Mr [redacted]
Ambassador, Deputy Permanent Representative
Permanent Representation of Sweden to the European Union

Brussels, 21 April 2023

Medicines for Europe priorities for the trilogue negotiations on the Fluorinated Greenhouse Gases Regulation to mitigate risks of shortages of metered-dose inhalers used to deliver lifesaving medicines for respiratory diseases

Dear Ambassador [redacted]

Medicines for Europe, representing generic, biosimilar and value-added medicines industries in Europe, has been following closely the discussions on the revision of the Fluorinated Greenhouse Gases Regulation and especially **the potential serious unintended consequences for patients suffering from respiratory diseases who rely on metered-dose inhalers** to treat conditions such as such as asthma, affecting almost 6% of the EU population in 2019,[1] and chronic obstructive pulmonary diseases (COPD), affecting almost 37 million Europeans in 2020[2].

While we support the EU's goal of carbon neutrality and our member companies are engaged in the complex switch to lower global warming potential (GWP) alternatives, we are concerned that the inclusion of propellants currently used in metered-dose inhalers (MDIs) in the F-Gas quota system fails to consider:

- **the limited availability of the new alternative propellants** HFC-152a and HFC-1234ze, which are not used in any MDIs approved and utilised by patients in Europe. This could be even more critical in case the use of currently used propellants HFC-134a and HFC-227ea and future alternative HFC-1234ze were to be banned or limited as a result of the ongoing discussions at the European Chemicals Agency (ECHA) on possible restrictions on PFAS
- **the uncertainty on the timelines needed for the switch to the new propellants**, due to the safety, efficacy and regulatory requirements and the need to adapt manufacturing capabilities. Even the five countries proponents of the PFAS restrictions are acknowledging that, in case a restriction is adopted in 2025 and followed by a 18-months transition period, "*whether this period will be enough to facilitate a complete transition away from the currently used propellants is unclear*"
- **the stronger impact that the new F-gas quota fees will have on the off-patent pharmaceutical industry**, due to its lower margins compared to the originator pharmaceutical industry. Generic MDIs account for 37% of MDIs in the European Union and their price is on average 70% or less of the originator product. Generic medicines are subject to strict price caps in market policies which make it impossible to adjust for the current cost inflation and that will not allow to absorb the additional costs of the quota system. Introducing new financial burdens reduces already low margins even more and threatens the viability of manufacturing generic metered-dose inhalers.

All these factors pose a risk of significantly reducing the presence of generic metered-dose inhalers on the market, with serious consequences for patients suffering from respiratory diseases who rely on these products. We acknowledge the environmental impact of MDIs (less than 0.1% of global greenhouse emissions), but we stress the need for a multifaceted approach focusing on patient safety and choice.

[1] Source: Eurostat
[2] Source : European Respiratory Journal, An estimate of the European prevalence of COPD in 2050

Preserving current inhaler options is essential for optimising treatment and clinical outcomes for individual patients.[3]

Nonetheless, we appreciate the efforts undertaken by the European Parliament and EU Council to introduce more guarantees for MDIs and therefore for patients compared to the original proposal.

To this end, building on the adopted negotiating mandates, we urge co-legislators to ensure that:

- **100% of current F-gas consumption is safeguarded for inhalers for 2024-26 and 2027-2029** (Annex VIII, point 1, paragraph 2)**.** This is crucial to provide a sufficient amount of HFC quotas to the MDI sector to ensure a smoother transition to safe alternative low Global Warming Potential propellants. While we appreciate the Council position ensuring 100% consumption until the end of 2028 as well as the Parliament safeguarding 70% consumption for 2029, we believe that this suggested combination of the two approaches **would be the most effective way to mitigate the risk of MDI shortages.** Ensuring 100% consumption also for 2029 would not make a difference in the quota allocation cycles, since the total F-gas amounts available for 2029 would be the same as those foreseen for 2027 and 2028
- **quota fees are set at a fixed rate of 2 euro per tonne of CO2 equivalent** in line with the Council position (article 17, paragraph 5). This is crucial to limit the impact on the off-patent pharmaceutical sector that provides high volumes of affordable inhalers with low margins
- **an EU agency,** such as EMA, **can also request the activation by the Commission of the "emergency brake"** allowing an exemption from the quota system for up to four years for specific products and also in case alternatives cannot be used due to **risks for public health,** as recommended by the European Parliament (article 16, paragraph 4)
- **representatives of manufacturers, patients and healthcare professionals** participate in the **Consultation Forum** providing advice and expertise in relation to the implementation of the Regulation, in line with the European Parliament position (article 33, paragraph 1 and recital 39)
- **Commission, Member States and their competent authorities and the EMA should cooperate closely** to ensure a smooth approval process of MDIs using alternative propellants, as requested by the European Parliament in order to avoid affecting the accessibility, availability and affordability of essential medicines (recital 13e)
- the **Commission report on the implementation of the Regulation** will be **published in 2027** and also include an assessment of the **impact on the availability of MDIs for the delivery of pharmaceutical ingredients**, as recommended by the European Parliament (article 35, paragraph 2)
- the **undesirable or unintended effects** justifying an amendment of the amounts due for the allocation of quotas and of the mechanism to allocate remaining quotas also include **effects on public health and users of MDIs**, in line with the European Parliament position (article 17, paragraph 6).

In order to ensure a level playing field between EU and non-EU manufacturers, we also support the Council and Parliament recommendation to **include in the quota system all metered dose inhalers charged with hydrofluorocarbons and placed on the EU market** (article 19, paragraph 1).

We are also concerned about the potential impact of the **restrictions on the use of Desflurane as inhalation anaesthetic** from 1 January 2026 foreseen in the original proposal. Desflurane is a highly effective anaesthetic gas that offers medical benefits to specific patient groups (paediatric, elderly, obese, patients) and capturing technologies already exist that reduce emissions of aesthetic inhalation gases. Therefore, we strongly support the European Parliament proposal to **allow the continued use of Desflurane based on strict medical need or if used in combination with a gas capture system** (article 13, paragraph 4), which would protect patient safety and be in line with the Council's amendments to article 4 on prevention of emissions referring to recapturing the gases emitted.

[3] Source: British Medical Journal Open Respiratory Research, Reducing carbon footprint of inhalers: analysis of climate and clinical implications of different scenarios in five European countries

As negotiations enter the decisive phase, we call on the co-legislators to ensure that the final text of the Regulation fully considers the serious consequences for patients in case of shortages of metered-dose inhalers or of restrictions to the use of Desflurane and includes all of the abovementioned provision and safeguards which would significantly mitigate these risks.

We thank you for the kind attention you will pose to these priorities, and we remain at your disposal for any clarification needed.

Yours respectfully,

[redacted],
Director General,
Medicines for Europe