Building Medicines Quality Control Capacity in Africa: Where are we?

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Outline

- QC before 2009
- QC 2009 – 2019
- QC capacity strengthening in Africa
  - USAID/USP: NOMCoL
  - USP/WAHO/AMRH: AMQF
- AMQF and its vision for building QC capacity in Africa
- 2 examples of QC success
- Challenges
- Recommendations for improved QC capacity in Africa
## Quality control landscape in 2009

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<th>Status</th>
<th>Details</th>
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<td><strong>40</strong>: Countries with official QC labs</td>
<td>Out of 55 AU member states</td>
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</table>
| **2**: WHO-prequalified OMCLs | LNCPP – Algeria (2005)  
| **1**: WHO-prequalified (private) | CENQAM – S. Africa (2005) |
| **1**: ISO/IEC 17025 (private) | In Lab – Cape Verde (2008) |
## Quality control landscape today

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<tr>
<td><strong>40:</strong> Countries with Official QC Labs</td>
<td>Out of 55 AU member states, <strong>15</strong> countries still do not have QC labs</td>
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| **6:** WHO-prequalified OMCLs | MCAZ – Zimbabwe  
TFDA – Tanzania  
NDQCL – Uganda  
NQCL – Kenya,  
LNCM – Morocco  
LNCPP – Algeria |
| **12:** ISO/IEC 17025 accredited OMCLs | FDA – Ghana*  
FMHACA – Ethiopia*  
NAFDAC(5)* – Nigeria  
NQCL – Kenya*  
MCAZ - Zimbabwe  
LNSP – Ivory Coast  
LNCM - Morocco  
NDQCL - Uganda |

**Private labs:**

1. ISO 17025 & WHO-PQ  
1. ISO/IEC 17025 & WHO-PQ  
1. ISO/IEC 17025 accredited  
1. WHO-PQ  
1. WHO-PQ | CENQAM – South Africa  
USP-Ghana - Ghana  
In Lab – Cape Verde  
M&L Laboratory services – South Africa  
MEDS – Kenya |

**13 NMQCLs with int’l recognition**  
**5 private labs with int’l recognition**  
**18 TOTAL QC labs in Africa with int’l recognition**  
**21 labs supported and 8 attained accreditation with support from USAID/USP**
USP QC systems strengthening support in Africa

- USP, with funding from USAID, has supported over 20 African countries in building the capacities of NMQCL since 2002 through these programs:
  - **Drug Quality and Information (DQI)/USAID:** 2000 – 2008
    - Focused on building local capacity in medicines quality and information
  - **Promoting the Quality of Medicines (PQM)/USAID:** 2009 – 2019
    - Focused on building QA/QC systems (Medicines regulations, QC, PMS, GMP)

- **USP-Ghana**
  - A regional leader in workforce development for medicines regulation and the pharma sector.
  - With state-of-the-art accredited labs,
  - NEPAD-AUDA designated RefCORE
  - Trained over 1000 regulators & med. Manufacturers, over 100 QC staff from 85% of existing QC labs in Africa
USP QC systems strengthening support in Africa

- QC labs network: NOMCoL-Africa
  - Established in 2009 with 5 members (USAID supported) and reached 18 members in 2017.
  - Building on lesson learned from other similar networks: LAC, EU, Asia, MENA
  - Brings together QC staff from OMCLs & creates a platform for learning together and sharing best practices.

- AMQF, a transformation from NOMCoL-SSA to reside under AMRH
  - Established in 2017 by USP in collaboration with WAHO and NEPAD-AUDA
  - Protect the African People’s health by ensuring quality of health commodities through harmonized quality control systems, strengthened national, interregional and continental collective responsibilities and mutual accountability.
Support through AMQF

- **An emanation from NOMCoL-Africa**
  - In 2017, in collaboration with West African Health Organization (WAHO), NOMCoL was transferred under the governance of AMRH/NEPAD and was since called the African Medicines Quality Forum (AMQF).

- **Membership - 40 countries with NMQCLs in Africa**

- **Vision**
  - Africa Free of Sub-Standard and Falsified Medicines

- **Mission**
  - To protect the African People’s health by ensuring quality of health commodities through harmonized quality control systems, strengthened national, interregional and continental collective responsibilities and mutual accountability.

- **Objectives**
  - Elimination/reduction of sub-standard and falsified medical products in Africa through capacity building of the National Quality Control Laboratories of Africa
AMQF Scope of Work

- Capacity Building
- Bioanalytical Testing
- Quality Management Systems
- Comms, Advocacy & Info sharing
- Proficiency Testing
- Regional Post-Marketing Surveillance

African Medicines Quality Forum (AMQF)
AMQF – Governance Framework

- AUDA-NEPAD/WHO is the secretariat
- Activities managed by a TWG headed by a chair and vice-chair
  - Provide technical leadership for AMQF
  - Develops annual workplans - aligned with its SOW for validation at annual meetings
  - Tracks workplan progress and disseminates AMQF documents
- AMQF entire membership (all African countries) convenes annually
- TWG working group convene face-face annually and as needed, virtually
- The AMQF Joint Action Group (JAG) has been established (kick-off meeting July 2019) and face to face meeting is scheduled for Oct. 2nd.
AMQF activities (2018 -2019)

- 2 rounds of inter-laboratory testing
  - 2018: 20 Labs participated and 95% pass
  - 2019: 31 Labs participated (deadline for completion 30/09/19).

- Establishment of a communications platform/tools
  - 2018
    • Database of all NMQCLs and email list
    • Dropbox data repository
  - 2019
    • Interactive platform provided by NU (CENQAM), in pilot phase
    • 1-pager advocacy documents

- Assessment of NMQCLs in Africa
  - AMQF QC lab assessment tool finalized
  - Labs self assessment ongoing: 50% labs assesses as of September 21 2019 (deadline is December 2019)

- Guidelines for regional PMS (2019)

- 2 annual meetings and 2 TWG meetings
QC capacity building successes

Nigeria

– Yaba (Lagos State), Agulu (Awka-Anambra State), and Kaduna (Kaduna State) accredited to ISO/IEC 17025 between 2016 and 2017

– The National Institute for Pharmaceutical Research and Development (NIPRD) and the National Control Laboratory for Vaccines and other Biologicals (NCLVB) accredited to ISO/IEC 17025 in 2018 and 2019 respectively.

– The results of tests performed by the 5 accredited laboratories informed NAFDAC's approval of 11,240 new or generic health products for the Nigerian market in 2017

– In the path to self-reliance
  • 2015–2018: PQM provided ~85% of total spending on QMS strengthening and testing in the 5 labs
  • 2019: PQM provided ~20% of total spending on QMS strengthening and testing in the 5 labs
QC capacity building successes and case studies

Ethiopia

- EFMHACA relies on test results from NQCL to inform decisions on medicines approvals.
- PQM provided TA and training to NMIE that would lead to ISO accreditation for calibration of pressure and temperature instrumentation in June 2017.
- With continued support from PQM, NMIE expanded the scope of its accreditation in 2018 to include length and dimension calibrations, completing the range of skills it would need to meet all of NQCL’s calibration requirements and eliminate reliance on foreign calibration services providers
  • Reduced yearly calibration costs at NQCL by 87 percent
- 2019: NQCL was used to conduct confirmatory testing of samples from the first regional RB-PMS study in the IGAD region.
Challenges in Medicines QC systems

- Lack of clear role/mandate of QC labs within health systems
- Limited human & financial resources to support NMQCLs systems strengthening
  - Lack of financial and management autonomy of NMQCLs rendering maintenance of quality systems unsustainable
- Weak role of the NMQCL in market surveillance of medicines
- Fragmentation of regulatory functions within different government institutions.
A lot has been done in the last decade with a significant increase of internationally recognised testing laboratories in Africa.

- However, most of the QC laboratories are still at GBT level 1/2 due to their limited testing scope (e.g., lack of capacity to test biological, medical devices, etc).

Way forward: Targeted and aligned support for QC capacity building in Africa through the African Medicines Quality Forum

- Continue to harmonize practices and procedures at the regional and continental level using AMQF data and tools
- Secure more coordinated support from donors and supporting partners (CIP and JAG)
- Implement the WHO Global Regulatory Competency Framework for QC
- Strengthen the role of NQCLs in regional RB-PMS at the country and the RECs levels
- Promote south-to-south collaboration between QC labs and strengthen information sharing
- Harmonize regional approaches in combatting SFs medicines under AMQF
- Build on the success made in QC to bring other regulatory functions to international standards
Thank You

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