European Federation of Allergy and Airways Diseases Patients' Associations

EFA proposed amendments to 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

Preamble (new) – EFA proposed Amendment 1

European Commission's proposal	EFA proposal
N/A	**MDIs are medicinal products subject to rigorous assessments including highly regulated clinical studies to ensure patient safety. MDIs are life-saving critical medicines subject to massive stockpiling and use in the event of cross-border health threats affecting the respiratory tract. As key treatments for chronic respiratory disease, the transition of the MDIs to low-GWP technologies requires information exchange, cooperation and monitoring between the European Commission, Member States and competent authorities, the European Medicines Agency and the Health Emergency Preparedness and Response Authority, to avoid shortages and ensure sustained patient access to life-saving medication.**

Justification: *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, the EC should collaborate with Member States, EMA and HERA to ensure both treatment and preparedness needs are fulfilled during the F-Gas transition period.*

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European Federation of Allergy and Airways Diseases Patients' Associations

Preamble (New) – EFA proposed Amendment 2

European Commission's proposal	EFA proposal
N/A	**The removal of the medical exemption for Metered-Dose-Inhalers (MDIs) from the quota system increases the obligation to transition to low-GWP solutions for medicinal products. The transition will entail deep changes in the management of asthma and chronic obstructive pulmonary disease (COPD) which are highly prevalent chronic diseases in Europe. While keeping the objective to reach climate neutrality by 2050, to ensure a smooth MDI transition the regulation implementation requires a health-in-all-policies approach. National healthcare systems should establish programmes to inform healthcare providers on the medicines available and educate patients on the treatments and inhalation techniques to treat their asthma and COPD.**

Justification: *Drug-device combinations such as MDIs are complex medicinal products that require patient education and adequate inhalation technique to be used. Life-saving medicines for chronic asthma and COPD patients cannot be changed massively overnight but rather be consensual in clinical guidelines and agreed between healthcare professionals and patients. Such a vast health management change needs to be supported by climate and healthcare education programmes aimed at improving patients' literacy on their disease, treatment and self-management.*

Preamble – Recital 11 – EFA proposed Amendment 3

European Commission's proposal	EFA proposal
11) To encourage the use of technologies with no impact or lower impact on the climate that may involve the use substances that are toxic, flammable or highly pressurized, the training of natural persons who carry out activities involving fluorinated greenhouse gases should cover technologies replacing or reducing the use of fluorinated greenhouse gases, including information on energy efficiency aspects and applicable regulations and technical standards. Certification and training programmes established under Regulation (EU) No 517/2014,	11) To encourage the use of technologies with no impact or lower impact on the climate that may involve the use substances that are toxic, flammable or highly pressurized, the training of natural persons who carry out activities involving fluorinated greenhouse gases should cover technologies replacing or reducing the use of fluorinated greenhouse gases, including information on energy efficiency aspects and applicable regulations and technical standards. Certification and training programmes established under Regulation (EU) No 517/2014,

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which may be integrated in national vocational training systems, should be reviewed or adapted enabling technicians to handle alternative technologies safely.	which may be integrated in national vocational training systems, should be reviewed or adapted enabling technicians to handle alternative technologies safely. **Healthcare professionals and patients relying on MDIs medicines shall be informed and educated on the use of existing and upcoming MDIs.**

Justification: *The adherence to treatment among to asthma and COPD patients, who are vulnerable groups heavily reliant on MDIs, is often poor, and patients declare not feeling involved in decisions around their therapy. This is largely due to limited patient education on how to treat their disease and lack or limited application of self-management plans. When transitioning to new technologies and MDIs, it is important that support is given to healthcare professionals and patients relying on MDIs, to not further deter and disconnect patients from the medicine they are reliant upon. It is crucial that patients are empowered and provided with opportunities to access patient education for a smooth transition to future MDIs, and a sound use of the current ones with global warming potential.*

Preamble – Recital 39 – EFA proposed Amendment 4

European Commission's proposal	**EFA proposal**
(39) In implementing this Regulation, the Commission should establish a so-called Consultation Forum to ensure a balanced participation of Member States' representatives and representatives of civil society, including environmental organisations, representatives of manufacturers, operators and certified persons.	(39) In implementing this Regulation, the Commission should establish a so-called Consultation Forum to ensure a balanced participation of Member States' representatives and representatives of civil society, including environmental organisations, **public health organisations,** representatives of manufacturers, operators and certified persons.

Justification: *As the health sector will be impacted by the regulation, healthcare providers and patients participate should be consulted so that the implementation of this Regulation does not come at the detriment of vulnerable groups highly reliant on the use of equipment and products manufactures with F-gases.*

Preamble – Recital 41 – EFA proposed Amendment 5

European Commission's proposal	**EFA proposal**
(41) In order to amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union ('TFEU') should be delegated to the Commission	(41) In order to amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union ('TFEU') should be delegated to the Commission

in respect of the establishment of a list of products and equipment for which the recovery of gases or their destruction is technically and economically feasible and the specification of the technologies to be applied; labelling requirements; the exclusion from quota requirements of HFCs in accordance with decisions of the Parties to the Protocol; concerning the amounts due for the allocation of quota and the mechanism to allocate remaining quotas; additional measures for the monitoring of substances and of products and equipment placed under temporary storage and customs procedures; the rules applicable to the release for free circulation of products and equipment imported from and exported to any entity not covered by the Protocol; the update of global warming potentials of listed substances. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making38. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	in respect of the establishment of a list of products and equipment for which the recovery of gases or their destruction is technically and economically feasible and the specification of the technologies to be applied; labelling requirements; the exclusion from quota requirements of HFCs in accordance with decisions of the Parties to the Protocol; concerning the amounts due for the allocation of quota and the mechanism to allocate remaining quotas; additional measures for the monitoring of substances and of products and equipment placed under temporary storage and customs procedures; the rules applicable to the release for free circulation of products and equipment imported from and exported to any entity not covered by the Protocol; the update of global warming potentials of listed substances. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, **in particular consultation with the Consultation Forum as set up according to Article 33 of this Regulation,** including at expert level and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making38. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Justification: *Given the setting up of a Consultation Forum within the scope of this Regulation for the purpose of providing advice and expertise, it is natural that when looking at adopting new delegated acts, the Commission takes into account also the advice of the Consultation Forum for the purpose of sound information and transparency.*

Article 16(4) – EFA proposed Amendment 6

European Commission's proposal	**EFA proposal**

4. Following a substantiated request by a competent authority of a Member State and taking into account the objectives of this Regulation, the Commission may, exceptionally by means of implementing acts, authorise an exemption for up to four years to exclude from the quota requirement laid down in paragraph 1 hydrofluorocarbons for use in specific applications, or specific categories of products or equipment, where it is demonstrated in the request that: (a) for those particular applications, products or equipment, alternatives are not available, or cannot be used for technical or safety reasons; and (b) a sufficient supply of hydrofluorocarbons cannot be ensured without entailing disproportionate costs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).	4. Following a substantiated request by a competent authority of a Member State, **or relevant Union bodies, offices, and agencies, or the Consultation Forum,** and taking into account the objectives of this Regulation, the Commission may, exceptionally by means of implementing acts, authorise an exemption for up to four years to exclude from the quota requirement laid down in paragraph 1 hydrofluorocarbons for use in specific applications, or specific categories of products or equipment, where it is demonstrated in the request that: (a) for those particular applications, products or equipment, alternatives are not available, or cannot be used for technical or safety reasons, **or risks public health**; and (b) a sufficient supply of hydrofluorocarbons cannot be ensured without entailing disproportionate costs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).

Justification: *Given the various sectors impacted by this Regulation, and the importance of specialised EU bodies and agencies, as well as the relevance of the Consultation Forum and its composition, it is essential other entities beyond competent authorities and Member States help in alerting on the unintended consequences of the application of the quota requirement. Moreover, considering the effects of the implementation of this Regulation on public health and the healthcare sector, and more specifically on the impact it for patients needing MDIs, the risks for public health should be specified as a premise for an exemption.*

Article 17 (6) - EFA proposed Amendment 7

European Commission's proposal	**EFA proposal**
6. The Commission is empowered to adopt delegated acts in accordance with Article 32 to amend paragraph 5 as regards the amounts due for the allocation of quota and the mechanism to allocate remaining quotas, where necessary to prevent major disruptions of the market of hydrofluorocarbons, or where the mechanism is not fulfilling its purpose and is having undesirable or unintended effects.	6. The Commission is empowered to adopt delegated acts in accordance with Article 32 to amend paragraph 5 as regards the amounts due for the allocation of quota and the mechanism to allocate remaining quotas, where necessary to prevent major disruptions of the market of hydrofluorocarbons, or where the mechanism is not fulfilling its purpose and is having undesirable or unintended effects, **such as risking public health. The Consultation Forum**

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	shall be consulted on the potential unintended effects that form a basis for a delegated act.

Justification: *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 transition to the quota system. To anticipate the effects of a proposed exemption from the quota system, 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.*

Article 33 - EFA proposed Amendment 8

European Commission's proposal	**EFA proposal**
The Commission shall establish a Consultation Forum for providing advice and expertise in relation to the implementation of this Regulation. The rules of procedure of the Consultation Forum shall be established by the Commission and shall be published.	(1) The Commission shall establish a Consultation Forum for providing advice and expertise in relation to the implementation of this Regulation. The rules of procedure of the Consultation Forum shall be established by the Commission and shall be published.
N/A	(2) **The Consultation Forum shall form dedicated ad-hoc working groups addressing the unintended effects on sectors relying on products and equipment that contain fluorinated greenhouse gases or whose functioning relies upon those gases listed in Annexes I and II.**
N/A	(3) **In reference to Article 33(2), the unintended effects on health, especially on patients with an MDIs treatment, shall be assessed in consultation with competent authorities, such as the European Medicines Agency. The European Commission with input from the Consultation Forum shall produce an annual report on the status of the transition towards low GHG technologies, such as MDIs and the availability of medicinal products, as of 2025. The European Commission shall**

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	act upon the yearly reports to adopt delegated acts in accordance with Article 32.

Justification: *While the main goal of the F-Gases proposal is to contribute to climate change mitigation, the legislative framework can have unintended effects on various sectors including public health. The EC proposal foresees a sharp curve down of around half per cent of the F-gases volume used on MDIs in Europe. It proposes 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, the community of asthma and COPD patients, dependent on such medicines, notes that inhalers are complex drug-device combinations and both the development and the regulatory requirements in case of significant changes in the excipient and the device might delay authorisation and market access for the sake of safety. In order to address the possible shortages and medication gaps, an annual Commission report looking at the status of the transition towards low GHG technologies, the readiness of the MDIs producers, of healthcare professionals and of MDIs users to transition to the GHG technologies can have a vital role in informing and monitoring the authorisation procedures and the real market access, in order to address any possible unintended effects on public health.*

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