

MEMORANDUM ON PMI INSECTICIDE-TREATED NET PROCUREMENT SPECIFICATIONS AND DATA REQUIREMENTS FOR MANUFACTURERS

SUBJECT: Revised insecticide-treated net (ITN) procurement specifications and data requirements for the U.S. President’s Malaria Initiative (PMI) program

DATE: October 25, 2019

Current PMI policy requires that ITN products, at minimum, be on the WHO Pre-qualification (PQ) list of [Prequalified Vector Control Products](#) to be eligible for PMI procurements. PMI also reserves the right to apply additional criteria related to label claims, past performance, financial viability and programmatic consistency to qualify ITN products for PMI procurements.

Furthermore, for those ITN products that have been deemed to be “equivalent” through the PQ conversion process, PMI specifically requires that they have a PQ listing and have demonstrated field effectiveness according to label claims (e.g., against resistant mosquitoes).

Manufacturers should follow the [WHO data requirements and protocols for non-inferiority](#), namely that the candidate ITN product must generate entomological evidence from at least two experimental hut trials to be included in an existing WHO intervention class. Two primary endpoints should be considered relative to the first-in-class product: i) the proportion of mosquitoes that are dead (mosquito mortality), and ii) the proportion of mosquitoes that are blood-fed. Absolute values should be given for both primary endpoints (i.e., not corrected for mortality or blood-feeding in the untreated net control). To be defined as non-inferior, a new product must show non-inferiority in terms of both mosquito mortality and blood-feeding inhibition.

The comparison arm must be either the first-in-class product or another second-in-class product that is pre-qualified and has been proven to be non-inferior to the first-in-class product.

Manufacturers are welcome to submit protocols to PMI as a courtesy, but PMI will no longer review protocols and provide feedback on an *ad hoc* basis.