Preserving access to medicines: call for a patient-centred approach to PFAS regulation

Medicines for Europe, the voice of the European generic, biosimilar and value-added pharmaceutical industry, expresses profound concerns regarding the proposed restrictions on Per- and Polyfluoroalkyl Substances (PFAS) used in the manufacturing and supply of medicinal products in Europe. Acknowledging the environmental risks associated with PFAS, we advocate for an approach that strikes a balance between environmental protection and maintaining patient access to essential medicines.

Achieving this equilibrium is crucial for the strategic autonomy of the European Union (EU) in the field of medicines manufacturing as well as preventing and mitigating critical medicines shortages in the years to come. **The proposed PFAS restriction, potentially the broadest ever put in place, could affect up to 10,000 substances, having an irredeemable impact on EU pharmaceutical industry, and subsequently, access to medicines.**

Impact on medicines manufacturing, EU Strategic Autonomy, and access to medicines:

The implications of a broad ban on PFAS in pharmaceutical manufacturing are extremely profound and wide ranging, potentially disrupting the production and availability of critical medicines, leading to prolonged shortages. Life-saving medications, dependent on PFAS technology in their manufacturing processes or containing PFAS as active pharmaceutical ingredients (APIs), excipients, or components in packaging and drug delivery devices, would be put in jeopardy.

The industry survey, conducted jointly by major associations of the European human pharmaceutical supply chain, reveals compelling evidence regarding the potential socio-economic impact of the proposed PFAS restriction. The survey finds:

- The companies participating in the survey identified **1922 active substances**, which will be impacted by the proposed restriction. At least 93% of APIs and/or medicinal products are produced in a manufacturing facility which depends upon PFAS use in piping, equipment (process/utilities), and consumables for process safety and regulatory reasons.
- Only 7% (139 out of 1922) of APIs contain the PFAS moiety, and therefore fall under the proposed derogation for APIs.
- 9.5 % (169 out of 1794) APIs were reported to be undergoing research and development (R&D) at an EU manufacturing facility, and would have to be produced at a non-EU facility.
- Only 86 APIs out of 1922 (4.4%) are manufactured completely outside of the EU showing the importance of pharmaceutical manufacturing in the EU.
- The share of critical medicines impacted if EU manufacturing operations are ceased, results in 61% - 78% when comparing with EU Member State critical medicines lists.
- 674 references are on the WHO essential medicines list.[1]

[1] https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02

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Recent EU developments highlight the urgency of safeguarding medicines manufacturing. This includes the numerous calls for action expressed by the European Parliament and the European Council for urgent measures to ensure sufficient production and availability of the most critical medicines and components and for a Critical Medicines Act[2]. The European Commission also emphasises the need for a resilient pharmaceutical sector in its Communication on the availability of medicines entitled 'Addressing medicine shortages in the EU'.[3]

The proposed PFAS ban contradicts the above-described EU efforts to bolster medicines manufacturing. It undermines the strategic autonomy that the European Commission aims to reinforce and poses a threat to the substantial investments made by Medicines for Europe members to establish new production sites within Europe. Adoption of the restriction proposal will jeopardise achievement of the objectives set in the Pharmaceutical Strategy for Europe intended to ensure a safe supply of medicines in Europe. These objectives include: (1) providing access to affordable medicinal products to patients; (2) supporting the pharmaceutical industry's competitiveness, innovation and sustainability in the EU, as well as the development of high-quality, safe, effective and more environmentally friendly medicines; (3) managing drug shortages, improving preparations for and responding to crisis, as well as improving diversified and safe supply chains; (4) ensuring that the EU has a high impact on the global pharmaceutical industry by promoting high-level quality, effectiveness and safety regulations.

While acknowledging and sharing concerns about the environmental impact of PFAS, Medicines for Europe urges decision-makers to consider the potential ramifications of an all-encompassing ban on medicines manufacturing. To safeguard availability of medicines, we advocate for a measured and balanced approach to PFAS that prioritises patient access and aligns with the realities of the pharmaceutical sector. Achieving a balance between environmental preservation, patient well-being, and the sustainability of the pharmaceutical industry is paramount. To ensure the continued manufacturing of life-saving therapies, **medicines should generally be derogated from a universal PFAS restriction, including all steps and equipment necessary for their manufacturing, packaging, and delivery devices in the EEA.**

[2] 25 October SANT held a hearing on Tackling access to and security of supply of critical medicines at https://www.europarl.europa.eu/committees/en/sant-hearing-on-tackling-access-to-and-s/product-details/20231025CHE12342

[3] Communication from the EC: Addressing medicine shortages in the EU. Available at https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf