

CARE FOR PEOPLE CARE FOR OUR ENVIRONMENT



CARE FOR PEOPLE

The pharmaceutical industry delivers treatments that allow people to live longer, healthier and more active lives.

Since the 1980s we have seen death rates from HIV fall by over 80%, since the 1990s deaths from cancer have fallen by 20% and recent pharmaceutical innovation means 90% of people living with Hepatitis C can be cured through a 12-week course of medicines.

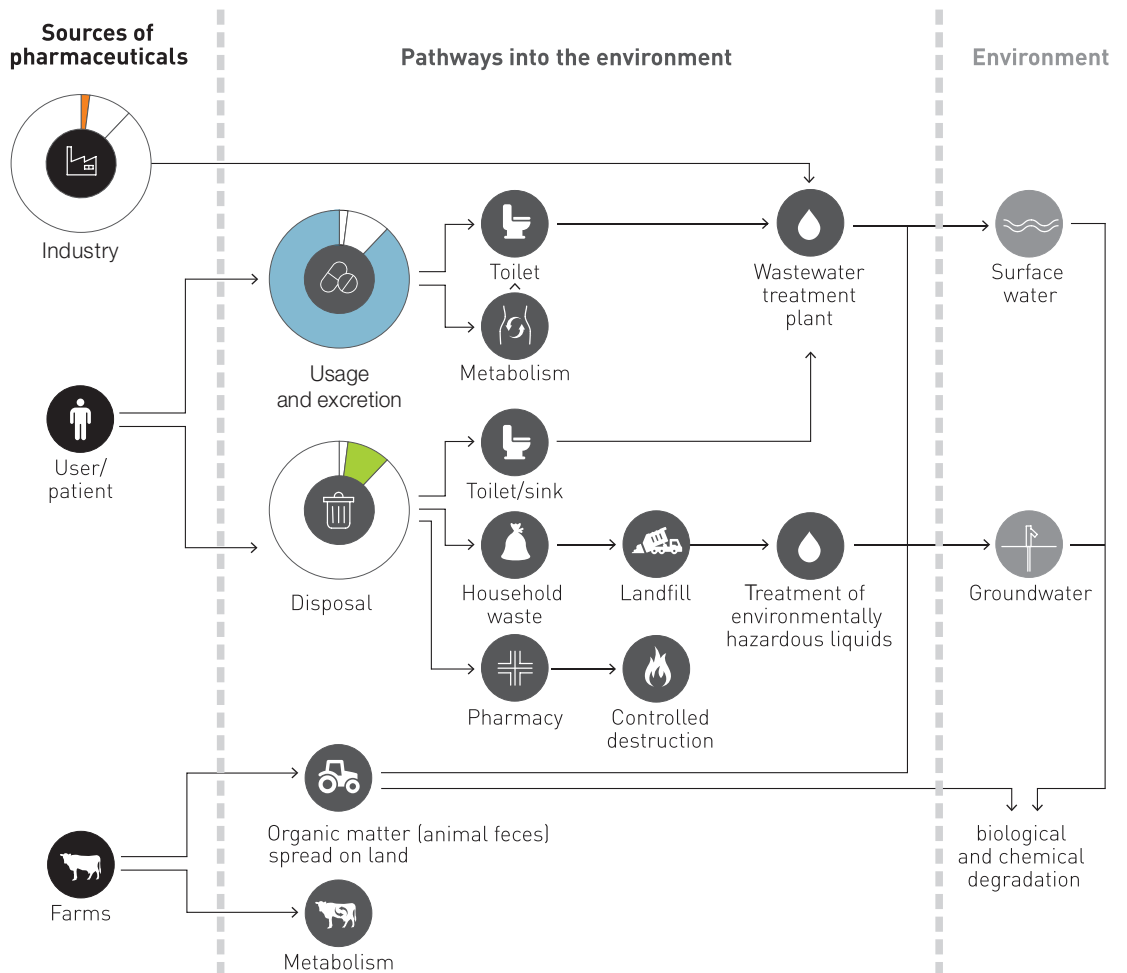
The European pharmaceutical industry, represented by AESGP, EFPIA and Medicines for Europe, recognises the concerns raised by stakeholders regarding the presence of pharmaceuticals in the environment (PIE) and we are committed to playing our role in addressing them.

CARE FOR OUR ENVIRONMENT

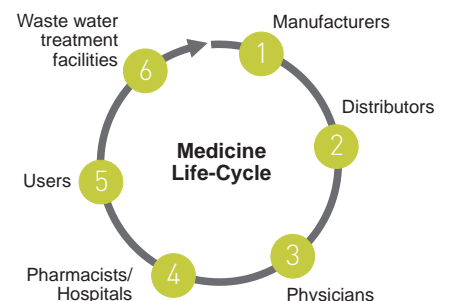
One of the unintended but inevitable results of delivering the life-changing medicines to patients is that our products can find their way into the environment.

There are three main pathways by which pharmaceuticals can reach the environment:

- In Europe only trace levels can be attributed to waste from production.
- A smaller fraction comes from the expired or unused medicines that are not correctly disposed of.
- The largest part is a result of normal patient and consumer use and excretion into wastewater treatment systems. The exact percentage however varies, depending on the medicines characteristics.



Pharmaceuticals can enter the environment at all stages of the product's life-cycle. Therefore, we believe that only a collaborative approach will allow us to meaningfully increase our mutual knowledge and understanding on how to minimise any potential impact, issue or concern that pharmaceuticals in the environment might pose.



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THE INDUSTRY PROPOSAL: THE ECO-PHARMACO-STEWARDSHIP

The industry has proactively developed the **Eco-Pharmaco-Stewardship (EPS)** concept, a proposal that strives to protect patient access to medicines while appropriately considering environmental aspects.

This life-cycle approach focuses on areas where we believe we can most effectively reduce the potential environmental risks that might result from industry activities:



PILLAR 1

ENCOURAGING FURTHER RESEARCH TO ASSESS THE IMPACT OF PIE

Intelligence-led Assessment of Pharmaceuticals in the Environment

- Public-private partnership with the European Commission under the umbrella of the Innovative Medicines Initiative (IMI).
- The project is being run from 2015-2018 and aims to develop a framework in which tools, assays and models could enable industry, regulators and interested academic researchers to **identify and prioritise medicines that are most likely to present a risk for the environment**.
- This multi-stakeholder project has created a database on environmental information including more than 2000 studies for hundreds of existing active pharmaceutical ingredients.
- You can find all details and the progress report on the project website: www.i-pie.org



PILLAR 2

MANAGING EFFLUENTS FROM PHARMACEUTICAL SITES EFFECTIVELY

- We are continuously implementing initiatives which further reduce discharges from manufacturing plants through **the exchange of good practices**. We identify improvement needs by a risk-based approach and take measures where needed.
- Coupled with this, we have developed a '**maturity ladder**' aimed at **helping companies and their suppliers to gauge their performance and continuously improve**.
- Additionally, many of our members are actively involved in **the Pharmaceutical Supply Chain Initiative (PSCI)** (www.pscinitiative.org), a group of pharmaceutical and healthcare companies who have joined forces to promote responsible supply chain management and better business conditions across the industry.
- Furthermore, we continue to monitor the issue of environmental impacts **from the production of antibiotics**. We have initiated several health-based commitments and are working, directly or via our member companies, through the **AMR Industry Alliance** to manage potential risks.



PILLAR 3

LIFE-CYCLE ASSESSMENT OF THE ENVIRONMENTAL RISK

Extended Environmental Risk Assessment (eERA)

- The current legislation requires that a pharmaceutical company assess the environmental risk only theoretically and only once, before the drugs are approved and launched, or when they are going to be used in new indications or combinations. We want to extend this framework.
- We believe that the ERA should be reviewed and, if necessary, updated **throughout the product's life-cycle** to reflect the latest information on the product's potential impact on the environment.
- However, we believe the focus should be on the level of the substance entering the environment (not the product, as it is now) and that resources should be **prioritised only on those substances that actually pose a potential risk to the environment**.

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#medsdisposal is a campaign to raise awareness on how to appropriately dispose of unused or expired medicines in Europe. A dedicated website and other virtual media material have been developed, providing information on current disposal schemes in European countries in a 'one-stop shop'.



This is a joint initiative between several European healthcare, industry and student organisations.

Most European countries have special medication disposal schemes in place in order to prevent pharmaceuticals from ending up in the environment. By using the interactive map on the webpage www.medsdisposal.eu you can easily find information for your country.

CONSTRUCTIVE DIALOGUE AND COOPERATION WITH ALL ACTORS INVOLVED

We encourage an **open and constructive dialogue** with stakeholders and policy-makers, taking into account environmental and public health aspects, as well as their policy ramifications.

As our scientific understanding improves, we will find new ways of detecting the trace amounts of pharmaceuticals in the environment and understand their impact. We, the industry, are striving to improve our processes and develop new ways of creating treatments that not only save lives, but that are also mindful of the environment.

We remain committed to continuing to address environmental concerns through the Eco-Pharmaco-Stewardship initiative whilst responding to patient needs and ensuring access to medicines, the paramount objective of our industry.



Association of the European Self-Medication Industry

www.aesgp.eu



European Federation of pharmaceutical Industries and Associations

www.efpia.eu



Medicines for Europe

www.medicinesforeurope.com

REFERENCES

- 1 - <https://www.efpia.eu/about-medicines/use-of-medicines/value-of-medicines/>
- 2 - www.astrazeneca.com/sustainability/environmental
- 3 - Caldwell DJ. 2015. A risk-based approach to managing active pharmaceutical ingredients in manufacturing effluent.
- 4 - Caldwell DJ. 2016. Sources of pharmaceutical residues in the environment and their control.



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