

Terms of Reference for the Technical Advisory Group on Snake Antivenom Immunoglobulin Listing (TAG-SAIL)

The Regulation and Prequalification Department, World Health Organization (WHO) has issued a call for applications to licensed manufacturers of snake antivenom immunoglobulin products who wish to have those products evaluated for potential procurement recommendation listing by WHO.

In 2018 the World Health Assembly adopted resolution 71.5 (2018: *Addressing the burden of snakebite envenoming*) which calls on WHO to ensure the quality and safety of snake antivenoms. WHO has developed a risk-benefit assessment procedure for antivenoms that supports decision-making by procurement agencies, public health officials and users of antivenoms based on an evaluation of an essential set of available quality, safety, efficacy, and performance data. Furthermore, it provides manufacturers with independent product analysis, evaluation of Good Manufacturing Practices (GMP) and potential product recommendations. The risk-benefit assessment process is aimed at improving the availability of safe, effective antivenom immunoglobulin products to all who need them.

As part of this procedure, the WHO Secretariat will require advice from an independent advisory group known as the Technical Advisory Group on Snake Antivenom Immunoglobulin Listing (TAG-SAIL) on whether these risk-benefit assessed antivenoms can be recommended for use.

The TAG-SAIL will include members with expertise in the fields of:

- Regulation of biological products such as vaccines or antivenoms
- Veterinary medicine related to animal use in the production of biological products
- Manufacturing or quality control technologies related to biological products
- Good Manufacturing Practice (GMP) for biological products
- Clinical management of snakebite envenoming
- Viral inactivation of equine or other viruses in biological products

The Technical Advisory Group on Snake Antivenom Immunoglobulin Listing (the “TAG-SAIL”) will act as an advisory body to WHO in this field.

I. Functions

In its capacity as an advisory body to WHO, the TAG-SAIL shall have the following functions:

1. To undertake a desktop review and risk-benefit assessment of the product dossiers submitted to the WHO Secretariat by respective manufacturers and prepare product dossier reports for WHO indicating specific deficiencies, data gaps and other areas of concern.
2. To subsequently consider the results of independent laboratory analysis of antivenom products, and the outcomes of Good Manufacturing Practice (GMP) inspections and based on these findings, and those of the dossier reviews, make final recommendations to WHO on whether the assessed antivenoms should be listed as recommended product under the SAIL procedure, and under what conditions.
3. To advise WHO on formulating conditions for the listing should the decision be positive. Conditions will include detailed post-listing commitments from the manufacturer.

II. Composition

1. The TAG-SAIL shall have up to 15 members¹, who shall serve in their personal capacities to represent the broad range of disciplines relevant to risk-benefit assessment of snake antivenom immunoglobulins. In the selection of the TAG-SAIL members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation, and gender balance.
2. Members of the TAG-SAIL, including the Chairperson, shall be selected, and appointed by WHO following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the TAG-SAIL;
 - to liaise with the WHO Secretariat between meetings.

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

3. Members of the TAG-SAIL shall be appointed to serve for a period of two years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the TAG-SAIL but is only permitted to serve as Chairperson for one term. Their appointment and/or designation as Chairperson 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.
4. TAG-SAIL 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.
5. Following a determination that a proposed member's participation in the TAG-SAIL 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 TAG-SAIL. Their appointment to the TAG-SAIL is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, TAG-SAIL 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.
6. As contemplated in paragraph II.4 above, WHO may, from time to time, request TAG-SAIL members to complete a new declaration of interest form. This may be before a TAG-SAIL meeting or any other TAG-SAIL-related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG-SAIL member's participation in the TAG-SAIL activity or engagement is subject to a determination that their participation would not give rise to a real, potential, or apparent conflict of interest.
7. Where a TAG-SAIL member is invited by WHO to travel to an in-person TAG-SAIL 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

¹ Members serve as full participants and partake in the decision-making process of the meeting in which they are involved.

shall not authorize travel by a TAG-SAIL member, until it receives a countersigned Temporary Adviser Letter.

8. TAG-SAIL members do not receive any remuneration from the Organization for any work related to the TAG-SAIL. 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 TAG-SAIL shall normally meet at least twice each year. However, WHO may convene additional meetings. TAG-SAIL meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

TAG-SAIL meetings may be held in open and/or closed sessions, 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 TAG-SAIL and essential WHO Secretariat staff.
2. The quorum for TAG-SAIL 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”. 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 internal due diligence and conflict of interest considerations in accordance with FENSA. Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the TAG-SAIL 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 adopting decisions and recommendations of the TAG-SAIL.

4. The TAG-SAIL may decide to establish smaller working groups (sub-groups of the TAG-SAIL) to work on specific issues. Their deliberations shall take place via teleconference or videoconference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the TAG-SAIL for review at one of its meetings.
5. TAG-SAIL members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the TAG-SAIL.
6. A yearly report shall be submitted by the TAG-SAIL to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from the TAG-SAIL 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 TAG-SAIL.

7. The TAG-SAIL 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 TAG-SAIL members, including in working groups, teleconferences, and interaction over email. TAG-SAIL members may, in advance of TAG-SAIL meetings, be requested to review meeting documentation and to provide their views for consideration by the TAG-SAIL.
9. WHO shall determine the modes of communication by the TAG-SAIL, including between WHO and the TAG-SAIL members, and the TAG-SAIL members among themselves.
10. TAG-SAIL members shall not speak on behalf of, or represent, the TAG-SAIL or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the TAG-SAIL, 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. (The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend).

V. Information and documentation

1. Information and documentation to which members may gain access in performing TAG-SAIL 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, TAG-SAIL 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 TAG-SAIL-related activities shall be exclusively vested in WHO.
2. TAG-SAIL members and Observers shall not quote from, circulate, or use TAG-SAIL 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 the TAG-SAIL, including deciding whether or not to publish them.