



Supplement C: Members of Advisory or Expert Committees or Panels

Please be advised that this supplement has not been developed as a standalone document and is a subsection of the [Supplemental Conflict of Interest Guidance Document](#).

Members of advisory or expert committees or panels are those who have been appointed in accordance with specific Terms of Reference.

General

1. Current committee or panel members are not permitted to participate in the Scientific Advice program.
2. A current member who has participated in providing Scientific Advice for a drug prior to appointment on the committee or panel, will not participate in discussions, deliberations, and recommendations for the same drug product and indication if it is later submitted to CDA-AMC.
3. In both chair and vice-chair, or co-chair models, the chair or co-chair(s) of the committee or panel meeting should have no conflict of interest in connection with any matter relevant to the committee's or panel's mandate.
4. It is the responsibility of every member who is aware of a conflict of interest on the part of another member to raise the issue for clarification, first with the member in question and, if still unresolved, with the committee or panel chair. A member may also report their concern to CDA-AMC as outlined in Section 16 of the CDA-AMC Supplemental Conflict of Interest Guidance Document.

Disclosure

5. During the nomination process, committee or panel candidates must complete and submit a declaration form, as directed by CDA-AMC.
6. If the candidate is not certain whether they are in a conflict-of-interest position, they should seek guidance from CDA-AMC.
7. Upon appointment, all committee and members are required to update their declaration form annually, at minimum; however, each member must disclose any conflict of interest as soon as the issue arises and before the committee or panel deals with the matter at issue.
8. If a member is not certain whether they are in a conflict-of-interest position, they should seek guidance from the committee or panel chair, or the CDA-AMC director or executive member that works most closely with the committee or panel.



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9. Declarations will be confidential to the following CDA-AMC designates (unless otherwise determined by CDA-AMC):
 - Committee or Panel Candidates:
 - Governance team
 - Interview Panel of Selection Committee
 - Relevant CDA-AMC Executive member, if required
 - Members of Committees or Panels
 - Governance team
 - Committee or panel chair
 - CDA-AMC director or executive member that works most closely with the committee or panel
 - President and CEO, if required.
10. Declaration forms, management plans and any other related documents for appointed members will be retained by CDA-AMC. If a candidate is not appointed to a committee or panel, the declaration and any related documents will be destroyed.
11. All members will be reminded to disclose any new or existing conflict of interest at the commencement of every meeting of the committee or panel. The disclosure and decision as to whether a conflict exists shall be duly recorded in the minutes of the meeting and the member will be required to update their declaration form.

Assessment of Disclosures

12. All declarations are reviewed by the Governance team.
13. During the nomination process, the assessment and decision regarding the existence of a conflict will be made by the Interview Panel of the Selection Committee.
14. The assessment and decision regarding existence of an appointed member's conflict will be made by the chair and the CDA-AMC director or executive member that works most closely with the committee or panel. Such determination will be final.
15. In determining whether a member has a conflict of interest, the chair and the CDA-AMC director or executive member that works most closely with the committee or panel shall be guided by the policy, Supplementary Guidance and Conflict of Interest (COI) Flow Chart for Advisory Committee, Expert Committee or Panel Members set out in Figure 1, below. The definitions for the terms used in the COI Flow Chart follow:

Discussion: With a proper disclosure of interest, a member with a COI can participate in discussions with other members of the committee or panel. A discussion will occur when the



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purpose of the meeting is to consider a matter in an open and informal setting, and where ideas are shared liberally (e.g., brainstorming, identifying options, etc.), but where there is no deliberation or decision.

Deliberation: A deliberation will occur when the purpose of the meeting is to consider the reasons for and against certain options (e.g., evaluating the options and potential recommendations). Refer to the COI Flow Chart to determine when a member may participate in deliberations.

Decision: A decision will occur when the purpose of the meeting is to arrive at a determination usually by way of a consensus or a vote (e.g., voting on which option will be recommended). Refer to the COI Flow Chart to determine when a member may participate in decision-making or voting.

Direct Impact: When considering if a particular matter or issue could have a direct impact on the member's interests, one must consider what benefit may result and if it is a benefit contemplated by Sections 7 and 8 of the CDA-AMC Policy. If it is a benefit, then one must answer yes and move on to the next question in the COI Flow Chart. If the interest is not relevant, then it is not a benefit, thus not a direct impact on the member's interests.

Essential: A member will become essential to the committee or panel when expertise is limited and, as a result, the member is required in order for CDA-AMC to fulfill its mandate.

Management of Disclosures

16. Together, the chair and the CDA-AMC director or executive member that works most closely with the committee or panel have the authority to exclude a member from the meeting when it is deemed that the conflict(s) impedes the individual's objectivity (real or perceived).
17. Except as otherwise provided in the policy, a member who has a COI must abstain from participation in any discussion on the matter, shall not attempt to personally influence the outcome, and shall refrain from voting on the matter. Unless otherwise decided by the chair and CDA-AMC director or executive member, the member must leave the meeting for the duration of any such discussion or vote. The time the member leaves and returns to the meeting will be recorded in the minutes.
18. In circumstances where the expertise pool is limited, and a member's participation is essential to the work of the committee or panel and reasonable efforts have been made without success to find a suitable replacement with no conflicts, the chair may grant a waiver in order to allow the member to participate and/or to limit the member's participation in the meeting, whether this participation be the member's right to vote or the member's right to participate in discussions or deliberations.



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Chair and Vice-Chair Model

19. The determination of whether the chair or vice-chair of the committee or panel, as applicable, has a COI shall be made by the CDA-AMC President and CEO.
20. If the chair is in conflict or potential conflict, the vice-chair shall act in their stead. In the event that both the chair and vice-chair have a COI, the CDA-AMC President and CEO shall appoint the chair of the meeting.
21. If it is determined that the chair or vice-chair, as applicable, has a COI on a matter relevant to the committee's or panel's mandate, the individual shall not participate in any deliberation or vote in respect of such matter.

Co-Chair Model

22. The determination of whether a co-chair has a COI shall be made by the CDA-AMC President and CEO.
23. If a co-chair is in conflict or potential conflict, the other co-chair shall be the sole chair of the meeting. In the event that both Co-Chairs have a COI, the CDA-AMC President and CEO shall appoint the chair of the meeting.
24. If it is determined that a co-chair has a COI on a matter relevant to the committee's or panel's mandate, the individual shall not participate in any deliberation or vote in respect of such matter.

Publication

25. Information about the conflicts of interest of members may be made publicly available, as identified in sections 19 and 20 of CDA-AMC's COI Policy.

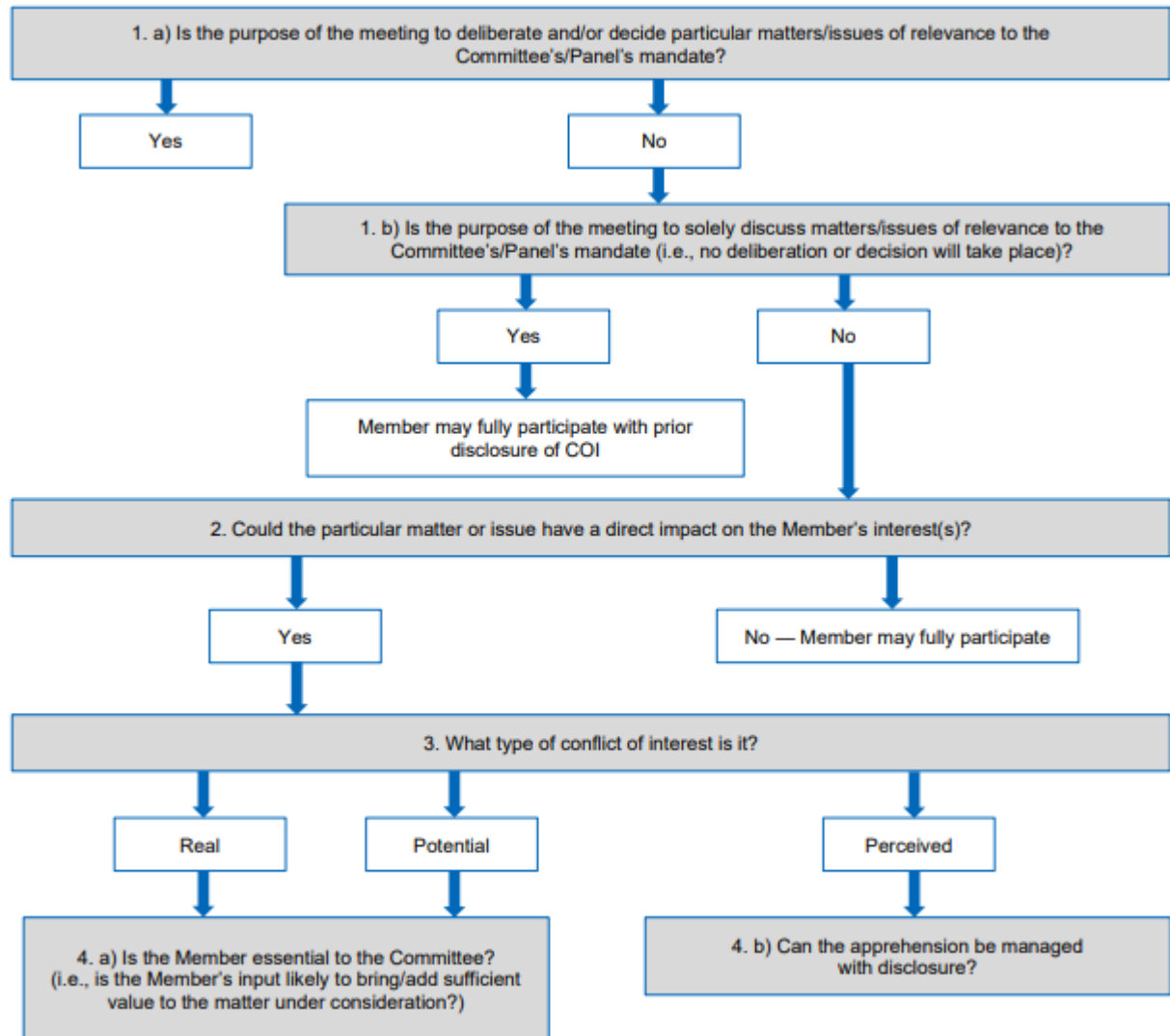


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Figure 1: COI Flow Chart for Advisory Committee, Expert Committee or Panel Members

COI Flow Chart

All Members are required to disclose COI's in accordance with the COI Guidelines.



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