

Controlling Counterfeit Medications

A New Role for Pharmacists?

➤ **Jane Nicholson**

➤ **BRAZIL 2006**

Illegal manufacture of medicines in private house

There's no such thing as a "good" counterfeit



ST 5/2006 11
THE WASHINGTON POST

ECM/COM

Smuggling of unapproved medicines



BY X2023 B
TM/SM/AG/2023/1

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Repacking of medicines to hide their true source and or identity



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**INTERNATIONAL PHARMACEUTICAL FEDERATION
FÉDÉRATION INTERNATIONALE PHARMACEUTIQUE**

Po Box 84200, 2508 AE The Hague, The Netherlands

F.I.P. Statement of Professional Standards

POLICY STATEMENT ON COUNTERFEIT MEDICINES

LISTS:-

- OBLIGATIONS OF NATIONAL PHARMACY ORGANISATIONS
- OBLIGATIONS OF PHARMACISTS

**WORKING GROUP SET
UP TO IMPLEMENT FIP POLICY STATEMENT
ON COUNTERFEIT MEDICINES**

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FIP to:

- Promote central reporting structure;
- Identify unreliable wholesalers;
- Urge Governments to provide robust legislation and tough penalties;
- Create awareness:-
 - ❖ amongst pharmacists/other healthcare workers
 - ❖ amongst patients;
- Collect data by collaboration with pharmacists/ medicines testing laboratories;
- Publicise available training materials;

Reporting form for counterfeit medicines detected in pharmacies				
Definition: A counterfeit medicine is deliberately and fraudulently mislabelled with respect to identity, composition and/or source. (WHO)				
Please tick the respective box or write in block letters				
Rx	OTC	Source of supply:		
			local wholesaler	re-import
			other pharmacy	other source
Brand name* (of the suspected counterfeit medicine) main active substance: strength: dosage form: package size: batch number: expiry date:				
Is the medicine suspected to be counterfeit or substandard? Counterfeit Substandard				
Why is this medicine suspected to be counterfeit?				
How was the suspected counterfeit medicine detected? Visual inspection Laboratory test Other investigation (specify)				
What measures were taken to prevent the risk of possible harm by the suspected counterfeit?:				
What is the most likely source for the suspected counterfeit medicine?:				
What is the suspected country of origin of the counterfeit medicine?:				
Name of Pharmacist (please print) Phone number Date:		Name of the pharmacy: Street (or P.O.B.) postal code and city:		



- Home
- What are Counterfeit Medicines?
- What is RAS?
- Why RAS?
- Purpose and scope
- How does RAS work?
- Follow-up Action
- Reporting Form
- FAQ
- WHO/WPRO-Home
- Other Information Sites
- Who to Contact?

HIGHLIGHTS

Welcome to the Rapid Alert System website.

This system serves as a rapid alert mechanism for WHO, Member States, and partner organizations for combating counterfeit medicines in the Western Pacific Region. When counterfeit medicines are detected in the Region and reported through the Rapid Alert System, relevant authorities are alerted immediately and time-sensitive actions are taken.

Effective measures for combating counterfeit medicines require appropriate detection, rapid alert mechanism and exchange of information, appropriate follow-up action by relevant authorities and independent organizations, and last but not least, appropriate publi [\(more\)](#)

:: Login for Admin/Focal ::

ID :

Password:

WHAT'S NEW

- [Fake Artesunate warning sheet 5. edition](#)
- [Fake drug in 2 Jiangsu deaths](#)
- [DECLARATION OF ROME](#)

[\[Archive\]](#)

EXTRACT OF A LETTER TO FIP MEMBER ASSOCIATIONS IN 2004 FROM GENERAL SECRETARY

“In a recent report from a Federal Drug Administration (FDA) Task Force, one of the potential weak links is the practice of passing products through multiple wholesalers. Therefore, an additional task for community and hospital pharmacists in your country would be to help identify unreliable wholesalers”

**INDIA TO INTRODUCE DEATH PENALTY
FOR PEDDLING FAKE DRUGS WITH
MINIMUM PRISON SENTENCES OF 10 YEARS**
New Delhi Ganapati Mudur

India plans to introduce the death penalty for the sale and manufacture of fake and counterfeit medicines that cause grievous harm. The move follows widespread concern that existing regulations pose little deterrence to unscrupulous drug vendors.

BMJ 2003; 327:414 (23rd August)

**AN EXPERT COMMITTEE HAS PROPOSED A
CENTRAL DRUG ADMINISTRATION
TO CONTROL LICENSING OF ALL DRUGS**

**AT LEAST 11 STATES IN INDIA DO NOT HAVE
LABORATORIES FOR TESTING DRUGS.
IN 15 STATES WITH FUNCTIONAL
LABORATORIES, ONLY SEVEN ARE ADEQUATELY
EQUIPPED AND STAFFED**

Fake Drugs Flood Bangladesh

- Bangladesh has 80,000 unlicensed drugstores
- The Drug Administration Authorities have 25 branches with 40 drug superintendents and inspectors.
- Estimated 150 million dollars worth of fake drugs produced per annum. (of 5000 drug samples 300 counterfeit)
- Bangladesh exports to 52 countries





**Fake Valium Shipments
for one day, March 2004.**

**Fake Sildenafil, one day's
shipments, March 2004,
Miami International**

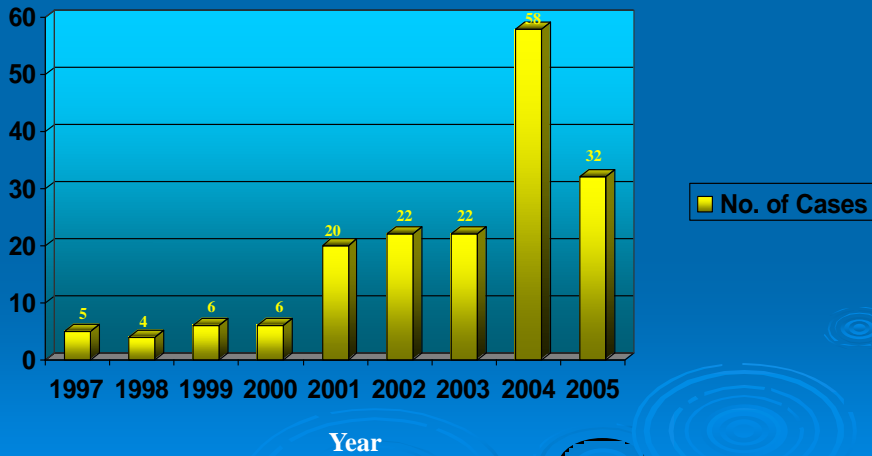


**Teddy bears
stuffed with
counterfeit
Viagra being
shipped to a
carpet
cleaning
business in
Ohio.**



Property of Marv Shepherd, University
of Texas

Trend in Number of FDA Counterfeit Drug Cases



Americans use Canadian and Mexican pharmacies because the medicines are cheaper

20 million packages containing medicines are sent annually to patients via the US mail

Canadians export an estimated \$1.1 billion medicinal products to US residents (about one third of the total Canadian drug bill)

Mexico sells 800 million dollars worth to US residents just from border "farmacias".

Most recent counterfeit medicines found in the USA:

**PROCRIT
LIPITOR
SEROSTIM
NEUPOGEN
EPOGEN
COMBIVIR
ZYPREXA
VIAGRA
DIFLUCAN**

Counterfeiters use “spoke and wheel” organisations.
Each spoke is not familiar with the next stage.

For example, ingredients are produced in one country (e.g. India), the product is formulated in another country, packaged in a third and shipped to a fourth to reach their final destination.

Difficult to track!!

F.I.P. Website address

- [http://www.](http://www.pharmacistscombatcounterfeiting.org)
- [pharmacistscombatcounterfeiting.org](http://www.pharmacistscombatcounterfeiting.org)”

Proposed Curriculum for a Hands-On Training Programme On Counterfeiting for Pharmacy Students

Objectives

At the end of the training session/tutorial students should:

1. Be able to define counterfeiting.
2. Have a good knowledge on the health legal and economic implications of counterfeiting.
3. Have a good knowledge of key players in preventing medical products counterfeiting.
4. Be able to identify the myriad roles pharmacists can play in fighting counterfeiting.
5. Develop a strategic plan for life-long learning and updating of skills and knowledge essential to recognise and preventing counterfeiting.

FIP WEBSITE LINKS TO WHO WEBSITE

www.who.int/medicines/organization/qsm/activities/qualityassurance/cft/counterfeit_factsheet.htm

and to websites of National Authorities providing information on counterfeit medicines

Website of the Authorities in Thailand Thai Drug Division

The situation of Thailand in the past 6 years

-----Select Year-----

Pictures of illegal medicines founded/
Unregistered/Smuggling Drug

-----Select illegal medicine below-----

Website of the Authorities in Thailand Thai Drug Division

Banned Pharmaceutical Products

-----Select illegal medicine below-----

Counterfeit/Unregistered Veterinary Drug

-----Select illegal medicine below-----

Counterfeit/Unregistered Psycholeptic

-----Select illegal medicine below-----

Psycholeptic Product

1. The front side and the back side of counterfeit Valium blister packed seized from the illegal manufacture.
2. Observation point of counterfeit : Font printed on the tablet surface is not smooth.

Unregistered/Smuggling drug

1. Anafranil which is registered in Thai drug system made in Switzerland and repacked in Thailand.
2. Unregistered/Smuggling drug made in Pakistan.

NIGERIA

The National Agency for Food and Drug Administration and Control (NAFDAC), alerts the general public on the identities of some notorious foreign companies who persistently indulge in dumping of fake and counterfeit drugs into the country. Impeccable top-level Federal security report and investigation by NAFDAC have reaffirmed the deep involvement of the under listed companies in the fake and counterfeit drug business.

1. Sinochem, Ningbo Import & Corp. China, Ningbo PR, China
 2. Yantai Foreign Economic & Technical Trade Corp.
17-2 Yuhangng West Road, Yantai, China
- listed are names and addresses of

5 Chinese Companies
14 Indian Companies

To ensure public safety, NAFDAC hereby directs as follows:-

- Nigerians are barred from importing drugs from companies from these companies forthwith;
- Any drug(s) imported from these companies will be seized and destroyed by NAFDAC without any conditions.

“The general public, particularly Drug Importers and Distributors are hereby notified in their own interest, to stop having any business dealings with the aforementioned companies”

SEAM TANZANIA*

**Quality Assurance Testing by Minilabs
At Port of Entry**

PRE-LAUNCH OBSERVATIONS

Failure rate 13% (counterfeiting contributed
To 25% failures)

POST-LAUNCH OBSERVATIONS

Failure rate 2%

Management Sciences for Health 2003*

COSTS

MINI-LAB KIT – 3,000 EURO plus VAT

**NEAR INFRA-RED
SPECTROSCOPY MACHINE –
15,000 EURO**

**FIP extract of message to member associations for
advise to patients on Internet sales**

PLAY SAFE WITH MEDICINES

Good health is one of the most important issues in everyone's life. If you do not agree now, you will certainly do so as soon as you fall ill. Fortunately, we are in a privileged position today. In most instances, there are medicines available to cure or improve the "ill-health" status.

We can find valuable information on the internet about diseases and the various possible treatments. This may help to make decisions if we are able to understand them. However, this is not always easy and if you are not sure about the advice, ask your pharmacist.---

Message to General Public from Royal Pharmaceutical Society of GB and Patient Association

Government should:

- Outline the hazards of buying drugs over the internet without consultation-side effects, risks from counterfeit medicines, interaction with other drugs.
- Draw public attention to the legal and regulatory framework relating to prescription drugs.
- Encourage the public to report dubious online pharmacies to the Medicines and Healthcare Products Regulatory Agency (MHRA) and the RPSGB

Message to General Public from Royal Pharmaceutical Society of GB and Patients Association

Service Providers should:

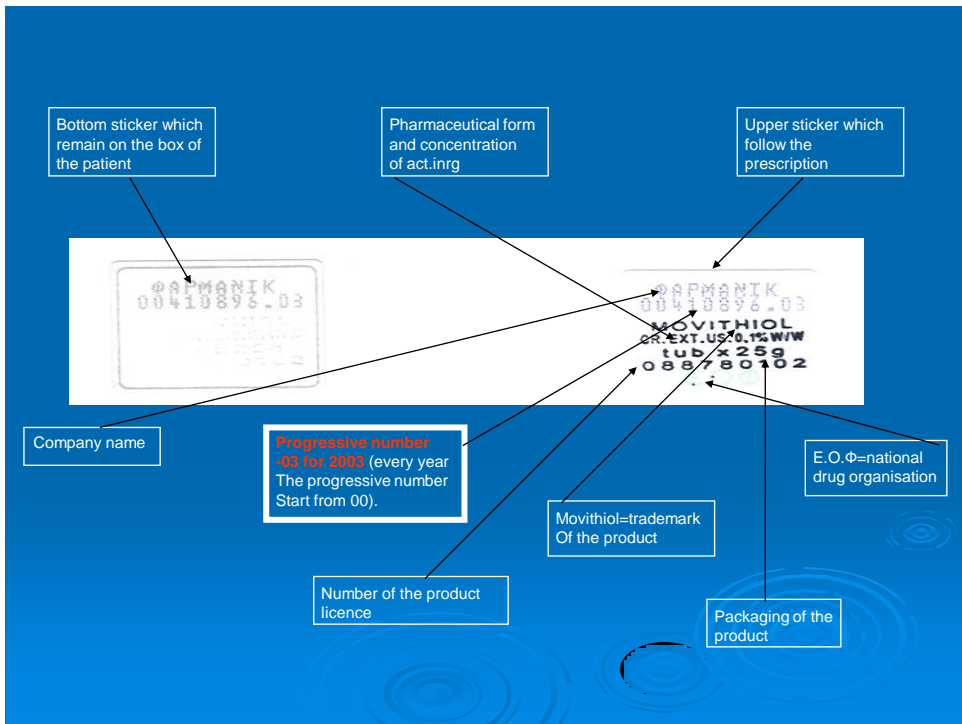
- Filter out drug-related spam and remove illegal sites from their servers.

Patients should:

- Buy medicines only from high-street or UK-based online pharmacies. Both these sources are regulated by the RPSGB.

Parents should:

- Install a firewall and e-mail spam filters on the family computer, and assume responsibility for the way it is used.



Packaging Security Devices and Tracing Systems

- Fluorescent fingerprinting
- Tamper Proof Coloured Stickers and Holograms
- DNS Bar Coding
- Readable Micro text in Cartons
- Printing and 3D Embossing
- Dry Peel Seals



Excellent to monitor the flow and verify product authenticity but will not stop counterfeiting

PHARMACEUTICAL SECURITY INSTITUTE

The Pharmaceutical Security Institute is a not-for-profit membership organization dedicated to protecting health, sharing information on the counterfeiting of pharmaceuticals, and initiating law enforcement actions through the appropriate authorities.

REVIEW OF CURRENT LEGISLATION WORLDWIDE

Pharmacy students at University of Illinois have obtained information on legislation from 93 countries

A post-graduate law student at DePaul University has spent the summer verifying the data obtained by the students

A table in the draft report shows by country, the current legislation, the definition of counterfeit drugs and the penalties for drug counterfeiting

The results are to be presented at a Conference in November 2006 at DePaul University with the aim of producing model Anti-Counterfeiting legislation

Jamaica's Respond To Counterfeit Questionnaire

- The Pharmaceutical Society is a professional body representing pharmacists.
 - The Pharmacy Council a body that is concerned with the registering of pharmacist, pharmaceutical students, pharmacies and owner's of pharmacies; the council also regulates the training of pharmaceutical students.
 - The MOH - Pharmaceutical Standards and Regulation Department – that body which ensures that the Food and Drug Act and Regulations are followed. Yes this body is also involved in inspection of sub-standard or counterfeit medicines.
- Each of the above mentioned organizations received a questionnaire. The results were as follows:
- PSJPCJMOHQuestion
 - #1aNo NoNo- Instead, recently, the S&RD publishes a list of all pharmaceutical preparations which can legally be purchased. This list highlights the manufacturer and the country of origin. The list is readily available to health professionals as well as the public.Question
 - #1bNoNoAs mentioned above. Question
 - #2Not to my knowledge No - The curriculum at our Rx School does not train Rx students on this topic partly because this is not popular here in Jamaica.

Conclusions

Is Controlling Counterfeit Medications a new role for the Pharmacist? – unfortunately YES

The activities of the Working Party are ongoing.

We are determined to keep bringing the subject of Counterfeit Medicines to the attention of all pharmacists .

Publicity is central to our work and we need your help to counteract this menace.