

FEVER DIAGNOSTIC REGULATORY, PROCUREMENT FINANCING & DISTRIBUTION MECHANISMS

STAKEHOLDER MAP

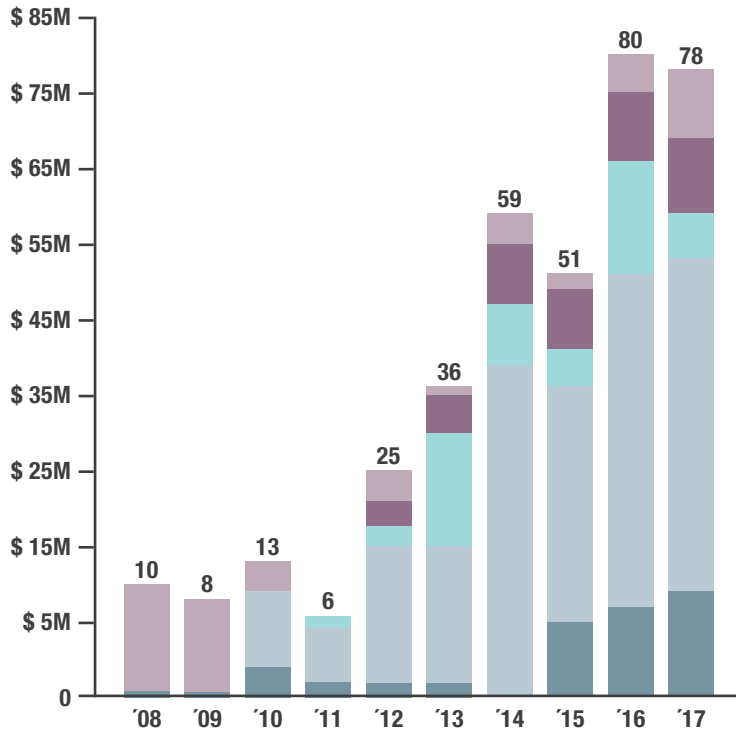
	DONOR-DRIVEN MARKETS		NON DONOR-DRIVEN MARKETS
	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS	MAIN STAKEHOLDERS
1. WHO IS USING RDTs?	Lower-level facilities Community level (VMWs) Clinics GPs	Hospitals Pharmacies	Private hospitals Major public hospitals
2. WHO IS PAYING FOR RDTs?		        	Patients
3. WHO IS BUYING RDTs?	 	       	Doctors
4. WHO IS DISTRIBUTING RDTs?	Vector-borne Disease Control Program (VBDCP) Central Medical Store Depot (CMSD)	    	Direct from manufacturer/ distributor CMSD

Stakeholders are numerous in Myanmar and international help and bi-national cooperation is very active

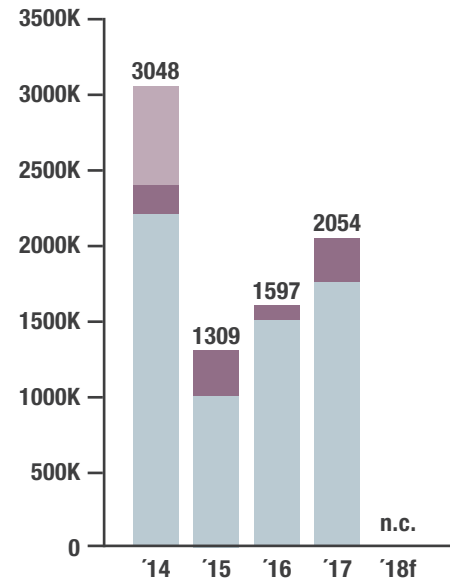


MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

SPECIFIC FUNDING FOR MALARIA (INCLUDING PREVENTION, DIAGNOSIS AND TREATMENT)



MALARIA RDT FUNDING (TESTS DISTRIBUTED)



LEGEND

- GOVERNMENT
- GLOBAL FUND
- UK
- PMI/USAID
- OTHER / NOT SPECIFIED / UNKNOWN

Distinct financing sources coexist for malaria diagnosis

- **RDTs are mainly financed by the Global Fund** (1.7M to 2.2M tests per year)
- **GF RAI2E** (Regional Artemisinin-resistance Initiative Elimination Program) **funding will cease in 2020**; the funding landscape for the post-2020 period is uncertain.
- **USAID / PMI might address potential gaps that may arise**, notably RDTs, ACT treatments, in-service training, accreditation of microscopy trainers, drug resistance monitoring, ...

There has been a strong growth in malaria financing in recent years, mostly led by the Global Fund

Post 2020, financing is uncertain

Sources: WHO, USAID-PMI, Global Fund, MOPH, Adventon



PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF mRDTs

PRODUCT SELECTION	The NMCP states that only WHO-PQ RDTs should be procured
PROCUREMENT	UNOPS is the primary source of procurement under the Global Fund. For donors other than UNOPS, like USAID/PMI, procurement is handled through other organizations, e.g. logistics specialists such as Chemonics
FORECASTING AND QUANTIFICATION	The NMCP is responsible for forecasting commodities needs based on epidemiological data and past consumption. Annual forecasting workshops are led by UNOPS with input from NMCP, WHO and other GF sub-recipients (including nongovernmental organizations)
CUSTOMS CLEARANCE	Government- and donor-procured products are primarily cleared by the CMSD* Customs Clearance Department

MARKET AUTHORIZATION PROCESS FOR RDTs

The Myanmar Ministry of Health's Food and Development Administration (FDA) oversees the safety and quality of medical devices and drugs.

The normal time for registration is comprised of 6-12 months, fees are ~USD 830, no plant inspection is mandatory and the registration is valid for 5 years.

Myanmar accepts the ASEAN Common Technical Dossier (ACTD), the agreed common format for the preparation of a well-structured

application submitted to ASEAN regulator authorities for the registration of pharmaceuticals for human use.

Imported medical devices must obtain an Import Recommendation and a Trade Permit, which is often difficult due to complicated administrative requirements and lengthy processing times.

Stringent authorities recognition (US FDA, CE) and WHO prequalification are taken into account in Myanmar's FDA decision.

NMCP and UNOPS are the key players for the RDT malaria procurement system
Market authorization process in Myanmar is simplified with the ASEAN Common Technical Dossier

Note: (*) Central Medical Store Depot. Sources: Andaman medical, WHO, FIND, Advention





CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	<p>Vector-borne Disease Control Program (VBDCP)</p> <p>Central Medical Store Depot (CMSD)</p>	<p>MSF (Médecins Sans Frontières) and PSI will handle the distribution of RDTs to private facilities and providers financed by the Bill & Melinda Gates Foundation, DFID (Department for International Development) and MoH</p>
DISTRIBUTION SYSTEM DESCRIPTION	<p>Health commodities are distributed through VBDCP and CMSD. A “pull” system is in place in which staff from lower-level facilities travel to retrieve commodities from higher levels of the health system. Transportation consists of a largely informal network of independent operators</p>	<p>Other malaria RDTs can be distributed directly from manufacturers and private distributors</p>
LOGISTICS QUALITY MONITORING	<p>A logistics management information system (LMIS) has been developed, although only a portion of the facilities conducting procurement have some basic procedures in place to capture data. Stock recording remains largely paper-based. An electronic LMIS based on the software mSupply is also being piloted</p>	
QUALITY ASSURANCE SYSTEM	<p>The Department of Food and Drug Administration (FDA) is responsible for quality assurance and control (QA/QC) of antimalarial products. To prevent the sale of artemisinin monotherapy, the Regional Artemisinin-resistance Initiative (RAI) grant is funding support to strengthen FDA's capacity to conduct drug-quality monitoring.</p>	
CENTRAL WAREHOUSE FACILITIES	<p>The first point of warehousing can be in one of several locations including CMSD, Myanmar Pharmaceutical Factory (MPF), suppliers, vendor warehouses, VBDC central warehouse and nongovernmental organization central warehouses.</p>	

VBDCP and CMSD are the key players for the public sector malaria distribution system

PSI and MSF are the key distributors for the subsidized private sector

Sources: WHO, FIND, Advention