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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Fifty-sixth Meeting
Doha, 8-12 November 2008

PROJECT PROPOSAL: PAKISTAN

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

Aerosol

• National strategy for transition to non-CFC MDIs and plan for phase-out of CFCs in the manufacture of pharmaceutical metered dose inhalers (MDIs)	UNDP, UNEP

PROJECT EVALUATION SHEET – NON-MULTI-YEAR PROJECT
PAKISTAN

PROJECT TITLE(S)	BILATERAL/IMPLEMENTING AGENCY
(a) National strategy for transition to non-CFC MDIs and plan for phase-out of CFCs in the manufacture of pharmaceutical metered dose inhalers (MDIs)	UNDP, UNEP

NATIONAL CO-ORDINATING AGENCY	National Ozone Unit

LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT

A: ARTICLE-7 DATA (ODP TONNES, 2007, AS OF OCTOBER 2008)

CFCs	170.3		

B: COUNTRY PROGRAMME SECTORAL DATA (ODP TONNES, 2007, AS OF OCTOBER 2008)

ODS	Aerosol	MDI		
CFC-11	0.0	18.4		
CFC-12	0.0	81.2		
Total	0.0	99.6		

CFC consumption remaining eligible for funding (ODP tonnes)	0.0

		Funding US $ million	Phase-out ODP tonnes
CURRENT YEAR BUSINESS PLAN ALLOCATIONS	(a)	US $1,009,091 (UNDP)	27.3
	(b)	US $200,000 (UNEP)	

PROJECT TITLE:	
ODS use at enterprise (ODP tonnes):	n/a
ODS to be phased out (ODP tonnes):	99.6
ODS to be phased in (ODP tonnes):	0
Project duration (months):	36
Initial amount requested (US $):	2,257,212
Final project costs (US $):	
Development Cost	207,050
Incremental Capital Cost:	313,115
Incremental Operating Cost:	69,173
Implementation Oversight and Verification	149,200
Contingency for ICC (10%)	31,311
Transition Strategy	70,000
Total Project Cost:	839,850
Local ownership (%):	GSK (21%), Zafa (100%), Macter (100%)
Export component (%):	0
Requested grant (US $):	839,850
Cost-effectiveness (US $/kg):	9.11
Implementing agency support cost (UNDP) (US $):	57,739
Implementing agency support cost (UNEP) (US $):	9,100
Total cost of project to Multilateral Fund (US $):	906,689
Status of counterpart funding (Y/N):	Y
Project monitoring milestones included (Y/N):	Y

SECRETARIAT'S RECOMMENDATION	For Individual Consideration

PROJECT DESCRIPTION

1. On behalf of the Government of Pakistan, UNDP as the lead implementing agency has submitted a national strategy for transition to non-CFC MDIs for phase-out of CFCs in the manufacturing of pharmaceutical metered-dose inhalers (MDIs) in Pakistan for consideration by the Executive Committee at its 56th Meeting. The total funding requested in the project as submitted is US $2,076,216 plus total support costs of US $155,716 for UNDP (investment component) and US $181,000 plus agency support costs of US $23,530 for UNEP (for the implementation of the transition strategy).

Background

2. At its 54th Meeting, the Executive Committee considered a request submitted by UNDP for the preparation of an MDI phase-out project in Pakistan at the amount of US $60,000. This was submitted with the supporting data required under decision 51/34(c), according to which such requests were to be considered by the Executive Committee on a case-by-case basis. Following a discussion, the project preparation was approved, on the understanding that it should cover only the enterprise and consumption identified at the time when the remaining eligible CFC consumption had been agreed on, and target only the percentage that was locally owned; and any new MDI production after the 42nd Meeting was not eligible for funding (decision 54/26).

Sector background

3. The manufacturing of CFC-MDIs in Pakistan was started in 1981 by GlaxoSmithKline (GSK) Pakistan Limited (with a 21 per cent local ownership share). Since then, the following two additional MDI manufacturing enterprises have been established:

(a) Zafa Pharmaceutical Laboratories, that established and registered its products in 1998; and

(b) Macter International, that purchased a used CFC-MDI production line in 2004, and where development and testing for two MDI products began in 2007 and the first three products were launched in 2008.

4. Currently, all MDIs manufactured in Pakistan are CFC-based, and there is no local capacity or capability to produce non-CFC-MDIs. In 2007, total CFCs used for the manufacturing of 4.21 million MDIs was 99.6 ODP tonnes. The active ingredients in MDIs manufactured in Pakistan are salbutamol (manufactured by the three enterprises), salbutamol/beclomethasone (manufactured by Macter and Zafa), and beclometahsone (two different doses), salmetrol/fluticasone (three different doses), ipratropium, salmeterol and triamcinolone acetonite (manufactured only by Macter).

5. The basic information on the enterprises manufacturing MDIs in Pakistan is presented in the Table below.

Enterprise	Date of equipment installation	Date of first production(*)	Production capacity (million MDIs/yr
GSK	1981	1981	4.0
Macter	1994	2008	10.0
Zafa	1998	2005	0.2

(*) Commercial production of MDIs.

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

6. In Pakistan, prices of all medicines are controlled by the Government to make them affordable to a wider portion of the population. In the case of locally manufactured MDIs, the price is the lowest in the region. These artificially low costs cannot be maintained if local production ceases. Therefore, the project proposes to assist the manufacturing enterprises to convert to HFA technologies with supporting public education and awareness activities; capacity building through technical workshops and seminars for the enterprises and the Ozone Unit; revision to ODS regulations; development and implementation of a system for fast-track adoption of non-CFC-MDIs; and assistance to develop procedures for essential use nominations for CFCs post-1 January 2010. The estimated cost of the transition strategy is US $181,000

7. The Government of Pakistan is proposing to launch a first batch of non-CFC-based MDIs 24 to 26 months after the MDI phase-out investment project has been approved by the Executive Committee.

Project description

8. The project consists of the following components:

(a) Phase-out of 82.6 ODP tonnes of CFCs (based on the 2006 MDI production level) used in the manufacturing of salbutamol at GSK by replacing the equipment in the current production line with a single Macromat filling line and associated pressure filling and preparation vessel, and modifying the existing area at a total cost of US $1,820,500 (before adjustment due to foreign ownership component). Incremental operating costs calculated for a one-year period and the 2006 production level have been estimated at US $2,329,997. No request has been included for development of the HFA-salbutamol MDI, as these costs will be covered by GSK;

(b) Phase-out of 1.2 ODP tonnes of CFCs (based on the 2007 MDI production level) used in the manufacturing of salbutamol and salbutamol/beclomethasone at Zafa, through the replacement of the equipment in the current production line by a manual filling line and associated pressure filling and preparation vessel, and modifications to the existing area at a total cost of US $308,000 (before counterpart contribution by the enterprise). Since the enterprise commenced commercially manufacturing CFC-MDIs in 2005, costs associated with product development will be covered by the enterprise; similarly, operating costs are not claimed; and

(c) Phase-out of 1.2 ODP tonnes of CFCs (based on the 2007 production level) used in the manufacturing of MDIs with several active ingredients at Macter through the installation of a single Macromat filling line and associated pressure filling and preparation vessel and modifications to existing area at a total cost of US $1,412,853 (before counterpart contribution by the enterprise). Since the enterprise commenced commercially manufacturing CFC-MDIs in 2008, costs associated with product development will be covered by the enterprise; similarly, operating costs are not claimed.

Total cost of the project

9. The total cost of the phase-out of CFCs used in the manufacture of MDIs in Pakistan has been estimated at US $2,076,202 after adjustments due to the foreign ownership component (79 per cent for GSK) and counterpart funding (30 per cent each for Zafa and Macter), plus US $181,000 for the implementation of the transition strategy. The project cost breakdown is presented below:

Enterprise	(US $)				
	Capital	**Operating**	**Subtotal**	**Adjustment***	**Total**
GSK	1,820,500	2,329,997	4,150,497	(3,278,893)	871,604
Zafa	308,000		308,000	(92,400)	215,600
Macter	1,412,853		1,412,853	(423,856)	988,997
Subtotal	3,541,353	2,329,997	5,871,350		2,076,202
Transition strategy					181,000
Total					**2,257,202**

(*) Adjustments due to the foreign ownership component (79 per cent for GSK) and counterpart funding (30 per cent each for Zafa and Macter).

10. The project will be completed by 2011.

SECRETARIAT'S COMMENTS AND RECOMMENDATION

COMMENTS

11. The Secretariat reviewed the project proposal in light of:

(a) The policy papers on MDIs considered by the Executive Committee at its 37th, 49th and 51st meetings;

(b) The project preparation request for the phase-out of CFCs in MDIs in Pakistan included under the UNDP work programme amendments submitted to the 54th Meeting;

(c) The MDI phase-out projects so far approved for Bangladesh, Cuba, Egypt, Islamic Republic of Iran, Mexico and Uruguay, and;

(d) Relevant decisions by the Executive Committee on MDIs, in particular decision 54/26 on the approval of funding for the preparation of the MDI project in Pakistan.

Essential use exemptions for CFCs

12. The Secretariat pointed out that in its decision 51/34, the Executive Committee requested, *inter alia*, that countries with MDI manufacturing plants should be advised of the timing for beginning to consider the need for essential use exemptions beyond the 2010 phase-out date, and that the preparation of a nomination for essential use exemptions might have been needed to begin in 2007 for submission to the Parties for their consideration in 2008. According to the project proposal, it is estimated that conversion will be completed by end of 2011, almost two years after the mandatory date for the complete phase-out of CFCs. However, the need for essential use exemptions for CFCs, or for stockpiling pharmaceutical-grade CFCs for a short period of time (i.e., one to two years) has not been considered either in the project proposal or the strategy. UNDP reported that this issue was seriously considered during the stakeholder consultations with the Government of Pakistan and the MDI enterprises. It was noted that there is no capacity in the country to allow for stockpiling of CFCs. Additionally, with the uncertainty of how stockpiling will be considered, it was difficult for Pakistan to intentionally place itself in non-compliance as a result of attempting to stockpile CFCs in 2008 and 2009 for consumption in 2010 and 2011. Therefore, the best option was for the Government to utilize the essential use nominations procedure.

Transition strategy

13. The Secretariat raised the following issues on the transition strategy for the phase-out of CFCs in MDIs in Pakistan, which were addressed by UNDP and UNEP as follows:

(a) There is no indication of the size of the population affected by asthma and the size of the population that has access to MDI therapy. Based on the number of MDIs available in the country, and the fact that between 5 to 10 per cent (or more) of the total population in Pakistan has asthma, the total population that could have access to MDI treatment is very small;

On this issue, the agencies reported that the access to MDIs is increasing and this is reflected in the increase in sales volume experienced in Pakistan. This was confirmed by doctors and industry during the preparation of the project. Currently, there is very little awareness on CFC-MDI phase-out and adoption of alternatives. Based on experiences in other countries, it would be necessary for implementing education and capacity building activities to facilitate smooth adoption of alternatives in this growing market.

(b) Worldwide production of CFC-based MDIs is progressively being replaced by alternative treatments, including HFA-MDIs and DPIs. Therefore, as the demand for MDIs increases in Pakistan (as indicated in the project), it is expected that the availability of non-CFC based treatments for asthma will also increase. Currently, HFA-based salmetrol/fluticasone, fluticasone salbutamol and salmeterol are available in the country (albeit in small quantities);

The agencies reported that, as non-CFC alternatives are more expensive, this would be a deterrent to adopting this alternative. There has to be a "push" strategy for promoting alternatives. The focus of information dissemination and capacity building activities would also be on allaying apprehensions related to the use of CFC-free alternatives, which is essential for the adoption of CFC-free alternatives;

(c) It is not clear how the proposed technical support to the industry through south-south cooperation on technology transfer will accelerate implementation of the MDI phase-out project. The US $20,000 being requested cannot be justified;

The agencies indicated that these sessions would be helpful for companies in Pakistan, which need support for technology transfer. It would help them minimize the time taken to convert to HFA technologies, thereby minimizing use of CFCs. This is also expected to reduce the demand for essential uses of CFCs in Pakistan (if any).

(d) The request for US $70,000 for distribution of printed material and video cannot be fully justified, due to the very small population with asthma that has access to MDI treatment and the availability of other non-CFC MDIs in the country;

The agencies indicated that the primary objective is to facilitate conversion to non-CFC alternatives. The videos are designed to provide ongoing support to users/medical colleges on safe and correct use of alternatives to CFC-MDIs.

14. Subsequently, the level of funding for the transition strategy was agreed at US $70,000.

Eligible CFC consumption and manufacturing lines

15. In reviewing the proposal, the Secretariat pointed out that:

(a) Pakistan's country programme update, submitted by the Government of Pakistan to the 41st Meeting, reported that GSK was the only company manufacturing MDIs in the country with a CFC consumption of 69.4 ODP tonnes;

(b) At its 51st Meeting, the Executive Committee considered a policy paper on MDIs (UNEP/OzL.Pro/ExCom/51/39), which contained information submitted by relevant Article 5 countries with MDI manufacturing enterprises. Information provided by Pakistan indicated that, besides GSK, there was also another company (Zafa Pharmaceutical), established since 1973 and that started production of CFC-MDIs in 2005;

(c) As per decision 54/5 (d)(iii), requests for MDI investment activities "should provide documentation and certify that the facilities producing MDIs and seeking funding were producing CFC MDIs in the year in which the national phase-out plan (NPP) or sector plan had been prepared". Both Zafa and Macter were not producing MDIs in the year when the last CFC phase-out project was prepared; and

(d) At its 54th Meeting, the Executive Committee approved funding for the preparation of an investment project for the phase-out of CFCs used in the MDI sub-sector in Pakistan, on the understanding that "project preparation should cover only the enterprise and consumption identified at the time when the remaining eligible CFC consumption had been agreed, and target only the percentage that was locally owned; and any new MDI production after the 42nd Meeting, at which the last sector plan for Pakistan had been approved, was not eligible for funding consistent with approvals made for similar investment projects in that sector." (decision 54/26).

16. Based on the above decisions, only the locally-owned portion of the MDI production line of GSK with a production output of 2,556,277 MDIs and a CFC consumption of 61 ODP tonnes (2003) was eligible. However, UNDP indicated that both the Government of Pakistan and Zafa had submitted official data showing that the enterprise submitted a request to the Ministry of Health for the registration of a CFC salbutamol MDI in November 1998, and conducted stability studies on three different batches of 1,000 salbutamol MDIs each from January 2002 to January 2005. In light of the new information received, UNDP had requested that the conversion of CFC-MDI production line at Zafa be included in the proposal.

17. In light of the new official data submitted by the Government of Pakistan through UNDP pointing to the production of three batches of CFC-MDIs for stability tests from 2002, the Executive Committee might wish to consider whether the conversion of the CFC-production line at Zafa is eligible for funding. On the issue of Macter given that the manufacturing of CFC MDIs by this enterprise commenced in 2007, the request for funding for Macter was ineligible and therefore removed from the project.

Production by GSK

18. In regard to the CFC-MDI production line at GSK, a number of issues were raised concerning the baseline equipment, the apparent high cost of some of the equipment items being requested, and the very high level of the operating costs (i.e., US $2,329,997), which were calculated based on an incremental cost of US $0.65/MDI and the 2006 production of MDIs (3,584,611 units). UNDP explained that the very high level of capital and operating costs was due to the methodology used by GSK in filling HFA-MDIs. The active ingredient in several of the HFA-MDIs that have been developed by GSK is in suspension (and not in solution) in HFA, which requires more complex equipment (i.e., to allow for a single stage filling) and the use of specific cans (from plain aluminium to PTFE coated at a cost US $0.37), metering valve (US $0.15) and a metering actuator (US $0.05).

19. UNDP also indicated that further to discussions between GSK Pakistan with its parent company the initial proposal, with GSK providing the HFA formulation to GSK Pakistan, was no longer viable due to environmental conditions in the country, which will make it difficult to ensure the quality of the product. As such, the parent company has authorized GSK Pakistan to produce its own HFA-MDI formulation. Although US $800,000 would be required for the development of a salbutamol HFA-MDI by GSK Pakistan, the new formulation will require a simpler MDI production line that allows for filling the cans in two stages and, therefore, at a lower cost (US $796,700) and lower operating costs (US $609,384 based on the 2006 level of consumption) as compared to the original project. Based on further discussions, the level of funding agreed for the conversion of the MDI manufacturing line at GSK (before any adjustments) was reduced to US $1,556,084 (i.e., US $2,594,413 lower than the original request), calculated on the basis of the 2003 MDI production levels.

Production by Zafa

20. On the basis of the new production data provided by Zafa, UNDP revised the original proposal to include in addition to the request for equipment (US $196,000 after deducting counter part funding), a request for development of HFA-MDIs for salbutamol (US $80,500) and salbutamol/beclomethasone (US $105,000) and operating costs (US $5,292 based on the 2007 level of production). The revised project cost is US $386,792.

21. In regard to the level of funding being requested the Secretariat notes as follow:

(a) The level of funding associated with the additional equipment required for the conversion of the CFC-MDI production is adequate;

(b) The request for development of the salbutamol/beclomethasone is not eligible since there was no production of MDIs with this active ingredient in 2003; and

(c) The request for incremental operating costs is not eligible since the commercial production of CFC-MDIs commenced only in 2005;

(d) Based on the above observations, the cost of the conversion of Zafa is US $276,500.

Total funding

22. The total level of funding requested, in case that the CFC-MDI production line at Zafa is eligible for funding, is US $100,800 plus US $70,000 for the transition strategy with the following breakdown:

Description	**(US $)**			
	Project cost	**Counterpart**	**Ownership**	**Total**
GSK Pakistan				
Product development	150,000	(45,000)	(82,950)	22,050
Capital cost	796,700	(239,010)	(440,575)	117,115
Operating cost	435,000	(130,500)	(240,555)	63,945
Sub-total GSK Pakistan	1,381,700	(414,510)	(764,080)	203,110
Zafa				
Product development (salbutamol)	115,000	(34,500)		80,500
Capital cost	280,000	(84,000)		196,000
Operating cost	-	-		-
Sub-total Zafa	395,000	(118,500)	-	276,500
Total (GSK and Zafa)	1,776,700	(533,010)	(764,080)	479,610
Adjustment (national phase-out plan)				(378,810)
Total cost				100,800
Transition strategy				70,000

23. Given the low level of funding that will result after adjustments to the MDI project in Pakistan are applied, the resulting support costs of US $9,072 will not allow UNDP, as the lead implementing agency, to implement the project adequately. Therefore, an additional US $100,000 is being requested to provide oversight and verification of the conversion in all the MDI manufacturing enterprises in case conversion of both enterprises is funded.

24. However, in the event that the conversion of the production line at Zafa is ineligible, the total calculated adjustments associated with the 30 per cent contribution by GSK (US $414,510), the ownership component (US $764,080) plus the adjustment to avoid double counting from the national phase-out plan (US $378,810), are higher (i.e., US $1,178,590) than the revised cost of the investment component of the project (i.e., US $203,110). So the only element eligible would be the transition strategy totalling $70,000. UNDP would need an additional US $70,000 to assist GSK in converting its CFC production line.

RECOMMENDATION

25. The Executive Committee might wish to consider the national transition strategy for the phase-out of CFC MDIs in Pakistan in light of the Secretariat's comments.

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