# PERSPECTIVES FROM IPAC ON CFC-FREE METERED DOSE INHALERS (MDIs)

*34TH MEETING OF THE OPEN-ENDED WORKING GROUP OF THE PARTIES TO THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER*

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*The International Pharmaceutical Aerosol Consortium (IPAC) is a group of companies that manufacture medicines for the treatment of respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD). IPAC has long supported and remains firmly committed to a timely and effective MDI transition that balances patient health and environmental concerns.*

- IPAC congratulates the Parties on their nearly complete transition away from CFC MDIs. With only one Party still seeking essential use volumes for MDI use, the TEAP/MTOC now foresee "the imminent global phase-out of CFC MDIs."
- Ensuring patient care by maintaining HFC-based treatment options should be an overriding objective when evaluating future controls on HFCs. As TEAP/MTOC noted in the Decision XXV/5 Task Force Report – Additional Information on Alternatives to ODS (Draft): "*HFC MDIs will remain an essential therapy for the foreseeable future, and completely avoiding high-GWP alternatives in this sector is not yet technically or economically feasible.*"

## Essential Use Nominations For 2015

IPAC congratulates the Parties for achieving substantial progress towards completing the global MDI transition. Only one Party (China) submitted a nomination for MDI essential use volumes for 2015. As detailed in the TEAP/MTOC Essential Use Nominations Report ("EUN Report"), the global transition of CFC MDIs is proceeding well and nearing completion. The reduction in Article 5 Party nominations since the beginning of their essential use process five years ago has been especially encouraging: 2400 tonnes in 2009 to a single request for 217 tonnes this year.

In general, IPAC supports the MDI essential use recommendation for 2015 as set forth in the EUN Report. IPAC does not have access to the detailed information supporting China's nomination and therefore is not in a position to independently assess it. Nevertheless, we find the conclusions and recommendations on the nomination set forth in the EUN Report to be reasonable and sound. According to the EUN Report, China submitted detailed information supporting the nomination and it was carefully assessed by MTOC members.

IPAC wishes to express particular support for the following TEAP/MTOC conclusions and recommendations:

- "Some parties are still reporting that CFC MDIs are being imported into and are available in their markets. Removal of import licenses for CFC MDIs would resolve this issue."
- China has informed the Parties that 2015 will be the final year for the manufacture of CFC-based salbutamol MDIs. "Thus, this will be the last year of nomination by China for salbutamol, with a complete phase-out of salbutamol CFC MDIs by December 31, 2016."
- "It is possible that China may be able to manage its CFC phase-out from CFC stockpiles, although this is not yet clear. Despite reported stockpiles, MTOC is recommending an essential use exemption for CFC production and consumption for 2015 in the expectation that China would supply its requirements from accumulated stockpile, with new CFCs produced only if absolutely necessary."

Given this, it appears that the complete global phase-out of CFC MDIs should be achievable within the next few years. We encourage the Parties to be vigilant in monitoring developments and promoting actions that will achieve this important objective.

## Amending The Montreal Protocol To Control HFCs

The United States, Canada, and Mexico re-submitted a proposed amendment to the Montreal Protocol to control HFCs (the so-called "North American Proposal"). IPAC continues to believe that the proposal is thoughtful and constructive, and shows promise as a workable path forward in seeking to combat global climate change. IPAC encourages the Parties to formally consider the proposal during this OEWG meeting.

The "Summary Points" accompanying the North American Proposal note that one of its key elements is the recognition that "there may not be alternatives for all HFC applications and therefore utilizes a gradual phasedown mechanism with a plateau, as opposed to a phaseout."

Avoiding a phase-out is essential, and any phase-down must be structured to ensure that adequate, safe, and secure supplies of HFCs remain available to meet patient need over the long term. To date, no alternative propellant to HFCs qualified for use with medicinal products has been shown to be suitable for use with existing active ingredients or drug delivery systems, let alone proven to be safe for patients. This is in contrast to the circumstances under which the international community agreed to phase-out CFCs for MDIs, where work had been completed demonstrating HFC-134a and HFC-227 as promising alternatives to CFCs in terms of their safety profile and technical/performance characteristics. Absent a self-implementing exception for MDIs, even a phase-down of HFCs generally could pose unintended threats to patient care. For example, shortages of medicines and/or increased costs for medicines could result from overall diminished demand for HFCs and related supply chain disruptions or challenges. Existing data illustrates that asthma, COPD, and other respiratory illnesses are undertreated in many Parties. It is a

fundamental public health goal to expand the availability of medicines and encourage appropriate treatment for patients. Restrictive policies are inappropriate in this context. This is a particularly important consideration in establishing baselines, especially for Article 5 Parties.

It is critical that the Parties ensure there will be no negative implications for patient health *before* adopting measures that could phase-down HFCs. This evaluative process should include expert advice from the MTOC, national health experts, and all impacted stakeholders taking into account the important "lessons learned" in the CFC MDI transition. The essential use process created for the CFC MDI phase-out is resource intensive and requires significant effort from Parties, TEAP/MTOC, and MDI companies. It would not be prudent or necessary to impose a restrictive and burdensome process in the context of an HFC phase-down, especially given the minimal emission reduction opportunities for the MDI sector and important patient care considerations.

The MTOC provided important observations and technical background on these issues in the recent Decision XXV/5 Task Force Report, as well as the 2010 Assessment Report. In addition, a 2004 paper published in the JOURNAL OF DRUG ASSESSMENT (cited by TEAP/MTOC) provides useful background and context on patient care issues – *The Importance of Preserving Choice in Inhalation Therapy: The CFC Transition and Beyond* (Volume 7, pp. 45-61). TEAP/MTOC noted that if the MDI sector was required to phase down HFC usage in the short to medium term it "would have adverse health and economic implications for patients, pharmaceutical companies and countries."

In conclusion, IPAC recommends that any amendment to control HFCs should provide unambiguous and self-implementing protections for medical uses of HFCs.

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