



Quality Assurance Team

QA Informative Note 2018/01

Objective of this note.

The present note has been developed to brief on the recent changes to the GF Quality Assurance Policy for the procurement and testing of Malaria Rapid Diagnostic Test (RDTs).

Historical controls applied to malaria Rapid Diagnostic Test

Historically, the eligibility of malaria RDTs was driven by WHO recommendations, based on positive results of the various rounds of WHO Product testing of malaria RDTs as well as listing by WHO prequalification of Diagnostics.

In past versions of the GF QA policy on diagnostic products¹, Recipients were encouraged to arrange for lot testing at pre-shipment stage, using the WHO FIND Lot Testing Program at its recognized laboratories.

New Policy requirements for malaria RDTs applicable since 1 January 2018

Product eligibility

As of 1st January 2018, the revised Quality Assurance Policy for Diagnostic Products² requires that malaria RDTs must meet one of the following standards:

- (i.) prequalification by the WHO Prequalification of In Vitro Diagnostics Programme; or (...)
- (iii.) authorization for use by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (high risk classification) ; or
- (iv.) acceptability for procurement using Grant Funds, as determined by the Global Fund, based on the advice of the WHO Expert Review Panel.

NOTE: There is currently no authorization for use for malaria RDTs given by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed.

Post-marketing surveillance activities

The revised QA Policy amended in 2017 states that Recipients shall arrange for the monitoring of the quality of Diagnostic Products procured with grant funds in line with relevant WHO guidelines on Post-Market Surveillance of In Vitro Diagnostics³.

QA Policy Interpretation

Product eligibility

Based on the above changes only WHO prequalified or ERPD recommended malaria RDTs can be procured using GF funds. The list of diagnostics products eligible for procurement with GF funds is published, regularly updated and made publicly available in GF webpages.⁴

¹ GF Quality Assurance policy for diagnostic products issued in 2010 and amended in February 2014

² GF Quality Assurance policy for diagnostic products issued in 2010 and amended in May 2017

³ Available at: http://www.who.int/diagnostics_laboratory/postmarket/en/

⁴ Available at https://www.theglobalfund.org/media/5891/psm_qadiagnosticsmalaria_list_en.pdf?u=636529252530000000

Lot testing

Because the WHO prequalification process is comprehensive in assessing data on design, manufacturing and quality control testing of the product, the performance of individual products is likely to be consistent among lots over time. Therefore GF no longer recommends pre-shipment lot testing for batches of malaria RDTs before deployment to the field.

Furthermore, GF does not recommend post-shipment testing for lots (batches) of malaria RDTs before deployment to the field, except for specific circumstances which can justify further investigations e.g. temperature excursion out of manufacturer's recommendations.

Post marketing surveillance

Recipients shall set up quality monitoring activities for Diagnostic products at different points in the supply chain up to the end-users. A separate GF QA document should be developed in collaboration with WHO to provide guidance to GF Recipients on how to best implement this new requirement.

The cost of conducting such post marketing monitoring activities may be budgeted in Global Fund grants.

Geneva, 31st January 2018