

EUROPEAN UNION DRUGS AGENCY

SCIENTIFIC COMMITTEE RULES OF PROCEDURE

The Scientific Committee of the European Union Drugs Agency (EUDA):

Having regard to Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006, in particular Recital 34 and Articles 10, 22 and 31 thereof, which define the role, composition and tasks of the EUDA Scientific Committee,

Having regard to the rules of procedure of the Management Board of the EUDA, in particular Article 25 thereof, which requires that the EUDA Scientific Committee adopts its own rules of procedure,

Whereas the above referred rules of procedure of the EUDA Management Board (Annex II, Article 5) states that 'The members of the Scientific Committee will be entitled to receive an allowance for each day of attendance at meetings of the Scientific Committee, meetings of the Management Board, where they represent the Scientific Committee at the request of the Chair of the Management Board, and other meetings where they represent the Scientific Committee at the request of the Executive Director. The members of the Scientific Committee will also be entitled to the refunding of travel and subsistence costs for their attendance to the above referred meetings, in accordance with the applicable EUDA rules; has adopted the following rules of procedure:

Rules of procedure

ARTICLE 1

Appointment of the Scientific Committee Chair and Vice-Chair

1. The Scientific Committee shall elect a Chair and a Vice-Chair, among and by its members, at the first meeting of its mandate.
2. The Chair and the Vice-Chair of the Scientific Committee shall be elected, with a two-thirds majority, for a term of four years, with a possibility of one renewal for a maximum of four years.
3. If the two-thirds majority is not reached in the third ballot, the Chair and Vice-Chair are elected by simple majority.
4. The secretariat of the Scientific Committee shall organise the voting procedures.
5. Members may submit their candidatures up to one hour before the voting. Members can opt to be candidates for Chair, Vice-Chair, or both. Candidatures must be sent to the secretariat via email.
6. Voting shall be organised by secret ballot during the first meeting of each mandate of the Committee.
7. If a member is unable to attend the meeting, another member can vote by proxy. In the case of a vote by proxy, the member concerned should address an email to the secretariat of the Scientific Committee, stating the name of the member of the Scientific Committee authorised to vote for him/her. This authorisation will be valid only for the duration of the concerned voting.
8. The Vice-Chair will carry out the duties of Chair in their absence.
9. If the Chair or Vice-Chair resigns, a new Chair or Vice-Chair is elected for the remaining mandate.

ARTICLE 2

Meetings of the Scientific Committee

1. The Scientific Committee shall meet on a regular basis at least once a year. Normally, however, two meetings will be held each year.
2. In addition, the Scientific Committee shall carry out risk assessment on new psychoactive substance(s), according to Article 10 of the of Regulation (EU) 2023/1322 and as stated in Article 12 of these rules of procedure.
3. Meetings of the Scientific Committee will normally be held face-to-face at the EUDA premises. Exceptionally, meetings may be held online or in hybrid mode, if suggested by the Chair and agreed with the Executive Director.
4. Further meetings of the Committee may be convened at the duly justified request of its Chair, the Chair of the Management Board or the Executive Director, and subject to budget availability.
5. For each convocation, the Chair will notify each member of the date of the meeting not less than four weeks in advance. A draft agenda, approved by the EUDA Executive Director, will be sent simultaneously.
6. The members of the Management Board will be informed with four weeks' notice about the date and the draft agenda of each Scientific Committee meeting.

ARTICLE 3

Agenda

1. At the beginning of a meeting, the Scientific Committee shall adopt the agenda, based on the draft agenda referred to in Article 2 (5) above and any other item proposed by the Chair or, in accordance with paragraph 2 of this Article, by one or more of the members. Members shall state any potential conflicts of interest related to agenda items as stated in Article 10 of these rules of procedure.

2. Any request by one or more members of the Scientific Committee for the inclusion of an item on the agenda or the deletion or substitution of an item shall give reasons for this request, to be sent in writing to the Chair at least five working days before the date of the meeting.

ARTICLE 4

Attendance at meetings

1. Members are expected to attend all Scientific Committee meetings as well as risk assessment meetings. If the member does not attend two consecutive Scientific Committee meetings or risk assessment meetings, without justified reasons, the Management Board can decide to withdraw her or his membership.
2. The Scientific Committee or the Executive Director may request the presence at its meetings of EUDA staff qualified in matters under consideration.
3. The spokesperson of the national focal points may be invited to the Scientific Committee's meetings as an observer.
4. The Scientific Committee may decide on an ad hoc basis and in agreement with the Executive Director, to invite experts to attend meetings of the Committee, when this is considered essential for its deliberations.
5. The presence of at least half of the Scientific Committee members shall constitute the quorum for valid decisions.
6. The Scientific Committee may decide to hold meetings or address specific agenda items in restricted session, i.e. excluding non-members.

ARTICLE 5

Drafting and adoption of opinions

1. The Scientific Committee is called to deliver a formal opinion on the EUDA programming documents and an opinion on any scientific matter concerning the Agency's work which the Management Board or the Executive Director may submit to it.
2. Consensus finding shall be the fundamental principle of the Scientific Committee's work.
3. If consensus is not possible, opinions of the Scientific Committee shall require a two-thirds majority of members present, including proxy votes, for their adoption.
4. The opinions of the Scientific Committee shall be published on the EUDA public website.

ARTICLE 6

Voting arrangements

1. Where the Chair considers that consensus cannot be reached, they may initiate a voting procedure.
2. Voting shall be by show of hands, or by roll call in cases of dispute in a vote by show of hands. The vote will be by secret ballot, if a majority of members request it.
3. If a member is unable to attend the meeting, another member can vote by proxy. In the case of a vote by proxy, the member concerned should address an email to the Chair of the Scientific Committee, stating the name of the member of the Scientific Committee authorised to vote for him/her and items for which the member is entitled to vote by proxy; this authorisation will be valid only for the duration of the concerned agenda items.
4. Every motion to exclude questions from the Scientific Committee or to postpone consideration of a matter shall be subject to a majority vote before dealing with the substance of the matter.
5. A draft opinion or decision which deals with several questions shall be divided into its individual parts if so requested.

ARTICLE 7

Written procedure

1. In the event of an opinion having to be expressed in between meetings, the Chair may initiate a simplified written procedure.
2. The draft opinion shall be forwarded to the members, who may make written objections within the deadline fixed by the Chair but not less than two weeks following receipt of the communication. If no objections are lodged, the opinion shall be considered adopted. If objections are lodged, the Chair shall decide either to suspend the simplified written procedure and call an extraordinary meeting of the Scientific Committee, or to circulate an amended draft decision with the objections attached. In the latter case, the deadline shall be extended by a new period of seven working days.

ARTICLE 8

Minutes of Scientific Committee meetings

1. The secretariat of the Scientific Committee shall take minutes of each meeting of the Scientific Committee. These shall include:
 - List of participants
 - Record of proceedings
 - Opinions or decisions adopted with a record of the voting figures for each vote
 - Any declaration of conflict of interest made by the Scientific Committee members regarding the items on the agenda.
2. The Scientific Committee shall adopt the text of the minutes at the next meeting, or by written procedure.
3. The draft minutes shall be submitted for adoption only if a draft copy has been sent to members at least two weeks before the meeting. Should this draft not have been sent in time, the adoption will be held over until the following meeting or by written procedure.
4. The final minutes of the Scientific Committee meetings will be published on the EUDA website, except for minutes of restricted sessions.

ARTICLE 9

Remuneration of members of the Scientific Committee

1. The members of the Scientific Committee will be entitled to an indemnity for each Scientific Committee meeting day they attend, and when representing the Scientific Committee at Management Board meetings at the request of the Chair of the Management Board or the Executive Director and at institutional or external meetings at the request the Executive Director. The amount of this indemnity shall be equivalent to the amount paid by DG Research of the European Commission for independent experts ⁽¹⁾.
2. Members will also be reimbursed for travel expenses and will receive a subsistence allowance in accordance with the rules applied for the payment of daily allowances and refunding of travel and accommodation expenses occurred in relation to meetings organised by the EUDA. The entitlement to these allowances shall be subject to the condition that this entitlement is stated in the invitation sent by the EUDA and that the participant has not received or is entitled to a similar allowance from another organisation or person for attending the meeting in question.

ARTICLE 10

Conflict of interest

1. The members of the Scientific Committee are appointed on a personal basis by the Management Board.

⁽¹⁾ At €450 at the time of adoption of these rules of procedure.

2. Upon nomination, members of the Scientific Committee are required to sign a declaration of interest in line with the EUDA policy for the prevention and management of conflict of interest. These declarations are published on the EUDA public website.
3. It is the responsibility of each member of the Scientific Committee to keep her or his declaration of interest updated.
4. Members undertake to inform the Executive Director, through the Chair, should she or he have a conflict of interest with any topic on the agenda of any of the Scientific Committee meetings and on any other issue she or he is asked to examine. The Chair, in consultation with the Executive Director, takes all the necessary steps to remove such conflicts of interest, for example, by the member not participating in discussions on such issues.

ARTICLE 11

Secretariat of the Scientific Committee

1. EUDA staff supporting the EUDA Chief Scientist shall prepare and organise the work of the Scientific Committee and shall provide the secretariat for meetings and additional tasks of the Committee under the guidance of the Scientific Committee's Chair and the Chief Scientist.
2. Correspondence intended for the Scientific Committee shall be addressed to the secretariat.
3. The secretariat is responsible for archiving Scientific Committee papers and opinions.
4. The secretariat is responsible for travel arrangements and reimbursement of daily indemnities and travel and subsistence allowance according to Article 9 of these rules of procedure.

ARTICLE 12

Risk assessment of new psychoactive substances

1. The Scientific Committee of the EUDA has a central role in the assessment of the risks associated with new psychoactive substances.
2. In order to carry out a risk assessment and following a request from the European Commission to the Agency, the EUDA shall convene a risk assessment meeting under the auspices of its Scientific Committee.
3. For the purpose of assessing the risks posed by a new psychoactive substance or a group of new psychoactive substances, the Scientific Committee may be extended as considered necessary by the Executive Director, acting on the advice of the Chair of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance or the group of new psychoactive substances. The Executive Director shall designate those experts from a list of experts. The Management Board shall approve the list of experts every four years.
4. For risk assessment meetings, rules specified in Articles 10 and 31 (6) of Regulation (EU) 2023/1322 apply.

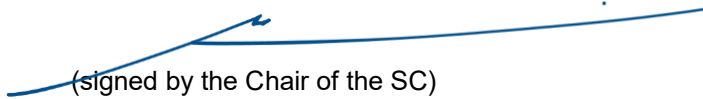
ARTICLE 13

Entry into force and revision of the rules of procedure and annexes

1. The present rules of procedure of the Scientific Committee enter into force after their adoption by the EUDA Scientific Committee and endorsement by the Executive Director.
2. The Scientific Committee can decide by a two-thirds majority of members to revise the rules of procedure, to be subsequently endorsed by the Executive Director.
3. Changes adopted shall take effect at the Scientific Committee meeting following the endorsement by the Executive Director. The secretariat will provide the members of the Scientific Committee with amended rules of procedure before the next meeting takes place.

4. The Rules of Procedure shall be reviewed at the beginning of each new mandate of the Scientific Committee

Done at Lisbon on 27 June 2025, for the Scientific Committee of the EUDA.



(signed by the Chair of the SC)