



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

FOR THE 18TH MEETING OF THE PARTIES TO THE MONTREAL PROTOCOL
New Delhi, India (30 October - 3 November 2006)

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 MDI transition that balances patient health and environmental concerns.

IPAC is concerned that as the transition nears completion in non-Article 5 Parties, excessive or inappropriate essential use allocations could undermine the transition and possibly put patients at risk. IPAC believes the draft decision put forward by the European Community addresses this concern and, with minor modifications, should be adopted at MOP-18.

IPAC moreover believes that at this stage of the transition, CFC-free alternatives are available in non-Article 5 Parties for all but a few CFC MDI products. The Parties should therefore begin to assess the continued need for and feasibility of annual essential use authorizations versus a final campaign production for those few remaining essential products of companies that are diligently conducting R&D on CFC-free replacements.

► Ensuring Appropriate Allocations

- IPAC has for several years supported the position that essential use CFCs should not be authorized for:
 - Single-moiety salbutamol MDIs intended for sale or distribution in non-Article 5(I) Parties;
 - CFC MDI products for which the company has launched a CFC-free alternative (after an adequate post-marketing period);
 - MDI companies that are not currently conducting sincere and concerted efforts to develop CFC-free alternatives;

► EC Draft Decision

- The EC decision (par. 1 and Annex) would rescind the U.S. 2007 authorization. Approximately 700 to 800 tonnes of the U.S. authorization for 2007 is for single-moiety salbutamol; the Parties should cut the U.S. authorization by that amount. Most of this volume was requested by the U.S. for one company, Schering Plough, which has announced that it will cease manufacturing CFC salbutamol in early 2007.
- The EC decision (par. 1 and Annex) would approve the U.S. 2008 nomination explicitly not for single-moiety salbutamol. This is consistent with TEAP's recommendation and with the U.S. nomination itself.
- The EC decision (par. 2) would prohibit Parties from allocating domestically any CFCs for single-moiety salbutamol for sale in a non-Article 5 market. CFC-free salbutamol MDIs are widely available in non-Article 5 countries. The limited CFCs available should only be used for products for which there are no CFC-free alternatives.

- The EC decision (par. 3) would require Parties to use pre-1996 CFC stock before new CFCs are used (taking into account some companies use a blend of different types of CFCs). While this is consistent with TEAP's recommendation, IPAC believes that full implementation of the one-year operational supply provision (Decision XVII/5 par. 3) would make it unnecessary to differentiate between pre- and post- 1996 CFC stock. IPAC agrees with TEAP, however, that pre-1996 CFC stock should only be used for essential MDIs.
- The EC decision (par. 4) would prohibit authorization of CFCs to companies that: (a) have no "practical prospect" of completing R&D on their CFC-free replacement by 2009, and (b) are not diligently transitioning their markets. IPAC fully supports the second of these, but with respect to the first believes that some flexibility should be made for companies that are diligently pursuing R&D of replacements to their CFC products for which there are no CFC-free alternatives.
- The EC decision (par. 5) would set a deadline of "in time for consideration at" MOP-19 for Nominating Parties to submit plans of action phasing out remaining uses of CFCs in MDIs. MOP-19 is tentatively scheduled for September 2007, which should be ample time for the countries to which this applies. These countries have been on notice since the adoption of Decision XV/4 in November 2003 that such plans of action are needed.

➤ Final Campaign

- IPAC also recommends that the Parties request TEAP to assess the feasibility of having MOP-19 declare 2008 to be the last year for essential use authorizations, with a final campaign production for certain limited, specified post-2008 uses.
- Establishing a date-certain end to new CFC production for essential uses furthers the overarching goals of the Montreal Protocol. IPAC recommends that the Parties request TEAP to assess whether 2008 can be the last year for essential use authorizations, if it is coupled with a final, limited campaign production of pharmaceutical-grade CFCs specifically for:
 - Article 5 MDI needs, and
 - Companies producing MDIs (other than single-moiety salbutamol) for non-Article 5 markets which are diligently conducting R&D on replacements for their CFC products for which there are no CFC-free alternatives.

ASTRAZENECA ■ BOEHRINGER INGELHEIM ■ CHIESI FARMACEUTICI
GLAXOSMITHKLINE ■ INYX, INC. ■ SEPRACOR

IPAC CONTACT AT MOP-18
Peter Blenkinsop
Oberoi Hotel
(+91) 11.2436.3030
Mobile: (+1) 312.771.8056
Email: pblenkinsop@gcd.com