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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

AMENDMENTS TO UNDP WORK PROGRAMME FOR 2007

COMMENTS AND RECOMMENDATION OF THE FUND SECRETARIAT

1. UNDP is requesting approval from the Executive Committee for US $813,345 in respect of amendments to its 2007 Work Programme, plus agency support costs of US $56,745.

2. The activities proposed in UNDP's Work Programme Amendments are presented in Table 1 below:

Table 1: UNDP's Work Programme Amendments

Country	Activity/Project	Amount Requested (US $)	Amount Recommended (US $)
SECTION A: ACTIVITIES RECOMMENDED FOR BLANKET APPROVAL			
A.1. Renewal of institutional strengthening			
Brazil	Institutional strengthening: Phase V	351,000	351,000
Colombia	Institutional strengthening: Phase VI	275,600	275,600
	Subtotal for blanket approval:	626,600	626,600
SECTION B: ACTIVITIES RECOMMENDED FOR INDIVIDUAL CONSIDERATION			
B.1 Project preparation			
Colombia	PRP for MDI investment project	30,000	For individual consideration
India	PRP for MDI investment project	100,000	For individual consideration
	Subtotal for individual consideration:	130,000	
Subtotal for sections A and B:		756,600	
Agency support costs (7.5 per cent for project preparation and institutional strengthening, and for other activities over US $250,000, and 9 per cent for other activities under US $250,000):		56,745	46,995
Total:		813,345	673,595

SECTION A: ACTIVITIES RECOMMENDED FOR BLANKET APPROVAL

A.1. Renewal of institutional strengthening

Brazil: Institutional strengthening: (Phase V): US $351,000
Colombia: Institutional strengthening: (Phase VI): US $275,600

Project descriptions

3. UNDP submitted requests for the renewal of the institutional strengthening projects for Brazil and Colombia. The descriptions of the institutional strengthening projects for the above countries are presented in Annex I to this document.

Fund Secretariat's comments and recommendations

4. The Fund Secretariat recommends blanket approval of the institutional strengthening renewal request for Brazil and Colombia at the level of funding shown in Table 1. The Executive Committee may wish to express to the Governments of Brazil and Colombia the comments which appear in Annex II to this document.

SECTION B: ACTIVITIES RECOMMENDED FOR INDIVIDUAL CONSIDERATION

B.1 Project preparation

Project Preparation for CFC-MDI conversion projects: Colombia and India

Background

5. The Executive Committee, at its 51st Meeting, agreed in decision 51/34, *inter alia*, "to consider, on a case-by-case basis the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that they must include a comprehensive justification from the country concerned for the need to receive assistance and, as a minimum, should provide the following detailed information:

(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."

6. UNDP submitted two requests for project preparation of conversion projects in the MDI sector for Colombia and India. Data provided by UNDP for each request as required under the above decision is summarized below.

Colombia: PRP for MDI investment project: US $30,000

Project Description

7. On behalf of the Government of Colombia, UNDP is submitting a request for project preparation to phase out CFC use in the MDI manufacturing sector. The national CFC phase-out plan for Colombia[1] reported that all CFC-MDIs were imported into the country, and that the country had no CFC-MDIs manufactured locally. At that time, the Government was not aware of the one CFC-MDI producer based in Colombia. During the preparation of the national CFC phase-out plan, the country recognised that although CFC consumption for MDIs was nil, the

[1] The plan was approved by the Executive Committee at its 41st Meeting in 2003 (UNEP/OzL.Pro/ExCom/41/29) (decision 41/52).

Government of Colombia and the health authorities were concerned about the MDI sub-sector and requested funding for the development of an MDI transition strategy that will establish a clear schedule for import of alternatives to CFC-MDIs. Regulations would also be needed that will promote and support the phase-out of these products, and a programme that will raise physician awareness and patient acceptance of alternatives to CFC-MDIs.

8. In support of their submission for project preparation funds in response to decision 51/34, UNDP indicated that the Government of Colombia has one nationally owned CFC-MDI manufacturing enterprise, Laboratorios Chalver de Colombia S.A. This company was established in 2002, and has only one production line with an operational capacity of 2,000 to 3,000 units per hour.

9. The report further states that in 2006, the company produced 113,000 units of CFC-MDIs. Out of this production, around 60 percent is for domestic consumption, while the remaining 40 percent is exported. The annual production over the past three years is shown in the table below. In 2007, production has so far has reached 61,000 units for the moieties listed below.

Moiety	**Annual production (units/year)**			
	2003	**2004**	**2005**	**2006**
Salbutamol	144,000	300,000	-	72,000
Salbutamol/Ipratropium	-	-	10,000	5,000
Salbutamol/Beclomethasone	6,000	3,000	36,000	15,000
Beclomethasone	63,000	69,000	3,000	9,000
Ipratropium	-	42,000	78,000	12,000
Total production	213,000	414,000	127,000	113,000

10. The table below shows the trend in CFC use for the MDI sector which is consistent with that reported in the annual country programme implementation report, as follows:

Substance	**2003**	**2004**	**2005**	**2006**
CFC-11	2.52	2.80	0.80	0.56
CFC-12	3.56	5.28	1.00	1.65
Total	6.08	8.08	1.8	2.21

11. The company is considering the retrofit of their production line to HFA, however, they are concerned about HFA formulations that are currently on the market. It also estimates that it will need two-three years for the retrofitting process to be completed while ensuring the production of a drug with a quality equivalent to the CFC-MDI currently being produced and imported.

12. Colombia imports non-CFC-MDIs mostly through multinational companies. The document does not provide data on the volume of imports, although they have provided a list of the active ingredients where either dry powder inhalers or HFA formulations are available.

Fund Secretariat's comments

13. The project preparation request is being submitted to enable the phase-out of 2.1 ODP tonnes of CFCs used in the manufacture of CFC-MDIs. In reviewing the data submitted, the Secretariat noted that the trend in production from 2003-2006 is generally decreasing as evidenced by the total number of units being produced. In responding to the Secretariat's query for reasons for this decrease in production, UNDP indicated that this is due to the availability of cheap CFC-MDIs imported from India which are currently on the market.

14. The Secretariat also sought clarification on the reasons for the hesitation of the company to move towards HFA propellants for their production process when there is no technical limitation indicated for doing so. UNDP responded that the changes for the conversion to HFA will consist mostly of modifications to the production line, mainly the change in the dose pumps and the filling head. It has not yet been determined if new equipment will be required, and this will depend on the formulation selected during the preparation of the project.

15. The Secretariat also requested UNDP to provide data on the imports of non-CFC-MDIs into the country, as required in decision 51/34. From the list provided, it can be observed that there are non-CFC-MDIs that are imported into Colombia for beclomethasone and salbutamol. These two are also being produced and marketed as CFC-MDIs in the country. The other non-CFC-MDIs imported are products that are not currently being produced in Colombia.

16. Whilst reviewing the funding being requested in relation to the number of companies to be converted, the CFC phase-out to be achieved and the status of availability of non-CFC-MDIs in the country, the Secretariat recommended to UNDP that project preparation may be undertaken at an amount not more than US$30,000. UNDP agreed with the Secretariat's recommendation of a lower cost for the project preparation for Colombia.

Fund Secretariat's recommendation

17. In the light of the comments above, the Executive Committee may wish to consider approval of the request for project preparation at the funding level of US $30,000, as indicated in Table 1 above. The Committee may also wish to confirm whether the information provided is consistent with the requirements of decision 51/34.

18. In approving this project UNDP is requested to note that, in developing the investment project, the final document must include elements of a transition strategy to assist the MDI sector and to support the full implementation of the investment project, pursuant to decision 51/34. It should also be noted that no further funds for a separate transition strategy for this sector will be available.

<u>India: PRP for MDI investment project: US $100,000</u>

Project Description

19. UNDP, on behalf of the Government of India is submitting a request for the preparation of a project for the conversion of CFC-MDI producing plants in the country. In their national CFC phase-out plan, India reported a consumption of 120 ODP tonnes for MDI manufacturing. While they had initially indicated that this consumption would not be covered by the phase-out

plan as this would focus on the refrigeration sector, India would now like to initiate the conversion of their CFC-MDI manufacturing facilities to phase out the use in this sector with the assistance of UNDP. This request is supported by the fact that the consumption of CFCs in this sector has grown to more than 700 ODP tonnes as of 2006.

20. As part of the information required under decision 51/34 which supports the request for project preparation, UNDP indicates that there are seven CFC-MDI manufacturing companies in India comprising a total of nine production plants. Cipla, one of the companies, has three production plants.

21. Out of these seven manufacturers, four are 100 percent nationally owned, one enterprise has 70 percent national ownership, and another has 49.3 percent, while the last one has 10 percent national ownership. The table below summarises these facilities, their dates of establishment, percentage of national ownership, and their production capacities.

Name of Companies	Date established	Percent national ownership	Production capacity
AstraZeneca Pharma India Ltd.	November 1981	*producing on loan only since 2006	*producing on loan only since 2006
Cadila Health Care Ltd.	May 1995	100	1 production line with capacity of 8 million/year
Cipla Ltd , Kurmumbh, Mh	November 1993	100	3 plants, production lines with total capacity of 70 million/year
Cipla Kundaim, Goa	October 1997		
Cipla Verna, Goa	January 2000		
GlaxoSmithkline Pharmaceuticals Ltd.	1990	49.3	1 production line with capacity of 3 million/year
Midas Care Pharmaceuticals Pvt. Ltd.	1993	100	2 production lines, each with capacity of 7.5 million/year
Natco Pharma Ltd.	1981	10	1 production line with capacity of 3 million/year
Sun Pharmaceutical Industries Ltd.	2001	70	1 production line with 2 million units per year

22. UNDP has also provided information on the annual production output of these plants for 2005, and the use of CFCs in MDI production for the last three years, as shown in the table below.

Name of Companies	Annual production output (2005)	Quantity of CFCs (MT) used for MDI Production		
		2003	2004	2005
AstraZeneca Pharma India Ltd.	* production on loan with Midas	3.6	2.3	0.5
Cadila Health Care Ltd.	1.2 million units	3.0	4.8	7.5
Cipla Ltd (Kurmumbh)	42 million units	573.0	688.0	674.0
Cipla (Kundaim, Goa)				

Cipla (Verna, Goa)				
GlaxoSmithkline Pharmaceuticals Ltd.	0.8 million units	29.2	24.6	27.6
Midas Care Pharmaceuticals Pvt. Ltd.	2 million units	18.8	21.3	29.8
Natco Pharma Ltd.	10,000 units	3.3	1.1	1.0
Sun Pharmaceutical Industries Ltd.	0.4 million units	8.3	7.2	6.9
Total	~46 million units	639.2	749.3	747.3

23. The report further indicates that out of these nine production plants, only five have plans to shift to non-CFC production, and that one company, Astra Zeneca Pharma India Ltd., switched its production on a loan basis at Midas Care Pharmaceuticals Pvt. Ltd. from 2006. UNDP also provided brief descriptions of these plans to shift to non-CFC production, with estimated conversion times ranging from two to ten years. UNDP indicates that the Government of India proposes to assist all seven manufacturers, as they will need financial assistance to change their production capacity to non-CFC in order for India to meet its obligations under the Montreal Protocol.

24. India does not import non-CFC-MDIs. At present, there are two companies that produce HFA-MDIs in the country, Cipla and Midas Care. Below is a summary of the number of units produced per year, per active ingredient for these two companies.

Company name	**Active Ingredient (Manufactured)**	**Units (2005)**
Cipla - Kundaim, Goa	Salbutamol	2270000
	Budesonide	8695000
	Beclomethasone	40000
	Budesonide + Formoterol	34000
	Fluticasone	18000
Cipla - Verna, Goa	Beclomethasone Dipropionate	615632
	Ipratropium Bromide	4600
	Salbutamol	1226726
	Salmetrerol Xinafote	1921
	Salbutamol & Ipratropium Bromide	7480
	Salmeterol & Fluticasone Propionate	8137
Midas Care	Salbutamol	5000
	Formoterol + Budesonide	20000
	Salmetrerol + Fluticasone	10000
	Total	~ 13 million units

Fund Secretariat's comments

25. This project preparation request is submitted to enable the phase-out of around 700 ODP tonnes of CFCs used in the manufacture of CFC-MDIs. The data on CFC use provided by UNDP for India, shows an increasing consumption between 2003 and 2004, and a slight

decrease in 2007. The document provides no explanation for this decrease, however, discussions with UNDP indicated that since the decrease is minimal it could be due to changes in formulation of the MDIs.

26. The Secretariat notes that out of the seven companies indicated above, the three that are 100 percent locally owned are also the largest manufacturers of CFC-MDIs. Two of these companies, Cipla and Midas Care are likewise the local manufacturers of non-CFC-MDIs. As noted in para. 20 (b) of document UNEP/OzL.Pro/ExCom/51/39 presented at the 51st Meeting of the Executive Committee, "the second-largest pharmaceutical company by market share in India launched CFC-free inhalers in 2000.[2] Currently, the company is selling both CFC and HFA-MDIs to several Article 5 and non-Article 5 Parties." The other four companies are owned by a majority by private and multinational companies who would be bound by the parent company's policy of shifting to a non-CFC alternative, if costs allow it.

27. It was also noted and discussed with UNDP that the report does not provide data on the growth trends of CFC-MDI production in units for the last five years. The Secretariat was informed that while there is some data available, the country was reluctant to provide this primarily because the information lacked field verification, and because of issues of confidentiality. UNDP indicated that the increase in CFC use for MDI manufacturing could be used as the basis for showing a growing trend in CFC-MDI production in India.

28. The Secretariat also noted that as per paragraph 24 above, HFA technology is already available in India for certain active ingredients of MDIs, and that non-CFC-MDIs are already being locally produced and available on the market. It recommended to UNDP that project preparation could therefore be done at a lower funding level of US$70,000.

29. In discussions, UNDP indicated that considering the number of manufacturers with a number of plants located in geographically distant areas in the country, the numerous types of CFC-MDI products and, more importantly, the limited availability and the high cost of international consultant(s) required to assist in the project preparation process, project preparation should be recommended at the level requested. They have also indicated that a wide consultation process will need to be undertaken while the project is being prepared to ensure that all stakeholders understand the process, and that the transition will be smooth.

Fund Secretariat's recommendation

30. In the light of the comments above, the Executive Committee may wish to consider approval of the request for project preparation at the funding level of US $100,000, as indicated in Table 1 above. The Committee may also wish to confirm whether the information provided is consistent with the requirements of decision 51/34.

[2] Following the successful introduction of CFC-free salbutamol inhalers, Cipla also launched the world's first CFC-free budesonide inhaler (Source: The Director's Sixty-Fourth Annual Report of the Company and Audited Accounts for the year ended 31 March 2000).

31. In approving this project UNDP is requested to note that, in developing the investment project, the final document must include elements of a transition strategy to assist the MDI sector and to support the full implementation of the investment project, pursuant to decision 51/34. It should also be noted that no further funds for a separate transition strategy for this sector will be available.

Annex I

INSTITUTIONAL STRENGTHENING PROJECT PROPOSALS

Brazil: Renewal of institutional strengthening

Summary of the project and country profile	
Implementing Agency:	UNDP
Amounts previously approved for institutional strengthening (US $):	
Phase I: July 1993	403,100
Phase II: March 1998	270,000
Phase III: Dec. 2000	270,000
Phase IV: July 2004	351,000
Total	1,294,100
Amount requested for renewal (Phase V) (US $):	351,000
Amount recommended for approval for Phase V (US $):	351,000
Agency support costs (US $):	26,325
Total cost of institutional strengthening Phase V to the Multilateral Fund (US $):	377,325
Equivalent amount of CFC phase-out due to institutional strengthening Phase V at US $12.1/kg (ODP tonnes):	n/a
Date of approval of country programme:	July 1994
ODS consumption reported in country programme (1993) (ODP tonnes):	10,861.6
Latest reported ODS consumption (2005) (ODP tonnes):	2,076.9
Baseline consumption of controlled substances (ODP tonnes):	
(a) Annex A Group I (CFCs) (Average 1995-1997)	10,525.8
(b) Annex A Group II (Halons) (Average 1995-1997)	21.3
(c) Annex B Group II (Carbon tetrachloride) (Average 1998-2000)	411.6
(d) Annex B Group III (Methyl chloroform) (Average 1998-2000)	32.4
(e) Annex E (Methyl bromide) (Average 1995-1998)	711.6
Latest consumption of controlled substances (2005) (ODP tonnes):	
(a) Annex A Group I (CFCs)	967.2
(b) Annex A Group II (Halons)	3.0
(c) Annex B Group II (Carbon tetrachloride)	0.0
(d) Annex B Group III (Methyl chloroform)	0.0
(e) Annex E (Methyl bromide)	259.5
(f) Annex C Group I (HCFCs)	847.2
Amount approved for projects (US $):	90,926,718
Amount disbursed (as at March 2007) (US $):	69,356,952
ODS to be phased out (ODP tonnes):	12,441.1
ODS phased out (as at March 2007) (ODP tonnes):	11,116.7

1. Summary of activities and funds approved by the Executive Committee:

	Summary of activities	**Funds approved (US $)**
(a)	Investment projects:	85,134,468
(b)	Institutional strengthening:	1,443,028
(c)	Project preparation, technical assistance, training and other non-investment projects:	4,349,222
	Total:	90,926,718

Progress Report

2. During Phase IV of Brazil's institutional strengthening project, the National Ozone Unit (NOU) actively continued working towards the achievement of compliance with the Montreal Protocol phase out schedules. The Brazilian Government has fostered actions aimed at protecting the ozone layer and at energy efficiency, to prevent global warming. This phase also saw the completion of training for Customs officers to control trade in ODS and to prevent the illegal trafficking. The training led to the seizure of smuggled ODS. Regular consultations were also actively engaged with the private sector, some associations such as the Brazilian Association of Refrigeration, Air-Conditioner, Ventilation and Heating – ABRAVA, the Association of Household Appliances - ELETROS and the associations in the agriculture sector that are oriented to ornamental flowers. Awareness raising activities were also completed, and included the translation of the video "OZZY OZONIO" which was disseminated in the national language to different audiences, including a Brazilian airline company. Other information materials on the health effects of ozone depletion were also produced and distributed to the general public. The project also allowed for the participation of the Ozone Unit team in refrigeration-related fairs, to make presentations on the Montreal Protocol, and at seminars in public and private organizations to disseminate information on protection of the ozone layer.

Plan of Action

3. During the coming Phase V of the institutional strengthening of Brazil, the Government of Brazil, through its NOU will continue to contribute to ozone layer protection with hopes of attaining complete phase-out in 2007, as the country is working on an accelerated phase-out schedule. The servicing sector will be a main focus with projects executed to provide training to refrigeration workers in domestic and commercial refrigeration. Recovery and recycling machines will also be distributed during this phase, and five reclamation centres will be established to serve the domestic and commercial refrigeration sectors in the regions with higher consumptions of CFC. Likewise, attention will focus on the mobile air conditioning sector where reclamation will be encouraged at the CFC recycling centres. During this period a detailed market survey on the use of MDIs will also be conducted to understand the situation of the use of CFCs in MDI manufacturing in Brazil.

Colombia: Renewal of institutional strengthening

Summary of the project and country profile	
Implementing Agency:	UNDP
Amounts previously approved for institutional strengthening (US $):	
Phase I: March 1994	317,790
Phase II: March 1998	212,000
Phase III: March 2000	212,000
Phase IV: Nov. 2002	275,600
Phase V: April 2005	275,600
Total	1,292,990
Amount requested for renewal (Phase VI) (US $):	275,600
Amount recommended for approval for Phase VI (US $):	275,600
Agency support costs (US $):	20,670
Total cost of institutional strengthening Phase VI to the Multilateral Fund (US $):	296,270

Equivalent amount of CFC phase-out due to institutional strengthening Phase VI at US $12.1/kg (ODP tonnes):	n/a
Date of approval of country programme:	March 1994
ODS consumption reported in country programme (1992) (ODP tonnes):	1,973.6
Latest reported ODS consumption (2005) (ODP tonnes):	709.3
Baseline consumption of controlled substances (ODP tonnes):	
(a) Annex A Group I (CFCs) (Average 1995-1997)	2,208.2
(b) Annex A Group II (Halons) (Average 1995-1997)	187.7
(c) Annex B Group II (Carbon tetrachloride) (Average 1998-2000)	6.1
(d) Annex B Group III (Methyl chloroform) (Average 1998-2000)	0.6
(e) Annex E (Methyl bromide) (Average 1995-1998)	110.1
Latest consumption of controlled substances (2005) (ODP tonnes):	
(a) Annex A Group I (CFCs)	556.9
(b) Annex A Group II (Halons)	0.0
(c) Annex B Group II (Carbon tetrachloride)	0.3
(d) Annex B Group III (Methyl chloroform)	0.0
(e) Annex E (Methyl bromide)	0.0
(f) Annex C Group I (HCFCs)	152.1
Amount approved for projects (US $):	21,009,985
Amount disbursed (as at March 2007) (US $):	14,830,664
ODS to be phased out (ODP tonnes):	1,861.3
ODS phased out (as at March 2007) (ODP tonnes):	1,042.0

4. Summary of activities and funds approved by the Executive Committee:

	Summary of activities	**Funds approved (US $)**
(a)	Investment projects:	18,646,360
(b)	Institutional strengthening:	1,445,921
(c)	Project preparation, technical assistance, training and other non-investment projects:	917,704
	Total:	21,009,985

Progress report

5. During Phase V of Colombia's institutional strengthening project, the National Ozone Unit (UTO) continued working towards the achievement of compliance with the Montreal Protocol phase-out schedules. As a result, the country achieved compliance with the 50 percent reduction measure of CFC and CTC in 2005 and started to implement a comprehensive plan to comply with the subsequent 2007 reduction. During this phase the Government of Colombia continued improving the legal framework to support the ODS phase-out and continued successful coordination of individual and umbrella investment projects. The terminal umbrella project in the foam sector was completed as well as the last commercial refrigeration project, which was part of the national phase-out plan (NPP). The NPP commenced implementation with the establishment of regional centres that helped to identify additional technicians to be trained, have a better understanding of the servicing sector in different regions, increase activities impact and achieve a better control of ODS consumption. As traditionally done in previous phases, the National Ozone Unit was very active with the implementation of public awareness activities through TV/radio, newspapers, public presentations and celebration of the International Ozone Day.

Plan of action

6. Phase VI of the institutional strengthening of Colombia will have special importance as the country will achieve total phase-out of CFCs by the end of 2009. During this phase the Government of Colombia through its NOU, aims to strengthen and ensure sustainability of the activities being implemented in the servicing sector as part of the NPP, strengthen the legal framework that support these activities, start activities in the end users sector and enhance ODS trade and imports. The NPP activities will continue being implemented through the regional focal points, to ensure impact in all regions. During this phase Colombia will also consolidate the strategies to phase out ODS in sectors where the consumption is low, such as CTC, where an investment project will be implemented by UNDP.

Annex II

VIEWS EXPRESSED BY THE EXECUTIVE COMMITTEE ON RENEWALS OF INSTITUTIONAL STRENGTHEING PROJECTS SUBMITTED TO THE 52nd MEETING

Brazil

1. The Executive Committee has reviewed the terminal report presented with the institutional strengthening project renewal request for Brazil and notes with appreciation the outstanding achievements made by Brazil's National Ozone Unit during the implementation of the Fourth Phase. In particular the Executive Committee notes the progress made by Brazil in reducing their CFC-12 consumption from 8,052 ODP tonnes in 1999 to 477.8 ODP tonnes in 2006, which is below the 50% reduction level. The Executive Committee also notes the progress on the implementation of phase-out projects in key ODS-consuming sectors, including the completion of activities in the foam sector and the continuation of activities in the servicing sector under the national CFC phase-out plan. The Executive Committee commends the Government of Brazil for its achievements during the current phase and expresses the expectation that, in the next two years, Brazil will continue the implementation of its programmed activities with outstanding progress, and will sustain and build upon its current levels of reductions in CFCs.

Colombia

2. The Executive Committee has reviewed the terminal report presented with the institutional strengthening project renewal request for Colombia and notes with appreciation the outstanding achievements made by Colombia's National Ozone Unit during the implementation of the Fifth Phase. In particular the Executive Committee notes the progress made by Colombia towards achieving the 50% reduction in CFC and 85% in CTC consumption in 2005 and maintaining compliance in 2006 with the schedules established in all the controlled substances. The Executive Committee also notes the progress on the implementation of phase-out projects in key ODS-consuming sectors, including the completion of the terminal umbrella project in the foam sector and the continuation of activities under the national CFC phase-out plan through the regional centres established. The Executive Committee commends the Government of Colombia for its achievements during the current phase and expresses the expectation that, in the next two years, Colombia will continue the implementation of its programmed activities with outstanding progress, and will sustain and build upon its current levels of reductions in CFCs.

EXECUTIVE COMMITTEE OF THE MULTILATERAL FUND FOR THE IMPLEMENTATION OF THE MONTREAL PROTOCOL
(52nd Meeting, 23 – 27 July 2007, Montreal)

2007 WORK PROGRAMME AMMENDMENT

OF THE

UNITED NATIONS DEVELOPMENT PROGRAMME

Request for Project Preparation and Non-Investment Projects at the 52nd Executive Committee Meeting

Submitted 28 May 2007
Revised 21 June 2007

2007 UNDP WORK PROGRAMME AMMENDMENT

52nd Executive Committee Meeting (23 – 27 July 2007, Montreal)

This Work Programme document contains all non-investment and project preparation programmes that are being requested at the 52nd Meeting of the Executive Committee. These requests amount to US$ 756,600 plus US$ 56,745 of support cost, as elaborated upon below.

1) Institutional Strengthening Renewal Requests.

The following Institutional Strengthening Renewal Requests are being submitted at the 52nd meeting of the Executive Committee:

Nr	COUNTRY	TITLE	ODP	BUDGET	SUPPORT COST	TOTAL
1	Brazil	Institutional Strengthening Phase V		351,000	26,325	377,325
2	Colombia	Institutional Strengthening: Phase VI		275,600	20,670	296,270
Sub Total Institutional Strengthening Projects				**626,600**	**46,995**	**673,595**

Documents for the IS Renewal Requests have been submitted separately by UNDP.

2) Requests for Technical Assistance Projects.

There will be no submission of Technical Assistance Projects to the 52nd Executive Committee Meeting.

3) Requests for Project Preparation in the Refrigeration Servicing Sector.

There will be no submission of Project Preparation Funds for the Refrigeration Servicing Sector to the 52nd Executive Committee Meeting.

4) Requests for Activities in the MDI Sector.

Nr	COUNTRY	TITLE	BUDGET	SUPPORT COST	TOTAL	REMARKS
1	Colombia	PRP for MDI Investment Project	30,000	2,250	32,250	Details in Annex 1
2	India	PRP for MDI Investment Project	100,000	7,500	107,500	Details in Annex 2
Subtotal PRP-Proposals (Other Sectors)			**130,000**	**9,750**	**139,750**	

Project preparation requests listed above are related to the development of investment projects

for Metered Doses Inhalers (MDIs). Funds would be used for international consultants, national consultants, stakeholders workshops and sundries. Based on precedent experience the level of funds requested for PRP activities for MDI is higher than the level of funds requested for PRP activities in other sectors due to the level of fees for international experts on this field, which is higher than in other fields due to its very specialized nature. In the case of India there will be seven companies involved in different cities, for this reason the level of funds requested is higher than in the other two countries.

Detailed information required to submit these preparation activities as per Decision 51/34 of the Executive Committee is available in Annex 1 (Colombia) and Annex 2 (India).

ANNEX 1

COLOMBIA MDI

Justifications for the need to receive assistance by India for phasing out of CFC in MDI sector as required under decision 51/34 Para (c).

Colombia became aware of the CFC consumption in the MDI sector after the approval of the National Phase Out Plan in 2003. During the collection of data undertaken for the preparation of the NPP, the company Chalver consuming CFC in the manufacturing of MDI was not identified as it had recently started production and it was not very well known as a MDI producer yet. By the time the company started to establish its production line of MDI (2001 – 2002), HFA technologies were not available in developing countries, only few companies in Article 5 countries had developed this technology. Since the confirmation of the CFC consumption in the MDI sector in Colombia by Chalver, this consumption has been yearly reported to the Multilateral Fund Secretariat as part of the Country Programme Implementation Report.

Chalver is the only local company manufacturing CFC MDI in the country.

The adaptation of HFA-based MDI propellant technology in developing countries is a recent phenomenon and has not yet been fully deployed. It would take about 2-3 years to fully convert from CFC-based MDI to HFC-based MDI technology (including the time taken to register and launch the final approved and reformulated product in the market). The industries are not fully equipped to transit cost-effectively from CFC-based MDIs within the timeframe available, especially against the background of rapidly growing demand.

In view of above, the Executive Committee may be requested to consider Colombia's proposal for project preparation funding in light of the paragraph 1 and 2 of Decision XVIII/16 of the 18th Meeting of the Parties (MOP) and Decision 51/34 of the Executive Committee.

Information as required by the Executive Committee (ExCom) under its Decision 51/34 (Para C)

I. 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

BASIC INFORMATION	
Name	**LABORATORIOS CHALVER DE COLOMBIA S.A**
I.D.	**890.203.194-1**
Address	**Av. 68 No. 37B –31 Sur**
Date of establishment of the production line	**There is one production line established in the year 2002**
Production Capacity for each line	**The operational capacity of the production line is between 2000 and 3000 units/hour.**

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

Pharmaceutical Form	**Active Ingredients**	**Propellant used**	**Annual Production 2006 (units/year)**
Aerosol Nabumex	Beclomethasone Dipropionate	Diclorodifluoromethane Triclorofluoromethane	9,000
Aerosol Aspromio	Ipratropium Bromide	Diclorodifluoromethane Triclorofluoromethane	12,000
Aerosol Airmax	Salbutamol	Diclorodifluoromethane Triclorofluoromethane	72,000
Aerosol Oxitone	Salbutamol+ Beclomethasone	Diclorodifluoromethane Triclorofluoromethane	15,000
Aerosol Salpromio	Salbutamol+ Ipratropioum Bromide	Diclorodifluoromethane Triclorofluoromethane	5,000
Aerosol Inflabon	Budesonide	Diclorodifluoromethane Triclorofluoromethane	0
Aerosol Frudexan	Fluticasone	Diclorodifluoromethane Triclorofluoromethane	0
Aerosol (Undetermined)	Formoterol Fumarate + Budesonide	Diclorodifluoromethane Triclorofluoromethane	0
TOTAL			113,000

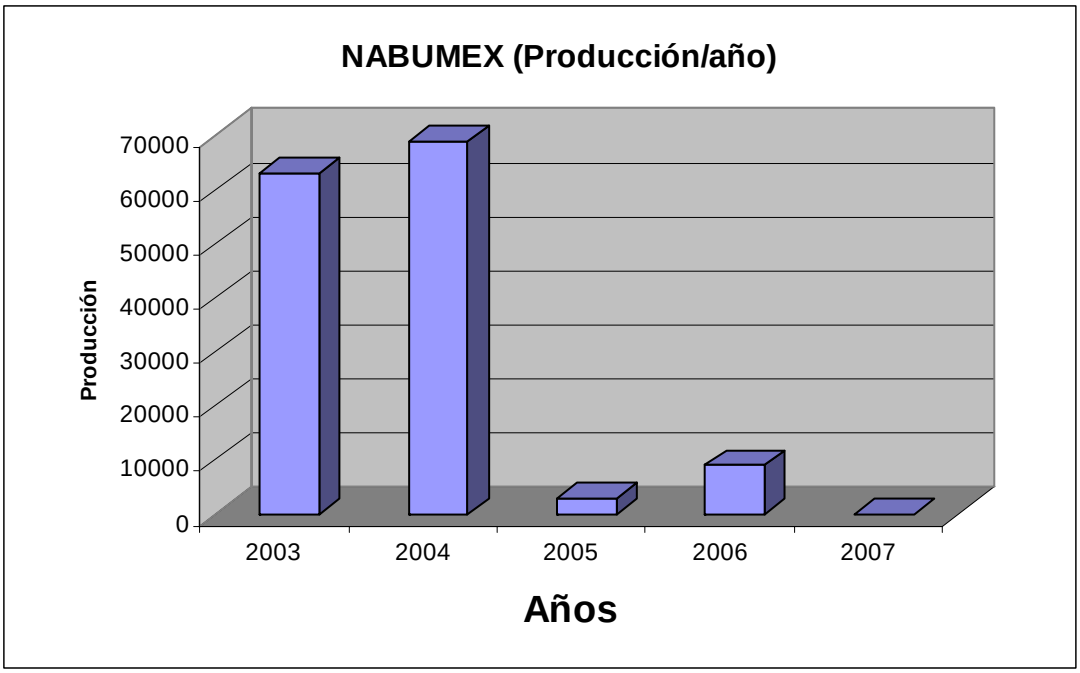
III. Growth patterns of CFC- MDI production over the past three years

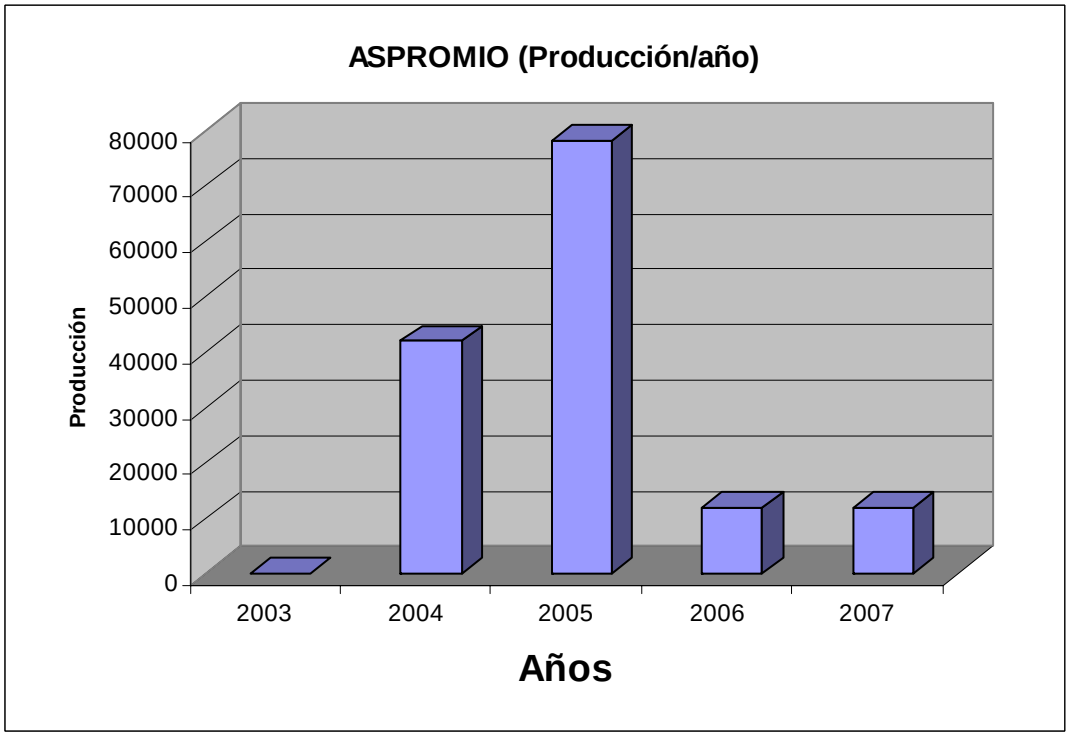
Pharmaceutical Form	Annual Production (units / year)				
	2003	2004	2005	2006	2007 (*)
Aerosol Nabumex	63,000	69,000	3,000	9,000	-
Aerosol Aspromio	-	42,000	78,000	12,000	12,000
Aerosol Airmax	144,000	300,000	-	72,000	40,000
Aerosol Oxitone	6,000	3,000	36,000	15,000	6,000
Aerosol Salpromio	-	-	10,000	5,000	3,000
Aerosol Inflabon	-	-	-	-	-
Aerosol Frudexan	-	-	-	-	-
Aerosol (Undetermined)	-	-	-	-	-
TOTAL	213,000	414,000	127,000	113,000	61,000

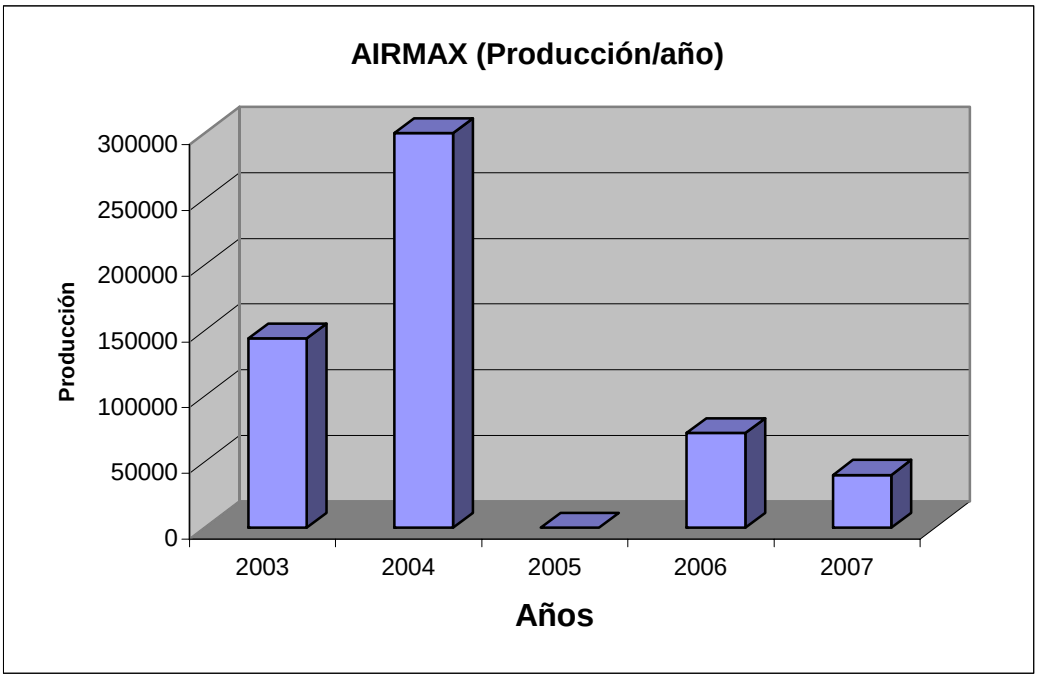
Production levels have decreased due to import of CFC MDI from India at very low cost levels. Laboratorios Chalver is the only national producer of MDIs.

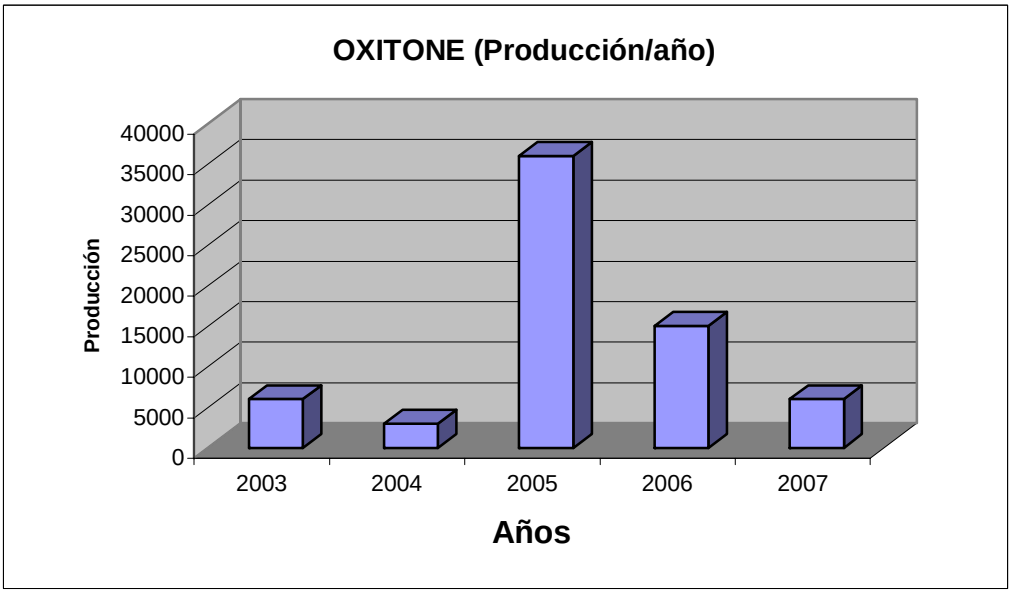
The MDI produced in 2004 has the following distribution:

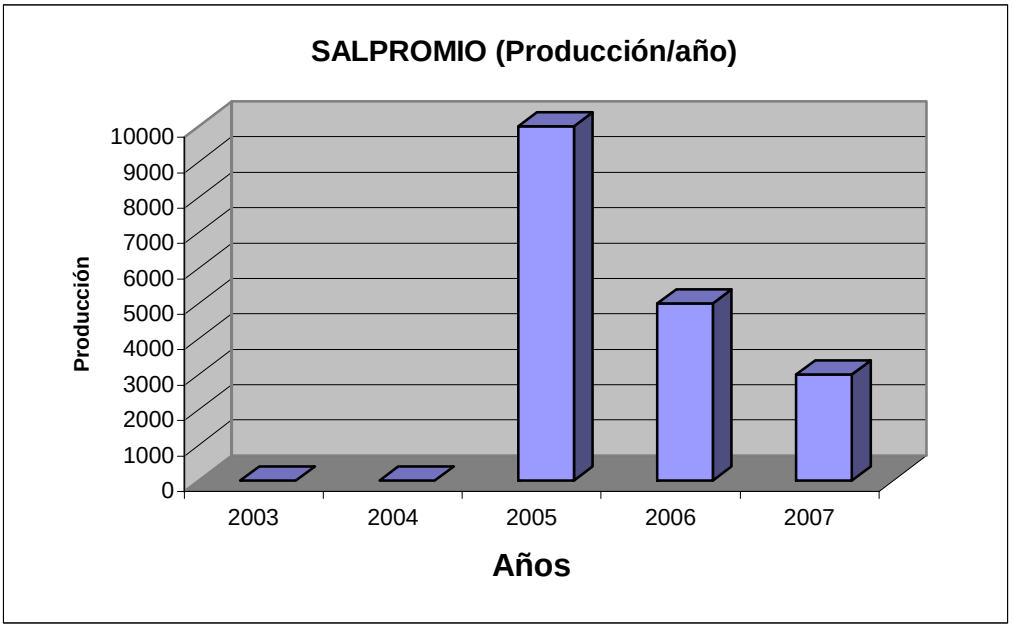
Amounts	Percentage	Market
265.000 Units	59.15 %	Nacional Market
183.000 Units	40,85%	Export to other Article 5 Parties.


NABUMEX (Producción/año)
Producción
70000
60000
50000
40000
30000
20000
10000
0
2003
2004
2005
2006
2007
Años


ASPROMIO (Producción/año)
Producción
80000
70000
60000
50000
40000
30000
20000
10000
0
2003
2004
2005
2006
2007
Años


AIRMAX (Producción/año)
Producción
300000
250000
200000
150000
100000
50000
0
2003
2004
2005
2006
2007
Años


OXITONE (Producción/año)
Producción
40000
35000
30000
25000
20000
15000
10000
5000
0
2003
2004
2005
2006
2007
Años



Consumption in the sector has accordingly been reported as part of the CP implementation Report submitted to the Multilateral Fund Secretariat as follows:

Substance	2003	2004	2005	2006
CFC 11	**2.52**	**2.80**	**0.80**	**0.56**
CFC 12	**3.56**	**5.28**	**1.00**	**1.65**
Total	6.08	8.08	1.80	2.21

IV. Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC MDIs and what those alternatives were

Laboratorios CHALVER is considering undertaking the retrofit of the production line in order to be able to produce HFA MDI. As part of this process the company has expressed particular concern on the development of the HFA formulations. The company has not been able to undertake the conversion to HFA MDI for several reasons, the first one that it does not have the corresponding formulations, the second that the new product would have still a higher price in the market and the company has already reduced its production due to competition with CFC MDI product imported a very low price.

V. Each production facility plans for phasing out CFC consumption

Production Line	Plan to eliminate consumption of CFC	Time	Cost
Línea 1 Pamasol mixing vessel filler, crimper.	Retrofitting of certain line components in order to be able to produce alternative HFA MDI drugs equivalent to the CFC MDI drugs currently produced.	2-3 years	To be determined depending on alternative formulations

The necessary changes for the conversion to HFA will consist mostly on modifications to the production line, mainly the change in the dose pumps and the filling head.. It has not been determined if a new vessel is required, and this will depend on the formulation selected during the preparation of the project. In addition to the incremental capital costs mentioned the company will incur in costs for the development of the new formulations and developing of the HFA products based on the formulations. The company will require assistance from a technology provider to develop the new products, but will not have to outsource the whole process as it has adequate laboratories to undertake part of the development activities, reducing costs.

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

The company is not producing HFA MDI medication and has not reported any production of Dry Powder Inhalers. Multinational companies affiliated to IPAC have reported imports of the alternatives below, however the volume of imports is not known yet:

HFA MDI Beclomethasone DP.
DPI Budesonide
DPI Budesonide & Formoterol
DPI Fluticasone P.
HFA MDI Fluticasone P.
HFA MDI Fluticasone/Salmeterol
DPI Fluticasone/Salmeterol
DPI Formoterol
DPI Salbutamol
HFA Salbutamol
DPI Salmeterol
DPI Terbutaline

The information available on imports is presented inthtable below:

Ingrediente activo	Fabricante	Propulsor	Inhaladores de dosis medida importados/año		
			2003	2004	2005
Salbutamol Micronizado	Glaxo Wellcome Mexico S.A. De C.V.	Triclorofluorometano, Diclorofluorometano			173,799
Salbutamol	Cipla Limited	Monofluorotriclorometano, Diflurodiclorometano			204,430
Salbutamol	Mckesson	Difluorodiclorometano, Monofluorotriclorometano			288,646
Salbutamol	Merck	Difluorodiclorometano, Monofluorotriclorometano			300,497
Salbutamol	Medyspray Laboratories Private Limited	Difluorodiclorometano, Monofluorotriclorometano			90,953
Salmeterol	Glaxosmithklaine	Difluorodiclorometano, Monofluorotriclorometano			40,077
Bromuro De Ipratropio	Mckesson	Difluorodiclorometano, Monofluorotriclorometano			92,171
Budesonida	Laboratorios Biogen De Colombia S.A. (Importador)	Difluorodiclorometano, Monofluorotriclorometano			44,166
Budesonida Micronizada	Boehringer Ingelheim International	Difluorodiclorometano, Monofluorotriclorometano			148,787
Propionato De Fluticasona (Micronizado)	Glaxosmithklaine	Difluorodiclorometano, Monofluorotriclorometano			60,423
Bromuro De Ipratropio	Mckesson	Difluorodiclorometano, Monofluorotriclorometano			56,841
Bromuro De Ipratropio	Cipla Limited	Difluorodiclorometano, Monofluorotriclorometano			41,336
Beclometasona Dipropionato	Laboratorios Aldo Union S.A.	Difluorodiclorometano, Monofluorotriclorometano			12,634
Beclometasona Dipropionato	Cipla Limited	Monoflurotricloro Metano, Diflurodicloro Metano			40,510
Bromuro De Ipratropio	Boehringer Ingelheim Do Brasil Quimica E Farmaceutica Ltda	Tricloromonofluorometano, Tricloromonofluorometano/Diclorodifluorometano/1, 2-Diclorotetrafluoroetano			317,655

ANNEX 2
INDIA MDI

Justifications for the need to receive assistance by India for phasing out of CFC in MDI sector as required under decision 51/34 Para (c).

India became aware of high CFC consumption in its pharmaceutical MDI sector in 2006 while collecting information for preparation of the country program progress report for 2005. The CFC consumption in 2005 was reported to the Fund Secretariat. Further, in response to the Secretariat's questionnaire circulated during the network meeting held in Colombo during 4-8 December, 2007, the detailed information was sent to the Secretariat. Based on the information, the MLF Secretariat had prepared the document no. 51/39 for the consideration of the 51st Executive Committee meeting.

Constraints on accurately establishing consumption

Due to the rapidly rising demand for MDI products due to the growing incidence of asthma and related diseases with significant public health and social implications, the consumption of CFC-based MDIs has grown quite significantly. At the time of approval of India's NCCOPP, the estimated consumption was not significant and therefore it was considered by the Government not to seek additional funding. However, presently, with more accurate estimates of consumption, which is significantly high (over 700 tonnes annually) and consequent implications/challenges for the health services in the country, and due to the technological and financial constraints for cost-effective conversion to HFC-based MDI technology, the Government now seeks the assistance of MLF in addressing this consumption.

Technology constraints

The first HFC-based propellants for MDIs were developed only in 1995 and the technology was established and made commercially viable by 2000. The adaptation of HFC-based MDI propellant technology in developing countries is a recent phenomenon and has not yet been fully deployed. It would take about 2-3 years to fully convert from CFC-based MDI to HFC-based MDI technology (including the time taken to launch the final approved and reformulated product in the market). The industries are not fully equipped to transit cost-effectively from CFC-based MDIs within the timeframe available, especially against the background of rapidly growing demand.

The high consumption of CFC in MDI sector and looking at possibilities of its increase in future years would result in potential non-compliance for India in 2007 and future years.

In view of above, the Executive Committee may be requested to consider India's proposal for project preparation funding in light of the paragraph 1 and 2 of Decision XVIII/16 of the 18th Meeting of the Parties (MOP) and Decision 51/34 of the Executive Committee.

Information as required by the Executive Committee (ExCom) under its Decision 51/34 (Para C)

I. 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

S. No.	Name of the MDI Manufacturers	Percentage of National Ownership	Date of Establishment	Production capacity
1	AstraZeneca Pharma India Ltd.	10%	Nov-81	Production at own location until 2005. Since 2006 products made on loan basis at Midas Care
2	Cadila Health Care Ltd.	100%	15-May-95	1 production line with 8 million units/year
3	Cipla Ltd., Kurmumbh, Mh	100%	Nov-93	3 production lines each with 20 million units/year; 1 production line with 10 million units/year Total: 70 million units/year
	Cipla Ltd., Kundaim, Goa	100%	17-Oct-97	
	Cipla Ltd., Verna, Goa	100%	11-Jan-00	
4	GlaxoSmithkline Pharmaceuticals Ltd.	49.3%	1990	1 production line with 3 million units/year
5	Midas Care Pharmaceuticals Pvt. Ltd.	100%	1993-94	2 production lines each with 7.5 million units/year Total 15 million units/year
6	Natco Pharma Ltd.	70%	1981	1 production line with 3 million units/year
7	Sun Pharmaceutical Industries Ltd.	100%	2001-2005	1 production line with 2 million units/year

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

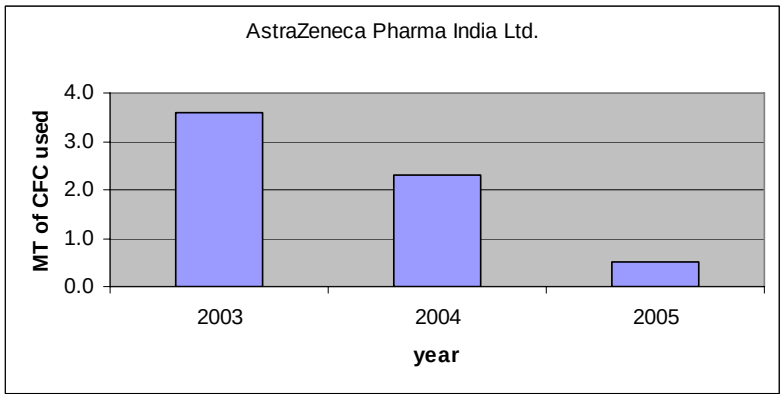
S.No.	Name of the MDI Manufacturers	By Active Ingredients	Annual Production output (unit/year)
1	AstraZeneca Pharma India Ltd.	1.Budesonide 2.Terbutaline Sulphate	Products manufactured on loan basis CFC Consumption: 2003: 3.4 MT 2004: 2.3 MT 2005: 0.5 MT
2	Cadila Health Care Ltd.	1.Budesonide BP 2.Budesonide BP + Formoterol Fumarate 3.Formoterol Fumarate 4.Ipratropium Bromide BP 5.Salbutamol Sulphate IP + Ipratropium Bromide 6.Salmeterol Xinafoate + Fluticasone Propionate	1.2 million units/year CFC Consumption: 2003: 3.2 MT 2004: 4.9 MT 2005: 8.1 MT
3	Cipla Ltd., Kurmumbh, Mh	1.Beclomethasone Dipropionate 2.Beclomethasone Dipropionate + Salbutamol 3.Budesonide 4.Fluticasone Propionate 5.Ipratropium Bromide 6.Salbutamol 7.Salmeterol Xinafoate	42 million units/year CFC Consumption: 2003: 573 MT 2004: 688 MT 2005: 674 MT
	Cipla Ltd., Kundaim, Goa	1.Beclomethasone 2.Beclomethasone + Salbutamol 3.Budesonide 4.Budesonide + Formoterol 5.Fluticasone + Salmetrol 6.Formoterol 7.Ipratropium Bromide 8.Salbutamol 9.Salmeterol	
	Cipla Ltd., Verna, Goa	1.Beclomethasone Dipropionate 2.Beclomethasone Dipropionate + Salbutamol 3.Budesonide 4.Fluticasone Propionate 5.Formoterol Fumarate 6.Ipratropium Bromide 7.Levosalbutamol 8.Salbutamol 9.Salbutamol + Ipratropium Bromide 10. Salmeterol Xinafoate 11. Salmeterol + Fluticasone Propionate 12. Sodium Cromoglicate 13. Tiotropium Bromide 14. Tiotropium Bromide + Formoterol Fumarate	
4	GlaxoSmithkline Pharmaceuticals Ltd.	1.Beclomethasone 2.Salbutamol	0.8 million units/year CFC Consumption: 2003: 29 MT 2004: 25 MT 2005: 28 MT
5	Midas Care Pharmaceuticals Pvt. Ltd.	1.Beclomethasone 2.Budesonide 3.Cicllesonide 4.Fluticasone 5.Formoterol 6.Formoterol + Budesonide 7.Ipratropium Bromide	2 million units/year CFC Consumption: 2003: 18.8 MT 2004: 21.3 MT 2005: 29.8 MT

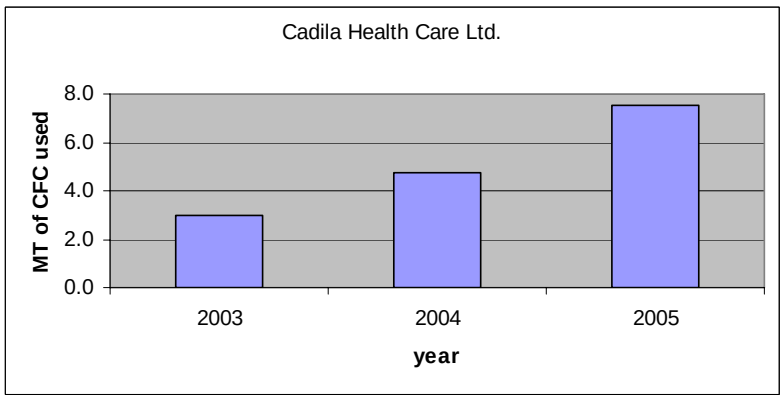
		8.Ipratropium + Salbutamol 9.Salbutamol 10.Salbutamol + Beclomethasone 11.Salmeterol + Fluticasone 12.Sodium Cromoglicate 13.Terbutaline 14.Tiotropium Bromide 15.Tiotropium Bromide + Formoterol	
6	Natco Pharma Ltd.	1.Beclomethasone 2.Salbutamol	10,000 units/year CFC Consumption: 2003: 3.32 MT 2004: 1.08 MT 2005: 0.98 MT
7	Sun Pharmaceutical Industries Ltd.	1.Budesonide 2.Budesonide + Formoterol Fumarate 3.Fluticasone Propionate 4.Fluticasone Propionate + Salmeterol Hydroxy Napthoate 5.Salbutamol 6.Salmeterol Hydroxy Napthoate 7.Tiotropium Bromide Monohydrate 8.Tiotropium Bromide Monohydrate + Formoterol Fumarate	0.4 million units/year CFC Consumption: 2003-2004: 8.3 MT 2004-2005: 7.2 MT 2005-2006: 6.9 MT

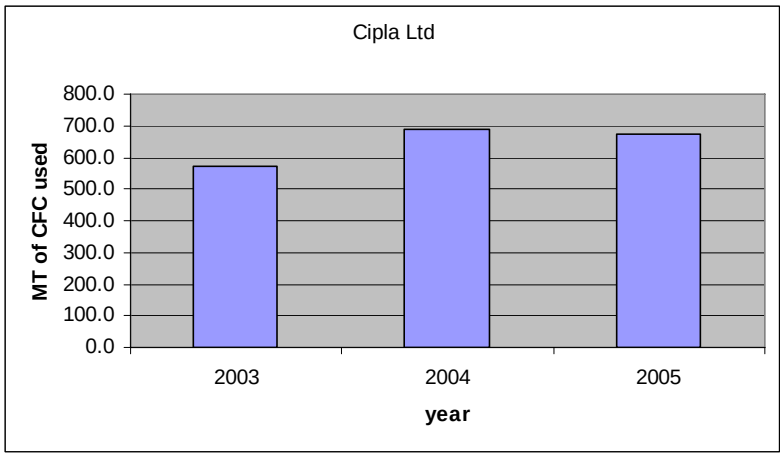
III. Growth patterns of CFC-MDI production over the past three years (2003-2005), based on consumption of CFC in MDI manufacturing, are indicated in the table below. It is noted that as CFC consumption differs in different formulations and among different industries, the "units of CFC-MDI produced" without being properly verified by the Ozone Cell, do not truly reflect the demand on CFC and thus the CFC phase-out efforts required.

Name of Companies	Quantity of CFCs (MT) used for MDI Production		
	2003	**2004**	**2005**
AstraZeneca Pharma India Ltd.	3.6	2.3	0.5
Cadila Health Care Ltd.	3.0	4.8	7.5
Cipla Ltd	573.0	688.0	674.0
GlaxoSmithkline Pharmaceuticals Ltd.	29.2	24.6	27.6
Midas Care Pharmaceuticals Pvt. Ltd.	18.8	21.3	29.8
Natco Pharma Ltd.	3.3	1.1	1.0
Sun Pharmaceutical Industries Ltd.	8.3	7.2	6.9

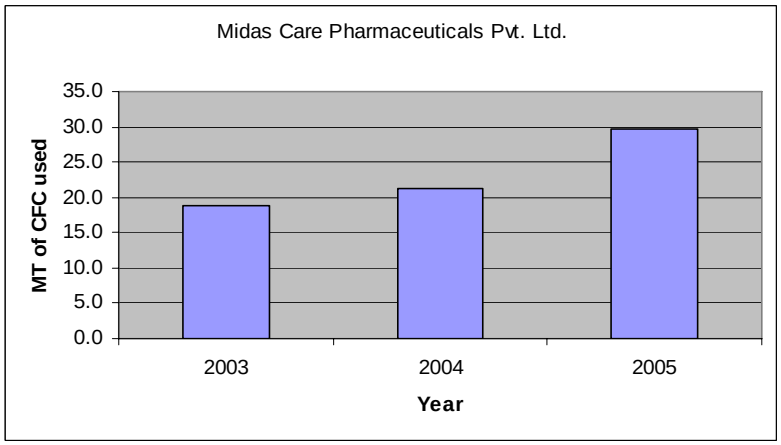
Growth patterns in graphical representation for each plant.

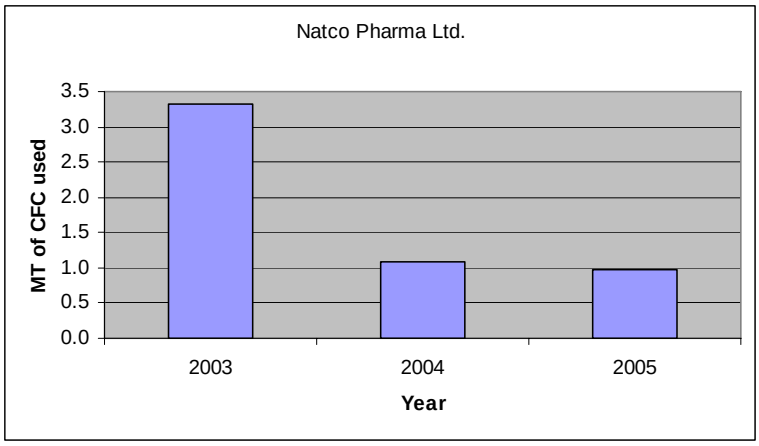


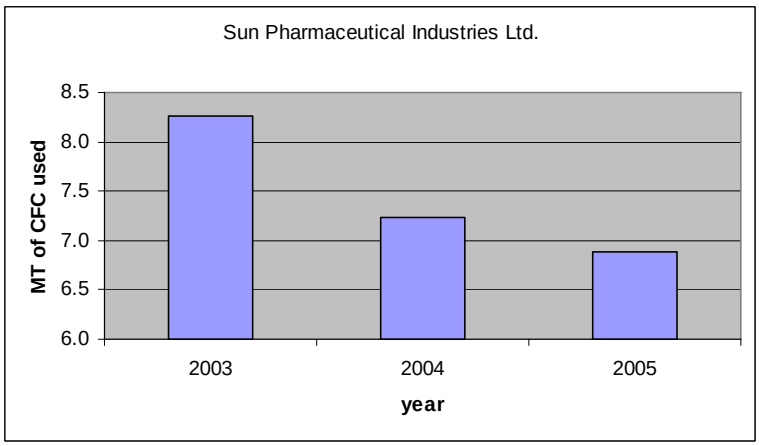



Cipla Ltd
800.0
700.0
600.0
500.0
400.0
300.0
200.0
100.0
0.0
MT of CFC used
2003
2004
2005
year


GlaxoSmithkline Pharmaceuticals Ltd.
30.0
29.0
28.0
27.0
26.0
25.0
24.0
23.0
22.0
MT of CFC used
2003
2004
2005
Year


Midas Care Pharmaceuticals Pvt. Ltd.
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
MT of CFC used
2003
2004
2005
Year


Natco Pharma Ltd.
MT of CFC used
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
2003
2004
2005
Year


Sun Pharmaceutical Industries Ltd.
MT of CFC used
8.5
8.0
7.5
7.0
6.5
6.0
2003
2004
2005
year

IV. Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC MDIs and what those alternatives were

S.No.	Name of the MDI Manufacturers	Alternatives to CFC MDIs by active ingredient using HFA
1	AstraZeneca Pharma India Ltd.	NIL
2	Cadila Health Care Ltd.	NIL
3	Cipla Ltd., Kurmumbh, Mh	NIL
	Cipla Ltd., Kundaim, Goa	1.Beclomethasone 2.Budesonide 3.Budesonide + Formoterol 4.Fluticasone 5.Salbutamol
	Cipla Ltd., Verna, Goa	1.Beclomethasone Dipropionate 2.Ipratropium Bromide 3.Salbutamol 4.Salbutamol + Ipratropium Bromide 5.Salmeterol Xinafoate 6.Salmeterol + Fluticasone Propionate
4	GlaxoSmithkline Pharmaceuticals Ltd.	NIL
5	Midas Care Pharmaceuticals Pvt. Ltd.	1. Formoterol + Budesonide 2. Fluticasone 3.Cicllesonide 4.Salbutamol 5.Salmeterol + Fluticasone
6	Natco Pharma Ltd.	1.Beclomethasone 2.Salbutamol Sulphate
7	Sun Pharmaceutical Industries Ltd.	1.Cicllesonide

V. Each production facility plans for phasing out CFC consumption

S.No.	Name of the MDI Manufacturers	Plan for phasing out CFC consumption	Time	Cost
1	AstraZeneca Pharma India Ltd.	No	-	-
2	Cadila Health Care Ltd.	Yes*	2-3 yrs	Rs. 30 crores
3	Cipla Ltd., Kurmumbh, Mh	Yes*	10 yrs	Rs. 90 crores
	Cipla Ltd., Kundaim, Goa	Yes*		
	Cipla Ltd., Verna, Goa	Yes*		
4	GlaxoSmithkline Pharmaceuticals Ltd.	No	-	-
5	Midas Care Pharmaceuticals Pvt. Ltd.	Yes*	3 yrs	Rs. 5 cr (capital expenditure)
6	Natco Pharma Ltd.	Yes*	3 yrs	USD 3.37 million for equipment
7	Sun Pharmaceutical Industries Ltd.	Yes*	1½ yrs	Rs. 250 lacs capital cost

** All plans are attached in Appendix-1.*

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

S.No.	Name of the MDI Manufacturers	No. of non-CFC MDIs sold in India (By active ingredient) (Year 2006)	Dry-powder inhalers sold (Year 2006)
1	AstraZeneca Pharma India Ltd.	NA	NA
2	Cadila Health Care Ltd.	NA	Yes
3	Cipla Ltd., Kurmumbh, Mh	NA	1.Beclomethasone 2.Budesonide 3.Cicllesonide 4.Cicllesonide + Formoterol 5.Fluticasone Propionate 6.Formoterol Fumarate + Budesonide 7.Ipratropium Bromide 8.Levosalbutamol 9.Levosalbutamol + Ipratropium Bromide 10.Salbutamol 11.Salbutamol + Beclomethasone 12.Salmeterol Xinafoate 13. Salmeterol + Fluticasone 14. Tiotropium Bromide 15. Tiotropium + Formoterol Fumarate
	Cipla Ltd., Kundaim, Goa	1.Beclomethasone 2.Budesonide 3.Budesonide + Formoterol 5.Fluticasone 6.Salbutamol	
	Cipla Ltd., Verna, Goa	1.Beclomethasone Dipropionate 2.Ipratropium Bromide 3.Salbutamol 4.Salbutamol + Ipratropium Bromide 5.Salmeterol Xinafoate 6. Salmeterol + Fluticasone Propionate	
4	GlaxoSmithkline Pharmaceuticals Ltd.	NIL	NA
5	Midas Care Pharmaceuticals Pvt. Ltd.	163494 units/year 1.Cicllesonide 2.Fluticasone 3.Formoterol + Budesonide 4.Salbutamol 5. Salmeterol + Fluticasone	NA
6	Natco Pharma Ltd.	NIL	NA
7	Sun Pharmaceutical Industries Ltd.	NIL	NA

Non-CFC MDIs are produced by 2 companies: Cipla and Midas Care. There is no Non-CFC MDI import into India.

Cipla produces “Beclomethasone, Budesonide, Budesonide + Formoterol, Fluticasone, Salbutamol, Ipratropium Bromide, Salmeterol Xinafoate” formulations and a total of 36,000 units/year.

Active ingredient wise numbers are presented in the table below

Cipla - Kundaim, Goa	
Active Ingredient (Manufactured)	**Units (2005)**
Salbutamol	2270000
Budesonide	8695000
Beclomethasone	40000
Budesonide + Formoterol	34000
Fluticasone	18000
Cipla - Verna, Goa	
Active Ingredient (Manufactured)	**Units (2005)**
Beclomethasone Dipropionate	615632
Ipratropium Bromide	4600
Salbutamol	1226726
Salmetrerol Xinafote	1921
Salbutamol & Ipratropium Bromide	7480
Salmeterol & Fluticasone Propionate	8137
TOTAL	**~ 13 million units**

Midas Care produces “Cicllesonide, Fluticasone, Formoterol + Budesonide, Salbutamol, Salmeterol + Fluticasone formulations and a total of 1,63,494 units/year.

Active ingredient wise numbers are presented in the table below

Active Ingredient (Manufactured)	**Units (2005)**
Salbutamol	5000
Formoterol + Budesonide	20000
Salmetrerol + Fluticasone	10000
Fluticasone	
Cicllesonide	
TOTAL	**~ 35000**

Starting 2005, part of its production at Astra Zeneca is produced on loan basis at Midas Care. From last year i.e. 2006, Astra Zeneca switched its entire production on loan basis at Midas Care.

Appendix-1

Plan for phasing out CFC consumption

1. AstraZeneca Pharma India Ltd.

- No

2. Cadila Health Care Ltd.

- Estimated time required for implementing transition projects: Two to three years.
- Estimated cost of implementing transition projects: 30 crores (This includes all costs like Formulation Development/Analytical Development / Stability and equipment's).
- Projected activities required for smooth transition in India: Technology souring / Patent search / suitable equipment's / source of materials / Development studies / pilot scale studies / commercial production.

3. Cipla Ltd., Kurmumbh, Mh / Cipla Ltd., Kundaim, Goa / Cipla Ltd., Verna, Goa

- Estimated time required for implementing transition projects: 10 years.
- Estimated cost of implementing transition projects: In order to change over from CFC to HFA, we require the following funds.

Funds Requirement for the Transition to HFA		
	Item	**Funds Requirement (Rs. Crores)**
1.	HFA MDI filling machine and accessories - 3 Nos.	60
2.	High pressure manufacturing vessels - 6 Nos.	15
3.	Restructuring of manufacturing area*	10
4.	Patient & Doctors education#	5
	TOTAL COST (Rs. Crores)	**90**

* *Alcohol is used as co solvent, which require flame proof manufacturing area and also use of alcohol invites a higher excise duty whereby it will increase the cost of the product.*

\# *This includes cost to be incurred on account of promotional camps, literature printing & distribution, free supply of samples, traveling expenses etc.*

- Projected activities required for smooth transition in India: The following issues need to be resolved in order to ensure smooth transition.

  The development of CFC Free MDIs involves a lot of R & D development with all parts related to the metered dose inhaler.

  - **Development of New Formulations**

    The HFA gases have poor solubilities, hence formulator had to try new excipients such as alcohol, glycols etc. This took considerable time and effort as the stability of the formulation was carried out for almost 2 years per formulation. Moreover, the formulation needed to be efficacious and safe as the previous CFC formulations. The cost of HFA propellants is higher than the existing CFC propellants.

- **Development of Packaging Components (CAN, Valve and Actuator)**
  The use of new excipients, new propellants led to formulation issues to moisture ingress, stability, pressure, drug adhesion. This led to a whole new development of the metering valve, new elastomers, various special types of CANS (coated, anodized), changes in the design of the actuator. All of the components are imported which incur a high cost. As there are no Indian mfgrs. for the CAN and the Valve the MDI manufacturer will need subsidies from the Government of India on imported material required for CFC Free MDIs. At present the import duty is at 7.5%.

- **Development of Manufacturing Machinery (High pressure)**
  It involves the reorganizing of the manufacturing area, import of very expensive machinery, changes in the design of the machinery and the manufacturing vessels.

- **Development of New Filling Systems**
  Filling machinery and methods are required to be redesigned because of changes in pressure. The time frame for getting this new filling machinery is almost 2 years.

- **Development of New Testing Methods**
  New testing methods are needed to be developed and sensitive and highly sophisticated analytical instruments are required to be procured.

- **Clinical Trial Programmes**
  For the formulations developed Clinical Trial Programmes are required to determine the safety & efficacy of the HFA formulations.

- **Education programmes for Doctors & Patients**
  Resistance from medical fraternity for the change to HFA as CFC based MDIs are well established and time tested. Doctor needs to be educated on the new excipients used in HFA formulations. Resistance from patient can be anticipated as taste of the HFA formulation is different. Hence doctor and patient education will need to be done on a massive scale.

  HFA inhalers not economically viable (cost almost double that of CFC based inhalers).

  Thus an overall redevelopment programme needs to be put in place for transition to CFC Free MDIs. This is an ongoing process.

4. GlaxoSmithkline Pharmaceuticals Ltd

- No

5. Midas Care Pharmaceuticals Pvt. Ltd.

- Estimated time required for implementing transition projects: This may take around 3 years provided other supports are easily available.

- Estimated cost of implementing transition projects: This may be difficult, at this stage, for us to comment as many critical machineries and balancing equipments are not available locally and have to be imported. Still roughly the CAPEX cost of implementing transition project may be

around Rs. 5 cr and that this figure may change. Formulation development and other related costs will be extra depending on the molecules and formulations.

- Projected activities required for smooth transition in India: There are many activities required to achieve transition from CFC based MDIs to HFA based MDIs.

6. Natco Pharma Ltd.

- Estimated time required for implementing transition projects: 3 years.
- Estimated cost of implementation transition projects: USD 3.37 millions for equipment.
- Projected activities required for smooth transition in India: Facility Upgradation.

7. Sun Pharmaceutical Industries Ltd.

- Estimated time required for implementing transition projects: 18 months.
- Estimated cost of implementation transition projects
  - **Capital Cost**

    We have contacted the equipment manufacturers and taken some estimates of capital expenditure. The capital cost involved in switching from CFC to HFA will be approximate Rs. 250 lacs based on our current understanding. This may change in future, when we implement the project.

  - **Packaging material cost/Stability Studies/Analytical method development cost**

    For the above mentioned product, we have estimated that annual cost would be approximate Rs. 90 lacs. This again is approximate and may change in future, once the project is implemented.

- Projected activities required for smooth transition in India: Facility upgradation.
  - Evaluation of existing IPR
  - Primary packaging material selection (valve, can & actuators)
  - Analytical method development
  - Preformulation studies
  - Stability studies
  - Scale up
  - New equipments/Machineries for R&D and plant