



IPAC

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM

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

FOR THE 19TH MEETING OF THE PARTIES
Montreal, Canada (17-21 September 2007)

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.

ON THE OCCASION OF THE 20TH ANNIVERSARY OF THE SIGNING OF THE MONTREAL PROTOCOL, IPAC WOULD LIKE TO ENTHUSIASTICALLY CONGRATULATE THE PARTIES ON THEIR EXCEPTIONAL COMMITMENT AND TIRELESS EFFORTS AIMED AT HEALING AND PROTECTING THE EARTH'S OZONE LAYER.

The transition from CFC MDIs to CFC-free alternatives has now reached a mature stage in non-Article 5(I) Parties. In order to sustain this progress toward completion of the essential use process, it is critical to effectively manage the "end game" of the transition. Excessive or inappropriate essential use allocations could undermine the transition. Measures needed to achieve this important objective are detailed below. In addition, with the phase-out deadline for Article 5(I) Parties rapidly approaching, IPAC recommends that the Parties implement, on a priority basis, the measures adopted last year in Decision XVIII/16.

► Ensuring Appropriate Essential Use Allocations of CFCs for MDIs

The following principles should be applied in authorizing and licensing essential use CFCs for MDIs:

- CFCs should no longer be allocated for use in the manufacture of single-moiety salbutamol CFC MDIs intended for non-Article 5(I) markets.
 - The US is the sole remaining non-Article 5(I) Party where CFC salbutamol MDIs remain essential. The US did not allocate CFCs for salbutamol MDIs in 2007 and has proposed not to allocate CFCs for these products in 2008 (final allocation is pending), consistent with their nomination for 2008. Similarly, the 2009 nomination indicates that the US is not requesting CFCs for these products based upon the 31 December phase-out date. *To ensure that this positive direction continues, the Parties should explicitly state in the essential use Decision this year that CFCs must no longer be allocated for single-moiety salbutamol MDIs intended for use in non-Article 5 markets.*
- CFCs should only be allocated to companies diligently engaged in research and development of a corresponding CFC-free alternative and whose R&D efforts have reached an advanced stage (i.e., phase 3 clinical trials).
 - At this late stage, it is counterproductive to continue to allocate CFCs for products for which reformulation is not at an advanced stage and, thus, may never be transitioned.
 - National regulatory bodies should be encouraged to conduct timely review of applications for CFC-free replacements consistent with Decision VIII/11(2). At this late stage in the transition, it is particularly important for health regulatory bodies to address the review and consideration of applications for CFC-free products on an urgent and expedited basis.

please see reverse 

- The Parties should reiterate that Protocol decisions governing stockpiles must be effectively implemented.
 - In this end-period of the transition it is important that excessive stockpiles be used before new CFC production is authorized. Strictly adhering to the stockpile provisions in Decisions XVI/12, XVII/5, and XVIII/7 concerning one-year operational supply will ensure that new CFCs are only produced when truly necessary.

➤ Essential Use Nominations for 2008 and 2009

- IPAC notes that TEAP/MTOC has recommended approval of the European Community's and United States' nominations for 2008 and 2009. IPAC firmly believes that it would be best to defer until 2008 a final authorization – if needed at all – for essential use volumes for 2009 in the US. Importantly, the US has recently indicated that in light of existing stockpiles it does *not* expect that production of pharmaceutical-grade CFCs will be needed during 2009. As noted above, it is important to use existing stockpiles wherever possible to avoid new production of CFCs. In addition, critical information will be available next year regarding CFC needs in the US – particularly the US FDA rulemaking on the phase-out timeframe for the CFC MDIs remaining on the market there.

➤ MDI Transition in Article 5 Parties

- TEAP's 2007 Progress Report provides a detailed assessment and analysis of the MDI transition in Article 5(I) Parties, including issues related to the potential need for supply of pharmaceutical-grade CFCs for MDIs beyond the January 1, 2010 phase-out date. The Report expresses "serious concerns about the security of supply of diminishing quantities of pharmaceutical-grade CFCs if the option of annual production of CFCs for 2009, 2010, and beyond was chosen." In light of these concerns, IPAC recommends that the Parties – in coordination with the TEAP/MTOC as appropriate – undertake on a priority basis a more definitive assessment of the future CFC needs for MDIs in Article 5(I) markets and consider how these needs will be met. It is also important for Decision XVIII/16 to be fully implemented by the Parties, including paragraphs 7 and 8 which call for the preparation of "export manufacturing transition plans" by MDI manufacturers for certain Article 5(I) markets.

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

IPAC CONTACT AT MOP-19
Maureen Hardwick
InterContinental Hotel
Hotel Telephone: 514.987.9900
Mobile: (+1) 301.980.7837
Email: maureen.hardwick@dbr.com