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

26TH MEETING OF THE PARTIES TO THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER

Paris, France (17-21 November 2014)

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 ozone protection and climate change response measures that balance patient health and environmental interests.

- IPAC congratulates the Parties on nearly completing the 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 (presented to the Parties in July): *"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 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. Given this, it appears the complete global phase-out of CFC MDIs can be achieved in the next two to three years. We encourage the Parties to be vigilant in monitoring developments and promoting and enforcing measures already in place that are designed to achieve this important objective.

IPAC supports the draft Decision on essential use authorizations developed at the 34th Meeting of the Open-Ended Working Group (OEWG) for consideration by the Parties at this meeting.

IPAC is especially supportive of the following provisions of the draft Decision:

- To encourage parties with essential-use exemptions in 2015 to consider initially sourcing required pharmaceutical-grade chlorofluorocarbons from stockpiles where they are available and accessible, provided that such stockpiles are used subject to the conditions established by the Meeting of the Parties in paragraph 2 of its decision VII/28;
- To encourage parties with stockpiles of pharmaceutical-grade chlorofluorocarbons potentially available for export to parties with essential-use exemptions in 2015 to notify the Ozone Secretariat of those quantities and to provide it with the details of a contact point by 31 December 2014;
- To request the Secretariat to post on its website details of the potentially available stocks referred to in paragraph 4 of the present decision;
- To request that parties consider domestic regulations to ban the launch or sale of new chlorofluorocarbon-based metered-dose inhaler products, even if such products have been approved; and
- To encourage parties to fast-track their administrative processes for the registration of metered-dose inhaler products in order to speed up the transition to chlorofluorocarbon-free alternatives.

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"), which has gained broadening support since first proposed several years ago. 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 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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