APEC LSIF Anti-Counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: *Building International Cooperation to Protect Patients*

Final Report & Proceedings

APEC Life Science Innovation Forum

APEC Committee on Trade and Investment

February 2009

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FINAL REPORT

APEC LSIF Anti-Counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: *Building International Cooperation to Protect Patients*

I. Summary and Background:

This seminar was jointly organized by the USFDA and USDOC. Over 100 participants attended the seminar from 10 APEC economies (Mexico, Chile, Peru, the United States, Indonesia, Malaysia, Singapore, Vietnam, Philippines, and China) and six non-APEC Latin American countries (Brazil, Argentina, El Salvador, Honduras, Panama, and Uruguay).

The seminar included presentations (http://www.amcham.com.mx/Envios/Invitacion/Invitacion.htm) and panels related to the global counterfeit medical products problem including 1) how APEC economies combat counterfeit medical products, 2) the importance of intra government coordination, 3) industry perspectives on the counterfeit medical products problem, 4) the international and public health aspects of the counterfeit medical products problem, 5) quality of medicine activities and mobile laboratory detection of counterfeit medicines, 6) the role of the judiciary and law enforcement, and 7) public awareness.

The Mexico City seminar was the third seminar in a series of seminars funded by the APEC Life Science Innovation Forum (LSIF). The first two seminars took place in Singapore (January and March 2008). The findings of the first two Singapore seminars were presented to APEC Ministers during the August 2008 LSIF annual meeting in Peru.

The findings and action plans developed during the Mexico City seminar will be presented to APEC Ministers during the LSIF annual meeting during July 2009 in Singapore.

II. Development of Action Plans:

The seminar participants were divided into the following three breakout sessions - 1) criminal investigation, 2) penalties and legislation, and 3) public awareness.

Below are the major finding of each breakout session:

A. Criminal Investigation:

- Agreement was reached that all APEC economies do not have sufficient resources for effective criminal investigation and prosecution of medical product counterfeiters. Agreement was also reached that there needs to be

more effective communication between law enforcement stakeholders, and that improvement will lead to better criminal investigation results.

- The participants in this breakout group also agreed that industry and government cooperation would be useful and that future APEC training on cooperation of industry, customs and law enforcement officials was recommended.

- Participants also agreed that it is very important for each APEC economy to establish a single point of contact (SPOC) for criminal investigations.

B. Penalties and Legislation:

- Agreement was reached that a study of the extent of the existence of counterfeit medicines and counterfeit medical product activities within APEC economies would be useful. This study should be conducted by an academic, with input from health professionals, government officials, industry and NGOs.

- Participants also agreed that APEC should develop a common definition for counterfeit medical products for the purpose of this study. It was recommended that APEC use the 1992 WHO definition with the addition of including medical devices.

- The participants also agreed that there should be harmonized legislation and penalties for prosecuting medical product counterfeiters within APEC economies. There was also recognition that there may be differences in approaches to legislation and penalties based upon regional or country differences.

- The participants also agreed that WHO IMPACT guidance documents would be a useful starting point in developing harmonized penalties and legislation.

C. Public Awareness:

- Participants agreed to endorse the recommendations from the March 2008 Singapore seminar.

- Participants also agreed that APEC should conduct a study on counterfeit medicines sold on internet sites including both APIs and formulations.

- The participants also agreed to finish the additions to the communication and public awareness action plan by the end of June. USFDA agreed to serve as the coordinator for this effort, and participants from Brazil, Argentina and Peru volunteered to lead on various portions of the action plan.

- The revised action plan will include education campaigns for consumers and health professionals.

III. Next Steps and Future APEC Anti-counterfeit Medical Products Activities:

During the concluding session of the seminar the activities of a possible future APEC project was discussed. Agreement was reached that the next APEC project should focus on specific activities, rather than on a seminar with broad coverage. As was the case for the previous APEC anti-counterfeit projects, we anticipate requesting an APEC waiver to enable key non-APEC economies to be invited since the global counterfeit medical products problem is not limited to the APEC region.

Below is a listing of possible future APEC activities discussed during the concluding session of the seminar:

- A focused workshop on mobile laboratory detection for counterfeit medicines. China proposed to host this workshop at Peking University.

- A workshop focused on the regulation of APIs and activities to stop the transshipment of APIs globally that are used in the production of counterfeit medicines.

- A workshop focused cooperation between law enforcement, customs and industry on counterfeit medicine criminal investigations. A possible location for this seminar is the new Korea APEC Regulatory Harmonization Center.

- A workshop focused on establishing counterfeit medical product single points of contact for enforcement and public awareness. A possible location for this seminar is the new Korea APEC Regulatory Harmonization Center.

- A workshop focused on public awareness of counterfeit medical products. Peru offered to host this workshop.

- Funding to conduct a study of the extent of the existence of counterfeit medicines and counterfeit medical product activities within APEC economies. This study should be conducted by an academic, with input from health professionals, government officials, industry and NGOs.

- Funding to conduct a study on the extent of the impact of counterfeit medicines entering APEC economies through internet sites, including both dosage form medicines and APIs.

IV. Summary of Participants Evaluation of the Seminar

Following the seminar, participants were asked to fill out a brief evaluation form capturing their thoughts of the event. The analysis of these evaluation forms provides productive feedback as well as guidance for future events. In total, 50 evaluations were received, of which 34% identified themselves as health regulators.

There was a large representation of APEC economies at the seminar. Evaluation forms were received from participants from the following countries: Argentina,

Brazil, Chile, China, European Union, Honduras, Indonesia, Malaysia, Mexico, Panama, Peru, Singapore, Uruguay, United States and Viet Nam. 38% of the evaluation forms were submitted by participants from Mexico, suggesting that Mexico had the highest attendance rate of any of the countries represented.

80% of the participants who completed the evaluation reported that they had not attended either of the first two workshops held in 2008 in Singapore; however, 76% rated the seminar either "Excellent" or "Very Good," and 18% rated it "Good."

When asked to rate the best aspect of the seminar, 48% of those who completed the evaluation selected the format of the event, which "allowed for active discussion**,"** "Effective forum for interaction" or "Group Discussions." Other highly rated elements of the seminar included the trainers' expertise and knowledge, the ability of government officials to meet experts, and providing a good opportunity to network.

Participants were also asked to provide suggestions on future seminars. The most common response received was a request for more time to work in breakout groups. Other suggestions included increased participation of judicial and political authorities and the request for handouts and presentations to be conducted only in English, as opposed to both English and Spanish.

Agenda - 2/11/09
Asia Pacific Economic Cooperation, Life Sciences Innovation Forum
Anti-Counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: *Building International Cooperation to Protect Patients*
February 17 - 19, 2009, Mexico City, Mexico

Secretaría de Relaciones Exteriores (Foreign Relations Ministry)
Av. Juárez No. 20, Col. Centro 06010, México, D.F.

(Note: Most participants will be staying at the Sheraton Centro Historico in Mexico City; however, the seminar will take place at the Mexico Foreign Relations Ministry. This is a short walk from the hotel and there will be staff with signs in the hotel lobby to direct participants how to walk to the seminar.)

Tuesday, February 17

8:00 - 9:00 a.m.	**Registration and Check-In**
9:00 - 9:55	**Welcome and Opening Remarks** ***Ambassador Rogelio Granguillhome Morfin,*** Head of the Office of Economic Relations and International Cooperation, Ministry of Foreign Affairs ***Miguel Ángel Toscano Velasco,*** Mexico Ministry of Health, Federal Commissioner of COFEPRIS, (Federal Commissioner of (Federal Commission for the Protection from Sanitary Risks) ***Lic. Jorge Amigo Castañeda***, Director of the Mexico Patent and Trademark Office (IMPI) ***Paul Seligman,*** Director of Latin America Regional Office, U.S. Food and Drug Administration ***Jim Williard,*** Acting Deputy Chief of Mission, U.S. Embassy, Mexico City ***Speaker,*** American Chamber of Commerce of Mexico
9:55 - 10:00	**Five minute break -- please remain seated**
10:00 - 10:30	Summary of Asia APEC Seminars and WHO International Medical Products Anti-Counterfeiting Task Force (IMPACT) ***Valerio Reggi***, Executive Secretary, International Medical Products Anti-counterfeiting Task Force (IMPACT), WHO

10:30 - 11:30	Examples of How APEC Economies Combat Counterfeit Medical Products ***Elizabeth Carmelino García***, Executive Director, Control and Sanitary Vigilance, DIGEMID, Peru ***Raúl Chavarría Salas,*** Mexico Sanitary Promotion Commissioner ***Wan Hamid Wan Ibrahim,*** Deputy Director of Enforcement (Operations), Ministry of Health, Malaysia
11:30 - 11:45	**Coffee Break**
11:45 - 12:30	How APEC Economies Combat Counterfeit Medical Products (Continued) **Kelvin Tan,** Deputy Director, Enforcement Branch, Health Products Regulation Group, Singapore Health Sciences Authority Q and A Session
12:30 - 1:00	***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines, Partnership for Safe Medicines - Proposal for Expanded Latin American Participation
1:00 - 1:30	**Group Photo**
1:30 - 2:30	**Lunch**
2:30 - 4:30	**Panel Discussion: Importance of Intra-Government Collaboration to Detect and Deter the Counterfeiters - Regulatory, Enforcement and Judicial Aspects** **Moderator:** to be determined ***Tom Kubic***, President, Pharmaceutical Security Institute ***Paul Seligman,*** Director of Latin America Regional Office, U.S. Food and Drug Administration ***Valerio Reggi***, Executive Secretary, International Medical Products Anti- Counterfeiting Task Force (IMPACT), WHO ***Ramiro Esquivel,*** Prosecutor on Intellectual Property Rights from the Attorney General's Office, Panama
4:30 - 4:45	**Coffee Break**
4:45 - 5:15	***Jeffrey Gren***, Director Office of Health and Consumer Goods, Manufacturing and Services, U.S. Department of Commerce, International Trade Aspects of the Counterfeit Medicines Problem

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Wednesday, February 18

9:30 - 11:00 a.m.	**Panel Discussion: Industry Perspectives**

	Moderator: ***Lew Kontnik,*** Director of Brand Protection, Amgen Inc, Vice-chair PhRMA Anti-counterfeiting Working Group ***Tom Kubic****,* President, Pharmaceutical Security Institute, Pharmaceutical Industry Perspective ***Scott Miller,*** Director, Global Trade Policy, Procter & Gamble, Consumer Health Products Industry Perspective ***Leon Atencia,*** Director Latin American Regulatory Affairs, Amgen ***Thomas Warren,*** Director, Health Policy Johnson & Johnson Government Affairs & Policy, Medical Devices Industry Perspective
11:00 - 11:15	**Coffee Break**
11:15 - 1:00	**Panel Discussion - Quality Medical Products** **Moderator: Jeffrey Gren,** U.S. Department of Commerce ***Tom Layloff****,* Principal Quality Assurance Advisor, Supply Chain Management System, Arlington, VA, USA, Pharmaceutical Supply Chain Issues, E-Pedigree, and Insuring Quality Pharmaceutical Ingredients ***Prof. Shaohong Jin****,* Executive Director, National Institute for Control of Pharmaceuticals and Biological Products, People's Republic of China, Success Story - China Counterfeit Medicine Detection Program ***María José Sánchez,*** General Coordinator, ANMAT, Argentina, Example of Argentina's Counterfeit Medicine Detection Program
1:00 - 1:30	**Breakout Sessions - Overview and Instructions** ***Valerio Reggi****,* Executive Secretary, IMPACT, WHO
1:30 - 2:30	**Lunch Break**
2:30 - 4:30	**Panel Discussion - The Role of the Judiciary and Law Enforcement in Stopping the Spread of Counterfeit Medical Products and Prosecuting Counterfeiters** **Moderator:** ***Valerio Reggi****,* Executive Secretary, IMPACT, WHO ***Jose Antonio Villamil,*** Director of the Patent Division of Uruguay´s Intellectual Property Directorate ***Patrick Ford,*** Senior Director Americas Region, Global Security, Pfizer Inc. ***Lucy Delgado,*** Criminal Lawyer, DIGEMID, Peru
4:30 - 4:45	**Coffee Break**
4:45 - 6:30	**Panel Discussion - Educational Efforts to Stop the Spread of Counterfeit Medical Products (public awareness campaigns,**

efforts to educate consumers on the dangers of purchasing drugs through the internet, role of health professionals)

Moderator: ***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines
Valerio Reggi, Executive Secretary, IMPACT, WHO
Industry Speaker
Maristela Almeida, Management of Quality Monitoring, Control and Inspection of Supplies, Medicines and Products Unit, Brazilian National Health Surveillance Agency (ANVISA)
Eric Conte, Director of the Drugs and Pharmacy Department of the Ministry of Health, Panama

7:30 - 9:30 **Hospitality Reception -** Hotel Sheraton Centro Histórico, Av. Juárez No. 70, Col. Centro, C.P. 06010, México, D.F., Room - Don Diego I

Thursday, February 19

Breakout sessions will be divided into two smaller workgroups that will develop action plans to be implemented by APEC economies based upon recommendations of the two Asia seminars. Sessions run concurrently offering participants the opportunity to contribute to two breakout group. Participants will build upon the recommendation of the January and March 2008 APEC funded Asia (Singapore) seminars. Recommendations from the Asia seminar will be provided to Latin American seminar participants.

9:30 - 11:15 a.m. **First Set of Breakout Sessions:**

A. Criminal Investigation - Development of Action Plans on How Law Enforcement, Customs, and Regulators Can Cooperate (both within each APEC economy and among APEC economies) to Prosecute and Stop the production of Counterfeit Medical Products.
Moderator: ***Tom Kubic***, President, Pharmaceutical Security Institute
Co-moderator: ***Lucy Delgado,*** Criminal Lawyer, DIGEMID, Peru

B. Penalties and Legislation - Development of Actions Plans on Developing Deterrent Penalties, and Legislation to Provide Custom and Law Enforcement Officials the Tools to Stop Counterfeiters.
Moderator: ***Maria Beatriz Dellore,*** Regional IP Specialist for Latin America, U.S. Consulate General - Rio de Janeiro

U.S. Patent and Trademark Office
Co-moderator: ***Kelvin Tan,*** Deputy Director, Enforcement Branch, Health Products Regulation Group, Singapore Health Sciences Authority

C. **Communications and Detection -** Development of Action Plans on Communication to Educate Stakeholders on the Dangers of Counterfeit Medical Products, Detection of Counterfeit Medical Products by Identifying Legitimate and Falsified Medical Products, and on the Use of the WHO Rapid Response Database.
Moderator: ***Valerio Reggi,*** Executive Secretary, WHO IMPACT, WHO
Co-moderator: ***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines

11:15 - 11:30 **Coffee Break**

11:30 - 1:30 **Second Set of Breakout Sessions:**

A. Criminal Investigation - Development of Action Plans on How Law Enforcement, Customs, and Regulators Can Cooperate (both within each APEC economy and among APEC economies) to Prosecute and Stop the production of Counterfeit Medical Products
Moderator: ***Tom Kubic***, President, Pharmaceutical Security Institute
Co-moderator: ***Lucy Delgado,*** Criminal Lawyer, DIGEMID, Peru

B. Penalties and Legislation - Development of Actions Plans on Developing Deterrent Penalties, and Legislation to Provide Custom and Law Enforcement Officials the Tools to Stop Counterfeiters
Moderator: ***Maria Beatriz Dellore,*** Regional IP Specialist for Latin America, U.S. Consulate General - Rio de Janeiro U.S. Patent and Trademark Office
Co-moderator: ***Kelvin Tan,*** Deputy Director, Enforcement Branch, Health Products Regulation Group, Singapore Health Sciences Authority

C. **Communications and Detection -** Development of Action Plans on Communication to Educate Stakeholders on the Dangers of Counterfeit Medical Products, Detection of Counterfeit Medical Products by Identifying Legitimate and

Falsified Medical Products, and on the Use of the WHO Rapid Response Database.
Moderator: ***Valerio Reggi,*** Executive Secretary, IMPACT, WHO
Co-moderator: ***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines

1:30 - 2:30 **Lunch Break**

2:30 - 3:30 Presentation of Action Plans from Breakout Group Moderators

3:30 - 3:45 **Coffee Break**

3:45 - 5:15 **Open Discussion/Next Steps**

- Summary
- Action Plan
- Relationship with WHO IMPACT

5:15 - 5:30 **Concluding Comments and Adjournment**

Anti-counterfeiting Medical Product and Pharmaceutical Product Safety Seminar:Building International Cooperation to Protect Patients

APEC - LSIF

Elizabeth Carmelino García

DIRECCIÓN GENERAL DE MEDICAMENTOS INSUMOS Y DROGAS
DIGEMID
REPUBLICA DEL PERU

February 17 – 20, 2009, Mexico

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ORGANIZATION
GENERAL DIRECTION OF MEDICAL PRODUCTS (DIGEMID)

MINISTRY OF HEALTH

DIGEMID

- DIRECTION OF SANITARY AUTHORIZATIONS
- DIRECTION OF ACCESS AND RATIONAL USE OF DRUGS
- DIRECTION OF CONTROL AND SANITARY SURVEILLANCE
  - TEAM OF CONTROL AND SURVEILLANCE OF PRODUCTS
  - TEAM OF CONTROL AND SURVEILLANCE OF ESTABLISHMENTS
  - TEAM OF CONTROL OF ILLEGAL TRADE
  - TEAM OF ADVERTISING CONTROL

ECONOMY POLICY GUIDELINES

- **Universal access to essencial medicines.**
- **Regulation and quality of medical products**
- **Promotion of the rational use of medicines**

DRUG POLICY GUIDELINES

Regulation and Quality of Medical products

- To eradicate smuggling, informal trade and counterfeit of medical products
- To strengthen the current activities and to implement working plans involving multisectorial participation.
- To apply criminal and administrative mechanisms to strengthen the control o f smuggling and counterfeiting.

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GENERAL INFORMATION

	PERÚ
POPULATION	28 220 764
DENSITY (inhab. /km2)	21.9
REGIONS	25
SUBREGIONS	05
HEALTH DIRECTIONS	03

ILLEGAL COMMERCE OF DRUGS

Sanitary observations

- EXPIRED
- MISBRANDED
- WITHOUT SANITARY REGISTRATION (SMUGGLING)
- SELLING of MEDICAL SAMPLES
- COUNTERFEIT
- UNKNOWN ORIGIN
- STOLEN FROM PUBLIC

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COUNTERFEIT PRODUCTS
DEFINITION OF COUNTERFEIT MEDICINES (WHO)

"A counterfeit drug is manufactured improperly ,so deliberately and fraudulently in regard to their identity or origin. They may include products with right ingredients or with wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging".

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CHECKING A COUNTERFEIT PRODUCT

Inspections and raids

Presumedly counterfeit medicine

Organoleptic check with the owner of the Sanitary Register

Quality Control at the State Laboratory (INS – CNCC)

Public Ministry

COUNTERFEIT

EL PERU AVANZA

ILLEGAL COMMERCE OF PHARMACEUTICAL PRODUCTS

It comes through:

- **Inspections to pharmaceutical establishments**
- **Presence in customs**
- **Followed up of complaints received and reids**
- **Multisectoral participation**
- **Education and diffusion**

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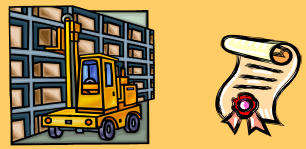
COMBATING ILLEGAL COMMERCE

1. INSPECTIONS TO PHARMACEUTICAL ESTABLISHMENTS

Laboratory

GMP Certificate

Drugstores



GSP Certificate

Dispensing Establishments

Compliance to GSP (Inspections)

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2. Working in Customs

Since 2007 we have inspectors in customs warehouses in the airport, this to verify the entrance of products into the country.

3. Complaints and raids

Doing follow up to complaints from people and/or coordinating actions with Police / Prosecutor

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Multisectorial Participation: CONTRAFALME

4. Multisectorlal Participation

TECHNICAL GROUP MULTISECTORIAL TO PREVENT AND COMBAT SMUGGLING, ILLEGAL COMMERCE AND COUNTERFEITING OF PHARMACEUTICALS AND RELATED

contrafalme
Grupo Técnico Multisectorial de Prevención y Combate al Contrabando, Comercio Ilegal y Falsificación de Productos Farmacéuticos y Afines

Ministerial Resolution Nº 047-2006-PCM

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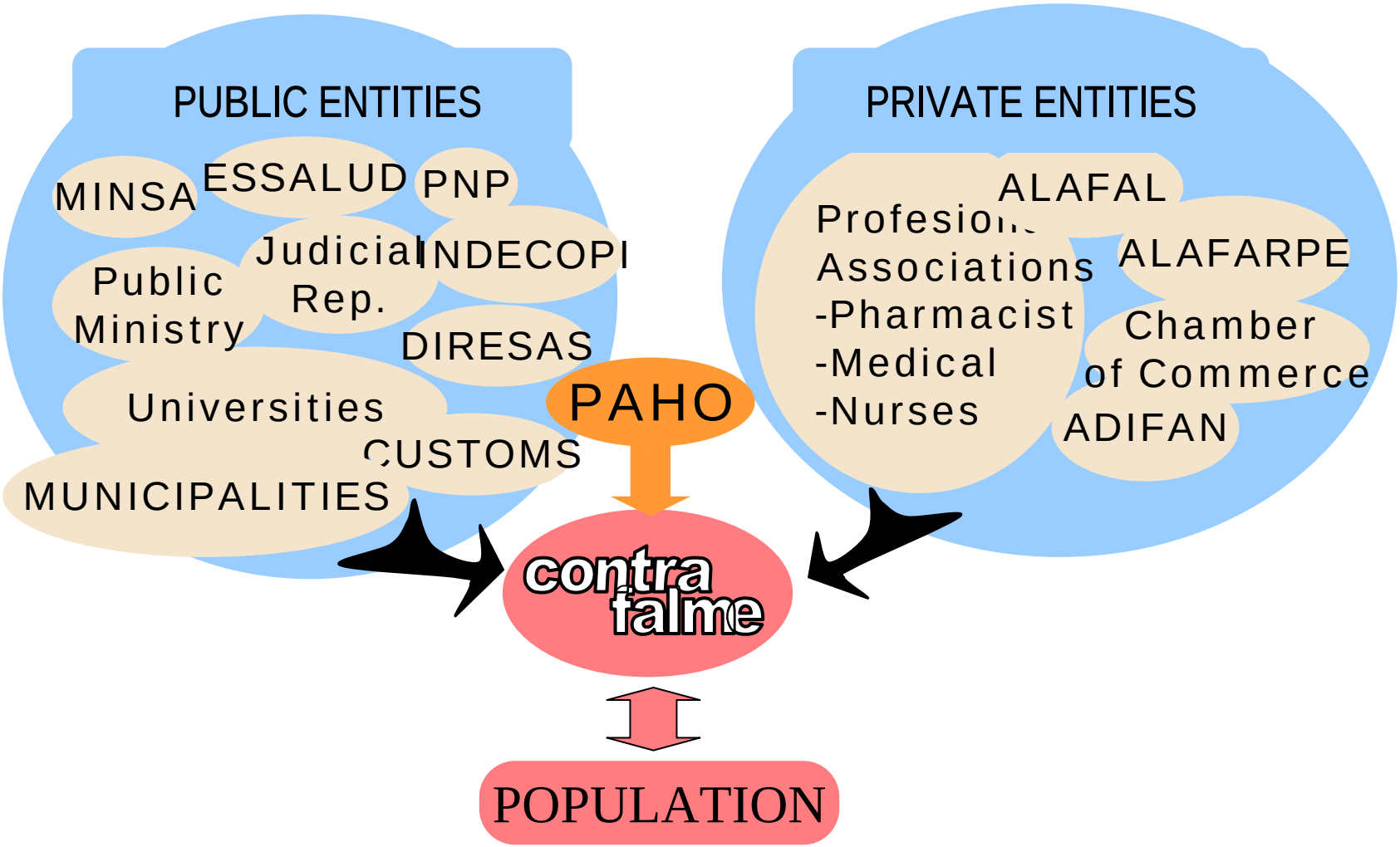
Multisectorial Participation: CONTRAFALME



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Multisectorial Participation

Objective of CONTRAFALME

- Develop a plan to combat smuggling, illegal commerce, counterfeiting of pharmaceuticals and related products also to promote the implementation of operational strategies and concrete actions for preventing and combating illegal commerce through inter-agency coordination at national and international levels to safeguard health and life of the population.

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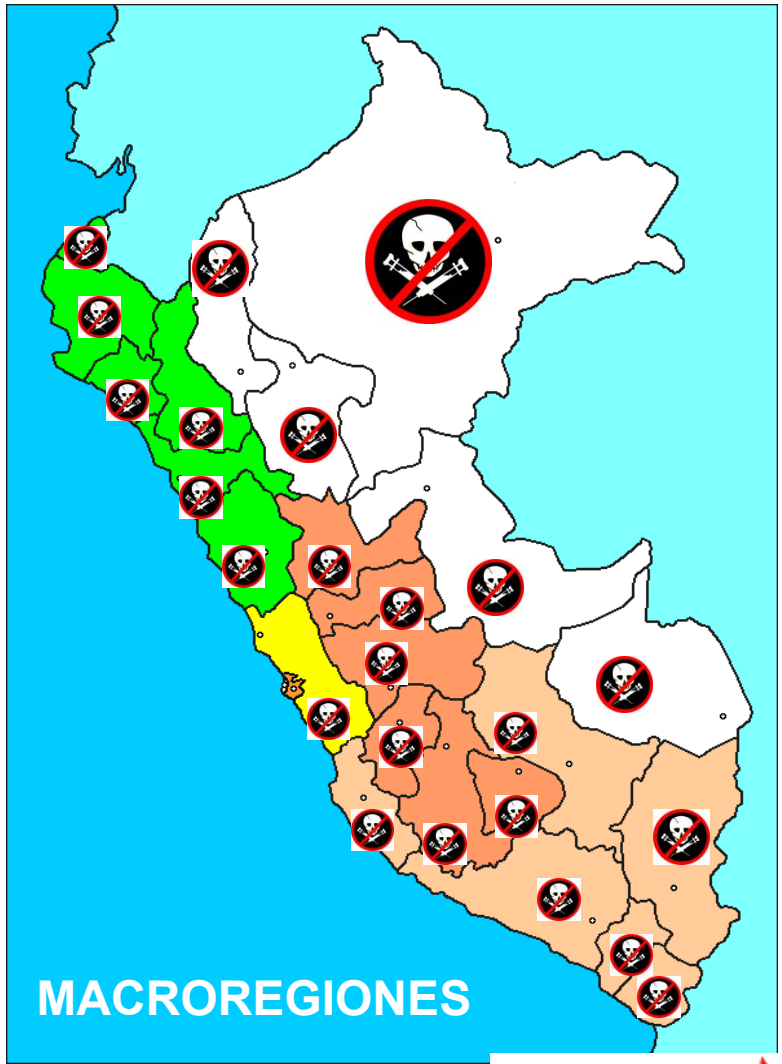
Multisectorial Participation

PERU is currently experiencing a process of decentralization

25 REGIONS
5 SUBREGIONS
3 HEALTH DIRECTIONS

AT ECONOMY LEVEL EACH REGION HAS A MULTISECTORIAL TECHNICAL GROUP FORMED WITH AUTHORITIES RELATED TO THEIR REGIONAL PROBLEM

9 DIRESAS have formally a Regional Resolution.



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Multisectorial Participation

Working Groups - CONTRAFALME

1. Legislation
2. Control and Sanitary Intelligence
3. Financing
4. Education and diffusion

Multisectorial Participation

Working Group OF LEGISLATION

- It has been working on ammending the Penal Law to increase penalties and improve characterization
- Ammendments are now in the Congress.

Multisectorial Participation

Working Group OF CONTROL AND SANITARY INTELLIGENCE

DIRINCRI PNP

DIVISIÓN DE INVESTIGACIÓN DE HOMICIDIOS

DEPARTMENT OF INVESTIGATION OF FRAUDULENT MEDICAL PRODUCTS

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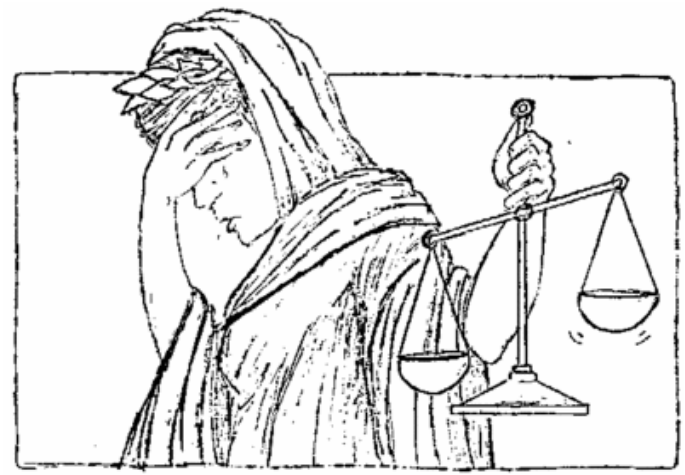
Multisectorial Participation
WORKING GROUP OF CONTROL AND SANITARY INTELLIGENCE

Working Group OF CONTROL AND SANITARY INTELLIGENCE

- **We are working to have a specialized prosecutor office**



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Multisectorial Participation
WORKING GROUP OF CONTROL AND SANITARY INTELLIGENCE

Working Group Of Financing

- There are activities thet require coordinations that CONTRAFALME members may support however nowadays most of them are done with our own resouces

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EDUCATION AND DIFFUSION

CAMPAIGNS

In the year 2007 two campaigns were realised

"FOR YOUR HEALTH , KEEP AN EYE ON THE MEDICINES YOU TAKE

"FAKE MEDICINE KILLS"

- Hospitals
- Markets of supplies
- Squares and plazas
- Universities
- Schools

Ministerio de Salud
Personas que atendemos personas

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"LA MEDICINA BAMBA MATA"

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EDUCATION AND DIFFUSION

CAMPAIGNS

In the year 2008 two campaigns were realised

"IF YOU WANT TO GET WELL, THEN LEARN HOW TO USE MEDICINES"

- Hospitals
- Markets of supplies
- Squares and Plazas.
- Universities
- Schools

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EDUCATION AND DIFFUSION

CAMPAIGNS

GIGANTOGRAFIA PARA SER EXHIBIDOS EN LOS MODULOS DE DIFUSION EN LAS DIRECCIONES DE MEDICAMENTOS A NIVEL NACIONAL Y DURANTE LAS EXPOSICIONES Y CAPACITACIONES.

AFICHE PARA SER PEGADOS EN LOS LOCALES QUE COMERCIALIZAN PRODUCTOS FARMACEUTICOS O AFINES Y OTROS LOCALES QUE LO SOLICITAN Y AUTORIZAN. (TAMAÑO DE PAPEL A1)

GORRO MOD.1

GLOBOS

ROTATORIO

ROTATORIO

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EDUCATION AND DIFFUSION

GUIDED VISITS

Because our allies are used to see what is wrong……

Speech /sensitization from our Director

Following GMP rules in place……

EDUCATION AND DIFFUSION

GUIDED VISITS

Divided into groups we visit the facility

We started on 2007 and since then we have had 5 GUIDED VISITS

1. **Media – Press – 40**
2. **Penal Prosecutors and of Prevention of Crime from Lima and the North Side – 100 (3 meetings)**
3. **Judges from the Judicial of Lima – Callao and North Side - 34.**

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EDUCATION AND DIFFUSION

RADIO AND PRESS

Spaces obtained in local media that maintains the presence of DIGEMID beyond campaigns.

HASTA JULIO LA DIGEMID CERRÓ 20 FARMACIAS COMO MEDIDA DE SEGURIDAD SANITARIA

Advierten mayor presencia de medicinas adulteradas

➤ Locales se ubican cerca de hospitales y en distritos urbano-marginales de Lima

LESLY BAHAMONDE HIDALGO

Productos farmacéuticos falsificados en 2004

PRODUCTOS FALSIFICADOS	CASOS	(%)
NEUROBION INYECTABLE	50	28
EPANIN 100	30	17
HEPASKONTA INYECTABLE	26	15
DIPROSPAN 8P	8	5
APRONAX 550	9	5
ERODERM	8	5
CYNODAN DEPOT	3	3
HEPASKONTA GRAGEAS	3	3
VONTROL 80 MG	3	3
CLOROTRIMETÓN 8P	3	3
OTROS	9	9
TOTAL	169	100

cómo detectarlas

- Los envases deben estar intactos, sin tachaduras o sobreetiquetados.
- La impresión de los datos tiene que ser nítida, legible.
- Los productos deben tener fecha de vencimiento, número de lote y registro sanitario.
- Las tabletas deben ser uniformes; las soluciones no deben estar precipitadas o turbias; los inyectables no deben tener cuerpos extraños.
- Toda farmacia, botica o droguería tiene que contar con la presencia de un químico-farmacéutico durante el horario de atención.

• Gustavo Bravo, director de Digemid.

Al respecto, Bravo hizo un llamado a la ciudadanía a que tome conciencia del riesgo que significa adquirir medicinas en establecimientos informales no autorizados.

Ante este panorama, la Digemid trabaja en la ejecución de estrategias multisectoriales en las que participan la Policía Nacional, Indecopi, la Sunat, las municipalidades y el sector privado, con la finalidad de aunar esfuerzos para luchar contra el mercado ilícito de medicamentos.

Sanción y decomiso

Gustavo Bravo manifestó que si el producto es observación en materia de investigación, se procede al decomiso, y si presentan objeciones sanitarias que ponen en riesgo la salud de las personas, se procede al cierre del establecimiento.

Asimismo, si se encuentran más infracciones al medicamento, la sanción puede ir de dos hasta 100 Unidades Impositivas Tributarias (cada UIT = S./3,100 nuevos soles).

"Cuando el caso es considerado un delito, se pone en conocimiento del Ministerio Público para que sea incluido la denuncia respectiva ante el Poder Judicial, y se sancione penalmente al dueño del establecimiento". Sin embargo, reconoció que es lamentable que las sanciones legales punitivas no resulten muy severas.

...urga cárcel por falsificar ...as pese a 324 denuncias

...BOTICA NACIONAL FARMA

Penas son bajas e inaplicables

¿NO PASÓ NADA?

MÁS DATOS

PRUEBA

s comunes de adulteración

- Venden muestras médicas, borran este título y lo comercializan como un medicamento que se encuentra al alcance de todos.
- Se comercializan productos robados de las instituciones publicas.
- Lavan la parte del blister (tira laminada) y vuelven a imprimir el nombre de la marca del producto utilizando solventes. Estos líquidos contaminan aun mas el medicamento.

De enero a junio de este año, la Digemid realizó 20 operaciones en diversas boticas, farmacias y droguerías de los distritos de Breña, Cercado de Lima, Comas, Huacho, San Juan de Lurigancho, Callao y Cañete, entre otros, que determinaron el cierre temporal o el decomiso de los "medicamentos".

"Las personas que negocian este tipo de productos conocen el daño que pueden causar en la salud de la población; sin embargo, para ellos el fármaco representa sólo un bien comercial y de lucro a cualquier costo."

DIARIO OFICIAL **El Peruano** FUNDADO EN 1825 POR EL LIBERTADOR SIMÓN BOLÍVAR

Director: Gerardo Barraza Soto
www.elperuano.com.pe
Nº 21245 / 5 secciones
Precio: S/. 2.00

Año de la Infraestructura para la Integración

Jueves 11 de agosto de 2005

DIRECCIÓN GENERAL DE MEDICAMENTOS INSUMOS Y DROGAS
DIGEMID
REPÚBLICA DEL PERÚ

contra falme
Grupo Técnico Multisectorial de Prevención y Combate el Contrabando, Comercio Ilegal y Falsificación de Productos Farmacéuticos y Afines

EL PERU AVANZA

EDUCATION AND DIFFUSION

Training Specialists in the regions and having internships in the central regulatory entity

To strengthen and improve the capabilities of the specialist working in the country doing the control and sanitary surveillance in the regions contributing tothe reduction of illegal commerce of medical products

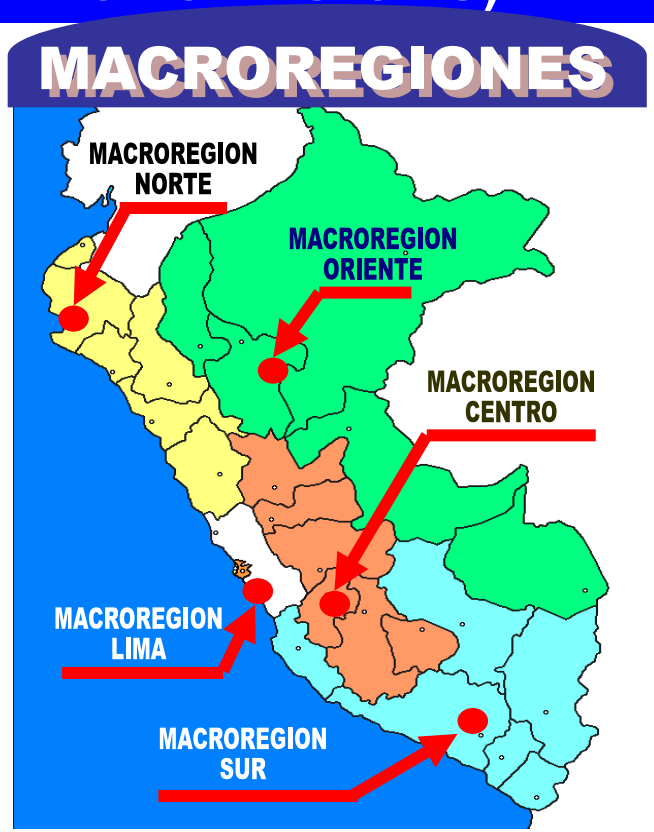
DIRECCIÓN GENERAL DE MEDICAMENTOS INSUMOS Y DROGAS
DIGEMID
REPUBLICA DEL PERU

contra falsificación
Grupo Técnico Multisectorial de Prevención y Combate al Contrabando, Comercio Ilegal y Falsificación de Productos Farmacéuticos y Afines

EL PERÚ AVANZA

EDUCATION AND DIFFUSION

ECONOMY AND INTERNATIONAL FORUMS WITH THE REGIONAL CONTRAFALMES OF PERU (MACROREGIONS)



TARGET: Implementing strategies to reduce illegal comerce of medical produts in their macroregion.

In 2008:

First International Forum to combat Illegal Commerce – North Macroregion.

In 2009:

Macroregión Central, Eastern and Lima
II Internacional Forum – South Macroregion

DIRECCIÓN GENERAL DE MEDICAMENTOS INSUMOS Y DROGAS
DIGEMID
REPUBLICA DEL PERU

contra falme

EL PERU AVANZA

EDUCATION AND DIFFUSION

OTHER STRATEGIES

- Coordination with Ministry of Education to include in the curriculum of the schools these matters.

- Strategic alliances with the Universities to include some of this topics in the Currícula of Health Professionals , as well as in the Social Communicators

- Strategic alliances with Services business to include messages on receipts

- Improve our WEBSITE for reporting alerts and risks of counterfeit medical products

Thank you for your attention

Machupichu

HOW APEC ECONOMIES COMBAT COUNTERFEIT MEDICAL PRODUCTS –

MALAYSIA'S PERSPECTIVE

WAN HAMID BIN WAN IBRAHIM
DEPUTY DIRECTOR,
PHARMACY ENFORCEMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
TEL: 603-78413377/3387 FAX 603-79682251
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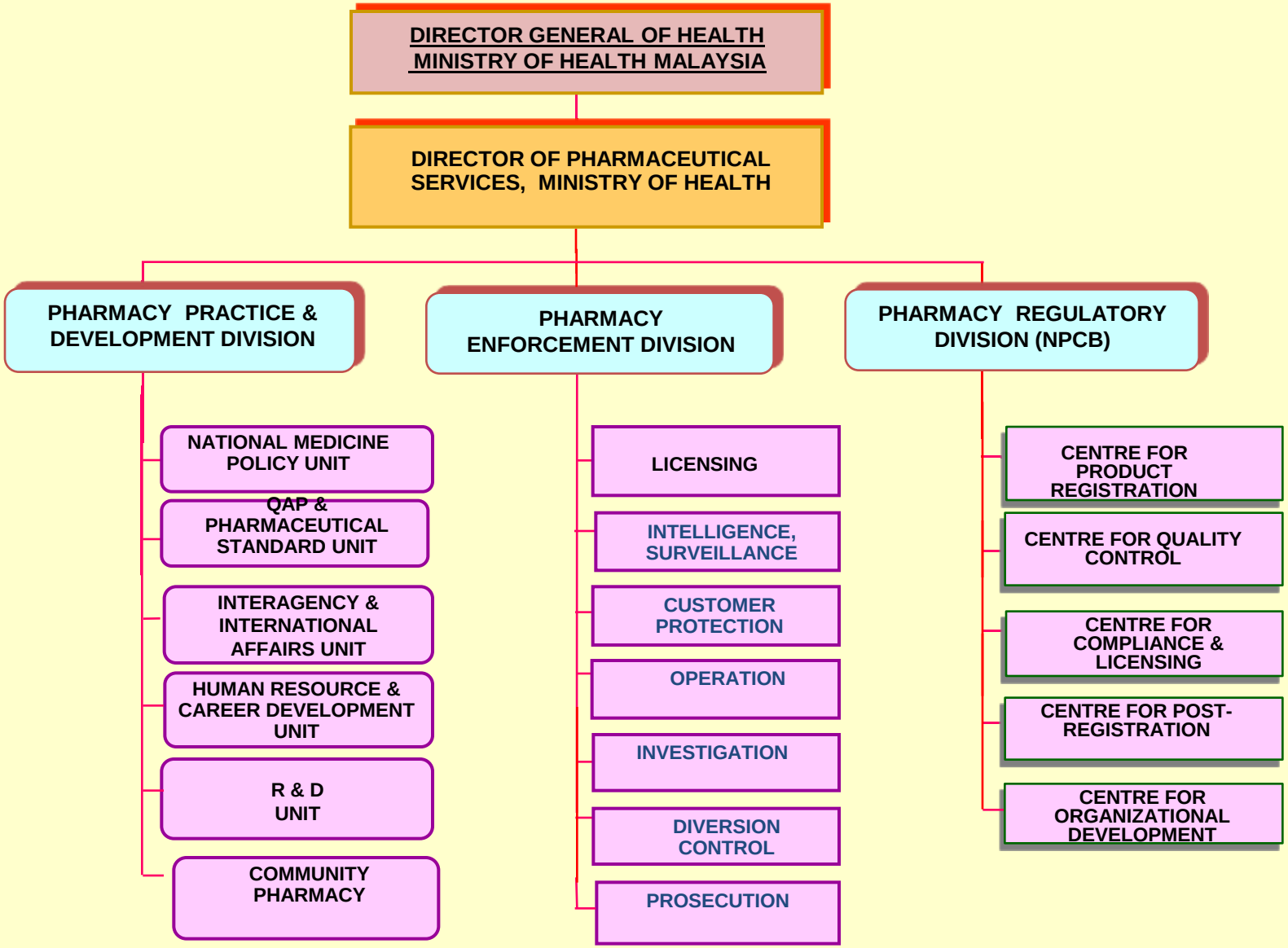
SOUTHEAST ASIA
CHINA
INDIA
BURMA
LAOS
THAILAND
VIETNAM
CAMBODIA
Phnom Penh
Bangkok
Vientiane
Hanoi
Rangoon
Mandalay
Akyab
Kunming
Chengdu
Chongqing
Wuhan
Nanchang
Changsha
Guiyang
Hefei
Shanghai
Hangzhou
Ningbo
Wenzhou
Fuzhou
Xiamen
Shantou
Guangzhou
Nanning
Haiphong
Vinh
Da Nang
Nha Trang
Ho Chi Minh City
Taipei
Naha
Kao-hsiung
Taiwan
Hong Kong S.A.R.
Macau S.A.R.
Hainan Dao
Paracel Islands
Spratly Islands
Philippine Sea
Manila
PHILIPPINES
Cebu
Davao
Zamboanga
Koror
Palau
Malaysia
MALAYSIA
Kuala Lumpur
Singapore
Phuket
Songkhla
George Town
Banda Aceh
Medan
Padang
Palembang
Tanjungkarang Telukbetung
Jakarta
Semarang
Bandung
Surabaya
Denpasar
Christmas Island
Cocos (Keeling) Islands
Samarinda
Banjarmasin
Makassar
Kendari
Manado
Ambon
Jayapura
Merauke
Kupang
EAST TIMOR
INDONESIA
Indian Ocean
North Pacific Ocean
AUSTRALIA
Darwin
Fort Hedland
Karratha
Mount Isa
GREAT SANDY DESERT
Scale 1:32,000,000 at 5°N
Mercator Projection

Outline

- Introduction
  - Structure, Function, Legislation
- Counterfeit Situation
  - Global Scenario, Malaysian Situation
- Challenges
  - Adulterations, Parallel Importation, Smuggling, Tampering
- Combating Counterfeit
  - Multi-pronged Approach
- Conclusion

Overall Structure



CORE FUNCTIONS

- REGISTRATION
- PHARMACOVIGILANCE
- SURVEILLANCE
- ANALYSIS
- INSPECTIONS
- LICENSING
- ENFORCEMENT

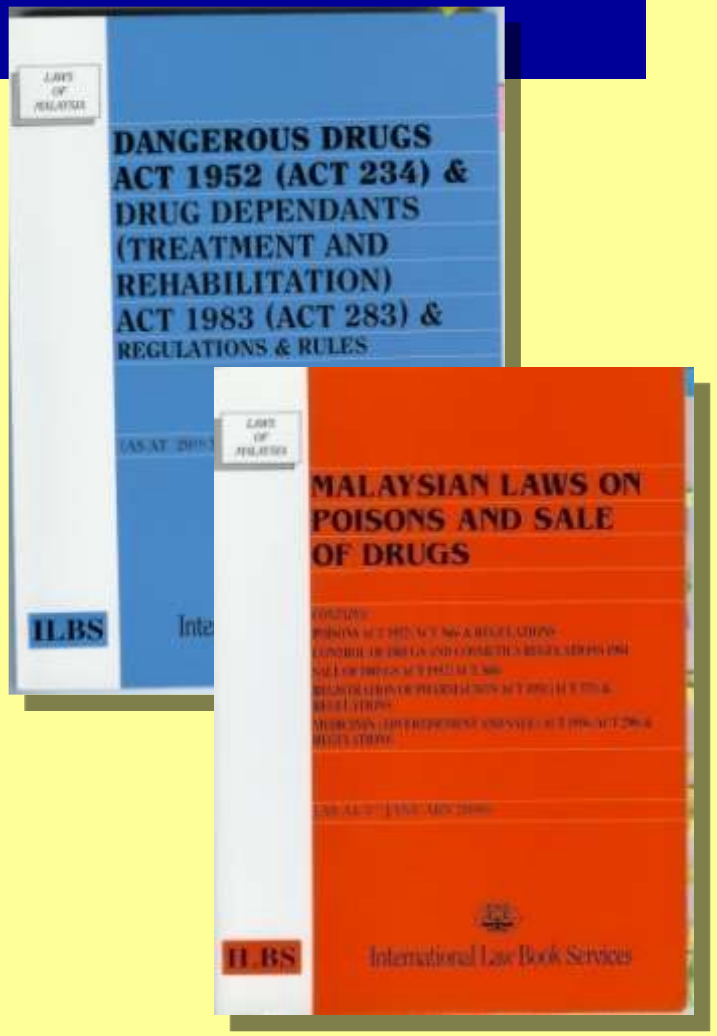
  -Intelligence (Information gathering) , Operation, Investigation, Prosecution
- CONSUMER EDUCATION

.

.

Legislation

- Registration of Pharmacist Act 1951 (revised 1989)
  & Regulations
- Poisons Act 1952 (revised 1989) & Regulations
- Sale of Drugs Act 1952 (revised 1989)
  Control of Drugs and Cosmetics Regulations 1984 (revised 2006)
- Dangerous Drugs Act 1952 (revised 1980)
- Medicines (Advertisement and Sale) Act (revised 1983) & Regulations



Global Scenario

.COUNTRIES AFFECTED

-BASICALLY EVERY COUNTRY WITH VARYING DEGREE OF SEVERITY

.SELLING OF COUNTERFEIT PRODUCT IS ILLEGAL IN ALL COUNTRIES

.CIRCULATION OF COUNTERFEIT DRUGS COMPRISES 6-10% OF WORLD MARKET (USD 35 BILLION) – WHO

- 30-50% IS IN DEVELOPING AND EMERGING NATIONS. THE POORER THE COUNTRY, THE HIGHER THE PERCENTAGE.

Global Scenario

- In 2004, World Customs Organization (WCO) reported that its members conducted more than 4,000 seizures involving more than 166 million counterfeit or pirated goods.
- International Pharmaceuticals Manufacturers Group (IMPG) Indonesia estimated pirated drugs constitute 25% of Indonesia's USD2billion pharmaceutical market.
- In 2004, counterfeit *Reductil* (sibutramine) and *Cialis* (tadalafil) detected by Medicines & Healthcare Product Regulatory Authority (MHRA), UK.
- In Philippines, 2003 report estimated 30% of food and drug outlets carry and sell counterfeit drugs.

Situation in Malaysia

- **5.28% - Market Study on Self-Medication Products in 1997**
- **4.8% - Market Survey done in 2006 by Pfizer Malaysia on Innovator Drugs (*Viagra, Norvasc & Lipitor)***
- **245 of 32,067 products seized in 2006**
- **129 of 13,774 products seized in 2007**
- **Before 2005-Poor public awareness on illegal products including counterfeit medicines.**
- **Awareness study 2008 – 77% respondent aware.**

Challenges

- Unregistered products
- Adulterations
- Counterfeits
- Smuggling
- Parallel importation
- Diversions
- Tampering
- Internet sale

What is counterfeit medicine ?

WHO definition

'A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source'
It can apply to branded & generic products

Counterfeit medicines may include;

Correct ingredient
Wrong ingredient
Insufficient active ingredients
Without active ingredient
Fake packaging

Why counterfeit medicine matter ?

- *Health implications*
  - *patient safety*
  - *morbidity and mortality*
  - *poor & rural area is more prone*

- *Economy development*
  - *jeopardizes the credibility of health system*
  - *jeopardizes medicine industry development*

BEFORE 2005, IDENTIFICATION OF COUNTERFEIT MEDICINE IS BY COMPARING WITH THE ORIGINAL PRODUCT. CONFIRMATION BY THE PRODUCT OWNER

Genuine	vs.	Counterfeit

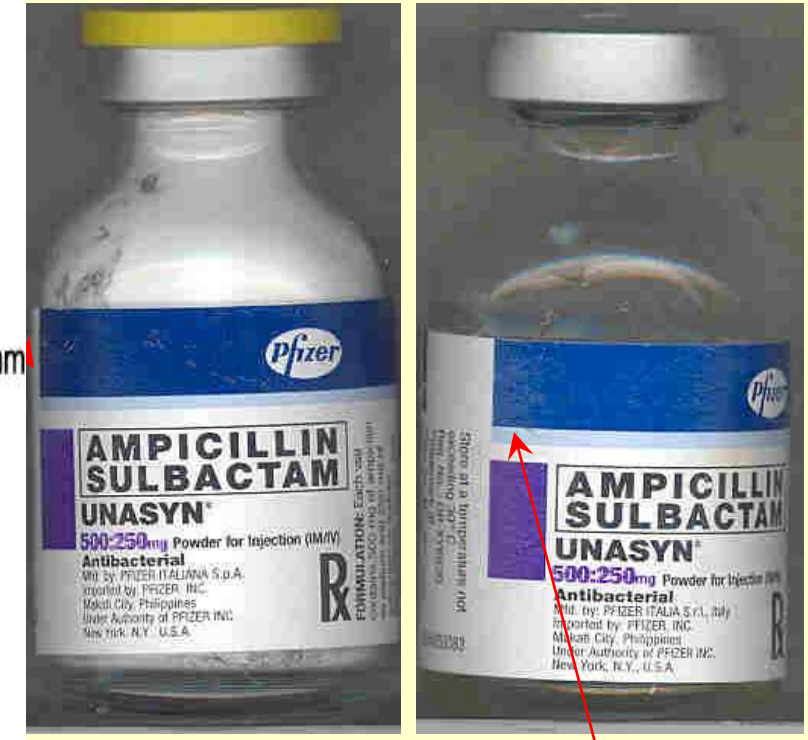
Original

Counterfeit

Ampicillin Sulbactam

Original

Counterfeit



Light Blue

Fake Sex Stimulants

Illegal Factory

Multi-Tiered Strategy

- **Strong political will** – National Medicines Policy, Good Medicines Governance
- **Sound legal provisions**
- **Structure** – Quality system, PIC/S, WHO Collaborating Centre
- **Regulatory system** – Registration, Licensing, Surveillance, Testing, ADR Monitoring, Information
- **Enforcement system** – Inspection, Investigation, Prosecution, Confiscation, Consumer Education
- **Collaboration and Networking** –Economy, International, Industry organizations, Consumer groups, Professional bodies
- **Technology** – Security labels (hologram), ICT

The Approaches Taken By The Pharmacy Enforcement Division, Ministry Of Health Malaysia

1. REACTIVE APPROACH
2. PROACTIVE APPROACH

1. REACTIVE APPROACH

   Legislation

   Registration

   Licensing

   Inspection

   Raids

   Prosecutions

   Post marketing quality surveillance

   Safety surveillance

   etc

Legislation & Regulation

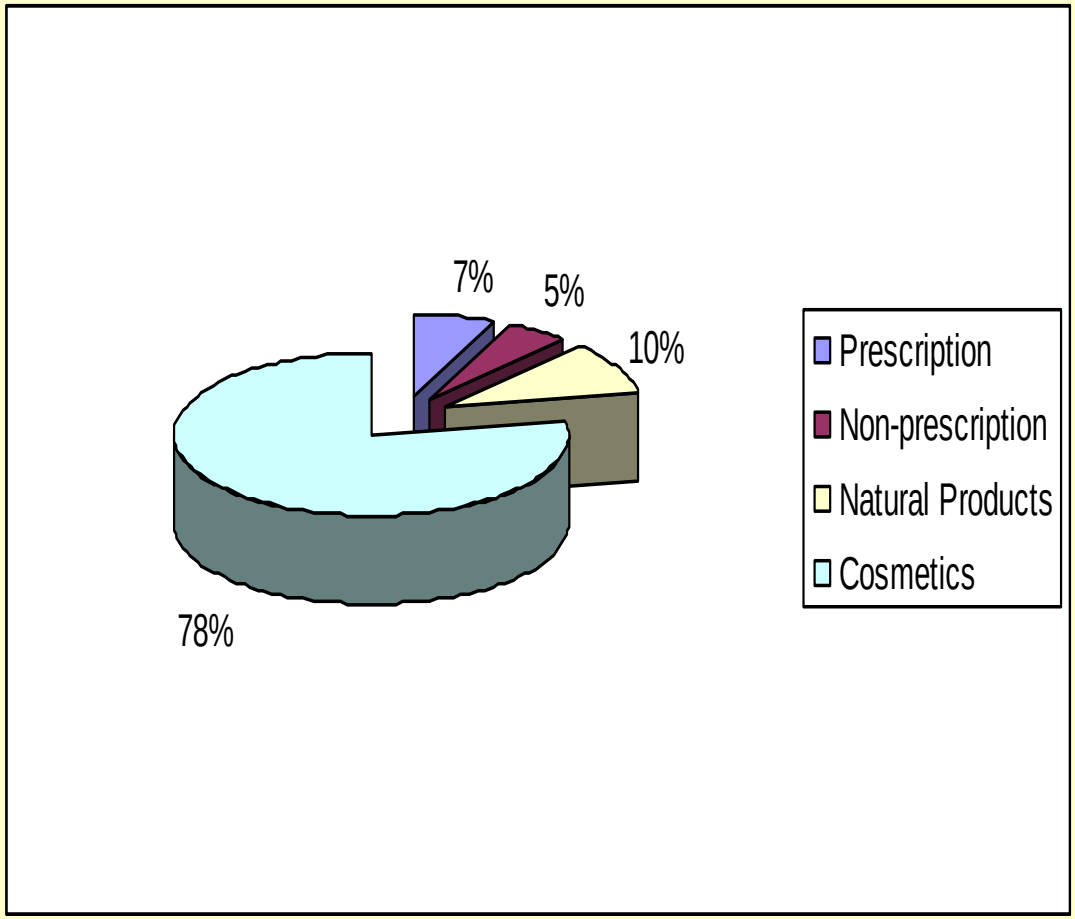
- **Strengthening of legislation and regulation including more deterrent penalties- minimum mandatory jail sentence, include definition of counterfeit medicines in line with the WHO definition. Better implementation and enforcement of laws and regulations.**

C0NTROL OF DRUGS AND COSMETICS REGULATION 1984 (Sales of Drug Act 1952) Revised 1984

- **REGULATION 7- Prohibition against manufacturing, sale, supply, importation, possession & administration.**
- **(1) No person shall manufacture, sell, supply, import, possess or administer any product unless;**

  (a) the product is a registered product.
- **(1A) No person shall manufacture, sell, supply, import, possess, or administer any product-**
- **(f) whose label is not complying to the directive or guideline issued under regulation 29**

Number of Registered Products (Cumulative) 1991 – December 2007



Product category	Total
Prescription	11,805
Non-prescription (OTC)	9,098
Natural Products (Traditional)	18,200
Cosmetics	136,643
Total	175,746

Effective 1st January 2008 Registration of Cosmetics replaced by Procedure of Notification

ALL REGISTERED PRODUCT MUST BE PRINTED WITH REGISTRATION NUMBER

EXAMPLE OF REGISTRATION NUMBER ACCORDING TO PRODUCT CATEGORY

MAL20022544A

Prescription Medicines – mark with the letter A

MAL20030080X

Over The Counter Medicines – mark with the letter - X

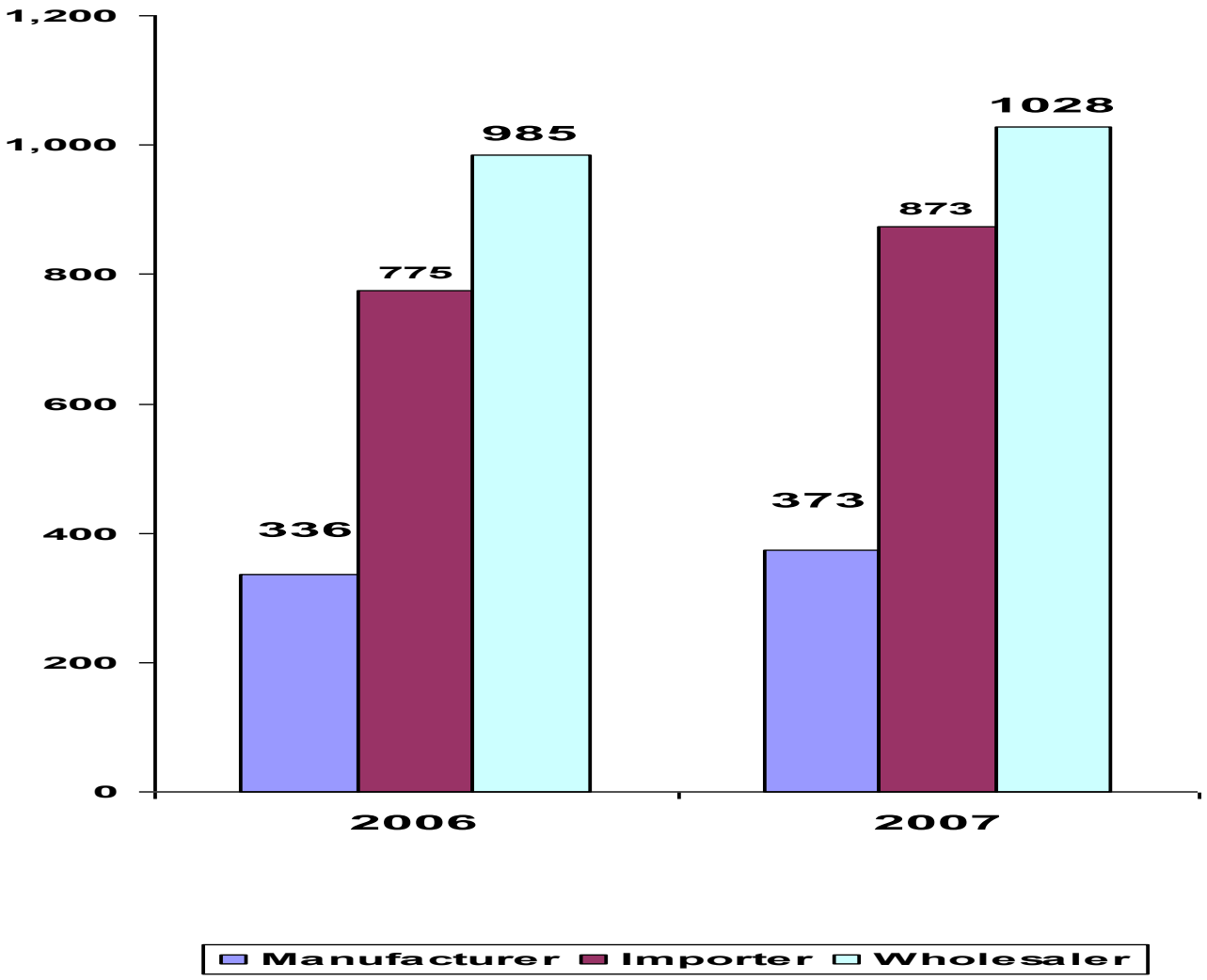
MAL20024420T

Traditional Medicines – mark with the letter - T

MAL03023343K

Cosmetics – mark with the letter - K

Licensed Premises : 2006 - 2007



Inspection & Raids

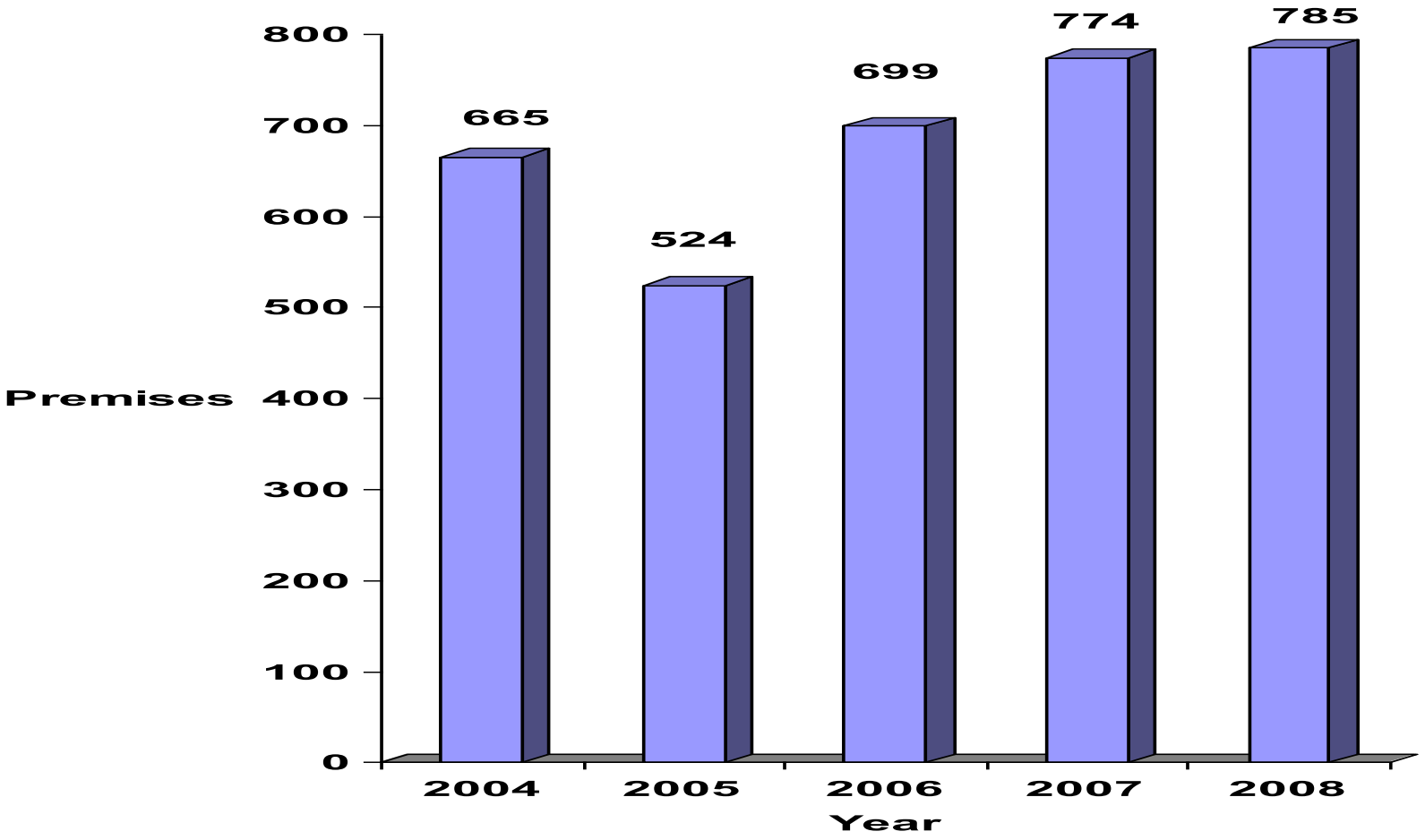
Enforcement

Illegal Traditional Medicine Factory

Raids on Premise selling unregistered products

Raid on residential premise used as an illegal store

Raids


800
700
600
500
400
300
200
100
0
Premises
665
524
699
774
785
2004
2005
2006
2007
2008
Year

Seizures

RECENT- PHARMACY ENFORCEMENT SUCCESS STORY

- Interception at Custom Entry Point (Miagra)
- Set up- Cialis internet sale-Alibaba.com
- Ugly Act by Beauty Saloon-Vit C from China relabeled into Swiss made.
- Counterfeit Panadol seizure

INTERCEPTION ON A 20 FOOTER CONTAINER LOADED WITH 1.4 MILLION TABLETS OF MIAGRA(SILDENAFIL) AT THE CUSTOM ENTRY POINT

SET-UP OPERATION ON A SYNDICATE SELLING COUNTERFEIT CIALIS THROUGH INTERNET

40,000 AMPOULES OF COUNTERFEIT INJECTION VITAMIN C SEIZED FROM A BEAUTY SALOON

- **10 DECEMBER 2008**
- **A BEAUTY SALOON SMUGGLED INJECTION VITAMIN C FROM CHINA AND RELABELED AS SWISS MADE**
- **UGLY ACT FOR HIGHER PROFIT**


Star
people's paper

NST NATION

Beauty centre's ugly act

Customers sold China-made products 'refilled' into branded bottle

18 Dec 2008- Raid on a Beauty Saloon smuggled Inj. Vit C from China and relabeled as Swiss made. Market value USD 1.5 mil.


NEW STRAITS TIMES

Illegal drugs seized at beauty salon

Residential premise used as repacking site

THE NEWS WERE PUBLISHED IN 10 NEWSPAPERS IN 3 DIFFERENT LANGUAGES ie ENGLISH, MALAY AND CHINESE

NEWS IN 3 DIFFERENT CHINESE NEWSPAPERS


中國報
CHINA PRESS
中國便宜貨充瑞士貴貨
30令吉美容品賣500

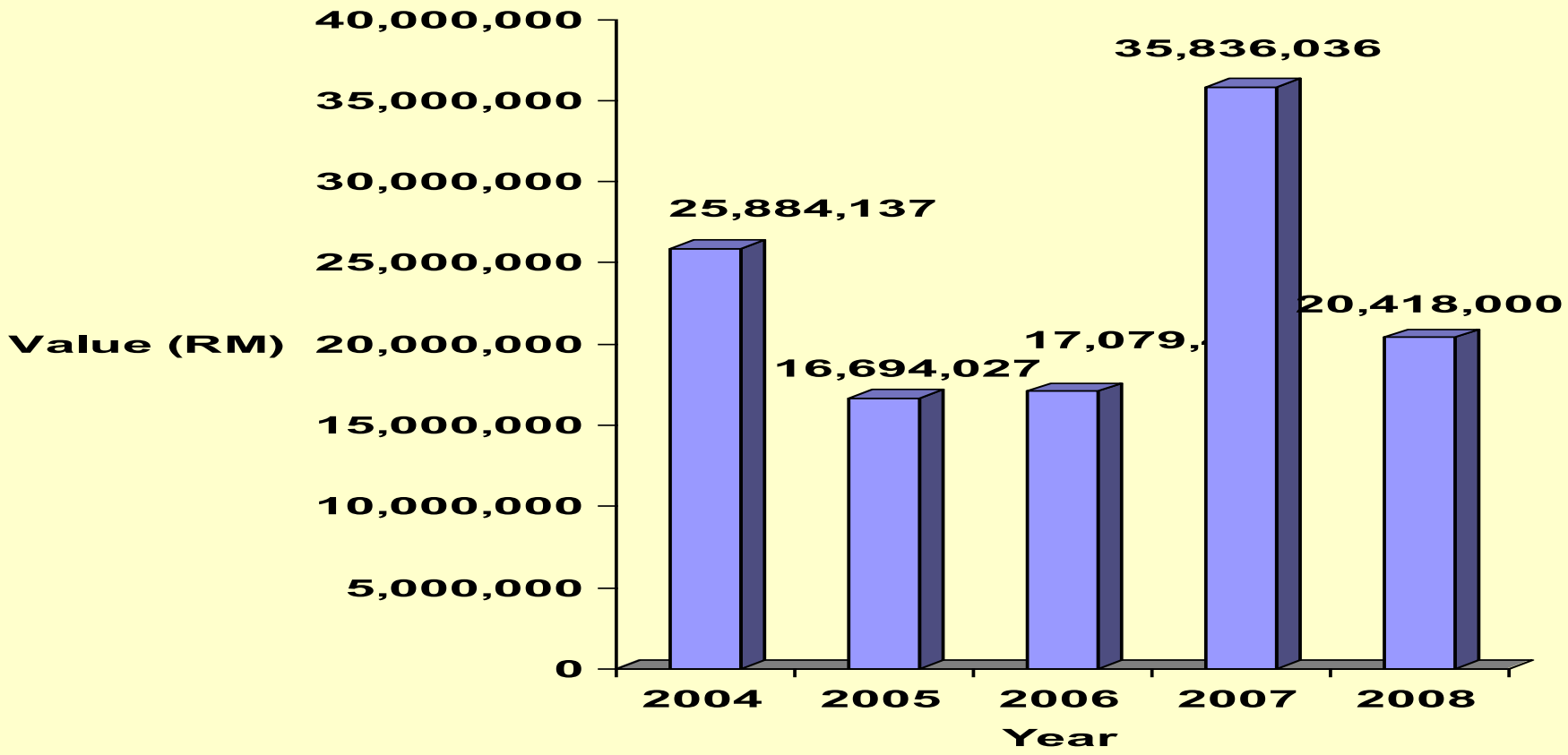

星洲日報
SIN CHEW DAILY
擒破550萬冒牌"雪柔"


光明日報
Guang Ming DAILY
2008年12月11日（星期四）
B1
衛部突擊美容院
超580萬非法美容品


星洲日報
SIN CHEW DAILY
2008年12月11日（星期四）
成本3令吉藥水售50
負責人否認涉及倉庫假貨

21st January 2009 Counterfeit PANADOL seized from a wholesaler. Detection by using Hologram Decorder

Value of seizures

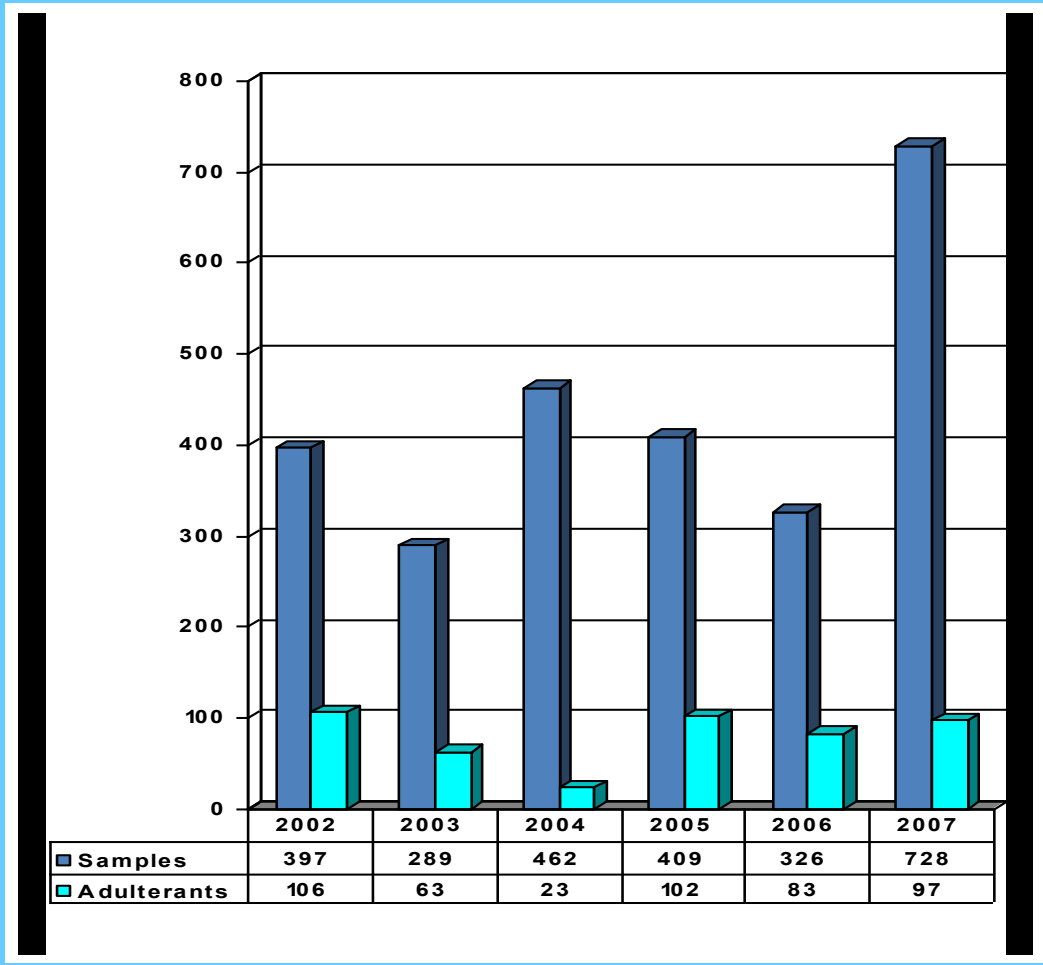


Products Seized (%) 2007

Category	%
Sex stimulants	40
Traditional medicines	23
Scheduled poisons	18
Slimming products	10
Cosmetics	6
Psychotropic	2
Others	1

Surveillance

Adulterants Detected



	2002	2003	2004	2005	2006	2007
Samples	397	289	462	409	326	728
Adulterants	106	63	23	102	83	97

- Sildenafil & Analogues
- Tadalafil
- Whitening Agents
  - Hydroquinone
- Ibuprufen
- Slimming Agents
  - Sibutramine
- Antihistamine
- Phenylbutazone
- Steroids
- Progesterone
- Minoxidil
- Metformin
- Combinations
  - Sildenafil + Glibenclamide
  - Sildenafil + Paracetamol

2. PROACTIVE APPROACH

- **Innovative Technology**
- **Consumer Education and Awareness**

INNOVATIVE TECHNOLOGY

Proactive Approach: Innovative Technology – HOLOGRAM MEDITAG

- Malaysia is using *innovative technology* by making compulsory for every medical products to be label with *MediTag Hologram*
- Use of security label as a tool for identificarn of registered products marketed.
- *Meditag Hologram* is serialised
- Cabinet (Parliament) directive , mandatory use of Meditag label for pharmaceuticals and self-medication products.
- Apply to both locally manufactured as well as imported products.
- Exemptions for cosmetics and cold chain items

Proactive Approach

- Serialised Hologram –Enforcement Date. 1st May 2005

  Amendment of *Regulation 2* of Sale of Drug Act

  Definition - Label means a display of information, safety marks or features -

  (a) accompanying a product ; or

  (b) on or attached to a container and package in relation to a product

  Safety marks or features may refer to any kind of security tools/technology such as hologram, imprints or even micro chips.

  Legal provisions in place to ensure effective implementation.

Now all medicinal products must have/bear Registration number and security label

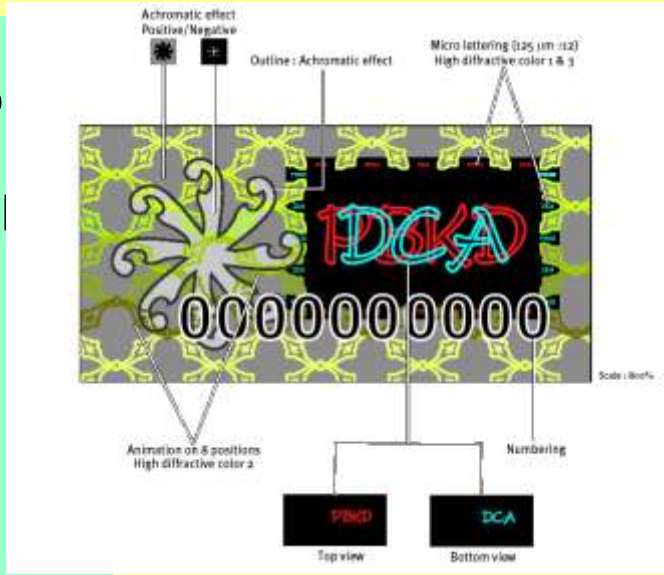
HOLOGRAM MEDITAG®

(exemption to cosmetics products and external personal care products: anti acne, anti dandruff, mouth care products, skin protection and anti bacteria)

External features on the Hologram that can be seen by consumers

Impact of Meditag™ Hologram

- 4 cases of products which were found to be adulterated were traced to the manufacturer thro the serial number on the Meditag™ hologram .
- 5 case of a counterfeit products were detected. It a fake hologram.
- Benefits to Government – Enforcement & Image
- Benefits to Industry – Trade & Economy
- Benefits to Consumers – Quality & Safety
- Increase in seizures of unregistered products
- Assist tracking of adulteration, counterfeits and unregistered products & parallel importation
- Facilitate tracing of illegal manufacturers/importers
- Public Awareness



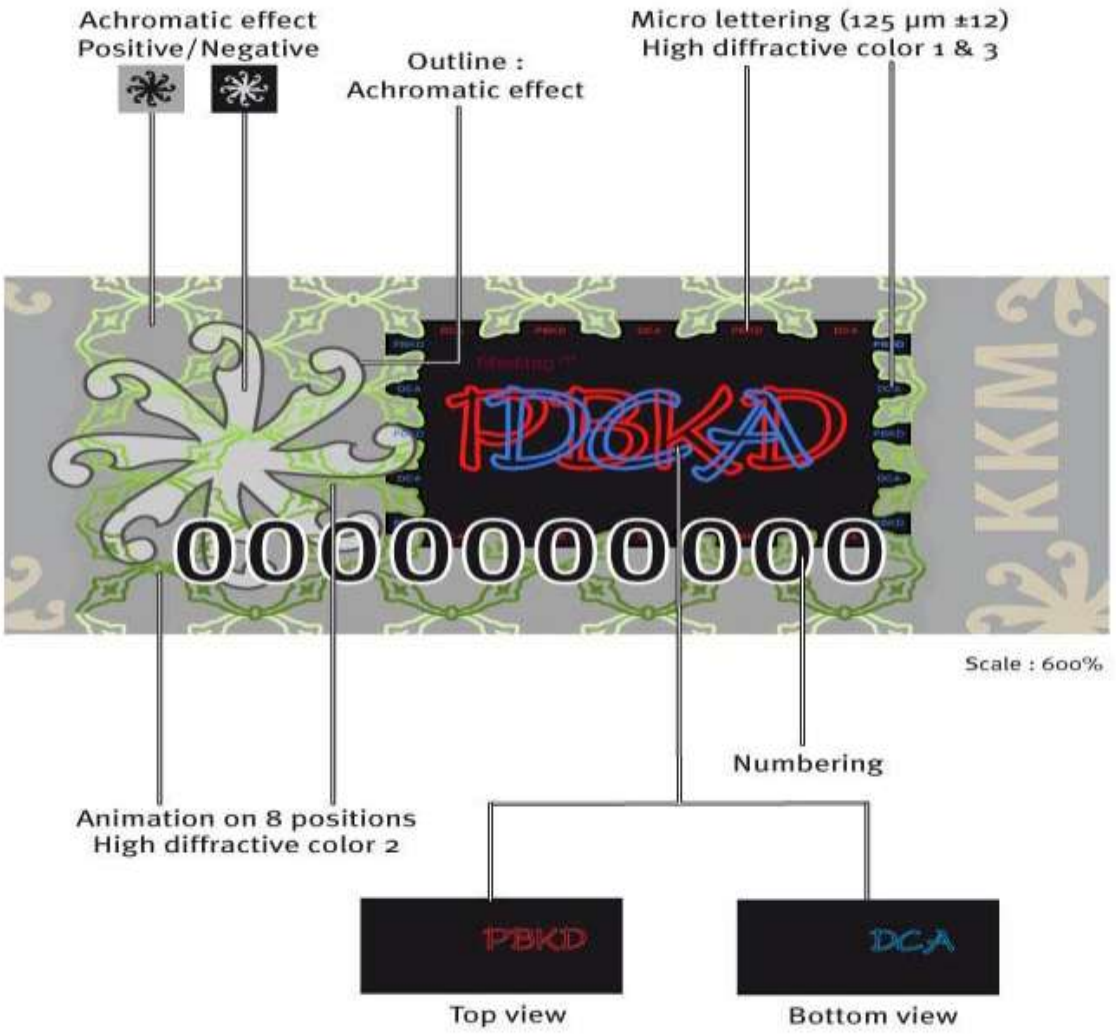
Challenges

- Unregistered products
- Adulterated products
- Smuggling
- Parallel importation
- Diversion
- Tampering
- Repackaging & re-labelling
- Counterfeit hologram

Hologram first version (2005)

Hologram latest version (Sept 2006)

1st level authentication



DIAGRAM®
Final size : 18 x 8 mm


THE ALPHABET "KKM" CAN BE SEEN BEFORE SLIDING THE DECORDER
A38643621
MEDI

BY SLIDING THE DECORDER THE LETTER **KKM** DISAPPEARED

THE LETTER KKM REAPPEARED

Meditag Decorder

Involvement of consumer & The Private sector


Dekod
Meditag
di sini
MEDITAG
Panadol
Hemo Rid
CEFUROXIME 250
HISTA


ORIGINAL
COUNTERFEIT
EYE MO
eye drops
Relieves Minor
Eye Irritation
49726LLE51
CARING PHARMACY
037 R M 4.50

Collaboration -Economy

- Ministry of Domestic Trade & Consumer Affairs
- Customs Department
- Police
- AG Chambers
- Chemistry Department
- Industry Associations
- Consumer Groups
- Health Professionals

International Networking

- WHO – IMPACT(International Medical Products Anti Counterfeit Taskforce)
- PIC/S – Rapid Alerts
- ACCSQ PPWG – Post Marketing Alert System
- ASEAN WGTCP
- Bilateral & Multi-lateral Cooperation

SEMINARS/CONFERENCE

- 1ST INTERNATIONAL PHARMACY ENFORCEMENT CONFERENCE JULY 2008. 100 local participants and rep. from The ASEAN countries

- WIPO (World Intellectual Property Organization) Seminar was held on 22-23 DEC 2008

  - 30 pharmacy enforcement officers participated in the seminar together with the officers from other enforcement agencies

DIALOGUE AT THE INDONESIAN EMBASSY

- DISTRIBUTORS FOR PRODUCTS IMPORTED FROM INDONESIA
- REPRESENTATIVES FROM THE INDONESIAN MANUFACTURER

Strengthening The Enforcement

- Increase manpower
- Continuous education
- Post-graduate studies
  - Masters Law
- Incentive allowance
  - Critical & special
- Quality initiatives
  - Quality Assurance Program
  - Key Performance Indicators
- R&D

More Improvements

- Forensic laboratory-2008
- Test kits
- PCs
- Alerts
- Computerized network
- New Pharmacy Bill

Public Awareness

- "Know Your Medicine" Campaign
- Posters/post-cards
- Calendars with messages
- Newspapers
- TV and radio talks
- School exhibitions
- Open Day
- Road-shows
- Media announcements

Awareness

ACTIVITIES ORGANISED BY THE CONSUMER EDUCATION UNIT

VISIT BY THE PRIME MINISTER AT THE EXHIBITION BOOTH

EXHIBITION HELD IN SCHOOL, OFFICE & SPORTS DAY

Launching of Campaign:

"KNOW YOUR MEDICINE" Jun 2007.

Calendars


2006
Kenali Ubat Anda
2008
Kalendar
Ubat Anda
Kalendar
2007
Kenali
Ubat Anda
Cawangan Penguatkuasa Farm
Farmasi Kementerian K
www.pharmac
www.pharmacy.gov.my
KALENDAR 2009
www.knowyourmedicine.gov.my
JOM KENALI UBAT KITA
www.pharmacy.gov.my

Inside calendars

Posters & Info cards

Risalah dan Bahan Pendidikan yg dikeluarkan kpd setiap negeri

GET YOUR MEDICINE FROM THE RIGHT SOURCE

ADVICE FROM

PHARMACY ENFORCEMENT DIVISION

MINISTRY OF HEALTH MALAYSIA

Buy Your Medicine from Pharmacy

Buy Your Medicine from a licensed premise


ADVISE: DON'T BUY


ADVISE: DON'T BUY

What should you know about medical advertisements?

1. Ensure the advertisement has been approved by the Medicine Advertisement Board.
   Example > KKLIU1234/2005/ABC
2. According to the Medicine (Advertisement and Sale) Act 1956, it is an offense to advertise:
   - 20 types of Prohibited Diseases.
   - Medicinal products and services without the approval from the Medicine Advertisement Board.
3. Penalty: RM 3000 or ONE year imprisonment or both

20 types of diseases prohibited from being advertised:

1. Diseases or defects of the kidney
2. Diseases or defects of the heart
3. Diabetes
4. Epilepsy or fits
5. Paralysis
6. Tuberculosis
7. Asthma
8. Leprosy
9. Cancer
10. Deafness
11. Drug addiction
12. Hernia or rupture
13. Diseases of the eye
14. Hypertension
15. Mental disorder
16. Infertility
17. Impotency
18. Impairment of the sexual function or impotency
19. Venereal disease
20. Nervous debility or other complaint or infirmity arising from or relating to sexual intercourse

EXAMPLE OF UNAPPROVED ADVERTISEMENT

Cures all!!!

One bottle only RM199!!

Offer price

Treats
Rheumatism
Painful Joints
Soothes pain
Arthritis

Do not be easily influenced by medical advertisements. Make sure that the advertisements are approved by the Medicine Advertisement Board.

A message from:
Pharmacy Enforcement Division
Pharmaceutical Services
Ministry of Health, Malaysia
Tel: 03-7841 3200 Fax: 03-7968 2251
Website: www.pharmacy.gov.my
Email: pharmacy1@moh.gov.my

DON'T BUY

medicinal products through the Internet, Post or Courier Services

Do not be easily taken in by medical advertisements on the Internet. Purchasing medicinal products at an online pharmacy over the Internet is not only an offence, but it may also put your health at risk.

Products sold over the Internet are doubted because of:
- Uncertain quality control and safety
- Incomplete advice and counselling regarding the proper use of the medicine

Ensure that the medicinal products you buy is registered with the Ministry of Health, Malaysia, and has the MAL registration number and Medtag hologram label.

A message from:
Pharmacy Enforcement Division
Pharmaceutical Services
Ministry of Health, Malaysia
Tel: 03-7841 3200 Fax: 03-7968 2251
Website: www.pharmacy.gov.my
Email: pharmacy1@moh.gov.my

Adulteration of Aminotadalafil in Candy

Conclusion

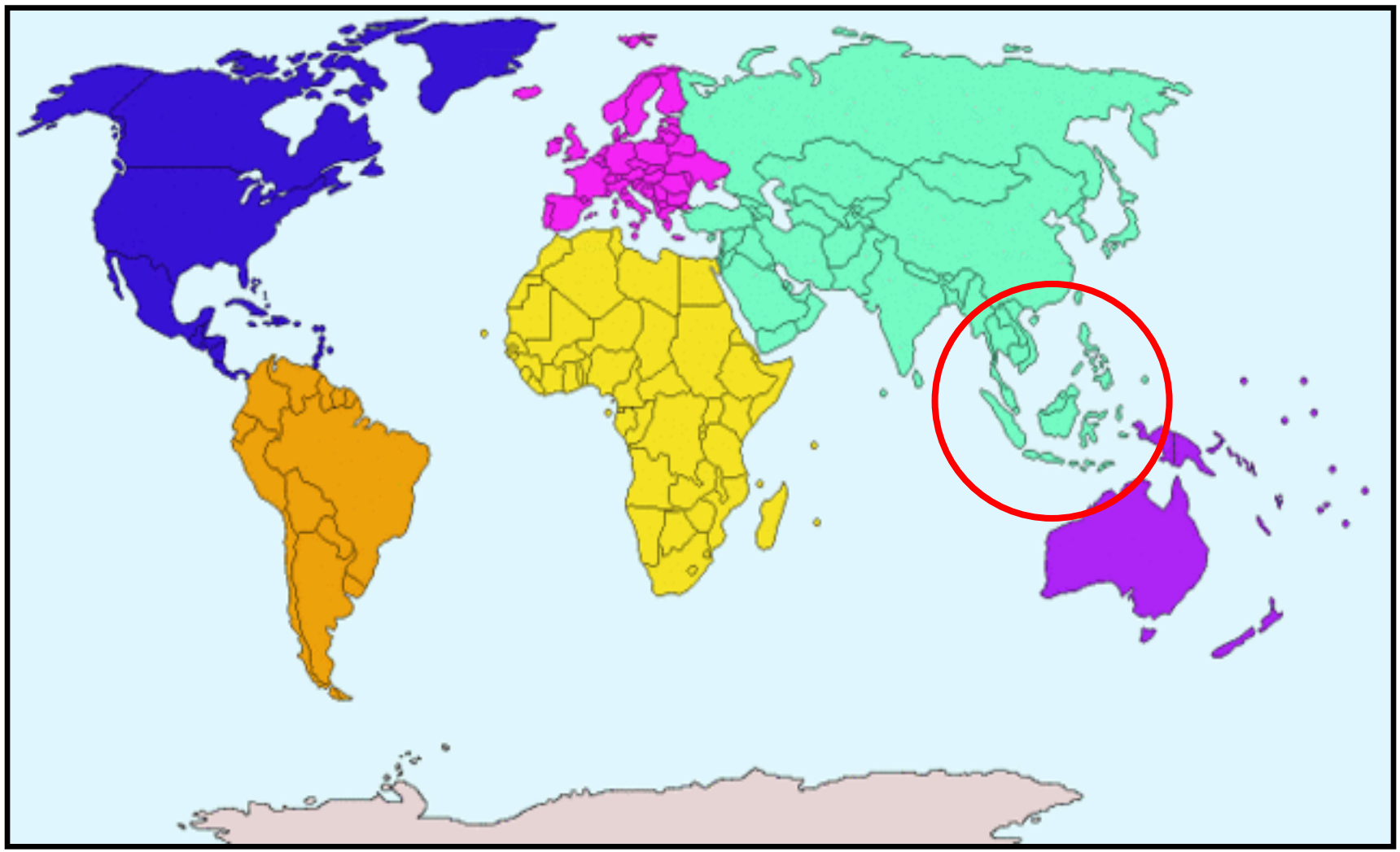
- Counterfeiting a global issue
- Serious public health concern
- Sound legal provisions
- Efficient regulatory system
- Vigilant enforcement
- Innovative technology (MediTag Hologram)
  - **Serves as an additional measure to combat rampant presence of unregistered products.**
  - **Provides a useful tool for enforcement officers to check on products marketed.**
  - **Complement and strengthen the existing multi-pronged strategy**
  - **Significant increase of illegal items confiscated from the market and at the entry points.**
  - **Builds confidence and safeguard public health.**
- Public Awareness program

APEC-LSIF Seminar
Mexico City – February 2009

Combating Counterfeit Medical Products
- Singapore -

Kelvin Tan
Health Products Regulation Group
Health Sciences Authority – Singapore

Singapore (?)



Singapore (?)

Singapore (!)

Singapore

About Singapore

- Located off southern tip of Malay Peninsula, bordering Malaysia and Indonesia
- 1 main island + over 60 surrounding islets
- Small country – total land area ~700 sq km
- Total population ~4.8 million
  - multi-ethnic – Chinese, Malay, Indian, others
- Densely populated, urban landscape

Singapore

➢ Healthcare in Singapore

- Healthcare system based primarily on allopathic ‘Western’ medical science
- Well-developed medical infrastructure and expertise
  - 29 hospitals and over 2,000 medical clinics
  - over 7,000 medical practitioners
  - all hospitals and clinics as well as all medical practitioners are regulated by Ministry of Health

Health Sciences Authority

➢ About Health Sciences Authority (HSA)

- Statutory board under Ministry of Health
- Established by Act of Parliament
- Key duties and functions :
  - national regulator of health products (including medical products)
  - national blood bank and transfusion service
  - provider of specialised scientific services (i.e. forensic medicine and sciences, criminalistics, laboratory analysis)

HSA – Organisation

Regulation of Medical Products

➢ Before year 2007

- No laws for regulating medical devices
- Laws for regulating medicines
  - spread out over several different pieces of legislation (e.g. Medicines Act, Poisons Act, Sale of Drugs Act)
  - did not have specific definition for “counterfeit medicine”
  - did not provide specific provisions against dealing in counterfeit medicines

Regulation of Medical Products

➢ Before year 2007

- Anti-counterfeiting measures
  - only in intellectual property laws (i.e. Trade Marks Act)
  - applied generally to all manner of counterfeit goods (e.g. clothing, bags, watches)
  - did not have specific provisions to deal with counterfeit medicines
  - depended mainly on trademark owners to initiate action and assert private rights

Regulation of Medical Products

➢ Health Products Act

- New law recently passed by Parliament
- Will come into force in stages over next few years, and eventually replace existing medicines control laws
- Will be applied to medicines and medical devices as well as other categories of “health products” (e.g. health supplements, cosmetics)

Regulation of Medical Products

➢ Improvements in Health Products Act

- Has specific definition for “counterfeit health product”

  “A health product is counterfeit if –

  – *it is presented in such a manner as to resemble or pass off as a registered health product when in fact it is not; or*

  – *it is presented with any false information as to its manufacturer or origin.”*

Regulation of Medical Products

➢ Improvements in Health Products Act

- Specific prohibitions against dealing in counterfeit health products
  - manufacture
  - import
  - supply
- Harsher penalties for offences relating to counterfeit health products – fine of up to S$100,000 and imprisonment for up to 3 years per charge

Regulation of Medical Products

➢ Regulatory Framework

- Key activities in distribution of health products are regulated
  - manufacture
  - import
  - supply (wholesale as well as retail)
- Dealers (e.g. manufacturers, importers, wholesalers) subjected to licensing control
- Products subjected to pre-market registration

Counterfeit Medical Products

➢ Situation in Singapore

- Counterfeits are known to be present, but confined to ‘black market’ outside the legitimate supply chain (e.g. illegal peddlers in ‘red-light’ areas)
- Volume is insignificant and usually involve ‘lifestyle’ drugs, especially for male erectile dysfunction (e.g. *Viagra*, *Cialis*)
  - contents are inconsistent, erratic and dangerous (e.g. counterfeit *Cialis* containing glibenclamide)

Counterfeit Medical Products

➢ Situation in Singapore

- **No** penetration into legitimate supply chain and mainstream healthcare system
- Supply of essential therapeutic medicines (e.g. antibiotics) **not** affected by counterfeits
- Counterfeit problem under control due to :
  - strong regulatory framework for medical products and dealers
  - effective enforcement

HSA's Approach

- Protect integrity of legitimate supply chain
- Curb and disrupt supply of illicit medical products (including counterfeit products)
- Reduce consumer demand for illicit medical products (including counterfeit products)

HSA's Approach

Strategies

- Maximise intelligence-sharing and exchange of information on counterfeit products
- Have coordinated enforcement actions with other regulatory and enforcement agencies
- Collaborate with pharmaceutical industry to tap on specialist knowledge and intelligence
- Educate consumers on dangers of counterfeit medical products

National Coordination

➢ Role of HSA in Enforcement

- National “single point of contact” for matters relating to counterfeit medical products
- Shape policies and lead on issues relating to counterfeit medical products
- Coordinate and lead enforcement actions against counterfeit medical products
- Guide enforcement partners on matters concerning counterfeit medical products

National Coordination

- **HSA's Key Enforcement Partners in Singapore**
  - Immigration & Checkpoints Authority (ICA)
  - Singapore Customs (SC)
  - Singapore Police Force (SPF)
  - National Environmental Agency (NEA)

National Coordination

➢ Immigration & Checkpoints Authority

- ICA responsible for security of Singapore's borders against entry of undesirable persons and cargo by land, sea and air
- ICA checkpoints include :
  - airports
  - land-crossings
  - ferry terminals
  - cargo container terminals
  - parcel post centre

National Coordination

➢ Immigration & Checkpoints Authority

- ICA usually first point of contact for persons and items entering Singapore
- Items identified by ICA as medical products but without import licence or authorisation are detained and referred to HSA
- HSA investigates and decides whether to release or confiscate – enforcement action if necessary

National Coordination

➢ Singapore Customs

- Key function of SC includes enforcement of customs duties and revenue
- SC investigates cases of contraband goods – particularly tobacco
- SC has close working relationship with HSA against common enemy (i.e. smugglers and their smuggled goods)

National Coordination

➢ Singapore Police Force

- HSA and Police conduct joint operations against illegal activities involving medical products, particularly in ‘red-light’ areas
- Leverage on full police powers for greater enforcement impact, especially when organised syndicates and dangerous criminal elements are involved
- Leverage on larger number of personnel for large-scale operations

National Coordination

➢ National Environment Agency

- NEA has large pool of inspectors enforcing environmental and public health laws
- NEA regularly conducts inspections of markets and public spaces to check on illegal hawking and peddling
- Suspect medical products found on illegal peddlers are seized by NEA and referred to HSA for investigation

National Coordination

➢ Benefits of Collaboration

- Enforcement agencies often have ‘first contact’ in the field (e.g. border control by ICA, neighbourhood patrols by Police)
- Able to leverage on strength of other agencies
  - larger pool of trained officers
  - more extensive enforcement powers (e.g. power of arrest)
  - more skills and experience in enforcement

International Collaboration

- **Participation in International Networks**
  - Permanent Forum on International Pharmaceutical Crime (PFIPC)
  - WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT)
  - ASEAN Post-Marketing Alert System
  - ASEAN-China Collaboration on Counterfeit Medicines

International Collaboration

PFIPC

- International forum for enforcement practitioners
- Aimed at combating pharmaceutical crimes – including counterfeit medical products
- Comprised of representatives from :
  - national regulatory and enforcement agencies (e.g. Australian TGA, US FDA, Canadian RCMP)
  - international organisations (e.g. Interpol, WCO, WHO)

International Collaboration

➢ PFIPC

- Annual meetings to discuss enforcement issues, developments and trends
- More importantly, provides trusted and close-knit network to facilitate intelligence-sharing and exchange of information between members

International Collaboration

➢WHO IMPACT

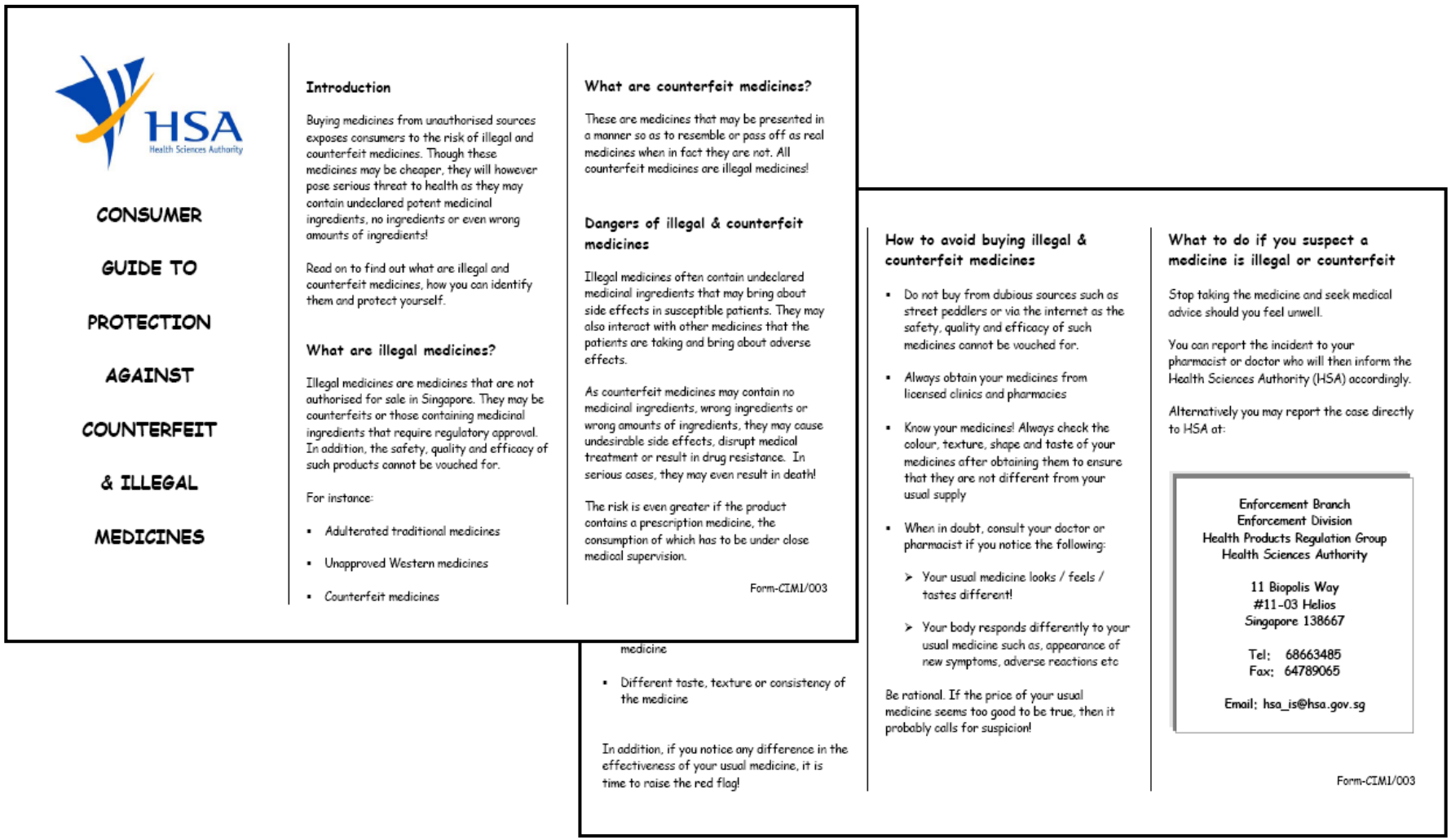
- Initiative by WHO, launched in February 2006
- Comprised of members from :
  - national drug regulatory authorities
  - law enforcement agencies
  - pharmaceutical manufacturers associations
  - international and non-governmental organisations with interest in fighting counterfeit medical products

International Collaboration

➢WHO IMPACT

- 5 Working Groups covering areas on :
  - legislative and regulatory infrastructure
  - enforcement
  - regulatory implementation
  - technology
  - communication
- Representative from Singapore HSA elected as Vice-Chair of IMPACT and member of IMPACT Planning Group

Consumer Education



CONSUMER GUIDE TO PROTECTION AGAINST COUNTERFEIT & ILLEGAL MEDICINES

Introduction

Buying medicines from unauthorised sources exposes consumers to the risk of illegal and counterfeit medicines. Though these medicines may be cheaper, they will however pose serious threat to health as they may contain undeclared potent medicinal ingredients, no ingredients or even wrong amounts of ingredients!

Read on to find out what are illegal and counterfeit medicines, how you can identify them and protect yourself.

What are illegal medicines?

Illegal medicines are medicines that are not authorised for sale in Singapore. They may be counterfeits or those containing medicinal ingredients that require regulatory approval. In addition, the safety, quality and efficacy of such products cannot be vouched for.

For instance:

- Adulterated traditional medicines
- Unapproved Western medicines
- Counterfeit medicines

What are counterfeit medicines?

These are medicines that may be presented in a manner so as to resemble or pass off as real medicines when in fact they are not. All counterfeit medicines are illegal medicines!

Dangers of illegal & counterfeit medicines

Illegal medicines often contain undeclared medicinal ingredients that may bring about side effects in susceptible patients. They may also interact with other medicines that the patients are taking and bring about adverse effects.

As counterfeit medicines may contain no medicinal ingredients, wrong ingredients or wrong amounts of ingredients, they may cause undesirable side effects, disrupt medical treatment or result in drug resistance. In serious cases, they may even result in death!

The risk is even greater if the product contains a prescription medicine, the consumption of which has to be under close medical supervision.

Form-CIM1/003

medicine

- Different taste, texture or consistency of the medicine

In addition, if you notice any difference in the effectiveness of your usual medicine, it is time to raise the red flag!

How to avoid buying illegal & counterfeit medicines

- Do not buy from dubious sources such as street peddlers or via the internet as the safety, quality and efficacy of such medicines cannot be vouched for.
- Always obtain your medicines from licensed clinics and pharmacies
- Know your medicines! Always check the colour, texture, shape and taste of your medicines after obtaining them to ensure that they are not different from your usual supply
- When in doubt, consult your doctor or pharmacist if you notice the following:
  - Your usual medicine looks / feels / tastes different!
  - Your body responds differently to your usual medicine such as, appearance of new symptoms, adverse reactions etc

Be rational. If the price of your usual medicine seems too good to be true, then it probably calls for suspicion!

What to do if you suspect a medicine is illegal or counterfeit

Stop taking the medicine and seek medical advice should you feel unwell.

You can report the incident to your pharmacist or doctor who will then inform the Health Sciences Authority (HSA) accordingly.

Alternatively you may report the case directly to HSA at:

Enforcement Branch
Enforcement Division
Health Products Regulation Group
Health Sciences Authority

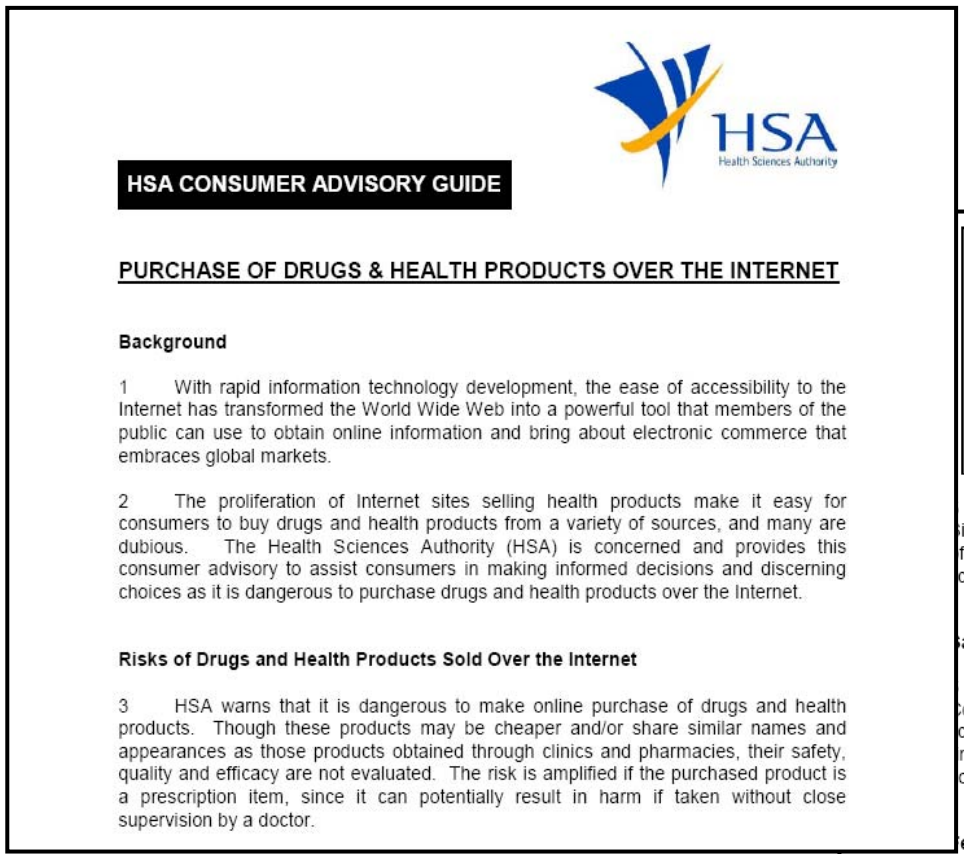
11 Biopolis Way
#11-03 Helios
Singapore 138667

Tel: 68663485
Fax: 64789065

Email: hsa_is@hsa.gov.sg

Form-CIM1/003

Consumer Education



HSA CONSUMER ADVISORY GUIDE

PURCHASE OF DRUGS & HEALTH PRODUCTS OVER THE INTERNET

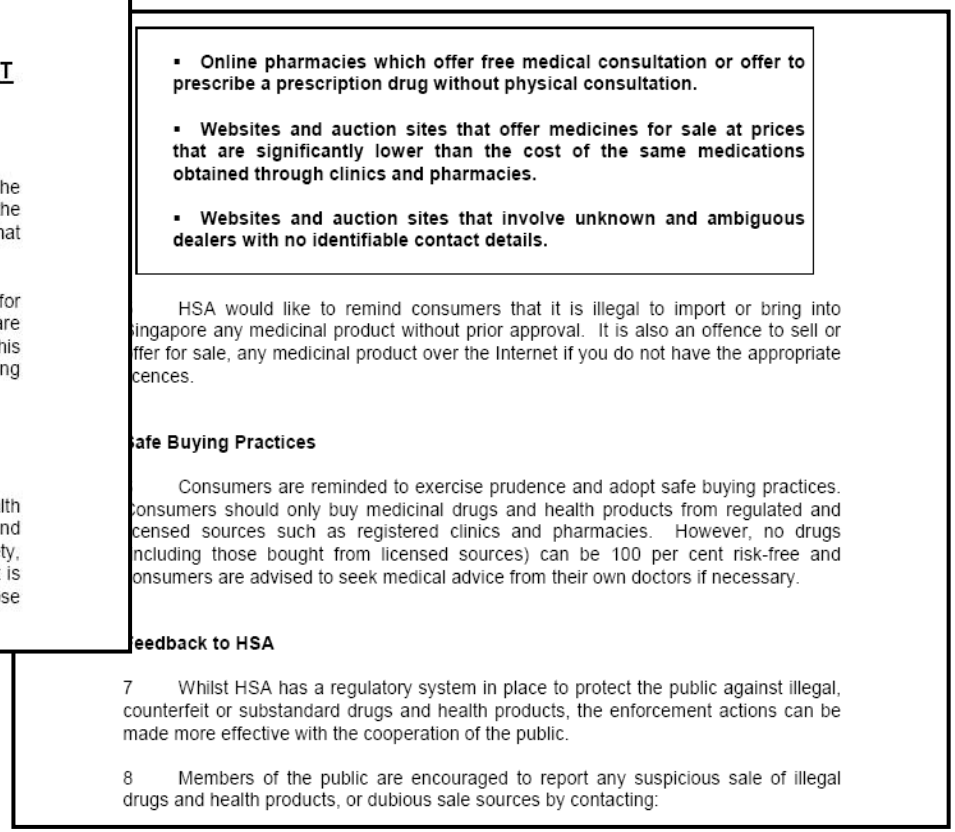
Background

1 With rapid information technology development, the ease of accessibility to the Internet has transformed the World Wide Web into a powerful tool that members of the public can use to obtain online information and bring about electronic commerce that embraces global markets.

2 The proliferation of Internet sites selling health products make it easy for consumers to buy drugs and health products from a variety of sources, and many are dubious. The Health Sciences Authority (HSA) is concerned and provides this consumer advisory to assist consumers in making informed decisions and discerning choices as it is dangerous to purchase drugs and health products over the Internet.

Risks of Drugs and Health Products Sold Over the Internet

3 HSA warns that it is dangerous to make online purchase of drugs and health products. Though these products may be cheaper and/or share similar names and appearances as those products obtained through clinics and pharmacies, their safety, quality and efficacy are not evaluated. The risk is amplified if the purchased product is a prescription item, since it can potentially result in harm if taken without close supervision by a doctor.



- **Online pharmacies which offer free medical consultation or offer to prescribe a prescription drug without physical consultation.**
- **Websites and auction sites that offer medicines for sale at prices that are significantly lower than the cost of the same medications obtained through clinics and pharmacies.**
- **Websites and auction sites that involve unknown and ambiguous dealers with no identifiable contact details.**

HSA would like to remind consumers that it is illegal to import or bring into ingapore any medicinal product without prior approval. It is also an offence to sell or ffer for sale, any medicinal product over the Internet if you do not have the appropriate cences.

afe Buying Practices

Consumers are reminded to exercise prudence and adopt safe buying practices. onsumers should only buy medicinal drugs and health products from regulated and censed sources such as registered clinics and pharmacies. However, no drugs ncluding those bought from licensed sources) can be 100 per cent risk-free and onsumers are advised to seek medical advice from their own doctors if necessary.

eedback to HSA

7 Whilst HSA has a regulatory system in place to protect the public against illegal, counterfeit or substandard drugs and health products, the enforcement actions can be made more effective with the cooperation of the public.

8 Members of the public are encouraged to report any suspicious sale of illegal drugs and health products, or dubious sale sources by contacting:

Consumer Education

➢ Core Messages

- DON'T buy or consume medical products from dubious sources, including peddlers and unfamiliar Internet websites
- DO seek professional medical advice for medical conditions
- DO report suspicious sales of illegal medical products to HSA
- DON'T gamble with your health

Conclusion

- Counterfeit medicines are a threat to global public health
- No country is completely spared from this problem, and no single organisation or agency can manage this problem by itself
- Collaboration and coordination, both national as well as international, is crucial to tackling this problem successfully

European Alliance for
Access to Safe Medicines

EAASM – a working model for patient safety

Jim Thomson, Chair, EAASM

APEC LSIF anti-counterfeiting Forum

Mexico City, February 2009

Topics covered

- Overview of Counterfeit Medicines
- Why and how a multi-sectoral alliance gains traction
- EAASM outputs to date – why we selected them and how they worked
  - Recruitment
  - The Harper Report
  - www.eaasm.eu + e-newsletters
  - The Counterfeiting Superhighway
  - Industry-neutral media source
  - Holding hands with the MHRA
- 2009 and beyond – maintaining momentum and building on successes
- Show and Tell

The growing danger of counterfeit medicines

- Counterfeit medicines represent a huge public health challenge
- The World Health Organization estimates that sales of counterfeit medicines are:[1]
  - **1%** in developed countries
  - **10%** in developing countries
  - **50%** for medicines purchased over the internet from sites that conceal their physical address
- If 1% of medicines in Europe are counterfeit then **many millions of European patients are at risk**
- According to the Center for Medicine in the Public Interest in the US, counterfeit drug sales will reach **US$75 billion** globally by **2010**[1]

1. World Health Organization. Available at: www.who.int/mediacentre/factsheets/fs275/en. Date accessed 29/05/08.

The growing danger of counterfeit medicines (2)
MEDIFAKE

From mid-October to mid-December 2008, DG Taxud co-ordinated Medifake

Project ran across all 27 Member States on a risk-assessed basis

Unprecedented participation by Customs authorities

Medicines deemed “at risk” were closely examined

An altogether unexpected number of fake medicines were uncovered….

34 million, including, according to DG Taxud, a high proportion of live-saving medicines

In Brussels, 2.2 million in a single seizure – inc. 1.6m painkillers and 600k anti-malarials. Belgium is not the natural home of the anopholes mosquito.

Where were these destined for? How many per annum across the full range? What route to market?

And the Profits?

Towards the end of the 20th Century, street prices of narcotics began to fall in real terms.

It is a harsh reality of life in the 21st Century that the profit margin on fake Viagra is approximately 2000 times the profit margin on real cocaine.

Fighting back – a multi-sectoral response

- The PSM

- EAASM launched in November 2007
- Ethos is to involve **all** stakeholders
- Funding initially pharma but now devolving
- Recognised by major institutions
- Primarily concerned with awareness-raising
- Patient safety-focussed….always!

Output 1 – Recruitment
Funding partners committed to the Alliance

To date, the following commercial organisations (funding partners) have committed their support and involvement:

Pfizer
Lilly
Boehringer Ingelheim
aegate™ a PA Group company
Wyeth
AMGEN
IDIS
Ahura Scientific
BAYER
NYCOMED
Johnson & Johnson

Output 1 – Recruitment
Members of the EAASM

- European Men's Health Forum
- The Centre for Mental Health
- European Depression Association
- European Federation of Neurological Associations
- Stroke Alliance for Europe
- European Parkinson's Disease Association
- European Dystonia Federation
- Global Alliance of Mental Illness Advocacy Networks
- Dr Jonathan Harper, Author of the Council of Europe Report on Counterfeit Medicines
- Hendrick de Jong, Chair of the European Pharmacopoeia Commission
- Net Enforcers
- European Sexual Dysfunction Alliance
- New Era Alliance
- Society for Fighting Pain
- European Coalition for Positive People

Output 1 – Recruitment
Supporters committed to the EAASM

- Dr Jolanta Dičkuté, MEP
- John Bowis, MEP
- Bill Newton Dunn, MEP
- Ria Oomen-Ruijten, MEP
- Karin Riis-Jørgensen, MEP
- Liam Aylward, MEP
- Baroness Sarah Ludford, MEP
- Thomas Ulmer, MEP
- Dr Charles Tannock, MEP
- Jaroslav Zvěřina, MEP
- Interpol
- Katherine Eban, Author, Dangerous Doses
- Roger Kampf, World Trade Organization
- Tsveta Schyns, European Association for research on alternating hemiplegia

Output 2 – “The Harper Report”

- *European Patient Safety and Pharmaceutical Parallel Trade – a potential public health disaster?* – a report authored by Dr Jonathan Harper.
  - Mairead McGuinness, MEP asked what would be the European Commission’s response to the EAASM’s report warning that counterfeit and substandard medicines are found in the European supply chain
  - Günter Verheugen, Vice President of the European Commission, responded:

    “… parallel trade brings a considerable risk for the safety of the patients… I will prioritise the issue of parallel trade with fake pharmaceuticals”

PPT – a Potential Public Health Disaster

In 2007, the EAASM commissioned Dr Jonathan Harper to write an independent report on the European distribution system.

The Report was published in Brussels on November 20th 2007 and immediately began to inform the debate at EP level.

Harper's findings were general and specific to PPT and included specific comments regarding CEE.

About the report

A comprehensive discussion about the issue of medicines safety, ultimate patient safety and health consumer choice in Europe

A critical examination of PPT in the EU/EEA, examining the issue from different perspectives, including:

- PPT contribution towards the achievement of the 'single European pharmaceutical market'
- the national differences in European pricing and reimbursement systems and the economic incentives employed
- the impact of the forthcoming new Member State derogation closure on overall European PPT
- counterfeit medicines and European pharmaceutical supply chain security
- weaknesses and costs of the legal and regulatory situation in relation to PPT

PPT and counterfeiting in Europe

Since the EU/EEA is a single market with no internal border controls, there is no way of knowing where PPT products end up

PPT products have the potential to change hands (up to 20 times in some cases) and have to be repackaged prior to being dispensed

In 2006 more than 140 million individual drug packages were parallel imported throughout the EU and a secondary wholesaler repackaged each and every one

In 2007, tens of thousands of fake medicines reached UK patients via parallel distribution

Although the WHO estimates the prevalence of counterfeit medicines in Europe to be one per cent, there is a rapid rise in the detection of counterfeit medicines over the past two years in the EU

The European institutions have now taken action to combat the increasing number of fakes found in the legitimate supply chain

Europe's supply chain complexity

Neither the EC nor EFPIA is able to compile an accurate map of European pharmaceutical distribution; this situation also makes it difficult for authorities and manufacturers to track a product

Full-line European level distributors, parallel distributors, national full-line distributors, European and national-level short-line distributors, national-level parallel distributors, pharmacy distributors, distributor manufacturers …make the European supply chain highly complex

A complex and dynamic horizontal and vertical integration process: different Member States have different rules and regulations for the allowance of pharmacy chains etc.

The problems (or – dangers)

Inadequate regulation and enforcement means the quality, safety and efficacy of both imported and locally manufactured medicines in many developing markets cannot be guaranteed

Medicines exported from many industrialised countries are not regulated to the same level as those domestically consumed

Repackaging process through the cross-border trade of products creates inherent danger to the patients

Parallel trade in prescription medicines causes safety problems and provides counterfeiters with a back door they can exploit for huge profits, causing immense danger to the public health of Europe

European Alliance for
Access to Safe Medicines

Key Conclusions

European pharma market and patient safety

- Europe's pharmaceutical market suffers from a syndrome of „invisibility, biohazard and system failure'
- EU expansion has added to „system stress'
- Achievements have been made, though Europe is far from attaining a single pharmaceutical market
- Europe's pharmaceutical pricing and reimbursement system suffers major divergence and inefficiencies
- Europe's pharmaceutical distribution system is extremely complex and potentially puts patient safety at risk
- The functioning of the European pharmaceutical market should not be an academic/philosophical/political entity, but should be something that all stakeholders can understand and benefit from
- European patients, doctors, pharmacists, manufacturers and the pharmaceutical supply chain business need a single point of control (SPOC) for reporting medicine „product defects'

European PPT

- PPT provides marginal health economic benefit at best
- Benefits or otherwise of PPT have focused largely on pure economic considerations, tending to neglect the important pharmaceutical regulatory, supply chain security and patient safety issues
- PPT exploits inefficiencies, divergence and rigidity within the EU pricing and reimbursement system
- Legal and regulatory issues surrounding PPT should provide more concise, rational and firm regulatory guidance
- Personalised medicines trading through the increasing trend of mail order and internet pharmacy is likely to have a complex interaction with the business of PPT which will make distribution chain regulation and supply chain security much harder
- Evidence suggests that PPT undermines patient safety in terms of inaccurate dispensing, patient confusion and the risk of counterfeit and adulterated medicines entering the supply chain

Specific concerns for CEE

Common borders with known sources of CMs
Emerging regulatory environments
Emerging commercial environments
Relative strength/weaknesses of economic systems
Phasing out of derogation, will it….
Create an import market for PMs and therefore open the door to CMs…or
Create an export market and therefore shortages, opening the door to CMs

Is the CEE area ready for the challenges of PPT?

CEE – the emerging battleground

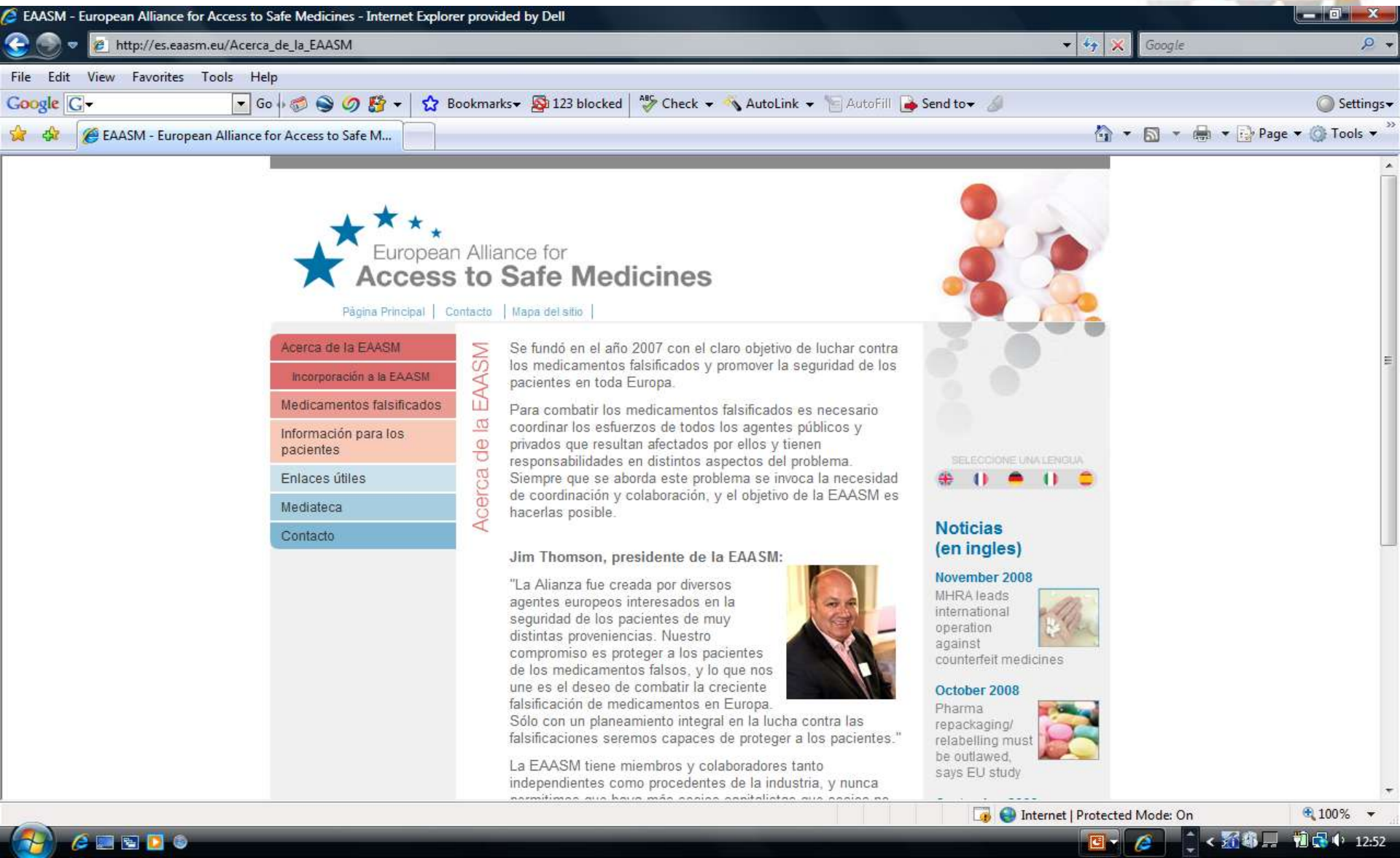
- Budapest, April 2008, 15th Annual CEE Regulatory Affairs Conference
- Radical differences in regulation pre/post accession
- Tremendous pressure to adapt regulatory systems to conform with EU template(s)
- Common issues were identified by a number of national regulators
- Help and support is needed and should be offered

What happened?

- DG Enterprise & Industry consulted widely
- Draft Report called for a ban on repackaging
- 18 out of 27 votes went against the current draft
- Legislative package “postponed” and then watered-down
- What price free trade? What price patient safety?

Output 3 – www.eaasm.eu

Output 3 – HTML e-newsletters



Output 4 – combating internet drug-sellers

- *The Counterfeiting Superhighway* – an in-depth report detailing shocking results of:
  - desk research of over 100 online pharmacies
- expert and chemical analysis of over 30 packets of prescription-only medicines bought online
  - as well as conclusions and recommendations to tackle the growing threat

Background

- The World Health Organization estimated that over 50% of websites concealing their physical address are selling counterfeit medicines

- Internet security experts believed that nearly 25% of all emails – 15 billion messages a day – are spam advertising medicines

Why do consumers purchase medicines online?

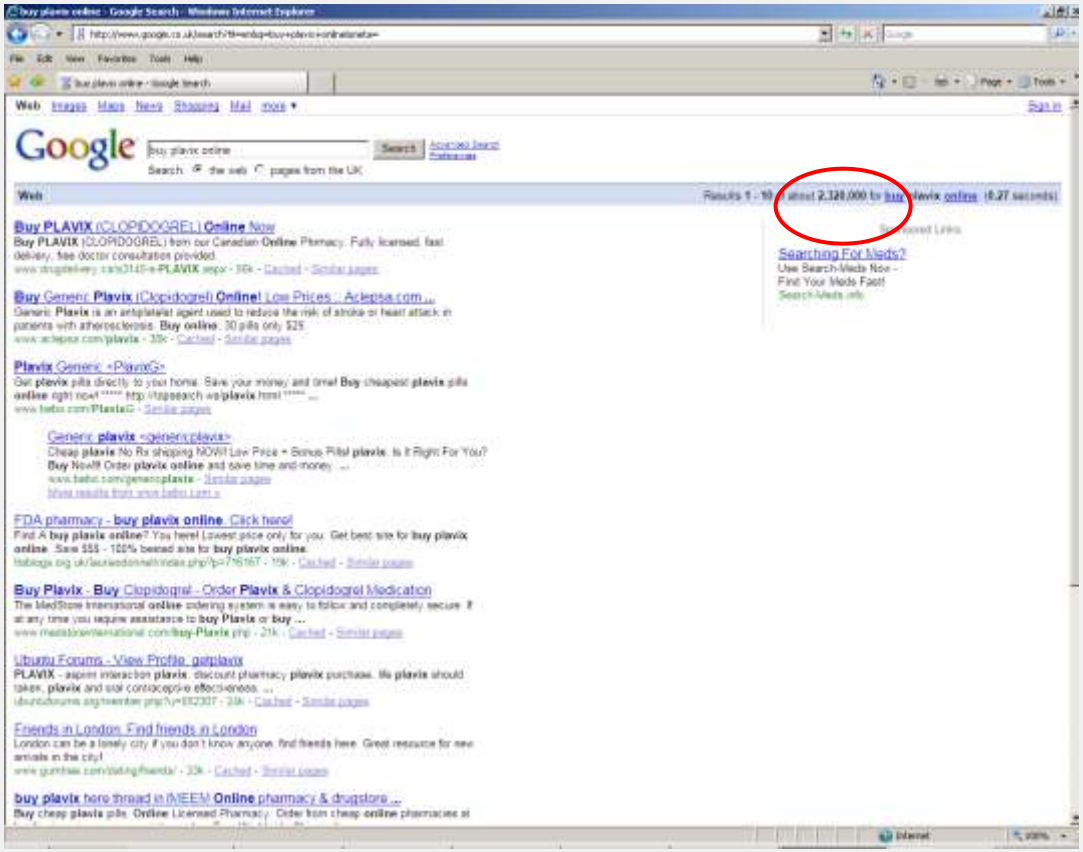
- Speed and convenience of access
- When they are too embarrassed to ask their doctor for medicines
- When they do not want employer/authorities to know about their condition
- When they want to get hold of a medicine that they suspect a doctor might be reluctant to prescribe for them
- Sidestep the gate-keeping functions of the medical system

Searching for medicines online

- ★ „Via' from the Latin, used to mean „by way of'
- ★ 'Buy' still means „to purchase'
- ★ So…'buy via' should mean „to purchase by way of'
- ★ Turn on Google's predictive search feature and type in „buy via'

- ★ Complete the name of that medicine and Google will return a large number of search results
- ★ Every single result will relate to a well known medicine, not a means of making a purchase
- ★ How many?... **…. 11.9 million**

2.3 million options when searching Plavix...



The scale of the problem

- Every type of prescription-only medicine (POM) can be found on the internet
- From generic to blockbuster, from life-style to life-saving drugs
- Illegitimate online pharmacies are selling POMs without prescription, no questions asked
- Credit card companies process payment to these sites
- International couriers will deliver the „medicines'

  - **It's time to address this**
  - **It's time to inject some responsibility into the internet**
  - **It's time to get back to real healthcare**

The EAASM response

- *The **Counterfeiting Superhighway*** research
- Comprehensive, ground-breaking research, aiming to highlight:
  - the dangers of purchasing medicines online
  - how frequently counterfeit medicines are being sold through internet pharmacies
  - recommendations to minimise risks and tighten legislation

The Counterfeiting Superhighway Report

- The research asked two key questions:
  - What proportion of internet pharmacies, as sampled, selling prescription-only medicines is acting unlawfully?
  - Of the medicines sold by internet pharmacies, what percentage is counterfeit or substandard?

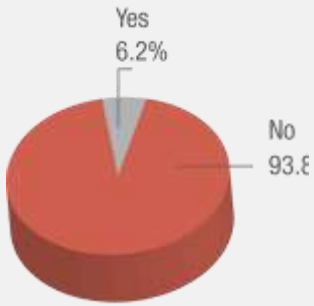
- Three phases were completed to answer these questions:
  - Phase 1 – Desk research: finding and inspecting online medicines traders
  - Phase 2 – Purchasing medicines online
  - Phase 3 – Unwrapping and expert analysis

Phase1 – Desk research

- Online pharmacies were randomly selected using:
  - search engines (including Google, AltaVista, MSN and Yahoo!)
  - links from spam emails advertising medicines online
  - online medicine supermarkets
- Over 100 websites were identified and assessed according to a checklist which comprised the key questions consumers should ask of online medicine traders purporting to be genuine

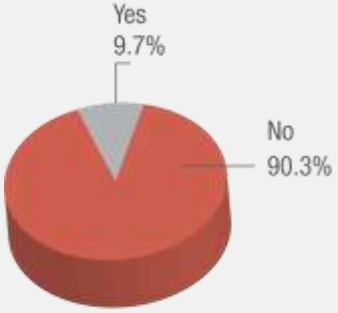
Results

Is there a named verifiable pharmacist?



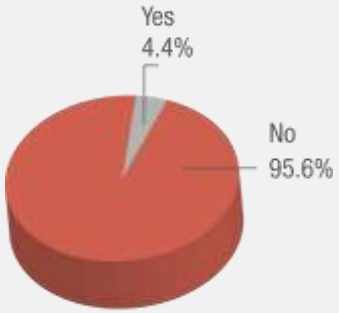
93.8% provided no proper medical control or guidance for people purchasing medicines online

Is a prescription required for prescription-only medicines?



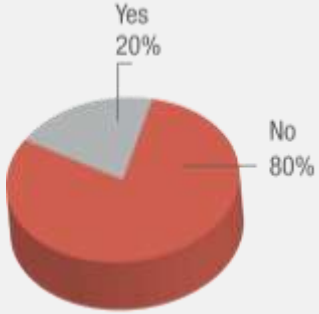
Over 90% illegally and dangerously provide consumers with POMs, without requiring a prescription

Is the website listed as a legitimate pharmacy?



Fewer than 5% are licensed by a board of pharmacies or appropriate pharmacy listing

Is there a 'stamp' of approval by a recognised society?



One in five has an online „pharmacy approval' stamp – 86% of these are fake

Phase 2 – Purchasing medicines online

- Commonly purchased prescription-only medicines were ordered
  - Medicines ordered included those indicated to treat neurological disorders, cardiovascular disease, mental health, obesity and erectile dysfunction
- All medicines bought online were stored in a fireproof safe until packages were opened and inspected by an expert panel

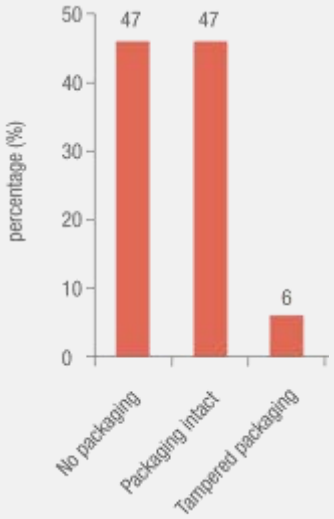
Men's Health	Cardiovascular/ Respiratory	Mental Health	Alzheimer's Disease	Other
Cialis, Lilly	Lipitor, Pfizer	Zyprexa, Lilly	Aricept, Pfizer	Reductil, Abbott
Levitra, Bayer-Schering	Seretide, GSK	Efexor, Wyeth	Reminyl, Shire	Zoton, Wyeth
Viagra, Pfizer	Plavix, sanofi-aventis	Risperdal , J&J		Mirapex, Boehringer-Ingelheim
Propecia, MSD	Coversyl, Servier			
	Micardis, Boehringer-Ingelheim			
	Spiriva, Boehringer-Ingelheim			

The buying experience

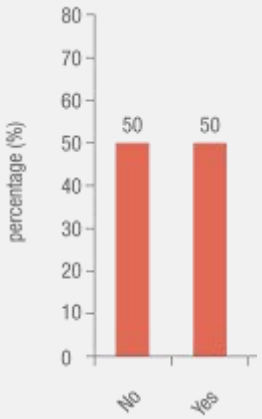
- Finding online traders and placing orders for prescription-only medicines without an(y) authorised prescription was quick, simple and straightforward
- Few questions were asked and no advice was given*
- No pharmacist, physician, nurse or any other healthcare professional was involved in the purchasing process to provide assessment or guidance
- Rare „online consultations' were easily bypassed or completed with entirely false information

Results

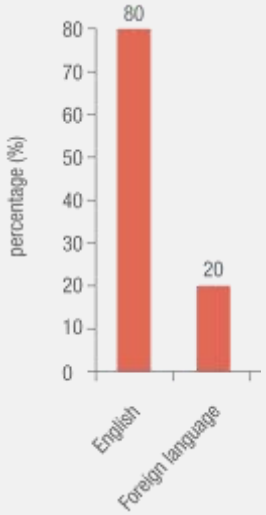
Packaging



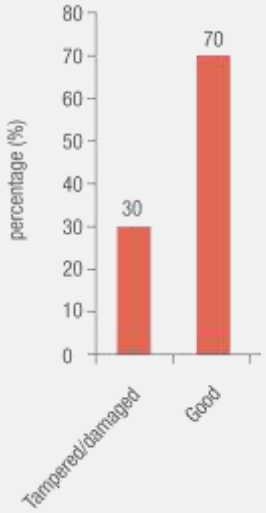
Patient information leaflet supplied



Patient information leaflet – language



Condition of blister pack

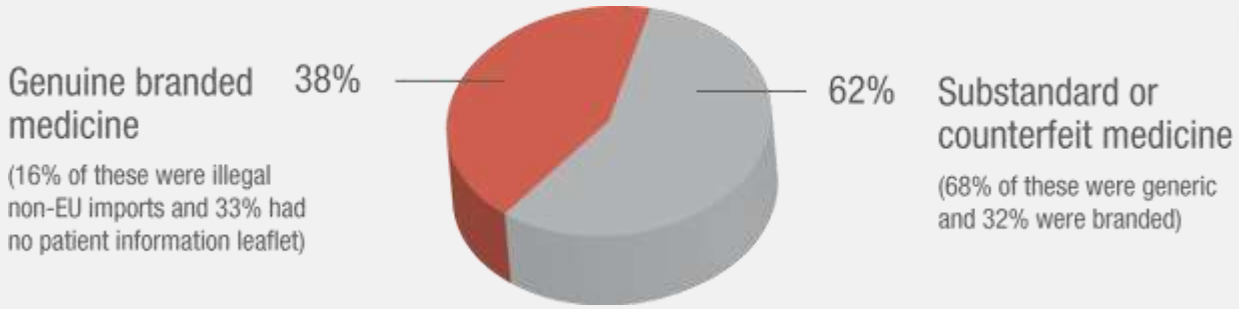


- "Packaging" included: dirty blister packs wrapped in newspaper or enclosed in envelopes; loose tablets in plastic bags; incorrect/poorly copied manufacturer or brand logos; unorthodox box size/blister pack arrangements, etc.

Phase 3 – Unwrapping and expert analysis

- Packages were unwrapped during a dedicated meeting held at the Royal Society of Medicine's premises in London, UK, in April 2008
- An expert panel comprised 22 members including representatives from:
  - key European patient associations
  - security specialists
  - pharmacists
  - pharmaceutical manufacturer employees
  - independent security experts
  - former senior police officers
  - government liaison personnel
  - an international courier and delivery organisation.
- Each group visually scrutinised and evaluated the medicines packages using a uniform set of criteria

Results



- Of the prescription-only products received:
  - **100% were supplied illegally, without a prescription**
  - 62% were counterfeit or substandard
  - Only 38% were genuine branded medicines, of these:
    - 16% of these were illegal non-EU imports (genuine products, imported into the EU illegally from a non-EU country)
    - 33% did not have patient information leaflets

Summary

- The report findings demand action. Consumers are susceptible to fake medicines which could harm their health, and in extreme cases be deadly
- There is a need for overall corporate responsibility – stakeholders must take action and halt this dangerous trend:
  - Search engines to disable online access to illegal pharmacy websites and warn consumers of the potential risk of visiting illegitimate websites
  - Credit card companies must stop financial transactions for illegal online pharmacies
  - Regulators to take appropriate action to raise public awareness and provide more information about this dangerous practice
  - Customs authorities and agencies should increase public protection measures
  - Professional pharmacy societies should create an accessible database of regulated online pharmacies
  - Patient Advocacy Groups must do more to help raise awareness

Output 5 – Media Coverage of CM issues (1)

- PR campaign following the official EAASM launch and publication of the Harper report resulted in pan-European coverage, including:
  - Sweden, Germany, Poland, Spain, Portugal and the UK
- The EAASM has been present at or spoken at:
  - 13 major international conferences/congresses in the UK, Europe and the USA
  - Briefed Governments / inter-governmental agencies, also in the above
- DG Enterprise and Industry submission – a 12-page submission document providing the patient perspective
- The EAASM produces bi-monthly e-newsletters sent to all members/ supporters and available on the EAASM website

PharmaTimes

SCRIP

BMJ

4TH Global Forum on PHARMACEUTICAL ANTICOUNTERFEITING

Pharmaceutical marketing

Output 5 – Media Coverage of CM issues (2)

- CS Report attracted overwhelming media attention, including leading national printed newspapers, online, radio and television coverage:
  - 100 items in **France**
  - 30 pieces each in **Germany**, the **UK** and **Italy**
  - 70 items in the **USA**
  - two dozen items in **Belgium**
  - 45 pieces in **Spain**

Output 6 – Hand-holding…

- In November 2008, EAASM & MHRA staged a joint conference for patient safety and advocacy groups. The purpose was to raise awareness of each other's role(s) and seek help to spread the word
  - Patient groups unanimously promised to feature CM in constituent communications
  - Plans being made to upgrade www.eaasm.eu to accommodate polling
  - MHRA & EAASM to co-operate further, across Europe

So, did we get results?….

In year 1, the EAASM

- Engaged a wide range of members and supporters
- Produced two ground-breaking reports
- Launched a range of patient-information resources, including
- a web portal in 5 main European languages
- Achieved unprecedented coverage of CM issue
- Proved that a multi-sectoral approach is the most relevant one

Moving Forward – 2009 and beyond

The EAASM has ambitious plans to build on these foundations….

- Interactivity on the website – inc. webinars
- Polling “patient experience and perceptions” research through European patient groups & www.eaasm.eu
- EAASM/Regulator/patient grp meetings in Europe (inc. CEE)
- EU Safe Distribution campaign
- 1st annual publication of “Trends”
- Rollout of Counterfeiting Superhighway Report

Moving Forward – 2009 and beyond

Fighting counterfeit medicines is the most important thing I have ever done

It is why I founded the EAASM

The counterfeiter does not acknowledge borders & goes wherever there is profit

You could pass him in the street and never know

You will never recognise the counterfeiter or his product

Secure supply is our only option to protect ourselves

The EAASM stands ready to help anyone committed to this fight, anywhere in the World. We will happily share our experiences, knowledge and energy. Just ask.

Show & Tell

European Alliance for
Access to Safe Medicines

Jim Thomson
Chair, EAASM
European Liaison, Partnership for Safe Medicines
Member, Institute for Health Law Studies, California Western School of Law
Contact: jim.thomson@eaasm.eu

Thank You!

APEC FUNDED ANTI-COUNTERFEIT MEDICAL PRODUCTS SEMINAR

February 17-19, 2009

Topic: The Impact of Globalization of the Pharmaceutical Industry on the Spread of Counterfeit Medical Products

Mexico City, Mexico

Jeffrey Gren, Director

Office of Health and Consumer Goods

U.S. Department of Commerce

Outline

- Introduction
- The impact of globalization of the pharmaceutical industry
- The substandard and counterfeit medicines global problem
- DOC anti-counterfeit medical product activities
- Possible solutions
- Summary and conclusions

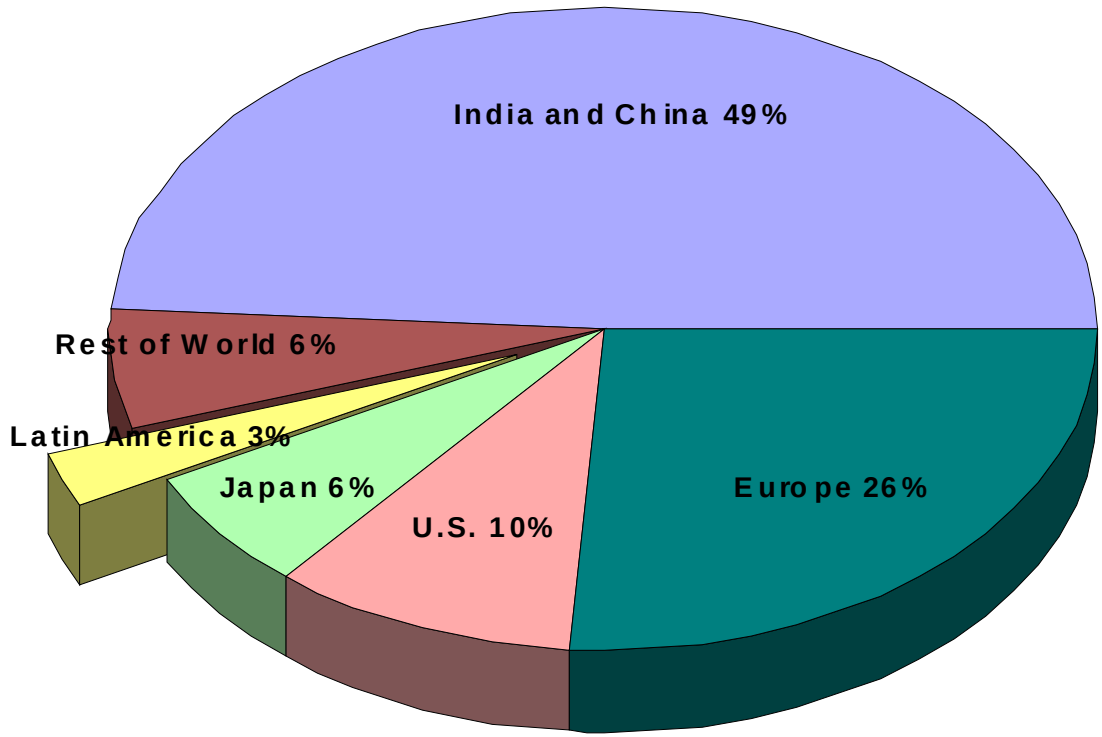
Introduction

- U.S. Department of Commerce (DOC) is the advocate for business in the U.S. government and DOC's international trade role is to promote U.S. trade by strengthening industry competitiveness and reducing trade barriers
- I direct the Office of Health and Consumer Goods and my office focuses on medical devices, pharmaceuticals, biotechnology, and a wide array of consumer goods products
- An outcome of the globalization of the pharmaceutical industry is a significant increase in substandard and counterfeit medicines

Introduction (cont'd)

- During the past several years DOC has been very active in the global battle to stop the spread of counterfeit medicines and we work very closely with U.S. FDA and industry in our activities
- We are also currently exploring drug quality issues such as the global substandard medicines problem and ways that DOC can work with industry and regulators to address this problem
- The percentage of counterfeit and substandard medicines on the market increases each year as manufacturing of API and finished dosage form medicines shifts from developed to lesser developed markets

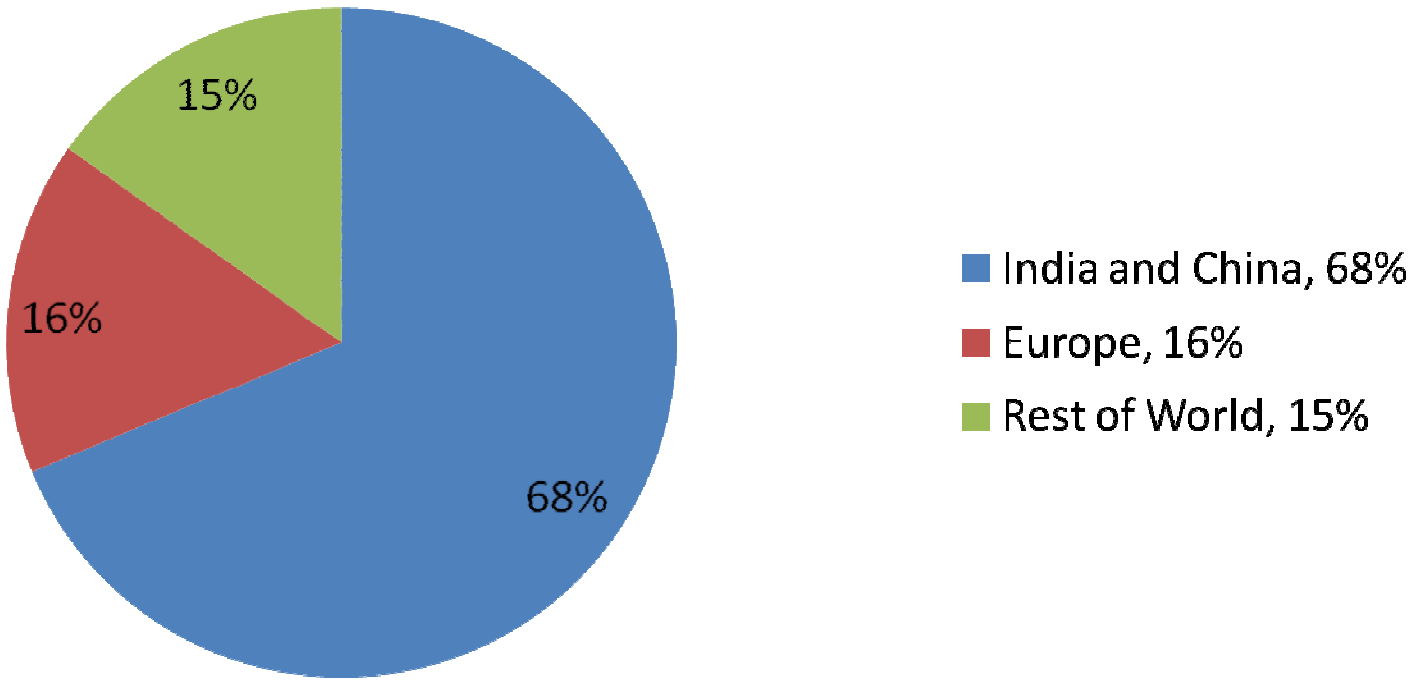
Industry Trends Impacting the Problem: Global API Manufacturing - 2004



Total Global Number of API Manufacturers Sites approximately 2,000

*Source: Newport Horizon Sourcing, October 2004

Industry Trends: Global API Manufacturing 2007



Total Global Number of API Manufacturers Sites approximately 1,144

*Source: Newport Horizon Sourcing, October 2007

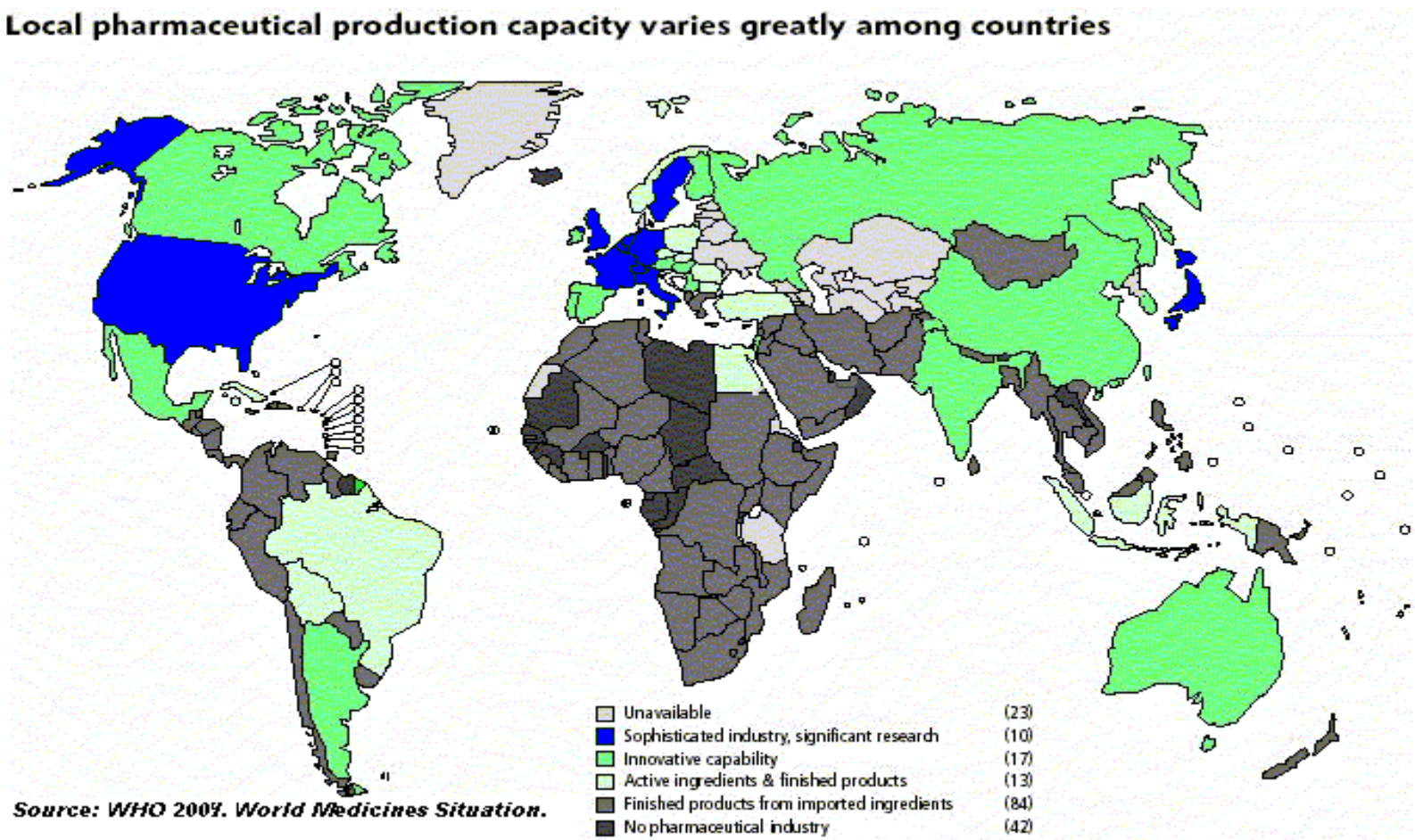
Industry Trends

- IMS Health: India will be the dominant country for API production for the next 20 years, and over the next 50 years China will become more dominant for API production
- Currently most API manufacturing in India and China is for the generic drug market, but this will change over time due to:
  - lower developmental costs
  - complex synthesis capabilities
  - shifting pharmaceutical drug production
  - regulatory compliance and adherence to CGMP and CGCP

Industry Trends: Generic Production

- Generic production is growing at a faster rate than innovator drug production
- Shift in the global production of generic drugs – countries/regions with significant growth of generic production include India, China, South East Asia, Brazil, Middle East, Russia, Mexico
- According to IMS, India is currently producing about 70% of the global generic medicines.

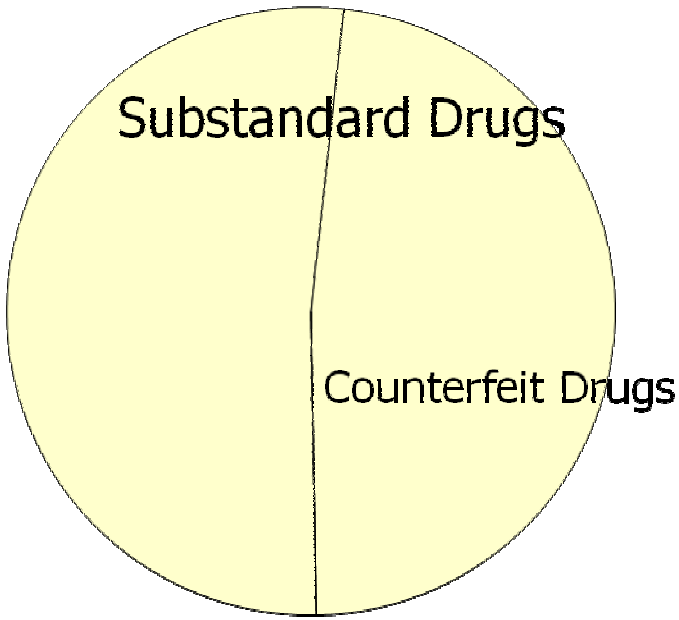
Industry Trends: Global Pharmaceutical Manufacturing



Industry Trends Impacting the Problem (cont'd)

- The shift in API and finished dosage form production away from the developed markets can contribute to the counterfeit and substandard medicines problem
- The regulatory regimes and standards established by pharmacopeias are much weaker in developing and least developed countries
- It is important to note that counterfeit medicines are not limited to innovative drugs. In fact, we are seeing an increasing number of counterfeit incidences involving generic and over the counter medicines

Counterfeit vs. Substandard Drugs



- All counterfeit drugs are substandard
- Only a portion of substandard drugs are counterfeit

Counterfeit vs. Substandard Drugs

- Notably, there is a significant difference between counterfeit and substandard drugs
- WHO defines counterfeit drug as “a drug that is deliberately mislabeled with respect to identity and/ or source”
- Counterfeit drugs are produced by criminals and meet the “fraudulent and the deliberate” aspects of the WHO definition of counterfeit medicines
- Substandard drugs are medicines manufactured below established standards of safety, quality and efficacy

Counterfeit vs. Substandard Drugs (cont'd)

- However, neither counterfeit or substandard medicines generally meet regulatory requirements such as cGMPs, bioequivalence, or pharmaceutical equivalence
- The public health impact of substandard and counterfeit medicines is the same since both can have correct APIs, wrong APIs, no APIs or less than effective APIs

Counterfeit vs. Substandard Drugs

- In our view all medicines that have the potential to cause unnecessary harm to patients are unsafe
  - Counterfeit: deliberately and fraudulently mislabeled with respect to identify and source
  - Substandard: do not meet the requisite pharmaceutical regulatory / therapeutic specifications
- The substandard and counterfeit medicines problem varies significantly among countries and regions
- Countries and regions with weak regulatory oversight are more suspect to substandard medicines

Counterfeit vs. Substandard

- The consequences of the use of either counterfeit or substandard medicines is the same:
  - Direct harm to patients
  - Therapeutic failure
  - Weakens public confidence in health system
  - Affects reputation of supply chain

Counterfeit vs. Substandard Drugs (cont'd)

- There are no reliable statistics to measure global impact of counterfeit and substandard medicines
- 10-20 years ago most counterfeit medicines had no APIs
- Now increasing number of counterfeit medicines contain real APIs

Counterfeit vs. Substandard Drugs (cont'd)

- A single global figure is misleading
- Developed markets with strong regulatory oversight are estimated to have less than 1-2% of the drug supply as counterfeit. However, 1-2% of the U.S. or EU drug supply is a huge number

Counterfeit vs. Substandard Drugs (cont'd)

- Internet sales of drugs is a huge problem – a recent study cites that 63% of drugs purchased on the internet are counterfeit and all are illegal
- Much of the world (SE Asia, Africa, China, Latin America) has areas where patients regularly encounter counterfeit and substandard medicines
- A US Pharmacopeia 2004 study of medicines in SE Asian countries documents that selected drugs tested had a 25 - 75% incidence of substandard or counterfeit

Counterfeit Vs. Substandard Drugs

The most expensive drug is the one that does not work!!

Counterfeit Medical Devices

- Most of the counterfeit medical products focus has been on counterfeit pharmaceuticals.
- There is clearly significantly more reporting incidences for counterfeit pharmaceuticals than for counterfeit medical devices
- However, there is an increasing number of incidences of counterfeit medical devices
- Based upon feed back from industry the most frequent incidences for counterfeit medical devices are in IVD reagents and solutions, contact lenses, medical test kits, combination products (medical devices and drugs), and component parts, such as semi-conductors used in medical imaging equipment

DOC Involvement / Activities

- DOC/FDA led Anti-Counterfeiting Task Force
- APEC Life Science Innovation Forum activities, such as anti-counterfeit medical product Asia and Latin America seminars (with USFDA)
- U.S. - China Pharmaceutical and Medical Devices JCCT Subgroup
- U.S. - India HTCG Biotechnology and Life Sciences Working Group

Potential Solutions

- Global cooperation among health regulations, customs, law enforcement and industry to stop the flow of counterfeit pharmaceutical ingredients
- Global cooperation on plant inspections/audits – no one country can do this alone
- Regulators need to enforce standards, and take action against poor performances
- Manufacturers need to be responsible for product quality

Potential Solutions (cont'd)

- Continue global harmonization efforts, including training and harmonized standards (ICH and country or region specific activities)
- Encourage track and trace technologies, verification of ingredient programs, authentication technologies to protect supply chain integrity
- Continue to focus on regional dialogues – APEC, ASEAN, PAHO, WHO, PANDRA, etc.
- World Health Organization (WHO)

Potential Solutions (cont'd)

- "Partnership for Safe Medicines" is a coalition of patients, physicians, pharmacists, universities, industry, and other professional organizations, committed to protecting the public from counterfeit – Avoid – Detect – Report
- SafeMeds Alert System: www.safemedicines.org Countries can sign up to participate
- Risk of doing nothing – prevalence of substandard and counterfeit medicines **will** continue to grow

Summary and Conclusions

- The globalization of the pharmaceutical industry has contributed to an increase in counterfeit and substandard medicines
- Notably, the global shift in the production of API and finished dosage form medicines adds to the global counterfeit and substandard medicines problem
- Any meaningful solution requires cooperation and coordination among various stakeholders, including customs, regulators, law enforcement, and industry

Summary and Conclusions (cont'd)

- Progress is being made, but a focused global approach is needed
- I look forward to the day when we can announce there are less substandard and counterfeit medicines in the world than there were the previous year

Thank You!

Jeffrey Gren, Director

Office of Health and Consumer Goods

U.S. Department of Commerce

Phone: 202-482-2587

Email: Jeffrey.Gren@mail.doc.gov

Website: www.export.gov/health

Mexico City
2009

Importance of International Cooperation

PHARMACEUTICAL
SECURITY
INSTITUTE

Overview

Briefing Objectives

- Introduction to PSI
- Identify Resources of PSI
- Practical ways to build international cooperation

PHARMACEUTICAL SECURITY INSTITUTE

PSI's Mission is in its Name

The Pharmaceutical Security Institute is a fact finding, non-profit organization dedicated to:

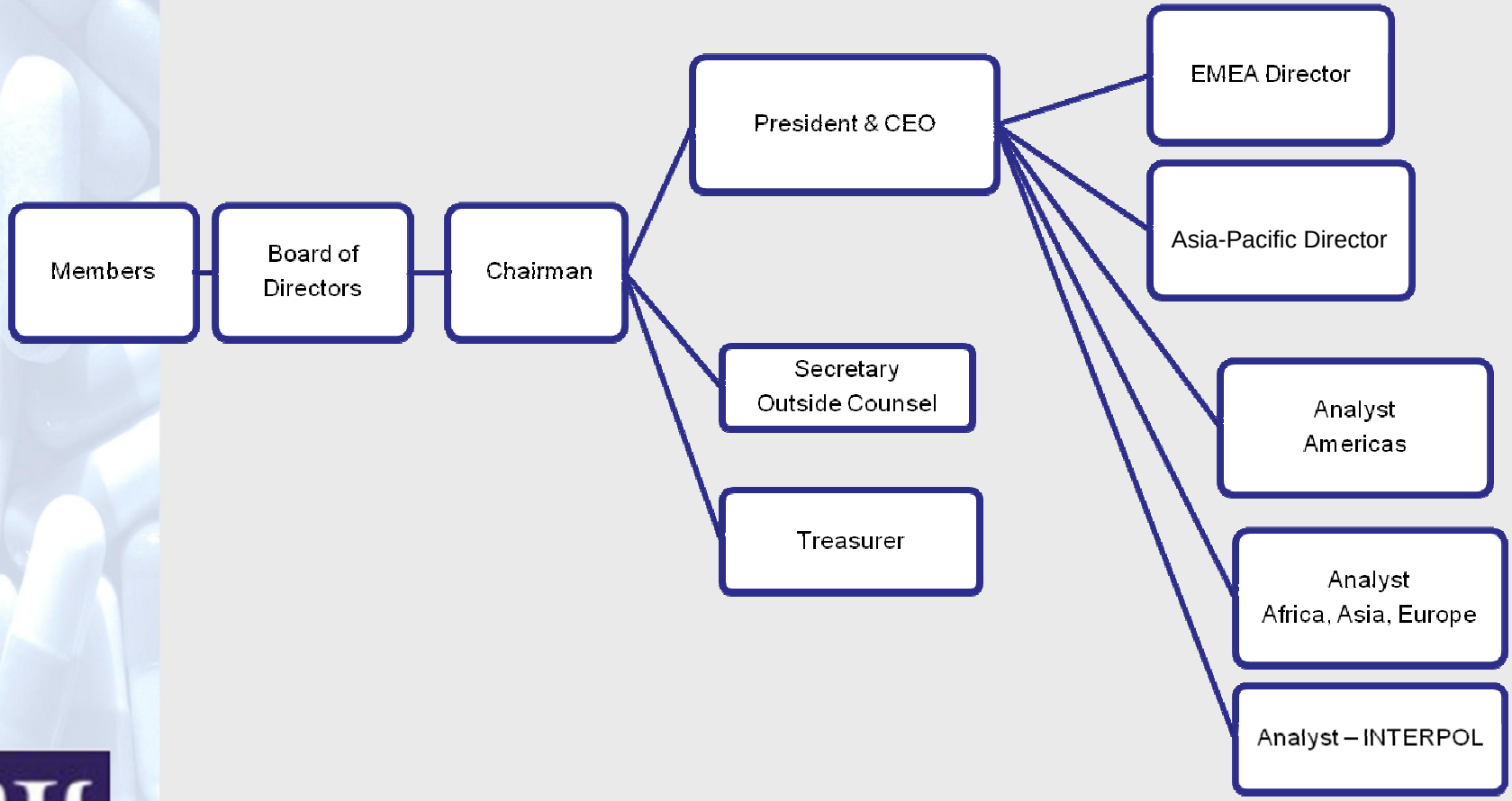
Protecting the Public Health

Sharing Information on Counterfeiting Activity

Initiating Enforcement Actions with the Appropriate Authorities

PHARMACEUTICAL SECURITY INSTITUTE

PSI Structure 2009



The Institute

Unique non-profit in Vienna, Virginia

- Funded by innovative pharmaceutical manufacturers
  - 26 Security Directors
  - Most former senior law enforcement
  - Dedicated anti-counterfeiting resources
- Primary focus
  - Collect, analyze and share information
  - Improve coordination
  - Disrupt and dismantle counterfeiting groups

PHARMACEUTICAL SECURITY INSTITUTE

PSI Members

PHARMACEUTICAL SECURITY INSTITUTE

Building International Cooperation

Suggested steps

Presentations to increase dialogue –
Explain business operations

Information on counterfeiting
Strategic and operational intelligence

Laboratory Examinations
Can determine product authenticity

Liaison meetings to
Maximize result by working together

PILL

PHARMACEUTICAL SECURITY INSTITUTE

P = Presentations

Coordinate LEA and DRA seminars:

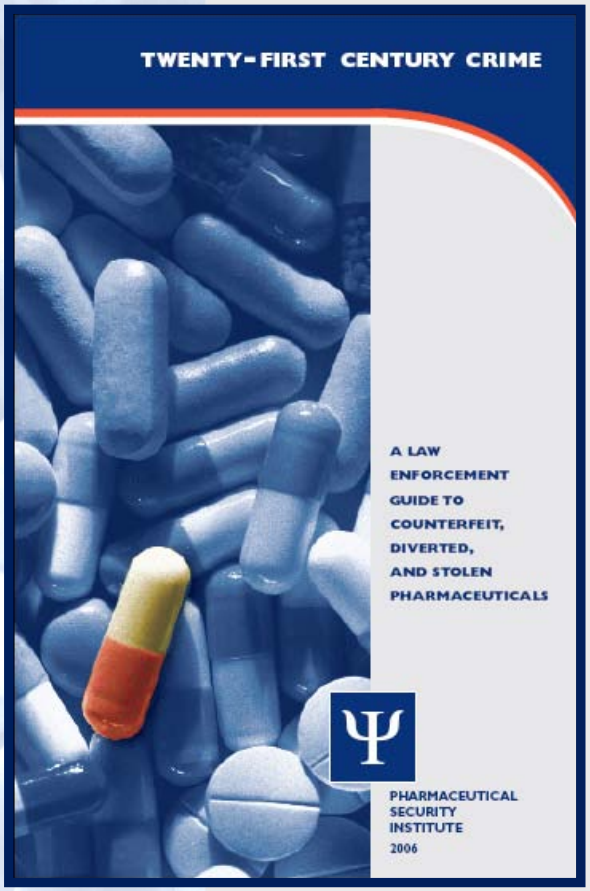
- Identify information shortfalls
- Develop and provide seminars
- In 2008, briefing included:
  - —FBI, ICE, Health Canada
  - —Argentina, Canada, China, Japan, Singapore, Thailand

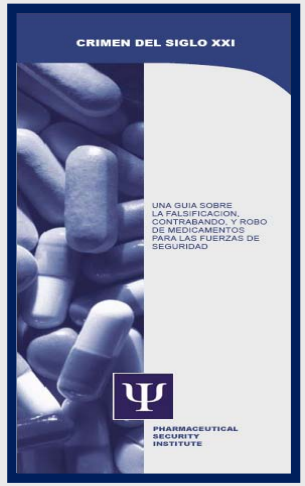
Goal – information exchanges help to:

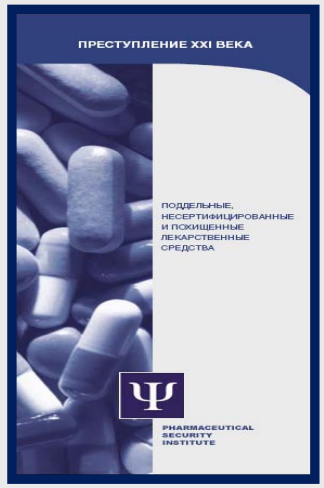
- Foster understanding
- Improve enforcement efforts
- Build relationships

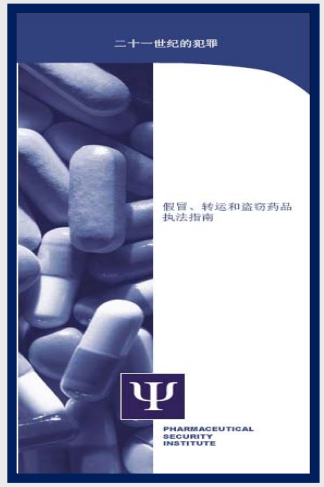
PHARMACEUTICAL SECURITY INSTITUTE

Presentations: Briefing Materials









Multi-lingual training guides to alert the authorities

I = Information

- Operational Reports
  - Timely, case specific reports identifying investigative linkages
- Country Reports
  - Country or regional counterfeit, theft, and diversion analyses
- Special Projects
  - Customized projects or studies to match unique needs

L = Laboratory Examinations

SAFE MEDICINES .org

AUTHENTICITY EVALUATION
ANALYTICAL TESTING REPORT

Impacted Product:	Our Drug
Samples:	Purported, 100-mg, Name Tablets and Packaging Obtained by the Public Health Service in the Country
Company Internal Identifications:	05974-642-S505598
Agency/ Submitting Country:	Self-Explanatory
Conclusions:	S505598: Counterfeit Drug Product Tablets and Packaging

Chain of Custody Information:

Received by (name):	Company Senior Analytical Chemist
Date Received:	Day/Month/Year, Internal Mail; EP S505598
Receiving Laboratory:	Counterfeit Testing Laboratories, Quality Operations, City, State, COUNTRY
Sample from (name/dept):	Top Notch Investigator (Global Security, Country)
Date(s) of Testing	Day/Month/Year

L = Laboratory Examinations

Description of sample, visual evaluation, and spectroscopic comparison:

Sample Description (see Figure 1):

The analytical sample **05974-642-S505598** was received from Global Security, COUNTRY, in sealed evidence bag S505598.

The subject sample **05974-642-S505598** consisted of one ten-tablet blister pack of purported Our Drug 100-mg tablets, an IFC and a PIL. The IFC and blister lot number and expiry are 832718474 and 08-2007 respectively.

The subject sample is a representative sample of 375 blisters, cartons and leaflets that were found in a hotel near a city in Asia.

Packaging Evaluation 05974-642-S505598 (see Figures 2-5):

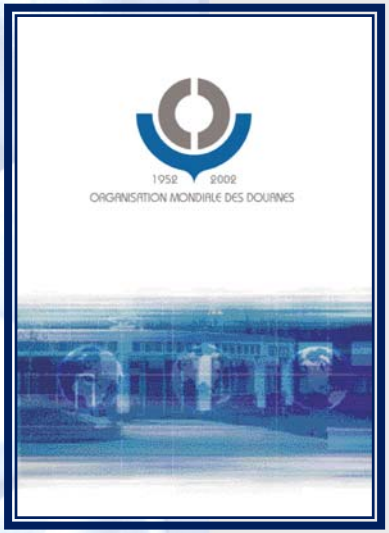
Individual Folding Carton (See Figure 2): The subject sample **05974-642-S505598** IFC was received unformed but with the lot number, expiry date and manufacturing date already printed on the carton. The IFC is elegant and fully purports to be Our Drug 100mg manufactured by Our Company, USA. The IFC artwork and box codes are 8408120 and 103541 respectively.

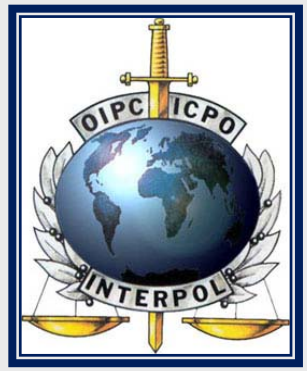
These codes are valid for an Arabian market pack of 50-mg of Our Drug and not for a 100mg of Our Drug pack. The lot number 832718474 along with the manufacturing date of 08-2004 and the expiry date of 08-2007 are printed on the IFC and have been confirmed as not valid for any authentic Our Drug manufactured in the USA.

The carton shape is consistent with the code 103541 however there are errors in the artwork of the IFC including: 'Our Name' font in the logos is incorrect; the carton states "100mg" when the authentic is for 50mg and there is text missing from the back of the carton. There are no security features or box seals present.

L = Liaison

Case Related seminars





Paris 2008

PHARMACEUTICAL SECURITY INSTITUTE

L = Liaison

Derived from the Latin word meaning “to bind.”

Every international and national organization recognizes the need for public private partnerships to address counterfeit medicines

Shared responsibility to the patients of the world

Effective liaison leads to understanding the nature and extent of this threat - actions.

Effective liaison

- Better coordination of cases impacting over diverse geographic areas;
- Improved communication with manufacturers security departments;
- Increased opportunities to seize counterfeit medicines; and,
- Save lives and prevent harm to innocent patients.

Effective liaison in Latin America

WCO – Interpol Operation Jupiter:

- 2005 Multi-nation – Multi-product anti-counterfeiting operations in Latin America;
- 2006 Five countries – three month operation seized $35 M in counterfeit goods; and,
- 2007 More countries involved - Argentina, Bolivia, Brazil, Chile, Paraguay, Peru and Uruguay.

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Investigator Comments

Many thanks for your fast response and the detailed report. Interesting stuff! – UK

Great job PSI. Thanks for the info I will share your work with my colleagues. – US LEA

Have a once-over and let me know ...I figure you know more than anyone else on this stuff. - DRA, Caribbean nation

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Conclusion

PSI can help you:

- reduce investigative time
- conserve resources
- build better cases

Call, fax or email – all services are available at no charge.

PHARMACEUTICAL SECURITY INSTITUTE

Conclusion

Remember the PILL

- Presentations
- Information
- Laboratory
- Liaison

PHARMACEUTICAL SECURITY INSTITUTE

Contact Details

Pharmaceutical **S**ecurity **I**nstitute
8100 Boone Blvd., Ste. 220
Vienna, VA 22182, USA
Tel: 703-848-0160
Email: psi@psi-inc.org

Checkout the Website
http://www.psi-inc.org

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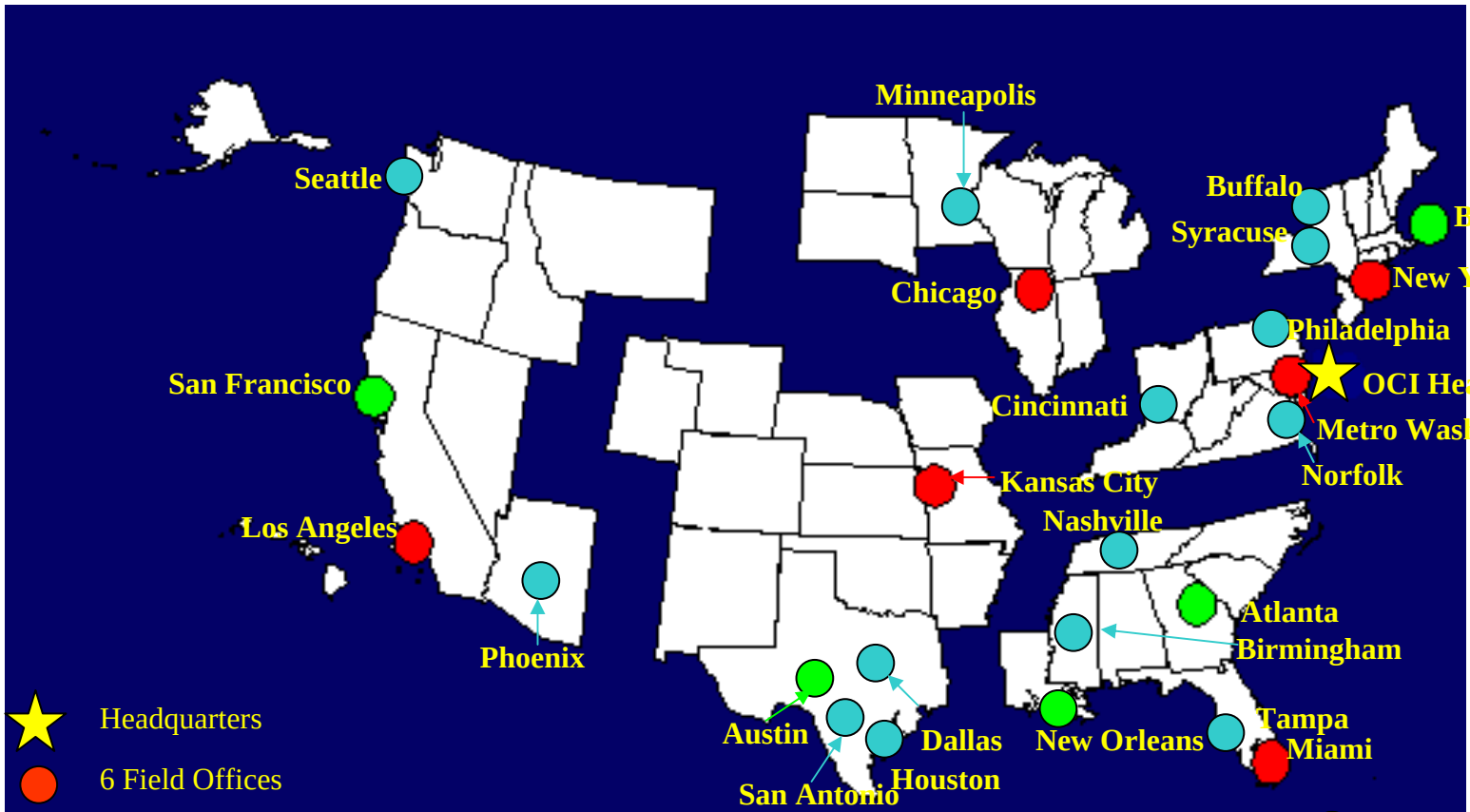
Detection and Deterrence of Counterfeiting
US FDA Experience

Paul J. Seligman, MD, MPH
Regional Director – Latin American Office
Office of International Programs
US Food and Drug Administration
Asia-Pacific Economic Cooperation
February 17, 2009

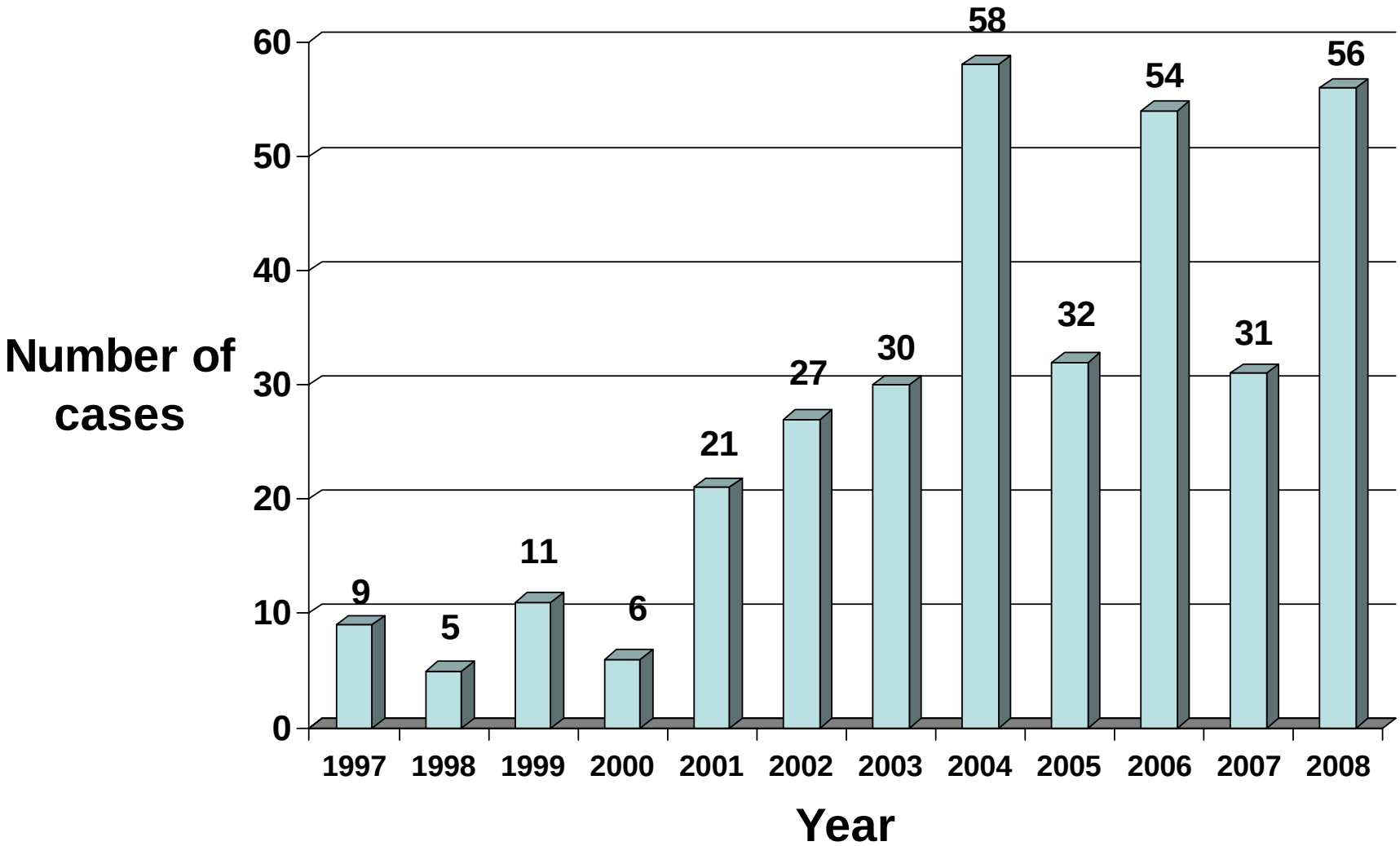
FDA Components typically involved in counterfeit cases

- Office of Criminal Investigation (OCI)
- FDA Laboratories
- Center for Drug Evaluation and Research or Center for Biologics Evaluation and Research
  - Risk analysis
  - Compliance
- Office of the Commissioner
- Office of Regulatory Affairs
  - Regional offices
  - Recall office
  - Crisis Management
- Press office
- Lawyers
- International affairs

FDA/Office of Criminal Investigation Field and Resident Offices



Counterfeit drug cases opened by FDA's Office of Criminal Investigations per fiscal year



A counterfeit drug case in the U.S. may involve….

- Food and Drug Administration
- Federal Bureau of Investigation (FBI)
- Drug Enforcement Administration
- Immigration and Customs Enforcement (ICE)
- U.S. Marshal Service
- Secret Service
- State/Local law enforcement
- State/Local regulatory agencies
- Department of Justice
- Others…


U.S. Intelligence Community
Federal Law Enforcement Agencies
U.S. Attorney's
State/Local Law Enforcement Agencies
Federal/State Health Authority
Foreign Law Enforcement Agencies
Private Industry
FOOD AND DRUG ADMINISTRATION
FDA
OFFICE OF
US
CRIMINAL INVESTIGATIONS
SPECIAL AGENT

Legal theories for prosecution

- Federal Food Drug and Cosmetic Act
  - Counterfeit Drugs
  - Misbranded, Adulterated or Unapproved Drugs
- Trafficking in Counterfeit Goods (Reg. Trademark)
- Federal Fraud Statutes
- Money Laundering
- Smuggling / Customs Violations

Statutory Penalties

Counterfeit Drugs

21 U.S.C. § 331(i)

- **1-year misdemeanor & significant fines**
  - **21 U.S.C. § 333(a)(1)**

- **2nd offense or intent to defraud:**
  - **3-year felony & significant fines**
    - **21 U.S.C. § 333(a)(2)**

Statutory Penalties

U.S. Federal Criminal Code

Trafficking in Counterfeit Goods or Services

18 U.S.C. § 2320

- **Individuals**
  - **10-year felony; $2 million maximum fine**
    - **First offense**
  - **20-year felony; $5 million maximum fine**
    - **Second offense**
- **Businesses**
  - **$5 million maximum fine**
    - **First offense**
  - **$15 million maximum fine**
    - **Second offense**

Policy Coordination in U.S.

- Intra-Governmental Working Group on Counterfeit Medical Products
  - FDA
  - Commerce
  - Trade
  - Patents/Trademark
  - Homeland Security
  - State Dept
  - Justice Dept
- Public/Private Sector Working Group
- FDA Counterfeit Drug Initiative

WHO Assessment Questions in Tool for Evaluating National Situation

National collaboration

- *Is there a national medicines anti-counterfeiting taskforce?*
- *Is there collaboration with and involvement of key stakeholders in the control of counterfeit medicines?*
  - Customs…….
  - Police……..
  - Judiciary…….
  - Pharmaceutical manufacturers…….
  - wholesalers and other distributors……..
  - Retail pharmacies and other dispensing outlets….
  - Health Professional and their Associations……..
  - NGOs……..
  - Consumers…….

WHO Assessment Questions in Tool for Evaluating National Situation

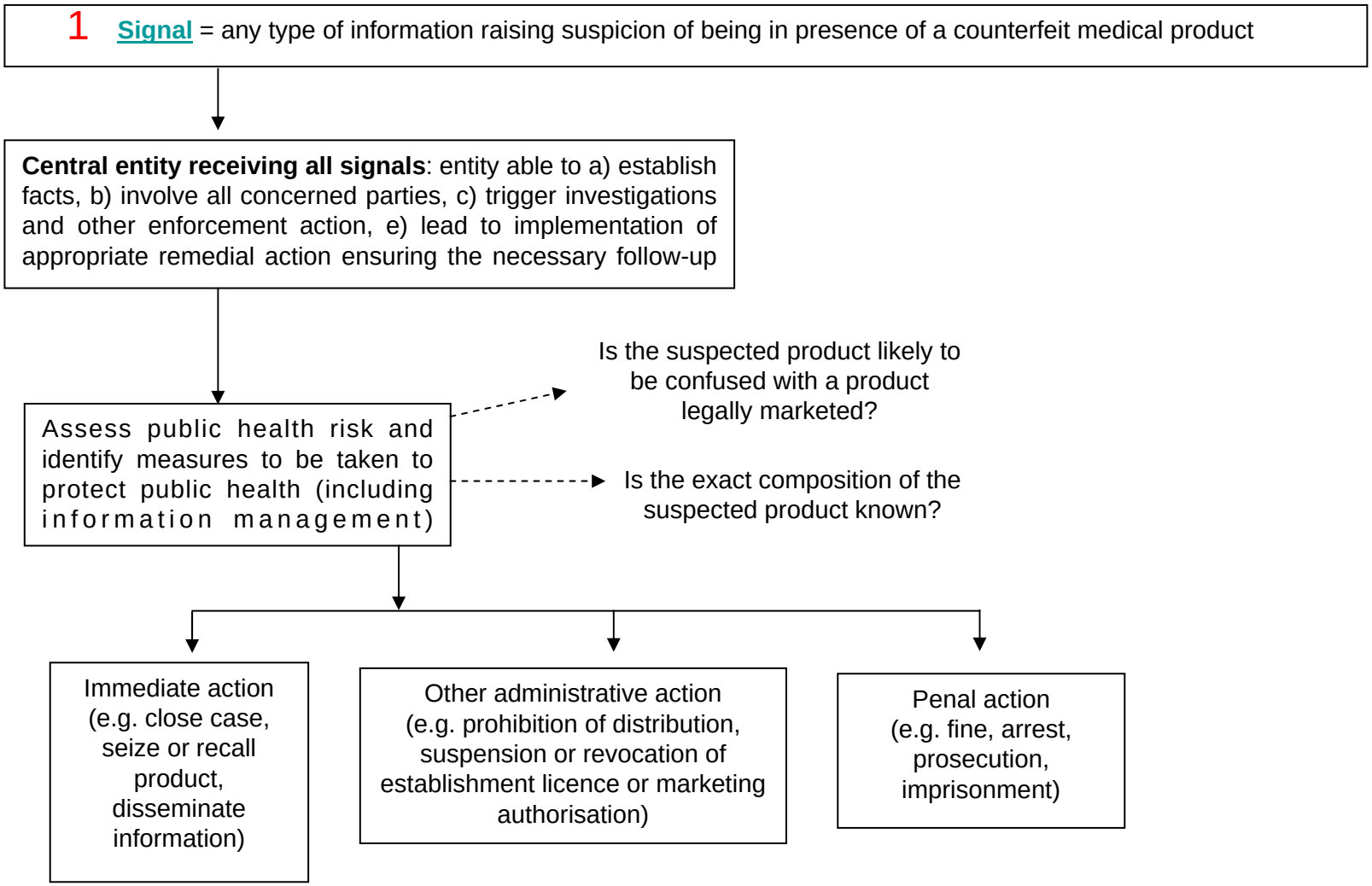
- *Is the collaboration with stakeholders formalized?*
  - If Yes Explain how…….
- *What is the level of their involvement?*
- *Is there a comprehensive national plan of action involving government agencies (NMRA, Customs, Police and Judiciary), pharmaceutical manufacturers, wholesalers and other distributors, retail pharmacies and other dispensers, health professionals and their associations, consumers, non-governmental and international organizations for combating counterfeit medicines?*
- Are there enough resources to support medicines counterfeit strategies?
  - If Yes; how much (% allocation against need)?
    - Financial Resources…….
    - Human Resources……..

Summary/Conclusion

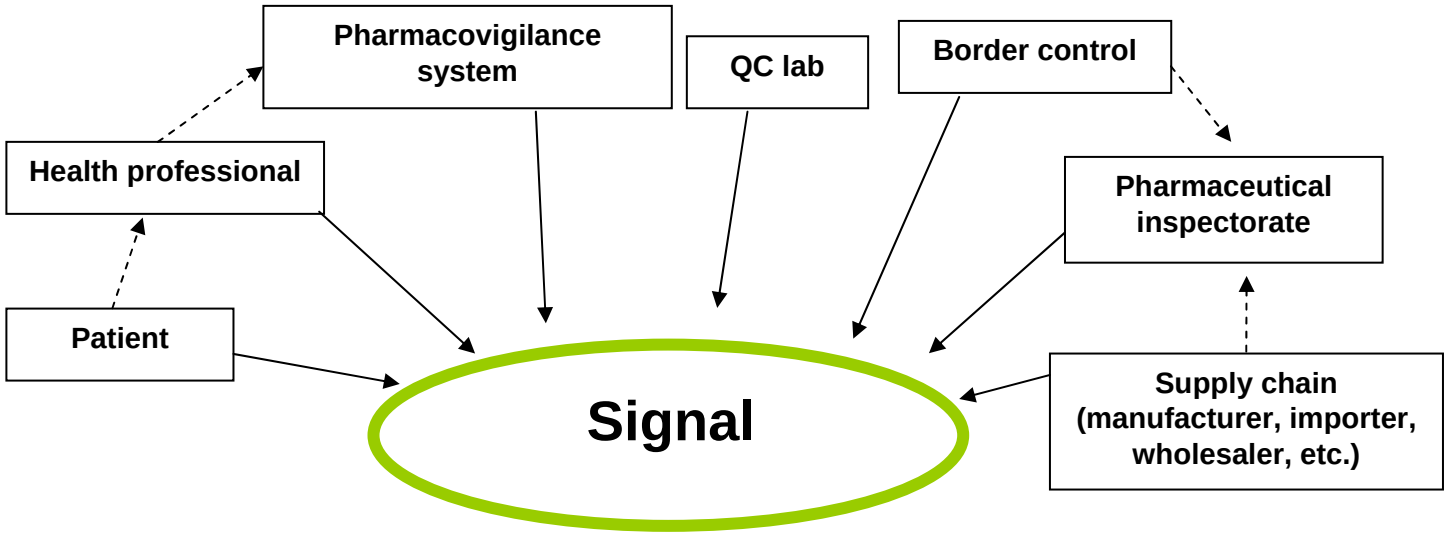
- Effective detection/deterrence requires:
  - Many agencies
  - Multiple disciplines
  - Various levels of government
  - Public/private sector cooperation
- Efforts to evaluate country-specific capabilities have led to the development of a useful assessment tool
- Counterfeiting will continue to be both a major economic and public health issue that requires close international cooperation and regular interaction

Rapid Response in case of a suspect counterfeit medicine

From signal to action: a conceptual framework



A number of different sources may produce a signal

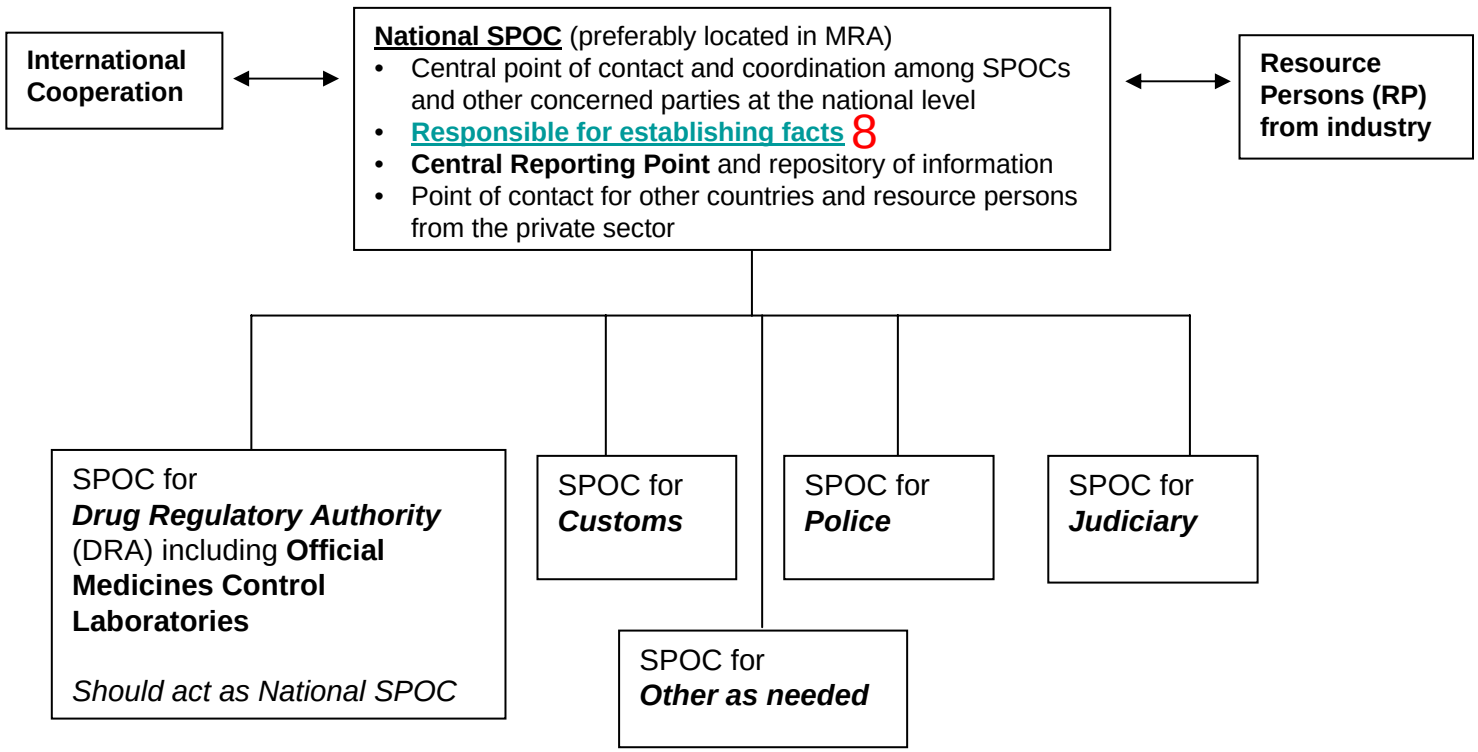


There are two preconditions for signals to be reported and properly managed:

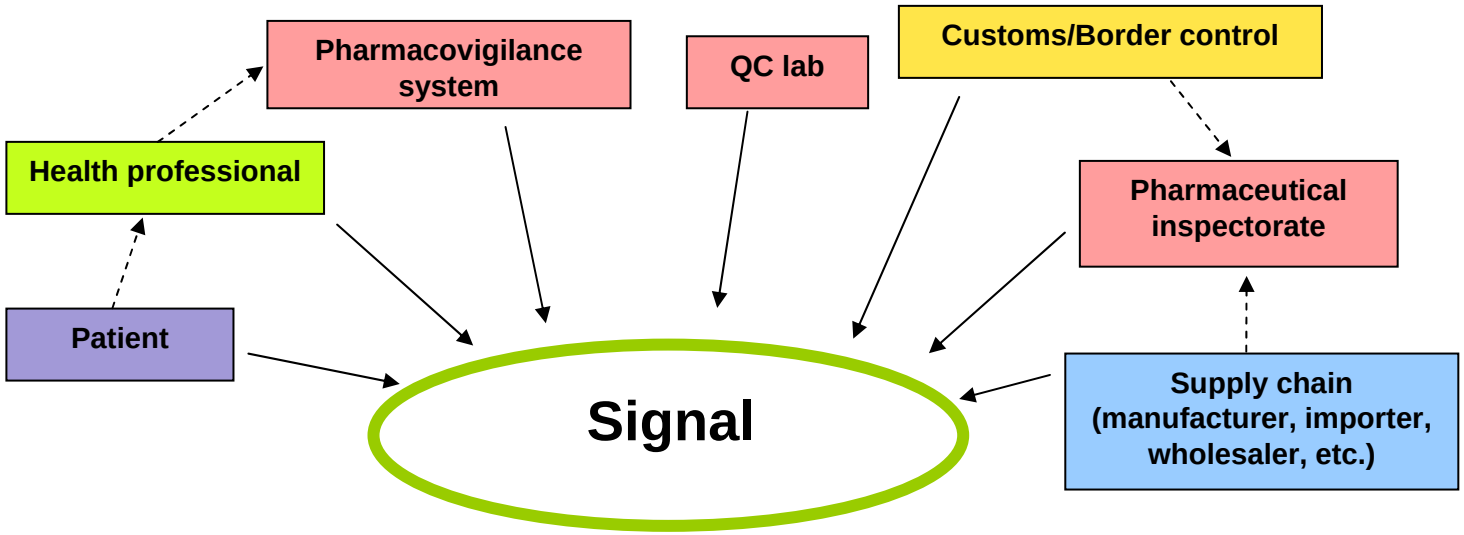
1. **Sources know how and to whom to report a signal.** 2
2. **The central entity that receives the signal can rely on a network of concerned parties who can be quickly involved, can act promptly, and have the necessary competence and possibility to act.** 4

Central entity receiving all signals: the National SPOC

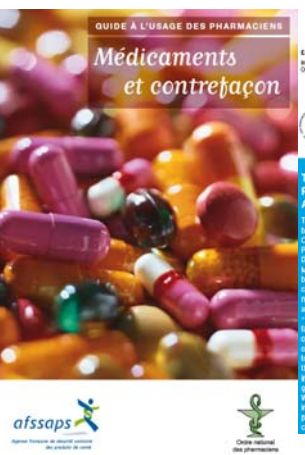
Should be at the centre of a network based on the concept of Single Points of Contact (SPOC) 5
The Medicines Regulatory Authority (MRA) is the preferred location for the National SPOC; however some countries may need to choose another entity as National SPOC

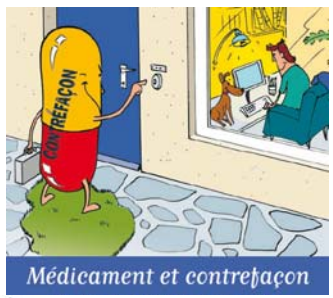


Sources must know how and to whom to report a signal



Specific guidance must be made available to different potential sources





MHRA - aide memoire for establishing facts

WHERE

where is the product now
where it is supplied and is it in the regulated or unregulated supply chain
where does the product represent a risk (location, international, country specific)
where are any ADR taking place

WHEN

when were regulatory authorities or the source notified
when was CF product made available to the public or location/source first identified
when was CF product purchased/sold
when did any ADR take place

WHO

who is the source
whose product is it
who has possession of it
who supplied it
who else is/was involved in the transaction
who was it supplied to/forwarded onto
who is at risk (patient profile). Legitimate supply chain (patients), self prescriber

WHAT

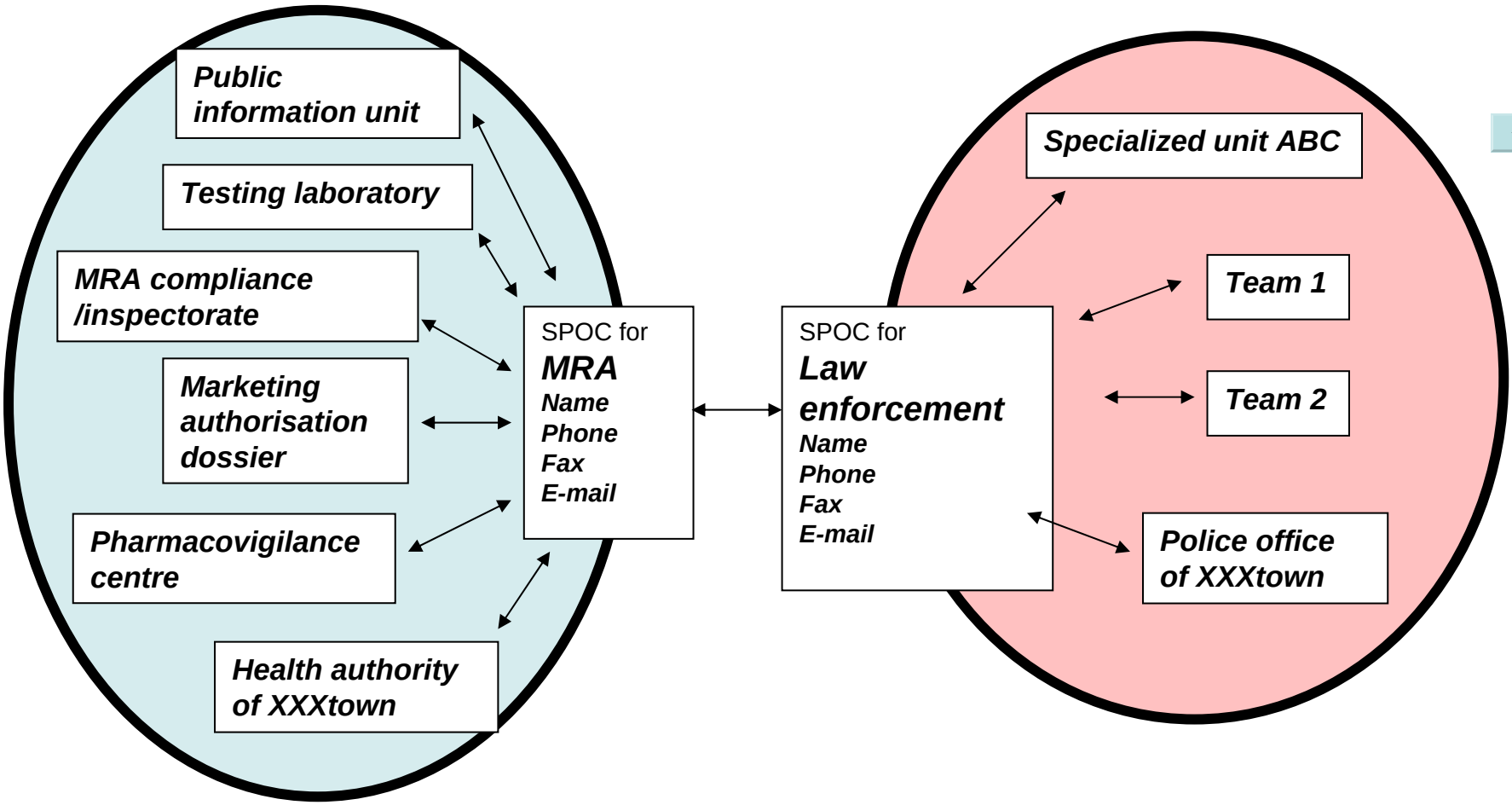
what product(s)
what batch number(s), authentic? for which market?
what expiry date(s)
what is the throughput of the authentic product(s)
what condition is the product designed to treat
what packaging is it in (country specific, parallel trade)
what is the product licence number, authentic?

HOW

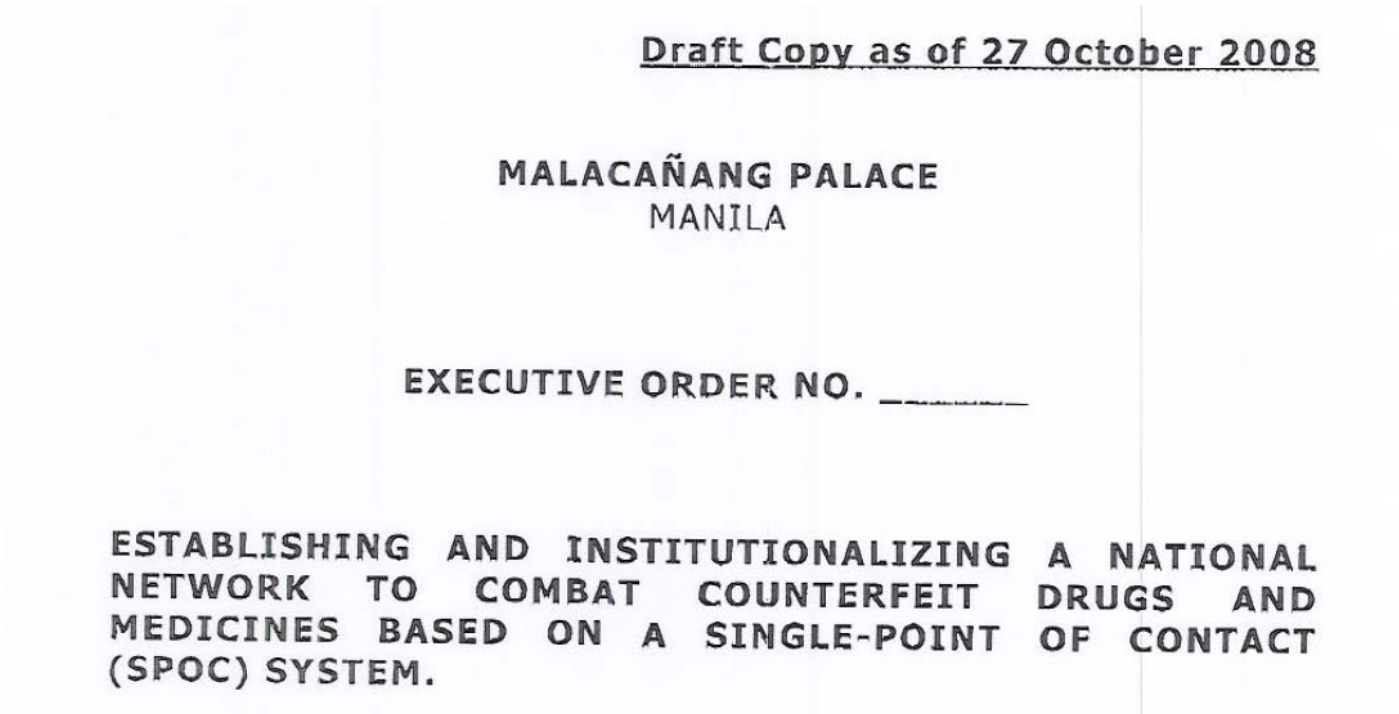
how far has the regulated supply chain been penetrated
how do we get a sample (6 samples required)
how do we test (govt laboratory, manufacturer, where is a reference sample for testing)
how much of the product is available
how much does it cost (counterfeit and authentic)
how big is the market for the authentic product (national and international)

Single Point of Contact (SPOC): entity responsible for operational management of a signal in its own area of responsibility and for the exchange of information

Example: the MRA SPOC only needs to have a SPOC for the Police who will then know how and with whom to communicate within the Police organisation. Similarly, the Police SPOC just needs to have one SPOC to contact for MRA, Judiciary, Customs, etc….



A national network of Single Points of Contact (SPOC) is more effective if it is formally established on the basis of locally applicable procedures.



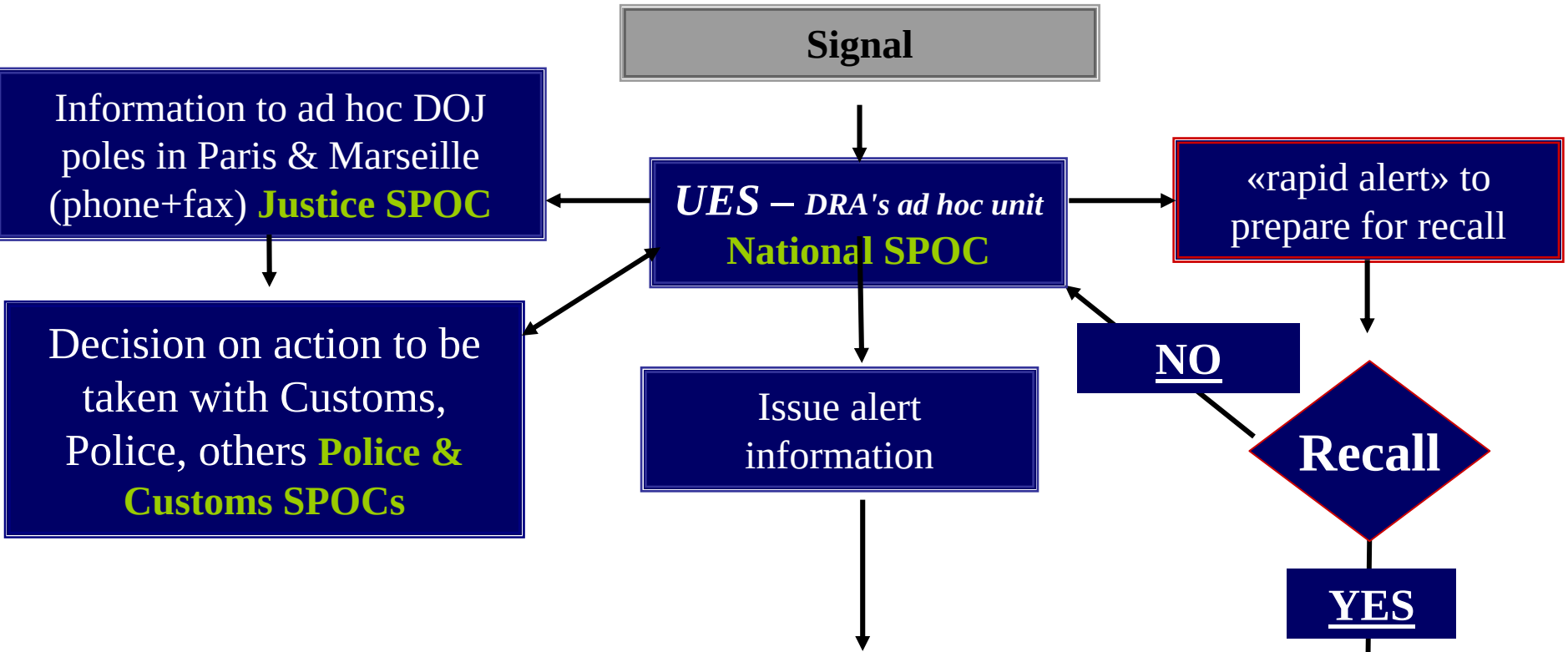
Draft Copy as of 27 October 2008

MALACAÑANG PALACE
MANILA

EXECUTIVE ORDER NO. _____

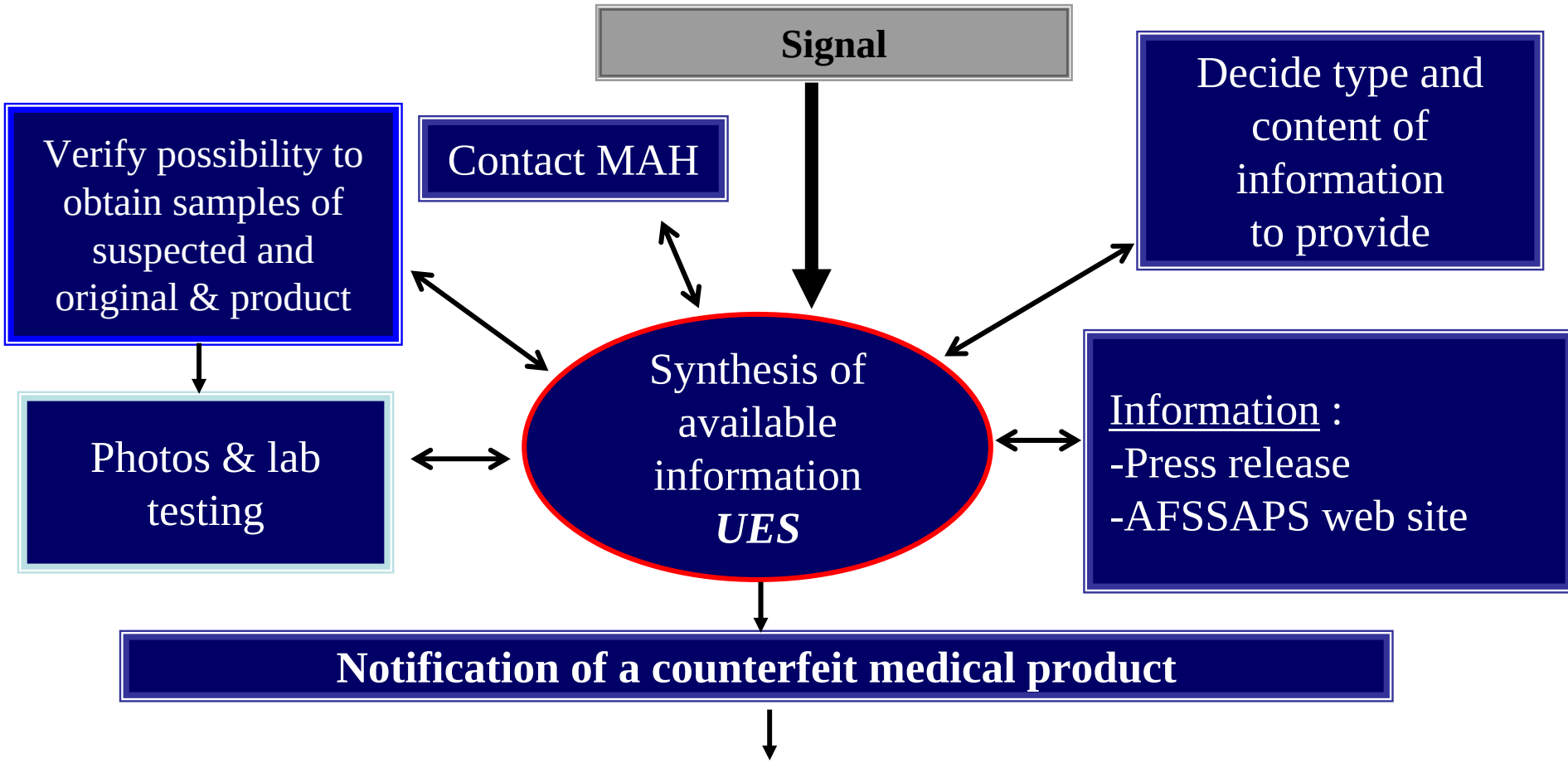
ESTABLISHING AND INSTITUTIONALIZING A NATIONAL NETWORK TO COMBAT COUNTERFEIT DRUGS AND MEDICINES BASED ON A SINGLE-POINT OF CONTACT (SPOC) SYSTEM.

An example: France



Abroad	Within France
- HMA WGEO - Council of Europe - WHO	MOH: DRASS – DGS – DHOS – Depending on investigators advice: BRDP – BCRCIA-OCRTIS – OCLAESP – DNRED – DGDDI – DGCCRF – DDASS. (Ad hoc contacts, France)

An example: France



Abroad	Within France
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RETRAIT DE LOT / ALERTE CONTREFAÇON
RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

(Ref : M05- .02)

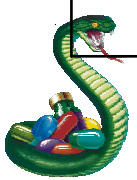
1. To / à : (voir liste jointe, si plus d'une) (see list attached, if more than one)		
2. Product Recall Class of Defect / Classe du retrait : I II		3. Counterfeit /Fraud – Contrefaçon /Fraude *(specify - spécifier)*
4. Product / Produit :	5. MA number / numéro AMM : For use in humans	
6. Brand name / nom de marque :	7. INN / DCI :	
8. Dosage form / forme pharmaceutique :	9. Strength/dosage :	
10. Batch number / numéro de lot :	11. Expiry date / date de péremption :	
12. Pack size / conditionnement :	13. Date manufactured / date de fabrication :	
14. MA holder / titulaire AMM		
15. Manufacturer*/fabricant* :	Contact person / personne contact : Telephone :	
16. Recalling Firm (if different)/Exploitant :	CONTACT PERSON / PERSONNE CONTACT : TELEPHONE :	
17. Recall number assigned EU : F 05 /	French number : MED 05 /	
18. Details of defect, reason for recall / Description du défaut :		
19. Information on distribution including exports (type of customer, e.g. hospitals) / information sur la distribution y compris l'exportation :		
20. Action taken by issuing Authority / Mesures prises par l'autorité émettrice : retrait du (des) lot(s) concerné(s)/ recall of the batch(es)		
21. Proposed action / Mesures envisagées :		
22. From (issuing Authority)/Origine (autorité émettrice) : FRANCE : AFSSAPS	23. Contact person / Personne à contacter : Stéphane LANGE (stephane.lange@afssaps.sante.fr) Telephone : (00.33) 01.55.87.40.83	
24. Signed / Signature	25. Date :	26. Time / heure :

* : the holder of an autorisation referred to under article 16 of directive 75/319 EEC and the holder of the authorisation on behalf of whom the Qualified Person has released the batch in accordance with article 22 of directive 75/319 EEC

* : Détenteur de l'autorisation de fabrication : en référence à l'article 16 de la directive 75/319 CEE : détenteur de l'autorisation au nom duquel la personne qualifiée a libéré les lots conformément à l'article 22 de la directive 75/319CEE

MHRA - COUNTERFEIT MEDICINE HANDLING PROCEDURE - AIDE MEMOIRE

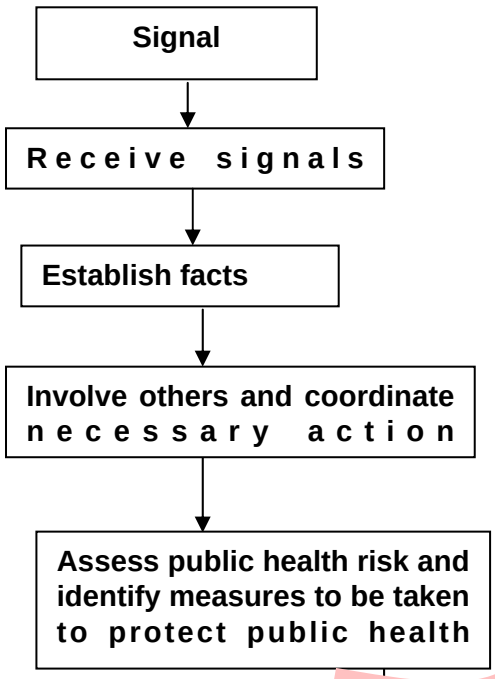
REPORT	Report/signal is received
ESTABLISH FACTS	Contact source Assess reliability of source Establish facts (see Appendix A)
ASSESS HEALTH RISKS	–consider risk to public health –have any ADR been reported –who is at risk –what medical assessment –has suspect product reached consumers (pharmacy, internet, other means) –is product/packaging designed to deceive a pharmacist that it is genuine –consult manufacturer of genuine product: is batch number/expiry date authentic, if so when was authentic released how quickly would a batch be sold to patients has manufacturer received any complaints about that batch or product
IMMEDIATE PROTECTION OF PUBLIC HEALTH	–quarantine any suspected products –secure six samples of suspect product –obtain genuine product from manufacturer for comparison –has product entered the regulated distribution chain –establish if suspected product was supplied with any other medicines, if so check their authenticity –if so, check any other stock from same supplier



LABORATORY ANALYSIS	–3 samples of suspect product to govt lab –3 samples of suspect product to genuine manufacturer laboratory –if confirmed as counterfeit go to next stage	
HANDLING PROCEDURE	–establish counterfeit incident handling team, consider involvement of inspectorate, enforcement, laboratory, defective medicines unit, media relations, any other relevant specialist –establish handling strategy (see appendix B)	
	↓	↓
LONG TERM PROTECTION OF PUBLIC HEALTH	<u>Evidence of counterfeit at pharmacy level</u>: –conduct recall at appropriate level –release appropriate press statement –contact relevant patient groups –Send Rapid Alert to relevant agencies and SPOCs –Inform INTERPOL, PFIPC, WGEO members	<u>Evidence of counterfeit in supply chain but not known to have reached pharmacy level</u>: –no evidence of counterfeit reaching patient supply chain –consider contact with wholesale dealers, parallel importers and retail outlets alerting them to be more vigilant for the identified counterfeit product
	↓	↓
INFORMATION GATHERING	–capture information from recall –how much reported/returned –from where returned –identify any hotspots in the supply chain –follow up any new lines of enquiry	

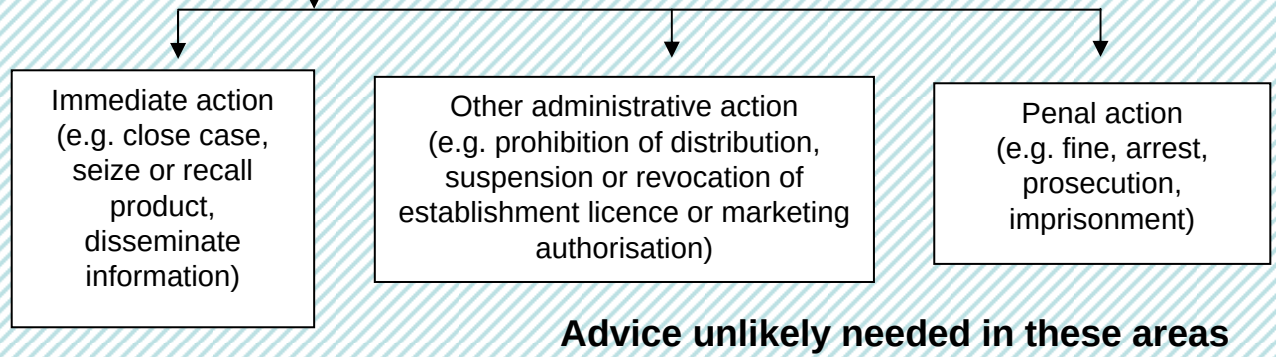
Rapid Response in case of a suspect counterfeit medicine

From signal to action: <u>how should IMPACT help?</u>



Consolidate into one guide general advice and examples of materials developed by national authorities on:

- Improving awareness and reporting of suspected cases,
- Coordination among concerned entities (SPOC network)
- Procedural aspects (e.g. sampling, authentication, investigation)
- Assessing public health risk



Advice unlikely needed in these areas

Thank you

Ténquiu

IMPACT
International Medical Products
Anti-Counterfeiting Taskforce

a WHO initiative to combat counterfeit medical products

Dr V. Reggi
World Health Organization

IMPACT
International Medical Products
Anti-Counterfeiting Taskforce

What is IMPACT ?

1) **IMPACT: voluntary coalition of stakeholders** that has the purpose of coordinating international activities aimed at combating counterfeit medical products;

2) **IMPACT is led by WHO to keep focus on the public health implications of counterfeiting rather than on IPR-related aspects.**

IMPACT
International Medical Products Anti-Counterfeiting Taskforce

Why do we need strengthened international collaboration?

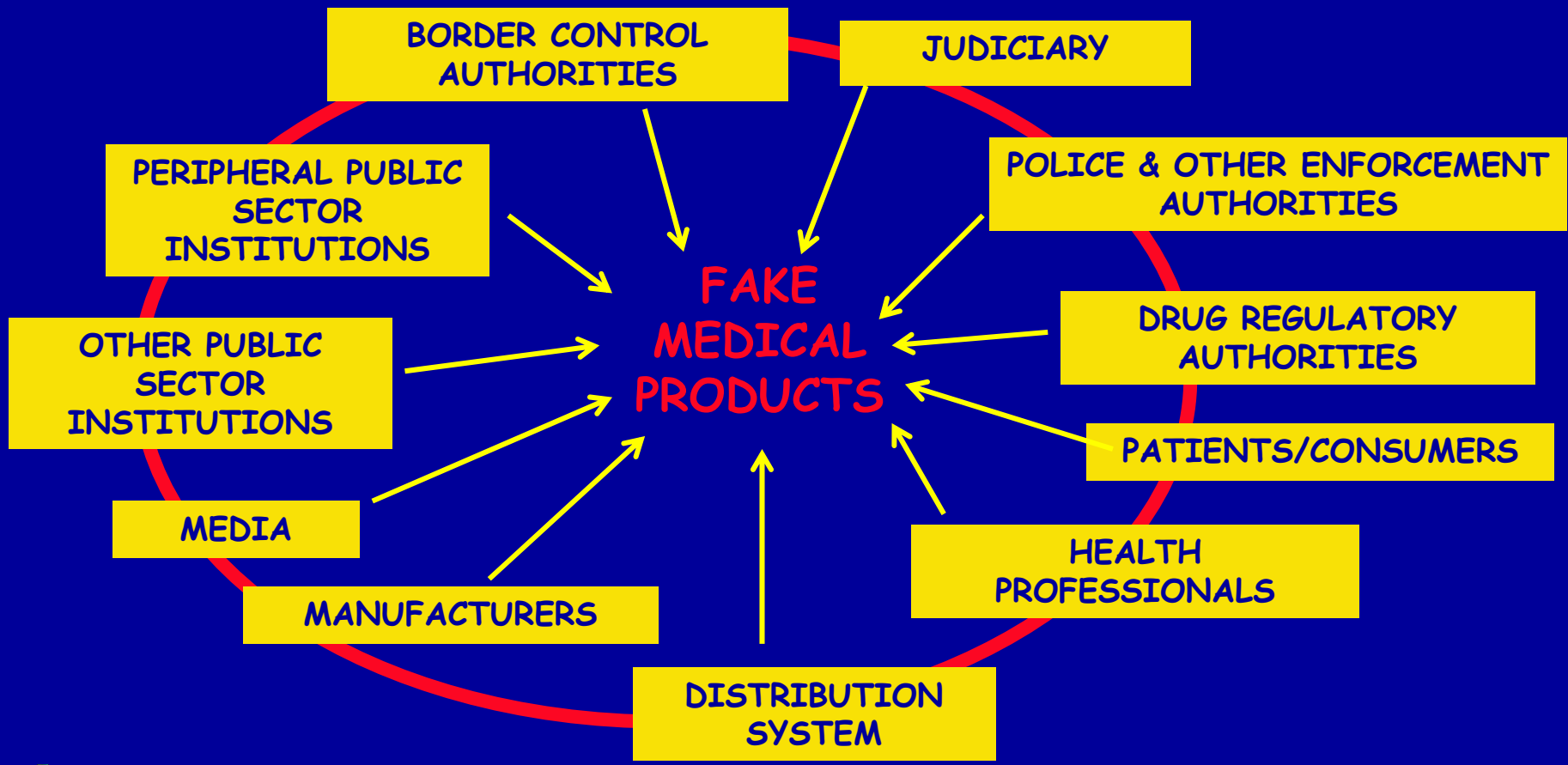
Criminals are not stopped by borders, regulation and enforcement must be able to effectively act internationally

Globalization of economies is helping to 'globalize' the problem

Increased commercial use of the Internet contributes to the expansion of the problem

IMPACT International Medical Products Anti-Counterfeiting Taskforce

"IMPACT approach": collaboration among all those concerned is essential



IMPACT International Medical Products Anti-Counterfeiting Taskforce

Who is/should be in IMPACT ?

All 193 WHO Member States and all major international stakeholders, such as:

How does IMPACT work?

Secretariat: WHO

5 working groups, focusing on the areas where action needs to be taken at national and international level:

- ➡ legislative and regulatory infrastructure
- ➡ regulatory implementation
- ➡ enforcement
- ➡ technology
- ➡ communication

IMPACT International Medical Products Anti-Counterfeiting Taskforce

LEGISLATIVE & REGULATORY INFRASTRUCTURE

IMPACT

International Medical Products Anti-Counterfeiting Taskforce

Principles and Elements for National Legislation against Counterfeit Medical Products

Text endorsed by IMPACT General Meeting Lisbon, 12 December 2007

http://www.who.int/entity/impact/events/FinalPrinciplesforLegislation.pdf

Currently being updated

IMPACT International Medical Products Anti-Counterfeiting Taskforce

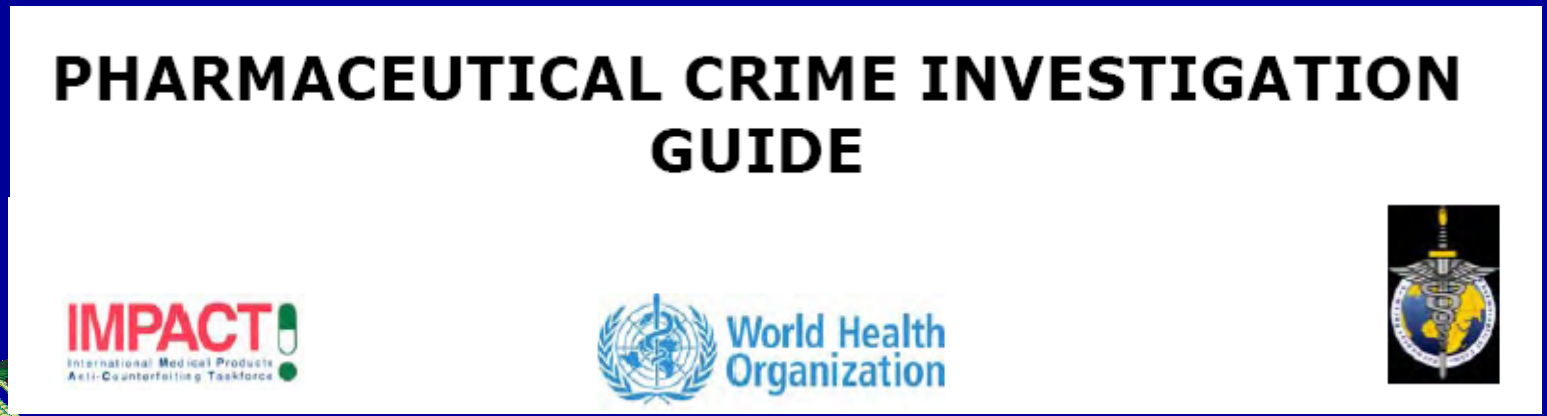
REGULATORY IMPLEMENTATION

- **Recommendations for revision of GDP with emphasis on counterfeit medical products;**
- Check lists and decision trees on action upon cases/signals;
- Amendments/Improvements to 1999 WHO guidelines on measures to combat CMP;
- Data Collection Tool on assessment of national situations
- Sampling strategy
- Initiative to address trade of counterfeit medical products though the Internet

IMPACT International Medical Products Anti-Counterfeiting Taskforce

ENFORCEMENT

- Coordination of operations among participating countries
- Internet monitoring and purchases
- Training materials and manuals to improve skills of enforcement officers
- Data/reports on issues/gaps hindering action at national level



ENFORCEMENT

Strengthened Interpol-WHO collaboration

"ASEAN+China" Conference - November 2007, Jakarta
ASEAN Secreatriat, 10 ASEAN Member Countries+China

INTERPOL officer based in WHO-Geneva

Result:

- launched the establishment of a SPOC-based network;

- new coordinated operation in 2008 in the Mekong sub-region and in Uganda and Tanzania: sources of counterfeits, seizures and prosecutions

IMPACT International Medical Products Anti-Counterfeiting Taskforce

COMMUNICATION

- Agreed 'IMPACT messages'
- Develop IMPACT web site
- Event organization/participation strategy
- Model materials addressing different audiences (health professionals, distribution system, patients, enforcement officials, media, etc.)
- Short films

IMPACT International Medical Products Anti-Counterfeiting Taskforce

TECHNOLOGY

Supply system security

- **IMPACT role**: foster dialogue and exchange of information among technology developers, regulators, manufacturers, wholesalers, retailers

Mobile testing technologies

- Laboratory testing is too expensive and complex for many developing countries: need to further develop cheaper screening/testing technologies and deploy them to field level

IMPACT International Medical Products Anti-Counterfeiting Taskforce

Asia Pacific Economic Cooperation,
Life Sciences Innovation Forum
2 Asia Anti-Counterfeiting Medical Products SeminarS
"Building International Cooperation to Protect Patients"
January & March/April 2008
Singapore

1. APEC members should consider a harmonized definition of "counterfeit medical products," based on the WHO IMPACT definition, in order to improve collaboration and cooperation on anti-counterfeiting efforts.

2. APEC members should take all necessary measures to effectively deter counterfeiting by ensuring that there is a strong legal framework, severe penalties, and active enforcement of applicable laws and regulations.

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3. APEC members should cooperate in combating the growing problem of illegal internet sales of medical products to consumers and businesses, including educating consumers and health professionals.

4. APEC members should involve health professionals in educating consumers on detecting, avoiding, and reporting counterfeit medical products.

5. APEC members should educate health professionals to consider counterfeit medical products as a possible cause of adverse reactions and therapeutic failure and report suspected incidences to authorities and the manufacturer, as appropriate.

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6. APEC members should perform a self-assessment of its counterfeit medical products landscape and apply outcomes towards improving policy

7. Each APEC member should identify a single point of contact (SPOC) for international communications concerning counterfeit medical products.

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8. APEC members should increase internal communication and collaboration among various authorities that have competence for combating counterfeit medical products and establish mechanisms for government and industry to work together to rapidly respond to reports of suspect counterfeit medical products.

9. APEC LSIF should work with other APEC Fora on anti-counterfeiting efforts for medical products to improve public health and safety, such as the "Intellectual Property Experts Group", "Law Enforcement Group", and "Customs Working Group".

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WHO's 1992 definition

"a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging"

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2. …… strong legal framework …

IMPACT

International Medical Products Anti-Counterfeiting Taskforce

Principles and Elements for National Legislation against Counterfeit Medical Products

Text endorsed by IMPACT General Meeting Lisbon, 12 December 2007

http://www.who.int/entity/impact/events/FinalPrinciplesforLegislation.pdf

- Obligations for governments, manufacturers, operators of distribution chain, other operators
- Illegal acts
- Sanctions

3. …… illegal internet sales …

- Comprehensive strategy being addressed by IMPACT: legislation, regulatory, enforcement, technology and communication aspects
- TRIPS: no obligation to control exportation and small quantities of goods
- Postal/customs regulations: parcel belong to sender until addressee gets it, what's 'counterfeit'?, 'personal use'
- Pop-up when payment takes place: needs cooperation from ISP and …banks!
- IPR= Inward-Processing-Release

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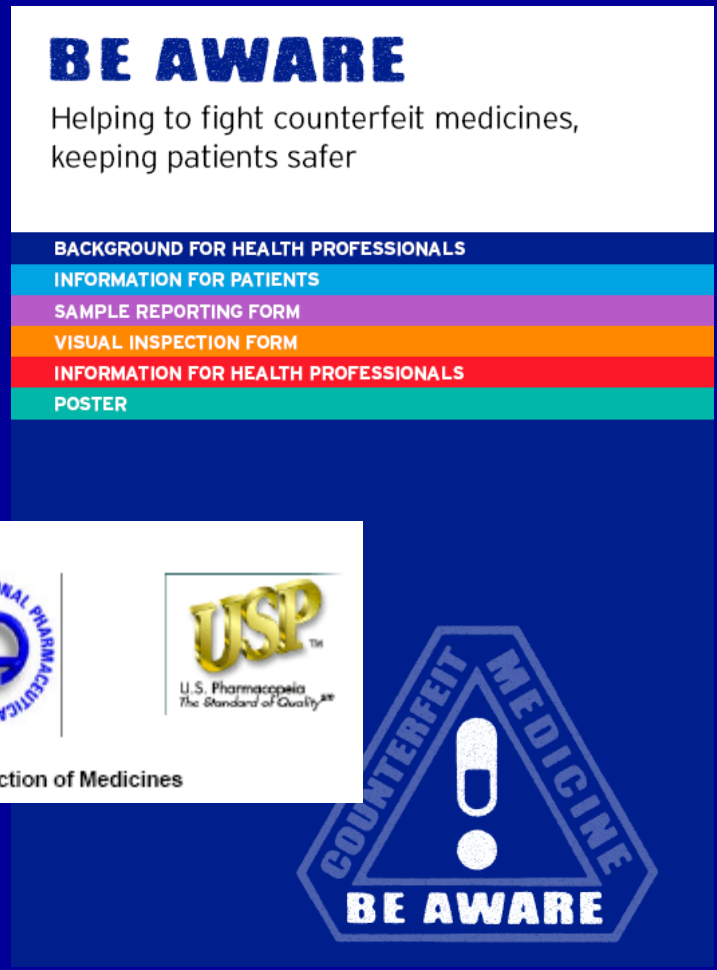
4. …… involve health professionals in educating consumers …

- Need to educate health professionals first!
- WHPA already very active
- Need more local initiatives
- Requires improved reporting/case stories



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International Medical Products Anti-Counterfeiting Taskforce

5. …… health professionals should also consider counterfeit medical products as a possible cause of adverse reactions or therapeutic failure …

- Need to strengthen adverse reaction reporting systems first
- 2007: WHO's International Drug Monitoring Programme included counterfeit issue in training course for national officers
- Need to gather cases into comprehensive set to be used for training and advocacy

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6. …… perform a self-assessment of counterfeit medical products landscape …

- Methodology for assessment of situation
- Purpose is identifying weaknesses, quantification is impossible
- IMPACT Data Collection Tool being field-tested in Uganda-Kenya-Tanzania

IMPACT International Medical Products Anti-Counterfeiting Taskforce

7. and 8. …… a single point of contact (SPOC) for national and international communications …

Collaboration can be *ad hoc* for isolated cases, but for effective and sustained action, collaboration should be structured within a network of members with defined roles and procedures.

Within networks, single points of contact (SPOCs) are the basis to achieve effective collaboration and results.

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…… a single point of contact (SPOC) for national and international communications …

International Cooperation

National SPOC (preferably located in DRA)
Point of contact for other countries
Central point of contact and coordination among the other SPOCs at the national level
Central Reporting Point and repository of information

Resource Persons (RP) from industry

SPOC for
Drug Regulatory Authority
(DRA) including Official Medicines Control Laboratories
Regulatory status of product
Health Risk Assessment
National SPOC

SPOC for
Customs

SPOC for
Police

SPOC for
Judiciary

SPOC for
Other as needed

IMPACT International Medical Products Anti-Counterfeiting Taskforce

Lesson learnt: IPR approach is inadequate to address counterfeiting of medical products

1. **IPR have broad scope and no focus on public health: fake T-shirt considered as serious as fake medicine;**

Trademark laws define counterfeiting broadly and impose a wide range of potentially harsh civil and criminal penalties, regardless of the type of good being copied or the possible **impact of counterfeiting on consumers**.

Who sells a $20 "Rolex" to a bargain-hunting consumer should not be in the same category with a counterfeiter who sells a sugar pill to a sick and unsuspecting AIDS patient. The respective levels of moral culpability and economic harm are not remotely comparable.

IMPACT International Medical Products Anti-Counterfeiting Taskforce

Lesson learnt: IPR approach is inadequate to address counterfeiting of medical products

2. **IPR approach identifies right-holder as the victim and requires right-holder to trigger/sustain enforcement action and prosecution**

   in the case of medical products, the real victim of counterfeiting is the patient and legislation should enable patients and health authorities to undertake appropriate procedures regardless of IPR holders' action.

IMPACT International Medical Products Anti-Counterfeiting Taskforce

Lesson learnt: IPR approach is inadequate to address counterfeiting of medical products

3. Counterfeiting medical products does not always entail violating IPR (e.g. heparin, 'Brainy', 'Artrin');

4. Complex pharmaceutical regulations warrant more specific approach than one based on IPR;
5. Some WHO MS fear that addressing counterfeit medicines through IPR could result in hindering trade in legitimate generics.

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Conclusions

Counterfeiting medical products:

- is a serious crime that puts human lives at risk
- jeopardizes progress achieved in public health and challenges the effectiveness of major initiatives aimed at priority diseases
- challenges people's confidence in the entire health system, affecting the reputation of manufacturers, wholesalers, pharmacists, doctors, private organizations and government institutions alike.

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International Medical Products Anti-Counterfeiting Taskforce

Conclusions

Broad collaboration among many stakeholders is essential to combat counterfeit medical products

Vulnerabilities that make counterfeiting possible to be identified and addressed in each setting

Act simultaneously on legislation, regulations, enforcement, technology and communication

IPR approach is insufficient because it does not empower patients and health authorities

IMPACT needs to be strengthened

IMPACT
International Medical Products Anti-Counterfeiting Taskforce

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2009

Integrating Brand Protection into Pharmaceutical Company Processes

Lew Kontnik
Director, Brand Protection

Amgen: A Biotechnology Pioneer

- **Founded in 1980, Amgen was one of the first biotechnology companies to successfully discover, develop and make protein-based medicines**

- **Today, we're leading the industry in its next wave of innovation by:**
  - **Developing therapies in multiple modalities**
  - **Driving cutting-edge research and development**
  - **Continuing to advance the science of biotechnological manufacturing**

Summary-Agenda

- **Counterfeiting: An External Problem Fought Through Internal Controls**
- **How the Industry is Approaching the Challenge**
- **Summary of Amgen's Approach**

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Counterfeiting: An External Problem Fought Through Internal Controls

Medicines are a critical part of our complex world health system

- **Health care spending is a major component of the global economy**
- **$2.3T US ’07; 6-15% GDP in OECD countries ‘05**

- Medicines are critical tools in over all healthcare
- $600B ’05 Worldwide; 8-30% of Healthcare spending in OECD ‘05

AMGEN

The discovery, production and distribution of medicines is complex and exacting

- Innovator biopharmaceutical companies are highly regulated
  - Approval, GMP, Formulary
- Management quality systems define most activities

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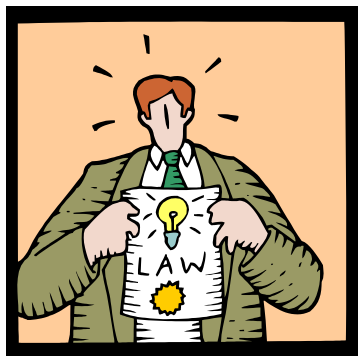
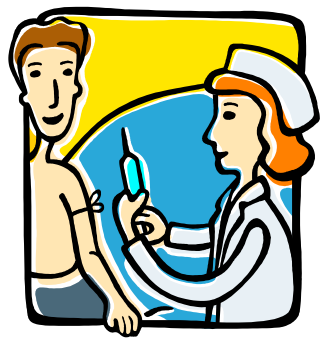
Manufacturer's control is limited to a small part of the entire system

- Global trade
- $272B exports 2005
- Internet



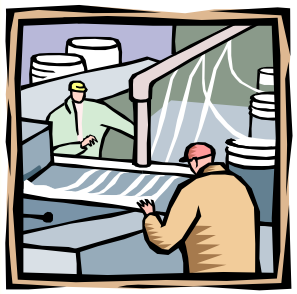
- Distribution systems
- Regulations
- Health care systems



- Prescribing
- Dispensing
- Compliance

Counterfeiters operate outside the manufacturer's area of direct control

- Insertion of fakes into the distribution system
- Use of the internet
- Sales to health delivery organizations



- Manufacturer's control ends at the first commercial customer
- Oversight beyond direct span of control accomplished indirectly

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Security controls must be fully integrated with other systems/processes to be successful

- Integration into manufacturing, regulations, business practices
- International perspective, effective in distribution channel, etc.

- Narrow focus can produce skewed understanding
- Regulators and security providers can miss the larger view

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How the Industry is Approaching the Challenge

How are manufacturers looking at the Brand Protection issue?

- Increasingly, a global, integrated approach
- Through cross-functional teams
- More international organizational engagement
- Emergence of company patterns

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Recent studies are defining categories of performance for Brand Protection programs

Formal Governance
- Dedicated Resource
- Budget

Security Features/Process
- Formal assessment
- Periodic review

Serialization of Products

Distribution Agreements
- Restricted chain
- Audits

Transport Initiatives

- Law Enforcement Collaboration
- Work with Trade Partners
- Internet Surveillance

- Public Awareness Program
- Point of Use Authentication

- Formal Incident Tracking
  - Response SOP
- Authenticate Returns

Counterfeit Prevention Study (Clarescent, April 2008)

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Recent studies suggest how companies are implementing Brand Protection programs

Formal Governance 40%
- Dedicated Resource 70%
- Budget 40%

Security Features/Process
- Formal assessment 62%
- Periodic review 30%

Serialization of Products

Distribution Agreements
- Restricted chain 46%
- Audits 62%

Transport Initiatives 30%

- **Law Enforcement Collaboration** 70%
- **Work with Trade Partners** 62%
- **Internet Surveillance** 38%
- **Public Awareness Program** 54%
- **Point of Use Authentication** 70%
- **Formal Incident Tracking** 85%
  - Response SOP 80%
- **Authenticate Returns** 30%

Counterfeit Prevention Study (Clarescent, April 2008) Percentage of 17 responding companies with system in place

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Other qualitative observations

- **Counterfeiting perceived as serious and growing problem**
- **Patient safety the overwhelming driver for programs**
- **Larger companies generally more advanced**
- **Two organizational models**
  - **Small dedicated staff/budget, governance team (66%)**
  - **Distributed operations team-no dedicated staff (33%)**
- **Opportunities for business processes enhancements**
- **Companies need regulatory leadership**
  - **Guidance, standards and industry alignment**
  - **Appreciation of change impacts**

Drawn from Counterfeit Prevention Study (Clarescent, April 2008)

International organizations are becoming more engaged in the pharmaceutical counterfeiting issue

- PhRMA
  - Supply Chain Security Task Force
  - International Anti-Counterfeiting Working Group
- EFPIA
  - Anti-Counterfeiting ad hoc Group
  - Distribution ad hoc Group (Coding Initiative)
- IMPACT (International Medical Products Anti-Counterfeiting Taskforce) WHO
- Pharmaceutical Security Institute (PSI)
- Other organizations and commercial venues

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Summary of Amgen's Approach

Mission: To prevent the counterfeiting of our products and to minimize the impact of attacks

- **We must:**
  - **Maintain a secure, accountable supply chain**
  - **Enable authentication of our products**
  - **Analyze and adjust to threats in the system**
  - **Be prepared to respond and recover from attacks**
  - **Enable the protection of our patients and supply chain through appropriate communication**
  - **Understand and plan for risks of new market entry**
- **We must not:**
  - **Prevent the flow of product to patients**

Our Program helps safeguard patients, our product franchises and investors

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Amgen's program structure supports global development and implementation

Brand Protection Steering Committee

Chair International Commercial

Core
- Global Supply Chain
- Intl Operations
- Product/Pkg Devel
- Manufacturing
- Operations Risk Management
- N. American Commercial
- Quality

Extended
- Security
- Gvmt Affairs
- Finance
- IS
- Legal

Integration Core Team

BP Staff (NA, Intl) and Commercial Reps (NA, Intl)

NA BP Team

Chair BP Staff Lead

- GOL
- NACO
- GGA
- Security
- Dist. Audit
- Legal
- Finance
- Quality
- DPDD
- Distribution
- ACM
- IS
- Corp Comm
- Reg Affairs

International BP Team

Chair BP Staff Lead

- Quality
- DPDD
- Distribution
- Security
- Corp Comm
- Returns
- ICO
- GGA
- Safety
- Legal
- Dist. Audit

Our Operations Manual translates our Imperatives into functional requirements

Supply Chain	Authentication	Threats	Incident Recovery	Empower Patients	Program Operations
• Contracts • Distribution • Returns • Audits	• Security Feature • Feature Adoption	• Market Monitoring • Investigation • Regulatory Issue Management	• Response & Recovery • Recalls	• Complaints • External Comm's	• Product, Country Risk Assessment • Functional Standards • Annual Report • Legal

Brand Protection Requirement Integrate into Amgen's Corporate Processes

Commercialization
Clinical Comparator Products
International Expansion
Crisis Management/Recall

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Thank you for your attention

Questions

Pharmaceutical Security Institute

February 2009

Industry Views

Combating Counterfeiting Medicines

Pharmaceutical Security Institute

What is the PSI?

The Pharmaceutical Security Institute is a fact finding, non-profit organization dedicated to:

P*rotecting the Public Health*

S*haring Information on Counterfeiting Activity*

I*nitiating Enforcement Actions with the Appropriate Authorities*

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PSI Mission and Services

Intelligence: to disrupt well established counterfeiting groups;

Assistance: to coordinate multi-corporate inquiries to link disparate cases.

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PSI Mission and Services

Coordinate LEA and DRA training:

- *Identify needs*
- *Develop program*
- *Deliver programs*

Goal – use training to:

- *Foster understanding*
- *Improve enforcement*
- *Build relationships*

Buenos Aires, Argentina's

2008

Pharmaceutical Security Institute

Build Awareness

Pharmaceutical Counterfeiting: Understanding the Extent of a New Transnational Crime

By Thomas T. Kubic, Executive Director, Pharmaceutical Security Institute, Vienna, Virginia; and Former Deputy Assistant Director, Criminal Investigative Division, U.S. Federal Bureau of Investigation

The pervasive presence of counterfeit pharmaceuticals worldwide, especially in developing countries, causes serious harm to users, including injuries and deaths due to ineffective or toxic treatments. Self-administered by patients who are unaware of the danger, these medicines cause adverse reactions with potentially fatal results. As illustrated by the following cases, these incidents can occur in both developed and developing countries.

Investigators believe that sometime in March 2006 at a small store a few blocks east of downtown San Diego, California, a 21-year-old woman bought an ampoule of penicillin. Once home, she took the antibiotic, went into shock, and died a short time later.[1]

On July 5, 2007, Panamanian prosecutor Dimas Guevara said that tests show at least 94 people have died from taking medicine contaminated with diethylene glycol since the previous July and that 293 more deaths were under investigation.[2]

On July 6, 2007, Coroner Kerry Clarke issued his report confirming that the death of Marcia Ann Bergeron was due to metal poisoning after she ingested

mine the precise extent and nature of this problem.[3] In 2006, the World Health Organization (WHO) recognized this problem when it highlighted the importance of timely exchanges of information with the active participation of public and private stakeholders.[4]

Pharmaceutical companies face the dilemma of how to respond to well-organized criminal groups that manufacture, transport, and distribute counterfeit medicines indiscriminately. Several innovative multinational manufacturers took the lead by establishing PSI, the world's only organization devoted exclusively to the collection and analysis of information on pharmaceutical crime. PSI collects data on such illicit activities as counterfeiting, illegal diversion, and theft. Multilingual analysts, in coordination with experienced investigators, manage a consistent flow of information, as data are collected, analyzed, and disseminated in support of individual inquiries. Strategic trend information, essential for gaining a full understanding of the nature of the counterfeiting threat posed by international criminal conspiracies, is regularly produced.

medicine following a government inspection. This member, using the Web-based system, submits critical data needed for analysts to positively identify this incident as either new or related to a previously submitted incident.

The data necessary for effective analysis include fields such as the date, time, and location of the incident. Information regarding the pharmaceutical's characteristics, therapeutic category, quantity involved, and information concerning the individual suspects and the business responsible for counterfeiting are included.

In just a few years, the CIS has become a reliable source for counterfeiting information. A survey of European Union (EU) member states and stakeholders conducted in 2003 and 2004 disclosed that the CIS database was the best-known counterfeit medicine information system.[5]

Definitions

To understand PSI's data collection and analytical methodologies, it is necessary to define its terms. PSI recognizes that many of these terms have an official, specific definition developed by either regulatory authori-

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The industry's view

- *Counterfeit medicines are a reality!*
  - *They impact patients worldwide*
  - *They can be found in normally safe outlets*
  - *They come in all shapes and sizes*

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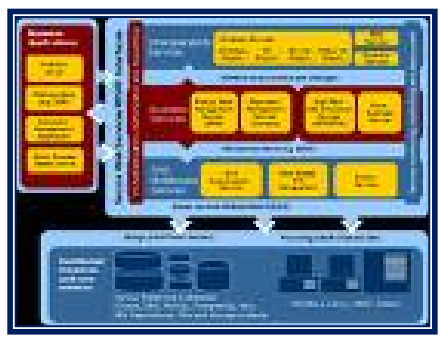
Counterfeit Incident System

Counterfeiting Incident System (CIS), captures incidents of counterfeiting, illegal diversion and theft of pharmaceutical products worldwide.

"…a discrete event triggered by the discovery of counterfeit, illegally diverted or stolen pharmaceuticals."



CIS reports come from:

- *Media reports*
- *PSI member company submissions*
- *Public – private sector partnerships*

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How often are medicines counterfeited?

Number of Incidents CY 2006 – CY 2007			
	2006	**2006 update**	**2007**
	(as of 12/31/2006)	(as of 12/31/2007)	(as of 12/31/2007)
Counterfeit	1,184	1,216	1,513
Diversion	133	140	188
Theft	54	56	58
Total	**1,371**	**1,412**	**1,759**

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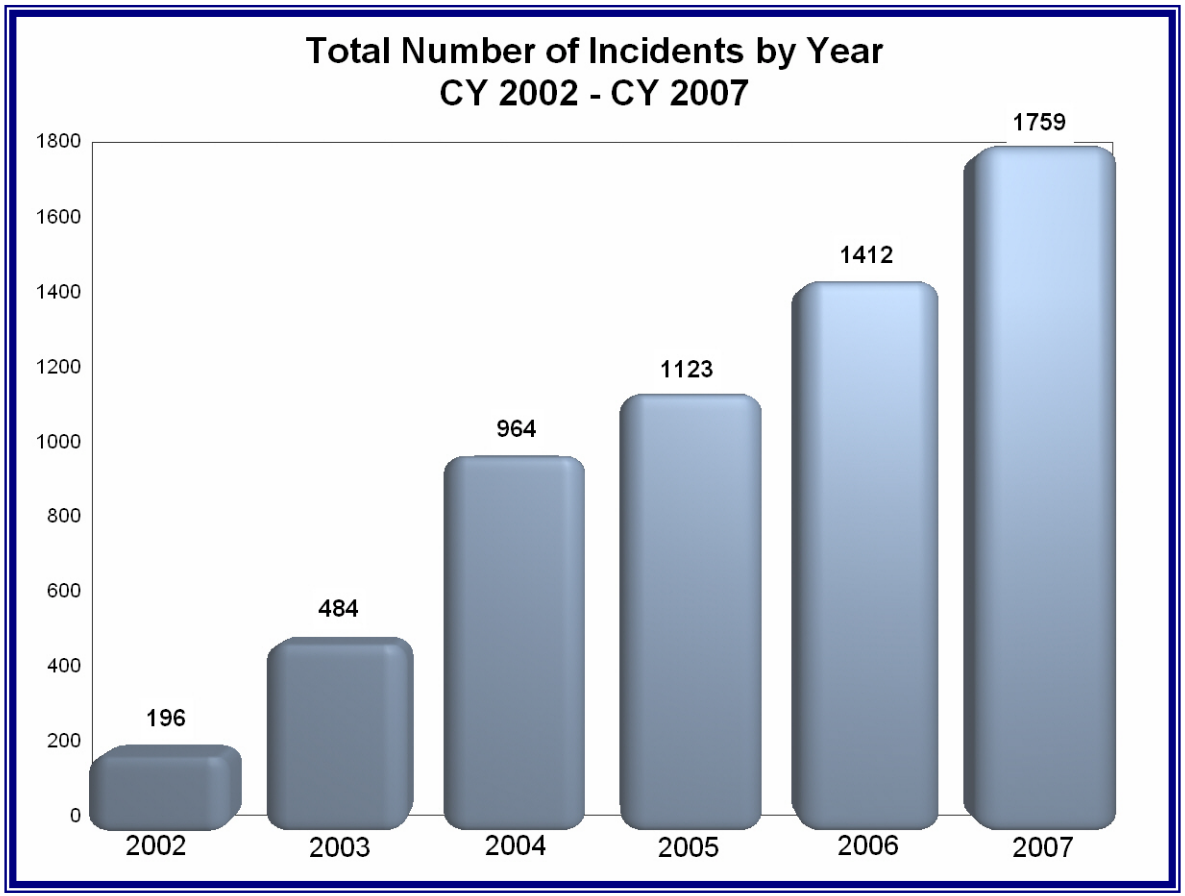
Six year upward trend



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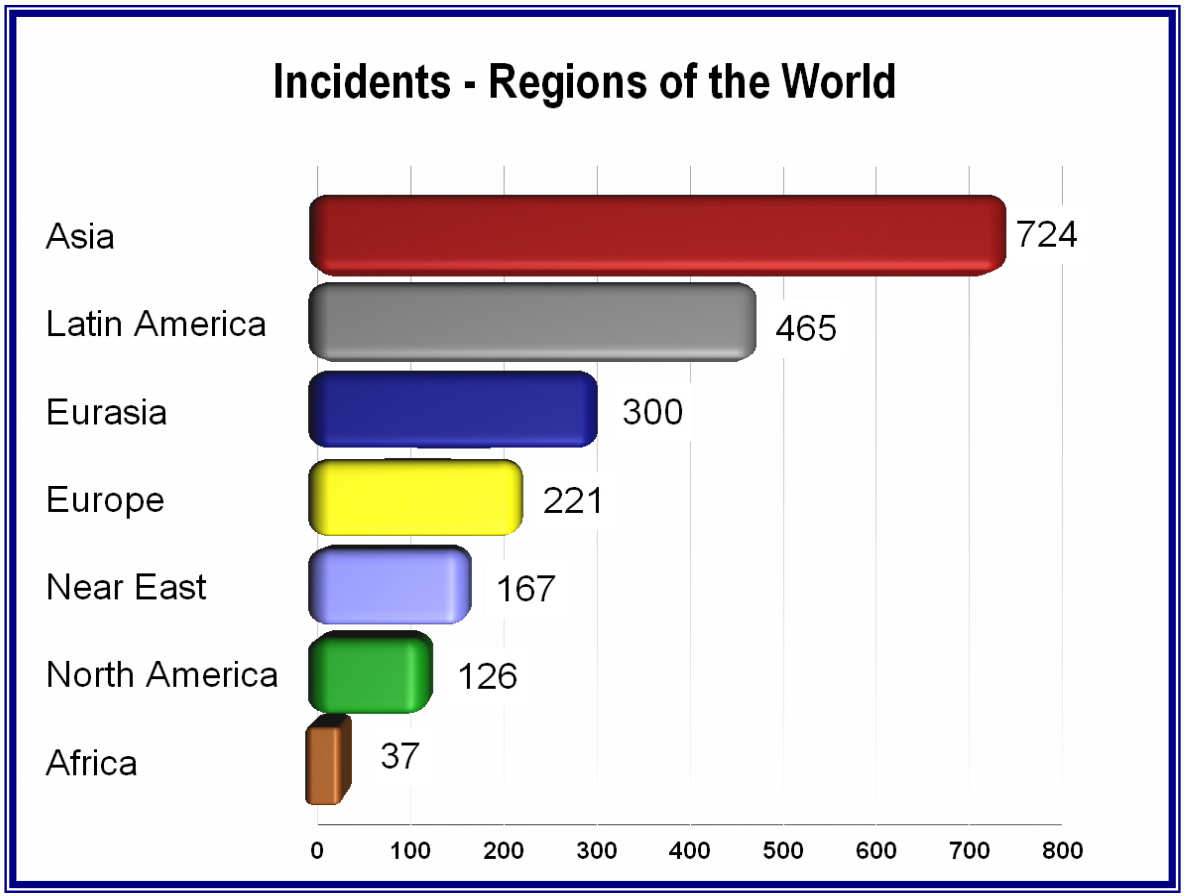
Incidents by Region



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What countries were impacted?

Top Ten Ranked Reported Incidents CY 2007					
	Country	**Counterfeiting**	**Diversion**	**Theft**	**Total Incidents**
1	China	395	6	0	401
2	India	130	3	0	133
3	United States	63	43	14	120
4	Peru	107	11	1	119
5	Russia	101	9	6	116
6	Brazil	60	30	12	102
7	Uzbekistan	86	4	0	90
8	Colombia	60	22	1	83
9	Japan	79	0	0	79
10	Korea	68	1	0	69

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Where was it seized? Where did it come from?

Top Ten Ranked
Counterfeit Products Seized/Discovered
CY 2007

	Country	Seizures/Discoveries
1	China	217
2	Peru	100
3	Russia	99
4	Uzbekistan	85
5	Japan	73
6	Korea	62
7	Colombia	60
8	Brazil	58
9	Germany	55
10	United States	53

Top Five Ranked
Counterfeit Products Origin
CY 2007

	Country	Origin
1	China	178
2	India	81
3	Paraguay	22
4	United Arab Emirates	7
5	Peru	6
5	Korea	6
5	Syria	6
5	Thailand	6

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Manufacturing Sites

Top Five Ranked Counterfeit Manufacturers CY 2007		
	Country	**Raids**
1	China	12
2	India	11
3	Colombia	9
4	Bangladesh	5
5	Peru	5

Exterior of the target factory

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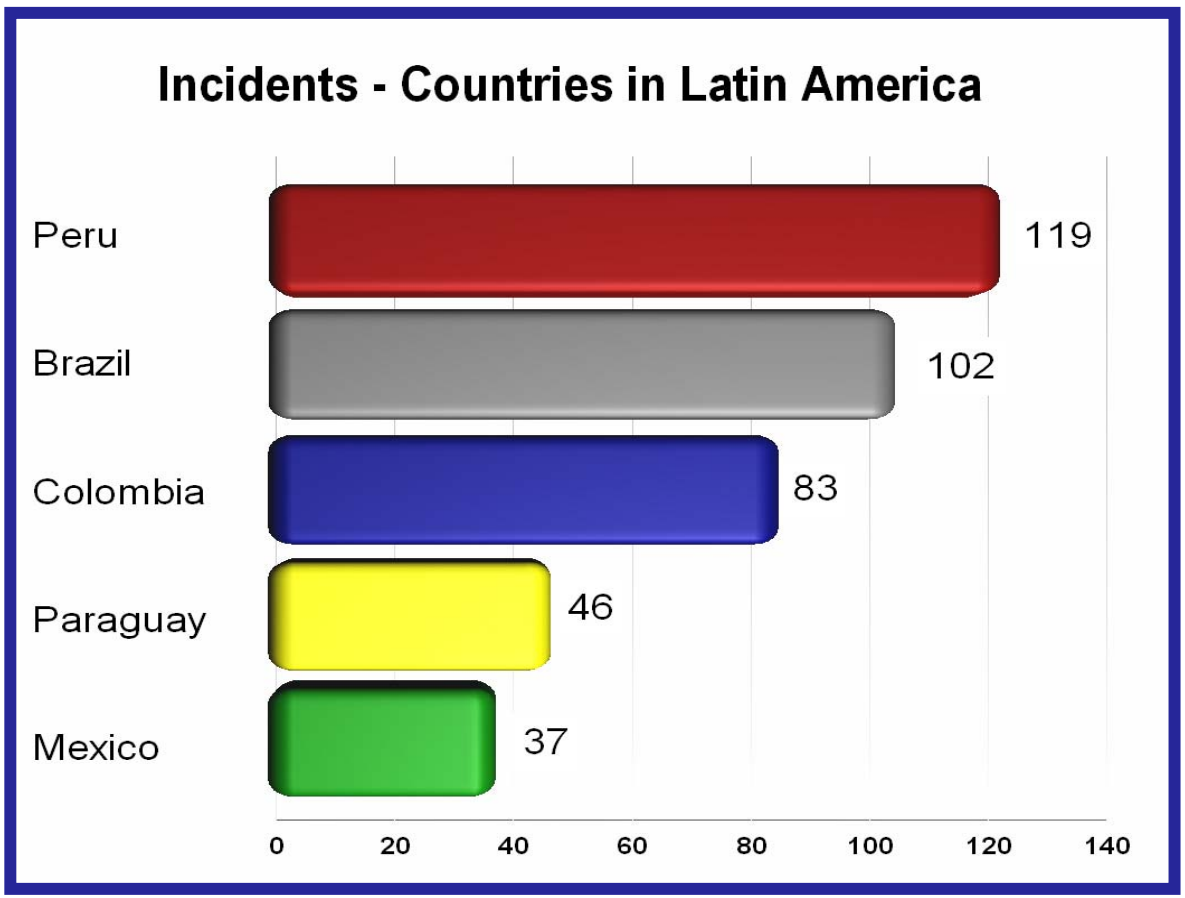
Incidents within Latin America Region



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Incidents in Latin America

Incidents were up 39% from CY 06 to CY 07.

Medicines counterfeited:

- *Injectable and oral antibiotics*
- *AIDS drugs*
- *Cancer treatments*

The risk to the public is substantial

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Incidents in Mexico

Incidents were down 11% from CY 06 to CY 07.

Monthly enforcement action:

- *January 2007 Three tons seized in Merida*
- *June 2007 COFEPRIS seizes 1000 lbs. expired at Hidalgo*
- *September 2007 Twelve tons of sample and expired products seized in Guadalajara*

Similar sustained efforts seen in 2008

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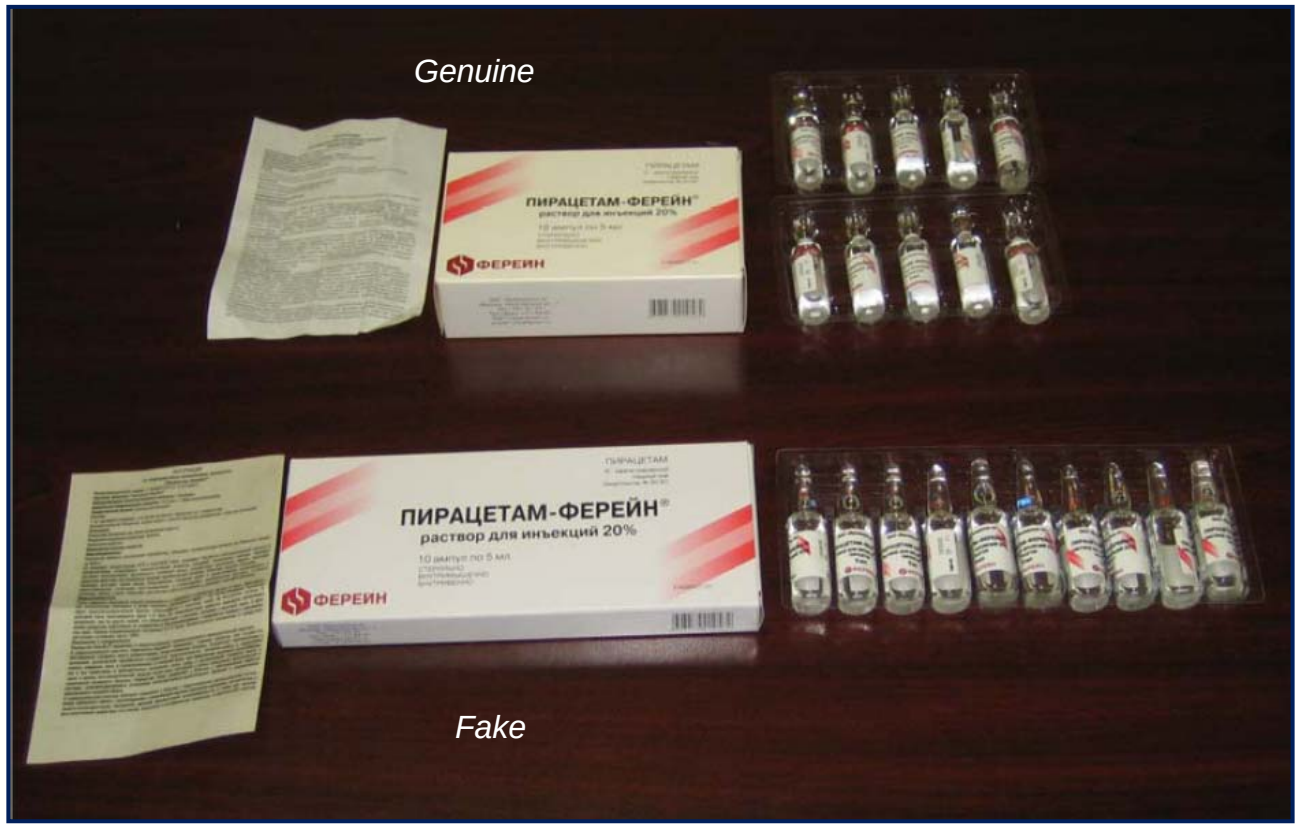
Top categories being counterfeited

Counterfeiters in court – Moscow



Genito-urinary

Anti-infectives

CNS

No product is safe!!

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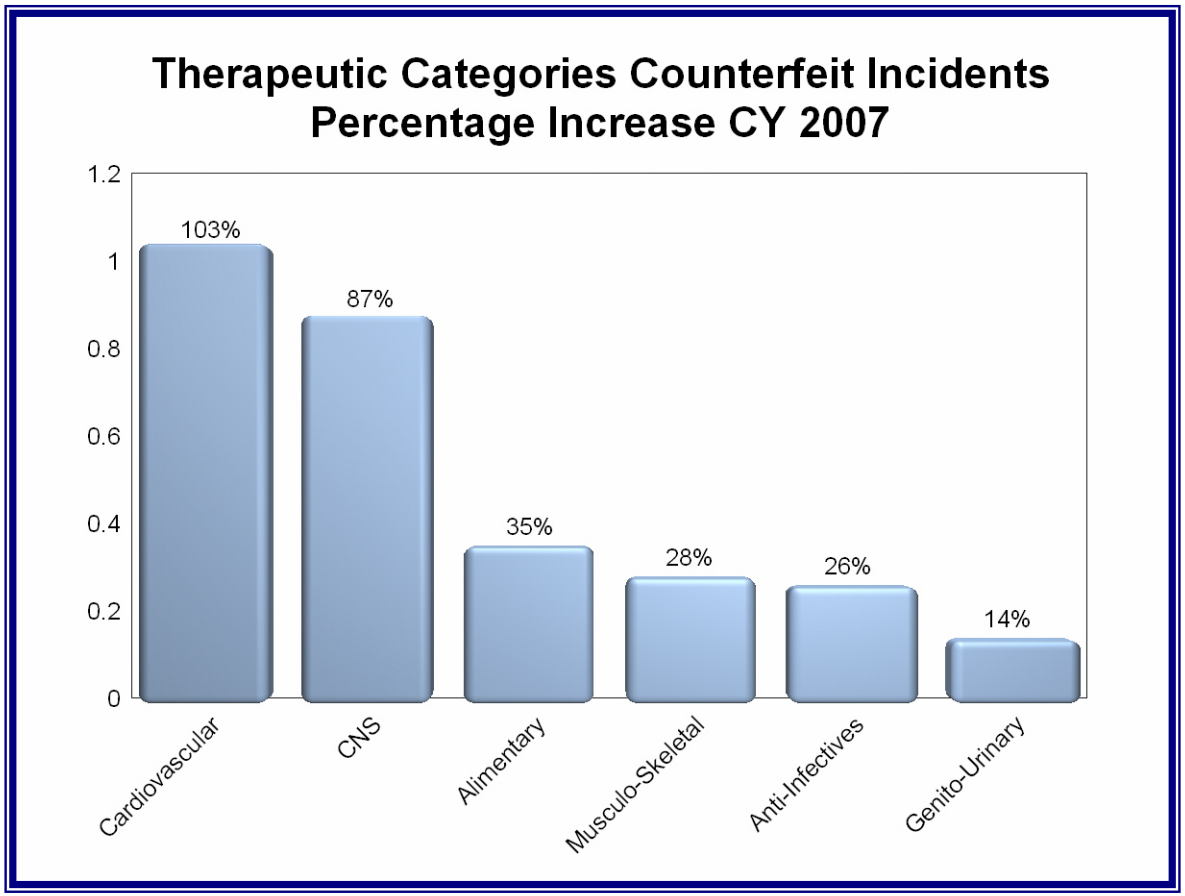
Largest increase - Cardiovascular



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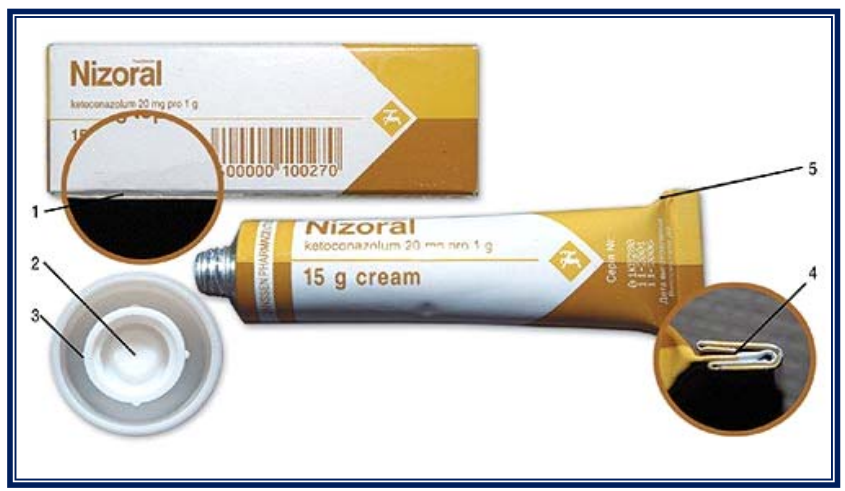
Formulations of Counterfeit Medicines

Vials of CF antibiotics

CF analgesic tablets



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What's being done? - International Partnerships

1952 2002
ORGANISATION MONDIALE DES DOUANES

OIPC ICPO
INTERPOL

DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION

HM Customs and Excise

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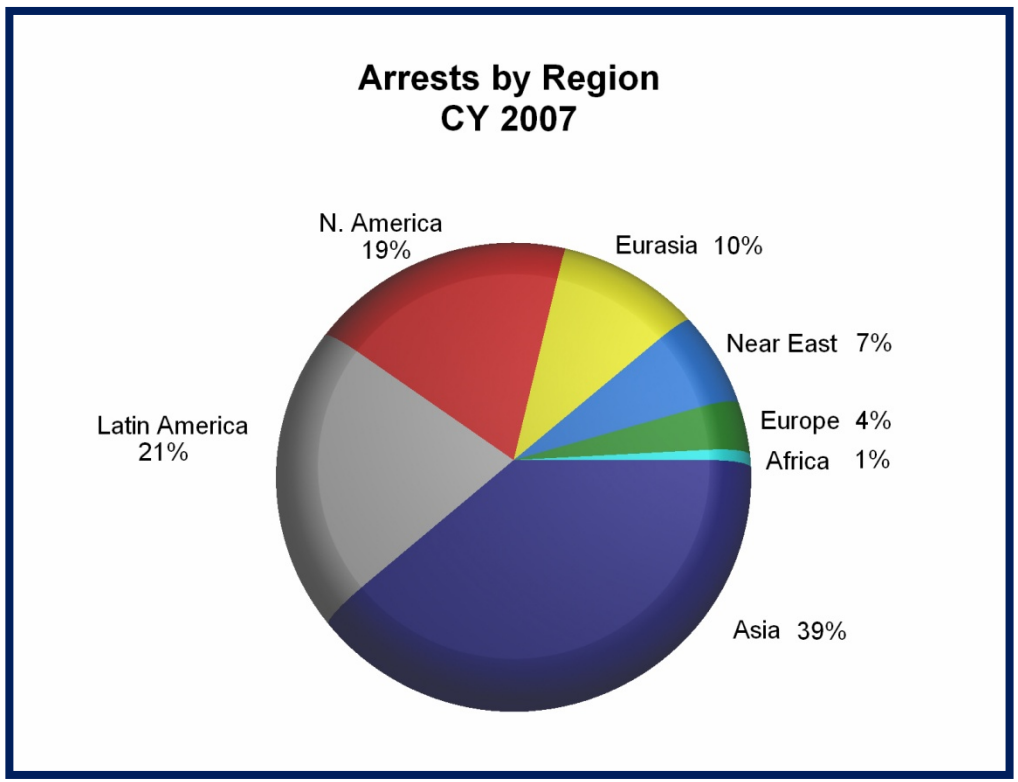
More arrests – better quality arrests



Increase in arrests

- *CY 2006 755*
- *CY 2007 1,047*

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Arrest – Country analysis

Top Ten Countries
Arrests – Activity of Subjects
CY 2007

	Country	POS	Trans	Dist	Mfg	Theft	Unk	Total
1	United States	39	3	16	12	3	124	**197**
2	China	51	0	18	37	0	0	**106**
3	Turkey	9	11	2	7	0	71	**100**
4	Brazil	7	55	18	4	12	0	**96**
5	India	28	1	5	23	0	0	**57**
6	Korea	4	17	34	0	0	0	**55**
7	Colombia	2	5	15	27	0	0	**49**
8	Philippines	19	0	20	6	0	0	**45**
9	Chinese Taipei	31	0	4	0	0	0	**35**
10	Israel	26	2	1	0	0	0	**29**

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CIS data tells us

- *Pharmaceutical crime is increasing worldwide – up 24.5% in 2007;*
- *Counterfeiting is most often linked to China increasingly in 2008 to India;*

- *Global nature of problem is evident as the number of countries linked to incidents rose 12% to 112;*
- *Incidents show increases in counterfeiting of life saving drugs.*

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2007 Major Trends

- *Counterfeiters improved visual presentation of their counterfeits National Institute for Public Health – Netherlands*
- *Legitimate Supply chain compromised as CF cancer drugs, anti-psychotic drugs and heart medications found in UK.*

  MHRA
- *Chinese raids found leukemia to flu medications and rabies vaccinations*

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2008 Major Trends

- *WHO's Dr. Chan identifies 'illicit global networks' which*
  - *make a business out of counterfeit drugs, and,*
  - *subvert public agencies.*
- *More countries recognize need for collaboration, as,*
  - *India began setting up a task force,*
  - *Dominican Republic customs sets up national program,*
  - *Spain, MOH joins with industry group in public awareness*

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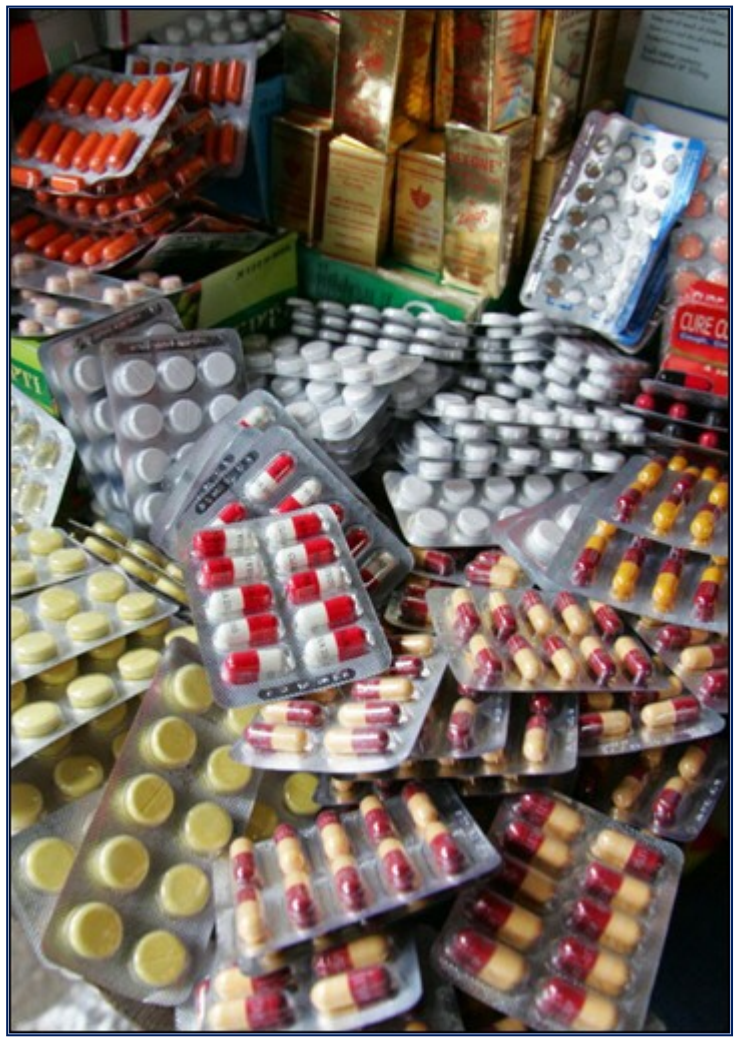
2008 Enforcement Trends

- *Increase activities by African LE*
  - *Nigerians arrest 500 illegal operators – close 3000 premises, and,*
  - *Kenyans shut 225 illegal businesses in seven provinces.*
- *Matched by increased efforts in Asia, as authorities,*
  - *Pakistan, in 60 days – 37 "medical" stores and clinics were closed for selling counterfeit medicines, and,*
  - *Vietnam Prime Minister ordered urgent measures to fight against counterfeit medicines.*



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2008 Enforcement Trends - EU

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Medi-Fake Background

- *What?*
  - *27 Countries' Customs Services in coordination with DG Taxud joined to stop CF medicines*
  - *Business sector, coordinated by PSI, shares information about CF medicines.*
- *When?*
  - *Two phases – 2008 summer and 2008 fall*
- *Where?*
  - *Phase one at five major postal centers;*
  - *Phase two included ports of entry in 27 countries.*

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Roles of Medi-fake participants

- ***PSI** general information on routes, packing characteristics, method used for traffic of fake medicines*

- ***Right holders** specific information on individual products being counterfeit, known routes used, and known indicators of counterfeit medicines.*

- ***Member States** risk information on fake medicine traffic in their country*

- ***General** information on trade of medicines in Europe*

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Members provide details of legitimate shipping

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Members provide details of legitimate shipping

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Zaventem discovery

- *Principals include:*
  - *A pharmaceutical company, Bombay, India*
  - *Togo, Africa.*
- *9/1/08 Seven parcels weighing 488 kg containing 400,000 Fansidar 25 mg tablets in blisters*
  - *Fansidar used to treatment malaria.*
  - *No packaging or PILs present.*
  - *Blisters tied together with rubber bands.*
  - *Declared as 'personal effects and household goods'.*

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Second Seizure: India – Belgium - Togo

- *Principals include:*
  - *The same pharmaceutical company, Bombay, India*
  - *Togo, Africa.*
- *9/23/08 Three parcels weighing 178 kg containing 146,000 Fansidar tablets*
  - *No packaging or PILs present.*
  - *Blisters tied together with rubber bands.*
  - *Declared as 'pharmaceuticals'.*
  - *Manufacturer declares product CF*

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A Bit of Background

- *SWIPHA's background:*
  - *Swiss Pharma of Nigeria –Exclusive manufacturer and distributor in Nigeria for Roche*
  - *Manufactures OTC for Bayer and Bio-Strath, AG, Switzerland.*
- *Roche has not authorized any Indian manufacturer to produce Fansidar.*
- *Fansidar's background:*
  - *In market for approximately forty (40) years.*
  - *Genuine product includes "Roche style" lot numbers along with expiration date*

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What's known about shipper?

- *The Indian pharmaceutical company:*
  - *2003 "Persistently dumps fake and counterfeit drugs into Nigeria." Blacklisted by NAFDAC*
  - *2005 Another PSI member is notified that 12,500 units of a mimic of their product was shipped into Ghana. Nothing seized.*
  - *2008 Fandisar seizures totalled 666 kilograms and over 540,000 tablets.*
  - *and ....*

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Third shipment: India – Belgium - Togo

- *Same principals:*
  - *The pharmaceutical company, India*
  - *Togo, Africa.*
- *9/23/08 Eight parcels weighing 562 kg containing 1,600,000 TRAMAL tablets*
  - *No packaging or PILs present.*
  - *Blisters were loose.*
  - *Declared as 'pharmaceuticals'.*
  - *Supposed manufacturer a German company Grünenthal.*
  - *Manufacturer declares product CF*

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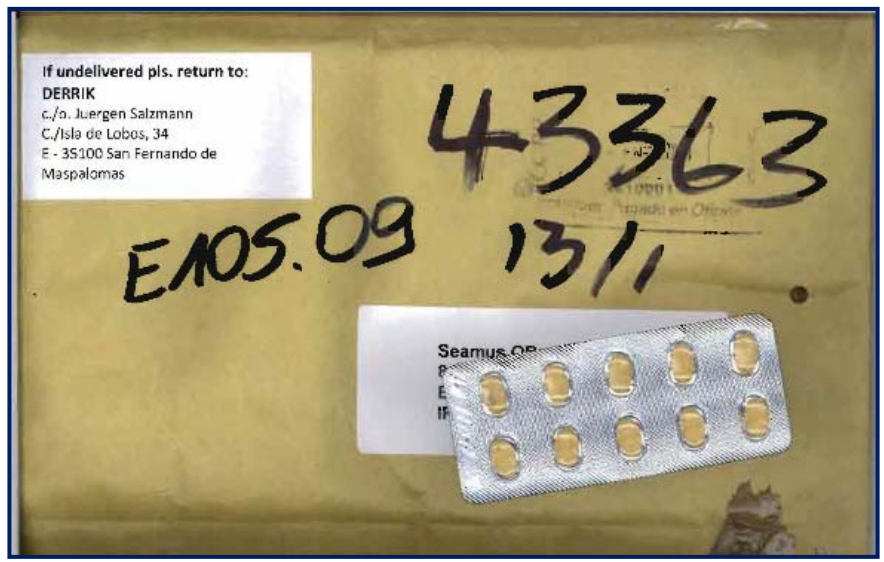
2009 India - Spain - Ireland

- *Internet sales and small parcels remain a problem*

- *CF Cialis identified and seized by agents Irish Medicines Board*
  - *Originates in India and,*
  - *transited through Gran Canaria, Spain*
  - *Spanish return address – suspected as bogus*



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Summary

- *Past seven years documented increases in pharmaceutical crime worldwide – approaching 9,000.*
- *Better attention to the issue, but sustained efforts by counterfeiters are now aided by 'access to medicines' advocates who are unaware of the problem.*
- *Number of countries linked to incidents likely to rise again.*
- *Public awareness growing*

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Conclusion

Every manufacturer ranks patient safety is a top priority!

PSI members are committed to:

- *detecting counterfeiting activities,*
- *and, helping to prosecute counterfeiters.*

Cooperation is the key to success.

Brand Protection Issues For Consumer Health Products

R.S. Miller
Procter &Gamble
February, 18, 2009

What's Different About Consumer Health Products?

- Distribution: sold everywhere, used by everyone
- Absence of "learned intermediary"
- Consumer intends to purchase genuine brand

Key Challenges

- Counterfeiting is a transnational criminal enterprise.

- CHP counterfeits are consumer fraud.
  - » At best: ineffective
  - » More likely: harmful/dangerous

- Advances in technology and trade liberalization help counterfeiters.

“The Ideal”

Manufacturers/Rightsholders

- Focus on fakes (vs. diversion, trademark infringement)
- Manage the supply network
- Support government enforcement efforts

Governments

- Protect borders
- Deter illicit networks
- Prosecute criminals

Steps Taken By P&G

2007: Appointment of Regional Brand Protection Managers

: Forensics: 24-hour turnaround

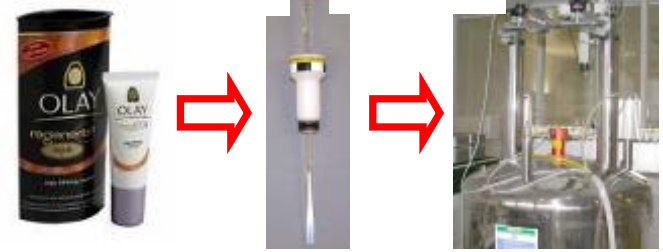
2008: Expanded Analytical Capabilities

: Centralized Customs Recordals

NMR for Liquids

- Applicable to all chemical based products.
- Simple sample preparation/ and easy to acquire data.
- Very robust.
- Electronic data very easy to share.

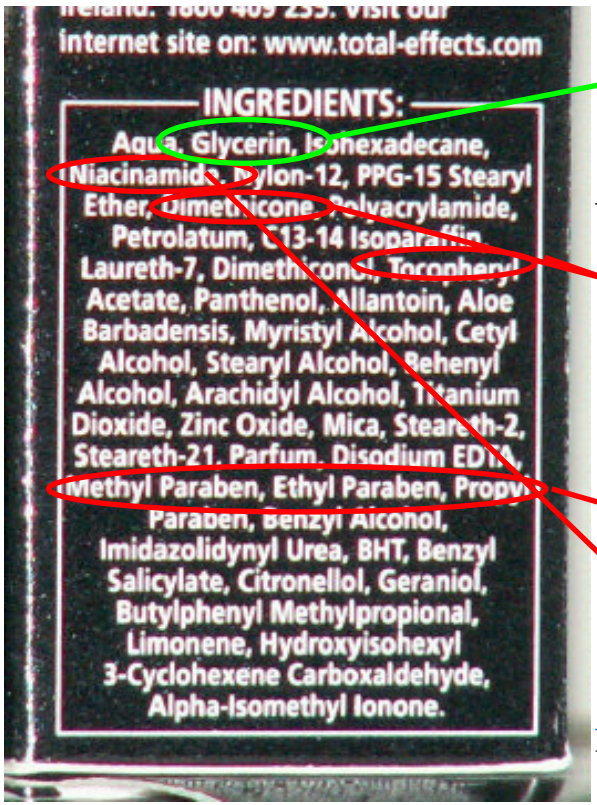
5mins 30mins

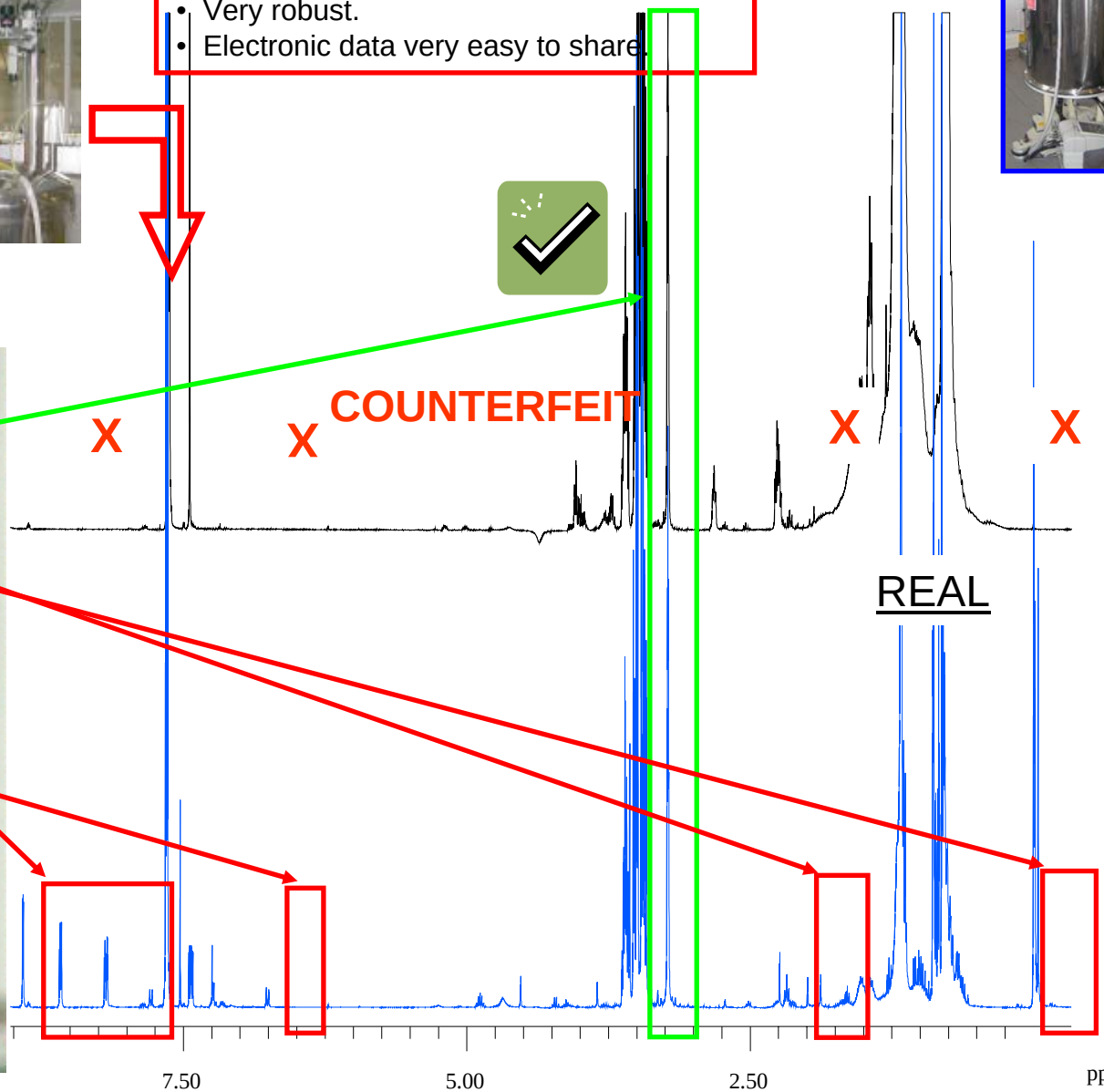


FAKE

REAL

X X COUNTERFEIT X X





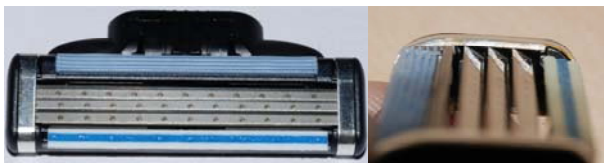
Suspect Blades

BLADE SAMPLE ARRIVES

send out email receipt

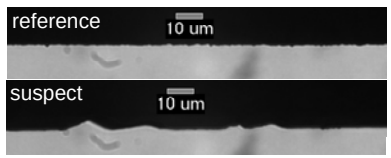
Enter sample details in 'blades' spreadsheet

Photograph cartridge from front and side



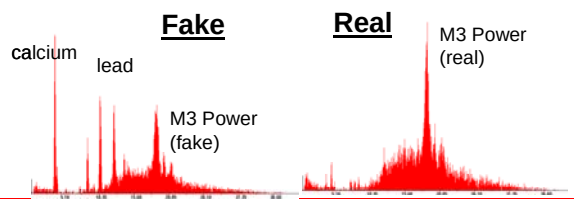
Are they parallel?
Are they clean?

Check blade edge via optical microscopy



Are the edges free from nicks?

Generate XRF data on cartridge components



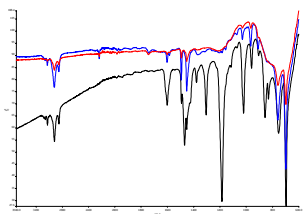
Is the lubristrip metal free?

Does the plastic contain the zinc filler?

DECISION: enough data to conclude real or fake?

NO

Generate ATR-FTIR data on cartridge components



Do the components match the reference spectra?

YES

Store data on \\pgp-lab server, write report.

Send out report attached to the original email thread, upload report to \\pgp-lab.

“In-field” Counterfeit Product Detection Test Kit

Pantene/ Olay Total Effects (ammonium, niacinamide)

Dentifrice (fluoride)

Fine fragrance (benzophenone)

SKII (Pitera - glucose)

H&S (ZPT)

SPF skin creams (UV absorbers)

Steps For 2009

- Strategic forensic collaboration: key ports/Customs Authorities

- Serialization

Government Actions

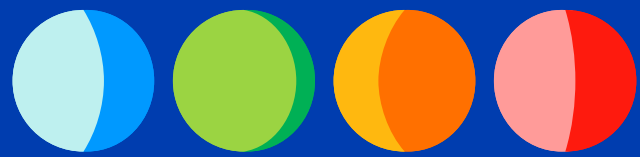
- Benchmarks / “Model Measures”

  - APEC Experts Group
  - US FTA IP Chapters
  - ACTA (6 APEC Economics)

“Wish List” For Governments

- Minimum/effective standards for fines, damages
- Disruption of counterfeit goods through FTZs
- Adequate customs powers/border measures
- Restriction of online advertising/sale of counterfeits
- Capacity building (enforcement and judiciary)

Touching lives, improving life. P&G™



APEC Panel
Anti-Counterfeiting Measures
Industry Perspectives

Thomas Warren

Director, Health Policy

February 18, 2009

Johnson & Johnson
Government Affairs & Policy

Agenda

- **Counterfeiting Challenges**
- **Brand Protection Strategies**
- **Reducing Risk in the Supply Chain**
- **Influence the Environment**

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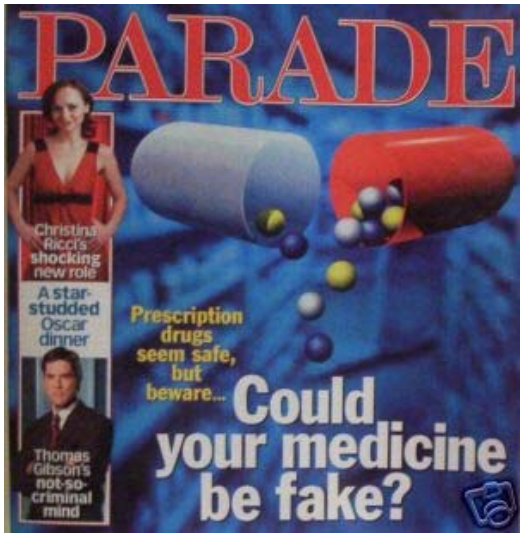
Effects of counterfeits gaining media attention



(WSJ)-- Heparin Likely Cut With Cheap Counterfeit Ingredient (3/19/08)

Associated Press

(CIO Magazine) --- Cracks in the Pharmaceutical Supply Chain

(NY Times) -- In the World of Life-Saving Drugs, a Growing Epidemic of Deadly Fakes (2/2/07)

DATELINE

Dateline's Chris Hansen investigates how fake prescription drugs have popped up at pharmacies and how this can be stopped

BBC News: China milk poisoning cases rise

Nearly 53,000 children in China are now known to have been made ill by milk powder contaminated with melamine, officials say. (9/22/2008)

Washington Post- FDA Scrutiny Scant In India, China as Drugs Pour Into U.S. (6/17/07)

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Counterfeit health care products…the Johnson & Johnson position

At Johnson & Johnson we believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products. In today's global economy, where patients and consumers may be exposed to counterfeit products of all kinds, we must take tangible steps to ensure they receive the genuine products of the Johnson & Johnson family of companies.

Counterfeiting of health care products is a serious and growing concern because it can undermine confidence in product safety and effectiveness while putting people's health and lives at risk. Counterfeiting is a global problem and while difficult to quantify, the World Health Organization reports the incidence of counterfeiting is growing. Additionally, the United States based Center for Medicines in the Public Interest predicts that counterfeit drug sales alone will reach $75 billion globally in 2010, an increase of more than 90% from 2005.

Johnson & Johnson companies take a variety of approaches to identify and mitigate the risks of counterfeit health care products. They include a range of product and packaging security measures that help distinguish the authentic product from a counterfeit, and aid in minimizing the potential for tampering. We are working to make improvements in the supply chain -- from sourcing of ingredients and manufacturing through distribution -- to help minimize the risk of counterfeit products entering the system.

We monitor markets and investigate counterfeiting activities. We collaborate with regulatory and law enforcement authorities, as well as our business partners, to locate and remove counterfeits from the market, seize and destroy the manufacturing equipment, and prosecute or take civil action against the perpetrators.

We work with governments and regulators to identify opportunities to strengthen laws and enforcement efforts in order to ensure the integrity of distribution channels. And, we are working to raise awareness of the dangers of counterfeit health care products and to educate stakeholders on the role they can play in helping to eliminate this illicit trade.

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Overview of the Health Care Challenge

Counterfeiting is a large and growing business

- **The World Health Organization estimates that:**
  - **8-10% of the world's drug supply is fake**
  - **30% of drugs in developing markets are counterfeit**
  - **50% of drugs purchased over the internet from sites that *conceal their physical address* are counterfeit**
- **Drugs & medical devices - 3rd most counterfeited category**
- **10% of US Customs seizures in '08 were pharmaceuticals ($28M) up 152% from '07**

Diversion enables counterfeiters

- **Insertion point for illicit product into legitimate channels**
- **May add additional risk to genuine products**

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Scope of Brand Protection

- **Four main classifications:**
  - **Counterfeit product/packaging**
  - **Tampered product/packaging**
  - **Trademark infringement**
  - **Illegal diversion**

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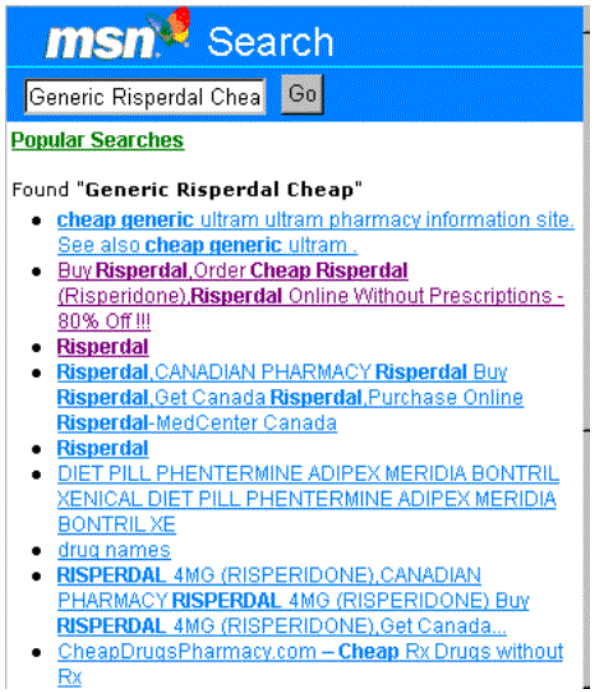
Product Risk Example: Risperdal®
High price, high volume, history of tampering



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Top 10 Supply Chain Vulnerabilities*

1. **Business trading borders weakening**
2. **Policy enforcement lacking**
3. **Arbitrage through pricing opportunities**
4. **Suppliers do not dictate to whom their trading partners may sell**
5. **Repackaging & Re-labeling**
6. **Uncoordinated anti-counterfeiting measures across supply chain**
7. **Weak penalties for counterfeiters**
8. **Diversion encouraged - market segment favored by counterfeiters**
9. **Consumer trading borders weakening**
10. **Internet**

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* The Blue Fin Group

Diversion

Definition:

- **The redirection of goods from the manufacturer's intended area of sale to a different geography or distribution channel**
- **Also known as the secondary market, parallel trade, gray market and third party importation**

Examples:

- **Movement from a low price market to a high price market**
- **Purchase at contract price and resell into different class of trade**
- **Resell of donated product for profit, rather than distribution to intended population**
- **Theft**

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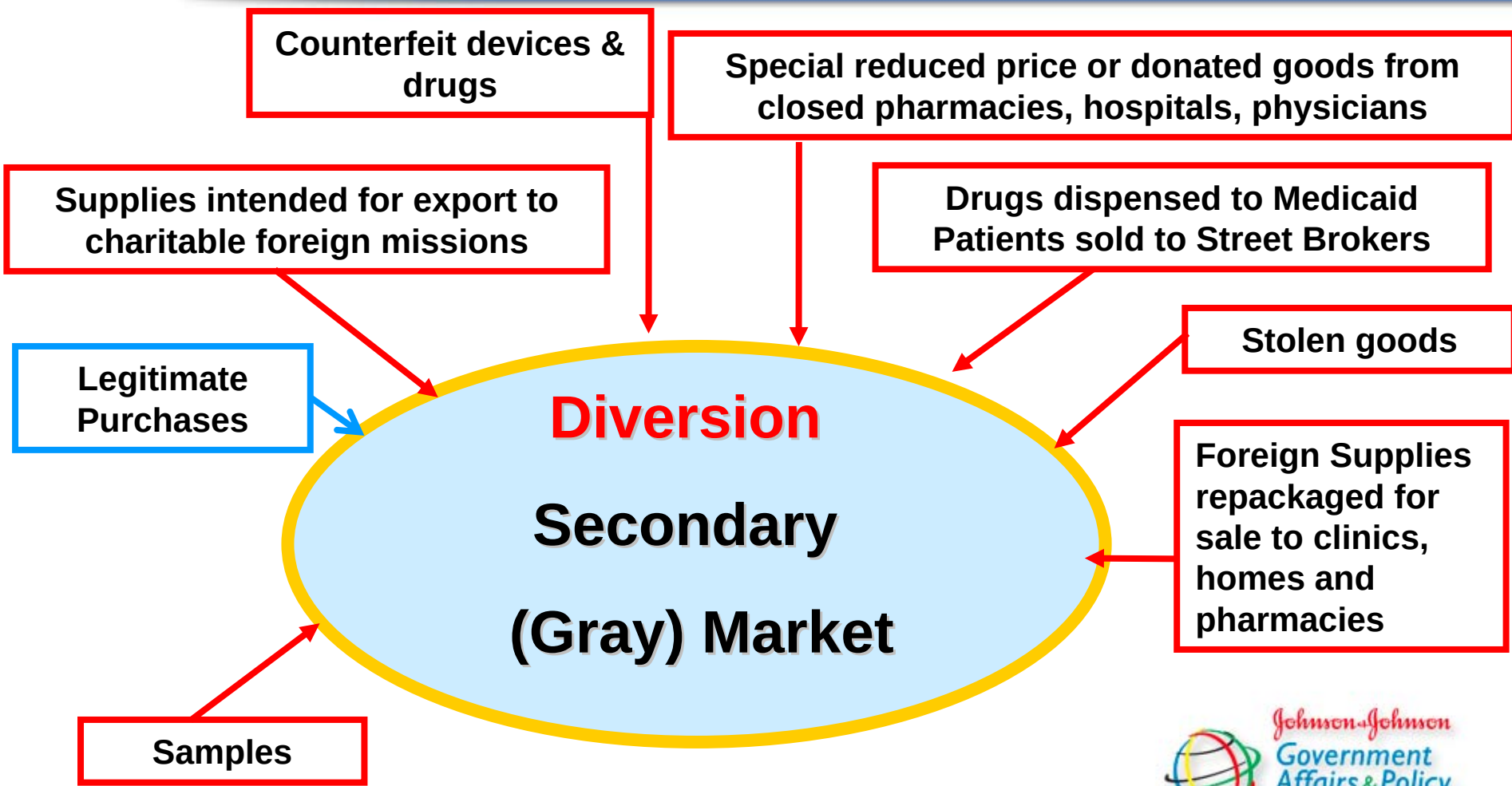
The Secondary Market



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Challenges in Addressing Diversion

- Diversion can be difficult to identify
- Diversion between countries is legal or tacitly condoned
- Diversion between classes of trade within a country is not illegal
- Diversion is not a priority for enforcement authorities

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Strategies to Reduce Diversion

- Market Monitoring & Data Mining
- Early Detection – Quality Systems & Call Centers
- Authorized Distributor of Record Anti-Diversion Policy
- In-Market Auditing
- Track & Trace Systems via Product Serialization
- Authentication Technology Application
- Aggressive Stance with Re-sellers & Re-packagers

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Strategies to Prevent Illicit Trade

1. Build anti-counterfeiting measures into your supply chain contracts
2. Know your sources of supply and monitor their activities
3. If the price is too good to be true…
4. Product normally flows downstream - avoid lateral/backwards trade – ask for pedigree information if unsure of authenticity
5. Manufacturers should insist on authorized distributors only buying their product from them
6. Avoid internet purchases unless the source is known
7. Purchase product only in original packaging
8. Ask manufacturer about authentication features on Package/product
9. Formalize your supply chain integrity organization
10. Collaborate with government agencies and legislators

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External environment

Healthcare providers

- Ask manufacture what controls are in place
- Discuss with your distributor
  - Purchasing process/sources
  - Validate relationship with supplier
  - Contractual relationships
- Buy either from manufacturer or authorized distributor/wholesaler
- Be very wary of Internet promotions, e-mails, and flyer promotions

Governments

- Growing public health concern
- Invest in enforcement –collaboration with industry
- Increase criminal penalties

Industry

- Create barriers to counterfeiting
- Increase contractual obligations of 3rd party suppliers
- Market education
- Engage with government regulators and enforcement agencies

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Supply Chain Security Summary

Conclusions

- Counterfeiting and diversion are growing problems in the global healthcare industry impacting patient safety and business value
- The industry is collaborating to secure the global supply chain prompted by the proliferation of illicit traders, new patient safety legislation and business value protection.
- Legislation & regulations governing healthcare supply chains are inescapable and ubiquitous
- The industry is responding pro-actively to safeguard the supply chain, achieve regulatory compliance and create new value

Summary

- Patient safety concerns and anti-counterfeiting laws are driving new business models in healthcare distribution which will require significant investments in technology and process development

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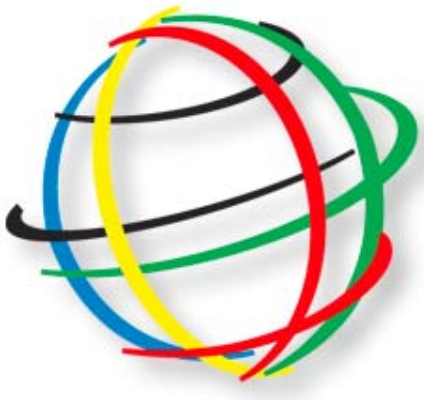

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Pharmaceutical Supply Chain Issues, E-Pedigree, and Insuring Quality Pharmaceutical Ingredients

Thomas Layloff, Ph.D., Senior Quality Assurance Advisor

Supply Chain Management System

Providing Quality Medicines for People Living With and Affected by HIV and AIDS

www.scms.pfscm.org tlayloff@pfscm.org

The views expressed here are those of the author and may not be those of USAID, SCMS, FDA, or MSH.

www.layloff.net tom@layloff.net

The Elephants in Drug Product Quality

Elephants are big animals which we learn to walk around and also ignore when we don't know what to do with them.

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Drug Product Quality Elephants

- The Active Pharmaceutical Ingredient (API)
  - The FDA has a public listing of drug suppliers, called drug master files. But the listing is neither up to date nor entirely reliable, because drug makers are not required to disclose supplier information
- The formulation/manufacturing process
  - One federal database lists nearly 3,000 overseas drug plants that export to the United States; the other lists 6,800 plants. Nobody knows which is right. "Drug Making's Move Abroad Stirs Concerns," By Gardiner Harris, Published NYT January 20, 2009
- The distribution system
  - The American drug system is undercut by a growing illegal trade in pharmaceuticals, fed by criminal profiteers, unscrupulous wholesalers, rogue Internet sites and foreign pharmacies. The diverters pave the way for counterfeiters who produce near-perfect copies of the most popular and expensive drugs. Washington Post, October 19, 2003

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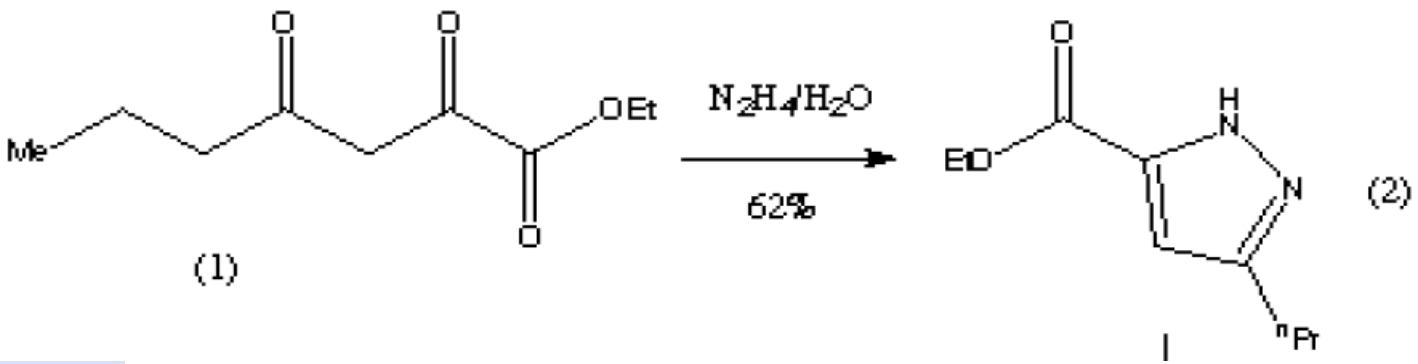
An Example of a Sildenafil (Viagra) API Synthesis

Step 1—Yield 62% -- 38% of material is lost to waste



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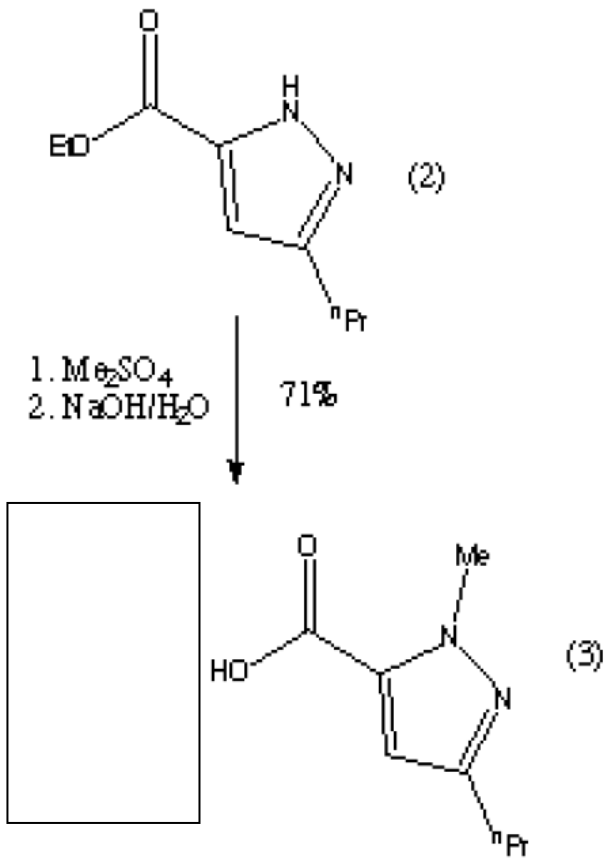
Step 2 -- 71% yield -- 29% is lost to waste



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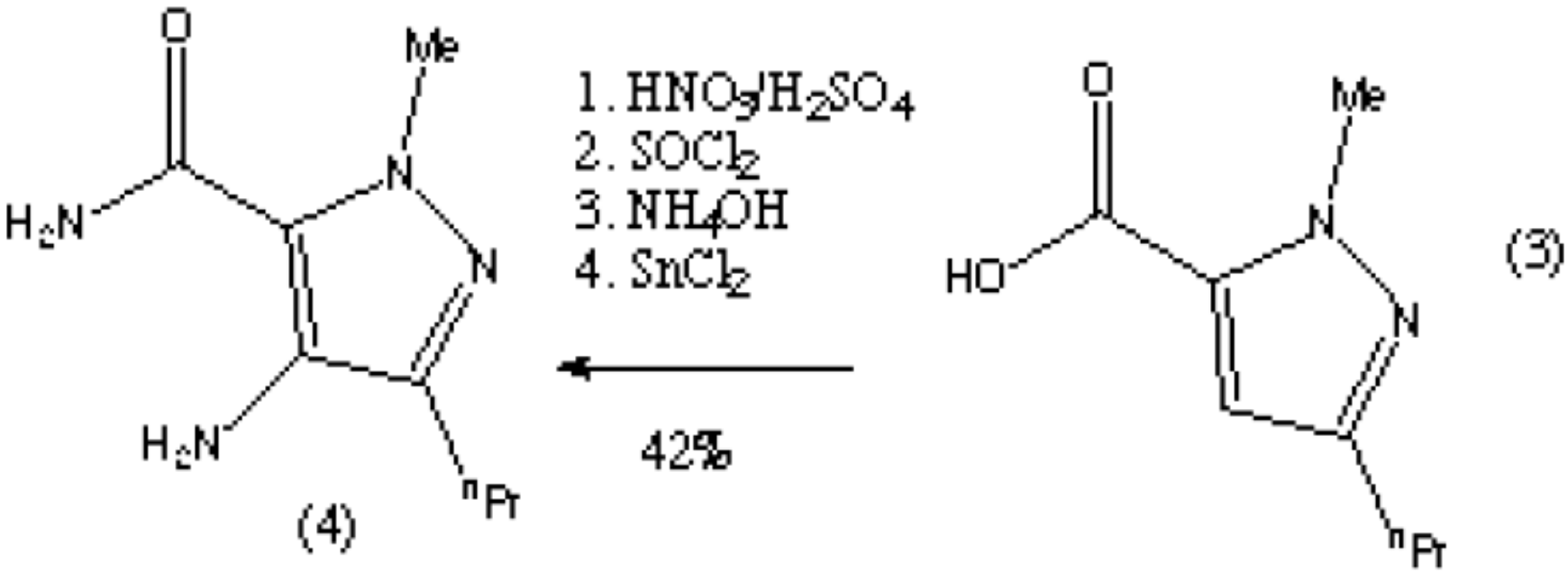
Step 3 - 42% Yield -- 58% lost to waste



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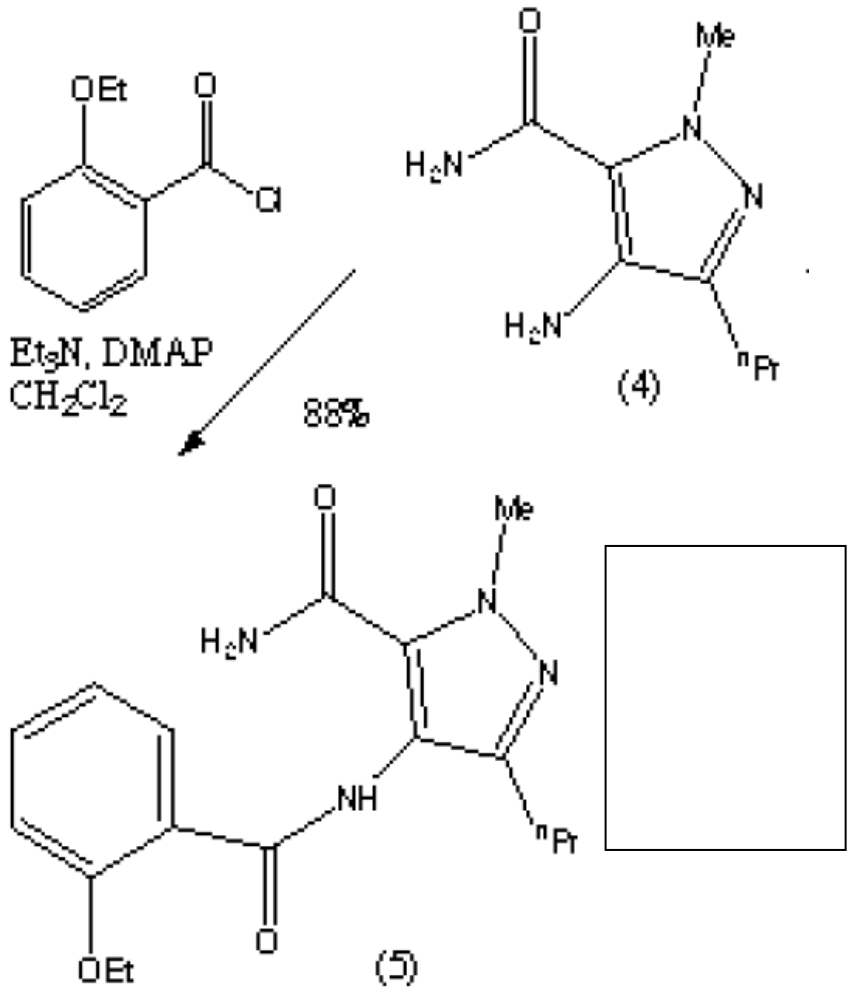
Step 4 - 88% Yield - - 12% to waste



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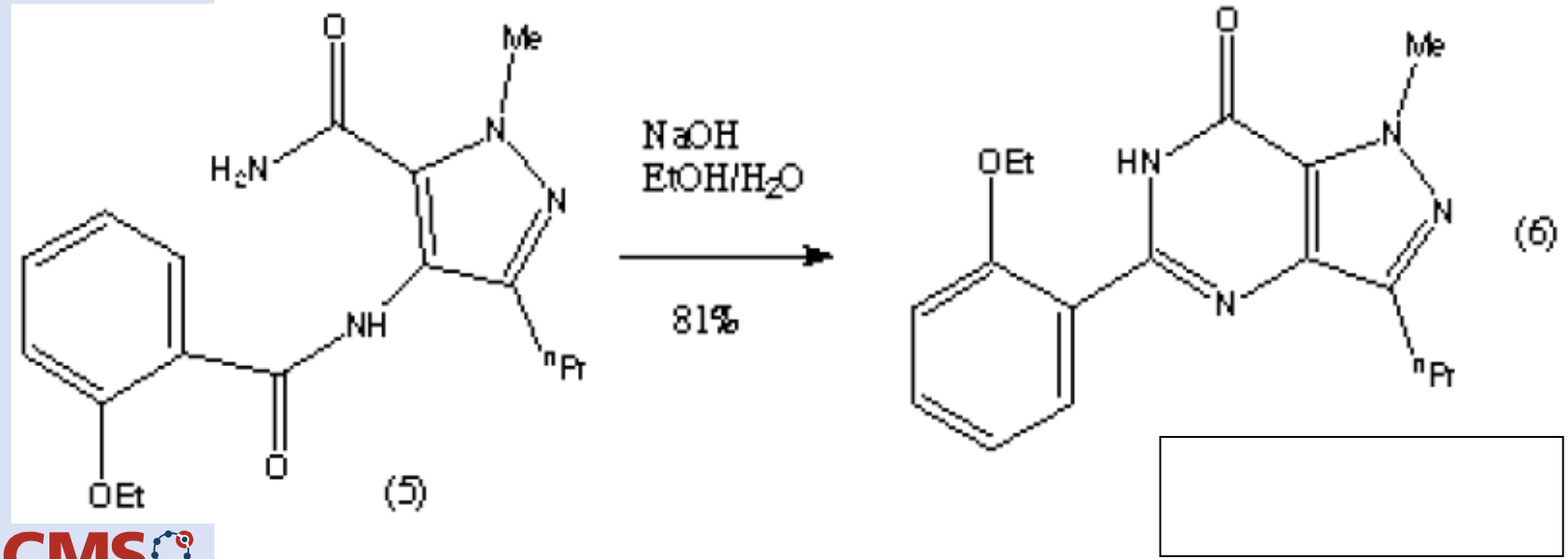
Step 5 – 81% Yield -- 19% Waste Plus Solvents and Catalysts



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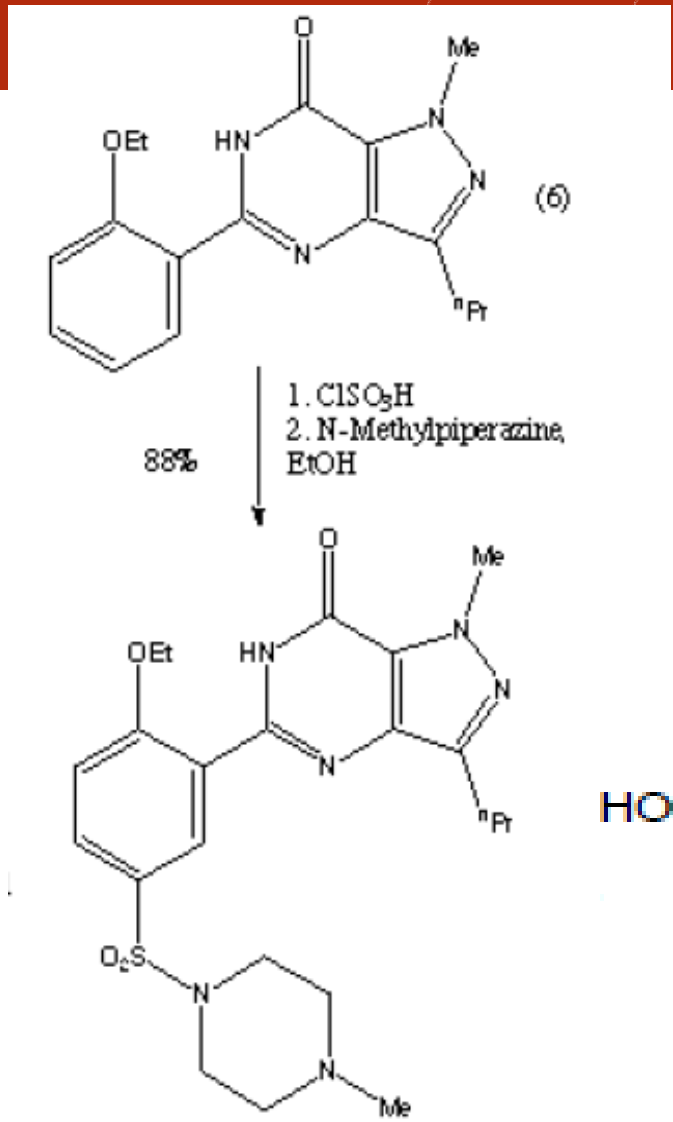
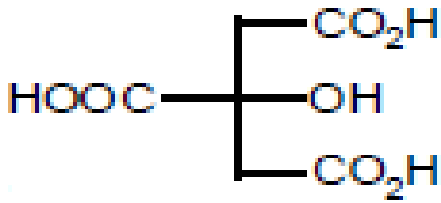
Step 6 – 88% Yield to Sildenafil -- 12% Waste



Sildenafil
(7)



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Overall Yields

Step	% Yield per Step (Overall % Yield)
1	62 (62)
2	71 (44)
3	42 (18.5)
4	88 (16)
5	81 (13) Penultimate Product
6	88 (11) Desired Product

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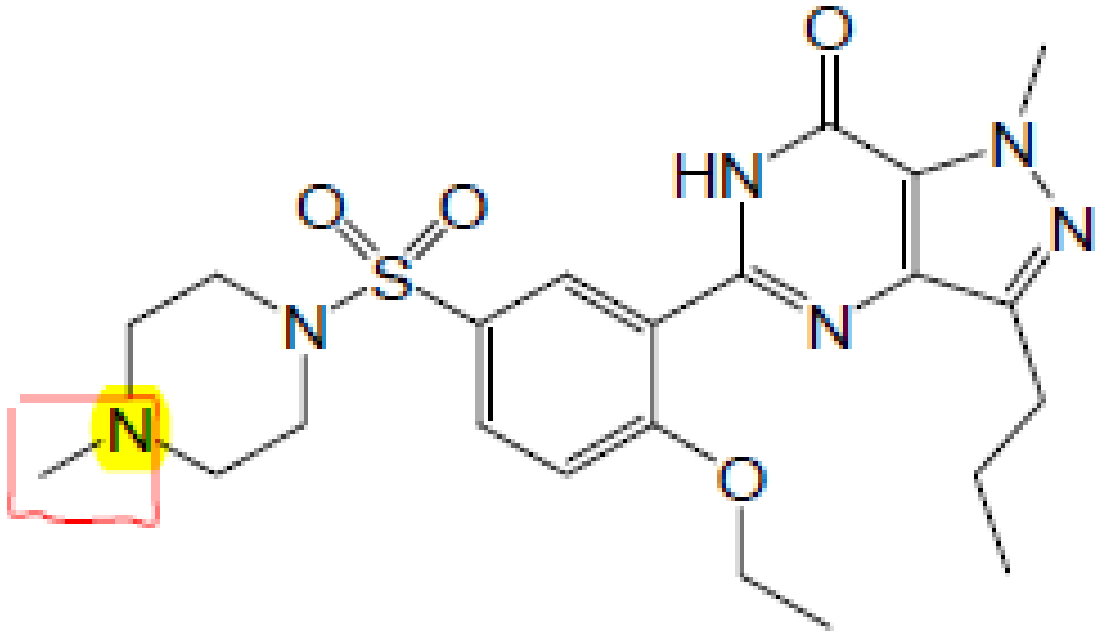
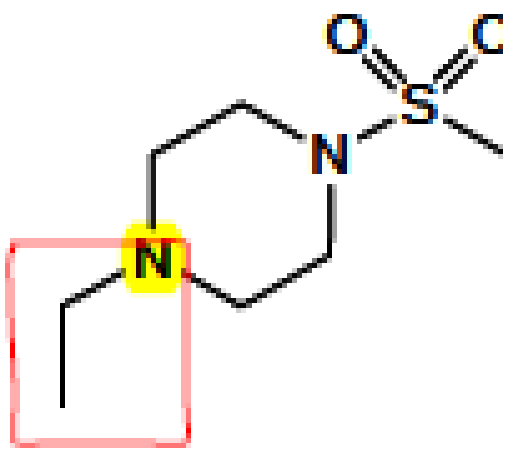


sildenafil



homosildenafil

Comments on the Synthesis

- The overall yield to the desired product is 11%. Throughout the synthetic steps solvents, catalysts and unwanted intermediates must be removed and disposed or recovered and the desired product either recovered or carried forward in the synthesis. Reaction vessels and containers generally must be cleaned generating more waste materials.
- The synthesis up to the penultimate product can be considered fine chemical processes while the last step is the drug synthesis to the Active Pharmaceutical Ingredient (API).

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Viagra Formulation—25 mg, 50 mg, 100 mg

- In addition to the active ingredient, sildenafil citrate, each tablet contains the following inactive ingredients:
  - microcrystalline cellulose,
  - anhydrous dibasic calcium phosphate,
  - croscarmellose sodium,
  - magnesium stearate,
  - hydroxypropyl 2-methylcellulose,
  - titanium dioxide,
  - lactose,
  - triacetin, and
  - FD&C Blue #2 aluminum lake.

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FDA Inspections

- The GAO estimated that, each year, the FDA inspects about 8% of foreign manufacturing plants that export to the United States.
- "At this rate, it would take the agency more than 13 years to inspect these establishments once. In contrast, FDA estimates that it inspects domestic establishments about once every 2.7 years," according to the report.

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Prof. Michael Anisfeld's Comments on Inspections

"As all QA people in this business know, **an audit is a snapshot of a moment in time.** I have visited many **companies that can in the space of a few months either move from a dreadful GMP compliance profile to a good profile; or that can in the space of a few months move in the opposite direction.** As such the value of an audit performed more than 3 months previous to the databank deposited audit report is of dubious value."

- Prof. Michael Anisfeld's letter to the Editor in "Industrial Pharmacy," March, 2008, **17**, pp 22-23

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WHO Prequalification Caveats

- "**Inclusion in this list does not constitute an endorsement, or warranty of the fitness**, by WHO of any product for a particular purpose, including in regard to its safety and/or efficacy.
- WHO does not furthermore warrant or represent that:
  - the list is complete or error free; and/or
  - **that the products and manufacturing sites which have been found to meet the standards recommended by WHO, will continue to do so**; and/or
  - that the products listed have obtained regulatory approval for its specified use or any other use in any country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws."
    - See http://healthtech.who.int/pq

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Médecins Sans Frontières Observations 1

- The circulation of substandard medicines in the developing world is a serious clinical and public health concern. Problems include under or over concentration of ingredients, contamination, poor quality ingredients, poor stability and inadequate packaging. There are multiple causes. **Drugs manufactured for export are not regulated to the same standard as those for domestic use**, while regulatory agencies in the less-developed world are poorly equipped to assess and address the problem.
- **Poor compliance with GMP standards** can lead to substandard production. This may be accidental (such as human error) or the result of insufficient resources (expertise, appropriate manufacturing infrastructure, or human and financial resources). **Other deliberate causes are often ignored or underestimated.**

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Médecins Sans Frontières Observations 2

"Quality audits of manufacturing sites done by MSF pharmacists (180 sites visited over the last 4 years) have found that **manufacturers that regularly pass the most stringent inspections adjust their standards to that of the recipient country.** In our observations, **parallel productions can exist in the same 'GMP compliant' facilities**: a high standard of production for the strictly regulated markets and for exacting clients such as UN organizations and international aid agencies; an intermediate standard of production for middle-income countries; and **a much lower standard for poorly regulated countries**."

- **J.-M. Caudron, N. Ford, M. Henkens, C. Macé, R. Kiddle-Monroe and J. Pinel, "Substandard medicines in resource-poor settings: a problem that can no longer be ignored," Trop. Med. and Int. Health, 2008, 13, pp1062-1072**

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Access To Malaria Drugs In Uganda

- 174 different formulations and strengths of often outdated drugs for sale
- Fewer than 14% of private drug outlets sell ACTs
- ACTs are up to 60 times more expensive than other drugs
    - Science, 232, p 1174. 21 Nov 08

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Killer Paracetamol: “My Pikin” Death Toll Rises to 34 Children

- **Mr. Okunola** admitted buying 40 litres of “Propylene glycol” from Tranxell Ltd. This was sold in a plastic jerry can.
- **Mr. Ikem Omalu** of Tranxell Ltd said that he bought from a shop owned by **Mr Emeka Onwalia**
- **Mr. Emeka Onwalia** claimed he bought from Mr. **Kenneth Azogba**.
- **Kenneth** claimed that he bought from one Mr. **Chinwendu Morako**, who claimed that he **bought from someone on the run**.
- All this took place in the same open market at Ojota bus stop.
- This is how the **diethylene glycol** entered into “My Pikin” teething mixture Batch No.02008.
- We suspect that Chinwendu Morako is not his real name. He, together with Ikem Omalu, Emeka Onwalia, and Kenneth Azogba, are also unregistered chemicals marketers and have all been arrested by the Nigeria National Agency for Food and Drug Administration and Control.

03 December 2008 http://www.vanguardngr.com/content/view/23217/42/

Take Your Pick

A street vendor in Niger—one of 11 countries targeted for the new program—has a huge variety of drugs for sale, including many for malaria.

•Science, 232, p 1174. 21 Nov 08

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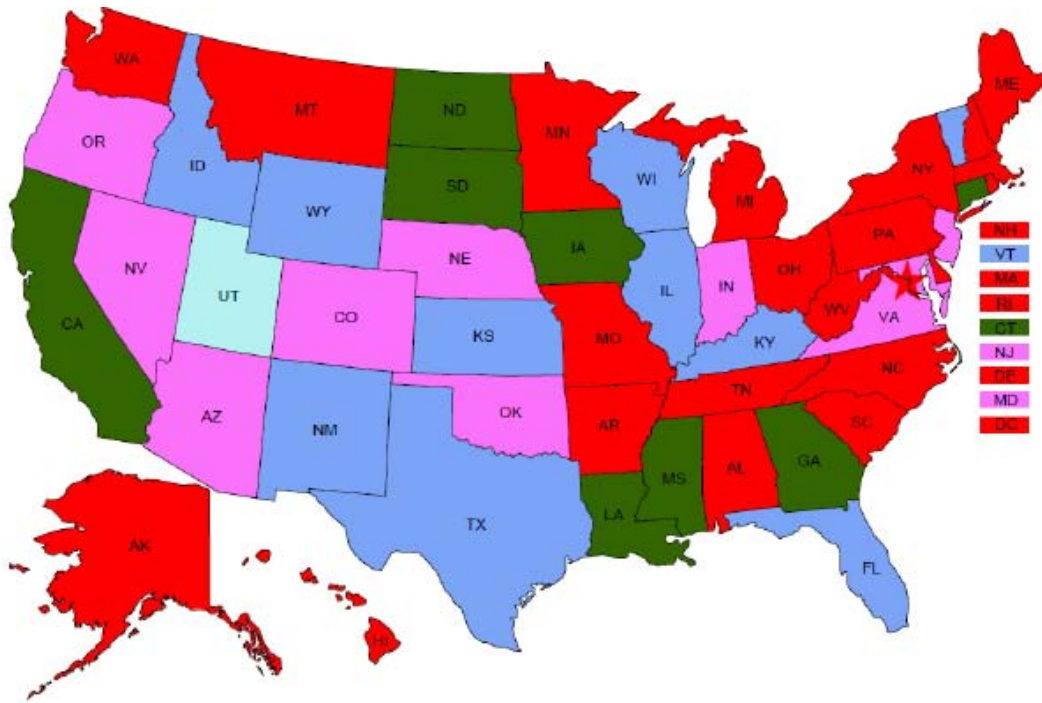
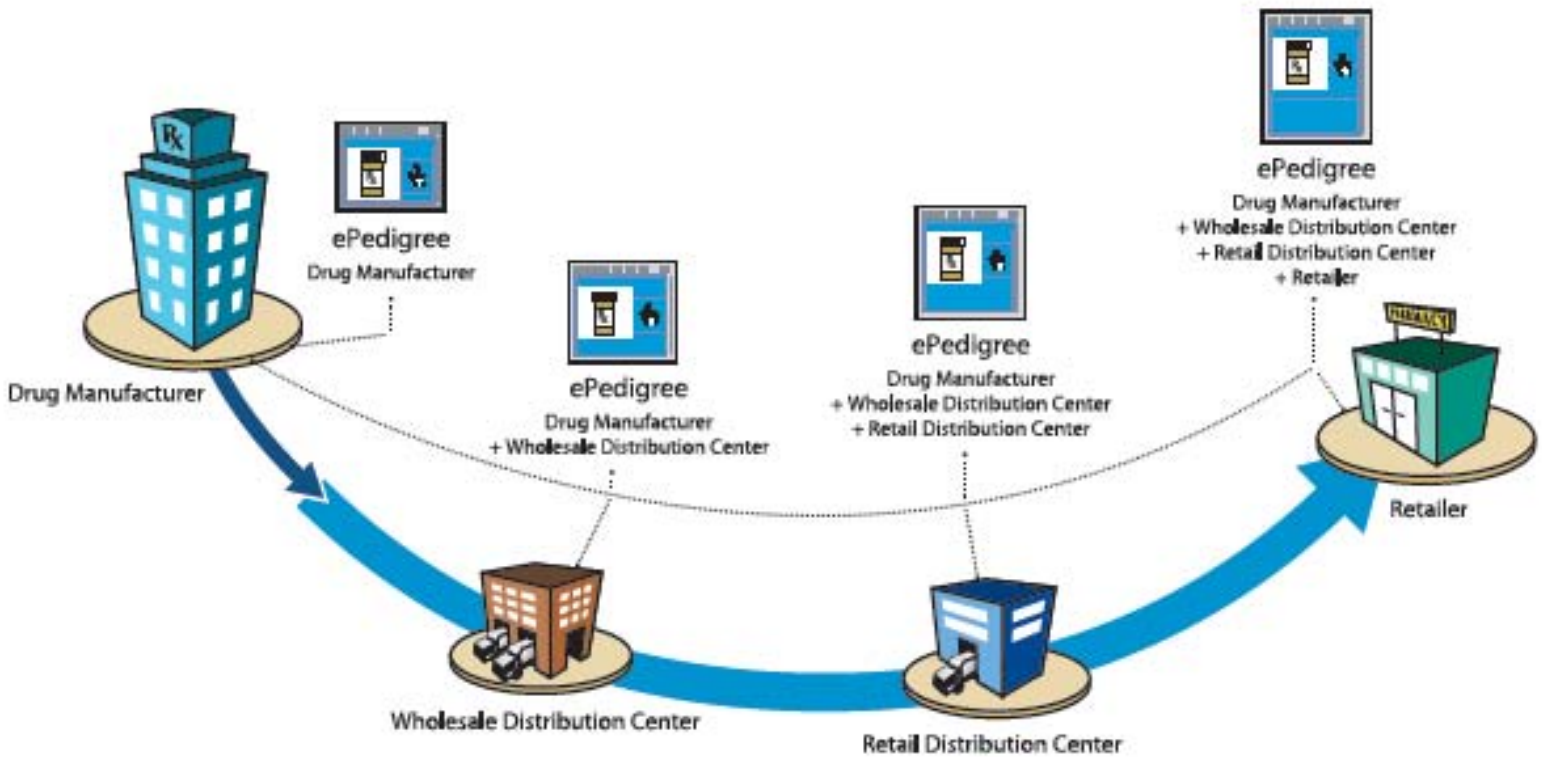
Distributor Licensing and Pedigree Requirements by State

Current as of 11/20/08			
21	No legislation or regulations	0	Proposed legislation
10	Enacted legislation; rules pending	0	Legislation vetoed
1	Rules pending, no legislation		
8	Enacted legislation		
10	Final rules adopted		



Radio Frequency Identification (RFID)



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January 14, 2009: FDA Launches Pilot Program To Improve the Safety of Drugs and API Produced Outside the United States

- Companies wishing to participate in the two year pilot program must meet certain criteria, including:
  - For finished drug products, the applicant must hold an FDA-approved drug application or must be the foreign manufacturer identified in an FDA-approved application;
  - The active pharmaceutical ingredients imported must be used only to make FDA-approved drugs;
  - Foreign drug manufacturers and U.S. establishments receiving drugs must be FDA-registered and comply with Good Manufacturing Practices; and
  - Applicants must show that their drug products use a secure supply chain.

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Very Difficult and Complex Problems

- Of the 1,154 pharmaceutical supplier plants mentioned in generic drug applications to the Food and Drug Administration in 2007.
  - 13 % were from United States,
  - 43% were from China and
  - 39% were from India.
- Excipients are generally food grade which are intended to meet food manufacturing standards and not pharmaceutical GMPs.

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The Trade Secret Dilemma

- Since drug makers often view their supply chains as trade secrets, the true source of a drug's ingredients can be difficult or impossible to discover.
- "Pharmaceutical companies do not like to reveal where their sources are," for fear that competitors will steal their suppliers.
- Drug labels often claim that the pills are manufactured in the United States, but the listed plants are often the sites where foreign-made drug powders are tableted into pills and packaged.

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Conclusions

- It is very difficult to trace APIs or track finished dosage forms in commerce.
- All of the various policies and regulations to assure quality work if all of the participants are conscientious and honest.
- The only good defense is product assessment either with various fingerprinting technologies or complete testing of the product to determine if it meets specifications.
- The fingerprinting technologies generally can discern counterfeit products unless they are identical.

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A Successful Story------ Mobile Labs Developed in China for Detection of Counterfeit Drugs

Prof. Jin Shaohong

National Institute for the Control of Pharmaceutical and Biological Products **(NICPBP)**

P.R. China

I . Scale of the Problems in China

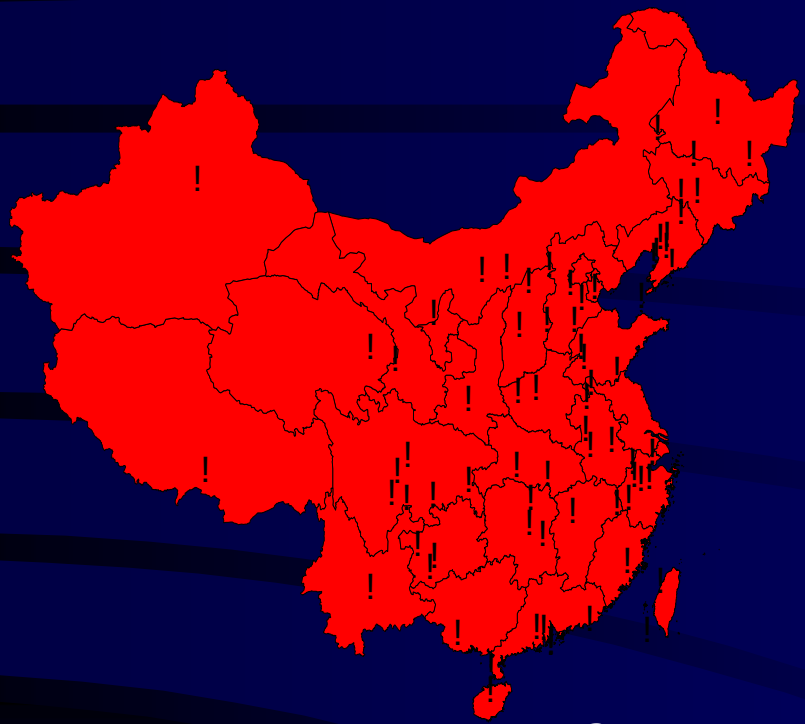
II. New Field Testing Technology — Mobile Labs Developed in China

III. Roles Played by Mobile Labs for Drug Safety in Rural Areas of China

IV. Current Progress of Mobile Labs

V. Future plan of mobile labs for combating counterfeits

I. Scale of the problems in China



Pharmaceutical manufacturers: 4700 (including about 2,000 Traditional Chinese Medicine (TCM) manufacturers and 400 bio-tech companies

Area: 9.6 millions km^2

31 provinces 333 districts

2861 counties

Population: 1.3 billions (70% living in countryside)

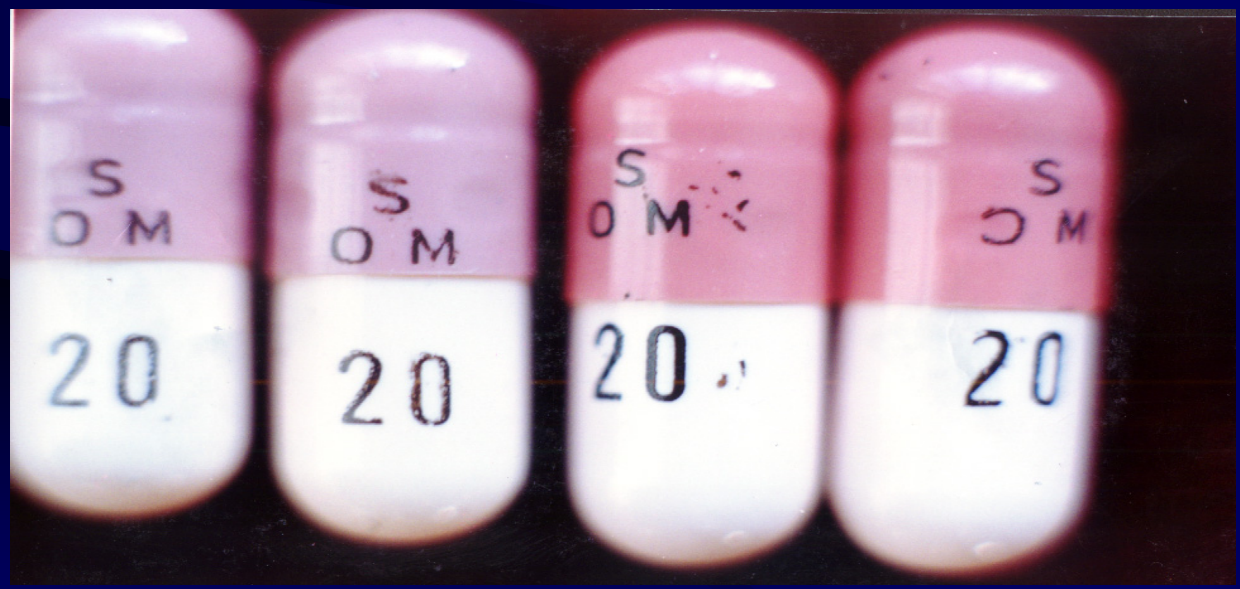
Definition of counterfeit drug according to WHO

A product that is deliberately and fraudulently mislabelled with respect to source and/or identity. Counterfeiting can apply to both generic and branded products. Counterfeit products may include: products with the correct ingredients, with the wrong ingredients, without ingredients, with incorrect quantities of active ingredients, with fake packaging.

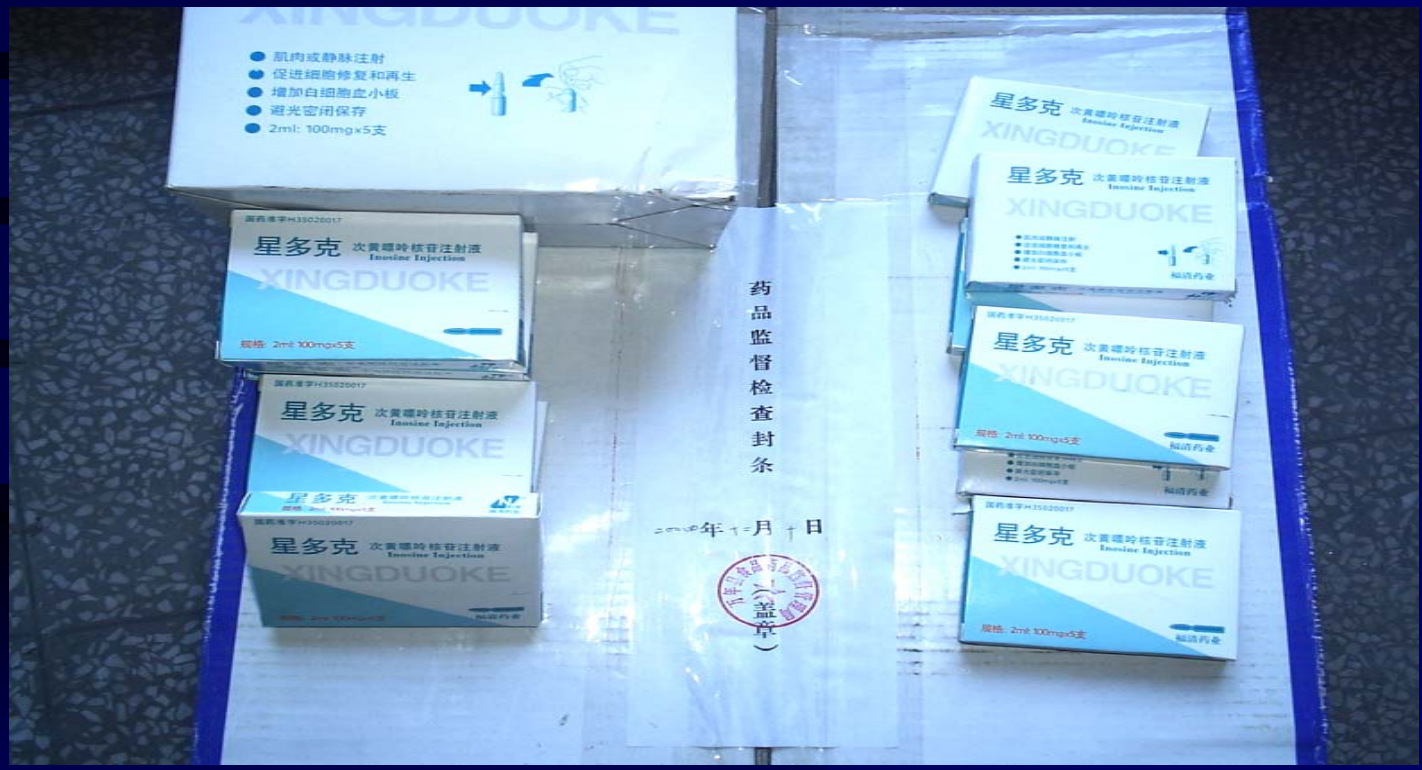
Some cases of counterfeits and substandard drugs found in China

1) Without Active Pharmaceutical Ingredient (API)

Amoxicilline

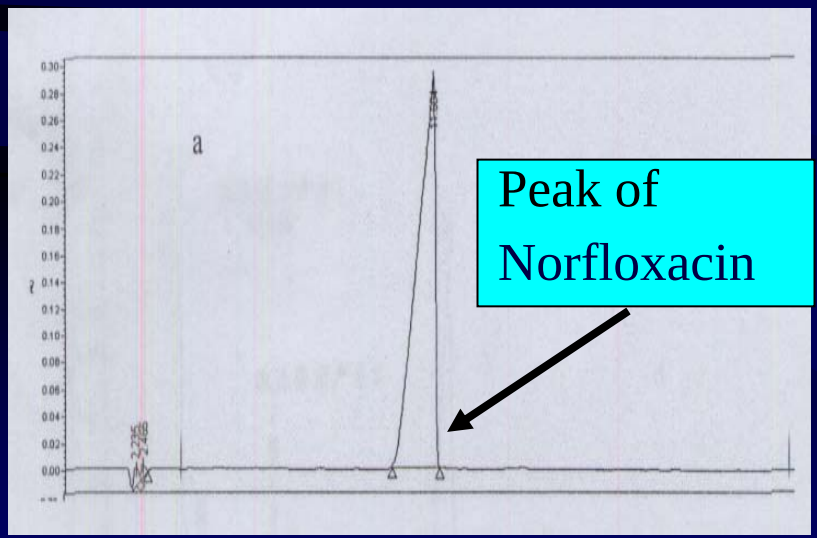


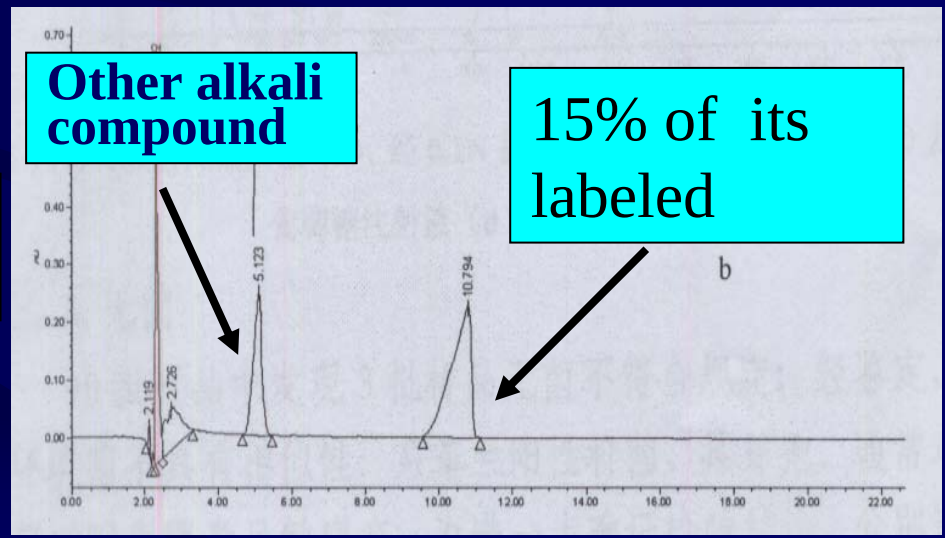
2) With wrong API
(XingDuoKe Injection, Inosine Injection)



3) With incorrect quantities of active ingredients

In 1998 the results of a special program of the quality surveillance of Norfloxacin Capsules showed 14% of tested samples contained less quantity than its labeled.
In one ceased batch, there was only 15% of Norfloxacin found by HPLC method.



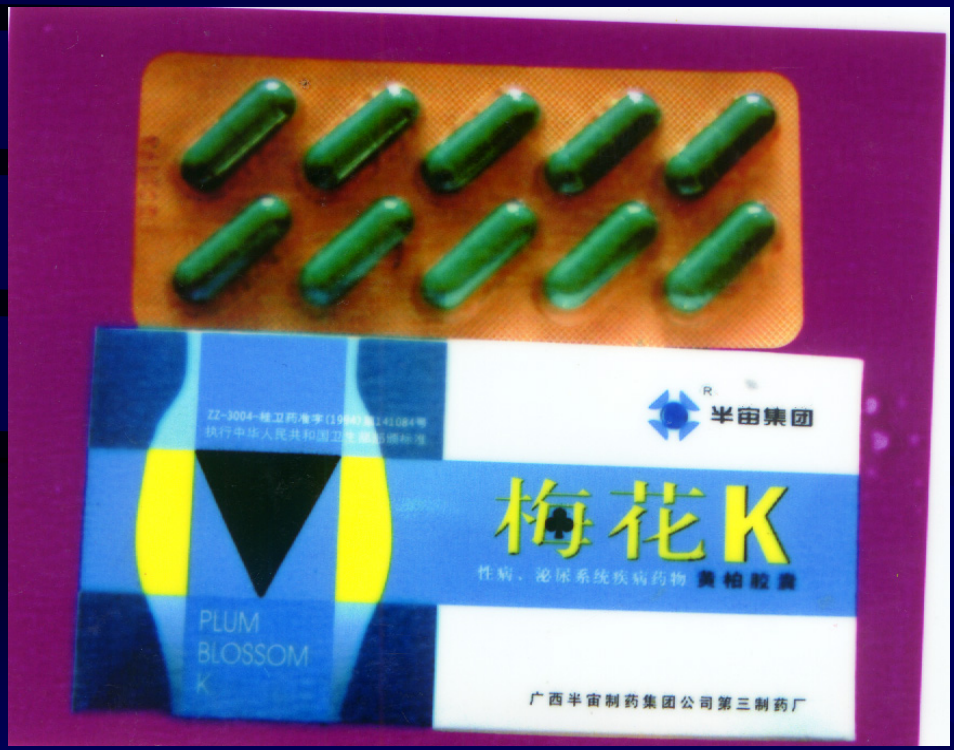


4) *With correct ingredients but fake packaging*

5) Traditional Chinese Medicine (TCM)

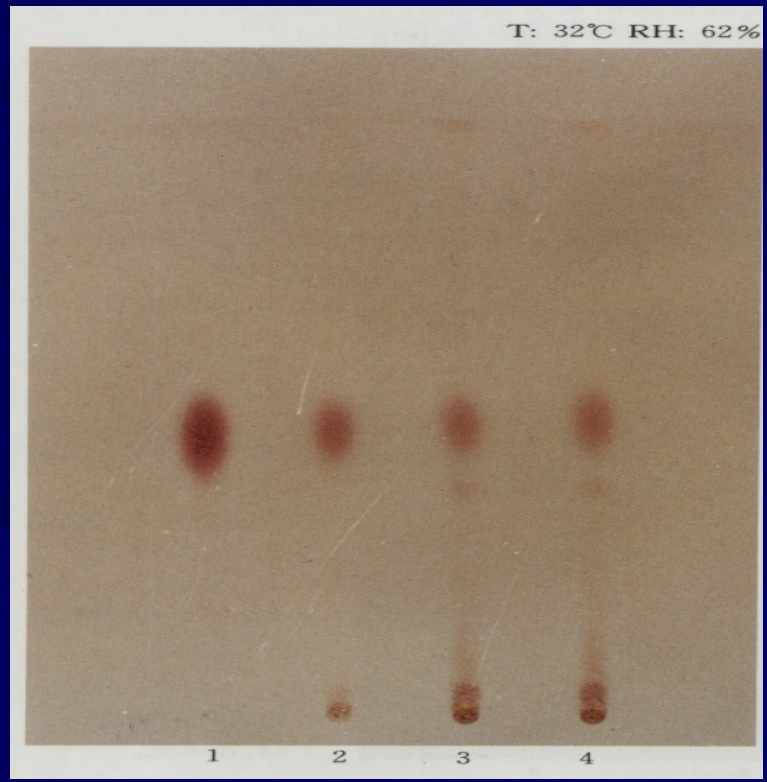
adulterated with chemical drugs

71 people were hospitalized after took the Huangbo Capsules in 2003



Huangbo Capsules (Cortex Phellodendri)

(Berberine Hydrochloride)



Tetracycline Hydrochloride

In January 2009 two people in Xinjiang province died after took the TCM Tangzhinin Capsules

The capsules were adulterated with Glyburide

The criminals were arrested

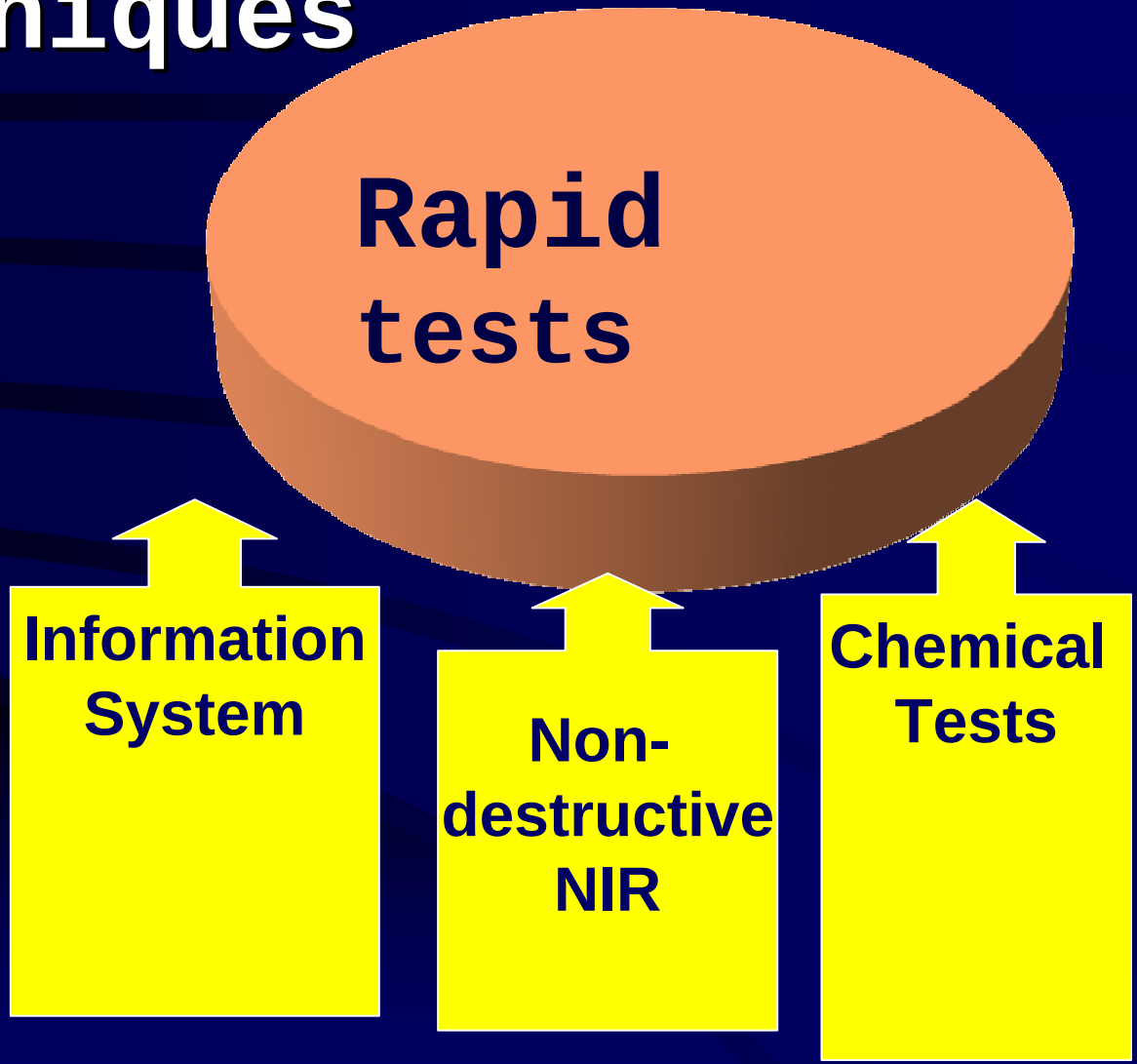
II. New Field Testing Technology — Mobile Labs Developed in China

In order to combat the counterfeit and /or substandard drugs distributed in rural areas of China, the SFDA instructed National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) to develop mobile labs to be used in fields for drug screening tests

Goals


Easy-to-use
Specific
Rapid Screening Testing Methods
Quick
On-Side

Combination of Three Techniques



1, Equipments of mobile labs

a. the modified van : inside

Ventilation

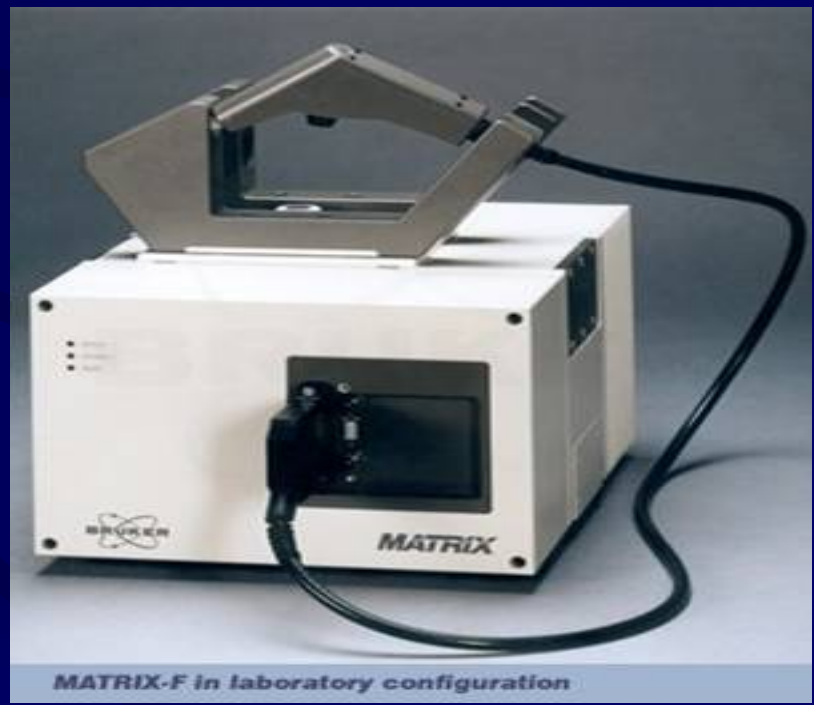
Dual power supply

Air condition

Information inquired by internet

b, TLC system

c, Non-destructive instrument : NIR



2,Characteristics of mobile lab

a. Information system

1, Manufacturer Information (about 200,000 entries)
Pharmaceutical Manufacturer's Names, Addresses
Product Names, Licensed Numbers, Dosage forms,Strengths

2, Quality Information (up-to-date annually)
Unqualified or withdrawn Product Names, Batch Numbers , Manufacturer's Names listed in National or Provincial "Drug Quality Bulletin"

3, Electronic version of Screening test methods and libraries

b. Technical parts

More than 800 drug preparations including anti-malaria, anti-AIDs, anti-TB,Chinese herb medicines and other essential drugs could be tested in mobile Lab including

1,Classical screening methods

- Chemical functional group reaction
- TLC systems for quick identification
- Microscopic Pictures for Herb Medicine Identification

2,Non-destructive testing method -----NIR

Chemical methods

Example 1: Screening test for detection of herb medicines adulterated with Sidenafe

A. Acid solution shake,filter

B. Oxidizing agent --- color fading

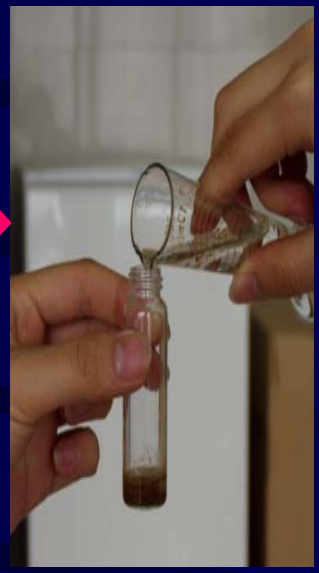
C. Trinitrophenol solution - yellow precipitate ring

Characteristic Rapid :few minutes

Low cost: 1 Dollar/Sample

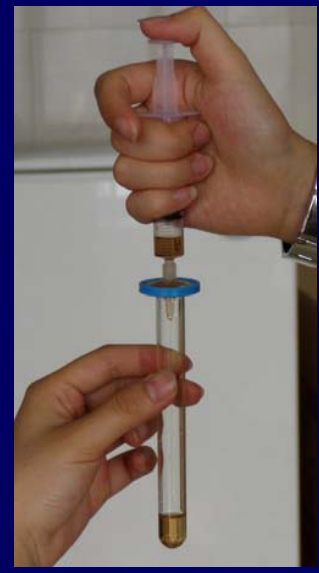
Accuracy 99.2% 1083 Batches

Pills



Sulfuric Acid

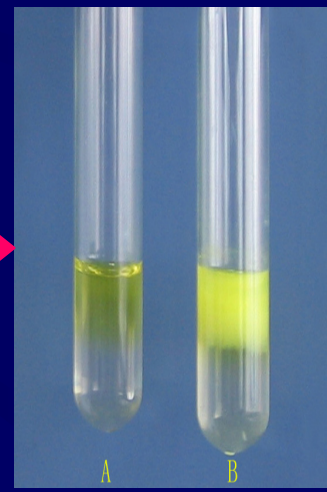
Shaking



Filtering

Filtrate

Color fading



Yellow precipitate

Chemical methods

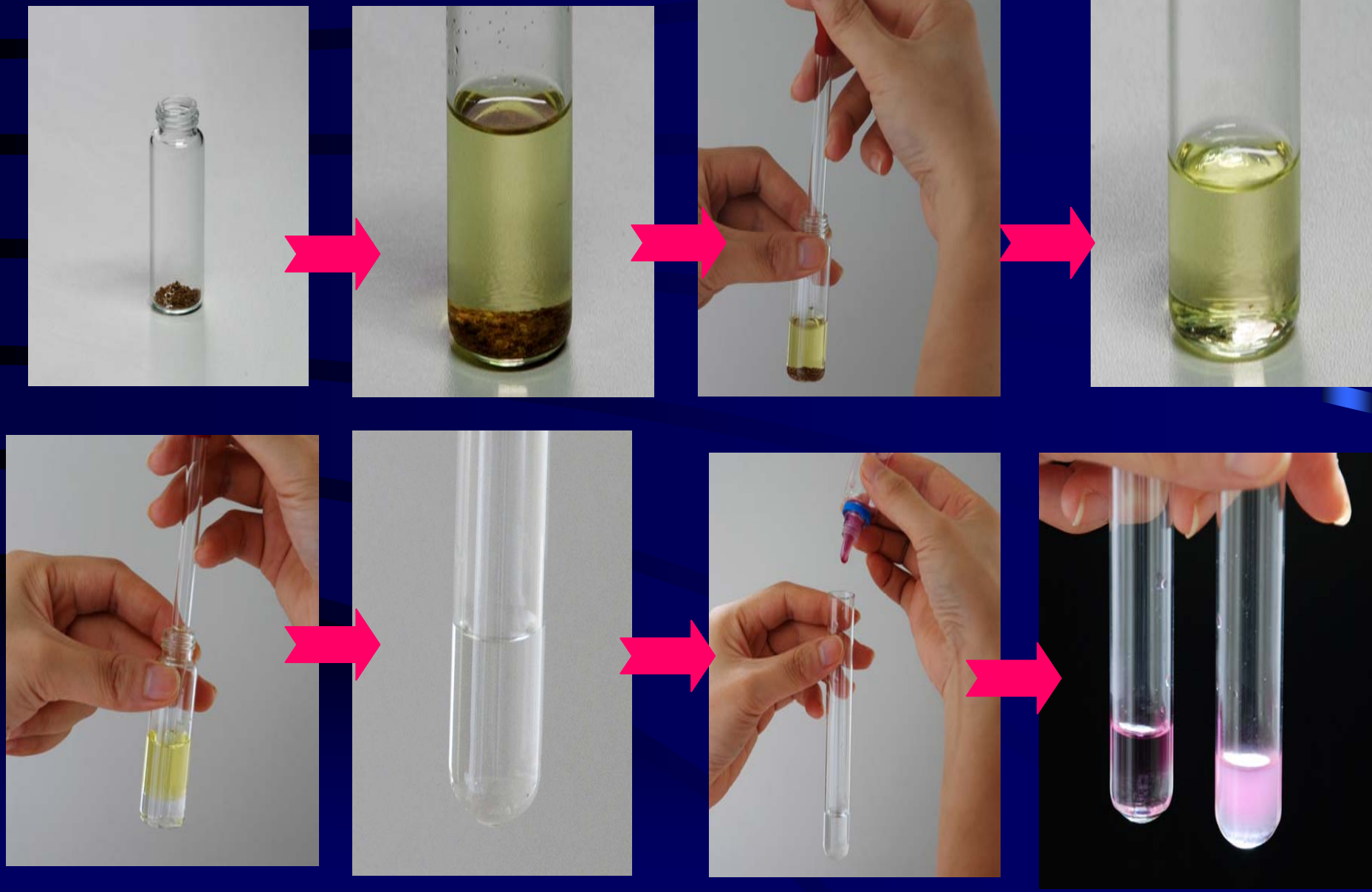
Example 2: Screening test for detection of herb medicines adulterated with Sibutramine

1. Dissolve with Ethyl Acetate
2. Extract with Dilute Phosphate Acid
3. Check if precipitation forms with Ammonium Reineckate

Time: less than 5 Min.

Cost: 0.2 Dollar

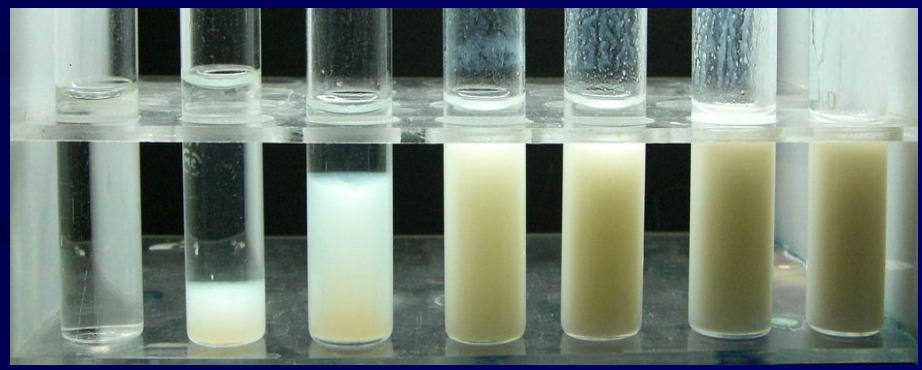
Accuracy; 99.0% 820 Batches



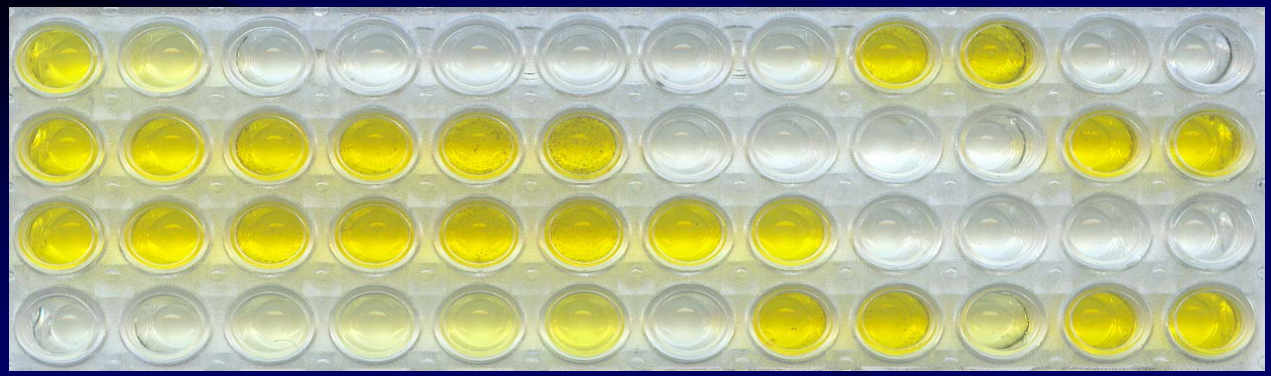
Chemical methods

Example 3: Screening tests for detection of certain biological products

For human albumin preparations(chemical reaction)

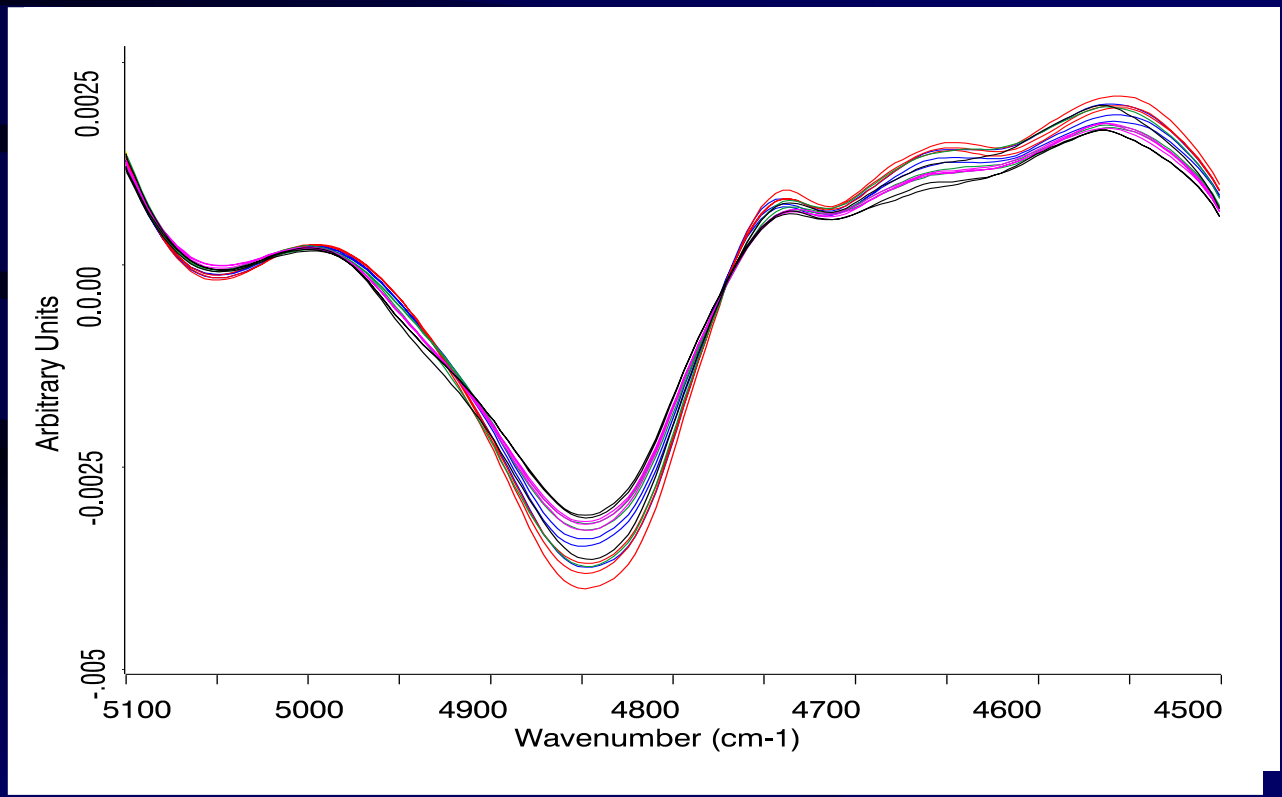


For Rabies vaccines (ELISA method)



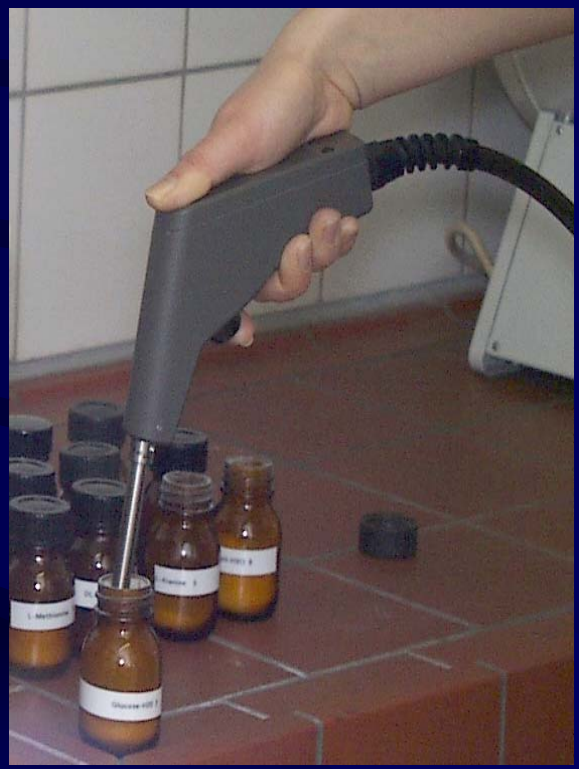
Modern Fast and Non-destructive Methods

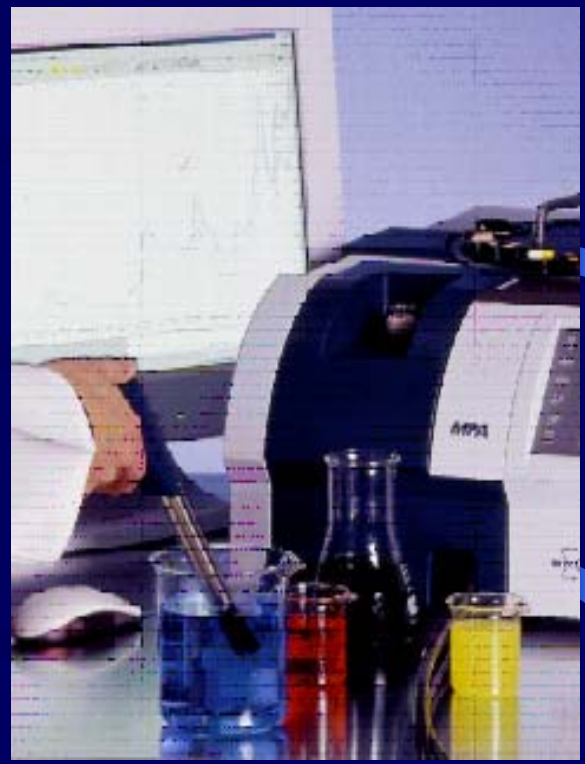
- Near Infra-Red (NIR) Spectrophotometer
- Data bank of NIR Reference Spectra for Specified Drugs



Modern Fast and Non-destructive Methods

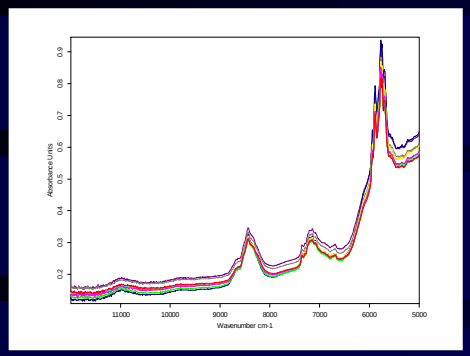
Establishing NIR Reference Spectra Database



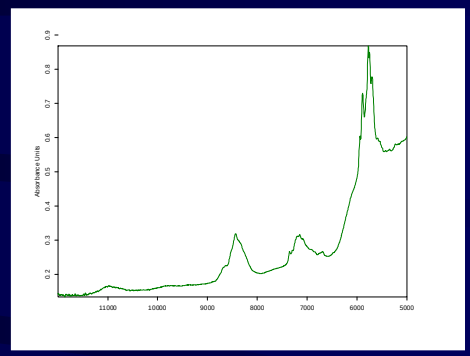


Principles of NIR calibration models

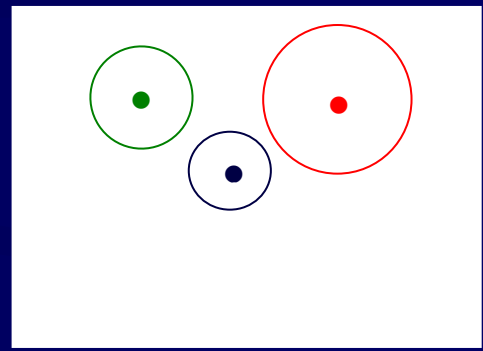
1 Qualitative Models



1. Spectra collection



2. Average spectra calculation



3.Establishing qualitative model

4, Unknown sample determination

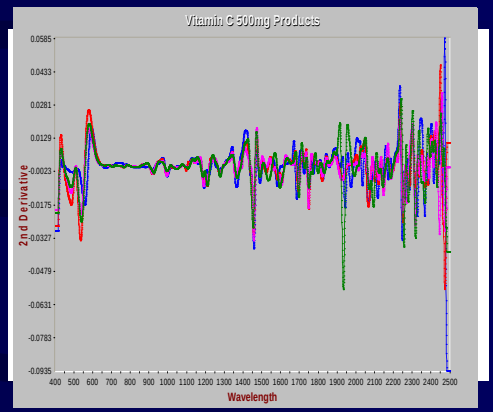
5. Retrieve the model

6. Identification of the tested sample

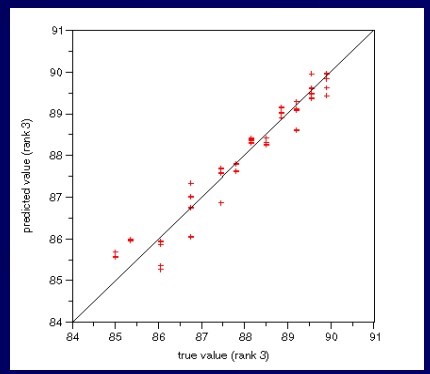
Principles of NIR calibration models:
(2) Quantitative Models

Component	A	B	C
Units	%	%	%
spectrum1	71.30	7.03	21.67
spectrum2	79.30	3.06	17.64
spectrum3	78.40	8.34	13.26
spectrum4	84.03	4.32	11.65
…	…	…	…
spectrum11	85.02	1.34	13.64
spectrum12	78.34	3.85	17.81

1.Results from official methods



2. Spectra collection



3. Correlation between NIR and official method

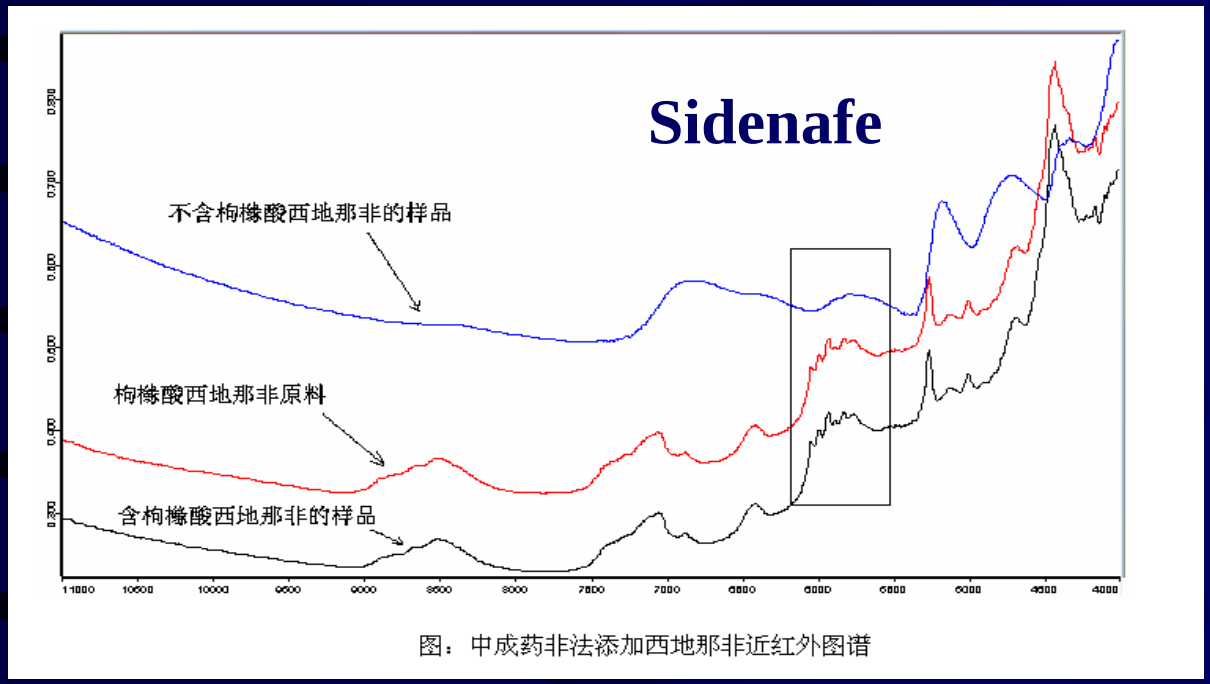
4. Determination of Unknown sample

5. Retrieve the quantitative model

Report	
Sample #081897-049	
Component A	81.55%
Component B	5.38%
Component C	13.06%

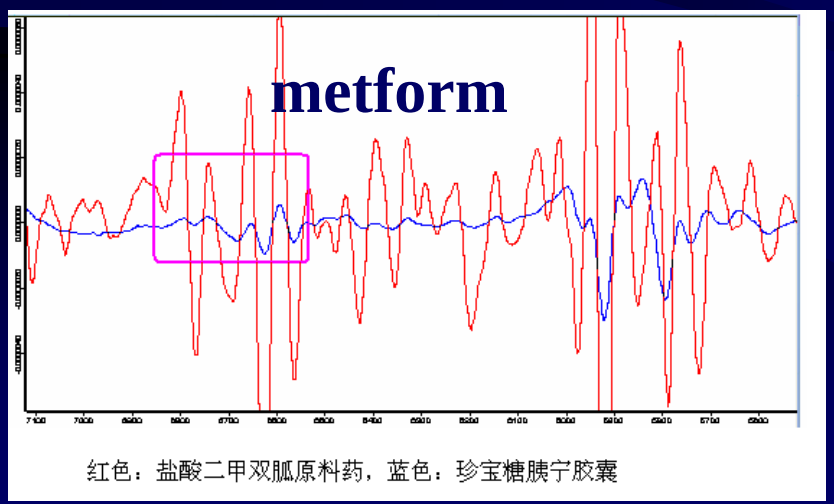
6. Quantitative estimation

Screening Sidenafe, metform adulterated in TCM by NIR

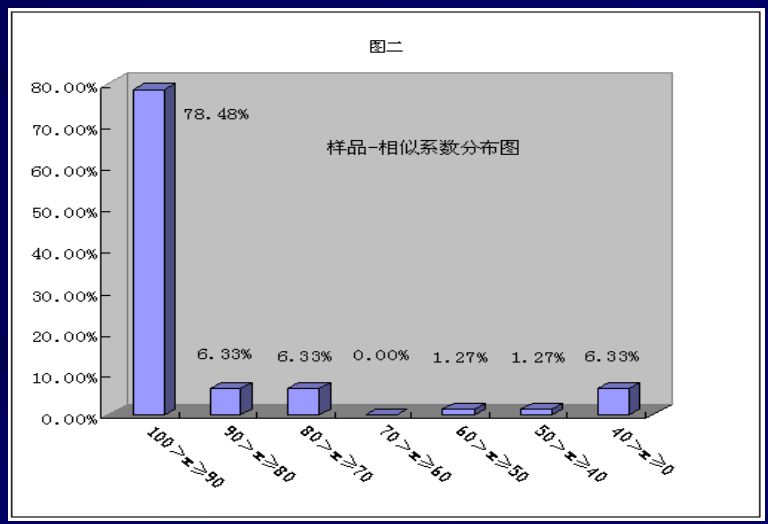


图：中成药非法添加西地那非近红外图谱

Successful screening rate: about 85%



红色：盐酸二甲双胍原料药，蓝色：珍宝糖胰宁胶囊



Former Vice Primer of China Ms.Wu Yi inspecting the NIR testing

III. Roles Played by Mobile Labs for Drug Safety in Rural Areas of China

- China central government has provided 70 million dollars for about 400 mobile labs to combat counterfeit drugs and to protect the health of people living in rural areas of China
- Since March 2006 a total of 379 mobile Labs have been equipped for 29 provinces
- Very important roles have been played and some counterfeits and substandard drugs were detected

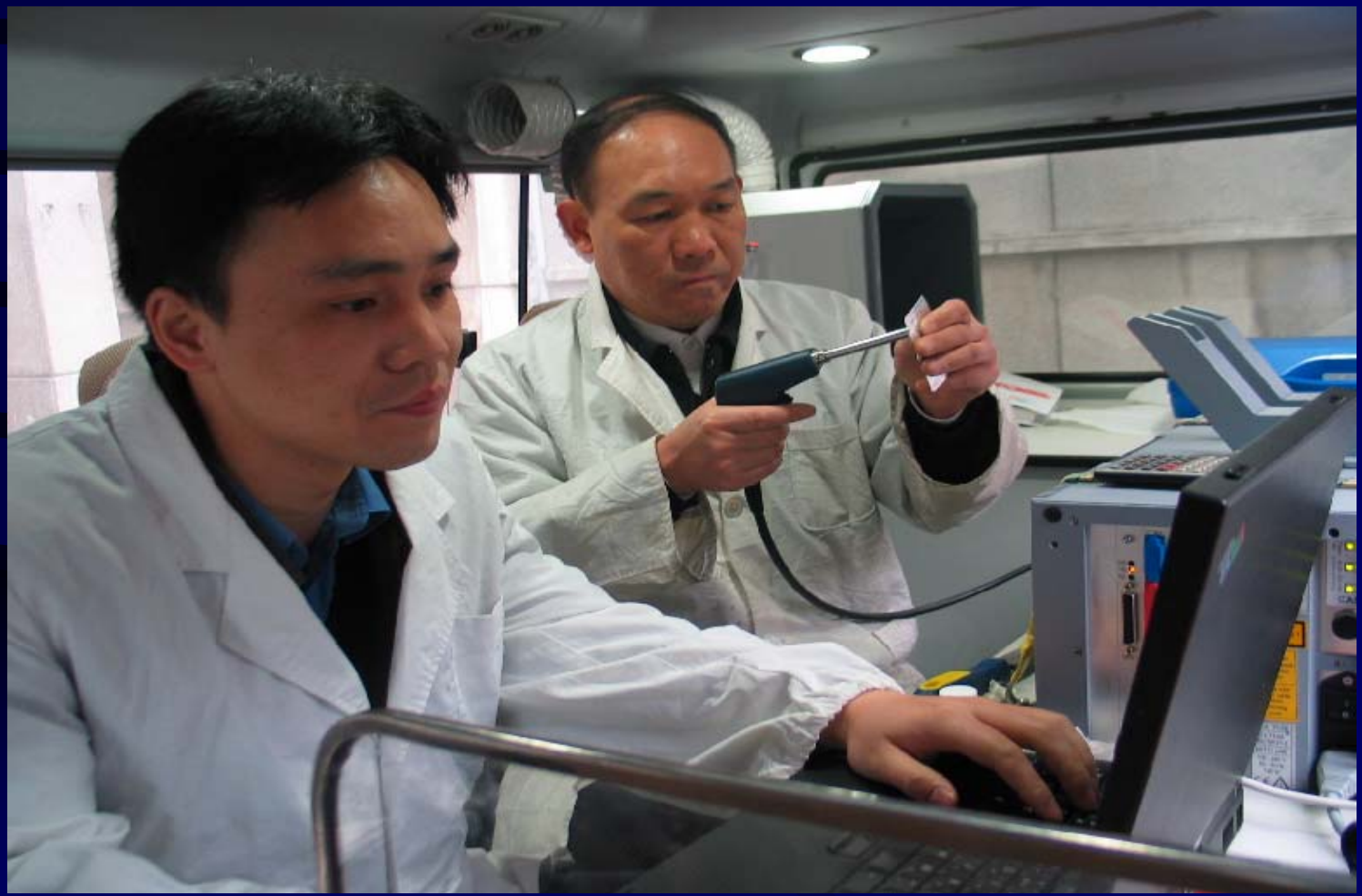
Mobile Labs Running in Rural Areas of China-- in Hu Bei province

Mobile Labs Running in Rural Areas of China in An Hui Province

Sampling in drug store in rural area

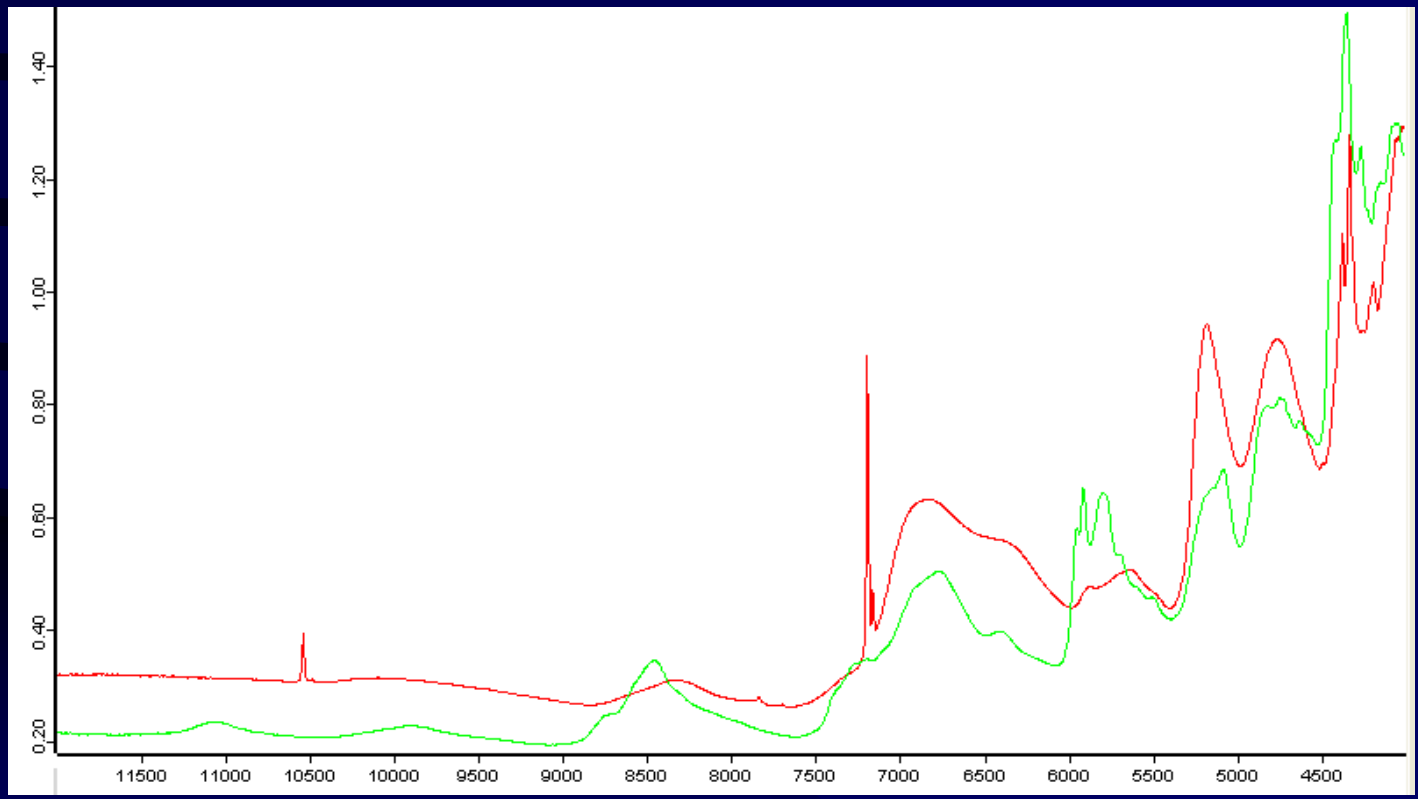
Samples labeled as “Erythromycin Ethylsuccinate Tablets”

NIR sample measurements and analysis in mobile labs

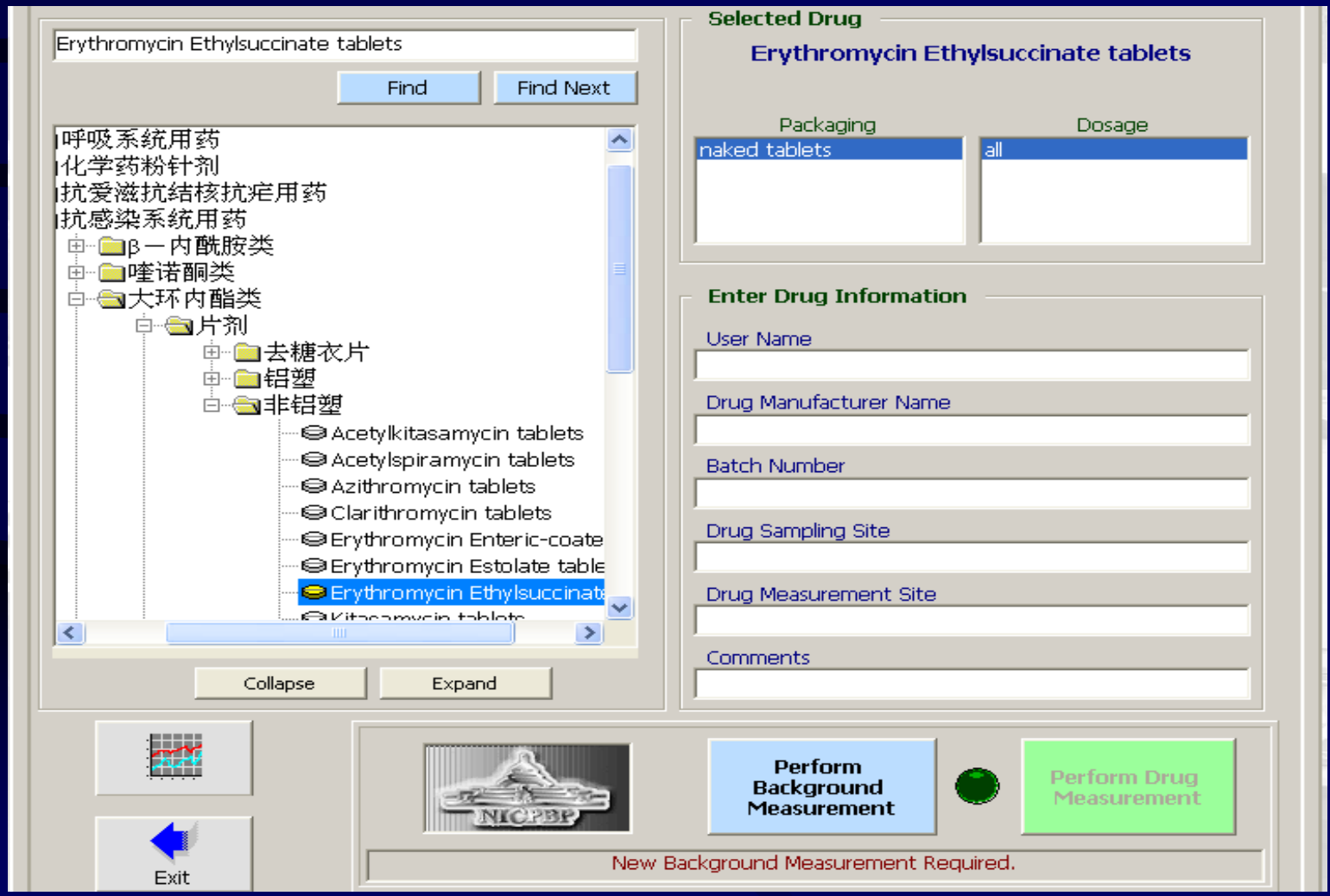


NIR spectra collected from real and fake Erythromycin Ethylsuccinate Tablets

green line is real, red line is fake



Retrieve the reference spectrum and method of tested drug from NIR database



Reports from NIR analysis

Result of IDENT Evaluation:

Sample: D:\谱图\0209310-11.0
Method File: D:\谱图\Macrolide qualitative analysis model.FAA
Date and Time: 08/10/2005 08:52:31.080 (GMT+2)

Hit No.	Sample Name	Hit Qual.	Threshold	Group
1		0.06075	0.49047	Erythromycin Ethylsuccinate tab
2	瑞邦3	1.00934	0.19223	Meleumycin tablets
3	信谊1	1.11465	0.25000	Acetylspiramycin tablets
4	利君2	1.26807	0.51258	Erythromycin Enteric-coated tab
5		1.30361	0.78147	Roxithromycin tablets
6	依托红霉素	1.34150	0.25000	Erythromycin Estolate tablets
7		1.35457	0.65896	Azithromycin tablets
8	利君1	1.36376	0.28329	Clarithromycin tablets
9	吉他霉素	1.36986	0.25760	Kitasamycin tablets
10	乙酰吉他霉素	1.39464	0.25000	Acetylkitasamycin tablets

IDENTIFIED AS Erythromycin Ethylsuccinate tablets

OK

Result of IDENT Evaluation:

Sample: D:\谱图\0306075-7.0
Method File: D:\谱图\Macrolide qualitative analysis model.FAA
Date and Time: 08/10/2005 08:59:03.090 (GMT+2)

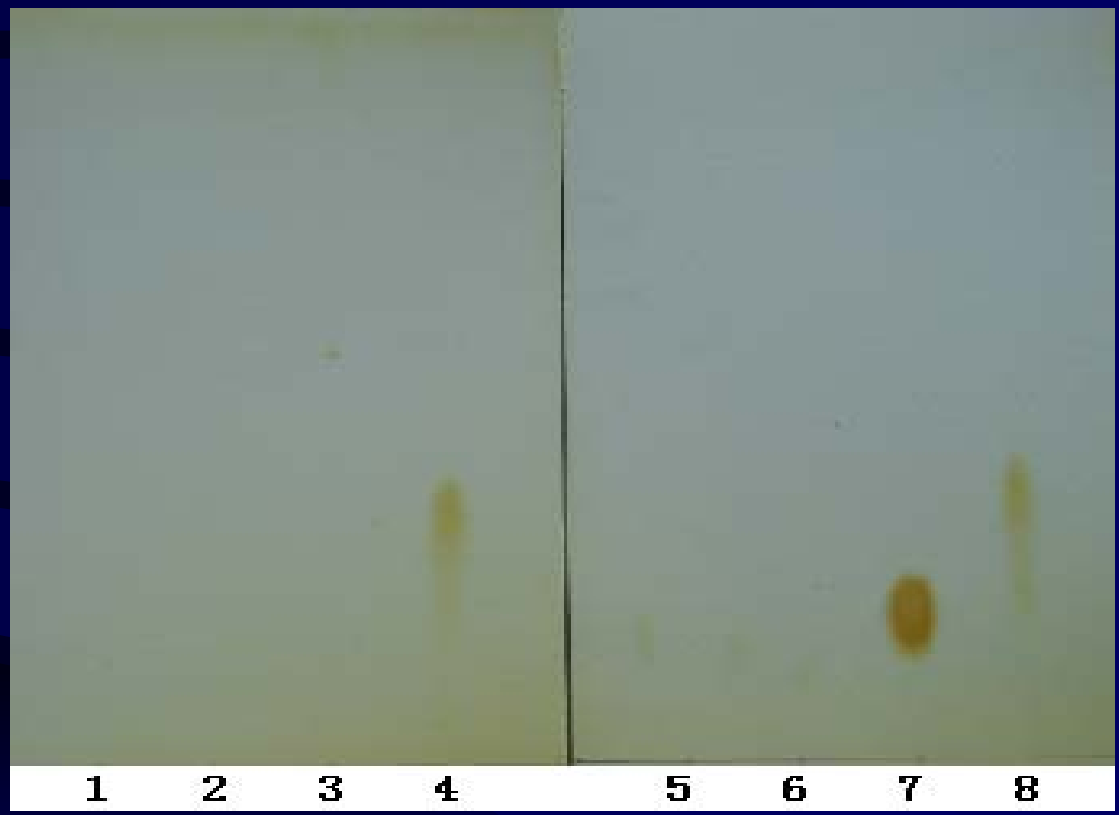
Hit No.	Sample Name	Hit Qual.	Threshold	Group
1	吉他霉素	0.26056	0.25760	Kitasamycin tablets
2	信谊1	0.52291	0.25000	Acetylspiramycin tablets
3	瑞邦3	0.64592	0.19223	Meleumycin tablets
4	依托红霉素	1.17776	0.25000	Erythromycin Estolate tablets
5	乙酰吉他霉素	1.21259	0.25000	Acetylkitasamycin tablets
6		1.23006	0.78147	Roxithromycin tablets
7	利君2	1.23435	0.51258	Erythromycin Enteric-coated tab
8		1.23595	0.65896	Azithromycin tablets
9	利君1	1.26103	0.28329	Clarithromycin tablets
10		1.55046	0.49047	Erythromycin Ethylsuccinate tab

NOT IDENTIFIED

NOT
OK

Performing chemical reaction in mobile lab

Verified using TLC test method in the mobile lab



Only No. 4 and 8 are real, the rests are fake

Counterfeit labeled as legitimate "Erythromycin Ethylsuccinate Tablets"

Up to now, a total of 379 Mobile Labs were deployed and more than 900 technicians were trained in China

Achievements of mobile labs nationwide

From Jan. 2008 ~ Dec. 2008 379 mobile labs

Achievements of mobile labs nationwide

Drug dispensaries inspected (including drug stores, clinics) **30,000**

Rural area covered **70%**

Batches Screened more than	Batches of suspicious drugs sampled(including raw Chinese herbs)	Batches of counterfeit and substandard drugs confirmed
130,000	**17500**	**5061**

The successful screening rate was 28.9%

Examples: One province (Guang xi) in the first year (2007)

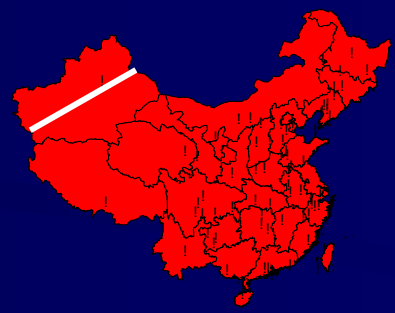
- mobile labs 16
- Drug dispensaries inspected : 22,110
- Rural area covered **89 %**

Batches Screened	Batches of suspicious drugs sampled(including raw Chinese herbs)	Batches of counterfeit and substandard drugs confirmed
31,742	**5,405**	**2,135**

The successful screening rate was 39.5%

Examples: One District (Keshi district, Xinjiang province) in one year (2008)

- Area: 160,000 Km^2
- Border line 888 Km

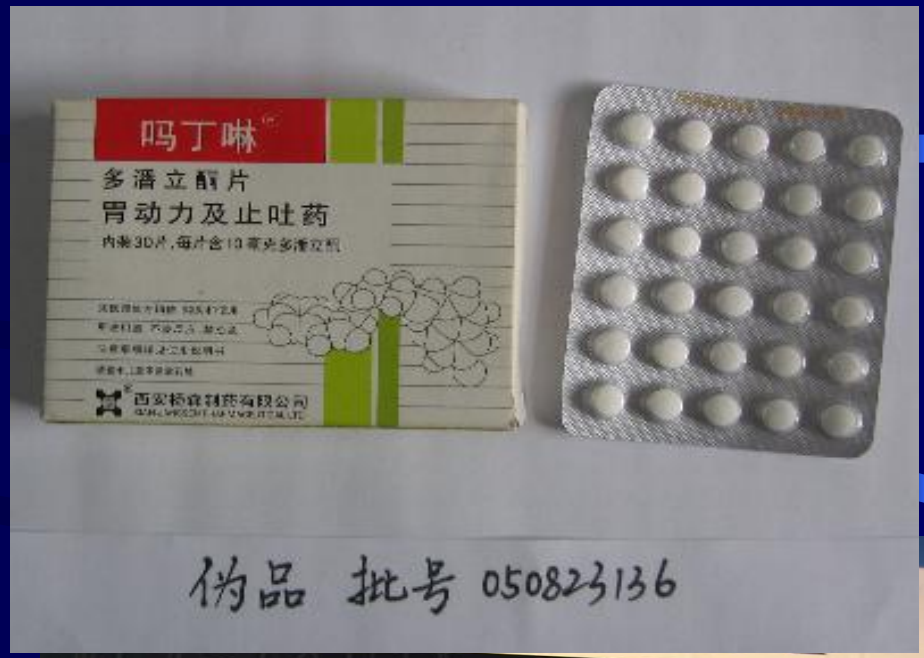


•Drug dispensaries inspected 120
(only **7~8%** of the administrate area)

Batches Screened	Batches of suspicious drugs sampled(including raw Chinese herbs)	Batches of counterfeit and substandard drugs confirmed
1500	**178**	**110**

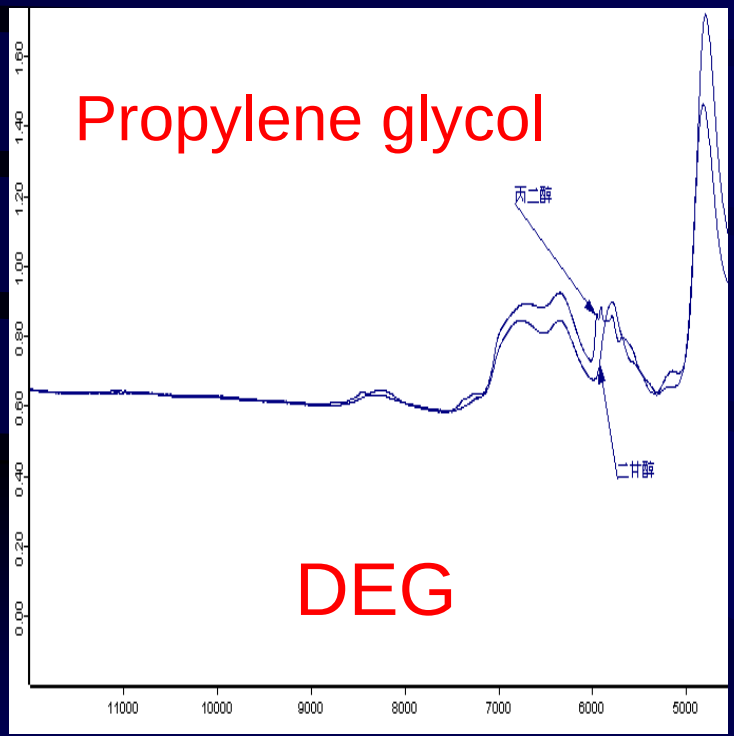
The successful screening rate was 62%

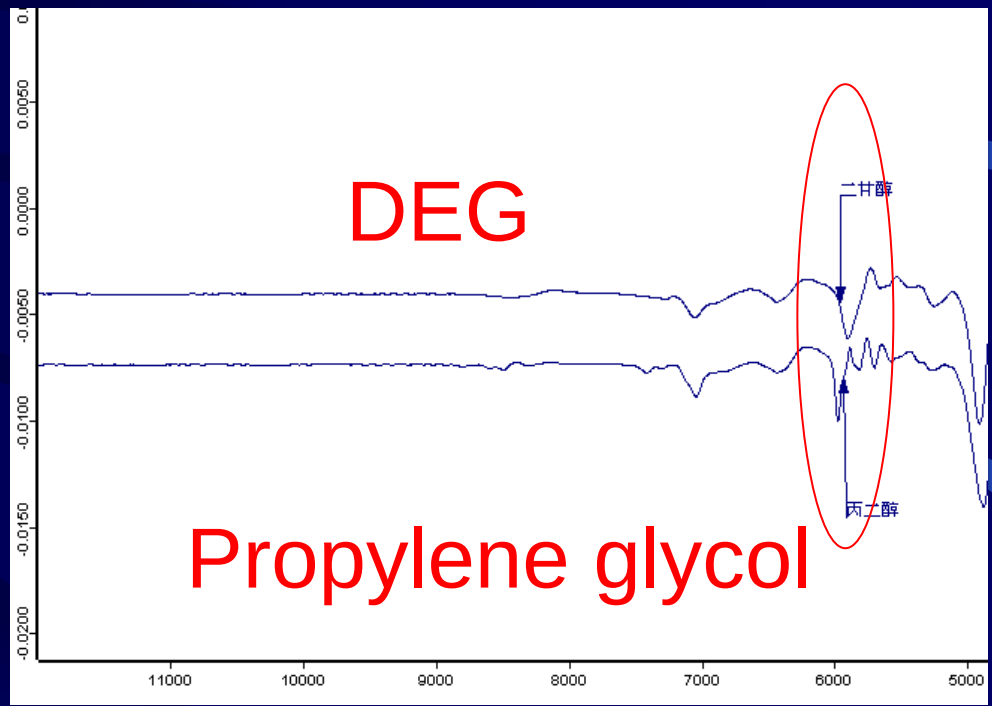
Counterfeits detected and seized by mobile forensic Labs



Mobile Labs have played very important roles in some emergency responses

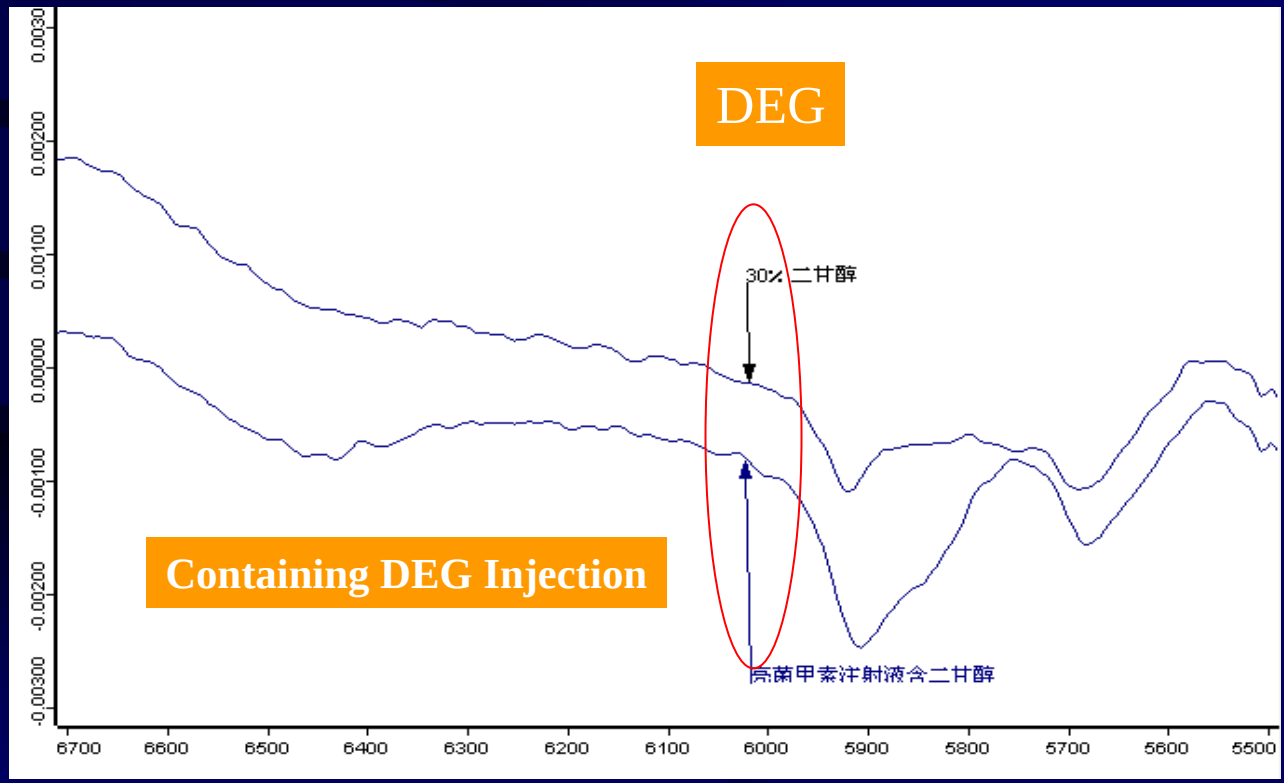
Example 1: Detection of DEG Using NIR Spectra





Mobile Labs have played very important roles in some emergency responses

Armillarisin A Injection



Mobile Labs have played very important roles in some emergency responses

Armillarisin A injections contaminated with DEG were detected

Mobile Labs have played very important roles in some emergency response

Example 2: Shi Chuan Earthquake

The disaster of Wuncui earthquake in May 12, 2008

The district drug control labs were destroyed

Mobile labs were dispatched

Sampling the donated drugs in the tent

Testing in the mobile lab

Primer Mr. Wan Jiabao extended his regards to the scientists working in the mobile labs to ensure the quality and safety of the donated drugs for injured patients

IV. Recent progress of Mobile Labs

Authorities in both SFDA and Local FDA devoting much attention to the full use of mobile labs.

Director of SFDA inspecting

Local FDA meeting

Recent progress of Mobile Labs

Continuing training for technicians working in the mobile labs

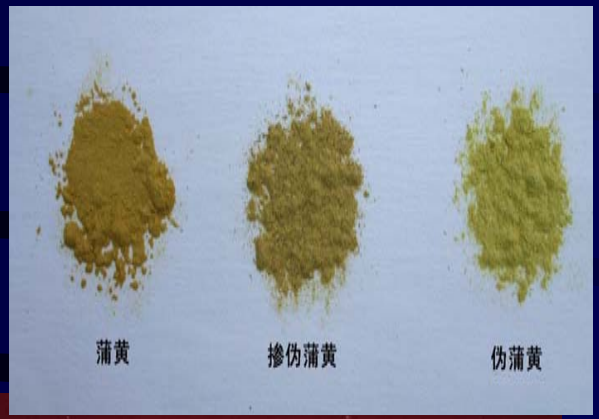
Training Course

Proficiency test using blinded samples

Recent progress of Mobile Labs

Initiatives of the local scientists

Building up the library for authentic and fake crude herb medicines and TCM by NIR technology



Recent progress of Mobile Labs

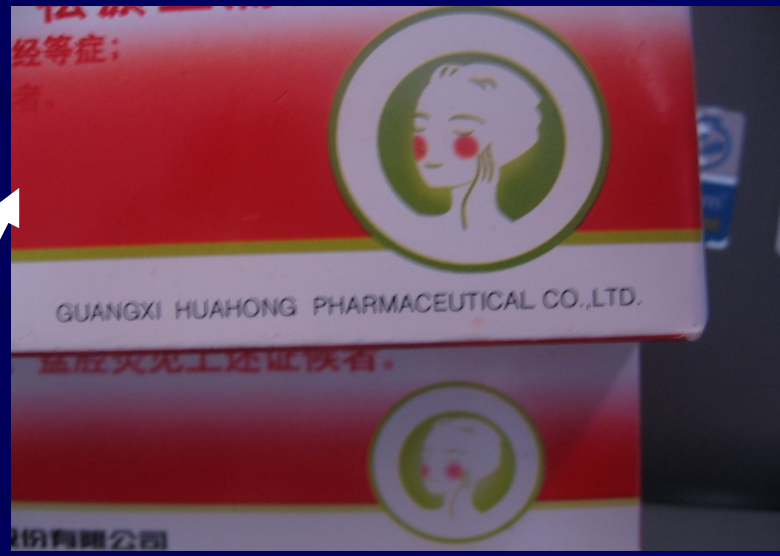
Building up the libraries of characteristic packeg label for authentic drugs

Compare the labeling characters and logo

Recent progress of Mobile Labs

Using the UV light (florescence)

fake



real

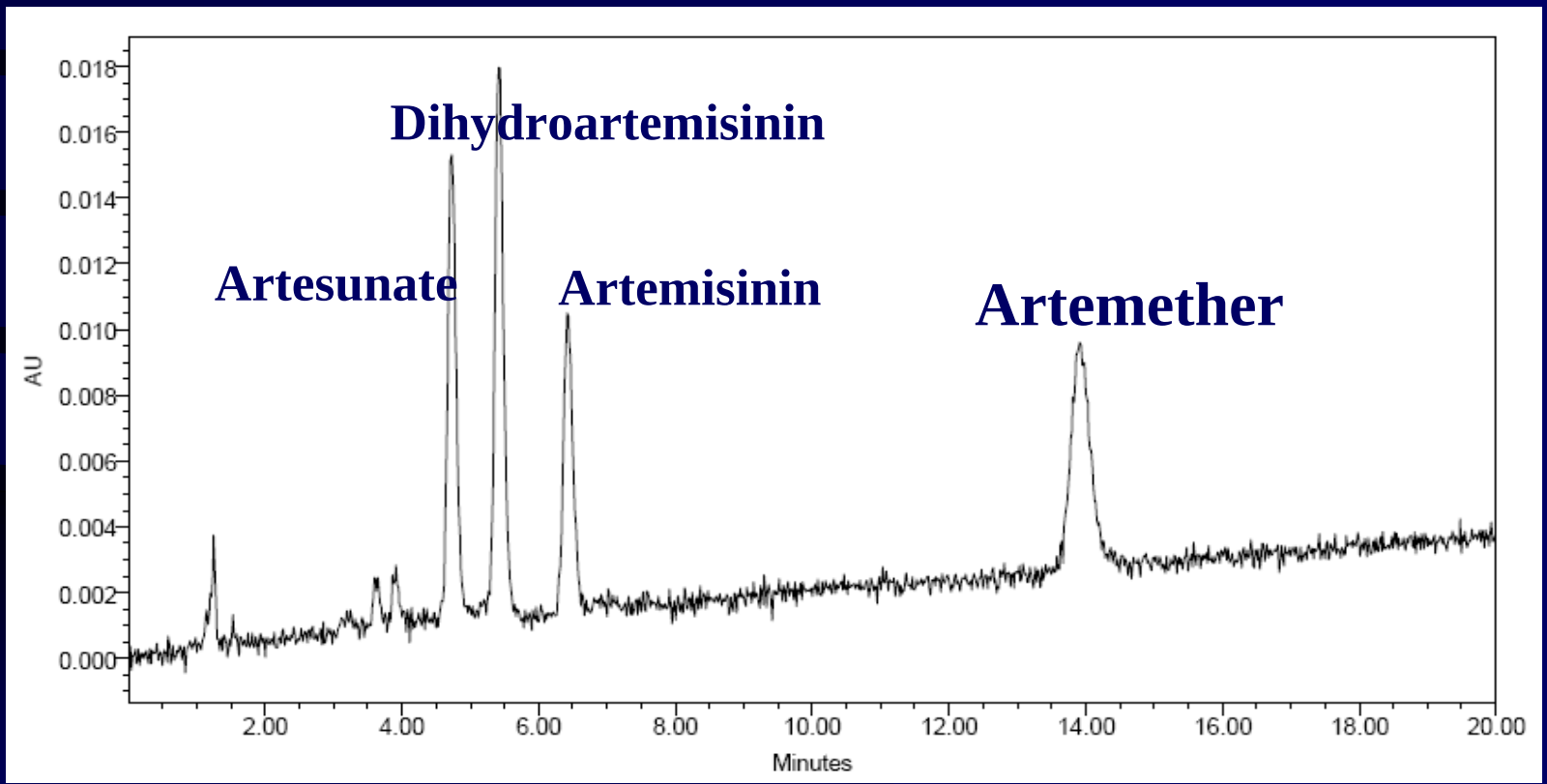
Recent progress of Mobile Labs

Second generation mobile lab has been developed----equipped with patented “Green HPLC system” (environment friendly)

The suspected fake drugs detected by NIR could be confirmed by HPLC in the mobile Lab

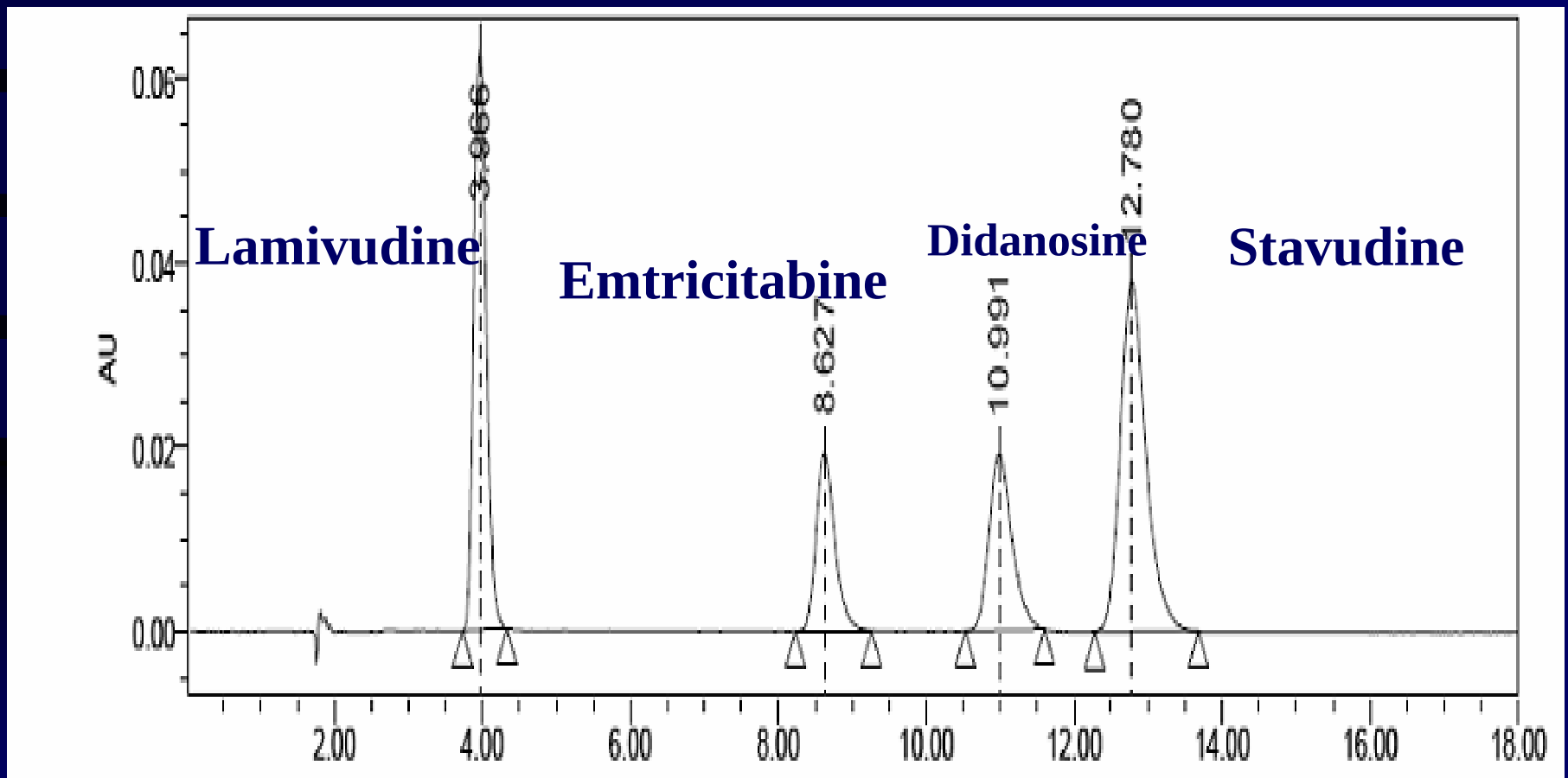
Pilot study of green HPLC

Anti-malaria Drugs



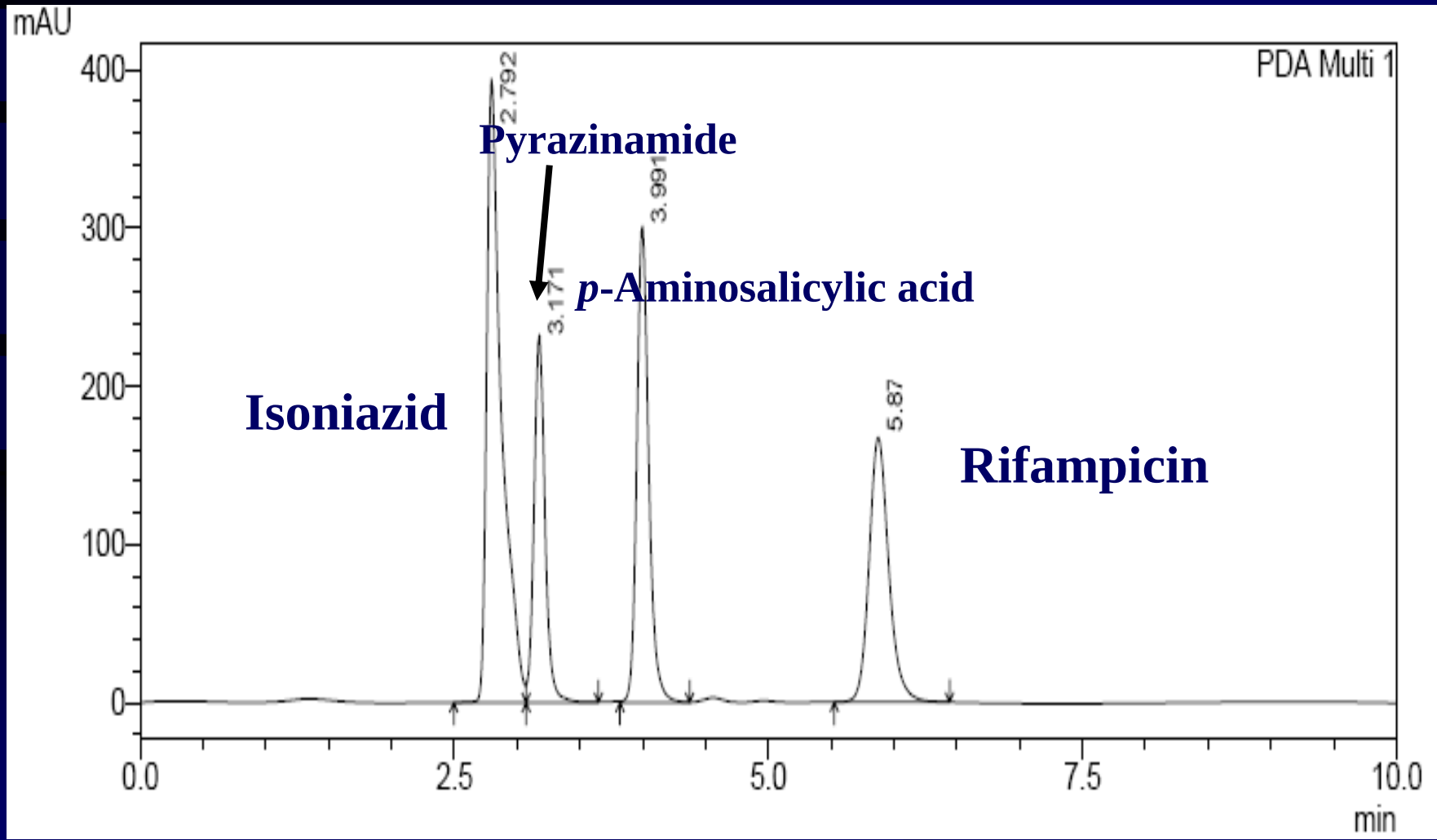
Pilot study of green HPLC

- Anti-AIDS Drugs



Pilot study of green HPLC

- Anti-TB



V. Future plan of mobile labs for combating counterfeits

1) Expanding NIR models to further increase the efficiency of the mobile labs

Supported by central government to build up one to one NIR models to increase the screening efficiency

Essential drugs
TCM
Crude herb medicines
Import drugs
Branded drugs
Adulterated TCM or dietary supplement
Library for ceased counterfeit drugs

2) Continuing to work in China

- Financial support from provincial governments to ensure the mobile labs working properly
- Establishing the "National Mobile Lab Web-Site" for Information sharing nationwide
- Building up the "National Counterfeit Drug Collection Center" and the data base
- Continuing training courses for different level technicians working in the mobile labs
- Setting up Mobile Lab Forum to exchange the experiences and achievements annually

3)Willing to cooperate with WHO IMPACT Program

4) Willing to cooperate with other APEC members for drug quality surveillance

Thailand FDA officers visiting the mobile lab twice in year of 2007

Cooperation programme in the area of anti-counterfeit is written in MOU between NICPBP China and USP

5) Willing to serve for international drug procurements


Thanks all

ANMAT
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Ministerio de Salud
Presidencia de la Nación

APEC – LSIF Anti-Counterfeiting Medical Products Seminar

"*Building International Cooperation to Protect Patients*"

February 17 to 19 – Mexico City

Quality of Medicines:
"Argentine National Program for Research of Illegal Medicines"

Farm. Maria Jose SANCHEZ

Coordinator - Nacional Program for Research of Illegal Medicines
NATIONAL INSTITUTE OF MEDICINES – A.N.M.A.T. – ARGENTINA

msanchez@anmat.gov.ar

Introduction

- ***Counterfeit drugs are a global public health problem causing death, disability and injury affecting adults and children. No country is free of this problem, which plagues developing and developed countries alike.***

- ***National Medicines Regulatory Agencies must devise pro – active strategies to prevent and fight it efficiently.***

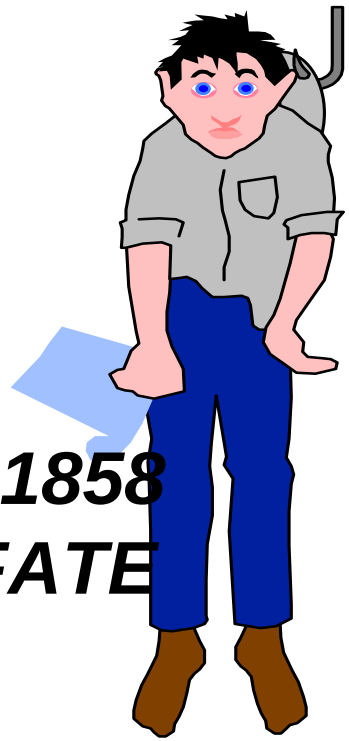
Counterfeit Medicine

WHO defines a counterfeit medicine as:

"a medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging"

COUNTERFEIT DRUGS BACKGROUND

IS NEW IN ARGENTINA ?



THE FIRST CASE REPORTED WAS IN 1858 AND THE FIRST PRODUCT WAS SULFATE THE QUININE.

Research Program

The primary aim of the Program is to counteract the commerce of counterfeit drugs in order to guarantee quality, effectiveness and security of the pharmaceutical products.-

The Program is based on a rigid control of the legal drugs distribution channels.-

The methodology is based on:

- *Visual and organoleptic inspection of pharmaceutical products*
- *Research of the documents that support the acquisition or holding of the products*
- *Drugs sampling along the national distribution chain*

Organization chart

COORDINATOR

↓

ALTERNATE COORDINATOR

- **INSPECTORS STAFF**
- **LEGAL ADVISOR**
- **TECHNICAL SUPPORT STAFF**
- **ADMINISTRATIVE STAFF**

Illegal Drugs

"Illegal Drug" is a broader concept than "Counterfeit Drug".
"Illegal Drug" includes the following products:

- *Counterfeit drugs*
- *Products without authorization from the health authority*
- *Adulterated pharmaceutical products*
- *Smuggled products*
- *Stolen drugs*
- *Trading of products after expiration dates*

Main elements to be considerated at seeing Pharmaceutical products' packaging

Aesthetic features:

- ***Differences in weight/grammage or quality of cardboard used***
- ***Differences in the folding of patient information leaflets***
- ***Differences in colour and size of tablets/pills***
- ***Differences in the text (missing letters, space between lines)***
- ***Changes in the definition or print details of the product as a whole***
- ***Use of a different kind of stamps, as to the shape or print***
- ***Different colour, brightness or print quality of aluminium foils***

COUNTERFEIT PRESUMPTION

Legitimacy test at original drug manufacturer

+

Analytical test at official labs

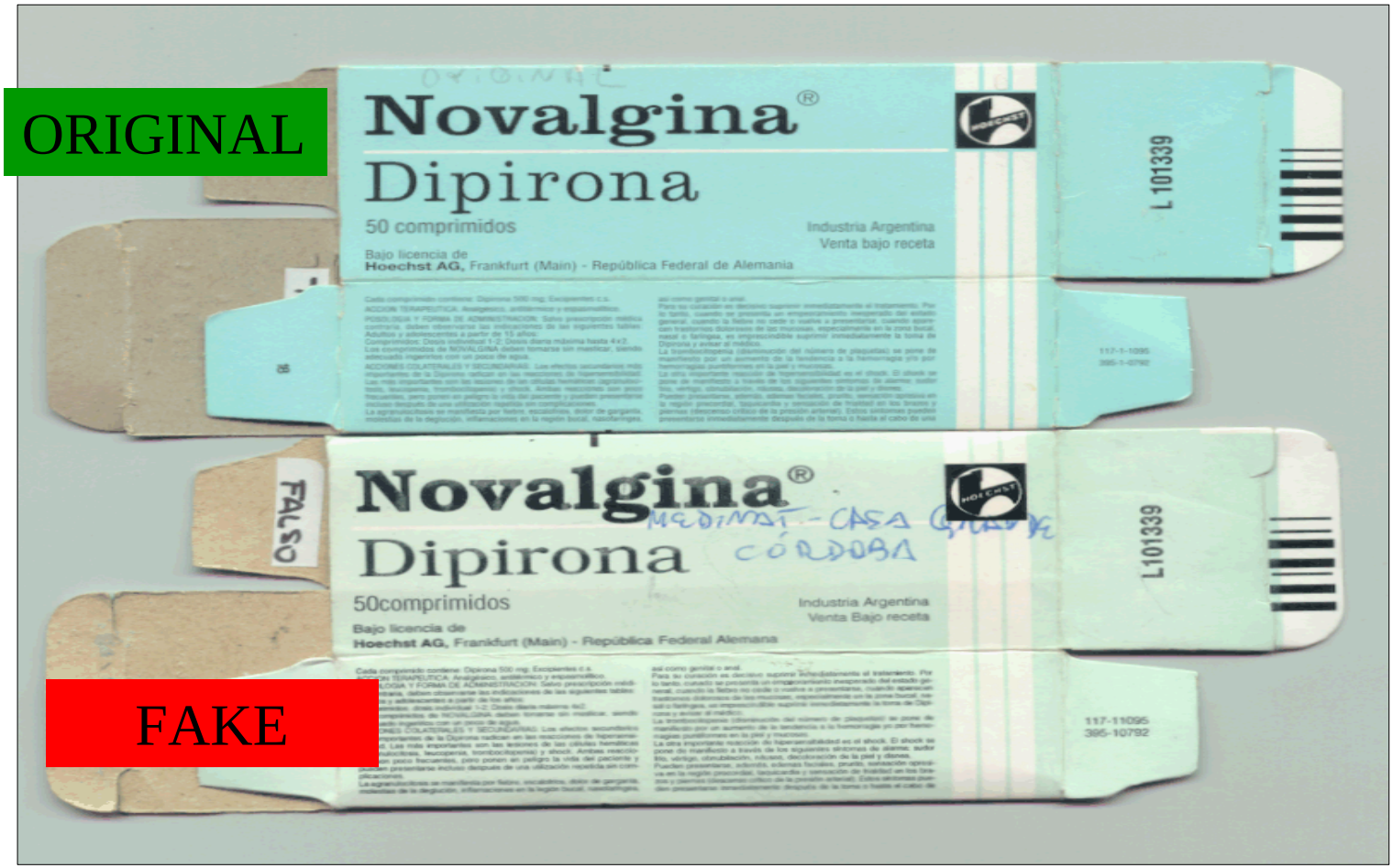
COUNTERFEIT

ORIGINAL

Measures

- Use and commerce prohibition at national level
- Report to Justice
- Product follow-up in the market
- Case diffusion

Examples of counterfeiting

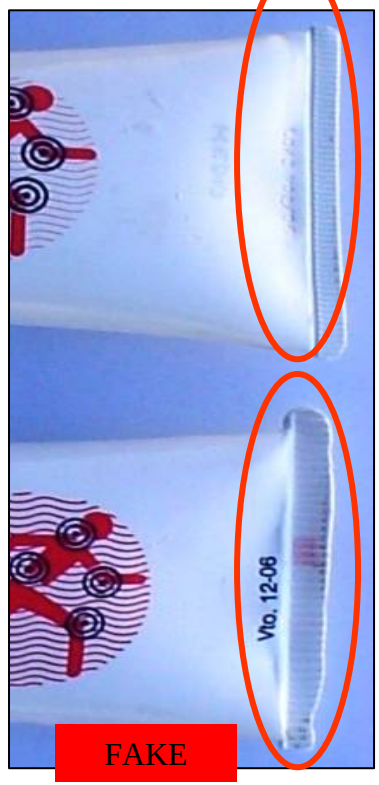


ORIGINAL

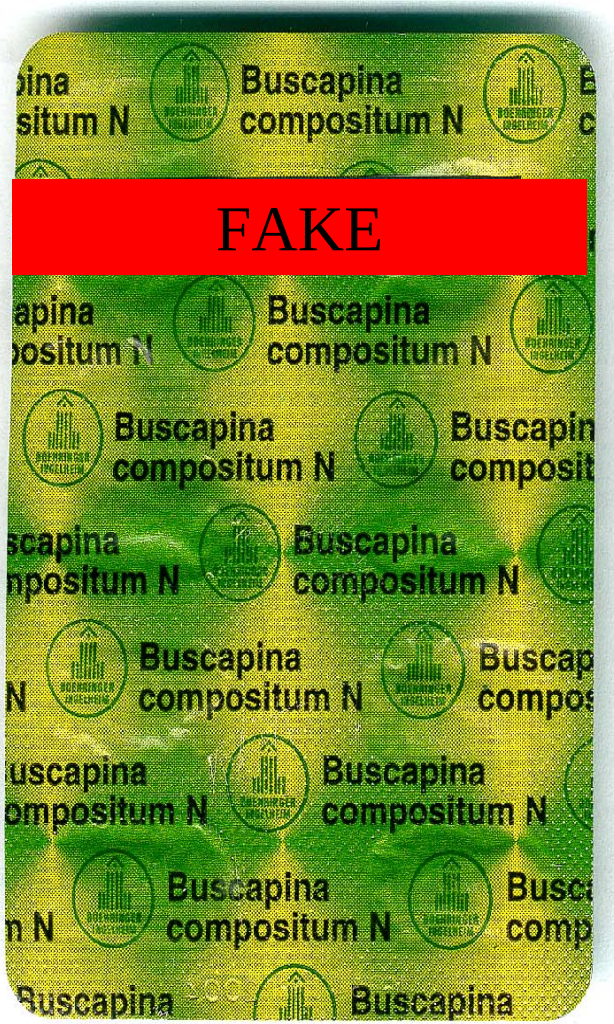
FAKE

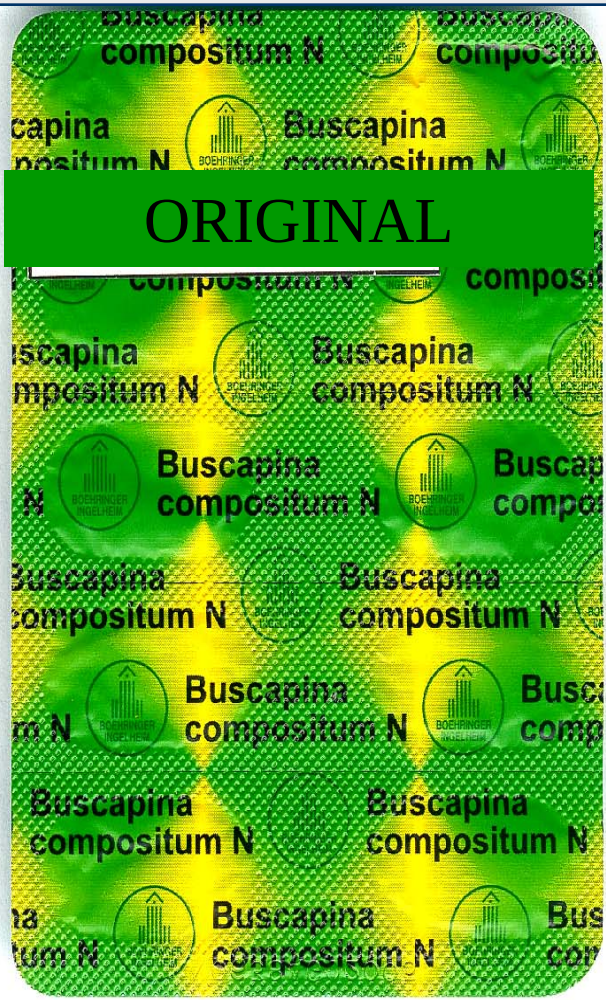
ORIGINAL

ORIGINAL



FAKE


FAKE
Buscapina compositum N


ORIGINAL
Buscapina compositum N

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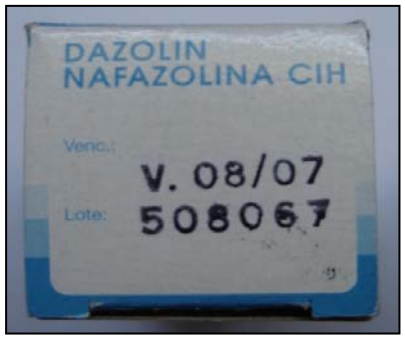

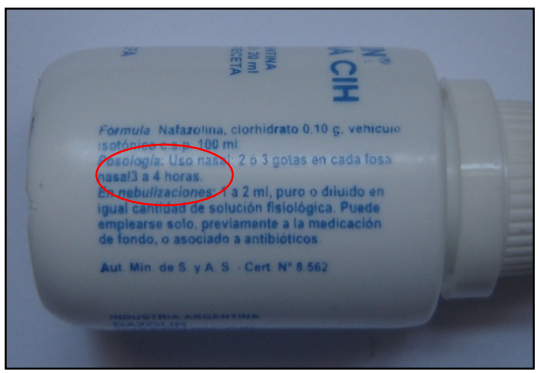

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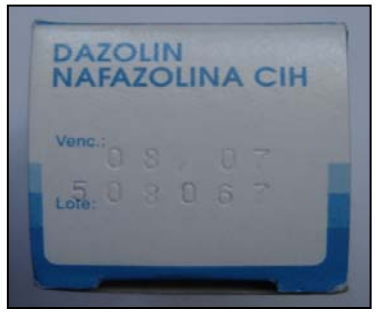
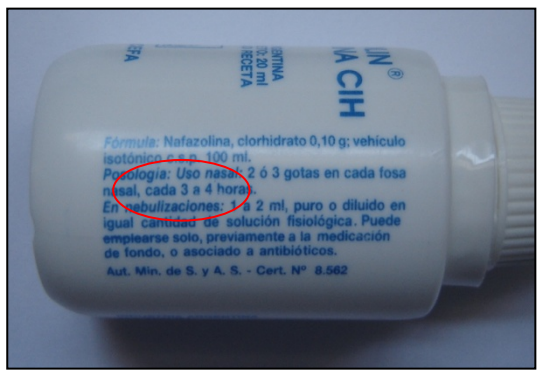
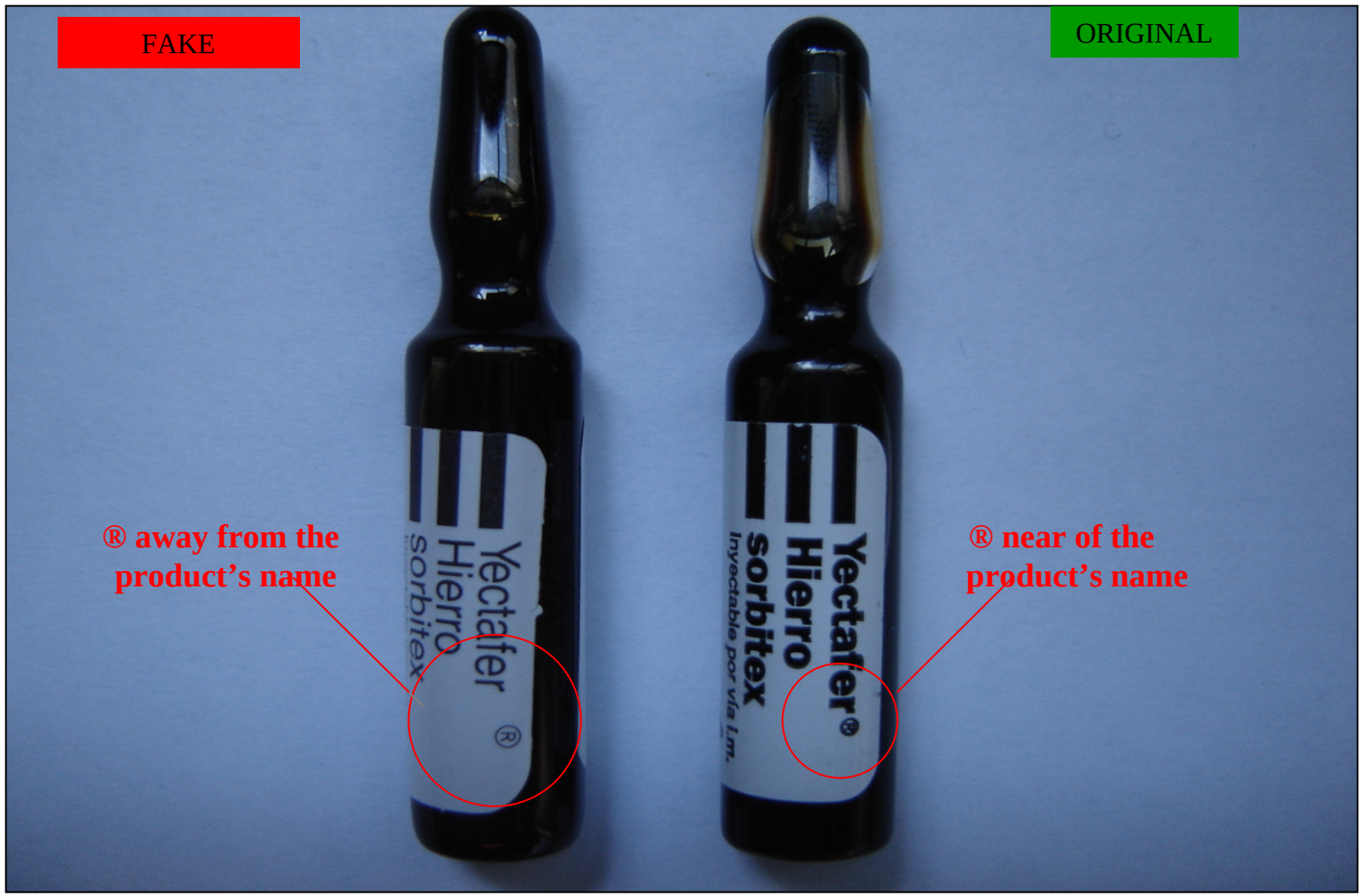
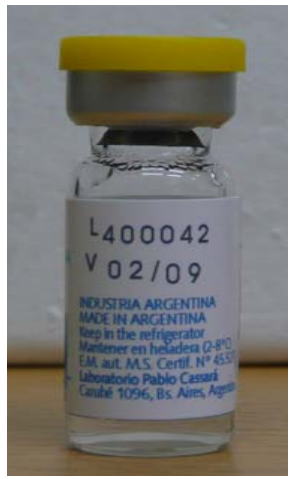





FAKE
ORIGINAL
® away from the product's name
® near of the product's name
Yectafer ®
Hierro
sorbitex
Yectafer®
Hierro
sorbitex
Inyectable por vía I.m.

FAKE



ORIGINAL

Resultados en cifras

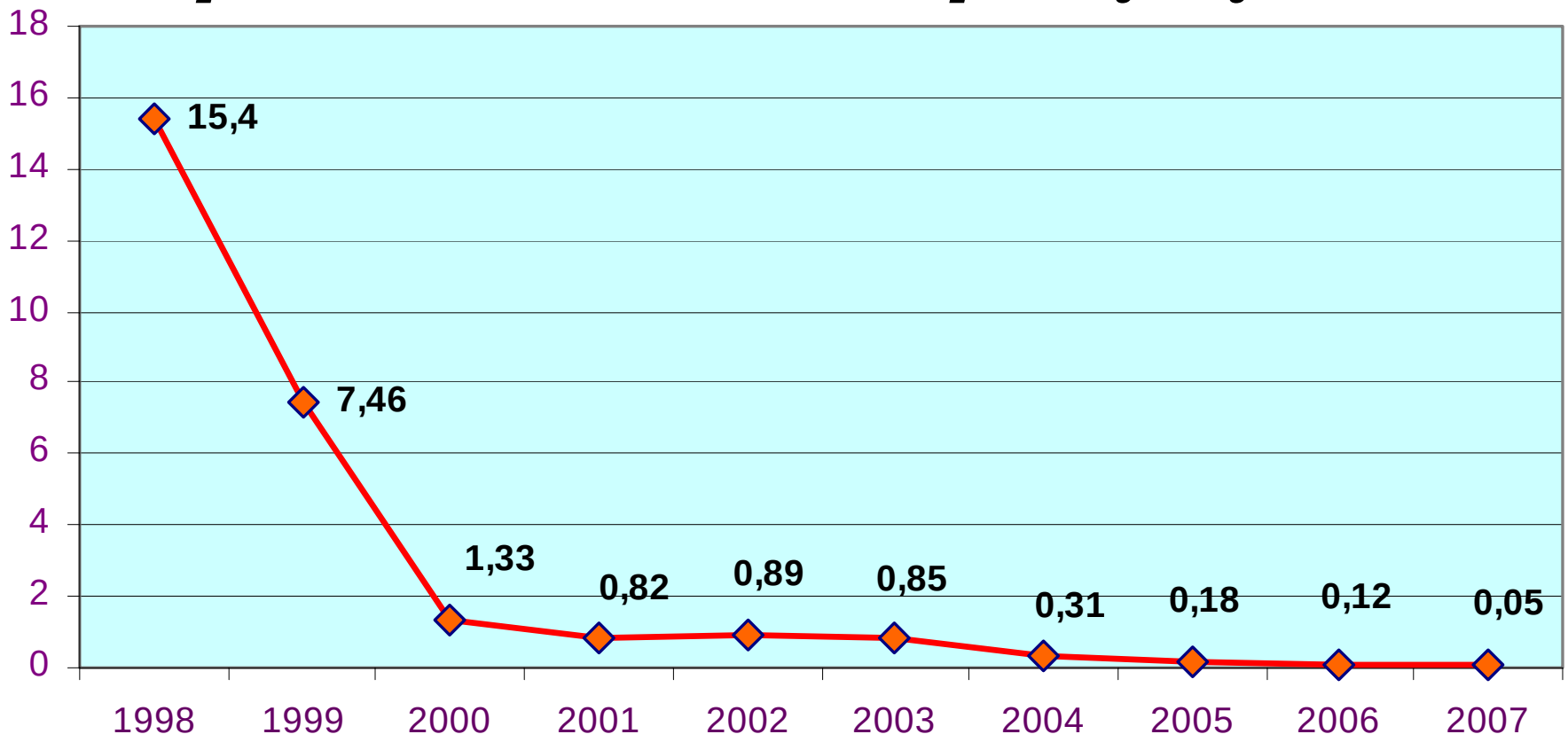
Período 1997-2008

- **Número total de inspecciones: 31.347**

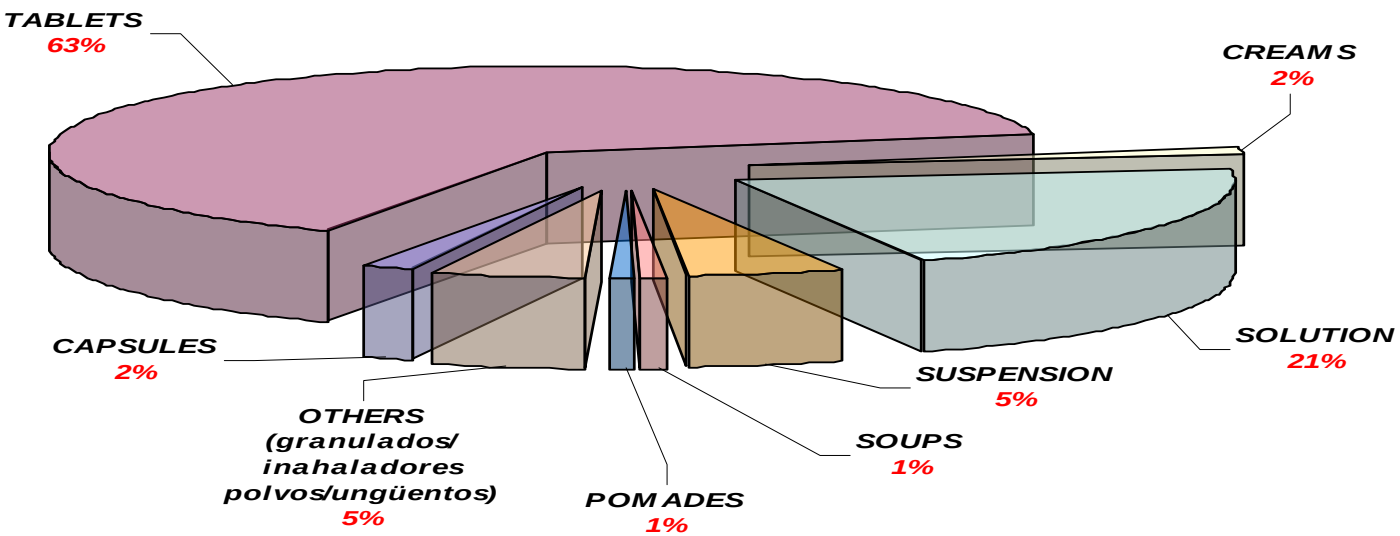
Año	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Nº insp.	736	2626	3781	3520	3249	2809	2936	2582	2178	2601	2280	2049

- **Actos dispositivos dictados por ANMAT a sugerencia del Programa: 544 prohibiciones**

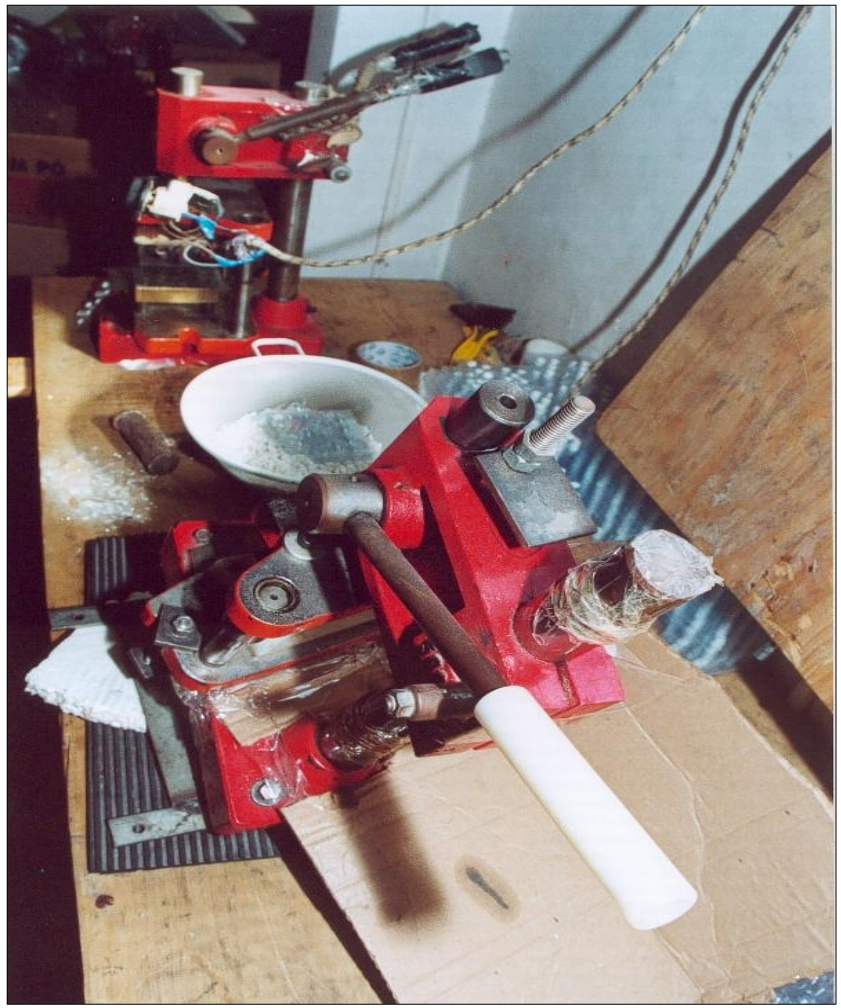
Porcentaje de inspecciones donde fueron detectadas especialidades medicinales completas falsificadas

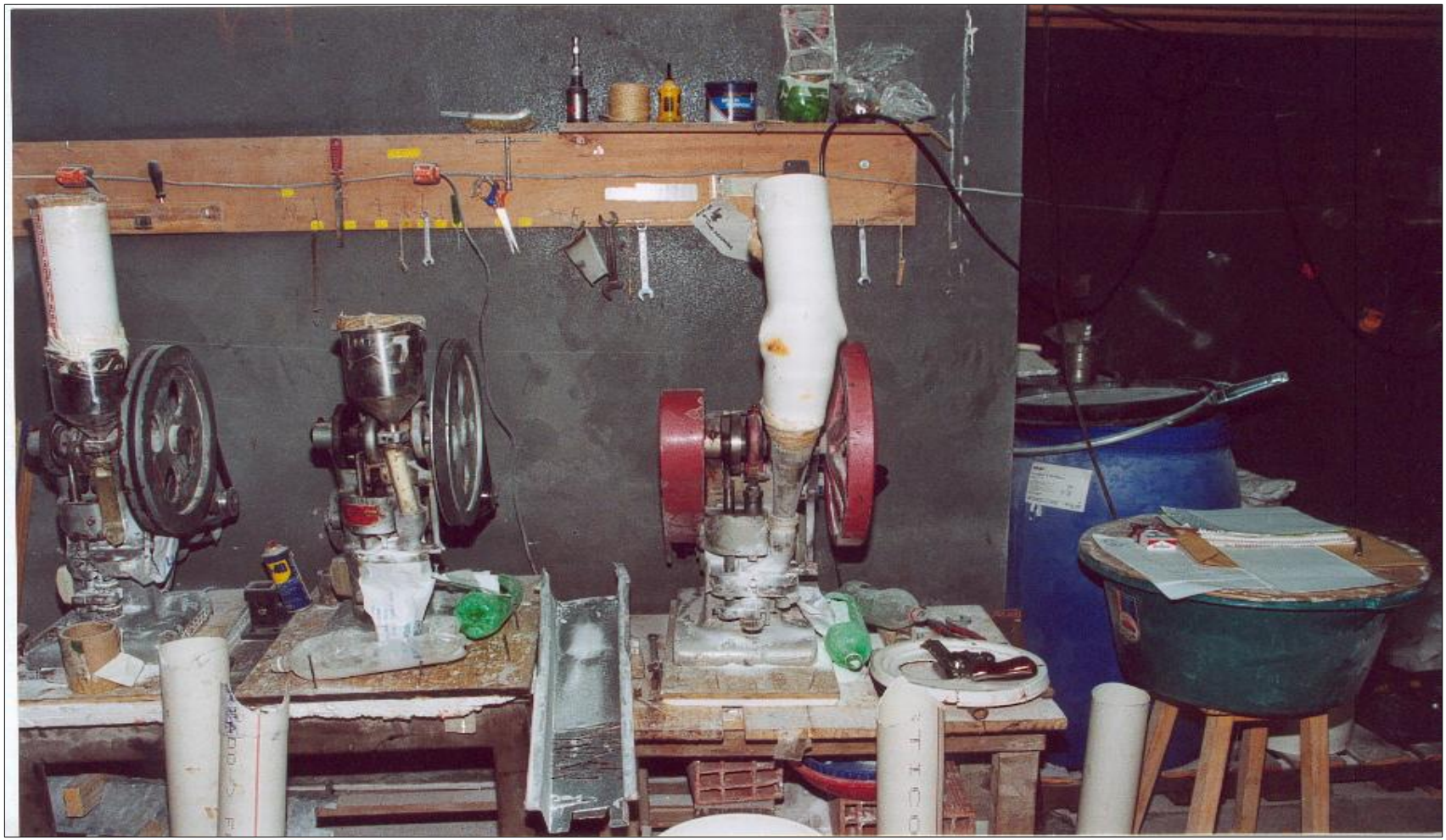


Counterfeit pharmaceutical forms



Proceedings at Illegal Labs






17 3'99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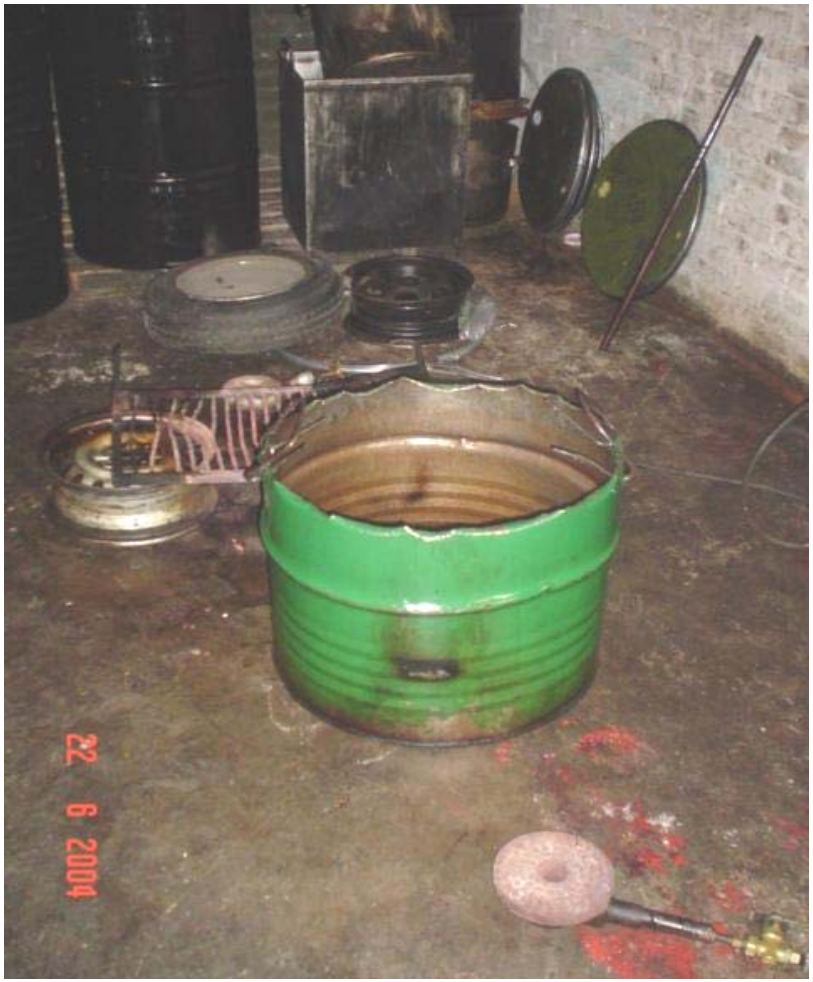
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CUSTOMS

EDUCATIONAL INSTITUTIONS

JUDICIARY

PHARMACEUTICAL INDUSTRY

HEALTH CARE CENTERS

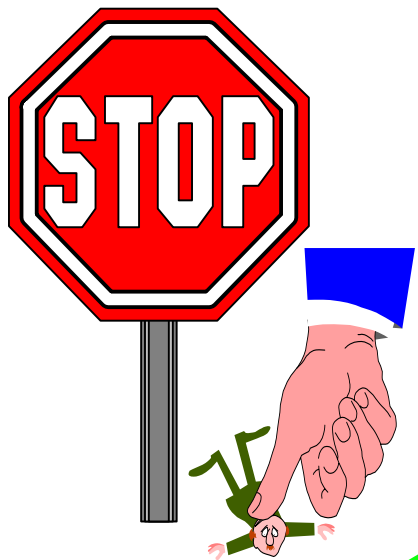
POLICE FORCES

WHOLESALERS

HEALTH CARE PROFFESIONALS

PATIENTS

HEALTH CARE AUTHORITIES



ANMAT
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Ministerio de Salud
Presidencia de la Nación

Farm. Maria Jose SANCHEZ

Coordinator - Nacional Program for Research of Illegal Medicines
NATIONAL INSTITUTE OF MEDICINES – A.N.M.A.T. – ARGENTINA

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Anti-counterfeiting health products Seminar. Building International Cooperation to Protect Patients

Mexico City

Feb 17 -19, 2009

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Anti-counterfeiting health products Combat
A perspective from a small Latin American developing country

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I - The counterfeit of health products in the framework of the national policies on innovation, industrial development and public health

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The counterfeit affects the pharmaceutical innovation proccesses and the access of population to medicines

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New medicines are focused
in general on diseases of great
incidence in human health
Their prices are generally high
because they refer to top technologies

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The counterfeit of new medicines not only damage public health, but the innovative enterprises and also the public policies oriented to science, technology and industrial development.

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The negative consecuences in the innovation proccesses are very important in the developing countries,that focus their growth strategies in technology development and invest strongly in R&D

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The transformation of pharmaceutical generic industries in innovation focused ones demand strong private and public funding specially in small developing countries

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The innovation in pharmaceutical sector needs great investment and comprises long and complex proccesses, from which only few of the tested options become successful products

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The big international pharmaceutical corporations lead an important part of the research oriented to generate new medical products

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From TRIPS agreement, is taking place a transformation of an important number of pharmaceutical industries from developing countries into innovative ones

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Generic local pharmaceutical industry has sometimes the technological background to make possible the transformation into an innovative one

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Such processes are usually part of the national policies designed in developing countries to promote innovation and industrial development

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In general, those policies involve an important transfer of public investment in terms of technical assistance, incentives and financing

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A long term development perspective, imply to pay attention to the industrial sectors considered the keys of those strategies

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Those policies are also oriented to attract private funding for the selected sectors by means of public incentives

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That is why the achievement of those projects and strategies, like the private and public investments
applied to them, become an important public interest matter to be protected

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That public priority include the protection of private investment applied to innovative or R&D projects in the, due the high risk they usually involve

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Once is defined that the development must be based on technological innovation, the protection of inventions became one of the tools to promote private investment, applied to the creation, use and dissemination of new technologies

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Public polices oriented to foster innovation in the pharmaceutical sector of the developing countries, help also to build capability to assure the internal supply of medicines, and furthermore that necessary for export

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In the field of local pharmaceutical innovation, there is an special interest in apply part of the R&D efforts on local diseases, on which international companies
do not pay enough attention

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The development of local pharmaceutical industries,innovative or generic ones,helps moreover to the supply of medicines at lower costs, and at the same time, is a way of maintaining the budget of the public health under control

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Then, it appears to be an important interelation (at least in the developing countries) among: innovation, technological development, the building of industrial capabilities, the access to medicines and their prices, and the Intellectual Property

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One proof of the importance of those matters and their interconexion, is that all of them have been considered in the TRIPS agreement, the negotiations to its conclusion, the results of the Doha round, the resolution of TRIPS Council issued on December 2007, and the discussions that are taking place nowadays in that Council.

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In terms of public health, the offer of generic medicines of quality would improve the competition, the supply and the lower prices of them, at the same time that favour, as said, the development of the industrial capabilities of those countries

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But that assertion does not contradict the other that consider the Intellectual Property Rights, and specially the patents, as an important tool to be used by the policies of innovation and industrial development

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To keep the balance, and looking not to affect the supply and prices of medicines, the free competition, the innovation process and the growth of the local pharmaceutical industry; the monopoly coming from the patents and other IP rights need to be limited to avoid some excesses

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The counterfeiting activities damage the policies for the supply of medicines, and at the same time the competition in the pharmaceutical market, likewise the innovative and the generic based companies

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In similar way, the counterfeit damage the IP rightholders specially those on trademarks and patents

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The counterfeit of medicines becomes in that sense a problem for the national strategies for industrial and technological development

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That negative phenomenon produce a negative effects on the balance among different players, harming their agreements and alliances

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II – The anti-counterfeiting Combat, Drafting an Strategy

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The axis of that possible anti-counterfeiting strategy would be focused more in the demand than in the supply

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The best scenario would be that of a reduced market due to a minimal demand for the counterfeit products

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That hypothetical scenario would meet in special the following characteristics:

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A) One health system that would be able to cover the whole population, to assure the access to medicines of good quality, to take care of the most important diseases, and that gives priority to education and prevention

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B) A regulation and control system proper, efficient and respected, that covers the whole chain that goes from production to delivery and selling of medical products; assuring their security,effectiveness and quality

C) An information and alert system, which includes all the members of the pharmaceutical process, and coordinated with the health agencies of the other countries.

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D) A work of the justice and the police focused, efficient, and effective, with high capabilities, modern technical means, and a flexible and coordinated organization, strongly connected with the national and international agencies and organizations working in this matter.

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The proliferation of operations and convictions, could affect the disuasive capability of police and justice, besides the huge amount of resources that they demand

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In short, a combination of incentives penalties and benefits that keeps the balance among stimulus, dissuasion and repression

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The keys of the anti-counterfeit system are:

Education
Prevention
Coordination
Cooperation
Dissuasion

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III – The counterfeit of medicines and the organized crime

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The counterfeiting of medicines is a form, in most of the cases,of the organized crime

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The peculiar characteristics of such kind of criminal activities, makes necessary to relay on a legal, technical and operative means proper for an efficient response

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In the legal field comprises the need of a specific civil and criminal legislation and a specialized justice

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At the operative level, public health sections and police, need also to count with special task forces

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Considering the complexity of counterfeiting activities, the action of judges, prosecutors and police, would depend on the technical capabilities of health authorities

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Looking at the great differences of resources with the criminal organizations existing in the small developing countries, the cooperation and coordination among the different entities becomes a fundamental factor of success

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Independent and high qualified technical agencies, contribute to the respect to law, and provide guaranties to the different players of the system

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Also, those type of technical services contribute to maintain the fair competition among private players in the strongly regulated market of medicines

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The counterfeit of medicines is an international problem, then the struggle is not a task of a sole country or organization, it needs the coordination and cooperation among countries and international organizations

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IV – URUGUAY: Recent initiatives in the anti-counterfeiting medicines combat

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Creation of two new criminal courts specialized in organized crime with its adequate staff.
Two criminal prosecutors were assigned to this matter.

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An special team engaged in anti-counterfeiting on the Health Department is addressed to handle this matter at national, regional and international level

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Regulations about Manufacture and Commercialization of medical products have been updated, and the capabilities of Analysis and Control have been improved

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Participation in regional and multilateral fora about the matter , specially in the OMS, OPS and MERCOSUR

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Information an coordination meetings have been organized with the participation of all the involved parts, specially Police customs authorities and Justice

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V - MERCOSUR

The strong activity on harmonization in health matters includes a chapter on anti-counterfeiting of medicines

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Resolution 13/08 of the Common Market Group of June 20,2008 "Guidelines concerning the counterfeiting and fraud of medicines and medical products in the MERCOSUR"

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The health authorities of the parties must develop and improve their actions in the combat to counterfeit, based on the references and guidelines issued by the WHO and PAHO

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Health authorities must develop their activities in coordination with the other government agencies working in the topic, specially with police, judicial and custom authorities

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Health authorities must encourage the training of agents and the promotion of informative campaigns for the society, so as to restrain the circulation of medicines manufactured or marketed out of the legal framework

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Those authorities will look for defining strategies for the adoption of mechanisms of tracking and authenticity of medicines in the whole line of manufacturing and commercialization.

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V – Falsification of medicines and Intellectual Property

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Although falsification could occur in coincidence with infringements to IPRs, it is necessary to make a careful distinction between both in order to avoid distortions and counter–productive effects.

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The recent definitions of the concept of falsification at multilateral level, take care of its independence with regard the IPRs infringements

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Recommendations issued by the IMPACT Group of WHO at the meeting in Hammamet on December, 2008 (“Principles to be promoted by the stakeholders”)

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The primary focus of the combat to counterfeit medical products is the protection of public health, because the main victims of counterfeiters are patients

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Ensure that combating counterfeit medical products does not result in hinderig the availability of legitimate generic medicines

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Patent violations or disputes must no be confused with counterfeiting of medical products

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Medical products (both generic or branded) that are not authorized for to be marketed in a given country but authorized elsewhere are not considered counterfeit

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A definition of counterfeit medical product was agreed, which, in the line with recommendations, exclude in particularly the violations or disputes about patents

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The confusion of the concepts between counterfeit and infringement of IPRs, may lead to harm the essential activities guided to protect public health

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That could happen if the scarce available resources are misguided, the actions focused on counterfeiting are distorted, or the access to medicines for citizens from developing countries are in some way affected

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The interferences between activities directed to prevent the commerce of counterfeited medicines and the actions to defend the IPRs, may admit an approach focused in the cooperation among the different players

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That approach may be based in the recognition of the differences and peculiariities existing in each ground, the different hierarchy of the involved rights, and the search for common fields of action

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In the framework of a cooperation oriented vision, the coincidence of both types of infraction may result an opportunity to join different actors in a common strategy against the counterfeit of medicines

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As counterfeit affect many different interests, then the involved actors could cooperate to carry out a more effective fight against it

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Alliances among the representative organizations of the different sectors of the pharmaceutical industry, including both producers of generics and those of patented medicines, do have precedents in other matters.

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Presentation of
José Antonio Villamil,
Director of Patents Division
DNPI - URUGUAY
Montevideo, February 3, 2009

Combating the Counterfeiting of Prescription Drugs

Patrick Ford
Senior Director, Americas Region
February 18, 2009

Product Integrity Goal

It is the goal of Pfizer that
every patient who buys a Pfizer product
receives an authentic Pfizer product.

Pfizer Product Integrity Steering Committee

Partnering with Enforcement Authorities

- Training Enforcement Authorities
- Developing Anti-Counterfeiting Strategies
- Developing and Providing Leads
- Verifying Lot Numbers
- Testing Products for Authenticity

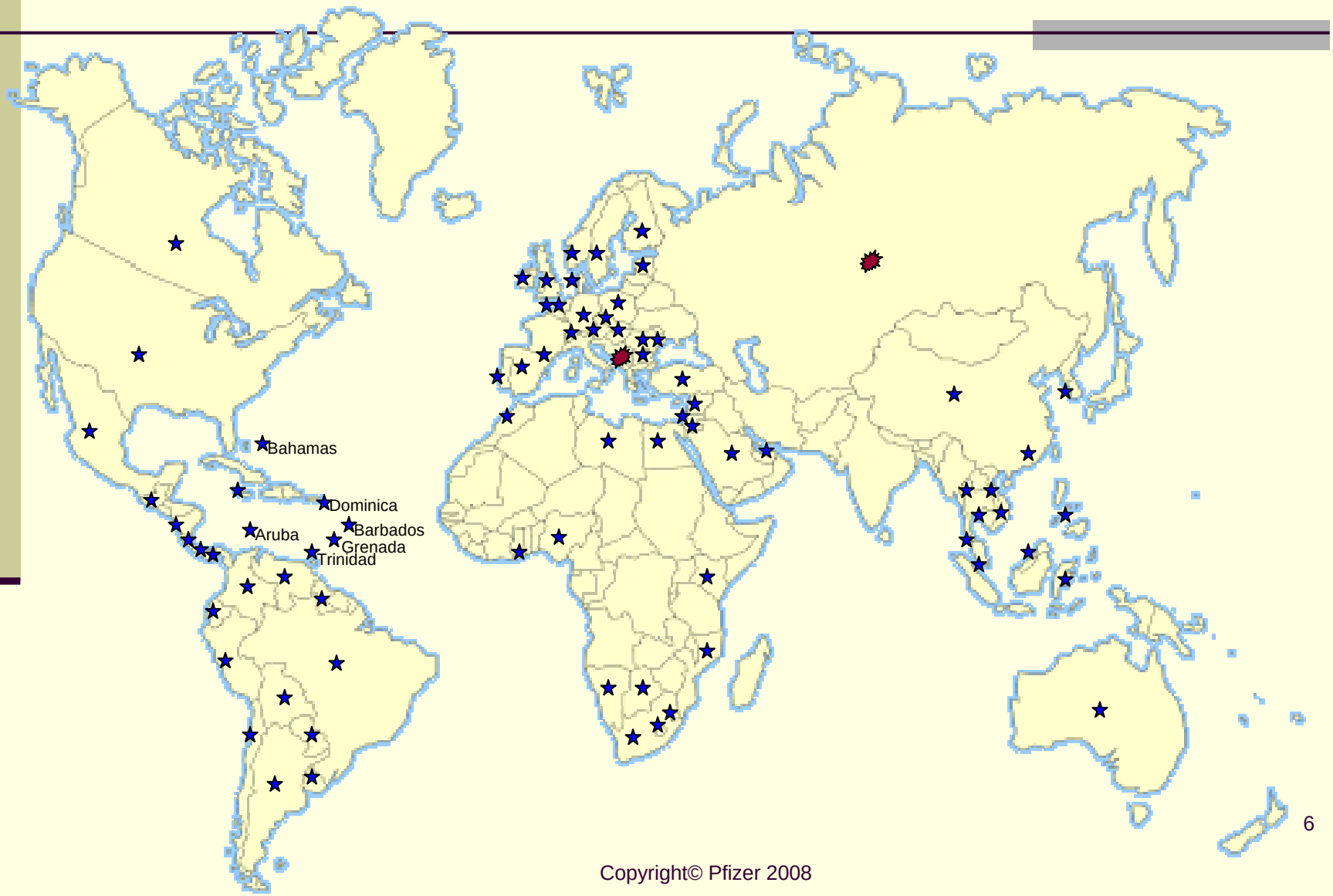
The Anti-Counterfeiting Environment

- Anti-Counterfeiting Laws
- Criminal Penalties
- Trademark and Patent Laws
- Customs (Importation) Laws
- Enforcement Capabilities, Priority
- Prosecution Capabilities, Priority
- Judicial Understanding
- Political Will

Commandments

- Good Cases Only
- Build your reputation
- Follow the law, FCPA
- Be available, responsive, accurate
- Follow through to the end
- Be an expert or find one
- One way street, FGJ
- Results driven, no excuses
- No hidden agenda, feedback
- Be Patient, but follow-up

Training Enforcement Authorities



What is a Counterfeit?

Any non-authentic Pfizer tablet, capsule or packaging that appears the same as the authentic Pfizer product. A counterfeit product may or may not contain the same active pharmaceutical ingredient (API) as the authentic product.

United States 2003

North Carolina 2004

Counterfeit Ponstan (Colombia)

Packaging

Raid at Papyrus S.A.
Ciudad Del Este – Paraguay
February 11, 2009

Raid at Papyrus S.A.

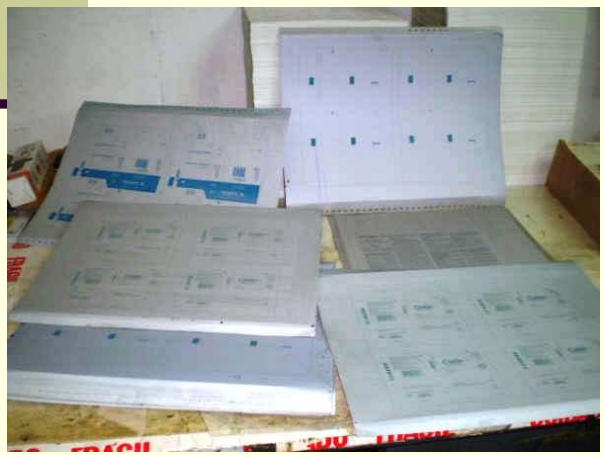
(a printing operation used to counterfeit labels, packaging, and boxes of counterfeit goods destined for the Brazilian market)

Ciudad Del Este – Paraguay

February 11, 2009

Papyrus S.A. is a major clandestine printing operation for counterfeit packaging of multiple brand name products to be smuggled into the Brazilian market.

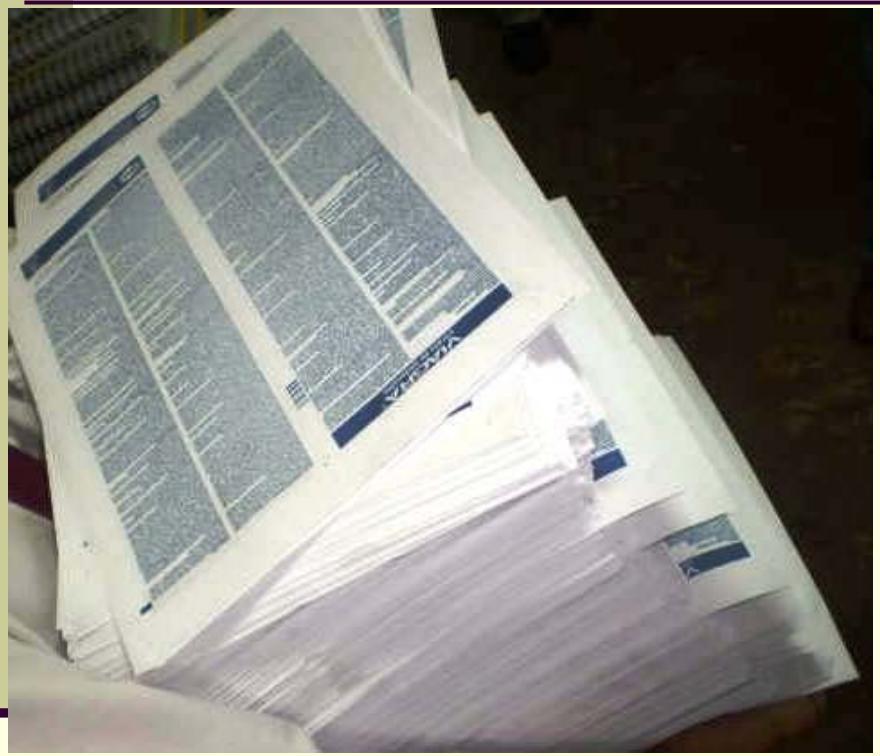
Printing machine & templates used to print counterfeit IFCs and PILs for Viagra in Portuguese

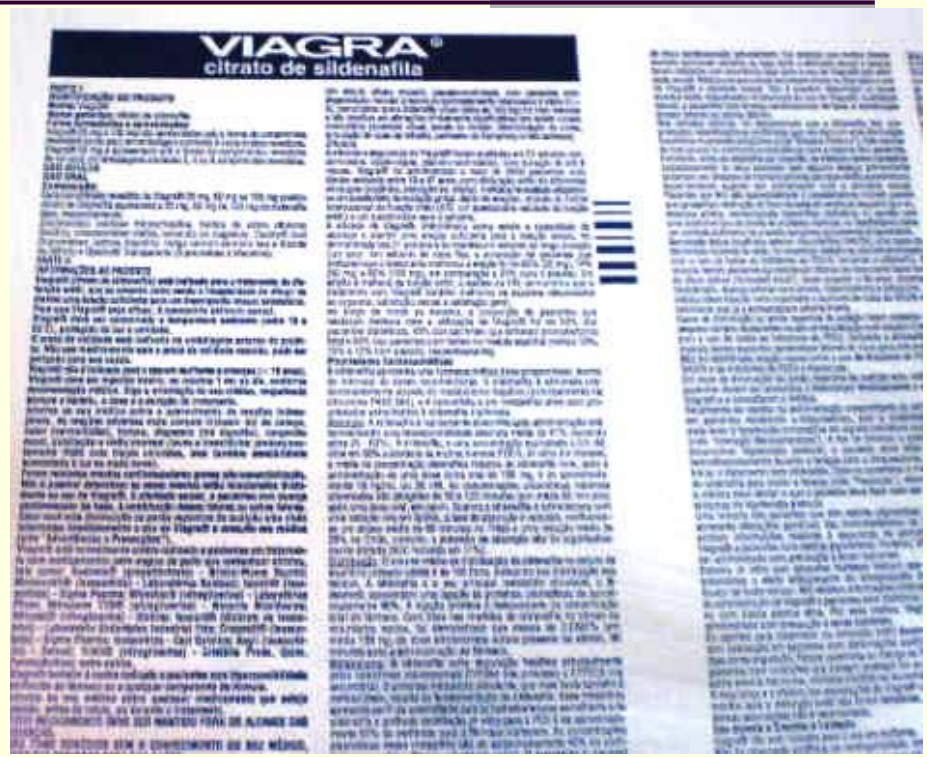


Counterfeit Individual Folding Cartons (IFCs) for Viagra 50mg

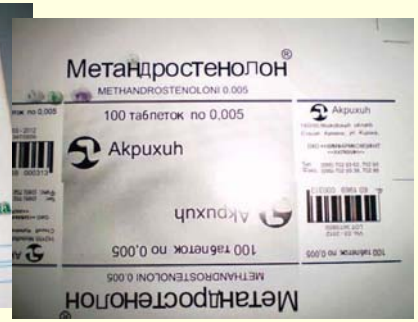
- Printed in Portuguese for Brazilian market
- Known counterfeit Lot number used on counterfeit IFCs

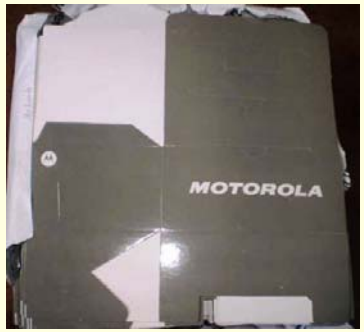
Counterfeit Patient Information Leaflets (PILs) for Viagra in Portuguese





Counterfeit IFCs & PILs, templates for other Branded Products of Lilly, Sanofi, Colgate, J&J, Russian product, Nokia, Motorola, Sony Ericson, DVDs and others.





Drug Products

FABRICA TERRAMICINA IPIALES-COLOMBIA

MAQUINARIA INCAUTADA

IMPRENTA PARA MARCACION DEL ALUMINIO

MAQUINA TABLEATADORA

MAQUINA MEZCLADORA MATERIA PRIMA

MAQUINA BLISTEADORA

MATERIALES UTILIZADOS

PAPEL ALUMINIO

PLASTICO TERMOFORMADO

Packaging

Raid in Ciudad Del Este-Paraguay

Raid on the house of Samir ESGAIB and false compartment used to store counterfeit packaging and branded products

Boxes found in hidden compartment contained counterfeit Patient Info Leaflets (PIL) in Portuguese language for packaging of counterfeit Viagra 50mg for Brazilian market (20,000 PILs seized)

Boxes containing counterfeit Individual Folding Cartons (IFC) in Portuguese for packaging counterfeit Viagra 50 mg for sale into the Brazilian market (2000 IFCs seized)

Evidence seized at the warehouse of Samir ESGAIB by Prosecutor

IPR Coordination Center

- Who:
  - Department of Justice
  - US Immigration and Customs Enforcement
  - Federal Bureau if Investigation
  - US Customs and Boarder Protection
  - US Department of Health & Human Services
  - Department of Commerce
  - US Postal Inspection Service
- Where: 2451 Crystal Drive, Suite 200, Arlington, VA 22202
- Contact:
  - IPRCenter@DHS.gov
  - (866) IPR-2060

THANK YOU

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Wayne Roberts
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(908)901-6496

THE ROLE OF THE JUDICIAL AUTHORITY IN ORDER TO STOP THE SPREAD OF COUNTERFEIT MEDICAL PRODUCTS AND THE JUDICIAL PROSECUTION AGAINST THE COUNTERFEITERS

ANA LUCY DELGADO CARBONERO

Criminal Lawyer

Februarv 2009

EL PERU AVANZA

INTRODUCTION

In 2006, it was realized the Diagnosis and Measurement of the Illegal Market of Medicines in Lima and Callao. We found that between 2002 and 2005 there were 3,123 effective action, including 123 control operations.

By these operations were interposed 1,476 establishments and seized 4'291,292 units of pharmaceutical and related products. The seizure included counterfeit medicaments, in a bad state of conservation, with the date expired and those stolen from public institutions.

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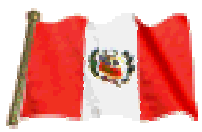

EL PERU AVANZA

INTRODUCTION

As for the **judiciary aspect**, we have until July 15, 2007, from 324 reports lodged to the Judiciary Power, 160 were resolved (49%), leaving 214 still to be resolved (35.5%) and 50 were closed (15.5%). Such a balance, with slight variations continues with similar percentages.

About the resolved causes, we understand that counterfeiters think, as they no purge jail or not to receive severe enough penalties, they would choose to continue their illegal activities

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EL PERU AVANZA

SANITARY OBSERVATIONS IN THE PERUVIAN LEGISLATION

It presents 6 observations:

1. COUNTERFEITS PRODUCTS
2. Products with the date “expired”.
3. Products which were stolen from the public institutions (MINSA, ESSALUD FOSPOLI, FOSPEME).
4. Products with the label adulterated or erased.
5. Products without the sanitary record.
6. Products with unknown origin.

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THE ILLEGAL TRADE OF THE COUNTERFEIT MEDICINES

Counterfeit medicines and their effects in the pharmacies:

The illegal trade has gained space on the shelves of pharmacies.

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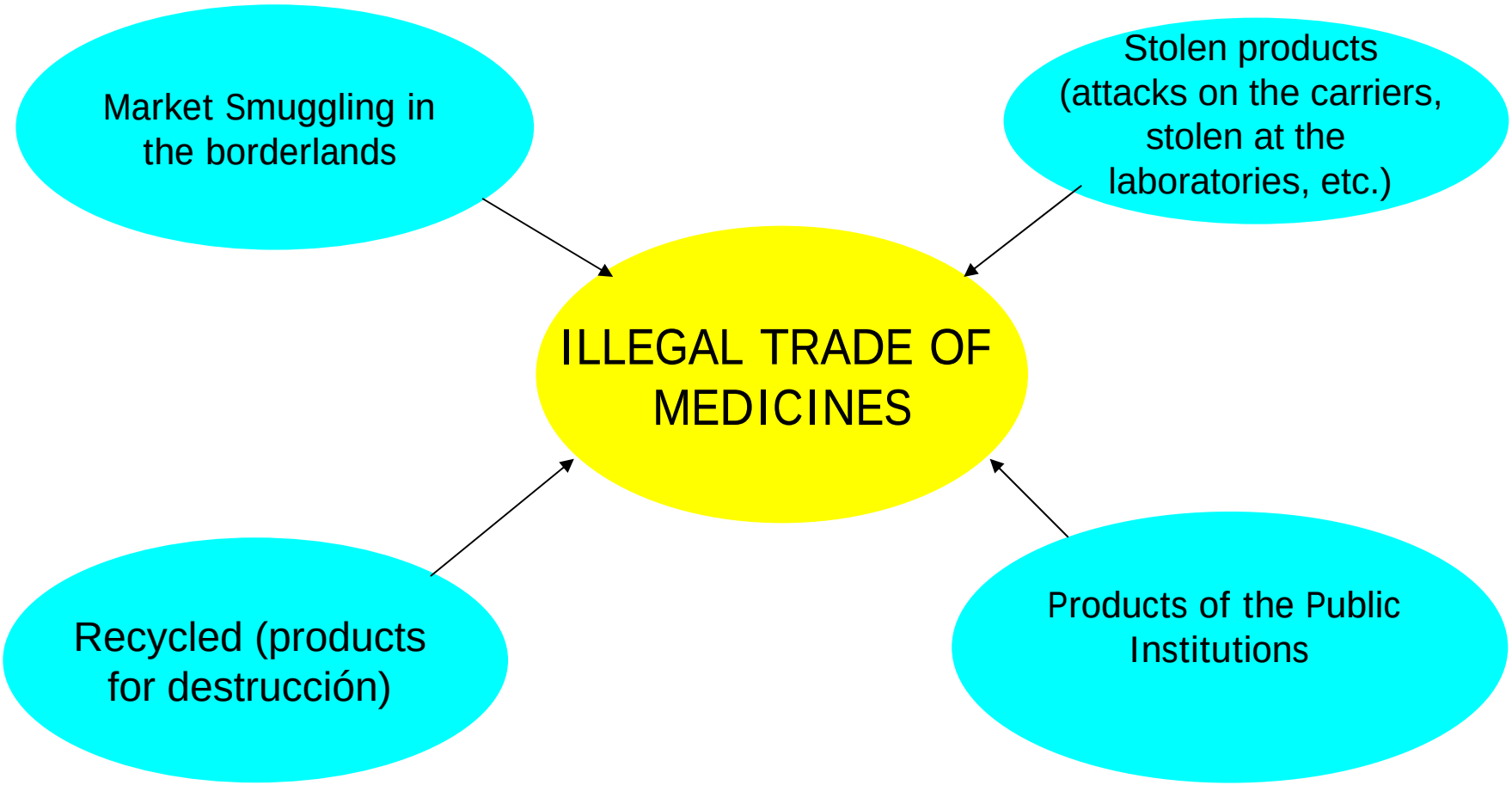
ORIGIN OF THE ILLEGAL TRADE OF MEDICAMENTS



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EL PERU AVANZA

LEGAL DISPOSITIONS

MAIN LAWS

The Political Constitution of Peru
The General Law of Health
The regulations of pharmaceutical products
The regulations of pharmaceutical establishments

- The last two regulations are in process of modification

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LEGAL DISPOSITIONS

R.M. Nº 1240-2004-MINSA – The National Policy of medicines.

R.M. Nº 047-2006-PCM – Technical Group – CONTRAFALME

This norm was proclaimed by the Ministers Council

Law Nº 29316 which modifies, incorporates and regulates diverse dispositions, including the General Law of Health in order to implement the agreement of free Trade signed between Peru and USA.

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THE GENERAL LAW OF HEALTH

The General Law of Health

The modification of the General Law of Health about the pharmaceutical establishments:

Since january 14, 2009 those have to get a previous sanitary authorization for working.

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THE GENERAL LAW OF HEALTH

The changes of the sanitary records of the pharmaceutical products with the new law.

Since the same modification, the medical products have a previous evaluation in order to get the sanitary record.

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ADMINISTRATIVE DISPOSITIONS

Administrative Rules: About products and establishments

Sanitary Measures: Immobilization, confiscation, temporary closing and definitive closing.

Sanctions: Fines.

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LEGAL FRAMEWORK OF PERU

The Criminal Code of Peru:

For these type of crimes it had to the collective health as juridical protected good and is an interest of the state to protect it from the danger that imports the utilization of harmful medicines.

Article 286º

Article 287º

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LEGAL FRAMEWORK ON WHICH DEVELOPS PERUVIAN JUDGES

The Criminal Code of Peru

Article 288º

Article 294º

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LEGAL FRAMEWORK ON WHICH DEVELOPS PERUVIAN JUDGES

It must be mentioned , that the article 288º was modified in 2005 by the Law Nº 28513.

Previously, it regulates only the trade or the trafic of harmful products.

It introduces, the medicinal substances with date “expired”.

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LEGAL FRAMEWORK ON WHICH IT DEVELOPS PERUVIAN JUDGES

The need to change these laws:

- They no mean an individual type of crime for the counterfeit medicines.
- The penalty should be higher.

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LEGAL FRAMEWORK ON WHICH IT DEVELOPS PERUVIAN JUDGES

- However, judges with those rules, dictate sentences, giving validity to the results of the raids which execute "DIGEMID" in coordination with the Public Ministry and the National Police of Peru - DIRINCRI-SIMFA.

- The desirable thing is that the judges have legal dispositions more drastics in order to send to jail to the counterfeiters.

PENALTIES AND LEGISLATION: DEVELOPMENT OF THE ACTIONS, PLANS, DISSUASIVE SANCTIONS, AND THE RULES ABOUT THE INSTRUMENTS FOR ACTION TO STOP THE COUNTERFEITERS

Replacing text of the articles 286º, 287º, 288º y 294º of the Criminal Code:

The changes are very important in order to dissuade those who wants to incurre on these criminal acts.

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The advantages of those modifications:

- The medical products will be separated of the harmful food and they will have their own address.
- The punishment will be aggravated for the health professional perpetrators

PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

The new text changes 3 articles:

The articles 286 º, 287 º and 288 º limit them to the sanction to punish the pollution and altering the food for human consume and substances or goods from public use, as well as the trade or illegal traffic of food for public use.

By the article 294 º, it changes the term of medical susbstances to the pharmaceutical and related products.

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

The new text incorpore 2 articles

Article 294-A: It punishes the pollution, counterfeit or alteration of expiration date of pharmaceutical or related products; or who imports, trades, stores, transports, or distributes in such conditions, as well as who imports or trades pharmaceutical or related products with due dates which guarantees their good condition. And it aggravates the penalty if the counterfeiter is owner, technical director or pharmaceutical regent.

Article 294-B: The penalties are stronger if the crime caused serious injuries or the death.

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

With an independented criminal type of medical products by the Article 294 º-A, the criminal penalty will be established in prison not less than 4 or not more than 8 years, an also it is increased the penalty until 10 years for the cases when the counterfeiter is the Owner, Technical Director or Regent.

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

And the modification will add the fine penalty which goes from 180 to 365 fine days; as well as the penalty of disqualification for:

(1) the practice a profession or commission done by the agent,

(2) inability to obtain a job or a public commission

(3) and inability to practice by their own or through other persons a profession, business or industry about medical products.

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

In 2008, these draft amendments, were approved by the Committees of Health and Justice of the Peruvian Congress; however, despite being placed on the agenda of the assembly it was not evaluated.

We hope that in this new legislature, we have a greater political commitment of the legislative and executive powers, for its approval.

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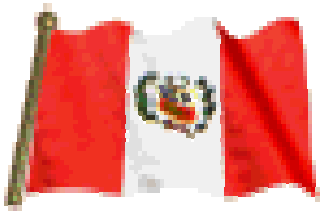


THANK YOU

SUNAT
SUPERINTENDENCIA NACIONAL DE ADMINISTRACION TRIBUTARIA

EXPERIENCE OF CUSTOMS IN PERU : MEDICCAL PRODUCTS

M. ANDRADE
Anti-smuggling Division - Customs PERU

MEXICO -2009

Potential “Revenue”

- ***100% profit on sale of kilogram of cocaine***
- ***420% profit on sale of heroin***
  - ***Global Illicit Drug Trends 2002, United Nations Office for Drug Control***
- ***800% profit on sale of Pirate DVDs in UK (distributed: Malaysia)- Internal MPA Research (2002)***
- ***900% profit on pharmaceuticals***

Who Cares?
Who Benefits?

- ***Smuggling Activities increasing on demand .***
- ***Only groups of organized crime have the infrastructure, expertise, financial backing, and capability to meet the demand for smuggling on a commercial scale.***

Why is Important to combat counterfeiting

- Effective Anti counterfeiting Enforcement:
  - Protects Public Health & Safety
  - Economically and Socially Beneficial
- Counterfeit products are dangerous
- To avoid IPR Violations
- To allow Creative development of Economies & Individuals

Some examples .....

CUSTOMS DELITS

1. Smuggling for all products
2. Smuggling plus restringed goods for pharmaceutical products and others derived (this includes counterfeit)
3. Counterfeit of products different than those in 2 → coordination through IPR rules

Borderlines measures

Current situation:

- Increase of the free world trade without precedents
- Latin America: trend to economic integration and free trade
- Increase in the commercialization of counterfeit pharmaceuticals
- Global increase of the violations to the rights of intellectual property

BORDERLINES MEASURES - PERU

- LEGISLATIVE DECREE 1092 Approves borderlines measures for the protection of copyright and related rights and the rights of brand 12 /01 /2009.
- Measure adopted in fulfillment of the agreements signed by the Peruvian State (World Trade Organization, CAN) and implementation of the Trade Promotion Agreement.

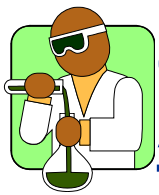
Borderlines measures

Objectives :

- To avoid the introduction of illegal goods to the commercial circuits, protecting the economy of the countrry
- To constitute a line of defense against the piracy and counterfeiting in: land, sea and air

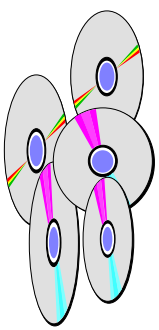
Agreement on the ADPIC Borderlines measures

Counterfeit Goods



GOODS IN WHICH THERE APPEARS WITHOUT AUTHORIZATION A BRAND OF FACTORY OR TRADE DUE REGISTERED OR WHICH DAMAGE THE RIGHTS OF THE HOLDER OF THE BRAND.

- **COPIES MADE WITHOUT THE CONSENT OF THE OWNER OF THE COPYRIGHT OR DULY AUTHORIZED PERSON**



Regarding pharmaceuticals

Bordelines measures plus existing Crime Customs Legislation allow criminal interpose because of the crime of traffic of restringed goods

What to do against the trade of counterfeit goods ?

Better coordinations between all involved: sensibilization and training

- Judges
- Public Ministry
- Legislators
- Customs officials
- State and municipal authorities
- IPR office

What to do against the trade of counterfeit goods ?

Work harder to improve legislation

THANK YOU

mandrader@sunat.gob.pe
marsea16@hotmail.com

IMPACT

International Medical Products
Anti-Counterfeiting Taskforce

An overview of the

IMPACT COMMUNICATIONS STRATEGY

A.J.M Hoek
Chair of IMPACT WG Communications
CEO and General Secretary FIP

The overall vision of IMPACT is to fight for eradication of all counterfeit medical products. The immediate goal is that all counterfeit medical products will be eradicated from supply chains of the developed world and be reduced by two thirds in the developing world by 2020

3 main approaches and objectives

Increase awareness

- Raise awareness of counterfeit medical products as a threat to public health worldwide in a safe and coordinated way that leads to action.

Promote IMPACT

- Provide a platform that reflects and communicates the objectives and actions of the IMPACT and all its working groups.

Influence change

- Support enforcement of pharmaceutical and penal legislation, efficient prosecution, application of GMP/GDP, increase national drug regulatory capacity and performance

Increase awareness

- Through media campaigns and news releases via a variety of communication channels in print, TV/radio, events and online information, IMPACT will reinforce the fact that all patients and the general public should only purchase their medicines from known and reliable sources.
- Raise awareness amongst national and regional authorities and decision-makers in order to advocate for effective legislative measures in order to combat counterfeit medical products

Promote IMPACT

- Improve collaboration amongst governments, organisations, institutions, agencies and associations engaged in combating counterfeit medical products at the national, regional and/or international levels
- Disseminate technical tools and guidelines developed by IMPACT to all relevant stakeholders
- Increase the vigilance of healthcare professions and all stakeholders in the legitimate pharmaceutical supply chain for counterfeit medicines

Influence change

- Obtain commitment from key stakeholders to prevent infiltration of the genuine medicines supply chain at global, national and regional levels.
- Promote behaviour change leading to the public and private procurement of medicines from known and reliable sources.
- Provoke actions leading to policy change, utilising key messages that promote appropriate measures to combat counterfeit, as recommended by IMPACT

IMPACT key messages

Patients and Public	• Only get your medicines from known and reliable sources
Health Professionals	• When treatment fails, consider counterfeits as possible suspects
Media	• Counterfeit medicines are a threat to personal and public health worldwide
Pharmaceutical Supply Chains	• The road to success – the joint combat against counterfeits of all stakeholders in the supply chain
Enforcement Officers	• When existing laws are not adequate and rigorously enforced, crimes such as counterfeiting tend to perpetrate
Governments	• Medicines should not be traded as a commodity

Current achievements (1/3)

Patients and Public

- WHPA "BE AWARE" brochure - Information for patients, sample reporting form, posters
- IAPO Patient Safety Toolkit - counterfeit medical products

Health Professionals

- WHPA "BE AWARE" toolkit – background, information for health professionals, poster, visual inspection form

Current achievements (2/3)

Media

- IMPACT FAQ sheet
- 5 IMPACT flyers developed in conjunction with IMPACT video
- Opportunities for a Public Service Announcement explored

Pharmaceutical Supply Chains

- An IMPACT global forum was organised in Singapore, bringing together technology developers of anti-counterfeiting technologies and key impact stakeholders (Feb 2008)
- IMPACT guidance on combating Internet trade of counterfeit medical products

Current achievements (3/3)

Enforcement Officers

- A short video footage illustrating the hidden dangers and rapid transnational operations of the illegitimate supply chain developed with Interpol

Governments

- FIP organised a briefing at the 61st WHA for IMPACT on the topic of the role of governments, NGOs and other international organizations in combating counterfeit medicines (May 2008)

1st IMPACT Global Report on the Counterfeit Medicines Epidemic

- An IMPACT 2009/2010 report that will present the first comprehensive worldwide analysis of counterfeit medical product prevalence and control efforts.
- This policy package report should provide Member States with all the necessary tools for strengthening legislation, regulation, enforcement, technology & communication.
- Extensive media coverage should be planned on its launch.

International Anti-Counterfeit Medicines Day

- There is a need to create a high profile event in countries around the world, serving as a focal point in the year for a vast number of anti-counterfeiting advocacy activities.
- Each year, WHO IMPACT will select a theme in advance of the day itself to ensure that a strong and unified message resonates around the globe.
- Unique campaign materials should be developed for each theme.

Internet based anti-counterfeiting campaign initiative

- In 2008, the European Alliance for Access to Safe Medicines report “The Counterfeiting Superhighway” revealed that a frightening 62% of medicines purchased online are counterfeit or substandard.
- IMPACT needs to launch a comprehensive Internet campaign to raise awareness of the dangers of buying medicines online.
- This should be done in at least 6 languages.

Patients directed social network on safe use of medical products

- With Web 2.0, social networking websites and online communities have been proven to a powerful driver as to how we live our lives and make decisions.
- IMPACT can consider developing a web presence within online patient communities and major social networking platforms.
- Working with “patient champions” reinforces key messages to fellow patients on safe use and buying of medical products from known sources.

TV broadcast documentary series on counterfeit medical products

- IMPACT should be supporting local, national and international media campaigns and workshops, as well as by using an increasing number of multimedia tools including video clips and animations.
- We need to work with major TV broadcast companies such as BBC/CNN on a documentary series on counterfeit medical products.
- We need to materialize the actual dangers of counterfeit medicines to patients.

IMPACT Communications Officer

- To work closely with the WHO IMPACT secretariat:
  - Develop the IMPACT communications strategy 2009-2013 and plan for the first International Anti-Counterfeit Medicines Day in 2009, including acting as focal point for the outsourcing of specific items of the strategy and managing contracts with external communications agencies to implement aspects of the strategy and the production of specific campaign materials.
  - Support and coordinate the development of a comprehensive stakeholder engagement plan for the first "IMPACT Global Report on the Counterfeit Medicines Epidemic 2009/2010" in collaboration with relevant internal and external stakeholders.
  - Support each Working Groups in developing project-specific communications and publications as required.

A MODEL FOR A NETWORK OF SINGLE POINTS OF CONTACT (SPOCs) TO COMBAT COUNTERFEIT MEDICAL PRODUCTS

REV (4) 13 DECEMBER 2007

INCLUDING COMMENTS RECEIVED FROM PFIPC MEMBERS, OTHER MEMBERS OF IMPACT'S ENFORCEMENT WORKING GROUP, AND ASEAN-CHINA CONFERENCE ON COMBATING COUNTERFEIT MEDICAL PRODUCTS

This version is based on a document developed by some members of PFIPC for the Council of Europe's Ad hoc Group on Counterfeit Medicines.

Background

Counterfeit medicines and pharmaceutical crime in general are fast upcoming phenomena which directly involve public health and do need a multidisciplinary, multisectorial and cross-border approach. The basic principles of an adequate approach are collaboration and responsibility among several concerned parties both at the national and international level.

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Collaboration can be set up *ad hoc* for isolated cases but in order to ensure effective and sustained action, collaboration should be structured within a network with defined roles and procedures. Within networks, single points of contact (SPOCs) should collaborate to meet the pre-set objectives.

In the conclusions of the Council of Europe 2005 and 2006 international conferences on counterfeit medicines the participants called for the establishment of a network of Single Points of Contact for speeding up effective co-operation and public health protection in the case of suspect/confirmed cases of counterfeit medicines.

The Council of Europe Ad hoc Group on Counterfeit Medicines developed a model for a network and SPOCs which has been the basis for this document.

The purpose of networks based on SPOCs is to streamline effective collaboration among concerned parties at the national and, where necessary, international level, in view of taking the necessary urgent action for protecting public health and disrupting supply of suspect/confirmed cases of counterfeit medical products.

A model for a network based on SPOCs is presented in this document. This model is the conceptual basis for establishing or strengthening national and regional collaboration systems based on SPOC networks.

Definitions

Central Reporting Point: located at the SPOC authority where all information on pharmaceutical crime is centralised and information is disseminated to network partners on a need to know basis. Information/signals from stakeholders (such as pharmacists, patients) should be channeled through appropriate fast and effective channels to the national SPOC

National SPOC: operates as contact point within the international network and, preferably, belongs to the DRA.

Network: formal or informal collaboration between SPOCs at national level.

Networking: activities between network members consisting of operational management and information exchange in relation to pharmaceutical crime

Official Medicines Control Laboratories: national medicines control laboratories. They may be organized in an international network[a], are important partners and should be involved on a regular or *ad hoc* basis.

Pharmaceutical crime: any crime with medicinal products or health products comprising counterfeiting, adulteration, tampering, manufacture/distribution and possession of unlicensed medicines, or otherwise unlawful medical products, diversion, trafficking, peddling and unlawful activities through the internet

[a] An example of a network of Official Medicines Control Laboratories (OMCL) is the OMCL Network co-oridnated by the European Directorate for the Quality of Medicines (EDQM) and Healthcare Link : News of the European Directorate for the Quality of Medicines - Pharmacopoeia on the WWW

Signal: any appearance of a problem with medicinal or health products which can be considered as pharmaceutical crime

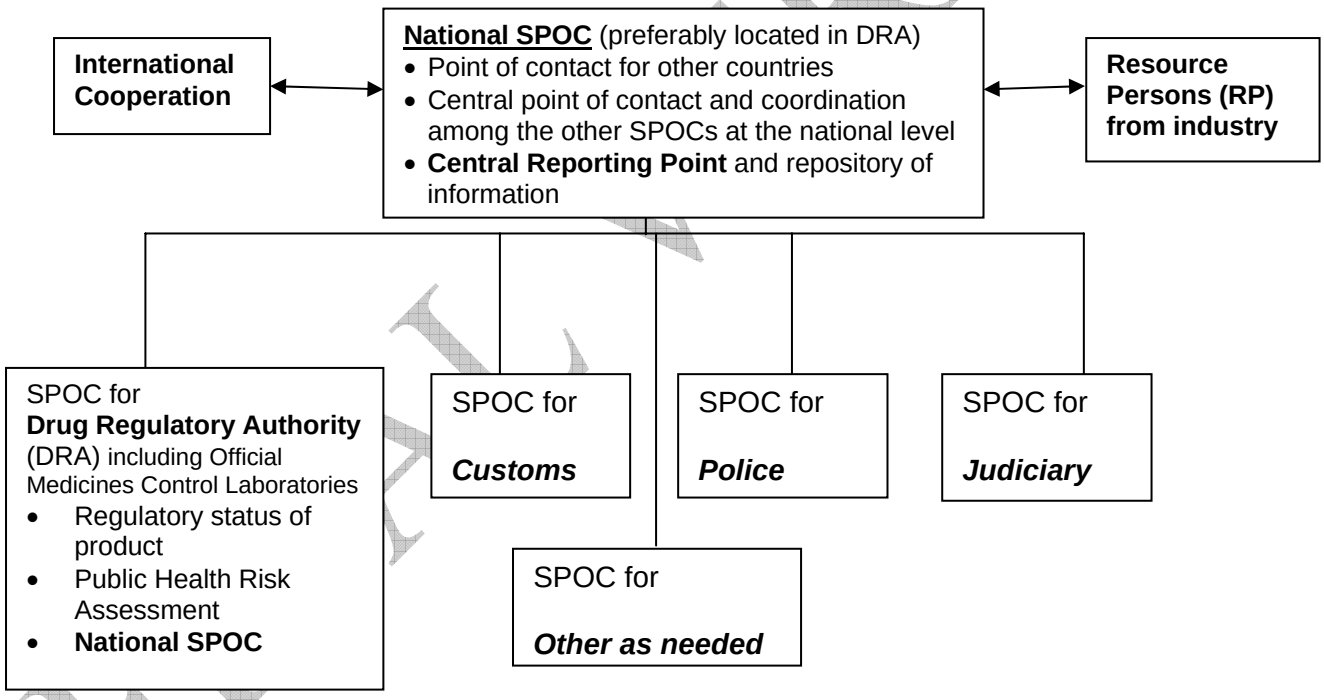
Single Point of Contact (SPOC): an entity responsible for the operational management of a signal in their own area of responsibility and the exchange of information

Responsible person or SPOC for industry (RP): the pharmaceutical industry is part of the network but has no enforcement authority. Pharmaceutical industry staff is often an important part to the case and are involved on an *ad hoc* basis. Each company should provide a RP or SPOC

Purpose

This model should be the basis for
- establishing the concept of a SPOC network at regional and global levels ;
- countries checking their existing networks or establishing new SPOC networks at regional and global levels.

Structure of the network - (Agree to prefer DRA as National SPOC; however some countries don't have strong DRA and may need choose another entity as a National SPOC)



SPOCs and a network are inseparably linked with each other. A national network should be set up by and between the main national authorities who are competent for handling pharmaceutical crime. For most countries the official authorities are DRA, Police, Customs and Justice. Depending on specific national situations, each one of these can correspond to different specific institutions and definitions..

It is proposed that the National SPOC is located within the DRA.

The DRA encompasses all technical and administrative functions related to drug regulation and control, which also includes quality control laboratories

Objectives of the national network

1. Regular and ad hoc meetings should be organised and a secretariat installed. All information should be collected and stored in a structured secure database at the level of the SPOC and the network. The network uses a Rapid Alert Form[b] if necessary. The network shall create national procedures for handling suspect cases of counterfeit medical products and other pharmaceutical crime signals (e.g. theft of medical products, internet post office parcels) and develop training opportunities.

2. The network will be based on appropriate informal or formal agreements between the participating institutions and with external concerned parties such as industry and health professionals.

3. The network is responsible for an annual report which reflects all data collected in relation with pharmaceutical crime, the recognition of new trends in pharmaceutical crime, initiatives taken for improving legislation, training programs set up for the different network partners and awareness programs at different audiences.

4. The network actively updates its references at international level and sets up procedures for co-operation, information exchange, data collection and management.

5. Stakeholders should notify any signal/ suspected case to the Central Reporting Point who informs the network if necessary.

Profile and function of a SPOC within a national network

It is desirable that the National SPOC should have or have access to the following knowledge:

1. The SPOC should have a broad knowledge on medicinal products.

2. The SPOC should be experienced in enforcement in the area of pharmaceutical crime (including field investigation in pharmaceutical crime).

3. The SPOC should have a good knowledge of medicines legislation and intellectual property rights.

4. The SPOC should have a basic knowledge in criminal law, investigation and procedure (e.g. handling of evidence).

All SPOCs should have the following competences and tasks:

1. The SPOC represents its institution as contact point within the network.

2. The SPOC manages incoming and outgoing information and - if required- reports a case to the other national SPOCs on a need to know basis.

3. The SPOC handles the information flow in accordance with the applicable legislation on data protection legislation. Confidential information such as patient names and/or names of notifiers etc should not be included in the information database but managed according to specific procedures.

4. The SPOC develops and applies a model procedure for managing counterfeit cases and pharmaceutical crime cases within his/her authority.

[b] Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

5. The DRA SPOC co-ordinates the risk assessment of pharmaceutical crime suspected cases. The suspected cases shall be identified, analysed, evaluated, and treated. The risk management procedure shall be continuously reviewed and improved. In any case, the protection of public health has priority.

6. The operational SPOC takes the lead in investigation when appropriate.

7. The SPOC may set up a Pharmaceutical Crime Unit consisting of an operational and an intelligence section.

8.The SPOC has the competence of giving detailed information to other SPOCs in the international and national network. Regarding information flow, it is important to differentiate between information (analysed and interpreted data) and evidence (information being relevant for proceedings and which may be used in court). Information should only be exchanged between SPOCs and between countries having regard to privacy laws and legal procedures. However, no legal procedure should prevent fast information exchange in life threatening situations.

9. When providing information to other SPOCs, each SPOC should ensure that it is adequate and can be effectively used to take appropriate action.

A SPOC needs not necessarily to be a single person, but also may be an entity such as a group or a department within an agency. If the SPOC consists of several persons, then only one e-mail address and one phone/fax number needs to be indicated in order to ensure precise contact and to avoid unclear responsibility.

Reporting procedure for SPOCs

The model procedure on how to manage counterfeit medicines on a national level has been described in the "Guidance of the management of counterfeit medicines – Co-operation structures and model procedure": diagram, see Attachment.

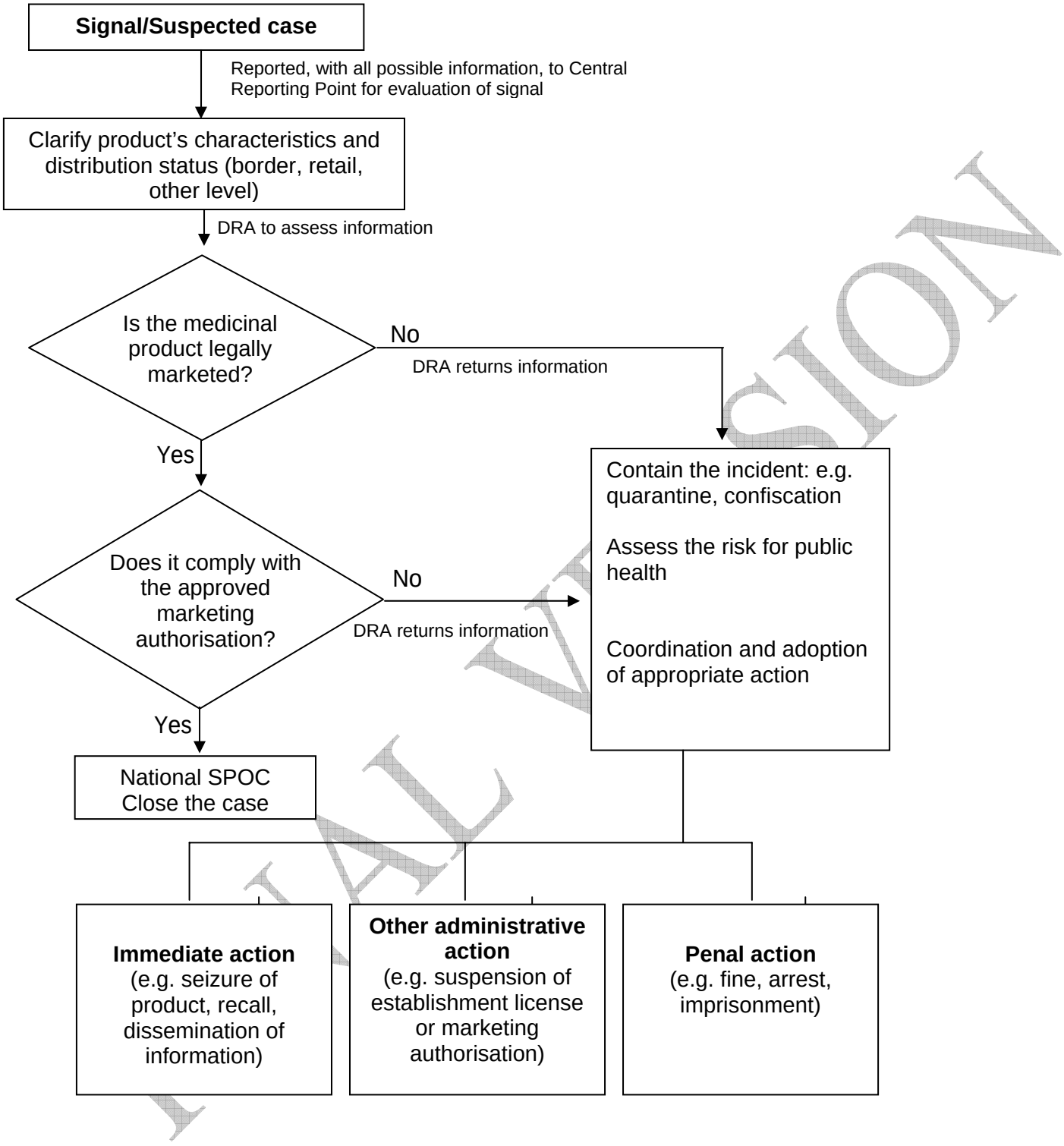
At international level, the national SPOC may use a Rapid Alert Form[c] for reporting pharmaceutical crime to other National SPOCs.

Network implementation

With a view to effective implementation of a network at regional and global levels it is recommended to
1. establish a list of National SPOC's
2. list of all SPOC's for each country
3. prepare a list of all SPOCs for each participating country

[c] Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

Model flow of information-for-action for a suspected case of counterfeit medical product



Asia-Pacific Economic Cooperation

Purpose:

To develop Action Plans on how Law Enforcement, Customs, and Regulators can cooperate (both within each APEC economy and among APEC economies) to prosecute and stop the production of counterfeit medical products

Asia-Pacific Economic Cooperation

Criminal Investigations

What is our current understanding of the problem?
What resources are currently dedicated to the problem?
What can the manufacturers do to assist?
Is international coordination effective?
Is there a single point of contact?
What do you see as a workable Action Plan ?

Asia-Pacific Economic Cooperation

Criminal Investigations First Session

Clearly, more communication is needed

- Regular
- Case related
- Public – Private combined effort

Improved communication will lead to better cooperation and coordination

Asia-Pacific Economic Cooperation

Criminal Investigations Second Session

SPOC are needed and a desirable mechanism

- Most have not seen the proposed SPOC
- Strong support for the concept
- Need more time to assess – review responsibilities

Development of action plans – multi-national need further consideration and work

Asia-Pacific Economic Cooperation

Criminal Investigations Findings:

Participants in this conference, generally, should serve as interim Points of Contact

Formal SPOC will require in-country consultations to ratify, modify or formally endorse

Asia-Pacific Economic Cooperation

Criminal Investigations Findings

Public education is essential – offer from Chile to have industry participate in novel programs in the schools.

Modification of laws not within our authority – but consideration should be given to harmonization of law and particularly, sanctions.

Asia-Pacific Economic Cooperation

Closing thoughts:

More work is needed to develop action plans and their implementation.

Who will assess our work and how will we know if we succeed?

Asia-Pacific Economic Cooperation

A) Conduct a pilot study assessment of counterfeit medical product activities in the region and/or individual economies. This study should be conducted by an independent facilitator.

Asia-Pacific Economic Cooperation

- Study on extent of counterfeit problem should engage involvement of as wide a range of stakeholders as possible
  - Academics/universities – to do actual study
  - WHO IMPACT – to support/facilitate
  - PAHO/regional organisations – to support/facilitate
  - Health authorities
  - Health professionals (e.g. doctors, pharmacists)
  - Pharmaceutical manufacturers / brand owners
  - Law enforcement
  - Consumers
  - NGOs (e.g. OXFAM)

Asia-Pacific Economic Cooperation

- Initial study should be predicated on the 1992 WHO definition of “counterfeit medicines”

- Draw on experience of those countries that have already started on this initiative

- Explore sources of financial support for such studies – particularly international bodies (e.g. World Bank, OECD, APEC)?

Asia-Pacific
Economic Cooperation

- Important for the results and findings of such studies to made known and shared, and acted upon by economies' authorities

Asia-Pacific Economic Cooperation

B) Coordinate with WHO IMPACT to develop strong legal frameworks within each APEC economy to combat counterfeit medical products leveraging recommendations contained in IMPACT´s “Principals and Elements for National Legislation Against Counterfeit Medical Products”. This legal framework should include a draft model Health Product Anti-Counterfeiting Act. The Act should include the establishment of a special investigator for counterfeit medical products.

Asia-Pacific Economic Cooperation

- Legislation on counterfeit medical products, whether in national/federal laws or in local laws, must be consistent and, andbetter coordination of action by local authorities

- Make clear in law that offences relating to counterfeit medical products are serious since they endanger human life and affect public health, and should not be considered the same as IPR violations relating to other counterfeit goods. Criminal penalties for offences relating to counterfeit medical products should be comparable to serious crimes (e.g. homicide, drug trafficking)

Asia-Pacific
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- The model legislation should serve as a benchmark/guidance, possibly to help achieve certain degree of international harmonisation/standardisation, but for the individual countries to implement according to their respective local situation

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- To have specialists or investigative units with emphasis/specialisation to support the authorities in enforcing laws on medical products (including counterfeit medical products as well as other illegal medical products)
  - Important to consider adequate training on health issues for law enforcers and investigators

C) Enhance judicial training programs sponsored by APEC, including increased education for judges on the extent of the counterfeit medical product problem, and increased foreign judges exchanges

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- Increase awareness of judges to understand the nature of counterfeit medical products, and how they are different from other forms of counterfeit infringements, so that they better understand and are able to exercise their judicial authority in sentencing more appropriately (IPR awareness?)
  - Draw on experience of those countries that have already started on this initiative
- Increase awareness of legislators to better appreciate the seriousness of the problem of counterfeit medical products – so that they can make more appropriate laws to address this problem

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- Training for enforcement officials to better understand the administrative process and implementation of the relevant laws
- Increase education and awareness of consumers about the dangers of using counterfeit medical products
  - Promote safe practices (e.g. buy only from reliable & trusted sources)
  - Maximise exposure of message through the mass media, educational institutions

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- Review and improve enforcement process – to make full use of all legislative tools available (whether in health laws or intellectual property laws) to improve effectiveness of border controls and enforcement

The Detection and Communication group:

a. endorsed the recommendations of the Singapore seminars;

b. recognized that the aim of a communication strategy is to secure social, political and economic support for anti-counterfeiting activity;

c. suggested that a number of specific initiatives be undertaken to collect the necessary information to trigger social, political and economic support.

A number of proposals were discussed and the following is suggested:

1. to conduct a survey of the situation in APEC economies concerning the prevalence of counterfeit medical products and the preparedness/vulnerabilities of the regulatory, enforcement, communication and supply systems. The survey should be conducted by adapting the existing IMPACT data collection tool.

2. to collect best practices, experiences, and other useful elements of information that will contribute to developing an APEC-wide repository of reference materials to be made available to all APEC members

3. to conduct studies on counterfeit medical products sold over the internet to answer questions such as ‘what proportion of internet sites selling prescription-only medicines is acting unlawfully?’, ‘of the medicines sold, what percentage is counterfeit or substandard?’.

The outcome of these initiatives will provide the raw material to build an appropriate communication strategy to support ongoing and future APEC members' anti-counterfeiting activities.

Some of the participants have volunteered to undertake the above work.