OPEN LETTER ON EU REGULATION ON FLUORINATED GREENHOUSE GASES

January 2023

Ensuring access to critical medicines and technologies while achieving important climate goals with a revised EU Fluorinated Greenhouse Gases Regulation

The signatories of this letter, representing the health community stakeholders to the revision of the EU Regulation on Fluorinated Greenhouse Gases (F-Gases), support the EU's goal of carbon neutrality. It is well documented that climate change has a significant impact on respiratory health.[1] While at the same time, medical inhalers for respiratory patient care contribute to healthcare's greenhouse gas emissions.[2]

Achieving ambitious climate action objectives should go hand in hand with the needs and safety of patients in the EU and globally whose health, in the foreseeable future, continues to rely on the limited use of F-Gases. Therefore, patient safety and access to life-saving medicines and technologies should be prioritised throughout the entire process of transitioning to new medicines and technologies with lower Global Warming Potential (GWP).

Adopting a no-harm patient-centric, effective approach, considering both the needs of patients and healthcare professionals and the environment

The Proposal for revising the F-Gas Regulation foresees eliminating the medical exemption from the F-Gases quota system to reduce the greenhouse footprint of F-Gases (currently less than 0.1% of EU-reported GHG emissions).[3]

As the use of F-Gases remains essential in the medical field, we call for this legislative revision to strike the right balance between setting ambitious environmental targets and ensuring continued access to basic, life-saving medicines and technologies and services for patients and healthcare professionals across the EU and globally.

The objectives of the Regulation's revision can be achieved in ways which protect both patients' health and treatment needs, as well as healthcare professionals' clinical decisions.

Ensuring a smooth transition to climate-friendly solutions to avoid unintended consequences for the healthcare sector in Europe

Recommended approaches for evolving the F-Gas Regulation Proposal for protecting public health:

- Implement a smooth transition to medical gases with low GWP that considers the uncertainty around timelines for both research, development and clinical trials, the regulatory authorisation and validation processes for medicinal and medical technologies in the EU and globally, based on their sectoral legislations.[4]

[1] D'Amato, G., *et al.* 2014. *European Respiratory Review.* 2014 23: 161-169

[2] Pernigotti D, *et al.*. *BMJ open respiratory research.* 2021;8(1):e001071.

[3] Source: United Nations Framework Convention on Climate Change (UNFCCC) Greenhouse Gas Reporting Data (Greenhouse Gas Inventory Data - Time Series - Annex I (unfccc.int), reported for 2020; *accessed on 12 January 2023*.

[4] For medical technologies, the sectoral legislation is: Medical Devices Regulation 2017/745 and *In Vitro* Diagnostic Medical Devices Regulation 2017/746.

- Establish a formal consultative process facilitated by the European Commission to ensure that different sectors in the medical field (pharmaceutical, medical devices, medical gases, and medical professionals) are on track to transition without risking loss of patients' access to life-saving products and services, and include health community stakeholders in the monitoring system, such as patient organizations, public health stakeholders, regulatory authorities, e.g. the European Medicines Agency, and healthcare manufacturing sectors.
- Support efficient regulatory authorisation procedures for inhaled medicines with lower GWP.

Avoid shortages of treatments, technologies and solutions

Putting safeguards in place for the use of medical-grade HFCs for medical products will prevent shortages of essential technologies and services for patients and professionals in the EU and globally, such as:

- Safe and effective inhaled anesthetic agents for surgical procedures; securing the intended functioning of machines for safe general anesthesia; ventilators and patient monitoring devices used to support the patient's life and safety during the induced coma state need to be periodically calibrated/serviced using test gases mixtures comprising of either Sevoflurane or Desflurane
- Gas propellants in medical inhalers for delivering life-saving medicines to treat asthma and chronic obstructive pulmonary diseases (COPD); there is a growing need due to prevalence and better diagnosis
- Refrigerants for blood, sample or vaccine storage
- Clinical chemistry diagnostic testing instruments for *in vitro* diagnostics
- Critical component of pneumatic retinopexy surgery to treat detachment of the retina and restoration of vision.
- *In Vitro* diagnostic (IVD) centrifuge systems; f-gases are used to separate liquid and solid components, for example, blood and other biological fluids for processing, analysis, etc.

The healthcare sector has already started reducing the footprint of the F-gases emitted by medicinal products and medical devices. For example, the use of the anesthetic agent Desflurane for surgery is used selectively for specific patient profiles and procedures where it is needed to deliver safe and effective outcomes and clinical benefits. Technologies to capture F-Gases exhaled by patients during anesthesia, which already exist and are used in different hospitals across Europe, are very effective to minimize the release of gases into the atmosphere while continuing to allow the clinician to choose the most appropriate agent for their patient, and therefore provide a better option to achieving the Commission's ambition than only restricting the use of Desflurane.

In the pressurised Metered-Dose-Inhalers (pMDIs) sector, substantial investment and progress has been made towards lower GWP propellants. This transition involves a portfolio of pMDIs with different medicines and, thus, is complex and requires time. The suitability of alternatives either on the drug substance level or reformulated products to the current pMDI marketed portfolio cannot just be assumed. The role of the European Medicines Agency (EMA) and local health authorities in the development and licensing of pMDIs containing low GWP propellants will be crucial too, as millions of asthma and COPD patients rely on these treatments in the EU, and worldwide. In fact, several pMDIs produced in the EU are listed in the WHO Essential Medicines List and EU manufacturers supply millions of patients around the world, including to many low- and middle-income countries. In short, the transition goals require multidimensional healthcare decisions in respect of patient and health care professionals' clinical care, not just technical acts.

Investing in a patient-centered approach

We believe in the value of educating citizens, healthcare professionals and patients on how to manage their disease and use their treatment. Transparency, patient information and education, and health literacy can already considerably reduce the environmental impact of their medications. Ensuring a patient's disease is well controlled is also positive for the environment and leads to lower carbon emissions.[5,6]

We see merit in having the European Commission assess, together with the World Health Organization, the potential impact of the EU F-Gases Regulation on the health care and treatments in third countries, especially in terms of access to basic medication for asthma and COPD.

We remain at your disposal to work towards a smooth transition to technologies and services that consider the health and safety needs of patients while contributing to achieve greener health for Europe.

Kindest regards,

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

European Federation of Pharmaceutical Industries and Associations (EFPIA)

European Patients' Forum (EPF)

Global Allergy & Airways Patient Platform (GAAPP)

International Pharmaceutical Aerosol Consortium (IPAC)

The International Primary Care Respiratory Group (IPCRG)

Medicines for Europe

MedTech Europe

[5] ERS Statement on Asthma and Climate Change. ERS publishes position statement on asthma and environment - ERS - European Respiratory Society (ersnet.org)

[6] Williams, S., Tsiligianni, I. IPCRG is committed to lower cost, lower environmental impact and improved social impact: the triple bottom line in global primary care. *npj Prim. Care Respir. Med.* **31**, 44 (2021). https://doi.org/10.1038/s41533-021-00256-6

About our organizations

- 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. EU Transparency Register No. 28473847513-94.
- The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 38 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. EU Transparency Register No. 38526121292-88.
- The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 78 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. EU Transparency Register No. 61911227368-75d.
- The Global Allergy & Airways Patient Platform (GAAPP) is a nongovernmental organization comprised of more than 90 patient advocacy organizations in allergic and airways diseases. GAAPP works with healthcare and governmental organizations – such as WHO, EAACI, ERS, GINA, GOLD, WHO GARD, and IPCRG – to improve patients' lifestyles and reduce the impact of these diseases. Serving as an equal partner, we can make dynamic, beneficial changes to health and social policy and global decision-making while exchanging information and best practices with our member organizations. We also strive to improve the quality of diagnosis and therapy within the field. As a global platform, GAAPP aims to serve as an intermediary among patient organizations, enabling the amplification of local. voices and encouraging communication across the globe. We also strive to demand global standards – including an increase in air quality by reducing pollution – that will ultimately empower patients and their communities and improve their lifestyles. We also support the establishment of patient organizations in low and middle-income countries, helping improve allergy, airways, and atopic disease care and support worldwide.
- The International Pharmaceutical Aerosol Consortium (IPAC) is comprised of AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, Cipla, GSK, Kindeva, Organon and Teva. IPAC's mission is to ensure that environmental policies relevant to inhaled therapies are patient-centric and appropriately balance both patient care and sustainability objectives. IPAC has developed Principles to help guide policy discussions that reflects the lessons learned in our work on the Montreal Protocol on Substances that Deplete the Ozone Layer. EU Transparency Register No. 602537137644-70.
- The International Primary Care Respiratory Group (IPCRG) is a clinically-led charitable company that works locally in primary care and collaborates globally to improve respiratory health. Our vision is that, through universal access to the right care, everyone can breathe and feel well. We are an alliance of 37 national primary care respiratory organisations, reaching over 155,000 GPs and other primary care professionals around the world. We are also a community of practice, collaborating globally on respiratory research and innovation, and exchanging knowledge about best practice and impact. We advise the World Health Organization and WONCA, extend academic learning into communities, develop global collaborative networks, and lead in the promotion of a culture of critical inquiry and public reasoning about the best ways to deliver effective respiratory care.
- Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information visit www.medicinesforeurope.com and follow us on Twitter @medicinesforEU. EU Transparency Register No. 48325781850-28.
- MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. EU Transparency Register No. 433743725252-26.