

IPAC PERSPECTIVES ON THE TRANSITION TO CFC-FREE METERED DOSE INHALERS (MDIs)

FOR THE 21ST MEETING OF THE PARTIES TO THE MONTREAL PROTOCOL

PORT GHALIB, EGYPT (4-8 NOVEMBER 2009)

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

IPAC wishes to emphasize the following points regarding the CFC MDI transition and the Parties' consideration of possible control of HFCs under the Montreal Protocol:

- When authorizing and licensing essential use chlorofluorocarbons (CFCs) at the domestic level, it is important that the Parties adhere to the following core principles: (i) allocate CFCs only for use in the few MDIs, including combination MDIs, that remain essential for patients and (ii) effectively manage existing stockpiles of pharmaceutical-grade CFCs pursuant to Decisions of the Parties – particularly Decisions XVI/12, XVII/5, and XVIII/7 – and within commercial constraints, to ensure that new essential use CFCs are produced only when truly necessary.
- Safe and secure supplies of HFCs must remain available to meet patient need. Therefore, any amendment to phase-down HFCs should include a self-implementing mechanism to protect HFCs for MDIs. Ensuring patient care should be the fundamental objective when evaluating medical uses of HFCs. As the IPCC/TEAP Special Report concluded: “Both MDIs and DPIs play an important role in the treatment of asthma/COPD and no single delivery system is universally acceptable for all patients. It is critical to maintain the range of therapeutic options.”

► Essential Use Nominations for 2010 and 2011

IPAC commends the TEAP/MTOC for their commitment and hard work in evaluating the numerous essential use nominations submitted this year. In general, IPAC supports the MDI essential use recommendations set forth in the 2009 TEAP Progress Report and wishes to highlight the points noted below.

Non-Article 5 Parties

IPAC understands that the European Community (EC) will be completing its CFC MDI transition by the end of this year, and we wish to congratulate it for achieving this significant milestone.

IPAC applauds the United States (US) for its consistent and disciplined application in recent years of the core principles noted above. Its actions have significantly reduced the volume of essential use allowances licensed to US MDI companies. For example, the US EPA allocated only 7% of the allowances authorized by the Parties for 2008 (i.e., 27 out of the 385 tonnes). This should provide a positive example to Article 5 Parties as they implement domestic processes to allocate essential use CFCs for MDIs.

IPAC notes the TEAP/MTOC's questions regarding the US nomination for 2011 intended for use in epinephrine CFC MDIs (revised downward in August 2009 from 67 tonnes to 52 tonnes). IPAC believes there would be little risk to patients in deferring a final nomination until next year (consistent with TEAP/MTOC's recommendation). Indeed, this could allow additional information to be on hand regarding the availability of existing CFC stockpiles to meet 2011 needs and the status of the patient transition.

Article 5 Parties

IPAC does not have access to information supporting the nominations submitted by the eight Article 5 Parties (Argentina, Bangladesh, China, Egypt, India, Iran, Pakistan, and Syria). We therefore are not in a position to meaningfully assess them. However, as presented at OEWG-29, TEAP/MTOC carefully reviewed each nomination and, in particular, endeavored to fully understand the availability and affordability of alternatives to CFC MDIs in each Party. IPAC has confidence in the TEAP/MTOC's evaluation of the respective nominations, and believes the conclusions and recommendations set forth in the Progress Report are reasonable and sound based upon the available information. We especially support the decision - in this first year of nominations from Article 5 Parties - to err on the side of patient interests in the face of incomplete (or unclear) nominations.

IPAC concurs with the TEAP/MTOC that in order to adequately assess essential use nominations, it is critical that sufficient information be available to the TEAP/MTOC members and particularly supports the following recommendations:

- Parties may wish to remind all Parties to collect data on CFC and CFC-free MDIs and provide it annually to the Ozone Secretariat, in accordance with Decision XIV/5.
- Parties may wish to remind all Parties to notify the Ozone Secretariat of any MDI products determined to be non-essential, pursuant to Decision XII/2(3), so that the Secretariat can post the information to its website in a timely manner.
- Parties may wish to consider qualifying any approval of 2010 essential use exemptions with the condition that any Party exporting CFC MDIs will get prior consent from the importing government for such exports.

IPAC agrees that the changes to the Handbook on Essential Use Nominations suggested by the Contact Group Co-Chairs during OEWG are reasonable and consistent with these recommendations. These revisions, if adopted, would enhance the TEAP/MTOC's ability to effectively and accurately evaluate future essential use nominations.

IPAC strongly supports TEAP/MTOC's conclusion that it is unlikely to recommend approval of essential use CFCs intended for products not yet on the market in Article 5 Parties. Approving CFCs for products still in development and not yet even approved for patient use is unnecessary and wholly counterproductive to achieving a timely transition.

► Amending the Montreal Protocol to Control HFCs

In mid-September, the US, Canada, and Mexico submitted several suggested revisions to the Protocol amendment proposed by the Federated States of Micronesia and Mauritius in advance of OEWG-29. IPAC believes that the so-called “North American Proposal” is thoughtful and constructive, and takes into account much of the dialogue that occurred during OEWG-29.

IPAC wishes to emphasize, however, that it is critical to ensure that safe and secure supplies of HFCs remain available to meet patient need over the long term. IPAC recommends that any amendment to control HFCs should provide unambiguous and self-implementing protections for medical uses of HFCs. Reformulating CFC MDIs to use HFCs was a complex and resource-intensive effort taking close to two decades and impacting millions of patients that rely on these life-saving medical devices. At present, no alternative medical propellant to HFCs has been proven safe for patients. The CFC MDI transition is still underway in the United States and many Article 5 Parties. Impeding or slowing the CFC MDI transition would be counterproductive in terms of protecting the ozone layer, as well as from a climate change perspective. In addition, and importantly, restrictions on the availability of HFCs generally could pose unintended consequences for patient care (e.g., shortages of medicines or increased costs). These must be carefully explored and avoided. Existing data illustrates that asthma, COPD, and other respiratory illnesses are currently 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 particularly inappropriate in this context.

It is extremely important to fully evaluate the implications for patient health and to the ongoing CFC MDI transition in advance of adopting measures that could restrict access to HFCs for medical uses. 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, the TEAP/MTOC, and MDI companies. It would not be prudent or necessary to impose a restrictive and burdensome process in the context of a HFC phase-down, especially given the minimal emission reduction opportunities for the MDI sector and important patient care considerations. IPAC believes that a self-implementing mechanism could be established to ensure long-term security of HFCs for MDIs. For example, a paragraph could be inserted in Article 2J of the North American Proposal (as paragraph 9) stating: “The calculated level of consumption under this Article shall not include amounts used by the Party for metered-dose inhalers.” As needed, subsequent decisions of the Parties could address a process for further consideration of the use of HFCs for MDIs.

TEAP Decision XX/8 Task Force Report: IPAC Comments Related to Medical Inhalers

The TEAP Task Force Report contains a brief section related to inhaled therapy. IPAC notes the report states that dry powder inhalers (DPIs) are “available for most inhaled drugs, and could replace the majority of propellant MDIs” and “provide a suitable technical alternative to MDIs for almost all patients.” IPAC agrees that DPIs represent an important and valuable treatment option for millions of patients. Indeed, IPAC members research, develop, manufacture and market a range of DPIs globally. (See IPAC’s Global Database on CFC-Free Products, available at: http://www.ipacmdi.com/documents/IPAC_Database_Nov_2009.pdf.) As reflected in the data set forth in the 2009 Progress Report, DPI usage is increasing worldwide, and the market growth for DPIs exceeds that for MDIs. As TEAP/MTOC point out, DPIs represent an important CFC-free option and could play a valuable role in accomplishing the CFC MDI transition in Article 5 Parties.

When considering “alternatives” for hydrofluorocarbons (HFCs) in the context of mitigating climate change, however, IPAC is concerned that some statements in the Task Force Report could be misinterpreted as supporting a mandated transition from HFC MDIs to DPIs or other restrictions on HFC MDIs. IPAC strongly believes such policies are environmentally unwarranted and could negatively impact patient health. Limiting patient access to HFC MDIs in any way to achieve very minor emission reduction potential is inconsistent with the conclusions of the IPCC/TEAP Special Report on Safeguarding the Ozone Layer and Protecting the Global Climate System: Issues Related to Hydrofluorocarbons and Perfluorocarbons. In this regard, IPAC wishes to highlight the following findings and conclusions set forth in the Medical Aerosols chapter of the Special Report:

- “Both MDIs and DPIs play an important role in the treatment of asthma/COPD and no single delivery system is universally acceptable for all patients. It is critical to maintain the range of therapeutics options.”
- “The choice of the most suitable inhaler is a complex medical decision taken in consultation between the doctor and patient.”
- “The provision of a range of safe alternatives is critical before enforcing change on environmental grounds. Any environmental policy measures for the future that could impact patient use of HFC MDIs would require careful consideration and consultation with physicians, patients, national health authorities, and other health-care experts.”
- “The health and safety of the patient is of paramount importance in treatment decision and policymaking that might impact those decisions.”
- “The environmental benefits of converting HFC MDIs to DPIs are small.”
- “If one assumes a hypothetical switch for the most widely used inhaled medicine (salbutamol) from HFC MDIs to DPI, the projected recurring annual costs would be on the order of US\$ 1.7 billion with an effective mitigation cost of between 150-300 US\$/tCO₂-eq.”

The concept of “alternatives” – which implies a one-for-one essentially equivalent substitute – does not fit well within the context of medical inhalers. As the IPCC/TEAP Special Report highlights, the choice of inhaler is a complex medical decision. In addition, it is important to preserve therapeutic options for patients and maintain patient choice. The inhaler market and health care system in each Party is unique, ever-changing, and impacted by a myriad of complicated factors. A 2004 paper published in the JOURNAL OF DRUG ASSESSMENT provides useful background and context – The Importance of Preserving Choice in Inhalation Therapy: The CFC Transition and Beyond (Volume 7, pp. 45-61). IPAC would be pleased to provide technical support and guidance to the Parties on issues relevant to the HFC MDI sector, as needed.



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