Substandard and Falsified Medical Products

Technical Briefing Seminar
12 October 2017
Agenda –
Substandard and Falsified Medical Products (SF)

Definitions

Case Studies

Member State Mechanism

Global Surveillance System

Causes

Solutions
A common understanding

Counterfeit Medicine

Falsified Medicine

Spurious Medicine

Fake/Substandard Medicine

Falsificado Medicamento

Fraudulent, Falsely labelled, Forged, Copied, Adulterated, Pirated, Fake
Examples

A common understanding for synchronised action

**SUBSTANDARD**
Also called ‘out of specification’, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.

**FALSIFIED**
Medical products that deliberately /fraudulently misrepresent their identity, composition or source.

**UNREGISTERED / UNLICENSED**
Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to conditions under national or regional regulation and legislation.
Definitions

Registered medical product

Genuine Medical Product

(manufactured in compliance with National Specifications)

Sub Standard

Out of specification due to degraded, expired, or manufacturing error

Unregistered medical product

Falsified

Deliberately Misrepresents its identity, composition or source

Unregistered

Not licensed or assessed for safety, quality and efficacy in Country of marketing
Democratic Republic of Congo

Remote rural area
Low literacy levels
Poor access to medicines
Civil unrest
Diazepam?

A combination of vulnerabilities

- 3 medical centres and 100 medical staff dealt with over 1000 hospitalizations and at least 11 deaths
- Containers labelled Diazepam containing an overdose of anti-psychotic medicine
- Irrational use of Diazepam
- Limited Access in the region
- Illegal cross border supply
- Unethical / Criminal practice by distributors
- Little regulatory oversight
The role of the WHO

The WHO two pronged approach to protect public health

**POLITICAL, TECHNICAL AND OPERATIONAL RESPONSE**

*Member State Mechanism*
- Political support
- Promote access to affordable, safe, efficacious, and quality medical products
- Effective Member States’ collaboration and coordination

*Global Surveillance and Monitoring System*
- Immediate technical and operational support
- NRA capacity building and policy guidance
- Improve current knowledge for in depth analyses. landscape, SWOT, etc.
WHO Member State Mechanism

**MANDATE**

World Health Assembly 65.19 ; 2012

Recognised as an unacceptable threat to public health

**GOVERNANCE**

- 1 Chair (Spain)
- 11 Vice Chairs
- Regional Rotation

**PURPOSE**

International collaboration from a public health perspective on substandard and falsified medical products
Member State Mechanism Steering Committee

- **African Region**
  - Tanzania
  - Togo

- **Americas Region**
  - Brazil
  - USA

- **Eastern Mediterranean Region**
  - Iran
  - Morocco

- **European Region**
  - Spain (Chair)
  - United Kingdom

- **South East Asia Region**
  - India
  - Indonesia

- **Western Pacific Region**
  - China
  - Malaysia
Prioritized technical activities

- Develop training material for Member States
- Expand and maintain the global focal point network
- Improve understanding on detection technologies, methodologies and track and trace models
- Increase knowledge on links between access and SF medical products
- Risk communication and awareness raising campaigns
- Enhance Member States capacity to promote their work on the prevention detection and response to SF medical products
- Promote a shared understanding of the intervention on medical products in transit form a public health perspective
- Address strategies to understand and address the supply of medical products via the internet
WHO Study Launch

3pm Wednesday 29th November 2017 The Graduate Institute of Geneva
Globalization = Increased Vigilance

December 2012, Pakistan
50 deaths

WHO International Alert

September 2013, Paraguay
46 patients hospitalised

WHO International Alert

Colombia and Peru
trace the API

Global Impact
8 Countries
4 Continents
### Purpose of a Global System

#### Operational and strategic benefits

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<th>UNDERSTAND THE PROBLEM</th>
<th>RESPOND AND SUPPORT</th>
<th>LONG TERM IMPACT</th>
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<td>- Identify the <strong>medical products</strong> most at risk</td>
<td>- Provide immediate technical and/or operational assistance</td>
<td>- Identify needs for strengthened capacity and financial investment</td>
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<td>- Identify <strong>vulnerabilities in supply chains</strong></td>
<td>- Guide market surveillance</td>
<td>- Identify the <strong>economic and social costs</strong></td>
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<td>- Systematically collect <strong>reliable reports</strong></td>
<td>- Collate and analyze data from different sources</td>
<td>- <strong>Change policies</strong> by identifying sustainable risk mitigating strategies</td>
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<td>- Maintain a <strong>global database</strong></td>
<td>- Crosscutting links between stakeholders</td>
<td>- <strong>Improve access</strong> to safe and efficient medical products</td>
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<td>- Accurate assessment of the <strong>scope, scale and harm caused</strong></td>
<td>- Issue WHO Medical product alerts</td>
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*World Health Organization*
Global Surveillance and Monitoring System

**Technical Support**
- Laboratory Support
- Experts – Specialists
- WHO Rapid Alerts
- National Focal points access to WHO database

**Strategic Support**
- Validated reliable evidence
- Identifies vulnerabilities, weaknesses and high risk products
- Enables evidence and risk based policy
- Identifies areas for capacity building
WHO Global Surveillance System

✓ Available in English, French, Spanish and Portuguese
✓ 141 Member States trained
✓ 550 Regulatory personnel trained
✓ 18 large procurement agencies sensitized
✓ 1500 Suspect Products Reported
✓ Incidents occurred in 106 countries
✓ 20 WHO Global Drug alerts and numerous warnings
✓ 20 Workshops in all regions
✓ WHO Technical Assistance in over 100 Cases
Surveillance and Monitoring

How it works

Step 1
Reports of suspected substandard or falsified medical products from Public, Healthcare Professionals, Industry, Supply Chain, Customs, Police, Procurers, NGO’s to NMRA

Step 2
Assessment and response by National/Regional Medicine Regulatory Authority (NMRA)

Step 3
NMRA Focal point searches and reports to WHO Surveillance and Monitoring System database

Step 4
• Immediate technical assistance and alerts where appropriate
• Validated data informs policy, procedure, processes, investment and the work of the Member State Mechanism
Risk assessment and prioritization

Risks Types:
- Critical
- Associated
- Historic
Reports come from all WHO regions

WHO GSMS data; August 2017

WHO African Region: 42%
WHO Region of the Americas: 21%
WHO European Region: 21%
WHO Western Pacific Region: 8%
WHO Eastern Mediterranean Region: 6%
WHO South-East Asia Region: 2%
Medical products reported by therapeutic category

WHO GSMS data; August 2017

- Antiinfectives
- Antiparasitics
- Nervous system
- Alimentary tract and metabolism
- Genito-urinary
- Antineoplastics and immunomodulators
- Musculo-skeletal system
- Cardiovascular system
- Various
- Respiratory system
- Blood and blood forming organs
- Systemic hormonal preparations
- Dermatologicals
- Sensory organs
African Customs Seizure Angola

**Coartem – Anti malarial**
1,383,528 packs

**Postinor 2 – Emergency Contraceptive**
4,930 packs

**Vermox – Worming treatment**
1,534 packs

**Clomid – Fertility treatment**
36,550 packs

**Clamoxyl - Antibiotic**
744 packs
SF products and the threat of AMR

Key points and findings from the GSMS database

- Over 40% of the GSMS reported cases are antimicrobials—usually comprising zero or insufficient API.

- Substandard and falsified versions of 24 antimicrobials WHO-designated as critically important for human use are regularly reported from all regions.

- Of the reported antibiotics to the WHO GSMS, approximately 90% are listed by WHO as either critically or highly important antimicrobials.

- First and last line treatments are regularly reported for different diseases, including Malaria, Tuberculosis, pneumonia and Hepatitis C, (Rifampicin, linezolid, amoxicillin, sofosbuvir, etc.)
Falsified antibiotics in West Africa

- Wide spectrum antibiotic for treatment of infections e.g. pneumonia
- Falsified versions in tablets, syrup and injectable formulations
- Found in Nigeria, Cameroon and Cote d'Ivoire
- Falsified packaging also discovered
- Zero Active Ingredient
- WHO antimicrobial resistance watch list
- WHO essential medicines list
- Need for targeted market surveillance
Essential Drugs Programme logo drugs
West Africa 2013 to 2016
Importance of sub-regional networks
Case study: Substandard Cospherunat

Working in partnership is key

- Free of charge antimalarial discovered by a pharmacist in a public healthcare centre
- Investigation detected another fraudulently manufactured product: rapid diagnostic test for malaria (6000 tests distributed)
- Fraudulent manufacture of the product in France but distributed in 4 African countries (8 million capsules distributed)
- Importance of coordination with the laboratory and need for technical capacity
- Paris High Court declared the manufacturers had threatened human health due to non GMP compliant manufacture and the risk of AMR
Laboratory analysis indicate zero Active Pharmaceutical Ingredient

Available in public and private health care facilities

WHO pre qualified products

Genuine batch numbers

WHO alerts issued

Members of the public contacting rapidalert@who.int
West Africa - Smuggling
Falsified vaccines around the world

Source: National Ministries of Health Alerts and Govt Press releases

1995 Niger
- Meningitis
- 2500 Deaths

2015-2017
- Meningitis
- Shortage
- Public Supply

2010 Cameroon
- Meningitis
- High prices
- Stock Shortage

2010 China
- Rabies
- 1 Death
- 8 Arrests

2013
- Rabies
- 10,800 Doses
- 17 Arrests

2009 Philippines
- Influenza

2013-2016
- Tetanus
- Rabies
- Vaccine Clinics

2016 Bangladesh
- Yellow Fever
- Public procurement

2016 Indonesia
- Hepatitis B, Tuberculosis, Polio, Tetanus
- 23 Arrests
Falsified Yellow Fever Vaccine

- Falsified vaccines discovered in Bangladesh
- Local wholesaler supplied by a bogus employee pretending to work for the genuine manufacturer
- No antigens present
- Global WHO Alert Issued
Immunization Programme Indonesia

- Diptheria
- Pertussis
- Tetanus
- Polio
- HIB Vaccine
- Hep B
- Snake Venom Sera
- TB diagnostic Test kit
WHO Alerts 2017
Global Surveillance and Monitoring Alerts

• Avastin and Sutent. Cancer Medicines. Uganda
WHO Alerts 2017

Global Surveillance and Monitoring Alerts

Quinine Sulphate, Malaria, Democratic Republic of Congo
WHO Alerts 2017

Global Surveillance and Monitoring Alerts

Meningitis C Vaccine  Niger
Scope and Impact of SF products

A recognised threat to public health

- All products are targeted: all therapeutic categories, all price ranges, all formulations, any manufacturer type…
- Often difficult to detect by patients, consumers and even by trained professionals
- Harm caused is varied: therapeutic inefficiency to toxic contamination
- Manufactured and available in all countries
- Undermine efforts to strengthen health systems
- Weaken medical product markets and supply chains
- Reduce access to affordable, safe, efficacious, and quality products
- Contribute to antimicrobial resistance and impair treatment strategies
Using the data - Innovative approaches

Making use of the data to identify needs and develop practical tools

SMART PHONE APPLICATION
- National ownership of information flow
- Pilot studies in Tanzania and Indonesia
- Lack of efficacy as an early warning signal
- HCP → NRA → WHO

WHO PORTAL
- Report tool: streamlined information, Guidelines to establish the facts
- Search tool: Immediate validation of suspect products; duplicate detection; Technical guidance
- Training material
Vulnerabilities

Increasing the likelihood of SF products penetrating the supply chain

**Unregulated supply chains**
- Poor procurement practice: pharmacists and hospitals purchase products from unlicensed sources
- Weak post market surveillance

**Limited access to quality and safe products**
- Shortages and stockouts
- Price differentials
- Lack of awareness

**Poor Governance**
- Effective legal framework
- Porous borders
- Unethical behaviour and corrupt practices
Driving forces
A cross cutting issue

- Limited Access
- Weak Technical Capacity
- Poor Governance

SF
Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products

The existence of substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products is an unacceptable risk to public health. They affect every region of the world, and medicines from all major therapeutic categories have been reported, including vaccines and diagnostics. They harm patients and undermine confidence in medical products, healthcare professionals and health systems. WHO is working with stakeholders to minimize the risks from SSFFC medical products by collecting data and transferring knowledge and good practices to countries.

SSFFC Medical Products Activities

WHO Member state mechanism
Surveillance and monitoring system
Regulatory Strengthening and capacity building

RSS Feed Alerts
Any questions?

Thank you

Global Surveillance and Monitoring System

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