SUBSTANDARD, SPURIOUS, FALSELY LABELLED, FALSIFIED AND COUNTERFEIT (SSFFFC) MEDICAL PRODUCTS

Global Surveillance and Monitoring Project

World Health Organization
Case Study – Postinor 2- Sub Saharan Africa
(levonorgestrel)

- Discovered at Lagos Airport
- Smuggled in mobile phone cases
- Zero active pharmaceutical ingredient
- WHO Prequalified Medicine
- Previously seen across Africa
- WHO International Drug Alert 2013
Case Study - Avastin *(Bevacizumab)* - USA

- Product does not include any API
- Two incidents of similar product reported in February and April 2012
- Product reached patients through clinics and hospitals in the US
- Supply chain stretches across 3 continents so far, passing through a web of wholesalers, brokers and dealers
Case Study – Coartem – West Africa
( Artemether /Lumefantrine)

- Reported by Global Fund and NGO
- Zero active pharmaceutical ingredient
- WHO prequalified product
- AMFm programme medicine
- Millions of doses seized by Customs
- Found in several W.African countries
- Subject of WHO Drug Alert May 2013
Project Rationale

Understand the Global Picture through validated evidence

Identify vulnerabilities in Health Systems and influence change

Provide technical support and capacity building to protect public health
PROJECT OBJECTIVES

Scale
• Quantity

Scope
• Medicines
• Vaccines

Extent
• Geographic coverage

Harm
• Public Health

Reduce the harm caused to Public Health by SSFFC medical products
METHODOLOGY - RAPID ALERT FORM

First Part: Alert

Second Part: Action

Reporting Person

Details of and discovery of product

Public health Impact; Lab Analysis

Communication; Dissemination

Investigation; Regulation
Incident

Risk Assessment

Suspect Product

How was the suspect product discovered?

Investigation

Internet Distribution

Payment Route

Comments Area

Notes and Article

Incident Closure

Rapid Alert Form Fields

Health Analysis and Impact

Dissemination and exchange

Classification

METHODOLOGY - DATABASE
## Interaction example:
**Rapid Alert and Focal Point**

<table>
<thead>
<tr>
<th>Time and date</th>
<th>Event</th>
<th>Action By</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time and date</td>
<td>Event</td>
</tr>
<tr>
<td>30.10.2013</td>
<td>At 13:45</td>
<td>RAF received by system</td>
</tr>
<tr>
<td>30.10.2013</td>
<td>At 13:47</td>
<td>Automatic response</td>
</tr>
<tr>
<td>31.10.2013</td>
<td>At 09:54</td>
<td>Initial Risk Assessment</td>
</tr>
<tr>
<td>31.10.2013</td>
<td>At 10:11</td>
<td>Supplementary Information requested to FP</td>
</tr>
<tr>
<td>31.10.2013</td>
<td>At 10:43</td>
<td>Response by FP</td>
</tr>
<tr>
<td>31.10.2013</td>
<td>At 15:58</td>
<td>Genuine manufacturer contacted</td>
</tr>
</tbody>
</table>
Trained Countries as of October 2013

[Map showing trained countries across the world with annotations for WHO regions.]
Operational Benefits

- Technical support
- Co-ordination
- Capacity building

Rapid Alerts
Guide Market Surveillance
Link similar incidents
Laboratory Analysis
Identify medicines most at risk
INTERNATIONAL CO-ORDINATION

Pakistan, Dec 2012, 50 Deaths from 2 Cough Syrups containing DXM
Aug 2012, India, API DXM Manufactured
Paraguay, Sept 2013, 46 Confirmed cases of ADR'S from flu remedies containing DXM
Identify supply chain weaknesses

Establish scale and scope of problem

Identify harm caused to public health

Identify vulnerabilities

Encourage multi-stakeholder engagement

**Strategic Benefits**

From **DATA**... to **VALUE**
Vulnerability

1. Current testing methodology does not identify this type of contamination

2. WHO have tasked collaborating centres to develop new testing techniques

3. Methodology will be published in International Pharmacopeia

4. Information circulated to manufacturers

5. Minimise the risk of future similar events
High Level Statistics

- 101 Incidents
- 199 Different Batches of medical products
- 99 Different Medical Products
- 84 "primary" Active Pharmaceutical Ingredients
- Reported from 41 Member States (57 MS Currently trained)
- 21 medical products involved serious adverse reactions
- 7 involved fatalities
- 4 WHO International Drug Alerts
All Therapeutic Categories reported by WHO region

- WHO European Region
- WHO Western Pacific Region
- WHO African Region
- WHO Region of the Americas
- WHO South-East Asia Region
- WHO Eastern Mediterranean Region
Top 5 Therapeutic categories

- Antineoplastic and immunomodulating agents
- Antiparasitic products, insecticides and repellents
- Genito-urinary system and sex hormones
- Antiinfectives for systemic use
- Alimentary tract and metabolism
Expected Outcomes

- Significantly improve our knowledge
- Enable evidence based policy making
- Protect Public Health
CONCLUSION

- Report suspicious medical products to WHO rapidalert@who.int

- Watch the WHO Essential Medicines website for Drug Alerts www.who.int