



# METERED DOSE INHALERS

## SOCIETAL IMPORTANCE

Metered dose inhalers (MDIs) are pressurized, hand-held devices that use propellants to deliver doses of medication to the lungs of a patient. MDIs and the medicines they deliver are critically important to public health and play a particularly significant role in treating respiratory illnesses such as asthma and chronic obstructive pulmonary disease (COPD). Stringent technical and performance criteria must be met (e.g., low toxicity) in order for a propellant to be deemed safe for patient use.

## Critical Application Considerations

**HFCs are the solely available medical propellants that have been demonstrated to be safe and effective for patients. No alternatives have been identified. Therefore it is critical to ensure that HFCs remain available to meet public health needs.**

Asthma is a disease of the lungs and airways with symptoms of breathlessness, tightness of the chest, wheezing and cough. It is a chronic condition and frequently impacts individuals beginning in childhood and continuing throughout their lives. Asthma varies in severity from very mild to severe, and can be life-threatening. With proper, ongoing treatment asthma can be well-managed, and serious complications prevented. Asthma currently affects more than 300 million people worldwide. COPD, such as emphysema and chronic bronchitis, are progressive diseases and while the symptoms can be managed, the diseases are generally irreversible and often lead to premature death. COPD also impacts hundreds of millions of individuals globally and is currently the fourth leading cause of death worldwide.

**Inhaled therapy is the mainstay of treatment for asthma and COPD.** Inhalers deliver drugs directly to the lungs enhancing the symptomatic benefit and minimizing side effects. In addition to MDIs, dry powder inhalers (DPIs) are also inhalation devices used to treat asthma and COPD. It is important to note that not all devices are compatible with all drug products, or suitable for all patients. Selecting a therapy for a patient, including choosing a device, is a complex process driven primarily by the physician and patient. It is imperative to preserve a range of therapeutic options for patients. **The Medical Technical Options Committee (MTOC) under the Montreal Protocol noted that “no single delivery system is considered universally acceptable for all patients”** and “any consideration of policy measures to control HFCs should carefully assess patient health implications with the goals of ensuring patient health and maintaining a range of therapeutic options.” The MTOC also recognized that “each country has its own unique and complex makeup in terms of availability of medicines, overarching health care systems, and patient preferences.”

## Environmental Considerations

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**For decades, CFC-based MDIs served as the “gold standard” inhalation treatment for patients with asthma and COPD illnesses.** In response to the mandates of the Montreal Protocol, pharmaceutical manufacturers undertook an exhaustive search for chemically, environmentally, and medically suitable alternative to CFCs. Once HFCs emerged as the single viable alternative medical propellant, companies jointly conducted multi-year pre-clinical safety testing programs. In parallel, individual companies embarked on lengthy, resource-intensive efforts to research and develop HFC-based alternatives to their specific CFC MDI formulations. Reformulating MDIs with HFCs was an enormously complex and time-consuming effort. Most CFC MDI components proved incompatible with HFCs and had to be newly engineered. Each new HFC MDI was required to undergo the rigorous testing, regulatory review, and an approval process

associated with researching and developing wholly new drug products. The challenging transition to CFC-free alternatives was an unprecedented and resource-intensive undertaking impacting millions of patients and their health care providers.

The CFC MDI transition is still underway in several countries, but substantial progress toward closure of the essential use process has been achieved in recent years. It is currently estimated that developing countries will cease nominating essential use CFCs for MDIs by 2015-2016 and many countries around the world have already completed their transition. It is critical that the transition to HFC MDIs and other CFC-free alternatives proceed toward closure without questions or concerns regarding the long-term availability of pharmaceutical-grade HFCs.

## Technology Trends

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**No alternative medical propellant to HFCs currently exists.** Medical propellants must be very low in toxicity and must also meet several other stringent criteria, including non-flammability, chemical stability, appropriate solvency and density, and acceptable smell and taste. The industry concurs with the MTOC’s assessment that “for a new propellant development programme, there is major risk, significant investment, and no guarantee of success.” The MTOC also appropriately recognized the reality that for existing MDIs there would be “limited benefit to patients” given that the “active ingredient will remain the same and the performance characteristics are likely to be comparable to saturated HFCs.” Therefore, **pharmaceutical-grade HFCs must remain readily available to meet patient need for MDIs.**

**The use of HFCs in MDIs is quite small, as compared to other sectors** (estimated at approximately 2-3% of overall global HFC usage). HFC MDIs have approximately 8 times less climate impact than CFC MDIs. The major impact in reducing global warming potential with respect to MDIs is the completion of the CFC MDI transition. **Sound MDI manufacturing operations and responsible disposal/recycling are critical to minimizing HFC emissions.**



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The Alliance is an industry coalition that was organized in 1980 to address the issue of stratospheric ozone depletion. It is presently composed of about 100 manufacturers and businesses which rely on HCFCs and HFCs.

Today, the Alliance is a leading industry voice that coordinates industry participation in the development of international and U.S. government policies regarding ozone protection and climate change.