IPAC
International Pharmaceutical Aerosol Consortium

Perspectives From IPAC On CFC-Free Metered Dose Inhalers (MDIs)

36TH MEETING OF THE OPEN-ENDED WORKING GROUP OF THE PARTIES TO THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER

Paris, France (20-24 July 2015)

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.

Acknowledging an Important Milestone: The Global Phase Out Of CFCs For Metered Dose Inhalers (MDIs).

IPAC congratulates the Parties on the imminent completion of the transition away from CFC MDIs. It appears that 2015 will be the final year of essential use exemptions for metered dose inhalers (MDIs). This is an impressive achievement. IPAC commends the Parties and the Medical Technical Options Committee on their diligence and commitment in managing this important process over close to two decades.

LOOKING TOWARD THE FUTURE: PATIENT CARE AND HFC MDIs

IPAC supports consideration of the various proposals from Parties to amend the Montreal Protocol to control HFCs. IPAC urges the Parties to engage substantively on these proposals with the goal of identifying pragmatic strategies to combat global climate change and furthering the numerous accomplishments of the Montreal Protocol.

We renew our recommendation from prior Montreal Protocol meetings that any phase down is structured to ensure that adequate, safe, and secure supplies of HFCs remain available to meet patient need over the long term. IPAC specifically recommends that any amendment to control HFCs should provide unambiguous and self-implementing protections for medical uses of HFCs. A burdensome and resource-intensive essential use process like that undertaken in the context of the phase-out of CFCs should not be necessary, especially given the minimal emission reduction opportunities for the MDI sector and important patient care considerations.

The Medical Technical Options Committee (MTOC) has concluded that "MDIs, dry powder inhalers (DPIs), and novel delivery systems all play an important role in the treatment of asthma and COPD, and no single delivery system is considered universally acceptable for all patients" (2014 Assessment Report). MTOC members and health care providers believe that a range of therapeutic options is important. In addition, it is important to note that not all medicines are equally available in the MDI or DPI delivery system. At present, there are no alternative medical propellants to HFCs that have been proven safe and effective for patient use.

The lessons learned from the lengthy phase out of CFCs in MDIs illustrate that complex, sometimes unexpected, patient care, cost, and other issues can arise. (See, example: *The Importance of Preserving Choice in Inhalation Therapy: The CFC Transition and Beyond* (Volume 7, pp. 45-61)). The MTOC's 2014 Assessment Report carefully and thoroughly details the issues relevant to consideration of alternatives to HFC MDIs.

"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."
MTOC 2014 Assessment Report

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

IPAC members are committed to responsibly managing HFCs during the manufacture of MDIs. For example, companies employ strategies to minimize fugitive emissions during the manufacturing process. As noted by the MTOC, companies are exploring further opportunities to reduce HFC emissions associated with unused and waste inhalers.

IPAC
International Pharmaceutical Aerosol Consortium

IPAC Contact at OEWG-36
Maureen Donahue Hardwick
Secretary and Legal Counsel
Mobile Telephone: (01) 301.980.7837
Email: maureen.hardwick@dbr.com