



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 March 2022
EMA/555794/2021 - Adopted
Emergency Task Force

Composition of the Emergency Task Force (ETF) for the therapeutic response to the COVID-19 pandemic

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.

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 pandemic. COVID-19 is a viral disease which requires specific expertise including on infectious diseases, vaccinology, anti-virals, clinical trials, virology, immunology and immunotherapy.

The proposed composition of the ETF set out in this document builds on the experience with the existing membership of the COVID-19 EMA Pandemic Task Force that was 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 will be defined in the Rules of Procedure.

Following the approval of the composition by the Management Board and a favourable opinion on the Rules of Procedures by the Management Board and by the European Commission, the Emergency Task Force will become fully operational pursuant to Regulation 2022/123. The existing COVID-19 EMA Pandemic Task Force (COVID-ETF) will continue to address the ongoing emergency until the Emergency Task Force becomes fully operational as set out above.



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

The ETF is chaired by a staff member of the Agency appointed by the Executive Director of the Agency and co-chaired 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, should be 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.
- 3) The following number of representatives of the following Working Parties (WPs): 7 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 nominations of the ETF members listed in section 3 of this document have been agreed with the entities they represent. The composition is 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. The members of the ETF are appointed for the term of the public health emergency.

The rules for the review and update of the ETF membership will be addressed in the Rules of Procedure, which this newly composed ETF will establish as its first activity.

3. Co-chairs and list of members for the ETF

Based on section 2, the following ETF co-chairs and members were nominated by the different entities specifically for the COVID-19 pandemic:

Co-chairs

Name	Affiliation
Marco Cavaleri	EMA

Name	Affiliation
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. Daniel Morales	PRAC member (independent scientific expert)
10. Yuansheng Sun	PDCO alternate
11. Sara Galluzzo	PDCO member
12. Eva Agurell	PDCO member
13. Ewa Balkowiec-Iskra	SAWP and CHMP member
14. Ingrid Schellens	SAWP member
15. Maria Jesus Fernandez Cortizo	IDWP chair
16. Regine Lehnert	IDWP member
17. Nathalie Morgensztejn	IDWP member
18. Mair Powell	VWP chair and IDWP member
19. Mikael Andersson	VWP member
20. Eleonora Wijnans	VWP member
21. Charlotta Bergquist	VWP member
22. Agustin Portela	VWP member
23. Edwige Haelterman	On behalf of VWP
24. Svein Rune Andersen	On behalf of VWP
25. Ralf Wagner	On behalf of BWP

Name	Affiliation
26. Florian Klinglmueller	On behalf of BSWP
27. Anita Simonds	HCPWP member
28. Tiago Villanueva	HCPWP member
29. Francois Houyez	PCWP member
30. Jose Drabwell	PCWP member
31. Tiina Johanna Holmberg	GCP IWG
32. Rui Pedro da Costa Vilar	CMDh member
33. Janet König	On behalf of CMDh (clinical expert)
34. Ann Marie Janson Lang	CTAG member
35. Frits Rosendaal	Clinical trial expert on behalf of CTCG
36. Thomas Sudhop	Clinical trial expert on behalf of CTCG
37. Manuela Mura	EMA staff member
38. Eugenia Di Meo	EMA staff member