





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?	 The Global Fund <small>To Fight AIDS, Tuberculosis and Malaria</small>	Basic Health Centers	Private hospitals and private labs	Public hospitals
2. WHO IS PAYING FOR RDTs?	 The Global Fund <small>To Fight AIDS, Tuberculosis and Malaria</small>	Patients	Patients	
3. WHO IS BUYING RDTs?	 The Global Fund <small>To Fight AIDS, Tuberculosis and Malaria</small>	State MoHs and prescribing physicians	Private hospitals and private labs	Public hospitals
4. WHO IS DISTRIBUTING RDTs?	 The Global Fund <small>To Fight AIDS, Tuberculosis and Malaria</small>	State MoHs	Manufacturers or local distributors	State MoHs

The Global Fund has the main role regarding the use of donor-driven RDTs for febrile illnesses in Pakistan, in both the public and the private sector

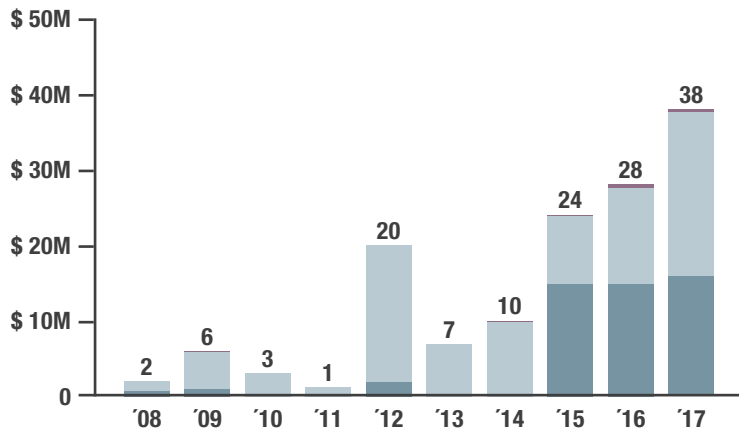
Non donor-driven RDTs are relatively nascent and mainly used in private settings

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



MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

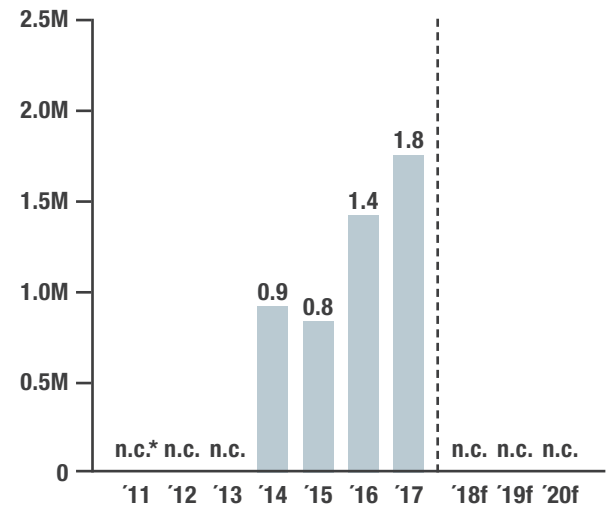
SPECIFIC FUNDING FOR MALARIA (INCLUDING PREVENTION, DIAGNOSIS AND TREATMENT)



LEGEND

- GOVERNMENT
- GLOBAL FUND
- OTHER

MALARIA RDT FUNDING (TESTS DISTRIBUTED)



Malaria-specific funding is provided almost evenly by the Global Fund and the Government of Pakistan (incl. state governments)

- Before the 2015-2020 national malaria plan, the Government did not isolate specific funding for malaria in its budget
- The Global Fund is the main donor and is strongly involved in the organization of malaria response in Pakistan, including ensuring the availability of diagnostic test equipment in the highest-transmission districts
- Microscopy remains the preferred diagnostic tool for malaria in official guidelines, so government funding for malaria diagnostics is exclusively for microscopy equipment, training and reagents

Malaria diagnosis RDTs are exclusively financed by the Global Fund

Note: (*) not communicated. Sources: WHO, World Bank, Global Fund, National MoH, Advention



PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS FOR RDTs

The Global Fund is the sole procurer of RDTs for the public sector, and supplies the majority of the private sector

- Procurement is organized through the Global Fund's Pooled Procurement Mechanism, and is restricted to WHO prequalified products
- Other private sector providers include distributors and local manufacturers, whose products are either bought in bulk by hospitals and labs or on annually negotiated contracts

Financing of tests is almost exclusively secured by the Global Fund, who establishes the evaluation criteria for the purchasing process

- Global Fund-procured tests are funded entirely by the Global Fund, with limited third party input in the purchasing process
- Tests purchased in both the private and public sector, including through the Global Fund must have a local market authorization
- Other private sector providers using RDTs not provided by the Global Fund do not receive specific donor or government funding for RDTs, and self-finance the tests (up to the out-of-pocket payment by the patient of the test and service)

MARKET AUTHORIZATION PROCESS FOR RDTs

RDTs are regulated by the Drug Regulation Authority of Pakistan (DRAP), with the latest rules published in 2017

- Blood-based RDTs are in class B (the second-lowest) if they include lancets, or in class A (the lowest) if they do not
- Class A medical devices have a simplified enlistment process
- Devices that are approved for sale or manufactured according to local standards in certain countries (EU, USA, Japan, Canada, Australia) also have a simplified registration process where they are considered pre-authorized
- The authorization process covers the quality of the test, but does not include any cost-benefit evaluation

Regulation of medical devices is still nascent in Pakistan, and many private practitioners may still use un-registered devices

- Before 2015, there was no regulation for medical devices in Pakistan, except for a small number of highest-risk implants
- Initial rules in 2015 proved too difficult to implement, resulting in the revised and simplified rules published in 2017

The Global Fund has an independent procurement process for RDTs

Authorization for RDTs is relatively simple in Pakistan, with pre-authorization for tests manufactured in certain countries including the USA and the EU



CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
DISTRIBUTION SYSTEM DESCRIPTION	<p>RDTs purchased by the Global Fund are delivered to state warehouses or Tehsil HQ hospitals</p> <p>RDTs are distributed through a 'cascade' model, with larger facilities providing the tests to the smaller facilities they oversee</p>	<p>RDTs purchased by the Global Fund are used in Global Fund-organized labs, with distribution managed directly by the Global Fund and the manufacturer or local distribution partner</p> <p>RDTs not purchased by the Global Fund are distributed directly to the lab or hospital by the manufacturer or distributor</p>
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	<p>State medical agencies</p> <p>Global Fund</p>	<p>Global Fund</p> <p>RDT distributors appear to have only regional or local capacities</p>
QUALITY ASSURANCE SYSTEM	<p>Local quality assurance is managed by the State MoH and Tehsil HQ hospital staff, including when lot testing and stock testing are considered necessary</p> <p>The Global Fund also uses the WHO-FIND lot testing quality assurance system</p>	<p>Quality assurance is managed by the distributor or the purchaser depending on contract specifications</p> <p>The Global Fund uses the WHO-FIND lot testing quality assurance system</p>
LOGISTICS QUALITY MONITORING	<p>Logistics quality monitoring is managed by the State MoH and Tehsil HQ hospital staff with support from Global Fund teams</p>	<p>Logistics quality monitoring is supervised internally by both the distributor and the purchaser, however there may be weaknesses regarding their interface</p> <p>The Global Fund ensures internal logistics quality monitoring for their facilities</p>

The Global Fund is the main distributor of malaria RDTs, and is involved in quality assurance and logistics monitoring for both the public and private sector

Sources: interviews, Advention

