Long Lasting Insecticidal Nets - Target Product Profile

Disease Area: Malaria
Candidate: Long Lasting Insecticidal Nets (LLIN)

Version: 2.2

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1   Medical Need / Differentiation Strategy/Use Case:

Medical Need:

LLIN is an effective way to prevent mosquito nigh biting and to improve their control. The goal is to protect people sleeping under bed nets against malaria transmission.

LLIN has been shown to be an effective way of reducing malaria transmission. LLINs target night indoor biting mosquitoes which are the major source of malaria transmission. LLINs provide both personal and community wide protection.

Intended Use Case Scenario:

Insecticide treated bed nets are most often distributed in endemic countries by National Malaria programmes funded by donor agencies. They are targeted whole populations or targeted groups especially at risk (pregnant women and young child).

Critical Assumptions:

One of the main objective is to help the market introduction of new solutions helping to prevent insecticide resistance build up in mosquito population.

2   Executive Summary with Annotations

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*
EFFICIENCY			
WHOPES threshold	Achieves WHOPES criteria for a Long Lasting Net.		
Wash resistance (lab)	In laboratory trials retains activity in WHO cone Bioassays after 20 washes.		
Wash resistance (huts trials)	Performs better than a conventional net after washing to near exhaustion (20 washes) in experimental huts trials.		
Field efficiency	In large scale field trials after 3 years of field use at least 80% of the distributed nets should achieve 80% mortality in WHO cone bioassay tests		
Target species	Effective against Anopheles gambiae s.str., and Anopheles arabiensis including existing resistant strains. (Except where existing products are being reformulated). Resistant strains to include: Kdr, Mace, Rdl, Metabolism (oxidative; esterase; GST)	Effective against all other Plasmodium transmitting Anopheles mosquitoes and nuisance mosquitoes (culicines and Aedes sp.).	
Repellency		Demonstrates spatial repellency and excito-repellent effects which contribute to control efficacy	

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Other benefits		Demonstrates rapid knock down Demonstrates inhibition of entry into houses Resistance to wear and handling	
COST OF IMPLEMENTATION			
Cost of implementation	Market Cost competitive for an LLIN ($3-5 per net 2012)	Lifetime cost effective for an LLIN	
SAFETY AND REGULATORY			
International standards	All active ingredients used must hold a registration in a major regulatory authority(EPA, EU, Japan)		
WHOPES	An initial positive risk assessment with the active ingredients used in the WHOPES risk assessment model		
Risk Assessment	Final product passes WHOPES risk assessment for ITNs		
Toxicology	No GHS categories 1a or 1b for Carcinogenicity, Mutagenicity or Reprotoxicity. No risk of endocrine disruption	Low dermal penetration If Neurotoxic Mode of Action, no neuropathology At least Category 4 (GHS) for acute oral, dermal and inhalation toxicity of product Non bio-accumulating: log Kow <3, Bio-concentration factor < 2000	

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Non target species	Risks to non-target species in line with accepted standards for PHPs at the time of registration submission. It is expected that environmental exposure will be minimal for LLINs		
END USER SUITABILITY			
Irritancy and skin sensitization	No classification for irritancy or skin sensitisation		
Odour	No unacceptable odour		
Staining	No staining		
FINAL PRODUCT			
Supply chain	Active ingredients available to the company developing the product		
Formulation	Final formulation produced in easy to use packaging Net suitable for manufacturing in existing plant on standard equipment	Local manufacturing possible	
INTELECTUAL PROPERTY			
IP	IP available and/or obtainable by IVCC		

3   Additional Variables of Interest

Variable	Minimum *The minimal target should be considered as a potential go/no go decision point.*	Optimistic *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.*	Annotations *For all parameters, include here the rationale for why this feature is important and/or for the target value.*

4   Change Management

Version	Key Changes from previous version	Change Made By
2.0	Re-formatting according to BMGF template	Mathias Mondy
2.1	Some corrections in the "medical need" and "toxicology" sections	Robert Sloss
2.2	Renaming of technology to reflect WHOPES terminology (LLIN)	Mathias Mondy