

Metered Dose Inhaler Transition Issues at the 23rd Meeting of the Open-Ended Working Group of the Montreal Protocol

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The International Pharmaceutical Aerosol Consortium (IPAC) appreciates the work of the Technology and Economic Assessment Panel (TEAP) in considering issues surrounding the transition to CFC-free metered dose inhalers (MDIs). In its May 2003 Report, TEAP made recommendations concerning essential use nominations for MDIs. The 2003 Report also (i) reviews the status of the MDI transition around the world and (ii) reviews issues related to CFC supply for the production of MDIs.

TEAP makes several observations about the status of the transition, particularly the need for additional action by the Parties to ensure that the transition proceeds in a prompt, orderly manner.

IPAC wishes to affirm its commitment to a timely, efficient transition to CFC-free products and requests that the Parties undertake the actions described below in furtherance of this important objective. In particular, IPAC requests the Parties to adopt a decision this year to facilitate phase-down and closure to the MDI transition.

ESSENTIAL USE NOMINATIONS

European Community

TEAP's May 2003 Report recommends approval of the European Community's nomination for 2005 of 800 tonnes of CFCs. The Report notes that the volumes requested for 2005 represent a greater than 50% decline from the quantity requested in 2004. The TEAP Report observes that the fact that 11 Member States and Norway have declared CFC salbutamol MDIs non-essential is a significant step for the EU's

transition. More than half of the volumes requested by the European Community for 2005 are for the manufacture of MDIs intended for export to other Parties.

United States

The United States has requested the Parties to authorise 1902 tonnes of CFCs for the manufacture of MDIs in 2004. TEAP's May 2003 Report recommends approval of the 2005 nomination. The Report notes, however, that the volumes requested for 2005 are larger than the volumes actually used in 2002. TEAP also observes that over 90% of salbutamol (albuterol) MDIs in the United States still use CFCs, although two salbutamol HFC MDIs have now been available in the United States for more than a year. Therefore, IPAC believes that it is time for the US to initiate the process established in its national transition strategy to phase out salbutamol.

Other Parties

TEAP's May 2003 Report also recommends approval of essential use nomination requests from Poland, the Russian Federation, Switzerland, and the Ukraine. TEAP observes that two countries previously requesting CFCs for essential uses – Australia and Japan – did not submit nominations for this year. The data from these two countries shows an overall trend of decreasing CFC usage for MDIs.

IPAC requests that the OEWG support TEAP's recommendations on essential use allowances.

Data on Salbutamol MDIs

TEAP also observes that while salbutamol CFC MDIs comprised the majority (60%) of all MDIs

prior to the transition, now a range of suitable CFC-free alternatives are available worldwide and some Parties have declared salbutamol CFC MDIs to be non-essential. However, CFC MDIs still constitute a major part of CFC consumption in some Parties, and TEAP notes that Parties should consider identifying the proportion of their future essential use allowances intended for the manufacture of salbutamol MDIs in order to better inform the nomination process.

IPAC agrees and requests that the Parties consider how best to put this into effect. Also, as noted in more detail below, IPAC firmly believes it is time for the Parties to agree on a cessation of essential use authorisations for CFC salbutamol MDIs.

STATUS OF MDI TRANSITION

Transition in Non-Article 5(1) Countries

TEAP's May 2003 Report observes that while the transition in non-Article 5(1) countries is well underway much still remains to be done. IPAC concurs with TEAP's assessment that the launch of CFC-free products alone will not lead to a timely completion of the transition and that clear, effective and binding national transition strategies, as well as further regulatory action, is necessary to achieve this important objective. IPAC agrees with TEAP's assessment that additional steps are necessary for an effective transition, particularly "ceasing the supply of CFC MDIs where alternatives exist." In this regard, IPAC proposes that additional Protocol measures be adopted this year in order to ensure the MDI transition is driven effectively to closure.

The transition of salbutamol MDIs is critical to the overall transition given that these products represent at least half of the worldwide market. Completion of the salbutamol transition will significantly reduce CFC usage. For example, should the US deem salbutamol non-essential, its CFC usage could be decreased by approximately 50%. Therefore, TEAP appropriately focuses much of its 2003 report on these products. TEAP notes that two or more CFC-free

salbutamol MDIs are available on the market in approximately 30 non-Article 5(1) countries. In addition, one or more CFC-free salbutamol MDI products is on the market in at least 30 Article 5(1) countries.

The wisdom of TEAP's assessment that complete transition requires regulatory action can be seen by contrasting the current transition status in the major markets in the developed world. In the US, where no CFC products have yet been determined non-essential, despite two CFC-free salbutamol MDI products being available for over a year, more than 90% of salbutamol MDIs still use CFCs. In contrast, Canada, Australia, and Japan have set firm dates for phasing out CFC MDIs and thereby have been able to advance the transition to final closure. In addition, these three countries, as well as twelve countries in Europe, have declared the use of CFCs in salbutamol MDIs to be non-essential.

In its 2002 Report, TEAP noted that although Decision XII/2 provides that all non-Article 5(1) Parties should develop and submit their national transition strategies by 31 January 2002, only 8 of 43 countries had done so. This year, TEAP reports that no additional countries have submitted strategies during the past year. This trend is of concern and, as detailed below, serves as an important rationale for adoption of additional Protocol-level measures to progress the transition in non-Article 5(1) Parties.

Transition in Article 5(1) Countries

TEAP's Report estimates that as much as 1,600 tonnes of CFCs may be used for MDIs in Article 5(1) countries and observes that these quantities appear to be increasing. IPAC concurs with TEAP's assessment that while multinational companies that export CFC MDIs to these countries will exercise some control over the phase out of these products, "there are no clear strategies for that proportion of CFC MDIs produced by local manufacturers."

In its 2002 Report, TEAP recommended that it is important for Article 5(1) countries to develop now national transition strategies. IPAC concurs with this recommendation.

Transition in Countries with Economies in Transition (CEIT)

TEAP's Report estimates that over 500 tonnes of CFCs are used for MDIs in CEIT. TEAP notes that only 2 of 17 CEIT have submitted national transition strategies to the Ozone Secretariat. TEAP concludes that insufficient data exists in many CEIT to assess the status of the transition and make recommendations with regard to assuring an effective transition.

IPAC supports TEAP's request for enhanced participation of MDI experts from these countries on its technical options committee.

PROPOSED MEASURES TO PROGRESS THE TRANSITION IN NON-ARTICLE 5(1) PARTIES

As noted above, there has been some progress on the transition, particularly in those countries that have proactively implemented clear, effective national transition strategies. However, IPAC remains concerned that a significant portion of the decline in essential use volume requests in recent years is due largely to the voluntary actions of a few pharmaceutical companies and, therefore, that this trend will not continue uninterrupted to a timely closure of the transition. This concern is amplified by the fact that only a minority of non-Article 5(1) countries have even adopted national transition strategies and of those that have, some have proven to be ineffective.

While CFC-free products are increasingly available across the developed world, TEAP has recognised that market forces alone will not ensure completion of the transition and that additional action is necessary. IPAC shares this view and believes that it is important, and feasible, to adopt a Protocol decision this year that establishes a firm closure date for the completion of the essential use process in the developed world accompanied by strong interim measures designed to achieve significant near-term reductions in CFC usage.

IPAC proposes that the year 2007 be the last year for which essential use volumes are authorised by the Parties for non-Article 5(1) countries. In order to protect patient health, this 2007 closure date should be subject to a narrow exception which would permit the Parties to approve, on a case-by-case basis, after TEAP review and recommendation, limited annual essential use authorisation of CFC production for a CFC MDI product destined for a market in which the product is clearly indispensable for patient care.

In addition, IPAC proposes the adoption of the following near-term measures to ensure that the 2007 closure date is met:

- No CFCs should be authorised for use after 2005 to manufacture single-moiety salbutamol CFC MDIs for sale or distribution in non-Article 5(1) countries.
- CFCs should not be authorised for products that are not evidenced to be under active reformulation.

The first of these near-term measures will assure that CFCs are only used where absolutely needed for patients. The second measure will assure that CFCs are only used by companies that are making a good faith effort to transition their products.

It is also important to keep in mind that in light of their responsibility to review and approve CFC-free therapies for patients, national health authorities play a critical role in the MDI transition. Therefore, the pace of regulatory approvals for CFC-free products remains a major issue. Decision VIII/11, paragraph 2, requests national authorities to expedite approval of such products. To date, however, IPAC is not aware of any Parties that have taken such action. Therefore, a Protocol decision establishing a closure date to the essential use process should strongly urge all Parties to conduct expedited review of CFC-free products consistent with patient health, and not to discriminate against CFC-free products in pricing or reimbursement decisions solely on the basis of cost.



CFC SUPPLY FOR MDIS

TEAP notes that the CFC production facility in Weert, the Netherlands is expected to close by the end of 2005. TEAP acknowledges that this could present issues for some Parties, particularly the United States, if there is a need for CFCs after 2005 in amounts that exceed existing stockpiles and if no alternative just-in-time source of supply is available. IPAC believes that issues of CFC supply will not arise if Parties undertake to proactively implement effective national transition strategies and thereby bring the transition to a timely closure.

IPAC concurs with TEAP's assessment that it is premature now to make definitive plans for campaign production. However, the uncertainty of continued pharmaceutical-quality CFC supply heightens the need for a Protocol decision this year to cease CFC use for products, such as salbutamol, where adequate CFC-free substitutes are widely available.

GLOBAL DATABASE ON MDIS AND DPIS

IPAC welcomed Decision XIV/5 which calls for the development of a global database summarising the worldwide availability of CFC

MDIs and CFC-free products. IPAC believes such a database could serve as an important resource for ATOC, TEAP, and the Parties in evaluating annual requests for essential use CFC volumes and ensuring that CFCs are authorized only where necessary to serve patient need. Therefore, IPAC supported the efforts of the European Community and other Parties during the data collection process. However, TEAP's Report notes that while some information has been submitted, the Parties have adopted varying database templates making it difficult to understand and analyse the data. IPAC concurs with TEAP's recommendation that the Parties consider harmonising the databases.

In addition, IPAC firmly believes that public access to non-confidential data should be promoted to enhance the transparency of the process and further the MDI transition. Therefore, IPAC has compiled non-confidential data related to the worldwide availability of CFC-free products produced by its member companies. The database can be accessed at www.ipacmdi.com. IPAC also believes the Parties would benefit if all non-confidential data submitted under Decision XIV/5 were posted on the Protocol Secretariat website, and therefore IPAC requests that the Parties authorise the Secretariat to do so.

IPAC RECOMMENDATIONS

IPAC supports TEAP's recommendation on essential use authorisations.

IPAC requests that the OEWG support adoption at MOP-15 of a Protocol decision to:

- (a) cease further essential use authorisations for single-moiety salbutamol for sale or distribution in non-Article 5(1) countries after 2005;**
- (b) cease essential use authorisations for CFC products not actively being reformulated and progressed to market after 2005; and**
- (c) establish a 2007 closure date, with a narrow exception, for the essential use process in non-Article 5(1) countries.**

IPAC looks forward to working with Protocol delegates, national governments, stakeholders and TEAP on these important CFC MDI transition issues.

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