

Publication: April 2022

Updated version: 05 May 2022

The FEAM European Biomedical Policy Forum in sponsorship with the Federation of Veterinarians of Europe (FVE) and the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Pharmaceuticals in the Environment | Webinar 29 March 2022



Background

Over 100,000 tonnes of pharmaceutical products are consumed globally every year (24% in Europe). During their manufacture, use, and disposal, active pharmaceutical ingredients and other chemical ingredients are released into the environment. The introduction of huge quantities of pollutants emitted into the air, water, and soil is currently a growing concern that is gaining more attention around the world. Over the past 30 years, international organisations, the scientific community and the pharmaceutical industry have been sounding the alarm about the detrimental impact that pharmaceutical products have on the environment on a global scale. In 2012, the [World Health Organization \(WHO\)](#) published a comprehensive report on the risk assessment of pharmaceuticals in drinking water, which contains recommendations to prevent and reduce the leakage of chemical compounds in the water cycle. On the 25th November 2020, the [European Commission](#) published a [Pharmaceutical Strategy](#) that analyses the entire lifecycle of pharmaceuticals, from scientific discovery to manufacturing and commercialisation. One of the main objectives of the strategy aims to guarantee that innovation and emerging science and technology caters to the therapeutic needs of patients while reducing its environmental footprint.

In light of this growing concern, on the 29th March 2022, the [FEAM European Biomedical Policy Forum](#) – with the support of [the Federation of Veterinarians of Europe](#) (FVE) and [the European Federation of Pharmaceutical Industries and Associations](#) (EFPIA) – hosted a webinar discussion with

expert policymakers, academics, and both industry and civil society representatives, on the topic of ‘**Pharmaceuticals in the Environment**’. This allowed for the opportunity to exchange opinions and to emphasise and raise awareness on this issue, providing practical recommendations on how to better manage and reduce the waste of drugs in the environment.

Broader Policy Overview

In recent years, there has been an increasing embrace of the ‘One Health’ concept amongst policymakers, as evidenced by a string of policy initiatives which either advertently or inadvertently aim to tackle the issue of pharmaceuticals in the environment. A useful starting point to note is [the European Green Deal](#), which was introduced by the European Commission in 2019. Notably, this proposal contained the ambition for a toxic-free environment, as well as the promotion of fresh air, clean water, healthy soil, and biodiversity. Therefore, the European Green Deal highlighted a growing recognition that we need to protect human health from the potentially harmful impact of pharmaceutical residues in the environment.

The European Green Deal announced **three relevant strands of action**:

1. [The Chemicals Strategy for Sustainability](#)
2. [The Zero pollution action plan](#)
3. [The Farm to Fork strategy](#)

In March 2019, the European Commission adopted [the Strategic Approach to Pharmaceuticals in the Environment](#). This included a large range of actions and covered all phases of the lifecycle of pharmaceuticals, from design and production through use to disposal. It was noted that this pharmaceutical strategy was generally positively received by the European Parliament and the Council. However, it did face criticism from the European Parliament for not going far enough and lacking concrete proposals. The European Council’s conclusions were also somewhat critical, calling for an acceleration of concrete and ambitious actions to reduce the risk from pharmaceuticals and their residues to the environment. In particular, the European Parliament [resolution](#) referenced the [2019 OECD report](#) on Pharmaceutical Residues in Freshwater to illustrate that the current policy approaches to manage pharmaceutical residues are inadequate. Finally, the European Parliament has made it clear that it aspires to have a legal framework which further protects environmental and public health, increases public awareness of prudent use of pharmaceuticals, intensifies efforts towards greener manufacturing, and improves waste management.

Stakeholder Perspectives

There remains considerable concern about the problem of pharmaceuticals in the environment from an **ecotoxicological perspective**. Advanced monitoring instruments enable hundreds of chemical compounds to be easily monitored. Recent available field data which detailed the chemical composition of agricultural fields showed that metabolites were detected at much higher levels than the original compound. For example, antibiotic medicines are commonly found to have very high concentrations of by-products, which can be defined as products produced in an industrial or biological process in addition to the principal product. Therefore, it is important to consider the by-products of a pharmaceutical when monitoring specific products.

In European surface water, there are several hundred pharmaceutical residues which can be detected in the aquatic environment. However, the concentration of pharmaceuticals can vary greatly depending on the river type, the molecule(s) in question, and the country, ranging from less than 1 nanogram per litre to several milligrams per litre in other instances. In a survey conducted by the University of Namur in Belgium, with the collaboration of a Wallonia water company (SWDE) and other partners of an INTERREG project (DIADeM, 2017-2020), over 1500 surface water sites were tested for traces of pharmaceuticals. Although the presence of pharmaceutical traces in groundwater is generally very low, the survey found that analgesics represent about 50% of the pharmaceutical residues detected, and that cardiovascular drugs and neuroleptics are also well-represented in Belgian surface waters, representing up to 20 percent of all the pharmaceutical traces. There is some concern from ecotoxicologists that even relatively low doses of these pharmaceuticals can still pose a serious risk to aquatic organisms and, consequently, the environment.

Bioconcentration is the ratio between the levels of a certain chemical in the body of an organism and the concentration of the same chemical in the environment. It was noted that the bioconcentration may vary considerably depending on the organism. For example, in the liver of fish, it is possible to find bioconcentration levels several thousand times higher than in the surrounding water. The recent 4-year research INTERREG project DIADeM conducted by the Universities of Namur and Reims Champagne-Ardennes, in collaboration with other French and Belgian research centres, examined the impact of pharmaceutical residues when they are released from wastewater treatment plants on aquatic life. For most aquatic organisms, the impacts were rather moderate. However, alterations to the reproductive and immune systems of several contaminated organisms were detected after only 3 weeks of exposure.

Antimicrobial resistance is a major public health problem, which directly causes [1.27 million deaths worldwide per year](#). The steep increase in antimicrobial resistance can be directly linked to increased antibiotic use in agriculture, livestock, and humans. As around 80 percent of Western antibiotic demand is manufactured and produced in China and India, their environment can be seen as a mirror of this human activity. As antibiotic resistance is increasing, so too is antibiotic pollution. The concentration of antibiotics in the environment is usually low, ranging from 10- 100 nanograms per litre. However, extremely high concentrations have been detected in manufacturing wastewater. In 2006, Ciprofloxacin was detected in a river in India, at concentrations up to [31,000 micrograms per litre](#).

Therefore, it is evident that increased pharmaceutical waste is contributing to increased pollution and antimicrobial resistance, which is posing a serious global threat.

A **One Health** perspective is hugely important when considering the impact of pharmaceuticals in the environment. Since the process began in 1992 and the guidelines were formalized in 2005, all products for veterinary use in the EU must pass a strict environmental risk assessment in order to enter the market. Furthermore, veterinarians are already educated in a manner which acknowledges the interconnected risk of disease across animals, humans, and the environment. The prescription of veterinary medicines always comes with advice on proper administration, proper distribution of waste, and the handling of by-products. In addition, the **veterinary perspective** has been firmly behind the 'One Health' concept for many years, promoting responsible waste reduction strategies as part of the responsible use practices.

From the **healthcare professional** perspective, the emphasis is on achieving the appropriate balance between promoting environmental protection and ensuring sufficient access to medicines for all. It was noted during the discussion that healthcare professionals can have a significant impact on improving patient use of pharmaceuticals and medicines, through education and awareness campaigns. To ensure a **more sustainable healthcare sector**, it is important to consider that pharmaceutical residues can enter the environment across the life cycle, i.e., in manufacturing, excretion, and disposal. A [recent University of York study](#), which looked at over 1000 sampling sites in more than 100 countries, highlighted that the highest pharmaceutical concentrations occurred in areas associated with poor wastewater and waste management infrastructure and pharmaceutical manufacturing. Most alarmingly, concentrations of at least one pharmaceutical ingredient were found to be above levels considered safe for aquatic organisms, or of concern in terms of selection for AMR, at a quarter of all monitored sampling sites.

Industry Perspective

The **pharmaceutical industry** shares the cross-sector concern about the impact of drugs in the environment. However, it is very important to stress that the vast majority of pharmaceutical substances pose no threat to human or environmental health. The industry estimates that 88 percent of pharmaceutical waste stems from human excretion, with 10 percent stemming from improper use and only 2 percent from manufacturing. Despite this, the industry is determined to eliminate the negative impacts of pharmaceuticals in the environment and lower their carbon footprint, whilst also prioritising secure access to vital medicines for all, through initiatives like the [Eco-Pharmaco-Stewardship initiative](#), [IMI PREMIER](#), [AMR Industry alliance](#) and [PSCI](#).

The way forward

The level of cross-sectoral awareness and concern about the impact of pharmaceuticals in the environment is evidently high. Furthermore, the nature of the issue has been highlighted as complex, multi-faceted, and widespread. Looking ahead, the discussion also provided several practical recommendations on how to better manage and reduce the waste of drugs in the environment. **Six practical recommendations** were suggested by the speakers:

1. Education and training

The overconsumption of pharmaceuticals is a huge source of waste. This can be greatly alleviated by increasing both public and healthcare professionals' awareness of prudent medicine use. For example, personalised medicine, such as prescription requirements, can certainly help to limit waste. Furthermore, educating patients on what to do with their expired or unused medicine, and when to return it, would also help. Finally, training in the concept of 'One Health' should be developed further for patients and medical professionals.

2. Greener Manufacturing

The pharmaceutical industry can play a major role by designing more environmentally friendly alternatives. For example, [MITHRA pharmaceuticals](#) have produced an [Estetrol \(E4\)](#), which is a natural oestrogen used as an alternative to the synthetic version present in contraceptives. The results strongly indicate that E4 induces much fewer endocrine-disrupting effects on aquatic organisms, therefore this is an excellent example of a greener manufacturing alternative.

3. Better waste management

Urban wastewater treatment plants are not designed to remove micropollutants. Increasing the efficiency of wastewater treatment would be very costly and energy-intensive, but maybe necessary based on a cost-benefit analysis, at least in some cases as for pharmaceutical factories, and [only as a complement to source-directed and use-orientated measures](#). The European Commission is hoping to alter the legislation on wastewater treatment to include a mechanism which ensures a fair contribution of the industry according to the polluter pays principle.

4. Strengthening environmental risk assessments

There is a limited scope of environmental risk assessment for pharmaceuticals. The current European guidelines were only introduced in 2005 for veterinary medicines and 2006 for human medicines, and they did not apply retroactively. In Germany, for example, environmental data is only available for around 40 percent of the pharmaceutical ingredients found in surface water.

5. Greater transparency

There is a need for greater transparency and a stronger legislative framework to regulate pharmaceutical production. Over 80 percent of the manufacturing of Western antibiotic demand takes place in India and China, yet there is a blatant lack of transparency within the supply chains that makes it difficult to hold the pharmaceutical industry accountable for the emissions of pharmaceutical residues that can occur during the manufacturing processes.

6. One Health Approach

The health of animals, humans, and the environment are interconnected. Environmental health contributes to public health and animal health and vice-versa. Therefore, at the heart of all joint efforts should be a 'One Health' mindset to tackle pharmaceutical waste at all stages of the life cycle to enhance human, animal, and environmental health.

Additional material available:

1. [Agenda and speaker information](#)
2. [Full Recording of the event](#)

Note:

The updated version of the summary report contains a few additional links suggested by the EFPIA speaker and secretariat:

- 1) <https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-and-sustainability/>
- 2) [Eco-Pharmaco-Stewardship initiative](#), [IMI PREMIER](#), [AMR Industry alliance](#) and [PSCI](#)

For general enquiries:

Dr Elisa Corritore
FEAM Forum Scientific Policy Manager
Email: elisa.corritore@feam.eu

Patrick Hurst
FEAM Junior Policy Officer
Email: patrick.hurst@feam.eu

Disclaimer:

Opinions expressed in this report do not necessarily represent the views of co-sponsor organisations – the *Federation of European Academies of Medicine (FEAM)*, the *Federation of Veterinarians of Europe (FVE)* and the *European Federation of Pharmaceutical Industries and Associations (EFPIA)*. Views may not be shared by all participating companies and attendees.

About FEAM, the Federation of European Academies of Medicine

FEAM is the European umbrella group of national Academies of Medicine, Pharmacy and Veterinary Science, or national Academies via their medical division. It brings together under one umbrella 23 National Academies representing thousands among the best scientists in Europe. FEAM's mission is to promote cooperation between National Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community. The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information or becoming a partner, please contact elisa.corritore@feam.eu.