



**IPAC**

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM

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

FOR THE 20<sup>TH</sup> MEETING OF THE PARTIES  
Doha, Qatar (16-20 November 2008)

*IPAC is a group of companies that manufacture medicines for the treatment of respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD). IPAC has long supported and remains firmly committed to a timely and effective MDI transition that balances patient health and environmental concerns.*

## ► Principles to Ensure Appropriate Essential Use Allocations for MDIs

The transition from CFC MDIs to CFC-free alternatives has now reached a mature stage in non-Article 5 Parties. In order to sustain the progress toward completion of the essential use process, IPAC recommends that these core principles be applied by the Parties in authorizing and licensing essential use CFCs for MDIs:

- Allocate CFCs only for use in the few products, including combination products, that remain essential for patients *and* where the corresponding CFC-free alternative is either under active review by regulatory authorities or on track to generate a near-term (by end 2008) comprehensive submission for regulatory approval (e.g., new drug application).
- 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.

## ► Essential Use Nominations for 2009 and 2010

IPAC notes that TEAP/MTOC was unable to recommend approval of the European Community's (EC) and United States' (US) nominations for 2009 and 2010, respectively. IPAC appreciates the TEAP/MTOC's careful review and expert conclusions.

Regarding the EC nomination, this summer IPAC and its members engaged with the EC in its good faith effort to identify and facilitate the transfer of available CFC stockpiles to reduce its 2009 nomination. IPAC understands that (i) the EC's effort has enabled it to reduce its 2009 nomination from 38 to 22 tonnes and (ii) the EC has provided the TEAP/MTOC with supplemental information and data supporting that reduced amount. IPAC applauds the EC's efforts to minimize its final essential use nomination. Consistent with the principles above, IPAC supports the Parties' approval in 2008 of the EC's revised nomination for those products, including combination products, that have reached a very advanced stage of R&D and where existing stockpiles may not be available to meet 2009 needs.

Regarding the US nomination, IPAC concurs with TEAP/MTOC that it is not possible to accurately predict this year needs for 2010 – if any – given pending regulatory rulemakings and the potential availability of stockpiles. Therefore, at a minimum, it would be best to defer until 2009 a final authorization of essential use volumes – if even needed – for 2010. Important information will be available next year, including final regulations on the phase-out timeframes for the CFC MDIs remaining on the US market. IPAC commends the US for substantially reducing its 2010 nomination via use of existing stockpiles and reducing the volume of essential use allowances licensed to MDI companies this year (US EPA allocated only 27 out of the 385 tonnes authorized by the Parties for 2008).

## ► MDI Transition in Article 5 Parties

The Ozone Secretariat's *Review of Essential Use Decisions (UNEP/OzL.Pro.20/8)* assesses all relevant decisions on essential uses and considers how they could be extended to Article 5 Parties. IPAC believes this will be a helpful resource for the Parties and wishes to emphasize the following points and recommendations:

- Decision IV/25 was the starting point for the essential use process and subsequent Decisions taken by the Parties have provided important guidance and helped progress the MDI transition toward completion. The essential use process is a temporary exception and should be rigorously implemented to limit the allocation of essential use CFCs only to those circumstances where truly needed for patient health. Therefore, it is critical to ensure that all of the relevant decisions are applied to Article 5 Parties should an essential use process be needed after 1 January 2010.
- Parties seeking essential use nominations must provide comprehensive and detailed supporting data. Ensuring that the relevant essential use decisions are effectively applied to Article 5 Parties will also support the MTOC/TEAP's central and important role in providing technical and expert advice to the Parties.
- In its Review, the Secretariat identified a category of decisions that established deadlines that have passed. For example, Decision XII/2(2) states that any CFC MDI product approved after 31 December 2000 for treatment of asthma or COPD is not an essential use unless the product meets the criteria established in Decision IV/25 1(a). IPAC firmly supported this provision which discourages the introduction of new CFC-containing MDIs and considers it to be a very positive addition to the essential use process. IPAC urges the Parties to apply a similar provision to Article 5 Parties – and suggests a deadline of 1 January 2009. IPAC further urges the Parties to consider establishing interim deadlines for key milestones in the Article 5 transition like those that were adopted for non-Article 5 Parties. For example, a firm deadline for submission of plans of action on the phase-out of salbutamol like that set forth in Decision XV/5. IPAC suggests that these plans of action should be submitted no later than the 21st Meeting of the Parties (tentatively scheduled for 23-27 November 2009).
- At this late stage, and in a circumstance of declining CFC supply, it makes most sense from a patient health perspective to preserve pharmaceutical-grade CFCs for those products with a realistic opportunity to accomplish a seamless transition to a direct replacement. Decisions VIII/10 and XIX/13 contain important provisions requiring pharmaceutical companies to demonstrate ongoing research and development of CFC-free alternatives for the treatment of asthma and COPD. These decisions should be fully applied to Article 5 Parties. Ensuring that companies receiving essential use allocations are undertaking diligent efforts to research and develop ozone-friendly alternatives is an effective means to progress the CFC MDI transition toward closure.
- A wide range of CFC-free products is currently available in Article 5 Parties. IPAC's *Global Database on the Availability of CFC-Free Products* provides significant data in this regard (available at [www.ipacmdi.com](http://www.ipacmdi.com)). This data illustrates that the global transition to CFC-free products is well advanced in Article 5 markets and, therefore, the need for an essential use process beyond 2010 would appear to be quite limited both in terms of volume of CFCs authorized and duration.

## IPAC COMMITMENTS ON MDI TRANSITION

IPAC recognizes that multinational companies continue to play an important role in promoting smooth and timely transitions – consistent with patient health – in both Article 5 and non-Article 5 Parties. In this spirit, IPAC member companies reiterate their commitment to the following:

- To **not** seek new production of essential use CFCs after 2008 for use in MDIs intended for either Article 5 or non-Article 5 Parties, absent compelling evidence that existing stockpiles are unavailable – an exceptional and unlikely circumstance. This will provide a critical signal to patients, health care providers, manufacturers, and – importantly – Article 5 governments, that the MDI transition is near conclusion.
- To **not** engage in “dual-marketing” of a CFC MDI in a Party where the company has launched the corresponding CFC-free alternative (after an adequate parallel marketing period – no more than 12 months – needed for patient safety), unless infeasible because of government action or pre-existing contractual obligations.
- To **not** manufacture CFC MDIs for sale in Article 5 markets after 2009, except in the very narrow circumstance where: (i) the replacement for a CFC MDI has reached an advanced stage of research and development (i.e., phase III clinical trials); (ii) the product is essential for patients; and (iii) a relatively limited additional period of time is needed to accommodate a seamless transition to the direct replacement. Consistent with the first bulleted commitment above, it is anticipated that CFCs for these MDIs would be sourced from existing stockpiles, rather than from new production. Rationalizing small quantities of already produced CFCs to meet patient needs in Article 5 (as well as non-Article 5) Parties, rather than simply destroying all remaining stockpiles, is a pragmatic approach.



---

ABBOTT ■ ASTRAZENECA ■ BOEHRINGER INGELHEIM ■ CHIESI FARMACEUTICI  
GLAXOSMITHKLINE ■ TEVA ■ SEPRACOR INC.

---

IPAC CONTACT INFORMATION  
Maureen Hardwick  
Secretary and Legal Counsel  
[Maureen.Hardwick@dbr.com](mailto:Maureen.Hardwick@dbr.com)