

The Global Impact of Fake Medicine

Building a Coalition: A Call to Action

American Enterprise Institute: June 10, 2009

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Executive Director,
Partnership for Safe Medicines (PSM)

Counterfeit Drugs...

- Defraud consumers
- Deny patients therapies that can alleviate suffering and save lives
- Include products that are intentionally:
 - Too strong or too weak
 - Missing key ingredients
 - Made with dangerous ingredients
 - Contaminated with foreign, even toxic, materials
 - Made in unsanitary or unsterile conditions
 - Created using unsafe standards
 - Improperly labeled, stored, or handled

International Public Health Hazard

- At their worst...
 - Cause significant harm and fatalities
- At the least...
 - Defraud consumers
 - Deny ill patients therapies that can alleviate suffering and save lives
 - Contribute to the creation of drug-resistant diseases
- And an international problem...
 - Flourish in those countries with poor government oversight or lack the resources needed to enforce their anti-counterfeiting laws
 - Often made by sophisticated, multinational criminal organizations



Tracing a Trade Route

The authorities say that drugs sold by a Canadian online pharmacy, RxNorth, did not originate in Canada, but were made in China and shipped to the United States along a complex intercontinental trade route.



- 1** Drugs from an unknown manufacturer on the Chinese mainland were trucked to Hong Kong.
- 2** From Hong Kong, the drugs were shipped to a free trade zone in the emirate of Sharjah.
- 3** From the United Arab Emirates, the drugs were flown to London Heathrow Airport.
- 4** The drugs were shipped to the Bahamas, where pharmacists filled the individual orders.
- 5** The packaged drugs were sent back to Britain, then mailed to buyers in the United States.

Sources: Drug company investigators and British law-enforcement officials

IMAGE COURTESY OF CTV/THE NEW YORK TIMES

2007/2008 Counterfeit Drug Statistics

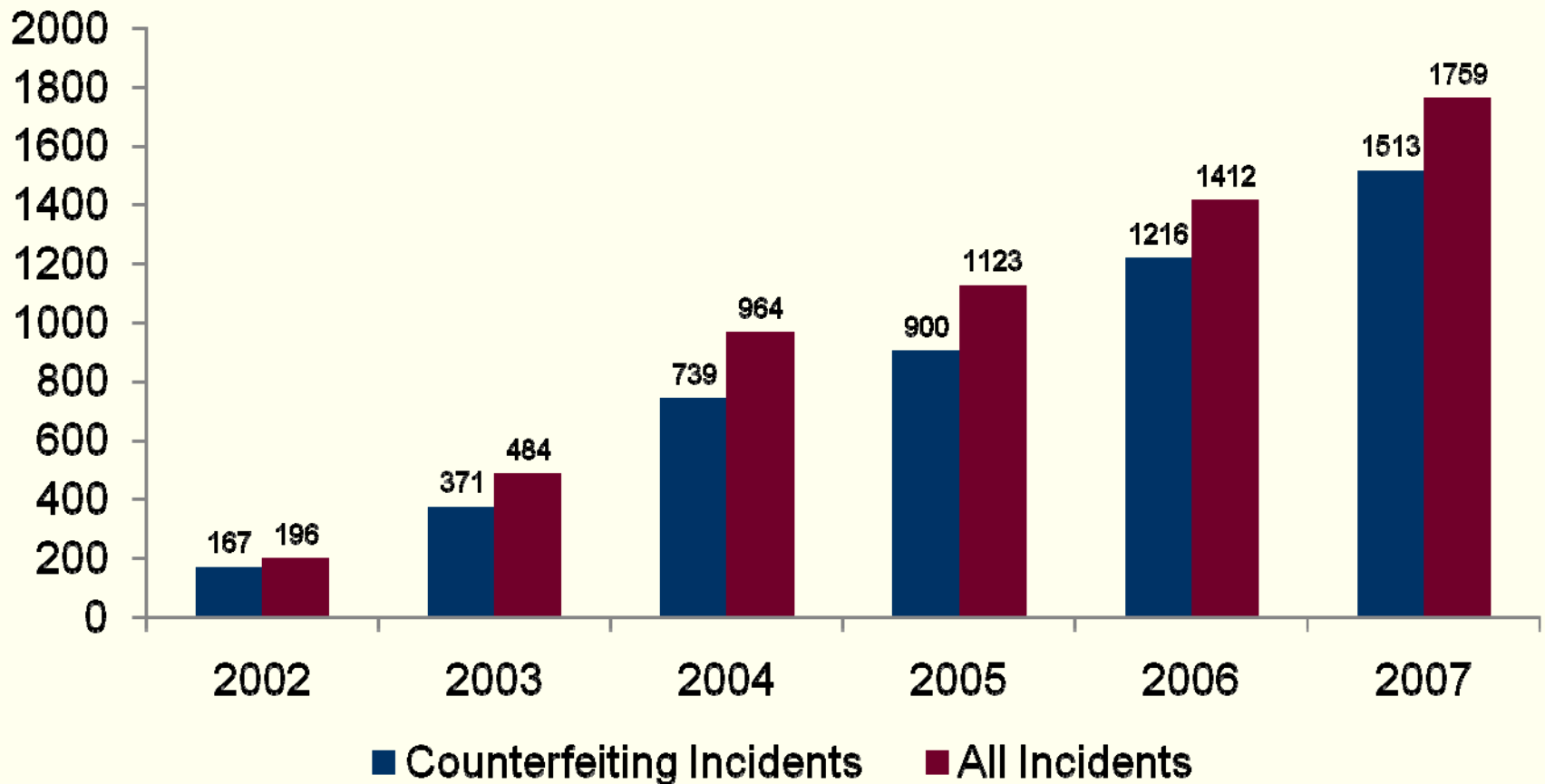
The Bad News...

- In 2008, there were at least 651 different types of counterfeit branded, generic and over-the-counter drugs, and *with improved appearance and packaging have made their fake goods even harder to detect****
 - That is up from 639 different pharmaceutical products in 2007
- *More* countries are finding counterfeit drugs
 - 115 countries identified these products in 2008
 - 112 countries in 2007, 12 percent more than 2006

***Data provided by the Pharmaceutical Security Institute, a PSM Affiliate

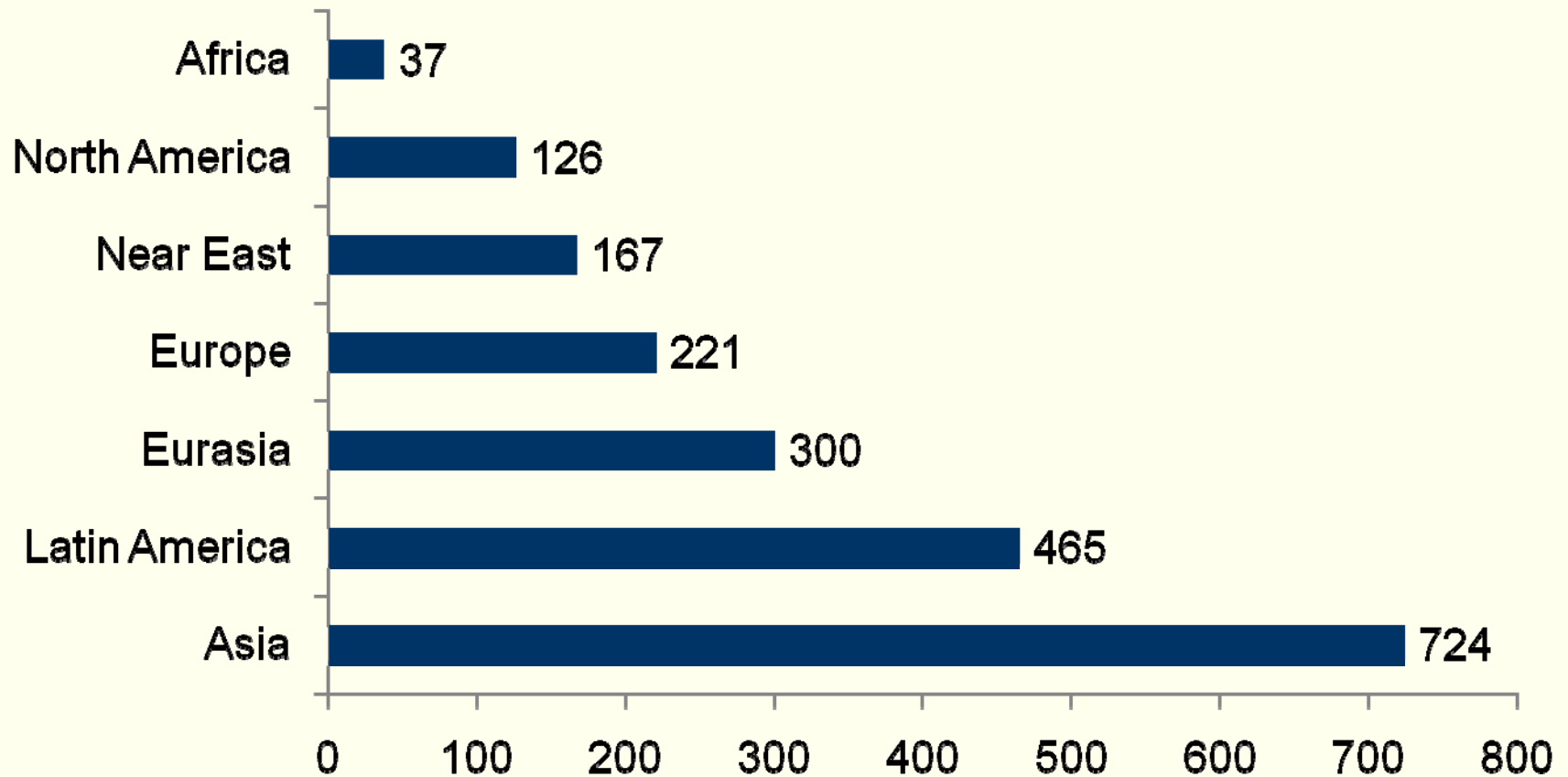
PSI Counterfeiting Incident System

Total Number of Incidents by Year



PSI Counterfeiting Incident System

Incidents by Regions of the World



The Good News...

- **More** arrests in 2007
 - Increased 39 percent from 2006)
- **More** organizations taking a stand against counterfeit drugs
- **More** countries recognizing the inadequacy of their anti-counterfeiting resources
- **More** governments taking steps to address these shortcomings
- **More** international cooperation



The Partnership for

SAFE MEDICINES

- A group of organizations and individuals that have policies, procedures, or programs to protect consumers from *counterfeit* or *contraband* medicines
- Serves as an informational and educational resource for
 - Consumers
 - Government and Policy Makers
 - Healthcare Industry
- Provides expert opinions
- Shares best practices and resources

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Membership

- PSM's Partners include:
 - American Pharmacists Association
 - World Health Organization
 - Pharmaceutical Security Institute
 - Pharmaceutical Industry Labor Management Association
 - National Alliance on Mental Illness
 - Healthcare Leadership Council
 - Vietnam Veterans of America
 - U.S. Chamber of Commerce

More than 50 partner organizations and growing

Website Resources For Every Audience



WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS.



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Outreach to Healthcare Professionals

The Partnership for **SAFE MEDICINES**
SAFEMEDICINES.org

L.E.A.D.E.R.'s Guide for Pharmacists

The World Health Organization estimates that as much as 10 percent of medicines sold worldwide are believed to be counterfeit. As healthcare professionals, consumers often rely on us to keep them safe.

With today's global environment, we are faced with a dangerous problem when these potentially unsafe products move through the drug supply chain undetected and without regard to storage and handling requirements.

As pharmacists, you understand that counterfeit drugs defraud consumers, deny ill patients the therapies that can alleviate suffering and save lives and can harm patients' health.

Although most of the counterfeit drugs in America are not introduced into the "normal supply chain" that delivers medication to community and hospital pharmacies nationwide, it is important for all pharmacies to be aware of the dangers of counterfeit drugs as well as be able to recognize and help prevent counterfeit drugs from reaching patients.

The Partnership for Safe Medicines encourages pharmacists to take an active role in helping to protect the supply chain and protect their customers from counterfeit drugs. Here are 6-steps for becoming a L.E.A.D.E.R. in the fight against counterfeit drugs.

Learn about contraband and counterfeit drugs. Discover why counterfeit drugs are an illicit public health threat and arm yourself with information using the SafeMeds emails and news archive.

Educate your staff and customers. Help your customers safeguard their health and avoid counterfeit drugs with educational materials from the Partnership for Safe Medicines. Your customers can discover how to save money while ensuring the safety of their medications, find safe online pharmacies and learn what to do if they need help paying for medicines.

Avoid unsafe medicines and vendors. Learn the simple steps for S.A.F.E. Sourcing.

Decline suspicious offers. Uncover how to find to evaluate unsolicited sales offers and recognize the warning signs a suspicious vendor.

Evaluate your medicines. Learn how to detect counterfeit drugs by evaluating the products, packaging, and labeling.

Report counterfeit drugs and suspicious vendors. Help stop counterfeit drugs by reporting suspected counterfeit medicines and suspicious vendors to the proper authorities.

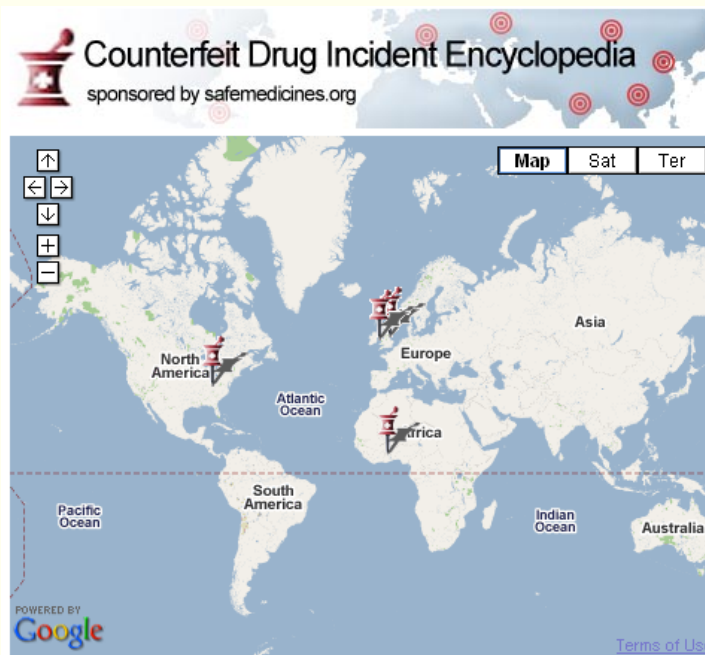
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info@safemedicines.org
www.safemedicines.org

- *L.E.A.D.E.R.'s Guide for Pharmacists*
 - Updated and expanded resource about safe sourcing
- Archive of peer-reviewed counterfeit drug research

Outreach to Policymakers/Media

- *Counterfeit Drug Incident Encyclopedia*
 - One page briefing on previous counterfeit incidents
- *Principles for Drug Safety*
 - Guide for policymakers for protecting the supply chain, regulating online sales and combating counterfeit drugs



[View Larger Map](#)

Incidents available

- [Nigeria-bound HIV/AIDS Drugs Seized by Netherlands](#): November 12, 2008
- [Thousands of Fake Pills Removed from UK Pharmacies](#): June 2007
- [Counterfeit Heparin Blamed for Worldwide Deaths](#): Reports span from January 2008-May 2008
- [Nigerian Children Killed By Contaminated Teething Medicine](#): first incident Nov. 2008

International Principles for Drug Safety

- Secure and Protect the Supply Chain
- Regulate Online Drug Sellers
- Unify in the Fight Against Counterfeit Drugs

The Partnership for
SAFEMEDICINES

Counterfeit drugs, whose origin, manufacturer and quality is disguised, hidden or unknown, are intrinsically unsafe and put patients around the world at risk.

Sellers of counterfeit drugs defraud patients and deny patients therapies that can alleviate suffering and save lives. The harm and fatalities from contraband and counterfeit medicines must stop.

The Partnership for Safe Medicines is a coalition of more than 50 patient, physician, pharmacist, university, industry and other professional organizations committed to the safety of prescription drugs and protecting consumers against unapproved, counterfeit, substandard, mishandled or otherwise unsafe medicines.

Learn more about the dangers of contraband and counterfeit drugs at www.safemedicines.org or contact us at info@safemedicines.org.

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International Principles for Drug Safety

Patient safety is being compromised due to counterfeit drugs. Around the world, patients are encountering fake medicines. The packaging seems right, the tablets or capsules look the same—but these fakes are really imitations of government-approved drugs created in unsanitary or unsterile conditions with unsafe manufacturing practices. Counterfeit drugs may be too strong or too weak, missing key ingredients or made with dangerous, even toxic substances. Drug safety can also be compromised improperly labeled, stored or handled the drugs, as well as taking medications past the expiration date.

The Partnership for Safe Medicines has developed the following international principles to support quality assurance programs and establish a drug distribution system that is without compromise so people in every corner of the globe can feel secure that the medicines they receive are legitimate, safe pharmaceuticals approved by their country's regulators.

Secure and Protect the Supply Chain

- There is strong need for strict, rigorous oversight when pharmaceuticals are transported between countries, including the regulation of its storage throughout the distribution system of imported pharmaceuticals.
- Distribution facilities should be subject to inspection and government agencies should have sufficient funding to inspect all the facilities that manufacture drug products or components of drug products for foreign or domestic use.
- Field offices staffed with both inspectors and criminal investigators should be established to inspect facilities in key exporting areas.
- The public and private sectors should continue to work together to standardize drug pedigrees and documentation.

Regulate Online Drug Sellers

- Online drug sellers and pharmacies should be to the same rigorous oversight and high standards as traditional pharmacies.
- There should be mandatory Internet accreditation programs created by a country's pharmacy board protect patients from rogue online drug sellers.
- All Internet drug sellers, regardless of which state, territory or country they are based, must comply with the pharmaceutical licensing and survey requirements for every area in which they sell pharmaceuticals.
- No one should be able to purchase prescription drugs, including controlled substances, over the Internet without a valid prescription and physician oversight.

Unify the Fight Against Counterfeit Drugs

- Counterfeit drugs, tainted medicines, and rogue online drug sellers are global public health problems that require an international solution.
- International cooperation must occur between government agencies, legislatures, law enforcement, and diplomatic corps to prosecute drug counterfeiters.
- Criminal penalties against the manufacturers, sellers, distributors, and purveyors of counterfeit medicines must be increased to reflect the gravity of their offenses.
- Government authorities should be granted the power to destroy unapproved, unlicensed, tainted, and/or counterfeit drugs entering a country's border rather than returning them to the criminals who sent them.

Outreach to the Public



- Materials
 - Safe Savings Brochure
 - SAFE DRUG Checklist
 - Facts About Importing Drugs From Canada
 - FAQs
- Languages
 - English
 - Spanish
 - Chinese
 - Vietnamese
 - Tagalog

SafeMeds Tools

- **SafeMeds News Archive:** comprehensive list of all relevant news stories from around the globe
- **SafeMeds Weekly Update:** free weekly email summarizing what's happening around the world
- **SafeMeds Email Alert System:** free email service that sends official alerts from government agencies around the world to subscribers when specific counterfeit drug incidents are detected
 - Part of the US FDA's Alert Network
- **Safe Medicines Blog:** regular, expert commentary from our board members

How to Start a Partnership for Safe Medicines

The Partnership for
SAFEMEDICINES

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How to Start a Partnership for Safe Medicines

1. Find Partners

Potential partners in the fight against counterfeit medicines include non-governmental organizations (NGOs), governmental departments and agencies, and for-profit companies who are committed to the safety of prescription drugs and protecting consumers from counterfeit drugs. Partners may come from universities, pharmacists and other healthcare professional organizations, as well as from the business and pharmaceutical sectors.

2. Designate a Main Contact

One of the partner organizations needs to take the lead and designate a staff person to serve as your partnership's executive direct and coordinate activities. This person can act as a spokesperson if needed, or you can recruit spokespersons from among the partners.

3. Collect Existing Information on Safe Medicines

Survey your partners to see if they have already created materials about counterfeit medicines, Internet safety problems or related issues. Put these in an electronic archive that you can use in step 4.

4. Create a Web site on Safe Medicines

You can use the Internet to create a Web site where you can post partners' existing materials (step 3), new materials created by your partnership, and news stories relevant to the Partners. If you want to use a page from safemedicines.org, contact the U.S. Partnership at info@safemedicines.org.

5. Join the SafeMeds Alert System

The SafeMeds Alert System is a free email service offered by the U.S. Partnership that sends official alerts from the FDA and other government agencies around the world to anyone—private citizens, public groups, corporations, healthcare practitioners, associations—when specific counterfeit drug incidents are detected. Individuals can enroll online at www.safemedicines.org or you can send a list of email addresses to info@safemedicines.org.

6. Expand the SafeMeds Alert System

Contact your local drug regulatory authority or relevant Health Ministry to see if it would participate in the SafeMeds Alert System. Ask it to send an email to U.S. Partnership at info@safemedicines.org when specific counterfeit drug incidents occur and the U.S. Partnership will forward them through the SafeMeds Alert System.

7. Start a Local Weekly News Update

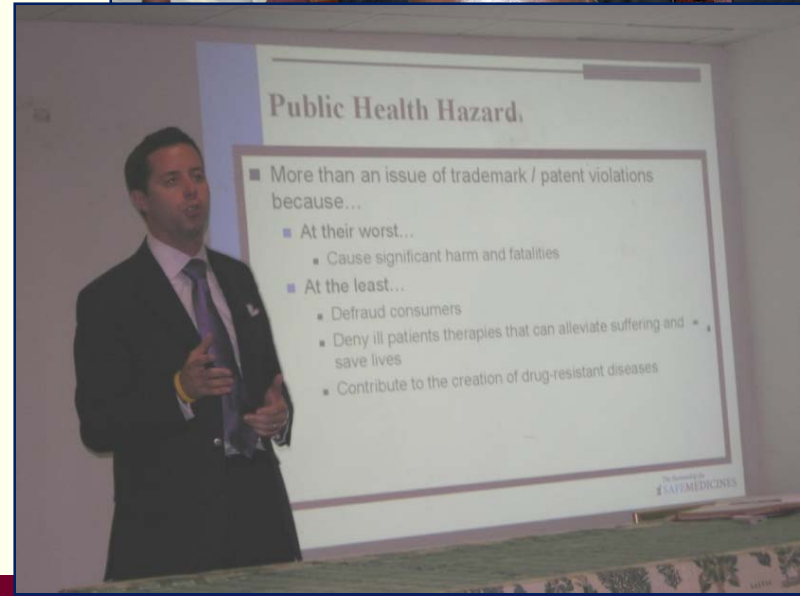
Every week, the U.S. Partnership sends free weekly email that provides readers with a weekly roundup of what's happening around the world regarding counterfeit drugs, as well as the latest blog entry from its experts. For an example of a current newsletter, contact the U.S. executive director at info@safemedicines.org.

8. Develop Educational Materials

Hold meetings with your partners to develop appropriate educational materials. You can use existing Partnership materials as templates; especially the "S.A.F.E. D.R.U.G." checklist for patients, the "L.E.A.D.E.R.'s Guide for Pharmacists" and the "Principles for Drug Safety" doctrine.

- Eight step process to begin a Safe Medicines affiliate in your country

International Affiliate: Ghana 2008



Ghana 2008: Press Coverage



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Agyarko: FDB will ensure drug safety

Cynthia Boakye , 10/09/2008



The Chief Executive of the Food and Drugs Board, Emmanuel Agyarko has assured the nation that his outfit will do everything within its power to ensure that drugs used in the country are not injurious to health.

He said the FDB would work together with other stakeholders in the world to ensure that drugs that are brought into this country meet the right standards.

Briefing the media on safe medicines in Accra yesterday, he said there was the need for a continuous dialogue, frank exchanges across the divides of regulation, governance, commerce, industry and technology provision, in terms of safe drugs in the country.


In his address Scott A. LaGanga, Executive Director of the Partnership for Safe Medicines, said there should be a combined effort from all countries to fight counterfeiting of drugs, saying that "if we want to avoid more deadly incidents both in West Africa and the United States, we must unify in the fight against counterfeit drugs".



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Don't Sell Counterfeit, Expired Medicine - Ashitey

The Deputy Minister for Health, Dr Mrs Gladys Ashitey, yesterday called on health professionals and licensed medicine retailers not to play on the ignorance of clients and sell counterfeit and expired drugs to them.

She said they should not compromise the health of Ghanaians by dealing in unprofessional acts that can undermine the health of their clients.

Speaking at a stakeholder forum organised by the Food and Drugs Board (FDB) on Global Partnership for Safe Medicines in Accra, she noted that safe medicines should not be a privilege but a necessity for all Ghanaians.

The forum which coincided with the completion of the final report of the July National Dialogue on Counterfeit Drugs brought together a delegation led by Mr Scott LaGanga from Partnership for Safe Medicines in the USA and their Ghanaian counterparts.

Deliberations centred on the need to increase attempts to globalise the fight against fake medicines, the importance of interagency co-operation in the development of effective legal and regulatory bodies; the need to modernise on-going efforts to fight the fake product menace and the harmonisation of existing efforts at the implementation level through the formation of a National Anti-counterfeit Taskforce.

According to the FDB, completion of the final report of the dialogue on counterfeit product marked an important first step in the wholesale revamping of the on-going exercise of combating the menace in Ghana and the sub-region. He, however, conceded that the fight cannot succeed in a stand alone fashion.

Thank you

www.safemedicines.org