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PROMOTING THE QUALITY OF MEDICINES



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Capacity of AMI Countries to Implement the Three-level Approach for Ensuring Malaria Medicine Quality

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Three-Level Approach for Quality Control

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- ▶ The use of three levels for quality assessment of medicines, using methodologies
 - Different from each other
 - Of increasing complexity
 - Complementary to each other
- ▶ Level 1 (L1): Visual and physical inspection
- ▶ Level 2 (L2): Basic analytical tests
- ▶ Level 3 (L3): Compendial/validated tests

Characteristics of Three Levels of QC

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Level	Type of Analysis	Type of Test
1	Visual & Physical Inspection	Visual: -Labeling and packaging properties Physical: -Appearance, conditions and physical characteristics of medicine
2	Basic Tests	- Disintegration - Colorimetric reactions - Thin Layer Chromatography (TLC) - Other analytical techniques
3	Compendial or Other Validated Tests	According to registration specifications

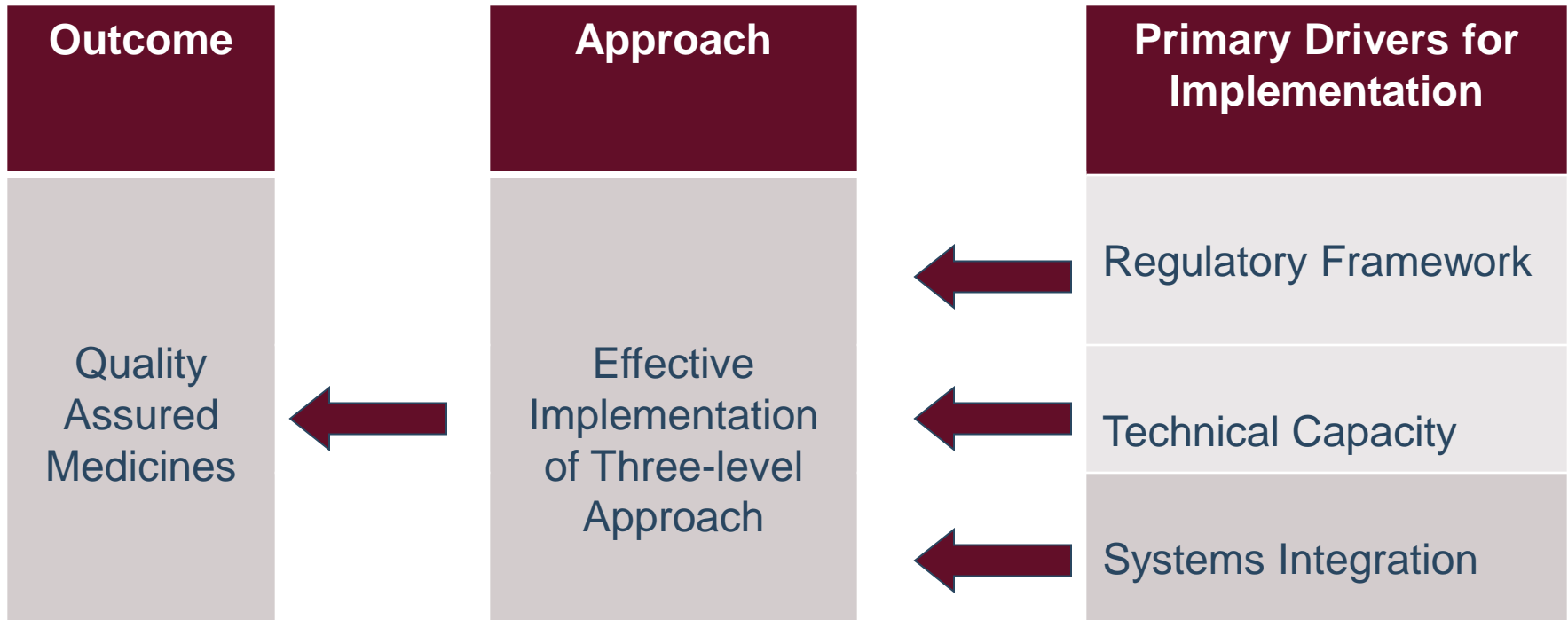
Benefits of Implementing the Three-Level Approach

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- Increases number of medicines evaluated for quality
- Expands geographical coverage of Medicine Quality Monitoring activities
- Provides ready data to stakeholders for implementation of corrective actions
- Maximizes human and financial resources

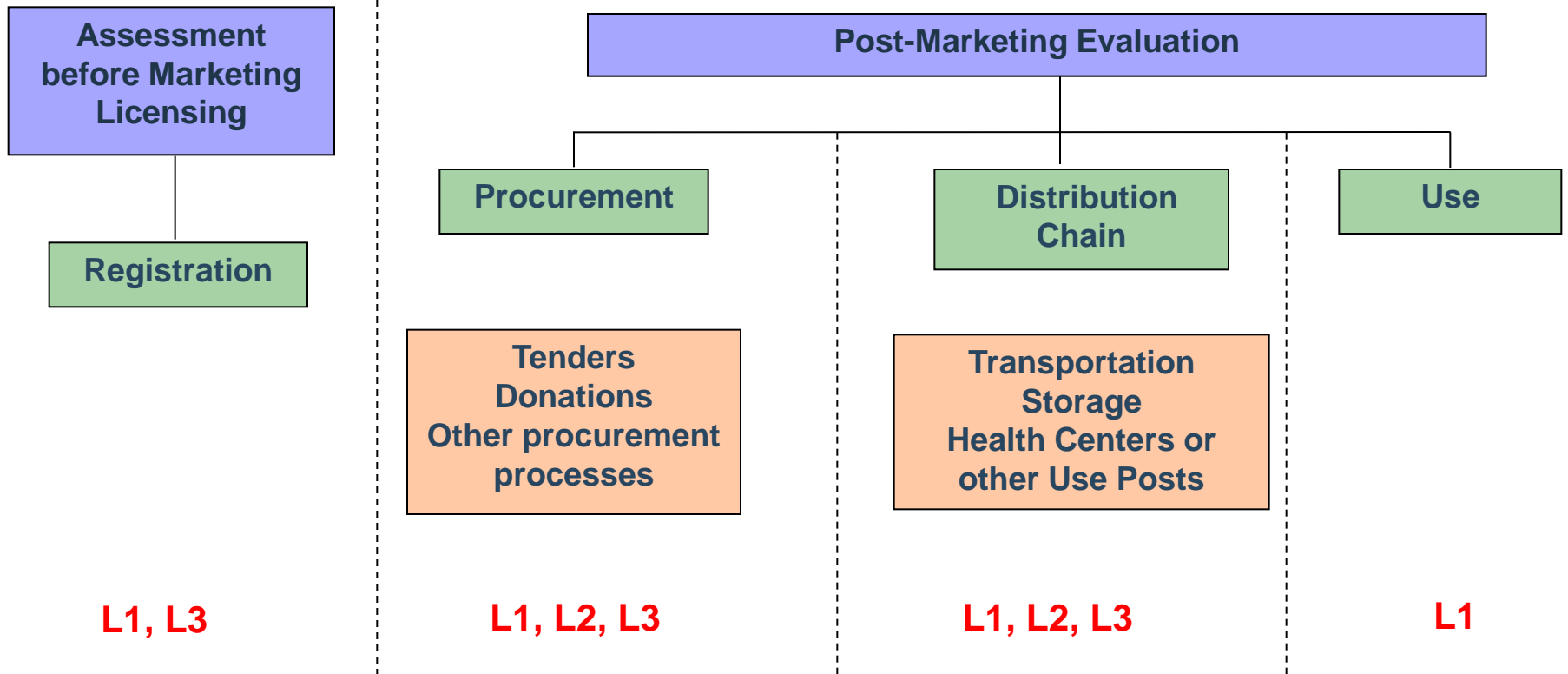
Public Health Rationale

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Three Level Approach within the Quality Assurance Framework

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Primary Drivers for Implementation

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- Regulatory Framework
- Technical Capacity
- Systems Integration

Regulatory Framework

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Secondary Drivers:

- 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

Technical Capacity

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Secondary Drivers:

- 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
 - Infrastructure and Equipment
 - Reference Standards/materials & reagents to perform L3 analysis
- Country equipped to perform L2 analysis in field and OMCL
- Trained personnel to perform L2 and L3
- Current MQM sampling protocols

Systems Integration

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Secondary Drivers:

- 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

Next Steps

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- Continue supporting implementation of the approach
- Finalize the development of secondary drivers
- Assess the progress of implementation

Questions

Thank You

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