Mandate and Rules of Procedure of the MSP Advisory Group

Informative session for the ad hoc representatives of the ACT EU Multi-stakeholder Platform Advisory Group

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1. Mandate and objectives

- Key stakeholder groups who are **directly impacted by clinical trial-related activities in the EU**
- Opportunity to **meet with ACT EU's regulatory partners and ethics committee representatives** on a regular basis
- **Discussions** encompass **all aspects of clinical trials**
- Composition, mandate and rules of procedures **revised every 3 years**

Mandate and rules of procedure was **adopted** on 20 March 2024

by the MSP Advisory Group and is published

2.1. Composition

- Formed by **nominated permanent stakeholder representatives** (and alternates)
- **Ad hoc representatives** based on the topics of discussion (participate to the meetings on behalf of one organisation only)
- **One permanent representative** in addition to an alternate representative
- Each representative participates to the meetings on behalf of **one organisation**
- **Composition** is adopted by the **ACT EU Steering Group**
- **Mandate** and **rules of procedures** are revised and agreed by the **Advisory Group**

2.1.1. Roles and responsibilities – permanent representatives

- Providing the ACT EU Steering Group with their views and strategic advice on the ACT EU multi-annual workplan
- Identifying stakeholder needs, concerns, challenges and priorities, and communicating these to the ACT EU regulatory partners
- Advising ACT EU regulatory partners on stakeholder engagement and communication
- Keeping their respective stakeholder group informed of the output from ACT EU MSP initiatives and overall ACT EU activities
- Reviewing and agreeing on the mandate, workplan and any governance-related documents of the advisory group

2.1.1. Roles and responsibilities – permanent representatives

- Discussions are of a **non-confidential** nature and do not refer to any ongoing medicine specific evaluations
- If stakeholder organisation is not represented at **three consecutive meetings** (physically or remotely), the ACT EU Steering Group may consider a replacement from another organisation.

2.1.2 Process for involvement – ad hoc representatives

1. Priority action coordinator(s) & co-lead(s) flag the need to involve the relevant ad hoc representatives in the discussions when drafting of the MSP Advisory Group meeting agenda
2. The proposals are discussed with the co-chairs
3. The secretariat follows up with the identified ad hoc representatives (4 weeks in advance)

2.1.3 Selection of stakeholders

5 Patients/consumers

4 Healthcare professionals

4 Pharmaceutical industry EU trade organisations

4 Non-commercial European clinical data and translational research organisations and networks

4 Research funders

- Selection via a public call for expression of interest.
- Additional extension to other stakeholder groups shall be considered after first mandate.
- For additional information in Annex 2.

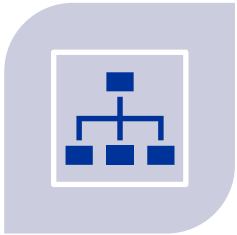
2.1.3 Ethics committees, ACT EU regulatory partners and ad hoc expert representation

- Two **ethics committee** representatives
- **ACT EU regulatory partners**: priority action co-leads and coordinators, participate in the meetings, highlighting areas of activity where stakeholder advice is needed
- **Ad hoc** experts are directly appointed by the relevant group, see Annex 3.

2.2. Co-chairs and selection procedure

- **Regulatory** and **Stakeholder** co-chairs (One co-chair shall deputise for the other co-chair if they are unable to chair)
- Selected for a **term of at least 2 years** and responsible for ensuring the advisory group runs efficiently
- Regulatory co-chair is a **rotating** position (**EMA, HMA, EC**); directly appointed ACT EU Steering Group
- Stakeholder co-chair selected from the **non-commercial** advisory group representatives following a call for candidates
- Stakeholder co-chair agreed by the **ACT EU Steering Group**

2.2.1. Stakeholder co-chair selection procedure



Non-commercial organisation

Capacity/availability to contribute

Previous experience in chairing meetings with one or more stakeholder groups

Experience in clinical trials, including involvement in relevant groups/platforms

3. Operations of the MSP Advisory Group

- The group meets **at least twice a year** (hybrid or virtual). Additional ad hoc meetings or written consultations can take place when needed.
- Physical meetings are held at EMA. The meeting dates are proposed annually by the MSP Advisory Group secretariat and agreed with the co-chairs, in consultation with the MSP Advisory Group permanent representatives.
- When a permanent representative is **unable to participate**, they must inform both the secretariat and the nominated alternate in advance. Such declarations shall be recorded in the minutes of the meeting in question.
- **The relevant ad hoc representatives** are invited to meetings depending on the topics to be discussed and the need for involvement

3. Operations of the MSP Advisory Group

- **Agenda topics** submitted at least **6 weeks** before next meeting; should be linked to mandate and ACT EU multi-annual workplan
- Draft agenda/documents **circulated** ideally **4 weeks** before the meeting to the MSP AG representatives for comments and to the ACT EU Steering group for awareness
- **The relevant ad hoc representatives** are informed if their participation is needed 4 weeks in advance of the meeting
- Draft minutes, including action points, are circulated for comments to the MSP AG. Minutes are shared with the ACT EU Steering Group before publication of the relevant highlights
- **Agendas and meeting highlights** are **published** on the ACT EU website together with other meeting-related documents (e.g., presentations) and will be also circulated to the ad hoc representatives

3.2. MSP Advisory Group feedback

- Upon request of ACT EU regulatory partners, the MSP AG discusses relevant topics in agenda and provides advice reflecting stakeholder perspectives.
- Generally, the advice provided is not considered a formal recommendation or position as such, however, in the case that this is requested by the EMA, HMA and/or EC, the MSP AG shall seek to reach a conclusion by consensus.
- The quorum required for adoption of a recommendation(s) or position(s), shall be reached when two thirds of the total MSP AG permanent representatives are present (physically or remotely). If consensus cannot be reached, objections or divergent position should be noted in the minutes.

Any questions?

Further information

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