Ensuring continued access to essential inhaled respiratory medications: a call to action from the Inhaled Respiratory medicine Innovation and environmental Sustainability (IRIS) group

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Shareable abstract (@ERSpublications)
The supply of pMDIs for our patients is about to be switched off. IRIS calls for greener next generation propellants (HFA-152a and HFO-1234ze) used in pMDIs to be excluded from the EU F-gas regulation and the proposed PFAS restriction. https://bit.ly/3OxQ2ry

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Globally, more than 650 million children and adults live with COPD or asthma, 48% of whom depend upon pressurised metered-dose inhalers (pMDIs) to deliver their inhaled medication [1, 2]. Inhaler choice is key to the effective management of these chronic respiratory diseases. Patient capability, engagement and satisfaction are important determinants when considering device selection and adherence [3]. It is, therefore, important to prescribe the "right" device to the appropriate patient. pMDIs deliver essential medications, as defined by the World Health Organization, and often are the only choice for some of the most vulnerable populations, including children <10 years old, those with more severe lung disease or suffering from acute attacks of breathlessness, and people who live in low- and middle-income countries (LMICs) [4].

The Inhaled Respiratory medicine Innovation and environment Sustainability (IRIS) group was established to support the right of every person around the world to access inhaled therapy in an inhaler best suited to their needs, to improve outcomes for all. Currently comprising respiratory and environmental experts from seven countries, we advocate for 1) the importance of inhaled medicines and appropriate inhaler choice for all patients, 2) continued access to these inhalers, and 3) preservation of inhaler choice while promoting long-term environmental sustainability, thus simultaneously providing long-term clinical benefits and protecting the environment (https://www.sustainable-respiratory-medicines.com/). IRIS, as an organisation, has no potential, actual, or perceived conflicts of interest related to the availability and use of pMDIs.

In response to both national and international initiatives, pMDIs have appropriately come under the environmental spotlight in recent years, due to their propellant gas constituents which contribute most to the pMDI carbon footprint. At the European level, the F-gas Regulation requires a phase-down and

ultimate phase-out of fluorinated gases (F-gases) with a high global warming potential (GWP). Separately, under the European Union (EU) REACH Regulation, a proposal has been made to ban per- and poly-fluoroalkyl substances (PFAS), even when used as propellants in inhaled medicines [5, 6]. After the F-gas regulation was enacted, pharmaceutical companies that produce pMDIs quickly began a next generation propellant (NGP) transition programme, shifting from F-gases with high GWP to greener alternatives. However, the subsequent proposed ban on PFAS effectively moved the goalposts, potentially setting back the development of NGPs to square one.

As approximately 75% of pMDIs manufactured in the EU are exported to the rest of the world, these restrictions are likely to have a global impact. While this article primarily focuses on the European legislative landscape, we recognise that A5 countries, under the Kigali Amendment to the Montreal Protocol, have exemptions regarding current hydrofluorocarbons (HFCs). These exemptions acknowledge differing national circumstances by allowing a more lenient phase-down schedule, access to multilateral fund support for conversion costs, and flexibility in implementation strategies. However, the protocol is broad and comprehensive, aimed at reducing overall HFC emissions, not just those related to pMDIs. Exemptions may be requested, but this is implemented at the national level. Unfortunately, NGPs used in pMDIs have been inadvertently affected by these broader regulatory frameworks, potentially compromising future availability even in markets with current exemptions.

Currently approved propellants tend to have a high GWP – listed as 1260 kg carbon dioxide equivalent (CO_2e) for hydrofluoroalkane (HFA)-134a and 3600 kg CO_2e for HFA-227ea [7] – and fall within scope of the EU F-gas Regulation. One NGP (HFA-152a) is also subject to the F-gas Regulation, even though its GWP of 164 kg CO_2e is 87% lower than that of HFA-134a (the most common currently used pMDI propellant) [7]. The other NGP, hydrofluoroolefin (HFO)-1234ze, already approved in one inhaled medicine in the UK and the EU, has a near-zero GWP (1.37 kg CO_2e) [7], leaving it out of scope of the F-gas phase-out. However, its future is uncertain because it is chemically characterised as a PFAS, even though it is not toxic nor bioaccumulative, and rapidly degrades in the atmosphere. Both the F-gas Regulation and the proposed PFAS restriction affect the use of current propellants and NGPs, meaning that, in effect, the supply of pMDIs for our patients is about to be negatively impacted (figure 1), restricting clinician and/or patient choice, and impacting the most vulnerable.

It would seem logical that moving to a non-propellant-based inhaler is the least environmentally harmful and responsible solution, and for some people, it will be. However, this is not an option for all. It is important to consider the negative implications of enforcing such a switch to patients, and to payers, and to more accurately consider the environmental consequences thereof (figure 1). Firstly, there is no universally available alternative to pMDIs for children, frail and elderly individuals, or those experiencing acute exacerbations and/or requiring mechanical ventilation. Millions of patients will be at risk for adverse outcomes and even death. Secondly, patients' ability to use dry powder inhalers (DPIs) correctly varies (ranging from 6% to 96%), with up to 48% of patients failing to execute a forceful and deep inhalation, which may lead to insufficient drug delivery and lung deposition [8]. Thirdly, enforced inhaler switch has been associated with reduced adherence, considerable negative clinical implications, including worsening disease control, and increasing use of healthcare resources [9, 10], although this may be mitigated with appropriate patient education. Although the removal of propellants from pMDIs would undoubtedly deliver an immediate environmental benefit, this gain could be offset by increased emissions arising from loss of disease control. The indirect environmental price tag associated with loss of control is a consequence of an increase in emissions due to exacerbations and associated higher demand for healthcare resources – particularly hospitalisations [11]. A 5.2–23.0% increase in greenhouse gas emissions has been reported for patients with uncontrolled *versus* controlled asthma [11]. Finally, in contrast to pMDIs, which are cheap and widely available, the availability of DPIs varies significantly by region and country. The great majority of people with asthma and COPD live in LMICs, which have disproportionately high respiratory disease-related morbidity and mortality. In these countries, the primary "inhaler preference" is heavily driven by the availability and affordability of medication, and is predominantly a pMDI.

Inhaler devices and the medicines contained within them are therefore not necessarily interchangeable [12]. The issue has been highlighted by international management guidelines, which caution that "*too rapid an implementation of these restrictions* [F-gas phase-downs and a possible PFAS restriction as applied to pMDIs], *would adversely affect the lives of many people worldwide*" and urge authorities to consider "*safety for patients as well as safety for the planet*" [13], since the least environmentally harmful inhaler is one that the patient can, will and does use [14]. The European Respiratory Society has also emphasised the need for a policy of coherence to consider the whole life cycle and wider environment, including plastic levels in all medical devices – improving our climate and skies above, but not at the expense of our oceans below [15].

The problem

The supply of pMDIs for our patients is about to be switched off.

- Currently approved pMDI propellants (HFA-134a and HFA-227) are being phased out under the EU F-gas Regulation [6].
- One NGP (*i.e.* HFA-152a) is also subject to the F-gas Regulation. The other NGP (HFO-1234ze) is at risk of a ban under the proposed PFAS restriction [5, 6].
- However, not all F-gas and PFAS are the same; both NGPs reduce GWP to near DPI levels [7], and HFO-1234ze is not toxic nor bioaccumulative, and rapidly degrades in the atmosphere.

The impact

Lack of access to essential medications delivered by pMDI.

Forced switch to DPIs and SMIs has negative implications for patients and the environment, associated with:

- Reduced adherence and worsening disease control [9, 10, 12] and
- Increased healthcare resource use [9–12].

The call to action

For governments and policymakers to recognise the importance of continued access to essential life-saving inhaled medications for millions of people worldwide living with chronic respiratory conditions.

For greener NGPs used in pMDIs to be excluded from ECHA's F-gas Regulation and the proposed PFAS restriction.

FIGURE 1 Protecting patient access to pressurised metered-dose inhalers (pMDIs) – the problem, the impact and the call to action. HFA: hydrofluoroalkane; EU: European Union; F-gas: fluorinated gases; NGP: next generation propellant; HFO: hydrofluoroolefin; PFAS: poly-fluoroalkyl substance; GWP: global warming potential; DPI: dry powder inhaler; SMI: soft mist inhaler; ECHA: European Chemicals Agency.

Carbon emissions from pMDIs could be reduced through a combination of appropriate inhaler selection, improved prescribing practices, and technological innovation. Where clinically suitable, switching from pMDIs to lower-carbon alternatives such as DPIs or soft mist inhalers can substantially reduce emissions, while recognising that pMDIs remain necessary for a small subsection of patients. Further reductions can be achieved by transitioning to pMDIs that use low-GWP propellants, optimising inhaler technique and adherence to minimise wasted doses, and avoiding overprescribing through regular medication reviews and improved disease control. Finally, promoting inhaler recycling (*e.g.* inhaler return schemes) and incorporating environmental impact into shared decision-making with patients may help limit the release of residual propellant and support more sustainable respiratory care.

In conclusion, limiting pMDI supply and restricting clinician and/or patient choice could negatively impact the most vulnerable, put millions at risk for clinical adverse events, and increase global health inequities. Considering the low GWP of NGP pMDIs, removing them from the treatment armamentarium is unlikely to have a significant impact on global warming trajectory, but is likely to have a detrimental effect on patient outcomes (a lose/lose scenario). IRIS calls on governments and policymakers to recognise the importance of continued access to essential lifesaving inhaled respiratory medications for millions of people worldwide living with chronic respiratory conditions. We call for greener NGPs used in pMDIs to be excluded from the European Union's F-gas Regulation and the proposed European PFAS restriction (figure 1). NGP pMDIs are an effective, environmentally responsible, and sustainable option to deliver essential medications to people living with chronic respiratory disease.

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