AstraZeneca

Our Approach to Pharmaceuticals in the Environment

February 2025

Introduction

Pharmaceuticals entering the environment is an unavoidable result of delivering life changing medicines to patients. We recognise our most material water pollution risk as the Active Pharmaceutical Ingredients (APIs) found in our products. APIs are biologically active molecules and may interact with and impact wildlife and biodiversity when in the environment.

At AstraZeneca, our aim is to minimise the environmental impact of our products for more sustainable healthcare. To achieve this, we follow the science to understand and effectively manage the environmental risks associated with our products.

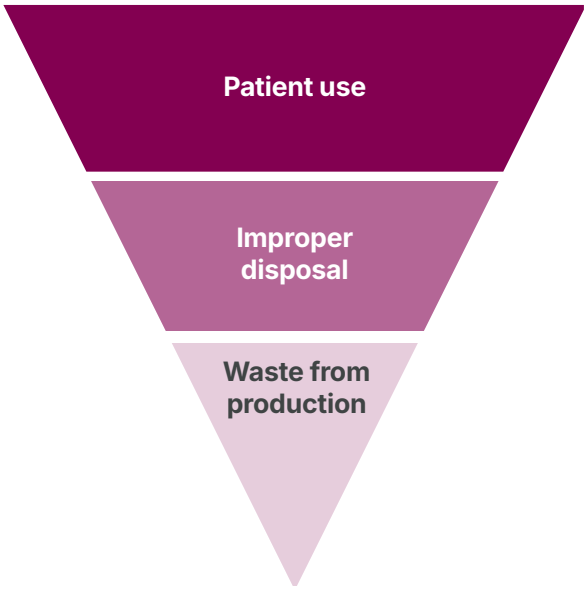
There are common misconceptions around the sources that contribute to pharmaceutical residues detected in the environment. However, the largest global contributor to PIE is patient use.[1,2]

Find out more in our short introduction to PIE video on our website.

What is PIE?

Pharmaceuticals in the Environment, or PIE, typically occur via three main routes:

- Patient use, as some APIs can pass through our bodies and into waterways.
- Improper disposal of unused medicines.
- Waste from production.



Why we are taking action

Trace amounts of pharmaceuticals have been detected in the environment for more than 20 years, and we recognise that the levels of PIE will likely rise, particularly in regions where there is an increased consumption of pharmaceuticals due to improved access to medicines and/or as a result of an ageing population.[3]

Scientific research published in the last five years has shown that most drugs pose low risk;[4] however, as we continue to discover and develop medicines which offer patients improved outcomes and a better quality of life, and with an everchanging climate, it is important we continue to understand the risk profiles of our medicines.

A number of pharmaceuticals are now routinely detected in water bodies near where people live, and some can cause location-specific environmental risks, especially in regions where there may be inadequate sewage infrastructure, a high population density and rivers with low flow conditions.

It is therefore essential that we are equipped with the tools we need to:

- Understand the environmental risk that our products might pose.
- Proactively reduce the environmental risk associated with the manufacture of our medicines.
- Monitor the global environmental risk of our medicines, so that we can act where a substantial environmental risk is identified.

Our commitment

At AstraZeneca, we believe that even though most pharmaceutical residues are present at low concentrations, the risks associated with PIE should be determined, minimised, and managed based on available scientific evidence.

Our goal is to help lead our industry in understanding and mitigating the environmental risks of pharmaceuticals.

To do this, we aim to:

- Assess the environmental risk of our medicines to support drug marketing authorisations.
- Actively manage the environmental risks resulting from our manufacturing processes.
- Support industry and government efforts to improve medicine disposal programs and education.
- Co-sponsor scientific research and collaborations to fill knowledge gaps to understand and mitigate the risks of PIE.

Our PIE approach in practice

Improper disposal

To tackle the improper disposal of unused pharmaceuticals we actively encourage our patients to return unwanted medicines for safe disposal. We also support the #medsdisposal campaign which aims to raise awareness on how to dispose of unused or expired medicines appropriately in Europe.

Waste from production

We establish discharge concentration targets for our manufacturing operations and report our compliance against these discharge targets in our Sustainability Data Annex.

While waste from the manufacture of medicines is only a small proportion of the pharmaceuticals found in the environment globally, it is a local, intermittent issue that is important to manage. As production is the part we can control, it is the area where AstraZeneca can make the most impact. While there are currently no, or few, regional regulatory requirements, we run a 'Safe API Discharge' programme for both our production sites and those of our suppliers. We follow the methodology described by Murray-Smith et al[5] and in an article in the Chemical Engineer,[6] and we report our Active Pharmaceutical Ingredient Discharge Concentration Targets.

We assign two discharge concentration targets for each API, one for long-term exposure, an Environmental Reference Concentration (ERC), and one for short-term exposure called a Maximum Tolerable Concentration (MTC). If a site identifies an exceedance of either of these reference concentrations, we conduct a thorough investigation and implement the necessary corrective actions.

To further support responsible effluent management[7] across the industry, AstraZeneca also participates in the Pharmaceutical Supply Chain Initiative (PSCI) and collaborates with the European Federation of Pharmaceutical Industries and Associations (EFPIA).

efpia
European Federation of Pharmaceutical Industries and Associations

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Patient use

To understand the risk of our products from patient use we complete an Environmental Risk Assessment (ERA) before the approval of a new medicine in compliance with the relevant regulatory requirements. We do this by generating environmental fate and toxicity data, when appropriate, according to international standards. These data are used to establish Predicted Environmental Concentrations (PECs) and Predicted No Effect Concentrations (PNECs). The PNEC of an API is the concentration below which we do not expect it to have any effect in the environment. We submit these assessments and associated data to Regulatory Authorities as formal ERA reports, and also make a summary of this information publicly available via our website, where you can read the environmental risk summaries of our products.

Following calls to improve the regulatory ERA procedure,[3] AstraZeneca has contributed to the extended Environmental Risk Assessment (eERA) proposal.[8] This proposal aimed at addressing many of the existing challenges within the field of environmental risk assessment to strengthen the ERA process in the EU.

EcoPharmacoVigilance (EPV)

To ensure that our ERAs and discharge concentrations remain current and reflect the latest science[9] we established our ecopharmacovigilance (EPV) programme in 2014. Our EPV process involves searching externally published scientific literature for data on our APIs, including any reports of our medicines having had an effect on environmental species or being detected in the environment. We use this information to sense-check our environmental risk assessments, which include some conservative assumptions and predictions, against the emerging real-world evidence. Any reported measurements of our APIs in effluents, surface waters or drinking water are displayed in our EPV dashboard on our website, which shows more than 95% of the detected concentrations pose an insignificant risk.

"We have a history and track record of leadership in this space, and we continue to invest in partnerships to progress science and regulation in the area, and to be transparent about our findings."

Dave Ennis,
VP Environmental Protection

Research

We conduct targeted environmental research to address our critical knowledge gaps and improve the level of environmental protection we offer. If you'd like to know more about our research in this space, visit our peer-reviewed scientific publications page. We also support the next generation of environmental scientists by funding PhDs studentships.

To support our work in PIE we are the industry lead of the PREMIER project, which brings together 27 partners from the public and private sectors, who are working to contribute to a sustainable future by proactively managing the environmental impact of medicines.

AstraZeneca are also a member of the Inter Association Initiative Task Force on PIE (IAI PIE TF), which was developed for the European pharmaceutical industry to address environmental policy and science issues relating to human pharmaceuticals.[1]

PREMIER
PRIORITISATION AND RISK EVALUATION OF MEDICINES IN THE ENVIRONMENT

Footnotes

1. EFPIA (2023) Pharmaceuticals in the environment. Available at: https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/pharmaceuticals-in-the-environment-pie/ (Accessed 09 Feb 2024).
2. Daughton & Ternes (1999). Pharmaceuticals and personal care products in the environment: agents of subtle change? Environmental Health Perspectives 100 (6) 907-938.
3. OECD (2019), Pharmaceutical Residues in Freshwater: Hazards and Policy Responses, OECD Studies on Water. OECD Publishing.
4. Gunnarsson et al. (2019) Pharmacology beyond the patient – The environmental risks of human drugs. Environment International, 129, 320-332.
5. Murray-Smith et al (2012). Managing emissions of active pharmaceutical ingredients from manufacturing facilities: an environmental quality standard approach. Integrated Environmental Assessment and Management, 8 (2) 320–330.
6. Hargreaves et al (2017). Something in the Water: Managing the safe discharge of active pharmaceutical ingredients during drug production. The Chemical Engineer, November 36-41.
7. IAI (Inter Association Initiative) (2022), Responsible Manufacturing Effluent Management Technical Guidance Document. Available at: https://efpia.eu/media/677262/technical-guidance.pdf (Accessed 09 Feb 2024).
8. IAI (Inter Association Initiative) (2022) Proactively managing the environmental risks associated with the patient use of human medicinal products: an extended Environmental Risk Assessment (eERA) proposal by the European pharmaceutical industry associations EFPIA, AESGP, and Medicines for Europe. Available at: https://efpia.eu/media/677261/interassociation-paper-on-extended-environmental-risk-assessment.pdf (Accessed 09 Feb 2024).
9. Holm et al (2013) Ecopharmacovigilance in Practice: Challenges and Potential Opportunities. Drug Safety, 36 (7) 533–546.