



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2023
EMA/233390/2023¹ – 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 the two ongoing Public Health Emergencies of International Concern (COVID-19 pandemic and Mpox) have been declared over by the World Health Organisation (WHO) on 5 May² 2023 and on 11 May³ 2023 respectively.

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 Monkeypox 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.

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

¹ Replaces EMA/687738/2022 "Composition of the Emergency Task Force (ETF) for the therapeutic response to the COVID-19 and Mpox PHEICs" of 8 November 2022.

² [https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)

³ [https://www.who.int/news/item/11-05-2023-fifth-meeting-of-the-international-health-regulations-\(2005\)-\(ihr\)-emergency-committee-on-the-multi-country-outbreak-of-monkeypox-\(mpox\)](https://www.who.int/news/item/11-05-2023-fifth-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-on-the-multi-country-outbreak-of-monkeypox-(mpox))



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: two from the PRAC, four 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): 6 from the Vaccine WP (VWP), 4 from the Infectious Disease WP (IDWP), 1 from the Scientific Advice WP (SAWP), 1 from the Methodology WP (MWP), 1 from the Health Care Professional WP (HCPWP), and 1 from the Patients and Consumers WP (PCWP).
- 4) Two 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 reduced in line with the decreased workload of the group as compared to the just concluded emergency status. 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, following adoption of the ETF for COVID-19 by the Management Board in March 2022 and Mpox in August 2022, and with reference to the required update stated in section 3, the following ETF co-chairs and members are proposed for handling preparedness activities:

Co-chairs

Name	Affiliation
Marco Cavaleri	EMA
Bruno Sepodes	CHMP vice-chair

Members

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

Name	Affiliation
19. Agustin Portela	VWP member
20. Edwige Haelterman	On behalf of VWP
21. Florian Klingmueller	MWP member
22. Anita Simonds	HCPWP member
23. Jose Drabwell	PCWP member
24. Rui Pedro da Costa Vilar	CMDh member
25. Ann Marie Janson Lang	CTAG member
26. Thomas Sudhop	Clinical trial expert on behalf of CTCG
27. Agnieszka Dzierwa	Clinical trial expert on behalf of CTCG
28. Manuela Mura	EMA staff member
29. Eugenia Di Meco	EMA staff member