

# Composition of the Emergency Task Force (ETF) for the therapeutic response to the COVID-19 and Monkeypox Public Health Emergencies

## 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. At the present time a Public Health Emergency of International Concern (COVID-19 pandemic) has been declared by the World Health Organisation (WHO) on 30 January 2020 and has been further confirmed on 13 January 2022. In addition, on 23 July 2022, the WHO declared the monkeypox outbreak a Public Health Emergency of International Concern.

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 for the COVID-19 and Monkeypox public health emergencies. Both are viral diseases which require specific expertise including on infectious diseases, vaccinology, anti-virals, clinical trials, virology, immunology and immunotherapy.

The composition of the ETF set out in this document builds on the experience with the membership of the COVID-19 EMA Pandemic Task Force that was initially established for COVID-19 in March 2020 (COVID-ETF) following the pandemic declaration by WHO.

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 and by the European Commission, the Emergency Task Force became fully operational pursuant to Regulation 2022/123 on 22 April 2022.

<sup>1</sup> Replaces EMA/555794/2021 "Composition of the Emergency Task Force (ETF) for the therapeutic response to the COVID-19 pandemic" of 30 August 2022.



Following the WHO's declaration on 23 July 2022, the ETF is now also mandated to handle activities related to the Monkeypox emergency as well. See sections 3 and 4 for new information related to the impact on the composition of the ETF.

## **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.

In view of the specific needs of the ongoing COVID-19 pandemic, 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 and vice-chair the Pharmacovigilance Risk Assessment Committee (PRAC); chair or vice-chair of the CHMP; chair of the Paediatric Committee (PDCO);
- 2) The following number of representatives from the following committees in addition to the (vice)chairs: three from the PRAC, three from the CHMP and two from PDCO (or three in replacement of the PDCO chair).
- 3) The following number of representatives of the following Working Parties (WPs): 6 from the Vaccine WP (VWP), 3 from the Infectious Disease WP (IDWP), 1 from the Biologics WP (BWP), 2 from the Scientific Advice WP (SAWP), 1 from the Biostatistics WP (BSWP), 2 from the Health Care Professional WP (HCPWP), 2 from the Patients and Consumers WP (PCWP) and 1 from the GCP Inspection Working Group (GCP IWG).
- 4) Two staff members of the Agency with expertise relevant to the public health emergency nominated by the Executive Director of the Agency.
- 5) Two representatives of the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).
- 6) Two 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 appointed for the term of the public health emergency.

The nomination of the ETF members listed in section 4 of this document was based on the membership of the COVID-19 EMA Pandemic Task Force (COVID-ETF) convened as of March 2020 under its previous mandate to ensure continuity of expertise and were agreed with the entities they represent.

## **3. Updates to the ETF composition related to the therapeutic response to the monkeypox public health emergency**

The existing ETF composition as described in section 2 of this document for the COVID-19 pandemic is considered to have the necessary expertise for handling activities related to the monkeypox emergency too.

## 4. Co-chairs and list of members for the ETF for COVID-19 and monkeypox

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 with reference to the required update stated in section 3, the following ETF co-chairs and members are proposed for the COVID-19 and monkeypox public health emergencies:

### 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 and IDWP member
4. Sol Ruiz	CHMP co-opted member for biologicals and BWP chair
5. Sabine Strauss	PRAC chair
6. Martin Huber	PRAC vice-chair
7. Jean-Michel Dogne	PRAC member
8. Ulla Wändel Liminga	PRAC member
9. Yuansheng Sun	PDCO alternate
10. Sara Galluzzo	PDCO member
11. Nanna Borup Johansen	PDCO member
12. Ewa Balkowiec-Iskra	SAWP and CHMP member
13. Ingrid Schellens	SAWP member
14. Maria Jesus Fernandez Cortizo	IDWP chair
15. Regine Lehnert	IDWP member
16. Nathalie Morgensztejn	IDWP member
17. Mair Powell	VWP chair and IDWP member
18. Mikael Andersson	VWP member
19. Eleonora Wijnans	VWP member

Name	Affiliation
20. Charlotta Bergquist	VWP member
21. Agustin Portela	VWP member
22. Edwige Haelterman	On behalf of VWP
23. Ralf Wagner	On behalf of BWP
24. Florian Klinglmueller	On behalf of BSWP
25. Anita Simonds	HCPWP member
26. Tiago Villanueva	HCPWP member
27. Francois Houyez	PCWP member
28. Jose Drabwell	PCWP member
29. Tiina Johanna Holmberg	GCP IWG
30. Rui Pedro da Costa Vilar	CMDh member
31. Janet König	On behalf of CMDh (clinical expert)
32. Ann Marie Janson Lang	CTAG member
33. Thomas Sudhop	Clinical trial expert on behalf of CTCG
34. Nomination awaited	Clinical trial expert on behalf of CTCG
35. Manuela Mura	EMA staff member
36. Eugenia Di Meco	EMA staff member