

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 39 national associations from 24 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 European Commission's Green Deal and all sectoral legislative revisions that it entails, including those targeting climate change and air quality both indoors and outdoors. Allergy, asthma and COPD patients are directly impacted by climate change and air quality. The weather-related events and impact on biodiversity and plant life cycles are directly linked to worsening and onset of allergy and respiratory symptoms. Tragically, climate change events which affect air quality, such as heatwaves, have been recently documented as increasing mortality rates among the patients we represent. EFA has integrated [our recommendations](#) throughout the DG CLIMA consultation on a new EU strategy on climate change adaptation, calling for fully integrated health considerations, as well as patient care concerns, into all future EU climate actions.

We welcome the review of the F-Gases regulation as an opportunity to demonstrate to patients and the world, that despite asthma and COPD patients being victims of climate change, they are also key actors to reduce greenhouse gases (GHG). However, the access to the care they need cannot be compromised, as that would be against their health, and impact their social and fundamental rights.

Asthma and chronic obstructive pulmonary disease (COPD) in Europe

Asthma is a non-communicable chronic inflammatory disease that causes inflammation of the smaller airways deep in the lungs (bronchioles) that narrows the airways. It often starts in childhood and affects one in five school children (20%) in Europe¹. Today, there are 30 million children and adults under 45 years of age who live with asthma in Europe. However, asthma affects people of all ages. Approximately 10% of adults with asthma suffer from a severe form of the disease and life-threatening symptoms².

Chronic obstructive pulmonary disease (COPD) is an umbrella term that describes chronic limitations in the lung airflow. It is a progressive and irreversible disease that causes inflammation in the lungs, damages lung tissue permanently, and narrows the airways - making breathing progressively worse. COPD mainly affects people over the age of 40. It is estimated that 10% of the European population lives with COPD³.

¹ Childhood asthma, European lung white book, European Respiratory Society, 2013:

<https://www.erswhitebook.org/chapters/childhood-asthma/>

² Adult asthma, European lung white book, European Respiratory Society, 2013:

<https://www.erswhitebook.org/chapters/adult-asthma/>

³ Chronic obstructive pulmonary disease, European lung white book, European Respiratory Society, 2013:

<https://www.erswhitebook.org/chapters/chronic-obstructive-pulmonary-disease/>

F-Gases are used in asthma and COPD medication

F-Gases are greenhouse gases with a relatively high Global Warming Potential (GWP) and can remain in the atmosphere for many years. Hydrofluorocarbons (HFCs) are a type of F-gases found mostly in the refrigeration and air-conditioning sectors. A small proportion of the total is used in the pharmaceutical sector for human use.

Pressurised metered dose inhalers (pMDI) contain a hydrofluoroalkane (HFA) molecule that acts as a propellant to quickly release the liquid medication into the lungs effortlessly. pMDI are mainly used in asthma and COPD relievers as a life-saving medication to avoid or stop asthma attacks and COPD exacerbations, or as an additional rescue medication in case of an attack for any stage of asthma.

MDIs are fully integrated into the current asthma and COPD management guidelines^{4,5}. In practice, they are mostly recommended to patients who, due to their young age (children), old age (older people) or their disease severity (severe stage of pulmonary obstruction), encounter difficulties breathing in deeply from dry-powder inhalers, which are F-Gases free⁶.

To our knowledge, there is not a clear EU estimation of the number of patients who follow an asthma or COPD treatment with F-Gases based inhalers in Europe. There are several comparative studies on the prescription of pMDI and dry-powder inhalers that show gigantic differences. For example, in England in 2017, 70% of all inhalers sold were MDI, whereas the corresponding figure for Sweden was 13%.⁷ This may be due to national practices in prescribing rescue medication, coupled with maintenance therapy choices, price and access.

A new issue regarding inhalers that contain F-Gases during the COVID-19 pandemic is that clinicians are proposing patients changes in their inhaler treatment to substitute aerosol because of the higher risk of COVID-19 contamination when the asthma or COPD medicine is nebulised⁸.

People with asthma and COPD report difficulties controlling their disease

Despite being major chronic diseases affecting millions of people in Europe, not only there is no cure for adult asthma and COPD, but also scarce knowledge around the underlying mechanisms developing the disease that could help prevention and curative treatments.

Unfortunately, the limited understanding of asthma means that for decades it has been conceived and treated as one disease. However, ground-breaking biomarker research has opened a path towards further classification of asthma, and therefore a more personalised approach to

⁴ Pocket guide for asthma management and prevention, Global Initiative for Asthma, 2020:

https://ginasthma.org/wp-content/uploads/2020/04/Main-pocket-guide_2020_04_03-final-wms.pdf

⁵ Pocket guide for COPD diagnosis, management and prevention, Global Initiative for Chronic Obstructive Pulmonary Disease, 2019: <https://goldcopd.org/wp-content/uploads/2018/11/GOLD-2019-POCKET-GUIDE-DRAFT-v1.7-14Nov2018-WMS.pdf>

⁶ Choosing an appropriate inhaler device for the treatment of adults with asthma or COPD, Usmani, Capstick, Saleem, Scullion, 2020: <https://www.guidelines.co.uk/respiratory/inhaler-choice-guideline/455503.article>

⁷ <https://thorax.bmj.com/content/75/1/82>

⁸ Acute asthma management during SARS-CoV2-pandemic 2020, World Allergy Organisation Journal, May 2020: <https://pubmed.ncbi.nlm.nih.gov/32411315/>

treatment^{9,10}. We hope future scientific developments around the disease will contribute to prevent it and treat it better, with new F-Gases-free therapies to help those whose asthma is uncontrolled today.

As patients' representatives, EFA is concerned about the potential outcomes of asthma and COPD care in Europe, if human health and care is not part of the evaluation on F-gases. If inhalers containing F-gases are banned, or the medical exemption is not prolonged, will patients have access to the right medicine for them, and at an affordable price? Will they be explained and monitored on their inhaler technique performance in case of change? Would they be able to afford purchasing new medication? How would this unintentionally affect patients in third countries such as in the developing world?

In our evidence based survey on asthma and COPD care, asthma patients reported that their asthma is most commonly treated with inhaled corticosteroids (72%) and use emergency relief (62%) medication¹¹. 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 year¹².

Hospitalisations occur even more often among COPD patients. Despite treatment and frequent follow-up consultations, one in three COPD patients are admitted to the emergency room every year. This situation dramatically increases with severity: over half of patients with severe COPD rely on emergency services at least once a year¹³.

It is disconcerting that one in three asthma and COPD patients do not feel involved in decisions regarding their treatment. Less than half have a written management plan and, even worse, many patients with COPD (33%) and asthma (20%) indicate that they have "never heard about" written management plans. Many patients do not know they have a role in their treatment and the potential benefits to their Quality of Life, as well as the environmental impact of their treatments¹⁴.

Tackling climate change and air quality indoors and outdoors is crucial to reduce worsening symptoms and mortality of allergy and airways diseases. There is, however, a pressing need to tackle asthma and COPD care in Europe. This requires an urgent investment in health literacy and the development of self-management plans that fully involve patients.

Treatment choices can and should be improved to meet environmental requirements. They should still be achieved while taking on board health management considerations such as the healthcare

⁹ The quest for the grail: multidimensional efforts for understanding and targeting severe asthma, Mina Gaga, Paul L.P. Brand, Neil C. Thomson, European Respiratory Journal 2015 46: 1227-1231:

<https://erj.ersjournals.com/content/46/5/1227>

¹⁰ U-BIOPRED (Unbiased BIOMarkers in PREDiction of respiratory disease outcomes), EU funded project:

<https://www.europeanlung.org/en/projects-and-research/projects/u-biopred/publications/>

¹¹ 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

¹² *Idem.*

¹³ *Idem.*

¹⁴ *Idem.*

professional's knowledge, the patient's inhalation capacity, the disease severity, the patient's ability to use their device correctly, and the patient's personal preferences¹⁵.

F-Gases and health: need for an specific EU impact assessment

As patients representatives EFA fears that phasing down pMDI could negatively impact the health and wellbeing of asthma and COPD patients. We therefore encourage the European Commission to:

- **Fully integrate the human and patient health aspects in all the EU and national strategies**, including impact and policy scenario assessments, and policies and actions to phase down F-Gases, especially those used as propellants in asthma and COPD treatments, so that there are no unintended negative impacts on health;
- Work with patient organisations representing the people affected, and with primary and secondary healthcare professionals and producers to understand the health needs of patients with asthma and COPD. To ensure this while considering a **realistic timeframe to implement technological change. This way all facts can be known in order to take any decision regarding medical exemption during this change**;
- Conduct quantitative and qualitative **research on the impact on patients** when changing treatment, including economic aspects such as accessibility. To also consider adherence to treatment and the psychological aspects, including fear due to change; and the treatment changes during the pandemic;
- Promote and stimulate the **development of green smart inhalers** that are recyclable;
- Inform **citizens and patients** how they can contribute to a healthy environment without compromising on their care and treatment; Patient and healthcare professional organisations are partners to reduce the environmental impact of our medications through health literacy, inhaler techniques and simple information;
- Encourage health authorities and healthcare professionals to invest in the implementation of asthma and COPD disease management guidelines, such as GINA and ERS-ATS to ensure that every patient has a **self-management plan**, to support them in becoming in control of their symptoms and therefore reduce their need for relief medication;
- Connect with the World Health Organisation to estimate how potential changes in the EU F-Gases Regulation might **impact health care and treatments in third countries**, especially the poorest populations in terms of access to basic medication for asthma and COPD.

Submitted by EFA with the support of EFA COPD- and Allergy & Asthma Working Groups of Members.



The Global Allergy & Airways Patient Platform (GAAPP) represents more than fifty patient organisations in respiratory health, including EFA, and fully supports EFA's position relative to F-Gas policy.

¹⁵ British guidelines on the management of asthma, British Thoracic Society/Scottish Intercollegiate Guidelines Network, 2019: <https://www.brit-thoracic.org.uk/standards-of-care/guidelines/btssign-british-guideline-on-the-management-of-asthma/>