



Pharmaceuticals in the Environment

Veterinary medicines

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"Core" medicinal products legislation

- Directive 2001/82/EC – Community code relating to veterinary medicinal products – amended by Directive 2004/28/EC
- Directive 2001/83/EC – Community code relating to medicinal products for human use – amended by Directive 2004/27/EC
 - **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

- Guideline on Environmental impact assessment for veterinary medicines in support of the VICH guidelines GL6 and GL38 (2008) – last update 2016
- Guideline on the ERA of medicinal products for human use (2006) – last update 2015
- 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?

- **PIE strategic approach Roadmap published on 28 April 2017:** http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630_en
- **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.**