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EFPIA's ONE Vision: Outlook On A Regulatory System For Medicines And Combined Products

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EFPIA's ONE Vision: Outlook On A Regulatory System For Medicines And Combined Products



The European Federation of Pharmaceutical Industries and Associations (EFPIA) has published ONE Vision¹, setting out a North Star for a future-ready regulatory system for medicines and combined products. Its ambition is to ensure Europe remains agile, competitive, and able to bring innovation to patients faster.

Europe's regulatory framework is a cornerstone of its life sciences ecosystem, robust and globally respected. But it is now at a turning point. Scientific advances, digitalisation, and increasingly integrated products are transforming how medicines and combined products are developed, while geopolitical pressure and global competition are intensifying.

At the same time, Europe has a strong and globally recognised foundation to build on.

With more than 12,700 medicines² in development and hundreds expected to launch in the coming years, Europe must ensure its regulatory system can keep pace with this wave of innovation. As a globally recognised reference system, the EU also has a unique opportunity to shape international regulatory collaboration and standards – supporting faster access to innovation for patients in Europe and beyond.

To realise this opportunity and to ensure the EU does not lose its importance at global scale, however, the regulatory system must evolve.

Why Change Is Needed

Today's EU regulatory system continues to operate through multiple sequential steps. Different authorities are involved at different stages of development, often without continuity, which can impact efficiency and timelines. A medicine or a combined product may move back and forth between national authorities, notified bodies, and the European Medicines Agency (EMA) for different phases of assessment.

This challenge is becoming more visible as innovation blurs traditional boundaries. Medicines are increasingly developed alongside devices, diagnostics, and digital tools, yet are still assessed through separate frameworks despite being scientifically interconnected.

"Fragmentation in decision-making also creates silos where data and learnings from one stage of development or one authority may not seamlessly inform others," says Katrin Rupalla, Head of Global Regulatory Affairs at Johnson & Johnson Innovative Medicine and co-chair of the EFPIA Regulatory Strategy Committee.

At the same time, multiple legislative and policy initiatives are advancing in parallel across Europe, making coordination across frameworks increasingly important to ensure coherence and predictability.

In recent years, the EU has put forward proposals to modernise the 20-year-old regulatory framework, such as the overhaul of the pharmaceutical legislation which was agreed at the end of last year.

However, these proposals were developed in a different context before the current acceleration in global competition and uncertainty. Incremental change alone may not be enough to respond to the evolving environment.

"The complexities and fragmentation across the EU hit small biotechs hardest," Rupalla adds. "With constrained resources, they often lack the capacity to navigate the system efficiently, slowing patient access to innovation."

At the same time, the EMA plays a critical global role. "The EMA serves as a reference authority for many countries worldwide" says Sabine Atzor, Head of EU Regulatory Policies at Roche and co-chair of EFPIA's Regulatory Strategy Committee. "Timelines in EU approvals can therefore have repercussions for patients beyond Europe."

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ONE Vision: From Fragmentation To An Integrated System

EFPIA's ONE Vision is intended as a shared 'North Star' – a direction of travel towards a more aligned and agile regulatory system for medicines and combined products across Europe.

At its core are four mutually reinforcing pillars:

- **One Evidence Lifecycle** – shifting from fragmented submissions to a continuous flow of evidence across the lifecycle, from preclinical research to real-world use.
- **One Process** – replacing sequential regulatory steps with a coordinated, end-to-end approach that enables early and continuous scientific dialogue, supports iterative assessment, and ultimately shortens timelines to approval.
- **One System** – creating interoperable and cloud-based digital infrastructure so data can be shared, reused, and assessed seamlessly.
- **One Governance** – strengthening coordination across the network, with an empowered EMA acting as a single-entry point and system orchestrator for medicines and combined products, while continuing to leverage the scientific expertise of Member States.

Together, these pillars represent a shift from a milestone-based system to a connected and continuously learning regulatory approach, where evidence and decision-making build over time.

A more integrated and continuous approach to scientific dialogue is central to this shift. Earlier and ongoing

engagement between developers, regulators, and other stakeholders can help align evidence expectations, address issues proactively, and support more predictable and timely decision-making.

"ONE Governance and ONE System are foundational drivers for a holistic thinking inherently reinforcing the other two pillars," says Atzor of ONE Vision. She clarifies that "this is about strengthening coordination, governance, and interoperability so we operate as one European system rather than disconnected parts."

A key element of this shift is continuity of knowledge across the lifecycle – an area where the current system can be further strengthened. "It is essential for patient safety that we pick up early signals from clinical data that can inform clinical development, authorisation, post-marketing, and risk management. We need faster access to innovation by the integration of knowledge that can accelerate regulatory decision-making and adaptive regulatory pathways," says Rupalla.

ONE Vision therefore proposes the introduction of a lifecycle regulatory stewardship, ensuring that expertise and data follow a product from early development through to post-authorisation.

"Accumulating data and deep expertise make for good regulatory decisions and an understanding of risk, efficacy, risk-based trade-offs in a much more integrated way. That's why we need lifecycle stewardship," she adds.

Delivering this transformation will also require sustained investment in regulatory capacity – including scientific expertise, digital infrastructure, and new ways of working across the European network. Strengthening capabilities across both the EMA and Member States will be essential to ensure the system can operate effectively as one, while keeping pace with increasing scientific complexity.

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From Vision To Dialogue

ONE Vision sets out a proposed direction of travel, which is now open for dialogue. The next step is to engage with regulators, policymakers, and the broader health community to build a shared understanding and shape how it can be translated into positive impact.

Atzor concludes: "We hope and believe ONE Vision can catalyse a shared ambition for regulators and industry alike: faster, predictable access to safe and effective medicines and combined products for patients across Europe."

References:

1. EFPIA, EFPIA's ONE Vision, Nov. 2025: https://efpia.eu/media/riglunsl/efpia_one-vision.pdf
2. IFPMA, Always Innovating, Pharmaceutical Industry Facts & Figures, Dec. 2024: <https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures/>



The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 40 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

Learn more at <https://www.efpia.eu>.

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