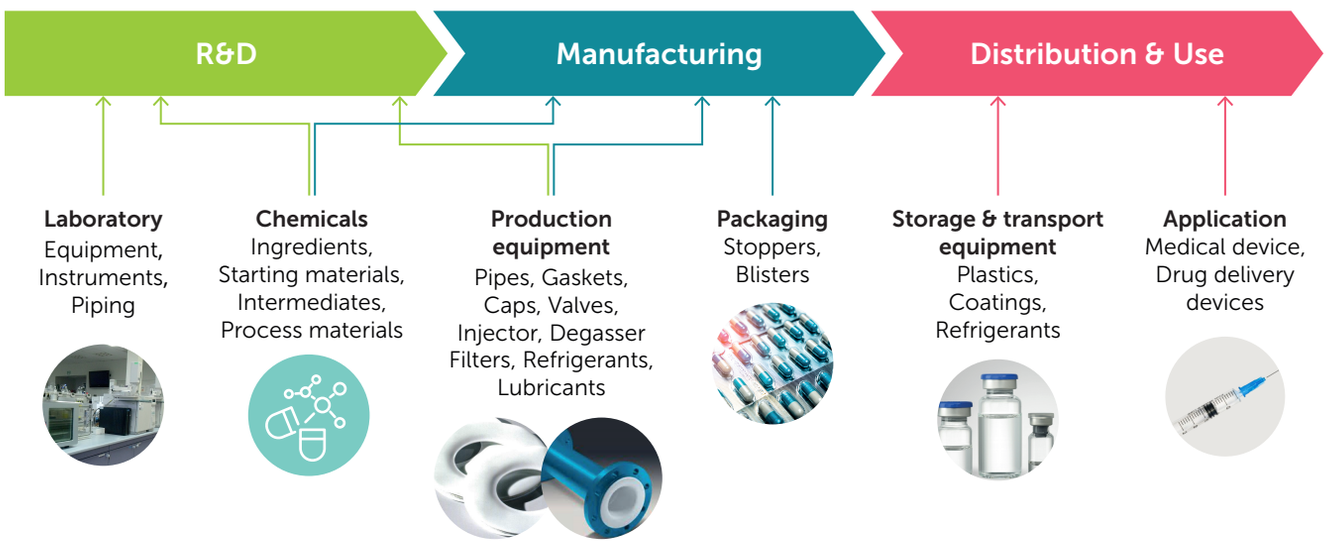
PFAS substitution in medicines: working together towards science-based solutions

PFAS are a group of chemical substances. Due to environmental and health concerns linked to some PFAS, a Europe-wide ban is currently under discussion. **The scope of this restriction is exceptionally wide, covering thousands of substances and uses — including those with established safety profiles in medicines.**

Companies are working to identify technically feasible, safe, and sustainable alternative. However, replacing PFAS is only possible where alternatives are scientifically, technically, clinically and regulatorily available. Even then, implementation requires sufficient time for validation, regulatory approval and phased introduction to avoid disruptions to patients and supply chains.

To safeguard patient access to medicines, EFPIA calls for time-unlimited derogations for pharmaceuticals. These derogations should remain proportionate, science-based, and aligned with existing pharmaceutical legislative frameworks.

Where are PFAS used in medicines development?



PFAS help medicines be **more stable, more effective, longer-lasting**, and **safer to manufacture**, enabling better patient outcomes.

What could this mean for patients?

A broad PFAS restriction carries significant consequences for medicine availability worldwide.

~1,900 active substances potentially affected by a broad restriction

600+ essential medicines on the WHO model list could face disruption

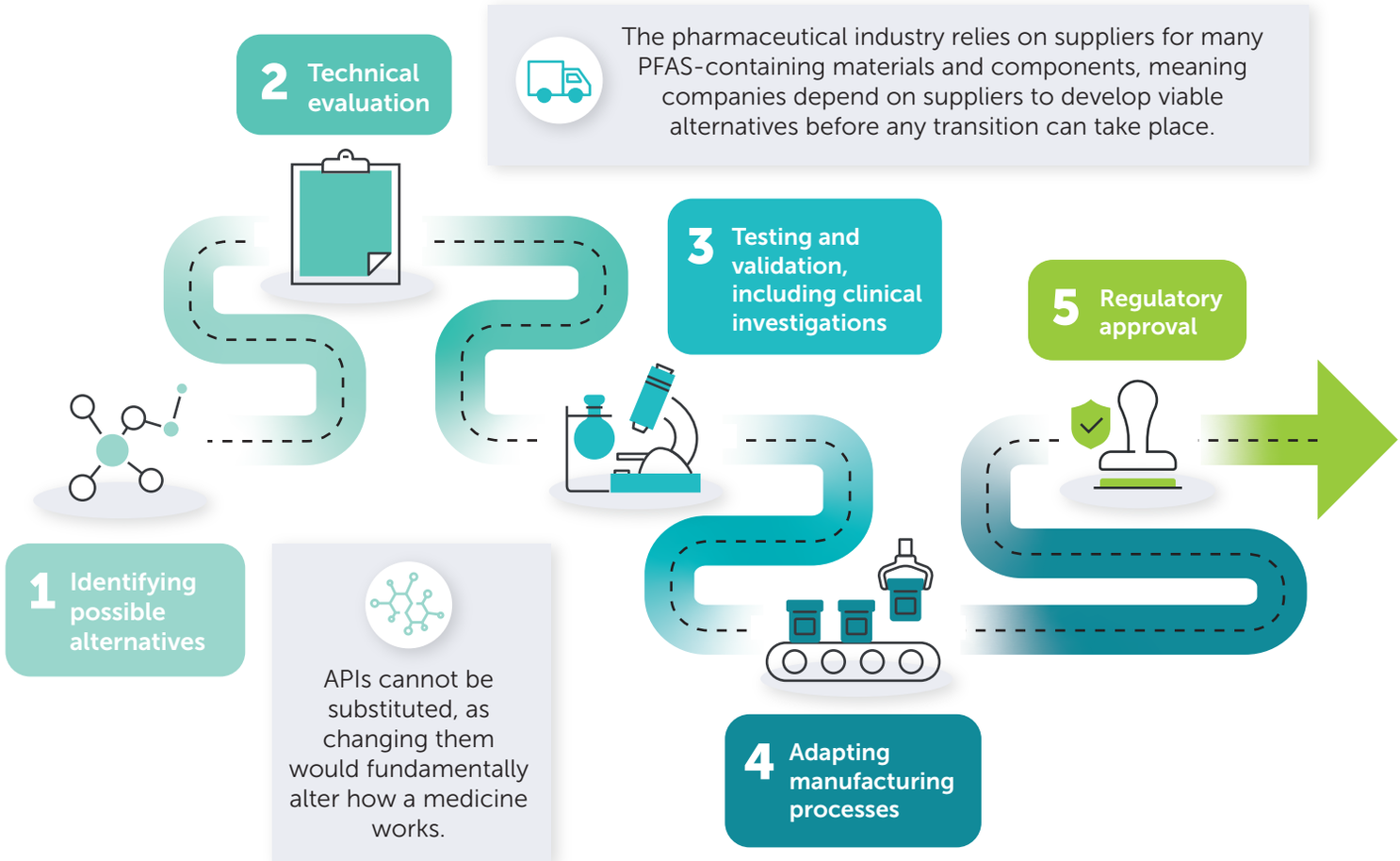
Potential impact

- **Shortages** of treatments across therapeutic areas
- **Reduced availability** of critical and life-saving medicines
- Risk of **reduced European manufacturing and R&D**
- **Increased dependence** on third-country production
- **Weakening** of EU strategic autonomy and resilience

- The estimated economic impact reaches **EUR 96 billion.**
- Up to **53,000 jobs** could be affected.

Substitution is complex and uncertain. Derogations must take into account the regulatory timelines.

Developing a new medicine takes 10–15 years and investments of at least €2.3 billion.
Every medicine is approved by regulators based on highly specific manufacturing, packaging and testing protocols. If any material or production equipment is replaced, companies must repeat parts of this lengthy process, including testing and marketing authorisation approval to prove the medicine remains safe and effective. This would create an unprecedented bottleneck at EMA.[1]



- Indicatively, reformulating an inhaler requires **6 to 10 years**.
- Replacing filtration components in manufacturing may take up to **20 years**.

Industry efforts on substitution

Companies are actively working to reduce their environmental footprint by exploring safe and sustainable alternatives. In parallel, they contribute to major European public–private research initiatives:

IMI PREMIER, IHI PHARMECO, and IHI ENKORE

aim to advance environmental monitoring, improve understanding of pharmaceutical emissions, and develop solutions for more sustainable manufacturing and waste management.

The IHI PFAROS project

A major multi million euro, cross-sector European research initiative bringing together industry, academia and regulators to improve understanding of PFAS use in healthcare, accelerate the development of safe and sustainable alternatives where feasible, strengthen environmental monitoring, and support evidence-based regulatory decision-making.

1 EMA submission #10229

Sources:
EFPIA *Socio-Economic Analysis on PFAS* (2023)
Use of Fluoropolymers and Fluoro-Elastomers in Medicinal Product Manufacturing Facilities