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Addendum

DESK STUDY FOR EVALUATION OF METERED-DOSE INHALERS (MDI) PROJECTS

This document is issued to:

- **Add** paragraph 21(bis) as follows:

21(bis). At its 51st meeting, the Executive Committee considered the specific situation of some Article 5 Parties that manufactured CFC metered-dose inhalers (MDIs) but had committed to phasing-out all their remaining CFC consumption without further requests for funding. . At that meeting, the Executive Committee adopted decision 51/34, which allowed consideration, on a case-by-case basis, of the submission of requests for project preparation for the conversion of CFC-MDI production facilities in such Parties. The decision also required the countries concerned to provide a comprehensive justification and detailed information, including:

(a) Name of nationally owned CFC-MDI manufacturing facilities, the date when the CFC production lines were established and the production capacity of each production line;

(b) Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/year);

(c) Growth patterns of CFC-MDI production over the past five years;

(d) Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDIs and what those alternatives were;

(e) Each production facility's plans for phasing out CFC consumption; and

(f) The number of non-CFC MDIs and dry-powder inhalers sold or distributed within the Party, by active ingredient, brand/manufacturer, and source.

- **Add** paragraph 22(bis) as follows:

22(bis). The Secretariat presented the draft Guidelines at the 37th meeting of the Executive Committee. Through its decision 37/61, the Executive Committee decided:

(a) To take note of the draft guidelines;

(b) To request members of the Executive Committee to submit comments on the issue to the Secretariat in time for a further discussion at the 40th Meeting of the Executive Committee; and

(c) In the meantime, to allow consideration of some projects on a case-by-case basis, taking into account the relative need of the country to have an MDI project to ensure compliance, the relative cost-effectiveness of the project and the possibility that essential use applications for MDIs might be considered by the Parties as early as 2008.

Even if not officially adopted it is clear that the guidelines have influenced the project proposal formulation. Principles and issues listed in the guidelines can be found at different degrees in all the project proposals analyzed by the desk study.

- **Replace** the heading of Section VI, and paragraphs 67 to 70 as follows:

ISSUES TO BE ADDRESSED DURING THE 2ND PHASE OF THE EVALUATION OF PROJECTS FOR THE CONVERSION OF CFC-BASED METERED DOSE INHALERS (MDI) TO NON-CFC TECHNOLOGIES

67. The evaluation will follow the suggestions made in the desk study. The following issues will be addressed:

Assess the effectiveness of the transition strategy in facilitating the achievement of project objectives i.e. the replacement of CFC with CFC–free MDIs by taking into account:

(a) The relevance of the institutional setting. What were the institutions involved in project implementation? What structural changes had to be implemented to facilitate the implementation of the project?

(b) Organizational practices, including cooperation among various stakeholders. Who were the major stakeholders and what was their contribution to the implementation of the MDI transition strategy? Which were the major challenges and hurdles?

(c) Role of the regulatory framework. Was legislation amended or developed to support the implementation of the project? If so what was the effectiveness of the regulatory framework in project implementation?

(d) Access to technology. Examine issues related to formulation patents, intellectual property, joint ventures and other modalities that facilitate access to non-CFC technology.

(e) Access to medicine and health services. What was the degree of availability of alternative medicine to the population to treat asthma and chronic pulmonary diseases? Did the MDI transition strategy change the existing situation and if so how? What were the attitude and role of the medical profession in relation to the replacement and phase out of CFC MDI?

(f) Impact of awareness campaigns. What was the impact of the awareness activities in relation to adoption of CFC-free MDI? What were the major elements and instrument of the campaigns as well and their relevance to the target population?

(g) Training and skill development. What were the results of any training activity conducted under the transition strategy? Did the strategy contribute to building relevant capacity among stakeholders within the medical community?

Adequacy of funding:

(a) How it affected the achievement of the project objectives.

(b) Level of co-financing (and specific items) contributed by the beneficiary enterprise to implement the project.

Causes of delays:

(a) Assess the main causes of delays and the solutions adopted. What lessons can be learned from this experience?

(b) Based on project implementation experience, make recommendations on what specific areas of project implementation could have been done differently.

Technical issues:

Assess the main challenges related to the selection and operation of technology. Examine issues related to equipment destruction.

Potential issues to consider:

(a) Technology transfer or product development:

- Method used to obtain the technology (specific molecules with HFA);
- Assessment of this method against other available possibilities, if any (cost, complexity, risk of non-success, advantages and disadvantages);
- Challenges and lessons learned from the type(s) of molecules(s) selected (one step or two step production, use of ethanol or not, use of solutions versus suspension);
- Main challenges faced in the transfer (or development) of the technology;
- Challenges and lessons learned from product testing (lab batches, first commercial batches, stability test results 3 months, 6 months, 9 months, 1 year);
- Challenges and lessons learned from the process of registration in the regulatory entity;
- Main issues identified in the use of the introduced HFA MDIs by the patients and how have they been addressed; and
- What were the main drivers to select HFA MDI as alternative to CFC MDI in comparison with other therapeutic alternatives (dry powder, nebulizer, others)

(b) Incremental capital investments:

- Equipment supplier selected;

- Issues identified on the selection and delivery of the new (or retrofitted) equipment and issues identified during its operation; and
- Challenges and lessons learned from the validation of the production processes for each product.

(c) Incremental operating costs:

- Actual level of incremental operating cost after commercial production as compared to the estimated cost in the project proposal; and
- Availability and affordability of key components in the production of HFA-MDI (HFA, valves, actuators, cans).

EXPECTED OUTPUT

68. The consultants will provide a case study report for each country visited. The information and conclusions summarized in the case studies, together with the information presented in the desk study will help draft the final evaluation report.
