

Metered Dose Inhaler Transition Issues at the 15th Meeting of the Parties of the Montreal Protocol

Nairobi, Kenya (10-14 November 2003)

INTRODUCTION

At the 23rd Meeting of the Open-Ended Working Group (OEWG) in July 2003, the delegates:

- recommended to the Parties that the CFC volumes nominated by the European Community, Poland, the Russian Federation, Switzerland, Ukraine, and the United States be authorised for the manufacture of MDIs in the years 2004 and 2005;
- considered a proposal by the European Community that would establish Protocol-level measures to promote the future closure of the essential use process for CFCs for MDIs in non-Article 5(1) Parties (UNEP/OzL.Pro/WG.1/23/CRP.7); and
- received an update on the information submitted by the Parties for the global database on MDIs and DPIs required pursuant to Decision XIV/5.

The International Pharmaceutical Aerosol Consortium (IPAC) requests that the 15th Meeting of the Parties (i) adopt the decision proposed by the European Community to establish Protocol-level measures to promote the future closure of the essential use process in non-Article 5(1) countries; and (ii) support the OEWG's recommendations regarding essential use allowances for 2004 and 2005.

STATUS OF MDI TRANSITION

Transition in Non-Article 5(1) Countries

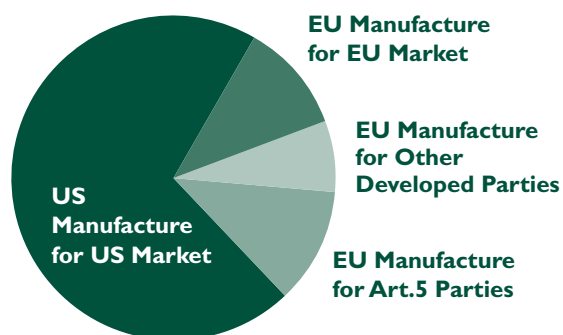
TEAP's May 2003 Report observes that while the transition in non-Article 5(1) countries is

well underway much remains to be done. TEAP reiterated this point during its report to the delegates at the OEWG 23 meeting in July, and noted that action now by the Parties is needed to complete the phase out of CFCs for MDIs. TEAP also reported to the delegates its recommendation that the most effective approach to achieving transition was government/industry cooperation to define a firm date by which CFC MDI sales should cease once sufficient alternatives are available.

The basis for 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. This disparity illustrates well the reality that meaningful uptake of CFC-free replacement products will not occur absent government intervention.

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%. The chart below illustrates the

significant positive impact that the declaration of non-essentiality of salbutamol CFC MDIs in Europe has had on the EU's volume requests for 2005, as compared to the United States. The EU's total request represents well less than half of the United States' request. In addition, a significant portion of the EU's request is intended for use in product exported outside of the European Union.



Indeed, the United States noted in its 2005 nomination request that “removal of albuterol MDIs as an essential use would result in a substantial reduction in future US nominations,” and expressed its hope that the “transition will proceed in a manner that obviates the need for the US to use the full amount requested [for 2005].”

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.

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.

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, as detailed below, 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.

It should also be remembered 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 critical issue. Decision VIII/11 requests national authorities to grant timely approval of such products.

IPAC urges all Parties to conduct timely review and approval 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.

Transition in Article 5(1) Countries

TEAP 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 emphasized the importance of all Article 5(1) countries developing and implementing effective national transition strategies. IPAC concurs with this recommendation.

Transition in Countries with Economies in Transition (CEIT)

TEAP 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. TEAP also stated that it would welcome experts from CEIT in addition to those already serving from Russia and Poland.

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

PROTOCOL MEASURES TO PROMOTE THE CLOSURE OF ESSENTIAL USE NOMINATIONS FOR MDIS

At the 23rd OEWG meeting, the European Community proposed a decision that would establish several Protocol-level measures to promote the closure of the essential use process for MDIs in non-Article 5(1) Parties. In introducing the proposal, the European Community acknowledged TEAP's recommendation that Protocol measures coupled with regulatory action are necessary to complete the CFC MDI transition, and detailed the following additional rationale for the decision:

- the transition is proceeding much more slowly than expected;
- the essential use exemption was always intended to be temporary to allow for the development of sufficient CFC-free alternatives and implementation of effective national transition strategies. However, approval of essential use authorisations has become "almost business as usual, with little opportunity to debate whether there is a real need for the CFC volumes requested;"
- the countries that have successfully phased out categories of CFC MDIs – such as Japan, Canada, and Australia – have done so by establishing clear deadlines with enough lead-time to allow physicians, patients, and MDI producers to plan effectively for the transition so that it proceeds in a manner consistent with patient care; and
- there is a "likelihood that the MDI transition will fail completely unless several measures for

phase out are affirmed and additional Protocol measures are taken to promote the end of CFCs for MDIs."

As stated in its intervention during OEWG 23, IPAC supports the decision proposed by the European Community and firmly believes that measures must be taken now to plan for the future completion of the essential use process.

The European Community's proposed decision establishes two important milestones for the essential process in developed countries:

- after 2005, no CFCs would be authorised for use to manufacture MDIs where the only active ingredient is salbutamol intended for sale or distribution in non-Article 5(1) countries; and
- 2007 would be the last year for which essential use volumes are authorised by the Parties for use in any MDIs intended for sale or distribution in non-Article 5(1) countries.

These milestones should be very achievable based on the current and projected availability of CFC-free products and the additional elements of the proposed decision that would ensure that CFCs are not authorised for products not under active reformulation or not being progressed timely to the market. Defining target deadlines now will provide sufficient time for the requisite planning and preparation to ensure a smooth transition for patients. Further, and importantly, the proposed decision provides for a process whereby essential use CFCs could be authorised in the event that they are "clearly indispensable for patient care."

2005 ESSENTIAL USE NOMINATIONS

TEAP has recommended that the Meeting of the Parties approve essential use nominations for the European Union, Poland, the Russian Federation, Switzerland, United States, and part of Ukraine's nomination. TEAP noted that the EU's 2005 request was 50% less than its 2004 request. TEAP further noted that Australia and Japan did not



**Armstrong
Pharmaceuticals**

AstraZeneca

**Aventis
Pharmaceuticals**

**Boehringer
Ingelheim**

**Chiesi
Farmaceutici**

GlaxoSmithKline

IVAX

submit essential use nominations, and IPAC further notes that Canada and New Zealand also did not submit nomination requests for 2005. IPAC commends the progress of these countries in advancing the MDI transition.

FUTURE CFC SUPPLY FOR MDIS

As noted in TEAP's 2003 Report, 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 adopt and implement the EU-proposed decision at MOP-15 and proactively implement effective national transition strategies.

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 calling 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.

Therefore, IPAC fully supports Paragraph 6 of the European Community's proposed decision calling for development of a standard reporting form for use by the Parties in reporting data pursuant to Decision XIV/5. Further, IPAC concurs that this data should be segregated into confidential and non-confidential sections and that the Ozone Secretariat should post all non-confidential data submitted pursuant to Decision XIV/5 on its website.

IPAC RECOMMENDATIONS

In conclusion, IPAC requests that the Parties adopt the decision introduced by the European Community regarding measures to promote closure to the essential use process for CFCs. IPAC also supports OEWG's recommendation on essential use authorisations. IPAC looks forward to working with Protocol delegates, national governments, stakeholders and TEAP on these important CFC MDI transition issues.

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