

NATIONAL TRANSITION STRATEGIES FOR MDIs

NATIONAL TRANSITION STRATEGY OF HUNGARY OF PHASING-OUT CFCs IN METERED DOSE INHALERS (MDIs) FOR THE TREATMENT OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASES (COPD)

(Prepared and to be submitted to the Parties to the Montreal Protocol in accordance with Decision IX/19)

Objectives

Metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary diseases are the only exemption amongst aerosol products, for which totally safe alternatives acceptable and feasible from every respect have not yet been fully developed and introduced. It became obvious that it is not possible to develop a single alternative, that transition from existing MDIs with CFC propellant to CFC-free products will take several years and that the strategy of transition will depend on the different circumstances of individual countries. The Parties to the Montreal Protocol in their Decision IX/19 requested those Parties, which produce MDIs to prepare and present a National Transition Strategy. Since MDIs are produced in Hungary, the following strategy was elaborated.

Background

The round figure of population in Hungary is 10.1 million. The number of asthma patients is steadily growing. Its rate is between 1-3% according to different assessment methods. Because of incomplete coverage of the estimations probably at least the higher value is realistic.

There is one pharmaceutical company in Hungary manufacturing MDIs, selling its products exclusively on the home market. The company used about 10 tons CFCs in 1996 and about 5 tons in 1997 approved by the essential use process. The essential use exemption requested for 2000 and 2001 will be 1.75 tons/year. The company plans to reformulate its products with HFC propellant by 2002-2003.

The total sale of MDI units is increasing by 10% annually and in 1998 it will be about 1.4 million. The rate of the domestic products has decreased from 9% to 4% in the period of 1995-1998. The major part of the import comes from the European Union and about 25% from Poland.

The registration/market approval for CFC-MDIs ceased by 1 January 1996.

Hungarian Approach

1. Harmonisation with the EU

Hungary as a candidate member state to the European Union will harmonise its MDI phase-out programme basically with the strategy of the EU. The objective is to provide for the gradual elimination of CFC-MDIs and their replacement with other types by 2003-2004 so that most patients can be treated with metered-dose inhalers without CFCs.

At the same time the Hungarian producer will further seek opportunities to reduce the quantities approved for use in the manufacture of MDIs. It is recognised by all those involved that it is their primary obligation to ensure that all patients continue to receive the medicines they require. It is the common understanding of all those closely concerned, that

- they will promote the transition to non-CFC alternatives, that
- the health and safety of patients during the transition will be safeguarded.

2. Education, training and raising of awareness

The national public health authorities are aware of the importance of education/training of physicians, nurses and patients. The transition away from CFC MDIs has already started in Hungary as well. The knowledge on awareness of non-CFC MDIs and dry powder inhalers (DPIs) is still limited. Patients must be adequately informed and advised by their doctors, other health professionals and patients' associations/groups before, during and after the transition. Guidelines will be elaborated and workshops will be organised to promote this activity.

3. Packaging, naming, identifying and approval of alternatives

Information dissemination and awareness raising has to be led and co-ordinated by the national public health authorities. Beyond the support of health and environmental professional, health services, patients and patients' associations and manufacturers of the medicines, advice and help from more advanced countries and/or organisations will be needed.

Special care should be taken to differentiate the naming, packaging and identifying of CFC and non-CFC MDI products. As it was mentioned earlier, the registration/market approval for CFC MDIs ceased by 1 January 1996. The approval procedures of alternative medicines will be harmonised with those of the EU.

As it can be seen the scope of action for Hungary is rather limited for establishing an independent MDI transition strategy. The relevant authorities/institutions for environment, national health care and industry will continue along the factors mentioned above to elaborate the transition strategy in a more detailed way. It can be expected that it will be available about in the middle of the year 2000.

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