



Current efforts for clinical research during emergencies in the EU

EMA ETF workshop on Lessons Learned on Clinical trials in Public Health Emergencies

Laurent Muschel

Director HERA, European Commission

Introduction

- ❖ One of the key lessons learned from the COVID-19 pandemic was the **lack of a coordinated clinical trials infrastructure at EU level** that could have been activated/acted early on
- ❖ HERA was established to, among others, **promote advanced research and development of medical countermeasures (MCMs)** and related technologies (Commission Decision C(2021) 6712)

PREPAREDNESS MODE

- ❖ HERA will **identify gaps** (where authorised treatments are not available) and needs in terms of market interest on MCMs for a **short list for R&D**
- ❖ HERA will **support the development of a limited number of high-priority MCMs**

CRISIS MODE – Council Regulation on the emergency framework 2022/2371

- ❖ HERA will activate **emergency research plans** for R&D (incl. clinical trials) of novel/repurposed MCMs
- ❖ HERA will support **production and deployment** of (un)authorised MCMs

Support for Clinical Trials

Mpox

Mobilisation of up to €12 million Horizon 2020/Europe funds under the emergency procedure for **two complementary therapeutic trials**, MOSAIC and EPOXI, **on Mpox**

Response to
Health Threats

Ebola

Contribution of €5 million under EU4Health Programme for 2023 to the **conduct of late stage clinical trials in Africa under WHO sponsorship** to evaluate vaccines and/or treatments for filovirus infections toward regulatory submission

Support for Clinical Trials

Preparedness

- ❖ **EU4Health 2023 programme:** €84 million to support the speeding up of the development of, access to and/or uptake of innovative technologies and critical medicines, including vaccines.
- ❖ **CEPI:** has received several grants (€106million) from H2020 and Horizon Europe programme to advance vaccines development for COVID-19, Chikungunya and for Rift Valley Fever viruses, Ebola
- ❖ **ECDTP:** €11million to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa, including clinical development of therapeutics

Strengthening the development of crisis-relevant medical countermeasures in the EU and globally

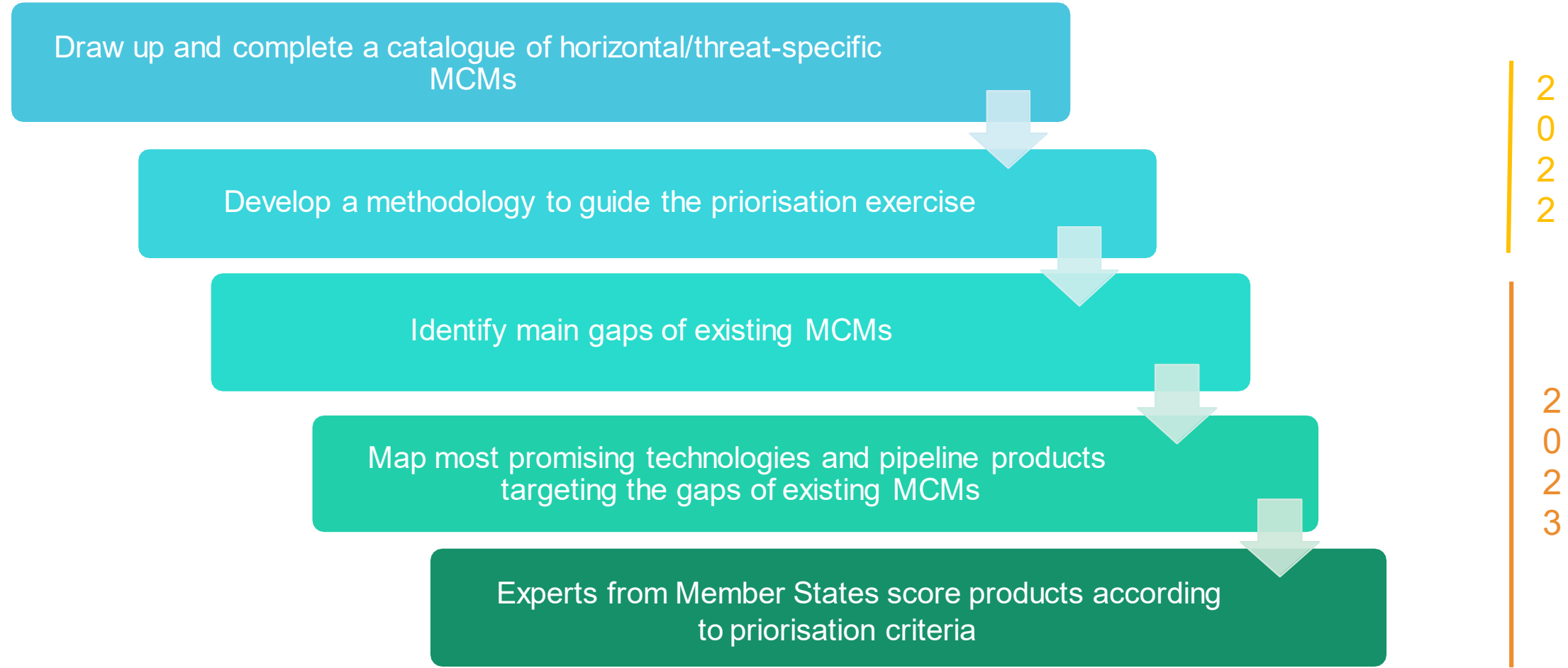
HERA Invest

Preparedness

- ❖ **€100 million** fund to support MCM development via venture loans to European companies at preferential interest rates
- ❖ **Implemented by EIB** as top-up to InvestEU
- ❖ **Leverages investments:** HERA Invest covers max 50% of development costs, other private or public investments need to fund remaining half
- ❖ **Eligibility criteria:**
 - ❖ Companies active in MCMs against HERA's priority health threats
 - ❖ Final recipient needs to be established in the EU
- ❖ **Operational by September**

Creating a dedicated envelope of R&D financing for priority cross-border health threats

Prioritisation of Medical Countermeasures in Development



➔ **Priority list will be used to guide R&D support through HERA funds**



Conclusion and Outlook

- ❖ A **harmonised framework for coordinating** the clinical trial landscape, as the proposed Coordinating Committee, could be a **very good tool to avoid fragmentation and to improve coordination**
- ❖ The **establishment of fast funding strategies in emergency settings** is key to accelerate the development of critical medical countermeasures
 - ❖ possibilities under the EU funding instruments need to be further reinforced

Thank you



© European Union 2020

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

Slide xx: [element concerned](#), source: [e.g. Fotolia.com](#); Slide xx: [element concerned](#), source: [e.g. iStock.com](#)

