21 April 2022
EMA/336551/2021
Emergency Task Force, Adopted version

Rules of procedure of the Emergency Task Force (ETF)

1. General Considerations

The ETF is a multidisciplinary expert group established by Regulation (EU) No 2022/123 (hereinafter "the Regulation") within the European Medicines Agency (hereinafter 'the Agency') in preparation for and during a health emergency to provide scientific advice and to review scientific data on medicinal products targeting the emergency, to provide recommendations with regards to the use of such medicinal products and to provide scientific support to facilitate clinical trials for such medicinal products.

It includes the co-chairs in addition to a number of members who shall be nominated based on expertise and convened as defined in these Rules of Procedures. The ETF shall perform its tasks as an advisory and support body separate from, and without prejudice to, the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the medicinal products concerned and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products.

Article 55 of Regulation (EC) No 726/2004 of 30 April 2004 establishes the European Medicines Agency with the responsibility for coordinating the existing scientific resources put at its disposal by Member States (MSs) for the evaluation, supervision and pharmacovigilance of medicinal products.

Article 15 of Regulation (EU) No 2022/123 of 25 January 2022 establishes the Emergency Task Force (ETF) within the Agency.

During public health emergencies, the Emergency Task Force shall undertake the tasks listed in Article 15(2) of Regulation 2022/123.

The Emergency Task Force (ETF),

Having regard to Article 15(6) of Regulation (EU) 2022/123,

Having consulted the European Commission and the Management Board of the Agency on the basis of Article 15(6) of Regulation (EU) 2022/123,

Have adopted the following Rules of Procedure:

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Rules of Procedure

Composition

Article 1 - Members

1) The ETF is chaired by a representative of the Agency, and co-chaired by the (vice)chairperson of the Committee for Medicinal Products for Human Use (CHMP) (hereinafter referred to as the co-chairs of the ETF).

2) The membership of the ETF should be based on necessary expertise and its operation agile in order to ensure effective scientific debate and timely conclusions.

3) In addition to the Agency chair and CHMP co-chair, the ETF shall be composed of:

   - chairs or vice-chairs, or both, of the relevant scientific committees of the Agency;

   - other representatives of relevant scientific committees and working parties of the Agency, including representatives of the Patients and Consumers Working Party (PCWP) and the Healthcare Professional Working Party (HCPWP);

   - staff members of the Agency;

   - representatives of the coordination group established in accordance with Article 27 of Directive 2001/83/EC ('CMDh');

   - representatives of the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014 ('CTAG');

   - other clinical trial experts representing national competent authorities for medicinal products.

4) The co-chairs of the ETF will propose which scientific committees and working parties of the Agency should be invited to nominate representatives and how many representatives of each should be included in the ETF, taking into account the specific expertise relevant for the therapeutic response to the public health emergency. The entities concerned will be invited to nominate their representatives accordingly.

5) The proposed composition of the ETF is presented by the Agency to the Management Board for approval taking into account the specific expertise relevant for the therapeutic response to the public health emergency concerned.

6) The composition may be reviewed and adapted whenever needed, at the initiative of the ETF co-chairs and as approved by the Management Board. The composition will be reviewed when the ETF is called to prepare for or following declaration of a public health emergency and may be updated as needed during a public health emergency. After a public health emergency is declared over, the ETF co-chairs will revise the specific ETF composed for that public health emergency. In preparation for public health emergencies, the ETF co-chairs will propose the composition for an ETF to develop the preparatory measures (refer to Article 6 of this Rules of Procedure). After nomination by the different entities in line with the co-chairs indication, the Management Board will endorse the new composition.

7) In the event that an additional public health emergency is declared whilst one is still ongoing, the activities of the ETF related to the new emergency may need to be supported by additional expertise and resources depending on the nature of the threat. The co-chairs will review the current membership and consider the need to propose new members or invite additional *ad hoc* experts.

Article 2 – Additional experts, observers and other stakeholders

1) Members of the scientific committees of the Agency such as CHMP and PRAC are entitled to attend meetings of the ETF. The CHMP and PRAC Rapporteurs, once appointed, of the products intended to address the public health emergency will be invited to attend the relevant meetings of the ETF.

2) External experts may be appointed to the ETF as necessary on an *ad hoc* basis. The need to appoint such external experts shall be identified by the co-chairs, who will make a proposal to ETF for agreement. Such experts shall have proven experience in their field of expertise and be included in the European experts database. External experts with relevant expertise, including in veterinary science, may also be appointed in the cases referred to in Article 5(3) of the Regulation such as public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health.

3) Representatives of other Union bodies and agencies shall be invited on an *ad hoc* basis, as necessary, to participate in the work of the ETF, especially in the cases referred to in Article 5(3) of the Regulation as mentioned above.

4) The Executive Director of the Agency or the representative of the Executive Director, as well as representatives of the European Commission and of the Management Board of the Agency are entitled to attend all meetings of the ETF.

5) The ETF co-chairs may invite other representatives of MSs, members of scientific committees and working parties of the Agency, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, product developers, clinical trial sponsors, representatives of clinical trial networks, independent clinical trial experts and researchers, and representatives of healthcare professionals, patients and consumers to attend its meetings as observers, as deemed appropriate and necessary by the co-chairs.

6) For the purpose of regulatory cooperation, and within the framework of confidentiality arrangements where required depending on the topic, representatives from non-EEA regulatory authorities such as World Health Organization, third countries and international scientific organisations may be invited by the co-chairs to participate as observers to the ETF meetings for specific topics on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergency, as necessary.

Responsibilities of chairpersons

Article 3

The co-chairs, supported by the ETF secretariat, are responsible for the management of the ETF activities and shall in particular:

a) Advise the Agency on the proposed composition of the ETF or changes to it for submission to the Management Board of the Agency for approval.

b) In consultation with ETF members, plan the work of the ETF meetings and decide on the need for attendance of other experts or observers as per Article 2 of this Rules of Procedure.

c) Monitor that the rules of procedure are respected.

d) Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the ETF, and, especially for virtual meetings, that all persons attending the meeting have declared their presence.

e) Chair the discussions of the ETF meetings and aim to achieve consensus on issues discussed by the ETF.

f) Ensure the regulatory and scientific consistency of ETF outputs where appropriate.

g) Coordinate the work of the ETF with that of other relevant scientific committees, working parties, and scientific advisory groups of the Agency.

h) Inform the CHMP and other scientific committees of the Agency regarding the activities of the ETF and the status of the health threat or public health emergency on a regular basis.

i) May propose to the scientific committees of the Agency the need for additional advisory/expert groups or meetings of the committees to consider strategic directions or to provide advice on specific questions related to the public health emergency.

j) At least one of the co-chairs must always attend the ETF meetings. In case of non-attendance due to causes of force majeure, an acting chair shall be designated on an *ad hoc* basis at the start of the meeting by the members present.

ETF coordinator

Article 4

1) An ETF coordinator is appointed among the members of the ETF to lead the scientific assessment required in the context of a procedure of the ETF, as specified under Article 5 of these Rules of Procedure.

2) The role of the coordinator is to perform the scientific evaluation and to draft a report according to the timetable agreed for the procedure, taking into account the public health need and where applicable the timeframe laid down in the Regulation.

3) ETF coordinators may be supported by experts from national competent authorities, the Agency or other external experts with relevant expertise. The names, roles and affiliations of these experts shall be notified to the ETF Secretariat and they shall be included in the European experts list when it is proposed that they attend ETF meetings.

Procedures and tasks under the ETF responsibility

The ETF shall undertake the following procedures and tasks during a declared public health emergency and as applicable for preparedness for an emerging public health emergency.

Article 5 - Procedures

1. Scientific advice (Articles 15(2)(a) of the Regulation)

    a) The ETF shall provide scientific advice on the development of medicinal products with the potential to treat, prevent or diagnose the public health emergency.

    b) The ETF shall appoint a coordinator to perform the assessment of the scientific advice application.

    c) The ETF may request data from product developers and engage with them in preliminary discussions, as applicable.

d) Scientific advice procedures may need to be accelerated based on the emergency of the situation, on the status of development of the specific medicine and its potential to address the unmet medical need.

e) The advice shall be finalised by the ETF, endorsed by the CHMP and the final advice shall be sent to product developers within the agreed timetable.

2. Scientific advice on clinical trials or clinical trial protocols (Article 16 of the Regulation)

    a. The ETF shall provide scientific advice on the main aspects of clinical trials and clinical trial protocols for medicinal products with the potential to treat, prevent or diagnose the public health emergency.

    b. The ETF shall appoint a coordinator to perform the scientific assessment of the scientific advice application.

    c. In the preparation of the scientific advice, the ETF shall involve representatives of the MSs with clinical trial expertise, in particular in cases where an application for authorisation of a clinical trial is submitted or is intended to be submitted. In such cases, the Member State(s) where the clinical trial application will be assessed will be informed of the request for scientific advice. In general, the reporting MS, where known, and at least one of the MSs concerned, if applicable, will be invited.

    d. The ETF may request data from product developers and engage with them in preliminary discussions, as applicable.

    e. The advice shall be finalised by the ETF and endorsed by the CHMP and the final advice shall be sent to product developers within 20 days from the start of the procedure.

3. Recommendations to CHMP for an opinion on the use of unauthorised medicinal products to address the emergency (Articles 15(2)(e) and 18(3) or the Regulation)

    a. Following a request from one or more MSs, or the European Commission, the ETF shall prepare recommendations on the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004.

    b. Following a request from MS(s) or the European Commission, the ETF shall prepare recommendations on the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC.

    c. If necessary, an ETF coordinator may be appointed in discussion with the ETF co-chairs and the CHMP Rapporteurs of the product, if already appointed.

    d. The ETF may consult the MSs concerned and request provision of any available information or data that the MS used for its decisions to make the medicinal product available for compassionate/emergency use.

    e. The ETF shall provide such recommendations to the CHMP, who shall adopt its opinion on the use of such unauthorised medicines, including on the conditions to be imposed on the use and distribution of the medicinal product concerned and on the patients targeted.

4. Scientific reviews and recommendations for medicinal products addressing the public health emergency (Articles 15(2)(e) and 18(1) and (2) of the Regulation)

    a. Following the recognition of a public health emergency, the ETF with the support of the Agency may undertake a scientific review of the available data on medicinal products

which have the potential to be used to address the public health emergency. An ETF coordinator should be appointed to prepare the scientific recommendation on the use of the concerned medicinal product(s).

b. During the scientific assessment, the ETF may liaise as needed: i) with marketing authorisation holders and product developers to request information and data or to engage with them in preliminary discussions; ii) with the agencies for medicinal products of third countries with respect to additional information and data exchange.

c. The ETF may also make use of health data generated outside of clinical studies, where available, taking into account the reliability of those data.

d. Before finalising its review, the ETF will consult with relevant scientific committees, working parties, or scientific advisory groups of the Agency. The ETF will adopt and publish its recommendation.

5. Advice to scientific committees of the Agency on pre- and post- marketing authorisation procedures

a) The ETF shall review available evidence to inform when and for which product with the potential to address the public health emergency a review of the available data in preparation for a marketing authorisation (a so-called "rolling review") should be initiated, where agreed by the ETF and the CHMP. The rolling review will be led by the CHMP Rapporteur.

b) The ETF will advise to the CHMP on when the rolling review is sufficiently advanced to allow the submission of a marketing authorisation application.

c) The ETF will advise the CHMP and the PRAC on the assessment and Lists of Questions, including Risk Management Plans, to be adopted by the CHMP during the rolling review procedures and marketing authorisation application assessments of the medicinal products concerned.

d) The ETF will advise the relevant committees on key post-authorisation procedures for medicinal products authorised to address the public health emergency, including PRAC-led activities on critical pharmacovigilance issues related to the public health emergency.

e) The ETF will advise the PDCO on aspects regarding the paediatric development of products with the potential to address the public health emergency in the context of the overall development plan for the product to support the assessment of Paediatric Investigational Plans and related requests for modification.

f) The ETF shall take account of any scientific opinion issued by the scientific committees of the Agency in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

Article 6 – Tasks

1. Communication regarding the work of the ETF

a) The ETF, in the context of its activities and in cooperation with national competent authorities, will provide information to the public and relevant interest groups with regard to its work, including specific scientific guidance for developers of products with the potential to address the public health emergency.

b) The ETF will issue public health communications to respond to and counteract misinformation regarding medicinal products intended to address the public health emergency or other aspects related to the work and the role of the ETF as appropriate.

c) At the request of the Executive Director of the Agency the ETF shall draw up a recommendation on any scientific matter concerning the public health emergency or the evaluation of medicinal products for human use intended for or with the potential to address the public health emergency.

2. Support activities

a) The ETF shall provide scientific support to facilitate clinical trials conduct for medicinal products addressing the public health emergency. The support includes advice to sponsors of similar or linked planned clinical trials on the establishment of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Article 2(14) and Article 72 of Regulation (EU) No 536/2014. In this respect ETF will liaise with public health sponsors and investigator networks who might conduct research to address the public health emergency.

b) The ETF will liaise with the expert panels on medical devices used for delivery or administration of medicinal products which have the potential to treat or prevent the public health emergency on matters related to medical devices or in vitro diagnostics as necessary.

c) The ETF will liaise with the Medicines Shortages Steering Group (MSSG) on matters related to safety and efficacy of critical medicines. This includes contributing to the review of the list of critical medicines in accordance with Article 6(3) of the Regulation.

d) The ETF will contribute to the activities of the Agency regarding independent studies on the use, effectiveness and safety of medicinal products intended to treat, prevent or diagnose a disease related to the public health emergency.

3. Cooperation with other bodies

a) The ETF co-chairs may nominate experts to cooperate and interact with national competent authorities, expert groups of the European Commission, Union bodies and agencies, the World Health Organization, third countries, and international regulators and scientific organisations on scientific and technical issues relating to -or in preparation for- a public health emergency and to medicinal products which have the potential to address public health emergencies.

b) The ETF may issue, in conjunction with other relevant EU bodies, recommendations on vaccination strategies and on other aspects for use of medicinal products in public health policies.

4. Preparedness activities

a) In preparation for an emergency, the ETF will take account of the monitoring carried out by the Agency in accordance with Article 4(1) of the Regulation and information from relevant entities, such as ECDC and WHO regarding emerging pathogens and their epidemiological situation. The ETF will monitor outbreaks and epidemics that may become public health emergencies and the development of possible countermeasures, and will liaise with relevant scientific committees, working parties and scientific advisory groups of the Agency as required in order to advance regulatory science and define paths that could allow regulatory actions.

b) The ETF will provide scientific advice on clinical trials, including platform trials, and other aspects of medicinal product development which have the potential to address a future public health emergency. The advice shall be finalised by the ETF and endorsed by the CHMP.

c) The ETF may develop requirements and strategy on vaccines and therapeutics for emerging pathogens to facilitate development and regulatory review of such medicines in preparation for public health emergencies.

d) In preparation for public health emergencies, the ETF will maintain an overview of medicinal products, which may have the potential to address public health emergencies.

e) In preparation for potential public health emergencies, the ETF will maintain information on potential radiological, chemical or bioterror agents that may occur accidentally or deliberately (e.g. terrorism).

f) The EFT will contribute to the preparation and follow up of lessons learnt during and after a public health emergency in its role of addressing preparedness for public health emergencies.

Adoption of ETF recommendations and scientific advice

Article 7

1. Whenever possible, recommendations and scientific advice of the ETF shall be adopted by consensus. If a consensus cannot be reached, the recommendation or scientific advice will be adopted if supported by the majority of the members of the ETF.

2. If a vote for the adoption of a recommendation or a scientific advice is required, more than half of the total number of members eligible to vote must be present (absolute majority) either in person or remotely or by nominated proxy in the person of another ETF member. Only members shall vote, provided they don't have declared conflicts of interest on the topic. Co-chairs and additional experts shall not vote. The votes shall be positive or negative. Divergent views will also be recorded in the recommendation. In the event there is no absolute majority in favour of adoption, the ETF outcome is deemed to be negative.

3. A member of the ETF may represent only one other member, when this member is unable to participate in a meeting. The member that is being represented shall inform the ETF Secretariat in advance.

4. Exceptionally, at the initiative of the co-chairs, it will be possible to adopt a recommendation or a scientific advice of the ETF via written procedure. Depending on the comments received, the co-chairs may decide whether the written procedure should be suspended and the adoption of the draft recommendation or scientific advice conducted at the next meeting of the ETF.

Organisation of the ETF meetings

Article 8

1) The ETF secretariat shall provide scientific, technical, and administrative support to the ETF, including organisation of the meetings.

2) The ETF co-chairs, in consultation with the ETF Secretariat, propose a meeting schedule to be adopted by the ETF including dates and intended duration of each meeting. The ETF may hold in-person or virtual meetings. In the event of virtual meetings, members participate through a remote connection. In case of in-person meetings, members who are prevented from participating in person, can participate through a remote connection.

3) The meeting frequency will be adapted to the level of activity required. Although the meeting frequency will be planned as far as possible, *ad hoc* meetings at short notice may be arranged whenever required at the discretion of the co-chairs or at the request of the Executive Director of the Agency.

4) When an ETF meeting is held virtually and members are connected remotely, or in case of an in-person meeting when a member is prevented from participating in person, members can express their position or their vote on the adoption of a recommendation or scientific advice remotely. In case a member of the ETF temporarily faces difficulties to connect remotely, it is acceptable that their position or vote is shared via email making clear the name of the member involved. For transparency reasons, the member's position or vote shared via email shall be brought immediately to the attention of the co-chairs and other members of the ETF.

5) ETF members should endeavour to attend all meetings due to the inherent responsibilities of the group during a public health emergency. When a member of the ETF is exceptionally unable to attend a meeting where the adoption of a recommendation or other ETF outcome is due to take place, he/she may nominate a proxy (another ETF member) to convey his/her views or vote on the matter. They must inform in writing the ETF secretariat, who will keep a record, in advance of the meeting of their inability to attend and the choice of proxy.

6) The meetings shall be held and related documentation prepared in English.

7) The draft agenda for every meeting shall be circulated by the ETF secretariat before the meeting together with the relevant documentation, in consultation with the co-chairs.

8) Whenever meetings between the ETF (or some of its members) and product developers (or relevant stakeholders) take place, outcomes of these discussions shall be finalised by the lead member conducting the meeting and made available to the ETF and the relevant scientific committees of the Agency.

Guarantees of independence

Article 9

1) The members and the additional experts of the ETF 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 an annual declaration of interests or shall provide an updated declaration when a new interest arises.

2) When a member or an expert is unable to participate to a meeting or part of a meeting due to a competing interest, he/she must inform the ETF Secretariat in advance, who shall keep a record.

3) All members of the ETF and additional experts attending a meeting of the ETF shall declare at the beginning of each meeting any specific interest, which has not yet been declared or which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded.

4) The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMA Policy 0044 on the handling of Competing Interests of Scientific Committees' Members and Experts, shall be applicable to ETF members and additional experts.

5) Any incomplete and/or incorrect declarations of interests will be handled according to the Agency's breach of trust procedure on declarations of interests for scientific committees' members and experts.

6) ETF members and additional experts shall not accept from the Member States any instructions incompatible with the tasks incumbent upon them within the Agency. It is essential for these tasks to remain strictly scientific in nature.

Code of Conduct

Article 10

Members of the ETF and additional experts participating in the ETF's activities shall abide by the principles set out in the EMA Code of Conduct.

General provisions

Article 12

1) The composition of the ETF shall be made publicly available. As stated in Article 15(8) of the Regulation, Article 63 of Regulation (EC) No 726/2004 will apply to the EFT as regards transparency and independence of its members, and Agency will publish the CV and Declarations of Interest of all ETF members.

2) The members of the ETF, as well as additional 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 professional secrecy.

3) When participating in international or other fora or in the drafting of scientific publications on behalf of the Agency/ETF or other committees or groups, ETF members and experts shall ensure compliance with the EMA Policy on scientific publication and representation:

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

4) The decision to adopt or to amend these rules of procedure shall be taken by consensus or by the majority of the members of the ETF.

5) The rules of procedure or any amendment to them shall enter into force after receiving a favourable opinion from the European Commission and the Management Board of the Agency and will be made publicly available.

Adopted by ETF: 31 March 2022

Favourable Opinion of the European Commission: Date

Favourable Opinion of the Agency Management Board: Date