For donor-driven market, the stakeholder map is pretty straightforward in Thailand; the GF funds BVBD procurement while PMI/USAID have their own procurement network; all public RDTs are distributed through the BVBD network.

Sources: WHO, Advention
Until 2020, malaria diagnosis will be mainly financed by the Global Fund
Starting in 2020, the government and potentially USAID/PMI will have to take over funding

Sources: WHO, USAID-PMI, Global Fund, MoPH, Adventon

Distinct financing sources coexist for malaria diagnosis

- RDTs are mainly financed by the Global Fund (80K to 100K tests per year)
- GF RA2E (Regional Artemisinin-resistance Initiative Elimination Program) funding will cease in 2020, funding landscape for the post-2020 period is uncertain. The Thai government will probably take over the funding for RDTs
- USAID / PMI might address potential gaps that may arise, notably for RDT procurement
PROCUREMENT PROCESS OF mRDTs

The BVBD selects malaria tests among WHO prequalified RDTs

The BVBD procures RDTs under the Global Fund Pooled Procurement Mechanism (PPM). Procurement occurs on an annual basis

The Global Fund Principal Recipient, the MoH, is responsible for RDT forecasting, which is based on the previous year’s consumption, with a 20% buffer

Companies manage customs clearance themselves based on the “hazardous substances trade” procedures

MARKET AUTHORIZATION PROCESS FOR RDTs

The Medical Device Control Division of the country’s Food and Drug Administration (FDA) is the competent authority for market authorization.

The FDA automatically accepts medical devices that are approved by the main stringent authorities.

Otherwise, the process is rather painless:

- Diagnostic tests are not submitted to clinical efficacy evaluation from randomized control trials before market approval
- Registration takes 2-4 weeks and relies on a risk-based classification system. RDTs fall under Class III (except HIV RDTs)
- Then an import license must be obtained before the device can be imported or sold in Thailand. It generally takes between 3 to 5 months for a Class III device

The ASEAN Medical Device Directive aims to standardize authorization process within the ASEAN member network

- RDTs might be reclassified
- A change in Thai FDA regulation would be necessary and would probably mean submitting samples for evaluation

BVBD is the key player for the RDT malaria procurement system

Authorization process is quite short and easy, particularly if the test is already approved by a stringent authority

Notes: (*) Bureau of Vector Borne Diseases; (**) Association of Southeast Asian Nations Medical Device Directive. Sources: Business Sweden, Pacific bridge medical, WHO, Advention
CURRENT RDT DISTRIBUTION STRATEGY

<table>
<thead>
<tr>
<th>PUBLIC INSTITUTIONS</th>
<th>PRIVATE INSTITUTIONS</th>
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<tbody>
<tr>
<td>NMCP</td>
<td>Over 10,000 operators are active in the sector and of these, almost all (99%) are SMEs, which together take 60% of income</td>
</tr>
</tbody>
</table>

**KEY DISTRIBUTORS OR IDENTIFIED PLAYERS**

**DISTRIBUTION SYSTEM DESCRIPTION**

**LOGISTICS QUALITY_monitoring**

**QUALITY ASSURANCE SYSTEM**

**CENTRAL WAREHOUSE FACILITIES**

NMCP and BVBD are the key players for the public sector malaria distribution system

Private institutions rely on distributors or purchase directly from manufacturers

Sources: Krungsri, WHO, FIND, Advention