


FEVER DIAGNOSTIC REGULATORY, PROCUREMENT FINANCING & DISTRIBUTION MECHANISMS

STAKEHOLDER MAP

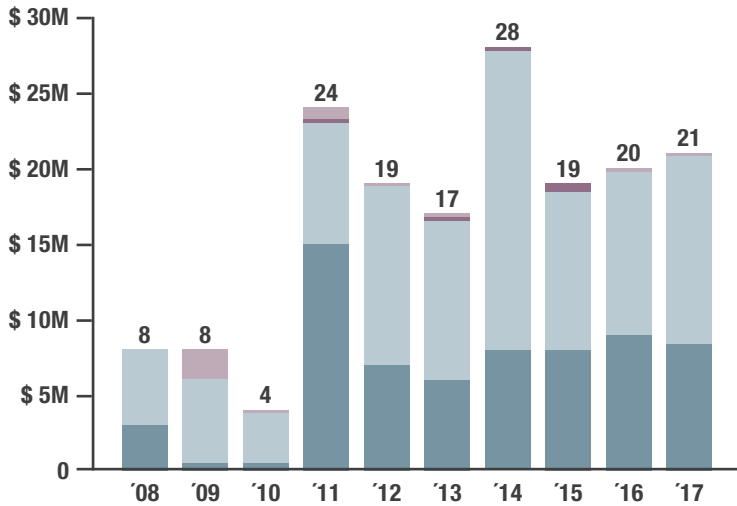
	DONOR-DRIVEN MARKETS		NON DONOR-DRIVEN MARKETS
	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS	MAIN STAKEHOLDERS
1. WHO IS USING RDTs?	Lower-level facilities	Community and Health Promotion Hospitals	Private hospitals Major public hospitals
2. WHO IS PAYING FOR RDTs?	 The Global Fund To Fight AIDS, Tuberculosis and Malaria	BVBD/MoH	National Health Security Office (NHSO) Private hospitals
3. WHO IS BUYING RDTs?	BVBD (Bureau of Vector Borne Diseases)/MoH		MoH Doctors
4. WHO IS DISTRIBUTING RDTs?	BVBD (Bureau of Vector Borne Diseases)		Direct from manufacturer/distributor MoH distribution network

For donor-driven market, the stakeholder map is pretty straightforward in Thailand; the GF funds BVBD procurement while PMI/USAID have their own procurement network; all public RDTs are distributed through the BVBD network

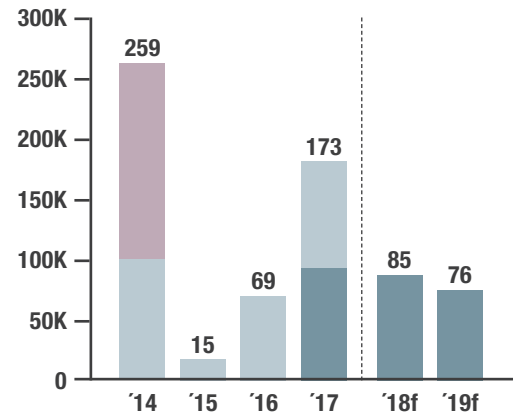


MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

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



MALARIA RDT FUNDING (TESTS DISTRIBUTED)



LEGEND

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

Distinct financing sources coexist for malaria diagnosis

- RDTs are mainly financed by the Global Fund (80K to 100K tests per year)
- GF RAI2E (Regional Artemisinin-resistance Initiative Elimination Program) funding will cease in 2020, funding landscape for the post-2020 period is uncertain. The Thai government will probably take over the funding for RDTs
- USAID / PMI might address potential gaps that may arise, notably for RDT procurement

Until 2020, malaria diagnosis will be mainly financed by the Global Fund
Starting in 2020, the government and potentially USAID/PMI will have to take over funding

Sources: WHO, USAID-PMI, Global Fund, MoPH, Advention

PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF mRDTs

PRODUCT SELECTION	The BVBD selects malaria tests among WHO prequalified RDTs
PROCUREMENT	The BVBD procures RDTs under the Global Fund Pooled Procurement Mechanism (PPM). Procurement occurs on an annual basis
FORECASTING AND QUANTIFICATION	The Global Fund Principal Recipient, the MoH, is responsible for RDT forecasting, which is based on the previous year's consumption, with a 20% buffer
CUSTOMS CLEARANCE	Companies manage customs clearance themselves based on the "hazardous substances trade" procedures

MARKET AUTHORIZATION PROCESS FOR RDTs

The Medical Device Control Division of the country's Food and Drug Administration (FDA) is the competent authority for market authorization.

The FDA automatically accepts medical devices that are approved by the main stringent authorities.

Otherwise, the process is rather painless:

- Diagnostic tests are not submitted to clinical efficacy evaluation from randomized control trials before market approval
- Registration takes 2-4 weeks and relies on a risk-based classification system. RDTs fall under Class III (except HIV RDTs)
- Then an import license must be obtained before the device can be imported or sold in Thailand. It generally takes between 3 to 5 months for a Class III device

The ASEAN Medical Device Directive aims to standardize authorization process within the ASEAN member network

- RDTs might be reclassified
- A change in Thai FDA regulation would be necessary and would probably mean submitting samples for evaluation

BVBD is the key player for the RDT malaria procurement system

Authorization process is quite short and easy, particularly if the test is already approved by a stringent authority

Notes: (*) Bureau of Vector Borne Diseases; (**) Association of Southeast Asian Nations Medical Device Directive. Sources: Business Sweden, Pacific bridge medical, WHO, Adventon



CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	The National Malaria Control Program (NMCP)	Over 10,000 operators are active in the sector and of these, almost all (99%) are SMEs, which together take 60% of income
DISTRIBUTION SYSTEM DESCRIPTION	The National Malaria Control Program (NMCP) within the Bureau of Vector-Borne Disease (BVBD) manages the delivery of commodities. RDTs are delivered to the central Vector-Borne Disease Centers (VBDCs) twice a year, and distribution to the local Vector-Borne Disease Units (VBDUs) and to malaria clinics occurs monthly at scheduled meetings where RDTs are collected	Distribution is organized directly by the manufacturer or partner distributors to the laboratory or hospital In the case of laboratory or hospital groups/chains, the group may manage distribution from local warehouses
LOGISTICS QUALITY MONITORING	There is currently no system that reports regularly on commodities, although once a year, data on stock status, consumption and need are consolidated to decide on procurement levels for the following year. Excel spreadsheet files are used to track stock status of RDTs every quarter	
QUALITY ASSURANCE SYSTEM	Quality assurance and control (QA/QC) is led by the BVBD. Once a year, random sampling of antimalarials is conducted in the field, although this is not formalized through guidelines. The Bureau of Drug and Narcotics (BDN), under the Department of Medical Sciences, conducts testing on behalf of the BVBD	Quality assurance is managed by the distributor or the purchaser depending on contract specifications
CENTRAL WAREHOUSE FACILITIES	The BVBD is responsible for storing commodities at its central warehouse. Regional offices also have warehouses, but in some cases, private rental of warehouses may be necessary for temporary storage if there is a lack of space at the regional level	Logistics quality monitoring is monitored internally by both the distributor and the purchaser

NMCP and BVBD are the key players for the public sector malaria distribution system

Private institutions rely on distributors or purchase directly from manufacturers