Substandard and Falsified Medical Products
Recent WHO Reports (November 2017)

http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en
Methodology

Specific request from the WHO Member State mechanism, with objectives focused on:

1. Need for Evidence
   - Literature review covering 10-years of publications
   - 100 publications that matched inclusion criteria

2. Assess the Extent of the Problem
   - Over 48,000 samples analysed
   - Quality surveys in 88 countries
   - Aggregation of observed failure rates

3. Making the Case for Attention and Investment
   - Multiplier method to estimate spending based on country pharmaceutical sales
   - Results grouped by income level of World Bank country classification
Socio Economic Study - Results

**Observed failure rate** of analysed medical product samples from low and middle-income countries

10.5%

**Estimated spending** on SF medical products in low and middle-income countries based on unweighted estimates of pharmaceutical sales

US$ 30.5 Billion
Impact Models Findings:

72,430-169,271

Deaths

31,000 - 116,000

Deaths

US$ 38.5 Million

Estimated deaths caused by SF antibiotics used by children under 5 with childhood pneumonia*

Estimated deaths caused by SF products used by patients suffering from malaria in sub-Saharan Africa**

Estimated spending on SF anti-malarials in sub-Saharan Africa

* University of Edinburgh
** London School of Hygiene and Tropical Medicine
Medical Products Reported by Therapeutic Category

WHO GSMS data; 2013-2017

Therapeutic Category

- 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

[Bar chart showing reported medical products by category]
Constrained access to medicines

- Availability
- Affordability
- Acceptability

Weak Technical Capacity
- Poor oversight
- Lack of resources
- Limited awareness

SF Medical Products
- Poor procurement
- Unethical practice
- Corruption

Poor governance practices
Prevention, Detection and Response
## Key Messages: Systemic Needs

<table>
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<tr>
<th>From global policy to local impact</th>
<th><strong>POLITICAL WILL</strong> is required to translate policy agreed at the global level to <strong>SUSTAINABLE ACTIONS</strong> on the ground with <strong>APPROPRIATE FINANCIAL AND HUMAN RESOURCES</strong></th>
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<td>Sound investment strategies</td>
<td><strong>STRENGTHENING REGULATORY CAPACITY AND SYSTEMS</strong> is a key step and <strong>GOOD INVESTMENT</strong> to safeguard the manufacture, distribution and supply of medical products</td>
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<td>Cooperation and coordination</td>
<td>Improved <strong>REPORTING SYSTEMS</strong> and greater <strong>TRANSPARENCY</strong> within and between countries is required, together with wide and <strong>EFFECTIVE MULTI STAKEHOLDER ENGAGEMENT</strong></td>
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Lessons learned, procurement and supply chain assessments, data harmonization initiatives
National integration

Public, program and private sector engagement and compliance is complex

Systeme d’approvisionnement des produits pharmaceutiques au Mali, 2008
Harmonization of data across the health system touches many areas

Global Public Goods (harmonized data tools and standards)

- Civil society (CHESTRAD, AEHIN)
- Country action & regional collaboration
- Digital health systems and interoperability
- Health systems monitoring
- Facility and community data
- Data analytics and use
- Global / country data and statistics
- Global / country data and statistics
- Logistics Management Information Systems
- RHIS / disease surveillance
- Facility surveys
- Community data
- Health workforce
- Health finance
- Quality of care / PHCPI

Country & regional platforms
Existing collaborative platforms
HDC Working Groups
Interoperability affects national, regional and global activities.
**Lessons learned**

Brief summary from published, pending and informal review

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<th>Literature review, data standard</th>
<th>Rapid review, procurement</th>
<th>Maturity models</th>
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<td>Legislation is diverse and a significant factor in design, compliance and interoperability; Standards for defining and describing medicines exist e.g., ISO, ICMER; Existing fragmentation of systems across countries will create complexity in investment strategies.</td>
<td>Political will around collective negotiations, harmonization is generally dependant on multi-sectoral approach; Most harmonization schemes started outside of the health sector, e.g., defence or agriculture; Predicted versus actual benefits were not always consistent, but generally outweighed costs.</td>
<td>Assessments document challenges with digital maturity in virtually all countries identified in publicly available assessments; Digital maturity factors did not address the life cycle of technology, level of investment or other resources required.</td>
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Thank you

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