

13 March 2025 EMA/35247/2025¹ - Adopted Emergency Task Force Management Board

Composition of the Emergency Task Force (ETF) for preparedness

1. Introduction

The Regulation (EU) No 2022/123 (hereinafter 'the Regulation') was adopted on 25 January 2022. Article 15 of the regulation establishes the Emergency Task Force (ETF) as part of the European Medicines Agency (EMA) and defines its tasks and composition.

Article 15(1) also establishes that the ETF should be convened during a public health emergency as well as for preparedness. At the present time a new² Public Health Emergency of International Concern (Mpox) has been declared by the World Health Organisation (WHO) on 14 August 2024³. As Mpox is not a declared emergency in the EU/EEA by the European Commission, the ETF continues its activities in preparedness mode as of May 2023.

Articles 15(3) and 15(4) of the Regulation specify the composition of the ETF and its approval by the Management Board (MB) of the Agency. The composition presented in this document and the list of members proposed are based on the expertise required to prepare for future potential public health emergencies of biological origin, i.e. the type of public health emergency most likely to occur based on past experience.

The composition of the ETF set out in this document builds on the experience with the membership for the COVID-19 and Mpox public health emergencies. Both are viral diseases that require specific expertise including on infectious diseases, vaccinology, anti-virals, clinical trials, virology, immunology and immunotherapy, which remains applicable in the current context of preparedness considering the vast majority of health threats are of biological origin. Additional ad-hoc experts will be involved to cover for activities related to other potential threats of chemical, nuclear or radiation origin.

Articles 15(3) and 15(5) of the Regulation foresee that additional experts and observers to the ETF are nominated on an ad hoc basis at the discretion of the ETF co-Chairs, and this process is defined in the Rules of Procedure.

³ https://www.who.int/emergencies/situations/mpox-outbreak; https://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern



Replaces EMA/341319/2023 "Composition of the Emergency Task Force (ETF) for preparedness" of 21 July 2023.

² A Public Health Emergency of International Concern on the international spread of poliovirus was declared on 5 May 2014 to allow specific international measures to be put in place (<u>Public Health Emergency status – GPEI</u>). It remains ongoing subject to regular revision.

Following the approval of the ETF composition by the Management Board in March 2022 (EMA/555794/2021) and a favourable opinion on the Rules of Procedures by the Management Board and by the European Commission, the Emergency Task Force became fully operational pursuant to Regulation 2022/123 on 22 April 2022.

2. Composition of the ETF in accordance with Regulation (EU) 2022/123

The ETF is co-chaired by a staff member of the Agency appointed by the Executive Director of the Agency and by the Chair or vice-Chair of the Committee for Human Medicinal Products (CHMP). The Chair and the vice-chair of the CHMP have agreed who will be the co-chair of the ETF and have communicated this to the Executive Director of the Agency. Whichever is not the co-Chair may then be a member of the ETF.

To ensure balanced representation and to keep membership expertise-based and agile, the ETF, in addition to the co-chairs, is composed of the following members:

- 1) Chair of the Pharmacovigilance Risk Assessment Committee (PRAC); chair of the Paediatric Committee (PDCO);
- 2) The following number of representatives from the following committees in addition to the chairs: one from the PRAC, five from the CHMP and one from PDCO (or two in replacement of the PDCO chair).
- 3) The following number of representatives of the following Working Parties (WPs): six from the Vaccine WP (VWP), five from the Infectious Disease WP (IDWP), two from the Scientific Advice WP (SAWP), one from the Methodology WP (MWP), one from the Health Care Professional WP (HCPWP), and one from the Patients and Consumers WP (PCWP).
- 4) Three staff members of the Agency with expertise relevant to the public health emergency nominated by the Executive Director of the Agency.
- 5) One representative of the Coordination Group for Mutual Recognition and Decentralised Procedures Human (CMDh).
- 6) One representatives of the Clinical Trials Coordination and Advisory Group (CTAG).
- 7) Two clinical trial experts proposed by Clinical Trials Coordination Group (CTCG) representing national competent authorities for medicinal products.

The members of the ETF are in principle appointed for the term of the public health emergency, if one is ongoing, or for activities in preparedness when there are no declared emergencies.

The nomination of the ETF members listed in section 4 of this document was agreed with the entities they represent.

3. Updates to the ETF composition related to preparedness activities

The existing ETF composition as described in section 2 of this document for the COVID-19 pandemic and the Mpox public health emergency is considered to have the necessary expertise for handling activities related to preparedness. The number of experts has been updated in line with the needs of the group. However, the breadth of activities on preparedness still requires a substantial participation of different types of expertise, which will be called on an *ad hoc* basis.

4. Co-chairs and list of members for the ETF for preparedness

Based on the composition set out in section 2, and with reference to the required update stated in section 3, the following ETF co-chairs and members are appointed for handling preparedness activities:

Co-chairs

Name	Affiliation
Marco Cavaleri	EMA
Bruno Sepodes	CHMP chair

Members

Name	Affiliation
1. Jean-Michel Race	CHMP alternate
2. Jan Müller-Berghaus	CHMP co-opted member and CAT member
3. Filip Josephson	CHMP alternate
4. Sol Ruiz	CHMP co-opted member and VWP vice-chair
5. Kristina Nadrah	CHMP member
6. Ulla Wändel Liminga	PRAC chair
7. Jean-Michel Dogne	PRAC member
8. Yuansheng Sun	PDCO alternate
9. Sara Galluzzo	PDCO and SAWP member
10. Ewa Balkowiec-Iskra	SAWP and CHMP member
11. Anders Lignell	SAWP alternate and IDWP member
12. Maria Jesus Fernandez Cortizo	IDWP chair
13. Regine Lehnert	On behalf of IDWP
14. Nathalie Morgensztejn	IDWP member
15. Maja Sommerfelt Grønvold	IDWP and VWP member
16. Ellen Pantke	On behalf of IDWP
17. Mair Powell	VWP chair, IDWP and SAWP member
18. Mikael Andersson	VWP member and SAWP alternate
19. Eleonora Wijnans	VWP member
20. Charlotta Bergquist	VWP member

Name	Affiliation
21. Martin Oleksiewicz	VWP member and SAWP alternate
22. Edwige Haelterman	On behalf of VWP
23. Florian Klinglmueller	MWP member
24. Anita Simonds	HCPWP member
25. Manuel Arellano	PCWP member
26. Rui Pedro da Costa Vilar	CMDh alternate
27. Ann Marie Janson Lang	CTAG member
28. Thomas Sudhop	Clinical trial expert on behalf of CTCG
29. Agnieszka Dzierwa	Clinical trial expert on behalf of CTCG
30. Manuela Mura	EMA staff member
31. Eugenia Di Meco	EMA staff member
32. Radu Botgros	EMA staff member