A universal PFAS ban: availability of medicines, manufacturing, jobs and economic growth will be put at risk

efpia

The pharmaceutical industry shares concerns about the environmental impact of PFAS[1]. However, PFAS is a broad non-specific term which does not inform whether a compound is harmful, and not all PFAS present the same risks[2] to the environment or health. The potential impact of a Europe-wide ban on PFAS in pharmaceutical products, packaging and operations is significant:

- The pharmaceutical industry relies on PFAS for **safe manufacturing, distribution and use** of medicinal products.
- The proposed derogation for PFAS Active Pharmaceutical Ingredients (APIs) does not derogate medicinal products, and only applies to **less than 10% of medicinal products in the EU market impacted by the ban[3]**.

We need strategic planning and alternative approaches to avoid disruptions in patient care.

Impact on patient access to medicines

98%
of the Market Authorisations of innovative medicines would need to be amended

93%
of the EU's active substance manufacturing relies on fluoropolymers[4]

>70%
of critical medicines in European Member States could be in short supply

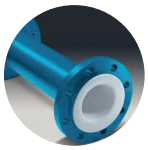
Examples of the widespread impact:

R&D → **Manufacturing** → **Distribution & Use**

Laboratory
Equipment, Instruments, Piping

Chemicals
APIs, Starting materials, Intermediates, Process materials

Production equipment
Pipes, Gaskets, Caps, Valves, Injector, Degasser Filters, Refrigerants, Lubricants



Packaging
Stoppers, Blisters

Storage & transport equipment
Plastics, Coatings, Refrigerants

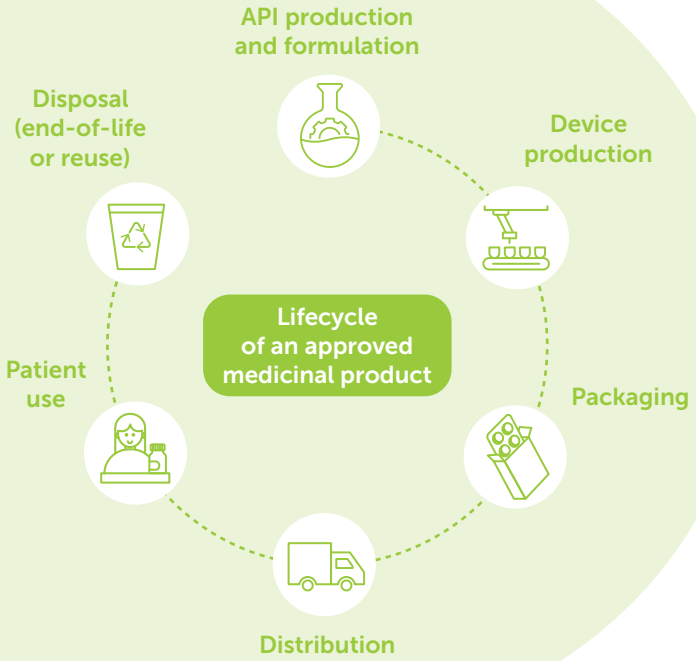
Application
Medical device, Drug delivery devices

Our recommendations

- Derogations until suitable alternative solutions are commonly agreed and qualified
- Develop partnerships throughout supply chains to better manage emissions
- Global health authorities expedite approvals of suitable fluorine-free alternatives

PFAS derogations ensure uninterrupted access to key medicines in pharmaceutical production and supply

The challenges



- Not all PFAS substances present **the same human health and environmental risk**.
- The basis for a restriction under REACH must be a profound hazard and risk assessment including socio-economic and risk-benefits. Restrictions on uses of substances which do not pose a risk is **not in line with the principles of REACH**.
- The scope of the EU Restriction deviates from other jurisdictions. This broad-brush approach impacts patients globally and puts EU-based companies and associated manufacturing at a **major competitive disadvantage**.
- Derogations do not allow **sufficient time** to identify suitable alternatives and further develop waste treatment technology and analytical methods.
- Pharmaceutical production in EEA will be impacted by **shortage of key raw materials** if suppliers cannot produce or import into the EEA.

Strategic Autonomy – strong pharmaceutical manufacturing footprint in Europe

1 million people
are working in the pharmaceutical manufacturing sector in the EU-27[5]

EEA production of medicinal products amounts to **€226.4 billion**. Europe is the 2nd largest market representing **22.4% share** of the world pharmaceutical (prescription) market[6]

Without an exemption for medicines and derogations for the supply chain, the proposed restriction contradicts other EU policy objectives.

Pharmaceutical industry supports substitution

Replacing PFAS-containing materials in a highly regulated sector like the pharmaceutical one is challenging:

- in most cases **no alternatives are currently available**;
- available alternatives must be analysed for their superior environmental performance and must not compromise patient safety;
- when a viable and scalable alternative is identified, **implementation will require time and collaboration** amongst different stakeholders in the value chain, including regulatory procedures.

Fluoropolymers[7] are highly resistant to heat, chemicals, and degradation. Potential replacements that provide the same benefits will be hard to find and may also be persistent in the environment.

Packaging materials and **drug delivery devices** specified in the marketing authorisation of a medicinal product may contain PFAS components. To ensure product quality, medicinal products regulation mandates toxicological evaluations, extractive and leachable studies, and product stability evaluations. Regulatory requirements will apply to any suitable alternative.

1 The PFAS (per- and polyfluoroalkyl substances) Ban or Restriction, which was created by five national authorities (Germany, the Netherlands, Sweden, Norway and Denmark) is currently being assessed by ECHA (European Chemicals Agency).

2 Certain PFAS have been identified as environmental pollutants, resulting in protective measures e.g., drinking water standards. This substance group, includes short and long chain fluorosurfactants or telomers.

3 Human Health Medicinal Products Sector Survey - Impact of Proposed PFAS Restriction on Patient Access to Medicines & EU Strategic Autonomy.

4 A wide range of therapeutic areas could be impacted e.g. cardiovascular disease, chronic respiratory disease, cancer, diabetes and mental health disorders but to name a few. The sector survey identifies over 600 medicines on the WHO Essential medicines list. Member State "Critical Medicines Lists" e.g. 78% of the critical medicines list in Norway could be impacted by the proposed Restriction.

5 Employment data for European countries can be obtained from Eurostat here: Statistics | Eurostat (europa.eu).

6 the-pharmaceutical-industry-in-figures-2023.pdf (efpia.eu).

7 "Fluoropolymers" represent a distinct subset of fluorinated polymers, based on a carbon-only polymer backbone with F atoms directly attached to it, e.g. polytetrafluoroethylene (PTFE); though some fluoropolymers also have Cl or O directly attached to the backbone. [Buck et al (2011) Perfluoroalkyl and polyfluoroalkyl substances in the Environment: Terminology, Classification and Origins]