20 March 2024
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ACT EU Multi-stakeholder Platform Advisory Group (MSP AG)

Inaugural meeting, 20 March, from 10:00 to 12:30 (CEST), Webex

Co-Chairs: Melanie Carr (EMA), Maria Jesús Lamas (MSP AG Regulatory co-chair)

1. Welcome and opening remarks by the Head of the Stakeholder and Communication Division, EMA

Melanie Carr (EMA), opened the meeting, welcoming all participants. Maria Lamas, the recently appointed MSP AG regulatory co-chair and executive director of the Spanish agency of medicines and medical products, was introduced and the overview of the agenda was provided.

2. Welcome and opening remarks by the Executive Director of the Spanish Agency of Medicines and Medicinal Products (AEMPS)

Maria Lamas welcomed all participants and emphasized the importance of fostering innovation in clinical trials in Europe and the key role of the established MSP advisory group. She outlined the objectives of the group, stating that the main goal was to underscore stakeholders' contributions to making the EU the premier location for clinical trials, benefiting patients and healthcare professionals (HCPs).

She further explained the objectives of the meeting, aiming for participants to get to know each other, discuss the ACT EU workplan, agree on the mandate and rules of procedure, and launch the call for expression of interest for the stakeholder co-chair nomination. Maria Lamas highlighted that the advisory group represents a unique opportunity to bring together diverse voices of European stakeholders involved in clinical trials.

3. ACT EU workplan and key priorities - expected contribution from MSP AG

Peter Arlett (EMA) provided an overview of the ACT EU workplan and priorities, the benefits that the programme aims to deliver to stakeholders over the next four years and the link between the MSP AG and the programme. Importantly the role of the MSP AG in providing both strategic and operational advice to the ACT EU Steering Group and programme representatives was discussed, highlighting key activities in the course of the year, and the expected contribution to the revision of the ACT EU multi-annual workplan (see presentation).

Denis Lacombe (EORTC) questioned whether there would be a place for stakeholders to share their priorities, challenges, and specific experiences, thereby facilitating shared learning between different groups and ensuring room for discussion of specific issues and solutions.

Peter Arlett (EMA) highlighted the complexity of the clinical trials landscape and the existence of multiple channels for stakeholders to provide feedback, such as the CTIS forum and the annual surveys from the European Commission (EC). It was agreed that EMA would take an action to provide a more comprehensive response to this question, to ensure issues are addressed in the right forum. It was confirmed that the purpose of the MSP AG meetings is to ensure stakeholders' ideas are heard, and EMA pledged to include opportunities for fostering discussion in the agenda.

Lada Leyens (EFPIA) confirmed the alignment of ACT EU priorities with those of EFPIAs clinical trial strategy (e.g. use of novel methodologies and technologies, the implementation of the clinical trials regulations and alignment on scientific advice process). Lada highlighted EFPIA's ability to provide specific data points and case studies to support discussions, to help identify actionable points for progress towards common solutions. The possibility of having dedicated topic-specific discussions to go into more detail and identify solutions was requested. The importance of having concrete outcomes and action points for the ACT-EU MSP that led to concrete solutions was highlighted. Further, she commented on the importance for the ACT-EU MSP AG to also focus and communicate on the benefits of running clinical trials in Europe. While all stakeholders recognise the current challenges there are also positive aspects (e.g. high data quality, strong research centres, etc) that need to be emphasized.

EMA welcomed the proposal for use of case studies and data points and confirmed willingness to consider dedicated breakout discussions on specific topics if needed.

Marén Ulrike Koban (EuropaBio) specifically highlighted the challenge of accessing information, both general, and regarding trial participation, and expressed the hope that the group could collaborate to identify actionable steps to address this issue. In addition, she noted the importance for ACT-EU to support the facilitation of clinical trials for innovative products to address unmet medical needs.

Melanie Carr (EMA) emphasised the group's commitment to transparency and information sharing, expressing openness to suggestions for improvement.

Francois Houyez (Eurodis) questioned whether the MSP AG input should focus on this year's ACT EU workplan, or on the future workplan. He confirmed that the ACT EU priorities were mostly aligned with those of stakeholders, however suggested that understanding different stakeholder interpretations of each priority would be important to identify more precisely where priorities are aligned. Additionally, he emphasised the importance of fostering engagement beyond information sharing, suggesting a two-way communication approach between the MSP AG representatives, and the broader MSP, and to explore new methods to engage stakeholders beyond existing tools.

Peter Arlett (EMA) provided insights on the ongoing work in 2024 and suggested that if stakeholders identify a blind spot in the current plan as a top priority, the workplan activities could be reprioritized accordingly. Overall, the focus is on shaping the future plan, noting that many activities will span over a number of years. The idea of exploring new engagement tools, including the use of new technologies for more interactive stakeholder engagement, was underlined as an area the MSP AG could advise on.

Faiez Zannad (ESC) raised a query regarding potential alignment with the World Health Organization (WHO) global initiative on strengthening clinical trials, seeking synergies or collaboration between the initiatives.

Ana Zanoletty (EMA) highlighted the close connection between ACT EU and the work of the WHO, noting that although the scope of the WHO activity is broader in nature, they are supportive of the progress of ACT EU in Europe. She also mentioned the efforts to identify synergies between the two groups.

Marianne Lunzer (AGES) acknowledged the awareness of the similarities in problems and proposed solutions between the initiatives, emphasizing the close contact between the groups.

Peter Arlett (EMA) provided clarification on the distinct responsibilities between ACT EU and WHO. While WHO is a convenor that provides recommendations and guidelines on diverse topics, with some individual projects, ACT EU focuses on the EU jurisdiction, currently with a focus on the implementation of the clinical trials regulation and activities which will improve the EU landscape. The activities will be mostly aligned, but the work of ACT EU has to be seen through the lens of EU stakeholders. The possibility of inviting WHO for specific discussions within the advisory group, enabling collaboration with international partners was confirmed in line with the group's mandate.

Nikos Dedes (EATG) addressed the importance of the ACT EU mapping and governance activity outlined, noting the existence of other EU groups such as the Clinical Trials Coordination Group. The need, especially for newer members, to understand the relationships between multiple EU clinical trials groups was underlined, suggesting that the mapping could be provided earlier than envisaged by the workplan (Q3 2024) or to provide a compilation of key documents to facilitate review of the full architecture.

In response, Ana Zanoletty (EMA) acknowledged his point and informed that an overview of the landscape will be available sooner than originally envisaged. She highlighted the importance of providing documentation related to group mandates, roles, and responsibilities, as well as addressing changes in the landscape due to the recent creation of the EU ethics platform (MedEthicsEU).

Tarec Christoffer El-Galaly (EHA) emphasised the importance of using case studies to drive solutions, and the need to have sufficient time to discuss these both within the relevant organisations and in the advisory group. The need for alignment on high-level solutions for common problems that all groups can accept was pointed out, recognizing that not all individual preferences may be fully met for a given solution.

Melanie Carr (EMA) agreed that members of the group should act as "amplifiers", involving their organizations in the discussion and contributing to the development of concrete actions and solutions.

4. Membership of the MSP AG - tour de table

Representatives from thirty-two (32) stakeholder organisations attended the meeting. Each participant introduced themselves, briefly discussing their activities and those of their respective organizations.

During the tour de table the ethics committee representatives and ACT EU regulatory partners also

had the opportunity to introduce themselves.

5. Mandate and rules of procedure of the MSP AG

Ana Zanoletty (EMA) presented the mandate and rules of procedure of the MSP AG. The aim of the presentation was to inform the MSP AG of the key points of the document and seek endorsement by the group (see presentation).

Tarec Christoffer El-Galaly (EHA) highlighted the importance of timely meeting dates for attendance planning.

Lada Leyens (EFPIA) raised a comment regarding the exclusion of commercial sponsors from the nomination process for stakeholder co-chair and called for reconsideration of this position or an alternative solution (e.g. 3rd co-chair).

Melanie Carr (EMA) emphasised that the composition of the advisory group aimed for a multi-stakeholder approach, with industry playing a crucial role in the group's functioning. She clarified that the group was not merely an information forum, but will advise and shape the work program, as well helping to set the ACT EU priorities. Melanie further explained that building on the EMA framework for stakeholder engagement and individual frameworks for interaction, and with the aim of enhancing the understanding of medicines regulation and the role that non-commercial stakeholders play in that process, priority is given to non-commercial stakeholders in the co-chair role. She assured industry stakeholders of the group's commitment to inclusivity and its consultative approach to setting agendas. She expressed confidence that industry stakeholders would feel fully involved and reassured about governance aspects once the group was operational and expressed openness to discuss further in future if concerns remained.

Lada Leyens (EFPIA) supported Melanie's explanation.

Faiez Zannad (ESC) inquired about the focus of the group, particularly on medical devices.

Peter Arlett (EMA) clarified that the primary focus is on clinical trials on medicines under the Clinical Trials Regulation (CTR); the pain points existing at the interface of the CTR with the medical device and in vitro diagnostics regulations were acknowledged and may be something that the group can focus on.

Isabelle Clamou (EC) confirmed the strong link between these areas, explaining however, that due to differences in implementation governance for the medical device regulation (MDR) and in vitro diagnostics regulation (IVDR), they do not fall directly under ACT EU. She further elaborated on the COMBINE project which is analysing the issues at the interface of these regulations, and which will soon publish an analysis report. Building on this report, the MSP AG will be instrumental for the development of solutions and their implementation.

Ana Zanoletty (EMA) confirmed the intention to discuss this further during the annual meeting of the MSP.

Martin O'Kane (EFPIA) sought clarification on how advice from the group would be used and how feedback would be provided.

Ana Zanoletty (EMA) explained that in the upcoming months, stakeholders should reflect on their priorities and suggested holding a meeting early in the summer to consolidate these priorities. She

mentioned that a similar process occurred last year without an advisory group, where stakeholder priorities were discussed in a kick-off meeting and fed back to the ACT EU steering group. She outlined the advisory process, stating that stakeholders' recommendations would be channelled directly to the steering group, with feedback provided on program development. She emphasised the importance of stakeholder input in various areas, including workshops and expert involvement. She anticipated extensive two-way communication, with 3 or 4 large meetings annually and smaller, ad hoc meetings to dive into specific topics. She assured stakeholders that their advice would be considered, with regular feedback on its implementation provided to them.

Martin O'Kane (EFPIA) reiterated the point regarding involving commercial sponsors as co-chairs in the future, and questioned whether the mandate could be updated to reflect possible review of the governance in the future.

Melanie Carr (EMA) agreed to capture the comments from EFPIA and her response in the minutes of the meeting as a solution. Melanie then sought agreement to adopt the mandate and rules of procedure, or to provide further time for written consultation if needed.

No further comments were received on the mandate and rules of procedure, which were considered adopted by consensus.

6. Launch of call for stakeholder co-chair

Melanie Carr (EMA) launched the official call for expressions of interest for the stakeholder co-chair, outlining the process and underscoring the significance of the role. She detailed the responsibilities of the stakeholder co-chair as per the mandate and rules of procedure, and the criteria for screening of nominations in line with Annex 4 of the document.

Nominations should be sent by 24 April 2024, to the MSP AG Secretariat (msp-agsecretariat@ema.europa.eu), including a brief resume outlining background and experience, and a motivation letter.

The ACT EU Steering Group will appoint the stakeholder co-chair on 3 May 2024.

The organisation to which the new Co-chair is affiliated will be requested to nominate a new representative to replace the Co-chair within the advisory group.

Tarec Christoffer El-Galaly (EHA) inquired whether the stakeholder co-chair would receive support from the secretariat in managing minutes, scheduling meetings, and preparing agendas.

Ana Zanoletty (EMA) confirmed that this would be the case.

7. Conclusions and next steps – forward planning of the meetings

Ornela Ademi (EMA) concluded the meeting by summarising the outcomes and outlining the next steps.

An information session for the ad hoc representatives of the MSP AG is scheduled for 11 April 2024, with the regulatory co-chair participating.

The MSP AG meeting calendar for the 2024-2025 period is currently under preparation. Once confirmed by the co-chairs, a written consultation with the permanent representatives of the MSP AG will be launched to adopt the dates.

To close the meeting Melanie Carr (EMA) provided a summary of the key points raised during the discussion, and Maria Lamas (AEMPS) provided her closing remarks, thanking all the participants for their contributions and strong engagement with the ACT EU initiative.