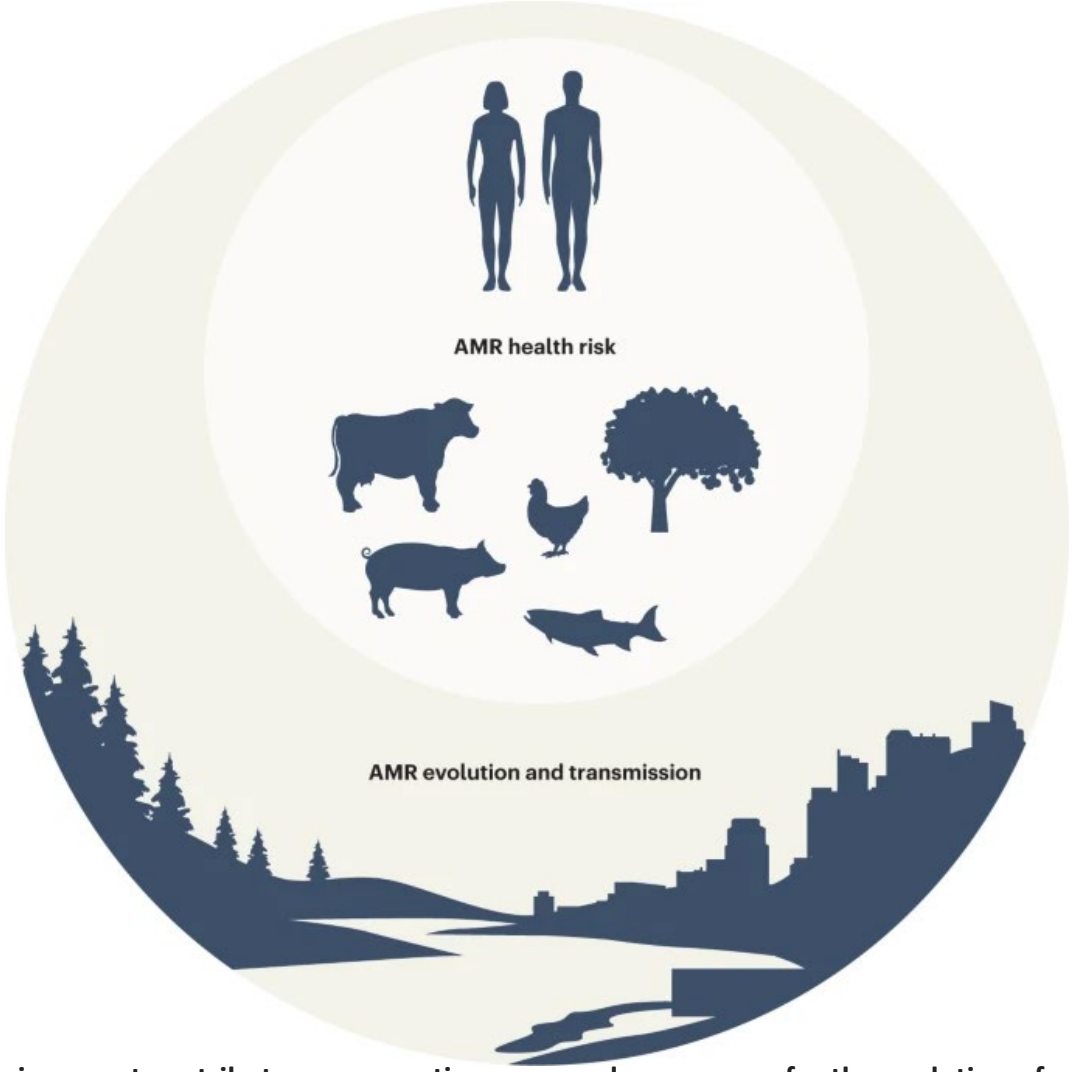
AMR One Health Network
Environmental Risk Assessment in the Revision of the EU pharmaceutical legislation

29 February 2024

DG SANTE



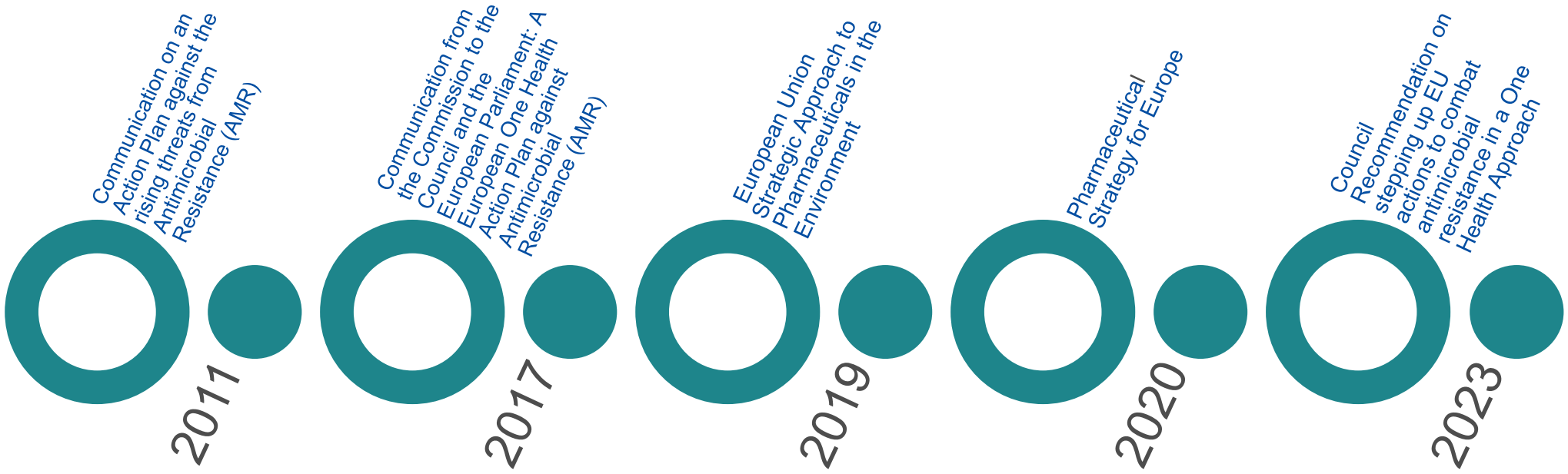
The environment contributes as a genetic source and as an arena for the evolution of new forms of resistance, and as a transmission pathway for many resistant pathogens.

AMR, One Health and the environment, Larsson et el 2023

Layout of the presentation

- Pharmaceuticals in the environment and AMR
- Strengthening the ERA requirements in the revision of the EU pharmaceutical legislation
- The risk of AMR selection in the scope of ERA

Commission acknowledges that Pharmaceuticals in the environment may play a role to AMR



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European Commission

Pharmaceuticals in the environment and AMR

1

Several antimicrobial (antibiotic and antifungal) pharmaceuticals from the treatment of humans and animals have been found in water and soil: their presence may play a role in accelerating the development, maintenance and spread of resistant bacteria and fungi.

European Union Strategic Approach to Pharmaceuticals in the Environment

2

Different types of sources of antibiotic pollution typically give rise to different levels of exposure to aquatic bacterial communities. This, in turn, provides a reflection of the probability of environmental selection Antibiotic resistance in the environment
D. G. Joakim Larsson and Carl-Fredrik Flach 2022

3

Environmental pollution with antimicrobials may also contribute to the development of resistance, in both non-pathogenic and pathogenic microbes, thereby threatening the effectiveness of antimicrobials as therapeutic agents in humans, farmed and domestic animals and crops

Larsson et al. 2023

Strengthening the ERA in the revision of the EU pharmaceutical legislation

Include a stand-alone ground of refusal if ERA does not sufficiently substantiate + address risks to the environm. and public health (AMR)

(DIR Art 47, REG Art 15)

Add the risk for AMR selection in the environment due to the manufacturing, use and disposal of antimicrobials into the protection goals of ERA (DIR Art 4(33)

Compliance with EMA scientific guidelines on ERA becomes mandatory

(DIR Art 22)

Update ERA in light of new information (DIR Art 22)

Obligation to conduct post-authorisation ERA studies at the time of MA and after authorisation

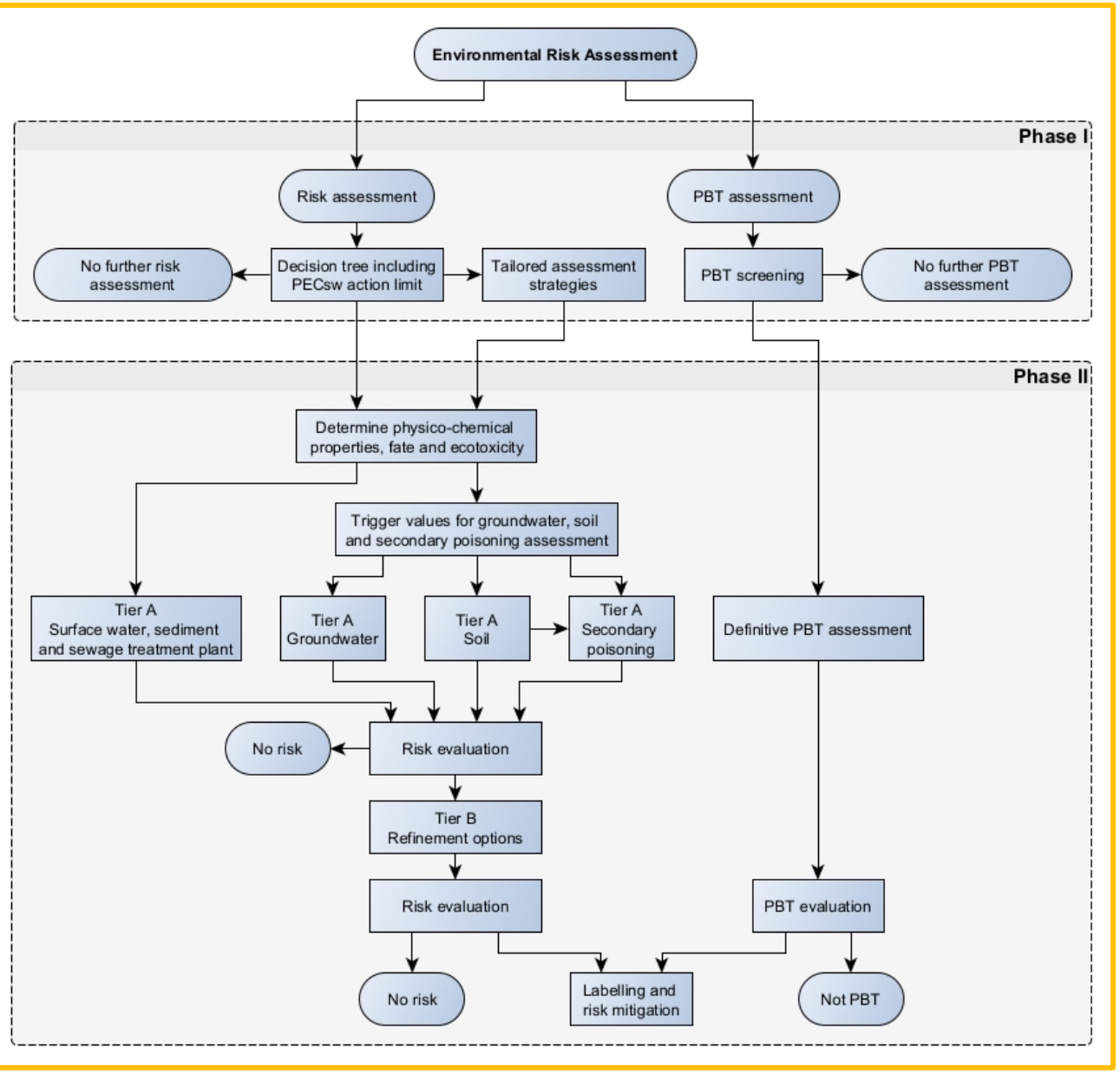
(DIR Art 44, 87, REG Art 20)

Grounds for suspension, variation, revocation of MA +prohibition of the supply of medicines in case of environmental concerns

(DIR Art 195, 196)

Definition of **environmental risk assessment (ERA) in the Pharma proposal**

- Definition of environmental risk assessment (ERA)
  - for MPs (use and disposal) and
  - for MPs with an antimicrobial mode of action (**manufacturing**, use and disposal)
- ***'environmental risk assessment'*** *means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product*;



EMA's Guideline on the Environmental Risk Assessment (ERA) of Medicinal Products for Human Use

- The ERA report is composed of
  - **risk-based** and
  - **hazard-based** (also called persistence, bioaccumulation and toxicity, or PBT) assessments.
- The risk and PBT assessments are divided into Phase I and Phase II

The risk of AMR selection in the scope of ERA

Tailored Assessment for Antibiotics in the current EMA Guideline	• Only from use & disposal • Only ecotoxicological effects
AMR selection risk assessment	• Manufacturing, use and disposal • AMR selection

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