The Global Fund is the main stakeholder regarding RDTs in fever diagnostics, as they finance tests which are provided free of charge to communal- and district-level health facilities in areas with high malaria endemicity.

Note: (*) Based on identified use cases for tests in scope. Sources: interviews, Advention
Malaria diagnosis is mainly financed by the Global Fund, who finances and selects RDTs which must meet both WHO quality and country regulatory specifications.

Note: (*) not communicated. Sources: WHO, Global Fund, MoH, interviews, Advention
PROCUREMENT PROCESS OF DIAGNOSTIC TESTS AND MARKET AUTHORIZATION PROCESS

PROCUREMENT PROCESS OF RDTs

**PRODUCT SELECTION**
NMCP oversees product selection, and its policy development body, is comprised of multiple stakeholders. Products are listed in the national treatment guidelines.

**PROCUREMENT**
NMCP is responsible for yearly tendering. Lead times are long, taking approximately six months from submission of forecast to receiving goods in Viet Nam at the NIMPE* warehouses.

**FORECASTING AND QUANTIFICATION**
NMCP leads annual forecasting, with support from NIMPE for technical inputs; and requests from provinces. Consumption data, epidemiological factors and requests from provinces are used to develop forecasts that are consolidated nationally by NMCP.

**CUSTOMS CLEARANCE**
Antimalarials are procured locally and shipped to NIMPE warehouses. The GFPMU** conducts customs clearance for internationally procured RDTs.

**PROCUREMENT PROCESS OF OTHER TESTS**
Public: direct from manufacturer/distributor for hospitals & labs (tbc)
Private: direct from manufacturer/distributor (variation tbc)

MARKET AUTHORIZATION PROCESS FOR RDTs

Authorization for sale is a highly administrative process which requires the applicant to follow-up with various departments to ensure timely processing:
- The process takes around 3 months, but incomplete or erroneous submissions cannot be amended and must be entirely resubmitted.
- Departments involved in the authorization process are not necessarily highly reactive, and applicants are encouraged to remain involved with the administration to ensure rapid processing.

For non-donor funded tests, approval and negotiation with the Social Health Insurance (SHI) is obligatory to achieve widespread use in Viet Nam:
- Tests not included on the SHI list can be financed through donors (like mRDTs financed by the Global Fund) or pure out-of-pocket expenses by patients.
- Pure out-of-pocket diagnostic tests are absent currently in Viet Nam, and both public and private facilities are reluctant to offer them.
- SHI approval is highly complex, as it requires significant proof of cost-effectiveness and test quality to be generated locally.
- SHI is updated annually, with a negotiated reimbursement price that will be the baseline for the test cost in public hospitals.

NMCP is the key player for the RDT malaria procurement system.
The reimbursement of tests not financed through donors is negotiated with SHI.

Notes: (*) National Institute of Malariology, Parasitology and Entomology (NIMPE); (**) GFPMU Global Fund Project Management Unit. Sources: WHO, FIND, Advention.
## CURRENT RDT DISTRIBUTION STRATEGY

<table>
<thead>
<tr>
<th>PUBLIC INSTITUTIONS</th>
<th>PRIVATE INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>KEY DISTRIBUTORS OR IDENTIFIED PLAYERS</strong></td>
<td>Under Vietnamese law, only business entities registered in Viet Nam that have an import license are eligible to distribute medical devices. Manufacturer subsidiaries appear to be the main distributors</td>
</tr>
<tr>
<td><strong>DISTRIBUTION SYSTEM DESCRIPTION</strong></td>
<td>Private institutions are generally independent, and are supplied directly by the manufacturer subsidiary</td>
</tr>
<tr>
<td><strong>LOGISTICS QUALITY MONITORING</strong></td>
<td>Logistics quality is ensured by test suppliers</td>
</tr>
<tr>
<td><strong>QUALITY ASSURANCE SYSTEM</strong></td>
<td>Laboratory teams typically ensure quality assurance processes in-house</td>
</tr>
<tr>
<td><strong>CENTRAL WAREHOUS. FACILITIES</strong></td>
<td>Based on the cascade model, warehousing is organized centrally by MoH. Regional facilities also exist and may be dedicated to specific types of drugs or disease programmes</td>
</tr>
</tbody>
</table>

MoH distribution is organized on a cascade model for district and commune level facilities, with specific paths disease programmes (NIMPE and IMPE for malaria) and self-management of stocks at provincial and central level facilities. Under Vietnamese law, only business entities registered in Viet Nam that have an import license are eligible to distribute medical devices. Manufacturer subsidiaries appear to be the main distributors.

NIMPE/IMPE are the key players for the public sector malaria distribution system. MoH ensures a centralized cascading distribution system, although provincial and central-level facilities may also purchase tests independently, like private facilities.

Sources: WHO, FIND, interviews, Advention