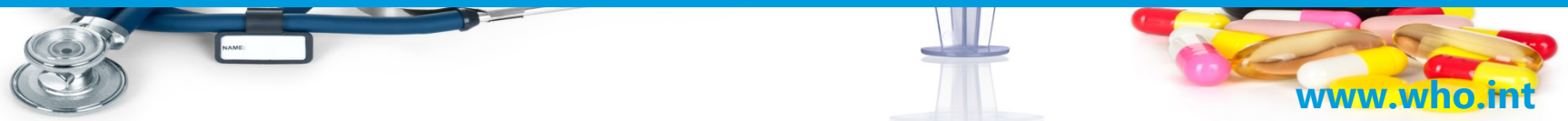
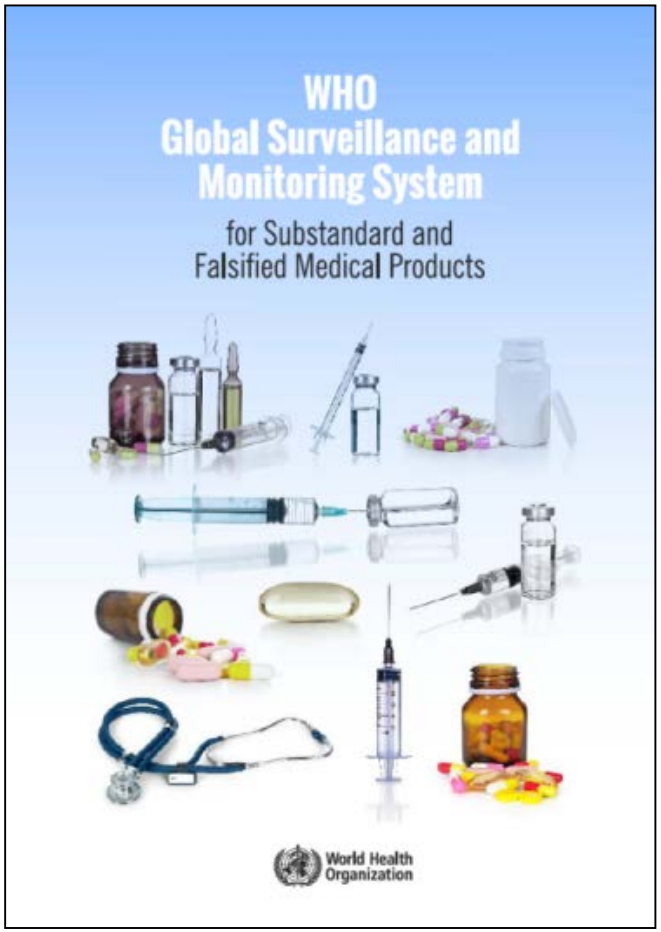
Substandard and Falsified Medical Products



www.who.int

Recent WHO Reports (November 2017)

http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/
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**

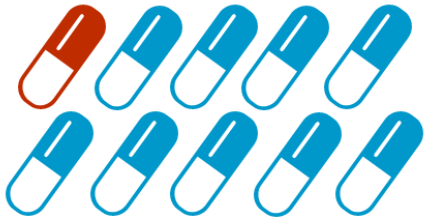
3. Making the Case for Attention and Investment

- **Multiplier method to estimate spending** based on country pharmaceutical sales
- Results **grouped by income level** of World Bank country classification

Socio Economic Study - Results

World Health Organization

10.5%



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

US$ 30.5 Billion

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

Socio Economic Study - Results

Impact Models Findings:

72,430-169,271 Deaths

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

31,000 - 116,000 Deaths

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

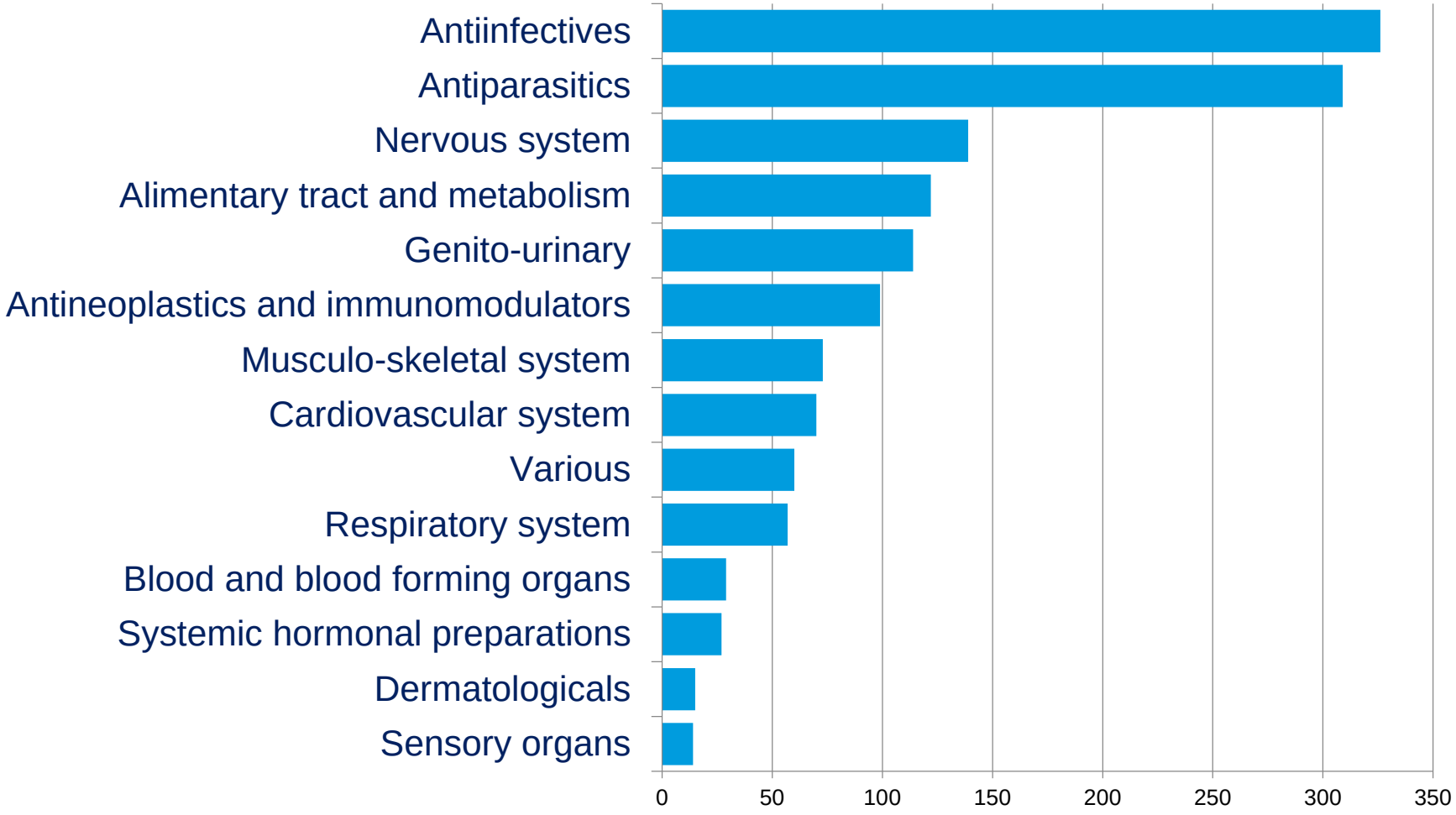
US$ 38.5 Million

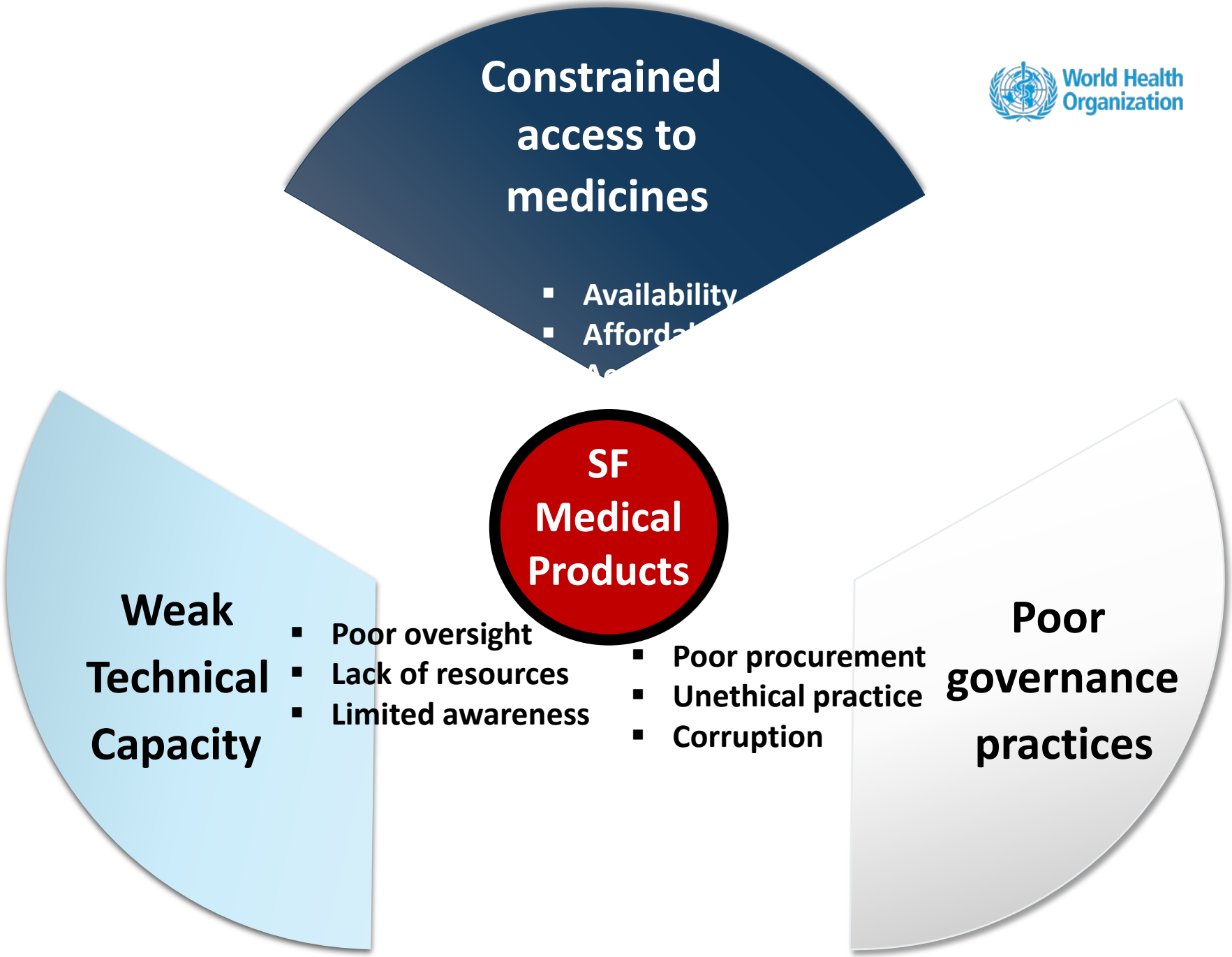
Estimated spending on SF **anti-malarials** in sub-Saharan Africa

* University of Edinburgh
** London School of Hygiene and Tropical Medicine

Medical Products Reported by Therapeutic Category

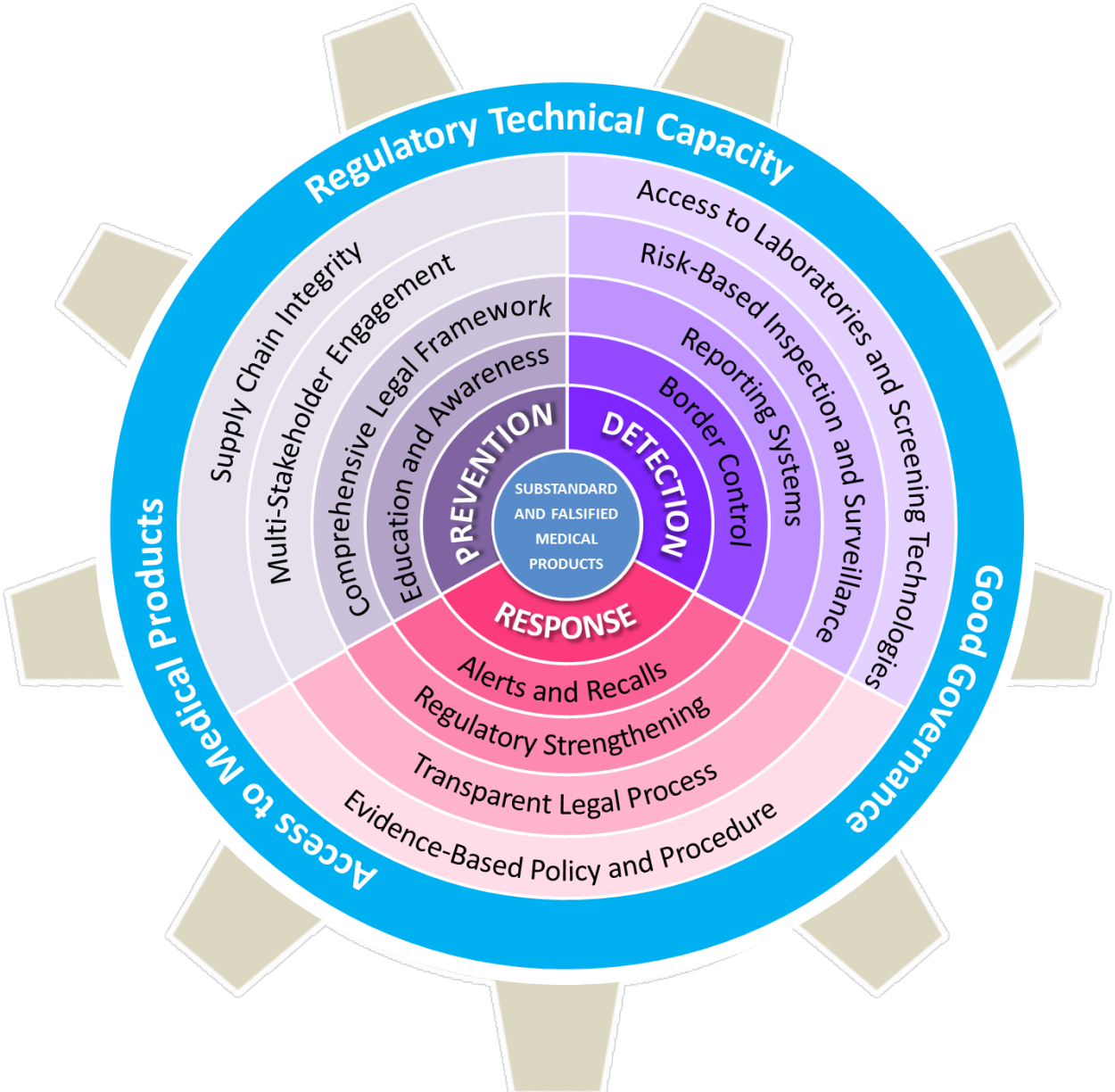
WHO GSMS data; 2013-2017




Constrained access to medicines
Availability
Afford
SF Medical Products
Weak Technical Capacity
Poor oversight
Lack of resources
Limited awareness
Poor procurement
Unethical practice
Corruption
Poor governance practices

Prevention, Detection and Response

World Health Organization

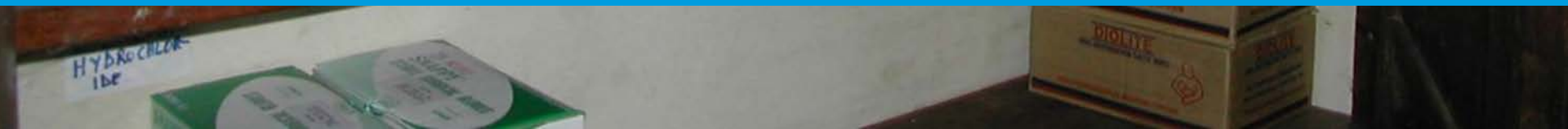


Key Messages: Systemic Needs

World Health Organization

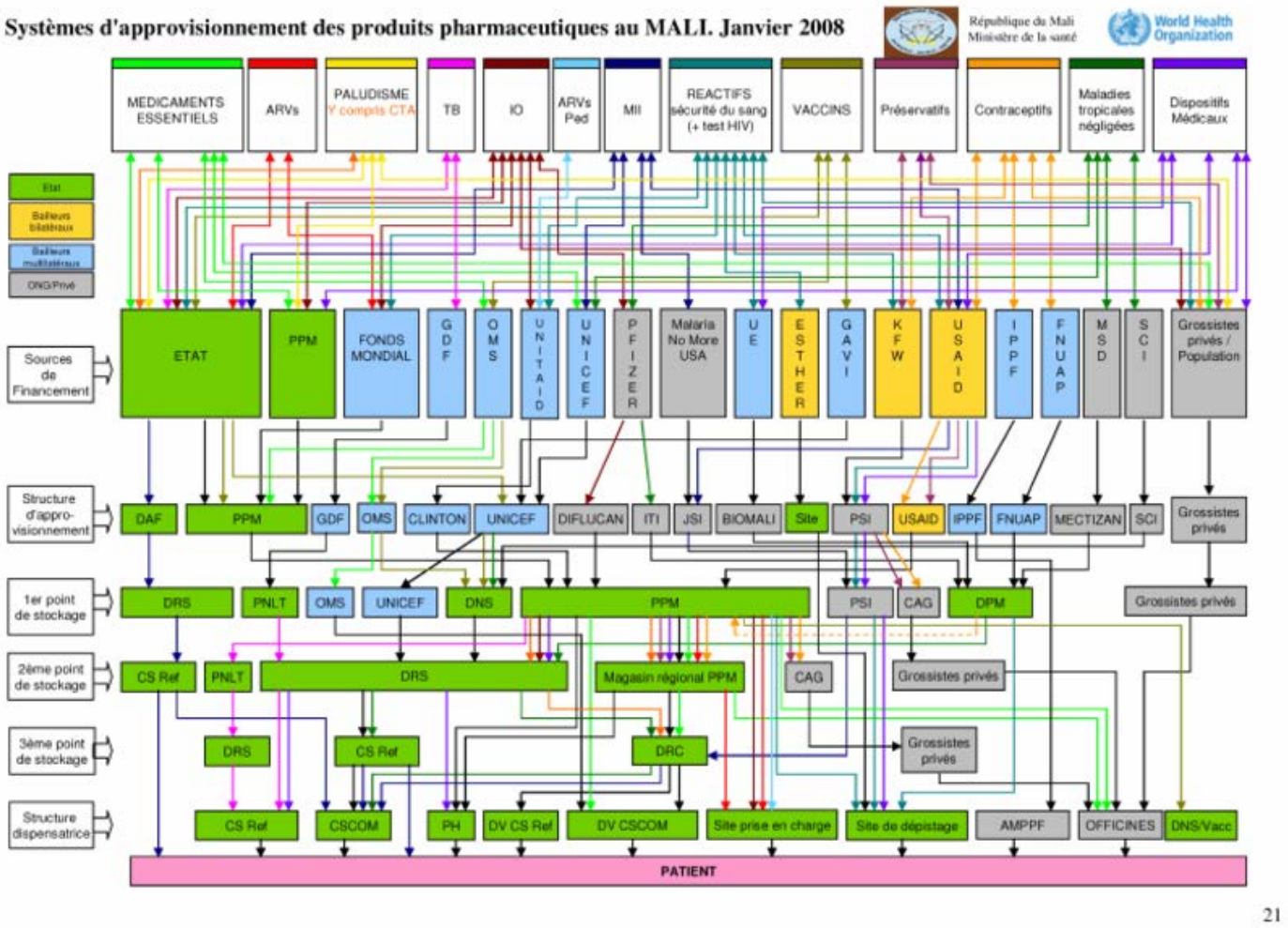
From global policy to local impact	**POLITICAL WILL** is required to translate policy agreed at the global level to **SUSTAINABLE ACTIONS** on the ground with **APPROPRIATE FINANCIAL AND HUMAN RESOURCES**
Sound investment strategies	**STRENGTHENING REGULATORY CAPACITY AND SYSTEMS** is a key step and **GOOD INVESTMENT** to safeguard the manufacture, distribution and supply of medical products
Cooperation and coordination	Improved **REPORTING SYSTEMS** and greater **TRANSPARENCY** within and between countries is required, together with wide and **EFFECTIVE MULTI STAKEHOLDER ENGAGEMENT**

Lessons learned, procurement and supply chain assessments, data harmonization initiatives



National integration

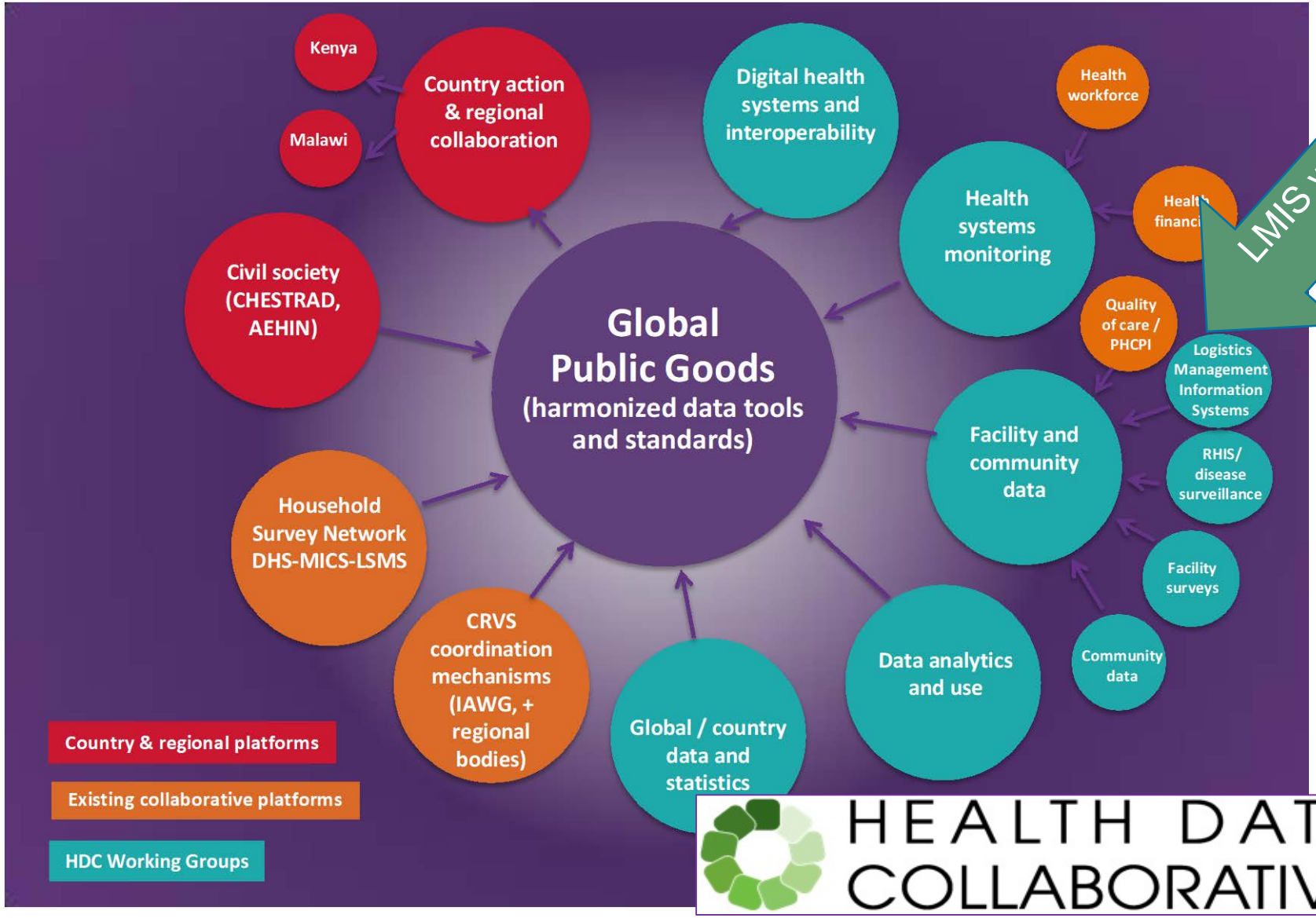
Public, program and private sector engagement and compliance is complex



Systemes d'approvisonnement des produit pharmaceutiques au Mali, 2008

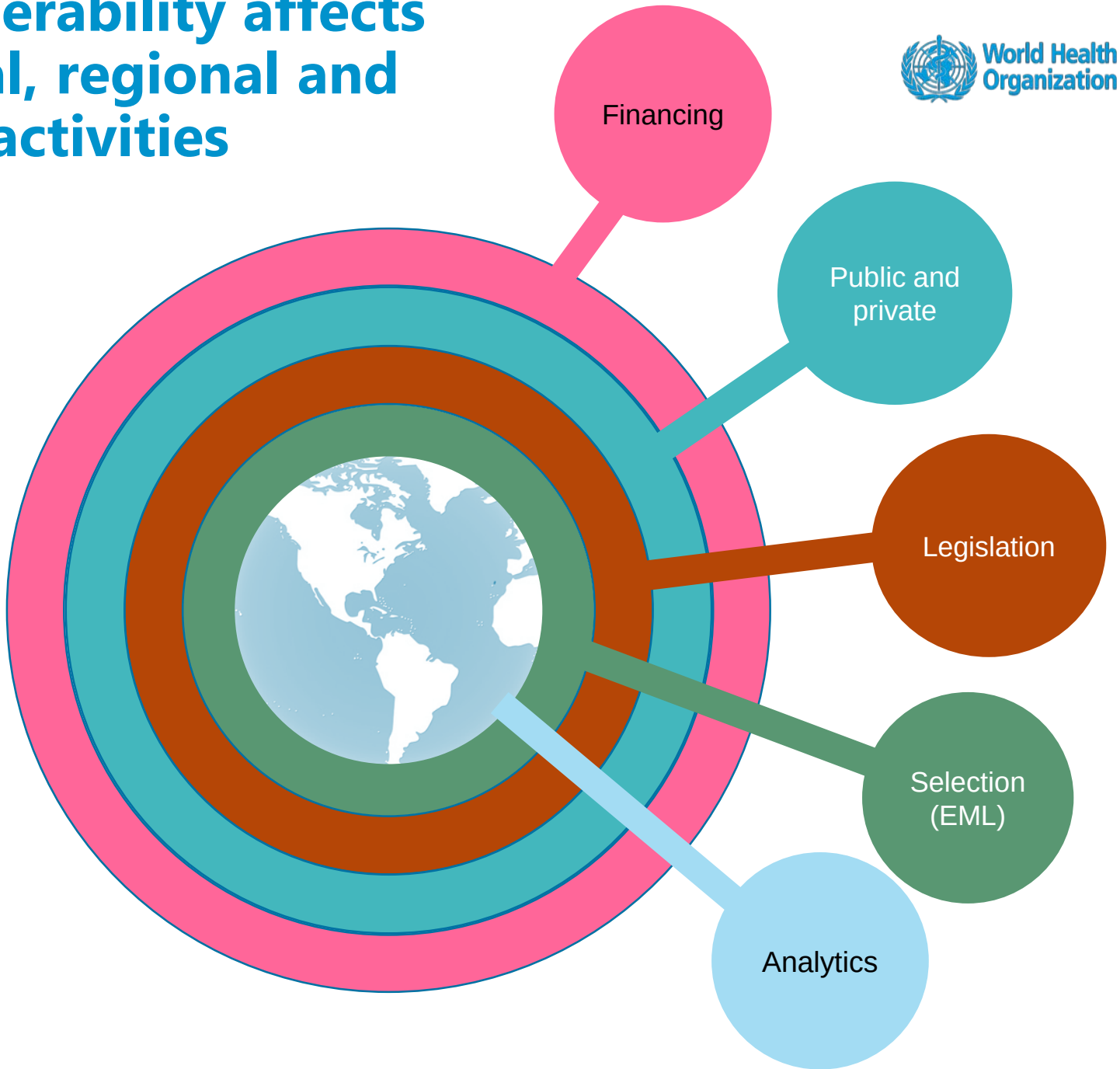
Harmonization of data across the health system touches many areas

World Health Organization



HEALTH DATA COLLABORATIVE

Interoperability affects national, regional and global activities



Lessons learned

Brief summary from published, pending and informal review

Literature review, data standard

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.

Rapid review, procurement

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.

Maturity models

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.

Thank you

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