

Economic Burden of Counterfeit Medicine in Africa: Situation Analysis and Proposed Solution

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Disclosure

- Head of Market Access for Novartis MENA Region (Dubai-based)
- Adjunct Visiting Professor, University of Illinois at Chicago (UIC) College of Pharmacy
- Chair, Policy and Market Access Committee for the Pharmaceutical Research and Manufacturers Association in the Gulf (PhRMAG)
- Invited speaker on Pricing, Reimbursement, Market Access and Health Policy Regionally and Internationally
- Major publications in peer-reviewed journals and presentations in international congresses (100+)
- Earned Doctorate degree (PharmD) from the University of Illinois, College of Pharmacy (1994), and completed Post-doc Residency in Pharmacy and Ambulatory Care Medicine at Jesse Brown VA-Medical Center (Chicago 1995)

Disclaimer

Opinions and views expressed in this presentation are mine and do not represent the views of Novartis Pharmaceuticals

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Agenda

- Background and Current Status
- Economic Consequences of Counterfeit Medicine
 - Patient
 - Health Care System
 - Economy
- Summary and Conclusion
- Recommendations

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Background (1)

Definitions

- **Generic pharmaceuticals ≠ substandard drugs**
- **Substandard medicine (WHO)**
 - Products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient.
 - Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting.
- **Counterfeit Medicine (WHO)**
 - Part of the broader phenomenon of substandard pharmaceuticals.
 - They are deliberately and fraudulently mislabeled with respect to identity and/or source.
 - Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

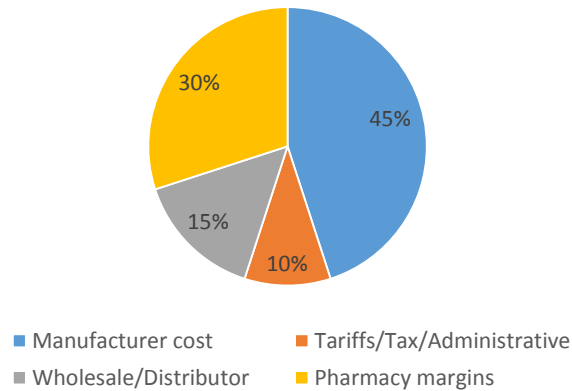
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Pharmaceutical price structure (1)

Legend Products

ILLUSTRATIVE

Cost Structure of Legend Pharmaceutical Product

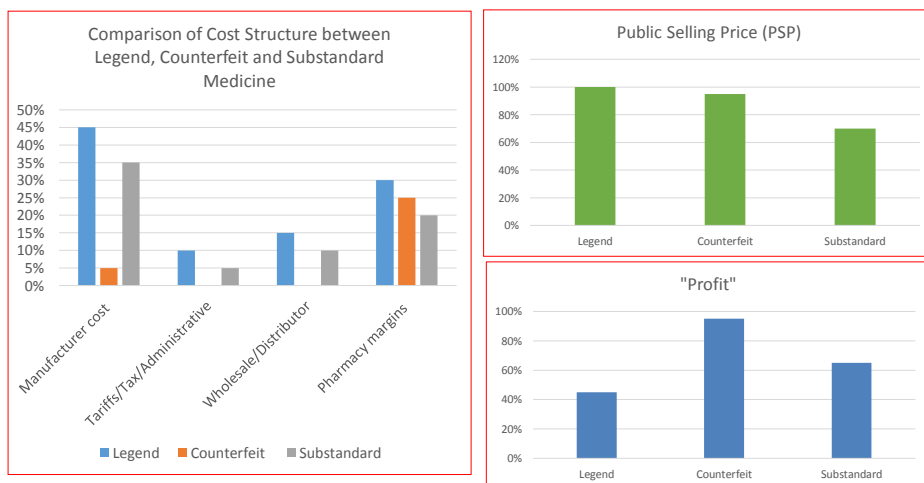


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Pharmaceutical price structure (2)

Counterfeit business yields huge profits to traffickers

ILLUSTRATIVE



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Background (2)

Counterfeit medicine is a Global problem

- According to the WHO, Substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products may cause harm to patients and fail to treat the diseases for which they were intended.
- They lead to loss of confidence in medicines, healthcare providers and health systems.
- They affect every region of the world.
- SSFFC medical products from all main therapeutic categories have been reported to WHO including medicines, vaccines and in vitro diagnostics.
- Anti-malarials and antibiotics are amongst the most commonly reported SSFFC medical products.
- Both Generic and Innovator medicines are falsified including very expensive products for cancer to very inexpensive products for treatment of pain.
- They can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals.

• WHO website. Accessed 2016 October 22:

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Background (3)

Counterfeit medicine is a Global problem

- While the World Health Organization (WHO) estimates that 10 to 15 percent of the global drug supply is fake, **in Africa fake medicines may account for up to 30% of medicines in circulation. Some sources put the number as high as 60%.**
- **1 in 10 drugs** sold worldwide is counterfeit; this figure reaches **7 out of 10** in some countries (LEEM 2011)
- For every \$1,000 invested, criminals can generate \$20,000 in profits from heroin trafficking and \$400,000 by trafficking counterfeit medicines.
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• Source: Health24 Online. Accessed October 22nd, 2016 at 21:45.

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Counterfeit medicine in Africa is a global challenge

- About 100,000 deaths a year in Africa are linked to the counterfeit drug trade, according to the World Health Organization (WHO).
- Poverty stricken continent as Africa is vulnerable to drug counterfeiting because it is sold on the street at cheaper price, hence its proliferation “as an industry.”
- Lack of access to quality healthcare will always create the environment for fake pharmaceuticals to come to African Borders and kill thousands of people and cause harm to population

- Source: Health24 Online. Accessed October 22nd, 2016 at 21:45.
- <http://www.un.org/africarenewal/magazine/may-2013/counterfeit-drugs-raise-africa%E2%80%99s-temperature>. Accessed October 22, 2016.

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 **World Health Organization**

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Ref: RHT/SAU/MD/EA.131 25 March 2014

Information Exchange System

Drug Alert No. 131

Falsified antimalarial medicines in west and central Africa

BACKGROUND

This drug alert concerns three separate falsified antimalarial medicines discovered in Cameroon, Ghana and Liberia.

None of the medicines were manufactured by the companies named on the labels. Two of the medicines contain less than 2% of the active pharmaceutical ingredient and analysis is awaited concerning the third.

- All three products are contained in tubs of 1000 tablets designed for hospitals and clinics.
- The labelling on all three products is in English and French and contains spelling mistakes. They also show a previous WHO Essential Drugs Programme logo (no longer in use by WHO). Please see photographs in annex.

These products have been intentionally falsified.

Details on the falsified products and advice can be found on the following pages. Photographs of each product are compiled in the annex to this drug alert.

FALSIFIED MEDICAL PRODUCTS DETAILS

CAMEROON: Sulfadoxine Pyrimethamine BP

In June 2013, a nongovernmental organisation active in Cameroon discovered, at a wholesaler, the following medicine which later proved to be falsified:

- **Product name:** Sulfadoxine Pyrimethamine BP
- **Manufacturer:** Riverpharm Laboratories
- **Dosage:** 500mg + 25mg
- **Batch number:** 1833
- **Expiry date:** 02/2014
- **Manufacturing date:** 02/2011

Following laboratory testing which revealed less than 2% of the active pharmaceutical ingredient, WHO issued a warning to African regulatory authorities requesting increased vigilance for this batch. Riverpharm Laboratories have confirmed they have not manufactured this product for 15 years.

Please see photograph in Annex.

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Source: Bloomberg News. July 31, 2015. Many Ghanaians shop for pills in open-air markets, where the fake may be indistinguishable from the real.

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Fake drugs at a market in Abidjan, Cote d'Ivoire

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From Africa Renewal: [May 2013](#). Drugs on sale at a market in Mali.

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Consequences of counterfeit and substandard medicine

Serious social and economic impact

- The Patients
 - Poisoning
 - Hospitalization, disability and/or death
 - Treatment Failure
 - Serious public health issues (communicable diseases)
 - Increased diagnostic work-up, additional consultation
 - Prolonged courses of therapy
 - New/repeat course of therapy, resistance to treatment
 - Untreated Disease
 - Long-term complications, increased morbidity
 - Premature death
- The Health Care System
- The Economy

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Consequences of counterfeit and substandard medicine

Serious social and economic impact

- The Patients
- The Health Care System
 - Wasted drug budget (Public, Private, Tenders, OOP) in an already financially strained system
 - Significant increase in overall health care budget (public, private)
 - Additional medical costs and consultations, hospitalizations, etc.
 - Loss of confidence in the health care system
 - Loss of confidence in Public Institutions
- The Economy

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Consequences of counterfeit and substandard medicine

Serious social and economic impact

- The Patients
- The Health Care System
- The Economy
 - Lost productivity (absenteeism, life-years lost, etc.)
 - Shift in expenditure (medical expenditure is largest component)
 - More spend on health care, less spend on other business sectors
 - Increased corruption
 - “Global impact”
 - Travel restrictions
 - Testing, employment

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Summary and conclusion

- Substandard and counterfeit medicines are distinct entities with unique challenges
- While both pose great hazard to public health, substandard receives less attention than counterfeit, and thus is a greater problem to address
- Economic impact of substandard medicines on countries is very high, especially low-, to middle-income countries with limited health care resources
- Efforts to address the counterfeit problem require close collaboration between Regulatory, Pharmaceutical Companies, and systems to ensure consistent supply of high quality products

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Recommendations (1)

- **Education (key)**
 - **General Public**
 - Not to purchase medicine from street vendors and peddlers
 - To report any perceived lack of efficacy from any medication they have taken
 - To report any adverse drug event experienced when taking medication
 - Utilize new technology/smart devices to ensure dispensed medicine is legit
 - **Government Officials**
 - On severity and the prevalence of the problem
 - On the risk it poses to the general public
 - **Vendors and Street Peddlers**
 - On the harm they are causing to society

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Recommendations (2)

- **Strengthen Regulatory Oversight**
 - Strong country-level regulatory oversight
 - Global and regional collaboration
 - Develop technical capabilities for quality testing
- **Enact Strong Legislation**
 - Criminalize offenders
 - Severe punishment to offenders to serve as deterrence
- **Consider Regulation of Vendors and Street Peddlers**
 - Go after the economic source of the problem
 - Instead of ousting illegal vendors off the streets, governments should consider pros and cons of initiatives to regulate these vendors to ensure that they are at least selling the appropriate products that are safe.
 - Pushing them out of business will inevitably fail, as poor, desperate people will always go for cheap vendors.
 - As such, effective measures to regulate them may well be an appropriate way to ensure the safety of African patients

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Recommendations (3)

- **Enhance Supply Chain**
 - Minimize the number of supply chain and distribution players
 - Work with legal companies on tracking system to identify substandard and/or counterfeit medicines
 - Deal only with select suppliers with proven product quality
 - Consider different models of distribution system
- **Public – Private Partnerships**
 - Partnership with MNC to deliver sustainable high quality medicine at affordable prices utilizing special access schemes
 - Work with Interpol to combat counterfeit
 - Work with WHO and other NGO on programs to enhance Access to medicine and pharmaceuticals

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Thank You

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