

**FOOD AND DRUGS BOARD
ENHANCING CONSUMER SAFETY THROUGH
INTERAGENCY
AND SUB-REGIONAL
COLLABORATION**

**THE WORLD HEALTH ORGANIZATION'S AFRICA
ANTI-COUNTERFEIT INITIATIVES**

By

Dr. J. Saweka

WHO Country Representative/Ghana

Presentation Outline

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- What are Counterfeit Medicines
- Who are the Counterfeiters
- Factors that Favour Circulation
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Introduction

- Background
 - Counterfeiting pharmaceuticals
 - is a global public health problem
 - Causing death,
 - affects finished products, active pharmaceutical ingredients, medical devices, diagnostics, kits and other health care related items
 - Involves both branded and generic medicines
 - It is estimated that up to 15 per cent of the global medicines supply chain is illegal, rising to 25 per cent in some countries

What are counterfeit medicines?

- A product manufactured with the deliberate intent to mislead the end-users, be they patients or health professionals.
 - Definition allows distinguishing counterfeits from substandard medicines
- Counterfeiters tend to operate where there is high demand or high profits to be made.
 - antibiotics or antivirals, expensive products such as cancer therapies or antiretrovirals, or lifestyle medicines such as hormones and steroids.

Who are the counterfeiters?

- counterfeiting of medicines does not require sophisticated equipment or a large criminal network.
- counterfeiters may operate alone or in a group, in a factory or in a garage, or even in a home
- they could even be manufacturing these products in the house next-door to yours.
 - therefore detection of counterfeiters is a major challenge.

Factors that favour the circulation of counterfeit medicines

- The global trend towards free international commerce
- Legal systems
 - Often not equipped and
 - penalties for counterfeiters are often inadequate to act as deterrents.
- The high demand for medicines and final users are generally unable to tell the difference between real and fake.
- In many countries there are no social security or health insurance systems - to pay for medicines out-of-pocket leads people to look for cheaper products off the street.

Factors favouring the circulation of counterfeit medicines

- In many countries regulatory oversight of pharmaceuticals is ineffective, especially of distribution channels.
- Some governments are not ready to admit that counterfeit medicines circulate in their country.
- Equally, some companies are hesitant to make public the discovery of counterfeit versions of their own products.

What actions can be taken?

- **appropriate legislation and penal sanctions;**
- **international harmonization;**
- **sufficient administrative and regulatory capacity;**
- **International information networks;**

Actions to be taken

- **streamlined distribution channels;**
- **national drug policies that prioritize public-health aspects**
- **international monitoring of 'extraterritorial' zones;**
- **evaluation of medicine prices**
- **increased public information;**
- **Low or high tech solutions.**

WHO/IMPACT

International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

– Is a WHO initiative to combat counterfeit medical products

- **Secretariat: WHO**

– **5 working groups:**

- legislative and regulatory infrastructure
- regulatory implementation
- enforcement
- technology
- Communication

Legislative and regulatory infrastructure

- Taskforce to draft principles and elements for National Legislation against counterfeit medical products
 - Member States Parliaments to debate national legislation based on agreed principles in 2008

REGULATORY IMPLEMENTATION

- **Task Team has developed drafts:**
 - **Revised GDP and GPP with emphasis on counterfeit medical products;**
 - **Check lists and decision trees on action upon cases/signals;**
 - **Data Collection Tool on assessment of national situations drafts to be finalised**

Communication

- IMPACT communication strategy
- Agreed 'IMPACT messages'
- IMPACT web site
- Event organization/participation strategy
- Model materials addressing different audiences (health professionals, distribution system, patients, enforcement officials, media, etc.)
- Short films

TECHNOLOGY

- There is no “worldwide” applicable technology
- No one global “solution” exists
- Developing countries should prioritize GMP, GDP and GPP
- RFID implementation will take many more years
- Technologies already available (cheaper) are preferred (e.g., bar-codes)
- Any technology needs to be sustainable and locally appropriate

WHO/IMPACT

- WHO/IMPACT establishing ongoing dialogue between drug regulatory authorities, manufacturers, distributors and technology providers in order to permit to assess recent trends in anti-counterfeiting technologies

CONCLUSION

- National, regional, and international strategies aimed at combating counterfeit medicines should be based on:
 - a) political will, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on the health of individuals and on public health and providing the necessary tools for a coordinated and effective law enforcement
 - b) inter-sectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools

CONCLUSION

- c) creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public
- d) development of technical competence and skills in all required areas
- e) appropriate mechanisms for ensuring vigilance and input from healthcare professionals and the public.