

Metered Dose Inhaler Transition Issues at the 16th Meeting of the Parties to the Montreal Protocol

Prague, Czech Republic (22–26 November 2004)

INTRODUCTION

At the 24th Meeting of the Open-Ended Working Group (OEWG) in July 2004, the delegates considered a draft decision proposed by the European Community on essential use nominations for non-Article 5(1) Parties. The decision would approve certain volumes of CFCs for essential uses in 2005 and 2006 and provide for reassessment next year of volumes intended for use in salbutamol (albuterol) metered dose inhalers (MDIs).¹ In addition, the decision would also implement further Protocol-level measures designed to progress the transition toward completion in developed countries.

IPAC wishes to reiterate its commitment to a timely, effective transition to CFC-free products and, for the reasons detailed below, requests that the 16th Meeting of the Parties adopt the decision proposed by the European Community on essential use nominations for non-Article 5(1) countries.

PROPOSED DECISION ON ESSENTIAL USE NOMINATIONS FOR MDIS

The Need for Further Protocol Measures

Last year, the Parties recognized the need to establish Protocol-level measures to progress the MDI transition and adopted Decision XV/5. That Decision acknowledges the “urgent need to accelerate the phase-out of CFC-containing metered dose inhalers” in developed countries and appropriately focuses on encouraging the transition of salbutamol products, including requiring all non-Article 5(1) Parties to develop a plan of action to phase out these products.

Decision XV/5 was an important step toward a final transition roadmap. Additional concrete measures are needed, however, to ensure the timely and effective transition to CFC-free MDIs.

As noted in IPAC’s prior statements, the transition of salbutamol MDIs is critical to the overall transition given that these products represent at least half of the global market for CFC-based products. Completion of the salbutamol transition will significantly reduce CFC usage. For example, 70 percent of the United States’ essential use nomination for 2006 is for salbutamol — even though two safe and effective CFC salbutamol MDIs have been on the market for over two years in the United States. A third HFC-based salbutamol MDI was recently approved. Indeed, TEAP reports that two or more CFC-free salbutamol MDIs are available on the market in more than 30 non-Article 5(1) countries.

At the 24th OEWG meeting, the European Community introduced a decision addressing the 2005 and 2006 essential use nominations and implementing several actions intended to progress the MDI transition. For the reasons set forth below, IPAC fully supports the decision and encourages Parties to support its adoption at MOP-16.

As noted in the preamble to the proposed decision, the essential use process was intended to be temporary. The preamble also acknowledges the need for strict scrutiny of all essential use nominations from 2005 on, in order to move toward closure of the essential use process for non-Article 5(1) Parties. As detailed below, IPAC firmly believes that additional measures proposed in this decision are necessary and should be taken now to promote the future completion of the essential use process.

1 All references to salbutamol MDIs are intended to refer only to MDIs where salbutamol is the sole active ingredient.

Detailed Review of the Proposed Decision's Elements

Paragraph 1 (Authorization of CFCs for MDIs for 2005/2006 where sole active ingredient is not salbutamol)

Paragraph 1 of the proposed decision would authorize for 2005 and 2006 the production and consumption of essential use CFCs for MDIs where the sole active ingredient is not salbutamol and for single-moiety salbutamol MDIs intended for sale in Article 5(1) Parties. The CFCs intended for use in single-moiety salbutamol products for non-Article 5(1) Parties would be reassessed next year. (See Annex I to the proposed decision). It is IPAC's strong view that essential use CFCs are not needed for salbutamol MDIs beyond 2005 in non-Article 5(1) Parties. The proposed decision falls short of a clear Protocol determination of non-essentiality for salbutamol. If the Parties cannot agree to a clean cut-off of CFCs for salbutamol MDIs intended for non-Article 5 markets, then at a minimum the Parties should not approve CFCs for this use for 2006, pending TEAP review in 2005 as provided for in this proposed decision.

It should be noted that in the United States, where a regulation has been proposed to deem CFC salbutamol MDIs non-essential, there is strong support for setting a non-essentiality effective date of 31 December 2005. Importantly, the relevant MDI manufacturers have confirmed that sufficient production capacity for CFC-free salbutamol MDIs can be in place by this date.

IPAC fully supports the authorization of essential use CFCs for the production of MDIs where the sole active ingredient is not salbutamol as specified in Annex I of the decision.

Paragraphs 2 and 3 (Timeframes for submission of Decision XV/5 plan of action and supplementary data)

Paragraph 2 of the proposed decision would require Parties to submit the "plan of action" for phasing out salbutamol CFC MDIs in non-Article 5 markets pursuant to Decision XV/5(4) to the Ozone Secretariat no later than four weeks before the 2005 ATOC meeting. Paragraph 3 would set this same deadline for submitting essential use nominations. This is consistent with TEAP's recommendation that it should review the plans of action at the same time that it is reviewing the essential use nominations.

We believe that TEAP should independently review both the nominations and plans of actions to assess whether they are consistent with the terms of Decision IV/25 and taking into account the availability of CFC-free products.

IPAC fully supports having a date-certain for submission of the "plan of action," provided that the date is reasonably in advance of next year's ATOC meeting.

Paragraph 4 (Assessment of essential use nominations)

Paragraph 4 of the proposed decision calls on TEAP to reassess the salbutamol portion of the 2006 essential use nominations, to review any essential use nominations for 2007, and to issue its report by 30 April 2005. This paragraph also reaffirms that TEAP's review should be in accordance with paragraph 3 of Decision XV/5, which calls for assessment on an active-by-active, market-by-market basis. IPAC supports this paragraph.

Based on the wide availability of CFC-free salbutamol MDIs in non-Article 5(1) countries and progress of the transition, to date, these products should be declared non-essential and removed from the marketplace by end 2005 in all developed countries. Therefore, the Parties should direct TEAP to assess the salbutamol volumes in light of the nominating Party's plan of action. IPAC believes that the intent of this provision is for TEAP to make an independent evaluation of whether the terms of Decision IV/25 are met — and not to simply "rubber stamp" a Party's plan of action.

Paragraphs 5 and 6(a) (Clarification of appropriate level of CFC stockpiles)

Decision IV/25(b)(ii) requires that production of essential use CFCs only be allowed if "not available in sufficient quantity and quality from existing stocks." This is intended to minimise the volume of new CFCs produced, as well as the quantity of CFCs that must be destroyed at the end of the MDI transition. In its 2004 Report, TEAP noted that "individual companies may hold a substantial, and, perhaps, disproportionate [stockpile]" and recommended that Parties "pay careful attention to the amounts of stockpiled materials held by individual companies."

IPAC shares this concern and has long supported TEAP's recommendation that 12 months of CFC

supply represents a reasonable level for a safety stockpile. Under paragraphs 5 and 6(a), each company's essential use request would be reduced by the amount that a company's stockpile exceeds a 12-month level. These provisions are necessary to fully implement Decision IV/25.

Paragraphs 6(b) (Requirement for demonstration of ongoing research and development)

Pursuant to Decision VIII/10(1), the Essential Use Handbook requires each Nominating Party to assure that all MDI companies applying for essential use nominations "demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts." IPAC has previously recommended that the Parties urge TEAP not to recommend approval of any nominations if the nominating Party has not submitted information to assure TEAP that each company requesting essential use CFCs has fully complied with Decision VIII/10(1).

IPAC is concerned that past essential use nominations have included amounts for companies that have not demonstrated ongoing research and development of CFC MDI alternatives as required by Decision VIII/10. Indeed, TEAP notes that "ATOC has assumed that a lack of demonstrated research and development is not an absolute prohibition to recommending essential use volumes" and, therefore, has requested that the Parties clarify this provision. Clarifying and strengthening the requirement for ongoing research and development is wholly consistent with the Protocol's objectives. Therefore, IPAC supports paragraph 6(b) of the proposed Decision, which requests Nominating Parties to provide information to demonstrate that each company requesting essential use volumes has complied with the provisions of Decision VIII/10.

It is important to protect the confidentiality of commercially sensitive, company-specific information. IPAC believes that the provision in paragraph 6 allowing a Nominating Party to specify that any confidential information be viewed only by the TEAP and ATOC co-chairs will adequately protect such confidentiality.

Paragraph 7 (TEAP deferral of recommendation when Party fails to submit information on stockpiles and R&D)

There is ample precedent for TEAP not recommending approval of essential use volumes when a Party does not submit sufficient information. This paragraph will signal to Parties the importance of providing adequate information to TEAP to enable it to assess nominations. Therefore, IPAC fully supports this paragraph of the proposed Decision.

Paragraph 8 (Revisions to the Essential Use Handbook)

IPAC believes it is important for TEAP to revise the Essential Use Handbook to incorporate the provisions of Decision XV/5 as the Parties have requested, and believes that the modifications suggested in this paragraph would not materially weaken the effect of that Decision. Therefore, IPAC fully supports this paragraph.

FOR ALL OF THE REASONS NOTED ABOVE, IPAC STRONGLY SUPPORTS ADOPTION OF THE EUROPEAN COMMUNITY'S PROPOSED DECISION BY THE 16TH MEETING OF THE PARTIES.

STATUS OF MDI TRANSITION

Transition in Non-Article 5(1) Countries

It is important to recall TEAP's prior conclusion that "the availability of CFC-free products alone will not lead to a timely conclusion of the transition and that additional steps are necessary for an effective transition" — particularly "ceasing the supply of CFC MDIs where alternatives exist." That this is the correct conclusion is evident from the experience of several major developed countries. 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. As a result, Canada, Australia, and Japan have not requested essential use volumes for 2006. In the European Union, at least twenty countries have declared the use of CFCs in salbutamol MDIs to be non-essential. The EU's essential use request, which includes its need for export production, represents a substantial reduction from prior years.

The United States presents a distinct contrast to the progress outlined above. At present, no CFC MDIs have yet been determined non-essential, despite two CFC-free salbutamol products being available for over two years, and more than 90% of salbutamol MDIs still use CFCs. Consequently, the



significant majority of the US nomination for 2006 – 70% – is intended for use in single-moiety salbutamol products.

AstraZeneca

**Boehringer
Ingelheim**

**Chiesi
Farmaceutici**

GlaxoSmithKline

Sanofi-Aventis

Patient access to treatments should be assured in the US because there are numerous patient assistance programs. Moreover, at least one manufacturer of CFC-free salbutamol in the US has pledged to freeze its price and to provide two million free salbutamol MDIs annually.

Therefore, IPAC has strongly urged the US to follow the positive examples set by Australia, Canada, Japan, and the European Community, and has called for the US to deem CFC salbutamol MDIs non-essential effective 31 December 2005.

Transition in Article 5(1) Countries

In response to the Parties’ request in Decision XV/5, TEAP undertook an assessment this year of the potential impacts of the phase-out of CFCs in non-Article 5(1) Parties on the availability of inhaled therapy in Article 5(1) Parties. TEAP notes that CFC MDIs are supplied to Article 5(1) countries via three main avenues: (i) importation from multinational pharmaceutical companies located in Europe or other developed countries; (ii) local manufacture in the Article (5) country; and (iii) local manufacture in the Article (5) country by a subsidiary of a multinational company that is headquartered in a non-Article 5(1) country. IPAC generally concurs with TEAP’s assessment on these issues, and, in particular, agrees that the phase-out of CFC MDIs in non-Article 5(1) countries “need not have a significant impact on treatment availability in Article 5(1) countries.”

TEAP has previously recommended that it is important for Article 5(1) countries to develop

national transition strategies now. IPAC concurs with this recommendation and congratulates the countries (e.g., South Africa, Colombia and Malaysia) that have already done so.

Transition in Countries with Economies in Transition (CEIT)

TEAP’s 2003 Report estimated that over 500 tonnes of CFCs are used for MDIs in CEIT. TEAP notes this year that still only 2 of 17 CEIT have submitted national transition strategies to the Ozone Secretariat. TEAP has concluded 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 concurs with the expectation that these circumstances may change as several CEIT joined the European Union in May of this year and as others respond to Decision XV/5.

Regulatory Approval and Reimbursement of CFC-Free Treatments

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 an important issue. Decision VIII/11(2) 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.

1301 K Street, NW
Suite 900, East Tower
Washington, DC
20005-3317 USA

+1 202 230 5133
telephone

+1 202 230 5300
facsimile

IPAC RECOMMENDATIONS

In conclusion, IPAC requests that the Parties adopt the decision introduced by the European Community regarding essential use nominations for MDIs. IPAC strongly supports not approving essential use volumes for salbutamol MDIs intended for non-Article 5 markets. Taking these actions will ensure the timely and effective completion of the CFC MDI transition. IPAC looks forward to working with Protocol delegates, national governments, stakeholders and TEAP on these important CFC MDI transition issues.