Pharmaceuticals in the Environment
Veterinary medicines

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"Core" medicinal products legislation


- Both require environmental risk assessments (ERA) to be conducted.
- Both require Member States to ensure that appropriate collection systems are in place for unused medicinal products.
- The summary of product characteristics has to include special precautions for disposal of a used medicinal product or derived waste materials, if appropriate.
Veterinary medicines: Draft Regulation

✓ ERA remains compulsory for all new veterinary medicines
✓ Generics: currently fully compulsory and proposal only in certain specific cases
✓ Old products: environmental re-assessment (harmonisation SPCs)
✓ Pharmacovigilance: detecting risks to the environment
✓ Collection systems
Veterinary medicines: Draft Regulation

European Parliament: AMs adopted (Report March 2016)

✓ ERA of generics: only if increased risk to env compared to the reference product (AM 109)

✓ SPC harmonisation: if no prior ERA in the EU (AM 174)

✓ Pharmacovigilance: any adverse, unforeseen, or unintended impact in the environment (AM 179)
Veterinary medicines: Draft Regulation

Council: ongoing discussion

- Generics: Article 16 (6)
- SPC harmonisation: Article 70 (3)
- Pharmacovigilance: Article 73 (c)
ERA: EMA guidelines and papers


- Concept paper on the revision of the 'guideline on the ERA of medicinal products for human use' (Consultation until May 2016)

- Reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances (May 2017)
Second study on the environmental risks of medicinal products

✓ The Deloitte study (ongoing)
✓ Contracted by DG ENV
✓ Better knowledge of the issue
✓ More sustainable production, consumption and disposal patterns in a circular economy (lifecycle!)
✓ Cost-efficient measures to mitigate associated risks
✓ Public consultation foreseen
✓ Final study report expected towards the end of 2017
Several possible options for consultation

✓ Public consultation on about 30 possible options identified by consultant, for example:

✓ Provide further EU funding for research and encourage MS to fund relevant research to improve knowledge of the problem

✓ Ensure scientific robustness and use of ERA

✓ Promote greener manufacturing processes

✓ Identify and address post-marketing environmental impacts

✓ Promote sustainable use

✓ Ensure appropriate collection and disposal of pharmaceutical waste

✓ Promote more effective treatment of waste water, manure and sludge

✓ When? Probably starting within a few weeks
Several possible options for consultation

Ensure scientific robustness and use of ERA

✓ Ensure that all relevant environmental endpoints for pharmaceuticals placed on the market are systematically made publicly available in a standardized format

✓ Develop comprehensive substance-based ERA

✓ Ensure that ERAs adequately consider PBT for the APIs
Where are we regarding the strategic approach?

- Public consultation to be launched shortly
- Study report, including analysis of consultation inputs) expected later this year, to inform development of strategic approach.
- Aim for Commission to adopt the strategic approach early next year.
- Options in the strategic approach to be followed by proposals for measures, subject to impact assessment.