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## SUPPLEMENT TO WHO VACCINE POSITION PAPERS

### **GUIDELINE DEVELOPMENT GROUP:**

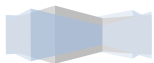
Vaccine position paper development at the World Health Organization is a complex, rigorous, multifaceted process involving many stakeholders and occurring over roughly a two-year timeline. The Guideline Development Group consists of the Strategic Advisory Group of Experts on Immunization (SAGE) supported by a SAGE Working Group.

SAGE is an independent body and represents the principal advisory group to WHO on all aspects pertaining to vaccines and immunization. The complete terms of reference (ToR) of SAGE are publically available. SAGE members come from a broad range of disciplines and professional affiliations, and have diverse geographies (their short biographies are publically available). SAGE members serve in a personal, individual, and voluntary capacity, and as such are not representative of any government, agency, company or other entity. As an advisory group, SAGE has no executive or regulatory function. SAGE members receive no funding for serving on SAGE, though travel expenses and cost of board and lodging are covered when attending SAGE and Working Group meetings.

SAGE Working Groups are time-limited entities that help address specific questions for SAGE by reviewing and providing evidence-based draft recommendations, which are ultimately decided upon by SAGE. Working Groups normally consist of two SAGE members (one of whom functions as Chair) and 8-12 additional subject matter experts for covering the range of necessary expertise. Consideration is also given to the geographic representation and the gender balance.

Both SAGE and its Working Groups have robust and transparent processes for maintaining independence and managing conflicts of interest: the composition of each body, the process for member selection, the ToRs, and the procedures for managing conflicts of interest are publically available (please find ToRs listed at the specific Working Group link).

Declaration of potential conflicts of interest is required from SAGE members ahead of each meeting. SAGE member's relevant interests will be made publically available four weeks in advance of the meeting for public comments. To identify SAGE members involved in the formulation of a particular position paper, as well as their professions, affiliations, areas of expertise and declaration of interests (DOIs), please link to the SAGE meetings where the position paper was discussed (SAGE meetings where the topic was addressed are identified in the position paper itself).



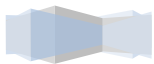
DOIs for members of SAGE Working Groups are assessed before their appointment and are publically available. To identify Working Group members involved in the formulation of a particular position paper, as well as their professions, affiliations, areas of expertise and DOIs, refer to the relevant Working Group.

## **GUIDELINE DEVELOPMENT/UPDATE PROCESS:**

The process for Position Paper development requires the formulation of a relevant and answerable question. This is performed by SAGE, and subsequently SAGE approves the ToRs for the Working Group.

The questions are further refined by the Working Group. Evidence is gathered, using an inclusive principle, by the Working Group and the WHO Secretariat. The Working Group examines and synthesizes the evidence and presents the following deliverables at a SAGE meeting: background to the issue, grading tables that assess the quality of the scientific evidence, an evidence-to-recommendation table and proposed recommendations (please see link for the “Guidance For The Development Of Evidence-Based Vaccine-Related Recommendations”). Based on this, SAGE accepts or modifies the proposed recommendations, or states the need for revisiting steps in the process. In the latter case, the issue is revisited at a later SAGE meeting. SAGE decisions are reached by consensus as opposed to using a voting mechanism, thus promoting in-depth discussion of the evidence and careful weighing of benefits and harms. SAGE is the arbiter with respect to the recommendations included in the position paper and is independent of WHO. However, final ownership of, and responsibility for, the published paper and its recommendations ultimately rests with WHO.

After the background, the evidence-to-recommendation table, and proposed recommendations have been endorsed by SAGE, SAGE secretariate for shapes and assimilates them into the format required for the Weekly Epidemiological Record (WER). This initial draft is reviewed by the WHO Editorial Board (EdB) which consists of seven members: the Executive Secretary for SAGE, two WHO staff with expertise in regulatory standards and safety standards, two with significant vaccine research experience, and two others with vaccination program expertise. All WHO staff, participating in the EdB including diseases focal points which may join the EdB meeting for the discussion on a specific vaccine position paper, underlie the conflict of interest management and assessment of WHO Office of Compliance, Risk Management and Ethics.



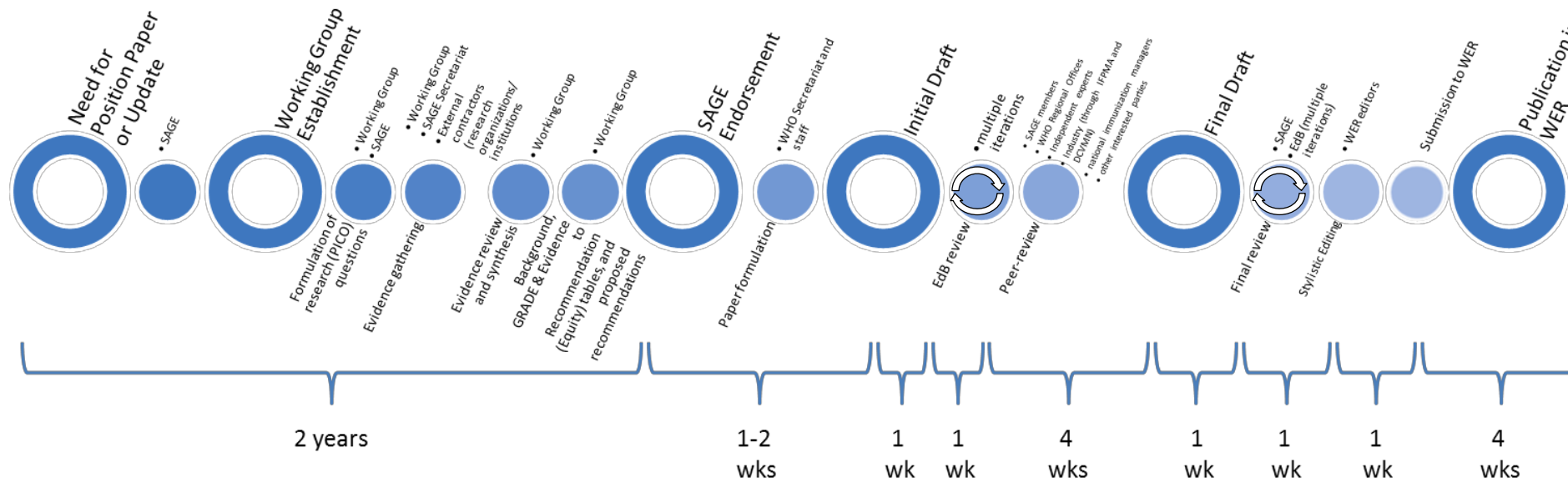


Figure 1: Position Paper Process

After the initial draft has been refined it is subject to broad peer-review. Reviewers include members from the related SAGE Working Group, SAGE members, WHO Regional Offices, external subject matter experts, selected national immunization managers, other interested parties, who have not been involved in the evidence review and SAGE related process and industry: request for peer-review from industry is channeled through the International Federation of Pharmaceutical Manufacturers Association (IFPMA) and the Developing Country Vaccine Manufacturer Network (DCVMN). The list of peer reviewers is available on demand from the Executive Secretary for SAGE. This feedback is compiled by the Executive Secretary for SAGE, under the explicit direction of the EdB, to produce a final draft of the paper. The final draft is circulated exclusively among SAGE members and the EdB for approval, ensuring that the essence of the initial recommendations remains and is clearly communicated.

Once the final draft has been approved, the revisions are reviewed by the EdB. The final vaccine position paper is published in the WER in both English and French and subsequently translated into the additional four official WHO languages (Chinese, Russian, Arabic, and Spanish) after initial publication. The whole process from SAGE endorsement until publication in the WER takes 15 weeks.



## GUIDELINE UPDATING PROCESS:

The need to update a vaccine position paper is reviewed by the Executive Secretary for SAGE at a minimum frequency of once every two years and potentially sooner, depending on the availability of new scientific evidence and public health priorities. A review may also be initiated by SAGE, key partners or WHO Regional Offices. A brief update concerning a specific recommendation in a paper is released when warranted.

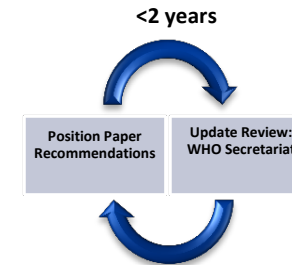
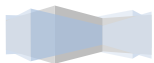


Figure 2: Guideline Update Process

## FUNDING FOR GUIDELINE DEVELOPMENT:

A dynamic funding mechanism is set in place for the process of developing WHO vaccine position papers : it is difficult to isolate the financial contributions of any particular source for an individual document or to make blanket statements concerning funding for guidelines in general. However, the structures and principles guiding resource acquisition and allocation to guideline processes are designed to safeguard the independence of parties involved in guideline construction, as well as to ensure that funders do not influence content or recommendations. Private industry is not permitted to fund any activities related to the development of WHO Position Papers.

Funding for WHO, SAGE, and Working Group activities related to guideline development can be categorized into distinct groups based on the provisos and scope of the financing provided (funding type) or based on the identity of the funders themselves (funder category):



Funding type	Source	Description
Core	Member States	Assessed contributions for essential operations
Voluntary (flexible)	Member States	Allocation decisions rest entirely with WHO, external reporting not required
Voluntary (earmarked)	Governmental and UN agencies, NGOs, charity organizations	Designated for specific functional areas or disease categories, external reporting required

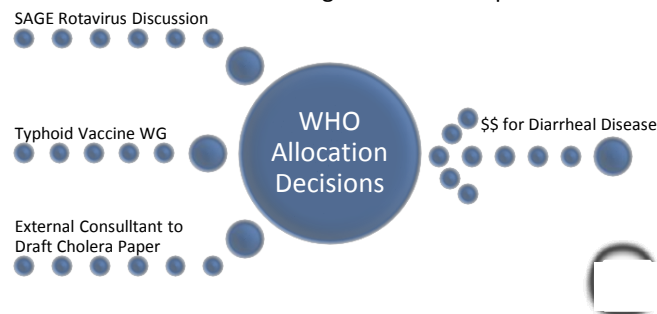
**Table 1: categorizing WHO Position Paper funding based on funding type**

Funder Category*	Examples
Member States	Canada, France, Angola
Governmental Agencies	Centers for Disease Control (CDC), German Federal Ministry of Economic Cooperation and Development
United Nations Agencies	United Nations Fund for International Partnerships (UNFIP)
Charities/NGOs	The Bill and Melinda Gates Foundation, The Global Alliance for Vaccines and Immunization (Gavi)

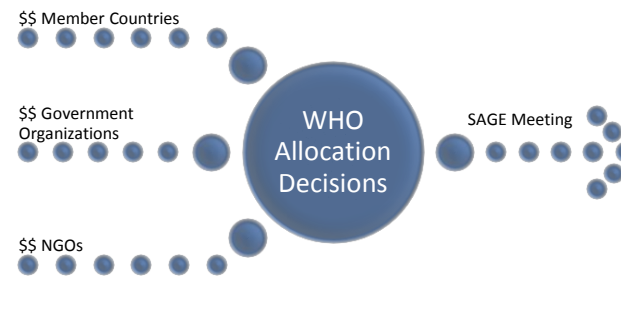
\*Private industry does not fund any activities related to the development of WHO Position Papers.

**Table 2: categorizing WHO Position Paper funding based on funding source**

While earmarked funding is assigned to particular functional areas or disease categories, WHO retains significant freedom of allocation within these assignments. Funding is not tied to specific activities *per se* as much as it is labeled for expenditure within a particular subset of activities. Furthermore, any individual activity (for example, a SAGE meeting) may be funded by a variety of sources. Thus, the interests of funders remain divorced from activities related to guideline development.



**Figure 3: WHO control of earmarked funding**



**Figure 4: Multiple funding sources for individual activities**

For further questions on the development of WHO vaccine position papers, please consult our websites or contact [sageexecsec@who.int](mailto:sageexecsec@who.int).

