

SUBSTANDARD AND FALSIFIED (SSFFC) MEDICAL PRODUCTS

Fake Anti Malarials – Start with the Facts
28th May 2015 - Geneva



World Health Organization



World Health
Organization

WHO MEMBER STATE MECHANISM

MANDATE



**World Health
Assembly 65.19
2012**

PURPOSE



**International collaboration from a public health
perspective on substandard and falsified
(SSFFC) medical products**

GOVERNANCE



**1 Chair
11 vice Chairs
Regional rotation**

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

WHY SURVEILLANCE AND MONITORING?



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

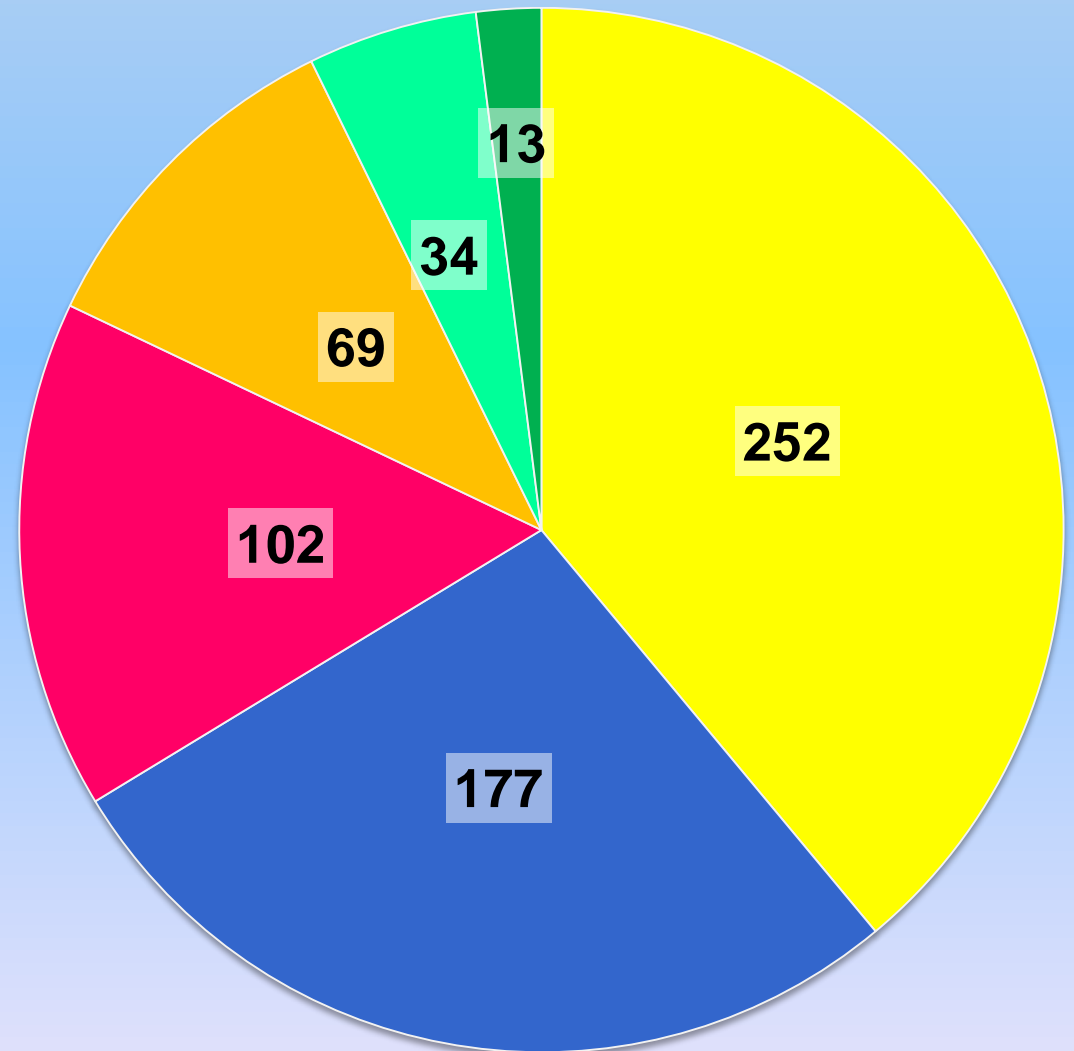
- Geographic
- Social determinants

PARTICIPATION

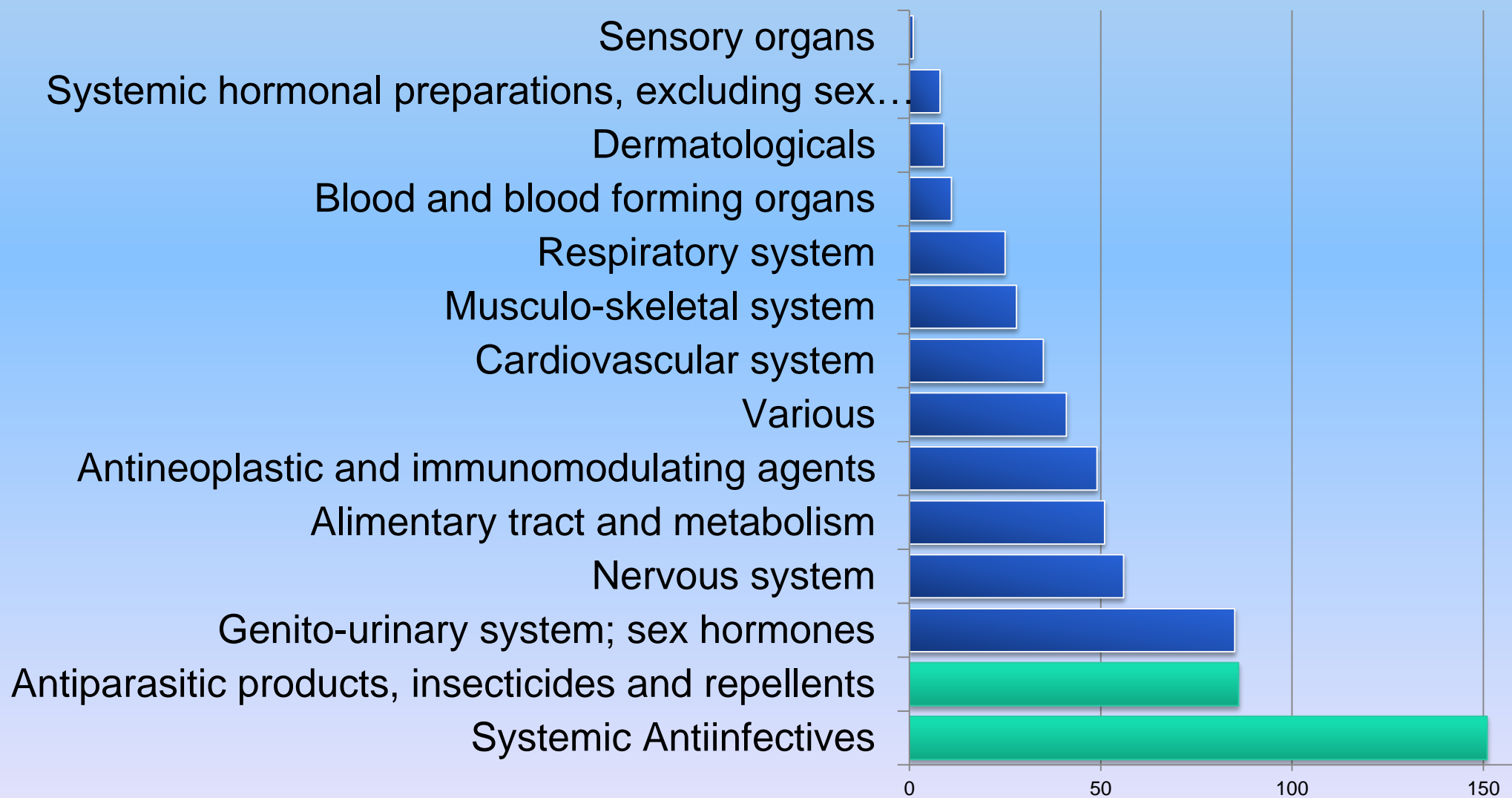
- 
- A world map with a light blue background. The landmasses are colored in shades of yellow and orange. A semi-transparent white box is overlaid on the map, containing a list of achievements. The box is positioned over the Americas, Europe, and parts of Africa and Asia.
- ✓ System commenced roll out **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

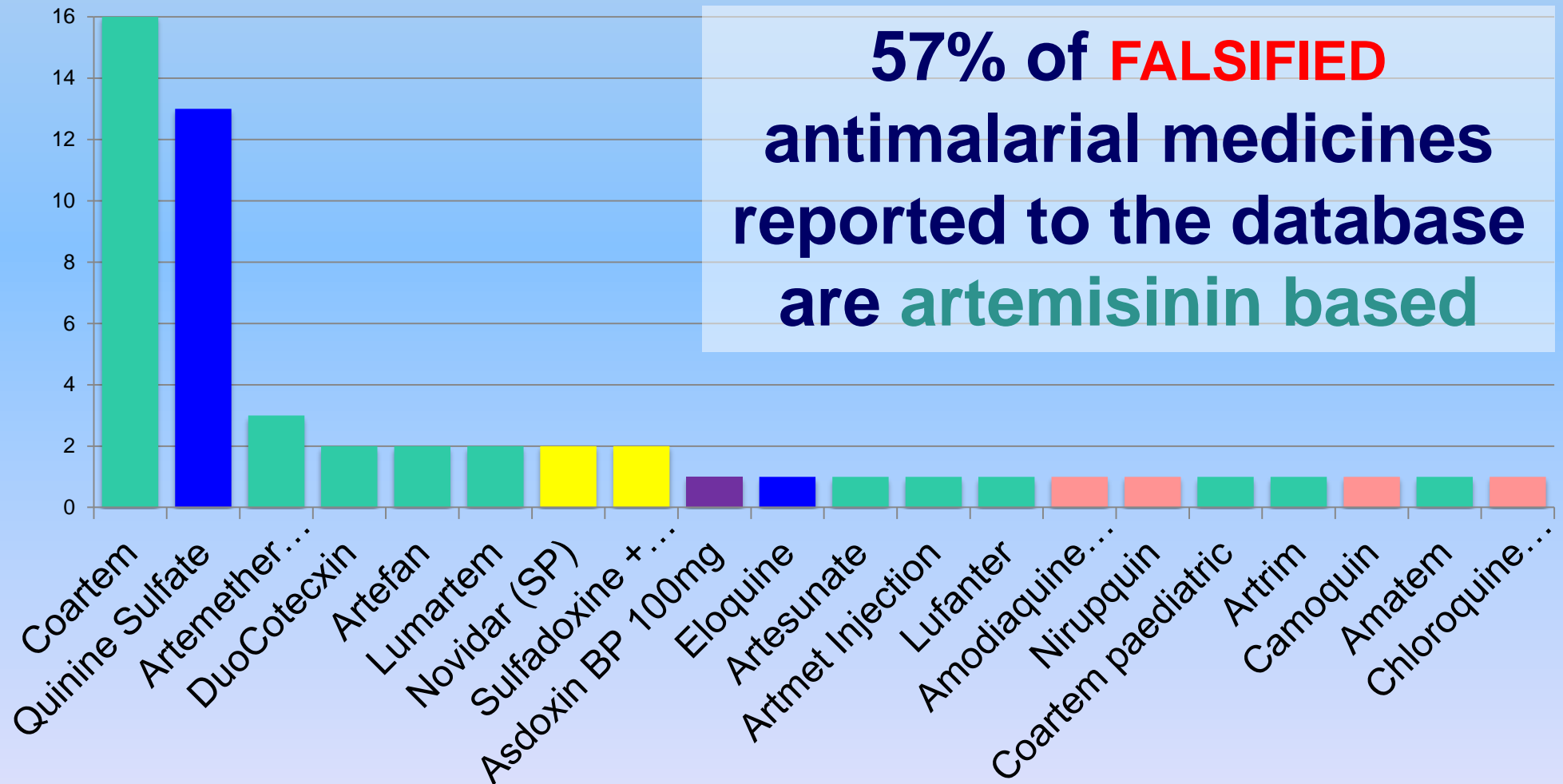
- African region
- European region
- Region of the Americas
- Western Pacific region
- Eastern Mediterranean
- South East Asia region



REPORTING BY THERAPEUTIC CATEGORIES



FALSIFIED ANTIMALARIAL BY PRODUCT NAME



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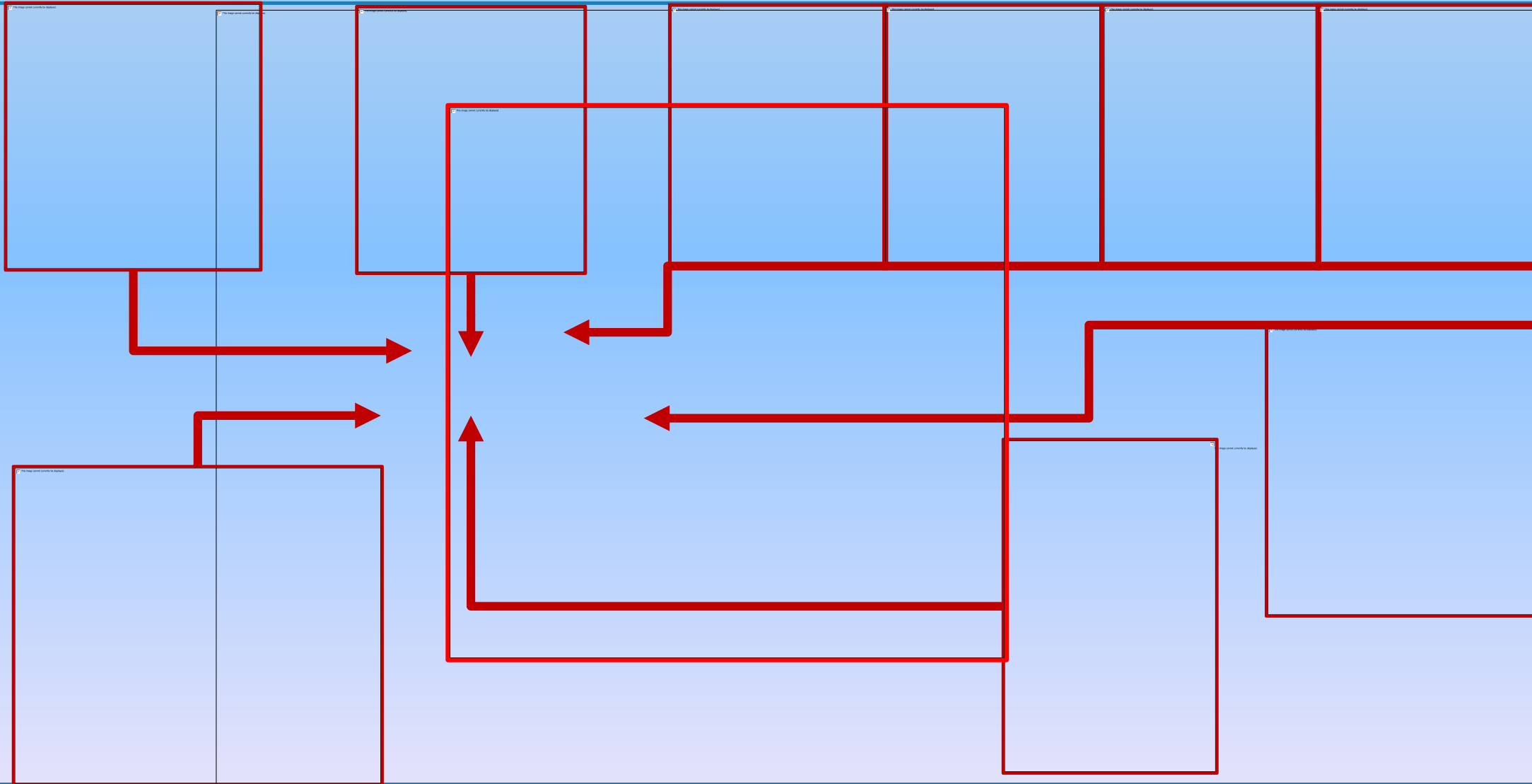


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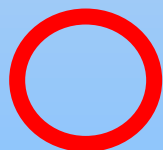
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Importance of Networks (*West Africa 2012-14*)

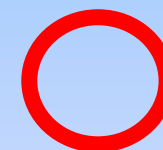
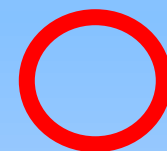


Falsified Artemether / Lumefantrine 2014/15

- 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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1.Prevention

2.Detection

3.Response

AFRICAN CUSTOMS SEIZURE 2012



Coartem – Anti malarial

1.383,528 packs



Postinor 2 – Emergency Contraceptive

4930 packs



Vermox – Worming treatment

1534 packs



Clomid – Fertility treatment

36,550 packs



Clamoxyl - Antibiotic

744 packs

WHO Drug Alerts

<http://www.who.int/medicines/publications/drugalerts/en/>

**Validated
Report**
(e.g.. Lab analysis)

**Significant
threat to
public health**

**Product in
recent
circulation**

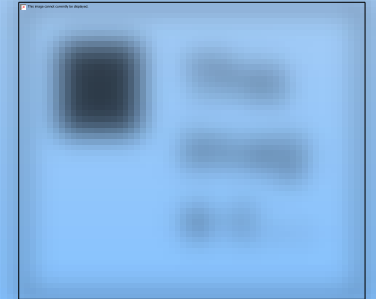
**Extended
geographic
risk**



RELIABLE DATA = EVIDENCE DRIVEN ACTION

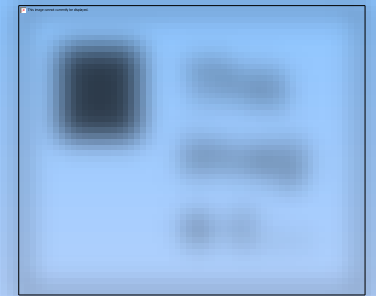
Regulatory Strengthening

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



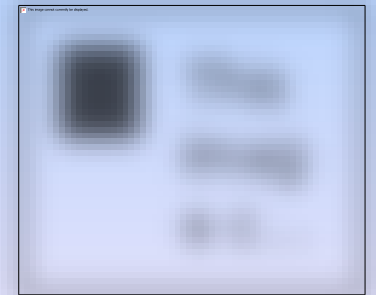
Awareness Raising

- 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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