



HERA initiatives on medical countermeasures (MCM) relevant to combat AMR

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*Assessment of health threats and
intelligence gathering on MCM*

HERA

- 16 September 2021: Decision 2021/C 393 I/02 establishing the **Health Emergency Preparedness and Response Authority** (DG HERA)
- Overarching mission: improve EU preparedness and response to serious cross-border threats in the area of medical countermeasures (MCM)
- Tasks:
 - Assessment of health threats and intelligence gathering on MCM
 - **Promoting R&D on MCM and related technologies**
 - **Addressing market challenges and boosting EU strategic autonomy**
 - **Procurement, distribution, stockpiling of MCM**
 - Knowledge and skills in MCM preparedness and response
- Budget: €6Bn 2022-2027

From existing EU funding programmes: Horizon EUROPE, EU4Health, RescEU

HERA and AMR

- AMR is included in HERA's preliminary list of priority threats (HERA WP 2022)
- HERA aims at promoting the development and availability of **preventive, diagnostic and therapeutic MCM** relevant to AMR
- **Funding, operational & legislative** mechanisms, in coordination with other EU services (SANTE, RTD, INTPA, ...) and global initiatives
- HERA launched two studies to identify the most relevant actions
Result to be delivered in Sept. and Nov. 2022

Study 1 Bringing AMR MCM on the market

PwC – 9 months

1. Systematic review of existing and upcoming AMR MCM + gap analysis
2. Survey to assess needs in EU MS and stakeholders (*June – HERA Board*)
3. Analysis of options for action, including cost-benefit analysis

Study 2 Stockpiling options for antimicrobials

McKinsey – 6 months

1. Identify the antimicrobials and APIs most needed in the EU
2. Identify gaps in access and supply chain vulnerabilities
3. Survey on existing and future stockpiles (*May – SPOC network*)
4. Identify and describe 3 options for stockpiling (physical and virtual)

Next steps - actions envisaged

- **Need assessment & priority signaling** intelligence gathering, HERA Board & Forum
- **R&D funding** coordination with EU initiatives (OH AMR & ECTP-3 Partnerships, IMI/IHI, EIC, EIT) and global initiatives (JPIAMR, CARB-X, GARDP, REPAIR, AMR Action fund...)
- **Implementation of pull support mechanisms, e.g.**
 - Joint tender coordinate EU-level (EU-JAMRAI proposal)
 - Innovation Partnership (call for CSA organized by RTD)
- **Manufacturing, stockpiling, procurement** MS actions support & coordination (& EU own actions?)
- **Improving continuity of supply** intelligence gathering activity + legal provisions + targeted stockpiling (coordination with SANTE for revision of EU pharma legislation)