



VIA MAIL
SITO sì
IFO sì

**Ai Presidenti degli Ordini
dei farmacisti**

**Ai Componenti
il Comitato Centrale**

Loro Sedi

Si informa che l'Agenzia Europea dei Medicinali (EMA) ha completato e pubblicato la composizione e gli obiettivi della sua Task Force contro la pandemia da COVID-19, denominata COVID-ETF (cfr. all. 1), che ha lo scopo di assistere gli Stati membri e la Commissione Europea nella gestione dei piani di sviluppo e delle procedure di autorizzazione e monitoraggio della sicurezza delle terapie e dei vaccini destinati al trattamento o alla prevenzione del COVID-19.

Obiettivo principale è quello di far ricorso alle competenze della rete europea delle Agenzie regolatorie dei medicinali e garantire una risposta rapida e coordinata alla pandemia in corso. La COVID-ETF dovrà, tra l'altro:

- valutare i dati scientifici disponibili sui medicinali contro il COVID19 e identificare possibili farmaci promettenti;
- chiedere dati aggiuntivi agli sviluppatori e interagire preliminarmente per l'analisi di tali dati;
- offrire supporto scientifico in collaborazione con il CTFG (Clinical Trials Facilitation and Coordination Group) per facilitare gli studi clinici condotti nell'UE;
- fornire feedback sui piani di sviluppo dei medicinali per il COVID19 quando non è possibile condurre formalmente una consulenza scientifica rapida;
- fungere da consulente dello Scientific Advice Working Party (SAWP) o del Comitato per i medicinali ad uso umano (CHMP) per la consulenza scientifica formale e la valutazione dei prodotti e contribuire alle attività del Comitato per la valutazione dei rischi per la farmacovigilanza (PRAC) sulle questioni di sicurezza relative al COVID19;
- assicurare una stretta cooperazione con le parti interessate e le organizzazioni europee e internazionali.

Per ogni ulteriore approfondimento si rinvia al documento allegato.

Cordiali saluti.

Roma, 15 aprile 2020

All.1



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2020
EMA/166423/2020
Biological Health Threats and Vaccines Strategy

Mandate, objectives and rules of procedure of the COVID-19 EMA pandemic Task Force (COVID-ETF)

1. Introduction

The European Medicines Agency (EMA) is the European Union body responsible for coordinating existing scientific resources for the evaluation, supervision and pharmacovigilance of medicinal products. Within the framework of [Decision 1082/2013/EU](#) on serious cross-border threats to health, the EMA [Health Threat Plan](#) explains the principles upon which the Agency will operate in the event of an emerging health threat to humans, and describes high level process, responsibilities and desired outcomes.

One of the main objectives of the plan, among others, is to manage and coordinate the discussions on development, authorisation and surveillance of relevant medicinal products, which are under the remit of EMA, and post-authorisation follow-up of all relevant EU authorised medicinal products to be used to address the health threat. EMA has the mandate under the Health Threat plan to convene specific expert groups such as the EMA Task Force (ETF) to assist the CHMP, PRAC and PDCO or take part on behalf of the CHMP in early scientific discussions and products reviews as needed. This methodology resulted successful for a greater coordination in previous outbreaks.

In the context of the COVID19 pandemic, following a call from Member States (MSs) and European Institutions, the mandate of the ETF has been revised to adapt to the unprecedented challenges and specificities of the ongoing health threat crisis. Such challenges are represented particularly by the complexity of the disease, of which much is yet to be understood, the consequent plethora of potential or repurposed medicinal products for prophylaxis or treatment, and the need to conduct and coordinate clinical trials in a timely manner across Europe. In addition to such challenges, the capacity of the Network itself is affected by the COVID-19 outbreak, limiting its ability to channel the flow of requests.

Therefore, the composition and the objectives of the ETF have been modified in order to better support the regulatory activities and public health needs of the Member States and the European Commission during this pandemic.

2. Mandate and Objectives of the COVID-ETF

Under direction of the Committee for Medicinal Products for Human Use (CHMP) and in collaboration with other EMA Scientific Committees, the Coordination Group for Mutual Recognition and

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Decentralised Procedures – Human (CMDh), National Competent Authorities (NCAs), the Clinical Trials Facilitation and Coordination Group (CTFG) and the European Commission, in relation to vaccines, antivirals or other medicinal products intended for treatment or prevention of COVID-19:

- Review the available scientific data on COVID-19 medicinal products and identify promising candidates, including requesting data from developers and engaging with them in preliminary discussions.
- Review protocols and provide comments on development plans to manufacturers developing COVID-19 medicinal products, when formal rapid scientific advice is not feasible.
- Provide scientific support in collaboration with CTFG to facilitate clinical trials conducted in the European Union for the most promising medicinal products candidates for COVID19.
- Contribute to formal rapid or standard scientific advice procedures as advisor to Scientific Advice Working Party (SAWP)/CHMP.
- Contribute to product-related assessments acting as Peer Reviewer and as forum for discussion on the rolling data assessment.
- Contribute to the Pharmacovigilance Risk Assessment Committee (PRAC) activities on emerging pharmacovigilance issues related to COVID-19.
- Provide scientific input to EMA's committees/working parties (WPs)/CMDh and other groups as needed.
- Prepare specific scientific positions and provide input to public communications as applicable (although not responsible for drafting material).
- Interact with stakeholders and cooperate with other relevant European and International regulators and bodies as required.

The COVID-ETF is accountable to CHMP for all activities mentioned above.

3. Composition and rules of participation¹

The COVID-ETF shall be chaired by the EMA scientific lead for the COVID19 pandemic and shall comprise the following members:

- CHMP Chair/Vice-chair, Chairs of Paediatric Committee (PDCO) and Pharmacovigilance Risk Assessment Committee (PRAC).
- (Vice-)Chairperson of the following groups or a nominated alternative: Scientific Advice Working Party (SAWP), Vaccine Working Party (VWP) and Infectious Disease Working Party (IDWP) as applicable, Biologics Working Party (BWP) and Quality Working Party (QWP), Safety Working Party (SWP), Blood Product Working Party (BPWP), Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).
- 2 additional CMDh representatives.
- 2 members from the Clinical Trial Facilitation Group (CTFG)².

¹ It is important to check prior to the initiation of COVID-ETF meetings the requirements for expert nominations, declarations of interests and confidentiality undertakings to ensure compliance with policies on handling of competing interests and inter-institutional confidentiality agreements. The general principle for experts is that all experts involved in EMA activities should be included in the EMA Experts database with a valid DoI and CV. Their DoI should be evaluated prior to the involvement in the activity.

The general principles for observers are summarised in the EMA Internal Guidance on observers participating in EMA scientific meetings.

- CHMP Rapporteur and Co-rapporteur for products intended for treatment or prevention of COVID-19, as well as three CHMP peer reviewers (across all products, not per product).
- Specific experts from the rapporteurs'/peer reviewers' teams.
- A representative from Reference Member State (RMS) for products in the context of MRP/DCP and intended for treatment or prevention of COVID-19.

The Executive Director of the Agency and representatives from the European Commission shall be entitled to attend all meetings of the COVID-ETF.

The following may be invited on an ad-hoc basis as necessary:

- Members from Inspectors Working Groups (GCP IWG, PhV IWG, GMDP IWG).
- Observers from the World Health Organisation (WHO).
- Observers from the European Centre for Disease Prevention and Control (ECDC).
- Observers from the European Directorate for the Quality of Medicines (EDQM) appointed Official Medicines Control Laboratory (OMCL).³
- Observers from other international regulatory authorities with whom EMA has a confidentiality agreement.
- External experts with advisory function to COVID-ETF.

The Agency secretariat shall check that expertise in quality, non-clinical, virology, immunology and infectious diseases are included in the group or propose additional experts.

To facilitate the handling of expected virtual meetings, a restricted group of experts is envisaged. Communication to all NCAs shall be achieved by distribution of all COVID-ETF documents to all CHMP members, NCAs and Rapporteurs/coRapporteurs, as relevant.

Additional experts from the assessment team who are required for specific agenda items may still be invited as well as other additional experts for particular topics for which specific expertise is required, subject to agreement from the COVID-ETF chair.

4. Duration of activity

In principle the COVID-ETF will remain convened until the emergency/pandemic is considered over. Although meeting frequency shall be planned as far as possible, it is inevitable that ad-hoc meetings shall be arranged when required. It ceases to function when advised by CHMP (meetings however would only be arranged where necessary).

² A personal confidentiality undertaking (https://www.ema.europa.eu/en/documents/template-form/confidentiality-undertaking-observers_en.pdf) could also be required in case the CTFG observer does not belong to an EU/EEA medicines agency (e.g. Netherlands) – this should be however highly exceptional as normally all CTFG members have submitted a DoI.

³ If not already available, the participant should be requested to sign the confidentiality undertaking (https://www.ema.europa.eu/en/documents/template-form/confidentiality-undertaking-observers_en.pdf) on a personal basis since no institutional confidentiality agreements are in place with either the EDQM/ any specified OMCLs.

5. Rules of procedure

5.1. Responsibilities of COVID-ETF chairperson

The Chairperson is responsible for the scientific conduct of the business of the COVID-ETF in an efficient manner and shall in particular:

- Agree the schedule of work of the COVID-ETF together with the CHMP Chair/Vice-chair as far as possible.
- Ensure that the rules of procedure are respected.
- Ensure that at the beginning of each meeting any potential competing interest is declared and especially for virtual meetings, all experts attending the meeting have declared their presence.
- Aim to achieve consensus on issues discussed by the COVID-ETF.
- Ensure, together with the CHMP Chair/Vice-chair, the regulatory and scientific consistency of the recommendations.
- Coordinate together with the relevant Chairs and scientific secretariats the work of the COVID-ETF with that of the other relevant WPs, Committees and groups.
- Report on the activities of the COVID-ETF to the CHMP and other EMA Scientific Committees as needed.
- Inform CHMP, EMA Executive Director and European Commission of any relevant deliberations related to gathered evidence for any investigational agent for COVID-19.
- May propose to the CHMP the need for additional advisory/expert groups or meetings of parent committees to consider strategic direction to provide advice on specific pandemic questions.

The CHMP Chair shall take the role of the COVID-ETF Chairperson in his/her absence in all above mentioned responsibilities and functions.

5.2. Guarantees of independence

The members of the COVID-ETF and experts referred to above shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality.

They shall undertake to act in the public interest and in an independent manner and shall make a declaration of their financial and other interests at least on an annual basis or when new interests arise. The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMA's Policy on the handling of competing interests for scientific committees' members and experts are applicable to COVID-ETF members and experts participating in the scientific activities of the Agency.

When a member is unable to participate to a meeting or part of meeting, due to a competing interest, he/she must inform the Secretariat in advance.

All attendees of the COVID-ETF shall declare at the beginning of each meeting any specific interest, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded in the working notes of the meeting.

5.3. Code of conduct

Members of the COVID-ETF and all other attendees to the meetings shall abide by the principles set out in the European Medicines Agency Code of Conduct.

5.4. COVID-ETF secretariat

Under the authority of the Executive Director, the Agency secretariat shall provide technical, scientific and administrative support to the COVID-ETF.

6. Relationship with other WPs, committees and groups

COVID-ETF interacts with the CHMP, CMDh, PDCO, PRAC, VWP, IDWP, BWP, BPWP, QWP, PRAC, GCP IWG, GMDP IWG, PhV IWG and CTFG (or other WPs or groups as applicable depending on the type or products under discussion).

Members may also propose to the Agency/ COVID-ETF (for approval by CHMP) the need for additional advisory/expert groups or meetings of parent committees to consider strategic direction.

7. General provisions

The Members of the COVID-ETF, as well as experts and all observers shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by the Agency policy on confidentiality.

When participating in international or other fora on behalf of the EMA/CHMP or other Committees or groups, COVID-ETF members shall follow the conditions described in the relevant document:

https://www.ema.europa.eu/en/documents/other/policy-scientific-publication-representation-european-medicines-agency-scientific-committees-their_en.pdf