EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4. The Emergency task force (ETF)

EMA extended mandate – update on implementation

Industry Standing Group (ISG) meeting, 21 June 2022

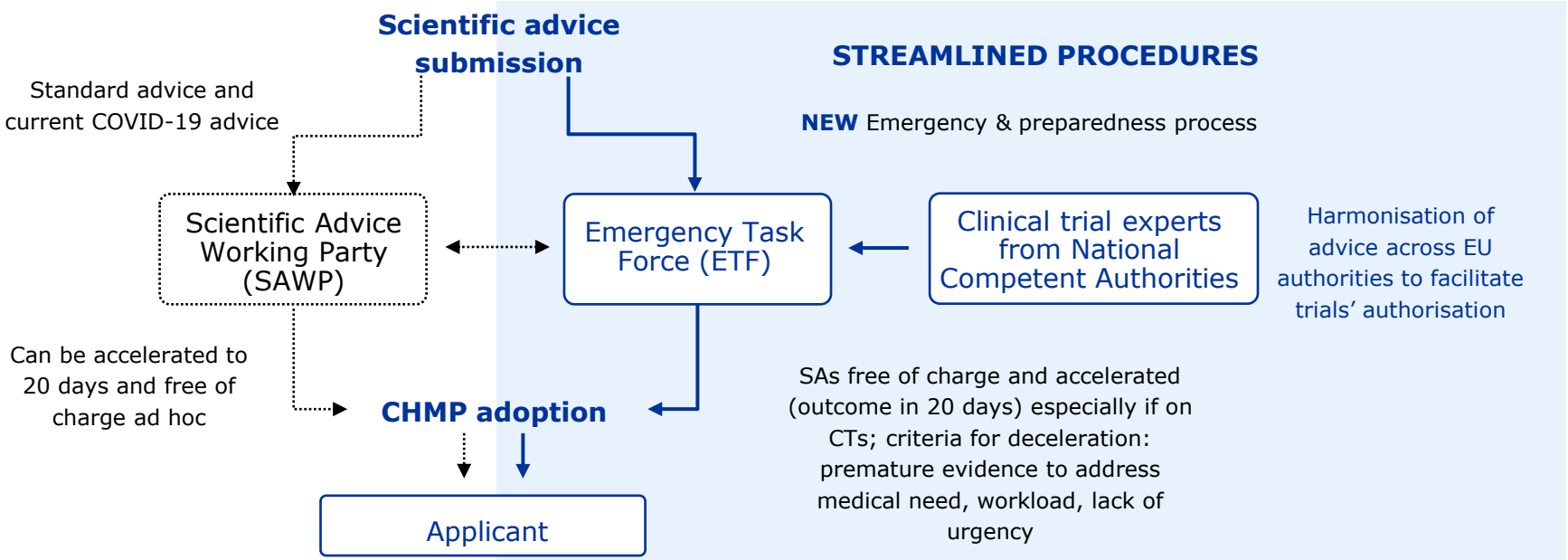
Presented by Manuela Mura – Scientific Officer, Health Threats and Vaccines Strategy

Overview of ETF tasks and responsibilities

Update on implementation status of the new Regulation concerning ETF

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

KEY BENEFITS

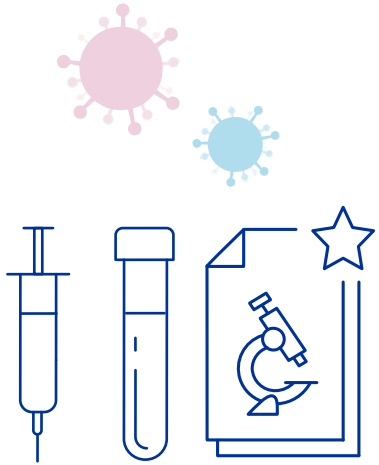
• Systematic review and recommendations **on medicines targeting the emergency**, published by EMA:	• **Reduce use of medicines with insufficient evidence** (e.g. hydroxychloroquine, ivermectin, inhaled corticosteroids in COVID-19) • **Increase safe and harmonised use across EU** ahead of authorisation (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)

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 (appt of Rapps and start of RR), 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 to CHMP)**
- recommendations or position statements on scientific or **public health matters** related to the emergency (including jointly with ECDC)



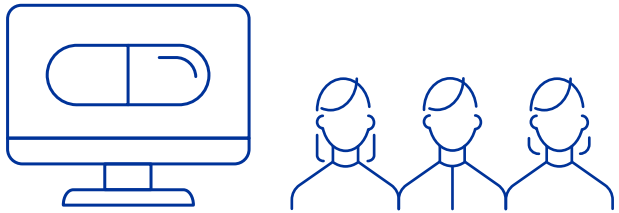
Scientific guidance for developers

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

Increased transparency



Publish:

- List of medicines under assessment addressing a declared emergency (RR and CMA)
- List of **medicines with the potential to address the ongoing emergency,** on top of medicines which received SAs (inform MSs and HSC ahead)
- Maintain **lists of medicines to address future potential PHE** and list of agents (radio, chemical etc) that can be accidentally o deliberately released

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**

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 webpages and guidance to industry ongoing – current target date for publication end of June
- Refinement of IT tools - e.g. IRIS interface with developers for SA procedure ongoing with first deliverables during summer; SharePoint sites for secure exchange of documents not related to formal submissions
- 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

  PHEearlyinteractions@ema.euroma.eu for manufacturers to discuss with EMA/ETF their development programs or plans for scientific advice prior to any kind of formal submission

Applicant portal – Administrative information tab

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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

(drop down list)

Appears when the answer is Yes

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

(drop down list)

Appears when answer to 1 & 2 is Yes

Fee reduction

* Mandatory information – only one can be yes

Preparedness ETF activities for potential emergencies (Monkeypox)

- ETF monitoring the ongoing outbreaks with the following preparedness 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 discussion 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

Any questions?

Further information

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