

## **NATIONAL TRANSITION STRATEGIES FOR MDIs**

### **TRANSITION TO NON-CFC METERED DOSE ASTHMA INHALERS: THE NEW ZEALAND STRATEGY**

#### **Summary of basic elements**

- New Zealand has a long-standing concern to reduce and repair ozone depletion. New Zealand is also a country with a very high incidence of asthma and chronic obstructive pulmonary disease. It is therefore strongly committed to the timely elimination of CFCs from MDIs.
- New Zealand has a proven system of fast track registration of CFC-free MDI products. CFC-free MDIs have been on the market at no cost disadvantage to users for over twelve months.
- New Zealand has a comprehensive legislative environment which includes the capacity to deal with the false or misleading advertising of all products including CFC MDIs.
- Monitoring and consultation is being undertaken along with consideration of possible future action, such as additional targeted education and information programmes and the role of guidelines for the return and disposal of expired, defective or redundant CFC MDIs.
- The transition to CFC-free MDIs will accelerate as additional types and alternatives become available.
- A co-operative and gradualist market based strategy has the best potential in New Zealand for achieving a transition that takes into account patient needs, cost factors and environmental considerations.

#### **Background**

1. New Zealand's combination of clean air and unique geographic factors involves particular risks from depletion of the ozone layer. It has therefore been especially committed to the timely elimination of chlorofluorocarbons (CFCs) and all other ozone depleting substances (ODS).
2. Following the elimination of CFC imports on 1 January 1996, as required by the Montreal Protocol, attention has moved to the need to phase out other ODS such as hydrochlorofluorocarbons (HCFCs) and methyl bromide. As far as practicable, the phase out of those few mainly medical uses of CFCs such as asthma and chronic obstructive pulmonary disease (COPD) related metered dose

inhalers (MDIs), currently exempted from the 1996 import ban, should also be considered.

3. New Zealand manufactures neither CFCs nor MDIs. MDI requirements are imported from Australia and other suppliers.

4. The Eighth Meeting of Parties to the Protocol in 1996 requested developed country Parties (Decision VIII/12(3)) that have developed a national transition strategy to report this to the Protocol's Technical and Economic Options Panel (TEAP) and its Technical Options Committee (ATOC). Although over the past few years there have been a range of non CFC treatments available for asthma and COPD illnesses in New Zealand, including dry powder inhalers (DPIs), and these have gained a reasonable market share, for various reasons they have not in New Zealand formed a generally acceptable alternative to CFC MDIs.

5. CFC MDIs form a relatively minor source of ozone depleting substances, both in New Zealand and globally. For example, it has been calculated that CFC MDIs have over the past thirty years contributed less than 1 per cent of total global CFC emissions. Nonetheless, there is a need, now that non CFC MDIs are becoming available, to address the question of how these should be introduced to markets and users. The prospect of an increasing scarcity of medical grade CFCs for the continued manufacture of MDIs will hasten this consideration.

### **The New Zealand approach**

6. New Zealand has one of the world's highest incidences of asthma with one in five children suffering from this compared with one in 25 in China. About 450,000 New Zealanders have been diagnosed with the illness which now costs more than \$100 million in pharmaceuticals each year, approximately one seventh of the pharmaceutical budget.

7. A non CFC bronchodilator MDI has been approved and made available on the market for users in New Zealand since early 1996. This product attracts the same full subsidy as the CFC MDI. Since 1996 the New Zealand approach to the introduction of non CFC MDIs has been to:

- approach the issue of the financial disincentives for users and merits of CFC and non-CFC MDIs in a neutral manner;
- ensure that there are no unnecessary impediments to the approval or introduction of non CFC products;
- leave the responsibility for marketing and promotion of the relevant products on the suppliers/manufacturers.

8. The request incorporated in Decision VIII/12(3) and associated Decisions provides an opportunity to review the above strategy so as to ensure that a smooth transition that provides for the health and safety of asthma and other COPD sufferers continues to occur.

### **Factors to be considered**

#### 9. The Broad Regulatory Approach

(i) One option would be the forced removal from the market, according to a pre-determined timetable, of CFC product. This, however, would be at some risk to patient safety objectives. It would also involve complicated administrative, regulatory and enforcement procedures. Nor would it in itself create incentives for the speedy reformulation of alternatives for the whole range of CFC MDI products. It is also worth noting that decisions relating to what particular brands of CFC MDIs are licensed or purchased do not necessarily result in additional usage or emissions.

(ii) An alternative is to continue to pursue the environmental objectives involved through persuasion and education of medical practitioners and patients while monitoring the process for avoidable impediments. This approach minimises the risk to patients and recognises that asthma and COPD are highly stressful and dangerous illnesses and some patients may experience considerable difficulty from changes to current medicines. Such an approach recognises that while CFC MDIs may in the future be difficult to obtain it is preferable for the majority of patients to make the change to non CFC treatments voluntarily at their own pace in consultation with their doctor, as alternative products become available.

### **Packaging and marketing**

10. Decision VIII/10(3) asks that non-Article 5(1) Parties request companies applying for MDI essential use exemptions to demonstrate that they, or companies distributing or selling their products, are differentiating the packaging of the companies CFC and non CFC MDI products, and are applying other appropriate marketing strategies, in consultation with the medical community, to encourage doctor and patient acceptance of the firms non-CFC alternatives subject to health and product safety considerations. Relevant companies in New Zealand are largely just importing and distributing agencies for overseas firms. It is understood that all are, or will be, differentiating their products. Where there is a continuation of established brand names, we understand that distinctive logos will be employed to distinguish alternative CFC and non CFC products.

## **Advertising**

11. Paragraph 4 of Decision VIII/10 requests that developed country Parties encourage companies not to engage in false or misleading advertising targeted at either CFC or non-CFC MDIs. It is considered that current New Zealand legislation is adequate to cover this situation.

## **Ongoing education**

12. Paragraph 2 of Decision VIII/10 asks that developed country Parties request companies applying for MDI essential use exemptions demonstrate that they are undertaking individual or collaborative industry efforts, in consultation with the medical community, to educate health care professionals and patients about other treatment options and the transition to non-CFC alternatives. No New Zealand company will be applying for an MDI essential use exemption under the Montreal Protocol. It is known that importing and distributing companies in New Zealand are, however, providing information to health care professionals and patients. The Decision raises the question as to the degree to which additional education and the provision of information could facilitate a smooth transition to non-CFC MDIs in New Zealand. Physicians are provided with relevant information by suppliers who provide patients with appropriate information and advice on the range of non-CFC treatments available. The New Zealand pharmaceutical funding agency has contracted with the supplier of the first non-CFC MDI to provide an information campaign in conjunction with the launch of this product. Ongoing consultation with professional bodies, stakeholders and the community will take place so as to ascertain doctors needs for any additional information, and whether a policy of requesting new patients to be introduced to non-CFC MDIs would be likely to provide benefits.

## **Product review and approval**

13. Paragraph 2 of Decision VIII/11 asks that developed country Parties request national authorities to expedite the review of applications for non-CFC treatments provided that such action does not compromise patient health and safety. In this connection it is noted that New Zealand has had a non-CFC MDI on the market for over 12 months. Many countries have yet to approve any alternatives for introduction. It is considered that New Zealand has a relatively efficient product approval system.

## **Procurement and reimbursement**

14. Paragraph 3 of Decision VIII/11 asks that national authorities review the terms for public MDI procurement and reimbursement so that purchasing policies do not discriminate against non-CFC alternatives. New Zealand's systems and

policies of pharmaceutical procurement do not discriminate against non CFC alternatives and policies designed to ensure that there are no financial disincentives to the use of non-CFC MDIs are applied.

### **Disposal of expired, defective and returned CFC MDIs**

15. Decision VIII/10 asks that Parties, “request companies manufacturing, distributing or selling CFC MDIs to dispose of expired, defective and returned MDIs containing CFCs in a manner that minimises CFC emissions.” Initial enquiries reveal that although the major suppliers have appropriate procedures and practices in place a number of smaller suppliers may not. The issue of whether an industry guideline might be helpful is to be taken up with relevant firms.

### **Conclusion**

16. A review of current policies and strategies in regard to the transition to non CFC MDIs indicates that the appropriate processes and incentives are in place. New Zealand has formed the view that while the market penetration of non-CFC products has been limited to date, this process will gain momentum and achieve significant progress as additional CFC free products become available. This will occur without risk to patient safety and without government intervention to restrict products or patient behaviour. The progress of firms in developing and producing non-CFC products has been good and further progress is expected. It is recognised that the environmental impact of MDIs is limited but nonetheless patients and medical practitioners need to be kept informed of the limited future for CFC based products and the inevitability of non-CFC based technology.