competent Authority]

- **CA may delegate powers to Officers in Pharmaceutical Services for purpose of carrying into effect the provisions of the Act.**

NEW CONTROL ON MEDICINES

- **Classification and registration of medicinal products on the advise of Evaluation Committee**

LICENCES

Registration on all pharmacy premises

- **New license for Clinical Trial**
- **New license for professionals and industries**

EVALUATION COMITTE

- ✓ The Committee assists the CA for purpose of classification of medicinal products & substance , registration of medicinal products and evaluate medicinal claims before registration.

- ✓ A Pharmacist in Public Sector appointed by CA to be the Chairman
  - 21 permanent members which consist of fully registered pharmacists in the public service.
  - 6 associate members

    With relevant expertise; specialist qualification or experience in medicine, pharmaceutical sciences or veterinary medicine which consist of at least a fully registered pharmacist in the private sector specializing in manufacturing of products, a toxicologist and registered veterinary surgeon

Harmonisation of Product Classification

Present Law :

First Schedule

- *Part I Poison*
  (Group A, B, C & D Poisons)
- *Part II Poisons*

Second Schedule

- *Non Poison*

Third Schedule

- *Psychotropic Substances*

New Pharmacy Law

3 Classifications of Medicinal Products

1. Prescription Only Medicine
2. Pharmacist Only Medicinal Product
3. General Sale List

1. Prescription Only Medicine:
   - Registered psychotropic medicine
   - Registered Narcotic Medicine
   - Registered Medicine *(Group B Poison under the present Poisons Act 1952)*

2. Substance/Pharmacy Only Medicinal Product

   Active Substance of Psychotropic/Precursors (Previously Group B or C)

   Pharmacy Only Medicinal Product – available from a registered pharmacist without a prescription - *(Previously Group C)*

   (finished product to be dispensed containing antihistamine, pholcodeine, antidiabetic, external preparations containing antibiotic/steroid)

3. General Sale List :-
   - Industrial usage for precursor substance, acid and alkali solvents
   - Registered products like traditional preparations, supplements or notified cosmetic s available *over-the-counter*.

Harmonisation on Licenses

Present Law :

- *Licenses for wholesale / manufacture/import issued by PKPF*
- *Type A,B,C,D,E Licenses issued by State Licensing Officer*

New Pharmacy Law

- CA issues Licenses for Wholesale, Import, Manufacture and Clinical Trial for Medicinal Products.
- Power can be delegated to the respective State Deputy Director of Health (Pharmacy)

Harmonisation on the Control of Precursors

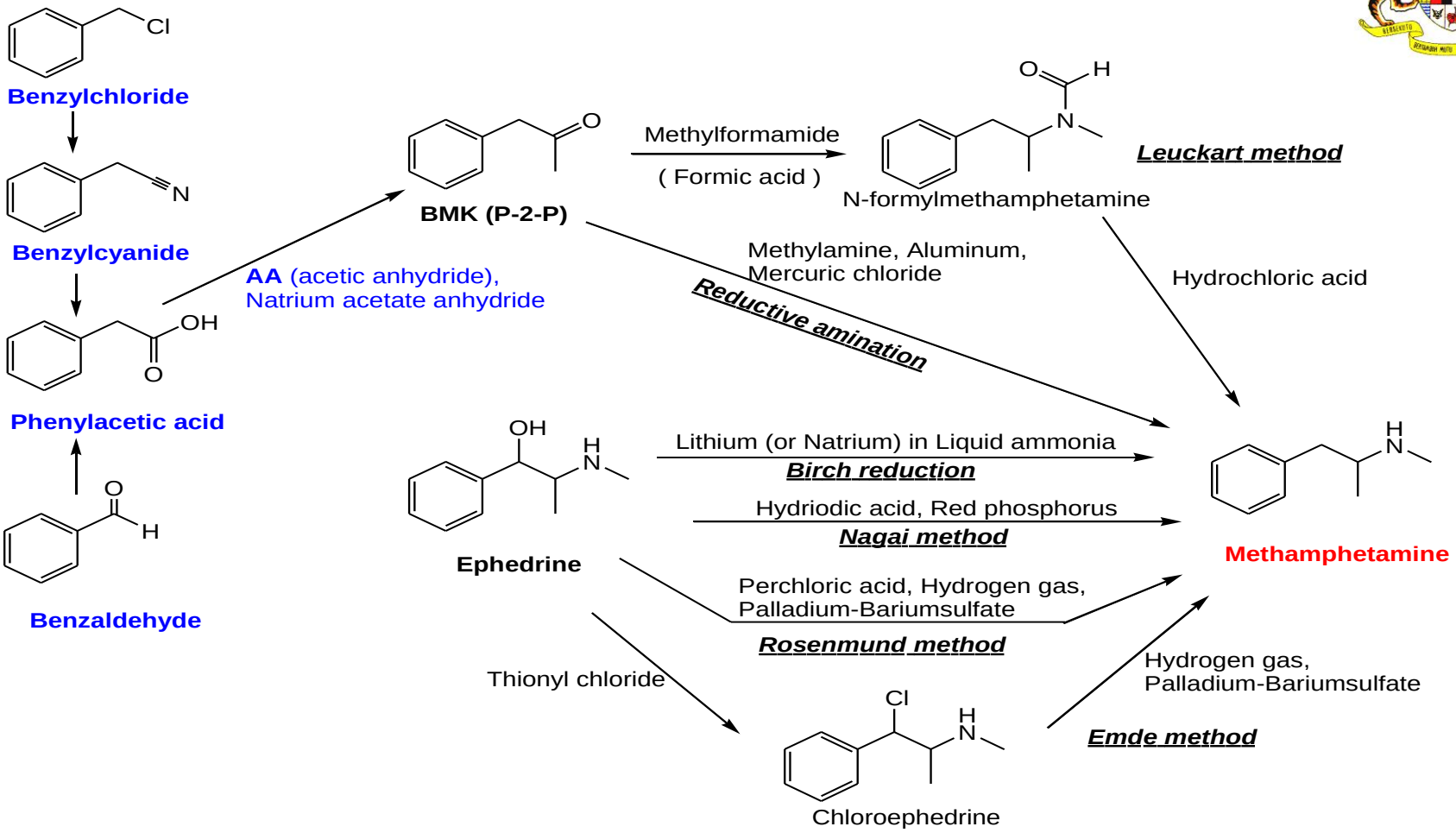
Present Law :

- *No control on the brokers of precursor substances*
- *Prevent the Country as transit point for precursors*

New Pharmacy Law

- Broker license
- User License for Industries/Commercial
- End-user Declaration
- Advantage for the country as hub for development of pharmaceutical industry)

Interrelationship of methamphetamine and main precursor substances



Tiger Woods

Malayan Tiger

Rahsia kepala harimau belang

Dibentuk menggunakan syabu dan dibawa dari Doha, Qatar sebagai cenderamata oleh pelancong Iran

PENYELUDUP dadah antarabangsa sejak kebelakangan ini sangat kreatif apabila pelbagai teknik baharu digunakan untuk membawa dadah melepasi pemeriksaan pihak berkuasa di Lapangan Terbang Antarabangsa Kuala Lumpur (KLIA) di Sepang.

Kelmarin, polis menahan seorang lelaki Iran berusia 26 tahun dan merampas satu replika berupa kepala harimau belang yang rupa-rupanya diperbuat menggunakan 8.4 kilogram dadah jenis syabu.

Suspek yang mengambil penerbangan dari Doha dan memasuki negara ini sebagai pelancong mendakwa kepala harimau itu merupakan satu cenderamata.

Sehari sebelum itu, polis menahan seorang lelaki Nigeria yang membawa 15 ekor ikan kering dalam penerbangan dari Dubai ke KLIA.

Pemeriksaan menemui sejumlah satu kilogram dadah syabu yang disumbatkan ke dalam setiap ekor ikan kering itu.

BERITA DI MUKA 2

SEBAHAGIAN ikan kering yang disumbat dengan syabu.

INILAH replika kepala harimau yang sebenarnya diperbuat daripada syabu yang dirampas di KLIA, Sepang Selasa lalu.

KHAMIS 4 OGOS 2011 RM1 www.kosmo.com.my

Liberalization for Community Pharmacy

Present Law :

- *Type A License is tied up with one premises.*
- *Body Corporate to be registered by Pharmacy Board*

New Pharmacy Law

- Practicing Certificate allows a pharmacist to practice at several premises
- Pharmacy premises are registered

Liberalization through self regulation for advertisements of medicinal products and cosmetics

Present Law :

- *Advertisement to be approved by Medicine Advertisement Board (MAB/LIU)*
- *Advertisement Guidelines are not legally binding*

New Pharmacy Law

Advertisement Guidelines are legally binding

- Advantage:-
  - ✓ *Promote Health Tourism*
  - ✓ *Strict liability offence for unregistered product*
  - ✓ *Advertisement on services and medical devices are no longer controlled by the Act*

Stiffer punishment

> New act to make it tough on those who adulterate products with harmful poisons and controlled medicines

BY ***HEMANANTHANI SIVANANDAM***
newsdesk@thesundaily.com

PETALING JAYA: The Health Ministry is consolidating five acts for products that contain poisons or controlled medicines into one which imposes heavier penalties against those who violate their use.

Health Minister Datuk Seri Liow Tiong Lai said yesterday there is an alarming trend of irresponsible parties who adulterate their products of traditional food or beverages and cosmetics with poisons or controlled medicines harmful to their users.

He said the present penalties are not severe enough.

"Realising the need to impose more deterrent penalties for such offenders and profiteers, the Pharmaceutical Services Division is reviewing the existing acts," he said after visiting the Pharmaceutical Control Bureau here yesterday.

"A new act will be introduced soon that imposes more severe penalties to deal with crimes that jeopardise public health."

He said the ministry is looking to introduce the new act next year.

The five acts are Registration of Pharmacists Act 1951(revised 1989), Poison Act 1952 (revised 1989), Sale of Drugs Act 1952 (revised 1989), Dangerous Drugs Act 1952 (revised 1980), and Medicines (Advertisement and Sale) Act 1956 (revised 1983).

Liow said that at present, the control of pharmaceutical and food-based products or beverages that are adulterated with drugs or controlled medicines is under the Sale of Drugs Act 1952.

"Upon conviction, a fine of RM25,000 or three years imprisonment, or both, for an individual and a fine of RM50,000 for a company can be imposed," he said.

He said the prevalent adulterants are used as active ingredients for male sex stimulants, to suppress appetite, anti-inflammatory agents, and cosmetics that are adulterated with whitening agents.

Such products with the active ingredients can cause side effects like heart attack, stroke, brain haemorrhage, kidney failure and skin cancer if taken without proper consultation by health professionals

Liow noted that there are several manufacturers with Good Manufacturing Practice (GMP) status involved in this "pharmaceutical crime" either in their own factories or with illegal manufacturers that claim themselves as food or cosmetic manufacturers.

He said the ministry has suspended the licences of 19 manufacturers with GMP status since 2008.

He warned manufacturers, distributors, retailers or those in direct selling to stop such activities.

Liow said 6,632 products valued at RM4,546,906 were seized from January to June this year. "The latest seizures on July 1 show the greed of these entrepreneurs when it was discovered that the same source of active ingredients was being used in at least 23 different types of products valued at up to RM4,933,760," he said.

"These products are available as traditional medicines, beverages in the form of coffee and tea, candies, and food based on milk and collagen," he said.

"The packaging and the labels are attractive and convincing with creative illustrations purposely to deceive the public."

Referring to recent reports on *Want Want* crackers from Shandong province in China, said to contain coliform bacteria, Liow said he has instructed the ministry's Food Safety Division to test the products and place them at Level 5 of the Food Safety Information of Malaysia (FOSIM).

"We are taking samples in the market for analyses of coliform and escherichia coli or E coli. We will inform the public once we get the results but, for now, we are not issuing any warnings to the public yet," he said.

ONLINE

FOR MORE INFO go to:
the National Pharmaceutical Control Bureau at www.bpfk.gov.my *or the Pharmaceutical Control Bureau at* www.pharmacy.gov.my.

Malaysia; herbals adulteration problem.

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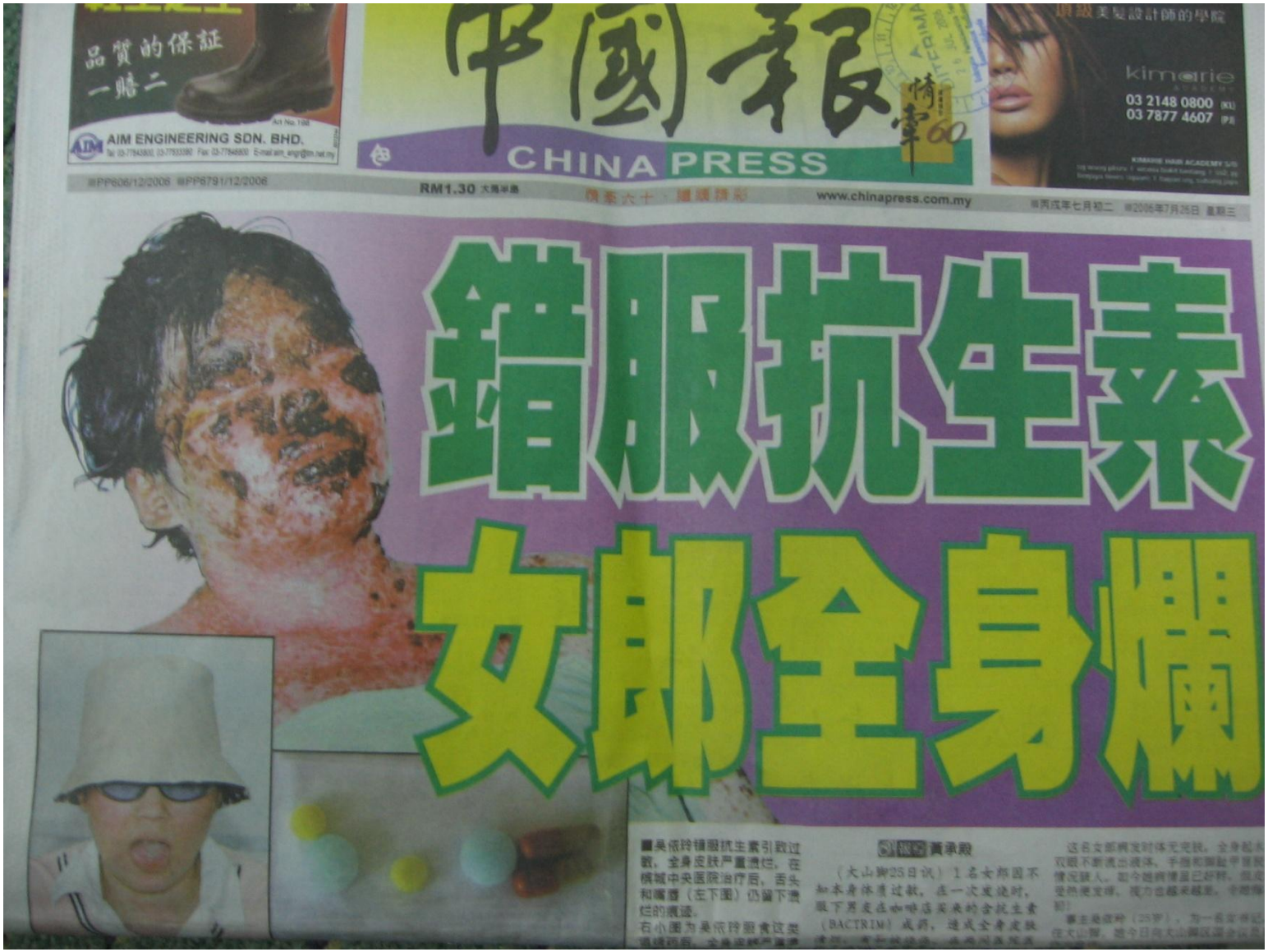
Publication Date: 01-AUG-07
Format: Online
Delivery: Immediate Online Access

Article Excerpt

The problem of adulterated medicines in Malaysia is now more apparent in herbal products, according to global drugs giant Pfizer. Its corporate affairs director for Malaysia and Singapore, Narinder Kaur, reported by Bernama. com, said the adulterated medicines - where the product contains active pharmaceutical ingredients - were commonly...

More articles from Nutraceuticals International
Taiwan's UPEC debuts Reducol milk drink., August 01, 2007
Merck KGaA Bion 3 licensed to Sato Japan., August 01, 2007
Schisandrin B protects against heart damage, August 01, 2007

Sex Stimulant in Goji and Mentalk Candy



Effect of Adulteration

MORE DETERRENT PENALTIES

Present Law :

- *RM 3000 for poison cases*
- *RM10,000 for psychotropic*
- *RM25,000 for unregistered products*
- *Issue of low /non deterrent penalties*
- *Being raised in Parliament*
- *Do not guarantee public safety*
- *NKRA lab suggested a more deterrent penalties*
- *May reduce crime rate*
- *Do not rectify the need of international convention*

New Pharmacy Law

- Mandatory imprisonment and higher fines for cases:-
  - counterfeit medicines,
  - adulterated products,
  - trafficking and diversion of psychotropic and precursors

Proposed penalty:-

Eg. Penalty upon conviction on trafficking of psychotropic substances:-

"Imprisonment for a term not less than six years and not exceeding twenty years "

11 July 2006 Tuesday
Nation | N3
THE STAR

Police bust syabu plant

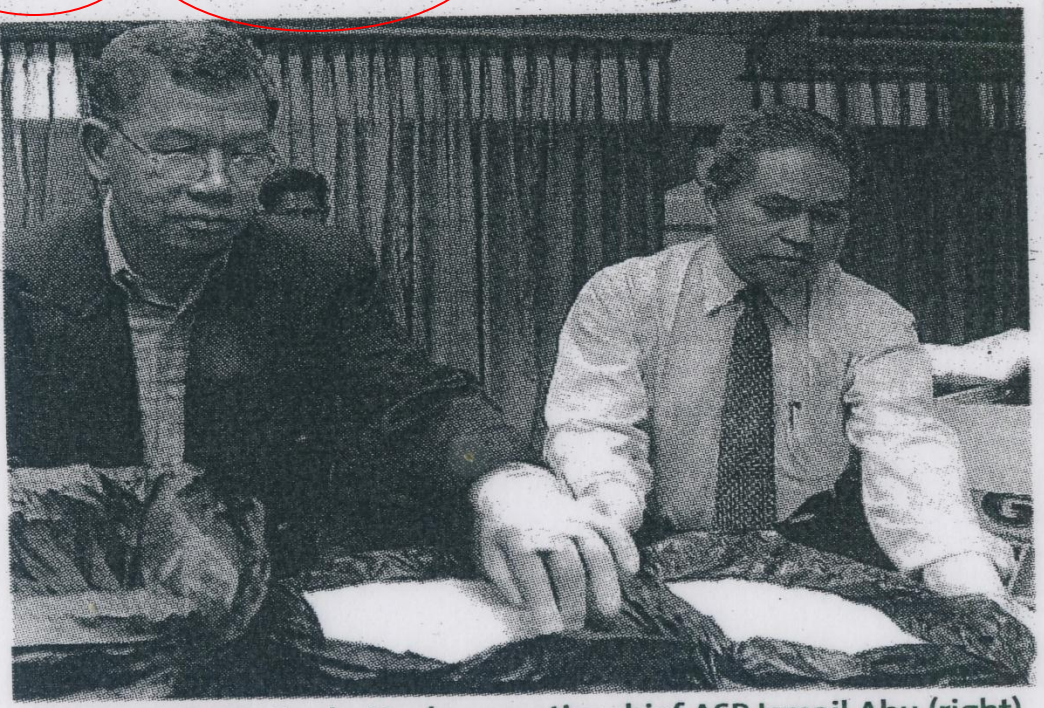
RM14mil of 'ice', Ecstasy pills seized

KULIM: One of the region's biggest and most sophisticated *syabu* producing laboratories with international links was busted when police seized *syabu* and Ecstasy pills worth a whopping RM14mil from a factory in Taman Makmur, Lunas, here.

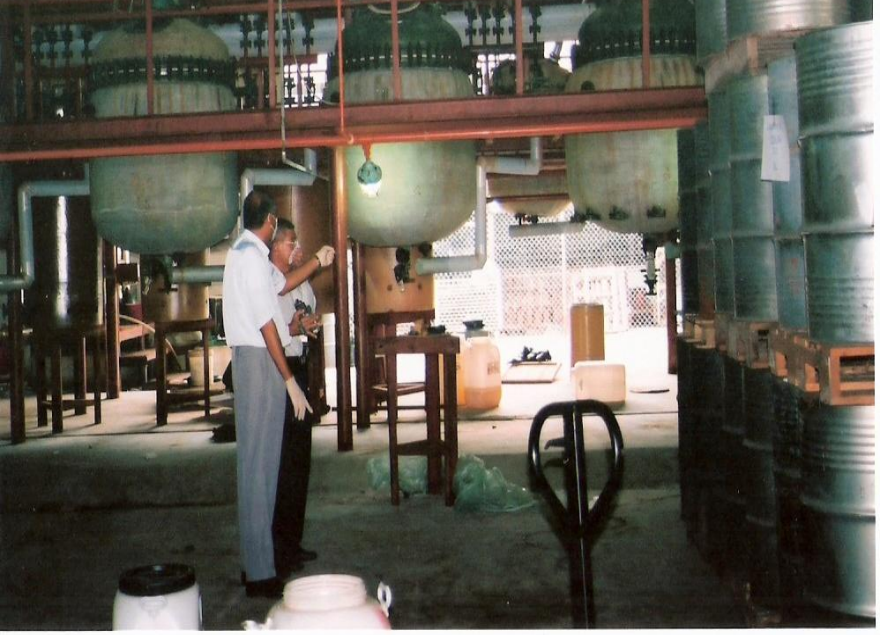
Twenty-one people, including a family of four, a Taiwanese chemist and a Hong Kong national, were arrested during a massive joint operation involving police from Bukit Aman and the Kedah narcotics department at about 4pm last Sunday.

The family of four was a 48-year-old man, his 44-year-old wife and their two children, aged 21 and 19.

Federal Narcotics Crimes



DEADLY STUFF: Kuala Muda narcotics chief ASP Ismail Abu (right) and Najib showing the seized syabu at the press conference.



Methamphetamine clandestine laboratory **in Kulim using Precursor Chemicals**

Sri Hartamas

Cland lab
(Sri Hartamas)

Cland lab
(Klang)

Integration Processes of Substance Classification, Registration of Products and Advertisement of Medicines to Overcome Bureaucracy

Present Law :

Through several processes

- *Poisons Board meeting for the classification of poisons*
- *Drug Control Authority Meeting for products registration*
- *The Medicines Advertisements Board meeting for approval of advertisements*

New Pharmacy Law

Integration Process of Substance Classification, Registration of Products and Advertisement of Medicines

- Through Senior Director of Pharmaceutical Services as Competent Authority
- Evaluation Committee as the secretariat

Integration of issuance of Instructions / Guidelines by the competent authority to address bureaucracy in amending the law

Present Law :

- Each new amendment would undergo several processes for approval in Parliament

New Pharmacy Law

The Competent Authority may:

- issue instructions or guidelines that are "Legally binding“
- advise the Minister to amend the fee schedule, product classification

Integrate the process of appointing authorities to tackle bureaucracy

Present Law :

- *Appointment of authorised officer by the Minister for cases of advertisements*
- *Appointment of inspectors by Chief Minister for Product cases*
- *Appointment of enforcement officers by Director General of Health*

New Pharmacy Law

- Competent Authority appoints enforcement officers
- Police and Customs also be appointed as ex-officio in the case of psychotropic substances and precursors

Country's obligation in rectifying legislation in line with international convention

Present Law :

- *There are no specific provisions for precursors as 1988 Convention on illicit traffic of psychotropic substances and precursors*

New Pharmacy Law

- more specific provisions, In line with international conventions, for control of psychotropic substances and precursors, including trafficking in psychotropic substances and precursor diversion

Overcoming lacuna in the current law

Present Law :

- *Cannot prosecute cases for possession of poison("possession per se")*
- *Control of Drugs and Cosmetics Regulations 1984 can be interpreted as more restrictive than the parent act i.e. Sale of Drugs Act 1952*
- *Case s under Sale of Drugs Act 1952 should be charged at court within 60 days*
- *No provision for "Counterfeit medicines", "Trafficking of psychotropic", "Drug diversion", "Data Exclusivity"*
- *No power to shut premises*

New Pharmacy Law

- Previous regulations are upgraded to be incorporated as sections in the Pharmacy Bill

  (Eg. Regulation of drug registration, the registration of pharmacists, psychotropic etc.)

- Provide provisions in the New Law

Overcoming lacuna in the current law

Present Law :

No provisions for:

- *Audit accountability*
- *Imposing minimum CPD points for renewal of annual certificate*
- *"Counterfeit medicine"*
- *Computerized transaction record*
- *Sampling for huge seizures*

New Pharmacy Law

- Provisions provided in the New Law

Implementation

- **No significant financial implications**
- **New Act could be implemented once it is approved by Parliament because there are provisions of *"saving and transition."***

TO SECURE CONVICTION

FOR CRIMINAL CASES

STANDARD OF PROOF IS BEYOND REASONABLE DOUBT

FOR CIVIL CASES

STANDARD OF PROOF IS BALANCE OF PROBABILITY

THANK YOU