EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role of EMA Emergency Task Force (ETF)

Workshop on Clinical Trials in emergencies

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An agency of the European Union

The Emergency Task Force (ETF) in emergency

- ETF established by Regulation 123/2022 with formal legal mandate as an **advisory and support body on medicines for public health emergencies and preparedness based on expertise**

Co-Chairs: EMA (Marco Cavaleri), CHMP vicechair (Bruno Sepodes)

- Main procedures and activities during emergencies:

Scientific advice and support to clinical trials conduct	Scientific reviews of evidence on medicines	Recommendations on scientific & public health matters and on investigational medicines

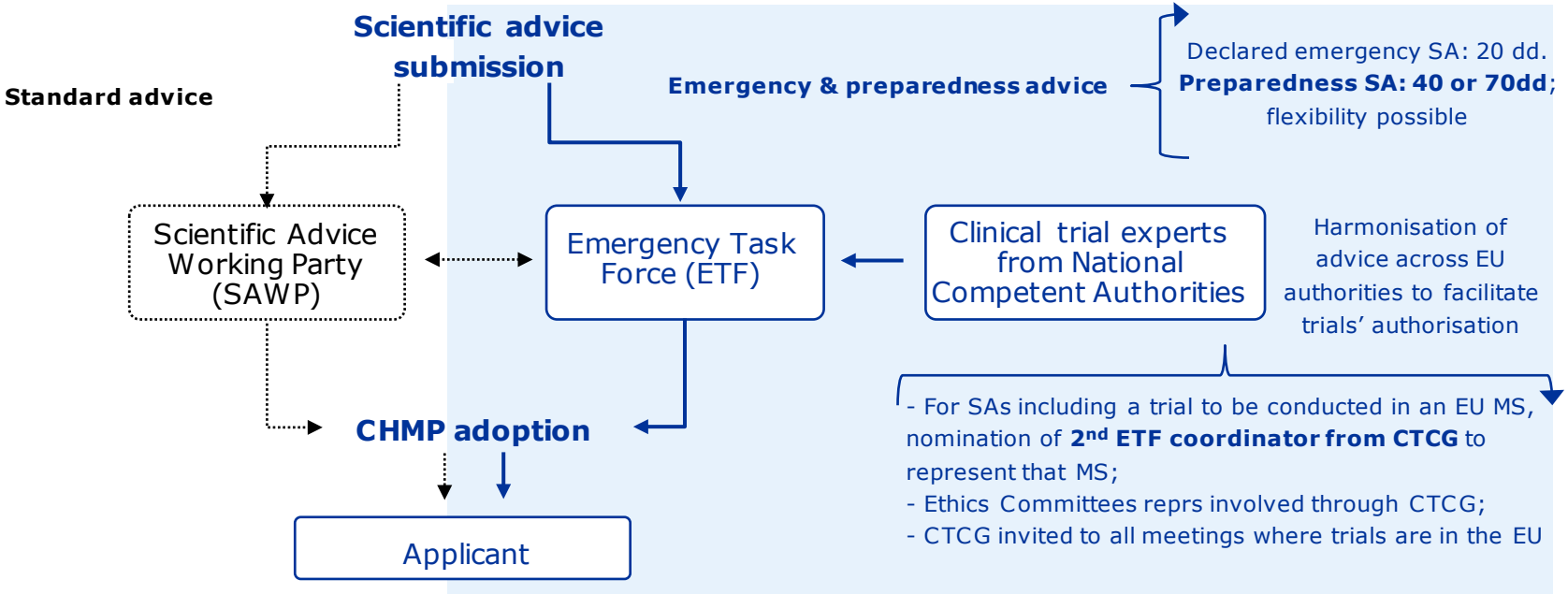
ETF continues to work beyond declared emergencies

ETF follows emerging outbreaks and performs the following activities limited to selected pathogens with pandemic potential (e.g. ZIKA, influenza) and other threats (chemical, radiological and nuclear origin):

1. **Scientific advice** (formal applications or informal discussions via TC)
2. **Facilitate large multinational trials and platform trials** by providing sponsors with i) review of protocols and ii) interactions with CTCG and NCAs for coordination/acceleration of CTA;
3. **Review of available evidence** and (joint EMA/ECDC) **recommendations** on medicines, could be published by EMA or used to support e.g. DG-HERA activities with MSs
4. Scientific support to CHMP/EC/MSs on the **use of imported/unauthorised medicines** for national exemptions / emergency authorisations in case of outbreaks
5. **Support activities with EU/international bodies** including DG-HERA, ECDC, WHO and other international regulators (research funding, advanced purchase agreement, recommendations to MSs and the public)

Scientific Advice procedure (art 16): collaboration with CTCG critical

Aim: no pre-assess CTA but tackle potential bottle necks and harmonise views



CTCG: CLINICAL TRIALS COORDINATION GROUP
CTA: CLINICAL TRIAL APPLICATION

Support to clinical trial conduct - art 15(2)(c) Reg 123/2022

- Article 15(2). *During public health emergencies, the ETF shall undertake the following tasks:*

  *(c) providing **scientific support to facilitate clinical trials** for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency;*

  *The support referred to in the first subparagraph, point (c), shall include **advice to sponsors of similar or linked planned clinical trials on the establishment of joint clinical trials** and may include **advice on establishing agreements to act as a sponsor or as co-sponsor** in accordance with Article 2(2), point (14), and Article 72 of Regulation (EU) No 536/2014.*

Scientific support to facilitate clinical trials - Mpox

- First case an academic study for tecovirimat against Mpox
- ETF actions: i) ultrarapid scientific review of the protocol; ii) facilitate larger multinational trial with same protocol
- ETF contacted by sponsors and several MSs of the EU plus UK: help with defining interventional vs. observational, harmonisation of protocol, harmonisation of approval in a centralised and accelerated way, help with CTIS application
- ETF involved HERA, DG-RTD, CTCG/MSs representatives where the study was planned to be conducted, and facilitated an emergency CTCG meeting to reach EU-level consensus

- **Need to improve process (coordination, timelines (national approval faster?), roles)**

ETF support to clinical trial conduct

- ETF to liaise with sponsors & investigator networks who might conduct research to address the public health emergency – Sponsors can initiate contact via phesupportct@ema.europa.eu

(more info https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/guidance-developers-companies/covid-19-guidance-research-development)

- ETF includes 4 permanent members from CTCG and CTAG
- COORDINATOR PLATFORM: involve additional /all members of the CTCG + reprs from Ethics committees, provide scientific comments on protocols, coordinate / support interactions across all entities to facilitate merging of smaller trials/protocols/applications, support CTIS filing
- This activity is key in preparedness for future emergencies

Monitoring medicines after authorisation

Coordinate independent monitoring **observational** studies on use, effectiveness and safety of medicines (art 18 Regulation 123/2022)

For vaccines targeting a (potential) emergency: new vaccines monitoring platform (VMP) (EMA/ECDC), building on learnings from COVID-19 studies extended to all vaccines:

- Joint Advisory Board (NCAs/PHAs) established to discuss study protocols and results on safety and effectiveness of vaccines, define research agenda
- ETF reviews protocols for studies under consideration by VMP

Any questions?

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