Advancing Medicines Quality Assurance Systems in LMICs: Celebrating 10 Years of PQM Program Achievements

June 27, 2019
Crystal Gateway Marriott, Arlington, VA

PQM: Where we came from and what we have achieved

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- PQM strengthened quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health.
- We still have to address issues of accountability, transparency, sustainability, and information management.
- Accomplishments:
  - Strengthened regulatory authorities
  - Strengthened quality assurance
  - Provided timely access to essential medicines
  - Improved the capacity for inspection and dossier evaluation
  - Protected more patients from harmful products
  - Strengthened laboratories and surveillance capacity to avert thousands of deaths
  - Helped developed 7 monographs
  - Trained 6,700 individuals in quality control
  - Tested 31,200 medical product samples
- Country highlight: Pakistan
  - In 2012, Pakistan did not have any laboratories. Now it has laboratory capacity, including five International Organization for Standardization (ISO)-accredited laboratories and one WHO-prequalified laboratory.
- Country highlight: Liberia
  - One measure of resilience is how countries rebuild when they are faced with a challenge. In 2018, the only laboratory in Liberia burned down. It was rebuilt quickly and was able to continue testing products.
- Millions of patients are treated with quality-assured medicines. PQM has been able to work with more than 100 manufacturers to create a wave of interest in adopting international standards.
- PQM has also had a positive impact on maternal and child health and contributed to preventing child and maternal deaths.

- Lessons learned:
    - Sustainable regulatory systems require adoption of international standards, risk-based approaches, and self-reliance.
    - Medicines quality surveys can serve as a diagnostic tool that reveals weaknesses in quality assurance systems.
    - Access to a quality control laboratory that generates reliable results is integral to effective medicines regulation.
    - Strengthening pharmaceutical production should go in tandem with strengthening systems for quality assurance.
    - Integrated regulatory information management supports effective preapproval review, post-marketing surveillance, and public accountability.
- Challenges remain:
    - Two billion people globally still lack access to essential medicines, and millions are at risk of harm from poor-quality medicines.