

Steering Board of the Critical Medicines Alliance

Second Meeting – 30 May 2024

Minutes

Participants:

Chair: Health Emergency Preparedness and Response Authority (HERA)

Member States:

Belgium

- Federal Agency for Medicines and Health Products (FAMHP)
- Flanders Innovation & Entrepreneurship (VLAIO)

Spain

- Spanish Agency of Medicines and Health Products (AEMPS)
- Ministry of Industry

Hungary

- National Centre for Public Health and Pharmacy
- Ministry of Economy

Industry:

- European Federation of Pharmaceutical Industries Associations (EFPIA)
- Association of the European Self-Care Industry (AESGP)
- European Fine Chemicals Group (EFCG)
- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- Medicines for Europe (MFE)

Civil Society:

- European Patient Forum (EPF)
- Pharmaceutical Group of the European Union (PGEU)

EMA:

- European Medicines Agency (EMA)
- Executive Steering Group on Shortages and safety of Medicinal Products (MSSG)

European Commission:

- Health Emergency Preparedness and Response Authority (HERA)
- Directorate General for Health and Food Safety (DG SANTE)
- Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)
- Secretariat General

1. Election of the Vice-Chairs of the Steering Board

BE (FAMPH) and MFE representatives had presented themselves as candidates prior to the meeting. They were unanimously elected Vice-Chairs of the Steering Board.

Members of the Steering Board are kindly asked to keep them in copy of any communication addressed to the Secretariat.

2. Adoption of the Rules of Procedure of the Steering Board

AEMPS requested that Rules of Procedure be amended to clarify the appointment and role of alternate members. Other members supported that change, and the Rules of Procedures of the Steering Board were subsequently unanimously adopted.

3. Discussion on Working Group 1 focusing on strengthening manufacturing capacities in the EU

HERA presented the composition of Working Group 1 and the proposed topics to be covered, on the basis of inputs from the members of the Steering Board and of Working Group 1.

EFCG asked about the involvement of the Steering Board in the Working Group, and whether additional topics were foreseen. The Chair answered that the Steering Board was to be informed of the progresses made in the Working Groups. The technical discussions should however take place in the Working Groups, while the Steering Board's mandate is to steer the work of the Alliance. HERA explained that members of the Steering Board and of the Working Groups would be able to comment on the list of topics to be tackled by the Working Groups.

EUCOPE requested that members of the Steering Board are invited to the Working Groups in order to coordinate internally in their own organisations. The Chair suggested for members of the Steering Board be in copy of all documents communicated to the Working Groups but not for professional association to be represented through their secretariat in working groups. The Steering Board agreed with that proposal.

MFE raised the idea to prioritise topics to be tackled by the Working Groups. The Chair supported that idea and encouraged members of the Steering Board to provide input on topics they consider as priorities.

4. Discussion on Working Group 2 focusing the diversification of supply chain, international partnerships, and cooperation

HERA presented the composition of Working Group 2 and the proposed topics to be covered, on the basis of inputs from the members of the Steering Board and of Working Group 2.

MFE underlined the need to consider major global producing countries and determining which among them are potential partners. In the event of a crisis, the EU would indeed need to care for EU citizens, while at the same time delivering medicines to the rest of the World. MFE considers that there is still no sufficient data to find a balance between those two necessities. The Chair agreed, reaffirming the need to build honest cooperation with EU partners, while being aware of the necessity to be ready for complete autonomy in case of a major health emergency.

5. Presentation on the Critical Medicines Study

HERA presented the context of the study, its objectives, timeline, and deliverables.

6. Next steps and AOB

The Chair presented the timeline for the coming months for both Working Groups and noted the need for an additional meeting in July before the summer break.