

RULES OF PROCEDURE FOR

THE CRITICAL MEDICINES ALLIANCE WORKING GROUP: Strengthening manufacturing capacity in the EU for critical medicines to better prevent and fight their shortages

The working groups of the Critical Medicines Alliance (the “Working Groups”),

Having regard to the Critical Medicines Alliance (CMA)’s Terms of Reference and to the rules of procedure of the Critical Medicines Alliance Steering Board,

Have adopted the following rules of procedure:

Chairmanship

1. The Working Group shall elect two Co-Chairs for 2 years. The two Chairs shall exercise their duties in agreement and without representing any particular interest. A single Co-Chair can exercise the duties of the Co-Chairs when the other Co-Chair is not available, or if it has provided its agreement in advance.
2. The Co-Chairs shall be elected by simple majority of the Members of the Working Group (hereinafter: Members) attending the vote. In case of more than two candidates, each Member attending the vote shall be able to cast votes on two different candidates. The candidates with the two highest vote count shall be considered elected.
3. The Co-Chairs of the Working Group, assisted by the Secretariat, shall be responsible for organising the Working Group’s meetings.
4. The Co-Chairs of the Working Group, assisted by the Secretariat, shall ensure that the action points identified by the Working Group are followed up.

Secretariat

5. HERA shall provide secretarial support for the Working Group.

Meetings

6. Meetings of the Working Group are convened by the Co-Chairs of the Working Group, assisted by the Secretariat. The dates of the meetings shall be confirmed at least one month in advance, unless the meeting was convened urgently in an exceptional case.

7. Meetings can be held physically (on Commission premises or exceptionally at other place) or virtually, depending on the circumstances. Members of the Working Group shall make their best efforts to ensure their participation at the meetings of the Working Group.
8. The provisional agenda shall be drawn up by the Co-Chairs and the Secretariat, taking into account suggestions from the Members.
9. Depending on the subject matter foreseen for discussion, relevant stakeholders may be invited by the Co-Chairs or by the Secretariat, on an ad-hoc basis, to attend parts of meetings of the Working Group or to provide written contributions.
10. At each meeting, the Secretariat shall draw up an attendance list.
11. All participants shall ensure confidentiality regarding the discussions and information shared during the meetings.

Documentation to be sent to participants

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

Decisions of the Working Group

15. In general, the Working Group will propose documents to the CMA Steering Board, including opinions, recommendations, and reports by consensus.
16. If no consensus can be found, the Co-Chairs 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.
17. If necessary, decisions may be obtained by written procedure. To this end, the Co-Chairs, assisted by the Secretariat, shall submit to the Members the proposals on which the group's agreement is sought. Written comments should be sent to all Members. Any Member who does not express his or her opposition or comments on the proposal within the time-limit specified by the Co-Chairs shall be considered to have given his tacit agreement to the proposal. The time-limit may not be less than 3

working days.

Minutes of the meetings

18. Minutes shall be drafted by the Secretariat under the responsibility of the Co-Chairs and circulated to the Members within two weeks of the meeting.
19. Minutes of discussion on each point on the agenda and on the opinions delivered by the Working Group at its formal meetings shall be meaningful and complete, without disclosing the identity or affiliation of the speakers.
20. If agreed upon by the Working Group, a list of "Action points" shall be annexed to the minutes. These action points shall clearly state who is responsible for carrying out each specific work or task.

Reimbursement of expenses

21. Each Member of the Working group shall bear all travel and subsistence expenses incurred in connection with the meetings of the Working Group.

Transparency

22. The following data on the Members of the Working Group 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.
23. The Secretariat shall publish minutes, background documents and recommendations of the Working Group on the CMA's website. Access to website shall not be submitted to user registration or any other restriction.

24. 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

25. 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

26. These Rules of Procedure shall enter into force on the day of their adoption by the Working Group.

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).