

Gates Foundation Strategy on Substandard and Falsified Medical Products

Murray M. Lumpkin, M.D., M.Sc., DTM&H
Lead for Global Regulatory Systems Initiatives
Gates Foundation
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Context:

Substandard and Falsified Medicines at GF



Foundation has had a long time focus on regulatory systems



Only recent focus on SF in last two years with pilots, etc.

Continue to hear that SF is one of the biggest public health problems
In AMA treaty

Undercuts medical products leading to lack of efficacy,
morbidity/mortality, antimicrobial resistance, undermines confidence



Our Internal Vertical Disease Programs like MNCNH beginning to invest



This presentation will focus on current areas of emphasis

GF SF Focus Areas

Goals

- **Strengthen NRAs and national systems**
 - Towards ML3 on market surveillance and control module (lowest implemented of all GBT modules)
- Sustainably **reduce the prevalence of SFMPs** in the foundation's focus geographies and PST commodities

Support national plans

Develop/ update national plans to fight SFMPs, **anchored in NRAs**

- Burkina Faso
- Ethiopia
- The Gambia
- Guinea
- Kenya
- Nigeria
- Togo (via Brazzaville Foundation)

Provide transnational / continental global support

Continental plan on SFMP with AUDA-NEPAD

AMRH SF steering committee (to AMA)

Work w/ WHO SF team re national plans, **MS Mech**, etc.

Support technologies to fight SFMPs

Development of decision dashboard for screening and detection technologies

Development of DEG detection technology

Work with GH Labs on Pillscan sustainability

Support Internal Disease Program Strategies

Work with MNCH team on SF/MNCH projects in Nigeria and Kenya



Deeper Dive on Areas of Emphasis

- 
- Support national plans
 - Provide transnational/continental/global support
 - Support technologies to fight SF
 - Support internal disease program strategies

Support National Plans

- Spur intersectoral cooperation (NRA in lead) to organize activities
- Bolster market surveillance and control module towards ML3/ML4/WLA
- Metrics for benchmarking and performance monitoring
- Highlight critical gaps and implementation needs
- High level government sign-off, rollout, execution, monitoring

Nigerian Example

- Major action on regulation of informal markets in Nigeria – seized 130 truckloads of meds (IV oxytocin, gentamicin, misoprostol, antimalarials, etc.), review 11000 vendors, now working to register/license, enabled by national plan/whole of government work (national security, etc.)

TVC NEWS

TVC BREAKFAST

WAR AGAINST ILLICIT DRUGS

NAFDAC SHUTS OVER 11,000 SHOPS IN LAGOS, ABIA, ANAMBRA STATES

07:06

ENTERTAINMENT

AYRA STARR ADMITS BEING A FORMER ONLINE TROLL

Support Internal Disease Program Strategies (SF/MNCH Work)

- Support NRA work re market sampling/testing on priority public health commodities
- Better understand SF landscape, gaps in systems
- Support NRAs to take action on SFs and problematic manufacturers
- Malaria, HIV, other disease areas in the future TBD

Provide Transnational/Continental/Global Support

- Support new SF technical committee under AMRH / AMA
- Support priority areas
 - **MSM** – Support African NRA participation
 - **SF champion / potential SF trust fund** (head of state level)
 - **Data systems** reporting systems, databases, data synthesis, NRA/AMA interface
 - **Tiered manufacturing** (reliance/verification procedures)
 - **Regulatory-procurement interface** (factor quality into selection)
 - **Country + continental manufacturer “watch” lists** for repeated compliance issues (based on recall data)

Support Technologies to Fight SFMPs

- Identify helpful mix of detection technologies for LMICs
- Support deployment
- Piloting Pillscan detection device in Kenya, considering expansion
- WHO guidance on detection devices
- Detection device dashboard/low cost detection methods for diethylene glycol, etc.