Mandate and Rules of Procedure of the MSP Advisory Group

Inaugural meeting of the ACT EU Multi-stakeholder Platform Advisory Group
20 March 2024

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An agency of the European Union

Background and objective

- Circulation of draft mandate and rules of procedure: 21 February 2024
- Feedback deadline: 13 March 2024
- **No comments** received
- Summary presentation: 20 March 2024

Objective: to agree the mandate and rules of procedure with MSP Advisory Group

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2. 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**

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3.1. Composition

- Formed by **nominated permanent stakeholder representatives** (and alternates)
- **Ad hoc representatives** based on the topics of discussion
- **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**

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3.1.1. Roles and responsibilities

- 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

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3.1.1. Roles and responsibilities

- Discussions are of a n**on-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.

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3.1.2. 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 Annexes 1 & 2.

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3.1.4. 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.

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3.2. Co-chairs and selection procedure

- **Regulatory** and **Stakeholder** co-chairs
- 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 permanent and alternate representatives following a call for candidates
- Stakeholder co-chair agreed by the **ACT EU Steering Group**

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3.2. Co-chairs and selection procedure

Fundamental role in driving discussions and promoting balanced dialogue.

Responsibilities:

- run the MSP Advisory Group meetings;
- plan the MSP Advisory Group's work, based on the ACT EU multi-annual workplan;
- steer the discussion to achieve collaboration and consensus on issues and proposals discussed and ensure that all participants views are reflected in the meeting highlights;
- report to the ACT EU Steering Group.

One co-chair shall deputise for the other co-chair if they are unable to chair.

Should one of the co-chairs resign, the other co-chair shall take the chair until the ACT EU Steering Group has made a new appointment. Appointment of a new co-chair shall only be for the remainder of the current mandate.

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3.2.1. Stakeholder co-chair selection procedure

1. Call for candidates at least 3 weeks prior to the ACT EU SG meeting

2. Candidates express interest by writing to the MSP Advisory Group secretariat (msp-agsecretariat@ema.europa.eu)

3. Candidatures received in accordance with the criteria outlined in Annex 4 are discussed by the ACT EU Steering Group and a decision is made on the most suitable candidate

4. The organisation to which the new co-chair is affiliated shall nominate a new representative to replace the co-chair as a representative in the advisory group

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4. 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.

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4. 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
- Draft minutes, including action points, are circulated for comments. 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).

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4.2. 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.

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Discussion and agreement

After the presentation and the preliminary commenting phase, does the MSP Advisory Group agree with proposed mandate and rules of procedure?

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Any questions?

Further information

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