

**Promoting the Quality of Medicines (PQM) Program  
 Quarterly Reports: FY 2011**

| Activity   | Staff Lead | Quarter   |    |    |    |
|--|------------|---|----|----|----|
|  |            | Q1  | Q2 | Q3 | Q4 |
| <b>Common Agenda</b>   |            | P Lukulay   |    |    |    |
| <b>Raise the profile of the PQM program and increase awareness about the importance of medicines quality</b> |            |   |    |    |    |
| Attend and present at national, regional and international conferences                                       | P Lukulay  | Attended AAPS conference in New Orleans; conducted a joint presentation with Interpol and AEI on "Medicines Quality in Developing Countries"<br><br>Registered for global anti-counterfeiting conf in London in May   |    |    |    |
| Use available media outlets to advocate the need for medicines quality assurance                             | P Lukulay  | Conducted several interviews arranged by USP Media Relations; several pickups in new outlets, including Nature Magazine, Drug Discovery and Development, the Pharma Letter, In-Pharma Technologist and PharmTech Talk |    |    |    |
| <b>Produce up-to-date information about current issues in medicines quality and appropriate use</b>          |            |   |    |    |    |
| Collect and publish reports on incidents of poor-quality medicine use  | M McGinnis | Added 27 new reports; received 2,075 website hits   |    |    |    |
| Maintain and update PQM website  | M Foster   | Added 8 articles, 9 pics, updated 1 p; revised/rewrote 14 pp of copy & prepared 12 pics for PQM "interim site"  |    |    |    |

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| <b>Explore improved tools to ensure quality control or increase the knowledge base about quality assurance</b>               |            |  |    |    |    |
| Support research to improve the accuracy and reliability of field-based quality control technologies                         | P Lukulay  | Developed proposal with Boston University (BU) for jointly-funded project; in process of finalizing contract.  |    |    |    |
| <b>Develop a pool of experts in medicines regulation in the three USAID priority regions</b>                                 |            |  |    |    |    |
| Identify experts in medicines regulation and QC; assist in forming an association  | P Lukulay  | Developed proposal for building regional expertise in medicines regulation; working with West African Health Organization to establish a business organization for the initiative            |    |    |    |
| <b>Tuberculosis (TB)</b> P Lukulay   |            |  |    |    |    |
| <b>Increasing availability of quality-assured second-line medicines</b>  |            |  |    |    |    |
| Provide TA to mfrs of SL-ATBs identified in FY10 are seeking WHO PQ (Kilitch, Sintez, Unilab, Cipla, Marinha, Farmanguinhos) | E Toledo   | Sintez to start accelerated stability study (at least 3 months of data is required); will withdraw application and resubmit the new and complete dossier by April 2011, using the new format |    |    |    |
| Represent PQM at SWG and PQ Assessors meetings; attend WHO Dossier Assessment Training                                       | E Toledo   | Two PQM GMP specialists attended the WHO assessors meeting in Copenhagen to gain familiarity with new Common Technical Dossier format  |    |    |    |
| Update current literature on PQM TA  | M Foster   | Revised list of qualifying drugs to reflect WHO  |    |    |    |

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| and update website   |              | 10th invitation for EOIs  |    |    |    |
| Develop Minilab <sup>®</sup> test methods for Cycloserine and Ethionamide; prepare for publication         | S Phanouvong | Minilab methods in final stages of development for the three SLD medicines  |    |    |    |
| <b>Reduce the prevalence of substandard and counterfeit TB medicines</b>                                   |              |   |    |    |    |
| Conduct research in select countries to assess quality and availability of SL-ATBs in private sector       | P. Lukulay   | Two countries have been identified (India and South Africa). USAID in process of contacting counterparts in the countries to arrange PQM visit to start the survey. |    |    |    |
| Develop database of WHO GMP-compliant suppliers of APIs, and GCP-compliant contract research organizations | D. Vanscoy   | A draft of the list of approved API suppliers and CROs has been compiled.   |    |    |    |
| <b>Increase demand for participation in the WHO Prequalification Programme</b>                             |              |   |    |    |    |
| Develop database of countries that can expedite/waive dossier assessment for prequalified products         | P. Lukulay   | Initial contacts have been made with one regulator in Ghana to request inclusion in the medicines regulation to expedite registration of WHO preapproved SLD.       |    |    |    |
| <b>Malaria</b>   | K Chibwe     |   |    |    |    |
| <b>Support NAMCOL activities</b>   |              |   |    |    |    |
| Enhance performance & skills of NQCLs via training, inter-laboratory testing & resource-sharing            | M. Hajjou    | Training manual developed, participants identified, travel arrangements made  |    |    |    |

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| Exchange and share info via NAMCOL Virtual Forum   |            | Trial of the forum conducted; forum will open in January 2011   |    |    |    |
| <b>Survey the quality of antimalarial medicine syrup formulations</b>                    |            |   |    |    |    |
| Harmonize laboratory procedures and practices among network members                      |            | Awaiting USAID response to these proposed activities; activities may change   |    |    |    |
| Revise QAMSA protocol for sampling methodologies to suit survey of AM syrups             |            |   |    |    |    |
| Train country analysts in sampling AM syrups and documenting collection                  |            |   |    |    |    |
| Analyze collected samples at USP Headquarters lab  |            |   |    |    |    |
| Develop report and disseminate results   |            |   |    |    |    |
| <b>Support USP-PQM initiative to establish an African Reference Standards program</b>    |            |   |    |    |    |
| Identify and invite five countries to participate in African Reference Standards program | R. Okafor  | Four countries signed off on the contract to provide reference and documentary standards; shipments to three countries have started |    |    |    |
| Conduct workshop to inform participating NQCLs about African RS program                  | R. Okafor  | Workshop has been planned in Ghana for the countries  |    |    |    |
| Train NQCL staffs on proper use of reference standards                                   | R. Okafor  |   |    |    |    |
| <b>Develop quality assurance policy and assessment tool</b>                              |            |   |    |    |    |

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| Develop country assurance policy template that can be adapted to fit varied countries' situations   | A. Smine   | In progress   |    |    |    |
| Develop an assessment tool to shape QA policy   |            |   |    |    |    |
| Develop a QA policy for one country receiving PMI funding   |            |   |    |    |    |
| <b>Maternal Health and Child Survival</b>   |            | E Toledo  |    |    |    |
| <b>Prevent and treat childhood diarrheal illness</b>  |            |   |    |    |    |
| Conduct QC and GMP assessments of zinc salt mfrs for global and local supply (DJPL, Shelys, Zenufa) |            | Shelys finished addressing WHO dossier queries and is awaiting the arrival of new equipment to be installed as part of CAPA plan; will address deficiencies by Q2 and submit report to WHO. PQM to visit Tanzania in Q2 to prepare Shelys for WHO GMP re-inspection and to visit Zenufa |    |    |    |
| Develop at least one add'l pharmacopeial monograph on zinc acetate in syrup form                    |            | Analytical method validation to start Q2. USP India will conduct corroborative testing of samples as part of validation activities  |    |    |    |
| Test zinc samples sent by UNICEF, USAID missions and partners                                       |            | Samples will start coming in Q3   |    |    |    |

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| <b>Improve newborn health outcomes</b>   |            |  |    |    |    |
| Conduct QC and GMP assessments of chlorhexidine mfrs for global and local supply   |            | The assessment was re-scheduled for January 19-26, 2011(due to holidays in Nepal)                                |    |    |    |
| <b>SUB-SAHARAN AFRICA</b>  |            |  |    |    |    |
| <b>Benin</b>   | M Hajjou   |  |    |    |    |
| <b>Strengthen the capacity of the National Quality Control Laboratory (DGLCQ)</b>  |            |  |    |    |    |
| Strengthen technical capacity by training on Dissolution   |            | Quotes for a dissolution tester requested; training materials being prepared                                     |    |    |    |
| Evaluate the Dissolution training  |            |  |    |    |    |
| <b>Ethiopia</b>  | Eshetu W.  |  |    |    |    |
| <b>PEPFAR</b>  |            |  |    |    |    |
| <b>Establish operational PQM office in Addis Ababa</b>   |            |  |    |    |    |
| Obtain registration certificate for PQM  |            | Documents submitted; awaiting decision of Ministry of Foreign Affairs, which is the final stage for registration |    |    |    |
| Establish operational office   |            | Hired two consultants to provide support in medicines registration, GMP, and quality control                     |    |    |    |
| <b>Get baseline information on the regulatory and quality assurance capacity of FMHCAC, identify gaps, and recommend solutions</b>                         |            |  |    |    |    |
| Review regulatory and quality assurance capacity of FMHACA using assessment tool   |            | SOW prepared for discussion with FMHACA; assessment will start in February                                       |    |    |    |
| <b>Improve/strengthen medicine registration and licensing system to ensure that medicines approved by FMHACA are of good quality, safe and efficacious</b> |            |  |    |    |    |
| Improve capacity and skills of new staff   |            | 22 new staff trained on basic principles of dossier assessment   |    |    |    |

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| Improve capacity and skills of existing staff   |            | 25 staff trained on basic principles of GMP  |    |    |    |
| Update existing registration & licensing guidelines and procedures  |            |  |    |    |    |
| Develop new guidelines & procedures for medicine registration and licensing                                 |            |  |    |    |    |
| Campaign for assessment of dossiers in backlog  |            | 213 dossiers in backlog reviewed/assessed  |    |    |    |
| Establish data management and information system  |            |  |    |    |    |
| <b>Strengthen GMP and GCP inspection system to improve the quality of medicines</b>                         |            |  |    |    |    |
| Review and update GMP, GCP guidelines & inspection templates  |            |  |    |    |    |
| Train staff on GMP inspection   |            | GMP training by WHO and PQM staff will occur in March  |    |    |    |
| Train staff in GCP inspection   |            |  |    |    |    |
| <b>Strengthen the FMHACA quality control laboratory to make it WHO-prequalified and ISO17025-accredited</b> |            |  |    |    |    |
| Build quality systems at all levels of QC lab   |            | ACLASS mock audit planned for June. PQM staff will visit in February to prepare lab for ACLASS audit |    |    |    |
| Train QC lab analysts   |            |  |    |    |    |
| Assist QC lab in move to new facility and   |            |  |    |    |    |

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| make it operational   |            |   |    |    |    |
| Provide supplies and reference materials  |            | ARV and antimalarial reference standards ordered and shipped to FMHACA laboratory   |    |    |    |
| <b>Post-marketing surveillance of medicines for HIV/AIDS, opportunistic infections, and malaria</b> |            |   |    |    |    |
| Update sampling and QC protocols for ARVs, OIs and AMs  |            | In progress   |    |    |    |
| Train sentinel site staff in sampling and testing   |            |   |    |    |    |
| Collect samples, test, and report   |            |   |    |    |    |
| <b>PMI</b>  |            |   |    |    |    |
| <b>Post-marketing surveillance of medicines for HIV/AIDS, opportunistic infections, and malaria</b> |            |   |    |    |    |
| Update sampling and QC protocols for ARVs, OIs and AMs  |            | In progress   |    |    |    |
| Train sentinel site staff in sampling and testing; provide all needed equipment                     |            |   |    |    |    |
| Collect samples, test, and report   |            |   |    |    |    |
| <b>Ghana</b>  | P Lukulay  |   |    |    |    |
| Conduct medicines quality monitoring in five sentinel sites   |            | Budget for sentinel sites will be finalized in February; sampling to start in March                                       |    |    |    |
| Hire a local consultant to be based in Accra  |            | Resumes from 100 applicants have been reviewed and top five candidates selected. Final interviews will occur in February. |    |    |    |
| Promote efforts to support FDB  |            | PQM and FDB will issue press release when all   |    |    |    |

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| enforcement actions  |            | MQM results are final   |    |    |    |
| Provide TA toward ISO accreditation  |            | PQM QMS specialist will visit Ghana in March to develop implementation plan   |    |    |    |
| Sensitize local communities and promote enforcement actions by FBD   |            | Messages on raising awareness against counterfeit medicines are being developed; will be shared with community leaders  |    |    |    |
| <b>Kenya</b>   | L El Hadri |   |    |    |    |
| <b>Continue to strengthen antimalarial MQM at established sentinel sites and examine implementation of protocol guidelines</b> |            |   |    |    |    |
| Carry out one round of sampling and testing at five sites; increase number of collected medicines                              |            | Provided budget to carry out the second round of MQM activities in 5 sentinel sites; provided sampling templates and reporting forms; second round will start in March 2011 |    |    |    |
| Organize Minilab <sup>®</sup> training of trainers at NQCL; assign team leaders  |            | Training prepared and team leaders assigned for training 10 staff from the 5 sites and 6 staff from the NQCL; training will occur Feb 2011                                  |    |    |    |
| Conduct onsite visits and M&E of Minilab <sup>®</sup> activities   |            | M&E visit planned for Q2  |    |    |    |
| Conduct confirmatory testing at NQCL lab; develop TLC methods for testing DHAP and liquid formulations                         |            | Samples for developing TLC methods submitted to GPHF laboratories; some TLC methods will be available in Q2<br><br>Confirmatory testing for                                 |    |    |    |

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|  |            | round 1 is ongoing at NQCL   |    |    |    |
| <b>Provide planning to the PPB and DOMC to detect/remove SCMs based on MQM results</b> |            |  |    |    |    |
| Review data and report on levels 1 & 2; share results with stakeholders                |            | Round 1 data revised and recommendations to improve reporting provided; results of level 1 and 2 provided to PPB, DOMC and USAID.<br><br>PPB took actions against 16 unregistered antimalarials from 10 manufacturers and sent memos to remove all expired antimalarials |    |    |    |
| Provide data to DOMC & PPB to remove SCMs and non-registered medicines                 |            | Action will be taken after confirmatory testing by NQCL is complete  |    |    |    |
| Share findings of MQM round 2 at national meetings/conference                          |            |  |    |    |    |
| <b>Liberia</b>   | L El Hadri |  |    |    |    |
| Support LMRC in establishing priority medicine regulations and raising awareness       |            | First draft on major policies will be submitted by the end of Q2   |    |    |    |
| Provide equipment and build QC capacity  |            | UV-vis spectrophotometer procured and installed. LMRA staff trained on its use and maintenance; more lab supplies will be procured in Q2.  |    |    |    |

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|  |            | Hands-on Dissolution and TLC training will be provided in Q2 and Q3.  |    |    |    |
| Assist LMRA to obtain additional funding to purchase HPLC and support other activities |            | Requested additional \$100,000 from LMRC to procure HPLC and to train LMRA staff  |    |    |    |
| <b>Mali</b>  | M Hajjou   |   |    |    |    |
| <b>Strengthen the capacity of the National Laboratory of Health (LNS)</b>              |            |   |    |    |    |
| Procure equipment, conduct training, and teach equipment troubleshooting               |            | Refresher training in Dissolution and HPLC provided; training materials for Karl Fischer and titration being prepared.                          |    |    |    |
| Train in developing SOPs, efficiency training and self-audit                           |            | SOPs for training identified; training material being prepared  |    |    |    |
| Evaluate trainings   |            |   |    |    |    |
| <b>Support the Medicine Quality Monitoring program</b>                                 |            |   |    |    |    |
| Prepare and facilitate new round of sampling and testing                               |            | Round 1 reports from sentinel sites reviewed; PQM assisted in conducting confirmatory testing at LNS<br><br>LNS is preparing the annual report. |    |    |    |
| Monitor and Evaluate MQM activities  |            |   |    |    |    |
| Raise awareness about substandard and counterfeit medicines                            |            |   |    |    |    |
| <b>Strengthen the National Pharmacovigilance Program</b>                               |            |   |    |    |    |
| Review the roles and   |            | Ministerial decree on   |    |    |    |

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| responsibilities of DPM and CNAM  |            | pharmacovigilance reviewed and changes proposed  |    |    |    |
| Enhance ADE reporting   |            |  |    |    |    |
| <b>Coordinate PQM Activities</b>  |            |  |    |    |    |
| Hire an associate staff member in Mali  |            | On hold  |    |    |    |
| <b>Mozambique</b>   | A Barojas  |  |    |    |    |
| <b>Assess the QA/QC capacity of the Pharmaceutical Department to evaluate the infrastructure, capacity, resources, and QMS of the LNCQM</b> |            |  |    |    |    |
| Meet stakeholders and evaluate the QA/QC procedures of PD and LNCQM   |            | Performed rapid QA/QC assessment, focusing on QC lab, Dec 2010   |    |    |    |
| Participate in SPS “Strengthening the Pharmaceutical Sector” Workshop   |            | Participated and chaired QA working group in Dec workshop; QA/QC assessment and workshop allowed PQM to identify areas to provide TA. Based on trip findings, submitted FY 11 WP to Mission. |    |    |    |
| <b>Strengthen the capacity of the National Laboratory for Medicines Quality Control</b>   |            |  |    |    |    |
| Review LNCQM 2009–2014 strategic plan and provide recommendations   |            | Plan has been received and the revision process has begun  |    |    |    |
| Sponsor two LNCQM staff for NAMCOL training in Nairobi  |            |  |    |    |    |
| Perform a hands-on analytical training at LNQCM facilities  |            |  |    |    |    |
| <b>Perform a study to evaluate the magnitude of medicine quality problems for a small selection of essential medicines</b>                  |            |  |    |    |    |
| Identify target areas   |            |  |    |    |    |

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| and medicines;<br>develop sampling and<br>analysis protocol   |            |  |    |    |    |
| Share testing results;<br>promote efforts to<br>support enforcement<br>actions based on data  |            |  |    |    |    |
| <b>Rwanda</b>   | A Smine    |  |    |    |    |
| Assess Rwanda's<br>existing medicine<br>quality control systems<br>and capacity and<br>recommend possible<br>improvements             |            | On hold pending<br>approval by the Rwanda<br>Malaria Control Program |    |    |    |
| Equip and ensure<br>repairs of NUR Faculty<br>of Pharmacy QC lab<br>and provide reagents<br>needed to test<br>antimalarial medicines  |            | On hold  |    |    |    |
| Train NUR QC Lab<br>staff, MOH-PTF<br>pharmacists, and a<br>local manufacturer in<br>key QC methods                                   |            | On hold  |    |    |    |
| Build capacity through<br>QC testing of<br>antimalarials from<br>private and public<br>sectors by NUR QC<br>Lab and PQM<br>evaluation |            | On hold  |    |    |    |
| <b>Senegal</b>  | L El Hadri |  |    |    |    |
| <b>Conduct medicines quality monitoring in nine sentinel sites</b>  |            |  |    |    |    |
| Select and equip two<br>additional sentinel<br>sites and train staff  |            | 2 sites selected;<br>Minilabs will be provided<br>in Q2              |    |    |    |

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| Conduct 1 round MQM for meds & contraceptives at 9 sentinel sites  |            | Sampling strategies and collecting sites established; budget provided to conduct 1 round at 9 sites |    |    |    |
| <b>Hire a local consultant, based in Senegal, and support Monitoring &amp; Evaluation (M&amp;E) visits</b>                             |            |   |    |    |    |
| Hire a local consultant  |            | Will be discussed with USAID/Senegal in Feb 2011  |    |    |    |
| Provide M & E at selected sites  |            | Will be conducted by the end of Q2  |    |    |    |
| <b>Raise awareness about medicine quality and promote corrective actions</b>   |            |   |    |    |    |
| Promote IEC activities to raise awareness on SCMs at regional level  |            | IEC activities approved by USAID/Senegal; Plans will be made during PQM visit in Feb 2011           |    |    |    |
| <b>Continue to strengthen Senegal National Pharmacovigilance System</b>  |            |   |    |    |    |
| Harmonize PV materials and hand-outs, etc., for training   |            | PV activities will be conducted in Q2 and Q3  |    |    |    |
| Help CAP procure PV causality assessment documents   |            | PV documents will be provided in Q2   |    |    |    |
| Provide benchmarking assistance to report challenging ADEs   |            | Benchmarking will be provided in Q2 and Q3  |    |    |    |
| Help fund production, printing & distribution of PV tools  |            | Will be discussed with PV group during Feb 2011 visit   |    |    |    |
| <b>ASIA</b>  |            |   |    |    |    |
| <b>RDM-A Mekong Malaria S. Phanouvong</b>  |            |   |    |    |    |
| <b>Obtain evidence-based data on antimalarial, selected antibiotics, and HIV/AIDS medicines through a regional monitoring program.</b> |            |   |    |    |    |
| Collect data through MQM to support regulatory actions   |            | Replenished Minilab reference standards and QC supplies (Cambodia, Laos, Vietnam)                   |    |    |    |

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|  |            | <p>Finalized MOCs with Cambodia, Laos, Thailand, Vietnam, SohoFilms, and ANEQAM partners)</p> <p>Presented malaria MQM data from 2005-2010 at the 60<sup>th</sup> IMC Meeting in Bangkok</p> <p>An overview of 5-year accomplishments and progress was presented at the 59<sup>th</sup> ASTMH meeting in Atlanta</p> |    |    |    |
| <b>Strengthen national and regional capacities in medicines regulation, enforcement and QA/QC systems, building on ANEQAM success.</b> |            |  |    |    |    |
| Strengthen authorities for regional regulatory action & enforcement  |            | <p>“Guidelines for Taking Appropriate Enforcement Action Against Substandard Medicines” being translated into Thai and Khmer</p> <p>Note: Guidelines were translated into Lao in FY10; Laos is adapting and distributing these</p>   |    |    |    |
| Establish a regional Task Force for info-sharing & enforcement   |            | Initial consultations with MRAs in Cambodia, Laos, and Thailand took place; invitations for kick-off meeting drafted   |    |    |    |
| Promote collaboration among partners for collective action   |            | Discussed with and sent requests to in-country partners to share past  |    |    |    |

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|   |            | published MQM data in an online global database  |    |    |    |
| Finalize the Regional Five-Year Strategic Document  |            | Incorporated comments from stakeholders; second draft will be distributed in Q2  |    |    |    |
| Develop "Modern Medicines Registration Software" program                                  |            | Consulted with USP IT and explored potential collaboration with SPS  |    |    |    |
| Review guidance doc on MQA indicators for pharmacy procurement                            |            | Reviewed indicators and other sources from Laos; materials to be developed in Q2   |    |    |    |
| Develop pilot "Retail Pharmacy Accreditation Scheme"                                      |            | Consulted with partners in Cambodia, Philippines, and Thailand on existing schemes to be adapted or further developed  |    |    |    |
| Provide TA to Laos NQCL to achieve ISO 17025 accreditation                                |            | FDQCC quality manual translated into English for review  |    |    |    |
| Provide TA to Thailand NQCL to pursue WHO Prequalification                                |            | Application for WHO PreQ submitted; comments and site visit expected in Q2   |    |    |    |
| <b>Raise public awareness about the dangers of counterfeit and substandard medicines.</b> |            |  |    |    |    |
| Broadcast PSAs in Laos, Vietnam and Thailand  |            | Vietnam broadcast planned for Q2 (contract approved with O2 TV Vietnam)<br><br>Written approval obtained from Laos and PSA broadcasted; verbal approval obtained |    |    |    |

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|   |            | Q1   | Q2 | Q3 | Q4 |
|   |            | from Thailand  |    |    |    |
| Contribute to production of Pharmacide, the online PSA  |            | In post-production; to be finalized in Q2  |    |    |    |
| Contribute to the production of the one-hour regional documentary re: the problem of counterfeits in the GMS  |            | In pre-production stages   |    |    |    |
| Support community outreach orgs to raise awareness on SCMs  |            | Action planning conducted with URC on dissemination of flyers; to be implemented in Q2-Q4  |    |    |    |
| Submit 2nd article on AM cross-border study to peer-reviewed journal  |            | Article presenting cross-border data on Cambodia side drafted, to be finalized in Q2; will resubmit the article with Cambodia and Thailand data combined in Q2 |    |    |    |
| <b>Establish a Medicine Quality Monitoring program in Burma</b>   |            |  |    |    |    |
| Provide a new Minilab and necessary RS and reagents and solvents to Burma FDA (this work is in close collaboration with WHO Country Office and MMP) |            | Held discussions with WHO MMP, PMI, and RDM-A; implementation planned for Q2   |    |    |    |
| Conduct training on Establishing an MQM in strategic sites  |            | Planned for Q2   |    |    |    |
| Collect and test samples  |            | Planned for Q3   |    |    |    |

Promoting the Quality of Medicines (PQM Program)  
 Quarterly Reports: FY11

| Activity  | Staff Lead    | Quarter   |    |    |    |
|---|---------------|---|----|----|----|
|   |               | Q1  | Q2 | Q3 | Q4 |
| <b>RDM-A Tuberculosis</b>   | S. Phanouvong |   |    |    |    |
| <b>Obtain evidence-based data on quality of anti-tuberculosis medicines through a regional monitoring mechanism</b>                     |               |   |    |    |    |
| Collect MQM data to support regulatory actions in region  |               | <p>Replenished Minilab reference standards and QC supplies (Cambodia, Laos, Vietnam)</p> <p>Finalized MOCs with Cambodia, Laos, Thailand, Vietnam, SohoFilms, and ANEQAM partners)</p> <p>Presented malaria MQM data from 2005-2010 at the 60<sup>th</sup> IMC Meeting in Bangkok</p> <p>An overview of 5-year accomplishments and progress was presented at the 59<sup>th</sup> ASTMH meeting in Atlanta</p> |    |    |    |
| Help each country organize training for sentinel sites on new Minilab <sup>®</sup> methods  |               | <p>Completed trainings on ATB Minilab testing methods for sentinel site staff in Cambodia and Vietnam</p> <p>Coordinating with Mahidol University to conduct 2 GMP trainings in Cambodia and Laos in Q2</p>   |    |    |    |
| <b>Strengthen national and regional capacities in medicines regulation, QA/QC systems, and enforcement , building on ANEQAM success</b> |               |   |    |    |    |
| Strengthen authorities  |               | "Guidelines for Taking  |    |    |    |

Promoting the Quality of Medicines (PQM Program)  
 Quarterly Reports: FY11

| Activity   | Staff Lead | Quarter  |    |    |    |
|--|------------|--|----|----|----|
|  |            | Q1   | Q2 | Q3 | Q4 |
| for regional regulatory action & enforcement                   |            | Appropriate Enforcement Action Against Substandard Medicines” being translated into Thai and Khmer<br><br>Note: Guidelines were translated into Lao in FY10; Laos is adapting and distributing these |    |    |    |
| Establish a regional Task Force for info-sharing & enforcement |            | Initial consultations with MRAs in Cambodia, Laos, and Thailand took place; invitations for kick-off meeting drafted   |    |    |    |
| Promote collaboration among partners for collective action     |            | Discussed with and sent requests to in-country partners to share past published MQM data in an online global database  |    |    |    |
| Finalize the Regional Five-Year Strategic Document             |            | Incorporated comments from stakeholders; second draft will be distributed in Q2  |    |    |    |
| Develop “Modern Medicines Registration Software” program       |            | Consulted with USP IT and explored potential collaboration with SPS  |    |    |    |
| Review guidance doc on MQA indicators for pharmacy procurement |            | Reviewed indicators and other sources from Laos; materials to be developed in Q2   |    |    |    |
| Develop pilot “Retail Pharmacy Accreditation Scheme”           |            | Consulted with partners in Cambodia, Philippines, and Thailand on existing schemes to be adapted   |    |    |    |

Promoting the Quality of Medicines (PQM Program)

Quarterly Reports: FY11

| Activity  | Staff Lead | Quarter  |    |    |    |
|---|------------|--|----|----|----|
|   |            | Q1   | Q2 | Q3 | Q4 |
|   |            | or further developed   |    |    |    |
| Provide TA to Laos NQCL to achieve ISO 17025 accreditation  |            | FDQCC quality manual translated into English for review  |    |    |    |
| Provide TA to Thailand NQCL to pursue WHO Prequalification  |            | Application for WHO PreQ submitted; comments and site visit expected in Q2   |    |    |    |
| <b>Raise public awareness about the dangers of counterfeit and substandard medicines</b>  |            |  |    |    |    |
| Broadcast PSAs in Laos, Vietnam and Thailand  |            | Vietnam broadcast planned for Q2 (contract approved with O2 TV Vietnam)<br><br>Written approval obtained from Laos and PSA broadcasted; verbal approval obtained from Thailand |    |    |    |
| Help w/production of "Pharmacide: On line, a global documentary"  |            | In post-production; to be finalized in Q2  |    |    |    |
| Support community outreach orgs to raise awareness on SCMs  |            | In pre-production stages   |    |    |    |
| <b>Support National Tuberculosis Programs to specify and evaluate the quality standards of ATB medicines they plan to procure</b> |            |  |    |    |    |
| Develop materials for TOT in procurement, distribution, storage and dispensing  |            | Planned for Q2   |    |    |    |
| Conduct a regional TOT workshop for NTP on PDS&D above  |            | Planned for Q2-Q4  |    |    |    |
| <b>Involvement in policy and strategy design and development by RDM-A Mission to prevent and control MDR-TB for GMS</b>           |            |  |    |    |    |
| Participate in RDM-A-strategy meetings to prevent/contain spread  |            | No notification/invitation received from RDM/A   |    |    |    |

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 Quarterly Reports: FY11

| Activity  | Staff Lead       | Quarter   |    |    |    |
|---|------------------|---|----|----|----|
|   |                  | Q1  | Q2 | Q3 | Q4 |
| of MDR-TB in GMS  |                  |   |    |    |    |
| <b>Cambodia</b>   | <b>N. Bauers</b> |   |    |    |    |
| <b>Support the Cambodian MOH to detect and take action against poor-quality medicines circulating in the Cambodian market</b> |                  |   |    |    |    |
| Support existing PMS; apply new protocol w/DDF & NHQC   |                  | <p>Replenished Minilab reference standards and QC lab supplies</p> <p>Local consultant will visit sites with MOH in Q2</p> <p>Began special MQM investigation in 6 provinces (which are not part of the regular program); samples pending NHQC results</p> <p>NHQC conducted Minilab refresher training and training on 2<sup>nd</sup> line ATBs for 12 provincial site staff</p> |    |    |    |
| Coordinate with GFATM, JPMA, WHO to streamline PMS  |                  | Supported IMC meeting in Dec 2010; local consultant attended  |    |    |    |
| Strengthen authorities for regional regulatory action & enforcement   |                  | <p>Presented at the MOH-USAID partners meeting in Battambang</p> <p>Met with reps from 7 provinces not currently included in MQM to discuss possible expansion</p>  |    |    |    |
| <b>Building capacity of the NHQC and DDF</b>  |                  |   |    |    |    |
| Procure, equip, supply & guide NHQC toward  |                  | PQM, QC lab, and an expert consultant   |    |    |    |

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 Quarterly Reports: FY11

| Activity   | Staff Lead | Quarter  |    |    |    |
|--|------------|--|----|----|----|
|  |            | Q1   | Q2 | Q3 | Q4 |
| WHO PQ, and plans for new QC lab   |            | reviewed plan for new QC lab building and proposed recommendations for meeting ISO requirements; official report from consultant expected Q2 |    |    |    |
| Update curriculum for pharmacy students w/ QA-QC & regulations   |            | Obtained 5-year curriculum outline from Intl Univ. in Cambodia for Pharmacy Students for adaptation  |    |    |    |
| Assist DDF to create a national QA policy  |            | Obtained current National Medicines Policy for review  |    |    |    |
| Strengthen pharmacy accreditation program through trainings  |            | Initiated collaboration with Dean of IU and DDF to obtain and share existing pharmacy certification programs                                 |    |    |    |
| Assess DDF; install meds regis software; train DDF staff to use it   |            | Planned for Q2   |    |    |    |
| Maintain local PQM consultant for success of activities  |            | Local consultant involved in implementing activities; attended local meetings and events representing PQM                                    |    |    |    |
| <b>Raise awareness about medicine quality issues and disseminate information among regulators, health care professionals, and the public</b> |            |  |    |    |    |
| Collaborate with PAC to promote actions against SCMs   |            | Meet with PAC president to discuss FY activities<br><br>1 PAC bulletin was issued this quarter with remaining FY10 funds                     |    |    |    |

Promoting the Quality of Medicines (PQM Program)  
 Quarterly Reports: FY11

| Activity  | Staff Lead | Quarter  |    |    |    |
|---|------------|--|----|----|----|
|   |            | Q1   | Q2 | Q3 | Q4 |
|   |            | PAC workshop conducted in December with remaining FY10 funds   |    |    |    |
| Facilitate regional collaboration to share SCM data among countries & INTERPOL                              |            | Met with MOH partners to discuss sharing published data via the Medicines Quality Database and potential participation in networks |    |    |    |
| Coordinate with donors to avoid duplication on priority meds to DDF & health programs                       |            | Met with DDF, CNM, MOH, USAID/Cambodia, URC, CHAI, and AMFm to discuss FY11 activities/collaboration                               |    |    |    |
| <b>Indonesia S Phanouvong</b>   |            |  |    |    |    |
| <b>Assist Indonesian TB medicine manufacturers to obtain WHO prequalification for selected TB medicines</b> |            |  |    |    |    |
| Conduct QC/GMP pre-assessments of TB meds manufacturers (Indofarma, Phapros, and Kimiafarma)                |            | Pre-assessments completed and action plans for TA to the 3 manufacturers developed   |    |    |    |
| Conduct QC/GMP assessments of selected TB meds manufacturers above  |            | Planned for Q2   |    |    |    |
| Assist manufacturers in dossier prep and submission to WHO  |            | Planned for Q2-Q3  |    |    |    |
| Conduct drug quality testing of TB samples  |            | Planned for Q3-Q4  |    |    |    |
| <b>Facilitate the registration of TB medicines by the Indonesia drug regulatory authority</b>               |            |  |    |    |    |
| Assess registration capability & dossier reviews of Indonesia FDA (BPOM-NA-DFC)                             |            | Planned for Q3-Q4  |    |    |    |

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 Quarterly Reports: FY11

| Activity   | Staff Lead | Quarter   |    |    |    |
|--|------------|---|----|----|----|
|  |            | Q1  | Q2 | Q3 | Q4 |
| Establish improved registration system and PMS of TB medicines quality   |            | Planned for Q4  |    |    |    |
| <b>Assist Meiji Pharmaceutical obtain WHO prequalification for Kanamycin Powder</b>  |            |   |    |    |    |
| Perform GMP audit of manufacturing facility  |            | Planned for Q2  |    |    |    |
| Assist Meiji prepare dossier submission for WHO PQ team  |            | Planned for Q2-Q3   |    |    |    |
| Conduct QC testing of Kanamycin Powder for injection batches to be submitted to WHO  |            | Planned for Q2-Q3   |    |    |    |
| Help NA-DFC with registration procedures for Kanamycin   |            | Planned for Q3-Q4   |    |    |    |
| <b>Indonesia – MQM S. Phanouvong</b>   |            |   |    |    |    |
| <b>Obtain evidence-based data on the quality of TB and selected essential antibiotics (ABTs) by establishing a Medicine Quality Monitoring program (MQM) at selected sites</b> |            |   |    |    |    |
| Conduct assessment of QA/QC systems for TB medicines   |            | Met with manufacturer in November to establish work plans and time line; planned for Q2 |    |    |    |
| Identify target areas, choose meds & adapt protocols   |            | Planned for Q2  |    |    |    |
| Purchase necessary testing lab supplies  |            | Planned for Q2-Q3   |    |    |    |
| Train on basic tests using Minilabs <sup>®</sup> for field & NQCLDF staffs   |            | Planned for Q3  |    |    |    |

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 Quarterly Reports: FY11

| Activity  | Staff Lead | Quarter   |    |    |    |
|---|------------|---|----|----|----|
|   |            | Q1  | Q2 | Q3 | Q4 |
| Train on pharm. methods for NQCLDF, regional, and provincial QC lab staffs  |            | Planned for Q3  |    |    |    |
| Collect samples, conduct testing, and report data   |            | Planned for Q3-Q4   |    |    |    |
| <b>Raise public awareness about the dangers of counterfeit and substandard medicines, particularly related to TB medicines.</b> |            |   |    |    |    |
| Develop & distribute materials and present at nat'l & int'l meetings  |            | Planned for Q4  |    |    |    |
| <b>Strengthen national capacities in medicines QA/QC systems, regulation and enforcement</b>                                    |            |   |    |    |    |
| Strengthen NQCLDF capacity in GLP compliance  |            | Planned for Q3-Q4   |    |    |    |
| Strengthen NA-DFC's registration dossier evaluation and PMS   |            | Planned for Q3-Q4   |    |    |    |
| Establish investigation and enforcement task force w/rep in SEA BREMERE TF  |            | Planned for Q3-Q4   |    |    |    |
| <b>Philippines N. Bauers</b>  |            |   |    |    |    |
| <b>Ensure continued post-marketing surveillance of TB medicines at six sentinel sites and examine project implementation</b>    |            |   |    |    |    |
| CHD and LGU staffs perform sampling, testing & reporting  |            | FDA staff and local PQM consultant conducted training for 3 Cebu CHD staff regarding TA and re-orientation on TLC<br><br>Q1 samples collected/tested per site |    |    |    |
| PQM will visit two sites in FY11 with FDA/DOH staffs  |            | Planned for Q2-Q4   |    |    |    |
| Establish Task Group,   |            | Letter requesting   |    |    |    |

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 Quarterly Reports: FY11

| Activity   | Staff Lead | Quarter  |    |    |    |
|--|------------|--|----|----|----|
|  |            | Q1   | Q2 | Q3 | Q4 |
| define roles, responsibilities; PQM provide feedback & TA                        |            | establishment of Technical Working Group sent to FDA Director  |    |    |    |
| Conduct training at FDA on TB & essential meds used in Quality Basket Initiative |            | Planned for Q2   |    |    |    |
| Revise protocol for proper disposal of chemicals, etc.                           |            | Current FDA protocol to be provided to PQM and ANEQAM in Q2  |    |    |    |
| Coordinate activities, equip & supply, and report progress                       |            | Local consultant involved in implementing activities; attended local meetings and events representing PQM  |    |    |    |
| <b>Strengthening the capacity of the FDA</b>                                     |            |  |    |    |    |
| Develop QA/QC training materials for EU Pharm Mgmt manual                        |            | Planned for Q2<br><br>[to follow up with an activity from FY10, 2 scientists completed a 10 week USP Scientist Fellowship Program to improve the QC Lab international standard performance; they have returned to FDA] |    |    |    |
| Purchase needed lab equipment/references not included budgets                    |            | Sent USP-NF, Martindale and other publications requested by FDA<br><br>Sent small equipment supplies to antibiotic and drug laboratories at FDA  |    |    |    |
| Support discussion   |            | Planned for Q2-Q3  |    |    |    |

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 Quarterly Reports: FY11

| Activity   | Staff Lead | Quarter  |    |    |    |
|--|------------|--|----|----|----|
|  |            | Q1   | Q2 | Q3 | Q4 |
| group meetings<br>RA9711 rules & regs  |            |  |    |    |    |
| Develop materials & train on stability data, study design/ methodology, & mfg process validation                     |            | Planned for Q3-Q4  |    |    |    |
| <b>Obtain evidence-based quality data on selected generic anti-infective medicines</b>                               |            |  |    |    |    |
| Obtain data on quality of selected generic anti-infective meds   |            | Initiated discussion with local PQM consultant and FDA partners to develop list of most common branded anti-infectives and their generic equivalents; final list expected Q2 |    |    |    |
| <b>Vietnam S. Phanouvong</b>   |            |  |    |    |    |
| <b>Obtain formal Government clearance for the "Methadone Local Production" project and select manufacturing firm</b> |            |  |    |    |    |
| Discuss process and procedures w/partners; recommend mfrs  |            | Visit planned in Q2  |    |    |    |
| Submit formal letter of request for official clearance   |            | Top 5 local manufacturers identified; letter planned for Q2  |    |    |    |
| Conduct inspections to determine best manufacturer   |            | A list of potential manufacturers was obtained and a questionnaire developed to provide selection criteria for local manufacturers   |    |    |    |
| <b>Secure high-quality active pharmaceutical ingredient of methadone and select API supplier(s)</b>                  |            |  |    |    |    |
| Identify & select 1-2 reliable source(s) for Methadone HCl API   |            | Identified methadone manufacturers through various databases,  |    |    |    |

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| Activity  | Staff Lead | Quarter  |    |    |    |
|---|------------|--|----|----|----|
|   |            | Q1   | Q2 | Q3 | Q4 |
|   |            | WHO and UNODC publications   |    |    |    |
|   |            | Enquiry letters sent to prospective candidates.  |    |    |    |
| Test Methadone HCl API using compendial specifications                          |            | To be completed in Q2  |    |    |    |
| Facilitate import of Methadone HCl API into Vietnam                             |            | <p>PQM studied UNODC guidelines on "Step-by-step' Algorithm for the Procurement of Controlled Substances for Drug Substitution Treatment" and WHO's "Access to Controlled Medications Programme," developed in consultation with the International Narcotics Control Board</p> <p>Identified persons at ACMP and INCB for guidance on importing methadone API into Vietnam</p> |    |    |    |
| <b>Establish product quality specifications and GMP compliance requirements</b> |            |  |    |    |    |
| Develop quality specs for Methadone HCl syrup finished dosage                   |            | Planned for Q2.  |    |    |    |
| Recommend how to address GMP deficits to selected firm                          |            | Planned for Q2-Q3  |    |    |    |
| Check mfr to ensure full GMP compliance before pilot production                 |            | Planned for Q3   |    |    |    |

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| Activity   | Staff Lead | Quarter   |    |    |    |
|--|------------|---|----|----|----|
|  |            | Q1  | Q2 | Q3 | Q4 |
| Establish and validate process control and QA/QC   |            | Planned for Q3-Q4   |    |    |    |
| Perform quality control check of 3 consecutive pilot batches/lots                          |            | Planned for Q4  |    |    |    |
| Develop protocols for stability studies under storage conditions; mfr to carry out studies |            | Planned for FY11Q4-FY12Q1   |    |    |    |
| <b>Europe and Eurasia</b>  |            |   |    |    |    |
| <b>Russia</b>  |            |   |    |    |    |
| <b>K. Burimski</b>   |            |   |    |    |    |
| Work with Sintez to get Kanamycin & Levofloxacin WHO prequalified                          |            | <p>Worked with Sintez to correct the dossiers on Kanamycin 0.5 and 1.0 powder for injection according to WHO comments</p> <p>Sintez is planning to purchase a climate control camera to conduct accelerated stability studies according to WHO requirements</p> |    |    |    |
| Extend TA to Russian mfrs of 2nd-line TB meds to reach WHO prequalification                |            | <p>Updated <i>Expression of Interest Questionnaire</i> for SLD manufacturers to make it shorter and continued disseminating it to Russian and Ukrainian SLD manufacturers</p> <p>One of the Russian SLD manufacturers,</p>                                      |    |    |    |

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| Activity  | Staff Lead | Quarter  |    |    |    |
|---|------------|--|----|----|----|
|   |            | Q1   | Q2 | Q3 | Q4 |
|   |            | <p>Pharmasintez, filled out and submitted the <i>Expression of Interest Questionnaire</i>.</p> <p>Conducted telecon with Pharmasintez to plan further steps; PQM sent WHO Prequalification documents to Pharmasintez</p> <p>Together with Pharmasintez identified preliminary dates for PQM GMP team visit</p> |    |    |    |
| Mentor Russian scientists at USP to help w/mfr follow-ups, translate WHO regs                 |            | Continued search of candidates for the mentorship  |    |    |    |
| Conduct Outreach Workshop for Russian mfrs on WHO PQ with WHO and GDF                         |            | <p>Drafted preliminary agenda for the workshop</p> <p>Secured Roszdravnadzor's approval, support and participation in the workshop</p>   |    |    |    |
| Document and report medicines quality data in selected TB clinics using Minilabs <sup>®</sup> |            | <p>Signed Memorandum of Collaboration with Oryol and Vladimir TB Clinics</p> <p>Central Moscow TB Institute started testing antiTB medicines with Minilab<sup>®</sup></p>  |    |    |    |
| Equip & train two add'l clinics on Minilab <sup>®</sup>                                       |            | Together with USAID/Russia identified  |    |    |    |

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 Quarterly Reports: FY11

| Activity   | Staff Lead | Quarter  |    |    |    |
|--|------------|--|----|----|----|
|  |            | Q1   | Q2 | Q3 | Q4 |
| project  |            | up to six new TB clinics to receive Minilabs <sup>®</sup><br><br>Drafted and delivered to selected clinics a letter proposing participation in the Minilab <sup>®</sup> activity |    |    |    |
| Conduct PE training for Roszdravnadzor regional NQCLs  |            | Together with Roszdravnadzor identified potential dates and list of courses to be delivered  |    |    |    |
| Provide TA to Roszdravnadzor regional NQCLs in WHO PQ  |            | Together with Roszdravnadzor identified new labs to provide TA   |    |    |    |
| Train Roszdravnadzor GMP inspectors on GMP & Validation  |            | Together with Roszdravnadzor identified potential dates, participants and instructors of the courses   |    |    |    |
| Train Roszdravnadzor staff at USP on key meds quality issues   |            | Together with Roszdravnadzor identified potential candidates to participate in the training and list of topics to cover  |    |    |    |
| <b>Latin America and the Caribbean</b>   |            |  |    |    |    |
| <b>Amazon Malaria Initiative</b> V. Pribluda   |            |  |    |    |    |
| <b>Implementation of three-level approach for sustainable MQM activities throughout the supply chain</b> |            |  |    |    |    |
| Conduct regional workshop to develop protocols for 3-level approach in supply chain in varied settings   |            | The concept paper on the 3-level approach is currently under editorial review.   |    |    |    |

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 Quarterly Reports: FY11

| Activity  | Staff Lead | Quarter   |    |    |    |
|---|------------|---|----|----|----|
|   |            | Q1  | Q2 | Q3 | Q4 |
| Provide TA to OMCLs Colombia to implement 3-level approach  |            | 2 Minilabs for the National Network of Laboratories shipped.  |    |    |    |
| <b>Strengthening south-south collaborations, facilitating communication, and sharing information between MRAs and OMCLs across AMI and CA&amp;C countries</b> |            |   |    |    |    |
| Support internships & S-S TA for at least two countries (Ecuador & Peru)  |            |   |    |    |    |
| Assist Peru OMCL to deliver inter-lab proficiency testing scheme for add'l tests  |            | Second round of 2010 proficiency testing sponsored by Peru OMCL (CNCC) finalized, with the participation of Bolivia, Brazil (4 OMCLs), Colombia, Costa Rica, Guatemala, Guyana, Jamaica, Panama, and Peru                   |    |    |    |
| Launch web-based forum & facilitate use by OMCLs and MRAs   |            | Initial development of the web-based forum completed. Access will be given to users in Q2.  |    |    |    |
| <b>Implementation of stringent Quality Management Systems</b>   |            |   |    |    |    |
| Assist Bolivia OMCL obtain WHO PQ for microbiology tests  |            |   |    |    |    |
| Follow up CAPAs from QMS audits of Colombia, Panama, Guatemala OMCLs  |            | Report of two CNCC staff's visit to Guatemala OMCL was distributed. Guatemala has developed a plan to remediate findings. Plan has been distributed to PQM and CNCC and both parties will program follow-up activity in Q2. |    |    |    |

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| Activity   | Staff Lead | Quarter  |    |    |    |
|--|------------|--|----|----|----|
|  |            | Q1   | Q2 | Q3 | Q4 |
| <b>Ensuring the availability of good quality malaria medicines</b>                 |            |  |    |    |    |
| Conduct regional workshop for GMP inspectors & support S-S MRA collaboration       |            |  |    |    |    |
| Help Farmanguinhos obtain WHO PQ of ASMQ; recommend interventions                  |            | cGMP assessment planned for Q2   |    |    |    |
| Assess QA systems & help establish QC for AMs in Suriname                          |            |  |    |    |    |
| <b>Assist with antimalarial MQM activities</b>                                     |            |  |    |    |    |
| Evaluate quality of AMs in areas of illegal commerce in Guyana, Colombia, Suriname |            | <p><u>Guyana</u> - 68 of 78 AMs collected in Guyana completed full analysis by the PQM lab; 14 failed. The results of the 10 remaining samples will be available in Q2.</p> <p><u>Suriname</u> - 10 AMs from Suriname were analyzed by the PQM lab; all passed. All of the samples collected were Artecom (Dihydroartemisinin, Piperaquine phosphate, and Trimethoprim ) FDC tablets co-blister packed with one Primaquine phosphate tablet of unknown strength. This AM is not registered in the country nor is it part of the national treatment</p> |    |    |    |

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| Activity   | Staff Lead | Quarter   |    |    |    |
|--|------------|---|----|----|----|
|  |            | Q1  | Q2 | Q3 | Q4 |
|  |            | <p>guidelines.</p> <p><i>Colombia – The Report of the First Part of a Study to Assess the Quality of Antimalarials in the private and informal sector in three departments in Colombia</i> has been received from the consultant and is under review by PQM and PAHO/Colombia. The First Part of the study was to identify facilities that sell malaria medicines and the type of medicines being sold at those facilities.</p> |    |    |    |
| Support NMCP MQM at sentinel sites using Minilabs® & updated protocols       |            | Reference standards for malaria medicines for the Minilab sent to Colombia's NMCP   |    |    |    |
| Study availability & quality of AMs in all sectors in Nicaragua and Honduras |            | This activity has not been approved by USAID and will be reprogrammed during Q2   |    |    |    |
| <b>Dissemination of results on the quality of antimalarial medicines</b>     |            |   |    |    |    |
| Write an article with results of MQM at sentinel sites, esp. public sector   |            | In progress   |    |    |    |
| Write an article on studies of AM quality in private & informal              |            | Submitted preliminary summary report of Quality of Antimalarial   |    |    |    |

Promoting the Quality of Medicines (PQM Program)  
 Quarterly Reports: FY11

| Activity  | Staff Lead | Quarter  |    |    |    |
|---|------------|--|----|----|----|
|   |            | Q1   | Q2 | Q3 | Q4 |
| sectors of Colombia, Guyana & Suriname  |            | Medicines results for Guyana to in-country partners and USAID. Summary reports and articles on AM quality in Guyana and Suriname in progress.  |    |    |    |
| Launch and maintain online database of MQM results  |            | Countries' data is being downloaded to the database. Web design is being finalized and late IT development issues are being addressed. Approval from several countries to include data is expected in Q2; launch expected in Q2. |    |    |    |
| <b>Promote and implement evidence-based decisions on accessibility, quality, and use of appropriate diagnosis and treatment</b>   |            |  |    |    |    |
| Participate in AML and other meetings   |            |  |    |    |    |
| <b>Maternal and Child Health</b> V Pribluda   |            |  |    |    |    |
| <b>Dissemination of results from studies performed in Guatemala and Peru</b>  |            |  |    |    |    |
| Share study results via conferences, & pubs to nat'l/int'l stakeholders   |            | Two venues identified for the presentation of results to obstetricians and nurses  |    |    |    |
| <b>Follow-up on studies to assess the quality of selected obstetric and neo-natal medicines utilized in primary care health Facilities in decentralized regions in Peru and Guatemala</b> |            |  |    |    |    |
| Identify source of problems found in Peru & Guatemala studies; share with stakeholders  |            | 1) Most of medicines sampled in Peru have been analyzed and a final report on results is expected by Q2<br>2) Revised version of the study proposal in Guatemala sent to MoH. The proposal was                                   |    |    |    |

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| Activity   | Staff Lead | Quarter   |    |    |    |
|--|------------|---|----|----|----|
|  |            | Q1  | Q2 | Q3 | Q4 |
|  |            | discussed with MoH representatives during a PQM trip to Guatemala in December 2010. The revised version has been approved and will be signed in January 2011 by the MoH, following which the sampling protocol will be implemented. |    |    |    |
| Develop CAPAs with stakeholders & help implement   |            |   |    |    |    |
| If no critical issues from studies, expand to Peru or Guatemala or another country               |            |   |    |    |    |
| <b>South American Infectious Diseases Initiative (SAIDI) A. Barojas</b>                          |            |   |    |    |    |
| <b>Introduction of SAIDI approach, focusing on AMR for TB, in one department in Peru</b>         |            |   |    |    |    |
| Assist SAIDI partners identify dept in Peru to introduce approach                                |            | SAIDI SC has decided to introduce SAIDI approach in "Madre de Dios" district.   |    |    |    |
| Develop Terms of Reference for base-line study on TB resistance                                  |            | SAIDI SC has developed ToR for consultant and work has begun. Consultant results will be presented in Q2 workshop   |    |    |    |
| Coordinate local workshop to disseminate results of base-line study & develop plan to combat AMR |            | Baseline study will be presented at workshop in March. Local stakeholders and SAIDI SC will identify priority actions and work towards developing a   |    |    |    |

Promoting the Quality of Medicines (PQM Program)  
 Quarterly Reports: FY11

| Activity  | Staff Lead | Quarter                          |    |    |    |
|---|------------|----------------------------------|----|----|----|
|   |            | Q1                               | Q2 | Q3 | Q4 |
|   |            | logical framework to combat AMR. |    |    |    |
| <b>Publish article on MQM activities performed in all SAIDI countries</b> |            |                                  |    |    |    |
| Identify target audience and publications                                 |            |                                  |    |    |    |
| Develop & circulate draft among int'l & nat'l partners                    |            |                                  |    |    |    |
| Submit paper to selected publications                                     |            |                                  |    |    |    |