EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SESSION 2

Addressing public health emergencies through the ETF

Introduction by topic lead

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Outline

1. EMA role in public health emergencies
2. The new Emergency Task Force (ETF) and its composition
3. Overview of the ETF tasks and responsibilities
4. Summary and next steps for the new ETF
5. Tasks for EMA to support ETF work based on new Regulation 2022/123
6. Conclusion

EMA role in public health emergencies

UNTIL NOW

Crisis-related regulatory activities (interaction with manufacturers and data evaluation) led by a dedicated expert group **EMA Pandemic Task Force (ETF):**

- Operating since 2009 (H1N1v, Ebola, Zika) – EMA Health Threat Plan & Decision 1082/2013/EU on cross-border health threats
- Mandate was expanded to cope with COVID-19 specificities

Regulation (EU) 2022/123

- Role of the ETF as an **Emergency Task Force** is set in legislation and strengthened building on past experience
- ETF to operate after declaration of public health emergency by WHO or EC under Decision 1082/2013/EU & for preparedness during non-emergency periods

The new Emergency Task Force (ETF)

- ETF established with formal legal mandate as an **advisory and support body on medicines for public health emergencies and preparedness**
- Regulation sets out objectives and composition, but allowing flexibility & membership based on expertise
- **Strengthened** existing ETF responsibilities building on successful experience during past emergencies & COVID-19

Scientific advice and support to clinical trials

- assessed **directly** by ETF
- free of charge & fast-track for clinical trials and protocols
- **support study conduct**

Scientific reviews

- **systematic** assessment of evidence on medicines

ETF recommendations

- **on medicines not yet authorised**
- on scientific or **public health matters**

When will the new ETF start working?

Official activities started on **1 March**, date of implementation of the Regulation

Adopt ETF composition

- Composition builds on existing ETF for continuity of expertise
- Nominees proposed by the various entities
- Management Board adopted ETF composition on **16 March**

Adopt ETF procedural rules

- New ETF adopted its Rules of Procedure (RoP) on **31 March**
- RoP to be approved by Management Board & Commission by mid April

New ETF is operational

- New ETF to start operating based on new mandate by **2nd half of April**

Transitional phase: existing COVID-ETF to continue with current practice

ETF composition for COVID-19

Co-Chairs: EMA chair, CHMP vicechair

Representatives from groups based on expertise:

Scientific Committees (CHMP, PRAC, PDCO, CMDh) **and EMA Representatives**

14

Working Parties' experts on vaccinology, biologics, infectious disease treatment, biostatistics, inspection, clinical trials, scientific advice assessment

19

Patients and Healthcare professionals identified by PCWP and HCPWP to bring the views of their respective communities

4

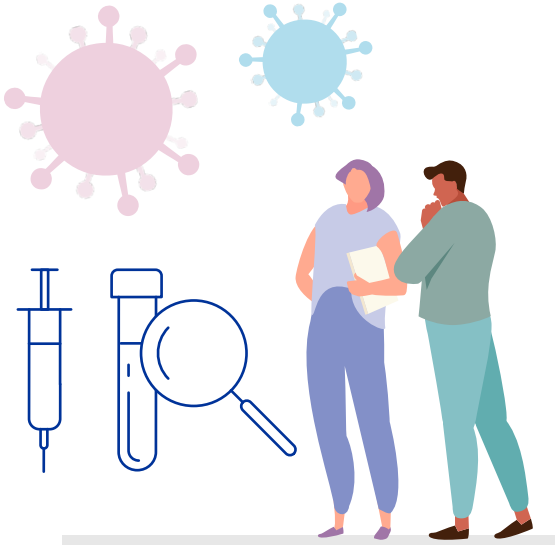
Clinical trial experts from various EU Member States (Clinical Trials Advisory Group (CTAG) and Clinical Trials Coordination Group (CTCG))

4

Additional experts and observers from academia, EU national or international regulators, EU bodies

ETF composition based on the emergency

- **ETF composition adapted after declaration of an emergency or during an emergency** to better focus on specificities of emergency
- At the end of a crisis, **emergency-specific membership revised** to adapt to preparatory measures
- **If new emergency occurs whilst one is ongoing**, new or ad-hoc members may be included depending on the nature of the new threat



Overview of ETF tasks and responsibilities

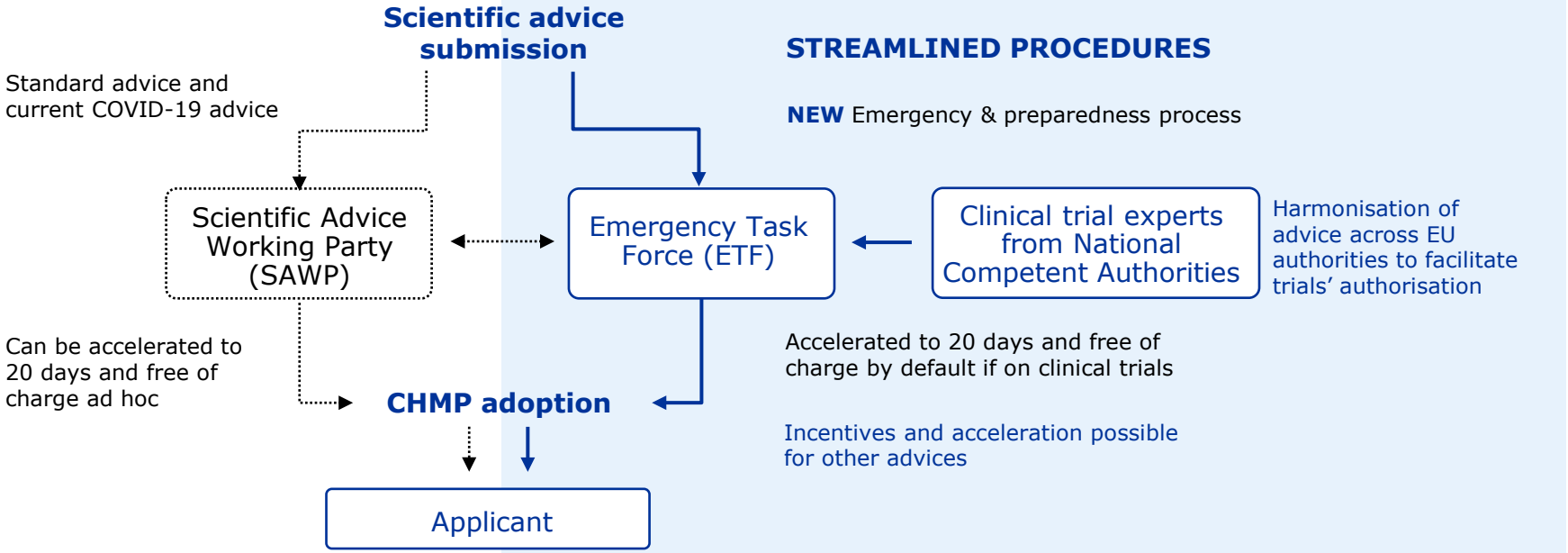
Scientific advice and support to clinical trials

Scientific reviews

Scientific recommendations

Overview of ETF tasks and responsibilities

Scientific advice and support to clinical trials | Scientific reviews | Scientific recommendations



PUBLIC HEALTH EMERGENCIES

Overview of ETF tasks and responsibilities

Scientific advice and support to clinical trials | **Scientific reviews** | Scientific recommendations

KEY BENEFITS

• Systematic review and recommendations **on medicines targeting the emergency**, published by EMA:	• **Reduce use of medicines with insufficient evidence** (e.g. hydroxychloroquine, ivermectin, inhaled corticosteroids in COVID-19) • **Increase safe and harmonised use across EU** ahead of authorisation (e.g. COVID-19 vaccines mix&match & safety during pregnancy)
• Screening evidence on medicines in the pipeline to prepare for potential marketing authorisation application:	• **Improve access to medicines** (amount of evidence needed to start rolling review)

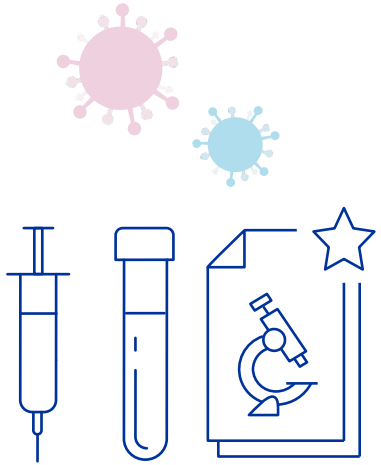
PUBLIC HEALTH EMERGENCIES

Overview of ETF tasks and responsibilities

Scientific advice and support to clinical trials | Scientific reviews | **Scientific recommendations**

Systematic recommendations to relevant Committees on medicines for emergency:

- pre-authorisation: paediatric plans, rolling review applications, Risk Management Plans
- post-authorisation: applications for major changes in use of medicines, e.g. vaccine boosters, critical pharmacovigilance issues
- use of investigational products or compassionate use programs - can be evaluated by ETF directly **(article 18(3) ETF recommendations)**
- recommendations or position statements on scientific or **public health matters** related to the emergency
    - including joint recommendations with other bodies such as ECDC



Other tasks of the ETF

ETF

	KEY BENEFITS
• **Clinical trials sponsors** • **Competent authorities** for trial authorisation	Facilitate large multinational clinical trials
• Medicines Shortage Steering Group (**MSSG**) • **Expert panels** on medical devices	Cross-links during public health emergencies
• European Centre for Disease Control (**ECDC**) • International Coalition of Medicines Regulatory Authorities (**ICMRA**) • World Health Organisation (**WHO**) • US Food and Drug Administration (**FDA**), UK Medicines and Healthcare products Regulatory Agency (**MHRA**), Health Canada Regulatory Authority (**HC**), Swiss Medicines Agency (**Swissmedic**) • Networks for observational studies, Vaccine Monitoring platform	Improved preparedness, global harmonization and support, coordination for better RWE, publication joint recommendations

Preparedness activities for future emergencies

- **Monitor outbreaks and epidemics** that could become serious threats and development of countermeasures
- **Provide scientific advice** on, and develop strategy and requirements for, medicines with potential to address future emergencies
- **Maintain an overview of medicines in development for future emergencies**, and up- to-date information on potential radiological, chemical or bioterrorism agents
- **Coordinate activities** with relevant EU bodies including European Health Emergency Preparedness and Response Authority (DG HERA), ECDC and WHO

EMERGENCY TASK FORCE (ETF)

Summary and next steps

1 March 2022

New regulation establishes ETF as expert group for leading regulatory activities in preparedness and during public health emergencies

16 March 2022

Adoption of the ETF composition

31 March 2022

Adoption of ETF Rules of Procedure

1st half April 2022

The Rules of Procedure will **enter into force** after endorsement by EC and EMA's Management Board

2nd half April 2022

1st operational meeting of the new ETF

Until then, existing COVID-19 EMA Pandemic Task Force (COVID-ETF) continues to **address the ongoing emergency**

TASKS FOR EMA TO SUPPORT ETF WORK BASED ON NEW REGULATION

An IT platform for real world evidence

A platform for generation of reliable and timely real-world evidence from routinely collected electronic health data outside of clinical studies

→ DARWIN EU® - Data Analysis and Real World Interrogation Network

- Provide a source of high-quality, validated real world data on the use, safety and efficacy of medicines
- Address specific questions by e.g. carrying out non-interventional studies or interrogating relevant data sources
- Establishment of DARWIN EU® started in Feb 2022 and first studies expected to be performed later in 2022

TASKS FOR EMA TO SUPPORT ETF WORK BASED ON NEW REGULATION

Monitoring medicines after authorisation

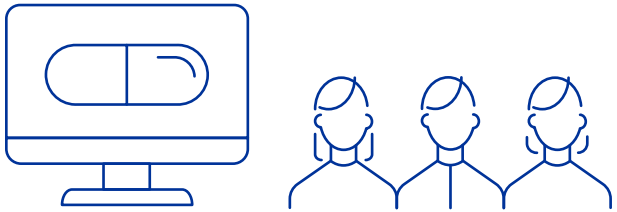
Coordinate independent monitoring studies on use, effectiveness and safety of medicines.

For vaccines targeting an emergency: new vaccines monitoring platform (VMP) (EMA/ECDC), building on learnings from COVID-19 studies:

- Joint Advisory Board (NCAs/NITAGs) established to discuss study protocols and results on safety and effectiveness of COVID-19 vaccines
- High level blueprint for the VMP under discussion with ECDC

TASKS FOR EMA TO SUPPORT ETF WORK BASED ON NEW REGULATION

Increased transparency



Publish:

- **Information and counteract disinformation** on the work of ETF
- **List of ETF members** & **Rules of Procedures**
- List of medicines under review for an emergency and **medicines with the potential to address the ongoing emergencies**

Maintain other transparency requirements related to Committees' decisions:

Publish:

- CHMP opinions on use of medicines not yet authorised (Art 18(4) of Reg 2022/123)
- Product Information, EPARs (**within 7 days from authorisation**) and **entire Risk Management Plans** of medicines addressing emergencies
- Clinical data submitted to EMA in support of above applications **within 2 months from authorisation**

Conclusion

- **ETF legally established**, with new tools to facilitate and accelerate approval of medicines in emergencies, building on COVID-19
- **Importance of preparedness:** ETF role to lead and coordinate activities for future emergencies
- **Facilitate large multinational studies** for emergencies with higher quality results by supporting clinical trials sponsors (in line with Clinical Trial Regulation)
- **Improved collaboration and coordination** across stakeholders and EU Agencies, DG HERA, clinical trials groups (CTCG, CTAG) and ECDC
- **Better preparedness and response to emergencies** guarantee protection of public health in the EU and globally