



Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities

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Interagency Supply Chain Group

Informal Partnership of 16 Actors



Informal Working Structure





ISG Vision Statement

“Promote global health goals through better supply chain management.”

ISG Mission Statement

“The Interagency Supply Chain Group is a global collaboration forum to support country level supply chain improvement efforts.”



The Role of the ISG

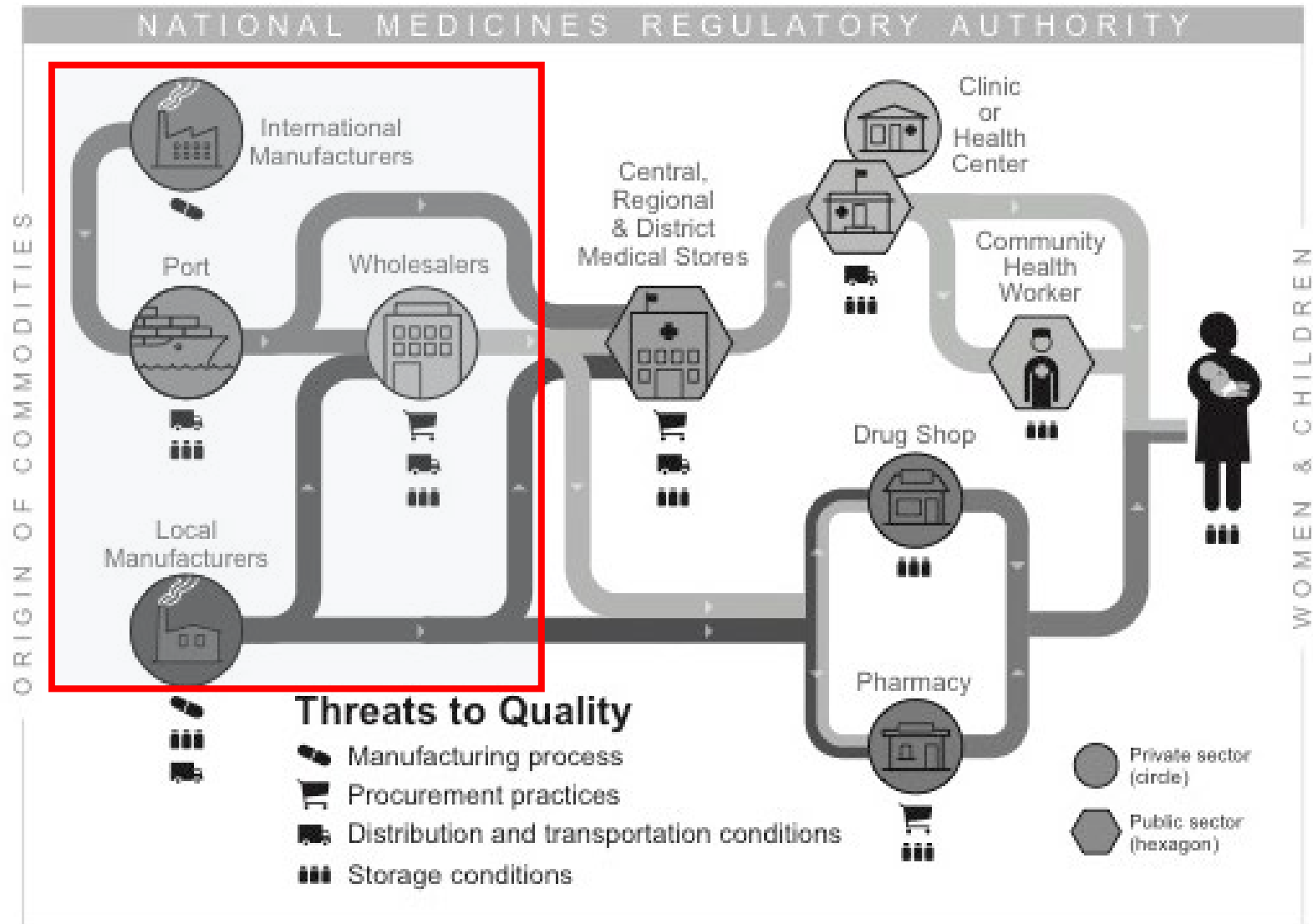
- The ISG coordinator functions as a neutral and independent secretariat vis-à-vis the ISG and does not speak on behalf or represent the host agency.
- Identify and engage with major donors and financiers of supply chain investments. Foster collaborative partnerships and networks between donors and agencies with the ISG.
- Facilitate information sharing and intelligence gathering for the ISG and create an environment of information transparency, trust and visibility.
- Ensure in-country bottlenecks related to advancing national supply-chain system strengthening efforts that may require greater support or interventions from global or regional level are brought to the attention of the ISG for resolution.
- **Financed by the Bill and Melinda Gates Foundation. Prior support from NORAD and Gavi**



What is the ISG trying to address?

- Investments that are fragmented, could be better aligned
- Proliferation of data technologies, information systems, performance indicators
- Encourage collaboration and investment in private sector
- Serious consideration of future PSM systems and models is urgent.
- Efforts to harmonize systems need to be both strategic, operational, and require incentives.
- Investments on the part of countries is considerable, but could be better quantified and should move to sustainability

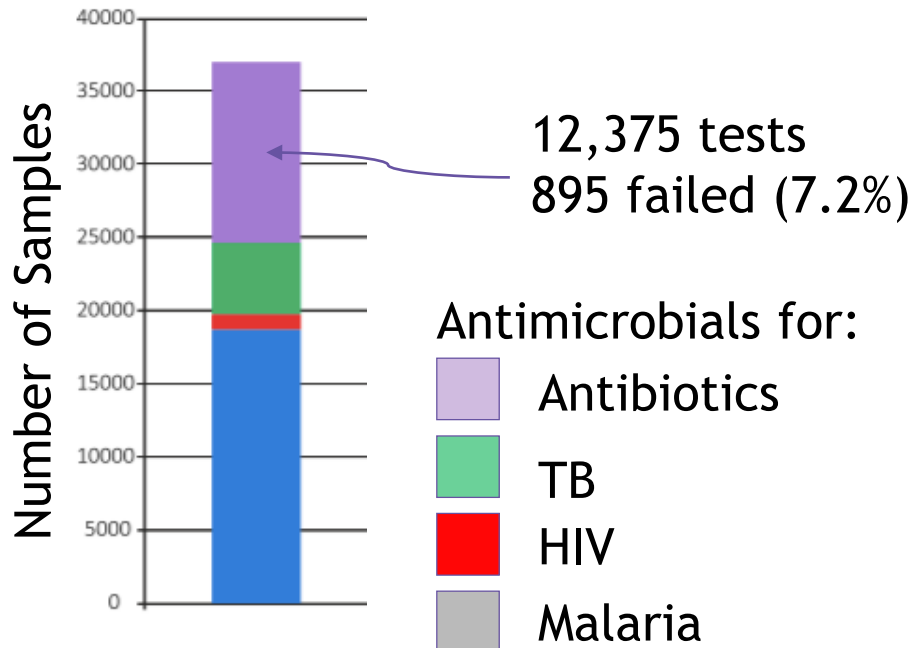
Supply Chain: Where are threats to Quality?



Substandard & Falsified Products (SFs)

Evidence for:

- WHO survey of 100 published studies of medicine quality in 88 LMICs (2017)
- Finding: ~10.5% samples were substandard or falsified
- Testing: MiniLab or HPLC

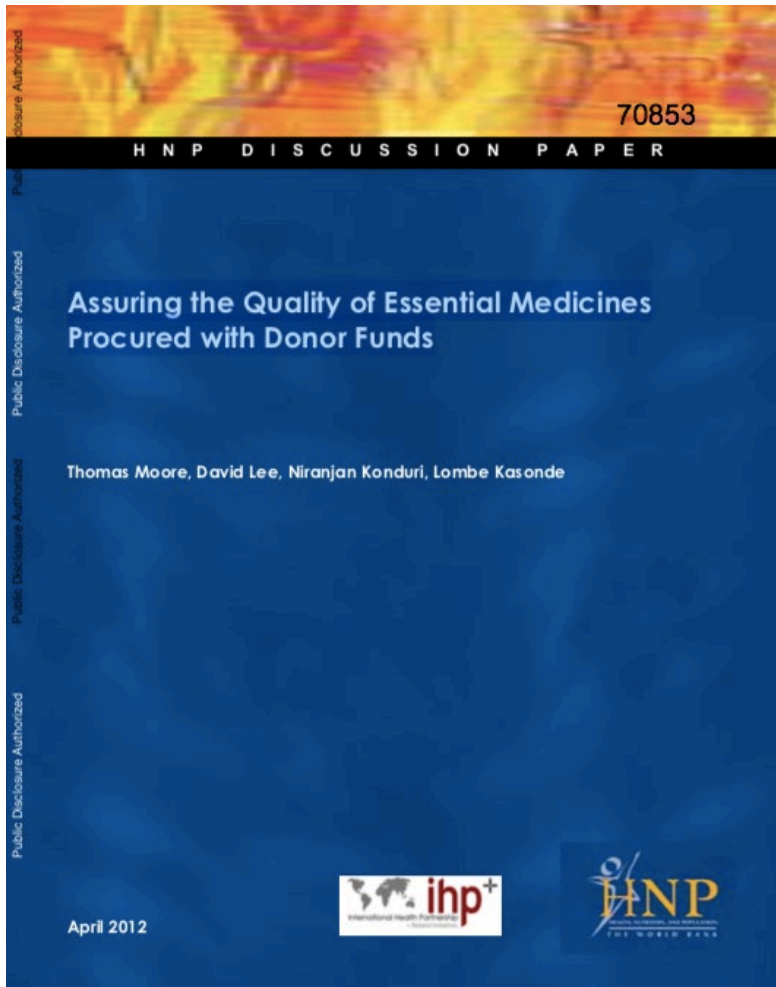


Preventing:

- Reporting to Global Surveillance and Monitoring System, GSMS For 2013-2017: 244 reports for antibiotics



Assuring the Quality of Essential Medicines Procured with Donor Funds (April 2012)



... beyond the WHO Prequalification of Medicines Program and the Global Fund Expert Review Panel, which focus only on medicines for treating HIV/AIDS, tuberculosis, and malaria (ATM).

Commissioned as part of an Interagency Pharmaceutical Coordination Group (IPC) workstream



Roadmap to Assure Quality Essential Medicines (suggested in 2012)

- Development of risk-based categorization of (non-ATM) essential medicines
- Harmonization of quality assurance policies
- Harmonization of MQAS-based quality assurance system assessment tools
- Phased-strengthening of NMRA-QA capacities
- Information sharing



Background

- Request for support from the GFF Investors Group, March 2017
- ISG Meeting, Geneva, June 2017 [hosted by Gavi]
- ISG Meeting, London, September 2017 [hosted by DFID]
- Small donor group convened [DFID, Dutch MoF, GAC, KFW, NORAD, Sida, USAID, BMGF], October 2017
- Survey administered to bilateral and multilateral partners, October 2017 [jointly developed by WHO, UNFPA, USAID]
- WHO IPC Meeting, Geneva, December 2017
- USP engagement, February 2018 [Supported by USAID]
- Essential elements of a quality framework for donors, February, 2018, [TGF, UNICEF, WHO]
- ISG Meeting, Washington DC, March 2018 [Hosted by World Bank]
- WHO IPC Meeting, Geneva, December 2018
- WHO Feedback, [RHT, MVP], February 2019
- Final Version, March 2019

Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities

November 2018

A. Background

This document outlines the set of agreed guiding principles for the quality assurance of essential medicines and other health care commodities, which donors will require of countries, bilateral, multilateral and third-party procurers when they use donor funds to purchase essential medicines. These agreed guiding principles would help ensure consistency in requirements for quality standards of essential medicines procured with donor funding and will provide uniformity in the application of these standards. These principles have important considerations, including that manufacturers who invest in assuring that their products meet international quality standards, are not disadvantaged, but are instead incentivized to remain in these markets.

Donors realize that a disease cannot be treated with a poor-quality product and should not be treated with a product whose quality is uncertain. Any amount of poor-quality medicine is unacceptable because it increases morbidity and mortality¹, jeopardizes the credibility of health services and programs, and in the case of antimicrobials contributes to the development of antimicrobial resistance. In addition, one cannot extrapolate the clinical trial experience (in which quality assured products are used) to the larger patient experience if non-quality assured products are used.

This set of agreed guiding principles provides the framework to help assure the quality of finished pharmaceutical products that are procured with donor funds.

**This document sources content from the UK Department for International Development (DFID) Quality Assurance Policy for Reproductive Health Commodities, Jan 2013*

¹ Impact of poor-quality medicines in the 'developing' world Trends Pharmacol Sci. 2010; 31(3): 99-101.

Objectives for Harmonization of Donor QA

Phase 1: QA Principles

Principles

Create guiding principles for quality assured standards to be applied when donor funds are used to purchase essential medicines

Backup Plan

Plan for when no QA commodities are available

Agreement

Agreement among the donors, and ultimately inclusion in contracts/grants with LMIC governments

Phase 2: Verification

70% of donor survey responses support development of a harmonized accountability mechanism, but few donors have such a mechanism.

Principles for Quality Assurance



Meets international standards of **manufacturing** quality (i.e., ICH or WHO), assessed independently by qualified experts

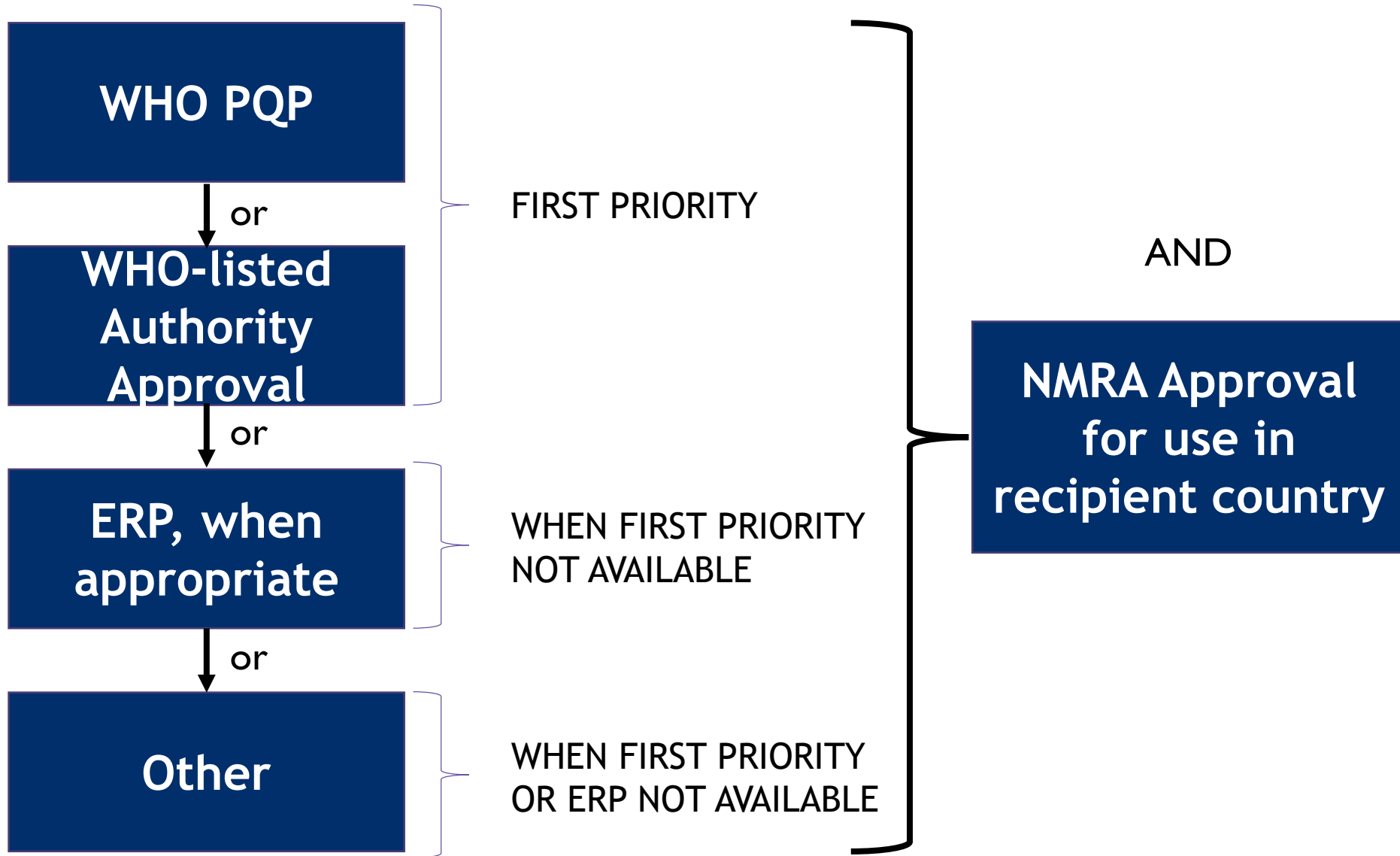


Assured compliance with international **cGMP** (i.e., ICH or WHO) after site inspection by independent experts



Assessed by an organization that can impose significant **consequences** for non-compliance

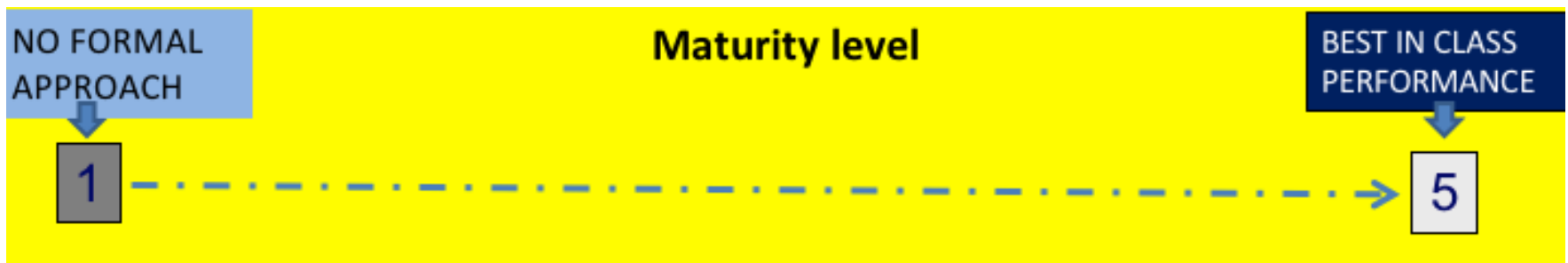
“Acceptable” Product for Procurement





WHO-Listed Authority: National Medical Regulatory Authorities (NMRAs)

- NMRA assures:
 - quality, safety, and efficacy of medical products
 - relevance and accuracy of product information
- WHO Benchmarking Tool - to assess **maturity** of NMRAs
- WHO tool to measure **reliance** of NMRAs?
- What is the decision making process?

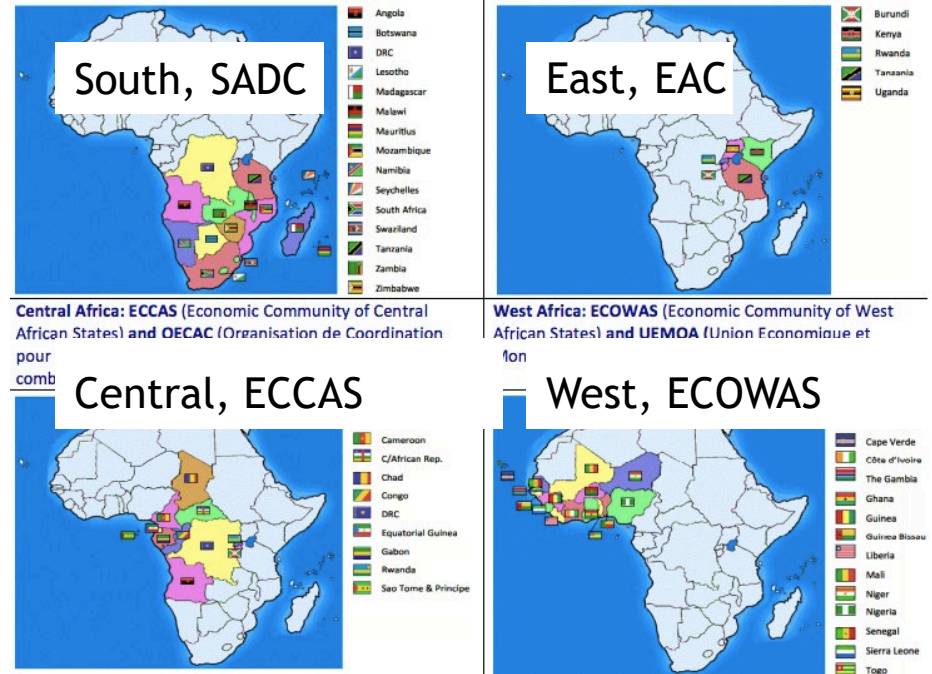


National Medical Regulatory Authorities (NMRAs)

Mechanisms to improve fragmented regulatory systems:

African Medicines Regulatory Harmonization (AMRH) Initiative working through Regional Economic Communities (REC)

- Harmonized guidelines for medicines registration
- Joint dossier assessment





Ongoing Activities

- Uptake and adoption by donors
- Advocacy (EU Health Experts, WHA 2019)
- Define a verification/accountability process.
- Consider consequences for manufacturers (competition, monopoly).
- Consider how to keep small, low cost manufacturers in the market.

Principles provide:

Important credibility for the use and spend of Overseas Development AID (tax payer \$\$) on essential medicines and other health commodities.



Considerations for donors

Setting milestones that will trigger progress toward implementation of the different principles.

- Legislate the principles or at the minimum, consider appending to supplier contracts
- Agreed and phased transition with suppliers, wholesalers, SMAs to mitigate supply disruption
- Expansion of the ERP/D and other risk assessment mechanisms to other medical products of relevance to donor procurement and / or funding
- Agreed expansion of scope of PQ to other medical products of relevance to donor procurement and / or funding



Considerations for donors

Setting milestones that will trigger progress toward implementation of the different principles.

- Availability of reference list of wholesalers compiled through a transparent and robust procedures
- Expansion of the list of SRAs/WLAs based on agreed concepts taking into consideration of a robust regulatory system and competence
- Establishment of mechanisms to ensue medical products evaluated through international/regional mechanisms (PQ, SRA, WLA, ERP/D, etc.) are authorized for use at the national level
- Incentives structures for national governments (utilization of basket resources)



Questions and Discussion

Issues:

1. What does transition look like & what risks to consider?
2. Incentive structures for recipients of ODA vis-a-vis single and multi-donor funding mechanisms
3. What role can we play in advocating for positive change with donors, Governments, regulatory and procurement agencies?
4. Medicines quality working group at the RHSC [civil society, donors, Government, manufacturers, multilateral partners]

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