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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Fifty-second Meeting
Montreal, 23-27 July 2007

PROJECT PROPOSAL: BANGLADESH

This document consists of the comments and recommendation of the Fund Secretariat on the following project proposal:

Aerosol

• Phase-out of CFC consumption in the manufacture of aerosol metered-dose inhalers (MDIs)	UNDP
• Transition strategy for phasing out use of CFCs in the manufacturing of MDIs	UNEP

PROJECT EVALUATION SHEET – NON-MULTI-YEAR PROJECT
BANGLADESH

PROJECT TITLE(S) BILATERAL/IMPLEMENTING AGENCY

(a) Phase-out of CFC consumption in the manufacture of aerosol metered-dose inhalers (MDIs)	UNDP
(b) Transition strategy for phasing out use of CFCs in the manufacturing of MDIs	UNEP

NATIONAL CO-ORDINATING AGENCY	Department of Environment Ministry of Environment and Forest

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2005, AS OF JUNE 2007)

CFC	263.0		

B: COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES, 2005, AS OF JUNE 2007)

ODS	Subsector/quantity	Subsector/quantity	Subsector/quantity	Subsector/quantity
CFC-11	MDI/24.81			
CFC-12	MDI/37.00			

CFC consumption remaining eligible for funding (ODP tonnes)	n/a

CURRENT YEAR BUSINESS PLAN ALLOCATIONS		Funding US $ million	Phase-out ODP tonnes
	(a)	UNDP: 1,803,000	48.7
	(b)	UNEP: 0	0

PROJECT TITLE:	(a)	(b)
ODS use at enterprise (ODP tonnes):		
ODS to be phased out (ODP tonnes):	76.3	0
ODS to be phased in (ODP tonnes):	0	0
Project duration (months):	48	48
Initial amount requested (US $):	4,089,527	235,000
Final project costs (US $):		
Incremental Capital Cost:		
Contingency (10 %):		
Incremental Operating Cost:		
Total Project Cost:		
Local ownership (%):	100 %	
Export component (%):	5 %	
Requested grant (US $):		
Cost-effectiveness (US $/kg):	54	
Implementing agency support cost (US $):		
Total cost of project to Multilateral Fund (US $):		
Status of counterpart funding (Y/N):		
Project monitoring milestones included (Y/N):	Y	

SECRETARIAT'S RECOMMENDATION	For individual consideration

PROJECT DESCRIPTION

1. On behalf of the Government of Bangladesh, UNEP has submitted the national strategy for the phase-out of CFCs in metered dose inhalers (MDIs) in Bangladesh, and UNDP has submitted an investment project proposal for the phase-out of 76.3 ODP tonnes of CFC-11 and CFC-12 used in the manufacture of MDIs, for consideration by the Executive Committee at its 52nd Meeting.

Background

2. At its 49th Meeting, the Executive Committee considered a policy paper prepared by the Secretariat on options for addressing the situation of countries referred to in decision XVII/14 (UNEP/OzL.Pro/ExCom/49/39). The paper examined the specific circumstances of some Article 5 Parties with manufacturing plants for MDIs that might be at serious risk of not meeting the 85 per cent reduction in CFC consumption in 2007. Following a discussion, the Executive Committee decided, *inter alia*, to request the Government of Bangladesh to submit to the 50th Meeting a proposal for the development of a transition strategy for the phase-out of CFC-based MDIs (decision 49/33 (b)).

3. At the 50th Meeting of the Executive Committee, on behalf of the Government of Bangladesh, UNEP submitted a request for the formulation of a transition strategy for MDIs, pursuant to decision 49/33(b). During the Meeting, it was suggested that the amount of US $60,000 originally requested by UNEP should be shared equally between UNDP and UNEP for project preparation for the phase-out of CFCs in the MDI sector. Accordingly, the Executive Committee decided to approve US $30,000 for the formulation of an MDI transition strategy by UNEP and, taking into account the exceptional circumstances of Bangladesh, to approve US $30,000 for the preparation of a project for the phase-out of CFCs in the MDI sector by UNDP. Funding for these activities was approved on the understanding that: “The Government would sign the project document with UNDP for the national ODS phase-out plan (NPP) and commence implementation of activities in other sectors that would result in reductions of CFC consumption, and that the transition strategy would be developed taking into account decision XVIII/16 of the Eighteenth Meeting of the Parties” (decisions 50/19 and 50/20).

Sector background

4. Of the 150 million inhabitants of Bangladesh, approximately 30 million patients suffer from asthma and chronic obstructive pulmonary disease (COPD) in the country. However, only 10 per cent of patients, mainly located in urban areas, have access to MDIs. Most of the population in Bangladesh resides in rural areas where more affordable but less preferable treatments are used, such as oral medication and injectable treatment.

5. The MDI, as therapeutic treatment for asthma and COPD, is relatively new in Bangladesh. The first CFC-MDI was only developed and launched in 1997, with production reaching 507,000 units. The demand for MDIs in Bangladesh is satisfied primarily by the following three locally-owned manufacturing enterprises:

(a) Beximco Pharmaceutical: The company began manufacturing CFC-MDIs in 1997, with the production of 270,000 salbutamol and salmeterol MDIs. Currently, the company has a production capacity of 2.4 million MDIs per year based on a

single production line, and produces MDIs with over ten different active ingredients. Since 2002, Beximco has manufactured salbutamol CFC-MDIs for GlaxoSmithKline (680,000 MDIs produced in 2006); and since 2006 for Eskayef (30,000 MDIs). In 2006, Beximco invested in the development of HFA salbutamol and beclomethasone MDIs through collaboration with Bespak, United Kingdom;

(b) Square Pharmaceutical: The company began manufacturing CFC-MDIs in 1997 with the production of 240,000 salbutamol, beclomethasone and salmeterol MDIs, and currently produces MDIs with over nine different active ingredients. The MDI formulation technology has been based on in-house research work. In 2002, Square began producing dry powder inhalers (DPIs) that were developed by the enterprise. Currently, the company manufactures single dose (capsule) DPIs of salbutamol, and salmeterol plus fluticasone;

(c) Acme Pharmaceutical: The company began manufacturing CFC-MDIs in 2004 with the production of 100,000 salbutamol, beclomethasone and salmeterol MDIs. In 2006, a total 250,000 MDIs were produced with four different active ingredients. Also in 2006, Acme produced 210,000 DPIs with four different active ingredients (salbutamol, salmeterol, salmeterol plus fluticasone and beclomethasone).

6. Production levels of CFC-MDIs in Bangladesh over the 2004-2006 period by active ingredient are shown in the table below:

Active ingredient	**Beximco**			**Square Pharmaceutical**			**Acme**		
	2004	**2005**	**2006**	**2004**	**2005**	**2006**	**2004**	**2005**	**2006**
Salbutamol	1,225,437	1,167,517	1,300,000	276,000	325,000	388,500	57,082	92,197	181,188
Salbutamol+ipratropium		30,724	25,000		52,500	105,000			
Levosalbutamol			20,000			15,000			
Beclomethasone	101,128	104,462	95,000	125,000	160,000	199,500	22,463	13,411	20,842
Salmeterol	47,590	36,869	40,000	31,500	52,500	21,000	21,233	7,864	15,417
Salmeterol+fluticasone	41,641	47,930	85,000	10,000	32,000	32,000		15,575	22,568
Ciclesonide			28,000	24,000		33,000			
Budesonide	17,846			42,000	43,000	31,500			
Ipratropium		6,145			33,000	10,500			
Triotropium			3,000						
Total MDIs	**1,433,642**	**1,393,647**	**1,596,000**	**508,500**	**698,000**	**836,000**	**100,778**	**129,047**	**240,015**
CFC (ODP tonnes)*	**49.5**	**44.2**	**52.9**	**10.3**	**14.3**	**17.3**	**2.5**	**3.3**	**6.1**

* In 2006, 13.6 and 0.6 ODP tonnes of CFCs were used by Beximco for the production of MDIs for GlaxoSmithKline and Eskayef respectively.

7. Only some 127,900 HFA seretide MDIs and 26,427 seretide multi-dose dry powder inhalers (DPIs) are imported into the country.

National strategy for the phase-out of CFC-based MDIs

8. Of the total current CFC-MDI production in Bangladesh, MDIs containing salbutamol, beclomethasone, salbutamol plus ipratropium, and salmeterol plus fluticasone represent over 90 per cent of the total production. Therefore, the Government of Bangladesh, together with the three manufacturing companies, the Drug Regulatory Agency, the Lung Association and the

medical community, decided to only convert these MDIs to HFA propellant, based on the following criteria:

(a) The specific needs of the patients in regard to their characteristics and demographic distribution;

(b) The efforts and resources invested during the last few years in introducing the use of MDIs, and the resulting familiarity of existing patients with the MDI;

(c) The CFC-MDIs currently manufactured by the three companies, the existing experience and skills of the personnel in the companies; and the maturity and established commercialization of HFA-MDI technology;

(d) The poor experience with the use of DPIs, the problems that these products are presenting, the difficulties that patients are having with these devices, and the higher development costs of multi-dose DPIs.

9. The Government of Bangladesh is proposing to implement the transition strategy with adequate awareness activities for enhancing MDI use and regulations aligned to the phase-out timing by the industry. The main elements of the strategy include:

(a) Implementing the investment project to phase out CFCs used for the production of MDIs by the three locally-owned manufacturing enterprises;

(b) Designing and implementing regulations to facilitate the phase-out of CFCs used in the production of MDIs and also to promote the adoption of non-CFC alternatives;

(c) Implementing awareness and capacity building among relevant stakeholders on the adoption of CFC-free alternatives; and

(d) Designing and implementing monitoring and verification protocols to confirm and report on status of CFC phase-out in the MDI subsector.

10. The rationale for developing DPI single dose products in Bangladesh was to cover the needs of a specific group of elderly patients who have coordination difficulties when it comes to applying MDI products, but not with the intention to replace CFC-MDIs as therapeutic treatment for asthma and COPD for all patients. However, doctors still prefer MDIs because of their ease of use and the effectiveness with which the formulation reaches the patients' respiratory system. DPIs are found to produce throat irritation and coughing, which affect the product's effectiveness.

11. Due to non-availability of non-CFC formulations for ipratropium bromide, triotropium and salmeterol combination, these MDIs have not been considered for product development in the project. The future need for these products was discussed with the Government of Bangladesh and the Lung Foundation. As a result, it has been decided to allow stockpiling of 45.4 ODP tonnes of CFCs for the continued production of MDIs for a three-year period starting in 2010 as shown in the table below. It is expected that the conversion process would be undertaken by the industry in Bangladesh as soon as feasible conversion options are available for these formulations.

Company	Products	CFC (ODP tonnes)
Beximco	Salmeterol, ipratropium bromide, triotropium bromide	22.43
Square	Salmeterol, ipratropium bromide, triotropium bromide	17.84
Acme	Salmeterol, ipratropium bromide	5.11
Total		**45.38**

12. The estimated cost of the transition strategy (excluding agency support costs), to be implemented by UNEP, is presented in the table below:

Activity	Cost (US $)
Awareness	150,000
Design and implementation of regulations	30,000
Project management, monitoring and reporting	55,000
Total	**235,000**

Project description

13. The production of MDIs at the three manufacturing plants utilizes the pressure filling process. CFC-11 is used for the preparation of a suspension slurry of the active ingredient to facilitate filling the precise quantity into the open aerosol container, after which the MDI container is closed with the aerosol metering valve, and the CFC-12 (as the propellant) is injected into the container under pressure through the metering valve.

14. Replacement equipment for the use of HFA propellant can be installed beside the existing equipment and, therefore, expansion of the production facilities will not be required. Beximco is requesting retroactive funding of US $107,746 for equipment already purchased for the production of HFA-MDIs in addition to US $281,240 for new additional equipment including a pressure vessel to allow for single-stage filling of salmeterol plus fluticasone. Equipment costs for Square (US $514,183) and Acme (US $467,783) include the procurement of suspension pressure vessels, pumps and ancillary equipment. Installation of the equipment needed for the conversion will be conducted by a reputable provider of aerosol equipment. Given that GlaxoSmithKline and Eskayef are only marketing products produced by Beximco, these two companies have not been included in the project.

15. The project proposes that a third party company will provide technical assistance for the development of the formulation for each specific drug molecule and strength, and transfer the technology to each one of the three MDI manufacturing enterprises. These enterprises will then use their own staff to adapt to the new technology with the supervision of the service provider's technical expert. This approach will represent significant savings on the cost of product development. For all the other products it is expected that only one formulation per product will be purchased for the three companies. Additional funding is being requested for the development of salbutamol and beclomethasone for Square and Acme since sharing these two HFA formulations that were developed for Beximco were not part of the agreement with the technology provider. The total cost for product development amounts to US $2,009,507, with the following breakdown:

Active ingredient	Retroactive (US$)	Development cost (US$)	Transfer cost (US$)			Total cost (US$)
			Beximco	Square	Acme	
Salbutamol	117,697	154,675*		40,000	40,000	352,372
Salbutamol+ipratropium		242,675	45,000	45,000	45,000	377,675
Salmeterol+fluticasone		242,675	45,000	45,000	45,000	377,675
Beclomethasone	113,380	128,055*	0	35,000	35,000	311,435
Ipratropium		132,675	30,000	30,000	30,000	222,675
Ciclesonide		262,675	35,000	35,000	35,000	367,675
Total	231,077	1,163,430	155,000	230,000	230,000	2,009,507

(*) Development costs for Square and Acme.

16. In the case of the salbutamol plus ipratropium, there is currently no suitable HFA-MDI approved. It is expected that the development of formulations for these MDIs will take approximately one year. During this time there will be a need for consultation with suitably experienced experts to advise the technical staff at the companies on the technical aspects of this project.

17. Incremental operating costs, calculated on the basis of the difference in prices between CFCs and HFC-134a, and the increased costs of canister, metering valve and actuator, have been estimated at US $693,926 for a two-year period.

18. The total overall cost of the phase-out of CFCs used in the manufacture of MDIs in Bangladesh has been estimated at US $4,089,527 (excluding the MDI transition strategy at US $235,000) with a cost-effectiveness of US $54.00/kg. The project cost breakdown is presented below:

MDI transition strategy US $265,550
Capital costs US $1,508,047
Technology transfer US $2,009,507
Operating costs US $571,972

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

19. The Secretariat reviewed the national strategy for the phase-out of CFCs in MDIs in Bangladesh and the investment phase-out project in light of:

(a) The MDI policy papers considered by the Executive Committee at its 37th Meeting (UNEP/OzL.Pro/ExCom/37/58), 49th Meeting (UNEP/OzL.Pro/ExCom/49/39) and 51st Meeting (UNEP/OzL.Pro/ExCom/51/39);

(b) The MDI phase-out projects so far approved for Cuba (UNEP/OzL.Pro/ExCom/41/33 and paragraphs 4 to 17 of document UNEP/OzL.Pro/ExCom/46/19), Uruguay (UNEP/OzL.Pro/ExCom/43/44) and Egypt (UNEP/OzL.Pro/ExCom/50/29);

(c) The NPP for Bangladesh (UNEP/OzL.Pro/ExCom/42/25) approved by the Executive Committee at its 42nd Meeting at a cost of US $1,355,000 plus agency support costs of US $119,775 for UNDP as the lead implementing agency and UNEP as cooperating agency (decision 42/19). The NPP also included an Agreement between the Government of Bangladesh and the Executive Committee.

Selection of alternative technology

20. According to the 2006 Medical Technical Options Committee report, single-dose DPIs may have a role in some countries because they require simple manufacturing technology, and can provide the opportunity to purchase a small number of doses at an affordable cost. Though there are concerns regarding the aggregation of particles in a hot and humid climate, they have been generally found to be effective. Noting the relatively simple technology involved in manufacturing DPIs and their potentially low cost, the Secretariat pointed out that the extended use of these devices would appear to be a cost-effective alternative in Bangladesh for the following reasons:

(a) There are 30 million patients who suffer from asthma and COPD. Less than 3.5 million MDIs are manufactured annually;

(b) As reported in the proposal, most of the population of Bangladesh resides in rural areas where more affordable but less preferable treatments are used. In these areas, oral medication and injectable treatment are the most common ones in the control of asthma and COPD;

(c) Considering that the annual per capita income in the country is around US $400 access to MDI treatment would be limited to a small portion of the population. As reported in the MDI transition strategy, in the last two years non-CFC MDIs have been sold at higher prices than CFC MDIs.

(d) Based on these observations, it would have been expected that the project would have addressed the issues concerning the low level of acceptance of the DPIs in Bangladesh.

21. On this issue, UNDP and UNEP indicated that:

(a) The use of DPIs as an alternative to CFC-MDIs was discussed with the enterprises in Bangladesh, two of which currently have a range of DPIs. It was determined that the DPI option does not represent a viable replacement for all the MDIs in use in the country. MDIs were also preferred over other medications for the efficacy, ease of use and affordability;

(b) The MDI is a treatment that has been recently introduced in Bangladesh as a step towards properly treating patients with an affordable and easily used product. Although the cost of the MDI is approximately US $2.00, the Government purchases MDIs and provides them free of charge to the population. In this regard, access to the use of MDIs is not limited to those who can afford it;

(c) The low production number of MDIs compared to the number of patients is because acceptance by patients is still being built and it will take some time before the products penetrate into rural areas.

Adjustment from the funding approved for the NPP for Bangladesh

22. In the context of the Executive Committee agreement on strategic planning (decision 33/54), the Committee agreed at its 35th Meeting that further funding must be predicated on a commitment by the country to achieve sustainable permanent aggregate reductions in consumption and production, as relevant. The Committee also acknowledged that some future years' reported consumption may go above or below the levels that result from the agreed calculation, if consumption numbers go above the resulting levels, such increases in consumption would not be eligible for funding. The resulting numbers represent maximum residual ODS that the Fund will pay to reduce, and existing Fund guidance related to eligibility of projects would be maintained in all respects (decision 35/57).

23. Based on decision 35/57, the Government of Bangladesh selected Option 2 as the starting point for determining the sustained reduction in CFC consumption in Bangladesh. Accordingly, the NPP for Bangladesh was approved for the phase-out of 260.5 ODP tonnes, representing the total remaining consumption eligible for funding (Annex VIII of document UNEP/OzL.Pro/ExCom/42/54). Since the remaining eligible consumption has already included the amount of CFCs that was used for manufacturing MDIs, the NPP should be adjusted accordingly to avoid double counting. For the calculation of this adjustment, the Secretariat notes as follows:

(a) In 2003, over 39.0 ODP tonnes of CFCs were used for the production of CFC-MDIs by two manufacturing plants: Beximco and Square. In 2004, this consumption increased to 62.3 ODP tonnes and one additional manufacturing plant, Acme, started production of MDIs.

(b) The NPP for Bangladesh was approved in early 2004. The cost of the NPP for Bangladesh (as well as for the majority of the NPPs for non-LVC countries) was calculated on the basis of a cost-effectiveness value of US $5.00 per kg of CFC used in the refrigeration servicing sector.

24. Therefore, the NPP for Bangladesh would need to be adjusted to reflect a CFC consumption of 198.2 ODP tonnes of CFCs (which excludes 62.3 ODP tonnes of CFCs used in the MDI sub-sector) and a reduction of US $311,500 in the overall funding level (i.e., based on a CFC consumption of 62.3 ODP tonnes and a cost-effectiveness value of US $5.00/kg). Also, on the basis of decision 35/57 (i.e., commitment by the country to achieve sustainable permanent aggregate reductions in consumption and production, as relevant), the level of CFC consumption in the MDI sub-sector in Bangladesh that might be considered as eligible for funding is 62.3 ODP tonnes. UNDP advised the Secretariat that it was still discussing this issue and was also having consultations with the Government of Bangladesh.

Scope and cost of the national strategy

25. In regard to the transition strategy for the phase-out of CFCs in MDIs, the Secretariat pointed out that:

(a) Currently, CFC and HFA-MDIs are manufactured in Bangladesh by locally owned enterprises.

(b) The law in the country prevents the importation of products from foreign companies when they are already produced by local companies. Also, for those MDIs where non-CFC alternatives involve either a carrier change or a change in the method of application, and because the alternatives are already listed in the European and British Pharmacopeia, the Directorate of Drug Administration of Bangladesh could register the products without referring to the Drug Control Committee;

(c) All manufacturers of MDIs have already been registered with the Directorate of Drug Administration of Bangladesh; therefore, all of them comply with good practices pertaining to manufacturing of drugs, including MDIs;

(d) It has been proven in both Article 5 and non-Article 5 countries that alternatives to CFC-MDIs are safe and effective in treating asthma and COPD. Furthermore, salbutamol and bechlomethasone HFA-MDIs and several DPIs are currently available on the market in Bangladesh;

(e) Bangladesh as a least developed country (LDC) under the World Trade Organisation has a patent right exemption for pharmaceutical products until 2016. Therefore, patent rights and protection issues are not expected to have an impact on the conversion process to HFA-MDIs;

(f) The project proposal for the conversion of three locally-owned MDI manufacturing plants has been prepared with the participation of major stakeholders, all of which have analyzed the technical and economic feasibility of the conversion of each of the CFC-MDI products available on the market. As a result, a group of CFC-MDI products was selected for conversion to alternative technologies;

(g) A strategy for stockpiling CFCs currently used for active ingredients that could not be converted to HFA-MDIs due to non-availability of formulations (i.e., ipratropium bromide, triotropium and salmeterol) has been prepared by the Government of Bangladesh and the Lung Foundation.

26. It should be noted that, as part of the NPP for Bangladesh, the Executive Committee approved US $214,000 for the establishment of a monitoring and management unit and US $60,000 for public awareness and information dissemination activities. An additional US $130,000 has been approved for the renewal of the institutional strengthening project (so far, total funding for institutional strengthening amounts to US $480,000).

27. Based on the above observations and taking into account the current situation of the MDI sector in Bangladesh, the request for US $265,550 for the implementation of the transition strategy cannot be justified. Only a modest technical assistance activity will be needed to complement the full introduction of HFC-134a MDIs in Bangladesh.

28. On this issue, UNEP advised that:

(a) The MDI manufacturing enterprises will have to give a commitment that they will be able to satisfy the country's MDI needs. Otherwise, the Government may decide to allow MDI imports, keeping in mind the critical health needs linked to these products;

(b) Experience in developing countries shows that any incremental specific needs when converting to non-CFC alternatives (e.g., HFA specific requirement) would require additional effort from the companies;

(c) At the country level, publicity, education and targeted awareness is needed for the market to understand that only the carrier and solvent have changed and the product does not have an adverse impact on patient health;

(d) The Directorate of Drug Administration undertakes registration of pharmaceutical products in close consultation with the Drug Control Committee, therefore, there is a need to work with the Directorate closely during the transition process. Other regulatory measures need to be defined and implemented, such as: a ban on licensing of CFC-MDIs from markets for formulations where alternatives are available; monitoring and reporting of CFC procurement; stockpile management and use for MDI manufacturing; cessation of CFC use by MDI manufacturing companies; and declarations and reporting on CFC-MDI imports;

(e) Although the project proposal has been endorsed by stakeholders other than the manufacturing companies, it should not be construed that all stakeholders played a role in assessing the technical and economic feasibility of each of the products. Uncertainty in product adoption is an issue that was highlighted during various consultations and hence needs to be addressed.

(f) In Bangladesh, there are three enterprises manufacturing more than 10 MDI formulations. There is a need for intense awareness efforts supported by regulatory interventions for MDI phase-out. Project Management is also a critical component for ensuring timely completion of phase-out activities.

Technical and cost issues related to the production facilities

29. The Secretariat and UNDP discussed technical and cost issues regarding the conversion of the three manufacturing plants from CFC to HFA propellant. The issues were, specifically: the request for retroactive payment for Beximco, and the request for additional equipment when the company is already producing HFA-MDIs; the eligibility of all the new equipment being requested for Acme and Pharma, taking into consideration that their production lines are relatively new; and the level of operating costs.

30. Subsequently, UNDP is considering adjustments to the cost of the projects by: removing some pieces of equipment that were already purchased by Beximco; retrofitting the existing mixing vessels in the production lines of Square and Acme; and reducing the capacities of the suspension vessels at Beximco and Acme. The operating costs are also being recalculated on the basis of the CFC consumption levels for the production of MDIs at the time of approval of the NPP for Bangladesh over a one-year period.

Technology transfer

31. The Secretariat and UNDP discussed several issues regarding technology transfer for the development of HFA-MDIs in Bangladesh. These issues were, specifically: the eligibility of the request for the development of a salbutamol plus ipratropium HFA-MDI when this CFC-MDI was only manufactured from 2005; the level of funding requested for development of ipratropium and ciclesonide HFA-MDIs, taking into consideration the relatively low levels of production and the fact that production of ciclesonide commenced only in 2004 by one company; and the technical capacity available in the country, considering that one enterprise has already developed two HFA-MDIs and the other two enterprises had already developed DPIs.

32. UNDP indicated that the approach for product development in Bangladesh consists in providing assistance for some formulations to each company, and additional technical support to self-develop other formulations in a timely manner. On this basis, of the ten different MDIs currently manufactured, six MDIs will be developed for the use of HFA propellant. Assistance from the Fund is being requested for product formulation for four MDIs and for technical assistance to be provided to local experts for the development of the other two MDIs. Formulation costs for MDIs with the same active ingredient have been reduced by sharing the formulation among the manufacturing enterprises. Furthermore, product development of each active ingredient will be done for one of the strengths of the drug only. Costs associated with the formulation of ciclesonide and the combined salbutamol with ipatropium HFA-MDIs will be covered by the enterprises and only funds for technical assistance will be requested.

33. Furthermore, some of the costs associated with product development will be covered both in an effort to build the capacity of the companies as well as to keep costs down, as shown in the table below:

Funded by the project	**Funded by the enterprises**
Formulation and product development (including specification development)	Standard analytical method development and validation of all analytical methods (US $3,500)
Component and raw material testing	Overheads for trial batches, such as electricity, utilities, staff time (US $5,000)
Materials for stability batches	Laboratory testing of trial batches (US $8,000)
Manufacturing of stability batch supervision	Stability testing (US $211,000)
Technical supervision of laboratory testing of trial batches	Formal equipment and process validation (US $5,000)
Analytical method development where specific to non-CFC formulation	
Technical support during validation	

Revision to the agreement between the Government and the Executive Committee

34. The current agreement between the Government of Bangladesh and the Executive Committee addresses all the remaining CFC consumption eligible for funding, including 62.3 ODP tonnes of CFCs that were used for the manufacturing of MDIs at the time of approval of the NPP. Therefore, in case the project for the phase-out of MDIs in Bangladesh is approved by the Executive Committee, the current agreement should be modified accordingly.

Agreed level of funding

35. The Secretariat and UNDP and UNEP are finalizing discussions on cost-related issues. Outcomes of the discussions will be communicated to the Executive Committee prior to the 52nd Meeting.

RECOMMENDATION

36. Pending.

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