NATIONAL TRANSITION STRATEGIES FOR MDIs

INTERIM APPROACH AUSTRALIA

Below is an interim report forwarded to UNEP by Australia (reproduced in the Report of the Technology and Economic Assessment Panel, April 1997, Volume II) which provides a broad outline of Australia's general approach to the phaseout of CFC-based asthma treatments. Australia advised at the time that this report represented an initial indication of the direction being taken within Australia, rather than a final strategy.

BROAD OUTLINE OF AUSTRALIA'S GENERAL APPROACH TO THE TRANSITION TO NON-CFC TREATMENTS OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Introduction

Australia is committed to the timely elimination of CFCs and all other ozone-depleting substances and fully recognises the need to reduce and remove the current exemption which allows for the production and import of CFCs for Metered Dose Inhalers (MDIs). Australia also recognises the need for a national strategy for the phaseout of CFC-based MDIs in order to ensure a smooth and efficient transition to non-CFC treatments of asthma and Chronic Obstructive Pulmonary Disease (COPD) in a way which will protect the health and safety of patients. To develop this strategy, consultation has commenced with health professionals, respiratory medicine companies, health regulatory bodies and major user groups. This process has already resulted in broad agreement on a number of issues. The aims of the on-going consultative process are to:

- ensure that the interests and welfare of all patients are protected during and after the transition process;
- ensure that environmental objectives are met as speedily as possible, consistent with the first objective;
- ensure that the health professionals are fully informed of all relevant issues before and after the transition process; and
- establish policies for government and industry in Australia to facilitate a seamless transition to non-CFC treatments of asthma and COPD.

Australia is pleased to provide a broad outline of the general approach that is currently being developed for the transition to non-CFC treatments of asthma and COPD. As the consultation process is continuing with industry, users and regulatory authorities this report represents an initial indication of the direction

being taken in Australia, rather than a final strategy. Australia hopes to be in a position to provide additional information as the consultation process continues throughout the year.

Broad Regulatory Approach to Phaseout

In considering ways to achieve a smooth and efficient transition which also protects the health and safety of patients, two broad approaches have been considered in Australia. These were:

1. regulations on a substance-by-substance basis, whereby substances are required to be removed from the market following the approval of one or more equivalent CFC-free alternatives; or

2. an agreed reduction timetable, with percentage reductions against a baseline, for the import of bulk CFCs for MDI production purposes, possibly with a complementary timetable for total quantities of CFCs contained in finished products.

The first approach of regulating on a substance-by-substance basis is not supported by most stakeholders in Australia. The primary reasons are because this type of regulation was seen to be incredibly complicated and would require detailed administration and regulation with large associated costs. It was recognised that substance-by-substance regulation does not in itself provide incentives for speedy formulation of alternatives for the whole range of CFC-based products.

A reduction timetable for the import of quantities of CFCs was favoured for a number of reasons. This approach is relatively simple and provides incentives for ongoing research, development and approval of non-CFC treatments. A reduction timetable is consistent with the supply-control approach normally taken under the Protocol and is likely to achieve similar environmental benefits to the more complicated substance-by-substance approach. It also provides greater flexibility to national governments in developing implementation arrangements which will suit the circumstances of each country.

As part of the process of considering possible reduction timetables, companies operating in Australia were asked to provide estimates of the percentage reductions in imports of CFCs for MDI purposes that may be achievable by the year 2000. Similarly, companies were also asked to indicate in what year a virtual phaseout was likely to be achievable. In developing these estimates, industry was asked to take into account the time necessary for research, development, approval and market penetration of CFC-free alternatives. Industry was also asked to take

into account the time required for the necessary educational programmes for health professionals and patients.

On the basis of the estimates provided by industry, it is suggested that a reduction of between 60 and 70 per cent against a 1996 baseline could be achieved by the year 2001. Similarly it is suggested that a virtual phaseout may be achievable by 2005. The term ‘virtual phaseout’ is used as there are some specialised products which, due to small quantities used, are not viable for reformulation.

Due to uncertainties involved in developing these estimates, the suggested reduction percentages and virtual phaseout date should be considered as an indicative target only at this stage and will need to be reviewed regularly as the transition proceeds.

Product Review and Approval

As an important element of the development of an appropriate national transition strategy, national environmental and health authorities in Australia are engaged in detailed and ongoing consultation. In accordance with paragraph 2 of Decision VIII/11, these authorities are discussing the possibility of expediting the review of marketing, licensing and pricing applications of CFC-free treatments in Australia. Industry stakeholders also agree that they need to consult regularly with regulatory authorities in the interest of expediting processing of CFC-free product applications. Consideration is also being given to the possibility of establishing some form of priority review system for CFC-free products.

As part of the strategy to phaseout CFC treatments of asthma and COPD, Australia would like to stop the introduction of any new products containing CFCs at an appropriate time. However, under current Australian legislation, regulatory authorities cannot refuse to accept new applications for MDIs containing CFCs. In the interim, industry is being advised that the process of transition is underway and that essential use exemptions will not be available indefinitely.

Reimbursement Policies

Paragraph 3 of VIII/11 requests that national authorities review the terms for public MDI procurement and reimbursement, so that purchasing policies do not discriminate against non-CFC alternatives. Australia is working to ensure that there are no financial disincentives to the introduction or use of non-CFC alternatives. To do this it is recognised that pricing authorities will need to consider factors such as the sale price requested by industry, the actual cost of manufacture, overseas pricing experience, the availability and pricing of

alternative products (such as Dry Powder Inhalers) and the relative efficacy and safety of the new product as compared to the CFC equivalent.

The national pharmaceutical pricing authority is encouraging early consultation with industry well before any product is released on the market in an attempt to ensure that pricing structures for MDIs do not impact negatively on the phaseout.

Controls on Advertising

Paragraph 4 of Decision VIII/10 requests that Parties encourage companies not to engage in false or misleading advertising targeted at either non-CFC alternatives or CFC MDIs. In Australia there are no additional specific actions required in response to this decision as:

- all companies believe that the Australian Pharmaceutical Manufacturer's Association already has adequate mechanisms in place, through its Code of Conduct, to prevent false or misleading product advertisement, promotion or representation by sales representatives; and

- the Australian Trade Practices Act also provides protection against false and misleading claims.

Packaging and Marketing of CFC-free Products

Paragraph 3 of Decision VIII/10 requires Parties to request that companies selling MDIs will differentiate packaging between CFC-containing and CFC-free MDIs and apply other appropriate marketing strategies to encourage patient acceptance of CFC-free alternatives.

Australian companies have different views on the best way to encourage patient acceptance. Some companies feel that consistency in product name and packaging would be the most effective way to encourage acceptance. There is, however, general agreement that there would be value in CFC-free products carrying a uniform logo announcing these products as CFC-free. The National Asthma Campaign, Australia's leading asthma advisory body, is attempting to develop a universally acceptable logo in consultation with all industry stakeholders.

Ongoing Education Campaign

Paragraph 2 of Decision VIII/10 requests that Parties undertake efforts to educate health-care professionals and patients about other treatment options and the transition to non-CFC alternatives.

Stakeholders in Australia generally agree that the National Asthma Campaign, in collaboration with industry stakeholders, should conduct national advertising

campaigns for health professionals and patients throughout the changeover period. All stakeholders agree that continued participation by Environment Australia will be very important to reinforce the environmental messages in the ongoing education campaign.

Minimising Unnecessary Emissions of CFCs

Paragraphs 6 and 7 of Decision VIII/10 require Parties to request companies manufacturing MDIs to take all economically feasible steps to minimise CFC emissions during manufacture and to encourage the responsible disposal of unusable MDIs. In Australia there is no additional specific action required in response to this decision as:

- Australian manufacturers of MDIs already have in place procedures to recover CFCs from MDIs which have been returned or have expired; and

- the value of the CFCs used in manufacture is high and companies have advised that they already take all feasible steps to minimise emissions.