



Industry Views

Combating Counterfeiting Medicines





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*



PSI Mission and Services

Intelligence: to disrupt well established counterfeiting groups;

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





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 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

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.³

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 author-



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*



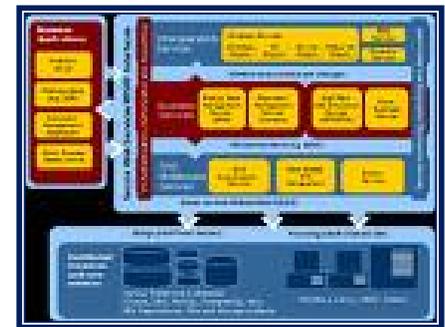
Counterfeit Incident System

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*



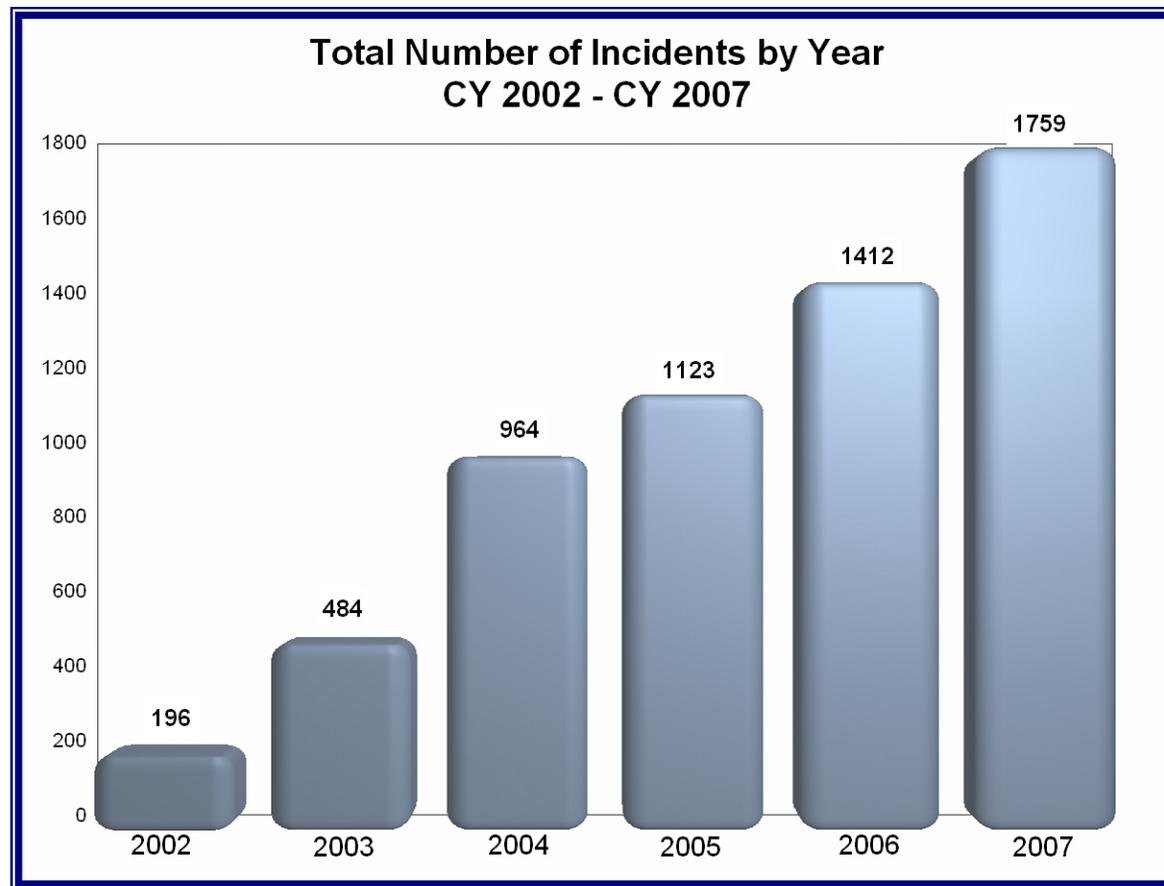


How often are medicines counterfeited?

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

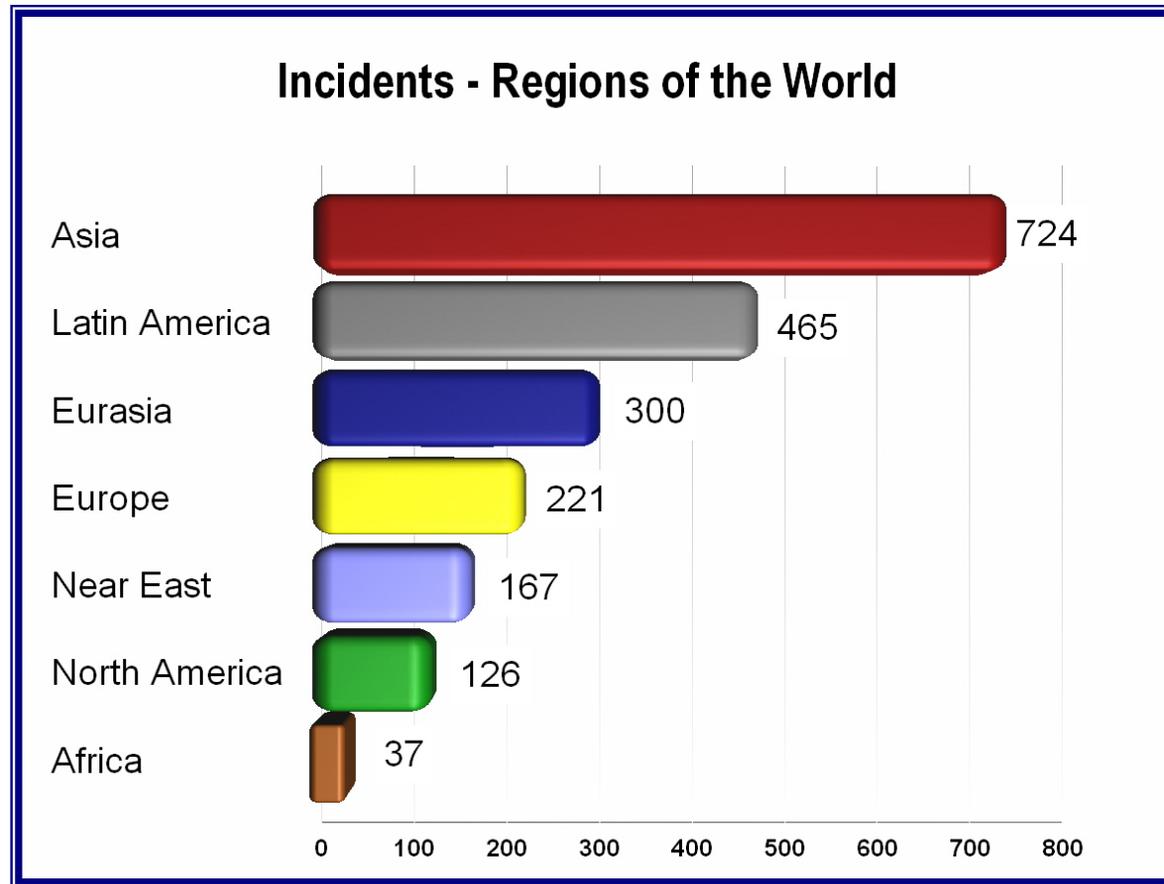


Six year upward trend





Incidents by Region





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



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



Manufacturing Sites

Top Five Ranked Counterfeit Manufacturers CY 2007

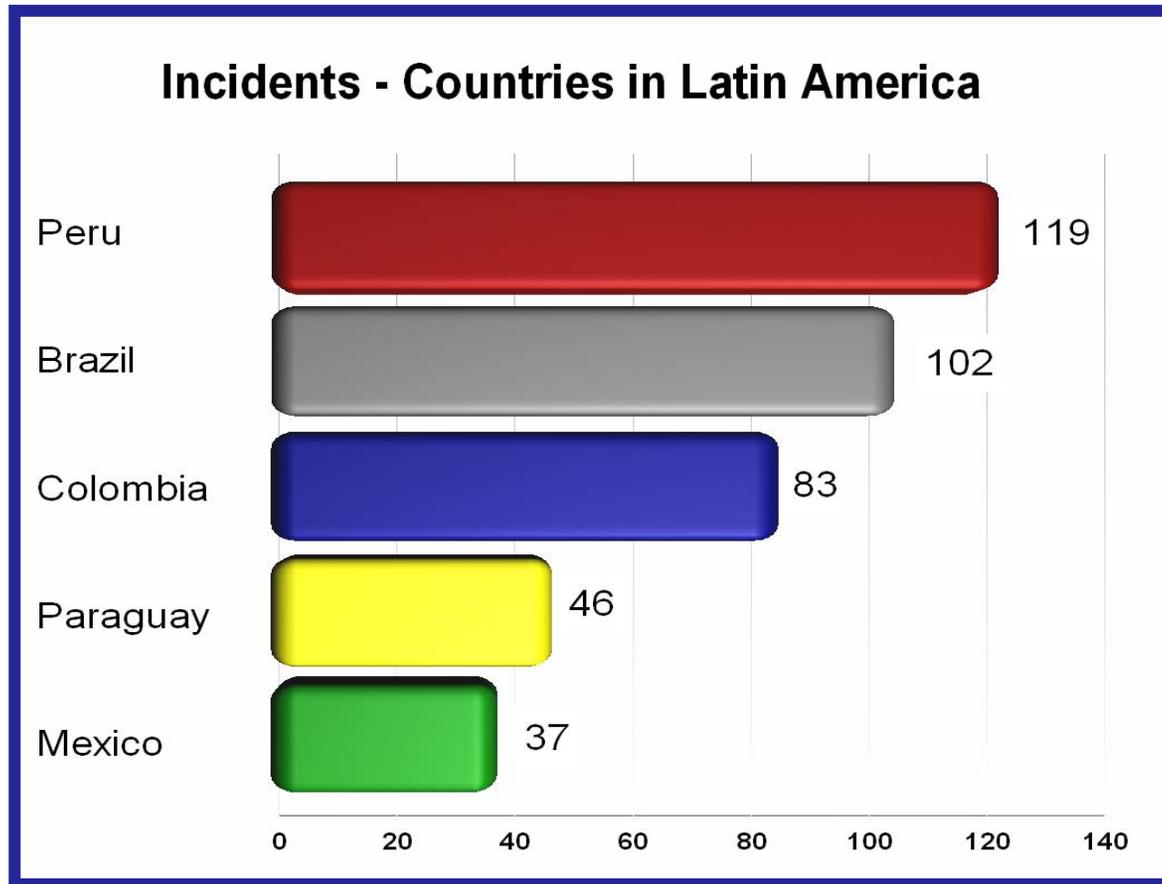
	Country	Raids
1	China	12
2	India	11
3	Colombia	9
4	Bangladesh	5
5	Peru	5



Exterior of the target factory



Incidents within Latin America Region





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



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



Top categories being counterfeited



Counterfeiters in court – Moscow

Genuine



Genito-urinary
Anti-infectives
CNS

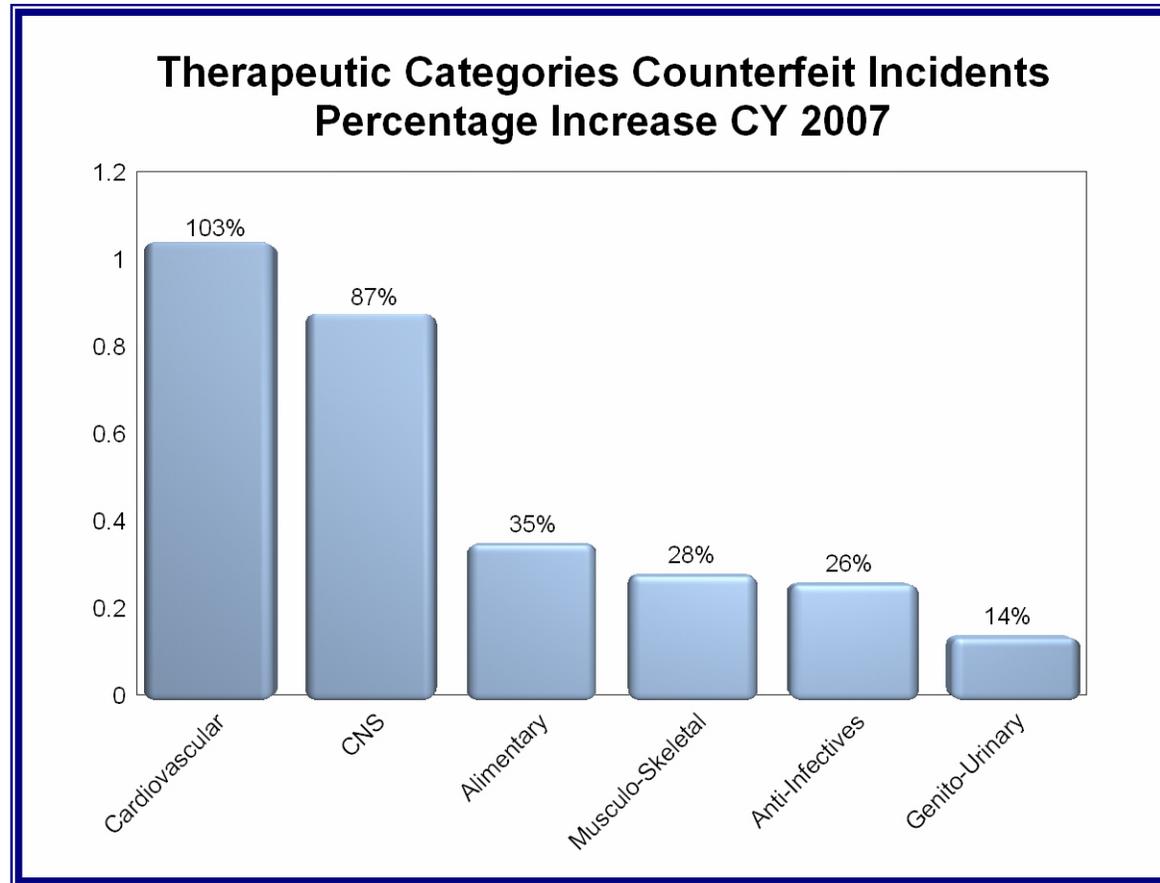
Fake



No product is safe!!



Largest increase - Cardiovascular





Formulations of Counterfeit Medicines



Vials of CF antibiotics

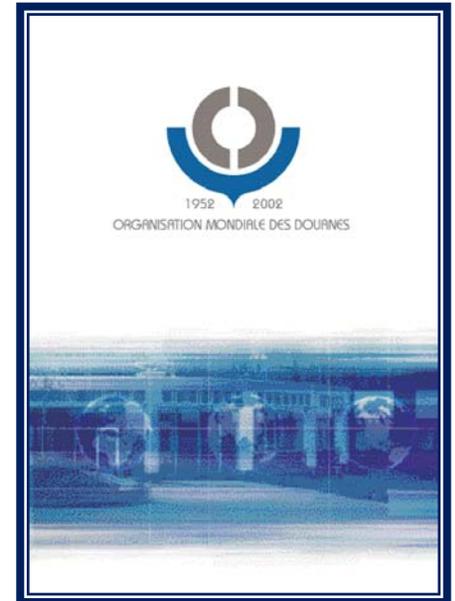


CF analgesic tablets



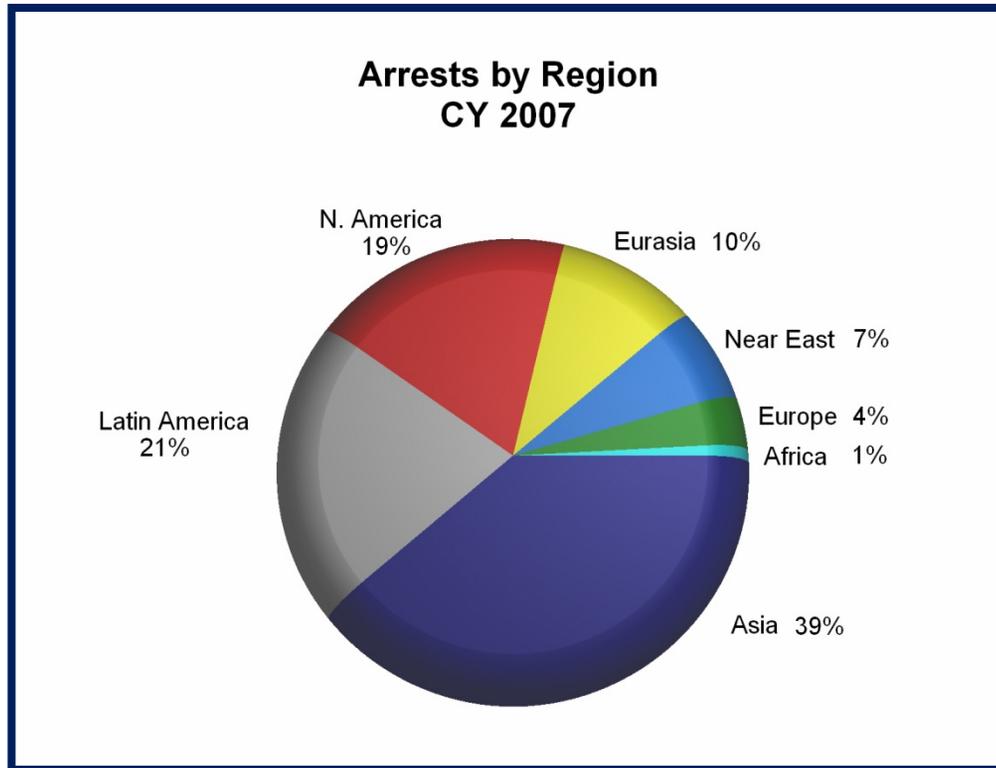


What's being done? - International Partnerships





More arrests – better quality arrests



Increase in arrests

- CY 2006 755
- CY 2007 1,047



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



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.*





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*



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*



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.*





2008 Enforcement Trends - EU





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.*



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*



Members provide details of legitimate shipping





Members provide details of legitimate shipping





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'.*





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*





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*



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*



Third shipment: India – Belgium - Togo

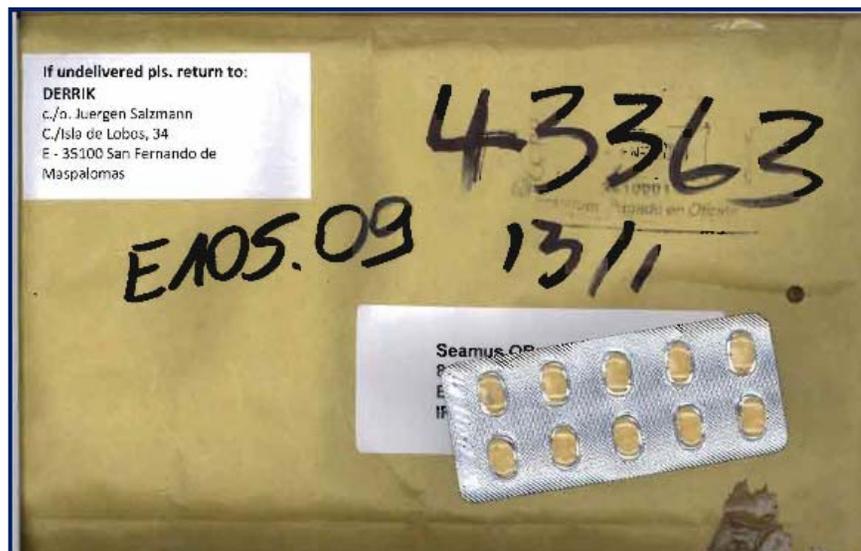
- *Same principals:*
 - *The pharmaceutical company, India*
 - *Togo, Africa.*
- *9/23/08 Eight parcels weighing 562 kg containing 1,600,000 TRAMAL tablets*
 - *No packaging or PILs present.*
 - *Blisters were loose.*
 - *Declared as 'pharmaceuticals'.*
 - *Supposed manufacturer a German company Grünenthal.*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





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*





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*



Conclusion

Every manufacturer ranks patient safety as a top priority!

PSI members are committed to:

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

Cooperation is the key to success.