EFPIA Briefing on PFAS and the Pharmaceutical Sector

Executive Summary

EFPIA supports ambitious actions to reduce emissions from persistent substances into the environment and recognises the need for effective measures to address PFAS pollution. The research-based pharmaceutical industry is committed to reducing environmental impacts, improving lifecycle management and advancing alternatives where these are scientifically, technically and clinically feasible[1].

The pharmaceutical sector shares the objective of minimising PFAS emissions and is already investing in collaborative solutions. Industry is actively supporting initiatives such as the Innovative Health Initiative (IHI) PFAROS project, PharmEco, ENKORE and IMI PREMIER, which collectively aim to improve understanding of PFAS uses, develop alternatives, strengthen waste and wastewater management approaches, support green chemistry innovation and generate the evidence needed for future regulatory decision-making.

At the same time, **medicinal products present a unique case within the proposed PFAS restriction framework.** PFAS are used throughout the pharmaceutical lifecycle, including in active pharmaceutical ingredients (APIs), manufacturing processes, packaging, drug delivery devices, filtration technologies and other critical infrastructure that help ensure the quality, safety, efficacy and reliable supply of medicines. In many cases, **viable alternatives are not yet available or cannot be implemented within foreseeable timelines** due to scientific, technical, regulatory and supply-chain constraints.

- The **proposed universal PFAS restriction framework does not fully reflect the complexity of pharmaceutical development and manufacturing**. Medicines are authorised on the basis of fixed formulations, validated processes and approved packaging systems. Changes to PFAS-containing materials may require redevelopment, GMP revalidation, stability studies, supplier qualification, regulatory variations and, in some cases, additional clinical data. Substitution must also be managed across globally integrated supply chains.
- **A successful transition will therefore depend not only on the availability of alternatives but also on the capacity of medicines regulators to assess and approve changes across large numbers of authorised products**. If substantial parts of the pharmaceutical portfolio require simultaneous reformulation, revalidation or reauthorisation, both industry and regulatory authorities could face significant implementation bottlenecks. This is particularly relevant given the concurrent implementation of the revised EU pharmaceutical legislation and other major environmental and industrial policy initiatives. Transition timelines and future review mechanisms should therefore reflect both scientific realities and regulatory capacity constraints.

An updated 2026 socio-economic analysis involving 18 EFPIA member companies illustrates the scale of pharmaceutical dependence on PFAS-containing materials.

- The participating companies collectively employ more than 205,000 people within the EEA and
- reported more than 250 medicinal products containing PFAS, representing approximately 60% of their product portfolios. The impact extends beyond finished medicines, as many additional products rely on PFAS-containing materials and technologies throughout the manufacturing process.
- The analysis estimates that a full restriction scenario could generate economic impacts exceeding EUR 96 billion and affect more than 53,000 jobs across the European pharmaceutical ecosystem. These estimates are likely conservative given the complexity of global pharmaceutical supply chains and the partial coverage of the analysis.

1 https://efpia.eu/about-medicines/development-of-medicines/environment-health-safety-sustainability/pfas-working-toward-a-sustainable-future-while-protecting-patient-care/

The discussion is closely linked to Europe's broader objectives on healthcare resilience, competitiveness and strategic autonomy. As the EU seeks to strengthen critical supply chains and pharmaceutical manufacturing, policy decisions should carefully consider impact on investment and innovation in Europe. Measures that do not reflect pharmaceutical realities risk shifting manufacturing and innovation activities outside the EU without delivering equivalent environmental benefits globally.

Importantly, **medicinal products are governed by one of the world's most comprehensive regulatory frameworks**. Existing and evolving legislation, including EU pharmaceutical legislation, Good Manufacturing Practice (GMP), environmental risk assessment requirements, the Industrial Emissions Directive (IED), the Urban Wastewater Treatment Directive (UWWTD) and the Water Framework Directive (WFD), increasingly addresses environmental risks and lifecycle impacts. The revised General Pharmaceutical Legislation will further strengthen these requirements from 2028 onwards, providing additional opportunities to reduce emissions while maintaining patient access and healthcare resilience.

EFPIA believes **Europe can achieve its environmental and public health objectives through a proportionate, science- and risk-based approach**. This should include derogations covering the full medicinal product lifecycle, alongside a value-chain approach that ensures the availability of critical upstream inputs, including fluoropolymers and other essential materials, where no suitable alternatives exist. Where substitution is feasible, implementation timelines should reflect pharmaceutical development, validation and regulatory approval processes, supported by periodic reviews of technological progress and alternative availability.

Such an approach would support environmental protection, patient access, healthcare resilience and Europe's competitiveness as a global leader in pharmaceutical innovation and manufacturing.

Policy and Regulatory Context

The EU PFAS restriction proposal represents one of the broadest chemicals restrictions ever considered under REACH. The restriction process has progressed through ECHA's scientific committees, the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC).

While EFPIA recognises the environmental concerns associated with PFAS emissions, the pharmaceutical sector differs fundamentally from most industrial and consumer sectors included within the proposal. Medicines are essential healthcare products directly linked to patient care, healthcare resilience and public health. Regulatory decisions about medicines are based on a formal risk–benefit assessment that weighs clinical and public-health benefits against safety and environmental hazards, and that considers mitigation measures and proportionality before reaching policy or regulatory conclusions.

Unlike most industrial products, **medicinal products are authorised on the basis of fixed formulations, validated manufacturing processes, approved packaging systems and strict quality specifications**. Even seemingly minor changes to manufacturing materials, sterile filtration systems, elastomers, coatings or packaging components may require extensive comparability exercises and potential clinical trials, extractable and leachable assessments, stability studies, process validation and regulatory variation approvals across multiple jurisdictions worldwide.

The pharmaceutical supply chain is highly globalised and interconnected. APIs, intermediates, packaging systems and drug delivery device components are sourced through complex international supply networks. In many cases, it is not operationally feasible to maintain separate "PFAS-free EU-only" manufacturing systems while continuing to supply global markets. Measures that diverge significantly from regulatory approaches in other major jurisdictions therefore risk discouraging investment in EU manufacturing, accelerating the relocation of production and innovation activities outside Europe, and undermining broader EU objectives related to pharmaceutical security of supply, industrial competitiveness and strategic autonomy.

The ECHA scientific committees' opinions continue to leave significant questions regarding pharmaceutical uses unresolved. EFPIA is particularly concerned that the pharmaceutical sector has not been assessed as a distinct sector within the restriction process. The sector's uses are fragmented across multiple use categories, including APIs, sealing applications, lubricants, technical textiles, broader industrial uses and other medical applications – all requiring assessment. Furthermore, key PFAS uses relevant to pharmaceutical production

remain insufficiently identified in both the restriction proposal and the related opinions. This fragmentation creates major uncertainty regarding the status of medicinal products, existing market authorisations and upstream manufacturing uses essential to pharmaceutical supply chains. SEAC has also acknowledged that it has not assessed all pharmaceutical uses and has proposed temporary derogations pending future evaluation. This creates a "cliff-edge" scenario whereby pharmaceutical uses may ultimately face restriction without clear long-term regulatory certainty or implementation pathways.

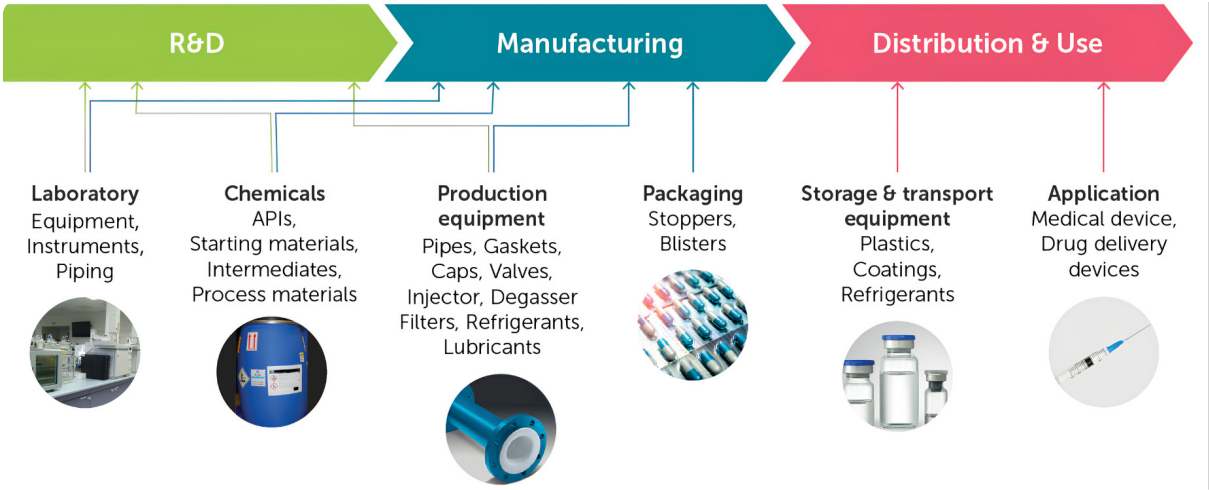
In the absence of a sector-specific socio-economic assessment by ECHA, neither the costs nor the environmental benefits of including medicines in a horizontal restriction have been validated; the proportionality balance for this sector therefore rests on assumptions, not evidence. Many pharmaceutical PFAS uses are characterised by bonded application formats, GMP-controlled waste management, and regulated effluent treatment - emission profiles materially different from dispersive consumer applications - and the incremental environmental benefit of restricting these uses has not been quantified at sector level.

EFPIA remains particularly concerned that:

- a complete socio-economic assessment of impacts on medicines availability was not performed;
- the restriction proposal and subsequent opinions do not comprehensively reflect the full range of PFAS uses necessary for pharmaceutical manufacturing;
- the consequences for patient access impacts and indirect healthcare system costs (hospitalisation, therapeutic switching, treatment failure, lost workforce productivity) have not yet been comprehensively quantified;
- the proposal creates regulatory conflict with pharmaceutical legislation and health authority competences. Furthermore, the cumulative compliance burden across the integrated regulatory framework already governing the sector and burdens on regulators (REACH restriction + GMP + ERA + variation procedures + New pharmaceutical legislation + UWWTD) was not assessed;
- the current derogation architecture creates legal and operational uncertainty for companies and healthcare systems;
- The pharmaceutical sector should not be treated in the same manner as non-essential or dispersive consumer uses.

PFAS Uses in the Pharmaceutical Sector

PFAS are used across a broad range of pharmaceutical applications because of their unique functional properties, including chemical inertness, thermal resistance, lubricity, low extractables and leachables, barrier performance and compatibility with sterile GMP manufacturing.



Active Pharmaceutical Ingredients (APIs)

Fluorinated chemistry plays a major role in modern medicinal chemistry because fluorine atoms can profoundly influence the biological and physicochemical properties of medicines. The introduction of fluorinated groups can improve target selectivity, metabolic stability, membrane permeability and bioavailability while reducing dosing frequency and off-target effects. In many cases, these characteristics are directly linked to the therapeutic performance of the medicine itself.

Fluorinated chemistry is intentionally incorporated into approximately 7 - 10% of APIs[2]. Replacing fluorinated moieties within an authorised API is not equivalent to substituting an industrial additive or processing aid. It fundamentally changes the molecular identity, safety and efficacy profile of the medicine itself. In practical terms, substitution would frequently require the discovery, development and authorisation of an entirely new medicinal product.

Pharmaceutical manufacturing and processing

PFAS are used extensively in reagents, catalysts, solvents, processing aids, product-contact surfaces, tubing, gaskets, valve systems and controlled manufacturing environments. Substances such as trifluoroacetic acid (TFA), trifluoroethanol and hexafluoroisopropanol are widely used in peptide synthesis, biologics production and advanced manufacturing processes.

PFAS-containing materials are also widely used in upstream and ancillary manufacturing operations that may not be visible within the final medicinal product itself. These include equipment linings, processing machinery, specialised coatings, fluid handling systems and cleanroom infrastructure essential to GMP-compliant pharmaceutical production.

Fluorinated substances additionally play a critical role in validated analytical systems used throughout pharmaceutical development and manufacturing. TFA is widely used in reversed-phase high-performance liquid chromatography because it improves chromatographic resolution, reproducibility and impurity detection. Replacing such substances would require extensive redevelopment and revalidation of analytical methods used for quality control and batch release. These uses are typically industrial, contained and managed under GMP and waste management frameworks.

PFAS use in Heating, Ventilation, and Air Conditioning (HVAC) systems in cleanrooms and GMP environments rely on fluorinated refrigerants (HFOs and HFCs) for precise temperature and humidity

2 https://www.efpia.eu/media/b1rcqvlt/annex-2-patient-impact-survey_human-health-associations.pdf and Driving Breakthrough Therapies: Why PFAS Motifs Matter in Drug Design https://chemrxiv.org/doi/full/10.26434/chemrxiv.15002892/v1

control - a regulatory requirement under GMP. Multiple substitution barriers apply: ammonia is toxic and restricted in occupied buildings, carbon dioxide systems require very high operating pressures incompatible with retrofit, and hydrocarbons are flammable and restricted in production zones[3].

Drug delivery devices and combination products

PFAS materials[4] can be essential in drug delivery systems, including prefilled syringes, autoinjectors, reusable injection pens and pressurised metered-dose inhalers (pMDIs). Fluoropolymers help ensure accurate dosing, reduced friction and activation force, product stability and reliable device performance over the full product lifecycle.

In injectable medicines, PFAS-coated plungers and stoppers help maintain container closure integrity and smooth device functionality, particularly for sensitive biologics and advanced therapies. No universally applicable non-fluorinated alternatives currently exist for many of these applications.

Other medical applications including packaging

PFAS-containing materials are used in coated vial stoppers, blister packaging, transdermal patches, packaging barriers and ophthalmic and dermatological excipients. These materials are selected for performance characteristics essential to sterility assurance, long-term product stability and patient safety. Packaging often forms part of the market authorisation of the medicinal product.

Technical textiles, filtration and manufacturing infrastructure

PFAS-containing materials are embedded throughout pharmaceutical manufacturing infrastructure, including sterile filtration systems, HEPA and ULPA filtration, bioprocessing membranes, lined reactors, water purification systems, tubing, seals and cleanroom environments.

Fluoropolymers such as PTFE, ETFE, PVDF and FFKM provide a unique combination of chemical resistance, thermal stability, low extractables and mechanical durability critical for GMP-compliant sterile manufacturing.

Many manufacturing systems operate under aggressive chemical environments and repeated sterilisation cycles involving high temperatures, solvents and cleaning agents. Alternative materials frequently fail to provide equivalent durability, contamination control or process integrity.

Sealing applications

Fluoropolymer and PFPE-based sealing materials are widely used in GMP production equipment, sterile processing systems and high-temperature manufacturing environments. These materials provide a combination of flexibility, chemical resistance and sealing performance not currently replicated by alternative materials.

Key Areas of Concern

Risk to medicines availability and patient access

The most significant concern arising from the proposed PFAS restriction is the potential disruption to the supply and availability of medicines within Europe. Industry surveys submitted during the ECHA consultation in 2023[5] identified that the proposed restriction could potentially affect tens of thousands of marketing authorisations globally and medicines across major therapeutic areas including oncology, cardiovascular disease, diabetes, respiratory disease and infectious diseases.[6]

3 https://www.efpia.eu/media/jc1lcupo/annex-3_industrial-use-of-fluoropolymers-in-pharma-manufacturing_final.pdf and The Synthetic Role of PFAS in Drug Substance Manufacturing: An IQ Consortium Working Group Review on the Potential Impact of PFAS Restrictions on Patient Access to Medicines https://chemrxiv.org/doi/full/10.26434/chemrxiv.15003710/v1

4 The Use of PFAS in Drug Product Presentations including Formulations, Primary and Secondary Packaging, and Delivery Devices: The Survey Conducted by the IQ Consortium Drug Product PFAS Working Group to Review the Potential Impact of PFAS Restrictions on Patient Access to Medicines https://chemrxiv.org/doi/full/10.26434/chemrxiv.15005577/v1

5 https://www.efpia.eu/media/3balrcsd/revised-efpia-report-in-response-the-annex-xv-pfas-restriction-proposal.pdf

6 https://www.efpia.eu/media/b1rcqvlt/annex-2-patient-impact-survey_human-health-associations.pdf

Approximately 1,922 active pharmaceutical ingredients (APIs) either are an API containing fluorine (139)[7] or use a PFAS material during their production; packaging and storage. These may fall within the scope of the proposed restriction, without derogations. This concern is further heightened by SEAC's conclusion that the proposed time-unlimited derogation for APIs has not been sufficiently justified, creating significant uncertainty for pharmaceutical manufacturing, supply continuity and patient access to medicines.

The pharmaceutical supply chain is globally integrated. Companies cannot realistically redesign manufacturing systems, reformulate products and obtain global regulatory approvals within the timelines currently proposed under the restriction.

Where suitable alternatives cannot be identified, validated and globally approved, companies may be forced to withdraw products from the EU market, relocate manufacturing outside Europe, face shortages and supply disruptions or delay innovation and clinical development. The combination of incomplete derogations, limited substitution possibilities and unresolved regulatory uncertainty creates a risk that authorised pharmaceutical uses could become restricted by default. This may affect a large number of authorised medicines and reduce treatment options available to patients across Europe[8].

The public health implications of medicine shortages and reduced manufacturing resilience have not yet been adequately addressed within the current SEAC assessment. The SEAC does not fully assess broader public health implications, including impacts on continuity of care, healthcare system resilience, strategic stock management, reduced workforce productivity, lost economic output and Europe's long-term manufacturing capacity for essential medicines.

Regulatory constraints

Medicinal products are authorised on the basis of fixed formulations, manufacturing processes and specifications. Any change to APIs, manufacturing reagents, packaging materials, sterile filters, drug delivery components or sealing systems may trigger extensive regulatory obligations.

These obligations may include validation and requalification exercises, extractables and leachables assessments, toxicological evaluations, process comparability studies, stability testing, supplier qualification and global regulatory variation procedures.

Regulatory timelines cannot be compressed beyond certain scientific and legal limits. Changes affecting authorised medicines must often be reviewed and approved across multiple global jurisdictions simultaneously, including the EU, US and other major regulatory markets. These processes are inherently resource-intensive and frequently extend over many years.

On average, the development and approval of a new medicine requires approximately 10–15 years. Even where full medicine redevelopment is not required, substantial parts of the regulatory and validation process must often be repeated.

If large product portfolios require simultaneous reformulation and regulatory review, both industry and regulatory authorities could face major capacity constraints, further extending implementation timelines. The cumulative effect of simultaneous reformulation requirements across multiple product portfolios could create substantial bottlenecks for both pharmaceutical companies and medicines regulators, delaying implementation even where technically feasible alternatives may eventually emerge.

The scale of the transition challenge is particularly relevant in the context of Europe's efforts to strengthen pharmaceutical manufacturing capacity. Simultaneous reformulation, revalidation and reauthorisation requirements across large portfolios could divert significant resources away from innovation, manufacturing expansion and supply resilience initiatives.

7 https://www.efpia.eu/media/b1rcqvlt/annex-2-patient-impact-survey_human-health-associations.pdf

8 https://efpia.eu/media/bgvfnbrg/pfas-substitution-in-medicines-working-together-towards-science-based-solutions.pdf

Lack of suitable alternatives

The updated industry socio-economic assessment confirms that no single substitute or group of substitutes can replace PFAS across the full range of pharmaceutical applications. For many pharmaceutical uses, alternatives:

- do not currently exist;
- are not available at pharmaceutical grade;
- cannot deliver equivalent performance;
- have not been validated for GMP use;
- may create new environmental or safety concerns; or
- may require redesign of entire manufacturing processes.

The existence of a theoretical alternative does not mean that a technically, regulatory accepted and commercially viable substitute is available.

For APIs in particular, substitution is fundamentally not feasible because the therapeutic activity of the medicine is intrinsically linked to its molecular structure. APIs cannot be replaced on a like-for-like basis, and therapeutic alternatives are not scientifically, clinically or regulatorily interchangeable.

The pharmaceutical sector must also avoid regrettable substitution scenarios where replacement materials introduce reduced product performance, contamination risks, inferior sterility assurance or alternative environmental concerns.

Incomplete assessment and legal uncertainty

SEAC has explicitly acknowledged that several sectors and derogations linked to pharmaceutical uses were not fully assessed. EFPIA remains concerned that:

- unassessed uses remain effectively subject to a blanket ban;
- proportionality has not been fully demonstrated;
- derogations remain inconsistent and insufficiently granular; and
- the proposal creates significant legal and operational uncertainty.

Emissions control

EFPIA supports effective measures to minimise environmental emissions associated with PFAS. A transition should be risk-based, proportionate, operationally feasible and aligned with existing pharmaceutical regulatory frameworks.

The pharmaceutical sector already operates under one of the most comprehensive environmental and product regulatory frameworks globally. In addition to REACH, pharmaceutical manufacturers are subject to a broad range of sector-specific legislation and controls. The ongoing revision of the EU pharmaceutical legislation will further strengthen environmental obligations through enhanced environmental risk assessments (ERAs), greater consideration of persistent, bioaccumulative and mobile substances, lifecycle-oriented risk management measures and strengthened environmental conditions linked to marketing authorisations.

Leveraging these existing frameworks would allow environmental objectives to be achieved while avoiding unnecessary duplication, preserving regulatory efficiency and supporting Europe's competitiveness as a location for pharmaceutical research, development and manufacturing.

Most pharmaceutical PFAS applications occur in highly contained industrial settings with advanced waste management, wastewater treatment and incineration systems designed to minimise environmental releases. Pharmaceutical uses are therefore fundamentally different from many dispersive applications.

EFPIA supports approaches focused on actual emissions, exposure pathways, lifecycle management, manufacturing and environmental performance rather than blanket structural grouping approaches that do not sufficiently differentiate between the actual properties and behaviours of substances, and contained industrial and dispersive uses.

Innovation and industry action

The pharmaceutical and healthcare sectors are actively investing in collaborative research initiatives to better understand PFAS uses, emissions and substitution opportunities.

IMI Premier (Prioritisation and risk evaluation of medicines in the environment) (Kicked off September 2020): aims to deliver a novel assessment system for characterising the environmental risks of APIs, and which can be used to:

- screen and prioritise legacy APIs for a tailored environmental assessment;
- identify potential hazards associated with APIs in development and explore the options to steer the design process in a greener direction;
- make relevant environmental data on APIs more visible and accessible to all stakeholders.

PHARMECO (Advancing Safe and Sustainable by design Practices in Pharmaceutical Manufacturing) kicked off in November 2024 and will run until 31 October 2030. The goal of the project is to 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.

ENKORE (Propelling the shift towards the future of circular, safe and sustainable packaging and single-use device ecoDesigned solutions through healthcare environments) kicked off on the 1 January 2025 and will run until 31 December 2028. The project aims to develop an eco-design framework for single-use medical devices and packaging and to focus on materials that minimise waste, optimise resource usage and reduce the carbon footprint, while ensuring devices are safe and fit for use.

PFAROS 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.

Industry is also actively collaborating across supply chains, for example through the Pharmaceutical Supply Chain Initiative (PSCI) and Pharmaceutical Manufacturing forum (PMF), to identify sustainable alternatives where technically feasible and to minimise environmental emissions through improved waste handling, treatment technologies and process optimisation.

These initiatives demonstrate that the pharmaceutical sector is already taking proactive measures to address environmental concerns while safeguarding patient access and continuity of supply by actively pursuing science-based substitution and emissions reduction pathways where technically feasible. However, current research programmes themselves confirm that many alternatives remain at an early stage of development and are not yet available for large-scale pharmaceutical implementation.

EFPIA Recommendations

EFPIA supports effective, proportionate, science-based and risk-based measures to reduce harmful environmental emissions associated with PFAS. However, the current proposal requires substantial adjustment to avoid serious unintended consequences for healthcare systems, medicines availability and European competitiveness.

- **Time-unlimited derogation for medicinal products (including their full value chain)**
  Given the essential societal role of medicines and the absence of viable alternatives for many critical pharmaceutical applications, medicinal products and their supply chains require either a clear exemption or a time-unlimited derogation under the proposed restriction. This should encompass APIs, manufacturing processes, packaging systems, drug delivery devices, technical textiles, sterile filtration systems, sealing applications, development and clinical uses and essential upstream supply chain applications.

- **Alignment with pharmaceutical legislation**
  The restriction must avoid overlap and conflict with EMA competences, national medicines authorities, pharmaceutical authorisation frameworks and existing and emerging environmental requirements under pharmaceutical legislation.

- **Involvement of health authorities**
  Given the direct implications for patient access and medicines availability, health authorities and pharmaceutical regulators should be fully involved in decision-making relating to pharmaceutical derogations, implementation timelines and risk management measures.

- **Risk-based and emission-focused regulation**
  Future regulatory approaches should focus on actual emissions, exposure pathways, environmental performance, lifecycle management and waste treatment rather than relying solely on broad structural grouping approaches. A blanket structural grouping approach is not appropriate for pharmaceuticals.

- **Support European competitiveness and strategic autonomy**
  Regulatory decisions affecting critical pharmaceutical manufacturing inputs should be assessed against broader EU objectives relating to competitiveness, security of supply, resilience and strategic autonomy. Measures that risk shifting pharmaceutical manufacturing, innovation or environmental impacts outside Europe should be carefully evaluated to avoid unintended consequences for European healthcare systems and industrial policy objectives.

- **Realistic transition timelines**
  Where substitution is technically feasible, transition timelines must reflect the realities of pharmaceutical development and manufacturing, including alternative development, supplier qualification, GMP validation, regulatory submissions and approvals across multiple jurisdictions, and implementation throughout complex global supply chains. For many applications, introducing a single alternative may require more than 10–15 years from identification to full implementation.

  Importantly, substitutions cannot be undertaken simultaneously across all PFAS-dependent products, processes and manufacturing systems. Given the scale and complexity of pharmaceutical operations, changes must be prioritised and implemented sequentially. As a result, while individual substitutions may take 10–15 years, achieving a broader sector-wide transition would likely require 20–25 years or more.

- **Socio-economic and public health assessment**
  A complete socio-economic and public health assessment is lacking to support any restriction measure, including assessment of:

  - medicine shortages;
  - healthcare system impacts;
  - regulatory implementation capacity;
  - industrial competitiveness;
  - innovation impacts; and
  - global supply chain effects.

Conclusion

The PFAS discussion is not solely an environmental or chemicals management issue. For the pharmaceutical sector, it is fundamentally linked to patient access, healthcare resilience, industrial competitiveness, Europe's strategic autonomy and the long-term viability of pharmaceutical manufacturing within the European Union. At a time when the EU is seeking to strengthen resilience, reduce strategic dependencies and rebuild critical manufacturing capacity, regulatory measures should support rather than inadvertently weaken Europe's position as a global centre for pharmaceutical innovation and production. Medicinal products are not interchangeable consumer products; they are essential healthcare tools that depend on highly controlled, globally interconnected and rigorously validated manufacturing systems. A restriction framework that does not sufficiently account for pharmaceutical realities risks undermining Europe's ability to manufacture and supply essential medicinal products while shifting production and environmental burdens outside the EU.

EFPIA supports effective environmental protection and continued action to reduce emissions. However, a blanket PFAS restriction applied without a fully developed understanding of pharmaceutical supply chains, regulatory realities and patient impacts risks creating major unintended consequences for European healthcare systems, innovation and patients. The PFAS discussion is therefore not solely about chemicals management. It is also about preserving Europe's ability to supply medicinal products, maintain healthcare resilience and support long-term pharmaceutical innovation and manufacturing capacity within the EU.