



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4. The Emergency task force (ETF)

EMA extended mandate – update on implementation

Industry Standing Group (ISG) meeting, 26 September 2022

Presented by Manuela Mura – Scientific Officer, Health Threats and Vaccines Strategy / ETF member

An agency of the European Union





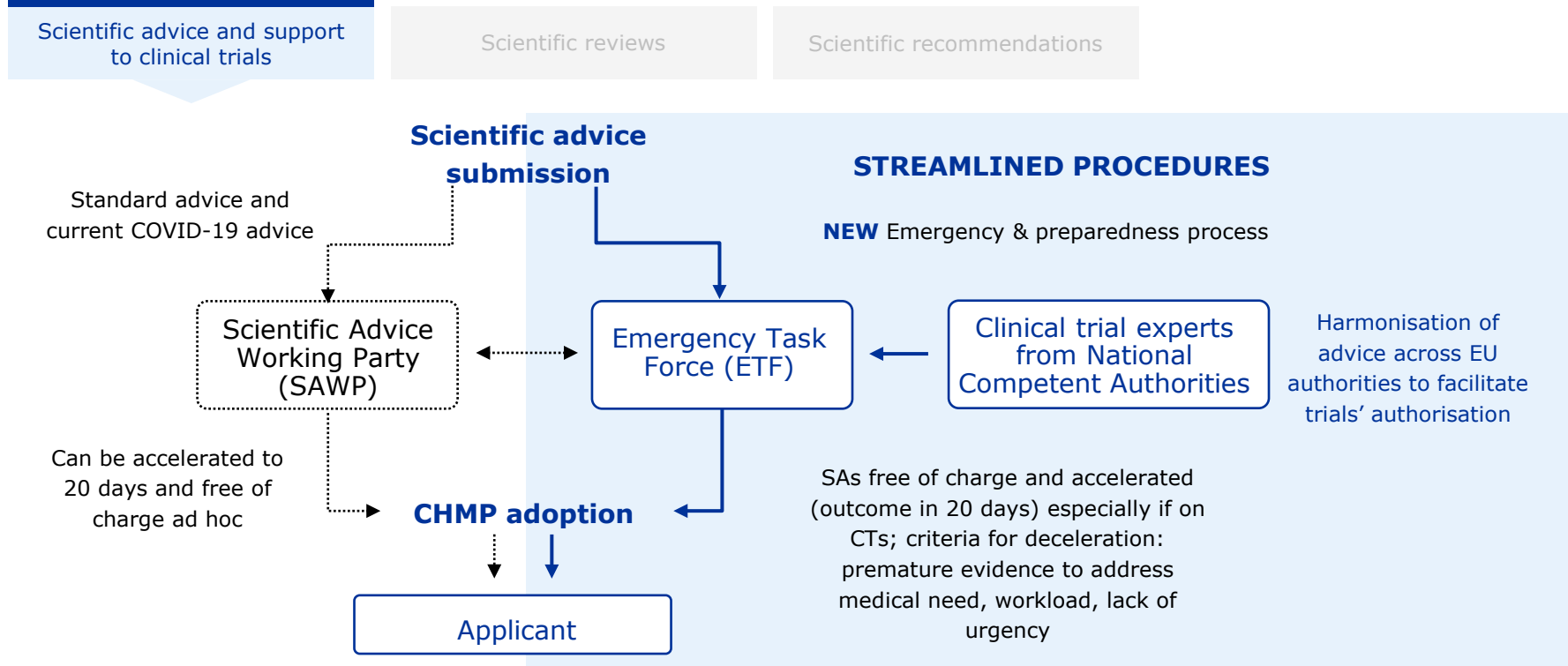
Update on implementation activities concerning ETF

- ETF dedicated webpage is live including composition and RoP:
<https://www.ema.europa.eu/en/committees/working-parties-other-groups/emergency-task-force-etf>
- Update of guidance to industry for scientific advice and support to academia for CT conduct ongoing
- Refinement of IT tools - e.g. IRIS interface with developers for SA procedure to go live on 11 October; SharePoint sites for secure exchange of documents not related to formal submissions ongoing
- Reminder → two new functional mailboxes for developers and CT sponsors:

PHEsupportCT@ema.europa.eu for CT sponsors to request EMA/ETF support for facilitating CTA and approval and sponsors agreement to conduct larger multinational trials

PHEarlyinteractions@ema.europa.eu for manufacturers to discuss with EMA/ETF their development programs or plans for scientific advice prior to any kind of formal submission
- In addition, COVID-19 existing functional mailbox will continue to be monitored 2019ncov@ema.europa.eu

Overview of ETF tasks and responsibilities



Process types: Initial and FU Scientific Advice - Human

1. Is this a request for standard Scientific Advice?* Yes No

2. Is this a request for a declared Public Health Emergency? (art. 15 and 16 of [Regulation \(EU\) 2022/123](#))* Yes No

Please specify the public health emergency

} **Appears when the answer is Yes**

3. Is this a request for a potential Public Health Emergency?* Yes No

Please specify the pathogen

} **Appears when the answer is Yes**

Please indicate in which country a CTA is submitted or intended to be submitted *

} **Appears when answer to 1 & 2 is Yes**

Fee reduction

* Mandatory information – only one can be yes



ETF activities for Monkeypox as PHEIC

- All the legal provisions applicable to COVID-19 are now extended to Monkeypox as this is a declared emergency e.g. rolling review, rapid scientific advice.
- ETF monitoring the declared emergency with the following main activities:
 - facilitate large multinational trials on the use of tecovirimat and Imvanex against monkeypox in the EU MSs by providing sponsors with i) review of protocols and ii) interactions with CTCG and NCAs for coordination/acceleration of CTA assessment and approval;
 - Supporting the Committees' discussions related to updates of the dossiers of authorised medicines
 - Consider needs for scientific support to MSs on the use of imported medicines against monkeypox in view of national exemptions / emergency authorisations
 - Provide scientific advice to applicants



ETF activities for preparedness

- ETF monitors relevant ongoing outbreaks and performs the following main activities as appropriate:
 - facilitate large multinational trials and platform trials on the use of therapeutics or vaccines by providing sponsors with i) review of protocols and ii) interactions with CTCG and NCAs for coordination/acceleration of CTA assessment and approval;
 - Interact closely with HERA and EC/ECDC for strategic discussions on access to medicines and data collection;
 - Supporting discussions related to updates of the dossiers of authorised medicines at the request of the Committees
 - Consider needs for scientific support to MSs on the use of imported/unauthorised medicines in view of national exemptions / emergency authorisations in case of outbreaks
 - Provide scientific advice to applicants for the following key pathogens: Ebola virus, Zika virus, pandemic influenza, chikungunya virus, coronaviruses including MERS and SARS, others*

* Requests for scientific advice pertaining to other (re)emerging pathogens that have the potential to cause future emergencies (e.g. Lassa virus, Nipah virus, pathogen X) will be considered on a case by case basis based on relevance and on ETF workload



Any questions?

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