



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Emergency Task Force

## Consolidated 3-year work plan for the Emergency Task Force (ETF)

**Chairpersons:** Marco Cavaleri and Bruno Sepodes

Work plan period: January 2023 – December 2025 (with a first review point after one year)

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# 1. Strategic goals

The Emergency Task Force (ETF) is a multidisciplinary expert group established 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. Fulfilment of broad long-term goals linked to the establishing [Regulation \(EU\) No 2022/123](#) and the EMA/EMRN<sup>1</sup> [Regulatory Science Strategy to 2025](#):

## 1.1. Short-term goals

- Revision of the reflection papers on development of COVID-19 vaccines ([Regulatory requirements for vaccines intended to provide protection against variant strain\(s\) of SARS-CoV-2 - Scientific guideline](#) - EMA/117973/2021- and [EMA considerations on COVID-19 vaccine approval](#) EMA/592928/2020).
- Revision of the [Guideline on Influenza Vaccines, Non-clinical and Clinical Module](#), and of the [Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU](#).
- Draft a new guideline on clinical and non-clinical requirements for antivirals and monoclonals against COVID-19.
- Contribute to the revision of the guideline on clinical investigation of medicinal products for the treatment of patients with acute respiratory distress syndrome.
- Support the clinical development of treatment/prevention options for long COVID and monitoring of long-term effects of SARS-CoV-2.
- Identify experts on chemical, biological, radiological or nuclear (CBRN) agents that are considered potential health threats, to enrich the composition of the ETF for preparedness.
- Prepare Scientific Advice final letters for the CHMP for selected health threats during preparedness, with involvement of MSs experts on clinical trials and Ethical committees representatives in case of clinical trials conducted in the EU.
- Facilitate conduct of large multinational trials and establishment of platform trials for developing products to address future public health emergencies.
- Simplify processes to support interactions with academia and SMEs.
- Support generation and use of Real-World Evidence (RWE) in the EU on effectiveness and safety of medicines and vaccines addressing ongoing or potential public health emergencies.
- Continued collaboration with National Immunisation Technical Advisory Groups (NITAG) and European Centre for Disease Prevention and Control (ECDC) and issue recommendations on use of vaccines and on other aspects for use of medicinal products in public health policies as needed.

## 1.2. Long-term goals

- Catalysing the integration of science and technology in medicines' development:
  - Support development of biomarkers for medicines targeting a declared or potential emergency

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<sup>1</sup> European Medicines Regulatory Network, the EU Network

- Strengthen the availability of medicines and medical devices to protect the health of EU citizens, e.g. via supporting Health Emergency Preparedness and Response (HERA) activities on procurement and stockpiling
- Driving collaborative evidence generation – improving the scientific quality of evaluations:
  - Leverage non-clinical models and 3Rs principles
  - Develop network competence and specialist collaborations to engage with big data
- Enabling and leveraging research and innovation in regulatory science:
  - Leverage collaborations between academia and EU-funded clinical trial networks to address regulatory science research questions
  - Organise and convene workshops on specific scientific topics
  - Increase the interactions with international partners such as WHO, [Coalition for Epidemic Preparedness Innovations](#) (CEPI), Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R), and regulators, e.g. International Coalition of Medicines Regulatory Authorities (ICMRA).
  - Disseminate and exchange knowledge, expertise, and innovation across the network and to its stakeholders.

## 2. Tactical goals: activities/projects to deliver the strategic goals

### 2.1. Guideline activities

#### COVID-19 vaccines reflection papers

The current guidance documents for vaccine development need to be revised based on current criteria for approval of new COVID-19 vaccines including guidance on immuno-bridging strategies and scenarios in which use of immune makers for inferring protection is not appropriate.

#### Guideline on Influenza Vaccines, Non-clinical and Clinical Module (EMA/CHMP/VWP/457259/2014)

This guideline was adopted in 2016. Since that time, several requests for CHMP scientific advice as well as new MAAs have pointed to the need to update and clarify certain sections of this guidance to make it clearer and more comprehensive on specific matters. This revision will be done in collaboration with VWP.

#### Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU

This guidance focuses on the requirements for annual enhanced safety surveillance to rapidly detect any increased local and systemic reactogenicity, or other unexpected adverse immune response that may arise during the influenza vaccine product life cycle. It also outlines principles to be followed for improved continuous routine surveillance for influenza vaccines.

Based on the experience gathered so far, there is the need to revise the current requirements to improve the quality and quantity of the data collected for regulatory appraisal. This revision will be done in collaboration with VWP and PRAC.

#### Guideline on the evaluation of medicinal products indicated for treatment of influenza

The ETF in conjunction with the Infectious Disease Working Party will draft a guideline on clinical development of antivirals and monoclonals against influenza.

### Guideline on clinical and non-clinical requirements for antivirals and monoclonals against COVID-19

Based on the experience gained with the development of antivirals for treatment and/or prevention of COVID-19, this new guideline should cover the set of non-clinical and clinical investigations that could support approval of new antivirals, including both chemical entities and monoclonal antibodies.

### Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome (ARDS)

Following the experience accrued during the COVID-19 pandemic with several products developed for ARDS, the existing guidance document will be revised by the Rheumatology Immunology Working Party (RIWP) with the contribution of the ETF.

### Guideline on clinical evaluation of vaccines

Contribute to the activities of the VWP in developing an addendum to this existing guideline on clinical trials for vaccines on immunocompromised individuals.

## **2.2. Training activities**

none

## **2.3. Communication and stakeholder activities**

The ETF may issue, also in conjunction with other relevant EU bodies, scientific positions or recommendations on vaccination strategies or therapeutic policies and on other aspects for use of medicinal products in public health policies.

## **3. Operational Objectives**

The ETF will assess the scientific advice applications related to medicines addressing an ongoing public health emergency or a potential public health emergency caused by a pathogen or by chemical, biological, radiological and nuclear (CBRN) agents (see Annex 1), including medicines intended for use outside of the EU.

The ETF will provide product-related support systematically during public health emergencies and upon request during preparedness. In the absence of specific requests, the ETF may provide comments to CHMP on selected procedures related to medicines targeting potential public health emergencies.

The ETF will contribute to the activities of the Agency regarding coordination and assessment of independent studies on the use, effectiveness and safety of medicinal products intended to treat, prevent or diagnose a disease related to an ongoing or potential public health emergency. Related to vaccines, the contribution will be provided in the context of the Vaccine Monitoring Platform (VMP) on vaccine effectiveness and safety studies on authorised vaccines, organised jointly with ECDC. This includes support in defining the research agenda of the VMP.

The ETF will discuss specific research questions on any scientific topic with impact on the benefit-risk balance of medicines targeting a public health emergency, for example to investigate the pathophysiological mechanisms related to adverse reactions to vaccines such as thrombosis with thrombocytopenia syndrome (TTS) and myocarditis.

The ETF will produce systematic reviews and recommendations to support MSs and HERA activities as requested.

The ETF will assess the available evidence on investigational medicines targeting public health emergencies to prepare for potential marketing authorisation.

The ETF will publish and keep up to date:

- List of medicines with the potential to address ongoing public health emergencies.
- Lists of medicines to address future potential public health emergencies and list of agents (CBRN) and relative medical countermeasures that can be accidentally or deliberately released for bioterror in accordance with art.57q of regulation 726/2004.

## Priorities for 2024

### 4. Guidelines

#### 4.1. EU Guidelines

##### *Action: Lead*

##### [Guideline on clinical and non-clinical requirements for SARS-CoV-2 vaccines](#)

**Target date** Concept paper by Q2 2024; revised guideline for public consultation by Q4 2024

**Comments**

##### *Action: Lead*

##### **Guideline on clinical and non-clinical requirements for antivirals and monoclonals against COVID-19**

**Target date** Concept paper by Q2 2024; new guideline to be ready for public consultation by Q4 2024

**Comments**

##### *Action: coLead*

##### [Guideline on Influenza Vaccines, Non-clinical and Clinical Module](#)

**Target date** revision for public consultation Q4 2024

**Comments** This is a revision of the existing guideline, jointly with VWP

##### *Action: coLead*

##### [Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU](#)

**Target date** revision for public consultation by Q4 2024

**Comments** This is a revision of the existing guideline together with PRAC and VWP.

### *Action: contribution*

#### **Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome**

**Target date** 2024 (concept paper released in 2023)

**Comments** This is a revision of the existing guideline, supporting RIWP

### *Action: contribution*

#### **Guideline on clinical evaluation of vaccines**

**Target date** addendum for public consultation by Q4 2024

**Comments** This is a revision of the existing guideline to add an addendum, supporting VWP

## **5. Other publications**

None

## **6. Training for the network and knowledge building**

None

## **7. Contribution to dialogue and engagement with stakeholders and external parties**

### ***Workshops***

none

## **8. Collaboration with interest parties and other stakeholders**

Consortiums: PROMISE, DRIVE, PREPARE, VMP, STRIVE, ECRAID, TCB, CCB, EU-funded trial and cohort consortia (including but not limited to trial coordination boards, cohorts' coordination board, Vaccellerate)

Industry: ISG meetings

EU bodies: HERA, European Commission, ECDC, WHO, EU NITAGs, ACT-EU, CTCG, CTAG

## **9. International activities**

Attendance to Vaccine and antiviral Clusters' virtual meetings on efficacy and safety issues related to vaccines and therapeutics on an ad hoc basis.

Attendance to ICMRA meetings

## 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:

- Alphaviruses such as Chikungunya virus and Venezuelan equine encephalitis virus
- Arenaviruses such as Lassa virus and Lujo virus
- *Bacillus anthracis*
- *Brucella* species
- Bunyavirales such as Rift Valley Fever virus
- *Burkholderia mallei* (glanders) and *burkholderia pseudomallei* (melioidosis)
- *Chlamydia psittaci* (psittacosis)
- Coronaviruses (such as Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-COV-1 and 2))
- *Corynebacterium diphtheriae* (anti-toxins)
- *Coxiella burnetii* (Q fever)
- *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*
- Influenza viruses<sup>2</sup>
- Nipah virus and Hendra virus
- Orthonairovirus such as Crimean-Congo haemorrhagic fever
- Polioviruses
- *Rickettsia prowazekii* (typhus fever)
- *Salmonella* species (salmonellosis, typhoid)
- *Shigella* species (shigellosis)
- *Yersinia pestis*
- Variola major (smallpox) and other related pox viruses
- *Vibrio cholera*
- Pathogens currently unknown to cause human disease

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<sup>2</sup> Development programs for seasonal influenza vaccines to be considered on an ad hoc basis



**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 such as mustards (nitrogen or sulphur), organic arsenicals (lewisite) and phosgene oxime or dichloroformoxine (CX);
- Nerve agents and other highly toxic organophosphates such as G-gases (tabun, sarin, soman, cyclosarin) and V-gases (VX);
- Dichlorodiphenyltrichloroethane (DDT);
- Blood agents such as cyanides [hydrogen cyanide (HCN) or prussic acid and its sodium (NaCN) and potassium salts (KCN)], arsine and cyanogen or dicyanogen (CN<sub>2</sub>) and its halides (CNCl, CNBr);
- Lung-damaging agents or choking agents such as phosgene, diphosgene and chlorine;
- Incapacitating agents such as stimulants, depressants, psychedelics and deliriants [BZ (3-quinuclidinyl benzilate), LSD (D-Lysergic acid diethylamide), fentanyl and other potent opioids when used outside of therapeutic settings);
- Lachrymatory chemical agents (tear gas) such as chloropicrin, capsaicin, ethyl iodoacetate and adamsite;
- Others: Acrylamide, N,N-Diethyl-meta-toluamide (DEET), benzene, cadmium, mercury, dioxins and dioxin-like substances, lead;
- Toxins such as botulinum, diphtheria, ricin and abrin toxins;
- Accidental or intentional exposure to radiation.

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<sup>3</sup> [Medicinal treatment against Chemical threats \(europa.eu\)](#); [10 chemicals of public health concern \(who.int\)](#); [Chemical Threat Agents \(cdc.gov\)](#)