

## Terms of Reference for the Strategic Advisory Group of Experts (SAGE) on Immunization Working groups on Dengue vaccination

The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 1999 to provide policy and strategy advice on vaccines and immunization to the Director-General of the World Health Organization (WHO). SAGE is the principal advisory group to WHO for vaccines and immunization. All vaccine-and immunization-related topics of public health relevance for which WHO requires strategic and policy advice need to be reviewed by SAGE.

This SAGE Working Group on Dengue vaccination (from now on referred as SAGE WG) is established by the Secretariat as a resource intended to support WHO in the preparation of SAGE deliberations by reviewing and providing evidence-based information and options for policy or strategy recommendations to be decided by SAGE. This SAGE WG is tasked to work on specific issues and address critical questions on behalf of SAGE, to prepare the background material for SAGE.

### I. Functions

The SAGE WG will be expected to formulate critical questions, as outlined below, for which an in-depth review of evidence is needed to address its workplan. With the support of Secretariat, this Working Group will perform or coordinate, a systematic assessment of the evidence in accordance with the SAGE process for evidence–review and development of recommendations.

In its capacity as an advisory body to WHO, the SAGE WG shall have the following functions:

1. *To prepare an independent evaluation of the scientific and technical evidence via a systematic process<sup>1</sup>, where applicable. The areas to be covered include*
  - a. *the global prevalence and burden of disease caused by dengue virus infection, including outbreaks*
  - b. *safety, efficacy, duration of protection, schedules, and co-administration of TAK-003 dengue vaccine;*
  - c. *data and label changes for CYD-TDV since 2018*
  - d. *data on cost-effectiveness and cost-utility of dengue vaccination*
  - e. *programmatic and feasibility of dengue vaccine introduction into routine immunization schedule*
  - f. *acceptability and equity impacts of dengue vaccination*
2. *To provide options for policy and strategy development and describe the broader implications of those options;*
3. *To present the results of the evidence review as requested by WHO; and*

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<sup>1</sup> In adherence to the SAGE [Guidance for the development of evidence-based vaccine-related recommendations](#)

4. *To highlight knowledge gaps and research questions from the review of evidence, including an assessment of vaccine products in the pipeline and needs for future products.*

## **II. Composition**

1. The SAGE WG shall have up to 15 members, who shall serve in their personal capacities to represent the following disciplines: “epidemiology/public health, immunology, vaccinology, clinical trials, infectious diseases, virology, arboviral diseases, health economics, social sciences”. In the selection of SAGE WG members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.
2. Members of the SAGE WG shall be selected and appointed by WHO following an open call for experts. Suitable individuals who expressed interest to past open calls for other advisory groups (such as SAGE) may also be considered.
3. The Chairperson’s functions include the following:
  - to chair the meeting of the SAGE WG;
  - to liaise with the WHO Secretariat between meetings.

In appointing the Chairperson, consideration shall be given to gender and geographical representation.

4. Members of SAGE WG shall be appointed to serve for a period of up to 3 years and shall be eligible for reappointment. Their appointment and/or designation as Chairperson is terminated when the SAGE WG is closed after completion of its mandate (see section *I. Functions*) and may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a member’s appointment is terminated, WHO may decide to appoint a replacement member.
5. SAGE WG members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall 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. Following a determination that a proposed member’s participation in the SAGE WG would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the SAGE WG. Their appointment to SAGE is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, SAGE WG members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.

7. As contemplated in paragraph II.4 above, WHO may, from time to time, request SAGE WG members to complete a new declaration of interest form. This may be before a SAGE WG meeting or any other SAGE WG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the SAGE WG member's participation in the SAGE WG activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.
8. Where a SAGE WG member is invited by WHO to travel to an in-person SAGE WG meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter'). WHO shall not authorize travel by a SAGE WG member, until it receives a countersigned Temporary Adviser Letter.
9. SAGE WG members do not receive any remuneration from the Organization for any work related to the SAGE WG. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

### **III.     Operation**

1. The SAGE WG accomplishes most of its work virtually via video or teleconferences. One or more SAGE WG meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO).

SAGE WG meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

- (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 Observers (as defined in paragraph III.3 below).
- (b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the AG and essential WHO Secretariat staff.

2. The quorum for SAGE WG meetings shall be two thirds of the members.
3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as "observers"<sup>2</sup>. Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-State actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the advisory group. Invitations to observers attending as representatives from non-State actors will be subject to WHO internal due

diligence and risk assessment including conflict of interest considerations in accordance with the Framework for engagement with non-State actors (FENSA). Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the AG at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of deliberation and drafting of recommendations of the SAGE WG.

4. The SAGE WG may decide to establish smaller working groups (sub-groups of SAGE WG) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the SAGE WG for review at one of its meetings.
5. SAGE WG members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the SAGE WG.
6. All conclusions and recommendations from the SAGE WG are submitted to WHO for consideration and are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered and recommended by the SAGE WG. WHO uses the analysis and recommendations to inform policy development by SAGE.
7. SAGE WG shall normally make 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.
8. Active participation is expected from all SAGE WG members, including in subgroups, teleconferences, and interaction over email. SAGE WG members may, in advance of SAGE WG meetings, be requested to review meeting documentation and to provide their views for consideration by the SAGE WG.
9. WHO shall determine the modes of communication by SAGE WG, including between WHO and SAGE WG members, and the SAGE WG members among themselves.
10. SAGE WG members shall not speak on behalf of, or represent, the SAGE WG or WHO to any third party.

#### **IV. Secretariat**

WHO shall provide the secretariat for SAGE WG, including necessary scientific, technical, administrative 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 Observers will be determined by the WHO Secretariat.

**V. Information and documentation**

1. Information and documentation to which members may gain access in performing SAGE WG related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, SAGE WG members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their SAGE WG-related activities shall be exclusively vested in WHO.
2. SAGE WG members and Observers shall not quote from, circulate or use SAGE documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.
3. WHO retains full control over the publication of the reports of SAGE WG, including deciding whether or not to publish them.