



Reducing the Environmental Footprint of Pharmaceuticals Across the Lifecycle

**Evidence and policy-relevant recommendations
from the ENVIROMED project**

Why This Matters

Pharmaceuticals deliver essential health benefits. At the same time, their environmental footprint is shaped by decisions and processes occurring across multiple lifecycle stages: from molecular design and manufacturing to use, wastewater treatment, and environmental exposure.

Reducing the environmental impact of pharmaceuticals requires a co-ordinated lifecycle strategy combining

upstream prevention, sustainable production, integrated monitoring, and proportionate regulatory action.

ENVIROMED demonstrates how innovation and environmental assessment across these stages can support EU sustainability objectives and contribute to the effective implementation and continuous strengthening of existing regulatory frameworks.



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A Lifecycle Strategy for Environmental Sustainability

ENVIROMED generated integrated evidence across four key intervention stages:

1. Designing Safer Pharmaceuticals

- In-silico tools enable early screening of active pharmaceutical ingredients (APIs) and relevant metabolites for ecotoxicity and bioaccumulation potential.
- Predictive models support tiered Environmental Risk Assessment (ERA) approaches.
- Structural alert identification contributes to safer-by-design strategies before large-scale development.

Policy relevance:

Supports EMA ERA guidance, REACH chemical assessment frameworks, and upstream pollution-prevention objectives of the EU Zero Pollution Action Plan.

2. Sustainable and Digitalised Manufacturing

- Continuous biomanufacturing demonstrated lower energy demand and water consumption compared to repetitive fed-batch systems.
- Digital twins and advanced control strategies support process optimisation and resource efficiency.
- Liquid monitoring and surface inspection technologies enable chemical-specific, near-real-time optimisation of cleaning processes.
- Life Cycle Assessment identified sterilisation energy demand as the main environmental hotspot in biomanufacturing.

Policy relevance:

Relevant to the EU Pharmaceutical Strategy for Europe, the Chemicals Strategy for Sustainability, circular economy objectives, and EU decarbonisation targets.

3. Environmental Monitoring Across the Water Cycle

- Clinical facilities can act as episodic high-intensity emission sources, where short-lived concentration peaks may significantly influence pollutant loads but remain undetected in low-frequency monitoring schemes.
- Monitoring confirmed continuity of contamination pathways from hospital effluents through wastewater treatment plants to receiving marine waters.
- Conventional wastewater treatment shows variable removal efficiency for selected pharmaceuticals, leading to their continued presence in treated effluents and receiving waters.
- High-frequency and on-site monitoring improves detection of discharge events, reducing the risk of underestimating pollutant loads.

Policy relevance:

Directly relevant to the implementation of the Urban Wastewater Treatment Directive (UWWTD), the Water Framework Directive (WFD), and EU risk-based prioritisation mechanisms.

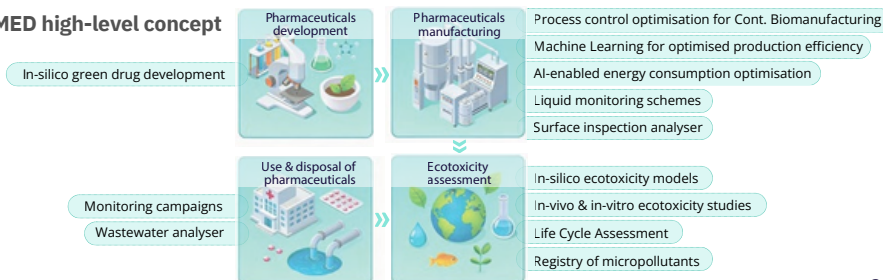
4. Ecotoxicity and Environmental Effects Assessment

- Effect-based ecotoxicity assays indicated that pharmaceutical residues may induce sublethal biological responses even when concentrations remain below acute toxicity thresholds.
- Differences in organism sensitivity highlight the importance of environmental context and site-specific vulnerability.
- Predictive models complement monitoring by supporting qualitative understanding of combined exposure patterns across substances and environmental pathways.

Policy relevance:

Supports environmental risk interpretation under EMA ERA frameworks and complements monitoring and prioritisation processes under the WFD.

ENVIROMED high-level concept



Key Insights

- Pharmaceutical pollution is lifecycle-driven and systemic.
- Upstream prevention reduces downstream mitigation burdens.
- Manufacturing configuration and process optimisation are important sustainability levers.
- Integrating chemical, biological, and predictive evidence enhances environmental assessment.
- Innovation can support the effective implementation and progressive evolution of existing regulatory structures, without necessarily requiring new obligations.

Policy Recommendations

The following recommendations aim to reinforce lifecycle-oriented environmental sustainability by strengthening implementation and coherence within existing EU regulatory frameworks.

A. Strengthen Upstream Environmental Prevention

1. Integrate early environmental screening within existing frameworks

- Encourage structured use of validated in-silico tools for screening APIs and relevant metabolites.
- Support tiered approaches combining predictive models and experimental data.
- Facilitate data-sharing initiatives to improve model validation and applicability.

These measures can enhance the implementation and practical effectiveness of EMA ERA guidance and REACH assessment processes, without replacing mandatory testing requirements.

B. Recognise Sustainable Manufacturing as a Pollution-Prevention Lever

2. Support operational optimisation as a sustainability strategy

Policies may recognise continuous processing, advanced control strategies, and digital twin-based optimisation as viable approaches for reducing energy, water, and raw material use in pharmaceutical manufacturing, provided product quality and safety remain unchanged.

Life Cycle Assessment evidence indicates that process configuration significantly influences greenhouse gas emissions and water demand. Integrating sustainability considerations during development can reduce downstream environmental pressures, supporting objectives under the Pharmaceutical Strategy for Europe and broader EU industrial and sustainability policy objectives.

3. Encourage advanced monitoring technologies as optimisation tools

Chemical-specific and near-real-time monitoring technologies, including liquid monitoring and surface inspection systems, can complement established GMP-compliant methods by:

- Supporting risk-based optimisation of cleaning cycles
- Reducing water and solvent use
- Strengthening process evidence generation

Their use supports pollution-prevention objectives without altering compliance requirements under existing GMP frameworks, and contributes to EU pollution prevention and resource efficiency objectives, including under the Zero Pollution Action Plan.

4. Promote alignment with GMP and PAT principles

Broader uptake of advanced monitoring and digital tools can be facilitated through compatibility with established Good Manufacturing Practice (GMP), Process Analytical Technology (PAT), data integrity, and traceability standards, ensuring sustainability-driven optimisation remains aligned with quality and safety requirements, within the EU pharmaceutical regulatory framework.

C. Enhance Integrated Monitoring Across the Water Cycle

5. Strengthen lifecycle-oriented monitoring strategies

Monitoring approaches may integrate:

- Upstream sources, including large clinical facilities
- Wastewater treatment plant influent and effluent
- Receiving environments

High-frequency and on-site analytical tools can complement laboratory methods by improving temporal resolution and identifying episodic emissions.

Such approaches can strengthen proportionate and evidence-based implementation of the UWWTD and WFD, supporting EU water policy objectives.

D. Support Evidence-Based Risk Prioritisation

6. Combine chemical, biological, and predictive assessment tools

Integrated interpretation of chemical monitoring data, effect-based biological assays, and predictive models can improve understanding of combined exposure patterns relevant to regulatory prioritisation.

Such approaches support proportionate, risk-based decision-making under the WFD, UWWTD, EMA ERA guidance, and REACH frameworks.

Added Value for EU Policymakers

ENVIROMED shows that prevention, optimisation, monitoring, and environmental assessment must operate together across the pharmaceutical lifecycle.

By integrating upstream innovation with downstream environmental evaluation, the project contributes to EU ambitions under the European Green Deal, the Zero Pollution Action Plan, the Pharmaceutical Strategy for Europe, and EU water and chemicals legislation, while reinforcing regulatory coherence, proportionality, and evidence based decision making.

About ENVIROMED

ENVIROMED is a Horizon Europe project developing and validating technological and assessment solutions to reduce the environmental footprint of pharmaceuticals across their lifecycle.

Further resources

Information on the project's results and policy-relevant findings is available via the [ENVIROMED project website](#), including public deliverables and publications. The ENVIROMED deliverable *D7.2 – Fact-based report to regulatory authorities* provides a more detailed presentation of these findings and an extended set of policy-relevant recommendations underpinning this brief.

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