Target Product Profile Intended Use and Scope

Date	Version modification
17/10/2024	Strategic alignment of TPP requirements

Intended use of this document:

1. Alignment of internal development direction
2. Alignment reference to be shared with development partners prior to embarking upon a development partnership
3. Capture aspirational targets where appropriate which are relevant for the anticipated market setting of a new development

Scope: This document provides a clear and concise description of the desired characteristics of a product to align expectations, guide and streamline development, and increase the likelihood of creating a commercially successful product with public health impact.

It also provides a general overview of IVCC expectations from a Manufacturing Partner.

This TPP serves the following purposes:

- **Defines the product:** Outlines the key features, performance expectations, and intended use of the product, creating a shared understanding among stakeholders.
- **Guides product development:** Serves as a roadmap for research and development, ensuring resources are focused on achieving the desired outcomes.
- **Facilitates decision-making:** It helps assess whether a candidate product is meeting its goals and supports decisions related to further development, regulatory submissions, or commercialisation.
- **Enhances communication:** It improves communication between project teams and stakeholders involved in product development, such as researchers, developers, regulators, and marketers.

The TPP should be specific to the product, i.e., an 'ITN designed to kill host-seeking insecticide-resistant mosquitoes', or an 'ITN designed to sterilize and/or reduce the fecundity of host-seeking insecticide-resistant mosquitoes'.

TARGET PRODUCT PROFILE:
Insecticide Treated Net (ITN) designed to kill host-seeking, insecticide-resistant mosquitoes

DESIRED CHARACTERISTICS OF THE PRODUCT:

Measure	Criteria	Reference
EFFICACY AND DESIGN		
Semi-field studies	For mosquito mortality and other selected outcome(s), the ITN (unwashed and 20x washed) shows non-inferiority to a dual-AI ITN under semi-field conditions."	Link NI guidelines
Target species	The ITN is effective against malaria vectors with diverse resistance profiles to current insecticides present in the intended area of use.	Link
User acceptance	The ITN should have physical attributes which supports user adoption and retention at least to a level comparable to existing ITNs.	IVCC preference
DURATION OF EFFECTIVE ACTION		
Residual life under field conditions	The estimated median survival of the ITNs distributed in the field in serviceable condition is 3 years.	Awaiting guidance document
Regeneration	The ITN retains its intended entomological effect within 7 days post washing.	Link
Biological durability	For the duration of the ITNs lifetime it retains it entomological effect.	Link
Physical durability	The ITN must achieve an RD score of ≥50 and maintain its physical durability characteristics throughout its lifecycle.	Will be updated when applicable
MANUFACTURING		
Manufacturing details and scale	Product Manufacturing Details meet WHO PQ guidance. Additionally, production can be scaled in an economically viable manner to meet demand forecasts.	Link
SAFETY AND REGULATORY		
WHO PQ Generic Risk Assessment Models	The intended dose rate for the active ingredient on the ITN passes the WHO-GRAM for ITNs. For all major categories of toxicological importance, risks are defined, understood, and considered to be manageable.	Link
Irritancy	The ITN does not have any characteristics (such as irritancy, skin sensitization or foul odour) that discourages users from sleeping under it.	

Environmental Risk Assessment	Use, disposal or degradation of the ITN should not pose an undue environmental hazard.	
Ecotoxicology	Risks to non-target species must adhere to mandated environmental and ecotoxicology standards at the time of registration.	
Product Chemistry	Product satisfies all product chemistry regulatory requirements for manufacture and use (CIPAC methods, JMPS).	
Storage Shelf Life	The product should remain in specification under recognised (CIPAC) storage stability testing regime of temperature and time.	Link
MARKET FIT		
Policy positioning	The ITN is covered by an existing WHO policy recommendation.	Link Link
Market segment	Alternative to a dual-AI ITN (chlorfenapyr-pyrethroid).	
Target Price	The ITN can be made commercially available at steady state at a unit price that is affordable as projected by the IVCC analysis of public purchasers' willingness to pay.	
Market Geographies	Malaria Disease Endemic Countries	

EXPECTATIONS OF IVCC ON MANUFACTURING PARTNERS:

Measure	Criteria	Reference
MANUFACTURING		
Upstream Supply chain	A reliable supply of raw materials must be available to the company developing the ITN product to ensure continuity of supply.	
Quality, Environment, Health and Safety	The manufacturer has an effective Quality Management System in place and adheres to relevant ISO standards. Additionally, robust environmental and health and safety (EHS) systems are in place to protect worker well-being and minimize environmental impact.	
SAFEGUARDING AND ED&I		
Safeguarding and ED&I	The manufacturer must demonstrate a commitment to safeguarding, as well as promoting equality, diversity, and inclusion in the context the product development partnership.	
FREEDOM TO OPERATE		
License to Operate	All active ingredients used must be registered with a stringent regulatory authority or a WHO CAG assessment must be completed. The ITN manufacturer must confirm the access to the AI regulatory package held by the AI manufacturer. Production route is known, and all parties have access to any relevant rights to use raw ingredients, IP and know-how to synthesis the insecticides or do anything else required during the manufacturing process.	
Product Components	Manufacturers have access to all product components, including formulations, and have freedom to manufacture in the intended geography.	
MARKET		
Deployment Strategy	The ITN can be deployed using existing delivery channels, i.e. mass campaigns and/or continuous distribution channels. Little to no training requirement for deployment and use.	