AFM thanks the World Health Organization Pesticide Evaluation Scheme (WHOPES) for its response to the Occasional Paper "WHOPES and Its Impact on Long-Lasting Insecticidal Net (LN) Availability". AFM's mission is to make malaria control more transparent, responsive and effective. Coticelli's (2007) Occasional Paper does not advocate rushing unsafe or inadequate technologies to the field. It explains the technical role and practical effects of WHOPES review on donor-driven production and distribution of LNs. AFM would like to clarify the following points. First, the WHO states:

Between 2001 and 2006, three LN products (Olyset; PermaNet and Interceptor) received WHOPES interim recommendations, not two, as stated by Coticelli.

BASF's Interceptor® was granted WHOPES interim recommendation at the Tenth WHOPES Working Group Meeting, December 11-14, 2006. The report was not published and the officially certified letter was not received by BASF until January 2007. The Roll Back Malaria (RBM) Partnership[i] and African governments will confirm that until BASF received and could present official WHOPES certification, Interceptor® could not compete for public tenders. So while WHOPES technically recommended a third LN in December 2006, that recommendation could not practically be used against malaria until January 2007.

Second, the WHO states:

Coticelli (2007) argues that WHOPES data collection and review could take six months but that, in practice, it has taken recent applicants an average of two years to receive interim recommendations. Noting that the majority of LN submissions to WHOPES by industry have had limited data in support of the efficacy of their product and that it has therefore been necessary to conduct full laboratory and field testing, the six-month evaluation time proposed by the author is unrealistic. It ignores not only the time needed for testing and evaluation of the product in accordance with the Guidelines, but also fails to consider the time needed for the conclusion of agreements with research institutions; for obtaining relevant national and ethical clearances; for the payment by industry of the cost of the testing and evaluation process and last but not least, for the provision of the testing material.

Rather than explain why six months is unrealistic, this paragraph simply refers to WHOPES LN-testing Guidelines[ii] – which do not explicitly state how much time each testing phase requires – and lists other administrative requirements. According to AFM's consultations with WHOPES scientists, generating Phase I and II data should take no more than three months each. The WHO cites the time needed to conclude agreements with research institutions and obtain ethical clearances as further constraints. Considering that the RBM Partnership has made scaling up LNs an urgent priority for malaria control and

1050 SEVENTEENTH STREET, NW, SUITE 520
WASHINGTON DC, 20036
TEL (202) 223 3298 CELL (202) 420 1837
rtren@fightingmalaria.org
www.fightingmalaria.org

that an African child dies of malaria every 30 seconds, how long should these administrative processes be expected to take?

Finally, the WHO expects its recommendations to be supplemented by national authorities:

*WHO **is not a regulatory authority. The regulatory approval of pesticide products is the sole prerogative of national authorities** [emphasis in original]…The absence of WHO recommendations should not be seen as a constraint to procurement of those LNs by national programmes, provided that their safety and efficacy have been adequately assessed by national authorities.*

Yet the WHO also states that national authorities cannot conduct product evaluations:

***Given the limited resources and infrastructure of malaria endemic countries to carry out proper product assessments** [emphasis added], there is a clear risk that substandard and counterfeit products will enter the market and endanger the lives of millions of people, unless internationally agreed quality-control standards are in place…WHO recommendations on the use of public health pesticides are valid ONLY when linked to WHO specifications for their quality control.*

The WHO's quality control specifications are useless in a vacuum. Ultimately, WHOPES prefers an academic role and declines responsibility for ensuring the products it recommends are the products actually being sold and distributed by member states to protect people from malaria. Therefore, the RBM Partnership needs to urgently scale up national regulatory capacity for LNs and conduct quality control assessments wherever possible. AFM suggested that UNICEF perform this function because it is the only multilateral agency conducting post-market surveillance and factory inspection for LNs.

WHOPES is a valuable technical resource, but it needs to cultivate a practical, responsive and responsible role in malaria control. It can start by making its data publicly available throughout the evaluation process. As WHO implies, some companies submit products to WHOPES having already completed independent safety and efficacy evaluations. WHOPES could reflect this with a product checklist updated in real time on its website. This would allow countries to make informed procurement decisions without waiting up to two years for WHOPES interim recommendation.

Limited personnel and laboratory facilities are poor excuses for delaying products reviews when tremendous new resources are available for malaria control. Instead of defending the status quo, the WHO and RBM Partnership should invest in expanding the capacity of WHOPES, testing centers and malaria-endemic country laboratories. WHOPES could provide technical support necessary to decentralize LN review, and RBM Partners could pay for the equipment and training needed to prevent bottlenecks.

Mandating WHOPES recommendation for LN procurements, as RBM Partners currently do, may not be the most cost-effective use of limited public funds to control malaria. The WHO, the RBM Partnership and the malaria advocacy community should urgently discuss how to streamline and strengthen the WHOPES review process for LNs.

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[i] RBM Board Members are referred to collectively as "The RBM Partnership": http://www.rollbackmalaria.org/index.html
[ii] http://whqlibdoc.who.int/hq/2005/WHO_CDS_WHOPES_GCDPP_2005.11.pdf