

RULES OF PROCEDURE FOR THE CRITICAL MEDICINES ALLIANCE STEERING BOARD

The Steering Board of the Critical Medicines Alliance (the “Steering Board”),
Having regard to the Critical Medicines Alliance (CMA)’s Terms of Reference,
Has adopted the following rules of procedure:

Role and tasks of the Steering Board

1. As stated in the Alliance’s Terms of Reference, the Steering Board prepares the CMA Forum, ensures consistency and integration of the work of the different working groups and with the other existing structures, maintains a roadmap of the implementation of the actions proposed by the CMA and supports the European Commission in facilitating, communicating, and monitoring the work of the CMA, as well as validating its outputs.

Chairmanship

2. The Steering Board is chaired by the representative of the European Commission, namely DG Health Emergency Preparedness and Response Authority (HERA).
3. The Steering Board shall elect two Vice chairs for a mandate of 1.5 years, except for the first mandate which shall be 6 months.
4. The two Vice chairs shall be elected by simple majority of the Members attending the vote.
5. The Chair shall be responsible for organising the Steering Board’s meetings and managing the documentation to be circulated to the Members.
6. The Chair shall ensure that the action points identified by the Steering Board are followed up.

Secretariat

7. HERA shall provide secretarial support for the Steering Board.

Meetings

8. Meetings of the Steering Board are convened by the Chair at least once every three

months or at the reasoned request of a Member. The Chair shall confirm the dates of the meetings at least one month in advance, unless the meeting was convened urgently in an exceptional case.

9. Meetings can be held physically (on Commission premises or exceptionally at other place) or virtually, depending on the circumstances. Members of the Steering Board shall make their best efforts to ensure their participation at the meetings of the Steering Board. Members of the Steering Board shall appoint a substitute and shall indicate ahead of the meetings any absence and replacement by the substitute.
10. The provisional agenda shall be drawn up by the Chair, assisted by the Vice chairs, taking into account suggestions from the Members.
11. Depending on the subject matter foreseen for discussion, relevant stakeholders may be invited by the Chair, on an ad-hoc basis, to attend parts of meetings of the Steering Board or provide written contributions.
12. At each meeting, the Chair shall draw up an attendance list.

Documentation to be sent to participants

13. The Chair shall send the invitations to the meetings and the draft agenda to the Members at least three weeks before the date of the meeting and the working documents at least two weeks before the date of the meeting.
14. In urgent or exceptional cases, the time limits for sending the documentation may be reduced to five calendar days before the date of the meeting.
15. Documents submitted to the Steering Board should indicate if they include confidential information.

Decisions of the Steering Board

16. In general, the Steering Board shall adopt documents, including opinions, recommendations, and reports by consensus.
17. If no consensus can be found, the Chair may put the decision to vote. The outcome of the vote shall be decided by simple majority of the Members attending the meeting. Members who have voted against or abstained shall have the right to add the reasons for their position annexed to the opinions, recommendations or reports.
18. If necessary, decisions may be obtained by written procedure. To this end, the Chair shall submit to the Members of the Steering Board the proposals on which the agreement of the group is sought. Written comments should be sent to all Members of the Steering Board. Any Member who does not express his or her opposition or

comments on the proposal within the time-limit specified by the Chair shall be considered to have given his tacit agreement to the proposal. The time-limit may not be less than 10 calendar days, or – in urgent and exceptional cases – less than 3 working days.

Minutes of the meetings

19. Minutes shall be drafted by the Secretariat under the responsibility of the Chair.
20. Minutes of the discussion on each point on the agenda and on the opinions delivered by the Steering Board at its formal meetings shall be meaningful and complete.
21. The draft minutes shall be circulated to the Members within four weeks after the formal meeting, which shall have 10 calendar days to comment on the draft minutes.
22. The minutes shall be adopted by the Steering Board.
23. In case agreed by the Steering Board, a list of "Action points" shall be annexed to the minutes. These action points shall clearly state who is responsible for carrying out any specific work or task.

Reimbursement of expenses

24. Each Member of the Steering Board shall bear all travel and subsistence expenses incurred in connection with the meetings of the Steering Board.

Transparency

25. The following data on the Members of the Steering Board shall be published on the CMA's website:
 - a) the name of Member States' authorities;
 - b) the name of other public entities;
 - c) the name of member organisations and the interest represented;
 - d) the name of observer organisations.
26. The Secretariat shall publish all relevant documents to the meetings of the Steering Board, including the agendas, background documents, meeting minutes and the participants' submissions on the CMA's website. Access to website shall not be submitted to user registration or any other restriction.

27. Exceptions to publication shall only be possible where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001¹.

Protection of personal data

28. All processing of personal data for the purposes of these rules of procedure shall be in accordance with Regulation (EU) 2018/1725.²

Entry into force

29. These Rules of Procedure shall enter into force on the day of their adoption by the Steering Board.

¹ These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. (OJ L 295, 21.11.2018, p. 39).