INDIA

FIND
Because diagnosis matters

FEVER DIAGNOSTIC REGULATORY, PROCUREMENT FINANCING & DISTRIBUTION MECHANISMS

STAKEHOLDER MAP

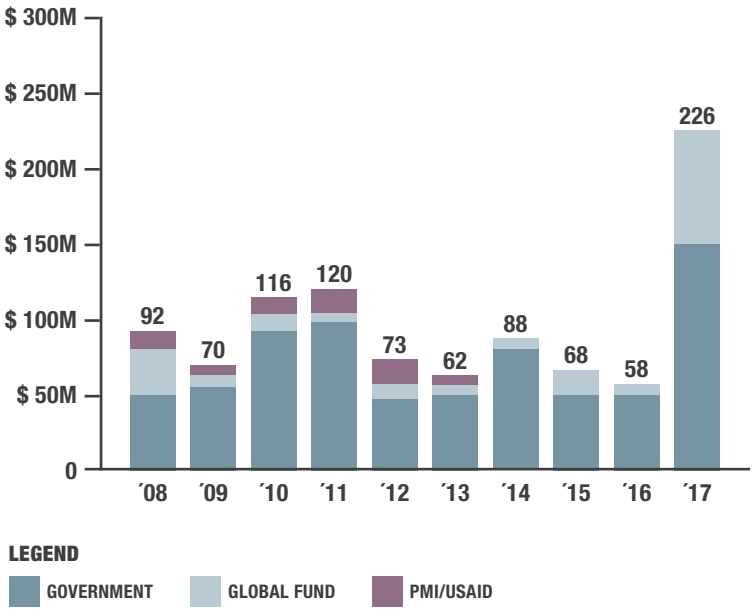
	NON DONOR-DRIVEN MARKETS*	
	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS**
1. WHO IS USING RDTs?	Sub-Health & Primary Health Centers Private laboratories	Private clinics and hospitals
2. WHO IS PAYING FOR RDTs?	Patients	National and State MoHs (malaria only)
3. WHO IS BUYING RDTs?	National and State MoHs & Private laboratories	Prescribing physicians
4. WHO IS DISTRIBUTING RDTs?	Regional private distributors	State MoHs and health agencies

Presently, the public healthcare system through the State agencies are the main stakeholders regarding RDTs for malaria, CRP and pathogens in the fever multiplex

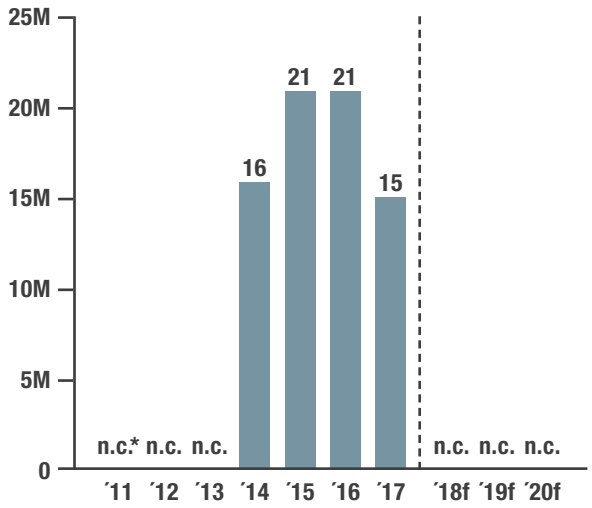
Notes: (*) in India, malaria is not a donor-driven market, as such all tests in scope are in non-donor driven markets; (**) based on identified use cases for tests in scope.
Sources: interviews, Advention

MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

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



MALARIA RDT FUNDING (TESTS DISTRIBUTED)



Malaria-specific funding is mainly provided for by the Government of India

- **The government has committed significant resources to fighting malaria,** but these remain limited on a per-capita basis
- Government reports of low case numbers and excellent case management mean **India is not considered a priority country for donors** despite representing an estimated 4% of malaria cases worldwide and 52% of cases outside of the WHO Africa region
- **Donors have experienced difficulties in the past when attempting to finance malaria projects:** a $200M Global Fund & World Bank project for insecticide-treated nets awarded in 2008 ended up being scrapped in 2014 with no payments made as the government had not managed to organize the purchasing process in a manner consistent with the grant rules. A similar Government-lead project with $80M funding by the Global Fund was launched in 2017, explaining the significantly higher funding provided in 2017 versus previous years

Malaria diagnosis RDTs are exclusively financed by the government

Notes: (*) not communicated. Sources: WHO, World Bank, Global Fund, Ministry of Health & Family Welfare, Advention

PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF RDTs

Public procurement of RDTs is through state medical agencies or national disease programmes

- Malaria diagnostics are 90% procured centrally through government funding for the NVBDCP, with the tendering and purchasing process being managed by the CMSS; the remaining 10% are purchased individually by the state malaria programmes
- Other diagnostics (including CRP and laboratory multiplexes) used in the public sector are purchased through the state medical agencies who manage the tendering process with relevant state agencies
- Public sector patients can be referred to private labs for testing if the facility does not have the required test available

Private procurement of RDTs is direct from manufacturers or distributors based on the hospital's internal purchasing processes.

Contracts in both the public and private sector are usually for one year, with clauses in private sector contracts to opt out if a higher-performance test becomes available.

MARKET AUTHORIZATION PROCESS FOR RDTs

Market authorization for tests is regulated by the Central Drug Standard Control Organization (CDSCO)

- Clinical performance evaluation and approval of new tests is performed directly by the CDSCO
- Matters relating to the regulation of sales, stocks, exhibits or offers for sale or distribution are delegated to the State Licensing Authority
- Any in vitro test for malaria antigens or CRP falls under class C (2nd highest) or D (highest) diagnostic regulations, for which higher standards of proof are imposed
- At least one trial in local settings appears to be necessary to demonstrate the test's quality and performance, although supporting evidence from foreign trials is accepted

Authorization is sufficient for sales to the private sector, but guideline inclusion is needed for the public sector

- The public sector generally does not purchase products that are not included in standard guidelines, whilst the private sector is more open to establishing their own guidelines
- Guidelines are developed at both the national and state level by a wide range of agencies, but the National MoH&FW is working since 2014 on standardization

As healthcare is a state policy in India, states participate strongly in market authorization, establishing guidelines and purchasing tests

Private healthcare providers require only that the test be authorized by the CDSCO*

Notes: (*) Central Drugs Standard Control Organisation. Sources: MoH&FW, interviews, Advention

CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
DISTRIBUTION SYSTEM DESCRIPTION	State medical agencies are responsible for ensuring the distribution of purchased diagnostic tests to the relevant facilities Distribution generally works on a cascading model, from central warehouses to hospitals, from hospitals to rural and basic health centers, and so forth.	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
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	State medical agencies National disease programme coordinators for relevant tests (e.g. NVBDCP for Malaria)	Distribution is strongly regionalized Identified players include ImmunoConcept, Vishat Diagnostic, Instrukem and Krishgen BioSystems
QUALITY ASSURANCE SYSTEM	Quality assurance is managed by the State medical agency, including when necessary lot testing and stock testing	Quality assurance is managed by the distributor or the purchaser depending on contract specifications
LOGISTICS QUALITY MONITORING	Logistics quality monitoring is managed by the State medical agency Logistics quality monitoring may be weak in some cases due to gaps in information systems and reporting processes	Logistics quality monitoring is monitored internally by both the distributor and the purchaser, however there may be weaknesses regarding their interface

Public healthcare distribution strategy is entirely controlled by the state medical agencies

Private institutions rely on distributors which are generally regional players or purchase directly from manufacturers

Sources: interviews, Advention