22 November 2021

To: Deputy Directors-General:

Ms. Clara de la Torre, DG CLIMA
Mr. Pierre Delsaux, DG SANTE
Mr. Hubert Gambs, DG GROW
Ms. Maria Martin Prat, DG TRADE
Ms. Mechthild Wörsdörfer, DG ENER
Ms. Signe Ratso, DG RESEARCH

Via Electronic Mail

Review of the rules for Medical Inhalers under the F-Gas Regulation: Managing the green transition of life-saving medicines in an ethically responsible way

Dear Madams and Sirs,

We write from the International Pharmaceutical Aerosol Consortium (IPAC) regarding the ongoing revision of Regulation (EU) No 517/2014 on Fluorinated Gases. The so-called "F-Gas Regulation" is important for the environment, for patients suffering from asthma and chronic obstructive pulmonary disease (COPD), and for EU global leadership in supplying medical inhalers to treat these conditions. IPAC believes the revision can achieve holistic benefits for the environment, public health, and EU jobs and competitiveness.

IPAC members have made firm commitments on sustainability and responding to climate change, including innovating lower carbon medical inhalers. Reducing the environmental impact of medical inhalers is necessary and will require careful management, resources, and time. The revision of the F-Gas Regulation should support this sustainable journey. Patients, and their need for a diverse range of cost-effective, life-saving therapeutic choices should remain at the centre of the discussion around environmental policies.

Medicines delivered to the lung via an inhaler device are the backbone of treatment for asthma and COPD. These conditions take a significant toll on patients' lives and on the healthcare systems that treat them. Every year, 176 million asthma attacks occur worldwide. COPD worsens with time and will be the third leading cause of death worldwide by 2030. In the EU, there are around 30 medical inhalers delivering molecular combinations marketed for different therapies and serving millions of patients. The total number of medical inhalers prescribed in the EU is around 150 Million (including the UK) or 90 Million (excluding the UK) per year between 2017 to 2019.

With Europe being a global manufacturer of medical inhalers, revising the F-Gas Regulation also has bearing on the supply of this segment of life-saving pharmaceutical products to countries far outside Europe. Various EU Member States host strategic production sites, including France, Germany, Italy, Spain, and Ireland. The approximate total number of medical inhalers produced in the EU (including

the UK) is estimated to be between 300 to 400 Million in 2018. Approximately half of them get exported to the rest of the world. For example, EU-produced medical inhalers make up around half of all medical inhalers marketed in the US.

There are three major types of handheld inhalers: pressurised metered dose inhalers (pMDIs), dry powder inhalers (DPIs) and soft mist inhalers (SMIs). Pressurized MDIs deliver a range of medicines which are indispensable for specific patient groups. It is not a single product, but rather an extensive portfolio each with unique considerations. pMDIs rely on F-Gases as the propellant. Following significant product improvements in previous years, fugitive emissions account for < 0.1% of total EU greenhouse gas emissions. Going forward, a new generation of propellants with low global warming potential (GWP) have been identified. However, this does not mean that alternative next generation propellants are available today.

In the future, every product that uses a new propellant will require regulatory approval - by the European Medicines Agency or by EU national competent authorities for EU patients and by the competent regulatory agencies in all export markets for patients worldwide. Transition timelines will vary greatly per product and per market. There is no one-size-fits-all replacement for propellants with low GWP in medical inhalers.

Existing and ongoing innovative efforts offer significant promise for both patient care and environmental benefit. Any transition will require careful management, resources, and time. Ex-post efforts to modify the implementation deadlines of adopted legislation, such as currently in the case of the EU Regulations on medical and in-vitro diagnostic devices, illustrates the importance of carefully anticipating capacity bottlenecks and negative impact on patient access to life-saving treatments upfront. Similarly, a poorly managed transition between medical treatments could lead to worse health and environmental outcomes.

pMDIs are not a life-style choice, but a life-saving medicine. While we appreciate the intention of the F-Gas quota system to internalise the cost of climate change, we do not believe it is ethically justifiable to put life-saving medical uses of F-Gas in competition with other commercial uses. This could be to the detriment of patient access and treatment costs for already strained healthcare systems.

To avoid such a scenario without jeopardising the goals of the EU F-Gas Regulation, we encourage the European Commission to take the following measures:

- Sustain the existing medical exemption until at least 2030 to ensure that there are no unintended consequences or disruptions in supply.
- Involve the EMA and EU national competent authorities in a multi-stakeholder process to plan the regulatory processes for the approval of inhalers with low GWP.
- Avoid any de jure or de facto ban of propellants with high GWP in medical inhalers and protect the EU ability to manufacture inhalers with HFCs 134a and 227ea for export to patients in third countries with slower regulatory approval processes or different approaches to sectorial effort sharing under the Montreal Protocol.
- Maintain the existing export rules under Article 15 of the F-Gas Regulation to maintain the EU's position of a leading pharmaceuticals exporter by ring-fencing available F-Gas volumes for European patients from F-Gas quantities used in medical inhalers produced for export.

We thank you for your urgent consideration of this important issue. We would be delighted to have the opportunity to discuss these matters in more detail with you. We will be in touch with your respective offices.

Yours sincerely,

A. R. Rignall -

Andy Rignall
Chair of IPAC Board of Directors

c.c.
Ms. Bente Tranholm-Schwarz, DG CLIMA
Mr. Sylvain Giraud, DG SANTE
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Ms. Irene Norstedt, DG RESEARCH

About IPAC

IPAC was formed in 1989 in response to the mandates of the Montreal Protocol and fully supported a timely and effective transition away from chlorofluorocarbons (CFCs) under the Montreal Protocol that balanced patient health and environmental concerns. 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. HFC pressurized metered dose inhalers (MDIs) played a critical role to the transition as one of the key ozone-friendly alternatives developed to replace CFC MDIs. IPAC's members are AstraZeneca, Chiesi, Cipla, Boehringer Ingelheim, GlaxoSmithKline, Kindeva, Organon and Teva.

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