Implementation of the Council Recommendation on AMR

State of play of Commission's actions

AMR One Health Network Meeting
29 February 2024

Outline

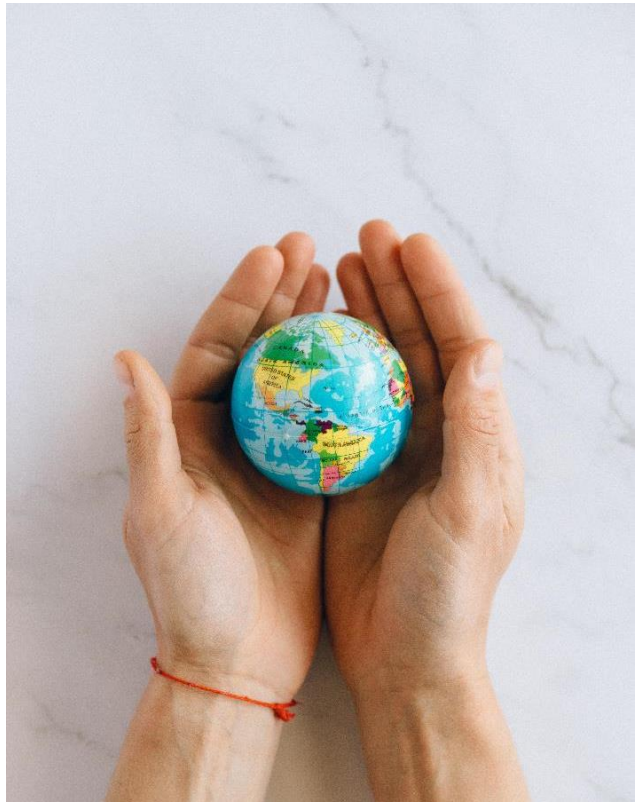
- Development of a monitoring framework to assess progress in EU actions against AMR
- Feasibility study on integrated surveillance systems on AMR
- Developments in human health: The EU Regulation on serious cross-border threats to health
- R&D and incentives: HERA initiatives on AMR and actions by RTD

Development of a monitoring framework to assess progress in EU actions against AMR

- Council Recommendation Point 38: *"Develop a **monitoring framework** to assess the progress and results achieved in implementing the 2017 AMR Action Plan and this Recommendation."*
- To obtain the desired effects, the implementation of the 2017 AMR Action Plan and the Council Recommendation on AMR needs to be **monitored regularly** to:
  - measure the effectiveness and performance of the actions,
  - modify them if necessary, and
  - identify possible gaps in the EU-level efforts to tackle AMR.
- In December 2023, the Commission launched a 10-month **external study** for the design of the monitoring framework.

Study on the design of a monitoring framework of the EU One Health actions against AMR

- **Objective:** To design a cost-effective monitoring framework to assess the effectiveness, progress and results achieved in implementing the **2017 AMR Action Plan** and the **2023 Council Recommendation on AMR**.
- **Geographical scope:** EU-27 Member States (MS), Norway & Iceland.
- **Temporal scope:** 2017 – present.
- **Expected results:**
  - Provide a **monitoring framework** that shall allow for a dynamic, systematic and regular follow-up of the progress made in **combating AMR** in the EU.
  - Provide a flexible and coherent framework to support the implementation of the **2017 AMR Action Plan and 2023 Council Recommendation** and future evaluations.



Consultation activities with AMR One Health Network

Online presentation

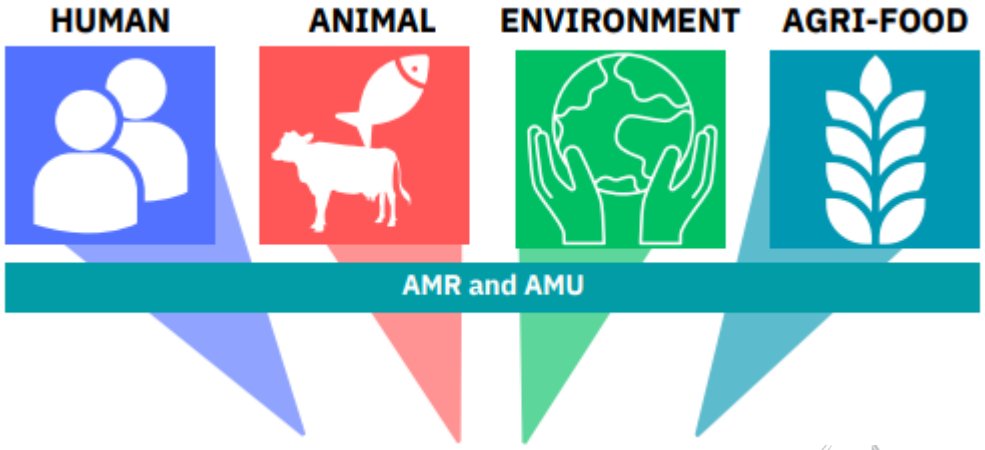
- Late May 2024
- Short online webinar with OHN members (1.5 hour) to present the draft framework and explain the consultation process
- Save the date with draft agenda will be sent in coming weeks

Targeted written consultation

- Late May - Mid July 2024
- Survey of OHN members on proposed indicators for the framework

Feasibility study on integrated surveillance systems

- Council Recommendation Point 5e: *"… developing integrated systems for the surveillance of AMR and AMC encompassing human health, animal health, plant health, food, wastewater and the environment (in particular water and soil), taking into account the Commission* ***feasibility study on integrated systems*** *…".*
- To support Member States, the Commission will launch a feasibility study on integrated surveillance systems on AMR and antimicrobial use from the human, veterinary and plant production and environmental sectors.
- **Funding:** EU4Health
- **Budget:** EUR 500 000
- **Timeline:** to be launched after the summer



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Human health: main developments

- Regulation (EU) 2022/2371 on serious cross-border threats to health – key articles relevant to AMR:
  - Article 2: identifies AMR and healthcare associated infections as serious cross-border threats to health
  - Article 7: reporting on prevention, preparedness and response planning => Commission Implementing Regulation (EU) 2023/1808 on the template for provision of information
  - Article 8: assessment by ECDC
  - Article 9: EU state of health preparedness report, AMR included in 2023 edition
  - Article 10: coordination in the EU Health Security Committee, TWG on AMR
  - Article 13: epidemiological surveillance, improvements made to existing reporting
  - Article 15: EU Reference laboratories including AMR

Human health: main developments contd.

- Regulation (EU) 2022/2371 on serious cross-border threats to health – other important elements:
  - Articles 4, 10 and 21: EU health security committee, coordination of preparedness and response
  - Article 12: Joint procurement of medical countermeasures
  - Article 18: Early Warning and Response System (EWRS)
  - Article 20: Public health risk assessment now more encompassing
  - Article 23 and 25: Public health emergency at Union level, triggering other legislation
  - Article 24: Advisory committee on public health emergencies

HERA's role on AMR

AMR = one of HERA three priority threats to prepare against

HERA's role: to ensure the development of and access to proper AMR **medical countermeasures**, including **antimicrobials** (both novel and older antibiotics), **diagnostics** (rapid point-of-care diagnostics, antimicrobial sensibility testing) and **vaccines** (against resistant pathogens)

Legal framework

- Regulation on Serious cross border threat to health
- Commission Decision establishing HERA
- Regulation on "Emergency framework for ensuring the supply of crisis-relevant medical countermeasures
- New EU pharma legislation
- EU Council recommendation on AMR

EU funding programmes

- EU4Health
- Horizon EUROPE
- rescEU

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HERA initiatives on AMR

- **Priority signaling** - funding WHO for maintaining global priority pathogens lists, pipeline analyses and target product profiles, + adaptation of prioritization to EU context
- **Strengthening surveillance capacities** - funding capacities for sequencing and wastewater monitoring (EU + non-EU) ; initially for SARS-Cov-2 now extended to AMR
- Contribute to **push funding** for AMR MCM (calls under EU4Health to speed-up innovation for AMR vaccines, metagenomic diagnostics, child-friendly formulation for TB medicines, funding of GARDP for clinical trials for novel antibiotics)
- Design and implement **EU pull incentives** through procurement mechanisms
- Improving **continuity of supply** through intelligence gathering, support to manufacturing & stockpiling of AMR MCM
- **International dimension** : participation in global fora to advocate for initiatives supporting the development of and access to AMR MCM (pandemic treaty, G7, G20, TATFAR, Global R&D AMR Hub…)

Pull incentives : Commission's strategy

- 26 April 2023 : Commission proposal for a **new EU pharma legislation** and Commission's proposal for Council recommendation

« Toolbox » of pull incentives

  - Transferable data protection vouchers for the development of new antimicrobials
  - Procurement-based pull incentives to improve access to new and existing antimicrobials

- 13 June 2023 : **Council recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach**

  - Commission to "*design of an EU multi-country pull incentive scheme to improve innovation, the development of new antimicrobials and access to existing and new antimicrobials where Member States can participate on a voluntary basis*"

Pull incentives : HERA pilot project

- Aim = to improve **ACCESS** to antibiotics **recently approved**
- **EU multi-country revenue guarantee** for access that should
  - not interfere with the MS competencies on pricing and reimbursement
  - be funded by EU budget (EU4Health)

= Similar approach than the project implemented in Sweden, adapted to EU context

- Pilot will build on previous experience and initiatives, including EU-JAMRAI-1, and be carried out with support from EU-JAMRAI-2 (WP-9 : Access)
- MS experts designated by the HERA Board met in September 2023 and 2024 to discuss the candidate antibiotics and the design of the scheme
- Pilot expected to be launched in 2025

Thank you

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