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PROMOTING THE QUALITY OF MEDICINES



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Collaborating and Leveraging Resources to Strengthen Drug Quality Assurance: Case of Guyana

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Current Status

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	Institution		
	FDD	MMU	NMCP
Analysis Capabilities	L1, L2, L3	L1, L2	L1, L2
Sector	Public, Private	Public	Public, Private
Information Flow	1-way	1-way	1-way

Example of GAPS

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- Systems Thinking:
 - Flow of information between stakeholders
- Technical Capacity:
 - L3 analysis
 - Insufficient field staff to perform L2
 - Limited MQM coverage of private and informal sectors in endemic regions

Resolutions

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1. Provide training in collaboration with FDD and MMU
 - Increase number of qualified staff to perform L2 analysis by including Pharmacy Assistants
 - Expand MQM coverage
 - Endemic regions
 - Private and informal sectors
 - Revise protocols for information flow for data reporting to FDD and sharing with NMCP and MMU

Resolutions

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- 2. MOU between FDD, NMCP and MMU to redefine roles and responsibilities to ensure malaria medicine quality
 - Enhance “Systems Thinking”:
 - 1. NMCP receive medicine quality data on all market sectors
 - 2. FDD receive information on malaria transmission and outbreaks
 - Technical Capacity
 - 1. Staff flexibility in performing L2 analysis

Implementation of Three-level Approach in Guyana

<i>Regulatory Framework</i>	
• Regulatory framework with appropriate legislation	
– Legal provisions for sampling and testing samples of medicines on the market	
– Regulations to deal with non-compliant medicines	
– Effective recall procedure to remove products from market	
– Authority to implement corrective actions	
• Periodic review of strategy and surveillance program	
• Ability to enforce regulations	

Implementation of Three-level Approach in Guyana

<i>Technical Capacity</i>	
• Functioning OMCL or access to a qualified lab	
• Evidence-based data on the quality of medicine obtained via MQM or a medicines quality study	
• OMCL - Quality Management System	
• OMCL - Infrastructure and Equipment	
• OMCL - Reference Standards/materials & reagents to perform L3 analysis	
• Country equipped to perform L2 analysis in field and OMCL	
• Current MQM sampling protocols	

Implementation of Three-level Approach in Guyana

<i>Systems Integration</i>	
• Integration of national activities (i.e., NMCP, MRA and OMCL) focusing on malaria	
• MQM program covering both public and private sectors	
• Support decentralized MQM activities at national level	
• Utilization of organizational data to increase efficiency of approach	

Questions

Thank You

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