



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Topic 4: HERA-EMA JICF joint working group on data collection update

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- Industry Standing Group (ISG) meeting, 21 March 2023



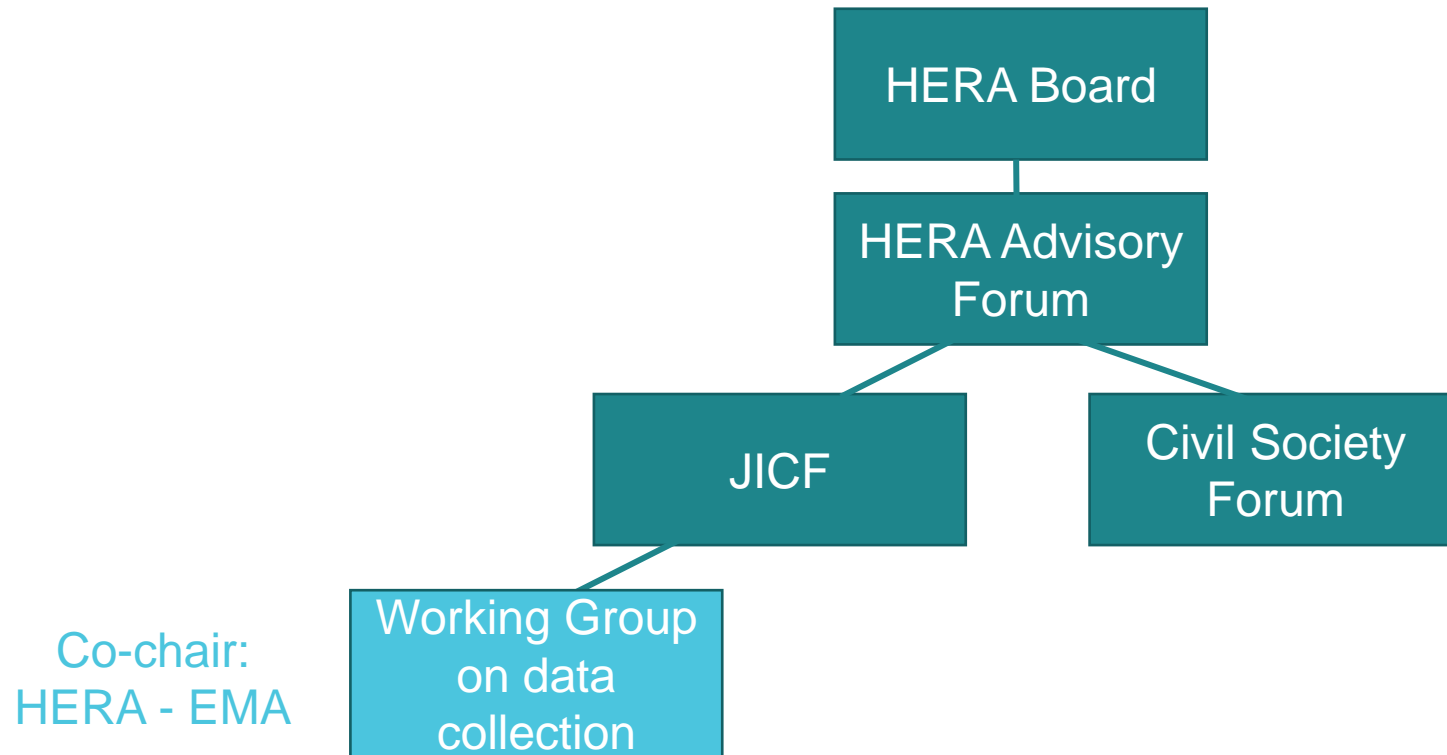


# 4th EMA Industry Standing Group (ISG) meeting

HERA-EMA JICF joint working group on data collection update

*21 March 2023*

# Joint Industrial Cooperation Forum (JICF)



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# JICF Working Group on data collection: set-up

- Created early 2023
- Co-chaired by HERA and EMA

## Objectives:

- Clarify EMA and HERA's data requests
- Receive stakeholders' feedback on data collection processes
- Discuss proposals to avoid the duplication of data requests
- Support the development of HERA and EMA IT solutions (e.g. EMA IT platform on medical devices)
- Explore measures to foster data sharing during preparedness



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# JICF Working Group on data collection: First meeting – 24 January 2023

- Over 15 industry associations and over half Member States represented
- Agenda:
  - Presentation by HERA and EMA of their data collection mandates and activities across their operational phases (preparedness and crisis)
  - Presentation of ongoing HERA/EMA collaboration to avoid duplication of data requests
  - Discussion on the objectives of the working group
  - Discussion on working methods and next steps
- The working group will report to EMA Industry Standing Group and to the HERA Joint Industrial Cooperation Forum



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# HERA/EMA data activities – coordination

- HERA and EMA both monitor the supply chains of relevant medicines/medical devices/MCMs
- They each have a specific mandate and product coverage
- Coordination and coherence will be ensured via:
  - Collection of information from marketing authorisation holders and Member States avoiding duplications
  - Joint interaction with stakeholders via JICF WG on data collection
  - Representation of EMA in HERA governance and vice-versa



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# JICF Working Group on data collection: next steps

- The work will be organised in different 'priority topics'
  - EMA Medical Device IT platform
  - EMA/HERA data collection
- JICF members will be asked to nominate experts
- Technical meetings by topic



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# Q&A



# Thank you



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