VIET NAM

FIND
Because diagnosis matters

FEVER DIAGNOSTIC REGULATORY, PROCUREMENT FINANCING & DISTRIBUTION MECHANISMS

STAKEHOLDER MAP

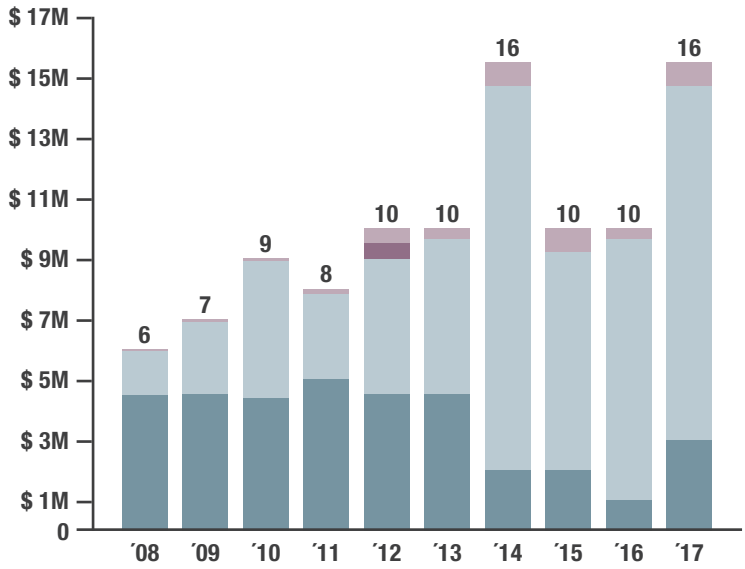
	DONOR-DRIVEN MARKETS		NON DONOR-DRIVEN MARKETS	
	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS*
1. WHO IS USING RDTs?	Communal Health Centers (MoH)	District Hospitals (MoH)	Communal Health Centers (MoH)	District Hospitals (MoH) Private clinics
2. WHO IS PAYING FOR RDTs?	The Global Fund To Fight AIDS, Tuberculosis and Malaria		Social Health Insurance	Patients
3. WHO IS BUYING RDTs?	The Global Fund To Fight AIDS, Tuberculosis and Malaria	NMCP (Procurement)	MoH (Commune & District level facilities)	Individual Hospitals (public & private)
4. WHO IS DISTRIBUTING RDTs?	NIMPE Communal Health Centers	MoH	MoH	

The Global Fund is the main stakeholder regarding RDTs in fever diagnostics, as they finance tests which are provided free of charge to communal- and district-level health facilities in areas with high malaria endemicity

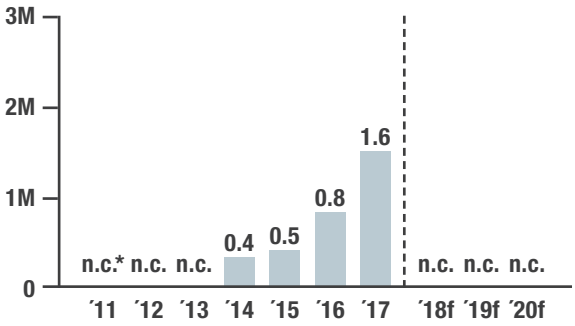
Note: (*) Based on identified use cases for tests in scope. Sources: interviews, Advention

MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

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



MALARIA RDT FUNDING (TESTS DISTRIBUTED)



LEGEND

GOVERNMENT | GLOBAL FUND | WORLD BANK | OTHER / NOT SPECIFIED / UNKNOWN

Distinct financing sources coexist for malaria diagnosis

- RDTs are mainly financed by the Global Fund (0.4 - 0.9M tests per year), with additional volumes from other donors (0.4M tests in 2016 and 0.7M in 2017)
- Equipment and reagents for microscopy diagnosis are co-financed by the Global Fund and MoH
- In 2016-2017, there was a major stock-out of RDTs in all 15 provinces supported by the Global Fund's New Funding Model but not by the Regional Artemisinin-resistance Initiative. Global Fund-selected products did not have the necessary import permit or free-sales certificates required by MoH despite this being flagged as a requirement by NIMPE before the start of the procurement process

Malaria diagnosis is mainly financed by the Global Fund, who finances and selects RDTs which must meet both WHO quality and country regulatory specifications

Note: (*) not communicated. Sources: WHO, Global Fund, MoH, interviews, Advention

PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF RDTs

PRODUCT SELECTION

NMCP oversees product selection, and its policy development body, is comprised of multiple stakeholders

Products are listed in the national treatment guidelines

PROCUREMENT

NMCP is responsible for yearly tendering. Lead times are long, taking approximately six months from submission of forecast to receiving goods in Viet Nam at the NIMPE* warehouses

FORECASTING AND QUANTIFICATION

NMCP leads annual forecasting, with support from NIMPE for technical inputs; and requests from provinces. Consumption data, epidemiological factors and requests from provinces are used to develop forecasts that are consolidated nationally by NMCP

CUSTOMS CLEARANCE

Antimalarials are procured locally and shipped to NIMPE warehouses. The GFPMU** conducts customs clearance for internationally procured RDTs

PROCUREMENT PROCESS OF OTHER TESTS

Public: direct from manufacturer/distributor for hospitals & labs (tbc)

Private: direct from manufacturer/distributor (variation tbc)

MARKET AUTHORIZATION PROCESS FOR RDTs

Authorization for sale is a highly administrative process which requires the applicant to follow-up with various departments to ensure timely processing

- The process takes around 3 months, but incomplete or erroneous submissions cannot be amended and must be entirely resubmitted
- Departments involved in the authorization process are not necessarily highly reactive, and applicants are encouraged to remain involved with the administration to ensure rapid processing

For non-donor funded tests, approval and negotiation with the Social Health Insurance (SHI) is obligatory to achieve widespread use in Viet Nam

- Tests not included on the SHI list can be financed through donors (like mRDTs financed by the Global Fund) or pure out-of-pocket expenses by patients
- Pure out-of-pocket diagnostic tests are absent currently in Viet Nam, and both public and private facilities are reluctant to offer them
- SHI approval is highly complex, as it requires significant proof of cost-effectiveness and test quality to be generated locally
- SHI is updated annually, with a negotiated reimbursement price that will be the baseline for the test cost in public hospitals

NMCP is the key player for the RDT malaria procurement system

The reimbursement of tests not financed through donors is negotiated with SHI

Notes: (*) National Institute of Malariology, Parasitology and Entomology (NIMPE); (**) GFPMU Global Fund Project Management Unit. Sources: WHO, FIND, Advention

CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	MoH distribution is organized on a cascade model for district and commune level facilities, with specific paths disease programmes (NIMPE and IMPE for malaria) and self-management of stocks at provincial and central level facilities	Under Vietnamese law, only business entities registered in Viet Nam that have an import license are eligible to distribute medical devices. Manufacturer subsidiaries appear to be the main distributors
DISTRIBUTION SYSTEM DESCRIPTION	The system of distribution is a needs-based "pull" system. For malaria, once a year, provincial staff visit their respective NIMPE/ IMPE and collect their commodities for the year. District-level distribution takes place at meetings and involves the hand carry of commodities	Private institutions are generally independent, and are supplied directly by the manufacturer subsidiary
LOGISTICS QUALITY MONITORING	Stocks reports are part of the routine reporting system as quarterly reporting form. While an electronic malaria information system is in use from district level and above, reporting and usage rates are low. Hard copy data are thus still is use, and are compiled in and Excel spreadsheet at the central level overseen by NIMPE	Logistics quality is ensured by test suppliers
QUALITY ASSURANCE SYSTEM	All MoH facilities adhere to ISO 9001 quality assurance and are overseen by the National Institute for Drug Quality Control. Disease programmes also provide facilities, with 17 laboratories providing QA testing for malaria tests	Laboratory teams typically ensure quality assurance processes in-house
CENTRAL WAREHOUS. FACILITIES	Based on the cascade model, warehousing is organized centrally by MoH. Regional facilities also exist and may be dedicated to specific types of drugs or disease programmes	

MoH ensures a centralized cascading distribution system, although provincial and central-level facilities may also purchase tests independently, like private facilities

NIMPE/IMPE are the key players for the public sector malaria distribution system

Sources: WHO, FIND, interviews, Advention