

Pharmaceutical Counterfeiting Fact Sheet 2010

I. What is a counterfeit medicine?

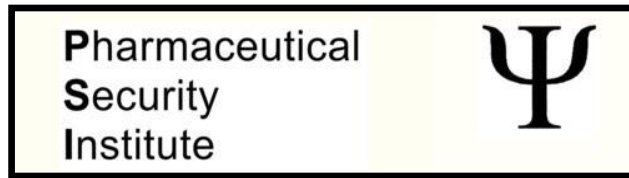
The World Health Organization has attempted to provide a definition for general use that encompasses language accepted by both the public and private sector. The definition is important in that it must differentiate counterfeit medicines from substandard products, or in other words, medicines of poor quality that were manufactured with the appropriate intentions but without the appropriate practices. Incidents of substandard medicines, if recorded in the Counterfeiting Incident System (CIS) database, would thwart our ability to understand the criminal nature and extent of the counterfeiting phenomenon.

For CIS submission, a counterfeit incident is the discovery of a medicine which was deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. The definition applies to both branded and generic products. Counterfeit products may contain less than or more than the actual amount of active ingredient in the authentic version. The product may even be authentic, but be repackaged in counterfeited packaging. Any incident submission involving these types of products, including those where only counterfeit packaging has been found, is identified in CIS as a counterfeit incident.

II. Where are counterfeit medicines found?

While the problem of counterfeit drugs is more prevalent in developing countries, they are found in virtually every country in the world. The following bullets illustrate this fact.

- According to the World Health Organization, the problem of counterfeit drugs is not limited to developing countries only. They are also found in developed countries. But, the problem is more in countries where drug regulation is ineffective, smuggling of drugs is rampant, clandestine manufacturing exists, sanctions are absent or very weak, and there is high corruption. No country is immune to the problem.
- During 2009, PSI recorded 2,003 new incidents of counterfeiting, illegal diversion and theft of pharmaceuticals involving 118 different countries into the CIS database. There were 1,693 incidents of counterfeiting, 245 of diversion and 65 of theft. The top five countries in terms of counterfeiting incidents for 2008 included: China, India, Peru, Brazil, and the United States. In 517 of these incidents the entire packaging and product contained were reported as counterfeit. Concerning specific pharmaceuticals, 808 individual products were identified as been seized during these incidents. Oral dosage forms accounted for 88% of the products and injectable forms for 9%. The three pharmaceutical categories which experienced the largest increase on a year to year basis were: alimentary, anti-infective, and musculo-skeletal.



III. Can you provide examples of the worldwide counterfeit medicines prevalence?

PSI identified many reports reflecting the prevalence of counterfeit drugs in specific countries. The problem is more often seen in countries where corruption is widespread, manufacturing and distribution go uncontrolled, there is lax enforcement, and contraband is epidemic. The following statements illustrate the prevalence of counterfeit medicines worldwide:

Ghana	In 2009, quantities of a prescription medication for treating malaria were identified in Ghana as lacking any active ingredient. Authorities ordered the product removed from the market. The discovery was made by a patient who contacted the Medicines Quality Monitoring program that was set up by the USAID-supported Drug Quality and Information (DQI) Program, implemented by the U.S. Pharmacopeial Convention. ¹
Vietnam	The Vietnam Drug Administration announced in May 2009 that three counterfeit drugs with dubious origins were being sold in the country. These products didn't have legitimate register numbers. Further discrepancies found on the packaging of the products were identified so consumers could spot fake drugs, which included anti-infective medications. ²
Russia	A St. Petersburg businessman was charged with the unlicensed production of medications. The case was initiated in December 2008 when a manufacturing operation was uncovered in a factory for packaging sugar. The police discovered mixing machines, bags of sugar, paracetamol, and sodium citrate used to produce counterfeit medicines. ³
European Union	According to the European industry commissioner, the trade in counterfeit medicines in the European Union has exceeded the body's worst fears. The EU has seized 34 million counterfeit tablets in just two months, including antibiotics and cancer medications. ⁴
Brazil	The Brazilian Federal Police raided 20 pharmacies in Caruaru, Pernambuco, and seized half a ton of counterfeit, stolen and smuggled pharmaceuticals. Eight people were arrested. The investigations were initiated several months before when the police received complaints

¹ Science News Wire, *Counterfeit Antimalarial Drug Discovered in Ghana*, July 22, 2009, <http://www.physorg.com/wire-news/9714935/print.html>.

² Saigon GP Daily, *VDA Cautions Against Three Fake Drugs On Market*, May 21, 2009, <http://www.saigon-gpdaily.com.vn/Health/2009/5/70927/#>.

³ Gorodskaya klinicheskaya bolnitsa imeni S.P. Botkina, *Sankt-peterburgskogo predprinimatelya budut sudits za falsifikatsiyu lekarstva ot grippa*, December 8, 2009, <http://www.botkinmoscow.ru/rus/news/11259.html>.

⁴ The Straits Times, *Fake Drugs Trade On the Rise*, December 7, 2009, http://www.straitstimes.com/BreakingNews/TechandScience/Story/STIStory_463562.html.

	concerning the sale of illegal products brought from Bolivia and Paraguay. More than 40 stores were inspected and 20 of those raided. The products were sent to the local Federal Police delegation for testing. ⁵
Jordan	The Jordan Food and Drug Administration (JFDA) closed down a total of 180 pharmacies after seizing counterfeit pharmaceuticals in addition to medications stolen from the Ministry of Health during the past two years. The JFDA General Manager Dr. Mohammad Al-Rawashdeh stated that the total value of the confiscated medications reached up to JD17 million. ⁶
Canada	The Canada Border Service Agency stated that between July 2009 and November 2009, the Vancouver mail centre intercepted 15,000 packages “containing unauthorized pharmaceuticals.” Most of the products are coming from China and are believed to be Internet orders. ⁷

IV. What is the risk to public health?

The rise in counterfeit medicines, with concomitant problems of toxicity, instability and ineffectiveness, is an often underestimated danger especially affecting the developing countries. This is a hidden risk because it goes largely overlooked in the official public health statistics as data is gathered in categories that fail to reveal the risk. In cases where deleterious adverse reactions are not self-evident the problem often goes undetected. The patient is unknowingly taking ineffective medicines that fail to restore his/her health. The following representative cases illustrate that the potential harm to public health loom large.

- According to the Pharmacist Inspector in Bas-Congo, the Democratic Republic of the Congo, 900 counterfeit ampoules of a medicine used for the prevention and control of postpartum hemorrhage have been recalled in Matadi. The counterfeit products led to a significant increase in the deaths of mothers: 116 cases for the first quarter of 2009 as against 251 deaths for all 2008. They found seven other types of counterfeit medicines.⁸

⁵ Rede O Globo, *Oito são presos com meia tonelada de remédios falsificados em Caruaru*, December 9, 2009, <http://pe360graus.globo.com/noticias/interior/agreste/2009/12/09/NWS,503762,41,470,NOTICIAS,766-OITO-PRESOS-MEIA-TONELADA-REMEDIOS-FALSIFICADOS-CARUARU.aspx>.

⁶ AG-IP News, *JFDA Seizes Counterfeit Medicines, Shuts Down 180 Pharmacies in Jordan*, March 2, 2009, http://www.ag-ip-news.com/GetArticle.asp?Art_ID=6746.

⁷ Global TV BC, *Thousands of Counterfeit Pharmaceuticals Intercepted*, Kim Bolan, November 19, 2009, <http://www.globaltvbc.com/world/Thousands+counterfeit+pharmaceuticals+intercepted/2242256/story.html>.

⁸ Syfia Grands Lacs, *Interview : les intérêts des pharmacies passent avant la vie des malades*, Alphonse Nekwa Makwala, May 14, 2009, <http://syfia-grands-lacs.info/index.php5?view=articles&action=voir&idArticle=1410>.



- In May 2009, the National Agency for Food and Drug Administration and Control (NAFDAC) stopped the importation of fake and adulterated antimalarial drugs with an estimated street value of N32.1 million. Officials intercepted the container load of fake drugs as it was about to be cleared. Director General, NAFDAC, Dr. Paul Orhii, said the interception of the fake drugs may have saved hundreds of thousands of Nigerians from possible effects such as treatment failure, drug resistance, complications like anemia and death had the drugs entered into the open market. Two men, along with their companies, were charged for importing the counterfeits.⁹
- In Nigeria, at least 84 children died after taking a medicine called My Pikin Baby Teething Mixture, which is used to relieve teething pain. The medicine contained diethylene glycol, an industrial solvent used antifreeze and brake fluid.¹⁰
- In December 2009, a Chinese court sentenced a Jordanian to life in prison and a second suspect to 12 years after finding them guilty of selling fake pharmaceuticals. A third Jordanian was also sentenced to 12 years in jail. The counterfeits sold by the Jordanians have reportedly caused death to some people in several countries in the Middle East and Latin America. Last year, Chinese police raided the workplaces of the two suspects in the southeastern Chinese city of Shenzhen, arrested them and referred them to justice.¹¹

V. What should be done?

- Increase the level of awareness and understanding of this issue among the general audience, law enforcement agencies and public health authorities.
- Maximize the exchange of information through a meticulous collection, analysis and dissemination of counterfeiting incident reports through PSI.
- Dismantle and disrupt criminal counterfeiting organizations through an increased number of international investigations, seizures and prosecutions in strong partnership with law enforcement and public health authorities.

⁹ All Africa, *NAFDAC Seizes N32 Million Fake Anti-Malarial Drugs*, Sola Ogundipe, June 2, 2009, <http://allafrica.com/stories/200906020015.html>.

¹⁰ The New York Times, *84 Children Are Killed by Medicine in Nigeria*, Lydia Polgreen, February 6, 2009, <http://www.nytimes.com/2009/02/07/world/africa/07nigeria.html?ref=world>
Associated Press, *12 arrests made in Nigeria tainted formula case*, Bahsir Adigun, February 11, 2009, <http://www.google.com/hostednews/ap/article/ALeqM5hZgOAOQLjyJXvAHPxo7Gs1LEem2bQD969J8603>
Reuters Africa, *Nigeria tightens import rules after drug deaths*, February 12, 2009, <http://af.reuters.com/article/topNews/idAFJJOE51B0E820090212?pageNumber=1&virtualBrandChannel=0>

¹¹ Jordanian News Agency, *Chinese Court Charges Two Jordanians With Selling Fake Medicine*, December 8, 2009.