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Emergency Task Force

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

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Work plan period: January 2023 – December 2025

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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[1] 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) jointly with VWP.
- 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. Jointly with VWP and PRAC.
- Draft a new guideline on clinical and non-clinical requirements for antivirals and monoclonals against COVID-19 jointly with IDWP.
- Draft a concept paper and subsequently text for a guideline on clinical and non-clinical requirements for orthopoxvirus vaccines including mpox vaccines. This guideline will be done jointly with VWP.
- 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.
- Draft a reflection paper on use of animal models to support demonstration of benefit for medical countermeasures for CBRN for which efficacy clinical trials are deemed unfeasible. This document will be drafted in collaboration with different working parties in the Agency.
- Contribute to the development of a concept paper on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev.1).
- Identify experts on chemical, biological, radiological or nuclear (CBRN) agents that are considered potential health threats, to contribute to the activities of the ETF.
- Prepare Scientific Advice final letters for the CHMP for selected health threats during preparedness (see Annex 1), 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.

[1] European Medicines Regulatory Network, the EU Network

- 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.
- Support the Agency activities related to antimicrobial resistance, including advancing the European Medicines Agencies Network Strategy on AMR, such as engaging with academia, SMEs and international stakeholders. Identify experts on AMR to contribute to the activities of the ETF.
  - Establish a pilot scheme for scientific advice and support to CHMP in selected areas of unmet need and warranting international cooperation, such as tuberculosis, gonorrhoea, new vaccines for bacterial pathogens, and new antibacterial treatments in areas of unmet need related to multidrug resistance.

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
- 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), European Society of Clinical Microbiology and Infectious Diseases (ESCMID) 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. This revision will be done jointly with VWP.

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.

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 is done jointly 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 jointly with VWP and PRAC.

Guideline on vaccines against orthopoxvirus

Considering the latest developments in terms of vaccines against orthopoxvirus, there is a need to generate a new guideline on the nonclinical and clinical requirements. A VWP-ETF joint concept paper on this matter is intended to be produced in 2025.

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. This revision will be done in collaboration with IDWP.

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 the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease

Contribute to the development a concept paper followed by updating the guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev.1) This revision will be done in collaboration with the IDWP.

Reflection paper on use of animal models to demonstrate efficacy of medicinal products targeting health threats

The use of animal models as key evidence to support the efficacy of medicinal products that cannot be studied in clinical trials to demonstrate efficacy in the intended use, require consideration on the experience gained so far and the most relevant aspects of study design both for the animal studies and for the bridging studies in humans.

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 targeting AMR and/or 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/or 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 2025

4. Guidelines

4.1. EU Guidelines

Guideline on clinical and non-clinical requirements for SARS-CoV-2 vaccines

Target date	draft revised guideline ready for public consultation in 2025
Comments	This is a VWP-ETF joint revision of the existing reflection paper
Action	CoLead

Guideline on clinical evaluation of vaccines

Target date	addendum finalised after public consultation by Q1 2025
Comments	This is a joint VWP- ETF revision of the existing guideline to add an addendum
Action	Colead

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

Target date	draft guideline ready for public consultation by Q2 2025
Comments	This is an IDWP-ETF joint drafting
Action	coLead

Guideline on Influenza Vaccines, Non-clinical and Clinical Module

Target date	draft revised guideline ready for public consultation in 2025
Comments	This is a VWP-ETF joint revision of the existing guideline
Action	CoLead

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

Target date	draft revised guideline ready for public consultation in 2025
Comments	This is a VWP-PRAC-ETF joint revision of the existing guideline
Action	coLead

Guideline on vaccines against orthopoxviruses

Target date	Draft concept paper ready for public consultation by Q4 2025
Comments	This is a VWP-ETF joint drafting.
Action	Co-Lead

Update the Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev. 1).

Target Date:	Draft concept paper ready for public consultation by Q4 2025
Comments	
Action:	Contribution to IDWP

Reflection Paper on use of animal models to demonstrate efficacy of medicinal products targeting health threats

Target date	Draft to be ready for publication by Q1 2026
Comments	Consultation with several Working Parties, such as IDWP, VWP, NcWP expected
Action	Lead

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

Target date	draft revised guideline ready for public consultation by Q1 2025
Comments	This is a revision of the existing guideline; ETF is supporting RIWP
Action	Contribution to RIWP

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

1) Primary efficacy endpoints for antivirals intended to treat respiratory viruses – Q2 2025

2) Workshop to discuss aspects related to the development of influenza vaccines in the context of the consultation on the revised of influenza guideline, in collaboration with VWP – Q2/3 2025

3) Workshop on use of animal models to determine efficacy for medicinal products targeting health threats, Q4 2025

4) Workshop on innovative medicinal products to tackle AMR, such as phage therapy, Q3/4 2025

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, VACCELERATE)

Industry: ISG meetings

EU bodies: HERA, SANTE, RTD, 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 for emerging health threats and AMR.

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:

- 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*

- Influenza viruses[2]
- 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.

List of other threats[3] 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., 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),);
- 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.

[2] Development programs for seasonal influenza vaccines to be considered on an ad hoc basis
[3] Medicinal treatment against Chemical threats (europa.eu); 10 chemicals of public health concern (who.int); Chemical Threat Agents (cdc.gov)