Supporting Sustainable Transition in Pharma: Policy and Industry Perspectives

Public symposium - Espoo, Finland

11/09/2026

Funded by the European Union

This project has received funding from the European Union's Horizon Europe research and innovation program under grant agreement N° 101057816.

Kirsty Reid; Director Science Policy; EFPIA

2019 – 2026 - EU Legislative Landscape: Complexity Meets Urgency

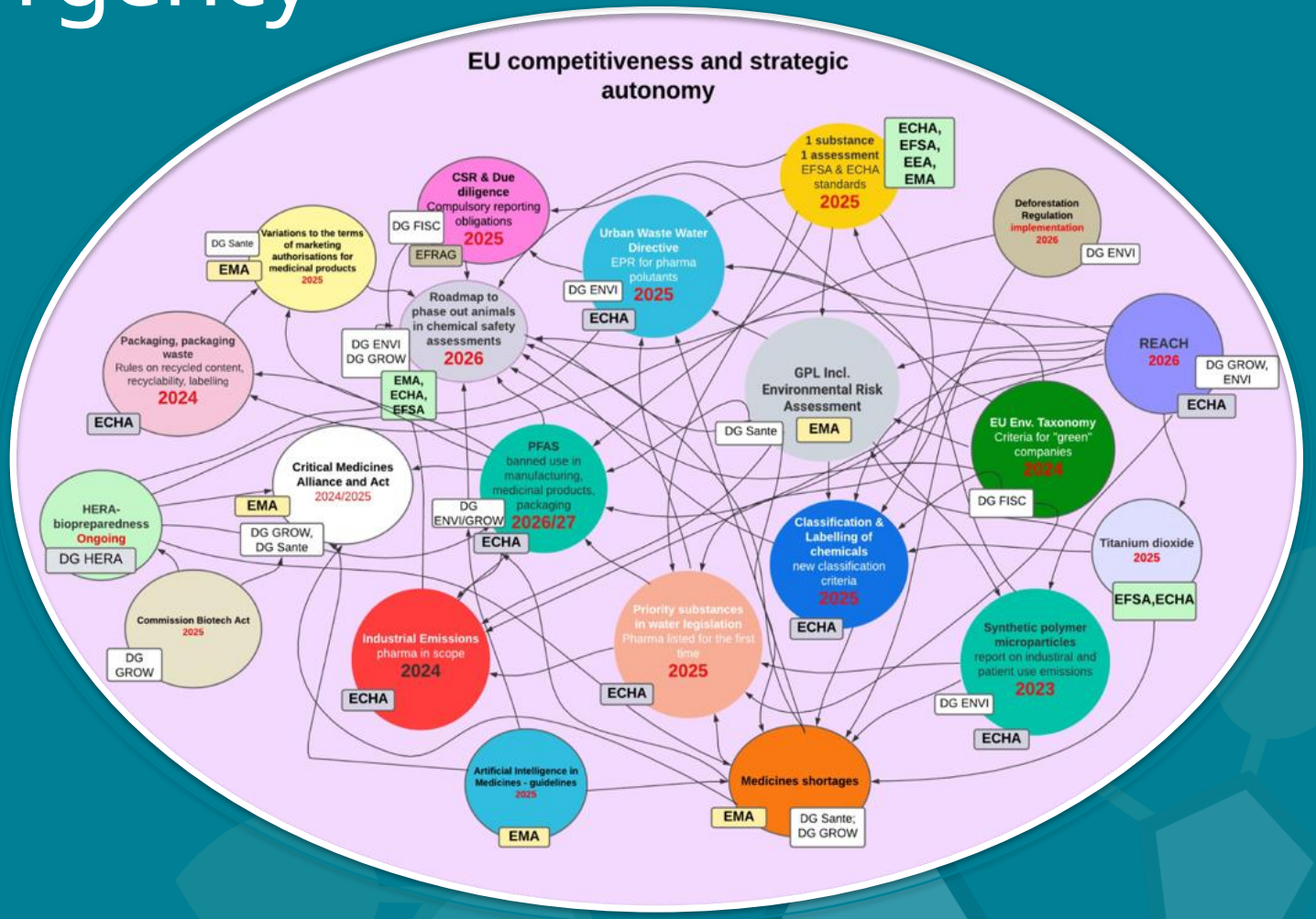
There are significant linkages between pharma, chemical, food, animal and environmental legislations leading to complexity

- Figure indicates identified **links** between pharma specific items and with chemicals, environment and food legislations

- It is more **complicated** for innovators and regulators to navigate the landscape (multiple interplays and moving targets)

- **Risk of disruption** to R&D and supply (manufacturing, shortages and availability) – impacting also on Europe's competitiveness

- EMA is **not always in the lead**, even if the B/R evaluation of medicinal products is impacted



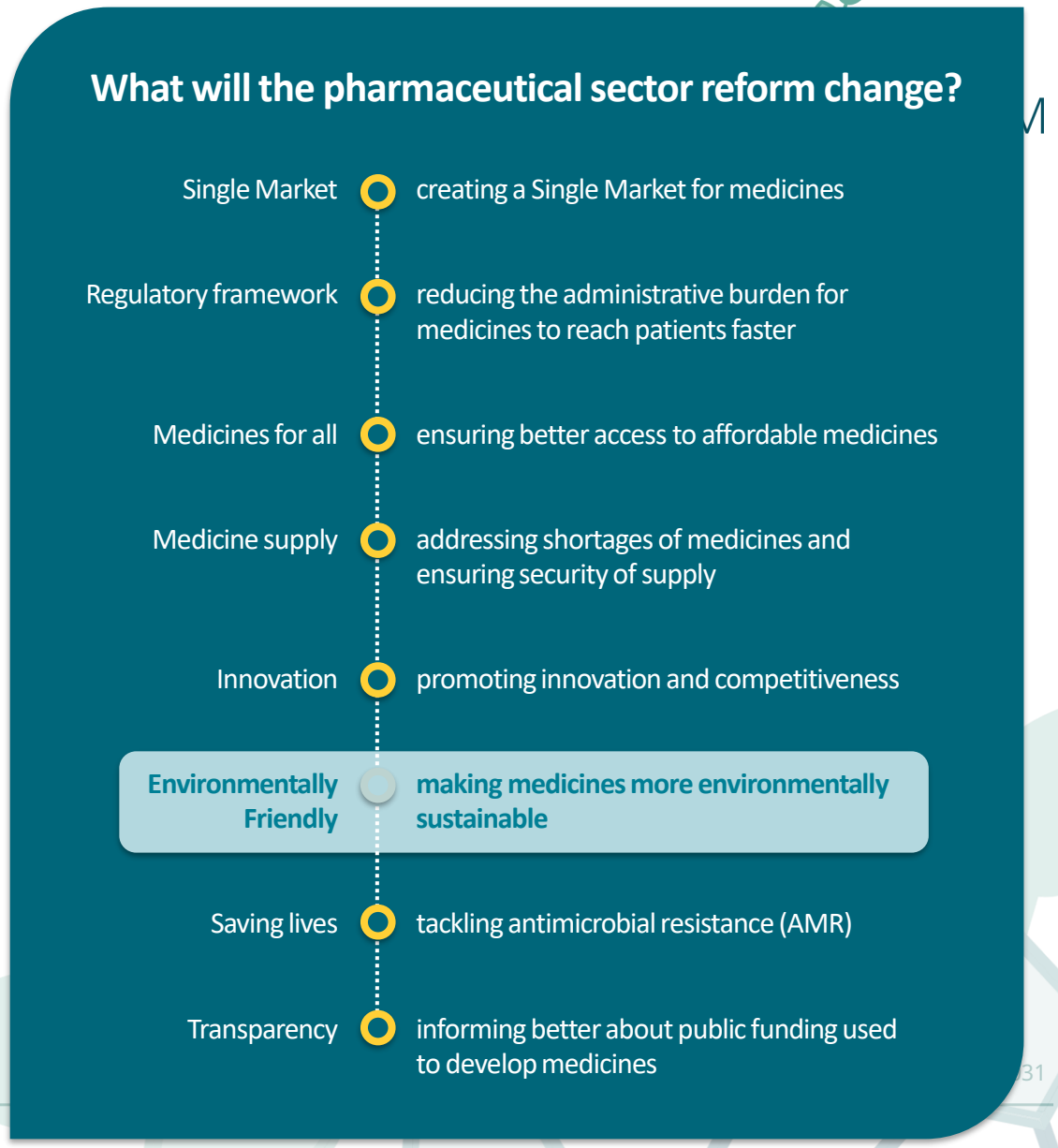
The reform of the EU pharma legislation

A milestone of the European Health Union and a crucial step in our collective effort to pave the way towards a healthier, more resilient, and more equal Europe.

Aims to make medicines more environmentally-friendly.

- Demonstrates the focus of EU pharmaceutical policymakers on greener pharma practices.
- However, still in an early stage and more specific policies and regulations will be needed.
- Despite growing attention, a lot of work remains to be done in shaping and developing the policies and regulations needed in the years to come.

Source: Reform of the EU pharmaceutical legislation website



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EU’s competitiveness and decarbonisation agenda

June ‘24

EU Election

EU Leaders Setting Strategic Agenda 2024-2029

EC President’s Political Guidelines

Sep ‘24

Draghi Report

Jan ‘25

Competitiveness Compass

Feb ‘25

2026

EU Clean Industrial Deal

Environmental omnibus

Industry Accelerator act

TRANSPHARM RESTRICTED – Under Consortium Agreement, Confidential until June 1st 2031

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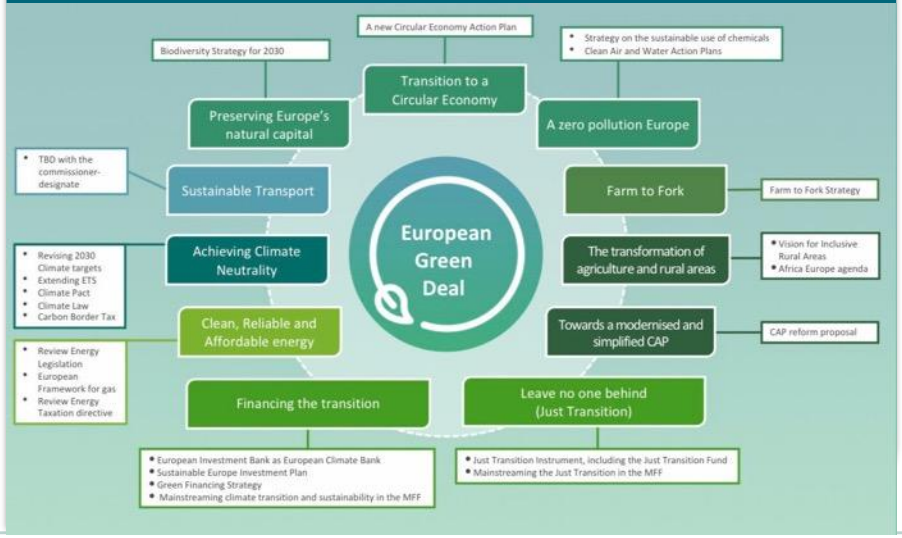
Transitioning to the Competitiveness narrative

Green Deal

The European Green Deal was launched by the Commission in December 2019.

package of policy initiatives, which aims to set the EU on the path to a green transition, with the ultimate goal of reaching climate neutrality by 2050.



Clean Industrial Deal

Launched in February 2025 – A plan for EU competitiveness and decarbonisation

Main elements:

- Affordable energy
- Boosting demand for clean products
- Financing the clean transition
- Circularity and access to materials
- Acting on a global scale
- Skills and quality jobs

The Clean Industrial Deal is our business plan to **accelerate decarbonisation** and **competitiveness** for European industry - by boosting innovation and reinforcing our resilience.

Become **climate neutral** by **2050**

The Clean Industrial Deal **focuses on:**

Energy-intensive industries

to safeguard competitiveness from high energy costs and unfair global competition

Clean-tech sector

to allow it to expand in the EU as it is a key enabler of competitiveness and decarbonisation

Funded by the European Union

A Policy agenda that is converging fast

Environmental expectations on medicines are moving from a specialist topic to a mainstream policy agenda. These are no longer separate conversations.

1

Pharmaceuticals in the Environment

Water policy, chemicals regulation and ERA risk assessment

2

Manufacturing & Climate

Emissions, restrictions, resource intensity and climate resilience

3

Supply & Circularity

Security of supply, circularity and end-of-life policy

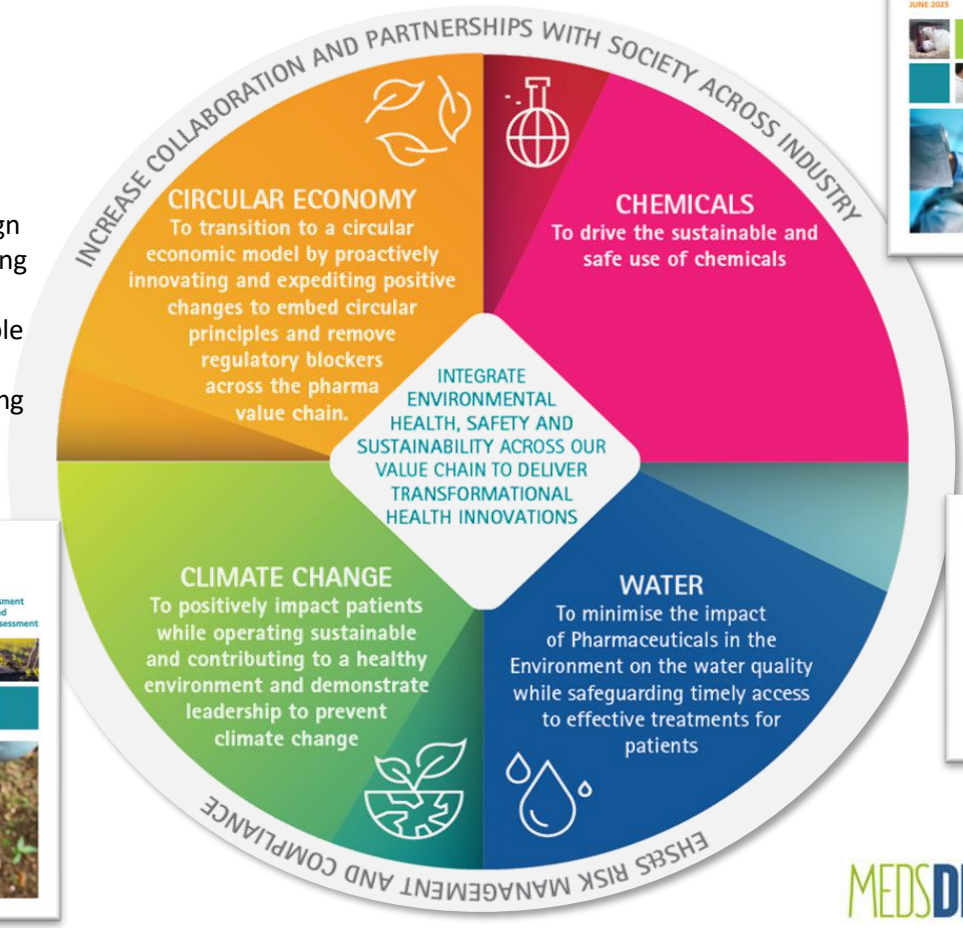
Supporting the green and industrial agenda in Europe

PHARMECO

Advancing Safe and Sustainable by design Practices in Pharmaceutical Manufacturing

ENKORE
ECO HEALTHCARE

Accelerating circular, safe, and sustainable eco-designed solutions for single-use medical, healthcare devices and packaging



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innovative health initiative

IHI Pfaros PFAS project – Launched September 2026

MEDSDISPOSAL

PREMIER
PRIORITISATION AND RISK EVALUATION OF MEDICINES IN THE ENVIRONMENT

Prioritisation and Risk Evaluation of Medicines in the Environment - Managing the environmental risks of medicines

Significant emissions reductions were achieved (2019–2024)

- **Scope 1 emissions down 18%** on average; 3 companies cut by half, 4 by a third.
- **Scope 2 emissions down 64%** on average, driven by renewable energy adoption.
- **Scope 3 emissions** -averaging **17% decrease**.

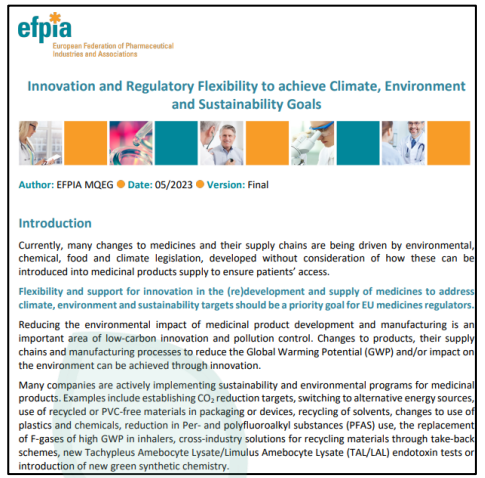
Sustainability and Climate: EFPIA members' initiatives

Many ambitious initiatives:*

- **Sustainable materials**
  - Recycling/circularity, bio-derived, PVC-free packaging, ePIL….
- **Chemistry**
  - Low-carbon or recycled solvents, use of surfactants, green chemistry routes….
- **Raw Materials**
  - F-Gas, PFAS replacement, non-animal derived materials…
- **Manufacturing**
  - Process intensification, water, energy use, sterilisation, transport and storage….

Critical enablers

1. **Consistent frameworks to assess climate & environmental impact**
2. **Medicines regulators' input to enable innovation to meet climate and environmental goals**



efpia
European Federation of Pharmaceutical Industries and Associations

Innovation and Regulatory Flexibility to achieve Climate, Environment and Sustainability Goals

Author: EFPIA MQEG Date: 05/2023 Version: Final

Introduction

Currently, many changes to medicines and their supply chains are being driven by environmental, chemical, food and climate legislation, developed without consideration of how these can be introduced into medicinal products supply to ensure patients' access.

Flexibility and support for innovation in the (re)development and supply of medicines to address climate, environment and sustainability targets should be a priority goal for EU medicines regulators.

Reducing the environmental impact of medicinal product development and manufacturing is an important area of low-carbon innovation and pollution control. Changes to products, their supply chains and manufacturing processes to reduce the Global Warming Potential (GWP) and/or impact on the environment can be achieved through innovation.

Many companies are actively implementing sustainability and environmental programs for medicinal products. Examples include establishing CO_2 reduction targets, switching to alternative energy sources, use of recycled or PVC-free materials in packaging or devices, recycling of solvents, changes to use of plastics and chemicals, reduction in Per- and polyfluoroalkyl substances (PFAS) use, the replacement of F-gases of high GWP in inhalers, cross-industry solutions for recycling materials through take-back schemes, new Tachypleus Amebocyte Lysate/Limulus Amebocyte Lysate (TAL/LAL) endotoxin tests or introduction of new green synthetic chemistry.

***Source: EFPIA MQEG and EHSEG joint brainstorm, February 2024**

efpia
European Federation of Pharmaceutical Industries and Associations

Brussels, 8 July 2024

Ref.: 68.058

To: Dolores Hernan, EMA, Marcel Hoefnagel, CEB and Veronika Jekerle, EMA

Dear Dolores, Marcel and Veronika,

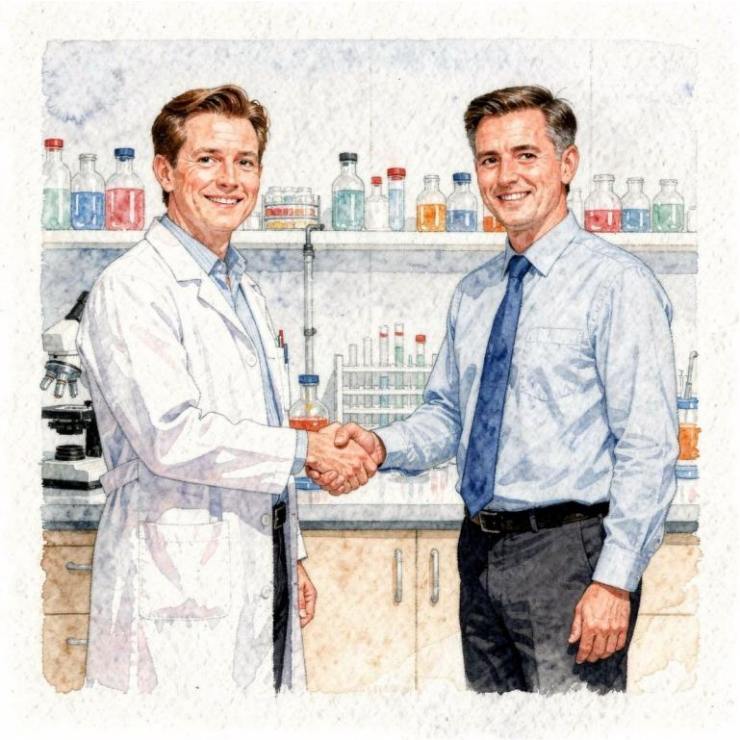
EFPIA and VE would like to compliment the EMA and the EU regulatory network on the ongoing evolution of the Quality Domain. The recent developments in particular the nascence of the Quality Innovation Group (QIG) have been welcome for EFPIA members. They have clearly benefited the development of innovation in manufacturing and quality in the EU.

EFPIA herein wishes to provide additional feedback for consideration regarding potential future topics for the QIG and the Quality domain. We acknowledge that some of these may benefit from input by experts outside of the Quality domain, noting that including additional non-Quality expertise lies within the official QIG remit. These areas include, e.g.,

- **Enabling innovation** in product design and development, manufacture and controls to meet **climate, environment and sustainability goals.**
- **Novel, automated sterile manufacturing and cleaning technologies** to enable rapid development and supply allowing multiple (mainly biological) products being manufactured in one multi-purpose facility.
- **Technologies & strategies to support in-vitro assessment of comparability following changes** (such as in silico biopharmaceutics modelling (PBBM and PBBK) for chemical drugs and COA-based assessment of biological products. Such a focus should also focus on how to enable the use of multi-facility manufacturing supply chains to enable greater security of supply.
- **Analytical innovations** with focus on biological products such as multi-attribute methods using LC-MS to replace in-vivo testing (e.g., potency assays) by automated in-vitro tests (e.g., cell analysis), rapid microbiological QC technologies etc.
- Enabling **drug delivery through advanced dosage forms** facilitated by **innovation in drug device**

ALIGNMENT

Where Industry actions and TransPharm align



Greener & Sustainable-Design APIs

Explicit TransPharm objectives — and genuine industry priorities, not imposed constraints.

Upstream Impact Reduction

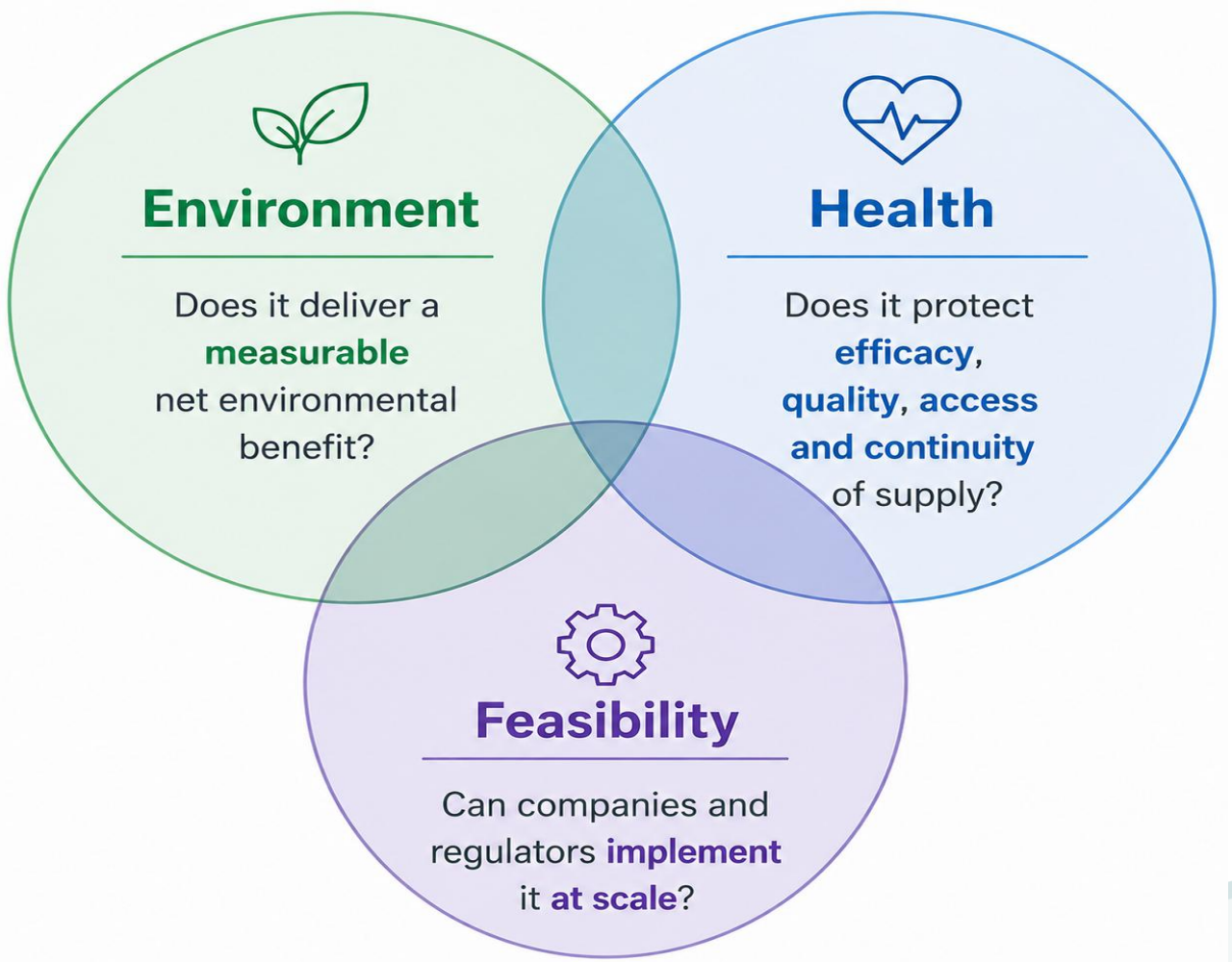
Benign-by-design and improved manufacturing processes address environmental impacts at source, rather than relying on downstream mitigation alone.

A Competitive European

TransPharm's vision of a more independent sector delivering sustainable therapeutics maps directly onto EFPIA's strategic direction.

Three Tests for sustainable pharmaceutical policy

Every policy intervention should be measured against three questions — with innovation at the centre.

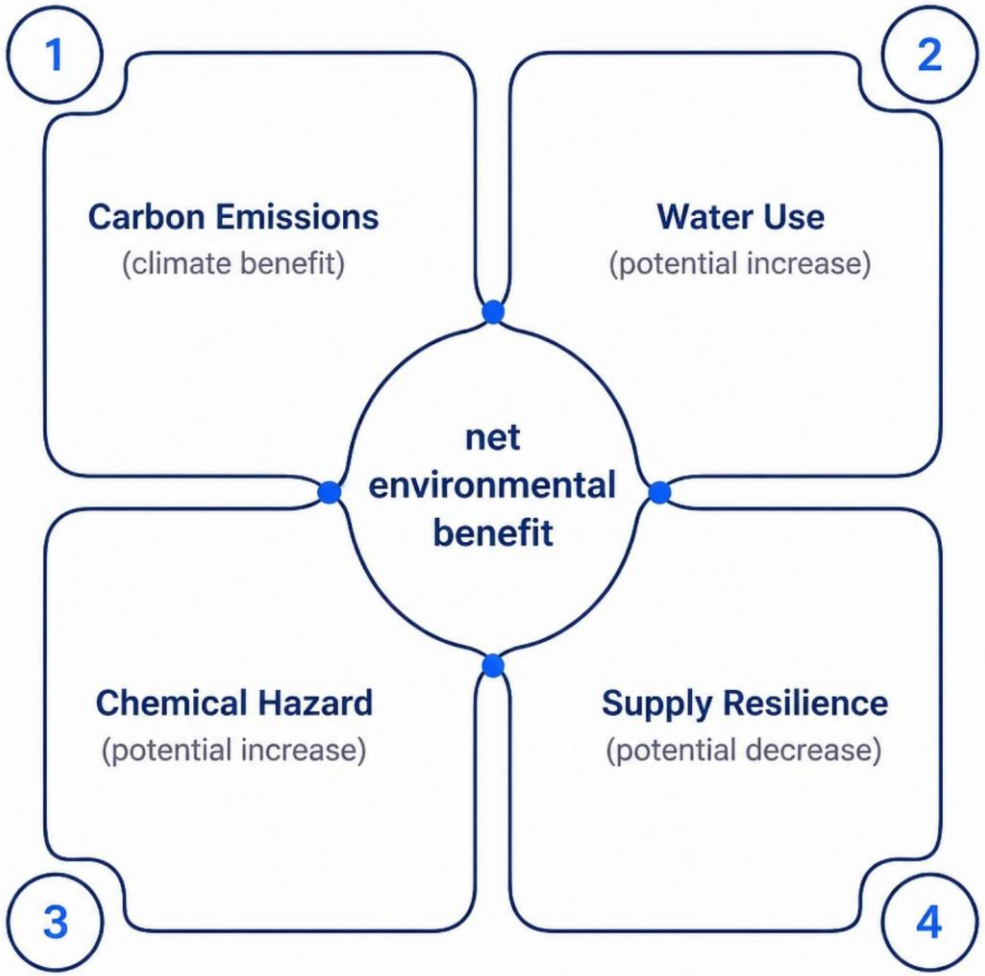


The Measurement Beyond Conventional LCA

Life Cycle Assessment alone is not enough. The risk of simply **shifting impacts** — reducing carbon while increasing water use, chemical hazard, waste or supply vulnerability — is not progress. It is displacement.

TransPharm's work on sustainability assessment directly addresses this gap. But creating a system that covers all sustainability dimensions simultaneously is genuinely difficult — the earlier TransPharm/PREMIER discussions recognised this openly.

> The goal is a methodology that reveals true net benefit, not one that optimises a single variable at the expense of others.



Five Enabling Conditions for Real-World Uptake

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1

Scientifically Robust Metrics

Evidence that companies and policymakers can actually use — proportionate, validated and decision-ready.

2

Regulatory Pathways

Pathways that recognise and reward sustainable innovation rather than treating it as a compliance burden.

3

Incentives, Not Only Penalties

The direction of travel matters. Positive incentives accelerate voluntary adoption far more effectively than enforcement alone.

4

Patient Access Protected

Supply continuity and patient access must be maintained throughout any sustainability transition.

5

Partnership Across Systems

Industry, regulators, healthcare systems, academia and wastewater authorities must work together.

innovative health initiative

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PHARMECO

iHi factsheet

Pharmeco

Advancing Safe and Sustainable by design Practices in Pharmaceutical Manufacturing

01/11/2024 – 31/10/2030

Project Goal:

Revolutionise pharma manufacturing: select technologies based on their potential to reduce the use of solvents, substances of very high concern, energy, and water; covering chemical synthesis, biomanufacturing and decontamination

Budget: **45M €**

ENKORE ECO HEALTHCARE

iHi factsheet

Enkore

Propelling the shift towards the future of circular, safe and sustainable packaging and single use device ecoDesigned solutions through healthcare environments

01/01/2025 - 31/12/2028

Project Goal:

Develop an eco-design framework for single-use medical devices and packaging. Focus on materials that minimise waste, optimise resource usage and reduce the carbon footprint, while ensuring devices are safe and fit for use

Budget: **17M €**

une 1st 2031

Funded by the European Union

innovative health initiative

TRANS PHARM

PREMIER

PRIORITISATION AND RISK EVALUATION OF MEDICINES IN THE ENVIRONMENT

iHi factsheet

Premier

01/09/2020 - 31/08/2026

Project Goal:

- Contributing to a sustainable future by proactively managing the environmental impact of medicines.
- Reduce environmental risks from APIs: prioritize legacy APIs, identify hazards, promote greener design, enhance data accessibility for sustainable decisions.

Budget: **11M €**

Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

IHI Factsheet

The action under this topic must contribute to all the following outcomes:

- Replace PFAS: new environmentally sustainable materials as alternatives to PFAS that maintain patient safety are developed for the benefit of the healthcare industry and the citizens;
- Reduce / re-use PFAS: improved usage of PFAS materials and minimised exposure is achieved for the benefit of the environment and therefore citizens and society;
- A mapping of the types and applications of PFAS throughout the supply chain is available for healthcare technologies and products, including collaborating with upstream suppliers;
- A database of alternatives to PFAS is available;
- New disposal processes of PFAS are available for the benefit of the environment and therefore citizens and society.

Call closed on 23 April

Budget: **23.4 M €** from Com, the indicative contribution from industry beneficiaries is 20. 2 **M €**

une 1st 2031

Funded by the European Union

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Thank you

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Contact/Questions?

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https://transforming-pharma.eu/