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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: COLOMBIA**

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

Aerosol

- Phase-out of CFC in the manufacturing of MDIs

UNDP

**PROJECT EVALUATION SHEET – NON-MULTI-YEAR PROJECT  
COLOMBIA**

**PROJECT TITLE(S)****BILATERAL/IMPLEMENTING AGENCY**

(a) Phase-out of CFC in the manufacturing of MDIs	UNDP
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**NATIONAL CO-ORDINATING AGENCY**

Ozone Technical Unit (UTO)

**LATEST REPORTED CONSUMPTION DATA FOR ODS ADDRESSED IN PROJECT****A: ARTICLE-7 DATA (ODP TONNES, 2007, AS OF OCTOBER 2008)**

CFCs	263.1		

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

ODS	Aerosol	MDI		
CFC-11	0.0	1.1		
CFC-12	0.0	2.9		
CFC-13	0.0	0.0		
Total	0.0	4.0		

**CFC consumption remaining eligible for funding (ODP tonnes)**

0.0

**CURRENT YEAR BUSINESS PLAN  
ALLOCATIONS**

Funding US \$ million

Phase-out ODP tonnes

(a)	0.185	5.0

**PROJECT TITLE:**

ODS use at enterprise (ODP tonnes):	
ODS to be phased out (ODP tonnes):	7.42
ODS to be phased in (ODP tonnes):	n/a
Project duration (months):	36
Initial amount requested (US \$):	409,359
Final project costs (US \$):	409,359
Incremental Capital Cost (including product development):	756,315
Contingency (10 %):	75,631
Incremental Operating Cost:	95,000
Adjustment Required under Decision 52/30 (b):	(30,500)
Counterpart Funding under Decision 54/5(d):	(487,087)
Total cost to the Fund	409,359
Local ownership (%):	100%
Export component (%):	0%
Requested grant (US \$):	409,359
Cost-effectiveness (US \$/kg):	55.16
Implementing agency support cost (US \$):	30,701
Total cost of project to Multilateral Fund (US \$):	440,060
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 Colombia, UNDP has submitted a project proposal for the phase-out of CFCs in the manufacturing of metered-dose inhalers (MDIs) in Colombia for consideration by the Executive Committee at its 56<sup>th</sup> Meeting. The total funding requested in the project as submitted is US \$1,076,740. However, the Government is only requesting US \$409,359 plus agency support costs of US \$30,701 for UNDP. The remaining funding of US \$667,381 will be covered by the enterprise (a letter of commitment by the enterprise to that effect has been attached to the project proposal).

### Background

2. At its 54<sup>th</sup> Meeting, the Executive Committee considered a request submitted by UNDP for the preparation of an MDI phase-out project in Colombia at the amount of US \$30,000. The submission contained 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 request was approved (decision 54/27).

### Sector background

3. MDIs are used in Colombia for the treatment of asthma and chronic obstructive pulmonary disease (COPD). The MDI market is supplied by imported CFC- and HFA-MDIs and locally produced CFC-MDIs in a lower proportion.

4. Laboratorios Chalver is the sole locally-owned enterprise producing CFC-MDIs. The MDI production line was established in 2001 with the first batch manufactured by the end of 2002. The enterprise has developed CFC-MDIs with seven different active ingredients, as shown in the table below:

Active ingredient	MDI (units) CFC consumption (ODP tonnes)									
	2003		2004		2005		2006		2007	
	MDI	CFC	MDI	CFC	MDI	CFC	MDI	CFC	MDI	CFC
Beclomethasone	63,000	1.1	69,000	1.2	3,000	0.1	9,000	0.2	45,366	0.8
Ipratropium	0	-	42,000	0.7	78,000	1.3	12,000	0.2	118,819	2.0
Salbutamol	144,000	2.4	300,000	5.0	0	-	72,000	1.2	239,501	4.0
Salbutamol/beclomethasone	6,000	0.1	3,000	0.1	36,000	0.6	15,000	0.3	32,750	0.5
Salbutamol/ipratropium	0	-	0	-	10,000	0.2	5,000	0.1	8,913	0.1
Budesonide	0	-	0	-	0	-	0	-	0	-
Fluticasone	0	-	0	-	0	-	0	-	0	-
Total	213,000	3.6	414,000	6.8	127,000	2.1	113,000	1.9	445,349	7.4

5. In 2007, Laboratorios Chalver was able to reduce the MDI costs to continue offering products at competitive prices. Currently, this enterprise is an important supplier of MDIs to national health care institutions in Colombia.

6. The National Institute of Food and Drug Surveillance is responsible for the registration of new drugs. In May 2004, the Drug Review Commission allowed the use of CFC-MDIs until 2010. In 2008, the Ministry of Health issued a ban on the registration of new CFC-MDIs and the renewal of existing registered CFC-MDIs, and established December 2009 as the deadline for the conversion of CFC-MDIs except for those active ingredients where conversion is not feasible.

### Project description

7. The project is to assist Laboratorios Chalver to phase out CFC consumption in the manufacturing of pharmaceutical MDIs by converting its production line to HFA technology by 2012. The project

involves the development of HFA-MDIs for the following active ingredients, at a total cost of US \$556,000. An additional US \$50,000 is included for technical assistance as part of the development of HFA-MDIs and expert advice throughout implementation of the project:

<b>Active ingredient</b>	<b>Year of production</b>	<b>Cost (US\$)</b>
Beclomethasone (150 mg)	2003	106,000
Beclomethasone (250 mg)	2003	86,000
Ipratropium	2004	129,000
Salbutamol	2002	106,000
Salbutamol/beclomethasone	2003	129,000
Technical assistance		50,000
<b>Total</b>		<b>606,000</b>

8. The production line would need to be partially retrofitted and re-equipped to allow for filling HFA-MDIs both in single-stage and two-stage modes (when operated in two-stage filling mode, the micro-filler will be used to introduce the ethanol solution, the vacuum crimper will be adjusted to apply a light vacuum during crimping and the diaphragm filler will be configured to fill with propellant only). The total capital cost has been estimated at US \$354,946. One-year incremental operating costs have been calculated at US \$115,790 on the basis of the 2007 level of MDI production.

9. The total cost of the project is US \$1,076,740, before any adjustments as required by relevant decisions by the Executive Committee.

### **SECRETARIAT'S COMMENTS AND RECOMMENDATION**

#### **COMMENTS**

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

- (a) The policy papers on MDIs considered by the Executive Committee at its 37<sup>th</sup>, 49<sup>th</sup> and 51<sup>st</sup> meetings;
- (b) The project preparation request for the phase-out of CFCs in MDIs in Colombia included under the UNDP work programme amendments submitted to the 54<sup>th</sup> Meeting;
- (c) The MDI phase-out projects so far approved for Cuba at its 41<sup>st</sup> and 46<sup>th</sup> Meetings, Egypt at its 50<sup>th</sup> Meeting, Iran at its 52<sup>nd</sup> Meeting, Mexico at its 53<sup>rd</sup> Meeting and Uruguay at its 43<sup>rd</sup> Meeting, and;
- (d) Relevant decisions by the Executive Committee on MDIs.

#### Essential use exemptions for CFCs

11. 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 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 2012, three 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 aerosol-grade CFCs for a short period of time (i.e., one to two years) was not addressed in the project proposal. UNDP reported that an import quota level has been issued to the MDI manufacturing plant for 2009 that would create the

possibility of stockpiling for 2010 without any risk of non-compliance. Colombia would therefore not need to ask for essential uses for that year. Requests for future years (i.e., 2011 and 2012), would depend on the progress achieved in the implementation of the project, the levels of CFC stockpile and MDI needs in Colombia (based on the progress on implementation of the project in 2009, the Government will determine whether additional imports (under the maximum allowed level) should be authorized for 2011 and 2012).

#### Technical and cost issues

12. The objective of the investment project is to phase out 7.42 ODP tonnes of CFCs used in the manufacture of MDIs with the following active ingredients: beclomethasone, salbutamol, salbutamol/beclomethasone and ipratropium. However, at the time the national phase-out plan for Colombia was approved by the Executive Committee (41<sup>st</sup> Meeting in December 2003), only 6.1 ODP tonnes of CFCs were used in the manufacturing of MDIs. Furthermore, CFC-MDIs with ipratropium were manufactured only from 2004. On this issue, UNDP pointed out that, in 2003, Laboratorios Chalver established an MDI production plant with the capacity to produce 3.3 million units per year. As the installed capacity has not changed since 2003, UNDP took the latest CFC consumption (which is within this capacity level) as the amount to be phased out. Production of ipratropium was included in the proposal, as it was produced in 2003, since for a product to be licensed and approved, activities at production scale (stability batches) need to be undertaken up to a year in advance. Therefore established production capability of ipratropium existed in 2003.

13. As reported in the project proposal, the level of CFC-MDIs manufactured by Laboratorios Chalver decreased in 2005 and 2006 due to the arrival of CFC-MDIs from India at lower prices. Given the relatively low level of MDI production by the enterprise over the last six years and the very high quantity of cheaper MDIs produced in India, the Secretariat questioned the economical viability and long-term sustainability of converting the enterprise to non-CFC technologies. UNDP reported that the challenge posed by the MDIs imported from India was confronted by Laboratorios Chalver by reducing production costs; as a result, sales recovered to the point that production in 2007 was four times that of 2006.

14. The Secretariat discussed with UNDP issues related to the capacity of the production line, estimated at 3.3 million MDIs/year, compared to the maximum levels of actual production (i.e., 445,349 MDIs in 2007), the prices of equipment items to be installed in the existing production line, and the technical assistance to be provided by UNDP. All these issues have been successfully addressed. The request for the reformulation of ipratropium was withdrawn since manufacturing of this MDI commenced only in 2004; and incremental operating costs were recalculated based on the 2003 CFC consumption of 6.1 ODP tonnes and not on the 2007 reported consumption of 7.4 ODP tonnes.

#### Adjustment from the funding approved for the NPP for Colombia

15. The adjustment to avoid double counting, as there is no remaining CFC consumption eligible for funding in Colombia, amounts to US \$30,500 (calculated on the basis of US \$5.00/kg as the cost-effectiveness of the servicing sector component of the national phase-out project for Colombia and a CFC consumption of 6.1 ODP tonnes).

Agreed level of funding

16. The Secretariat and UNDP concluded their discussions on cost-related issues, and agreed on the following level of funding for the project for the phase-out of CFC consumption in the manufacture of MDIs in Colombia:

<b>Description</b>	<b>US \$</b>
Capital cost	354,946
Product development (excluding ipratropium)	477,000
Operating costs (one year based on 2003 consumption)	95,000
Total cost	926,946
Adjustment required under decision 52/30 (b)	(30,500)
Counterpart funding under decision 54/5(d)	(487,087)
Total cost to the Fund	409,359

17. The Secretariat notes that the counter part contribution from the enterprise represents over 52 per cent of the total cost of the project.

**RECOMMENDATION**

18. The Executive Committee might wish to consider approving the project for the phase-out of CFCs in the manufacture of metered-dose inhalers in Colombia at the amount of US \$409,359 plus agency support costs of US \$30,701 for UNDP, having taken into account a deduction of US \$30,500 from the total to eliminate double-counting of funds provided under the national phase-out plan and US \$487,087 as a counterpart contribution by the enterprise and in light of the comments by the Secretariat.

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