European Federation of Allergy and Airways Diseases Patients' Associations

European Federation of Allergy and Airways Disease Patients' Associations (EFA)

Position Paper European Chemical Agency Committee (ECHA) for Socio-economic Analysis (SEAC) draft opinion on PFAS restrictions

The Case of Inhalers for the Treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD)

June 2026

Introduction

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 38 national associations from 24 countries and channel their knowledge and patients' needs to the European institutions. Our vision is a Europe where all the over 200 million patients with allergies, asthma and COPD in Europe have the right to best quality of care, are involved in decisions on their health and have the right to safe environment. EFA is accredited stakeholder to the European Chemicals Agency (ECHA) since 2017.

EFA has drafted this position paper which presents the use of substances classified in the EU restrictions proposal as Per- and polyfluoroalkyl substances (PFAS) and are used in asthma and COPD inhalers as the next generation propellant following the EU Fluorinated Gases restrictions proposed in 2022 and implemented in 2024[1]. EFA embraces, and advocates for proposals for prevention and healthy environment for the patients we represent, and the European population. However, this position paper explores the impacts of the generalised PFAS restrictions on respiratory patients and provides key recommendations for ECHA and the European Commission for the revision the REACH proposal.

The recommendations are based on the input from EFA's member community of patients. These give the real-life patient impact of the restrictions proposed.

This position paper is addressed to the ECHA, who will take into consideration the stakeholder responses to draft the final SEAC opinion. It is also addressed to the European Commission and Member States who will decide whether and how to adopt the restriction, and its' scope. If adopted, the restrictions could start applying from around 2028 – 2029, with transition periods.

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.[2]

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

[1] https://climate.ec.europa.eu/eu-action/fluorinated-greenhouse-gases/f-gas-legislation_en

[2] 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

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78% of those used globally. [3] Regarding pressurised meter-dosed inhalers (pMDI), approximately 75% of devices manufactured in the EU are exported to the rest of the world[4]. Restrictions on the manufacture and use of pMDIs risk causing supply shortages and necessitating forced treatment switches, which are associated with variable clinical outcomes and can undermine the physician–patient relationship[5]. Environmental legislation affecting pMDIs must therefore take into account the broader socioeconomic consequences arising from reduced access to these essential medicines.

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

There are three HFCs currently approved by EMA (HFA-134a, HFA-227ea, HFA-152a)[6]). HFA-134a and HFA-227ea will be phased out under the EU F-Gas Regulation. HFA-152a and HFO-1234ze are next-generation propellants developed to reduce the carbon footprint of pMDIs. However, HFA-152a may also come in scope of the F-Gas Regulation's phase-down, and HFO-1234ze, 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 MDIs.

MDI devices available today contain materials that are categorised as PFAS, such as propellant gases and canister coating, and fall within the scope of SEAC's support for an EU-wide restriction subject to derogations. EFA acknowledges the different persistence in the environment across the types on PFAS. There are differences in PFAS' resistances of natural degradation (in water, soil, air) and the persistence generally increases with longer carbon chain lengths. These differences must be looked at when considering the levels of restrictions. Certain propellant gases used for inhalers have not been classified as PFAS in other world regions because of the non-persistence in the environment.

Given the uncertainties on the readiness of the products, and the scarce options, and that propellants are not interchangeable, and not all medicines can be reformulated with any propellant EFA recommends ECHA to consider avoiding any situation in which there would not be an alternative propellant for medical use, as medicines may need to be taken off the market. Having only one propellant 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.

EFA's recommendations

1. **Consider health in the SEAC assessment**

[3] 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
[4] https://www.ipcrg.org/24041#:~:text=The%20highest%20pMDI%20use%20was%20observed%20in,(84%25)%2C%20the%20Middle%20East%20(74%25)%2C%20Europe%20(71%25)%2C
[5] https://www.ipcrg.org/24041
[6] https://www.celegence.com/eu-fluorinated-greenhouse-gases-regulation-guidance-for-pharma-manufacturers/

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EFA notes our concern with the lack of health emphasis in SEAC's assessment, and that Pressurised Metered Dose Inhaler (pMDIs) and their associated components (such as HFC propellants) are categorised under "Other medical applications". SEAC could not entirely assess such PFAS uses in time and therefore could not assess if proposed time limited derogations were justified for this sector. Without this evidence, the risks of restrictions for patients with asthma and COPD is high. Our patient community is ready to collaborate for this evidence on impact. We further recommend involving the European Medicines Agency for this evidence.

2. **Consider the legal basis for REACH and ECHA**

We believe that the SEAC opinion has not been made within the spirit of the legal basis for both REACH and ECHA. The fact that no assessment has been made balancing the health benefits of PFAS use in medical products, and environmental health, only the relative health risks associated with such use, runs counter to the legal basis of REACH and indeed of the legal basis for ECHA itself. Both ECHA and REACH are based on the need for a high degree of protection of human health, yet no assessment has been undertaken for the health benefits of PFAS use within medical products in general and MDIs in particular, when millions in the EU depend on MDIs to manage their condition and protect their health. Instead, blanket assertions have been made to justify a ban with only a time limited derogation for medical products, explicitly without any assessment of the scale of health benefits of substance, classified by ECHA as PFAS use in medical products, despite acknowledgement of these benefits.

3. **Support the economic transition for patients**

Innovation towards less polluting medicines requires research and development, medicine authorisation procedures, and market placement. This investment should not become a cost and burden to be carried by patients. Patients should still have access, even if more expensive devices like inhalers replace cheaper inhalers.

4. **Assist the clinical transition for patients**

Any restrictions and legislation affecting basic and essential 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). 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.

While there is a 6-year derogation period foreseen for MDIs in SEAC's draft opinion, followed by a ban, we can only assume that this is based on an assumption that this is a sufficient period to find alternative gases, given that no impact assessment was carried out.

5. **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

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middle-income countries, which account for 96% of asthma deaths.[5] EFA is concerned about the impact the ECHA blanket restriction proposal can have on access to healthcare and basic treatments in third countries, especially among the poorest populations. Linking with the WHO essential medicines should also be considered.

6. **Include 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 or medical device, 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, and patients' contribution to healthy environment.

Conclusion

In exercising its responsibilities under Article 76(1)(d) of the REACH Regulation, SEAC is required to assess whether a restriction is appropriate in light of its socio-economic impacts, including effects on human health and the functioning of healthcare systems. Within this framework, the specific needs of respiratory patients warrant explicit consideration, as this population may be disproportionately affected by measures that alter the availability, performance, or safety of substances used in medicinal products or medical devices. Failure to adequately factor in patient-level impacts, such as continuity of treatment, feasibility of substitutes, and risks associated with changes in clinical practice could give rise to unintended adverse health outcomes. Therefore, in the context of the ongoing consultation closing on 25 May, SEAC should ensure that its opinions are informed by robust evidence on respiratory patient needs, in order to fulfil the objectives of REACH while ensuring a proportionate, balanced, and health-protective outcome consistent with Union public health principles.

This position paper is drafted with the support of EFA's members associations representing patients with allergies, asthma and COPD in Europe. We remain engaged open for engagement with the Commission and the European Chemical Agency to help inform this regulation for the right balance for environmental and patient health.

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