SOUTH AFRICA

FIND
Because diagnosis matters

FEVER DIAGNOSTIC REGULATORY, PROCUREMENT FINANCING & DISTRIBUTION MECHANISMS

STAKEHOLDER MAP

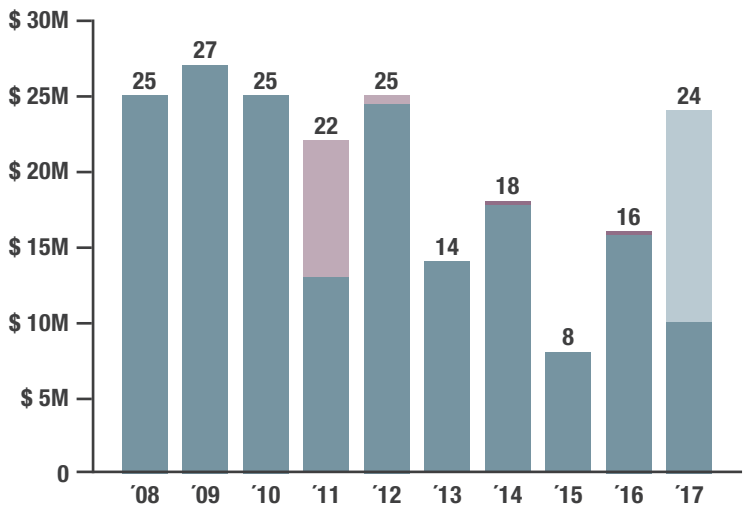
	DONOR-DRIVEN MARKETS		NON DONOR-DRIVEN MARKETS
	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS	MAIN STAKEHOLDERS
1. WHO IS USING RDTs?	Lower-level facilities	Hospitals and labs when microscopy not available Private sector	Public and private facilities
2. WHO IS PAYING FOR RDTs?	NDOH	Private sector	NDOH and patients
3. WHO IS BUYING RDTs?	NDOH	Private sector	Mainly public facilities Private facilities
4. WHO IS DISTRIBUTING RDTs?	NMCP and BVBD (Bureau of Vector Borne Diseases)	DSV Healthcare	NDOH DSV Healthcare

The stakeholder map is pretty lean in South Africa as most distribution is done through the government and DSV Healthcare for the private sector

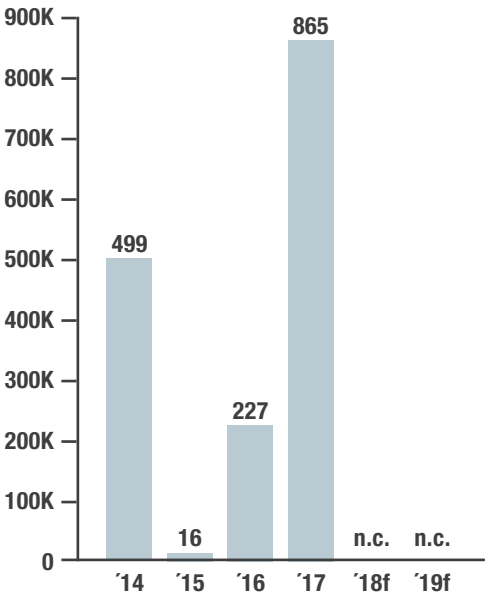
Sources: WHO, Advention

MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

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



MALARIA RDT FUNDING (TESTS DISTRIBUTED)



LEGEND

GOVERNMENT | GLOBAL FUND | UK | OTHER / NOT SPECIFIED / UNKNOWN

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

- RDTs are generally financed by the SA government and is eligible for regional Global Fund malaria grants
- The government has committed significant resources to fighting malaria, but these are decreasing as the malaria burden decreases
- An estimated 6.4 million South Africans are living with HIV/AIDS and over 60 percent are co-infected with tuberculosis, yet the annual malaria parasite incidence is 0.17 percent. Thus, maintaining focus and adequate resources for malaria elimination is a serious challenge

Malaria diagnosis RDTs are usually financed by the government

Sources: CDC, WHO, USAID-PMI, Global Fund, MoH, Advention

PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF mRDTs

PRODUCT SELECTION	The National Department of Health (NDOH) in consultation with the malaria program, selects malaria commodities based on whether they are recommended by the WHO prequalified
PROCUREMENT	The pharmaceutical unit of the NDOH procures RDTs through competitive bidding Procurement occurs every two years NDOH can select multiple tests providers "NDOH is very strict on WHO PQ." NICD, South Africa, Medical Scientist
FORECASTING AND QUANTIFICATION	NDOH is responsible for RDT forecasting
CUSTOMS CLEARANCE	Companies manage customs clearance themselves South African regulation is complex and a local partner is recommended

MARKET AUTHORIZATION PROCESS FOR RDTs

Since 2017, the Medicines Control Council (MCC) has been replaced by SAHPRA South African Health Products Regulatory Authority as the key interface to register, evaluate and assess IVD devices.

IVD Devices are divided into 4 classes depending on risks relating to the patient risk, the intended user or the risk on public health: Class A being low risk and Class D high risk. (N.B. mRDTs are probably classified as C or D).

Manufacturers must obtain a medical device establishment license. Requirements vary per type of IVD classes

- Domestic manufacturers, distributors and wholesalers are required to apply for licenses; foreign-based manufacturers are not

Once the establishment license is granted, the manufacturer can proceed to the registration of medical devices

- It is mandatory for foreign manufacturers to provide their importers and domestic distributors with basic device information, including notably Global Medical Device Nomenclature codes
- Manufacturers and distributors of IVD devices are required to show proof of pre-market approval or registration for a IVD device from at least one of the stringent regulatory authorities as part of their SA registration: the European Competent Authority, US FDA, etc…

NDOH is the key player for the RDT malaria procurement system

The SAHPRA is the competent authority to register an RDT

Sources: SAHPRA, SAMJ, Advention

CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	The National Malaria Control Program (NMCP) DSV Healthcare	DSV Healthcare
DISTRIBUTION SYSTEM DESCRIPTION	The National Malaria Control Program (NMCP) within the Bureau of Vector-Borne Disease (BVBD) manages the delivery of commodities. Medicines are delivered to the Vector-Borne Disease Centers (VBDCs) twice a year, and distribution to the Vector-Borne Disease Units (VBDUs) and to MCs occurs monthly at scheduled meetings where medicines 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 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 BVBD	Quality assurance is managed by the distributor or the purchaser depending on contract specifications
CENTRAL WAREHOUSE FACILITIES	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 like DSV and purchase directly from manufacturers

Sources: WHO, FIND, Advention