CAMBODIA

FIND
Because diagnosis matters

FEVER DIAGNOSTIC REGULATORY, PROCUREMENT FINANCING & DISTRIBUTION MECHANISMS

STAKEHOLDER MAP

	DONOR-DRIVEN MARKETS	
	MAIN STAKEHOLDERS	OTHER RELEVANT STAKEHOLDERS
1. WHO IS USING RDTs?	Health Centers / Health Posts VMWs / MMWs	Formal private sector
2. WHO IS PAYING FOR RDTs?	The Global Fund To Fight AIDS, Tuberculosis and Malaria	PMI
3. WHO IS BUYING RDTs?	CNM	PMI UNOPS
4. WHO IS DISTRIBUTING RDTs?	CNM	PSI Cambodia (PSK)

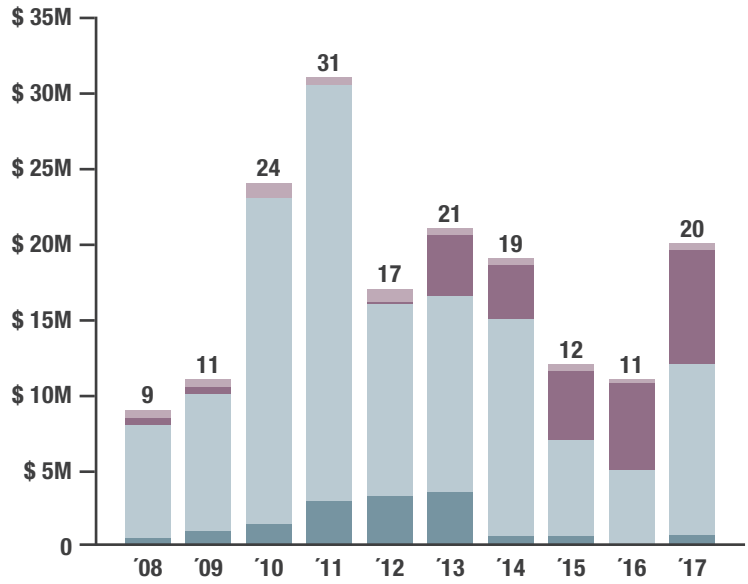
Donors such as GF and PMI heavily support the CNM for the funding and procurement of malaria RDTs

CNM and PSK are distributing malaria RDTs to the private sector which is another relevant stakeholder in Cambodia's malaria landscape

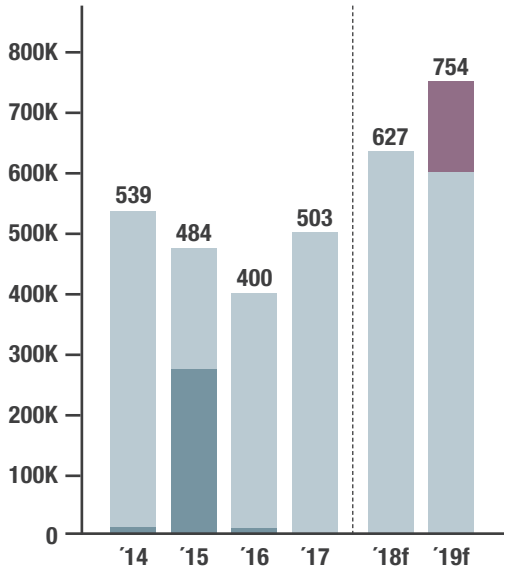
Sources: WHO, Advention

MALARIA DIAGNOSIS FINANCING AND STAKEHOLDERS

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



MALARIA RDT FUNDING (TESTS DISTRIBUTED)



LEGEND

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

Distinct financing sources coexist for malaria diagnosis

- **RDTs were mainly financed by the Global Fund** (0.4M to 0.5M tests per year), **the two mechanisms in place in Cambodia were active until 2017.** A second phase of the Regional Artemisinin-resistance Initiative Elimination programme (RAI2E) grant for 2018–2020 has been initiated by the Global Fund, with the United Nations Office for Project Services (UNOPS) being the principal recipient
- **GF RAI2E funding will cease in 2020; funding landscape for the post-2020 period is uncertain.** USAID / PMI might address potential gaps that may arise, notably for RDTs, ACT treatments, in-service training, accreditation of microscopy trainers, drug resistance monitoring

Malaria RDTs are mainly financed by international donors: GF and PMI

Post 2020, financing is subject to question

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

PROCUREMENT OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF MALARIA RDTs

PRODUCT SELECTION	Products are selected by the CNM's* Technical Bureau and Pharmacy Unit in line with WHO and Cambodia treatment guidelines Going forward, RDTs and antimalarials will be selected among WHO-prequalified suppliers
PROCUREMENT	The UNOPS is the primary source for procurement and manages the entire procurement process for the GF for RDTs and other goods and services The procurement cycle is based on the length of GF grants and the CNM provides the needs at the beginning of each year
FORECASTING AND QUANTIFICATION	While various partners across Cambodia have developed quantifications of malaria commodity needs, the MoH prepared a 2-y commodity forecast in 2015 with support from JSI/USAID, using reported malaria cases, as well as stock data from the public and private sectors The CNM aims to develop annual forecasts of all malaria commodities and submit procurement plans to the procurement partner
CUSTOMS CLEARANCE	UNOPS and the particular manufacturer are in charge of the customs clearance All products are then stored at CMS warehouse facilities in Phnom Penh

MARKET AUTHORIZATION PROCESS FOR RDTs

The Department of Drugs, Food, Medical Devices and Cosmetics (DDF) under the Ministry of Health (MoH) is the main regulatory body in Cambodia.

The product registration process should normally take three to six months; however, it might take up to 10 months to one year depending on the Ministry of Health's product registration workload.

The registration certificate is valid for three years from the date of issuance. The company must re-apply for a new registration certificate six months before the expiration of the previous certificate.

Medical devices are divided into four categories according to their levels of risk: low, fairly low, fairly high, and high. Registration of the latter three categories also requires registration certificates from the country of export, an analysis report from the manufacturer, and technical documents.

The minimum required documents for registration include an application form, GMP or ISO certificates, a free sale certificate, a letter of authorization, and the product manual.

All imported pharmaceutical products are required to have at least 18 months validity before the expiry date.

CNM and UNOPS are the key players for the malaria RDT procurement system

The Department of Drug and Food (DDF) is the competent authority for registering an RDT and uses a relatively straightforward system

Note: (*) The National Center for Malariology, Parasitology, and Entomology (CNM). Sources: Export.gov, Thompson Reuters Practical Law, WHO, Advention

CURRENT RDT DISTRIBUTION STRATEGY

	PUBLIC INSTITUTIONS	PRIVATE INSTITUTIONS
KEY DISTRIBUTORS OR IDENTIFIED PLAYERS	The National Center for Malariology, Parasitology, and Entomology (CNM)	Distribution in the private sector is organized as for the public sector. Indeed, the CNM and PSK are distributing mRDTs for the licensed private sector
DISTRIBUTION SYSTEM DESCRIPTION	Commodities flow in a cascade model from the MoH operated Central Malaria Store (CMS) down to VMWs. CMS is responsible for distributing essential medicines and commodities on a quarterly basis, based on a "pull" system	The government instituted a Public-Private Mix (PPM) programme under which private providers are trained on early diagnosis and treatment according to national guidelines, provided with RDTs, and incorporated into the national malaria surveillance system
LOGISTICS QUALITY MONITORING	The logistics management database, which is maintained by Department of Drug and Food (DDF) and the CMS, contains data on stocks of mRDTs supplies. At the health center level, staff use paper forms while at higher levels, data are entered into drug databases which can lead to human errors	Provinces with evidence of multi-drug resistance are managed by the CNM, and private providers are supplied with free malaria commodities in exchange for the submission of used RDTs and paper reports
QUALITY ASSURANCE SYSTEM	The DDF, the National Health Products Quality Control Center (NHQC), and the CNM are involved in quality assurance and control (QA/QC). UNOPS carries out QC testing of private procured mRDTs in collaboration with DDF	Private providers in other provinces are managed by PSK, and are sold RDTs by PSK sales teams, at their place of work and at a subsidized price, submitting either paper based or electronic reports, used RDTs, and participating in scheduled QA assessments and biannual refresher trainings
CENTRAL WAREHOUSE FACILITIES	Public sector procured commodities are received and stored at CMS. Commodities are then distributed and stored at provincial and district levels	In 2018, after evaluation of both methodologies of the PPM programme, the PSK network is to begin to transition the management of private providers to the CNM

The CNM is the key stakeholder for malaria commodities' distribution for both the public and the private sector completed by PSK for the latter

QA/QC are implemented by CNM and UNOPS

Sources: ACTWatch, WHO, FIND, Advention