Cumulative legislative impacts of the environment, food and animal legislations on the pharmaceutical sector: a call for coherence

efpia

EFPIA members are committed to sustainability:

- We support the EU's climate and environmental goals
- We lead initiatives to minimise the impact of medicines and operations on the environment, including through the Innovative Health Initiative (IHI)[1,2,3]

However overlapping regulations...

- Delay patient access to medicines
- Slow down innovation
- Undermine long-term sustainability
- Harm Europe's competitiveness

We must act now to ensure that environmental ambition and healthcare resilience go together hand in hand–not head-to-head.

The Legislative Labyrinth

The **EU Green Deal**, chemical strategy, and circular economy initiatives have triggered a wave of overlapping legislation impacting pharma.

The **Clean Industrial Deal**, launched in February 2025, reflects a broader EU ambition to enhance competitiveness while decarbonising the economy.

Accumulation of requirements and inconsistencies amongst new and proposed EU legislations will affect every stage of the medicine value chain

Patient Access

- Shortages, product withdrawals, and higher prices due to **reformulations** and **Extended Producer Responsibility (EPR) fees**.
- Over **600 essential medicines** threatened by PFAS restrictions.
- **60-70% of oral medications at risk** if titanium dioxide is banned.

Innovation & Competitiveness

- Regulatory instability and tight timelines are redirecting R&D **away from Europe**.
- Stringent EU Taxonomy rules may **misrepresent pharma's sustainability progress**, deterring green investment.
- Putting the cost of treating urban wastewater solely on the pharmaceutical and cosmetics industries will **fail to incentivise other sectors to reduce micropollutants** in the water.

Regulatory Complexity

- **Conflicting rules** between EU agencies and with global standards.
- Legal uncertainty and misalignment across new **chemical, water, and packaging legislation**.
- Legislative requirements must align with the **animal testing** phaseout roadmap to avoid contradictory obligations that could undermine progress of non-animal methods.

Environmental & Data Compliance

- New **reporting obligations** risk exposing commercially sensitive data.
- Unclear rules on **IP, clinical trials, and reformulated drugs** add further business uncertainty.
- Complex regulations mean that new sustainable innovative manufacturing is very **hard to implement**.

Let's ensure policy coherence across legislations to secure resilient development, manufacturing and supply chains of innovative medicines in Europe.

Our recommendations – Building a legislative framework that works for the patients, the planet and the industry

1

Align & Coordinate: Create an EU Office for Life Sciences to monitor and drive coherence across green, chemical, and pharma policy.

2

Better Regulation: Ensure legislation respects competitiveness, health security, and avoids duplication.

3

Continuous Impact Assessment: Evaluate cumulative effects of new laws and ensure broad stakeholder engagement before finalising.

4

Flexible Timelines: Adjust implementation schedules as scientific evidence and feasibility evolve.

8

Science-Based Green Deal Transition: Develop a resilient supply chain plan that balances environmental goals with innovation capacity and industrial competitiveness.

7

Early Engagement: Consult EMA early in legislation that impacts medicines and support regulatory sandboxes.

6

Protect Patient Access: Allow targeted exemptions for medicinal products in non-pharma legislation following an evidence and risk-based approach.

5

Clear Guidance: Issue timely and transparent implementation documents–developed with industry input.

9

Engage Broadly: Work with industry, patients, academia, and suppliers to find alternative sustainable solutions and manage risks.

10

Enable & Incentivise Innovation: Recognise the unique needs of advanced therapies and secure Europe's leadership in biomedical innovation.

Read the full impact report ›

1 https://efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-sustainability/circular-economy/

2 https://efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-sustainability/climate-change

3 https://efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-sustainability/water-pharmaceuticals-in-the-environment/