SUBSTANDARD AND FALSIFIED (SSFFC) MEDICAL PRODUCTS

Fake Anti Malarials – Start with the Facts
28th May 2015 - Geneva
International collaboration from a public health perspective on substandard and falsified (SSFFC) medical products
**PRIORITIZED ACTIVITIES**

- Guidance on risk classification and development of training material
- Creation of a Global focal point network
- Survey of track and trace technologies and field detection devices
- Report on WHO areas focusing on access to medical products
- Guidance on communication and awareness campaigns
- Socio-economic study of harm caused by SSFFC medical products
Globalization

• Inter-regional trade in pharmaceuticals requires inter-regional vigilance

Immediate Technical Support

• WHO support when requested in urgent cases and issue of drug alerts

Validated evidence for Policy Makers

• Accumulate a body of reliable evidence to influence policy and allocation of resources
SURVEILLANCE AND MONITORING - OBJECTIVES

**SCOPE**
- Medicines
- Vaccines
- Diagnostics
- API's

**HARM CAUSED**
- Public health
- Economic damage

**SCALE**
- Quantity
- Market size

**EXTENT**
- Geographic
- Social determinants

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PARTICIPATION

- System commenced roll out July 2013
- 94 Member States trained in 9 workshops
- Over 200 Regulatory personnel trained
- 18 large procurement agencies trained
- Over 700 Suspect Products Reported
- Incidents occurred in 75 countries
- 11 WHO Drug alerts and numerous warnings
REPORTING BY REGION

- African region: 252
- European region: 69
- Region of the Americas: 102
- Western Pacific region: 34
- Eastern Mediterranean: 177
- South East Asia region: 13

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**Reporting by Therapeutic Categories**

- Sensory organs
- Systemic hormonal preparations, excluding sex hormones
- Dermatologicals
- Blood and blood forming organs
- Respiratory system
- Musculo-skeletal system
- Cardiovascular system
- Various
- Antineoplastic and immunomodulating agents
- Alimentary tract and metabolism
- Nervous system
- Genito-urinary system; sex hormones
- Antiparasitic products, insecticides and repellents
- Systemic Antiinfectives

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57% of FALSIFIED antimalarial medicines reported to the database are artemisinin based.
SUBSTANDARD AND FALSIFIED (SSFFC) MEDICAL PRODUCTS

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SUBSTANDARD AND FALSIFIED (SSFFC) MEDICAL PRODUCTS
Importance of Networks

(West Africa 2012-14)
Falsified Artemether / Lumefantrine 2014/15

- Slide body text
- Calibri
- Min 20

- Innovator and generic
- Life saving medicines
- Essential Medicines
- WHO Pre Qualified
- Global Fund Logo
SUBSTANDARD AND FALSIFIED (SSFFC) MEDICAL PRODUCTS

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<table>
<thead>
<tr>
<th>Drug</th>
<th>Category</th>
<th>Quantity</th>
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<tr>
<td>Coartem</td>
<td>Anti malarial</td>
<td>1,383,528</td>
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<td>Postinor 2</td>
<td>Emergency Contraceptive</td>
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<td>Worming treatment</td>
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<td>Clamoxyl</td>
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**AFRICAN CUSTOMS SEIZURE 2012**
WHO Drug Alerts

- Validated Report (e.g., Lab analysis)
- Significant threat to public health
- Product in recent circulation
- Extended geographic risk
RELIABLE DATA = EVIDENCE DRIVEN ACTION

Regulatory Strengthening
- Prevention, detection and response
- Laboratory access and capability
- Post Market Surveillance

Awareness Raising
- Healthcare Professionals
- Patient reporting
- Supply chain actors

Stakeholder Engagement
- Customs and Police
- Civil Society
- Private sector
GLOBAL VULNERABILITIES

Unregulated supply chains
- Under resourced Regulatory Agencies
- Poor stakeholder engagement
- Poor procurement practices

Poor access to quality and safe products
- Stock shortages
- Price differentials
- Lack of awareness

Lack of effective law and criminal justice system
- Lack of deterrents
- Porous Borders
- High levels of corruption

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