European Federation of Allergy and Airways Diseases Patients' Associations

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EFA Statement on the Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) welcomes the ambition of the European Commission (EC) to reduce greenhouse emissions generated in the European Union. Climate change negatively affects human health, and more specifically the health of vulnerable people such as patients living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) that EFA represents.

While its main objective is to contribute to climate change mitigation, the proposal for the F-Gases Regulation foresees a sharp curve down of around half per cent of the F-Gases volume used on metered dose inhalers (MDIs) in Europe. The proposal is based on an optimistic scenario in which many inhalers would presumably be transitioned and available by 2027, with no impact for the patient. However, inhalers are complex drug-device combinations, and their development and regulatory requirements might delay authorisation and therefore readiness to be used by patients. It is imperative that such potential delays are identified at the earliest stage, so that necessary action is taken in a timely manner.

To ensure that patients' needs and safety are addressed throughout the entire process of transitioning to new technologies and MDIs, and that potential shortages of medicines are foreseen, EFA has provided feedback at all stages of the consultation process[1,2,3] of the European Commission on the revision of the F-Gases framework, and proposes patient-centred amendments[4] to the proposal with the following recommendations:

1. **Couple climate change mitigation policies with programmes to educate healthcare professionals and patients on the use of MDIs**

Most asthma and COPD patients do not know their basic medication has global warming potential, as they have not been presented either with a self-management plan to cope with their disease in an optimal way. While the F-Gases proposal includes now the obligation to label the carbon footprint of MDIs, such requirement falls short on patient literacy about their medicines. Drug-device combinations such as MDIs are complex medicinal products that require patient education and adequate inhalation technique to be used. They are life-saving medicines for asthma and COPD that should not be changed massively overnight. Instead, we call on the EU to include premises for Member States to couple the implementation of the F-Gases Regulation with climate and healthcare education programmes aimed at improving patients' literacy on their disease, treatment, and self-management. We also request such a process is inclusive, so that healthcare professionals and patients adopt a consensual approach towards the changes on clinical guidelines the F-Gases regulation might bring to the EU

[1] EFA response to the European Commission's Roadmap to Review of EU rules on fluorinated greenhouse gases consultation (September 2020), available at https://www.efanet.org/images/2020/EFA_response_to_EC_consultation_on_F-Gases.pdf.

[2] EFA response to the European Commission's Evaluation and Impact Assessment of the F-Gas Regulation (December 2020), available at https://www.efanet.org/images/2021/EFA_Response_F-Gases_questionnaire_Contribution7577042d-0faf-47c2-8ac2-964cc7d4ea5c.pdf.

[3] EFA response to the European Commission's Proposal for a Regulation on Fluorinated Greenhouse Gases (July 2022), available at https://www.efanet.org/images/2022/EFA_response_to_EC_consultation_on_F-Gases.pdf.

[4] EFA Amendments to the EU F-Gases Regulation Proposal (November 2022), available at https://efanet.org/images/2022/Amendments_to_EU_F-Gases_Regulation_proposal_2022.pdf.

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respiratory practice. Patients can be agents of change and reduce their carbon footprint, but first they need to be informed and empowered to act on it. *[EFA proposed Amendments 2 & 3]*

2. **Strictly monitor the status of the transition towards low GHG technologies through a yearly report of the European Commission**

To address the possible shortages and medication gaps that might arise in the process of transitioning to new low GHG technologies, and to firmly respond to unintended effects on health, especially on patients with and MDI treatment, the European Commission, with input from the Consultation Forum, should produce an annual report on the readiness of the MDIs producers, of healthcare professionals and of MDIs users. It is vital that such a report acts as a basis for the adopted delegated acts envisioned in the framework of this Regulation. *[EFA proposed Amendment 8]*

3. **Strengthen the role of the foreseen Consultation Forum in addressing potential unintended effects on health**

With the quota system in place, it is imperative that unintended risks to public health are identified in a timely manner, as patients needing an MDI treatment should not be suddenly changed or left without their life-saving medicine as a consequence of the quota system. To anticipate the effects of a proposed exemption from the quota system, the Consultation Forum should ensure the participation of public health organisation, and the Commission should inform and make use of the expertise of the Consultation Forum to inform the decision and the duration leading of a delegated act. *[EFA proposed Amendments 4, 5, 6, 7 & 8]*

4. **Ensure cooperation between European Commission, Member States and competent authorities, the European Medicines Agency (EMA) and the Health Emergency Preparedness and Response Authority (HERA) on the availability of treatment for the airways**

MDIs undergo rigorous regulatory assessments including clinical studies to ensure patient safety and are life-saving critical medicines subject to stockpiling in the event of cross-border health threats, and thus subject to HERA's response against a health crisis. As treatment and preparedness might compete over F-Gases containing inhalers from 2027, the Commission should establish a smooth collaboration with Member States, EMA, and HERA, to ensure both MDI treatment and preparedness needs are fulfilled during the F-Gas transition period. *[EFA proposed Amendment 1]*