

RULES OF PROCEDURE OF THE MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

THE MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT,

Having regard to Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU¹ (hereinafter “the HTAR”), and in particular its Article 3(7)(a),

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Article 1

Membership

1. The Member State Coordination Group on Health Technology Assessment (“the HTACG”) acts in accordance with provisions of the HTAR, the implementing acts referred to in the HTAR and the present Rules.
2. The members of the HTACG are member organisations designated by the Member States. The members of the HTACG shall appoint their representatives and alternates on an *ad hoc* or permanent basis.
3. In order to provide expertise on health technology assessment (“HTA”) for medicinal products and medical devices, members and their respective representatives and alternates are designated/appointed for two configurations of the HTACG: on medicinal products (CG-MP) and medical devices (including *in vitro* diagnostic medical devices) (CG-MD).

Unless specified otherwise, “the HTACG” in the present Rules refers to each of the two configurations of the HTACG.

4. The members of the HTACG shall appoint one representative and up to three alternates for each member organisation. They shall notify the names, affiliation, job title and contact details (postal and email address) of the appointed representatives and their alternates to the HTACG Secretariat. Any changes in member organisations and/or their representatives and alternates shall be notified to the HTACG Secretariat as soon as possible and at the latest twenty calendar days before a planned HTACG meeting to allow the HTACG Secretariat to circulate invitations and relevant documentation in due time before the meeting.
5. Meetings of the HTACG shall be chaired and co-chaired by representatives of two members from the HTACG, from different Member States, elected in accordance with Article 3. Joint meetings of the HTACG shall be co-chaired by the Chairs of the two HTACG configurations, unless otherwise decided by the HTACG.
6. Notwithstanding paragraph 3, until the date of application of the HTAR, the HTACG will operate in a joint configuration. This joint configuration will have a Chair and two Co-Chairs, one with expertise on medicinal products and one on

¹ OJ L 458, 22.12.2021, p. 1.

medical devices, elected from among the members of the HTACG, from different Member States. This arrangement will be reviewed and revised as necessary six months before the date of application of the HTAR.

“Co-Chair” in the present Rules refers also to both Co-Chairs of the joint configuration of the HTACG.

Article 2

Responsibilities of the Chair and Co-Chair of the HTACG

1. The Chair, and in his/her absence the Co-Chair, is responsible for the efficient conduct of the business and shall in particular:
 - a) Chair the meetings of the HTACG;
 - b) With support from the Chairs of the subgroups referred to in Article 9, ensure that the work of the HTACG and its subgroups is of the highest scientific quality and delivered in a timely manner, respecting independence, impartiality and transparency requirements;
 - c) With support from the Chairs of the subgroups, ensure that scientific consistency is maintained throughout the work of the HTACG and its subgroups;
 - d) With support from the HTACG Secretariat, ensure the coordination of the HTACG work between its configurations and with its subgroups, as well as transparent and timely communication between the HTACG members;
 - e) In line with Article 15, at the beginning of each meeting, invite the representatives and other relevant attendees to immediately inform of any relevant changes to the information previously provided to the Commission concerning conflict of interest and ensure that the procedure for assessing a potential conflict of interest is triggered;
 - f) Make all necessary efforts to ensure that the HTACG decisions are reached by consensus;
 - g) Following consultation of the HTACG members, conclude when a vote is necessary;
 - h) Following input from the HTACG members, conclude on the final agenda for each meeting;
 - i) Following feedback on the draft minutes from the HTACG members, conclude on the final draft of the minutes of the HTACG meetings to be adopted by the HTACG at the beginning of its next meeting;
 - j) Represent the HTACG at meetings of external parties where necessary and inform the HTACG thereof via the HTACG Secretariat;
 - k) Having consulted the HTACG members call for meetings outside the meetings’ planning;
 - l) Ensure cooperation with relevant Union level bodies as set out in Article 3(7)(i) of the HTAR, as well as appropriate involvement of stakeholder organisations and experts as set out in Article 3(7)(j) of the HTAR.

2. The Co-Chair is responsible for the efficient conduct of the business of the HTACG in the absence of the Chair. In addition, the Co-Chair shall in particular:
 - a) Deputise for the Chair when the latter is unable to chair either all or part of the HTACG meeting. On such occasions, the Chair seeks the agreement of the Co-Chair as early as possible prior to the meeting and the HTACG Secretariat shall be informed immediately;
 - b) Support the Chair in all its duties and in agreement with the Chair, take the lead for specific topics and tasks.

Article 3

Election of the Chair and the Co-Chair

1. The Chair and Co-Chair of each configuration of the HTACG shall be elected by and from amongst the representatives or alternates of its members for a term of three years, which may be renewed once. The term of the Chair and Co-Chairs of the joint HTACG configuration is limited until the date of application of the HTAR, unless the HTACG decides otherwise. Serving as Co-Chair of the HTACG does not prevent a subsequent election as Chair. The Chairs and Co-Chairs of the HTACG shall be representatives of HTACG members from different Member States. If decided by the HTACG and provided that the specificities of the configurations are taken into account, both configurations may have the same Chair and/or Co-Chair.
2. Nominations for Chair and Co-Chair should be submitted in writing to the HTACG Secretariat with a motivation letter and up to date CV of the nominee, no later than fourteen calendar days prior of the HTACG meeting at which the election is to take place, unless the HTACG decides to accept nominations that arrived at a later date. The HTACG Secretariat shall share the documentation related to the nominations with the HTACG members as soon as possible. Each Member State can submit one nomination for each of the positions from among its representatives or alternates already appointed to the HTACG, specifying the position of the nominee: Chair, Co-Chair or both. If the same representative or alternate is appointed for both HTACG configurations, nominations should clearly specify the HTACG configuration: CG-MP, CG-MD or both.
3. The election starts with the position of the Chair. Once the Chair has been elected, he/she leads the proceedings for the election of the Co-Chair. The same procedure applies for the election of the Co-Chair. Nominees for both positions who were not elected as Chair, qualify for the election of the Co-Chair position, unless they are from the same Member State as the elected Chair or they have already served as a Co-Chair for two terms.
4. The election shall be by a simple majority of the Member States' votes and by secret ballot. Election by proxies is acceptable if communicated in advance to the HTACG Secretariat and technically possible. If a simple majority is reached in the first round, the election is concluded. If the simple majority is not reached, the procedure shall continue with additional round(s).
5. At each round, the candidate(s) with the lowest number of favourable votes is automatically withdrawn. If there is a tie amongst the candidates with the lowest

number of votes, all tied candidates are eliminated, and if needed a further voting round is organised with the remaining candidate(s) only.

6. If there is only one (remaining) candidate, to be elected Chair or Co-Chair, she/he needs favourable votes from a simple majority of the Member States' votes. If the only (remaining) candidate does not get a simple majority, the election is suspended, and a new election is convened following the same procedure. The same applies where there are two (remaining) tied candidates.
7. The Chair and Co-Chair shall be impartial and independent, therefore cannot vote on behalf of their Member States for the duration of their mandate. The Member States whose representatives were elected as Chair or Co-Chair, will either appoint a new representative to the HTACG or entrust its responsibilities to its appointed alternate.
8. In the event of resignation of the Chair, the Co-Chair shall take over the tasks of the Chair until a new election is convened. In the event of resignation of the Co-Chair, the Chair will take over his/her tasks until a new election is convened. In the event of resignation of both Chair and Co-Chair, a representative of the HTACG member from the Member State holding the presidency of the EU Council and of the Member State holding the next presidency of the EU Council respectively will be Chair and Co-Chair *ad interim* to manage day-to-day tasks and chair meetings until a new Chair and Co-Chair are elected according to these Rules.

Article 4

Convening a meeting

1. Meetings of the HTACG are convened by the HTACG Secretariat, with the agreement of the Chair and Co-Chair.
2. After consulting the Chair and Co-Chair, the HTACG Secretariat shall develop the meetings' planning for each HTACG configuration, based on anticipated workload and corresponding deadlines. The number of meetings shall be included in the HTACG annual work programme, without prejudice to the provisions in paragraph 4.
3. Joint meetings of the two configurations of the HTACG shall be organised for issues of interest for both configurations, either replacing the meetings of individual configurations or in addition to those dedicated for individual configurations. In line with Article 1(6) of the present Rules, in the transitional period until the date of application of the HTAR, the HTACG is meeting in a joint configuration.
4. The Chair, having consulted the HTACG members, can call for a meeting outside of the meetings' planning.
5. In principle, meetings of the HTACG shall be held in Commission's premises. Taking into account the earmarked budget and the impact of commuting on energy resources, meetings may also be held virtually or in a hybrid mode, depending on the circumstances. In principle, meetings outside of the meetings' planning shall be held virtually.

6. Joint meetings of the HTACG with relevant Union level bodies as set out in Article 3(7)(i) of the HTAR, as well as stakeholder organisations may be convened to discuss matters falling within their respective areas of responsibility.
7. Meetings of the HTACG are held in English. Documents for discussion and decision are to be submitted in English. Minutes are drawn up in English.

Article 5

Agenda

1. The HTACG Secretariat shall draw up the agenda under the responsibility of the Chair and Co-Chair and send it to the members of the HTACG.
2. The HTACG Secretariat shall ensure via a standing invitation that HTACG members have the opportunity to propose agenda items for the next HTACG meeting. Proposals for items to be included on the agenda shall reach the HTACG Secretariat at least twenty calendar days before the meeting, except for urgent items.
3. The agenda shall be adopted by the HTACG at the start of the meeting.

Article 6

Documentation to be sent to the HTACG members

1. The HTACG Secretariat shall send to the HTACG members the invitation to the meeting, the draft agenda and any relevant documents no later than fourteen calendar days before the date of the meeting, except for urgent items.
2. The HTACG members may submit clarification questions on the documents circulated by the HTACG Secretariat, as soon as possible and no later than three calendar days prior to the HTACG meeting.

Article 7

Decisions of the HTACG

1. In accordance with Article 3(4) of the HTAR, the HTACG shall, in principle, act by consensus. Where consensus cannot be reached, the decision of the HTACG shall be taken by vote. When possible, the agenda shall indicate if endorsement of a document is expected.
2. In the event of a vote, the decision shall require the support of the HTACG members representing a simple majority of the Member States. Each Member State shall have one vote on each configuration of the HTACG, as well as one vote where decisions on issues relevant to both configurations are taken in a joint meeting.
3. The results of the votes shall be recorded in the minutes of the HTACG meetings. Where a vote takes place, the Member States that have voted against or abstained may ask for divergent opinions to be recorded in the minutes of the meeting in which the vote took place.

4. By way of derogation from paragraph 2, and in accordance with Articles 3(5) and 3(7)(b) and (c) of the HTAR, where consensus cannot be reached, for the adoption of the annual work programme, annual report and strategic direction for the work of its subgroups, the HTACG decisions shall be adopted by a qualified majority as defined in Article 16(4) TEU and Article 238(3), point (a), TFEU.

Article 8

Written procedure

1. If necessary, the HTACG decision on a specific question may be delivered via a written procedure if such a procedure was agreed at a prior meeting of the HTACG. To this end, upon request of the Chair, the HTACG Secretariat circulates to the HTACG members the document(s) on which the HTACG is being consulted and sets a time limit of at least fourteen calendar days, within which the HTACG members shall have the possibility to state that they reject the proposed decision or abstain from the voting. No response within the set time limit shall be considered as an abstention.
2. The HTACG Secretariat shall, at the expiry of the set time limit, inform the HTACG members of the outcome of the written procedure. A decision having received the required majority of affirmative votes shall be considered adopted on the last day set for the period within which the HTACG members were asked to respond.
3. However, if a simple majority of Member States asks for the question to be examined at a meeting of the HTACG, the written procedure shall be terminated without result and the HTACG Secretariat shall convene a meeting of the HTACG as soon as possible.

Article 9

Subgroups

1. In accordance with Article 3(7)(k) of the HTAR, the HTACG shall establish subgroups, in particular for the following: joint clinical assessments; joint scientific consultations; identification of emerging health technologies; development of methodological and procedural guidance. If considered appropriate by the HTACG, joint subgroups serving both configurations may be established, in particular, in the transitional period until the date of application of the HTAR. All subgroups, including *ad hoc* subgroups referred to in paragraph 4, shall operate on the basis of terms of reference defined by the HTACG, and in compliance with these Rules. The terms of reference shall be published on the publicly accessible webpage of the IT platform referred to in Article 30 of the HTAR.
2. The members of subgroups are designated by the HTACG members in each configuration. The members of the HTACG may designate more than one member to a subgroup, including the member of the HTACG, without prejudice to the rule that each Member State shall have one vote. The members of the subgroup shall appoint in the subgroup on an *ad hoc* or permanent basis one representative and one alternate for each member organisation. The appointed representatives and alternates shall have the appropriate HTA expertise. Where

there is a need for specific knowledge, members of the subgroup may appoint more than one representative.

3. Each subgroup shall elect its Chair and Co-Chair by and from amongst its representatives and alternates for a term of three years, which may be renewed once. The Chair and Co-Chair of each subgroup shall be representatives from different Member States. The election procedure set out in Article 3 of these Rules apply *mutatis mutandis*.
4. In agreement with the HTACG Secretariat, the HTACG may decide to establish additional permanent or *ad hoc* subgroups to discuss specific topic. *Ad hoc* subgroups shall be dissolved as soon as their mandate is fulfilled.
5. In order to ensure timely and efficient exercise of its competences laid down in the HTAR, the HTACG may delegate certain tasks to a subgroup, in accordance with their respective terms of reference and with the exception of final endorsement of joint work. The HTACG can withdraw the delegation anytime. In these cases, the subgroup shall regularly report to the HTACG on the progress of their work. Where necessary, Chairs and Co-Chairs of the subgroups that are not members of the HTACG may be invited to attend the HTACG meetings.

Article 10

Observers²

1. Without prejudice to the EEA Joint Committee decision incorporating the HTAR into the EEA Agreement, the EEA EFTA States may on a provisional basis attend the meetings of the HTACG and its respective subgroups as observers.
2. The observers referred to in paragraph 1 wishing to attend the meetings of the HTACG and/or its subgroups shall notify in writing to the HTACG Secretariat the name and address of their designated institutions, as well as up to one representative and one alternate for each designated institution, informing about their name, affiliation, job title and contact details (postal and email address).
3. The observers referred to in paragraph 1 shall have the right to take part in the discussions, as well as provide written input. They shall not have any voting rights. The representatives and alternates of the observers shall abide by the conflict of interest rules set out in the HTAR, as well as in the general procedural rules to be adopted in accordance with Article 25(1)(a) of the HTAR.

Article 11

Stakeholders and invited experts

1. In agreement with the Chair and Co-Chair of the HTACG, and acting on behalf of the HTACG, the HTACG Secretariat convenes meetings with the Stakeholder Network as set out in Article 29(5) of the HTAR.

² This Article applies until the entry into force of the EEA Joint Committee decision incorporating the HTAR into the EEA Agreement.

2. The HTACG or a subgroup may invite, on a case-by-case basis, individual external experts with relevant in-depth specialised expertise and other third parties (e.g. representatives of the European Medicines Agency, or of the Medical Device Coordination Group) to participate in the meetings and contribute to the discussions of the HTACG or its subgroup and/or provide written input. At the request of the Chair and Co-Chair of the HTACG or of a subgroup, the HTACG Secretariat shall ensure the participation of such experts and other third parties, in accordance with the requirements set out in Articles 5 and 28(b) of the HTAR, as well as the general procedural rules to be adopted in accordance with Article 25(1)(a) of the HTAR.

Article 12

Secretariat

The Commission services (DG SANTE) shall provide secretarial support for the HTACG and its subgroups, as laid down in Article 29 of the HTAR. The HTACG Secretariat acts in accordance with the Rules of Procedure of the Commission³, including their Provisions on Document Management.

Article 13

Minutes of the meetings

1. Minutes of the HTACG meetings shall be drafted by the HTACG Secretariat and agreed by the respective Chair and Co-Chair before presenting them to the HTACG members.
2. The draft minutes shall be shared with the HTACG members for their feedback within fourteen calendar days after the meeting. If no objections or requests for change to the draft minutes are made to the HTACG Secretariat in writing at the latest fourteen calendar days following receipt, the draft minutes are considered finalised and are submitted to the HTACG for adoption at its next meeting.
3. Once the minutes are adopted by the HTACG, the HTACG Secretariat publishes their summary on the publicly accessible webpage of the IT platform in accordance with Articles 28(g) and 30(3) of the HTAR.

Article 14

Attendance list

At each meeting, the HTACG Secretariat shall draw up an attendance list specifying: the representatives/alternates of the HTACG members attending the meeting; the representatives/alternates of observers attending the meeting; invited experts and representatives of third parties; staff from relevant Commission services.

³ C(2000) 3614, OJ L 308, 8.12.2000, p. 26.

Article 15

Conflicts of interest

1. The Commission decides on conflict of interest in accordance with the requirements set out in Articles 5 and 28(b) of the HTAR, as well as in the general procedural rules to be adopted in accordance with Article 25(1)(a) of the HTAR.
2. The HTACG Secretariat shall check that before attending the meeting of the HTACG or its subgroup, all representatives and other attendees have complied with their obligations concerning transparency and conflict of interest as set out in the HTAR, as well as in the general procedural rules to be adopted in accordance with Article 25(1)(a) of the HTAR. At the beginning of each meeting, the Chair of the HTACG and of a subgroup shall invite the representatives and other relevant attendees to immediately inform of any relevant changes to the information previously provided to the Commission concerning conflict of interest.
3. Any declarations regarding conflict of interest and the decisions of the Commission regarding these, as well as information on their application in accordance with Article 5(4) of the HTAR, shall be reported in the minutes of the meeting.

Article 16

Correspondence

1. Correspondence relating to the HTACG shall be addressed to the HTACG Secretariat.
2. Correspondence to the HTACG members shall be sent to their representatives and alternates to the email addresses provided for that purpose.

Article 17

Transparency

The HTACG Secretariat shall ensure the timely publication of information and documents listed in Article 30(3)(a)-(r) of the HTAR on the publicly accessible webpage of the IT platform.

Article 18

Financing for the participation in the HTACG and its subgroups' meetings

The financing for the participation of Member States' designated members in the HTACG and its subgroups' meetings under Article 27(2) of the HTAR includes a daily allowance and, where appropriate, an accommodation allowance in accordance with Commission Decision C(2007)5858⁴.

⁴ Commission Decision C(2007)5858 of 5 December 2007 "Rules on the reimbursement of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity".

Article 19

Access to documents

Applications for access to documents held by the HTACG shall be handled in accordance with Regulation (EC) No 1049/2001⁵.

Article 20

Amendments to the Rules

The HTACG may update or amend these Rules where necessary in a joint meeting of the two configurations of the HTACG. The HTACG shall act in accordance with Article 3(4) of the HTAR.

⁵ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).