

Update on EMA Emergency Task Force (ETF)

12th Industry Standing Group

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ACT EU

Emergency Task Force (ETF)

The Emergency Task Force (ETF) is an advisory and support body that such as a pandemic.

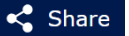
Human Innovation





Overview

Emergency Task Force (ETF)



The Emergency Task Force (ETF) is an advisory and support body that handles regulatory activities in preparation for and during a public-health emergency, such as a pandemic.

Human

Innovation

- What is the ETF, its remit and its new role on AMR-related activities
- EU initiatives on scientific advice to developers
- The scientific advice process under ETF vs. SAWP
- Changes to the ETF scientific advice process to improve the interactions with clinical trials assessors and ethics committees of the EU MSs
- Changes to IRIS scientific advice application form for industry to improve clarity and reflect the updated process

Emergency Task Force (ETF) supports EMA on AMR-related activities

[ETF](#): Expert group managing regulatory science related to public health emergencies and preparedness
[Consolidated 3-year work plan for the Emergency Task Force \(ETF\)](#)

Annex 1

The lists below are intended to illustrate the scope of the ETF activities during preparedness but are not fully exhaustive and can be changed based on evolving knowledge and epidemiology.

List of pathogens which could potentially cause a public health emergency to be considered within the scope of the ETF:

- Abrin toxin
- Alphaviruses such as Chikungunya virus and Venezuelan equine encephalitis virus
- *Bacillus anthracis*
- *Brucella* species
- Bunyavirales such as Rift valley fever virus, Lassa virus and Lujo virus, Crimean-Congo haemorrhagic fever virus
- *Burkholderia mallei* and *burkholderia pseudomallei*
- *Chlamydia psittaci*
- *Clostridium botulinum* toxin
- *Clostridium perfringens* Epsilon toxin
- Coronaviruses (such as Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-COV-1 and 2))
- *Corynebacterium diphtheriae* toxin
- *Coxiella burnetii*
- *Escherichia coli* (enterohaemorrhagic)
- Filoviruses such as Ebola virus and Marburg virus
- Flaviviruses such as Zika virus, West Nile virus, Tick-borne encephalitis virus and Dengue virus
- *Francisella tularensis*

List of other threats³ with the potential to cause a public health emergency to be considered within the scope of the ETF:

- Blister or vesicant agents (e.g., mustards, organic arsenicals, phosgene oxime);
- Nerve agents and other highly toxic organophosphates;
- Cyanides;
- Lung-damaging agents (e.g., phosgene; chlorine);
- Incapacitating and other pharmaceutically-based agents (e.g., Fentanyl, BZ, Indoleamines, phenylalkylamines);
- Crowd control agents (e.g., 1-chloroacetophenone (CN), ochlorobenzylidene malononitrile (CS), bromobenzylcyanide (CA), and dibenz(b,f)-1,4-oxazepine (CR),);
- Water/soil/air contaminants: acrylamide, DEET, DDT, benzene, cadmium, mercury, dioxins and dioxin-like substances, lead;
- Accidental or intentional exposure to radioactive and nuclear material.

- Influenza viruses²
- Nipah virus and Hendra virus
- Polioviruses
- Ricin toxin
- *Rickettsia prowazekii*
- *Salmonella* species
- *Shigella* species
- Staphylococcal enterotoxin B
- *Yersinia pestis*
- Variola major (smallpox) and other related pox viruses
- *Vibrio cholera*
- Pathogens currently unknown to cause human disease
- In the context of AMR related activities, the following will be specifically addressed: TB, gonorrhoea, new vaccines for bacterial pathogens, new antibacterial treatments in the areas of unmet need related to multidrug resistance.

EU initiatives on scientific advice procedures

1. **SAWP-CTCG scientific advice pilot** on requirements for clinical trials and marketing authorisation applications - coordinated by EMA under ACT-EU
2. **Pre-CTA advice pilot** to provide technical and regulatory support on the dossier of a CTA prior to its submission through CTIS – coordinated by CTCG under ACT-EU

<https://www.ema.europa.eu/en/news/two-new-advice-pilots-improve-clinical-trials-europe>

3. **Simultaneous National Scientific Advice** (SNSA) from national competent authorities (NCAs) – coordinated by the EU Innovation Network (EU-IN)

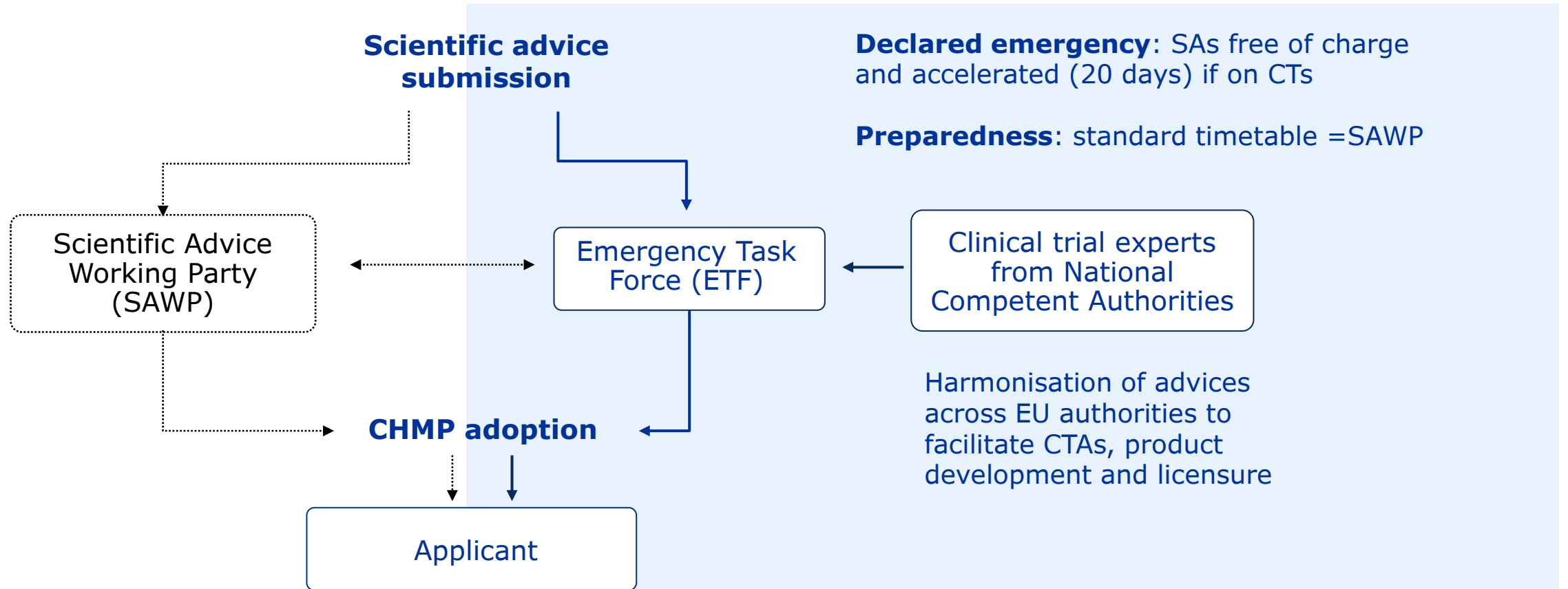
<https://www.ema.europa.eu/en/committees/working-parties-other-groups/eu-innovation-network-eu>

4. **ETF-CTCG-EAG scientific advice** on requirements for clinical trials and marketing authorisation applications - coordinated by EMA

EMA ETF scientific advice on medicines for public health emergencies & for preparedness

SAWP scientific advice

ETF scientific advice



Improved process for ETF SA on clinical trials (CTs)

- Since 2022, ETF had 1 coordinator per SA, and 4 member of the ETF belonging to the Clinical Trials Coordination group (CTCG) and the Clinical Trial Advisory Group (CTAG) provided input into SA.
- Request for advice to the ETF will be evaluated by 2 coordinators
- If questions on aspects related to clinical trial applications to be filed in EU, Coordinators will be preferentially the proposed Reporting MS (RMS) and MS Concerned (MSCs)
- The application will be assessed by the 2 coordinators together with the CT Unit in their MS
- The views of the MSCs will be harmonized during a dedicated meeting embedded in the procedure
- Process similar to the SAWP/CTCG pilot in ACT-EU – SAWP and ETF will align on lessons learned
- Specific experts from EU ethics committees will be involved via the Ethics Advisory Group created under ACT-EU (public health emergency)
- The ETF aims at harmonising the advice on CTAs and MAAs across EU authorities → **facilitate CTAs, product development and licensure**

Changes to the IRIS application form for SA

UPDATED Drop down menu

- Antimicrobial resistance (AMR), e.g. TB, Gonorrhoea, new vaccines for bacterial pathogens, new MDR antibacterial treatment
- Abrin toxin
- Alphaviruses
- Bacillus anthracis
- Brucella species
- Bunyavirales
- Burkholderia mallei and burkholderia pseudomallei
- Chlamydia psittaci
- Clostridium botulinum toxin
- Clostridium perfringens Epsilon toxin
- Coronaviruses
- Corynebacterium diphtheriae toxin
- Coxiella burnetii
- Escherichia coli (enterohaemorrhagic)
- Filoviruses
- Flaviviruses
- Francisella tularensis
- Influenza viruses
- Nipah virus and Hendra virus
- Polioviruses
- Ricin toxin
- Rickettsia prowazekii
- Salmonella species
- Shigella species
- Staphylococcal enterotoxin B
- Yersinia pestis
- Poxviruses
- Vibrio cholera
- Pathogen X
- Blister or vesicant agents (e.g., mustards, organic arsenicals, phosgene oxime)
- Nerve agents and other highly toxic organophosphates
- Cyanides
- Lung-damaging agents (e.g., phosgene; chlorine)
- Incapacitating and other pharmaceutically-based agents (e.g., Fentanyls, BZ, Indoleamines, phenylalkylamines);
- Crowd control agents (e.g., 1-chloroacetophenone (CN), ochlorobenzylidene malononitrile (CS), bromobenzylcyanide (CA), and dibenz(b,f)-1,4-oxazepine (CR),)
- Contaminants: Acrylamide, DEET, DDT, benzene, cadmium, mercury, dioxins and dioxin-like substances, lead
- Exposure to radioactive and nuclear material
- Other **ADD OPTION TO SPECIFY**

The EMA Emergency Task Force (ETF) is responsible for assessing scientific advice applications pertaining to specific pathogens and health threats which are listed in the [Annex 1 of the ETF workplan](#) as well as in the drop down menu for the point 2 below. Any other applications will be assessed by the Scientific Advice Working Party (SAWP). Link to https://www.ema.europa.eu/en/documents/work-programme/consolidated-3-year-work-plan-emergency-task-force-etf_en.pdf

Type of request

Is this a request for Scientific Advice under the remit of the SAWP?*

Yes/No selection

Is this a request for Scientific Advice under the remit of the ETF for any of the following health threats ([ETF workplan Annex 1](#))?*

Yes/No selection

Is this a request for Scientific Advice under the remit of the ETF for a declared Public Health Emergency? (art.15 and 16 of Regulation (EU) 2022/123)*

Yes/No selection

Does the request for Scientific Advice contain scientific questions related to clinical trials applications(s) planned to be submitted in any EU MSs

Yes/no

Drop down menu including all EU MSs



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Thank you

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