

Briefing Note

Post-market Surveillance of Insecticide-treated Nets Financed by the Global Fund

Allocation Period 2023-2025

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NOTE: Any questions or comments regarding this Briefing Note should be directed to the Quality Assurance Team at HealthProductQualityAssurance@theglobalfund.org

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Executive Summary

As insecticide-treated nets (ITNs) play a crucial role in ending the threat of malaria as a public health concern, it is particularly important that Global Fund grant implementers ensure that they select and purchase ITNs that meet quality standards, remain of good quality throughout their life cycle, and benefit households in malaria-susceptible regions.

This Briefing Note provides technical guidance and information on how, when, and where to carry out post-market surveillance (PMS)¹ of ITNs prior to distribution.

Recipients of Global Fund grants are authorized to procure ITNs that have either: 1) been pre-qualified under the World Health Organization (WHO) Prequalification Programme or 2) have been determined to be acceptable by the Expert Review Panel (ERP) of the Global Fund. PMS activities serve to confirm that the procured ITNs still meet performance standards as approved and should be undertaken with a risk-based approach, in consultation with key stakeholders (in particular the National Regulatory Authority (NRA)) and the data shared with the Global Fund. These activities may include:

- Visual verification of the packaging and labelling of ITNs
- Review of the certificate of analysis (COAs) and test reports
- Collection of information on the ITN products which have been procured, especially ITNs where poor performance or quality signals have been received from users
- Chemical analysis and physical testing of ITNs as per product specifications or as per a subset of product specifications
- Testing bio-efficacy

This Briefing Note outlines the roles and responsibilities of key stakeholders, including the quality assurance (QA) coordinator, health product management (HPM) specialist, the quality control (QC) laboratory, the ministry of health (or relevant ministry handling pesticides), the NRA and the manufacturer.

Countries are encouraged to ensure that PMS activities are an integral part of the country's strategy for responding to malaria, with a detailed annual plan which includes the selection of products to test; checking and testing the products; sampling and a documentation check as well as appropriate budget.

Also discussed are reporting requirements for the Global Fund, which is essential to ensuring that the Global Fund can collect and collate market data globally and take action when and where necessary.

¹ In this instance, "post-market" is defined as taking place after goods have been delivered to the purchaser but before they are distributed either to the organizations delivering to the end users or, in the case where there are no intermediaries, before distribution directly to the individuals or families who are the end users of the nets.

Glossary

Quality assurance:

Quality assurance is the totality of the arrangements to ensure that health products are of the quality required for their intended use, including quality monitoring.

Quality control:

Quality control is part of quality monitoring and includes all measures taken - including the setting of specifications, sampling, testing and analytical clearance - to ensure that health products conform to established specifications.

Quality monitoring:

For the purpose of this note, quality monitoring means all activities undertaken to ensure that insecticide-treated nets continue to conform to the manufacturer's established quality specifications during storage and distribution and perform as required.

1. Introduction

1.1 Background

ITNs are a key tool in global vector-control strategies for the fight against malaria. The Global Fund puts a high value on ensuring that Global Fund-financed ITNs meet quality standards, remain of good quality throughout their life cycle, and benefit households in malaria-susceptible regions.

As per the [Guide to Global Fund Policies on Procurement and Supply Management of Health Products](#) (June 2021), otherwise known as the PSM Guide, recipients of Global Fund grants are authorized to procure vector control products (including ITNs) only when those products are:

- pre-qualified under the WHO Prequalification Programme;² or
- acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the ERP.

While maintaining QC is important, implementing upstream QA in design and manufacturing is equally critical. WHO-approved specifications for pesticides continue to provide an international point of reference against which products can be judged and thus prevent the procurement of poor-quality product under the grants.

In addition to QC activities performed at the pre-shipment stage, recipients should carry out PMS activities to monitor the quality of the ITNs at every stage of the supply chain. The PMS activities should be performed in close collaboration with the relevant NRA and key stakeholders.

PMS activities are a critical means of confirming that the procured ITNs still meet performance standards as approved, as well as for measuring the validity of predictions (based on registration data) regarding the efficacy, safety and environmental effects of a particular pesticide product. Such monitoring may reveal that the product is of poor quality, or that it may have caused unacceptable risks to human health or the environment.

Strong national PMS programs are capable of monitoring the overall quality of products in the market, a fundamental function to the effective regulation of ITNs. Principal Recipients (PRs) should undertake efforts to strengthen PMS activities in a prioritized manner, based on a risk-based approach, in a well-coordinated way and in consultation with all the key stakeholders. PRs should manage the data generated and share it with key stakeholders and use it to inform decisions.

² Assessment of vector control products was previously managed through WHO's Pesticide Evaluation Scheme, or WHOPES, which then was transitioned to WHO Pre-Qualification Program since 2017/2018.

PRs must perform PMS activities, which may include QC testing of grant-funded ITN products, by obtaining samples at various points along the supply chain and reporting the results to the Global Fund. The use of a risk-based approach is a key factor to ensuring a sustainable PMS program for ITNs for PRs. This ensures PMS activities are not conducted as sporadic activities, but are well planned, and resources are optimally used. The United States Pharmacopeia Promoting the Quality of Medicines (USP PQM) has published a useful *Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries*³ which can be applied similarly for the PMS activities for ITNs.

It is advisable that PMS activities be performed along the supply chain in the country in a logical manner. Ideally, the definition, programming and operations of market surveillance activities should be established under the format of a country strategy and may include:

- Visual verification of the packaging and labelling of ITNs
- Review of the certificate of analysis (COAs) and test reports
- Collection of information on the ITN products which have been procured, especially ITNs where poor performance or quality signals have been received from users
- Chemical analysis and physical testing of ITNs as per WHO product specifications or as per a subset of product specifications
- Testing bio-efficacy

1.2 Purpose

This Briefing Note serves to support the implementation of the Global Fund QA requirements for PMS activities in order to ensure a consistent approach for ITNs procured with Global Fund grants. The note covers the PMS activities to be implemented by PRs to monitor the quality of ITNs. For bio-efficacy testing, PRs are requested to perform such testing as per the WHO Guidelines for laboratory and field-testing of long-lasting insecticidal nets (available on the WHO website⁴).

The Briefing Note does not cover assessing the durability of insecticide resistance of ITNs, which is addressed in other WHO related guidelines⁵.

1.3 Limitations

Some of the major challenges for PMS activities in many low- and middle-income countries include: lack of resources (financial and human); no legal mandate to carry out such activities or enforcing them; poor coordination; and the sampling and testing methodology being poorly defined and/or poorly planned. A further limitation is a lack of clarity on what the outcome of the testing will inform. Part of that includes apparent lack of ability to require reimbursement/re-supply etc. from suppliers in the case of poor-quality product. Although

³ <https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based-post-marketing-surveillance-feb-2018.pdf>

⁴ <https://apps.who.int/iris/handle/10665/80270>

⁵ <https://apps.who.int/iris/handle/10665/44610>

some ITN PMS activities may be undertaken by PRs, these are often limited, and data collected from these activities is not reported to the Global Fund, the NRA or the WHO Prequalification Programme and thus this data is not available for decision-making.

1.4 Scope

This Briefing Note is applicable to all brands of ITNs prequalified under the WHO Prequalification Programme or ERP-reviewed ITNs procured with Global Fund grant funds.

2. Roles and Responsibilities

2.1 Global Fund Quality Assurance Team

The role of the Global Fund Quality Assurance Team includes:

- Providing detailed and operational guidance to PRs to guide them in implementing PMS activities for ITNs.
- Proposing additional training and support to ensure adequate implementation.
- Raising awareness on the benefits of PMS activities for ITNs.
- Considering any outputs, non-compliance or other kind of signal of poor quality or performance, lack of efficacy and follow-up as necessary.

2.2 Principal Recipient

As per Section 6.4 of the Global Fund PSM Guide, the main responsibility of the PR is to ensure that quality monitoring of ITNs procured with Global Fund grant funds is implemented.

The PR should primarily engage with the NRA and other relevant stakeholders (such as the national malaria program) in order to establish a coordination mechanism and promote a shared responsibility for assuring the quality and performance of ITNs. PRs should make their best efforts to integrate these activities within existing PMS practices in the country in order not to duplicate activities, in line with the present Briefing Note.

If there are no opportunities to engage the NRA, the PRs will have to implement the PMS activities as per this Briefing Note. PRs should budget for these activities and ensure that the data generated is shared and appropriately used in decision-making regarding the procurement of ITNs.

2.3 Principal Recipient Quality Assurance Coordinator

The PR should designate a Quality Assurance Coordinator who will be responsible for ensuring the adequate planning, implementation and in-time reporting of PMS activities. In most instances, this coordinator role can be allocated to the QA focal point designated by the PR.

The coordinator should be a person who is adequately qualified and familiar with ITN QA systems in the country and who has relevant supply chain management experience. For example, a staff member of the national QC laboratory or the NRA (in countries where these organizations exist) could take on this function.

The designated QA Coordinator should have the adequate delegation to represent the PR in all meetings organized in the framework of the quality monitoring activities relevant to the PR's main responsibilities.

2.4 Health product management specialists

To ensure PRs are able to carry out PMS activities, HPM specialists should:

- Support PRs in implementing this Briefing Note.
- Ensure PRs allocate funding for PMS activities in their country's funding request.
- Support PRs in handling of non-compliant or out-of-specification (OOS) products emerging from the PMS activities, with the involvement of the Global Fund QA team.
- Ensure PRs report the results of PMS activities to the Global Fund QA team through the HPM/Country Team.

2.5 Quality control laboratory

PRs should ensure that the testing lab chosen has the accreditation required to test ITNs (ISO 17025-accredited laboratory or Good Laboratory Practices certified, having the test methods in its scope of accreditation).

The QC lab should also: -

- Perform testing according to WHO-approved specifications and the methods of the Collaborative International Pesticides Analytical Council (CIPAC) (if existing)
- Provide technical information on QC tests to be done, and number of net units per sample to collect, information on net stability and proper handling
- Ensure that raw data and documentation of the specific methods used are included or available to support study reports
- Report testing results to the PR and NRA
- Support the PR in OOS investigations

2.6 Ministry of Health or relevant ministry handling pesticides

To ensure effective PMS activities, the Ministry of Health (or other relevant ministry) should set up the necessary regulatory framework, including the delegation of authority to a national entity in charge of implementing national PMS activities for ITNs. For clarity, the Global Fund will only fund PMS activities for ITNs procured with its resources.

2.7 National Regulatory Authority

NRAs regulate and control the safety, efficacy, quality and performance of health products such as medicines, vaccines, blood products, vector control products and medical devices.

The NRA should:

- Collect information reported by the national reporting system for vector control products and/or pesticides
- Collaborate with the PR in planning PMS activities for ITNs
- Coordinate sampling and testing of ITNS with the PR and all other stakeholders
- Work with the PR to sample ITN products according to the PMS protocol
- Check storage conditions of ITNs
- Share data and results with other regulatory authorities, including the WHO Prequalification Programme
- Take regulatory action when ITN products, practices and facilities are found to be non-compliant with regulations and standards

The PR should plan to work with the NRA in carrying out PMS activities for vector-control products, as in some cases the NRA for vector-control products may be different to the one involved in regulation of other health products.

2.8 Manufacturer

Manufacturers are required to ensure their marketed products meet the quality standards in terms of identity, quality, safety, composition and labelling and that they are produced as per approved manufacturing and control methods. The manufacturer should, in particular:

- Support the PMS activities and provide, at the request of the country, methods for the analysis of any active ingredient or formulation that they manufacture and provide the necessary analytical standards
- Retain an active interest in following their products to the end user, keeping track of major uses and the occurrences of any problems arising from the use of their products as a basis for determining the need for investigations and changes as necessary in labelling, directions for use, packaging, formulation or product availability

3. Considerations and Description of Post-market Surveillance Activities

3.1 Country strategy

Each PR is encouraged to contribute to an existing strategy or design and implement its own strategy in the absence of any currently implemented in the country. This strategy should discuss the following aspects:

- The mechanisms put in place to collect and consolidate the data
- The internal and external collaborations, both those in place and those envisaged
- The mechanism to mobilize resources
- The modalities to assess the effectiveness of the current strategy and future improvements after implementation of periodic plans (three years)
- The priorities identified nationally, regionally, or externally
- The mechanisms in place, such as proactive surveillance, reactive surveillance and/or or surveillance by project

3.2 Planning and preparation

Before carrying out PMS activities for ITNs, the PR must establish a PMS plan or PMS protocol for a limited period of one year. The plan will have to identify the following:

- the products selected
- the locations
- the actors and human resources involved in the verification activities (including planning)
- logistical arrangements
- timing of said activities, including reporting
- provisional budget with expenses and resources
- procedures implemented

3.3 Step-wise approach of verification activities

Among the critical challenges faced when implementing PMS is the scarcity of financial resources available. This is why it is of critical importance to use the funds in the most efficient way. Another major challenge for PRs is limited testing capacities due to lack of accredited vector-control product laboratories in their countries, regionally and worldwide.

As a result, there is need to implement a tiered approach to ITN surveillance in order to maximize the level of effectiveness of the funds spent. Such an approach is also promoted by the USP PQM guideline on risk-based PMS in low- and middle-income countries (LMICs)⁶, which can be a useful resource for engaging such principles.

(a) Level 1

This stage involves visual verification of the packaging and labelling of ITNs. This can identify characteristics related to net quality, such as registration status, release date, product packaging, batch number, company logo, manufacturer address, color. etc. Each ITN label or bale label should be visually inspected for falsely or incorrectly labelled nets, poor appearance or nets unregistered by the NRA, which can be an indication of a poor-quality net.

Visual examination should focus on the elements selected at the time of the design of the verification activities, as well as any comments reported in the sampling form at the time of initial sampling. In most cases, the verification is related to:

- The primary packaging quality and integrity, and any sign of damage or inconsistencies (which might indicate possible mix-ups or fraud)
- The labelling of the immediate packaging of the ITNs, including the verification of the labelling in line with the declared labelling by the manufacturer/or recommended by ERP. Specific attention should be given to the adequacy of the indications for use, as well as the date related to the release, production, and/or shelf life. The verification should also assess if the labelling is not promoting the ITNs for an indication or a purpose which is not the one which has been approved.
- The accessories which are included should be the ones which have been approved.

Such activities can be combined with a review of the QA documents such as the supplier COA, inspection and testing reports, which can also help detect a poor-quality product. At this stage, basic non-compliance will be quickly identified without a big investment. Suspicious or non-compliant nets identified at this level can be escalated to a higher level as necessary.

(b) Level 2

Contrary to what is suggested in the case of pre-shipment testing, market surveillance activities are more flexible and imply a risk-based approach tailored to specific objectives and weaknesses which have been identified at earlier stages. Recalling that the objective is not to test for compliance purposes but to act as a screening mechanism will help to focus on the products which have the highest likelihood of failure. This stage should not consider the full spectrum of approved specifications but target some tests and allow for a wider

⁶ <https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based-post-marketing-surveillance-feb-2018.pdf>

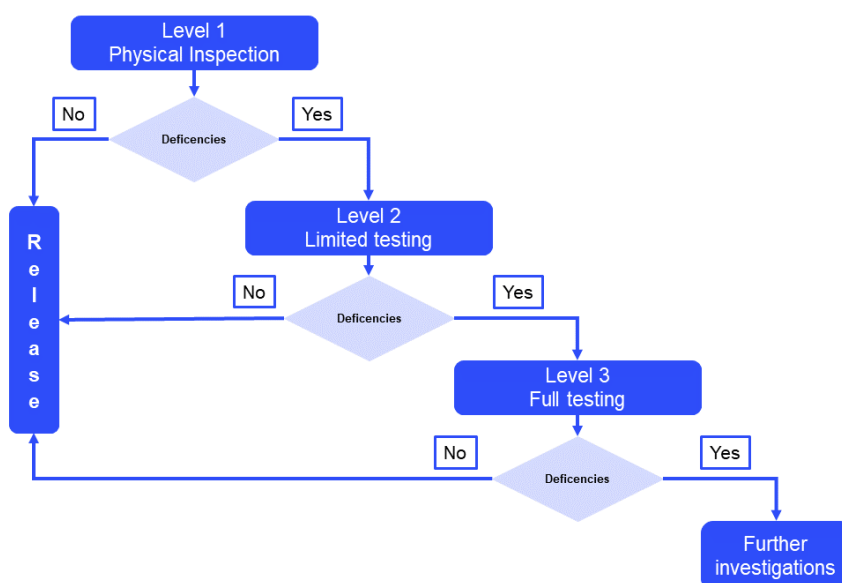
number of batches to be tested. At this stage, physical properties can be the easiest to identify as well as active ingredient identification and testing.

Innovative technologies to detect the surface-active ingredient via infrared technology or other technologies are under development at the time of the publication of this Briefing Note but recent developments are quite encouraging. This can reduce the number of nets which need to be tested by an accredited lab, saving time and financial resources. Suspicious or non-compliant nets identified at this level can be escalated to a higher level as necessary, as no concrete conclusions on the compliance can be reached.

(c) Level 3

This level provides the most concrete information on net quality but is more expensive and time-consuming. This level involves testing less nets, but testing for *all* approved WHO specifications. At this level, the sample analysis should not be limited to the main critical element of the approved specifications such as active ingredient content, wash resistance index or flammability. The method and the specifications should be tailored to the weaknesses identified at previous steps or by the information collected. The method and the specifications are the ones which are approved and those on which concrete decisions on compliance can be taken.

Figure 1. Waterfall market control



- *Level 1: Visual inspection to include assessment of registration status, expiration date, labelling, batch number, ITN name, company logo, number of units per bale, manufacturer’s address, presence of a package insert, damage to packaging.*
- *Level 2: Screening may include assessment of a product’s identity, e.g., presence or absence of active ingredient (a.i) and other screening tests as applicable.*

(d) Level 4

Depending on the deficiencies identified, the PR may be willing to implement within their PMS activities some bio-efficacy testing of the nets. Such activities are extremely time- and resource-consuming and should not be implemented as a standalone measure, except in specific circumstances. PRs are requested to liaise with the Global Fund QA team before performing such tests, as there may be potential for sharing resources in such a circumstance.

3.4 Information collection

Before initiation of PMS activities, the PRs must ensure their capacity to collect, organize and retrieve at least a minimum amount of information on the following:

- Vector-control products procured, imported, and circulating in the market
- National registration or any other authorization (such as WHO Prequalification)
- Actors involved in the distribution/supply chain
- Non-compliance, OOS or any other quality issues noted during PMS activities

In theory, it is the responsibility of the NRA in charge of vector-control products to keep track of such information. To have access to the relevant information, the PRs should engage with the relevant institution and major stakeholders (such as the ministries of agriculture, health, finance and those in charge of customs and municipalities).

3.5 Continuous evaluation and update

PRs are strongly encouraged to collaborate with their NRA and other stakeholders like ministries of health, finance and customs to review and assess the current PMS practices and to identify the strengths and weaknesses of these activities. This should be useful to amend the strategy implemented and/or improve the current PMS processes.

4. Post-market surveillance process

4.1 Operationalization of post-market surveillance activities

Before carrying out PMS activities, the PR needs to develop operational plans for performing the sampling, verification and testing of ITNs. PRs (in consultation with the NRA) should develop a pre-defined sampling and QC testing plan in consultation with the sampling agent and contracted QC laboratory. The plan should stipulate the product's name, the number of batches to test, and the location within the supply chain. It is recommended to phase in the testing plan over several months. This will allow the PR and the QC laboratory to build capacity while addressing any logistical challenges.

4.2 Selection of products

When designing PMS activities, PRs and other key stakeholders should make a selection of the ITNs in their market as well as the type of verification activities they would like to apply. The following elements should be considered when designing such a plan, based on established inclusion and exclusion criteria and taking into consideration the following dimensions:

- Extent and number of quality defects previously found for a specific ITN or supplier
- Recently prequalified ITNs with limited historical data of procurements
- ITNs produced at a new manufacturing site
- Occurrence (frequency) of known and reported quality problems during a specific period of time with a particular ITN or supplier
- Severity of known and reported quality problems during a specific period of time with a particular ITN or supplier, including the ones leading to a recall
- History of ITNs for which a WHO alert related to quality problems has been published or a Global Fund Quality Notice
- Country-specific conditions, such as ITNs stored for a long duration

Other elements can help to prioritize testing, such as the quantity of ITNs procured or planned to be procured from each supplier and/or information collected at the pre-shipment stage.

4.3 Product check and testing

To determine ITN compliance, the PR or the sub-contractors need to perform various checks and tests. Depending on the PMS plan, these should include checks of labels and documents, physical and chemical laboratory tests, and other examinations of the product as specified in Section 3.3.

If a decision has been made to test a product, the product is usually subjected to partial testing that focuses on certain features determined beforehand at the planning stage without covering all the requirements concerning the product. PMS QC testing should be performed in accordance with applicable international harmonized standards, i.e., CIPAC methods or other suitable standards or methods.

4.4 Sampling

Independent of the verification activities performed, the sampling is always a critical step which can have a large impact on the rest of the activities, the follow-up and/or potential challenges being raised by suppliers regarding product integrity. Before the sampling, the PR needs to:

- Select an independent sampling agent
- Select an independent sampling officer

It is important to ensure that appropriate logistical arrangements and sampling apparatus are available, to avoid contamination from outside sources.

(a) Sampling method

Samples are to be drawn and handled as per the WHO guidelines on procurement for public pesticides⁷. Samples should not be taken from products previously opened. Only ITNs in their original packaging should be sampled (either as a single packaged net or as nets packaged in a bale). Random sampling should be used and, if not practicable, the method of selecting samples should be noted in the sampling report.

(b) Sampling procedure

Samples should be taken only by appropriately trained and qualified staff and strictly in accordance with a written sampling standard operating procedure.

When taking samples, the following practices will help to maintain the quality and traceability of the ITN samples:

- Sampling should be done only by trained personnel in the presence of supervisors from the site and should be documented in writing.
- Sampling should be performed in such a way that sufficient stock of all products remains available at the site and is not damaged due to sampling.
- Samples to be sent to the laboratory should be unopened, intact in original packages (including package inserts), with at least six months remaining shelf life to allow for completion of testing before the product expires.
- In case of bales, only unopened sample nets should be sent for QC testing.
- Samples should be handled in such a way as to preserve their integrity and prevent mix-ups.

Information about each collected sample should be captured in a sample collection form, which will accompany the sample from the time of sampling until it is tested at the laboratory.

All fields in the sample collection form should be completed. Whenever the required information is not available, this should be indicated by writing “n/a” or any other applicable remark in the appropriate space.

Where possible, reporting forms used by the national authorities should be used or adopted, making sure that they cover all aspects as recommended by WHO. (An example of a sample collection form as recommended in WHO guidelines is available in Annex 1).

⁷ <https://www.who.int/publications/i/item/9789241503426>

(c) Examination of samples

While taking samples, the sampling team should take note of the physical and environmental conditions in which the products are stored or handled. This should be documented as much as possible with relevant information regarding the temperature, humidity, and cleanliness of the storage space.

Packaging of the samples should be briefly inspected. Documentation regarding the origin of the ITNs should be collected, as well as any other documentation which can be made available such as certificate of analysis, packing list or any other documentation.

In case of any suspicion regarding the origin of the products and/or any suspected fraudulent behavior, these should be indicated in the sample collection form. In such a case, this should be reported immediately to the PR, who should inform the NRA without delay.

(d) Sample transportation

Every precaution should be taken to prevent damage to samples during transit to the QC laboratory. All samples must be stored and transported according to the manufacturer's requirements. (Storage conditions for the product are always indicated on the label and should always be followed so as not to damage the pack in any manner.)

Packaging and mode of transport should be agreed with the QC laboratory to ensure that products will not be damaged by transport conditions. The time lapse between the sampling and the forwarding of the samples to the designated QC laboratory should be as short as possible. Use of fast courier service is recommended where hand delivery is not possible. Any anomalies observed on arrival of the sample at the QC lab should be recorded on the sample collection form.

Samples must be packaged in such a way that they can always be identified and protected from heat, air, light and moisture. For example, each sample should have a label showing all information about the sample and the name of the person who did the sampling. A plastic bag and the accompanying documents can be placed into a labelled envelope to keep out the light.

(e) Sample size

The sample size for testing purposes is defined based on the scope of testing performed and the need for keeping two other set of samples for further investigations until expiry date. The WHO Guidelines for procuring public health pesticides advises a sample size of three entire nets in their original packaging, taken randomly from the same batch. However, based on experience and the need to keep some samples in case of further investigations, the recommended sampling size should be based as per the QC laboratory requirement to ensure enough quantity to carry out two more analyses (if needed).

(f) Sampling record

Each sample should be marked with the date of sampling and with a unique identifier on the outer packaging at the time of the sampling by the sampling team. The codifying system should include at a minimum the following elements:

- The site the sample was taken from
- Name of the net
- Date of sampling
- Name of the sampling agent

The information to be collected at each sampling step is recorded in a sampling report. The bale number for each sample taken should be recorded, if available. In case an individual identification number is attached to each individual ITN, this number should be recorded.

The environmental storage conditions under which ITNs are kept at the time of sampling should be described in the reports for each location. A typical sampling report is provided in Annex 4 of the WHO guidelines for procurement of public health pesticides.

(g) Documentation to accompany the sample.

The sample collection form should accompany the sample throughout transport and be archived for evidence. Any abnormalities observed to have taken place during transport by the QC laboratory receiving the products should be recorded on the form.

The following documents should accompany each sample to the laboratory.

- A sample collection form (see Annex 1 for a suggested format, to be adapted as appropriate)
- A checklist of information present on the packaging
- A copy of the manufacturer's batch certificate of analysis
- A written request for QC testing with reference to the contract with the QC laboratory

If samples are to be shipped outside the country, a written statement to facilitate customs transit, indicating that the samples are sent for laboratory testing purposes only, not be used on humans or animals, have no commercial value and will not be placed on the market. This undertaking ensures smooth transit through customs.

4.5 Documentation check

Documentation regarding the origin of the ITNs collected at the time of the sampling should be reviewed, as well as any other documentation which can be made available, such as COA, packing list or any other documentation.

The documentation should confirm that:

- the nets that have been procured are eligible and from an approved source in line with the relevant approval body (WHO Prequalification Programme or ERP)
- the specifications of the nets tested are in line with the WHO-approved specifications
- the batches received have been tested by the manufacturer for release

5. Quality Testing

5.1 Selecting a quality control laboratory

To ensure that the laboratories which are performing testing activities with Global Fund funds have adequate expertise and capacity, the Global Fund has established QA requirements which must be satisfied before the laboratory can be selected to perform testing. The QC laboratory must meet one of the following criteria:

- Accredited in accordance with ISO 17025
- Good Laboratory Practices-certified laboratory with the test methods in its scope of accreditation

In general, accreditation according to ISO 17025 through a national body is preferable to the QA scheme under Good Laboratory Practice, because it meets the specific needs of an official QC laboratory. However, considering the scarcity of laboratories in this area of work, the second option is maintained as an alternative.

Aside from accreditation status, PRs should also ensure that the laboratory has the methods accredited for the required type of tests as per the methods of CIPAC (if existing) and testing is done according to WHO-approved specifications.

Depending on the type of testing activities envisaged, the PRs may have to select two different laboratories (such as one for the chemistry part, one for the textile (physical) part), as some laboratories may not have the full spectrum of testing needed to test a specific net.

To help PRs identify quickly suitable laboratories, a list of QC laboratories that meet the Global Fund's QA requirements for testing of vector-control products can be found on the Global Fund [Quality Assurance page](#) .

(a) Contractual agreement with a quality control laboratory

A contract should be established between the accredited laboratory and the party requesting the testing, signed by the analyst or laboratory manager in charge and agreed by the party requesting the analysis. The contract should consider/refer to the current standard operating procedures (SOPs) established by both parties. The typical contents of the contract for analysis are provided in the WHO guidelines for procuring public health pesticides under Section 9. The testing activities performed should be implemented as per the plan designed.

Flexibility should be provided in the contract for the laboratory to adapt its charges on a case-by-case basis by prior agreement with the PR if additional tests are needed, or if testing methods change. For more information on testing of ITNs, please refer to the Global Fund's Briefing Note on [Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets](#) .

5.2 Reporting and follow-up

(a) Reporting by the quality control laboratory

The QC laboratory will issue an analytical test report with a description of the tests done, specifications and limits used, detailed results, and conclusions as to whether the sample was found to be within or outside the limits of the specifications used. Please refer to a sample of the analytical test report shown in Annex 2.

A routine check of the report should be done by the PR Quality Assurance Coordinator to verify that the specifications and methods are reflected correctly, and that the conclusions are consistent with the acceptance limits and results stated in the report.

(b) Interpreting results and risk assessment

It is recalled that QC results should be interpreted with due care. Wrongly interpreted results may lead to wrong decisions, which can be costly and can cause reputational damage to the PR, the treatment program and the manufacturer.

In case the QC laboratory is reporting non-compliant results, it is important for the PR to first ensure that QC test results are confirmed before they are reported further.

In this regard, the PR should request the QC lab to investigate and confirm the non-compliant results within a predetermined period. Following its own internal SOP, the QC lab should provide for a detailed report of its investigations confirming or not the OOS result.

(c) Handling and reporting non-compliant results

Risk assessment is an overall process that includes the identification of risks, risk analysis and an assessment of the significance of the risk. Based on the possible shortcomings or faults discovered during PMS activities, the PR will identify whether the product complies with requirements. With a preliminary risk assessment, the PR can assess how serious the possible consequences of the product's non-compliance could be and can determine the most suitable protective measures to implement in the particular situation.

In such case, the PR is encouraged to take precautionary measures to avoid further distribution of the products and discuss the actions to be taken to reject or recall the product if deemed necessary.

In case the OOS result is confirmed, the PR should immediately inform the NRA, the Global Fund Secretariat Quality Assurance Team (through the HPM Specialist/Country Team) and the manufacturer without delay.

The QC laboratory can advise the PR on possible causes of quality failures, considering the nature of the failure, the history of the product and other QC results reported for the same batch (e.g., from other buyers or from testing of retention samples). The PR should then take corrective measures that are within their control. For example, if the failure is attributed to a manufacturing issue, the PR could increase the number of samples tested at pre-shipment testing, change suppliers, or explore possibilities for the manufacturer to improve production processes. If products are degraded, the PR can upgrade the storage facilities or reconsider its distribution strategy. If illicit products are found, security measures in the supply chain may need to be strengthened.

It will be the responsibility of the NRA to enforce corrective measures in the country. If a recall is initiated, the PR should ensure the safe custody of the recalled consignment until further action.

If the non-compliance is found to be due to a fault at the manufacturer/supplier level, the PR should initiate appropriate action in accordance with the purchasing contract. Depending on the severity of the non-compliance, such action could include replacement of products at the manufacturer's/supplier's expense or termination of contract or both. This will be left to the PR's discretion.

5.3 Global Fund reporting requirements.

The PR should report the results of PMS activities relating to ITNs procured with Global Fund financing to the HPM Specialist/Country Team no later than two months after the receipt of the PMS activity report, as per the agreed PMS plan. All relevant COAs should be attached to the PMS report. In case of OOS, COAs are reported separately as indicated on Section 5.2 (c).

The report should provide at least the following elements:

- Name of PR
- Grant number
- Name of the QC laboratory
- Period of implementation of the plan
- Name of manufacturer of the ITN product tested
- Name of the ITNs tested
- Number of batches sampled and tested

- Point in the supply chain at which ITNs were sampled
- Information/data on the transport and storage conditions of the ITNs to that point
- Number of batches with confirmed OOS results
- OOS results observed
- Reference to the notification to the Global Fund and to the NRA
- Any other comments

In case of delays or deviations in implementing the PMS plan, also include a brief description of the reasons, challenges, progress and timelines for implementation or adaptation of the PMS plan as applicable.

The Global Fund QA team will create a repository within the appropriate product category on the Global Fund [Quality assurance page](#) where PMS results/reports can be uploaded.

The PR should ensure that the Global Fund is authorized to use these results/reports and can share them with other agencies (WHO Prequalification Programme, its partners and donors).

6. Record-keeping

All records related to PMS activities should be archived by the PR for at least seven years, except if specific document-retention rules apply, such as for UN agencies. Records should be made available to the Global Fund upon request.

6.1 Principal documentation to be maintained

The PR's Quality Assurance Coordinator should maintain day-to-day updated records of all activities related to QC testing. For this purpose, a reliable software or manual register should be maintained which allows easy retrieval of all details pertaining to any product when required.

A minimum set of records for each product tested must be maintained to be easily retrieved, preferably under the format of a database and/or Excel sheet including:

- Name of the product
- Name of the manufacturer
- Batch number
- Manufacturing date

- Expiry date
- Date of receipt in the country (for consignments on arrival)
- Global Fund reference number (for consignments on arrival)
- Invoice number (for consignments on arrival)
- Sampling site
- Required storage conditions.
- Date of sampling
- Name of person(s) who did the inspection and sampling.
- Date of forwarding to QC laboratory
- Name of the QC laboratory
- Date of receipt of result
- Result of analytical test report
- Action taken in case of OOS results
- Remarks (any information on the product sampled, for example poor storage conditions)

Other documentation of importance is to be archived, including:

- Copies of duly filled and signed Sample Collection Forms for each sample collected
- Copies of manufacturers' batch analysis certificates for every batch sampled
- Documents for dispatch of sample to QC laboratory (official letter, courier receipt, etc.)
- Analytical test report. The Quality Assurance Coordinator should maintain a record of QC results and related documentation
- Communication with the national medicines regulatory authority in case of OOS results and actions taken thereafter, such as batch recall, etc.
- Communications with the QC laboratory
- Communication with Global Fund with respect to testing activities
- Original analytical test report issued by the QC laboratory, filed by date

6.2 Local Fund Agent verification

The PR should make the necessary arrangements to archive the above-mentioned documentation to be available for verification purpose by the Local Fund Agent, as per Global Fund record-keeping requirements.

7. Budget Considerations

A detailed budget should be elaborated to carry out PMS activities, and the main budget lines should relate to the following:

- Sampling agent-related costs
- Sample transportation and customs clearance costs
- Testing laboratory costs, retention and/or destruction of remaining samples
- Coordination and planning management costs
- NRA inspectors-related costs (time, transportation, per diems); as necessary.

The cost of conducting PMS activities for ITNs may be included in the grant budget to be paid with grant funds, as part of the procurement and supply management cost.

8. References

1. Guide to Global Fund Policies on Procurement and Supply Management of Health Products June 2021. https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf
2. Global Fund Briefing Note Visual Inspection of Insecticide-treated Nets https://www.theglobalfund.org/media/12436/psm_visual-inspection-itn_briefingnote_en.pdf
3. Guidelines for laboratory and field-testing of long-lasting insecticidal nets. World Health Organization 2013. <https://www.who.int/publications/i/item/9789241503426>
4. The United States Pharmacopeia Promoting the Quality of Medicines (USP PQM) Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries, February 2018. <https://www.usp-pqm.org/sites/default/files/pgms/article/risk-based-post-marketing-surveillance-feb-2018.pdf>
5. Global Fund Briefing Note Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets. https://www.theglobalfund.org/media/12437/psm_pre-shipment-sampling-testing-reporting-itn_briefingnote_en.pdf
6. CIPAC Handbooks. The Collaborative International Pesticides Analytical Council Limited, 17 Claygate Avenue, Harpenden, Herts AL5 2HE, UK. (access at <https://www.cipac.org>) WHO/FAO International Code of Conduct on the distribution and use of Pesticides - Guidelines for Quality Control of Pesticides, 2011
7. Guidelines for laboratory and field-testing of long-lasting insecticidal nets. World Health Organization. <https://apps.who.int/iris/handle/10665/80270>

List of Abbreviations

CIPAC	Collaborative International Pesticides Analytical Council
COA	certificate of analysis
ERP	Expert Review Panel
FAO	Food and Agriculture Organization
HPM	health product management
ISO	International Organization for Standardization
ITN	Insecticide-treated net
NRA	national regulatory authority
OOS	out of specification
PDI	pre-delivery inspection
PMS	Post-market Surveillance
PQM	promoting quality of medicines
PQT	Prequalification Team
PR	Principal Recipient
PSM	Procurement and Supply Management
QA	quality assurance
QC	quality control
SOP	standard operating procedure
USP	United States Pharmacopeia
WHO	World Health Organization

Annex 1: Example of a Sample Collection Form

This form has been adapted from what was kindly provided by the WHO technical office in charge of prequalification of quality control laboratories.

Sample Collection Form

This Sample Collection Form should always be kept with the sample collected.

Proper sampling procedures should be followed.

1. Country: _____ Sample code: _____
(Country code/product abbreviation/sequence number/sampling date (ddmmyy))
2. Sample code system can be extended to be appropriate for a particular country collection system
3. Name of location/place where sample was taken:
4. Address (with telephone, fax number and email address, if applicable):
5. Organization and names of people who took samples:
6. Product name of the sample
 - Name of active ingredient(s) with strength on the net
 - Package size, type and packaging material of the net
 - Batch/lot number
 - Date of manufacture/ Release..... Expiry date.....
 - Regulatory status in the country, registration number (if applicable)
 - Name and address of the manufacturer:
 - Quantity collected (number of sample units or of multidose containers taken):

Storage/climatic conditions at sampling site/point (temperature and humidity, indication of conditions during daytime only is acceptable, comments on suitability of premises where products are stored at the particular site for the national medicines regulatory authority's information):

Abnormalities, remarks or observations that may be considered relevant, if any:

Date:

Signature of person(s) taking samples

Signature of representative of the establishment where sample(s) was taken (optional)

.....

Note:

Samples collected must remain in their original packaging, intact and unopened

Annex 2: Example of an Analytical Test Report

An analytical test report usually includes a description of the test procedure(s) employed, results of the analysis, discussion and conclusions and/or recommendations for one or more samples submitted for testing.

The Analytical Test Report should, in accordance with Good Practices for Quality Control Laboratories, provide the following information:

- Name and address of the laboratory performing the sample testing
- Number/code of the Analytical Test Report
- Name and address of the originator of the request for testing
- Laboratory registration number of the sample
- Sample code from the Sample Collection Form
- Date on which the sample was received
- Name of the country where the sample was collected
- Sample product name, active ingredients, strength, package size, type and packaging material of the net
- Description of the sample
- Batch number of the sample, expiry date and date/release date, if available
- Name and address of the manufacturer
- Reference to the specifications used for testing the sample, including the limits
- Reference to the reference standards used for quantitative determinations
- Detailed results of all the tests performed (numerical results, if applicable), including any observations made during analysis
- Conclusion as to whether or not the sample was found to be within the limits of the specifications used
- Discussion of the results obtained
- Date on which the test was completed
- Signature of the head of the laboratory or authorized person