



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

FOR THE 17TH MEETING OF THE PARTIES TO THE MONTREAL PROTOCOL
Dakar, Senegal (12 to 16 December 2005)

➤ **Negotiate from the EU's proposed decision on essential use authorizations.**

- The EU's proposed decision represents a good-faith attempt to incorporate TEAP's recommendations; the US's proposed decision is simply a restatement of its nominated amounts, which TEAP did not recommend.

➤ **Authorize 2006 essential use volumes that are lower than proposed in the draft decision by the European Community.**

- The United States' authorization for 2006 should be a single number equal to "1242 minus any available pre-1996 stockpile that satisfies the United States regulatory requirements sold into the United States market for use in MDIs".
- However, this amount should be further *reduced* by at least 100 tonnes, due to the fact that certain products which used CFCs in 2004 (and thus were counted in the 1242 figure) have been converted to CFC-free.
- No further quantities should be added to the US authorization:
 - The additional 180 tonnes for CFC salbutamol imported from the EU should not be added to the US total, because that amount is included in the EU nomination, and because the importing company has a CFC-free salbutamol MDI on the market in the US.
 - No additional amount for "recycled and destroyed" should be added to the US authorization, because such quantities are already counted in the 1242 figure.
- Effective 2 December 2005, GlaxoSmithKline sold its entire stockpile of pharmaceutical-grade pre-1996 CFCs, 605 tonnes, into the US market exclusively for MDI use.

➤ **Adopt the provision in the EU's proposed decision to apply a one-year stockpile limit at the time of essential use licensing.**

- TEAP has recommended many times that a one-year stockpile is sufficient; larger stockpiles will impede the transition.
- The US has publicly stated that it does not believe that current Protocol decisions require it to apply the one-year rule at the time of licensing, yet the US has a stockpile in excess of two-years of current use.

➤ **Adopt the provision in the EU's proposed decision that Parties not grant essential use licenses to companies for products for which the company has a corresponding CFC-free alternative.**

- Granting essential use licenses to companies for products more than a year after approval of a corresponding CFC-free alternative is counter to Decision IV/25. It also violates the spirit of Decision VIII/10's obligation that companies conduct research and development on non-ODS alternatives.
- In particular, TEAP/MTOC have expressed strong concern that companies continue to receive essential use volumes for salbutamol MDIs when they have CFC-free salbutamol MDIs on the market.
- The Meeting of the Parties should not defer operation of this provision until 2007, but make it effective upon adoption.

➤ **Adopt the provision in the EU's proposed decision that Nominating Parties submit essential use nominations only one year in advance.**

- This was strongly recommended by TEAP, "given the rapidly changing technical and economic environment in these final stages of transition."
- IPAC believes that this need not present regulatory problems in the EU or the US, the two Parties in which its member companies receive essential use allocations.

IPAC is a group of companies that manufacture medicines for the treatment of respiratory illnesses, such as asthma and COPD. We are firmly committed to a timely, effective transition that is smooth and safe for patients.

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

IPAC CONTACT AT MOP-17
Maureen Donahue Hardwick
Le Meridien President Dakar
(01) 221.869.6969
Mobile: (01) 301.980.7837
Email: mhardwick@gcd.com