FIRST MEETING
OF THE
VECTOR CONTROL ADVISORY GROUP

JULY 2013
WHO HQ
GENEVA, SWITZERLAND

World Health Organization

Design & Layout: Patrick Tissot WHO/HTM/NTD

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WHO Library Cataloguing-in-Publication Data

First meeting of the vector control advisory group.

1.Pest control, Biological. 2.Insect control. 3.Disease vectors - prevention and control. 4.Pest control. 5.Malaria. I.World Health Organization.

ISBN 978 92 4 150745 5 (NLM classification: QX 650)

Printed in France

WHO/HTM/NTD/VEM/2014. 1

CONTENTS

Introduction ——— iv

Declarations of interest ——— iv

1. DECLARATIONS OF INTEREST ---------- 1

2. NEW PARADIGMS IN THE PIPELINE – Presentations by partners ---------- 1

3. VCAG OPERATIONAL PROCEDURES ---------- 4

4. APPENDIX ---------- 11

Appendix I: List of Participants ——— 11
Appendix II: Agenda ——— 15
Appendix III. Terms of Reference for VCAG ——— 16
Appendix IV: Application Form for Submission to VCAG ——— 19

5. ANNEX ---------- 21

INTRODUCTION

The first meeting of the Vector Control Advisory Group (VCAG), an expert group to the WHO on new forms of vector control for malaria and other vector-borne diseases, was convened at WHO headquarters in Geneva, Switzerland, from 10–12 July 2013. The objective of the meeting was to initiate the work of VCAG in setting policy agenda and encouraging innovation and product formulation for vector control.

The meeting was opened by Dr Lorenzo Savioli, Director, Department of Control of Neglected Tropical Diseases (NTD), and Dr Robert Newman, Director, Global Malaria Programme (GMP). In their opening remarks, Drs Savioli and Newman welcomed participants and discussed WHO initiatives and the importance of vector control. Dr Newman discussed ongoing collaborations between GMP and NTD, and the need to encourage innovation in vector control product development in order to bring new tools to market for public health purposes. Additionally, special attention was given to the functions and terms of reference of VCAG and its role as an entry platform for innovation in novel vector control strategies, giving an opportunity for innovators to discuss with experts, and in mediating further policy action through recommendations to STAG and MPAC.

The meeting was attended by 12 of the 13 selected members of VCAG, partners from industry, observers and special invitees (see Appendix I: List of participants). Dr Marc Coosemans was appointed Chair of the meeting and Drs Ashwani Kumar and Michael Macdonald were appointed Rapporteurs. The meeting was divided into open and closed sessions (see Appendix II: Agenda). The open session (10 July – whole day, and 11 July – morning) provided the opportunity for all stakeholders to participate in and understand the functions of VCAG. The closed session (11 July – afternoon, and 12 July – whole day) allowed VCAG members and the secretariat to discuss the operational procedures for VCAG, including dossier formatting, timelines for VCAG submission and dates of future VCAG meetings.

DECLARATIONS OF INTEREST

In accordance with WHO policy for the management of Conflicts of Interest, all 13 VCAG members submitted declarations of conflict of interest prior to the meeting, which were reviewed and assessed by the NTD secretariat. The following interests were declared:

Dr Tom Burkot, James Cook University, Australia, disclosed receiving a donation through his University of insecticide-treated netting for evaluation in a field trial from Vestergaard Frandsen, Switzerland.

Professor Marc Coosemans, Institute of Tropical Medicine of Antwerp, Belgium, disclosed receiving funding from the European Union, WHO and the Gates Foundation for his research work. He also received a donation of repellents from S.C. Johnson & Son, Inc. USA for his research work.

The interests declared were assessed by the WHO secretariat in consultation with the Office of the Legal Counsel. For the purpose of this meeting, no potential conflict of interest was found to prevent either member from participating in formulating recommendations; however, in the future, should personal repellents be discussed in the VCAG, Professor Coosemans will be excused from participating in the formulation of recommendations.

1. INTRODUCTORY REMARKS

Introductory presentations were made by Drs Marc Coosemans, Raman Velayudhan, Abraham Mnzava. Dr Velayudhan discussed the functions and terms of reference of VCAG and its role as an entry platform for innovation in novel vector control strategies, as an opportunity for innovators to dialogue with experts, and in mediating further policy action through recommendations to STAG and MPAC and in collaboration with WHOPES. Dr. Mnzava reported to the group on the recent meeting of the Vector Control Technical Expert Group for Malaria (VCTEG), and the roles and responsibility of VCTEG in providing guidance to countries and partners for capacity building in malaria vector control.

2. NEW PARADIGMS IN THE PIPELINE – PRESENTATIONS BY PARTNERS

The open meeting session allowed for presentations by innovation partners on new vector control paradigms in the development pipeline. Presentations were made by Dr Tom McLean of the Innovative Vector Control Consortium (IVCC), Dr Egon Weinmüller of Croplife International, Dr Graham White of the Armed Forces Pest Management Board, and Dr Karl Malamud-Roam from the IR-4 Project Headquarters.

2.1 VCAG AND THE IVCC

While welcoming the constitution of VCAG, Dr Tom McLean commended the complementary roles of IVCC and VCAG in stimulating innovation in vector control product development. VCAG will evaluate the public health value of new tools, approaches and technologies, and make recommendations on their use in the context of integrated vector management programmes in multi-disease settings. As a product development partnership programme, the IVCC helps industry and end-users in disease-endemic countries to define and validate new vector control paradigms as well as their associated target product profiles.

Dr Mclean informed the group on the IVCC Strategic Roadmap and listed IVCC supported vector control innovations and products in the pipeline. The IVCC approach to new paradigm product development is comprehensive and coordinated, and comprises a framework for the validation of new paradigms and product categories. Currently, IVCC is defining criteria for the assessment of new paradigms including repellents and bi-treated insecticidal nets and for the early stage evaluation of novel impregnated materials and emanators. Dr Mclean described four stages of new product development recognized by IVCC:

- Development of intervention concept and draft TPP
- Proof of concept

- Verification of epidemiological efficacy and confirmation of TPP
- Policy endorsement and product category adoption

For each stage of paradigm/product development, data must be generated for the following categories: entomology, epidemiology, economics, technology development, manufacturability, sustainability, user compliance/acceptability, delivery/implementability, regulatory, safety, environmental impact, target product profile and, finally, policy and strategy.

Dr Mclean concluded with a summary of products in the IVCC pipeline that may be of interest to VCAG, including bi-treated nets, novel insecticides that are non-repellant, slow acting, or have alternate modes of action; repellants, emanators, clothing and a portfolio of new paradigm options that are yet to be defined.

2.2 PARTNERSHIPS WITH INDUSTRY

Dr Egon Weinmüller, representing CropLife International, spoke about public health vector control from an industry perspective. Vector Control Members of CropLife International are corporate global leaders in public health interventions committed to developing sustainable, lasting and innovative contributions to the fight against malaria and other vector-borne diseases. Dr Weinmüller discussed CropLife International's support of WHOPES as a transparent reference framework for public health products. He opined that R&D of vector control alternatives must include cooperation from all stakeholders in an environment fostering innovation; he stressed that the industry is committed to quality control, product stewardship, responsible use and IVM/IRM. Additionally, increased resources are required for regulatory harmonization to enable access to market. CropLife International is committed to working with all stakeholders to address procurement processes and compliance guidelines.

2.3 VECTOR CONTROL INNOVATION WITH DOD

Dr Graham White briefed the group on vector control research and development within the United States Department of Defense (DoD) Armed Forces Pest Management Board, which is responsible for advising and coordinating all entomological (medical and pest related) activities of the United States military services. In collaboration with academics, industry partners and multinational governments, the group focuses on selecting target sites to disrupt basic physiological functions of vectors and pathogens, namely host-seeking behaviour, lifespan, fecundity, fitness, and pathogen replication and transmission.

Dr White described a number of innovative products and platforms being assessed by the DoD.

- Attractive Targeted Sugar Baits (ATSBs), registered with the EPA in 2012, are targeted for mosquitoes and sand flies and shown to reduce sandfly populations by >90%.
- Combined systemic and feed-through control of adult and larval sand flies (Genesis Labs). Insecticidal (Imidachloprid, Fipronil) treatment of fat sand rats (Psammomys obesus) and jirds (Meriones spp.) leads to near 100% adult mortality in phlebotomine spp. (P. papatasi) sand flies for 3 weeks following treatment. Genesis Labs has received an EPA supplemental label for sand fly control.
- Ovitraps have been explored for container breeding mosquitoes, in particular lethal, pyriproxyfen disseminating, and the use of insecticidal paints.
- RNAi-Based Molecular Biopesticides. In 2006, it was determined that topically applied dsRNA silenced gene expression in adult mosquitoes, and that this construct was effective when delivered in a sugar meal. This same dsRNA construct was successfully applied to silence target gene expression in sand flies. Further trials on the formulation, sequence design and efficacy are ongoing.
- Permethrin Impregnated Uniforms. Factory-Treated and IDA-Kit Treated Army Combat Uniforms providing efficacy >80% against insect bites after 50 washes.
- Fast Acting Pyrethroids in combination with pesticide delivery technologies, such as TL-I-139 sleeve treatments, which significantly reduce insect bites compared with permethrin treatment, and functional microdispensers (e.g. velcro wrist bands), which function as wearable personal and area protection devices.

2.4 THE IR-4 PUBLIC HEALTH PESTICIDE PROGRAM

Dr Karl Malamud-Roam presented on IR-4 activities and specifically the IR-4 Public Health Pesticide (PHP) Program, whose key functions include identifying, evaluating, and inventorying PHP materials and practices, and communicating with pest-product managers, developers and regulators to improve product development and the registration process. Dr Malamud-Roam reviewed the PHP Inventory & Database with the group, which includes reviews of 500+ existing or underutilized materials for public health and veterinary use, including data sets on specification, characterization, bioactivity (efficacy + toxicology) and regulatory status. Sources of this data include materials/methods used by other nations for veterinary and agricultural purposes, private and public chemical libraries, and scientific literature. Some examples of data in the PHP inventory include lethal ovitraps, examples of botanicals (essential oils and extracts, e.g. neem, mint, citrus), insect pathogens, and tactics such as RNAi and Wolbachia. Additionally, IR-4 endeavours to retain out-of-use products, for example DDT, fenthion, bendiocarb and allethrins. A second edition of the PHP Inventory is in progress and will include additional sources (USDA Archives, etc.), pests (fleas, other flies, etc.) and data (efficacy, regulatory, toxicology) and will be generated from an online database.

3. VCAG OPERATIONAL PROCEDURES

The World Health Organization (WHO) has established a Vector Control Advisory Group (VCAG) on New Tools to serve as an advisory body to WHO on new forms of vector control for malaria and other vector-borne diseases.

3.1 FUNCTIONS

The VCAG has the following functions:

1. To review and assess the public health value, "proof of principle" (epidemiological impact) of new tools, paradigms, approaches and technologies; and

2. To make recommendations on their use for vector control within the context of integrated vector management in a disease or multi-disease settings.

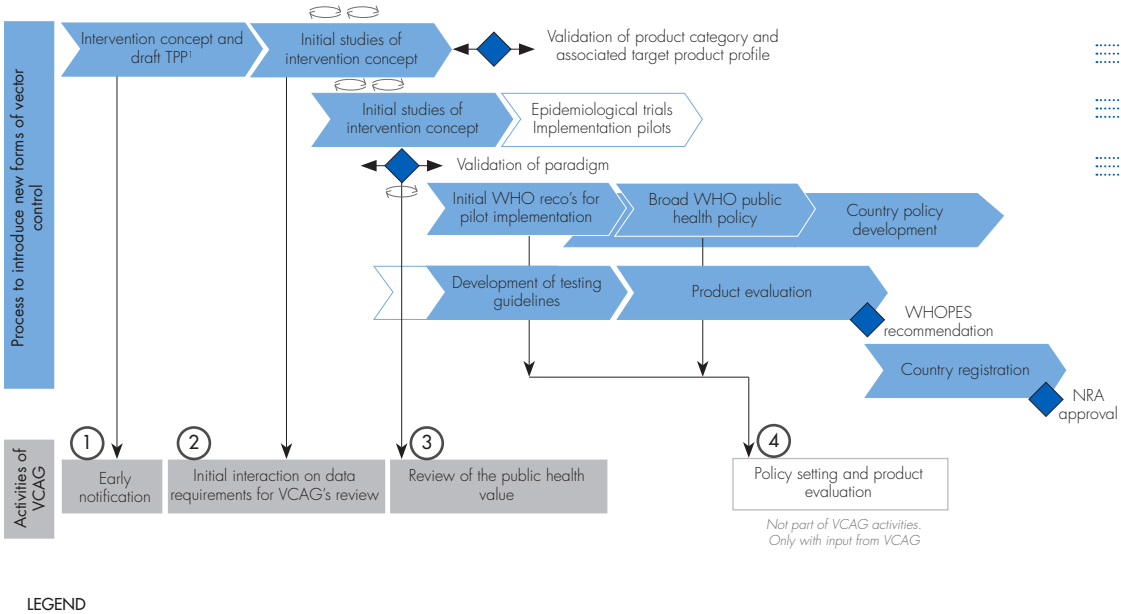
3.2 WHEN IS A PARADIGM OR CATEGORY "NEW"?

A product, technology or approach is considered a new paradigm if one or more of the following conditions are met:

- An intervention or combination of interventions that protects humans against a different group of vectors or in different transmission settings (or contexts), different human populations or via a different mechanism from existing methods, e.g. an odour-baited trap or a genetically-modified insect.
- An intervention where one or more of its characteristics is sufficiently changed that entomological effect alone is not sufficient to imply epidemiological effect, e.g. a resistance-breaking bednet.
- When a product is not adequately described by an existing target product profile (TPP) and validation will result in the development of a new TPP, and hence a new product class.

For new candidate vector control technologies/paradigms, the process of obtaining a recommendation from WHO will in most cases begin with an assessment by VCAG of "proof of principle"; that is, an assessment of whether the evidence about the intervention is sufficient to justify its potential application for some public health purpose in one or more environmental settings. The assessment will ensure that the evidence generated is relevant for obtaining a public health policy recommendation. The activities performed by VCAG will depend on the stage [or status] of the proposed new form of vector control in the innovation process. There are three major steps of the innovation process in which VCAG can play an essential role, and a fourth step in which its input would be required (*Figure 1*).

Figure 1. Major steps where VCAG has a role to play



Step 1: Early notification

During the very early stages of innovation, scientists and product developers can bring new ideas or new intervention concepts to VCAG. The secretariat will log these notifications in a confidential list, which will be regularly shared with VCAG members, so that VCAG can anticipate future requirements; e.g. expertise needed for future assessments and potential issues to consider. The VCAG secretariat will respond to any general enquiries about the review process; e.g. nature of assessment and timelines. Key steps needed in the development of the intervention concept are given in *Table 1*.

Table 1. Developing an intervention concept – Stage 1

Parameters	Requirements (to be considered by the applicant)
Entomology	Define the key measurements that will indicate entomological impact, according to mode of action. Consider a resistance or product failure risk analysis.
Epidemiology	Creation of a credible case that the new category will add a significant impact in disease control – by complementing or replacing existing interventions. This may include simulation modeling based on expected entomological impact.
Economics	Estimate the expected cost of protection per person (at scale). Potential demand. Is the impact worth the cost and effort?
Technology development	Review technical feasibility of making a prototype. How will the prototype be applied?
Manufacturability sustainability	Initiate discussion with potential manufacturers to explore issues and opportunities. Solve, in principle, any Intellectual Property (IP) issues.
User compliance/ acceptability	Define target user groups and expected mode of application. Record and summarize initial reactions to the product concept.
Delivery and feasibility of implementation	Identification of distribution routes and first discussions with potential distributors to identify issues that will need to be resolved.
Regulatory/ safety/ ethical and environmental impact	Identify safety/environmental issues to be tested. Identification of new risk assessment models that may be required.
Target product profile (TPP) [1]	A first draft of the TPP is created highlighting gaps and unknowns to be filled in as the intervention matures.

Logical data, yes or no

Output(s) of this step: VCAG secretariat generates a list of projects notified by product developers and communicates it regularly to VCAG members.

The product developers can seek advice on the key parameters mentioned above in order to move to Step 2.

Step 2: Initial interaction on data needs

If the product developers wish, VCAG can provide advice on the type and depth of evidence that will likely be used for the assessment, providing an opportunity for product developers to align with VCAG on overall evidence requirements before the launch of resource-intensive activities such as large-scale epidemiological trials (randomized control trials with epidemiological end-point).

The advice will be provided in individual discussions between the product developers and the group at the VCAG meeting. It may cover, for instance, the needs concerning evidence of epidemiological and entomological outcomes, epidemiological mode of action, economic feasibility or user acceptability. To support its deliberations, VCAG may consider the initial results of tests and studies carried out by the product developers. Some of the key steps needed in the development of the proof of concept are given in *Table 2*.

[1] The definition of a target product profile (TPP) for each vector control intervention category, linking the primary effect and other characteristics of the category to its epidemiological outcome, is crucial to the process.

Table 2 Developing the proof of concept – Stage 2

Parameters	Requirements (to be considered by the applicant)
Entomology	Laboratory, semi-field and small-scale field trials with proxy and progressively refined prototype products to show that the basic parameters of the TPP can be achieved and that they have the anticipated primary (entomological) impact.
Epidemiology	Plans for randomized controlled field trials to demonstrate the efficacy of the prototype or new approach with pathogen-specific outcomes for a category/paradigm and its TPP and products, if applicable. Consider the additional value of models for entomological correlates (if appropriate) as proxy for epidemiological end-points.
Economics	Initial cost analysis of prototype or approach and comparison with sustainability model. Explore financing mechanism with key donors/purchasers.
Technology development	Manufacturers/developers supply proxy or early prototype quality-assured products. Manufacturers/developers develop prototype products, ending in final product stage. Technical issues of feasibility are challenged at this stage.
Manufacturability sustainability	Business case for manufacturing. Advance on addressing IP issues.
User compliance/ acceptability	User reactions to the proxy or prototype products tested in detail; e.g., focus group studies.
Delivery and feasibility of implementation	Identify, test and resolve issues and opportunities in delivery of the product. Review distribution routes and confirm potential distributors for the trial.
Regulatory/ safety/ ethical and environmental impact	Identification of safety/environmental and ethical issues to be tested. Risk assessment model developed and data generated for most parameters. Prototypes assessed against risk assessment model. Identification of Institutional Review Boards (IRBs) and the review process of protocols for use of human subjects for the planned trial.
Target product profile (TPP)	TPP evolves from draft to refined status.
Policy/strategy	innovator should initiate VCAG communication and dialogue.

Output(s) of this step: VCAG provides advice to innovators on the type of evidence that will likely be used in the review in step 3 to help them strengthen their dossier. VCAG will report to the Malaria Policy Advisory Committee (MPAC) of the WHO Global Malaria Programme (GMP) and also to the Strategic and Technical Advisory Group (STAG) of the WHO Department of Control of Neglected Tropical Diseases (NTD) the advice that was provided to the innovator to determine if there are additional elements relevant in the broader context of the targeted diseases.

VCAG can organize discussions, teleconferences between experts or VCAG members and product developers depending on the needs identified by the group.

Step 3: Review and assessment of public health value

Once a relevant body of evidence has been presented to VCAG, which contains at least some indication of the epidemiological outcome of the new form of vector control, VCAG will review all available evidence (which may include available sources other than the data presented by the product developers).

Based on this review, VCAG evaluates the public health value of the new intervention by answering questions such as: "Is this new intervention efficacious for some defined public health purpose (in disease prevention through vector control) and in some defined circumstances, and will it be useful to and feasible for its intended users?" The answer might in some instances require additional evidence.

As soon as VCAG decides that the answer to this question is "yes", and that proof of principle has indeed been established for the new form of vector control, responsibility within WHO for further assessment will pass (a) to the advisory bodies (MPAC and STAG) of the technical department(s) (GMP and NTD) responsible for the particular vector-borne disease(s) against which the new intervention is considered likely to be useful and (b) if applicable to the WHO Pesticide Evaluation Scheme (WHOPES).

Hence, after validating the value of the new form of vector control, VCAG will present its results to MPAC and STAG in their respective meetings, expressing its opinion on the usefulness of the new intervention. In particular, VCAG will detail the epidemiological mode of action and value of the new paradigm in a given setting.

In the case of establishing a proof of principle, VCAG may submit a technical data package to MPAC, STAG and WHOPES (if necessary) for further use in policy and

Table 3 Developing epidemiological end-points and confirming the target product profile – Stage 3

Parameters	Requirements (to be considered by the applicant)
Epidemiology	Randomized controlled field trials to demonstrate the efficacy of the prototype with pathogen specific outcomes for a category/paradigm and its TPP and products, if appropriate. Consider level of compliance and coverage issues in relation to efficacy testing.
Economics	Projection of cost per person protected and cost-efficacy of prototype in new category/paradigm.
Technology development	Prototype or product is essentially mature, but may require minor changes to improve the method in response to trial outcomes.
Manufacturability sustainability	Confirmation of commercial sustainability by manufacturer/producer. Early manufacturing/production runs at volume. IP issues resolved and commercial production possible.
User compliance/ acceptability	Completion of studies of user acceptability/compliance.
Delivery and feasibility of implementation	Demonstrate feasibility of implementation of intervention.
Regulatory/ safety/ethical and environmental impact	Experimental registration of the product to allow trials. Check for adverse events during the trials. Plan product stewardship.
Target product profile (TPP)	TPP confirmed by trials noted above.
Policy/strategy	Engagement of national control programme/institutes in the trials process. VCAG reviews trials outcomes and reports to MPAC and STAG. If applicable, WHOPES starts work on category draft.

product standard setting. In parallel, product developers are informed of VCAG's opinion of the technology reviewed.

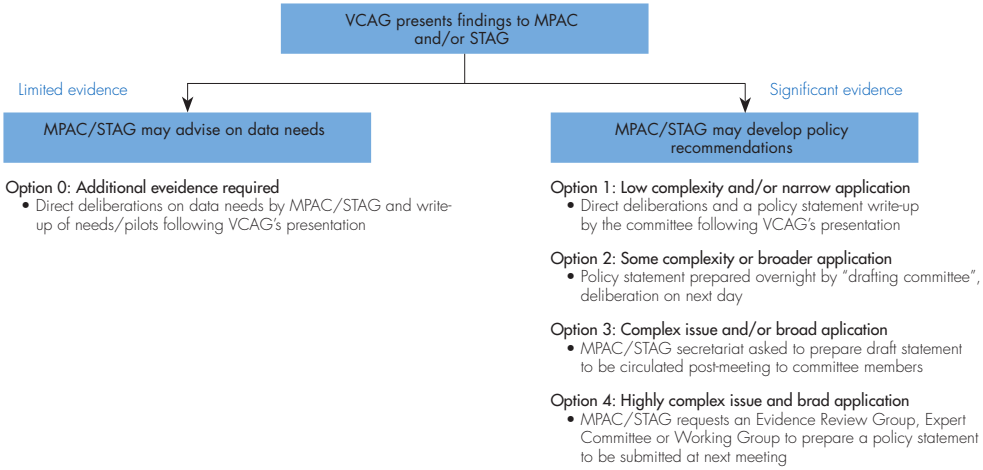
Output(s) of this step: VCAG prepares a report including its assessment of the public health value of the new form of vector control. It may advise product developers on the need for additional evidence in some instances. VCAG presents to MPAC and STAG its findings, through the expression of its recommendation ("yes", "no", "maybe" and describing the specific considerations to take into account). A technical data package is also transmitted to MPAC, STAG and WHOPES, if relevant.

Step 4: Policy development and product evaluation.

[In this step, VCAG mainly provides input]. Once VCAG has presented its findings at the MPAC and STAG meetings, the task of defining what public health roles and functions are appropriate for the new form of vector control in the context of the disease(s) will transfer to MPAC and STAG. In particular, they will establish the role of the new intervention for a specific disease and eco-epidemiological setting, and in relation to other disease control interventions. While VCAG will concentrate on the characteristics of the intervention itself and whether it is technically efficacious, MPAC and STAG work at a higher strategic level on the role of the intervention vis-à-vis other interventions within specific disease control programmes; i.e. **when**, **where** and **how** the intervention should be deployed.

Illustrative options of how the articulation between VCAG and MPAC/STAG could work

[Initial propositions for consideration by MPAC and STAG; may require adaptation]



In parallel to the VCAG review, WHOPES - where appropriate - can develop or adapt risk assessment, efficacy testing and quality control procedures to ensure that commercial products using the same technology are evaluated with a common set of criteria, and to give suitable recommendations to prospective purchasers. Innovative forms of control may need new procedures and assessment processes, which VCAG can recommend to MPAC and STAG.

In order to minimize the time of developing these guidelines, WHOPES will be in close contact with the VCAG secretariat and participate in VCAG meetings/communications throughout the VCAG process. This will enable WHOPES to develop draft guidelines (with relevant experts) in parallel with the VCAG review, using VCAG's ongoing assessment as primary input for defining relevant indicators and guidelines. Once the VCAG review has finalized establishing the public health value of a new tool, technology or approach, and where necessary, WHOPES will then proceed to a larger consultation of the draft guidelines for finalization and publication.

Although VCAG reviews classes of technology, some evidence considered by VCAG may refer to a "first-in-class" commercial product. If this product is also submitted to WHOPES, WHOPES will build on VCAG's work, taking all the already existing evidence fully into account to avoid duplication of efforts.

Output(s) of this step: GMP and NTD publish policy recommendations, based on the advice of their respective policy committees, MPAC and STAG. WHOPES will publish product category testing/assessment guidelines and product recommendations for specific products.

Handling of confidentiality

As some documentation presented to the meetings may include prepublication copies of research reports or documents of commercial significance, VCAG members will sign a confidentiality agreement at the beginning of their term. They will also sign a WHO standard declaration of interest form before each meeting. A synopsis of the declaration of interest statements will be made publicly available on the WHO website at the conclusion of each meeting. VCAG deliberations, other than those published in the meeting reports, will be kept confidential and will not be publicly disclosed by members. VCAG's assessment will inform MPAC and STAG for the policy-setting process related to new forms of vector control. Therefore, the evidence that will be used to support the public health recommendations made by MPAC and STAG will need to be in the public domain, to ensure full transparency of these public health recommendations.

Proprietary business information will be kept fully confidential.

The assessment made by VCAG on a new class of technology will apply to all products of this class. To decrease risks for individual innovators, product developers may wish to establish cost-sharing mechanisms between product manufacturers and/or other funders, e.g. through private or private–public consortiums. All parties (from industry, academia and others) interested in a new form of vector

Submission of applications

WHO welcomes submission of dossiers for evaluation of innovative vector control tools under new paradigms. A Letter of Intent can be submitted as the first step to WHO by e-mail (velayudhanr@who.int and mnzavaa@who.int).

Please refer to the Guidance for submission of applications for further details. (http://www.who.int/neglected_diseases/vector_ecology/VCAG/en/)

4. APPENDIX

4.1 LIST OF PARTICIPANTS

First Vector Control Advisory Group (VCAG) meeting
WHO/HQ, Geneva, Switzerland – 10–12 July – Room M-505

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Special Programme for Research & Training in Tropical Diseases (TDR)

Dr Yeya Timoko Touré, Unit Leader

4.2 AGENDA

10 July (whole day) & 11 July (morning)

1. Opening
    - Welcome remarks – (Directors of GMP and NTD)
    - Administrative arrangements and introduction of participants

2. Appointment of the Chair and Rapporteur

3. Introductory presentations
    - VCAG –an introduction – Drs Raman Velayudhan and Abraham Mnzava
    - Proof of principle and few examples –Dr Marc Coosemans
    - VTEG – updates – Drs Abraham Mnzava and Mike MacDonald

    Discussion

4. New paradigms in the pipeline – presentations by partners
    - IVCC – Dr Tom McLean
    - Croplife – Dr Egon Weinmüller
    - AFPMB – Dr Graham White
    - IR-4 Project - Dr Karl Malamud-Roam

    Discussion

5. The operational procedures for VCAG
    - Brief presentation to be followed by discussion
    - Review of format of the dossier
    - Time lines for submission
    - Dates of the VCAG meetings in 2014

Restricted and Closed session limited to VCAG members & Secretariat only

11 July (afternoon) and 12 July (whole day)

1. Finalization of the operational procedures

2. Review and finalization of the report

3. Conclusions and recommendations

Closing

4.3 TERMS OF REFERENCE FOR VCAG

VECTOR CONTROL ADVISORY GROUP (VCAG) ON NEW TOOLS

The World Health Organization (WHO) has established a Vector Control Advisory Group (VCAG) on New Tools to serve as an advisory body to WHO on new forms of vector control for malaria and other vector-borne diseases.

1. Functions

The VCAG has the following functions:

1. To review and assess the public health value, "proof of principle" (epidemiological impact) of new tools, approaches and technologies; and

2. To make recommendations on their use for vector control within the context of integrated vector management in multi-disease settings.

2. Composition

1. The VCAG will have up to 13 members, who shall serve in their personal capacities to represent the broad range of expertise relevant to practical vector control, including vector biology, ecology and management, insecticides and insecticide resistance, epidemiology of vector-borne diseases, study design and statistics, operational research, as well as management of vector control programmes. In the selection of the members, consideration will be given to attaining an adequate technical distribution of expertise, geographical representation and gender balance.

2. Members of the VCAG, including the Chairperson, will be selected and appointed by the Assistant Director-General of HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases, taking into consideration advice from the Director of the Global Malaria Programme (GMP) and the Director of the Department of Control of Neglected Tropical Diseases (NTD).

3. The Chairperson's functions include the following:

   - to chair the meeting of the VCAG; and
   - to liaise with the WHO secretariat between meetings.

   In addition, the Chairperson of the VCAG may be invited to attend the meetings of the WHO Malaria Policy Advisory Committees (MPAC) and the WHO Neglected Tropical Diseases Scientific and Technical Advisory Group (STAG) as an observer.

4. Members of VCAG, including the Chairperson, will be appointed to serve for an initial term of three years, and shall be eligible for reappointment (once only) for an additional term.

5. Members must respect the impartiality and independence required of WHO. In performing their work, they may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of real,

potential or apparent conflict of interest. To this end, proposed members/members will be required to complete a declaration of interest form and their appointment, or continuation of their appointment, will be subject to the evaluation of completed forms by the WHO secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

6. VCAG members will not be remunerated for their participation in VCAG. However, in accordance with paragraph III.7 below, WHO will cover their travel cost and per diem in accordance with the applicable WHO rules and policies.

3. Meetings and meeting participants

1. The VCAG will normally meet once each year in both open and closed sessions. WHO may convene additional meetings, including through teleconferences and videoconferences, on an ad hoc basis. WHO may furthermore request members to carry out activities in between meetings of the VCAG, i.e. in preparation for or as follow-up to such meetings.

   WHO may decide to invite additional experts, as advisers, to the open sessions of a particular VCAG meeting, to provide advice on specific issues under consideration at that meeting.

   In addition, WHO may invite organizations active in the field of vector control, umbrella associations representing the vector control industry, individual manufacturers with an interest in the development of vector control technologies and academic institutions engaged in vector control technology research to attend the open sessions of VCAG meetings as observers.

   Upon invitation from the Chairperson, the above mentioned observers may present the views and policies of their organizations and contribute to the discussions of the VCAG by sharing their experience and/or expertise in specific aspects of vector control. Alternatively, observers may, in advance of any meeting of the VCAG, submit the views and policies of their organizations and/or share their experience or expertise in a specific aspect of vector control to the WHO secretariat in writing. Outside VCAG meetings, observers shall exclusively communicate with VCAG members on VCAG matters through the WHO secretariat.

   a. Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views and may be attended by the invited advisers and observers.
   b. Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the VCAG and held as closed sessions.

   Advisers and observers shall not in any way participate in the process of adopting the recommendations and other advice, and shall thus not attend any closed sessions of, the VCAG.

2. VCAG members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the VCAG and appoint a replacement.

3. Reports of each VCAG meeting will be submitted by the Chairperson of the VCAG to WHO (the Assistant Director-General of HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases, ADG/HTM). All recommendations from the VCAG are advisory to WHO, which retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the VCAG. WHO also retains full control over the use and publication of the reports of the VCAG, including whether or not to use and/or publish them and/or to provide such reports to other advisory groups or third parties, which could include the Malaria Policy Advisory Committee (MPAC) and/or the Neglected Tropical Diseases Strategic and Technical Advisory Group (NTD STAG), all the foregoing subject to the protection of confidential information, including confidential business information.

4. The quorum for VCAG meetings shall be seven members.

5. The VCAG will normally make decisions and recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

6. VCAG members and advisers invited by WHO may, in advance of VCAG meetings, be requested to review meeting documentation and to provide their views for consideration by the VCAG.

7. WHO will arrange and pay for travel and per diem of the members and advisers to the VCAG in accordance with the applicable WHO rules and policies. Observers shall attend the meetings of the VCAG at their own expense, and shall be responsible for making their own arrangements in that regard.

8. VCAG meetings will be conducted in the English language.

9. VCAG members, advisers and observers shall not purport to speak on behalf of, or otherwise represent, the VCAG and/or WHO to any third party.

4. Secretariat

WHO shall provide the secretariat for the VCAG, including any necessary scientific, technical and other support. In this regard, the WHO secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to advisers and observers will be dependent on their nature, as determined by the WHO secretariat.

5. Information and documentation

1. The information and documentation to which VCAG members and advisers will gain access during or in relation to the meetings of the VCAG, may include confidential and proprietary information. To protect the proprietary and confidential nature of such information, all VCAG members and advisers will therefore be required to sign an appropriate confidentiality undertaking.

2. VCAG members, advisers and observers shall refrain from quotation from, and circulation and use of, VCAG documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

4.4 APPLICATION FORM FOR SUBMISSION TO VCAG

VECTOR CONTROL ADVISORY GROUP

Guidance for submission of applications

The World Health Organization (WHO) Vector Control Advisory Group (VCAG) welcomes submission of dossiers for evaluation of innovative vector control tools under new paradigms.

A formal application in hard copy (with an electronic copy on a CD or memory stick/flash drive) along with the information/data listed below should be provided by the manufacturer/developer[1] of the product/tool under a new paradigm to the VCAG secretariat at the following address:

Coordinator
Vector Ecology & Management
Department of Control of Neglected Tropical Diseases
World Health Organization
20 Avenue Appia
1211 Geneva 27
SWITZERLAND

The application should not be submitted by e-mail, although applicants can be informed about its status by e-mail to WHO (velayudhanr@who.int and mnzavaa@who.int).

Cover letter:

Please attach a cover letter clearly mentioning the name of the product/tool/paradigm to be evaluated, the names of the manufacturers/developers and the name of the person who will serve as the official contact point for all communications with WHO/VCAG.

INFORMATION AND DATA REQUIREMENTS

1. Manufacturer/producer/researcher (any developer):

   - Name(s) of manufacturer/developer
   - Full contact details of manufacturer/developer including postal address, telephone and fax number, e-mail addresses
   - Name and contact details of the person who will serve as the official contact point

2. Description of the paradigm (please refer to VCAG operational procedures for definition)

3. Paradigm claim

4. Description of mode of action of the prototype of the tool under a paradigm (entomological, epidemiological and/or mode of the chemical/product, if appropriate)

[1] May be a researcher, an institute or any innovative developer.

5. **Summary of the product claim**: (justification and reason for the innovative claim) e.g. entomological and, if available, epidemiological efficacy.

(Please refer to VCAG operational procedures and fill out the table below based on the listed steps)

Parameters	Requirements (to be filled by the applicant)	VCAG comments
Entomology		
Epidemiology		
Economics		
Technology development		
Manufacturability sustainability		
User compliance/ acceptability		
Delivery and feasibility of implementation		
Regulatory/safety/ethical and environmental impact		
Target product profile (TPP)		
Policy/strategy		

6. **Summary and results of key studies supporting the claim**: entomological and epidemiological efficacy (safety, health and environmental risk assessments reviewed by other bodies) and acceptability.

    - Provide a full report of any laboratory or field testing conducted on the product. Where applicable, provide a statement certifying that the materials used in the reported studies complied with the product's manufacturing specifications.

7. **If the prototype or the final product submitted for evaluation contains chemicals**, please provide necessary information in *Annex 1*. Any other product (non-chemical) may provide additional relevant analogous data if applicable.

8. Supporting documentation

Provide all supporting documents as annexes to the dossier, such as a list of:

- published papers (electronic copies to be provided on a memory stick or CD)
- unpublished reports (electronic copies to be provided on a memory stick or CD)
- confidential information (electronic copies to be provided on a memory stick or CD).

9. Concluding statement (optional)

5. ANNEX

5.1 INFORMATION ON PRODUCTS CONTAINING CHEMICALS

1. Registration status:

- List the countries where the product is currently registered for sale and use, if applicable. If not registered or sold in any country, clarify if it is under research and development or if it is in its final form.

2. Name of the insecticide or active ingredient and type of formulation(s) and the trade name.

3. Physical and chemical properties of the active ingredient (generated with your product as defined through the manufacturing specification).

- Use the standard template "proposer's data entry form"

4. Human and environmental safety

- Provide a copy of the Material Safety Data Sheet for the technical material and the formulation(s).
- Summarize the data/information on hazard in the standard template "proposer's data entry form" (generated with your product as defined through the manufacturing specification).
- Provide a draft risk assessment for the intended application.

5. Label recommendations

- Provide a copy of the label (or the draft label) if it is a final product.

The newly established Vector Control Advisory Group (VCAG) supports national and global efforts to control and eliminate vector-borne diseases worldwide by strengthening WHO's capacity to assess the public health value of new vector control innovations and to develop appropriate technical recommendations. This report details the proceedings and outcomes of its first meeting, held in July 2013, which finalized the operational procedures to allow the evaluation of new tools, technologies or approaches in public health vector control. VCAG is jointly managed by the Global Malaria Programme and the Department of Control of Neglected Tropical Diseases and will serve as an advisory body to WHO on new forms of vector control for malaria and other vector-borne diseases.

Vector Control Advisory Group (VCAG)
Vector Ecology and Management (VEM)
Department of Control of Neglected Tropical Diseases (NTD)
and
Vector Control Unit (VCU)
Global Malaria Programme (GMP)
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland