Terms of Reference for the Advisory Committee on Safety of Medicinal Products (ACSoMP)

The Advisory Committee on Safety of Medicinal Products (ACSoMP) shall provide advice to the World Health Organization Director-General on pharmacovigilance policy and issues related to the safety and effectiveness of medicinal products.

The ACSoMP will act as an advisory body to WHO in this field.

I. Functions

In its capacity as an advisory body to WHO, ACSoMP shall provide advice to WHO secretariat on issues related to:

1. Pharmacovigilance systems by:
   a. responding to the needs of WHO programmes for introducing and/or integrating safety monitoring of medicines within an appropriate timeframe;
   b. providing guidance on advancing vigilance systems in countries and regions using appropriate tools (e.g., protocols, data collection apps), mechanisms (e.g., reliance and work-sharing) and platforms;
   c. guiding the development of metrics and methodologies for assessing the performance of pharmacovigilance systems;
   d. providing recommendations to assist WHO in formulating policies regarding vigilance functions, with a focus on LMICs and countries with PV systems of low maturity and sharing the recommendations with WHO through the appropriate channels. WHO may decide to share these recommendations further as needed.

2. Pharmacovigilance methods by:
   a. providing guidance on innovations, novel methods and approaches to collect and interpret safety data, to complement routine pharmacovigilance activities;
   b. furthering the principles and scope of pharmacoepidemiology and its application in the risk assessment of medicines;
   c. advising WHO on promoting risk minimization and risk communication strategies, guiding their implementation and measuring their impact in countries.

3. Safety of medicines by:
   a. rigorously and transparently reviewing the latest knowledge, in all fields ranging from basic sciences to epidemiology, concerning any aspect of medicines, in particular medicines that are WHO prequalified or medicines recommended by WHO public health programmes and WHO disease treatment guidelines;
   b. advising WHO on responding to current and potential safety issues important to national and international programmes (e.g., HIV, malaria, TB) to improve programme implementation/roll out and/or prevent any potential adverse effects if safety issue is not resolved;
c. advising WHO on the monitoring, evaluation, risk minimization, risk communication strategy on the safety of priority medicines, soliciting background information on adverse events of special interest, guiding safety monitoring in special populations such as pregnant women and children. This function can be operated using ad hoc smaller working groups as described in section III.4;

d. advising WHO on training and capacity building in pharmacovigilance in countries where priority medicines are introduced.

II. Composition

1. The ACSOMP shall have up to 20 members¹, who shall serve in their personal capacities to represent the broad range of disciplines relevant to ACSOMP. In the selection of the ACSOMP members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

2. Members of the ACSOMP, 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 ACSOMP;
   - 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 ACSOMP shall be appointed to serve for a period of 3 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the ACSOMP, 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. ACSOMP 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. In addition, nominees, after acceptance of the invitation for membership, are required to sign confidentiality agreements prior to confirmation by WHO of their appointment as ACSOMP members. All papers and information provided to members, which may include pre-publication copies of research reports, or documents of commercial significance, shall be treated as confidential. ACSOMP deliberations are

¹ Members serve as full participants and partake in the deliberations and the adoption of the recommendations of the meeting in which they are involved.
confidential and may not be publicly disclosed by members. A register of members' interests and signed confidentiality agreements shall be maintained by WHO. Membership of the ACSOMP may be terminated when a breach of confidentiality is found.

5. Following a determination that a proposed member’s participation in the ACSOMP 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 ACSOMP. Their appointment to the ACSOMP is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, ACSOMP members have an ongoing obligation to inform the WHO of any interests real or perceived that may give raise to a real, potential or apparent conflict of interest.

6. As contemplated in paragraph II.4 above, WHO may, from time to time, request ACSOMP members to complete a new declaration of interest form. This may be before a ACSOMP meeting or any other ACSOMP-related activity or engagement, as decided by WHO. Where WHO has made such a request, the ACSOMP member’s participation in the ACSOMP 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 ACSOMP member is invited by WHO to travel to an in-person ACSOMP 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 an ACSOMP member, until it receives a countersigned Temporary Adviser Letter.

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

ACSOMP 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 ACSOMP and essential WHO Secretariat staff.
2. The quorum for ACSOMP 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 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 ACSOMP 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 recommendations of the ACSOMP.

4. The ACSOMP may decide to establish smaller working groups (sub-groups of the ACSOMP) 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 ACSOMP for review at one of its meetings.

5. ACSOMP members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the ACSOMP.

6. Reports of each meeting shall be submitted by the ACSOMP to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from the ACSOMP are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the ACSOMP.

7. The ACSOMP 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 ACSOMP members, including in working groups, teleconferences, and interaction over email. ACSOMP members may, in advance of ACSOMP meetings, be requested to review meeting materials and to provide their views for consideration by the ACSOMP.

9. WHO shall determine the modes of communication by the ACSOMP, including between WHO and the ACSOMP members, and the ACSOMP members among themselves.

10. ACSOMP members shall not speak on behalf of, or represent, the ACSOMP or WHO to any third party.
IV. Secretariat

WHO shall provide the secretariat for the ACSOMP, 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 ACSOMP 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, ACSOMP 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 ACSOMP-related activities shall be exclusively vested in WHO.

2. ACSOMP members and Observers shall not quote from, circulate or use ACSOMP 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 ACSOMP, including deciding whether or not to publish them.

4. Members play a critical role in ensuring the reputation of ACSoMP as an internationally-recognized advisory group in the field of medicines safety. It is recognized that ACSoMP members may be approached by non-WHO sources for their views, comments and statements on particular matters of public health concern and asked to state the views of ACSoMP. ACSoMP members shall refer such enquiries to WHO.

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