

MEMORANDUM ON PMI LONG LASTING INSECTICIDE-TREATED NET PROCUREMENT SPECIFICATIONS

SUBJECT: Revised long lasting insecticide-treated net (LLIN) procurement specifications for the President's Malaria Initiative (PMI) program

DATE: January 7, 2013

Background

Current PMI policy requires that LLIN products have, at minimum, an interim status recommendation from WHO Pesticide Evaluation Scheme (WHOPES) to be eligible for PMI procurements. PMI also reserves the right to apply additional criteria related to past performance, financial viability and programmatic consistency to qualify LLIN products for PMI procurements. The WHOPES testing process is described in Annex 1. The WHOPES Equivalency Process allows new LLIN brands to receive WHOPES recommendation status (interim or full) based on their chemical equivalency to the innovator¹ net product. These "comparator"² products are granted WHOPES interim or full recommendation status based only on results from WHOPES Phase 1 testing. In contrast, to achieve interim recommendation status, an innovator LLIN must have passed both Phase 1 and 2 testing, and to achieve full recommendation it must have passed Phase 1, 2 and 3 testing. There are three "comparator" LLIN products that currently have interim or full status based on their chemical equivalency to innovator products that hold those statuses.

After a technical review, PMI has determined that the equivalency status based only on Phase 1 laboratory studies is insufficient to determine eligibility for PMI procurement because these studies do not determine how the LLIN product functions in the field where other factors come into play, particularly physical durability and long-term bioefficacy. In addition, there may be additional requirements for environmental assessments for these products.

The WHOPES Equivalency Process

The WHOPES Equivalency Process allows new LLIN brands to receive WHOPES recommendation status (interim or full) based on their chemical equivalency to the innovator net product. These "comparator" products are granted WHOPES recommendation status based on results from only the Phase 1 testing. As noted in Annex 1, there are three "comparator" LLIN products that currently have interim or full status. PMI has identified the following issues with this process.

¹ An innovator LLIN is an original product using unique manufacturing processes to meet WHOPES minimum requirements for an LLIN recommendation. These products are submitted for a full evaluation, and are subjected to, over time, all three phases of the WHOPES review process.

² A comparator LLIN is a product that has copied an innovator LLIN product and has been found to be chemically equal to the innovator LLIN product through the WHOPES equivalency policy. Comparator products are only required to go through the WHOPES Phase 1 review to confirm chemical equivalency to the innovator product. Once that is confirmed, the comparator products receives the same WHOPES recommendation status as the innovator product.

- The granting of a WHOPES recommendation through the equivalency process is based on limited data which consists of only Phase 1 laboratory studies and does not determine how the LLIN product functions in the field. Field-based LLIN performances could vary significantly from the innovator net in areas such as physical durability and long-term bioefficacy. Preliminary results from large-scale PMI LLIN durability studies indicate differences in physical durability between innovator LLINs as early as six months after deployment.
- While additional competition and price decreases in the LLIN market are welcomed and feasible, the current market availability of LLINs is sufficient for current and projected demand, and the unit costs of LLINs are currently at historic low prices and continue to decrease. Promotion of equivalent LLIN products could have a negative impact on future research and development of new products (e.g., more durable nets, non-pyrethroid nets, etc.) since comparator LLIN companies would be able to get products to market by investing in Phase 1 testing only.
- A WHOPES equivalency determination only means that chemical and biological assays of the comparator net are equivalent to the innovator net in Phase 1 laboratory studies. It does not look at the binder process, or other factors such as weave or bursting strength that could affect physical durability under field conditions.
- Chemical and biological equivalency is just one of many factors that must be considered when procuring LLINs. Operational LLIN factors (e.g. one comparator net requires washing first to “activate it”) may cause significant variance from standard LLIN distribution and implementation procedures, and are justifiable reasons to not select a product.
- A WHOPES equivalency determination does not ensure that manufacturers of comparator LLIN products meet the same quality assurance and quality control standards to which the manufacturers of innovator LLIN products are held. Quality assurance of production must be maintained.
- PMI reserves the right to require additional environmental assessments of all LLIN products.

Policy Recommendations:

1. Require comparator products to go through Phase 2 WHOPES testing before becoming eligible for PMI procurement. Innovator products that pass Phase 1 testing are required to then go through experimental hut studies as part of Phase 2 testing. Experimental hut studies are usually conducted in 2-3 sites and require six weeks of data collection. Products that meet the criteria for Phase 2 testing are granted interim recommendations from WHOPES. Adding this requirement would address concerns about the field performance of these products and would bring them in line with requirements for innovator products to obtain interim recommendation. This is unlikely to place undue burden on manufacturers of comparator products. After passing Phase 2 testing, the comparator products would be eligible for consideration through the procurement bids via PMI’s procurement agents, assuming the product also meets any other programmatic, financial and past performance criteria required to ensure vendor responsibility and appropriate programmatic context.

2. Upon completion of Phase 2 testing, PMI reserves the right to gather data on quality assurance and durability. All innovator products are currently subjected to quality assurance testing and are currently undergoing PMI efficacy and durability studies to evaluate actual performance of the product in the field. PMI may consider, but will not require, comparator nets to be included in the same testing to determine if the product performs equal to or better than its innovator equivalent at the 6-month and 12-month marks. PMI will assess results of quality testing of the comparator LLINs when production is scaled up and PMI may consider inclusion in PMI durability research studies. Comparator nets that pass quality assurance should be examined by PMI for durability after 6 and 12 months to determine field-performance of the product. Data from other independent, objective studies could be included in our final recommendations.

Annexes:

Annex 1: Additional background information

Annex 2: WHOPES Phase 2 Testing Process

ANNEX 1

Procurement of LLINs approved through the WHOPEs Equivalency Policy: PMI Technical Procurement Policy

Background:

WHOPEs requires LLIN products to go through three phases of testing in order to receive a full recommendation status. These three phases are: Phase 1: laboratory and washing tests (~20 washes) to determine bioefficacy and persistence of insecticide on the nets; Phase 2: hut testing (over ~6 weeks); Phase 3: full field test (over 4 years).

To date, the only innovator LLIN products that have received full recommendation are PermaNet 2.0®, Olyset, and Interceptor®.

- Yorkool® LLIN, a comparator LLIN, received a full status through the WHOPEs equivalency policy, once it was determined to be chemically equivalent to the PermaNet 2.0® innovator product.

To date, seven innovator products have received interim recommendation status, meaning they have successfully gone through Phase 1 and Phase 2 testing and are currently undergoing Phase 3 testing.

- Two comparator products have received interim recommendation status through the WHOPEs equivalency policy, once they were both determined to be chemically equivalent to the innovator product:
 - MagNet® (Duranet® is the innovator product)
 - Royal Sentry® (Duranet® is the innovator product)

Current PMI policy requires that LLIN products have, at minimum, an interim status recommendation from WHOPEs to be eligible for PMI procurements. PMI also reserves the right to require that procurement agents also apply additional criteria related to past performance, financial viability and programmatic consistency to qualify LLIN products for PMI procurements.

ANNEX 2

WHOPES Phase 2 Testing Process

Experimental huts are used to determine the efficacy of LLINs in terms of blood-feeding inhibition, deterrence, induced exophily, and mortality on susceptible, free-flying, wild mosquitoes. The trial should include:

- 1) Determination of the efficacy of washed and unwashed LLINs and their impact on the behavior of susceptible wild mosquitoes (anophelines and, where possible, culicines); and
- 2) Recording the perceived side-effects of the LLIN among users.

The following treatment arms should be tested:

- o Unwashed LLIN
- o LLIN washed 20 times
- o LLIN washed according to manufacturer's claim (or maximum washes determined in Phase I)
- o Polyester, conventionally treated net washed under Phase II conditions until just before exhaustion
- o Polyester, conventionally treated net washed 20 times
- o Untreated net (use of the same fabric and mesh size as the test LLIN is preferred)

For complete testing guidelines

see: http://apps.who.int/iris/bitstream/10665/69007/1/WHO_CDS_WHOPES_GCDPP_2005.11.pdf