

## Promoting the Quality of Medicines (PQM) Program in Nigeria

February 2015



### BACKGROUND

The PQM program, funded by USAID through the President's Malaria Initiative (PMI) and implemented by the U.S. Pharmacopeial Convention (USP), has partnered with Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) and National Malaria Control Program (NMCP) since 2012 to strengthen the country's capacity to assure the quality of antimalarial medicines. In 2013 the Mission's Office of Maternal and Child Health also began funding PQM activities to extend those efforts to select Nigerian manufacturers that produce maternal, newborn, and child health (MNCH) priority commodities of the United Nations (UN) Commission on Life-Saving Commodities for Women and Children.

After an evaluation of the quality of antimalarial medicines (including artemisinin-based combination therapies) revealed the prevalence of poor quality products in Nigeria's market, in April 2013 PQM conducted a rapid assessment of the overall quality assurance and quality control (QA/QC) capabilities of Nigeria's NAFDAC and NMCP. Then, with approval of the Minister of Health and other stakeholders, PQM introduced activities to strengthen the Agency—establishing a strong medicines quality monitoring program, building up the Central Drug Quality Control Laboratory (CDCL), and providing technical assistance to local manufacturers to meet international standards of Good Manufacturing Practices (GMP).

### HIGHLIGHTS OF ACCOMPLISHMENTS

#### Strengthen NAFDAC regulatory capacity

*Assisting NAFDAC CDCL to attain ISO 17025 accreditation*

- Procured lab supplies, reagents, reference standards, and publications
- Trained lab staff in analytical techniques & quality management system
- Lab successfully participated in proficiency and inter-laboratory testing
- Observed internal audit, assisted with CAPAs, and prepped for ISO audit
- NAFDAC Yaba Lab awarded ISO 17025 Accreditation in February 2015

*Bolstering regulatory functions*

- Provided technical support in medicines registration & dossier evaluation
- Trained inspectorate in GMP & supply chain and distribution inspections

*Establishing medicines quality monitoring (MQM)*

- Launched MQM activities in six geographical zones
- Completed one round of sampling & testing of 800 antimalarial samples
- Resulted in failure rate of 3.75%, monotherapies & unregistered found

#### Strengthen quality assurance of medicines nationally

- Participated in workshop to draft a national quality assurance policy for all medicines and diagnostics; provided recommendations draft sections

#### Strengthen capacity of manufacturers to meet international standards and reach WHO Prequalification for MNCH medicines

*Child Health*

- CHI Pharmaceuticals audited & approved for zinc, WHO PQ—early 2015
- USAID issued waiver for locally procured drugs due to PQM testing/GMP
- Working w/four manufacturers of ORS & amoxicillin dispersible tablets

*Newborn Health*

- Drugfield Pharmaceutical is first mfr in SSA to produce/register CHX gel