European Federation of Allergy and Airways Diseases Patients' Associations

25 September 2023

EFA's response to European Chemicals Agency Annex XV restriction report on Per- and polyfluoroalkyl substances (PFAS)

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the voice of over 200 million people living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 45 national associations from 26 countries and channel their knowledge and patients' needs to the European institutions. EFA is accredited stakeholder to the European Chemicals Agency (ECHA) since 2017.

EFA appreciates ECHA's ongoing evaluation of a proposal from several Member States on wide-ranging restrictions on the manufacture and use of PFAS (per- and polyfluoroalkyl substances) in the EU. The proposal aims to address risks to the environment and public health posed by PFAS-containing applications and products. The scope of the proposal looks at restricting a category of PFAS, hydrofluorocarbons (HFCs), which are used in chronic respiratory disease reliever medication.

Asthma and COPD inhaled medication and PFAS

Asthma affects 30 million children and adults under 45 years of age in Europe and it is estimated that COPD affects 10% of the population in Europe.[1]

Inhaled medicines are the most used medicines in respiratory care in Europe and worldwide. In 2021, metered dosed inhalers (MDIs) accounted for 76% of all inhalers used in Europe, and 78% of those used globally.[2] Most MDI medicines available today contain PFAS and fall within the scope of the restriction proposal by ECHA.

Authorised by the European Medicines Agency (EMA), these MDIs are lifesaving medications where the PFAS-HFCs acts as a propellant to push and drive the medicine into the airways, effortlessly for the patient. These inhalers are considered worldwide critical medicines to treat the obstruction of the airways.

The International Pharmaceutical Aerosol Consortium (IPAC) reports that there are only two HFCs currently approved by EMA.[3] To reduce the carbon footprint of these propellants, there are two new gases under development for inhaled medical use. However, one of these upcoming solutions falls under the scope of the current proposal for restriction of PFAS, leaving only one future HFC option as valid to transition the current PFAS based MDI portfolio.

---

[1] Soriano JB, Kendrick PJ, Paulson KR, et al. Prevalence and attributable health burden of chronic respiratory diseases,
1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet Respir. Med. 2020;8(6):585-96

[2] Bell J, et al. An Assessment of Pressurized Metered-dose Inhaler Use In Countries In Europe And the Rest of the World. Poster Presentation at American Thoracic Society (ATS) international congress, 2023 19-24 May

[3] IPAC, Supplemental Joint IPAC/IPAC-RS Comments on "PFAS REACH Annex XV Restriction (Public Consultation)", September 2023:
https://www.ipacinhaler.org/_files/ugd/056ab5_0f1f642c546a4fbb8ad8e19add395e17.docx?dn=IPAC%20IPAC-RS%20ECHA%20REACH%20Feedback%20FINAL%20Submission%2020%20September%202023.docx

35 Rue du Congrès • 1000 Brussels • Belgium
Tel.: +32 (0)2 227 2712 • Fax: +32 (0)2 218 3141 • E-mail: info@efanet.org
Transparency Register Identification Number: 28473847513-94

#ShowLeadership

As the industry works to consolidate the effective use of the two alternatives, regulators have started to discuss the data needed to submit for them approval. The EMA has recently launched a consultation on the data requirements to approve HFC as excipients.[4]

Given the uncertainties on the readiness of the products, and the scarce options, EFA recommends ECHA to consider avoiding any situation in which there would not be an alternative HFC for medical use. Having only one HFC option for inhaled medical use; would theoretically lead to higher raw material dependence, supply chain fragility and therefore, more vulnerability to shortages and underserved patients. Any restriction to PFAS for medical use should balance vulnerable people's needs and pollution reduction, while avoiding that a basic excipient becomes a global monopolised commodity.

Health and social impacts of the PFAS restriction

The HFCs under the ECHAs restriction proposal are also under scrutiny by the EU co-legislators reviewing since 2020 the F-Gases Regulation 517/2014. As in those discussions, it is alarming to see the limited scientific evidence available on the (unintended) consequences the transitioning of medication could have on people, especially the respiratory patients concerned.

While EFA works unstintingly to advocate for healthier environments and the reduction of harmful exposure to environmental pollution impacting allergy and respiratory health, we invite EU regulatory agencies like ECHA to give due consideration to the potential unintended consequences these policies might have on human health, patients' symptoms and lives. In particular:

- **Economic transition for patients:** innovation towards less polluting medicines requires investment in research and development, medicine authorisation procedures, and market placement. This investment should not become a cost and burden to be carried by patients.
- **Clinical transition for patients:** any restrictions and legislation affecting basic medication and treatment options would need to be thoroughly discussed with the respiratory disease community, especially medical societies and patient groups. Moreover, any major change in medication like the one proposed by this draft restriction entails sensitive health decisions that can have unintended consequences for patients (i.e. from individual stockpiling to respiratory exacerbations, even death). Finally, asthma and COPD inhalers cannot and should not be changed overnight, even less so when they are administered through a device that requires patient education and adequate inhalation technique to be used.
- **Global transition for patients across borders:** Asthma and COPD are global diseases with an enormous burden in developing countries. According to the Global Initiative for Asthma (GINA), too rapid implementation of these restrictions would adversely affect the lives of many people worldwide – especially in low- to middle-income countries, which account for 96% of asthma deaths–.[5] EFA is concerned about the impact the ECHA restriction proposal

[4] EMA, Questions and answers on data requirements when replacing hydrofluorocarbons as propellants in oral pressurised metered dose inhalers", March 2023: https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-data-requirements-when-replacing-hydrofluorocarbons-propellants-oral-pressurised_en.pdf

[5] Levy M. et al. Global access and patient safety in the transition to environmentally friendly respiratory inhalers: the Global Initiative for Asthma perspective, The Lancet Volume 402, 1012-1016, September 16, 2023: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01358-2/fulltext

can have on access to healthcare and basic treatments in third countries, especially among the poorest populations.

- **Information transition for patients:** people with asthma and COPD have the right to be informed about issues affecting their medication. This right includes information about the composition of their medicine, the environmental footprint of their treatment and its presentation, as well as how to dispose of it. Informative campaigns addressing their questions will be necessary to ensure a successful transition for all.

PFAS restriction: Opportunity for better lung health

As patient representatives, EFA is a strong supporter of a health-in-all-policies approach. This perspective entails that changes in this medication could also be achieved through positive, rather than restrictive, EU action. Healthcare professionals are also urging to focus on "optimal treatment" when considering policies affecting people and the planet.[6]

It is well documented[7] how there is currently an overuse of rescue medication among chronic respiratory patients, as well as specific challenges such as lack of adherence and health literacy, patients treating only symptoms, no support to patients' self-management, lack of alternatives available for certain vulnerable groups, or even reimbursement considerations.

This ECHA restriction proposal is therefore an opportunity to look at the bigger picture around inhaler use in Europe, and further address the health needs, way beyond the environmental needs, to reduce PFAS-based MDI use in Europe, by analysing issues such as:

- the application of clinical guidelines for asthma and COPD at international, European, and national levels;
- patients' rights, needs and treatment choices: patients are part of the solution to reduce pollution from medicines, not the problem;
- personalised medicine and alternative medicine development and affordability.

All the above-mentioned aspects are necessary to scale down the use of PFAS-based MDIs to the strictly necessary circumstances.

EFA requests transparency and information on scenarios for patients who use these medicines presently. We offer our network of patient advocates to involve and inform patients, and wholeheartedly support healthy climate targets for lung health.

[6] GINA, Global Initiative for Asthma (GINA) urges authorities and clinicians to consider safety for patients as well as safety for the planet, Press Release, 19 July 2023: https://ginasthma.org/global-initiative-for-asthma-gina-urges-authorities-and-clinicians-to-consider-safety-for-patients-as-well-as-safety-for-the-planet/

[7] Asthma patients reported that their asthma is most commonly treated with inhaled corticosteroids (72%) and use emergency relief (62%) medication. These results confirm the persistent reliance and overuse of emergency relief (in part pMDI). Worryingly, patients are treating asthma symptoms instead of inflammation and end up to the emergency room at least once a year. Active Patients Access Care report, 2019 European Federation of Allergies and Airways Diseases Patients' Associations (EFA): https://www.efanet.org/images/ShowLeadership/Report-Showleadership_FINAL.pdf