



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

FOR THE 26TH MEETING OF THE OPEN-ENDED WORKING GROUP

Montreal, Canada (3-6 July 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.

► Therefore, IPAC recommends that the OEWG forward to the Parties for adoption at MOP-18 a decision that prohibits the authorization and allocation of CFCs for:

- Production of single-moiety salbutamol MDIs intended for sale or distribution in non-Article 5(i) Parties
 - Sufficient CFC-free alternatives to these products are widely available in all developed countries
 - In the United States, four CFC-free alternatives to salbutamol MDI products have been approved and are now on the market with adequate production capacity
- CFC MDI products for which the company has launched a CFC-free alternative (after an adequate post-marketing period)
 - TEAP has recognized that “dual marketing” of both a CFC and CFC-free alternative by a company is inconsistent with Decision IV/25
 - In the U.S., one company has used thousands of tonnes of CFCs over the past decade, despite having an approved CFC-free replacement on the market
- MDI companies that are not currently conducting sincere and concerted efforts to develop CFC-free alternatives
 - The essential use exemption was never intended to be indefinite
 - It is counter-productive at this point in the transition to allocate CFCs for products where research and development of the CFC-free alternative has not yet reached an advanced stage.

► IPAC also requests that the Parties consider the following points relevant to progressing the MDI transition:

- Decision XVII/5 requires Parties to submit, in advance of MOP-18, a date by which time a regulation or regulations to determine the non-essentiality of the vast majority of non-single moiety salbutamol MDIs will have been proposed. CFCs should not be allocated for use in any products that have been declared non-essential.
- Should the US nomination for 2008 be approved by the Parties this year (as recommended by TEAP), any non-essentiality determinations effective before or during 2008 must be taken into account at the allocation stage. In addition – and as further recommended by TEAP – the 2008 authorisation should be clearly restricted for use only in those active ingredients identified in the US nomination: flunisolide, metaproterenol, ipratropium and salbutamol (in combination), pirbuterol, epinephrine, triamcinolone, cromolyn, and nedocromil, and *not* for use in single-moiety salbutamol MDIs.
- It is important for Parties to proactively and effectively implement the existing Protocol decisions relevant to the management of pharmaceutical-grade CFC stockpiles (Decision XVI/12 and Decision XVII/5). Consistent with TEAP's recommendation, the Parties should require that pre-1996 CFC stocks be used before new CFCs are produced (keeping in mind that some companies use a blend of different types of CFCs and all may not be available in stocks).
- IPAC agrees with TEAP that there is an urgent need for Article 5(1) Parties to develop national MDI transition strategies and this should be a priority.
- As noted by TEAP, IPAC companies are already marketing a range of CFC-free alternatives in many Article 5(1) Parties. IPAC members will continue to seek approval for, and strive for a timely launch of, additional CFC-free alternatives in these countries. A summary of the availability of CFC-free products launched by IPAC companies in Article 5(1) Parties can be found at: <http://www.ipacmdi.com/documents/IPAC%20Database%20Art5.pdf>.

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