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EMA Emergency Task Force

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

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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 declared or potential future emergencies (herein called 'relevant medicines'; see Annex 1 for a comprehensive list), 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.

The ETF strategic goals are linked to the provisions reflected in Regulation (EU) No 2022/123 and to the relevant themes of the EMA/EMRN[1] Regulatory Science Strategy to 2028:

1.1. Short-term strategic goals

- Facilitate development of and authorisation to relevant medicines by means of:
    - Drafting scientific guidelines on non-clinical and clinical aspects of product development in collaboration with relevant CHMP working parties.
    - Providing scientific advice and support to CHMP for medical countermeasures for health threats and antimicrobial resistance (AMR), including bacterial vaccines.
    - Fostering involvement of MSs experts on clinical trials and Ethical committees' representatives in the assessment of scientific advice concerning clinical trials conducted in the EU.
    - Facilitating conduct of large multinational trials and establishment of platform trials for developing relevant medicines.
- Support the Agency activities related to AMR, including advancing the European Medicines Agencies Network Strategy on AMR, such as engaging with academia, SMEs and international stakeholders, and supporting rational use of antibacterial agents.
- Support the development of treatment/prevention options for long COVID and monitor emerging data on long-term effects of SARS-CoV-2.
- Support generation of Real-World Evidence (RWE) in the EU on effectiveness and safety of vaccines or other relevant medicines by providing advice on research priorities and study protocols.
- Continued collaboration with Health Technology Assessment (HTA) bodies on antimicrobials, and with National Immunisation Technical Advisory Groups (NITAG) and European Centre for Disease Prevention and Control (ECDC), including release of recommendations on use of vaccines and on other aspects for use of medicinal products in public health policies as needed.
- Facilitate the development and evaluation of relevant in vitro diagnostics and medical devices used for delivery or administration of relevant medicinal products, in liaison with the expert panels.
- Contribute to Agency activities on One Health for infectious diseases, including contributing to discussions on the use of human antibacterials in animals in collaboration with the Antimicrobial Working Party (AWP) and Committee for Veterinary Medicines (CVMP).

1.2. Long-term strategic goals

- Catalysing the integration of science and technology in medicines' development:

[1] European Medicines Regulatory Network, the EU Network

- Support the discovery and evaluation of biomarkers to infer efficacy or safety for relevant medicines, including approaches based on AI or other innovative technologies.

- Strengthen the availability of relevant medicines and medical devices, including in vitro diagnostics, 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 innovative non-clinical and in vitro models and 3Rs principles
    - Develop network competence and specialist collaborations to engage with new approaches to identify pathogens that may cause emergencies and support screening of MCMs libraries once emergency occurs.
- 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 to advance strategic thinking on specific scientific topics
    - Foster 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 international regulators, e.g. through 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. Guidance activities

(A) Activities ongoing/to be finalised in 2026

COVID-19 vaccines guidance revision

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 is done jointly with VWP.

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.

Reflection paper on non-clinical and clinical requirements for antivirals and monoclonal antibodies during the COVID-19 pandemic and potential use of this experience for pandemic preparedness against other coronaviruses

Based on the experience gained with the development of antivirals for treatment and/or prevention of COVID-19, this new reflection paper should cover non-clinical and clinical investigations that supported approval of new antivirals against COVID-19, including both chemical entities and monoclonal antibodies, as stated in the Concept paper EMA/CHMP/70203/2024, and the potential use of this experience for pandemic preparedness against other coronaviruses. This paper is done in collaboration with IDWP.

Concept paper for a 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 IDWP.

(B) Activities to be started in 2026

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

Relevant regulatory experience has been accumulated in recent years on the use of animal models as key evidence of efficacy for the approval of medical countermeasures for which no human efficacy studies can be conducted, including aspects of study design in animals and immunobridging to humans. This reflection paper will bring together the current scientific and regulatory considerations in the field, with focus on advances and challenges in the generation, interpretation and use of animal efficacy data for inferring efficacy in humans. This paper will be done in collaboration with VWP, MWP and NcWP.

Concept paper for a new 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. This concept paper will be done in collaboration with VWP.

Concept paper on the revision of the Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to Mycobacterium Tuberculosis

A revision of the Addendum should be considered in light of the latest development and emerging data in the areas of treatment against TB. This revision will be done in collaboration with IDWP.

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

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 IDWP.

(C) Activities to be started in 2027-2028

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

A new Guideline on the evaluation of medicinal products indicated for treatment of influenza will be drafted in line with the Concept Paper (EMA/CHMP/EWP/808940/2016). This guideline will be done in collaboration with IDWP.

Ongoing support to ICH guidelines

None

2.2. Training and workshop activities

1. Workshop to discuss aspects related to clinical trials and evidence generation during emergencies, Q4 2026
2. Workshop on innovative medicinal products to tackle AMR, such as phage therapy, Q3/4 2026
3. Workshop to discuss aspects linked to the approval of pneumococcal vaccines, including correlates of protection and real-world evidence, Q2/3 2026
4. Workshop on development of paediatric medicines against bacterial pathogens including TB, Q4 2026.

2.3. Communication and stakeholder activities

European level

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.
ETF interactions with EU bodies: HERA, SANTE, RTD, ECDC, WHO, EU NITAGs, ACT-EU, CTCG, CTAG

The Innovation Task Force (ITF) is working on an EU-IN Horizon Scanning Report focused on Bacteriophage Therapy for human use. The ETF will participate in the project.

International level

Attendance to Vaccine and antiviral Clusters' virtual meetings on efficacy and safety issues related to relevant vaccines and therapeutics including AMR.

Attendance to ICMRA meetings.

Multidisciplinary collaboration

Consortia and initiatives such as PROMISE, PREPARE, VMP, STRIVE, ECRAID, TCB, CCB, EU-funded trial and cohort consortia (including but not limited to trial coordination boards, cohorts' coordination board,)

Industry: ISG and MSP meetings

3. Operational goals

3.1. Pre-submission activities

- 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 produce reviews and recommendations to support MSs and EC activities as requested.
- The ETF will assess the available evidence on relevant investigational medicines to prepare for potential marketing authorisation.

3.2. Evaluation and supervision activities

- 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 of relevant medicines.
- The ETF will contribute to the activities of the Agency regarding coordination and assessment of independent studies on the use, effectiveness and safety of relevant medicinal products.
- 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 identify specific research questions on any scientific topic with impact on the benefit-risk balance of relevant medicines, for example to investigate the pathophysiological mechanisms related to adverse reactions to vaccines.
- The ETF will keep up to date the 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.
- The ETF will establish a modus operandi with the experts' panels to discuss relevant in vitro diagnostics or medical devices.

Annex 1 – Threats under ETF remit

The four lists below are intended to define the scope of the ETF preparedness activities. The lists can be changed based on evolving knowledge and epidemiology and therefore should not be considered as final or exhaustive.

1. Viral pathogens, including those prioritised by WHO[2]:

- *Arenaviridae* (e.g. *Mammarenavirus lassaense* and *Mammarenavirus lujoense*)
- *Coronaviridae* (e.g. Subgenus *Sarbecovirus* and Subgenus *Merbecovirus*)
- *Filoviridae* (e.g. *Orthoebolavirus zairense*, *Orthoebolavirus sudanense* and *Orthomarburgvirus marburgense*)
- *Flaviviridae* (e.g. *Orthoflavivirus flavi, Orthoflavivirus dengue, Orthoflavivirus zikaense, Orthoflavivirus encephalitidis* and *Orthoflavivirus nilense)*
- *Hantaviridae* (e.g. *Orthohantavirus hantanense* and *Orthohantavirus sinnombreense*)
- *Nairoviridae* (e.g. *Orthonairovirus haemorrhagiae*)
- *Orthomyxoviridae* (Influenza types A and B)
- *Paramyxoviridae* (e.g. *Henipavirus nipahense*)
- *Picornaviridae* (e.g. *polioviruses)*
- *Phenuiviridae* (e.g. *Bandavirus dabieense* and *Phlebovirus riftense*)
- *Poxviridae* (e.g. *Orthopoxvirus variola* and *Orthopoxvirus monkeypox*)
- *Togaviridae* (e.g. *Alphavirus chikungunya* and *Alphavirus venezuelan*)

2. Bacterial pathogens, including:

- *Acinetobacter baumannii*
- *Bacillus anthracis*
- *Brucella* species
- *Burkholderia mallei* and *Burkholderia pseudomallei* species
- *Chlamydia psittaci* species
- *Citrobacter* species
- *Corynebacterium diphtheriae* (antitoxin only)
- *Coxiella burnetii* species
- *Enterobacter* species
- Enterococci
- *Escherichia coli* species (e.g. enterohaemorrhagic serotypes (EHEC))
- *Francisella tularensis* species

[2] https://www.who.int/teams/blueprint/who-r-and-d-blueprint-for-epidemics

- Group A Streptococci
- Group B Streptococci
- *Haemophilus influenzae* species
- *Klebsiella pneumoniae* species
- *Neisseria gonorrhoeae* species
- *Neisseria meningitidis* species
- *Morganella* species
- *Mycobacterium tuberculosis* species
- *Bordetella pertussis*
- *Proteus* species
- *Pseudomonas aeruginosa*
- *Rickettsia prowazekii* species
- *Serratia* species
- *Salmonella* species
- *Shigella* species
- *Staphylococcus aureus*
- *Streptococcus pneumoniae*
- *Vibrio cholerae*
- *Yersinia pestis*

3. Parasites:

- *Cryptosporium parvum*

4. Toxins:

- Abrin biotoxin (plant derived, *Abrus precatorius*)
- Botulinum toxin (bacterium derived, *Clostridium botulinum)*
- Epsilon toxin (bacterium derived, *Clostridium perfringens* strains B and D)
- Ricin biotoxin (plant derived, *Ricin communis*)
- Staphylococcal enterotoxin (SEB) (bacterium derived, *Staphylococcus aureus*)

5. Chemical and radio-nuclear threats[3]:

- 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.

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