GLOBAL MALARIA PROGRAMME

World Health Organization

Innovation to Impact – WHO change plan on evaluation of pesticides

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WHO leadership is strongly committed to vector control reform

WHO has initiated ambitious reforms in response to needs of vector control community

- WHO **recognizes the need for reforms** regarding evaluation of innovative tools, improving quality in the system, standardized vector control evaluation and timely development of normative guidance, etc.
- To support the development, evaluation, quality control, adoption, and sound management of pesticides, **an initial change plan was presented at last Stakeholder Convening** in Feb and June 2015.
- Since then, **WHO has been detailing its plans to reform** evaluation systems and procedures, and to strengthen vector control normative functions
- Plan shown today is the **result of joint work across several WHO teams** relevant to vector control (NTD and GMP) and prequalification (PQ/HSI)

WHO leadership clearly expressed full support of this change

Quotes from selected members of WHO leadership

"A global health agenda that gives higher priority to vector control could save many lives and avert much suffering."

"I fully support this WHO vector control change and am looking forward to see significant progress by the end of 2016 and celebrate success in 2017."

Margaret Chan,
Director-General WHO

"I2I is a really important vector control reform, in line with WHO reforms for drugs, vaccines and diagnostics."

Marie-Paule Kieny,
Assistant Director-General for Health Systems and Innovation

Background : WHO PESTICIDE EVALUATION SCHEME (WHOPES)

WHOPES provides the following range of functions and activities:

1. **testing and evaluation of pesticides and pesticide products for public health, with the aim of facilitating their acceptance, national registration and use by Member States;**

2. **normative functions such as setting norms and standards for the evaluation and use of pesticides and pesticide-related products, and promoting and monitoring their judicious use in various settings;**

3. **technical support for vector-control policies and strategies, operational guidance, monitoring global insecticide use, building institutional capacity, and disseminating valuable knowledge; and**
4. **policy for pesticide and pesticide-related products used in a public health context.**

Key areas for improvement

Several key areas have been identified for improvement:

- **shorten timelines to bring products to market;**
- **increase transparency and improve communication with stakeholders;**
- **streamline product-evaluation processes to comply with ongoing practice in medicines, vaccines and diagnostics (under the WHO Prequalification programme);**
- **include pre- and post-marketing quality assurance (QA); and**
- **facilitate registration, quality control (QC) and sound management of pesticides by working with national authorities.**

WHO reform aims to deliver 4 primary outcomes

1. **Stimulate development of more innovative products**
   Increased drive for innovation in development of vector control products for public health

2. **Accelerate availability of vector control products**
   Improved efficiency and transparency of WHO vector control evaluation process

3. **Improve quality of vector control products**
   Enhanced quality management by WHO for vector control products across the system

4. **Increased appropriate use of innovative vector control interventions**
   Strengthened normative guidance functions

Target system will ensure effective, safe, high quality and innovative vector control tools

WHO will reinforce several areas of vector control and build additional capabilities to achieve these outcomes

1 Stimulate development of more innovative products	2 Accelerate availability of vector control products	3 Improve quality of vector control products	4 Increased appropriate use of innovative vector control interventions
A Trial data generated by manufacturers	Provided specific systematic pre-submission guidance	E Standards, team and process in place to conduct pre-marketing manufacturing site inspections	Facilitated insecticide resistance monitoring and management
Established network of sufficient GLP sites	D Reduced time required for dossier evaluation to < 100 days		F Enhanced evidence-based normative guidance available
B Reviewed technical criteria for equivalents	Increased transparency to allow tracking of evaluation progress	Standards, team and process in place to conduct post-marketing QA and manage complaints from procurers and countries	Assisted countries in implementing IVM strategies
Optimized evaluation of public health value of new paradigms	Pesticide evaluation system harmonized to WHO-PQ		Strengthened countries in pesticide life cycle management, including effective registration processes and insecticide resistance management
C Revised review committee procedures and composition to maintain independence			

X *Details on following slides*

Note: Does not reflect all proposed changes

Context for shifting data generation to manufacturers

WHO has agreed to move the generation and ownership[1] of testing data to manufacturers

As a result, WHO together with IVCC will help build an infrastructure of GLP sites

- That would guarantee high quality data and provide confidence in testing quality

Building this infrastructure will take time, so WHO has developed a transition plan

- To start shifting data generation to manufacturers with stringent WHO oversight during the testing
- And to allow GLP sites to be used as soon as they become available

1. Ownership will not reside with WHO anymore, it will be a manufacturer/testing site discussion

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Rationale and approach of reviewing equivalency

Rationale:

Need to review criteria of equivalency in vector control product evaluation

WHO to organize technical consultation with a broad range of experts and the goal to review and align on technical criteria for equivalency for vector control tools

Approach for reviewing equivalency:

Determine reason for issue

- At last I2I convening, all stakeholders recognized that this is a technical issue that can be solved by technical experts
- WHO has started to collect the technical issues that manufacturers see in the current criteria of evaluation process

Organize technical consultation

- WHO will hold expert consultation to review technical criteria for equivalency
- Criteria is different for each type of health product and is an area where expertise from other health fields can also be leveraged (e.g., from drugs, vaccines, diagnostics)

Review criteria

- Equivalency determined according to agreed upon criteria
- Technical criteria for equivalency revised if/as necessary

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New evaluation process, operating model and set of experts

Rationale:

Need for improved and evaluation process to accelerate high quality product availability

WHO to revise review committee composition for broader expertise, evaluation model to ensure independent recommendations and reviewing frequency to enable faster evaluation process

Process for changing evaluation process:

	Current state	Target state
Review frequency	▪ Review 1x/year	▪ Assessment of dossier completeness within 30 days ▪ Review of product dossier within 100 days of complete dossier submitted
Evaluation model	▪ All recommendation decisions taken by one main review committee	▪ Presentation of all testing results to full committee ▪ Recommendation decisions made by core members not affiliated with testing or development of products under evaluation
Review experts	▪ Mostly entomologists, one statistician, QC expert, and epidemiologist	▪ Number of review experts will expand ▪ Breadth of expertise will increase to include (more) statisticians, epidemiologists, regulatory, and product development experts

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Pre-/post-marketing quality control

Rationale:

Need for improved quality of vector control products in the field

WHO to establish QA criteria for manufacturing facilities, conduct site inspections and establish regular post-marketing quality testing to assure quality standards are met by all recommended products

Approach for establishing pre-/post-marketing quality control

Establish standards and team	Establish process	Execute QA
▪ Establish criteria, baselines and formalized procedures for quality management, for both pre- and post-marketing quality control ▪ Build and train a quality assurance team at the WHO	▪ Update product evaluation process to include manufacturing inspections ▪ Provide assistance to manufacturing site for QA compliance	▪ Complete manufacturing site inspections for all products under evaluation (***pre-marketing***) ▪ Conduct quality testing for recommended vector control products on the market (***post-marketing***)

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Change reform to strengthen six areas of normative functions

Expected outcomes	Description
I Facilitated insecticide resistance management in NTDs/malaria vectors	▪ Develop global policy on insecticide resistance management ▪ Build capacity to support **monitoring and managing insecticide resistance**
II Enhanced evidence-based normative guidance available	▪ Develop/update testing guidelines, specifications and risk models for evaluation of VC ▪ Enable timely development of **normative guidance** (< 6 mos) for new product & categories ▪ Standardize and enhance required entomological procedures and practices
III Assisted member countries in implementing IVM strategies	▪ Develop and publish policies, recommendations and topical guidance for countries ▪ Develop operational guidelines for **non-pesticide vector control tools** and their evaluation
IV Optimized situational targeting of vector control products in countries	▪ Develop LLIN **durability standards** for quality control (e.g., expert review of intra-lab tests) ▪ Develop guidance on best targeting of vector control interventions
V Strengthened countries in registration processes for vector control products	▪ Increase **registration process efficiency** at country level by providing technical and normative support to countries & regional networks in pesticide registration (trainings and tool kits)
VI Strengthened countries in regulation of pesticides lifecycle management	▪ Develop and update guidelines and support countries on life-cycle management of pesticides ▪ Set up routine **monitoring of insecticide use** by member states

Overall impact

- **WHO** aims to support the development, evaluation, QC, adoption and sound management of pesticides and their products for the control and elimination of vector-borne diseases.
- **Vector-control product manufacturers** will benefit from faster, clearer and more transparent vector-control product-evaluation systems, including a new independent evaluation review process.
- **National regulatory authorities** will benefit from a more transparent global evaluation system in support of countries and regional systems, and stronger support for national registration through more transparent global evaluation.
- **Procurement sectors** will benefit from a larger array of products and strengthened development of normative guidance for deployment of innovative tools.
- **WHO Member States** will benefit from decreased incidence of vector-borne disease because of the availability of high-quality and effective products in the field, and strong normative support to monitor and manage insecticide resistance and manage pesticides over their life cycle.