

# Proposed Evidence Review Group (ERG) on determining non-inferiority of ITN and IRS products within an established class



Malaria Policy Advisory Committee Meeting  
Geneva, Switzerland  
11 – 13 April 2018

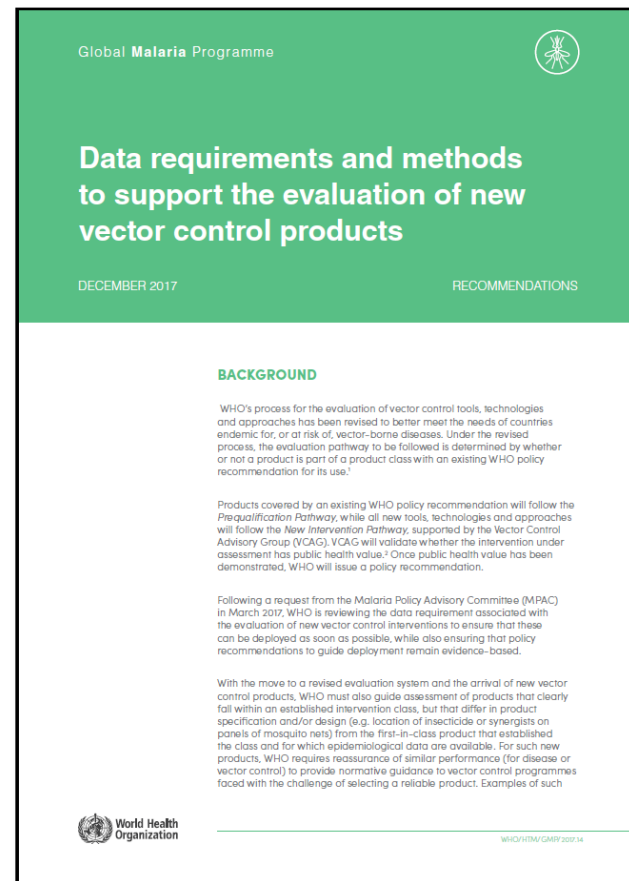
Global **Malaria** Programme



**World Health  
Organization**



- New products not covered by policy need to generate epidemiological data → first-in-class
- Second and subsequent in class not required to generate epi data, but need to show that they are 'as good as' first-in-class → demonstrate non-inferiority
- WHO has been requested to develop guidance to support implementation of standardised and rigorous study design and analysis to determine non-inferiority
- Most pressing need is further evaluation of pyrethroid-PBO nets
- Opportunities to define method(s) for other ITNs and IRS products should be realized concomitantly





To develop methodology designed to assess the non-inferiority of second-in-class\* ITN and IRS products. For ITNs the methodology needs to be suitable for assessment of pyrethroid-PBO nets, but ideally be applicable to compare other ITN products within their respective classes.

\* Second-in-class refers to all products other than the first-in-class product for which epidemiological data were generated to assess its public health value



1. Review existing data on laboratory and experimental hut studies conducted on pyrethroid-PBO nets to:
  - a) familiarize themselves with the evaluation methodologies used to date, and the variation in results shown between products
  - b) familiarize themselves with the data available and the performance of the products evaluated through the former WHOPES process against key performance indicators. An overview of the available data will be provided by WHO for this purpose.
  - c) familiarize themselves with the guidance given to date by GMP and PQ on these products. An overview of the available data and current guidance will be provided by WHO for this purpose.
2. Review draft methodologies proposed for the assessment of non-inferiority of:
  - a) pyrethroid-PBO nets developed with the aid of mathematical modelling drawing on data from earlier experimental hut studies, and
  - b) second-in-class IRS products, based on recent experience with the evaluation of SumiShield WG.
3. Refine the study methodologies where required to support the generation of high quality data to inform development of WHO guidance on the deployment of second-in-class products.



1. Study protocol specifically developed for determination of non-inferiority of pyrethroid-PBO nets
2. Generic study protocol for determination of non-inferiority of ITNs (based on output 1, but highlighting potential areas of divergence, if applicable)
3. Generic study protocol for determination of non-inferiority of IRS products



- Does MPAC support the convening of the proposed ERG meeting in principle?
- Do the proposed objectives and outputs of the ERG accurately reflect the needs as outlined in the 2017 Information Note on *Data requirements and methods to support the evaluation of new vector control tools* or are modifications to the ToRs needed?