EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ETF role in preparedness

Planned activities outside of declared emergencies (ISG March 2023)

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

ETF continues to work beyond declared emergencies

EMA/ETF monitors emerging and ongoing outbreaks and performs the following activities:

1. Provide **scientific advice** to applicants on selected pathogens with pandemic potential and other threats
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 CT assessment and approval;
3. **Reviews of available evidence** and (joint EMA/ECDC) **recommendations** on medicines, could be published by EMA or used to support DG-HERA activities with MSs
4. **Support dossier assessment** for new MAAs or updates of authorised medicines at the request of the Committees
5. Scientific support to CHMP/EC/MSs on the **use of imported/unauthorised medicines** in view of national exemptions / emergency authorisations in case of outbreaks
6. **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)

Pathogens under ETF scope (based on CEPI, WHO and NIH)

- Alphaviruses such as **Chikungunya virus** and Venezuelan equine encephalitis virus
- Arenaviruses such as Lassa virus and Lujo virus
- *Bacillus anthracis*
- *Brucella* species
- Bunyavirales such as Rift Valley Fever virus
- *Burkholderia mallei* (glanders) and *Burkholderia pseudomallei* (melioidosis)
- *Chlamydia psittaci* (psittacosis)
- **Coronaviruses (such as MERS-CoV and SARS-CoV1 and 2)**
- *Coxiella burnetii* (Q fever)
- *Corynebacterium Diphtheriae* (toxin)
- *Escherichia coli* (enterohaemorrhagic)
- Filoviruses such as **Ebola** and Marburg
- Flaviviruses such as **Zika**, West Nile, Tick-borne encephalitis and Dengue
- *Francisella tularensis*
- **Influenza viruses** (pandemic and seasonal)
- Nipah virus and Hendra virus
- Orthonairovirus such as Crimean-Congo haemorrhagic fever
- *Polioviruses*
- *Rickettsia prowazekii* (typhus fever)
- *Salmonella* species (salmonellosis, typhoid)
- *Shigella* species (shigellosis)
- *Yersinia pestis*
- Variola major (smallpox) and **other related poxviruses**
- *Vibrio cholerae*
- Pathogen X

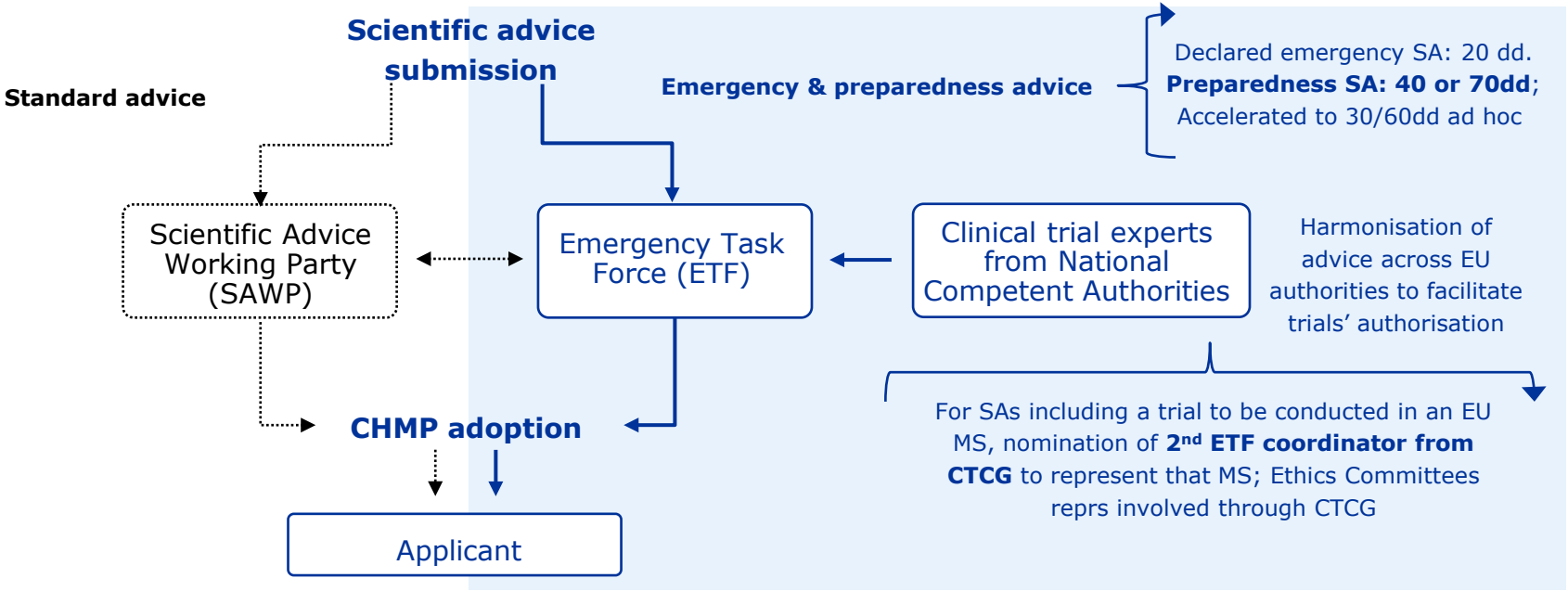
List not comprehensive and subject to change based on evolving scientific knowledge and epidemiology

Other threats under ETF scope

- **Blister or vesicant agents** such as mustards (nitrogen or sulphur), organic arsenicals (lewisite) and phosgene oxime or dichloroformoxine (CX);
- **Nerve agents** and other highly toxic organophosphates such as G-gases (tabun, sarin, soman, cyclosarin) and V-gases (VX);
- Dichlorodiphenyltrichloroethane (DDT);
- **Blood agents** such as cyanides [hydrogen cyanide (HCN) or prussic acid and its sodium (NaCN) and potassium salts (KCN)], arsine and cyanogen or dicyanogen (CN2) and its halides (CNCI, CNBr);
- **Lung-Damaging agents or chocking agents** such as phosgene, diphosgene and chlorine;
- **Incapacitating agents** such as stimulants, depressants, psychedelics and deliriants [BZ (3-quinuclidinyl benzilate), LSD (D-Lysergic acid diethylamide), fentanyls and other potent opioids used outside of therapeutic settings;
- **Lachrymatory chemical agents** (tear gas) such as chloropicrin, capsaicin, ethyl iodoacetate and adamsite;
- **Others**: Acrylamide, N,N-Diethyl-meta-toluamide (DEET), benzene, cadmium, mercury, dioxins and dioxin-like substances, lead;
- **Toxins** such as botulinum, ricin and abrin toxins
- Accidental or intentional exposure to **radiation**.

List not comprehensive and subject to change based on evolving scientific knowledge

Overview of Scientific Advice procedure



CTCG: CLINICAL TRIALS COORDINATION GROUP

EUROPEAN MEDICINES AGENCY

Process types: Initial and FU Scientific Advice - Human

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

2. Is this a request for a declared Public Health Emergency? (art. 15 and 16 of Regulation (EU) 2022/123)* ○ Yes ○ No → **ETF**

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 → **ETF**

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

Timelines for SA SAWP will be used for ETF

Acceleration ad hoc (Exceptional cases)

2023 Submission deadlines - Scientific advice, protocol assistance, qualification of biomarkers

Submission and validation phase					Evaluation phase					
	Preparatory meeting**				**SAWP1**	**SAWP2**	**D40**	**SAWP3**	**D70**	
	Yes		No							
Start of procedure	Application submission via IRIS	Preparatory meeting period	Application submission via IRIS	Final briefing document by	Start of procedure	Reports discussed	CHMP Adoption	Discussion Meeting (if required)	CHMP adoption	PRAC endorsement (PASS procedures only)
9 – 12 Jan 2023	24 Oct 22	2 Nov 22 – 22 Dec 22	5 Dec 22	4 Jan 23	9 – 12 Jan 2023	6 – 9 Feb 2023	20 – 23 Feb 2023	13 – 16 Mar 2023	27 – 30 Mar 2023	11 – 14 Apr 2023
6 – 9 Feb 2023	5 Dec 22	14 Dec 22 – 23 Jan 23	9 Jan 23	1 Feb 23	6 – 9 Feb 2023	13 – 16 Mar 2023	27 – 30 Mar 2023	11 – 14 Apr 2023	24 – 26 Apr 2023	8, 10 – 12 May 2023
13 – 16 Mar 2023	9 Jan 23	18 Jan 23 – 27 Feb 23	13 Feb 23	8 Mar 23	13 – 16 Mar 2023	11 – 14 Apr 2023	24 – 26 Apr 2023	8, 10 – 12 May 2023	22 – 25 May 2023	5 – 8 Jun 2023
11 – 14 Apr 2023	13 Feb 23	22 Feb 23 - 27 Mar 23	13 Mar 23	5 Apr 23	11 – 14 Apr 2023	8, 10 – 12 May 2023	22 – 25 May 2023	5 – 8 Jun 2023	19 – 22 Jun 2023	3 – 6 Jul 2023
8, 10 – 12 May 2023	13 Mar 23	22 Mar 23 - 24 Apr 23	11 Apr 23	3 May 23	8, 10 – 12 May 2023	5 – 8 Jun 2023	19 – 22 Jun 2023	3 – 6 Jul 2023	17 – 20 Jul 2023	28 – 31 Aug 2023
5 – 8 Jun 2023	11 Apr 23	20 Apr 23 - 22 May 23	8 May 23	31 May 23	5 – 8 Jun 2023	3 – 6 Jul 2023	17 – 20 Jul 2023	28 – 31 Aug 2023	11 – 14 Sep 2023	25 – 28 Sep 2023
3 – 6 Jul 2023	8 May 23	17 May 23 - 19 Jun 23	5 Jun 23	28 Jun 23	3 – 6 Jul 2023	28 – 31 Aug 2023	11 – 14 Sep 2023	25 – 28 Sep 2023	9 – 12 Oct 2023	23 – 26 Oct 2023
28 – 31 Aug 2023	5 Jun 23	14 Jun 23 - 14 Aug 23	17 Jul 23	23 Aug 23	28 – 31 Aug 2023	25 – 28 Sep 2023	9 – 12 Oct 2023	23 – 26 Oct 2023	6 – 9 Nov 2023	27 – 30 Nov 2023
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March CHMP (30 dd outcome w/o discussion meeting (DM) or with DM but immediate response)

April CHMP (60 dd outcome, with DM with 2 weeks clock stop)

Need to align with CHMP plenaries for adoption of the SA (discuss issues, Q at BWP/QWP)

Draft proposal subject to agreement

SA ETF on specialised areas

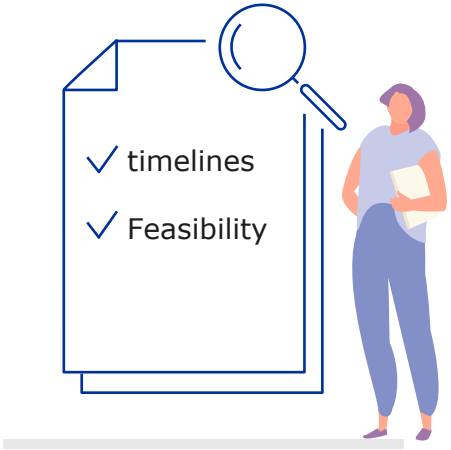
- Post-authorisation effectiveness or safety study design
- Adaptive design and trials for special populations
- Broad scientific questions covering e.g. a class of medicinal products, several indications, general manufacturing issues, platform trials
- Art 58 products
- Paediatric developments
- Potential radiological, chemical or bioterror agents
- Option to provide ETF/FDA parallel advice (global development programs) and ETF/NITAGs consultations (need for specific studies/data)

Other ETF activities in preparedness

- **PRIME** applications for products under ETF remit
- **Guidelines for developers (ETF/CHMP)**; Q&A documents; workshops; think-tank meetings on specific and rapidly evolving topics (ETF workplan under preparation)
- **Overviews of pipeline medicines** with potential to address future public health emergencies due to pathogens or due to potential radiological, chemical or bioterror agents that may be used accidentally or deliberately (e.g. **terrorism**)
- **Data outside of clinical trials** (RWE): Vaccine Monitoring Platform and DARWIN EU: ETF involved in VMP activities for vaccines (IVMAB)

Feedback from industry on:

1. structure and timelines of the ETF SA procedure proposed for preparedness
2. the new IRIS interface for ETF SA application
3. the pathogens and threats under ETF remit for preparedness (comprehensive list in IRIS for SA needed?). Any possibility to clarify eligibility for ETF procedure if a specific virus/pathogen is not listed? PHEearlysupport@ema.europa.eu
4. Do you expect a positive impact of the proposed ETF role on your activities and on the EU preparedness for future emergencies? Comments for improvement?
   a) Inclusion of Methodology Working Party in SA procedure
5. Has the ETF support improved the Agency's handling of the ongoing pandemic? any suggestions to improve?



COVID-19 guidance: research and development | European Medicines Agency (europa.eu)

Any questions?

Further information

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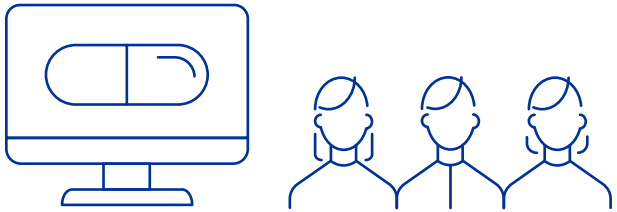
Increased transparency



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**