

Strategic Approach to Pharmaceuticals in the Environment

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**Meeting of the One-Health
Network on AMR
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Background

- **Origin:** Environmental Quality Standards Directive 2008/105/EC as amended by Directive 2013/39/EU – Article 8c
- **Main driver:** Protection of water environment and human health via water environment, but wider environment is being considered (NB pharmacovigilance legislation requires this)
- **Major contribution:** To the environment pillar of the One-Health Action Plan on AMR.
- **Adoption:** Communication was adopted on 11 March 2019 as COM(2019) 128 final

Objectives of strategic approach

- Identify **actions** to be taken or further investigated **to address potential risks** from pharmaceutical residues in the environment, **not least to combat AMR**;
- Encourage **innovation** where it can help to address the risks, and promote the circular economy (recyclability of sewage, manure etc);
- Identify remaining **knowledge gaps** and solutions for filling them;
- Ensure that actions to address the risk do not jeopardise **access** to safe and effective pharmaceutical treatments for humans/animals.

Important points

- Approach considers **whole life cycle** of pharma
- **Several policy areas** relevant, incl. env, health, agri, trade
- **Actions** are identified in **six areas**
 1. Increase awareness and promote prudent use
 2. Support development of greener pharma and manufacturing
 3. Improve environmental risk assessment
 4. Reduce wastage and improve waste management
 5. Expand environmental monitoring
 6. Fill other knowledge gaps

Actions most relevant to AMR - 1

INCREASE AWARENESS/PROMOTE PRUDENT USE

- Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment
- Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development
- Aim to limit the preventive use of veterinary antimicrobials by ensuring correct implementation of the new VMP Regulation

Actions most relevant to AMR - 2

SUPPORT DEVELOPMENT OF GREENER PHARMA AND MANUFACTURING

- ...fund R&I to support the development of “greener” pharma that degrade more readily, to harmless substances
- Engage directly with pharma industry on its contribution, e.g. on potential role of EPR in improving water treatment
- Under the WFD, consider specific pharmaceuticals for inclusion in the Priority Substances list...
- Encourage action on emissions from manufacturing in third countries

Actions most relevant to AMR - 3

IMPROVE ENVIRONMENTAL RISK ASSESSMENT

- In collaboration with EMA and MS – seek to improve environmental expertise in the Committees
 - Consider developing guidance on ERA of MPs for aquaculture
 - Emphasise importance of timely completed ERA – to support risk management measures
- Following up new VMP Regulation, report on feasibility of EU-wide review system based on active pharma ingredients
- Initiate systematic catching-up procedure for ERA of VMPs; consider results of IMI project for HMPs

Actions most relevant to AMR – 4a

REDUCE WASTAGE AND IMPROVE WASTE MANAGEMENT

- In collaboration with MS and EMA
 - Explore possibility of optimising package size and safely extending use-by dates so that fewer medicines have to be thrown away
 - Facilitate exchange of best practices on safe disposal of medicinal products and clinical waste, and collection of residues
- In relation to urban waste water treatment
 - Use Union programmes to invest in technologies to improve removal of pharma and ARGs
 - Assess whether UWWT legislation sufficiently controls pharma emissions

Actions most relevant to AMR – 4b

REDUCE WASTAGE AND IMPROVE WASTE MANAGEMENT

- Assess the possibility of working with MS on improving Codes of Good Agricultural Practice to cover management of pharma in manure
- Assess whether IED should address intensive dairy farming

Actions most relevant to AMR – 5

EXPAND ENVIRONMENTAL MONITORING

- Possibly include additional pharma in the surface water Watch List, and consider the feasibility of monitoring AMR microorganisms and ARGs
- Support research on monitoring individual substances and mixtures of substances in the environment using conventional analytical and other techniques
- Explore with stakeholders the gathering of relevant data on effluents from potential hotspots...
- Include antimicrobials and possibly ARGs in the next phase of the LUCAS soil survey

Actions most relevant to AMR – 6

FILL OTHER KNOWLEDGE GAPS

- Eco-toxicity and environmental fate of pharma
- Links between the presence of antimicrobials in the env (if possible also the entry and natural presence of ARGs) and the development and spread of AMR
- Possible effects on humans of (chronic) exposure to low levels of pharma
- Cost-effective methods for reducing the presence of pharma including antimicrobials in slurry, manure and sewage sludge

Initial actions

- Workshop (May 2019): (organised jointly with NL) for MS and stakeholders
- Discussion with SRSS re possible peer support to MS
- Meetings with stakeholders: healthcare professionals, water industry, NGOs, pharmaceutical industry
- Planning of further stakeholder engagement on specific actions
- Completion of Fitness Check of water legislation
- Revision of surface water Watch List (AMR?)

Initial actions cont'd

- Presentation to Member States in context of Green Public Procurement Advisory Group
- Exchanges with WHO
- Ongoing revision of ERA guidance
- Forthcoming meeting of Pharma Committee
- Implementation of new Veterinary Medicinal Products Regulation
- EMA/CVMP reflection paper on AMR in the env.
- Planning of Horizon Europe – possible Partnerships on AMR and follow-up to the Innovative Medicines Initiative



Information

Strategic Approach to PIE

https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

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