



Pharmaceuticals in the environment

Make ideas work!

A perspective from the European Parliament

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Key EP activities on pharmaceuticals in the environment: legislature 1999 - 2004

Major review of EU pharmaceutical legislation (human, veterinary, EMA)

- for vet medicines, EP expanded the definition of “risk” (risks relating to quality, safety, efficacy) to also include “*any risk of undesirable effects on the environment*”
 - **EP insisted on including environmental risk into the central approval criterion (risk/benefit balance)**
- ❖ Note: Greens/EFA also wanted this for human medicines (2001), but failed to get majority support within ENVI

Key EP activities on pharmaceuticals in the environment: legislature 2004 - 2009

Water framework legislation (priority substances)

- in first reading (2007), EP listed 28 substances/groups of substances for specific review for identification of priority/priority hazardous substances, 5 thereof being pharmaceuticals (Clotrimazole, **Diclofenac**, Carbamazepin, Amidotrizoate, Iopamidol)
 - the final law adopted in 2008 listed 13 substances for such review, but no pharmaceuticals (COM and MS were opposed, allegedly not enough data to substantiate any concern)

Key EP activities on pharmaceuticals in the environment: legislature 2009 – 2014 (1/2)

Review of EU pharmaceutical legislation for humans to modify provisions on pharmacovigilance

- EP insisted on introducing a recital
 - pollution of waters and soils with pharmaceutical residues an emerging environmental problem
 - Member States to consider measures to monitor and evaluate the risk of environmental effects
 - COM to produce a **report** on the scale of the problem and **assess** the need to amend pharmaceutical legislation
- ❖ Note: EPP coordinator tabled AM to modify risk definition for human medicines to include environmental risk (2008), but failed to get majority support in ENVI (“out of context”)

Key EP activities on pharmaceuticals in the environment: legislature 2009 – 2014 (2/2)

Water framework legislation (priority substances, EQS)

- COM proposed three pharmaceuticals to be identified as priority substances (estradiol, ethinylestradiol, diclofenac) + EQS
 - EP and Council merely agree to put these substances on the first watch list “to gather monitoring data to facilitate the determination of appropriate measures to address the risk posed by those substances” (=no more EQS, less sampling) ☹️
 - EP insisted on requirement for COM to develop a strategic approach to pollution of water by pharmaceutical substances ☺️
 - (as far as possible) by September 2015: including how to take into account more effectively the enviro impacts of medicines in approval
 - by September 2017: COM to propose measures, where appropriate, to address the possible environmental impacts of pharmaceutical substances with a view to reducing discharges, emissions and losses of such substances into the aquatic environment

Key EP activities on pharmaceuticals in the environment: legislature 2014 – 2019

Review of EU pharma legislation of vet medicines (ongoing)

- in first reading (2016), EP adopted various amendments to strengthen the proposal with regard to the environment, inter alia
 - COM feasibility study of a substance-based review system ('**monographs**') for the environmental risk assessment (ERA) of vet med + leg proposal, if appropriate, 6 mo before application
 - all vet medicines to have an **ERA** (not just reassessment of some w/o any compulsory update of documentation)
 - **update of ERA** in case of new data changing the risk
 - **pharmacovigilance database** to include env. monitoring data
 - **no PBT or vPvB or endocrine disrupters**
 - **manufacturing**: data about emissions, discharges and losses; no authorisation if manufacturing poses unacceptable risks

Summary

- EP clearly **concerned** about pharmaceuticals in the environment
- EP clear **track record** over last 15 years of **greening/trying to green** EU pharma/enviro laws with respect to pharmaceuticals in enviro
 - EP was key in making enviro effects relevant for approval of veterinary medicines
 - EP was less ambitious than DG ENV on three specific pharmaceuticals to be identified as priority substances
 - EP was more ambitious than DG SANTE/DG ENV in general
 - EP wanted big report on pharma in the environment
 - EP wanted strategic approach to pharma in environment
- **EP still committed to it:**
 - ENVI listed COM delivery on pharma strategic approach amongst 10 priorities for COM WP 2017
 - EP wants to strengthen new vet med proposal in many ways

Green outlook – mind the political context...

- **New Commission structure:**
 - full political control by Vice-Presidents and First Vice-President
- **New Commission agenda**
 - Focus on jobs and growth in line with the ten priorities of President Juncker's Political Guidelines:
 - *"We will not present proposals that do not contribute to these priorities."*
 - *"And we will apply political discontinuity and will take off the table pending proposals that do not match our objectives"*
 - Better Regulation (*"small on small things, big on big things"*)
- **New internal Commission working methods**
 - full political control over all COM initiatives right from the start
 - SecGen central power, disempowering the actual services
 - **Result: Health and environment protection clearly downgraded by the new Commission**
 - **Action on pharma in the enviro: a victim of the above?**₈



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Make the new Commission work – it is overdue!

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Health Care Without Harm Europe

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