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FACT SHEET 3

The Amazon Malaria Initiative: Antimalarial Medicine Quality

HIGHLIGHTS OF AMI PROGRESS IN ANTIMALARIAL MEDICINE QUALITY

- Strengthening QA and QC throughout the supply chain.
- Strengthened the official medicine control laboratories in each country by providing laboratory training and supplies, and guidance on quality management systems.
- Assisted in implementing a decentralized methodology to monitor and control medicine quality by promoting and facilitating the use of portable laboratories for medicine quality testing.
- Raised awareness about the need for improved medicine quality in participating Amazon Basin countries: Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname.

OVERVIEW: ANTIMALARIAL MEDICINE QUALITY

Poor quality antimalarial medicines may exacerbate the burden of malaria in the Amazon Basin subregion. Antimalarial medicines that do not meet regulatory requirements are divided in two main groups: (i) **sub-standard medicines** that are legitimate medicines from the identified manufacturer that do not meet quality specifications, due to poor manufacturer practices or improper storage conditions; and (ii) **counterfeit medicines** that are deliberately mislabeled with respect to the product's identity, and/or manufacturer and content.*

Providing populations with high quality antimalarial medicines is challenging for several reasons: there may be weaknesses in medicine regulatory authorities or difficulties in enforcing existing regulations; and countries may have a limited capacity to test medicine quality.

An essential component to ensuring high-quality medicines is the development and implementation of comprehensive quality assurance (QA) and quality control (QC) systems that operate in such a way that ensure only good quality medicines are procured, and that the quality of the medicines is maintained and controlled at every stage of the distribution chain until it reaches the patient. The quality of antimalarial medicines has been assessed mostly in the public sector, at dispensing sites in sentinel sites, where the prevalence of poor quality medicines has been shown to be relatively low. Currently, studies are underway to assess the quality of antimalarials in the private and informal market, where the risk of finding sub-standard and counterfeit medicines is higher.

AMI GOALS AND PRIORITIES

Goals

1. Ensure malaria control programs incorporate selected best practices.
2. Improve malaria control at the sub-regional level.
3. Contribute to decreased malaria morbidity and mortality.

Priorities

Provide effective malaria control and treatment by:

a. Assessing efficacy of currently used medicines and suitable replacements;
b. Choosing and implementing new treatment policies;
c. Improving diagnostic quality assurance and quality control;
d. Expanding access to diagnostic tests and good quality antimalarial medicines;
e. Strengthening vector surveillance and control;
f. Disseminating information.

AMI OBJECTIVE IN ANTIMALARIAL MEDICINE QUALITY

Ensure the sustained availability of effective, good quality antimalarial medicines.

AMI INVOLVEMENT IN ANTIMALARIAL MEDICINE QUALITY

In an effort to assure good quality antimalarial medicines, AMI has conducted activities in four complementary areas: (i) strengthening QA and QC throughout the supply chain; (ii) strengthening the official medicine control laboratory (OMCL) in each country and increasing South-South collaboration; (iii) assisting in implementing a decentralized methodology in the subregion

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Pan American Health Organization
Regional Office of the World Health Organization
CDC SAFER·HEALTHIER·PEOPLE
msh Management Sciences for Health
USP U.S. Pharmacopeia The Standard of Quality
LINKS MEDIA Creating a Culture of Learning
RTI INTERNATIONAL

AMI INVOLVEMENT IN ANTIMALARIAL MEDICINE QUALITY *(continued)*

to monitor and control the quality of medicines; and (iv) raising awareness about the issue of antimalarial medicine quality among participating Amazon Basin countries.

Strengthening QA and QC throughout the supply chain. Regional workshops were held in Colombia and Guatemala in 2008 to improve the management of supply and QA systems for malaria. The primary objective was for each country to develop procedures to serve as the basis for the institutionalization and integration of processes that will result in an uninterrupted supply of medicines of guaranteed quality. Subsequently, AMI worked with individual countries to provide guidance for the development of standard operational procedures.

Strengthening the OMCL in each country and increasing South-South collaborations. Through country visits and regional workshops, AMI strengthened the OMCL in each country by providing hands on training in the laboratory and sustaining improvement in their quality management systems (QMS).

- AMI supported OMCLs in implementing stringent QMS to comply with internationally recognized standards (WHO and/or ISO). These activities resulted in one OMCL receiving ISO/IEC 17025:2005 accreditation and several others participating in the WHO prequalification program.
- Personnel of AMI's OMCLs have been trained in Good Laboratory Practices; basic technologies (dissolution, high performance liquid chromatography, UV testing); advanced analytical methods (gas chromatography; use of headspace apparatus), and proper interpretation of monographs.
- In a workshop delivered in Peru in 2009 with the participation of senior management of OMCLs from all AMI countries and several countries from Central America and the Caribbean, the fundamentals of a collaborative program between OMCLs were established to strengthen sustainability and South-South collaborations. Following this workshop, numerous trainings have been coordinated between OMCLs. Most AMI OMCLs participated in two rounds of the inter-laboratory proficiency test scheme coordinated by Peru's OMCL.

Assisted the implementation of a decentralized methodology for QC. AMI assisted in implementing a decentralized methodology in the subregion to monitor and control the quality of medicines. This methodology makes use of basic tests as a means to provide a decentralized, portable, rapid, cost-effective, and reliable tool for performing QC in the field. In addition to performing visual and physical inspection of the medicines, basic tests can assess four critical quality attributes, including identity, content, impurities, and, for solid dosage forms, disintegration. This methodology should always be utilized in coordination with the OMCL, as it enables the initial screening of a large number of samples, thus reducing the burden imposed on the OMCL.

- Minilabs® (portable laboratories from the Global Pharma Health Fund) were provided to all partner countries
- In addition, Minilabs® training workshops were held for the technical personnel from national and provincial laboratories in all AMI countries.
- Minilabs® are operational in all AMI countries and since inception, over 1500 field samples have been tested.

Raised antimalarial medicine quality awareness. By documenting shortcomings in QA systems, AMI raised awareness about the issue of antimalarial medicine quality among Amazon Basin countries.

- AMI is conducting QC of the antimalarials used in the private and informal sector in certain countries. Since national malaria control programs in AMI countries operate within the public sector only, these studies will provide important information about the quality of medicines in these sectors, where the risk of poor quality medicines is higher. The latter is particularly relevant for gold mining areas, where local and migrant population may have very limited access to public health assistance. In addition to the risks posed by ineffective poor quality medicines, illegal sale may increase the burden of the disease because self-medication and incorrect or incomplete treatment may lead to persistent transmission.
- The 2008 regional workshops held in Colombia and Guatemala, to improve the management of supply and QA systems for malaria, served as well to raise awareness among countries' stakeholders on the deficiencies of their QA and QC systems. Unless properly addressed, these deficiencies may result in a health hazard because of the inability to ensure the quality of the medicines provided to the population through the national programs.

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* World Health Organization Media Centre. 2003. *Substandard and counterfeit medicines.* http://www.who.int/mediacentre/factsheets/2003/fs275/en/;
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