European Federation of Allergy and Airways Diseases Patients' Associations

29 June 2022

EFA's response to the Review of EU rules on fluorinated greenhouse gases consultation (Directorate General for Climate Action)

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. We connect European stakeholders to ignite change and bridge the policy gaps on allergy and airways diseases so that patients live uncompromised lives, have the right and access to the best quality care, and a safe environment.

EFA welcomes the determination of the European Commission (EC) to reduce greenhouse emissions generated in the European Union. Climate change negatively affects human health, and more especially the health of vulnerable people such as allergy, asthma and COPD patients. We want to live in a region that #ShowLeadership against the climate emergency.

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

The proposal plans to eliminate the F-Gases exemption for medical use (in asthma and COPD medication) to fully align the EU to international climate law.

By eliminating the exemption inhalers will enter the EU F-Gases quota system (art 16.2) with a set volume of gas available, driving a progressive reduction of F-Gases in medicine, and therefore less greenhouse gases from asthma and COPD medication.

The caveat to this plan is that the operational side of EU adaptation to climate change is overlooked. Through this response to the consultation, we voice in lay language the adaptation and implementation uncertainties on access to care that raise within our European patient community.

Asthma and COPD inhalers and F-Gases

Metered-Dose-Inhalers (pMDIs) are medicines used to treat asthma and COPD all over the world. Given their dual nature of active compounds and medical devices, they can be considered as irreplaceable medical technologies. At EU level, they are classified as drug-device combinations, but are authorised as medicinal products by the European Medicines Agency (EMA).

Based on data from the EMA, currently, there are six medicines with a pressurised inhalation device evaluated and authorised through the centralised procedure in the EU. These are Bevespi Aeorosphere, Riltrava Aerosphere, Trixeo Aerosphere, Riarify, Trimbow and Trydonis. This list is not exhaustive as there might be other inhalers for asthma and COPD authorised at national level by Member States.

Medicines' transition, readiness and preparedness

F-Gases in inhalers are excipients that act as propellants, they serve to drive the medicine into the lungs. The change of excipients in medicines can be done by submitting a variation request to the regulatory authority. The procedure depends on the changes proposed by the applicant pharmaceutical company. While the inhalers discussed contain already authorised active

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ingredients, the transition towards greener propellants could entail from just replacing the gas (the excipient) to an important change in a component of the device. The latter situation would require more evidence and steps to properly assess the safety and efficacy of the drug.

The EC proposal for the F-Gases regulation foresees a sharp curve down of around half per cent of the F-Gases volume used on MDIs in Europe. The EC opts for an optimistic scenario in which many inhalers would presumably be transitioned and available by 2027, with no impact for the patient (Impact Assessment page 192). Yet, our community of asthma and COPD patients notes that inhalers are complex drug-device combinations and both the development and the regulatory requirements in case of significant changes might delay authorisation and market access for the sake of safety.

In case the technologies are not available in due time, the EC proposal includes the possibility to authorise exemptions (Regulation Article 16.4). However, the proposal does not detail precise criteria to activate an exemption. EFA therefore recommends the EC to monitor from 2022 the EU and national authorisation procedures and real market access to ensure there are no medication gaps and shortages for patients at any time.

Moreover, in view of the limited scientific evidence on the consequences of shifting asthma and COPD F-Gases based inhaled medication on patients, EFA requests the EC to conduct research to inform this hypothesis of no impact. With new inhalers foreseen to be ready by 2027 by the EC, medications for chronic respiratory disease cannot be changed overnight, even less so when they are administered through a device that requires patient education and adequate inhalation technique to be used.

Finally, rescue inhalers (including the current portfolio of F-Gas containing MDIs) are foreseen to be considered as critical medicines within the EMA Main Therapeutic Group (MTG) (EMA, Regulation 2022/123, art. 6), and therefore subject to EU and Member State stockpiling for preparedness and response against health crisis under the Health and Emergency Response Authority (HERA, Communication 2021/576, task 4). As treatment and preparedness might compete over F-Gas containing inhalers from 2027, we encourage the EC to collaborate with EMA and HERA to ensure both treatment and preparedness needs are fulfilled during the F-Gas transition period.

Health and social impacts of the legislation

As a patient organisation, EFA seeks and values co-design, co-decision on policies affecting patients' health, as well as transparency on the information and evidence used to inform policy decisions. In that spirit, we note some assumptions within the EC impact assessments that do not refer to publicly available information, despite having clear implications for patients.

- **F-Gas MDIs use:** the Impact Assessment has found an HFC increase of 45% in pMDIs between 2015-2020 (page 139), yet the figure remains unexplained.
    - As patient representatives, we request more information to understand the underlying reasons for such a steep increase (i.e. prevalence, treatment needs, commercial purposes) to fully inform the EC proposal and ensure a successful transition.
- **Direct costs**: the Impact Assessment estimates a very low cost for the newer, greener inhalers, which is based solely on the cost of the gas (page 91). On the one hand and while theoretically feasible, such estimation has not been proved, as the transition of the inhalers

could go beyond replacing the propellant and affect the whole drug-device combination, presumably impacting the final cost of the medicine. On the other hand, F-Gas inhalers will coexist with greener ones at a lower volume, and concur into the quota system. At EFA, we are concerned that soon our basic, life-saving medicine, will be indirectly left to the discretion of gas suppliers, who are free to practice their own pricing strategies.
    - EFA recommends scoping different cost scenarios for patients access to their basic asthma and COPD both inside and outside the EU and to do it for the future greener inhalers as well as for the F-Gas containing inhalers that will be subject to the quota system.
- **Indirect costs**: MDIs are rescue medications used among vulnerable patients such as advanced stage COPD patients and children with asthma. Changes in these medications are sensitive health decisions that can have unintended consequences for patients.
    - In view of a mass patient transition to greener inhalers in the medium term, EFA would require basic information on the evolution of asthma and COPD hospitalisations and deaths to measure the impact of this policy revisions from 2022.
    - EFA encourages the EU and national healthcare systems to document and generate evidence around climate friendlier asthma and COPD treatment plans to prepare healthcare professionals and allowed patients' informed choices, to structure the transition from a healthcare system perspective and to invest in patient education.
- **Impact in third countries:** Asthma and COPD are global diseases with enormous burden in developing countries. We are concerned about the impact the EC proposal will have on health care and treatments in third countries, especially the poorest populations in terms of access to basic medication for asthma and COPD.
    - EFA recommends the EC to connect with the World Health Organisation and the Global Alliance on Respiratory Disease (GARD) to share the EU F-Gases decisions and inform their national care planning.

Patients' have the right to know about their medication

With the introduction of F-Gases for medical use into the quota system, EFA welcomes the mandatory labelling for F-Gases containing inhalers that will inform patients about the global warming potential of their medicines (art 12). Patients are part of the solution to reduce emissions from medicines. However, mandatory labelling will only come into force in 2027, leaving information gaps for patients who might wonder already now if their inhaler is concerned.

Safety and transparency on medicinal products for human use is the foundation for patient trust in medicines. Transitioning to non-F-Gas containing inhalers is a major change in basic medicines for asthma and COPD, EFA therefore recommends the EC to work with EMA and **issue a factsheet for patients and healthcare professionals** addressing the asthma and COPD inhaler portfolio that is subject to the F-Gases regulation and outlining the next steps. Such public information addressed to patients would help them not base their treatment on assumptions or media coverage, as that situation would only add to their disease burden.

Finally, EFA welcomes the creation of a Consultation Forum for providing advice and expertise in relation to the implementation of this Regulation (art. 33) and we would like to be part of it to inform and be informed about the roll out of the future new law.

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Opportunity for better lung health

The F-Gases Regulation proposal focuses only on climate change mitigation. Regulating F-gases use in inhalers that deliver life-saving medicines into a general quota system of companies producing appliances such as refrigerators or air conditioning devices does not seem appropriate to us. Moreover, as it stands, it does not refer to health issues, the adaptation needs and the general management of asthma and COPD.

As patient representatives, we are strong supporters of a health-in-all-policies approach. We find the greenhouse gas reduction focus short-sighted to the inhaler challenge, as emissions from medication could also be achieved through positive, rather than restrictive, EU action. It is well documented[1] how there is currently an overuse of rescue medication within chronic respiratory patients, such as lack of adherence and health literacy, patients treating only symptoms, no support to patients' self-management, no alternative available for certain vulnerable groups, or even reimbursement considerations.

The EU Regulation on F-Gases is an opportunity to further address the health requirements to reduce MDI use in Europe, addressing issues such as:

- the application of clinical guidelines for asthma and COPD at international, European and national levels
- patients' rights, needs and treatment choices
- personalised medicine and alternative medicine development and affordability,

all the above are necessary aspects to scale-down the use of MDI to the strictly necessary circumstances.

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

[1] 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

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