

Pharmaceutical Counterfeiting: Issues, Trends, Measurement

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WIPO/OECD Workshop



Definition of Counterfeiting World Health Organization(WHO)

A counterfeit medicine is one which is *deliberately* and fraudulently *mislabeled* with respect to *identity and/ or source*.

Counterfeiting of medicines can apply to both branded and generic products. Generally, counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with in correct quantities of activities ingredients or with fake packaging

Note. We are not concerned here with patent infringements or legal generic versions of patented medicines: local laws dictate this, consistent within international rules.



The Many Faces of Counterfeit Medicines

Q. What are counterfeit medicines?

A. Products marketed with intent to deceive

- Counterfeit active/bulk ingredients
- Counterfeit finished products
- Unregulated diverted products
- Counterfeit labeling
- Mislabeled substances (e.g., generic antibiotics)

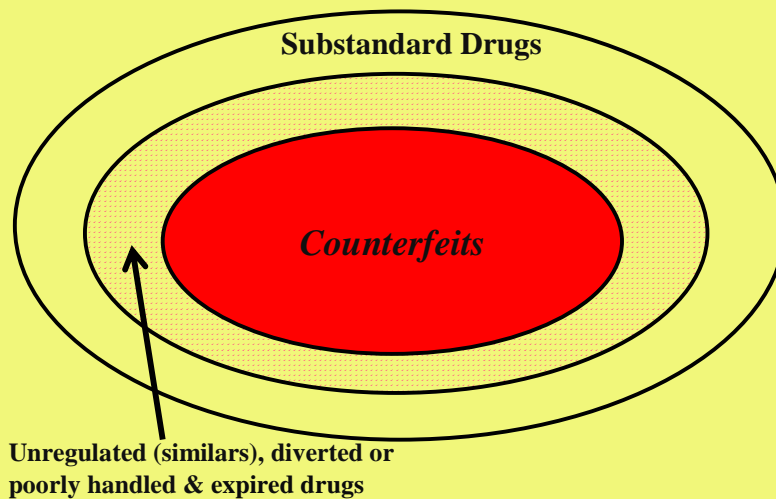


Range of Available Prescription Pharmaceuticals

- *Original brand-name medicines*
- *Bioequivalent:*
 - Unbranded generics: common in US/UK
 - Branded generics: common in LDC's/Europe
- *Non-bioequivalent:*
 - “Similar”: prevalent in Latin America, Turkey, etc.; tending toward being close to counterfeits
- *Counterfeits:* totally deceptive and not regulated at all; drugs diverted and mishandled; (does not include alleged patent infringements)



Substandard, Unregulated and Counterfeit Drugs



Why are Medicines a Target?

Medicines represent one of the most regulated sectors of industrial activity. Why do they attract counterfeiters?

- Fakes can be made relatively cheaply (at least as profitable as narcotics – lower risk)
- Many countries, especially in the developing world lack adequate regulation and enforcement
- Even in the industrialized countries, the risk of prosecution and penalties for counterfeiting are inadequate
- The way in which medicines reach the consumer is also different from other goods: the end-user has little knowledge of the product – a ‘credence’ good



What is Particular to Pharmaceutical Counterfeiting?

- Medicine counterfeiting is much more of a threat to public health than to company revenues
- Developing countries are the worst affected where regulatory structure is weaker and measurement and oversight is difficult; *consumers in LDC's often buy Rx drugs directly over the counter*
- Non-branded generics are very widely counterfeited (e.g., ampicillin, paracetamol)
- Prices vary widely across the world, and parallel trade is widespread, allowing counterfeit medicines to enter the supply chain
- People will not knowingly buy a counterfeit drug, but consumer detection is extremely difficult: price is not an indicator in insured markets



Current and Future Risks

- Treatment failure in malaria, TB and HIV/AIDS
- Growth of resistance to existing anti-infectives from use of sub-par treatments
- Spread of drug resistant pandemics, including HIV and influenza
- Use of illegal funds to finance further illegal manufacture of medicines and even terrorism
- Globalization of pharmaceutical production know-how drives counterfeiting: supply-driven
- Counterfeit drugs are increasingly showing up in OECD countries (see next slide)



EU Commission: Trans-Shipments to EU a Problem

As European officials are planning a broader strategy against counterfeit drugs, the issue of trans-shipment has resurfaced. The EU Commission is warning that counterfeits are making their way to the EU via seemingly innocuous states like Japan and the U.S. [It] is now proposing measures to increase customs enforcement and coordination with industry. In addition, the EU plans to meet with China in November to discuss how to curtail the counterfeit trade. EU Customs Commissioner Laszlo Kovacs will be setting up a Customs Cooperation Committee there..... European officials are also eager to meet with officials from India, Pakistan, and Latin America for the same purpose.

("EU commission proposes plan to boost protection against counterfeit and pirated goods," *Associated Press*, 11 October 2005; "Fake goods flooding EU by way of transshipment through 'safe' states," *Lloyd's List*, 14 October 2005).



Common But Erroneous “Data Point”

“The WHO also reports that the US Food and Drug Administration estimates that more than 10 percent of medicines in circulation in both developed and developing countries are counterfeit.”

Draft Final Report from Task Force 5 of the United Nations Millennium Development Goals Project: Infectious Diseases and Access to Essential Medicines (10/2004)

***Under both possible meanings of this sentence
it is factually wrong – it is logically
impossible***



Statistics – Nothing Precise

About 85% of the world pharmaceutical market is in developed world, where counterfeits are less than 0.2% of the market. The incidence of counterfeiting in the remaining 15% would have to be 66% to reach the 10% claim – and FDA denies the 10% estimate.

- No precise figure for the extent of counterfeit medicines is possible: the problem is greatest – in developing countries – where the regulatory and legal oversight is weakest
- Evidence is consumed; deaths are attributed normally to diseases' effects
- Probably is perhaps in the range of 2 percent, but this low average conceals and distorts the real nature of the problem:
 - US, EU, Japan, Canada: < 0.2%
 - Russia: >10% (Some survey work)
 - India: 15% - 20% (Hindu Business Line – 2003)
 - SE Asia: 5 - 10% (Some sampling)
 - Latin America: 10 - 20% (“Guesstimates”)
 - Africa: up to 60% (Anecdotal)



Number of Incidents of Counterfeiting, Diversion and Theft

Year	Counterfeit	Diversion	Theft	Total
2003	370	78	30	478
2004	444	144	55	643
2005* <small>*(9 months)</small>	243*	70*	35*	348*



Top 10 in 2004

1. China	6. Russia
2. United States	7. Peru
3. Colombia	8. Israel
4. India	9. South Korea
5. Brazil	10. United Kingdom



Need for More Collective Global Action

- The Internet is magnifying the problem of counterfeiting
- Police and judicial priorities are elsewhere
- Ignorance about the scope of the problem and its extent in sector of generic products
- Problem is not recognized as more than a “commercial issue”: association with “branded” products
- Confusion of counterfeiting issue with IP issues (“piracy”)
- Priority in global monitoring and control by police authorities given over to illegal drugs (heroin, etc.)
- Refusal of some regulatory agencies to admit problem
- WHO’s current disease focus; relatively low resource priority given to quality – at least until recently



Some Final Thoughts on Data

- Accurate estimates will be extremely difficult to develop in foreseeable future – problem is greatest where measurement is most difficult; generic medicines are widely counterfeited, but there is no company stake in this problem
- It is important to highlight incidents of counterfeiting, illegal diversion and theft – because they are linked
- Most important is to track the trends in both the level and geographic occurrences of counterfeiting

