

Common Quality Assurance Guidelines: towards harmonizing medicine procurement

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Is there a medicine quality problem?

- The quality of antimalarial medicines - 2003
 - Gabon, Ghana, Kenya, Mali, Mozambique, Sudan, Tanzania and Zimbabwe
- Study on the quality of antibiotics in Ghana – 2010
- Quality of Antimalarial Medicines in Sub-Saharan Africa (QAMSA) – 2010
 - Cameroon, Ethiopia, Ghana, Kenya, Nigeria and Tanzania



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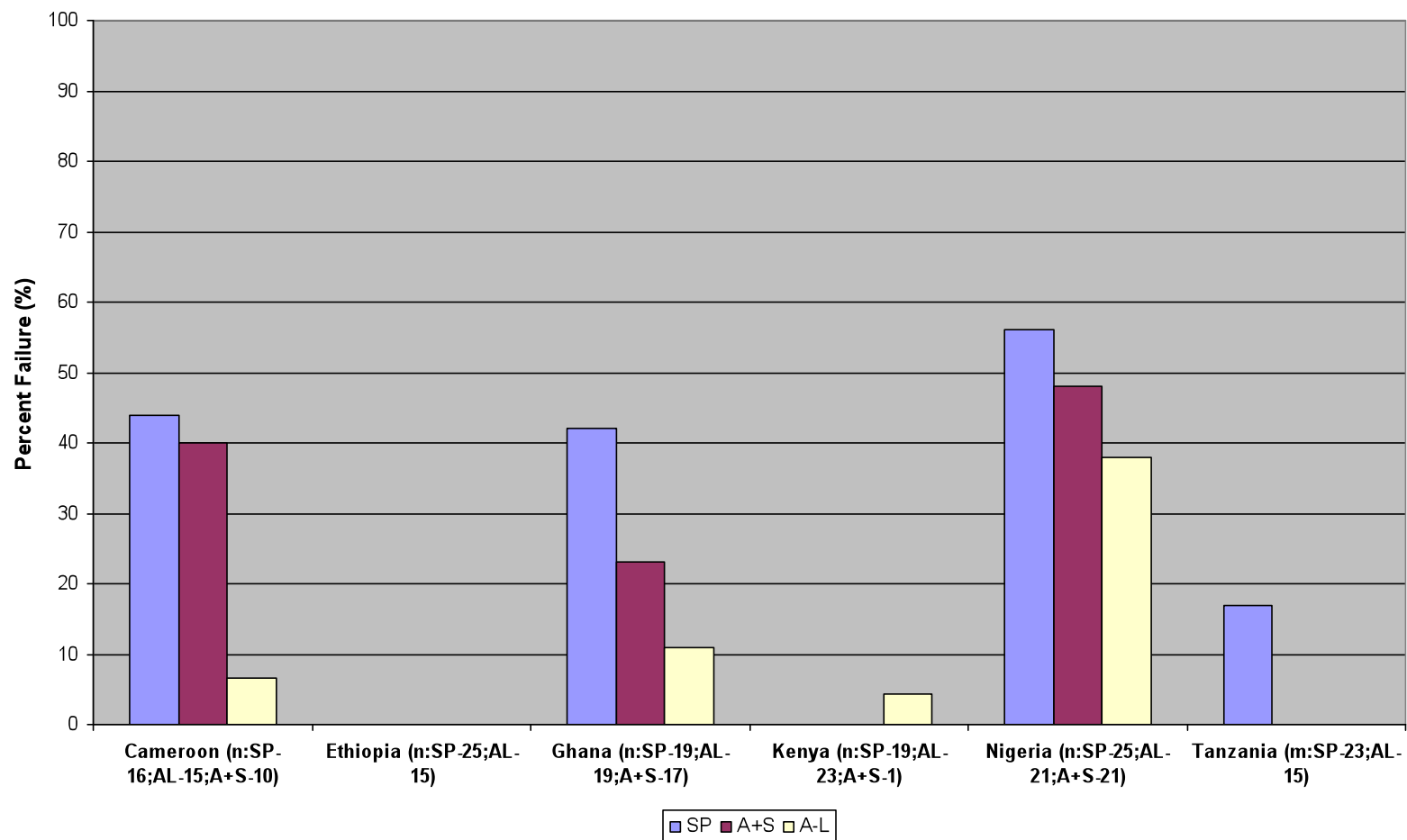
What is the nature of quality problem?

- High levels of substandard (content and dissolution) products:
 - chloroquine & sulphadoxine/pyrimethamine
- Approximately 15% of antibiotics not complying to quality standard:
 - Amoxicillin, Amoxicillin+Clavulanic acid, Ciprofloxacin
- Significant levels of Artemisinin-combination (ACT) products and sulphadoxine/pyrimethamine products do not meet quality standards
 - Artemether/lumefantrine, artesunate+amodiaquin, artesunate/amodiaquin and chloroquine & sulphadoxine/pyrimethamine

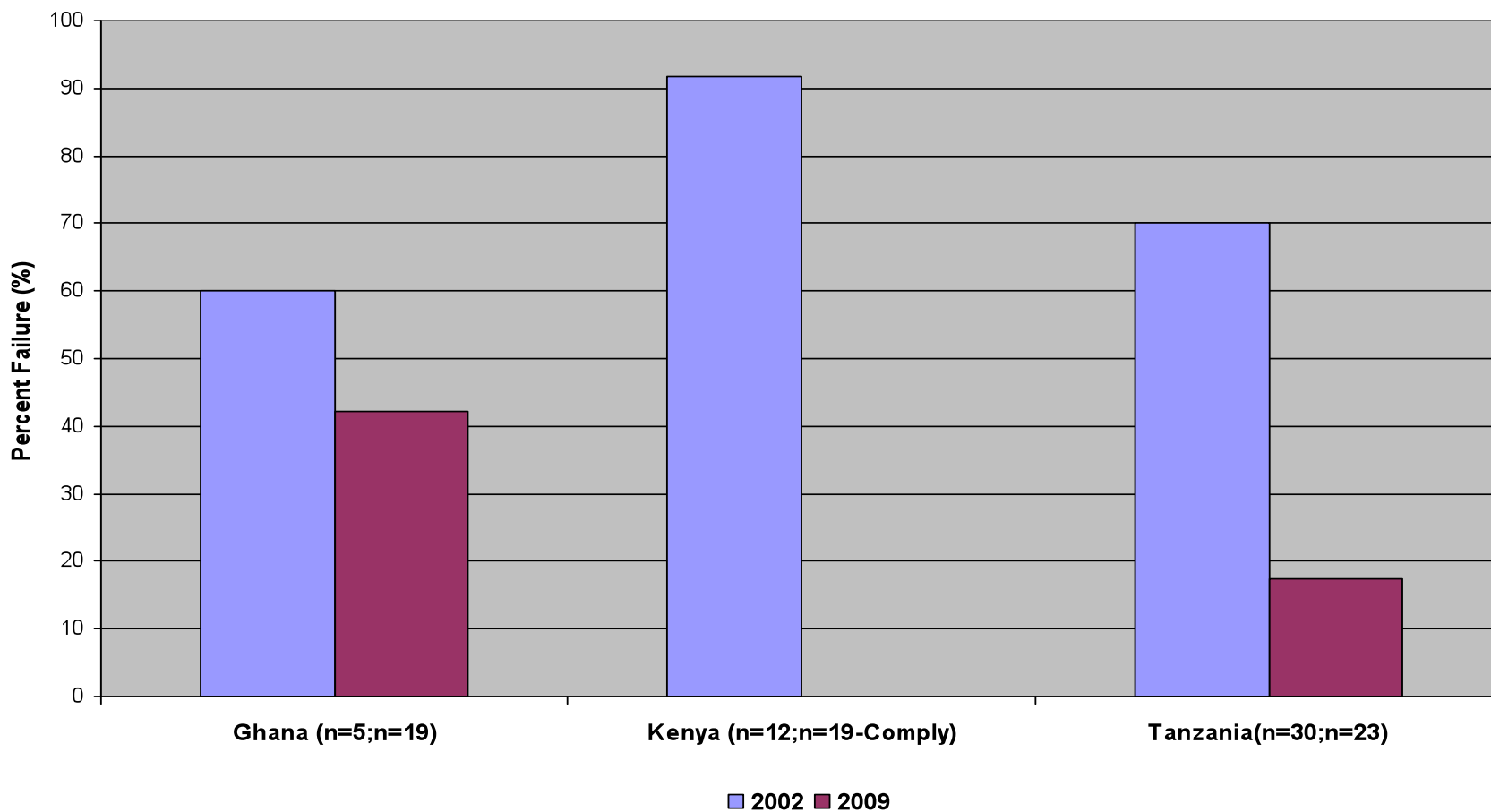


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Failure Levels: All Products



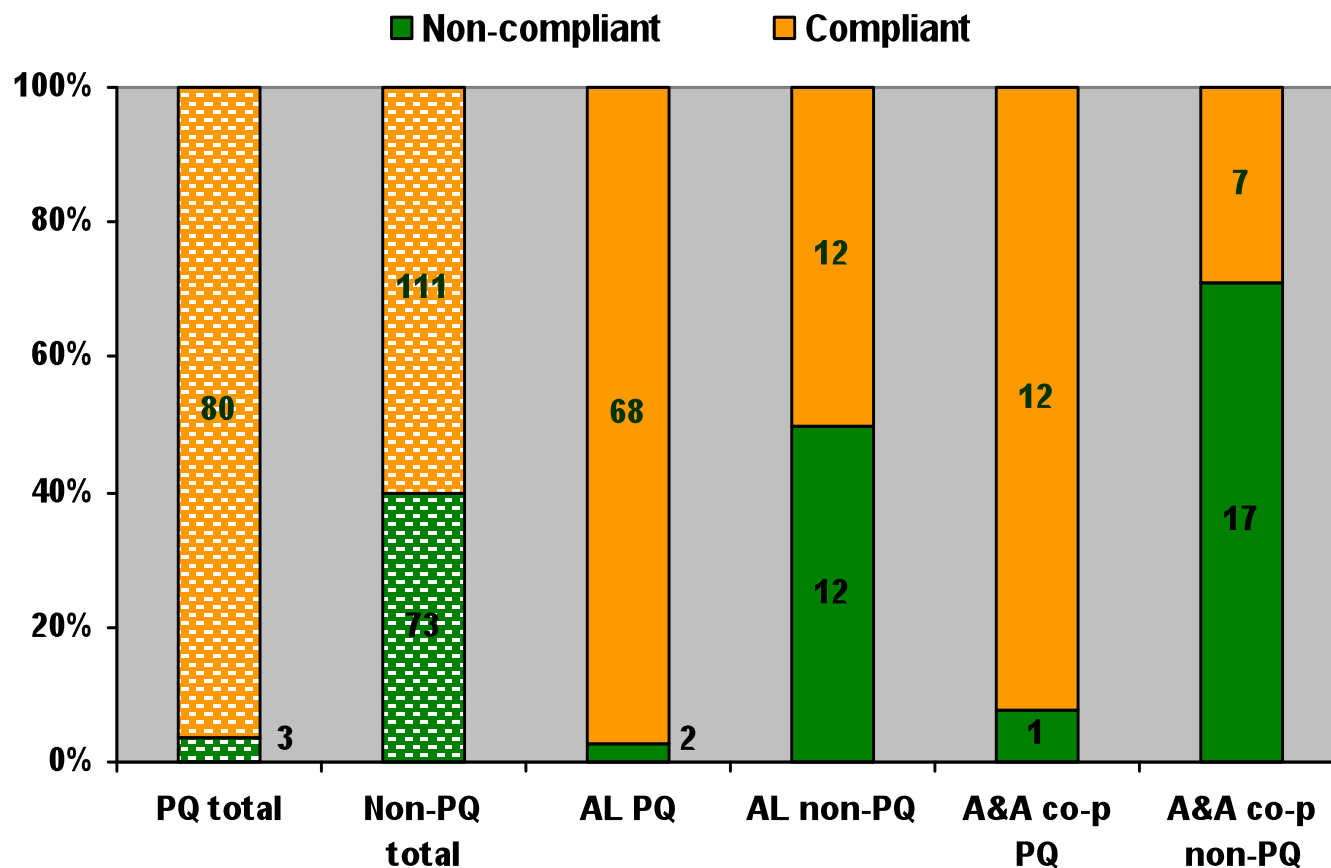
Quality of SP Tablets (Dissolution of Pyrimethamine Component)



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Does prequalification make a difference? QAMSA Study

AL: arthemether/
lumefantrine
AA: artesunate/
amodiaquine



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What if there is no prequalification mechanism?

- Next presentation



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