Pharmaceuticals in the Environment Development of Strategic Approach

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A few reminders

- Strategic approach is aimed at tackling risks from pharmaceuticals in the environment (PIE), including but not only antimicrobials.
- Obligation to develop the approach comes from Article 8c of Directive 2013/39/EU amending the Environmental Quality Standards Directive (EQSD, 2008/105/EC) re Priority Substances (PS) under the Water Framework Directive, but…
- Wider environment is being considered (pharmacovigilance legislation requires this), and…
- Strategic approach is important contribution to the environment pillar of the One-Health Action Plan on AMR.

What have we done so far?

- SANTE-sponsored report published 2014
- Follow-up workshop Sept 2014
- New study contract from November 2015 (Deloitte)
- Study → report providing update on scale of problem
- Roadmap published April 2017
- Study → background document on possible policy options, and summary
- Consultation – online and in meetings

Consultation activities

- Stakeholder consultation deadline 21 Jan 2018
- Public consultation deadline 21 Feb 2018
- Meetings with different stakeholder groups:
  - Pharma industry 19 Dec
  - WFD MS WG Chemicals and Groundwater 9 Jan
  - Water-treatment industry/research institutes 12 Jan
  - Vet Med regulatory committee 22 Jan
  - (Human Med regulatory committee)
  - Env NGOs 31 Jan (in addition to EP meetings)
  - Healthcare NGOs/Professional organisations 6 Feb
  - WFD Strategic Coordination Group discussion 8 Feb

Other activities and timeline

- Internal meetings (ENV and COM-wide) – several in Jan/Feb 2018
- Interservice consultation – March
- Adoption of strategic approach by end May – probably in the form of a Commission Communication supported by the study report with revised background document, and report of the public consultation

Important points

- Policy options relate to whole life cycle of pharma
- Not only water policy is implicated – also other env policy, agri, health, trade etc.
- Working particularly closely with DG SANTE but other DGs relevant
- Try to include concrete actions if possible, but no impact assessment (IA) at this stage - for any legislative action, full IA needed at second stage
- No fixed idea yet re number of options – aiming to include most realistic/feasible/cost-effective based on first assessment and consultation inputs

Possible options relevant to AMR

- Research (Options 1, 2 (AMR), 3 (greener pharmaceuticals), 26 (advanced water treatment))
- Medicinal product authorisation and follow-up etc (several options including 13 (ERA update), 15 (RMM follow-up), 17 (env in pharmacovigilance)
- Best-available Technique Reference Documents (BREFs)/BAT conclusions under Industrial Emissions Directive (Option 9)
- Green Public Procurement (GPP) – Good Manufacturing Practice (GMP) (Options 10 & 11)
- Prescription practices/OTC (Option 14)

Possible options cont'd

- Dialogue/info exchange between authorities (16)
- Environmental monitoring (18, 25) including effluents, soil, manure?
- Awareness-raising/training (Especially Options 19 & 20)
- Packaging size (Option 21)
- Extended Producer Responsibility (EPR) for disposal of hazardous waste and for unused pharma collection schemes; labelling of hazardous pharmaceuticals? (Options 22 & 23)
- Livestock farming (Options 18, 19, 28, 29)
- EPR for UWWT (Options 24, 25, 26, 27, 28)

Stakeholder consultation - I

- Approx 90 inputs to targeted consultation
- Water companies, human health, veterinary and environment authorities, pharmaceutical industry bodies, NGOs etc
- Initial analysis conducted – but trying to avoid drawing superficial conclusions from statistics on closed questions
- Significant amount of free text and several additional documents submitted
- Will be complemented by input to public consultation

Stakeholder consultation

- Important to differentiate between human and veterinary responses
- High level of concern re link between AMR and environment
- Some comments that methods for monitoring AMR in water not available