Illicit Trafficking in Fraudulent Medicines

The Situation, Initiatives and Responses within the Economic Community of West African States (ECOWAS)

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Introduction

• WAHO’s 2009-2013 Strategic Plan prioritizes issue of counterfeit medicines in West Africa

• It tackles the problem by working in close partnership with relevant stakeholders (Governments, civil society, at International, Regional and National levels)

• A major obstacle to effectively combating counterfeit medicine is the lack of consensus on definition, assessment tools and its prevalence in different regions of the world

• In ECOWAS region, there is the need to collate recent studies on counterfeit medicines and develop a common assessment tool to determine the extent of the problem
Review of Situation in ECOWAS Region

- The ECOWAS region with a population of about 365 million, large market size and the need for quick access of quality essential medicines due to its high disease burden.

- In general, all the countries have a huge burden of malaria (98 million cases per year), HIV/AIDS, Tuberculosis, neglected tropical diseases and other newly emerging diseases.

- Combined with these communicable and non-communicable diseases, poverty and malnutrition, which also impact on the types of medicines required.

- Porosity of our borders fueling illegal distribution of counterfeit medicines

- Despite efforts of regional and national bodies (ECOWAS/WAHO, National Medicines Regulatory Authorities) much remain to be done.
Counterfeit and Illicit Medicines Trade

- Counterfeit - A serious case of mistaken identity

- A global problem: Counterfeit Medicines gulp $40bn out of $280bn worth global commerce

- Counterfeiting is a deliberate act committed to fraudulently mislead buyers with respect to identity and source.

“Counterfeiting can apply to both branded and generic products, and may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”
Counterfeit and Illicit Medicines Trade

- According to WHO estimates:
  - 30% of medications on the Africa market are counterfeits
  - 30-50% in West Africa market are counterfeits

- Mimicks both brand and generic medicines
  - Packaging
  - Shape, colour, size
  - Imprints of genuine medicines
  - Difficulty in detecting ingredients of medicines without laboratory tests

- Significant Implication of counterfeit medicines:
  - Direct loss of lives, serious illness and treatment failure
  - Development of drug resistance
  - Public health risk
  - Revenue gained are possible sources of funding for organized crimes

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Why counterfeiters have a field day 1/2

- Absence or weak regulatory capacity and political will to detect defective products is low developing countries where
- Exorbitant prices of legitimate medicines
- Poor consumers preference for cheaper medicines fuels counterfeiting
- Counterfeiters know the market well and target medications in high demand
  - Antibiotics
  - Antiretroviral drugs
  - Antimalarials (West Africa has the highest estimated rate on the continent)
  - Tuberculosis
  - Painkillers
  - Anti hypertensives.
  - Anti diabetic agents
  - Life style drugs
- The desire to make medicines affordable as widely available, yet failing to strengthen the regional pharmaceutical manufacturing sector
Why counterfeiters have a field day 2/2

- Consumers have little disposable income and consider knockoffs as bargain - accept a price –quality trade-off (thus cannot afford genuine product)

- Ethics; they do not think it is illegal or immoral to do so

- Sentiment; they think the big businesses just want to make more money or are in fear of competition

- Ease; buy fake because they are easy to obtain - at the doorstep or the marketplace
Why counterfeits constitute a public health risk

✓ The products do not contain the active pharmaceutical ingredients
✓ Not made to regulatory standards, yet are sold at the legitimate medicines’ outlets and open market places
✓ Fake medicines are poor quality and can kill
Faces of Counterfeiting

Dividend of Anti-counterfeiting efforts.

Menace of street medicines
Worrisome

Indeed this is worrisome - these medicines find their way into the market from SO MANY different sources:

- India - 35% world’s fake drugs worth about $200m (WHO report)
- China
- Europe

Within the region:
- Local industry which are severely under-regulated - WA high activity in cross-border trade in pharmaceuticals with high volume come from Nigeria
Disease Burden: 25% Africa, 75% Rest of the World

Population: 89% Africa, 11% Rest of the World

Healthcare Expenditure: 99% Africa, 1% Rest of the World

Source: Africa Union, Council on Health Research for Development (COHRED), New Partnership for Africa's Development (NEPAD)

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"No poverty reduction program in Africa will work without simultaneously seeking long term solutions to the continent’s healthcare needs!"

Nearly two billion (1/3 of the world’s population) people lack access to essential medicines. [“WHO Medicines Strategy: Countries at the Core, 2004-2007”, (2004)].

In low and middle income countries (LMICs), 50% to 90% of the cost of medicines are paid by the patient out of pocket.
WAHO’s Strategic Initiatives in the ECOWAS Region 1/3

- Building a co-ordinated NETWORK among member countries to halt the production and distribution of counterfeit medical products in ECOWAS

- Institutionalizing Regional and National Action Plans for combating counterfeit medical products

- And consolidate strong linkages between WAHO and other Partners

- March, 2010, develop an Regional ACTION PLAN to combat to counterfeiting and illicit medicines trade

- June, 2010, a multi-sectoral meeting was held to validate the Action Plan and find ways of implementing the strategies
WAHO’s Strategic Initiatives in the ECOWAS Region 2/3

- Established an ECOWAS Medicines Anti-counterfeit Committee (EMACCOM) June, 2011 to be inaugurated by April, 2013 at the Assembly of Health Ministers

- Regional legal/legislative framework developed, validated and adopted by Member States; to be adopted by ECOWAS Parliament for adoption and implementation by National Parliaments

- Develop common assessment tools to compare data on the counterfeit situation internationally and in the sub-region

- Come out with a cost effective anti-counterfeit technologies for identification of counterfeit medicines:
  - Authenticating Pharmaceutical products- MAS- WAHO Collaboration with mPedigree 2010 (WAPMA, Health Access Network, PSGH, NAFDAC and FDB)
  - Truscan and minilab
Regional Collaboration in Detecting Counterfeiting-NMRAs
WAHO’s Strategic Initiatives in the ECOWAS Region

- Strengthen NMRAs and NQCLs in the region in ensuring quality of medicines including the use of minilabs

- Joint trainings on GMP

- Establish and strengthen Medicines Registration Harmonization (MRH) process in the region

- Develop communication strategies that will involve stakeholders, patients, and the media on combating counterfeit medicines

- Strengthen local pharmaceutical production of medicines in the region

- TRIPs policy and guidelines developed, validated and adopted by Member States IPO, OAPI, AR IPO

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Significant Breakthroughs

- High-impact Customs operation tackles illicit medicines in Africa

- 100 million counterfeit products, worth US$40m
- 110 maritime containers seized—84 contained counterfeit and illicit products— from South and East Asia and Middle East

- Member States develop national action plan—Guinea, The Gambia, Liberia and Nigeria
- Increased public enlightenment programs
- Consultative fora with stakeholders.
- Sensitization programmes
- Building capacity in regulatory staff

- Support of the local pharmaceutical sector to build appropriate capacity to produce drugs locally that meet international standards and reduce the dependence on imports

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Regional and National Collaborations - Inter-Agency collaboration

National Medicines Regulatory Authority

National Security and Civil Defence Corp

Consumer Protection Council

Professional Associations in ECOWAS Member States

Judiciary

National Police Force

National Customs Service

Civil Society

National Immigration Service

National Ports Authority

Standards Organization of Member States

National Ports Authority
a. Multi-sectorial workshop for the validation and adoption of the regional Action Plan in Dakar 2010

b. Visit to NAFDAC by Heads of NMRAs, Inspectors and Registrars of Medicines during the MRH workshop in Abuja Sept 2012.

Methodology in the detection of counterfeit medicines and regional coordination to combat counterfeiting was discussed at length.

Ways of Achieving Effective Regulation
- Product registration.
- Inspection of production facilities – GMP.
- Laboratory evaluation.
- Post marketing surveillance.
- Joint Enforcement activities.
- Inspection at Entry points.
- Pharmacovigilance
- Quality Management Systems
- Information Management Systems
- Building coordinated networks across nations for combating counterfeiting
- Mentoring each other to strengthen the MRH process
Challenges

The reality in West Africa is that, anti-counterfeiting is highly unsatisfactory due to:

- Weak, inadequate, outdated legislation and weak penal sanctions
- Weak regulatory and enforcement systems,
- Widespread and poorly regulated distribution channels
- Sale of medicines in the open market
- Weak porous borders and port controls
- Weak infrastructure
- Lack of access to independent and objective information
- Lack of awareness of the danger of counterfeit medicines
- Poor management capacity
- High cost of medicinal products
- Transactions involving many intermediaries
- Expansion and deregulation of trade
- Lack of Political will
The Way Forward

- To reduce the effects of counterfeit medicines and improve on availability of safe, quality, efficacious and affordable medicines in the ECOWAS region

1. More investment into the use of cutting-edge technologies for identification of counterfeit medicines
   - TruScan (Raman Spectroscopy)
   - Black Eye (Infra Red)
   - Radio Frequency Identification (RFID)
   - Minilab
   - Mobile Authentication Service (SMS TEXT Messaging)

2. Creating quality control reference centres of excellence

3. Strengthen the capacity of Manufacturers, and NMRAs on GMP, GLP, based on WHO requirements

4. Continue to enhance pharmacovigilance in ECOWAS Member States

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Conclusion

- The most effective mechanism that can defend the menace of counterfeit and/or substandard medicine rests within the ability to coordinate and collaborate all the activities of medicine registration and regulation in the West African Region.

- Effective coordination and committed collaboration with partners in terms of technological transfers and financial support to the region to fight against counterfeit and illicit medicines trade.

- Intelligence information sharing.

To obtain quality, safe and efficacious medicines to the population can be assured.

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