Malaria Policy Advisory Committee

Technical Expert Group on Antimalarial Drug Resistance and Containment

Terms of Reference

I. Background and rationale
The Malaria Policy Advisory Committee (MPAC) has been constituted to provide independent advice to the World Health Organization (WHO) for the development of policy recommendations for the control and elimination of malaria. The mandate of MPAC is to provide strategic advice and technical input, and extends to all aspects of malaria control and elimination. MPAC can recommend that specific technical issues are analyzed through a time-limited Evidence Review Group (ERG) or a standing Technical Expert Group (TEG).

The MPAC recommends a standing TEG on antimalarial drug resistance and containment as there is now - and will be in the future - a continual need to review new evidence on drug resistance, make recommendations on necessary actions, and set research priorities.

II. Role and functions of the Technical Expert Group on antimalarial drug resistance and containment
The TEG on drug resistance and containment is tasked with reviewing evidence, providing guidance and making draft recommendations on issues of drug resistance and containment. The TEG is constituted by and reports to the MPAC. While the issue of resistance to artemisinins is of urgent concern, resistance to other antimalarials is also of prime importance.

As the issue of drug resistance and containment is evolving quickly, the TEG may provide advice directly to GMP when necessary.

The responsibilities of the TEG on antimalarial drug resistance and containment will be to:

• Evaluate the accuracy and integrity of data on antimalarial drug resistance, in particular data suggesting new foci of artemisinin resistance;
• Provide evidence-based advice on norms, standards and technical guidelines on monitoring of antimalarial drug resistance;
• Provide evidence-based advice on policies, strategies and approaches for drug resistance prevention and containment in general, as well as in specific situation. This includes:
  – Determining the triggers for emergency response related to the detection of artemisinin resistance or resistance to an ACT partner drug;
  – Provide recommendations, based on ongoing evaluation and evidence, on the effectiveness and impact of the implementation of strategies to detect, prevent and contain antimalarial drug resistance;
• Identify priority research areas in the field of drug resistance or containment.
III. Membership and structure of the TEG
The TEG will have up to 15 members. TEG members will serve in an independent, personal and individual capacity.

The TEG composition should strive for appropriate geographical representation and gender balance, and should comprise individuals representing different areas of expertise and experience within antimalarial drug resistance and containment.

Members of the TEG must have excellent technical knowledge, scientific publications in peer-reviewed journals and more than 10 years experience in at least one of the areas listed below.

The following areas of expertise should be represented in the TEG:

- Molecular markers of antimalarial drug resistance
- In vitro assays of antimalarial drugs
- *Plasmodium vivax* drug resistance
- Clinical trials of antimalarial drugs
- Pharmacokinetics of antimalarial drugs
- Modelling on malaria control and elimination
- Cultural geography or political science with a focus on population movement
- Entomology / vector control
- Public health economics

In addition, the TEG should include members who have worked or are currently working as national malaria control programme managers with experience in conducting routine monitoring of antimalarial drug efficacy, as well as general malaria control.

The TEG members will be selected by a nomination panel appointed by MPAC and GMP. Members of the TEG shall be appointed to serve for an initial term of up to three years, renewable once, for a period of up to an additional three years.

Membership in the TEG may be terminated by WHO, including for any of the following reasons:

- failure to attend two consecutive TEG meetings;
- change in affiliation resulting in a conflict of interest;
- a lack of professionalism involving, for example, a breach of confidentiality.

Prior to being appointed as a TEG member and prior to renewal of term, nominees shall be subject to a conflict of interest assessment by WHO, based on information that they disclose on the WHO Declaration of Interest (DOI) form (Annex 1). In addition, TEG members have an ongoing obligation throughout their tenure to inform WHO of any changes to the information that they have disclosed on the DOI form. Summaries of relevant disclosed interests that may be perceived to give rise to real or apparent conflicts of interest will be noted in TEG reports.

In addition, prior to confirmation by WHO of their appointment as TEG members, TEG nominees shall be required to sign a WHO confidentiality agreement (See Annex 2). Although all papers presented at the TEG may be made publicly available on the GMP website, pre-publication manuscripts or confidential documents will be clearly labeled as such and will only be provided to TEG members for discussion.
IV. Responsibilities of TEG members
Members of TEG have a responsibility to provide MPAC with high quality, well considered, evidence-informed advice and recommendations on matters described in these ToR. The TEG has no executive or regulatory function. Its role is to work with the GMP secretariat to provide draft recommendations to MPAC.

TEG members may be approached by non-WHO sources for their views, comments and statements on particular matters within antimalarial drug resistance and containment, and asked to state the views of TEG or details related to TEG discussions. TEG members should refer all such enquiries to WHO/GMP.

V. Structure
GMP will submit a nomination for the first chairperson of the TEG to MPAC for endorsement. The chairperson will serve for 3 years, renewable once. Future chairpersons will be selected from among the appointed TEG members. A rapporteur will be elected at each meeting. Drug Resistance and Containment unit, GMP will serve as secretariat for the TEG.

VI. Working Procedures
With the coordinator of the Drug Resistance and Containment unit, the chairperson of the TEG will develop a plan for routine operations of the TEG. The TEG will meet at least once per year and have additional meetings and/or teleconferences as needed. When practicable, the TEG meetings will be scheduled in association with meetings of the TEG on chemotherapy and will share a session with the TEG on chemotherapy. TEG meetings should be anticipated at least three months in advance of the meeting. WHO will provide support for travel and accommodation for the purpose of TEG meetings.

Decisions on TEG recommendations will, as a rule, be taken by consensus. In the exceptional situation that consensus cannot be reached the chairperson shall report the majority and minority views. It is also the chairperson's responsibility to ensure there is clarity for TEG members on what exactly is being decided.

A representative from the Medicines for Malaria Venture (MMV) and a representative from the WorldWide Antimalarial Network (WWARN) will be invited to participate as standing observers in the TEG meetings. WHO/GMP may also invite other observers to the TEG meetings, including representatives from non-governmental organization, international professional organizations, technical agencies, and donor organizations. Additional experts, and Technical Resource persons, may also be invited to meetings by the secretariat with approval of the chairperson, as appropriate, to further contribute to specific agenda items. However, only TEG members can participate in voting or decision by consensus. Observers shall not take the floor unless requested to do so by the chairperson and shall under no circumstances participate in the formulation of TEG recommendations.

Relevant staff from WHO Headquarters and Regional Offices will attend as members of the Secretariat.
VII. Dissolution of TEG
The relevance of the TEG will be assessed annually by the MPAC. The terms of
reference will also be reviewed once a year by the TEG. Any proposed changes in the
ToR must be submitted to and approved by the MPAC.
ANNEX 1

DECLARATION OF INTERESTS FOR WHO EXPERTS

WHO's work on global health issues requires the assistance of external experts who may have interests related to their expertise. To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts serving in an advisory role must disclose any circumstances that could represent a potential conflict of interest (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgement (e.g. employer, close professional associates, administrative unit or department).

Please complete this form and submit it to WHO Secretariat if possible at least 4 weeks but no later than 2 weeks before the meeting or work. You must also promptly inform the Secretariat if there is any change in this information prior to, or during the course of, the meeting or work. All experts must complete this form before participation in a WHO activity can be confirmed.

Answering "Yes" to a question on this form does not automatically disqualify you or limit your participation in a WHO activity. Your answers will be reviewed by the Secretariat to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g. nature and magnitude of the interest, timeframe and duration of the interest).

The Secretariat may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied. The Secretariat (i) allows full participation, with public disclosure of your interest; (ii) mandates partial exclusion (i.e., you will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision making process); or (iii) mandates total exclusion (i.e., you will not be able to participate in any part of the meeting or work).

All potentially significant interests will be disclosed to the other participants at the start of the activity and you will be asked if there have been any changes. A summary of all declarations and actions taken to manage any declared interests will be published in resulting reports and work products. Furthermore, if the objectivity of the work or meeting in which you are involved is subsequently questioned, the contents of your DOI form may be made available by the Secretariat to persons outside WHO if the Director-General considers such disclosure to be in the best interest of the Organization, after consulting with you. Completing this DOI form means that you agree to these conditions.

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the Secretariat may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Name:
Institution:
Email:

Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.
**EMPLOYMENT AND CONSULTING**
Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?

1a Employment
Yes  ✗  No  ✗

1b Consulting, including service as a technical or other advisor
Yes  ✗  No  ✗

**RESEARCH SUPPORT**
Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?

2a Research support, including grants, collaborations, sponsorships, and other funding
Yes  ✗  No  ✗

2b Non-monetary support valued at more than US $1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)
Yes  ✗  No  ✗

Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?

**INVESTMENT INTERESTS**
Do you have current investments (valued at more than US $10,000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

3a Stocks, bonds, stock options, other securities (e.g., short sales)
Yes  ✗  No  ✗

3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company)
Yes  ✗  No  ✗

**INTELLECTUAL PROPERTY**
Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

4a Patents, trademarks, or copyrights (including pending applications)
Yes  ✗  No  ✗

4b Proprietary know-how in a substance, technology or process
Yes  ✗  No  ✗

**PUBLIC STATEMENTS AND POSITIONS** (during the past 3 years)

5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?
Yes  ✗  No  ✗

5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work?
Yes  ✗  No  ✗

**ADDITIONAL INFORMATION**

6a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage?
Yes  ✗  No  ✗

6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?
Yes  ✗  No  ✗

6c Excluding WHO, has any person or entity paid or contributed towards your travel costs in connection with this WHO meeting or work?
Yes  ✗  No  ✗
6d. Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this WHO meeting or work?  

6e. Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?  

7. **TOBACCO OR TOBACCO PRODUCTS** *(answer without regard to relevance to the subject of the meeting or work)*  
Within the past 4 years, have you had employment or received research support or other funding from, or had any other professional relationship with, an entity directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity?  

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.

<table>
<thead>
<tr>
<th>Nos. 1 - 4: Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.</th>
<th>Name of company, organization, or institution</th>
<th>Belongs to you, a family member, employer, research unit or other?</th>
<th>Amount of income or value of interest (if not disclosed, is assumed to be significant)</th>
<th>Current interest (or year ceased)</th>
</tr>
</thead>
</table>

Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details.
CONSENT TO DISCLOSURE. By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of WHO and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date: _______________
Signature________________________________
ANNEX 2

CONFIDENTIALITY UNDERTAKING

1. The World Health Organization (WHO), acting through its Department of ……………., has access to certain information relating to ……………., which information WHO considers to be proprietary to itself or to other parties collaborating with it (hereinafter referred to as "the Information").

2. The Undersigned, as a member of the …………….Committee ("the Committee"), may have access to the Information in the course of his/her participation in the Committee (whether at or in relation to Committee meetings, internet-based collaborative workspaces, telephone conferences or otherwise).

3. WHO is willing to provide the Undersigned the Information, or arrange for the provision of the Information to the Undersigned, for the purpose of performing his/her responsibilities in connection with the activities of the Committee ("the Purpose"), provided that the Undersigned undertakes to treat the Information as confidential and proprietary, and to disclose it only to persons who have a need to know for the purpose and are bound by like obligations of confidentiality and non-use as are contained in this Undertaking.

4. The Undersigned undertakes to regard the Information as confidential and proprietary to WHO or parties collaborating with WHO and agrees to take all reasonable measures to ensure that the Information is not used, disclosed or copied, in whole or in part, other than as provided in this Undertaking, except that the Undersigned shall not be bound by any such obligations if and to the extent he/she is clearly able to demonstrate that the Information:
   a) was known to him/her prior to any disclosure by or for WHO to the Undersigned; or
   b) was in the public domain at the time of disclosure by or for WHO to the Undersigned; or
   c) becomes part of the public domain through no fault of the Undersigned; or
   d) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality.

5. The Undersigned also undertakes not to communicate the deliberations and decisions of the Committee to persons outside this Committee except as agreed by WHO.

6. If requested to do so, the Undersigned agrees to return to WHO any and all copies of the Information.

7. The Undersigned furthermore agrees that any and all rights in the work performed by him/her in connection with or as a result of his/her membership of the Committee shall be exclusively vested in WHO. The Undersigned hereby irrevocably and unconditionally assigns all such rights to WHO and waives any moral rights attached such work. The Undersigned understands and agrees that WHO reserves the right (a) to revise such work, (b) to use it in a different way from that originally envisaged, or (c) not use or publish it at all.
8. The obligations of the Undersigned shall survive the termination of his/her Membership of the Committee.

9. Any dispute relating to the interpretation or application of this Undertaking shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

Name: 

Signature: 

Date: