

# Update on EMA Emergency Task Force (ETF)

ACT-EU Multi-stakeholder platform  
advisory 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



# The EMA Emergency Task Force (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*

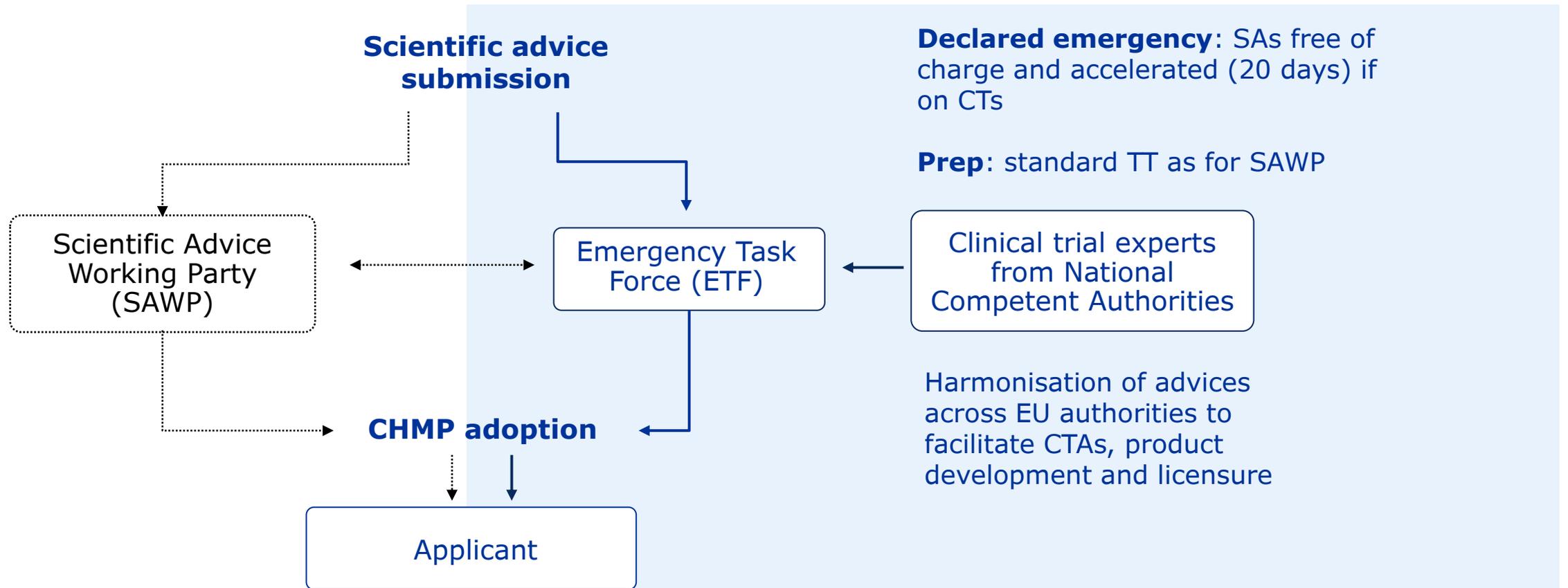
**List of other threats<sup>3</sup>** with the potential to cause a public health emergency to be considered within the scope of the ETF:

- 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), o-chlorobenzylidene 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 viruses<sup>2</sup>
  - 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.

# EMA ETF scientific advice on medicines for emergency & prep

## 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) (where the MSs are represented in the ETF)
- 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 (consolidated pilots) – 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 clinical trials across EU authorities → **facilitate CTAs, product development and licensure**

# Changes to the IRIS application form for SA

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](https://www.ema.europa.eu/en/documents/work-programme/consolidated-3-year-work-plan-emergency-task-force-etf_en.pdf)

<b>Type of request</b>	
<b>Is this a request for Scientific Advice under the remit of the SAWP?*</b>	
<i>Yes/No selection</i>	
<b>Is this a request for Scientific Advice under the remit of the ETF for any of the following health threats (<a href="#">ETF workplan Annex 1</a>)?*</b>	
<i>Yes/No selection</i>	
<b>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)*</b>	
<i>Yes/No selection</i>	

**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

## 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 malonitrile (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**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Thank you

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